THE CANCER LETTER INTERACTIVE

Vol. 29 No. 10
March 7, 2003

Price $305 Per Year

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

Abortion, Miscarriage Don't Increase Breast Cancer Risk, NCI Workshop Finds

Data from large epidemiologic studies demonstrate that abortions and miscarriages don't increase women's risk of developing breast cancer, an NCI-sponsored workshop concluded.

Last week, the Institute brought together about 100 experts to consider published studies as well as new, unpublished results probing the potential impact of pregnancy and its termination on breast cancer risk.

The absence of a link between abortion and breast cancer was so apparent that no debate about the issue was heard at the three-day

(Continued to page 2)

In Brief:

Slamon, Sherr Win Landon-AACR Prizes; Capecchi Wins Pezcoller Foundation Award

AMERICAN ASSOCIATION for Cancer Research announced its annual awards for 2003:

Dennis Slamon, director of the Revlon/UCLA Women's Cancer Research Program at the UCLA Jonsson Cancer Center, won the Dorothy P. Landon-AACR Prize for Translational Cancer Research, for development of the breast cancer drug Herceptin. The award is the largest prize offered to cancer researchers from a professional society of their peers, AACR said. Slamon will receive an unrestricted award of $200,000 and will present a scientific lecture at the AACR annual meeting next month in Toronto.

Charles Sherr, a Howard Hughes Medical Institute investigator based at the St. Jude Children's Hospital in Memphis, will receive the Kirk A. Landon-AACR Prize for Basic Research.

"The work of the two scientists underscores the importance of basic and translational research in accelerating progress against cancer and in bringing its benefits to patients, said **Margaret Foti,** CEO of AACR.

Mario Capecchi, University of Utah School of Medicine, received the 6th Pezcoller Foundation-AACR International Award for Cancer Research for discovery, development, and application of targeted mutagenesis in mouse embryonal stem cells.

Ronald DePinho, Dana-Farber Cancer Institute, was awarded the 43rd AACR-G.H.A. Clowes Memorial Award for basic research in the tumorigenic process.

Carlos Arteaga, Vanderbilt University School of Medicine, received

(Continued to page 7)

Click Here for Photocopying Guidelines

Updated Studies Still Find No Abortion-Cancer Link

(Continued from page 1)

conference. Instead, participants of the workshop Feb. 24-26 focused on studies of hormones present during pregnancy in humans and rodents.

The conference concluded that women who have their first child while still in their teens or early 20s have a lower lifetime risk of breast cancer, but for some years after pregnancy at any age, women are at a higher risk of the disease, said Leslie Bernstein, professor and senior associate dean at the University of Southern California Keck School of Medicine.

Some workshop participants suggested that it may be possible to help protect women from breast cancer by developing an intervention that mimics pregnancy, but far more research would be needed.

Bernstein presented the workshop conclusions at a March 3 meeting of the NCI Boards of Scientific Advisors and Scientific Counselors. The boards voted unanimously to accept the report.

The workshop findings are consistent with the NCI's "Abortion and Breast Cancer" fact sheet, which NCI Director Andrew von Eschenbach approved and then had removed from the Institute's Web site last year under pressure from members of Congress and antiabortion activists (**The Cancer Letter,** July 12, 2002).

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

World Wide Web: http://www.cancerletter.com

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

Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016
E-mail: news@cancerletter.com

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724
E-mail: info@cancerletter.com

Subscription $305 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc. Founded Dec. 21, 1973, by Jerry D. Boyd

Explaining his action to the advisory boards, von Eschenbach said that after receiving letters about the Web page, he started to worry about "potential conflicts and inconsistencies" in the available data. He decided to call the workshop to conduct a "state-of-the-science review," he said.

The Institute posted the workshop report on its Web site and said a new fact sheet is being written. The workshop report is available at http://www.cancer.gov/cancerinfo/ere-workshop-report.

Updated Studies: Still No Association

The current round of debate about the effect of abortion on breast cancer risk can be traced to a study by University of Washington epidemiologist Janet Daling, which found an increase in breast cancer risk among women who had had abortions. The study was published in the Journal of the National Cancer Institute (1994;86:1584).

Antiabortion groups acted aggressively on these findings.

Citing the Daling study and data from earlier studies, they lobbied states to change their informed-consent laws to include statements about the risk of breast cancer in the information that must be given to women considering abortion. Two states, Montana and Mississippi, passed laws requiring such changes in consent forms.

Antiabortion groups also paid for billboards in public transit systems of several cities, making proclamations about the alleged link between abortion and breast cancer.

Also responding to the Daling study, NCI developed a fact sheet stating that the data on abortion and breast cancer were inconsistent.

Then, a 1997 study by Mads Melbye, professor and head of epidemiology research at Statens Serum Institute in Copenhagen, laid the issue to rest, at least for most epidemiologists.

The Melbye study, using Danish health registries that included 1.5 million women and more than 10,000 cases of breast cancer, found no overall association between abortion and breast cancer. Since the study was so large and used medical records rather than women's self-reports, it was considered definitive.

Responding to Melbye's findings and three other studies, NCI epidemiologists early last year updated the Institute's fact sheet to state that "it appears that there is no overall association between spontaneous or induced abortion and breast cancer risk."

This was the Institute's strongest statement to

date on the issue.

Von Eschenbach approved the fact sheet last March. However, after HHS Secretary Tommy Thompson received a letter last June from Rep. Chris Smith (R-NJ) and 27 other members of Congress objecting to the fact sheet, von Eschenbach ordered the Web page taken down.

Von Eschenbach said to the advisory boards that "inconsistencies" in the Melbye study made him question the fact sheet's accuracy.

While the study found no overall statistically significant association between abortion and breast cancer, the study suggested that the risk of breast cancer increased with each week of gestation prior to abortion. Women whose abortion took place in the 18th week of pregnancy or later had an 85 percent increased risk of breast cancer.

"I recognized how important it was that we be absolutely precise and have absolutely the best scientific information," von Eschenbach said.

At the NCI workshop, Bernstein said that most of the studies that predated Melbye were not matched case-control studies, which means the results could have been confounded by many risk factors associated with breast cancer. Also, the results could have been biased by women's reluctance to reveal that they had had abortions.

Bernstein presented data from three other recent, large studies—the California Teachers Study, the Women's CARE Study, and a study of women under age 40—all of which found no association between breast cancer and abortion, no matter how long the duration of pregnancy. The study of women under the age of 40 is being published this month in the journal Cancer Epidemiology, Biomarkers and Prevention.

The workshop took the unusual step of closing a portion of the proceedings to the press so that scientists could consider the latest updates of studies. Reporters were allowed to listen to the findings if they signed statements promising not to publish the results.

"In the closed session, additional data were presented on duration of pregnancy at the time an induced abortion occurred," Bernstein said to the advisory boards. "In all of the new data that was presented, there was no impact at all on breast cancer risk associated with the duration of the pregnancy at the time that the abortion occurred. Some of the studies were based on recall, but there was also information presented in the closed session where it was determined from medical records, that, in fact, there was no effect."

Bernstein said new studies of the hormone hCG, which is present early in pregnancy, peaking at about eight weeks, provided some confirmation of an interesting epidemiologic finding in one of her first breast cancer studies. Bernstein found that women in Los Angeles who took part in a popular weight-loss regimen in the 1950s and 1960s, consisting of 42 shots of hCG, had a statistically significant decrease in the risk of breast cancer, unless they were morbidly obese.

"As a weight-loss regimen, it didn't work," she said. "But it did provide some protection from breast cancer. That is why I've always felt that, biologically, you wouldn't expect that a pregnancy that is progressing normally would increase a woman's risk of breast cancer" no matter how the pregnancy terminates.

At the workshop, antiabortion activist Joel Brind, an endocrinologist at Baruch College of the City University of New York, sought to defend the early studies that Bernstein said lacked clear reference groups. However, each time he spoke, other participants of the workshop rejected his analysis.

Brind's views on abortion and breast cancer were featured prominently in Rep. Smith's letter to HHS Secretary Thompson.

Six years ago, Brind testified as an expert witness for Christ's Bride Ministries, the organization that used billboards to claim that abortion increased breast cancer risk, in a suit against the Southeastern Pennsylvania Transportation Authority, which had pulled the ads after community protests. The Ministries won on free-speech grounds.

Breast cancer activists have questioned the NCI rationale for calling the workshop. Even if abortion did increase breast cancer risk, the effect was likely to be very small, compared to other risk factors, critics said.

"There doesn't seem to be a compelling scientific reason for NCI to do this at this time," said Jan Platner, of the National Breast Cancer Coalition. "There are many other issues that need to be dealt with. It does not seem to be a good use of resources."

A feminist group said it viewed NCI's actions as an attempt by the Bush Administration to impose a conservative ideology on science.

"The scientific, medical, and women's rights communities must continue to draw attention to the Bush Administration's stealth mission to undermine

the integrity of the scientific process by conservatively stacking various scientific panels and committees as a political payback to religious fundamentalists," said Beth Jordan, medical director of the Feminist Majority Foundation.

Early Pregnancy Associated With Lower Risk

The workshop ranked the following epidemiologic findings as having a "strength of evidence rating" of 1, meaning the findings are well established from human studies:

—Early age at first term birth is related to lifetime decrease in breast cancer risk.

—Increasing parity is associated with a long-term risk reduction, even when controlling for age at first birth.

—The additional long-term protective effect of young age at subsequent term pregnancies is not as strong as for the first term pregnancy.

—A nulliparous woman has approximately the same risk as a woman with a first term birth around age 30.

—Breast cancer risk is transiently increased after a term pregnancy.

—Induced abortion is not associated with an increase in breast cancer risk.

—Recognized spontaneous abortion is not associated with an increase in breast cancer risk.

—Long duration of lactation provides a small additional reduction in breast cancer risk after consideration of age at and number of term pregnancies.

Listed as a 2, where the weight of the evidence favors the statement:

—Pregnancy-induced hypertension is associated with decreased breast cancer risk.

Listed as a 3, suggested from human studies, but speculative:

—Maternal DEC exposure is associated with an increase in breast cancer risk.

Research Gaps

The workshop identified the following gaps in epidemiology research:

—By what mechanism does pregnancy at an early age protect against breast cancer?

—Do pregnancy and age at pregnancy modify radiation-inducted breast cancer risk?

—What are the effects of age at pregnancy on subgroups of women (e.g., those with BRCA-1 and 2 mutations)?

—What is the mechanism by which lactation affects breast cancer risk?

—What is the temporal pattern of breast cancer risk following lactation?

—What is the effect of lactation on women with BRCA-1 and 2 mutations?

—Does gender of offspring have an effect?

—Does birth weight of offspring have an effect?

—What is the impact of multiple births in the same pregnancy with and without assisted reproductive technology?

—What are the breast cancer risk implications of abnormal pregnancies (e.g., spina bifida, late fetal death, fertility treatment-induced pregnancy, preterm delivery, small for gestational age offspring)?

—What is the mechanism by which pre-eclampsia reduces breast cancer risk?

—Is there a distinction between hypertension and pre-eclampsia with respect to breast cancer risk?

—Is gestational diabetes associated with breast cancer risk?

Clinical findings and their ratings were:

—There are long-lasting decreases in mammographic density following pregnancy (2).

—There may be changes in breast histology that can be correlated with risk in premenopausal women (3).

—Prolactin, estradiol, and IGF-1 are decreased after pregnancy (3).

Animal model findings and their ratings were:

—Pregnancy protects against subsequent chemical carcinogen-induced breast cancer in rats and mice (1).

—Estrogen and progesterone combinations and hCG protect against carcinogen-induced cancer in rodents by mimicking pregnancy (1).

—Short-term estrogen exposure, at levels of estrogen mimicking pregnancy, is protective for carcinogen-induced cancer in rats (1).

Future research directions:

—Develop additional animal and treatment models, including further examination of existing models.

—Examine the molecular mechanisms of hormone-induced protection, including epithelial/stromal interactions.

—Integrate the methodology of genomics and proteomics into the study of pregnancy in relation to

risk of breast cancer.

—Pursue descriptive studies about human breast development in order to formulate new hypotheses.

—Pursue international studies to develop hypotheses for observed international differences in breast cancer risk.

—Develop surrogate markers to identify risk of breast cancer following pregnancy.

—Translate knowledge about protective effects of pregnancy into intervention trials with human populations.

—Promote interaction between epidemiologists, clinicians, and basic scientists.

—Consider a funding mechanism aimed at interdisciplinary research concerning pregnancy and breast cancer.

—Develop high-throughput technology for hormone measurement.

—Support the collecting, archiving, and sharing of relevant biospecimens.

ImClone News:

Samuel Waksal Pleads Guilty To Tax Evasion On $15M In Art

Samuel Waksal, the former president and CEO of ImClone Systems Inc., earlier this week pled guilty to criminal charges of wire fraud and conspiracy to commit fraud stemming from an effort to evade New York sales taxes on more than $15 million in modern art.

Though gallery invoices for the paintings indicated that the paintings would be delivered to the ImClone manufacturing plant at 22 Chubb Way in Sommerville, NJ, the paintings were either delivered directly to Waksal's SoHo loft, or made a brief layover in New Jersey.

The purchasing price of the paintings was $15.31 million. The New York city and state sales tax of 8.25 percent would have added about $1.26 million. At least technically, having pled to the two charges on March 3, Waksal could face an additional 10 years in prison and sizable fines.

Last October, Waksal pled guilty to seven charges of securities fraud, conspiracy, obstruction of justice, perjury, and bank fraud. Law enforcement officials said the remaining six charges involving stock transactions by members of Waksal's family are likely to be dropped.

Law enforcement officials said Waksal has been cooperating with prosecutors, and is likely to face five to eight years of imprisonment.

The paintings included "Untitled (Plum and Brown)," by Mark Rothko, purchased for $3.5 million; "Study from Human Body," by Francis Bacon ($3 million); "Mahoning II," by Franz Kline ($3 million); "Untitled V," by Willem De Kooning ($2.4 million); "Landscape with Seated Figure," by Roy Lichtenstein ($900,000) and "Solar Barge of Sesostris," by Cy Twombly ($800,000).

Waksal resigned from ImClone last May.

In a separate development, Bristol-Myers Squibb Co. gave ImClone $60 million. The payment was due in accordance with a March 2002 agreement for commercialization of the agent Erbitux.

Bristol agreed to make this payment on the one-year anniversary of the signing of the amended agreement.

"The $60 million payment is representative of the companies' strong collaborative working relationship and our mutual commitment to move the Erbitux program forward," Harlan Waksal, ImClone president, said in a statement. "Together we have developed and implemented a clinical development strategy for Erbitux that will explore the drug's potential in a variety of tumor types, the first of which is colorectal cancer."

The companies recently started an expanded access program that provides Erbitux to colorectal cancer patients who exhausted all treatment options and do not meet the criteria for clinical trials.

Professional Societies:

ASCO Supports Increase In Federal Tobacco Tax

The American Society of Clinical Oncology said earlier this week that it "strongly supports" the Interagency Committee on Smoking and Health report, which outlines a multi-faceted approach to address the public health crisis caused by tobacco.

The ICSH report was produced by the Subcommittee on Cessation of the Department of Health and Human Services, chaired by Michael Fiore, and submitted to HHS Secretary Tommy Thompson earlier this month.

Following is the text of ASCO's statement:

Two key proposals in the ICSH report are crucial: a substantial increase in the federal tobacco excise tax and the integration of smoking cessation into basic insurance coverage. Studies suggest that

increasing excise taxes may be the most effective means of deterring adolescents and teens from beginning to smoke, as well as encouraging existing smokers to reduce consumption or quit smoking. ASCO has long supported increases in the federal tobacco tax. The ICSH report's proposals to boost the federal excise tax and to commit the resulting revenues to fund its proposed initiatives are critical to reducing America's tobacco use.

We are encouraged that the ICSH report recommends that smoking cessation coverage be included in all federal health programs, including Medicare and Medicaid. Federal coverage standards often lead practice in the private sector, so this proposal could benefit not only those enrolled in federal coverage programs but also those who have private insurance.

ASCO urges that smoking cessation programs include several features that will increase their effectiveness in helping individuals quit smoking and in reducing the burden of tobacco addiction. Smoking cessation coverage should be extended to include multiple attempts to quit because the evidence suggests that those who successfully stop smoking often do so only after multiple attempts. We also recommend that smoking cessation programs include appropriate reimbursement for counseling by health care professionals, as availability of counseling has a significant impact on the success of smoking cessation programs.

ASCO commends the ICSH report and believes that implementation of the key recommendations in the report has the potential to reduce tobacco use and decrease its burden on our nation.

National Academies:

"Grand Challenges" Outlined For Chemists In New Report

Research in the chemical sciences must remain ambitious if the U.S. is to maintain its scientific and technological leadership during this century, a new report from the National Academies' National Research Council said this week.

The field must attract the very best minds, which means recruiting more women and minorities and revising undergraduate and high school curriculums to make chemistry more appealing to students with a variety of interests.

Also, undergraduate chemistry majors need more hands-on research experience, the report says. The method by which graduate chemistry and chemical-engineering students are trained must reflect the fact that they will be working alongside scientists from other disciplines throughout their careers.

Strong financial support from the federal government also will be needed, the report said. Industry can assist by offering fellowships for doctoral students in the chemical sciences and chemical engineering, the report said.

These steps can help chemists and chemical engineers meet 13 "grand challenges" for the 21st century, which are outlined in the report.

The challenges seek to stimulate advances that would benefit society in various ways, from finding cleaner energy sources, to curing diseases.

NCI was among the sponsors of the study.

Copies of the report, "Beyond The Molecular Frontier: Challenges for Chemistry and Chemical Engineering," are available from the National Academies Press, phone 202-334-3313 or 800-624-6242 or online at www.nap.edu.

Funding Opportunities:

NCI RAND Program

NOT-CA-03-009: Rapid Access to NCI Discovery Resource

Application Receipt Dates: April 1 and Oct. 1, annually.

Letter of Interest Receipt Date: Submitted via e-mail 30 days prior to application deadline.

The RAND program will make available contract resources of the NCI Developmental Therapeutics Program. The goal of RAND is to remove common barriers between basic research findings and their exploitation for discovery of new molecular entities. RAND does not fund grants; applications to the program are requests for NCI drug discovery and development resources to conduct specific tasks the applicants themselves are unable to carry out in their efforts to translate basic research findings to the discovery of new drugs and biologics.

Examples of tasks that may be requested include: production/characterization of molecular target proteins; high-throughput screening assay development; natural product isolation/ characterization; synthesis of combinatorial libraries; computer modeling, early pharmacology and in vivo efficacy studies. For information on process and procedure of requests for RAND resources, visit the DTP web site http://dtp.nci.nih.gov/. The notice is

available at http://grants.nih.gov/grants/guide/notice-files/NOT-CA-03-009.html.

Inquiries: RAND, Office of Associate Director, Developmental Therapeutics Program, NCI, Executive Plaza North Bldg., Suite 8020, 6130 Executive Blvd., Rockville, MD 20852, phone 301-496-8720; fax 301-402-0831; e-mail RAND@dtpax2.ncifcrf.gov

In Brief:

AACR 2003 Awards Listed; Colorado Gets $10 Million Gift

(Continued from page 1)

the 27th AACR-Richard & Hinda Rosenthal Foundation Award for advances in the understanding and treatment of breast cancer.

Malcom Stevens, University of Nottingham, was given the 22nd AACR-Bruce F. Cain Memorial Award for contributions to antitumor drug discovery and development.

Martin Blaser, New York University School of Medicine, received the 12th AACR-American Cancer Society Award for Research Excellence in Cancer Epidemiology and Prevention for contributions to the prevention of gastric cancer through the control of infection with Helicobacter pylori.

David Alberts, University of Arizona Cancer Center, was recognized with the 8th AACR-Joseph H. Burchenal Clinical Cancer Research Award for contributions to cancer prevention in a wide range of fields.

Graham Colditz, Channing Laboratory, Harvard Medical School, was awarded the 8th AACR-DeWitt S. Goodman Memorial Lecture for work on aspects of diet, physical activity, and hormone replacement therapy that have contributed to the understanding of how these exposures may be targeted for cancer prevention.

Janet Rowley, University of Chicago Medical Center, was recognized with the 6th AACR-Women in Cancer Research Charlotte Friend Memorial Lecture for contributions to the field of cancer research and through leadership or by example, furthering the advancement of women in science.

* * *

UNIVERSITY OF COLORADO has received a $10 million gift from an anonymous CU alumni couple, said **James Shore**, chancellor of the University of Colorado Health Sciences Center. The center will use the money for breast cancer research programs and will establish three endowed chairs in prevention and control, clinical research and basic/translational research, as requested by the donors. The rest of the funding will be used for research space in buildings under construction and other cancer center needs. . . . **JENNIFER KATZ BERZOK**, deputy director, government relations, at the National Breast Cancer Coalition, is moving to the Biotechnology Industry Organization, to become director of federal government relations. She will work on FDA-related matters, including intellectual property, Hatch/Waxman, judiciary issues and Medicare and Medicaid coverage. . . . **VIRGINIA BORGES** joined the University of Colorado Breast Center. Borges was at Dana Farber Cancer Institute conducting research on dendritic cell-based vaccines. . . . **CHRIS TAKIMOTO** was named chief of staff at the Cancer Therapy and Research Center in San Antonio. He is an associate professor of medicine at the University of Texas Health Science Center at San Antonio. . . . **NATIONAL CHILDHOOD Cancer Foundation** is sponsoring head-shaving fundraising events in more than 85 cities during March. The events, called St Baldrick's, began in New York City four years ago when volunteers shaved their heads in return for financial pledges of support. "St. Baldrick's Day is redefining St. Patrick's Day," said **Kathleen Ruddy**, director of major gifts at the NCCF. The event raised more than $975,000 last year. . . . **J. STEVEN HART**, chairman and CEO of Williams and Jensen, a law and lobbying firm in Washington, DC, has joined the board of directors of the Alliance for Lung Cancer, Advocacy, Support and Education. ALCASE was founded in 1995 by **Peggy McCarthy**. Co-founders include **Paul Bunn**, president of the American Society of Clinical Oncology, and **Robert Ginsberg**, a thoracic surgeon. . . . **RUPRECHT-KARLS-UNIVERSITAET HEIDELBERG** received a five-year $500,000 Unrestricted Infectious Diseases Research grant from Bristol-Myers Squibb Co. for research investigating hepatitis C virus. **Ralf Bartenschlager**, head of the Department of Molecular Virology, University of Heidelberg, and an HCV replication researcher, will serve as principal investigator. The Unrestricted Infectious Diseases Grants Program, begun 26 years ago by BMS, is one of six such programs that support research in cancer, cardiovascular diseases, infectious diseases, metabolic diseases, neuroscience and nutrition. . . . **ROSALEEN PARSONS** was appointed chairman of the Diagnostic Imaging Department at Fox Chase

Cancer Center. She had been clinical director of the Diagnostic Imaging Department at FCCC since 1999. . . . **CITY OF HOPE CANCER CENTER** Beckman Research Institute has recruited four scientists to its cancer biology and transplant programs, said **Art Riggs**, president and CEO. **Defu Zeng**, senior research scientist from the Stanford University School of Medicine, has joined the islet cell transplantation team in the Department of Diabetes, Endocrinology and Metabolism. **Karen Aboody** has joined the Division of Hematology/Bone Marrow Transplantation. She was an instructor at Harvard Medical School and senior scientist with Layton BioScience, Sunnyvale, Calif. **Wei Wen** will work on how blood vessels regulate cancer tumor growth at City of Hope. She was post doctorate fellow at Children's Hospital, Harvard Medical School. **Qiang Lu** work in the area of stem cell and developmental biology. Lu, a neuroscientist, was a postdoctoral fellow at Harvard Medical School. . . . **V. CRAIG JORDAN** has received the Third George and Christine Sosnovsky Award in Cancer Therapy. He was recognized for his achievements in the medicinal chemistry of cancer diseases and for his accomplishments in the prevention, control and cure of cancers using chemotherapy, including gene and immunotherapy. Jordan, known for his research into tamoxifen for breast cancer, is the Diana, Princess of Wales Professor of Cancer Research, Professor of Molecular Pharmacology and Biological Chemistry and Director of the Lynn Sage Breast Cancer Research Program for the Robert H. Lurie Comprehensive Cancer Center of Northwestern University. . . . **LEONIDAS PLATANIAS** was appointed deputy director of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University. He joined Northwestern last year as professor of medicine in the Feinberg School of Medicine. In his new position, he oversees the Shared Resource Core Facilities, a network of 19 facilities that provide various support services for cancer center investigators. He also directs the cancer center development efforts to procure research grants. Also, Platanias chairs several search committees and supervises the recruitment of oncology faculty and researchers for the university. In 2002, Platanias was named the Jesse, Sara, Andrew, Abigail, Benjamin and Elizabeth Lurie Professor of Oncology, honoring the children of Northwestern University Trustee Ann Lurie and her late husband, Robert.

THE CANCER LETTER

Vol. 18 No. 2
February 2003

Business & Regulatory Report

Clinical Trials:

Phase I Trial To Test Blood Reconstitution Following High-Dose Chemotherapy

Gamida-Cell Ltd. of Boston and Jerusalem said it has begun enrollment in a phase I trial of StemEx for advanced stages of hematologic malignancies.

The objective of the trial is to assess safety and the rate and durability of hematopoietic reconstitution after high dose chemotherapy, the company said. Umbilical cord blood will be expanded using the Gamida-

(Continued to page 2)

Oncology Management:

NCCN Begins New Journal, Offers Guidelines, Analyses In Oncology

National Comprehensive Cancer Network of Rockledge, Penn., has begun a quarterly publication, The Journal of the National Comprehensive Cancer Network, which focuses on the NCCN Clinical Practice Guidelines in Oncology and offers guideline recommendations for cancer care.

The journal, published by Jones and Bartlett Publishers, will include analyses from the NCCN Oncology Outcomes Database and other national databases as well as articles, research findings, and commentaries across the spectrum of oncology practice.

"The NCCN is responding to the call to improve communication and enhance collaboration between academic and community oncologists," said William McGivney, CEO of NCCN. "JNCCN will serve as an important forum for the presentation of the NCCN guidelines and for discussion of issues that arise from their use by physicians, patients, managed care companies, and policymakers, as well as other groups."

The 2003 NCCN Clinical Practice Guidelines in Oncology, the Colon and Rectal Cancer Treatment Guidelines contain new treatment recommendations regarding the use of the recently approved agent, oxaliplatin, and of radiation therapy in stage II, III, and IV disease.

"The inclusion of the new agent, oxaliplatin, in the guidelines almost immediately following its FDA approval demonstrates the capacity for these guidelines to provide the most current information about the state-of-the-art to practicing oncologists," said Rodger Winn, chairman of the NCCN Guidelines Steering Committee.

The recommendations are as follows: Rectal Cancer: for patients with distant, unresectable, or multiple metastatic lesions, combination

(Continued to page 8)

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

Study To Evaluate Infusion Of Cord Blood Cells

(Continued from page 1)

Cell technology that stimulated stem cell expansion with minimal cell differentiation in pre-clinical studies.

Adults and children without a related bone marrow/stem cell match will be enrolled, the company said.

Principal investigators Elizabeth Shpall, Marcos de Lima and John McMannis at M. D. Anderson Cancer Center will conduct the trial, the company said.

The study will include 10 patients 55 years or younger receiving high-dose myeloablative chemotherapy for acute myelogenous leukemia, acute lymphoblastic leukemia, non-lymphoblastic leukemia, non-Hodgkin's lymphoma or Hodgkin's disease, the company said. The year-long study is designed to evaluate the safety and rate of immune reconstitution associated with the infusion of the cord blood cells, which have been expanded ex vivo in the presence of the Gamida-Cell proprietary compounds, which control differentiation.

* * *

Lorus Therapeutics Inc. (OTC BB: LORFF) of Toronto said it has expanded a clinical trial of its lead antisense drug, GTI-2040 for renal cell carcinoma to five oncology centers in the U.S.

Frank Torti, director of the Comprehensive Cancer Center at Wake Forest University School of Medicine, is conducting the study, the company said.

Additional investigators and institutions include: Ronald Bukowski, Cleveland Clinic Foundation, Walter Stadler, University of Chicago Medical Center; Nancy Lewis of Fox Chase Cancer Center; Bernard Poiesz of the State University of New York Health Science Center; and David Quinn of the Norris Comprehensive Cancer Center, University of Southern California, the company said.

GTI-2040 is being studied in combination with capecitabine for advanced renal cell carcinoma where chemotherapy has failed, the company said. Capecitabine is an oral anticancer treatment that has shown response rates for metastatic renal cell carcinoma. Walter Stadler, of the University of Chicago, developed the concept and design of the trial.

GTI-2040 targets the R2 component of ribonucleotide reductase, a malignant determinant that can cooperate with a variety of oncogenes, the company said. Preclinical animal models showed GTI-2040 to have efficacy in inhibition of tumor growth in animal tumor models of renal cell carcinoma, alone or in combination with other agents.

"While immunotherapies have been used with very limited success in a sub-set of patients, serious toxicity with these agents can preclude their therapeutic usefulness," said Stadler. "Based on promising preclinical findings, and excellent tolerability in phase I studies, GTI-2040 offers potential as a new therapy in the treatment of this cancer."

* * *

Zivena Inc. of Columbus, Ohio, said the phase I trial of Resmycin, doxorubicin HCl inhalation solution, has been extended to lung metastases from soft tissue sarcoma.

"At Yale we have seen tumor response with Resmycin in soft tissue sarcoma patients during the phase I trial, even in a patient who previously received doxorubicin by the intravenous route," said John Murren of Yale University Medical Center, one of centers in the trial. "We are able to deliver higher concentrations of the chemotherapy drug to the lung than those achieved with standard doses given by the traditional intravenous route, but without many of the toxicities, like bone marrow suppression and hair loss, he said.

Zivena said it has submitted a phase II combination trial for review by several institutions for advanced non-small cell lung cancer.

THE CANCER LETTER

Member, Newsletter and Electronic Publishers Association

World Wide Web: http://www.cancerletter.com

Business & Regulatory Report

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

Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016
E-mail: paul@cancerletter.com

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724

Business & Regulatory Report, a supplement to The Cancer Letter, is available separately for $185 per year. ISSN 1053-9611.

Deals & Collaborations:

Two Biotech Firms Plan To Merge: Dendreon, Corvas

Dendreon (Nasdaq: DNDN) of Seattle and **Corvas** (Nasdaq:CVAS) of San Diego have signed a merger agreement under which Dendreon will acquire Corvas.

Under the agreement, each share of Corvas common stock will be exchanged for a fixed ratio of 0.45 shares of Dendreon stock in a tax-free reorganization. Based on Dendreon's closing share price of $5.79 on Feb. 24, the transaction is valued at $72.9 million.

The acquisition, approved by the boards of directors of both companies, is subject to approval by the stockholders. Following the closing of the acquisition, and payment of existing Corvas convertible debt, Dendreon is expected to have approximately $110 million in cash. Dendreon stockholders will own 68.6% of the combined company and Corvas stockholders will own 31.4%.

The companies said the transaction is anticipated to close in the second quarter of 2003.

"This deal enables us to continue our intense efforts to bring Provenge, Dendreon's phase III investigational therapeutic vaccine for the treatment of prostate cancer, to those patients suffering from advanced androgen independent prostate cancer who have few, if any, alternatives for treatment," said Mitchell Gold, CEO of Dendreon, who will continue as CEO of the combined company.

"We have multiple future product opportunities in the field of serine proteases, including small molecule inhibitors, antibodies and promising protease activated pro-drugs," Gold said.

* * *

AnVil Inc. of Burlington, Mass., said it has entered into an agreement with the **National Cancer Institute** to analyze NCI lung tumor databases for data that can be used to discover gene markers for lung cancer, diagnostics, treatments and therapy.

Under the agreement, AnVil will study the NCI gene expression data to predict which genes may be associated with lung tumors or normal lung tissue, the company said. AnVil will provide NCI with information for research into cancer targets and therapies.

* * *

ARIAD Pharmaceuticals Inc. (Nasdaq: ARIA) of Cambridge, Mass., said it has entered into a non-exclusive agreement to license its proprietary Agrent cell-signaling regulation technology to **GPC Biotech AG** (Frankfurt Stock Exchange: GPC).

ARIAD will receive guaranteed license fees of $2 million, including $1 million upon signing, the company said. GPC Biotech will use the technology both in its internal drug discovery efforts and in partnerships with pharmaceutical and biotechnology companies.

Under the agreement, GPC Biotech will pay ARIAD a percentage of revenues it receives from its partnerships utilizing the LeadCode three-hybrid technology platform, the company said.

GPC Biotech will make development and commercialization milestone payments and royalty payments to ARIAD based on GPC products resulting from the use of the licensed ARIAD technology in the GPC internal drug discovery programs, the company said.

* * *

Ardais Corp. of Lexington, Mass., said it has entered into an agreement with **AstraZeneca** (NYSE:AZN) to license access to the Ardais library of research-quality human tissue samples for drug discovery programs.

Financial terms and other details were not disclosed, the company said.

"Access to high quality human tissue and, equally important, highly structured associated clinical information, is now an essential part of this process," said Jeff Hanke, vice president for cancer discovery at AstraZeneca R&D Boston. "This emerging approach is already reducing time and costs previously associated with the pursuit of targets into drug discovery in the absence of a true clinical link."

The Ardais Biomaterials and Information for Genomic Research System encompasses a biorepository of more than 140,000 research-quality tissue samples and associated clinical data representing a diversity of disease states, the company said. The samples are collected through the National Clinical Genomics Initiative, collaboration between Ardais and four U.S. medical centers.

Clinical genomics is a multi-disciplinary approach to correlate molecular changes, including differences in patterns of gene expression, with the characteristics of human disease, the company said.

Ardais is a privately-held clinical genomics company.

* * *

Beckman Coulter Inc. (NYSE:BEC) of

Fullerton, Calif., said it has entered into a reagent development and distribution agreement with **Cell Signaling Technologies Inc.**

Under the agreement, Beckman Coulter will distribute CST reagents and newly co-developed cell signaling reagents for use in flow cytometry, the company said. In addition, the companies will co-develop multiplex panels of activation-state specific antibodies to explore, define and monitor major regulatory circuits controlling cell growth, differentiation and cell death using flow cytometry.

"The analysis of signaling pathways is increasingly central to cancer research," said Michael Melnick, director of business and corporate development at CST. "By combining flow cytometry with high quality activation state-specific antibodies from CST, it is now possible to examine complex signaling cascades in cell lines, dissociated tissues, aspirates, or hematology specimens."

Within cells, signal transduction pathways coordinate many cell functions and cell-to-cell interactions, the company said. Flow cytometry studies cell-signaling pathways in complex cell populations. The technology allows simultaneous measurements of events within single cells and provides a tool for identification of multiple molecules participating in cell signaling pathways.

* * *

GeneSage of San Francisco said it is collaborating with **Infinitelnfo** on a genetic health information system platform for managed care, pharmaceutical and consumer organizations.

The GeneSage Rx Platform on genetically-related conditions, clinical testing and other features provides a standard framework for genomic medicine and health risk assessments, the company said.

The database catalogs up to 350 conditions with specific fact sheets covering the most common at two levels: one, designed for consumers or patients, and another for healthcare professionals.

The databases can be searched by a variety of methods, including life stage and condition type, the company said.

The platform can be customized and Private Labeled for healthcare service lines such as women's health, cancer, and other population or condition specific portals or online information services, the company said.

* * *

IDEC Pharmaceuticals Corp. (Nasdaq: IDPH) of San Diego filed a suit against **Corixa Corp.** and **GlaxoSmithKline**, claiming patent infringement in connection with Corixa's Bexxar product and its use in the treatment of B-cell non-Hodgkin's lymphomas.

The suit was filed in the federal district court in the Southern District of California.

The complaint alleges that Corixa's and GlaxoSmithKline's conduct since the Oncologic Drugs Advisory Committee's recommendation for approval of Bexxar constitutes, or will constitute, infringement of U.S. Patent No. RE 38,008. The complaint seeks monetary damages and injunctive relief.

The patent, which was recently issued by the Patent and Trademark Office, covers methods for the use of radiolabeled antibodies in the treatment of non-Hodgkin's lymphoma.

* * *

North American Scientific Inc. (Nasdaq:NASI) of Chatsworth, Calif., said its subsidiary, **Theseus Imaging,** has entered into a clinical trial agreement with NCI to co-develop its Hynic-Annexin V agent for imaging cell death.

The agreement allows for interchange between Theseus staff members and the Biomedical Imaging Program of NCI, the company said. In addition, the agreement provides for planning between the parties for clinical development of the Hynic-Annexin V agent for imaging cell death.

Theseus and NCI said they would submit their own investigational new drug application to FDA for clinical studies of the agent. Additionally, the BIP will sponsor clinical trials in oncology patients.

Trials conducted under the agreement would be discussed prior to implementation of clinical testing, the parties said. They would participate jointly in meetings with FDA concerning Hynic-Annexin V.

"We expect to sponsor the U.S.-based trial of Hynic-Annexin V in lung cancer patients and to develop additional trials in lung cancer and other malignancies such as breast cancer, gastrointestinal cancer, brain cancer, and lymphoma in cooperation with BIP," said Neil Steinmetz, vice president and medical director of Theseus.

* * *

Cell Pathways Inc. (Nasdaq:CLPA) of Horsham, Penn., said it has signed an agreement to merge with **OSI Pharmaceuticals** (Nasdaq:OSIP) in a $32 million stock-for-stock transaction.

OSI will exchange .0567 shares of OSI for every share of Cell Pathways upon closing of the

transaction, which is expected to occur by Spring 2003, the company said.

Based on the OSI most recent closing share price, this represents $0.80 per share, a 58 percent premium to the last closing price of Cell Pathways, the company said. OSI said it would provide a five-year contingent value right through which each share of Cell Pathways held by shareholders of record on the date of the merger closure may be eligible for an additional .040 share of OSI in the event of a filing of a new drug application for either of the Cell Pathways clinical candidates: Aptosyn (exisulind) or CP461.

"We believe our platform represents an innovative and credible approach to the discovery and development of pro-apoptotic anti-cancer drugs," said Colin Goddard, CEO of OSI. "We are convinced that the OSI financial resources and deep clinical and regulatory expertise provide the best vehicle to draw out the value we believe inherent in these assets."

CIBC World Markets served as the financial advisor to Cell Pathways on the transaction, the company said.

In a related development, OSI has entered into a research agreement with **Cold Spring Harbor Laboratory** to use the CSHL RNAi technology platform in its cancer drug discovery programs.

The technology allows scientists to turn off specific genes in cancer cells and measure the consequences on cancer cell growth and survival, the company said. The approach will allow OSI to validate targets for anti-cancer drug discovery.

"RNAi technology is a new assessment tool that we feel will result in cost and time savings for our target validation programs and will ultimately improve the quality of scientific information associated with these potential anti-cancer drug targets," said Neil Gibson, vice president, research, OSI Pharmaceuticals.

* * *

SpectRx Inc. (NASDAQ:SPRX) of Norcross, Ga., said it has a $1.4 million grant award from NCI to co-develop its biophotonic, non-invasive cervical cancer detection device.

The grant will be used to fund clinical trials necessary for FDA approval, the company said. The clinical trials are expected to begin within 90 days.

The device uses proprietary biophotonic technology to identify cancers and precancers painlessly and non-invasively by analyzing light reflected from the cervix, the company said. The device creates an image of the cervix that highlights the location and severity of disease. The technology distinguishes between normal and diseased tissue by detecting biochemical and morphological changes at the cellular level.

Unlike Pap or HPV tests, the SpectRx test does not require a tissue sample or laboratory analysis, and results are available immediately, the company said.

More than 1,000 women have been tested with prototypes of the detection devices, with results indicating improved results over conventional tests, the company said.

* * *

SomaLogic Inc. of Boulder, Colo., said it has entered into an agreement with NCI to develop aptamers for NCI-supplied proteins.

Under the agreement, NCI investigators will be able to use the aptamers in specific research applications, while SomaLogic will retain the right to use the aptamers on its proteomic arrays, the company said.

The SomaLogic technology is based on aptamers, single-stranded DNA molecules that can bind to target molecules with high affinity and specificity, the company said. The aptamers, however, are synthetic and highly robust oligonucleotides.

* * *

Theragenics Corp. (NYSE:TGX) of Buford, Ga., said it has acquired the U.S. I-125 prostate brachytherapy business of **BEBIG Isotopen-und Medizintechnik GmbH**, which is distributed by **Isotope Products Labs**., subsidiaries of publicly traded German company **Eckert & Ziegler AG**.

Theragenics said it has acquired the exclusive U.S. manufacturing and distribution rights to the IsoSeed iodine-based medical device for prostate cancer, complementing its TheraSeed palladium-103 product.

Through a preferred purchase agreement with BEBIG, Theragenics will market the I-125 product in the U.S. under its existing brand name, IsoSeed, the company said. Theragenics also acquired an automated production line, which will be used to establish I-125 manufacturing capabilities by early 2004 at its Buford, Ga., facility.

The agreement also allows BEBIG to distribute TheraSeed in Europe on a non-exclusive basis.

"The acquisition enables us to manufacture and distribute both major products in the field of prostate Brachytherapy," said M. Christine Jacobs, chairman, president and CEO of Theragenics.

Emerging Technologies:

Firm Recovers Genetic Info From Degraded DNA

Rubicon Genomics Inc. of Ann Arbor, Mich., said it has begun the OmniPlexn whole genome restoration that can recover genetic information from unusable genetic materials.

The proprietary in vitro method restores large amounts of genetic information from very small amounts of degraded DNA, which has applications in gene-based target discovery, drug development, diagnostics and forensics, the company said.

"The commercialization of the whole genome restoration for formalin-fixed pathology and other degraded samples opens the door to retrospective studies on a large fraction of the 300 million DNA samples that have been archived in unusable form at major research institutions and clinics over the last 100 years," said Fred Beyerlein, president and CEO of Rubicon Genomics.

"Everyone is aware of the fact that genetic materials from extinct animals and plants have been accidentally trapped in amber for millions of years," said Vladimir Makarov, co-founder and chief scientific officer of Rubicon. "When physicians and surgeons biopsy patient tissue for the pathologist to examine, they have also trapped DNA that is stable for tens or perhaps hundreds of years. Previously, the genetic information in these pathology samples was hidden to effective genetic analysis, because the chromosomes recovered from those samples have been broken into tens of millions of tiny, random pieces."

Although OmniPlex cannot physically reattach the tiny pieces of DNA in the correct order, it does enable computers, using information from the Human Genome Project, to reconstruct genetic information as originally present in the tissue, the company said.

Product Approvals & Applications:

FDA Grants Fast-Track Review To Drug For Oral Mucositis

Aesgen Inc. of Princeton, N.J., said FDA has granted Fast-Track designation to its investigational new drug, Aesgen-14 (AES-14) for oral mucositis associated with cancer chemotherapy.

Phase III trials are underway in the U.S. and overseas with AES-14 treatment during chemotherapy for breast cancer, the company said. Aesgen said it plans to submit a new drug application in 2003 under the Fast-Track designation.

"There are no approved treatments for chemotherapy induced mucositis and AES-14 could reduce the incidence and severity of this condition," said Edward Shinal, president and CEO of Aesgen, Inc.

Oral mucositis, inflammation of the moist tissue lining the mouth that ranges from redness to severe ulceration, is a common side effect of cancer treatment in 40 percent of patients receiving chemotherapy and radiation, the company said. The use of morphine or other narcotic analgesics are indicated when severe pain accompanies the mucositis.

Aesgen Inc. is a privately owned specialty pharmaceutical company founded in 1994 by the Mayo Foundation for Education and Research and aaiPharma (Nasdaq:AAII), and whose other major investors include Medical Innovation Partners, Noro-Moseley Partners, MOVA Pharmaceutical Corp., Waters Enterprises and The Wakefield Group.

* * *

Aphton Corp. (Nasdaq:APHT) of Miami said FDA has reviewed and granted Fast-Track designation for its G17DT (anti-gastrin) immunogen in combination with cisplatin and 5-FU for stage IV gastric cancer to improve overall survival.

Aphton is conducting one phase III and three phase II trials, the company said.

The anti-gastrin targeted therapy induces antibodies that bind to both gastrin 17 and gly-gastrin and remove them from circulation before they can bind to the cancer cell and initiate cell growth, the company said. Gastrin 17 and gly-gastrin are central growth factors, or the initiating signals, for cell growth, cell proliferation and metastasis in gastric system cancers.

Inhibiting gastrin not only inhibits cell growth, proliferation and metastasis directly, but also unblocks a central pathway leading to cell-apoptosis, the company said. The effect is amplified synergistically when the drug is given together with a chemotherapeutic drug.

* * *

Corixa Corp. (Nasdaq: CRXA) of Seattle, said that following the favorable opinion of the European Agency for the Evaluation of Medicinal Products, the European Commission has granted Orphan Medicinal Product designation for the company's product candidate, tositumomab and Iodine I 131 radiolabelled

tositumomab (Bexxar therapy), for the treatment of follicular lymphoma.

The OMP designation has been granted on the basis that: follicular lymphoma affects fewer than five in 10,000 persons in the European Community; the condition is serious and life-threatening; although satisfactory methods of treatment have been authorized in Europe, tositumomab and Iodine I 131 radiolabelled tositumomab may be of significant benefit to those affected by the condition.

The OMP designation will result in reduced Marketing Authorization application fees, free access to scientific advice from the European Agency for the Evaluation of Medicinal Products and other potential research and development incentives. Furthermore, if a product with OMP designation is the first to receive marketing authorization in Europe for its designated indication, the product will be entitled to 10-year market exclusivity, which means that a similar drug is prevented from receiving authorization for the same indication during this period.

Registered as Bexxar therapy in the U.S., tositumomab and Iodine I 131 radiolabelled tositumomab is currently under review by the U.S. Food and Drug Administration for approval in the US. Bexxar therapy received a favorable review from the FDA's Oncologic Drugs Advisory Committee in December 2002. The product is being jointly developed by Corixa Corp. and Amersham plc in Europe where it will be registered under a different trade name.

* * *

Mylan Laboratories Inc. (NYSE:MYL) of Pittsburgh said FDA has approved its abbreviated new drug application for Tamoxifen Citrate Tablets USP, 10 mg and 20 mg.

Tamoxifen Citrate is the generic version of the AstraZeneca Nolvadex, which is indicated for metastatic breast cancer, the company said. Mylan will manufacture the product in its Puerto Rico facility.

In a related development, **IVAX Corp.** (AMEX:IVX)(LSE:IVX.L) said it has received final FDA approval for its ANDA for tamoxifen citrate tablets in 10 mg and 20 mg strengths. IVAX market tamoxifen citrate through its wholly owned subsidiary, IVAX Pharmaceuticals Inc, the company said.

In another related development, **Teva Pharmaceutical Industries Ltd.** (Nasdaq:TEVA) of Jerusalem said FDA has approved the its ANDAs for Tamoxifen Citrate Tablets USP, 10 mg and 20 mg. Shipments will begin immediately.

* * *

Axcan Pharma Inc., of Mont Saint-Hilaire, Quebec, said FDA has granted an approval letter for Photofrin, photodynamic therapy for high-grade dysplasia associated with Barrett's esophagus.

PDT is a two-step process that begins with the intravenous injection of a non-toxic drug, which is absorbed by both normal and malignant cells. Two or three days later, Photofrin concentrates in cancer cells and is reduced in normal cells near many cancers.

Non-thermal red lights, which is generated by a laser, is applied to a tumor. The light activates the therapy causing activation of the oxygen in the tumor, which attacks and destroys the cancer cells.

The NDA filing was based on a 208-patient study conducted North America, the institute said. 138 patients in the omeprazole (an acid reducer) plus Photofrin PDT group and 70 patients in the omeprazole only group were followed for a minimum period of two-years (median 3.5-year). Esophageal cancer occurred in 13 percent of patients treated with Photofrin PDT, plus omeprazole, compared to 27 percent of patients treated with omeprazole alone, a 52 percent reduction that is highly statistically significant ($p>0.02$).

* * *

Targeted Diagnostics & Therapeutics Inc. of West Chester, Penn., said it has received regulatory approval to offer its blood test, GCC-B1, for recurrent colorectal cancer.

TDT has been certified under the Federal Clinical Laboratories Improvement Amendment of 1988 for high-complexity laboratory testing, the company said.

The GCC-B1 test finds metastatic colorectal cancer that is often missed by other methods, the company said. It can find one cancer cell in 10,000,000 normal cells by detecting the presence of guanylyl cyclase C (GC-C), which is found on metastatic colorectal cancer cells. Detection of this marker in the blood is indicative of recurrent metastatic colorectal disease. In ongoing clinical testing, the test has been shown to have as high as 100 percent sensitivity and 91 percent specificity, the company said.

"By adding GCC-B1 to monitoring protocols, physicians will have a powerful new tool to detect the presence of metastatic colorectal cancer cells," said Harry Arena, president and CEO of TDT. "This

could lead to much earlier detection of recurrent disease."

Under CLIA '88 certification, the GCC-B1 blood tests can be processed only in the TDT laboratories, the company said.

Oncology Management:
NCCN, Pharmacia Award $1.8 Million For Clinical Trials

(Continued from page 1)

chemotherapy with 5-FU/leucovorin/oxaliplatin is now included as one of several treatment options found to be effective as palliative therapy. For stage IV patients with distant resectable metastases, radiation therapy to the pelvic area should now be considered as a therapeutic option as adjuvant therapy after combination chemotherapy and resection of the metastases and the rectal lesion.

Colon Cancer: for patients with unresectable or multiple metastatic lesions, 5-FU/leucovorin/oxaliplatin is now included as one of several treatment options found to be effective as palliative therapy. For stage II and III patients, combination regimens including irinotecan, oxaliplatin, and capecitabine cannot be considered as standard adjuvant therapy at this time but may be administered in the context of a clinical trial. For stage II or stage III patients with localized perforation or with close, indeterminate, or positive margins, radiation therapy is recommended as part of a therapeutic adjuvant regimen. For stage IV patients with resectable liver metastases, 5-FU/leucovorin/oxaliplatin is now included as one of several treatment options that is effective as neoadjuvant or adjuvant therapy.

In another development, **NCCN** said it and **Pharmacia Corp**. awarded $1,886,237 in research grants to 19 cancer centers to support investigator-initiated trials through the NCCN Clinical Trials Network.

* * *

Matria Healthcare Inc. (NASDAQ:MATR) of Marietta, Ga, said its subsidiary, **Quality Oncology Inc.** has managed cancer costs for its client, **Blue Cross Blue Shield of Florida,** during the third quarter that ended in January 2002.

The health plan netted $444 in savings per cancer patient, the company said. Net savings for the plan in the aggregate exceeded $4.3 million for program year three.

"These are clearly impressive savings in the face of the mounting health care inflation that all health plans are witnessing today," said George Mayzell, corporate-wide director of disease management. "Our program has proven that dollars can be saved from the cancer treatment field without negatively impacting patient outcomes or satisfaction. The cancer program recorded a 4.04 score (on a 1-5 scale) on patient overall satisfaction with the program, according to an annual satisfaction survey that queried the program's beneficiaries."

BCBSF engaged QO in 1999 for a pilot program for 190,000 commercial and 57,000 Medicare-risk lives, the company said. In 2002, after observing satisfactory results for the first two years of the pilot, BCBSF expanded the program statewide. In program year three, the average cost per cancer case grew by 1.9 percent from program year two.

However, the average case cost remained 4.8 percent below the baseline average case cost per cancer patient of $9,329.

Since the inception of the program, the plan has experienced a double-digit annual increase in cancer prevalence due to membership growth and a predictable retention of members with cancer, the company said.

* * *

OnCure Technologies Corp. (OTCBB: ONCU) of Newport Beach, Calif., said it has entered into an agreement with **Ninth City Landowners**, a general partnership, to form a joint venture named **FROG OnCure Southside, LLC,** and has acquired the assets of the Southside Cancer Center of Jacksonville, Fla.

"The acquisition of Southside fits perfectly into our network model in the Jacksonville market, which now consists of six centers," said Jeffrey Goffman, president and CEO OnCure Technologies. "In addition, the Southside patient base affords us the opportunity to increase the utilization and returns of our IMRT investment at our Wells Complex Clinic."

* * *

University of California Los Angeles Medical Center said it has purchased radiation oncology solutions, including three state-of-the-art ONCOR Impression Linear Accelerators, from **Siemens Medical Solutions** of Malvern, Pa., and Erlangen, Germany.

Slated to be the first ONCOR installations in the U.S., the systems will be the core of the radiation oncology treatment program for the UCLA Jonsson Comprehensive Cancer Center, the center said.

Copying Policy for The Cancer Letter Interactive

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

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

What you can do:

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

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

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

What you can't do without prior permission:

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

--Routinely copy and distribute portions of the newsletter.

--Republish or repackage the contents of the newsletter.

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

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

Click Here for
Photocopying Guidelines