THE NICAL CANCER LET

Cancer research news for clinicians

Cancer Screening:

Screening Mammograms In Young Women Have Low Accuracy, Detect Few Cancers

Screening mammograms in women under age 40 result in high rates of callbacks and additional imaging tests but low rates of cancer detection, according to a study published online May 3 in the Journal of the National Cancer Institute.

Many studies have assessed mammography in women over age 40 years, but little is known about its usefulness in younger women. Although screening mammograms are not generally recommended under age 40, about 29% of women between 30 and 40 report having had one.

To determine the accuracy and outcomes of mammograms in younger women, Bonnie Yankaskas, from the University of North Carolina at (Continued to page 2)

Cancer Statistics:

Lower Stomach Cancers Increasing In Younger U.S. Whites, Study Finds

Cancer of the lower stomach has decreased overall in American adults but has increased in whites age 25-39, a study finds. The work, led by researchers from the National Cancer Institute, is published in the May 5 issue of the Journal of the American Medical Association.

Cancers of the upper and lower parts of the stomach are thought to have different causes. Cancers of the upper stomach may be related to acid reflux, whereas a major cause of lower stomach cancers is infection with the bacterium Helicobacter pylori (H. pylori). Most stomach cancers are diagnosed in people 65 years of age or older.

In the U.S., stomach cancer is higher among African-Americans, Asian-Americans, and Hispanics.

"Overall stomach cancer incidence trends primarily reflect higher rates in older individuals," said study author William Anderson, Division of Cancer Epidemiology and Genetics, NCI. "But incidence rates that are specific to particular age groups can provide important clues about future cancer trends that may vary from group to group."

The research team analyzed data from NCI's Surveillance, Epidemiology and End Results program, which collects cancer incidence and survival data from population-based registries that cover 26 percent of the U.S. population.

The NCI team identified 39,003 cases of noncardia gastric cancer (Continued to page 2)

© Copyright 2010 The Cancer Letter Inc. All rights reserved.

Lung Cancer:

AE-941 Shark Cartilage Doesn't Improve Lung Cancer Survival

... Page 3

Pediatric Cancer:

Surgical Procedure Increased Survival Of Abdominal Cancers

... Page 4

Prevention:

Mothers' Smoking, Depression Influences Teen Smoking

... Page 4

Head & Neck Cancer:

Advanced Radiation Techniques Reduced Swallowing Problems

... Page 5

NCI-Approved Trials

... Page 8

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

Are Screening Mammograms Appropriate In Young Women?

(Continued from page 1)

Chapel Hill, and colleagues, pooled data from six mammography registries around the country. Their study included 117,738 women who had their first mammogram between the ages of 18 and 39.

The researchers followed the women for a year to determine the accuracy of the tests and their cancer detection rates. They analyzed data for both screening mammograms and diagnostic mammograms, which were performed because a woman had a warning sign or symptom, such as a lump.

No cancers were detected in women 25. Among the 73,335 women aged 35-39, the researchers found that screening mammograms had poor accuracy (sensitivity, specificity, and positive predictive value) and high rates of recall for additional tests. The cancer detection rate in this group was 1.6 cancers per 1,000 women.

For diagnostic mammograms, accuracy was better and the detection rate was 14.3 cancers per 1,000 women aged 35-39.

The authors conclude that in a theoretical population of 10,000 women having a screening mammogram between ages 35 and 39, 1,266 would be called back for further testing, 16 cancers would be detected, and therefore 1,250 women would have false positives.

In this population, they write, "our findings support

THE CLINICAL CANCER LETTER

Editor and Publisher: Kirsten Boyd Goldberg

Editorial, Subscriptions, and Customer Service:

202-362-1809 Fax: 202-379-1787 PO Box 9905, Washington DC 20016 Website: http://www.cancerletter.com

THE CLINICAL CANCER LETTER (ISSN 164-985X). Published monthly, subscription \$125 per year, by The Cancer Letter Inc. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, or transmitted in any form (electronic, photocopying, facsimile, or otherwise) without prior written permission of the publisher. Violators risk criminal penalties and \$100,000 damages.

a need for serious discussion about the appropriateness of mammography in women without the presence of symptoms."

In an editorial, Ned Calonge, of the Colorado Department of Public Health and Environment, notes that this "landmark descriptive study should inform women and physicians and guide research efforts" on early detection in younger women.

He emphasizes that even women in the study with a family history of breast cancer had the same detection and false positive rates as women without a known family history. This calls into question he says, the recommendation of some health groups that women with a family history start screening early.

He concludes that "the study by Yankaskas et al. is a powerful reminder that we must continue to strive for better tests and better treatments.... Furthermore, we should not be satisfied with better detection rates alone. We need evidence that early detection of these cancers translates to improvements in important health outcomes."

Cancer Statistics:

Increasing Rates Of Lower Stomach Cancers In Young

(Continued from page 1)

diagnosed from 1977 through 2006. They then compared changes in incidence rates during this 30-year period in groups defined by age, race, and other factors.

The researchers found that the overall incidence rates (cases per 100,000 people) of noncardia gastric cancers declined over the 30-year study period for all races.

Specifically, rates dropped from 5.9 to 4.0 among whites, from 13.7 to 9.5 among blacks, and from 17.8 to 11.7 among other racial groups. However, among whites, different age groups had markedly different incidence rate trends.

Even though incidence rates fell from 20 to 13 among people age 60-84, and from 3 to 2 among those ages 40-59, they increased from 0.27 to 0.45 among those ages 25-39. In contrast, incidence rates of noncardia cancer declined for nearly all age groups among blacks and people of other races.

While noncardia gastric cancer risk is substantially greater for Hispanic than non-Hispanic whites, the SEER data did not distinguish ethnicity-specific rates until 1992.

The investigators conducted an analysis for the

time period 1992-2006 among non-Hispanic whites and observed similar age-specific trends as seen as during the entire study period 1977-2006 among whites overall.

Because infection of the stomach lining by H. pylori is a primary cause of noncardia gastric cancer, changes in infection patterns during the last 50 years might explain the difference in incidence trends between younger and older whites. The declines in noncardia gastric cancer seen in the older cohorts are consistent with observed declines in H. pylori infection, reflecting improved hygiene and less crowding during childhood, when the infections are typically acquired. The increase in younger cohorts may indicate a change in the age at infection or even a reversal of the long-term decline in the prevalence of the infection.

The scientists say it may also be possible that a new carcinogenic process is emerging, perhaps unmasked by eradication of H. pylori.

Apart from H. pylori infection, nutritional exposures, such as consuming salt and salt-preserved foods, have been implicated as risk factors for noncardia gastric cancer. Tobacco smoking is another risk factor for upper and lower stomach cancers.

"Fortunately, the overall burden of stomach cancer has been declining among all racial groups in the United States. However, increasing rates in 25-to-39 year old whites could mean there is an important new risk factor to be identified," said Charles Rabkin, senior author of the NCI study.

The team concludes that additional studies are needed to confirm the trends and investigate risk factors for stomach cancer in younger whites.

Lung Cancer:

AE-941 Shark Cartilage Doesn't Improve Lung Cancer Survival

The anti-cancer drug AE-941, a shark cartilage derivative, did not improve overall survival in patients with inoperable stage III non-small cell lung cancer, according to a study published online May 26 in the Journal of the National Cancer Institute.

The study was one of the few phase III trials of a shark cartilage-derived pharmaceutical agent. Shark cartilage is known to have properties that are antiangiogenic, which means it is able to prevent the growth of new blood vessels around tumors. Antiangiogenic therapies have been shown to improve survival in non-small cell lung and other cancer patients.

To determine whether the addition of AE-941 to

standard chemoradiotherapy in treating patients with non-small cell lung cancer improves overall survival, Charles Lu, from The University of Texas MD Anderson Cancer Center, and colleagues, conducted a randomized, double-blinded, placebo-controlled phase III clinical trial in community and academic oncology centers in the United States and Canada.

The coordinating center was the Community Clinical Oncology Program Research Base at MD Anderson.

The study enrolled 379 patients with unresectable non-small cell lung cancer between May 2000 and February 2006. The patients were treated with chemoradiotherapy and either AE-941 or a placebo, given during and after chemoradiotherapy. The trial was closed early due to low accrual.

The researchers found no statistically significant differences in overall survival, progression-free survival, time to progression, and tumor response rates between the AE-941 and placebo arms of the study.

The placebo arm had a median overall survival of 15.6 months, whereas the AE-941 arm had a median survival of 14.4 months.

The placebo arm had a median time to progression of 10.7 months, compared to 11.3 months for the AE-941 arm.

There was also no difference in progression-free survival between the two arms. AE-941 was well-tolerated.

The authors conclude that, "The addition of AE-941 to chemoradiotherapy did not improve overall survival in patients with unresectable stage III NSCLC. This study does not support the use of shark cartilage-derived products as a therapy for lung cancer."

The authors also note the impetus for the trial comes from "the widespread use of poorly regulated complementary and alternative medicine products, such as shark cartilage-derived agents, among patients with advanced cancer, a population likely to be vulnerable to unsubstantiated marketing claims."

In an accompanying editorial, Jeffrey White, of the Division of Cancer Treatment and Diagnosis, National Cancer Institute, said that although the study does not provide much promise for the usage of shark cartilage extracts, there is growing interest in how purified shark cartilage might be used in therapeutics.

Furthermore, this study showed that "the slight but statistically significant decrease in grade 3 toxicities noted in the AE-941 treated group in the current study may be a sign of activity that is worthy of further investigation," the editorialist writes.

Pediatric Cancer:

An Adult Surgery Adapted To Children Increased Survival Of Rare Abdominal Cancer

A study by a pediatric surgical oncologist from The University of Texas MD Anderson Children's Cancer Hospital shows that an adult surgery adapted for use in young patients increased the survival of children with rare tumors in the abdomen.

The study, reported in the May 20 issue of the Journal of Pediatric Surgery, looked retrospectively at 24 pediatric patients diagnosed with a rare and aggressive pediatric cancer known as desmoplastic small round cell tumor (DSRCT). Patients who received the surgical procedure called hyperthermic intraperitoneal chemotherapy (HIPEC) or "heated chemotherapy," had an overall 3-year survival rate of 71 percent. For patients who received only standard treatment, 26 percent survived three years.

Andrea Hayes-Jordan, assistant professor at the MD Anderson Children's Cancer Hospital, is the first surgeon in the country to perform the adult procedure on children using heated chemotherapy.

"This study demonstrates that the surgical technique is safe and advantageous for patients who have multiple tumors in their abdomen," said Hayes-Jordan, first author of the paper. "In the past, these patients were told there was nothing else to be done, but now we can add months and often years to the lives of these young patients using this surgery."

Previous studies have shown the synergy created when chemotherapy is heated. With HIPEC, Hayes-Jordan will spend 10 to 12 hours removing, or debulking, the hundreds of tumors in a patient's abdominal cavity. Then she will run the chemotherapy, heated at 40 to 41 degrees Celsius (104 to 106 degrees Fahrenheit), throughout the cavity while the patient lies on a cooling blanket to keep the body's temperatures at a safe level. The chemotherapy helps to kill any microscopic tumor cells that are left behind after the debulking surgery. Within one to two months, patients are often fully recovered from surgery and back to their regular activities.

Patients ranging in age from 5 to 43 years were included in the study, but those receiving HIPEC ranged from 5 to 25 years old. Results indicated that younger patients had better outcomes from HIPEC than patients older than 18 years. Disease-free survival was also better for those who received HIPEC in addition to debulking surgery. At one year, disease-free survival was 14

percent for those who only received debulking surgery as compared to 53 percent who received HIPEC.

"We really are encouraged that this is going to help many children with abdominal tumors," said Hayes-Jordan. "We're sharing this technology with other centers so that they will also be able to help these children. In the years to follow, we hope to try different chemotherapies with the procedure to better the outcomes and decrease any toxicities."

DRSCT is a rare and aggressive soft tissue sarcoma that primarily presents as multiple tumors in the abdominal and pelvic area. The disease most often occurs in young Caucasian males, with less than 200 cases being reported worldwide since 1989. The overall survival rate for DSRCT is approximately 30 to 55 percent, which in part is due to the disease being resistant to chemotherapy and radiation often. Hayes-Jordan also attributes the poor outcomes to the tumor cells left behind after debulking surgery that spread in the abdomen and to other organs.

"Four years ago we had little hope to give to families facing this disease we know very little about," said Peter Anderson, professor of pediatrics and senior author on the study. "Using a multi-modality treatment that includes heated chemotherapy, we can see some of our patients experience milestones such as another birthday, a graduation, or even parenthood that they may not have had otherwise."

Hayes-Jordan hopes that the data published from the study will encourage more centers to begin performing HIPEC on pediatric patients with abdominal tumors. She also plans to extend the study to include cancers that metastasize to the abdominal area.

Prevention:

Mothers' Smoking, Depression Influences Teen Smoking

A new study reveals that adolescents aged 12 to 17 living with mothers who are current smokers or who have had a major depressive episode in the past year are far more likely to smoke than adolescents not living under these circumstances.

The study was sponsored by the Substance Abuse and Mental Health Services Administration.

Adolescents living with mothers who currently smoke were nearly three times more likely to take up smoking than adolescents living with non-smoking mothers (16.9 percent versus 5.8 percent). Similarly, adolescents living with mothers who have suffered

from a major depressive episode in the past year were almost twice as likely to take up smoking as adolescents not living in that situation (14.3 percent versus 7.9 percent).

The study revealed adolescents living with mothers who had a major depressive episode and were current smokers were more than four times more likely to smoke than adolescents living with mothers who had neither of these conditions (25.3 percent versus 5.6 percent).

More than 1 in 4 (25.6 percent) of adolescents live with mothers who currently smoke and nearly 1 in 10 adolescents (9.7 percent) live with mothers who have experienced a major depressive episode in the past year. About 1 in 27 (3.7 percent) of all adolescents live with mothers with both of these conditions.

"These findings highlight factors that influence smoking among adolescents. It also suggests that prevention of smoking requires attention to multiple risk factors, including mental illness in the family," said SAMHSA Administrator Pamela Hyde. "Knowing the factors that contribute to smoking helps to design and implement the best approach towards prevention and well-being."

These new data occur against the backdrop of an overall decline in past month smoking rates among adolescents—from 13.0 percent in 2002 to 9.3 percent in 2008. Despite this progress, however, an estimated 1.4 million persons aged 11 to 17 started smoking in the in the past 12 months.

"Adolescent Smoking and Maternal Risk Factors" is based on data collected during 2005 to 2007 from SAMHSA's National Survey on Drug Use and Health, which collected samples from 7, 359 mother-child pairs.

The full report is available at http://oas.samhsa.gov/2k10/166/166SmokingMoms.cfm.

Head & Neck Cancer:

Advanced Radiation Technique Reduced Swallowing Problems

Researchers at the University of Michigan Comprehensive Cancer Center have applied advanced radiation techniques for head and neck cancer to avoid treating critical structures that affect swallowing and eating. A new study shows these principles and techniques treated the cancer effectively while greatly reducing long-term swallowing complications.

The researchers applied highly conformal, intensity-modulated radiation therapy and knowledge of

the anatomy and physiology of the structures involved to carefully craft a novel treatment plan that avoids certain muscles in the mouth and throat that are most involved in swallowing. Generally, head and neck tumors do not spread to these structures.

Of the 73 patients treated with this technique, all but four were eating a normal diet after their treatment ended and only one was dependent on a feeding tube. Typically up to 20 percent of head and neck cancer patients remain dependent on a feeding tube after finishing an intensive course of radiation treatment concurrent with chemotherapy.

Results of the study appear online in the Journal of Clinical Oncology.

"More aggressive treatments for head and neck cancer have improved cancer control, but at the expense of quality of life. In this study, we did not compromise tumor control and we were able to improve this important quality of life measure," said study author Avraham Eisbruch, professor of radiation oncology at the U-M Medical School.

Scar tissue from radiation treatments to the head and neck often creates long-term problems with swallowing and eating solid foods, which does not improve over time.

In this study, 29 percent of the patients required a temporary feeding tube during treatment because of pain while swallowing. But by one year after treatment, only one of the 73 patients on the study still required a feeding tube.

Questionnaires to assess eating and swallowing function showed that on average, patients had only slight difficulties up to two years after treatment.

No patients had a spread of their cancer to the untreated structures and few cancers recurred overall, suggesting it was not harmful to avoid treating these areas. After three years, 88 percent of patients were cancer-free.

Eisbruch and his colleagues were also leaders in pioneering head and neck radiation treatments that avoid the salivary glands, reducing significantly the severity of permanently dry mouth, which has previously been a major complication of radiotherapy for head and neck cancer.

"We seek a cure for these patients, but we also seek quality of life. As cure rates have improved in recent years, quality of life issues become more and more important. Our next steps are to identify which patients are likely to do well with treatment and reduce the intensity of treatment to limit the burden of these side effects," Eisbruch said.

Causation:

Coffee, Soft Drinks Have Little Association With Colon Cancer

Drinking even large amounts of coffee and sugarsweetened, carbonated soft drinks is not associated with the risk of colon cancer according to a large study published online May 7 in the Journal of the National Cancer Institute.

Some previous studies have suggested that coffee and tea may lower the risk of cancer, but others show that they could increase the risk. Tea, for instance contains anti-oxidants that in theory help prevent cancer but also has polyamines, which in theory promote cancer. Sugar-sweetened soft drinks are associated with weight gain, obesity, and other conditions that are potential risk factors for colon cancer.

For this study, Xuehong Zhang, and colleagues at the Harvard School of Public Health analyzed data from 13 studies conducted in North America and Europe. Among 731,441 participants in these studies, there were 5,604 who developed colon cancer. Those who drank large amounts of coffee—more than six 8-oz cups a day—were no more likely to develop the disease than those who drank less.

Likewise, those who drank more than 18 oz daily of sugar-sweetened, carbonated beverages had no higher risk of colon cancer. But the authors note that the results for sugar-sweetened carbonated beverages should be interpreted with caution because only 2% of the study population drank more than 18 oz of these beverages daily.

The results were similar regardless of sex, smoking status, alcohol consumption, body mass index, level of physical activity, and location of the tumor.

The authors found a modest association between drinking high amounts of non-herbal tea—more than four 8-oz cups a day—and colon cancer risk. However, they note that very few people in the study drank that much tea and that the association could be due to chance.

"Drinking coffee or sugar-sweetened carbonated soft drinks was not associated with colon cancer risk," the researchers conclude. "However, a modest positive association with higher tea consumption is possible and requires further study."

In an accompanying editorial, Cynthia Thomson, and Maria Elena Martinez, of the Arizona Cancer Center, note that this study is a valuable contribution to the literature but that more research is needed on the links between childhood consumption of soft drinks

and disease.

"Contrary to coffee and tea consumption, intake of sweetened beverages begins in childhood in many countries," they write. "Furthermore, sweetened beverage consumption is generally much lower among older adults. These differences in exposure suggest that intake of sweetened beverages may need to be assessed earlier in life to adequately assess its association with health outcomes."

Brain Cancer:

Radiotherapy Provides Longer Life To Brain Cancer Patients

Patients who received hypofractionated stereotactic radiotherapy for their recurrent brain cancers lived longer lives, according to researchers at Thomas Jefferson University.

Not only does hypofractionated stereotactic radiotherapy (H-SRT) provide longer survival, patients do not experience side effects commonly seen with use of chemotherapies and targeted therapies, the researchers found. They believe these findings, reported online in the Journal of Clinical Oncology, set a new bar for the treatment of recurrent gliomas.

"In many centers, patients with tumor progression within six months after the initial conformal radiotherapy are denied a second radiotherapy course (such as H-SRT), based on the assumption that their prognosis is poor." said senior author Maria Werner-Wasik, professor of Radiation Oncology at Jefferson Medical College of Thomas Jefferson University and Co-Director of the Stereotactic Radiosurgery Program at Jefferson Hospital for Neuroscience. "Our findings support the recommendation that essentially all patients with progressive high-grade gliomas, who are in good shape and have tumors amenable to local radiotherapy, should be considered for H-SRT."

In this study of 147 patients – currently the largest published series examining re-irradiation of recurrent high grade gliomas using H-SRT – the median survival was about 11 months when H-SRT was used after cancer progressed. In comparison, the newest targeted therapy provides survival of about six months after cancer recurrence, the researchers said.

"These results are dramatic and we hope our experience influences how physicians treat patients with recurrent brain cancer," said study co-author David Andrews, professor of Neurological Surgery and Co-Director of the Stereotactic Radiosurgery Program.

"We will need to design a randomized clinical trial to compare this method of treatment with current standard of care, and these data provide a compelling foundation for the design of such a trial."

The role of chemotherapy with radiation therapy has not been defined for recurrent gliomas and few studies have reported on this.

"While not a randomized trial, our study did not demonstrate a survival advantage in combining chemotherapy with H-SRT at recurrence compared to patients who received H-SRT alone," said the study's first author, Shannon Fogh, M.D., chief resident, Radiation Oncology at Thomas Jefferson University Hospital. "We feel it is important for clinicians to consider this before adding other therapy with associated toxicity and cost."

Thomas Jefferson University Hospital pioneered the use of this particular technology, which uses a stereotactic linear-accelerator-based radiosurgery unit that delivers tightly focused beams of radiation to tumor while sparing the surrounding normal tissue. It does this by using both magnetic resonance imaging (MRI) and computerized tomography (CT) images to create a three-dimensional representation of a tumor that is both anatomically and spatially exact. The radiation is then delivered in doses that conform precisely to the tumor. By irradiating just the tumor, and sparing normal tissue in the brain, physicians can use much higher doses over shorter periods of time.

"We can give a dose that is 50 percent beyond what has been considered the maximum dose of radiation the brain can tolerate," said Dr. Andrews. "We have learned over a 15 year experience that this dose is not only safe, but has almost doubled survival for these patients."

H-SRT can be delivered over two weeks, compared to five or six weeks for standard fractionation, researchers said.

"A shortened treatment course is not only more beneficial to patients with respect to quality of life and convenience but also may represent a significant decrease in cost associated with re-treatment," Dr. Fogh said.

In this study, the researchers determined that the patients who have the longest survival when treated with H-SRT after recurrence are those who are younger, have smaller tumors, and a shorter time between diagnosis and recurrence.

"Perhaps the most surprising and relevant finding from our review is a good prognosis in patients who recurred shortly after initial treatment," Dr. Fogh said. "Only two prior studies have examined prognosis in patients who recur shortly after treatment, and they showed conflicting results. It may be that the larger number of patients examined in our study, compared to the others, allowed us to more accurately assess this phenomenon."

Researchers from the Division of Biostatistics and from the Department of Pharmacology and Experimental Therapeutics at Jefferson Medical College also participated in the study.

Kidney Cancer:

No Benefit To Kidney Removal For Elderly With Kidney Cancer

A new study indicates that patients aged 75 years or older who have confined kidney tumors do not live longer if they have their entire kidney removed.

The research reveals that these patients typically have other medical problems of greater significance and that many should receive more conservative cancer-related care, such as observation or treatments that spare the noncancerous parts of their kidneys.

The study is published early online in CANCER, a peer-reviewed journal of the American Cancer Society.

The incidence of kidney cancer has been on the rise over the past decade, and the greatest increase has been observed in the later years of life. Physicians currently struggle with deciding which treatment—observation, kidney-sparing surgery, or total kidney removal—will be most beneficial for elderly patients with localized kidney cancer.

To investigate whether surgical kidney removal, or nephrectomy, improves survival when compared with active monitoring or kidney-sparing surgery, Steve Campbell, of the Cleveland Clinic and his colleagues studied information from 537 patients with localized kidney tumors that were =7cm in diameter and were detected at age 75 years or older. Twenty percent of these patients were closely observed, 53 percent had kidney-sparing surgery, and 27 percent underwent a nephrectomy.

After an average follow-up period of approximately four years, 28 percent of patients died. The most common cause of death was heart-related (29 percent). Cancer progression was responsible for only four percent of deaths. Older age and additional medical conditions increased patients' risk of dying during the follow-up period, but choice of treatment did not.

The analysis also revealed that patients who had

a cancerous kidney removed experienced accelerated dysfunction of their remaining kidney. Kidney removal also appeared to increase patients' risk of dying from cardiovascular causes.

"Current research is indicating over-treatment of localized renal tumors, and our data suggest that active surveillance is a reasonable strategy and one that is greatly underutilized in the elderly population," the authors wrote. They added that the potential benefit of kidney-sparing surgery in elderly patients who have the lowest risk for heart-related deaths and the greatest life expectancy warrants further investigation.

ASCO Annual Meeting Abstracts Posted Online

The more than 4,000 scientific abstracts that will be presented at the American Society of Clinical Oncology Annual Meeting are now publicly available at http://abstract.asco.org.

Included in this release are the abstract titles and author names for all Late-Breaking, Clinical Review, and Plenary Abstracts; full-text versions of all other abstracts being presented at the meeting; and full-text versions of online-only abstracts published in conjunction with the Annual Meeting. All abstracts are fully searchable.

NCI Approved Clinical Trials

The National Cancer Institute Cancer Therapy Evaluation Program approved the following clinical research studies last month. For further information, contact the principal investigator listed.

Phase I

8298 A Phase I Study of the Histone Deacetylase Inhibitor Entinostat plus Clofarabine for Philadelphia Chromosome-Negative, Poor Risk Acute Lymphoblastic Leukemia or Bilineage/Biphenotypic Leukemia in Newly Diagnosed Older Adults or in Adults with Relapsed and Refractory Disease, Johns Hopkins University. Carraway, Hetty Eileen, (410) 502-3809.

Phase I/II

8384 A Randomized Phase Ib/II Study of Preoperative GDC-0449 and Androgen Ablation Compared to Androgen Ablation Alone Followed by Radical Prostatectomy for Select Patients with Locally Advanced Adenocarcinoma of the Prostate, MD Anderson Cancer Center. Logothetis, Christopher, (713) 792-2830.

Phase II

8341 Phase II Study of Azacitadine and Entinostat in Patients with Metastatic Colorectal Cancer, Mayo Clinic Rochester, Azad, Nilofer S. (410) 614-9169.

ABTC-0906 A Phase II and Pharmacodynamic Trial of RO4929097 for Patients with Recurrent/Progressive Glioblastoma, Adult Brain Tumor Consortium. Peereboom, David Marc, (216) 445-6068.

E1608 A Phase II Trial of GM-CSF Protein Plus Ipilimumab in Patients with Advanced Melanoma, Eastern Cooperative Oncology Group. Hodi, Frank Stephen, (617) 632-5053.

E1808 A Randomized Phase II Trial of Sunitinib/ Gemcitabine or Sunitinib in Advanced Renal Cell Carcinoma with Sarcomatoid Features, Eastern Cooperative Oncology Group. Balzer-Haas, Naomi Susanne, (215) 662-7402.

E1B09 A Phase II Trial of AMG 102 in Combination with Pemetrexed and Cisplatin in Patients with Malignant Pleural Mesothelioma, Eastern Cooperative Oncology Group. Stevenson, James Philip, (215) 662-8628.

E3108 A Phase II Prospective Trial Correlating Progression Free Survival with CYP2D6 Activity in Patients with Metastatic Breast Cancer Treated with Single Agent Tamoxifen, Eastern Cooperative Oncology Group. Stearns, Vered, (443) 287-6489.

GOG-0170QAPhase II Evaluation of Intraperitoneal EGEN-001 (IL-12 Plasmid Formulated with PEG-PEI-Cholesterol Lipopolymer) in the Treatment of Persistent or Recurrent Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer, Gynecologic Oncology Group. Alvarez, Ronald David, (205) 934-4986.

S0933 Phase II Study of RO4929097 in Advanced Melanoma, Southwest Oncology Group. Margolin, Kim Allyson (206) 288-7565.

Phase III

GOG-0263 Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy, Gynecologic Oncology Group. Ryu, Sang Young, 82-2-970-1227.

GOG-0263 Randomized Phase III Clinical Trial of Adjuvant Radiation Versus Chemoradiation in Intermediate Risk, Stage I/IIA Cervical Cancer Treated with Initial Radical Hysterectomy and Pelvic Lymphadenectomy, Gynecologic Oncology Group. Ryu, Sang Young, 82-2-970-1227.