THE CANCER LETTER

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NCI Exceeds Employment Ceilings, Must Cut Personnel In FY 2004, NIH Says

NCI will have to cut its full-time equivalent employment from 3,166 in fiscal 2003 to 3,074 for fiscal 2004, according to an internal memorandum obtained by **The Cancer Letter**.

It is not yet clear where the personnel cuts would be made. Documents show that the Office of the NCI Director has expanded over the past two years, while the rest of the Institute has remained the same.

The cuts, which are mandated by NIH, coincide with a precipitous drop in the Institute's budget growth, which has not tempered the Institute's plans for launching massive projects in bioinformatics, nanotechnology, and

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In Brief:

Brian Markison Leaving Bristol-Myers, Two Execs Promoted In Reorganization

BRIAN MARKISON, a long-time **Bristol-Myers Squibb** executive, is leaving the company "to pursue other career interests," according to a memorandum distributed by **Don Hayden**, executive vice president for the Americas. Markison spearheaded a $2 billion deal to acquire a stake in the **ImClone Systems Inc.** agent Erbitux. BMS is restructuring its operations into "a single U.S. pharmaceutical business," Hayden wrote in a memo dated Jan. 21. **Anthony Hooper** was promoted to the new position of president, **U.S. pharmaceuticals**, which includes primary care, neuroscience, oncology and virology businesses. Hooper will report to Hayden, the memo said. **Dean Mitchell** was appointed to the new position of **vice president, strategy**. He will report to **Andrew Bodnar**, senior vice president, strategy and medical & external affairs. "We will increasingly focus our customer efforts on the specialists and high-value primary care physicians who are critical to patient care in these disease areas," Hayden wrote. . . . **BRISTOL-MYERS SQUIBB FOUNDATION** awarded $4.6 million in unrestricted philanthropic research grants for AIDS, drug addiction, diabetes, cancer, and other diseases, said **PeterDolan**, chairman and CEO of BMS. The "Freedom to Discover" Grants are awarded in the six research areas of cancer, neuroscience, cardiovascular, infectious and metabolic diseases and nutrition. The ten recipients are: **Charles Sawyers**, UCLA School of Medicine; **Todd Golub,** Broad Institute of MIT and Harvard University; **Peter Tontonoz**, University of California, Los Angeles; **John Moore,** Weill Medical College of Cornell University; **Mahmoud Ghannoum,** Case Western Reserve University; **Daniel Drucker**, University of Toronto;

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Further FTE Cuts Expected Due To NIH Consolidation

(Continued from page 1)

biospecimen banking.

According to a Jan. 6 memorandum from NCI Financial Management Branch Chief Jim Dickens to NCI administrative resource center managers and the Executive Committee, the Institute would have to eliminate 92 positions this year. NIH expects the Institute to lower the FTE level to 3,066 by the end of fiscal 2005, sources said.

The Institute will have to develop a hiring plan that is acceptable to NIH to reach the FTE ceilings, or risk being put on a hiring freeze, the memo stated.

Earlier this fiscal year, NIH Director Elias Zerhouni "made a commitment to [HHS] that NIH will stay within its ceiling for FY 2004," the memo said. Zerhouni "reallocated FTE ceilings" among the Institutes and Centers to help support the NIH Road Map initiatives and to create an NIH director's reserve. NCI lost 14 FTEs to NIH as a result of that change.

NCI submitted a hiring plan to NIH last week, an NCI official said to **The Cancer Letter**. An outright "reduction in force" isn't likely, but it is not clear whether the decrease can come entirely from attrition, sources said.

NCI expects further FTE cuts this year in its extramural grants management staff as a result of an NIH consolidation under the Office of Management and Budget Circular A-76, a government-wide mandate to allow private firms to compete for federal jobs.

NIH won an A-76 competition last year and will keep control of extramural grants management support by consolidating these functions in a central service pool.

However, of the 909 NIH FTEs and contractors identified as providing clerical and administrative support, only 677 will be transferred to the new Office of Grants Support Services in the Office of Extramural Research in the NIH director's office. These employees will have to compete for their jobs at lowered pay grades. NIH employees who aren't rehired can receive training for jobs at other federal agencies. Also, NIH is offering buyouts to some employees.

The transition is scheduled to take place by April 1, but sources said NIH may need an extension. No one has been hired to direct the central unit yet. Until recently, the position was advertised at the GS14 level—too low, in the opinion of some NIH staff members, for a job of supervising 677 employees.

The position has since been upgraded to GS14/15. The annual salary for GS15 in the Washington area ranges from $83,300 to $127,400.

NCI FTEs by Division

Last summer, NCI Director Andrew von Eschenbach provided the Institute's division directors with "operational ceilings" that allowed directors to operate at five percent above the official FTE ceiling as a "kite" or "lapse" factor that takes into account delays in employee hiring and separation, the memorandum said.

That FTE model assumed "one hire for every loss," the document said. Under that plan, NCI's projected FTE usage would be 3,203 for fiscal 2004, or 129 over the official ceiling of 3,074.

In fiscal 2003, NCI exceeded its official ceiling of 3,139 full-time equivalent employees by 27 positions, according to the Jan. 6 memorandum.

"It is clear that NCI will be over the FY 2004 FTE ceiling," the memorandum said. "What we hope to demonstrate is that by submitting a reasonable plan and approach, NCI will be able to have selected hires that support our operating within the assigned FTE ceiling."

The Jan. 6 memorandum listed von Eschenbach's operational FTE ceilings for each NCI division:

Center for Cancer Research: 1,574

Div. of Cancer Epidemiology and Genetics: 140

Div. of Cancer Treatment and Diagnosis: 206

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Div. of Cancer Biology: 51

Div. of Cancer Prevention: 98

Div. of Cancer Control/Population Sciences: 143

Div. of Extramural Activities: 110

Office of Director: NCI-Frederick 10; Office of the Deputy Director for Extramural Sciences 59; Office of Management 440; Office of Communications 106; Center to Reduce Cancer Health Disparities 15; NCI Center for Bioinformatics 19; Other OD 119. Total OD: 768.

Total NCI: 3,090

It appears that von Eschenbach has added 33 FTEs to his office over the past two years. This amounts to a 4.5 percent increase, which makes the Office of the Director the second largest NCI unit, which employs nearly 25 percent of the Institute's FTEs.

The NCI FY 2002 Congressional Justification, a document submitted to appropriations committees, lists NCI's actual FTEs for FY 2002, which exactly match von Eschenbach's operational ceilings, listed above—except that in FY 2002, the director's office had just 735 FTEs.

Last year, NCI submitted a plan to Congress for FY 2004 that included 33 additional FTEs distributed over all of the Institute's divisions—not concentrated in the director's office, as the FY 2005 ceilings indicate.

In the FY 2004 Congressional Justification, NCI said it planned to use 739 FTEs in the director's office, only four more than in FY 2002. The Institute estimated it would also use 12 more FTEs in the Center for Cancer Research, 7 more in DCB, three more in DEA, two more in DCTD, one more in DCP, two more in DCCPS, and two more in DCEG. The total would be 3,090 FTEs.

NCI division directors have little say in the total allocation of the Institute's budget, sources said. The NCI director gives them their budgets, FTE allocations, and grant paylines.

Already, the divisions are under a de facto hiring freeze, sources said. When employees are replaced, the hiring process can take six to eight months through the NIH human resources office, sources said.

Civil service salaries have not kept up with compensation outside the government, sources said. However, an effort to address that problem—a special hiring program known as Title 42—has created an imbalance in salaries for similar positions.

The top salary in the Senior Executive Service is about $157,000. Experts hired under Title 42 can be paid between $130,000 to $200,000. Most new hires for leadership positions at NCI are coming in under Title 42, sources said.

Professional Societies:

ASCO To Try Another Method Of Proceedings Distribution

The American Society of Clinical Oncology is trying a new method of distribution of its books of abstracts.

The weighty volumes of "Proceedings" for the 2004 meeting will be sent out exclusively to ASCO members.

Others will be able to pick up the materials at the meeting, which will be held in New Orleans June 5-8, and on-line access to the documents will begin after the conclusion of the meeting.

The change—the third in as many years—is part of the society's efforts to balance its scientific mission with the harsh reality that findings reported in the abstracts influence the stock market.

Last year, the society refrained from mailing out the abstracts in what was described as an effort to combat the "ASCO effect," the fluctuation in the prices of stocks of biotechnology and pharmaceutical companies that begins immediately after the abstracts become available. The abstracts were kept under lock until the start of the 2003 annual meeting in Chicago.

The society first confronted the ASCO effect in 2002, when everyone who registered for the conference—more than 25,000 people—received the proceedings with an elaborate confidentiality notice (**The Cancer Letter**, April 19, 2002). That warning notwithstanding, Wall Street analysts and investors had little difficulty obtaining the abstracts, and the stocks of several biotech firms were traded heavily before the meeting.

Last year's approach of holding back distribution until the start of the meeting was abandoned because it made it difficult for ASCO members to plan their schedules, society officials said.

A survey conducted following the meeting showed that "a clear majority of respondents indicated that they prefer to review the abstracts before the meeting, and a substantial proportion said that they prefer to review the abstracts one to two weeks in advance," ASCO officials said in a recent letter to members.

The letter was dated Dec. 15 and signed by Margaret Tempero, ASCO president, and Charles Balch, executive vice president and CEO.

"Many of the ASCO members, in the scientific community in particular, felt that this interfered with their ability to get as much out of the meeting as they wanted to," Tempero said to **The Cancer Letter**. "It was our

sense that having such a restricted access to the abstract information—waiting until the meeting started—was preventing good dissemination of information among the scientists and the community oncologists."

The latest method of distribution doesn't change the embargo policy, Tempero said.

The confidentiality statement distributed with the abstracts will state that "information may not be reported on, used for trading purposes, or shared prior to presentation at the meeting."

Individuals who use the abstracts for trading are violating Securities and Exchange Commission rules, and risk prosecution, the warning states.

The SEC Regulation Fair Disclosure, which requires that publicly traded companies disclose material information to all potential investors at the same time, doesn't apply to nonprofit organizations.

"Our legal counsel—and we have an SEC expert—examined everything we are doing, and we are quite sure that ASCO policy is not in violation of the SEC fair disclosure regulation," Tempero said.

ASCO's impact on the markets was first reported by Adam Feuerstein, a reporter with TheStreet.com, a financial information service.

Last year, the practice of mailing out the abstracts was suspended at a time when SEC was "looking closely" at the practice of releasing market-moving scientific information, the professional society said (**The Cancer Letter**, Jan. 24, 2003).

At the time, ASCO said it was concerned about more than the fine points of SEC regulations.

"The perception that ASCO may be inadvertently facilitating selective disclosure, and that those with access to the abstracts may be using the information for purposes other than planning their meeting attendance, threatens to erode public trust in the scientific establishment and should be of concern to all those in the oncology community," the society said in a statement dated Jan. 17, 2003.

The society's motivation for making the latest change is not limited to the legal questions, either.

"I think the most important thing for everyone to understand is that it's all about making sure that the right information gets out," Tempero said. "The abstracts represent incomplete information, and the real spirit behind the embargo is to make sure that there is as much vetting of information as possible before it's released to the public.

"There are many times that abstracts are submitted based on preliminary data, and then the more mature data show something quite different," Tempero said.

Panel Advises NCI To Form Sarcoma Research Consortium

NCI should establish a research consortium to serve as a "focal point" for research and clinical trials on sarcomas, an advisory group told the Institute in a report last week.

In a report to the Advisory Committee to the NCI Director, the Sarcoma Progress Review Group said resources for studying the many types of sarcomas are "fragmented." Central coordination would improve multidisciplinary research and streamline the research process.

The report did not include any specific funding level for the proposed sarcoma research consortium, but suggested that funding could come from existing clinical cooperative groups, the pharmaceutical industry, and philanthropy.

Karen Antman, of Columbia University, and currently working at NCI on an intergovernmental personnel agreement, and Todd Golub, of Dana-Farber Cancer Institute, served as co-chairmen of the PRG.

The report is the 11th in a series of reports written by the PRGs in a process developed by NCI in 1997 to develop national plans for cancer research.

The full text of the report is available at: http://prg.nci.nih.gov/sarcoma/finalreport.html. Other PRG reports are available at http://planning.cancer.gov.

Excerpts of the report's Executive Summary follow:

Priority 1: Create a dedicated, sarcoma-specific organizational structure—the Sarcoma Research Consortium (SRC)—to serve as a focal point for sarcoma clinical trials and related clinical- and laboratory-based research and to enhance networks of investigators and centers committed to sarcoma research.

A unifying theme of the PRG was the need to create a new organizational structure that would maximize the delivery of state-of-the-art clinical care to sarcoma patients and facilitate the conduct of clinical- and laboratory-based sarcoma research. Therefore, the Roundtable proposed the creation of an SRC.

Implicit in the creation of the SRC is the notion that specialized expertise in sarcoma patient care and/or sarcoma research is required to move the field forward. The intent is not, however, to create a structure that is exclusive. Rather, the SRC represents an organizational umbrella that can accommodate, and indeed welcomes, participation by any investigator or center committed to sarcoma research.

SRC funding may be drawn from cooperative groups, grants, the pharmaceutical industry, and philanthropy. Centralizing the sarcoma research enterprise will streamline the research process and make the SRC attractive to funding sources.

The SRC will consist of the following:

1. A national, multidisciplinary group of investigators that provides leadership for sarcoma research A critical aspect of the SRC is the integration of clinical and laboratory investigators committed to sarcoma research. SRC leadership will include clinicians and researchers at SCEs, as well as additional leaders elected on a regular basis (e.g., every 4 years). SRC leadership positions will not be restricted to SCE members; investigators interested in sarcoma biology research who may not reside within an SCE will be encouraged to participate. Leaders will come from all relevant disciplines (e.g., surgery, medical oncology, pediatric oncology, radiation therapy, radiology, pathology, cancer biology, and patient advocacy).

The establishment of this national sarcoma leadership structure will ensure that the sarcoma research agenda receives adequate attention (which can be difficult for rare diseases within larger cooperative groups) and incorporates broad, multidisciplinary involvement of the sarcoma research community.

2. Sarcoma Centers of Excellence : SCEs will have both multidisciplinary expertise in sarcoma patient care (surgery, medical oncology, pediatric oncology, radiation therapy, pathology, and radiology) and see a sufficient number of sarcoma patients on a regular basis (> 50 patients per year). The SRC will establish criteria for an SCE and designate approximately 10 to 20 SCEs around the country. The seed money for the SCEs will come from money that is currently provided to cooperative groups for rare cancer research; funds will be augmented by money from other sources. SCEs will conduct sarcoma clinical trials and serve as clearinghouses for annotated clinical data (with associated tissue/blood/serum samples). They will work with other sarcoma researchers, advocates, and physicians to elevate the standard of care for all sarcoma patients. SCEs will provide care to as many sarcoma patients as is feasible, either in person or "virtually" through consultations and other interactions with community physicians. Using available evidence, the SRC will sanction treatment "best practices" and strongly encourage their use at SCEs.

3. A common infrastructure to support and accelerate sarcoma research. Such infrastructure would likely include the following goals:

• Establishing a centralized sarcoma tumor and tissue repository (possibly in coordination with the National Biospecimen Network). This repositioning will help rapidly achieve a "critical mass" of tissue for this collection of rare diseases, guarantee uniformity of pathological annotation, and facilitate the acquisition of material.

• Generating renewable biological resources (e.g., cell lines, animal models, antibodies, and DNA constructs).

• Generating selected data (e.g., DNA microarray data or molecular measurements in the context of clinical trials).

This task would likely be contracted to experienced laboratories, and the guiding principle would be to make such data freely available to the public as rapidly as possible. Within this framework, the SRC will take the following steps: Establish a national clinical trial agenda and oversee the conduct of such trials.

The SRC will schedule sarcoma clinical trials and assist in clinical trial design. This centralization will expedite testing of novel therapeutic approaches in this rare patient population; in addition, a more consistent approach to trial design will increase the comparability of clinical trial results. Clinical trials will continue to include both investigator-initiated and industry-sponsored trials and will be performed primarily, but not exclusively, at the SCEs. NCI Cancer Trials Support Unit members and cooperative groups will have access to these studies.

The SRC will coordinate certain aspects of the clinical trials, including (1) centralized statistical services, (2) standardized data collection methods and data storage, (3) centralized pathology review, and (4) centralized sample collection and banking. When possible, these activities will leverage existing organizations if this can be achieved in a cost-effective manner and if the results will be of sufficiently high quality.

Most patient samples will be obtained from SCEs, but a mechanism will be established whereby interested clinicians or patients can contribute available tissue material even if patients are not being treated on a clinical trial or being seen at an SCE.

A range of federal research agencies should be invited to partner scientifically and financially with the SRC to minimize the need for new infrastructure. Other potential support agencies include the National Institute of Environmental and Health Sciences, the National Institute of Allergy and Infectious Diseases, the National Institute of Diabetes & Digestive & Kidney Diseases,

the National Institute of Nursing Research, the National Institute on Aging, the Department of Veterans Affairs, the Department of Defense, the Centers for Disease Control and Prevention, the Centers for Medicare & Medicaid Services, and the Agency for Healthcare Research and Quality, and the Environmental Protection Agency. It is expected that Priorities 2-6 would be realized within the context of the SRC.

Priority 2. Fund and foster research focused on key areas of sarcoma biology most likely to advance the field. The following areas are included: the developmental biology of mesenchymal tissues, mutational targets in growth signaling pathways, downstream targets of fusion proteins, cellular checkpoints and apoptotic pathways in the sarcoma context, and immunobiology of human sarcomas.

These areas represent the major knowledge gaps in sarcoma biology; bridging these gaps will advance the field at both the basic and translational level.

A better understanding of mesenchymal developmental biology should allow for better transgenic models, help in interpretation of expression-profiling data, and identify shared mesenchymal differentiation pathways and antigens amenable to novel therapeutic approaches.

A focus on the mutational targets in growth signaling pathways should clarify the role of cooperating mutations in translocation sarcomas and may identify signaling pathways shared by diverse sarcomas.

A comprehensive analysis of fusion protein target genes will clarify the biology of translocation-associated sarcomas and may reveal common themes and pathways amenable to therapies with broad utility.

A better understanding of cellular checkpoints and apoptotic pathways in sarcomas may reveal new therapeutic targets.

Priority 3. Develop sarcoma-specific animal model systems (including new models and metastatic models). Model systems are important for both understanding the biology of cancer and identifying potential treatments, as well as diagnostic and prognostic markers. Most patients who die from sarcomas die from metastatic disease, but research in metastasis is hindered by the dearth of models specifically addressing sarcoma metastasis. Many sarcomas are hypothesized to result from fewer genetic abnormalities than many carcinomas because of the diagnosis of many sarcomas in children. Therefore, recapitulating metastatic disease in sarcoma models may be easier and more accurate than for more complex carcinoma-derived metastatic tumors. The results of investigating sarcoma metastases can be applied to other cancers.

Priority 4. Fund and foster comprehensive approaches to sarcoma profiling and target discovery. Approaches include the following:

• Comprehensive sarcoma profiling (genome, transcriptome, and proteome) to identify novel therapeutic targets, new markers for diagnosis, susceptibility, and prognosis, for prediction of treatment response and definition of intermediate endpoints.

• High-throughput screens and functional genomic approaches to identify novel therapeutic targets and critical pathways regulating sarcoma growth and survival. Because targeted screening of specific pathways is limited by current knowledge of sarcoma biology, screening (compounds, RNAi, and functional genomics) may be essential to identify novel targets associated with pathways not currently implicated in sarcomagenesis. Sarcoma profiling is currently fragmented and focuses largely on expression profiling. Global understanding of specific sarcomas remains elusive. Molecular profiling and targeted therapeutic interventions have the potential to alter the terrain of cancer research. The NCI and NIH have recognized these approaches as integral to future research and highlight them in their respective strategic plans.

Priority 5. Develop a centrally available toolkit of core reagents and access to technology platforms for sarcoma research including cell lines, model systems, annotated tissue banks, biomarkers, and imaging.

Current resources are inadequate for current or planned research endeavors. The toolkit will enable new technology to define novel and valid biomarkers, imaging, and surrogate markers to take advantage of the unique biology of sarcoma subsets and encourage rational, targeted, and timely clinical development.

Priority 6. Design prospective clinical trials whose principal objective is to compare early surrogate (intermediate) markers to conventional endpoints. Such trials should be tightly linked to appropriate tissue banking and incorporate novel statistical methodologies appropriate to sarcomas. These trials should be conducted concurrently with a series of innovative therapeutic trials.

In areas where controversy exists as to optimal therapy, a trial focused on a surrogate (intermediate) endpoint may be viewed as innovative and therefore attractive to patients and their physicians. Furthermore, successful identification of a surrogate endpoint will allow more rapid conduct of clinical trials and will be very attractive to the pharmaceutical industry.

NLST Reaches Accrual Goal

The National Lung Screening Trial has reached its goal of enrolling 50,000 current or former smokers, NCI said earlier this week.

The NCI-funded study, begun in September 2002, is a randomized, controlled trial to determine whether screening with either spiral computed tomography or chest X-ray before the appearance of symptoms can reduce deaths from lung cancer. Study participants will receive either a chest X-ray or a spiral CT once a year for three years, and their health will be monitored annually until 2009.

Further information: www.cancer.gov/nlst.

In The Cancer Centers:

Wilding Named Director, Univ. of Wisconsin Center

GEORGE WILDING was named director of the University of Wisconsin Comprehensive Cancer Center, effective immediately, said **Philip Farrell**, dean of the UW Medical School. Wilding, who is known for prostate cancer drug development, was appointed acting director of the UWCCC in November 2002 upon the resignation of **John Niederhuber**, who served as director from 1997 to 2002. Wilding served as the center's associate director for clinical research since 1998. From 1995 to 2003, he directed the center's Experimental Therapeutics Program. Wilding also is the Donald and Marilyn Anderson Professor of Medicine and head of the medical oncology section in the Department of Medicine at the UW Medical School. He is chairman of the Genitourinary Cancer Committee of the Eastern Cooperative Oncology Group, an NCI-sponsored clinical trials group. In the past year, UWCCC has won several major awards including: $7 million grant from HHS for new construction; $3 million grant from NCI and the National Institute on Aging; $5 million contract from NCI to form a consortium of five universities to conduct phase I and II trials of cancer chemopreventive agents; $10 million grant from NCI for a Center for Excellence in Cancer Communications Research. . . . **UNIVERSITY OF MIAMI Sylvester Comprehensive Cancer Center** has raised $50 million in its $137 million capital campaign, Momentum: The Campaign for the University of Miami, for the cancer center. Gifts have come from different sources, including the Sylvester family, the Papanicolaou Corps for Cancer Research, said **Joseph Rosenblatt**, scientific of UM/Sylvester. The UM School of Medicine is involved in a $700 million capital campaign, a component of the University's $1 billion *Momentum* campaign. UM/Sylvester is one of only two divisions seeking $137 million, along with the Department of Pediatrics. . . . **PHILIP ENGEL**, former president of Chicago-based CNA Insurance Companies, has been appointed chairman of the board of directors at City of Hope. Engel replaces **Jack Suzar**. **Sheri Biller**, current chairman of the board nominating committee, and **Terry Peets**, current chairman of the Development and Marketing Committee on the board, were both named vice chairs-elect. . . . **CITY OF HOPE** Cancer Center and the Tower Cancer Research Foundation announced an affiliation that will bring more clinical trials for cancer treatment to the Westside of Los Angeles. "Through the well-known expertise of Tower Cancer Research Foundation doctors, many of the hundreds of clinical trials underway at City of Hope will be available on the Westside," said **Michael Friedman**, president and CEO of City of Hope. "This relationship will benefit the community by bringing together leading cancer experts and giving patients access to new medications that may prevent, treat and cure cancers." Tower Cancer Research Foundation, founded in 1996, is a non-profit charitable organization. . . . **PENNSYLVANIA CANCER Control Consortium**, headed by the Pennsylvania Department of Health, has developed a statewide plan for cancer control that will be delivered to state lawmakers in Harrisburg. Representatives from 100 health organizations, government offices, cancer research centers and community organizations across the state participated in the five-year plan that outlines strategies in eight areas: prevention and healthy lifestyles; cancer screening and diagnostic follow-up; cancer treatment and care delivery; quality of life; access; research; and cancer-related information management and dissemination. The plan will build on the achievements of existing cancer programs; increase the number of partnerships to implement the priorities; assess the burden of cancer; identify and reduce race disparities; and use epidemiological data for an evidence-based approach to program planning and to validate plan evaluation. "By effectively harnessing the extensive expertise of Pennsylvania's nationally renowned cancer centers through close collaborations, we can, not only improve the health of Pennsylvanians, but also contribute to the state's economic vitality by increasing success in partnering with pharmaceutical and biotechnology companies," said **Ronald Herberman**, PAC3 co-chairman and director of the University of Pittsburgh Cancer Institute. . . . **CORRECTION:** Two cancer centers listed in the table titled "Cancer Centers by State (P30 Core Grants) Fiscal Year 2003," in the

Jan. 16 issue of **The Cancer Letter** should have been listed as "comprehensive" rather than "clinical" cancer centers. They were the Mayo Clinic Comprehensive Cancer Center, which regained its comprehensive status in 1998, and Vanderbilt-Ingram Cancer Center, which became comprehensive in 2000.

In Brief:

NABCO, Deciding Against Fundraising, To Close June 30

(Continued from page 1)

Florian Holsboer, Max Planck Institute of Psychiatry, Munich, **Eric Nestler,** University of Texas Southwestern Medical Center; **Kenneth Brown**, University of California, Davis; and **Sheila Innis,** University of British Columbia. . . . **NATIONAL ALLIANCE OF BREAST CANCER ORGANIZATIONS**, based in New York City, will cease operations on June 30, a decision the organization reached after a year of evaluation. NABCO was founded in 1986 by four pioneers in breast cancer advocacy: **Diane Blum, Nancy Brinker, Rose Kushner,** and **Ruth Spear**. "This organization has served as an essential catalyst for unprecedented growth in public awareness, and in the evolution of the informed medical consumer and the empowered patient," NABCO Executive Director **Amy Langer** and board president **Larry Norton** wrote in a Jan. 19 letter to the organization's supporters. "The breast cancer community has benefited greatly from nearly two decades of increasing public and private financial support, corporate involvement and media engagement. Breast cancer is now an established public cause. Competition continues to grow for resources that are limited. Given these realities, NABCO has decided not to change its individual approach and the quality of its programs, alter the scope of its mission, and shift significant time and focus to fundraising activities." The group intends to complete current projects, phase out services, and work with other organizations to "address continuing needs." Updates will be posted at www.nabco.org. . . . **CAROL KURZIG** was appointed to the new position of executive director, marketing and operations, Avon Foundation, said **Kathleen Walas**, president of the foundation and corporate social responsibility officer for Avon Products Inc. Kurzig also was elected to the foundation's Board of Directors. Kurzig will be responsible for the foundation's operations, including development of women's and breast cancer initiatives, as well as fundraising, communications, special grant programs, and event management for programs, including the Avon Walk for Breast Cancer and the Avon Breast Cancer Crusade. She was president of the New York City chapter of the National Multiple Sclerosis Society. . . . **ASCO** appointed four members to its board of directors: **George Bosl**, chairman, Department of Medicine, Memorial Sloan-Kettering Cancer Center; **Paul Bunn Jr**., director of the University of Colorado Cancer Center; **Nora Janjan**, professor, Department of Radiation Oncology, M.D. Anderson Cancer Center; and **LaSalle Leffall**, the Charles R. Drew Professor of Surgery, Howard University College of Medicine. Also, three current board members were appointed to serve second terms: **John Durant**, ASCO president in 1983-1984 and founding executive vice president from 1996-2000; **Lawrence Einhorn**, professor of medicine at the Indiana University School of Medicine and president of ASCO from 2000-2001; and **Allen Lichter**, dean of the University of Michigan Medical School. . . . **LYMPHOMA RESEARCH FOUNDATION** has awarded grants to nine institutions in the U.S. and Europe for mantle cell lymphoma, part of a $12.8 million funding initiative. The recipients are: City of Hope National Medical Center; H. Lee Moffitt Cancer Center & Research Institute; University Hospital Vienna, Austria; University Hospital Grosshadern, Germany; Instituto Nazionale Tumori, Italy; University of Nebraska Medical Center; Memorial Sloan Kettering Cancer Center; NCI; and the Cancer Institute of New Jersey. Funding for the initiative was made possible through an anonymous donation. . . . **KATHLEEN SAZAMA**, professor of laboratory medicine at The University of Texas M. D. Anderson Cancer Center, has been named president of the American Association of Blood Banks. . . . **PAUL COLUZZI** has joined VITAS Innovative Hospice Care of Orange County as medical director. Coluzzi is medical oncologist for the Breast Care and Oncology Center at The Cordelia Knott Center for Wellness in Orange County. . . . **NCI** staff changes: **Jill Bartholomew** has returned to NCI as deputy director of the new Center for Strategic Dissemination. She was on detail to the HHS Administration on Aging. She was deputy director of the NCI Office of Communications. Prior to joining NCI, she worked in the White House Office of National Drug Control Policy to begin the National Youth Anti-Drug Media Campaign. She also was director of the Armed Forces Military Recruitment Advertising and Market Research. **Lenora Johnson** was appointed director of the NCI Office of Education and Special Initiatives. She served as acting director of the office for the past year.

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Business & Regulatory Report

Product Approvals & Applications:

FDA Approves Eloxatin For First-Line Treatment of Advanced Colorectal Cancer

Sanofi-Synthelabo of Paris said Eloxatin (oxaliplatin for injection) in combination with 5-FU/LV has been approved by FDA for the first-line treatment of advanced colorectal cancer.

The treatment first received US approval in 2002 for second-line treatment of metastatic carcinoma of the colon or rectum. The data show that Eloxatin given in combination with 5-FU/LV as first-line therapy had a statistically significant improvement of nearly five months in median survival time compared treatment with a standard treatment of irinotecan

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Clinical Trials:

Abgenix, Amgen Begin Trial of ABX-EFG As Third-Line Therapy for Colorectal Cancer

Abgenix Inc. (Nasdaq: ABGX) of Fremont, Calif., and partner **Amgen Inc.** (Nasdaq: AMGN) of Thousand Oaks, Calif., said they have begun a trial of ABX-EGF, a fully human monoclonal antibody as a third-line monotherapy for colorectal cancer.

The trial follows the receipt of a special protocol assessment letter from FDA, which endorses the design of the trial to support a regulatory submission for an accelerated approval, the company said. ABX-EGF targets the epidermal growth factor receptor, which is expressed in cancers including lung, breast, pancreatic, bladder, prostate, colorectal, kidney and head and neck cancers, the company said.

Clinical studies to date have demonstrated single-agent activity and a favorable pharmacokinetic and tolerability profile, the company said.

* * *

Celsion Corp. (AMEX: CLN) of Columbia, Md., said it would begin a phase I trial of ThermoDox for liver cancer at the NIH Clinical Center.

The treatment is a proprietary temperature sensitive liposomal formulation, which encapsulates doxorubicin, the company said. Celsion said it had filed an Investigational New Drug application for the treatment with FDA late last year.

The trial would determine the maximum safely tolerated dose of ThermoDox when used in combination with radiofrequency ablation in the treatment of liver cancer, the company said. The approach would utilize the ablation zone of RFA (80 degrees C or above) to ablate the center of the tumor and the associated extended low temperature zone in

(Continued to page 3)

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Sanofi To Seek US Approval Of Eloxatin As Adjuvant

(Continued from page 1)

in combination with 5-FU/LV, the company said.

In a related development, Sanofi said it is seeking U.S. approval for Eloxatin as an adjuvant treatment of colon cancer. The company has submitted a supplemental New Drug Application with FDA, and an extension of indication in Europe, with France as Reference Member State.

"The major reduction in disease recurrence obtained with Eloxatin in the adjuvant setting will significantly impact the treatment of early stages of the disease, especially the ones with lymph nodes involvement," said Aimery De Gramont, head on the oncology division at Saint-Antoine Hospital, Paris.

Efficacy results of the multicenter international study of Oxaliplatin/5-FU/LV in the Adjuvant Treatment of Colon Cancer (MOSAIC) showed that the addition of Eloxatin to the standard post-operative chemotherapy (5FU/LV) for colon cancer, reduces the risk of recurrence by 23 percent ($p<0.01$) at three years after surgery for a primary tumor, the company said.

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Aphton (Nasdaq: APHT) of Miami said it has begun submission of regulatory documentation to the Australian Therapeutic Goods Administration for G17DT as monotherapy for advanced pancreatic cancer where chemotherapy is not elected or not tolerated.

"Many patients either cannot tolerate or elect not to take chemotherapy for their disease, since it adds only a relatively small clinical benefit at a cost of significant side-effects," said Patrick Mooney, chief medical officer at Aphton. "We believe that G17DT is a safe, targeted biological with negligible systemic side effects and that it is an effective alternative."

G17DT induces antibodies that bind to both gastrin 17 and gly-gastrin and removes them from circulation before they bind to the cancer cell and initiate cell growth, the company said. Gastrin 17 and gly-gastrin are believed to be central growth factors, or the initiating signals, for cell growth, cell proliferation and metastasis, in pancreatic, gastric, esophageal, colorectal and other gastrointestinal system cancers.

Recent findings have shown that inhibiting gastrin inhibits cell growth, proliferation and metastasis, leading to apoptosis, the company said. Gastrin also stimulates the secretion and expression of other growth factors and receptors within and on the surfaces of the cancer cells involved in tumor growth.

* * *

GP Strategies (NYSE: GPX) of New York said **Valera Pharmaceuticals,** formerly Hydro Med Sciences, a 31-percent-owned investment of GP Strategies, has submitted a New Drug Application to FDA for Vantas, a long-acting LHRH implant for prostate cancer.

By using the Valera Hydron Implant technology, Vantas has been designed for the continuous 12-month administration of Histrelin, a luteinizing hormone releasing hormone for the palliative treatment of metastatic prostate cancer, the company said.

The implant technology utilizes proprietary blends of hydrogel polymers, the same technology that originally led to the formulation of soft contact lenses, the company said. In addition to providing for the administration of small amounts of therapeutics at a controlled rate for up to a year or more, the technology platform allows for the formulation of compact, light weight, flexible and retrievable subcutaneous implants that can be inserted in a physician's office with a local anesthetic.

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OSI Pharmaceuticals Inc. (Nasdaq: OSIP) of Melville, N.Y., said it has initiated the rolling

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submission of an NDA with FDA for Tarceva (erlotinib HCl) for incurable stage IIIB/IV non-small cell lung cancer where standard therapy for advanced or metastatic disease has failed.

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

* * *

Varian Medical Systems Inc. (NYSE: VAR) of Palo Alto, Calif., said it has received FDA 510(k) clearance for its 3-D cone-beam computed tomography imaging system for tumors and surrounding anatomy.

Varian said it has integrated its Acuity image system with its software for image management and treatment planning, making it easy for doctors to review, verify, and finalize treatment plans.

"3-D imaging will make it possible for clinicians to achieve better outcomes by sparing more healthy tissue while concentrating more cancer-killing radiation within targeted tumors," said Timothy Guertin, president of oncology systems business at Varian. "Adding a cone-beam CT capability to our Acuity system improves the effectiveness of radiation therapy technologies."

The Acuity system 3-D cone-beam imaging also will be used for brachytherapy treatment planning and to guide the placement of catheters and seeds, the company said.

Clinical Trials:

Celsion Begins Phase I Trial Of Treatment for Liver Cancer

(Continued from page 1)

the tumor margins to activate and release the doxorubicin to kill viable cancer cells in the tumor margins.

"We believe that the mechanism of action of RFA in conjunction with ThermoDox, using heat sensitive nanoparticles to target cytotoxic drugs could result in high concentrations of the drug in the tumor," said Augustine Cheung, president and CEO of Celsion.

The data on the preclinical work by Bradford Wood, senior clinical investigator, Diagnostic Radiology Department, Imaging Sciences Program, NIH Clinical Center; Surgery Branch, NCI demonstrated ThermoDox used in this manner deposited two to four times more doxorubicin than conventional drug delivery.

The IND for of ThermoDox addresses unmet medical needs, including primary liver cancer, recurrent liver cancer and metastases to the liver, the company said.

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Cytheris of Vanves, France, and Rockville, Md., said it has begun a phase I trial of CYT 99 007, a recombinant human Interleukin-7 developed by Cytheris. This cytokine targets the immune reconstitution of immuno-compromised patients, undergoing cancer treatment, affected by AIDS, or recovering from a bone marrow transplant.

The first phase I trial is being performed in Bethesda in cooperation with NCI investigators, the company said. The trial, would evaluate the safety, the immune effects and surrogate markers of clinical activity, according to a classical dose escalation design, the company said.

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Light Sciences Corp. of Seattle said enrollment has begun at four sites to assess Litx, a next generation photodynamic therapy platform, in combination with the drug talaporfin sodium (LS11) refractory colorectal liver metastases.

Three sites in the U.S. include HealthOne Alliance/Presbyterian St. Lukes Medical Center, Denver; University of Pennsylvania Oncology, Philadelphia; Allegheny General Hospital, Pittsburgh, the company said. The fourth site will be in Germany, at the University Hospital Frankfurt, Johann Wolfgang Goethe-University.

The Litx Oncology trial protocol was developed by Jay Winship, chief medical officer, Light Sciences and James Chen, chief scientific and technology officer, Light Sciences, with input from Robert Lustig, clinical professor and associate chairman for clinical research of radiation oncology, University of Pennsylvania Cancer Center; Vincent DeVita, professor of medicine, Yale University Cancer Center; and Daniel Von Hoff, director of the Arizona Health Sciences Center Cancer Therapeutics Program at the University of Arizona, the company said.

* * *

Novacea Inc. of South San Francisco said it is stopping enrollment in a clinical trial DN-101, a single agent in myelodysplastic syndromes.

The company made the decision in keeping with the protocol's early stop rule, which stipulated a no go if fewer than five of the first 15 evaluable patients

achieved a response, the company said. While DN-101 was shown to be well tolerated in these patients, only two demonstrated a response of the 15 evaluated for the early stop rule.

"Novacea will continue developing DN-101 for our primary indications in solid tumors," said Brad Goodwin, CEO at Novacea. "We have seen encouraging results in earlier studies with the DN-101 active ingredient, calcitriol, and chemotherapy and have clinical trials ongoing with DN-101 and Taxotere in prostate and non-small cell lung cancers."

Novacea said it has reached target patient enrollment in its phase II/III trial of DN-101 and Taxotere (docetaxel) in advanced prostate cancer. Earlier studies demonstrated that calcitriol, enhances the effects of Taxotere in treating certain solid tumors, including prostate cancer, demonstrating as much as twice the activity based on PSA levels versus Taxotere alone, with severe toxicity similar to that reported for Taxotere alone. The DN-101/ Taxotere combination is also being studied in a phase I/II trial in non-small cell lung cancer, the company said.

DN-101 is a newly formulated pill that contains high amounts of calcitriol, a naturally occurring hormone and the biologically active form of vitamin D. DN-101 results in much higher blood levels of calcitriol than the body can produce from dietary vitamin D or vitamin D supplements. In high doses, calcitriol is synergistic with many commonly used chemotherapeutic agents, producing anti-tumor activity as measured in laboratory and animal models, the company said.

Novacea is a privately-held biopharmaceutical company.

* * *

ILEX Oncology Inc. (Nasdaq: ILXO) of San Antonio said the NCI phase III placebo-controlled trial of its investigational agent eflornithine (DFMO), for superficial bladder cancer, did not prevent the recurrence of cancer more so than placebo and that the trial has been discontinued.

The findings of an independent data monitoring board determined that no statistical significance among the treatment arms was observed, the company said.

NCI is continuing to study the agent in a number of clinical settings, the company said.

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Pro-Pharmaceuticals Inc. (Amex: PRW) of Newton, Mass., said it has begun a phase II study of Davanat with 5-fluorouracil for refractory colorectal cancer.

The trial is part of a multi-center, open-label, single dose level study for metastatic colorectal cancer where standard surgical, radiation and chemotherapeutic regimens have failed, the company said. The study will evaluate the efficacy and safety of intravenous Davanat in combination with 5-FU when administered in monthly cycles as third-line therapy for metastatic colorectal cancer. Concurrent with the phase II study, enrollment continues in a phase I trial, the company said.

Davanat, a carbohydrate technology, targets sugar-specific binding sites on cancer cells to improve the efficacy and reduce toxicity of chemotherapy drugs, the company said.

Cancer centers participating in the ongoing phase I trial include Norris Cotton Cancer Center at Dartmouth-Hitchcock Medical Center in Lebanon, NH, Comprehensive Cancer Center at the University of Michigan in Ann Arbor, Ochsner Cancer Institute in New Orleans, Florida Oncology Associates in Jacksonville.

In preclinical studies, the technology improved the effectiveness of 5-FU, while reducing its toxicity, the company said.

Deals & Collaborations:

Eli Lilly Enters Collaboration With Cellular Genomics Inc.

Cellular Genomics Inc., a privately held company based in Branford, Conn., said it has entered into a research collaboration with **Eli Lilly and Co.**, under which it would apply its chemical genetics Analog Sensitive Kinase Allele technology to study kinase drug targets selected by Lilly.

ASKAs are genetically modified kinases that retain all the functions of normal kinases, but can be inhibited with selectivity and specificity by a specially designed proprietary small molecule analog inhibitor, the company said. This promotes the understanding of the pharmacological consequences of kinase inhibition and, therefore, the likely therapeutic benefit of inhibiting the normal kinase target with a small molecule drug. CGI holds the exclusive worldwide license to the chemical genetics technology.

These include: cell pathway based target identification; pharmaceutically relevant in vivo target validation; proprietary high-content cell-based drug screens; and in vivo systems that provide therapeutic

index and drug safety information to guide the selection of optimal drug candidates for clinical development, the company said.

Under the agreement, CGI will use its ASKA technology to generate modified kinases for Lilly. The CGI P-inhibitor technology will be utilized to design and validate cell-based assays specific for the kinases of interest to Lilly, which could accelerate lead identification efforts against the kinase targets.

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BioStratum Inc., of Research Triangle Park, N.C., said it has signed a global research, development and marketing agreement with **Novo Nordisk A/S**.

Under the agreement, the companies said they would develop monoclonal antibodies against laminin-5 for the cancer.

Laminin-5 is a basal lamina protein that mediates the binding of specific cell types to the extracellular matrix, the company said.

Karl Tryggvason, a founding scientist of BioStratum and chairman of the Department of Medical Biochemistry and Biophysics at the Karolinska Institute, Sweden, discovered that laminin-5 is utilized by invasive tumors to promote tumor migration and metastasis through the extracellular matrix. In subsequent studies, the level of laminin-5 expression was shown to correlate with the invasive potential and clinical aggressiveness of certain tumor types, such as cervical, laryngeal and colorectal cancer, the company said.

Monoclonal antibodies developed by BioStratum have been shown to inhibit the migration of laminin-5-producing tumor cells through the extracellular matrix, and to inhibit tumor growth in various animal models of cancer, the company said.

Under the agreement, BioStratum has granted to Novo Nordisk the exclusive right to develop and market monoclonal antibodies that bind to laminin-5. The companies will jointly conduct a research program to be funded by Novo Nordisk. In addition to research funding, BioStratum would receive milestones of $80 million, as well as royalties on product sales, for each antibody.

* * *

Cetek Corp. of Marlborough, Mass., and **M. D. Anderson Cancer Center** signed a collaborative agreement to discover and develop drugs targeting cancer and inflammatory diseases.

Cetek will utilize its natural product technologies including the CE Assay to identify and isolate drug-like compounds, the companies said. The two interests will work together to develop the compounds further.

"M. D. Anderson is excited to advance natural product drug discovery using the Cetek novel technology platform," said Moshe Talpaz, chairman, Department of Bioimmunotherapy. "This is an excellent complement between a research institute and a leading biotech company to discover new compounds from this established source of anti-cancer and anti-inflammatory compounds."

* * *

Cytyc Corp. (Nasdaq: CYTC) of Boxborough, Mass., and **AmeriPath Inc**. of Riviera Beach, Fla., said they have entered into a purchase agreement to place the Cytyc ThinPrep Imaging Systems in the AmeriPath anatomical pathology laboratories.

Under the agreement ThinPrep Imaging Systems will be installed n two AmeriPath evaluation centers in Florida and Colorado, the companies said. The agreement extends the AmeriPath contract with Cytyc for the ThinPrep Pap Test through the end of 2006.

The ThinPrep Imaging System is an integrated, interactive computer system that assists cytotechnologists and pathologists in the primary screening and diagnosis of ThinPrep Pap Test slides, the company said.

In another development, Cytyc and **Abbott Labs.** (NYSE: ABT) of Abbott Park, Ill., said they have entered into a co-promotion agreement to develop and market ThinPrep UroCyte Slide Preparation System.

Efforts will focus on modifying the Cytyc proprietary ThinPrep sample preparation technology in conjunction with UroVysion, a DNA probe-based test for detection of bladder cancer recurrence. Both companies will promote the system following completion and regulatory clearance of the co-developed product, the companies said.

The UroVysion Bladder Cancer Recurrence Kit is an FDA-cleared molecular urine cytology test that uses DNA probes to identify chromosomal abnormalities where bladder cancer has been diagnosed.

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Chemicon International Inc. of Temecula, Calif., a division of Serologicals Corp. (NASDAQ: SERO) of Atlanta said it has entered into an exclusive licensing agreement with **Myriad Genetics Inc.** for the research use of the Myriad proprietary tumor suppressor and breast cancer susceptibility proteins and antibodies.

The patented targets licensed to Chemicon are referred to as BRCA1, BRCA2, p16, p15, and p14, which are used to study human malignancies, the company said. BRCA1 and BRCA2 are two major cancer susceptibility genes expressed in a high percentage of breast and ovarian cancers and cell lines. Cyclin-dependent kinase inhibitors p16, p15 and p14 act as tumor suppressor genes and are deleted or mutated in tumors.

Under the agreement, Chemicon said it obtains intellectual property in the research field of use. The agreement excludes commercial therapeutic and diagnostic rights and rights to fields of use that Chemicon does not serve.

"Our agreement with Myriad Genetics strengthens our commitment to provide the research community with enabling technologies, as well as the finest products needed to facilitate advances in the study of functional genomics and proteomics," said Jeffrey Linton, president of Chemicon.

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Cleveland Clinic and **Ricerca Biosciences** of Concord, Ohio, are collaborating on a targeted drug therapy that uses cobalamin, or vitamin B12, as the carrier of a cancer-killing agent.

Ricerca and Cleveland Clinic said they will conduct pre-clinical testing and toxicology studies of the vitamin B12 compound and prepare documentation for approval from FDA for a phase I trial.

Development of the compound is based on the work of Joseph Bauer and Daniel Lindner, of the Clinic Cancer Drug Discovery and Development Group, Cleveland Clinic Taussig Cancer Center. Bauer and Lindner have developed a modified cobalamin compound, nitrosylcobalamin (NO-Cbl), that preferentially targets cancer cells.

The drug takes advantage of the higher need for vitamin B12, by attaching nitric oxide to the B12 molecule, the interests said. Once the nitric oxide is released, apoptosis occurs.

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Enzon Pharmaceuticals Inc. (Nasdaq: ENZN) of Bridgewater, N.J., and **Inex Pharmaceuticals Corp.** (TSX: IEX) of Vancouver, Canada, said they have formed a strategic partnership to develop and commercialize the Inex proprietary oncology product Onco TCS.

Under the agreement, Enzon receives the exclusive North American commercialization rights for Onco TCS for all indications, the company said. The lead indication is relapsed aggressive non-Hodgkin's lymphoma for which Inex is submitting a rolling new drug application to FDA. The product is also in phase II trials for other cancer indications, including first-line NHL, the company said.

Inex receives a $12 million up-front payment and will receive up to a $20 million payment upon approval of the drug, the company said. Additional development milestones and sales based bonus payments could total $43.75 million, of which $10 million is payable upon annual sales first reaching $125 million and $15 million is payable upon annual sales first reaching $250 million. Inex will also receive a percentage of commercial sales of Onco TCS, which would increase as sales reach predetermined thresholds.

Inex said it has the option of complementing the Enzon sales efforts by co-promoting the product through the formation of a dedicated North American sales and medical science liaison force, the company said. The costs of building the co-promotion force would be shared equally and Enzon would record all sales in the licensed territories.

Enzon and Inex will share the future development costs for marketing approvals in North America, while Enzon will pay all sales and marketing costs and post-approval clinical development costs associated with commercialization activities.

Inex said it retains manufacturing rights and will manufacture and supply the drug and be reimbursed by Enzon.

Onco TCS is a proprietary drug comprised of the off-patent cancer drug vincristine encapsulated in the Inex TCS (liposomal) drug delivery technology.

The completed phase II/III multi-center trial of 119 NHL patients who had not responded to previous therapy or had responded and subsequently relapsed demonstrated overall response rate of 25 percent after treatment with the agent, the company said.

Inex said it has submitted two major sections of its rolling NDA to FDA seeking marketing approval of the agent for relapsed aggressive NHL.

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Helsinn Healthcare SA, of Lugano, Switzerland, and **TAIHO Pharmaceutical Co., LTD,** said they have entered into an exclusive license and distribution agreement under which Taiho acquires the rights to develop and commercialize palonosetron in Japan for nausea and vomiting after chemotherapy.

In the U.S., palonosetron is marketed under the trade name Aloxi by MGI Pharma for acute or delayed nausea and vomiting associated with initial and repeat

courses of moderately and highly emetogenic cancer chemotherapy, the companies said. The product is under regulatory review in Europe where it will be marketed by Italfarmaco in Italy and Spain under the trade name Onicita. In Korea the product will be marketed by CJ Corp.

Palonosetron hydrochloride is a selective 5-HT3 receptor antagonist with binding affinity and an extended plasma half-life of 40 hours, the companies said. Results from phase III trials demonstrate a single intravenous dose of palonosetron is effective in preventing both acute and delayed CINV for moderately emetogenic chemotherapy.

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Incyte Corp. (Nasdaq: INCY) of Palo Alto said it has signed a license agreement with **Roche Diagnostics** of Basel, Switzerland, for the Incyte Eberwine Linear RNA Amplification technology.

Roche said it would use the technology for diagnostics that identify gene expression patterns of diseases or disease subtypes.

The Incyte T7-based linear amplification, a method for RNA amplification, was developed by Van Gelder, Eberwine and co-workers, the company said. The method was published for comparisons of RNA transcripts from normal and diseased tissues or cells, including cancer cells. The method requires small starting amounts of RNA and replicates RNA in a linear fashion, maintaining the relative expression level for each of the genes found in the original sample, the company said.

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Infinity Pharmaceuticals Inc. of Cambridge, Mass., said it has entered into a collaborative agreement with **Amgen Inc**. to identify small molecule therapeutic agents.

Infinity said it would provide Amgen with non-exclusive access to a proprietary collection of small molecules for a three-year period during which time Amgen may screen against multiple targets and perform chemistry to identify small molecule drug leads.

Under the agreement, Amgen made a $25 million equity investment in Infinity, after which Amgen will own less than 15 percent of the company. During the three-year term of the collaboration, Amgen will make additional payments, which may include success-based payments and research funding. Infinity is eligible to receive milestones and royalties based on successful pre-clinical and clinical development and marketing of certain products resulting from the Amgen use of the Infinity compounds.

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Morphotek Inc. of Exton, Penn., said it has signed a Cooperative Research and Development Agreement with **NCI** to develop therapeutic antibodies to a cancer-associated protein identified by researchers at NCI.

Morphotek said it would apply its proprietary Morphodoma antibody technology to develop antibodies for pancreatic, ovarian and lung cancers. NCI will provide its expertise in characterizing and evaluating the lead antibodies for specificity and therapeutic efficacy.

"The NCI brings expertise in the evaluation and validation of lead antibodies to cancer-specific proprietary targets, while the Morphodoma antibody technology will provide the rapid creation of antibodies and attendant high-titer cell lines for scaleable manufacturing," said Nicholas Nicolaides, president and CEO of Morphotek.

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Nucletron B.V. of Veenendall, Netherlands, said it has signed a letter of intent with **RaySearch Labs. AB** for the integration and licensing of the RaySearch Intensity Modulated Radiation Therapy optimization software.

The agreement will allow Nucletron to integrate the RaySearch ORBIT optimization modules and future developments as part of its Oncentra Treatment Planning software, the company said.

IMRT cancer treatment allows higher radiation doses to be delivered to a tumor while reducing side effects in healthy tissue, the company said. Planning for IMRT requires optimization methods that tailor treatments to individual anatomy.

Oncentra Treatment Planning is the latest generation planning system and is a component of the Oncentra Information Management suite of products, the company said. The combination of the OTP advanced multi-modality image handling, contouring and radiation dose algorithms with ORBIT IMRT optimization will provide users with functionality and performance, the company said.

Nucletron B.V. is a subsidiary of Delft Instruments N.V.

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R2 Technology Inc. of Chicago said it has entered into a licensing agreement with the **University of Chicago Medical Center**, to develop a mammographic CAD workstation reference library for early breast cancer detection.

The investigational CAD reference library contains a database of both malignant and benign lesions, which radiologists can access for clinical comparison and relevancy, the company said.

"The University of Chicago has researched computer-aided detection and diagnosis for mammography for many years," said Maryellen Giger, professor of radiology at the University of Chicago. "Our group was one of the first to bring computer-assisted reading into the clinical arena nearly a decade ago, and we remain excited about the potential for computer-aided detection and diagnosis to improve mammography."

Clinical trials demonstrated that use of the ImageChecker CAD system could result in earlier detection of up to 23.4 percent of the cancers currently detected with screening mammography in those women who had a prior screening mammogram nine-24 months earlier, the company said.

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Seattle Genetics Inc. (Nasdaq: SGEN) of Bothell, Wash., said **Protein Design Labs Inc.** (Nasdaq: PDLI) has exercised an option for an exclusive license to an antigen target under their antibody-drug conjugate collaboration, triggering a payment to Seattle Genetics.

The collaboration between the companies was formed in June 2001 with Eos Biotechnology, and assumed by PDL in 2003 in its acquisition of Eos.

Under the collaboration, PDL has a license to use the Seattle Genetics ADC technology with antibodies against targets selected by PDL. PDL pays ongoing technology access and material supply fees and has agreed to pay progress-dependent milestone payments and royalties on net sales of any resulting ADC products. PDL is responsible for research, product development, manufacturing and commercialization of any products resulting from the collaboration.

ADCs utilize the targeting ability of monoclonal antibodies to deliver cell-killing payloads to specific cells, the company said. Seattle Genetics said it has developed improved ADC technology employing synthetic drugs that can be attached to antibodies through proprietary linker systems.

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SGX of San Diego and **UroGene S.A.**, of Evry, France, formed a joint research and development collaboration for small molecule inhibitors against urological cancer kinase targets.

The SGX Fragments of Active Structures lead discovery technology will be combined with the UroGene expertise in target validation and clinical studies for bladder cancer. SGX will have exclusive commercialization rights in North America to drugs developed under the collaboration, while UroGene will have exclusive commercialization rights within Europe.

Oncology Management:

MSKCC To Upgrade Eclipsys System For E-Records

Eclipsys Corp. (Nasdaq: ECLP) of Boca Raton, Fla., said **Memorial Sloan-Kettering Cancer Center** will use its SunriseXA clinical solution and workflow modules.

Memorial will upgrade to SunriseXA from Eclipsys' Sunrise Clinical Manager for a complete, organization-wide electronic medical record that integrates ambulatory and acute care settings, at a lower total cost of ownership, the company said. SunriseXA gives physicians and nurses immediate, secure access to medical content and patient information.

Memorial has used the Sunrise Clinical Manager in the ambulatory environment since 1999 for an automated, paperless system, the company said. The center processes 8,000+ orders daily and has deployed over 1,000 customized order sets for oncology-related treatments, the company said.

"One very important aspect to our selection is the Eclipsys desire and ability to work with us to configure the system to create advanced chemotherapy orders," said Patricia Skarulis, chief information officer at Memorial. "This provides an extraordinary patient safety benefit for the center.

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Sentillion Inc. of Andover, Mass., said **Fox Chase Cancer Center** has purchased its Vergence product suite, for single sign-on and single patient selection services between its caregiver portal, Siemens applications, and self-developed medical research and clinical data bases and applications.

The Vergence software will also ensure authentication and HIPAA privacy auditing across all applications, the company said.

"Fox Chase plans to link its clinicians and patients through a portal methodology that will allow our caregivers to deliver timely and comprehensive care using state of the art technology," said Frank Manion, CTO at Fox Chase.

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