

Cancer Care:

**Better Access Key To Higher Survival  
For African-Americans With Colon Cancer**

African-Americans with colon cancer are more likely to die from the disease than are whites, but a new study has found that those survival rate disparities virtually disappear when both groups have equal access to chemotherapy after surgery.

Led by investigators at Dana-Farber Cancer Institute, the research team also discovered that African-Americans were less likely than whites to experience some chemotherapy side-effects, including diarrhea and nausea.

The study, published in the Aug. 7 issue of the Journal of the National  
(Continued to page 2)

Clinical Trials:

**NCI Grant Supports Jefferson Trial To Study  
Test To Diagnose Colorectal Cancer Spread**

Researchers at Jefferson Medical College and the Kimmel Cancer Center at Thomas Jefferson University in Philadelphia, buoyed by a five-year, \$5 million grant from the National Cancer Institute, are beginning a clinical trial to determine whether a simple test for the protein that causes traveler's diarrhea will help provide surgeons and oncologists with a more accurate picture of the extent of colorectal cancer in patients.

The scientists hope the test will enable them to determine whether or not cancer has spread from the colon to the lymph nodes, and at the same time, result in improved diagnoses and more appropriate treatment.

The work, led by Scott Waldman, director of the Division of Clinical Pharmacology at Jefferson Medical College, may ultimately result in a blood test that could tell patients whether their colorectal cancer thought cured has returned.

The test looks for evidence of a protein, guanylyl cyclase C, or GCC, which is expressed only by intestinal cells and colorectal cancer cells. Most colorectal cancers originate in the cells that line the intestine, cells that normally make GCC. When the cells become cancerous, they continue to make GCC.

"It's apparent that the further the progression of disease, the worse the prognosis of the patient," he said. If the disease is found outside of the intestine, for example, most patients are given chemotherapy.

But such a system is flawed because most pathologists examine only a thin slice of lymph node tissue, potentially missing a cancer. Also,  
(Continued to page 3)

© Copyright 2002  
The Cancer Letter Inc.  
All rights reserved.

Survivorship:

**Lung Cancer Survivors  
Claim Good QOL,  
Despite Challenges**  
... Page 4

Radiology:

**Acceptable Quality  
Found In Chest X-rays  
At Half Normal Dose**  
... Page 5

**Higher Radiation Doses  
Increase Cure Rate  
For Prostate Cancer,  
But Cause More  
Side Effects, Study Finds**  
... Page 5

Cancer Prevention:

**Workers Quit Smoking  
When Health Messages  
Combined In Program**  
... Page 6

**NCI-Approved Trials**  
... Page 8

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

## Better Access To Care Key To Survival For Blacks

(Continued from page 1)

Cancer Institute, provides new evidence that a lack of access to quality care, rather than an innate biological difference, is largely to blame for the generally lower survival rates of African-Americans with colon cancer, the authors say.

“Most researchers have suspected that the lower survival rate among African-Americans with colon cancer is due to variations in the availability of adequate medical care rather than any unique characteristics of their tumors,” said the study’s senior author, Charles Fuchs, of Dana-Farber. “This study indicates that when African-American and white patients receive the same basic treatment for the disease—surgery followed by chemotherapy—they fare equally well.”

Data for the study came from a clinical trial designed to measure the effectiveness of chemotherapy for colon cancer patients who had undergone surgery to remove cancerous portions of their colons.

Fuchs and his colleagues compared survival rates and the level of side effects in 344 African-American and 3,036 white patients enrolled in the trial. The patients all had cancer of the colon that was removed surgically within the prior six weeks. As part of the trial, all patients received six to eight

weeks of chemotherapy after surgery.

The investigators found no major differences in survival rates for the two groups five years after treatment. The African-American patients had a 65 percent overall survival rate compared to 66 percent for the white patients. Similarly, they had a 57 percent recurrence-free survival rate and the white patients had a 58 percent rate.

The data also showed that white patients were significantly more likely than African-American patients to experience chemotherapy-related side effects, including diarrhea, nausea, vomiting, and stomatitis.

The reasons for differences in chemotherapy-related side effects aren’t clear, but may have to do with undefined genetic differences between whites and African-Americans.

Although previous studies have found that African-Americans with colon cancer generally don’t survive as long as whites with the disease, the new study is one of the first to compare survival rates when the availability of quality care is equal for all patients. If African-Americans as a group have poorer access to such care, their tumors are less likely to be detected and treated at an early stage, when prospects for recovery are best.

“Our study shows the value of the National Cancer Institute’s efforts to increase African-Americans’ participation in clinical trials,” said the study’s first author, A. David McCollum, who conducted the research while he was at Dana-Farber and is now a practicing oncologist in Texas. “Increased enrollment by members of minority groups will ultimately lead to better care for people in traditionally underserved populations.”

Contributing to the study were investigators at the University of Pennsylvania Cancer Center, St. Vincent Clinical Cancer Center in New York City, and Northwestern University.

The study was funded in part by grants from NCI and Dana-Farber.

### Race Not A Factor In Response To Implants

In another recent study, researchers found that race is not an independent predictor of whether a patient with clinically localized prostate cancer will be cured using permanent radioactive implants.

The study, conducted at Memorial Sloan-Kettering at Mercy Medical Center in New York, compared the biochemical freedom from recurrence rates between African American and white American

### THE CLINICAL CANCER LETTER

Member,  
Newsletter and Electronic  
Publishers Association

World Wide Web: [http://  
www.cancerletter.com](http://www.cancerletter.com)

**Publisher:** Kirsten Boyd 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](mailto:news@cancerletter.com)

**Customer Service:** 800-513-7042

**PO Box 40724, Nashville TN 37204-0724**

THE CLINICAL CANCER LETTER (ISSN 164-985X). Published monthly, subscription \$99 per year, by The Cancer Letter Inc. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, mechanical, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties and \$100,000 damages.

males treated with permanent prostate brachytherapy.

Between September 1992 and September 1999, 1,089 patients, including 246 African Americans, underwent permanent prostate brachytherapy alone or in combination with external beam radiation therapy. To study whether race affected the outcome of the treatment, researchers performed Cox regression analysis and found that race was not an independent factor in predicting treatment failure.

Using a computer-generated matching of the entire patient cohort, two identical groups of white Americans and African Americans were compared to further identify whether a difference based on race could be determined. This matched pair analysis controlled for the use of neoadjuvant androgen ablation, the pretreatment prostate specific antigen levels and Gleason scores in each subset.

Once again, no difference in biochemical freedom from recurrence could be ascertained between the white American and African American cohorts at five years.

“While this paper does not address differences in the incidence of prostate cancer in the African American and white American community, the results indicate that when prognostic factors are evenly matched, race is not an independent factor in predicting biochemical freedom from disease following permanent prostate brachytherapy,” said Louis Potters, clinical director, Radiation Oncology, Memorial Sloan-Kettering at Mercy Medical Center in New York and lead author of the study.

“After reviewing the data, we found that 84 percent of the African American patients remained disease free after five years, compared to 81 percent of white Americans, without any significant difference between the two groups,” Potters said.

The study was published in the June issue of the *International Journal of Radiation Oncology, Biology and Physics*.

### Clinical Trials:

## **Trial Seeks To Test New Method For Diagnosing Colon Cancer**

(Continued from page 1)

such a test lacks sensitivity, relying on a pathologist's eye to see colon cancer cells in a field of cells on a slide.

“There's clearly a problem with that system because about 20 percent of patients thought to have disease confined to the bowel show up with recurrent

disease and ultimately die of the returning disease,” Waldman said. “There's thought to be micrometastases that have escaped histopathological detection.”

Waldman uses RT-PCR analysis to magnify the presence of cancer cells, and couples it with GCC, which he hopes will be a very specific marker for cancer. “Then you can take a lymph node and use the amplification technique to amplify the signal for cancer,” he said.

GCC appears to be very specific to colon cancer cells outside the intestine, and is only expressed in metastatic colon cancer cells that have spread there. By combining the marker with the amplification technique, which can detect one cancer cell in 10 million cells, researchers may have a very specific and sensitive way to detect metastatic colon cancer cells in the lymph nodes of patients undergoing colorectal cancer staging, he says.

The trial is recruiting about 2,000 patients at five centers: Jefferson, Fox Chase Cancer Center in Philadelphia, the University of Florida in Gainesville, McGill University in Montreal and a community hospital, Conemaugh Memorial Medical Center in Johnstown, Pa.

The trial will examine RT-PCR-GCC analysis as a method to determine if disease spread to the lymph nodes and then follow those patients to see how they do clinically during the next five years.

“We expect to find the GCC-RT-PCR analysis will identify patients who have tiny amounts of cancer in the lymph nodes that were undetected by histopathology,” Waldman said. “The pathology will be done in parallel with testing for GCC. We believe that the patients who are histopathology negative but GCC positive will do worse in terms of clinical progression—they will develop recurrent disease that was missed the first time.”

In a previous trial, Waldman and his colleagues examined 21 colorectal cancer patients. One group of 11 patients had been disease-free for at least six years and deemed “cured.” The other group of 10 patients developed recurrent disease within three years after cancer surgery. The latter had been told initially that they had no signs of cancer in their lymph nodes after surgery, meaning their cancer had not spread.

When pathologists examined lymph node samples of each patient for the presence of GCC, they found the disease-free patients' lymph nodes showed no signs of the marker. Conversely, GCC

was present in every patient whose cancer had returned.

To participate in the trial, a patient must have a newly diagnosed colorectal cancer and be treated by a surgeon from one of the participating institutions. Further information about the study is available by calling 800-JEFF-NOW.

## **Lung Cancer Survivors Claim Good QOL, Despite Challenges**

New research at UCLA's Jonsson Cancer Center provides the first comprehensive examination of quality-of-life issues faced by long-term lung cancer survivors.

The findings, published in the July 1 issue of the *Journal of Clinical Oncology*, could help healthcare providers develop more effective rehabilitation programs for long-term lung cancer survivors. The findings also will better prepare patients and their families to cope with the non-medical challenges of daily life.

Rehabilitation for lung cancer patients traditionally has focused on remedying or managing physical problems. But the UCLA study strongly suggests that emotional quality of life factors also must be addressed.

Lead author Linda Sarna, a nurse-researcher at UCLA's Jonsson Cancer Center and a professor at the UCLA School of Nursing, said two findings surprised the research team: More than 50 percent of long-term lung cancer survivors—patients in remission for five or more years—said they have good quality of life despite decreased lung function caused by lung cancer surgery and a history of smoking. And in survivors who reported relatively poor quality of life, depression affected the quality of their lives more significantly than any physical challenges.

"We expected that the lung cancer survivors' emotional quality of life would be lower than long-term survivors of other cancers because they often face more life-long physical challenges, including significant breathing difficulties when they've had all or part of a lung removed. They also face problems due to many years of smoking, so we thought the physical challenges would very negatively affect their moods and sense of optimism," Sarna said. "Survivors also deal with a variety of medical conditions aside from the cancer. Some of these conditions most likely are due to a history of tobacco use, and some are

merely part of the aging process."

Sarna and her colleagues found that 50 percent of the 142 lung cancer survivors they studied said having cancer had helped them view their lives more positively, and 71 percent of the group described themselves as "hopeful" about the future.

About 50 percent of the survivors had moderate to severe limitations in lung function because their lung capacity had diminished by about 30 percent. Working harder to breathe may have affected their physical quality of life but overall, it did not affect their emotional state of mind or outlook on life.

Among the survivors who reported poorer quality of life, researchers found that depression—not the significantly reduced breathing capacity—had the greatest impact on the survivors' quality of life.

Donald Tashkin, a UCLA pulmonologist and co-author of the study, said that impaired lung function "was not nearly as important a predictor of poorer quality of life as depression."

Tashkin said this suggests that long-term survivors of lung cancer "can significantly offset the negative impact of their limited ability to breathe by working to overcome depression" instead of trying to physically manage or improve their lung capacity.

Although the American Cancer Society estimates that 169,400 Americans will be diagnosed with lung cancer this year, lung cancer survivorship is an understudied field because the disease has a very poor prognosis. Several studies have examined short-term quality of life after lung cancer surgery, but no major studies previously have evaluated long-term survivorship and quality of life in long-term survivors, Sarna said.

"There are about nine million cancer survivors in the United States, but there has been almost no information on the experiences of lung cancer survivors," Sarna said. "Most of the research on quality of life in lung cancer patients has focused on end-of-life aspects because survival rates are very bleak. Only 15 percent of all patients live longer than five years. But lung cancer is the most common cancer in the United States, so 15 percent could translate into more than 100,000 people diagnosed within the past 10 years."

Sarna and her colleagues conducted the study through interviews, asking the survivors questions about their emotional, spiritual and physical quality of life. Emotional quality of life measures moods, anxiety and depression, while spiritual quality of life measures optimism and opinions about life's meaning.

Physical quality of life measures physical challenges.

Overall, the long-term survivors' quality of life was as high or higher than that of other cancer survivors. The long-term survivors had better emotional quality of life than people with chronic lung disease and mentally, they were as healthy as other cancer survivors. However, their physical quality of life was slightly worse than other people with cancer or other lung diseases, Sarna said.

The study also hinted that gender, ethnic and cultural differences may affect long-term survivors' quality of life, but these findings warrant further study, Sarna said.

Men and women in the study reported similar overall quality of life, but women had better spiritual quality of life than men. White ethnicity was linked with poorer overall quality of life among men and women.

"The good news is that people do survive lung cancer," Sarna said. "With all of the current studies of new treatments and ways to improve early detection of lung cancer, hopefully there will be many more lung cancer survivors in the future. Our study will help healthcare professionals start tailoring effective recovery programs for those survivors."

## **"Acceptable" Images Found In Chest Scans Using Half Dose**

A recent study has found that chest CT scans using 50 percent less radiation can provide "acceptable" images of normal anatomic structures.

While standard-dose CT scans account for only 11 percent of all X-ray based exams in the United States, they are responsible for two-thirds of total radiation dose associated with medical imaging.

The findings of this study, conducted by Srinivasa Prasad, a research fellow of radiology at Massachusetts General Hospital in Boston, could lead to a significant reduction in the overall amount of radiation patients receive each year from radiological exams.

Prasad's study examined 24 cancer patients who were 65 years old and older using a multidetector-row helical CT. The patients were scanned at the standard tube current of 220-280 mAs and at a 50 percent reduced tube current of 110-140 mAs.

Two chest radiologists reviewed the images for image quality and detail using a 5-point scale (1, worst; 2, sub optimal; 3, adequate; 4, very good; 5, excellent).

While the study found the standard-dose images to be of better quality (average 3.79), the 50 percent dose images were "acceptable" (average 3.44).

"Reducing the radiation dosage used in CT scans is worth the minor sacrifice of image quality," Prasad said. Recent advances in CT technology allow for faster and better images, yet doctors "should judiciously consider the risk-benefit ratio before referring their patients for a CT," Prasad said.

Other ways to reduce radiation exposure in CT scans include reducing voltage, increasing scanning pitch and using new filters that allow for lower doses, Prasad said.

The article, "Standard-Dose and 50 Percent Reduced-Dose Chest CT: Comparing the Effect on Image Quality," was published in the August issue of the American Journal of Roentgenology.

## **More Radiation Increases Prostate Cancer Response**

Increasing the amount of radiation certain prostate cancer patients receive can improve their chances of a cure, according to the August 2002 issue of the International Journal of Radiation Oncology, Biology and Physics, the official journal of the American Society for Therapeutic Radiology and Oncology.

The study is a scheduled analysis of a randomized radiotherapy dose escalation trial undertaken between 1993 and 1998. At a 60-month follow-up, researchers found that intermediate-to-high risk patients benefited from an 8 Gy dose increase, but also suffered more side effects than earlier analyses had revealed.

The original study was designed to compare the efficacy of 70 versus 78 Gy in controlling prostate cancer. A total of 305 Stage T1-T3 patients were entered into the trial and, of these, 301 were assessable at a 60-month follow-up. The distribution of patients by randomization arm and stage, Gleason score and pretreatment PSA level was even. The primary end point was freedom from failure (FFF), including biochemical failure, which was defined as three rises in PSA level.

The FFF rate for the 70 and 78 Gy arms at six years was 64 percent and 70 percent, respectively. Dose escalation to 78 Gy preferentially benefited those with a pretreatment PSA greater than 10 ng/mL; the FFF rate was 62 percent for the 78 Gy arm versus 43 percent for those who received 70 Gy. For

patients with a pretreatment PSA of less than 10 ng/mL, no significant dose response was found, with an average six-year FFF rate of about 75 percent.

The side effects as a consequence of dose escalation were not insignificant. Although side effects related to dose were not observed in a previous preliminary report of this trial, the current report demonstrates that the incidence of rectal side effects was significantly greater in the 78 Gy group. The Grade 2 or higher toxicity rate at six years was 26 percent for the 78 Gy arm, and 12 percent for the 70 Gy arm. Grade 2 or higher bladder complications were similar at 10 percent.

“It is now clear that patients at intermediate-to-high risk should be targeted for dose escalation,” said Alan Pollack, chairman of Radiation Oncology at Fox Chase Cancer Center and lead author of the study. “With regard to the side effects patients experienced, it is important to note that the radiation therapy techniques used in the original trial several years ago are antiquated compared to the methods in use today. Using conformal or IMRT techniques from the beginning of treatment and minimizing exposure of the bladder and rectum appropriately should dramatically reduce side effects.”

## **More Workers Quit Smoking When Health Messages Combined**

Blue-collar workers are more likely to quit smoking when workplace smoking cessation programs are combined with other occupational health and safety messages, rather than when singled out, according to a study headed by Dana-Farber Cancer Institute researchers.

The findings may lead to a new approach to improving working-class people’s health.

The program, which was tested among workers at 15 manufacturing firms in Eastern Massachusetts, differed from previous smoking-cessation efforts in that it ran in tandem with a broader occupational health and safety initiative. The combination may have made the critical difference in the program’s effectiveness, researchers say.

A report on the study and its impact on workers at the participating companies was published in the August issue of the journal *Cancer Causes and Control*.

“Despite an overall drop since the 1960s in the number of people who smoke, the rate of decline hasn’t been equal for all groups,” said the study’s

lead author, Glorian Sorensen, director of Dana-Farber’s Center for Community-Based Research.

In 1997, the smoking prevalence among blue-collar workers was 37 percent for men and 33 percent for women, compared to 21 percent for men and 20 percent for women in white-collar occupations. Similar figures exist for other healthy habits such as eating sufficient fruits and vegetables.

“There’s evidence that although blue-collar workers attempt to quit smoking as often as other workers do, they tend to be less successful,” Sorensen said. “Also, when messages about quitting smoking and eating healthily are presented in the workplace, they often don’t have as big an impact on the habits of blue-collar workers as on others.”

Such programs might be more effective, researchers theorized, if they were incorporated into ongoing efforts to reduce workers’ exposure to health and safety hazards on the job. To test the idea, Sorensen and her colleagues randomly split the 15 participating companies into two groups. In one group, health-promotion activities such as smoking cessation and healthy eating would be offered on a stand-alone basis. In the other group, such activities would be integrated into occupational health and safety efforts.

At the end of two years, the investigators found that more than two times as many workers quit smoking in the second group of companies (those that used an integrated smoking-cessation message) than did their counterparts in the first group. This cessation rate was essentially the same as that of white-collar workers. In the area of fruit and vegetable consumption, however, no significant differences were found among the different groups.

“To our knowledge, this is the first smoking-cessation program that has produced markedly high rates of quitting smoking among blue-collar workers when tested in the workplace,” said Sorensen, who also a professor of health and social behavior at Harvard School of Public Health. “It offers real encouragement that similar programs could be effective on a broad scale.”

Investigators point to several possible reasons why the combined approach succeeded. One is that blue-collar workers may see job-related hazards as a greater threat to their health than smoking or bad nutrition.

As a result, tying stop-smoking and healthy-eating programs into occupational safety efforts may help motivate workers to take action on both fronts.

In addition, the combined approach “conveys a

sense that company management shares workers' concerns about their health and is willing to do its part to help workers lead healthier lives," Sorensen explains. "It addresses the broader priorities and concerns that workers have about their health."

As for the lack of increase in consumption of fruits and vegetables, researchers say a stronger case apparently needs to be made to workers about the benefits of good nutrition. They speculate that the connection between diet and occupational health may be weaker in workers' minds than that for smoking. More study of the issue is needed, they say, but suggest the need for programs that educate workers about how good nutrition can help them be fit for work, especially physical labor.

Collaborating with Sorensen on the study were researchers at Dana-Farber, the Harvard School of Public Health, the University of Massachusetts, and Monash Medical School in Victoria, Australia.

The study was funded by the National Cancer Institute, with support from the Liberty Mutual Insurance Group.

## **Local Labs Not As Accurate As Central Testing For HER2**

Two new studies suggest that local laboratories are not as accurate as central testing facilities at identifying women who are most likely to benefit from receiving trastuzumab (Herceptin) as adjuvant therapy for breast cancer.

Past studies have suggested that trastuzumab may benefit breast cancer patients whose tumors overexpress, or produce too much, of the HER2 protein, a condition that occurs in 20% to 30% of breast cancer patients. Trastuzumab is a monoclonal antibody that works by targeting the HER2 protein.

To maximize the drug's benefits, participation in trials of trastuzumab have been limited to women who, based on laboratory tests, overexpress HER2 or have an amplified HER2/neu gene, which can also lead to HER2 overexpression. To determine trial eligibility, laboratories use several testing methods, including immunohistochemical analyses such as the FDA-approved DAKO HercepTest (which measures HER2 protein overexpression) and fluorescence in situ hybridization (which measures HER2/neu gene amplification).

In one study, Patrick Roche, of the Mayo Clinic and Mayo Foundation in Rochester, Minn., and Edith Perez, of the Mayo Clinic in Jacksonville, Fla., and

their coworkers compared results from assays done by local laboratories of 119 patients enrolled in a collaborative trial of the North Central Cancer Treatment Group and the Mayo Clinic with assays performed by a central laboratory.

The authors found that only 74% of the positive local laboratory test results could be confirmed by central testing to have HER2 overexpression and only 66% had confirmed HER2 gene amplification. Of nine tumors reported to have HER2 gene amplification by local testing, only six (67%) could be confirmed by central testing.

"The overall performance of HER2 testing by local laboratories in this initial sample of 119 patients was disappointing, with unacceptably high levels of discordance with central testing [by experienced investigators]," the authors conclude, adding that as many as 26% of the patients already enrolled based on local laboratory test results may not be the best candidates to determine whether anti-HER2 monoclonal antibody therapy is advantageous as an adjuvant to chemotherapy.

In the second study, Soonmyung Paik, of the National Surgical Adjuvant Breast and Bowel Project, and coworkers compared HER2 assay results from 104 patients who entered a clinical trial coordinated by the NSABP based on positive results from HER2 assays conducted by local laboratories. The authors found that results of 18% of the assays done by local testing facilities could not be reproduced by a central testing facility, meaning that these people may not be the best candidates for evaluating trastuzumab. The authors also found that there was more agreement between large-volume laboratories and central testing facilities than smaller laboratories. "Given the cost and potential cardiotoxicity of Herceptin, it is reasonable to recommend that HER2 testing be done at large-volume reference laboratories," the authors note.

The findings appear in the June 5 issue of the *Journal of the National Cancer Institute*.

Since the studies, both trials have modified their eligibility criteria to require central laboratory testing to confirm HER2 status in patients being considered for the trial.

In an accompanying editorial, Jo Anne Zujewski, of the National Cancer Institute, notes that the increased costs of adding quality measures at the local level should translate to lower costs at a societal level. "Accurate measurement of HER2 in individual patients means smaller sample size for clinical trials,

fewer inconclusive or erroneous clinical trial results, and avoidance of costs associated with administering therapies to patients unlikely to benefit," writes Zujewski. "As we move into the era of molecular targets, the importance of accurately assessing the target cannot be overemphasized."

## **FDA Approves Aranesp For Chemo-Induced Anemia**

FDA has approved Aranesp (darbepoetin alfa) for treatment of chemotherapy-induced anemia in patients with nonmyeloid malignancies.

Aranesp, made by Amgen Inc., will compete with the Johnson & Johnson drug Procrit for a share of the U.S. oncology market, estimated at \$1.8 billion.

According to the package insert, Aranesp is contraindicated in patients with uncontrolled hypertension. The most common side effects in Aranesp trials were fatigue, edema, nausea, vomiting, diarrhea, fever, and dyspnea.

## **Clinical Trials Approved By NCI CTEP During July**

The National Cancer Institute's Cancer Therapy Evaluation Program Approved the following clinical research studies last month.

For further information about a study, contact the principal investigator listed.

### **Phase I**

Open-Labeled, Non-Randomized Phase I Study of Flavopiridol Administered with Irinotecan (CPT-11) and Cisplatin in Patients with Advanced Solid Tumors. Memorial Sloan Kettering Cancer Center, protocol 5700, Shah, Manish, phone 212-639-3113.

### **Phase I/II**

Phase I/II Trial of BMS-247550 for Treatment of Patients with Recurrent High-grade Gliomas. NABTT Brain Tumor Consortium, protocol NABTT-2111, Peereboom, David, phone 216-445-6068.

Phase II Study of Bevacizumab in Combination with Docetaxel in Patients with Advanced Breast Cancer. Ohio State University Hospital, protocol 2715, Shapiro, Charles, 614-293-7560.

Phase II Study of UCN-01 in Combination with Fluorouracil in Advanced Pancreatic Cancer. Memorial Sloan Kettering Cancer Center, protocol 5509, Schwartz, Gary, phone 212-639-8324.

Evaluation of Novel Therapeutic Agents

(Celecoxib) Against Breast Cancer: An Innovative Randomized Phase II Trial Design. Cancer and Leukemia Group B, protocol CALGB-40105, Shapiro, Charles, phone 614-293-7560.

Phase II Evaluation of CT-2103 in the Third-Line Treatment of Recurrent or Persistent Epithelial Ovarian or Primary Peritoneal Cancer. Gynecologic Oncology Group, protocol GOG-0186C, Sabbatini, Paul, phone 212-639-6423.

Phase II Trial of ST1571 in Patients with Recurrent Meningioma. North American Brain Tumor Consortium, protocol NABTC-01-08, Wen, Patrick, phone 617-632-5366.

Sequential Approach to the Treatment of Muscle Invasive, Non-Metastatic Urothelial Carcinoma of the Bladder: A Phase II Trial of Neoadjuvant Gemcitabine, Paclitaxel and Carboplatin With Molecular Correlates. Southwest Oncology Group, protocol S0219, Lara, Primo, phone 916-734-3771.

### **Phase III**

Randomized, Placebo-Controlled, Double Blind, Trial of the Administration of the MDR Modulator, Zosuquidar, During Conventional Induction and Post-Remission Therapy in Patients Greater than 60 Years of Age with Newly Diagnosed Acute Myeloid Leukemia, Refractory Anemia with Excess Blasts in Transformation or High-Risk Refractory Anemia with Excess Blasts. Eastern Cooperative Oncology Group, protocol E3999, Cripe, Larry, 317-274-3545.

Phase III Trial of Concurrent Radiation and Chemotherapy for advanced Head and Neck Carcinomas. Radiation Therapy Oncology Group, protocol RTOG-H-0129, Ang, Kie-Kian, phone 713-792-3400.

### **Other**

Groupwise Biology and Banking Study for Ewing Sarcoma. Children's Oncology Group, protocol AEWS02B1, Helman, Lee, phone 301-496-4257.

Scatter Factor/Hepatocyte Growth Factor as a Plasma Marker for Prostate Cancer [Companion Study to CALGB 9480]. Cancer and Leukemia Group B, protocol CALGB-150005, Humphrey, Peter, phone 314-362-0112.

Prospective Study of Melastatin Expression in Predicting the Risk for Developing Local Regional Metastases of Primary Melanoma. Cancer and Leukemia Group B, protocol CALGB-500105, Hodi, Stephen, phone 617-632-5053.