THE CANCER LETTER INTERACTIVE

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NIH Deputy Director Ruth Kirschstein Plans Transition To Senior Advisor Role

In a move that took most of the NIH by surprise, Deputy Director Ruth Kirschstein last week announced she will step down from the position she has held since 1993.

Kirschstein, a 44-year veteran of NIH who served for about three years in two stints as acting NIH director, will remain as a senior advisor to NIH Director Elias Zerhouni after her successor is chosen, she said.

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In Brief:

Iowa's Holden Center, Mayo Clinic, Hopkins Win SPOREs For Lymphoma Research

HOLDEN COMPREHENSIVE CANCER CENTER at the University of Iowa, in collaboration with the **Mayo Clinic Cancer Center**, has received a Specialized Programs of Research Excellence grant from NCI for lymphoma research. The grant, under the direction of **George Weiner**, director of the Holden center, and **Thomas Witzig**, of Mayo Clinic, will provide more than $2 million per year to both Holden and Mayo over a five-year period for five projects developing new approaches to lymphoma therapy. "The collaboration with Mayo Clinic on the SPORE grant was established because we had complementary strengths," Weiner said. "Mayo has particular expertise in the storing and evaluation of lymphoma tissue samples. The University of Iowa has a track record of using research laboratory advances to develop new treatments for cancers, including lymphoma." . . . **JOHNS HOPKINS UNIVERISTY** Department of Oncology has received an NCI SPORE award for lymphoma research. Principal investigator **Richard Ambinder** will lead four research projects, four cores, and a career development and developmental research program for translational research in lymphoma. List of projects in the Hopkins and Holden SPOREs are available at http://spores.nci.nih.gov/lymphoma/lymphoma.html. . . . **NCI** and the **Avon Foundation** partnership, the Avon-NCI Progress for Patients Awards Program, has presented grants totaling $2.5 million to 10 institutions. Funding will support early clinical research in breast cancer. The program began in October 2001 when NCI received a $20 million pledge from the Avon Foundation to fund translational research on breast cancer. The initial Avon-NCI Progress for Patients grant awards are as follows: University of Alabama, $197,736; Baylor College of Medicine (lead),

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NIH Director Zerhouni To Form "His Own Team"—Kirschstein

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A search committee to select a deputy director will be headed by Stephen Katz, director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Kirschstein said the decision was reached in discussion with Zerhouni, and did not stem from any disagreement over policy.

"It was a mutual decision," she said this week to **The Cancer Letter**. "We are very pleased that he is going to assemble his own team."

Kirschstein said she will remain an active participant on that team, continuing to work full-time as a senior advisor. Asked whether she plans to retire, Kirschstein said emphatically, "No."

Kirschstein received a standing ovation from institute directors at a Sept. 26 meeting where she and Zerhouni made the announcement, NIH sources said. Zerhouni told the directors he had worked well with Kirschstein and praised her highly, sources said.

Kirschstein apparently enjoyed her role as deputy director, but may have clashed with Zerhouni over matters of style more than substance, sources said. Kirschstein and Zerhouni have publicly expressed similar views on issues such as stem cell research.

Sources said Zerhouni plans to make the director's office more active and involved in the somewhat autonomous Institutes and centers.

Kirschstein served as acting NIH director for two years and five months between the departure of Harold Varmus in December 1999 and Zerhouni's appointment last May. She also was acting director from July to November 1993 after Bernadine Healy's departure. From 1974 to 1993, she was director of the National Institute of General Medical Sciences.

As NIH deputy director and acting director, Kirschstein was known for her strong working relationships with political appointees and staff in the Department of Health and Human Services. Known collectively at NIH as "downtown," these people in the Humphrey Building on Capitol Hill have the power to make things difficult for NIH. Kirschstein's role has been to act as liaison and listen, explain, and justify as needed.

In her major speeches and commencement addresses as acting director, a common theme was the importance of funding for clinical research at the academic medical centers.

Kirschstein began working at NIH in 1956 as a medical officer in clinical pathology. From 1957 to 1972, she was with the Division of Biologics Standards, which became the FDA Center for Biologics Evaluation and Research. She helped develop and refine tests to assure the safety of viral vaccines for polio, measles, and rubella. Her research led to the selection of the Sabin vaccine for polio. She was appointed deputy director of the division and later was FDA deputy associate commissioner for science.

She returned to NIH in 1974 as NIGMS director, and also was the first director of the NIH Office for Research on Women's Health, from 1990-91. Kirschstein also is credited with strong support for career development and training for women scientists and physicians.

Kirschstein received a BA magna cum laude from Long Island University in 1947 and an MD from Tulane University Medical School in 1951. She interned in medicine and surgery at Kings County Hospital, Brooklyn, and did residencies in pathology at Providence Hospital, Detroit; Tulane University School of Medicine; and the Warren G. Magnuson Clinical Center, NIH.

In 2000, Kirschstein received the Albert B. Sabin Heroes of Science Award from the Americans for Medical Progress Education Foundation. She has received many other awards and honors.

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Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016
E-mail: news@cancerletter.com

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
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NCI Programs:

Porter Novelli Wins Contract For 5 A Day Communications

NCI has selected the Washington, DC, office of Porter Novelli to coordinate the communications campaign for its 5 A Day for Better Health Program.

The Institute has more than doubled the funding for 5 A Day communications to $7.4 million over three years, inclusive of option years, to address health disparities, allocating a sizeable portion of the first year's budget to reach African Americans with the 5 A Day message to increase fruit and vegetable consumption to reduce risk of chronic diseases.

The program began in 1991 as a general public education effort. Porter Novelli worked with NCI from the 1991 launch of program through 2000.

The firm's Public Strategies and Outreach group within its Public Affairs practice will figure prominently into the campaign's initial focus on reaching African Americans, particularly men.

"We will find creative ways to bring the 5 A Day message to African Americans, a demographic group that suffers disproportionately from chronic diseases, in part, because of their poor eating habits," said Michael Frisby, director of public strategies and outreach and senior vice president at Porter Novelli Washington. "Our relationships with African American civic, political and community leaders across the nation will help forge partnerships that will shape our outreach program, and save lives."

The 5 A Day program is sponsored by NCI and the Produce for Better Health Foundation, a nonprofit consumer education foundation representing the fruit and vegetable industry. The goal of the program is to increase the consumption of fruits and vegetables in the U.S. to five to nine servings daily.

The program also seeks to inform Americans that eating fruits and vegetables can improve their health and reduce the risk of certain types of cancer, including heart disease, hypertension, diabetes and other diseases.

NCI provides leadership for the program through the implementation of a national media campaign, coordination of national partnership efforts and activities, and funding of nutrition behavior change research.

Porter Novelli is one of the world's 10 largest public relations firms. The firm is a wholly-owned subsidiary of Omnicom Group Inc., a global marketing and corporate communications company.

Hutchinson Center Wins Prostate Cancer SPORE

NCI has awarded $12.7 million to the Fred Hutchinson Cancer Research Center to lead a multi-center, five-year investigation into the genetic mechanisms of prostate-cancer progression.

Known as the Pacific Northwest Prostate Cancer Research SPORE (Specialized Program of Research Excellence), the initiative will involve more than 50 investigators in Seattle and Vancouver, BC.

Participating institutions in Seattle are Fred Hutchinson, the University of Washington and the Institute for Systems Biology. Vancouver partners are the University of British Columbia and its affiliate, The Prostate Centre at Vancouver General Hospital.

The strong history of collaboration among these institutions—themselves all major contributors to prostate-cancer research—was key to winning the grant, said principal investigator Paul Lange, professor and chairman of urology at the UW School of Medicine and an affiliate investigator in Fred Hutchinson's Public Health Sciences Division.

"This highly competitive award exemplifies the high caliber of prostate- cancer research among the major medical-research institutions in the Pacific Northwest and the significant ongoing collaborations among researchers from each of the participating institutions," Lange said.

During the past decade, for example, a working group of Seattle prostate- cancer investigators has met regularly to collaborate on projects focused on understanding the hereditary and lifestyle factors behind prostate cancer and developing innovative technologies to unravel the genetic mechanisms of the disease. Fruits of their labor include mapping the region of a gene associated with inherited prostate cancer and primary brain cancer, as well as better understanding the genes expressed in the more common forms of prostate cancer.

"The close relationship between these institutions and our long-standing track record of success was crucial to getting the grant," said co-principal investigator Janet Stanford, a member of Fred Hutchinson's Public Health Sciences Division and director of its Prostate Cancer Research Program.

The Pacific Northwest Prostate Cancer SPORE grant follows closely on the heels of another major prostate-cancer research coup for the Seattle researchers; in July, the University of Washington was

awarded $10.5 million from NIH to lead a multi-center, five-year investigation into the basic causes of why prostate cancer metastasizes, or spreads, to the bone. Participating institutions in this effort are Fred Hutchinson and the Institute for Systems Biology, co-founded by former UW geneticist Leroy Hood.

The goal of the consortium is to bring laboratory discoveries to patient bedsides throughout the Pacific Northwest. A variety of clinical partners will recruit and enroll patients for research studies to test the therapies that emerge. They will include the Seattle Cancer Care Alliance (the oncology patient-care arm of Fred Hutchinson, UW Academic Medical Center and Children's Hospital and Regional Medical Center) and the Veterans Affairs Puget Sound Health Care System in Seattle; the Oregon Cancer Institute/ Oregon Health & Science University in Portland; and Vancouver General Hospital/University of British Columbia in Vancouver.

The SPORE will support four main projects:

Project 1: Identifying genetic variants linked to prostate-cancer progression and mortality—This study aims to identify genetic variants that are linked to prostate-cancer recurrence and mortality with the goal of developing a simple blood test to determine which prostate-cancer patients are most likely to progress to advanced disease. The researchers will follow more than 700 Seattle-area men, all of whom were diagnosed with prostate cancer before age 65, to see if those who relapse share common genetic markers of disease progression. Project leaders: Janet Stanford, member, Fred Hutchinson Public Health Sciences Division; and David Penson, assistant professor of surgery, UW School of Medicine.

Project 2: Understanding the genetic differences between men who relapse and men who remain cancer-free after initial therapy for localized prostate cancer—Previous studies have found that many men with early-stage prostate cancer, even those who are cured with localized therapy such as surgery or radiation, in fact have prostate-cancer cells in their blood and bone marrow very early in the disease process. It is not known why some of these circulating cells turn into deadly metastatic cancer while others die or remain dormant. This study will examine blood samples from men who undergo surgery for early-stage prostate cancer to try and determine the genetic differences between those who remain cancer free and those whose cancer recurs. The ultimate goal would be to develop a genetic screening tool to identify which men are most likely to relapse and may benefit from more aggressive therapy upon initial diagnosis. Project leaders: Robert Vessella, professor and associate chair of urology; William Ellis, assistant professor of urology, both of the UW School of Medicine; and Barbara Trask, member and director, Fred Hutchinson Human Biology Division.

Project 3: Developing new treatments for men with advanced prostate cancer who no longer respond to androgen-deprivation therapy—The goal of this project is to develop new treatments for men with advanced prostate cancer who no longer respond to androgen-deprivation therapy. The idea is to harness antisense technology, which inhibits gene expression, to coax hormone-insensitive prostate-cancer cells to commit suicide. Such antisense drugs, when combined with novel chemotherapeutic agents or combinations of existing drugs, also may block the cellular processes that allow cancer to grow. Project leaders: Martin Gleave, professor of surgery and director of clinical research; and Colleen Nelson, assistant professor of surgery and head of the Gene Array Facility, both of the University of British Columbia/The Prostate Centre at Vancouver General Hospital.

Project 4: Understanding the molecular biology of prostate cancer throughout all stages of its progression—This project will analyze gene and protein expression in the entire spectrum of prostate tumors, from those that are clinically localized and slow-growing to those that are advanced and highly aggressive. The goal is to create a genetic blueprint to help understand the molecular biology of prostate cancer at all stages of its progression. A particular focus will be to understand the mechanisms that cause tumors to progress from being androgen-dependent and treatable to androgen-independent and drug-resistant. Deciphering the molecular pathways that allow disease progression could help identify new drug targets and new genes that are linked to tumor metastasis. Project leaders: Leroy Hood, co-founder and president, Institute for Systems Biology, and UW affiliate professor of bioengineering, immunology, and computer science and engineering; and Peter Nelson, assistant member, Fred Hutchinson Human Biology and Clinical Research divisions and assistant professor of medicine and biotechnology at the UW School of Medicine.

These projects will be supported by an infrastructure of SPORE-funded research cores that will provide resources and expertise in a variety of areas: administration, bioinformatics, biostatistics,

specimen collection and tissue banking, and clinical-trial design, recruitment and management.

The grant also will fund up to four pilot projects each year. Research proposals will be solicited from investigators within the four participating institutions.

NIH News:

Grants Awarded To Combat Tobacco In Developing World

The Fogarty International Center at NIH and eight partners have awarded 14 new research and training grants to combat the growing incidence of tobacco-caused illnesses and death in the developing world.

FIC led the development of the International Tobacco and Health Research and Capacity Building Program in collaboration with five NIH institutes, the Centers for Disease Control and Prevention, the Canadian Institutes of Health Research, and the World Health Organization's Tobacco Free Initiative. The combined financial commitment from FIC, its NIH partners, and CDC is about $3.8 million for the first year of these five-year awards. Total support will be approximately $20.5 million over the next five years.

"Smoking represents one of the greatest challenges to health, both in the U.S. and worldwide," said HHS Secretary Tommy Thompson. "This new NIH program supports critically needed research and training to identify ways to prevent or reduce smoking rates worldwide, especially in the developing world."

According to WHO, tobacco use is the leading cause of preventable death and disability in adults globally. More than 1 billion people—about one-third of the world's adult population—smoke, making tobacco use one of the greatest global health threats. Each year about 4 million people worldwide die from diseases caused by tobacco use. If current smoking patterns persist, the number of deaths caused by tobacco use is expected to reach 10 million annually by the 2025.

"We are launching this program to provide support for the development of scientific data necessary for decision-making about tobacco issues," said FIC Director Gerald Keusch. "As developing countries grapple with the enormous toll that tobacco will take on families and communities, and as they establish tobacco-control programs, it is essential that they have access to the best data. Our consultation with scientists from the developing world was crucial in helping us understand where the needs are most critical."

"We are delighted to see the range of approaches and the depth of expertise in these applications," said NCI Director Andrew von Eschenbach. "We expect that this new global tobacco research effort will yield results that will help us address prevention and intervention at home as well as globally."

The goals of the International Tobacco and Health Research and Capacity Building Program are to reduce the burden of tobacco consumption in low- and middle-income nations by conducting observational, interventional, and policy research of local relevance and to build capacity in epidemiological and behavioral research, prevention, treatment, communications, health services, and policy research.

Following are the grantees:

—David Brook, Mount Sinai School of Medicine, and collaborators from the Medical Research Council of South Africa.

—Linda Ferry, Loma Linda University School of Public Health, and collaborators from the National Center for Health Promotion, Cambodia; Centre of Information and Education for Health, Lao PDR; National Center for Health Development, Mongolia; and the Adventist Development Relief Agency in Cambodia, Lao PDR, and Mongolia.

—The-wei Hu, University of California, Berkeley, and collaborators from The World Bank, the Chinese Ministry of Health, Sichuan University, and Fudan University.

—Ebenezer Israel, University of Maryland School of Medicine, and colleagues in Cairo and Baltimore will work with collaborators from the Egyptian Ministry of Health and Population and Georgetown University.

—Prabhat Jha, University of Toronto, and three institutes in India: Epidemiological Research Center, National Institute of Mental Health and Neuro Sciences, and Institute of Health Sciences.

—Gary King, Pennsylvania State University, and three universities in Africa: Cape Town University, Universite Cheikh Anta Diop in Senegal, and University of Dar Es Salaam in Tanzania.

—Harry Lando, University of Minnesota, will lead a collaborative effort with the University of Arizona, the University of Missouri, Acutha Menon Centre for Health Sciences in India, and the Gadjah Mada University in Indonesia.

—Deborah Ossip-Klein, University of Rochester, and collaborators from the Dominican Republic.

—Eliseo Perez-Stable, University of California, San Francisco, and collaborators from the University of Jujuy in Argentina.

—Cheryl Perry, University of Minnesota, and collaborators in India.

—Richard Peto, of the Clinical Trial Service Unit in Oxford, UK, will collaborate with colleagues from the Chinese Academy of Preventive Medicine in China; Suez Canal University in Egypt; Epidemiological Institute, Regional Cancer Center, and Tata Institute of Fundamental Research in India; and the Russian Academy of Medical Sciences in Russia, to study death rates among two million people.

—Ken Resnicow, Emory University, will work with the Medical Research Council of South Africa, the University of Natal, and the University of Cape Town.

—Jonathon Samet, Johns Hopkins University, will collaborate with partners conducting tobacco-control research and training programs at the Chinese Academy of Medicine, the National Cancer Institute of Brazil, and the National Institute for Public Health in Mexico.

—Kenneth Ward, University of Memphis, will work with Virginia Commonwealth University and Aleppo School of Medicine in Syria.

* * *

NIH will award $6 million to 12 institutions to support the development of new research and the training of junior faculty researchers in women's health.

The program, Building Interdisciplinary Research Careers in Women's Health (BIRCWH), which began in 2000, seeks to increase the number of researchers working on women's health issues by pairing junior researchers with senior investigators working in mentored, interdisciplinary scientific settings. The Office of Research on Women's Health at NIH leads the BIRCWH initiative, which is administered by the National Institute of Child Health and Human Development.

The institutions receiving the awards in FY2002 are: Boston University, Brown University, Duke University, Magee-Women's Health Corp., University of Maryland, SUNY Downstate Medical Center, Oregon Health and Science University, University of Pennsylvania, Stanford University, Tulane University, University of Utah, and Vanderbilt University.

"The BIRCWH program offers tremendous opportunities to advance women's health research and to allow those at the beginning of their careers to gain valuable research experience and career mentoring by working with more experienced scientists in a variety of areas—basic, clinical, behavioral, health services and public health research—while approaching a scientific question from different perspectives," said ORWH Director Vivian Pinn.

In addition to ORWH, seven NIH institutes, the NIH Office of Dietary Supplements, and the Agency for Healthcare Research and Quality co-sponsor the program.

Junior faculty members, without prior research grant support, may apply to the grantee institutions to become Interdisciplinary Women's Health Research Scholars. Those selected have the opportunity to expand their research skills by being mentored in a research setting for two to five years. The mentors at each site are established investigators.

* * *

The NIH Fogarty International Center, the World Health Organization, and the World Bank have begun a three-year project to assess disease control priorities and produce science-based analyses and resource materials to inform health policymaking in developing countries.

The Disease Control Priorities Project is funded by $3.5 million grant from the Bill & Melinda Gates Foundation.

The DCPP plans to help developing countries establish health priorities and cost-effective health interventions based on careful analysis of the cost of disease burden and the cost of treatment and prevention.

"For prevention and treatment programs to work, policymakers must have access to the best possible research and analysis to ensure that their health investments save as many lives as possible," said Sally Stansfield, acting director of the Infectious Disease and Vaccines Program for the Gates Foundation. "The DCPP's work will lead to highly effective, affordable health solutions that can be emulated in countries around the world."

The information produced by DCPP will be shared through workshops, online discussions, working papers, and other publications, including the second volume of "Disease Control Priorities in Developing Countries," which will be available in print and online in 2005. The World Bank published the

first edition of "Disease Control Priorities in Developing Countries" in 1993.

* * *

A new technology that produces detailed, three-dimensional maps of nerve pathways in the brain, heart muscle fibers, and other soft tissues has been licensed by NIH.

The technology, called Diffusion Tensor Magnetic Resonance Imaging (DT-MRI) was invented by researchers now at the National Institute of Child Health and Human Development. NIH has signed an agreement with GE Medical Systems to produce and market the product.

DT-MRI produces sophisticated images of soft tissues by measuring the three-dimensional random motion of water molecules within the tissues. Brain surgeons planning tumor removal surgeries are beginning to use DT-MRI images to help them better distinguish between healthy brain tissue and tumors.

"If we could establish a strong connection between an anatomical deficit and a particular disorder, it might be possible to one day use DT-MRI as a screening tool," said Peter Basser, principal inventor of DT-MRI and chief of the NICHD Section on Tissue Biophysics and Biomimetics.

In addition to Basser, Dennis LeBihan and James Mattiello also contributed to the development of DT-MRI.

* * *

NIH awarded a contract to Chimp Haven Inc., a non-profit organization, to establish and operate a chimpanzee sanctuary to provide lifetime care for federally owned or supported chimpanzees that are no longer needed for biomedical research.

The 10-year, cost-sharing contract was awarded by the National Center for Research Resources. Over the term of the contract, NCRR will provide about $19 million in total costs, and Chimp Haven will contribute about $4 million toward direct costs.

Chimp Haven will construct the new sanctuary near Shreveport, La., on land donated by county government. Separate from the contract funding, NCRR also will award a $5 million grant to Chimp Haven to support construction costs. The construction, which is expected to be completed in Spring 2004, will initially provide housing in a free-ranging environment for about 75 chimpanzees.

A sanctuary system to provide for the lifetime care of retired research chimpanzees was mandated by The Chimpanzee Health Improvement, Maintenance, and Protection Act of December 2000.

Funding Opportunities:

RFA Available

RFA CA-03-016: Diet, DNA Methylation and Other Epigenetic Events, and Cancer Prevention

Letter of Intent Receipt Date: Feb.18, 2003

Application Receipt Date: March 18, 2003

NCI invites applications for new R01 and R21 grants on research leading to the elucidation of mechanisms by which dietary factors influence epigenetic processes as well as increasing the understanding of these processes in cancer prevention.

The approach is to encourage collaboration between nutrition and epigenetic /DNA methylation experts to study bioactive food components with cancer preventative properties, and to examine key epigenetic events in cancer processes (i.e., carcinogen metabolism, cell division, differentiation, apoptosis) so that investigators can begin to establish linkages between epigenetics, methylation pattern, and tumor incidence/behavior.

The RFA is available at http://grants1.nih.gov/grants/guide/rfa-files/RFA-CA-03-016.html.

Inquiries: Sharon Ross, Division of Cancer Prevention, NCI, 6130 Executive Blvd., Rm 3157, Bethesda, MD 20892, phone 301-594-7547; fax 301-480-3925; e-mail sr75k@nih.gov

Program Announcement

PA-02-169: Integrating Aging and Cancer Research

National Institute on Aging and NCI invite research grant applications R01s for studies that expand the knowledge base on aging- and age-related aspects of cancer in older persons. The PA is directed to researchers in the extramural scientific community at large.

The intention is to appeal to a broad-based community of investigators in cancer, aging, and other disciplines and professions, thereby underscoring the value of the creative ideas stemming from the cancer centers workshop and the urgent need to advance the knowledge base on cancer in older persons.

The PA is available at http://grants1.nih.gov/grants/guide/pa-files/PA-02-169.html.

Inquiries: Patricia McCormick, Cancer Centers Branch , NCI, 6116 Executive Blvd., Suite 700, MSC 8345, Bethesda, MD 20892-8345, phone 301-496-8531; fax 301-402-0181; e-mail pm60y@nih.gov

In Brief:

NIH Plans Hormone Therapy Workshop For Oct. 23-24

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Dana Farber-Harvard Cancer Institute, Johns Hopkins University, $391,743; Fred Hutchinson Cancer Center (lead), University of Alabama, Fox Chase Cancer Center, M. D. Anderson Cancer Center, $998,538; U. North Carolina Chapel Hill, $244,502; Duke University (lead), Dana Farber-Harvard Cancer Institute, U.C. San Francisco, U. North Carolina Chapel Hill, $447,383; Dana Farber-Harvard Cancer Institute, $230,793. Funding decisions, based on the rankings of the reviewed projects, were approved by NCI Director **Andrew von Eschenbach**. . . . **NIH WORKSHOP ON HRT**: On Oct. 23-24, NIH will hold a scientific workshop on menopausal hormone therapy in the main auditorium of the Natcher Conference Center on the NIH campus. The purpose of the workshop is to review the results from one component of the Women's Health Initiative clinical trial. "The workshop will place the results of this component of the WHI in the context of other completed and ongoing federally funded research on menopausal combination hormone therapy, along with recent considerations regarding the continuation or cessation of studies using postmenopausal combined hormone therapy," said NIH Deputy Director **Ruth Kirschstein**. Advance registration is required. For further information and registration, see http://www4.od.nih.gov/orwh. The workshop will also be webcast at http://videocast.nih.gov/. . . . **DOROTHY FOELLMER** was named acting special assistant for program coordination in the NCI Office of the Director. She has been director of the NCI Office of Policy Analysis and Response. **Susan Erickson** was named acting director of the OPAR, which works on legislative and Congressional activities. . . . **NCI's LIAISON ACTIVITIES** Branch in the Office of Communications has been moved to the Office of the Director, reporting to NCI Deputy Director **Alan Rabson**. . . . **NEW YORK** is the most recent state to take advantage of the federal Breast and Cervical Cancer Prevention and Treatment Act of 2000, which allows states to expand Medicaid coverage to women who otherwise would not have health coverage. HHS has approved the expanded Medicaid eligibility in 45 states.

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Business & Regulatory Report

Clinical Trials:

Genentech's Phase III Trial Of Avastin For Breast Cancer Failed To Meet Endpoint

Genentech Inc. (NYSE:DNA) of South San Francisco said a phase III study of Avastin (bevacizumab, rhuMAb-VEGF) for relapsed metastatic breast cancer did not meet its primary efficacy endpoint of progression-free survival.

Avastin is an investigational therapeutic antibody directed at vascular endothelial growth factor (VEGF), the company said.

The study randomized 462 women who had received treatment with both anthracycline and taxane-based chemotherapy regimens to receive

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Product Approvals & Applications:

Abbott's PathVysion Test Information To Be Mentioned In Herceptin Labeling

Abbott Labs (NYSE:ABT) of Abbott Park, IL, said FDA has approved the inclusion of information about its PathVysion fluorescence in situ hybridization gene test in labeling for Herceptin, a monoclonal antibody treatment for metastatic breast cancer.

PathVysion is a genomic disease management technology that detects HER-2/neu gene status and identifies which women are candidates for Herceptin, the company said.

"Gene amplification, as determined by FISH, provides the most accurate method for diagnosing HER-2 status, permitting those women with the molecular target for Herceptin to be most appropriately treated," said Michael Press, the Harold E. Lee Chair Professor for Cancer Research, Department of Pathology, Norris Comprehensive Cancer Center at the University of Southern California.

Determination of HER-2 gene status is a critical tool for selecting therapeutic options, because certain breast cancer treatments are more appropriate when multiple copies of the gene are found, the company said. A diagnostic test is required to identify which women have HER-2 positive disease and are candidates for treatment with Herceptin.

"Gene-based testing is a huge step toward personalized medicine that can offer the best breast cancer treatment, the first time," said Amy Langer, executive director, National Alliance of Breast Cancer Organizations.

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PO Box 9905
Washington DC 20016
Telephone 202-362-1809

Avastin Doesn't Extend Survival Of Breast Cancer

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Avastin with Xeloda (capecitabine) or Xeloda alone, the company said. One of the secondary endpoints, overall response rate, did achieve statistical significance, but did not translate into benefit in progression-free survival or 12-month survival.

The adverse event profile was similar to the observed events in phase II studies, the company said. Adverse events included venous thrombosis, hypertension and asymptomatic proteinuria, the company said. There was no increase in serious bleeding in the Avastin arm of the study, the company said.

"Given the prior phase II results with Avastin, we are disappointed in the phase III efficacy results," said Susan Hellmann, executive vice president, development and product operations, and chief medical officer at Genentech. "In view of the broad nature of our Avastin clinical program, we are encouraged by the overall safety profile observed in this study. We look forward to data from our 900-patient randomized phase III trial in colorectal cancer, the lead indication in our comprehensive clinical development program."

Data from a randomized phase II study in colorectal cancer demonstrated an increase in overall survival, time to disease progression and overall response rate with Avastin in combination with chemotherapy as compared to those treated with chemotherapy alone, the company said.

Results from the lead phase III study for colorectal cancer are expected in May 2003, the company said.

* * *

Galenica Pharmaceuticals of Birmingham said the University of Alabama at Birmingham Comprehensive Cancer Center has begun an NCI-sponsored phase I trial of a HER-2 vaccine containing the Galenica immune enhancer GPI-0100.

The trial will evaluate a HER-2 derived antigen therapeutic vaccine together with GPI-0100 in HER-2 overexpressing cancers, the company said. The antigen was derived at UAB and Ohio State University.

The company said pre-clinical studies showed that vaccination with the antigen, a synthetic peptide containing regions of the HER-2 receptor and the measles virus fusion protein, is effective in preventing breast cancer in transgenic mice overproducing HER-2. Vaccination stimulated not only blocking antibodies against HER-2, but also antibody-mediated killing of tumor cells overexpressing the HER-2 receptor, the company said.

"The development of effective and safe cancer vaccines would have a significant impact on the efficacy and cost of long-term cancer therapy," said Pierre Triozzi, associate professor of medicine at the UAB-CCC and principal investigator on the trial. "Vaccination using synthetic antigens would allow a focused immune response against the cancer cells, while avoiding the complications that may arise from the prolonged use of agents such as monoclonal antibodies."

* * *

NeoPharm Inc. (Nasdaq National Market: NEOL) of Lake Forest, IL, said enrollment has begun in the third ongoing phase I/II trial of IL13-PE38 for recurrent or progressive malignant glioma.

The trial is being conducted at six sites including University Hospital Eppendorf and University Hospital Kiel in Germany, Chaim Sheba Medical Center and Dana Hospital Tel Aviv in Israel, the Cleveland Clinic and the University of Colorado in the U.S., the company said.

IL13, an immune regulatory cytokine, is designed to detect and bind to IL13 receptors on the surface of malignant glioma cancer cells, the company said. The agent selectively delivers the bacterial

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PO Box 9905, Washington DC 20016
E-mail: paul@cancerletter.com

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724

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cytotoxic agent, PE38, derived from Pseudomonas bacterium, to destroy tumor cells while sparing healthy surrounding cells.

The drug is administered directly to the tumor through positive-pressure convection enhanced delivery that uses catheters inserted in the brain before and/or following surgical resection of the tumor to prevent recurrence of cancer cell growth.

"Premier research sites outside the U.S. have joined our cadre of centers to help expedite the world-wide development of the agent," said James Hussey, president and CEO of Neopharm. "NeoPharm has exclusively licensed IL13-PE38 from NCI and FDA, and is developing the agent under a cooperative research and development agreement with the FDA Center for Biologics Evaluation and Research."

The compound received orphan drug designation from FDA in November 2001, and from the European Community in May 2002. In addition, the IL13-PE38 development program has received FDA Fast-Track designation, the company said.

IL13-PE38 is in two other phase I/II trials for malignant glioma, the company said. The first study is being conducted through the NCI Clinical Trial Evaluation Program-funded New Approaches to Brain Tumor Therapy Consortium, the company said. Johns Hopkins University Medical Center is the coordinating site for NABTT.

A second study is being conducted through NeoPharm, and includes M.D. Andersen Cancer Center, Memorial Sloan Kettering Cancer Center, the University of California San Francisco and Yale University and participating centers. The clinical data presented to date has been promising, the company said.

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Novacea Inc. of South San Francisco said patient enrollment has begun in a phase II/III trial of DN-101, a formulation of calcitriol, in combination with Taxotere (docetaxel) for androgen-independent prostate cancer.

The ASCENT (AIPC Study of Calcitriol Enhancing Taxotere) study is a multicenter, randomized, double-blind trial of 232 AIPC patients at 20 U.S. medical centers, the company said.

The trial is supported by **Novacea Inc**., in collaboration with **Aventis**, the sponsor of Taxotere, the company said.

The primary endpoint is a reduction from baseline of 50 percent or more in prostate specific antigen with high dose pulse administration DN-101 (calcitriol) in combination with Taxotere versus Taxotere alone.

"Late stage prostate cancer patients have few treatment options, and we are cautiously hopeful that the study will further confirm and extend the promising results we've already seen with docetaxel in combination with high-dose pulse administration calcitriol," said Tomas Beer, study chair and assistant professor of medicine in the Oregon Health & Science University Cancer Institute.

In an open-label phase II AIPC study, 30 of 37 patients (81 percent) treated with high doses of commercially available calcitriol and Taxotere had a reduction of 50 percent or more in PSA, the company said. Four other open label phase II studies of Taxotere alone have reported 38 to 46 percent of AIPC patients had a reduction of 50 percent or more in PSA, the company said. Toxicity was similar to that reported for Taxotere alone.

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Protarga Inc. of King of Prussia, PA, said it has received comments from FDA that allow the company to proceed with two separate phase III trials of its cancer drug Taxoprexin Injection for the treatment of metastatic melanoma and pancreatic cancer.

The FDA determination follows Protarga's submission of phase II data from trials that treated more than 300 patients.

The first phase III study will evaluate Taxoprexinas a first-line treatment for metastatic melanoma. Approximately 560 patients are expected to be enrolled at numerous centers in the US, Europe and Australia. The study will compare survival in patients who receive Taxoprexin at a dose of 900 mg/m(2) given by intravenous infusion every three weeks to patients who receive dacarbazine, the current treatment for this disease, at a dose of 1,000 mg/m(2) given by intravenous infusion every three weeks.

FDA also provided comments on the design of a phase III study of Taxoprexin for pancreatic cancer which will begin next year, subject to the availability of financing, the company said.

The company said Taxoprexin is the first cancer drug to employ fatty acid targeting technology. To date, 28 oncology centers in the U.S. and Europe have participated in several multi-center phase II clinical studies. Protarga owns all rights to Taxoprexin and has been awarded composition and use patents on this compound in both the US and the EU.

* * *

US Oncology of Houston said has begun a clinical trial of Taxotere (docetaxel) in combination with Xeloda (capecitabine) as adjuvant therapy for early stage breast cancer.

The trial will evaluate whether Adriamycin plus Cytoxan followed by Taxotere and Xeloda improves the overall survival rate compared with AC followed by Taxotere alone, the company said.

"The trial will answer the question about whether the Taxotere/Xeloda combination will further increase the cure rate of early stage breast cancer," said Joyce O'Shaughnessy, US Oncology principal investigator, co-chair of the US Oncology clinical research breast committee and co-director of the breast cancer research program at Baylor-Sammons Breast Center in Dallas.

The study will enroll 1,810 patients, randomized to the chemotherapeutic combination of AC followed by Taxotere and Xeloda compared with AC followed by Taxotere, to determine if Taxotere and Xeloda are more effective prolonging survival, the company said.

Roche, the manufacturer of Xeloda, and Aventis, the manufacturer of Taxotere, are supporting the trial, US Oncology said.

Deals & Collaborations:

MSKCC, Va. Firm Sign Agreement For APIT

Actinium Pharmaceuticals Inc. of Alexandria, Va., and **Memorial Sloan-Kettering Cancer Center** signed a license, development and commercialization agreement in the field of alpha particle immunotherapy.

APIT combines the killing power of alpha particle emitting radioactive atoms (bismuth-213 or actinium-225) with specific monoclonal antibodies to target cancer cells. Once injected into the body, the radioactive drugs travel through the bloodstream until the antibody moiety locks onto or moves into a cell. Once at the target, the short-range radiation kills the cell.

"You can inject small doses of these molecules, which circulate, find their target cells, invade them and eventually kill the cells," said David Scheinberg, chief of the Leukemia Service at Memorial. "These are extremely potent drugs."

In a phase I study completed in 1999, MSKCC treated 18 patients with acute myeloid leukemia in a dose escalation study using bismuth-213. The therapy successfully eliminated large numbers of tumor cells without significant clinical side effects to the patient, researchers said. API is undertaking a follow-up study in which 11 AML patients have so far been treated with bismuth-213 in conjunction with cytarabine, a chemotherapy drug.

"API brings its supporting patent position for use of these unique, short half-life alpha-particle emitting radioisotopes actinium-225 and bismuth-213 to this collaboration," said Maurits Geerlings, API president and CEO. "We also bring extensive experience with radiochemical operations, broad-spectrum engineering expertise, and a commitment to make available future supply sources for these isotopes."

The isotopes originate from isotope byproducts of nuclear power plants.

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Ariad Pharmaceuticals Inc. (Nasdaq:ARIA) of Cambridge, Mass., said it has signed an agreement with the **WiCell Research Institute Inc**., an affiliate of the University of Wisconsin, that permits scientists at academic and other non-profit institutions working on human embryonic stem cells to utilize its Argent cell-signaling regulation technology to control the function and fate of the WiCell human embryonic stem cells.

The agreement also provides Ariad with an option to obtain licenses to available WiCell technology and patents on market terms to develop and commercialize discoveries, the company said.

"Based on our studies providing in vivo validation of the utility of the technology in regulating blood progenitor cells, we will expand and explore its application to human embryonic stem cells, especially in the treatment of genetic blood diseases," said C. Anthony Blau, associate professor of medicine at the University of Washington.

The ARGENT cell-signaling regulation technology addresses two of the limitations to the development of stem-cell based therapies: 1. the inability to transfer therapeutic or corrective genes into stem cells efficiently, and 2. the difficulty in reliably obtaining large numbers of specialized cells of the correct type and purity to administer, the company said.

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BioVex Ltd. of Oxford, England, said it has signed a worldwide patent license agreement with the **US Public Health Service** that allows it exclusive use of human melanoma antigens, MART-

1 and gp100, in therapeutic cancer vaccines based on herpes virus vectors.

The melanoma antigens were characterized in the laboratory of Steven Rosenberg at NCI, the company said. BioVex will utilize them in its therapeutic vaccine, ImmunoVEX tri-melan.

ImmunoVEX tri-melan is in pre-clinical development, the company said.

In addition to the MART 1 and gp100 antigens, the vaccine also contains the melanoma tyrosinase antigen, believed to be the only melanoma vaccine in development to contain all three antigens, the company said.

The dendritic cell-based platform technology is designed to prime the immune system to fight cancer and chronic infectious disease, the company said. Other platform-based vaccines will include products to treat cervical cancer and genital herpes infection.

"ImmunoVEX trimelan will be the second product into the clinic, following the recent entry of OncoVEX GM-CSF, an oncolytic cancer vaccine, into a phase I study," said Gareth Beynon, CEO of BioVex.

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diaDexus Inc. of South San Francisco said it has entered into a research agreement with the **University of Michigan** to use proteomic technologies to analyze cell surface membrane proteins cancer drug target and biomarker identification.

Under the multi-year agreement, diaDexus will provide research funding for the program in exchange for the exclusive option to license intellectual property rights for therapeutic and diagnostic products, the company said. The agreement also provides for milestone and royalty payments from diaDexus to the University of Michigan on products resulting from the research.

Financial terms were not disclosed.

The research will be directed by Samir Hanash, professor of pediatrics and communicable diseases in the University of Michigan Medical School, the company said.

"To date, we have not had effective strategies to deal with the limited quantity of surface membrane proteins and to resolve and identify such proteins," said Hanash. "Our approach will be to focus on cell surface proteins, a potentially rich source of novel targets and biomarkers. The strategy that we have developed and implemented both enhances the sensitivity of the quantitative analysis of surface proteins and assists subsequent identification of such proteins."

The agreement calls for the Hanash team to analyze normal and cancerous primary samples and cell lines using technologies developed to possess the requisite sensitivity to overcome the limitations of current approaches to expression proteomics, the company said.

* * *

Enzon Inc. (NASDAQ:ENZN) of Bridgewater, NJ, signed an agreement under which Enzon will acquire the North American rights to Abelcet (Amphotericin B Lipid Complex Injection) from Elan Corp. (NYSE:ELN).

Abelcet, a lipid complex formulation of amphotericin B, is an antifungal used in the hospital to treat invasive fungal infections related to cancer, organ transplantation and other conditions. The acquisition includes the operating assets associated with the development, manufacture, sales and marketing of Abelcet in North America, the companies said.

Enzon will pay a total of $370 million in cash upon the closing of the deal.

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Genopsys Inc. of Santa Cruz, CA, said it is offering royalty-free access to its patented molecular randomization technology for anti-cancer product development.

The technology is available through the Genopsys Project Against Cancer program, the company said.

The technologies covered in the program include: DISMAP technology which allows for the fully random deletion, insertion, or substitution of mono-or polynucleotides for the generation of optimized macromolecules; and RTRMAP technology, which permits the truncation of randomly sized fragments of DNA from the 3' or 5' ends of the gene to eliminate deleterious characteristics or functions the company said.

"Our objective is to focus our own efforts in molecular diagnostics and selected optimization services initially, but to achieve broad utilization and recognition of the value of our tools through an out-licensing approach," said Eric Lietz, founder and president of Genopsys.

"We believe that the benefit to Genopsys from waiving all claims to royalties for oncology products resulting from the application of our technologies will come from more rapid use in product development

for other diseases as well as faster implementation of our own product and partnering programs," Lietz said.

Genopsys retains rights to certain molecular diagnostics applications including diagnostic cancer applications the company is currently pursuing, the company said.

The company said it is designing enzyme cassettes for use with a range of important cancer markers. The cassettes are expected to be more sensitive, efficient and economical than antibody methods.

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GPC Biotech (Frankfurt Stock Exchange: GPC) of Martinsried/Munich said it has signed an agreement with **NeoTherapeutics Inc.** (Nasdaq: NEOTD) of Waltham, MA, granting GPC an exclusive worldwide license to satraplatin, an orally-administered anti-cancer agent for late-stage clinical development.

Under the agreement, NeoTherapeutics will receive a license fee of $2 million upon signing, and a payment of $1 million, plus a $1 million equity investment upon first dosing of a patient in a registrational study, the company said. GPC will pay additional milestones totaling up to $18 million.

GPC will fully fund development and commercialization expenses for the drug. Phase II studies have been completed for hormone-resistant prostate cancer, as well as other tumor types. GPC expects to begin phase III studies in 2003, with trials in the U.S. and Europe.

Satraplatin is a platinum derivative licensed from Johnson Matthey to Neotherapeutics, the company said.

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Laboratory Corp. of America (NYSE:LH) of Burlington, NC, and **Celera Diagnostics** of Alameda, CA, a joint venture between the Applied Biosystems Group (NYSE:ABI) and the Celera Genomics Group (NYSE:CRA) of Applera Corp., announced an agreement to collaborate in establishing the clinical utility of laboratory tests based on novel diagnostic markers for Alzheimer's disease, breast cancer and prostate cancer.

The collaboration will support current and future disease association studies at Celera Diagnostics that seek to identify genetic markers associated with these important diseases.

The agreement provides LabCorp with exclusive access to markers found to have clinical utility through the collaboration for a defined time, and establishes Celera Diagnostics as a preferred vendor to LabCorp for certain molecular diagnostic products, the companies said.

The disease association studies are being conducted by Celera Diagnostics.

Last June, Abbott Laboratories and Celera Diagnostics formed a long-term strategic alliance to develop, manufacture and market a range of in vitro molecular diagnostic products for disease detection, disease progression monitoring and therapy selection. The alliance focuses on development of nucleic acid-based tests for infectious and genetic diseases and cancer. The two companies are contributing current products to the alliance and collaborating on the development of products.

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Lynne Cohen Foundation for Ovarian Cancer Research of Los Angeles and **Kinetek Pharmaceuticals Inc.** of Vancouver, British Columbia, said they would co-fund a $92,000 gift to Gordon Mills, chairman of Molecular Therapeutics at the University of Texas M. D. Anderson Cancer Center in Houston for ovarian cancer therapy.

The project would investigate if inhibitors of the P13K pathway will stop the growth of ovarian cancer cells, the foundation said.

Preliminary data indicates that the P13K pathway may be important for the development of new blood vessels needed for the growth of ovarian and other cancers, the foundation said.

The P13 Kinase signaling pathway is dysregulated in many major cancer types and controls the processes of angiogenesis, apoptosis, cell invasion and proliferation, the foundation said. Cancers with defective P13K components are often highly aggressive, frequently metastasize, and may be resistant to conventional therapy.

* * *

Molecular Diagnostics Inc. (OTCBB: MCDG) of Chicago said it has entered into a three-year $350,000 agreement with **Perceptronix Medical Inc**. (PMI: Vancouver, British Columbia, Canada) to provide hardware and software technologies for the commercialization of the PMI early lung cancer detection system.

MDI is commercializing its InPath System for the screening of cervical, and other cancers, the company said. Components of the system are being made available to other cancer screening and

diagnostics organizations under strategic licensing and commercialization relationships.

The system includes two assays for the screening and management of cervical cancer, which in pre-clinical studies have demonstrated superiority to both Pap testing, and HPV DNA testing, the company said. Commercially known as Cocktail-CVX and In-Cell HPV, the assays use proteomic and biomolecular probes for detecting diseased cells.

Both assays are available from MDI globally, and in the U.S. as analyte specific reagents for use in research, and for inclusion in a laboratory-testing panel, the company said. Clinical trials for the Cocktail-CVX should be completed and submitted to FDA in the next 90 days. Trials for the In-Cell HPV assay are scheduled to begin in the next months.

The studies are expected to include multiple centers in the U.S., Canada, Europe, and other parts of the world, the company said.

* * *

Nomos Corp. and **MCP International Inc.** formed a collaboration to provide an Intensity Modulated Radiation Therapy solution that will include a linear accelerator, multileaf collimator, CT scanner and inverse treatment planning software.

Nomos's Peacock System will be coupled with the MCP refurbished digital linear accelerator and spiral CT scanning equipment to provide a turnkey, integrated equipment package available for less than the cost of a new IMRT-capable linear accelerator, the companies said.

"Marrying the product lines of our respective companies via this partnership will enable smaller community hospitals and freestanding radiation therapy clinics to acquire state-of-the-art IMRT technology, along with the equipment needed to deliver it, in a convenient, cost-effective manner," said John Manzetti, president and CEO of Nomos.

"The NOMOS/ MCP IMRT solution opens the door to facilities previously unable to implement IMRT programs due to economics to now provide cutting-edge IMRT to the patients they support."

* * *

Optimer Pharmaceuticals Inc. of San Diego said it has acquired an exclusive worldwide license from Memorial Sloan-Kettering Cancer Center for a cancer vaccine that is currently in clinical development.

Under the license, Optimer will oversee the commercialization of the Globo H vaccine, which is designed to induce antibodies against breast and prostate cancer. The license also includes rights to commercialize combination vaccines in which Globo H is linked to other cancer antigens.

Globo H is a chain of sugar molecules found on the surface of human cancer cells. It is a very complicated molecule whose synthesis was made possible by the pioneering research of Samuel Danishefsky at Memorial. Danishefsky is also a founder of Optimer and a member of its scientific advisory board.

* * *

Serenex Inc. of Durham, NC, said it has signed a drug discovery collaborative agreement allowing to use its Proteome Mining technology for drug targets and off-targets.

The collaboration could speed up drug discovery and identify, well in advance of clinical trails, any adverse or toxic side effects, the company said.

The collaboration will take advantage of the Chiron preclinical and clinical development product pipeline and its drug discovery expertise, and the Serenex abilitiy to screen Chiron drugs using the Functional Proteome Fractionation in an automated and parallel systems technology, the company said.

Chiron would supply Serenex with small molecule, drug-like compounds and Serenex will use its proprietary Proteome Mining and Functional Proteome Fractionation technologies to screen the Chiron compounds against thousands of protein targets simultaneously, the company said.

In addition to upfront payments for research funding, Serenex will receive milestone payments and royalties based on the successful development of drug candidates identified in the research program, the company said.

Oncology Profession:

Ortho Biotech Backs Web Site Cancer.Com For Information

Ortho Biotech Products L.P. of Bridgewater. NJ, said it has joined with cancer advocates to launch Cancer.com, a comprehensive Web-based resource directory of cancer links.

The Web site provides access to more than 200 cancer sites operated by cancer advocacy organizations, professional societies, treatment institutions, and government agencies, the company said. Arranged by topic area, the site includes a search function and links to a series of self-assessment tools and patient materials on cancer treatment, such as

pain, fatigue and infection. In addition, the site was designed with new technology to be accessible to the visually impaired through automated voice readers.

The site also offers links to downloadable patient materials, physician locators, and clinical trials information, the company said.

"Clinical trials offer cancer patients access to new, potentially more effective cancer therapies, yet many cancer patients are not aware that these trials are a treatment option," said Robert Comis, president of the Coalition of National Cancer Cooperative Groups and a member of the Cancer.com advisory committee.

The Web site can be accessed at http://www.cancer.com.

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Pharmaceutical Research and Manufacturers of America said it has launched a Web site that provides information about new medicines in development, patient assistance programs, and policy issues.

The redesigned site will enable users to indicate particular interests, such as Medicare prescription drug coverage, cancer medicines in development, or news about biotechnology drugs, the company said. Web users will receive email updates of developments in their areas of interest. The Web address is http://www.phrma.org.

Product Approvals & Applications:
G17DT Given Fast Track

(Continued from page 1)

Aphton Corp. (Nasdaq:APHT) of Miami said FDA has given the Fast Track designation for G17DT (anti-gastrin) immunogen together with gemcitabine for pancreatic cancer. Aphton said it is conducting one phase III trial and three phase II trials of the agent.

The anti-gastrin targeted therapy induces antibodies that bind to both gastrin 17 and gly-gastrin and remove them from circulation before they can bind to the cancer cell and initiate cell growth, the company said.

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Ivax Corp. (AMEX:IVX) (LSE:IVX.L) of Miami said has received tentative FDA approval for its abbreviated new drug application for tamoxifen citrate tablets in 10 mg and 20 mg strengths for breast cancer.

Upon final approval, the product will be sold through Ivax Pharmaceuticals Inc., its wholly owned subsidiary, the company said. Tamoxifen citrate is the generic equivalent of Nolvadex Tablets marketed by AstraZeneca, the company said.

Ivax said it has 34 ANDAs approvals and two tentative approvals pending at FDA.

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OSI Pharmaceuticals Inc. (Nasdaq:OSIP) of Melville, NY, said FDA has designated Tarceva (erlotinib HCl) a Fast Track product for second-or third-line treatment of incurable stage IIIB/IV non-small cell lung cancer after failed standard therapy for advanced or metastatic disease.

Tarceva, a small molecule HER1/EGFR inhibitor, is being developed in a global alliance with Genentech Inc., and Roche, the company said. In May, the alliance received Fast-Track designation for the treatment of chemotherapy-naive stage III/IV NSCLC. Two randomized phase III trials, conducted by Genentech and Roche comparing Tarceva plus front-line chemotherapy to chemotherapy alone, have recently completed enrollment.

OSI is collaborating with the NCI of Canada Clinical Trials Group in conducting an international, randomized, placebo-controlled phase III trial in second/third-line NSCLC that compares 150 mg/day of Tarceva as a monotherapy to best supportive care, the company said. The trial is the only ongoing single-agent controlled phase III study of an HER1/EGFR targeted agent designed to detect a survival advantage in refractory NSCLC, the company said.

The dose employed in the program of 150 mg/day is the maximum tolerated dose for the agent as determined in earlier phase I studies and used in a number of single-agent phase II studies, the company said.

OSI said it would increase enrollment from 330 to 700 in its second/third-line phase III NSCLC study studies in the overall clinical development program for Tarceva. The expanded sample size would provide a more robust dataset with which to examine improvement in survival and other clinical benefits of the drug, the company said.

OSI also said it would change the size of its phase III pancreatic cancer trial. The goal of the international, randomized, placebo-controlled study, also being conducted in collaboration with the NCI of Canada Clinical Trials Group, is to compare Tarceva plus gemcitabine to gemcitabine alone in the front-line treatment of pancreatic cancer with survival as the primary endpoint, the company said.

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