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Medicare Increases Cancer Infusion Fees, Begins Side Effects Demonstration Project

By Paul Goldberg

The decrease in payments to oncologists will not be as severe as originally forecast, the Centers for Medicare and Medicaid Services announced Nov. 3.

According to the worst-case analysis of an earlier version of reimbursement schedules proposed by CMS, about $500 million would have been taken out of the system starting next year.

However, following intensive lobbying by oncology organizations, the agency increased payments for infusion and launched a one-year

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In Brief:

UC Davis Wins Clinical Research Center Grant; CDC Awards DFCI $3 Million For Prevention

UNIVERSITY OF CALIFORNIA, DAVIS received a five-year, $5.5 million award from the National Center for Research Resources of NIH for a General Clinical Research Center at the Sacramento Veterans Affairs Medical Center. **Lars Berglund,** professor of medicine and assistant dean for clinical research at the UC Davis School of Medicine and a physician at VANCHCS, is program director of the GCRC. The award will support operating expenses, hospitalization and ancillary laboratory costs, and salaries of key personnel. The Sacramento GCRC will focus on areas of clinical research including AIDS, cancer, vascular biology, bone metabolism, and neuroscience. Proposed clinical trials include a study of mucosal immunity, an issue in HIV vaccine development; research into a newly identified neurodegenerative disorder that strikes males over 50 who possess the fragile X mental retardation 1 (FMR1) gene; and a test of the effectiveness of isoflavone-rich soy extract in protecting the bones of postmenopausal women. UC Davis Health System and the Veterans Affairs Northern California Health Care System, which have been affiliated since 1974, have been developing the necessary infrastructure for the GCRC since March 2000, said NCRR Director **Judith Vaitukaitis**. The 7,500 square foot state-of-the-art clinical research unit, lab and administrative space will be managed and administered by UC Davis faculty and staff. . . . **DANA-FARBER Cancer Institute** received two grants totaling $3 million from the Center for Disease Control and Prevention to develop workplace-based health promotion and prevention programs. The grants will support studies examining smoking behaviors, smoking cessation, job hazards, and obesity for workers in cooperation with the Massachusetts apprenticeship

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Payment Cuts To Oncologists To Be Less Severe, ASCO Says

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"demonstration project" that will pay doctors to assess the side effects of chemotherapy. According to an estimate by the American Society of Clinical Oncology, the cuts would now total $200 million.

The Medicare "final rule" that established the physician fee schedules for 2005 was better for oncologists than its earlier, interim version, said Joseph Bailes, co-chairman of ASCO's government relations committee.

"CMS has done something very positive in recognizing that the services that we feel are essential--such as treatment of nausea, vomiting, pain, and fatigue—are important, and has provided resources for that," Bailes said.

The magnitude of the cuts is a matter of dueling assumptions.

Using CMS numbers, and assuming no change in utilization of drugs and services, ASCO maintains that Medicare funds to support chemotherapy would drop by 30 percent from 2004 to 2005. Under an earlier version of the proposal, the decline would have been 50 percent, ASCO estimates.

Relying on historical data, CMS assumes that there would be an increase in use of oncology drugs and services, which would add up to an 8 percent increase in total payments to oncologists.

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According to ASCO's model, increased payments for infusion will add $110 million into the system, and the demonstration project will contribute another $190 million.

"These are very, very rough estimates," Bailes said. "We are still analyzing this."

For years, office-based oncologists have argued that they were underpaid for the services they provided, and that Medicare made up for that shortfall by letting them earn additional revenues by using a formula based on the "average wholesale price" of drugs they administer.

Congress and CMS attempted to cut the markup on drugs and increase payments for patient care, but oncologists argued that the new reimbursement formula was unrealistic and would force many practices out of business.

Starting Jan. 1, 2005, oncologists will be reimbursed for drugs at the rate based on "average sales price" of drugs plus six percent. The agency has collected ASP data for the first two quarters of 2004, and third-quarter data are currently being collected.

"We don't have the final ASP data, and we don't know what utilization will be like in 2005," Bailes said. On Jan. 1, 2005, reimbursement will be based on ASP data from the third quarter of 2004.

Oncologists have said that some practices may be unable to obtain drugs at prices approaching ASP. However, in a telephone conference earlier this week, CMS officials said they planned to help oncologists find drug wholesalers who sell drugs at acceptable prices.

Demonstration Project to Pay $130 per Visit

The CMS demonstration project would make control of side effects of chemotherapy a moneymaker for oncologists.

Physicians will be able to bill up to $130 per encounter for assessing pain control, nausea and vomiting, and fatigue in their patients.

According to an announcement made by CMS on Nov. 1, literally on the eve of the election, physicians would determine the patients' status by asking questions at the start of each chemotherapy session.

The agency said it would "collect data based on these assessments and on subsequent treatments to trace improvement in outcomes." Collected data would measure patient function and impact on the number of hospitalizations or emergency department visits.

"These steps may also help reduce the overall costs of cancer care, by avoiding hospitalizations with complications," the agency said. "In particular, clinicians

armed with appropriate assessments can intervene to reduce some of the unpleasant and frequent side-effects that often accompany cancer and chemotherapy treatment."

CMS officials said they designed the demonstration project with the help of ASCO and the National Coalition for Cancer Survivorship.

The project would give oncologists added incentives to monitor some of the more distressing side effects of treatment, said Ellen Stovall, president and CEO of NCCS.

"Whenever you are asked to report on something, it makes you much more conscious about what you are doing," Stovall said. "It's a little more than just checking off the box, because it's attached to a reward for doing the right thing. This is a very positive first step toward bringing balanced reform to oncology practice by emphasizing that quality cancer care is more than giving chemotherapy—it is also about assuring patients can enjoy a better quality of life while undergoing treatment."

The project is open to any health care provider who administers chemotherapy. By billing the designated codes, the practitioner in effect self-enrolls in the project.

"We are moving aggressively to provide more up-to-date, higher quality care for cancer patients on Medicare," CMS Administrator Mark McClellan said in a statement. "Seniors will have faster access to innovative cancer treatments that clearly work, and they will have better support for care that addresses the pain, nausea and fatigue that cancer patients too often face."

It's unclear how the demonstration project would be structured or evaluated. CMS officials said the data would be collected through the normal billing process and accumulated in the agency's internal claims database.

"I think the purpose of this is to recognize services that have certainly been important to patient advocacy groups and that we feel are essential, and that's management of symptoms, and these have not been traditionally specially recognized," said Bailes. "I think CMS's purpose here is to recognize these."

If the project is judged successful, monitoring side effects could become part of the agency's policy, Bailes said.

"If the projects collects the data and improves the quality of care, I think it's consistent with their philosophy of paying for those services," Bailes said. "A lot of it depends on how well it actually works."

The demonstration project may be controversial in part because patients or their insurance companies would be responsible for making co-payments for this service.

Logistics, too, could be a problem. Since development of the agency's CPT code book for 2005 was well underway at the time CMC was revising infusion codes and designing the demonstration project, the agency has introduced separate billing codes, called G-codes, to reflect these changes.

It remains to be seen how private insurers will choose to reimburse co--payments for services billed under these new codes, insiders said.

Drug Payment For Colon Cancer Trials

In related developments, CMS decided to cover off-label uses of approved colorectal cancer drugs in clinical trials and allowed a broader use of positron emission tomography (PET) scans.

The decision to cover off-label uses of colorectal cancer drugs is limited to nine clinical trials sponsored by NCI.

The drugs include Eloxatin (oxaliplatin), Camptosar (irinotecan), Avastin (bevacizumab), and Erbutux (cetusimab). Separately, CMS is proceeding with a "national coverage analysis" of these expensive new therapies.

Usually, drug companies provide investigational agents free of charge for use in clinical trials, and Medicare carriers often pay for drugs administered in such settings, observers said.

However, coverage can be useful when companies are unwilling to supply agents at no charge, which can happen when an approved drug is administered to a control group, or when the drug company is for whatever reason reluctant to ask a scientific question about its drug.

Medicare will pay for PET scans for cervical cancer, and for studies of PET for diagnosis and staging involving a broad range of additional types of cancer.

The proposed expansion in coverage for PET scans would make this test available for use in patients with cervical cancer, because the available evidence indicates that PET can provide more reliable guidance than existing imaging methods on whether the cancer has spread, the agency said.

It also would make PET scans available to patients with other cancers where the PET scan isn't covered, if the provider and patient are participating PET clinical trials, or if the provider and patient are participating in a PET registry.

2004 Elections:

Thompson Departure Unclear; Calif. OKs Stem-Cell Research; Oklahoma Tax Funds Center

By Kirsten Boyd Goldberg

Whether the second term of President George W. Bush brings changes in the federal agencies involved in health and biomedical research could depend on the plans of Tommy Thompson, Secretary of the Department of Health and Human Services.

Thompson let it be known more than a year ago that he didn't intend to stay at HHS during a second term, but he is reconsidering, according to news reports.

If Thompson were to leave, Mark McClellan, administrator of the Centers for Medicare and Medicaid Services and former FDA commissioner, is a likely candidate to replace him, sources said. A Texan and an M.D. who has a reputation for working well with Democrats and Republicans, McClellan breezed through Senate confirmation for FDA commissioner in 2002 and then moved over to head CMS early this year.

Another potential candidate for HHS Secretary could be NIH Director Elias Zerhouni, appointed by Bush in May 2002.

Whether or not Thompson leaves, Bush presumably will make an appointment for FDA commissioner. Lester Crawford has served as acting commissioner since McClellan's move.

NCI Director Andrew von Eschenbach, appointed by Bush in 2002, plans to remain in his job, a spokeswoman for the Institute said.

In Congress, Republicans retained control of the House and the Senate. In the Senate, Republicans increased their majority from 50 seats to 54 seats. One of the races remains undecided. Democrats will hold at least 44 seats, and an independent holds one seat.

In the House, Republicans won 229 seats. Five races remained undecided. Democrats won 200 seats, and an independent won one seat.

Calif. Voters Approve Stem-Cell Research

California voters approved Proposition 71 by a 59% to 41% margin, providing $3 billion for embryonic stem-cell research over 10 years, making the state the largest single funder of this research.

Last year, NIH spent about $25 million a year for research on stem cells derived from human embryos and about $190 million for research on human stem cells derived from adult tissues.

The initiative, proposed by Californians for Stem Cell Research and Cures, a group of scientists, venture capitalists, and patient advocates, will raise an average of $295 million a year for 10 years through the issue of state bonds. The funds will be used for a California Institute for Regenerative Medicine, at a University of California campus, as well as grants and loans for projects at other colleges in the state.

The measure bypasses restrictions on stem-cell research put in place by President Bush in 2001 and could position the state to become a magnet for biotechnology companies.

Under the California measure, the governor and state legislature will appoint a 29-member commission to distribute the funding. Awards will be made in a peer-review process.

Oklahoma Cigarette Tax To Fund Cancer Center

Voters in three states—Colorado, Montana, and Oklahoma—approved increases in sales taxes on cigarettes on Nov. 2.

In Oklahoma, the University of Oklahoma Cancer Center, the dean, and the provost worked with the state legislature for four years to design a new state excise tax on tobacco products, said Howard Ozer, director of the cancer center and head of hematology/oncology at the University of Oklahoma Medical Center, in Oklahoma City.

The measure, originally proposed by Gov. Brad Henry, put on the ballot by the legislature, and approved by voters 53 to 47 percent, establishes a state cigarette tax of 55 cents per pack—an increase of 26 cents—and increases taxes on other tobacco products. The tax goes into effect Jan. 1 and will raise an estimated $150 million in additional annual revenue.

Most of the funds will support indigent care and trauma care, but about $7 million a year is designated for the OU Cancer Center. "We are thrilled," said center director Ozer.

The tax, a permanent funding source independent of the tobacco settlement, could go a long way in helping the fledgling center in its quest for NCI cancer center designation. The university has an NCI P20 cancer center planning grant to begin its effort to compete for a P30 Cancer Center Support Grant.

Ozer said the university plans to float a bond issue for $75 million to build a new, 7-story building for the center. The facility will house administration, surgical subspecialties, multidisciplinary ambulatory care, clinical research, and translational research laboratories. The new building will wrap around a radiation facility and connect a recently completed research building with

existing clinical space. Groundbreaking may take place this spring, he said.

The measure also will provide about $5 million to build a cancer facility in Tulsa that will be a component of the cancer center.

The center also plans to begin a fundraising campaign for $50 million to fund 20 endowed chairs.

"This is obviously a tremendous boost," Ozer said. "We feel we are well-organized and we address all the issues necessary for a cancer P30 in terms of organization and support. Where we are deficient is in numbers of senior investigators with R01, P01, and SPORE funding from NCI. This will enable us to provide the space, and the fundraising will provide the endowed chairs to do the recruitment we need."

Previously, Oklahoma had the lowest cigarette tax of any non-tobacco producing state. The passage of the new tax puts Oklahoma at the national average. Tobacco companies spent $2 million on advertising to oppose the measure.

Ozer said it's unlikely that declining smoking rates will reduce the revenue source. "In every state where the cigarette tax has been increased, the revenue continues to rise," he said. "The only price-sensitive people who smoke are youth, pregnant women, and the poor. The revenues are more than made up by other smokers."

In Colorado, the state cigarette tax will increase from 20 cents to 84 cents per pack and double the tax on other tobacco products. The measure could raise an estimated $175 million a year in additional revenue. The state will spend 16 percent of the funds on detection and treatment of smoking-related diseases including cancer and heart disease, and 16 percent on anti-smoking programs. The remainder of the funds will be used for state child health and Medicaid programs.

In Montana, the state tax on cigarettes will increase from 70 cents to $1.70 per pack, the state tax on chewing tobacco will increase from 35 cents to 85 cents per ounce, and the state tax on other tobacco products will increase from 25 percent to 50 percent of the wholesale price. The measure is expected to raise $45 million a year. Most of the funds will be spent on health care programs.

Also in Montana, voters approved a measure to allow residents with chronic illnesses to grow, possess, and use marijuana for medical purposes.

In Oregon, voters defeated a measure that would have revised a 1998 Oregon law under which residents with chronic illnesses can obtain cards that allow them to use marijuana for medical purposes. The measure would have increased the amount of marijuana that registered patients can possess from three ounces to one pound, allowed designated caregivers to sell marijuana to as many as 10 registered patients, and established a network of marijuana dispensaries to sell marijuana to registered patients or caregivers.

National Academies:

National Cancer Policy Board To Become Cancer "Forum"

By Kirsten Boyd Goldberg

The National Cancer Policy Board of the Institute of Medicine, established and funded primarily by NCI since 1997, will cease to exist in its current form next May, IOM and NCI officials said last week.

In its place, NCI and IOM will enter into a contract for a National Cancer Policy Forum, which will allow federal government officials to serve as members. The decision represents a change of policy for NCI Director Andrew von Eschenbach, who had indicated earlier that the Institute might not fund any cancer entity at IOM.

"The NCI leadership felt it might be more useful to have some role in the discussions," board chairman Joseph Simone said to **The Cancer Letter**. "The board was an experiment. It was an unusual model for the IOM and I think the IOM is more comfortable with the forum model."

The board, proposed by former NCI Director Richard Klausner to provide a method for experts independent of the Institute to make policy recommendations, conducted "creative and productive" work, Simone said.

The policy board studied a wide variety of topics, issued reports, and made hundreds of recommendations. The board's early reports on tobacco were influential in shaping the tobacco settlement, Simone said.

"I am most proud of our series on quality of cancer care, which began in 1999," said Simone, who served on the board since its inception. "There were a whole series of reports with recommendations that have been pretty influential. We also have done some nice work in prevention, and are finishing up a report on survivorship."

Earlier this year, the board issued a report on large-scale science. "We examined the question of, 'Can the NIH and other agencies continue doing business as usual with the changes in science and the size of the teams needed?'" Simone said. "Our response was, 'No, adjustments had to be made.'"

The board's current members will complete their terms through next spring and the forum will begin as a new entity, Simone said.

"The bottom line is that there will continue to be a cancer-specific standing focus group at the IOM, and that's very important," Simone said. "Cancer is the only disease for which there is a disease-related focus group at the IOM."

Karen Antman, NCI deputy director for clinical and translational science, said the Institute and the Centers for Disease Control and Prevention, which co-funds the board, have contacted other agencies to determine their interest in joining the forum. Discussions with the Centers for Medicare and Medicaid Services, the Health Resources Services Administration, the Agency for Healthcare Research and Quality, and the Food and Drug Administration are underway, she said.

"Having federal agency representatives on the forum will expand the composition of the group and enhance the identification of cross-cutting issues," Antman said. "The forum should address broad policy issues that affect cancer in the United States and recommend ways to advance the nation's effort against cancer."

Antman praised the board's work. "NCI values the board's recommendations," she said. "The NCPB has addressed some of the most important issues facing the cancer community—from childhood survivorship, to describing death in America, to large-scale biomedical science."

The cost to NCI of funding the new forum hasn't been determined, because the contract hasn't been finalized, she said.

This year, support for the board will total about $1.8 million, said Roger Herdman, director of the board. The current five-year contract for the board that ends next year was $7.9 million, he said.

When it was established, the role of the board was to "examine ongoing research, new technologies, issues arising in delivery of care, and problems faced in the Nation's battle against cancer," the IOM said at the time. "The board's most distinctive contribution, however, will be to render advice and make recommendations to advance the Nation's effort against cancer" (**The Cancer Letter**, Nov. 29, 1996, Vol. 22 No. 46).

Under IOM rules, a forum will not render advice, but could ask other IOM committees to study a problem and make recommendations. For that reason, the forum is expected to cost about one-third less, because it will not fund specific projects, as the board has done.

Several other organizations provide funding for the board, including the American Cancer Society, UnitedHealth Group Foundation, the American Society of Clinical Oncology, and the pharmaceutical firms Abbot, Aventis, and Amgen.

The policy board's current projects, reports, and events are listed at http://www.iom.edu/board.asp?id=3798.

Funding Opportunities:

RFAs Available

RFA-TW-04-004: International Cooperative Biodiversity Groups

The RFA is available at http://grants1.nih.gov/grants/guide/rfa-files/RFA-TW-04-004.html.

Letter of Intent Receipt Date: Jan. 18

Application Receipt Date: Feb. 15

Participating agencies invite applications for International Cooperative Biodiversity Groups to address the interdependent issues of biodiversity conservation, economic capacity, and human health through discovery and development of therapeutic agents for diseases in developing countries, as well as developed countries. Particularly relevant disease areas and health needs include HIV-AIDS and its opportunistic infections and associated malignancies, tuberculosis, malaria, other emerging diseases, mental disorders of adults and children, cancer, drug abuse and cardiovascular and pulmonary diseases. Applicants are encouraged to consider marine coral reef organisms as well as new sources of previously unexplored or under explored microorganisms, including but not limited to those arising from symbiosis, extreme environments such as thermovents, and deep sea microbes. Applications that propose to work primarily with plants for pharmaceutical drug discovery are encouraged to propose research and training related to phytomedicine analysis. Research and capacity building toward the development of agricultural agents is permissible as a secondary activity where it complements work on human health agents.

Inquiries: For NIH--Joshua Rosenthal, deputy director, Division of International Training and Research, Fogarty International Center, Phone 301-496-1653; fax 301-402-0779; e-mail rosenthj@mail.nih.gov .

RFA-OD-05-001: Strengthening Behavioral and Social Science in Medical Schools

Letters Of Intent Receipt Date: Dec. 10

Application Receipt Date: Jan. 19

NIH invites applications for career development awards K07s to enhance medical education through behavioral and social sciences content and curricula. The award is supports schools of medicine and osteopathy at various stages of involvement in behavioral and social sciences curricula. The programmatic priorities are set to ensure that a diverse set of schools are funded with regard to educational approach, size, and maturity of existing curriculum in the behavioral and social sciences. The participating ICs intend to commit $1.5 million in FY 2005 to fund five to ten new grants.

The RFA has three objectives. The first is the

development of enhanced courses, curricula and education designed to increase medical students' knowledge and skills in the behavioral and social sciences related to health. Secondary targets of these curricula include physicians in training, faculty, other researchers, and practicing physicians. The second objective is to provide curriculum and other products for dissemination to other medical schools as well as other health care professional schools. The third objective is to promote health-related research and careers in behavioral and social science within medical school settings. The funding opportunity will use the NIH K07 award mechanism. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-05-001.html.

Inquiries: For NCI--Michael Stefanek , chief, Basic Biobehavioral Research Branch, Behavioral Research Branch , Division of Cancer Control and Population Sciences, phone 301-496-8776; fax 301-594-6787; e-mail Ms496r@nih.gov.

Program Announcement

PA-05-006: Effect of Racial and Ethnic Discrimination /Bias on Health Care Delivery

Application Receipt Dates: http://grants.nih.gov/grants/funding/submissionschedule.htm.

The purpose of the PA is (1) to improve the measurement of racial /ethnic discrimination in health care delivery systems through improved instrumentation, data collection and statistical/analytical techniques; (2) to enhance understanding of the influence of racial/ethnic discrimination in health care delivery and its association with disparities in disease incidence, treatment and outcomes among disadvantaged racial/ethnic minority groups; and (3) to reduce the prevalence of racial/ethnic health disparities through the development of interventions to reduce the influence of racial/ethnic discrimination on health care delivery systems in the U.S.

The funding opportunity will use the R01, R21, and R03 award mechanisms. The PA specifically encourages: Descriptive and analytical studies that examine racial/ethnic discrimination as a risk factor for racial/ethnic disparities in disease incidence, treatment, and outcomes; development of data resources including the identification and/or development of new data collection modalities and the evaluation of existing data collection instruments/modalities; development of innovative methods of measuring racial/ethnic discriminatory behavior, perception of exposure to racial/ethnic discrimination and novel approaches to the analysis of quantitative and qualitative data for the purpose of describing discriminatory behavior and exposure to racial/ethnic discrimination; examination of the prevalence of institutional racism in health care delivery systems or policies and its contribution to racial/ethnic health disparities; and development and evaluation of interventions that enhance cross-cultural communication and reduce discriminatory behavior, the perception of exposure to racial/ethnic discrimination, and health-related consequences of racial/ethnic discrimination. Studies that examine bias/discriminatory attitudes, beliefs and behaviors that may influence/limit access to diagnostic technologies and therapies for racial/ethnic minorities, particularly in areas for which serious disparities exist such as cardiovascular disease, cancer detection, infectious diseases and infant mortality. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-05-006.html.

Inquiries: For NCI--Vickie Shavers, Applied Research Program, Division of Cancer Control and Population Sciences, phone 301-594-1725; fax 301-435-3710; e-mail shaversv@mail.nih.gov.

CRADA Opportunity

CRADA ML-EPO-01: Development and Commercialization of Agents for the Diagnosis and Treatment of Tumors Expressing EPO Receptor

Letter of Intent Receipt Date: Nov. 26

National Institute of Neurological Disorders and Stroke is seeking a cooperative research and development agreement collaborator to work with NINDS in the development, manufacture and commercialization of agents for the diagnosis and treatment of tumors expressing EPO receptor. Of particular interest are agents useful in diagnosis or treatment of multiple tumors in different organs in patients with von Hippel-Landau disease, sporadic kidney tumors and kidney tumors in dialysis patients. NINDS is seeking a development and commercialization partner for identification of agents that act as antagonist to EPO, especially ligands that bind EPOR but do not activate the receptor. Further R&D Required: Identify ligands that bind to EPOR but do not activate receptor. Screen ligands for activity in vitro or in vivo. Plan for clinical trials to determine usefulness of ligands in diagnosing and/or treating tumors. Patent Status: Patent pending. Licensing of technology available. The solicitation is available at http://www.fbodaily.com/archive/2004/10-October/29-Oct-2004/FBO-00699611.htm.

Inquiries: Martha Lubet, NINDS Technology Transfer by TTB/ NCI; phone 301 435-3120; e-mail lubetm@mail.nih.gov.

In Brief:

DCI Prevention Program To Work With Labor Unions

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program for the building trades unions, and nationally with the International Brotherhood of Teamsters and the Motor Freight Carriers Association. "The aim of our research is to collaborate with these unions, building on their own training programs in health and safety and strong sense of community, to study the effectiveness of a smoking cessation intervention for their apprentices," said **Elizabeth Barbeau**, assistant professor at Harvard School of Public Health and principal investigator of the study. "We will focus on the worker's knowledge and concern about the dual threat of occupational hazards

and smoking.". . . **EDWARD OTTO**, chief operating officer of Intronn Inc., was named director of the Office of Cellular, Tissue and Gene Therapies in the FDA Center for Biologic Evaluation and Research. The office consolidates FDA resources and expertise to regulate product development within the three technologies. "Otto was selected because of his outstanding management skills and his scientific accomplishments, including gene therapy product research and development," said FDA Acting Comissioner **Lester Crawford**. . . "**CULTURE COMPETENCE In Cancer Care**: A Health Professional's Passport," is an 84-page pocket guide designed for health professionals in working with patients who are African American, Hispanic/Latino, Native American, Asian American, and Native Hawaiian. "This pocket guide is intended to be a reference along a cultural journey, which health care professionals can explore when providing cancer care," said **David Satcher**, former U.S. Surgeon General, in his foreword to the book. Written by **Patricia Matthews-Juarez** of Meharry Medical College and **Armin Weinberg** of Baylor College of Medicine and published by the Baylor College of Medicine Intercultural Cancer Council, the guide will be sent to more than 4,500 community health clinics across the country. For a copy of the guide, contact Monique DeLynn, Intercultural Cancer Council, phone 713-798-4617. . . . **CANCER INSTITUTE of New Jersey** received $800,000 raised at the Award of Hope Gala and Benefit Auction hosted by the Trump National Golf Club of Bedminster, N.J. The funds will be used for cancer research, treatment, prevention and education efforts at CINJ. Johnson & Johnson received the Award of Hope. **Mary Todd**, deputy director of CINJ and professor in the Department of Medicine, UMDNJ-Robert Wood Johnson Medical School, was given the Leadership in Patient Care Award, said **William Hait**, director of CINJ and associate dean of oncology programs and professor of medicine and pharmacology at UMDNJ-Robert Wood Johnson Medical School. . . . **CHEROKEE INSPIRED Comfort Award** was given to oncology nurses for service, sacrifice and innovation, service, sacrifice and innovation. The winners of the national healthcare recognition program are **Robert Wilkinson** of Kosair Children's Hospital in Louisville, KY; **Gaynell Stone** of Rex Hospital in Raleigh, NC; **Nomiki Vorgias** of Community Hospital in Munster, IN; and **Karen Ulmer** of Greater Baltimore Medical Center.

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THE CANCER LETTER

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Business & Regulatory Report

Product Approvals & Applications:

FDA Approves Femara For Breast Cancer Following Five Years of Tamoxifen

Novartis Oncology of East Hanover, N.J., said Femara (letrozole tablets) was approved by FDA for the extended adjuvant treatment of postmenopausal women with early breast cancer who have received adjuvant tamoxifen therapy for five years, the company said.

"Femara truly provides hope to women who have survived early breast cancer by offering them an improved chance of remaining cancer-free," said Diane Young, vice president, global head, Clinical Development, Novartis Oncology. "This priority review approval marks the first time

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Clinical Trials:

ARIAD Begins Phase II Trial of New Agent For Bone And Soft Tissue Sarcomas

ARIAD Pharmaceuticals Inc. (Nasdaq: ARIA) of Cambrige, Md., said it has begun enrollment in a multicenter phase II trial of its mTOR inhibitor, AP23573, as a single agent for bone and soft tissue sarcomas.

The non-randomized study would evaluate the benefit of AP23573 in four well-defined groups of up to 175 patients characterized by tumor type, the company said. AP23573 would be administered using a daily dosing regimen of drug.

"In our nearly completed phase I trials, evaluable patients with relapsed and/or refractory sarcoma had evidence of anti-tumor activity--a promising result that supports our decision to further evaluate AP23573 in this patient population in phase II trials," said Harvey Berger, chairman and CEO of ARIAD. "Despite advancements in anti-cancer therapy, available treatment options are extremely limited due the highly resistant nature of this cancer. Sarcoma remains a disease with high unmet medical need."

The study would also include use of pharmacodynamic and pharmacogenomic biomarkers, including functional imaging, to assess the effects of AP23573 on the mTOR pathway, the company said.

The small-molecule drug, AP23573, inhibits the cell-signaling protein, mTOR, which regulates the response of tumor cells to nutrients and growth factors, and controls tumor blood supply and angiogenesis through effects on Vascular Endothelial Growth Factor, the company said.

* * *

Bioenvision (Nasdaq: BIVN) of New York said enrollment has begun at Massachusetts General Hospital, in a phase II study of Modrenal (trilostane)

(Continued to page 3)

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Extended Adjuvant Treatment Indication For Femara

(Continued from page 1)

that the nearly 100,000 women in the United States who complete tamoxifen therapy each year will have a medical option to reduce their ongoing risk of breast cancer recurrence."

The term extended adjuvant describes the period following adjuvant treatment with tamoxifen. Approximately one-third of women with estrogen receptor positive early breast cancer experience a recurrence and over half of those recurrences occur more than five years after surgery.

While tamoxifen is beneficial for five years post surgery, if used beyond that, the risks associated with it outweigh the benefits. The approval for the extended adjuvant indication was based on results from an international study, which included more than 5,100 postmenopausal women and was coordinated by the NCI of Canada Clinical Trials Group at Queens University in Kingston, Ontario, and supported by Novartis. Initial results were published in the New England Journal of Medicine in October 2003.

The study showed that Femara reduced the risk of cancer coming back, or disease-free survival, by 38% and significantly increased a woman's chance of staying cancer-free. Femara also greatly reduced the chance of breast cancer returning to another part of the body, or distant metastases, by 39%.

Femara is also indicated for first-line treatment of postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer, and for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy. Novartis has filed in the European Union for the indication of extended adjuvant treatment of early breast cancer in postmenopausal women who have completed standard adjuvant (post-surgery) tamoxifen therapy.

Novartis Oncology is a unit of Novartis AG (NYSE: NVS) of Basel, Switzerland.

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American Pharmaceutical Partners Inc. of Schaumburg, Ill., said it has received FDA approval for the abbreviated new drug application of Carboplatin for Injection, USP, the lyophilized form of carboplatin.

The treatment is the generic equivalent of the Bristol-Myers Squibb Co. Paraplatin, the company said.

Marketing for carboplatin has begun, the company said. The ANDA for Carboplatin for Injection, the liquid form of the product, is still undergoing review.

Carboplatin is indicated for the initial treatment of advanced ovarian carcinoma in established combination with other approved chemotherapeutic agents, as well as for the palliative treatment of ovarian carcinoma recurrent after prior chemotherapy, the company said.

According to IMS, the U.S. market for carboplatin is $775 million, comprising both the lyophilized and liquid form, the company said. Last year, sales of the lyophilized form were $670 million and $114 million in the first half of 2004, reflecting some market conversion to the liquid form.

In an effort to reduce medication errors at the patient level, APP said it has enhanced the labeling for its carboplatin products by including bar codes and TALL man lettering, a method of differentiating look-alike, sound-alike products.

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Bedford Labs. of Bedford, OH, said it has received FDA approval to market Carboplatin Injection.

The product is the equivalent to Paraplatin Injection from Bristol-Meyers Squibb, which is indicated for advanced ovarian carcinoma in established combination with other approved chemotherapeutic agents; it is also indicated for the palliative treatment of ovarian carcinoma recurrent after prior chemotherapy, the company said.

The company said it would supply single dose vials, with a 10 mg/mL presentation in 5 mL, 15mL,

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and 45 mL vials, individually boxed.

Bedford Labs. is a division of Ben Venue Labs., a subsidiary of Boehringer Ingelheim Corp. of Ridgefield, Conn.

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OSI Pharmaceuticals Inc. (NASDAQ: OSIP) of Melville, N.Y., said FDA has accepted for filing and review the NDA for Tarceva (erlotinib HCl) as a monotherapy for advanced non-small cell lung cancer where chemotherapy has failed.

OSI also said the treatment has been granted priority review classification by FDA.

Clinical Trials:

Bioenvision's Modrenal Begins Phase II For Prostate Cancer

(Continued from page 1)
for prostate cancer.

The trial would target 43 individuals who are androgen independent and have rising prostate specific antigen levels, the company said.

The principal investigator of the study is Matthew Smith, assistant professor of medicine, Harvard Medical School.

Modrenal is approved for use in the U.K. for advanced, post-menopausal breast cancer following relapse on prior endocrine therapy, the company said. Over 800 patients with breast cancer have received Modrenal (trilostane) in clinical trials, and its anti-tumor activity is effective in a significant proportion of breast cancer patients, particularly those with hormone-sensitive tumors.

Bioenvision said it is conducting phase II (post-menopausal) and phase IV (pre-menopausal) studies in the U.K.

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CancerVax Corp. (NASDAQ: CNVX) of Carlsbad, Calif., said it has completed enrollment of 1,118 patients into its phase III trial of Canvaxin for stage III melanoma.

The international, randomized, double-blinded, placebo-controlled trial would evaluate the ability of the treatment, a specific active immunotherapy or therapeutic cancer vaccine, to extend survival following surgical resection of tumors.

With enrollment complete, CancerVax said it would focus on completing the treatment and follow-up in the study, as well as continue enrollment in its ongoing phase III trial of the drug for stage IV melanoma.

The two ongoing phase III trials, in addition to measuring a primary endpoint of overall survival, would also evaluate whether the treatment would prolong disease-free survival and disease-free interval compared to placebo, the company said.

Treatment with the agent in phase I and II trials has been well tolerated and retrospective, matched pair analyses have shown an improvement in median overall survival for stage III and stage IV melanoma when Canvaxin was received in one of the phase II trials when compared with the historical control group that did not receive the treatment, the company said.

"While patients who are diagnosed early and receive appropriate surgical treatment for stage I and II melanoma have high survival rates, at least 50 percent with stage III melanoma recur after surgery and only seven to 19 percent diagnosed with stage IV melanoma survive five years," said Merrick Ross, professor of surgical oncology at M.D. Anderson Cancer Center and one of the principal investigators for the phase III trial for stage III melanoma. "The Canvaxin trials for stage III and stage IV melanoma would evaluate a large patient population."

Canvaxin has both orphan drug and Fast-Track designations from FDA for invasive and metastatic melanoma, respectively, and is being studied in two international phase III trials for stage III and stage IV melanoma.

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Favrille Inc. of San Diego said it has initiated a phase III trial (FavId-06) for FavId, an active immunotherapy for indolent lymphoma, follicular B-cell non-Hodgkin's lymphoma.

The randomized double-blind trial would compare the median time to disease progression placebo or FavId following treatment with Rituxan, the company said. FavId-06 is enrolling patients who are either treatment-naive or relapsed following up to two prior treatments for their fNHL in U.S. oncology centers.

Favrille Inc., a privately held biopharmaceutical company.

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Metaphore Pharmaceuticals Inc. of Ft. Lee, N.J., said it has begun a phase II trial of M40403 for cancer pain.

The compound would be co-administered with opioids for moderate to severe cancer pain to evaluate analgesic response, the company said.

In earlier trials M40403, a non-narcotic medication, demonstrated amplified the pain relieving effects of opioids while reducing the unwanted side effects associated with both acute and chronic opioid use,

the company said. Previous findings also have shown that the compound improves the effectiveness and predictability of opioids.

Results from a phase II trial demonstrated that the addition of the drug to morphine improved the pain relieving profile of morphine in every measure of analgesic efficacy: faster onset, longer duration, greater peak effect and greater overall effect, the company said. Adding the agent to a low dose of morphine produced a two- to three-fold increase in the analgesic efficacy of the morphine without a concomitant increase in morphine side effects. The addition of M40403 also appeared to make the dose response curve more predictable.

"Inadequately treated pain is a major public health problem and a new chemical entity like M40403 would be needed to address this issue," said Russell Portenoy, chairman, Department of Pain Medicine and Palliative Care, Beth Israel Medical Center.

The trial is a randomized, double-blind, placebo-controlled, five center study whose primary objective is to evaluate the safety and analgesic activity of a single dose of M40403 co-administered with current pain medication (morphine, hydromorphone, or oxycodone), the company said. The study would enroll 24 cancer patients experiencing moderate to severe pain.

M40403iv is a synthetic version of a naturally occurring enzyme superoxide dismutase, the company said. SOD neutralizes free radicals (superoxides), thereby reducing inflammation, preventing tissue injury and reducing pain, the company said. Elevated levels of superoxides can overwhelm the natural production of SODs, resulting in a continuing cycle of cell injury, inflammation, and pain. Metaphore has developed SOD mimetics, which are synthetic compounds that mimic the actions of SODs and supplement the natural process of reducing inflammation, limiting cellular damage and relieving pain.

In addition, SODm can relieve pain associated with opioids, the company said.

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MethylGene Inc. (TSX: MYG) of Montreal said it has initiated a randomized, two-step phase II trial of MG98 in combination with interferon alpha for metastatic renal cell cancer.

In the first step of the trial, 30-50 patients without previous chemotherapeutic treatment would be randomized to two dosing schedules, which would combine MG98 with interferon alpha, the company said. In one schedule, MG98 would be given continuously for seven days, followed by seven days off. In the second schedule, MG98 would be given intermittently as a two-hour infusion, two days per week for three weeks, followed by one week of rest. In both schedules, interferon alpha would be given subcutaneously three times per week. The first step would evaluate the safety, tolerability, pharmacokinetics, optimal dosing regimen and activity of MG98 combined with interferon alpha.

The second step would enroll 200 patients at 35 sites in North America and Europe. Patients would be randomized with either a combination of MG98 and interferon alpha or interferon alpha alone. The MG98 dosing schedule for the second step would be selected based on the best results obtained in step one. The primary endpoint of the trial would be median progression-free survival. Secondary endpoints would be tolerability of the combination therapy, one-year survival, tumor response, and overall survival.

MG98 is a second-generation antisense oligonucleotide inhibiting the production of the enzyme DNA methyltransferase1 by targeting its mRNA, the company said. In collaboration with the Cleveland Clinic, MethylGene has demonstrated that when renal cancer cell lines resistant to interferon alpha were pre-treated with MG98, they became more sensitive to the induction of cell death by interferon alpha, the company said.

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Seattle Genetics Inc. (Nasdaq: SGEN) of Bothell, Wash., has begun a phase II trial of SGN-30 for primary cutaneous anaplastic large cell lymphoma, a type of non-Hodgkin's lymphoma that involves the skin.

The study is designed to evaluate the antitumor activity and tolerability of SGN-30 in up to 40 patients who have relapsed or are resistant to prior therapies, the company said.

Seattle Genetics said it is conducting additional phase II studies of SGN-30 in Hodgkin's disease and systemic ALCL. Data from the first five systemic ALCL patients treated with SGN-30, demonstrated that objective responses were observed in two patients.

SGN-30 is a genetically engineered monoclonal antibody that targets CD30-positive hematologic malignancies, including Hodgkin's disease and certain types of lymphomas and leukemias, the company said. The treatment has received orphan drug designations from FDA in both Hodgkin's disease and T-cell lymphomas, a category that includes ALCL. Seattle Genetics said it is also conducting preclinical studies to evaluate SGN-30 for immunologic diseases.

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Sunesis Pharmaceuticals Inc. of South San Francisco said it has begun the second of two phase I

studies of SNS-595, an anti-cancer small molecule drug for advanced solid tumor cancers.

The drug is a first-in-class cell cycle modulator that kills proliferating cancer cells by inducing apoptosis, the company said.

"In extensive pre-clinical evaluation, SNS-595 shows robust anti-tumor activity against a number of cancers," said Daniel Swisher, CEO of Sunesis Pharmaceuticals.

The open-label multi-center, dose-escalation study examines weekly dosing regimens of the treatment for safety, tolerability, and pharmacokinetics, the company said. Enrolled is taking place at four sites in the U.S.

Over a 28-day cycle, SNS-595 would be administered weekly on days zero, seven and 14, followed by a 14-day observation period, the company said. Up to six cycles of treatment could be administered.

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ViRexx Medical Corp. (TSX Venture: VIR) Edmonton, Alberta, said it has received authorization from Health Canada to initiate a phase I trial for Occlusin Injection in liver cancer patients.

The trial would be conducted at the Toronto General Hospital of the University Health Network under the direction of Morris Sherman, associate professor of medicine, University of Toronto, the company said.

The trial would examine the safety of Occlusin Injection when used as an embolizing agent as part of transcatheter arterial chemoembolization procedures, the company said.

Occlusin Injection is the lead product arising from the T-ACT (tumor starvation) technology platform and has been designed as an embolotherapeutic agent for solid tumors, the company said. Embolotherapy involves the delivery of agents directly to the blood vessels feeding a tumor with the intent of forming a site-specific clot. Occlusin Injection consists of deformable particles that, through the action of von Willebrand factor bound to the particle fibres, capture and activate platelets at the site of delivery leading to localized clot formation. Reducing the blood supply to the tissue to be treated leads to a reduction in oxygen and nutrients delivered to the tumors, the company said.

Deals & Collaborations:

Celera, Genentech Agree To Collaborate On Therapies

Celera Genomics Group (NYSE:CRA) of Rockville, Md., said it has entered into a collaboration with **Genentech Inc.** (NYSE:DNA) to discover and develop targeted therapies for cancer.

Under the multi-year agreement, Celera would nominate a number of cell-surface antigens discovered and validated through its proprietary proteomic platform, the company said. Genentech would make progress-dependent milestone payments to Celera based on achievement of preclinical, clinical and commercial milestones, and would pay royalties on net sales of resulting therapeutic products.

Celera Diagnostics, which is a joint venture between Celera Genomics and the Applied Biosystems Group (NYSE:ABI) of Applera, said it retains diagnostic rights associated with the designated targets.

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Aphton Corp. (Nasdaq: APHT) of Miami and **XOMA Ltd**. (Nasdaq: XOMA) of Berkeley, Calif., said they have signed a worldwide collaboration agreement for gastrointestinal and other gastrin-sensitive cancers using anti-gastrin monoclonal antibodies.

Under the agreement, Aphton and XOMA would share development expenses and commercialization profits and losses for product candidates on a 70/30 basis, respectively, the companies said. XOMA would have worldwide manufacturing rights for the products and the ability to share up to 30 percent in the commercialization efforts in the U.S. in accordance with the terms of the agreement. Aphton would share commercialization rights in the U.S. and would have exclusive rights to commercialize all products outside the U.S, the companies said.

The antibodies to be developed under the collaboration would bind and neutralize the hormones gastrin 17 and gly-gastrin 17, a gastrin precursor, that are known to be involved in tumor progression in gastrointestinal cancers, the companies said.

Gastrin is a hormone in the embryological development of the GI system, the companies said. Gastrin genes are reactivated in precancerous cells and polyps and in cancer cells early in the development of cancer; secretion and the expression of gastrin receptors increase as the cancer progresses. Gastrin works by signaling through its receptor, the gastrin receptor (CCK-2/Gastrin-R).

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Commonwealth Biotechnologies Inc. (NASDAQ: CBTE) of Richmond, Va., said it would conduct molecular screening assays for the early detection of bladder cancer genetic markers.

CBI said it would perform the assay under license from **Cangen Biotechnologies Inc**. of Bethesda, Md.

The multi-institutional clinical trial, sponsored by the **NCI Early Detection Research Network**, would involve three regional NCI-designated cancer centers, and ten clinical research institutions.

The trial is designed to test the effectiveness of the assay in detecting recurrent cancer, the company said. In addition to performing the laboratory assays, CBI would also act as the repository for the patient samples, which is collected and for the DNA, which is extracted.

Under the auspices of a previously completed development contract from Cangen, CBI said it implemented the assay on a capillary electrophoresis platform, and then validated the assay for human sample analysis. Over the course of the next two years, CBI said it expects to analyze more than 3,600 samples, the first of which have already been received.

The total valuation of the contract is $800,000, the company said.

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Cytyc Corp. (Nasdaq: CYTC) of Boxborough, Mass., said it has entered into a multi-year agreement with **Laboratory Corp. of America Holdings** (NYSE: LH) to place its ThinPrep Imaging System in LabCorp facilities and to extend its contract for the ThinPrep Pap Test.

Under the agreement, LabCorp said it would implement the cervical cancer screening instrument throughout its system of laboratories.

The system is a fully integrated, interactive computer that assists cytotechnologists and pathologists in the primary screening and diagnosis of ThinPrep Pap Test slides, the company said. The system combines imaging technology with human interpretive expertise to improve cervical cancer screening efficiency and performance.

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ImmunoGen Inc. (Nasdaq: IMGN) of Cambridge, Mass., and **Biogen Idec Inc**. (NASDAQ: BIIB) of San Diego said Biogen has licensed exclusive rights to use the ImmunoGen proprietary Tumor-Activated Prodrug technology with antibodies to an undisclosed tumor cell target.

Under the agreement, Biogen Idec would receive exclusive worldwide rights to develop and commercialize anticancer therapeutics that comprise an antibody developed by Biogen Idec to an undisclosed tumor cell target and a maytansinoid cell-killing agent developed by ImmunoGen, the companies said. ImmunoGen said it has developed its maytansinoid cell-killing agents for antibody-directed delivery to cancer cells.

Biogen Idec would be responsible for the research, development, manufacturing, and marketing of products resulting from the license, the companies said. ImmunoGen would receive from Biogen Idec an upfront payment of $1 million, up to an additional $42 million if predetermined milestones are met, and royalties on the sales of resultant products. ImmunoGen would also receive compensation for product development research done on its behalf, as well as for the production of preclinical and initial clinical materials.

The TAP technology provides tumor-targeting antibodies with anticancer activity, the companies said. ImmunoGen attaches to the antibody one of its proprietary cell-killing agents as a payload. The antibody delivers the payload selectively to cancer cells, and the cancer cells are killed, the companies said.

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IVAX Corp. (AMEX: IVX) (LSE: IVX.L) of Miami said it has entered into a licensing agreement with **Nippon Shinyaku** to develop and market HMN-214, an orally administered polo-like kinase inhibitor for pancreatic, prostate and other cancers.

HMN-214 is an enzyme that is over-expressed by malignant tumors and may promote the uncontrolled cell division of advanced cancer, the company said.

In a phase I trial for advanced cancer, the inhibitor was found to have early indications of anti-tumor activity, the company said.

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Maxim Pharmaceuticals (Nasdaq: MAXM) of San Diego said it is restructuring to reduce its cash burn rate.

The plan would ensure sufficient financial resources of regulatory submissions seeking approval of Ceplene for acute myeloid leukemia with complete remission, and other programs and opportunities that would provide shareholder value, the company said. The restructuring plan includes a workforce reduction of 50 percent.

Individuals affected by the restructuring, prompted by the negative outcome of the Maxim confirmatory phase III trial of Ceplene for advanced malignant melanoma, are eligible for a severance package that includes pay, benefits continuation and outplacement services, the company said.

"We believe it is prudent and necessary to reduce our workforce and take other measures to conserve our financial resources," said Larry Stambaugh, president and CEO of Maxim. "The measures, however, would provide us the opportunity to pursue AML regulatory filings with the FDA and EMEA, and continue our apoptosis modulator discovery program, and other

promising programs and initiatives, including hepatitis C and renal cell carcinoma. The measures would also provide us the flexibility to independently advance one of our apoptosis compounds into the clinic," said Stambaugh.

The workforce reduction is across all departments and programs, and includes two officers, Anthony Altig, chief financial officer at Maxim, and Kurt Gehlsen, chief scientific officer at Maxim. John Prunty, treasurer and controller, would be promoted to vice president of finance and chief financial officer. Larry Stambaugh, CEO, has voluntarily taken a reduction in salary for the fiscal year.

The company said following programs are of highest priorities under the restructuring plan: 1. pursuing regulatory submissions seeking approval of Ceplene for AML in complete remission with FDA and European Medicines Agency. 2. continuing of apoptosis modulator discovery and development program to identify anti-cancer compounds. 3. independently moving one of the apoptosis compounds into a phase 1 trial, and 4. evaluating clinical results from ongoing phase II trials of Ceplene therapy in hepatitis C and renal cell carcinoma.

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OriGene Technologies Inc. of Rockville, Md., said it has entered into an agreement to license a cancer target identified with the OriGene HTP- Rapid-Scan technology to **MacroGenics Inc.**

Under the agreement, MacroGenics has the exclusive right to develop compounds against the target and would focus on the development of therapeutic monoclonal antibody candidates to the molecule, the company said. In exchange, OriGene would be entitled to receive various option fees, milestones and royalty payments as the compounds are developed and commercialized.

HTP-Rapid-Scan Technology is a gene expression-profiling program that compares the expression of cDNAs obtained from the OriGene TrueClone Collection in cancerous versus normal samples representing 48 different tissue types, the company said.

Because the TrueClone Collection is the largest collection of human full-length cDNAs, HTP-Rapid-Scan Technology offers thorough and comprehensive solutions for identifying cancer therapy targets, the company said.

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Takeda Pharmaceutical Co. Ltd. of Osaka, Japan, said it has entered into an alliance agreement with **BioNumerik Pharmaceuticals Inc**. of San Antonio to market Tavocept (dimesna), a phase III chemoprotective agent developed by BioNumerik, in the U.S. and Canada.

Under the agreement, TPNA said it would market Tavocept following regulatory approval in the U.S. and Canada.

FDA granted Fast-Track development designation for the treatment, which is being studied to prevent or decrease the neuropathy caused by chemotherapy drugs, the company said.

Oncology Management:

MSKCC Begins Construction Of Outpatient Center In N.J.

Memorial Sloan-Kettering Cancer Center said it has begun construction of an outpatient cancer treatment facility in Basking Ridge, N.J.

"Frequently, cancer patients from Somerset County and other areas of central New Jersey must travel into Manhattan for all treatment services," said Abe Lopman, executive director of the MSKCC Regional Care Network. "Because seven percent of the patients are from New Jersey, the new Basking Ridge facility would allow many of them to receive outpatient cancer care in a more convenient setting."

The facility would offer outpatient chemotherapy, radiation oncology, comprehensive diagnostic radiology, medical and surgical consultations, ambulatory surgery, cancer screening and patient education, and integrative medicine.

The 85,000-square-foot facility is scheduled to open next summer, the center said.

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HCA's MidAmerica Division of Nashville, Tenn., and **Tennessee Oncology** said they have created the Sarah Cannon Research Institute, an institution designed to increase availability of clinical trials in the area.

"The Institute would take the Sarah Cannon Cancer Center to the next level of national prominence in cancer treatment and research by increasing the number of clinical trials," said Paul Rutledge, president of HCA's MidAmerica Division.

The center, which began in 1991, developed the Minnie Pearl Cancer Research Network with the help of its medical director F. Anthony Greco and the Tennessee Oncology physicians, the company said. It is the largest community-based clinical trial program in the country made up of 76 private oncology groups with over 500 oncologists conducting trials in 25 states.

HCA said it would increase the number of patients

in clinical trials from about 1,700 in 2004 to 7,000 by 2011. The company said it also plans to increase the types of clinical trials, particularly those that Sarah Cannon researchers initiate.

Mark Cianciolo was named CEO of the Sarah Cannon Research Institute, the company said. He was associate partner in the health and life sciences operating unit of Accenture, a global management and technology services organization. While with Accenture, Cianciolo worked with HCA's MidAmerica Division to create the strategy and model for the Sarah Cannon Research Institute.

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Lance Armstrong Foundation of Austin, Tex., said it has received a five-year, $500,000 gift from the **Nevada Cancer Institute** to establish the Lance Armstrong Foundation Survivorship Center at the Institute.

"The Lance Armstrong Foundation is committed to addressing the long-term emotional and physical consequences that accompany a cancer diagnosis and treatment," said Mitch Stoller, president and CEO of the LAF.

The center would be located within the NVCI patient and information library, which would contain resource materials, Internet access, translation and interpretation services, navigation services and general support, the foundation said.

The center would employ a "survivorship coordinator" who would provide full-time support, information and services, the foundation said. The coordinator would work with the NVCI medical researchers to study and determine the long-term effects of cancer survivorship.

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M. D. Anderson Cancer Center said it would acquire five Symbia systems, incorporating TruePoint SPECT-CT, Single-Photon Emission Computed Tomography-Computed Tomography technology, from **Siemens Medical Solutions** of Malvern, Pa.

The cancer center said it plans to install the systems in early 2005 in one of its newest facilities, the Ambulatory Care Building. The TruePoint SPECT-CT combines the functional sensitivity of SPECT with the anatomical detail of diagnostic multi-slice CT, providing imaging clarity, the company said.

With a single scan, the imaging technology captures comprehensive, accurate diagnostic information both on the molecular and anatomical levels, enabling detection of changes in molecular activity even before structural changes become visible, the company said.

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North American Scientific Inc. (Nasdaq: NASI) of Chatsworth, Calif., said its NOMOS Radiation Oncology Division has introduced ActiveRx, a set of real-time dose adjustment tools for Intensity Modulated Radiation Therapy treatment planning.

ActiveRx, which was incorporated into the latest version of the NAS software planning tool Corvus 6, is a set of fully automated, interactive tools that allow clinicians to directly manipulate dose volumes in real time, the company said.

Corvus is the inverse treatment planning technology that supports IMRT planning, and delivery on all major brands of linear accelerators equipped with multileaf collimators, the company said. The technology calculates a tumor dose based on specific parameters such as prescribed dose to the tumor, degree of uniform dose to a specified target, dose tolerance limits of sensitive organs and organ and patient motion.

"ActiveRx is really a step beyond IMRT in that it combines the power of inverse radiation therapy planning with the wealth of the user's clinical experience," said Martin Fuss, associate professor, Department of Radiation Oncology, University of Texas Health Science Center, San Antonio. "Clinicians can identify structures in the treatment plan that need to be encompassed by the prescription dose or better spared from radiation exposure by simply grabbing and dragging an isodose line. ActiveRx enables the user to fine-tune a dose distribution to the patient's individual needs, quickly and easily."

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VISTA Staffing Solutions of Salt Lake City said it has formed a staffing unit that would place medical, radiation, and hematologist oncologists in oncology practices and cancer centers across the nation.

"There is a constant, and growing, need for locum tenens oncologists to fill in for doctors who care for cancer patients," said Mark Brouse, president and CEO of VISTA. "Temporary physician coverage is needed during vacations, illness, medical meetings, continuing medical education training, maternity leave and military deployment. Locum tenens physicians also frequently help staff practices while permanent physicians are being recruited."

Oncologists seeking locum tenens assignments include military physicians and physicians who had recently completed training, and experienced physicians who want to transition into part-time work, the company said.

The oncology unit is based in Atlanta.