THE CANCER LETTER

Vol. 35 No. 15
April 17, 2009

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

Dendreon Claims "Clear Hit" On Provenge, But Skeptics Await Data Presentation

By Paul Goldberg

Dendreon Inc. announced April 14 that it has met the endpoint for approval of Provenge (sipuleucel-T), a vaccine for treatment of advanced prostate cancer.

The company didn't disclose data on either efficacy or toxicity, pending a presentation scheduled for April 28 at the plenary session at the American Urological Association.

At a conference call with analysts, Dendreon's President and CEO Mitchell Gold said that the data "meet the criteria and specifications" of the Special Protocol Assessment by FDA, thereby supporting renewal of the company's approval filing.

Gold described the data as "an unambiguous hit on the primary endpoint

(Continued to page 2)

In the Cancer Centers:

Emory University's Winship Cancer Institute Wins NCI Cancer Center Designation, $4.2M

EMORY UNIVERSITY'S Winship Cancer Institute received NCI cancer center designation, becoming the 64th center in the U.S. to hold an NCI Cancer Center Core Grant. The grant will provide $4,285,191 over the next three years.

"We are very proud of Emory's Winship Cancer Institute for achieving this important designation," **Georgia Gov. Sonny Perdue** said in a statement. "Cancer strikes more than 35,000 Georgians each year, and through initiatives such as the Georgia Cancer Coalition and the Georgia Research Alliance, we are working hard to place Georgia at the forefront of cancer research with the goal of eliminating this devastating disease. Winship has served as a model in establishing collaborative research programs and in working statewide to address the pressing issues related to treatment, education and access to care for cancer patients."

Winship was established in 1937 through a $50,000 gift to Emory from Coca Cola CEO Robert Woodruff, who named the center after his grandfather, Robert Winship. The Woodruff Foundation has continued to support Emory, and in 2002 Emory dedicated the 275,000 square-foot Winship Cancer Institute building, constructed with funds from the foundation.

"This designation is a tremendous honor and a reflection of the hard work and dedication that is exhibited by faculty and staff throughout the

(Continued to page 7)

Provenge Data To Be Released At AUA Plenary Session April 28

(Continued from page 1)

of overall survival in terms of statistical significance."

"It was a clear hit on a prespecified primary endpoint of overall survival," Gold said. "The results were robust, and they held up to multiple sensitivity analyses."

Dendreon's regulatory filings contain the following description of the company's SPA agreement with FDA:

"If the study demonstrates approximately a 22 percent reduction in the risk of death, based on 304 events, we would expect the study to meet its primary endpoint of overall survival. In such event, we believe these data would be sufficient to address the FDA's request for additional clinical information to support the proposed efficacy claim and we would amend our [Biologics License Application]."

At the conference call April 14, the company said it planned to submit the filing during the fourth quarter. After the announcement, the price of Dendreon's stock nearly tripled, from $6.3 on April 9 to $17.3 at the close of trading April 14.

Though SPAs constitute contracts with FDA, fulfillment of the terms doesn't guarantee approval, as the agency reserves the right to consider new information.

Prostate cancer experts contacted by The Cancer Letter said they are eagerly awaiting the release of trial data at AUA, and—more so—the contents of the application submitted to the agency should those become public.

The agent's history at FDA has been politically charged.

Two years ago, the Cellular, Tissue and Gene Therapies Advisory Committee voted 13 to 4 in favor of approving the drug. The recommendation was reached by a committee that lacks the oncology and clinical trials expertise of the Oncologic Drugs Advisory Committee. At various points during the meeting, committee members demonstrated that they didn't have full grasp of the approval criteria (The Cancer Letter, April 13, April 27, May 4, 2007).

The agency didn't follow the committee's recommendation, presumably after concurring with skeptics who stated that the drug trials presented at that time were fundamentally flawed. The findings were based on a post hoc analysis, skeptics said. Moreover, the company was in the midst of conducting a trial powered to determine survival and an approval could have undermined that trial.

After the agency issued an "approvable letter" seeking additional information, a group of patients and investors launched a pro-Provenge campaign that included threats against skeptics and picketing of the agency. The coalition also sued FDA in federal courts in Ohio. The case was ultimately tossed out on appeal.

If the application is indeed the slam-dunk claimed by Gold, the drug would be simply approved without any public controversy.

More likely, the agency will have to grapple with the peculiarity of the design of the phase III randomized, double-blind, placebo-controlled trial that enrolled 512 men with metastatic androgen-independent prostate cancer. The trial's name, IMPACT, stands for IMmunotherapy for Prostate AdenoCarcinoma Treatment.

IMPACT's crossover design allows patients on the control arm to receive the immunotherapy after progression. This is unusual, because the therapy to which patients cross over is not identical to Provenge.

At an investor conference, Gold pointed out the best-case scenario for the company—that the drug's efficacy was observed despite the crossover, which would ordinarily dampen the efficacy signal of an active agent. "We were able to show a survival element even in the face of a crossover arm," he said.

However, there is another possibility—that something on the control arm and the crossover is making the experimental arm look better by comparison.

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg

Editorial: 202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
Letters to the Editor may be sent to the above address.

Subscriptions/Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
General Information: www.cancerletter.com

Subscription $385 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.
Founded Dec. 21, 1973, by Jerry D. Boyd.

This possible explanation is making many oncologists all the more eager to see the data.

In earlier trials, about 75% of patients crossed over to a Provenge-like agent, and Gold said that a similar crossover rate was observed in IMPACT. The agent given to these control group patients on progression was not identical to Provenge.

Skeptics cite another potential problem: the delay of treatment with docetaxel of patients who progress. Patients who failed Provenge could move on to docetaxel sooner than patients who failed the control regimen and could cross over to the Provenge-like therapy.

Scher Noted Strokes on Placebo Arm in 2007

Questions about toxicity in the control arm weren't raised at the advisory committee meeting two years ago, but were voiced subsequently.

Reflecting on this problem, Howard Scher, an expert in prostate cancer at Memorial Sloan-Kettering Cancer Center who served on the advisory committee that considered Provenge in 2007, noted that an unusual incidence of cerebrovascular events was reported on the control arm of the company trial,

Scher described these problems in a letter to FDA officials. Though Scher was reflecting on data from the Provenge studies that were being considered by FDA at that time, these concerns may establish a framework for analysis of toxicity data from IMPACT.

An excerpt from the letter, published in the April 13, 2007, issue of The Cancer Letter, follows:

"This concern [CVAs] was based on the finding that 4.9% (17/345) of the Sipuleucel-T and 1.7% (3/172) of "placebo" treated patients who were enrolled on randomized trials for the indication, experienced a cerebrovascular event (p=0.092). The odds ratio for developing a cerebrovascular event was 2.92, with wide confidence intervals (0.82 to as high as 10 fold). Deaths due to CVA's were recorded in 1.5% of Sipuleucel-T patients and 0.9% of those receiving "placebo."

"Unclear is why there is no mention of CVA's in the published report of the study in the Journal of Clinical Oncology (JCO 24:3089, 2006). Given that the product is released for administration based on the increase in the proportion of CD54+ cells and not the absolute number of any particular cell type and that CD54+ cells actually represent only 20% of the final product, the contribution of the other cell populations and cytokines that may be present in the administered product on the development of a cerebrovascular event is not known.

"More important, and perhaps underappreciated during the discussion, is the recognition that the "placebo" used in this trial, a portion of the leukopheresis product that is cultured without the immunizing antigen and reinfused, may not be inert and in itself contributed to a relative worsening of survival for the control group in this trial.

"To place the frequency of the neurologic events in perspective, no cerebrovascular events were observed in TAX-327, a 997 patient three arm randomized trial that evaluated two different dose schedules of docetaxel in comparison to mitoxantrone, (NEJM 351:1052, 2004) or ASCENT1, a 251 patient randomized comparison of docetaxel weekly with or without high dose calcitriol (DN-101)(JCO 25:669, 2007). Neurologic events that were not detailed further were observed in 7% of the 338 patients who received estramustine which is known to be thrombogenic, in combination with docetaxel on the SWOG 99-16 trial (NEJM 351:1513, 2004)."

Provenge vs. Docetaxel

The Cancer Letter asked Walter Stadler, professor at the University of Chicago Departments of Medicine and Surgery Sections of Hematology-Oncology and Urology, to comment on concerns about potential toxicity of the initial treatment as well as treatment received at the time of crossover by patients on the control arm.

Stadler's comments follow:

"The [IMPACT] trial design was a comparison of autologous cultured WBC + an antigen (=experimental) versus refrigerated WBC (control). This makes sense because you are trying to modify only 1 variable (the antigen). However, the WBC are not processed in exactly the same manner and refrigerating WBC and then re-infusing is not really a placebo. If there is a difference between experimental and control it is theoretically possible that the control actually did worse than no therapy and the experimental therapy is doing the same as no therapy. It seems to me, at least scientifically, that this is unlikely because I can't think of a mechanism unless there is evidence of a higher rate of non-prostate cancer related deaths in control group than in the experimental group—suggesting some kind of toxic effect in the control.

"The trial endpoint was then further compromised by the fact that a high percentage of patients in the control arm received a form of the experimental therapy (Frozen WBC, then cultured + antigen). Once again not unreasonable and from a practical basis quite appropriate. In general, giving active therapy at a later date to the control group should decrease any benefit observed in the experimental group. Now since the cross-

over product is a little different it is at least theoretically possible that this modified product accelerated death whereas the primary product had no effect (or delayed death). Once again, I find this scientifically unlikely since I don't have a mechanism unless there is evidence of a higher rate of non-prostate cancer related deaths in the control arm—suggesting a toxic effect."

However, the agent's usefulness should be determined through comparison with docetaxel, Stadler said.

"This patient group has another option that has been shown to improve survival; namely, docetaxel," he said. "Other drugs are also being developed, have been utilized, and are promising. It is assumed that docetaxel as 'chemotherapy' is more toxic, but there is no data to demonstrate this. It will thus be critical to demonstrate that this product provides a greater patient benefit (which can be defined in other manners than just survival) than docetaxel."

Not Enough Data vs. Too Much Data

Dendreon's releases of data have been puzzling to clinical trials experts. On Oct. 6, 2008, the company issued a press release that released the results of the interim analysis, including the confidence interval.

"While Dendreon remains blinded to the data, the independent data monitoring committee (IDMC) reported to Dendreon a 20 percent reduction in the risk of death in the PROVENGE arm relative to placebo (Hazard Ratio= 0.80; 95% Confidence Interval [0.610-1.051])." The document is posted at http://investor.dendreon.com/ReleaseDetail.cfm?ReleaseID=338495&Header=News

Last month, a story in Forbes noted that the press release in effect unblinded the trial. The story is posted at http://www.forbes.com/2009/03/24/dendreon-provenge-business-healthcare-dendreon.html.

The composition of the data monitoring board isn't publicly known. The company didn't respond to questions from The Cancer Letter.

"There are several things that don't make sense here," said Donald Berry, chairman of the M.D. Anderson Cancer Center Department of Biostatistics. "FDA signed off on the data monitoring committee process, and the data monitoring committee [in October] gave interim results to the company."

Approval of a protocol that includes a crossover to a different treatment is similarly unusual.

"Using an experimental agent for which there is no evidence at all about benefits or harms preferentially in the placebo arm raises the possibility that you are actually doing harm," said Berry. "I would want to see, is there an effect on progression and what survival looks like after progression, by arm. I'd like to see what overall survival minus progression-free survival looks like. Just start the clock at progression. How long do patients live on one arm vs. the other arm? If those two things are different and in particular show a benefit for the treatment, I'd be more suspicious."

Berry said that it's conceivable that during negotiations of the SPA, FDA officials hadn't considered potential implications of toxicity on the control arm.

"This isn't normally something you think about," he said. "You usually say that crossovers are okay. The doc has to keep the patient alive, so he will do what he will. So you don't worry about it."

Professional Societies:

Clara Bloomfield To Receive ASCO David Karnofsky Award

The physician-scientist who was one of the first to investigate viable treatment options for older patients with acute myeloid leukemia and to discover that the disease could be cured in this population using chemotherapy is among the notable awardees to be honored by the American Society of Clinical Oncology.

Each year through the Special Awards Program, ASCO identifies those individuals whose personal commitment to furthering the progress against cancer has led to tremendous advances in the field. The 2009 Special Awards honorees include:

Clara Bloomfield is the recipient of the 2009 David A. Karnofsky Memorial Award for her groundbreaking contributions to clinical research and for her outstanding impact on the treatment of patients with cancer. Bloomfield was among the first physician-scientists to investigate viable treatment options for older patients with acute myeloid leukemia—previously believed to be fatal—and to discover that the disease could be cured in this population using chemotherapy. Bloomfield is a professor at Ohio State University Comprehensive Cancer Center, where she also is the William G. Pace III Endowed Chair in Cancer Research.

Bert Vogelstein, director of the Ludwig Center at Johns Hopkins, Investigator of the Howard Hughes Medical Institute, and Clayton Professor of Oncology and Pathology at the Sidney Kimmel Comprehensive Cancer Center, will receive the Science of Oncology Award. He was the first scientist to elucidate the molecular basis of a common human cancer. In

particular, he and his colleagues have demonstrated that colorectal tumors result from the gradual accumulation of genetic alterations in specific oncogenes and tumor suppressor genes. His group's discovery and analysis of these genes and their functions represent a landmark in the application of molecular biology to the study of human disease.

Olufunmilayo Olopade will be recognized for her outstanding efforts to reduce the global burden of cancer, her leadership and achievements in the field of breast cancer treatment, with the ASCO-American Cancer Society Award. She is the Walter L. Palmer Distinguished Service Professor in Medicine and Human Genetics, associate dean for global health, and director of the Center for Clinical Cancer Genetics at the University of Chicago. Olopade specializes in cancer risk assessment, prevention, early detection, and treatment of aggressive breast cancer that disproportionately affects young women.

Martine Extermann, associate professor of oncology and medicine at the H. Lee Moffitt Cancer Center & Research Institute at the University of South Florida, will receive the B.J. Kennedy Award for Scientific Excellence in Geriatric Oncology. Her main interest is understanding how the general health of the older patient interacts with the choice and the conduct of cancer treatment.

William Evans and **Mary Relling** will receive the 2009 Pediatric Oncology Award for their outstanding research in and devotion to the treatment of childhood leukemia. Evans is director and CEO of St. Jude Children's Research Hospital. For the past 30 years, his research has focused on the pharmacogenomics of anticancer agents in children. The major disease focus of his pharmacogenomics research is acute lymphoblastic leukemia in children. Relling is a member and chair of the Pharmaceutical Department at St. Jude. Relling has focused on improving drug therapy for childhood leukemia.

John Glick, professor of medicine and the Leonard and Madlyn Professor of Clinical Oncology at the University of Pennsylvania School of Medicine, will receive the Distinguished Achievement Award for his dedication to cancer research and his record of prominent leadership in the oncology community. Glick is a nationally recognized medical oncologist in the areas of Hodgkin's disease, non-Hodgkin's lymphoma, and breast cancer. His clinical research projects are currently focused on evaluating the effectiveness of novel therapies for Hodgkin's disease, lymphoma, and breast cancer.

Diane Blum is the recipient of the Partners in Progress Award for her dedication on behalf of people with cancer. She is the executive director of CancerCare, a national nonprofit organization that provides free, professional support services including counseling, education, financial assistance, and practical help to people with cancer. Blum serves as editor-in-chief of Cancer.Net, the ASCO website that provides oncologist-approved cancer information for patients and the public.

Richard Pazdur, director of the Office of Oncology Drug Products in the Center for Drug Evaluation and Research at FDA, will receive the Special Recognition Award for his achievements in cancer research and for his outstanding service to the oncology community. Pazdur's main research interests are in clinical trial design and drug development of anti-cancer agents in advanced colorectal cancer. He has performed numerous phase I, II, III, and adjuvant therapy trials in this disease.

Carlos Arteaga, director of the Breast Cancer Research Program of the Vanderbilt-Ingram Cancer Center, will receive the Gianni Bonadonna Breast Cancer Award and Lecture for his accomplishments in advancing the field of breast cancer research, in particular his discoveries of the pathogenesis of and molecular therapeutics in breast cancer. His research focuses on the role of signaling by growth factor receptors and oncogenes in the progression of breast tumor cells as well as the development of molecular therapeutics in breast cancer.

The ASCO Statesman Award recognizes ASCO members for their extraordinary volunteer service, dedication and commitment to the Society. Recipients of the 2009 Statesman Award have given 20 years of volunteer service and include **Gabriel Hortobagyi**, M. D. Anderson Cancer Center; **Scott Lippman**, M. D. Anderson Cancer Center; **Barbara McAneny**, New Mexico Cancer Center; **Monica Morrow**, Memorial Sloan-Kettering Cancer Center; and **Jamie Hayden Von Roenn**, Northwestern University.

The awards will be presented at the society's annual meeting in Orlando, May 29-June 3, with the exception of the Bonadonna award, which will be presented at the 2009 Breast Cancer Symposium Oct. 8-10 in San Francisco.

Also, the ASCO Cancer Foundation will award more than $6.1 million to support clinical and translational research designed to improve cancer prevention, treatment and care. The grants will be awarded to 63 researchers at the annual meeting.

In Brief:

NCI Advisor Susan Curry Named To AHRQ Task Force

CAROLYN CLANCY, director of the Agency for Healthcare Research and Quality, announced the appointment of three new members of the U.S. Preventive Services Task Force. They are: **Susan Curry**, dean of the College of Public Health and distinguished professor of health management and policy at the University of Iowa, vice chairman of the American Legacy Foundation board of directors and a member of the NCI Board of Scientific Advisors; **Joy Melnikow**, professor in the Department of Family and Community Medicine and associate director of the Center for Healthcare Policy and Research at University of California Davis; and **Wanda Nicholson**, associate professor in the departments of gynecology and obstetrics and population, family and reproductive health at the Johns Hopkins School of Medicine and Bloomberg School of Public Health. The Task Force consists of 16 health care experts in family medicine, pediatrics, internal medicine, obstetrics and gynecology, geriatrics, preventive medicine, public health, behavioral medicine and nursing. . . . **NIH ADVISORY COMMITTEE** to the Director has three new members. They are: **Maria Freire**, president of The Albert and Mary Lasker Foundation; **Beatriz Luna**, associate professor of psychiatry and psychology at the University of Pittsburgh; and **James Thrall**, the Juan M. Taveras Professor of Radiology at Harvard Medical School and radiologist-in-chief of the Massachusetts General Hospital. . . . **MELANOMA RESEARCH FOUNDATION** announced the recipients of five new research grants as part of its Career Development Grant Program and Established Investigator Grant Program. The Career Development Grant provides funding of up to $50,000 per year for two years to investigators who are beginning a research career emphasizing melanoma-related projects. The MRF's Established Investigator Grant provides funding of up to $100,000 per year for two years to established researchers in melanoma or those in closely related fields who wish to move into melanoma research. This year's recipients include: **Vitali Alexeev**, Thomas Jefferson University; **Ed Harlow**, Harvard Medical School; **SubbaRao Madhunapantula**, Pennsylvania State University College of Medicine; Vladislava Melnikova, M.D. Anderson Cancer Center; and **Keiran Smalley**, Moffitt Cancer Center and Research Institute. . . . **RADIATION ONCOLOGY INSTITUTE** has raised $7 million as part of its initial campaign goal including a pledge of $1 million from Elekta. Following an initial commitment of $5 million from the American Society for Radiation Oncology, individual radiation oncologists have pledged more than $1 million. Varian has pledged $2 million. "It is gratifying that so many of my colleagues believe in the vision of ROI to develop open, objective research that will demonstrate the value that radiation oncology brings to cancer care throughout the world," said **Theodore Lawrence**, of the University of Michigan and the campaign co-chairman, serving with **Colleen Lawton**, of the Medical College of Wisconsin. RO1 has a web site at www.roinstitute.org. . . . **LANCE ARMSTRONG FOUNDATION** said it plans to fund eight additional proposals in the 2008 grant cycle. In 2009, the LAF will be funding programs in nearly 100 U.S. communities through initiatives totaling nearly $3 million. The programs include: the Cancer Institute of New Jersey ($100,000); University of California, Irvine ($147,377); Emilio Nares Foundation ($149,050); Cancer Legal Resource Center ($149,513); The Breakfast Club Inc. ($50,000); M.D Anderson Cancer Center ($150,000); Familias en Accion ($140,151); and Aberdeen Area Tribal Group ($150,000). Also, LAF and the YMCA have partnered to create LIVESTRONG at the YMCA, an evidence-based physical activity and wellness program for people affected by cancer. The program is offered at YMCA branches in 10 cities. LAF also partnered with the Wellness Community to create Cancer Transitions: Moving Beyond Treatment, a six-week program for post-treatment cancer survivors. The program was piloted in 15 cities in 2007 and 2008; in 2009, 20 cities will participate in the program. . . . **FABRIZIO MICHELASSI** was installed as 2009-10 president of the Society of Surgical Oncology at the society's annual business meeting in Phoenix. Michelassi is the Lewis Atterbury Stimson Professor of Surgery and chairman of the Department of Surgery at Weill Medical College of Cornell University, and surgeon-in-chief at the New York Presbyterian Hospital-Weill Cornell Medical Center. He succeeds **William Cance**. Other officers elected to serve on the SSO Executive Council are: **Mitchell Posner**, president-elect; **James Economou**, vice president; and Executive Council members **Kelly McMasters**, **Ronald Weigel**, and **Sharon Weber**, councillor-at-large. . . . **DONALD GALLUP** was honored by the Society of Gynecologic Surgeons as the Distinguished Surgeon of the year. Gallup is professor, chair, and program director of obstetrics and gynecology at Mercer University School of Medicine. He is also the associate director of gynecologic oncology.

In the Cancer Centers:

V. Craig Jordan Named Lombardi Scientific Director

(Continued from page 1)

Emory system," said **Brian Leyland-Jones**, executive director of Winship, associate vice president for health affairs for the Woodruff Health Sciences Center, and a GRA Eminent Scholar. "The designation enables us to continue to develop research initiatives that will result in new therapies for patients throughout Georgia and beyond."

GEORGETOWN UNIVERSITY Medical Center and the Lombardi Comprehensive Cancer Center recruited **V. Craig Jordan** as scientific director for the cancer center and vice chairman of the department of oncology. He also will hold the Vincent T. Lombardi Chair of Translational Cancer Research.

"We are thrilled to have Dr. Jordan join Lombardi," said **Louis Weiner**, director of the cancer center. "His towering contributions to the field of breast cancer therapy are widely recognized and appreciated. I can think of no breast cancer researcher who has made more important observations, with more profound implications for improving the treatment of breast cancer.

A pharmacologist whose research focuses on the response of breast cancer cells to preventive and treatment agents, Jordan is recognized by many as the "father" the anti-cancer drug tamoxifen. Jordan serves as vice president and scientific director for the medical sciences at Fox Chase Cancer Center and holds the Alfred G. Knudson Jr. Chair in Cancer Research.

"Dr. Jordan will occupy a vital role at Lombardi," Weiner said. "While one of these prioritized areas certainly will be breast cancer, his charge extends to our entire scientific portfolio. As scientific director, he will work with me to prioritize areas for scientific investment, and will be charged with identifying, creating and nurturing high-impact, multidisciplinary, cancer-focused collaborations within Lombardi, across the Georgetown University Medical Center and with other institutions."

UNIVERSITY OF KENTUCKY appointed **B. Mark Evers** as director of the Markey Cancer Center and professor of surgery in the College of Medicine. Evers, a gastrointestinal and endocrine surgeon, also will be named physician-in-chief of the oncology service line and will hold the endowed Markey Cancer Foundation Chair.

Evers is professor of surgery, director of the University of Texas Medical Branch Comprehensive Cancer Center and the Sealy Center for Cancer Cell Biology and the Robertson-Poth Distinguished Chair in General Surgery.

Evers is currently principal investigator or director for seven externally funded studies, including an NIH Merit Award, and is a co-investigator for five others. He will bring to Kentucky around $5.5 million in multi-year grant funding, including more than $1 million in current-year support. Total grant funding for the research program Evers will bring to Kentucky is expected to be about $14 million at the outset.

The new director will help the center achieve long-term goals, including NCI designation as a comprehensive cancer center, said **Michael Karpf**, UK's executive vice president for health affairs. "Mark Evers represents the caliber of leadership that can take Markey to new heights of excellence," Karpf said. "As we work toward achieving NCI designation over the next few years, it will be critical to have a top-tier director at the helm."

UC DAVIS researchers received a $1.25 million grant from NCI for a five-year project to identify the biomarkers of kidney cancer and a diagnostic test for the disease. The research team will focus on identifying the metabolites unique to kidney cancer. **Robert Weiss**, professor of nephrology at UC Davis, chief of nephrology at the Veterans Affairs Northern California Health Care System, is principal investigator for the grant. Joining Weiss on the research team is **Ian Thompson**, professor of urology at the University of Texas Health Science Center in San Antonio; and, all from UC Davis, **Bertrand Perroud**, project scientist, and **Oliver Fiehn**, associate professor in the Genome Center and Bioinformatics Program; **Bruce Hammock**, professor of entomology; **Kyoungmi Kim**, assistant professor of public health sciences; **Ralph deVere White**, director of the UC Davis Cancer Center; and **Christopher Evans**, professor of urology. . . . **OHIO STATE UNIVERSITY** Comprehensive Cancer Center recruited **Arnab Chakravarti** as professor and chairman of the Department of Radiation Medicine and as a member of the experimental therapeutics program. Chakravarti was an associate professor and a radiation oncologist at Massachusetts General Hospital. Chakravarti also was chief of the Brian D. Silber Laboratory of Molecular and Cellular Radiation Oncology at MGH-Harvard. He is bringing at least six cancer researchers and lab technicians with him to Ohio State, in addition to at least

four adjunct faculty members from Harvard and around the world. Chakravarti also was named to the Max Morehouse Chair in Cancer Research. He is principal investigator and chairman of the Radiation Therapy and Oncology Group's Brain Tumor Translational Research Steering Group and co-chairman of the RTOG Brain Tumor Committee. . . . **UNIVERSITY OF NEW MEXICO** Cancer Center is partnering with the Mexican government to address cancer care among Hispanics in New Mexico. The Ventanilla de Salud program is a collaboration between the UNM Cancer Center, the Mexican Consulate, and the local not-for-profit Concilio CDS Inc. The program provides New Mexican Hispanics with bilingual, culturally relevant health information and referrals to low-cost providers. Trained volunteer educators conduct health information sessions at one-hour intervals throughout the day for Mexican Consulate customers awaiting services. Ventanilla de Salud is made up of three components: comprehensive health education and prevention programs, including tobacco cessation and secondhand smoke awareness; comprehensive cancer education program modules to be completed at the Consulate; and reducing health disparities. Since its inception in December 2008, the program has served more than 715 Hispanic community members with education and referrals. . . . **UNIVERSITY OF NORTH CAROLINA** at Chapel Hill appointed **Kimberly Kasow** as director of the UNC Pediatric Bone Marrow Transplantation program. Kasow is an associate professor of pediatrics and a member of the UNC Lineberger Comprehensive Cancer Center. She served as director of the autologous transplant program and the transplant quality officer at St. Jude Children's Research Hospital. . . . **M. D. ANDERSON CANCER CENTER** smoking prevention and cessation expert **Alexander Prokhorov**, professor in the department of Behavioral Science, will develop a videogame designed to help prevent and treat tobacco use in the U.S. military. The videogame and supporting program is part of a study to be funded by the U.S. Department of Defense to promote health and stress management among members of the armed forces. The $3.7 million dollar grant awarded to M. D. Anderson will solidify a partnership with the U.S. Army in Fort Hood, Texas, to develop and launch the program. "The tobacco use rates in the U.S. Army are alarming in that 38 percent of service members smoke cigarettes and 15 percent use smokeless tobacco," said Prokhorov, principal investigator for the study. "It's critical that U.S. Army service members realize that tobacco use may severely compromise physical and mental performance, and that we provide ways to help them kick these addictions or resist them in the first place." The prototype for the interactive and educational videogame is modeled after "Escape With Your Life," another tobacco-cessation videogame developed through Prokhorov's research at M. D. Anderson, designed for troubled, economically disadvantaged youth. The grant for the study was awarded by the Peer Reviewed Medical Research Program and the Congressionally Directed Medical Research Program. . . . **ST. JUDE CHILDREN'S** Research Hospital scientists who represent the interdisciplinary team studying acute lymphoblastic leukemia were recognized by the American Association for Cancer Research with the AACR Team Science Award. The St. Jude team has published more than 1,000 original articles in the past decade, appearing regularly in leading medical and scientific journals. The team includes **Dario Campana**, oncology; **Cheng Cheng**, biostatistics; **James Downing**, scientific director; **William Evans**, St. Jude director and CEO; **Melissa Hudson**, oncology; **Sima Jeha**, oncology; **Charles Mullighan**, pathology; **Ching-Hon Pui**, oncology chair; **Susana Raimondi**, pathology; **Mary Relling**, pharmaceutical sciences chair; and **Raul Ribeiro**, oncology. The team is donating the $50,000 prize to St. Jude, supporting students and postdoctoral trainees attending future scientific meetings to present their research findings.

Funding Opportunities:

NIH Notices, PAs Available

Notice of Intent to Publish a Request for Applications for a Cancer Immunotherapy Trials Network (U01) http://grants.nih.gov/grants/guide/notice-files/NOT-CA-09-016.html.

Notice of Intent to Publish a Request for Applications for Research Training Grants in Developing Research Capacity for HIV-Associated Malignancies in Africa http://grants.nih.gov/grants/guide/notice-files/NOT-CA-09-021.html.

Studies of Energy Balance and Cancer in Humans (R21) http://grants.nih.gov/grants/guide/pa-files/PA-09-149.html.

Pilot and Feasibility Clinical Research Studies in Digestive Diseases and Nutrition (R21) (PA-09-151) http://grants.nih.gov/grants/guide/pa-files/PA-09-151.html.

Etiology, Prevention, and Treatment of Hepatocellular Carcinoma (P01) (PAR-09-147) http://grants.nih.gov/grants/guide/pa-files/PAR-09-147.html.

Distribution Policy for The Cancer Letter

Thank you for your purchase of this issue of The Cancer Letter! Because issue and subscription sales are our major source of revenue, we wouldn't be able to provide you with the information contained in this newsletter without your support. If you have any questions or comments about the articles, please contact the editors (see page 2 of your issue for contact information).

We welcome your use of the newsletter and encourage you to send articles once in a while to colleagues. But please don't engage in routine distribution of The Cancer Letter to the same people week after week, unless your organization has purchased a site license or group subscription. If you aren't sure, ask the person who is paying for this subscription. If you are sending the newsletter to an unauthorized list, please stop; your actions are against Federal law. If you received this newsletter under an unauthorized arrangement, know that you are in receipt of stolen goods. Please do the right thing and purchase your own subscription.

If you would like to report illegal distribution within your company or institution, please collect specific evidence from emails or photocopies and contact us. Your identity will be protected. Our goal would be to seek a fair arrangement with your organization to prevent future illegal distribution.

Please review the following guidelines on distribution of the material in The Cancer Letter to remain in compliance with the U.S. Copyright Act:

What you can do:

- Route a print subscription of the newsletter (original only) or one printout of the PDF version around the office.
- Copy, on an occasional basis, a single article and send it to a colleague.
- Consider purchasing multiple subscriptions. We offer group rates on email subscriptions for two to 20 people.
- For institution-wide distribution or for groups larger than 20, consider purchasing a site license. Contact your librarian or information specialist who can work with us to establish a site license agreement.

What you can't do without prior permission from us:

- Routinely copy and distribute the entire newsletter or even a few pages.
- Republish or repackage the contents of the newsletter in any form.

If you have any questions regarding distribution, please contact us. We welcome the opportunity to speak with you regarding your information needs.

The Cancer Letter
PO Box 9905
Washington DC 20016
Tel: 202-362-1809
www.cancerletter.com