THE CANCER LETTER

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NCAB Forms Subcommittee To Develop A Biomedical Technologies Initiative

The National Cancer Advisory Board formed subcommittee on biomedical technology to advise NCI on the development of a "national advanced biomedical technologies initiative."

NCAB member Eric Lander, who said he has been "pushing" NCI for two years to begin such an initiative, will serve as chairman of the subcommittee. Lander was named director of the Broad Institute, a collaboration announced last June between Harvard University and the Massachusetts Institute of Technology, where Lander directs the MIT

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In Brief:

NCI Renews Roswell Park's Core Grant For Five Years; 100 New Faculty In 3 Years

ROSWELL PARK CANCER INSTITUTE received a five-year renewal of its Cancer Center Support Grant by NCI, retaining its status as an NCI-designated comprehensive cancer center, a recognition Roswell Park has held since 1974.

The institute's status was in question three years ago, when NCI gave the center only a three-year renewal.

"In the three years since the last renewal, RPCI has recruited over 100 new clinical and scientific faculty, has developed five integrated programs incorporating laboratory and clinical research, has increased the quality and volume of federal and foundation grants and patents, and has planned the construction of the Center for Genetics & Pharmacology," said David Hohn, president and CEO of the institute. "Renewal of the core grant is validation that we are moving in the right direction. We are very proud of what has been accomplished."

The five-year grant will provide financial support for multidisciplinary translational research programs in Biophysical Therapies, Cancer Prevention, Genetics, Tumor Immunology and Therapeutics, as well as shared scientific and clinical resources.

"New Yorkers have long known that Roswell Park Cancer Institute is a leader in cancer research and treatment and this five year renewal of its comprehensive cancer center designation makes it clear that it remains among the finest facilities of its kind in the nation," said New York State Governor George E. Pataki. "Western New Yorkers are fortunate to have a health care resource of this magnitude in their own back yard, and I am proud of the part the State has played in preserving and enhancing Roswell

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Eric Lander, Lee Hartwell Lead NCAB Technology Task Force

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Center for Genome Research and is a member of the Whitehead Institute.

The new Ad Hoc Subcommittee on Biomedical Technology will first form a task force to solicit advice for the initiative. Lander and Lee Hartwell, president and director of the Fred Hutchinson Cancer Research Center, will serve as co-chairmen of the task force.

"This has grown out of efforts the NCI has been involved in for many years," Lander said at the NCAB meeting Sept. 9. "NCI has been a leader in recognizing the importance of developing infrastructure, and particularly technological infrastructure, such as the Cancer Genome Anatomy Project.

"We are entering a period where there is just extraordinary opportunity for technology to accelerate and enable both basic science, further discovery in cancer, and also clinical application, therapeutics," Lander said. "There are common sets of tools, technologies, databases, that, if they were in the hands of everyone from basic researchers to the most clinical researchers, would let them get their jobs done much more effectively and let us get to the broad goals we have of elimination of death and suffering from cancer."

Lander said the NCI initiative could be "a little analogous to the Human Genome Project," to which he was a leading contributor. "We had to pull together to build infrastructure that undergirded everything," he said. "There's a sense here that there are many, many different sorts of approaches that are needed."

The task force will form "focus groups" of scientists "to talk about what is really needed by these different communities, what the opportunities really are, and come back thoughtfully with suggestions about what kinds of programs might be needed," Lander said. "We have no preconceptions about what programs might be needed, but a strongly held preconception that we have great opportunities, which, unless we think about them in an organized fashion, we may miss.

"I'm grateful to the NCI for pushing us along, and I have been pushing very hard on this point for the past two years, and have now pushed to a process that we will be able to bring back to the NCAB with options," Lander said.

NCI Director Andrew von Eschenbach said the task force will conduct a needs assessment, and examine models for technology development and the role NCI can play in the process.

"We see this as an enormous opportunity for NCI to step forward and to take a leadership role in helping to create and develop this initiative and provide an integrative force to bring all the parts and pieces together in a way that we synergize the effort in which the whole is much greater than the sum of its parts," he said to the NCAB.

"One of the things that's clear to me in terms of how we will continue to maintain this exponential growth and this trajectory that we are on in our expansion of our biomedical research agenda is the important integration of science with technology," von Eschenbach said. "If one looks at the tremendous progress we have made in our scientific understanding of cancer…a tremendous amount of that progress has been made possible, and has been nurtured and fostered by the equal spectacular development in technology.

"So, if we go forward strategically to the elimination of suffering and death due to cancer, one of the important opportunities for us is to continue to drive the integration of science and technology, to continue to drive the development of technology to provide even better tools to our investigators than they may have even had yesterday," von Eschenbach said.

In a statement posted on the NCI Web site, von Eschenbach described the initiative as "major hub and

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node components working together through an integrated network.

"The hub of the network will focus on the development of specific critical, often unique, resources, such as bioinformatics and function imaging, which can be provided to investigators across the biomedical research community nationwide," von Eschenbach wrote. "The hub will provide connectivity and coordination to the nodes in the network, and will facilitate access by the cancer research and care communities to the essential technological platforms being developed."

"Nodes" of the network would "provide excellence in a specific area of technology and/or offer unique capabilities in problem solving spanning from research to development and applications," von Eschenbach wrote. "They will link the most innovative biomedical scientists, physical scientists, clinicians, engineers, mathematicians and others in cutting-edge collaborations with each other, with people working at the initiative's hub, and with other key partners in academia, the biotechnology and pharmaceutical industries, and other government agencies."

According to the NCAB statement forming the subcommittee, "To meet the challenge goal to eliminate the suffering and death due to cancer by 2015, there must be a linking of technology development and biomedical research to create opportunities to accelerate our understanding of the genetic, molecular and cellular mechanisms that determine the development and behavior of diseases such as cancer."

The new subcommittee, the NCAB statement said, will advise the NCI director "on the development and application of biomedical technologies to cancer research, the nature and structure of centers and consortia (node) that integrate research, development and applications, and mechanisms that could facilitate the development of a network to integrate the discovery-development continuum and accelerate the delivery of new agents and technologies."

The subcommittee will form "working and focus groups to explore the potential contribution of current and future advanced technologies in the development of strategies to preempt cancer at various stages," the board said.

NCI Budget Outlook: 3.9% Increase

NCI will have to take a "more rigorous approach to business planning" in the current budgetary climate, von Eschenbach said to the NCAB.

Earlier this month, the Senate passed a $4.771 billion appropriation for NCI for fiscal year 2004, a $179 million increase, about 3.9 percent, over the fiscal year 2003 budget of $4.592 billion. The House also approved a $4.7 billion budget for the Institute.

In fiscal 2003, which ends Sept. 30, NCI had about a 10 percent increase over the previous year and funded almost 5,000 grants, of which 3,260 were competing awards, an increase of about 100 grants from fiscal 2002.

The overall grants "payline" this year dropped from the 22nd percentile to the 20th percentile. NCI officials said the drop is partly explained by a 7 to 9 percent increase in the number of applications submitted to the Institute, and efforts across NIH to increase the average funding for awards.

In fiscal 2003, the cancer centers, training, and prevention programs increased by 11 to 12 percent. The Specialized Program of Research Excellence grants program had a 25 percent increase, from $95 million to about $125 million.

For fiscal 2004, NCI officials said they expect intense pressure on the grants pool, with only $179 million in new funding expected. NCI expects to put $30 million of new funding for competing awards, but even so, the R01 payline can be expected to drop from this year's 20th percentile to the 18th or 19th percentile, said John Hartinger, director of the NCI Office of Management.

"To raise that to the 20th percentile would be in the range of 80 to 100 additional competing awards, and at an average cost of about $360,000, that's going to require quite a few millions to keep the percentile payline up," Hartinger said to the NCAB. "It's clear that…a 3.9 percent increase is going to present some challenges to maintain the payline and to fund some of the other initiatives."

The NCAB Research Project Grant Working Group is studying how to maintain the payline at the 20th percentile in the face of increasing number of applications and average cost. NCAB member Larry Norton serves as chairman of the group.

NIH Director Elias Zerhouni would have $35 million under the 2004 President's budget to fund his "Roadmap" initiatives. Institute directors submitted initiatives for those funds.

NCI's fiscal 2005 Bypass budget, a professional judgment budget, is scheduled to be released at the end of this month. However, the Institute is "participating actively in the NIH 2005 budget process," Hartinger said. The NIH budget request

has been submitted to the White House as part of the HHS budget.

The dismal budget outlook prompted NCAB members to question how NCI plans to fund the biotechnology initiative. Von Eschenbach hinted that the Institute might become financially creative.

"There are opportunities for looking at that outside our normal budgetary stream as a special initiative requiring a special appropriation," he said. "That's a work in process."

In other developments:

—Von Eschenbach told the NCAB that he hopes to announce the recruitments of senior leadership for the NCI extramural clinical research programs.

The vacancies include the jobs of a deputy director for extramural research and a permanent director for the Division of Cancer Treatment and Diagnosis. The two jobs were held by Robert Wittes, who moved to Memorial Sloan-Kettering Cancer Center in March 2002.

Though Wittes held both titles, von Eschenbach has been recruiting for two people to take the jobs.

Until these jobs are filled, NCI would be unlikely to proceed with implementation of the P30/P50 Working Group report released last spring that made recommendations for the Cancer Centers Program and the Specialized Program of Research Excellence.

Several cancer center directors have privately expressed irritation with NCI's inaction on the report.

—NCI has established a "Training Commission" led by Center for Cancer Research Director Carl Barrett, to review the Institute's intramural and extramural training programs.

—As a result of the war in Iraq, pediatric cancer care in that country is not available, von Eschenbach said.

The NCI-supported Middle East Cancer Consortium and international relief agencies have helped to identify children in need of care, and the government of Jordan has begun accepting the children for treatment at a cancer center in Amman.

NCI is beginning to look at ways to provide training opportunities to help Iraq rebuild its medical oncology infrastructure, von Eschenbach said to the NCAB.

"It's not something that NCI could ever do by itself, but by providing our particular piece, especially in terms of training and development of personnel, and working collaboratively with other agencies, the bottom line and the fact of the matter is, lives are being saved," von Eschenbach said. "There are children who would have died were it not for this effort."

—The NCI director's office has posted a new Web page, www.cancer.gov/directorscorner, for weekly messages from von Eschenbach, with links to his speeches and selected interviews.

"There are so many things that I would like to tell you, so many things that are going on," von Eschenbach said to the NCAB. "The level of activity is unprecedented, it's absolutely enormous, and we have come to believe that it's extremely important that we continue to find vehicles and ways in which we can communicate not only with you, but communicate with the entire public, about the initiatives and about the things that the National Cancer Institute is involved in.

"It's regrettable sometimes that these kinds of stories and these kinds of activities do at times get reported, but they may not necessarily get reported accurately, or get reported from the perspective of what is truly, fully involved in the initiative," von Eschenbach said.

"So I have taken the initiative to use our Web site, Cancer.gov, and have created The Director's Corner, in which I will be providing weekly updates to the entire community around many of the initiatives and around many of the activities that are going on within the NCI, and so that there will be this opportunity to engage in, if you will, conversation, and the ability to hear from me with regard to initiatives that we are undertaking, the rationale for many of those initiatives, our expectations and our hopes for many of those initiatives, and to continue to help us work collaboratively and cooperatively together towards our ultimate goal, which is the elimination of the suffering and death due to cancer."

The site currently includes links to von Eschenbach's Congressional testimony, and interviews with Urology Times, the Journal of the National Cancer Institute, and Benchmarks, an internal NCI publication.

—Von Eschenbach praised the American Association for Cancer Research for holding its annual meeting in July in Washington, D.C.

"[AACR CEO] Marge Foti and the entire group of the AACR deserve an enormous amount of credit for what was a spectacular meeting that had to be brought together under very, very difficult circumstances and within a very, very short timeline," he said. "NCI's participation in helping bring that

about is something that we are very proud and satisfied with, given the outcome."

The Institute provided about $2 million to help AACR pay for the meeting (**The Cancer Letter**, June 20, 2003).

—NCI is leading a trans-HHS project on the elimination of healthcare disparities, using its Program Review Group model for strategic planning and implementation.

"The Secretary was extremely enthusiastic about it," von Eschenbach said. NCI will provide the "model and infrastructure to address the problem…. There really, truly is now the opportunity for multiple agencies… to come together to work on a comprehensive solution to a critical problem, not only for cancer, but also in health care. It's an effort on the part of NCI to use its resources in a collaborative way to catalyze a process and help provide leadership for something that will not only benefit us, but benefit the entire group."

—The President's Cancer Panel is studying issues of cancer survivorship, particularly in childhood cancer, over the next year.

Panel member Lance Armstrong has become a consistent theme of von Eschenbach's recent speeches:

"I had the privilege in July to go to a follow-up event of the President's Cancer Panel, and as part of that event, I had the opportunity to witness a member of the President's Cancer Panel cross the finish line in Paris to win the Tour de France for the fifth consecutive time," von Eschenbach said to the NCAB. "Lance Armstrong has been an incredible model with regard to cancer survivorship to remind us not only of the ability to overcome cancer, but also to remind us about how much can be accomplished in life even after cancer, not just necessarily before. It was an extremely moving moment to me, and an extremely powerful opportunity…with regard to heightening cancer awareness and the important role of survivorship.

"It caused me to reflect on my own personal career as a urologic oncologist," von Eschenbach said. "The National Cancer Act was signed in 1971, the year Lance Armstrong was born. Five years later, in 1976, I began my career as a urologic oncologist a fellow at M.D. Anderson. In 1976, when I began taking care of testicular cancer patients, if somebody told me then that a young man with testicular cancer with metastasis to lymph nodes, to lung, and to brain would be alive five year later, I would have told you that was a dream. If you told me then that not only would that person be alive, but would win the Tour de France five consecutive times, I would have told you that was a fantasy.

"In 1976, it was a fantasy. In 1996, Lance Armstrong developed testicular cancer with metastasis to lymph nodes, to lung, and to brain, and in 2003, he crossed the finish line for the fifth consecutive time. What was fantasy in 1976 is reality in 2003.

"Some may think that eliminating suffering and death due to cancer is a dream, and some may think that doing that by 2015 would be a fantasy," von Eschenbach said. "But I believe that if we look at the incredible progress we have been making since 1971, and the continuing evolution of our understanding of cancer as a disease process, and our ability to look at the multiple steps that occur in that process from the point of our susceptibility to the disease to the point where we develop the disease and it evolves and progresses and it ultimately assumes a metastatic phenotype that becomes lethal, that we really, truly, have the opportunity to intervene in that process in a way that is a strategy of multiple integrated interventions that can prevent it, can detect and prevent it, can eliminate it, or modulate it such that no one suffers and dies as a result of cancer.

"To bring that about, to achieve the opportunity that is before us, is going to require us to continue to accelerate and develop our portfolio of discovery, development, and delivery."

Medicare Policy:

Most People Don't Know About Looming Cuts In Cancer Care, Don't Support It, Survey Finds

Most Americans are unaware that the Medicare prescription drug benefit bills now before Congress contain multi-billion dollar cuts for cancer treatment, and most, once told, expect President Bush to demand those cuts be removed before signing the legislation, according to a survey released Sept. 25 by two cancer organizations.

Nearly eight out of 10 (78%) respondents say Congress should remove the cancer care cut provision before the legislation is finalized, the survey of 1,026 adults found.

Three out of five (60%) voters surveyed expressed the view that they would prefer Congress pass no drug benefit bill at all rather than one

containing the cancer treatment cuts.

"An overwhelming margin of voters prefer that cancer care cuts be removed from the Medicare prescription drug bill," said pollster Kellyanne Conway, President and CEO of The Polling Company, who, along with polling firm StrategyOne, jointly conducted the poll for the National Coalition for Cancer Survivorship and the American Society of Clinical Oncology.

"The message from the American public is unmistakable—do not pass prescription drug benefit legislation that includes reduction in Medicare funding on cancer therapies," said ASCO President Margaret Tempero.

Other survey findings include:

—77% of those surveyed say they feel "angry and frustrated with Congress" for including such cuts in the legislation.

—78% say that if Congress sends legislation still containing the cancer-treatment cuts to the White House, President Bush should call on Congress to produce a new plan without the cuts.

Both versions of the drug benefit bills, now in a House-Senate conference to resolve differences, call for reductions of up to $16 billion in Medicare's reimbursements for chemotherapy agents and other cancer treatments, NCCS President Ellen Stovall said.

NCCS and a dozen other cancer groups sent a letter to House Speaker Dennis Hastert, calling the cuts "a significant and unprecedented reduction...that will seriously jeopardize patient access to cancer care, especially in rural and low-income communities, as well as to research and clinical trial enrollment."

"The cancer community is united in our opposition to these extreme cuts," Tempero said. "Patients, physicians, and nurses who've experienced cancer firsthand are convinced they will lead to massive disruption in access to treatment, including the closing of community cancer treatment centers in every part of the country."

Pollster Conway called the results "a wakeup call for every Congressional incumbent soon to vote on the legislation," adding, "Clearly, no member is going to have an easy time explaining to the voters how he or she ended up voting for a multi-billion dollar cancer-care cut in a bill that's supposedly about creating a new Medicare benefit."

More than 200 members of Congress have signed letters calling on the Conference Committee to reform Medicare reimbursements for cancer care so that "access to community-based cancer care will be preserved, as will be so much of the progress America has achieved in its War on Cancer."

Rep. Charlie Norwood (R-GA), a leader in this effort, said Congress should remove the cancer care cuts in the Medicare bill. "You don't have to be a pollster or mathematician to see that the vast majority of folks don't even know that cancer care cuts are in the Medicare bill... and once they know it, they think it's a bad bill... and they're right," Norwood said.

The phone survey was conducted from Sept. 5-9, and has a margin-of-error of +/- 3.1% at a 95% confidence level, the organizations said.

NIH News:

NIH Wins A-76 Competition For Administrative Support

NIH employees have won their first large competition begun this year under a competitive sourcing program known as A-76.

The 750-position Extramural Administrative Support Service group won when the sole proposal submitted by industry failed to meet the requirements of the solicitation. As a result, NIH has withdrawn its request for proposals and the employee-developed "most efficient organization" bid has prevailed.

The administrative support services group provides technical support and secretarial support to physicians and other scientists who review and administer NIH's grants.

NIH annually manages $22 billion worth of research to medical schools and private laboratories.

"I am delighted about this victory for three reasons: one, for the taxpayers, who are assured once more that we are managing wisely; two, for the employees, who prepared an outstanding bid and won the competition; and three, for the NIH as a whole, as this win reaffirms our ability to effectively carry out the NIH mission to improve people's health," said NIH Director Elias Zerhouni.

"At the same time, I realize that this winning bid means change and relocation for some employees," Zerhouni said. "For these members of our NIH family, we'll work to make this transition as smooth as possible."

Under regulations which require the federal government to use private contractors for services when they are more efficient and less costly, government-wide competitions have been required under the rules of Office of Management and Budget circular A-76; hence, the name A-76 reviews.

In Brief:

Ohio State To Study Expansion Of Cancer Center Facilities

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Park's success."

"Roswell Park has been on a mission to rebuild its stature as one of the world leading research facilities in the quest to cure cancer," noted Patrick P. Lee, Chairman of Roswell Park's Board of Directors. "While much has been accomplished in the past few years, the renaissance at Roswell Park has just begun."

Since the last NCI core grant review in 1999, RPCI has recruited more than 100 new clinical and scientific faculty including 11 senior leaders. The center also has improved its facilities; 60% of the RPCI campus is comprised of newly constructed facilities or renovated space. One of the most visible highlights was the demolition of the old hospital, replaced by WJK Park and Gardens, and the opening of the new hospital and outpatient facility, and the Medical Research Complex. Construction is scheduled to begin shortly on a Buffalo Life Sciences Complex to house RPCI's Center for Genetics and Pharmacology and UB's Center of Excellence in Bioinformatics.

Roswell Park ranks 42nd among more than 2,000 institutions, research universities, and companies that receive NCI funding. The ranking earns RPCI a place in the NCI's top 65 institutions in the country. RPCI ranks fourth among New York institutions in total funding.

RPCI faculty have received 43 grants since last January for a total value of $40.9 million and a first-year value of $11.2 million. These include two NCI program project grants. **Allan Oseroff**, chairman of the Department of Dermatology, is principal investigator on a five-year $10.9 million extension of a P01 grant for studies of photodynamic therapy. **John Subjeck**, of the Department of Molecular and Cellular Biophysics, is principal investigator on a five-year, $6.9 million grant to study the functional interactions of thermal stress, heat shock proteins and the immune response.

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OHIO STATE UNIVERSITY'S NCI-designated comprehensive cancer center, the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, has begun a feasibility study for expansion of basic and clinical research programs and facilities, including a significant increase in the number of inpatient beds, the center said this week.

Growth of the center's research programs over the past 10 years is one of the factors leading to an apparent need for expansion.

Michael Caligiuri was recently named center director, replacing **Clara Bloomfield**, who returned to full-time research. **David Schuller** is director of the James Cancer Hospital, which has 160 inpatient medical/surgical beds, a BMT inpatient and outpatient program, an experimental therapeutics program, outpatient clinics for surgery, hematology, and oncology, radiation therapy, and wet research labs.

The hospital is one of the largest freestanding cancer hospitals based within an academic medical center in the nation, and based on current high occupancies, additional beds will be required to meet the demand of the growing programs in clinical trials and translational sciences, the center said. Other basic and translational research is scattered throughout the campus in a number of buildings.

A goal of the project is to better organize existing programs and services while planning for expansion. To carry out this major financial feasibility study, OSU awarded a contract to Oncology Solutions LLC of Atlanta, a national oncology-consulting firm and their architectural consultants NBBJ Architects of Columbus. The financial feasibility study and site alternatives analyses are expected to be completed by Oncology Solutions in early 2004.

* * *

CITY OF HOPE'S Comprehensive Cancer Center designation has been renewed by NCI. The renewal comes with an award of $1l million over five years to support the six interdisciplinary cancer research programs and research infrastructure, and to develop new programs for treatment and control of cancer. **Theodore Krontiris** is the cancer center director and executive vice president, Medical and Scientific Affairs. . . . **JEROLD MANDE** was named associate director for policy at Yale Cancer Center by **Richard Edelson**, center director. Mande is a lecturer in the Departments of Pediatrics and Epidemiology and Public Health at Yale University School of Medicine. Mande's initial goal is to define the role for Yale in Connecticut's Cancer Control Plan in conjunction with the Connecticut Cancer Partnership. Mande hopes to work with the state department of public health, the University of Connecticut, and leading businesses and advocates to increase the funds spent on cancer research, care,

early detection, and prevention. Mande went to Yale last year as director of policy programs for Yale School of Medicine, after 20 years in Washington in public policy roles. On the White House staff, he advised Vice President **Al Gore** on cancer policy and President **Bill Clinton** on tobacco policy. He was deputy administrator of OSHA, and senior advisor and executive assistant to the FDA Commissioner from 1991-1997. He is a founding member of the National Dialogue on Cancer and has chaired the Task Force on State Tobacco Funding since 2001. . . . **BURTON EISENBERG** is the new deputy director at Dartmouth's Norris Cotton Cancer Center, as well as professor of surgery at Dartmouth Medical School and a surgical oncologist at Dartmouth-Hitchcock Medical Center. He joined Norris Cotton Cancer Center in September from Fox Chase Cancer Center, where he was chairman of the Department of Surgical Oncology. . . . **JURI GELOVANI** joined University of Texas M. D. Anderson Cancer Center as professor and chairman of the Department of Experimental Diagnostic Imaging, Division of Radiation Oncology. Gelovani was head of the molecular-genetic and cellular imaging section in the Department of Radiology at Memorial Sloan-Kettering Cancer Center. . . . **H. LEE MOFFITT** Cancer Center staff appointments: **Alan List**, leader of the Hematological Malignancies Program, was director of the Bone Marrow Transplant Program, University of Arizona Cancer Center. **Timothy Yeatman,** associate center director for clinical investigations and program leader of the Gastrointestinal Tumor Program, has served as interim associate center director. **Timothy Sellers,** associate center director for cancer control, was deputy director of the Mayo Cancer Center. **James Mule**, associate center director for translational science and technology transfer, was director of the Tumor Immunotherapy Program at the Comprehensive Cancer Center, University of Michigan Medical Center. . . . **CRAIG JORDAN** was named director of the hematologic malignancies translational research program at the James P. Wilmot Cancer Center. He was at the Markey Cancer Center, University of Kentucky. . . . **DINO STEA** was named head of the Department of Radiation Oncology at the Arizona Cancer Center. For the past year, Stea has served as interim head of the department, and was a resident in radiation oncology at NCI. . . . **NEAL FLOMENBERG** was named director of the Division of Medical Oncology at Jefferson Medical College, Thomas Jefferson University. He has been acting director of the Division of Medical Oncology since 2001 and director of the Hematologic Malignancies and Hematopoietic Stem Cell Transplant Program in the Division of Medical Oncology at TJU Hospital and Kimmel Cancer Center since 1994. He will retain the latter position. . . . **FOX CHASE Cancer Center** and **Wilex AG,** of Munich, Germany, have been awarded the first Biotechnology Clinical Partnership Award worth $3.9 million from the U.S. Department of Defense Breast Cancer Research Program. The award will support two clinical trials of a Wilex investigational agent, WX-UK1 for advanced breast cancer. **Lori Goldstein** is director of the Fox Chase Breast Evaluation Center and leader of the Breast Cancer Research Program. . . . **EDMUND LATTIME** was awarded $1 million, five-year grant from NCI to train 10 postdoctoral candidates in the development and testing of diagnostic and therapeutic cancer research. He is associate director for education and training at The Cancer Institute of New Jersey. . . . **KENNETH HONN** has been awarded a three-year $558,472 grant from the Department of Defense for prostate cancer research. Honn is a researcher at the Barbara Ann Karmanos Cancer Institute. . . . **BERT VOGELSTEIN**, of Johns Hopkins Kimmel Cancer Center, is ranked as the most-cited researcher of the last 20 years (1983-2002) with 361 papers and over 100,000 citations, according to the September/October 2003 issue of ScienceWatch. His 1983 paper in Analytical Biochemistry on radiolabeling DNA is the second most-cited paper with over 20,000 citations. Vogelstein and **Kenneth Kinzler**, also ranked in the top 20, co-direct the Molecular Genetics Laboratory at the Johns Hopkins Kimmel Cancer Center. Vogelstein also is a Howard Hughes Medical Institute Investigator. . . . **VIRGINIA COMMONWEALTH UNIVERSITY** researchers, led by **Rupert Schmidt-Ullrich**, were awarded a five-year, $4.5 million NCI program project grant to study how cancer cells respond to radiation. . . . **NATIONAL INSTITUTE** of Allergy and Infectious Diseases has named five Cooperative Centers for Translational Research on Human Immunology and Biodefense. About $85 million over four-and-a-half years will support research at **Baylor Research Institute, Dana-Farber Cancer Institute, Emory University School of Medicine, Stanford University School of Medicine,** and **University of Massachusetts Medical School**.

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Business & Regulatory Report

Oncology Management:

CMS Issues Hospital Reimbursement Coding Instructions For Bexxar Therapy

Corixa Corp. (Nasdaq:CRXA) of Seattle and **GlaxoSmithKline** (NYSE:GSK) of Philadelphia said the **Center for Medicare & Medicaid Services** has issued coding instructions to hospitals for obtaining reimbursement for Bexxar (Tositumomab and Iodine I 131 Tositumomab) under the hospital outpatient prospective payment system.

The instructions were published in the first "One-Time Special Notification" and are also the first to be issued under the agency's new

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Approvals And Applications:

ImClone And Bristol-Myers Submit Erbitux Biologics License Application To FDA

ImClone Systems Inc. (Nasdaq: IMCL) of New York and **Bristol-Myers Squibb Co.** (NYSE: BMY) of Princeton, NJ, said ImClone has submitted a biologics license application to FDA for the approval of Erbitux (cetuximab), in combination with irinotecan, for EGFR-expressing irinotecan-refractory metastatic colorectal cancer.

Erbitux is an investigational IgG1 monoclonal antibody that targets and blocks the epidermal growth factor receptor, which is expressed on the surface of cancer cells in multiple tumor types, the companies said. ImClone Systems has requested priority review of the application and accelerated approval consideration.

"The submission of the Erbitux BLA is a milestone that all of us at ImClone Systems have worked diligently to achieve on behalf of colon cancer patients," said Daniel Lynch, acting CEO.

In a related development, John Mendelsohn, the scientist who conducted preclinical development of the agent, did not run for re-election to the company's board of directors. Mendelsohn is president of M.D. Anderson Cancer Center. Joseph Fischer, a former executive with Johnson & Johnson and Dial Corp., joined the ImClone board and its audit committee.

* * *

Corixa Corp. (Nasdaq: CRXA) of Seattle said the Biologics and Genetic Therapies Directorate of **Health Canada** has accepted its new drug submission for Bexxar under a Priority Review.

FDA approved the agent in June 2003 for non-Hodgkin's lymphoma, the company said.

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CMS Issues Instructions For Bexxar Reimbursement

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Internet-only manual. The codes are retroactive to July 1.

Incorporating both existing and newly assigned codes, the CMS instructions provide reimbursement for all the procedures necessary to administer the Bexxar therapeutic regimen, including gamma camera scans, dosimetric calculations for the unique patient-specific therapeutic dose, and product administration.

The Bexxar regimen was approved by FDA on June 30, 2003, for the treatment of patients with CD20 positive, follicular, non-Hodgkin's lymphoma, with and without transformation, whose disease is refractory to Rituximab and has relapsed following chemotherapy.

The CMS One-Time Notification identified the following codes for hospitals to bill Medicare for Bexxar:

—G3001, Administration and supply of tositumomab, 450mg, for the infusion of non-radioactive tositumomab during the dosimetric step and the infusion of non-radioactive tositumomab during the therapeutic step. This is a new code and will be used twice during the course of Bexxar therapy.

—G0273, Radiopharmaceutical biodistribution, single or multiple scans on one or more days, pre-treatment planning for radiopharmaceutical therapy of non-Hodgkin's lymphoma, includes administration of radiopharmaceutical (e.g., radiolabeled antibodies) for the Bexxar dosimetric dose using Iodine I-131 tositumomab. An existing code, G0273 includes all scans taken during the dosimetric step and should be billed only once, no matter how many scans are performed.

—G0274, Radiopharmaceutical biodistribution, single or multiple scans on one or more days, pre-treatment planning for radiopharmaceutical therapy of non-Hodgkin's lymphoma, includes administration of radiopharmaceutical (e.g., radiolabeled antibodies) for the Bexxar therapeutic dose using Iodine I-131 tositumomab. G0274 is an existing code.

—CPT 77300, an existing code for dosimetry calculation.

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Altair Engineering Inc. of Troy, Mich., said the **Translational Genomics Research Institute, Arizona State University and the International Genomics Consortium** have selected its workload management software, PBS Pro, to manage its supercomputing infrastructure.

PBS Pro, which consists of a 1024 Beowulf IBM Linux cluster, will enable all three institutes to optimize its high-performance computing environment by aggregating computation resources into a virtual pool and scheduling computational workloads across the pool, allowing researchers to accomplish projects in record time, the company said. The Linux cluster focuses on genomic research for diseases including cancer.

"The amount of computing power necessary to conduct our research is enormous, so we needed a solution that allowed us to fully utilize our processing power," Ed Suh, chief information officer at TGen.

* * *

MercuryMD of Research Triangel Park, N.C., said **M. D. Anderson Cancer Center** has chosen its Mercury MD Data Enterprise System that integrates hospital data and delivers patient information directly to the physician on handheld devices, the company said. Data can include patient census lists, demographics, laboratory results, diagnostic reports, medication lists, consults and other transcribed reports, the company said.

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Molecular Imaging Corp. (OTC BB: MLRI) of San Diego said one of its subsidiaries has entered into definitive agreements with the **University of**

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California at San Diego, to open and operate the University of California, San Diego Center For Molecular Imaging, a facility that will offer Positron Emission Tomography imaging services.

Under the agreements, UCSD School of Medicine radiology faculty will provide clinical patient support services and the MIC will manage the business operations of the center, the company said.

The facility will serve the UCSD Healthcare patient population and the greater San Diego metropolitan area. UCSD and the MIC will up grade the current PET scanner to a PET/CT in the near future, and add a MicroPET imaging system for clinical research the San Diego area research and biotechnology companies.

* * *

National Comprehensive Cancer Network of Jenkintown, Pa., said it has updated the NCCN Multiple Myeloma Clinical Practice Guidelines.

The NCCN panel of oncologists has added bortezomib (Velcade) to its listing of chemotherapeutic agents for progressive or refractory multiple myeloma with prior treatment with conventional dose chemotherapy alone or followed by high dose chemotherapy and stem cell transplant, the network said. Bortezomib, aproteasome inhibitor, has been approved by FDA.

Another update is the inclusion of the combination of thalidomide (Thalomid) and dexamethasone for the primary treatment of disseminated disease, the group said. Thalidomide had been recommended for progressive or refractory multiple myeloma.

NCCN Clinical Practice Guidelines in Oncology are available free of charge on CD-ROM. They can be ordered from NCCN by calling 215-690-0300. The guidelines can also be found at www.nccn.org.

Approvals & Applications:

Health Canada Accepts Corixa's Bexxar Submission

(Continued from page 1)

Corixa and GlaxoSmithKline Inc. in Canada entered into an agreement in May 2003 that in the event of product approval, GSK would market the agent in Canada, the company said.

Under the agreement, GSK is responsible for registration, marketing and sales of the product in Canada. Corixa is responsible for the manufacture and supply of Bexxar therapy to GSK for the Canadian market. Bexxar is indicated in the U.S. for CD20 positive, follicular, non-Hodgkin's lymphoma, with and without transformation, where the disease is refractory to Rituximab and has relapsed following chemotherapy, the company said.

* * *

Dendreon Corp.(Nasdaq: DNDN) of Seattle said FDA has designated Provenge as a fast-track development program for asymptomatic, metastatic, androgen-independent prostate cancer.

Provenge is in a double-blind, placebo-controlled phase III trial to confirm previous results that the product may delay progression of disease and the development of disease-related pain.

Dendreon said it has received a positive assessment from FDA under the Special Protocol Assessment provision indicating the trial, D9902B, may serve as the basis for a biologics license application for the treatment.

Results of the trial demonstrated clinical benefit from Provenge treatment for androgen independent prostate cancer with a Gleason score of 7 or less, the company said. The probability of remaining progression free and free of cancer-related pain while on the study was more than two times higher than treatment with placebo.

Supporting the results were findings confirming the mechanism of action based on the immune response stimulated by Provenge treatment, the company said. Among men treated with Provenge, those with a Gleason score of 7 or less demonstrated a T-cell mediated immune response 7-fold greater than the immune response in men with a Gleason score of 8 or more.

Treatment was well tolerated, with mild infusion-related fevers and chills the most common adverse events, the company said.

* * *

Epeius Biotechnologies Corp. of Los Angeles said FDA has designated Rexin-G, a tumor-targeted injectable gene therapy vector, as an orphan drug for pancreatic cancer.

Epeius also said it has executed a screening agreement with NCI to evaluate the activity of the therapy and other targeted gene therapy products at NCI.

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TransMolecular Inc. of Birmingham, Ala., said it has received fast-track designation from FDA for 131-I-TM-601, a therapy for malignant glioma.

The agent was also designated an orphan drug

for the glioma indication. 131-I-TM-601 is comprised of TM-601, a synthetic form of a peptide derived from the venom of a giant yellow Israeli scorpion, conjugated to 131-I, a form of iodine. TM-601 specifically seeks out and binds to its target—a receptor selectively expressed on tumor cells, but not found on the surface of normal cells, the company said.

When TM-601 is chemically linked to known anti-cancer agents, the combination of the two creates a powerful anti-cancer drug, which very effectively deliver their therapeutic payload only to targeted tumor cells.

TransMolecular recently completed patient enrollment in a phase I/II trial of 131-I-TM-601 for recurrent glioma. A phase II multi-center study of 131-I-TM-601 for recurrent glioma is anticipated to begin later this year.

Clinical Trials:

Genentech, OSI Begin Phase II Trial of Tarceva for Glioma

Genentech Inc. (NYSE:DNA) of South San Francisco and **OSI Pharmaceuticals Inc.** (Nasdaq:OSIP) of Melville, N.Y., said enrollment has begun in a multi-center, open-label, phase II trial evaluating the safety and efficacy of Tarceva (erlotinib HCl), for malignant glioma.

Tarceva is designed to block tumor cell growth by inhibiting the tyrosine kinase activity of the HER1/EGFR signaling pathway inside the cell, the company said.

The HER1/EGFR signaling pathway is believed to be important in the growth of malignant glioma tumors where evidence of HER1/EGFR overexpression, gene amplification and expression of the EGFRvIII mutant form of the gene have all been documented, the company said.

The trial, designed to enroll up to 110 patients who have experienced a first relapse of malignant glioma, is being conducted by Genentech in collaboration with the Accelerated Brain Cancer Cure Clinical Network of neuro-oncology centers, the company said.

ABC2 is a non-profit foundation that funds novel translational science aimed at the discovery of a cure for brain cancer.

In a related development, FDA has granted the orphan drug status for Tarceva for the malignant glioma indication, the companies said. This is the first HER1/EGFR-inhibitor to receive such classification, the companies said.

* * *

Antigenics Inc. (Nasdaq: AGEN) said FDA is placing on partial clinical hold the phase III trials of Oncophage (HSPPC-96), a personalized cancer vaccine, under its investigational new drug application, which includes trials in kidney cancer and metastatic melanoma.

FDA has requested additional product characterization information from Antigenics, the company said. The hold was placed pending receipt and acceptance of such information.

According to the company, FDA said safety was not an issue, and patients already enrolled in the phase III studies would be allowed to proceed with vaccination. All other Oncophage trials, including phase I and II studies, are not affected and enrollment and vaccination will proceed as planned, the company said.

"We expect to provide the FDA with the required information within the next six to eight weeks," said Garo Armen, Antigenics chairman and CEO.

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Aurora Imaging Technology Inc., a privately held company based in North Andover, Mass., said it received the 510(k) market clearance from FDA for the RODEO (Rotating Delivery of Excitation Off-resonance) breast imaging method.

RODEO was developed and patented by Steven Harms and Duane Flamig. The RODEO pulse sequence provides robust fat-suppression, magnetization transfer contrast in an efficient high-resolution acquisition, the company said.

Fat-suppression is important in reducing the normally high intensity fat signal to maximize contrast with enhancing tumors. Magnetization transfer contrast is used to reduce signal from normal ductal tissue and avoid false positive enhancement from benign lesions.

* * *

Callisto Pharmaceuticals Inc. (OTCBB: CLSP) of New York announced the filing of an Investigational New Drug application with FDA for the cancer drug Atiprimod.

The planned phase I/IIa clinical trial is an open label study in relapsed multiple myeloma. The trial will be conducted at U.S. cancer hospitals, including M.D. Anderson Cancer Center, the company said.

Atiprimod has completed a phase I/IIa trial in rheumatoid arthritis, with patient dosing as long as

one year, the company said. The agent has shown activity against a range of solid tumors in in-vitro screens and will be evaluated in animal models of solid tumors to expand Atiprimod's clinical trial indications, the company said.

Callisto said it has an exclusive worldwide license from AnorMED Inc. to develop, manufacture, use, and sell Atiprimod.

* * *

Corixa Corp. (Nasdaq: CRXA) of Seattle said it has begun a phase I study of a vaccine for non-small cell lung cancer.

The vaccine is designed to trigger patient immune responses against an antigen expressed by certain lung cancer cells and, if successful, would be used to prevent disease recurrence in patients following prior treatment.

The vaccine contains recombinant plasmid DNA and a recombinant adenovirus, the combination of which may achieve a more substantial immune response to the designated antigen than either component alone.

The vaccine formulation was developed under Corixa's collaboration with Zambon and the pharmaceutical division of Japan Tobacco.

The phase I, open-label, dose-escalation trial is enrolling patients with stage IB, IIA or IIB NSCLC. To participate in the study, patients must have undergone surgical resection of their primary cancer within 12 months prior to study entry, have had no other treatment for their cancer and have no evidence of residual or recurrent disease prior to enrollment.

Corixa holds the U.S. rights to all antigens discovered in its lung cancer vaccine program. JT holds the Japanese rights, and Zambon holds the rights in Europe, the former Soviet Union, Argentina, Brazil and Colombia. Corixa shares commercialization rights with Zambon on a co-exclusive basis in China.

* * *

EXIMIAS Pharmaceutical Corp. of Berwyn, Pa., has begun a phase I/II combination trial of Thymitaq (nolatrexed dihydrochloride) with Taxotere (docetaxel).

The trial will evaluate the safety and efficacy of Thymitaq plus Taxotere in refractory advanced solid tumors, the company said.

Eric Rowinsky, director of clinical research for The Institute for Drug Development in San Antonio, is co-principal investigator of the trial.

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Kosan Biosciences Inc. (Nasdaq: KOSN) of Hayward, Calif., said it has begun several phase Ib trials of 17-allylamino-geldanamycin (17-AAG) in combination with other anti-cancer agents under a cooperative research and development agreement with NCI.

Kosan is co-developing 17-AAG with the NCI Cancer Therapy Evaluation Program under a CRADA signed in 2002, the company said.

The trials initiated to date include 17-AAG in combination with gemcitabine and cisplatin for solid tumors, with imatinib mesylate (Gleevec) for chronic myeloid leukemia, and with docetaxel (Taxotere) for advanced solid tumors, the company said.

Under the CRADA, additional phase Ib combination trials and phase II monotherapy trials of 17-AAG will begin by the end of the year, the company said.

17-AAG inhibits Hsp90, a protein chaperone that binds to several sets of signaling proteins, known as client proteins, the company said. The proteins include a targets such as mutated p53, Bcr-Abl, Raf-1, ErbB2 and others. When 17-AAG binds to Hsp90 it causes disruption of the Hsp90-client protein complexes, which in turn leads to their degradation by the proteosome.

In addition to the anti-cancer studies of 17-AAG as a single agent, preclinical studies suggest that the drug sensitizes cancer cells to other anti-cancer agents.

The phase Ib studies would test the safety of and determine a regimen for the 17-AAG in combination with approved anti-cancer agents.

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Light Sciences of Seattle said **Meiji Seika**, the licensor of its lead compound, LS11 (Laserphyrin in Japan), received a recommendation for approval by Pharmaceutical Affairs and Food Sanitation Council of the Ministry of Health, Labor and Welfare in Japan.

The approval will be granted for the photodynamic treatment of early endobronchial carcinoma. Light Sciences said it has successfully completed a phase I/II study of its lead combination product, Litx, in advanced stage solid cancers.

One of the key components of the Litx System is the light-activated LS11 drug that uses light emitting diodes for light generation and delivery at the site of treatment, the company said. Litx is designed to treat localized disease and is being studied in patients with solid tumors that have failed prior treatments including surgery, radiation and/or

chemotherapy. Light Sciences licensed LS11 from Nippon Petrochemicals and Meiji Seika Kaisha in early 2000, and has exclusive rights to develop, make and commercialize the compound for use in photodynamic therapy in multiple therapeutic applications outside Japan.

* * *

Lorus Therapeutics Inc., said FDA has approved the NCI investigational new drug application for a phase II trial to investigate the antisense drug, GTI-2040 in combination with capecitabine for metastatic breast cancer.

NCI will sponsor a series of phase II trials to investigate the safety and efficacy of GTI-2040 in six different cancer indications, while Lorus will provide the drug, the company said.

The trial of GTI-2040 in breast cancer is based on positive results obtained in previous preclinical and clinical investigations with the drug, and is the second clinical trial initiation in collaboration with the NCI to be approved by FDA, the company said. The first was a clinical study with GTI-2040 in combination with cytarabine for the treatment of acute myeloid leukemia. GTI- 2040 is also in a phase II trial in the U.S. for kidney cancer.

Helen Chew, of the University of California Davis Cancer Center, will be the lead investigator of the GTI-2040 phase II trial, the company said.

A total of three sites—the University of California Davis, the University of Southern California, and the City of Hope, together also known as the California Cancer Consortium—will be participating.

Deals And Collaborations:

Singapore Institute, Sagres, Sign Research Collaboration

Sagres Discovery Inc. of Davis, Calif., and the **Genome Institute of Singapore** have signed a research collaboration to determine the global effects of gene mutation in certain cancers and to discover networks of gene expression patterns in those cancers.

During the research collaboration, the GIS will apply its expression profiling technologies and bioinformatics tools to characterize a collection of Sagres' proprietary provirus-tagged mouse tumors.

Together, the GIS and Sagres will determine cancer-causing genes and pathways by analyzing the gene expression profile data. Human correlates will be investigated by comparison with GIS' and Sagres' growing databases of expression profiles of human cancers, a step toward the aim of mapping the genetic interaction pathways of the entire Oncogenome.

Under the agreement, Sagres Discovery will have the option to obtain from the GIS exclusive rights to the novel genes and pathways identified during the collaboration, with commercial terms to be agreed separately. The GIS will retain the right to use the results for its non-commercial research and development.

"We see a very strong synergy between our molecular profiling platform and expertise, and Sagres' smart functional genetics approach to cancer genes discovery," said Edison Liu, executive director of the Genome Institute of Singapore. "We believe the combination of GIS' and Sagres' capabilities has tremendous potential to provide unique knowledge for the characterization of cancer pathways and mechanisms, and to open the way for the development of novel and better diagnostics and therapeutics."

The GIS microarray and expression genomics laboratory provides the microarray infrastructure to support the research efforts of the institute and its collaborators. Its research focuses on the molecular characterization of human cancers and aspects of hormone signaling in cell growth and proliferation. Its genomic tool kit, which includes human, mouse, rat, zebrafish, and yeast cDNA and oligo arrays, supports a diverse range of research platforms that underlie the GIS orthologous approach to understanding biological and disease mechanisms.

Sagres Discovery created the Oncogenome, a list of genes that cause cancer, the company said. The HPT technology combines gene isolation and biological validation into one high-throughput procedure. Through molecular profiling of human disease tissues, clinical relevance is established concurrently with gene discovery and validation.

The technology is able to discriminate between those few genetic factors that cause disease and the confounding factors that respond to disease processes. Only genes that cause the specified phenotype are recovered and downstream effects are specifically excluded.

The Sagres approach eliminates most of the time- and resource-intensive secondary screening required by other approaches, the company said.

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Affimed Therapeutics AG of Heidelberg, Germany, and **Dyax Corp**. (Nasdaq: DYAX) of

Cambridge, Mass., said they have entered into a cross-licensing agreement for phage display technologies.

The Affimed licensed patents consist of two issued U.S. patents with broad claims that cover the generation of human antibody libraries derived from the IgM repertoire of the immune system, which is considered to be the most diverse naturally occurring repertoire of antibody genes, and the generation of synthetic antibody libraries, the company said.

"Natural diversity from the IgM repertoire has important advantages over purely synthetic diversity or other natural antibody repertoires," said Henry Blair, chairman and CEO of Dyax Corp. "This agreement is an extension of our strategy to bring a broader intellectual property base and improved technology to both our customers and our internal Dyax antibody development programs."

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Aptamera of Louisville, Ky., said it has it has signed a product development and license agreement with **Archemix Corp**., of Cambridge, Mass., for AGRO100, its investigational cancer drug.

Under the agreement, Archemix, the exclusive holder of rights to the Selex portfolio for aptamer therapeutics, will provide Aptamera with a non-exclusive license to aptamer technology for therapeutic uses of AGRO100 and AGRO100 derivatives.

Consisting of over 160 issued patents, the portfolio is the dominant intellectual property portfolio covering the selection and use of aptamers.

In addition, Archemix will provide Aptamera expertise and know-how in support of the programs. Aptamera remains responsible for the clinical development, and ultimately, marketing of AGRO100 and its derivatives, the company said.

The drug compound AGRO100 acts as an aptamer by binding to nucleolin protein on cancer cell surfaces, causing the arrest of the cycle of cancerous cell growth, inhibition of its DNA replication, and the initiation of apoptosis of the cells, the company said.

In a related development, Aptamera has begun a phase I trial of AGRO100 at the University of Louisville's James Graham Brown Cancer Center. Up to 20 patients with advanced solid tumors of differing types will be enrolled, the company said.

* * *

InNexus Biotechnology Inc. (TSX-V:IXS) of Vancouver and **Corixa Corp.** Nasdaq:CRXA) of Seattle said they have entered into an agreement to develop antibody candidates combining InNexus' SuperAntibody Technology with up to four antibodies from Corixa's therapeutic antibody development program.

InNexus' SAT technology can increase the binding strength of monoclonal antibodies, which allows them to cross-link their target antigen, the companies said. This process can trigger apoptosis, or the enhancement of complement-dependent or immune cell killing of pathogens, viruses or tumor cells, the companies said.

InNexus' technology platform can also be used to confer novel properties to antibodies such as the ability to penetrate cells and bind to intracellular targets such as virus components, and can allow antibodies to be converted into vaccines.

The InNexus/Corixa collaboration will initially focus on enhancing the anti-tumor activity of selected antibody leads that are currently in development, the companies said.

Under the agreement, following the potential creation of SuperAntibody conjugates and successful demonstration of increased therapeutic efficacy, Corixa has the right to license the technology from InNexus in exchange for upfront and milestone payments and royalties on potential net sales. In addition, Corixa will be responsible for all further product development.

In another development, DakoCytomation of Carpineria, Calif., said it has received exclusive worldwide rights to two antibodies for prostate cancer diagnostics and monitoring under a licensing agreement with Corixa.

Under the agreement, DakoCytomation will develop and commercialize immunohistochemistry diagnostics and the right to develop therapeutic drug monitoring products, P504S, a tumor specific marker, and P501S, specific for prostate cancer, the company said.

P504S has been shown to be highly expressed in prostate cancer and high-grade intraepithelial neoplasia, but not in benign prostatic tissue, the company said. The 382-amino acid protein was identified by cDNA library subtraction in conjunction with high-throughput microarray screening of prostate carcinoma.

P501S is the first reported organ-specific prostate marker, the company said. Expression of the P501S protein is limited to normal and malignant prostatic tissue. The 533-amino acid protein was also identified by cDNA library subtraction in conjunction

with high-throughput microarray screening of prostate carcinoma.

* * *

Fischer Imaging Corp. of Denver said it has received a $468,000 phase I small business innovation research grant from NCI for feasibility studies for the development of an integrated ultrasound and digital mammography system.

Fischer is collaborating with **Philips Medical Systems** (NYSE: PHG) ultrasound business to develop a prototype to simultaneously acquire optimal breast ultrasound and digital mammography images.

The Fischer SenoScan digital mammography workstation will permit a radiologist to determine the status of a mammographic abnormality by reviewing the correlated ultrasound images, thus reducing call backs and increasing cancer detection in dense breast tissue, the company said.

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Genaera Corp. (Nasdaq: GENR) of Plymouth Meeting, Penn., said researchers at the **University of California at Los Angeles Medical Center** and Jonsson Comprehensive Cancer Center have received a grant funding for squalamine research as a treatment for breast cancer.

The preclinical research at UCLA will be lead by Richard Pietras, associate professor of medicine, and funded through a $457,500 grant over three years from the U.S. Department of Defense, Army Medical Research and Materiel Command Breast Cancer Research Program.

UCLA researchers will test the hypothesis that treating both the breast cancer cell and its associated blood vascular supply may be more effective than treating the cancer cell alone, the company said. The antitumor effects of squalamine will be evaluated alone and in combination with other therapies.

Squalamine is an inhibitor of blood vessel growth in breast cancer in vivo models, the company said.

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IDEC Pharmaceuticals Corp. (Nasdaq: IDPH) of San Diego and **Biogen Inc**. (Nasdaq: BGEN) of Cambridge, Mass., said the FTC has completed its review of their proposed merger and granted early termination of the waiting period under the Hart-Scott-Rodino Act.

The transaction remains subject to various closing conditions, including the approval of stockholders of IDEC Pharmaceuticals and Biogen and other regulatory approvals and filings.

The combined company will be called Biogen IDEC Inc., the companies said.

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OncoGenex Technologies Inc. of Vancouver, British Columbia, and **Isis Pharmaceuticals Inc.** (Nasdaq: ISIS) of Carlsbad, Calif., said they have expanded their antisense drug development partnership to include the development of the second-generation antisense anti-cancer drug candidate, OGX-225.

OGX-225 is a bi-specific antisense inhibitor, a single-stranded antisense drug designed to inhibit the production of two proteins simultaneously, the company said. The agent targets both insulin-like growth factor binding protein- 5 (IGFBP-5) and insulin-like growth factor binding protein-2 (IGFBP-2), two molecules involved in the development of metastatic disease in hormone- regulated tumors such as prostate and breast cancers.

The expansion combines OncoGenex's patent position in inhibitors of IGFBP-5 and IGFBP-2 drug targets with Isis' second-generation antisense chemistry, called 2'-O-methoxyethyl, as well as Isis' IGFBP-5 target-specific intellectual property, the companies said.

The companies said they have completed initial drug discovery research, which led to the identification of OGX-225. OncoGenex will be solely responsible for the preclinical and clinical development of the drug. Under the financial terms of the agreement, OncoGenex will pay Isis an upfront fee, milestone payments for key clinical and regulatory achievements and royalties on product sales.

Tularik Inc. (Nasdaq: TLRK) of South San Francisco said it has received two phase I small business innovation research grants from NCI for $500,000 to research anti-cancer agents targeting KCNK9/TASK3 and WIP1/PP1MD.

KCNK9 encodes a potassium channel implicated in breast and lung cancers, and WIP1 is a protein phosphatase involved in breast and prostate cancers, the company said.

The lead scientists on the programs are Lin Pei, and Richard Austin, the company said. The two grants will support research to understand the cancer genes and to develop drugs that target the proteins encoded by the oncogenes.

Drug discovery efforts will include assay development, high throughput screening to identify lead molecules and medicinal chemistry.

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