THE CANCER LETTER INTERACTIVE

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NCI Advisors Approve New SPORE Grant Program In Cancer Communications

Advisors to NCI approved the Institute's plan to spend an estimated $45 million over the next five years to fund four or five grants for Centers of Excellence in Cancer Communications Research.

The NCI Board of Scientific Advisors voted 25-5 at its Nov. 16 meeting to approve the concept for the large Request for Applications. It was the second time the board had considered the program. At a BSA meeting earlier this year, NCI officials withdrew the concept after board members criticized it.

Barbara Rimer, director of the NCI Division of Cancer Control and

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In Brief:

ACS Increases Funding For Scholar Grants; NCI Posts Interim FY2001 Funding Policy

AMERICAN CANCER SOCIETY said it has restructured its cancer research program to increase funding to innovative cancer investigators. The majority of the awards, called ACS Research Scholar grants, now can be worth as much as $1 million to $2.5 million over four to five years, the society said. These awards are designed for beginning investigators in basic, translational, or clinical cancer research, or for independent investigators at any stage of their careers engaged in psychosocial, behavioral, health services, or health policy and outcomes research. The society recently announced the award of 68 Research Scholar Grants, including the largest research grant the society has ever funded, a five-year award for $1.716 million to **Gary Morrow**, of the University of Rochester, for predicting side effects of cancer treatment. In another development, **ACS** elected six new members to its 32-member Board of Directors at its annual meeting last month in Chicago. They are: **James Murray**, of Durham, NC; **Thomas Fogel**, of Ventura, CA; **Thomas Tachovsky**, of Bethlehem, PA; **Alan Thorson**, of Omaha, NE; **Carolyn Runowicz**, of New York City; and **John Whitehead**, of Atlanta and New York City. . . . **NCI INTERIM FY2001 FUNDING POLICY**, a draft version of which was published in last week's issue of **The Cancer Letter**, has been edited and posted at http://www.cancer.gov, under the "News" heading. . . . **WILLIAM DOOLEY**, director of the breast cancer program and chief of breast surgery at Johns Hopkins Medical Center, has been recruited to the University of Oklahoma Health Sciences Center in Oklahoma City. Dooley will head the Breast Health Institute and direct the department of surgery. He is currently

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"Centerpiece" Of NCI Initiative In Communications Approved

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Population Sciences, described the new grants program as "the centerpiece" of NCI's cancer communications initiative described in the FY2002 Bypass Budget (http://2002.cancer.gov).

The program will use the Specialized Programs of Research Excellence grants mechanism to support research that would lead to better understanding of cancer communication across a wide spectrum of topics, from risk communication, to patient decision-making and participation in clinical trials, to communication about genetic risk.

Due to uncertainty about the NCI budget for the current fiscal year, the RFA for the program will be delayed until later this winter, Rimer said to **The Cancer Letter**.

Rimer withdrew another proposed RFA after it came under severe criticism by the BSA. The program would have funded a Consortium for Colorectal Cancer Screening Surveillance. The BSA formed a subcommittee to work with the division staff to rewrite the concept statement.

"Over the next month, we will refine a much revised concept which we will then discuss with the subcommittee," Rimer said to **The Cancer Letter** earlier this week. "We are very concerned that this be clearly an endeavor with hypothesis-driven research questions that are important to the larger community. Also, we want to make sure that any system we create is able to assess the impact not only of today's screening technologies, but of tomorrow's molecular techniques."

The excerpted text of the communications centers grant program follows:

Centers Of Excellence In Cancer Communications Research (CECCRs). Concept for a new RFA, first year set-aside $10 million, four to five awards, total $45 million over five years. Program director: Gary Kreps, phone: 301-496-7984, e-mail: krepsg@mail.nih.gov.

This initiative is the centerpiece of NCI's Extraordinary Opportunity in Cancer Communications. The novelty and scope of this initiative reflects NCI's recognition that effective communications can and should be used to narrow the enormous gap between discovery and applications and to reduce health disparities among our citizens. The RFA uses the P50 SPORE mechanism to invite applications for Centers of Excellence in Cancer Communications Research. The Centers will include three or more individual research projects, pilot or developmental research projects, shared resources and career development. To be effective, the Centers' research should integrate cancer communications appropriately into one or more contexts of the cancer continuum--from prevention through treatment to survivorship. Communications research is needed about challenging topics such as cancer information seeking, decision making under uncertainty, and genetic testing. Centers' research also should provide insight into the processes underlying communication and its impact. It is expected that the Centers' interdisciplinary efforts will result in new and/or improved syntheses, theories, methods and interventions. The Centers will provide essential infrastructure to facilitate rapid advances in knowledge about cancer communications, translate theory and programs into practice, and train health communication scientists.

Purpose of RFA: CECCRs are expected to conduct research that will lead to major scientific advances in knowledge about cancer communications and their translation into practice. The focus can include, but is not limited to, cancer risk communication, evidence-based interventions to enhance cancer communication, communication methods for diverse and under-served populations, innovative communication strategies to increase

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informed decision making and participation in clinical trials, communication about genetic testing, survivorship and end of life issues, as well as communication interventions to improve cancer prevention and early detection behaviors. We also invite research to elucidate the psychological mechanisms underlying the cancer communication process, understand how people use cancer information, test innovative strategies to overcome the digital divide in access to cancer-related information, and develop and evaluate methods to enhance the dissemination of evidence-based cancer communication interventions. Messages and the way messages and information are developed, designed, displayed and communicated should be based on scientific evidence, and these areas represent avenues of potential inquiry. Centers can conduct basic, applied and dissemination research in a variety of settings, including laboratory, clinical and community settings. They do not have to cover all aspects of the cancer continuum; focus is expected. However, there should be a focus on translatability—from basic to intervention research to application and sometimes back again, depending on the problem.

Where possible, evidence-based research products should be put quickly into the public domain through Web-based access using open source tools. CECCRs investigators will be encouraged to share tools not only among themselves but also with the larger community. Software and other tools, such as common gateway interface (CGI) scripts and interactive data-gathering tools, should be thoroughly documented for purposes of replication and dissemination. Investigators must provide evidence that they have a mechanism in place by which to disseminate evidence based products and interventions that emerge from this research. Unnecessary reliance on or production of proprietary technologies that inhibit dissemination and replication is discouraged.

Applicants are encouraged to collaborate with other organizations. These may include any of the following, but the Centers are not required to do so nor are they limited to them: NCI-designated Comprehensive Cancer Centers, Cancer Information Service. Special Populations Networks, and other NCI-funded research projects, such as the Cancer Family Registries, Cancer Genetics Networks, Transdisciplinary Tobacco Use Research Centers and other SPORES as well as the Centers for Disease Control and Prevention, the American Cancer Society and other voluntary health associations, the Robert Wood Johnson Foundation. National Science Foundation grantees. and industry. In addition, collaborations should be considered with universities, including Schools of Public Health, Historically Black Colleges and Universities, public health agencies, community technology centers and other organizations. The active participation of advocacy groups and appropriate community organizations is encouraged. Relevant collaborations with NIH intramural programs can be included as well.

Research Questions: The level of specialization in different aspects of cancer communications research will vary from center to center, e.g., topics, points on the cancer continuum, populations, levels of analysis and types of research. However, the Centers should focus thematically on areas in which there are significant gaps in knowledge and critical needs--where focused, collective. interdisciplinary efforts could make a difference. It is expected that the CECCRs will catalyze problem solving and lead to more rapid advances in knowledge than would be possible by depending on individual investigators working in relative isolation. CECCRs should contribute to understanding what works and what does not work and why. In most cases, the studies will require a recognition of the cognitive, affective, and sociocultural influences on health behaviors.

The sine qua non of the Centers consists of at least 3 research projects with an integrative theme, cores and plans for career development and use of developmental funds.

Potential Research Topics: Note that these are examples only and will not constitute evaluation criteria.

Elucidate Basic Mechanisms in Cancer Communications:

• Answer questions about the mechanisms by which cancer messages exert their impact. including the mediators of cancer risk communication.

• Expand communications laboratory (analog research) methods to inform tailoring and other communications interventions. such as by evaluating message framing, risk perception. and bias (Abrams et al., 1999).

• Clarify how people seek, process and use health information and develop a greater understanding of how cognitive and emotional factors affect processing.

• Improve research designs to test theory and to inform basic mechanisms by including process-to-outcome evaluation methods.

• Move beyond basic “first generation” research

designs to more rigorous tests of the active ingredients in tailored communications.

• Develop improved methods for visually communicating numerical and other complex information.

• Examine how new technological tools can be used to enhance cancer communications by giving people accurate physiological feedback that can be used to increase patients' knowledge, improve decision making and/or motivate behavior change.

Explain the Communication Process:

• Assess the effect of factors such as age, ethnicity, income. education. geography and culture on response to communications and develop improved processes for use of cancer communications.

• Increase understanding of how people search for, use and respond to cancer information within the changing information environment.

Improve Decision Making:

• Qualitative and quantitative research are needed to improve understanding of how patients process complex information about the benefits and risks of different medical options and make decisions in the face of considerable uncertainty.

• Examine the impact of interventions to improve cancer-related decision making.

• Assess the impact of activated patients upon patient-physician communication and family communication.

Improve Risk Communication:

• People need help in understanding health risks and separating important from insignificant risks so that they can make informed choices. A number of important topics in risk communication research were identified as high priorities by experts who attended an NCI-sponsored meeting on cancer risk communication (December 1998). The papers from the meeting were published in a September, 1999 supplement to the Journal of the National Cancer Institute and include many potential topics.

• Identify the optimal formats for communicating cancer risks to diverse populations.

Improve Communication for Diverse Audiences:

• Promote knowledge about, access to and use of cancer information for low literacy, ``information poor," immigrant populations and other diverse audiences.

• Test strategies for improving cultural competence among health care providers and public health educators.

• Examine what interventions are needed for children and adolescents affected by cancer.

Design More Effective Interventions:

• Examine how presentation and format interact to affect message impact.

• Conduct research that contributes to an effective menu of communication choices for different audiences, including traditional communication methods, such as mass media. one-on-one and small group education strategies, print and telephone communication strategies: proactive strategies, such as telephone counseling and tailored print communications: and interactive technologies, such as the Internet, kiosks and CD-ROMs. What is the optimal mix of communication strategies? How can interventions be combined to maximize their impact"

• Conduct research on the relative contribution to improved outcomes of varying amounts of message intensity, complexity, burden on receivers, and development costs. Evaluate stepped-care approaches to communications. Examine contributions to health outcomes. health care utilization, and quality-adjusted life years saved.

• Examine the impact of integrated communications systems that include multiple channels of communication, including interpersonal, intrapersonal. mass media and new media to give people the information they want, how they want it, when and where they want it.

Use of the New Media: Wired for Health (http://scipich.health.org/pubs/finalreport.htm) and the recent IOM report, Networking for Health (http://www.nap.edu/catalog/9750.html) make a number of suggestions for research on the new media. Potential topics include:

• Examine potential use of the Internet and other media for informed decision making, health monitoring and feedback and improved communication between physicians and patients.

• Develop strategies to overcome the Digital Divide and involve diverse populations in use of cancer-related applications on the Internet and elsewhere.

• Examine how diverse audiences use the Internet and develop appropriate strategies to enhance its utility.

• Examine how wireless technology and/or the Internet can be used to deliver personalized cancer-related information to diverse audiences.

Improve Interpersonal Communication: Assess the impact of strategies to help physicians and nurses. who have limited time to spend with patients.

maximize their communications about cancer to help patients make informed decisions. Examine the role of interpersonal and group communication in promoting psychosocial adjustment. personal adaptation, and social support for individuals confronting cancer.

Understand and Improve Dissemination of Best Practices: In every aspect of cancer, from prevention to survivorship. there are best practices that must be disseminated. Research is needed to develop more effective communication-related dissemination strategies. Identify the fundamental mechanisms that enhance diffusion to populations in contrast to the basic mechanisms underlying individual chance over time.

NCI now funds many studies that compare tailored print interventions to usual care interventions or "Kitchen Sink" interventions to usual care. However, when these studies have not been successful in achieving significant impact, it usually has not been possible to identify the reasons. Research funded under this initiative should not be limited to studies that focus only on outcomes. Rather. the studies should represent a major advance in terms of innovation, theory testing, intervention strategy and methodology. A major emphasis should be to understand what works, what does not work and why, in order to identify general principles and processes of communication.

Budget: A new P50 SPORE application may request maximum annual direct costs of $1.5 million and maximum annual total costs of $2.5 million. In complying with the direct costs cap of $1.5 million, the indirect costs related to subcontracts to other institutions or organizations will not apply toward the direct costs cap, but the total dollar request may not exceed $2.5 million. Future year increases are limited to three percent and may not exceed this cap.

In the Cancer Centers:

Peters Replaced As Director Of Karmanos Cancer Center

William Peters has been replaced as director of Barbara Ann Karmanos Cancer Institute and the center's principal investigator on the NCI comprehensive cancer center grant.

Sources said the change in leadership, which was announced last week, comes as a result of routine peer review of the cancer center and is unrelated to controversy surrounding high-dose chemotherapy and bone marrow transplantation as a treatment for breast cancer, a procedure championed by Peters.

It is unclear whether Peters was removed or stepped down from his positions as the principal investigator and director of the cancer center.

However, the change occurred shortly after the center's leadership and the board of directors reviewed the results of peer review of the center.

Vainutis Vaitkevicius was named the interim director of the Institute until a new director is found. John Crissman, dean of Wayne State University School of Medicine, will serve as principal investigator on the core grant, Karmanos officials said.

Peters was named president of the newly-created Institute of Strategic Analysis & Innovation at the Detroit Medical Center, and president and CEO of Karmanos Cancer Institute's Center for Cancer Economics, Technology Assessment, Innovation and Development.

According to a statement, the two centers are focused on "expanding the use of technology in health care and understanding all aspects of its delivery—from cost to patient satisfaction—for improved strategic planning." Peters will retain the Karmanos Distinguished Chair in Oncology, will remain on the Institute's board, and has been named president emeritus, the statement said.

Peters, a high-energy man whose management style is described as entrepreneurial by colleagues, came to Karmanos from Duke University in 1995. His job was to build a single cancer center out of disparate programs of Wayne State's medical school, the Michigan Cancer Foundation, and the seven-hospital system of Detroit Medical Center.

Karmanos is important both to NCI, which would like to continue to fund a first-rate program to serve the city's diverse population, and to Detroit, where the center has the support of the political and business elites.

Thus, in June 1996, at the first site visit to his center, the reviewers were greeted by Mayor Dennis Archer, and were read a letter from Gov. John Engler. Sources say the review recommended that the center concentrate on developing an administrative structure for integration of science and care.

While the consolidation of programs made 1996 a time when an entrepreneurial style of management at Karmanos was reasonable to expect, the review became a benchmark for measuring development of the center's administrative structure.

Sources said that after the 2000 review was sent

to Detroit, a contingent of Karmanos officials traveled to Bethesda to discuss the "summary statement" of the evaluation. Peer review documents address the questions of integration of science and care, without making personnel recommendations. However, weeks after the meeting in Bethesda, Peters was replaced as the PI and the center director.

Peters declined to speak with a reporter.

A Karmanos statement describing the change in leadership credited Peters with making major improvements at the center.

The statement said that under Peters' leadership, the institute's portfolio of peer-reviewed grants grew from $22 million to $44.5 million.

Also, the Karmanos completed a $100 million fund-raising campaign, opened two prevention centers, an 80,000-square-foot translational research center, and an $8 million comprehensive breast cancer screening and diagnostics center; renovated three inpatient floors at Harper Hospital, which includes a bone marrow transplant unit.

"Bill Peters is an extraordinary, talented clinician, scientist and leader," Institute board chairman Thomas Angott said. "Because of him and his vision, the Karmanos Cancer Institute has achieved a notable level of local, regional and national prominence. This community owes him a enormous debt of gratitude."

In Washington:

Clinton Signs Bill Creating NIH Center On Minority Health

President Clinton last week signed a bill that would create the NIH National Center on Minority Health and Health Disparities.

The center, for which the new law authorized a $150 million budget during the current year, will coordinate intramural NIH research in health disparities, fund research on health disparities and minority health, support training of researchers from underserved populations, and provide education loan relief for health professionals who commit to perform health disparities research.

The center will replace the NIH Office of Research on Minority Health, which had the budget of $80 million last year. These funds were passed through to other institutes. The new center will focus all NIH research in health disparities, pursue its own programs, and fund educational programs and "centers of excellence," that would be able to use the funds for a broad range of activities—as well as for construction and endowments.

"The center promises to help all Americans who bear the burden of health disparities regardless of their race, ethnicity, gender, socioeconomic status, or geographic location," Clinton said at the signing Nov. 22. The legislation, S. 1880, is posted at http://thomas.loc.gov/.

In addition to establishing centers of excellence, the law authorizes repayment of as much as $35,000 in educational debt for researchers who agree to engage in minority health disparities research for each year of engaging in such research.

The law also authorizes the Agency for Healthcare Research and Quality to conduct and support activities and research to measure health disparities and identify causes and remedies. The Health Resources and Services Administration, too, is now authorized to support research and demonstration projects to train health professionals on reducing health care disparities.

To measure the extent of existing problems and the potential impact of the new programs, the law requires NIH to fund a study of data gathering methodology. That study will be conducted by the National Academy of Sciences within a year.

The Academy's report would:

—Identify the data needed to evaluate the effects of socioeconomic status, race and ethnicity on access to health care and other services and on disparity in health and other social outcomes and the data needed to enforce existing protections for equal access to health care;

—Examine the effectiveness of existing systems for collecting and analyzing such data;

—Contain recommendations for ensuring that HHS, in administering its entire array of programs and activities, collects, or causes to be collected, reliable and complete information relating to race and ethnicity.

The law sets the deadline of Dec. 1, 2003 for the center director to complete a report that would contain recommendations for the methodology that should be used to determine the extent of the NIH resources dedicated to minority health disparities research and other health disparities research.

The NIH report would measure the increases of NIH spending on minority health disparities research. Fiscal year 1999 would be used as a benchmark.

Though the creation of the center appears to nearly double NIH research funds devoted to health

disparities research, sources said it was unclear whether the creation of the center would represent a real increase in spending.

The NIH office which is being replaced by the center usually funded only the first-year of five-year grants by other NIH entities. Since the new center would fund grants in their entirety, the number of grants may not increase dramatically.

NCI To Lose $11 Million Transfer

For NCI, which has created its own center to study health disparities, the creation of the NIH center may mean the loss of an $11-million annual transfer that used to go to the now defunct NCI Office of Special Populations Research.

Another uncertainty is the potential subsidy of construction and research endowments at institutions that NIH would designate as centers of excellence in health disparities research. The law does not specify how much of the NIH center's budget would go to these centers.

Under the law, the NIH center's director would have the authority to provide funds for the endowments of institutions that meet the following conditions:

— The institution does not have an endowment that is worth in excess of an amount equal to 50 percent of the national average of endowment funds at institutions that conduct similar biomedical research or training of health professionals.

—The application of the institution has been recommended pursuant to technical and scientific peer review and has been approved by the Center's advisory council for this use of funds.

The law allows centers of excellence to use new funds to "expand, remodel, renovate, or alter existing research facilities or construct new research facilities for the purpose of conducting minority health disparities research and other health disparities research."

To be eligible for designation as a center of excellence, an institution must have "a significant number of members of minority health disparity populations or other health disparity populations enrolled as students."

Also, the institution must have a track record in "assisting such students of the institution to complete the program" and recruitment "to increase the number of minority or other members of health disparity populations serving in faculty or administrative positions at the institution."

Funding Opportunities:

Program Announcements

PA-01-020: Molecular and Cellular Biology of Tumor Cells

NCI and the National Institute of Diabetes and Digestive and Kidney Diseases invite exploratory/developmental grant applications to promote collaborations and facilitate scientific interchange between investigators, one with experience in the biology of metastasis and the other in a more basic scientific discipline such as molecular or cellular biology, or biochemistry. Therefore, prospective principal investigators need to identify a research collaborator. Support of this program will be through the NIH exploratory/development research grant R21.

Inquiries: For NCI—Suresh Mohla, chief, Tumor Biology and Metastasis Branch, Division of Cancer Biology, NCI, EPN, Suite 5000, Bethesda, MD 20892, phone 301-435-1878; fax 301-480-0864; e-mail sm82e@nih.gov

PA-01-021: Small Grants Program for Cancer Epidemiology

Application Receipt Date: April 20, Aug. 20, and Dec. 20, 2001; April 22, Aug. 20 and Dec. 20, 2002

The Division of Cancer Control and Population Sciences of NCI invites small grant applications for cancer epidemiology with a primary focus on etiologic cancer research. These are short-term awards intended to provide support for pilot projects, testing of new techniques, or development of innovative or high-risk projects that could provide a basis for more extended research. Support of the PA will be through the small grants R03 award mechanism.

Inquiries: A. R. Patel, Division of Cancer Control and Population Sciences, NCI, 6130 Executive Blvd.; Rm 239C; MSC 7395; Bethesda, MD 20892-7395; phone 301-496-9600; fax 301-402-4279; e-mail ap39f@nih.gov

NIH Notice

Centers of Excellence for Patient Safety Research and Practice (RFA-HS-01-002)

Agency for Healthcare Research and Quality will convene an application preparation technical assistance workshop in response to this RFA. The workshop will be held Dec. 13, 1 and 4 p.m. at 6010 Executive Blvd., 4th Floor, Rockville, MD.

Inquiries: For registration—Lisa Krever, phone 301-594-6625; e-mail lkrever@ahrq.gov. For conference information, Marge Keyes, Center for Quality Measurement and Improvement, Agency for Healthcare Research and Quality, 2101 East Jefferson St., Suite 502; Rockville, MD 20852; phone 301-594-1824; e-mail mkeyes@ahrq.gov

Roswell Park, Karmanos Read The Cancer Letter Interactive

The nation's oldest cancer center and one of its newer ones have contracted with The Cancer Letter Inc. to provide all employees access to **The Cancer Letter Interactive** over their intranets.

The site license agreements with Roswell Park Cancer Institute, of Buffalo, established in 1898, and the Barbara Ann Karmanos Cancer Institute, of Detroit, formed in 1995, enable all employees of those centers to read **The Cancer Letter Interactive** online and print out copies for personal use.

The Cancer Letter Interactive is published weekly on Fridays, 46 times a year, and includes the same content as **The Cancer Letter** print edition. The Adobe PDF format retains the same look as the print edition, with the added feature that users can click directly on any Web site link or email address mentioned in the newsletter or in its advertisements.

The new agreements bring the number of cancer center site licensees to **The Cancer Letter Interactive** to a total of four. Previously, the Dana-Farber Cancer Institute and University of Pittsburgh Cancer Institute contracted for the service.

In addition to site licensing for large organizations, **The Cancer Letter Interactive** offers Group Subscription discounts for smaller groups, or groups of users not linked by an Intranet. For further information on **The Cancer Letter Interactive**, site licensing and Group Subscriptions, or advertising, contact Publisher Kirsten Boyd Goldberg, email kirsten@cancerletter.com, phone 202-362-1809 x 11.

In Brief:

Saul Rivkin Receives ACCC Clinical Research Award

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an associate professor of oncology and surgery at Hopkins. **Howard Ozer** is director of the cancer center at University of Oklahoma. . . . **SAUL RIVKIN**, a medical oncologist with the Swedish Cancer Institute, of Seattle, received the Clinical Research Award from the Association of Community Cancer Centers. Rivkin is president of the Puget Sound Oncology Consortium, a clinical associate professor of medicine at University of Washington School of Medicine, and founding director of the Marsha Rivkin Center for Ovarian Cancer Research, named for his late wife. . . . **ONCOLOGY NURSING SOCIETY** dedicated its highest award for oncology nursing educators to the late **Mary Nowotny**, of Dallas, who was an ONS member and chairman of the ONS Education Committee. The ONS Mary Nowotny Excellence in Cancer Nursing Education Award is presented annual to recognize expertise in cancer education at the local, state, or national level. For application information, contact 412-921-7373 or customer.service@ons.org. . . . **GREGORY CROW** was named the first non-member director of the Oncology Nursing Society Board of Directors. Crow is professor, graduate coordinator, and program director of Nursing Leadership and Case Management Programs, Sonoma State University. . . . **NATIONAL FOUNDATION FOR CANCER RESEARCH** awarded a $300,000, three-year grant to **Lawrence Marnett**, at Vanderbilt-Ingram Cancer Center's A.B. Hancock Memorial Research Center, to identify and examine functional biochemical differences between COX 1 and 2. . . . **TWO CANCER CENTERS** announced that clinical trial information in "patient-friendly" format is available on their Web sites. Memorial Sloan-Kettering Cancer Center has placed a database of high-priority trials on its site at http://www.mskcc.org. Fox Chase Cancer Center has placed clinical trial summaries on its site at http://www.fccc.edu. . . . **PRESIDENT CLINTON** was scheduled to present the National Medals of Science and National Medals of Technology at a ceremony in Washington on Dec. 1. The recipients of the Medal of Science are: **Gary Becker**, Univ. of Chicago; **Nancy Andreasen**, Univ. of Iowa Hospitals & Clinics; **Peter Raven**, Missouri Botanical Garden and Washington Univ.; **Carl Woese**, Univ. of Illinois at Urbana-Champaign; **John Baldeschwieler**, California Institute of Technology; **Ralph Hirschmann**, Univ. of Pennsylvania; **Yuan-Cheng Fung**, Univ. of California, San Diego; **John Griggs Thompson**, Univ. of Florida, Gainesville; **Karen Uhlenbeck**, Univ. of Texas, Austin; **Willis Lamb**, Univ. of Arizona, Tucson; **Jeremiah Ostriker**, Princeton Univ.; **Gilbert White**, Univ. of Colorado, Boulder. The Medal of Technology awardees: **Douglas Engelbart**, Bootstrap Institute; **Dean Kamen**, DEKA Research & Development Corp.; **Donald Keck** and **Robert Maurer**, Corning Inc.; **Peter Schultz**, Heraeus Amersil Inc.; and IBM Corp. . . . **CORRECTION:** In last week's issue, an item on the retirement of NCI Clinical Investigations Branch Chief Richard Ungerleider incorrectly stated that he headed the Institute's Pediatric Branch. He was head of the Pediatric Section of CIB.

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Business & Regulatory Report

Formerly "Cancer Economics"

Oncology Management:

iKnowMed Buys CancerSource.com, Subsidiary Of Jones & Bartlet Publishers

iKnowMed, of Berkeley, CA, said it has acquired **CancerSource.com**, an online source for cancer information and services and a subsidiary of Boston-based Jones and Bartlett Publishers.

The iKnowMed Network, accessible to physicians who use the company's data management system, provides access to cancer treatment guidelines, automatic clinical trial eligibility screening, and access to treatment patterns and clinical outcomes, the company said.

The acquisition of CancerSource.com allows oncology nurses and

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Clinical Trials:

NeoRx Suspends Accrual, Treatment In Phase III Trial Using STR For Myeloma

NeoRx Corp. (Nasdaq: NERX) of Seattle, WA, said it has suspended accrual and treatment of its phase III trial for multiple myeloma and other skeletal targeted radiotherapy studies pending resolution of discussions with FDA.

A delayed side effect appeared in a small number of phase I/II patients who received STR at one site, the company said. The data suggest that differences in procedure may have been a contributing factor. An independent data safety monitoring board has recommended the study proceed, but with additional monitoring and standardization of its methods.

"We believe we can address the concerns raised by FDA," said Paul Abrams, CEO at NeoRx.

Four patients treated at one of the major phase I/II study sites, and none treated at the other major site, developed thrombotic thrombocytopenic purpura/hemolytic uremic syndrome, a serious delayed toxicity, the company said. TTP/HUS involves a combination of symptoms, including abnormal clotting of blood in small blood vessels and can lead to anemia, a low platelet count that can result in bleeding, and potential damage to organs.

Although relatively uncommon, TTP/HUS has triggering causes, including food contamination, toxic shock syndrome, post-viral infection, bone marrow transplantation and drug effects. Each of the affected patients had at least two known potential triggers of TTP/HUS, the company said.

"This is an unfortunate occurrence, but not unlike the course of many oncology drugs, where unexpected toxicities are noted, likely causes

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iKnowMed Says Its Network Will Gain With CancerSource

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physicians access to continuing education programs, a searchable drug database, tailored patient education, clinical trial information, cancer-related news, and online conferences and talks, the company said. The CancerSource.com content includes information published in the American Cancer Society's Consumers Guide to Cancer Drugs. The guide is published by the Boston area-based Jones & Bartlett.

The terms of the acquisition were not disclosed.

"It was clear that CancerSource was the perfect fit to dramatically enhance our current oncology knowledge network," said Richard Barker, president and CEO of iKnowMed. "Together, iKnowMed and CancerSource will empower providers and patients with unprecedented information and services."

The medical advisory board of CancerSource.com will now extend its expertise to iKnowMed operations, the companies said.

"The acquisition brings together two companies with complementary strengths and a shared vision dedicated to improving the quality of cancer care," said Vincent DeVita, chairman of the CancerSource.com advisory board and director of Yale Cancer Center.

"We are gaining tremendous value through the CancerSource Medical Advisory Board, which provides us with access to the foremost thought leaders in oncology, and close relationships with key industry organizations," Barker said. "Together we will make personalized cancer care a reality."

According to iKnowMed, the merger will make it possible to tailor both therapy and education to the needs of each cancer patient, combining therapy with patient information. Patients, whose physicians are members of the iKnowMed Network, will have access to their personal medical records and links to educational information and support for their specific disease and treatments.

CancerSource.com will continue to operate as a consumer site and to provide customized content to institutional clients, the companies said.

* * *

IntraLinks Inc. of New York, NY, said **Chiron Corp**. (Nasdaq: CHIR) of Emeryville, CA, has adopted its digital workspaces, a secure web-based collaborative service, to streamline international phase III clinical trials.

Chiron said it is using digital workspaces to integrate **PathoGenesis Corp**., a recent acquisition, into its drug development organization.

"The IntraLinks workspaces provide incredible benefits not only for our merger and acquisition activities, but also for clinical trial management, which have been driven by a laborious, paper-intensive process, with extensive multi-party participation," said Claire Weber, clinical program director at Chiron. "We believe workspaces will revolutionize these practices by enabling instant global collaboration and increase our resource capacity and reduce variable expenses by bringing together hundreds of our scientists, physicians and other parties in one controlled environment. By simplifying the labor intensive process of clinical trials, we take a giant step towards moving new cures to the market faster."

Chiron said it is implementing the services for a clinical trial application of Proleukin, an immunostimulator approved for treatment of advanced-stage kidney cancer and melanoma.

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US Oncology Inc. (Nasdaq: USON) of Houston earned $11.6 million ($0.12 per share) on revenues of $337.3 million for the third quarter ended Sept. 30, the company said. Last year's third-quarter profit was $14.9 million ($0.15 per share) and revenues $277.8 million.

"We are pleased with the progress we have made regarding our merger integration to date," said R. Dale

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Ross, chairman and CEO. "First, the timeliness and accessibility of our financial information has greatly improved, allowing us to use information to better manage our business. Second, our accounts receivable days have decreased from a high of 79 at the end of 1999 to a current level of 70. This decrease, coupled with the proceeds from the sale of the Ilex shares in a prior period, has allowed us to repay $64 million in debt and repurchase $16 million of USON common stock."

Ross said the company has recruited and affiliate with over 75 new physicians to date during 2000. "We are now progressing to the next phase of the merger integration," Ross said. "We anticipate developing a consistent model with our affiliated physicians by better aligning the incentives of physicians under the net revenue model with those of USON."

* * *

Response Oncology Inc. (Nasdaq: ROIX) of Memphis lost $947,000 ($0.08 per share) on revenues of $29.7 million for the third quarter ended Sept. 30, the company said. Last year, the third quarter loss was $164,000 ($0.01 per share) and revenues $32.6 million.

The performance of the IMPACT Centers continues to show the effect of controversial high dose chemotherapy breast cancer studies and the subsequent reduction in high dose referrals, the company said. Also, the company reported a decline in insurance approvals on the high dose referrals obtained. The decrease in pharmaceutical sales to physicians during the quarter is attributable to the termination of two pharmaceutical sales arrangements at the beginning of the quarter.

All operating and general expenses for the third quarter, excluding pharmaceuticals and supplies, were reduced by 19 percent, or $2 million, compared to third quarter 1999, the company said. The reduction is the result of management's cost reduction and containment program begun in the first quarter of 2000, the closing of 7 IMPACT Centers, and the decline in IMPACT patient volumes. Pharmaceuticals and supplies expense increased 4 percent, or $800,000, during the quarter, compared to the third quarter in 1999, principally due to greater utilization of new chemotherapy agents with higher costs in the PPM division, the company said.

A 12-percent increase in physician practice management service fees partially counteracted a 61 percent decline in net patient service revenue for high dose chemotherapy and an 8-percent decrease in pharmaceutical sales to physicians.

During the quarter, the company did not meet certain financial covenants of its credit arrangement, including those related to minimum cash flow requirements. This occurred primarily due to further erosion in high dose chemotherapy volumes, the company said. As a result of this event of default, the company's lenders adjusted the interest rates on the outstanding principal to the default rate of prime rate plus 3% and terminated any obligation to advance additional loans or issue letters of credit.

Delayed TTP/HUS Cause NeoRx To Suspend Accrual

(Continued from page 1)

identified and handled, and, with modifications, drug development proceeds," said Abrams. "In the case of STR, we believe bladder irrigation helps prevent bladder wall damage by preventing radiation from sitting in the bladder, and may help eliminate an increased incidence of TTP/HUS. We also believe that bladder irrigation has helped to prevent the more common problem of blood in the urine."

The method of STR administration at the only site reporting TTP/HUS differs from that used at the other major phase I/II site and from the current phase III protocol in the following respects: 1) the drug was infused more rapidly; 2) the calculated dose to be received by patients was somewhat higher; and, 3) the patients did not receive bladder irrigation during the procedure, the company said.

* * *

Aeterna Laboratories (Nasdaq: AELA, TSE: AEL) of Quebec, said it has submitted applications with FDA and the Health Protection Branch in Canada for a phase II trial of Neovastat/AE-941, an orally bioavailable naturally occurring antiangiogenic product, for multiple myeloma with refractory disease.

The 120-patient study will involve 20 sites across North America and Europe to evaluate the efficacy of Neovastat as monotherapy for multiple myeloma that does not respond to standard therapies.

The principal investigators are Sundar Jagannath, chief, Multiple Myeloma Service, St. Vincent Cancer Center, New York, and Chaim Shustik, associate professor of medicine at McGill University and The Royal Victoria Hospital, Montreal. Jean-Paul Fermand, professor of medicine and head of the Immuno-Hematology Unit of St. Louis University Hospital in Paris is the principal investigator in Europe.

"The multiple mechanisms of action of Neovastat, targeting more specifically VEGF and MMPs, as well as its good safety profile make this drug particularly attractive in the search for new alternatives to treat multiple myeloma," said Jagannath.

Neovastat is also being tested in non-small-cell lung cancer and renal cell carcinoma, the company said.

* * *

Antigenics Inc. (Nasdaq: AGEN) of New York, NY, said it has begun a phase II trial of Oncophage, a cancer vaccine for recurrent metastatic or unresectable soft tissue sarcoma.

Murray Brennan and Robert Maki, of Memorial Sloan-Kettering Cancer Center are the lead investigators, the company said. Expansion of the vaccine to the ninth clinical trial and seventh cancer indication is based on results from previous and ongoing trials in kidney, colorectal, gastric and pancreatic cancers, melanoma and non-Hodgkin's lymphoma, the company said.

* * *

Celsion Corp. (Amex: CLN), of Columbia, MD, said it has filed an application with FDA to begin phase II trials of its breast cancer treatment system.

The system is based on technology developed at MIT for the Star Wars Initiative, which uses adaptive phased array technology to focus microwaves directly to ablate cancerous with targeted heat. The application was filed after Robert Gardner, chief investigator, recommended moving forward.

"Our goal is that patients who normally expected to undergo mastectomy will undergo a lumpectomy instead making this a far more conservative procedure that preserves the breast," said Augustine Cheung, chairman and chief scientific officer at Celsion. "We will use the treatment system on a second group of patients with smaller tumors who will be candidates for a lumpectomy using the system to ablate the smaller tumors completely."

* * *

Ilex Oncology Inc. (Nasdaq: ILXO) of New York and **Symphar S.A.** of Geneva said they have begun a phase II study of Apomine, an orally active bisphosphonate tetra-ester derivative, for prostate cancer.

In the study, men who have shown no response to hormonal therapy and have rising prostate-specific antigen levels in three consecutive PSA screenings will be given a continuous daily dose for three months. Jean-Pierre Droz at the Centre Leon Berard in Lyon will conduct the study, the companies said.

"Apomine activates the farnesoid X receptor, an orphan receptor in the nucleus, and a cascade of biological signals within the cells that rapidly induce apoptosis without affecting normal, healthy cells," said Craig Bentzen, director of research and development at Symphar.

"We continue examining Apomine for broad use in all types of cancers," said Richard Love, president and CEO of Ilex. "Currently, there are no compelling data that show any one prostate cancer therapy has a clinically better chance of success over any other. The possibility of giving patients more treatment options holds significant therapeutic and commercial promise."

* * *

MGI Pharma Inc. (Nasdaq: MOGN) of Minneapolis, MN, said it would begin an international, phase III, multi-center trial of irofulven, an anti-cancer compound (also known as MGI 114, hydroxymethylacylfulvene, or HMAF), for advanced pancreatic cancer.

The trial will begin enrollment near the end of 2000, following finalization of a protocol under review by FDA. Daniel Von Hoff, professor of medicine and director at the Arizona Comprehensive Cancer Center will serve as the lead investigator, the company said.

"Following our end of phase II meeting with FDA, we now have a very clear understanding of the trial design and endpoints needed to seek marketing approval for irofulven," said Michael Cullen, vice president, clinical affairs and chief medical officer of MGI Pharma. "In earlier pancreatic cancer trials, irofulven has demonstrated promising anti-cancer activity."

In the phase III trial, irofulven will be compared to 5-fluorouracil. Median survival will be the primary endpoint, with objective tumor response and other clinical benefit measures as secondary endpoints. An intermittent, weekly dosing schedule will be used, based upon the greatly improved tolerance that was seen with this schedule in a dose optimization trial, the company said.

Side effects from irofulven are comparable to those seen with marketed chemotherapies and include bone marrow suppression, nausea, vomiting and fatigue, the company said.

* * *

Repligen Corp. (Nasdaq: RGEN) of Needham, MA, said it has received FDA concurrence to begin a

phase II trial with CTLA4-Ig, a soluble T cell regulatory protein, for stem cell transplant for leukemia or other malignancies.

The study, to be conducted at the Bone Marrow Transplantation Unit of the Comprehensive Cancer Center at the University of Alabama, Birmingham pending IRB approval, will determine if the protein, in combination with T cell depletion, can reduce the incidence or severity of graft vs. host disease in a stem cell transplant from a genetically mismatched donor, the company said.

"Clinical studies indicate that CTLA4-Ig may prevent or reduce the development of GVHD in this patient population" said Walter Herlihy, president and CEO of Repligen. "Expansion of the donor pool to mismatched family members will substantially reduce the cost of a stem cell transplant and eliminate treatment delays inherent in the search for a matched donor."

By using a matched donor the incidence of GVHD is reduced to 30 percent, but the process of identifying a suitable donor can cost $35,000-$50,000 and can delay treatment for months or longer, the company said.

In a phase I study, CTLA-Ig prevented the development of GVHD in 8 of 11 evaluable patients receiving a SCT for leukemia or other hematopoeitic malignancies (New England Journal of Medicine, 1999, 340 (22) 1704-1714), the company said.

* * *

Techniclone Corp. (Nasdaq: TCLN) of Tustin, CA, said it has begun a phase I study of Cotara, its collateral targeting technology for colorectal cancer, at **Stanford University Medical School**.

In the dose escalation study, safety, biodistribution, and dosimetry of intravenously administered Cotara will be determined, the company said.

Susan Knox, associate professor of Radiation Oncology will be the principal investigator along with sub-investigators George Fisher and Michael Goris, the company said.

"This is an important advancement for the use of Cotara for solid tumors in the U.S.," said John Bonfiglio, president and CEO of Techniclone. The tumor necrosis therapy can treat a wide spectrum of different solid tumors using a single antibody. The potential market size for the therapeutic use of this drug is in excess of a billion dollars annually. We look forward to the phase II brain cancer study and the addition of other solid tumor protocols scheduled by the end of the year and next year," he said.

The TNT technology, invented by Alan Epstein, professor of Pathology at USC, targets necrotic regions of solid tumors and is designed to be a single agent capable of treating a larger variety of tumor types, the company said.

In a related development, Techniclone said it has completed an agreement for a segment of its tumor necrosis therapy technology with **Merck KGaA** of Darmstadt, Germany.

Under the agreement, Techniclone said it would grant Merck the right to use its proprietary TNT antibodies for producing immunocytokines—antibody-cytokine fusion proteins used in the treatment of various diseases. Within Merck, the international team of its affiliate **Lexigen**, of Lexington, MA, will develop the immunocytokines using the TNT technology. The agreement involves an undisclosed upfront payment and a royalty upon commencement of commercial sales, the company said.

"The deal is structured so that Lexigen/Merck will provide all scientific, preclinical, clinical and commercialization resources as well as their know-how in the use of antibodies linked to cytokines, said Bonfiglio. "We will provide antibodies and the genes encoding them for use in the genetic engineering of immunocytokines. In return, we will receive a royalty for all products developed under this deal."

* * *

Valentis Inc. (Nasdaq: VLTS) of Burlingame, CA, said it has reached the halfway point in the enrollment phase of a phase IIb trial of a combination of an interleukin-2 (IL-2) gene medicine and chemotherapy for head and neck cancer.

Valentis said it would continue the 80-patient study, begun in late March 2000 under its collaboration with Roche Holdings Ltd., and expects to complete enrollment of additional 40 patients. The treatment phase of the trial is scheduled to end in Q1 2001.

Data indicate few adverse clinical responses to the addition of either the IL-2 gene or the Valentis lipid-based delivery system as compared to a standard chemotherapy regimen, the company said.

Valentis has two other combination gene medicine therapies in clinical trials, said Tyler Martin, vice president of medical and regulatory affairs at Valentis. One is a combination of IL-2 plus Superantigen B for melanoma. The second is a combination of Interleukin-12 plus Interferon-alpha for accessible solid tumors, which is currently recruiting patients, Martin said.

Deals & Collaborations:

Firm To Collaborate With R.W. Johnson On Vaccines

Dendreon Corp. (Nasdaq: DNDN) of Seattle said it has signed a collaboration agreement with **R.W. Johnson Pharmaceutical Research Institute**, a unit of **Johnson & Johnson** (NYSE: JNJ), for the advancement of cancer immunotherapies.

Under the agreement, PRI said it would provide financial support for research and development activities to be carried out by Dendreon. Dendreon said it would be responsible for clinical testing.

Dendreon and PRI said they would share products and technologies for the development of immunotherapies, such as dendritic cell-based vaccine therapy.

"PRI's innovation in biotechnology, coupled with our leadership in the cancer immunotherapy arena, provides a significant validation for this important area of clinical development and a strong groundwork for our future research and development activities," said David Urdal, chief scientific officer of Dendreon.

* * *

Genomica Corp. (Nasdaq: GNOM) a genomics software company of Boulder, CO, said it has licensed its Discovery Manager software to **Aventis Pharma**, the prescription drugs business of **Aventis S.A.** (NYSE: AVE) of Frankfurt, Germany.

"Discovery Manager is a genomics software product that performs large numbers of gene sequence analyses through a customizable sequence analysis algorithm pipeline," said Paul August, senior associate scientist in the molecular genomics department and manager of high throughput sequencing and cloning at the Aventis Cambridge Genomics Center.

Aventis Pharma will use Discovery Manager as a key technology in its functional genomics efforts, the company said.

The terms of the agreement were not disclosed.

* * *

Genzyme Molecular Oncology (Nasdaq: GZMO) of Framingham, MA, and **Purdue Pharma L.P**., a privately held biopharmaceutical subsidiary of **Purdue Pharma**, of Stamford, CT, said they have entered into a tumor antigen discovery and licensing agreement.

The agreement allows for Purdue Pharma to select a specified number of cancer antigens identified by Genzyme under the research program, the company said. Both may commercialize products using selected antigens based on delivery technology. Genzyme said it estimates that the selected antigens will be less than half of the total number it expects to discover during the research term and will retain rights to those antigens not selected by Purdue Pharma.

Purdue BioPharma L.P. said it would use its proprietary technologies, including its synthebody antibody engineering platforms, epitope strings, and anti-idiotype inducers against these antigen targets to develop cancer agents and vaccines. Genzyme would use its own proprietary technologies, including gene therapy, cell therapy, peptide, and protein-based technologies, against these antigen targets for its cancer product development, the company said.

Under the agreement, Genzyme said it would receive over $21 million in committed funding from Purdue Pharma, which includes technology access fees, research funding over a three-year period, and an equity investment in Genzyme at a premium to market. If Purdue Pharma selects antigens under the research program, Genzyme said it may receive in excess of $310 million in milestone payments related to research and development progress. Genzyme said it is entitled to receive royalties on sales of any Purdue Pharma therapeutic product containing antigens discovered under this agreement.

"Not only will we receive significant research funding for our program, but we may use the antigens discovered under the agreement in our own approaches for developing cancer vaccines," said Gail Maderis, president, Genzyme Molecular Oncology. We can leverage our antigen discovery platform with other partners interested in infectious disease and autoimmune disorders."

"With this agreement, we plan to enhance the depth and breadth of our cancer immunotherapy development program," said Paul Goldenheim, executive vice president for worldwide research and development of Purdue Pharma L.P. "This collaboration with Genzyme will yield novel antigen targets against which we can apply our proprietary technologies to develop new anticancer drugs and vaccines."

* * *

Impath Inc. (Nasdaq: IMPH) of New York, NY, said it has entered into an agreement with **Glaxo Wellcome Inc**. a subsidiary of **Glaxo Wellcome plc** (NYSE: GLX), of London to provide drug development support services for oncology therapeutics.

"The new relationship provides a structure under

which we will use our biorepository of well-characterized cancer tissue specimens to perform immunohistochemical and biochemical analyses to identify target markers in several cancer types," said Anu Saad, president and CEO of Impath. "Further work evaluating various testing platforms would identify appropriate patient populations for upcoming clinical trials and predict a patient's response to a new therapy."

* * *

Lorus Therapeutics Inc. (Nasdaq: LORFF)(TSE:LOR.) of Toronto, said it has formed a strategic supply alliance with **Proligo**, a nucleic acid chemicals supply enterprise, allowing Lorus to advance phase II trial for its antisense anti-cancer drug GTI-2040.

Proligo, a joint venture between SKW Trostberg AG and Gilead Sciences, said it would invest in capital assets and other resources to increase the capacity of the production process to supply higher volumes of drug product required by Lorus for multiple phase II clinical trials. Proligo said it would accelerate the progress toward cGMP manufacturing, thereby proactively adhering to regulatory standards. The combination of a streamlined process and higher production volumes will result in economies of scale and an overall decrease in the cost of GTI-2040 and other Lorus oligonucleotide compounds.

The interim results from the phase I/II clinical trial for GTI-2040, conducted at the University of Chicago, indicate that the drug is achieving the milestone clinical endpoints of safety and tolerability for advanced metastatic solid tumors or lymphoma, the company said. GTI-2040 gave outstanding anti-tumor results when tested alone or in combination chemotherapy with a wide variety of human cancers in animal models, the company said.

Richard Schilsky, of the University of Chicago, will conduct the trial, the company said.

* * *

Medarex Inc. (Nasdaq: MEDX) of Princeton, NJ, and **Eli Lilly and Co.** (NYSE: LLY) of Indianapolic, IN, said they have agreed that Medarex would produce fully human antibodies for a number of Lilly disease targets for the development as therapeutic pharmaceutical products.

Under the agreement, Medarex said it would receive an immunization fee for each target against which it raises an antibody. Medarex said it expects to receive license fees, as well as payments if products attain certain milestones and a royalty in sales.

"The Medarex technology will benefit our expanding therapeutic antibody discovery program by accelerating the introduction of antibody candidates into clinical investigation for several important disease targets," said Thomas Bumol, executive director, research technologies and proteins at Lilly.

* * *

Millennium Pharmaceuticals Inc. (Nasdaq: MLNM) of Cambridge, MA and **Bayer AG**, of Leverkeusen, Germany, said they have agreed to a five-year research alliance to move more than 70 disease-relevant validated drug targets into high-throughput screening or lead identification in two years.

The companies said they collaborated to streamline the drug discovery process with Millennium industrializing the rapid identification, characterization and validation of target proteins and Bayer conducting large-scale high-throughput screening. This approach to target discovery allows for the categorization of genes with disease relevance and is a key step in the process to enhance the productivity of drug discovery, the companies said.

In return for a total investment of up to $465 million, including an equity investment in Millennium over a five-year period, Bayer receives access to key technologies in modern genome research and a flow of new genomics-based targets for drug development, the companies said.

* * *

Northwest Biotherapeutics Inc., a private company of Bothell, WA, said it will collaborate with **Protein Sciences Corp**., a private company of Meriden, CT, to develop a high yield expression vector for production of a proprietary kidney cancer-specific protein as a treatment component for renal cell carcinoma.

"The collaboration extends our proprietary dendritic cell-based immunotherapy, DCVax, to other cancers with limited treatment options," said Alton Boynton, executive vice president and chief science officer of Norhtwest Biotherapeutics.

DCVax is currently being evaluated as a treatment for late-stage prostate cancer at M.D. Anderson Cancer Center and the University of California, Los Angeles, where patient recruitement is underway, the company said. Northwest Biotherapeutics said it is continuing pre-clinical evaluation of DCVax as a treatment for non-small cell lung cancer and for glioblastoma.

The terms of the agreement were not disclosed.

* * *

Progenics Pharmaceuticals Inc. (Nasdaq:

PGNX) of Amsterdam, The Netherlands, and **Cytogen Corp.** (Nasdaq: CYTO) of Princeton, NJ, said they have developed monoclonal antibodies of prostate cancer.

The antibodies, which are directed against prostate specific membrane antigen, are being developed for therapy in naked, radiolabelled and toxin-conjugated forms, the companies said.

"The antibodies uniquely recognize the three-dimensional structure of PSMA as presented on cancer cells," said Robert Israel, vice president of medical affairs at Progenics.

The joint venture involves a parallel development program for the development of therapeutic vaccines, which target PSMA, the companies said.

* * *

Viragen Inc. (Amex: VRA) of Plantation, FL, said its subsidiary, **Viragen**, is collaborating with **Memorial Sloan-Kettering Cancer Center** to begin production of human monoclonal antibodies of melanoma and other cancers.

"The evaluations to be carried out at Memorial will help us select the best antibody to take forward into clinical trials," Magnus Nicolson, chief operating officer of Viragen. "The antibody selected will bind specifically to the antigens on melanoma cells and elicit an immune response resulting in tumor killing. The antibody most effective in killing the tumor cells in vitro will be appraised via clinical trials."

The Memorial pre-clinical evaluations team include: Alan Houghton, chair of the Immunology Program at Memorial; Paul Chapman, clinical immunologist and associate professor of medicine at Cornell University Medical College; and Phillip Livingston, clinical immunologist and professor of medicine at CUMC, the company said.

As part of the collaborative agreement, Memorial said it would underwrite and coordinate the phase I and II trials. A part of the trials will evaluate the efficacy of the antibody treatment in association with the Viragen drug, Omniferon, currently in phase II trials in Europe for hepatitis C.

Product Approvals & Applications:

Isis 3521 Gets Fast-Track Status For FDA Review

Isis Pharmaceuticals (Nasdaq: ISIP) of Carlsbad, CA, said it has been granted Fast- Track review status by FDA for ISIS 3521, an antisense drug to treat non-small cell lung cancer.

A 600-patient, randomized phase III trial of the drug in combination with chemotherapy began in October, the company said.

In the phase II trial, ISIS 3521 added to carboplatin and paclitaxel has produced a median survival of 19 months for stage IIIb or stage IV non-small cell lung cancer, with minimal side effects, the company said. The typical median survival of patients receiving standard chemotherapy alone is approximately 8 months.

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Schering-Plough Corp. (NYSE: SGP) of Kenilworth, NJ, said it has received marketing authorization from the European Union Commission of the European Communities for Caelex, a long-circulating STEALTH pegylated liposomal formulation of doxorubicin hydrochloride cytotoxic agent for advanced ovarian cancer where a first-line platinum-based chemotherapy regimen has failed.

The study demonstrated advantages over topotecan, the standard approved agent. The authorization recommends the therapy be administered intravenously at a dose of 50 mg/m2 once every four weeks as long as tolerance continues and the disease does not progress, the company said.

Commission approval of the centralized Type II variation for the product results in a single Marketing Authorization with unified labeling that is immediately valid in all 15 EU-member states and follows the June 2000 recommendation for approval by the EU Committee for Proprietary Medicinal Products of the European Agency for the Evaluation of Medicinal Products, the company said.

Schering-Plough said it has exclusive international marketing rights to Caelex, excluding Japan and Israel, through a distribution agreement with **ALZA Corp.** (NYSE: AZA) of Mountain View, CA, which it markets in the U.S. under the tradename Doxil.

* * *

Sicor Inc. (Nasdaq: SCRI) a manufacturer and marketer of multi-source injectable pharmaceuticals of Irvine, CA, said **Gensia Sicor Pharmaceuticals Inc**., its wholly owned subsidiary, has received approval of an abbreviated new drug application from FDA for Leuprolide injection as a palliative treatment of advanced prostate cancer.

The product will be available in a shatter-resistant polymer plastic vial, an advantage over glass vials for patients who self-administer, the company said.

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