THE CANCER LETTER

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

Vol. 30 No. 40
Oct. 22, 2004

Price $335 Per Year

As Patients Worry About COX-2 Inhibitors, Scientists And FDA Review Toxicity Data

By Paul Goldberg

Scientists aren't alone in pondering the issues of toxicity in patients taking COX-2 inhibitors in chemoprevention trials.

Publicity around recent withdrawal of the Merck drug Vioxx (rofecoxib) is causing concern among patients enrolled in studies of other cancer prevention drugs, said John Baron, chairman of the steering committee for the Vioxx trial that demonstrated an increased risk of cardiovascular events among patients taking the COX-2 inhibitor.

"There are worries that the publicity regarding this will impair research

(Continued to page 2)

In Brief:

M. D. Anderson Wins Ninth SPORE Grant, $11.5 Million For Melanoma Research

M. D. ANDERSON Cancer Center has received its ninth NCI Specialized Programs of Research Excellence grant, and the first awarded exclusively for melanoma research. **Elizabeth Grimm**, professor in the Department of Experimental Therapeutics, is the director of the five-year, $11.5 million SPORE grant. **Jeffrey Lee**, professor in the Department of Surgical Oncology, is the co-director. "With the melanoma SPORE, we intend to look at biologic agents and ways of modulating the immune response, in part, but to also look at things we can alter that inhibit the immune response and inhibit response to chemotherapy, because melanoma is so resistant to chemotherapy," said Grimm. Project highlights include: developing a vaccine from the tumor of the patient and then returning it to the patient as treatment; predicting the likelihood of melanoma recurrence from the patient's DNA repair enzymes; identifying the genes that regulate immune response to melanoma to control and enhance immune response; determining which tumors will resist treatment by identifying the molecular markers and creating regulators to turn off the markers; and blocking melanoma tumor growth factors by using specially designed blocking antibodies. M.D. Anderson ranks first nationwide in the number of research grants and grant dollars awarded by NCI, the center said. M. D. Anderson's nine SPORE grants in the past eight years total more than $99 million. One $4.5 million grant for lung cancer research was awarded jointly to M. D. Anderson and the UT Southwestern Medical Center in Dallas in 1996; $6.5 million in renewed funding for that grant was received in 2003. A second, $10 million SPORE grant for ovarian cancer research was awarded in 1999. In 2001, M. D. Anderson received

(Continued to page 8)

Vioxx, Bextra Raise Concern On Class Vs. Molecule Effect

(Continued from page 1)

for other COX-2 inhibitors, because subjects may be reluctant to take part," Baron, a professor at Dartmouth Medical School, said at a cancer prevention research meeting of the American Association for Cancer Research.

"There are some scientific worries as well," Baron said at a special session of the meeting Oct. 18. "There are many people who believe that what we've seen in the Vioxx studies is a reflection of a COX-2 inhibitor class effect. This does create worries regarding Celebrex, Bextra, and any other COX-2 inhibitor. Certainly, pharmaceutical companies must be worried about their exposure to adverse publicity and adverse events risks."

These concerns affect the entire field of chemoprevention, Baron said. "By chance, I am in early phases of another adenoma prevention trial, using household items—vitamin D and calcium," he said. "We have had prospective subjects ask our coordinators if our intervention includes Vioxx. We have to take particular steps to reassure subjects that they are not affected in any way by Vioxx."

Last month, Merck announced that its trial of Vioxx for prevention of polyps had shown an increased relative risk of cardiovascular events among patients taking the drug for over 18 months (**The Cancer Letter**, Oct. 15). Last week, concern about COX-2 inhibitors deepened as Pfizer announced that its arthritis drug Bextra (valecoxib) was associated with an increase in cardiovascular events in patients who had received a coronary artery bypass graft.

To counter bad news, scientists would need to demonstrate that the adverse events in the Vioxx trial aren't caused by characteristics shared by the entire class of COX-2 inhibitors. However, this is something that can't be done, at least not yet. No one understands the mechanism of action of COX-2 inhibitors, and while it appears that molecular structures of drugs in this class differ greatly, it is impossible at this point to draw the line between the molecule effect and the class effect.

Only short-term studies led to Vioxx's approval for arthritis and other pain indications five years ago. It took long-term follow-up in a rigorously monitored, placebo-controlled, double-blind study required for the cancer prevention indication to demonstrate that the drug was associated with elevated risk of cardiovascular events.

Arguably, chemoprevention deserves some credit for discovering this Vioxx toxicity, Baron said. "Personally, I think the [Adenomatous Polyp Prevention on Vioxx] study did a service to cardiovascular investigators."

The spike in toxicity that begins within 18 months of initiation of treatment would have been invisible to any single investigator or any single institution.

"There are more centers in the study than confirmed thrombotic events in this analysis," Baron said. "There wasn't actually that much thrombotic cardiovascular action. And as an investigator, I have to confess to you that I was watching the aggregate number of events, and I thought, 'Gee, we are in trouble, we are not going to be very informative when it comes to cardiovascular disease, because there aren't that many exciting things happening.'

"Little did I know."

Though treatment in APPROVe has been stopped, the trial will produce an answer on prevention of colorectal cancer, Baron said.

"We were two-and-a-half months from the end of the study, 75 percent of subjects completed treatment when got the call from the data and safety monitoring board," he said. "That's good for the chemopreventive effect, because it means that we will be able to get a whole valid analysis of chemopreventive issues out of the results."

Focus On Toxicity

NCI, FDA, and drug companies are analyzing data

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

Editor & Publisher: Kirsten Boyd Goldberg
Editor: Paul Goldberg
Editorial Assistant: Shelley Whitmore Wolfe

Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016
Letters to the Editor may be sent to the above address.

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
Customer service FAQ: www.cancerletter.com

Subscription $335 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd.

from COX-2 inhibitors.

Implications for Celebrex are especially important, cancer prevention experts say. Like Vioxx, Celebrex was studied as an alternative to colonoscopy and surgical removal of recurrence of polyps.

The companies were hoping that their agents would decrease the number and size of such polyps, and that FDA would be convinced that this effect translates into reduction in colon cancer and a benefit for patients.

Earlier this month, FDA came under fire for what was described as failure to mandate additional trials of COX-2 inhibitors in patients at high risk of cardiovascular events. The criticism appeared in a New England Journal of Medicine commentary by Eric Topol, chief of cardiology at the Cleveland Clinic. The commentary is posted at www.nejm.edu.

In an apparent response to critics, FDA Acting Deputy Commissioner for Operations Janet Woodcock said the agency cannot require additional safety studies subsequent to approval. FDA can only move to take a drug off the market, she said at a meeting of the American College of Rheumatology earlier this week.

FDA officials said the agency plans to hold an advisory committee meeting in January to seek advice on the safety profile of Celebrex and Bextra.

"While the study data that we have analyzed so far on the oral formulations of these drugs do not concern us, we know that we need to continue to collect more data before making any conclusions," said an agency spokesman. "In addition, other recent studies suggesting that the COX-2s may have safety problems are still being analyzed by the agency."

FDA officials say the agency has the authority to pull drugs off the market, but cannot require sponsors to conduct trials of approved drugs. "We would consider—rather than say require—the need long-term trials for the other COX-2s as it would certainly behoove the companies to learn from Vioxx and to do the trials they need—at least 18 months—to get the appropriate information that the public will demand," a spokesman said.

NCI is reviewing safety data from the trials, said Ernest Hawk, chief of the Gastrointestinal and Other Cancers Research Group in the NCI Division of Cancer Prevention.

NCI is sponsoring a phase III trial and about 50 smaller cancer prevention studies of Celebrex.

"We have not had a similar level of safety concern with celecoxib as with rofecoxib," Hawk said at the AACR meeting. "There may be distinctions among these class members, but I think it's simply too early to know."

After learning about the toxicity of Vioxx, the Institute has been working with Pfizer to scrutinize the Celebrex toxicity data.

"Based upon the experiences that have been reported with rofecoxib, NCI is taking a number of steps to bolster the cardiovascular reporting characterizations analysis so we would have good data," Hawk said.

"Pfizer is doing the same thing," he said. "They have an independently funded trial involving approximately 1,500 patients, and we are having a cardiovascular committee look at both trials to adjudicate all events, which wasn't planned a priori in our studies, because we didn't know of this risk with celecoxib, if it indeed exists.

"We are planning to do a joint analysis and bring both data safety monitoring boards together to look at the data and do a bit of a safety meta-analysis," Hawk said.

Also, NCI is considering analyzing Celebrex data from studies conducted by other NIH institutes, he said.

In a related development, earlier this week Pfizer said it would sponsor a trial of cardiovascular effects of Celebrex. At a time when COX-2 inhibitors are implicated in cardiovascular toxicity, Pfizer will test the hypothesis that Celebrex would provide a heart benefit by fighting inflammation that could contribute to heart disease.

The multi-center, randomized, placebo-controlled study would enroll more than 4,000 patients who have had a recent heart attack and who also have a history of osteoarthritis, Pfizer said.

The study would begin next year and would last at least two years.

"Our strong confidence in the cardiovascular safety of Celebrex is based on the substantial body of experience that has accumulated over several years in multiple completed studies and ongoing trials," Joseph Feczko, president of worldwide development at Pfizer, said in a statement.

"In fact, small mechanistic studies suggest that Celebrex's anti-inflammatory properties as well as additional unique Celebrex-specific characteristics may improve vascular function in patients with established coronary artery disease," Feczko said. "That is why we feel it is important at this time to announce our plans to conduct the first large-scale clinical study involving the use of a COX-2 specific inhibitor to look at inflammation and cardiovascular events in osteoarthritis patients at high risk for cardiovascular disease."

In the Cancer Centers:

Fox Chase Plans $1 Billion Expansion To Double Its Size

Fox Chase Cancer Center earlier this week unveiled a 20-year, $1 billion expansion plan that calls for building a new hospital, a new outpatient treatment center, and new research facilities.

The expansion proposal, presented to the Fairmount Park Commission, seeks approval to use 25 acres in Burholme Park, most of which already is being used for commercial purposes.

"Cancer is primarily a disease of the aging, and as our population grows older, demand for treatment will continue to rise dramatically," said Fox Chase President Robert Young. "The demand for cancer care will explode in the next decade, and this development plan is the next step in the battle to treat and prevent cancer. Fox Chase is already operating at overcapacity and we need to grow. Our goal is to grow on our current campus right here in Philadelphia."

Fox Chase, with a 100-bed hospital, sees more than 6,500 new patients a year—a number that is expected to double by 2015.

The expansion plan followed a two-year process in which the center examined how to accommodate the growing need for patient care while also continuing to conduct the best scientific research in an environment of rapidly advancing technologies.

"We considered expanding by acquiring property in various parts of the region, but splintering our patient care operations and research is not consistent with what a 'comprehensive cancer center' is," Young said. "The interaction between scientists and physicians is key to the rapid translation of laboratory discoveries for patient care."

Fox Chase growth plan seeks the use of 20 acres in Burholme Park, currently being leased for commercial purposes, plus an additional five acres. Fox Chase proposes moving the commercial tract of land closer to its campus after the lease with the current tenant expires. Fox Chase would redevelop the former commercial footprint for recreational park uses, and the Center also would fund the purchase of an additional 25 acres of land at a site to be chosen by the Commission, so that there is no net loss of park land.

The plan also proposes to help the park commission with the upkeep of ballparks, recreational areas, and museum.

Fox Chase has more than 2,300 employees. The proposed expansion plan will double the size of the center and add more than 4,000 new jobs.

"We estimate that over the next five to seven years, the city will see an additional $40 million in wage taxes," said Young.

Fox Chase receives more than $53 million a year in federal funding and grants.

The presentation to the Park Commission is the first step in a process that also involves the City of Philadelphia and the communities surrounding the center.

NIH Programs:

Human Genome Project Describes Final Product

The International Human Genome Sequencing Consortium, led in the U.S. by the National Human Genome Research Institute and the Department of Energy, published its scientific description of the finished human genome sequence, reducing the estimated number of human protein-coding genes from 35,000 to only 20,000-25,000, a surprisingly low number for our species.

The paper appears in the Oct. 21 issue of the journal Nature. In the paper, researchers describe the final product of the Human Genome Project. The publication provides rigorous scientific evidence that the genome sequence has both the high coverage and accuracy needed to perform sensitive analyses, such as focusing on the number of genes, the segmental duplications involved in disease and the "birth" and "death" of genes over the course of evolution.

"Only a decade ago, most scientists thought humans had about 100,000 genes," said NHGRI Director Francis Collins. "When we analyzed the working draft of the human genome sequence three years ago, we estimated there were about 30,000 to 35,000 genes, which surprised many. This new analysis reduces that number even further and provides us with the clearest picture yet of our genome."

One of the central goals of the effort to analyze the human genome is the identification of all genes, which are generally defined as stretches of DNA that code for particular proteins. According to the new findings, researchers have confirmed the existence of 19,599 protein-coding genes in the human genome and identified another 2,188 DNA segments that are predicted to be protein-coding genes.

"The analysis found that some of the earlier gene models were erroneous due to defects in the unfinished, draft sequence of the human genome," said Jane Rogers,

head of sequencing at the Wellcome Trust Sanger Institute in Hinxton, England. "The task of identifying genes remains challenging, but has been greatly assisted by the finished human genome sequence, as well as by the availability of genome sequences from other organisms, better computational models and other improved resources."

The Nature paper also provides a peer-reviewed description of the finishing process, and an assessment of the quality of the finished human genome sequence, which was deposited into public databases in April 2003. The assessment confirms that the finished sequence now covers more than 99 percent of the euchromatic (or gene-containing) portion of the human genome and was sequenced to an accuracy of 99.999 percent, which translates to an error rate of only 1 base per 100,000 base pairs—10 times more accurate than the original goal.

There still remain 341 gaps in the finished human genome sequence, in contrast to the 150,000 gaps in the working draft announced in June 2000. The technology now available cannot readily close these gaps. Closing those gaps will require more research and new technologies, rather than industrial-scale efforts like those employed by the HGP.

"The human genome sequence far exceeds our expectations in terms of accuracy, completeness and continuity," said Eric Lander, director of the Broad Institute of MIT and Harvard in Cambridge, Mass. "It reflects the dedication of hundreds of scientists working together toward a common goal—creating a solid foundation for biomedicine in the 21st century,"

More than 2,800 researchers who took part in the International Human Genome Sequencing Consortium share authorship on the paper.

The finished human genome sequence and its annotations can be accessed through public genome browsers including GenBank, http://www.ncbi.nih.gov/Genbank.

Emory, Winship, Georgia Tech Win $10 Mill. Nanotech Grants

NIH awarded scientists from Emory University, Winship Cancer Institute, and Georgia Institute of Technology two collaborative research grants, totaling nearly $10 million, to establish a multidisciplinary research program in cancer nanotechnology and to develop a new class of nanoparticles for molecular and cellular imaging.

The primary focus of the new programs will be prostate cancer. Shuming Nie is principal investigator.

NCI awarded a five-year grant of $7.1 million to establish a multidisciplinary Bioengineering Research Partnership in cancer nanotechnology. This partnership will integrate the bioengineering strengths of Georgia Tech and the cancer biology and clinical oncology expertise of Emory University School of Medicine and the Winship Cancer Institute. The new program is part of the joint Coulter Department of Biomedical Engineering at Georgia Tech and Emory, established in 1997.

In addition, the National Institute of General Medical Sciences awarded Emory and Georgia Tech a four-year, $2.7 million exploratory center grant to develop nanoparticle probes for molecular and cellular imaging of cancer. This funding is part of the new NIH Roadmap Initiative.

In addition to basic knowledge on cancer biology and biomarkers, the Bioengineering Research Partnership is expected to produce a database linking molecular signatures with clinical outcome; a new class of nanoparticles for molecular profiling of cancer; and imaging microscopes and software that are integrated with the new discoveries in nanotechnology.

The exploratory center grant will be used to develop advanced nanoparticle quantum dot probes for molecular and cellular imaging. A nanoparticle is the basic building block of nanotechnology. Quantum dots are nanometer-sized luminescent semiconductor crystals that have unique electronic and optical properties due to their size and their highly compact structure.

"The goal of this exploratory program is to develop a new class of bioconjugated quantum dots that can both image and target single-molecule processes in single living cells," said Nie. "Quantum dots have novel properties, including improved brightness, resistance against photobleaching, and multicolor light emission. The larger size of the quantum dots also provides enough surface area for linking to other diagnostic and therapeutic agents."

Howard Hughes, NIBIB To Fund Training Programs

The Howard Hughes Medical Institute and the National Institute of Biomedical Imaging and Bioengineering said they plan to jointly fund graduate training programs that integrate the biomedical sciences with the physical sciences and engineering.

HHMI will award up to 10 three-year grants of as much as $1 million each to support the development and early phases of the interdisciplinary programs. NIBIB will provide five additional years of support to

the HHMI grantees through peer-reviewed institutional training grants.

"This groundbreaking partnership between the NIBIB and HHMI will produce researchers who are skilled in biomedical disciplines, bioengineering, and quantitative sciences," said NIH Director Elias Zerhouni.

HHMI will open a competition for up to 10 grants to educational institutions, for up to $1 million each. The grants will be awarded in November 2005. U.S. institutions that grant Ph.D. degrees in the biological sciences will be eligible for the three-year awards.

"HHMI can provide flexible support to catalyze the development of new, interdisciplinary programs," said Thomas Cech, president of HHMI. "The NIBIB will sustain these young programs once they are developed, as NIH does so well with traditional training grants."

Roderic Pettigrew, NIBIB director, said, "NIBIB is excited to enter into this historic alliance with HHMI to support training of the biomedical scientist of the future, one skilled in interdisciplinary research."

The graduate training program parallels HHMI's commitment to bring together biologists, computer scientists, engineers, physicists, chemists, and mathematicians to conduct collaborative research at Janelia Farm, HHMI's new research campus under construction in Loudoun County, Va.

NCI Programs:

EDRN Study Seeks To Validate Bladder Cancer Detection Test

The NCI Early Detection Research Network has begun a three-year study at 12 centers in the U.S. and Canada to validate a test to detect the recurrence of bladder cancer

By examining genetic changes in DNA obtained through urine samples, the test, if successfully validated, will provide a sensitive and non-invasive method of screening for bladder cancer recurrence.

"This is the first study of its kind," said Sudhir Srivastava, chief of the Cancer Biomarkers Research Group in the NCI Division of Cancer Prevention. "It's the first study testing a marker for bladder cancer, and the first phase III study for an EDRN-created test."

Bladder cancer, with over 60,000 estimated new cases this year, is both one of the more common cancers and one that has a high recurrence rate. Frequent surveillance of bladder cancer patients is critical, but current procedures have shortcomings. Urine cytology, which checks the number and appearance of cells in urine samples, often fails to detect early tumors. Cystoscopy can give patients a false-positive result in addition to being invasive and unpleasant.

The new EDRN-created test looks to improve upon these weaknesses. EDRN, established by NCI in 2000, is a broad, interdisciplinary consortium whose work is aimed at both identifying and validating cancer biomarkers for use in early cancer detection. Numerous proteins and genes have been linked with a variety of cancers, which can make them targets for therapy, as well as targets for identifying the risk of cancer onset, progression, or recurrence. The validation -- proving that the link accurately signifies the risk for or presence of cancer -- is the critical step to create a truly useful test.

The bladder cancer test uses a technology known as microsatellite DNA analysis. Microsatellites, also known as short tandem repeats, are repeating units of one to six nucleotides found throughout human chromosomes. These repeating regions are frequently mutated in tumors, either through deletions or by an extension of the number of repeats. For screening for recurrent bladder cancer, DNA can be easily extracted from cells that are normally present in urine, and compared to DNA sequences of unaffected cells, such as lymphocytes, from the same patients. Early studies have shown this non-invasive analysis can have over 90 percent accuracy.

In the validation study, overseen by Jacob Kagan, program director of the NCI Cancer Biomarkers Research Group, 15 different biomarkers in 300 patients diagnosed with bladder cancer will be examined in an effort to predict cancer recurrence. Individuals with healthy bladders and individuals with non-cancerous bladder problems that could be misdiagnosed as cancer, such as kidney stones or urinary tract infections, will be used as controls.

The participating institutions will collect samples from patients in this study, and the samples will be analyzed by Commonwealth Biotechnologies Inc., of Richmond, Va.

"The primary goal of this study is to monitor MSA for bladder cancer recurrence," said Srivastava. "But the longer goal is to also use the test for early detection of new bladder cancer occurrence."

After phase III validation, Cangen Biotechnologies Inc., which holds the license for this MSA test, plans to seek FDA approval for this test. EDRN is working on two other early detection tests involving examination of protein biomarkers in blood serum to detect early tumors of the prostate and liver.

Funding Opportunities:

Program Announcement

PA-05-004: Symptom Clusters in Cancer and Immune Disorders

Application Receipt Dates(s): Standard

The announcement invites applications to identify the presence of symptom clusters in one or more cancers or immune disorders, to manage them, and the to assess the impact of such management upon patient outcomes. It seeks to stimulate research on the characterization of symptom clusters, and the design and testing of interventions addressing symptoms that have demonstrated interactions and/or common pathways. The PA encourages both descriptive and intervention research. Descriptive research may describe groups of people affected by symptom clusters, individual behavior in relation to the experience of symptom clusters, and/or biological characteristics of the symptom clusters. Studies that describe the interaction of biological and behavioral mechanisms are especially encouraged. A strong rationale for selecting a group of symptoms as a cluster, and not just two or more symptoms that exist at the same time in members of a patient population, must be given. The PA also encourages the design and testing of interventions that lead to clear outcomes. Outcomes may include health related quality of life at any point in the disease trajectory (active treatment, end of life care, or late effects of treatment during the survivorship period), adherence to treatment, or other end-points that the investigator can demonstrate are linked to interventions for managing the identified symptom cluster in the target disease or disorder. The PA will use the R01 and R21 award mechanisms. The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-05-004.html.

Inquiries: For NCI-- Ann O'Mara, phone 301-496-8541; fax 301-496-8667; email omaraa@mail.nih.gov.

NOT-CA-05-001: Addendum-Specialized Programs of Research Excellence in Human Cancer for the Year 2004

The addendum clarifies the qualifying cancer sites for Gynecological Cancer SPOREs. The solicitation is intended for applications focused predominantly on cancers of the endometrium and/or cervix. Applicants cannot propose projects on ovarian cancer; Ovarian Cancer SPOREs are solicited independent of other GYN cancers. Any questions regarding the eligibility or responsiveness of a GYN Cancer SPORE application should be directed to Jane Fountain, the program director for the Gynecological Cancer SPOREs. Also, applicants should be reminded of the change in the Receipt Date for Gynecological Cancer SPOREs under PA PAR-03-158 (http://grants.nih.gov/grants/guide/pa-files/PAR-03-158.html).

New application receipt date: Feb. 1, 2005. New Letter-of-Intent receipt date: Dec. 1, 2004.

Inquiries: Jane Fountain, program director, Organ Systems Branch, Office of Centers, Training, and Resources, Office of Deputy Director of Extramural Sciences, NCI, phone 301-496-8528, email jf227t@nih.gov .

RFPs Available

RFP N02-CN-45005-46: Technical Information Research Resources for Cancer Preventive Agent Development

NCI Division of Cancer Prevention is seeking a contractor to provide technical information support resources for cancer preventive agent identification, development, and qualification for clinical trials. The contractor will be responsible for services that support the discovery and early development of new agents in chemoprevention through literature searching, class studies, and agent scoring. The preclinical and clinical drug testing is supported through a comprehensive system of documenting all test results and clinical activities related to the agent and agent combination through a computerized database. Offerors are required to respond to all task areas of the RFP as one package. Comprehensive details of the information management system would be provided by the offeror based on their knowledge of the disciplines required in the Statement of Work, as well as experience working in the multidisciplinary fields of chemoprevention. However, the information management system must be compatible with and migrate to the existing DCP Enterprise System Knowledge base requirements specified in the RFP. The task areas of the statement of work include:1) Cancer Preventive Agent Identification and Documentation; 2) Cancer Preventive Agent Data and Report Analysis, Status and Documentation; 3) Information Management System and 4) General Tasks.

The RFP is available at http://rcb.nci.nih.gov.

Inquiries: Schuyler Eldridge, phone 301-435-3794, email se29f@nih.gov.

RFP-N01-CN-55006-72 Preclinical Efficacy and Intermediate Endpoint Assays

Response Due: Dec 15

The mission of the Chemopreventive Agent Development Research Group, NCI Division of Cancer Prevention, is seeking proposals from qualified organizations that have the ability to establish the efficacy of potential cancer preventive agents or agent combinations in a variety of in vivo assays, to identify and validate surrogate intermediate endpoints for clinical trial use, and to establish collaborative groups to conduct these studies. The studies will assess the potential of various agents to inhibit, reverse, or delay early carcinogenesis by evaluating the effects of these selected agents on a variety of cancers and endpoints, measuring cancer incidence, multiplicity, tumor size and latency. In addition other studies would address the identification and validation of surrogate intermediate endpoints in animal models for use in clinical trials. The specific goals of this RFP are: 1) To establish the efficacy of potential cancer preventive agents (or combinations of agents) in various in vivo carcinogenesis assays, measuring the inhibition, reversal, or delay of the

carcinogenesis process and, 2) To identify and validate surrogate intermediate biomarkers for future use in clinical trials using in vivo assays of experimental carcinogenesis. The RFP is available at http://rcb.nci.nih.gov/.

Inquiries: Jacqueline Ballard, Prevention, Control and Population Sciences Section, Research Contracts Branch, NCI, phone 301-435-3795; fax 301-402-8579; e-mail ballardj@mail.nih.gov/.

In Brief:

Webber Leads USC Oncology; Weingart Heads DFCI Safety

(Continued from page 1)

both prostate and bladder SPORE grants, totaling $13.3 million and $13.9 million, and making it the first institution to hold two such genitourinary cancer grants. In 2002, the institution received a $12 million grant for head and neck cancer research. Last year, M. D. Anderson received three additional SPOREs, totaling $27.85 million, for leukemia and endometrial cancers, and one for pancreatic cancer. . . . **JEFFREY WEBER**, the Lucy and Berle Adams Endowed Chair in Cancer Research and associate professor of medicine at the Keck School of Medicine of the University of Southern California, was named chief of the Keck School Division of Oncology. Weber is known for his research on melanoma tumor vaccines and immune system enhancing drugs for high-risk and metastatic melanomas. He recently received a $2.5 million grant from NCI for a 75-patient study of an antibody booster to aid melanoma patients. "Weber is a well-funded researcher with major grants from NIH, NCI, the Beckman Foundation and other key organizations," said **Peter Jones**, director of the USC/Norris Comprehensive Cancer Center. . . . **SAUL WEINGART** was named vice president for patient safety and director of the Center for Patient Safety for Dana-Farber Cancer Institute. Weingart, a practicing physician and an expert on medical error prevention, was with Beth Israel Deaconess Medical Center. Weingart will devote 80 percent of his time to the Center for Patient Safety and 20 percent to patient care, said **Jim Conway**, DFCI chief operating officer and executive vice president. "He is the first internist to join the Dana-Farber staff, and will eventually concentrate his direct patient care work on the Perini Family Survivors' Center.". . . **TONYA MICAH** joined Vanderbilt-Ingram Cancer Center to lead cancer prevention, education and awareness initiatives targeting African-American and other underserved groups in Middle Tennessee. In the newly created position of minority outreach manager, Micah will be responsible for building relationships in the community, developing and implementing programs designed to address differences in cancer mortality and morbidity, and increasing interest in clinical trials. Micah joins VICC from Meharry Medical College, where she worked with the Southern Community Cohort Study, the largest population-based research study to focus on African-Americans. The study is a joint project of VICC, Meharry, the International Epidemiology Institute and federally funded community health centers throughout the Southeast. . . . **DAVID BROWN** was named the Edward Rotan Distinguished Professor and chairman of anesthesiology and pain medicine at M. D. Anderson Cancer Center. He was professor and chairman of the Department of Anesthesiology at the University of Iowa College of Medicine. . . . **LARRY OBERLEY**, professor of radiation oncology in the Roy J. and Lucille A. Carver College of Medicine at the University of Iowa, will receive the first Lifetime Achievement Award from the Society for Free Radical Biology and Medicine. Oberley is director of the Free Radical and Radiation Program, deputy director of the Holden Comprehensive Cancer Center at UI, and assistant director for basic research in the Center on Aging in the UI School of Public Health. . . . **INTERNATIONAL MYELOMA Foundation** will hold its IMF Ribbon of Hope-Making a World of Difference Gala Nov. 6 in Los Angeles with **Geraldine Ferraro** as honorary gala chairman. Guest of honor will be **Brian Durie**, co-founder and chairman of the IMF board of directors. **Robin Leach**, former host of "Lifestyles of the Rich and Famous," will serve as master of ceremonies. **Karen Talmadge**, co-founder and CSO of Kyphon Inc., will receive the Quality of Life Award. The Ribbon of Hope Award will go to the Los Angeles Multiple Myeloma Support Group. **Capt. Fred Gloor**, USMM (ret.), will receive the Courage Award. **David Brown** will accept the Visionary Award for his work with the IMF research initiative, Bank On A Cure, the first myeloma-specific cancer patient DNA bank. . . . **CYNTHIA BOHNE** was named foundation and corporate relations officer for the National Foundation for Cancer Research. Bohne was program analyst in the Educational Foundation for the National Geographic Society. . . . **"THE EMPTY ROOM:** Surviving the Loss of a Brother or Sister at Any Age," is the title of a newly published (Scribner) book by **Elizabeth DeVita-Raeburn**, daughter of former NCI director **Vincent DeVita**, describing how her brother Ted's life and death affected her. Ted was diagnosed with aplastic anemia in 1972 and lived in a "bubble room" at NIH until his death eight years later.

Copying Policy for The Cancer Letter Interactive

The software that comes with your issue allows you to make a printout, intended for your own personal use. Because we cannot control what you do with the printout, we would like to remind you that routine cover-to-cover photocopying of The Cancer Letter Interactive is theft of intellectual property and is a crime under U.S. and international law.

Here are guidelines we advise our subscribers to follow regarding photocopying or distribution of the copyrighted material in The Cancer Letter Inc. publications in compliance with the U.S. Copyright Act:

What you can do:

--Route the printout of the newsletter to anyone in your office.

--Copy, on an occasional basis, a single story or article and send it to colleagues.

--Consider purchasing multiple subscriptions. Contact us for information on multiple subscription discounts.

What you can't do without prior permission:

--Make copies of an entire issue of the newsletter. The law forbids cover-to-cover photocopying.

--Routinely copy and distribute portions of the newsletter.

--Republish or repackage the contents of the newsletter.

We can provide reprints for nominal fees. If you have any questions or comments regarding photocopying, please contact Publisher Kirsten Boyd Goldberg, phone: 202-362-1809.

We welcome the opportunity to speak to you regarding your information needs.