

PR Firm Hired By American Cancer Society Also Represents "Team KOOL Green"

The public relations company hired by the American Cancer Society to conduct a voter education campaign aimed at making cancer an issue for the 2000 presidential elections also represents tobacco companies, including Brown & Williamson Tobacco Corp.

Edelman Public Relations, widely known to represent tobacco clients internationally, remained in the shadows as it conducted the ACS Campaign Against Cancer, which at this point has entailed placing advertisements in conjunction with the Iowa caucus and the New Hampshire primary.

According to an Edelman press release, the campaign is aimed to
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In Brief:

Donald Coffey Is President-Elect Of NCCR; Coalition Elects Five New Board Members

NATIONAL COALITION FOR CANCER RESEARCH has appointed **Donald Coffey**, president-elect effective in November. Coffey is professor of urology, oncology, pathology, pharmacology and biological sciences at Johns Hopkins University School of Medicine. Re-elected to the NCCR board were: **Ann Barker**, president and CEO of BIO-NOVA, chairman of the Public Education Committee of the American Association for Cancer Research and immediate past chairman and member of the Integration Panel, Department of Defense Breast Cancer Research Program; **Kathi Mooney**, professor and interim associate dean for research, University of Utah College of Nursing and past president, Oncology Nursing Society; **Harmon Eyre**, executive vice president for research and medical affairs, American Cancer Society. Newly-elected NCCR board members are: **Joseph Bailes**, president, American Society of Clinical Oncology, executive vice president, clinical affairs at U.S. Oncology Inc.; **Robert Comis**, professor of medicine and director, MCP Hahnemann University Clinical Trials Research Center, president, board of directors, Coalition of National Cancer Cooperative Groups Inc. and group chairman, Eastern Cooperative Oncology Group; **Anatoly Dritschilo**, dean of graduate medical education and professor of radiation medicine, Georgetown University School of Medicine; **John Ruckdeschel**, center director and CEO, H. Lee Moffitt Cancer Center and Research Institute, professor of medicine, University of South Florida College of Medicine and College of Public Health; **Andrew von Eschenbach**, director of the Program Center-Genitourinary Cancers,
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"educate the presidential candidates on cancer issues and urge them to adopt a cancer cure and prevention agenda for the 2000 presidential election."

Edelman appears on a list of 70 "Tobacco Industry Supporters" compiled by the state of Florida two years ago, and figures prominently in materials posted on the Internet by anti-smoking activists.

On behalf of Louisville-based Brown & Williamson, Edelman handles publicity for Team KOOL Green that competes on the Championship Auto Racing Teams circuit.

Edelman operates a "mobile media coach," a 45-foot mobile home that serves as a media center for the Indianapolis-based team. "It looks like a motor-coach; a mobile-home-type motor-coach," Brown & Williamson spokesman Steve Kottak said to **The Cancer Letter**. "It's equipped with fax lines and modems, so the press can do stories on-site."

At a time when national promotional opportunities for tobacco products are becoming increasingly scarce, promoting the team, the sport—and ultimately KOOL cigarettes—is an important project for Brown & Williamson, which plans to invest \$50 million in the team between 1999 and 2001.

According to Brown & Williamson studies cited in *Business First*, a Louisville weekly, 15 of the 20

CART events are conducted in the US, draw mostly male crowds of about 150,000 per event, and are covered on national television.

Kottak as well as CART racing circuit officials identified Edelman Public Relations as the contact for Team KOOL Green. The team's 1999 media guide also lists a Tampa-based Edelman employee as a press contact. In a taped message, the employee identifies himself as "Ed Nicholls with Edelman Public Relations and Team KOOL Green."

"We are not engaged in public affairs on behalf of the tobacco industry in the U.S.," said Leslie Dach, vice chairman of Edelman's Washington office. However, Dach acknowledged that the agency's international division does work for tobacco companies. The company's client relationship with Brown & Williamson exists outside the U.S., he said. "The international division supports motorcar racing," Dach said.

Edelman official Eric Hoffman said Nicholls, despite being stationed in Florida, is not a U.S. employee. "He reports to our international operations," Hoffman said.

Edelman's representation of Brown & Williamson is the second embarrassment in a week for the Society that has a policy of not doing business with companies that handle tobacco. Earlier this week, ACS fired Shandwick International after learning that the public relations company also represents R.J. Reynolds Tobacco Holdings.

Shandwick's services to ACS included helping rewrite the National Cancer Act of 1971 as part of the Society-run National Dialogue on Cancer. The news of Shandwick's work for RJR appeared in the Jan. 21 issue of **The Cancer Letter**. [The issue is posted on **The Cancer Letter** web site, <http://www.cancerletter.com/032000.html>.]

"You reported something that you had learned, and we inquired, and we studied the facts, talked to Shandwick, and made a decision," ACS spokesman Greg Donaldson said to **The Cancer Letter**.

After being told by **The Cancer Letter** that Edelman, too, is involved in the tobacco business, Donaldson said the Society intends to not renew its contract with the firm.

"We certainly believe that we did due diligence on the front end of this relationship," Donaldson said. "However, that relationship will expire in 60 days, and we intend to not renew it."

Donaldson said the Society does not do business with firms that work for tobacco clients, foreign or



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Founded Dec. 21, 1973, by Jerry D. Boyd



domestic. “We hope that the folks at Edelman—just as we hope that the folks at Shandwick—will do the right thing and put themselves in a position where we can do business with them at some point in the future,” he said.

Edelman has made no secret of its tobacco ties. In April 1998, company chairman Daniel Edelman told *The Wall Street Journal* that the Florida list of 70 tobacco supporters was “a little extreme” and said that tobacco is a legal product.

Recently, on its web site, Edelman displayed a “case history” in which it took credit for creating an invitational golf tournament for Imperial Tobacco Ltd.

At the tournament, which coincided with du Maurier Ltd. Canadian Open, the chairman of the board of Imperial Tobacco invited selected guests to share 18 holes with golfers Jack Nicklaus and Arnold Palmer. The “prestige event” had “an impact on the company’s important client and customers,” Edelman materials said.

Edelman’s involvement with ACS was not as obvious as its representation of tobacco clients.

The company’s name does not figure in ACS press materials distributed at the campaign’s unveiling at a Jan. 13 press conference in Washington that featured Sens. Connie Mack (R-FL) and Dianne Feinstein (D-CA), and actor Eliot Gould.

The press contact named on the ACS press materials was a Society employee, and Hoffman is named as a contact for obtaining the television spot, but not identified as an Edelman employee.

Donaldson said the Edelman name was omitted at his request. “They were working on our behalf, but it seems to me that ACS should be an appropriate contact,” he said. “There was definitely no attempt to cover up anything.”

Tobacco business is spread out generously among lobbying, public relations and law firms in Washington, many observers said. Finding a public relations firm that doesn’t take tobacco clients is a challenge, especially among the top tier firms.

“The practical reality is that in this day and age of mergers and acquisitions, it is very difficult in some cases to get vendor support from certain areas where there has never been tobacco relationships,” Donaldson said. “Nonetheless, we are extremely mindful of the issue, and it’s very important to us.”

Firing Shandwick was probably the easiest of actions ACS could take in addressing the problems plaguing the National Dialogue on Cancer. Other problems include skepticism on the part of Dialogue

participants about the ACS claim that the process is aimed at enhancing communications between cancer groups rather than promoting the Society’s agenda.

Several leading participants of the Dialogue said they were disappointed by the appearance of a spin-off committee formed to advise Sen. Feinstein on the rewriting of the National Cancer Act. The decision to form the committee and the selection of its leadership were never discussed by the Dialogue’s Collaborating Partners and its Steering Committee.

On Jan. 20, the day before the story was published, Steering Committee chairman LaSalle Leffall sent a fax to all collaborating partners, pledging that the Dialogue would comment on the story.

“From discussions with [**The Cancer Letter**] editor we have reasons to believe that the article may be critical of certain aspects of Dialogue operations,” Leffall wrote. “When we receive the full text of the piece, we will share it, along with any explanations or rebuttals that may be indicated.”

As of this writing, **The Cancer Letter** has not received a response.

Professional Societies: **ASCO To Begin Large Study On Quality Of Cancer Care**

The American Society of Clinical Oncology plans to begin a study to develop a national monitoring system for cancer care in the U.S.

The 18-month pilot study, to begin next month, will assess the feasibility of a national cancer care monitoring system and develop a prototype for such a system, by initially examining the quality of care received by a sample group of adult breast and colorectal cancer patients. A panel of ASCO physicians and other health experts will oversee the study, which will be conducted by researchers at Harvard University and the RAND Corp.

“No national system currently exists to monitor the quality of cancer treatment,” said Joseph Bailes, ASCO president. “This study will provide the groundwork and the strategy to develop a national system that is urgently needed and help the cancer community ensure that patients nationwide receive the highest standard of care.”

Harvard and RAND researchers will review patient medical records, identified using the National Cancer Data Base, to better understand the level of care given to each patient, including the type of treatment provided and the kind of follow-up care



received. The researchers will administer patient surveys to help understand patients' experiences, the type of care received, where that care was received, insurance status and other information.

"This study is a constructive response to the Institute of Medicine's April 1999 report on Ensuring Quality Cancer Care, which called for improved information about the quality of cancer care nationwide," said Joseph Simone, a member of the National Cancer Policy Board and co-author of the IOM report. "I applaud ASCO's initiative in taking a leadership role so quickly, and at such a critical time."

The Susan G. Komen Breast Cancer Foundation will provide \$1 million in funding for the study. "Our commitment to patients and their families is what led the Komen Foundation to partner with ASCO and to help fund this quality of care initiative," said Nancy Brinker, founding chairman of the foundation. "What we learn from this initiative has the potential to impact each and every woman that will be diagnosed with breast cancer in the future."

Ellen Stovall, executive director of the National Coalition for Cancer Survivorship, said the study will help oncologists better serve cancer patients. "It is vital that a patient's treatment plan and experience receive this high caliber of attention and review by the largest medical society of physicians who treat cancer patients," she said.

Peter Eisenberg, of Marin Oncology Associates in Greenbrae, CA, and a member of ASCO's health services research committee, agreed. "It's incumbent upon physicians to know that they provide their patients quality cancer care," he said. "Physicians have never really been accountable for what they do, not only in oncology but in all disciplines."

Several organizations are joining ASCO in the study, including the American College of Surgeons, the Society of Surgical Oncology, the American Society for Therapeutic Radiology and Oncology, the Society of Gynecologic Oncologists, and the Oncology Nursing Society. Bristol-Myers Squibb, Amgen Inc., Aventis Pharmaceuticals, Agouron Pharmaceuticals Inc., and Ortho Biotech also contributed funding for the study.

Quality of Care Initiatives Growing

Efforts to address quality of care are underway in other cancer organizations, including:

—The National Cancer Policy Board of the IOM is finalizing a report with recommendations on improving data systems to enhance quality of care.

The report, a follow-up to the board's report last April, is expected to be made public in about two months.

—NCCS held a forum last December to design a model of quality cancer care from the perspective of patients. The coalition plans to hire a chief operating officer to build a business model that will allow the coalition to implement programs in quality improvement for cancer, Stovall said.

—The National Breast Cancer Coalition held a summit last year on quality of breast cancer care, and formed an advisory committee that is writing a position paper to describe quality of care. The committee identified six core values that capture a vision of quality of care: Information, access, respect, choice, accountability and striving to do better. NBCC also is developing a guidebook for breast cancer patients, and held meetings with Congressional staff members to discuss quality care.

—NCI is working with other federal agencies to establish research programs, define quality cancer care, and improve delivery of quality care (**The Cancer Letter**, Oct. 1, 1999).

***NIH Programs:* Adjuvant BC Therapy Is Topic Of Consensus Conference**

NIH is planning a Consensus Development Conference on Adjuvant Therapy for Breast Cancer, scheduled for Nov. 1-3, in Bethesda, MD.

Conference participants will consider new information on chemotherapy, hormonal therapy, and other aspects of treatment that have emerged in recent years. The meeting will culminate in recommendations for clinical practice.

"A substantial amount of new data has become available since the last consensus conference in 1990," said Jeff Abrams, of NCI's Cancer Therapy Evaluation Program, which is organizing the meeting. "NIH decided the time was ripe for another consensus conference because studies in the last decade have raised issues that need to be factored into treatment decisions."

During the conference, a panel of experts from outside NIH will hear presentations from leading researchers and then consider questions on specific topics. The agenda is under development.

To register for the conference, send an e-mail to breastcancer@prospectassoc.com or visit the NIH Web site for consensus conferences at <http://odp.od.nih.gov/consensus>.



NIH And E.I. Dupont Sign OncoMouse Agreement

NIH and E.I. DuPont said they have signed an agreement on the use of DuPont's proprietary OncoMouse transgenic animal technology.

The Memorandum of Understanding resolves long-standing issues of access by academics to this technology, originally developed through DuPont funding at Harvard University, and licensed exclusively to DuPont.

NIH and DuPont have reached terms by which the technology can be used in research conducted by or supported by NIH, without compromising DuPont's ability to receive appropriate value from commercial applications of the technology, NIH said in a statement.

The OncoMouse transgenic animal technology relates to animal models that develop tumors as a consequence of containing a recombinant activated oncogene sequence. First described by Philip Leder, the animal models are useful in basic medical research and are recognized as key model systems for the study of cancer and in testing the effectiveness of novel cancer therapeutics.

"This agreement will allow NIH scientists and grantees to continue to explore novel research avenues in the study of disease and in the basic underlying mechanisms that trigger it," said NIH Acting Director Ruth Kirschstein. "This agreement is also consistent with the newly promulgated NIH guidelines on research tools, and serves as a good example of how the principles in the guidelines can be implemented."

The MOU distinguishes between academic and commercial uses of the technology. DuPont has agreed to make the technology available at no cost to NIH researchers and grantee institutions for non-commercial purposes. Researchers affiliated with NIH may disseminate animals covered by the Leder patents to other academic laboratories and investigators for academic research under a Material Transfer Agreement. The recipient not-for-profit institutions need an agreement with DuPont if they wish to further transfer the animals provided by NIH.

NIH and DuPont recognize that academic institutions may want to transfer OncoMouse transgenic animal technology to commercial entities. Such transfer of materials requires the commercial entity to obtain a commercial research license. The full text of the agreement is available at <http://www.nih.gov/od/ott>.

Obituary:

Former Roswell Park Director Gerald Murphy, 65, In Tel Aviv

Gerald Murphy, a surgeon who was instrumental in the development of the prostate-specific antigen test for prostate cancer and directed Roswell Park Memorial Institute in Buffalo for 15 years, died Jan. 21 in Tel Aviv, Israel, while attending a meeting of the International Union Against Cancer (UICC). He was 65.

Murphy held the post of secretary-general of the UICC since 1974. He was instrumental in organizing national and international scientific conferences in prostate cancer research.

Murphy, a native of Seattle, earned his M.D. at the University of Washington in Seattle, interned at the Johns Hopkins Hospital in Baltimore, and was a resident at the Brady Urological Institute at Hopkins, where he was known for his phenomenal productivity, publishing more than 80 papers while still a resident. He was a research associate and chief in the Department of Surgical Physiology at the Walter Reed Army Institute of Research in Washington, DC.

Murphy established and directed a kidney transplantation unit at the University of Stellenbosch in Bellville, Capetown Province, South Africa. He organized a similar program, Western New York's first, on joining Roswell Park in 1967.

From 1970 to 1985, Murphy was director of Roswell Park. "Dr. Murphy can be remembered as a very dominant, active, effective and accessible director, contributing greatly to the expansion of research and clinical programs and facilities, ensuring that the institute and its mission were well represented in the state, national, and international cancer communities, and to the Board of Visitors," said Edwin Mirand, emeritus vice president for educational affairs at Roswell Park. Murphy worked with Mirand on early studies of erythropoietin.

In 1970, Murphy invited the Subcommittee on Health of the U.S. House of Representatives to hold a hearing at Roswell Park on the proposed National Cancer Act. At the Oct. 11, 1971, hearing, Murphy and others from the institute testified in support of the Act, which was signed by President Nixon on Dec. 23, 1971.

In 1972, Nixon appointed Murphy to the National Cancer Advisory Board, created by the Act. That year, Murphy also led the National Prostatic Cancer Project, one of five NCI "organ sites" projects to



test chemotherapeutic agents. In 1984, under Murphy's leadership, the center won the NCI grant for the Organ Systems Coordinating Center.

Through the Organ Systems grant, Murphy's research group at the State University of New York Medical School determined that prostate cancer tumors produce PSA. One of Murphy's colleagues, T. M. Chu, developed the PSA test.

Murphy was president of the New York State chapter of the American Cancer Society in 1974. He served as national president of ACS in 1983-84. He also held terms as president of the Society of Surgical Oncology and the Association of American Cancer Institutes.

Murphy left Roswell Park in 1985 over differences with the state health commissioner. He served as professor of urology and director of the Urologic Cancer Research Laboratory at the University at Buffalo. He worked as chief medical officer at ACS headquarters in Atlanta. He then became director and chief operating officer of the Pacific Northwest Research Foundation, and before his death, director of the Northwest Cancer Foundation.

"The cancer community has lost a great warrior and contributor with the passing of Gerald Murphy," said Donald Coffey, professor and director of research in the Department of Urology at Johns Hopkins University School of Medicine.

Murphy published more than 1,000 papers and received the Papal Medal for distinguished service to humanity in 1982.

He is survived by his wife, Bridget, and six children.

Funding Opportunities: **CTRF Seeks Applications In Clinical Cancer Research**

The Cancer Treatment Research Foundation, a non-profit organization, is accepting applications for new and pilot/feasibility clinical projects in cancer therapy. These areas include new, innovative anticancer therapies, biological response modifiers, immunotherapy, gene therapy, quality of life, and nutritional oncology. The Foundation is interested in both traditional and non-traditional approaches that have the potential to benefit cancer patients.

Inquiries or letter of intent: Joni Shulman, Grants Administrator, Cancer Treatment Research Foundation, 3455 Salt Creek Lane Suite 200, Arlington Heights, IL 60005, phone 847-342-6484.

Program Announcements

PAR-00-039: Established Investigator Award in Cancer Prevention, Control, Behavioral and Population Research

The purpose of this award is to provide established investigators protected research time and to act as mentors for new investigators. The target candidates are outstanding established scientists who have demonstrated a sustained, high level of productivity, research accomplishments, and contributions to cancer prevention, control, behavioral and population cancer research; and who can demonstrate the need to sustain an intensive research focus that will enhance the progress of their own research and provide them greater opportunity to serve as mentors to new scientists. The award provides salary support for a period up to five years, and is renewable for one additional five year period.

Inquiries: Lisa Begg, Cancer Training Branch Centers, Training and Resources Program, NCI, 6116 Executive Blvd., Suite 7011-MSC 8346, Bethesda, MD 20892-8346, phone 301-496-8580; fax 301-402-4472; e-mail begg1@mail.nih.gov.

PAR-00-040: Minorities in Clinical Oncology

The Comprehensive Minority Biomedical Branch, Office of Centers, Training and Resources, Office of the Deputy Director for Extramural Sciences, NCI, announces the availability of minority clinical oncology awards. The purposes of these awards are to encourage recently trained underrepresented minority individuals who hold a health-professional degree or its equivalent, or who are doctorally trained oncology nurses to acquire research experience in clinical oncology and to increase representation of minorities in clinical oncology research.

Inquiries: Eric Bailey, Comprehensive Minority Biomedical Branch, NCI, 6116 Executive Blvd., Bethesda, MD 20892-7405, Rockville, MD 20852 (express/courier service), phone 301-496-7344; fax 301-402-4551; e-mail baileye@mail.nih.gov

PAR-00-042: Mentored Patient-Oriented Research for Underrepresented Minorities

The NCI Comprehensive Minority Biomedical Branch announces the availability of a patient-oriented research career development award for minorities in clinical oncology. The purposes of this award are to encourage research-oriented minority clinicians to develop independent research skills and gain experience in advanced methods and experimental approaches needed to conduct patient-oriented research; and to increase the pool of minority clinical researchers who can conduct patient-oriented studies, capitalizing on the discoveries of biomedical research and translating them to clinical settings.

NCI is especially interested in increasing the number of minority clinicians trained to conduct high-quality,



patient-oriented clinical research. NCI intends to target a significant increase in funds for these entry-level career development awards through 2003.

Inquiries: Eric Bailey, Comprehensive Minority Biomedical Branch, NCI, 6116 Executive Blvd., Bethesda, MD 20892-7405, Rockville, MD 20852 (express/courier service), phone 301-496-7344; fax 301-402-4551; e-mail: baileye@mail.nih.gov

PA-00-046: Biobehavioral Research for Effective Sleep

NCI and other NIH institutes invite applications to investigate sleep deprivation in health and illness. The goal of this PA is to stimulate clinical and applied research on behavioral, psychosocial and physiological consequences of acute and chronic partial sleep deprivation in either chronically ill or healthy individuals and to develop environmental, clinical management, and other interventions with the potential to reduce sleep disturbances and significantly improve the health of large numbers of people.

Inquiries: Noreen Aziz, Office of Cancer Survivorship, Division of Cancer Control and Population Sciences, NCI, 6130 Executive Blvd, MSC 7339, EPN Suite 539, Bethesda, MD 20892-7339; phone 301-496-0598; fax 301-496-8675; e-mail: na45f@nih.gov

RFAs Available

RFA OD-00-003: Transitional Career Development Award in Women's Health Research

NIH Office of Research on Women's Health invites applications for the Transitional Career Development Award in Women's Health Research. The award is designed to support career development experiences leading to independence for clinical investigators interested in patient-oriented or population-based research related to women's health. The program will provide an opportunity for investigators to develop solid clinical research skills during two years of study and research within the environment of the NIH Intramural Research Programs. The award will include a follow-on two-year period of salary and research support at an academic institution of the candidate's choice.

Pfizer Women's Health of Pfizer Inc. will provide salary support through a grant to the Foundation for NIH for the intramural phase of the program. During the two-year period of career development, the candidate will engage in supervised clinical research and career development as a clinical or research fellow in the IRP of one of the NIH institutes or centers. Research support for this segment of the award will be provided by the assigned NIH Institute or Center. For the second phase of the award, research and salary support will be provided by ORWH in the form of an extramural career development award or K22 administered by the assigned NIH institute or center. The award will be activated when the candidate has

assumed a suitable, independent research position at an academic institution.

For NCI—related inquiries: Lester Gorelic or Andrew Vargosko, NCI Office of the Deputy Director for Extramural Sciences, Office of Centers, Training and Resources, Executive Plaza North Room 520 MSC 7390, Bethesda, MD 20892-7390, phone 301-496-8580; fax 301-402-4472; e-mail lg2h@nih.gov or av8b@nih.gov.

RFA HS-00-002: Making Quality Count for Consumers and Patients

Letter of Intent Receipt Date: Feb. 11

Application Receipt Date: March 24

Agency for Healthcare Research and Quality and NCI invite applications for demonstrations that facilitate consumer and patient use of information about quality. The demonstrations should (1) develop and test methods and models for developing information on quality for consumer and patient use in health care decisions; and (2) evaluate the impact of strategies to provide information about quality to consumers and patients.

AHRQ expects to award up to \$1 million and NCI expects to award up to \$ 0.5 million in fiscal year 2000 to support the first year total costs of 3 to 4 projects.

Inquiries: For NCI, Gary Kreps, Chief Health Communication and Informatics Research Branch, Behavioral Research Program, Division of Cancer Control and Population Sciences, NCI, Executive Plaza North, Room 239, 6130 Executive Blvd., MSC 7326, Bethesda, Maryland 20892-7326, phone 301-496-7984; fax 301-496-8675; e-mail Gary.Kreps@nih.gov.

RFA OD-00-006: Testing Interventions to Improve Adherence to Pharmacological Treatment Regimens

Letter of Intent Receipt Date: March 6

Application Receipt Date: April 6

Office of Behavioral and Social Sciences Research, NCI, and several other NIH invite applications for research project grants to encourage behavioral and social research on the effectiveness of interventions to improve adherence to therapeutic regimens in various settings.

Applications in response to the RFA must propose research on adherence to therapeutic treatment regimens where 1) the therapeutic regimen includes a pharmacological treatment; 2) the therapeutic regimen must be for an existing illness or condition, whether acute or chronic, as opposed to a health promotion regimen; 3) the adherence intervention has been (a) demonstrated to be efficacious in controlled settings, (b) tested only with limited populations or with short periods of follow-up, or (c) researched on a health condition or treatment regimen different from that in the proposed research; 4) the adherence intervention targets individuals, formal or informal health-care providers, and/or the social or institutional environment; and 5) there are measurements of (a) the delivery of the specified therapeutic regimen



and adherence intervention and of (b) adherence to the regimen.

NCI is making available \$3 million for the support of six new research grants in response to this RFA. Total project period may not exceed five years. Direct costs in the first year may not exceed \$350,000 and the accumulated direct costs over five years may not exceed \$1.75 million. Research projects with costs less than \$350,000 per year are encouraged.

NCI is interested in behavioral and social sciences research on promoting adherence to therapeutic regimens effective in the management of cancer. Therapeutic regimens are broadly defined to include not only active anticancer treatments, but also post-chemotherapeutic administration of compounds to prevent recurrence and post-treatment toxicities. NCI is interested in promoting research that may lower barriers to effective therapy for children, the aged, and the underserved.

Inquiries: For NCI, Roy Wu, Grants Program Director, NCI, 6130 Executive Blvd., EPN 734, Bethesda, MD 20892-7432, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, NCI, phone: 301-496-8866; fax 301-480-4663; e-mail: rw51j@nih.gov.

Notice: Availability of Supplemental Policy of NCI for Institutional National Research Service Awards

NCI announces supplemental policies that all applicants must use when submitting cancer research training programs to be supported by Institutional National Research Service Awards or T32 grants. The policy statement is available at the following website address: <http://deainfo.nci.nih.gov/awards/supT32guideline.htm>

Inquiries: Branch Chief, Cancer Training Branch, NCI, 6116 Executive Blvd., Suite 7011, MSC 8346, Bethesda, MD 20892-8346, phone 301-496-8580; fax 301-402-4472; e-mail lg2h@nih.gov.

In Brief:

Ganz Awarded Professor Of Survivorship By Komen

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special assistant for external affairs and professor of urology, University of Texas M.D. Anderson Cancer Center. . . . **PATRICIA GANZ**, director of the Division of Cancer Prevention and Control Research at the University of California, Los Angeles, Jonsson Cancer Center and professor in the Schools of Medicine and Public Health, has been awarded a professorship sponsored by the Susan G. Komen Breast Cancer Foundation. Her appointment as Professor of Survivorship includes a \$20,000 one-year honorarium for research on quality of life in cancer survivors. . . . **NCI DIRECTOR RICHARD**

KLAUSNER received the 12th Donald Ware Waddell Award from the Arizona Cancer Center in Tucson for his contributions to cancer research. Klausner gave two lectures at UA Health Sciences Center on Jan. 13. . . . **DAVID POPLACK** was presented with the John J. Kenny Award by the Leukemia Society of America, which recognizes medical professionals who have contributed to the mission of the society. Poplack is director of the Texas Children's Center in Houston. . . . **ROSWELL PARK CANCER INSTITUTE** made two administrative appointments: **Thom Loree**, assistant professor of surgery at the University of Buffalo School of Medicine and Biomedical Sciences, was appointed chief of the Division of Head and Neck Surgical Oncology/Plastic and Reconstructive Surgery at RPCI; **Wesley Hicks**, associate professor, Department of Otolaryngology, University at Buffalo School of Medicine and Biomedical Sciences, was appointed director of the fellowship program in the RPCI division. Both Loree and Hicks will continue to serve in their faculty positions at Buffalo. . . . **CHARTER OF PARIS AGAINST CANCER**, a declaration to raise international concern about cancer by calling for a bold commitment to scientific, social and political innovations for the best delivery of cancer care everywhere, will be signed at the World Summit Against Cancer on Feb.4, in Paris. The Charter (www.charteragainstcancer.org) encompasses 10 directives including: protecting and expanding patient rights; increasing the commitment to basic, clinical and translational research; improving access to clinical trials; prevention and screening programs; and addressing patients' quality of life issues. **Gabriel Hortobagyi** of M.D. Anderson Center and **David Khayat** of the Pitie-Salpetriere Hospital in Paris organized the summit. . . . **MARCIA NENNO**, a public educator for American Cancer Society, was appointed to lead the Ovarian Cancer National Alliance Ovarian Cancer Public Education project. Supported by a SmithKline Beecham grant, the project will educate women, health care providers, and managed care groups about the risks of ovarian cancer and the benefits of early detection. . . . **CALL FOR ABSTRACTS** for an NIH-sponsored conference, Nanoscience and Nanotechnology: Shaping Biomedical Research Symposium, scheduled for June 25-26, in Bethesda, MD. For further information, visit the symposium Web site at <http://grants.nih.gov/grants/becon/symposium2000.htm>.



Business & Regulatory Report

Formerly "Cancer Economics"

Product Approvals & Applications:

FDA Approves Celebrex For Colon Polyps, Taxotere For Advanced Lung Cancer

FDA has granted marketing approvals for:

—**Celebrex** (celecoxib), an arthritis drug, as adjunctive therapy for Familial Adenomatous Polyposis. Celebrex has been shown to reduce and regress colorectal polyps, a condition which often leads to colorectal cancer. The drug is sponsored by **G.D. Searle Co.**, a subsidiary of Monsanto.

—**Taxotere** (docetaxel) for locally advanced or metastatic non-small-cell lung cancer in patients whose disease has progressed despite
(Continued to page 2)

Oncology Management:

US Oncology Forms Two Operations: Physician Services, Cancer Information

US Oncology Inc. (Nasdaq: USON) of Houston, said it has realigned its core operations into two strategic business initiatives: Physicians Services Group; and Cancer Information and Research Group.

—The Physician Services Group will offer operational and development cancer services to the US Oncology network. David Chernow, chief development officer since 1993, will serve as group president.

—The Cancer Information and Research Group will include its cancer research initiative, cancer information management and cellular therapeutics. Atul Dhir, formerly of McKinsey & Co. and Monsanto, will serve as president.

“Since the completion of the merger six months ago, we have thoroughly analyzed our existing operations and believe this new structure will enable us to focus on our core competencies and better position the company for future growth,” said R. Dale Ross, chairman and CEO of US Oncology.

In another development, L. Fred Pounds announced his resignation as chief financial officer. The company said it has retained Korn/Ferry International and initiated a search for a new chief financial officer.

The company’s executive office will now include the Corporate Services Group that will provide the core business functions that support the strategic business initiatives. The Corporate Services Group will be led by Leo Sands as executive vice president and chief compliance officer.

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Targretin Approved To Treat Cutaneous T-Cell Lymphoma

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treatment with prior platinum-based chemotherapy. Taxotere is used for advanced breast cancer treatment. The drug is sponsored by **Rhone-Poulenc Rorer**.

—**Targretin** (bexarotene) capsules for the treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy. The indication includes patients diagnosed with all stages of refractory CTCL. The drug is sponsored by **Ligand Pharmaceuticals Inc.** (Nasdaq:LGND) of San Diego.

* * *

Berlex Laboratories Inc. of Montville, NJ, said its development partners, **ILEX Oncology Inc.** and **LeukoSite Inc.** filed a biologics license application to FDA for Campath (alemtuzumab) an investigational humanized monoclonal antibody.

The filing seeks marketing approval of Campath for the treatment of advanced B-cell chronic lymphocytic leukemia that is refractory to existing therapies. FDA has granted Campath an orphan drug designation, the company said.

Campath has received Fast Track designation from FDA and is expected to undergo a six-month priority review under the Prescription Drug User Fee

Act. The review period begins with the submission of the completed BLA, the company said.

Under an agreement reached in August 1999, Berlex obtained exclusive U.S. distribution and marketing rights for Campath from LeukoSite and ILEX.

* * *

Maxim Pharmaceuticals (AMEX:MMP, SSE:MAXM) of San Diego, said FDA has granted orphan drug status to Maxamine as an adjunct to cytokine therapy for the treatment of acute myelogenous leukemia.

Maxamine therapy treats AML patients in remission with a combination of Maxamine and low doses of the cytokine interleukin-2 to prevent relapse and prolong leukemia-free survival while maintaining the quality of life for patients during treatment, the company said. The combination therapy is intended to enhance the body's ability to scavenge and attack residual leukemic cells.

In a phase II study, patients treated in their first remission with Maxamine therapy have experienced a substantial increase in leukemia-free survival. The patients treated with Maxamine therapy have achieved a median time to relapse through the last date of evaluation of 28 months compared to a reported median of 12 months under the current standard of care, the company said.

Maxim is enrolling patients in a phase III trial of Maxamine and IL-2 as a remission therapy for AML. Doctors and patients in 12 countries, including sites in the U.S., Europe, Australia, Canada and Israel, are participating in the study.

* * *

Matritech Inc. (Nasdaq: NMPS) said FDA has cleared its NMP22 Test Kit for expanded use as an aid in testing for bladder cancer.

The company said NMP22 is cleared by FDA for monitoring the recurrence of bladder cancer. The test is also approved for screening in Japan and China, and is in use in Europe.

Last December, an FDA advisory panel recommended approval of the expanded use of the NMP22 Test Kit with two conditions which the company said have it has satisfied.

“With regard to high-risk individuals such as smokers or those with hematuria, NMP22 used as an adjunct to cystoscopy and urine cytology can facilitate early detection of bladder cancer,” said Ihor Sawczuk, professor and vice chairman of urology, Columbia University. “When detected early, tumors



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most often can be removed successfully, sparing the patient the need for more aggressive treatments such as the use of chemotherapeutic agents or, in extreme cases, removal of the bladder.”

“NMP22 is one of a select group of tests cleared by the FDA as an aid in diagnosis of urologic cancers,” said Robert Di Loreto, a urologist with the Michigan Institute of Urology and a member of the FDA panel that reviewed the NMP22 clinical data. “Given some time and clinical experience, NMP22 has the potential to enhance patient care by potentially reducing the invasiveness associated with hematuria evaluation.”

* * *

Wyeth-Ayerst Laboratories, of Madison, WI, the pharmaceutical division of **American Home Products Corp.** (NYSE: AHP), said FDA has assigned priority review status and accepted for filing the NDA for Mylotarg (gemtuzumab zogamicin) for CD-33 positive relapsed adult acute myeloid leukemia.

Mylotarg is a humanized recombinant antibody linked with a cytotoxic antitumor antibiotic called calicheamicin, isolated from a bacterium in caliche clay, a soil found in Texas. The antibody portion of Mylotarg is specific for the CD-33 antigen, a protein commonly expressed by myeloid leukemic cells.

The company said that, if approved, Mylotarg, would be the first in a new class of anticancer therapy known as antibody-targeted chemotherapy. The new class of therapy, based on an antibody/cytotoxin linker technology platform, is being developed jointly by Wyeth-Ayerst Laboratories and Celltech Chiroscience, a research-based pharmaceutical company in the U.K.

No chemotherapeutic drugs are specifically approved for treating patients with relapsed AML, the company said.

Oncology Management: **US Oncology Executives Shuffled In Forming Divisions**

(Continued from page 1)

Allen Pittman, chief administrative officer, Phil Watts, vice president and general counsel, and Joseph Bailes, executive vice president for clinical services, will continue to lead their respective areas.

Marc Kerlin, senior vice president for Managed Care, will continue to supervise managed care and explore new disease management opportunities. Mark Ahern, senior vice president for development, will direct the efforts to affiliate with new practices and

the continued expansion of cancer centers. William McKeon, senior vice president for Marketing and eCommerce, will lead both the marketing and eHealth business opportunities.

“Our company is evolving,” said Lloyd Everson, US Oncology president. “While still intently focused on our core operations, we have become a cancer information and disease management company.”

* * *

Salick Health Care Inc of Los Angeles, said it has formed **Logic Health Systems Inc.**, a subsidiary that will continue development of the company’s disease management program and software. The company said the creation of LHS enables it to focus on the core business of managing cancer centers.

LHS software business is based on the OMAR System, a proprietary case management software application developed by the company.

The system was first developed to meet the requirements of the SalickNet disease management program. The company said the OMAR System and SalickNet would be marketed by LHS to payers and large medical groups. LHS will be an outsourced application service provider for its technology solutions.

“Logic Health Systems offers payers innovative and critical tools to manage large member populations,” said Harlan Levine, president of Logic Health Systems.

Salick is a unit of AstraZeneca Corp.

Clinical Trials: **Celsion Begins Phase I Studies For Breast Cancer And BPH**

Celsion Corp. (OTC Bulletin Board: CELN) of Columbia, MD, said initial patients have been treated in both the phase I studies for its breast cancer treatment system and its expanded phase I studies for its benign prostatic hyperplasia system.

The company said its breast cancer system, a non-surgical and minimally invasive treatment that is non-toxic and side effect free, is designed to destroy cancerous tumors using heat alone.

After completing phase I clinical studies of the breast cancer treatment system, the company said it was granted approval from FDA to conduct an expanded study with revised protocol designed to shorten the treatment time and simplify its software requirements.



The company said the treatment system for benign hyperplasia utilizes a proprietary microwave balloon catheter designed to treat enlarged prostates. The expanded phase I BPH trials began in December at Montefiore Medical Center in New York City. A total of 10 patients are planned for this expanded study.

* * *

Genentech Inc. (NYSE:DNA) of South San Francisco, said it will proceed with phase III clinical trials studying recombinant humanized monoclonal antibody to Vascular Endothelial Growth Factor (rhuMab-VEGF) in combination with chemotherapy in metastatic colorectal cancer and metastatic non-small cell lung cancer.

The colorectal phase II study enrolled 104 patients with previously untreated metastatic disease. The open-label trial randomized patients to receive either 5-FU/leukovorin alone or in combination with rhuMab-VEGF, the company said.

The non-small cell lung cancer phase II trial enrolled 99 patients with previously untreated metastatic disease. The open-label trial randomized patients to receive either carboplatinum/paclitaxel alone or in combination with rhuMab-VEGF, the company said.

Genentech said it plans to sponsor the phase III trial in colorectal cancer and is in discussions with the Eastern Cooperative Oncology Group to study rhuMab-VEGF in conjunction with chemotherapy in a non-small cell lung cancer phase III trial.

* * *

Cephalon Inc. (Nasdaq: CEPH) of West Chester, PA, said it has begun a phase II clinical program with its oncology compound CEP-701. Cephalon's clinical partner TAP Holdings Inc. is initiating a phase II clinical program in patients with prostate cancer.

The phase II program will include a study in patients whose prostate is being surgically removed and a study in patients with hormone-resistant tumors to learn if CEP-701 will slow the growth of tumors. Cephalon and TAP recently completed phase I clinical testing with CEP-701, the company said.

"CEP-701 is the lead drug in our oncology program and reflects our substantial progress in developing an integrated cancer business," said Frank Baldino, president and CEO at Cephalon. "We have a unique group of signal transduction inhibitors that we believe will address the need for a more targeted and less toxic approach to treating cancer."

"There is a desperate need for new therapies to treat prostate cancer and a non-toxic, innovative compound such as CEP-701 will find ready acceptance in this marketplace," said Nicholas Vogelzang, Fred C. Buffett professor of medical oncology, and director of the Cancer Research Center at the University of Chicago.

* * *

Genta Inc. (Nasdaq: GNTA) of Lexington, MA, said NCI began phase I-II study of its anticancer compound, G3139 in combination with paclitaxel for the treatment of relapsed small lung cancer.

The goal of the study, conducted under the Cooperative Research and Development Agreement between Genta and NCI, is to provide new treatment options for patients with specific cancer indications and to obtain regulatory approval of G3139 as a commercial anticancer agent, the company said.

"There is extensive laboratory evidence from our group and others that Bcl-2 can make tumors very drug resistant. Over 90 percent of small cell lung cancers produce high levels of Bcl-2. We are very excited about bringing a laboratory observation into a clinical study for patients with small cell lung cancer, testing the idea that suppressing Bcl-2 may make a tumor that is notoriously difficult to treat much more sensitive to therapy," said Charles Rudin of the University of Chicago Medical Center and lead investigator.

The collaboration between NCI and Genta will include other studies of G3139 in combination with standard chemotherapies for treatment of patients with colorectal cancer and relapsed acute leukemia. "This series of studies represents Genta's focused strategy of using G3139 to enhance the cancer-killing actions of selected, major chemotherapeutic drugs," said Raymond Warrell, president and CEO of Genta. "The taxane chemotherapies such as paclitaxel are among the most common treatments for lung and other common malignancies. This new study in patients with small cell lung cancer will provide valuable clinical data about safety and efficacy of paclitaxel combinations with G3139."

* * *

Matrix Pharmaceutical Inc. (Nasdaq:MATX) of Fremont, CA, said it has completed the enrollment for its two phase III registration-directed clinical trials of IntraDose (cisplatin/epinephrine) Injectable Gel in head and neck cancer.

"This milestone is significant for Matrix because favorable results of these trials should allow the



company to file an NDA by the end of the year,” according to Michael Casey, Matrix president, CEO and chairman.

FDA granted IntraDose fast-track status last May which means that IntraDose is eligible for a priority FDA review when the New Drug Application is filed, the company said.

In addition to head and neck cancer, IntraDose is also being studied in other solid-tumor cancers including breast, esophageal, liver and malignant melanoma. Unlike systemic chemotherapy agents, IntraDose is designed to be injected directly into the tumor and to limit the drug’s circulation throughout the patient, resulting in a higher concentration of the drug at the disease site with fewer systemic side effects, the company said.

Two randomized, double-blind, placebo-controlled phase III trials of patients with recurrent or refractory head and neck cancer are being conducted. One trial is being conducted in the U.S. and Canada and the other trial is being conducted in countries outside of North America, the company said.

* * *

Targeted Genetics Corp. (Nasdaq: TGEN) of Seattle, said it has initiated a phase I trial of tgDCC-E1A for the treatment of ovarian cancer.

The study will enroll up to 21 patients and will assess the safety of tgDCC-E1A in combination with paclitaxel and cisplatin for advanced stage ovarian cancer, the company said. The trial is ongoing at the Arizona Cancer Center at the University of Arizona and is expected to open at M.D. Anderson Cancer Center, the company said.

“The ability to use tgDCC-E1A as either a single agent or in combination with chemotherapy should expand the indications for which this product may provide clinical benefit,” said Barrie Carter, executive vice president and director of research and development at Targeted Genetics. “This combination therapy may provide benefit for many cancer patients whose disease has not responded to or cannot be treated with standard therapies.”

The trial will evaluate tgDCC-E1A delivered by intraperitoneal administration at up to four dose levels in combination with intravenous paclitaxel and intraperitoneal cisplatin in up to 21 patients. Patients in the initial cohorts will receive three treatment courses at four-week intervals in order to evaluate the maximally tolerated dose. Upon identification of the mtd, up to six additional patients will receive six

treatment courses of tgDCC-E1A at this dose in combination with paclitaxel and cisplatin. Primary outcome measures include safety and definition of the mtd. Secondary observations will include measurement of E1A expression in tumor cells, evaluation of tumor response, and pharmacokinetics of paclitaxel and cisplatin, the company said.

* * *

Titan Pharmaceuticals Inc. (AMEX: TTP) of South San Francisco, said it has reached the accrual goal for its randomized, double blind, placebo controlled study of CeaVac for advanced colorectal cancer.

The study, which is being expanded to phase III, is designed to evaluate the safety and efficacy of CeaVac in previously untreated Dukes D colorectal cancer. Details of the expanded study protocol are currently being finalized with FDA, the company said.

In a related development, the company said it had been issued U.S. patent number 5,977,315 for CeaVac, used in generating immune responses to carcinoembryonic antigen, which is present on colorectal cancer cells and many other cancer cell types.

* * *

Vasogen Inc. (TSE:VAS; AMEX:MEW) of Toronto, said it has results of the final phase of its pre-clinical research in the prevention of Graft-versus-Host Disease.

The results have supported regulatory submissions to begin a clinical trial of its VAS981 cell processing technology in the prevention of GvHD.

Vasogen said research results demonstrated the treatment of donor immune cells with VAS981 prior to transplantation prevented GvHD in animal models. Recently completed research extended the studies to investigate the effects of VAS981 on human immune cells that are administered in bone marrow grafts and cause GvHD. The results showed VAS981-treated cells produced much lower levels of the inflammatory cytokines that are associated with GvHD. The in vitro changes seen in these laboratory studies on human cells closely mirrored those seen in vivo in the pre-clinical models, where they were associated with a dramatic reduction in GvHD, the company said.

“Bone marrow transplantation is a potentially life-saving procedure for many patients suffering from leukemia and lymphoma,” said David Spaner, Division of Cancer Biology Research, Sunnybrook Health Science Centre, University of Toronto.



“Unfortunately, the success of bone marrow transplantation can be compromised by GvHD. Overcoming this problem would represent a major breakthrough in the treatment of cancer patients and could extend the use of life-saving bone marrow transplantation to thousands more patients each year.”

Deals & Collaborations:

Calif. Firm To Own Xenomouse In Purchase From JT America

Abgenix Inc. (Nasdaq: ABGX) of Fremont, CA, said it would become the sole owner of the Xenomouse by acquiring all of the interest in the technology owned by **JT America Inc.**

Under the agreements, Abgenix said it will pay \$47 million to Japan Tobacco America for its 50 percent interest in Xenotech Inc., and Xenotech, L.P., an equally owned limited partnership between the two companies that created the Xenomouse. Abgenix will pay \$10 million as compensation to JT Inc. to relinquish certain option and license rights. The company said acquisition is expected to close by year-end and is contingent upon approval under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

Abgenix said Japan Tobacco would have a research license to use Xenomouse technology and options to license the technology for a small number of antigen targets each year. Abgenix said it will provide JT with licenses to related technology. In return for these licenses, JT will pay Abgenix \$10 million. JT also retains options to, or licenses on, several antigen targets it has previously nominated under the Xenotech structure. For all antibody products generated using Xenomouse technology and developed by JT, JT will make license fee payments to Abgenix as well as royalty payments on any product sales, the company said.

Abgenix said it had developed Xenomouse technology to enable the rapid generation of high affinity, fully human antibody product candidates to any disease target appropriate for antibody therapy. Abgenix said it has collaborative arrangements with multiple pharmaceutical and biotechnology companies involving its Xenomouse technology.

Abgenix collaborates with the U. S. Army Medical Research Institute of Infectious Diseases in which the Army uses the Xenomouse technology to make fully human antibodies that will be tested for their ability to provide protection against filovirus and poxvirus infections. Filoviruses, such as Ebola virus

and Marburg virus, and poxviruses, including smallpox, pose a potential biological warfare or bioterrorism threat, the company said.

* * *

Abbott Laboratories (NYSE: ABT) of Abbott Park, IL and **SuperGen Inc.** (Nasdaq: SUPG, SUPGW & SUPGZ) of San Ramon, CA, said they have signed a worldwide sales and marketing agreement for the cancer drug rubitecan.

Rubitecan is an oral chemotherapy compound in the camptothecin class and is currently in phase III studies for the treatment of pancreatic cancer, the companies said.

“Rubitecan is a potentially valuable addition to our Oncology franchise. Clinical data suggest rubitecan has the potential to become a safe and effective therapy for the treatment for pancreatic cancer, a disease for which there are limited treatment options available,” said Richard Gonzalez, senior vice president, hospital products at Abbott Laboratories. “Furthermore, feedback from patients and clinicians worldwide has indicated a great need for an oral chemotherapy alternative.”

Under the terms of the agreement, Abbott said it will make an initial equity investment in SuperGen. Abbott will have exclusive distribution and promotion rights for rubitecan outside the U.S. and co-promotion rights with SuperGen for rubitecan within the U.S. In addition, Abbott will become the exclusive U.S. distributor for Nipent, SuperGen’s treatment of hairy cell leukemia. SuperGen retains U.S. marketing rights for Nipent.

Rubitecan is currently being studied at more than 200 clinical sites for the treatment of pancreatic cancer. SuperGen has previously reported it expects to initiate clinical trials of rubitecan for additional tumor types. Under the agreement, SuperGen said it would be responsible for funding clinical development of a pancreatic claim for the drug.

* * *

ALZA Corp. (NYSE: AZA) of Mountain View, CA, said it has adopted a stockholder rights plan to help stockholders realize fair value and equal treatment in the event of a takeover and to protect itself and its stockholders against coercive takeover tactics.

The rights generally will not become exercisable until a person or group acquires 15 percent or more of ALZA common stock in a transaction that is not approved in advance by the board of directors. In that event, each right will entitle the holder, other than



the unapproved acquirer and its affiliates, to acquire, by payment of the then-applicable exercise price (initially \$200, subject to adjustment) shares of ALZA common stock with a market value equal to two times the exercise price.

In addition, if the rights were triggered by such a non-approved acquisition and the company were thereafter to be acquired in a merger in which all stockholders were not treated alike, stockholders with unexercised rights, other than the unapproved acquirer and its affiliates, would be entitled to purchase common stock of the acquirer with a value of twice the exercise price of the rights.

In a related development, ALZA Corp. said it would not complete the proposed merger with **Abbott Laboratories** (NYSE: ABT).

Despite considerable efforts, Abbot said the companies were unable to reach an agreement with the Federal Trade Commission that would satisfy antitrust concerns relating to the merger.

* * *

Coram Prescription Services of Orlando, FL, a specialty mail order pharmaceutical division of **Coram Healthcare** (NYSE:CRH), said it has entered into an agreement with **Roche Laboratories Inc.** to conduct a patient start program for the oral oncology medication Xeloda.

Under the agreement, CPS will provide a seven-day starter kit with medications. CPS said it will offer patients counseling on dosing as well as other information and assistance.

Roche sponsors the patient start program, makers of Xeloda. Xeloda is indicated for the treatment of metastatic breast cancer resistant to both paclitaxel and an anthracycline-containing chemotherapy regimen or resistant to paclitaxel and where further anthracycline therapy is not indicated, the company said.

* * *

Digene Corp. (Nasdaq: DIGE) of Beltsville, MD, said Johns Hopkins Medical Institutions will participate in its HPV Centers of Excellence program. Hopkins joins Yale University School of Medicine to promote the education of healthcare providers and women about the clinical value of testing for Human Papillomavirus in the detection of cervical cancer, the company said.

“The CEP enhances cervical cancer prevention for the under-served women in our community and in addition allows us to build on the work that we are doing towards preventing the disease world-wide,”

said Fredrick Montz, professor and director of gynecologic oncology at Hopkins.

* * *

Millennium Pharmaceuticals Inc. (Nasdaq: MLNM) of Cambridge, MA, said **Eli Lilly and Co.** (NYSE: LLY), one of its oncology partners, has accepted a validated target for drug candidate screening in the field of prostate cancer.

Company scientists identified a candidate gene of potential relevance to the treatment of androgen-resistant prostate cancer. Millennium said further study has allowed the collaboration to declare this gene a validated target for drug discovery under the terms of the Lilly-Millennium agreement.

“The innovation and productivity of our pharmaceutical discovery process has enabled us to quickly identify this novel target which may lead to the development of new therapeutics for patients with prostate cancer,” said Joseph Bolen, vice president of oncology at Millennium. “Lilly’s rapid acceptance of the target is representative of our true partnership in oncology research, and we hope to advance additional targets into screening and later stage development through our work together,” Bolen said.

* * *

Ligand Pharmaceuticals Inc. (Nasdaq: LGND) of San Diego, said **Pfizer Inc.** has narrowed its focus to one of two compounds for treatment of osteoporosis and breast cancer in post-menopausal women.

Pfizer said it intends to proceed to phase III trials for lasofoxifene, currently in phase II trials, and discontinue work on droloxifene, a first generation selective estrogen receptor modulator worked on by Ligand during the collaboration.

Under the terms of the agreement, Ligand said it is entitled to receive milestones for the continued development of lasofoxifene as well as a royalty equal to 6 percent of net sales. The royalty rate on droloxifene worldwide sales would have been substantially lower, 1 percent for breast cancer and 3 percent for indications other than breast cancer, including osteoporosis.

“Pfizer’s choice to continue development of lasofoxifene is encouraging for women who suffer from osteoporosis and breast cancer as well as for Ligand,” said Andres Negro-Vilar, Ligand senior vice president of research and CFO. “Unlike the first generation SERMs, the second generation SERMs such as lasofoxifene increase bone mineral density and reduce LDL cholesterol as well as or better than



currently available drugs, without the breast or uterine cancer risk associated with traditional hormone replacement therapies. Therefore, lasofoxifene represents a 'best in class' choice as a true second generation SERM," Negro-Vilar said.

Pfizer said one or both of these compounds would enter full phase III development based on the results of their respective phase II trials. Pfizer said it believes lasofoxifene is the most potent of the selective estrogen receptor modulators. According to information recently released by Pfizer, lasofoxifene increases bone mineral density as well as Prempro and reduces LDL by 25% versus 16% for Evista. The company said it would not go forward with droloxifene for any indications.

* * *

Monsanto Co. said its pharmaceutical subsidiary, **G. D. Searle**, is forming an alliance with **Cambridge Antibody Technology** of Melbourn, England, to pursue monoclonal antibody-based drugs for treatments ranging from cancer to arthritis.

Searle will pay \$12.5 million for a 6.9 percent stake in Cambridge. Searle said it has agreed to spend at least \$14.5 million to fund research for three years, Monsanto said.

Searle has the option of spending \$35 million to extend the research collaboration for an additional two years, Monsanto said. Cambridge said it could receive an additional \$150 million from Searle if the drug pipeline reaches certain development and regulatory milestones as well as additional royalties from drug sales.

Research on monoclonal antibodies stirred great interest among pharmaceutical companies in the late 1980s as researchers hoped they could prove to be a more effective way of delivering chemotherapy or radiation to cancer cells. But interest waned because of side effects.

The drug industry appears to be regaining interest in the development of new monoclonal antibody technology. Bayer AG, the German drug company, said it had made a research pact with another monoclonal-antibody biotech firm in early December.

Monsanto's investment in Cambridge comes just days after it announced a planned merger with Pharmacia & Upjohn of Peapack, N.J.

* * *

Prolifaron Inc., of San Diego, a privately held biotechnology company, said it has received an exclusive worldwide license to a catalytic antibody

technology from **The Scripps Research Institute** for use in the development of new selective chemotherapeutics through prodrug activation.

Cancer treatments using chemotherapeutic agents are associated with non-specific toxicity, a serious dose-limiting side effect. Prolifaron's catalytic antibody technology can localize the delivery of a cytotoxic drug to a specific cell or cancer type, the company said. The process involves a two-stage mechanism in which cancer cells are targeted with a specific monoclonal antibody linked to a catalytic antibody, and then prodrug substrate is added that is catalyzed to the active, toxic form by the targeting/catalytic antibody conjugate. As a result, higher concentrations of active drug can be delivered to the tumor cell, the company said.

"We believe the technology can be applied to several well known cytotoxic drugs to improve their safety and efficacy profile, said Katherine Bowdish, president and CEO of Prolifaron.

* * *

SuperGen Inc. (Nasdaq: SUPG, SUPGW & SUPGZ) of San Ramon, said it has acquired an equity interest in **AVI BioPharma Inc.** (AVI) (Nasdaq: AVII, AVIIW & AVIIZ) of Portland, OR.

Under the terms of the agreement, SuperGen said it acquired 7.5 percent of the AVI outstanding common stock for \$2.5 million and 100,000 shares of SuperGen common stock. Also, SuperGen said it acquired exclusive negotiating rights in the U.S. to Avicine, the AVI proprietary cancer vaccine currently in late-stage clinical testing against a variety of solid tumors.

Avicine is designed to elicit an immune response by targeting a tumor-associated antigen, human chorionic gonadotrophin. Malignant tumors usually coat themselves with hCG, as the hormone has the ability to promote cell growth, invasion and angiogenesis while evading the immune system. Avicine neutralizes the effect of hCG on cancer cells, while stimulating the immune system to react against the tumor, the company said.

Avicine has completed five clinical trials. Results from a phase II study using Avicine against advanced colorectal cancer showed that patients who responded to the peptides in the vaccine exhibited significant survival benefits compared to patients treated with chemotherapy alone. AVI has developed a phase III protocol for Avicine with assistance of leading oncologists and FDA for first-line therapy in metastatic colorectal cancer, the company said.



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