THE CANCER LETTER INTERACTIVE

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Interim Analysis Of Phase III Data Preferable For Accelerated Approval, FDA's Pazdur Says

Recent FDA approval of oxaliplatin for second-line treatment of advanced colorectal cancer represents a new approach to accelerated approval, a regulatory mechanism designed to speed up the drugs' entry on the market, FDA officials say.

Usually, drugs receive accelerated approval based on large, single-arm phase II studies that aim to demonstrate that a "surrogate endpoint," such as tumor shrinkage or delayed time to progression of the disease.

Accelerated approval is upgraded to full approval after the sponsor

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In Brief:

Richard Pestell To Lead Lombardi Center; NCCS Hires A Chief Operating Officer

RICHARD PESTELL was appointed director of the Lombardi Cancer Center at Georgetown University Medical Center in Washington, DC, effective Sept. 3. Pestell was chairman of the Division of Endocrine-Dependent Tumor Biology at Albert Einstein Cancer Center at Yeshiva University. He received his MD and PhD degrees from the University of Melbourne, Australia. "Dr. Pestell brings an exceptionally accomplished scientific background, proven leadership skills, and a deep commitment to research, clinical and educational excellence," said J. Richard Gaintner, interim executive vice president of Georgetown University Medical Center. Pestell's plans for Lombardi include the establishment of an oncology-genetics program, enhanced capabilities in biochemistry and epidemiology, creation of a self-sustaining molecular pathology laboratory, enhancement of the biostatistics and bioinformatics capabilities, support for transgenic facilities, a new program in medicinal chemistry, and recruitment of additional senior faculty. . . . **WILLIAM SCHMIDT** was named chief operating officer of the National Coalition for Cancer Survivorship. Schmidt was vice president of public affairs for the Juvenile Diabetes Research Foundation International, where he directed government relations, communications, media relations, and foundation relations departments. "Bill knows Washington and the politics of patient advocacy from various vantage points as a former Hill staffer, as a lawyer and as government relations expert," said **Ellen Stovall**, president of NCCS. . . . **KAREN GRAHAM,** president and chairman of the William S. Graham Foundation for Melanoma Research of California, was elected president of the Oncology Nursing Society. She will serve until April 2004.

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Oxaliplatin Trial An Example Of FDA's Preferred Approach

(Continued from page 1)

conducts randomized trials to demonstrate benefit to patients. Benefits could include longer survival, a better quality of life, or some other tangible improvement.

Paris-based Sanofi-Synthelabo (NYSE: SNY; Euronext: SAN), oxaliplatin's sponsor, adopted a different strategy. The company sought accelerated approval, but instead of using the conventional approach and conducting a large, single-arm phase II registration study to measure tumor shrinkage or some other surrogate endpoint, the company enrolled 821 patients in a randomized three-arm trial powered to detect oxaliplatin's impact on survival.

To seek accelerated approval, the company used data from a preliminary analysis, which was planned to occur after the first 150 patients received 120 days of treatment on each of the trial's three arms.

Oxaliplatin, trade name Eloxatin, was given priority review by the agency and approved on Aug. 12, within 46 days of completion of the submission of the New Drug Application, setting a record. The previous record was set in the review of Gleevec, which was approved within 72 days of completion of the application.

Eloxatin was approved for use in combination with infusional 5-FU/LV in patients whose disease recurred during or within six months of completion of first-line therapy with the combination of bolus 5-FU/LV and irinotecan.

"We want to move the industry in this fashion away from single-arm trials," said Richard Pazdur, director of the FDA Division of Oncology Drug Products and an expert in colorectal cancer.

Following enactment of accelerated approval legislation, companies started to conduct larger phase registration II trials in order to make these preliminary results look more persuasive.

However, a phase II trial, no matter how bloated, can do only so much. "Large phase II trials that many sponsors are using are a perversion of clinical trials," Pazdur said in an interview. "They are done only for regulatory purposes. There are very few reasons to do large phase II clinical trials of 100 to 200 patients. Usually, single arm trials are exploratory trials to detect drug activity. In general, they should enroll no more than 50 patients."

The Sanofi strategy still allowed FDA to get the drug on the market sooner, but with better data. "This trial emphasized how much more you get out of a randomized trial that we would never get out of a single-arm trial," Pazdur said.

Observers and FDA insiders acknowledge that accelerated approvals based on phase II data are likely to continue, but they also yearn for the depth of information that only a randomized trial can provide.

Pazdur and the investigators running the trial credit Sanofi for its willingness to listen to experts and regulators and ultimately develop this strategy for seeking accelerated approval.

In part, Sanofi wanted to avert another disaster on the U.S. regulatory front. In March 2000, ODAC voted down its application for full approval of oxaliplatin for the front-line indication based on studies that didn't define survival as a primary endpoint (**The Cancer Letter**, March 24, 2000). The drug was first approved in France in 1996.

"Sanofi listened to the recommendations from ODAC, FDA, and the investigators in designing these trials," said Mace Rothenberg, Ingram associate professor of cancer research at Vanderbilt University and the principal investigator in the Sanofi registration trial. "This demonstrates what can happen when a company responds appropriately to an unfortunate outcome, and comes back with additional data that are clear, compelling and clinically significant."

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Implications for Drug Development

Altogether, 12 cancer drugs have been approved since the accelerated approval program began in 1995. All but two drugs were approved on the basis of response rates. None of these drugs were initially approved based on interim analysis of phase III studies. None has ever been taken off the market as a result of a sponsor's failure to fulfill post-approval commitments.

That's a problem, because once drugs are approved, it becomes increasingly difficult to randomize patients to other experimental therapies.

"Its better to do randomized studies up-front," Pazdur said. "It's not always possible to go back and answer additional questions in the same populations, and phase III trials allow us to learn as much as possible as quickly as possible."

As treatments are being approved for many cancers, researchers are, in effect, painting themselves into a corner. As indications fill up, sponsors are forced to look for opportunities to treat increasingly refractory patients.

"With most indications taken, companies have to address the needs of progressively refractory patients—third and fourth-line treatments," Pazdur said. "Alternatively, they are looking at artificial niche populations to convince the agency of unmet medical needs."

Having to test drugs in heavily pretreated patients is risky, and single-arm phase II trials are too crude a tool for this delicate job.

"One of my biggest concerns is that as we look at response rates in progressively refractory populations—which get smaller and smaller with every line of prior treatment—we may miss potentially useful drugs, and do more harm than good to development of cancer drugs," Pazdur said.

Though Eloxatin is a cytotoxic chemotherapy, the three-arm trial in which it's being tested may be relevant to design of trials for cytostatic agents, which arrest tumor growth, but have little or no efficacy on their own. The approach would also be useful for testing monoclonal antibodies, and the combinations of these novel agents with cytotoxic drugs.

One agent that could have benefited from this approach was C225, a monoclonal agent for the treatment of colorectal cancer. Last year, the agent's sponsor, ImClone Systems Inc., attempted unsuccessfully to use two phase II trials to male a case for accelerated approval of the two-drug combination of irinotecan and C225.

To make a persuasive case for the two-drug combination, the company had to demonstrate the contribution of each of the two drugs to the efficacy of the regimen. ImClone attempted to make its case with two separate phase II studies.

No Efficacy For Single Agent Eloxatin, Infusional 5-FU/LV

In the Sanofi pivotal trial, patients were randomized to three arms: infusional fluorouracil and leucovorin; Eloxatin as a single agent, and Eloxatin with infusional 5-FU/LV, a regimen also known as FOLFOX4.

Patients who received Eloxatin with infusional 5-FU/LV had the response rate of 9 percent, compared to 1 percent response rate for Eloxatin alone and no response for infusional 5-FU/LV.

The superiority of the Eloxatin plus FU/LV was statistically significant, with the p-value of 0.0002. Tumor response was assessed every six weeks, and confirmed responses had to be based on two tumor assessments separated by at least four weeks.

Time to progression documented by radiographs was 4.6 months for Eloxatin plus 5-FU/LV, 1.6 months for Eloxatin as a single agent, and 2.7 months for 5FU/LV.

The time to progression appeared to be clinically meaningful, Pazdur said. However, time to progression was a secondary endpoint, and analysis of this finding was hampered by the fact that not all scans could be collected.

The absence of radiographs is a common problem in studies that involve terminally ill patients, who routinely drop off the study or die. In this study, scans documenting disease progression were not available for 18 percent of patients, the label states.

"It's a 9 percent response rate in the context of a randomized trial, which gives you a highly persuasive p-value, which cannot be demonstrated in a single-arm trial," Pazdur said. "In addition, there was a statistically persuasive time to progression analysis."

Imperfect information on time to progression is still useful, Pazdur said. "A randomized trial gives us TTP information, which we cannot obtain through a single-arm trial," he said.

The trial's results are likely to tell oncologists a great deal about the way oxaliplatin should be used and influence the treatment of advanced colorectal cancer, Pazdur said.

"First of all, this trial told us that in this patient

population, oxaliplatin as a single agent basically is worthless to use," Pazdur said. "It demonstrated a possible synergy between infusional 5-FU and oxaliplatin. In addition, it told us that infusional 5-FU, which has been generally used by medical oncologists almost as an act of desperation in refractory patients, is basically useless. It had a zero percent response rate."

The protocol allows crossover by patients on the control arm—5-FU/LV—to the Eloxatin as a single agent arm at the time they showed progression of disease.

Since Eloxatin has not demonstrated response, this crossover will be unlikely to diminish the magnitude of survival advantage the study may demonstrate, Rothenberg said.

"At the time we designed the study, we had no comparative data on Eloxatin as a single agent and FOLFOX4," Rothenberg said. "This is the first comparison of these two therapies."

By the same token, until the Sanofi trial, no credible data demonstrated the need to combine Eloxatin with 5-FU/LV.

"This randomized trial confirmed the need for the use of 5-FU/LV with Eloxatin," Pazdur said. "This could not be demonstrated with a single-arm trial. This possible drug synergy is a unique observation in colon cancer trials."

New Standards For Gauging Toxicity

To interpret the Eloxatin application, the agency developed a new approach to analyzing central and peripheral neuropathy associated with the drug.

"Neuropathy associated with oxaliplatin is different from standard toxicity observed with cancer drugs," said Steven Hirschfeld, a medical reviewer at the FDA oncology division. "To evaluate toxicity in this case, the FDA review team had to devise a new approach to evaluating toxicity. Our approach is based on duration of neurologic symptoms rather than specific types of symptoms."

The label describes two kinds of neurotoxicity:

—"An acute, reversible primarily peripheral, sensory neuropathy that is of early onset, occurring within hours or one or two days of dosing, that resolves within 14 days, and that frequently recurs with further dosing." This neuropathy, characterized by sensitivity to cold, was observed in 56 percent of patients who received Eloxatin with infusional 5-FU/LV. In any individual cycle, acute neuropathy was observed in 30 percent of patients, the label states.

—"A persistent (over 14 days), primarily peripheral, sensory neuropathy… that can interfere with daily activities [including] writing, buttoning, swallowing and difficulty walking." These forms of neuropathy occurred in 48 percent of patients receiving Eloxatin with 5-FU/LV.

"These symptoms may improve in some patients upon discontinuation of Eloxatin," the label states.

"Since this was a randomized trial, we were able to compare toxicity profiles on the three arms, separating the toxicity of the new agent from the disease symptoms," Pazdur said. "This allowed us to determine the cost and benefits to the patient. For example, in this trial, we were able to see plainly that late-stage patients getting 5-FU/LV infusion were experiencing toxicity with no benefit."

When it's completed, the Sanofi pivotal trial will produce survival data and data on time to tumor symptom worsening, a measurement of pain, analgesic consumption and weight loss.

When the trial is completed, it would support full approval for the second line indication.

The company is also considering filing a supplemental NDA for the first-line indication, based on the results of the North Central Cancer Treatment Group trial N9741, which found a statistically significant survival advantage and a delay in time to disease progression in patients receiving Eloxatin with 5-FU/LV in first-line treatment of advanced colorectal cancer (**The Cancer Letter**, May 31). Other ongoing trials of Eloxatin include a supportive trial sponsored by the company, and two adjuvant trials.

"We will be able to place the results of this trial in the context of all available clinical information, including the extensive European data and N9741," Pazdur said.

Pesticides Not A Risk Factor For Long Island Breast Cancer, NCI-Funded Study Finds

Organochlorine compounds do not appear to be a major risk factor for breast cancer for women in Long Island, N.Y., according to an article published in the August issue of Cancer Epidemiology, Biomarkers & Prevention.

Another article in the same journal concludes that polycyclic aromatic hydrocarbons (PAH) are associated with a modest elevation in breast cancer risk for these women.

The two reports emerged from the Breast

Cancer and the Environment on Long Island Study, a main component of the Long Island Breast Cancer Study Project. The study was designed to determine if organochlorine compounds, such as pesticides like DDT, and PAH, a pollutant caused by incomplete combustion of various chemicals, are associated with an increased risk for breast cancer among women on Long Island.

The study was sponsored by NCI and the National Institute of Environmental Health Sciences and conducted by Marilie Gammon, of the University of North Carolina at Chapel Hill.

Study participants included 1,508 women living in Nassau and Suffolk counties who were newly diagnosed with breast cancer, and a similar number of women who did not have cancer, making this study the largest to date to examine the association between breast cancer and PAHs or organochlorines.

This study is one of more than 10 research studies that make up the LIBCSP. The LIBCSP was initiated in 1993 to investigate possible environmental causes of breast cancer in Suffolk, Nassau, and Schoharie counties in New York and in Tolland County, Conn. The project includes population studies, a family breast and ovarian cancer registry, laboratory research to better understand the development of breast cancer, and a geographic information system that allows researchers to explore theories about environmental risk factors.

Gammon and her collaborators are conducting additional research with the Long Island study population, data, and biological specimens.

The articles are available at http://cebp.aacrjournals.org/cgi/content/full/11/8/686 and http://cebp.aacrjournals.org/cgi/content/full/11/8/677.

Further information about the Long Island project is available at http://epi.grants.cancer.gov/LIBCSP.

In The States:

Mass. Passes Law Requiring Coverage of Patient Care Costs

Massachusetts Governor Jane Swift has signed legislation that requires health plans to cover routine patient care costs of cancer-related clinical studies conducted by Massachusetts providers.

The new law, Chapter 257 of the Acts of 2002, becomes effective Jan. 1, 2003.

Chapter 257 was the result of consensus language developed by the American Cancer Society, Dana-Farber Cancer Institute and the Massachusetts Association of Health Plans, led by Harvard Pilgrim Health Care, Tufts Health Plan and Neighborhood Health Plan.

The legislation was sponsored by State Senator Mark Montigny (D-New Bedford) and championed by House Speaker Thomas Finneran and Senate President Thomas Birmingham with the support of the chairs of the Joint Committee on Health Care, Senator Richard Moore (D-Uxbridge) and Rep. Harriet Stanley (D-West Newbury).

"Our legislative leaders took a bold step in providing patients with access to cancer-related clinical trials, and we are proud to have played a role in this process," said Marylou Buyse, president and CEO of the Massachusetts Association of Health Plans.

"Many Massachusetts health plans are already covering services provided to patients in cancer-related clinical trials and the state's health plans have been instrumental in making new technology and treatment regimens more available to patients," Buyse said. "Chapter 257 will ensure that all patients have access to cancer clinical trials and is consistent with the focus MAHP member plans place on improving members' health outcomes, care experience and well-being."

"This law will provide increased access to clinical trials for patients in the Commonwealth, without the burden of extensive costs to either patients or insurance companies," said Edward Benz, president of Dana-Farber Cancer Institute. "Clinical trials represent an outstanding opportunity for scientific advancements as well as the development of novel treatments for those suffering from cancer."

Funding Opportunities:

NCI/NASA Announcement

N01-CO-27042-32: Fundamental Technologies for Development of Biomolecular Sensors

The NCI/NASA Fundamental Technologies for the Development of Bimolecular Sensors Program is soliciting projects to develop the fundamental elements of technology systems or system components that will measure, analyze, and manipulate molecular processes at appropriate scale in the living body.

The discoveries from this program are intended to enable the development of complete systems for the in vivo sensing of signatures of pathologic cell types or closely associated micro environmental factors that provide a seamless interface between sensing/detection

and delivery of signature-specific intervention. This is the second solicitation issued in support of this program. In FY2002, the NCI and NASA awarded 13 contracts to initiate the program. Under this solicitation, the NCI and NASA each anticipate awarding an additional 10-14 contracts, grants, or cooperative agreements.

The BAA is available at: http://rcb.cancer.gov/rcb-internet/appl/rfp/27042/toc.pdf

Inquiries: Richard Hartmann, Contracting Officer, NCI, Research Contracts Branch, TBSS, 6120 Executive Boulevard MSC 7193, Bethesda, MD 20892-7193, phone: 301-496-8620, fax: 301-402-6699; email inquiries to: hartmari@mail.nih.gov

Specialized Center of Research 2003 in Leukemia, Lymphoma and Myeloma

Full application due: March 15, 2003

Preliminary Application (submitted via Web site)**:** Nov. 1, 2003.

Leukemia & Lymphoma Society has initiated a program for interdisciplinary research teams.

The proposed center must be composed of at least three relevant scientific projects capable of interacting. The research may be fundamental or applied or an integrated combination of the two approaches. Basic research tied to a related translational research project is encouraged but not mandatory. The center grant will also support scientific core laboratories required by the component research programs.

An application may be submitted by an individual holding a M.D., Ph.D., or equivalent degree, working in a domestic or foreign non-profit organizations, such as a university, college, hospital, institute or laboratory. Applications may be multi-institutional. Applicants need not be U.S. citizens, and there are no restrictions on applicant age, race, gender, or creed.

The maximal annual total cost of the center, direct and indirect, cannot exceed $1 million. The aggregate costs over five years cannot exceed $5 million. The direct costs, if justified by the aggregate budget may be up to $825 thousand per year. The indirect or institutional costs cannot exceed 21.2 percent of the direct costs per year.

Information is available at the L&LS Web site at: http://www.leukemia-lymphoma.org.

Inquiries: Director of Research Administration, Leukemia & Lymphoma Society, 1311 Mamaroneck Ave., White Plains, NY 10605, phone 914-821-8859; e-mail researchprograms@tlls.org.

Career Development Program 2003 Leukemia – Lymphoma – Myeloma

Deadlines for Career Development Awards: Scholarship, Special Fellowship and Fellowship: Preliminary (2 page) Application (*submitted via website*): Sept. 15.

Complete Application Due: Oct. 1.

Scholar Awards: $100,000 (stipend $95,000 + $5,000 institutional overhead) per year for five years. Investigators are expected to hold independent faculty-level or equivalent positions. The grant is not intended for the support of well-established, tenured or senior investigators. Researchers should have obtained substantial support for their research from a national agency.

Scholar in Clinical Research: $100,000 (stipend $95,000 + $5,000 institutional overhead) per year for five years. Preference given to applicants whose research involves the clinical trial of new or innovative applications. See above award for eligibility

Special Fellow: 50,000 (stipend $ 47,000 + $ 3,000 institutional overhead) per year for three years. Eligibility requirements include the following: qualified investigators who have completed a minimum of two years of postdoctoral research training at the time of review (January) and are continuing their research under the direction of a research sponsor.

Fellow: $40,000 (stipend $37,500 + $2,500 institutional overhead) per year for three years. Promising investigators with less than two years of postdoctoral research training at the time of review (January). Fellows are encouraged to embark on an academic career involving clinical or fundamental research in or related to leukemia, lymphoma and myeloma under the direction of a research Sponsor.

Inquiries: Director of Research Administration, Leukemia & Lymphoma Society, 1311 Mamaroneck Ave., White Plains, NY 10605, phone 914-821-8859; e-mail researchprograms@tlls.org.

Program Announcement

PAR-02-126: Specialized Programs of Research Excellence in Human Cancer for the Year 2003

Letter of Intent Receipt Dates: Skin and Ovarian Cancer SPOREs: Dec. 1, 2002; Lymphoma, Leukemia and Gastrointestinal Cancer SPOREs: April 1, 2003; Brain, Head and Neck Cancer SPOREs: Aug. 1, 2003.

Application Receipt Dates: Skin and Ovarian Cancer SPOREs: Feb. 1, 2003; Lymphoma, Leukemia and Gastrointestinal Cancer SPOREs: June 1, 2003; Brain, Head and Neck Cancer SPOREs: Oct. 1, 2003.

Organ Systems Branch of the Office of the Deputy Director for Extramural Science at NCI invites grant applications for Specialized Programs of Research Excellence in organ-specific cancers.

The PA is available at http://grants.nih.gov/grants/guide/pa-files/PAR-02-126.html.

Inquiries: Jorge Gomez, chief, Organ Systems Branch, e-mail jg1w@nih.gov; Jane Fountain, program director (Ovarian and Skin SPOREs), e-mail jf227t@nih.gov ; Peter Ujhazy, program director,(Leukemia, Lymphoma, Brain, Gastrointestinal, Head and Neck SPOREs), e-mail pu5s@nih.gov. Phone 301-496-8528; fax 301-402-5319.

In Brief:

ONS Elects Graham President; Two Elected To AACI Board

(Continued from page 1)

Lillian Nail, the Dr. May E. Rawlinson endowed professor of nursing and senior scientist at the Oregon Health & Science University School of Nursing in Portland OR, received the ONS 2002 Distinguished Researcher Award. . . . **ASSOCIATION OF AMERICAN CANCER INSTITUTES** has elected two new members to its 12-member board of directors. **Lucile Adams-Campbell**, director of the Howard University Cancer Center, Washington DC, and **John Glick**, director of the Abramson Cancer Center of the University of Pennsylvania, Philadelphia, will serve three-year terms. **F. Jay McKay**, vice president of Fox Chase Cancer Center, was appointed to a three-year term as secretary-treasurer. All terms begin Oct. 1, following the AACI 2002 Annual Meeting in Chicago, Sept. 26-27. . . . **AMERICAN SOCIETY** for Therapeutic Radiology and Oncology elected new officers for 2003: **Ted Lawrence**, chairman of radiation oncology at University of Michigan, is president-elect; **Peter Blitzer**, of Radiation Therapy Associates in Cape Coral, FL, community practice member-at-large; and **Colleen Lawton**, professor of radiation oncology at Medical College of Wisconsin, academic clinician member-at-large. New nominating committee members: **Sarah Donaldson**, professor of radiation oncology at Stanford University School of Medicine; and **Minesh Mehta**, professor and chairman of human oncology at University of Wisconsin, Madison. Terms will begin during the Astro 44th annual meeting in New Orleans, La., Oct. 6-10, 2002. The society also granted honorary memberships—the highest honor ASTRO awards to cancer researchers other than radiation oncology, radiation physics and radiobiology—to **Ann Barrett**, of the University of East Anglia and registrar and dean elect of the faculty of the Royal College of Radiologists, and **John Curry**, of the American College of Radiology. . . . **RICHARD PAYNE**, chief of pain and palliative care service at Memorial Sloan-Kettering Cancer Center, was voted president-elect of the American Pain Society. . . . **LOUIS WEINER**, chairman of Medical Oncology at Fox Chase Cancer Center, was appointed vice president for translational research. His responsibilities will include the stimulation of interactive grants, startup funding for translational research collaborations, developmental funds for ongoing translational research, and creation of an institutional forum for discussion and presentation of interactive research. Weiner will be responsible for monitoring the NCI-funded Specialized Program of Research Excellence and Center of Excellence programs. . . . **FADLO KHURI,** associate professor of medicine and chief, Section of Molecular Therapeutics and Chemoprevention, Department of Thoracic/Head and Neck Medical Oncology at University of Texas M.D. Anderson Cancer Center, has been named associate director for clinical and translational research at Winship Cancer Institute, Emory University. He will oversee the coordination of basic science research with clinical application throughout the WCI, said **Jonathan Simons**, WCI director. Khuri serves as the principal investigator for five NCI-funded clinical trials. . . . **WINSHIP CANCER INSTITUTE** researchers have been awarded a five-year, $1.2 million National Institute of Environmental Health Sciences collaborative grant to study cellular responses to environmental stress. The awardees are: **Paul Doetsch**, Emory Professor of Biochemistry and Radiation Oncology and principal investigator of the study; **Gerald Shadel**, assistant professor of biochemistry; **Wolfram Siede**, assistant professor of radiation oncology; **Bernard Weiss**, professor of pathology; and **Yoke Wah Kow**, professor of radiation oncology. The project is comprised of five collaborative research initiatives, each investigating a different aspect of DNA repair, damage tolerance, and damage prevention in response to exposures to radiation or chemical agents that can corrupt cellular DNA. . . . **ROSWELL PARK CANCER INSTITUTE** appointed two physicians to the Department of Surgery. **Todd Demmy**, chief of thoracic oncology, associate professor of surgery and co-director of the Cardiac Transplant Program at the University of Missouri Hospital and Clinics, will serve as chief of thoracic surgery division. **Boris Kuvshinoff II**, chief, Section of Hepatobiliary and Pancreas Tumors, Division of Surgical Oncology and interim chief in the Division of Surgical Oncology, Department of Surgery at the University of Missouri HealthCare, was appointed to the Division of Gastrointestinal Surgery. . . . **CORRECTION:** An item in the Aug. 2 issue of **The Cancer Letter** incorrectly reported the amount of the endowment provided by Texas to the Children's Cancer Research Center at the University of Texas Health Science Center at San Antonio. The amount is $200 million.

BARBARA ANN KARMANOS CANCER INSTITUTE
The Detroit Medical Center
Wayne State University

Director, Bone Marrow Transplant

Barbara Ann Karmanos Cancer Institute
In affiliation with Wayne State University and The Detroit Medical Center

The Karmanos Cancer Institute at Wayne State University seeks an outstanding Director for the combined Adult Pediatric Stem Cell Transplantation program. The Director will build on existing clinical and research base by introducing innovative translational research and clinical research, partner with other existing intra-mural research programs, and strengthen our position as an important resource for Michigan by improving community affiliations.

The Bone Marrow Transplant team performs approximately 150 transplants annually including myeloablative and non-myeloablative matched sibling donor, matched unrelated donor and autologous stem cell transplants. The program has a state of the art inpatient unit and stem cell processing lab as well as a leukapheresis unit, day treatment unit, outpatient clinic, and web enabled data management unit. It has an active telemedicine program and weekly video conferencing with other transplant units. The program is well funded with a recently established minority based cord blood bank that includes a GMP grade umbilical cord stem cell processing unit and bank. A GLP immunotherapy laboratory is in place and construction has begun on a GMP grade cell therapy center that will offer opportunities for research in hemopoietic stem cells, dendritic cells and lymphocytes.

Karmanos Cancer Institute is part of a NCI designated comprehensive cancer center serving more than 3 million people and one of 13 national SEER registries. With more than 7,000 new patients annually, $186 million operating budget, 1200 staff, and 50 facilities in southeastern Michigan, the Institute is a national leader in the prevention, early detection, and treatment of cancer.

Candidates should send letter of interest accompanied by curriculum vitae, brief statements of clinical/research vision and administrative philosophy, and contact information for three (3) references to:

John C. Ruckdeschel, M.D., President & CEO
Barbara Ann Karmanos Cancer Institute
110 East Warren Avenue
Detroit, MI, 48201
Attn: Amy Ryder

Wayne State University is a premier institution of higher education offering more than 350 academic programs through 14 schools and colleges to more than 31,000 students in metropolitan Detroit. Barbara Ann Karmanos Cancer Institute, The Detroit Medical Center and Wayne State University are equal opportunity/affirmative action employers. www.karmanos.org

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