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THE
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Cancer research news for clinicians

Cancer Screening:

Aggressive Cancer Screening Increases Overdiagnosis, JAMA Paper Argues

Twenty years of screening for breast and prostate cancer—the most diagnosed cancers for women and men respectively—have not brought the anticipated decline in deaths from these diseases, argue experts from the University of California, San Francisco and The University of Texas Health Science Center at San Antonio in an opinion piece published in the Journal of the American Medical Association.

Instead, overall cancer rates are higher, many more patients are being

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Clinical Trials:

Cancer Centers Begin Free Genetic Tumor Testing Project For Lung Cancer Patients

The University of Colorado Cancer Center and 13 other leading centers will begin free genetic tumor screenings for lung cancer patients because of a $5.2 million Grand Opportunities grant, funded by the American Recovery and Reinvestment Act.

The project, called the Lung Cancer Mutation Consortium Protocol, aims to identify mutations in lung adenocarcinoma tumors for which there are specific, more effective and less toxic oral therapies.

Paul Bunn Jr., a lung cancer researcher and UCCC's founding director, will lead the consortium. Wilbur Franklin, professor of pathology at the University of Colorado Denver and UCCC member, is the Colorado principal investigator.

"We will be testing the tumors for specific mutations we know happen in lung cancer to understand their frequency, their relationship to each other and their association with the tumor's clinical features," said Bunn, professor of medical oncology at the University of Colorado Denver School of Medicine. "We will also be investigating what specific drugs work against these mutations and how often they work."

Patients who enroll in the clinical trial to have their tumor tested may also qualify for an existing clinical trial for a specific inhibitor drug, such as erlotinib for EGFR overexpression, the most common gene mutation seen in adenocarcinoma tumors of the lungs.

Last year, UCCC lung cancer scientists published a study that showed erlotinib combined with standard chemotherapy doubled the expected lifespan for lung cancer patients with EGFR-positive tumors. Those same

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Screening Hasn't Lowered Death Rates, Paper Says

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treated, and the incidence of aggressive or later-stage disease has not been significantly decreased, the authors conclude. Current screening programs are leading to "potential tumor over-detection and over-treatment," they write in the Oct. 21 issue of JAMA.

"People will think that we're saying screening is bad, and nothing could be further from the truth," said Ian Thompson, professor and chairman of the Department of Urology at the UT Health Science Center. "What we are saying is that if you want to stop suffering and death from these diseases, you can't rely on screening alone."

The authors said that breast cancer and prostate cancer screening has not led to a more significant drop in deaths in the U.S. for two primary reasons: Screening increases the detection of slow growing and idle tumors, and it often misses the most aggressive cancers because many may not be detected early enough for cure.

"The basic assumption that screening programs that find and treat early-stage disease will then prevent late-stage disease, or prevent cancer from spreading, may not always be correct," added Thompson. "If a tumor is aggressive, finding it early may not prevent death."

Thompson holds the Glenda and Gary Woods Distinguished Chair in Genitourinary Oncology at the Cancer Therapy & Research Center at the UT Health Science Center at San Antonio, and the Henry B. and Edna Smith Dielmann Memorial Chair in Urologic Science at the UT Health Science Center. He led the Prostate Cancer Prevention Trial, a study of 18,882 men from around the U.S., which demonstrated that the drug finasteride reduces a man's risk of prostate cancer by 24.8 percent.

"Screening does provide some benefit, but the problem is that the benefit is not nearly as much as we hoped and comes at the cost of over-diagnosis and over-treatment," said Laura Esserman, professor of surgery and radiology, director of the UCSF Carol Franc Buck Breast Care Center, and co-leader of the breast oncology program at the UCSF Helen Diller Family Comprehensive Cancer Center.

"We need to focus on developing new tools to identify men and women at risk for the most aggressive cancers, to identify at the time of diagnosis those who have indolent or 'idle' tumors that are not life-threatening," she added. "If we can identify groups of patients that don't need much treatment, or don't need to be screened, wouldn't that be great? Screening is by no means perfect. We should want to make it better. For both breast and prostate cancer, we need to invest in changing our focus from the cancers that won't kill people to the ones that do."

Otis Brawley, chief medical officer of the American Cancer Society, said the paper is right on target. "In the case of some screening for some cancers, modern medicine has overpromised. Some of our successes are not as significant as first thought," said Brawley, professor of hematology, oncology and epidemiology at Emory University. "Cancer is a complicated disease, and too often we have tried to simplify it and simplify messages about it, to the point that we do harm to those we want to help."

The two diseases account for 26 percent of all cancers in the U.S., with an estimated 386,560 patients diagnosed annually.

Because of remarkable survival rates when the diseases are treated before they spread, screening for both cancers has been promoted on the assumption that early detection and treatment is the best way to reduce deaths. Consequently, much of the U.S. population undergoes routine screening for the cancers: About half of at-risk men have a routine prostate-specific antigen test, and 75 percent have previously had a PSA test. About 70 percent of women older than 40 report having had a recent mammogram. More than $20 billion is spent annually screening for the two diseases in the U.S.

The screenings have resulted in a "significant

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increase" in early cancers being detected, according to the article authors. Because of PSA testing, the chances of a man being diagnosed with prostate cancer have nearly doubled: In 1980, a white man's lifetime risk of the cancer was one in 11; today it is one in six. Similarly, a woman's lifetime risk of breast cancer was one in 12 in 1980; today it is one in eight. And, if ductal carcinoma in situ is included, the risk of being diagnosed with breast cancer, like prostate cancer, has nearly doubled as well.

But the authors found that while deaths have dropped for both cancers over the last 20 years, "the contribution from screening is uncertain." They also found that many patients are undergoing treatment from cancers that actually pose minimal risk.

A comparison of prostate cancer incidence rates in the U.S. to the United Kingdom, where PSA screening has not been widely adopted, "did not result in significant differences in mortality," the authors write. For breast cancer the relative reduction in deaths from screening has also been limited.

Clinical Trials:

Centers Begin Gene Testing For Lung Cancer Patients

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UCCC scientists developed the screening tool for EGFR expression.

"We've shown in many studies now that if we know what the gene problems are in your tumor and we have drugs that takes advantage of those problems, then you are likely to get better results, have better quality of life and live longer than if we treat you with the old standard of care," Bunn said. "Cancer is no longer a one-size-fits-all disease. We have to have as much information as possible to give the exact right treatment to each and every patient. This project should give us much more information than we've ever had before."

Clinical trial enrollment is open in Colorado. Patients who wish to enroll in the study can schedule an appointment with the University of Colorado Cancer Center lung cancer team by calling Mary Jackson, 303-724-1650.

The free tumor testing is also taking place at: The Brigham and Women's Hospital, Dana Farber Cancer Institute, Emory University/Winship Cancer Center, Moffitt Cancer Center, Johns Hopkins/Sidney Kimmel Cancer Center, MD Anderson Cancer Center, Mass General Hospital Cancer Center, Memorial-Sloan Kettering Cancer Institute, National Cancer Institute, UCLA/Jonssen Cancer Center, University of Pittsburgh Cancer Institute, University of Texas-Southwestern Cancer Center, and Vanderbilt-Ingraham Cancer Center.

Pediatric Cancer:

New Protocol Could Improve Survival Of Rare Brain Tumor

A team of researchers led by University of Texas M.D. Anderson Cancer Center reported results from the largest-ever collaborative study addressing the treatment of a rare pediatric brain tumor. The findings suggest a new standard protocol could improve survival nearly two-fold for pediatric patients with choroid plexus tumors, as reported at the 41st Annual Meeting of the International Society of Pediatric Oncology.

Johannes Wolff, professor in the Children's Cancer Hospital at M. D. Anderson Cancer Center and lead investigator on the study, said that the protocol, consisting of three chemotherapy agents and radiation, had projected overall survival rates of 93 percent at one year, 82 percent at five years, and 78 percent at eight years.

"This SIOP 2000 study started 10 years ago and has grown to include more than 100 institutions from more than 20 countries," said Wolff. "With the data we have, we can tell which patients are prone to do better and which ones have a poor prognosis. In addition, we've established a promising standard protocol for these patients."

Choroid plexus carcinomas are malignant brain tumors that originate in the choroid plexus epithelium, which is the gland that produces cerebrospinal fluid. Often the tumors may block the flow of cerebrospinal fluid causing pressure to build in the brain and possibly enlarge the skull. It is a very rare tumor affecting approximately 1,500 children worldwide each year, occurring more often in infants.

Due to the rarity of the disease, there is no standard treatment protocol for the disease, but Wolff and other international researchers hope to change that through their studies. They also developed an innovative statistical module for institutions to use that will ensure quality and efficient data coming out of the study.

One surprising finding Wolff and fellow researchers discovered contradicted historical research, which originally showed the significant advantage of complete surgical resection. The SIOP 2000 study found that patients receiving the intense chemotherapy protocol had similar outcomes as those with complete resection,

reducing the need for surgical treatment.

"We think the better outcomes had to do with the fact that physicians will prolong chemotherapy treatment if there is residual tumor," said Wolff. "If we can prove this hypothesis, this would be an argument for extending treatment in the future."

Wolff said the next step will be to begin another study that will investigate a four-armed chemotherapy protocol. This would investigate the possibility of adding another chemotherapy to further improve survival rates. The SIOP 2000 study used carboplatinum, etoposide and cyclophosamide in combination with radiation.

The study was funded through the German Children's Cancer Foundation.

Breast Cancer:

Computer Learning May Help Women In Treatment Decision

A computer-based decision-making aid may make it possible for more women to have breast reconstruction after surgical treatment for cancer. The tool has helped women play a larger role in decision-making, according to results from a new study reported at the 2009 Clinical Congress of the American College of Surgeons.

Women who used the computer-based learning module were more involved in choosing reconstruction than those who did not, and they believed they were offered a greater number of options for breast reconstruction. The study was conducted at Beth Israel Deaconess Medical Center and Harvard Medical School.

Nearly three-quarters of 168 women who had access to the decision-making aid reported they were solely or mostly responsible for choosing breast reconstruction compared with a little over half of 87 women who did not use the tool. The women also retained more information and were more satisfied with the amount of information they received. Four times more women reported they had learned about four types of reconstruction if they had seen the computer-based learning module (24 percent) than those who had not (six percent). Eighty-four percent of women who used the tool were very satisfied compared with 75 percent of those who did not, according to Bernard Lee, an instructor in plastic surgery, Beth Israel Deaconess Medical Center and Harvard Medical School.

The computer-based decision aid explains each of five breast reconstruction options, presents data on outcomes from the clinical literature, and includes pictures and diagrams. "It talks about what the surgery is like, the postoperative recovery, and the different stages of the operation. It is very comprehensive, almost encyclopedic, but in a very user-friendly sort of format," Lee said.

The decision-making tool was given to patients in the form of a compact disc so they could view the information at home in privacy and at their leisure. "When patients are sitting in your office and you're going through a consultation with them, they may absorb only 10 percent or 20 percent of what you're talking about. However, if you offer patients one of these computer aids, they can sit at home in front of a computer, pop in the CD, and go back and forth to look at all the available pictures and information. There is no major rush," Lee said.

Use of the CD was not tested in physicians' offices. However, it could be a valuable adjunct to the education of patients following an operation for breast cancer. Patients that did not view the CD at home were also shown the presentation in the office prior to the standard consultation. These patients found it to be a valuable educational tool in presenting the different choices in breast reconstruction.

"Nowadays, it becomes difficult to spend a lot of time with patients explaining things to them during surgical consultations. We haven't looked at this [scenario] yet, but if you have a good framework for discussing the questions with patients, you could potentially reduce the time that you need to spend with patients but still increase their understanding of the problem," Lee said.

The underlying hope is to increase the number of women who have breast reconstruct-tion. Even though improvements in body image and self-esteem have been well documented following breast reconstruction, only about 20 percent of women undergo the procedure. A major reason is the lack of referrals for consultation about breast reconstruction.

In another new separate study reported at the ACS Clinical Congress, 92 percent of 313 patients who were referred for consultation underwent breast reconstruction. None of the 158 patients who were not referred had reconstructive surgery. "Patients who are being referred are much more likely to be reconstructed. If they aren't referred, the patients are not taking it upon themselves to find out about breast reconstruction. Patients should be given that option," said Beth Aviva Preminger, an instructor in plastic surgery at Columbia University who conducted the study under the direction of Christine Rhode, from New York Presbyterian Hospital, New York City.

The study emphasized the role of the breast surgeon as the gatekeeper for breast reconstruction procedures, Preminger said. "The breast surgeon is there for the treatment of cancer. The focus is obviously on getting the cancer out and treating the patients until they get well. Appropriately so. The question is whether breast surgeons are spending enough time discussing reconstruction with the patient, and if they're not, are they sending every patient to a plastic surgeon to be evaluated? Because breast surgeons do not necessarily always know who is or who isn't a good candidate for reconstruction," she added.

An emerging standard of care is to perform breast reconstruction immediately after cancer treatment so the patient can be spared another operation. "Patients can wake up from the operation thinking they have started on the way to recovery. But there are some instances when the patient is not a candidate for immediate reconstruction. These are issues that a plastic surgeon should have the opportunity to discuss with the patient. Our study underlines to general surgeons—breast surgeons in particular—the importance of sending patients to a plastic surgeon so patients can have that conversation and understand what their options are," Preminger explained.

The study also has a message for patients. "Patients need to be advocates for their own care. They need to ask for a referral if they are not getting one, so they make an informed decision about their care," she concluded.

FDA Approvals:

Arzerra Given Accelerated Approval For Leukemia

The U.S. Food and Drug Administration approved Arzerra (ofatumumab) for patients with chronic lymphocytic leukemia, a slowly progressing cancer of the blood and bone marrow.

Arzerra is approved for patients with CLL whose cancer is no longer being controlled by other forms of chemotherapy.

CLL primarily affects people older than 50 and arises from a group of white blood cells known as B-cells that are part of the body's immune system. Each year, about 16,000 people are diagnosed with CLL and about 4,400 people die from the disease.

Arzerra is a monoclonal antibody, a type of biotechnology product. Antibodies that occur in nature are produced by the immune system in response to invaders. Arzerra binds to a specific protein found on the surface of both normal and malignant B cells, making the cells more susceptible to immune system attack.

The product was approved under the FDA's accelerated approval process, which allows earlier approval of drugs that meet unmet medical needs. Products may receive accelerated approval based on a surrogate endpoint, such as a reduction in the size of the tumor or decrease in the number of cancerous white cells or in an enlarged spleen or lymph nodes. These indirect measures for clinical outcomes are considered reasonably likely to predict that the drug will allow patients to live longer or with fewer side effects of a disease.

"The approval of Arzerra illustrates FDA's commitment to using the accelerated approval process to approve drugs for patients who have limited therapeutic options," said Richard Pazdur, director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research.

The accelerated approval process requires further study of the drug. The manufacturer is currently conducting a clinical trial in CLL patients to confirm that the addition of Arzerra to standard chemotherapy delays the progression of the disease.

Arzerra's effectiveness was evaluated in 59 patients with CLL whose disease no longer responded to the available therapies.

The product's safety was evaluated in 181 patients in two studies in patients with cancer. Common side effects included a decrease in normal white blood cells, pneumonia, fever, cough, diarrhea, lower red blood cell counts, fatigue, shortness of breath, rash, nausea, bronchitis and upper respiratory tract infections.

The most serious side effects of Arzerra are increased chance of infections, including progressive multifocal leukoencephalopathy (PML), a brain infection that is generally fatal. Patients at high risk for Hepatitis B should be screened before being treated with Arzerra. Patients with evidence of inactive hepatitis should be monitored for re-activation of the infection during and after completing treatment.

Arzerra is manufactured by London-based GlaxoSmithKline.

GSK's Votrient Approved For Advanced Kidney Cancer

FDA approved Votrient (pazopanib), the sixth drug to be approved for kidney cancer since 2005.

Votrient is an oral medication that interferes with angiogenesis, the growth of new blood vessels needed for solid tumors to grow and survive.

Votrient is intended for people with advanced renal cell carcinoma, a type of kidney cancer in which the cancerous cells are found in the lining of very small tubes (tubules) in the kidney. In 2009, approximately 49,000 people were diagnosed with renal cell carcinoma and 11,000 people died from the disease.

"The last five years have seen dramatic improvements in treatment options for patients with kidney cancer. Before 2005, the options available offered only limited effectiveness," said Richard Pazdur, director, Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research.

The five other drugs approved for kidney cancer and their approval dates are: Sorafenib (December 2005), Sunitinib (January 2006), Temsirolimus (May 2007), Everolimus (March 2009), and Bevacizumab (July 2009).

The safety and effectiveness of Votrient was evaluated in a 435-patient study that examined a patient's progression-free survival – the length of time, following enrollment in the study, before the tumor began growing again or before the patient died. Progression-free survival averaged 9.2 months for patients receiving Votrient compared to 4.2 months for patients who did not receive the drug.

Adverse reactions included diarrhea, high blood pressure, hair color changes, nausea, loss of appetite, vomiting, fatigue, weakness, abdominal pain and headache. Votrient can also cause severe and fatal liver toxicity. Health care professionals should order blood tests to monitor liver function before and during treatment with the drug. Since Votrient can harm a fetus, it should not be used during pregnancy.

The drug has also been associated with heart rhythm irregularities. Patients receiving Votrient should be monitored with periodic electrocardiograms, which measure heart rhythm, and blood tests to monitor electrolytes since an electrolyte imbalance can lead to an irregular heart rhythm.

Votrient is manufactured by London-based GlaxoSmithKline.

Cervarix Vaccine Approved To Prevent Cervical Cancer

FDA approved Cervarix, a new vaccine to prevent cervical cancer and precancerous lesions caused by human papillomavirus (HPV) types 16 and 18. The vaccine is approved for use in girls and women ages 10 years through 25 years.

Genital HPV infections are the most common sexually-transmitted diseases in the United States, and HPV types 16 and 18 are the cause of about 70 percent of cervical cancers worldwide. There will be an estimated 11,270 new cases and 4,070 deaths from cervical cancer in the United States during 2009, according to the National Cancer Institute at the National Institutes of Health.

"The licensure of Cervarix adds another option in the prevention of cervical cancer" said Karen Midthun, acting director of the FDA's Center for Biologics Evaluation and Research. "It has the potential to save lives from cervical cancer as well as reduce the need for biopsies and invasive procedures associated with the necessary follow-up from abnormal Pap tests."

The primary clinical study for Cervarix included more than 18,000 women ages 15 years through 25 years in the United States and 11 other countries. Of these women, about 9,000 received Cervarix and 9,000 received Havrix, a licensed hepatitis A virus vaccine, as a control.

The results showed that among women who had not already been infected by HPV types 16 and/or 18 before the start of the study, Cervarix was about 93 percent effective in preventing precancerous cervical lesions caused by these HPV types. Among all Cervarix vaccinees, which included those who tested negative for HPV 16 and/or 18, and those who tested positive at the start of the study, Cervarix was approximately 53 percent effective in preventing precancerous cervical lesions.

Studies also were performed to measure the immune response to Cervarix in girls ages 10 years through 14 years. Their immune response was similar to that of women ages 15 years through 25 years, indicating that the vaccine should have similar effectiveness in the 10 through 14 year age group.

The current data show that Cervarix provides protection for about 6.4 years, but additional information on the length of protection is forthcoming.

No vaccine is 100 percent effective, and Cervarix does not protect against HPV infections that an individual may already have at the time of vaccination, nor does Cervarix necessarily protect against those HPV types not in the vaccine. Therefore, regular Pap tests continue to be recommended for all women who receive Cervarix. Pap screening remains critically important to detect precancerous changes, which would allow treatment before cancer develops.

Cervarix contains the adjuvant ASO4. ASO4 is a combination of aluminum hydroxide and monophosphoryl lipid A (MPL) and is the first vaccine licensed by the FDA that includes MPL as an adjuvant.

An adjuvant is a substance incorporated into a vaccine that enhances or directs the immune response of the vaccinated individual.

The safety of the vaccine was evaluated in about 24,000 girls and women, with about 13,000 of these receiving Cervarix. The most commonly reported adverse reactions in the Cervarix group included pain, redness, and swelling at the injection site, fatigue, headache, muscle and joint aches, and gastrointestinal distress.

Although Cervarix is not indicated for pregnant women, the FDA is requiring the manufacturer, GlaxoSmithKline Biologicals to conduct a postmarketing study to assess the safety of Cervarix in pregnant women following vaccination prior to identification of pregnancy. Women who are pregnant, or think that they may be pregnant, or plan to become pregnant during the vaccination course, should not use Cervarix.

Cervarix is administered in three separate shots, with the initial dose being followed by two additional shots at one and six months.

Cervarix is manufactured by GlaxoSmithKline Biologicals, based in the United Kingdom.

FDA also approved the HPV vaccine Gardasil for the prevention of genital warts in boys. Gardasil is already approved and is being actively used in girls and young women for the prevention of cervical cancer. Gardasil is a quadrivalent vaccine that is designed to specifically protect against infections with four HPV types: 16, 18, 6, and 11. HPV types 6 and 11, which are not considered to be oncogenic, cause genital warts.

The agency's approval of Gardasil for boys aged 9 to 26 is based on data from a randomized clinical trial of more than 4,000 males aged 16 to 26, which demonstrated 90 percent protection against HPV 6- and 11-related genital warts.

In a press statement announcing the approval, the FDA explained that for boys aged 9 to 15, studies have been conducted to measure their immune response to the vaccine, and "the results showed that the immune response was as good as that found in the 16- to 26-year-old age group, indicating that the vaccine should have similar effectiveness."

A number of studies have now linked infection with HPV 16 to certain types of head and neck cancers, in particular oropharyngeal cancer (the tonsils and base of the tongue), the rates of which have been increasing over the last decade. So there is a chance, some researchers believe, that widespread HPV vaccination of both males and females could have a broader cancer prevention effect.

NCI Cooperative Group Clinical Trials Approved

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

ADVL0916 A Phase I Study of Vorinostat and Bortezomib in Children with Refractory or Recurrent Solid Tumors, Including CNS Tumors and Lymphomas, COG Phase 1 Consortium. Muscal, Jodi (832) 822-1527.

GOG-9923 A Phase I Study of Carboplatin/Paclitaxel/CTEP Supplied Agent Bevacizumab and CTEP Supplied Agent ABT-888 in Newly Diagnosed Patients with Previously Untreated Epithelial Ovarian, Fallopian Tube or Primary Peritoneal Cancer, Gynecologic Oncology Group. Bell-McGuinn, Katherine Marie (212) 639-8396.

Phase II

8060 A Multicenter Random Assignment Phase II Study of Irinotecan and Alvocidib (Flavopiridol) Versus Irinotecan Alone for Patients with p53 Wild Type Gastric Adenocarcinoma, Memorial Sloan Kettering Cancer Center. Shah, Manish Arvind (212) 639-3113.

8340 Phase II Single-Arm Trial Comparing the Use of FLT PET to Standard Computed Tomography to Assess the Treatment Response of Neoadjuvant Docetaxel and Cisplatin in Stage IB-IIIA Resectable Non-Small Cell Lung Cancer, Johns Hopkins University. Wahl, Richard Leo (410) 614-3764.

8418 A Multi-Center, Double Blind, Placebo-Controlled, Randomized Phase II of Gemcitabine Plus GDC-0449, a Hh Pathway Inhibitor, in Patients with Metastatic Pancreatic Cancer, University of Chicago. Kindler, Hedy Lee (773) 702-0360.

ACRIN-6685 A Multicenter Trial of FDG-PET/CT Staging of Head and Neck Cancer and Its Impact on the N0 Neck Surgical Treatment in Head and Neck Cancer Patients,

American College of Radiology Imaging Network. Lowe, Val J. (507) 284-4104.

E4508 Three-Arm Randomized Phase II Study of Carboplatin and Paclitaxel in Combination with Cetuximab, IMC-A12 or Both for Advanced Non-Small Cell Lung Cancer Patients Who Will Not Receive Bevacizumab-Based Therapy, Eastern Cooperative Oncology Group. Hanna, Nasser H. (317)274-3515.

GOG-0126T A Phase II Evaluation of Belinostat and Carboplatin in the Treatment of Recurrent or Persistent Platinum-Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gynecologic Oncology Group. Dizon, Don S. (401) 453-7520.

RTOG-0839 Randomized Phase II Study of Pre-operative Chemoradiotherapy +/- Cetuximab Followed by Consolidation Chemotherapy +/- Cetuximab in Potentially Operable Locally Advanced (Stage IIIA, N2+) Non-Small Cell Lung Cancer, Radiation Therapy Oncology Group. Edelman, Martin J. (410) 328-2703.

RTOG-0926 A Phase II Protocol for Patients with Stage T1 Bladder Cancer to Evaluate Selective Bladder Preserving Treatment by Radiation Therapy Concurrent with Cisplatin Chemotherapy Following a Thorough Transurethral Surgical Re-Staging, Radiation Therapy Oncology Group. Shipley, William U. (617) 726-8146.

Phase III

AHEP0731 Treatment of Children with All Stages of Hepatoblastoma, Children's Oncology Group. Katzenstein, Howard Mark (404) 785-0853.

E3F05 Phase III Study of Radiation Therapy with or without Temozolomide for Symptomatic or Progressive Low-Grade Gliomas, Eastern Cooperative Oncology Group. Schiff, David 434-982-4415.

Other

8069 A Preoperative Biological Trial of Cetuximab, Dasatinib or the Combination in Colorectal Cancer Patients with Resectable Liver Metastases, Vanderbilt-Ingram Cancer Center. Chan, Emily (615) 322-4967.

8395 Evaluation of Food Effect on Pharmacokinetics of GDC-0449, an Inhibitor of Hedgehog Signaling, University of Chicago. Cohen, Ezra Eddy Wyssam (773) 702-4137.

AAML10B06 Mitochondrial Mutations and AML, Children's Oncology Group. Bielas, Jason H. (206) 667-3170.

AAML10B10 Stat3 Signaling Pathway Aberrancies in Pediatric AML, Children's Oncology Group. Redell, Michele Simmons (832) 822-4824.

AAML10B2 Identification of de novo Fanconi Anemia Patients Using FANCD2 Western Blots, Children's Oncology Group. Thakar, Monica S. (206) 667-5946.

AAML10B3 Pharmacogenetics of Mylotarg, Children's Oncology Group Lamba, Jatinder (612) 624-8651.

AAML10B4 Evaluation of Mer and Axl Expression in Acute Myeloid Leukemia Patient Samples, Children's Oncology Group. Eisenman, Kristen Michelle (303) 724-4007

AAML10B5 Implications of s-SHIP Expression and SHIP Alterations in AML, Children's Oncology Group. Ho, Phoenix (206) 667-7640.

AAML10B7 WT-1's Role in Leukemogenesis, Children's Oncology Group Moazam, Mustafa M. (330) 543-3325.

AAML10B8 NOD-SCID Mouse Engraftment: Characterization of LIC Phenotype and Assessment of LIC Frequency/Function in Cytogenetically-Defined Risk Groups in AML, Children's Oncology Group. Horton, Terzah M. 832-824-4269.

AAML10B9 Epigenetic Alterations in AML, Children's Oncology Group. Meshinchi, Soheil (206) 667-4077.

ACOSOG-Z4095 Reducing Futile Surgery for Pulmonary Nodules with a Clinical and Molecular Prediction Model Highly Specific for Lung Cancer, American College of Surgeons Oncology Trials Group. Grogan, Eric L. (615) 322-0248.

AOST10B1 Gene Discovery in Osteosarcoma, Children's Oncology Group. Gorlick, Richard G. (718) 741-2342.

AREN09B1 A Genome-Wide Association Study in Wilms Tumor, Children's Oncology Group. Grundy, Paul E. (780)407-8829.

E2L09T1 Comparison of Proteomic Signaling Read Outs Between Paired Bone Marrow and Peripheral Blood Samples from ECOG Study 3999, Eastern Cooperative Oncology Group. Paietta, Elisabeth (718) 920-9520.

S9032-S9300-A Gene Expression and Function Associated with Chronic Myeloid Leukemia Progression, Southwest Oncology Group. Oehler, Vivian Gudrun (206) 667-1340.