THE CANCER LETTER

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Research Poised For A "Platinum Age," As "Golden Age" Ends, NCI Director Says

By Kirsten Boyd Goldberg

The "golden age" of cancer research is concluding as science moves toward a "platinum age," NCI Director Andrew von Eschenbach said in an address at the annual meeting of the American Association for Cancer Research, held in Anaheim, Calif.

According to the Institute director, the new era, when scientists develop effective therapies for all cancers, will begin "as early as 2015," just as "the suffering and death due to cancer" come to a halt.

"By virtue of what we've created in terms of the elegance of the

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In Brief:

AACR Honors SWOG's Charles Coltman; Lombardi Center Receives $9.6 Million

CHARLES COLTMAN, who for 24 years has served as chairman of the Southwest Oncology Group, received the first Outstanding Service Award given by the American Association for Cancer Research at its annual meeting last week. The award was established to recognize significant and sustained contributions to the fight against cancer by an individual. . . . **LOMBARDI** Comprehensive Cancer Center at Georgetown University received $9.6 million from the estate of Charlotte G. Gragnani. This follows an endowment of $5 million from Gragnani in 2002, to support the Chair of Oncology and cancer center director. "Mrs. Gragnani's generosity has provided an extraordinary opportunity for the Cancer Center investigators to capitalize on the advances underway in biomedicine," said **Richard Pestell**, Lombardi center director. . . . **WOODROW WILSON** awards were presented to four leaders for public service and corporate citizenship. **Anne** and **John Mendelsohn** received Woodrow Wilson Award for Public Service and **Cheryl** and **Philip Burguières** were given the Woodrow Wilson Award for Corporate Citizenship. Anne Mendelsohn is chairman of the Houston Community Board of Teach for America. John Mendelsohn is president of M. D. Anderson Cancer Center. Cheryl Burguières, cancer survivor, writer, teacher and along with her husband Philip, who is vice chairman of the Houston Texans and chairman and CEO of EMC Holdings, is a supporter of M.D. Anderson Cancer Center. The Woodrow Wilson International Center for Scholars presented the awards April 26 in Houston . . . **MARIO SZNOL** was named vice chief, Section of Medical Oncology, at Yale Cancer Center. Sznol, known for his work in cancer immunotherapy and novel agents, is head

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Director Says "Platinum Age" Could Begin As Early As 2015

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science … we are actually on the verge of going from the golden age of cancer research to the platinum age of cancer research," von Eschenbach said in a keynote speech April 18. "As we move from the golden age to the platinum age, we move to a time when we can begin to not only understand cancer, but, in fact, be able to deal with cancer in ways that were unimaginable even a few decades ago."

In 2003, a year after President George W. Bush appointed von Eschenbach as NCI director, the former surgeon from M.D. Anderson Cancer Center established the "challenge goal" to render cancer harmless by the year 2015.

In the AACR address last week, von Eschenbach acknowledged that the aging of the U.S. and world populations will result in a higher incidence of cancer over the next several decades. But he maintained that cancer research has "delivered a return on investment" of the taxpayer dollars devoted to it. "We are, in fact, today saving lives that would have been lost," if not for that investment, he said.

Despite the fact that NCI's $4.8 billion budget is expected to remain flat next year, resulting in a tighter payline for investigator-initiated grants, "we have more money invested in cancer research by this nation than has ever been true before," von Eschenbach said.

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"We are at a magic moment, a moment in time in which we must look, not just to the past and what we've accomplished, but more importantly, to the future and what is within our grasp, and how to accomplish and achieve that future, by nurturing and building upon what we have created, and leveraging it to its ultimate goal, to its ultimate outcome," he said. "Because we have the ability to create progress that also has a purpose."

Stump Speech Retrospective

As NCI director, von Eschenbach relies heavily on business metaphors. His stump speech has emerged as something of a program document, which reflects his visions of the past, present, and future.

In his remarks to AACR last week, von Eschenbach employed nearly all the catch phrases and alliterations he has developed over the past three years.

Tracing the evolution of his own speech, von Eschenbach noted that in its earlier version, delivered at the AACR annual meeting in 2002, he declared that cancer research was at a "strategic inflection point," a phrase borrowed from Intel founder Andy Grove's book about the computer industry.

In 2003, von Eschenbach told AACR members about his 2015 goal.

"We talked about how might we imagine a goal of eliminating suffering and death due to cancer, of being able to preempt this cancer process in a way that we could prevent and eliminate its outcome," he said last week. "We talked about the opportunities that were being presented and discussed all around us, of understanding of the fundamental mechanisms that resulted in susceptibility, malignant transformation, progression, and ultimately, the acquisition of a lethal phenotype.

"Across this entire continuum of understanding, we were rapidly developing opportunities for interventions that could preempt the ultimate outcome of this process, and, in doing so, change the shape of cancer to a time when we prevented more cancers from ever occurring in the first place, we detected it and eliminated more cancers more safely and easily, and we hope that we controlled the cancer process such that we preempt the suffering and death that results from this disease."

Continuing with the review, von Eschenbach said that last year he discussed his "strategy … to accomplish that goal," which involved organizing NCI and its research into a "seamless continuum" of "discovery, development, and delivery."

"We talked about a strategy of discovery, development, and delivery where we recognize that

as a National Cancer Program, we must continue to nurture and drive the engine of discovery so that we could understand cancer's mechanisms more fully, but rapidly translate that knowledge into the development of interventions that could prevent and treat this disease, and to develop those interventions and deliver them in a way that the very context of delivery would in fact yield new knowledge of the fundamental mechanisms associated with the human expression of cancer," von Eschenbach said.

The metaphor of progression from the golden to platinum age hasn't appeared in earlier versions of the speech.

"If we stand here today and recognize that we have made certain for some the elimination of the suffering and death due to cancer, if we have made it possible for the 10 million cancer survivors such as myself, because of what we have accomplished as a cancer research community, then we must seize and leverage this moment and this opportunity so that what we have made certain for some, in the future, we will make possible for all," von Eschenbach said last week.

"That will be, not just the golden era of cancer research. That will be the platinum era, the era in which the richness of understanding of cancer is fully coupled with our ability to eliminate the suffering and death due to cancer."

Credit Card As Metaphor

The gold-to-platinum metaphor appears to come from credit card marketers, said business consultant Rick Brenner, of Boston-based Chaco Canyon Consulting (www.chacocanyon.com).

"This gold-platinum thing is fairly common these days," Brenner said. "Platinum is in the public mind because the credit card companies have metal-coded their products. Gold cards are a superior level of credit-worthiness, and platinum is the next level."

The gold-platinum metaphor is linear, Brenner said. "Although it makes sense to look at commodities in this way--ranking them by price per ounce--using it to rank eras in our understanding of cancer can be misleading," he said. "That linear thinking is contrary to what we're beginning to realize is the true structure of complex systems. Interconnectedness and systems thinking are far more valuable paradigms. I would hope that we could do a lot better than propagating linear thinking about cancer, which I view as fundamentally a systems problem."

In oncology, platinum is used in non-selective, toxic drugs that have been the mainstay of chemotherapy for decades.

Cisplatin, the first of these compounds, was identified in the 19th century, and its activity in cancer was discovered in 1965 by Barnett Rosenberg, of Michigan State University. The drug was approved for cancer treatment in 1978.

At the time, the leaders of the National Cancer Program promised that powerful, new cytotoxic drugs like cisplatin represented the paradigm for the cure.

For cancer researchers attempting to develop more specific, targeted therapies, the "platinum age" probably wouldn't connote 21st century progress, Brenner said.

"That's the main problem with any metaphor: baggage," he said. "We can't control what connections people make between a metaphor and their own experiences. There might be families who lost loved ones even though they were treated with cisplatin. For them, progress or not, the association with platinum might be painful."

Since people also associate platinum with credit cards, "reminders about credit cards can create unpleasant sensations, including the urge to turn the page or change the channel," he said. "Probably not what [NCI] has in mind."

True to the credit card metaphor, the title of von Eschenbach's talk—"Leveraging the Nation's Investment in Cancer Research"—suggested debt.

Brenner offered this advice to NCI: "If they are thinking of using a particular metaphor, and maybe incorporating it into a broad-use publicity campaign, I hope they have tested it with an appropriate set of focus groups. Testing turns up the most amazing connections."

Delivering Return on Investment

In his remarks, von Eschenbach said NCI's position as the largest of the institutes in NIH has made it a target for criticism. The Institute's special status under the National Cancer Act of 1971 also provided "a significant investment," making the NCI "the single largest force directed toward solving the problem of cancer," he said.

"There have been many who have begun to ask the question, with that significant investment, have we, the cancer research community, delivered a return on that investment?" he said, showing a slide of Fortune magazine from March 2004, which featured an article titled, "Why We're Losing the War on Cancer (And How To Win It)."

"Some have begun to question that and say 'No,'" von Eschenbach said. "They turn to statistics that look

at the differences that perhaps have been achieved in other diseases, such as heart disease, and look at the decline in mortality of heart disease over the past three decades as compared to what's happened in cancer, and question that return on investment.

"But we know that over those past three decades, what we have invested is the intellectual talent, and commitment, and passion of those of you in this room," von Eschenbach said. "And over those past few decades, we, along with other biomedical researchers, have, in fact, contributed to the development of a fund of knowledge, that for the first time today is truly producing a revolution in our ability to not only understand cancer, but to deal with cancer.

"So, though others say 'No,' as the director of the National Cancer Institute, I say, 'Yes.' Yes, we have delivered a return on that investment, and others agree. Others are beginning to appreciate that, by virtue of what we have done as a community, we have now created an entirely new frontier in cancer research, and, in fact, in medicine….

"The purpose of our investment is, in fact, that we will not just understand cancer, but be able to fulfill the promise that was begun in 1971 with the idea that we can conquer cancer," von Eschenbach said. "What we can see within our immediate grasp is the opportunity to eliminate the outcome of cancer, the suffering and death that we and others around this nation see around them each and every moment of each and every day."

NCI To Support "Big Science"

In his speech, von Eschenbach said that to better "leverage" its "investment," NCI plans to emphasize greater team science, as well as large-scale projects or "big science."

He claimed tangible achievements, declaring some of this work already completed.

"This meeting has been ample testimony of the enormous progress that has been made across this continuum of discovery, development, and delivery," von Eschenbach said. "We continue to be in the midst of a positive explosion in our knowledge of fundamental mechanisms, and we are seeing a more rapid transition of that knowledge and understanding into the creation of more specific, targeted, and effective interventions, and we've recognized the opportunity of tools of delivery of those interventions….

"There is, in fact, a seamless continuum now between our ability to understand fundamental mechanisms at the genetic level, and those expression into the formation of proteins that result in functional expressions of the malignant process, and then define and specify a unique and particular malignant behavior, for which we then have interventions that will change and alter the clinical outcome," he said. "This strategy will continue to be a fundamentally important part of our core elements of success."

Large projects in development or underway include the proposed Human Cancer Genome Project and the Cancer Bioinformatics Grid, he said. However, von Eschenbach didn't touch on specific milestones in either of these projects.

NCI's budget currently doesn't include funding for the HCGP, proposed earlier this year by an NCI advisory group (The Cancer Letter, March 18).

The bioinformatics project, called CaBIG, is working to enable NCI and its designated cancer centers around the country to share research data. The project is funded at about $200 million a year.

"We have built the infrastructure to continue to nurture this process of evolution of new knowledge," von Eschenbach said.

"NCI will continue to foster and develop programs that will enhance our ability to unravel the complexity across the continuum of discovery, development, and delivery by facilitating our collaboration and cooperation and bring together the diverse disciplines and talents that this enormous challenge demands," he said. "We see the impact already of opportunities by creation of consortia such as the tremendous advantages that have occurred in our Mouse Models Consortium by bringing individual excellence together into an integrated effort."

Allowing co-principal investigators on R01 grants will encourage team science, von Eschenbach said.

"We have enormous opportunity and infrastructure within our grasp as a nation to be able to come together as a National Cancer Program to use these tools to bring us together as a community, as a team, and as an opportunity to fulfill the promise that was made in 1971, a promise not only with regard to our ability to deal with cancer, but a promise and a vision to transform all of biomedical research using cancer as a model," he said.

"Because, if one goes back to 1971, to the origins of the National Cancer Act, which gave the NCI the authority and the beginning of the resources to create what we have seen around us today, it was, in fact, a very visionary effort that saw and looked ahead at the success we would accomplish and achieve," von Eschenbach said. "Back in 1971, the Senate report from the Yarborough Commission predicted that if we made that investment, there would come a time and an era of

molecular oncology that would be able to see cancer as a complex, diverse disease, and would be able to create changes that would be radical in nature and would go far beyond cancer itself.

"You have created that reality and that future," von Eschenbach said to AACR members. "You have fulfilled that promise. You have paid that return on our investment. Because of what you've accomplished, because of that commitment you made, we are, in fact, today saving lives that would have been lost if it were not for you."

FDA News:

Data Requirements Specified For Phase I IND Applications

FDA said drug sponsors have been providing more than a required minimum of data and documentation for the Investigational New Drug applications for early phase I studies.

"Sponsors have not taken full advantage of that flexibility and limited, early phase I studies… are often supported by a more extensive preclinical database than is needed for those studies alone," the agency said in a draft guidance published in Federal Register April 14.

The agency started accepting applications for early phase I studies last year, following the March 2004 Critical Path Report. These trials test lower doses than standard phase I trials. The studies are conducted over a limited period of time and have no therapeutic intent.

They are intended to help distinguish compounds that are likely to succeed from those that hold no promise.

"The common theme throughout this guidance is that, depending on the study, the preclinical testing programs for exploratory IND studies can be less detailed and more flexible than for traditional IND studies," the draft guidance states. "This is because for the approaches discussed in this guidance, which involve administering sub-therapeutic doses of a candidate product or products, the potential risks to human subjects are less than for a traditional phase I study."

The document is posted at www.fda.gov/cder/guidance/6384dft.pdf.

The guidance describes studies that are "consistent with regulatory requirements, but that will enable sponsors to move ahead more efficiently with the development of promising candidate products while maintaining needed human subject protections."

According to the agency, exploratory IND studies can serve the following goals:

• Gain an understanding of the relationship between a specific mechanism of action and the treatment of a disease.

• Provide important information on pharmacokinetics, including, for example, biodistribution of a candidate drug.

•Select the most promising lead product from a group of candidates designed to interact with a particular therapeutic target in humans.

• Explore a product's biodistribution characteristics using various imaging technologies.

Applications should include:

•A clinical development plan.

•Chemistry, manufacturing, and controls information.

•Pharmacology and toxicology information.

•Previous human experience with the investigational candidate or related compounds.

Professional Societies:

ASCO, AAMC To Assess Clinical Oncology Workforce

Concerned that the aging of the U.S. population is likely to lead to an increased need for cancer care over the next 20 years, the American Society of Clinical Oncology said it plans to work with the Association of American Medical Colleges to conduct a comprehensive study to assess whether the future supply of clinical oncologists will be sufficient to meet future healthcare needs.

The study is expected to be complete by June 2006, ASCO said.

Cancer incidence in the U.S. is expected to increase over the next 20 years as members of the "baby boom" generation start to reach age 65 in 2010. Also, since 64 percent of all cancer patients diagnosed as adults survive for five years or longer after their diagnosis, more people will need continuing care.

The study researchers will survey practicing oncologists, oncology fellows, and fellowship program directors to assess current practice patterns, career plans and expectations, and to obtain insights on the oncology workforce. The study will analyze the potential effects of expected demographic changes in the U.S. and how these are likely to affect the need for clinical oncology services.

The study will address several key questions, including:

• How many medical oncologists, hematologist/oncologists, pediatric hematologist/ oncologists, and

gynecologic oncologists will be needed in the U.S. over the next 15 years and beyond?

• What are the likely gaps in supply and demand in total, by oncology sub-specialty, and by region?

• What factors and trends are likely to affect future supply and demand for clinical oncologists?

• How many new clinical oncologists will need to be trained each year to ensure an adequate supply in the future?

• What are the workforce implications of alternative modes for delivering effective oncology services?

• What steps can ASCO and others take to better assure access to quality oncology services in the future?

"The number of medical school graduates entering clinical oncology appears to have dropped over the past decade, so we are concerned that there may be a shortage of oncologists to serve the U.S. population in the future," said ASCO President David Johnson, deputy director of the Vanderbilt-Ingram Cancer Center. "We are undertaking this study so we can better understand the forces likely to shape the specialty of oncology in the coming decades."

After an intensive analysis, the AAMC recently called for a 15 percent increase in U.S. medical school enrollment by 2015. The association also recommended additional workforce studies to monitor developments and trends in supply and demand for physicians across specialties.

"Because it takes many years to educate and train doctors, we must take a long view of future needs in order to know how best to respond today in preparing the nation's future physician workforce," said AAMC President Jordan Cohen. "By collaborating with ASCO and the clinical oncology community, we can effectively assess the public's need for this critical specialty in the decades to come."

AAMC's Center for Workforce Studies will be responsible for conducting the study and will work with ASCO's Workforce in Oncology Task Force to analyze the study's findings. AAMC also will collaborate with the Center for Health Workforce Studies at the University of Albany/SUNY on the study.

Funding Opportunities:

Program Announcement

PAS-05-092: Interactions Between Stem and Progenitor Cells and the Microenvironment In Vivo

Standard application submission dates, see http://grants.nih.gov/grants/funding/submissionschedule.htm.

Participating centers and institutes invite R01 and R21 applications for studies on the cellular and molecular signaling between the local environment within organisms and stem and progenitor cells that are either introduced as transplants or are normally resident within host tissues and organs. The objective is to promote a thorough exploration and characterization of the bi-directional communication between multipotent cells and the three-dimensional local milieu or niche that they encounter in vivo under normal and compromised states, such as with aging or following injury, disease or drug exposure. NCI is interested in the role of neural tumor stem cells in the progression and development of tumors of the nervous system, with particular emphasis on interaction of the neural tumor microenvironment on the proliferation and differentiation of neural tumor stem cells. The PAS is available at http://grants.nih.gov/grants/guide/pa-files/PAS-05-092.html.

Inquiries, for NCI: R. Allan Mufson, chief, Cancer/Immunology and Hematology Branch, phone 301-496-7815; e-mail am214t@nih.gov.

RFP Available

2005-N-01874: **Integrated Cancer Prevention and Control Information Development & Dissemination Services**

Response Due: May 30

The Centers for Disease Control and Prevention, National Center for Chronic Disease Control and Prevention, Division of Cancer Prevention and Control, is responsible for managing inquiries largely from the public, health professionals, media, partners, and Congress. DCPC's Office of Program and Policy Information maintains the Cancer Prevention and Control Website, a toll-free voice information system, and a series of databases. DCPC OPPI is also responsible for initiating and coordinating the development and production of DCPC's education and communication materials and tools, including program fact sheets, annual program review materials, program and partner profiles, disease burden summaries and various special reports. The contractor shall furnish personnel, materials, supplies and equipment for the purpose of providing assistance and technical support needed to conduct, maintain, and continue existing information development and dissemination activities. Broad descriptions are as follows:

1. Inquiry development, response and tracking; 2. Management and maintenance of division contacts information; 3. Web site design, content development, maintenance and promotion; 4. Exhibit design, maintenance, storage and shipping; 5. Support related to selected training, events and program-specific meetings; 6. Development, coordination, and maintenance of collateral materials, and education tools (fact sheets, brochures, flyers, visual presentations, etc.); 7. Publication development and promotion, tracking and fulfillment; 8. Development of special reports as required for Congressionally mandated programs; and, 9. Conduct legislative tracking, analysis, and report activities.

This project is 100 percent small business set-aside.

The RFP is available at http://www.eps.gov/spg/HHS/CDCP/PGOA/2005-N-01874/listing.html.

Inquiries: Lynn Walling, contract specialist, phone 770-488-2612, fax 770-488-2777, or Berta Biltz, contract specialist, phone 770-488-2643, fax 770-488-2670, e-mail: lqw5@cdc.gov or boh9@cdc.gov.

In Brief:

AACI To Hear From Hartwell, Hood, At Annual Meeting

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of the melanoma disease unit YCC, said Edward Chu, chief of Medical Oncology at Yale Cancer Center. Sznol was a senioriInvestigator and head of the Biologics Evaluation Section of the Investigational Drug Branch at NCI. . . . **ASSOCIATION OF AMERICAN Cancer Institutes** annual meeting in October in Washington, D.C., will honor **Leland Hartwell** and **Leroy Hood**. Hartwell will receive the 2005 Distinguished Scientist Award for his discovery of the universal mechanism that controls cell division in all eukaryotic organisms. Hartwell, president and director of the Fred Hutchinson Cancer Research Center and professor of genome sciences at the University of Washington, will deliver the keynote talk. Hood, president of the Institute for Systems Biology, will participate in a mini-symposium. With former colleagues at California Institute of Technology, Hood pioneered four instruments that comprise the technological foundation for contemporary molecular biology: the DNA gene sequencer and synthesizer, and the protein synthesizer and sequencer. . . . **GEORGIA TECH** and the **Emory University** Winship Cancer Institute have granted awards to eight scientists to develop technologies for cancer detection, prevention and treatment. The Georgia Tech-Emory Fund for Innovative Technology awards are made possible through a collaboration between The V Foundation, a charitable organization, and the Georgia Cancer Coalition. The awardees who will be collaborating on four separate projects are: **Rebecca Howell**, medical physicist, Emory University, and **Nolan Hertel**, professor, nuclear and radiological engineering, Georgia Tech, a $45,000 grant; **Ravi Bellamkonda**, associate professor, neurological biomaterials and Therapeutics, Georgia. Tech, and David Jaye, assistant professor, Department of Pathology and Laboratory Medicine, Emory University, a $45,000 grant; **William Hunt**, professor, electrical engineering, Georgia Tech, and **Dong Shin**, professor, hematology and oncology, Emory University **Georgia Chen**, associate professor, Georgia Tech, a $45,000 grant; **Rachel Chen**, associate professor, School of Chemical and Biomolecular Engineering, Georgia Tech, a $25,000 grant. The co-program directors of the FICT grant process are **Alfred Merrill**, professor of molecular cell biology at Georgia Tech and **Paul Doetsch**, associate director of basic research at the Winship Cancer Institute. . . . **JIANG YONG-QIN** will receive the 2005 Oncology Nursing Society International Award for Contributions to Cancer Care in China. She is vice director of the nursing department at Tianjin Cancer Institute and Hospital. Under her guidance, a hospice/palliative care ward was established at Tianjin Cancer Hospital, which has been recognized throughout China as a model of care for patients with advanced cancer. Tianjin is the third largest city in China, 85 miles southeast of Beijing. . . . **LONNIE ZELTZER**, researcher at the Jonsson Cancer Center at the University of California at Los Angeles and director of the Pediatric Pain Program at the Mattel Children's Hospital at UCLA, will receive a grant from the Lance Armstrong Foundation to study psychosocial, behavioral, and pain outcomes in childhood cancer survivors. . . . **OHIO STATE UNIVERSITY** Comprehensive Cancer Center scientists were elected to membership in the American Society for Clinical Investigation: **John Byrd**, director of the hematologic malignancies program, and **E. Antonio Chiocca**, chairman of the department of neurological surgery. . . . **CARLO CROCE**, director of human cancer genetics at Ohio State University, received the Jeffrey A. Gottleib Memorial Award from The University of Texas M.D. Anderson Cancer Center. Croce, professor and chairman of the department of molecular virology, immunology and medical genetics in the Ohio State College of Medicine and Public Health, was the first to identify key genetic mechanisms involved the development of Burkitt's lymphoma, follicular lymphoma and acute leukemias. . . . **BRADLEY WELLING** was named chairman of the Department of Otolaryngology at the Ohio State University College of Medicine and Public Health. Welling, who has been with the department since 1989, has been vice chair of the department since 2002 and director of the Division of Otology and Neurotology since 1989. The appointment is pending approval of The Ohio State University Board of Trustees. He would replace **David Schuller**, who was appointed to plan for the expansion of the cancer program and build a national reputation for the otolaryngology department. Schuller will be involved in the day-to-day activities of the department as a practicing physician and clinical researcher.

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THE CANCER LETTER

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Business & Regulatory Report

Clinical Trials:

Amgen, Abgenix Begin Phase III Trial Of Panitumumab For Colorectal Cancer

Amgen Inc. (Nasdaq: AMGN) of Thousand Oaks, Calif., and **Abgenix Inc**. (Nasdaq: ABGX) of Fremont, Calif., said they have begun a phase III study to evaluate the addition of panitumumab, an experimental fully human monoclonal antibody, administered every other week to Avastin (bevacizumab) as that agent is administered either with Eloxatin (oxaliplatin) or Camptosar (irinotecan) chemotherapy for the first-line treatment of metastatic colorectal cancer.

The Panitumumab Advanced Colorectal Cancer Evaluation clinical

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Oncology Management:

Philadelphia Firm Wins $1.7M NCI Grant To Enhance Electronic Data Exchange

Hx Technologies of Philadelphia said it received a $1.7 million grant from NCI to enhance the Philadelphia Health Information Exchange, a network launched two years ago to enable hospitals and clinics to exchange digital medical records for shared patients.

Built on the Hx Technologies iHistory platform, the network supports the Hospital of the University of Pennsylvania, Children's Hospital of Philadelphia, Presbyterian Medical Center and Pennsylvania Hospital. The funds will support expansion of the network to additional hospitals in the region, research for cancer diagnosis and management, and inclusion of interoperability standards to ensure compatibility with other networks as they emerge around the country, the company said.

The iHistory platform links to the existing archives at each site and permits healthcare providers on the outside to access the data online, subject to restrictions that meet the requirements of HIPAA privacy rule, the company said.

* * *

Ingenuity Systems of Mountainview, Calif., said the **NCI Center for Cancer Research** has licensed access to the Ingenuity Pathways Analysis software.

Under the agreement, all researchers at NCI will have access to the full functionality of the Ingenuity Pathways Analysis product, the company said.

The IPA helps researchers gain biological insight and understanding from their experimental datasets and is used from target identification and validation to biomarkers, predictive toxicology, and patient stratification,

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Phase III Trials Of Targretin Didn't Meet Endpoints

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trial—PACCE—is a randomized, multi-center, open-label study, with endpoints of progression-free survival, overall survival and response rate, the companies said. Enrollment would be approximately 1,000 patients, the companies said.

Panitumumab, co-developed by Amgen and Abgenix, inhibits the epidermal growth factor receptor, while bevacizumab targets the vascular endothelial growth factor involved in angiogenesis, the companies said.

* * *

Ligand Pharmaceuticals Inc. (Nasdaq: LGND) of San Diego said its two phase III studies of Targretin (bexarotene) capsules in front-line combination therapy with standard chemotherapy for advanced non-small cell lung cancer did not meet the endpoints of improved overall survival and projected two-year survival.

The studies were designed to evaluate whether adding Targretin to front-line cisplatin/vinorelbine or carboplatin/paclitaxel chemotherapy extends survival with advanced (stage IIIB with pleural effusion or stage IV) NSCLC, the company said.

In the SPIRIT I trial, patients were randomized to two arms, receiving either cisplatin/vinorelbine chemotherapy alone or in combination with Targretin capsules, the company said. SPIRIT II enrolled patients to two arms receiving either carboplatin/paclitaxel alone or in combination with Targretin capsules.

For both studies, the primary endpoint was overall survival and the secondary endpoint was Kaplan-Meier projected two-year survival, the company said. No statistically significant differences in primary or secondary endpoints in the intent to treat population were seen in either trial.

An initial trend analysis of sizeable sub-groups in the treatment arms of both trials suggests a relationship between Targretin dose intensity and biomarker response, i.e., triglyceride elevations, with survival, and is the subject of further evaluations in parallel with other risk factor analysis to better identify the determinants of benefit or risk to Targretin in a first-line setting, the company said.

The initial daily dose of Targretin in both trials was similar to that used in prior phase II studies in which a positive trend in survival had been observed, the company said. Doses of carboplatin and vinorelbine in SPIRIT I and carboplatin and paclitaxel in SPIRIT II were also consistent with standard chemotherapy regimens used in most recent large-scale trials.

Targretin is a selective retinoid X receptor modulator with proven efficacy as monotherapy in the treatment of cutaneous T-cell lymphoma, the company said. RXR levels in the tumor have been shown to be an independent predictor of survival in NSCLC and in other solid tumors.

"We are very disappointed in the lack of survival advantage of Targretin/dual chemotherapy triple therapy in first-line NSCLC patients, particularly in view of the consistent positive trends seen in several phase I/II studies and in the preclinical data that provided strong mechanistic support for a potentially beneficial Targretin/chemotherapy combination," said Andres Negro-Vilar, executive vice president for research and development and chief scientific officer at Ligand. "We know that several other targeted therapies combined with chemotherapy have also fallen short of a survival advantage in a first-line setting while in some cases proving efficacious in second- and third-line treatment. We believe SPIRIT I and II provided robust data to evaluate the value of adding Targretin to combo chemotherapy in the front-line setting and based upon those results now plan to continue to evaluate the potential of Targretin to provide benefit for second- and third-line patients."

Ligand said it would continue to analyze the data and plans to make a detailed scientific presentation at ASCO or other near-term scientific conferences.

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Adherex Technologies Inc. (AMEX: ADH) (TSX: AHX) of Research Triangle Park, N.C., said Health Canada has given regulatory clearance for a phase II clinical trial application for ADH-1, its anti-tumor biotechnology compound, also known as Exherin.

The trial, which would involve up to three cancer centers in Canada, will investigate repeated doses of ADH-1 in an every three week dosing schedule in tumors that express the molecular target N-cadherin, the company said.

The company said it would study eight different tumor types, including breast and lung, as well as adrenocortical and esophageal cancers.

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Adventrx Pharmaceuticals Inc. (AMEX: ANX) of San Diego said it has received a final advice letter from the European Medicines Agency for its proposed CoFactor trial protocol in pancreatic cancer.

The company said it would file a clinical trial application for a phase III multinational study following regulatory clearance.

CoFactor is a biomodulator that enhances drug 5-fluorouracil, the company said.

The primary endpoint of the trial is time to tumor progression with secondary endpoints of objective response, quality of life and overall survival, the company said. 480 patients will be randomized to receive either CoFactor/5-FU/gemcitabine or gemcitabine alone.

In a phase I/II trial in Europe, CoFactor in combination with 5-FU demonstrated stable disease or tumor response in 40 percent of pancreatic patients, the company said.

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Affymax Inc. of Palo Alto, Calif., said it has initiated a phase II trial of its lead investigational product Hematide, a synthetic, peptide-based erythropoiesis stimulating agent which would encourage production of red blood cells for anemia in chronic kidney disease and cancer.

The randomized, double-blind, placebo-controlled, sequential dose escalation study will evaluate the safety, pharmacodynamics and pharmacokinetics of a single intravenous injection of Hematide for CKD, the company said.

Results from the phase I dose-finding trial demonstrated that single doses of Hematide resulted in dose dependent increases in circulating reticulocytes in healthy volunteers, the company said. At the highest dose tested, the product also achieved a clinically and statistically significant increase in hemoglobin from baseline that was sustained for at least a month. Increases in hemoglobin and reticulocytes are indications of red blood cell production.

The product has an amino acid sequence that is unrelated to erythropoietin or to any other known naturally-occurring human sequences, the company said. In animal and laboratory studies the drug has demonstrated an excellent safety and efficacy profile, superior stability, and an extended duration of action compared to currently marketed recombinant erythropoietin products, the company said.

The company also said it plans to initiate phase II studies of Hematide for cancer where chemotherapy-related anemia has occurred.

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ARIAD Pharmaceuticals Inc. (Nasdaq: ARIA) of Cambridge, Mass., said it has begun enrollment in two multi-center phase 1b trials of mTOR inhibitor, AP23573, combined with paclitaxel or capecitabine for advanced cancer.

The non-randomized, dose-escalation studies will evaluate the safety and tolerability, pharmacokinetics, and anti-cancer activity of AP23573 in combination with paclitaxel or capecitabine, the company said.

The studies would determine the optimal dosing regimen for AP23573 when used in combination with each of the cytotoxic drugs for progressive breast, ovarian, non-small-cell lung, and prostate cancers, as well as certain sarcomas, the company said.

Up to 110 patients will be enrolled in the two trials at three to five centers in Italy and Switzerland, the company said.

The small-molecule drug, AP23573, a small molecule drug, inhibits the critical cell-signaling protein, mTOR, which regulates the response of tumor cells to nutrients and growth factors, and controls tumor blood supply and angiogenesis through effects on VEGF in tumor and endothelial cells, the company said. The drug also blocks the proliferation and migration of vascular smooth muscle cells, the primary cause of narrowing and reblockage of injured arteries, and is an analog of sirolimus, another mTOR inhibitor that has been approved for use in drug-eluting stents. AP23573 is phase I and II trials for solid tumors and hematologic cancers and has been designated a Fast-Ttrack product by FDA soft tissue and bone sarcomas, the company said.

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BioVex Ltd of Oxford, England, said it has begun an open label phase I/II trial of ImmunoVEXtrimelan for malignant melanoma at four centers in Canada and

two in the U.K.

The safety and biological activity of the treatment will be evaluated in 50 patients with the initial results expected during the first half of 2006, the company said.

ImmunoVEXtrimelan is a proprietary version of the herpes simplex virus, which loads multiple full-length protein antigen genes into dendritic cells, the company said. Dendritic cells loaded and activated in this way can prime the immune system for a cellular immune response.

Patients will be treated on an outpatient basis, donating blood samples from which dendritic cells will be prepared, the company said. After treatment with the vaccine, the dendritic cells will be returned to the patient in a series of inoculations.

The trial has started at the Jewish General Hospital, Montreal, under principal investigators Francois Patenaude of the Jewish General Hospital and Ronan Foley of the Hamilton Regional Cancer Centre, Ontario. The principal investigators at the other sites in Canada are Tina Cheng of the Tom Baker Cancer Centre, Calgary, Alberta; and Michael Smylie of the Cross Cancer Institute, Edmonton, Alberta. The principal investigators in the U.K. are Hardev Pandha of the Department of Clinical Oncology, St George's Hospital Medical School, London; and Nicholas Murray of the Cancer Research UK Oncology Unit, University of Southampton School of Medicine, Southampton General Hospital, the company said.

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ChemGenex Pharmaceuticals Ltd. (ASX: CXS) of Melbourne, Australia, said it has begun a multi-center phase II study of Ceflatonin (homoharringtonine or HHT) in combination with Gleevec (imatinib mesylate) for chronic myelogenous leukemia resistant to Gleevec .

Jorge Cortes, professor of leukemia at M.D. Anderson Cancer Center, is the principal investigator, the company said.

Gleevec is a targeted therapeutic with global sales in excess of US $1.6 billion last year, the company said. The drug was first approved in 2001 for advanced-stage CML, and it remains the dominant therapy for CML globally. Despite its effectiveness in early stage CML, responses in blastic phase patients are usually short-lived (3-6 months median duration), with only 15 percent experiencing a durable response. When used in earlier chronic stages of the disease, 20 percent have primary resistance to Gleevec and a further 20 percent develop resistance after 14 months, the company said.

The trial will be open-label for CML where the disease is in chronic, accelerated, or blast phase, the company said.

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Curis Inc. (Nasdaq: CRIS) of Cambridge, Mass., said that under a co-development agreement, **Genentech Inc.** (NYSE: DNA) has filed an IND with FDA to begin a clinical investigation of a drug candidate for basal cell carcinoma.

The drug candidate, discovered by Curis, is an antagonist of the Hedgehog signaling pathway, the company said.

"Preclinical research has suggested that the Hedgehog antagonists could selectively kill tumor cells while not harming adjacent normal cells, which contrasts with more traditional cancer treatments that often kill both cancer cells and normal cells," said Lee Rubin, senior vice president for research and chief scientific officer for Curis.

Under the collaboration, Curis said it retained a co-development option under which Curis may fund up to an equal share of the development costs and share in a commensurate portion of future net operating profits, if any, of clinical candidates that are topical formulations of compounds intended to treat basal cell carcinoma. In January 2005, Curis elected to exercise the co-development option.

The Curis co-development right applies solely to the U.S. marketplace and includes applications for basal cell carcinoma and any other indications for which a topically administered clinical candidate may be developed, the company said.

In a related development, Curis and Genentech established a collaboration to discover and develop small molecule modulators of a pathway in cell proliferation.

Under the agreement, Genentech said it would pay Curis an up-front license fee of $3 million and up to an additional $6 million over the next two years to support research at Curis dedicated to the collaboration. Genentech would make cash payments contingent upon the successful achievement of certain developmental, clinical, and drug approval milestones.

Genentech will also pay a royalty on net product sales if product candidates derived from the collaboration are successfully developed. In addition, Curis reserves the right to use small molecule modulators of the pathway that are discovered as result of the collaboration for ex vivo cell therapy purposes in areas outside of oncology and hematopoiesis, the company said.

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Epeius Biotechnologies Corp. of Los Angeles and New York said it has begun a phase I trial of Rexin-G, its tumor-targeted gene delivery system for metastatic colon and pancreatic cancer.

In 2003, Rexin-G gained FDA orphan drug designation for pancreatic cancer, the company said. Six out of six patients with advanced pancreatic cancer responded favorably to the treatment, as evidenced by shrinkage and/or disappearance of metastatic tumor nodules, or stabilization of disease, relief from pain, weight gain and extension of over-all survival time, without experiencing the side effects generally associated with standard chemotherapy, the company said. Clinical trials of Rexin-G have now been expanded to colorectal cancer that has spread to the liver.

The company said it has secured exclusive licensing rights to its pathotropic targeting platform, including the FDA-approved targeted delivery system for the treatment.

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GlycoGenesys Inc. (Nasdaq: GLGS) of Boston said it has begun a phase I/II dose escalation trial of GCS-100LE for multiple myeloma.

The first trial site will be at Dana-Farber Cancer Institute, the company said. The trial will be conducted under the direction of Kenneth Anderson, clinical director of the Jerome Lipper Multiple Myeloma Center at the Dana-Farber Cancer Institute and assistant professor of medicine, Harvard Medical School and Paul Richardson, the principal investigator, chief, Division of Hematologic Neoplasia at the Dana-Farber Cancer Institute and the Kraft Family Professor of Medicine, Harvard Medical School.

Anderson and Richardson were involved in pre-clinical testing, trial design and clinical trials that led to the regulatory approval of Velcade marketed by Millennium Pharmaceuticals and Johnson and Johnson for multiple myeloma, the company said.

Patients will receive GCS-100LE as a monotherapy in treatment cycles of two doses of GCS-100LE per week for two weeks followed by one week off therapy, the company said. If patients progress after two cycles or remain stable after 4 cycles, dexamethasone, a standard therapy, may be added to the treatment. Patients showing a partial or complete response on GCS-100LE as a monotherapy or GCS-100LE in combination with dexamethasone will continue on such treatment. The combination of GCS- 100LE and dexamethasone has been shown pre-clinically to have an additive effect on the killing of multiple myeloma cells, the company said.

The primary objective of the phase I/II dose escalation study is to evaluate the safety of GCS-100LE for relapsed or refractory multiple myeloma and to identify the recommended dose for future studies, the company said. Secondary objectives are to evaluate the response to GCS-100LE as a monotherapy and in combination with dexamethasone and determine the pharmacokinetics of GCS-100LE alone and with dexamethasone.

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Incyte Corp. (Nasdaq: INCY) of Wilmington, Del., said it has initiated a phase I trial of INCB7839, an orally-available sheddase inhibitor for solid tumors.

Sheddase is an enzymatic activity attributed to the ADAM (a disintegrin and metalloprotease) family of proteins that controls growth and spread of cancers regulated by members of the human epidermal growth factor receptor family of receptor tyrosine kinases, the company said.

The trial is a double-blind, placebo-controlled, single rising dose study to assess the safety and pharmacokinetics of INCB7839 in healthy volunteers, the company said.

"Our oral sheddase inhibitor, which targets the pathways at multiple points and acts more broadly than existing therapies, has shown excellent single agent activity in a number of preclinical models and has markedly improved the effectiveness of a variety of anti-cancer agents without causing incremental toxicity in the models," said Paul Friedman, president and CEO of Incyte.

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Inovio Biomedical Corp. (AMEX: INO) said it has begun a U.K. Medicines and Healthcare products Regulatory Agency approved phase I/II trial of its DNA delivery technology that delivers a therapeutic plasmid-based DNA vaccine to skeletal muscles for recurrent prostate cancer.

The trial, sponsored and led by the University of Southampton, of the U.K., would investigate whether the DNA vaccine can stimulate development of immune responses against prostate cancer and whether use of the Inovio electroporation system enhances the response, the company said.

The vaccine was developed in the laboratory of Freda Stevenson at the University of Southampton, the company said.

In the phase I/II open-label study, plasmid DNA encoding a prostate tumor antigen is delivered directly to skeletal muscles either by simple injection or using by the proprietary DNA delivery system, the company said.

The technology, which has been shown in preclinical studies to induce antigen production and generation of an immune response against the tumor antigen, uses electroporation to enable the entry and uptake of plasmid DNA into the muscle cells, the company said.

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Morphotek Inc. of Exton, Pa., said it has received an IND for a phase I trial of MORAb-003, a humanized monoclonal antibody for advanced ovarian cancer.

The study is designed as an open label single dose escalation safety study for chemo-refractive ovarian cancer, the company said.

The monoclonal antibody has high specificity for a number of different cancers, including ovarian, breast, colorectal, lung, renal, and brain, the company said. In pre-clinical cancer models the antibody has demonstrated that it can kill chemo-refractory tumors and suppress growth in xenograft studies.

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Novacea Inc.of South San Francisco said it has begun enrollment in a phase I/II open-label, dose-escalation study of banoxantrone, also known as AQ4N, a tissue-targeting cytotoxic prodrug.

The multi-center study will test banoxantrone in up to 55 patients with B-cell neoplasms, including Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia, the company said.

The primary objectives are to establish the maximum tolerated dose of banoxantrone, determine the pharmacokinetic profile of the agent and evaluate its safety and tolerability, the company said. In addition, the study will evaluate evidence of anti-tumor activity as measured by overall response rate.

Banoxantrone delivers an active cytotoxic compound to the site of the tumor while minimizing systemic toxicity, the company said. Previous studies also demonstrate synergy with radiation and chemotherapy.

Interim data from a U.K.-based phase I dose escalation study of banoxantrone in combination with radiation in esophageal cancer showed the agent to be well tolerated, with no sensitization of healthy tissues to radiation damage, the company said. The maximum tolerated dose and dose limiting toxicity were not reached with the doses used in this study.

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ZIOPHARM Inc. of New Haven, Conn., said FDA has approved its IND application of ZIO-101, its proprietary organic arsenic compound for cancer.

A dose-ranging phase I trial for hematological cancers would begin this month at M.D. Anderson Cancer Center, the company said.

ZIO-101 or organic arsenic, is a small molecule product from M.D. Anderson Cancer Center and Texas A&M University, the company said. A second organic arsenic from that broad licensing arrangement, ZIO-102, is expected to undergo further preclinical study this year as ZIO-101 progresses through phase I study in both hematologic and solid tumor cancers. A phase I/II trial of ZIO-101 should begin in the second half of this year.

Oncology Management:

Alliance Signs Agreement With Cardinal Health

(Continued from page 1)
the company said.

The web-delivered application makes use of the Ingenuity Pathways Knowledge Base, a curated database consisting of millions of individually modeled relationships between proteins, genes, complexes, cells, tissues, drugs, and diseases, the company said.

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National Oncology Alliance of San Rafael, Calif., said it has signed a three-year, preferred distribution agreement with **Cardinal Health** for oncology products**.**

Under the agreement, the NOA physician members have access to distribution capabilities and customer service, as well as state-of-the-art online ordering and reporting capabilities through the Cardinal Health Specialty Pharmaceutical Distribution group, the company said.

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Stone Bond Technologies of Houston said **M. D. Anderson Cancer Center** has purchased its EE-LIMS product to upgrade the paper-based workflow at one of their shared resource facilities to a fully automated Laboratory Request Management System.

The Microarray Core Facility, a shared resource center at M. D. Anderson, performs a variety of DNA and mRNA analyses for researchers working on problems ranging from identifying genetic variations associated with disease to discovering new drug targets, the company said. The EE-LIMS would give Microarray Core Facility researchers, administrators and lab technicians the ability to query, analyze and manage technical data from sample submission to delivery of analysis results. At the same time, EE-LIMS will handle billing and other administrative data flow as part of a single, integrated system, the company said.

Deals & Collaborations:

Abbott Licenses Material, Technology From BioCurex

Abbott Labs of Abbott Park, Ill., and **BioCurex** of Richmond, Va., said they have entered into a licensing agreement for the BioCurex Recaf material and technology.

Recaf, the receptor for alpha-fetoprotein, is a biomarker that could be used to develop cancer diagnostics tests, the company said. Recaf is found on malignant cells from a variety of cancer cell types but is absent in most normal and benign cells.

Under the agreement, Abbott said it obtains worldwide, semi-exclusive rights to commercialize products using the BioCurex Recaf technology. The agreement includes payment to BioCurex of up-front fees, product development milestones and royalties on any product sales.

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ChemDiv Inc. of San Diego said it has extended and expanded its existing collaboration with **Dendreon Corp**. (Nasdaq: DNDN) to develop targeted cancer therapies.

"Dendreon has repeatedly chosen ChemDiv Inc. for our expertise in lead optimization and custom chemistry and we support Dendreon in its small molecule program through our de novo synthesis of custom libraries and medicinal chemistry efforts," said Alex Kiselyov, vice president of Global Chemistry for ChemDiv Inc.

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DOBI Medical International Inc. (OTCBB: DBMI) of Mahwah, N.J., said it has signed a new distributor agreement for the ComfortScan system with **Prisma Imaging Western Europe S.r.l**. of Naples, Italy.

Under the agreement, Prisma would conduct a clinical trial in Rome to show the quality of the system and obtain local acceptance and registration specific to their respective countries, Italy, Portugal and Bulgaria, the company said.

The ComfortScan system is a light-based, noninvasive and gentle dynamic optical imaging tool that assists physicians in the diagnosis and management of breast cancer, the company said.

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Fujisawa Healthcare Inc. of Deerfield, Ill., and **Roche Pharmaceuticals** of Basel, Switzerland, said they have entered into a partnership for the U.S. co-promotion of Mycamine (micafungin sodium) injection, the Fujisawa newly approved product for esophageal candidiasis and for the propylaxis of Candida infections while hematopoietic stem cell transplantation is occurring.

Mycamine, an antifungal in the echinocandin class, inhibits an enzyme essential for fungal cell-wall synthesis and is fungicidal for Candida, the companies said. The treatment can be used concomitantly with other drugs, including the HIV protease inhibitor ritonivir and the transplant medications cyclosporine and tacrolimus.

Under the agreement, Roche will use it hospital sales force to augment the Fujisawa promotion of the drug in the U.S. Fujisawa said book sales and compensation to Roche will be based on product sales, the companies said.

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Implant Sciences Corp. (AMEX: IMX, IMX.WS) of Wakefield, Mass., said it was awarded a $750,000 phase II grant from NIH to develop and evaluate brachytherapy plaque for dural irradiation of tumors of the thoracic and lumbar spine.

The award is a follow-on award of a previous phase I grant. In the second phase, improvements would include the incorporation of more anatomically correct features into the device, and development of methods to efficiently manufacture the intra-operative radioactive device, the company said. The plaque and its dosimetry will be evaluated for clinical utility through a human trial in collaboration with Massachusetts General Hospital.

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Maxim Pharmaceuticals Inc. (Nasdaq: MAXM) (SSE: MAXM) of San Diego said it achieved a $1 million development milestone under an agreement with **Myriad Genetics**.

The milestone is based on the dosing of the first patient in a phase I program to evaluate the safety and pharmacokinetic profile of MPC-6827 for advanced solid tumors.

In pre-clinical studies, MPC-6827, an anti-cancer analog, demonstrated activity that was better than control using current standard-of-care chemotherapy in xenograft models of breast, pancreas, colon, ovary and prostate cancers, the company said. Other lead compounds discovered by Maxim include MX2167, MX2407 (f/n/a MX116407) and MX128504. MX2167 is a novel anticancer agent that targets the transferrin receptor leading to a previously uncharacterized rapid induction of apoptosis in preclinical tumor models. MX2407 is part of a novel class of microtubule inhibitors with vascular targeting activity and strong antitumor activity in pre-clinical in vitro and in vivo

studies. MX128504 targets a novel intracellular target and shows selectivity for breast and colorectal cancer.

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phase Forward (Nasdaq: PFWD) of Waltham, Mass., said it has entered into a multi-million dollar agreement with **Dana-Farber Cancer Institute**, on behalf of the Dana-Farber/Harvard Cancer Center, to license its InForm electronic data collection solution for principal investigator initiated clinical trials.

DFCI is standardizing the InForm solution for all DF/HCC investigator-initiated clinical studies across its clinical research platform for the member institutions of DF/HCC and 20 network affiliates that do clinical research in oncology to improve the efficiency and quality of clinical trial data collection and management, the company said. The Institute would use the InForm solution to reduce clinical trial cycle times, allowing improved access to data by the study teams and eventually populate the CRF's with the hospital's clinical systems data--furthering its impact on the research and treatments of cancers.

DFCI is the administrative center of the DF/HCC, which runs approximately 150 investigator-initiated oncology studies per year, and at any time, can have upwards of 450 open studies.

"At present, we have approximately 35,000 paper CRFs being generated yearly, and query management is handled by email and faxes," said Marina Nillni, corporate team leader, Clinical Trials IS, DFCI. "With new studies continually being initiated within the Institute, it was imperative that we increase the efficiency of our clinical trials process."

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Serologicals Corp. (Nasdaq: SERO) of Atlanta said that **Upstate Group**, its wholly owned subsidiary, obtained the rights from the **University of California** to sell the anti-ZAP-70 monoclonal antibody for diagnostic use.

Studies show that the levels of expression of the ZAP-70 protein can predict the aggressiveness of chronic lymphocytic leukemia, the company said.

"Anti-ZAP-70 was formerly only available for research use," said Ian Ratcliffe, president of Upstate. "The recently obtained rights will allow us to work more closely with diagnostic companies active in cell signaling."

Upstate said growth of the product could include the development of ZAP-70 diagnostic kits, development of ZAP-70 as a biomarker and the ability to offer GMP approved ZAP-70 quantities.

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Theragenics Corp. (NYSE: TGX) of Buford, Ga., said it has entered into an agreement to acquire **CP Medical** of Portland, Ore., a medical device company.

CP Medical manufactures and supplies sutures, cardiac pacing cables, brachytherapy needles/spacers, and other related medical products sold in the professional surgical and veterinary fields, the company said. Under the agreement, Theragenics would pay $19 million in cash and issue 1,885,370 shares valued at $6.25 million, for a total purchase price of $25.4 million.

Product Approvals & Applications:

Miami Firm Plans NDA For OrBec For iGVHD

DOR BioPharma Inc. (AMEX: DOR) of Miami said it would file a new drug application with FDA for orBec (oral beclomethasone dipropionate) for intestinal Graft-versus-Host Disease, after a pre-NDA meeting with FDA.

"The pivotal study provides a clear rationale for the use of orBec for iGVHD; control of iGVHD with an oral topical corticosteroid leads to less prednisone exposure, less systemic immunosuppression, fewer fatal infections, and possibly an enhanced graft-versus-leukemia effect," said George McDonald, head of the Gastroenterology/Hepatology Section at the Fred Hutchinson Cancer Research Center, inventor of orBec, and a consultant to DOR.

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BioAlliance Pharma of Paris said doxorubicin Transdrug has been granted orphan drug status by FDA for hepatocellular carcinoma.

The drug is completing phase I/II testing in the EU for hepatocellular carcinoma, the company said.

Transdrug technology employs a proprietary polymer formulated as a nanoparticle to deliver a proven active cancer drug (doxorubicin) to the site of the liver tumor via a catheter placed in the hepatic artery, the company said. The drug was developed using PIHCA (poly-iso-hexyl-cyanoacrylate), a proprietary polymer to formulate a number of anti-cancer drugs in nanoparticulate form, the company said. In the body, the drug-loaded nanoparticles, which can be formulated for delivery of drugs through the intra-arterial, intravenous, or oral route of administration, are translocated into the cancer cell where they can elicit anti-cancer activity.

Transdrug, which is designed to bypass MDR mechanisms, is capable of restoring the sensitivity of cancer cells, and overcoming resistance in cancer therapy, the company said.