Vol. 27 No. 10
October 2004

THE
CLINICAL CANCER LETTER

Cancer research news for clinicians

Sister Study To Examine Risk Factors For Breast Cancer In 50,000 Women

A new study that will look at 50,000 sisters of women diagnosed with breast cancer opened for enrollment across the U.S. earlier this month.

The Sister Study, conducted by the National Institute of Environmental Health Sciences, will investigate environmental and genetic causes of breast cancer. The study is the largest study of its kind to look at breast cancer risk factors.

Women of all backgrounds and ethnic groups are eligible for the study if they are between the ages of 35 and 74; live in the United States; have never had breast cancer themselves; and have a sister, living or deceased, who has had breast cancer. To recruit a diverse group of volunteers and to ensure the results benefit all women, researchers are especially encouraging African-American, Latina, Native American, and Asian women, as well as women 60

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ASTRO Annual Meeting:

Some Children With Hodgkin's Disease Can Reduce Or Skip Radiation, Study Finds

Some children with Hodgkin's Disease can skip or significantly reduce radiation therapy if the cancer has sufficiently shrunk due to chemotherapy, according to the results of a study presented at the American Society for Therapeutic Radiology and Oncology annual meeting held earlier this month in Atlanta.

Hodgkin's Disease, a malignant tumor of the lymph nodes typically treated with an intensive combination of chemotherapy and radiation, can lead to serious side effects in patients, particularly in children. But researchers at Moabit Hospital in Berlin, Germany, found that doctors can in some cases safely omit or reduce the amount of radiation therapy given to children with Hodgkin's Disease without sacrificing cure rates.

Between 1995 and 2001, more than 1,100 children with Hodgkin's Disease were divided into three groups and were treated with two, four or six cycles of chemotherapy.

Doctors eliminated the follow-up radiation in patients whose cancer went into complete remission after the chemotherapy. For patients whose tumors were reduced more than 75 percent, doctors administered lower doses of radiation. The remaining patients were treated slightly higher follow-up doses of radiation.

More than four years later, the survival rate was 97 percent for all the

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NIH Begins Sister Study For Breast Cancer Risk

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and older, to join the study.

"By studying sisters, who share the same genes, often had similar experiences and environments, and are at twice the risk of developing breast cancer, we have a better chance of learning what causes this disease Sisters may be the key to unlocking breast cancer risk mysteries," said Dale Sandler, chief of the Epidemiology Branch at NIEHS and the study's principal investigator.

Volunteers will complete several questionnaires and provide a sample of their blood, urine, toenails, and household dust.

The study will stay in touch with the volunteers for 10 years and compare those who develop breast cancer with the majority who do not. While past studies have largely focused on hormones, reproductive health, and lifestyle, the Sister Study will take the most detailed look ever at how women's genes, and things women come in contact with at home, at work, and in the community may influence breast cancer risk. Researches will study a range of environmental exposures, from personal care and household products, to workplace and other common exposures.

"Genes are important, but they don't explain it all," said Sandler. "The truth is that only half of breast cancer cases can be attributed to known factors." Two known genes linked to breast cancer, BRCA 1 and BRCA 2, play a role in only five to 10 percent of cases.

The Sister Study opened in pilot states, including Arizona, Florida, Illinois, Missouri, North Carolina, Ohio, Rhode Island, and Virginia, earlier in 2004, but is now open for nationwide enrollment.

Organizations that are in partnership with the Sister Study include the American Cancer Society, Sisters Network Inc., the Susan G. Komen Breast Cancer Foundation, and the Y-ME National Breast Cancer Organization, as well as many local community breast cancer support and advocacy groups.

To volunteer or learn more about the Sister Study, visit http://www.sisterstudy.org or call 1-877-4SISTER (877-474-7837).

Breast Implants Don't Cause Tissue Disorders, NCI Finds

Researchers from the U.S. National Cancer Institute found no convincing evidence that breast implants have an effect on the development of subsequent connective tissue disorders (CTDs).

The results are reported in the Oct. 1 issue of the American Journal of Epidemiology.

The researchers used data from one of the largest studies on the long-term health effects of breast implants. A large number of patients reported CTDs, but when their records were examined by two board-certified rheumatologists, few cases were considered likely.

In 1992, the U.S. Congress asked the National Institutes of Health to investigate the long-term safety of breast implants. Scientists at NCI, led by Louise Brinton, in the Division of Cancer Epidemiology and Genetics, examined the medical records of 13,500 women who had cosmetic breast implant surgery before 1989 and 4,000 women similar in age who had other types of plastic surgery. Although it was not the original intent of the study, the available information provided investigators with an opportunity to study the risk of CTDs in this population.

For some time, there has been uncertainty regarding whether breast implants might be associated with the development of certain CTDs. Most of the previous studies on this issue had small sample sizes, limited time to follow the clinical outcomes of the women after their surgeries, and imprecise information on either implant status or disease outcomes. This study included a large population of women with breast implants, detailed information on their implants, and patients' answers to questions about their disease experience and other

THE CLINICAL CANCER LETTER

Member, Newsletter and Electronic Publishers Association

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

Publisher: Kirsten Boyd Goldberg
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Editorial: 202-362-1809 Fax: 202-318-4030
PO Box 9905, Washington DC 20016
Customer Service FAQ at www.cancerletter.com

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

THE CLINICAL CANCER LETTER (ISSN 164-985X). Published monthly, subscription $119 per year, by The Cancer Letter Inc.

health characteristics, and long-term follow-up of up to 13 years.

Four major CTDs (rheumatoid arthritis, systemic lupus erythematosus, scleroderma, and Sjögren's syndrome) were more commonly reported by breast implant patients, with an approximate two-fold increase in risk. Attempts were made to review the medical records for three of these conditions where there were elevations in reported risks both before and after 1992, the time when breast implants were deemed investigational by the U.S. Food and Drug Administration. Only 30 percent to 40 percent of the medical records could be obtained. When these records were blindly reviewed by two expert rheumatologists, only 17 percent to 30 percent of the diagnoses were considered 'likely.' When only likely diagnoses were considered, the excess risk of CTDs became statistically non-significant, meaning they could have happened by chance. Further, the small number of confirmed cases of scleroderma and Sjögren's syndrome made interpretation of the risks difficult. The researchers also were unable to assess the existence of any new CTD specific to implant patients.

To further clarify the relationship of implants to the risk of CTDs, future research should include clinical examinations of patients using defined diagnostic criteria for these disorders. Given the rarity of conditions such as scleroderma and Sjögren's syndrome, a study would need to be very large to fully clarify the association between breast implants and these disorders.

Unscreened Women At High Risk of Breast Cancer

Women in integrated health plans are at the greatest risk for late-stage breast cancer when they haven't had screening mammograms even though they have access to this test, according to a new study.

Also, the study, published in the Oct. 20 issue of the Journal of the National Cancer Institute, found that older, unmarried, less educated, and lower income women are less likely to be screened.

The study was conducted by scientists at Group Health Cooperative and six other organized health plans in the Cancer Research Network—a consortium of healthcare organizations nationwide that studies the effectiveness of cancer-control interventions.

"This study tells us that in order to achieve the largest reduction in late-stage breast cancers, our highest priority should be reaching those unscreened women and encouraging them to have mammograms," said Stephen Taplin, who led the research in his role as senior investigator with Group Health Cooperative's Center for Health Studies. Taplin is now a member of the U.S. National Cancer Institute's Division of Cancer Control and Population Sciences.

"Screening is a process, not just a test," Taplin added. "Our goal was to learn where that process needs to be improved so that more women can achieve complete screening. For example, we wondered if women with positive tests were not being evaluated."

To find out where the screening process breaks down and where changes in care might have the greatest impact, the researchers examined data from 2,694 women aged 50 years and older who had breast cancer and were members of integrated health plans that provide both primary and specialty care.

They compared women who had been diagnosed with late-stage breast cancer with those who had been diagnosed with early-stage breast cancer and, on the basis of their care between three years and one year prior to their diagnosis, categorized the women into one of three groups: absence of screening (when no mammogram existed); absence of detection (when the earliest screening mammogram was negative); potential breakdown in follow-up (when a screening mammogram was positive, but the diagnosis occurred more than a year later).

The researchers found that 52 percent of the late-stage breast cancer cases were associated with an absence of screening, 39 percent with an absence of detection, and 8 percent with a potential breakdown in follow-up. They found that the odds of having late-stage cancer were nearly doubled among women with an absence of screening. Among women diagnosed with late-stage cancer, women were more likely to be in the absence-of-screening group if they were aged 75 years or older, unmarried, or did not have a family history of breast cancer. In addition, women who had less education or lower income were more likely to have been in the absence-of-screening group.

"For women, this study emphasizes the importance of getting screened regularly and within the appropriate time frame," said Taplin. "For doctors, it tells us that we need to identify the women in our practices who are not coming in even though they're receiving reminders, to listen to them, and to find ways to encourage them to come. And for healthcare systems, it means considering reminder systems to reach those women who may not be seeing their providers for care."

In addition, more research needs to be done to improve the use of current technology and to develop better tools for detecting cancer, Taplin said.

The Cancer Research Network is a consortium of 11 healthcare organizations that collaborate on studies of cancer epidemiology, prevention, early detection, and control in the context of health care delivery systems. Together, the participating organizations have access to healthcare data on 9 million people, or 3.5 percent of the U.S population. The CRN is supported by grants from NCI. Group Health Cooperative's Center for Health Studies provides scientific and administrative leadership for the network.

ASTRO Annual Meeting:

Study Finds HCL Responds To Immunotoxin Treatment

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children in the study. Of them, 90 percent had no trace of the disease or any other type of cancer.

Efaproxyn Improved Survival Of Patients With Brain Mets

Efaproxyn (efaproxiral, Allos Therapeutics Inc.) improved survival in patients with brain metastases, according to results of a phase III study presented at the ASTRO annual meeting.

A retrospective analysis of the results from the study led to the identification of the strongest prognostic factors for survival in patients with brain metastases. The study was presented by John Suh, clinical director for radiation oncology, Brain Tumor Institute at the Cleveland Clinic Foundation and the study's lead investigator.

Suh and colleagues evaluated certain factors influencing long-term survival of brain metastases patients, including Karnofsky Performance Status (KPS), site of primary, age, presence of extra cranial metastases, control of primary, gender, presence of liver metastases, timing of brain metastases diagnosis, prior brain tumor resection and number of brain metastases. Results of the analysis indicated that KPS, prior brain tumor resection, the presence of extra cranial metastases and gender were the strongest variables in predicting outcome. Moreover, the analysis affirmed the effectiveness of the study drug, Efaproxyn, in improving survival time across a heterogeneous patient population.

"This study has significant implications for the design of future randomized trials in brain metastases patients," said Suh. "Our findings confirm the impact of certain variables in determining survival outcome for brain metastases patients. Moreover, the results demonstrated an improvement in survival for patients with brain metastases who received Efaproxyn and whole brain radiation therapy (WBRT) with supplemental oxygen over those who received WBRT with supplemental oxygen only."

Results from Suh's retrospective analysis were incorporated into the study design of Allos' phase III, randomized, open-label, multi-center trial, called ENRICH (ENhancing Whole Brain Radiation Therapy In Patients with Breast Cancer and Hypoxic Brain Metastases), designed to compare the effect of whole brain radiation therapy with supplemental oxygen with or without Efaproxyn in women with brain metastases from breast cancer. The trial, which was initiated in February 2004, incorporated certain identified prognostic factors into the stratification and design, including KPS and presence of liver metastases.

The REACH study was a randomized, open label phase III clinical trial designed to demonstrate the safety and efficacy of Efaproxyn in treating patients with brain metastases and good performance status. Patients with SCLC, germ cell tumors or lymphoma were excluded. Prior brain tumor resection was allowed as long as measurable lesion(s) remained. The study enrolled 538 patients and compared the safety and efficacy of Efaproxyn plus WBRT and supplemental oxygen (271 patients) versus WBRT and supplemental oxygen (267 patients) in patients with brain metastases. The primary endpoint of the trial was survival.

Efaproxyn is the first synthetic small molecule designed to "sensitize" hypoxic (oxygen-deprived) areas of tumors during radiation therapy by facilitating the release of oxygen from hemoglobin, the oxygen-carrying protein contained within red blood cells, and increasing the level of oxygen in tumors.

Brachytherapy Better Than Surgery For Prostate Cancer

Results of the largest and longest study ever undertaken of permanent prostate brachytherapy, or "seed therapy," found overall survival rates for patients were equal to or better than surgery.

Brachytherapy, commonly called seeding, is a form of radiation therapy that fights prostate cancer with rice-sized radioactive seeds implanted inside the body.

Researchers from New York Prostate Institute followed 1,449 patients treated with permanent prostate brachytherapy between 1992 and 2000. Results showed a biochemical, recurrence-free survival rate of 81 percent, which is equal to or better than comparable

rates found in studies of other forms of treatment for men with clinically localized prostate cancer.

The study, "Twelve-Year Outcomes Following Permanent Prostate Brachytherapy In Patients With Clinically Localized Prostate Cancer," was presented at the ASTRO annual meeting.

Cancer Prevention:

Ohio Center Helps Women Stop Smoking, Reduce Cervical Cancer Risk

A team of investigators from The Ohio State University Comprehensive Cancer Center has launched a major research project to find the best way to help women beat the odds of getting cervical cancer. One of the best first steps may be to stop smoking.

The program, one of several large population studies funded by a $7.5 million grant from the National Cancer Institute, will compare two different approaches to helping women quit smoking and increase their use of Pap smears, a way of detecting the presence of any cervical cancer cells, or any suspicious looking tissue that might lead to the development of cervical cancer.

The OSU team, including Mary Ellen Wewers, a professor of nursing and co-director of the project, along with collaborators from the University of Michigan, the Fred Hutchinson Cancer Research Center, and the Centers for Disease Control and Prevention, are targeting their efforts to women in Ohio's 29-county Appalachian region, but the project has implications for women everywhere.

"We hope to help women understand risk appropriate use of Pap smears," said Electra Paskett, associate director of population sciences for the OSUCCC and lead investigator of the project.

Recently, public health guidelines changed: Women with no risk factors for cervical cancer are now told they need Pap smears only every three years, not yearly.

But Paskett worries about that change. There are three known risk factors for cervical cancer: smoking, the presence of the human papilloma virus (HPV) and the lack of appropriate Pap testing. Paskett said women who smoke, who have multiple sexual partners, or who are infected with HPV need Pap tests every year, no matter how old they are. She is afraid women might not have heard that addendum to the recent change in the guidelines, and may be neglecting to get their Pap tests, a key cancer prevention tactic.

The incidence and death rates from cervical cancer are higher in Appalachia than the national average, but the use of Pap testing is slightly lower than average. "We don't know much about the incidence of HPV infection; that's one of the things we hope to find out," Paskett said.

The relationship between smoking and the development of cervical cancer is not entirely clear, but scientists do know that carcinogens from smoke can actually be found in cervical mucous. There, they are able to damage cells and allow HPV to infect cells of the cervix. Still other studies have found that smoking can depress the immune system.

"One of our goals is to help women understand these things, and to offer them a strategy that can help them quit tobacco altogether," Paskett said.

Part of the research project will use lay health educators, respected and well-known members of the Appalachian community, to drive those messages home.

"Quitting smoking has well-documented health benefits, and we know that worldwide, the incidence of cervical cancer has plummeted where Pap screening is used appropriately," said Paskett. "No one should die of cervical cancer in 2004."

Smoking Cessation Training Follows Doctors Into Practice

Primary-care doctors who use smoking cessation methods while training as residents are twice as likely to continue doing so in their medical practice more than eight years later, new research at the University of North Carolina at Chapel Hill shows.

The study is believed to be the first to take a long-term look at the influence of residency education, specifically, preventive-care skills, on the behavior of physicians.

"Our study shows that training through exposure alone, albeit exposure to very robust smoking cessation intervention methods and materials, is almost worthless unless you managed to put it into play when you were a resident," said study principal author Katherine Hartmann, assistant professor of obstetrics and gynecology as well as epidemiology in UNC's schools of medicine and public health. "It's important we do more than just provide deluxe teaching and put charts, prompts and other materials into the learning environment. There must be serious expectations that residents use this training and are supervised while doing it during their residency."

U.S. residency education is based on the belief

that it influences long-term practice. But until now, follow-up studies assessing the influence of specialized components of residency education, such as smoking cessation intervention training, have been short-term, measured in weeks or months.

Hartmann, a member of the UNC Lineberger Comprehensive Cancer Center, said she is not aware of other publications on any topic in behavioral intervention training, including smoking cessation intervention, that have extended the follow-up of former residents "into the timeframe in which they have an established and mature practice style."

Study results were based on 291 doctors' responses to a three-page, 20-question written survey. All had been in residency training between 1986 and 1996 and are now primary-care practitioners in internal medicine, family medicine, obstetrics and gynecology, or pediatrics. The national group studied had been in practice an average of 8.5 years at the time of follow-up.

Half of these doctors had received smoking cessation intervention training and half had not. Such training included formal, uniform instruction from teachers trained in the National Cancer Institute's "Train the Trainer" workshops, the gold standard for smoking cessation intervention training, Hartmann said.

The primary outcome was based on responses to an item that gave participants a list of 16 possible smoking cessation interventions, including "best" practices such as identifying smokers, advising cessation, assisting with a plan and arranging for follow-up.

Overall, 42 percent of respondents were using best practices. But prior training alone was not associated with current use of best practices.

Moreover, those who reported use of best practices in residency were twice as likely to currently use them, even after more than eight years and in a wide range of clinical practice settings, Hartmann said.

"Our findings are compatible with educational theory: Imparting knowledge alone is not as powerful as knowledge coupled with experience," she said.

"To change future practice patterns, we will need to give resident physicians training, tools, time and guidance to become comfortable and experienced in conducting smoking cessation intervention," Hartmann said. "While 23 percent of adults in the U.S. population are smokers, there is ample reason to continue to assure that the next generation of physicians is optimally equipped to take on the challenge of promoting cessation."

The study appeared in the July issue of Preventive Medicine.

Prostate Cancer:

Degarelix Active In Phase II Trial In Prostate Cancer

Degarelix, a new GnRH blocker from Ferring, shows rapid onset and sustained activity in a phase II clinical study in men with prostate cancer, according to results of a study presented at the 27th Congress of the Société Internationale d'Urologie held earlier this month in Hawaii.

The findings from a multi-center trial in 129 men and conducted in the U.K. support positive results seen from earlier research on degarelix, and move it closer to phase III trials, say doctors involved in the study.

The study compared the effectiveness and safety of three different dosing regimens of degarelix in men with early and late-stage prostate cancer, who had an initial median PSA level of 61 ng/ml and were recommended as candidates for androgen (male hormone) deprivation therapy.

All three dosing schemes of degarelix had fast inhibitory effects on testosterone and PSA levels in a dose-dependent manner.

At the highest dose, 97.5 per cent of patients (n=32) experienced a reduction in testosterone to target levels of less than 0.5 ng/ml within three days of treatment. All the patients in this group reached target suppression levels within the first 28 days and this was sustained in 87.5 per cent of the patients on treatment through to the end of the six-month study period. Five weeks after initiation of treatment the median PSA-reduction in patients on treatment was 90 per cent compared to baseline.

There were no serious adverse events during treatment, however six (4.7 per cent) of the 129 patients withdrew from the study. The most frequently reported adverse reactions to therapy were associated with the drug's intended action in decreasing secretion of testosterone.

Ovarian Cancer:

Study Opens For Women At Risk of Ovarian Cancer

The Gynecologic Oncology Group, with funding from the National Cancer Institute, is seeking women at higher risk of developing ovarian cancer for a new clinical research study to improve early detection.

The Ovarian Cancer Prevention and Early Detection Study will enroll 3,400 women over the next two years who at higher risk of developing ovarian cancer because they have a strong family history of breast or ovarian cancer, or because they have tested

positive for changes in genes that are known to increase the risk of ovarian cancer.

The study will evaluate two methods for preventing ovarian cancer. Study volunteers will be divided into two groups. One group will include women who plan to have their ovaries and fallopian tubes removed. Researchers hope to determine whether this preventive surgery decreases the risk of developing ovarian cancer. The second group will include women who elect not to undergo surgery despite their increased risk. These study volunteers will be screened for early detection of ovarian cancer using a new technique based on frequent blood tests.

To be eligible, study volunteers must be at least 30, have a strong family history of breast or ovarian cancer or have themselves or a close relative tested positive for the BRCA1 or BRCA2 gene mutation.

Unlike most research studies, volunteers will be able to choose which arm of the study they would like to join.

Further information is available at the study's Web site at http://ovariancancer.gog199.cancer.gov/.

Mantle Cell Lymphoma:
Centers Recruting Patients With Mantle Cell Lymphoma

About 30 research centers in the U.S. and internationally are recruiting patients with relapsed or refractory mantle cell lymphoma to participate in a single-arm, open-label phase II trial of Velcade.

By blocking the proteasome, Velcade disrupts numerous biologic pathways, including those related to growth and survival of some cancer cells.

"Velcade is a novel therapy with a unique mechanism of action," said John Leonard, chief trial investigator, clinical director of the Center for Lymphoma and Myeloma and associate attending physician at New York-Presbyterian/Weill Cornell. "We're pleased to be able to participate in this trial because patients with treatment-resistant mantle cell lymphoma are in desperate need of potential new therapeutic options."

The primary endpoints of the trial are time to disease progression and response rates. Duration of response and overall survival also will be measured.

To be eligible for the study, adult patients must have:

--Documented relapse or progression following one or two chemotherapy regimens, with at least one regimen having included anthracycline or mitoxantrone;

--Pathologically confirmed mantle cell lymphoma with either cyclin D overexpression or (11;14) translocation;

--At least one measurable site of disease that has not been previously irradiated or has grown since previous irradiation;

--Karnofsky performance status > 50 percent (a performance scale that rates a person's normal activities and that can be used to evaluate a patient's progress after a therapeutic procedure); and

Other criteria specified by the investigators.

Upon completion of the 12-month treatment protocol, patients will be followed every six weeks until progressive disease is confirmed. Prospective participants can call 1-866-VELCADE (835-2233) for more information about eligibility or to find a study site in their area.

Velcade is approved in the U.S. for the treatment of multiple myeloma patients who have received at least two prior therapies and have demonstrated disease progression on the last therapy. Last April, the European Commission granted marketing authorization for Velcade for the treatment of patients with multiple myeloma who have received at least two prior therapies and have demonstrated disease progression on their last therapy.

Velcade is being co-developed by Millennium and Johnson & Johnson Pharmaceutical Research & Development; Millennium is responsible for commercialization in the U.S.; Ortho Biotech and Janssen-Cilag are responsible for commercialization in Europe and, subject to regulatory approvals, the rest of the world. Janssen Pharmaceutical K.K. will be responsible for Japan.

NCI-Approved Clinical Trials

The National Cancer Institute's Cancer Therapy Program approved the following clinical research studies last month. For further information about a study, contact the principal investigator listed.

Phase I

Phase I Study of Tirapazamine in Combination with Radiation and Weekly Cisplatin in Patients with Locally Advanced Cervical Cancer. Maccallum Cancer Institute, protocol 5485, Rischin, Danny, phone 613-9656-1804.

Phase I Study of XK469 in Patients with Refractory Hematologic Malignancies. M.D. Anderson Cancer Center, protocol 6939, Giles, Francis, phone 713-792-8217.

Study of Subcutaneous CYT 99 007 (Interleukin-

7) in Conjunction with Peptide Immunization in Patients with Metastatic Melanoma. NCI Surgery Branch, protocol 7222, Rosenberg, Steven, phone 301-496-4164.

Phase I/II

Phase I-II Study Of Idarubicin, Cytarabine and Zarnestra a Farnesyltransferase Inhibitor, in Patients with High-Risk Myelodysplastic Syndromes and Acute Myeloid Leukemias. M.D. Anderson Cancer Center, protocol 6625, Kantarjian, Hagop, phone 713-792-7026.

Phase I, Molecular Biology and Phase II Study of Lapatinib in Pediatric Patients with Recurrent or Refractory Medulloblastoma, Malignant Glioma or Ependymoma. Pediatric Brain Tumor Consortium, protocol PBTC-016, Fouladi, Maryam, phone 901-495-2094.

Phase II

Phase II Trial of Gemcitabine and Triapine in Refractory Metastatic Breast Cancer. Mayo Clinic Rochester, protocol 6292, Morgan-Meadows, Sherry, phone 608-263-5781.

Randomized Phase II Trial of Idarubicin + Cytarabine +/- Bevacizumab in Patients Age < 60 with Untreated Acute Myeloid Leukemia. M.D. Anderson Cancer Center, protocol 6484, Verstovsek, Srdan, phone 713-745-3429.

Phase II Clinical Trial of 17-Allyamino-17-Demethoxygeldanamycin in Chemotherapy Refractor Metastatic Breast Cancer. Wayne State University, protocol 6552, Gartner, Elaina, phone 313-745-915.

Phase II Study of BAY 43-9006 in Combination with Gemcitabine in Recurrent Epithelial Ovarian Cancer. Princess Margaret Hospital Phase II Consortium, protocol 6565, Oza, Amit, phone 416-946-2818.

Phase II Study of BAY 43-9006/Gemcitabine for Advanced Pancreatic Cancer. University of Chicago, protocol 6567, Kindler, Hedy, phone 773-702-0360.

Phase II Study of BAY 43-9006 in Patients with Metastatic Differentiated Thyroid Carcinoma. Ohio State University Hospital, protocol 6608, Shah, Manisha, phone 614-293-8629.

Phase II Study of GW572016 in Recurrent and/or Metastatic Adenoid Cystic Carcinoma, and Other EGFR-and/or erbB2-expressing Malignant Tumors of the Salivary Glands. Princess Margaret Hospital Phase II Consortium, protocol 6701, Siu, Lillian, phone 416-946-2911.

Phase II Study of SB-715992 in Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck. Princess Margaret Hospital Phase II Consortium, protocol 6803, Winquist, Eric, phone 519-685-8640.

Phase II Study of Decitabine in Myelofibrosis. University of Chicago, protocol 6814, Odenike, Olatoyosi, phone 773-702-3354.

Treatment of Patients with Metastatic Melanoma Using a Transplant of Autologous Lymphocytes Reactive with Tumor Following a Myeloablative Lymphocyte Depleting Regimen of Chemotherapy, Total Body Irradiation and Reconstitution with CD34+ Cells. NCI Surgery Branch, protocol 7025, Rosenberg, Steven, phone 301-496-4164.

Limited Access Phase II Trial of Cetuximab in Combination with Cisplatin in the Treatment of Advanced, Persistent, or Recurrent Carcinoma of the Cervix. Gynecologic Oncology Group protocol 0076DD, Farley, John, phone 808-433-6845.

Phase II Evaluation of Ixabepilone in the Treatment of Recurrent or Persistent Endometrial Carcinoma. GOG protocol 0129P, Dizon, Don, phone 401-453-7520.

Phase II Trial of Raf Kinase Inhibitor BAY 43-9006 as Single Oral Agent in Patients with Metastatic Breast Cancer Previously Exposed to Anthracyclin and/or Taxane. North Central Cancer Treatment Group, protocol N0336, Perez, Edith, phone 507-284-1159.

Phase II Study of SB-715992 in Patients with Locally Advanced, Recurrent or Metastatic Hepatocellular Carcinoma. NCI of Canada Clinical Trials Group, protocol NCIC-168, Knox, Jennifer, phone 416-946-2399.

Phase II Study of SB-715992 in Previously Untreated Patients with Metastatic or Recurrent Malignant Melanoma. NCIC-169, Christopher Wai, phone 604-930-2098.

Phase II Study of SB-715992 in Taxane-Resistant Androgen-Independent Metastatic Prostate Cancer. Southwest Oncology Group, protocol s0418, Beer, Tomasz, phone 503-494-0365.

Phase III

Phase III Randomized Controlled Trial to Determine Efficacy of L-Carnitine Supplementation for Fatigue in Patients with cancer. Eastern Cooperative Oncology Group, protocol E4Z02, Cruciani, Ricardo, phone 212-420-2337.

Other

Health-Related Outcomes for Hodgkin Disease Survivors. Children's Oncology Group, protocol ALTE04N1, Friedman, Debra, phone 206-987-2106.