THE CANCER LETTER INTERACTIVE

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Hopkins Begins Review Of All Studies After OHRP Lifts Research Suspension

The Department of Health and Human Services lifted a four-day suspension of research studies involving human subjects at Johns Hopkins University this week, but because of new restrictions imposed by the federal agency, it may take weeks or months for all studies to resume, the university said.

The HHS Office for Human Research Protections suspended all federally-funded research involving human subjects at seven institutions in the Hopkins complex on July 19. The action followed an investigation

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In Brief:

Karlan To Succeed Hoskins As Chairman, DOD Ovarian Cancer Program Advisory Panel

BETH KARLAN, director of the Division of Gynecologic Oncology, Department of Obstetrics/Gynecology at Cedars-Sinai Medical Center, was named chairman-elect of the Department of Defense Ovarian Cancer Research Program Advisory Integration Panel effective January 2002. She will succeed **William Hoskins**, chief of Gynecology Service and Deputy Physician-in-Chief for Disease Management at Sloan-Kettering Cancer Center. . . . **JOHANNES BERKEL** was named president and CEO of the Hipple Cancer Research Center in Dayton, Ohio. He created and directed the Cancer Prevention and Control Division of Feist-Weiller Cancer Center at Louisiana State University Health Sciences Center, Shreveport. Berkel, whose cancer research interests include gastroenterology, will hold the title of professor of epidemiology and director of the Division of Cancer Prevention and Control at Wright State University School of Medicine Department of Community Health, reflecting the collaboration on cancer prevention between Hipple and WSU. The Hipple center said its new mission is to conduct high-quality cancer prevention research in the Dayton area, decrease cancer incidence in the area through educational interventions, decrease morbidity and mortality through targeted programs of early detection, and to support the accrual of cancer patients to clinical trials. . . . **NCI CANCER THERAPY EVALUATION PROGRAM** awarded oversight of clinical research programs to eight institutions for investigational therapies considered interesting, promising, and novel. The institutional contracts are: $3,711,224 for the University of California at Davis whose studies will be performed under the auspices California Cancer

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Studies Resume At Hopkins, OHRP Approves Action Plan

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of the circumstances surrounding the death of a healthy volunteer who participated in an asthma experiment.

Hopkins officials said they worked with OHRP "intensively" over the weekend to address the agency's concerns and enable research to continue.

On July 23, OHRP approved a "corrective action plan" that Hopkins officials formulated as a result of its internal investigation into the death of 24-year-old Ellen Roche, a lab technician who died June 2 of lung damage and multiple organ failure attributed to her inhaling a gram of hexamethonium in an asthma study at Hopkins.

About 2,400 trials were suspended by the July 19 order, and only several hundred trials will resume without a new review, the university said.

According to a statement by Hopkins officials, principal investigators may continue research protocols if they believe it is in the best interests of the subjects.

To enroll new subjects, PIs will have to submit requests to the Institutional Review Board. "All requests for enrollment of new subjects will be reviewed by the applicable IRB and those determined to be appropriate will be forwarded to OHRP for its prior approval," the Hopkins statement said.

All protocols must be re-reviewed by the IRB. When a protocol has been re-reviewed, the requirement for new enrollment will no longer apply.

Some protocols received "expedited review" and have been reinstated, the statement said. All new protocols must be reviewed by the IRB under the corrective action plan procedures.

OHRP determined that the Hopkins IRBs were overburdened and understaffed, and that board members often did not understand federal regulations.

Hopkins officials outline their action plan in a July 21 letter to Michael Carome, director of the Division of Compliance Oversight at OHRP. The letter was signed by Edward Miller, dean and chief executive officer; Chi Van Dang, vice dean for research; and Gregory Schaffer, president of the Johns Hopkins Bayview Medical Center.

In the letter, Hopkins agreed to:

—Develop a standard to determine that a literature search conducted in support of an application for human research is adequate and comprehensive.

—Suspend all research involving non-FDA-approved substances and not proceed unless the criteria for FDA exemption are met or an IND is obtained. Investigators will be required to submit an IND application to the FDA for review or obtain a written opinion from the FDA that an IND is not needed on non-FDA approved substances, prior to any action taken by the IRBs on non-FDA approved substances.

—Ensure that drugs or other substances given to research subjects are of human grade. Commercial sponsors must provide evidence that an IND number or an appropriate exemption has been obtained. For investigator initiated studies, confirmation must be supplied that a substance meets GMP standards for preparation.

—Require that a pharmacist is involved in any study using a substance that is not already FDA approved for marketing or conducted under an IND number issued to an investigator by the FDA.

—Educate investigators to "reinforce the absolute requirement to submit protocol changes for IRB review and approval prior to initiation of such changes."

—Audit all gene therapy protocols begun this year. Hopkins previously audited gene therapy protocols conducted last year.

—Use a consent form checklist to specify the required eight basic elements in an informed consent document, "with particular attention to a description of the reasonably foreseeable risks and discomforts associated with the research."

—Develop policies to "define the steps requires

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to assure that research must be halted by an investigator when exposure of additional subjects to a research procedure would result in increased risk to subjects."

—Expand the number of IRBs and increase support staff.

—Assure that all protocols are presented individually to the IRB, and prepare minutes of the meetings in a more timely fashion.

—Develop informed consent documents that eliminate unnecessarily complex language.

—Further educate IRB members about HHS and FDA regulations.

The full text of the letter is available at: http://www.hopkinsmedicine.org/press/2001/JULY/ActionPlanLetter.htm

The asthma study was conducted by Alkis Togias, an associate professor of immunology at the university. Internal reviews at Hopkins found that Togias failed to find literature from the 1950's indicating that hexamethonium can be toxic to lungs and did not inform the IRB that an earlier subject in the study developed a cough and shortness of breath. Togias's research remains suspended.

Clinical Trials:

Trial Tests Selenium, Vitamin E In Prostate Cancer Prevention

NCI and the Southwest Oncology Group have begun a study to determine whether selenium and Vitamin E can prevent prostate cancer.

The Selenium and Vitamin E Cancer Trial (SELECT) requires an enrollment of 32,400 men, and will take 12 years to complete.

More than 400 sites in the U.S., Puerto Rico, and Canada are recruiting participants. SELECT is the first study designed to look specifically at the effects of vitamin E and selenium, both separately and together, in preventing prostate cancer.

"We are looking for quite a few good men to join SELECT because it is an incredibly important prostate cancer prevention study," said Charles Coltman Jr., chairman of SWOG and director of the San Antonio Cancer Institute.

"Previous research with vitamin E and selenium—in studies focused on other kinds of cancer—suggested that these nutrients might prevent prostate cancer. SELECT is focused on prostate cancer and, when the study is finished, we will know for sure whether these supplements can prevent the disease," Coltman said.

"It is crucial that men of all races and ethnic backgrounds participate in SELECT," said Leslie Ford, associate director for clinical research in the NCI Division of Cancer Prevention. "Since African-American men have the highest incidence of prostate cancer in the world, we especially encourage them to consider joining this trial."

The disease also strikes black men at a younger age, so they will be eligible to enroll in the study at age 50, rather than 55 for other racial and ethnic groups. There is no upper age limit for participation in SELECT.

"The men who join SELECT not only have a chance to prevent prostate cancer for themselves, but they also may help their sons and grandsons live free from the disease," said Ford.

Selenium and vitamin E, both naturally occurring nutrients, are antioxidants capable of neutralizing toxins known as "free radicals" that might otherwise damage the genetic material of cells and possibly lead to cancer. These nutrients were chosen for study because of the results of two other large cancer prevention trials.

In a study of selenium to prevent nonmelanoma skin cancer in 1,000 men and women, reported in 1996, investigators found that while the supplement did not reduce skin cancer, it did decrease the incidence of prostate cancer in men by more than 60 percent.

Another trial, published in 1998, in which beta carotene and vitamin E were tested to prevent lung cancer in 29,000 Finnish men who smoked, those who took vitamin E had 32 percent less prostate cancer. Neither beta carotene nor vitamin E prevented lung cancer. The men who smoked and took beta carotene were more apt to get lung cancer and die from it than men who didn't take this supplement.

"SELECT is the critical next step for pursuing the promising leads we saw for the prevention of prostate cancer," said Ford, who is responsible for all aspects of NCI's involvement in SELECT. "The only way to determine the real value of these supplements for prostate cancer is to do a large clinical trial focused specifically on this disease."

Study investigators hope to recruit all the study participants during the first five years of the trial, so that each man can be followed for at least seven years.

Men in the study will visit their study site once every six months. Upon enrollment, they will be assigned by chance to one of four groups. One group will take 200 micrograms of selenium daily plus an

inactive capsule, or placebo, that looks like vitamin E. Another group will take 400 milligrams of vitamin E daily along with a placebo that looks like selenium. A third group will take both selenium and vitamin E. And a final group will be given two placebos.

Men who join SELECT will not need to change their diet in any way, but they must stop taking any supplements they buy themselves that contain selenium or vitamin E. If participants wish to take a multivitamin, SWOG will provide, without charge, a specially formulated one that does not contain selenium or vitamin E.

Men may be able to participate in SELECT if they:

—are age 55 or older; age 50 or older for black men

—have never had prostate cancer and have not had any other cancer, except nonmelanoma skin cancer, in the last five years

—are generally in good health

For more information about SELECT and a list of participating centers:

—In the United States (including Puerto Rico), call the Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) for information in English or Spanish. The number for callers with TTY equipment is 1-800-332-8615.

—In Canada, call the Canadian Cancer Society's Cancer Information Service at 1-888-939-3333 for information in English or French.

—Visit the NCI Web site at http://cancer.gov/select or visit SWOG's Web site at http://swog.org and choose SELECT.

Four pharmaceutical companies are providing selenium and vitamin E capsules and multivitamins for the study: Roche Vitamins Inc., of Parsipanny, NJ; Sabinsa Corp., of Piscataway, NJ; Nutricia Manufacturing USA Inc., of Greenville, SC; and BioAdvantex Pharma Inc., of Mississauga, Ontario, Canada.

NIH Programs:

NTP Plans Look At Radiation, Viruses, In Carcinogen Report

The National Toxicology Program plans to review three viruses, three forms of radiation, two substances formed in cooking, and a variety of industrial exposures for possible listing in the eleventh edition of the federal Report on Carcinogens, scheduled for publication in 2004.

The NTP, at the National Institute of Environmental Health Sciences, prepares the report every two years. The report is mandated by Congress to help assure that substances or conditions that are likely to cause cancer are properly recognized by the public and regulatory agencies. Substances may be listed as "known" or as "reasonably anticipated" human carcinogens.

The NTP announcement of its plans, which was published in the "Federal Register," asks the public and scientists to comment during the next 60 days on the nominations and to provide any data on whether they are carcinogenic, how much is produced, how they are used and in what ways people are exposed.

The 16 nominations for NTP's planned review are:

—1-Amino-2,4-dibromoanthraquinone, a vat dye used in the textile industry.

—2-Amino-3,4-dimethylimidazo[4,5-f]quinoline (or MeIQ), a substance formed in food during heating or cooking and found in cooked meat and fish.

—Cobalt Sulfate, which is used in electroplating and electrochemical industries, as a coloring agent for ceramics, as a drying agent in inks, paints, varnishes and linoleum and as a mineral supplement in animal feed.

—Diazoaminobenzene (DAAB), which is used to promote adhesion of natural rubber to steel, as a polymer additive and an intermediate in the production of a number of pesticides, dyes and other industrial chemicals.

—Diethanolamine (DEA), which is used in preparing liquid laundry and dishwashing detergents, cosmetics, shampoos and hair conditioners, as well as in textile processing and other industrial uses.

—Hepatitis B Virus (HBV), a small DNA-enveloped virus that is transmitted through contact with blood and blood products or other body fluids.

—Hepatitis C Virus (HCV), an RNA-enveloped virus mainly transmitted in blood as is HBV above.

—High Risk Human Papillomaviruses (HPVs), small non-enveloped viruses that infect genital mucous membranes. HPV infections are common throughout the world.

—X-radiation and gamma radiation, used in medical diagnosis and treatment, and produced in the use of atomic weapons.

—Neutrons, which may affect patients getting neutron radiotherapy and the passengers and crew of aircraft, which are naturally bombarded by the particle.

—Lead: occupational exposures to lead and lead

compounds, as in lead smelting and refining, battery manufacturing, steel welding and cutting, and construction.

—Naphthalene, which is used in making many industrial chemicals, and as an ingredient in some moth balls and toilet bowl deodorants.

—Nitrobenzene, which is used in the production of aniline, a major chemical intermediate in the production of dyes.

—Nitromethane, a stabilizer added to many halogenated solvents and aerosol propellants.

—Phenylimidazopyridine, which, like MeIQ (second item), is formed in food during heating and cooking and is found in cooked meat and fish.

—4,4'-Thiodianiline, which is an intermediate in the manufacture of several dyes.

Comments or questions should be addressed to C.W. Jameson, Room 3118, NIEHS/NTP, 79 Alexander drive, Building 4401, PO Box 12233, Research Triangle Park, NC 27709, or to Jameson@niehs.nih.gov

Professional Societies:

FASEB Urges Congress To Fund Stem Cell Research

At a Senate hearing last week, Mary J. C Hendrix, the past president of the Federation of American Societies for Experimental Biology, urged lawmakers to allow for federal funding of research involving stem cells.

"The public has every right to know exactly what type of human embryonic stem cell research is being performed in our country," Hendrix said. "For that to happen, the government must provide funding and the appropriate oversight for these new research opportunities. In the absence of federal support and oversight, this exciting line of research will occur only behind closed doors."

To ban federal support for such research, she said, "is to delay the prospect of life enhancing biomedical breakthroughs."

Hendrix made these comments before the Senate Labor/HHS Appropriations Subcommittee.

"There is great promise in human embryonic stem cell research, because we might learn how to grow specialized cells for therapeutic purposes," she said. "In my own field of cancer biology, stem cell research holds great promise. That special intrinsic property of stem cells, their ability to renew themselves indefinitely, may shed light on the similar, although uncontrolled growth of cancer cells. By understanding how embryonic stem cells are able to replicate themselves, we might be able to understand the cellular mechanisms by which tumor cells become immortal and grow out of control until they kill the patient."

Hendrix explained the limitations of using adult stem cells in research. "First, it is difficult to identify and isolate adult pluripotent stem cells," she said. "Secondly, adult stem cells appear to be much more restricted in their ability to differentiate into different cell types in the body, and it remains to be proven whether adult stem cells can truly give rise to all cell types in the body. Finally, the ability of adult stem cells to replicate is not as robust as embryonic stem cells."

She also reaffirmed FASEB's support of the NIH Guidelines for Research Using Human Pluripotent Stem Cells.

"Federal funding means medical progress under federal oversight," she said. "Scientists working under the NIH Guidelines and with federal oversight will be allowed to conduct the research and provide the cures and therapies that we are all seeking."

The full text of Dr. Hendrix's testimony is available online at http://www.faseb.org/opar/cloning.pi.page.html

Following is the text of the FASEB Statement on Human Cloning and Human Cloning Legislation:

As a community of scientists, we strongly oppose reproductive human cloning and view this as an irresponsible and misguided act. In animal species where cloning has been attempted, most clones do not survive to term or die at birth, and many that survive have abnormalities. For these reasons, and for the many ethical and moral issues surrounding cloning human beings, FASEB adopted a five-year voluntary moratorium on reproductive human cloning in September 1997.

In this statement, we define "cloning human beings" as "the duplication of an existing or previously existing human being by transferring the nucleus of a differentiated, somatic cell into an enucleated human oocyte, and implanting the resulting product for intrauterine gestation and subsequent birth."

It is critical to distinguish clearly between reproductive human cloning, which we denounce, and other uses of cloning technology that have enormous potential to treat human diseases and repair damaged tissues or organs. The technique of somatic cell nuclear transfer where the nucleus of one cell is removed and replaced with the nucleus of a specialized

cell has the potential to produce large numbers of cells which can then differentiate into many different cell types, such as neurons, pancreatic islet cells, or cardiomyocytes.

These techniques may also make it possible to reprogram an individual's mature cells into specific cell types needed to repair the individual's own damaged tissue. Thus, these cloning techniques would offer therapeutic benefits without the risk of immune rejection. The potential for treating human disease in this exciting area of regenerative medicine is enormous.

We believe that there should be severe penalties for anyone who attempts reproductive human cloning. However, we fear that broadly crafted legislation that attempts to ban human cloning will also prevent the use of cloning techniques. This will block important research and hinder the progress toward uses of this technology in the treatment of disease.

We would support legislation that bans reproductive human cloning, specifically the implantation of cloned cells into a human uterus. However, we believe that such legislation must allow the use of human somatic cell nuclear transfer technology to produce molecules, cells, and tissues for research and therapeutic use. Research into the uses of these techniques must continue, both as a means to understand the complex biology of cellular cloning, and as a way to further therapeutic medicine.

Thus, legislation should be carefully crafted to prevent the use of these techniques only for the purpose of creating a cloned human embryo destined for implantation, gestation and subsequent birth.

HHS News:

HHS Forms Rural Task Force To Study, Improve Programs

The Department of Health and Human Services has formed a Rural Task Force to conduct a department-wide examination of how HHS programs can be strengthened to better serve rural communities.

"The Task Force will reach across all 12 divisions in HHS and will work to assess how we can do a better job of expanding and improving the provision of health care and social services in rural America," HHS Secretary Tommy Thompson said in a speech to the Joint International Summit on Rural and Community Development. "It's a high priority for this administration."

According to HHS, about 54 million Americans who live in rural areas. Health care can represent up to 20 percent of a community's employment and income. In some lower income communities, federal support may account for as much as 50 percent of the income in the community. Medical care and a strong social services network are also important factors for employers who might consider moving to or expanding into rural communities.

Thompson, speaking to an audience of 1,200 via teleconference, told attendees that the Task Force would search for existing regulatory and statutory barriers to serving rural individuals and families. It will examine each division to determine ways to strengthen existing programs and services. The Task Force will explore ways to enhance state health and social service delivery systems. The Task Force will identify places where additional funding might be needed.

"The Task Force will consider any and all ideas," Thompson said. "However, it is imperative as we begin this effort that we remember that rural Wisconsin is different than rural Maine, rural California, or rural Georgia. In health care, rural hospitals and their needs will differ, too, even as the underlying challenges remain the same—financing, personnel, or facilities."

Thompson charged the Task Force with returning within three months a report, recommendations for improvement, and a strategic plan.

Other activities Thompson announced include:

—Developing a "tool chest" of options to help improve the performance of small, rural hospitals. The tools under consideration include access to the same range of expert support services and technical advice now available to urban medical centers as well as the development of small-hospital assessment and performance and improvement tools.

—Working to increase rural hospitals' access to the capital necessary for upgrading technology, equipment and facilities. HHS will work with the Departments of Housing and Urban Development and Agriculture to improve their hospital financing programs.

—Examining the use of Title XII of the Public Health Services Act, which gives HHS broad authority over Emergency Medical Service provider funds for training, recruitment and retention grants. HHS' goal is to keep good EMT personnel on the job in rural America, where EMS systems are stretched thin.

—Working to improve services to older individuals in rural areas through the Administration on Aging's Older Americans Act service network.

Letter to the Editor:

UPCI Clarifies Agreement Between Eli Lilly And PCRN

To the Editor:

We appreciated your excellent coverage on the recently announced agreement between Eli Lilly and Company and Pittsburgh Clinical Research Network (**The Cancer Letter**, Vol. 27. No. 27, July 6).

There were a few statements, however, that we thought important to correct for your readership:

—Pittsburgh Clinical Research Network (PCRN) is a wholly owned for-profit subsidiary of UPMC Health System Diversified Services Inc. (the for-profit arm of UPMC Health System); it is not a spin-off of the University of Pittsburgh.

—The agreement is between Eli Lilly and PCRN, not between Lilly and the University of Pittsburgh.

—While PCRN has a subcontract relationship with the University of Pittsburgh for the conduct of clinical trials, PCRN's subcontracts for clinical trials are handled in accordance with standard University contracting practices.

—The agreement is confined to clinical trials and does not include pre-clinical research. While the University of Pittsburgh and UPMC Health System are closely affiliated tax exempt organizations, neither organization controls, or is controlled by, the other organization.

Ronald Herberman

Director, University of Pittsburgh Cancer Institute; Associate Vice Chancellor for Health Sciences Research, University of Pittsburgh

Funding Opportunities:

ASCO Offers Awards For Young Investigators

Paper Deadline: Nov. 2, 2001

Online Deadline: Nov. 9, 2001

The grant, which has a clinical research focus, is for a one-year period for the total amount of $35,000.

It is comprised of $31,000 to support the grant project, $1,500 for travel related to the project, and $2,500 for the institution. The applicant must be a physician (MD or DO) who, at the time of grant award (July 2002), is in the final year of a fellowship program or in the first year post fellowship.

An institutional commitment at time of grant submission is not required but the applicant should be working in an oncology laboratory or clinical research setting, and should be planning an investigative career in clinical oncology. The applicant should spend at least 60 to 75 percent of his/her time in research during the award period. The applicant must either be a member of the Society or submit a membership application along with the grant application.

Paper applications are currently available. Online applications will be available at http://www.asco.org on Aug.1. Contact the ASCO Training Division at galvinn@asco.org to obtain an application.

Inquiries: American Society of Clinical Oncology, Education, Science and Publications Department, Training Division , 1900 Duke St., Suite 200, Alexandria, VA 22314, phone 703-797-1926; fax 703-299-1044; e-mail fellows@asco.org; Web site http://www.asco.org.

ASCO Clinical Research Career Development Award

Paper Deadline: Nov. 2, 2001

Online Deadline: Nov. 9, 2001

The grant, which has a clinical research focus, is for a three-year period for the total amount of $170,100, paid in three increments of $56,700.

It is comprised of $50,000 per year to support the grant project, $2,500 per year for travel related to the project, and $4,200 per year for the institution. The applicant must be a physician (MD or DO) who, at the time of grant application deadline, is within the first three years in a full-time, primary faculty appointment in a clinical department at an academic medical institution. The applicant should spend more than 50 percent of his/her time in research during the award period. The applicant must either be a member of the Society or submit a membership application along with the grant application.

Paper applications are currently available. Online applications will be available at http://www.asco.org on Aug.1. Contact the ASCO Training Division at galvinn@asco.org to obtain an application.

Inquiries: See preceding award.

Foundation Offers Pancreatic Cancer Research Grants

Application Receipt Deadline: Oct. 12, 2001

Lustgarten Foundation for Pancreatic Cancer Research invites applications for one-year grants of up to $100,000 for research into the biology, diagnosis, treatment modalities, including active, palliative and

supportive, and prevention of adenocarcinoma of the pancreas. National and international applicants will be considered. Funding may be renewed based on first-year results.

Inquiries: The Lustgarten Foundation, 1111 Steward Ave., Bethpage, NY, 11714; fax 516-803-2303; Web site http://www.lustgartenfoundation.org.

In Brief:

NCCS Plans Rays Of Hope Event At Ellipse On Sept. 15

(Continued from page 1)

Consortium, a collaborative, NCI-funded group consisting of the UC Davis Cancer Center, City of Hope National Medical Center and the University of Southern California Norris Comprehensive Cancer Center; $2,904,886 for M.D. Anderson Cancer Center; $3,763,751 for Mayo Clinic; $2,918,547 for Sloan-Kettering Institute for Cancer Research; $2,845,299 for Montefiore Medical Center; $2,689,269 for University of Chicago; $2,716,065 for University of Pennsylvania; and $2,341,727 for Princess Margaret Hospital. . . . **NATIONAL COALITION FOR CANCER SURVIVORSHIP** announced its plans for the 2001 Rays of Hope-Celebrating Survival-Fighting for Victory celebration. Marking 30 years since President Nixon declared war on cancer, Rays of Hope is a day-long event of reflection and inspiration, NCCS said. The event will bring together cancer survivors, families, friends, caregivers, representatives from cancer advocacy organizations, members of Congress, policymakers and celebrities on the Ellipse of the White House on Sept. 15, from 2-8:30 p.m. . . . **LEUKEMIA & LYMPHOMA SOCIETY** Web site won best professional Web site and best patient education Web site by a healthcare/professional society in the World Wide Web Health Awards Competition sponsored by the Health Information Resource Center, a national clearinghouse for consumer health information. The redesigned site lets users access targeted and tailored information ranging from the latest clinical trials to society programs, events and multi-media services. Entries were judged for their accuracy, success in reaching targeted audiences and overall quality. The Web site is available at http://leukemia-lymphoma.org. . . . **KAISER FAMILY FOUNDATION** of Menlo Park, CA, has launched State Health Facts Online, a free Internet resource for journalists, state and federal policymakers, researchers and others, that offers comprehensive and current health information for all 50 states, the District of Columbia and U.S. territories. Users can access health policy information including managed care, health insurance coverage and the uninsured, Medicaid, Medicare, women's health, minority health, and HIV/AIDS. Information can be viewed for a single state or compared and ranked data across all 50 states and compared to U.S. totals. Information on more than 200 topics is displayed in easy-to-read tables and color-coded maps, and can be downloaded for customized comparisons. The Web site is available at http://www.statehealthfacts.kff.org. . . . **PUBLIC AGENDA AND ALBERT AND MARY LASKER FOUNDATION** have begun the Online Guide to Medical Research Issues, with links to background materials, including a synthesis of survey data from organizations such as the Pew Center for People and the Kaiser Family Foundation, a timeline that highlights medical breakthroughs over the last century, and a chart describing FDA guidelines for testing the effectiveness of new drugs in humans. The guide is available at http://www.publicagenda.org/issues/frontdoor.cfm?issue_type=medical_ressearch. . . . **PETER SMALL**, independent management consultant to the health care industry, was named executive director of the University of Pittsburgh Medical Center Health System Pittsburgh Clinical Research Network, effective Aug. 1. Small will report to **Thomas Detre**, president of PCRN and executive vice president of international and academic programs and director of international medical affairs of the UPMC Diversified Services Division. He will work with **Clifford Schold**, recently named chief medical officer at PCRN and assistant vice chancellor for clinical research in the Schools of the Health Sciences at UP to support the clinical research and clinical trials needs of investigators based both within the University and throughout UPMC. PCRN provides project-management services for conducting clinical trials and serves as a single point of entry into UPMC for industry sponsors of trials such as pharmaceutical, biotech and medical device companies. "Creating a well-aligned relationship between the Office of Clinical Research at the University of Pittsburgh and PCRN will better facilitate access to the clinical research experience and expertise among the UP faculty, while at the same time retain a focus on the needs of the pharmaceutical and medical device communities for businesslike partnerships in evaluating potential new therapies, said Schold.

THE CANCER LETTER

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Business & Regulatory Report

Formerly "Cancer Economics"

Oncology Management:

Quality Oncology Wins Pilot Contract For Cancer Management Services In Fla.

Centers for Medicare and Medicaid Services, formerly the Health Care Financing Administration, said it has awarded a five-year federal pilot project to **Quality Oncology Inc.**, a subsidiary of **LifeMetrix Inc**., of Sunrise, FL, to provide care management services to over 1,000 Medicare-eligible cancer patients in South Florida.

QO will coordinate cancer care for the fee-for-service Medicare population, the company said.

QO model of care management and care management tools include

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Product Approvals & Applications:

FDA Approves NDA For Mylan's Paclitaxel For Ovarian And Breast Cancer Treatment

Mylan Laboratories Inc. (NYSE:MYL) of Pittsburgh said FDA approved its abbreviated new drug application for Paclitaxel injection, 6 mg/mL, packaged in 30 mg/5 mL, 100 mg/16.7 mL, and 300 mg/50 mL multiple-dose vials.

Paclitaxel is the generic equivalent to Taxol from the Bristol Myers Squibb Co. Pharmaceutical Research Institute, the company said. Taxol is indicated as first-line and subsequent therapy for advanced carcinoma of the ovary and for breast cancer, the company said.

Mylan said it will market the product through its UDL Division, and shipments will begin immediately.

* * *

Cephalon Inc. (Nasdaq: CEPH) of West Chester, PA, said that Actiq (oral transmucosal fentanyl citrate) has been granted marketing authorization in 16 European countries via the mutual recognition procedure.

The action follows initial approval in October 2000 for marketing and sale in the U.K., the company said.

Cephalon said it has entered into European marketing and distribution partnerships with the following companies: Elan Pharmaceuticals Ltd. in the UK, Grupo Ferrer Internacional SA for Spain and Portugal, Laboratoire L. Lafon for France, Swedish Orphan AB for Iceland, Finland, Norway, Denmark and Sweden, and Elan Pharma for the remaining European Member States.

Actiq is the first drug to be indicated for the management of breakthrough cancer pain in patients with malignancies who are already

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

LifeMetrix Forms Partnership With Colon Cancer Alliance

(Continued from page 1)

the LifeMetrix Integrated Care Management System, a proprietary web-based care management computer application that tracks patient treatment and monitors compliance with clinically established best practices, the company said.

"The challenge facing the healthcare industry is controlling costs without losing track of the primary mission of providing the best care possible for patients," said Edmund Bujalski, chairman and CEO of QO parent company, LifeMetrix. "The QO model of cancer care management accomplishes both goals and can be applied to the management of many other chronic diseases. The pilot project will validate our experience in the commercial sector."

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LifeMetrix Information Services, a subsidiary of LifeMetrix Inc., a cancer care management services provider of McLean, VA, said it has formed a partnership with the **Colon Cancer Alliance**, a nonprofit advocacy group, to create a claims-based, syndicated report on patterns of care and cost of care for colorectal cancer.

"CCA decided to work with LifeMetrix, because they have a wealth of longitudinal data on colorectal cancer," said Kevin Lewis, chairman of the CCA board. "As patient advocates, we want to know as much as possible about actual treatments and patterns of care for patients with colorectal cancer. Lifemetrix is offering data and query capabilities heretofore unavailable to us."

The project will be the first syndicated oncology information resource that traces the longitudinal history of colorectal cancer patients over time, across settings, across specialties, while including all forms of treatment," said Bill Dupere, executive vice president of LifeMetrix Information Services. Furthermore, the report will be the first syndicated resource that documents the actual cost of care."

* * *

IMPAC Medical Systems Inc. of Mountain View, CA, an integrated clinical and administrative management systems provider for oncologists, said it has started marketing PhAST Note (physician assisted structured template note), an electronic noting system that allows oncologists to document patient evaluations in under three minutes.

By using logically structured templates, PhAST Note generates the complete text of a patient note as part of the electronic medical record, eliminating the need for dictation and transcription services the company said.

The technology includes a charge capture/coding feature to enable oncology practices to capture revenue that would have been lost due to undercoding, the company said.

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Barbara Ann Karmanos Cancer Institute at Wayne State University and **Aastrom Biosciences Inc.** (Nasdaq: ASTM) announced the establishment of the Center for Cell Therapy for cancer and other diseases.

The CCT is funded through a $2.2 million grant from the Michigan Economic Development Corp. by the Michigan Life Sciences Corridor Initiative, along with other contributions from the institute and Aastrom, the institute said.

"Innovative cell-based therapies are actively being developed around the world and are beginning to demonstrate positive clinical responses," said Roy Baynes, director of the Bone Marrow Transplantation Program at Karmanos. The CCT will provide the institute access to Aastrom products for ex vivo cellular production and activation, and will allow us to promote the development of new cellular therapies in our clinical environment. Together, we should enable more rapid access to therapeutic cell therapies by patients and their physicians."

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The CCT will begin clinical studies with the AastromReplicell System using cord blood-derived cells that provide a normal blood and immune system in leukemia patients, the institute said. The center will use both the AastromReplicell System and Dendricell cell product to produce dendritic cell-based vaccines for cancer treatment.

The Institute said it has received a $1 million gift from the J.P. McCarthy Foundation to establish a cord blood stem cell bank, and a $1 million gift from the Carls Foundation to create a stem cell processing laboratory, the institute said. The J.P. McCarthy Cord Stem Cell Bank and the Carls Foundation Stem Cell Processing Laboratories will store donated umbilical cord blood for use in stem cell transplants for young and small-size patients to increase the availability of cord blood for minority populations, the institute said.

Product Approvals & Applications:

FDA Approves Trelstar For Advanced Prostate Ca.

(Continued from page 1)

receiving and who are tolerant to opioid therapy for underlying persistent cancer pain, the company said. Actiq is formulated as a drug matrix on a handle, containing fentanyl citrate, an opioid analgesic. It uses a patented oral transmucosal drug delivery system for administration. The most common side effects are somnolence, nausea, vomiting, and dizziness.

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Debiopharm S.A., part of the Debio group of Lausanne, Switzerland, said FDA has granted marketing authorization to its luteinizing hormone releasing hormone agonist, triptorelin pamoate, Trelstar, for advanced stage prostate cancer.

Trelstar is a controlled release formulation of triptorelin that delivers triptorelin continuously over three months after intramuscular injection, the company said.

Clinical studies comparing the effectiveness of the already approved one-month controlled release formulation of triptorelin (Trelstar Depot 3.75mg) and the new three-month formulation of triptorelin (Trelstar 11.25mg) have proven that three-monthly administrations of triptorelin induce and maintain castration levels of serum testosterone as effectively as monthly injections, the company said.

Trelstar, which has an optimal patent life protection in the U.S., is approved in two different presentations: as a vial alone, containing triptorelin pamoate to be reconstituted in sterile water for injection, or as Trelstar DebioClip single-dose delivery system, developed by Debiotech, Switzerland, which consists of a vial of triptorelin pamoate and a pre-filled syringe containing 2 ml sterile water for injection. The DebioClip is device that allows for safe lyophilized drug constitution, and avoids accidental exposure to needlesticks by healthcare workers, the company said.

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EDG Capital Inc. (OTCBB: EDGN) of Garden City, NJ, a developer of nuclear pharmaceuticals for cancer therapeutics, said its subsidiary, **Isotope Solutions Inc.**, received FDA clearance to initiate the first clinical study of its radioactive cisplatin technology for liver cancer.

The study would determine how the tumors and organs take up the radioactive cisplatin (195mPt-Cisplatin) and how it is distributed the body, the company said.

Radioactive Cisplatin takes advantage of cisplatin's ability to bind directly to tumor cell DNA and deliver intense, localized radiation within solid tumors and minimizing injury to surrounding tissues and organs, the company said.

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Millennium & Ilex Partners L.P., a joint venture of **Millennium Pharmaceuticals Inc.** (Nasdaq: MLNM) of Cambridge, MA, and **Ilex Oncology Inc.** (Nasdaq: ILXO) of Boston, said the European Commission has granted marketing authorization to the MabCampath (alemtuzumab) humanized monoclonal antibody for B-cell chronic lymphocytic leukemia patients who have been treated with alkylating agents and have failed fludarabine therapy.

Under the authorization, M&I Partners is granted a single license for marketing MabCampath in the European Union, the companies said. The drug will be marketed by **Schering AG** (NYSE: SHR) of Germany.

MabCampath binds to CD52+, an antigen present on the surface of certain leukemic lymphocytes, and induces antibody-dependent lysis following binding, which results in the removal of the malignant lymphocytes from the blood, bone marrow and other affected organs, the companies said. The CD52+ antigen is also found on nonmalignant lymphocytes, monocytes, macrophages, NK cells, some granulocytes and some normal bone marrow cells.

M&I Partners will conduct a post-approval

clinical trial of MabCampath versus chlorambucil, the standard frontline treatment, the companies said.

In the U.S., Campath (alemtuzumab) is marketed by **Berlex Labs Inc**., the U.S. affiliate of Schering AG.

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Nucletron BV, of Veenendaal, The Netherlands, said it has received FDA marketing clearance for its stereotactic planning software and multi-modality image fusion software for radiation therapy planning.

Stereotactic radiosurgery is used for small brain lesions where radiation therapy offers advantages over other treatment methods, the company said. The SRS system adds features such as automatic optimization that reduce the time needed for the radiation dose distribution. The system is headframe independent, and can be used with all major models and headframes available.

The software offers capabilities to correlate images from different imaging modalities with a choice of correlation methods, the company said. These include the use of user-defined reference points, a stereotactic frame, or manual adjustments of over-laid images. This flexibility makes the technique applicable for planning a wide range of radiation therapy treatments, the company said.

Image fusion allows image sets to be correlated and the target volume transferred to the CT images, the company said. The Nucletron module, PLATO IFS, can be used for both stereotactic radiosurgery planning as well as other radiation therapy methods.

Interest in image fusion continues to increase for both external beam and brachytherapy, where different imaging modalities are used during different planning stages, the company said.

* * *

Varian Medical Systems Inc. (NYSE: VAR) of Salt Lake City said its VariSeed 7.0 software for prostate cancer, received 510(k) clearance from FDA.

The latest version of its VariSeed treatment planning software for permanent seed implant brachytherapy is designed to overcome technical difficulties associated with the protocol, to allow real time planning in the procedure room, and to enable functional image guided therapy, the company said.

"Real-time planning gives the clinician the complete dosimetry picture right there in the procedure room, while there is still time to do something with it," said William Hyatt, general manager of Varian Medical Systems.

With functional image guided therapy, images are fused with those from an ultrasound study and clinicians can create treatment plans that target the actual disease, rather than the entire prostate, the company said.

* * *

YM BioSciences Inc. of Mississauga, Ontario, said Health Products & Food Protection Branch of Canada has approved its investigational new drug application for a phase I/II study of its EGF receptor antibody, TheraCIM h-R3, in conjunction with radiotherapy for brain cancer resulting from metastases from non-small cell lung cancer.

Trials with EGF receptor antibodies together with radiation in head-and-neck cancers suggest that the effect of radiation is improved through combination with antibody, the company said. The trial would test the premise in cancers metastasizing to the brain from NSCLC.

TheraCIM h-R3, a humanized monoclonal antibody tyrosine kinase inhibitor, targets EGFr, which has been shown to be overexpressed in cancers of epithelial origin such as head-and-neck, lung, colorectal, stomach, kidney, esophogeal, renal carcinoma, breast cancer, ovarian, prostate, glioma and others, the company said.

Clinical Trials:

EntreMed Begins Phase I/II Trial For Endostatin

EntreMed Inc. (Nasdaq: ENMD of Rockville, MD, said it has begun enrollment in a phase I/II study to assess the efficacy and safety of recombinant human Endostatin (rhEndostatin), a naturally occurring angiogenesis inhibitor.

The trial will be conducted at M.D. Anderson Cancer Center.

In phase I studies, rhEndostatin was shown to be without dose limiting toxicity and demonstrated biologic activity and clinical responses in a variety of tumor types, the company said.

Data showed that angiogenesis inhibitor lowered vascular endothelial growth factor levels, decreased tumor blood flow and tumor metabolism and induced endothelial cell death—indications that rhEndostatin may suppress blood vessel and tumor growth, the company said.

Also, a few patients experienced stable disease and tumor shrinkage in the early trials while receiving a single daily injection of rhEndostatin, the company

said. In the 30 patient phase I/II single-center, open label, dose-escalation study, the drug will be administered by continuous intravenous infusion for a variety of cancers, emphasizing those with sarcoma and melanoma, the company said. Roy Herbst is the principal investigator.

Phase I studies of continuous infusion of rhEndostatin are conducted at the Free University of Amsterdam, the Netherlands, and the Dana Farber-Harvard Cancer Center, the company said.

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Cell Genesys Inc. (Nasdaq: CEGE) of Foster City, CA, said it has initiated a second multicenter phase I/II trial of Gvax lung cancer vaccine for advanced stage non small-cell lung cancer.

The new trial will enroll 40 patients and will be conducted at eight medical centers in the U.S.

An ongoing phase I/II trial of the vaccine has demonstrated antitumor activity where chemotherapy and radiation treatments have failed, the company said.

The objective evidence of antitumor activity included a response rate of 18 percent in 22 patients, the company said.

Three patients, two of whom had failed chemotherapy and one who failed radiation therapy, showed a complete disappearance of metastatic tumors following treatment with the vaccine and a fourth patient who failed both radiation and chemotherapy had partial (greater than 50 percent) reduction in his tumor, the company said.

Four additional patients were reported to have stable disease. All of these responses were ongoing with a median follow-up time of approximately five months. Seven of eight patients with early-stage lung cancer who received the vaccine following surgery, were free of disease with a median follow-up time of seven months, the company said.

Gvax vaccines are genetically modified, irradiated tumor cells that produce an immune hormone, which stimulates an antitumor immune response, the company said. In contrast, Gvax prostate and pancreatic cancer vaccines are non patient-specific vaccines that can be developed as off-the-shelf pharmaceuticals. Lung cancer was selected for the evaluation of a patient-specific vaccine since, unlike prostate and pancreatic cancer, there are multiple types of lung cancer and therefore, a single non patient-specific product would be more difficult to develop, the company said.

Cell Genesys is testing both patient-specific and non patient-specific of the vaccines, the company said.

CG said it is evaluating two formats of a patient-specific lung cancer vaccine, one of which will be selected for phase III trials. In the ongoing trial, the patient's own tumor cells are directly modified to produce the immune hormone. In the newly initiated study, the patients' tumor cells are mixed with a non patient-specific product which produces the immune hormone and which is manufactured at Cell Genesys.

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Enzon Inc. (NASDAQ: ENZN) of Piscataway, NJ, said it has begun a phase II trial for Prothecan (PEG-camptothecin) for small-cell lung cancer.

The open-label study will enroll up to 60 patients and evaluate the anti-tumor activity of the drug, the company said. Prothecan is a PEG-enhanced version of the anti-cancer compound, camptothecin, a topoisomerase I inhibitor.

Camptothecin is an effective oncolytic agent, but drug delivery problems have limited its use, the company said. Two camptothecin derivatives, topotecan and irinotecan, have been approved by the FDA for the treatment of small-cell lung and colorectal cancers, respectively.

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Matrix Pharmaceutical Inc. (Nasdaq: MATX) of Fremont, CA, said it has begun a phase II study of IntraDose (Cisplatin/Epinephrine injectable gel) in hepatocellular carcinoma.

In the 60-patient open-label, multi-center study, patients will receive weekly percutaneous intra-tumoral injections under ultrasound guidance for four weeks and are eligible for re-treatment. The study endpoints include tumor response, duration of tumor response and survival.

The gel formulation, which is directed at locally recurrent or metastatic solid tumor cancers, is injected into tumors, delivering high concentrations of cisplatin for an extended time period while reducing systemic effects associated with intravenous administration, the company said.

* * *

MGI Pharma Inc. (Nasdaq:MOGN) of Minneapolis said it has initiated a combination phase I trial of its anti-cancer compound, irofulven, and Gemzar (gemcitabine hydrochloride) for advanced cancers.

The 30-patient dose-escalation trial will determine the maximum tolerated dose of the two drugs used in combination, the company said. Other

study objectives include safety, anti-tumor activity and the pharmacokinetic profile of the two drugs in combination.

Irofulven (also known as MGI 114, hydroxymethylacylfulvene, or HMAF), an acylfulvene, has demonstrated anti-tumor activity as a single agent in clinical testing against pancreatic, ovarian and prostate cancers, the company said.

Gemzar (gemcitabine hydrochloride) is a pyrimidine analog approved in the U.S. for the treatment of locally advanced or metastatic pancreatic cancer and in combination with cisplatin for the treatment of locally advanced or metastatic non-small cell lung cancer, the company said.

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Novuspharma SpA (Nuovo Mercato: NOV.MI) of Monza, Italy, said it has begun recruitment for a phase II trial of BBR 3464, its tri-platinum complex, for advanced pancreatic cancer.

The 50 patient, open label multi-center trial, to be conducted in the US, is being co-ordinated by Virginia Commonwealth University at Richmond, the company said.

The study complements other ongoing phase II studies with small cell lung cancer with one prior failed chemotherapy regimen in Europe, where BBR 3464 is being evaluated against non-small cell lung cancer, ovarian and gastric cancer.

The scientific team who founded Novuspharma, in collaboration with Nick Farrell, of the Virginia Commonwealth University, developed BBR 3464, a platinum compound, the company said.

The compound works by binding to the DNA within cancer cells, disrupting cell growth and replication and inducing apoptosis, the company said. However, the development of resistance occurs in platinum-based therapy with the effectiveness significantly reduced each time it is used.

In preclinical studies, the compound demonstrated that it binds in a different manner to the DNA in cancer cells, thereby increasing efficacy, as well as producing an effect in cisplatin- resistant tumors, the company said.

In phase I studies, conducted in Europe last year, the compound showed preliminary signs of biological activity against pancreatic cancer, melanoma and lung cancer.

Novuspharma said it has an exclusive international license to the technology from Hoffmann-La Roche. Under the license, HLR has a buy-back option on BBR 3464.

Deals & Collaborations:

BMS, Exelixis To Collaborate On Drug Development

Bristol-Myers Squibb Co. (NYSE: BMY) of Princeton, NJ, and **Exelixis Inc.** (Nasdaq: EXEL) of South San Francisco said they have entered into collaboration and licensing agreement to develop drugs for defective tumor suppressor gene pathways.

Exelixis said it would identify and validate molecular targets that trigger cell death in cancer cells, while leaving normal cells unharmed. BMS will validate the targets in human models.

Each company will have the option to obtain worldwide rights to equal numbers of validated targets, allowing them to develop small-molecule drugs, the companies said. BMS may use the Exelixis expertise in assay development, high throughput screening, medicinal chemistry and preclinical pharmacology for the selected targets.

Exelixis will receive a worldwide license to develop and commercialize Rebeccamycin, an analogue of the BMS anticancer compound, the companies said. The analogue has shown anti-cancer activity in phase I and early phase II trials being conducted by NCI under a clinical trials agreement. Bristol-Myers Squibb said it would provide access to its internal clinical development capabilities to Exelixis.

Each party has rights of first negotiation with respect to cancer compounds that result from the targets validated and licensed out, the companies said. In addition, BMS will make an equity investment in Exelixis and provide an up-front licensing fee and research support to Exelixis.

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Antigenics Inc. (Nasdaq: AGEN) of New York, NY, said it has acquired **Aronex Pharmaceuticals Inc.** (Nasdaq: ARNX) following approval by Aronex shareholders.

The merged company now includes the Aronex four mid-to-late-stage development products: Atragen, an intravenous formulation of ATRA (all-trans-retinoic acid) for leukemia and other cancers; Nyotran, a formulation of a topical polyene anti-fungal drug in phase III development; Aroplatin, a novel platinum analogue for kidney toxicity and biochemical resistance associated with current platinum drugs for cancer treatment; and Annamycin, an anthracycline analogue designed to overcome heart toxicity associated with current anthracyclines, the company said.

The Antigenics regulatory team is working with

FDA to address concerns in a non-approval letter for Atragen, the company said.

Under the terms of the merger agreement, Aronex shareholders will receive 0.0594 shares of Antigenics shares for each of their Aronex shares, the company said.

The acquisition is expected to be accretive to the Antigenics earnings in 2003, the company said.

* * *

Aventis Pharma of Bridgewater, NJ, the pharmaceutical company of **Aventis SA**, (NYSE: AVE) of Strassbourg, France, said it has entered into a worldwide licensing agreement with **Ajinomoto Co. Inc.** of Japan, to develop, manufacture and market AVE8062 (AC-7700) for tumors.

AVE8062, represents a new strategy for the treatment of solid tumors by targeting existing tumor blood vessels that supply nutrients and oxygen to tumor cells, the company said. In animal studies, the agent produced a blood flow shutdown of the established tumor vasculature, the company said. The agent has been shown to be active against many different tumor types with activity observed in late stage disease usually unresponsive to chemotherapy, the company said.

Under the agreement, Aventis receives worldwide rights to develop, manufacture and market the product in exchange for certain milestone payments and, ultimately royalty payments.

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Endocare Inc. (Nasdaq: ENDO) of Irvine, CA, said it has entered into a marketing alliance with **Healthtronics Surgical Services Inc.** (Nasdaq: HTRN) of Marrieta, GA, to establish the Cryocare system for primary and recurrent prostate cancer.

Endocare will supply cryoablation systems to the Healthtronics partner physicians and the companies will establish the Cryocare system.

Sales activities are expected to commence immediately, the company said. HSS is a urologic and orthopedic services provider to patients in thirty-five states through physician partnerships.

* * *

Boston Biomedica Inc. (Nasdaq: BBII) of West Bridgewater, MA, said its subsidiary **BBI Biotech**, of Gaithersburg, MD, has been awarded a five-year, $10.3 million contract from **NCI** for the processing and storage of biological specimens for cancer studies.

Under the contract, BBI Biotech will process and preserve biologic materials including blood products, tissues, and other biological specimens for long-term storage; distribute samples to collaborating investigators; maintain the existing specimen repository of 2.3 million samples; evaluate and pilot new technologies germane to the contract mission; and manage information on the quality, quantity and location of specimens for the biorepository and bioprocessing laboratories, the company said.

* * *

Cell Matrix Inc. of Los Angeles said it has been awarded $200,000 for two phase I small business innovation research grants from **NCI** for anti-angionenesis products discovery.

Cell Matrix said it is developing antibodies that block denatured extracellular matrix proteins, a pathway for downstream inhibition of the angiogenesis cascade.

* * *

Cray Inc. (Nasdaq:CRAY), a company that designs, builds and sells high-performance MPP, vector processor and general-purpose parallel computer systems, said it is collaborating with **NCI** to develop bioinformatics research tools, such as genome analysis software, capable of identifying and analyzing cancer and other genes.

In a demonstration project, scientists at the NCI Advanced Biomedical Computing Center in Frederick, MD, produced a comprehensive map of short tandem repeat sequences for the entire human genome, the company said. Using the Cray SV1 supercomputer at NCI, computations that previously took hours are being completed in seconds, enabling biologists to do full-scale analyses that previously were impractical, the company said.

* * *

Dianon Systems Inc. (Nasdaq: DIAN) of Stratford, CT and **UroCor Inc.** (Nasdaq: UCOR) of Oklahoma City, said Dianon would acquire Urocor in a stock-for-stock transaction with an equity value of approximately $180 million giving the company a leading market share in the urology and cancer diagnostics market.

The acquisition will be structured as a tax-free share exchange and will be accounted for as a purchase, the companies said. Each share of UroCor common stock will be converted into the right to receive 0.4064 shares of Dianon common stock up to a maximum of $18.00 per share of UroCor common stock. Kevin Johnson will continue as president and CEO, the companies said.

The acquisition is expected to close in the fourth quarter of this year, the companies said.

* * *

Genencor International Inc. (Nasdaq: GCOR) of Palo Alto, and **Epimmune Inc.** (Nasdaq: EPMN) of San Diego, said they have entered into a 30-month collaboration to develop therapeutic vaccines for three oncogenic viruses.

Genencor said it has exclusively licensed the Epimmune epitope and Padre technologies and related intellectual property rights for vaccines to treat or prevent hepatitis C, hepatitis B and human papilloma virus. Also, Genencor has taken an initial 10 percent equity stake in Epimmune.

Through the collaboration, Epimmune will receive an upfront payment, research and development funding, and milestone payments, the companies said. The company will also receive royalties on future product sales and Genencor will have exclusive commercialization rights to vaccines for the three oncogenic viruses, the companies said.

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Incyte Genomics Inc. (Nasdaq: INCY) of Palo Alto, and **Lexicon Genetics Inc.** (Nasdaq: LEXG) of The Woodlands, TX, said they would leverage the respective technology and intellectual property assets of both companies to develop a pipeline of therapeutic protein drug products.

The collaboration will consist of four major components: a therapeutic protein drug discovery alliance; the co-promotion by Incyte of the Lexicon LexVision database to pharmaceutical and biotechnology companies; access for Incyte to the Lexicon LexVision database and access for Lexicon to the Incyte LifeSeq Gold genomic database, the companies said. Financial terms were not disclosed.

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Myriad Genetics Inc. (Nasdaq: MYGN) of Salt Lake City said it would collaborate with **Bioscientia Ltd**., an international reference laboratory company of Ingelheim, Germany, to provide its BRACAnalysis predictive medicine products in Germany, Switzerland and Austria.

Under the agreement, Bioscientia will send test specimens for the comprehensive BRACAnalysis full-sequence test to Myriad for analysis, the company said. Myriad will transfer technical know-how for site-specific mutation detection to Bioscientia.

* * *

Wyeth-Ayerst Labs, the pharmaceutical division of **American Home Products Corp.** (NYSE: AHP) and **Taxolog Inc**., a privately held company of Fairfield, NJ, said they have entered into a collaboration and licensing agreement to research compounds for use as anti-tumor agents that Wyeth will exclusively develop, manufacture, and commercialize.

The terms call for Taxolog to receive an undisclosed up-front signing fee, research support funding, and payments upon reaching development milestones as well as royalties on sales, the companies said. AHPC said it would make an equity investment in Taxolog.

TL-139, a taxane and the first jointly developed compound, will enter phase I trials in July, the companies said. In preclinical studies, TL-139 demonstrated anti-tumor activity against human tumor cell lines that are sensitive or resistant to marketed taxanes.

Emerging Technologies:

Beckman Coulter Offers Immunoassay System

Beckman Coulter Inc. (NYSE:BEC) of Fullerton, CA, said it has launched the Access 2, a second-generation immunoassay system for diagnostic laboratories that incorporates proprietary networking technology to allow multiple units to function as a single system.

In a networked configuration, up to four Access 2 units can share information for a combined throughput of up to 400 tests per hour, providing flexibility to accommodate low-, medium- and high-volume laboratories, the company said. The technology runs individual tests and complete panels in the diagnosis and treatment of 36 medical conditions in the U.S., including cardiac, cancer, anemia, thyroid, fertility and infectious disease tests.

Among the cancer tests are the Access Hybritech PSA and free PSA tests, which diagnose and monitor prostate cancer in conjunction with digital rectal examination, the company said.

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Biomoda Inc. of Albuquerque, NM, said it has begun the commercialization process for Porvidx, its patented early cancer detection technology.

The company will market early lung cancer screening with an inexpensive, non-invasive lab test that detects cancer and precancerous cells in a sputum specimen as early as seven years before disease symptoms appear, the company said. The technology produced no false negative results in a lung cancer clinical study, the company said.

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