THE CANCER LETTER

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Charles Balch Resigns As ASCO CEO, Joseph Bailes Named Interim Executive

By Paul Goldberg

Charles Balch earlier this week resigned from his position as executive vice president and chief executive officer of the American Society of Clinical Oncology to "focus on oncology patient care, clinical research, and teaching."

In an Oct. 24 memo emailed to ASCO staff, Balch, 63, said he would be "relocating" to Johns Hopkins Medical Institutions and Sidney Kimmel

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In Brief:

Nevada Cancer Institute, Formed In 2002, Moves Into New Building, Hires More Staff

NEVADA CANCER INSTITUTE, the official cancer institute for the state of Nevada, dedicated a new research and care center in Las Vegas. The four-story, 142,000-square-foot outpatient facility, built at a cost of $52 million, is located on a six-acre campus and brings together the center's 19 faculty. NVCI, a non-profit organization, was established in 2002, and construction began on the facility in January 2004. "I'm amazed at how far wwe have come in such a short time," said **Heather Murren**, president and CEO of NVCI. "The center will help to facilitate state-of-the-art cancer research, treatment, and education." **Nicholas Vogelzang** is the center director. The center also announced four appointments. **Bryan Wong** was named assistant member, Department of Hematological Oncology. He joined NVCI from Memorial Sloan-Kettering Cancer Center, where he finished his fellowship medical oncology/hematology. **Burgess Freeman III** was named director of the Clinical Pharmacology Core. He completed a clinical pharmacology fellowship at St. Jude Children's Research Hospital. **Celena Kwong** was appointed clinical pharmacist in the Office of Clinical Trials. She was previously a senior clinical research specialist at Novartis Oncology. **Jeff Wyatt** was named director of clinical business systems. He was assistant dean for administration at University of Nevada School of Medicine. . . . **MEMORIAL SLOAN-KETTERING Cancer Center** received a $1 million pledge from the Lance Armstrong Foundation for cancer survivorship programs that focus on the transition from treatment to follow up. The funding includes recruitment and training of nurse practitioners for the clinics as well as adding a clinical psychologist, said **Mary McCabe**, director of Cancer Survivorship Program. . . . **CITY OF HOPE CANCER CENTER** has made three new appointments. **Richard Jove** was named deputy director of the

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Balch Returns To Patient Care, ASCO Seeks CEO Candidate

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Cancer Center, where he would be working full time as professor of surgery and oncology, a position he held part time while running ASCO.

According to ASCO's tax filings, Balch's salary and benefits last year were $482,374. The society said Balch's employment contract was signed in the fall of 2003 and was to expire in 2009.

In a separate letter, emailed to ASCO members, society President Sandra Horning praised Balch for "the many contributions that he has made" during six years at the society.

"He guided ASCO through the development of its strategic plan, the rapid growth of its membership and staff, and the launch of many new initiatives important to the organization in its role in the fight against cancer," Horning wrote in the letter dated Oct. 24.

In an interview, Horning said ASCO's volunteer leadership sets the direction for the society and will continue to do so.

"We have had a process of continuous and open dialogue between the board of directors, the president, and the EVP to work together on issues, to strategize, and to implement new programs, and we plan to continue that process as we move forward in the selection of a permanent EVP," said Horning, professor of medicine at the divisions of medical oncology and blood and marrow transplantation at Stanford University.

Balch was expected to complete a transition to Hopkins by the end of the week, and would serve as a consultant to the society for another six months, Horning said.

"Dr. Balch has had a dual role while at ASCO, working at Hopkins in a surgical capacity over the entire period of time that he was here at headquarters," Horning said to The Cancer Letter. "Getting back into the clinical setting is something he has considered for some time."

Balch declined to comment, referring questions too ASCO.

Bailes Named Interim EVP

Joseph Bailes, an expert in reimbursement issues and a former ASCO president, was named interim executive vice president.

"Dr. Bailes has been co-chair of ASCO's Government Relations Council for nearly two years, and has been at ASCO headquarters on a regular basis to serve in that capacity," Horning said. "He will be enhancing that level of activity as he takes over the interim EVP position. We have asked him to assume a role as interim EVP until a permanent replacement is found."

The search for the chief executive would take about six months, Horning said.

"This is really a great opportunity for the right person," she said. "ASCO is the leading organization for professionals who care for patients with cancer, a very vibrant organization that has enjoyed tremendous growth over the last five years. We are looking for someone who has energy and vision—someone who has experience in leadership and management positions, as well as stature in oncology community."

The next executive would lead the society through an important time in oncology, Horning said.

"I see this as a time where we have great opportunity to capitalize on the investment made in understanding the biologic underpinnings of cancer, and our challenge is to take all of that discovery and deliver it to patients," she said.

According to tax forms for the year ended Aug. 31, 2004, ASCO had gross receipts of $61.9 million. A related entity, ASCO Foundation, had gross receipts of $18.7 million.

Another oncology professional society, American Association for Cancer Research, had gross receipts of $47.1 million. In 2003, the compensation package for its top executive, Margaret Foti, totaled $534,934.

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Capitol Hill:

Inspector General Reviewing Crawford's FDA Departure

By Kirsten Boyd Goldberg

The HHS Inspector General has confirmed that the office is looking into Lester Crawford's resignation as FDA commissioner last month, members of Congress were informed earlier this week.

"This office is currently reviewing the circumstances regarding Dr. Crawford's resignation," Inspector General Daniel Levinson wrote in a letter to Rep. Maurice Hinchey (D-NY). "Depending upon the results of the review, we will determine the next appropriate action."

Identical letters were sent to others members of Congress who co-signed Hinchey's request for an inquiry into Crawford's resignation, including Reps. Sam Farr (D-Calif.), Marcy Kaptur (D-Ohio), Raul Grijavla (D-Ariz.), and Lynn Woolsey (D-Calif.), Levinson wrote.

Crawford resigned unexpectedly on Sept. 23, two months after his Senate confirmation, saying that "it is time at the age of 67, to step aside." Several news reports suggested that Crawford may have failed to disclose financial information.

In their letter to HHS, Hinchey and the other lawmakers said they were concerned about the possibility of "conflicts of interest such as inappropriate and undisclosed pharmaceutical company stockholdings."

The sudden resignation "raises significant questions," the lawmakers wrote, noting that FDA has been without a permanent commissioner for half of the duration of President George Bush's administration.

"The FDA has been in absolute turmoil for years," Hinchey said in a recent press release. "Dr. Crawford's sudden resignation is yet another example of why we need transparency at the FDA so we can finally restore integrity and stability to this vital agency. The American people deserve much better than what they've gotten recently out of the FDA."

Hinchey introduced the FDA Improvement Act of 2005 to "end the financial link and inappropriately close relationship between the drug industry and the FDA," by transferring industry user fees from FDA to the U.S. Treasury.

One component of the bill, a requirement that FDA advisory panels be composed of experts with no financial ties to companies who have a stake in the topic under discussion, has been approved by the House as an amendment to the FDA appropriations bill for fiscal 2006. The measure still needs to go before a House and Senate conference committee.

In the only interview he has granted since his resignation, Crawford denied having any inappropriate financial holdings. Crawford told Forbes.com that he was worn out after three years at the agency, particularly due to the controversy over the Plan B contraceptive by Barr Laboratories and the abortion pill RU-486. Also, the Government Accountability Office was starting another investigation of financial conflicts of interest, he said.

"I didn't think it was possible to be very effective anymore," Crawford said to Forbes.com "Another year of that stuff, I didn't think I was up to it."

Crawford said that around Sept. 1, he had decided to consider retirement, and received the details of his retirement package on Sept. 15.

The Forbes.com article is posted at http://www.forbes.com/facesinthenews/2005/09/28/crawford-fda-vioxx-cx_mh_0928autofacescan03.html.

However, the Wall Street Journal reported Oct. 26 that Crawford or his wife held stocks in companies that make products regulated by FDA as late as 2004, including Kimberly-Clark Corp., Teleflex Inc., Sysco Corp., and Embrex Inc.

According to the article, financial disclosure forms released under the Freedom of Information Act show that an FDA ethics official raised questions about information on the forms shortly before Crawford left the agency.

Senate Passes HHS Appropriations

The Senate Oct. 27 passed its version of a funding bill for the Departments of Labor, HHS and Education.

The bill, HR 3010, was passed by a 94-3 vote, and now it will be up to House and Senate conferees to iron out the differences between the two measures.

Under the House bill and the President's budget proposal, NIH is expected to get an increase of .5% over fiscal 2006. The Senate bill gives NIH a 3.7% increase.

According to the Federation of American Societies for Experimental Biology, the lower appropriations are eroding the effects of doubling of NIH funding between 1998 and 2003.

"Should NIH receive the House passed level of a .5% increase in 2006 and similar increases in 2007 and 2008, the gains from the doubling movement will essentially be eliminated," FASEB said in a legislative alert. "Pay lines and success rates, which are already

decreasing at alarming rates, will continue to plunge and opportunities will be lost."

Deliberating the bill, the Senate avoided issues related to abortion. This year, the Senate's biggest splurge was a measure to spend $8 billion on preparation for a pandemic of avain flu.

The measure was introduced by Sen. Tom Harkin (D-Iowa), ranking member of the subcommittee that funds NIH. The amendment appropriates $3.3 billion for development of vaccines, $3.1 billion for stockpiling antiviral drugs, $600 million for state and local health agencies; $750 million for hospitals to manage the possible pandemic, and $185 million for Centers for Disease Control and Prevention to handle the outbreak.

NCI Programs:

Patient Navigator Programs Awarded $25 Million In Grants

NCI announced a total of $25 million in grants to eight research institutions to develop a Patient Navigator Research Program to help cancer patients and their families overcome barriers to obtaining timely and appropriate cancer care and treatment.

The five-year grants will be administered by NCI's Center to Reduce Cancer Health Disparities.

The PNRP will test and evaluate interventions designed to improve access to cancer care and treatment following a cancer diagnosis. The program will emphasize four cancers for which screening tests are available: breast, cervical, prostate, and colorectal.

The grants will focus on cancer patients from racial/ethnic minority groups, patients with low socioeconomic status, and patients from medically underserved areas.

The grants were awarded to the following institutions and principal investigators:

Boston University Medical Center, Karen Freund; Denver Health and Hospital Authority, Peter Raich; George Washington University, Steven Patierno; H. Lee Moffitt Cancer Center & Research Institute, Richard Roetzheim; Northwest Portland Area Indian Health Board, Joshua Jones; Northwestern University, Charles Bennett; University of Rochester, Kevin Fiscella; University of Texas Health Sciences Center, San Antonio, Donald Dudley.

"In order to meet our challenge goal to eliminate suffering and death due to cancer, we must ensure that any patient with a suspicious finding is provided timely diagnosis and that patients who are diagnosed with cancer experience no delay in receiving high-quality cancer care, regardless of their race, ethnicity, socioeconomic status or geography," Harold Freeman, senior advisor to the NCI director on minority and underserved communities, said. "These projects will help improve access to quality, standard cancer care and could contribute to substantial progress in reducing cancer health disparities."

Nanotech Partnerships To Receive $35 Million

NCI has awarded $7 million in first-year funding for 12 Cancer Nanotechnology Platform Partnerships, a second component of its $144.3-million, five-year initiative for nanotechnology in cancer research.

The 12 partnerships will receive a total of $35 million over five years.

"The future of oncology—and the opportunity to eliminate the suffering and death due to cancer—will hinge upon our ability to confront cancer at its molecular level," NCI Director Andrew von Eschenbach said in a press release issued Oct. 17.

"Nanodevices, invisible to the naked eye and a tiny fraction the width of a human hair, will enable researchers to probe genetic defects inside cells, detect the earliest aberrations of cellular function that lead to cancer, and correct those errant processes long before they give rise to cancers large enough to be diagnosed by today's methods," said von Eschenbach, who is also acting FDA commissioner.

The awardees include: Mansoor Amiji, Northeastern University, Boston; James Baker Jr., University of Michigan, Ann Arbor; Panos Fatouros, Virginia Commonwealth University; Douglas Hanahan, University of California, San Francisco; Tayyaba Hasan, Massachusetts General Hospital; Kattesh Katti, University of Missouri, Columbia; Chun Li, University of Texas M.D. Anderson Cancer Center; Scott Manalis, Massachusetts Institute of Technology; Allan Oseroff, Roswell Park Cancer Institute; Paras Prasad, State University of New York, Buffalo; Jan Schnitzer, Sidney Kimmel Cancer Center, San Diego; and Raymond Sze, University of Washington, Seattle.

The other three components of the NCI Alliance for Nanotechnology in Cancer, all of which are now funded, include:

—Centers of Cancer Nanotechnology Excellence: Seven centers were funded with first-year funding totaling $26.3 million.

—Nanotechnology Characterization Laboratory: Established at NCI's Frederick, Md., facility in 2004, this laboratory is characterizing nanoparticles for academic and commercial researchers.

—Multidisciplinary research training and team development: NCI supports training and career development initiatives to establish integrated teams of cancer researchers, through mechanisms such as the NIH National Research Service Awards for Senior Fellows and NIH National Research Service Awards for Postdoctoral Fellows. Applications are being accepted for training awards (http://grants.nih.gov/grants/guide/rfa-files/RFA-CA-06-010.html).

Also, through NCI's collaboration with the National Science Foundation, a total of $12.8 million in grants were awarded last month to four institutions. These grants allow U.S. science and engineering doctoral students to focus on interdisciplinary nanoscience and technology research with applications to cancer.

NIH Programs:

HapMap Consortium Produces Catalog Of Genetic Variation

The International HapMap Consortium this week published a comprehensive catalog of human genetic variation—the 0.1 percent genetic difference between any two unrelated people.

The results, published in the Oct. 27 issue of the journal Nature, provide overwhelming evidence that variation in the human genome is organized into local neighborhoods, called haplotypes, which usually are inherited as intact blocks of information.

The project involving more than 200 researchers from Canada, China, Japan, Nigeria, the U.K., and U.S., began in 2002 to create a human haplotype map. The Nature paper marks the completion of phase I of the project, consisting of more than 1 million markers of genetic variation, called single nucleotide polymorphisms (SNPs). The consortium is also nearing completion of the Phase II HapMap that will contain nearly three times more markers than the initial version.

"The HapMap provides a powerful new tool for exploring the root causes of common diseases," said David Altshuler, of the Broad Institute of Harvard and MIT, who along with Peter Donnelly, of the University of Oxford, are the paper's corresponding authors. "Such understanding is required for researchers to develop new and much-needed approaches to prevent, diagnose and treat diseases, such as diabetes, bipolar disorder, cancer, and many others."

The HapMap shows the neighborhoods of correlated genetic variation, or haplotypes, across the entire human genome. With these haplotypes defined, HapMap provides an efficient method for choosing "tag SNPs" that captures the genetic variation in each neighborhood with a minimum amount of work. By using HapMap data to compare the SNP patterns of people affected by a disease with those of unaffected people, researchers can survey genetic variation across the whole genome and identify genetic contributions to common diseases.

The consortium cautioned the research community not to jump to conclusions too quickly when using HapMap data. "Rigorous standards of statistical significance will be needed to avoid a flood of false positive results," the paper said. Scientists should confirm any gene "discovery" by replicating the findings in independent studies that use the same set of SNP markers in different groups of people with the same disease or condition, the paper said.

The consortium produced the HapMap using DNA from blood samples collected from 269 volunteers from widely distributed geographic regions, including Yoruba in Ibadan, Nigeria; Japanese in Tokyo, Han Chinese in Beijing and Utah residents with ancestry from northern and western Europe.

The U.S. component of the $138-million international project is led by the National Human Genome Research Institute.

Researchers can access the HapMap Data Coordination Center at www.hapmap.org, the National Center for Biotechnology Information's dbSNP at www.ncbi.nlm.nih.gov/SNP/index.html, or the JSNP Database in Japan at http://snp.ims.u-tokyo.ac.jp/.

NIH Awards $30 Million For Facilities

The National Center for Research Resources said it will award nearly $30 million for 10 Research Facilities Improvement Program projects.

The awards will fund the design, construction, and fixed equipment costs for new research facilities such as the Northern Plains Center for Behavioral Research at the University of North Dakota; the Center for Human Genetics and Complex Traits at the University of Pennsylvania; and the Breast and Women's Cancer Laboratory at the University of California, Irvine.

The program will support new resources for research animals at Tulane University Health Sciences Center and the University of Alaska, Fairbanks; increased research imaging capabilities at the Massachusetts General Hospital and Vanderbilt University; and renovations to laboratories at Meharry Medical College, Montana State University, and the University of Washington.

Application guidelines are available at http://www.ncrr.nih.gov/resinfra/ri_rfip.asp.

NIH To Begin Electronic Grant Submission

Prospective NIH grantees soon will have to apply for funding electronically through the federal portal www.grants.gov.

Beginning with the receipt date of Dec. 1, NIH will require its Small Business Research Innovation Program and Small Business Technology Transfer Program applicants to electronically submit their competing grants.

NIH plans to transition all of its competing grant programs from paper to electronic by May 2007. The electronic submission timeline is available at http://era.nih.gov/ElectronicReceipt.

NIH expects to eliminate about 200 million pieces of paper a year and reduce the costs of scanning, data entry, data validation, printing, and reproduction. NIH is also moving from its PHS398 application form to the new SF424 Research and Related application form.

NIH advised grantees to begin preparing for electronic submission. Institutions must register with Grants.gov. Institutions and principal investigators must establish NIH eRA Commons accounts, at https://commons.era.nih.gov/commons/.

Applicant organizations that choose electronic forms-based submission need to download PureEdge software, available free from Grants.gov. Alternatively, to establish a system-to-system data exchange solution, institutions should contact Grants.gov or partner with an authorized service provider that already has developed a Grants.gov interface.

Further information on electronic submission is available at http://era.nih.gov/ElectronicReceipt.

NIH Invites Public Comment On Changes To NRSA Grants

NIH plans to hold a public meeting to hear comments about possible revisions to fiscal policies of the Ruth L. Kirschstein National Research Service Awards—the institutional training grants (T32 and T34s) and individual fellowships (F30, F31, F32, F33).

The meeting is scheduled for Nov. 30, in the Natcher Conference Center, Room E1/E2 on the NIH campus in Bethesda, Md.

NRSA programs currently support over 17,000 predoctoral and postdoctoral research training positions primarily in academic laboratories.

"While the budget for the NRSA programs grew smartly during the five years in which the overall appropriation for the NIH was doubled, since fiscal 2003, the last of the growth years, the appropriation for NRSA training programs has grown rather modestly," according to an NIH notice in the Federal Register Oct. 24. "Given this reality, the NIH must re-examine aspects of its NRSA policies that may not be sustainable in a period of limited budget expansion."

A major issue is funding for tuition for the institutional training grants. A formula provides for each T32 trainee the sum of $3,000 plus 60 percent of the institution's requested tuition in excess of $3,000.

Requests and outlays for tuition have risen faster than the program's ability to pay, causing NIH to freeze the tuition expenses on competing renewals of T32 awards in fiscal 2006.

"Barring other adjustments, the continuation of this trend in tuition growth will result in a significant annual decrease in the number of NRSA trainee positions, and to fewer programs supported by T32 training grants," the notice said.

According to the Federal Register notice, options being considered include retaining the current formula, but placing a ceiling on tuition in the range of $16,000 to $18,000; providing a fixed allowance; or retaining the current formula without modification, which would require decreases in the number of funded trainees.

NIH is accepting public comment, not to exceed two pages, and will invite some of those submitting comments to make brief oral presentations at the meeting. Statements may be submitted to NRSATownHall@mail.nih.gov by Nov. 4.

Those planning to attend the meeting are asked to register at http://pub.nigms.nih.gov/nrsameeting.

Funding Opportunities:

RFA Available

RFA-ES-05-007: Environmental Influences on Epigenetic Regulation. Letters of Intent Receipt Date: Dec. 19. Application Receipt Date: Jan. 18.

Institutes and centers are soliciting applications from scientists studying the mechanisms of action of environmental agents at the molecular level and focusing on alterations in gene expression and subsequent disease etiology or progression. NCI is interested in identifying high-risk populations that are exposed to environmental agents and may develop cancer. NCI is also interested in elucidating mechanisms by which diet influences epigenetic processes as well as increasing the understanding of such processes in cancer prevention. The initiative uses R21 and R01 mechanisms. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-05-007.html.

Inquires: For NCI--Mukesh Verma, phone 301-594-7344, email vermam@mail.nih.gov, and Sharon Ross, phone 301-594-7547; email rosssha@mail.nih.gov.

Program Announcements

PA-05-041: Small Business Innovation Research to Improve The Chemistry and Targeted Delivery of RNAi Molecules

Participating institutes and centers invite applications from the small business community to develop technological approaches and chemical modifications that will increase the long term stability, delivery and targeting of siRNAs in cells and tissues for laboratory and therapeutic applications.

Examples of projects that are being solicited include but are not limited to: Development and identification of chemical modifications to improve thermal stability of dsRNA, such as LNA (locked nucleic acids) or HNA (hexitol nucleic acids) Development of nucleic acid modifications, such as 2'-flurobases or 3'-5' phosphoramidate, leading to resistance to nuclease digestion but still allowing efficient processing by Dicer. Examples of projects that are being solicited include but are not limited to: Identification of chemical modifications leading to preferential strand uptake by RISC, that will enhance specificity and reduce off-target effects; Development of chemical modifications, such as 2,6-diaminopurine, that enhance base-pairing interactions between the siRNA and targeted mRNA; Development of chemical modifications that will allow or regulate distribution to target tissues, such as to and across the blood-brain-barrier; Identification of chemical modifications, such as phosphorothioate linkages that will enhance the pharmacokinetic properties of siRNA; Development of improved instrumentation that will synthesize long oligonucleotides reliably and with high fidelity. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-003.html.

Inquiries: For NCI--Suresh Arya, phone 301-496-8783, email aryas@exchange.nih.gov.

PA-06-008: **Bioengineering Nanotechnology Initiative.** This is an initiative of the trans-NIH Bioengineering Consortium. Research topics include: 1. Nanomaterials development of synthetic nanoscale building blocks for the formulation of bottom-up approaches to complex and multi-functional nano materials; 2. Nanoimaging: real-time imaging of subcellular structure, function, properties and metabolism; 3. Cell biology: nano-scale research on cellular processes, including biophysics of molecular assemblies, membranes, organelles, and macromolecules; 4. Molecular and cellular sensing/signaling: technologies to detect biological signals and single molecules within and outside cells; 5. Prosthetics: mechanical, chemical, and cellular implant nano-technologies to achieve functional replacement tissue architectures and tissue-compatible devices; 6. Environmental and health impact of nanotechnologies: ramifications of nanomaterial processing, use, and degradation on health and the environment; In-vivo therapeutics: development of nanoparticles that enable controlled release of therapeutic agents, antibodies, genes and vaccines into targeted cells; 7. Sensor technologies: detection and analysis of biologically relevant molecular and physical targets in samples from blood, saliva and other body fluids, or for use in the research laboratory, clinical specimens, and in the living body; 8. Nanosystem design and application: fundamental principles and tools to measure and image the biological processes of health and disease and methods to assemble nanosystems; 9. Bioinformatics for nanotechnology: algorithms and computer software to enable and support all of the above. The PA will use the STTR R41/R42 grant mechanisms. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-06-008.html.

Inquiries: For NCI--Piotr Grodzinski, phone 301-496-1550, email grodzinp@mail.nih.gov.

In Brief:

VICC Breast Clinic Offers Team Consultation For New Patients

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cancer center, chairman and professor of the Division of Molecular Medicine, and co-director of Experimental Therapeutics Program. Jove served as director of the Molecular Oncology Program and associate director of Basic Research at the H. Lee Moffit Cancer Center and Research Institute. **Hua Yu** was named professor of Cancer Immunotherapeutics & Tumor Immunology. Yu was associate professor of Immunology at Moffitt Cancer Center. **Behnam Badie** was named director of the Department of Neurosurgery in the Division of Surgery and director of the Brain Tumor Program. Badie was associate professor of neurosurgery and vice chairman of academic affairs at the University of Wisconsin Medical School. . . . **VANDERBILT-INGRAM** Cancer Center has established a new clinic in the Vanderbilt Breast Center that enables newly diagnosed breast cancer patients to see all three clinicians involved in their care in one visit. Every Wednesday, each new patient is evaluated by a nurse practitioner and meets with patient education experts to learn about the center's services and other community resources. Meanwhile, the multidisciplinary team meets to review the patient's history and develop treatment recommendations. Next, the patient meets with her cancer care team—the surgeon, medical oncologist and radiation oncologist. Clinical trials staff are also on hand to discuss potential participation in breast cancer trials. The program is directed by **Ingrid Meszoely**, assistant professor of surgery and clinical director of the center. . . . **SHANDS HEALTHCARE** and **University of Florida Health Science Center** said they plan to establish the Shands at UF Cancer Hospital at the Gainesville campus. The tower would provide 200 private rooms as well as diagnostic, and therapeutic

oncology care. Completion is expected in 2009, said **William Stratford May**, director of the UF Shands Cancer Center. . . . **TRANSLATIONAL Genomics Research Institute** received a $9 million unrestricted grant for research discoveries in a broad spectrum of diseases from the Flinn Foundation. The foundation has made a total commitment of $24 million to Tgen. One third of the $9 million grant will serve as a match challenge for the TGen Foundation Naming Campaign, said **John Murphy**, president and CEO of Flinn Foundation. The campaign allows donors to make a lasting contribution to research by naming spaces within TGen such as laboratory benches, conference rooms, and other areas. . . . **INTERNATIONAL GENOMICS CONSORTIUM'S** Expression Project for Oncology said it has collected its 1,000th frozen cancer specimen after 16 months of operation. The purpose of the project is to obtain cancer tissue samples under uniform and standardized conditions, perform gene expression analyses, and collect the long-term clinical outcome of the patient. The data is available online for researchers. "We overcame many challenges to perform complete gene analyses and to have the information freely available online, while also ensuring that we had addressed key issues of patient privacy and consent is a major step forward," said **Robert Penny**, executive director of expO and chief medical officer of IGC. IGC has established a standardization system for obtaining and processing these tumor samples. Over a three-year period, IGC expects to obtain 2,000 to 3,000 tumor specimens representing a broad spectrum of malignancies and 500-1,000 normal tissues. So far, IGC has collected a total of 5,083 biospecimens including frozen biosamples and paraffin tissue blocks containing normal, paranormal and malignant tissue and peripheral blood samples. The project receives financial support from GlaxoSmithKline, Bristol-Myers Squibb and Wyeth Pharmaceuticals. The clinically annotated dataset is available through the National Center for Biotechnology Information at www.ncbi.nlm.nih.gov/geo/. . . . **H. SHELTON EARP III** began a two-year term as president of the Association of American Cancer Institutes at the group's annual meeting earlier this month in Arlington, Va. Earp is director of the Lineberger Comprehensive Cancer Center at University of North Carolina, Chapel Hill. He also serves as principal investigator of an NCI Specialized Program of Research Excellence in Breast Cancer. Earp is the Lineberger Professor of Cancer Research and a professor of pharmacology and medicine at UNC. He also serves on the NCI Board of Scientific Advisors. **Edward Benz Jr.**, director of the Dana-Farber Harvard Cancer Center, is AACI vice president and president-elect. . . . **WALTER WILLETT** has been selected to receive the 25th Annual Bristol-Myers Squibb/Mead Johnson "Freedom to Discover" Award for Distinguished Achievement in Nutrition Research. Willett, chairman of the Department of Nutrition and Fredrick John Stare Professor of epidemiology and nutrition at the Harvard School of Public Health, and professor of medicine at Harvard Medical School, was selected for his pioneering work in the field of nutritional epidemiology, including the development of large-scale cohort studies and methods to assess dietary intake in large populations. In so doing, he uncovered significant relationships between nutrition and chronic diseases, including cancers, cardiovascular diseases and diabetes. . . . **CHARLES LOPRINZI** received the Association of Community Cancer Centers Annual Clinical Research Award for his significant clinical research activities, particularly in the area of prevention of symptoms related to cancer and cancer therapy. Loprinzi is a professor of oncology and the past chairman of the Division of Medical Oncology at Mayo Clinic Rochester. . . . **HAROLD DVORAK** received the Albert Szent-Györgyi Prize for Progress in Cancer Research, awarded by the National Foundation for Cancer Research. Dvorak, the Mallinckrodt Professor of Pathology at Harvard Medical School and chief of the Department of Pathology at Beth Israel Deaconess Medical Center, discovered vascular permeability factor/vascular endothelial cell growth factor, which led to a series of discoveries on the mechanisms of angiogenesis as well as the development of antibodies and small molecule therapies to inhibit VEGF, said **Sujuan Ba,** chief scientific officer of NFCR and co-chairman of the Szent-Györgyi Prize Committee. The award includes a $25,000 cash prize. . . . **BARRY FORMAN** was named the Ruth B. and Robert K. Lanman Endowed Chair at City of Hope National Medical Center, established with a $2.5 million gift from the Lanman family. The award will support multidisciplinary studies into the molecular and cellular processes of metabolic diseases. Forman, director and professor, Department of Gene Regulation and Drug Discovery, is the first scientist to hold the endowed chair. . . . **SEN. ARLEN SPECTER** (R- Penn.) will be honored with the American Association for Cancer Research Public Service Award for his work to strengthen biomedical research funding. Specter, a cancer survivor, is chairman of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies.

A Notch-Signaling Pathway Inhibitor in Patients with T-cell Acute Lymphoblastic Leukemia/Lymphoma (T-ALL)

An investigational study for children, adolescents and adults with relapsed and refractory T-cell acute lymphoblastic leukemia/lymphoma is now accruing patients at various centers around the country.

This study's goal is to evaluate the safety and tolerability of a Notch inhibitor as a rational molecular therapeutic target in T-ALL, potentially uncovering a novel treatment for these cancer patients.

Eligibility criteria and treatment schema for the study include:

Notch-Signaling Pathway Inhibitor in Patients with T-ALL	
Eligibility Criteria	Patient must be = 12 months with a diagnosis of T-cell acute lymphoblastic leukemia/lymphoma AND must also have: • Relapsed T-ALL • T-ALL refractory to standard therapy • Not be a candidate for myelosuppressive chemotherapy due to age or comorbid disease ECOG performance status =2 for patients >16 years of age OR Lanksy performance level >50 for patients 12 months to =16 years of age Fully recovered from any chemotherapy and >2 weeks from radiotherapy, immunotherapy, or systemic steroid therapy with the exception of hydroxyurea or intrathecal therapy Patient must be >2 months following bone marrow or peripheral blood stem cell transplantation No treatment with any investigational therapy during the preceding 30 days No active or uncontrolled infection
Treatment Plan	Open label and non-randomized, this study is conducted in two parts. Part I is an accelerated dose escalation to determine the maximum tolerated dose (MTD), and Part II is a cohort expansion at or below the MTD. MK-0752 will be administered orally. Plasma concentrations will be measured at defined time intervals.

For information regarding centers currently open for enrollment, please contact 1-888-577-8839.

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THE CANCER LETTER

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Business & Regulatory Report

Clinical Trials:

Genentech Discontinues Avastin Study In Ovarian Cancer Due To GI Perforations

Genentech Inc. (NYSE: DNA) of South San Francisco said enrollment in a multi-center, single-arm phase II study of Avastin (bevacizumab) for platinum-refractory ovarian cancer has been discontinued due to a higher rate of gastrointestinal perforations than in previous studies.

Enrollment was discontinued following reports of five GI perforations observed in the first 44 patients in the proposed 53-patient study, the company said. The patients still enrolled in the trial will be informed of the new safety information and, in consultation with their physician, may continue to receive protocol treatment with Avastin or elect to discontinue treatment.

"GI perforations are a known possible adverse event with Avastin;

(Continued to page 2)

Oncology Management:

ImClone Begins Head And Neck Cancer Registry To Track Treatment, Outcomes

ImClone Systems Inc. (NASDAQ: IMCL) of New York, NY, said it would begin an independent national registry for head and neck cancer known as Longitudinal Oncology Registry of Head And Neck carcinoma or LORHAN.

The registry would gather treatment and supportive care choices as well as recurrence and survival outcomes, into a national database via a confidential Web-based system, the company said. The registry would give physicians participating in the registry a comparison of treatment outcomes. LORHAN also will determine whether the results of treatment-changing clinical studies are being incorporated effectively into daily practice, and compare treatment practices in community and academic settings. An estimated 26,400 patients will be eligible to enter the system each year, of which approximately 1,000 would be enrolled.

In addition, the American Board of Internal Medicine has approved LORHAN for medical oncologists wanting to satisfy a part of their re-certification related to practice performance, the company said. ABIM Certification is designed to assure the public that a medical specialist possesses the knowledge, experience, and skills requisite to the provision of high quality patient care.

"Advances in head and neck carcinoma have come principally from randomized studies, but the degree to which these trials have changed clinical practice is largely unknown," said K. Kian Ang, professor, radiation oncology, M.D. Anderson Cancer Center, and chairman of the LORHAN Advisory

(Continued to page 8)

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Genentech Stops Enrollment In Phase II Avastin Trial

(Continued from page 1)

however, we chose to discontinue enrollment in the phase II study due to the observation of a higher rate seen in this study than in other trials of the drug in ovarian cancer or other tumor types," said Hal Barron, senior vice president, development, and chief medical officer at Genentech. "We are continuing to study the drug in ovarian cancer based on the activity seen to date and the significant unmet medical need in this patient population, and do not expect these results to affect our plans to study the agent in earlier-stage ovarian cancer or other tumor types."

"The limited overall number of GI perforations prevent us from ascertaining definitive risk factors for the adverse event," Baron said. "Patients enrolled in this study had more advanced disease, which typically involves the bowel, and had received more prior chemotherapy than in previous clinical trials of Avastin in ovarian cancer."

Genentech made the decision to discontinue enrollment in consultation with FDA, the company said.

Avastin inhibits Vascular Endothelial Growth Factor, interfering with the blood supply to tumors. FDA approved Avastin last year as a first-line treatment for metastatic colorectal cancer in combination with intravenous 5-FU-based chemotherapy.

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Based on data showing that VEGF may play a broad role in a range of cancers, Genentech said it is pursuing a late-stage clinical development program with Avastin for adjuvant and metastatic colorectal, renal cell, breast, non-small cell lung and ovarian cancers.

* * *

Aegera Therapeutics Inc. of Montreal said it has begun a second phase I trial for AEG35156, its proprietary second generation XIAP antisense therapeutic for solid tumors.

The trial of the drug in combination with docetaxel (Taxotere) is being coordinated by the NCI of Canada Clinical Trials Group at Queen's University.

Three Canadian cancer centers are conducting the trial: Montreal Jewish General Hospital; Princess Margaret Hospital in Toronto; and the BC Cancer Agency in Vancouver, the company said. Principal investigators for the three sites are Gerald Batist in Montreal, Lillian Siu in Toronto, and Kim Chi in Vancouver.

The objective is to determine the recommended phase II dose of AEG35156 in combination with docetaxel, the company said.

"The preclinical synergy shown with docetaxel in preclinical models makes this an interesting study design" said Gerald Batist from the Jewish General Hospital in Montreal, chairman of oncology at McGill University and study chairman of the trial.

AEG35156 inhibits the X-linked inhibitor of apoptosis protein, a protein that is proprietary to Aegera, the company said. XIAP is an inhibitor of apoptosis induced by both intrinsic and extrinsic death cues, and most cancer cell lines over-express XIAP and high levels of XIAP are correlated with poor prognosis in multiple cancers and leukemias, the company said.

* * *

AEterna Zentaris Inc. (TSX: AEZ; Nasdaq: AEZS) of Quebec City said it has begun a European multi- center phase II trial of perifosine, an oral signal transduction inhibitor, in combination with radiotherapy, for non-small cell lung cancer.

The double-blind, placebo-controlled 160-patient trial will assess the efficacy and safety of a 150 mg daily dose of the drug when combined with radiotherapy for inoperable stage III NSCLC.

Perifosine will be administered daily for 5 to 6 weeks, starting 7 days prior to radiotherapy, and will be followed up for at least 12 months, the company said. The primary endpoint will be the extent and duration of local control, i.e. the absence of tumor recurrence or progression in the area that has been irradiated.

The trial is led by Marcel Verheij, of the Department

of Radiation Oncology at the Netherlands Cancer Institute in Amsterdam, the company said.

Verheij was the lead investigator in a prior phase I trial with perifosine in combination with radiotherapy, the company said. Data demonstrated a total of 21 radiotherapy-naive patients, of whom 17 had advanced non-small cell lung cancer (one stage IIIA, 15 stage IIIB, one stage IV) and 14 had become refractory to prior chemotherapy, received oral perifosine doses ranging from 50 mg to 200 mg/day concurrently with standard doses of radiotherapy.

The data demonstrated acceptable safety and tolerability, with 150 mg/day established as the dose recommended for use in subsequent clinical trials; dose limiting toxicity (nausea/vomiting) at 200 mg/day; no bone marrow toxicity; and preliminary evidence of anti-tumor activity at all dosage levels, including complete or partial responses (complete disappearance and decreased tumor size, respectively), or stable disease, with a median follow-up for responders of 8 months, the company said.

In the cohort of 10 patients who were treated with 150 mg/day, there were three complete responses (two NSCLC and one esophageal cancer), three partial responses (two NSCLC and one prostate cancer), and four with stable disease, the company said. Also, a patient with bladder cancer who received 50 mg/day perifosine had a long-lasting complete response.

About 350 patients have been treated with perifosine at various doses and schedules. No dose-limiting toxicity, other than gastro-intestinal toxicity, has been observed, the company said. Perifosine has demonstrated single agent anti-tumor activity in phase I and phase II studies, the company said.

The agent was in a phase II program funded by NCI in collaboration with the AEterna Zentaris North American partner, Keryx Biopharmaceuticals (NASDAQ:KERX). Findings suggested that the agent in monotherapy could be further investigated in soft tissue sarcoma, melanoma, breast, prostate and non-small cell lung cancer, while the company was advised not to pursue studies with the treatment in monotherapy in head and neck and pancreatic cancer.

Keryx said it has begun a large phase II trial program with perifosine. In combination therapy, studies have been or will soon be initiated with agents such as Gemcitabine (pancreatic cancer), Paclitaxel/Taxol, Docetaxel/Taxotere, as well as with biologic agents such as Herceptin in breast cancer, the company said.

* * *

Avalon Pharmaceuticals Inc. (NASDAQ and ArcaEx: AVRX) of Germantown, Md., said an IND submission for AVN944 has been activated by FDA that permits a phase I trial for advanced hematological malignancies to go forward.

AVN944, an oral, small molecule inhibitor of the enzyme inosine monophosphate dehydrogenase, inhibits cell proliferation by denying dividing cells of the GTP necessary for synthesis of DNA and RNA, the company said.

The agent was in-licensed by Avalon from Vertex Pharmaceuticals Inc. this year, the company said. Vertex conducted a phase I trial in the U.K. in normal human volunteers where AVN944 was shown to be orally bioavailable and well-tolerated.

* * *

BioCryst Pharmaceuticals Inc. (NASDAQ: BCRX) of Birmingham, Ala., said it has filed a special protocol assessment with FDA for the design of a proposed registration trial of Fodosine (forodesine hydrochloride).

The trial would evaluate the efficacy and safety of Fodosine for relapsed or refractory T-cell leukemia, the company said.

The drug is a transition-state analog inhibitor of the target enzyme purine nucleoside phosphorylase and is in a phase IIa trial for T-cell leukemia and a combination IV and oral phase I pharmacokinetic trial in healthy volunteers, the company said. Fodosine also is being studied in a phase I trial with an oral formulation in cutaneous T-cell lymphoma and a phase II trial in chronic lymphocytic leukemia. BioCryst said it would initiate a phase I/II trial in B-cell acute lymphoblastic leukemia during 2005.

The treatment has been granted Orphan Drug status for three indications: T-cell non-Hodgkin's lymphoma, including CL; CLL and related leukemias including T-cell prolymphocytic leukemia, adult T-cell leukemia, and hairy cell leukemia; and for acute lymphoblastic leukemia, the company said.

The companies said they entered into a research collaboration in 2004 to advance two of the Array proprietary oncology programs into clinical development. In 2005, the agreement was expanded to include an additional oncology protein target.

* * *

ChemGenex Pharmaceuticals Ltd. (NASDAQ: CXSP) of Melbourne, Australia, said it has begun a phase II study for Ceflatonin (sHHT) for accelerated-phase chronic myeloid leukemia where there is resistance to Gleevec, the first line therapy.

"The trial builds on very positive results from

our recent phase I/II studies with sHHT in CML with resistance to Gleevec," said Greg Collier, CEO of ChemGenex. "In one trial 78 percent treated with sHHT had disease status down-graded from accelerated phase to chronic phase. In addition 67 percent showed a complete hematologic response and a return of white blood cell counts to normal."

The new study is designed so it can be expanded into a phase II/III study by increasing enrollment and adding chronic phase and blast phase cohorts, the company said.

"We have been granted an orphan drug designation for sHHT in Europe for CML," said Collier.

The phase II trial will be an open-label, six center study in France and the U.K. for accelerated-phase CML resistant to Gleevec, the company said. In the remission induction phase, 1.25 mg/m^2 sHHT will be administered by subcutaneous injection two times a day for 14 days, every 4 weeks, the company said. In the remission maintenance phase, 1.25 mg/m^2 sHHT will be administered by subcutaneous injection two times a day for 7 days, every 4 weeks.

The Simon Two-Stage study design will enroll 13 in stage I and then if sufficient efficacy is observed enroll another 14-50 in stage II for a total of up to 63, the company said. The primary and secondary endpoints are hematologic and cytogenetic response rates, respectively.

* * *

Idera Pharmaceuticals Inc. (AMEX:IDP) of Cambridge, Mass., said it submitted a protocol amendment to FDA for its ongoing phase II trial of HYB2055 for metastatic or recurrent clear cell renal carcinoma.

The submission was made in response to a higher than expected enrollment rate of treatment-naive patients in the phase II trial, the company said. The amendment provides for enrollment of up to 23 treatment-naive patients at each of the two dose levels being used, in addition to the 23 second- line patients per dose level described in the original study design.

HYB2055, also known as IMO-2055 or IMOxin, is the Idera Toll-like Receptor 9, TLR9, agonist for cancer and is based on its proprietary Immune Modulatory Oligonucleotide technology, the company said.

Toll-like Receptors are immune system receptors that recognize elements of pathogens such as bacteria and trigger a defensive immune response, the company said. The Idera IMO compounds mimic bacterial DNA and are specifically identified by TLR9. When TLR9 is activated, it stimulates a response that involves multiple immune system components acting to fight disease through both innate and adaptive immunity, the company said.

* * *

Kosan Biosciences (NASDAQ:KOSN) of Hayward, Calif., said it has discontinued its phase II trial of KOS-862 in hormone refractory prostate cancer.

Although clinical activity was observed, the interim analysis of the data revealed that KOS-862 did not meet the trial endpoint for the number responses to therapy, as measured by change in a tumor marker PSA levels, the company said.

The phase II monotherapy breast cancer trial continues enrollment, the company said. The phase Ib portion of the KOS-862 plus Herceptin trial has completed enrollment, with the phase II component expected to initiate enrollment this quarter.

"We are collaborating with Kosan on the assessment of KOS-862 for breast cancer, as well as KOS-1584, another epothilone compound currently in phase I testing," said Peter Hug, global head of Pharma Partnering at Roche.

The KOS-202 trial was conducted in advanced hormone refractory prostate cancer where progression was seen on docetaxel-based therapy for metastatic disease, the company said. KOS-862 was administered as single-agent therapy, with PSA response assessed every 4 weeks. Based on the data from the interim analysis, the toxicity profile in the KOS-202 trial was not dissimilar to the profile observed in the phase II trial of KOS-862 in non-small cell lung cancer, the company said. However, there was a higher incidence of adverse events resulting in patient withdrawal in the prostate cancer trial.

KOS-862 is a polyketide that uses the same mechanism as taxanes. Preclinical models have shown the agent to be effective against taxane-resistant tumors, the company said. Roche and Kosan also are evaluating KOS-862 in three phase Ib combination studies with Gemzar, Paraplatin and Herceptin.

* * *

Peregrine Pharmaceuticals Inc. (NASDAQ: PPHM) of Tustin, Calif., said M. D. Anderson Cancer Center has begun enrollment in a phase I trial of Tarvacin Anti-Cancer.

The trial would assess the safety and tolerability and study the pharmacokinetics of the agent for advanced solid tumor malignancies where failure to prior treatment has occurred, the company said.

Tarvacin Anti-Cancer is a monoclonal antibody that binds to phospholipids, a component of the cell

structure on the surface of tumor blood vessel cells, the company said. Once bound, the drug alerts the immune system to attack the tumor and its blood supply, while minimizing effects on non-targeted healthy cells.

The trial is underway at two cancer centers in Arizona and one in California, the company said.

Nuhad Ibrahim, associate professor of medicine at M.D. Anderson, is principal investigator of the study.

* * *

Xanthus Life Sciences of Cambridge, Mass., said it has begun a phase II study of Xanafid, amonafide malate, in combination with cytosine arabinoside, ara-C, for secondary acute myeloid leukemia (with antecedent myelodysplastic syndrome or prior exposure to leukemogenic therapy).

"We are encouraged by the 46-percent response rate achieved in the phase I trial of amonafide and ara-C for AML, together with the acceptable safety profile, given that the vast majority of enrollees in this phase 2 trial are likely to be elderly, with high-risk AML," said Robert Capizzi, chief medical officer at Xanthus.

The 60-patient study will administer a daily dose of Xanafide for five days in combination with a standard dose of ara-C as a continuous infusion for seven days. The primary endpoint is complete remission, and secondary endpoints include duration of remission and overall survival.

Xanafide, mamonafide malate, is an ATP-independent topoisomerase 2 inhibitor. In a phase I study, amonafide and ara-C for poor-risk AML demonstrated a clinical response rate of 46 percent (12/26), with 38 percent (10/26) achieving complete remission and two patients achieving near-complete remission, the company said. The median duration of remission was five months, with two patients remaining disease-free for over two years and over five years following post remission therapy.

Deals & Collaborations:

Genzyme Licenses Rights From UCLA To Develop Test

Genzyme Corp. (NASDAQ:GENZ) of Cambridge, Mass., said it has entered into a license agreement with the **Jonsson Cancer Center, University of California, Los Angeles,** for exclusive, worldwide diagnostic rights to its discovery of gene mutations that are drug resistant to Gleevec for chronic myeloid leukemia.

The license would allow Genzyme to develop and market a diagnostic test to detect secondary BCR-ABL mutations and monitor resistance in CML patients prior to, and during, treatment with Gleevec, the company said.

* * *

Access Pharmaceuticals Inc., (AMEX:AKC) of Dallas said today announced it has restructured itself to focus on oncology therapeutics and has sold its oral care business to **Uluru Inc**., of Delaware for up to $20.6 million.

Access said it sold its interest in Aphthasol, all OraDisc products, and all Residerm products. In addition, Uluru has licensed the Access nanoparticle hydrogel aggregate technology.

Access said it received $8.7 million at the closing of the agreement and could receive up to $3.7 million within twelve months after closing, and would receive an additional $1 million within 24 months after closing. Additional payments of up to $7 million will be made upon the achievement of certain milestones, the company said.

The company said it would continue development of its cytotoxic oncology product AP5346 with a phase II trial.

* * *

Array BioPharma (NASDAQ:ARRY) of Boulder, Colo., said it has extended and expanded its collaboration with **Genentech Inc.** (NYSE:DNA) for the discovery of targeted small molecule drugs for cancer.

Under the expanded agreement, Genentech would provide $50 million in research funding to access the Array Drug Discovery Platform over the next three years, the company said. Array would receive milestone payments based on the selection and progression of clinical drug candidates, as well as royalties on net sales of any products, the company said. Genentech would have sole

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CRYO-CELL International Inc. of Oldsmar, Calif., said it signed an exclusive strategic relationship agreement with **Plureon Corp.** Winston-Salem, N.C, to provide collection and preservation of the Plureon proprietary stem cells.

Under the agreement, CRYO-CELL said it would develop the proprietary methodology to collect, process and cryogenically preserve PSCs collected from placental tissue at the time of birth, the company said. The agreement establishes exclusive license rights for CRYO-CELL to market the service in the U.S., and first-rights-of-refusal for other global markets.

The exclusive worldwide rights to the PSCs, discovered in the Laboratory for Cell Therapy and Tissue

Engineering at Children's Hospital Boston, a Harvard Medical School teaching affiliate, were acquired by Plureon. The patent applications pertain for both collection/banking as well as therapeutic development, the company said.

* * *

Dendritic Nanotechnologies of Mount Pleasant, Mich., said it has entered into a characterization collaboration with NCI's **Nanotechnology Characterization Laboratory**.

The agreement with NCL will focus on the characterization by NCL of the DNT Starburst dendrimers as macromolecular dendrimer-based MRI contrast agents for sensitive, non-invasive cardiovascular diagnostics, the company said.

The Starburst and Priostar dendrimers are biopharmaceutical nanotechnology platforms that deliver a drug or contrast agent to a specific location, the company said. The DNT dendrimers will be subjected to an assay cascade of physical characterization, in vitro studies, and in vivo ADME/Tox protocols to determine their absorption, distribution, metabolism, excretion, and toxicity. The platform is also a targeted diagnostic and therapeutic drug delivery system to cancer cells, the company said.

The Nanotechnology Characterization Laboratory performs and standardizes the pre-clinical characterization of nanomaterials for cancer therapeutics and diagnostics developed by researchers from academia, government, and industry.

* * *

Genaissance Pharmaceuticals Inc. (NASDAQ: GNSC) of New Haven said it has entered into a pharmacogenomic research collaboration with **Otsuka Pharmaceutical Co**., Ltd., of Tokyo.

Under the agreement, Genaissance would apply its HAP Technology to identify genetic markers related to drug response, the company said. Genaissance and Otsuka would co-own the intellectual property resulting from the collaboration and both could receive royalties on revenues generated from diagnostic products.

* * *

Light Sciences Corp. of Seattle said it has entered into a $35 agreement with **Visient Therapeutics**, a venture syndicate owned by **Essex Woodlands Health Ventures,** for $35 million.

LSC would retain full ownership in Visient Therapeutics, and would also retain rights to develop Light Infusion Technology in other therapeutic areas.

LSC and its affiliated entities use Litx, a proprietary combination product containing a photo-reactive agent activated by non-coherent light infusion devices, for difficult-to-treat and life-threatening conditions, the company said.

Light Infusion Technology, or Litx, is a proprietary combination product containing a photo-reactive agent, LS11, activated by non-coherent light infusion devices, the company said.

* * *

MedImmune Inc. (NASDAQ:MEDI) of Gaithersburg, Md., said it has entered into a licensing and collaboration agreement with **Avidia Inc**. of Mountain View, Calif., to expand its oncology pipeline with products targeting cMET, a receptor tyrosine kinase.

The collaboration also calls for the development of two additional targets using the Avidia Avimer technology, the company said. Avimers are stable proteins that can act like antibodies and bind selectively to different receptors or ligands.

"Due to their size and potential versatility, the Avidia Avimers may provide advantages over monoclonal antibodies for the treatment or prevention of disease, said Peter Kiener, senior vice president, research at MedImmune.

Under the contract, MedImmune would be responsible for clinical development and commercialization of products; Avidia would provide research and development support and receive an upfront fee, development and regulatory milestone payments, as well as royalties, the company said.

Over-expression of cMET and its ligand, hepatocyte growth factor, associated with tumor growth, survival and metastasis, has been observed in head and neck, non-small cell lung, ovarian, breast, esophageal and colorectal cancers, the company said. Preclinical research has also linked high levels of cMET to shorter overall survival times based on samples in breast and esophageal cancers.

* * *

Monogram Biosciences Inc. (NASDAQ:MGRM) of South San Francisco said it has entered into an agreement with **Merck KgaA** (Xetra: Merck KGaA) of Darmstadt, Germany, for a cancer biomarker study with application to Erbitux, cetuximab, the Merck KGaA's IgG1 monoclonal antibody that targets the epidermal growth factor receptor.

Monogram said it would utilize its proprietary eTag assays to test formalin-fixed, paraffin-embedded tumor samples of colorectal cancer before treatment to identify individuals who would benefit most. The biomarkers represent activated, functioning targets

for the drug and control signal transduction pathways involved in tumor cell proliferation, survival and angiogenesis. The companies would then compare the predictions of response based upon eTag assay analysis with actual clinical outcomes, Monogram said.

Merck KGaA would make payments to Monogram for the project, the company said.

* * *

OncoGenex Technologies Inc. of Vancouver said it is collaborating with **Isis Pharmaceuticals Inc.** (NASDAQ:ISIS) on the third of four phase II trials of OGX-011, for hormone refractory prostate cancer.

The drug is a second-generation antisense that inhibits the production of clusterin, a cell-survival protein associated with resistance to standard treatments, the company said.

The open-label, randomized, non-blinded trial is being coordinated by the NCI of Canada Clinical Trials Group. It plans to accrue 80 patients, the company said. The OGX-011 arm of the study will receive the agent once per week and will also receive daily prednisone and docetaxel once every three weeks. The standard arm will receive daily prednisone and docetaxel once every three weeks, the company said. The study will evaluate the effect of OGX-011 and docetaxel on PSA, duration of response, serum clusterin levels and overall survival.

K. N. Chi, medical oncologist at British Columbia Cancer Agency, is the study chairman, the company said.

* * *

SeraCare Life Sciences Inc. (NASDAQ:SRLS) of Oceanside, Calif., said it has been awarded an expanded five-year $14,102,584 contract (#HHSN261200655000C) from NCI to provide laboratory support to NCI for the processing and storage of biomedical specimens of persons at high risk for cancer.

SeraCare would act as a repository for 2.9 million biological specimens and would perform the associated testing, services and clinical sample processing, the company said.

Product Approvals & Applications:

FDA Grants Orphan Drug Status For Amplimexon

AmpliMed of Tucson, Ariz., said Amplimexon, imexon inj., has been granted FDA Orphan Drug designation for ovarian cancer.

Pre-clinical studies indicate the drug is effective at killing ovarian cancer and has been shown to act synergistically with other drugs, such as taxotere and platinum-containing anti-cancer drugs, the company said.

The treatment has Orphan Drug designation for metastatic malignant melanoma, multiple myeloma and pancreatic cancer, and is completing a phase I dose-escalation study to establish safety and tolerability, phase I/II clinical studies in combination with gemcitabine for pancreatic cancer, and in combination with dacarbazine for metastatic melanoma, the company said.

Amplimexon is an injectable formulation of a cyanoaziridine compound, the company said.

* * *

Baxter Healthcare Corp. (NYSE:BAX). of Deerfield, Ill., said FDA has seized 6,000 Baxter-owned Colleague Volumetric Infusion Pumps and 850 Syndeco PCA Syringe Pumps at two facilities pending corrective actions.

Baxter said it had placed a voluntary hold on shipments of both pumps earlier this year.

The action affects Baxter-owned inventory, and does not affect customer-owned pumps being serviced by Baxter, the company said.

The company said it has developed an aggressive corrective action plan and remains in discussions with FDA.

There are 250,000 Colleague infusion pumps, including more than 200,000 in the U.S and 5,000 Syndeco pumps in use worldwide, the company said.

* * *

BioGenex Laboratories Inc. of San Ramon, Calif., said it has received FDA pre-market approval for InSite HER-2/neu, CB11, Monoclonal Antibody, which tests individuals eligible for Herceptin (Trastuzumab) treatment.

The test is a ready-to-use reagent, in manual and automated formats, and is allowed for use with BioGenex Super Sensitive Detection Systems, the company said. The automated format is approved for use on the BioGenex i6000 Automated Staining System and the Optimax Plus Consolidated Staining System. Both manual and automated versions of InSite HER-2/neu Monoclonal Antibody will be marketed worldwide.

* * *

Biogen Idec said FDA has approved a labeling supplement for the Zevalin, Ibritumomab tiuxetan, therapeutic regimen and also has approved the upgrading to the product safety information.

The product boxed warning will now include information stating that severe cutaneous and mucocutaneous reactions, some with fatal outcome, have been reported, the company said. The reactions

are rare, and in the three and a half years since Zevalin has been approved, have occurred in a limited number of patients, the company said.

* * *

Elekta Group of Atlanta said its Synergy Platform and X-ray Volume Imaging has received regulatory approval by Health Canada for cancer treatment.

The IGRT solution, known as Elekta Synergy, is a digital linear accelerator used in oncology centers, the company said. Synergy is used in conjunction with X-ray Volume Imaging to realize the image quality and soft tissue detail.

* * *

Pfizer Inc. of New York said it has received approval from FDA to market Aromasin, exemestane tablets, for adjuvant treatment of postmenopausal women with estrogen-receptor positive early breast cancer following two-to-three years of tamoxifen for a completion of five consecutive years of adjuvant hormonal therapy.

The approval was based on the Intergroup Exemestane Study, which showed that a switch to the drug after two to three years of tamoxifen, for a combined total of five years of therapy, had 31 percent more protection from cancer recurrence than remaining on five years of tamoxifen therapy, the company said.

The American Society of Clinical Oncology and the National Comprehensive Cancer Network updated their guidelines to support the use of a new switch regimen using Aromasin adjuvant treatment.

* * *

Telik Inc. (NASDAQ:TELK) of Palo Alto, Calif., said it has received permission from FDA to proceed under an IND application for an oral formulation of Telintra in myelodysplastic syndrome, which is in addition to the ongoing clinical trial using the parenteral formulation of Telintra.

The agent, a small molecule, demonstrated myelorestorative activity in preclinical data when administered orally or by infusion, the company said. It was discovered using the Telik proprietary TRAP small molecule drug discovery technology.

* * *

Viventia Biotech Inc. (TSX:VBI) of Toronto said it has received clearance from Health Canada to initiate a phase II study evaluating Proxinium for chemotherapy-refractory recurrent head and neck cancer.

Viventia said it also had been cleared by U.S. FDA to begin a phase II trial of the drug for the same indication. The trial would begin be the end of this year.

Proxinium combines a cytotoxic protein payload with the tumor-targeting characteristics of a monoclonal antibody, the company said. The antibody fragment of Proxinium targets EpCAM, an antigen expressed on head and neck cancer.

* * *

Vion Pharmaceuticals Inc. (NASDAQ:VION) of New Haven, Conn., said it has received Fast-Track designation from FDA for Cloretazine, an anti cancer agent, for poor-risk acute myelogenous leukemia induction for those over 60 years of age.

"Based on our phase II data in this indication, Cloretazine has potential for the treatment of this unmet medical need," said Alan Kessman, CEO of Vion.

Oncology Management:

OTN Begins Pilot Program For Oncology Managed Care

(Continued from page 1)

Board. "Ultimately, information like this will help improve consistency of treatment and outcomes."

The registry is guided by an advisory board chaired by Ang that includes: Walter Curran, Thomas Jefferson University Hospital; Paul Harari, University of Wisconsin, Madison; Barbara Murphy, Vanderbilt-Ingram Cancer Center; Stuart Wong, Medical College of Wisconsin; and Amy Chen, Emory University, the company said.

The program is supported by ImClone Systems and implemented by MedNet Solutions Inc. of Minnetonka, Minn.

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Oncology Therapeutics Network of South San Francisco said it has begun a managed care pilot program with its customers and six regional managed care companies.

The program would improve affordable quality care and strengthen relationships between community-based oncologists and health plans, the company said.

Providers and payers will work to gather to review and analyze baseline treatment data, the company said. Payer participants will include six participating health plans with 7 million members across five states selected to represent regions including Florida and California.

"By bringing together oncologists and managed care companies, we hope to help payers better understand and standardize high-quality cancer care in the community oncology setting, which will lead to improved, more cost-effective care," said Mark Jolly, vice president of managed care for OTN.