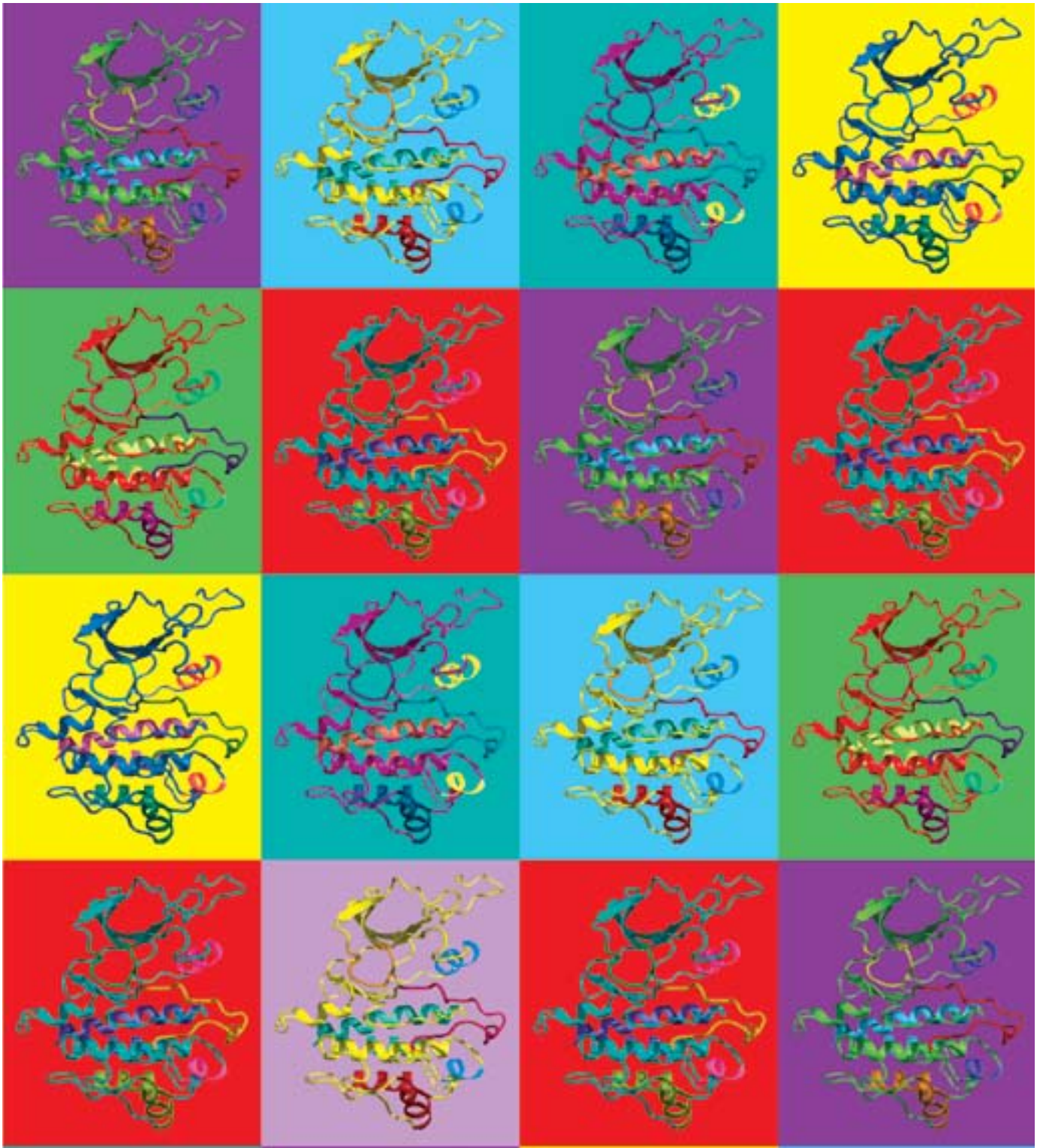
ASCO NEWS & FORUM

APRIL 2006

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

THE 2006 ASCO ANNUAL MEETING: Oncology for the 21st Century



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CML: A Disease of Increasing Molecular Complexity

At present, there is a considerable amount of knowledge on the molecular biology of chronic myeloid leukemia (CML), providing an unparalleled platform for molecularly targeted therapy. While the *BCR-ABL* gene remains the driving force in CML, ongoing research into the inhibition of additional molecular targets, including mutations of the *BCR-ABL* kinase, may lead to new therapies.[1,2]

CML Is a Disease With More Than One Target

BCR-ABL Kinase Mutations within the *ABL* kinase domain are emerging as the most frequent mechanism for the reactivation of *BCR-ABL* activity and, thus, represent important potential targets in CML.[2-5] The development of *BCR-ABL* mutations can occur through either genetic instability or secondary mutational events over the course of the disease and is not limited to late-stage disease.[5]

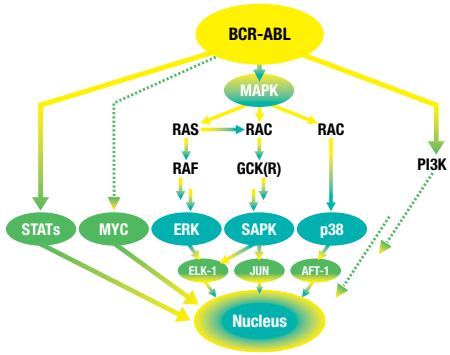
Recent evidence has also shown that certain mutations may bind and phosphorylate substrates distinct from wild-type *BCR-ABL* and have the potential to activate alternative signaling pathways, providing additional insight into why certain mutations are associated with poor prognosis.[6]

SRC-Family Kinases are independent oncogenic pathways that are believed to be involved in late-stage disease progression. Two members of the *SRC* family in particular, *LYN* and *HCK*, are highly overexpressed and activated in patients with blast crisis and have been implicated in leukemic tumor cell growth, apoptotic protection, and kinase inhibitory activity.[7,8]

Heat-Shock Family Proteins (Hsp) are molecular chaperones capable of maintaining the stability and function of *BCR-ABL*.[9,10]

Downstream BCR-ABL Signal Transduction Pathways are responsible for the development and proliferation of malignant cells through a signaling cascade of multiple oncogenic kinase events.[11] These pathways represent potential new targets for molecular therapy.[1]

BCR-ABL* Mitogenic Signaling Pathways[11]



Reprinted with permission from Deininger MWN, et al.

* Note: This is a simplified diagram of the *BCR-ABL* signaling pathways. Numerous additional downstream targets have been reported.

Potential Multi-Targeted Approaches to CML Therapy

Significant progress has been made in the development of therapeutic agents directed against molecular targets specifically expressed or abnormally activated in patients with CML.[1] While *BCR-ABL* remains the primary target for CML therapy, there is hope that new research investigating synergistic approaches, simultaneously addressing multiple targets, may lead to new therapies for patients with CML.

Bristol-Myers Squibb is committed to investigating the molecular causes of cancer and developing potential new treatment alternatives to help address the needs of people living with cancer.

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- Non-Small Cell/Small Cell Lung Cancer
- Ovarian Cancer
- Pancreatic Cancer
- Prostate Cancer
- Rectal Cancer

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E-mail your comments and questions to NCCN at CMSDemo@nccn.org.

Watch www.nccn.org for enhancements to the NCCN Guidelines to support your participation in the 2006 CMS Oncology Demonstration Program.

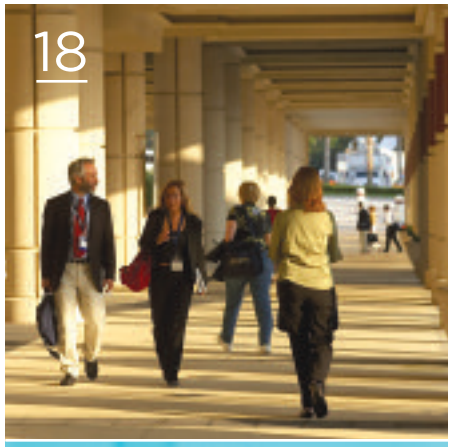
C-N-0271-0406

Inside NEWS & FORUM

APRIL 2006

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

FEATURES



UP FRONT

NEWS

ASCO

NEWS & FORUM

APRIL 2006 VOLUME 1, NO. 2

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ASCO News & Forum Mission Statement

ASCO News & Forum represents the interests and expertise of the members of the American Society of Clinical Oncology and others in the oncology community. The publication, available in print and electronic media, is the primary source of information about ASCO programs, benefits, and resources. The publication also provides summaries of research from oncology-related meetings and the literature (especially the *Journal of Clinical Oncology*), including commentary on controversial issues by recognized experts in the field.

ASCO®
AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Letter from the Editor

Dear Colleagues,

Welcome to the April 2006 edition of *ASCO News & Forum*, the second issue of the relaunched membership magazine (formerly *ASCO News*). Reader feedback about the January issue has been positive, with several members noting the improved graphic quality of the redesigned publication, as well as the enhanced scientific content and commentary.

This month's cover story features a preview of the 2006 Annual Meeting (page 18). Scientific Program Committee Chair Branimir I. Sikic, MD, and Cancer Education Committee Chair Mary L. Disis, MD, discuss the development of the Meeting program, as well as new initiatives designed to complement this year's increased focus on clinical science.

Two-part coverage of the ASCO.org relaunch is also included in this issue (page 30). A feature article contains commentary from Robert S. Miller, MD, and Ronald Blum, MD, Chair and Chair-Elect, respectively, of the Information Technology Committee, about the decision to redesign the website, as well as the resources used to complete this enormous project. The "*ASCO News & Forum* Guide to ASCO.org" is an eight-page pull-out booklet that provides users with an introduction to several of the new features available on the website.

In her last column as President, Sandra J. Horning, MD, reports on scientific initiatives that have been undertaken or supported by ASCO during her tenure (page 8). The Society will welcome its new leaders at the Annual Meeting, and to familiarize readers with these individuals and their goals, results of the 2006 ASCO election are available on page 12.

Making its debut in this issue is "Current Controversies in Oncology," which provides a forum for debate between two oncologists with divergent opinions on topical issues (page 14). The inaugural topic is the use of intraperitoneal therapy for ovarian cancer. Maurie Markman, MD, argues for its immediate adoption as the standard of care for patients with advanced disease, while Robert F. Ozols, MD, PhD, explains his rationale for a more gradual incorporation of this technique.

"Inside the JCO" features an interview with Charles L. Loprinzi, MD, Editor of the "Art of Oncology" series in the Journal (page 36). Dr. Loprinzi discusses the importance of the topics addressed in these articles, which focus on issues related to the treatment of patients with terminal cancer. "JOP Outlook" features a question-and-answer session with Brent DuBeshter, MD, who describes the clinical utility of the IntelliDose chemotherapy computer order entry system, which was reported on in detail in the March issue of JOP (page 39).

I encourage members to submit comments about the revised *ASCO News & Forum* to asconews@asco.org. I would especially appreciate feedback about "Current Controversies in Oncology," which was conceived as a forum for member dialogue about oncology research likely to have immediate clinical impact. I look forward to receiving your valuable input.

Sincerely,

Jonathan S. Berek, MD, MMS
Editor, *ASCO News & Forum*

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From the Office of the EVP

ASCO Initiates Program Evaluation to Maximize Quality of Society Resources

ASCO has enjoyed tremendous growth during the past decade, and the pace of that growth seems unlikely to slow in the near future. Between 2000 and 2005, the Society added 2,000 new members annually. Today, ASCO has more than 23,500 members from more than 100 countries around the world. We've come a long way since 12 oncologists met to form our Society more than 40 years ago.

This phenomenal growth is, in part, a direct result of ASCO's commitment to enhancing existing member services and to its ongoing outreach efforts to oncology professionals worldwide. The expanding variety of programs and services offered to members reflects the Society's diversity and its growing influence within the international cancer community.

As our programs grow in size and complexity, it is appropriate—and necessary—for the Society's leadership to ensure both the sound investment of funds and that the hundreds of volunteers who commit their time and talent to service on ASCO committees are focused on the development and expansion of initiatives that are of the most value to the membership as a whole.

To that end, the Board of Directors has initiated an evaluation of ASCO programs to assess their quality, responsiveness to member needs, and reflection of goals outlined in the 2004-2007 Strategic Plan. The project, spearheaded by 2005-2006 ASCO President, Sandra J. Horning, MD, will involve all committees by asking each to:

- Prioritize and assess the value or success of its current programs
- Formalize accountability and measures of success for each program
- Determine if a program should be continued, changed/enhanced, or re-evaluated

At the Board of Directors meeting in February 2006, committees were asked to select a program from their respective rosters and submit a plan for its evaluation. Committees will examine whether the program is accomplishing what it was designed to achieve at its inception and will determine if the program is consistent with ASCO's missions and goals. In February 2007, the first evaluation process will be complete, and a program adjustment will be made based on the committee recommendations.

By conducting this comprehensive self-evaluation, it is our hope that program content will remain sharp, current, and balanced, as well as applicable to the varied professional interests of the membership. As part of the new evaluation program, committees will annually evaluate selected programs and provide their recommendations to the Board of Directors. Using these recommendations, the Board will be able to provide strategic direction to both new and existing programs.

As cancer care is constantly evolving and developing, so are the concerns and interests of our membership. ASCO must remain sensitive to this environment and deliver programs that are both timely and relevant. You can help. At various times during the coming year, you may receive surveys and other communications soliciting your opinions and feedback about ASCO products and services. I encourage you to take a few moments to give us your thoughts and suggestions. We value the input and will use it to develop and modify the programs most helpful to you and your colleagues. (*See box below for contact information.*) The most important thing to remember is...we're listening. AN&F

Joseph S. Bailes, MD
Interim EVP and CEO

For more information about the Program Evaluation project, contact the ASCO Cancer Policy & Clinical Affairs Department at 703-299-1050 or send an e-mail to publicpolicy@asco.org.

From the President

Integration of Research into Clinical Practice

Sandra J. Horning, MD
2005–2006 ASCO President

Clinical research is one of the major pillars upon which ASCO was founded. Like my predecessor, Dr. Johnson, I strongly believe that ASCO must remain scientifically relevant in the oncology community by fostering clinical and translational research. To address this need, ASCO has formed a new Cancer Research Department, under the leadership of Nancy R. Daly, MS, MPH, and has engaged a group of talented and committed individuals to serve on the Cancer Research Committee, led by Chair Michael A. Friedman, MD, of City of Hope. During my term, Task Forces on Translational Research and Biomarkers and Imaging are being constituted to advise the Society in these important areas. As the explosion of scientific information increases the need for credible and unbiased presentation and interpretation of data, ASCO will continue to propose novel methods for scientific exchange and instruction tailored to the specific needs, learning styles, and time constraints of its members.

Insufficient enrollment in and suboptimal design of clinical trials threaten the development and optimal use of new cancer treatments and diagnostics and informative correlative science. By focusing on the necessity for rigorous evaluation of new diagnostics and therapeutics and by promoting clinical trials, ASCO will continue to stimulate a progressive environment in which clinical research assumes a prominent role at both the community and academic levels. To that end, ASCO will partner with the National Cancer Institute in realizing selected recommendations of the Clinical Trials Working Group.

The 2004-2007 ASCO Strategic Plan identifies three objectives integral to the implementation of the Society's clinical science agenda:

- Increase participation in high-quality clinical trials in the community and in academia
- Develop and advocate for tools, resources, and regulatory oversight required to facilitate clinical and translational research
- Advocate for greater resources essential to the training of investigators and the conduct of high-caliber cancer research

In the past year, ASCO has become more proactive on issues surrounding access to high-quality cancer care, cancer research advocacy, and the development of criteria for the evaluation of new drugs and procedures. Its efforts and activities in these areas are described below.

Formation of Cancer Research Committee and Government Relations Council

To more effectively address the growing scope of its members' research activities and to increase awareness of the Society's advocacy and efforts on behalf of clinical science policy, in June 2004, ASCO re-established the former Public Issues Committee as two distinct yet complementary bodies: the Cancer Research Committee and the Government Relations Council. The Committee coordinates all ASCO policy activities related to cancer research and also develops cancer research-related policy and analysis. The Council coordinates issue advocacy in Congress and the Administration and works closely with relevant Committees, including the Cancer Research Committee, to appropriately represent the key policy issues of the Society.

This change creates separate but overlapping mechanisms well equipped not only to address the needs of members engaged in all areas of research development—from basic and translational research to community clinical investigation—but also to coordinate communication among the sectors—academic, industry, and governmental—that influence the development of research policy.

"ASCO is uniquely positioned at the interface of research and health care delivery and must engage physicians, patients, funding agencies, regulatory authorities, payers, and the pharmaceutical industry in meeting these challenges in bold and constructive ways," says Richard L. Schilsky, MD, Chair-Elect of the Cancer Research Committee and a member of the Government Relations Council. "Through its meetings, publications, committees, and websites, the Society must continue to send the message that there is no aspect of cancer care that cannot be further improved through research and education."

It has been a great privilege to serve as ASCO President, and I am honored to be able to end my term at an Annual Meeting whose themes—survivorship, clinical science, and oncology quality care—have been so central to the Society's activities during my term. These emerging issues will likely influence cancer research and practice priorities for some time to come, and I am proud to have presided over the development of projects and initiatives to support members' efforts in these areas. Please join me in welcoming Gabriel N. Hortobagyi, MD, FACP, as the 2006-2007 ASCO President. AN&F

As the explosion of scientific information increases the need for credible and unbiased presentation and interpretation of data, ASCO will continue to propose novel methods for scientific exchange and instruction tailored to the specific needs, learning styles, and time constraints of its members.

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Oncology MKSAP, 3rd Edition

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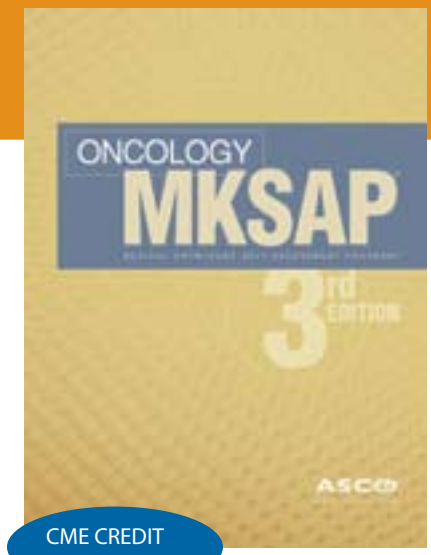

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The American Society of Clinical Oncology (ASCO) is pleased to offer the third edition of *Oncology MKSAP.* Developed in collaboration with the American College of Physicians–American Society of Internal Medicine (ACP–ASIM), this valuable resource is designed to help physicians assess their level of knowledge in the various areas of oncology and offers an overview of the current understanding of cancer, its treatment, and the supportive care needed to optimize the quality of life for patients with cancer.

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The ASCO Foundation

Patients Make Donations after Benefiting from Pioneering Cancer Treatments

THE ASCO FOUNDATION


Michael Troner, MD

Recently, two patients of Michael Troner, MD, of the Oncology/Hematology Group of South Florida, contributed to The ASCO Foundation. Dr. Troner, current Foundation Chair, discusses the importance of his patients' charitable contributions, and how donations such as these can help to support future cancer research.

When two of his patients benefited from recently developed, innovative cancer treatments, they were "very pleased with their care," explains Dr. Troner. The patients decided to support additional quality research initiatives by contributing to The ASCO Foundation.

"These are patients," says Dr. Troner, "who have benefited from the advances we have made in oncology, and specifically in various solid tumors." Five or ten years ago, he notes, both of these patients would have fared much worse, without access to the advanced treatment options available to them today.

Dr. Troner's patients expressed a desire to support further research in hopes that other patients with cancer will have access to even more effective therapies in the future. "These donors thought, 'How can I advance treatments as rapidly as possible?' They are the kind of people who can envision the future," Dr. Troner adds, "believing that 'this has helped me; maybe I can help others.'"

These two donors exemplify the ways in which individual patients can benefit from progress in clinical science supported by organizations such as The ASCO Foundation. "We have a national Society that supports research based on excellence," says Dr. Troner, emphasizing that The Foundation is deeply committed to ensuring that advances in research continue. This dedication is evidenced by the research grants The Foundation supports for qualified candidates at the beginning and middle stages of their careers.

As Chair of The ASCO Foundation, Dr. Troner has made it a priority to educate ASCO members about "how The Foundation functions and what it can help to produce," both in terms of funding for research grants and for important patient support initiatives such as The ASCO Foundation Hurricane Relief Fund. Member awareness of The Foundation's work, Dr. Troner feels, will garner more support, and, in turn, will allow it to fund these high-quality cancer research initiatives.

For more information about making a charitable donation to The ASCO Foundation, or to make a gift to the Foundation online, visit the "Make A Gift" area on The Foundation's website, www.ascofoundation.org. AN&F

Genentech BioOncology™ to Support 2007 Advanced Clinical Research Award in Lung Cancer

The ASCO Foundation recently secured funding for an Advanced Clinical Research Award (ACRA), the second of its kind to be awarded to a qualified ASCO member. At the 2006 Annual Meeting, The ASCO Foundation will announce that a second ACRA is available to qualified applicants involved in lung cancer research. Genentech BioOncology™ will support this award.

The ACRA is The Foundation's largest monetary grant, providing $450,000 over three years to a mid-career clinical investigator. The application period will open in early May 2006. A Letter of Intent will be due by late June, and the final application submission deadline will be in early August. The award recipient will be notified in November 2006 (Lung Cancer Awareness Month), and the ACRA will be presented at the 2007 Annual Meeting.

The first ACRA, funded by the Breast Cancer Research Foundation, was awarded at the 2004 Annual Meeting to Vered Stearns, MD, of Johns Hopkins University, for her research, "Clinical Investigation of the Histone Deacetylase Inhibitor SAHA, Single Agent or in Combination in Women with Newly Diagnosed Breast Cancer."

Application guidelines and materials will be available on The ASCO Foundation website (www.ascofoundation.org) and in the "Grants" area of ASCO.org (www.asco.org) beginning in May.

2006 ASCO Election Winners

ASCO is pleased to announce the winners of the 2006 election. The new leaders and members of the Board of Directors and Nominating Committee are dedicated to advancing the ASCO mission and will work to promote policies to increase financial support for oncology research; to ensure the timely dissemination of new research; to improve access to clinical trials; and to advance basic, translational, and clinical research through collaborations with public and private entities.

President-Elect

Nancy E. Davidson, MD

Dr. Davidson is Director of the Breast Cancer Program at the Sidney Kimmel Comprehensive Cancer Center. Her primary research focus is the molecular and cellular biology of breast cancer.

The key focus of Dr. Davidson's presidency will be to advance the ASCO mission to enable access to high-quality care for patients with cancer and to promote prevention in well individuals. This will require close collaboration with public and private agencies in the United States and abroad to eliminate barriers to optimal care and to advocate for adequate resources.

Dr. Davidson believes that "ASCO should continue to strive to serve as the primary organization for all cancer practitioners and researchers, championing high-quality cancer care, excellence in clinical and translational research, and education of a multidisciplinary workforce."

Secretary-Treasurer

Bruce J. Roth, MD

Dr. Roth is Professor of Medicine and Urologic Surgery at Vanderbilt-Ingram Cancer Center. His research interests include the development of novel therapeutics in germ cell tumors, urothelial malignancies, and prostate cancer.

Dr. Roth views the biggest challenge facing the Board of Directors as the identification of new revenue streams that will provide organizational stability despite a rapid increase in services to members, as well as the development of financial resources that will allow ASCO to further distance itself from reliance on support from the pharmaceutical industry.

Board of Directors

Undesignated Specialty, Oncology or Hematology/Oncology

Howard A. Burris III, MD

Dr. Burris is Director of Drug Development at The Sarah Canon Research Institute and an associate with Tennessee Oncology, PLLC. His research interests include the development of investigational agents and phase I and II trials to test these compounds.

Dr. Burris will provide leadership in the dialogue between oncologists and those entities that regulate and administer health care decisions to address the conflict between scientific breakthroughs and financial pressures. He believes that timely accrual to clinical trials, and the dissemination of research results to oncologists, will be critical to the efficient integration of emerging cancer therapies currently in development.

"A sense of excitement and enthusiasm needs to be maintained around the practice of oncology in order to attract the best and brightest physicians into our field," he says.

Waun Ki Hong, MD, FACP, DMSc

Dr. Hong is Head of the Division of Cancer Medicine and Professor at M. D. Anderson Cancer Center. His research interests include the biology, therapy, and prevention of lung cancer and head and neck cancers.

Dr. Hong plans to expand The ASCO Foundation Grants program, to further strengthen ASCO's prevention and screening programs, and to develop Society policies to increase the availability of clinical trials to community oncologists.

"With ASCO's leadership, we can begin to resolve the tremendous shortfall in research progress caused by inadequate government funding and too few physician-scientists with dedicated time for conducting translational research," he says.

Community Oncologist

Thomas A. Marsland, MD

Dr. Marsland is board certified in Internal Medicine and Medical Oncology. He serves as President of Integrated Community Oncology Network, a medical and radiation

oncology group in northeast Florida.

Dr. Marsland will encourage the Board to advocate the design of more accessible clinical trials and will work with current federal regulatory agencies to minimize paperwork and to establish a sound fiscal basis for the practice of oncology though continued relationships with other cancer groups.

"ASCO truly has the ability to bring the power of the cancer community to bear on accessibility problems, and I think that with strong efforts from the Board of Directors, patients with cancer will continue to benefit from new lifesaving treatments."

Specialty other than Medical/Hematology Oncology—Pediatric Oncologist

Gregory H. Reaman, MD

Dr. Reaman is Group Chair of the Children's Oncology Group and Professor of Pediatrics at the George Washington University School of Medicine and Health Sciences and the Children's National Medical Center.

Dr. Reaman believes that, "the Society has a responsibility to defend, support, and ensure a responsible cancer research agenda in the current biomedical research and health financing environment, which is characterized by competing priorities and diminishing resources."

He will assist ASCO's public policy experts in the development of initiatives designed to maintain and increase federal funding for basic, translational, and clinical research in cancer, and will work with ASCO committees to evaluate disparities in cancer care delivery to adolescent and young adult populations.

Non-U.S. Oncologist

Martine J. Piccart-Gebhart, MD, PhD

Dr. Piccart-Gebhart is Director of the Medicine Department at Institut Jules Bordert, Belgium.

One of Dr. Piccart-Gebhart's goals is to address the challenge of meeting the needs of ASCO's rapidly expanding international membership. She hopes to increase the number of regional education programs and tailor them to the needs of oncologists conducting research and practicing in specific regions; reinforce partnerships with other scientific societies; and foster communication with regulatory authorities, pharmaceutical industry representatives, and patient advocates. "I am passionate about education and look forward to pursuing my involvement in ASCO-related teaching activities," she says.

Nominating Committee

Edith A. Perez, MD

Dr. Perez is Professor of Medicine at the Mayo College of Medicine. She has developed a range of translational clinical trials to explore the use of new agents for the treatment and prevention of breast cancer.

Dr. Perez believes ASCO must continue to improve access to care and clinical trials, have a strong voice at the regulatory level, and ensure appropriate reimbursement for practice and participation in clinical trials. As a member of the Nominating Committee, she will guide the selection of the best potential leaders able to contribute their dedication and intellect to the governance of the Society.

Eric P. Winer, MD

Dr. Winer is Director of the Breast Oncology Center at Dana-Farber Cancer Institute, as well as Co-Chair of the Breast Committee of Cancer and Leukemia Group B.

Dr. Winer will identify candidates for the Board of Directors who have the knowledge, creativity, and energy to tackle the challenges that the oncology community will encounter in the years ahead. He believes that ASCO's leadership must promote the highest quality cancer care available today and work to ensure that cancer care and research will continue to evolve in the future. AN&F

Meet ASCO's New Leaders at the 2006 Annual Meeting

The President-Elect, Secretary-Treasurer, and new members of the Board of Directors and the Nominating Committee will be introduced on Monday, June 5, 2006, during the Annual Business Meeting and Highlights, held in conjunction with the Annual Meeting. Members are strongly encouraged to attend this event, where they will have the opportunity to meet the newly elected leaders and witness the passing of the presidential gavel.

Current *Controversies* in Oncology

Intraperitoneal Chemotherapy for Ovarian Cancer

Jonathan S. Berek, MD, MMS
Editor, *ASCO News & Forum*

A recent publication in the *New England Journal of Medicine* about a Gynecologic Oncology Group (GOG) study (Protocol 172) to evaluate intraperitoneal (IP) versus intravenous (IV) cisplatin and paclitaxel chemotherapy for stage III epithelial ovarian cancer has produced controversy (Armstrong et al. *N Engl J Med.* 2006;Jan 5;354:34-43). The authors reported that patients who received IP treatment had better rates of survival than those who received IV therapy, with a median survival of 15 months longer. The National Cancer Institute (NCI) issued a bulletin suggesting that, in women with stage III epithelial ovarian cancer, IP cisplatin should be considered for their treatment.

Maurie Markman, MD, forcefully advocates that IP cisplatin should be considered the standard therapy in these women. Dr. Markman argues that there are now three separate GOG trials that show an advantage to IP cisplatin therapy, and that the benefit is unequivocal. In each of these trials, he notes, there has been a survival advantage for the women who received IP chemotherapy, which prompted the NCI to issue its bulletin.

Robert F. Ozols, MD, PhD, expresses concern that, in these trials, there is no direct comparison with IV carboplatin and paclitaxel, which has been considered the standard treatment for patients with ovarian cancer. He contends that the rates of survival among women in GOG Protocol 158 who were treated with carboplatin and paclitaxel are comparable to the rates of survival of women treated with IP cisplatin and paclitaxel in GOG protocol 172.

Dr. Ozols notes that, in GOG 158, which compared IV cisplatin and paclitaxel with carboplatin and paclitaxel, the regimen containing carboplatin had a much more favorable toxicity profile than the regimen containing cisplatin, as well as a better survival outcome. In addition, he is concerned that only 42% of women randomly assigned to the IP arm actually completed six cycles of the treatment because of toxicity and catheter problems. Dr. Ozols advocates that, until there is a head-to-head comparison of IP cisplatin and paclitaxel with IV carboplatin and paclitaxel, the use of IP cisplatin should be optional and not routine.

Patient selection will undoubtedly be the cornerstone of the decision regarding these therapeutic alternatives. In any particular patient, the issue of which route and platinum compound is selected will depend on the patient's performance status, her age and related medical conditions, and whether or not stage III disease is truly optimal. Patients with suboptimal residual extensive carcinomatosis, those with stage IV disease, and those with serious co-morbid conditions, low performance status, and advanced age might not tolerate the added morbidity of IP therapy or derive any significant benefit over IV therapy. The challenge is always for clinicians to discuss with their patients these therapeutic alternatives with a clear understanding of the published data and a thoughtful sense of the risks versus benefits in individual patients.

Adopt IP Therapy As Standard of Care

Maurie Markman, MD
M. D. Anderson Cancer Center

Although the concept of intraperitoneal therapy for ovarian cancer was initially introduced during the earliest days of the modern chemotherapeutic era (1950s), a sound pharmacokinetic rationale for this strategy was not advanced until the late 1970s. The provocative suggestion that a tumor present within the abdominal cavity could be exposed to 10 to 1,000 times higher concentrations of a cytotoxic agent than safely achievable with systemic delivery led a number of investigators to explore this concept clinically.

Subsequently conducted phase I-II clinical trials confirmed the pharmacokinetic advantage of regional drug delivery, the safety of this approach for agents with known activity in ovarian cancer (e.g., cisplatin, carboplatin, paclitaxel), documented biologic activity (surgically confirmed complete responses in patients with ovarian cancer who had failed to achieve this state with primary platinum-based intravenous therapy), and the prolonged survival of a subset of patients with ovarian cancer receiving "second-line" platinum-based intraperitoneal chemotherapy.

While of interest, these non-randomized studies did *not* prove that regional treatment produced a superior survival outcome compared with IV delivery. However, the results of three well-designed and conducted NCI-sponsored cooperative group phase III trials have now *unequivocally* demonstrated that women with small volume residual advanced ovarian cancer (largest tumor mass persisting within the peritoneal cavity following completion of primary surgical cytoreduction less than 1-2 centimeters in maximum diameter) experience a 25% to 30% reduction in the risk of death if treated with a cisplatin-based IP chemotherapy program, compared with IV platinum-based therapy.

The space provided in this "mini-debate" does not permit a full refutation of the persistent, but progressively weaker, arguments that (for unclear reasons) continue to be advanced against a simple modification of routine drug delivery, which has been shown to substantially improve survival for women with this most difficult malignancy. However, it is relevant to note the overwhelming evidence supporting the value of this strategy: all three primary platinum-based phase III regional chemotherapy trials have shown a similar relative level of overall survival benefit resulting from IP treatment, in striking contrast to the previously "universally accepted gold standard" of IV cisplatin and paclitaxel, where two of four phase III randomized trials (ICON-3, GOG 132) failed to show a benefit from the addition of paclitaxel to the therapeutic program.

It is also rather perplexing that we hear some claim (quite inappropriately, based on an examination of the actual data, as well as a formal quality-of-life analysis) that "intraperitoneal cisplatin is excessively toxic," when in the same malignancy cisplatin was previously accepted as a "new standard" in the 1980s (replacing alkylating-agent based treatment), with far less evidence (number of phase III trials revealing an overall survival advantage for cisplatin-based treatment) and with dramatically more toxicity for a cisplatin-based IV program (compared with a non-platinum regimen).

Somehow, clinicians in that era were able to acknowledge the fact that cisplatin was more toxic (e.g., emesis, risk of renal insufficiency, neuropathy) but then to develop methods to reduce the side effects of the treatment program (e.g., hydration). This effort was justified, based on the highly reasonable conclusion that the more toxic regimen improved survival, just as is now the situation with the use of IP cisplatin.

Further, attempts to ignore—even disparage—the results of prospectively designed and meticulously conducted multicenter cooperative group trials, by claiming to "compare" the survival of those receiving the "experimental regimen" with a purposely selected, non-randomized (and absolutely non-comparable) patient population, would appear to be something that might have been done in the early days of the development of the field of oncology but hopefully not today.

As is generally the case in oncology, exciting new advances only lead to more questions and additional opportunities to improve the clinical outcome. Thus, it is clear that the administration of IP cisplatin at a dose of 100 mg/m^2 may cause considerable (and frequently excessive) systemic toxicity, and that there are complications associated with intraperitoneal catheters.

But the solution to these problems is NOT to ignore the major survival benefits associated with regional treatment (just as physicians in the 1980s did not refuse to use IV

cisplatin simply because it caused excessive emesis). Rather, the next step must be to explore strategies to reduce the toxicity of cisplatin and to avoid the complications of catheters. (Oncologists interested in this important topic are encouraged to read the review article about practical aspects of IP therapy, recently published in the *Journal of Clinical Oncology*.)

Future research efforts in the area should focus on strategies to enhance the definite benefits associated with regional drug delivery. For example, as the substantial impact on survival was observed in a setting in which a fairly large percentage of patients were unable to receive the full planned six courses of IP therapy, how much better would the outcome be if a method were found to decrease this dropout rate (e.g., employ a different type of catheter)? Other issues to explore include the regional administration of novel antineoplastic agents, particularly those whose activity appears to be enhanced by increasing either the concentration or duration of exposure.

In conclusion, the results of three phase III randomized trials have established a new standard of care in the primary chemotherapeutic management of small volume residual advanced ovarian cancer. An oncologist who does not feel comfortable with employing this approach, for a variety of reasons, may want to consider referral of appropriate patients to others. Finally, while the administration of IP chemotherapy may very well require development of new skills within an individual practice and considerable change in the treatment paradigm used for the management of ovarian cancer, it is essential to remember that the beneficiary of these efforts will be the patient.

More Research Is Necessary

Robert F. Ozols, MD, PhD
Fox Chase Cancer Center

The recent publication by Armstrong et al. describing the results of GOG Protocol 172, which compared IP therapy with IV cisplatin/paclitaxel in patients with optimally debulked ovarian cancer, formed the centerpiece for the NCI clinical alert that recommended that "consideration should be given to the regimen containing IP cisplatin (100 mg/m^2) and a taxane." GOG 172 and the NCI alert may overestimate the benefit of IP therapy. Until a well-controlled, prospective randomized trial demonstrates a survival advantage over standard chemotherapy, which consists of IV carboplatin/paclitaxel (instead of IV cisplatin/paclitaxel, the control arm in GOG 172), IP therapy need not be routinely administered to patients with optimal stage III disease.

IV Chemotherapy for Optimal Stage III Disease

GOG 158 reported a 16% reduction in the hazard ratio for death, as well as less toxicity, for patients treated with carboplatin/paclitaxel compared with cisplatin/paclitaxel (Ozols RF et al. *J Clin Oncol*. 2003; 21:3194-3200). This trial was instrumental in helping to establish IV carboplatin/paclitaxel as the standard of care for patients with ovarian cancer. In fact, all prospective randomized trials throughout the world use carboplatin/paclitaxel as the control arm to which new therapies are compared.

Unfortunately, since the results of GOG 158 were not known when GOG 172 was developed, the control arm in the latter trial was cisplatin/paclitaxel and not carboplatin/paclitaxel. It has been argued that carboplatin/paclitaxel and cisplatin/paclitaxel produce identical results in patients with ovarian cancer, and IV cisplatin/paclitaxel is an appropriate control in GOG 172. There have been three prospective randomized trials in ovarian cancer comparing IV carboplatin/paclitaxel with IV cisplatin/paclitaxel. Neijt et al performed an exploratory pilot study in stage II-IV ovarian cancer that was not intended as a definitive comparison due to small numbers (Neijt JP et al. *J Clin Oncol*. 2000; 18:3084-3092). The larger AGO trial, which enrolled 798 patients, also included patients with stage II-IV disease (du Bois A et al. *J Natl Cancer Inst.* 2003; 95:1320-1330). Although equivalency was demonstrated between these two combinations, in a subset of optimally debulked patients, there was an improvement in survival of 4 months for patients treated with carboplatin/paclitaxel (59.4 months compared with 55.4 months for patients treated with cisplatin/paclitaxel; relative risk [RR], 0.92; CI = 0.7-1.2). GOG 158 was the only study to prospectively compare these two regimens in optimally debulked patients with ovarian cancer. Although this study was designed as a noninferiority study, it did, as noted, result in an improvement in median survival of 8.7 months (RR, 0.84; CI = 0.70-1.02) for patients treated with carboplatin/paclitaxel.

Cross-Trial Comparison of Carboplatin/Paclitaxel with IP Cisplatin/Paclitaxel

GOG 158 and GOG 172 were sequential protocols using identical eligibility criteria

performed by the same group of investigators over a relatively short time span.
In a cross-trial comparison, there are very minimal differences in outcome: progression-free survival of 3.1 months and overall survival of 8.2 months. Median survivals are not a true comparison of outcome because of the relatively small number of events at this point in time. There is no difference in rates of two-year survival, and only a 4% to 5% difference in the rates of four-year survival. An even better comparison is the relative risk between the actuarial survival curves of patients treated on each arm. From the shape of the actuarial survival curves, it does not appear that there is a clinically significant improvement in survival outcome for patients treated with the IP regimen. Furthermore, 18% of patients randomly assigned to receive IP therapy received IV carboplatin/paclitaxel after discontinuing IP therapy because of toxicity. This cross-trial comparison, while not definitive, is robust due to the large number of patients (n = 598) treated on sequential protocols using identical eligibility criteria with superimposable control arms. This analysis suggests that IP therapy may not have a significant impact on survival if compared with IV carboplatin/paclitaxel instead of cisplatin/paclitaxel.

Toxicity Considerations

The difference in toxicities between IV carboplatin/paclitaxel and IP therapy are extreme. Patients treated with standard IV therapy receive six outpatient administrations during the entire course of their treatment, and in GOG 158, 87% of patients completed all six cycles. In contrast, the toxicity of IP therapy is formidable, and only 42% of patients could complete six cycles of therapy. Patients treated with IP therapy are more likely to have infection and fever, abdominal pain, nausea and vomiting, and increased neurologic toxicity compared with patients treated with IV carboplatin/paclitaxel. Even the NCI alert noted that, because of the toxicity of IP therapy, it was "not possible to specify a precise regimen."

Furthermore, instead of simple outpatient therapy, IP chemotherapy in GOG 172 consisted of a 24-hour infusion of paclitaxel followed by IP platinum on day 2 (together with hydration and antiemetics) and IP paclitaxel on day 8. Quality of life during therapy was significantly worse with IP therapy. Even though there was no difference in quality of life one year later, it should be emphasized that the comparison was with IV cisplatin/paclitaxel, which is a more toxic regimen than carboplatin/paclitaxel. It is also possible that, outside of a clinical trial, more elderly patients with comorbid illnesses may receive IP therapy from clinicians who are not familiar with the nuances of this complicated drug delivery system, which may result in even greater incidences of toxicity than reported by Armstrong et al.

Conclusions

IP therapy has been studied for more than two decades. Despite several clinical trials, no survival advantage has been reported compared with standard IV carboplatin/paclitaxel in patients with optimal stage III disease. It seems prudent that before IP therapy—with its formidable toxicity—was recommended for routine use, it should have been prospectively compared with a much less toxic, more convenient regimen of IV carboplatin/paclitaxel, which in a robust, exploratory cross-trial comparison appears to have very similar efficacy. GOG 172 will provide the basis for phase II trials exploring less toxic IP regimens, and patients should be urged to participate in these important studies. However, until a clearly defined IP regimen with acceptable toxicity is shown in a prospective randomized trial to be superior to IV carboplatin/paclitaxel, the latter combination remains an acceptable standard of care for patients with optimal stage III ovarian cancer. AN&F

Share Your Thoughts and Opinions in a Letter to the Editor

ASCO News & Forum is eager to receive reader feedback about the topics addressed in "Current Controversies in Oncology" in the form of Letters to the Editor. Correspondence should be less than 250 words and may be edited for length, clarity, and accuracy.

All letters, including those sent by e-mail, should include daytime and evening telephone numbers, current mailing address, and e-mail address. *ASCO News & Forum* cannot acknowledge or return letters. Letters become the property of ASCO and may be published in all media.

To submit a letter, send an e-mail to letters@asco.org; write to **Letters to the Editor, American Society of Clinical Oncology, 330 John Carlyle Street, Suite 300, Alexandria, Virginia, 22314**; or send a fax to 703-518-8157. We look forward to hearing from you.

DELIVERING
More Science More Efficiently

Time. It's a precious commodity that no oncologist can spare. ASCO understands this and has created a schedule for the 42nd Annual Meeting—to be held on June 2-6 in Atlanta, Georgia—that will enable attendees to experience more of the sessions, presentations, and workshops in which they are interested with relative ease. Tactical changes to the program schedule and types of sessions and workshops to be offered at the Meeting will allow attendees to maximize their time onsite. A new feature in 2006 is the specialized "Meeting within a Meeting" program, which will allow those who specialize in pediatric oncology, gynecologic oncology, and hematologic malignancies to attend back-to-back sessions in their areas of professional focus over the course of two to three consecutive days.

The theme of the 2006 Annual Meeting is "Advocating Survivorship, Clinical Science, and Oncology Quality Care." As 2005-2006 ASCO President Sandra J. Horning, MD, notes, "Recent advances in diagnostics and therapeutics have resulted in an unprecedented number of cancer survivors, further emphasizing the importance of quality oncology care." In addition, "as treatment and prevention become increasingly grounded by the biology of the tumor and the host, it is more crucial than ever for the global oncology community to better understand the science of clinical oncology." The emphasis on these topics within sessions at the 2006 Annual Meeting is, according to Dr. Horning, a reflection of "the Society's commitment to providing the most current and critical information on these interrelated issues to oncology experts worldwide."

"The whole point of the science that we present is to make an impact in the care of patients with cancer. It's got to have an immediate focus, an immediate impact on patients."

—Mary L. Disis, MD, Chair, ASCO Cancer Education Committee

Creating a Scientifically Sound, Educationally Balanced Meeting Program

The Annual Meeting program is developed as a collaborative effort between the ASCO leadership and members of the Cancer Education Committee and the Scientific Program Committee. The exhaustive planning process exemplifies the synchronization between the educational and scientific components of the Meeting program.

"This year more than ever, the Meeting has come together as more of a meld of the Cancer Education and Scientific Program Committees," says Mary L. Disis, MD, Chair of the ASCO Cancer Education Committee. "We are really working hand in hand," she observes. "The [Cancer] Education Committee meets early to start putting together content that will complement the scientific portions of the Meeting." The intent is to ensure that the Annual Meeting provides an "integrated continuum of information, some at a more basic level and some at a much higher, detail-oriented, scientific level," Dr. Disis says.

In addition to her collaboration with ASCO leadership and the Scientific Program Committee, Dr. Disis works with past Society leaders to ensure that the Meeting program and content continue to evolve from year to year. The involvement and input of past leaders facilitates an important exchange of Society knowledge from year to year, and provides the educational continuity and commitment to excellence that has become the hallmark of the Annual Meeting.

Planning the Annual Meeting

Several questions are asked when the planning process for each Annual Meeting is initiated:

- What are the biggest things happening in oncology this year?
- What are the new discoveries?
- What are the issues that should be highlighted in education?
- What are likely to be the hot-ticket events?

To answer these and other content-specific questions, members of the Cancer Education and Scientific Program Committees identify the likely "hot" topics in oncology for the coming year and invite experts in these practice or research fields to participate as faculty at the Annual Meeting. The abstract peer review process, conducted at a February meeting of the Scientific Program Committee, next helps to identify major topical themes from among the research submitted for consideration. Abstracts selected for presentation are then organized into thematic categories, or "tracks."

For the 2006 Annual Meeting, ASCO received more than 4,400 scientific abstracts, up from 3,807 submissions in 2005. "This surge in submissions is a result of a more flexible sponsorship rule put in place this year, and as the Chair of the Scientific Program Committee, I am very pleased by the significant increase," says Branimir I. Sikic, MD. The new rule allows ASCO members to sponsor more than one abstract. "Our overall goal is to increase both the breadth and depth of the science presented at the Annual Meeting," Dr. Sikic says.

New in 2006: Clinical Science Symposia

A new session type at the 2006 Annual Meeting, Clinical Science Symposia (formerly Integrated Education Sessions), has been designed to demonstrate how specific research findings can be applied in the clinical setting.

The 28 Clinical Science Symposia will incorporate the presentation of meritorious abstracts with a didactic lecture by an expert who places the abstracts in the appropriate context, with a focus on how oncologists can apply the findings in clinical practice.

Discussing the decision to transition from Integrated Education Sessions to Clinical Science Symposia, Dr. Disis explains, "we felt that Clinical Science Symposia much better described the goal of the sessions, which is really to integrate the clinical aspects—which are the scientific abstracts—with the science of the new molecularly targeted therapies."

Describing the proposed format for this new session type, Dr. Sikic says that "the symposia will be similar to the Integrated Education Sessions offered in the past, and will feature three abstract presentations and three discussants, including the Chair, within a 75-minute scientific session."

"We have increased the number of the sessions, from eight last year to 28 this year. This is a major enhancement of both the scientific and educational aspects of the Annual Meeting. Some of the scientific topics that attendees will learn about include molecular diagnostics in classifying

certain cancer types, measuring the quality of care for patients with cancer, novel therapeutic targets, combining targeted therapies, and survivorship issues, just to name a few," Dr. Sikic says. In addition, he points out that the inclusion of the Symposia has increased the number of scientific sessions from roughly 40% to more than 50% of the total Meeting program.

Advocating Survivorship, Clinical Science, and Oncology Quality Care

The Cancer Education and Scientific Program Committees have developed a Meeting program that highlights each aspect of the 2006 Annual Meeting theme.

"The science that we deal with is extremely translational, and the whole point of the science that we present is to make an impact in the care of patients with cancer," says Dr. Disis. "It's got to have an immediate focus, an immediate impact on patients."

Oncologists should consider how they are applying the science of oncology to patient care, according to Dr. Disis, and the types of treatments they put into the clinic, as well as their approach to the ways they treat patients with cancer.

"Then the endpoint is survivorship. At last, we're seeing survivorship. Cancer deaths are dropping, and I think that is the benefit of the investment that this country has made in developing both the science of oncology, as well as putting an investment in translating that science into the clinic," says Dr. Disis.

"My heart is lifted by thinking we have an ASCO Meeting where one of the themes is being a survivor of cancer. That's fantastic," she says. AN&F

2006 SPECIAL AWARD RECIPIENTS

Several ASCO members and other prominent leaders in the oncology community will be honored at the 2006 Annual Meeting with Special Awards. The 2006 ASCO Special Awards Selection Committee, chaired by Immediate Past President David H. Johnson, MD, chose to recognize the following individuals for their contributions to advancements in oncology research, clinical practice, and patient advocacy.

Other awards to be presented at the Annual Meeting include the Clinical Trials Participation Awards, the Donor Recognition Awards, and The ASCO Foundation Grants, which include Merit Awards, Young Investigator Awards, and Clinical Research Career Development Awards. Award presentation dates and times will be printed in *ASCO Daily News*, the official newspaper of the Annual Meeting, and will also be available on ASCO.org as the Meeting program is updated and finalized.

American Cancer Society Award and Lecture
V. Craig Jordan, OBE, PhD, DSc
Fox Chase Cancer Center

David A. Karnofsky Memorial Award and Lecture
Dennis J. Slamon, MD, PhD
University of California, Los Angeles

Distinguished Service Award for Scientific Achievement
Clara D. Bloomfield, MD
The Ohio State University

Distinguished Service Award for Scientific Leadership
Alan Stuart Coates, MD
University of Sydney School of Public Health

Partners in Progress Award
Kathy Giusti
The Multiple Myeloma Research Foundation

Pediatric Oncology Award and Lecture
Anna T. Meadows, MD
Children's Hospital of Philadelphia

Public Service Award
Joseph V. Simone, MD
Simone Consulting

Science of Oncology Award and Lecture
Francis S. Collins, MD, PhD
National Human Genome Research Institute

Special Recognition Award
Lance Armstrong
Lance Armstrong Foundation

TECHNOLOGY TO IMPROVE THE ANNUAL MEETING EXPERIENCE

ASCO continues to expand the scope of technologic resources available to enhance the Annual Meeting experience—in advance of the event, onsite, and afterward—and to keep attendees abreast of the latest technologic tools and products designed to simplify the practice of oncology.

Plan Your Annual Meeting on ASCO.org

A variety of interactive resources are available on ASCO.org (www.asco.org) to assist members in their preparation for the 2006 ASCO Annual Meeting.

General Information

- Register and make housing and travel arrangements for the Meeting
- Purchase discounted tickets for recreational tours and Atlanta-area attractions
- Review a list of ASCO services and resources available onsite at the Meeting

Online Pocket Program

- Create a customized Meeting schedule prior to arriving in Atlanta
- Print pre-made At-A-Glance Meeting schedules organized by track or date
- Search Meeting sessions by track, date, and keyword
- Download the Online Pocket Program to a personal digital assistant (PDA)

Oncology Product Directory (http://opd.asco.org)

- View the list of Meeting exhibitors
- Search exhibitors by company name, category, and keyword
- Learn more about exhibitor products and services

Direct links to all Annual Meeting-related information and materials—such as Meeting registration, housing reservations, continuously updated program information, continuing education credit, and visa information for international attendees—is now available directly from the ASCO.org home page or by visiting www.asco.org/annualmeeting.

Onsite Technology Resources at the Annual Meeting

Research Technology Pavilion

This new pavilion will highlight companies that provide the technology and processes to enable development of new methods of cancer treatment, prevention, and diagnosis. This area will provide an integrated forum of interest to academic oncologists and translational research investigators.

Practice Management and Information Technology Pavilion

This pavilion will once again highlight the latest advanced technologies for health care professionals, such as database management, electronic communications, personal digital assistant (PDA)-based solutions, and software, as well as other products related to the clinical practice setting.

Attendees are reminded to bring a laptop or wireless-enabled Internet device to the 2006 Annual Meeting to take advantage of free Internet access in the Wi-Fi Zone, located in Building B, Level 4, Lobby B.

Virtual Meeting Subscription Packages

Since its creation in 1999, the ASCO.org Virtual Meeting has grown to become the largest collection of oncology-related multimedia presentations on the Web. More than 25,000 abstracts and lectures from past ASCO Annual Meetings, as well as other small meetings and symposia, are available through the Virtual Meeting in a variety of media types.

This year, ASCO is offering the following Virtual Meeting packages. Intended for health care professionals unable to attend the Annual Meeting and for those attendees with busy onsite schedules, these packages offer unique resources to keep users up-to-date on the most valuable, practice-changing research presented at the 2006 Annual Meeting.

Note: All presentations become available to the public after 90 days.

Virtual Meeting Gold
(Members Attending, $49; Members Not Attending, $99)

- A three-DVD set of the Plenary and Highlights of the Day Sessions, to be shipped after the conclusion of the Meeting
- Live webcasts of the Plenary and Highlights of the Day Sessions
- Unlimited access to 2006 Annual Meeting Virtual Meeting presentations on ASCO.org (excludes ticketed sessions)

Virtual Meeting Silver
(Members Attending, $35; Members Not Attending, $75)

- Live webcasts of the Plenary and Highlights of the Day Sessions
- Unlimited access to 2006 Annual Meeting Virtual Meeting presentations on ASCO.org (excludes ticketed sessions)

Virtual Meeting Bronze
(FREE)

- Unlimited access to 2006 Annual Meeting Virtual Meeting presentations on ASCO.org (excludes Plenary Sessions, Highlights of the Day sessions, and ticketed sessions)

Services for International Attendees

As approximately half of attendees at the Annual Meeting travel from countries outside of the United States, ASCO continues to develop services and programs designed to meet their specific needs.

Prior to the Annual Meeting, attendees from outside of the United States are invited to visit ASCO.org for information about sessions in the International track, International Symposia, visa information, and information about the Atlanta area.

Onsite at the Meeting, international attendees can receive help at the International Assistance Desk, available in the ASCO Concierge Services area of the Georgia World Congress Center. The desk also offers information on international programs, travel inquiries, foreign consulates, local area information, and general Annual Meeting information. Language interpreters are available to assist attendees in French, Spanish, Portuguese, German, Italian, Japanese, and Mandarin Chinese, as well as in English.

Additionally, staff from the ASCO International Affairs Department will be present to provide information about ASCO's international educational initiatives and international events during the Annual Meeting, as well as information about the 2007 ASCO Foundation International Development and Education Award (IDEA) program. *(See page 46 for a list of the 2006 IDEA recipients.)*

6th Annual Oncology Career Fair

The 6th Annual Oncology Career Fair offers a convenient way for Meeting attendees to explore employment opportunities in all areas of the rapidly developing oncology profession, from entry-level to senior positions. Attendees are invited to meet with representatives from hospitals, academia, industry, and private practice and to submit their curriculum vitae online, allowing companies to review their qualifications for job matching. The Oncology Career Fair will be located in the Exhibit Hall of the Congress Center and will be open from 9:00 AM–5:00 PM on Saturday, Sunday, and Monday (June 3-5).

SPECIAL SESSIONS

Special Sessions include lectures delivered by recipients of 2006 Special Awards, as well as joint symposia developed and hosted by ASCO in collaboration with other oncology-related organizations. Topics for Annual Meeting Special Sessions are selected by members of the ASCO Cancer Education Committee, Scientific Program Committee, and Board of Directors on the basis of their timeliness and importance, as well as their likely professional relevance to Meeting attendees.

All Special Sessions are captured as part of the ASCO.org Virtual Meeting, and will be available at no charge to the general public 90 days after the conclusion of the Annual Meeting. For those who would like immediate access to these presentations in multimedia format, in 2006 ASCO has developed a Virtual Meeting Subscription Package that includes live Webcasts of the Plenary and Highlights of the Day sessions, as well as access to presentations from all other sessions. *(Access varies according to subscription pricing tier. More information about the Virtual Meeting Subscription Packages is available on page 22.)*

Friday, June 2

ASCO/American Academy of Physician Assistants/Oncology Nursing Society Symposium: Clinical Decision Making in Oncology Practice
3:00 PM–5:15 PM

Saturday, June 3

Presidential Address: Advocating Survivorship, Clinical Research, and Oncology Quality Care
(includes David A. Karnofsky Memorial Lecture)
10:00 AM–12:00 PM

Pediatric Oncology Award and Lecture
1:15 PM–2:30 PM

Sunday, June 4

ASCO/American Society of Hematology Symposium: Chronic B-Cell Malignancies—Can We Integrate Newer Prognostic Markers with Therapy?
8:00 AM–9:15 AM

ASCO/Oncology Nursing Society Symposium
8:00 AM–9:15 AM

Highlights of the Day I
8:00 AM–9:30 AM

Forum on Reimbursement
9:15 AM–10:30 AM

The Program Director's Guide to Academic Success
10:00 AM–12:00 PM

Sunday Plenary Session
(includes Science of Oncology Lecture)
1:00 PM–4:00 PM

Monday, June 5

Highlights of the Day II
8:00 AM–9:30 AM

The National Cancer Institute Cancer Biomedical Informatics Grid (caBIG™) Initiative: Tools for the Clinical Oncologist
10:30 AM–12:00 PM

ASCO/Federation of European Cancer Societies Symposium: Inflammation in Cancer Progression
11:30 AM–12:45 PM

Monday Plenary Session
(includes American Cancer Society Lecture)
1:00 PM–4:00 PM

The National Cancer Institute Cancer Biomedical Informatics Grid (caBIG™) Initiative: Activities Supporting Clinical Trials
1:00 PM–4:00 PM

Annual Business Meeting and Highlights
4:30 PM–5:30 PM

Tuesday, June 6

Highlights of the Day III
8:00 AM–9:30 AM

International Symposium: Common Cancers Around the World—Application of Knowledge
11:30 AM–12:45 PM

REPORT FROM THE 2006 GASTROINTESTINAL CANCERS SYMPOSIUM

EXPERTS DEBATE CLINICAL APPLICATION OF RECENT RESEARCH IN SEVERAL DISEASE SITES

The third annual Gastrointestinal Cancers Symposium: Multidisciplinary Approaches to the Prevention, Diagnosis, and Therapy of Gastrointestinal Cancers was held on January 26-28 in San Francisco, California. The 2006 event, which was co-sponsored by ASCO, the American Gastroenterological Association, the American Society for Therapeutic Radiology and Oncology, and the Society of Surgical Oncology, was the most well-attended to date: more than 2,100 gastroenterologists and medical, radiation, and surgical oncologists assembled to learn about the most recent developments in gastrointestinal cancer research.

The program featured more than 400 abstracts—a 34% increase from 2005—presented through a combination of oral abstract sessions, general poster sessions, and sessions on prevention, screening, and diagnosis; multidisciplinary treatment; and translational research in each of three disease areas: esophageal and stomach cancers; cancers of the pancreas, small bowel, and hepatobiliary tract; and colon and rectal cancers. The popular Controversies sessions, introduced in 2005, provided a forum for experts to present differing perspectives on current topics of clinical debate in their respective specialties. Summaries of these debates are reported below and include discussions about appropriate timing for adjuvant therapy in patients with resectable gastric cancer, the role of radiation as adjuvant treatment for pancreatic cancer, and the multimodality treatment of rectal cancer with synchronous liver metastases.

Neoadjuvant versus Postoperative Therapy for Patients with Resectable Gastric Cancer

In the Thursday Controversy session, David Cunningham, MD, FRCP, of Royal Marsden Hospital, debated Charles S. Fuchs, MD, MPH, of Dana-Farber Cancer Institute, about the respective advantages and drawbacks of preoperative epirubicin, cisplatin, and fluorouracil (ECF) versus postoperative chemoradiation for gastric cancer.

Dr. Cunningham reported results from the United Kingdom Medical Research Council Adjuvant Gastric Infusional Chemotherapy (MAGIC) trial, which evaluated 503 patients with resectable gastric cancer.[1] The study found that patients who received perioperative chemotherapy showed significant improvement in survival rates compared with those who received surgery alone. The study involved perioperative treatment with three pre and postoperative cycles of continuous infusion ECF—a regimen with proven efficacy in advanced disease, supported by randomized trials and a Cochrane meta-analysis.[2]

Dr. Cunningham observed that the trial has "shown that the use of perioperative therapy is associated with a significant improvement (p = 0.009) in the survival rates of patients with resectable gastric adenocarcinoma, as well as cancer of the lower esophagus and gastro-esophageal junction, compared with surgery alone."

Preoperative treatment has several potential advantages, according to Dr. Cunningham. These include:

- Downstaging/downsizing the primary tumor and sterilization of microscopic marginal involvement with tumor, which may facilitate curative (R0) surgical resection
- Eliminating disseminated micrometastatic disease
- Treating any undetected systemic disease weeks to months ahead of postoperative treatment
- Improving tumor-related symptoms such as dysphagia, pain, and nutritional impairment
- Demonstrating in vivo the sensitivity to the chosen chemotherapy regimen

With a median follow-up of at least three years, the median overall survival for patients who received perioperative chemotherapy was 24 months, compared with 20 months for patients who had surgery only; the five-year survival rates were 36% and 23%, respectively.

Despite the survival outcomes of patients enrolled in the MAGIC trial, Dr. Cunningham cautioned session attendees not to compare these results with those of the U.S. Intergroup 0116 study, which previously established postoperative adjuvant chemoradiotherapy as the standard of care for patients with curatively resected gastric cancer. Patients enrolled in the U.S. study were deemed eligible for entry into the study only after confirmation of complete resection, and were registered after sufficient surgical recovery. Participants were enrolled in the MAGIC trial after initial diagnosis.

Despite the differences in patient selection and study design, Dr. Fuchs suggested that clinicians may be interested in comparing the two studies.[3]

"Intergroup 0116 offers compelling evidence for postoperative chemoradiation, whereas MAGIC supports the use of preoperative and postoperative ECF," he said. He added that the trial demonstrated a significant survival benefit for patients who received postoperative chemoradiotherapy.

Ultimately, the question remains: Is preoperative ECF better than postoperative chemoradiotherapy? Dr. Fuchs noted that this is still unknown. Despite similar endpoints, the two trials are sufficiently different to preclude easy comparison, with each offering compelling data about the most effective treatment for gastric cancers.

Is Radiation Therapy Necessary for Adjuvant Treatment of Pancreatic Cancer?

In the Friday Controversy session, Christopher Willet, MD, of Duke University Medical Center, engaged in a pro-con debate with John P. Neoptolemos, MD, PhD, of the University of Liverpool, about the inclusion of radiation in adjuvant treatment for patients with pancreatic cancer.

At present, Dr. Willet stated, pancreatic cancer is curable only by surgery. Approximately 5% to 25% of patients have tumors that are amenable to resection. "Historically, patients who undergo resection for localized pancreatic cancer have a long-term survival of approximately 20% and a median survival of 13 to 20 months," he noted.

Despite some limited success with respect to survival outcome, local patterns of failure after surgery occur in 50% to 86% of

View Presentations from the 2006 Gastrointestinal Cancers Symposium Online

Multimedia presentations from the 2006 Gastrointestinal Cancers Symposium are now available for viewing on the ASCO.org Virtual Meeting. Presentations are available in audio/video format (oral abstract presentations) and in slide-only format (poster presentations). Visit www.asco.org/virtualmeeting to access this valuable enduring educational resource.

patients, and rates of distant metastases are high. "Local failure after resection results in pain, biliary gastric obstruction, and bleeding," Dr. Willet said, adding that, "efforts to improve local control [following surgery] have included postoperative radiation and chemotherapy as well as preoperative radiation and chemotherapy."

Dr. Willet referenced three randomized trials designed to evaluate chemoradiation in the postoperative setting, one conducted by the European Organisation for Research and Treatment of Cancer (EORTC), one conducted by the Gastrointestinal Tumor Study Group (GITSG), and one conducted by the European Study for Pancreatic Cancer (ESPAC-1). Although only the GITSG trial demonstrated a two-year survival benefit for patients who received postoperative chemoradiation, Dr. Willet believes that the collective results provide a compelling case for the addition of adjuvant radiation therapy to adjuvant chemotherapy in the treatment of pancreatic cancer.

Dr. Neoptolemos based his remarks on a combined analysis of results of the ESPAC-1 study, the ESPAC 2x2 study, and the ESPAC-1 plus study. Between 1985 and 1995, 100,313 patients with pancreatic cancer from 2,100 hospitals in the United States received adjuvant treatment. Of those, 9,044 had pancreatic resection alone, and 3,614 had pancreatic resection followed by adjuvant treatment. Among patients who had pancreatectomy only, the five-year survival rate was 23.3%. Those who had pancreatectomy followed by chemoradiation had a 13.3% five-year survival rate. Those who had a pancreatectomy plus chemotherapy treatment had a 17.4% five-year survival rate. Those who had a pancreatectomy plus a combination of radiation and chemotherapy had a 17% five-year survival rate.

"Adjuvant chemotherapy has a significant survival benefit in patients with resected pancreatic cancer and now has become the standard of care," Dr. Neoptolemos noted. "The role for adjuvant chemoradiation is uncertain. A further ESPAC study of adjuvant chemoradiation is planned in patients with positive resection margins, as adjuvant chemoradiation treatment appeared more effective in this patient subgroup."

He concluded that there is not sufficient evidence to indicate that chemoradiation is superior to chemotherapy alone in patients with advanced pancreatic cancer. He also noted that there is no evidence that adjuvant chemoradiation in resected pancreatic cancer is superior to chemotherapy alone, and that it may even reduce the significant survival advantage conferred by adjuvant chemotherapy.

Approaches to Treating Rectal Cancer and Synchronous Liver Metastases

At the final Controversies session of the symposium, experts engaged in a debate about treatment for a specific case, in addition to discussing treatment of general patient populations. Medical oncologist David. P Ryan, MD, of Massachusetts General Hospital, and radiation oncologist Robert Glynne-Jones, MBBS, FRCR, FRCP, of the U.K.-based Mount Vernon Cancer Centre, presented their views on appropriate treatment of rectal cancer and synchronous liver metastases.

The case that served as the basis for the discussion involved a patient with resectable T3 N0 rectal cancer located 8 centimeters from the rectal verge with circumferential margins of less than 2 millimeters. The liver metastases were located in a resectable, isolated 6-centimeter tumor.

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FDA Report

The views expressed are the result of independent work and do not necessarily represent the views and findings of the U.S. Food and Drug Administration.

Recently Approved Pharmaceutical Agent Sunitinib Malate (Sutent®)

By Edwin Rock, MD, Vicki Goodman, MD, Ramzi Dagher, MD, Martin Cohen, MD, Robert Justice, MDD

Division of Drug Oncology Products, Office of Oncology Drug Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Rockville, Maryland

On January 26, 2006, the U.S. Food and Drug Administration (FDA) granted approval for sunitinib malate (Sutent® capsules 12.5 mg, 25 mg, and 50 mg), a small molecule inhibitor of multiple receptor tyrosine kinases. Sunitinib was approved for the treatment of gastrointestinal stromal tumors (GISTs) after disease progression on or intolerance to imatinib mesylate (Gleevec®). Approval was also granted for the treatment of advanced renal cell carcinoma based on partial response rates and response duration under accelerated approval regulations. Post-approval trials in renal cell carcinoma are required to demonstrate clinical benefit, such as increased survival or improvement in disease-related symptoms.

Gastrointestinal Stromal Tumors

A single multicenter, randomized, double-blind, placebo-controlled trial was designed to evaluate the efficacy and safety of sunitinib in patients with GISTs who had disease progression during prior imatinib treatment or who were imatinib-intolerant. The starting dose was 50 mg daily, administered orally for 4 weeks, followed by 2 weeks of no treatment. Approximately 10% of patients had their dose reduced following each six-week cycle.

The primary study endpoint was time to progression, and external reviewers who were blinded to study treatment determined radiographic disease progression. Of the two treatment arms, 207 patients were randomly assigned to receive sunitinib and 105 patients received placebo. Baseline age, gender, race, and performance status were comparable between the two treatment arms. Most patients enrolled (96% in both arms) had disease progression at or within six months of completing prior imatinib therapy. Approximately 30% of patients in both groups were age 65 or older, and more than 98% had an Eastern Cooperative Oncology Group (ECOG) performance status of 0/1.

A planned interim efficacy and safety analysis was performed for both groups after 149 time to progression events had occurred. Significant advantages were observed among patients receiving sunitinib, both in time to progression (median, 27 weeks for patients on the placebo arm, compared with six weeks for patients on the sunitinib arm; $p < 0.0001$, hazard ratio = 0.33) and progression-free survival (median, 24 weeks for patients on the placebo arm, compared with six weeks for patients on the sunitinib arm; $p < 0.0001$, hazard ratio = 0.33). Partial response rates were 7% in the sunitinib arm (95% confidence interval [CI], 3.7-11.1) compared with 0% in the placebo arm (Pearson chi-square $p = 0.006$). Survival data are not mature.

A single-arm study conducted in patients with GISTs following progression on or intolerance to imatinib enrolled 55 patients following identification of the recommended phase II regimen. Five partial responses were observed (response rate, 9.1%; 95% CI, 3.0-20.0).

Renal Cell Carcinoma

Efficacy and safety for the treatment of renal cell carcinoma with sunitinib were evaluated in two single-arm, multicenter trials (Study 1 and Study 2) that enrolled a total of 169 patients with metastatic disease. All patients had either progressive disease or intolerance to interleukin-2 and/or interferon-alpha. The median age of patients enrolled in the two trials was 57 years (range, 24-87); 65% of trial participants were male. All patients had an ECOG performance score below 2 at screening. Ninety-five percent of the treated population had a component of clear cell histology and 97% had prior nephrectomy. Approximately half of the patients had three or more disease sites.

Overall response rate was the primary endpoint for both studies. No complete responses were observed in either study. Patients evaluated in Study 1 had a 25.5% partial response rate (95% CI, 17.5-34.9) [core radiology laboratory assessment]. Response duration is not mature. Patients evaluated in Study 2 had a 36.5% partial response rate (95% CI, 24.7-49.6) [investigator assessment]. The median response duration was 54 weeks (95% CI, 34.3-70.1).

Continued on page 56

NCI Program Highlights

NIH Launches Comprehensive Effort to Explore Cancer Genomics

The Cancer Genome Atlas Begins with Three-Year, $100 Million Pilot

After the unanimous endorsement of the National Cancer Institute's (NCI) Board of Scientific Advisors, NCI and the National Human Genome Research Institute (NHGRI) have initiated The Cancer Genome Atlas (TCGA) Pilot Project. This is a comprehensive and coordinated effort to accelerate our understanding of the molecular basis of cancer through the application of genome-analysis technologies, including large-scale genome sequencing.

Although more information is available now about the molecular basis of many cancers, there is still a great deal more to learn about this complex disease. A much deeper, systematic understanding of cancer genetics could provide important insights into the molecular pathways that—when disrupted—lead to the uncontrolled growth of cancer cells and enable them to spread throughout the body.

This genetic information could fuel powerful advances in cancer clinical research and disease management. It could also provide an expanded catalog of new therapeutic targets and suggest new ways to categorize tumors that would allow clinical trials to focus on those patients who are most likely to respond to specific treatments. Successes in the field of targeted therapies—such as imatinib (Gleevec®) for chronic myeloid leukemia and gastrointestinal stromal tumors and trastuzumab (Herceptin®), a drug for one form of breast cancer—have highlighted the promise of

treatments based on a solid genetic knowledge of specific types of cancer.

The full-scale TCGA project would attempt to develop a comprehensive catalog, or atlas, of the many genetic changes that occur in cancers, from chromosome rearrangements to DNA mutations and epigenetic changes. However, embarking on such an ambitious venture requires significant planning, so NCI and NHGRI are taking a phased approach to ensure that the appropriate technologies, systems, and processes will be developed and evaluated in the context of a high-throughput effort.

The first phase is the TCGA Pilot Project. Its milestones will be evaluated to provide a basis for undertaking a larger effort to include the following:

- Robust genomic analysis of two tumor types to produce a "pipeline" of candidate genes or regions for sequencing
- Verification of the ability to find and correlate genomic changes such as copy number changes, deletions, and amplifications through in-depth sequencing
- Verification of the ability to differentiate tumor subtypes based on genomic characterization and sequence data
- Establishment of a public database of genomic characterization, sequence, and clinical data to enable discovery and translational research
- Development of technology that provides the capability to differentiate significant genomic changes from "noise"

Meeting these milestones requires the development of improved genome characterization methods, better DNA sequencing technology, standardization and quality control in biospecimen handling, increased accuracy in data analysis, and further evaluation of the utility of data produced by large-scale genomic analysis of tumor biologic components. The TCGA Pilot Project will help both NCI and NHGRI assess the feasibility of a full-scale project.

The Human Genome Project, completed in 2003, provided the reference sequence for the TCGA Pilot Project. In addition, it served as a stimulus for the development of the high-throughput, cost-effective DNA sequencing. The Human Genome Project also showed the value of a collaborative community effort in undertaking a project of such magnitude.

Researchers have identified more than 300 genes that are associated with cancer, which has set the stage for a more systematic, integrated national effort. NCI and NHGRI each have pledged $50 million a year over three years for the pilot project. The components of the TCGA Pilot listed below will be supported by a combination of grants, cooperative agreements, and contracts.

- **Cancer Genome Characterization Centers (CGCC):** These centers will conduct a variety of analyses using established technologies (e.g., gene expression profiling, copy number analysis) to elucidate the spectrum of genomic changes found in human tumors and to identify interesting genomic regions for further characterization.
- **Genome Sequencing Centers (GSC):** The genes and other genomic targets identified by the CGCCs will be sequenced by the GSCs using high-throughput methods similar to those employed in the Human Genome Project.
- **Human Cancer Biospecimen Core Resource:** This core will support the collection, processing, and distribution of cancerous and healthy control tissue samples to the CGCCs and GSCs.
- **Data Management, Bioinformatics, and Computational Analysis:** The informatics component of the pilot project will involve developing the best ways to collect, store, and distribute the clinical and genomic data generated by the project.
- **Technology Development:** The technologic challenges presented by the TCGA Pilot Project include the need to improve molecular characterization methods, such as gene expression, with respect to quality, throughput, and cost; to further decrease the costs of DNA sequencing while maintaining quality; to improve the detection and throughput of technologies for detecting epigenomic changes, while also decreasing cost; and to develop new and better methods of correlating disease state with genomic changes.

The TCGA Pilot Project will place all of the data it develops into public databases for use by the broader cancer research community. The TCGA Pilot Project promises to not only address the question of potential scale-up, it may also lead to advances in the development of new cancer therapeutic and diagnostic interventions. AN&F

For more details about The Cancer Genome Atlas, including a question-and-answer section, a graphic illustration, a glossary, a brief guide to genomics, and a media library of available images, visit http://cancergenome.nih.gov. Additional information about the National Human Genome Research Institute can be found at www.genome.gov.

Redesigned ASCO.org Offers Disease-Specific Portals, Enhanced Search Capabilities

In January 2006, ASCO unveiled a new version of ASCO.org, redesigned to provide easy access to the most comprehensive collection of oncology-related information on the Web. First launched in 1996, ASCO.org has gone through several iterations. The website's mission is to be the "voice of oncology on the Internet," and with the addition of 12 portals to disease-specific sites, and easier access to cancer research, the new ASCO.org continues to be the authoritative voice of oncology online.

The website now features an innovative search engine and a more user-friendly interface, with links to some of the Society's most popular online features—Annual Meeting information and the ASCO.org Virtual Meeting—now centrally located on the home page. The new design also provides easy access to the online version of *ASCO News & Forum* (formerly *ASCO News*) as well as links to the other ASCO websites, including the *Journal of Clinical Oncology* (www.jco.org), the *Journal of Oncology Practice* (www.jopasco.org), People Living With Cancer (www.plwc.org), and The ASCO Foundation (www.ascofoundation.org). The website also provides a prominent link to the popular Clinical Practice Guidelines.

ASCO has enhanced the navigational capabilities of the website to place the most frequently accessed links on the home page. Many features within these areas have been regrouped based on user feedback and organized in a manner that makes the most intuitive sense to users.

Ronald Blum, MD, 2005-2006 Chair-Elect of the ASCO Information Technology Committee, defined the vision for the new website, which was developed "around the way users use it." Dr. Blum suggested that ASCO.org content be organized thematically, noting that clinicians often seek disease-oriented information because they have patients with a particular disease. The result was the development of 12 disease-specific portal sites, all of which are accessible from the website's home page.

The 12 portals allow users to link to vital information about specific cancer topics of their choice, including relevant presentations from the ASCO.org Virtual Meeting, articles from the *Journal of Clinical Oncology*, abstracts from past Annual Meetings, *Educational Book* manuscripts, and related articles available through PubMed. During the coming months, additional disease-specific portal sites will be launched.

The benefit to ASCO.org users is the ability to access unique content available through the website in one central location. In order to create a website that meets the needs of users who search thematically, it became evident that ASCO.org should have powerful searching capabilities and strategic content aggregation, to produce the most relevant search results. To maximize search results, ASCO selected the Vignette content management system and the innovative search engine Vivísimo around which to build the new site.

"The content developer used topic categories which thematically fit ASCO.org content and grouped it accordingly," Dr. Blum explains. "In the back end, we were able to track those topic categories to common data elements, so they could be tagged by a content management system like Vignette." Then, the Vivísimo search engine aggregates information in a hierarchical way, similar to what Windows Explorers users see when clicking through folders. The result is that users receive more relevant results to their search queries.

Robert S. Miller, MD, 2005-2006 Chair of the ASCO Information Technology Committee, echoes Dr. Blum's sentiments about the website's improved functionality. "The enhanced navigation tools, such as the one-click access to the *Journal of Clinical Oncology* and the *Journal of Oncology Practice*, will also enhance the browsing experience," he says.

Additionally, Dr. Miller notes, "ASCO is the world's leading organization representing health professionals who treat patients with cancer, and our members expect us to utilize and to bring to them the latest technologic tools that improve professional education and patient care. ASCO has a long history of embracing advanced technologies, such as streaming audio/video for the Virtual Meeting, and this has enabled us to deliver our content to oncologists worldwide, in a very short time frame after its creation." AN&F

Since it was first launched in 1996, ASCO.org has had several looks. The latest version maximizes user efficiency by employing a thematic layout.

1996

2002

2003

2006

Survey Says

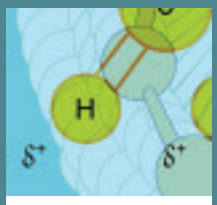
Before the ASCO.org redesign was initiated, the Society conducted a survey of member users to determine how they search for information. The Web-based survey of ASCO.org users revealed the top reasons for visiting the website. Nearly three-quarters of respondents indicated that they visit the site to find a list of upcoming ASCO meetings, 38% visit to find a list of other oncology meetings, and 22% visit to learn more about continuing education opportunities.

Of the ASCO publications that users search for online, 80% responded that the *Journal of Clinical Oncology* was the most important to them, followed by the *Educational Book*.

The survey also found that of respondents who visit the site for practice-related materials, 63% said that information related to clinical best practices was most important to them. Thirty-six percent of respondents find patient guides most important. One-third identified ASCO position statements as the most important Society resource available on ASCO.org.

Additionally, a 2004 member survey completed by 2,005 respondents revealed some interesting statistics about how members rate features of the ASCO.org site. On a scale of 1 to 10 (where 10 was defined as "Excellent"), respondents rated ASCO meeting information at 8.5 and access to scientific abstracts and clinical practice guidelines at 8.3.

These surveys, combined with extensive usability testing and user feedback, helped guide the development of what is now the new ASCO.org.



Scientific Highlights from Other Meetings

Recent Conferences Highlight Advances in Breast Cancer Research and Geriatric Oncology

28TH ANNUAL SAN ANTONIO BREAST CANCER SYMPOSIUM

San Antonio, Texas
December 8-11, 2005

By Antonio C. Wolff, MD, FACP
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins

More than 6,500 physicians, researchers, and caregivers from 82 countries assembled for the 28th Annual San Antonio Breast Cancer Symposium (SABCS), where they heard presentations that placed recent developments in breast cancer research into clinical perspective. In 2005, we benefited from a steadily improving ability to use predictive markers to identify those patients most likely to benefit from specific therapies, while reducing the risk of unnecessarily exposing many patients to a costly placebo. Recommendations from clinical practice guidelines and expert consensus panels increasingly emphasize the utility of markers as predictors of therapy benefit over those used primarily for prognostic risk stratification. Presentations during the most recent SABCS offered additional insight on the integration of aromatase inhibitors and trastuzumab in the adjuvant setting, and also contributed to the evolving discussion about gene expression profiles as molecular classifiers for various breast cancer subtypes.

Improving Outcome for Patients with Endocrine-responsive Breast Cancer

Paul E. Goss, MD, PhD, of Massachusetts General Hospital, presented an updated analysis of results of the National Cancer Institute of Canada (NCIC) Clinical Trials Group study MA.17, in which 5,187 postmenopausal women with breast cancer were randomly assigned to receive either letrozole or placebo following five years of tamoxifen therapy. The trial was unblinded in October 2003 after the first interim analysis, and women in the placebo arm were given the option of switching to letrozole. In the current analysis, researchers sought to evaluate the utility of late crossover from placebo to letrozole.

Follow-up treatment information was available for 2,247 women originally assigned to the placebo arm who were free of recurrence and alive when the study was unblinded. Among these women, 1,601 crossed over from placebo to letrozole. The most recent analysis shows a clinical benefit even for those patients who had received placebo for a few years, suggesting that even late introduction of an

aromatase inhibitor will be efficacious in patients who are free of disease and more likely to have endocrine-responsive disease. Further analysis is needed to determine optimal duration of letrozole treatment and long-term toxicities associated with its use; a recent protocol amendment allows patients who complete 10 years of sequential tamoxifen followed by letrozole to be randomly assigned to receive either placebo or letrozole in years 11 through 15.

Optimizing Trastuzumab Efficacy for Early-stage, HER2-positive Breast Cancer

Dennis J. Slamon, MD, PhD, of the University of California, Los Angeles, presented the first interim results from the Breast Cancer International Research Group 006 study to compare 8 cycles of doxorubicin and cyclophosphamide followed by docetaxel (AC → T) with 8 cycles of doxorubicin and cyclophosphamide followed by docetaxel and trastuzumab (AC → TH) with 6 cycles of docetaxel, carboplatin, and trastuzumab (TCH) in patients with HER2-positive, high-risk, early-stage breast cancer. This randomized phase III trial was designed to evaluate the use of adjuvant trastuzumab added to both an anthracycline-containing and a non-anthracycline containing regimen. The primary trial endpoint was disease-free survival, and patients in both trastuzumab arms who received one year of weekly trastuzumab starting after the anthracycline regimen (AC →TH) or from day one (TCH arm) had better survival outcomes.

At a median follow-up of 23 months, patients in the trastuzumab-containing arms had higher rates of disease-free survival than patients in the standard AC → T arm. There were more patients with a greater than 10% relative decline in left ventricular ejection fraction in the AC → TH arm (17.3%) compared with the AC → T (9%) and TCH (8%) arms ($p = 0.002$ and $p < 0.0001$, respectively).

Of great interest, co-amplification of the topoisomerase II alpha gene was observed in one-third of the patients with HER2-positive disease, and these patients appear to gain the most benefit from the use of trastuzumab following an anthracycline.

Heikki Joensuu, MD, of Helsinki University Central Hospital, Finland, discussed interim results from the FinHer trial, which examined the safety and efficacy of trastuzumab when given to patients with early-stage breast cancer for nine weeks concomitantly with presumably synergistic chemotherapy agents. Patients in this study (who were either node-positive or node-negative with high-risk tumors) received single-agent chemotherapy (docetaxel or vinorelbine) followed by three cycles of fluorouracil, epirubicin, and cyclophosphamide (FEC). Patients who were HER2-positive were further randomized to receive weekly trastuzumab (beyond the first nine weeks of therapy before FEC). Recurrence-free survival was significantly better in the docetaxel arm vs. the vinorelbine arm (91.3% vs. 86.5%; p = 0.005). For patients with HER2-positive disease, recurrence-free survival was significantly better among those who received trastuzumab for nine weeks compared with those who received no trastuzumab (89.3% vs. 77.6%; p = 0.01). Though small, this trial offers additional insight about the optimal duration of trastuzumab therapy and its continuation as a single-agent regimen beyond the chemotherapy period, an issue that remains unsettled.

Multi-Gene Prognostic Assays

John Foekens, DO, of Josephine Nefkens Institute, Germany, presented results from a multicenter validation study for a 76-gene prognostic signature for patients with lymph node-negative primary breast cancer. According to Dr. Foekens, 85% to 90% of patients with node-negative disease are currently recommended for systemic therapy, although only 5% to 15% will benefit from it. The 76-gene profile was originally generated using distant metastasis-free survival as the clinical endpoint, with a median follow-up time of 101 months. The initial training set included 80 patients with estrogen receptor (ER)-positive disease and 35 patients with ER-negative disease; no patients in either group had received previous adjuvant systemic treatment. The profile generated from this initial set was then validated in an independent set of 171 patients. The research Dr. Foekens presented involved a new set of 180 patients (164 ER-positive, 16 ER-negative; median follow-up, 100 months) from four different institutions. For this new set of patients, the gene signature gave a hazard ratio (HR) of 7.41 (95% confidence interval [CI], 2.63-20.9), even when corrected for traditional prognostic factors in the multivariate analysis (HR = 11.36; 95% CI, 2.67-48.4). Findings indicate that for both of these independent validation sets, the 76-gene signature was highly effective in identifying patients who will develop distant metastasis within five years. Interim analysis from an ongoing study suggests that the signature may potentially be useful for patients with node-negative, ER-positive disease who have been treated with tamoxifen.

Eleftherios Mamounas, MD, MPH, of the National Surgical Adjuvant Breast and Bowel Project (NSABP), discussed new research from a 21-gene recurrence score assay, Oncotype DX®. Researchers investigated the association between recurrence score and the risk of locoregional recurrence in patients with ER-positive, node-negative disease in two NSABP protocols (B-14 and B-20). Investigators determined that this assay, which was previously shown to have prognostic and predictive utility in identifying risk of systemic recurrence and systemic therapy benefit, respectively, also can be used to predict local or regional recurrence. This study evaluated 895 patients treated with tamoxifen (668 from B-14; 227 from B-20); 355 patients treated with placebo (from B-14); and 424 patients treated with both chemotherapy and tamoxifen (from B-20). Rates of 10-year local or regional recurrence among patients with low, intermediate, and high-risk recurrence scores are listed in Table 1. Dr. Mamounas noted that this data could have clinical implications relative to locoregional therapy decisions and follow-up requirements for patients with node-negative, ER-positive disease.

Exploring Treatment Options for Patients with Chemoresistant Disease

Gunter von Minckwitz, MD, PhD, presented first results from a phase III GEPARTRIO Study on behalf of the German Breast Group. In this study, patients with operable or locally advanced breast cancer received two cycles of docetaxel, doxorubicin, and cyclophosphamide (TAC); if tumor reduction was less than 50%, according to a breast ultrasound, patients were randomly assigned to receive either 4 additional cycles of TAC or 4 cycles of vinorelbine and capecitabine (NX). Between July 2002 and June 2005, approximately 2,050 patients were enrolled in this study. Preliminary data indicate that in vivo chemosensitivity testing by

Table 1. Risk of Locoregional Recurrence in Patients with ER-Positive, Node-Negative Disease

Treatment	Recurrence Score Group	10-year local or regional recurrence (%)	Log-Rank (p-value)
Placebo	Low-risk Intermediate-risk High-risk	10.8 20.0 18.4	p = 0.022
Tamoxifen	Low-risk Intermediate-risk High-risk	4.3 7.2 15.8	p < 0.0001
Chemotherapy plus tamoxifen	Low-risk Intermediate-risk High-risk	1.6 2.7 7.8	p = 0.028

early response evaluation is feasible and valid. Patients without an early response showed late clinical benefits—such as a breast conservation rate of 60%—but pathologic complete response rates were infrequent. The design of the GEPARTRIO study, therefore, provides a potential clinical model for testing new treatment approaches in an early chemoresistant population. The NX regimen also demonstrates a better toxicity profile for patients without an early response to TAC. Findings further suggest that patients without an early response to TAC benefit more from a switch to NX. However, Dr. von Minckwitz noted, there is a definite need to improve treatment options for this population.

Dose-dense Chemotherapy

Clifford Hudis, MD, of Memorial Sloan-Kettering Cancer Center, presented 5-year follow-up results of INT C9741 on behalf of researchers from Cancer and Leukemia Group B (CALGB), the Eastern Cooperative Oncology Group (ECOG), the Southwest Oncology Group (SWOG), and the North Central Cancer Treatment Group (NCCTG). Investigators compared efficacy and safety of a dose-dense, 2-week chemotherapy regimen using doxorubicin, paclitaxel, and cyclophosphamide with the standard 3-week treatment. The study sought to determine if more frequent administration at the same dosage would decrease the available time for tumor regrowth between cycles, allow for treatment of a smaller tumor volume, and result in greater overall cell kill.

The study enrolled patients with lymph node-positive disease using a two-by-two factorial design. Patients were randomly assigned to receive either 4 cycles each of sequential doxorubicin, paclitaxel, and cyclophosphamide or 4 cycles of doxorubicin and cyclophosphamide delivered concurrently, followed by 4 cycles of paclitaxel. Within each group, patients were further randomly assigned to receive treatment either every 2 or every 3 weeks.

When the study closed, in March 1999, 1,972 patients were available for evaluation. Researchers observed no significant difference in rates of disease-free survival between patients in the sequential and concurrent groups ($p = 0.65$); however, a significant difference was observed between the 2- and 3-week groups ($p = 0.012$). Additionally, no difference in overall survival rates in the sequential group compared with the concurrent group was observed; however, a significant improvement was observed in the 2- versus 3-week group and is maintained in this update ($p = 0.049$). An unplanned retrospective subset analysis suggests that there may be a greater absolute benefit in estrogen receptor-negative compared with estrogen receptor-positive disease.

SIXTH ANNUAL MEETING OF THE INTERNATIONAL SOCIETY OF GERIATRIC ONCOLOGY (SIOG)

Geneva, Switzerland
September 29-30, 2005

By Matti Aapro, MD
Executive Director, SIOG

The Sixth Annual Meeting of the International Society of Geriatric Oncology (SIOG), co-chaired by Gilbert Zulian, MD, of Geneva University Hospitals, Switzerland, and Harvey Cohen, MD, of Duke University Medical Center, attracted more than 250 attendees. The meeting was designed to update health care professionals on the latest developments in geriatric oncology.

Cancer in the older population accounts for more than 60% of all reported incidences worldwide and affects individuals across the globe. According to the International Union Against Cancer (UICC), as the median age increases in developing countries such as India and China, the number of cases of cancer in older patients will also grow and will require enhanced treatment resources. Oncologists and other health care professionals should encourage older patients with cancer to enroll in clinical trials to avail themselves of better treatment options and to bolster geriatric research efforts worldwide.

Evaluation and Treatment of Older Patients with Cancer

Proper evaluation of older patients can minimize the incidence of drug-related toxicity and help improve quality of life. Lodovico Balducci, MD, of H. Lee Moffitt Cancer Center & Research Institute, presented the National Comprehensive Cancer Network (NCCN) guidelines for optimal management of cancer in the older population. The NCCN committee responsible for geriatric oncology management generated guidelines related to cancer care for older individuals in four topic areas:

- Special evaluation in individuals older than age 65
- Pharmacokinetic changes of age

Review Presentations from the San Antonio Breast Cancer Symposium Online

Visit the San Antonio Breast Cancer Symposium website at www.sabcs.org to view streaming webcasts of presentations, to review abstracts, and to read scientific coverage in the daily symposium newsletter.

The 29th Annual SABCS will be held on December 14–17, 2006, in San Antonio, Texas. For more information about registration and the abstract submission process, visit www.sabcs.org.

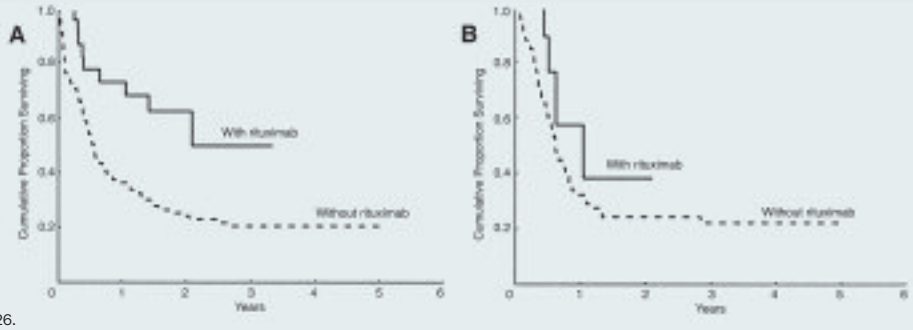


Fig. 1. Effect of rituximab-containing chemotherapy as salvage treatment at time of first progression on overall survival after progression: (A) in patients previously treated with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP; log-rank test, p = 0.00043); (B) in patients previously treated with rituximab plus CHOP (log-rank test, p = 0.076).

Reprinted from P. Feugier et al. *J Clin Oncol*. 2005:23(18);4117-26.

- Common forms of chemotherapy-related toxicity in older individuals
- Management of anemia

SIOG has a task force to examine glomerular filtration rate in patients older than age 65, which reported that the safe administration of chemotherapy is a key element in appropriate dose adaptation for many commonly used drugs. A frequent mistake is to look only at serum creatinine values.

Matti Aapro, MD, of Clinique de Genolier, Switzerland, reported results from the European Organisation for Research and Treatment of Cancer (EORTC) Granulocyte Colony-Stimulating Factor (G-CSF) Task Force. Level 1 evidence has shown that patient-related factors that increase the risk of febrile neutropenia include age and various chemotherapy regimens. Level 1 evidence also has demonstrated that G-CSF should be used to maintain the correct dose of chemotherapy and the relative dose intensity/density, reducing the incidence of febrile neutropenia.

Lazzaro Repetto, MD, of Istituto Nazionale Riposo e Cura per Anziani, Italy, reported the EORTC guidelines for use of erythropoietic proteins (EPO). For patients receiving chemotherapy and/or radiotherapy, treatment with erythropoietic proteins should be initiated at a hemoglobin (Hb) level of 9-11 g/dL based on anemia-related symptoms, provided other causes of anemia are excluded. Patients who have normal Hb values at the start of treatment should not receive EPO. For patients who achieve the target Hb level of 12-13 g/dL, individualized titration of the lowest effective maintenance dose should be repeatedly made.

Pain Management

Pain management in older patients with cancer needs thorough assessment, continuous monitoring, and reassessment, said Marit Jørdhoy, MD, of Norwegian University of Science and Technology. Claude Pichard, MD, of Geneva University Hospital, Switzerland, discussed how malnutrition has a negative effect on survival and tolerance to chemotherapy. Dr. Pichard recommended that a nutritional assessment be carried out in all older patients with cancer before the onset of therapy.

Breast Cancer

Multidimensional Geriatric Evaluation should be used to stratify patients based upon their physical strength in order to provide an optimal therapeutic approach. Older patients with breast cancer are being undertreated, particularly because of concerns over excessive toxicity; however, Hans Wildiers, MD, PhD, of UH Gasthuisberg, Belgium, demonstrated that taxanes can be a reasonable option for older patients with metastatic breast cancer.

Non-Small Cell Carcinoma

Hervé LeCaer, MD, of Service de Pneumologie, France, reported the results of a review of the usefulness of chemotherapy in lung cancer treatment for the older population. To date, single-agent chemotherapy with vinorelbine, gemcitabine, docetaxel, and paclitaxel are reasonable options. Dr. LeCaer emphasized that retrospective subset analyses from large randomized trials suggest that the efficacy and tolerability of platinum-based combination chemotherapy is similar in both older and younger patients.

Non-Hodgkin Lymphomas

Bertrand Coiffier, MD, of University Hospital, France, presented study results on behalf of the Groupe d'Etude des Lymphomes Digestifs (GELA). The GELA study enrolled 399 older patients with diffuse large cell lymphomas to compare 8 cycles of vincristine, doxorubicin, cyclophosphamide, and prednisone (CHOP) with 8 cycles of CHOP plus rituximab (R-CHOP). At the conclusion of treatment, 76% of patients in the R-CHOP arm experienced a complete response, compared with 63% of patients in the CHOP arm. Chemotherapy led to significant prolongation of both event-free survival and overall survival in older patients with diffuse large cell lymphomas, without significant additional toxicity (Fig. 1). This benefit was recently confirmed by the results of an ECOG-Intergroup study and by a population-based analysis conducted in British Columbia. A similar benefit was observed in three randomized studies of patients with follicular lymphoma comparing different chemotherapy regimens with or without rituximab.

Multiple Myeloma

As Nicholas Ketterer, MD, of Centre Pluridisciplinaire d'Oncologie, Switzerland, noted, qualified patients older than age 65 should not be excluded from intensive approaches using autologous stem cell transplantation. Dr. Ketterer discussed thalidomide and its analogs, as well as new targeted therapies such as bortezomib, which have all shown promising results and could be very attractive alternatives for the treatment of multiple myeloma in the older population. AN&F

The Seventh Annual SIOG Meeting will take place November 2–4, 2006, in The Netherlands. For more information, visit the SIOG website (www.cancerworld.org/siog).

Inside the JCO

The Art of Oncology: When the Tumor Is Not the Target

Charles L. Loprinzi, MD, Editor of the "Art of Oncology" series in the Journal of Clinical Oncology *(JCO), discusses this important resource for information about treating patients with cancer at the end of life.*

AN&F: **Why was the "Art of Oncology" originally conceived?**

Dr. Loprinzi: Evaluating how oncologists provide end-of-life care was a major initiative of Robert Mayer, MD, during his ASCO presidential tenure (1997-1998). Under his leadership, a task force was formed and a questionnaire was sent to all ASCO members to generate a better understanding of this complex topic. One important conclusion drawn from this work was that many oncologists feel uncomfortable about their ability to provide adequate end-of-life care to their patients. It was felt that this topic was not appropriated sufficient attention in JCO. To address this, a decision was made to dedicate a portion of the Journal to the discussion of end-of-life care, and I was invited to serve as the Editor for this section. The new series, entitled "The Art of Oncology: When the Tumor Is Not the Target," debuted in the January 1, 2000, issue of JCO. Since then, it has evolved to discuss issues related to end-of-life care, symptom control, communication with patients, and how oncologists cope with treating patients who have life-threatening diseases.

AN&F: **What format is used for these articles?**

Dr. Loprinzi: "Art of Oncology" articles are generally short, concise pieces that are clinically practical. Some of these pieces are emotionally charged, to get the reader to reflect on the issue being discussed. They are not meant to be long review articles, but are instead short pieces people can read over a cup of coffee, giving themselves time to reflect upon the powerful subject matter. The intent of these articles is not to abandon clinical science, but to enhance upon it. Although science is commonly integrated into these articles, more importantly, they address how oncologists put this science into clinical practice.

AN&F: **What topics have been covered in this section?**

Dr. Loprinzi: A variety of issues have been covered, such as how to be honest with patients about their condition; how to be realistic but simultaneously hopeful; and how to answer the difficult question of "How much time do I have left?" Practical guidance regarding hospice care and "do not resuscitate" orders are also included within this section.

AN&F: **How are people able to access this column, both in print and online?**

Dr. Loprinzi: The "Art of Oncology" is available on ASCO's patient information website, www.plwc.org, and in both the print and online versions of JCO. After the first three years of publication, the initial 36 articles were compiled into an anthology, which was distributed to ASCO members in May 2003. The response to the anthology has been really remarkable; people have repeatedly told me how much they enjoyed the collection. Copies of this anthology are still available through ASCO. One German physician, Dr. Serban Costas, was so impressed by the anthology that he developed a German-language edition, which was given to oncologists in Germany.

AN&F: **Although this series was originally created for physicians and other health care providers, have patients with cancer benefited from these articles?**

Dr. Loprinzi: Although these pieces are written for oncology professionals, there is substantial evidence that the educated lay public can also grasp their emotional meaning, as many are essentially human-interest essays. The section has been shared with various members of the general public, and these people have responded with a great deal of enthusiasm. To examine the value of the anthology for patients, a more formal study was conducted in which 30 people with advanced, incurable cancer were given a copy to read. They were then scheduled for a structured interview, about a month

The "Art of Oncology" Anthology Available for Purchase

To purchase the "Art of Oncology" anthology, visit the "ASCO Bookstore" on ASCO.org (www.asco.org) or call the ASCO Customer Service Department at 888-273-3508 or 703-519-1430.

later. Results showed that many of the patients felt that they had benefited from reading the articles. Although many of the patients clearly felt that some parts of the text were emotionally difficult, many of them also felt that the essays helped them come to terms with their cancer and its consequences. The results of the study were published in JCO in 2005 (Vickers KS et al. *J Clin Oncol.* 2005; 23(18):4013-20). In total, I believe that these pieces can be helpful for selected patients, family members, and other members of the lay public.

AN&F: **It sounds as if you have enjoyed being Editor of the "Art of Oncology."**
Dr. Loprinzi: The interest that "Art of Oncology" has garnered from both the medical and non-medical communities has been extremely satisfying to me; I hope individuals will continue to find these articles both powerful and intellectually stimulating. I thank ASCO for its help in creating this section of JCO, and for its dedication to educating clinicians and the general public about end-of-life care issues over the past six years. The Society is at the forefront of patient care initiatives, and its support of the "Art of Oncology" series further demonstrates its commitment to this important issue.

Read the most recent "Art of Oncology" article
"Deliberate Deceit of Family Members: A Challenge to Providers of Clinical Genetics Services" is available in the print version of the April 1 issue of JCO, as well as online at www.jco.org.

Practice-Changing Research featured in JCO Special Series

Original research in the JCO Special Series explores emerging translational oncology topics such as immunotherapy, genomics, proteomics, protein profiling, and cancer biomarkers. Among the research included in the April 10 issue are the following four studies:

- **"Estrogen-Regulated Genes Predict Survival in Hormone Receptor-Positive Breast Cancers."** Investigators developed a gene expression-based outcome predictor for patients with estrogen receptor-positive and/or progesterone receptor-positive breast cancer using biologic differences. This study provides new information concerning differences within hormone-receptor positive disease and a means of predicting long-term outcomes for patients treated with tamoxifen.

- **"Association of the PDCD5 Locus with Lung Cancer Risk and Prognosis in Smokers."** Researchers sought to identify genetic variants predictive of lung cancer risk in smokers and to confirm the identified variants in an independent sample. Findings suggest that the rs1862214 polymorphism in PDCD5 is a predictor of lung cancer risk and prognosis, and that PDCD5 may represent a novel tumor suppressor gene influencing lung cancer.

- **"Use of Cigarette Smoking History to Estimate the Likelihood of Mutations in Epidermal Growth Factor Receptor (EGFR) Exons 19 and 21 Adenocarinomas."** According to this study, the likelihood of EGFR mutations in exons 19 and 21 decreases as the pack-years increases. Researchers believe that these data can assist clinicians in assessing the likelihood of exon 19 and 21 EGFR mutations in patients with lung adenocarcinoma when mutational analysis is not feasible.

- **"Survival Improvement in Medullary Thyroid Carcinoma Patients Given Pretargeted CEA Radioimmunotherapy."** Investigators evaluated rates of overall survival in patients with medullary thyroid cancer who received pretargeted radioimmunotherapy (pRAIT) with bispecific monoclonal antibodies and a 131I-labeled bivalent hapten and in patients who received no treatment. pRAIT induced long-term disease stabilization and significantly longer rates of overall survival in patients at high risk compared with similar patients at high risk who were not treated.

To view the full text of the original research articles listed above, as well as other editorials and correspondence printed in this issue, visit www.jco.org, select "JCO Special Series," and choose the April 10, 2006, issue icon.

JCO Update

Final Results of 2005 Readership Survey

Journal of Clinical Oncology (JCO) readers were recently asked to complete a survey to gauge their opinions about the Journal, its content, and its readability. A total of 1,608 usable responses were received by the survey end date of December 2, 2005.

In general, respondents are very satisfied with JCO, collectively rating it an 8.0 on a 10-point satisfaction scale. More than 80% of respondents believe the Journal is superior to or equal in quality compared with similar journals on the market. When asked to rate it against the *New England Journal of Medicine*—widely considered the gold standard in the scholarly journal industry—nearly two-thirds of respondents identify JCO as better or about equal in quality.

Most respondents considered key current content features of JCO, including the publication of review articles, special articles, original reports, and editorials, very useful. Readers offered the following suggestions for making JCO even more useful:

- Increase coverage of select content areas such as hematologic malignancies, supportive care, translational research, surgical oncology, and clinical reviews
- Incorporate additional summaries and graphs
- Improve the online experience of JCO

Respondent comments about the JCO Review Series and Molecular Oncology Series, which debuted in January 2005, were generally positive. All four issues published in the Molecular Oncology Series at the time of survey circulation—Signal

Continued on page 53

JCO and ASCO Publications Booth at the Annual Meeting

The full roster of ASCO publications and resources will be available for purchase at the JCO and ASCO Publications Booth at the 2006 Annual Meeting. In addition to learning more about JCO and its online features, visitors can review the most recent issues of the *Journal of Oncology Practice* (JOP) and purchase copies of popular ASCO educational resources such as *Oncology MKSAP*, 3rd Edition, and *Practical Tips for the Practicing Oncologist*, 3rd Edition.

Visitors can sign up for trial subscriptions and renewals, register to receive free electronic JCO Table of Contents Alerts, activate online subscriptions, and receive a free gift. Sample issues of JCO, the JCO Special Series, Best of JCO, and the JOP will be available. Free domestic shipping is offered on all publications, and all journal subscriptions are offered at a 20% discount. The JCO and ASCO Publications Booth will be located in Publisher's Pavilion in the Exhibit Hall (Booth #4041).

2006 ASCO Annual Meeting Proceedings Distribution Schedule

The *2006 ASCO Annual Meeting Proceedings* (a supplement to JCO) contains all full-text abstracts accepted for the Meeting, with the exception of those accorded late-breaking status. As results of late-breaking abstracts are not available in time for publication, they are published separately as part of the *2006 ASCO Annual Meeting Proceedings, Part II (Late-Breaking Abstracts).*

The *Proceedings* will be circulated to all ASCO members, non-member Meeting attendees, and JCO subscribers according to the following schedule:

- ASCO members will receive the *Proceedings* by mail approximately two weeks prior to the Annual Meeting, as a supplement to JCO. The *Proceedings, Part II (Late-Breaking Abstracts),* will be mailed to all members with the June 20 issue of JCO.
- Non-member Meeting attendees will receive the *Proceedings* onsite at the Annual Meeting in the tote bag provided at registration. Additional copies of the *Proceedings* will be available for purchase at the ASCO Publications Sales Desk, located within the ASCO Booth (Booth #1300), and at the JCO and ASCO Publications Booth (Booth #4041), both in the Exhibit Hall.
- Non-member JCO subscribers will receive the *Proceedings* by mail with the June 20 issue of JCO. The *Proceedings, Part II (Late-Breaking Abstracts),* will be distributed with the same mailing.

JOP Outlook

Eliminating Errors with IntelliDose Chemotherapy Computer Order System

In the March 2006 issue of the *Journal of Oncology Practice* (JOP), Brent DuBeshter, MD, Director of Gynecologic Oncology at the University of Rochester Medical Center, reported results from a study conducted to evaluate IntelliDose, a chemotherapy-specific computerized physician order entry system.

Chemotherapy dosing errors can be fatal. IntelliDose is designed to decrease the type and frequency of chemotherapy administration errors and is suitable for use in medical, gynecologic, and pediatric oncology practices. The system performs the traditional safety checks: allergies, drug-to-drug interactions, contraindications, significant weight changes, dose limits/appropriate dosing, and lab values.

During the 12-month period described in the study, a multidisciplinary group of investigators used the computerized order entry system to review chemotherapy order sets. The group evaluated new chemotherapy order sets produced by the software. Sufficient information was included on the order sets for the pharmacy to recalculate all the dosages. The computer did not make any mathematical errors.

The order sets were reviewed for errors related to drug selection, dose calculations, and decimal point placement, as well as for instances in which the warning level set within the system was exceeded. The researchers also compared the time required to produce 10 chemotherapy order sets by hand with order sets processed using IntelliDose.

The investigators concluded that there were no errors in dose calculation, decimal point placement, or drug selection for the 2,558 drug administrations in 235 patients with cancer treated with 26 different chemotherapy regimens processed using the computerized system. They were able to classify the types of preventable orders, and to set a standard for this type of oncology order entry system.

AN&F: **What caused you and your colleagues to study the IntelliDose software?**
Dr. DuBeshter: The favorable comments of the pharmacists, physicians, and nurses using the software prompted us to do a formal evaluation; we knew we were saving time and effort using the software—especially compared with handwritten chemotherapy orders.

AN&F: **Are there other chemotherapy computer order entry systems you considered reviewing or have experience using?**
Dr. DuBeshter: A long time ago we tried another software system, but it was difficult to use and didn't accomplish what we wanted. We needed typewritten orders with all calculations done by the computer.

AN&F: **In your research, you wrote that physician order entry systems are not suitable for most office-based oncologists. Why is that?**
Dr. DuBeshter: The use of oral agents, whether targeted or cytotoxic, is likely to increase with time. The patient bears tremendous responsibility for correct administration, self-monitoring for adverse effects, and management of supportive care. It is important to realize these patients may need a great deal of support to ensure successful treatment.

AN&F: **How does the program safeguard against dosing errors?**
Dr. DuBeshter: The computer does all the calculations, all the doses are automatically checked against user set limits, and all the orders are typewritten. To our knowledge, we haven't had a chemotherapy dosage error in the 10 years we've been using this software.

AN&F: **What has been the reaction of doctors using the computerized system software?**
Dr. DuBeshter: Very favorable. Once trained on its use, no one wants to go back to handwritten orders or having to calculate dosages.

AN&F: **What chemotherapy ordering practices do you envision changing as a result of your research?**
Dr. DuBeshter: We hope that others will adopt this technology; we believe it's safer for patients and more efficient for health care providers.

AN&F: **Are there any HIPAA considerations that practices should be aware of when switching to a computer-based order system?**
Dr. DuBeshter: Appropriate passwords and security, which are incorporated into IntelliDose, need to be part of any software of this type. We don't share any patient-specific information, and the software is entirely HIPAA compliant.

Read the full text of "Experience with IntelliDose: a chemotherapy computer order entry system" in the March 2006 issue of JOP, available online at www.jopasco.org.

Publications Page

Annual Meeting Publications

ASCO members receive several Annual Meeting-related publications, including many valuable enduring resources based on the variety of educational and scientific presentations at this year's Meeting.

Educational Resources

2006 Educational Book
The *2006 Educational Book* contains 118 original articles by 193 speakers and chairs at the Annual Meeting, representing 67 Education Sessions and Scientific Symposia. For the first time, the *2006 Educational Book* will be available in print and on CD-ROM.

2006 ASCO Annual Meeting Proceedings (a supplement to the *Journal of Clinical Oncology*). Approximately two weeks prior to the Annual Meeting, ASCO members will receive the 2006 *Proceedings*, which contains all Meeting abstracts in a citable format. The late-breaking abstract "placeholder" abstracts without the final results and conclusions will be included in this supplement. *(See page 38 for detailed* Proceedings *distribution schedule.)*

2006 ASCO Annual Meeting Proceedings, Part II (Late-Breaking Abstract Supplement)
The *2006 ASCO Annual Meeting Proceedings, Part II*, containing the late-breaking abstracts with the final results and conclusions, will be available to attendees onsite on Saturday, June 3. (Members who do not attend the Meeting will receive this publication by mail after the Meeting.)

ASCO Daily News
The official newspaper of the ASCO Annual Meeting, this resource is written and published onsite each day of the Meeting. It is also available online to offer up-to-date coverage on the latest advances in cancer research to oncology professionals unable to attend the Meeting.

***ASCO Daily News* Wrap-Up Edition**
This issue of *ASCO Daily News* provides a review of the most exciting scientific and educational presentations at the Meeting across a wide variety of subspecialties.

Annual Meeting Summaries
Annual Meeting Summaries feature synopses of all the Oral Abstract Presentation Sessions and Plenary Sessions, providing a valuable review of the important clinical oncology research findings discussed at the Meeting.

Logistic Resources

Meeting Program
This publication includes the full Meeting program with session descriptions, schedules by day and track, and presented abstract titles. The daily shuttle schedule, exhibitor list, and continuing education credit information are also included.

Pocket Program
The Pocket Program contains detailed information about the Meeting schedule, including session room numbers and abstract titles, as well as logistic details about the Georgia World Congress Center.

Facility Guide
The *Facility Guide* offers logistic information about the Georgia World Congress Center, directions for finding session rooms, maps of each building, and details on the location of Specials Sessions and other ancillary events.

2006 Annual Meeting Exhibitor Directory
ASCO's print version of the online Exhibitor and Oncology Product Directory (http://opd.asco.org) provides a full list of Annual Meeting exhibitors by company name and category, company descriptions, and Exhibit Hall location.

2006 ASCO Symposia *Proceedings* Available for Purchase

The *2006 Multidisciplinary Prostate Cancer Symposium Program/Proceedings* and the *2006 Gastrointestinal Cancers Symposium Program/Proceedings* are now available for purchase. Each *Proceedings* contains all of the abstracts presented at and published in conjunction with the symposia, as well as educational summaries written by the general session faculty.

Cancer Advances Provides Relevant News and Information for Patients

Cancer Advances is a series of patient information resources designed to help consumers become better informed about various aspects of cancer, including its prevention, screening, diagnosis, treatment, and care. *Cancer Advances: News for Patients from ASCO's Meet the Expert Event* provides background information on several cancer topics and issues presented at Meet the Expert Events for health and medical reporters. The latest title, *Targeted Therapies—The Next Generation*, is based on information presented at the most recent Meet the Expert media event, held on December 2, 2005, in New York City. This edition discusses what targeted therapies are, how they work, and how they are changing the treatment of breast, colorectal, kidney, and lung cancers, as well as non-Hodgkin's lymphoma.

Cancer Advances: News from the 2006 ASCO Annual Meeting will be based on the Annual Meeting press program and is designed to provide patients with cancer and their families the latest information about cancer research, prevention, care, and treatment as presented at the 42nd ASCO Annual Meeting. In addition to research summaries, this publication explains how each finding relates to cancer care in a section called "What This Means for Patients."

Both issues of *Cancer Advances* will be available at the ASCO Booth at the Annual Meeting (Booth #1300) and on ASCO's People Living With Cancer website (www.plwc.org) in the "ASCO Resources" section. To obtain print copies of titles in the *Cancer Advances* series, call the ASCO Communications and Patient Information Department at 703-519-2927.

? HOW DO I PURCHASE ASCO PUBLICATIONS?
Call the ASCO Customer Service Department at 888-273-3508 or 703-519-1430 or visit the "ASCO Bookstore"on ASCO.org (www.asco.org).

ASCO Family of Websites

Helping Patients Navigate Their Disease

As an oncology nurse consultant for PLWC, Dorothy A. "Dot" Guccione, RN, MSN, MBA, OCN®, is an important patient resource. Ms. Guccione personally fields questions from patients with cancer, directing them to specific online cancer resources to help them gain a better understanding of their disease.

AN&F: **What are your responsibilities as a resource for patients with cancer?**
Guccione: I review all of the questions that patients submit and provide them with the most current information, either from People Living With Cancer (www.plwc.org) or from other accurate online resources.

AN&F: **What are the limits to what you can offer patients?**
Guccione: The most important limitation is that I cannot give patients any advice regarding their health care options. Rather, I guide them to informational resources so that they feel more equipped to make these treatment decisions themselves. I typically start by offering information about ASCO's patient resources, and then branching out to other patient information websites. If possible, I grasp what information the patient already has and complement it with other Web resources.

AN&F: **Oncology care involves a multidisciplinary approach. How does your role complement the role of the oncologist and others on the cancer health care team?**
Guccione: In working with patients with cancer for as long as I have, I know that even though physicians are often very thorough in their explanation, the patients—distressed after receiving a cancer diagnosis—cannot absorb everything. Patients then reach out, taking it upon themselves to research their disease. My hope is that by utilizing these suggested resources, patients can develop a greater understanding about their cancer, as well as the confidence to make the most appropriate treatment decisions.

AN&F: **What are the most pressing patient concerns?**
Guccione: Some recurring questions relate to disease state, particularly in instances of rare diseases for which resources may be more difficult to find. In these cases, I often refer patients to the PLWC website, which has an expanded section on rare cancers. People also are very concerned with the financial aspects of cancer treatment, especially now that managed care has changed so much and reimbursement issues are at an all-time premium. Questions about the different types of therapy are also common. Patients have become very knowledgeable in this regard—they hear about therapies, but are unsure exactly how they work and if they are available. International patients often ask for assistance and consultation, requesting information on therapies available in the United States but not overseas. In these cases, I direct patients to an international resource line. I also field questions from people who suspect they have cancer, but are afraid to seek medical advice.

AN&F: **How do you keep up-to-date with the most recent clinical advances?**
Guccione: I am a member of the Oncology Nursing Society (ONS) and ASCO, and attend both of these organizations' conferences. I read the *Journal of Clinical Oncology* (JCO) and the ONS monthly journal, in addition to other medical literature. As an oncology-certified nurse, I continue my professional education by taking many online CMEs and CEUs. I utilize a lot of resources to learn about what is current and/or FDA-approved.

AN&F: **What are the most important survivorship-related concerns that you hear?**
Guccione: Many patients are concerned with long-term side effects of treatment. Some therapies have been available longer, and their side effects are documented; some treatments, however, are so current that long-term effects, if any, have not yet been determined. Another question related to survival is, 'How will I know if my disease comes back?' or 'Now that I have had cancer, am I more susceptible to another cancer?' In these instances, I refer patients to sites that show different statistics on the risk rates for patients with previous cancers, and direct them to articles illustrating the importance of scheduling regular check-ups with their physicians.

Continued on page 56

Redesigned People Living With Cancer Website Features Enhanced Navigability and More Comprehensive Content

People Living With Cancer (www.plwc.org), ASCO's award-winning patient information website, has been redesigned to provide more user-friendly navigation capabilities for this important cancer resource. Based on findings of usability testing conducted with patients, family members, caregivers, and patient advocates, as well as feedback from interviews, the website now features eight easy-to-navigate sections and quick access to PLWC's comprehensive cancer type information. Three new sections—"Diagnosis & Treatment," "Survivorship," and "Library"—have been added in support of ASCO's mission to provide more comprehensive patient care information and resources. Launched in May 2002, PLWC is widely recognized as the authoritative cancer information website for patients and their families.

For free support materials to assist you in sharing PLWC with your patients, call 888-651-3038 or send an e-mail to contactus@plwc.org.

"Ask the ASCO Expert" Schedule

ASCO members are encouraged to talk to their patients about upcoming "Ask the ASCO Expert" forums hosted by leading ASCO experts on the People Living With Cancer website. Each month, PLWC hosts events that offer patients, families, and the public the opportunity to ask ASCO experts questions about cancer, either through live online chats or month-long question-and-answer forums. Transcripts from all previous "Ask the ASCO Expert" events are available in the "ASCO Resources" section of the website.

Live chats will be held from **2:00 PM–3:00 PM** (Eastern time)

April 1-21, 2006
Part 1: Cancer, Sexual Health, and Fertility
Lindsay Nohr Beck
Fertile Hope

Judith Shell, RN, PhD, AOCN
Osceola Cancer Center
Oncology Nursing Society
QUESTION-AND-ANSWER FORUM

April 25, 2006
Part 2: Cancer, Sexual Health, and Fertility
Leslie Schover, PhD
M. D. Anderson Cancer Center
LIVE CHAT

May 10, 2006
Caring for a Loved One with Cancer
Betty Ferrell, PhD, FAAN
City of Hope National Medical Center
LIVE CHAT

June 6, 2006
Top Advances in Cancer Research: News from ASCO's Annual Meeting
Roy Herbst, MD, PhD
M. D. Anderson Cancer Center
LIVE CHAT

June 2006
How to Cope with Common Side Effects of Cancer Treatment
Jamie Von Roenn, MD
Robert H. Lurie Comprehensive Cancer Center, Northwestern University

Thomas Smith, MD
Virginia Commonwealth University Health System

Charles L. Loprinzi, MD
Mayo Clinic

Georgia Decker, MS, RN, CS-ANP
Integrative Care, Oncology Nursing Society
QUESTION-AND-ANSWER FORUM

2006 ASCO Annual Meeting Coverage on PLWC

Encourage your patients to visit the "ASCO Resources" area of the PLWC website (www.plwc.org) during the Annual Meeting for the latest news and information on cancer care, treatment, and prevention. PLWC's extensive Meeting coverage gives patients and the general public a greater perspective on the importance of new research findings and includes links to related content and recommended reading.

Focus on Fellows & Junior Faculty

Grant Writing Workshop at the ASCO Annual Meeting: Essential Information for Fellows

By Dean Brenner, MD
University of Michigan

Many advances in medical care are channeled through a seemingly confusing process, but one with an important purpose—to identify and support the most innovative science possible, ensuring its progression to the patients' bedside. The National Institutes of Health (NIH) is an important component in the translation of fundamental research into effective treatments by sponsoring individual basic clinicians. However, the NIH traditionally has had difficulty in identifying qualified research candidates who merit government funding. The Institute, in collaboration with ASCO, found one important reason for the lack of funded scientists: few clinical investigators wrote grants of sufficient quality to garner federal support.

With this in mind, the two organizations developed a partnership to provide grant-writing resources for oncology clinicians, together creating the Clinical Oncology (CONC) Initial Review Group. With the support of 2003-2004 ASCO President Margaret A. Tempero, MD, and the NIH's Center for Scientific Research, the initiative was designed to conscientiously and fairly review clinical research proposals.

ASCO's steadfast support for CONC has allowed the Committee to recruit high-quality, experienced reviewers. CONC recognizes the needs of investigators—many of them young—to foster a better understanding of the grant review process and focuses on educational goals in addition to peer review. In their feedback, CONC reviewers provide comprehensive and detailed advice, establishing a "roadmap" for applicants. Utilizing CONC, experienced clinical scientists are able to disseminate research resources to their colleagues.

ASCO encourages its members to participate in this thorough process at the Annual Meeting, where a workshop will be held that allows attendees to design and implement their ideas in a high-quality, scientific process with limited industrial influence. This two-hour grants workshop will take place on Saturday, June 3, 2006, from 4:00 PM–6:00 PM. I encourage attendees to come meet and interact with members of CONC in an informal setting, where there will be an opportunity to have grants reviewed by an experienced panel of CONC reviewers and to participate in the review of other proposals.

For information about having your grant reviewed or to serve as a member of the panel, send an e-mail to dbrenner@umich.edu.

2006 ASCO Foundation YIA and CDA Awards

The ASCO Grants Selection Committee received 210 applications from oncology fellows and junior faculty for the 2006 ASCO Foundation Young Investigator Awards (YIAs) and Clinical Research Career Development Awards (CDAs). The 25-member committee, led by Ross Donehower, MD, met on February 2 and 3 at ASCO headquarters to deliberate over the top 113 applications. With these awards, The ASCO Foundation invests more than $4,000,000 to help support beginning oncologists. The growth of this program is made possible by the continued generous support from the pharmaceutical industry and private foundations.

The YIA is a one-year $35,000 grant, given to physicians during the transition from the fellowship program to a faculty appointment. The CDA is a three-year grant totaling $170,100 that supports clinical investigators who have received their initial faculty appointment. The Grants Selection Committee encourages fellows and junior faculty to apply for the 2007 ASCO Foundation Grants Program. Grant information will be available in the Fellows and Junior Faculty Lounge at the Annual Meeting and by request at grants@asco.org. The deadline for applications is November 2006, and information on eligibility, award terms, and the application process can be found in the Grants section of ASCO.org (www.asco.org).

Fellows and Junior Faculty Symposia

Historical Overview of the Treatments of Lung and Colorectal Cancers and Supportive Care Options
Patrick Loehrer, MD, *Chair*
Friday, June 2, 2006; 10:00 AM–2:00 PM
Room C306

Career Choices: Options in Academia, Private Practice, Industry, and Government
Robert Siegel, MD, *Chair*
Friday, June 2, 2006; 2:30 PM–5:30 PM
Room C204

Fellows and Junior Faculty Education Sessions

Grant Writing for Human Translational and Clinical Research: Key Concepts and Some Practice
Dean Brenner, MD, *Chair*
Saturday, June 3, 2006; 4:00 PM–6:00 PM
Room B216

Financial Planning and Managing Debt
Vandana Sharma, MD, PhD, *Chair*
Sunday, June 4, 2006; 9:45 AM–11:00 AM
Room B216

Negotiating Contracts
Jamie Von Roenn, MD, *Chair*
Sunday, June 4, 2006; 4:45 PM–6:00 PM
Room B216

How to Write an Outstanding Scientific Manuscript
Daniel Haller, MD, *Chair*
Monday, June 5, 2006; 9:45 AM–11:00 AM
Room B216

Evaluating Clinical Trials for Participation
Robert Siegel, MD, *Chair*
Monday, June 5, 2006; 11:30 AM–12:45 PM
Room B216

2006 ASCO Foundation Merit Awards

One hundred oncology fellows have been honored with ASCO Foundation Merit Awards for submitting outstanding abstracts to the Annual Meeting. Merit Award recipients are selected during the Scientific Program Committee's review of all abstracts. $1,500 awards are designed to encourage and promote further research in clinical oncology and to assist young physicians with travel expenses associated with attending the Annual Meeting. A list of all the Merit Award winners will be included in *ASCO Daily News*. To encourage fellows to support their peers, the list will also include the time and location where the award-winning research will be presented.

Fellows and Junior Faculty Welcome Reception

Immediately following the Career Choices Symposium

Friday, June 2, 2006
5:30 PM–6:30 PM
Building C, Level 3, Concourse

Fellows and Junior Faculty Lounge

Saturday, June 3–Monday, June 5
7:30 AM–6:00 PM
Tuesday, June 6 7:30 AM–12:00 PM
Rooms B212 and B213
ASCO Associate and Active-Junior Members only

Share ASCO Membership Benefits with Your Colleagues

ASCO Associate Membership dues are free for physicians participating in approved oncology subspecialty training programs.

ASCO Active-Junior Membership dues are half the price of Active membership.

Member Benefits:

- Discounted Annual Meeting registration
- Preferred Annual Meeting housing
- Annual Meeting Fellows program
- Access to the members-only Fellows & Junior Faculty Lounge at the Annual Meeting
- ASCO publications, including *Journal of Clinical Oncology*, *Journal of Oncology Practice*, the *ASCO Annual Meeting Proceedings*, *Educational Book*, *Annual Meeting Summaries*, *ASCO News & Forum*, and the Membership Directory

International Insight

Two International Cancer Conferences to Be Held in Washington, DC

The International Union Against Cancer (UICC) World Cancer Congress and the World Conference on Tobacco OR Health will meet in Washington, DC, on July 8-15, 2006, uniting the cancer and tobacco control communities and marking the first time these two events have been held in the same location.

The 13th World Conference on Tobacco OR Health will highlight the latest research on the effects of tobacco, and speakers will present relevant new data on topics including addiction, cessation, public policy, secondhand smoke, and smokeless tobacco.

The UICC World Cancer Congress offers a unique opportunity to bring together physicians, researchers, governmental agencies, and public health organizations.

By bringing together various facets of the oncology health care community, the Congress will translate groundbreaking research into health care practices that work to fight cancer in diverse communities worldwide, as well as facilitate an international dialogue and collaborate with key stakeholders across the cancer continuum.

For more information or to register for these events, visit www.2006conferences.org, call 404-417-5998, or send an e-mail to secretariat2006@cancer.org.

2006 International Development and Education Award Recipients Announced

With continued support from The ASCO Foundation and the International Affairs Committee, ASCO is pleased to announce the recipients of the 2006 ASCO Foundation International Development and Education Award (IDEA). *(See recipients below.)*

Created in 2002, the IDEA program affords oncologists in countries with limited resources the opportunity to attend the ASCO Annual Meeting. The monetary award is intended to cover expenses associated with recipients' Meeting attendance, such as airfare, hotel, ground transportation, and meals. Grant recipients also receive complimentary Meeting registration and tickets to

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2006 IDEA Recipients

Gustavo Almeida, MD .....Brazil
Mehmet Artac, MD.....Turkey
Ashwini Budrukkar, MD, DNB.....India
Tania Ceron-Lizarraga, MD.....Mexico
Roselle de Guzman, MD.....Philippines
Renata Duchnowska, MD.....Poland
Juan Garcia, MD.....Peru
Tejpal Gupta, MD.....India
Federico Nasroulah, MD .....Argentina
Temidayo Ogundiran, MBBS .....Nigeria
Ashutosh Pathak, MBBS, PhD.....India
Angelica Rodrigues, MD.....Brazil
Guianeya Santander, MD .....Uruguay
Thuan Tran, MD .....Vietnam
Zhen Wang, PhD.....People's Republic of China

Oncology in Egypt

By Mohamed M. Meshref, MD, DIU
Kasr El-Einy Oncology and Nuclear Medicine Center (NEMROCK)
Faculty of Medicine
Cairo University, Egypt

The Egyptian Ministry of Health began construction of seven smaller cancer centers with the assistance of USAID in 1993. The newest addition is the Pediatric Oncology/Hematology Hospital, which is scheduled to open within the next year.

Although Egypt is a developing country with limited funding, this North African nation has historically shown its commitment to providing the best available resources for both patients and medical professionals. Kasr El-Einy, part of Cairo University and a key player in Egyptian cancer care, established the country's first department of Radiotherapy and Radium Therapy in 1937. Oncology was recognized as a subspecialty in 1959 at Cairo University, and programs offering separate postgraduate qualifications in radiotherapy and radiodiagnosis became available in 1962. Kasr El-Einy evolved into a comprehensive cancer center in 1969, owing, in part, to the efforts of Mahmoud M. Mahfouz, MD. A National Cancer Institute opened later that year, and eventually five additional, university-based clinical oncology departments were established. In 1970, the Egyptian Cancer Society was created as an affiliate of the Egyptian Medical Association.

To address the needs of patients with cancer in more remote areas of the country, the Egyptian Ministry of Health began construction of seven smaller cancer centers with the assistance of USAID in 1993. The newest addition is the Pediatric Oncology/Hematology Hospital, which is scheduled to open within the next year.

Despite these resources, cancer is a growing health concern in Egypt. Although no national data are available, the Ministry of Health central cancer registry reports that there has been a particular increase in the incidence of liver cancer, which is now the leading cause of cancer-related death in the country as a result of the prevalence of the hepatitis C virus. The Bilharziasis endemic has created a historically high rate of squamous cell carcinoma in patients with bladder cancer, but through recent education and treatment efforts, this problem has moderately improved. Breast cancer and reticulo-endothelial cancer are also common in Egypt.

Although the Kasr El-Einy Oncology and Nuclear Medicine Center and other facilities are accessible to some patients, many people do not have access to high-quality cancer care because of financial constraints. The tremendous rise in cost of many new anticancer drugs prevents a good percentage of Egyptians from reaping the benefits associated with these innovative treatments. In addition, not all patients in Egypt can pay for the most advanced radiation therapies, chemotherapeutic agents, diagnostic tools, and surgeries.

Egyptian oncologists also have very few research resources. Currently, there is poor cooperation between the country's major cancer centers, and there is no national or regional cooperative research group. This deficiency has led to the design of only a handful of clinical trials, which are usually single-institution studies. There are also restrictions for Egyptian oncologists who are interested in joining Western

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Resources for Oncologists and Patients with Cancer in Egypt

National Cancer Institute/Egypt	**www.nci.edu.eg**
Cairo University	**www.cu.edu.eg**
Egyptian Medical Association	**42 Sharia Kasr El-Aini/Cairo, Egypt**

Spotlight on Education

2006 Best of ASCO Meetings

Cutting-Edge Science from the World's Premier Oncology Event

Again this year, the popular Best of ASCO Meetings will be offered in two locations—Beverly Hills, California, and Reston, Virginia. The meetings, which debuted in 2003, will feature high-impact abstracts from the ASCO Annual Meeting that represent the most relevant, cutting-edge research in oncology today.

These educational events will include a variety of session formats that focus on the latest scientific findings in primary disease sites and practice-changing advances in cancer prevention and treatment.

To facilitate the timely dissemination of these important developments in oncology research, the 2006 Best of ASCO Meetings will be held in closer proximity to the end of the Annual Meeting.

June 16-17, 2006	**June 23-24, 2006**
The Beverly Hilton	Hyatt Regency Reston
Beverly Hills, California	Reston, Virginia

Registration and housing reservations for these events are now available online. Visit www.asco.org/boa2006 to register and to obtain more information about the Best of ASCO Meetings.

2006 ASCO/COG Symposium

For the third consecutive year, ASCO and the Children's Oncology Group (COG) will collaborate to present a multidisciplinary symposium focused on ethical issues in pediatric cancer research. Held in conjunction with COG's semi-annual meeting, the 2006 symposium will feature presentations with a particular emphasis on issues related to genetics and genetic testing for pediatric investigators.

The symposium is designed to provide a forum for attendees to learn about research ethics in a multidisciplinary setting and is intended for pediatric oncology investigators, nursing professionals, behavioral scientists, fellows, clinical research assistants, institutional review board members, and patient advocates.

In addition, the course will fulfill the Department of Health and Human Services requirement mandating that all research grantees complete a course in research ethics prior to receipt of federal grant funds.

Visit the Meetings area of ASCO.org (www.asco.org) for up-to-date information about the symposium program, available continuing medical education credits, and housing and registration information.

2006 ASCO/COG Symposium	October 3, 2006	Los Angeles, California

Future Educational Events

June 16-17, 2006
Best of ASCO Meeting
The Beverly Hilton
Beverly Hills, California

June 23-24, 2006
Best of ASCO Meeting
Hyatt Regency Reston
Reston, Virginia

October 3, 2006
ASCO/Children's Oncology Group Symposium
Los Angeles, California

January 19-21, 2007
Multidisciplinary Gastrointestinal Cancers Symposium
Orlando, Florida

February 22-24, 2007
Multidisciplinary Prostate Cancer Symposium
Orlando, Florida

April 2007
EPEC-O Train-the-Trainer Workshop

Information about upcoming ASCO educational events is added to ASCO.org as it becomes available. Visit the Meetings area of the website frequently for the most up-to-date program and registration information related to these events.

ASCO & the Media

Press Program Expands Reach of Research Presented at the 2006 Gastrointestinal Cancers Symposium

A three-day press program was held at the third annual Gastrointestinal Cancers Symposium as a means of helping journalists to cover the event. Coordinated by the four co-sponsoring organizations—ASCO, the American Society for Therapeutic Radiology and Oncology (ASTRO), the American Gastroenterological Association (AGA), and the Society of Surgical Oncology (SSO)—the program was developed by members of a cross-organizational News Planning Team, including A. William Blackstock, MD, Leonard Gunderson, MD, C. Richard Boland, MD, and Nicholas Petrelli, MD, representing ASCO, ASTRO, the AGA, and the SSO, respectively.

The press program consisted of daily news briefings (simultaneously telecast) at which seven study authors were invited to present their research to members of the press. The daily briefings highlighted findings in each of three gastrointestinal disease sites.

The first day's briefing focused on research related to cancers of the esophagus and stomach, with a particular emphasis on the effectiveness of SU11248 for patients with gastrointestinal stromal tumors who are imatinib resistant. Results from a phase III study to evaluate the respective survival outcomes for patients with early-stage esophageal cancer treated with either combination therapy or surgery alone were also presented.

The Friday press briefing dealt with cancers of the pancreas, small bowel, and hepatobiliary tract. Featured research included a study examining racial disparities in the use of liver transplantation among patients with early liver cancer; a study assessing the effect of combination chemotherapy on rates of survival in patients with pancreatic cancer; and animal research evaluating the novel therapy salinosporamide A in pancreatic cancer.

The final briefing featured research developments related to cancers of the colon and rectum, including a new study assessing irinotecan in combination with standard chemotherapy for advanced colorectal cancer, as well as an examination of xaliproden in reducing the frequency of chemotherapy-associated neuropathy for patients with advanced colorectal cancer.

In addition to the press briefings, journalists had the opportunity to attend daily education sessions with members of the Program Committee, including Paul F. Mansfield, MD, Dr. Blackstock, and Jordan Berlin, MD. Speakers at these sessions put the day's research and presentations into perspective for the press and provided an opportunity for reporters to gain a better understanding of issues such as prevention, diagnosis, treatment, and management of various gastrointestinal cancers from recognized experts in the field.

A total of 26 reporters covered the meeting onsite, including representatives from United Press International, *Oncology Times*, *Hematology/Oncology Today*, *Oncology News International*, *Internal Medicine News*, Doctor's Guide, and MedPageToday.com. Additional news media participated in the press program via teleconference, including *USA Today*, Reuters, Dow Jones, and Bloomberg News.

Alfredo Falcone, MD (left), and James Cassidy, MD (right), MBB, MS, two press program presenters, discuss important research findings during their General Session Presentations.

Dr. Falcone and Dr. Cassidy collaborate at a Press Program event during the 2006 Gastrointestinal Cancers Symposium.

As a result of the press program, the 2006 Gastrointestinal Cancers Symposium garnered news coverage in the *Wall Street Journal, USA Today*, Reuters, UPI, Bloomberg News, Dow Jones, and numerous trade publications. *(See page 24 for additional coverage of the 2006 Gastrointestinal Cancers Symposium.)*

Research Issues & Resources

ASCO's Promotion of Central Review of Clinical Trials

In November 2002, ASCO adopted a policy statement recommending broad implementation of central review for multisite cancer clinical trials. The Society recognizes that use of centralized review has the potential not only to help ensure more uniform and expert review of cancer research and eliminate duplication of efforts, but also to improve efficiency of clinical trial review and potentially open trials more rapidly (*J Clin Oncol.* 2003;21(12):2377-2386).

Since the adoption of this statement, ASCO has been collaborating with federal and private sector stakeholders in the research community to encourage broader use of centralized review. The barriers to greater use of central review are well known: perceived or actual legal and regulatory concerns; institutional commitment to local review; concentrated power in the hands of a few; and knowledge of local research context. The Society has focused its efforts to bring the key stakeholders together to address these obstacles. The initial stakeholder meeting, held at ASCO offices in May 2004 under the leadership of then-President Margaret A. Tempero, MD, of the University of California, San Francisco Comprehensive Cancer Center, has led to broader initiatives with other federal and non-profit partners.

At ASCO's recommendation, the Department of Health and Human Services' Secretary's Advisory Committee on Human Research Protections (SACHRP) devoted part of its October 2004 meeting to central review. Lowell Schnipper, MD, Chair of the ASCO Oversight of Clinical Research Task Force that drafted the policy statement supporting central review, has spearheaded ASCO's efforts in this arena and testified to the SACHRP on the Society's behalf. As a result of that panel discussion, the SACHRP decided to host an invitation-only workshop to further explore issues related to central review and to identify different models that might be more widely adopted.

In November 2005, ASCO co-hosted a workshop with the SACHRP, the National Institutes of Health (NIH), and the Association of American Medical Colleges (AAMC). The two-day event brought together federal regulators—the Office for Human Research Protections (OHRP), the U.S. Food and Drug Administration (FDA), the NIH, and the Veterans Administration—investigators, institutional review board (IRB) chairs and administrators, patient advocates, legal counsel, independent review board administrators, and pharmaceutical company executives. The discussion helped clarify the issues at stake and identified possible next steps and alternative models to encourage its broader use. A report of the workshop will be presented to the SACHRP at an upcoming meeting.

ASCO hopes to see the OHRP and the FDA issue joint guidance to strongly encourage institutions to use central review, especially as the federal government wants to eliminate costs associated with duplicative reviews, particularly for federally-funded trials. The FDA issued a draft guidance on central review in March 2005 (available at www.fda.gov/cder/guidance/OC273dft.pdf), and although ASCO submitted comments on this draft, the Society believes that the OHRP and the FDA should address this issue together. Although federal regulations clearly allow institutions to utilize central, or non-institutional, review of trials, additional federal guidance would help address the real or perceived barriers to its use.

ASCO's focus on the issue of central review has helped lead to federal regulators and other stakeholders in the research community, such as the AAMC, recognizing its importance. Although the process will take time, there has been some progress, and the Society looks forward to future collaboration with SACHRP, the AAMC, the NIH, and the FDA to help ensure greater use of central review.

Recommendations of the Oversight of Clinical Research Policy Statement

1. Centralized review mechanism to provide review by highly trained IRB members, allowing local IRBs to take advantage of the central review and devote resources to continuing review of onsite trials.
2. All members of both the research team and IRB should receive comprehensive education on conducting scientifically and ethically valid clinical research.
3. IRBs and investigators should primarily focus on the informed consent process, not only the documents.
4. Federal government should unify and streamline its regulations for the oversight of clinical research.
5. IRBs should receive sufficient funding, resources, and institutional support to enable them to provide effective oversight of clinical research.
6. Adoption of standards for the identification, management, and, where appropriate, elimination of conflicts of interest, whether they are actual, potential, or apparent.

Clinical Trials Resources

ASCO is committed to increasing patient accrual to cancer clinical trials worldwide, and the Society encourages its members to stay abreast of current investigational studies in their practice areas. The clinical trials listed below represent a range of disease sites and treatment approaches.

PET Scan in Treating Patients with Metastatic Prostate Cancer
Phase: III
Trial Lead Organization: Memorial Sloan-Kettering Cancer Center
Contact: Steven M. Larson, MD
Phone: 212-639-7373 or 800-525-2225

Gemcitabine and Radiation Therapy Compared with Gemcitabine Alone in Treating Patients Who Have Undergone Surgery for Pancreatic Cancer
Phase: II, III
Trial Lead Organization: European Organisation for Research and Treatment of Cancer
Contact: Jean-Luc Van Laethem, MD, PhD
Phone: 32-2-555-3712
E-mail: jvlaethe@ulb.ac.be

Lenalidomide in Treating Patients Who are Undergoing Autologous Stem Cell Transplant for Multiple Myeloma
Phase: III
Trial Lead Organization: Cancer and Leukemia Group B
Contact: Philip McCarthy, Jr., MD
Phone: 716-845-8707 or 800-685-6825
E-mail: philip.mccarthy@roswellpark.org

Combination Chemotherapy with or without Bevacizumab in Treating Patients Who Have Undergone Surgery for Stage II or Stage III Colon Cancer
Phase: III
Trial Lead Organization: Jonsson Comprehensive Cancer Center at UCLA
Contact: Joel Hecht, MD
Phone: 310-206-4303 or 888-798-0719

Radiation Therapy in Treating Women Who Have Undergone Surgery for Ductal Carcinoma In Situ or Stage I or Stage II Breast Cancer
Phase: III
Trial Lead Organization: National Surgical Adjuvant Breast and Bowel Project
Contact: Frank Vicini, MD, FACR
Phone: 248-551-1219 or 800-633-7377

Phase III Randomized Study of Pixantrone versus Other Chemotherapeutic Agents as Third-Line Single Agent Therapy in Patients with Relapsed Aggressive Non-Hodgkin's Lymphoma
Phase: III
Trial Lead Organization: Jonsson Comprehensive Cancer Center at UCLA
Contact: Gary Schiller, MD
Phone: 310-825-5513 or 888-798-0719
E-mail: garyjs@ucla.edu

The publication of clinical trials information in ASCO News & Forum *does not indicate or imply that ASCO endorses, recommends, or favors specific trials. Items in the preceding list are arranged in random order. Due to clinical trial protocols and specific eligibility criteria, some of these trials may no longer be actively accruing patients.*

Symposium Highlights Clinical Trial Design

Basic Clinical Trial Design, Methodology, and Conduct
Friday, June 2, 2006
10:00 AM–2:00 PM
Thomas J. Murphy Ballroom

Symposium faculty will discuss the basic elements of effective clinical trial design and methodology to help illustrate how to determine the quality and validity of trial results. Topics for discussion will include randomization, statistical significance, and criteria for selecting clinical trial endpoints. Faculty will then apply these design issues to specific types of trials, clinical trial endpoints, laboratory correlates, biomarkers, and ethical and safety considerations. The final presentation will use instructive examples to discuss what makes a clinical trial successful. The session is organized by Michael P. Link, MD, of Stanford University School of Medicine and Sylvan B. Green, MD, of Arizona Cancer Center.

Additional registration is required for this ticketed event. Tickets are available for purchase online on ASCO.org (www.asco.org) or onsite at the Georgia World Congress Center.

What's New in Policy & Practice

Results from National Study on Cancer Care Quality Released

Detailed results from the first study on national cancer care quality were released in the February 1 issue of the *Journal of Clinical Oncology* (Malin JL et al. *J Clin Oncol.* 2006; 24:626-634). The National Initiative on Cancer Care Quality (NICCQ) analyzed data from approximately 1,800 patient surveys and medical records of people with early-stage breast and colorectal cancers and found that the majority of patients are receiving high-quality care.

Commissioned by ASCO and undertaken by researchers at the Harvard School of Public Health and the RAND Corporation, the study showed higher adherence than anticipated to processes of care believed to be essential for improving patient outcomes. The study—whose preliminary findings were presented at the 2005 ASCO Annual Meeting—sought to measure to what degree patients with cancer received elements of care that were consistent with evidence-based clinical recommendations and ASCO-approved clinical practice guidelines. The NICCQ is unique in that it evaluated and cross-referenced several sources of information, including hospital cancer registries, patients surveys, and patient medical records.

Study findings illustrate that patients with early-stage breast cancer received 86% of generally recommended care, based on 36 quality care measures, whereas patients with early-stage colorectal cancer received 78% of generally recommended care, according to 25 such quality measures.

"We are very pleased to see such a high level of adherence to many quality care measures," says Ezekiel J. Emanuel, MD, PhD, Chair of the ASCO Task Force on Quality Cancer Care. "However, a large part of our goal was to target areas for improvement so ASCO and other professional societies, patient advocacy groups, the National Cancer Institute, and others could direct their attention to these areas."

The study identifies lack of documentation in patients' medical records as an area in need of improvement. For patients with breast cancer, the percentage whose planned chemotherapy regimen was actually noted in their charts ranged from 46% to 78% across the five cities evaluated. The range for patients with colorectal cancer was between 50% and 68%.

Joseph S. Bailes, MD, ASCO Interim EVP and CEO, who initiated the NICCQ study during his presidential term (1999-2000), notes that this was the first national study to comprehensively evaluate the quality of cancer care in the United States. Although he believes that the study found cancer care to be excellent in most cases, he adds that the study "reveals important opportunities to improve care. We hope this research will inform professional societies, training programs, and clinicians involved in cancer care on the specific steps needed to improve care for people with cancer."

ASCO plans to incorporate the findings of the NICCQ into its educational programs, policies, and communications to member oncologists. The Society is taking steps to improve documentation for care provided, particularly in the area of chemotherapy administration, and is in the process of developing tools for oncologists to use in the clinical practice setting.

"The NICCQ study provides valuable information that will enable us to better educate physicians about the best ways to treat patients with cancer," notes 2005-2006 ASCO President Sandra J. Horning, MD. "The quality measures identified in the NICCQ study can be incorporated into patients' medical records, so doctors will be able to better document the care patients are receiving through all stages of treatment."

ASCO also is working with the National Comprehensive Cancer Network (NCCN) to use the NICCQ quality measures as a means of developing a subset of guidelines to enhance accountability for breast and colorectal cancer care, which will be specified, pilot tested, and disseminated. In addition, ASCO is interested in partnering with the National Cancer Institute and other public and private organizations to advance cancer care quality initiatives.

"Using careful methods to systematically identify and track the ways in which patients with cancer are or are not receiving needed care provides a solid foundation for clinicians and policy makers to diagnose aspects of cancer care that don't work well and would benefit from modifications. We don't measure quality of care just for the numbers. We do it to identify opportunities for improvement," says Katherine Kahn, MD, study co-author and Senior RAND Scientist and Professor of Medicine at University of California, Los Angeles (UCLA) School of Medicine.

Additional detailed results from the NICCQ will be published in national medical journals throughout 2006.

2006 GI Cancers Symposium, *continued from page 26*

Dr. Ryan advocated for a combination of surgery and chemotherapy for patients with rectal cancer and synchronous liver metastases. For the patient in the example, he recommended resection of the primary cancer first, followed by six cycles of chemotherapy prior to liver resection and subsequent reassessment. Pending the results of patient reassessment, Dr. Ryan recommended careful consideration about whether to administer six more cycles of chemotherapy. He would hold off on chemoradiation.

From a general perspective, "Chemoradiation should be limited to those patients with extensive local disease that is symptomatic," he said. "If patients are symptomatic from their local disease with extensive metastatic disease and want to avoid surgery, options to control local symptoms include chemoradiation, laser ablation, and placement of a stent."

Dr. Ryan asked audience members to consider whether postoperative chemotherapy would be likely to improve survival outcome in a patient who had liver resection.

He referenced a European Intergroup Study that "showed a trend toward improvement in disease treatment and overall survival," in patients who received postoperative chemotherapy, noting, however, that "it was not statistically significant."

Similarly, Memorial Sloan-Kettering Cancer Center (MSKCC), Eastern Cooperative Oncology Group (ECOG), and German studies to evaluate liver resection followed by adjuvant hepatic artery infusion chemotherapy also did not show statistically significant overall improved survival rates. However, the same studies also demonstrated improvement in rates of disease-free survival and freedom from liver metastases.

Dr. Glynne-Jones framed his discussion by noting that "randomized studies focused on resectable rectal cancer have documented an increase in locoregional control with preoperative, concomitant 5-fluorouracil-based chemoradiation, but have failed to show an improvement in disease-free and overall survival when compared [with] radiation alone or postoperative chemoradiation." As a result, investigators are now testing intensified regimens with oxaliplatin and irinotecan—as well as cetuximab and bevacizumab—as radiation enhancers.

Dr. Glynne-Jones recommended systemic treatment for the patient example, identifying it as appropriate because of the size and location of the metastases. He also recommended radiotherapy for local control because of the higher risk of local recurrence. Lastly, he said, the patient should have surgery to increase the odds of cure.

Dr. Glynne-Jones concluded by noting that physicians should move away from the traditional surgical teaching, "which advocates initial resection of the primary tumor, since surgical resection is associated with high levels of morbidity and mortality. Studies have shown that future risks of intestinal obstruction, perforation, or hemorrhage are often limited. The majority will die from systemic disease before developing a major complication relating to the primary tumor.[4] Noninvasive imaging, such as computed tomographic (CT) colonography, may identify patients with a risk of subsequent obstruction. However, nonsurgical alternatives such as endoluminal stenting can provide rapid symptom relief and preclude the need for surgical intervention." AN&F

References

1 Cunningham D et al. Perioperative chemotherapy in operable gastric and lower oesophageal cancer: final results of a randomised, controlled trial (the MAGIC trial, ISRCTN 93793971). *J Clin Oncol.* 2005;23: suppl, abstr 4001.

2 Wagner A et al. Chemotherapy for advanced gastric cancer. Cochrane Database Sys Rev. 2005;CD004064.

3 Macdonald JS et al. Chemoradiotherapy after surgery compared with surgery alone for adenocarcinoma of the stomach or gastroesophageal junction. *N Engl J Med.* 2001;345: 725-730.

4 Scoggins CR et al. Nonoperative management of primary colorectal cancer in patients with stage IV disease. *Ann Surg Oncol.* 1999;6:651-657.

Information about press coverage of the 2006 Gastrointestinal Cancers Symposium is available on page 49.

JCO Update, *continued from page 38*

Transduction, Epigenetics, Receptor-Based Therapy, and Angiogenesis—were rated highly. Of respondents who were aware of the Molecular Oncology Glossary, most identified it as quite useful.

Most respondents believe that JCO authors clearly identify potential conflicts of interest. Other highly esteemed editorial policies include the online availability of full-text articles dating back to 1983; the online manuscript submission and review system; and free public access to full-text articles one year after initial publication.

Most respondents indicate that they read JCO thoroughly, and nearly all respondents read or peruse all or most of each issue of JCO. Most readers skim for articles of interest or begin with the Table of Contents to locate such articles.

Most respondents are satisfied with the JCO online features and visit JCO.org regularly. Of particular value to online users is the availability of Annual Meeting abstracts, selected articles released ahead of print, advanced searching capabilities, and the ability to download figures in slide format.

International Insight, *continued from page 46*

select Meeting sessions. Eligible recipients also receive three years of complimentary ASCO membership.

During the Annual Meeting, recipients are paired with a mentor and junior mentor chosen from a pool of ASCO leaders (both domestic and international) and oncology training program directors. The mentors:

- Participate in the Extended Tour Award
- Communicate with recipients prior to and after the Annual Meeting
- Attend Meeting sessions with recipients
- Provide career advice
- Attend IDEA events at the Annual Meeting

An additional monetary award, the Extended Tour Award, is available for recipients to visit their mentors' workplace for one week, either prior to or immediately following the Meeting.

For information about the 2007 IDEA program, visit ASCO.org (www.asco.org), call the ASCO International Affairs Department at 703-797-1928, or send an e-mail to idea@asco.org.

State Affiliate News Watch

State Oncology Societies Booth at the 42nd ASCO Annual Meeting

For the third year, ASCO is providing complimentary exclusive exhibit space to State/Regional affiliates at the Annual Meeting. The State Oncology Societies Booth provides an opportunity for participating affiliates to showcase their organizations' activities to the more than 25,000 attendees expected at the Meeting. To date, representatives from 22 state societies plan to participate in the booth. ASCO staff will also be onsite to promote the services offered through the State/Regional Affiliate Program and to stress the importance of state society membership and participation. Visit Booth #1405 in the Exhibit Hall to meet the leaders of your state oncology society.

State/Regional Affiliate Meeting Calendar

Delaware Society of Clinical Oncology
April 27, 2006
Montchanin, Delaware
Contact: www.dsco-delawareoncology.org

Georgia Society of Clinical Oncology
April 28-30, 2006
Hilton Head, South Carolina
Contact: www.gasco.us

The Arizona Clinical Oncology Society
April 29, 2006
Phoenix, Arizona
Contact: www.tacos-oncology.com

New York State Society of Medical Oncology & Hematology
May 3, 2006
New York, New York
Contact: www.nyssmoh.org

Iowa Oncology Society
May 5, 2006
Des Moines, Iowa
Contact: www.ios-iowa.com

Louisiana Oncology Society
May 12-13, 2006
Natchez, Mississippi
Contact: www.laoncologysociety.org

Mississippi Society of Oncology
May 12-13, 2006
Natchez, Mississippi

Delaware Society of Clinical Oncology
May 18, 2006
Wilmington, Delaware
Contact: www.dsco-delawareoncology.org

Northern New England Clinical Oncology Society
May 23, 2006
Concord, New Hampshire
Contact: www.nnecos.org

Michigan Society of Hematology & Oncology
June 24, 2006
Dearborn, Michigan
Contact: www.msho.org

Connecticut Oncology Association
July 8, 2006
Mystic, Connecticut

Updates from State/Regional Affiliates

Association of Northern California Oncologists (ANCO)

ANCO's annual San Antonio Breast Cancer Symposium Highlights took place on January 18, 2006. Faculty from surrounding universities reviewed the most clinically relevant research results presented at the December symposium. Visit www.anco-online.org/sabcs.html to download presentations from this event.

ANCO's annual Medicare update programs were held on January 24-26, 2006. Speakers provided information on the most recent changes in Medicare reimbursement, as well as how to analyze the effect on oncology practices.

More information is available online at www.anco-online.org/medicareupdate2006.html.

Florida Society of Clinical Oncology (FLASCO)

FLASCO recently co-sponsored the "Highlights of American Society of Hematology" and made a $5,000 contribution to The ASCO Foundation Hurricane Katrina Relief Fund.

In addition, society representatives and FLASCO's Executive Director, among other groups, are working to provide the Medicare Provider with all updated compendia.

The FLASCO website has been enhanced and now contains a Job Opportunity category. Visit www.flasco.org for more information.

Georgia Society of Clinical Oncology (GASCO)

GASCO conducted its first Webcast on December 6, 2005, on advances in the treatment of prostate cancer; a second Webcast, "Targeted Approaches to Renal Cell Carcinoma Therapy," was held February 28, 2006. Members were able to log on to watch a live presentation and ask questions. Visit www.gasco.us for a recorded version of these sessions.

GASCO will be monitoring many cancer-care related bills and budget measures in Georgia's legislative session to try to protect oncology programs from budget cuts. Other legislation will improve access to palliative care for patients in hospice settings.

The society will offer an affiliate function at ASCO's 2006 Annual Meeting. Other GASCO meetings planned for 2006 include the Annual Administrators' Association Meeting in Hilton Head, South Carolina, and the GASCO Annual Meeting, to be held November 3-5, 2006, in Atlanta, Georgia.

See www.gasco.us for more details and to register for these events online.

Massachusetts Society of Clinical Oncologists (MSCO)

MSCO honored Senate President Robert E. Travaglini with the society's 2005 Audesse Award for his significant contribution in the areas of cancer care and treatment, health care reform, and patients' rights in the Commonwealth of Massachusetts.

MSCO held its fourth Tumor Board on January 12, 2006, where physicians participated in peer-review and discussion of difficult cases of non-Hodgkin's lymphoma.

Recognizing the changes within the state, MSCO is working to develop a Mentor Program for Fall 2006 to assist residents and fellows with their questions and discuss practice options in Massachusetts.

Montana Society of Clinical Oncology

The Montana Society of Clinical Oncology held a CME accredited meeting, "Reality Hematology," jointly sponsored by the American School of Oncology and Medical Education Collaborative, on March 11, 2006.

Northern New England Clinical Oncology Society (NNECOS)

NNECOS' third annual reimbursement meeting, which will be held May 23, 2006, will feature panel presentations, discussions, and breakout sessions related to office-based, hospital-based, and radiation oncology.

Oklahoma Society of Clinical Oncology (OSCO)

OSCO led Oncology Perspectives 2006—a joint meeting with the Arkansas Clinical Oncology Association, Louisiana Oncology Society, and Missouri Cancer Coalition—on February 4-5, 2006, in Tulsa, Oklahoma.

After OSCO representatives met with them in Washington, DC, Congressmen Dan Boren, Tom Cole, and Frank Lucas signed on to co-sponsor HR 4098. Posters signed by physicians, nurses, staff, and patients were created to thank the Congressmen.

FDA Report, *continued from page 27*

Safety

The most common treatment-emergent adverse events—which occurred more frequently among patients in the sunitinib arm of the placebo-controlled GIST study—included diarrhea, skin discoloration, mucositis/stomatitis, asthenia, and altered taste. Hypertension in the randomized, controlled trial was reported in 15% of patients receiving sunitinib and in 11% of patients receiving placebo; grade 3 hypertension was reported in 4% of patients receiving sunitinib and in none of the patients who received placebo. Hypothyroidism was observed in 4% of patients receiving sunitinib; hypothyroidism was not observed on the placebo arm. Grade 3/4 events that were more common with sunitinib included diarrhea, hypertension, and asthenia. Grade 3/4 treatment-emergent laboratory abnormalities occurring more commonly with sunitinib included neutropenia and thrombocytopenia. The safety profile for patients enrolled in the renal cell carcinoma single-arm trials was similar to that in the GIST randomized study.

Decreases in left ventricular ejection fraction (LVEF) have been noted with sunitinib. Although spontaneous recovery has been observed in some patients, dose reduction and/or addition of antihypertensive or diuretic medications may be required. Patients should be monitored for signs and symptoms of congestive heart failure, and treatment with sunitinib should be discontinued if these are observed.

Adrenal toxicity was noted in nonclinical repeat dose studies of 14 days to nine months in rats and monkeys at plasma exposures as low as 0.7 times the plasma exposure observed in clinical studies. Although no patients in the trials described here were reported to have clinical evidence of adrenal insufficiency, physicians prescribing sunitinib are advised to monitor for adrenal insufficiency in patients who experience stress such as surgery, trauma, or severe infection.

A small number of fatal and life-threatening tumor-related hemorrhages have been noted in patients receiving sunitinib. Elevations in amylase and lipase have been observed, and pancreatitis has been observed rarely.

Sunitinib is metabolized in part by the cytochrome P450 CYP3A4 isoform. Dose modification of sunitinib should be considered for patients who must receive a concomitant CYP3A4 inhibitor or inducer. AN&F

Full prescribing information—including clinical trial information, safety, dosing, drug-drug interactions, and contraindications—is available at on the FDA website at www.fda.gov/cder/foi/label/2006/021968lbl.pdf.

ASCO Family of Websites, *continued from page 42*

AN&F: **How has patient care changed over the course of your nursing career? What have been some of the most promising recent advances in this field?**

Guccione: The medical team approach and patient education have simultaneously evolved, with nurses playing a more vital role in education. Physicians are busy today, and although nurses certainly do not provide all the patients' education, they do provide a percentage of it. Collaboration between nurses and physicians has grown, as physicians today have a great deal of confidence in nurses to provide the best instruction to their patients.

AN&F: **How successfully do you think ASCO has addressed patient care concerns and issues, and how can the Society contribute even more to this important issue in the future?**

Guccione: ASCO is respected by many people, not only health care professionals, but also patients. I think the Society is very dedicated to patient needs and keeps health care professionals educated and informed so that they can deliver the best care possible. A service such as PLWC, which provides information to meet such a diversity of needs, is so important and a clear indication of ASCO's commitment to patient care.

International Insight/Egypt, *continued from page 47*

cooperative groups or in performing joint research with Western centers, although a small number of Egyptian centers do provide opportunities for collaboration with Western clinical investigators.

Although much progress has been made, there are still many improvements that can be made to further develop cancer care and oncology resources in Egypt. National treatment protocols and a national research group will be of great assistance in our mission to create a better oncology environment. International collaboration, especially in terms of research and education, will be of great mutual benefit. ASCO has been an invaluable resource for us, and I hope that in the future, the Society will continue to be instrumental in improving cancer care in developing nations such as Egypt.

Membership Notes

Member Benefit: Discounted Registration for ASCO Meetings and Symposia

ASCO members are entitled to significantly reduced registration fees for Society-sponsored events such as the Annual Meeting, the Best of ASCO regional meetings, and other symposia and workshops. Members also receive discounted tickets for Annual Meeting Meet the Professor and Clinical Problems in Oncology sessions, as well as for the educational symposia and workshops to be held on Friday, June 2.

The easiest way to register for ASCO-sponsored educational events is through ASCO.org. For questions regarding event registration, contact the ASCO Registration Center at 703-449-6418 or 888-788-1522, or send an e-mail to ascoregistration@jspargo.com.

ASCO Traveling Booth

The ASCO Traveling Booth provides services to members as they attend oncology meetings throughout the year. Members who visit the booth may update their professional information, pay their membership dues, and purchase ASCO publications. In addition, staff at the ASCO Booth are able to provide the latest information on ASCO meetings and other Society resources.

Members planning to attend the following meeting are encouraged to visit the ASCO Booth to review their member information and to pick up the most up-to-date ASCO meetings materials.

ASCO Traveling Booth Upcoming Dates

International Union Against Cancer (UICC) World Cancer Congress
July 8-12, 2006, Washington, DC

Safeguarding Your Username and Password

It is always important for ASCO members to safeguard their member login and password against inappropriate use. Never leave this information where others can easily access it. Only you and a personal assistant should know your username or password. Protection of your username and password ensures that information such as ASCO members' contact information and e-mail addresses found in the ASCO Membership Directory are not used inappropriately.

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To better serve you, ASCO now accepts membership dues payments online. Visit ASCO.org and select "Pay Your Membership Dues." Payment can also be remitted by phone at 888-282-2552 or 703-299-0158, or via fax at 703-299-0255.

Remember to update your address and other membership information when you sign in to ASCO.org. Don't let your membership benefits lapse.

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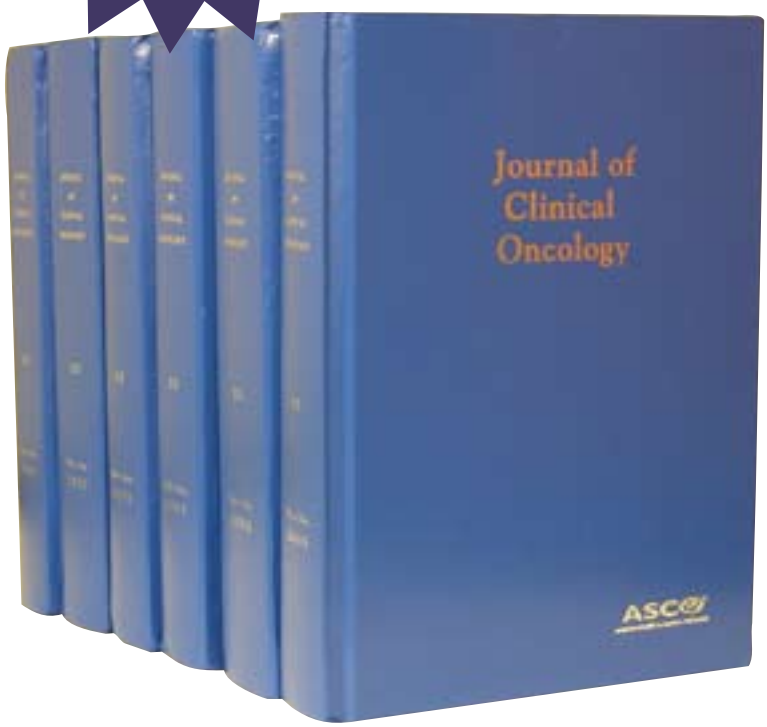

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B206A217

Notables


Jose Baselga, MD


Henry C. Fung, MD, FRCP, CCRI


Veda N. Giri, MD


Henry Kuerer, MD, PhD, FACS


Rolf Stahel, MD


Craig Stevens, MD, PhD


Magesh Sundaram, MD, MBA, FACS

Jose Baselga, MD, of Vall d'Hebron University Hospital, Spain, was named President-Elect of the European Society for Medical Oncology (ESMO).

Henry C. Fung, MD, FRCP, CCRI, was named The Coleman Foundation, Inc. Chair for the Director of the Bone Marrow Transplant Center, at Rush University Medical Center and was appointed Professor of Medicine at Rush Medical College.

Veda N. Giri, MD, has been named Director of the Prostate Cancer Risk Assessment Program at Fox Chase Cancer Center.

Henry Kuerer, MD, PhD, FACS, is the sole clinician recipient of the M. D. Anderson Cancer Center Faculty Scholar Award. The award is $30,000 for three years and is given to support Dr. Kuerer's clinical research program in cancer.

Ingrid Meszoely, MD, has been appointed Clinical Director of the Breast Center Department at Vanderbilt-Ingram Cancer Center.

Rolf Stahel, MD, of the University Hospital of Zurich, Switzerland, is the new ESMO Educational Committee Chair.

Craig Stevens, MD, PhD, was named Professor of Radiation Oncology and Division Chief at the H. Lee Moffitt Cancer Center and Research Institute.

Magesh Sundaram, MD, MBA, FACS was named Chief of Surgical Oncology at West Virginia University's Department of Surgery. He has also been appointed State Chair of the Commission on Cancer for the West Virginia Chapter of the American College of Surgeons.

In Memoriam

Diane J. Fink, MD

David Gustin, MD

James A. Mailliard, MD, FACP

Mark Your Calendar

3rd International Symposium on Ovarian Cancer and Other Gynecologic Malignancies
April 21–22, 2006
New York, New York
Contact: www.cancerconferences.com

Sixth Annual New Strategies in Breast Cancer Conference
April 28–29, 2006
Philadelphia, Pennsylvania
Contact: www.thecbce.com

American College of Radiology National Conference on Breast Cancer
April 28–30, 2006
San Diego, California
Contact: www.acr.org

American Society of Pediatric Hematology/Oncology 19th Annual Scientific Meeting
April 28–May 1, 2006
San Francisco, California
Contact: www.aspho.org

Oncology Nursing Society 31st Annual Congress
May 4–7, 2006
Boston, Massachusetts
Contact: www.ons.org

10th International Pediatric Hematology and Oncology Update Meeting
May 18–19, 2006
Edinburgh, United Kingdom
Contact: www.iphoum.com

American Urological Association Annual Meeting
May 20–25, 2006
Atlanta, Georgia
Contact: www.auanet.org

4th Research Forum of the European Association for Palliative Care (EAPC)
May 25–May 27, 2006
Venice, Italy
Contact: www.eapcnet.org/research2006

2006 ASCO Annual Meeting
June 2–6, 2006
Atlanta, Georgia
Contact: www.asco.org

Society of Nuclear Medicine's 53rd Annual Meeting
June 3–7, 2006
San Diego, California
Contact: www.snm.org/am

4th European Spring Oncology Conference
June 14–16, 2006
Marbella, Spain
Contact: www.asco.org

8th World Congress on Gastrointestinal Cancer
June 28–July 1, 2006
Barcelona, Spain
Contact: www.imedex.com

11th Congress of the European Hematology Association
June 15–18, 2006
Amsterdam, The Netherlands
Contact: www.ehaweb.org

8th Joint FECS/AACR/ASCO Workshop on Methods in Clinical Cancer Research
June 17–23, 2006
Flims, Switzerland
Contact: www.fecs.be

Multinational Association of Supportive Care in Cancer/International Society for Oral Oncology 18th International Symposium of Supportive Care in Cancer
June 22–24, 2006
Toronto, Canada
Contact: www.mascc.org

31st Federation of European Biochemical Societies Congress: Molecules in Health and Disease
June 24–29, 2006
Instanbul, Turkey
Contact: www.febs2006.org

23rd International Conference: Advances in the Application of Monoclonal Antibodies in Clinical Oncology
June 26–28, 2006
Mykonos, Greece
Contact: www.immunology.org

7th International Lung Cancer Congress
June 28–July 1, 2006
Maui, Hawaii
Contact: www.cancerconferences.com

International Union Against Cancer (UICC) World Cancer Congress 2006
July 8–12, 2006
Washington, DC
Contact: www.2006conferences.org

13th World Conference on Tobacco OR Health
July 12–15, 2006
Washington, DC
Contact: www.2006conferences.org

AACR/ASCO Methods in Clinical Cancer Research Workshop
July 22–28, 2006
Vail, Colorado
Contact: www.vailworkshop.org

Third Interamerican Breast Cancer Conference
July 27–29, 2006
Cancun, Mexico
Contact: www.imedex.com

Aranesp®
(darbepoetin alfa)

ARANESP® (darbepoetin alfa) For Injection

INDICATIONS AND USAGE

Aranesp® is indicated for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitantly administered chemotherapy.

CONTRAINDICATIONS

Aranesp® is contraindicated in patients with:

- uncontrolled hypertension
- known hypersensitivity to the active substance or any of the excipients

WARNINGS

Cardiovascular Events, Hemoglobin, and Rate of Rise of Hemoglobin

Aranesp® and other erythropoietic therapies may increase the risk of cardiovascular events, including death. The higher risk of cardiovascular events may be associated with higher hemoglobin and/or higher rates of rise of hemoglobin. The hemoglobin level should be managed carefully to avoid exceeding a target level of 12 g/dL.

In patients treated with Aranesp® or other recombinant erythropoietins in Aranesp® clinical trials, increases in hemoglobin greater than approximately 1.0 g/dL during any 2-week period were associated with increased incidence of cardiac arrest, neurologic events (including seizures and stroke), exacerbations of hypertension, congestive heart failure, vascular thrombosis/ischemia/infarction, acute myocardial infarction, and fluid overload/edema. It is recommended that the dose of Aranesp® be decreased if the hemoglobin increase exceeds 1.0 g/dL in any 2-week period, because of the association of excessive rate of rise of hemoglobin with these events.

Hypertension

Patients with uncontrolled hypertension should not be treated with Aranesp®; blood pressure should be controlled adequately before initiation of therapy. Blood pressure may rise during treatment of anemia with Aranesp® or Epoetin alfa. In Aranesp® clinical trials, approximately 40% of patients with CRF required initiation or intensification of antihypertensive therapy during the early phase of treatment when the hemoglobin was increasing. Hypertensive encephalopathy and seizures have been observed in patients with CRF treated with Aranesp® or Epoetin alfa.

Special care should be taken to closely monitor and control blood pressure in patients treated with Aranesp®. During Aranesp® therapy, patients should be advised of the importance of compliance with antihypertensive therapy and dietary restrictions. If blood pressure is difficult to control by pharmacologic or dietary measures, the dose of Aranesp® should be reduced or withheld (see **DOSAGE AND ADMINISTRATION: Dose Adjustment**). A clinically significant decrease in hemoglobin may not be observed for several weeks.

Seizures

During the first several months of therapy, blood pressure and the presence of premonitory neurologic symptoms should be monitored closely. While the relationship between seizures and the rate of rise of hemoglobin is uncertain, it is recommended that the dose of Aranesp® be decreased if the hemoglobin increase exceeds 1.0 g/dL in any 2-week period.

Thrombotic Events and Increased Mortality

An increased incidence of thrombotic events has been observed in patients treated with erythropoietic agents. In patients with cancer who received Aranesp®, pulmonary emboli, thrombophlebitis and thrombosis occurred more frequently than in placebo controls (see **ADVERSE REACTIONS: *Cancer Patients Receiving Chemotherapy*, Table 4**).

In a randomized controlled study with another erythropoietic product in 939 women with metastatic breast cancer receiving chemotherapy, patients received either weekly Epoetin alfa or placebo for up to a year. This study was designed to prevent anemia (maintain hemoglobin levels between 12 and 14 g/dL or hct 36 to 42%). Treatment with Epoetin alfa was associated with a higher rate of fatal thrombotic events (1.1% Epoetin alfa versus 0.2% placebo) in the first 4 months of the study. Based on Kaplan-Meier estimates, the proportion of subjects surviving at 12 months after randomization was lower in the Epoetin alfa group than in the placebo group (70% vs 76%), p = 0.012, log rank. However, due to insufficient monitoring and data collection, reliable comparisons cannot be made concerning the effect of Epoetin alfa on overall time to disease progression, progression-free survival, and overall survival. Until further information is available, the recommended target hemoglobin should not exceed 12 g/dL in men or women.

Pure Red Cell Aplasia

Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin have been reported in patients treated with Aranesp®. This has been reported predominantly in patients with CRF receiving Aranesp® by subcutaneous administration. Any patient who develops a sudden loss of response to Aranesp®, accompanied by severe anemia and low reticulocyte count, should be evaluated for the etiology of loss of effect, including the presence of neutralizing antibodies to erythropoietin (see **PRECAUTIONS: Lack or Loss of Response to Aranesp®**). If anti-erythropoietin antibody-associated anemia is suspected, withhold Aranesp® and other erythropoietic proteins. Contact Amgen (1-800-77AMGEN) to perform assays for binding and neutralizing antibodies. Aranesp® should be permanently discontinued in patients with antibody-mediated anemia. Patients should not be switched to other erythropoietic proteins as antibodies may cross-react (see **ADVERSE REACTIONS: Immunogenicity**).

Albumin (Human)

Aranesp® is supplied in two formulations with different excipients, one containing polysorbate 80 and another containing albumin (human), a derivative of human blood (see **DESCRIPTION**). Based on effective donor screening and product manufacturing processes, Aranesp® formulated with albumin carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

PRECAUTIONS

General

The safety and efficacy of Aranesp® therapy have not been established in patients with underlying hematologic diseases (e.g., hemolytic anemia, sickle cell anemia, thalassemia, porphyria).

Lack or Loss of Response to Aranesp®

A lack of response or failure to maintain a hemoglobin response with Aranesp® doses within the recommended dosing range should prompt a search for causative factors. Deficiencies of folic acid, iron or vitamin B_{12} should be excluded or corrected. Depending on the clinical setting, intercurrent infections, inflammatory or malignant processes, osteofibrosis cystica, occult blood loss, hemolysis, severe aluminum toxicity, and bone marrow fibrosis may compromise an erythropoietic response. In the absence of another etiology, the patient should be evaluated for evidence of PRCA and sera should be tested for the presence of antibodies to erythropoietin (see **WARNINGS: Pure Red Cell Aplasia**).

Hematology

Sufficient time should be allowed to determine a patient's responsiveness to a dosage of Aranesp® before adjusting the dose. Because of the time required for erythropoiesis and the RBC half-life, an interval of 2 to 6 weeks may occur between the time of a dose adjustment (initiation, increase, decrease, or discontinuation) and a significant change in hemoglobin.

In order to prevent the hemoglobin from exceeding the recommended target (12 g/dL) or rising too rapidly (greater than 1.0 g/dL in 2 weeks), the guidelines for dose and frequency of dose adjustments should be followed (see **WARNINGS** and **DOSAGE AND ADMINISTRATION: Dose Adjustment**).

Allergic Reactions

There have been rare reports of potentially serious allergic reactions, including skin rash and urticaria, associated with Aranesp®. Symptoms have recurred with rechallenge, suggesting a causal relationship exists in some instances. If a serious allergic or anaphylactic reaction occurs, Aranesp® should be immediately and permanently discontinued and appropriate therapy should be administered.

Tumor Growth Factor Potential

Aranesp® is a growth factor that primarily stimulates RBC production. Erythropoietin receptors are also found on the surfaces of normal, non-hematopoietic tissues and some malignant cell lines and tumor biopsy specimens. However, it is not known if these receptors are functional. The possibility that Aranesp® can act as a growth factor for any tumor type, particularly myeloid malignancies, has not been evaluated.

In a randomized, placebo-controlled study in 314 anemic subjects with advanced lung cancer randomized to either Aranesp® or placebo, statistically significant differences in time-to-progression (TTP) or overall survival (OS) were not observed; however, the study was not designed to detect or exclude clinically meaningful differences in either TTP or OS (see **CLINICAL STUDIES**).

Two additional studies explored the effect on survival and/or disease progression following administrations of two other erythropoietic products (ie, Epoetin alfa and Epoetin beta) with higher hemoglobin targets. The first study was a randomized controlled study in 939 women with metastatic breast cancer receiving chemotherapy where patients received either weekly Epoetin alfa or placebo for up to a year. This study was designed to prevent anemia (maintain hemoglobin levels between 12 and 14 g/dL or hct 36 to 42%). Mortality at 12 months was significantly higher in the Epoetin alfa arm (see **WARNINGS: Thrombotic Events and Increased Mortality**). This difference was observed primarily in the first 4 months of the study with more deaths attributed to breast cancer progression in the Epoetin alfa group (6% Epoetin alfa versus 3% placebo). Due to insufficient monitoring and data collection, reliable comparisons cannot be made concerning the effect of Epoetin alfa on overall time to disease progression, progression-free survival, and overall survival. The second study was a randomized controlled study in 351 head and neck cancer patients where Epoetin beta or placebo was administered to achieve target hemoglobins of 14 and 15 g/dL for women and men, respectively. Locoregional progression-free survival was significantly shorter (median of 406 days Epoetin beta vs 745 days placebo, p = 0.04) in patients receiving Epoetin beta.

There is insufficient information to establish whether use of Epoetin products, including Aranesp®, have an adverse effect on time to tumor progression or progression-free survival.

These studies permitted or required dosing to achieve a hemoglobin level greater than 12 g/dL. Until further information is available, the recommended target hemoglobin should not exceed 12 g/dL in men or women.

Laboratory Tests

After initiation of Aranesp® therapy, the hemoglobin should be determined weekly until it has stabilized and the maintenance dose has been established (see **DOSAGE AND ADMINISTRATION**). After a dose adjustment, the hemoglobin should be determined weekly for at least 4 weeks, until it has been determined that the hemoglobin has stabilized in response to the dose change. The hemoglobin should then be monitored at regular intervals.

In order to ensure effective erythropoiesis, iron status should be evaluated for all patients before and during treatment, as the majority of patients will eventually require supplemental iron therapy. Supplemental iron therapy is recommended for all patients whose serum ferritin is below 100 mcg/L or whose serum transferrin saturation is below 20%.

Information for Patients

Patients should be informed of the possible side effects of Aranesp® and be instructed to report them to the prescribing physician. Patients should be informed of the signs and symptoms of allergic drug reactions and be advised of appropriate actions. Patients should be counseled on the importance of compliance with their Aranesp® treatment, dietary and dialysis prescriptions, and the importance of judicious monitoring of blood pressure and hemoglobin concentration should be stressed.

It is recommended that Aranesp® should be administered by a healthcare professional. In those rare cases where it is determined that a patient can safely and effectively administer Aranesp® at home, appropriate instruction on the proper use of Aranesp® should be provided for patients and their caregivers, including careful review of the accompanying "Information for Patients" insert. Patients and caregivers should also be cautioned against the reuse of needles, syringes, or drug product, and be thoroughly instructed in their proper disposal. A puncture-resistant container for the disposal of used syringes and needles should be made available to the patient.

Drug Interactions

No formal drug interaction studies of Aranesp® have been performed.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Carcinogenicity: The carcinogenic potential of Aranesp® has not been evaluated in long-term animal studies. Aranesp® did not alter the proliferative response of non-hematological cells in vitro or in vivo. In toxicity studies of approximately 6 months duration in rats and dogs, no tumorigenic or unexpected mitogenic responses were observed in any tissue type. Using a panel of human tissues, the in vitro tissue binding profile of Aranesp® was identical to Epoetin alfa. Neither molecule bound to human tissues other than those expressing the erythropoietin receptor.

Mutagenicity: Aranesp® was negative in the in vitro bacterial and CHO cell assays to detect mutagenicity and in the in vivo mouse micronucleus assay to detect clastogenicity.

Impairment of Fertility: When administered intravenously to male and female rats prior to and during mating, reproductive performance, fertility, and sperm assessment parameters were not affected at any doses evaluated (up to 10 mcg/kg/dose, administered 3 times weekly). An increase in post implantation fetal loss was seen at doses equal to or greater than 0.5 mcg/kg/dose, administered 3 times weekly.

Pregnancy Category C

When Aranesp® was administered intravenously to rats and rabbits during gestation, no evidence of a direct embryotoxic, fetotoxic, or teratogenic outcome was observed at doses up to 20 mcg/kg/day. The only adverse effect observed was a slight reduction in fetal weight, which occurred at doses causing exaggerated pharmacological effects in the dams (1 mcg/kg/day and higher). No deleterious effects on uterine implantation were seen in either species. No significant placental transfer of Aranesp® was observed in rats. An increase in post implantation fetal loss was observed in studies assessing fertility (see **PRECAUTIONS: Carcinogenesis, Mutagenesis, and Impairment of Fertility: Impairment of Fertility**).

Intravenous injection of Aranesp® to female rats every other day from day 6 of gestation through day 23 of lactation at doses of 2.5 mcg/kg/dose and higher resulted in offspring (F1 generation) with decreased body weights, which correlated with a low incidence of deaths, as well as delayed eye opening and delayed preputial separation. No adverse effects were seen in the F2 offspring.

There are no adequate and well-controlled studies in pregnant women. Aranesp® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

It is not known whether Aranesp® is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Aranesp® is administered to a nursing woman.

Pediatric Use

The safety and efficacy of Aranesp® in pediatric patients have not been established. Pharmacokinetic data, obtained in 14 subjects, suggest that the pharmacokinetics in children between the ages of 5 and 18 years with nonhematologic malignancies were similar to those seen in adults with nonhematologic malignancies.

Geriatric Use

Of the 1598 CRF patients in clinical studies of Aranesp®, 42% were age 65 and over, while 15% were 75 and over. Of the 873 cancer patients in clinical studies receiving Aranesp® and concomitant chemotherapy, 45% were age 65 and over, while 14% were 75 and over. No overall differences in safety or efficacy were observed between older and younger patients.

ADVERSE REACTIONS

General

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of Aranesp® cannot be directly compared to rates in the clinical trials of other drugs and may not reflect the rates observed in practice.

Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. Neutralizing antibodies to erythropoietin, in association with PRCA or severe anemia (with or without other cytopenias), have been reported in patients receiving Aranesp® (see **WARNINGS: Pure Red Cell Aplasia**) during post-marketing experience.

In clinical studies, the percentage of patients with antibodies to Aranesp® was examined using the BIAcore assay. Sera from 1501 CRF patients and 1159 cancer patients were tested. At baseline, prior to Aranesp® treatment, binding antibodies were detected in 59 (4%) of CRF patients and 36 (3%) of cancer patients. While receiving Aranesp® therapy (range 22-177 weeks), a follow-up sample was taken. One additional CRF patient and eight additional cancer patients developed antibodies capable of binding Aranesp®. None of the patients had antibodies capable of neutralizing the activity of Aranesp® or endogenous erythropoietin at baseline or at end of study. No clinical sequelae consistent with PRCA were associated with the presence of these antibodies.

The incidence of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies across products within this class (erythropoietic proteins) may be misleading.

Cancer Patients Receiving Chemotherapy

The data described below reflect the exposure to Aranesp® in 873 cancer patients. Aranesp® was evaluated in seven studies that were active-controlled and/or placebo-controlled studies of up to 6 months duration. The Aranesp®-treated patient demographics were as follows: median age of 63 years (range of 20 to 91 years); 40% male; 88% Caucasian, 5% Hispanic, 4% Black, and 3% Asian. Over 90% of patients had locally advanced or metastatic cancer, with the remainder having early stage disease. Patients with solid tumors (e.g., lung, breast, colon, ovarian cancers), and lymphoproliferative malignancies (e.g., lymphoma, multiple myeloma) were enrolled in the clinical studies. All of the 873 Aranesp®-treated subjects also received concomitant cyclic chemotherapy.

The most frequently reported serious adverse events included death (10%), fever (4%), pneumonia (3%), dehydration (3%), vomiting (2%), and dyspnea (2%). The most commonly reported adverse events were fatigue, edema, nausea, vomiting, diarrhea, fever and dyspnea (see **Table 3**). Except for those events listed in Tables 3 and 4, the incidence of adverse events in clinical studies occurred at a similar rate compared with patients who received placebo and were generally consistent with the underlying disease and its treatment with chemotherapy. The most frequently reported reasons for discontinuation of Aranesp® were progressive disease, death, discontinuation of the chemotherapy, asthenia, dyspnea, pneumonia, and gastrointestinal hemorrhage. No important differences in adverse event rates between treatment groups were observed in controlled studies in which patients received Aranesp® or other recombinant erythropoietins.

Table 3: Adverse Events Occurring in ≥ 5% of Patients Receiving Chemotherapy Aranesp® (n = 873), Placebo (n = 221) BODY AS A WHOLE: Fatigue, 33%, 30%, Edema, 21%, 10%, Fever, 19%, 16%, CNS/PNS: Dizziness, 14%, 8%, Headache, 12%, 9% GASTROINTESTINAL: Diarrhea, 22%, 12%, Constipation, 18%, 17% METABOLIC/NUTRITION: Dehydration, 5%, 3% MUSCULOSKELETAL: Arthralgia, 13%, 6%, Myalgia, 8%, 5% SKIN AND APPENDAGES: Rash, 7%, 3%.

Table 4: Incidence of Other Clinically Significant Adverse Events in Patients Receiving Chemotherapy All Aranesp® (n = 873), Placebo (n = 221) Hypertension, 3.7%, 3.2%, Seizures/Convulsions (includes the preferred terms: Convulsions, Convulsions Grand Mal, and Convulsions Local) 0.6%, 0.5%, Thrombotic Events, 6.2%, 4.1%, Pulmonary Embolism, 1.3%, 0.0%, Thrombosis (includes: Thrombophlebitis, Thrombophlebitis Deep, Thrombosis Venous, Thrombosis Venous Deep, Thromboembolism, and Thrombosis) 5.6%, 4.1%.

OVERDOSAGE

The maximum amount of Aranesp® that can be safely administered in single or multiple doses has not been determined. Doses over 3.0 mcg/kg/week for up to 28 weeks have been administered to CRF patients. Doses up to 8.0 mcg/kg every week and 15.0 mcg/kg every 3 weeks have been administered to cancer patients for up to 12-16 weeks. Excessive rise and rate of rise in hemoglobin concentration, however, have been associated with adverse events (see **WARNINGS** and **DOSAGE AND ADMINISTRATION: Dose Adjustment**). In the event of polycythemia, Aranesp® should be temporarily withheld (see **DOSAGE AND ADMINISTRATION: Dose Adjustment**). If clinically indicated, phlebotomy may be performed.

Rx only

This product, or its use, may be covered by one or more US Patents, including US Patent No. 5,618,698, in addition to others including patents pending.

AMGEN®

Issue Date: 01-06

Manufactured by:
Amgen Inc.
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

For chemotherapy-induced anemia (CIA)

As far as you can go between injections

- **Provides a sustained erythropoietic effect** to reach and maintain anemia treatment goal[1]—NCCN target Hb range of 11–12 g/dL[2]
- **Proven efficacy in 2 dosing forms**—only Aranesp® is available in vials and prefilled syringes

Aranesp® (darbepoetin alfa) is indicated for the treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies. The recommended starting dose is 2.25 mcg/kg/week.

*For CIA in the hematology/oncology clinic setting based on reimbursement claims data.[3]

Please refer to the accompanying brief summary of the Aranesp® prescribing information.

Important Product Safety Information—Aranesp® is contraindicated in patients with uncontrolled hypertension. Erythropoietic therapies may increase the risk of thrombotic events and other serious events. The target hemoglobin (Hb) should not exceed 12 g/dL. If the Hb increase exceeds 1.0 g/dL in any 2-week period, dose reductions are recommended. In a study with another erythropoietic product, where the target Hb was 12–14 g/dL, an increased incidence of thrombotic events, disease progression, and mortality was seen.

Cases of pure red cell aplasia (PRCA) and of severe anemia, with or without other cytopenias, associated with neutralizing antibodies to erythropoietin have been reported in patients treated with Aranesp®. This has been reported predominately in patients with chronic renal failure receiving Aranesp® by subcutaneous administration. A sudden loss of response to Aranesp®, accompanied by severe anemia and low reticulocyte count, should be evaluated. If anti-erythropoietin antibody-associated anemia is suspected, withhold Aranesp® and other erythropoietic proteins. Aranesp® should be permanently discontinued in patients with antibody-mediated anemia. Patients should not be switched to other erythropoietic proteins.

The most commonly reported side effects in clinical trials were fatigue, edema, nausea, vomiting, diarrhea, fever, and dyspnea.

References: 1. Vansteenkiste J, Pirker R, Massuti B, et al. Double-blind, placebo-controlled, randomized phase III trial of darbepoetin alfa in lung cancer patients receiving chemotherapy. *J Natl Cancer Inst.* 2002;94:1211-1220. **2.** Guidelines for supportive care: cancer- and treatment-related anemia. *Clin Pract Guide Oncol* [serial online]. Version 2.2005. National Comprehensive Cancer Network Web site. Available at: http://www.nccn.org/professionals/physician_gls/PDF/anemia.pdf. Accessed January 16, 2006. **3.** SDI claims data (unprojected electronic reimbursement claims), hematology/oncology clinic segment only. September 2003-February 2005.

Aranesp®
(darbepoetin alfa)

Embrace every moment™