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Danish Researchers Post Long-Awaited Aranesp Results—Ever So Discreetly

By Paul Goldberg

A study eagerly awaited by physicians, investors, regulators, and payers around the world showed a significantly inferior therapeutic outcome from adding Aranesp to radiation treatment of patients with head and neck cancer.

The study conducted by the Danish Head and Neck Cancer Group was highlighted three years ago by Aranesp's sponsor, Amgen Inc., as one of a series of rigorous trials designed to assess the impact of erythropoietin on "hard endpoints," including survival and disease progression.

The EPO agents were approved based on their ability to decrease the need for blood transfusions, and the question of their impact on disease remains unsettled.

Despite the buildup, even informed observers have been largely unaware

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In Brief:

ASCO Members Pick Schilsky As President-Elect; Five Elected To Society's Board Of Directors

RICHARD SCHILSKY, an expert in gastrointestinal cancers, cancer pharmacology, and drug development, was elected president of the American Society of Clinical Oncology for a one-year term beginning in 2008. He will take office as president-elect during ASCO's annual meeting in June.

Schilsky is associate dean for clinical research at the University of Chicago Pritzker School of Medicine. Since 1995, he has served as chairman of the Cancer and Leukemia Group B, an NCI-sponsored clinical trials cooperative group. His laboratory and clinical research have been continuously funded by NCI since 1987.

"It's an honor to have run for this office in the company of my dear friend and colleague Dr. **Hyman Muss**," Schilsky said in a statement. "I am deeply committed to ASCO's mission of improving cancer care and prevention and look forward to the opportunity to serve ASCO in this new capacity, and to work through this great organization to help improve the lives of those living with cancer."

Schilsky, an ASCO member since 1980, served on the board from 2002–2005, and has served on many ASCO committees. From 1990-1993, he was a member of the Editorial Board for the Journal of Clinical Oncology.

Schilsky also has served as chairman of the FDA Oncologic Drugs Advisory Committee. He has been a member of the NCI Board of Scientific

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Amgen Didn't Tell Wall Street About Results Of Danish Study

(Continued from page 1)

that the Danish study was temporarily stopped on Oct. 18, 2006, and that the decision not to resume the study was made on Dec. 1, 2006, and posted on the Web by the principal investigator, Jens Overgaard.

Experts say that the hypothesis underlying the study—that avoidance of anemia would result in a better radiation effect—now appears to be disproved. More importantly, locoregional failure on the Aranesp arm had increased significantly. A detailed analysis of causes of death remains to be conducted. However, it appeared that non-cancer-related deaths, including those linked to thromboembolic events, were not increased.

The text of the report appears on page 4.

Though Overgaard's report stated that the company would be informed about the disappointing results, the trial was not mentioned in Amgen's public disclosures or in a Jan. 25 conference call discussing Amgen's annual financial results, nearly two months after it was posted by Danish investigators.

"You know roughly as much about this as we," said Roy Baynes, Amgen vice president for oncology supportive care. "What's on this Web page is all we know at this point. This is a high hemoglobin study conducted by an independent cooperative group in Denmark. This is not our study."

Baynes said he couldn't remember when Amgen was first informed about the results. However, the company "communicated with the regulatory authorities within 24 hours of getting the information," he said.

Observers in oncology and on Wall Street said this decision not to announce the result is puzzling, particularly because in a May 2004 presentation before the FDA Oncologic Drugs Advisory Committee, Amgen highlighted the Danish trial as one of the five studies that would answer the efficacy question for Aranesp.

Commenting on Amgen's earnings call, Wall Street analysts noted that they were awaiting the results of the efficacy trials, specifically mentioning the Danish study. "If the outcome of these trials is negative… doctors could be more cautious about using EPO-stimulating drugs in cancer patients," a Merrill Lynch analyst explained in an update. Similarly, a Jan. 30 slide presentation by Bear Stearns listed the five efficacy trials as ongoing, presumably without realizing that one of those trials had been stopped three and a half months earlier.

Several Wall Street sources who monitor Amgen confirmed that they have been awaiting these results and were not aware of them until hearing about the closing of the trial from this reporter.

Amgen's Baynes said the company had no information to communicate to the financial community. "We have not seen the data," he said to The Cancer Letter. "We don't generally comment on third-party reports. We don't have any sense of how complete these data are, or what analyses on them have been done."

The fact that Amgen listed the Danish study in its 2004 ODAC presentation doesn't make it more significant than others, Baynes said.

"We listed it as a study that was ongoing," he said. "We made it very clear that it was an independent study, so it was not an Amgen study. In the meantime, there have been a lot of studies that have come out. We don't communicate each one of these out as they come in, whether they are positive, negative, or neutral."

Scientists and physicians who study EPO have been largely unaware of the Danish result. Michael Henke, a German oncologist who conducted a similar trial that raised concern about the Roche version of EPO in 2003, heard from a colleague that something was amiss with the Danish group's study, called DAHANCA 10.

"I found it by Google," said Henke, an oncologist at Klinik fuer Strahlenheilkunde in Freiburg, Germany.

Over the past four years, Henke has been advancing the hypothesis that EPO agents may stimulate disease progression by binding to EPO receptors that are known to exist on some tumors.

His hypothesis represents the worst possible

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

scenario for EPO drugs. "There is a biologic process going on: EPO will protect tumor from therapy," said Henke, who views the Danish study as confirmation of his results, which in part led to the ODAC hearing in 2004, and which are published in the Oct. 10, 2006, issue of the Journal of Clinical Oncology.

Henke hypothesizes that this effect would be observed across indications and would not be dependent on the hemoglobin targets.

According to Amgen's 2004 presentation before ODAC, the Danish study sought to raise hemoglobin to 15.5 g/dL. U.S. guidelines generally aim at the level of less than 13 g/dL, mostly out of concern that higher levels of hemoglobin may be associated with an increase in thromboembolic events.

"We know this in the case of head-and-neck cancer, because it's the only entity we have been looking at so closely so far," Henke said. "If it's really a cytoprotective effect, which is going through EPO receptors, it must happen at lower hemoglobin levels as well. Why wouldn't it?

"I think the time has come that people have to reconsider how to prescribe EPO to cancer patients," Henke said to The Cancer Letter.

Baynes said Amgen has been in contact with Overgaard, the Danish study's principal investigator, "to see how we can support getting the data in." Efforts by The Cancer Letter to reach Overgaard were unsuccessful. Overgaard is a scientist at the Department of Experimental Clinical Oncology of the Danish Cancer Society Aarhus University Hospital. He is a former president of the European Society for Therapeutic Radiology and Oncology.

Oncologists contacted by The Cancer Letter said the study warrants serious consideration.

"It looks like it's a well-designed study," said David Steensma, associate professor of medicine and oncology at Mayo Clinic and an expert on EPO, after this reporter guided him to the Web document. "It's well stratified, and at least at first blush, they are reporting that adverse events didn't seem to account for the poorer outcome in the [Aranesp] group, so it was just disease progression, which is concerning.

"There is an important set of questions about whether there really is a significant effect on cancer growth as a result of how the flow of blood changes within the tumor when changing the hemoglobin," Steensma said. "Hopefully, the study team will present this paper quickly in a broader forum, so we can scrutinize it more closely."

Steensma said the findings wouldn't immediately affect his practice, since he tries to keep his patients' hemoglobin around 11-12 g/dL, and does not aim for a higher level.

Charles Bennett, an oncologist at Northwestern University and an expert on adverse reactions to cancer drugs, said the Danish results suggest that target levels of hemoglobin could be irrelevant. "I just don't think it's a matter of 10, 11, or 12, or 13," Bennett said. "I think this is more of a tumor-related issue. I think the question from the scientific point of view is, do tumors really have EPO receptors? If they do, how many do? Is this, in fact, something we should be looking at before we treat patients with these drugs?"

Bennett is involved in developing the EPO use guidelines for the American Society of Clinical Oncology and the American Society of Hematology, and reviews EPO data as part of the Cochrane Collaboration, an international meta-analysis group.

Bennett first learned about the Danish results from a European colleague last week, he said. The finding is consistent with Henke's 2003 study in head and neck cancer and the Johnson & Johnson study that used Procrit, that company's version of EPO, beyond correction of anemia in breast cancer patients, Bennett said. The J&J study was stopped early, after demonstrating an adverse effect on survival (The Cancer Letter, Oct. 24, 2003).

In his announcement, Overgaard indicates that the Danish researchers intend to conduct immunohistochemistry analysis of the EPO receptor. In an analogous study, Henke analyzed the tumors of 154 patients, finding that 104 were positive for receptor expression. His study concluded that EPO "might adversely affect prognosis of head and neck cancer patients if cancer cells express erythropoietin receptors."

The results of the Danish study are "consistent with what we knew before this study, from the German study and the study in metastatic breast cancer, which showed that EPO is detrimental," said Scott Lippman, chairman thoracic/head and neck medical oncology at M.D. Anderson Cancer Center. "There haven't been any randomized trials prior to this one that would have suggested benefit. In the German study, the patients who were receptor-negative weren't harmed, but weren't benefited, either.

"Therefore, when we treat patients with curative intent, the vast majority of our group will not give EPO," Lippman said.

Howard Ozer, chief of hematology and oncology and Eson chair and professor of medicine at the

University of Oklahoma Cancer Center, said that while the design of earlier studies has been criticized, "the DAHANCA study is, from what I can tell, a well-constructed, well-stratified randomized trial that confirms some of the endpoints already identified by Henke," Ozer said. "That makes it especially important that, number one, the study be reported and presented; number two, that the scientific community pay close attention to the results; number three, that other confirmatory survival trials be done."

FDA and sponsors of EPO products should pay attention to this result, too, Ozer said. "Simply because we don't understand the biological mechanism that may be causing this effect doesn't allow us the luxury of ignoring a potentially harmful agent, and we must figure out what's going on," he said.

Last month, Amgen announced the results of a randomized study demonstrating that patients with cancer-induced anemia who were not receiving cancer therapy were more likely to die if they received Aranesp rather than placebo.

Also, the 1,000-patient trial, which set hemoglobin targets within parameters recommended by ASCO and ASH, failed to reduce the need for blood transfusions. The company announced these results in the Jan. 25 earnings call, and subsequently posted a "Dear-Doctor" letter on the FDA MedWatch adverse events reporting system.

In an interview at the time, Baynes said to The Cancer Letter that since the study wasn't designed to assess mortality, it may be impossible to determine the causes of death on the study (The Cancer Letter, Feb. 2).

Unlike the Danish trial, the study of Aranesp in cancer-related anemia wasn't highlighted by the company during its 2004 ODAC presentation, which appears on page 6.

Danish Group Finds Inferior Outcome On Aranesp Arm Of Head & Neck Cancer Study

The text of the Danish cooperative group's communication follows:

Study of the importance of Novel Erythropoiesis Stimulating Protein (Aranesp) for the effect of radiotherapy in patients with primary squamous cell carcinoma of the head and neck.

The background: The DAHANCA 10 trial was temporarily stopped on October 18 due to information about potential unexpected negative effects related to immunohistochemical estimation of the socalled EPO receptor.

As this happened almost simultaneously with the planned interim analysis it was decided to temporarily stop intake of protocol and await the outcome of the analysis before any further decision was taken.

This analysis has now been performed and discussed at the recent DAHANCA meeting on November 28, 2006.

The interim analysis: Prior to the analysis a patient chart review was performed in order to update the data, and in addition the data was run against the central person register in order to get complete survival information as per date (24 November).

This latter analysis revealed approximately 20 new deaths in patients with no known failures and the cause of these deaths needs to be explored, but they are in the current analysis considered to be non-cancer related. There is an equal distribution among such deaths in the two groups.

In total 522 patients have been randomized (of a planned intake of 600). Of these six were found to be non-eligible (two had simultaneous oesophagus cancer, two had too high haemoglobin, two withdrew consent after randomization but before completion of treatment). Of the remaining 516 32 were included after July 2006 and are therefore just about to complete treatment or in short follow-up. These patients were included from analysis due to lack of a sufficient follow-up time. The remaining 484 patients are included in the interim analysis.

The following description of the analysis will not in detail describe the events because there is still some additional modification to be done and we will therefore only preserve the overall conclusion and major observations.

The interim analysis has been performed based on intention to treat irrespective of whether the patients have completed the planned radiotherapy and drug treatment according to protocol.

The outcome: Among the 484 patients 158 have experienced a locoregional failure (the primary study endpoint). The planned interim analysis was supposed to after 150 failures, and the additional 8 have been found during the more detailed update we have performed.

There have been 196 deaths of which 140 are known to be of the cancer in question.

Overall, the patients have been evenly distributed according to the stratification parameters which also were found to be important and were all separating the material significantly except from the parameter of

larynx and pharynx site which yield almost the same outcome (the stratification parameters were gender, T and N classification, and tumour site). In addition the patients were stratified according to institution, and there was no difference in outcome as a function of this parameter.

The compliance to Aranesp has been good and by far most of patients have achieved the planned and expected increase in haemoglobin (this has not been part of the interim analysis, but this information was generated in connection with the London meeting, January 2006).

The treatment with Aranesp has not caused ecxess major serious adverse events and has been well tolerated by the patients included. Thus, there is no knowledge of excess side effects and there is no difference in the probability of dying without cancer as a function of randomization group.

Regarding the primary endpoint of locoregional failure there is a small but significant poor outcome in the patients treated with Aranesp. The 3-year actuarial value is in the order of a difference of 10% and with a p value of $p = 0.01$ which is also maintained in a multivariate analysis taking the stratification parameters into consideration.

When evaluating the endpoint of rall failure including failure in the T, N, and distant metastasis site there was a similar difference in the order of approximately 10% in disfavour of Aranesp and with a p value of 0.01.

A separate analysis of the distant failure in patients with distant metastasis alone showed exactly the same pattern in the two randomization groups indicating no excess in distant metastasis rate in patients without a prior locoregional failure.

The overall survival showed a smaller non-significant difference in disfavour of Aranesp ($p = 0.08$). A similar difference was found for the endpoint of disease-specific death whereas there was no difference at all in the death rate of patients dying from other causes not related to the cancer in question.

All univariate analyses were confirmed to be of the same magnitude in a multivariate setting.

The conclusion: Based on these outcome results the DAHANCA group concluded that the likelihood of a reverse outcome, i.e. that Aranesp would be significantly better than in control was almost non-existing even if we await a longer follow-up and additional inclusion of the remaining planned 78 patients. It was therefore decided that the trial should be terminated and futher inclusion stopped. This information will be communicated to the Ethical Committee, the Danish Drug Agency "Lægemiddelstyrelsen", to the involved departments and to Amgen.

In addition, the present report will be communicated to a task force which is evaluating the role of the use of erythropoietin in Denmark. They are planning an update of the recommendations and have been awaiting our preliminary results.

No further reports or detailed information will be disclosed until further analysis and evaluation of the still missing data have been collected.

The future: Based on the above-mentioned conclusions we are planning the following: Continue follow-up and update of information of the patients included in the trial. This includes exploration of cause of death in patients with this parameter being unknown and to collect the still remaining and missing data from a few patients. Furthermore, the follow-up will be continued and planned. The GCP study visits and evaluation will continue until all necessary information has been achieved.

The planned collection of biological material, including the collection of the paraffin blocks has been initiated and the immunohistochemistry analysis of the "EPO receptor" should be performed similar to what has been done in the German study. We are well aware of the problems related to the specificity of this analysis, but still feel that we should perform it similar to the German study irrespective of what it in fact may measure. In addition, we plan to explore more detailed into the possibilities of making a more exact estimate of the true receptor based on RNA expression from RNA fragments to be extracted from the paraffin blocks. We have access to a rather successful technique in that respect. With that purpose the blocks will be collected at the Clinical Trials Centre in Aarhus which will organize the further analysis.

Additional analysis of the compliance and response to Aranesp will also be performed as a part of an already planned Ph.D. study which is expected to start in April 2007. There is abundant material collected in association with the current study and we must expect that this analysis is going to take some time before the data are available.

The structure of the DAHANCA 10 study was in fact more elaborate than just the randomized trials because we also formed and registered patients with high haemoglobin. The analysis of this overall material will therefore also be an integrated part of the final evaluation of the study, especially in order to see whether this cohort of patients here in fact do have a poorer outcome

than similar patients with a higher haemoglobin.

The DAHANCA group has done a substantial work in trying to perform this trial which by far is the largest dealing with this specific question.

Obviously, we are disappointed with the apparent outcome, but this is indeed the reason why we are doing such clinical trials. We are a bit puzzled by the cause of the specific negative outcome and will on a scientific basis explore that as detailed as possible.

Aarhus, 1 December 2006
Jens Overgaard
Principal investigator
The DAHANCA 10 protocol

Amgen Noted Importance Of Danish Study At 2004 ODAC

On May 4, 2004, Amgen highlighted the five efficacy studies and its "pharmacovigilance program" at a meeting of the FDA Oncologic Drugs Advisory Committee. In this document, the DAHANCA 10 trial is identified as Trial SE-2002-9001. An excerpt from the company's presentation appears below:

Aranesp has had no detrimental effect on disease progression or overall survival in completed oncology placebo-controlled trials evaluating anemia outcomes.

In order to more rigorously evaluate relevant cancer endpoints such as tumor response, time to tumor progression, and survival, oncology studies are typically randomized, controlled trials in patient populations with a uniform tumor type, stage, and treatment history.

Treatment groups are balanced for important outcome predictors for specific malignancies. In addition, they contain prospective inclusion of survival as an endpoint; and adequate sample size, follow-up, and power to detect a clinically meaningful effect. Amgen has initiated one large oncology trial and is supporting investigators conducting additional trials as part of the ongoing Aranesp Pharmacovigilance Program.

Amgen believes that most studies designed to investigate anemia outcomes do not provide definitive information on tumor progression or survival endpoints. Amgen further does not believe that it is helpful to append survival outcomes to short chemotherapy-induced anemia studies that, although designed rigorously for hematologic and patient-reported outcome endpoints, do not contain essential design elements to allow conclusive assessment of cancer outcomes.

To more formally and prospectively address disease progression and survival endpoints in patients who are receiving Aranesp therapy, the Aranesp Pharmacovigilance Program includes 5 randomized, prospective clinical trials designed to evaluate specific cancer endpoints in a variety of malignancies. These clinical trials include both investigator-sponsored studies (FR-2003-3005, DE-2001-0033, DE-2002-0015, and SE-2002-9001) and an Amgen-sponsored study (20010145). The investigator-sponsored trials are open-label, randomized studies of Aranesp versus observation, and Amgen is collaborating with the investigators to support optimum study design, study conduct, and safety monitoring.

[T]he Amgen-sponsored study (20010145) is randomized, double-blind, and placebo-controlled. Endpoints include event-free survival, relapse, overall survival, and locoregional control in patients receiving combination chemotherapy for extensive small-cell lung cancer. The pharmacovigilance program includes large trials in patients with breast cancer and head-and-neck cancer (DE-2001-0033, DE-2002-0015, and SE-2002-9001), the 2 tumor types included in the INT-76 and ENHANCE trials. As Aranesp has received marketing approval for the treatment of chemotherapy-induced anemia in all non-myeloid malignancies, studies also were included in patients with small-cell lung cancer (20010145) and non-Hodgkin's lymphoma (FR-2003-3005).

These investigator-sponsored studies are being conducted in conjunction with data safety monitoring boards and interim safety analyses to ensure careful monitoring. One trial being conducted in patients with head-and-neck cancer receiving curative radiotherapy includes patients with hemoglobin concentrations up to 14.5 g/dL and has a hemoglobin target of 15.5 g/dL (SE-2002-9001). This trial has been the subject of a recent interim safety analysis, and the monitoring committee has recommended continuation of the trial as planned. All studies directly sponsored by Amgen are conducted in accord with the approved product labeling for both dosing and hemoglobin targets.

Three of the European trials (20010145, DE-2001-0033 and DE-2002-0015) use a target hemoglobin value of 14 g/dL, which corresponds to approved label upper limit for dosing in the European Aranesp Summary of Product Characteristics. Although this number differs from that outlined in the United States package insert (13 g/dL), it was also the target selected for pivotal trials 980297 and 20000161, studies that revealed no increase in tumor progression or survival in conjunction with Aranesp therapy.

Capitol Hill:

Bills Would Give FDA Authority To Approve "Biogenerics"

By Kirsten Boyd Goldberg

Identical bills introduced in the House and Senate Feb. 14 would give FDA the legal authority to approve generic versions of biotech drugs, which are produced from living cell cultures rather than synthesized chemically.

Currently, biotech drug manufacturers can charge monopoly prices indefinitely. The Access to Life-Saving Medicine Act of 2007 would create a clear regulatory pathway for generic versions of these drugs, sponsors of the legislation said.

"We learned 22 years ago that generic drug competition brings consumers affordable, safe, and effective medicines," Rep. Henry Waxman (D-Calif.), one of the bill's sponsors, said in a statement. "The time has come to apply this competition to biotech drugs. This bill will give FDA the clear legal authority to approve safe and effective copies of biotech drugs."

Generic drugs have saved patients and payers $10 billion a year, Waxman said.

Besides Waxman, original co-sponsors of the House bill are Reps. Jo Ann Emerson (R-Mo.), Frank Pallone Jr. (D-N.J.), and Rep. Rahm Emanuel (D-Ill.). In the Senate, the co-sponsors are Charles Schumer (D-N.Y.), Hillary Rodham Clinton (D-N.Y.), David Vitter (R-La.), Debbie Stabenow (D-Mich.), Patrick Leahy (D-Vt.), and Susan Collins (R-Me.).

"The bill gives complete discretion to the FDA to decide when it is scientifically appropriate to approve a copy of a biotech drug, and complete discretion to decide what studies are necessary before the FDA will approve it," Waxman said. "The drug industry has been telling people that the bill somehow requires the FDA to approve drugs without adequate evidence of safety or effectiveness. This is such a gross distortion of the bill, it is a good indicator of how desperate they are to avoid competition."

The text of the House bill is available at www.henrywaxman.house.gov/issues/health/generic_biologics.htm.

* * *

Senate Approves FY 2007 Funding: The Senate on Feb. 14 voted 81-15 to approve the $463.5 billion fiscal 2007 omnibus appropriations bill that includes a $619 million increase for NIH. The legislation funds federal agencies through Sept. 30. The House approved the bill last month.

In Brief:

AstraZeneca Gives $10 Million To ACS For Navigator Program

(Continued from page 1)

Advisors since 1999 and was recently appointed to the NCI Clinical Trials Advisory Committee.

Five ASCO members were elected to the Board of Directors: **Dean Bajorin**, of Memorial Sloan-Kettering Cancer Center, **Deborah Schrag**, of MSKCC and Weill-Cornell Medical College; **Kathleen Pritchard**, of Toronto-Sunnybrook Regional Cancer Centre; **Joel Tepper**, of University of North Carolina Chapel Hill; and **Robert Miller**, of Sacramento Center for Hematology and Medical Oncology Inc.

New members of the Nominating Committee are: **Karen Kelly**, of University of Kansas Cancer Center; and **Eric Small**, of University of California, San Francisco.

* * *

ASTRAZENECA said it will give $10 million to the American Cancer Society to support patient navigators in U.S. hospitals. The navigators are ACS employees in 60 hospitals who guide patients to support services, transportation, and financial assistance services. The gift will allow the program to expand to 50 more locations. The gift is the second-largest to ACS, which receives nearly $1 billion in gifts and grants each year. AstraZeneca, based in London, had sales of more than $26 billion last year. . . . **AMERICAN SOCIETY** for Therapeutic Radiology and Oncology added three staff members. **Shana Trege**, project manager for accreditation services at the American National Standards Institute, and **Jessica Sayer**, who managed the education program the National Association of Nurse Practitioners in Women's Health, were hired as education managers. **Christina Cleveland**, meetings coordinator for the American Geophysical Union, is meetings manager for ASTRO. . . . **"CARTOONISTS** Take Up Smoking," an exhibition of original newspaper editorial cartoons, can be viewed through March 31 at the National Museum of Health and Medicine at Walter Reed Army Medical Center in Washington, D.C. **Alan Blum**, founder and director of the University of Alabama Center for the Study of Tobacco and Society, prepared the materials from the center's archives, retracing the battle over cigarettes since the 1964 Surgeon General's report. "The assembled cartoonists' work rival any scalpel we have on display for their sharpness," museum director **Adrianne Noe** said. Museum information: www.nmhm.washingtondc.museum.

In the Cancer Centers:

Mayo, ASU Collaborate On A Cancer Vaccine

MAYO CLINIC and **ARIZONA STATE UNIVERSITY** are collaborating on a cancer prevention vaccine. Researchers at the Biodesign Institute at ASU in Tempe and Mayo Clinic will use developments in laboratory and clinical sciences to find components in cancer, such as protein signatures, that could be shared among different types of cancer and lead to broad protection from multiple tumors, said **Michael Tracy**, deputy director of the institute. The project is the first initiative under a partnership called the Mayo Clinic/ASU Center for Cancer-related Convergence, Cooperation and Collaboration. Mayo Clinic and ASU have invested seed funds to start the project. Research space has been allocated in a new facility on Mayo's Scottsdale campus, and more faculty are being hired to support this phase of the project. . . . **MEMORIAL SLOAN-KETTERING** announced appointments. **Maureen Killackey**, of St. Luke's–Roosevelt Hospital Center and the Bassett Healthcare System in upstate New York, was named deputy physician-in-chief and medical director of the MSKCC Regional Care Network. Killackey also was appointed attending surgeon on the gynecology service. She is a member of the New York State Ovarian Cancer Advisory Panel and the NYS Breast and Cervical Cancer Detection and Education Program. **Alexandra Joyner**, a mouse molecular geneticist, was appointed member in the developmental biology program and named incumbent of the Courtney Steel Chair in Pediatric Cancer Research. Also, **W. Douglas Wong**, chief of the colorectal service in the Department of Surgery and incumbent of the Stuart H.Q. Quan Chair in Colorectal Surgery, was named president-elect of the American Society of Colon and Rectal Surgeons. . . . **WILLIAM FRENCH ANDERSON**, the world-renowned pioneer in gene therapy, was sentenced Feb. 2 to 14 years in prison for sexually abusing the daughter of a researcher at his lab at University of Southern California. Anderson had faced a maximum sentence of 18 years for his conviction on four counts of continuous sexual abuse and lewd acts toward a child younger than 14. He was also ordered to pay $52,000 in restitution to the victim and $16,000 to the state. Anderson resigned in September 2006 from USC, where he had worked since leaving NIH in 1992. Anderson achieved prominence in 1990, when he and two colleagues implanted a healthy gene to correct a child's defective immune system.

Funding Opportunities:

MSKCC Seeks Nominations For Paul Marks Prize

Memorial Sloan-Kettering Cancer Center invites nominations for the Paul Marks Prize for Cancer Research.

Established in 2001, the annual prize recognizes a maximum of three young investigators under the age of 45 working in basic or clinical cancer research. The winners will present their work at MSKCC and will share a cash award of $150,000. Nominations deadline is April 30.

Nomination packets must include a letter from the nominator outlining the accomplishments for which the candidate should be recognized. This should be accompanied by a one-page scientific biography of the candidate, a list of up to eight published papers with a brief--fewer than 100 words--explanation of the importance of each one, a curriculum vitae, and up to three supporting letters. For more information: http://www.mskcc.org/marksprize.

E-mail nominations to: marksprize@mskcc.org. or mail to: Paizhe Pressley, executive assistant, Office of the President, Memorial Sloan-Kettering Cancer Center, 1275 York Ave., NY, NY 10021.

NIH Funding Opportunities

RFA-CA-07-505: American College of Radiology Imaging Network. Limited Competition U01. Letters of Intent Receipt Date: March 10; Application Receipt Date: April 10. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-505.html. Inquiries: Barbara Galen, 301-594-5225; bgalen@mail.nih.gov.

RFA-CA-07-046: Lung Cancer and Inflammation. R01. Letters of Intent Receipt Date: March 23; Application Receipt Date: April 23. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-CA-07-046.html. Inquiries: R. Allan Mufson, 301-496-7815; mufsonr@mail.nih.gov.

PAR-07-214: Academic-Industrial Partnerships for Development and Validation of In Vivo Imaging Systems and Methods for Cancer Investigations. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-07-214.html. Inquiries: Guoying Liu, 301-496-9531; guoyingl@mail.nih.gov.

RFP N02-CP-71002-50: Interdisciplinary Studies of Occupational and Environmental Cancer. Response Due Date: April 2. Full text: http://www.fbodaily.com/archive/2007/02-February/08-Feb-2007/FBO-01226423.htm. RFP may be accessed through the NCI Office of Acquisition Web site: http://rcb.cancer.gov/rcb-internet. Inquiries: Karen McFarlane, 301-435-3782, km63k@nih.gov. or Sharon Miller, 301-435-3783, sm103r@nih.gov.

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