THE CANCER LETTER INTERACTIVE

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Bush Keeps Klausner As NCI Director; Senate Confirms Thompson For HHS

The Bush Administration will retain Richard Klausner as director of the National Cancer Institute, HHS officials informed the Institute last week.

The word from HHS came on the morning of Jan. 19, the day Klausner would have had to leave office if the Bush transition team had accepted his pro forma resignation.

Top NCI officials were informed of the decision in an email circulated by MaryAnn Guerra, NCI deputy director for management. "For those of

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In Brief:

Golde To Step Down As Physician-in-Chief At Memorial Sloan-Kettering Next Year

DAVID GOLDE will step down as physician-in-chief at Memorial Sloan-Kettering Cancer Center, effective next January. Golde, an oncologist, has held the position since January 1996.

"David has accomplished a great deal during his tenure and will continue that record of achievement during the next year," said MSKCC President **Harold Varmus**. "He has enhanced our program of clinical research, overseen a major expansion and improvement in patient facilities and recruited outstanding physicians to our staff."

Varmus said a major international search will be undertaken to identify Golde's successor. The search committee will include members of the Board of Scientific Consultants, the Boards of Overseers and Managers and Memorial Sloan-Kettering staff.

Golde, 60, will remain at Memorial Sloan-Kettering, devoting time to his laboratory and clinical activities, as well as writing a book. Prior to becoming physician-in-chief, he was head of the Division of Hematologic Oncology in the Department of Medicine. He joined Memorial Sloan-Kettering in 1991 from UCLA, where he was chief of the Division of Hematology-Oncology at the UCLA School of Medicine and director of the Medical Oncology Program Area at the Jonsson Comprehensive Cancer Center. Golde received his medical degree from McGill University.

Golde's research has focused on the biology of normal and leukemic blood cells, and he was the first to purify human granulocyte-macrophage colony-stimulating factor, a substance that promotes the growth of infection-

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Klausner Retained At NCI; Senate Confirms Thompson

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you who worried—you can stop," Guerra wrote.

Klausner, appointed as NCI director by President Clinton on Aug. 1, 1995, thus becomes the seventh of 11 directors since the Institute's formation in 1937 to serve under two Administrations, and the fifth to serve in both Democratic and Republican Administrations.

No NCI director has been removed from office due to a change in Administration.

Over the past five years, Klausner has developed a good working relationship with both Republicans and Democrats on Capitol Hill. NCI's budget has grown by 50 percent over that time.

Klausner, who was traveling to Davos, Switzerland, to attend the World Economic Forum, was unavailable for comment.

Senate Confirms Thompson For HHS

The Senate on Jan. 34 unanimously confirmed Wisconsin Gov. Tommy Thompson as Secretary of the Department of Health and Human Services.

Thompson was praised for his work on welfare reform in Wisconsin.

Satcher, Three Other Clinton Appointees Remain

Surgeon General David Satcher remains in office because the post is a four-year appointment. His term began in February 1998 and expires in February 2002.

Satcher also held the position of Assistant Secretary for Health, a political appointment. He resigned from that position. Arthur Lawrence was named acting principal deputy, Assistant Secretary for Health.

The Bush Administration also will retain three other top public health and biomedical officials, Acting NIH Director Ruth Kirschstein said to **The Cancer Letter**. They are: Jeffrey Koplan, director of the Centers for Disease Control and Prevention; John Eisenberg, administrator of the Agency for Healthcare Research and Quality; and Earl Fox, administrator of the Health Resources and Services Administration.

Jane Henney, FDA commissioner since October 1998, was informed Jan. 18 that Bush had accepted her resignation. Bernard Schwetz, acting deputy commissioner, will serve as acting commissioner.

Cancer groups have already presented their recommendation for FDA commissioner: Richard Pazdur, director of the FDA Division of Oncology Drug Products. The Cancer Leadership Council, a patient-led forum on cancer policy, endorsed Pazdur in a letter to Thompson (**The Cancer Letter**, Jan. 19, Vol. 27 No. 3).

Kirschstein said she did not know when a new NIH director would be appointed.

Sources said Thompson is likely to look for an active scientist who is either a Nobel Laureate or a member of the National Academy of Sciences. The NIH director is a Presidential appointment requiring Senate confirmation.

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Professional Societies:

FASEB Calls For 15% Increase For NIH Next Fiscal Year

The Federation of American Societies for Experimental Biology called for a 15 percent increase for NIH in fiscal 2002. With this increase, the NIH budget would be $23.7 billion.

The recommendations, contained in the umbrella group's annual funding report to Congress, were formulated by a committee of scientists who represented the 21 professional societies that make up FASEB.

The committee met last month to review the life sciences research portfolios of government agencies engaged in life sciences research.

Along with a funding increase for NIH, FASEB

recommended:

—An increase in the budget directed towards supporting investigator-initiated grants, so as to fund more high-quality proposals.

—Enhancing the opportunities for funding of new investigators.

—Increasing compensation for post-doctoral fellows. Low pay "constitutes a crisis in biomedical research, as we are not able to attract the best and brightest young minds into careers in life-sciences research," the report said.

—An increase in the base salaries of NRSA-funded post-doctoral fellows and benefits comparable to those received by permanent employees.

—NIH, other federal agencies and the biomedical research community address the growing administrative costs associated with increased regulation, such as for human subjects protection and animal care, the report recommended. "These costs should be fully funded by the sponsoring agency," the report said.

Improve Opportunities For Young Investigators

Describing the recommendations, FASEB president Mary J.C. Hendrix said NIH needs to attract more young investigators to biomedical research. "But in order for that to happen, we need sufficient resources in the peer review system to create opportunities for this group to break into the system," Hendrix said in a statement.

Low compensation for postdoctoral fellows "constitutes a crisis in biomedical research," Hendrix said. "It makes it difficult to attract the best and brightest intellects into careers in life-sciences research.

"Post-docs work an average of 50 to 70 hours a week, but they are paid considerably less than technicians who don't have advanced degrees and who work for the most part fewer hours in the lab," Hendrix said. "Furthermore, unlike institutional employees, post-docs cannot expect cost-of-living salary increases. We believe that this unacceptable situation may lead to a `brain gap' that will surely hamper progress in biomedical research.

"So, we are recommending a substantial increase in the base salaries of NRSA-funded post-doctoral fellows and benefits comparable to those received by permanent employees," Hendrix said.

The report also makes funding recommendations for the National Science Foundation, the departments of Agriculture, Energy, Veterans Affairs, and NASA. This year's report also makes recommendations for the Department of Defense.

The document will be available on the web at www.faseb.org/opa in mid-February, the society said.

In The Cancer Centers:

Holden Center At U Of Iowa Designated Comprehensive

Just a few months after winning a Cancer Center Support Grant from NCI, the Holden Cancer Center at The University of Iowa has achieved further recognition: NCI Comprehensive Cancer Center status.

The center is now called Holden Comprehensive Cancer Center at The University of Iowa.

"Becoming an NCI-designated comprehensive cancer center is the highest honor a cancer center can receive from the National Cancer Institute," Center Director George Weiner said. "This designation places us in the top tier of cancer centers across the nation."

NCI has two major conditions that must be met before an NCI-designated cancer center can become an NCI-designated comprehensive cancer center. First, a comprehensive cancer center must have broad expertise in basic, clinical and population cancer research and integrate these research programs to draw strength from each other. Second, comprehensive cancer centers must provide outstanding clinical care while also offering cancer-related outreach, educational and informational activities for cancer patients throughout their region.

"There are currently 60 NCI-designated cancer centers in the nation, and of those, only 37 are comprehensive cancer centers. Many large states do not have one," Weiner said. "The comprehensive designation is a guarantee to patients across the state that they can receive state-of-the-art compassionate cancer care here in Iowa."

The Holden center has 31,000 annual outpatient visitors and 2,500 annual inpatient visitors to the John and Mary Pappajohn Clinical Center.

NCI provides $1.2 million annually in research support to the center.

"This has been a remarkable year for our center," Weiner said. "In addition to receiving NCI-designation earlier this year, and now being awarded comprehensive status, we also received a landmark gift from the Holden family that will allow us to strengthen even further the research, education, and clinical cancer activities recognized by the NCI through these awards."

The center's Web site: http://www.cancer.vh.org.

Obituary:

George Santos, Hopkins Cancer Treatment Pioneer

George Santos, professor emeritus of oncology and medicine at the Johns Hopkins University School of Medicine, died Jan. 21 due to complications from cancer. He was 72.

A world-renowned expert in bone marrow transplantation, Santos founded the Johns Hopkins Oncology Center's bone marrow transplant program and served as its director from 1968 until his retirement in 1994.

Among his extensive research and clinical accomplishments was development of the regimen to prepare patients for the procedure by using the anticancer drugs busulfan and cytoxan, which quickly became the worldwide standard. His animal studies in transplantation biology continue to serve as guides in the development of new therapeutic approaches.

"As one of the first Oncology Center faculty members, George Santos played a critical role in establishing the field of oncology as a specialty," said Martin Abeloff, director of the Johns Hopkins Oncology Center. "I was privileged to have worked with him and learned from him as an oncology fellow and later as a colleague. Many of the great strides we have made today in bone marrow transplantation as therapy for cancer and other diseases can be directly traced to the early research of Dr. Santos."

In 1960, Santos came to Hopkins as a fellow and conducted the institution's first marrow transplantation studies in animals. He performed his first human bone marrow transplant in 1968 in the Hopkins Oncology Unit at Baltimore City Hospital, now known as Johns Hopkins Bayview Medical Center.

Throughout his career at Hopkins, he was instrumental in developing what is considered today the standard-of-care in marrow transplantation. In addition to the preparative regimen, which provided an alternative to total body radiation, he was among the first to test the drug cyclosporine for the treatment of a life-threatening transplantation complication known as graft-versus-host-disease.

Other research included use of the drug 4-HC to purge a patient's diseased marrow of cancer cells allowing them to self-donate, treatments to prevent and manage opportunistic infections in immuno-compromised bone marrow transplant patients, and techniques in T-cell depletion that reduced both complications and relapses.

Recognizing the urgency of effective cancer treatments, Santos was among the first "translational" scientists to focus on rapidly moving laboratory discoveries from the bench to the bedside.

In his office, Santos kept a wall of photographs of the patients he had treated. One of his fondest memories was of attending the wedding of a patient he had cared for 15 years earlier. When he retired, Hopkins honored Santos with a reunion of more than 200 transplant patients he and his staff had treated over his career.

"A whole generation of Hopkins-trained translational scientists looked to George as their intellectual and spiritual mentor," Richard Jones, professor of oncology and current director of the Hopkins bone marrow transplant program. "The world of biomedical science has recently embraced the concept of translational research, but George was showing the Hopkins community how to do this long before it was in vogue."

At the 25th anniversary of the Hopkins Oncology Center, in 1998, Santos reflected on his years at Johns Hopkins: "I was privileged to witness the birth of oncology into a subspecialty. A freestanding center in a university setting was quite unique at the time. I was allowed to pursue my interests in bone marrow transplantation in a place with a strong research base in an environment where it could be transferred to the clinic. It was a wonderful opportunity for me and a wonderful opportunity for patients."

His significant contributions to the field of oncology earned Santos many awards, including the Bristol Myers Squibb Award for Distinguished Achievement in Cancer Research and the American Society for Blood and Marrow Transplantation Lifetime Achievement Award. The Hopkins Oncology Center's inpatient bone marrow transplantation unit was named in his honor at the opening of the new clinical facilities last year. In addition, he is the author of numerous articles and book chapters.

Santos received his bachelor's degree in quantitative biology at the Massachusetts Institute of Technology and a master's degree in physical biology also from MIT. He received his medical degree and completed a residency and fellowship at Johns Hopkins. He developed an interest in bone marrow transplantation while serving in the Naval Reserves at the U.S. Naval Radiologic Defense Laboratory in San Francisco from 1956 to 1958.

Following his retirement from Hopkins in 1994,

Santos moved to Hilton Head, SC. He is survived by his wife Carole and four children by his first wife, Joanne . They are Susan Carey of Baltimore, George Santos of Sparks, Md., Kelly Santos of Columbus, Ohio, Amy Cauley of Jensen Beach, Fla. He is also survived by two grandchildren, Caeley and Walker.

In lieu of flowers, the family requests that donations be sent to the Johns Hopkins Oncology Center's Bone Marrow Transplant Patient and Family Fund.

News @ Cancer.Gov:

Course on Human Research Protections Goes Online

A new continuing education program on the protection of human participants in research is now available online at http://cme.nci.nih.gov.

Developed by NCI for NIH, the Web-based course offers continuing medical education credit for physicians and contact hours for nurses and other members of research teams.

The new program also responds to the mandate requiring education on human subjects protection for all investigators who apply for or receive NIH funds for research involving people.

Titled Human Participant Protections Education for Research Teams, the course incorporates interactive modules, case studies, and exercises. Topics covered include:

--Roles and responsibilities of researchers and their key personnel

--Guiding ethical principles for research

--Federal regulations

--Informed consent

--Institutional review boards

--Ongoing protections throughout the course of the study

--Data and safety monitoring

--Reporting of adverse events

--Privacy and confidentiality

--Historical events that have impacted policy and legislation

NCI led the development of the program in collaboration with other NIH offices, including the National Institute of Allergy and Infectious Diseases, the National Heart, Lung and Blood Institute, the National Institute of Neurological Disorders and Stroke, the National Institute of Mental Health, and the NIH Clinical Center Bioethics Program.

The program offers up to two hours of category 1 credit of the Physicians Recognition Award of the American Medical Association. Cine-Med., a continuing medical education provider, is accredited by the Accreditation Council for Continuing Medical Education to sponsor the credits. Application for nursing contact hours is in progress.

Funding Opportunities:

RFAs Available

RFA HD-01-004: Extramural Associates Research Development Award: Faculty Research Enhancement Support Program

Letter of Intent Receipt Date: March 1, 2001

Application Receipt Date: April 13, 2001

National Institute of Child Health and Human Development, NIH, announces the faculty research enhancement support program to increase participation in biomedical and behavioral research and research training through an integrated residency and an institutional support program. A major focus addresses strategies and processes for attracting women and underrepresented minority undergraduate students into research experiences toward biomedical and behavioral research careers. The RFA will use the NIH Extramural Associate Research Development Award G11 mechanism.

Inquiries: Matthew Kinnard, director, Extramural Associates Program, National Institute of Child Health and Human Development, NIH, 6701 Rockledge Dr, Rm 6198, MSC 7910, Bethesda, MD 20892-7910, phone 301-435-2736; fax 301-480-0393; e-mail KinnardM@mail.nih.gov

RFA CA-01-007: NCI Scholars Program (Reissued)

The RFA provides new investigators with research experience in the basic, clinical or population-based sciences, mathematics, or in technology-based research, obtained in a variety of environments and who have no more than five years of postdoctoral research training experience (clinical training does not count against the five years of research experience), to establish their first independent cancer research program within the special environment of NCI and to continue their careers at an institution of their choice. The program provides the resources to initiate an independent research program for three to four years in the NCI Intramural laboratories, followed by support through an extramural funding mechanism K22 of their research program for two years at the

extramural institution to which they are recruited.

Inquiries: Lester Gorelic, program director, Office of Deputy Director of Extramural Sciences, Cancer Training Branch, phone 301-496-8580; e-mail lg2h@nih.gov

Other Funding Notices

Notice of Legislative Mandates Contained in the FY2001 Omnibus Appropriations P.L. 106-554; Signed Dec. 21, 2000

The notice provides information on the following statutory provisions that limit the use of funds on NIH grant, cooperative agreement, and contract awards: (1) acknowledgement of federal funding (2) anti-lobbying (3) continued salary limitation (4) ban on funding of human embryo research (5) purchase of American-made equipment and products (6) limitation on use of funds for promotion of legalization of controlled substances (7) restriction on distribution of sterile needles.

Inquiries: For information on policies relating to grants: http://grants.nih.gov/grants/policy/policy.htm. For information on contract policy: http://ocm.od.nih.gov/contracts/contract.htm.

In Brief:

Golde To Step Down At MSK; Porter Joins Hogan & Hartson

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fighting white cells. He is also the co-discoverer of the second known human retrovirus (HTLV-II). More recently, his research has focused on blood growth factor receptor biology and the regulation of molecular transport in normal and cancerous tissues. His laboratory discovered the universal mechanism of vitamin C uptake by cells.

"Memorial Sloan-Kettering is on a marvelous trajectory to realize the scientific and clinical potential of the recent advances in biologic knowledge, and I look forward to playing a vigorous role in our noble quest to control human cancer," said Golde. "Harold is the ideal person to lead the institution in this endeavor."

* * *

JOHN PORTER, who retired from the House last year (R-Ill.) has joined the Washington-based law firm Hogan & Hartson, according to The Washington Post. Porter is working on legislative strategy for a year before he will be able to lobby Congress. He specializes in health, legislative, and education issues.

. . . **THE GROUP ROOM**, the weekly syndicted radio call-in talk show about cancer, is expanding internationally and broadcasting its first live show from Europe at The Royal Marsden Hospital in London, England, Jan. 28, from 4-6 p.m. ET (9-11 p.m. GMT). The live town-hall meeting will be the first time patients and physicians have an international dialogue about cancer over the airwaves and will be the inaugural collaborative broadcast between Vital Options and The Group Room and The Royal Marsden Hospital and its in-house radio station, Radio Marsden. The Royal Marsden, the world's oldest cancer hospital, is celebrating its 150th anniversary this year.The Group Room, in its fifth year, is hosted by **Selma Schimmel**, CEO and founder of Vital Options.Joining Schimmel at the broadcast will be **Ian Smith**, consultant medical oncologist and medical director at The Royal Marsden, as well as other cancer experts from the Marsden and several other European nations. . . . **RONALD LEVY** will be honored by the naming of a scientific research fellowship in his name. The American Cancer Society said IDEC Pharmaceuticals Corp. and Genentech Inc. will sponsor a fellowship program, in honor of Levy, who is the Robert K. Summy and Helen K. Summy Professor of Medicine, chief, division of oncology, Stanford University School of Medicine, and an American Cancer Society Clinical Research Professor. The program will award research fellowships of $50,000 to two post-doctoral students each year for the next five years. . . . **UCLA JONSSON** Cancer Center received a five-year grant from NCI to develop a new molecular imaging center to view gene-based therapies at work in the human body. The $9.8-million UCLA Center for In Vivo Imaging in Cancer Biology is the first such molecular imaging center on the West Coast, Jonsson Cancer Center researchers said. **Harvey Herschman** is principal investigator for the imaging center and director of basic research at Jonsson. Herschman and his colleagues developed two tracking systems to image gene therapies non-invasively. The systems use specially engineered genes called "reporter" genes, which were successfully tested in laboratory models. The tracking systems will be tested in cancer patients for the first time this year, Herschman said. The reporter genes are attached to the therapeutic genes and can be made to glow "hot" during a PET scan. Researchers will be able to monitor the gene therapy's behavior soon after it has been administered to a patient. NCI also funded imaging centers at Harvard and and Memorial Sloan-Kettering Cancer Center.

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Business & Regulatory Report

Formerly "Cancer Economics"

Product Approvals & Applications:

FDA Approves Femara As First-Line Treatment For Advanced Breast Cancer

FDA approved Femara (letrozole tablets) for the first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer. The drug is sponsored by **Novartis Oncology** of Hanover, NJ.

Approval for the indication followed a priority review by the FDA and a unanimous recommendation from the Oncologic Drugs Advisory Committee. The recommendation was based on data from the largest study

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Oncology Management:

NCCN Updates Treatment Guidelines To Include CEF For Early Breast Cancer

National Comprehensive Cancer Network has updated its treatment guidelines to include CEF (cyclophosphamide, epirubicin and fluorouracil) for early breast cancer that has spread to the lymph nodes.

The anthracycline Ellence (epirubicin hydrochloride injection), part of the CEF regimen, increases five-year survival and reduces the risk of cancer recurrence over CMF (cyclophosphamide, methotrexate and fluorouracil), a standard therapy in post-surgical treatment of early breast cancer, the publication reported.

"The inclusion of this option for women with breast cancer is a result of a comprehensive body of data that demonstrate the efficacy of epirubicin in treating early stage breast cancer," said Robert Carlson, chair of the breast guidelines committee of NCCN.

A recent NIH consensus conference on adjuvant treatment of breast cancer concluded that chemotherapy regimens containing anthracyclines have demonstrated survival advantages over those that do not. Combination therapy with Ellence has been shown to offer survival benefit in breast tumors both hormone receptor positive (fueled by estrogen) and negative.

Ellence, marketed by **Pharmacia Oncology,** a subsidiary of **Pharmacia** (NYSE: PHA), of Peapack, NJ, as Farmorubicin outside the U.S., has the potential for severe myelosuppression and may be associated with myocardial toxicity and an increased risk of acute myelogenous leukemia.

The guidelines for physicians are also accompanied by treatment

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Femara Approved For HR+ Advanced Breast Cancer

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to evaluate a hormonal therapy in this setting. The study found that Femara was significantly more effective than tamoxifen in multiple efficacy endpoints, the company said.

Femara, an aromatase inhibitor, is a once-a-day oral treatment first approved in 1997 for advanced breast cancer in postmenopausal women with disease progression following anti-estrogen therapy.

The drug was approved based on a phase III head-to-head, randomized, double-blind multi-center trial comparing Femara with tamoxifen in more than 900 postmenopausal women with stage IIIB disease, metastatic disease, or recurrences not amenable to treatment with surgery or radiotherapy.

Time to progression was 9.4 months for Femara and 6 months for tamoxifen. Results also indicated significant differences between Femara and tamoxifen with respect to overall tumor response rates (30% vs. 20%), clinical benefit (49% vs. 38%) and time to treatment failure (40 weeks vs. 25 weeks), the company said. Femara and tamoxifen were equally well tolerated.

"Femara shows great promise for becoming the new first-line therapy of choice for postmenopausal women with advanced breast cancer," said Robert Smith, of South Carolina Oncology Associates, a lead investigator in the first-line study. "It is the first therapy to challenge tamoxifen in multiple endpoints, including time to progression, response rates and overall clinical benefit."

The adverse reactions in the first-line study were generally mild to moderate, and were consistent with those seen in the second-line studies. The most commonly reported adverse events for Femara vs. tamoxifen were bone pain (20% vs. 18%), hot flushes (18% vs. 15%), back pain (17% vs. 17%), nausea (15% vs. 16%), dyspnea or labored breathing (14%vs. 15%), arthralgia (14% vs. 13%), fatigue (11% vs. 11%) and coughing (11% vs. 10%).

"Approval of this new indication means that thousands of postmenopausal women with advanced breast cancer will finally have a more effective hormonal treatment option," said David Parkinson, vice president, clinical research at Novartis Oncology.

* * *

Advanced Magnetics Inc. (Amex: AVM) of Cambridge, MA, said it has submitted a supplemental new drug application to FDA for an expansion of the indications for Feridex I.V., its MRI contrast agent for liver lesions.

The sNDA seeks approval for claims characterizing the lesions as benign or metastatic as well as asking for a more convenient, rapid infusion, dosing regimen, the company said.

Berlex Laboratories Inc., of Montvelle, NJ, a subsidiary of Schering A.G. of Germany, markets Feridex I.V. in the U.S., the company said.

* * *

Ilex Products Inc. of San Antonio, TX, a subsidiary of **Ilex Oncology Inc.** (Nasdaq: ILXO) said it has submitted an investigational new drug application to FDA for ILX-651, an orally active anticancer compound.

ILX-651 is a synthetic pentapeptide analog of dolastatin, with a mechanism of action that is analogous to taxanes, the company said. A tubulin interactive, anti-mitotic compound, ILX-651 appears to be active in taxane-resistant tumors in preclinical animal models in human breast carcinoma. The agent appears to be active for a variety of solid tumors in in vitro cell models including human breast, ovarian and lung carcinoma as well as melanoma and leukemia, the company said.

Ilex said it in-licensed the compound through an exclusive, worldwide license agreement with BASF Pharma of Ludwigshafen, Germany.

"ILX-651 has shown activity in a variety of solid

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tumor models in early preclinical testing," said Ze'ev Shaked, president of Ilex Products. "Considered a second-generation dolastatin, the compound is chemically modified to provide improved pharmacologic properties, with a potentially enhanced therapeutic window over first-generation dolastatins."

Clinical Trials:

US Oncology To Participate In Firm's Ovarian Cancer Trial

AltaRex Corp. (TSE: AXO) (OTC: ALRXF) of Waltham, MA, said it has engaged **US Oncology Inc.** (Nasdaq: USON) of Houston to participate in its OvaRex MAb phase II trial for the watchful waiting stage of ovarian cancer.

US Oncology brings over 20 satellite sites to the OvaRex study, in addition to 13 sites that had already begun enrolling patients, the company said.

The study is designed to test the observations regarding immunity and efficacy, which established that 51 percent of OvaRex MAb treated patients mounted a specific immune response (Ab2 > 100 ng/ml) with a median time to disease relapse of 18.9 months, as compared with 7.4 months for treated patients that did not mount this immune response, the company said.

A separate 12-patient phase II recurrent disease trial, assessing the value of combining OvaRex MAb immunotherapy and salvage chemotherapy in late stage patients, is also open for enrollment at the US Oncology Center in Dallas, the company said.

"We will continue to address the enrollment of these two open trials and the transfer of manufacturing technology," said Richard Bagley, AltaRex president and CEO. "We remain in close communication with FDA regarding both our clinical trial program and our manufacturing plans."

Multiple OvaRex clinical trials are fully enrolled and are near completion for primary analysis, the company said. The lead study is a 345-patient double-blind placebo-controlled phase IIb trial of the drug in the watchful waiting stage and is scheduled for primary analysis in mid 2001; the second phase IIb study of 55 patients, also in watchful waiting, is scheduled for primary analysis during the second quarter of 2001.

In a related development, AltaRex Corp. said it has completed laboratory analyses of serum samples of BrevaRex Mab, a monoclonal antibody, for multiple myeloma and would begin a phase I/II trial at the Myeloma and Transplantation Research Center of the University of Arkansas for Medical Sciences in Little Rock.

We hope that the selective targeting of myeloma cells would provide clinical benefit without the negative side effects of standard chemotherapy and open a new avenue for the research and treatment of multiple myeloma," said Barlogie, head of the trial.

In the phase I study, BrevaRex MAb demonstrated it could elicit B and T cell immune responses to the MUC1 tumor associated antigen, the company said. In some of the patients the immune response is to multiple binding sites of the antigen. The so-called multi-epitopic response is the subject of the Genta intellectual property portfolio, the company said.

"The findings could be important to selectively targeting the diseased blood cells and avoiding harm to normal cells, while providing a robust immune response to multiple epitopes of the tumor associated antigen," said Richard Bagley, president and CEO at AltaRex.

* * *

Celsion Corp. (Amex: CLN) of Columbia, MD, said FDA has signed off on its phase II breast cancer trials using focused microwave thermotherapy technology, an application originally developed for missile detection and destruction in the Strategic Defense Initiative, exclusively licensed from **MIT**, of Cambridge, MA.

In the trials, more than 100 women would receive thermotherapy to heat breast cancer cells to about 115 degrees Fahrenheit, killing the cells without burning the skin, the company said.

"This is an out-patient procedure," said Alan Fenn, senior staff member in the Air Defense Technology Division at the MIT Lincoln Laboratory and inventor of the technique.

"In the phase I trial, patients went home with only one or two tiny band-aids." said Fenn. "Our goal is to destroy all visible and microscopic cancer cells and pre-cancerous cells in the breast. If the thermotherapy can destroy the cells, breast surgery could be reduced or eliminated. There is also the potential to reduce or eliminate conventional radiation to the breast."

In the phase I trial, one to three weeks after a single limited-dose heat-alone treatment, "advanced breast tumors typically had been reduced in size or destroyed by about 50 percent in 8 out of the 10 patients," Fenn said.

Among the sites conducting the phase II trials would be Columbia Hospital, FL, UCLA Medical Center, Massachusetts General Hospital and Hammersmith Hospital, London, the company said.

* * *

Genta Inc. (Nasdaq: GNTA) of Berkeley Heights, NJ, said it has initiated two clinical trials of Genasense, in leukemia. The two trials involve patients with acute myeloid leukemia and chronic lymphocytic leukemia, respectively. M.D. Anderson Cancer Center in Houston, TX is the lead center for both trials.

Genasense attacks Bcl-2, a protein that is over-expressed in many forms of leukemia. Bcl-2 appears to be a major factor that contributes to resistance of these diseases to standard treatment. Genta is using its proprietary antisense approach to first decrease the expression of Bcl-2, and then to administer state-of-the-art anticancer therapy, in an effort to improve patient outcome.

Both of the new trials announced today involve patients who have relapsed from front-line therapy. The study in chronic lymphocytic leukemia is a single-agent study of Genasense alone. The trial in acute myeloid leukemia uses Genasense in combination with a recently approved drug, known as Mylotarg (gemtuzumab ozogamicin; Wyeth/Genetics Institute).

"The CLL study will complement our pending randomized trial of Genasense(TM) plus chemotherapy for patients who have failed first-line treatment," said Raymond Warrell, Genta president and CEO. "The AML study uses Genasense in combination with Mylotarg, an antibody/toxin conjugate, that was approved for older patients with relapsed AML. Our study targets that same population and seeks to significantly improve patient outcome compared with the use of Mylotarg alone."

* * *

OSI Pharmaceuticals Inc. (Nasdaq: OSIP) of Uniondale, NY, said **Pfizer Inc.** (NYSE: PFE) has filed an IND application for phase I trials in the U.S. to evaluate a small molecule anticancer drug designed to inhibit angiogenesis.

The compound is an orally active, potent and selective inhibitor of the vascular endothelial growth factor receptor, a key receptor tyrosine kinase involved in blood vessel growth, the company said.

In pre-clinical studies the compound was shown to be an effective inhibitor of tumor growth in animals, the company said.

"Moving forward we would continue our focus on the discovery and development of promising small molecule candidates, that are directed against specific gene targets involved in major disease areas including cancer," said Colin Goddard, chairman and CEO of OSI Pharmaceuticals.

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OXiGENE Inc. (Nasdaq: OXGN) of Watertown, MA, said it has begun a phase II study for Declopramide, an apoptosis-inducing and NF-kappa beta inhibiting anti-cancer drug candidate.

In the study, the drug would be administered in combination with 5-fluorouracil and Leucovorin as a second line therapy for colorectal cancer, the company said.

In phase I trials, Declopramide exhibited a promising safety and tolerance profile, therapeutic window and incidences of disease stabilization including one confirmed complete response in a colon cancer patient and a partial response in one patient with head and neck cancer, the company said.

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SciClone Pharmaceuticals (Nasdaq: SCLN) of San Mateo, CA, said it has begun a phase II study of Zadaxin, an immune system enhancer, in combination with radio frequency ablation for hepatocellular carcinoma.

RFA destroys tumors by radio waves delivered via a probe-bearing needle, and is used to treat primary liver cancer as an alternative to surgical resection or localized chemotherapy, the company said. The lead investigator of the trial is Adrian Di Bisceglie, associate chairman of medicine, Saint Louis University and medical director of the American Liver Foundation.

In the open label, controlled study, patients would be randomized to each of two treatment arms: RFA alone or RFA plus Zadaxin., the company said. The immune system enhancer would be given for 6 months, and all patients would have an additional 12 months of follow-up to evaluate whether an enhanced immune response may contribute to the effectiveness of tumor therapy with RFA.

Primary efficacy endpoints would be tumor response and survival. Tumor response would be measured by assessing the number of patients with undetectable tumors and those with metastases or new tumors. A secondary endpoint would be the number of patients who become eligible for liver transplantation due to a reduction of tumor burden, the company said.

"The study is part of the beginning of an aggressive and broad-based U.S. oncology program," said Alfred Rudolph, chief operating officer at

SciClone. "We have seen early indications of Zadaxin's effect in combination therapies for other types of cancer such as malignant melanoma, where trials have recently begun in Australia."

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Sonus Pharmaceuticals Inc. (Nasdaq: SNUS) of Bothell, WA, said patients are being enrolled in a phase I clinical study with the Company's first drug delivery product, S-8184, an injectable paclitaxel emulsion formulation.

Using the company's Tocosol drug delivery system, S-8184 was shown in pre-clinical studies to be less toxic than the currently marketed formulation of paclitaxel. Sonus has launched its clinical development program to determine if this lower toxicity can result in a reduction or possible elimination of premedications in patients taking paclitaxel and permit administration of a higher dose of the drug. In addition, because of the anticipated lower toxicity of S-8184, the product will be given to patients in a matter of a few minutes compared to hours of infusion with the currently marketed formulation of paclitaxel.

The phase I clinical study, conducted by Howard Burris at the Sarah Cannon Cancer Center in Nashville, TN, is a dose-escalating safety study in approximately 25 patients with advanced cancers, who have failed other therapies. S-8184 will be administered as a single, quick injection instead of the 3- to 24-hour infusion typically required with other paclitaxel formulations, the company said. The study will also test whether premedications, which are used to suppress allergic-type reactions to the currently marketed formulation of paxlitaxel, may be eliminated with S-8184. Sonus expects patient enrollment in the S-8184 phase I study to be completed in late 2001.

"The possibility of eliminating premedications and reducing administration time with S-8184 could, if proven, provide significant advantages to patients and physicians over the paclitaxel formulation currently in use," Burris said.

Deals & Collaborations:

Atrix, Sanofi In Marketing Deal For Leuprogel Products

Atrix Laboratories Inc. (Nasdaq: ATRX) of Fort Collins, CO, said it has entered into an exclusive North American marketing agreement with **Sanofi-Synthelabo** of Paris, France, for Leuprogel 1-, 3- and 4-month products, leuprolide acetate for subcutaneous depot injection, for advanced prostate cancer.

In the agreement valued at approximately $60 million, Atrix said it received a license fee, R&D support and payments for clinical, regulatory and sales milestones. Sanofi-Synthelabo purchased $15 million of Atrix common stock, received an option to develop a 6-month product for prostate cancer and Leuprogel products for other indications, the company said. The parties have received FTC clearance, the company said.

Sustained levels of leuprolide, a leutinizing hormone-releasing hormone agonist, decrease testosterone levels to suppress tumor growth in patients with hormone-responsive prostate cancer, the company said. The liquid products are injected with a small gauge needle, forming a solid implant in the body that slowly releases the leuprolide as the implant is bioabsorbed.

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BioPulse International Inc. (OTC Bulletin Board: BIOP) of San Ysidro, CA, said it has entered into a development agreement with **Covance Inc.** (NYSE: CVD) to commercialize its TK1 early detection cancer test.

"Given that our TK1 test may become the new industry standard for general screening and patient evaluation, Covance would be extremely important with regulatory agencies as well as in commercializing the test," said Jonathan Neville, CEO of BioPulse.

BioPulse said it licensed the technology for the TK1 test from Brigham Young University. The test is useful in clinical applications, for prognostics and as a general cancer-screening test, the company said.

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Celsion Corp. (Amex: CLN) of Columbia, MD, said it is developing temperature-sensitive, drug-laden liposomes for use with its "focused heat systems" to target prostate, liver, ovarian and other cancers.

Celsion said it will undertake this development using exclusive licenses from Massachusetts Institute of Technology for its "Smart Bomb" Adaptive Phased Array (APA) focused heat technology and from Duke University to commercialize its' temperature-sensitive liposomes.

On March 1, Aug. 15, and Dec. 15, 2000, Duke researchers published three separate scientific articles in the journal Cancer Research on using temperature-sensitive liposomes in combination with focused heat system to achieve targeted drug delivery.

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Cytoclonal Pharmaceutics Inc. (Nasdaq: CYPH) of Dallas, TX, and **Bristol-Myers Squibb Co.** (NYSE: BMY) have agreed to extend their research and development agreement to develop technology based on microbial fermentation to produce taxane therapeutics and paclitaxel.

The extension involves payments by Bristol-Myers Squibb of $2 million in research support to Cytoclonal and is part of a licensing arrangement initiated in 1998, the company said.

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Genta Inc. (Nasdaq: GNTA) of Berkeley Heights, NJ, said it has signed an exclusive worldwide licensing agreement with NIH for cancer therapy decoy aptamers.

A separate cooperative research and development agreement will be executed to fund Yoon Cho-Chung at NCI, a co-inventor of the technology, the company said.

The technology uses short sequences of oligonucleotides, the company said. When taken up by cancer cells, decoy aptamers attach themselves to transcription factors, prevent their binding to normal DNA and inhibit the production of cancer causing proteins.

"We believe using decoy aptamers is an extraordinarily powerful approach not yet recognized by the pharmaceutical community," said Robert Klem, chief scientific officer at Genta. "The technology represents an extension of our work into a new platform for designing novel agents for cancer treatment."

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IVAX Corp. (AMEX: IVX) of Miami, said it has entered into an exclusive agreement with NIH to develop and market a treatment for brain cancer. The compounds licensed to Ivax were developed by Ira Pastan, chief of the laboratory of molecular biology at NCI, the company said.

"They were specifically designed to target tumors in the brain," said Stephen Marcus, vice president of oncology and biotechnology at IVAX. "The drugs have the potential to be the most specific and potent to treat this lethal disease."

The compounds not only bind to the EGF receptor, they also transport a highly potent poison directly into the malignant cell, resulting in rapid cell death, the company said. A phase I trial is will begin at Duke University Medical Center.

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Matritech Inc. (Nasdaq: NMPS) of Newton, MA, said it has entered into a distribution agreement with **Timm Medical Technologies**, whereby Timm will become the sole U.S. distributor to the urology community of a non-instrumented, point-of- care format of Matritech s NMP22 test for bladder cancer.

Timm Medical Technologies, a privately held company located in Eden Prairie, MN, is a manufacturer and supplier of products used by urologists. More than 6,000 of the 8,000 urologists in the United States use products sold by Timm. The terms of the multi-year agreement include an initial equity investment by Timm in Matritech, marketing fees, milestone payments and increasing minimum NMP22 purchases.

The distribution agreement is based upon FDA clearance of the point-of-care format for the NMP22 test, which Matritech intends to file for in 2001. If the minimum product purchases are met, the up- front payments and product purchases could exceed $23 million, spread over six years. Matritech's microplate format NMP22 Test Kit measures the level of a specific nuclear matrix protein associated with bladder cancer to accurately detect disease. Recent clinical studies have shown NMP22 to be twice as sensitive as conventional urine cytology in detecting low-grade bladder cancer tumors. NMP22 employs voided urine samples and is thus non-intrusive and pain-free.

While NMP22 has been used as a monitoring tool to predict disease recurrence since 1996, in early 2000, the test was cleared by the FDA for expanded use as an aid in testing previously undiagnosed individuals who have symptoms of or are at risk for bladder cancer. Matritechs nuclear matrix protein (NMP) core technology correlates levels of NMPs in body fluids to the presence of cancer. Multiple published clinical studies have validated this ability of NMPs to detect early-stage cancerous abnormalities.

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Medarex Inc. (Nasdaq: MEDX) of Princeton, NJ, **Eli Lilly and Co.** (NYSE: LLY) of Indianapolis, IN and **Biosite Diagnostics Inc.** (Nasdaq: BSTE) of San Diego, CA, said they have entered into a collaborative agreement for antibody research using Trans-Phase Technology.

Under the terms of the agreement, Biosite and Medarex would use the technology to generate high-affinity, fully human antibodies to genomics-derived targets provided by Lilly, the companies said. Lilly would use the antibodies to identify and validate targets.

Lilly said it has agreed to provide Biosite with targets on an annual basis for a period of three years.

Biosite would receive technology access fees, development fees upon delivery of a target, annual target maintenance fees, milestone fees upon the achievement of preclinical and clinical development milestones and royalties from products. For antibodies developed through clinical development and commercialization, Medarex would receive license fees and milestone payments, as well as royalty payments from Lilly, the companies said.

Trans-Phage Technology is a high throughput method of creating fully human antibodies that combines the immunological power of the Medarex HuMAb-Mouse with the speed of the Biosite Omniclonal phage display technology, the companies said.

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OSI Pharmaceuticals Inc. (Nasdaq: OSIP) of Uniondale, NY, **Genentech Inc.** (NYSE: DNA) of South San Francisco, CA and **Roche** of Basel, Switzerland, said they have entered into concurrent agreements for the global co-development and commercialization of the anti-cancer drug, OSI-774.

An inhibitor of the epidermal growth factor receptor, the drug is in phase II studies for non-small cell lung, head & neck and ovarian cancers, the companies said.

The agreements could result in up to $187 million in upfront fees, equity investments, and scheduled milestone payments to OSI, the companies said. Milestone would be made at filing and registration of the drug in major markets, the companies said. Genentech and OSI would employ an equal cost and profit sharing arrangement for commercialization in the U.S.; Roche would pay royalties on net sales to OSI in markets outside of the U.S. The overall costs of the tripartite development program would be split equally among the three parties, the companies said.

Under the agreement, Genentech and Roche agreed to purchase $35 million of OSI common stock and pay up-front fees. Although OSI has retained certain co-promotion rights in the U.S., Genentech would be responsible for commercializing the product in the U.S. should the product gain FDA approval. Roche would be responsible for gaining regulatory approval and marketing in territories outside the U.S, the companies said.

"The agreements ally OSI with a Genentech team that has already demonstrated success in developing and marketing next generation anti-cancer drugs, and a Roche team that represents a strong worldwide oncology portfolio," said Colin Goddard, chairman and CEO of OSI. "Moreover, this collaboration not only produces a substantial strategic and economic benefit to us, it provides all of the essential elements for the rapid, comprehensive and competitive development of OSI-774."

"EGFR inhibitors represent a promising class of novel anti-cancer agents," said Franz Humer, CEO at Roche.

In another development, Hoffmann-La Roche Inc. of Nutley, N.J., the U.S. prescription drug unit, said that as a result of the merger between SmithKline Beecham and Glaxo Wellcome, it has acquired all rights to the anti-nausea and vomiting drug Kytril (granisetron).

As part of the transaction, SmithKline Beecham acquired sole U.S. rights to Roche's Coreg (carvedilol), a drug used in patients with congestive heart failure or hypertension, in exchange for worldwide rights to Kytril. The agreement highlights Roche's focus on key therapeutic areas, such as oncology, with high growth potential, the company said.

Kytril (granisetron hydrochloride), a 5-HT_3 receptor antagonist available in oral and intravenous dosing forms, is used for the prevention of nausea and vomiting associated with chemotherapy and radiation.

The injectable form was approved in 1993 by FDA for chemotherapy-induced nausea and vomiting. In 1999, oral Kytril tablets were approved for use with radiation therapy-induced nausea and vomiting.

Oncology Management:

NCCN Updates Guidelines For Breast Cancer Treatment

(Continued from page 1)

guidelines that have been rewritten for patients (Breast Cancer Treatment Guidelines for Patients, Version III). Available on the American Cancer Society's web site: http://www3.cancer.org/cancerinfo/breast-cancer-guidelines.pdf.

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Response Oncology Inc. (Nasdaq: ROIX) of Memphis, TN, said it plans to close 14 of its IMPACT Centers by the first quarter of 2001. The one-time cost would be $400,000, the company said.

"The reduction in the network would allow management to focus on the remaining centers and business segments that possess the greatest opportunities for the company and its stakeholders,"

said Anthony LaMacchia, president and CEO of Response Oncology.

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Harvard Pilgrim Health Care, a not-for-profit health plan of Wellesley, MA, said it has entered into an agreement with **HealthTrio**, a Nashville, TN, e-health connectivity company, to improve patient and provider Web-based administrative transaction services.

The features offered by HealthTrio would allow providers using the Harvard Pilgrim online service, HPHConnect, to save time and reduce administrative costs by performing a variety of tasks over the Internet including verification of eligibility, benefits and claim status, the company said. Enhancements that give providers the ability to do on-line referrals, authorizations and claims submission would be added throughout the year.

HealthTrio gives physician offices uniform access to any health plans using HealthTrio, rather than forcing providers to use a different e-health application for each health plan, the company said.

Harvard Pilgrim Health Care serves 900,000 members in Massachusetts, New Hampshire and Maine and has a provider network of 19,000 physicians and other health care professionals, the company said.

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Memorial Sloan-Kettering Cancer Center said it has begun an e-Learning initiative to improve patient care developed by **click2learn.com Inc.** (Nasdaq: CLKS) of Bellevue, WA.

The endeavor will enable the center to deliver customized training to thousands of newly hired clinicians, nurses, interns and administrative staff, and track and measure their learning experience, the center said.

The first phase of the initiative focuses on the Order Management System, which is used to place electronic orders for patient care and track results. The second phase focuses on the online training sequences for the hospital electronic medical record system, picture archival and communication systems and disease management system, the center said.

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Andrx Corp-Cybear Group (Nasdaq:CYBA) of Boca Raton, FL, said it has agreed to provide **Dianon Systems Inc**, a U.S. company that provides anatomic and molecular pathology testing services, with its Web-based laboratory ordering and results delivery system.

The Dr. Chart system and other Internet applications would allow Dianon customers to submit lab orders and to access lab results through the Cybear physician portal, the company said.

Dianon supplies specialized diagnostic testing services to more than 12,000 surgeons and oncologists. Cybear has agreed to customize its portal and Dr. Chart application for Dianon enhance their cancer and genomic diagnostic testing services, the company said.

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Eli Lilly and Company has launched http://www.lillydirect.com, a web site for community medical oncologists and their staffs.

The web site is designed to save oncology health care professionals time by streamlining many of their business-related responsibilities. Through the site, health care professionals are able to access major wholesale distributors of oncology products through a single web site, the company said.

The features of the Web site include on-line ordering of oncology products from Cardinal Health/National Specialty Services, Bergin-Brunswig Oncology Supply and Priority Health Care, access to the Lilly Oncology Reimbursement Assistance Program, a system for messaging patients, and links to information on clinical trials, publications, scientific meetings, cooperative groups and associations.

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Pittsburgh Clinical Research Network has commissioned a series of surveys of the clinical trials community.

The surveys will be published quarterly beginning early this year in a new publication called The PCRN Monitor. The findings also will be posted on the PCRN Web site at: http://www.pcr-n.com.

The surveys will be developed by PCRN in collaboration with an independent opinion research firm. The surveys will be based on telephone interviews with a broad range of participants in the clinical trials community, including pharmaceutical, biotech, and medical device companies; contract research organizations; regulatory authorities; clinical investigators; and clinical trial participants.

"We thought it timely to create a database of opinion on key issues," said Thomas Detre, president of PCRN and executive vice president of international and academic programs of the UPMC Health System. "By broadly distributing the findings, we will make a valuable contribution to advacing the goal of informed debate among all the players in our industry."

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