THE CANCER LETTER INTERACTIVE

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

Bill To Rebalance Chemo Drug Payments, Physician Services, Introduced In House

A bill introduced in the House earlier this week would reform Medicare reimbursement policies that overpay for cancer chemotherapy drugs and underpay for physician services, cancer organizations said.

The Quality Cancer Care Preservation Act (H.R. 1622), introduced by Reps. Charles Norwood (R-GA) and Lois Capps (D-CA), is supported by the Cancer Leadership Council, a group of 29 cancer patient advocacy

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In Brief:

UNC Lineberger Center Recruits GI Expert Richard Goldberg From Mayo Cancer Center

RICHARD GOLDBERG, of the Mayo Cancer Center, will move to the UNC Lineberger Comprehensive Cancer Center. Goldberg was appointed associate director for clinical research, chief of the Division of Hematology and Oncology, Department of Medicine, and director of oncology services for the University of North Carolina Health System. Goldberg, an internationally renowned clinical researcher in the gastrointestinal malignancies, was professor of medicine and chief of the Mayo Cancer Center Gastrointestinal Research Program. "The recruitment of such a distinguished clinician and clinical researcher completes our leadership team at a time when the melding of fundamental, preventive, and clinical sciences hold such promise for our patients," said **Shelton Earp**, Lineberger director. "Richard brings superb clinical research experience and skills that complement perfectly our center's strengths." . . . **JOHN LAZO**, professor and chairman, Department of Pharmacology, University of Pittsburgh School of Medicine, has been selected as the next chairman of the American Cancer Society Extramural Grants Council. Lazo, co-director of the molecular therapeutics/drug discovery program at the University of Pittsburgh Cancer Institute, will assume his role at ACS in April 2003. As chairman of the EGC, Lazo will lead a multidisciplinary panel of midlevel and senior scientists to determine ACS funding for investigator-led projects at cancer centers across the country, as well as training grants in selected health professions. . . . **DANA-FARBER CANCER INSTITUTE** and the **National Foundation for Cancer Research** have established the NFCR Center for Therapeutic Antibody Engineering. The center, which will be located at Dana Farber,

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House Bill Seeks Balance In Chemo, Services Payments

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organizations, professional societies, and research organizations.

"The current system is clearly broke, and needs to be fixed," said Paul Bunn Jr., president of the American Society of Clinical Oncology and director of the University of Colorado Cancer Center. "Congressionally-mandated Medicare reform that properly reimburses both cancer drugs and cancer care services is ultimately the best solution to fixing the current system."

Medicare reimburses chemotherapy drugs at rates higher than their actual cost to oncology practices, but the overpayment has compensated for under-reimbursement for essential patient services, including costs of nurses to administer chemotherapy, patient and family counseling, and specialized equipment, ASCO said.

"More than 80 percent of chemotherapy treatment is conveniently provided on an outpatient basis, either in a doctor's office or a hospital outpatient center," Bunn said. "However, if drug reimbursement levels are lowered without increasing payments for other patient services, the convenience of outpatient chemotherapy will no longer be as widely available to patients."

The bill would correct the imbalances by implementing a number of reforms:

—Cancer drugs would be reimbursed at rates based on the manufacturer's sales price with an additional amount that would cover the costs of handling the drugs including procurement, capital invested in inventory, storage, waste, and bad debt.

—The full costs of administering chemotherapy would be covered, including oncology nurse time, specialized equipment, and supplies.

—Medicare would establish reimbursement for services that oncologists provide, including counseling on treatment, side effects, and end-of-life care, as well as nutrition counseling, psychosocial services, and social work support.

Bill Would Require IOM Study

"The Quality Cancer Care Preservation Act is a first step in improving the flawed Medicare reimbursement methodology," said Ellen Stovall, president of the National Coalition for Cancer Survivorship. "A critical next step is to gather data on which to make long-term adjustments in the system of reimbursement for cancer care in all settings where this care is provided."

As suggested by the patient advocacy groups, the bill would require a study by the Institute of Medicine on cancer care reimbursement.

"We believe that the IOM's collection of data about the processes of providing quality care, including the entire range of evidence-based practices that we know benefit cancer patients and their families, will assist federal policymakers in the ongoing process of refining Medicare reimbursement of cancer care," said Catherine Harvey, chairman of the NCCS Board of Directors.

Last February, the New York attorney general filed suits against Pharmacia and GlaxoSmithKline alleging that using a formula based on the "Average Wholesale Price" of drugs constitutes illegal activity (**The Cancer Letter**, Feb. 14).

In another development, the Access to Cancer Therapies Act was introduced recently by Reps. Deborah Pryce (R-OH), Lois Capps (D-CA), Steve Israel (D-NY), and Sue Myrick (R-NC).

The bill would to provide Medicare coverage of oral chemotherapy drugs.

Currently, Medicare covers the cost of most anti-cancer treatments because these treatments are administered intravenously as part of a doctor's office visit. However, Medicare does not provide coverage for most oral cancer treatments.

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Capitol Hill:

FDA, NCI, Congress Shape Pediatric Drug Proposals

FDA, NCI, and Congress have put together proposals in recent weeks that are likely to shape development of cancer drugs for children.

—At FDA, the pediatric subcommittee of the Oncologic Drugs Advisory Committee recommended that data from pediatric studies should be included on drug labels, even when the studies are negative or inconclusive.

—The agency spelled out the criteria for initiating phase I studies of cancer drugs and biologics in children.

—On Capitol Hill, six Senate members introduced legislation that would allow FDA to require companies to perform pediatric studies for diseases where pediatric and adult indications are similar. The bill—S.650—would be similar to the agency's Pediatric Rule, which was invalidated by a federal judge last year (**The Cancer Letter**, Oct. 25, 2002).

—NCI has initiated development of a pediatric oncology pre-clinical screening consortium.

"Real Progress Has Been Made"

Creation of the pre-clinical consortium was mandated by Congress in the Best Pharmaceuticals for Children Act. The 2002 law requires the Institute to "expand, intensify, and coordinate" development of pre-clinical models for pediatric cancer.

NCI scientists Barry Anderson and Malcolm Smith recently developed a model Material Transfer Agreement to foster collaboration between industry, academia and the government.

"With the help of partners such as the NCI, the American Academy of Pediatrics, the Children's Oncology Group and the Pharma Pediaric Oncology Working Group, real progress has been made in reducing the barriers to provide access to new agents for children with cancer with reductions in the gap between starting adult and pediatric studies and the formation of a consensus framework that will allow consistent development," said Steven Hirschfeld, a pediatric oncologist with the FDA Center for Drug Evaluation and Review.

"One example of the progress is the fact that about 15 drugs still under development for adult oncology use are being tested in pediatric populations in response to FDA requests," Hirschfeld said. "The previous paradigm was that adult development had to be completed or almost completed prior to making a drug available for pediatric use."

Pediatric ODAC Recommends Expanded Label

At a meeting March 4, the ODAC pediatric subcommittee recommended that information from studies in pediatric patients should be disclosed on the drug label, regardless of whether the studies are positive or negative.

Pediatric studies are conducted in some cases to comply with "Written Requests" issued by FDA.

A Written Request is the first step in an incentive program contained in the Best Pharmaceuticals for Children Act of 2002, a law that has provisions that allow the FDA to grant an additional six months of exclusivity when pediatric studies requested by FDA are submitted to the agency for review.

There is no need for the pediatric disease to be a disease or condition that exists in adults. If a disease or condition does exist in both adults and children, a "proof of concept" study would be sufficient to extend adult efficacy findings to a pediatric population.

In proof of concept studies, an agent is tested in a small number of pediatric patients, and the responses expected in adults are observed in children.

At the March meeting, the pediatric ODAC subcommittee recommended that drug labels include data on dosing, safety, pharmacokinetics, the toxic dose and dose limiting toxicity.

Also, the label should contain information on study outcomes, the committee recommended.

If the study outcomes do not support an indication, the label should state that efficacy was not established based on data submitted to the FDA.

These recommendations are intended to recognize that the product label should not be regarded as a summary monograph of what is known about the product, but only what was reviewed by the FDA. If negative data were unequivocal, a statement that the product is not effective for the indication, could be considered, the committee said.

In cases where no data exist, a statement could read, "Data to establish dosing, safety, and efficacy in children were not submitted to the FDA."

The meeting was notable for the participation of many constituents, including investigators from the Children's Oncology Group and several other countries, patient advocates, pediatric oncologists from the pharmaceutical industry, and regulators from the European Medicinal Evaluation Agency, the United Kingdom, France and Germany.

Criteria for Pediatric Phase I Studies

Earlier this year, FDA published the criteria for initiating phase I studies in children with cancer who have relapsed or who are refractory to available anti-cancer therapy and would be candidates for investigational drugs. The criteria are based on recommendations of pediatric ODAC of Oct. 17, 2002.

The text of the criteria follows:

1) Pediatric oncology drug development should generally be coordinated with oncology drug development for adults, as part of an overall drug development plan.

2) The evidence burden for initiating clinical studies in children with cancer should include biological plausibility of the product having activity against a pediatric tumor, (which could be obtained from preclinical data), some expectation of potential benefit, a reasonable expectation of safety, and sufficient information to choose an appropriate starting dose.

3) Case-by-case determinations of when to initiate pediatric oncology studies can be made on the basis of the type of agent, the mechanism of action, what is known about the safety profile, and the potential indication.

4) Current practice would recommend that if a scientific rationale and a population of pediatric cancer patients with no available anti-cancer therapy exists then pediatric oncology clinical studies will be initiated, in most cases, immediately following adult Phase I studies.

5) As preclinical models continue to become validated for activity, pharmacology, and safety, the necessity of adult studies prior to pediatric studies may diminish and pediatric patients may be the first patients to receive a new agent. These recommendations are intended to facilitate a more timely and rational introduction of new agents into the pediatric population.

Bill Seeks to Revive Pediatric Rule

The Senate bill, introduced by Sen. Michael DeWine (R-OH), seeks to give back to FDA the authority to demand pediatric trials for diseases that are the same in children and adults.

The agency claimed that authority in the 1999 Pediatric Rule, but last year Judge Henry Kennedy Jr. of the U.S. District Court for the District of Columbia ruled that the agency lacked authority to enforce it.

Although the FDA has not filed an appeal, the American Academy of Pediatrics and the Elizabeth Glaser Pediatric AIDS Foundation are pursuing the case in court.

HHS Secretary Tommy Thompson said earlier this year that the Administration would support new legislation to convert the Pediatric Rule into law.

Last year, several legislators tried unsuccessfully to give the agency a clear legislative mandate to enforce the rule. The pediatric oncology subcommittee, in a series of meetings in 2000 and 2001 outlined criteria and made specific recommendations for cases when adult and pediatric diseases should be studied together.

Professional Societies:

July In DC? AACR Polls Registrants On Meeting Date

The American Association for Cancer Research began polling its annual meeting registrants this week about their availability for a rescheduled conference in July in Washington, DC.

The tentative new date for the meeting is July 11-15, at Washington's newly-expanded convention center. The email poll was sent to more than 12,000 people who registered for the society's annual meeting in Toronto that was cancelled last week (**The Cancer Letter**, April 4).

"Because the AACR annual meeting is the cancer community's most important yearly venue for sharing scientific information, the AACR is now investigating the feasibility of rescheduling the meeting," the email poll said. Participants were asked to submit their response by April 13.

AACR cited the outbreak of Severe Acute Respiratory Syndrome in Toronto as the reason for canceling the meeting, which was expected to attract 16,000 participants and earn about $1 million for the association. It was the first time in AACR's 96-year history that its annual meeting was cancelled.

In an April 8 email to registrants, Margaret Foti, AACR chief executive officer, said the decision to cancel the meeting was prudent.

"By the time we took this difficult action, cancer institutions, commercial firms, and some countries had circulated cautionary advisories about Toronto and SARS," Foti said. "A large number of advance registrants and exhibitors had already cancelled their participation in the annual meeting or were in the process of doing so; these cancellations included

invited speakers as well as poster presenters. In particular, many of our clinical researchers were urged by their institutional officials not to attend, given their clinical care responsibilities. Clearly the meeting in Toronto would have been severely compromised because of all of these events.

"Based on these factors, and our overriding concern for the safety and well being of our attendees and their patients, we chose the prudent course and decided to cancel the meeting in Toronto," Foti said.

Research centers around the country this week began releasing the results of studies their scientists had hoped to present at the AACR meeting in Toronto.

NCI scientists set up posters in the NIH Clinical Center exhibit hall for an informal "poster session."

The Holden Comprehensive Cancer Center at University of Iowa held an "AACR in Iowa" on April 7, where research results were presented.

"Our students, faculty, and staff all worked very hard to conduct their research and to prepare their presentations," said George Weiner, director of the center. About 15 students and faculty from Holden were planning to attend the AACR annual meeting.

Cancer Prevention:

Study: 2 Million U.S. Women Could Benefit From Tamoxifen

More than 10 million women in the U.S. have a high enough risk of developing breast cancer that they could consider taking the breast cancer chemoprevention drug tamoxifen, according to Andrew Freedman and his colleagues at NCI.

When the scientists examined this group of women using a risk-benefit analysis of the drug, they found that more than 2 million women would be likely to derive overall benefit from the drug without undue risks. The results were reported in the April 2 issue of the Journal of the National Cancer Institute.

Tamoxifen was approved five years ago as the first drug to prevent breast cancer. It can halve the incidence of breast cancer in women who are most likely to develop the disease.

Side effects of tamoxifen are rare, but serious—endometrial cancer, stroke, deep vein thrombosis, and pulmonary embolism. The study weighed these risks, which are especially high for older women, against the benefits of tamoxifen to determine how many women in the U.S. are likely to have a net benefit from the drug.

"Our study makes progress in evaluating the potential public health impact of tamoxifen use and identifies subgroups of women who may especially benefit from tamoxifen," said Freedman. "Although these findings suggest a benefit of tamoxifen for certain women, the choice to take tamoxifen is an individual one. Women with increased risk of breast cancer must carefully consider the benefits and risks in consultation with their physicians."

The decision to take tamoxifen will depend on a woman's age, breast cancer risk factors, family history, how she weighs the benefits and risks, and her specific medical situation, lifestyle, personal values, and preferences, said Worta McCaskill-Stevens, one of the co-investigators on the NCI study. "Tamoxifen therapy may not be appropriate for all women who are at increased risk for breast cancer," said McCaskill-Stevens.

Tamoxifen was approved as a chemoprevention drug for breast cancer by FDA in 1998, after NCI released the results of the Breast Cancer Prevention Trial, a six-year study of the drug. In BCPT, tamoxifen was found to reduce the incidence of breast cancer by 49 percent. Based on that study, FDA approved the drug for women at high risk of developing invasive breast cancer. High risk was defined as women age 35 and older who have a five-year risk of at least 1.67 percent.

Using data on cancer risk factors from the 2000 National Health Interview Survey, Freedman and colleagues calculated the number of U.S. women eligible to take tamoxifen based on FDA-approved indications. They also projected the number of white and black women who would most likely have a net positive benefit from taking the drug based on a benefit-risk analysis. Because accurate data on the frequency of adverse tamoxifen effects in Hispanic women were not available, estimates of how many Hispanic women would likely benefit from the drug could not be calculated, Freedman said.

The researchers estimated that 15.5 percent of women 35 to 79 years old, or about 10 million, would be eligible to take tamoxifen based on breast cancer risk alone.

When analyzed by race, 18.7 percent of white women ages 35 to 79 in the U.S., or 9.4 million, would be eligible for tamoxifen, but only 4.9 percent, or 2.4 million, are likely to benefit from the drug. About 6 percent of U.S. black women in the same age range, or 430,000, would have a high enough risk to take the drug, but only 0.6 percent, or 43,000, would likely

derive a net benefit from it.

The rates are lower for black women than white women, because the overall risk for breast cancer in black women is lower and because the rates of stroke, deep vein thrombosis, and pulmonary embolism are higher than among white women. The results for black women, however, are less stable than those for white women, because less is known about breast cancer risk and the incidence of some of the side effects in this group, said Freedman.

In examining who would do well on tamoxifen, the researchers found that an overall net positive benefit was related to age. Younger women are less likely than older women to experience the drug's adverse affects. If a 40-year-old woman and a 60-year-old woman had the same breast cancer risk, the younger woman would likely derive a better overall benefit from the drug.

When the researchers did the age analysis, they found the highest percentage of women likely to benefit overall from tamoxifen were age 40 to 59. More than 8 percent of these women would potentially gain from chemoprevention, compared to 2.1 percent for women age 60 to 69.

In terms of preventing actual breast cancers, the researchers estimated that among the 2.4 million white women who could likely benefit overall from taking tamoxifen, 58,148 breast cancers would develop over the next five years. But, if all these women took the drug for that length of time and experienced the 49 percent reduction in breast cancer, 28,492 cases could be prevented or deferred.

Funding Opportunities:

DOD To Release 9 Funding Mechanisms For FY2003

The fiscal year 2003 Defense Appropriations Act provides $150 million to the Department of Defense Breast Cancer Research Program. The FY03 BCRP will be releasing nine different funding mechanisms.

BCRP Funding Mechanisms Proposal Submission Deadlines:

Center of Excellence Award: Full proposal due Aug. 7. **Clinical Translational Research Award:** Full proposal due Aug. 7. **Idea Award:** May 14. **Innovator Award:** April 16. **Clinical Research Nurse Training Award:** May 14. **Historically Black Colleges and Universities/Minority Institutions Partnership Training Award:** Full proposal due Aug. 7. **Physician-Scientist Training Award:** May 14. **Predoctoral Traineeship Award:** May 14. **Postdoctoral Traineeship Award:** May 14.

Descriptions of each of the mechanisms, evaluation criteria, and submission requirements are available in the program announcement corresponding to that mechanism. Each program announcement is available for downloading from the CDMRP Web site at http://cdmrp.army.mil/. Applicants will be required to submit an electronic version of their proposal as a PDF file.

DOD Ovarian Cancer Research Program

The FY2003 Defense Appropriations Act provides $10 million to the DOD Ovarian Cancer Research Program to support ovarian cancer research.

Proposals are sought in etiology and early detection/diagnosis. The proposal submission deadline is April 23, 5 pm. ET. These announcements will call for proposals in the following two mechanisms:

Idea Development Awards encourage approaches to research in the etiology and early detection of ovarian cancer; and are intended to stimulate and reward research ideas that may be viewed as high risk but have the potential for high gain in scientific and clinical knowledge. The proposals should start, create, or introduce a unique or unusual approach to the study of ovarian cancer. The research may represent a new paradigm, challenge existing paradigms, or investigate an existing problem from a new perspective. All investigators are eligible to submit proposals.

New Investigator Awards recognize and support postdoctoral fellows with at least 5 years of postdoctoral training, and faculty through the level of assistant professor (or other individuals with comparable experience holding non-academic positions of equivalent rank) that have innovative ideas applicable to the etiology and early detection of ovarian cancer.

The program announcements are available at t http://cdmrp.army.mil/. Applicants will be required to submit one electronic version of their proposal as a PDF file.

Inquiries: Gail Whitehead, public affairs coordinator , Azimuth, Inc. for the DoD, USAMRMC, Congressionally Directed Medical Research Programs, phone 301-619-7783; e-mail Gail.Whitehead@det.amedd.army.mil

Program Announcement

PAR-03-083: Institutional Clinical Oncology Research Career Development Program

Letter of Intent Receipt Date: May 1

Application Submission Date: June 1

The NCI Institutional Clinical Oncology Career Development Program intendeds to train clinical researchers whose career focus will be on patient-oriented therapeutic research. The program would like to increase the number of medical doctors and nurses who are motivated and properly trained to: 1) perform clinical oncology research that develops and tests scientific hypotheses based on fundamental findings; 2) design and test hypothesis-based clinical protocols and manage all phases (i.e., pilot/phase I, phase II, and phase III) of cancer therapeutic clinical trials, and 3) communicate and collaborate with basic research scientists in order to expedite the translation of basic/behavioral research discoveries into patient-oriented therapeutic cancer research. The PA is available at http://grants1.nih.gov/grants/guide/pa-files/PAR-03-083.html.

Inquiries: Lester Gorelic, Cancer Training Branch, NCI, 6116 Executive Blvd., MSC 8346 Suite 7025, Bethesda, MD 20892-8346, phone 301-496-8580; fax 301-402-4472; e-mail gorelicl@mail.nih.gov.

In Brief:

Antibody Engineering Center Formed By DFCI, Foundation

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will be directed by **Wayne Marasco**, of the Department of Cancer Immunology and AIDS. The center will conduct therapeutic antibody research and provide high affinity human single-chain antibodies for NFCR scientists. Other NFCR centers have been established at Oxford, Yale, Pennsylvania State University, University of California Berkeley, University of Arizona, Freie Universität Berlin, and the Institute of Medicinal Biotechnology in Beijing, said **Michael Wang**, director of research at NFCR. . . . **FOX CHASE Cancer Center** appointed two faculty in the Division of Medical Science. **Robert Uzzo** was appointed member, Department of Surgical Oncology. Uzzo joined the department in 2000 as an attending surgeon. His work is in kidney, prostate, testicular and bladder cancer and procedures for urinary diversion. **Eric Horwitz** was promoted to member, Department of Radiation Oncology. Horwitz joined the department in 1997. He is known for his work in prostate cancer and head and neck cancers. . . . **K. MICHAEL CUMMINGS** was awarded the 2003 Joseph W. Cullen Memorial Award by the American Society of Preventive Oncology at its annual meeting March 11. Cummings is chairman, Department of Health Behaviors in the Department of Cancer Prevention and Population Sciences, Roswell Park Cancer Institute. He was recognized for his contributions to national tobacco control efforts. . . . **DAVID IRWIN** was appointed associate director for administration, Lombardi Cancer Center, Georgetown University Medical Center and Georgetown University Hospital, effective April 14. He is associate director for administration, St. Jude Children's Research Hospital, St. Jude's Cancer Center, said **Richard Pestell**, director of Lombardi Cancer Center and chairman, Oncology Department, GUMC. . . . **JAMES ASHER** was appointed executive director of the Alliance for Lung Cancer Advocacy, Support, and Education. Asher was treasurer of the Board of Directors for ALCASE and is a non-small cell lung cancer survivor. ALCASE, founded in 1995, is based in Vancouver, WA, with staff in Washington, DC. . . . **SAID SEBTI**, director of the Drug Discovery Program at the H. Lee Moffitt Cancer Center & Research Institute, was awarded the Endowed Chair for Drug Discovery. The endowment, a gift of board of directors member **Manuel Garcia** and his wife Adeline, was created not only to support Sebti as an individual scientist but also his program and laboratory. He is working on the family of farnesyltransferase drugs as a cancer therapeutic. . . . **DONALD SMALL**, associate professor of oncology, pediatrics, cellular, and molecular medicine in the Kimmel Cancer Center at Johns Hopkins, has received a five-year, $750,000, Translational Research Award from the Burroughs Wellcome Fund for his work in pediatric AML and infant ALL. . . . **ANTONIO GIORDANO** has received the National Lifetime Achievement Award in Medical Research from the National Italian-American Political Action Committee for "his accomplishments as a world-renowned researcher, scientist, and member of the Italian-American community." He is director of The Sbarro Institute for Cancer Research and Molecular Medicine in the Temple University College of Science and Technology. Giordano founded the institute in 1993 with **Mario Sbarro**, owner of Sbarro Inc., the

international fast food chain. Giordano is known for his work in cell cycle, gene therapy, and the genetics of cancer. Giordano is an adjunct professor at the Universities of Siena, Naples, Rome, and Bologna. . . . **AMERICAN SOCIETY for Therapeutic Radiology and Oncology** has made staff changes. **James Roberts** is division director of education, meetings and corporate relations, said **Laura Thevenot**, executive director of ASTRO. He will supervise annual meetings, corporate relations, research, and educational opportunities. Roberts was vice president at e-displaystore.com, an event-marketing agency. Staff member **Trisha Crishock** was promoted from assistant director to director of healthcare policy and economics. . . . **VITAL OPTIONS** International TeleSupport Cancer Network is celebrating its 20th anniversary this month with a series of young adult-oriented programs on The Group Room, the syndicated weekly radio call-in cancer talk show. On the April 6 program, **Selma Schimmel,** host of The Group Room and CEO and founder of Vital Options, was joined by guests **Randi Rosenberg**, president of the Young Survival Coalition and breast cancer survivor; **Doug Ulman**, CEO and founder of the Doug Ulman Cancer Fund for Young Adults; **James Metz**, assistant professor, Department of Radiation Oncology, University of Pennsylvania Medical Center, three-time cancer survivor and editor-in-chief of OncoLink; and **Wendie Jo Sperber**, CEO and founder of WeSpark Cancer Support Center. Further information and previously aired programs are available at www.vitaloptions.org. . . . **EMORY UNIVERSITY** has developed a Web site that provides scientific knowledge about cancer and includes interactive graphics and a built-in dictionary. The site can be found at www.cancerquest.org. "I found that there is not much out there that really teaches the biology of cancer, that can explain to people what is happening to them," said **Gregg Orloff**, senior lecturer in biology at Emory who led the development of CancerQuest after his wife's experience with breast cancer. . . . **CORRECTION:** A story in the March 21 issue of **The Cancer Letter** incorrectly described the analysis of a study that led to accelerated approval of Eloxatin (oxaliplatin). The agent was approved following protocol-prespecified analysis carried out after 150 patients per arm of the three-arm study received 120 days of treatment. Altogether, 821 patients were enrolled.

THE CANCER LETTER

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Business & Regulatory Report

Product Approvals & Applications:

FDA Approves Emend For Nausea Associated With Chemotherapy

Merck & Co. Inc. of Whithouse Station, N.J., said FDA has approved Emend (aprepitant) for nausea and vomiting associated with initial and repeat courses of emetogenic chemotherapy, including high-dose cisplatin.

The treatment, a substance P/neurokinin 1 (NK(1)) receptor antagonist, is an oral capsule used in combination with other anti-vomiting medicines, the company said.

The agent is taken once daily for three days. The recommended

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Oncology Management:

University Signs Agreement With Precyse To Co-Market Management Services

University of Pennsylvania Cancer Network said it has signed a three-year exclusive agreement with **Precyse Solutions** of King of Prussia, Penn., to co-market the Precyse Oncology and Health Information Management services to its network of 29 community hospitals in Pennsylvania and New Jersey.

Under the agreement, UPCN will promote Precyse services exclusively, and it has agreed to offer special terms on its oncology and HIM services to PENN network hospitals, the company said.

The services include: Cancer Registry abstracting for ACoS and state reporting hospitals, interim management, cancer program assessment, operational analysis, pre-survey consultations, new ACoS program development, compliance audits, registry system networking, training, and total outsourcing of a hospital's cancer registry department.

Precyse said it will provide medical transcription, medical coding services, and HIM consulting and interim management services.

* * *

Easton Hospital in Easton, Penn., has affiliated with **Fox Chase Cancer Center** in Philadelphia.

The expanded program will include access to programs for people at high risk of developing cancer, cancer prevention studies and cutting-edge cancer treatments.

The affiliation establishes the Easton Regional Cancer Center and makes Easton Hospital a member of Fox Chase Network, a group of 28 community hospitals in Pennsylvania, New Jersey and Delaware.

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FDA Approves Emend For Chemo-Induced Emesis

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dosing regimen is Emend 125 mg orally one hour prior to chemotherapy treatment (Day 1) and 80 mg once daily in the morning on Days 2 and 3.

Chronic continuous use of Emend for prevention of nausea and vomiting is not recommended, because it has not been studied and the drug interaction profile may change during chronic continuous use, the company said.

In two clinical trials, Emend in combination with a 5-HT(3) receptor antagonist and a corticosteroid (regimen with Emend) was compared with a 5-HT(3) receptor antagonist and a corticosteroid alone (standard therapy), the company said.

The dose of corticosteroid in the regimen with Emend was reduced to achieve drug levels similar to those achieved with standard therapy.

In the studies, the regimen with Emend provided significantly improved protection for five days against both acute (within 24 hours of chemotherapy) and delayed nausea and vomiting compared to standard therapy, the company said.

In both studies, more patients on the regimen with the medicine as compared with standard therapy had a complete response to therapy—defined as no vomiting and no use of rescue medicines, the company said. The improvement in overall complete response in each study was approximately 20 percentage points.

The analysis of the impact of nausea and vomiting on patients' lives showed that more patients on the regimen with Emend reported minimal or no impact of nausea and vomiting on their daily lives compared to standard therapy (Study 1: 74% versus 64%; Study 2: 75% versus 64%).

More than two-thirds of patients in the trials received more than one cycle of chemotherapy in the two clinical studies, and approximately one-third continued through six cycles, the company said. The results from extension studies showed that the improved prevention of nausea and vomiting with the regimen with Emend was maintained cycle after cycle of chemotherapy.

The overall safety was evaluated in approximately 3,300 individuals, the company said. In two controlled clinical studies in patients receiving highly emetogenic chemotherapy, 544 patients were treated with aprepitant during the first cycle of chemotherapy, and 413 of these patients continued into the multiple cycle extension for up to six cycles of chemotherapy.

The regimen with Emend was generally well tolerated in these clinical studies. The most commonly reported side effects were tiredness, nausea, hiccups, constipation, diarrhea, and loss of appetite, the company said.

* * *

Delcath Systems Inc. (Nasdaq: DCTH) of Stamford, Conn., said it has received approval from the Australian Therapeutics Goods Administration for a phase III trial at the Sydney Melanoma Unit for liver cancer.

The study protocol, which has also been approved by U.S. FDA, calls for 122 subjects using doxorubicin, the company said. The clinical goal is to test whether the Delcath patented drug delivery system experience statistically longer survival versus a control group.

The system delivers high dose chemotherapy directly to the liver via the hepatic artery, then uses special catheters and filters to direct and trap the toxic chemicals, protecting the rest of the body from excessive toxicity, the company said.

The principal investigator is John Thompson, director of the Sydney Melanoma Unit and professor of surgery (melanoma and surgical oncology) at the University of Sydney, the company said.

The Delcath system is also being used by NCI

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in a phase I study, the company said. A phase II trial is expected to begin soon, the company said. Both trials will be using the drug melphalan.

NCI is using the Delcath system in place of a more invasive procedure that reportedly limits the full potential of isolated perfusion therapy, the company said. The system achieves vascular isolation of an organ such as the liver in an outpatient setting with a minimally invasive, non-surgical procedure, the company said. It removes the majority of the drug from the blood through a catheterization and filtration process.

Delcath has hired **Omnicare Inc.** (NYSE: OCR) to manage the Australian trial. The Therapeutic Goods Administration requires than an Australian based entity represents organizations that are not located in that country, the company said.

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ILEX Oncology Inc. (Nasdaq:ILXO) of San Antonio, through its wholly owned subsidiary **ILEX Pharmaceuticals L.P.**, has been granted an option by **BTG International** to extend its worldwide, exclusive Campath (alemtuzumab) license to include all non-oncology human-related therapeutic uses of the drug.

"Campath's unique mechanism of action, targeting and depleting T-cells, has been well established and could be effective in many areas besides oncology, such as autoimmune and autoimmune-related diseases," said Jeffrey Buchalter, president and CEO at ILEX.

In addition to autoimmune and related diseases, Campath may also prove effective in treating a number of illnesses in which mediation of T-cells could play a role, the company said.

The drug is a humanized monoclonal antibody that binds to a specific target, CD52, on cell surfaces, leading the destruction of malignant cells and deplete B- and T-cells that are instrumental in disease, the company said. Campath was granted accelerated approval by FDA in May 2001 for B-cell chronic lymphocytic leukemia who have been treated with alkylating agents and have failed fludarabine treatment.

Schering AG, Germany (FSE:SCH) (NYSE:SHR) holds exclusive worldwide marketing and distribution rights to Campath. Berlex Laboratories Inc., a U.S. affiliate of the Schering AG Group, markets the product in the U.S.

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Millennium Pharmaceuticals Inc. (Nasdaq: MLNM) said it has been granted priority review for a new drug application for Velcade for relapsed and refractory multiple myeloma.

The NDA submission was based on the results of the phase II SUMMIT trial, a multi-center study of 202 patients.

Velcade blocks the proteasome and interferes with chemical messengers associated with unregulated cancer cell growth and survival, the company said.

Millennium said it also is conducting an international, multi-center, phase III APEX trial with Velcade, one for metastatic colorectal cancer and the other for advanced non-small cell lung cancer.

Oncology Management:

Firm Offers Chemotherapy By Mail To Physician Offices

(Continued from page 1)

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Prescription Solutions of Costa Mesa, Calif., a subsidiary of **PacifiCare Health Systems Inc.** (Nasdaq:PHSY), said that it would provide unmixed chemotherapy agents through its mail service facility.

The company said it introduced Specialty Pharmacy in 2001 to manage the cost of injectable cancer medications, AIDS, hepatitis and multiple sclerosis.

"The expansion of our Specialty Pharmacy program to include oncology agents via mail service demonstrates our commitment to provide our clients with access to the programs and services that will directly impact cost, outcomes and overall quality," said Christine Chow, manager for Prescription Solutions Specialty Pharmacy.

Unmixed oncology drugs are sent to physicians' offices for administration to specific patients, the company said. Mixed chemotherapy agents will be offered through a network of home infusion partners, the company said.

More than 2.5 million patients nationwide are covered under the Prescription Solutions Specialty Pharmacy program, the company said.

Components of the PSSP include clinical guidelines for injectables, prior authorization to ensure that patients are using the right medicine and the right dose for the right duration, utilization management, as well as care management, the company said.

PSSP said it uses National Drug Codes, instead of the coding used by nearly 80 percent of the industry,

Healthcare Common Procedure Coding System, or J codes.

Clinical Trials:

Salmedix Begins Phase II Trial Of SDX-102 For Lung Cancer

Salmedix Inc. of San Diego has initiated a multi-center phase II trial for its second drug, SDX-102 (L-alanosine), in non-small cell lung cancer, mesothelioma, pancreatic cancer, osteosarcoma and soft tissue sarcoma.

Based on recently discovered differences in metabolic pathways in normal cells and certain types of cancer cells, scientists at University of California, San Diego, proposed and patented a new approach to use the compound, the company said.

Salmedix said it has developed a laboratory test, which can be conducted on tumor biopsy specimens, to identify patients who are predicted to be selectively sensitive to SDX-102 and, therefore, most likely to respond to the drug.

Laboratory research studies on a broad range of tumors have shown that about 30 percent to 60 percent of patients with selected tumor types, including non-small cell lung cancer, mesothelioma, pancreatic cancer, osteosarcoma and soft tissue sarcoma may be candidates for therapy with SDX-102, the company said.

The trial will be conducted at more than 15 cancer centers, and will enroll only those patients identified by the proprietary test.

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Cell Pathways Inc. (Nasdaq: CLPA) of Horsham, Penn., said it has completed enrollment in a phase III trial of its drug Aptosyn (exisulind) in combination with Taxotere for non-small cell lung cancer.

The double-blind, placebo-controlled study is evaluating the combination of Aptosyn with Taxotere (docetaxel) versus Taxotere/placebo in 600 patients with advanced NSCLC, the company said.

The primary endpoint for the study is increased survival (overall and one-year) for patients receiving the Aptosyn/Taxotere combination compared to those receiving Taxotere/placebo.

"The investigators will track patient survival for 12 months before the study results are unblinded," said Rifat Pamukcu, chief scientific officer at Cell Pathways. "The study is designed to support a product registration for Aptosyn in combination with Taxotere for advanced NSCLC where a first-line platinum-containing combination therapy has failed."

Aptosyn, a selective apoptotic antineoplastic drug, triggers apoptosis in cancerous and precancerous cells, but not in normal cells, the company said.

The agent inhibits certain cyclic GMP phosphodiesterases that are expressed at high levels in the abnormal cells, thus freeing those damaged cells to die through normal cellular processes.

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CollaGenex Pharmaceuticals Inc. (NASDAQ: CGPI) of Newtown, Penn., said the AIDS Malignancy Consortium has completed enrollment in and closed to accrual a phase II study evaluating the efficacy of Metastat, an orally-active angiogenesis inhibitor, for HIV-related Kaposi's sarcoma.

The study is being sponsored by NCI pursuant to the CRADA between CollaGenex and NCI for Metastat, the company said.

The multi-center open-label study of 75 patients who received one of two different doses of Metastat for six months, the company said.

The primary objectives of the study were to evaluate the tumor response rate and response duration as well as to evaluate the biologic activity of Metastat by measuring serum levels of pro-angiogenic mediators.

The results are expected to be available in eight months, the company said.

The study is based on a phase I/II dose-escalation study of Metastat in 18 patients with recurrent KS, the company said. The data demonstrated a 44 percent clinical response rate and indicated that the drug was generally well tolerated.

Metastat is based on the CollaGenex proprietary IMPACS (Inhibition of Multiple Proteases and Cytokines) technology, the company said.

The compound has a dual mechanism of action, with anti-tumor activity conferred by its combined broad inhibition of several tissue-destructive enzymes and the down-regulation of various inflammatory cytokines that are implicated in metastasis.

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Tularik Inc. (Nasdaq: TLRK) of South San Francisco, said it has begun enrollment in the registration trial for T67, a drug candidate for the treatment of hepatocellular carcinoma.

The two-arm, randomized, global study is comparing the survival for those who receive T67

versus those receiving doxorubicin, the company said.

Doxorubicin is the current systemic chemotherapy standard of care for HCC, although FDA has not approved it for this indication, the company said. The study will enroll up to 750 in up to 75 sites in the U.S. and abroad.

T67 binds to beta-tubulin, a known anti-cancer drug target, the company said. The treatment is distinguished from other tubulin-binding agents, such as Taxol, because it retains activity against multiple drug resistant tumors in animal models.

In phase I and phase II studies, T67 has shown activity for HCC and a clinically acceptable toxicity profile, the company said. Tularik said it retains 100 percent worldwide rights to T67.

Deals & Collaborations:

Accuray Signs Five Contracts For CyberKnife System

Accuray Inc. of Sunnyvale, Calif., said it has signed five contracts to purchase and place the CyberKnife Stereotactic Radiosurgery System.

The sales include Atlantic Health System, Summit, N.J.; Wellmont Bristol Regional Medical Center, Bristol, Tenn.; and the CyberKnife Center of the Americas, LLC in Miami, Fla., the company said.

Placement contracts were signed with Sinai Hospital of Baltimore, Md., and St. Joseph's Hospital, a member of HealthEast Care System in St. Paul, Minn., the company said.

Under the placement program, the hospitals will partner with Accuray in a revenue/risk-share business arrangement, the company said. Installation at all five sites should be complete in 2003, bringing the total number of CyberKnife sites in the U.S. to 17.

The CyberKnife is a robotic radiosurgery device that incorporates image-guidance to non-invasively ablate tumors and other lesions in the body through the delivery of multiple beams of high energy x-rays, the company said.

The hospitals plan to utilize the CyberKnife for traditional neurosurgical applications in the brain as well as for radiosurgery for lesions or tumors of the spine and spinal cord, an application not feasible with other existing radiosurgical technology, the company said. Expansion to other clinical targets in the body such as tumors of the lung is also planned.

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AmeriPath Inc. (Nasdaq: PATH) of Riviera Beach, Fla., said its stockholders have approved the merger with **Amy Acquisition Corp.**, an entity formed by Welsh, Carson, Anderson & Stowe, a New York-based private equity firm.

AmeriPath is a provider of cancer diagnostics, genomics, and related information services.

Under the merger, each of the AmeriPath 30.6 million outstanding shares of common stock, other than shares held by Welsh Carson, have been converted into the right to receive $21.25 in cash, the company said.

AmeriPath said it has appointed American Stock Transfer & Trust Co. as the agent for payment of the merger consideration.

In conjunction with the debt financings for the transaction, Amy received $360 million in equity and subordinated debt financing from Welsh Carson and other investors, which was used to pay the cash merger consideration, refinance approximately $128 million of indebtedness of AmeriPath, provide a reserve for an estimated $67 million of contingent note obligations and pay transaction expenses, including approximately $3 million in expenses associated with the restructuring of operations in connection with the transaction, the company said.

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Confirma Inc., of Kirkland, Wash., said it has entered into a research agreement with the Robert M. Berk Magnetic Resonance Institute at the **University of California, San Diego.**

The Magnetic Resonance Institute is a leader in the development of new applications for breast magnetic resonance imaging.

The MRI Institute will conduct breast MRI research using CADstream, Confirma's system for breast MR image processing and analysis.

The purpose of the agreement is to further evaluate CADstream for breast MR image processing and its impact on breast MRI interpretation. The first study will focus on measuring the effect of CADstream processing on reader sensitivity and specificity — two important criteria in measuring the efficacy of MRI.

CADstream is the first CAD system for analysis of breast MRI studies, the company said.

CADstream automates breast MR image processing functions and registers study data to correct for patient movement. After registering images, the system performs a number of user-defined processes, providing subtraction images, contrast uptake and washout curves, angiogenesis maps (color maps that correspond to contrast uptake

and washout curves), maximum intensity projections, multiplanar reformatted images and ROI summary series (summary of contrast dynamics and diameters for a specific region). CADstream standardizes breast MRI processing and analysis, and results in higher quality imaging studies and improved breast MRI economics.

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Cylex Inc. of Columbia, Md., said it has entered into a distribution arrangement with **Quest Biomedical** for ImmuKnow, the Cylex Immune Cell Function Assay and other products into clinical laboratories in the U.K.

The assay is used to measure the immune response of patients receiving immunosuppressant therapy for organ transplantation and is the first product cleared by FDA for measuring global cell-mediated immunity, the company said.

"Quest Biomedical is a uniquely complementary distribution partner because of their existing customer relationships with important transplantation HLA laboratories throughout the U.K.," said Judith Britz, president at Cylex. "Through Biomedical, our FDA-cleared assay for the detection of cell-mediated immunity will be offered for the first time outside of the U.S. addressing a worldwide need for assessment of immunity in immunosuppressed patients."

ImmuKnow should be used as an adjunct to post-transplantation drug level monitoring along with other clinical indicators, the company said.

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H3 Pharma Inc. of Montreal said it has finalized a licensing and an investment undertaking with **OncoMab GmbH**, a start-up biotech drug discovery company of Würzburg, Germany.

The deal is a multimillion-dollar transaction including an exclusive royalty-bearing license for the first product and its molecular target, an exclusive option for a license on three other products targeting other forms of cancer and the purchase of an equity stake in the company, the company said.

H3 Pharma said it would take charge of the clinical development and worldwide registration for the four products.

The first product, SC-1, is a fully human monoclonal IgM antibody targeting an isoform of CD55 present in 60 percent of stomach carcinomas, the company said.

In a prospective study of 51 patients, the antibody was administered prior to surgery and was shown to induce tumor apoptosis.

Two-year survival after SC-1 treatment and curative resection was 75 percent versus less than 60 percent in a comparable patient population. The statistically significant survival benefit was further increased after three years**,** the company said.

"SC-1 will likely be the first human antibody of the IgM class to be registered," said Didier Coquoz, vice president research and development at H3 Pharma. "IgM antibodies like SC-1 directly induce cell death; these antibodies could, therefore, be more potent than IgGs in classical oncology settings in addition they could be effective in more aggressive cancers."

OncoMab GmbH is a spinout of the Institute of Pathology, University of Würzburg.

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Kalypsys Inc. of San Diego said it has entered into an agreement that provides **Merck & Co. Inc.** with its proprietary, high-throughput lead discovery system.

The companies also said they would to collaborate to extend the capabilities of the system to increase the Merck screening capacity and enable high-throughput target and pathway-based screening across multiple therapeutic areas.

"The Kalypsys industrial lead discovery technologies are complementary to our existing capabilities and will enable us to routinely screen our entire compound collection in either biochemical or cellular formats in an efficient and cost effective manner," said Berta Strulovici, executive director of basic research at Merck.

Kalypsys uses compact, integrated and stand alone systems based on proprietary hardware and software to run diverse biological assays in 1536-well format, the company said.

The same systems used for compound library screening can also be used to screen libraries of antibodies, recombinant proteins or genes for drug or target discovery. The system is also designed as an open platform that can incorporate customer-selected external devices.

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Interferon Sciences Inc. (OTC-BB:IFSC) of New Brunswick, N.J., said it entered into a licensing agreement with **Hemispherx Biopharma Inc.** for its Alferon N Injection product.

In exchange for the inventory and license, ISI received HEB common stock with a guaranteed value of $675,000, an additional 62,500 shares of HEB common stock without a guaranteed value, and a

royalty equal to 6 percent of the net sales of Alferon N Injection, the company said.

The HEB common stock will be subject to selling restrictions. In addition, HEB assumed $400,000 of the ISI payables and various other commitments.

ISI and HEB also entered into another agreement in which ISI will sell to HEB its real estate property, plant, equipment, furniture and fixtures, rights to Alferon N Injection and all of its patents, trademarks and other intellectual property related to its natural alpha interferon business, the company said.

In exchange, ISI will receive $675,000 of HEB common stock with a guaranteed value, an additional 62,500 shares of HEB common stock without a guaranteed value and a royalty equal to 6 percent of the net sales of all products sold containing natural alpha interferon.

HEB will assume $1.5 million of ISI indebtedness that currently encumbers its assets, the company said. In addition, HEB said it would fund the operating costs of the ISI facility pending the completion of this transaction.

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Matritech Inc. (NASDAQ:NMPS) of Newton, Mass., and **Mitsubishi Kagaku Medical Inc**. said they have formed a partnership to develop NMP66, a blood test for the early detection of breast cancer.

The NMP66, a protein biomarker present in the blood of women with breast cancer, will be in a validation study using specimens from women in Japan, the companies said.

Mitsubishi will then perform a clinical trial in Japan. Mitsubishi plans to offer the test initially through its clinical laboratories in Japan and possibly other laboratories.

"In Japan, there is a low utilization rate of mammography; we believe a blood test will encourage more women to be tested and thus find the disease at an early, treatable stage," said Yasuhiro Morinaka, of Mitsubishi Kagaku Medical.

Japan has the second largest diagnostic market in the world, and more than 35,000 new cases of breast cancer are detected in the country each year even with low utilization of mammography, the companies said.

Mitsubishi Kagaku Medical is a division of Mitsubishi Chemical, a $13 billion diversified international corporation that includes clinical reference laboratories, the companies said.

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MetriGenix Inc. of Gaithersburg, Md., and **Waban Software** of Cambridge, Mass., said MetriGenix would integrate the Waban Software Waban Explorer into the MGX 4D Array System, to manage genomic data.

Waban Explorer allows for the integrated management of data collected during drug discovery and development processes, the company said.

Based on its Flow-Thru Chip technology, the 4D Array System combines public and proprietary genomic and proteomic content to enable scientists in pharmaceutical and biotechnology companies, academic and government institutions to perform differential gene expression studies, the company said.

By integrating the system with Waban Explorer, MetriGenix users can capture, store, analyze and manage data from the microarray platform within a single database, the company said. Researchers can also develop and share analyses, reports and findings within an integrated system, and access data from multiple public databases, such as OMIM and GenBank.

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OncoGenome Sciences of Liege, Belgium, and Durham, N.C., said it has raised 14 million Euro from European venture capital funds.

OncoGenome Sciences said it develops clinical diagnostic testing services and kits. Herman Spolders, former vice president of business development & operations at Virco founded the company in 2002.

The lead investor in the first round of funding is **Bank Brussels Lambert SA** of Brussels, the company said. The round was co-led by funds advised by **PolyTechnos Venture-Partners** of Munich, **Life Sciences Partners** of Amsterdam, and followed by **Technowal SA** of Liege, **Meusinvest**, and **S.I.B.L.**, both also of Liege.

"We are impressed by the OncoGenome Sciences business plan, industrial biotech experience, and the broad access to intellectual property rights and transatlantic research collaborations," said Alain Parthoens, Bank Brussels Lambert. "The early diagnosis of the major cancer types has a large market potential and OncoGenome Sciences is poised to become a significant player in the field."

OncoGenome Sciences collaborates molecular oncology scientists, including Stephen Baylin, James Herman and David Sidransky, of Johns Hopkins University.

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OSI Pharmaceuticals Inc. (NASDAQ:OSIP)

of Melville, N.Y., and **Serono S.A.** (virt-x: SEO and NYSE: SRA) of Geneva said they have entered into an agreement for OSI to market and promote Novantrone (mitoxantrone concentrate for injection) for the approved oncology indications in the U.S.

OSI will pay Serono initial fees totaling $55 million plus maintenance fees in return for commissions on net sales in oncology, the companies said. OSI would build a sales force and an associated marketing and sales management infrastructure for the drug.

Novantrone is approved by FDA for acute nonlymphocytic leukemia, which includes myelogenous, promyelocytic, monocytic and erythroid acute leukemias, and the relief of pain associated with advanced hormone-refractory prostate cancer, the companies said. The drug is also approved for certain advanced forms of multiple sclerosis.

Serono acquired from Amgen the U.S. rights to Novantrone for both MS and oncology in December 2002, the companies said.

Novantrone, a DNA-reactive agent that intercalates into DNA through hydrogen bonding, causing crosslinks and strand breaks, is a synthetic antineoplastic anthracenedione used intravenously as an anti-cancer agent, the companies said. The product also interferes with RNA and is an inhibitor of topoisomerase II, an enzyme responsible for uncoiling and repairing damaged DNA.

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SourceOne Healthcare Technologies Inc. has entered into an agreement to distribute a line of mammography products by **Planmed Inc.** of Cleveland.

The three-year contract, which took effect March 31, is expected to generate more than $30 million in total sales for the Cleveland-based imaging distributor, the companies said.

The agreement grants SourceOne exclusive distribution rights for Planmed's MaxView and mobile mammography product line in a majority of the US.

Patents:

Genzyme Issued Patent For Peptide For HER-2

Genzyme Molecular Oncology (Nasdaq: GZMO) of Framingham, Mass., said it has been issued a patent for a peptide corresponding to HER-2 for breast and ovarian cancers.

The discovery was made by Charles Nicolette, director of antigen discovery for Genzyme Molecular Oncology, using the patented SPHERE (Solid PHase Epitope REcovery) screening technology, the company said.

"The peptide is significant because it could provide the basis for an active immunotherapy that uses T-cells to attack and destroy cancer cells that overexpress the HER-2 antigen," said Gail Maderis, president of GMO.

"We have found that this class of peptides can trigger a more powerful immune response *in vitro* than the native antigen," said Nicolette. "The discovery provides for the potential development of a cancer vaccine directed at the HER-2 antigen, known to be an important tumor antigen in multiple cancer indications."

The patent covers the amino acid sequence of the peptide, the company said. A continuation application also has been filed for additional claims. Sphere is a method of identifying antigens from tumor cells, the company said.

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Oregon Health & Science University of Portland and **Novacea Inc.** of San Francisco said OHSU has been issued a patent for DN-101, a vitamin D formulation for cancer.

DN-101, a pill that contains high amounts of calcitriol, is a naturally occurring hormone and the biologically active form of vitamin D, the company said. Novacea said it has the exclusive worldwide rights to the OHSU technology for high-dose pulse administration of calcitriol and its analogs.

Both Tomasz Beer, and W. David Henner, vice president, oncology at Novacea, are the developers of calcitriol and the inventors listed on the patent, the company said. Beer, an investigator in the OHSU Cancer Institute, led the phase II/III AIPC Study of Calcitriol Enhancing Taxotere at 60 medical centers in the U.S. and Canada.

DN-101 results in much higher blood levels of calcitriol than the body can produce from dietary vitamin D or vitamin D supplements, said Novacea. The company said it will study DN-101 in multiple cancers as a monotherapy and in combination with several chemotherapeutic agents.

Novacea is collaborating with Aventis in a phase II/III ASCENT trial, the company said. The trial is evaluating DN-101 in combination with Taxotere (docetaxel) for androgen-independent prostate cancer. Novacea said it is also conducting a phase II trial of DN-101 for myelodysplastic syndrome.

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