THE CANCER LETTER

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FDA Approval Of Abraxane Sets Stage For Competition Between Taxane Drugs

By Paul Goldberg

On Jan. 7, American Pharmaceutical Partners Inc. of Schaumburg, Ill., received FDA approval for the drug Abraxane, a new formulation of paclitaxel that eliminates the cremophor solution, and with it the need for pre-treatment to control its toxicity.

FDA's action caused great consternation among short-sellers, who, as of December, held about half of the company's shares that are freely tradable on the stock market. APP (Nasdaq: APPX) is a publicly traded subsidiary of American Bioscience Inc., a Santa Monica, Calif., based privately held

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In Brief:

NCI Designates Siteman As Comprehensive, Center Secures $10 Million From Foundations

ALVIN J. SITEMAN Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital received "comprehensive" designation and a five-year extension of a cancer center support grant with $21 million from NCI. Siteman won its first NCI cancer grant in 2001. The center also received a $5 million donation from Charles F. Knight and Joanne Knight to establish the Joanne Knight Breast Health Center and Breast Cancer Program, said Siteman director **Timothy Eberlein**. The center is conducting the first large multicenter study comparing digital mammography to conventional mammography in the detection of breast cancer. **Matthew Ellis**, head of the Breast Cancer Program and section head of medical oncology, will begin an interdisciplinary initiative next year on the causes of breast cancer at a molecular level. Knight, former CEO, chairman, and now chairman emeritus of Emerson, also secured a $10 million commitment from the Emerson Charitable Trust and the Anheuser-Busch Foundation for the center. . . . **UNIVERSITY OF KENTUCKY** Markey Cancer Center made the following appointments: **Kevin McDonagh**, of University of Michigan, was named chief of hematology/oncology, professor of internal medicine, and deputy director of the center. He also will hold the Markey Foundation Chair in Clinical Oncology. **John Rinehart**, director of hematology/oncology and associate director for clinical research at the University of Alabama-Birmingham Comprehensive Cancer Center, was named professor of internal medicine, Division of Hematology/Oncology, and associate director for clinical research. Rinehart will hold the Kentucky Lung Cancer Research Chair. **Thomas Tucker** was named associate director

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APP's Abraxane Approved For Second-Line Breast Cancer

(Continued from page 1)

company that owns most of APP's stock.

Short-sellers were betting that the Abraxane data—which showed a higher response but no survival advantage in a non-inferiority comparison with a dusty old regimen of paclitaxel—would be laughed out of the agency.

It was not. Abraxane's approved indication—second-line breast cancer—is relatively narrow, and the data from the registration trial that compared Abraxane with an approved but no longer state-of-the-art breast cancer indication of paclitaxel offers only limited guidance, clinicians say.

Abraxane (paclitaxel albumin protein-bound particles for injectable suspension) received a regular approval based on section 505(b)(2) of the Food, Drug and Cosmetic Act, which applies to new dosage forms and delivery routes for previously approved drugs. In this case, APP was able to rely on the FDA's findings of safety and efficacy for the comparator drug, Taxol.

"In this case, the response rate wasn't really necessarily a surrogate, because we did give them a regular approval for this," said Ramzi Dagher, head of the medical team that reviewed Abraxane at the FDA Division of Oncology Drug Products. "The response rate in this case provided adequate evidence of benefit, given the fact that paclitaxel itself has previously been approved for the indication."

This is not an unusual stance for the agency, Dagher said. "It's not a secret that there are indications where response rates, combined with appropriate information of the response duration, are in and of themselves adequate evidence of benefit for *de novo* drugs. Leukemia, for example. Or, for example, we have accepted response rates plus time to progression data for hormonal therapy for breast cancer."

The drugs were compared in a non-inferiority trial conducted in 460 patients with metastatic breast cancer who were randomized to receive either Abraxane 260 mg/m^2 administered as a 30-minute infusion or paclitaxel 175 mg/m^2 given over three hours every three weeks. The trial was conducted primarily in Russia.

According to the label, the objective response rate verified by central review was 21.5% (95% CI: 16.2% to 26.7%) for Abraxane compared to 11.1% (95% CI: 6.9% to 15.1%) for paclitaxel (p=0.003).

Some FDA-watchers and, likely, the vast majority of short-sellers, pointed to a low response rate—11.1 percent—in the paclitaxel arm of the company's trial as a sign of questionable reliability of the trial.

FDA saw it differently. "Here, in a randomized setting, we had a chance to evaluate the patient demographics and patient characteristics in the two treatment arms, and they appeared to be very comparable," Dagher said to **The Cancer Letter**. "We didn't detect any major imbalances in the prognostic factors or the patient characteristics between the two treatment arms."

The company used an independent radiologic review board to verify responses, and the agency subsequently evaluated the images. Ultimately, the results of a randomized trial appear to have trumped historical data.

"In the previous literature, different studies have often used slightly different response criteria, so depending on the set of response criteria you use, you might come up with somewhat different response rates when you are comparing single-arm studies in different populations," Dagher said. "And that's why the best test of these issues is a randomized study."

The 11.1% response rate to paclitaxel isn't too surprising, agreed George Sledge, a breast cancer expert at Indiana University Medical Center and a former member of the FDA Oncologic Drugs Advisory Committee.

"It's not particularly unusual, given that many of the patients had received fairly extensive prior therapy," Sledge said "You might remember that the control

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

palitaxel arm in Genentech's pivotal Herceptin trial reported a fairly low response rate even as front-line therapy, suggesting that a lot of this relates to who is included in the trial."

ABI Chief Medical Officer Michael Hawkins said the paclitaxel response rate was low because the company defined rigorous response assessment criteria.

"We had defined prospectively a fairly complicated response rate to try to remove as much bias from the response determination as possible, because you could not blind the study," Hawkins said. "The response rate that's quoted in the package insert is what's called a 'reconciled target lesion response rate.' The response rates are lower than what you typically would expect to see in the literature for paclitaxel, but the response rates are lower than those reported by investigators."

The investigators initially reported a 19% response rate for paclitaxel and a 33% response rate for Abraxane in the company trial.

According to the label, 59% of patients enrolled in the trial had received one or more prior chemotherapy regimens, and 77% had received an anthracycline-containing regimen.

According to the label, grade 3 or 4 adverse events included neutropenia (9% with Abraxane and 22% with paclitaxel), myalgia/arthralgia (8% vs. 4%) and vomiting (4% vs. 1%). Ten percent (24 patients) treated with Abraxane developed grade 3 peripheral neuropathy; 14 of these patients showed some improvement of neuropathy at a median of 22 days. Two percent of patients receiving paclitaxel developed grade 3 peripheral neuropathy.

The drug's label is posted at www.fda.gov/cder/foi/label/2005/021660lbl.pdf.

Uncertain Clinical Significance In Breast Cancer

When ABI and APP's top official Patrick Soon-Shiong talks about establishing Abraxane's foothold in oncology, he speaks of "taxanes," not just paclitaxel, a drug pioneered as Taxol by Bristol–Myers Squibb and now also available in generic form.

The taxane category also includes the Sanofi-Aventis drug Taxotere (docetaxel), with which Abraxane hasn't been compared in head-to-head trials.

"This is the first time there is a solvent-free taxane," said Soon-Shiong, executive chairman of APP and chairman, president and CEO of ABI. "So, from our perspective, there is an opportunity to have the next generation taxane, which would be solvent-free, and which takes advantage of an albumin-bound nanoparticle technology."

"Nanoparticle albumin-bound" technology is the trademarked name for the technology platform on which Abraxane is based.

"My discussions with some of the thought leaders is that they've always known taxanes to be effective molecules," Soon-Shiong said to **The Cancer Letter**. "But until this point in time they had no alternative other than to administer them with the solvents, recognizing that solvents cause harm. And here is now an opportunity to unleash the full potential of the active molecule itself while still protecting the patient. That, from a physician's perspective, is a very attractive possibility."

A lot of work remains to be done to determine Abraxane's place in the treatment of breast cancer and other diseases where taxanes are used, oncologists and industry observers say.

"Certainly, going forward, it would be valuable to perform a head-to-head comparison with docetaxel," said Indiana University oncologist Sledge.

"Replacing every-three-week paclitaxel with Abraxane might be acceptable from a regulatory standpoint, but doesn't carry us very far from a real world standpoint," Sledge said. "For instance, would the slightly higher response rates and time to progression in a refractory setting translate to superiority in the adjuvant setting, where paclitaxel sees its greatest use? Is it equivalent to or better than docetaxel in the metastatic setting?"

Otis Brawley, a breast cancer expert at Emory University and a member of ODAC, described Abraxane as a "me-too drug."

"Still, if there is a benefit over standard dose Taxol at 175 mg/m^2 every three weeks, it should be approved," Brawley said "The advantage is possibly in response and in the elimination of cremophor and complications with which it's associated. It is likely they got more drug into the patient with their formulation.

"This says nothing about this drug against Taxol weekly, against Taxotere for relapsed breast cancer, or against any drug for adjuvant use," Brawley said.

Soon-Shiong said the price of Abraxane hasn't been set.

"We will be finalizing the pricing analysis within the next two weeks," he said. "We've done the pharmaco-economic analysis of the savings that this next generation taxane will embody as the absence of toxicities, the absence of steroid pre-medication, the absence of the need—at least in our trial—for growth factors like G-CSF, and, obviously, the high response rate."

On Demographics and "Nanotechnology"

Immediately after FDA approved Abraxane, the company's press release referred to "nanoparticle albumin-bound" technology. The press release states also that 215,990 women in the US "are expected to be diagnosed with breast cancer that had already spread."

The words "nanoparticle" or "nanotechnology" do not appear anywhere in the Abraxane's FDA label, and the drug's indication—metastatic breast cancer—doesn't affect 215,990 women a year. Experts estimate that around 60,000 new patients a year receive second-line therapy for breast cancer in the U.S.

It is unusual for drug companies to challenge FDA by making statements that appear to be inconsistent with the label. When the agency declined AstraZeneca's request to put the word "targeted" in the label of the drug Iressa, the company refrained from using that word. Earlier, AstraZeneca's predecessor Zeneca similarly avoided using the word "prevention" in connection with tamoxifen, settling for a reduction of risk of breast cancer in a high-risk population.

Also, in the aftermath of the controversy involving FDA's handling of the ImClone Systems Inc. agent Erbitux, Congress has been alerted to the relationship between FDA actions, company claims, and the behavior of the market. An apparent lack of communication between FDA and the Securities and Exchange Commission has been one of the principal directions of the ImClone investigation by the House Committee on Energy and Commerce.

APP and ABI officials stand by their use of the word "nanoparticle," arguing that it refers to the underlying technology on which Abraxane is based. Also, NCI and its director, Andrew von Eschenbach, recognize Abraxane as a nanotechnology drug, company officials said.

FDA officials said they disagreed with the claim that Abraxane was either a "nanotechnology" agent, or a "nanoparticle."

"We did seriously consider it," said John Leighton, a supervisory pharmacologist at the FDA Division of Oncology Drug Products. "We had multiple discussions on it. We take these issues very seriously, and we did not put it in the label."

Leighton said the agent didn't meet the size standards for being designated as "nanotechnology" or a "nanoparticle."

"From our understanding, nanotechnology particles are generally described as something between 1 and 100 nanometers diameter, and Abraxane didn't meet that technical characteristic," Leighton said. "It's larger." The label estimates a mean particle size at about 130 nanometers.

The words "nanotechnology" and "nanoparticle" figure prominently in the company's post-approval blitz aimed at the media and Wall Street. Soon-Shiong mentioned "nanoparticle technology" in a Jan. 10 conference call with analysts. "FDA has recognized that Abraxane warrants the creation of a new category of drugs now designated as 'protein-bound particles.'" Soon-Shiong said at the conference call.

FDA's Leighton said the agency hasn't established a new category of drugs. "I wasn't aware that we called it a new category of compounds," Leighton said to **The Cancer Letter**. "We did call it a protein-bound drug. The proof is really in the clinical efficacy and safety data. It was really approved on those endpoints."

The agency's administrative structure recognizes three categories of cancer agents: drugs, biologics and radiopharmaceuticals. Abraxane was classified as a drug, and while it is the first protein-bound therapeutic, the agency has approved many prophylactic vaccines that are protein-bound.

On Jan. 11, in an unprompted call to **The Cancer Letter**, a public relations agent promoting Abraxane used the word "nanotechnology" to describe the product, and followed up with an email, which stated that "this approval marks a new class of 'protein-bound particle' drugs, now made possible by nanoparticle albumin-bound (nab™) technology.

"Abraxane, the first in this new class of drugs, provides a much-needed, novel treatment option for the more than 215,000 women diagnosed with the disease annually," the email states.

This is not the population for which the drug was approved, said ODAC member Brawley, who is also an expert in cancer epidemiology.

"The ACS estimates that 215,990 women and 1,450 men—total 217,440—will be diagnosed with breast cancer in U.S. this year," Brawley said. "Of these 59,390 will be ductal carcinoma *in situ*, for whom the only adjuvant hormonal or chemotherapy will be tamoxifen or an aromatase inhibitor."

Of the 158,050 invasive cancers diagnosed this year, fewer than half would ultimately become candidates for second-line chemotherapy, Brawley said. "Many will not be candidates for years," he said. According to industry figures, about 60,000 women would receive second-line treatment for breast cancer this year.

Yet, the words "nanotechnology" and the number of people who allegedly stand to benefit from the drug

has caught on in the press coverage of Abraxane.

"If you or a loved one suffer from breast cancer, listen up," said a news report on WNEP, a Pennsylvania television station. "The government has just approved the first ever chemotherapy drug that uses nanotechnology to fight metastatic breast cancer. It's called Abraxane. It replaces toxic chemical treatment with tiny packages of the drug paclitaxel and the natural protein albumin…. The drug offers new hope for more than 215,000 women diagnosed with malignant breast cancer each year."

ABI's Hawkins said the use of the words "nanoparticle" was appropriate and consistent with the use of the word by NCI.

"American BioScience has been working in the area of protein-based nanoparticle technology since the early 1990's and trade-marked the term 'nanoparticle albumin bound (*nab*™)' in 2003 to describe our technology that binds water-insoluble compounds to albumin in nanometer sized particles," Hawkins said.

"The FDA approved labeling describes Abraxane as 'an albumin-bound form of paclitaxel with a mean particle size of approximately 130 nanometers.' Dr. von Eschenbach acknowledged in the NCI's 'Cancer Nanotechnology Plan' (May, 2004) that nanoscale objects are 'typically, though not exclusively, with dimensions smaller than 100 nanometers.'

"The NCI Alliance for Nanotechnology has referred to Abraxane as a 'nanoparticulate formulation' and recognized it as a 'real world example of the promise of nanotechnology', stating that 'the field of nanotechnology has already yielded specific products and proofs of principle demonstrated to be of value in clinical applications,'" Hawkins said.

"However, we should not lose sight of the major advance that Abraxane represents," Hawkins said. "Abraxane, as the first solvent-free taxane, can be administered without premedication, was well tolerated despite a 50 percent increase in the dose of paclitaxel delivered and almost doubled the response rate in women with metastatic breast cancer."

The NCI nanotechnology website is at http://nano.cancer.gov/alliance_q-and-a.asp#13.

Soon-Shiong said the breast cancer statistics in the press releases were stated to present background information on the disease.

"I think you are misunderstanding the purpose of that information," Soon-Shiong said. "That information was to provide merely a backgrounder of the demographics of breast cancer and was not to construe in any way either the market opportunity or the patients who would receive Abraxane."

NCI Programs:

Bypass Budget Seeks $6.17B For Cancer Research In FY '06

By Kirsten Boyd Goldberg

NCI Director Andrew von Eschenbach submitted a professional judgment budget request of $6.17 billion for fiscal 2006 to Congress and the White House last month.

The request is $1.3 billion above the Institute's FY 2005 appropriation of $4.86 billion in the omnibus bill signed by President George W. Bush on Dec. 9.

The Congressionally-mandated document is known as NCI's "bypass budget," because it was intended to bypass NIH and HHS review and go directly to the White House. The National Cancer Act of 1971 gave NCI the authority to prepare a budget request that would describe all available scientific opportunities. NCI's actual budget is developed the same way as that of other NIH institutes.

The bypass budget serves as a planning and communications tool with Congress, scientists, and the public.

In its real budget for the current fiscal year, NCI faces a decrease of $203.8 million from last year after obligatory taps, reductions, and grant and salary increases are paid, Institute officials said.

While the $4.86 billion appropriation represents an increase of $141 million over the previous fiscal year, the funding bill requires an 0.8 percent across the board reduction, and further reductions for administrative costs.

Also, NCI will have to follow NIH policy to provide noncompeting research project grants with an average 3 percent cost of living adjustment, contribute to the NIH Roadmap Initiatives, and increase federal salaries.

The FY 2006 Bypass budget, titled "The Nation's Investment in Cancer Research," describes seven priorities for increased funding: cancer prevention, early detection, and prediction; overcoming cancer health disparities; the strategic development of cancer interventions; an integrated cancer trials system; advanced technologies; integrative cancer biology; and molecular epidemiology.

The $6.17 billion request doesn't include funding for a proposed National Advanced Technologies Initiative for cancer, under development by a subcommittee of the National Cancer Advisory Board.

The Bypass budget is available at http://plan.cancer.gov.

NCI Appoints 15 Consumers To Director's Liaison Group

NCI has named 12 consumer advocates and reappointed three members to the Director's Consumer Liaison Group.

Douglas Ulman, director of survivorship at the Lance Armstrong Foundation and a returning DCLG member, was appointed chairman of the federally chartered advisory committee.

The DCLG, begun in 1997, advises the NCI director about issues, programs, and research priorities from the perspective of people whose lives are affected by cancer. Besides Ulman, members are:

Margaret Anthony, South Carolina Chapter, Yul Brynner Head and Neck Foundation/Hollings Cancer Center/Medical University of South Carolina.

Vernal Branch, Virginia Breast Cancer Foundation/ National Breast Cancer Coalition.

William Bro, chief executive officer of the Kidney Cancer Association.

Lourie Campos, assistant director of policy for special populations, Community Health Partnership.

Nancy Davenport-Ennis, founding executive director of the National Patient Advocate Foundation and the Patient Advocate Foundation.

Bobbi de Córdova-Hanks, founder and director of the Bosom Buddies program of the Women's Center of Jacksonville, Fla.

Beverly Laird, member of the American Cancer Society regional affiliates and the North Central Alabama affiliate of the Susan G. Komen Breast Cancer Foundation.

Sylvia Ramos, board member and former president of People Living Through Cancer, member of the Intercultural Cancer Council, and clinical professor of surgery, University of New Mexico School of Medicine.

Eric Rosenthal, freelance medical journalist affiliated with EvocaTalk Reports and columnist for Oncology Times.

Mary Jackson Scroggins, member of the board of directors of the Ovarian Cancer National Alliance.

Sue Sumpter, patient services manager, Leukemia and Lymphoma Society, and vice president, Candlelighters Childhood Cancer Foundation.

Marisa Weiss, oncologist and founder of breastcancer. org and Living Beyond Breast Cancer.

Celeste Whitewolf, founder and director, Native People's Circle of Hope.

James Williams, co-chairman, board of directors, Pennsylvania Prostate Cancer Coalition.

SAIC-Frederick Makes Proteomics Awards

NCI said its contractor, SAIC-Frederick Inc., has made two-year awards under a competitive solicitation totaling $13.4 million to two research teams from 10 cancer research institutions.

The researchers will use transgenic mouse models of human cancers to study current proteomic technologies, compare results, and provide reference data sets and biological resources for use by cancer researchers. One of the teams is headed by Samir Hanash, of University of Michigan. Other members include: Gilbert Omenn and David States, of University of Michigan; Raju Kucherlapati and David Sarracino, of Harvard Partners Center for Genetics and Genomics; Tyler Jacks and Alice Shaw, of Massachusetts Institute of Technology; Ronald Dephino and Nabeel Bardeesy, of Dana Farber Cancer Institute; Brian Haab, of Van Andel Research Institute; and Harold Varmus, of Memorial Sloan-Kettering Cancer Center.

Martin McIntosh and Amanda Paulovich, of Fred Hutchinson Cancer Research Center, lead the other team, whose members include: Christopher Kemp, of Fred Hutchinson Cancer Research Center; Ruedi Aebersold, of Institute for Systems Biology; Richard Smith, of Pacific Northwest National Laboratory; and N. Leigh Anderson, of Plasma Proteome Institute.

Cancer Statistics Report Released

Prostate cancer is the leading cancer diagnosed overall in men in the U.S., and breast cancer is the most common form of cancer diagnosed in U.S. women, according to the latest federal report on state-specific cancer rates.

The leading cause of cancer death for both men and women is lung cancer, said the report, "U.S. Cancer Statistics: 2001 Incidence and Mortality." The report includes incidence data from 43 states, six metropolitan areas, and the District of Columbia, covering 92 percent of the U.S. population, up from the coverage rate of 84 percent for the report issued last year. The report supplies state, population, racial, ethnic and gender information.

The report is available at www.cdc.gov/cancer/index.htm and www.seer.cancer.gov/statistics.

Medicare:

Smokers May Get Counseling Through Medicare, HHS Says

Medicare intends to allow certain beneficiaries who smoke to receive counseling services to help them quit, HHS officials said last month.

An estimated 9.3 percent of those age 65 and older smoke cigarettes. About 10 percent of elderly smokers quit each year, with 1 percent relapsing.

"The evidence available fully supports the hope

that seniors at risk of the diseases caused by smoking can quit, given the right assistance," Centers for Medicare and Medicaid Services Administrator Mark McClellan said.

CMS proposes to extend smoking cessation coverage to beneficiaries who smoke and have been diagnosed with a smoking related disease or are taking drugs whose metabolism is affected by tobacco use. The coverage decision involves Medicare beneficiaries who have an illness caused or complicated by smoking, including heart disease, cerebrovascular disease, lung disease, weak bones, blood clots, and cataracts. It also applies to beneficiaries who take any medications whose effectiveness is complicated by smoking, including insulins and medicines for high blood pressure, seizures, blood clots and depression.

Medicare's new prescription drug benefit will cover smoking cessation treatments that are prescribed by a physician. In 1993, smoking cost the Medicare program about $14.2 billion, or approximately 10 percent of Medicare's total budget.

The proposed coverage policy is posted for public comment at www.cms.hhs.gov/coverage.

Funding Opportunities:

NIH Director's Pioneer Award

Nomination Dates: Between March 1 and April 1

As a component of the NIH Roadmap for Medical Research and unlike other NIH grants, which support research projects, the Pioneer Award supports individual scientists at all career levels and in any field of research provided they are interested in exploring biomedically relevant topics and willing to commit the major portion of their effort to Pioneer Award research. Awardees must be U.S. citizens, non-citizen nationals, or permanent residents. There will be five to ten awards of up to $500,000 in direct costs per year for five years.

The self-nomination process includes a three- to five-page essay, a biographical sketch, a list of current research support and the names of three references. Nominations may be submitted on the Pioneer Award Web site, at http://nihroadmap.nih.gov/pioneer.

Inquiries: The complete Pioneer Award announcement is posted at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD- 05-021.html.

ACS Postdoctoral Fellowships

Letter of Intent Receipt Date: Feb. 15. Application Deadline: March 1.

The Canary Fund in partnership with the American Cancer Society has created a postdoctoral fellowship program for the early detection of cancer**.** Research should be directed at approaches to improve clinical methods for the screening of cancer including, but not limited to, research in the following areas: minimally invasive strategies for early detection; biomarker identification or discovery, particularly protein biomarkers; and imaging, including novel molecular imaging strategies

The five 3-year awards will have progressive stipends of $40,000, $42,000, and $44,000 per year, plus $4,000 per year for institutional allowance. To reserve funding for full 3 year fellowships, applications will only be accepted from scientists who at the time of application have had no more than 2 years of research experience beyond their terminal degree (MD or PhD). Applicants must be US citizens or permanent residents working with an accomplished mentor at a non-profit institution. Information about program policies and applications is available at www.cancer.org/research.

Inquiries: Christopher Widnell, phone 404-329-7552; e-mail christopher.widnell@cancer.org or William Phelps, phone 404-329-6835; e-mail william.phelps@cancer.org.

RFAs Available

RFA-CA-06-006: Application of Emerging Technologies for Cancer Research (SBIR/STTR)

Letter of Intent Receipt Dates: Jan. 17, May 17, Sept. 18. Application Receipt Dates: Feb. 17, June 17, Oct. 18

The RFA supports projects that evaluate emerging technologies in biological contexts to assess reproducibility and to produce preliminary data that answers a biological or clinical question. Technologies proposed for the RFA should be sufficiently advanced in development to be applied in a clinical or biological context. The funding opportunity will utilize the Small Business Innovation Research and Small Business Technology Transfer mechanisms. The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/rfa-ca-06-006.html.

Inquiries: Gregory Downing, NCI OTIR, phone 301-496-1550; fax 301-496-7807.

RFA-CA-06-007: Innovations in Cancer Sample Preparation (SBIR/STTR)

Receipt Dates: see preceding RFA.

NCI invites applications for research projects involving the development and enhancement or adaptation of sample preparation methodologies and technologies, the development of assays to assess sample quality, and studies designed to judge sample quality. The RFA supports phase I STTR R41 or phase I SBIR grants R43, or phase II STTR 2-R42 or phase II SBIR 2-R44 grants, or the SBIR/STTR Fast-Track option 1-R42 or 1R44 as described in the SBIR/STTR Omnibus Solicitation. NCI would commit $1,250,000 dollars in FY 2006 to fund eight to twelve phase I, phase II, and/or Fast-Track applications under the SBIR/STTR set-aside funding mechanism. The funding opportunity will use the STTR R41/R42 and SBIR R43/R44 grant mechanism(s). The RFA is available at http://grants.nih.gov/grants/guide/rfa-files/rfa-ca-06-007.html.

Inquiries: See preceding RFA.

In Brief:

CWU Renames Cancer Center; Gerson Appointed Director

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for cancer prevention and control. He will remain as chairman of the Department of Epidemiology in the UK College of Public Health. He succeeds **Stephen Wyatt**, newly appointed dean of the COPH. . . . **CASE COMPREHENSIVE** Cancer Center is the new name for the cancer center at Case Western University. Under the reorganization, member institutions involved in research conducted by the center include Case Western Reserve University, University Hospitals of Cleveland's Ireland Cancer Center, and the Cleveland Clinic Foundation. **Stanton Gerson** was appointed director of the CCCC, succeeding **James Willson**, who became director of the University of Texas Southwestern Cancer Center. Three new appointments were made at the center. **Scot Remick** is associate director for clinical research. He is the principal investigator for a phase I U01 grant with the NCI Cancer Therapy Evaluation Program. **Bryan Williams** is associate director for basic research for the Cleveland Clinic Lerner Research Institute, and **Derek Raghavan** is associate director for the Cleveland Clinic Taussig Cancer Center. . . **MAYO CLINIC** Cancer Center received a $10.8 million Specialized Programs of Research Excellence grant from NCI for brain cancer research. Neurologist **Brian O'Neill** is the principal investigator for the SPORE. O'Neill and geneticist **Robert Jenkins**, co-principal investigator, will lead a team of 12 basic, clinical, and population science investigators conducting four research projects on adult gliomas. Over the next five years, research may also extend to gliomas of children and adolescents. . . . **H. KIM LYERLY**, director of the Duke Comprehensive Cancer Center, was named chairman-elect of the Department of Defense Breast Cancer Research Program Integration Panel. Lyerly will serve on the executive committee of the Integration Panel in 2005 and become chairman in 2006. Lyerly, the George Barth Geller Professor of Cancer Research chair at Duke University, also directs Duke's Specialized Program of Research Excellence grant in breast cancer, and holds appointments in surgery, pathology, and immunology at Duke University Medical Center. . . . **WALTER CURRAN** received an honorary membership from the European Society of Therapeutic Radiology and Oncology on Oct. 24, at the organization's annual meeting in Amsterdam. Curran is professor and chairman of the Department of Radiation Oncology at Jefferson Medical College of Thomas Jefferson University and clinical director of the Jefferson Kimmel Cancer Center. The award was given for his contributions to clinical research in oncology through his leadership of the Radiation Therapy Oncology Group. Curran has served as RTOG group chairman since 1997. . . . **HAROLD MAURER**, chancellor of the University of Nebraska Medical Center and a pediatric oncologist, was named "Midlander of the Year" by the Omaha World-Herald. Maurer was recognized for his tenure during the most impressive growth period at UNMC. The 12-page section in the Jan. 2 edition highlighted Maurer's accomplishments, which include increasing UNMC research funding by 234 percent since becoming chancellor in 1998, from $30.9 million to $72.5 million. Maurer arrived at UNMC in 1993. . . . **ACADEMY OF MOLECULAR IMAGING** announced its 2005 Distinguished Scientist Awards. **Anthony Shields**, professor of medicine and oncology at Wayne State University and associate director of clinical research at Karmanos Cancer Institute, will receive the Peter Valk Distinguished Clinical Scientist Award. Shields is also chief of the Gastrointestinal Oncology section and program leader of developmental therapeutics. The Distinguished Basic Scientist Award will be presented to **Joanna Fowler**, senior chemist and director of the PET program at Brookhaven National Laboratory and the Brookhaven Center for Translational Neuroimaging. Each awardee receives $20,000, presented in March at the annual AMI conference in Orlando. The awards are funded by CTI Molecular Imaging and GE Healthcare. . . . **C. EVERETT KOOP** received the Surgeon General's Medallion from Surgeon General **Richard Carmona** for promoting public health. Koop served as the 13th Surgeon General from 1982-1989 under President **Ronald Reagan**. He received the award at the Anchor & Caduceus Society luncheon to celebrate the 116th anniversary of the Public Health Service Commissioned Corps. . . . **ERROL COOK,** vice president and treasurer of the Lymphoma Research Foundation, was elected its president, said **Jerry Freundlich**, co-founder of LRF. Cook, a lymphoma survivor, is a retired venture banker. . . . **CHARLES LOPRINZI** received the Susan G. Komen Breast Cancer Foundation Professor of Survivorship award for his research on concerns of breast cancer survivors. Loprinzi is a medical oncologist at the Mayo Clinic. The award includes a gift of $20,000 for advancing breast cancer survivorship at the discretion of the professor. Loprinzi also received the Komen Foundation's 2002 Brinker International Award for Breast Cancer Research.

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