Vol. 27 No. 9
September 2004

THE
CLINICAL CANCER LETTER

Cancer research news for clinicians

New Approaches To Improve Diagnoses In Urogenital Cancers Presented At AUA

By Lawrence M. Prescott

SAN DIEGO--A change in emphasis of several well-known diagnostic approaches may improve the prognosis of patients with renal cell carcinoma (RCC) and prostate cancer, according to investigators presenting their findings at the 80th Annual Meeting of the Western Section of the American Urological Association.

P53 in Localized Renal Cell Carcinoma

Results from a custom kidney cancer tissue microarray point out that P53 is the only independent molecular predictor of tumor recurrences for patients undergoing treatment for localized RCC, said Oleg Shvarts, urology resident,

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Breast Cancer:

Younger Patients, More Advanced Stages, More Likely To Die From Breast Cancer

Women who are diagnosed with breast cancer at a young age, or at an advanced stage at any age, are more likely to die from the disease than from all other causes of death combined, according to a new study by scientists at the U.S. National Cancer Institute.

The probability of death from breast cancer varies greatly according to stage, tumor size, estrogen receptor (ER) status, and age at diagnosis in both blacks and whites, the researchers wrote in the Sept. 1 issue of the Journal of the National Cancer Institute.

"To our knowledge, this study is the first comprehensive risk analysis to examine in detail both the risk of death from breast cancer and other causes following a breast cancer diagnosis," said Catherine Schairer, the study's lead author and an epidemiologist in the Division of Cancer Epidemiology and Genetics at NCI. "These results can provide important prognostic information to physicians and patients, and may help in weighing the risks and benefits of various treatment options."

To calculate the probabilities of death from breast cancer vs. all other causes combined among breast cancer patients, Schairer and her colleagues analyzed data from NCI's Surveillance, Epidemiology and End Results Program for more than 400,000 breast cancer patients diagnosed between 1973 and 2000. They computed probabilities of death from breast cancer and all other causes combined over a 28-year follow-up period according to

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Variety of Approaches Tested For Urologic Cancer Detection

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department of urology, David Geffen Medical School at University of California, Los Angeles.

"This marker successfully identifies a subset of patients with a significantly higher probability of recurrence who could derive the greatest benefit from more stringent post-surgical surveillance and adjuvant clinical trials," Shvarts said.

To determine which clinical and molecular variables can best predict cancer recurrence following nephrectomy for RCC, tumor specimens from 366 patients were examined using a custom kidney cancer tissue microarray, Shvarts said. A total of 193 patients who underwent nephrectomy for localized RCC at UCLA between 1989 and 2000 were identified. The array then was analyzed by immunochemistry for a number of well-known tumor markers including CAIX, CAXII, Ki67, Gelsolin, p53, EpCAM, pTEN, and Vimentin. The medical records of these patients were then reviewed for clinical data such as age, sex, TNM stage, tumor size, nuclear grade, ECOG performance status, recurrence status (both local and metastatic), and, when applicable, time to recurrence. Univariate and multivariate analyses were used to determine clinical and molecular predictors of tumor recurrences.

In this group of patients, 15% (29 pts) had recurrences following nephrectomy. Univariate analysis showed that tumor size, T stage, ECOG performance status, Ki67, EpCAM, and p53 had an impact on recurrence. Multivariate analysis, however, pointed out that the only independent predictors of recurrence were T stage and p53.

The Clinical Cancer Letter

Member, Newsletter and Electronic Publishers Association

World Wide Web: 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
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.

Prostates With Abnormal DREs

Digital rectal examination, a simple and routine procedure in urological practice, may prove to be of greater value than previously thought in the diagnosis of prostate cancer, according to Kirk Lin, director, genitourinary and immunochemistry services, AmeriPath, of Salt Lake City.

"In our study, one-third of the prostates with abnormal digital rectal examinations were malignant," Lin said. "When the PSA level was greater than 4 ng/ml, the cancer detection rate was 52%, 2.6 times grater than the 20% rate seen with PSA levels less than 4 ng/ml in the situation of abnormal digital rectal examinations."

To investigate the frequency in which cancer and other pathologic entities are encountered with an abnormal digital rectal examination, a study was carried out to assess 618 patients who underwent prostate biopsies for abnormal digital rectal examinations. These cases represented 34% of the 1,825 consecutive prostate biopsies received from January 2002 to March 2004. The final diagnoses were made by a urological pathologist performing microscopic examination of H & E slides and immunostained slides, when supplied by urological pathologists.

One-third of all 618 patients were malignant, with 133 of 256 patients or 52% who had a PSA level greater than 4 ng/ml having prostate cancer, Lin said. The cancer detection rate in patients with PSA levels less than 4 ng/ml was 20% (71/362 pts). The remaining 177 patients (29%) were classified as having benign prostate cancer.

Small Tumors With Increasing Number of Prostate Biopsies

The use of more than six prostate biopsies results in the detection of smaller volume low grade prostate cancers, independent of serum PSA and Gleason grade, with extended pattern biopsy templates contributing to the downward stage migration of prostate cancer detection which may contribute to the risk of overdetection, said Viraj Master, clinical instructor of urology, department of urology, University of California San Francisco School of Medicine.

"Doctors nowadays take more and more biopsies and this may lead to finding cancers of very small volume," Master said. "Taking six or more biopsies

is all right if a prostate cancer of significant volume is found but we must be careful that overdetection does not lead to overtreatment."

To test the hypothesis that an increasing number of prostate biopsies results in the detection of small volume prostate cancer, independent of serum PSA and Gleason grade, a retrospective review of 378 patients who had undergone radical prostatectomy by a single surgeon from 2001 to 2003 was performed. Patient and tumor-specific variables including age, PSA, number of biopsies, biopsy Gleason grade, tumor volume in the surgical specimen, and surgical specimen were studied.

Complete data was available for 317 men, of whom 119 had six core biopsies and 198 had eight or more core biopsies. Mean PSA values were 5.6 ng/mL, ranging from 2 to 18.8 ng/mL and 6.0 ng/mL, ranging from 2 to 30.80 ng/mL, respectively. The percentage of patients with primary Gleason values of 4 or 5 was 13% in the six-core biopsies group and 12%, in those with 8 or more core biopsies. Neither patient age, PSA values, or Gleason pattern was statistically significant between groups.

There were no differences due to the number of biopsy cores in the distribution of the biopsy Gleason sum or the pre-surgery PSA, Master said. Mean tumor size, however, was 3.85 cc for patients with six biopsies versus 2.04 cc for patients with more than six biopsies. Using multiple regression analysis, six versus eight or more biopsy cores was a significant predictor of outcome, adjusting for both Gleason score and PSA separately or together.

Breast Cancer:

ER- Tumors, Larger Tumors More Deadly, Study Finds

(Continued from page 1)

stage and age at diagnosis, and over an 11-year follow-up period according to tumor size and ER status for a subset of cases.

The researchers found that breast cancer patients with ER-negative tumors were more likely to die from their cancer than those patients with ER-positive tumors, and that patients with larger tumors were more likely to die from their cancer than patients with smaller tumors.

For patients diagnosed with localized breast cancer before age 50, the probability of death from breast cancer was greater than that from all other causes. The authors found the same to be true for patients diagnosed with regional disease before age 60, or with distant disease (cancer that has spread to distant organs or distant lymph nodes) at any age.

As the age at breast cancer diagnosis increased, the risk of death from other causes increased and the risk of death from breast cancer generally decreased. However, even among older patients, death from breast cancer still accounted for a significant portion of mortality.

The researchers also found that while the probability of death from breast cancer varied greatly according to stage, tumor size, ER status, and age at diagnosis in both blacks and whites, mortality from breast cancer and other causes was generally higher in blacks than in whites even after accounting for these factors.

The scientists write that these results are consistent with those of other analyses that have shown generally poorer breast cancer survival in black patients than in white patients.

The NCI researchers suggest, as have other researchers, that this higher probability seen in blacks may be due to differences in treatment and to a higher prevalence of obesity and obesity-related health conditions in black patients, among other factors.

"Understanding these probabilities of death from breast cancer based on stage, tumor size, ER status and age can provide useful information for patients and physicians alike" said Schairer.

"Future studies, such as similar analyses for other cancers and more in-depth analyses for breast cancer according to tumor size and hormone receptor status, could generate additional valuable tools for physicians and patients."

MRI Effective For Women With BRCA Gene Mutations

MRI is more accurate for detecting breast cancer than mammography, ultrasound, or clinical breast examination alone in women who carry the BRCA1 or BRCA2 gene mutation, according to a study in the Sept. 15 issue of the Journal of the American Medical Association.

Women with BRCA1 and BRCA2 mutations who do not undergo prophylactic surgery have a lifetime risk of breast cancer of up to 85 percent, with a significantly higher risk of breast cancer than the general population from age 25 years onward, according to background information in the article.

Current recommendations for women who have a BRCA1 or BRCA2 mutation are to undergo

breast surveillance from age 25 years onward with mammography annually and clinical breast examination every six months. However, many tumors are detected at a relatively advanced stage. Magnetic resonance imaging and ultrasound may improve the ability to detect breast cancer at an early stage.

Ellen Warner, of Toronto-Sunnybrook Regional Cancer Centre, Toronto, compared the sensitivity and specificity of four methods of breast cancer surveillance (mammography, ultrasound, MRI, and CBE) in women with hereditary susceptibility to breast cancer due to a BRCA1 or BRCA2 mutation.

The study included 236 women aged 25 to 65 years with BRCA1 or BRCA2 mutations who underwent 1 to 3 annual screening examinations, consisting of MRI, mammography, and ultrasound at a teaching hospital between 1997 and 2003. On the day of imaging and at 6-month intervals, CBE was performed.

During the study period, there were 22 cancers detected (16 invasive and 6 ductal carcinoma in situ). Of these, 17 (77 percent) were detected by MRI vs. 8 (36 percent) by mammography, 7 (33 percent) by ultrasound, and 2 (9.1 percent) by CBE. All 4 screening modalities combined had a sensitivity of 95 percent vs. 45 percent for mammography and CBE combined.

"This study of 236 BRCA1 and BRCA2 mutation carriers demonstrates that the addition of annual MRI and ultrasound to mammography and CBE significantly improves the sensitivity of surveillance for detecting early breast cancers," the authors write. "… our results support the position that MRI-based screening is likely to become the cornerstone of breast cancer surveillance for BRCA1 and BRCA2 mutation carriers, but it is necessary to demonstrate that this surveillance tool lowers breast cancer mortality before it can be recommended for general use."

In an accompanying editorial, Mark Robson and Kenneth Offit, of Memorial Sloan-Kettering Cancer Center, write that Warner et al have clearly documented the risks and benefits of breast MRI screening in women at the highest levels of hereditary risk.

The findings "strongly suggest that women with BRCA mutations should be offered such screening. Women and their physicians must, however, be aware that both sensitivity and specificity of screening MRI may be substantially less than described if different imaging protocols are followed or if experienced radiologists and suitable technology, including the capability to perform magnetic resonance-guided biopsies, are not available.

"A technology assessment by one large insurance carrier has already supported the rationale for MRI screening of BRCA mutation carriers and other women at high hereditary risk for breast cancer, even in the absence of a randomized controlled trial demonstrating a mortality benefit. Remaining questions, largely centered on specificity, recall rate, and positive predictive value, argue against routine application of MRI screening for women at lesser degrees of risk without carefully designed studies, preferably randomized controlled trials, delineating test performance in those specific populations," the authors conclude.

Study Supports Immediate Breast Reconstruction

Performing breast reconstruction surgery at the time of mastectomy does not delay post-operative chemotherapy for women with breast cancer, according to the first study designed to answer the question.

The study appears in the September issue of Archives of Surgery.

"At most academic centers that routinely care for women with breast cancer, immediate breast reconstruction is the norm for women who opt for mastectomy," said Richard Bold, associate professor of surgical oncology at the University of California Davis Cancer Center and senior author of the study. "However, a number of our patients come to us after having been told elsewhere that they should not have immediate reconstruction because it delays chemotherapy. We felt it was an important question to settle."

Breast reconstruction has been shown to lessen the impact of mastectomy on a woman's self-image and psychosocial wellbeing; these benefits are more pronounced when reconstruction is performed at the time of mastectomy rather than in a later surgery. However, some surgeons—concerned about skin infections and other wound complications that might delay chemotherapy—advise women to postpone reconstruction.

Chemotherapy is typically initiated four to six weeks after mastectomy. Longer delays may increase the risk of cancer recurrence or jeopardize survival. Because chemotherapy drugs can slow wound healing, patients with severe wound complications may have to postpone the therapy until the wound improves.

Bold and his colleagues reviewed the charts of 128 women who underwent mastectomy at UC Davis Cancer Center between 1995 and 2002. They found that while wound complications were more common with immediate reconstruction, the complications were too mild to warrant any delay in starting chemotherapy.

Of the 128 women, Bold and his colleagues identified four whose chemotherapy was delayed beyond six weeks because of wound complications. Two of the four women had undergone immediate breast reconstruction. Two had mastectomy alone without reconstruction.

"The findings weren't a surprise to us, but we wanted to document the safety of immediate breast reconstruction so that surgeons in other settings can have the same confidence in the approach," Bold said.

Cosmetic outcomes also tend to be better with immediate surgery, Bold said. "When we begin the reconstruction process at the time of mastectomy, we do a skin-sparing mastectomy that preserves more skin," he said. "Reconstruction tends to look better when native skin can be used rather than stretched or transplanted skin."

UC Davis Is U.S. Site For Trial Of Exemestane For Breast Ca.

Healthy, post-menopausal women at high risk for breast cancer may be eligible to participate in a major new international study to determine whether the drug exemestane can prevent the disease.

University of California Davis Medical Center is the first center in the U.S. chosen to participate in the study, funded by the Canadian National Cancer Institute. Ultimately more than 5,000 women will be enrolled in the trial, which will last five years.

"Exemestane may present a new breakthrough in the prevention of breast cancer, and has the potential to greatly decrease the risk of this deadly disease, with fewer side effects than currently available preventive medications," said John Robbins, professor of general medicine at UC Davis School of Medicine and Medical Center and principal investigator of the study.

Exemestane is one of a new class of anti-cancer medications known as aromatase inhibitors. Aromatase inhibitors have shown promise in preventing breast cancer recurrences in women previously treated for the disease, but have not yet been clinically studied as a way to prevent breast cancer in high-risk women. The new study is the first designed to answer this question. In addition, the new study will determine whether exemestane plus an anti-inflammatory drug is more effective at preventing breast cancer than exemestane alone.

The drug tamoxifen has already been shown to prevent breast cancer in high-risk women, but many women have found its side effects, including hot flashes, unacceptable. Preliminary research suggests that exemestane will have fewer side effects than tamoxifen.

For the purposes of the study, women are considered at high risk of developing breast cancer if they have had a prior breast biopsy that yielded atypical findings, have had a previous ductal carcinoma (localized breast cancer), have a strong family history of breast cancer or are age 60 or older, among other factors. All participants must be between the ages of 40 and 75, with no history of invasive breast cancer, and in general good health.

Study volunteers will be randomized into one of three groups. In the first group, participants will receive oral exemestane daily for five years along with an oral placebo for the first three years. In the second group, participants will receive oral exemestane daily for five years along with oral celecoxib, an anti-inflammatory agent, for the first three years. In the third group, patients will receive an oral placebo daily for five years. The study will be "double-blind," meaning that neither the participants nor the study investigators will know who is taking the placebo until after the study is over.

For further information, contact Elizabeth Winward at 916-734-5562, or e-mail jarobbins@ucdavis.edu.

Surgery, Radiation Effective For Older Women, Study Finds

Surgery plus radiation therapy is an effective way to treat early breast cancer in women aged 70 and older, according to a new study published in the Sept. 1 issue of the International Journal of Radiation Oncology*Biology*Physics.

For early breast cancer, the standard of care is surgery to remove the cancerous lump followed by radiation therapy, thereby allowing the patient to keep her breast. However, older women are not always offered this option. Some older breast cancer patients are treated with tamoxifen alone while others are encouraged to have a mastectomy to "simplify" their treatment, even though the loss of a breast can be depressing for a woman of any age. This study sought to evaluate whether breast-conserving surgery plus radiation was as effective for older women as it is for women under age 70.

In the study, 196 women aged 70 and older from France and Italy underwent surgery to remove the cancer followed by external beam radiation therapy. Two-thirds of the patients also received tamoxifen and 16 percent received chemotherapy.

Researchers found that the breast-conserving

therapy was just as effective for older women as it was for younger ones. After 5 years, the disease-specific survival rate was 92 percent. At 10 years, that rate was 88 percent. The overall survival rate was 81 percent at five years and 62 percent at 10 years. The study also found that the older women tolerated the treatment as well as their younger counterparts.

"Since approximately 30 percent of all breast cancers are diagnosed in women aged 70 and older, my hope is that these results will encourage more older women to avoid a disfiguring mastectomy and opt for breast-conserving surgery plus radiation," said Bruno Cutuli, lead author of the study and radiation oncologist in the Department of Radiation Oncology at Polyclinique de Courlancy in Reims, France.

Immune Therapy Possible For Metastatic Breast Cancer

Researchers at the U.S. National Cancer Institute have found evidence that immune cell transplant therapy can help shrink tumors in patients with metastatic breast cancer.

Michael Bishop, of NCI, led the study, which was published Aug. 16 on the Web site of the Journal of Clinical Oncology. Scientists at the Experimental Transplantation and Immunology Branch of NCI's Center for Cancer Research studied 16 women with breast cancer that had progressed to an average of three metastatic sites after conventional treatments, including chemotherapy and hormones; six of these women had tumor shrinkage after cellular immune therapy.

Bishop's group gave study patients a treatment similar to a bone marrow transplant. Each patient received cells donated by a sibling. This transplant included lymphocytes and the adult stem cells that produce blood cells. The active, anti-tumor component of this cellular immune therapy regimen was a class of lymphocytes called T cells, which attack and kill tumor cells.

Because the recipient's immune system may attack donor cells, the scientists gave subjects an immune-suppressing chemotherapy regimen before the transplant. To help protect subjects' bodies from the toxic effects of the transplant, scientists followed the chemotherapy with a course of transplant-conditioning drugs.

Each subject received transplants with the same concentration of T cells. The initial transplants had a relatively low concentration of these cells; infusions given at 42, 70, and 98 days after the first transplant had exponentially increasing numbers of T cells. Increasing the concentration over this time period helped NCI researchers isolate patients' reactions to the transplant from their reaction to the chemotherapy, and established T cells as the active element in the transplant.

Six patients of the 16 had partial or minor responses to the treatment lasting an average of three months. The transplants had a toxic effect in many of the women, causing not only anti-tumor activity but also attacking normal cells. This graft-vs.-host disease (GVHD) was observed in a majority of subjects: 10 had acute GVHD; of 13 available for a follow-up examination, four had chronic GVHD.

"Although it was hoped that the women would garner clinical benefit from this research, the study was not designed to demonstrate that this immune cell therapy results in an improvement of outcome, specifically survival," Bishop said.

"The study demonstrated that immune-based therapies, specifically the lymphocyte-based therapy we used, could result in tumor regression," Bishop said. However, it is crucial to improve cellular immune therapy by lowering the risk of toxic effects, especially GVHD. Collaborating laboratories are currently testing specialized T cells they hope will cause little GVHD while retaining strong anti-tumor effects.

"These data provide support to continue efforts to develop better immune-based therapies to augment currently available therapies for metastatic breast cancer," stated Bishop.

FDA Approvals:

PET Tracer Drug Approved, Developed At Weill Cornell

A drug manufactured at Weill Cornell Medical College received U.S. Food and Drug Administration approval last month for use in diagnosing tumors, cardiovascular problems, and centers of epileptic activity in the brain, using positron emission tomography.

The FDA's approval for Fludeoxyglucose F18 injection ([18F]FDG) is the second such approval in the country for this type of radiopharmaceutical application.

Because the FDA is still working on guidelines regulating PET tracer drugs, they have so far not required FDA approval. For that reason, [18F]FDG is already used widely in PET centers throughout the country.

"Weill Cornell has raised the bar for everyone else in the quality of their radiopharmaceuticals and in terms

of patient safety," said Harry Lander, assistant dean for research administration at the Weill Medical College of Cornell University.

Lander credited the efforts of Weill Cornell researcher Shankar Vallabhajosula in getting the NDA approved for [18F]FDG in just six months, in a process where most drugs take years to get approved. That effort was made even more daunting by the fact that, under federal rules enacted in 1997, formal FDA approval of new PET drugs ground to a halt as agency officials worked on guidelines for this special class of compounds.

"Industry was waiting for the FDA to act," said Vallabhajosula, professor of radiochemistry in radiology at Weill Cornell, and attending radiologist at NewYork-Presbyterian Hospital/Weill Cornell Medical Center. "But I went to the FDA and I said 'Why do I have to wait?'"

As soon as officials gave him the green light, Vallabhajosula submitted the NDA for [18F]FDG last March.

[18F]FDG is a glucose analog, a chemical "mimic" of glucose, the body's prime energy source.

"Tumors, because their cells are dividing so rapidly, need energy, and that energy is glucose," Vallabhajosula said. "The major fuel for brain activity--including bursts of energy associated with epileptic seizures--comes from glucose, as well. And while the heart usually relies on fatty acids for its fuel, it can turn to glucose when things go wrong. All three of these mechanisms mean glucose is a great vehicle for PET diagnoses."

[18F]FDG resembles glucose in all but one atom, he added, so as cells "cry out" for glucose, they pull the drug toward them. But that one-atom difference means [18F]FDG goes unused, piling up around centers of high glucose activity.

"It's working like a probe, showing where glucose metabolism has increased or decreased," Vallabhajosula said. On PET scans, this allows doctors to get a detailed outline of the location and internal structure of tumors, cardiovascular abnormalities, and other trouble spots.

Several hundred PET centers are using FDG, in over 400,000 patients every year, the researcher said.

FDA approval of [18F]FDG may soon benefit those hoping for concrete FDA approval guidelines on radiopharmaceuticals, too. "The FDA encouraged Weill Cornell's NDA application, and may use it as a model to encourage other institutions around the country to follow," Lander said.

Other FDG-type drugs are in the pipeline, including some under development at Weill Cornell.

Clinical Trials Approved By NCI Listed For September

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

Multicenter Phase I Trial of 17-N-allylamino-17-demethoxy geldanamycin in Patients with Recurrent/ Refractory Pediatric Malignancies. Memorial, protocol 6323, Trippett, Tanya, phone 212-639-8267.

Phase I Trial of BAY 43-9006 for Patients with Recurrent or Progressive Malignant Glioma. New Approaches to Brain Tumor Therapy Consortium, protocol NABTT-0401, Nabors, Louis, phone 205-934-143.

Phase I/II

Phase I/II Study of PS-341 in Combination with Paclitaxel, Carboplatin, and Concurrent Thoracic Radiation Therapy for Non-Small Cell Lung Cancer, North Central Cancer Treatment Group, protocol N0321, Adjei, Alex, phone 507-538-1079.

Phase II

Treatment of Patients with Metastatic Renal Cell Cancer Using Cultured, Reactive Lymphocytes and Interleukin-2. NCI Tumor-Surgery Branch, protocol 5774, Yang, James, phone 301-96-1574.

Phase II Study of Single Agent Depsipeptide (FK228) in Recurrent, Platinum Sensitive Adenocarcinoma of the Ovary or Peritoneum. Wake Forest University, protocol 6321, Miller, Brigitte, phone 336-716-4304.

Phase II Study of 17-N-Allylamino-17-Demethoxy Geldanamycin (17-AAG) in Metastatic Renal Cell Carcinoma. Memorial, protocol 6479, Drucker, Beverly, phone 646-422-4466.

Phase II Randomized Trial of BAY 43-9006, a Novel Raf Kinase Inhibitor, versus BAY 43-9006 plus Paclitaxel/Carboplatin in Women with Recurrent Platinum Sensitive Ovarian, Peritoneal or Fallopian Tube Cancer. Case Western Reserve University, protocol 6557, Vongruenigen, Vivian, phone 216-884-6011.

Phase II Study of BAY 43-9006 (Sorafenib) in Metastatic, Androgen-Independent Prostate Cancer. NCI Medicine Branch, protocol 6594, Dahut, William, phone 301-435-8183.

Immunization of Patients with Renal Cancer Using

HLA-A2 and HLA-A3-Binding Peptides from Fibroblast Growth Factor 5. NCI Surgery Branch, protocol 6622, James Chung-Yin, phone 301-496-1574.

Phase II Study of Fludarabine + Rituximab Induction Followed By Alemtuzumab Administered Subcutaneously as Consolidation in Untreated Patients with B-Cell Chronic Lymphocytic Leukemia. Cancer and Leukemia Group B, protocol CALGB-10101, Byrd, John, phone 614-293-9321.

Phase II Study of C225 (Erbitux or Cetuximab) in Combination with Cisplatin and Definitive Radiation in Unresectable Stage IV Squamous Cell Carcinoma of the Head and Neck. Eastern Cooperative Oncology Group, protocol E3303, Langer, Corey, phone 215-728-2985.

Phase II Evaluation of Bay 43-9006 in the Treatment of Persistent or Recurrent Epithelial Ovarian or Primary Peritoneal Carcinoma. Gynecologic Oncology Group, protocol GOG-0170F, Matei, Daniela, phone 317-278-0070.

Phase II Study of Capecitabine in Combination with Vinorelbine and Trastuzumab for the First Line Treatment of HER2+ Metastatic Breast Cancer (Previously Treated with Neoadjuvant or Adjuvant Taxane). North Central Cancer Treatment Group, protocol N0337, Tan, Winston, phone 507-284-1159.

Phase II Trial of Neoadjuvant Therapy with Concurrent Chemotherapy and High Dose Radiotherapy Followed By Surgical Resection and Consolidative Therapy for Locally Advanced Non-Small Cell Lung Carcinoma. Radiation Therapy Oncology Group, protocol RTOG 0229, Suntharalingam, Mohan, phone 410-328-6080.

Phase II Study of Radiation Therapy Plus Low Dose Temozolomide Followed by Temozolomide Plus Irinotecan for Glioblastoma Multiforme. Radiation Therapy Oncology Group, protocol RTOG-0420, Lieberman, Frank, phone 412-692-2600.

Phase II Surgical Trial of Intralesional Resection of Low-Grade Intracompartmental Chondrosarcoma of Bone. Southwest Oncology Group, protocol S0344, Randall, R., phone 801-585-0300.

Phase II Study of the RAF-Kinase Inhibitor BAY 43-9006 in Combination with Interferon-Alpha 2B in Patients with Advanced Renal Cancer. Southwest Oncology Group, protocol S0412, Ryan, Christopher, phone 503-494-8487.

Phase II Studies of Two Different Schedules and Two Different Doses of the Farnesyl Transferase Inhibitor R115777 for Previously Untreated Acute Myeloid Leukemia in Patients of Age 70 or Older. Southwest Oncology Group, protocol S0432, Erba, Harry, phone 734-647-8921.

Phase III

Phase III Randomized Study of Farnesyl Transferase Inhibitor R115777 in Acute Myeloid Leukemia Patients in Second or Subsequent Remission or in Remission After Primary Induction Failure. Eastern Cooperative Oncology Group, protocol E2902, Luger, Selina, phone 215-662-6348.

Phase III, Adjuvant Trial Comparing Three Chemotherapy Regimens in Women with Node-Positive Breast Cancer: Docetaxel/Doxorubicin/Cyclophosphamide (TAC); Dose-Dense Doxorubicin/Cyclophosphamide followed by DD Paclitaxel; DD AC followed by DD Paclitaxel Plus Gemcitabine. National Surgical Adjuvant Breast and Bowel Project, protocol NSABP-B-38, Swain, Sandra, phone 301-451-6882.

Phase III Clinical Trial Comparing Infusional 5-Fluorouracil, Leucovorin, and Oxaliplatin (mFOLFOX6) Every Two Weeks with Bevacizumab to the Same Regimen without Bevacizumab for the Treatment of Patients with Resected Stages II and III Carcinoma of the Colon. National Surgical Adjuvant Breast and Bowel Project, protocol NSABP-C-08, Allegra, Carmen, phone 412-330-4600.

Phase III Trial Comparing Whole Brain Radiation and Stereotactic Radiosurgery Alone versus with Temozolomide or Gefitinib in Patients wtih Non-Small Cell Lung Cancer and 1-3 Brain Metastases. Radiation Therapy Oncology Group, protocol RTOG-0320, Sperduto, Paul, phone 952-442-6000.

Other

Multi-Drug Resistance Gene Expression in Wilms Tumors: Correlation with Outcome Henrique. Children's Oncology Group, protocol Other AREN03B, Malogolowkin, Marcio, phone 323-669-4514.

Master Protocol for Pharmacogenetic and Genomic Studies. Eastern Cooperative Oncology Group, protocol EIY03, O'Dwyer, Peter, phone 215-662-8947.

Association of Breast Density Changes, Serum Estrogen Changes and Breast Cancer Recurrence--A Companion Study to NCIC CTG MA.27. North Central Cancer Treatment Group, protocol Other N0434 (MA.27D), Ingle, James, phone 507-284-2511.

Pilot

Treatment of Late Isolated Extramedullary Relapse from Acute Lymphoblastic Leukemia (Initial CR1 >/= 18 months). Children's Oncology Group, protocol AALL02P2, Barredo, Julio, phone 843-792-2957.