THE CANCER LETTER

Vol. 31 No. 3
Jan. 21, 2005

Price $335 Per Year

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

FDA To Discuss Negative Iressa Trial With Advisory Committee In March

By Paul Goldberg

FDA has decided to discuss the negative trial of the AstraZeneca drug Iressa (gefitinib) with the Oncologic Drugs Advisory Committee, the agency said.

It is unclear whether the agency would seek specific advice or general guidance from the advisory committee when it considers the data at the meeting March 3-4, but in an earlier statement, the agency said it is considering withdrawing the agent from the market.

AstraZeneca officials didn't confirm that Iressa would be on the

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In Brief:

David Alberts Is Director at Arizona Center; RPCI Appoints New VP For Center Support

DAVID ALBERTS was appointed director of the Arizona Cancer Center. Alberts, regents professor of medicine, pharmacology, nutritional science, and public health, joined the University of Arizona in 1975 and has served as director of the Cancer Prevention and Control Program since 1989. Between 1988 and 1996, he served as deputy director of the center, and between 1996 and 2002, he served as associate dean for research in the College of Medicine. Since 1987, Alberts has served as the principal investigator for two NCI-funded cancer prevention program project grants: the Colon Cancer Prevention Program Project and the Chemoprevention of Skin Cancer Program Project. The emphasis of his laboratory-based and clinical research has been the preclinical screening and clinical trials of chemical and biological agents for the chemoprevention of precancerous lesions. Alberts received his M.D. in 1966 from University of Virginia School of Medicine and interned at University of Wisconsin before becoming a clinical associate at the NIH Baltimore Cancer Research Center. He served his residency at University of Minnesota and was a faculty member at University of California, San Francisco, for five years. He serves on the NCI Board of Scientific Advisors and has been chairman of the Cancer Prevention Committee of the Gynecologic Oncology Group since 1994. . . . **ALDONA CYTRAUS** was named vice president of science and cancer center support administration at Roswell Park Cancer Institute. She was principal and senior operations consultant at Real Intelligence Co. of Cleveland. . . . **NATIONAL COALITION for Cancer Survivorship** appointed five to its board of directors for three-year terms: **Richard Payne**, director of the Duke Institute on Care at the End

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ODAC To Consider Iressa's Negative Trial In March

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ODAC agenda, but said that they were in discussions with the agency. "We have confirmed that nothing has been posted regarding the FDA schedule for ODAC in March, and we cannot confirm whether Iressa will be on the agenda or not, until FDA has posted what the agenda is for that meeting," said Mary Lynn Carver, a spokesman.

In 2002, ODAC recommended accelerated approval for Iressa based on what was widely viewed as weak data, and the agency followed the committee's advice, approving the drug (**The Cancer Letter**, Sept. 27, 2002, May 9, 2003).

Though technically an accelerated approvals can be withdrawn, no drug approved under that program has been pulled off the market. FDA regulations don't specify how many tries a sponsor has to demonstrate that the surrogate endpoint that led to accelerated approval translates into a benefit to patients.

Safety problems would be more likely than failure to demonstrate a benefit to lead to a withdrawal, agency sources said. No new signs of safety concerns related to Iressa have emerged since its approval. A sponsor's failure to initiate studies could, in principle, lead to a withdrawal.

However, AstraZeneca has sponsored multiple trials of the drug, and is continuing to analyze data from the most recent study.

THE CANCER LETTER

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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.

Last December, Zeneca announced that its Iressa Survival Evaluation in Lung cancer (ISEL) trial with 1,692 patients showed that the agent failed to significantly prolong survival in comparison to placebo in the overall population (HR 0.89, p=0.11, Median 5.6 vs. 5.1 months), or in patients with adenocarcinoma (HR 0.83, p=0.07, Median 6.3 vs. 5.4 months).

The trial demonstrated a statistically significant improvement in tumor shrinkage. According to the company, "prospective subgroup analyses suggested survival benefits in patients of Oriental origin and in patients who never smoked." After the negative study was announced, the company withdrew its application for approval in Europe and ceased promotional activities in the U.S.

AstraZeneca's Carver said the company is analyzing the subset data to determine EGFR expression and mutations in the patients who were involved in the company trial.

"There are two regularly scheduled ODACs coming up, one in March and one in May, either or both may be appropriate times to discuss Iressa, but the subset data and biomarker information will definitely not be available for the March ODAC," Carver said to **The Cancer Letter**.

Separately from the trial, two teams of researchers from Massachusetts General Hospital and DanaFarber Cancer Institute found somatic mutations of the epidermal growth receptor gene that correlate with response to Iressa (**The Cancer Letter**, April 30, 2004).

After Iressa received and accelerated approval for third-line treatment of lung cancer based on the surrogate endpoint of response. Another, similar drug, Tarceva (erlotinib), sponsored by Genentech Inc. and OSI Pharmaceuticals Inc., received full approval for the treatment of locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen.

Observers say the Tarceva approval makes Iressa's position more precarious: if Iressa is pulled off the market, patients would still have a treatment option, Tarceva. The FDA statement on the Iressa trials demonstrates that the agency is considering withdrawal:

"After the approval of Iressa in 2003, AstraZeneca conducted a study... to determine whether the drug would in fact prolong survival in comparison to patients taking placebo," the agency said in a statement dated Dec. 17. "The results... indicate that the drug did not prolong survival. "Under FDA's accelerated approval

program, the agency has the authority to remove a drug from the market if a post-marketing clinical study fails to verify clinical benefit. After FDA has evaluated the recent study results, FDA will determine whether Iressa should be withdrawn from the market or if other regulatory actions are appropriate."

Tarceva Label Indicates Feasibility Of EGFR Expression Analysis

The Tarceva (erlotinib) label includes an analysis of a subset of patients whose EGFR protein expression status was known.

The subgroup analysis apparently played no role in the approval of Tarceva—the drug was approved based on the survival advantage in the overall population in the trial—but it set the stage for later study of EGFR status and its potential correlation with the outcomes.

The Tarceva label includes the following discussion of the relationship between the results and the patients' EGFR protein expression status, as determined by immunohistochemistry:

"Analysis of the impact of EGFR expression status on the treatment effect on clinical outcome is limited because EGFR status is known for only 238 study patients (33%). [Altogether, 731 patients were enrolled in the randomized, double-blind, placebo-controlled trial.]

"EGFR status was ascertained for patients who already had tissue samples prior to study enrollment. However, the survival in the EGFR tested population, and the effectof Tarceva were almost identical to that in the entire study population, suggesting that the tested population was a representative sample. A positive EGFR expression status was defined as having at least 10% of cells staining for EGFR in contrast to the 1% cut-off specified in the DAKO EGFR pharmDx kit instructions. The use of the pharmDx kit has not been validated for use in non-small cell lung cancer.

"Tarceva prolonged survival in the EGFR positive subgroup (N = 127; HR = 0.65; 95% CI = 0.43 – 0.97) and the subgroup whose EGFR status was unmeasured (N = 493; HR = 0.76; 95% CI = 0.61 – 0.93), but did not appear to have an effect on survival in the EGFR negative subgroup (N = 111; HR = 1.01; 95% CI = 0.65 – 1.57). However, the confidence intervals for the EGFR positive, negative and unmeasured subgroups are wide and overlap, so that a survival benefit due to Tarceva in the EGFR negative subgroup cannot be excluded.

"For the subgroup of patients who never smoked, EGFR status also appeared to be predictive of Tarceva survival benefit. Patients who never smoked and were EGFR positive had a large Tarceva survival benefit (N = 30; HR = 0.27; 95% CI = 0.11 – 0.67). There were too few EGFR negative patients who never smoked to reach a conclusion.

"Tumor responses were observed in all EGFR subgroups: 11.6% in the EGFR positive subgroup, 9.5% in the EGFR unmeasured subgroup and 3.2% in the EGFR negative subgroup. An improvement in progression free survival was demonstrated in the EGFR positive subgroup (HR = 0.49; 95% CI = 0.33 – 0.72), the EGFR unmeasured subgroup (HR = 0.56; 95% CI = 0.46 – 0.70), and less certain in the EGFR negative subgroup (HR = 0.91; 95% CI = 0.59 – 1.39)."

Safety Warnings Added On Erythropoietin, Avastin

By Paul Goldberg

Amgen Inc. and Johnson & Johnson have added warnings to their versions of erythropoietin that in several studies, the drugs were associated with increased mortality and thrombotic vascular events.

The studies in question sought to boost the cancer patients' hemoglobin levels to 12 grams per deciliter or beyond. The findings emerged in studies of the J&J version of the drug as well as by Roche (**The Cancer Letter**, Oct. 24, 2003).

The warnings concern off-label uses of the drugs.

The Amgen "dear-doctor" letter was dated Jan. 18. The text of the letter is posted at www.fda.gov/medwatch/SAFETY/2005/safety05.htm#aranesp Last summer Ortho Biotech, a unit of J&J, sent out a similar letter to physicians. The text of that document was posted by FDA last December: www.fda.gov/medwatch/SAFETY/2004/safety04.htm#procrit.

Last May, the Oncologic Drugs Advisory Committee considered the emerging data on apparent toxicity of EPO, recommending further study of the agents. The toxicity emerged in studies of the Roche and J&J versions of the agent.

J&J explored boosting hemoglobin into the normal biologic range in a population of cancer patients, and Roche, in a single study, sought to test the "hemoglobin" effect in radiation therapy. Amgen never conducted such studies.

The trials were discussed with ODAC last year (**The Cancer Letter**, May 7, 2004).

In a separate development, FDA and Genentech revised the label of the drug Avastin to warn about "arterial thromboembolic events, including cerebral

infarction, transient ischemic attacks, myocardial infarction (MI), and angina." In some instances, the events were fatal, the label states.

Avastin, used in combination with intravenous 5-fluorouracil–based chemotherapy, is indicated for first-line treatment of patients with metastatic carcinoma of the colon or rectum.

The revised label states:

"In randomized, active-controlled studies, the overall incidence of arterial thromboembolic events was increased with the use of Avastin in combination with chemotherapy (4.4% vs. 1.9%).

"The incidences of both cerebrovascular arterial events (1.9% vs. 0.5%) and cardiovascular arterial events (2.1% vs. 1.0%) were increased in patients receiving Avastin in combination with chemotherapy. In addition, there was a correlation between age (65 years and over) and the increase in risk of thromboembolic events."

The warning is posted at www.fda.gov/medwatch/SAFETY/2005/safety05.htm#Avastin.

Cancer Statistics:

Cancer Accounts For 23% Of All U.S. Deaths, ACS Says

By Kirsten Boyd Goldberg

Cancer accounted for about 23 percent of all deaths in the U.S. in 2002, ranking second only to heart disease, according to a report by the American Cancer Society, released Jan. 19.

When death rates were age-adjusted, cancer became the leading cause of death among men and women under age 85, followed by heart disease. The number of Americans under age 85 who died from cancer was 476,009, compared to 450,637 deaths from heart disease.

In 2002, the most recent year for which actual data are available, a total of 557,271 cancer deaths were recorded in the U.S., 3,500 more than were recorded in 2001. The increase is due to growth and aging of the population, according to the annual ACS report, "Cancer Facts and Figures."

The report projects that there will be 1,372,910 new cases of cancer in the U.S. this year, and 570,280 deaths. Cancer is the leading cause of death among women aged 40 to 79, and among men aged 60 to 79, the report said.

One-third of cancer cases are caused by tobacco smoking and another third are related to poor nutrition, physical inactivity, and obesity, the society said.

"We need to encourage cessation among people who continue to smoke, and we need to maintain efforts to decrease initiation of smoking among young people," said Elizabeth Ward, director of surveillance research at ACS. "We also need to reverse the epidemic of overweight and obesity that's overtaken our society both in children and adults."

ACS plans to emphasize environmental changes that promote healthy diet and physical activity, as well as a focus this year on colorectal cancer screening, Ward said.

From 1993 to 2001, overall cancer death rates declined 1.5 percent per year for men; for women, the annual decline was 0.8 percent from 1992 to 2001.

This decline in mortality rate is primarily attributable to progress in tobacco control, Ward said. Per capital cigarette consumption in the U.S. has fallen by about half from its peak prior to the 1964 Surgeon General's report, and in 2000, the rate was roughly equivalent to the 1940 level.

Despite the progress, lung cancer remains the leading cause of cancer death, accounting for 31 percent of cancer deaths in men and 27 percent in women. However, the incidence of lung cancer continues to decline in men, and for the first time, appears to be stable or declining in women.

"For the first time, we are seeing a decline in incidence rate that is statistically significant, which we think signals that the lung cancer epidemic has peaked in women," Ward said.

Overall, Americans are surviving longer following a cancer diagnosis. Since the 1970s, the five-year survival rate increased from 43 percent to 64 percent for men, and 57 percent to 64 percent for women.

For children up to age 14, cancer is the second leading cause of death in the U.S., behind accidents. The most common cancers in children are leukemia (particularly acute lymphocytic leukemia), brain and other nervous system cancers, soft tissue sarcomas, non-Hodgkin lymphoma, and renal (Wilms) tumor.

The five-year survival rate for cancer in children has improved significantly over the past 25 years, from 56% for patients diagnosed in 1974 to 1976, to 79% for those diagnosed in 1995 to 2000.

This year's report highlighted cancers caused by infectious diseases. Worldwide, 17 percent of new cancers are attributable to infection, the society said. These include liver cancer caused by hepatitis B and C, cervical cancer caused by human papillomavirus, stomach cancer caused by Helicobacter pylori bacterium, and Kaposi's sarcoma and lymphoma caused by HIV.

Rates of these cancers are highest in Africa and Asia, but these areas also have little in the way of prevention or vaccination programs.

The report is available at www.cancer.org/statistics.

NCI Programs:

NCI Plans 21% Success Rate, R01 Payline At 16th Percentile

The success rate for research project grants funded by NCI is expected to be 21 percent for fiscal 2005, resulting in funding for 1,346 grants, Institute officials said last week.

The R01 payline for percentiled grants will be set at the 16th percentile. Competing renewal grants will get increases ranging from 5 to 10 percent above their current levels, while full cost-of-living adjustments will be given to noncompeting (type 5) nonmodular grants.

The funding policies were announced at a retreat of three NCI advisory boards. The retreat was closed to the public.

The Institute's allocated budget for FY 2005 increased by 1.8 percent, but the full increase is not available for program initiatives, officials said. NCI will have about $62 million less to spend this year than last year, due to obligations from the years the NIH budget doubled.

NCI plans to spend $2.223 billion, or 46 percent of its budget, on research project grants, an increase from last year. The Institute also expects to increase funding for cancer centers.

Meanwhile, funding for training, cooperative clinical research groups, Specialized Programs of Research Excellence, and the intramural program will remain flat.

Policy Reports:

Panel Calls For More Research, Attention To End-Of-Life Issues

Despite progress in end-of-life research, important aspects of this life stage remain poorly understood, according to a panel convened by NIH last month.

The lack of continuity of care and poor communication between healthcare practitioners, patients, and family members make the end-of-life period a struggle for many Americans, according to the report of the NIH State-of-the-Science Conference on Improving End-of-Life Care, held Dec. 6-8.

In light of the projected dramatic increase in the number of older adults who will require end-of-life care, the panel called for the rapid development of research infrastructure to improve our understanding of what works and what doesn't in different groups of patients, and enhanced resources to deliver quality care to patients and their families at the end of life.

"We can begin by refining and agreeing upon our definitions of 'end of life,' 'palliative care,' and 'hospice'--the terms have been used inconsistently, and often interchangeably, which hinders not just the research enterprise, but effective communication between providers and patients as well," said Margaret Heitkemper, panel chairman and professor and chairman of the Department of Biobehavioral Nursing and Health Systems at the University of Washington School of Nursing.

The design of Medicare hospice benefits limits the availability of the full range of interventions that many people need at the end of life, the panel said. Specifically, the panel cited the eligibility requirement of a prognosis of six months or less to death, the forced selection of either skilled nursing or hospice care for patients entering nursing homes from hospitals, and limits on certain therapies such as radiation that may help manage symptoms.

Among the panel's other conclusions and recommendations:

--Enhanced communication among patients, families, and providers is crucial to high-quality end-of-life care.

--Recruit under-represented populations to future studies and ensure that these studies are sufficiently powered to evaluate subgroup differences, to aid in understanding health disparities in end-of-life care.

--Create new and support existing networks of end-of-life researchers and well-defined cohorts of patients to facilitate coordinated, interdisciplinary, multi-site studies.

The text of the panel's statement is available at http://consensus.nih.gov.

Report Urges Greater Rewards For Interdisciplinary Research

Advances in science and engineering increasingly require the collaboration of scholars from various fields, but interdisciplinary research is impeded at many institutions by policies on hiring, promotion, tenure, and resource allocation that favor traditional disciplines, according to a report from the National Academies.

The report urged academic institutions to explore new models that foster and reward interdisciplinary interactions. Industrial and national laboratories have traditionally operated successful interdisciplinary programs because their research goals are established and pursued in terms of projects rather than by discipline. Teams of researchers from various fields are formed to solve particular problems, an approach that stimulates interdisciplinary interactions.

Academic institutions also should revise recruitment and hiring practices to reach across departments, placing greater emphasis on people with valuable interdisciplinary backgrounds. Promotion criteria should include methods to evaluate interdisciplinary faculty and programs.

The committee concluded that the process by which institutions evaluate interdisciplinary research programs is often imperfect. The peer review process for both people and programs should include researchers with interdisciplinary expertise, in addition to experts in single disciplines. Also, greater flexibility in resource allocation is often needed to serve the needs of these programs.

Funding organizations can enhance their evaluations of interdisciplinary research programs and projects, the report said. The review process should include scientists with interdisciplinary expertise, along with experts in discrete disciplines.

Professional societies could serve as incubators for generating and facilitating interdisciplinary programs and projects, the report said. These organizations could produce intersociety reports on cutting-edge research developments, offer opportunities for researchers from different fields to interact, publish interdisciplinary journals, and recognize excellence in interdisciplinary research, the committee said.

The report calls on undergraduate and graduate students and postdoctoral scholars to actively seek out interdisciplinary experiences, and to pursue training and study in one or more fields in addition to their own. Junior researchers also should take advantage of networking opportunities and identify mentors favorable to interdisciplinary research. Faculty members who hire postdoctoral researchers from other fields should assume responsibility for educating them in the new specialty and also take the initiative to learn about the postdocs' expertise.

The study was sponsored by the National Academies Keck Futures Initiative. The report, "Facilitating Interdisciplinary Research," is available at www.nap.edu.

CAM Therapies Should Be Held To Conventional Standards

Stating that health care should strive to be both comprehensive and evidence-based, a new report from the Institute of Medicine of the National Academies calls for conventional medical treatments and complementary and alternative treatments to be held to the same standards for demonstrating clinical effectiveness.

The same general research principles should be followed in evaluating both types of treatments, although innovative methods to test some therapies may have to be devised, said the committee that wrote the report.

The committee noted in particular the escalating popularity of dietary supplements as well as the lack of consistency and quality in these products, which are an important component of several complementary and alternative approaches. Product inconsistency hinders health professionals' abilities to guide patients on the use of supplements and researchers' ability to study them. The report calls on Congress to work with stakeholders to amend the regulation of supplements to improve quality control and consumer protections and to create incentives for research on the efficacy of these products.

"Ideally, health care should be comprehensive, grounded in the best available scientific evidence, and centered on patients' needs and preferences," said committee chairman Stuart Bondurant, interim executive vice president for health sciences and executive dean, Georgetown University Medical Center.

"Health professionals and patients should have sufficient information about safety and efficacy to take advantage of all useful therapies, both conventional and complementary and alternative," Bondurant said. "To that end, we believe that the same research principles and standards for showing effectiveness should apply to both conventional and complementary and alternative treatments. And because evidence is a key element of prudent decision-making, we need to change the current regulation of dietary supplements in this country to encourage more studies of these widely used products and to ensure their quality."

Written to assist NIH in developing research methods and setting priorities for evaluating products and approaches within complementary and alternative medicine, the report also assesses what is known about Americans' reliance on these therapies. Use of CAM is widespread, with more than one-third of adults reporting that they have pursued some form of these treatments,

which include products such as herbal remedies, techniques such as acupuncture, and schools of practice such as naturopathy.

Fewer than 40 percent of CAM users have disclosed their use of such therapies to their physicians. More than half of physicians report that they would encourage patients to talk to them about using CAM and would refer them for treatments that fall into that category. However, much is still unknown about how and why people use these therapies in conjunction with or in lieu of conventional therapies.

A common set of methods and standards for generating and interpreting evidence is necessary if health care providers are to make informed decisions about the use of both conventional treatments and CAM, the report said. It has been argued that characteristics of CAM therapies—such as customization of treatments, variations in how practitioners perform treatments, or the holistic nature of many of these practices—make it difficult to apply traditional clinical studies to them.

Randomized controlled trials are the gold standard for providing evidence of efficacy, the committee said, but other study designs can generate useful information on treatments that do not lend themselves to RCTs. Observational studies, case control studies, and studies that specifically measure patients' expectations, emotional states, and other self-healing processes can provide useful data. Some conventional treatments, such as psychotherapy, also have similar characteristics that make them incompatible with RCTs, but they have been successfully evaluated via other methods, the committee noted.

Because many CAM products and approaches have not undergone formal testing and because resources to conduct research are finite, the report outlined several criteria to help determine which CAM therapies to prioritize for study. These same criteria apply equally well to as-yet untested conventional treatments, the committee noted. They include the prevalence and severity of the target health condition; existing evidence that the therapy is effective or may have safety issues; whether there is a plausible biological mechanism by which the therapy might work or the likelihood that research will discover a mechanism; and the likelihood that research will yield unambiguous results. Inability to meet any one of the criteria should not necessarily exclude a therapy from consideration, the report said.

To foster more research on the effectiveness and safety of CAM—as well as on how these therapies compare with one another or with conventional treatments—practitioners need to be trained in research principles and methods. Studies depend on the involvement of those who understand the therapies' characteristics and goals, but CAM training programs focus on preparing students for practice, and few practitioners learn how to conduct research. At the same time, because CAM use is becoming so widespread, all doctors, nurses, and other health care providers should receive education about these treatments during their professional education, the committee urged.

Dietary supplements, such as herbal products and vitamin pills, are among the most widely and increasingly used forms of CAM; use of herbal products jumped 380 percent between 1990 and 1997, for example. The Dietary Supplement Health and Education Act mandates that supplements be regulated as foods rather than drugs, which means that supplement manufacturers are not required to conduct safety or efficacy tests on their products.

Given that manufacturers are not required to conduct testing and are unable to patent many supplements, there is little incentive for supplement makers to invest in research on the effectiveness of these products. Moreover, the general lack of quality control for dietary supplements is problematic because researchers need consistent samples to conduct studies that could further elucidate these products' effectiveness and potential uses, the report said.

The committee also noted that although there are some restrictions on what information and claims can be included on labels, officials at the Federal Trade Commission have described a proliferation of unfounded and exaggerated claims for supplements. This is of concern because many consumers use these products without consulting a health care professional.

To remedy this situation, the report calls on Congress and the appropriate federal agencies to work with industry representatives, researchers, consumers, and other stakeholders to amend DSHEA to implement quality-control standards for each step of the manufacturing process and to enforce more accurate labeling and disclosures and other consumer protections. In addition, the broader regulatory scheme for supplements should be revised to create incentives for privately funded research on the effectiveness of products and brands and on how consumers use these products.

The study was sponsored by NIH and the Agency for Health Care Research and Quality.

The report, "Complementary and Alternative Medicine in the United States," is available at www.nap.edu.

Funding Opportunities:

Lance Armstrong Foundation Offers Community Grants

Letter of Intent Deadline: Feb. 15

Lance Armstrong Foundation is accepting applications for funding through the Community Program. The LAF would offer financial support and advise to community non-profit organizations serving the needs of cancer survivors as identified by the National Action Plan for Cancer Survivorship. Two grants will be offered in support of cancer survivorship initiatives that impact people in their local communities. The RFP and additional guidelines and procedures are available at www.laf.org in the Public Health section.

Inquiries: LAF, phone 512-236-8820.

RFP Available

RFP N02-CM-57006-48: Central Institutional Review Board Initiative

Response Due Date: March 14

NCI Cancer Therapy Evaluation Program has a requirement to develop and implement a centralized model of Internal Review Board review for multi-site NCI-sponsored clinical trials. The goal of the initiative is: 1) To decrease the duplicative burden of protocol review that occurs at hundreds of local IRBs nationwide on NCI-sponsored multicenter trials by providing a single, centralized review that can be used by local IRBs participating in these trials, and 2) to maintain, and enhance, high standards for the protection of research participants by providing consistent, expert IRB review at the national level. The CIRB initiative would serve the 2,000 sites that conduct Cooperative Group trials. Major tasks required of the contractor include the following: 1) Manage and provide administrative/regulatory support for two Central IRBs, one for adult trials and one for pediatric trials; 2) Manage and support current and newly enrolled participating local sites; 3) Conduct the recruitment and integration of new sites into the Initiative; 4) Provide informatics support and system integration; 5) Support the NCI internal and external communications efforts regarding all aspects of the Initiative; 6) Implement and manage an Initiative-wide Quality Improvement Plan; 7) Provide support for the formal accreditation of both CIRBs in contract year 2 or 3, as determined by NCI; 8) Develop and implement a system for utilizing central review for sites that do not have a local IRB; 9) Establish and support a second Board for adult trials if needed to handle the growth in the menu of phase II protocols. One contract will be awarded on an incrementally funded basis for three years with options for three additional years. The RFP is available at http://www.fbodaily.com/archive/2005/01-January/15-Jan-2005/FBO-00734458.htm.

NOT-CA-05-008: Addendum–Comprehensive Minority Institution/Cancer Center

Applicants responding to RFA-CA-05-021 who are applying for a competing renewal (type 2) of their MI/CCP grant, should address past performance and progress during the previous funding period in the Background and Objectives Institutional Commitment; Review of Prior Planning and Priority-Setting; Scientific and Administrative Leadership, etc. sections of the RFA. This notice is available at http://grants1.nih.gov/grants/guide/notice-files/NOT-CA-05-008.html.

Inquiries: Sanya Springfield, NCI, Office of Centers, Training, and Resources, Comprehensive Minority Biomedical Branch, phone 301-496-7344; fax 301-402-4551; email springfs@mail.nih.gov.

In Brief:

NCCS Appoints New Directors; ONS To Honor Stamp Advocate

(Continued from page 1)

of Life, Duke University Divinity School; **Patrick Gaston**, president of Verizon Foundation; **Tamra Bentsen**, consultant for Susan G. Komen Breast Cancer Foundation, the Bristol-Myers Squibb Tour of Hope, the Rose-Community Awareness and Capital Project, the National Children's Alliance, and the National Hospice Foundation; **Tucker Melançon**, U.S. District Judge for the Western District of Louisiana; **Soraya**, a Colombian-American singer-songwriter and Latin spokesman for the Komen foundation. . . . **BALAZS BODAI** will receive the 2005 Oncology Nursing Society Award for his commitment to transforming cancer care. Bodai lobbied for the Breast Cancer Stamp. He is director of Breast Surgical Services at Kaiser Permanente in Sacramento, Calif., clinical professor of surgery at the University of California at Davis, president of B and B Medical Research Technology Inc., and medical director of Liv International and Medical Infrared Systems, Inc. The award will be presented at the ONS 30th Annual Congress in Orlando April 28. **Susan Bauer-Wu**, director at the Phyllis F. Cantor Center for Research in Nursing and Patient Care Services at Dana-Farber Cancer Institute, was named presenter of the 2005 ONS Foundation Mara Mogensen Flaherty Memorial Lectureship. . . . **FDA Office of Science and Health Coordination** opened a Web site on regulation of nanotechnology products. Because regulation of nanotechnology products involves more that one center, FDA has formed a NanoTechnology Interest Group, which meets quarterly and is made up of representatives from all the centers. Information about how nanotechnology products are regulated by FDA is available at www.fda.gov/nanotechnology/.

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