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THE CLINICAL CANCER LETTER

Cancer research news for clinicians

In the Cancer Centers:

Nomograms 66% Correct In Predicting Outcome For Brachytherapy, Study Finds

Researchers at **Memorial Sloan-Kettering Cancer Center** have pioneered the use of computerized devices to help patients and their physicians decide among the major treatment choices for early stage prostate cancer.

Such tools, called nomograms, have been developed to predict outcomes for surgery and radiation therapy, and now, brachytherapy (radioactive seed implantations) for early stage prostate cancer.

In a retrospective analysis of prostate cancer patients treated with

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Clinical Trials:

SWOG Phase III Trial To Test Treatment For Inoperable, Locally Advanced NSCLC

Southwest Oncology Group said it has begun an NCI-funded phase III trial for locally advanced non-small-cell lung cancer, S0023, to compare conventional chemoradiotherapy with cisplatin, etoposide, radiation, and docetaxel, followed by maintenance therapy with the investigational agent Iressa versus the same chemoradiotherapy without the Iressa maintenance therapy.

Iressa is an oral selective epidermal growth factor receptor tyrosine kinase inhibitor that blocks pathways that are involved in the growth of cancer cells.

"Recent studies have shown that Iressa shrinks tumors in patients with NSCLC and is also associated with mild side effects," said Karen Kelly, study coordinator and associate professor of medicine at University of Colorado Health Sciences Center.

Standard treatment is chemoradiotherapy, which produces a median survival rate of about 13 to 17 months and a 3-year survival of about 20 percent, said SWOG.

Chemotherapy involving cisplatin/VP-16 with radiotherapy followed by consolidation therapy with docetaxel produced a median survival of 26 months and a 3-year survival rate of 40 percent; a much better rate than a previous SWOG trial in which chemoradiotherapy was followed by two additional cycles of the same chemotherapy, the group said. The primary objectives of the trial are to determine whether treatment with Iressa improves overall survival and progression-free survival in inoperable NSCLC patients who have been treated with

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Nomogram May Help Patients Evaluate Treatment Options

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brachytherapy between 1992 and 2000, researchers found that the nomogram offers about 66% accuracy in predicting five-year prognosis following the treatment. According to the results of the study, which are published in the September issue of Urology, 80 percent of patients remained free of disease recurrence five years after seed implantation.

"The pretreatment nomogram is useful to physicians and patients in estimating how successful brachytherapy will be based on individual factors such as PSA levels, Gleason score, and the stage of the patient's disease," said Michael Kattan, a researcher at Memorial Sloan-Kettering and lead author of the study. "Rather than relying on general risk groups of patient populations who share similar characteristics, nomograms provide specific information that will help a patient decide which treatment option for localized prostate cancer will offer him the best prognosis."

The study authors have facilitated the computations of all three nomograms by compiling the statistical aids into a Palm-based software application called Prostogram, available to physicians at no charge at http://www.nomorams.org.

The brachytherapy nomogram was developed using information from the medical records of 920 patients treated at Memorial Sloan-Kettering Mercy Medical Center in Rockville Centre, New York. Researchers used data from more than 2,000 other patients treated at the Seattle Prostate Institute and Arizona Oncology Services to validate those results, representing the largest study yet of prostate brachytherapy with permanent implants.

"This pretreatment nomogram will provide a beneficial tool to help weigh the risks and benefits of brachytherapy," said Peter Scardino, chairman of the Department of Urology at Memorial Sloan-Kettering and senior author of the study.

However, the study authors emphasize that the development of the present nomogram was based on a group of patients already treated with brachytherapy, and both physician and patient biases affected the selection of treatment among these patients, as is the case for both the surgical and radiotherapy nomograms. "The role of all the pretreatment nomograms will be better defined in a larger decision analysis which incorporates individual patient preferences into the decision making process," said Scardino.

* * *

A low-fat, high-fiber diet and regular exercise can slow prostate cancer cell growth by up to 30 percent, according to a new study by researchers at UCLA's **Jonsson Cancer Center** and UCLA's Department of Physiological Science.

"This is the first study to directly measure the effects of diet and exercise on inhibiting prostate cancer cell growth," said William Aronson, a researcher at UCLA's Jonsson Cancer Center and senior author of the study. "We used a new method, developed by our research team, to evaluate how effectively these lifestyle changes might help slow the growth of prostate cancer cells, and we are extremely encouraged by the results."

The research is published in the August issue of the Journal of Urology.

"It's too early to say that diet and exercise can prevent prostate cancer from developing or progressing, but our study strongly suggests that a low-fat diet and exercise regimen appears to favorably affect the levels of hormones or growth factors that influence prostate cancer growth," said Aronson, who also is an associate clinical professor in the Department of Urology at the UCLA School of Medicine. "Based on the results of our study, we have begun a new clinical trial at UCLA to evaluate new nutritional programs that men with prostate

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cancer may hopefully use in the future to prevent the progression of their disease."

The new research method developed by the UCLA research team involved evaluating serum obtained from study volunteers who adhered to a low-fat, high-fiber diet and exercise regimen. The serum—blood from which red blood cells and clotting factors have been extracted, leaving behind hormones and growth factors—was combined with prostate cancer cells in test tubes and evaluated to see how it affected the cells' growth. Aronson called the method "a novel and more direct way to evaluate the potential of specific diets to affect prostate cancer development or progression."

Researchers collected serum samples from two groups of healthy men—a short-term group and a long-term group. The short-term group included 13 overweight men aged 42 to 73 who had neither been eating a healthy diet nor exercising regularly. These men participated in a strict 11-day diet and exercise regimen in which they ate a low-fat, high-fiber diet and exercised regularly. The long-term group included eight men aged 38 to 74 who had eaten a healthy diet and exercised regularly for more than 14 years.

Meals in the 11-day diet regimen contained less than 10 percent of calories from fat, 15 to 20 percent of calories from protein (primarily non-animal sources with limited amounts of fish and fowl) and 70 to 75 percent of calories from carbohydrates (primarily vegetables, fruits, legumes and whole grains). Alcohol, tobacco and caffeinated beverages were not permitted.

The exercise component involved walking at a quick pace for 30 to 60 minutes four to five days a week, and once or twice a week at a slower pace for 40 to 60 minutes. A "quick pace" was defined as a training heart rate of 70 to 85 percent of a person's maximum heart rate on a treadmill exercise tolerance test.

At the end of the 11-day regimen, prostate cancer cells immersed in serum from the short-term group showed a 30 percent slower growth rate than the cells that had been immersed in baseline serum samples taken prior to the regimen.

Prostate cancer cells exposed to serum from the long-term group showed a 40 percent reduction in prostate cancer cell growth when compared to baseline samples from the short-term group. Baseline serum samples were not available for the long-term group, although their medical histories indicated long-term adherence to low-fat, high-fiber diets and regular exercise.

Additional health benefits for the short-term group included significant weight loss and lower cholesterol, although on average they still remained overweight.

The theory that a high-fat diet and sedentary lifestyle may increase prostate cancer risk already has been established. The rate of prostate cancer deaths is 15 times higher in the U.S. than in Asian countries, which have the lowest rates of prostate cancer deaths and where men traditionally adhere to a low-fat diet.

However, Chinese and Japanese men who immigrate to the United States and consume a typical high-fat Western diet develop an increased risk of prostate cancer compared to men in their native countries. This suggests that environmental factors such as a high-fat Western diet may contribute to prostate cancer development, Aronson said.

"For patients whose prostate cancer has not responded to radiation or surgery, or for patients undergoing the 'watchful waiting' strategy where treatment is delayed while tumors are monitored closely, it would be extremely useful if we could find ways as simple as diet and exercise to help them effectively control their disease," Aronson said.

The UCLA study was limited in that researchers were not able to separate the exercise and dietary components, which makes it difficult to attribute the results to the diet, the exercise or a combination of the two, Aronson said.

"However, most health agencies recommend both diet and exercise, and we feel this is the best approach for prostate cancer prevention," he said. "Obesity is an epidemic in the United States due to poor diet and inactivity, and we desperately need to reduce the number of prostate cancer deaths in this country. It's clear that eating a healthy diet and exercising regularly is an important step in the right direction."

* * *

Researchers at the **University of Pittsburgh School of Medicine** found that a treatment program that focuses on reducing women's concerns about weight is the first treatment to significantly improve smoking cessation in weight-concerned women.

Previous interventions for weight-concerned women assumed that the best approach to fostering smoking cessation was to help them prevent any weight gain after they quit smoking. This study, as

well as other research, indicates that this assumption is not correct, and that directly reducing the concerns about weight, rather than the weight gain itself, is what will help these women quit smoking.

The study, by a research team led by Kenneth Perkins and Marsha Marcus, is published in the August issue of Journal of Consulting and Clinical Psychology.

The Pittsburgh investigators randomly assigned 219 women smokers who wanted to stop smoking, but were worried about gaining weight, to one of three smoking cessation groups.

One of the groups received standard smoking cessation therapy, where weight gain was not explicitly addressed. Another group received the same smoking cessation program plus diet advice to prevent weight gain (i.e. weight control). The third group received the standard smoking cessation program and therapy to reduce their concern about gaining weight, but dieting was discouraged in this group.

Among the factors emphasized in this counseling was that the health benefits of quitting smoking superseded the health risks of even large amounts of weight gain.

In each of the groups, 10 sessions were conducted over 7 weeks. No medication of any kind was provided.

One year after treatment, 21 percent of the women who received therapy to allay their concerns about weight gain had completely quit smoking (with no relapses), compared to 13 percent of the weight control group, and 9 percent of the standard therapy group.

The women in the study did gain weight after quitting smoking. Those in the weight control group initially had the smallest weight gain, as expected, but as time went on, their weight gain was comparable to women in the standard therapy group. Surprisingly, the women in the group receiving therapy to allay their concerns about weight gain fared the best in terms of preventing weight gain. At one-year follow-up after treatment, they had gained less weight than women in either the weight control or the standard therapy groups. Women in the weight counseling group gained, on average, 5.5 pounds, while women in the weight control and the standard therapy groups gained on average 11.9 pounds and 16.9 pounds, respectively.

The results indicate that "the critical factor influencing smoking relapse in women concerned about gaining weight may be the women's over-concern about weight gain, rather than the experience of weight gain itself," Perkins said.

* * *

How important is the physical environment to the control of a cancer patient's pain?

Very important, said Dore Shepard, administrative manager for the **Barbara Ann Karmanos Cancer Institute** in Detroit.

Studying 22 inpatient records of 11 patients admitted to the Institute last year, the Institute found a 16.4 percent reduction in pain medication used on patients in a newly renovated unit, as compared to the old unit.

"Consistent with the growth of health-care consumerism aimed at providing safe patient care and improving clinical outcomes, there is a vigorous and growing advocacy to measure patient satisfaction and clinical outcomes with the physical environment of health-care facilities," Shepard said.

Working with the Center for Health Design and its Pebble Project, the Institute planned for standardized evaluation methodology of its renovated inpatient units at Karmanos Cancer Institute.

The mission of the 12-year-old Center for Health Design is to promote life-enhancing health-care environments by demonstrating the value of evidence-based design in improving health and the quality of life.

The Pebble Project emphasizes how organizational behavior changes as a result of the planning and design process. It also explores the development of a standardized evaluation methodology that can lead to comparison of outcomes, identification of best practices and continuous improvements in health-care design.

"One of our evaluation areas centered on clinical outcomes, specifically the effect the healing environment has on pain control," Shepard said.

The Institute studied the records of the 11 patients admitted under DRG 395: Red Blood Cell Disorders 18+ and who had an admitting and principal diagnosis of 28262: Hb-S Disease with Crisis.

All patients assessed were admitted between Nov. 1, 2000 and Feb. 28, 2001, to control for weather variables. All 11 patients were admitted to the old unit. All 11 patients experienced a separate admission to the new, renovated unit, within that same time frame.

All patients were placed on the Vaso-Occlusive

Pain Crisis Pathway that included Patient Controlled Analgesia to manage pain. This pathway was developed by Paul Swerdlow.

The outcome revealed a 16.4 percent reduction in pain medication (PCA+PRN+Scheduled Narcotic) used on the new renovated unit, as compared to the old unit, to control the same degree of pain.

The patients were the same, the diagnosis was the same and the medical treatment plan was the same. The only difference was the inpatient units, Shepard said.

* * *

University of Pittsburgh researchers have found the combined PET/CT scanner is the most powerful imaging tool available for localizing, evaluating and therapeutic monitoring of head and neck cancer and may be equally useful for other cancers that are difficult to pinpoint.

Results of a study showing PET/CT has a distinct advantage over PET or CT alone were presented at the annual meeting of the Society of Nuclear Medicine.

According to the researchers, the prototype of the combined PET/CT machine at the University of Pittsburgh Medical Center is able to effectively localize cancerous activity in the head and neck, an area of the body that presents substantial challenges to other imaging methods because of densely packed tissue structures and the frequent involvement of lymph nodes.

Separately, computed tomography (CT) and positron emission tomography (PET) do not provide images with the necessary combination of clear structural definition and metabolic activity that is achieved with the PET/CT.

"The PET/CT tells us the exact size, shape and location of the cancer and provides a specific target for surgery or other treatment," said Carolyn Cidis Meltzer, associate professor of radiology and psychiatry and medical director of the University of Pittsburgh Medical Center's PET facility. "The PET/CT can also be used to help us develop the best course of treatment for an individual, then monitor that individual's progress during treatment."

Head and neck cancers often have already involved lymph nodes when first discovered and can spread rapidly if they are not found and treated quickly. Images from the combined PET/CT scanner are particularly useful in allowing a radiologist to see cancerous activity at a metabolic level and pinpoint its exact location in the tissue so a biopsy can be performed and proper treatment begun.

Tumors among the skeletal muscle, salivary glands and lymphoid tissue in the head and neck area are difficult to separate from healthy tissue in standard PET images, which look like blotches of color amidst fuzzy structures. With CT, unless they are clearly swollen, cancerous lymph nodes may look normal.

Size matters when radiologists evaluate lymph nodes for signs of cancer. Seen by CT, lymph nodes under one centimeter are considered normal and not biopsied.

The PET/CT, developed in part by David Townsend, senior PET physicist, professor of radiology at the University of Pittsburgh School of Medicine, and a co-director of the University of Pittsburgh PET facility, works by combining PET technology, in which the scanner reads cellular metabolism of glucose, and CT, which builds a clear cross section of tissue structures using x-rays.

"Because head and neck cancer starts small and spreads rapidly, the PET/CT will provide doctors with a means for earlier diagnosis and treatment to potentially save lives," said Townsend. "With PET/CT an accurate diagnosis of cancer could be provided months earlier than with any other imaging method."

The groundbreaking research done by Townsend and Meltzer in Pittsburgh led the FDA to approve the PET/CT, known commercially as the Biograph, earlier this year for use as a diagnostic and therapeutic tool for cancer treatment.

NCI Research:

Hairy Cell Leukemia Patients Have CRs In Phase I Trial

Eleven of 13 patients with hairy cell leukemia had complete remissions after receiving adequate treatment with the recombinant immunotoxin BL22, according to scientists from the U.S. National Cancer Institute.

A recombinant immunotoxin is an antibody that has been bioengineered to recognize and directly deliver a deadly toxin to tumors, in this case, hairy cell leukemia cells. The patients, all of whom failed previous chemotherapy, were treated in a phase I clinical trial, an early study designed primarily to determine how to administer a drug, not cure the

disease.

The results of the study were reported in the July 26 issue of the New England Journal of Medicine

"We expected that some patients would respond to the treatment," said Ira Pastan, a senior author on the paper and leader of NCI's immunotoxin therapy group. "But we didn't imagine in our wildest dreams that almost all of the patients would go into complete remission. Half of the patients went into complete remission after a single cycle of treatment, and that was exciting to see."

Pastan said the two other patients in the study who received adequate treatment had partial remissions, and they continue to receive BL22.

Pastan said BL22, developed in the laboratory jointly with NCI scientists Robert Kreitman and David FitzGerald, was licensed over a year ago to AlbaPharm, Inc., of Rockville, Md. The company, in collaboration with Pastan's group, is now planning a larger clinical trial with the immunotoxin that will involve hairy cell leukemia patients from throughout the country.

According to Kreitman, the principal investigator of the clinical trial and a senior author on the paper, BL22 is made by cloning portions of antibodies to portions of a toxin secreted by the bacteria Pseudomonas aeruginosa. "Recombinant DNA techniques allow cloning part of the antibody and part of the toxin to make a smaller recombinant immunotoxin that gets into the tumor faster and reduces the toxicity to the body," said Kreitman.

The antibody portion of BL22 specifically binds to the CD22 receptor, which is found in abundance on the surface of many types of leukemia cells. CD22 is also found, in lower amounts, on the surface of normal B cells. Therefore, it seems likely that BL22 would bind to and destroy both leukemic cells and normal B cells. Because stem cells—the progenitors of normal B cells—do not have CD22, any B cells lost in the short-term treatment should be replaced by the patient's untouched stem cells. Kreitman and his colleagues did not detect a decrease in normal B cells of patients.

"Malignant stem cells—the progenitors of the leukemic cells—may be CD22-positive as well and be lost, too," Kreitman said. "But only further follow-up will determine if this is correct."

Therefore, it is thought that this treatment may not only clear the body of malignant circulating cells but may remove the source of the cells, the malignant stem cells.

The most serious side effect of BL22 immunotoxin treatment was a decrease in platelet and red blood cell counts. This decrease was associated with the clotting and breaking up of red blood cells in the kidney, which can cause kidney failure. However, both patients experiencing the side effect completely recovered and had complete remissions of HCL. Using a modified method of BL22 administration, this side effect was not detected in many patients treated later in the study.

It is possible that the BL22 immunotoxin will prove to be useful in treating more than just hairy cell leukemia. The phase I trial includes patients with other types of leukemia and, while Kreitman and his colleagues saw the most dramatic response in HCL, a significant benefit was seen in chronic lymphocytic leukemia.

Clinical Trials:

SWOG Begins Testing Iressa For NSCLC In Phase III Trial

(Continued from page 1)

chemotherapy and radiation and to assess the safety of its long-term use, SWOG said. An additional goal is to establish a lung cancer specimen bank, which will store tissues from lung cancer patients for use in current and future scientific research studies.

Participants will be randomized at the group's Statistical Center to receive one of two treatment regimens: cisplatin, etoposide, and radiation followed by docetaxel and Iressa; or cisplatin, etoposide, and radiation followed by docetaxel and placebo, SWOG said.

* * *

Magee-Womens Hospital in Pittsburgh is now enrolling newly diagnosed ovarian cancer patients in a clinical study to evaluate the safety and efficacy of a treatment combining traditional chemotherapy with a peptide that has shown cancer-fighting properties.

The peptide, called IM862, appears to interfere with tumor blood vessel development, said Robert Edwards, medical director of gynecological oncology at Magee-Womens Hospital and director of the gynecologic oncology center at the **University of Pittsburgh Cancer Institute**.

"The treatment is given in nose drops that patients can administer themselves," added Edwards, who also is an associate professor and medical director in the division of gynecologic oncology at

the University of Pittsburgh School of Medicine. "So far, initial testing indicates few side effects, and the peptide also seems to be very active. It's exciting."

Developed by Seattle-based Cytran Inc., IM862 is also being tested as a possible immune system booster. Magee-Womens Hospital is among 18 centers nationwide now taking part in clinical trials using IM862, which is also being evaluated for its effectiveness in treating patients with prostate, breast and colorectal cancers. Cytran is funding the Magee study.

"Since the symptoms of ovarian cancer can be subtle, many women are not diagnosed until the disease is in an advanced stage," said Holly Gallion, director of the National Center of Excellence in Ovarian Cancer at Magee. "So these sorts of trials are essential to the development of possible new treatments."

Aggressive surgery followed by chemotherapy is the current standard of care for ovarian cancer treatment. Women 18 years of age or older who are newly diagnosed and have had surgery but not chemotherapy are being targeted to take part in the study. Patients who have had previous chemotherapy treatment are ineligible.

Patients will be randomly assigned to one of three study groups that receive different doses of IM862 along with six cycles of traditional chemotherapy. At the conclusion of treatment, a "second look" surgery will be performed to assess the presence of the disease. Those who have no, or microscopic, evidence of disease recurrence will receive treatment with IM862 for an additional 24 weeks. Patients who have no clinical evidence of disease at the end of the additional 24 weeks will be followed periodically for a year.

To date, IM862 has been tested in clinical trials involving more than 400 cancer patients with a range of cancers. Additional information on IM862 is available on the Cytran Inc. Web site at http://www.cytran.com.

* * *

University of California, Los Angeles, Jonsson Cancer Center is seeking volunteers for a phase III clinical trial that will test the safety and effectiveness of individually tailored vaccines to fight a common type of lymphoma.

The vaccines will be manufactured to target proteins unique to each patient's lymphoma, said Christos Emmanouilides, director of the Clinical Lymphoma Research Program at the center and principal investigator for the multi-center study. The vaccine therapy, which will be combined with chemotherapy, has prompted encouraging results in earlier phase studies of about 100 people conducted at Stanford University, Emmanouilides said. To qualify for the study, volunteers should have untreated follicular lymphoma. This type of lymphoma is considered incurable in most cases, Emmanouilides said.

Volunteers will have a sample of their cancerous tissue removed. The sample will be used to manufacture the vaccine. Volunteers will undergo eight rounds of chemotherapy and then will be injected with the vaccine, which researchers hope will prompt the body's immune system to fight off the cancer while leaving healthy cells alone. Volunteers must undergo five weekly injections of the vaccine.

The injections will be done at UCLA's Jonsson Cancer Cancer. However, volunteers can get the chemotherapy at oncology offices in their own communities, Emmanouilides said.

In previous studies of the vaccine, patients remained in remission much longer than expected, Emmanouilides said. For more information, patients may call 310-825-2516 or 310-794-4376.

NCI-Approved Clinical Trials

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

Combination Antibody Therapy with Apolizumab (1 D10) and Rituximab (CD20) in Relapsed Lymphoma and CLL. NCI Medicine Branch, protocol 2410, Wilson, Wyndham, phone 301-435-2415.

Phase I Trial of the Farnesyltransferase Inhibitor, R115777, and Radiotherapy in Patients with Non-small Cell Lung Cancer. University of Pennsylvania Cancer Center, protocol 5150, Hahn, Stephen, phone 215-662-7296.

Phase I Pharmacokinetic Study of STI571 in Patients With Advanced Malignancies and Varying Levels of Liver Dysfunction. University of Pittsburgh, protocol 5331, Ramanathan, Ramesh, phone 412-648-6507.

Phase I Pharmacokinetic Study of STI571 in

Patients with Advanced Malignancies and Varying Degrees of Renal Dysfunction for the CTEP-Sponsored Organ Dysfunction Working Group. Case Western Reserve University, protocol 5340, Remick, Scott, phone 216-844-9541.

Phase I Study of HeFi-1 Antibody Therapy in Hodgkin's and Ki-1 Lymphomas. Beth Israel Deaconess Medical Center, protocol 870, Junghans, Richard, phone 617-432-7004.

Phase I/II

Phase I/II Study of Percutaneous Radiogrequency Ablation of Bone Metastases Using CT Guidance. American College of Radiology Oncology Imaging Network, protocol ACRIN-6661, Dupuy, Damian, phone 401-444-5184.

Phase II Trial of PS-341 in Metastatic Breast Cancer. M.D. Anderson Cancer Center, protocol 1855, Cristofanilli, Massimo, phone 713-792-2817.

Phase II Trial of Fenretinide in Recurrent Ovarian Cancer and Primary Peritoneal Carcinoma. USC-LA, protocol 19, Garcia, Agustin, phone 323-865-0470.

Phase II Study of Bevacizumab and Interferon-Alpha-2b in Metastatic Malignant Melanoma. Ohio State Hospital, protocol 2669, Carson, William, phone 614-293-6306.

Phase II Study of Thalidomide and Interferon-Alfa-2b in Mycosis Fungoides (Cutaneous T-cell Lymphoma) Stage IB-IVB. Ohio State University Hospital, protocol 670, Porcu, Pierluigi, phone 614-293-7808.

Phase II Trial of Interleukin-12 Followed by Interferon Alfa-2B in Patients with Metastatic Malignant Melanoma. Cancer and Leukemia Group B, protocol CALGB-500001, Carson, William, phone 614-293-6306.

Phase II Trial of Gemcitabine, 5 Fluorouracil and Radiation Therapy in Locally Advanced Non-Metastatic Pancreatic Adenocarcinoma. Cancer and Leukemia Group B, protocol CALGB-80003, Mamon, Harvey, phone 617-732-6310.

Phase II Evaluation of SU5416 in Persistent or Recurrent Squamous Cell Carcinoma of the Cervix. Gynecologic Oncology Group, protocol GOG-0227B, Burger, Robert, phone 714-456-6570.

Phase II Evaluation of Thalidomide in the Treatment of Recurrent or Persistent Endometrial Carcinoma. Gynecologic Oncology Group, protocol GOG-0229-B, McMeekin, Scott, phone 405-271-8707.

Phase II Evaluation of Thalidomide in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus. Gynecologic Oncology Group, protocol GOG-0230-B, McMeekin, Scott, phone 405-271-8707.

Randomized Phase II Study of Interleukin-12 in Combination with Rituximab in Patients with non-Hodgkin's Lymphoma. North Central Cancer Treatment Group, protocol N0087, Ansell, Stephen, phone 507-284-0923.

ZD1839 for Treatment of Recurrent or Progressive Malignant Astrocytoma or Glioblastoma and Recurrent or Progressive Meningioma: A Phase II Study with a Phase I Component for Patients Receiving EIAEDs. North American Brain Tumor Consortium, protocol NABTC-00-01, Lieberman, Frank, phone 412-692-2600.

Randomized Phase II Trial of Weekly Gemcitabine, Paclitaxel and External Irradiation (50.4 GY) Followed by the Farnesyl Transferase Inhibitor R115777 for Locally Advanced Pancreatic Cancer. Radiation Therapy Oncology Group, protocol RTOG-PA-0020, Rich, Tyvin, phone 804-924-9412.

Phase II Trial of Sequential Vinorelbine and Docetaxel in Advanced Non-Small Lung Cancer Patients Age Seventy and Older, or with Performance Status 2. Southwest Oncology Group, protocol S0027, Hesketh, Paul, phone 617-789-2317.

Single Agent Docetaxel for Metastatic Breast Cancer in Patients Aged 70 Years and Older (and in a Cohort of Patients Younger than 60 Years). Southwest Oncology Group, protocol S0029, Martino, Silvana, phone 310-998-3961.

Phase III/Other

Phase III Evaluation of Benefin Shark Cartilage in Patients with Advanced Cancer. North Central Cancer Treatment Group, protocol NCCTG-97-11-51, Loprinzi, Charles, phone 507-284-8964.

Correlative Trial of EF5, an Agent for the Detection of Tumor Hypoxia. University of Pennsylvania Cancer Center, protocol 3950, Hahn, Stephen, phone 215-662-7296.

IND BB-8454 EntreMed IND Studies with Endostatin. Entremed, protocol 5728, Herbst, Roy, phone 713-792-6363.

ABTR01B1, Children's Oncology Group Protocol for Collecting and Banking Pediatric Research Specimens. Children's Oncology Group, protocol ABTR01B1, Grundy, Paul, 780-432-8512.