THE CANCER LETTER

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NCI Director Apologizes To Cancer Centers For Inaction On Working Group Report

NCI Director Andrew von Eschenbach said he was "embarrassed" and "frustrated" that NCI has done nothing to implement the recommendations of a report on the Cancer Centers Program and the Specialized Programs of Research Excellence.

Speaking at the annual meeting of the Association of American Cancer Institutes, von Eschenbach apologized for the Institute's failure to respond to the report of the P30-P50 Working Group.

Von Eschenbach's remarks indicate that no steps have been taken

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In Brief:

Duke Wins Avon-NCI Funding; Fox Chase Ranked "Best Place To Work In Academia"

DUKE COMPREHENSIVE CANCER CENTER has been awarded a grant by the Avon-National Cancer Institute Progress for Patients Awards Program to fund research in the Duke Breast Cancer Research Program. The two-year $500,000 grant will focus on prevention strategies, and is being led by **Victoria Seewaldt**, a Duke oncologist. Others involved in the project include **Kelly Marcom**, **H. Kim Lyerly, Wendy Demark-Wahnefried, John Olson**, **George Light**, **Heather Shaw, Paul Mosca,** and **Scott Pruitt**. . . . **FOX CHASE Cancer Center** was ranked number 1 in The Scientist magazine 2003 Best Places to Work in Academia (Oct. 20). Non-commercial researchers from around the world were invited to take part in an online survey used for the rankings. The questionnaire asked respondents to assess their working conditions and environments by indicating their level of agreement with 56 positive statements in 12 different areas. Rounding out the top 10 in ranking order are Purdue University, Yale University, the University of California, the University of Minnesota, Cornell University, the National Cancer Institute, Michigan State University, the University of Nebraska, and the Southwestern Medical Center at the University of Texas. . . . **MICHAEL PRADOS** of University of California at San Francisco was elected president of the Society for Neuro-Oncology. **Susan Chang**, also of UCSF, will serve as vice-president, and **Corey Raffel**, of Mayo Clinic, as secretary-treasurer. **Minesh Mehta** of the University of Wisconsin-Madison Medical School is the newly elected as radiation oncology representative to the board of directors, and **David Louis** of Massachusetts General Hospital was re-elected as Pathology

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Karen Antman To Work At NCI On Centers, SPORE Programs

(Continued from page 1)

to implement the recommendations of the working group, which von Eschenbach himself had convened, and which issued its report last February.

"I would love to have had that much, much further along," von Eschenbach said at the Oct. 28 meeting, acknowledging discontent on the part of the directors of the cancer centers.

"Quite honestly, it has been slowed and limited by the fact that I wanted to broaden the conversation, and I also wanted to create appropriate leadership with which to manage the process," von Eschenbach said. "It has been a little slow by my own personal timetable, and I think it has been slow by some of your timetables as well. I plan within the next six months to really ramp up that pace, and the horsepower is now assembling as we speak. I expect to see sparks fly."

For almost two years, von Eschenbach has sought to fill NCI's two top clinical and extramural research positions that were held by Robert Wittes, who left NCI in March 2002 to become physician-in-chief of Memorial Sloan Kettering Cancer Center. Wittes was deputy director for extramural research and director of the Division of Cancer Treatment and Diagnosis, but von Eschenbach has been trying to recruit two people to fill the jobs.

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At the AACI meeting, Von Eschenbach said Karen Antman, chief of the Division of Medical Oncology at Columbia University and director of the Herbert Irving Comprehensive Cancer Center, will come to NCI under an intergovernmental personnel agreement. Antman's job would be to provide "direct leadership for the continuing conversation, and discussion, and the continuing implementation of many of the issues that have arisen as a result of the P30-P50 Working Group," von Eschenbach said.

Following his remarks at the meeting, von Eschenbach declined to take questions from a reporter. Asked for further details about Antman's appointment, an NCI spokesman said von Eschenbach had asked Antman to join NCI in "a senior leadership position," the details of which were not disclosed.

The NCI spokesman released the following statement attributed to von Eschenbach: "Her current position as a cancer center director and her extensive clinical research experience makes her ideally suited to provide the kind of leadership needed to move the cancer research agenda forward."

An IPA allows a faculty member to leave the university for some period of time to work for a federal agency while retaining an academic salary and benefits.

"I'm delighted to have this opportunity to contribute to the National Cancer Program," Antman said in an email to **The Cancer Letter**.

Antman serves as president of the American Association for Cancer Research. She served as president of the American Society of Clinical Oncology in 1994-95, and of the American Society of Blood and Marrow Transplant in 1996-97.

The P30-P50 Working Group report, developed by a panel of outside advisors primarily from cancer centers and academic institutions, recommended slowing the growth of NCI's SPORE grant program, while increasing funding for Cancer Center Support Grants at a rate greater than that of individual investigator-initiated R01 grants. Also, the report recommended that NCI streamline the review process for center grants, provide partial salary support for clinical investigators, and support cancer control and early detection research and outreach to state agencies and the Centers for Disease Control and Prevention.

The report is available at http://deainfo.nci.nih.gov/ADVISORY/ncab/p30-p50/index.htm.

The cancer centers and SPORE programs

accounted for $379 million, or 8 percent, of NCI's $4.6 billion budget in fiscal year 2003.

Earlier this year, Brian Kimes, director of the NCI Office of Centers, Training, and Resources, which oversees the two programs, said he plans to leave NCI on Feb. 1 (**The Cancer Letter**, July 11). The centers and SPORE programs reside in the NCI director's office.

Centers Central To 2015 Goal

In his remarks to the AACI, von Eschenbach said cancer centers are "central" to achieving the goal for NCI that he established earlier this year, to "eliminate the suffering and death due to cancer by 2015" (**The Cancer Letter**, Feb. 14).

"The tremendous investment we have made over the past 30 years in the infrastructure of centers now positions us in a way that we have extraordinary platforms of discovery, development, and delivery," von Eschenbach said. "If we can continue to nurture and develop those platforms, and even more important, further accelerate the integration and coordination of what exists in these platforms, then we, in fact, will really, truly, even more substantially, accelerate the pace of progress to eliminate the suffering and death due to cancer…. We need to continue to look to the cancer centers as a very important part of our strategic investment in the future."

Von Eschenbach said he has visited many of the cancer centers in the past two years and enjoys these "opportunities… to really learn and understand and appreciate the challenges, the opportunities, the concerns, the needs, and most importantly, the way in which we can work together and use the talents and gifts and resources that God has given us, that this incredible country has given us, so that we can truly make a difference in people's lives."

The 2015 goal is "a destination" for NCI, von Eschenbach said. "Cancer is such an extraordinarily complex problem that we may not know when the day will come that there will be no cancer," he said. "But what we can see is a day not so very far away, in which as we have begun to understand and fully appreciate as a disease process, and as we have been able to intervene in that process in many steps in many places along the way, we can begin now thinking about a destination in which we can pre-empt that process, such that it is within our grasp to eliminate, not cancer, but to eliminate suffering and death that results from cancer, and to bring that about by 2015.

"That has been NCI's pledge, goal," von Eschenbach said. "It has been our rallying cry. It is for all of us, I think, our destination. There's much work that has to be done if we are going to achieve this. But, I believe that working together as a community, pooling the resources that we have, that goal is achievable."

NCI can "achieve that goal" through its "continued investment in a balanced portfolio of discovery, development, and delivery," von Eschenbach said. "The NCI's role is to further our continued strategic investments in discovery and our understanding of fundamental mechanisms of cancer, and to rapidly translate that knowledge into development of interventions, and to bring that to people's lives and apply those new interventions in a way that the very intervention gives rise to a greater understanding of the biology of cancer in the human condition."

Von Eschenbach acknowledged that some center directors expressed reservations about the 2015 goal.

"When I first presented the fact that we had committed to a challenge goal of eliminating the suffering and death due to cancer and bring that about by the year 2015, there were many of you who thought that perhaps I'd lost my mind, and certainly, perhaps, my credibility," he said. "I must tell you, that there has not been one place I've visited in which I have been not absolutely convinced that that goal is within our grasp and within our reach, because of what you are doing, because of what you are making possible, and because of what is on the horizon.

"Our commitment at the National Cancer Institute is simple: it is to enable to support you in being as successful as you possibly can," he said. "There is no doubt in my mind that that goal of no one suffering and no one dying as a result of cancer will, in fact, come true."

NCI Budget: "It's Never Enough"

NCI's budget "is a lot like my personal checking account," von Eschenbach said to the center directors. "It doesn't matter how much is in it, it's never enough. That literally is true today, and even more true than it was a few years ago, because the rate of growth of the NCI budget is, in fact, dramatically slowed.

"Instead of double-digit increases in which there was a substantial amount of new additional dollars coming into NCI each year with which one could embrace new, exciting programs, we now are seeing

a flattening of that growth to single digits, and that really alters and changes our business planning for the future," von Eschenbach said.

Funding for the cancer centers and SPORE programs grew by 161 percent from 1993 to 2003, while the NCI budget grew 132 percent over the decade, according to data von Eschenbach presented.

"It is growth that needs to be sustained," von Eschenbach said. "It is growth that is going to have to occur with different kinds of mechanisms and different kinds of processes with regard to budget planning and resource development and allocation.

"Recognizing that, when I first came to NCI, and recognizing the trajectory and concerns for the future, many of you know I pulled together a working group to look at our cancer centers and SPOREs and look at them from a strategic perspective, and this group worked exceedingly hard and came forward with a number of very important recommendations."

The "obvious observation" of the P30-P50 Working Group report "was the fact that you are critically important to the future of our programs, but we do need to make much better use of our cancer centers as entrepreneurial resources and enhance their efficiency, effectiveness, and evaluation," von Eschenbach said.

"We are now, based on the insights developed from this report, moving towards an implementation process in which one of the goals is to create more vertical and horizontal integration among the centers," he said. "It's clear, and especially as I have had the opportunity to visit many of you, that within individual centers, especially the NCI-designated centers, there are areas of extraordinary opportunity and talent, and those areas may be different from one center to another.

"We need to find mechanisms and alter and change guidelines, perhaps, to allow a little bit more autonomy to pursue areas of excellence and opportunities, while at the same time, maintaining a level of proficiency and excellence across the board," he said.

"In return for that ability to achieve opportunities of excellence that are extraordinarily unique, there needs then to be a much greater commitment to horizontal integration among the centers so that we can wed and match those areas of excellence in a way that becomes synergistic," von Eschenbach said.

Von Eschenbach noted that NCI-designated cancer centers are not evenly distributed throughout the U.S.

"In addition to horizontal integration among each other, there are obviously many gaps in many areas in which this particular resource has not yet been able to be adequately disseminated," he said.

"Clearly, the ability to continue to create centers in itself is limited by our fiscal reality, as well as our programmatic reality," he said. "But new mechanisms that will allow cancer centers to partner and collaborate in consortia development may be a very important potential mechanism for achieving our ability to broaden the horizon and the critical mass of centers, while at the same time, not continuing to simply try to duplicate models that are already in place."

He noted that NCI awarded a cancer centers planning grant to Tulane and Louisiana State University to develop a consortium center. "That may be an important model for emerging centers as we look to broaden the overall platform of centers," he said.

"Cancer centers have enormous opportunities with regard to not just horizontal integration among each other, but vertical integration," von Eschenbach said. "Vertical integration with regard to NCI and NIH, as well as vertical integration at the community level with cancer care delivery systems, be they systems of clinical trials infrastructure, or systems of state cancer plans, or large, integrated health care networks.

"The ability of cancer centers to play that pivotal role to develop and disseminate state-of-the-art technology and integrate that into the community, and at the same time benefit and profit from the experience that is occurring, again becomes an extremely important part of our planning initiative with regard to the implementation strategy of the P30/P50 Working Group Report," he said.

"Strategic Priorities" for 2004

Von Eschenbach said he had established a list of seven "strategic priorities" for 2004. These include: Molecular epidemiology; early detection and prevention; integrative cancer biology; strategic development of targeted therapies; an integrated clinical trials system; overcoming cancer health disparities; and bioinformatics.

Further information about initiatives with each of the areas is available at www.cancer.gov/directorscorner/directorsupdate-08-27-2003.

Among von Eschenbach's highest priorities is the clinical trials infrastructure, he said. NCI plans to

examine "how we manage the clinical trials process and the various opportunities that exist for more integration and coordination of our clinical trials infrastructure," he said.

"We also need to look at opportunities in terms of not just making our management more efficient, but in terms of reengineering our clinical trials specifically around the question of what will we need and require as we go forward in the next decade, to create a clinical trials infrastructure that is a match to and compatible with the implications of the discovery and development continuum based on the revolution in biomedical research," he said.

"Our clinical trials infrastructure has been built on a model of empiricism," von Eschenbach said. "It now needs to be built on a model of mechanism."

Von Eschenbach offered two recently completed trials as "examples of why that's so important."

The study of finasteride to prevent prostate cancer—"a very large trial, very significant investment, and a very substantial timeline"—demonstrated that men who took finasteride had a decrease in the occurrence of prostate cancer, but those men who did develop prostate cancer had a higher grade of tumor.

"What this trial pointed out to us is that we can no longer build and design studies that give us a simple endpoint, but rather, have to also be able to give us insight into the biology of cancer," von Eschenbach said. "This question now of the underlying biology of prostate cancer will be further addressed, and has to be addressed, for us to come to understand the full utility of the implications of finasteride being a possible preventive drug in prostate cancer.

"We need to continuously build biology into our clinical trials design and infrastructure as we continue to go forward," he said.

The Prostate Cancer Prevention Trial laid the groundwork for answering the fundamental questions of biology of prostate cancer by rigorously monitoring 18,000 asymptomatic men. The trial produced a collection of serum, prostate tissue, and tumor samples, and raised questions about usefulness of testing for prostate specific antigen in detection of clinically relevant disease (**The Cancer Letter**, June 27).

Von Eschenbach's second example was the recently released study of letrozole, which was stopped because of the observation that breast cancer recurrences were reduced by 43 percent in women who received the drug, compared to those who received a placebo (**The Cancer Letter**, Oct. 17).

"The reaction around this particular trial has demonstrated the confusion that's occurred by needs of more effective communication of our scientific rationale and our scientific implementation of these studies and the importance of scientific rigor," von Eschenbach said. "We need to do a much more effective job of being able to be certain that in design and implementation of studies, that our use of opportunities like early cessation of trials for a positive outcome are complemented by the ability for the lay community, as well as the scientific community, to build subsequently on that effort."

"Ready, Fire, Steer"

To advance bioinformatics, NCI has begun an initiative called the Cancer Biomedical Informatics Grid, or CaBIG, to create a biomedical informatics network that will connect teams of investigators, data, and tools, von Eschenbach said.

NCI plans to fund cancer centers to develop data-management applications. Further information on the initiative is available at www.cancer.gov/directorscorner/directorsupdate-10-21-2003.

The "rollout" of CaBIG "is a model we are using for all of these strategic initiatives," von Eschenbach said. "That is, we are no longer in a mode of 'ready, aim, fire,' which is unfortunately, too often, 'ready, aim, aim, aim, and then fire.'

"I apologize for my surgical personality, but my aim is, 'ready, fire, and then steer,'" von Eschenbach said. "That is, in fact, what you will see in many of our initiatives. We are moving towards action. Once we have a very adequate and satisfactory assessment of the goal and the opportunity, recognizing that we may not know everything yet we need to know, and we have to engage in a constant dialogue and a constant input, so that we can shape and mold and steer.

"We will steer our implementation of the P30-P50 Working Group report and our cancer centers and SPOREs program. We'll steer our commitment to a national bio repository. We'll steer our commitment to outlaying a bioinformatics platform, but we will do it, and we will do it now. Because it's essential that we rapidly accelerate the pace of progress, and rapidly accelerate our ability to achieve our 2015 goal of no one suffering and no one dying as a result of cancer."

Von Eschenbach also described the Advanced Biomedical Technology initiative, led by the National

Cancer Advisory Board (**The Cancer Letter**, Sept. 26).

"Our ability to understand cancer and its fundamental mechanisms is critically linked to our development of technology," von Eschenbach said. "Could you imagine what Einstein could have done with a laptop? If we are going to move forward in our agenda, we must move forward in the development, creation, and utilization of enabling technologies.

"One of the critical steps that will limit our ability to fully utilize the benefits of proteomics will be all of the informational and computational sciences that are required with regard to dealing with the data that is associated with pattern recognition," he said. "We need to make this not a multi-disciplinary effort, but a trans-disciplinary effort that reaches out to technologies that have not yet been applied to biomedical research, that reaches out to create technologies that we recognize within biomedical research would be important enabling technologies. We have begun to expand the planning process around this…. Centers will be an important part of this effort and these consortia."

Welcomes "Critical Comments"

Concluding his remarks, von Eschenbach said he looked forward to "one-on-one" discussions with directors of the cancer centers.

"I'm trying to find new mechanisms and new ways for meaningful communication to you, so you hear it from me and not filtered," he said. "One of the things I've done is the Director's Corner, on the Web, so that on a weekly basis I will put out the things I am thinking about and I think are timely. We will be looking at other mechanisms, so that you could really have an opportunity to get first-hand from me, and I have the opportunity to hear back from you, so that it really is a dialogue, it really is a conversation.

"I really meant what I said, that the only way to steer is to get the appropriate inputs," he said. "So I need to hear from you.

"If I have to change my deodorant, or if I have to use a different brand of toothpaste, it's OK, you can tell me that, too," von Eschenbach said. "I don't take it as anything other than you trying to, in a conscientious and really collaborative kind of way, helping to inform us, so that we can make better decisions. So, I don't have any problem with critical comments at all. We need that.

"I have a blanket agreement across NCI: I promise to always listen. I don't promise I'll do what you tell me, but I do promise to listen. My kids never got the difference.

"But, please don't hesitate to find whatever vehicle or pathway, letter, phone call or email," von Eschenbach said. "I'm looking at a broader way by which you can have access or input, and we'll see that unfold in the next months."

Cancer Centers:

M.D. Anderson Awarded Three New SPORE Grants From NCI

The University of Texas M.D. Anderson Cancer Center was awarded three new Specialized Programs of Research Excellence grants—$12.75 million for leukemia, $10.4 million for endometrial, and $4.7 million for pancreatic cancer research. The center also received $6.5 million in renewed funding for its lung cancer SPORE, first awarded in 1996. With the new, five-year grants, M.D. Anderson now holds eight SPOREs and ranks first in the number of grants received nationwide from NCI.

M.D. Anderson's eight SPORE grants over the past seven years total more than $88 million. Before the new $6.5 million renewed award to M.D. Anderson, the grant for lung cancer research was originally given jointly to M. D. Anderson and the UT Southwestern Medical Center in Dallas in 1996. A second, $10 million SPORE grant for ovarian cancer research was awarded in 1999. In 2001, M.D. Anderson received both prostate ($13.3 million) and bladder ($13.9 million) grants, the first institution to hold two genitourinary cancer grants. A $12 million grant for head and neck cancer was awarded in 2002.

"We are grateful that M. D. Anderson has again been recognized by the NCI for its innovative and productive interdisciplinary research efforts," said John Mendelsohn, president of M.D. Anderson. "With these three new SPORE grants for leukemia, endometrial, and pancreatic cancers, as well as renewed funding for our lung cancer SPORE, we will continue to build on our collaborative approach in the research and treatment of these diseases."

In 2002, M.D. Anderson spent more than $262 million for research, an increase of more than 110 percent in the last six years. About 45 percent, $118 million, of the center's research expenditures came from federally funded grants.

Principal investigators and co-PIs of the new and renewed SPOREs are: Leukemia, **Hagop**

Kantarjian and **Jean-Pierre Issa**; endometrial, **Thomas Burke**, **Russell Broaddus**, **Karen Lu**, and **George Stancel**; pancreatic, **James Abbruzzese**, **Douglas Evans**, and **Mien-Chie Hung**; lung cancer, **John Minna** and **Jack Roth**.

Reimbursement:

CMS To Delay Publication Of Final Rule For Oncology

The Centers for Medicare and Medicaid Services will delay publication of the final rule that would change the reimbursement structure for office-based oncologists, sources said.

Originally, the final rule was expected to go in effect on Jan. 1, 2004, which would have required its submission to the Federal Register on Nov. 1. The agency delayed publication in order to allow Congress to set the reimbursement structure for oncologists as part of Medicare reform, sources said.

House and Senate conferees are debating the provisions of the bill, and it is unclear when the work would be completed.

Insiders described several versions of the compromise bill's provisions for reimbursement for office-based oncologists.

One version suggests that in 2004, reimbursement would be set at 85 percent of the average wholesale price, a decrease from the current level of 95 percent of AWP. On the following year, reimbursement would be based on the "average sales price."

Sources described several formulas for reimbursement, ranging from ASP plus 4 percent to ASP plus 12 percent. The drop in reimbursement would be accompanied by an increase in payment for professional services. The increase was said to be in the range from $400 million to $550 million.

CMS appears to have been in a rush to implement the change in reimbursement, but in order to do so, the agency would have needed to finalize its rule, and respond to comments on the "proposed rule," which was published last August. Several observers said this schedule seemed unrealistic.

Early in November, the agency is expected to release its final rule on the prospective payment system for the hospitals. The regulation will address the level of reimbursement for Aranesp, an erythropoietin sponsored by Amgen Inc., which is competing with the Johnson & Johnson product Procrit.

The agency argued that the two agents are "functionally equivalent," and HHS mandated NCI to conduct a head-to-head trial of the two agents to determine a conversion ratio for Aranesp.

However, the Institute broadened the trial to ask more fundamental questions about erythropoietin, and ultimately no trial has been conducted.

Obituary:

Former NCAB Chairman Paul Calabresi Dead At 73

Paul Calabresi, a former chairman of the National Cancer Advisory Board and member of the President's Cancer Panel, and a founding faculty member of Brown University Medical School, died Oct. 25 of cancer. He was 73.

Calabresi was one of the pioneers in the pharmacological treatment of cancer and developed approaches that led to the cure of such diseases as Hodgkins lymphoma.

Calabresi was born on April 5, 1930, in Milan, Italy. He was the son of Dr. Massimo Calabresi and Professor Bianca Maria Finzi-Contini Calabresi. His family was active in the anti-fascist resistance and fled to the U.S. in September 1939 when he was nine years old. They settled in New Haven, Conn.

A graduate of Yale University (B.A., 1951; M.D., 1955), Calabresi served his internship and residency on the Harvard Medical Services of the Boston City Hospital. He was on the faculty of the Yale University School of Medicine until 1968 when he came to Brown University as professor of medical science and physician-in-chief at Roger Williams General Hospital. Calabresi was the founding director of the Brown University Cancer Center, and in 1974, became chairman of the Brown University Department of Medicine.

In 1990, with his brother Guido, Calabresi endowed the Finzi-Contini Lectureship at Yale University in memory of their mother. Finzi-Contini was a scholar of European literature.

In 1991, while continuing his teaching at Brown, he transferred to Rhode Island Hospital and was appointed chairman of the National Cancer Advisory Board by President George H.W. Bush. In 1995, he was appointed to the President's Cancer Panel by President Bill Clinton.

In 1995, Calabresi, along with Nobel Prize winner Michael Bishop of the University of California at San Francisco, authored what became known as

the Bishop-Calabresi report that recommended reorganization of the NCI Intramural Research Program.

In 1998, he was invited to serve on the Steering Committee for the National Dialogue on Cancer, and he was the chairman of its Nominating Committee. In 1999, Calabresi was appointed to the National Cancer Legislation Advisory Committee by Sen. Dianne Feinstein (D-Calif).

At his death, Calabresi was a member of the Board of Overseers at the E. Bronson Ingram Cancer Center at Vanderbilt University, and the Board of Overseers at Tufts University School of Medicine. He was also a member of the Institute of Medicine of the National Academy of Sciences and a master of the American College of Physicians.

He received the Oscar B. Hunter Memorial Award in Therapeutics from the American Society of Clinical Pharmacology and Therapeutics and the St. George Medal for distinguished volunteer service from the American Cancer Society. He served as president of the American Society of Clinical Oncology (1969-70), and was a member and an officer of more than a dozen professional societies. He served on nearly two dozen committees and study sections of NCI, and the editorial boards of 13 journals, including The New England Journal of Medicine. Calabresi authored or edited more than 220 manuscripts and books on the pharmacology of antineoplastic agents and the management of cancer.

Calabresi was chairman of the Scientific Advisory Committee to the T.J. Martell Foundation and chairman of the Clinical Pharmacology Advisory Committee to the PhRMA Foundation. He was chairman of the Advisory Committee for the Yale Cancer Center, University of Wisconsin Cancer Center, and Columbia University Cancer Center, and was a member of the National Board of Trustees for the Leukemia and Lymphoma Society, and an honorary life member of the Board of Directors of the American Cancer Society, having served as president of the Rhode Island Division from 1990 to 1992, and president of the New England Cancer Society from 1994 to 1995. He was president of the International Society for Geriatric Oncology, and President of the Rhode Island Cancer Council.

Calabresi was known as a caring and compassionate physician. He continued to look after his patients until his death.

He is survived by his wife of 49 years, the former Celia Treadway Gow; three children, Steven of Brookline, Mass., professor of law at Northwestern University; Janice Calabresi Maggs of Arlington, Va., a lawyer; and Peter of Baltimore, Md., an associate professor of neurology at Johns Hopkins University; eight grandchildren; and a brother, Guido, of Woodbridge, Conn., former dean and Sterling Professor Emeritus at the Yale University Law School and Judge on the U.S. Court of Appeals for the Second Circuit.

In Brief:

Neuro-Oncologists Elect New Officers, Board Members

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representative. Other members of the board include **Abhijit Guha** of University of Toronto, **Howard Fine** of NCI, **Lisa DeAngelis** of Memorial Sloan-Kettering Cancer Center, **Peter Phillips** of Children's Hospital, Philadelphia, and **Melissa Bondy** M.D. Anderson Cancer Center. **Edward Shaw** of Wake Forest University is immediate past president. . . . **RICHARD MESSMANN** has been appointed director of cancer research at Great Lakes Cancer Institute. He was a clinical research physician for medical therapeutics at Eli Lilly. Prior to that, he was deputy associate director for the NCI Developmental Therapeutics Program. . . . **COLLABORATIVE PROSTATE CANCER** Project received $7.6 million grant from NCI to study the pathways and mechanism for prostate cancer metastasis to bone. **Leland Chung**, director of Urological Research in Department of Urology at Emory University and a faculty member at the Winship Cancer Institute, is the primary investigator and leader of the project. The project team consists of investigators from Emory School of Medicine, Winship Cancer Institute, Departments of Urology, Pathology, Biostatistics, and School of Public Health. In addition, researchers from the University of Delaware, University of Virginia, Stanford University and the Fred Hutchinson Cancer Research Center will participate. The collaboration consists of three separate but interrelated projects. The primary projects are: the biology of tumor-stroma interaction, led by Chung; heparan sulfate proteoglycans in prostate cancer bone metastasis, led by **Mary Farach-Carson**, of the University of Delaware; mitochondrial DNA mutations in prostate tumorigenesis and stromal and epithelial interaction, led by **John Petros**, associate professor of urology at Emory University.

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Business & Regulatory Report

Deals & Collaborations:

Abgenix, AstraZeneca To Collaborate On Antibody Development For 36 Targets

Abgenix Inc. (Nasdaq: ABGX) and **AstraZeneca** said they have closed an oncology collaboration agreement between the two companies. Under the agreement, Abgenix issued convertible preferred stock to AstraZeneca for an immediate payment of $100 million by AstraZeneca.

The alliance calls for the joint discovery and development of therapeutic antibodies for up to 36 cancer targets to be commercialized exclusively worldwide by AstraZeneca.

Abgenix may receive milestone and royalty payments, as well as payments for preclinical studies, early clinical research, process development, and both clinical and commercial manufacturing.

The collaboration will involve the selection and development of an additional pool of antibodies by Abgenix, which the companies may elect

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Clinical Trials:

Tarceva Phase III Trial In Lung Cancer Didn't Meet Survival Endpoints

Genentech Inc. (NYSE: DNA), **OSI Pharmaceuticals Inc.** (Nasdaq: OSIP), and **Roche** (SWX Zurich) said two first-line phase III studies of Tarceva (erlotinib HCl) plus standard chemotherapy in metastatic non-small cell lung cancer did not meet their primary endpoints of improving overall survival.

In the first study, named TRIBUTE, one of the secondary endpoints, time to symptomatic progression, achieved statistical significance, but did not translate into improvements in overall survival or time to disease progression, the company said.

The multi-center, randomized, controlled phase III studies evaluated Tarceva at 150 mg/day in combination with standard chemotherapy in patients with stage IIIB/IV metastatic non-small cell lung cancer, the companies said.

The 1,050 patients enrolled in the TRIBUTE study were randomized to receive Tarceva plus standard chemotherapy (carboplatin and paclitaxel) or standard chemotherapy plus a Tarceva placebo. In the second study, named TALENT, 1,200 patients were randomized to receive either Tarceva in combination with standard chemotherapy (gemcitabine and cisplatin) or standard chemotherapy plus a Tarceva placebo.

The studies, conducted by Genentech in the U.S. and Roche outside

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Intel Corp. Building System At Fred Hutch For Research

(Continued from page 1)

to further develop on an equal cost and profit sharing basis. As part of the collaboration, AstraZeneca has made a $100 million investment in Abgenix convertible preferred stock, convertible into Abgenix common stock by AstraZeneca at $30 per share, the companies said. Upon the achievement of certain milestones, Abgenix may also require AstraZeneca to invest an additional $60 million in Abgenix convertible preferred stock.

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Intel Corporation and the **Fred Hutchinson Cancer Research Center** announced a collaboration to apply Intel's expertise in nanotechnology to develop improved methods of studying, diagnosing and preventing cancer.

"To launch the effort, Intel is building an Intel Raman Bioanalyzer System at the Fred Hutchinson Cancer Research Center in Seattle," said Andrew Berlin, lead researcher, Intel's Precision Biology program. "The instrument beams lasers onto tiny medical samples, such as blood serum, to create images that reveal the chemical structure of molecules. The goal is to determine if this technology, previously used to detect microscopic imperfections on silicon chips, can also detect subtle traces of disease."

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The Intel Raman Bioanalyzer System is based on a technique known as Raman spectroscopy Intel uses this technique to analyze subtle chemical compositions during the chip fabrication process. By shining a laser beam at an object, molecules within the substance are stimulated to give off a spectrum that can be detected by sensors in a Raman spectrometer. Since every substance has a unique chemical composition, every substance produces a unique Raman spectrum—the equivalent of a chemical barcode tag.

Researchers at Fred Hutchinson will use the specially designed instrument in an effort to identify proteins in human blood serum that foretell the susceptibility, presence or prognosis of diseases such as cancer.

"This collaboration is a unique and exciting interaction," said Lee Hartwell, Nobel laureate and center president and director. "Biologists have never before had such a method for studying the molecular structure of biology. This is true discovery-based research; we don't know what we will see or learn. It may lead to a new era of molecular diagnostics and improved methods of early disease detection."

Intel's Precision Biology is a research team of chemists, engineers, biologists and physicists. They combine expertise in microbiology and molecular analysis with Intel's core expertise in microelectronics, MEMS and nanotechnology.

* * *

Celera Diagnostics said it has entered into a research collaboration with **Merck & Co. Inc.** to identify and validate genetic markers for development of prognostic tests and therapeutics for selected cancers.

Celera Diagnostics is a joint venture between the Celera Genomics Group (NYSE: CRA) and Applied Biosystems Group (NYSE: ABI) of Applera Corp.

The agreement provides Celera Diagnostics access to gene expression data and intellectual property of Merck through its wholly owned subsidiary, Rosetta Inpharmatics LLC. Also, it provides Merck access to selected research data from Celera Diagnostics for use in developing cancer therapeutics, the companies said.

While the collaboration is focusing initially on breast cancer, the agreement provides for possible extension into other cancers.

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Dow Chemical Co. (NYSE: DOW) and **Sunol**

Molecular Corp. said they have signed a collaborative research agreement to produce a therapeutic protein in transgenic plants and compare its properties with those of the same antibody produced in mammalian cell culture.

Under the agreement, Dow will express in plants an anti-tissue factor antibody developed by Sunol for multiple types of cancer, the companies said. The research will look at glycosylation, in vivo testing, and effector function. Knowledge gained would demonstrate the utility of plant production for injectable biopharmaceuticals, the companies said.

The agreement includes an option for Dow and Dow AgroSciences to evaluate the antibody as a cancer treatment for companion animals, the companies said.

* * *

Dyax Corp. (Nasdaq: DYAX) said it has granted to **MedImmune Inc.** (Nasdaq: MEDI) a non-exclusive license to its proprietary antibody phage display libraries for the discovery of therapeutic antibodies.

Under the agreement, Dyax will receive upfront and annual technology license fees, clinical milestone payments, and royalties on net sales of products from use of the libraries, the companies said.

The agreement gives MedImmune a license to the Dyax antibody phage display technology and patent rights, as well as sublicenses to third-party antibody phage display patents used with the antibody phage display technology.

* * *

Lorus Therapeutics Inc. of Toronto said its subsidiary, **NuChem Pharmaceuticals Inc**. and **Cyclacel Ltd**., of the U.K., have entered into an exclusive worldwide license agreement to develop and commercialize the Lorus pre-clinical compound NC 381.

The agreement extends to other drug candidates that Cyclacel may identify from a library of clotrimazole analogs licensed by NuChem from Harvard Medical School in 1997, the company said.

Under the agreement, Lorus will receive upfront fees of $400,000 and milestone payments, which would total US $11.6 million for NC 381, and similar milestone payments for each of any other compounds developed from the compound library. In addition, Lorus will receive royalties based on product sales. Cyclacel will be responsible for all future drug development costs.

"Lorus, in collaboration with the U.S. NCI, has identified the promise of NC 381 and several other compounds for the treatment of cancer," said Jim Wright, CEO of Lorus.

* * *

MethylGene Inc., a private Canadian drug discovery and development company, has entered into a collaboration, license and commercialization agreement with **Taiho Pharmaceutical Co. Ltd**., a Japanese oncology specialty company, on a small molecule inhibitor program against histone deacetylases (HDACs) for oncology.

Under the agreement, MethylGene will receive an upfront license fee, equity investment and research payment of $3.75 million, the companies said. In addition, MethylGene may attain milestone payments based on successful development, regulatory approval, and commercialization of an HDAC oncology product totaling up to $16.25 million.

Taiho will provide MethylGene with research funding support for eight scientists for a minimum of two years as well as fund preclinical and clinical development costs in North America for an HDAC inhibitor in cancer. MethylGene will receive royalties based on sales of an HDAC oncology product in Japan, Korea, Taiwan, and China.

Taiho is responsible for development of the HDAC oncology product in their territories. MethylGene retains commercialization rights in the rest of the world. All potential payments to MethylGene from Taiho based on successful development for an HDAC oncology product could total $37.5 million.

MethylGene's first HDAC oncology clinical candidate, MGCD0103, is in late preclinical development and an IND is expected to be filed by the end of this year in the US and Canada. MGCD0103 appears to be a highly potent, orally available, and selective inhibitor for the HDAC isoforms the company believes are involved in cancer.

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The state of **Michigan** said it has invested $2.3 million it received from its settlement with the tobacco industry to be carried out by **Wayne State University** and **Asterand**, a company that operates a global tissue research bank on the campus of Wayne State University.

Richard Everson will lead the university research team using genomics technology for treatment and diagnosis of cancers and other diseases. This will include genotyping of blood, mouthwash and tissue samples.

The research data will be marketed by Asterand.

Under an agreement with the Michigan State Life Sciences Fund, Asterand will repay a portion of the award to the state from future revenues. In addition, the State has negotiated the right to buy shares in Asterand.

* * *

Molecular Imaging Corp. (OTC BB: MLRI) of San Diego said it has signed a strategic alliance agreement with **Siemens Medical Solutions** of Malvern, Penn.

The agreement provides for the two companies to collaborate and exchange information about medical service providers, the company said.

Under the five-year agreement, MLRI has committed to purchase MI equipment from Siemens at a discount from list price, and Siemens will provide sales and marketing support to MLRI, in addition to equipment and project financing, the company said.

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Samaritan Pharmaceuticals Inc. (OTCBB: SPHC) of Las Vegas and said it has amended its research collaboration with **Georgetown University** to expand its scope of research to include a series of preclinical studies to develop a diagnostic blood test for breast cancer.

The blood test would measure whether a breast cancer tumor is aggressive in nature, that is, the likelihood of a cancerous tumor to metastasize and spread cancer throughout the body, the company said.

Samaritan, through its collaboration with Georgetown University, has the exclusive license for a breast cancer diagnostic that measures the aggressive behavior of breast cancer cells in breast biopsies, the company said.

* * *

Transgenomic Inc. (Nasdaq: TBIO) of Omaha, Neb., said it would provide an additional supply of modified nucleic acid building block compounds to **Geron Corp.** (Nasdaq: GERN) for the synthesis of the Geron thio- phosphoramidate-based telomerase inhibitor anti-cancer drugs, GRN163L (formerly named GRN719).

Thio-phosphoramidate-based oligonucleotides have demonstrated advantages over earlier-generation oligonucleotide chemistries, including enhanced sequence-specific DNA and RNA binding activity, a high resistance to nuclease degradation and improved cellular uptake and biodistribution, the company said.

Clinical Trials:

Tarceva Didn't Extend Survival, Genentech, OSI, Roche Say

(Continued from page 1)

of the U.S., evaluated Tarceva at 150 mg/day in combination with standard chemotherapy, the company said.

Tarceva is a small molecule oral therapy that inhibits the tyrosine kinase activity of the HER1/EGFR signaling pathway inside the cell, which may block tumor growth, the company said.

The addition of Tarceva to chemotherapy was generally well tolerated and adverse events were similar to those previously reported with chemotherapy treatment and with Tarceva, the companies said. Adverse events that occurred more often with Tarceva included diarrhea and rash.

* * *

Aptamera of Louisville, Ky., said it has begun a phase I trial of its anti-cancer drug AGRO100 for solid tumors. The trial, which is being conducted at the University of Louisville James Graham Brown Cancer Center, is the first to test nucleic acid aptamers for cancer, the company said.

Nucleic acid aptamers are small segments of either DNA or RNA that can exert therapeutic activity by assuming specific shapes that recognize and bind to biologically relevant proteins, the company said. Up to 20 patients with advanced solid tumors will be enrolled.

AGRO100 is a G-rich oligonucleotide that binds to nucleolin, halts cancer cell reproduction and induces programmed tumor cell destruction. Initial tests demonstrate the anti-cancer agent has robust performance against multiple types of the disease in experimental systems, including lung, prostate, breast, and colon cancer, the company said.

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Bayer Pharmaceuticals Corp. (NYSE: BAY) and **Onyx Pharmaceuticals Inc.**

(Nasdaq: ONXX) said they have begun an international, multi-center phase III trial of the investigational drug BAY 43-9006, a novel signal transduction inhibitor, in advanced renal cell carcinoma .

The trial's primary endpoint is survival, the companies said. The study will also assess time-to-disease progression, overall response rate, safety, quality of life and the pharmacokinetics of BAY 43-9006.

The lead investigator is Ronald Bukowski, director of the Cleveland Clinic Cancer Center. More than 800 patients will be enrolled worldwide. To be eligible for the study, individuals with unresectable and/or metastatic disease must have failed a previous systemic therapy.

BAY 43-9006 is an orally active inhibitor of the enzyme Raf kinase. By inhibiting Raf kinase, BAY 43-9006 blocks the Ras/MEK/ERK signaling pathway in cells, an important mediator of tumor cell proliferation, the companies said. External researchers have demonstrated that Raf is involved in angiogenesis, the companies said.

* * *

Callisto Pharmaceuticals Inc. (OTCBB: CLSP) said it had filed an investigational new drug application with FDA for Atiprimod for refractory or relapsed multiple myeloma.

The planned phase I/IIa trial is an open label safety and efficacy study, the company said. The trial will be conducted at cancer hospitals in the U.S., including M.D. Anderson Cancer Center, and will be coordinated by Moshe Talpaz.

The primary objectives are to identify the maximum tolerated dose and safety of the agent, the company said. The secondary objectives are to evaluate the response of relapsed multiple myeloma patients, measure the drug pharmacokinetics and evaluate a wide variety of surrogate markers to better define the mechanisms of action.

Atiprimod has completed a phase I/IIa trial for rheumatoid arthritis with patient dosing as long as 1 year, the company said. The drug has shown activity against a range of solid tumors in in-vitro screens, and will be evaluated in animal models of solid tumors to expand its clinical trial indications, the company said.

Callisto has an exclusive worldwide license from **AnorMED Inc**. to develop, manufacture, use and sell Atiprimod.

* * *

ILEX Oncology Inc. (Nasdaq: ILXO) of San Antonio said it has begun a multi-center phase II study of ILX-651 for solid tumors.

The study will examine the efficacy and tolerability of the tubulin-interactive agent in recurrent or metastatic melanoma at 19 sites throughout the U.S, the company said. In addition, ILEX said it would open a non-small cell lung cancer study later this year.

ILX-651 is a third-generation synthetic pentapeptide analog of the natural substance dolastatin and has a mechanism of action that targets tubulin, the company said. The drug has been chemically modified to provide improved pharmacological properties and is orally bioavailable, the company said. The agent has demonstrated anti-tumor activity in preclinical models in a wide range of solid tumors, including cancer cells that are resistant to other tubulin-interactive drugs, such as the commonly prescribed taxanes.

* * *

Metabasis Therapeutics Inc. of San Diego said it has begun clinical testing of MB7133, a liver-specific prodrug of the anti-cancer drug cytarabine.

The trial is being conducted at two sites, one in the US and one in Hong Kong. The prodrug will be administered by continuous infusion for hepatocellular carcinoma, the company said. Drug safety, tolerability and pharmacokinetics will be monitored.

MB7133 was developed using the Metabasis proprietary HepDirect technology, a prodrug technology that targets production of the biologically active form of the drug specifically to the liver, the company said. In the case of MB7133, Metabasis developed a HepDirect prodrug of the anti-cancer drug cytarabine. Cytarabine is used as first-line therapy for leukemia but is not effective against liver cancer because unlike leukemic cells, the liver is unable to convert cytarabine to its active form.

In contrast, HepDirect prodrugs of cytarabine, such as MB7133, are designed with the goal of bypassing the rate-limiting step in the liver cell and thereby enabling production of high levels of the tumor killing form of the drug and may help reduce exposure of tissues outside the liver to the active drug and thereby reduce side effects, the company said.

Product Approvals & Applications:

ILEX Submits Clofarabine NDA For Pediatric Acute Leukemia

ILEX Oncology Inc. (Nasdaq: ILXO) of San Antonio said it has submitted the first part of a New Drug Application to FDA for clofarabine for the treatment of refractory or relapsed acute leukemia in children.

The remainder of the application will be submitted on a "rolling" basis and is expected to be completed in the first half of 2004.

"This filing represents a milestone for ILEX and we are pleased that it may provide new hope to very sick children," said ILEX CEO and President Jeff

Buchalter.

In September, ILEX was granted a Fast Track designation for clofarabine in refractory or relapsed pediatric acute lymphoblastic leukemia.

Investigators reported interim phase II results in May at the American Society of Clinical Oncology meeting, which demonstrated an overall response rate of 28% for clofarabine in heavily pretreated children with ALL or acute myelogenous leukemia. The overall response rate included complete remission, complete marrow remission in the absence of platelet recovery and partial remission.

ILEX initiated phase II studies of clofarabine in children with refractory ALL and AML in 2002. These studies remain open and continue to enroll new patients, the company said.

Clofarabine was previously granted orphan drug designation for the treatment of adult and pediatric ALL and AML.

Clofarabine is a purine nucleoside antimetabolite. Nucleoside analogs are antimetabolites that affect DNA synthesis. ILEX obtained the right to develop clofarabine in the U.S. and Canada from Bioenvision, Inc. (Amex: BIV), which maintains its rights to develop clofarabine outside of those areas.

* * *

Aurora Imaging Technology Inc. of North Andover, Mass., said it received the FDA 510(k) market clearance for its rotating delivery of excitation off-resonance breast imaging method.

RODEO was developed and patented by Steven Harms and Duane Flamig and is being commercialized by Aurora, the company said.

The proprietary RODEO pulse sequence provides robust fat-suppression, magnetization transfer contrast is a high-resolution acquisition, the company said. Fat-suppression reduces the normally high intensity fat signal to maximize contrast with enhancing tumors. Magnetization transfer contrast is used to reduce signal from normal ductal tissue and avoid false positive enhancement from benign lesions.

"With conventional MRI systems fat suppression and magnetization transfer contrast requires multiple complex pulses that are time consuming and prone to artifact generation," said Harms. "The Aurora integrated design, together with RODEO, will improve diagnostic capabilities further and increase the acceptance of RODEO as the standard for high quality in the breast imaging community."

As a diagnostic tool, the system can be used for a range of applications in breast disease management including: characterizing lesions, detecting occult cancer, determining the extent of cancer, monitoring cancer therapy, evaluating the extent of cancer, monitoring cancer therapy, evaluating patients with positive surgical margins for residual cancer, excluding the existence of cancer in high risk women and evaluating implant integrity and detecting cancer in women with breast augmentation, the company said.

* * *

Aton Pharma Inc. of Tarrytown, N.Y., said FDA has granted orphan drug designation for SAHA, an inhibitor of histone deacetylase, for multiple myeloma.

Aton also said it has begun in a phase I trial of SAHA for advanced multiple myeloma at the Dana-Farber Cancer Institute. The open-label study will enroll 34 patients. SAHA is in phase II trials forcutaneous T cell lymphoma, peripheral T-cell lymphoma and recurrent or metastatic squamous cell cancer of the head and neck, the company said. It is also being studied in patients with advanced leukemias and myelodysplastic syndromes in an open-label phase I trial.

The trial of SAHA for advanced multiple myeloma at the DFCI will be led by Paul Richardson, of the Jerome Lipper Center for Multiple Myeloma. Kenneth Anderson, and Constantine Mitsiades, of DFCI, led the pre-clinical development of SAHA in myeloma.

* * *

Genta Inc. (Nasdaq: GNTA) of Berkeley Heights, Calif., said it has received FDA approval to market Ganite (gallium nitrate injection) for cancer-related hypercalcemia that is resistant to hydration.

Genta said it has begun GentaCARES, an assistance program for patient access to Ganite treatment. Reimbursement services include benefit verification, prior authorization, claims tracking, appeals, and a patient assistance program for qualifying uninsured patients.

"In several randomized double-blind clinical trials, Ganite has proven to be effective against hypercalcemia in patients with a variety of cancers, said Christopher Chitambar, an investigator for an ongoing Ganite trial and professor of medicine at the Medical College of Wisconsin. "Ganite's increased availability now represents a promising treatment alternative for my patients."

Ganite was originally developed by NCI as a cancer chemotherapy drug. A separate series of studies showed that the drug markedly reduced the

loss of calcium from bone—an observation that suggested the drug may be useful in hypercalcemia, as well as other conditions associated with loss of bone mass, the company said.

The drug has proven safe and effective in normalizing high levels of blood calcium by inhibiting calcium resorption from bone, the company said.

* * *

ImClone Systems Inc. (Nasdaq: IMCL) of New York and **Bristol-Myers Squibb Co.** (NYSE: BMY) of Princeton, N.J., said FDA has accepted its biologics license application for filing and review for the use of Erbitux (cetuximab) in combination with irinotecan for EGFR-expressing irinotecan-refractory metastatic colorectal cancer.

The companies also said the request for accelerated approval has been granted priority review designation by FDA.

Erbitux is an investigational IgG1 monoclonal antibody designed to exclusively target and block the Epidermal Growth Factor Receptor.

* * *

Introgen Therapeutics Inc. (Nasdaq: INGN) of Austin, Tex., said its investigational cancer therapy, Advexin, received Fast Track designation from FDA for loco-regional disease progression in unresectable squamous cell carcinoma of the head and neck.

Introgen has two ongoing phase III studies of Advexin in head and neck cancer, the company said. In one study, the effect on survival time (primary endpoint) of Advexin mono-therapy is compared to that of methotrexate. Secondary endpoints are objective response rate, time to progression and tumor growth control. In the second study, a combination of Advexin with platinum and 5-fluorouracil is compared to that of the combined chemotherapies. The primary endpoint in here is time to progression. Secondary endpoints include survival time, objective response rate and tumor growth control.

* * *

Light Sciences of Seattle said **Meiji Seika**, the licensor of its lead compound, LS11 (Laserphyrin in Japan), received a recommendation for approval for the photodynamic treatment of early endobronchial carcinoma by Pharmaceutical Affairs and Food Sanitation Council of the Ministry of Health, Labor and Welfare in Japan.

The Japanese regulatory decision in the world second largest healthcare market comes as Light Sciences has successfully completed a phase I/II study of its lead combination product, Litx for advanced stage solid cancers, the company said.

One of the components of the Litx System is the light activated LS11 drug, the company said.

"The Japanese recommendation for approval of our lead drug coincides with the initiation of our phase II oncology program internationally," said Albert Luderer, president and CEO of Light Sciences.

Light Sciences licensed LS11 from Nippon Petrochemicals and Meiji Seika Kaisha in early 2000, and has exclusive rights to develop, make and commercialize the compound for use in photodynamic therapy in multiple therapeutic applications worldwide, outside of Japan, the company said.

Litx is based on a next-generation model of light activated drugs using tiny, cost-effective light emitting diodes for light generation and delivery, the company said, The product is designed to treat localized disease and is being studied in solid tumors that have failed prior treatments including surgery, radiation and/or chemotherapy.

* * *

Sonus Pharmaceuticals Inc. (Nasdaq: SNUS) said FDA has granted Fast Track designation for TOCOSOL Paclitaxel for metastatic or locally advanced, inoperable transitional cell carcinoma (TCC) of the urothelium. The most common form of urothelial TCC is bladder cancer.

Sonus has completed patient enrollment in three phase IIa studies using TOCOSOL Paclitaxel for the treatment of bladder, ovarian and non-small cell lung cancers.

Concurrent with the plan to pursue approval for bladder cancer, Sonus will seek approval of TOCOSOL Paclitaxel for other indications through a development program comparing the product to Taxol.

TOCOSOL Paclitaxel, a reformulation of paclitaxel, is a ready-to-use formulation, does not require reconstitution, dilution or preparation as with the currently marketed paclitaxel products and other paclitaxel formulations under development. The agent is administered in a short 15-minute infusion, compared to the three-hour infusion required with other paclitaxel products.

* * *

Tularik Inc. (Nasdaq: TLRK) said FDA has granted Fast Track designation for T67 for first line therapy in patients with unresectable hepatocellular carcinoma.

T67 is a small molecule drug candidate that binds irreversibly to beta-tubulin, which distinguishes

it from other tubulin-binding agents. Interfering with beta-tubulin function induces programmed cell death, or apoptosis, in cancer cells. With over 260 patients dosed in phase I and phase II studies, T67 has been well tolerated and has shown activity in patients with HCC. Tularik retains worldwide rights to T67.

Oncology Management:

NCCN Updates Guidelines For Antiemesis Treatment

National Comprehensive Cancer Network of Jenkintown, Penn., said it has updated its NCCN Antiemesis Clinical Practice Guidelines. The panel of oncology experts has added aprepitant (Emend), a NK1 receptor antagonists, to its recommended multidrug regimens for nausea and vomiting in highly and moderately emetogenic chemotherapy regimens, the network said.

Aprepitant, which is given on day one and then at a reduced dose on days two and three of chemotherapy, is recommended by the panel to prevent both acute and delayed vomiting associated with highly emetogenic regimens, to prevent acute vomiting, and as an option for preventing delayed vomiting associated with moderately emetogenic regimens, the network said.

NCCN Clinical Practice Guidelines in Oncology can be found at www.nccn.org and are available on CD-ROM, which can be ordered by calling 215-690-0300.

* * *

Ardais Corp. of Lexington, Mass., said it has begun its BIGR (Biomaterials and Information for Genomic Research) Biospecimen Management System, for biorepository management.

The BIGR Biospecimen Management System is a set of software, standard operating procedures, and services for biospecimen collection, processing, and repository management, the company said.

The system is a comprehensive set of services and licenses that enable biomedical researchers in pharmaceutical, biotechnology and academic medical research institutions to collect, annotate, manage and distribute their human biological material resources, the company said.

Ardais and its partner medical institutions have used the system to enroll over 14,000 donors and collect over 180,000 tissue samples for clinical genomics research.

* * *

Crittenton Hospital Medical Center of Rochester, Mich., and the **Barbara Ann Karmanos Cancer Institute** of Detroit said they have signed an affiliation agreement.

"This affiliation agreement between Crittenton and the Institute is great news for cancer patients and the physicians engaged in their care," said John Ruckdeschel, president and CEO of the institute. "Specifically qualified and credentialed Crittenton physicians will now be able to refer cancer patients to the Institute where face-to-face ongoing personal consultation is our standard of care."

* * *

GE Medical Systems of London and Fairfield, Conn., said it has developed the LightSpeed RT, a computed tomography system for radiation therapy planning.

First displayed at the **Varian Medical Systems** (NYSE:VAR) exhibit at the American Society of Therapeutic Radiology & Oncology annual meeting in Salt Lake City, the system is the first multi-slice CT scanner to feature an extra wide gantry opening with a series of advanced oncology applications, including the GE Advantage Sim, Advantage Fusion and the exclusive Advantage 4D respiratory gating package, the company said.

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Highmark Inc. of Pittsburgh said it has formed **Medmark Inc**., a specialty pharmaceutical distribution company, which has agreed to acquire the assets of **Fisher's SPS**, a specialty pharmacy. Fisher's SPS, founded in 1998 and serving 35,000 patients, provides specialized pharmacy care for special or chronic medication needs, including cancer.

As part of the initiative, Highmark has recruited a management team for Medmark led by CEO L. Peter Smith and Stanley Blaylock who will serve as CEO/CFO and chief administrative officer, the company said.

Smith was CEO of CorSolutions, a health services company, and Blaylock was global co-head of Health Care Investment Banking at Deutsche Bank.

* * *

Matria Healthcare Inc. (NASDAQ:MATR) of Marietta, Ga., said its subsidiary, **Quality Oncology Inc**., has opened a cancer support call center in Houston. The QO cancer disease management program includes 24-hour-a-day, seven-day-a-week phone access to a QO team of cancer nurses, the company said.

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