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Bush Proposes $2.8 Billion Increase For NIH In FY2002, Vows $4.1B Next Year

President George W. Bush earlier this week proposed to increase the NIH budget by $2.8 billion, or 13.7 percent, to bring the Institute's funding to $23.1 billion in fiscal 2002.

The budget proposal, submitted to Congress Feb. 28, includes the increase to NIH as a "Presidential initiative." The White House said the increase would continue the effort to double the NIH budget over five years, beginning from the 1998 level of $13.6 billion to $27.2 billion in 2002.

Completing the doubling of the NIH budget was one of Bush's

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In Brief:

ACOR Opens Cancer-pain.org; Connie Mack Joins Washington Office Of Shaw Pittman

CANCER-PAIN.ORG is a new Web site for cancer patients begun by the Association of Cancer Online Resources, the largest online community of cancer patients. The site includes sections on the causes of pain, breakthrough cancer pain, pain treatment options, and tools to help cancer patients communicate effectively with physicians about their pain. The site, at http://www.cancer-pain.org, also has a complete list of medications available to treat pain, information about complementary and alternative methods of pain control, and a section on the special needs and issues of caregivers. Cancer-pain.org includes an interactive section where patients and caregivers can exchange information. "We hope this site helps educate patients about new advances in the understanding and treatment of pain, including breakthrough cancer pain, which can seriously diminish quality of life," said **Gilles Frydman**, president of ACOR. "Encouraging patients to exchange information about what works and what doesn't, as well as dispelling the myth of addiction, are two of the reasons we have developed this site to be a resource for patients and caregivers." ACOR, a non-profit organization that hosts and manages online resources for cancer patients, caregivers, healthcare professionals, and scientists, has a Web site at http://www.acor.org. Cancer-pain.org is supported through an educational grant from Cephalon Inc. . . . **FORMER SEN. CONNIE MACK** (R-FL) has joined the government relations practice of Shaw Pittman as senior policy adviser in its Washington, DC, office. Mack chose not to seek reelection and retired in January after serving 18 years in Congress, including the past 12 years in the Senate. During his political career, Mack played a key

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Bush Pledges NIH Increases To 2003, Then Leveling Off

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campaign promises.

Tommy Thompson, Bush's Secretary of Health and Human Services, said that if Congress approves the NIH budget proposal for 2002, Bush would seek a $4.1 billion increase for the Institutes for 2003. Thompson made the remark during a Feb. 28 press conference on the NIH campus in Bethesda, MD.

Over the past three years, NIH has received annual increases of about $2 billion, $2.2 billion, and $2.5 billion, the White House said.

"NIH is working to meet the management challenges that can arise when an agency receives a substantial infusion of resources over a short period of time," according to a White House statement.

NIH plans to develop policies "to maximize budgetary and management flexibility in the future," the statement said. "Such strategies could include funding the total costs of an increasing number of new grants in the grant's first year and supporting some one-time activities such as high-priority construction and renovation projects."

The Administration said it plans to scale back the increases after 2003.

"Once the doubling effort is complete, NIH will receive stable, moderate funding increases to continue to support investments in biomedical research that improve the health of all Americans," according to a White House statement.

The budget "blueprint" released this week did not include funding amounts for each of the Institutes. A more detailed budget proposal would be released by April 4, NIH sources said.

Thompson said he would let NIH decide how to distribute the funding. "They are the experts," he said in the press conference.

However, Thompson, who said he lost hearing in his right ear, joked that he asked NIH to spend "a good chunk of the money" on hearing deficiency research.

"My preference would be to put a lot of research dollars into areas in which we might have some immediate success, but that's not my decision," Thompson said. "That's got to be NIH's. You are always going to have a tremendous emphasis on cancer, on AIDS, diabetes—and, hopefully, hearing loss."

Acting Director Ruth Kirschstein said NIH is "very grateful" for the proposed budget. "We will use it well, we will have the appropriate stewardship," she said.

Thompson "Very Impressed" With NIH Tour

Thompson spent about three hours at NIH on Feb. 28, touring the Clinical Center, visiting several patients and physicians, meeting with Institute directors and scientists, and taking questions from the press.

"President Bush and I certainly understand the importance of these Institutes," Thompson said in prepared remarks. "We know that the work done here and the results achieved here represent one of America's greatest contributions as a nation."

The proposed budget "will enable NIH to support the highest level of total research project grants in NIH history," Thompson said. "The nice thing about it is that these grants are going to be given to research hospitals and researchers and scientists all over the country. I believe 75 to 80 percent of the dollars are given out in research grants to places across America."

Responding to a question about the Administration's plan to review the NIH policy on stem cell research, Thompson encouraged stem cell researchers to put in their grant applications by the March 15 deadline.

The Administration's policy would be clear by the time funding decisions would have to be made four months later, he said. "My recommendation will

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be within the time frames, so that if it's legal to go ahead, we'll not delay the grant dollars," he said.

Thompson also said the search for an NIH director is "very high on my agenda," and candidates are being interviewed, but the process would take some time. "We've got some great names," he said. "It just takes a long period of time. It's something that needs to be done yesterday."

The former Wisconsin governor said he was "very impressed" with his NIH tour. "As someone who's been passionate about research for a long period of time, I was excited about being here and having a chance to go through the Institutes and see some of the wonderful research that's going on here," he said. "I don't know if people really realize—for most Americans, I don't think they realize the tremendous group of individuals we have representing these Institutes. We have the world's greatest scientists, doctors, and researchers right here, and I can't tell you how humbled I am to be the Secretary of the department with such wonderful people."

Thompson said the Institute directors discussed several problems with him, including retention of skilled professionals at NIH, an expected shortage of nurses, and ways to encourage young people to enter biomedical research.

"This is truly a place where the future is made a better future for all Americans, and for the whole word, through long-term investments and a lot of hard work from some very courageous scientists," Thompson said. "I salute all the scientists who are carrying out NIH-sponsored research all over our country, and likewise, I salute the patients who enroll in NIH-sponsored research. They come here with a strong faith that their participation will help contribute to medical progress, and their faith is very well placed."

The positive note was echoed by several Institute directors who Thompson invited to speak at the press conference.

"We feel we sit in a very privileged and lucky place, to be at what is undoubtedly and definitely the most extraordinary time in the history of knowledge about biology, about health, and about disease, so beautifully captured two weeks ago by the publication of the human genome sequence," NCI Director Richard Klausner said. "This is a unique time and we deeply appreciate all that we will be able to do with this continued support."

The President's budget proposal is posted at http://www.whitehouse.gov and at http://w3.access.gpo.gov/usbudget/index.html.

Transition:

Cancer Groups In Campaign To Draft Pazdur For FDA

Patient advocacy groups and professional societies are conducting an unusual campaign to nominate the FDA oncology division director Richard Pazdur to the job of FDA Commissioner.

The campaign includes the American Association for Cancer Research, as well as 26 groups that belong to Cancer Leadership Council, a patient-led forum on cancer policy. As part of the campaign, John Mendelsohn, director of M.D. Anderson Cancer Center, recently endorsed the Pazdur candidacy in a letter to the Bush Administration.

Pazdur, a colon cancer expert with a solid track record in clinical trials and drug development, is not circulating his own curriculum vitae, and his supporters claim ownership of the idea of advancing his candidacy.

"This Administration has been very candid about not wanting a lot of Washington insiders to dominate the government, and Rick Pazdur, to me, is the epitome of someone who has come to Washington with fresh ideas and new ways of looking at things," said Ellen Stovall, executive director of National Coalition for Cancer Survivorship and the mastermind of the Draft Pazdur campaign.

Stovall and other supporters say Pazdur would enthusiastically accept the job if it's offered. Pazdur was traveling and was not available for comment.

It is unclear who else is vying for the top job at FDA. According to The Pink Sheet, a publication covering the pharmaceutical industry, contenders include former acting commissioner Michael Friedman, the University of North Carolina School of Public Health Dean William Roper, FDA official Murray Lumpkin, former acting commissioner Mark Novitch, and Georgetown University Associate Dean Raymond Woosley.

There is no reliable way to separate serious candidates from those merely floating trial balloons. Still, it appears that, thanks to the campaign waged by the patient groups and professional societies, the 48-year-old Pazdur is uniquely positioned as a candidate with enthusiastic support of a broad constituency.

At a time when the agency is trying to organize its disparate oncology review programs and harmonize its drug approval criteria with state-of-the-art science, Pazdur's expertise could introduce clarity to the

regulatory process, supporters say.

Pazdur would not be the first oncologist to head FDA. The previous commissioner, Jane Henney, and her predecessor, Friedman, are oncologists. However, Pazdur would be the first hands-on clinical trialist and drug development expert to take the job.

"The process of review and approval for new drugs and other products by the FDA is of vital importance to our members and to the millions of cancer patients who will benefit from the rapid, efficient, and safe introduction of the multitude of novel therapies that are under evaluation by the agency," AACR President Tom Curran and CEO Margaret Foti wrote in a letter to HHS Secretary Tommy Thompson.

"We believe that Dr. Pazdur possesses the scientific expertise, experience, personal skills, and leadership qualities that will be essential to guide the FDA in carrying out its critical and important mission," Curran and Foti wrote in a letter dated Feb. 5

In his letter to Thompson, M.D. Anderson President Mendelsohn said FDA will need a commissioner with a deep understanding of drug development. "I believe that Dr. Pazdur has the skills and knowledge to bring about the changes that *must* be instituted by FDA to efficiently and effectively manage the onslaught of new drugs and biological agents, including gene therapies, which will be submitted for evaluation and approval during the next four years," Mendelsohn wrote in a letter to Thompson.

New Strategies Needed

The next FDA Commissioner will have to change the standards now used to evaluate drugs, said Richard Schilsky, associate dean for clinical research at the University of Chicago Biological Sciences Division, chairman, Cancer and Leukemia Group B, and former chairman of the FDA Oncologic Drugs Advisory Committee.

"The FDA will be flooded with new agents in the years ahead," Schilsky said. "They owe it to the American public to work closely with sponsors and investigators to develop new strategies to evaluate these agents as efficiently as possible.

"We will have to get away from the traditional paradigms of drug development, because there are simply too many agents and not enough patients available to test every new drug in the traditional phase III paradigm," Schilsky said.

An oncologist would be especially well positioned to implement these changes, Schilsky said.

"Oncology is leading the way in development of molecularly targeted therapies and these issues will play out over and over again in other therapeutic areas," Schilsky said. "The issues we grapple with in oncology drug development—patient selection, individualization of therapy, surrogate markers of effect and benefit, quality of life and risk assessment—are relevant to other therapeutic areas."

Pazdur's decision to leave M.D. Anderson to become director of the FDA Division of Oncology Drug Products in the summer of 1999 surprised many of his colleagues. As a tenured professor, principal investigator on over 30 grant-funded trials involving a variety of agents, and an author of over 100 articles in peer-reviewed journals, he didn't need to pay his dues by joining an unwieldy, frequently maligned bureaucracy.

FDA is not known for attracting people of this caliber for mid-level jobs. What went wrong?

Over the past 18 months, Pazdur has told hundreds of people that he joined the agency because he wanted to shape cancer policy and drug regulation. His story is consistent: I'm just a guy who took a six-figure pay cut in order to do some good. Amazingly, it seems to withstand scrutiny.

"I think you have to accept his explanation," Schilsky said. "It would appear that in the academic environment, he had achieved about all that anyone could achieve. He was renowned as an investigator in colorectal cancer. He had an outstanding clinical practice. He had reached the pinnacle of promotion. If he was attracted to the idea of trying to improve the oncology drug development process by working within the system, that would be a logical reason as to why he went to FDA to begin with.

"Now that he is there, it would seem that if he wants to have the greatest opportunity to affect change, then surely that would be from the Commissioner's office," Schilsky said.

Fittingly for a clinical trialist, Pazdur came to work with a prospective plan to end the isolation of the oncology division, making it a part of the greater oncology community, which includes basic and clinical researchers, patients, and pharmaceutical companies.

The plan also called for altering the drug approval standards to reflect mainstream science and finding a way to increase the involvement of patients in the regulatory process.

"He wasn't beholden to a hierarchy," said Steven Hirschfeld, a medical officer at the division. "He has

emphasized that FDA is not in isolation, but is part of a continuum of people who are all trying to further progress in cancer therapeutics."

As a result, medical officers were encouraged to publish, take part in outside meetings, consult patient advocates, and explore different methods of evaluation of drug data. "By giving people flexibility and support for their initiatives, he has opened the door toward more responsive and more efficient organization," Hirschfeld said.

Though the plan called for expanding the roles for patients and professional societies, nothing in Pazdur's experience prepared him to design the mechanisms for integrating these constituencies into the FDA review process.

Here, Pazdur needed to become a student of the practice of oncopolitics. He dove into this work with great enthusiasm, supporters say.

"In my opinion, he has been doing the work of liaison between FDA and the cancer community," said Stovall. "He has literally been pounding the pavement, soliciting input, without preaching his philosophies. He has been a good listener. He has encouraged a relationship with FDA that is uncommon for a regulatory agency."

Pazdur also became a regular at the meetings of the NCI National Cancer Advisory Board, where FDA has a seat at the table. At the same time, he tried to get the input of both AACR and the American Society for Clinical Oncology in developing drug review standards.

In fact, at the next ASCO annual meeting, Pazdur will be part of a symposium on "domestic and foreign guidelines for new drug approval and their impact on clinical trial design worldwide."

Other panelists at the May 13 symposium include Schilsky and pharmaceutical industry consultant Stephen Carter.

A bid for the commissioner's job seems to be an unplanned protocol alteration in Pazdur's prospective plan for his FDA stint.

When a letter proposing Pazdur for the Commissioner's job was circulated to CLC, all but three groups signed on (**The Cancer Letter**, Jan. 9). "Most of the groups had either an interaction with him through CLC or through their organizations," Stovall said.

"In his own self-effacing way, he was surprised that patients would think of him as a candidate for this job," Stovall said. "As we see it, he has the makings of a great FDA Commissioner."

NCI Programs:

NCI Seeks 150 Advocates For Advice On Plans, Policies

NCI has developed a new program to bring cancer patient advocates into its advisory groups and is accepting applications from individuals interested in being part of the program.

The program, Consumer Advocates in Research and Related Activities, matches cancer advocates with opportunities to help NCI in its mission to conduct and support cancer research, training, health information dissemination, and other programs.

Through CARRA, NCI invites cancer advocates to represent survivors' concerns, providing their ideas and viewpoints directly to NCI staff and supplying critical links between the advocacy communities and NCI. Once accepted into CARRA, an advocate may help develop and review cancer education pamphlets, videos or Web sites, participate in meetings about NCI research plans and policies, or evaluate patient-oriented studies at cancer research centers.

CARRA will recruit 150 consumer advocates to serve three-year terms at NCI. Advocates must be a cancer survivor; or family member or life partner; or people with three or more years of involvement in cancer-related activities (for example, support groups or hotline workers). Individuals selected for CARRA will participate in activities either from home or at the NCI campus in Bethesda, MD. NCI will also ask CARRA members to regularly provide their community's viewpoints on issues important to NCI.

The program, developed in consultation with consumer advocates and NCI staff, replaces informal methods of advocate involvement with a clear and well-defined system.

Once selected, advocates will receive a general orientation about NCI. Advocates and NCI staff will receive orientations regarding the roles and responsibilities of CARRA members. New members will be provided with mentors experienced with NCI's programs and the role of advocates. NCI will also provide additional advocate training tailored for each activity and compensation for travel and expenses.

To request a CARRA program application package, see http://liaison.cancer.gov/CARRA or email requests to liaison@od.nci.nih.gov, or call 301-594-3194, or fax 301-480-7558, or mail to: NCI Liaison Activities, 6116 Executive Blvd., Suite 3068A, MSC 8324, Bethesda, MD 20892-8324.

Applications must be postmarked by April 16.

Tobacco Regulation:

"Harm-Reduction" Products Not Proven, IOM Report Says

Pharmaceutical and modified tobacco products designed to reduce the health risks of smoking cannot yet be proved to reduce tobacco-related disease, according to a report from the Institute of Medicine.

Products developed to lessen the risk of disease by reducing exposure to toxic chemicals are scientifically feasible, but in the absence of rigorous research, no one knows if these products decrease the incidence of tobacco-related disease or actually increase it by encouraging smoking.

The report outlines how tried-and-true public health tools—research, surveillance, communication, and regulation—should be used to ensure that the availability of these products confers less risk to the individual and to the population as a whole compared with conventional tobacco products. It recommends a regulatory strategy to assure that these products reduce risk of disease.

In 1999, FDA called on the IOM to provide a framework for assessing "harm-reduction" products that allow the user to continue to smoke. Drugs such as an antidepressant and nicotine in gum, patches, inhalers, and nasal spray are regulated by FDA for short-term use to help people quit smoking, but they are not approved for long-term use in harm reduction. Modified tobacco and cigarette-like products are not regulated by the FDA or any federal agency for their potential to reduce tobacco-related disease.

The recent introduction of these products and growing competition between the industries to develop more of them make it urgent that such products are studied, and that information about them is easily and accurately communicated to consumers, the committee said.

The report, "Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction," will be available from the National Academy, 202-334-3313 or 800-624-6242.

Funding Opportunities:

DOD Breast, Prostate Cancer Program Announcements

The Fiscal Year 2001 Defense Appropriations Act provides $175M to the Department of Defense Breast Cancer Research Program (BCRP) to support innovative research directed toward the eradication of breast cancer. This program is administered by the U.S. Army Medical Research and Materiel Command through the Office of the Congressionally Directed Medical Research Programs.

For the FY01 BCRP, two Program Announcements will be released.

FY01 BCRP Program Announcement I, released Feb. 16, offers funding for: Clinical Translational Research (CTR) Awards, Collaborative-CTR Awards, Breast Cancer Center of Excellence Awards.

Both CTR and Collaborative-CTR Awards require a pre-proposal submission, which is due by March 14.

New this year: Breast Cancer Center of Excellence Awards These awards are intended to support the establishment of multi-institutional collaborations among highly accomplished scientists from diverse backgrounds to focus on a major scientific problem in breast cancer. Proposal receipt deadline for this mechanism is June 27.

FY01 BCRP Program Announcement II is anticipated to be released on or about March 14, with proposal receipt in June.

For more information about the BCRP, BCRP awardees, previous BCRP Program Announcements, and other CDMRP-sponsored programs and events, see http://cdmrp.army.mil.

DOD Prostate Cancer Program:

FY01 PCRP Program Announcement II invites proposals though five new mechanisms: Health Disparity Training-Prostate Scholar Awards, Health Disparity Research-Prostate Scholar Awards, Historically Black Colleges & Universities Collaborative Partnership Awards, Prostate Cancer Clinical Trial Awards, and Prostate Cancer Consortium Development Awards.

Proposal receipt deadline for the Consortium Development Award is Aug. 29. Proposal receipt deadline for all other mechanisms in Program Announcement II is June 6.

Health Disparity Training-Prostate Scholar Awards are intended to support research training that focuses on the disparate burden of prostate cancer in African Americans. They are designed for predoctoral students, postdoctoral trainees, and physicians who recently completed postresidency training. Funding may be requested for up to $90,000 for Predoctoral; $147,000 for Postdoctoral; and $300,000 for Postresidency Traineeships (direct and indirect costs) over a 3-year period.

Health Disparity Research-Prostate Scholar Awards are intended to support research that focuses on the disparate burden of prostate cancer in African Americans. They are designed for scientists or physicians at the Assistant Professor level or equivalent who are not yet established researchers. Funding may be requested for up to $300,000 per award (direct costs) over a 3-year period.

HBCU Collaborative Partnership Awards are intended to create partnerships between the applicant HBCU and a collaborating non-HBCU to establish and sustain independent research and training programs at the HBCU that address prostate cancer disparity in the African American population. Funding may be requested for up to $600,000 (direct costs) over a 3-year period.

Prostate Cancer Clinical Trial Awards are intended to support prospective Phase I or II clinical trials that incorporate a plan to collect correlative data that address mechanisms of clinical efficacy. They are intended for investigators at all levels of experience. Funding may be requested for up to $2M (direct costs) over a 3-year period.

Prostate Cancer Consortium Development Awards are intended to support initial developmental phases required to establish a consortium that will address a major, coordinated, goal/product-driven research effort that is national in scope. Proposals for the full Consortium Award will be requested in FY02 pending receipt of FY02 funds. Funds for the FY01 Consortium Development Award may be requested for up to $150,000 (direct and indirect costs) for a 1-year period.

Detailed descriptions, evaluation criteria, proposal submission requirements, and additional related information for all award mechanisms can be found in the FY01 PCRP Program Announcements. Both documents may be downloaded from the CDMRP website at http://cdmrp.army.mil.

RFAs Available

RFA CA-01-020: Shared Resources for Scientists Not at NCI Funded Cancer Centers

Letter of Intent Receipt Date: June 5, 2001

Application Receipt Date: July 10, 2001

The RFA requests applications to establish cancer-related research resources. To be eligible, applicant institutions must not have an NCI funded cancer center and the application must identify six or more NCI funded investigators who will use the proposed resource. Applicable resources include but are not limited to complex technologies, specialized databases, instrumentation facilities, human tissue specimens, and animal models. The RFA will use the NIH research resource grant R24.

Inquiries: Roger Aamodt, Division of Cancer Treatment and Diagnosis, NCI, 6130 Executive Blvd, Rm 6035A, Bethesda, MD 20892-7399, Rockville, MD 20852 (for express/courier service); phone 301-496-7147; fax 301-402-7819; email ra32u@nih.gov

RFA AI-01-004: Etiology of Chronic Disease: Novel Approaches to Pathogen Detection

Letter of Intent Receipt Date: April 16, 2001

Application Receipt Date: May 15, 2001

National Institute of Allergy and Infectious Diseases, National Institute of Diabetes and Digestive and Kidney Diseases and NCI are soliciting applications for the development of novel technologies or the improvement of established technologies to identify and validate the role of microbial pathogens in chronic diseases and cancer for which an infectious etiology is suspected. Areas of particular interest include studies using recent technological approaches in genomics, molecular biology, proteomics and computational biology. Interdisciplinary collaborative research teams are encouraged. Support will be through the R01 and exploratory/developmental research project grant R21.

Inquiries: For NCI—Jack Gruber, Division of Cancer Biology, NCI, Rm 5012, MSC-7398, Executive Plaza North, Bethesda, MD 20892-7398, phone 301-496-9740; fax 301-496-2025; e-mail jg65y@nih.gov

Program Announcements

PAR-01-053: Small Grant Program for NIDCR

Application Receipt Dates: April 3, Aug. 3 and Dec. 3, 2001; April 3, Aug. 3 and Dec. 3, 2002; April 3 and Aug. 3, 2003

National Institute of Dental and Craniofacial Research small grant R03 program has been modified to provide support only to new investigators for pilot research that is likely to lead to a subsequent individual research project grant R01 application. Research must be focused on one or more of the areas within the biomedical and behavioral scientific mission of the NIDCR: craniofacial anomalies and injuries; infectious diseases and immunity; neoplastic diseases; chronic diseases; biomimetics, bioengineering, and tissue engineering; and clinical, behavioral and health promotion research. Among the research objectives listed by NIDCR is basic and applied research related to oral cancers. The PA will use the NIH small grant R03 award mechanism.

Inquiries: Rochelle Small, Craniofacial Anomalies and Injuries Branch, National Institute of Dental and Craniofacial Research, Natcher Bldg, Rm 4AN-24K, Bethesda, MD 20892-6402, phone 301-594-9898; fax 301-480-8318; e-mail rochelle.small@nih.gov

NIH Regional Seminars in Program Funding and Grants Administration

Registration for two regional seminars covering NIH extramural program funding and grants administration are available at the following Web sites:

March 15-16, 2001, Houston, TX, http://www.mdanderson.org/nihseminar

June 7-8, 2001, Portland, OR, http://www.ohsu.edu/ra/spa/nih/nih.html

The two-day seminars feature sessions for research faculty and administrators on grant preparation, review, and administration. Information on regional seminars is available on the NIH Web site at: http://grants.nih.gov/grants/seminars.htm.

In Brief:

Richard Wood, ICRF, Accepts Appointment At Pittsburgh

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role in the passage of laws dealing with banking, health care, modification of the tax code, public housing reform and the environment. He was instrumental in increasing funding for medical research, and helped pass legislation calling for the doubling of funding for NIH. Also joining Shaw Pittman as a senior government relations adviser will be **Mark Smith**, who served as Mack's chief legislative aide on health care issues for the past 12 years, and **Susan Dubin**, Mack's long-time executive assistant. The firm has 440 lawyers with offices in Washington, DC, Northern Virginia, New York, Los Angeles, and London. . . . **RICHARD WOOD**, of the Imperial Cancer Research Fund, was appointed the Richard M. Cyert Chair in Molecular Oncology and director of the molecular and cellular oncology program at the University of Pittsburgh Cancer Institute. Wood, who joins the faculty March 8, will also hold appointments as professor in the University of Pittsburgh School of Medicine's department of pharmacology and in the department of biological sciences. Wood was a principal scientist and an honorary professor in the department of biochemistry and molecular biology at University College in London. Prior to joining the ICRF in 1985, Wood was a post-doctoral associate at Yale University in the department of molecular biophysics and biochemistry. He received his doctorate in biophysics from the University of California, Berkeley, and his bachelor's degree from Westminster College in Salt Lake City, Utah. The Cyert chair was established in 1997 and funded by a $1.5 million grant, half from the Vira I. Heinz Endowment and half from the H.J. Heinz Company Foundation. . . . **DONALD TRUMP**, deputy director for clinical investigations at the University of Pittsburgh Cancer Institute and chief of the division of hematology and oncology in the University of Pittsburgh's department of medicine, has been honored as Vectors/Pittsburgh Science Man of the Year for 2001. Vectors/Pittsburgh recognizes those individuals who dedicate their services to making Pittsburgh a better place to live. Trump joined UPCI in 1992. . . . **MICHAEL BRATTAIN** was appointed chairman of the Department of Pharmacology and Therapeutics at Roswell Park Cancer Institute, effective this summer. Brattain is associate director for basic research at the San Antonio Cancer Institute. Brattain's research has centered on signal transduction pathways in breast and colon cancer. . . . **SANDRA MURDOCK** was named associate director for administration and chief operating officer of the Winship Cancer Institute of Emory University. Murdock was the associate vice president for operations and ambulatory services and interim chief administrative officer at the University of Texas M.D. Anderson Cancer Center. Murdock is also involved in policy planning for the Georgia Cancer Coalition, a $1 billion commitment for funds from Georgia's tobacco settlement. . . . **CHARIS ENG**, director of the Clinical Cancer Genetics Program at the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute, was elected to the membership of the American Society for Clinical Investigation. Eng was invited to present her research at the ASCI meeting in April. Eng uses DNA-based methods to identify and characterize genes that cause susceptibility in inherited cancer syndromes, determine their role in sporadic cancers, and perform molecular analyses that may relate to future clinical applications. . . . **KANSAS BOARD** of Education "made a courageous decision" by overturning the actions of the previous board and reinstating study of the origins of life and the cosmos to school science education standards, according to a statement by the American Association for the Advancement of Science, National Academy of Sciences, and National Science Teachers Association. The groups noted that the new Kansas standards "should serve as a model for other states that are considering revising their own standards." The statement is available at http://www.nationalacademies.org/. NAS also maintains a Web site on science and creationism, which includes resources for science organizations and teachers, at http://www4.nas.edu/opus/evolve.nsf . . . . **NATIONAL FOUNDATION** for Cancer Research Center in Berlin has been formed by the Industrial Investment Council and the Freie Universität Berlin. The center, a collaboration between scientists at the Freie Universität and the RNA Network, is funded by the National Foundation for Cancer Research, of Bethesda, MD. The center will focus on cancer-related RNA derived research directed by **Volker Erdmann**, chairman of RiNA e.v. Erdman is chairman of the RNA Network and a professor at the Institute of Biochemistry at the Freie Universität. NFCR funds centers at Oxford University, University of California, Berkeley, Yale University and the Institute of Medicinal Biotechnology in Beijing.

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Business & Regulatory Report

Clinical Trials:

MGI Pharma's Irofulven In Phase III Trial Vs. 5-FU For Advanced Pancreatic Cancer

MGI Pharma Inc. (Nasdaq: MOGN) of Minneapolis said it has begun patient dosing in a phase III trial of irofulven, for advanced-stage pancreatic cancer.

The randomized, multi-center, international trial assesses disease progression after treatment with gemcitabine, the company said. Irofulven is being compared to 5-fluorouracil. Survival is the primary endpoint, with objective tumor response and other clinical benefit measures as secondary endpoints, the company said.

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Product Approvals & Applications:

FDA Approves Two PSA Tests By Roche; Onconase Gets EU Orphan Designation

Roche Diagnostics of Indianapolis announced that it has received FDA approval for two prostate-specific antigen assays. Both blood tests are automated:

—The Elecsys Total PSA (tPSA) immunoassay is a screening test indicated for use in conjunction with a digital rectal exam as an aid in the detection of prostate cancer in men 50 years or older. Additionally, tPSA is used in monitoring the treatment progress of prostate cancer patients.

—The Elecsys Free PSA (fPSA) immunoassay is used with the Elecsys Total PSA immunoassay to develop the ratio (% PSA) of fPSA to tPSA. This ratio is useful in distinguishing prostate cancer from benign prostate conditions in men who have an elevated tPSA (4 ng/ml to 10 ng/ml) but a normal DRE. A prostate biopsy is required for the diagnosis of prostate cancer.

Both the Elecsys Total PSA and the Elecsys Free PSA assays are performed on Roche Elecsys immunoassay systems, which are available in different configurations for different healthcare settings, such as ambulatory care centers and medium- or large-size hospitals.

* * *

Alfacell Corp. (OTCBB: ACEL) of Bloomfield, NJ, said its anti-cancer agent, Onconase, has received orphan medicinal product designation in Europe for malignant mesothelioma.

The designation regulation facilitates registration of ethical pharmaceuticals in small patient populations and offers financial incentives to the sponsor, such as registration fee reductions and a 10-year marketing exclusivity for the therapeutic indication, the company said.

(Continued to page 4)

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Irofulven Enters Phase III; TNF Product In Phase I

(Continued from page 1)

Irofulven is being used in an intermittent, every other week dosing schedule. 5-FU will be given as a continuous intravenous infusion. A 2:1 randomization will be used where two patients will be treated with irofulven for each patient receiving 5-FU, the company said.

"Irofulven has caused regressions of some patients' pancreatic cancer in phase I and II trials," said Daniel Von Hoff, professor of medicine, lead investigator for the trial and director at the Arizona Cancer Center. "This pivotal clinical trial, with the new dose regimen, will define the role irofulven will have in the treatment of patients with advanced pancreatic cancer."

* * *

GenVec Inc. (Nasdaq: GNVC) of Gaithersburg, MD, has initiated phase I clinical trials with TNFerade, a product candidate intended for use in combination with radiation therapy to improve the treatment of cancer.

TNFerade delivers the tumor necrosis factor alpha gene to the tumor, where it directs the production of TNFa, the company said. TNFa is a therapeutic protein that has been found to both directly fight cancer and increase the effectiveness of radiation therapy. The broad clinical use of TNFa has been limited due to the protein's toxicity when administered systemically.

Participants in the phase I study will include patients who have failed standard treatment and those who currently receive radiation for local tumor control, the company said.

"Continuous refinement of radiation techniques has made radiation increasingly important in the treatment of cancer," said Henrik Rasmussen, vice president of clinical research and regulatory affairs at GenVec. "However, radiation-induced toxicity remains an issue and limits the effectiveness of radiation. By capitalizing on the synergistic effect between TNFa and radiation, we hope to be able to either increase the effect of radiation, reduce radiation-induced toxicity, or both."

TNFerade is GenVec's second drug candidate to enter human clinical trials. Biobypass angiogen, is now in phase II human clinical studies for the treatment of coronary artery disease and peripheral vascular disease, and is being developed in collaboration with Pfizer Inc.

* * *

EDG Capital Inc. (OTCBB: EDGN) of New York said it is resuming clinical trials of Colloidal 32P Phosphorus and Macroaggregated Albumin for brain cancer.

FDA had asked for assurances that the P32 and MAA products meet a specific endotoxin purity requirement before enrollment could continue, the company said. The supplier has agreed to comply with the FDA requirements.

* * *

Genta Inc. (Nasdaq: GNTA) of Berkeley Heights, NJ, said it has begun a phase III randomized trial of its antisense drug, Genasense, for advanced multiple myeloma.

The study, which will be conducted at 65 centers in the U.S., Canada and Great Britain, will test whether the addition of Genasense improves response rates, response duration, and quality of life, compared with dexamethasone alone, the company said.

Martin Oken, director of the Virginia Piper Cancer Institute in Minneapolis will be the principal investigator of the study, the company said.

"Preclinical studies have shown that Genasense is rapidly taken up by myeloma cells, and that Bcl-2 protein is reliably down-regulated with this treatment," said Yair Gazitt, of the University of Texas Health Sciences Center in San Antonio, one of the centers participating in the study. "Genasense can specifically

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counteract factors involved in drug resistance in myeloma patients. Laboratory studies have shown that the combination of Bcl-2 antisense plus dexamethasone or chemotherapy is more effective in killing myeloma cells than each drug alone."

* * *

Nastech Pharmaceutical Co. Inc. (Nasdaq: NSTK) of Haupauge, NY, said it has begun a phase I trial in the U.S. to evaluate the nasal administration of interferon alpha.

The objective of the multi-dose study is to determine nasal absorption, tolerance, and safety of interferon alpha, the company said.

Interferon alpha is indicated for the treatment of cancer and hepatitis and is administered by injection only.

"Interferon alpha is a major therapeutic tool in the treatment of a number of important and serious medical conditions, including hairy cell leukemia, malignant melanoma, follicular lymphoma, condylomata acuminata, AIDS-related Kaposi's sarcoma, and chronic hepatitis B and C," said Eric Rowinsky, director of clinical research, Cancer Therapy and Research Center, San Antonio, and an advisor to Nastech.

* * *

Novogen (Nasdaq: NVGN) of Stamford, CT, said it has been granted FDA clearance to begin a phase I trial of its anti-cancer drug phenoxodiol.

The study will focus on advanced solid tumors, with an emphasis on prostate cancer, the company said.

Phenoxodiol, a new generation cancer drug with a wide range of effects on signal transduction mechanisms within cancer cells, will be administered by continuous intravenous infusion, a method of treatment already developed that will allow drug levels to be maintained in the blood in a steady state, the company said.

In pre-clinical studies, phenoxodiol has proven to be active against a wide range of human tumour cell lines, representing all three general tissue categories of epithelial, mesenchymal and neural, the company said.

* * *

Protein Design Labs Inc. (Nasdaq: PDLI) of Fremont, CA, said a phase II trial has begun to evaluate its SMART1 D10 Antibody in relapsed or refractory B-cell non-Hodgkin's lymphoma.

The multicenter, open-label, two arm, randomized study in 60 patients will evaluate the safety, overall response rate, and response duration of two different dosing regimens of SMART 1D10. The primary efficacy endpoint will be the percentage of patients who achieve complete and/or partial tumor regression.

SMART 1D10 binds to an HLA-DR determinant found on many pre-B and B-cell lymphomas, the company said. Its target differs from other antibodies being marketed or studied for the treatment of non-Hodgkin's B-cell lymphoma, which bind to the CD20 or CD22 antigens. HLA-DR is also present on cancer cells from acute and chronic lymphocytic leukemia and on some solid tumors, the company said.

* * *

Therion Biologics of Cambridge, MA, and NCI said they have initiated a phase I trial for a new generation of colorectal cancer vaccines, CEA-TRICOM, a vaccine that incorporates a triple dose of costimulatory molecules as well as the CEA tumor antigen.

In preclinical studies to date conducted by the NCI and Therion, researchers have demonstrated that this combination of three co-stimulatory molecules dramatically boosts the immune response to eradicate cancer in murine models, the company said.

The is designed to demonstrate proof-of-principle for using multiple co-stimulatory molecules in conjunction with a tumor antigen to improve the strength of cellular immune responses. The study is conducted under a Cooperative Research and Development Agreement between Therion and the NCI's Laboratory of Tumor Immunology and Biology.

Therion is developing both CEA- TRICOM and ALVAC-CEA/B7.1 together with Aventis Pasteur as part of ongoing collaboration for the advancement of therapeutic cancer vaccines.

CEA-TRICOM is a recombinant, pox virus-based vaccine that targets carcinoembryonic antigen, a protein found on the surface of colorectal, pancreatic, breast and lung cancer cells. In the trial, CEA-TRICOM is administered in a priming and boosting protocol using two unique pox virus vectors, rV-CEA-TRICOM and rF-CEA-TRICOM.

The TRICOM component of the vaccine consists of three co-stimulatory molecules known to elicit strong cellular immune responses necessary for complete tumor destruction.

The multi-stage, dose-escalation study will assess the safety and immunologic effects of CEA-TRICOM in up to 42 patients who have advanced metastatic colorectal cancer.

Subjects will receive rF-CEA-TRICOM alone, rV-CEA-TRICOM followed by booster vaccinations with rF-CEA-TRICOM, or rV-CEA-TRICOM followed by rF-CEA-TRICOM and GM-CSF adjuvant. The primary measure of immune response will be the level of CEA specific T-cells stimulated by vaccination, with levels of CEA-expressing tumor cells in the blood used as a potential secondary measure of treatment effect.

Principal investigator John Marshall, of Georgetown University Medical Center, will lead the study at the Vincent T. Lombardi Cancer Center.

* * *

Vical Inc. (Nasdaq: VICL) of San Diego said it has begun a multi-center phase II trial of Allovectin-7 for early-stage cancer of the oral cavity and oropharynx.

In the trial, patients will receive two doses of Allovectin-7 followed by surgical intervention, the company said. The goal is reduction in tumor size prior to surgery and includes assessment of the immune response to Allovectin-7, safety, and analysis of the time to disease progression.

"The fact that we saw partial and complete remissions in our previous trials offers great encouragement for the current trial," said Vijay Samant, president and CEO of Vical.

In a related development, the company said it has begun a multi-center phase II Allovectin-7 trial for late-stage metastatic melanoma.

* * *

Vion Pharmaceuticals Inc. (Nasdaq: VION) of New Haven, CT, said it will proceed with a phase I trial of VNP40101M from its Sulfonyl Hydrazine Prodrug family of novel and potent alkylating agents.

The company said the trial would begin within two months and would enroll 20 to 30 patients.

In addition to damaging DNA, VNP40101M inhibits a key enzyme (AGT) involved in the repair of the DNA damage, the company said. Thus, the agent blocks a major mechanism of drug resistance common to several of the standard alkylating agents, the company said.

According to preclinical tests, VNP40101M also exhibited excellent penetration across the blood brain barrier in mice, and a high degree of antitumor activity against intra-cranially implanted leukemia cells, the company said. Overall, VNP40101M demonstrated a broad spectrum of antitumor activity in preclinical animal models, including activity against tumor cells that are resistant to several of the alkylating agents in common use today.

"VNP40101M is among the most active anticancer agents we have tested in animal models," said Alan Sartorelli, professor of pharmacology at the Yale University School of Medicine, a member of Vion's board of directors and scientific advisory board, and lead scientist in the initial discovery and development of the SHP family of agents. "Not only does it inhibit a common mechanism of resistance to certain standard alkylating agents, the DNA damage that it causes is difficult to detect by the tumor cell's repair mechanisms."

Product Approvals & Applications:

EU Designates Onconase As Orphan Medical Product

(Continued from page 1)

The marketing approval of an orphan drug designated product, which uses the centralized procedure by the European Agency for the Evaluation of Medicinal Products and Medicines for Human Use, makes the product available to all patients within the European Community. Individual registrations are not required in each of the member states, the company said.

* * *

Computerized Thermal Imaging Inc. (AMEX: CIO) of Layton, UT, said it has received pre-market approval application from FDA for the administration of Module 4, the fourth of five modules in its Computerized Thermal Imaging System, for breast cancer detection.

If approved, the system would be used as an adjunctive diagnostic test to the mammogram and to the clinical examination, the company said. The patented system uses a sophisticated heat sensitive camera to record thermal images of breast tissue, which are processed by proprietary computer algorithms. The test is simple, painless and involves no radiation, breast compression, electrodes or electrical current, the company said.

Module 4 containes information on non-clinical testing such as bio-compatibility testing, electrical safety, electromagnetic compatibility, environmental assessment, reliability and durability, and stress and wear, the company said.

* * *

Enterix Inc. of Falmouth, ME, and Sydney, Australia, said its colorectal cancer screening test, !nSure, has received premarket clearance from FDA.

The test, an immunochemical fecal occult blood test that could indicate a developing cancer in the lower intestine, addresses the compliance-limiting deficiencies associated with existing FOBTs, most of which are based on 30-year-old technology, the company said. The older tests have dietary and medicinal restrictions and patients must take fecal smears on three consecutive days.

Individuals who test positive are referred for colonoscopy. The test has led to detection and removal of numerous cancers and pre-cancerous polyps, the company said.

"Our studies show that removing dietary restrictions and improving the sample collection method increases compliance," said Graeme Young, director of gastroenterology, Flinders University, Adelaide, Australia, and lead investigator of the clinical trials. "The test provides an excellent means for selection of asymptomatic individuals more likely to have colonic neoplasia and benefit from more invasive diagnostic evaluation by methods such as colonoscopy."

* * *

Lorus Therapeutics Inc. (OTCBB: LORFF)(TSE:LOR.) of Toronto said FDA has granted orphan drug status to its anti-cancer drug Virulizin in the treatment of pancreatic cancer.

The orphan status carries seven years of market exclusivity in the U.S. independent of patent protection, if a drug is approved.

Virulizin is an immunotherapy that recruits killer cells, monocytes and macrophages, to attack tumor cells, the company said. The compound is in development as second-line therapy for advanced pancreatic cancer patients who are refractory or intolerant to conventional first line therapies.

Lorus said it is planning a pivotal phase III clinical trial for Virulizin in North America later this year.

Deals & Collaborations:

Ilex Oncology Buys Symphar, Controls Drug For Bone Mets

Ilex Oncology Inc. (Nasdaq:ILXO) of San Antonio, TX, said it has acquired **Symphar S.A.** of Geneva, Switzerland, for $30 million in equal amounts of cash and Ilex Oncology common stock.

Symphar is combining a targeted medicinal chemistry platform with its biology expertise in regulating gene expression by modulating the activity of certain nuclear receptors, such as the Farnesoid X Receptor or FXR, important in controlling cellular functions including apoptosis and lipid and calcium metabolism, the company said.

"The acquisition gives us complete ownership of Apomine, the compound we are co-developing, access to follow-on compounds in bone metastasis and allows us to combine our research capabilities with one of the most experienced groups in phosphonate/bisphosphonate chemistry and biology," said Richard Love, president and CEO of Ilex Oncology.

Ilex and Symphar are conducting a phase II trial of Apomine in prostate cancer and will begin phase II trials in prostate cancer, lung cancer, breast cancer, melanoma and leukemia in 2001, the company said. In phase I trials, Apomine was well tolerated and has demonstrated antitumor activity in heavily pretreated cancer patients.

* * *

BioTransplant Inc. (Nasdaq: BTRN) of Charlestown, MA and **Novartis Pharma AG** (NYSE: NYS) of Basel, Switzerland, said their company, **Immerge BioTherapeutics Inc**, of Boston would develop therapeutic applications for xenotransplantation of cells, tissues and organs.

Julia Greenstein, formerly chief scientific officer at BioTransplant has been appointed president and CEO of Immerge, the companies said.

"The Immerge BioTherapeutics focus on xenotransplantation allows BioTransplant to strengthen its focus on human cell transplantation with applications in cancer and other life threatening diseases," said Elliot Lebowitz, president and CEO of BioTransplant.

Immerge is 67 percent owned by Novartis and 33 percent owned by BioTransplant, the companies said. Novartis said it retains the rights to commercialize research in return for technology and financial support. BioTransplant said it will contribute technology to Immerge and will receive royalty payments from future Novartis sales of products.

* * *

CoPharma Inc. of Hopkinton, MA, said it has acquired worldwide rights from **Dana-Farber Cancer Institute** to Beta-Lapachone (C0-501), a pre-clinical compound for cancers, including ovarian, breast, and prostate.

Beta-Lapachone, in combination with Taxol, provides synergistic effects over either compound given alone, said researchers at Dana-Farber.

CO-501 remains highly effective against tumor cells resistant to conventional drugs, such as Cis-Platinum.

"The agreement is consistent with our strategy to develop early to mid-stage compounds through in-licensing and innovative partnering," said Samuel Ackerman, president and CEO of CoPharma.

* * *

Faulding Pharmaceuticals the U.S.-based global pharmaceuticals division of F. H. Faulding & Co. Ltd. Of Adelaide, Australia, it has entered into an agreement to acquire the rights to the FUDR brand of sterile floxuridine from **Hoffmann-La Roche Inc.**

FUDR brand of floxuridine is a freeze-dried injectable antineoplastic drug that is indicated for use in the palliative management of gastrointestinal adenocarcinoma metastatic to the liver. Sales of FUDR were interrupted in 1999. Prior to that interruption, product sales were $6.3 million and had been growing steadily over recent years. The product was approved by FDA in late 1970.

Faulding said it purchased the rights for $6 million.

* * *

IGEN International Inc. (Nasdaq: IGEN) of Gaithersburg, MD, and **NCI** have signed a letter of intent to start joint development of techniques and products based on IGEN's ORIGEN biological detection technology.

As the next step, the letter of intent contemplates that IGEN and NCI would finalize a Cooperative Research and Development Agreement to expand the joint research program and provide IGEN with the right to license patents developed during the collaboration.

The research plan calls for development of ORIGEN-based assays and reagents that can be used to detect ubiquitin, a molecule that plays a key role in the signaling and control processes of cells by targeting proteins for degradation, the company said.

Abnormalities in the amount of ubiquitin attached to certain proteins may play a critical role in various processes such as cancer, inflammation, tissue regeneration, muscle wasting, and apoptosis, or programmed cell death. Compounds that inhibit or modulate ubiquitin attachment to proteins could prove useful in research and may lead to new approaches to cancer diagnosis and treatment. Another aim of the research plan is to use an ORIGEN-based assay to screen for such compounds.

* * *

Magainin Pharmaceuticals Inc. (Nasdaq: MAGN) of Plymouth Meeting, PA, and the **Ludwig Institute for Cancer Research** of Brussels announced a collaborative agreement for genes and proteins as pharmaceutical targets and therapeutics.

Under the agreement, Magainin and LICR are assigned primary commercial rights to intellectual property of genes and proteins with therapeutic potential, which were discovered during joint genomics and biological research conducted under a prior research agreement from 1996 as well as genes and proteins discovered by the Brussels branch of LICR, the companies said. The joint research program has been extended for two years.

"The alliances would provide therapeutic products for asthma, cancer, and other diseases, based on our combined efforts in genomics and biological research, said Roy Levitt, president and CEO of Magainin. "The expertise of the Ludwig Institute in the area of biological discovery, and in developing new therapeutics such as monoclonal antibodies, brings further depth to our genomics, target validation, and product development programs."

The Ludwig Institute for Cancer Research is a global not-for-profit organization that conducts long-range cancer research programs. The Cytokine Group of the Ludwig Institute studies the biology of interleukin-9, discovered by the group in 1989.

* * *

Medarex Inc. (Nasdaq: MEDX) of Princeton, NJ and **Seattle Genetics Inc.** of Bothell, WA, said they have formed a strategic alliance to utilize the Medarex UltiMAb Human Antibody Development System to jointly develop and commercialize monoclonal antibody-based therapeutic products against cancer targets.

Under the alliance, Seattle Genetics said it would provide the cancer targets to which Medarex said it would generate fully human antibodies. The companies will share preclinical and clinical development costs and have the right to jointly commercialize any resulting products. In addition, Medarex said it would purchase $2 million of common stock from Seattle Genetics in a private placement concurrent with the company's proposed initial public offering.

* * *

Onyx Pharmaceuticals Inc. (Nasdaq: ONXX) of Richmond, CA, said it has entered into a strategic process development and manufacturing agreement with **Xoma LLC** (Nasdaq: XOMA) of Berkeley.

Under the agreement, Xoma said it will develop

a large-scale process and will manufacture CI-1042, ONYX-015, for clinical trials and large-scale production.

Onyx said it will provide Xoma with an upfront payment; support for development efforts on the process scale-up and production of bulk drug materials; and milestone payments associated with attainment of large-scale production.

"The agreement allows us to increase the supply of CI-1042 for our various clinical trials and for commercial launch under our collaboration with Pfizer," said Hollings Renton, chairman of the board, president and CEO of Onyx Pharmaceuticals Inc.

CI-1042, a tumor-selective, modified adenovirus that has been genetically engineered to replicate in and lyse cancer cells that have abnormal p53 pathway while sparing normal cells which have p53 protein, is in a phase III trial and phase I/II trials.

The phase II trials where the drug is administered intravenously received a preferential supply of materials over the phase III clinical trial. As a result, the accrual of clinical sites and the enrollment of patients in the phase III study in recurrent head and neck cancer had been slowed, the company said. Drug supplies have been available to two clinical sites.

* * *

SuperGen Inc. (Nasdaq: SUPG & SUPGZ) of Dublin, CA, said it has licensed its vascular targeting agent, a platform drug-targeting technology, from **Peregrine Pharmaceuticals** (Nasdaq: PPHM) of Tustin, CA, formerly known as **Techniclone Corp**.

The licensed technology, a proprietary platform designed to target the blood supply of a tumor and destroy it with attached therapeutic agents, is related to vascular endothelial growth factor, the company said.

Terms of the agreement include an upfront equity investment in Peregrine, and subsequent milestone payments, that could total $8 million, the company said. SuperGen will pay royalties to Peregrine based on the net revenues of any drugs commercialized using the VEGF technology.

Oncology Management:

Response Oncology Sells Practice Back To Physicians

Response Oncology Inc. (Nasdaq: ROIX) of Memphis, TN, said it has sold the assets of Oncology/Hematology Group of South Florida, to the physician group.

Also, the management contract for the 13-physician oncology practice was terminated. The parties signed a pharmacy management agreement for Response Oncology to provide pharmacy management services, the company said.

"The transaction is consistent with our goal toward higher-margin, strong cash-generating areas, such as specialty pharmacy management services," said Anthony LaMacchia, president and CEO of Response Oncology. "In just one step, we have replaced an underperforming asset with a new, profitable revenue stream, exchanged fixed costs for variable costs, and improved our cash flow."

A non-cash, pretax charge of $9.5 million will be recorded to write off the original OHG transaction, the company said. The writeoff is projected to reduce fiscal 2001 amortization expense by $900,000, the company said. Response Oncology said it would continue to operate IMPACT Center of Dade County, which is affiliated with OHG, for the administration of high-dose chemotherapy.

* * *

PacifiCare of Oregon and **PacifiCare of Washington** said they have published the PacifiCare Quality Index, a medical group measuring system, for the Northwest.

The index, which represents more than 3,000 physicians serving 300,000 members in Oregon and Washington, allows consumers to see how medical groups rated in three broad areas: overall score, clinical scores and service scores. Practices that scored in the top ten percent of each specific measurement are designated best practices, and receive a notation in the Quality Index, the company said.

"Health plans like PacifiCare have been held accountable by employers, consumers, and regulatory agencies such as the state of Oregon for years," said Steve Lynch, vice president and general manager of PacifiCare of Oregon. "The report simply allows that accountability to flow through to the professionals who deliver the care."

* * *

Interwoven Inc. (Nasdaq: IWOV) of Sunnyvale, CA, a content management software provider, said **Stanford University Medical Center** has selected its software to manage the content on the Stanford Hospital and Clinics and the Lucile Packard Children's Web sites.

The software, called TeamSite, will empower the clinical staff and management to contribute content to the sites.

The Web site will include a database of clinical trials in the cancer center, physicians' profiles, facility maps, visitor hours, and other information.

"An open architecture was the most critical criteria for our content management system," said Mary Ellen Fontana, vice president of marketing and communications of Stanford Hospital and Clinics.

* * *

Barbara Ann Karmanos Cancer Institute at Wayne State University in Detroit, and **Aastrom Biosciences Inc.** (Nasdaq: ASTM) of Ann Arbor, MI, said the **Michigan Economic Development Corp.** has awarded a $2.2 million Michigan Life Sciences Corridor grant to establish the Center for Cell Therapy at the Institute for diseases including cancer.

The grant funds developmental research and clinical trials, cellular therapies for clinical use, licensing of collateral technologies and commercializing the manufacturing processes for producing cells and therapies, the awardees said.

First year objectives will include operations and integration of the Aastrom Replicell System product platform into the CCT to begin clinical trials. Therapies will include cord blood stem cell therapy for leukemia patients and dendritic cell vaccines for the treatment of cancer.

Funding is subject to incorporation of the CCT, which is underway and subject to approval by the Michigan Economic Development Corp.

Patents:

EntreMed Issued U.S. Patent For Active Parts Of Endostatin

EntreMed Inc. (Nasdaq: ENMD) of Rockville, MD, said it has been issued U.S. patent No. 6,174,861, which covers all fragments of Endostatin protein that have antiangiogenic activity.

The patent is owned by Children's Hospital in Boston and has been exclusively licensed on a world-wide basis to EntreMed Inc, the company said. With issuance of this patent, EntreMed now owns the use of all forms of the Endostatin molecule derived from the collagen XVIII and the collagen XV and the pregastric esterase molecule for treatment of angiogenic- mediated diseases.

"In clinical studies, Endostatin was very well tolerated, moreover, there were some signs of clinical benefit which will help guide its clinical development as an anticancer therapy," said John Holaday, chairman and CEO of EntreMed. "The patent has expanded our preclinical program to include collagen-derived antiangiogenic molecules in our clinical studies in cancer."

* * *

Avax Technologies Inc. (Nasdaq: AVXT) of Kansas City, MO, said it has been awarded U.S. patent 6,136,845 for the combination of its alkyl PCDFs with tamoxifen, to inhibit growth of estrogen-dependent tumors, such as breast cancer.

Avax licensed the technology, invented by Stephen Safe and Sid Kyle, professor of toxicology at Texas A&M University, which acts on the arylhydrocarbon receptor without causing ArH-related toxicity, the company said.

"In developing our antiestrogen technology, our goal was to combine it with a promising breast cancer therapy to bring about beneficial therapeutic synergies," said Jeffrey Jonas, president and CEO of Avax Technologies. "The combination of antiestrogens with tamoxifen allow us to lower the tamoxifen dosage in preclinical models, inhibiting certain damaging side effects, while preserving and enhancing the therapeutic benefits of treatment. The antiestrogen compounds could have a role in the treatment of breast cancer not only used alone, but used in combination with therapies such as tamoxifen."

* * *

Immunomedics Inc. (Nasdaq: IMMU) of Morris Plains, NJ, said it has received U.S. patent 6,187,287 for humanized and chimerized forms of its CD22 antibody for non-Hodgkin's lymphoma.

The patent includes claims to amino acid sequences and the DNA sequences encoding them in the epratuzumab antibody, either as a humanized antibody or as a chimeric antibody, the company said.

"The patent has claims to many forms of anti-CD22 antibodies, antibody fragments, and conjugates with diagnostic and therapeutic agents, including mammalian cell vectors for expression and production of these antibody forms," said Cynthia Sullivan, president and chief operating officer of Immunomedics.

Amgen (Nasdaq: AMGN) concluded a license agreement with Immunomedics to develop and commercialize epratuzumab in North America and Australia, the company said. Amgen has assumed sponsorship of the FDA-approved clinical trials.

In another development, Immunomedics said it has been issued U.S. patent 6,187,284 for the fluorination of proteins and peptides with F-18 positron emission tomography.

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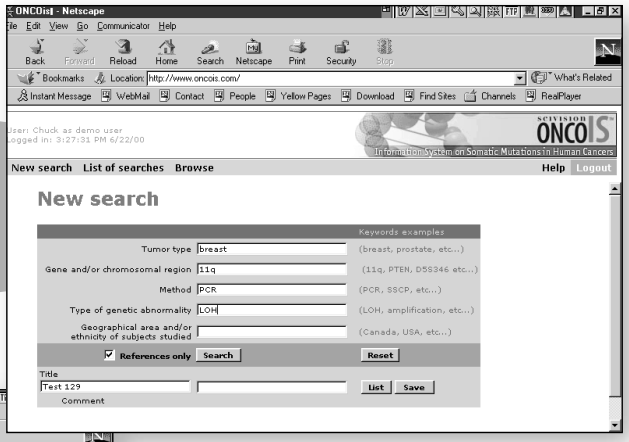

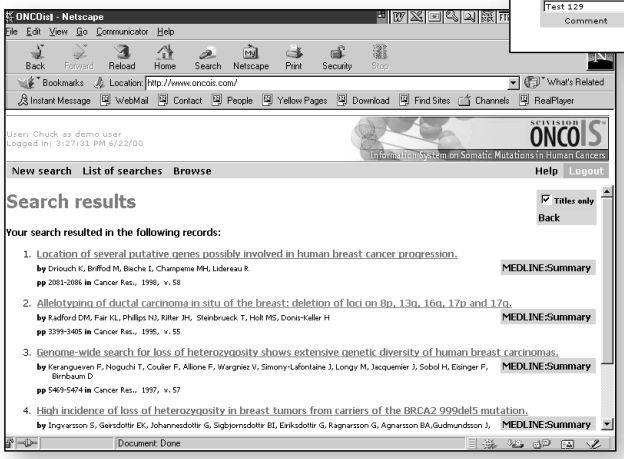

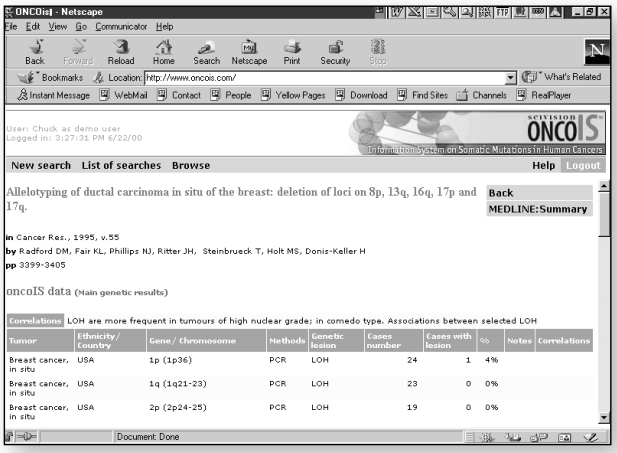

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