THE CANCER LETTER INTERACTIVE

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ASCO Backs Central IRB For Cancer Trials, Stiffens Conflict-of-Interest Policies

The American Society of Clinical Oncology this week recommended that ethical oversight of cancer clinical trials be centralized, reducing the burden on local Institutional Review Boards and streamlining review.

The society also revised its conflict of interest policy, requiring clinical cancer researchers seeking to publish or present trial outcomes to disclose virtually all financial ties to trial sponsors, and restricting the financial interests of principal investigators and other clinical trial leaders. The requirements apply to all those engaged in ASCO activities.

"Clinical trials are a critical part of patient care, and are essential to

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In Brief:

Duke Picks Lyerly To Direct Cancer Center; Parkinson Heads Oncology At Amgen

H. KIM LYERLY was selected director of the Duke Comprehensive Cancer Center, said **R. Sanders Williams**, vice chancellor for academic affairs and dean of the School of Medicine at Duke. Lyerly is professor of surgery, associate professor of pathology, and assistant professor of immunology at Duke University Medical Center. He is also a member of the cancer center. Lyerly succeeds **Michael Colvin.** Lyerly was part of the team of investigators who first reported the use of AZT for the treatment of HIV infection. He is a fellow of the American College of Surgeons, and serves as vice-chairman of its oncology group and chairman of the Basic and Correlative Science Committee. He is a councilor and member of the Executive Council of the Association for Academic Surgery. . . . **DAVID PARKINSON** was named Oncology Therapeutic Area Head at **Amgen Inc.** Parkinson, who leaves Novartis Oncology as vice president for translational development, was involved in developing the agents Gleevec, Femara, and Zometa. Before joining Novartis six years ago, he was the associate director of the NCI Cancer Therapy Evaluation Program. . . . **JOHN REED**, president and CEO, The Burnham Institute of La Jolla, Calif., received a five-year, $500,000 Unrestricted Cancer Research Grant from Bristol-Myers Squibb Co. The grant provides seed funding for the institute's cancer drug discovery programs. Reed is credited with the discovery of numerous proteins that regulate the programmed cell death pathway in cancer and demonstrating that resistance to anti-cancer drugs is linked to anti-death genes that cancer

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Stricter Conflicts Policy Goes Into Effect In 2004

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making advances that may ultimately cure cancer," said ASCO President Paul Bunn, Jr. "These policies are designed to improve the cancer research system in America, and preserve public trust in clinical trials."

The policies were developed by a Task Force on Oversight of Clinical Research, led by Lowell Schnipper, chairman of the ASCO Ethics Committee. The policies will appear in the June 15 issue of the Journal of Clinical Oncology and were published online April 29 at www.jco.org.

Central IRBs

Over the past four years, the movement for support of centralized review boards has gained momentum. NCI formed a pilot CRB two years ago to test how the concept would work. Institutional buy-in to the concept has been slow, NCI officials have acknowledged.

Proponents of a CRB for cancer clinical trials include the NCI-funded clinical trials cooperative groups, as well as the National Cancer Policy Board of the Institute of Medicine, which supported the concept in a recent report.

Since a majority of cancer clinical trials are conducted at multiple institutions, sometimes hundreds of local IRBs are asked to review the same trials.

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"IRBs are completely overburdened," Schnipper said. "The feel they are sub-optimally financed, and the clinical trials are growing. There is a tremendous duplication in expense."

IRBs also may not have access to people with the wide range of expertise needed to competently review complex trials, Schnipper said. In the current drop-off in hospital income, some small community hospitals are considering shutting down their IRBs, thus not providing patients the option of enrolling in trials.

"What has evolved in our thinking is a regionalized IRB that is populated with individuals with great expertise in the clinical trials process," Schnipper said. "We propose developing a model system, starting with the cooperative group system. By centralizing, or regionalizing, we firmly believe we will reduce duplication of effort, reduce the cost of the entire research budget, and sustain consistency in oversight."

ASCO did not way how much it might cost to operate a central IRB, but proposed that it be paid for out of NIH and industry funds.

The centralized system would be a conduit for safety information to local IRBs.

Under the system proposed by the ASCO task force, a centralized review board would be responsible for the initial ethical review of a trial, would coordinate data gathering, monitor adverse events, and would give local IRBs an analysis and summation of adverse events across the trial sites.

The policy statement does not recommend changing the local IRB role in monitoring patient safety onsite during a trial or ensuring proper staffing and adherence to protocol.

The ASCO task force also made the following recommendations:

—*Education and Training:* All IRB members, investigators, and members of the research staff should receive comprehensive, ongoing education and training on the ethical conduct of research to ensure the safety of research participants and the scientific integrity of research.

—*Informed Consent*: The IRB should focus attention on oversight of the informed consent process, not chiefly the informed consent document. Where possible, informed consent forms should be simplified to ensure understanding by potential trial participants.

—*Federal Oversight*: The HHS Office of Human Research Protections and FDA should

provide clear regulatory support and uniform guidance to local IRBs and modify regulations to allow greater use of CRBs.

—*Resources Supporting Clinical Research Infrastructure*: Institutions should devote adequate funding and institutional support to their research review system to ensure effective research oversight.

—*Conflict of Interest*: In addition to revising its conflict of interest policy, ASCO recommends that all those involved in the clinical research team make disclosures of their financial interest in the trial sponsor to a standing institutional committee for review. The informed consent form should include basic information on how the trial is funded, and the IRB should determine what additional information about the clinical investigator should be disclosed.

Bunn said ASCO and NCI will meet to discuss the evaluation of the NCI pilot CIRB, and the potential for setting up a non-governmental CIRB. NCI's CIRB is "slower and more cumbersome than the ideal," Bunn said.

Conflict-of-Interest Policy

Since ASCO adopted its first conflict of interest policy in 1996, cancer clinical research has become increasingly dominated by private, rather than public, investment, resulting in heightened concern over the financial ties between investigators and private industry, the society said.

"This updated policy seeks to ensure public trust in the clinical research system by ensuring disclosure of nearly all financial ties and by restricting the financial interests of people in trial leadership positions," Schnipper said. "While we remain confident in the integrity of clinical investigators, the goal of this policy is to increase the transparency of clinical cancer research overall."

Background research conducted by ASCO found a wide range of disclosure requirements, depending on the trial sponsor. NIH requires disclosure of payments or holdings of stock in excess of $10,000 per year, while some universities had a threshold of $100,000 for non-NIH trials. Trials conducted under the auspices of the FDA require investigators to disclose payments from a trial sponsor in excess of $25,000 during a clinical trial and for one year after the trial, and holdings of more than $50,000 equity interest in the sponsor.

ASCO's previous guidelines required disclosure of ownership of $1,000 or more in publicly-traded companies sponsoring the clinical trial as well as honoraria in excess of $2,000 per year or $5,000 over a five-year period. The new policy requires researchers submitting abstracts or making presentations at the ASCO annual meeting, authors submitting papers to JCO, and anyone serving on the ASCO board or committees to disclose virtually all financial ties to entities having a commercial interest in the subject matter. Financial ties that must be disclosed include:

—Money earned through an advisory role, employment, leadership position or expert testimony

—Stock ownership (except when invested in a diversified fund not controlled by the individual)

—Honoraria

—Research funding

—Any other remuneration such as trips (excluding research-related), travel and gifts with a value of over $100.

"With more than 3,700 abstracts submitted to ASCO's annual meeting this year, 500 studies published in JCO each year, and 20,000 ASCO members, these policies will affect a substantial proportion of the clinical cancer research community," Bunn said.

The guidelines also restrict individuals in a trial leadership role—including principal investigators, members of the data safety monitoring board, and members of the trial's executive committee—from receiving or holding any of the following:

—Stock or equity interest in the trial sponsor (except when invested in a diversified mutual fund not controlled by the individual).

—Royalties or licensing fees from the product or treatment under investigation.

—Patents for the product or treatment under investigation.

—Position as officer, board of directors' member, or employee of the trial sponsor.

—Travel or trips paid by the trial sponsor to attend scientific or educational meetings, not including travel or trips for either: widely attended and independently sponsored scientific meetings with the primary purpose of making a presentation on the trial, or investigator meetings related to the conduct of the trial.

—Research-related payments substantially exceeding actual research costs from the trial sponsor.

—Honoraria or gifts from the trial sponsor, excluding research compensation related to the time and efforts of the researcher and his/her staff.

The Task Force also identified the following activities as inappropriate for any cancer researcher: accepting any payments for referral or accrual to a trial; accepting payments contingent on particular research outcomes; and signing research contracts in which the sponsor has the ability to override the decision to publish or present trial results.

The new conflict-of-interest policy will take effect May 1, 2004.

NCI Programs:

NCI Says Men, Especially Blacks, Should Eat "9 A Day"

NCI and the Department of Health and Human Services last week began a public education campaign to encourage African-American men to eat more fruit and vegetables.

The goal of the campaign, launched during National Minority Cancer Awareness Week, April 20-26, is to motivate black men to eat nine servings of fruits and vegetables a day to reduce their risk for diet-related diseases that disproportionately affect the black community.

"African-American men suffer much higher rates of almost every type of cancer than white men, and they're more likely to have heart disease and high blood pressure," said HHS Secretary Tommy Thompson. "These leading causes of death are largely preventable through changes in our lifestyle choices. The 9 A Day campaign will help us to start emphasizing prevention of this epidemic by letting African-American men know the vital importance of eating fruits and vegetables to their overall health."

NCI has updated its recommendations for fruit and vegetable consumption. A minimum of five servings a day is recommended for children under 6 years. Older children and most women should eat seven servings of fruits and vegetables a day and teenage boys and most men should eat nine, NCI said. The recommendation also supports the Dietary Guidelines for Americans 2000 and the U.S. Department of Agriculture's Food Guide Pyramid.

Although black men are among the most seriously affected by diet-related chronic diseases, they have the lowest consumption of fruits and vegetables overall, eating an average of only 3.1 servings a day of the 9 recommended for men by federal nutrition policy, NCI said. Only 3 percent of black men are aware that men should eat 9 servings of fruits and vegetables a day for better health.

"We must not ignore the excessive burden of cancer in black men," said NCI Director Andrew von Eschenbach. "Black men have the highest rates of prostate, lung, colon, oral, and stomach cancers and are over 140 percent more likely to die from cancer than white men. Since we recognize one third of all cancers are related to diet, this is one area that demands our attention. By eating 9 servings of fruits and vegetables a day, the risk of diet-related diseases affecting the African-American community can be lowered."

HHS and NCI will work with African-American organizations and other health organizations on the campaign, the American Cancer Society, National Medical Association, National Association for the Advancement of Colored People, National Association of Black Journalists, and Black Entertainment Television. "This campaign to reach African-American men is a major priority for NCI," said Lorelei DiSogra, director of the National 5 A Day for Better Health Program, which promotes the general recommendation for Americans to eat five to nine servings of fruits and vegetables a day. "We are committed to driving a national, multi-year, multi-faceted communications and education campaign to get the 9 A Day message to African-American men."

The campaign also includes: National radio advertisements that are airing on ABC's Urban Advantage Network, as well as additional radio in the Washington, D.C., market; a Web page, www.9aday.cancer.gov; and a brochure for black men about the health benefits of eating more fruits and vegetables and tips on how to eat 9 A Day.

To support the new "eat five to nine servings of fruits and vegetables a day" recommendation, NCI has updated its official campaign logo.

* * *

NCI Files Opposition to Protect "5 A Day" Logo: On April 9, NCI filed an opposition with the U.S. Patent and Trademark Office to protect the trademark for its 5 A Day campaign.

The opposition concerns Dairy Management Inc.'s use of the slogan and logo "3 A Day" for a campaign encouraging dairy product use. NCI said the dairy campaign " will cause confusion" with its 5 A Day campaign.

"The NCI has spoken with the Dairy Council about the issue and is committed to working with its 5 A Day program partners and with Dairy Management Inc. to resolve the current situation and ensure that consumers aren't confused by different

recommendations about what to eat or drink," the Institute said in a statement.

* * *

NCI Restores Abortion Fact Sheet: NCI has posted a new fact sheet on abortion, miscarriage, and breast cancer risk to replace the statement the Institute removed from its Web site last year under political pressure (**The Cancer Letter**, July 12, 2002, Vol. 28 No. 28).

The new statement, posted at http://cis.nci.nih.gov/fact/3_75.htm, reaffirms the conclusions reached by a workshop earlier this year that abortion does not increase a woman's risk of breast cancer (**The Cancer Letter**, March 7). It replaces an "interim" fact sheet posted last fall.

* * *

HHS will begin promoting new public service announcements and materials to encourage colorectal cancer screening for persons over age 50.

The Screen for Life campaign was developed by the Centers for Medicare & Medicaid Services, CDC, and NCI.

For further information, see www.cdc.gov/cancer/screenforlife.

* * *

Cancer Control: NCI, CDC, and the Substance Abuse and Mental Health Services Administration last week released Web-based tools for comprehensive cancer control planning, implementation, and evaluation.

The tools, which the agencies said could help communities better understand and address their cancer burden, are available through a Web portal called the Cancer Control PLANET (Plan, Link, Act, Network with Evidence-based Tools) and were developed in collaboration with the American Cancer Society: http://cancercontrolplanet.cancer.gov.

"Cancer control programs at the state and community level are often developed on an 'ad hoc' basis," said NCI's Jon Kerner, PLANET development team director. "PLANET helps take the guesswork out of program planning and implementation by providing easy access to a set of evidence-based tools, including the latest cancer and risk factor statistics and research-tested programs."

NCI plans to add resources to PLANET on sun safety, breast, cervical and colorectal cancer screening, informed decision-making interventions for screening where benefits are uncertain (e.g., prostate cancer), and 5 to 9 A Day fruit and vegetable dietary interventions.

16 Institutions Win NCI Grants For Early Clinical Trials

NCI has awarded 16 U01 cooperative agreements for Early Clinical Trials of New Anti-Cancer Agents with Phase I Emphasis.

The grant program, which NCI began 30 years ago, provides support for the development of new cancer treatments. Total funding for the first year of the program is $7.2 million. Prior to the new awards, there were 14 U01s and eight contracts with single sites and consortia for the performance of early clinical trials with phase II emphasis.

The new awards provide improved geographic access to early clinical trials, incorporating new sites at Duke University, University of Colorado, University of Pittsburgh, and Vanderbilt University, said Louise Grochow, chief of the NCI Investigational Drug Branch, which directs the program.

"These cooperative agreements will allow NCI to support conduct of outstanding initial clinical and laboratory correlative studies of promising anti-cancer agents available either from NCI's drug screening program or referred to NCI from pharmaceutical companies, biotechnology companies, and academia," Grochow said.

"The expanding understanding of molecular targets for cancer treatment and the increasing identification of potential novel therapeutic strategies provides an extraordinary opportunity for NCI, in partnership with clinical investigators and the pharmaceutical industry, to expeditiously evaluate these approaches in early clinical trials," Grochow said.

The Vanderbilt U01 will leverage a research partnership with Meharry, paralleling the N01 (phase II contract) support between Mayo and Howard University, Grochow said.

Vanderbilt will receive $115,000 per year over a five-year grant cycle to support infrastructure. However, the importance of the designation as a phase I center far exceeds the dollar amount, said Mace Rothenberg, professor of Medicine, Ingram Professor of Cancer Research and director of VICC¹s Phase I Drug Development Program.

"By being recognized in this program, we are one of the 16 sites that the NCI looks to for the most innovative clinical, laboratory and translational research," Rothenberg said. "It gives us an important seat at the table."

Phase I clinical trials, as the very first test of

new drugs in patients, represent an important linchpin between research that shows promise in the laboratory and ultimate advances in clinical care. Phase I centers are expected under the cooperative agreement to conduct studies of new cancer therapies provided by NCI and the pharmaceutical industry.

"The number of new agents has grown exponentially over the past decade, from about 40 to about 350 at any given time," Rothenberg said. "The NCI and the pharmaceutical industry really needs these centers to evaluate these new agents."

Under its agreement, VICC will be expected to conduct at least one clinical trial each year. "This will give us time to really ramp up slowly and do things right," Rothenberg said. "In the first year or two of the agreement, I expect that one or two of the eight or 10 phase I trials we conduct each year will be done through this agreement."

Trials done under the agreement require rigorous reporting of data to NCI on a bi-weekly basis. These trials include a strong translational component, including studies looking for biologic markers of drug activity.

The VICC will most likely use the infrastructure support from the NCI to cover personnel costs for tissue sample collection and informatics to maintain and process data, Rothenberg said.

The drugs that will be tested through the agreement are selected through a "Letter of Intent" process. The NCI periodically issues calls for these proposals, which are then peer-reviewed and those that are selected are then often tweaked further by the NCI. Any center can compete for these awards, but the designated phase I centers have an advantage, because they have NCI support for infrastructure, including coverage of personnel costs for tissue sample collection and informatics.

"A lot of the drugs we¹ve chosen to evaluate, including COX-2 inhibitors and inhibitors of the epidermal growth factor receptor, illustrate how we can tie into our historical strengths in basic research," Rothenberg said. "I anticipate that we¹ll be able to put together some innovative and exciting proposals to spotlight these institutional strengths."

Following are the 16 institutions and the principal investigators:

Case Western Reserve University, Remick; City Of Hope National Medical Center, Doroshow; CTRC Research Foundation, Rowinsky; Dana-Farber Cancer Institute, Kufe; Duke University, Colvin; Johns Hopkins University, Carducci; Mayo Clinic Rochester, Erlichman; Memorial Sloan-Kettering Cancer Center, Spriggs; Ohio State University, Grever; University of Chicago, Ratain; University of Colorado Health Sciences Center, Eckhardt; University Of Pittsburgh, Belani; University Of Texas M.D. Anderson Cancer Center, Kurzrock; University of Wisconsin Madison, Wilding; Vanderbilt University, Rothenberg; Wayne State University, Lorusso.

Cancer Prevention:
EPIC, PLCO Studies Show Benefits Of High Fiber Diet

Scientists at the International Agency for Research on Cancer, the UK Medical Research Council, and Cancer Research UK said strong scientific evidence links a high fiber diet with a reduced incidence of both cancer and pre-cancerous polyps of the colon and rectum.

In two articles to be published May 3 in the Lancet, the scientists reported results fro the EPIC study, a large, multidisciplinary project begun 10 years ago and designed to investigate the role of diet, lifestyle, metabolic, and genetic characteristics in cancer causation and prevention. The study is based on 522,000 individuals aged 25-70 from 24 centers in Denmark, France, Germany, Greece, Italy, the Netherlands, Norway, Spain, Sweden, and the UK.

After an average follow-up of 4.5 years, the study could diagnose 1,065 cases of colorectal cancer, according to Elio Riboli, chief of the Nutrition and Cancer Unit at IARC, and EPIC coordinator.

"Individuals in the top 20% for fiber intake, that is who ate 35 grams of fiber per day on average, saw their risk of colorectal cancer reduced by 40% compared with others consuming 15 grams per day on average," Riboli said. "The major breakthrough of this particular study is it shows that it is possible to significantly reduce bowel cancer risk by moderately increasing consumption of whole cereals, fruit and vegetables, which are the main sources of dietary fiber."

The second study was conducted within the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial, a randomized controlled trial designed to evaluate methods for the early detection of cancer. The study compared fiber intake of 33,971 participants who were sigmoidoscopy-negative for polyps, to 3,591 cases with at least one histologically verified adenoma in the distal large bowel (i.e., descending colon, sigmoid colon, or rectum).

The study found that high intakes of dietary fiber were associated with a lower risk of colorectal adenoma (non-malignant polyps which are often a precursor of malignant disease). Participants in the top 20% for dietary fiber intake (more than 30 grams per day) had a reduction in risk of adenoma by about ¼ compared to individuals in the lowest 20% for fiber intake (less than 15 grams per day).

"These two studies (EPIC and PLCO) suggest that it has been premature to dismiss a role for dietary fiber in the prevention of colorectal cancer," said Ulrike Peters, of the NCI. "While the results from both studies did not, and could not address, the effects of changes in dietary patterns on cancer risk, taken together, they provide a strong body of evidence to support cancer prevention campaigns, aimed at advocating for a higher level of dietary fiber intake for all."

Funding Opportunities:

Program Announcements

PAR-03-104: Howard Temin Award

The award promotes the research careers of outstanding junior scientists (M.D.s and Ph.Ds) in basic research who are committed to developing research programs relevant to human biology and human disease as it relates to the etiology, pathogenesis, prevention, diagnosis, and treatment of human cancer. The award offers candidates up to five years to gain additional skills and knowledge in human cancer research during a period of one to three years in a mentored environment, followed by transition to the equivalent of a junior faculty position to develop an independent research program.

Inquiries: Cynthia Pond, program director, Cancer Training Branch, NCI, 6116 Executive Blvd., Suite 7011, Bethesda, MD 20892-8346, Rockville, MD 20852 (express/courier service), phone 301-496-8580; fax 301-402-4472; e-mail pondc@mail.nih.gov.

PAR-03-101: NCI Transition Career Development Award for Underrepresented Minorities K22

NCI Comprehensive Minority Biomedical Branch invites applications for an award that will facilitate the transition of a minority postdoctoral research scientist from the mentored to the independent stage of their careers in cancer research. Individuals may apply without a sponsoring institution while they are still in a mentored position. This is a novel program that supports and enhances the likelihood of success for underrepresented minority postdoctoral and newly independent investigators who have committed to basic, clinical, and prevention and population-based research careers in cancer. Awardees must apply for an R01 research grant or equivalent prior to the end of the second year of the award. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PAR-03-101.html.

Inquiries: Belinda Locke, program director, Comprehensive Minority Biomedical Branch, NCI, 6116 Executive Blvd., Suite 7031, Bethesda, MD 20892-8350, Rockville, MD 20852 (express/courier service), phone 301-496-7344; fax 301-402-4551; e-mail lockeb@mail.nih.gov.

PAR-03-099: Cancer Prognosis and Prediction: SBIR/STTR Initiative

Letter of Intent Receipt Dates: May 14 and Nov. 13

Application Receipt Dates: June 11, Dec. 11

NCI Cancer Diagnosis Program invites small business applications for research projects to evaluate the utility and pilot the application of new strategies for determining prognosis or predicting response to therapy. The PAR will use the Small Business Innovation Research and Small Business Technology Transfer mechanisms. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PAR-03-099.html.

Inquiries: Tracy Lugo, Division of Cancer Treatment and Diagnosis, NCI, 6130 Executive Blvd., Rm EPN 6035A, Bethesda, MD 20892, phone 301-496-1591; fax 301-402-7819; e-mail lugot@mail.nih.gov, (general inquiries and projects related to breast, gynecologic, gastric, pancreatic cancer or brain tumors); Magdalena Thurin, e-mail thurinm@mail.nih.gov (colon and skin cancers including melanoma, sarcomas, or acute leukemias); James Tricoli, e-mail tricolij@mail.nih.gov (prostate, renal or bladder cancer, liver cancer, lymphomas or chronic leukemias); Barbara Conley, e-mail conleyb@mail.nih.gov (lung, head and neck, or esophageal cancer).

PAR-03-106: Innovations in Biomedical Computational Science and Technology

Participating Institutes and Centers of NIH invite applications in biomedical computing or biomedical information science and technology. This includes database design, graphical interfaces, querying approaches, data retrieval, data visualization and

manipulation, data integration through the development of integrated analytical tools, and tools for electronic collaboration, as well as computational and mathematical research, including the development of structural, functional, integrative, and analytical models and simulations.

Programs may target one or multiple areas of biomedical computing that will enable progress in biomedical research. Examples of data types that could be considered include but are not limited to genomic sequences, biomedical images, qualitative descriptors for health and social science, remote sensing and geospatial images, and chemical formulae. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PAR-03-106.html.

Inquiries: James Cassatt, NIGMS, 45 Center Dr., Rm 2AS.19C, Bethesda, MD 20892-6200, phone 301-451-6446; fax 301-480-2004; e-mail jc12b@nih.gov

Other Funding Notices

Administrative Supplements to Support the Bio-Active Nutrient Gene Expression Omnibus Project: Requests for BANGEO supplemental support will be accepted on May 15 and Nov. 15, 2003; March 15 and Nov. 15, 2004l and March 15, 2005.

NCI Division of Cancer Prevention has funds to support the Bio-Active Nutrient Gene Expression Omnibus project to supplement NCI-funded research project R01, MERIT R37, cooperative agreement U01 program project P01 grants, NCI Cancer Center P30 or SPORE P50 grants in the collection of tissue samples, isolation of RNA and shipment to NCI for RNA expression analysis by a dedicated microarray facility operated by the Center for Cancer Research and the Division of Cancer Prevention.

The BANGEO project will support collaborative activities between ongoing NCI-supported studies examining the effects of bio-active nutrients associated with cancer prevention and the microarray facilities of the NCI Advanced Technology Center, as well as the gene expression analysis resources available under the auspices of the NCI Center for Bioinformatics. Further information: http://www3.cancer.gov/prevention/nutrition/funding.html.

Inquiries: Harold Seifried, NCI, NIH, Department of Health and Human Services, Executive Plaza North, Rm 3158, Bethesda, MD 20892-7381, phone 301-594-7657; fax 301-480-3925; e-mail hs41s@nih.gov.

In Brief:

Ralph Lauren Center Opens In Harlem, Led By Freeman

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cells use to avoid being killed by chemotherapy. . . . **RALPH LAUREN CENTER For Cancer Care,** a Harlem-based partnership between Memorial Sloan-Kettering Cancer Center, North General Hospital, and Polo Ralph Lauren, will provide prevention and screening services for colon, prostate, cervical, and breast cancers, said **Harold Freeman**, medical director, Ralph Lauren Center. The center also will provide state-of-the-art treatment programs. . . . **PETER PITTS** was appointed Associate FDA Commissioner for External Relations. Pitts was managing partner of Wired World, a marketing consultancy. Pitts will be the senior communications adviser to FDA Commissioner **Mark McClellan**. He will supervise the FDA Office of Public Affairs, Office of the Ombudsman, Office of Special Health Issues, Office of Executive Secretariat, and Advisory Committee Oversight and Management Staff. . . . **ASCO** has published Cancer Care in the Older Population, a curriculum that addresses geriatric oncology. The interdisciplinary curriculum, which is available in print and CD-ROM formats, is designed for both teaching and self-directed learning, and is designated as a maximum of 28 hours of Continuing Medical Education Category 1 credits toward the American Medical Association Physician Recognition Award. The curriculum was edited by the late B.J. Kennedy, who died earlier this month (**The Cancer Letter**, April 16). **Jamie Von Roenn** is the curriculum series editor. . . . **HHS Annual Mortality Report** found that life expectancy in the U.S. rose to 77.2 years in 2001 across racial, ethnic, and gender groups, while age-adjusted deaths hit an all time low. The report, which now includes a category for terrorism homicide, documents the national age-adjusted death rate decreased slightly from 869 deaths per 100,000 population in 2000 to 855 deaths per 100,000 in 2001. Among leading causes of death, there were declines in mortality from heart disease (nearly 4 percent), cancer (2 percent), stroke (nearly 5 percent), and accidents/unintentional injuries (nearly 2 percent). The biggest decline in mortality among leading causes of death was for influenza/pneumonia (more than 7 percent). The report, Deaths: Preliminary Data for 2001, is available at www.cdc.gov/nchs.

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Business & Regulatory Report

Bristol-Myers, State Attorneys General Propose Settlement Of Taxol Suit

State attorneys general and Bristol-Myers Squibb last week submitted a proposed agreement to settle the antitrust lawsuit involving the drug Taxol.

The agreement, filed April 24 with U.S. Federal District Court Judge Emmet G. Sullivan in the District of Columbia, requires court approval before it becomes effective.

Under the proposed agreement, the states will receive $55 million in damages and penalties.

BMS has also agreed to injunctive relief for 10 years to prevent

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Oncology Management:

Cooperative Group Coalition Begins Online Patient Education Service

Coalition of National Cancer Cooperative Groups of Philadelphia has begun an online educational service for cancer patients and caregivers.

The service, called Cancer Research: A Guide to Clinical Trials, can be accessed at www.CancerTrialsHelp.org.

"About 80 percent of patients use the Internet for health information," said Robert Comis, president of the coalition, chairman of the Eastern Cooperative Oncology Group; and director of the MCP Hahnemann University Clinical Trials Research Center. "People living with cancer are especially reliant upon the Internet, because they need to make quick decisions about their treatment."

The program's five modules include Cooperative Groups, Cancer Clinical Trials, Drug Development, Surgical and Radiation Therapies, and Protecting Research Participants.

* * *

e-Security Inc. of Vienna, Va., a provider of Security Event Management software, said **M. D. Anderson Cancer Center** has selected its software to ensure that state and federal regulations are met on patient records and pharmaceutical research and development data.

The center will implement the e-Security SEM solution to manage security systems, intrusion detection systems, firewalls, virus-protection applications, security logs and other related systems, the company said.

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Bristol-Myers To Settle Suit With State Attorneys General

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Bristol from engaging in anti-competitive conduct, and has agreed to provide a supply of free Taxol for needy patients.

"This is a significant victory for the State of Maryland," J. Joseph Curran, Maryland attorney general, said in a statement. "This settlement will help compensate consumers, as well as the State of Maryland, who overpaid for this drug." The agreement involves all 50 states, the District of Columbia and the five U.S.

A major component of the complaint was the allegation that the manufacturer unlawfully blocked the entry of less expensive generic drugs into the marketplace.

If the agreement is approved, the attorneys general will implement claims administration process for consumers who purchased Taxol or its generic equivalent between Jan. 1, 1999 and Feb. 28, 2003.

The approval of the this agreement with the attorneys general would complete Bristol's $670-million settlement of all claims related to anti-competitive behavior in maintaining market exclusivity for Taxol, BuSpar and Platinol. The settlement includes the states, as well as the Federal Trade Commission and Bristol's competitors (**The Cancer Letter**, March 14, 2003).

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The BuSpar settlement added up to $535 million, which settled claims by direct and indirect purchasers, generic competitors and state attorneys general. Overall, the Taxol settlement with the attorneys general, the competitors and the purchasers added up to $135 million.

The Taxol agreement filed last week obligates Bristol to pay $50 million in cash that would be allocated to consumer and state agencies.

Another $3 million would be allocated to attorneys' fees, and $2 million to consumer notice costs.

Under another provision of the proposed settlement with the attorneys general, Bristol will have to provide the states with 13,000 vials of Taxol free of charge. These will incluse 5,000 300 mg vials, 2,300 100 mg vials, and 5,700 30 mg vials.

The drug will be distributed by the states to patients of limited means who receive no public or private assistance from third-party payers for the purchase of the drug.

A proposed injunction that was also submitted to Kennedy states that Bristol would not:

—"Make a patent infringement claim that a Taxol patent is infringed by any drug product or the use of any drug product where the subject of the patent infringement claim is the making, using, selling, offering to sell, or importing Taxol, or

—"Receive royalties or other fees from another person rursuant to a license of a Taxol patent to make, use, sell, offer to sell, or import Taxol."

However, the injunction does not preclude BMS from "claiming a method of using Taxol in combination with another oncological active ingredient or a composition of matter patent claiming Taxol in combination with another oncological active ingredient."

The injunction bars Bristol from claiming 30-month stays of FDA approval of any Abbreviated New Drug Application involving the Taxol NDA.

Also, the injunction bars the company from claiming 30-month extensions for later-listed patents, prohibits Bristol from engaging in "inequitable conduct" before the Patent and Trademark Office, and providing "false or misleading" information for listing in the Orange Book.

FTC took the lead in negotiating the antitrust provisions of the settlement agreement with Bristol.

The text of the agency's complaint against the company is available at www.ftc.gov/opa/2003/03/bms.htm.

ImClone Board Fires Waksal, Goldhammer In Shake-Up Over Tax Liability On Stocks

The board of directors of ImClone Systems Inc. has ousted the company's president and CEO Harlan Waksal as well as the chairman of the board Robert Goldhammer.

The company said the move was preceded by "internal review" launched to determine the company's tax liability stemming from failure to withhold federal and state taxes on the sale of stock options and warrants held by the company's founder Samuel Waksal, Harlan's brother and his predecessor as president and CEO.

Having failed to withhold taxes, the company became responsible for the tax liability as well as interest and penalties stemming from Samuel Waksal's windfall proceeds of the sale of ImClone shares to Bristol-Myers Squibb.

ImClone estimates that its federal and state tax liability would range from $23.3 million to $60 million, plus penalties and interest.

The recently discovered tax problem has forced ImClone to restate its financial statements, causing two delays in announcing annual financial results.

The controversy has also caused an investigation by the Securities and Exchange Commission as well as a move by Nasdaq to "delist" ImClone stock for failure to file its 2002 Form 10-K in a timely manner.

The company's trading symbol was changed by Nasdaq from IMCL to IMCLE. The symbol would revert to IMCL after the company files its financial results.

In the shakeup, Harlan Waksal was demoted to Chief Scientific Officer, with responsibility for research, clinical, regulatory, quality assurance, and manufacturing. Prior to replacing his brother and president and CEO, Harlan Waksal served as ImClone's executive vice president.

Goldhammer will not run for re-election to the board at the next shareholders' meeting, and will serve out his current term as a director, the company said.

Waksal will be replaced temporarily as CEO by Daniel Lynch, currently senior vice president, finance, and chief financial officer. Lynch, who will keep his current jobs in addition to being promoted to chief administrative officer, will serve as acting CEO while the company conducts a search for a permanent chief executive.

"The company's current difficulties led the independent members of the board of directors to conclude that a change in leadership was appropriate," ImClone said in a statement. "The company has commenced a search for a permanent CEO. ImClone Systems will continue to benefit from Harlan Waksal's scientific leadership in his new role as Chief Scientific Officer."

ImClone officials said the company remains "committed to finalizing the review of the circumstances relating to the previously disclosed withholding tax issues" and to filing the annual report and a 10-K Form.

Oncology Management:

RapidTrials Creates Tool For Clinical Trials Budgeting

(Continued from page 1)

The medical center is governed by Texas state laws and regulatory commissions mandating best practices for security of data.

M. D. Anderson will also leverage the e-Security SEM solution to meet the Healthcare Insurance Portability and Accountability Act, the federal law requiring protection of healthcare information, the company said.

"As a hospital, we have an ongoing concern about confidentiality of data and privacy of medical records," said Lewis Wagner, chief information security officer at M. D. Anderson. "We also perform a great deal of drug research, and that data is worth millions of dollars to the pharmaceutical companies sponsoring the research, so there's a very pressing business need as well."

* * *

RapidTrials of Wayne, Penn., said it has created Budget Builder, a clinical trial budgeting tool, that uses market-driven pricing data to generate study and site-specific budgets for clinical trials.

Unlike template budget programs that look only at procedure prices in a vacuum, Budget Builder generates low, median and high price points for each budget line item based on up-to-the-minute real world pricing data collected from hundreds of studies across therapeutic areas, the company said.

The system also provides a Medicare base line for each procedure for comparison.

The system generates rates for each clinical trial line item based on a six step process that takes 20 minutes, the company said. It prompts users—site administrators, Sponsor contract and grants administrators, or project managers—to capture and record all information and resources required to conduct a specific protocol on a per site basis, the company said.

Budget Builder also identifies and plans for fixed costs such as advertising, added equipment costs, patient stipends and archiving fees, the company said. Based on information entered, the Budget Builder proprietary database automatically generates a range of pricing options for each study procedure code listed.

* * *

Decision Resources Inc. of Waltham, Mass., a research and advisory pharmaceutical and health care firm, forecast that Celgene will dominate the multiple myeloma drug market through 2011.

Thalomid and its analogues will revolutionize the second-line treatment market for the disease, the company said.

According to a Pharmacor study, Thalomid will generate $50 million in sales in 2006 and thalidomide analogues will garner sales of $81 million in 2011.

"Although the Thalomid dominance will be short-lived, Celgene will still dominate the market by producing analogues of thalidomide that will prove themselves to be equally potent, but better tolerated than Thalomid in phase II and III clinical trials," said Andrew Paramore, an analyst at Decision Resources.

The study also predicts the promise of orphan drug status will encourage many companies to continue to invest in research and development of drugs for myeloma.

* * *

Cytyc Corp. (Nasdaq:CYTC) of Boxborough, Mass., said Blue Cross and Blue Shield of Oklahoma, Coventry Health Care, and the Cleveland Clinic Health System Employee Health Plan have extended insurance coverage for the FirstCyte Breast Test, a ductal lavage technology for breast cancer risk assessment.

The procedure is used for high risk for breast cancer, the company said. The technology detects atypical cells lining the milk ducts, where an estimated 95 percent of all breast cancers originate. The procedure can be performed in an office setting in less than an hour.

* * *

Quality Oncology Inc. said the outcomes from its efforts to manage cancer care in Kentucky on behalf of CHA Health of Lexington, have been reported in Disease Management, Vol. VI, No. 1.

The company is a unit of Matria Healthcare Inc. (NASDAQ: MATR) of Marietta, Ga.

The article, "Improving Cancer Care in a Kentucky Managed Care Plan: A Case Study of Cancer Disease Management," was co-authored by Timothy Costich, chief health services officer of CHA HMO Inc., and Frederick Lee, a senior executive at QO.

The paper cites a 11.13 percent two-year reduction in average cancer case costs compared to the baseline 12-month period of September 1998 to August 1999, the company said.

On average, the health plan netted $1,258 in savings per cancer patient. Net savings for the plan in the aggregate for the two-years under QO management were just shy of $1.5 million.

"These are very impressive results given the rapidly escalating double-digit inflation that all health plans are experiencing," said Tim Costich. "Our program has proven that dollars can be saved in oncology without harming patient outcomes or undermining patient satisfaction."

The cancer program recorded a 4.64 score (on a 1-5 scale) on patient overall satisfaction with the program, according to a satisfaction survey completed by some of the program's enrolled cancer patients, the company said.

The program emphasizes proactive management of side effects, the company said. By helping patients with the severe dehydration from chemotherapy side effects, for instance, QO cut back on the use of the hospital for treatment of side effects.

The plan instituted a process improvement initiative aimed at the misuse of supportive care drugs for anemia-related conditions, the company said.

In another development, the Centers for Medicare and Medicaid Services chose Quality Oncology to provide care management services to over 1,000 Medicare-eligible newly diagnosed cancer patients in Broward and Dade Counties of South Florida, the company said.

Clinical Trials:

FDA Removes Partial Hold On Canvaxin Production

CancerVax Corp. of Carlsbad, Calif., said FDA informed the company that its submission of additional information related to the production, testing, and characterization of the vaccine is satisfactory and that the partial clinical hold has been lifted.

The company said it will continue enrollment in its two international phase III trials of the Canvaxin therapeutic cancer vaccine for the post-surgical treatment of stage III or stage IV melanoma.

"We will continue to work cooperatively with the FDA to make progress towards a license application for the Canvaxin vaccine," David Hale, president and CEO of CancerVax. "The process will be expedited by the Fast-Track designation recently granted by FDA."

The partial clinical hold on new patient enrollment was not the result of any clinical practice or safety concerns related to the vaccine, the company said.

Patients in the two phase III trials who were already receiving the vaccine were permitted to continue to do so without interruption.

* * *

Favrille Inc. of San Diego said it has expanded its multi-center phase II trial with the investigational agent FavId in combination with Rituxan, to include patients who have not received treatment for low-grade or follicular non-Hodgkin's lymphoma.

The study now includes patients who have not received any prior treatment for their lymphoma, as well as those who are relapsed or refractory to their prior treatments, the company said.

Prior treatments may include chemotherapy alone, Rituxan alone, or chemotherapy and Rituxan used in combination.

"Our study may give alternatives to existing therapies, such as chemotherapy, by combining an approved drug (Rituxan) followed by an investigational vaccine (FavId)," said John Longenecker, president and CEO at Favrille. "Chemotherapies are limited by their degree of toxicity and inability to provide longer-term remissions."

The treatment schedule calls for Rituxan first, followed eight weeks later with monthly FavId vaccinations for six months, which can be administered at the oncologist's office, the company said.

Rituxan is approved for low-grade or follicular, relapsed or refractory, non-Hodgkin's lymphoma and acts by shrinking the tumor, the company said. FavId, following Rituxan, could stimulate the immune response to the tumor, the company said.

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ILEX Oncology Inc. (Nasdaq: ILXO) of San Antonio said it plans to begin phase II studies of tubulin-interactive agent ILX-651 for breast and lung cancer.

"In phase I studies, ILX-651 has demonstrated activity in breast cancer and non-small cell lung cancer," said Jeffrey Buchalter, president and CEO of ILEX. "In addition, the compound has a good safety profile and has been well tolerated."

ILX-651 is a third-generation synthetic pentapeptide analog of the natural substance dolastatin, the company said.

Study results are expected at the 2003 annual meeting of the American Society of Clinical Oncology, which begins May 31 in Chicago, the company said.

* * *

NeoRx Corp. (Nasdaq: NERX) of Seattle said FDA has lifted the clinical hold on theits Skeletal Targeted Radiotherapy product candidate for multiple myeloma.

The decision follows the NeoRx study data submission from a dosimetry study of STR, in which multiple myeloma patients were treated and detailed radiation dosimetry data were collected, the company said. NeoRx said it continues to follow the patients for safety and efficacy results. Three-year survival data on the STR phase I/II patients will be available in by the end of 2003.

NeoRx said it has submitted a proposal for further clinical development of STR to FDA, and expects to submit a full phase III study protocol before the end of the second quarter of this year.

"This is certainly good news for multiple myeloma patients and their physicians," said William Bensinger, member, Fred Hutchinson Cancer Research Center, co-principal investigator and member of the NeoRx Clinical Advisory Panel for STR. "STR is the only therapeutic in late-stage development that has demonstrated a significant complete response rate and offers thepotential for prolonged progression-free survival and overall survival.

* * *

Praecis Pharmaceuticlals Inc. (NASDAQ: PRCS) Waltham, Mass., said it has submitted an Investigational New Drug application to FDA for a phase I clinical study of PPI-2458, for non-Hodgkin's lymphoma.

PPI-2458 is a proprietary molecule based on the fumagillin class of compounds prevent both abnormal cell growth and anti-angiogenesis, the company said.

In proposed study would evaluate an oral formulation of PPI-2458 in non-Hodgkin's lymphoma patients who are no longer deriving benefits from other therapies, the company said.

The company said it expects the trial to begin during the second half of 2003.

"This event comes on the heels of the resubmission of our New Drug Application for Plenaxis, for advanced prostate cancer, for which we are awaiting FDA action," said Malcolm Gefter, chairman and CEO of Praecis. "PPI-2458 has demonstrated preclinical anti-cancer activity across a broad range of tumor cell lines at NCI, as well as in animal models at Praecis."

Deals & Collaborations:

Vogelstein Lab Licenses Digital PCR To Exact Sciences

EXACT Sciences Corp. (NASDAQ:EXAS) of Maynard, Mass., said it has signed an exclusive licensing agreement for the digital-PCR technology developed by the Bert Vogelstein laboratory at Johns Hopkins Kimmel Cancer Center for colorectal cancer detection.

The agreement provides EXACT Sciences with a technological platform to develop colorectal cancer screening and detection technologies that enhance its PreGen-Plus assay, the company said.

Digital-PCR is the underlying technology for digital protein truncation (dig-PT), and digital BAT-26. PreGen-Plus is a non-invasive fecal DNA test for the early detection of colorectal cancer.

In studies to date, PreGen-Plus has demonstrated a sensitivity of 65-70 percent and a specificity of approximately 96 percent, the company said.

The company said it expects that its current version of PreGen-Plus will be commercially available within the next several months.

Under his employment relationship with the Johns Hopkins University, Vogelstein is entitled to a share of the amounts received by Johns Hopkins as a result of the license agreement, the company said.

* * *

Althea Technologies Inc., of San Diego said it has received a four-year NIH contract to assist the **National Institute of Allergy and Infectious Diseases** with the development, scale-up and production of candidate vaccines, as well as to perform the necessary characterization tests required for release of vaccines for clinical use.

"The timing of this award is terrific as we move into our new 30,000 square foot facility," said Rick Hancock, senior vice president of operations. "We have also added the capability to formulate and fill clinical products in either syringes or vials."

Services of the company include gene expression analyses using its proprietary eXpress Profiling technology, custom genomic analyses using real-time PCR, and cGMP plasmid DNA and protein production, and formulation and fill services, Althea Technologies said.

* * *

Bio-Reference Labs Inc. (NASDAQ:BRLI) of Elmwood Park, N.J., said it has executed a strategic marketing agreement with **Bioview Inc.** of Billerica, Mass., giving BRLI rights to the Bioview Duet System for advanced hematological cancer analysis.

Under the agreement, BRLI can offer the molecular data generated by the system for diagnosing and monitoring of hematological cancers such as leukemia, lymphoma and plasma cell disorders, the company said.

The technology links morphological analysis with FISH technology so that a genetic mutation can be visually identified in specific blood cell type.

The SMA grants Bio-Reference marketing rights to use the system for hematological oncology analysis, BRL said.

The system is being released to clinical laboratories and research sites for research use, pending application to FDA for clearances, the company said.

* * *

Elron Electronic Industries Ltd. (NASDAQ:ELRN) of Tel Aviv said **Galil Medical Ltd**., an Elron subsidiary, and **Amersham** (LSE, NYSE, OSE: AHM) have signed a definitive agreement to merge the Amersham Health

brachytherapy business with the urology business of Galil Medical.

The combined sales of the contributed businesses in 2002 were approximately $90 million.

Galil Medical will hold 25 percent of the new company, said Elron. Galil Medical has developed third-generation cryotherapy, a minimally invasive advanced hyper-cooling technology, that allows fast, high-resolution and controlled destruction of cancerous tissue, the company said.

The growing technology is used to treat advanced stages of prostate cancer or recurrent disease. It complements the brachytherapy in which Amersham is the market leader. Both minimally invasive techniques offer physicians and patients effective alternatives to prostatectomy.

The transaction is expected to close by the end of July 2003, the company said.

* * *

Iceland Genomics Corp. of Reykjavik, Iceland, said results from its Icelandic Cancer Project have identified genetic regions at increased risk of cancer, including breast and prostate cancers.

The ICP is a joint research effort by IGC and its collaborators, which include the Icelandic Cancer Clinicians Group, the two principal Icelandic hospitals and the Icelandic Cancer Society, IGC said.

The company said it has completed the first phase of the largest population-wide cancer association study.

The first phase involved analysis of selected regions of the genome in 2500 cancer patients and 1500 healthy controls. Five loci were mapped which contribute towards an increased risk of cancer. The IGC team is preparing to validate these results in other populations and is working towards isolating the genes involved.

"It has been known for a long time that Iceland is particularly suitable for genetic studies but the emphasis has usually been on linkage analysis of large families. This is concrete evidence that our approach, i.e. to use association studies, is also valid for the identification of genes which contribute to cancer susceptibility in this population" said Snorri Thorgeirsson, chairman of the IGC Scientific Advisory Board. "We plan to market diagnostic tests and services based on our discoveries. We will use our database for identification and characterization of drug targets to develop cancer therapeutics."

"Reaching this milestone was made possible by the overwhelming public support for this project," said Thorvaldur Jonsson, primary clinical investigator for the project.

* * *

Implant Sciences Corp. (AMEX: IMX, IMX.WS) of Wakefield, Mass., said it has received a grant from **NCI** to develop a permanent implant for radiation treatment of malignant biliary tumors.

The medical implant will be in the form of a proprietary metal coating on a commercially available self-expanding stent, the company said. It should reduce the dose to radiosensitive normal tissue.

The aims of the $100,000 phase I program are: to develop a permanent brachytherapy source for the palliative treatment of malignant biliary obstructions; assess the dose distribution both theoretically and experimentally; and determine how to properly compensate for all of the physical and biological factors that will affect the total treatment, the company said.

Emerging Technologies:

Beckman Coulter Creates Epitope Mapping System

Beckman Coulter Inc. (NYSE: BEC), of Fullerton, Calif., said it has created a proprietary technology used in epitope discovery and development.

"Pharmaceutical and biotechnology companies engaged in vaccine development are evaluating proteins to understand their mechanism of action," said Robert Raynor, director of business development, Beckman Coulter Biomedical Research Division. "The epitope discovery system assists the vaccine development community with the tools to better understand the mechanism of action for selected proteins and evaluate which protein fragments, or epitopes, for clinical development."

The epitope mapping system allows biopharmaceutical companies to develop vaccines for diseases in various states such as HIV, hepatitis, and cancer, the company said.

In another development, Beckman Coulter said it has launched Access OV Monitor, a laboratory test for the management of ovarian cancer.

The test, which has been cleared by FDA for diagnostic use, detects cancer antigen 125 (CA 125) levels in human serum and plasma, the company said.

"CA 125 antigen levels that consistently rise in ovarian cancer patients may reflect a progression of the disease, while decreasing levels may indicate a positive response to therapy," said Bernard Cook, medical information scientist at Beckman Coulter.

Access OV Monitor produces first results in 20 minutes, the company said.

* * *

Planmed Inc. of Roselle, Ill., said its Planmed MaxView System, a mammography system, enables the capture of up to 30 percent more breast tissue than other imaging systems.

The system brings the maximum amount of breast tissue into the imaging field of view, resulting in a higher percentage of lesion detection and earlier cancer diagnosis, the company said.

Developed in conjunction with Daniel Kopans, professor of radiology, Harvard Medical School, and director of the Breast Imaging Department, Massachusetts General Hospital, the system uses moving, hygienic, disposable, radiolucent sheets positioned on the upper and lower compression paddles of the mammography system that help to gently and evenly pull the breast into the imaging field of view, the company said.

The feature can bring up to two centimeters more tissue into the imaging field than conventional mammography systems. The roll effect associated with the MaxView System can spread tissue sideways, minimizing superimposed tissue in the image.

The upper and lower sheet can be independently manipulated for maximum tissue spread, the company said.

"When reviewing films, the comparison between the MaxView and conventional images speak for themselves," said Kopans. "Not only can you view a greater amount of tissue in the breast itself, imaging the tissues close to the chest wall is significantly improved—an area often missed by other imaging systems."

The MaxView System is being used by hospitals and imaging clinics including Massachusetts General Hospital; Breast Center of Harlem; Imaging Associates; Harbor-UCLA; Mills Memorial Hospital of Terrance, British Columbia.

Patents:

Firm Wins Patent On Inbitors Of Hedgehog Pathway

CURIS Inc. (NASDAQ: CRIS) of Cambridge, Mass., said it has been issued a patent on small molecule inhibitors of a biological signaling pathway controlled by a protein called Hedgehog.

CUR-61414, a compound under development by CURIS for basal cell carcinoma, is among the small molecules covered, the company said.

The compound can selectively kill tumor cells while not harming adjacent normal cells in two models of basal cell carcinoma, said a report in The Proceedings of the National Academy of Sciences.

"The ability to selectively kill cancer cells while leaving healthy cells intact represents the next generation of cancer treatments that are in development," said Lee Rubin, chief science officer at Curis.

"In addition to basal cell carcinoma, the Hedgehog signaling pathway has been implicated in the progression of several cancers, including small cell lung cancer, medulloblastoma, and others," said Daniel Passeri, president and CEO of Curis. "We are evaluating other cancer types to determine those tumors that also may be responsive to Hedgehog signaling pathway inhibition."

* * *

Geron Corp. (Nasdaq: GERN) of Menlo Park, Calif., said it has granted a patent covering use of GRN163, a oligonucleotide drug to inhibit telomerase.

GRN163 is a specific and non-toxic inhibitor of telomerase in cancer cells, the company said. It is a short (13 base) oligonucleotide made using proprietary chemistry that confers stability and enhanced cellular uptake to the compound.

The drug is active against all major human tumor types in vitro and in animal models of human brain, prostate, lymphoma, myeloma and cervical cancers.

Unlike most anti-cancer drugs, GRN163 has not caused toxicity in animals at therapeutically effective doses, the company said.

The compound is undergoing IND-enabling GLP toxicology studies, the company said. Geron said it expects to file an IND with the FDA for glioblastoma.

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