THE CANCER LETTER INTERACTIVE

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Pryce Introduces Bill To Reimburse For Orally Administered Cancer Drugs

Rep. Deborah Pryce (R-OH) last week introduced a bill that would provide Medicare reimbursement for orally administered cancer drugs.

The bill, Access to Cancer Therapies Act (H.R. 1624), proposes to amend the Social Security Act to extend Medicare Part B coverage to such drugs. Under existing regulations, only injectable drugs administered

(Continued to page 2)

In Brief:

H. Lee Moffitt Cancer Center Designated A Comprehensive Cancer Center By NCI

H. LEE MOFFITT CANCER CENTER & RESEARCH INSTITUTE at the University of South Florida has been recognized by NCI as a Comprehensive Cancer Center, identifying it both as a research center in basic, clinical and prevention, control and population sciences and as a community and regional resource for cancer information, education and outreach. Cancer occurs in one-third of the Florida population, said Moffitt. The designation brings NCI grant support and other federal grant funding. “There is no greater honor than earning NCI comprehensive status,” said John Ruckdeschel, director and CEO of the Moffitt Center. . . . **WAUN KI HONG** was appointed head of the Division of Cancer Medicine at M.D. Anderson Cancer Center, the center’s largest clinical division. His selection followed a nationwide search. The division was formed along with the Division of Internal Medicine last year when the former Division of Medicine was divided in two units. The Division of Cancer Medicine includes 206 faculty members in 13 departments, about 35 percent of the faculty. Oncologists in these departments provide front-line care for many of the 60,000 patients that come to M.D. Anderson each year. Hong said his top priority is to facilitate translational research at the center. Hong, who joined the center in 1984, retains his titles as Charles A. LeMaistre Distinguished Chair in Thoracic Oncology, and professor and chairman, Department of Thoracic/Head and Neck Medical Oncology. He also is an ACS clinical research professor, and president of the American Association for Cancer Research. His new appointment was effective April 1. . . . **ROBERT GROSSMAN** was named chairman of the Department of Radiology at NYU School of Medicine and director of radiology at NYU Hospitals Center. He will hold the Lewis Marx Professorship. Grossman, a 1999 NIH Javits Neuroscience Investigator

(Continued to page 8)

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On The Hill: ASCO, CLC Support Bill On Oral Drugs

(Continued from page 1)

in conjunction with physician services are covered by Medicare.

Medicare also covers some oral drugs, but only if they have injectable equivalents.

The Pryce bill has the support of the American Society of Clinical Oncology and the Cancer Leadership Council, an informal, patient-run forum for discussion of cancer policy issues.

CLC and ASCO say they would rather see the enactment of a comprehensive Medicare drug benefit, but both groups recognize that such a major enhancement of the federal program would not be feasible in the near future.

"The patient advocate, health professional, and research organizations in CLC support a comprehensive Medicare prescription drug benefit, but are nevertheless mindful of the difficulties facing the Congress in fashioning legislation in the near term to achieve that result," CLC groups wrote in a letter to Pryce, dated April 25,

CLC said the Pryce bill "would provide immediate and meaningful relief for people with cancer, seeking to expand their access to life-extending new anticancer drugs."

An ASCO "action alert" notes that the cost-sharing formula in Medicare Part B is more favorable to patients than the formula likely to be included in a comprehensive drug benefit. Also, the mandatory coverage standard in the Medicare Part B program includes coverage for off-label use, the ACSO document notes.

The legislation is important because many of the new anticancer agents are orally administered.

"Some of the most impressive of these new drugs will be on the market during this calendar year—probably well in advance of any comprehensive Medicare drug coverage," the CLC letter states.

The bill is co-sponsored by Reps. Ken Bentsen (D-TX), Lois Capps (D-CA), Sue Myrick (R-NC), Roy Blunt (R-MO), Bob Erlich (R-MD), Mark Foley (R-FL), Tony Hall (D-OH), David Hobson (R-OH), and Vic Snyder (D-AR).

The measure was introduced April 26 and referred to the House Energy and Commerce and Ways and Means committees.

* * *

Breast and Cervical Cancer Screening Program: Medicaid coverage for breast and cervical cancer treatment for women diagnosed through a screening program operated by Centers for Disease Control and Prevention is now legally mandated in seven states.

Over the past month, the governors of Idaho, Mississippi, North Dakota and Virginia, have signed bills extending coverage for the treatment of women screened through the National Breast and Cervical Cancer Detection Program.

Three more states—Maryland, New Hampshire and West Virginia—chose to take the administrative route to offering coverage. Their revisions to Medicaid plans were approved by HHS Secretary Tommy Thompson March 30.

The list is likely to grow in a matter of days. Four more states—Rhode Island, Massachusetts, Ohio and Utah—are expected to submit plans to Thompson, and bills are on the way to the governors of Arizona, Florida, Hawaii, Illinois, Indiana and Nebraska. In Montana, the bill is pending in the House, with the governor's proposed amendments.

Altogether, 66 bills mandating coverage have been introduced in the legislatures of 35 states. The bills are tracked by the National Conference of State Legislatures and posted on its Web site: http://www.ncsl.org/programs/health/cancerch.htm

Eleven states have not introduced legislation or taken administrative steps to provide coverage. They are: Delaware, Georgia, Kentucky, Louisiana,

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Michigan, Pennsylvania, South Carolina, South Dakota, Tennessee, Vermont and Wyoming. One state—New Mexico—has rejected the option.

Prior to passage of the Medicaid amendments, the CDC program provided only screening, and women who did not qualify for Medicaid and did not have private health insurance were not guaranteed treatment. Typically, these were the working poor.

The National Breast Cancer Coalition made it a top legislative priority to change the rules, and spent three years shepherding the treatment bill through Congress and the Clinton Administration, and is now activating its grassroots network to conduct the campaigns in the states.

Last year, the NBCC bill cleared Congress and was signed into law by the President Bill Clinton last Oct. 24 (Public Law 106-354). The law gives states the option to expand Medicaid coverage for women who were screened through the CDC program and found to have breast or cervical cancer, including precancerous conditions.

Health Care Financing Administration recently issued a guidance on implementing the law (HCFA Guidance on Implementing PL 106-354) and posted a Web page at http://www.hcfa.gov/medicaid/bccpt/default.htm to provide guidance on the option.

Drug Regulation:

Generic Paclitaxel Approval Withstands Court Challenge

The FDA approval of a generic paclitaxel withstood a court challenge, as a federal judge denied a petition to rescind the agency's action and pull the generic off the market.

Judge Colleen Kollar-Kotelly of the U.S. District Court for the District of Columbia denied a motion by American Bioscience Inc. of Santa Monica, CA, to stop the generic drug maker Baker Norton Pharmaceuticals, a unit of Miami-based IVAX Corp., from marketing its version of paclitaxel.

Claiming that Bristol-Myers Squibb, the sponsor of Taxol, the branded drug, has infringed its patent, ABI sought to protect Bristol's market share—and with it the value of its claim—from being eroded by generics.

ABI sought a temporary restraining order against FDA.

Kollar-Kotelly's denial of the ABI claim on April 19, is the judge's second ruling in the case. An earlier ruling, also a denial, was vacated by the U.S. Court of Appeals last month.

In an opinion dated March 30, the higher court vacated the earlier ruling, stating that FDA failed to provide administrative record pertaining to its decision to disregard the ABI claims and proceed with the approval of the IVAX Abbreviated New Drug Application for paclitaxel.

After FDA satisfied the procedural requirement by filing its administrative record, Kollar-Kotelly denied the ABI motion for a preliminary injunction.

The ruling paves the way for generic competitors to enter the paclitaxel market. Originally, Baker Norton enjoyed a 180-day period of exclusivity as the first generic to file an ANDA.

Baker Norton's first-to-file protection expired on April 20, and the paclitaxel market has opened up for other players.

The judge said the ABI complaint failed to demonstrate that approval of generic paclitaxel would cause irreparable harm to the Santa Monica-based company. Moreover, ABI failed to demonstrate any harm it sustained during the past six months, the time period since the Baker Norton drug first became available, the judge wrote.

"While ABI contends that it will suffer additionally when [Baker Norton's] period of market exclusivity ends, it completely fails to articulate how," the judge wrote. "These allegations do not simply amount to a weak showing of irreparable injury; rather they fail to demonstrate irreparable injury at all."

Obituary:

J. Gale Katterhagen, NCAB's First Community Physician

J. Gale Katterhagen, one of the founders of the Association of Community Cancer Centers and the first community physician appointed to the National Cancer Advisory Board, died April 10 of metastatic renal cell carcinoma at his home in Tacoma, WA. He was 65.

Katterhagen was instrumental in encouraging small community hospitals to develop cancer programs that would incorporate new treatments and become involved in clinical trials. He and a small group of physicians formed ACCC in 1974 to dispel the myth that community physicians were not interested in state-of-the-art cancer care. Katterhagen served as ACCC president from 1976 to 1978.

Katterhagen was a community oncologist in Tacoma, and served as director of oncology for

MultiCare Medical Center from 1971 to 1986, and medical director for Hospice of Tacoma from 1977-86.

In 1974, Katterhagen developed a cancer program at Tacoma General Hospital that served as a prototype for programs around the U.S. Katterhagen was appointed to the NCAB in 1979 after Congress amended the National Cancer Act to include a seat for a community physician on the board.

During the late 1970s, ACCC urged NCI to provide a mechanism for involving community physicians more directly in research. In 1982, NCI began the Community Clinical Oncology Program, which provides funding to support research in community hospitals, working with clinical trials cooperative groups and cancer centers. Katterhagen, as chairman of the NCAB Committee on Cancer Control and Prevention, played a key role in developing the CCOP concept.

"He was one of the first to stress the role of guidelines in upgrading the quality of cancer care, a practice that has regained credibility in the last few years," said Leslie Ford, associate director for clinical research in the NCI Division of Cancer Prevention and one of the NCI officials involved in the development of the CCOP program.

In 1986, Katterhagen left Tacoma to develop cancer programs in hospitals in Springfield, IL; Burbank, CA; and San Francisco. Wherever he worked, he seemed to inspire colleagues with his deep caring for cancer patients, his graciousness and sense of humor.

"Gale fundamentally changed the way cancer patients can be treated in the community, and all cancer patients can thank him for leading that charge," said Marsha Fountain, vice president for health care consulting, The Stichler Group, who worked with him in Springfield. "His favorite statement was 'Keep Slugging!' That probably best dignifies his philosophy."

In April 2000, Katterhagen returned to Tacoma to become medical director of the Regional Cancer Center and Cancer System at MultiCare Health System. He also was medical director of the Cancer Program and Breast Center at Mills-Peninsula Health Services, in San Mateo and Burlingame, CA, part of the Sutter Health network, a system of 25 hospitals and seven medical groups in Northern California. He led the Sutter Health Breast Project.

Katterhagen was treated three times for two cancers. "I now see through a patient's eyes," he said in a press release about his return to MultiCare. "What you want when you have cancer is no mystery: the latest scientific knowledge delivered effectively and with compassion. Easy to say, hard to deliver."

"To deliver, a cancer system must demand excellence and at the same time encourage and reward those who care," he said. "Many cancer programs say they do this, but in truth, it's a rare commodity. Such excellence requires a commitment not only from the medical community, but also from the whole system—administrators, nurses, and others."

In recent years, he became involved in efforts to measure and improve patient outcomes data, including clinical, quality of life, and patient satisfaction measures.

Katterhagen was born in Calgary, Canada. His family moved to Seattle in 1942 and operated a small truck farm. He attended Seattle University and graduated from Creighton University Medical School in 1961.

He is survived by his wife of nearly 40 years, Anne, three daughters, Denise, Chris, and Colette, and four grandsons.

Services were held April 16 at St. Theresa's Catholic Church in Tacoma. A memorial was held at Memorial Medical Center in Springfield, IL, on April 25. Donations in his name may be made to MultiCare Health Foundation, PO Box 5296, Tacoma, WA 98405, designated to either MultiCare Regional Cancer Center or Hospice of Tacoma.

News@Cancer.Gov:

NCI Invites "Extraordinary Opportunities" For Research

NCI has posted a Web site inviting the submission of ideas for "Extraordinary Opportunities for Investment" in cancer research for the next three-year cycle of the Institute's annual plan and budget proposal.

Every three years, NCI seeks suggestions from researchers, clinicians, and others for emerging research investment areas. In 1998, NCI received more than 250 suggestions from grantees, advisory board members, and advocacy groups.

Deadline for submitting ideas is Oct. 15.

Ideas will be reviewed and considered for inclusion in NCI's annual plan and budget proposal, "The Nation's Investment in Cancer Research."

An Extraordinary Opportunity is defined as:

—A broad-based, overarching area of scientific

discovery that holds tremendous promise for creating important new knowledge about cancer and dramatically advancing progress toward reducing the human burden of the disease.

—A scientific frontier—created by past scientific successes and technological breakthroughs—that, if pursued, will provide an invaluable foundation for all avenues of cancer research, and lead to new and better prevention, detection, diagnosis, and treatment strategies.

—An investment that will considerably accelerate the pace of cancer research at all levels and improve the ability to better care for those touched by cancer.

Ideas may be emailed to extraordinary-opportunities@cancer.gov or faxed to 301-435-3876, or mailed to the Office of Science Planning and Assessment, NCI Bldg 31 Room 11A03, Bethesda, MD 20892.

For further information, see http://extraordinary-opportunities.cancer.gov.

* * *

NCI has developed a set of Web design guidelines based on research studies in the field.

The Research-Based Web Design and Usability Guidelines represent several years of effort by NCI to identify Web design-related research and compile a practical set of guidelines.

The guidelines are located at: http://usability.gov/guidelines. They cover content development, fonts, navigation issues, download time, and other topics.

NCI maintains about 130 Web sites across the Institute, managed by more than 50 webmasters. NCI began its Usability.gov site earlier this year.

NCI's Communication Technologies Branch, in the Office of Communication, led the development of the guidelines. The branch was formed last year. As more research becomes available, NCI plans to eventually publish a larger set of about 400 research-based guidelines.

Cancer Advocacy:
Groups Planning Promotion Of Cancer Clinical Trials

The Summit Series on Cancer Clinical Trials, which held four meetings over the past two years to discuss ways to promote patient enrollment in cancer clinical trials has released an update on its activities since its Summit IV held last fall in the Washington, DC, area.

Following are excerpts from the report:

On Jan. 12, the Summit Conveners, representatives of the current convening groups of the Summit Series and a few invited guests met to review the recommendations from Summit IV, to identify the next steps in increasing public awareness of cancer clinical trials, and to begin discussion about the theme and format of Summit V.

Summit IV Recap: The results of several surveys were presented which revealed, and in come cases, confirmed misperceptions among the public, and barriers to participation by physicians. Summit IV focused on increasing public awareness and participation in cancer clinical trials. Attendees discussed specific topics relating to the theme including attitudes towards clinical trials, communication barriers to participation, communication models of success. Several breakout groups provided in-depth discussion of each topic. The result was general agreement that a very visible, ongoing, public awareness campaign must be conducted to educate the general public about clinical research, and to increase adult participation in cancer clinical trials.

Summit IV Mandate: Increasing Clinical Trial Participation Rate from 3 to 5 percent to 10 to 15 percent—Independent Activity Now Underway

Patient advocate groups, cancer research organizations, cooperative groups, medical centers – all are working to improve the care of cancer patients, to increase awareness of cancer clinical trials, and to educate the public and patients about the importance of early detection and screening. Here are a few of the many efforts underway:

—NCI is expanding its Cancer Clinical Trials Education Program to include materials directed to basic, intermediate, and advanced levels of understanding. It will also include a web-based program.

—The Coalition of National Cancer Cooperative Groups is running an eight-page insert in the May 7 issue of Newsweek, and October issue of Fortune, and creating a program for cable TV on cancer clinical trials. The Newsweek insert will contain basic information about clinical trials, what they are, why they are important, questions to ask before participating, information on patient advocate groups and the cooperative groups.

—The National Coalition of Cancer Survivorship is working with General Motors to test and evaluate key messages among their employees. NCCS is developing a marketing program directed to employers who need to be educated about cancer clinical trials

before they buy insurance coverage on behalf of their employees.

—ASCO is sponsoring the National Initiative on Cancer Care Quality, a survey among members of ASCO.

—The National Dialogue on Cancer, led by co-chairs former President George Bush and Barbara Bush and vice-chair Senator Diane Feinstein (D, CA), is dedicated to eradicating cancer as a major public health problem at the earliest possible time. Participants include many prominent patient advocates, oncology professionals and researchers, television personalities and celebrities. One of the dialogue's priority areas of focus is clinical trials.

Campaign Options Discussed

The group discussed various campaign options for increasing clinical trial participation including a national campaign, state-directed, or decentralized campaigns encouraging each organization to manage its own awareness program. The committee finally recommended that a national campaign be developed including development of key messages, securing major media placement, and identifying a national celebrity spokesperson. This national program would be supported on the grass roots level by building on the momentum created by the national program. The national program would also include the development of a "How-To" kit for organizations. This how-to kit would be filled with promotional ideas and resources that each organization can pick and choose from according to its interest and budget.

Fund Raising: Several members of the committee volunteered to serve on a fund raising subcommittee to begin development of a plan to recruit and hire a professional fund raiser and to generate initial gifts to get the effort started. The committee estimated one year to raise funds, hire a fundraiser, and select an advertising firm; one year to develop the materials; and three to five years to conduct the campaign.

The Summit Series on Cancer Clinical Trials will convene for the fifth time this fall. Location and date have not been announced.

Funding Opportunities:

Ethics of Public Health and Prevention Fellowship Program

Application Deadline: Sept. 1, 2001

Appointment Start Date: July 1, 2001

NCI's Cancer Prevention Fellowship Program invites applications for a new program in postdoctoral studies of ethical issues in cancer prevention research and their application in public health practice.

Applicants must have M.D., D.D.S., or D.O. degree or a J.D., Ph.D. or doctoral degree in a related discipline (epidemiology; biostatistics; and the biomedical, nutritional public health, or behavioral sciences). Fellows may obtain Master of Public Health training at an accredited university during the first year of their fellowship, which is followed by mentored research at the NCI, NIH Clinical Center, Department of Clinical Bioethics, the DHHS Office of Research Integrity, and at local universities, including but not limited to: Johns Hopkins University and the Georgetown University Kennedy Institute of Ethics.

Fellows will take the five-week NCI Summer Curriculum in Cancer Prevention. Duration of the appointment will be up to five years. Stipend will be determined by the degree help by the applicant and years of relevant postdoctoral experience.

Inquiries: Douglas Weed, director, Cancer Prevention Fellowship Program, NCI, 6120 Executive Blvd., Suite T-41, MSC 7105, Bethesda, MD, 20892-7105 or Barbara Redding, phone 301-496-8640; fax 301-402-4863; e-mail br24@nih.gov.

Gustaves and Louise Pfeiffer Research Foundation

Letter of Intent: Aug. 15

Application deadline: Sept. 15

The Gustaves and Louise Pfeiffer Research Foundation offers Research Grants-in-Aid, consisting of various awards for up to $50,000 for applied research in cardiovascular diseases, cancer, and immunology.

The current fields of interest of the foundation include: predictive factors in cardiovascular diseases; prostate, breast and ovarian cancer; and gerontological immunology.

A letter of request in advance of the submission of a formal application is required. There is no U.S. citizenship or permanent residence requirement.

Contact: Gustaves and Louise Pfeiffer Research Foundation, 300 State Street Suite 450, P.O. Box 1153, Redlands, CA 92373, phone: 909-845-1198.

RFAs Available

RFA-LM-01-002: Internet Connection for Health-Related Institutions

Letter of Intent Receipt Date: May 25, 2001

Application Receipt Date: June 22, 2001

National Library of Medicine is offering grants to give health professionals and consumers a means of accessing the medical literature provided by NLM and other databases, of transferring files and images, and of interacting by e-mail with others throughout the world. The NLM program was created in recognition that many health-related organizations, particularly smaller ones and those in rural and/or urban health-underserved areas, lack resources to initiate Internet access. The RFA uses the NLM resource grant G08 mechanism. Facilities and administrative costs are not provided. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-LM-01-002.html.

Inquiries: Valerie Florance, Division of Extramural Programs, National Library of Medicine, Rockledge One Bldg., Suite 301, 6705 Rockledge Dr., Bethesda, MD 20892, phone 301-594-4882; fax 301-402-2952; e-mail floranv@mail.nlm.nih.gov

RFA-LM-01-003: Publication Grants for Preparation of Scholarly Documents

Letter of Intent Receipt Date: June 11, 2001

Application Receipt Date: July 11, 2001

National Library of Medicine plans to award small grants for up to three years for the preparation of book-length manuscripts and other scholarly documents of value to U.S. health professionals.

Grants are awarded for historical studies, major critical reviews, state-of-the-art summaries, and other useful organizations of knowledge in the biomedical field. Publication in formats other than print, (e.g. digital or film) is acceptable, as are innovative ways of presenting information. Publication grants do not support journals or other serials and are not suitable for operation of established databases. This RFA will support awards through the NLM publication grant G13 mechanisms. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-LM-01-003.html.

Inquiries: Susan Sparks, Division of Extramural Programs, National Library of Medicine, Rockledge One Bldg. Suite 301, 6705 Rockledge Dr., Bethesda, MD 20892, phone 301-594-4882; fax 301-402-2952; e-mail sparkss@mail.nlm.nih.gov

RFA-HS-01-008: Patient Safety Research Dissemination and Education

Letter of Intent Receipt Date: May 10, 2001

Application Receipt Date: May 24, 2001

Agency for Healthcare Research and Quality announces the availability of four to seven cooperative agreements U18 for professional associations, educational leadership organizations and provider organizations to demonstrate and evaluate innovative approaches to provider education; to disseminate patient safety research results and best practices; and to promote positive safety culture.

AHRQ would support projects that can be replicated on a larger scale; AHRQ is interested in programs that make maximum use of active learning through the use of simulation, team training, and web-based instruction as well as traditional educational approaches to disseminate, implement, and evaluate provider education to improve patient safety. The RFA is the last in a series of patient safety research solicitations issued by AHRQ in FY01. The administrative and funding instrument will be a cooperative agreement U18, an assistance mechanism.

The RFA is available at the AHRQ Web site http://www.AHRQ.gov and by fax to 301-594-2800.

Inquiries: Francis Chesley, Office of Research Review, Education, and Policy, Agency for Healthcare Research and Quality, 2101 East Jefferson St, Suite 400 W, Rockville, MD 20852, phone 301-594-6410; fax 301-594-0154; e-mail training@ahrq.gov

Other NIH Funding Notices

NOT-AI-01-021: Inter-Institute Program for the Development of AIDS-Related Therapeutics

Letter of Intent: May 1, 2001

Application Receipt Date: June 1, 2001

National Institute of Allergy and Infectious Diseases and NCI invite proposals to a drug development program to help AIDS research investigators facilitate the preclinical development of: 1) therapies for the treatment of HIV disease, AIDS-associated malignancies, opportunistic infections and tuberculosis associated with AIDS, and 2) microbicide-based prevention strategies for HIV. The program does not fund grants. Instead, applications to the program are requests to NIAID and NCI to use their drug development resources to conduct specific tasks the applicants themselves are unable to carry out in their efforts to translate basic research findings to applied or clinical practice. Examples of tasks that may be requested include high throughput screen assay development, evaluation in animal efficacy models, good manufacturing practice scale-up synthesis of small molecules and biologics, clinical dosage formulation and manufacturing, and good laboratory practice toxicology. Information is available at the program Web site http://dtp.nci.nih.gov/docs/dart.html. The notice is available at http://grants.nih.gov/grants/guide/notice-files/NOT-AI-01-021.html.

Inquiries: Inter-Institute program coordinator, 6130 Executive Blvd, Suite 8000, Rockville, MD 20852, phone 301-496-8720; fax 301-402-0831; e-mail iip@dtpax2.ncifcrf.gov

NCI Policy on Small Research Grants R03

Acceptance of the grants will be considered only in response to an NCI announcement specifically inviting such applications. Four PAs inviting small research grant R03 applications are ongoing annually:

—PA-01-021, Small Grants Program for Cancer Epidemiology: http://grants.nih.gov/grants/guide/pa-files/PA-01-021.html

—PAR-00-025, Cancer Prevention Research Small Grant Program: http://grants.nih.gov/grants/guide/pa-files/PAR-00-025.html

—PAS-00-121, Small Grants for Geographic-Based Research in Cancer

Control and Epidemiology: http://grants.nih.gov/grants/guide/pa-files/PAS-00-121.html

—PAR-99-006, Small Grants Program for Behavioral Research in Cancer Control: http://grants.nih.gov/grants/guide/pa-files/PAR-99-006.html

The notice is available at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-01-012.html.

Inquiries: referral officer, Program Coordination & Referral Branch, Division of Extramural Activities, NCI, 6116 Executive Blvd., MSC 8326, Bethesda, MD 20892-8326, phone 301-496-3428; e-mail ncirefof@dea.nci.nih.gov

In Brief:

DeMets Receives Lectureship On Epidemiology From NIH

(Continued from page 1)

Award winner, was associate chairman of radiology, professor of radiology, neurosurgery and neurology, and chief of neuroradiology at the University of Pennsylvania School of Medicine. . . . **DAVID DEMETS** of the University of Wisconsin Comprehensive Cancer Center received the Robert S. Gordon, Jr. Lectureship for contributions to research in the field of epidemiology or clinical trials. The lectureship is awarded by NIH on the advice of the Office of Disease Prevention in the Office of the Director and the recommendation of the Epidemiology & Clinical Trials Interest Group advisory committee of epidemiologists. . . . **ANN PAULEN** of the of the University of Wisconsin Comprehensive Cancer Center/University of Wisconsin Hospital and Clinics is retiring after 32 years as oncology nurse. Paulen, one of only a handful of oncology nurses in 1969 when she began her career, is a founding member of the Oncology Nursing Society has been involved nationally in developing the specialty of oncology nursing. . . . **WARREN ALPERT FOUNDATION,** associated with Harvard Medical School, has awarded researchers whose discoveries at the basic science, pre-clinical or clinical levels collectively gave rise to Glivec, a once-a-day pill formerly known as STI-571 for chronic myelogenous leukemia. The pill is being developed by Novartis Pharmaceuticals Corp. The five awardees are: **Owen Witte**, an investigator in the Howard Hughes Medical Institute, a scientist at the Jonsson Cancer Center and a professor of microbiology, immunology & molecular genetics at the UCLA School of Medicine; **David Baltimore**, president of the California Institute of Technology in Pasadena and professor of biology; **Nicholas Lydon**, vice president for small molecule drug discovery at Amgen, Inc., in Thousand Oaks, CA; **Alex Matter**, head of oncology research at Novartis Pharma AG; and **Brian Druker**, professor of medicine at Oregon Health Sciences University. Witte and Baltimore pioneered the research linking the mutant gene Bcr-Abl, to CML. The findings have served as a basis for the evolution of Glivec, a signal transduction inhibitor which targets the Bcr-Abl protein. A $150,000 honorarium will be divided among the recipients. . . . **PETER DOLAN** was appointed CEO of Bristol-Myers Squibb. A 13-year veteran of the company, he retains his title of president and remains a member of the board of directors. As CEO, Dolan will implement the plan to double sales, earnings and earnings-per-share by 2005 through a greater focus on the BMS medicines business, external development and an accelerated pipeline of new products, among other measures. Dolan is an overseer for Tufts Medical School, a member of the American Cancer Society CEO Advisory Board and a member of the Steering Committee of the National Dialogue on Cancer. He succeeds **Charles Heimbold**, who was named U.S. ambassador to Sweden by President Bush. Heimbold will remain chairman of the board until his retirement. . . . **UNIVERSITY OF CALIFORNIA,** San Francisco, Department of Neurological Surgery established the Michael Douglas Pediatric Brain Tumor Research Center. A benefit, attended by the actor and his family, raised $1.3 million for research. **Mitchel Berger** is the director of the Brain Tumor Research Center at UCSF. . . . **SUBSCRIBE ONLINE** to The Cancer Letter Interactive edition. Visit http://www.cancerletter.com.

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Business & Regulatory Report

Product Approvals & Applications:

FDA Approves Xeloda For Colon Cancer; Phase III Data Not Reviewed By ODAC

Hoffmann-La Roche Inc. of Nutley, NJ, said FDA has approved Xeloda (capecitabine) for metastatic colorectal cancer.

Xeloda is indicated as first-line treatment of patients with metastatic colorectal cancer when treatment with fluoropyrimidine therapy alone is preferred. Combination chemotherapy has shown a survival benefit compared to 5-FU/LV alone, the company said. A survival benefit has not been demonstrated with Xeloda monotherapy, as with the combination chemotherapy.

Use of Xeloda instead of 5-FU/LV combinations has not been

(Continued to page 2)

Oncology Management:

M.D. Anderson Buys Record System For In-Patient Services From Atlanta Firm

Per-Se Technologies Inc. (Nasdaq: PSTI) of Atlanta said M. D. Anderson Cancer Center has purchased its Patient1 computer-based patient record system for in-patient services.

The system will be used at the 400-bed center to manage complex chemotherapy regimens through computerized order entry, reduce clinician dependency on paper charts, and improve operational efficiency via embedded rules and workflow.

"Purchasing a computer-based patient record system is essential for our success and future growth," said Rich Pollack, vice president and chief information officer, ad interim, at M. D. Anderson. "By providing an integrated data repository, full clinical decision support can be implemented at the point of order entry. Per-Se's Patient1 application will assist the organization in further achieving its mission of eliminating cancer in Texas, the nation and the world."

The system that operates on a single database.

"In addition to its proven track record of handling huge volumes of transactions, the CPR's architecture employs a high availability redundant configuration, meaning the chances of unplanned downtime are nearly eliminated," Pollack said.

Initially, the cancer center will use Patient1 to create customized screens of stored 25 years of laboratory and pathology results. Later, the

(Continued to page 8)

PO Box 9905
Washington DC 20016
Telephone 202-362-1809

FDA Approves Xeloda For Metastatic Colon Cancer

(Continued from page 1)

adequately studied to assure safety or preservation of the survival advantage, the company said. The drug was never reviewed by the agency's Oncologic Drugs Advisory Committee.

The FDA decision was based on the results of two multinational phase III clinical trials in metastatic colorectal cancer that demonstrate that Xeloda shrinks tumors better than a standard of care intravenous 5-FU and leucovorin. Xeloda requires two daily oral doses.

Xeloda is the first approved oral drug that works through enzymatic activation of 5-FU. The human body produces the enzyme thymidine phosphorylase, which converts Xeloda into 5-FU, the company said.

The drug was approved on the basis of two multinational clinical trials that included 1,200 patients and were conducted globally at 120 hospitals and cancer centers.

Approximately half the patients in the study received Xeloda at 1,250 mg/m(2) twice daily given for two weeks followed by a one-week rest period.

The other half received treatment with intravenous 5-FU and leucovorin (the Mayo Regimen). In both studies, time to disease progression and survival were similar to the Mayo Regimen. In one of the trials, the overall response rate for Xeloda was almost double that of the Mayo Regimen (21 percent vs. 11 percent); in the other study, the overall response rate for Xeloda was 30 percent higher than intravenous 5-FU + LV (21 percent vs. 14 percent), the company said.

Median time to disease progression was 137 days with Xeloda and 131 days with 5-FU/LV in one study (hazard ratio 0.97) and 128 days with Xeloda and 131 days with 5-FU/LV in the other study (hazard ratio 0.99), the company said.

Median survival was 404 days for Xeloda and 369 days for 5-FU/LV in one study (hazard ratio 0.92) and 380 days for Xeloda and 407 days for 5-FU/LV in the other study (hazard ratio 1.00).

Xeloda is indicated as first-line treatment of patients with metastatic colorectal cancer when treatment with fluoropyrimidine therapy alone is preferred.

Combination chemotherapy has shown a survival benefit compared to 5-FU/LV alone.

A survival benefit has not been demonstrated with Xeloda monotherapy as with the combination chemotherapy. Use of Xeloda instead of 5-FU/LV combinations has not been adequately studied to assure safety or preservation of the survival advantage.

* * *

AstraZeneca (NYSE:AZN) of Wilmington said it has submitted a new drug application, requesting priority review of Faslodex (fulvestrant) for locally advanced or metastatic breast cancer in postmenopausal women who have progressed following hormonal therapy.

Faslodex, an estrogen receptor downregulator, represents a new way to attack cancer cells resistant to hormonal treatments by targeting and degrading the estrogen receptor, the company said.

The FDA submission was based two phase III trials which compared Faslodex to Arimidex (anastrozole), the most widely prescribed aromatase inhibitor, in measures of time to progression and response rate, the company said.

In both the North American and the European trial, the time to progression and objective response rate were similar for Faslodex and Arimidex, the company said.

In the North American trial the median duration of response was nearly 9 months longer with Faslodex than with Arimidex (588 days vs. 320 days). In the

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European trial, the duration of response for Faslodex and Arimidex were similar.

Faslodex is administered as a monthly intramuscular injection, the company said. Commonly reported adverse experiences with Faslodex were hot flashes, nausea, injection site reactions/pain, asthenia and headache.

"Sequential treatment of advanced breast cancer with different hormonal therapies is significantly improving the way advanced breast cancer is treated," said Gerard Kennealey, vice president of medical oncology for AstraZeneca. "If approved, Faslodex will offer an additional treatment option that works differently than currently available therapy."

AstraZeneca said it is evaluating Faslodex in a head-to-head trial with tamoxifen for first line advanced breast cancer.

* * *

Atrix Laboratories Inc. (Nasdaq: ATRX) of Fort Collins, CO, said it has submitted a new drug application for one-month Leuprogel, 7.5 mg leuprolide acetate for subcutaneous depot injection in advanced prostate cancer.

The Leuprogel prostate cancer products are being developed by Atrix and will be marketed in North America by **Sanofi-Synthelabo**, the company said. Atrix will receive milestone payments in addition to royalties on sales and will manufacture the products at its facility in Fort Collins, CO.

The formulations are based on the Atrix proprietary Atrigel drug delivery system, the company said. Leuprogel is injected into the body subcutaneously, as a liquid, where it solidifies and releases a predetermined dose of leuprolide acetate continuously for 1-, 3- or 4-months as the implant bioabsorbs, the company said.

Sustained levels of leuprolide, a luteinizing hormone-releasing hormone agonist, decrease testosterone to suppress tumor growth in hormone-responsive prostate cancer.

* * *

Avax Technologies Inc. (Nasdaq: AVXT) of Kansas City, MO, said that FDA has placed clinical activities for its M-Vax and O-Vax autologous cancer vaccines on clinical hold pending further review.

The company said it believes the interaction is a result of evolving agency requirements for cell-derived products as they progress toward licensure.

"While we are disappointed that FDA has taken this unexpected action, we believe that it has no long-term impact on our future prospects," said David Tousley, chief operating officer of Avax Technologies.

"We have employed the highest standards when handling tumor cells and have continued to meet and/or exceed all of the FDA requirements," said Tousley. "The sterility issue involves an extremely limited number of tumors received by the company. Based on the information currently available to us, we believe that this is a short-term situation, which can only be characterized as temporary."

* * *

Cell Therapeutics Inc. (Nasdaq: CTIC) of Seattle said the European Commission has granted orphan medicinal product designation to Trisenox (arsenic trioxide) injection for multiple myeloma and myelodysplastic syndromes.

"Orphan designation for medicinal products in Europe provides up to 10 years of market exclusivity," said James Bianco, president and CEO of CTI.

Orphan designation for Trisenox for multiple myeloma was granted to Cell Therapeutics Ltd., of the UK, and is granted for treatments that may offer significant benefit in serious or life threatening diseases that occur in not more than 200,000 patients.

In February, EMEA validated the marketing authorization application submitted for Trisenox for acute promyelocytic leukemia, the company said.

* * *

Millennium & Ilex Partners, L.P., a joint venture of **Millennium Pharmaceuticals Inc**. (Nasdaq:MLNM) of Cambridge, MA and **Ilex Oncology Inc**. (Nasdaq:ILXO) of San Antonio, along with **Schering AG** (NYSE:SHR) of Germany, said the European Medicines Evaluation Agency Committee on Proprietary Medicinal Products has recommended approval under exceptional circumstances of the MabCampath investigational humanized monoclonal antibody for chronic lymphocytic leukemia after treatment with alkylating agents and failed fludarabine therapy.

Approval under exceptional circumstances requires a phase III confirmatory safety and efficacy study of MabCampath versus chlorambucil, the standard frontline treatment, the company said.

The post-approval trial is already planned to begin later this year. Under the marketing authorization, expected in July, M&I Partners would be granted a single license for marketing MabCampath in the 15 member states of the E.U, and would receive national licenses in two additional countries, Iceland

and Norway, the company said.

"MabCampath is one step closer to providing an option that may help patients with CLL enjoy their lives for a longer period," said Michael Keating, principle investigator and deputy chairman of the Department of Leukemia, M.D. Anderson Cancer Center.

The Marketing Authorization Application for MabCampath was submitted to the EMEA in March 2000 and accepted for review in April 2000.

In the U.S., the drug is under review by FDA, would be marketed by **Berlex Laboratories Inc**., the U.S. affiliate of Schering AG, Germany.

* * *

SkyePharma PLC (Nasdaq: SKYE; LSE: SKP) of London said the European Committee on Proprietary Medicinal Products has recommended granting market authorization to DepoCyte, cytarabine liposome injection, for lymphomatous meningitis.

Once the European Commission ratifies the recommendation, SkyePharma said it would receive a single license for marketing throughout the E.U, making it the only intrathecal treatment for lymphomatous meningitis approved by the CPMP centralized approval procedure.

"We have substantial interest from potential European marketing partners and physicians for DepoCyte and hope to be able to announce a licensee in the near future," said Michael Ashton, CEO of SkyePharma. "We are continuing to make progress on the introduction of DepoCyte in Japan and other parts of the world."

DepoCyte gradually releases cytarabine into the cerebral spinal fluid and extends the dosing interval to once every two weeks as compared to the standard intrathecal chemotherapy dosing of two times per week, the company said.

DepoCyte is approved for marketing in the U.S. and Canada under the trademark DepoCyt. Chiron Corp. holds the marketing rights for DepoCyt in the U.S. and Paladin Labs Inc. in Canada.

Clinical Trials:

Genetronics Phase II Trials For Head & Neck Completed

Genetronics Biomedical Ltd. (Amex: GEB; Toronto) of San Diego said it has completed phase II data review for three trials for squamous cell cancer of the head and neck.

In one controlled study of electroporation therapy and bleomycin, the tumors were first treated with intratumoral bleomycin alone, the company said. The tumors treated with bleomycin alone were largely unresponsive. Of 37 treated tumors in 25 patients only 1 tumor (3 percent) showed a partial (>/= 50 percent shrinkage) response.

Subsequently, 20 tumors in 17 of these patients were treated with EPT and bleomycin. Six tumors (30 percent) demonstrated complete responses and 5 tumors (25 percent) showed at least a 50 percent reduction in size. The total objective response rate in these 20 tumors was 55 percent.

The response rates in the other two trials were similar, the company said. In the second trial 25 patients with 31 tumors were treated with EPT and bleomycin upon initial presentation.

There were 6 tumors (19 percent) that demonstrated complete response and 12 tumors (39 percent) had a partial response. The overall objective response rate was 18 of the 31 tumors (58 percent).

In the third trial, 12 patients had 18 tumors treated. Complete responses occurred in 5 of 18 tumors (28 percent) and partial response occurred in 5 of 18 tumors (28 percent) for an overall response rate of 56 percent.

"Given these positive results in the treatment of head and neck tumors and our successful ongoing work in gene therapy, we have organized our staff to further focus our energy and resources in the areas of oncology and gene therapy," said Martin Nash, CEO of Genetronics Biomedical.

* * *

GlycoDesign Inc. (TSE:GD) of Toronto said it plans to start five phase II trials of GD0039 for multiple cancer indications in the U.S. and Europe later this year.

GD0039 is an orally administered anti-cancer drug whose mechanism of action blocks the production of specific carbohydrates important for cancer metastasis, the company said. The drug stimulates the immune system and offers effectiveness with fewer side effects.

The expanded clinical program for GD0039 includes five phase II trials in four different cancer indications: two trials for metastatic renal cancer, conducted at the Institut Gustave Roussy, Paris, and at the Cleveland Clinic.

* * *

MGI Pharma Inc. (Nasdaq: MOGN) of Minneapolis said it has initiated an additional phase II trial of irofulven using an intermittent dosing schedule to treat hormone-refractory prostate cancer.

The randomized, multi-center trial conducted in Europe will evaluate the anti-tumor activity, safety, and clinical benefit of the compound as a single agent and in combination with prednisone, with up to 54 patients treated on an every-other-week dosing schedule, the company said.

Decrease in prostate-specific antigen is the primary endpoint, along with objective tumor response.

Time to disease progression, duration of response, overall survival and clinical benefit will also be assessed, the company said.

In the prior phase II trial where irofulven was dosed daily for five days every 28 days, all 32 patients who were evaluable for PSA response had stable or decreasing PSA levels and four had partial PSA responses (defined as a decrease of at least 50 percent for at least one month), the company said. One of the nine patients who had measurable disease had an objective partial response.

Improved tolerance and an ability to deliver more drug over multiple courses of treatment has been observed in an ongoing dose-optimization trial using an every-other-week dosing schedule, which will be assessed in this new trial, the company said.

Irofulven, also known as MGI 114, hydroxymethylacylfulvene, or HMAF, has demonstrated promising anti-tumor activity as a single agent in clinical testing against pancreatic, ovarian and prostate cancers, the company said.

* * *

North American Scientific Inc. (Nasdaq:NASI) of Chatsworth, CA, said its subsidiary, **Theseus Imaging Corp**., has begun a phase II study of Apomate, an imaging agent for the detection of early response to treatment for breast cancer, lung cancer and lymphoma.

In phase I studies, the agent provided an early indication of response to treatment by localizing in areas of cell death, the company said.

"Apomate imaging will provide evidence of response to anti-cancer treatment in hours, rather than weeks," said Allan Green, president of Theseus.

The phase I studies demonstrated that uptake of the imaging agent in treated tumors, suggesting tumor cell death, was correlated with good response to treatment. Just as important is the absence of Apomate uptake soon after treatment, which may suggest lack of efficacy and may provide physicians with an earlier opportunity to offer alternative, more effective anti-cancer treatment before the tumor increases in size and before patients suffer additional toxicity from ineffective treatment."

* * *

Peregrine Pharmaceuticals Inc. (Nasdaq:PPHM) of Tustin, CA, said it has initiated a phase I study of Cotara, intravenous 131I-chTNT-1/B, for advanced soft tissue sarcoma at Stanford University.

Susan Knox, associate professor of radiation oncology at Stanford, will be the principal investigator, the company said.

Cotara, a tumor necrosis therapy, is a radiolabeled monoclonal antibody that binds to the necrotic core of tumors and uses beta-radiation to kill the tumors from the inside out, the company said.

The technology is part of a multi-center phase II study for brain cancer and a phase I study colorectal cancer at Stanford University, the company said.

* * *

Receptron Inc, a privately held biopharmaceutical company of Mountain View, CA, said it has begun a phase I trial of RCN-01303 to prevent platelet deficiency.

The study is conducted at the Greenebaum Cancer Center at the University of Maryland in Baltimore, the company said.

The compound acts by a mechanism, which modulates the endogenous thrombopoietin receptor, the company said.

* * *

SuperGen Inc. (Nasdaq: SUPG & SUPGZ) of Dublin, CA, said it has begun an open-label, randomized phase III study of decitabine, an anticancer compound for advanced myelodysplastic syndrome.

The study, which will be conducted at 15 U.S. medical centers, will enroll 160 patients, 80 of whom will receive decitabine and 80 of whom will receive standard of care therapy.

In a phase II study of the compound evaluated for efficacy, the observed overall response rate was 49 percent, with a 64 percent response rate in high-risk patients as defined by the International Prognostic Scoring System, the company said.

The results confirmed a previous observation

that decitabine therapy was effective in half of the patients studied with high-risk MDS, especially patients with the worse prognosis.

The decitabine mechanism of action occurs through the mediation of gene expression, which in turn potentiates the effect of alpha interferon in multiple myeloma, the company said. These data support the clinical use of low-dose decitabine as a gene therapeutic induction agent in addition to its role as a traditional cytotoxic agent.

* * *

Titan Pharmaceuticals Inc. (Amex: TTP) of South San Francisco said it has initiated randomized, controlled, multi-center phase II testing of gallium maltolate for metastatic prostate cancer and refractory multiple myeloma.

The study would evaluate three dose levels of gallium maltolate administered in 28-day cycles in an outpatient setting. Study endpoints include safety, and clinical and radiographic evidence of tumor response, the company said.

Donald Northfelt, assistant clinical professor of medicine at UC-San Diego, and medical oncologist at Eisenhower Medical Center in Rancho Mirage, CA, is principal investigator.

Gallium maltolate is an orally active formulation of gallium, a semi-metallic element that that inhibits ribonucleotide reductase, an enzyme that promotes tumor growth, the company said. The formulation concentrates in malignant tumors and sites of infection, and favorably impacts calcium deposition, making bones more resistant to degradation from cancer metastasis.

In phase I studies, the therapy had a very good safety profile, attaining targeted serum drug levels, and pharmacokinetics that support twice a day or once a day dosing, the company said.

In 1991, intravenously administered gallium nitrate was approved in the U.S. for hypercalcemia of malignancy, the company said.

In published clinical studies, intravenously administered gallium nitrate demonstrated preliminary evidence of anti-tumor activity in several cancer indications, including multiple myeloma, lymphoma and bladder cancer.

* * *

In another development, Titan said it has begun a phase II study of combination therapy with its monoclonal antibodies, CeaVac and TriAb, for non-small cell lung cancer.

The multi-center trial is funded by NCI and conducted by the Radiation Therapy Oncology Group, the company said.

The study, under the direction of Benjamin Movsas at Fox Chase Cancer Center, would assess the safety and preliminary efficacy of CeaVac and TriAb in combination with radiation therapy in stage IIB and stage IIIA non-small cell lung cancer, the company said.

CeaVac mimics the carcinoembryonic antigen present in a number of tumor types, including non-small cell lung cancer, colorectal cancer, pancreatic cancer and gastric cancer, the company said.TriAb mimics the human milk fat globule antigen present in high density on tumor types, including non-small cell lung cancer.

Titan also has initiated a phase I/II study of Pivanex for liver tumors.

The 25 patient study, under the direction of Tony Reid of Stanford University Medical Center at the Palo Alto Veteran's Affairs Medical Center, would assess the safety and preliminary efficacy of Pivanex in either metastatic or primary hepatic tumors, the company said.

The endpoints of the study are safety, tumor response and survival.

Pivanex, an analog of butyric acid, is a small molecule drug that attacks cancer cells through the mechanism of cellular differentiation, the company said.

Unlike traditional cancer therapies, the treatment induces changes in gene expression in cancer cells, causing them to undergo apoptosis, while sparing normal healthy cells, the company said.

Administration of Pivanex via hepatic arterial infusion is an improvement over existing treatment options by allowing a maximum dosage of the drug to be delivered to the tumor site reducing systemic toxicity, the company said.

Deals & Collaborations:

Biomira Ends Agreement On Lymphoma Vaccine

Biomira Inc. (Nasdaq: BIOM) (TSE:BRA) of Edmonton, Alberta, said it has terminated its agreement with **Biovector Therapeutics SA** of Toulouse, France, for the co-development of the Biomira idiotypic vaccine against B-cell lymphoma

and plans to pursue the autologous vaccine program independently.

The vaccine, which contains a patient-specific tumor antigen obtained from the cancer cells of the patient, is combined with IL-2 and encapsulated in a liposome for more effective delivery, the company said.

"Biomira has regulatory clearance to move the autologous vaccine product candidate into a further phase Ib trial in 2001," said Alex McPherson, president and CEO of Biomira.

The program is being conducted through the Biomira wholly owned subsidiary, Biomira USA of Cranbury, NJ in collaboration with NCI and other cancer centers in New Jersey, the company said.

* * *

DuPont Pharmaceuticals Co., of Wilmington, DE, a subsidiary of Dupont (NYSE: DD) said it would license its Cre-lox technology that deciphers gene function to **Bristol-Myers Squibb Co.**, **Novartis Pharma AG** and **Pharmacia Corp.**

The Cre-lox technology involves site-specific recombination of DNA using Cre recombinase and lox DNA sites, the company said. Cre-lox site-directed recombination has shown great utility in developing transgenic mouse models where specific genes can be deleted at specific times and in specific tissues, the company said.

With the announced agreements, nine of the top ten major pharmaceutical companies are current commercial research licensees of the DuPont technology, including Merck & Co., Pfizer Inc., and GlaxoSmithKline, the company said.

More than 250 academic centers have received a license from DuPont Pharmaceuticals granting free use of the technology, the company said.

The Cre-lox technology is made available to the NIH and the Jackson Laboratories for academic research.

* * *

Ingenico S.A. (Paris Bourse: 12534-ING) of Puteaux Cedex, France and **IVI Checkmate Corp.** (NASDAQ: CMIV) of Atlanta said they have entered into a merger agreement in which Ingenico would acquire IVI.

The acquisition is valued at $55.3 million or $3.30 per share, the companies said.

The acquisition will strengthen the position of Igenico as a provider of products and systems in the field of secured transaction technologies and serves as a platform to expand its operations in North America, the company said.

Simultaneously with the execution of the merger agreement, Ingenico made a direct investment in IVI Checkmate by purchasing 2.6 million shares of its newly issued common stock for an aggregate purchase price of $5.177 million, the company said.

The merger is expected to close during the third quarter of 2001, the company said.

* * *

MGI Pharma Inc. (Nasdaq: MOGN) of Minneapolis said it is promoting Hexalen capsules (altretamine) and Mylocel ablest (hydroxyurea) in the U.S. oncology market.

The company said it purchased the exclusive worldwide rights to Hexalen capsules, a second-line therapy for persistent and recurrent ovarian cancer, from **MedImmune Inc.** last November.

Barr Laboratories selected MGI Pharma to be the exclusive marketer of Mylocel tablets, a hydroxyurea tablet for treating certain malignancies, in January, the company said.

Hexalen capsules are an orally administered chemotherapeutic agent approved in the U.S. for ovarian cancer in patients with persistent or recurrent disease following first-line therapy with cisplatin and/or alkylating agent-based combination chemotherapy, the company said.

Without active promotion, Hexalen Capsules previously produced approximately $2 million in annual sales.

Physicians who treat ovarian cancer and prescribe the product primarily include gynecological and medical oncologists, the company said.

Mylocel tablets are an antineoplastic agent for melanoma, resistant chronic myelocytic leukemia, and recurrent, metastatic, or inoperable carcinoma of the ovary, the company said.

It is also indicated for use in combination with radiation therapy for certain head and neck cancers. The U.S. market for all forms of hydroxyurea totals approximately $20 million annually.

Recently approved by the FDA, Mylocel tablets are the only triple-scored, 1000-mg. hydroxyurea tablet available, which offers simplified dosing in 250 mg. increments and the possibility of once-daily dosing with a single tablet.

Physicians who prescribe the product primarily include medical oncologists and hematologists, the company said.

Oncology Management:

Firm Provides Web System For CareFirst Of Baltimore

(Continued from page 1)

system will be used to combine clinical data from other multiple departments such as radiology, pharmacy and nursing. The system can be used to present patient-centric data from a comprehensive, longitudinal record in clinician-specific views.

* * *

Quality Oncology said it will provide a Web-based system for managing cancer care for **CareFirst BlueCross BlueShield** of Baltimore.

The program is expected to serve 1,000 CareFirst patients in the first year, the company said. Participation is voluntary, confidential and provided at no additional cost to patients.

CareFirst members will be assigned to a Quality Oncology nurse who monitors their progress in conjunction with the treating physician's care plan. Quality Oncology nurses are available 24 hours a day to provide information about chemotherapy and radiation therapy, pain management, and other concerns and arrange for pharmacy benefits, home health, hospice, and other services provided under their health benefit plan and available in the community, the company said.

Quality Oncology is a subsidiary of **LifeMetrix.**

* * *

e-MedSoft.com (AMEX:MED), a health care portal solutions application service provider of Jacksonville Beach, FL, said it has agreed to provide the technology for Web-based oncology clinical trials management to the Texas-based **Oncology Study Group**, an independent, physician-run cancer research organization.

IOSG is comprised of over 170 oncologists from 85 institutions located in 22 countries, the company said.

Under the agreement, e-MedSoft would develop a customized, interactive portal utilizing its clinical trials software platform, MedTrials, through which clinical trial data will be securely and electronically captured from the IOSG clinics to a central information repository accessible to investigators, monitors, sponsors and administrators, the company said.

* * *

Endocare Inc. (Nasdaq: ENDO) of Irvine, CA, said the Health Care Financing Administration has published new reimbursement codes for transitional pass-through payment for outpatient prostate cancer cryoablation.

"This eliminates economic obstacles for patients and hospitals who wish to take advantage of this important treatment option on an outpatient basis," said Paul Mikus, chairman and CEO of Endocare.

Targeted cryoablation combines cryosurgery with ultrasound and temperature monitoring, enabling physicians to visualize the freezing process and thereby improve safety and efficacy, the company said.

* * *

A survey by **Pharmaceutical Research and Manufacturers of America** indicates that research projects have doubled in six years with 402 cancer medicines in development as alternatives to standard radiation and chemotherapy treatments.

Altogether, 170 pharmaceutical and biotechnology companies and NCI are conducting the research, with 93 of the 402 medicines in development by NCI either in conjunction with companies or by itself, the survey said.

The medicines include: 68 for lung cancer, 59 for breast cancer, 55 for colon cancer, 52 for skin cancers including melanoma and 52 for prostate cancer, PhRMA said. Of these, 17 have already completed 12 to 15 years of testing and are either waiting for or currently in review by FDA.

The full survey can be found at the PhRMA Web site: http://www.phrma.org/cancer.

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Response Oncology Inc. (OTC Bulletin Board: ROIX) of Memphis, TN, said its wholly owned subsidiaries, Response Oncology Management of South Florida Inc., Response Oncology of Fort Lauderdale Inc. and Response Oncology of Tamarac Inc., filed voluntary petitions for relief under Chapter 11 of the U.S. Bankruptcy Code in the U.S. Bankruptcy Court for the Western District of Tennessee.

Patients, affiliated physicians and customers will continue to receive services while a plan is being developed to reorganize its capital structure and strengthen its financial condition, the company said.

For the year ended Dec. 31, the company lost $14.4 million ($1.17 per share) on revenues of $130.8 million. In 1999, the company lost $1.7 million ($0.14 per share) on revenues of $135.6 million.

Last year, the company experienced a 50 percent decline in net patient service revenue for high dose chemotherapy, and a 62 percent decline in clinical research revenue.

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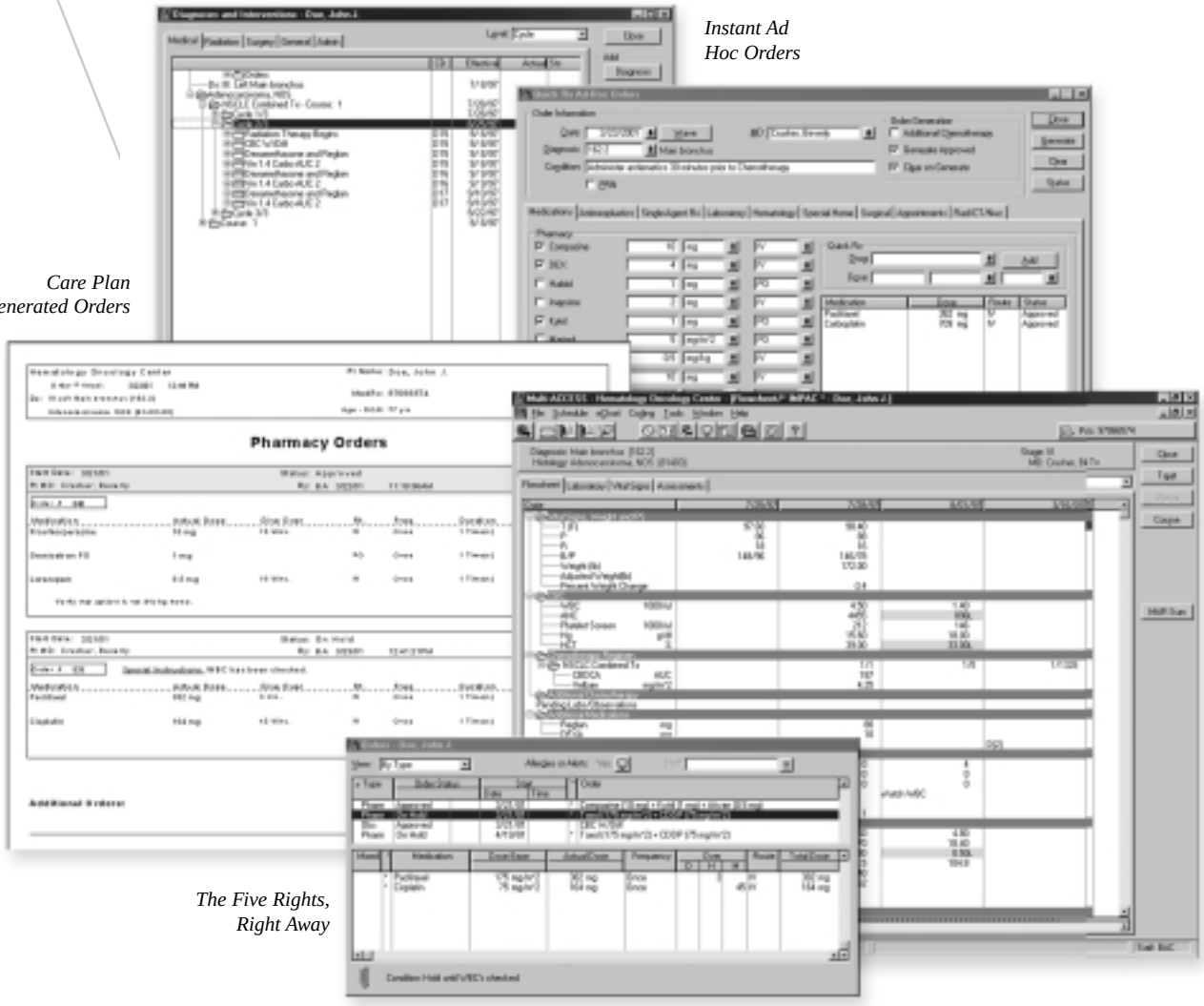

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