### THE NICAL CANCER LI

Cancer research news for clinicians

### Neuroblastoma:

### **New Immunotherapy Increased Survival** Of Neuroblastoma In Phase III Trial

Administering a new form of immunotherapy to children with neuroblastoma increased the percentage of those who were alive and free of disease progression after two years. The percentage rose from 46 percent for children receiving a standard therapy to 66 percent for children receiving immunotherapy plus standard therapy, according to the study in the Sept. 30 New England Journal of Medicine.

The randomized phase III clinical trial was coordinated by the Children's Oncology Group, a national consortium of researchers supported by NCI.

Neuroblastoma is responsible for 12 percent of all deaths due to cancer in children under 15 years of age. It is the most common non-brain solid tumor in children. Nearly 50 percent of patients with neuroblastoma have a (Continued to page 2)

### End-of-Life Care:

### Cancer Patients Who Die In Hospital Or ICU Have Worse QOL: Caregivers Affected, Too

Cancer patients who die in the hospital or an intensive care unit have worse quality of life at the end-of-life, compared to patients who die at home with hospice services, and their caregivers are at higher risk for developing psychiatric illnesses during bereavement, according to a study by researchers at Dana-Farber Cancer Institute.

One striking finding of the study, reported in the Journal of Clinical Oncology, was that bereaved caregivers of patients who died in an intensive care unit (ICU) were five times more likely to be diagnosed with Posttraumatic Stress Disorder (PTSD), compared with caregivers of patients who died at home with hospice services.

"This is the first study to show that caregivers of patients who die in ICUs are at a heightened risk for developing PTSD," wrote the authors, led by Alexi Wright, a medical oncologist and outcomes researcher at Dana-Farber. The American Medical Association Glossary defines PTSD as "feelings of anxiety experienced after a particularly frightening or stressful event, which include recurring dreams, difficulty sleeping, and a feeling of isolation."

In addition, families and loved ones of patients who died in the hospital, though not in an ICU, were at higher risk of developing Prolonged Grief Disorder (PGD), an intense and disabling form of grief which lasts more than six months.

The report comes at a time of growing concern over the appropriateness (Continued to page 6)

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### **Neuroblastoma Study Results To Change Clinical Practice**

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high-risk form of the disease and have poor long-term survival despite very intensive treatment.

"We expect these findings will change clinical practice, setting a new gold standard of treatment for this often-deadly disease," said John Maris, a co-author of the study and director of the Center for Childhood Cancer Research at The Children's Hospital of Philadelphia. Maris is the chair of the neuroblastoma committee of the Children's Oncology Group.

The previously established standard treatment for neuroblastoma uses high doses of chemotherapy to destroy as many cancer cells as possible. But this form of chemotherapy (myleoablative therapy) also destroys some normal blood-forming cells, so it is followed by giving back previously collected blood-forming cells to restore immune system function and blood cell formation.

Patients who respond to this therapy are then given the drug isotretinoin to further treat any remaining cancer cells. Isotretinoin is a derivative of vitamin A and is also used to treat severe acne. Moreover, it has been found to prevent the proliferation of neuroblastoma cells. More than half of the patients with high-risk neuroblastoma treated in this manner succumb to the disease. Researchers are searching for a more effective approach to treatment.

A newer approach to cancer treatment is

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immunotherapy, which in this instance uses an antibody called ch14.18 to target a substance on the surface of tumor cells called GD2. The GD2 is expressed by cancers such as neuroblastoma but is also present on some normal nerve cells. Early-phase studies demonstrated the safety and activity of ch14.18 when it was given with other drugs that boost the immune system. Those drugs include a factor which stimulates white blood cell growth and a hormone that increases the number and activity of certain types of immune cells.

In this study, 226 children with high-risk neuroblastoma who had responded to myeloablative therapy were randomly assigned to receive standard therapy (isotretinoin), or isotretinoin, ch14.18, and the immune system boosting drugs. The median time these patients were followed in the study was approximately two years. Although the original plan had been to compare outcomes after three years, the study stopped early because of the strongly positive results, allowing those on standard therapy to switch to ch14.18 immunotherapy if they wished.

"The phase III trial results establish ch14.18 immunotherapy as a new standard treatment for children with high-risk neuroblastoma," said Alice Yu, University of California, San Diego and study chair of the clinical trial.

Toxicities, including pain, low blood pressure, capillary leak (leakage of blood from capillaries in the circulatory system to the surrounding tissue), and hypersensitivity reactions, were encountered with the immunotherapy treatment at a significantly greater rate than compared to those who just received the standard therapy. However, side effects in the immunotherapy group were temporary and primarily resolved when treatment was stopped.

Because there was no pharmaceutical company to make ch14.18 when the phase III trial started, NCI manufactured the agent and provided it to COG for the clinical trial. NCI continues to manufacture ch14.18 and to make it available to children with high-risk neuroblastoma through ongoing Children's Oncology Group clinical trials.

"These manufacturing activities illustrate the institute's commitment to developing new treatments for patients with rare cancers for whom treatments are not likely to be developed by industry," said James Doroshow, director of NCI's Division of Cancer Treatment and Diagnosis.

NCI has identified a pharmaceutical partner, United Therapeutics Corp., of Silver Spring, Md., that will eventually take over responsibility for manufacturing ch14.18 and which will be responsible for obtaining FDA approval of ch14.18 for the treatment of high-risk neuroblastoma. The further development of ch14.18 by United Therapeutics is being done under a cooperative research and development agreement with NCI.

"Despite the remarkable success of the ch14.18 phase III trial, there is still much work that needs to be done," said Malcolm Smith, associate branch chief, Pediatrics, NCI Clinical Investigations Branch, NCI. "We need to identify more effective and less toxic ways to use ch14.18 as well as to develop novel treatments to help children not cured with currently available therapies."

In addition to the current immunotherapy study, Maris also co-authored a second study in the same issue of the NEJM, reporting on a separate COG phase III clinical trial of intermediate-risk neuroblastoma. The corresponding author was Katherine Matthay, of the University of California, San Francisco. That study found that physicians could substantially reduce the dose and duration of chemotherapy used for neuroblastoma, and still achieve very high survival rates of 98 percent among children receiving the treatment. The benefits of lower doses include better quality of life, reduced costs, and an expected reduction in late effects of chemotherapy, which may occur years after treatment.

"Together, these studies report important advances in care for children with this challenging cancer," said Maris. "We will continue to investigate treatments to further refine the standard of care."

### <u>Leukemia:</u>

### Rituximab Prolonged Survival Of CLL In Phase III Study

The monoclonal antibody rituximab given in addition to a standard chemotherapy regimen of fludarabine plus cyclophosphamide significantly prolonged the lives of patients with chronic lymphocytic leukemia compared with standard chemotherapy alone in a phase III trial.

The findings were published in the cancer special Issue of The Lancet.

Typically, chemotherapy has been used to treat CLL, but with limited success. Promising results have been achieved in phase II studies combining rituximab with the chemotherapy drugs fludarabine and cyclophosphamide, reporting the highest response rates so far for first-line treatments in patients with CLL.

To further evaluate this therapeutic strategy, the German Chronic Lymphocytic Leukemia Study Group

phase III trial was established in 190 centres in 11 countries. In the trial, 408 previously untreated patients were randomly assigned to receive chemoimmunotherapy with fludarabine, cyclophosphamide, and rituximab, and 409 patients to chemotherapy with fludarabine and cyclophosphamide.

Almost half of the patients in the chemoimmunotherapy group achieved complete remission after three years compared to less than a quarter in the chemotherapy group.

After three years of treatment, 65 percent of chemoimmunotherapy patients had no disease progression compared to 45 percent of patients receiving chemotherapy.

Treatment with chemoimmunotherapy significantly increased the likelihood of patients surviving three years or more. At three years, 87 percent of patients receiving chemoimmunotherapy were alive compared with 83 percent having chemotherapy alone.

Grade 3 and 4 neutropenia (34 percent vs 21 percent) and leucocytopenia (24 percent vs 12 percent) were more common in the chemoimmunotherapy group. But no other side-effects were increased by chemoimmunotherapy treatment. There were eight (2 percent) treatment-related deaths in the chemoimmunotherapy group compared with 10 (3 percent) in the chemotherapy group.

Improvement in survival was not uniform across all clinical and genetic subgroups. In particular, patients with chromosome 17p deletion (or p53 dysfunctional CLL) had a poor response, with fewer than 5 percent achieving complete remission even with chemoimmunotherapy treatment. By contrast, the rate of complete remission increased by more than three times with chemoimmunotherapy in patients with chromosome 11q deletion, a group considered to have a poor prognosis.

"These results might help establish a new treatment model in which the choice of a specific first-line treatment improves the natural course of chronic lymphocytic leukemia," the authors concluded.

### Cervical Cancer:

## A Low-Cost Vaccine To Enter Clinical Trials In A Year

University of Colorado Cancer Center researchers are beginning to test a low-cost cervical cancer vaccine in human trials.

Cervical cancer, caused by infection with high risk types of human papillomavirus, kills more than 350,000

women each year worldwide. Although the disease is less prevalent in the U.S. and developed nations, it is rampant in developing countries such as India where women don't have easy access to regular PAP screens and where two cervical cancer vaccines now on the market—Gardasil and Cervarix— are impractical due to their cost (about \$360 for each three-shot vaccine).

"The incidence of cervical cancer is primarily localized to resource-poor countries," says Bob Garcea, UCCC member and professor in molecular, cellular, and developmental biology at the University of Colorado at Boulder. "We need a vaccine that can reach those people."

Gardasil and Cervarix are expensive because they use fully assembled virus-like particles (VLPs) made from HPV proteins to stimulate the immune system against the virus. Garcea discovered that an HPV vaccine doesn't require VLPs to work. Instead, subunits called capsomeres work just as effectively at activating the immune system to prevent infection. What's more, capsomeres can be manufactured in large quantities at a fraction of the cost of VLPs.

Garcea has worked for 25 years in the development of effective cervical cancer vaccines. His early work helped lead to the development of the VLP-based vaccines. He received a National Cancer Institute grant in 2002 as well as a \$3.4 million grant in 2005 from the Bill and Melinda Gates Foundation to fund his work.

"This trial is the next important step toward bringing a low-cost HPV vaccine to women most in need," he said. He anticipates the first human trials of the vaccine will begin in a year.

The clinical trial will be funded by the NCI as part of an \$11.5 million Specialized Program of Research Excellence (SPORE) grant awarded to the University of Alabama at Birmingham Comprehensive Cancer Center. This SPORE grant in cervical cancer will help fund cervical cancer prevention and treatment research at UAB, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University and UCCC. Garcea is co-leader of the SPORE project that will develop the clinical trial.

### **HPV DNA Testing Reduced Cervical Cancer Precursors**

Women in South Africa who underwent human papillomavirus DNA-based testing or visual inspection of the cervix followed by treatment of test-positive women with cryotherapy had a statistically significant reduction in high grade cervical cancer precursors, compared with women in a control group, according to a study published online Sept. 30 in The Journal of the National Cancer Institute.

In many developing countries, especially in sub-Saharan Africa, cytology-based screening is unavailable. To counter this lack of availability, non-cytological screening methods such as DNA testing or visual inspection of the cervix have been developed, methods that do not require the same laboratory infrastructure as cytology and allow for the immediate treatment of women with detected lesions. The approach of screening using non-cytological methods and then treating all test positive women is referred to as "screen-and-treat" and access to such cervical cancer prevention programs may be able to reduce cervical cancer mortality where cytology-based screening is unavailable.

To determine whether HPV DNA-based screening and visual inspection of the cervix reduced cervical cancer, Thomas Wright, of Columbia University, and colleagues, conducted a randomized trial of 6637 unscreened South African women aged 35-56 years, who were assigned to three study arms: HPV DNA screenand-treat, in which women with a positive HPV test, VIA screen-and-treat in which women with a positive visual inspection test underwent cryotherapy; or a control group, in which further evaluation and treatment were delayed for 6 months. The researchers tested the women for 36 months, and measured cervical cancer lesions of grade two or worse, also known as CIN 2+ for cervical intraepithelial neoplasia.

The researchers found that after 36 months of follow-up, the women who developed CIN2+ included 1.5% in the screen-and-treat arm, 3.8% in the visual inspection-and-treat arm, and 5.6% in the control arm. The authors write, "This study demonstrates that an HPV DNA-based screen-and-treat program for cervical cancer is highly effective and produces a durable reduction in CIN 2+."

Furthermore, they write: "These results suggest that cryotherapy may have long-term implications for low-resource settings where it is difficult and costly to re-screen women at regular intervals."

In an accompanying editorial, Julia Gage and Philip Castle of the National Cancer Institute write that the advent of accurate low-cost HPV DNA testing bodes well for women in low-income settings—provided political will and monetary investment accompany technological advancement. "With low-cost accurate HPV screening tests coming online, cervical cancer prevention is becoming more effective, affordable, and feasible for low-resource settings," they write.

### Cancer Screening:

### Targeting Men At High Risk Finds More Head & Neck Cancer

The University of Michigan Health System this year improved how it attracts the people most at risk to its annual free head and neck cancer screening clinic.

A research study analyzing data from the UM clinics held 1996 to 2009 showed that participants were at higher risk for suspicious lesions when the following risk factors were present: neck mass or oral pain, tobacco use, lack of health insurance, male gender, and separated marital status.

At this year's clinic April 17, organizers refined their usual recruitment strategy based on the study results.

"We reached out more personally and more broadly this year," said Norman Hogikyan, professor of otolaryngology at the UM Medical School, who has directed the clinics since their inception 14 years ago and is the senior author of the research study.

Staff stepped up direct contacts with regional free health clinics and asked for help identifying at-risk patients. People with the risk factors got priority in scheduling screening appointments, too.

The study results were presented at the annual meeting of the American Academy of Otolaryngology-Head and Neck Surgery Sept. 29 by first author and resident surgeon Andrew Shuman, of the UM Department of Otolaryngology-Head and Neck Surgery. The study appears in the September issue of Otolaryngology-Head and Neck Surgery.

This spring, the Cancer Center's community outreach and Cancer AnswerLine staff not only mailed information about the clinic to caregivers at more than 60 free clinics in southeast Michigan, but also called and asked staff at the clinics to help identify and encourage high-risk patients to go to the screening.

"We asked the nurses scheduling appointments to ask about insurance status, tobacco use and symptoms, rather than allowing people to purely self-select for attending the screenings. Our goal was to get more of the higher-risk people in the door," Hogikyan said.

The number of 2010 clinic participants who had suspicious lesions was more than double the average number seen annually during the years the study covered.

The study also found that more than half of the people who had a suspicious lesion did not return for the follow-up visit scheduled for them at U-M. Some may have gone to their own primary providers, while

others may have chosen not to follow up to see if cancer was indeed present.

"Based upon the study results, we have taken an active rather than passive approach to follow-up this year," Hogikyan said, with phone calls and mailings not used before, and offers of transportation assistance for follow-up visits if needed.

# Half Of Mexican-Origin Women With Breast Cancer Diagnosed Before Age 50, Study Finds

Specific prevention and education strategies are needed to address breast cancer in Mexican-origin women in this country, according to a study at The University of Texas MD Anderson Cancer Center, which was published online in the journal Cancer.

Among the Mexican-origin women with breast cancer who were surveyed, half were diagnosed before age 50, years earlier than the national average for non-Hispanic white women. This puts them outside the recently released U.S. Preventive Task Force guidelines that recommend screening, including mammograms, begin at 50. The guidelines have been controversial, and MD Anderson opted to continue to recommend screening beginning at age 40.

"Under the revised Task Force guidelines, up to half of Mexican-origin women with breast cancer may be undiagnosed or diagnosed in late stages, possibly increasing disparities in rates of breast cancer mortality," said Patricia Miranda, a Kellogg Health Scholar post-doctoral fellow in the Department of Health Disparities Research at MD Anderson and the study's lead author. "Hispanic women are not recognized in the guidelines as a high-risk group, and we would like to see that decision revisited."

Breast cancer is the leading cause of death among Hispanic women in the U.S. Previous studies have shown they are more likely to be diagnosed with advanced breast cancer and 20 percent more likely to die from the cancer than non-Hispanic white women.

"As the new national health care policy is implemented, if a one-size-fits all screening recommendation is implemented as the Task Force recommends, we fear a huge number of breast cancer cases won't be picked up at an early stage, especially with the growth of the Hispanic population in this country," said Melissa Bondy, professor in the Department of Epidemiology and senior corresponding author.

The study, which is among the first to use a nonclinical, population-based sample to examine the risk of breast cancer in this group, identified 714 Hispanic women in the Houston area from MD Anderson's Mano a Mano Mexican-American Cohort Study: 119 with breast cancer and 595 without cancer.

Women at highest risk for breast cancer—twoand-a-half times other women surveyed—had a family history of the disease, spoke English well and were born in Mexico.

The strongest risk factor was family history, which increased odds fourfold and was found to be true of 85 percent who had breast cancer. This indicates that women with a strong family history of breast cancer should receive earlier and more frequent screening, Bondy said.

The role of acculturation was striking too. Women who spoke English well had two-and-a-half times the risk of women who did not. The longer a woman had lived in the U.S., the higher her risk.

Single women were almost twice as likely as married women to develop breast cancer, and women without insurance were one-and-a-half times more likely than those with insurance to be diagnosed. Women who do not have insurance are less likely to be screened.

Although the study is fairly small, researchers believe it shows the need for clear action on several fronts.

"We believe it's essential to create education programs specifically for this population, especially if any of the screening guidelines change," Miranda said.

In addition, the study recommends assistance with acquiring health insurance, which may increase access to screening and early detection, and working with affected communities to help formulate policy agendas.

MD Anderson, which has been studying Mexican-American health through the Mano A Mano study for 10 years, is involved in a major study of Hispanic women in Mexico, Arizona and Texas.

### End-of-Life Care:

# **Aggressive Care Causes More Distress For Caregivers**

(Continued from page 1)

of aggressive, hospital-based end-of-life care for terminal cancer patients. The authors noted that although most cancer patients would prefer to spend their last days at home, 36 percent die in a hospital and 8 percent in an ICU and may be subjected to invasive and painful procedures at the end of life.

In contrast to home or hospice care that emphasizes alleviating pain and discomfort and providing a peaceful death, ICU care can be traumatic for patients and their family and caregivers, said Wright.

The report, whose senior author is Holly Prigerson, director of Dana-Farber's Center for Psycho-oncology & Palliative Care Research, contains findings from a prospective, longitudinal study of advanced cancer patients recruited at seven cancer centers from 2002 to 2008. Patients and caregivers—mainly family members—were interviewed at the beginning of the study. Their medical charts were reviewed at that point and after the patients died, on average 4.5 months later. Within two weeks of the death, researchers interviewed the caregiver most closely involved with the patient's care during the last week of life; they interviewed the caregiver again six months later.

In the interviews, the researchers asked the caregivers to assess the patients' quality of life and physical and psychological stress during the last week of life. The researchers also evaluated the caregivers' own mental health at the beginning of the study—to uncover any pre-existing psychiatric illnesses—and again six months after the patient's death.

After analyzing the data on 342 patient-caregiver pairs, the investigators found that patients who had died in the hospital or an ICU experienced more physical and emotional distress and worse quality of life than those dying at home. Among the caregivers, they determined that 4 of 19 caregivers (21 percent) of patients dying in an ICU developed PTSD, compared with 6 of 137 (4.4 percent) when death occurred in the home/hospice setting. A similar elevated risk of prolonged grief disorder was found in caregivers when patients died in the hospital, but not in an ICU.

#### Colon Cancer:

### Multivitamin Use Doesn't Impact Outcomes, Study Finds

Patients with colon cancer who used multivitamins during and after being treated with post-surgical chemotherapy did not reduce the risk of the cancer returning or their dying from it, according to researchers at Dana-Farber Cancer Institute.

In a study of patients with stage III colon cancer – characterized as cancer in the large bowel area with some cancer cells in a few nearby lymph nodes -- the researchers found that while multivitamin use had no beneficial effect on patients' outcomes, it also did not have a detrimental effect. The findings are reported

online in the Journal of Clinical Oncology and later will be published in a print edition.

Kimmie Ng, the paper's first author and a gastrointestinal oncologist at Dana-Farber, said that despite conflicting evidence on the efficacy of multivitamins to reduce cancer risk and death, studies suggest that approximately 30 percent of Americans take multivitamins to prevent and treat chronic diseases such as cancer. Among cancer survivors, between 26 and 77 percent report using multivitamins.

"With such a high proportion of cancer patients utilizing multivitamin supplements in the belief that it will help them fight their cancer, we felt it was important to really examine the data to see what impact multivitamins had on cancer recurrence and survival," said Ng.

The researchers used two questionnaires to track multivitamin use during and after chemotherapy. Of the 1,038 patients who completed the first survey, nearly half (518) responded they used multivitamins while receiving chemotherapy. Of the 810 cancer-free patients who completed the second survey six months after chemotherapy, more than half (416) reported multivitamin use.

Ng and her colleagues found no statistically significant differences in the rates of disease-free survival, recurrence-free survival, or overall survival between those who used multivitamins and those who didn't. They also determined that an array of factors, including socio-economic status, household income, multivitamin and individual vitamin dosage, and consistency of multivitamin use did not impact their findings.

However, they did find a small beneficial association between age and weight and the use of multivitamins while receiving chemotherapy. Those 60 and younger experienced some survival benefit, as did obese patients. There were no benefits for either subgroup when the multivitamins were taken after chemotherapy was completed.

### 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

8500 Safety and Efficacy of RO4929097 in

Combination with Temsirolimus: A Pharmacokinetic and Pharmacodynamic Phase I Study in Patients with Advanced Solid Tumours with an Expansion of Cohort with Patients with Recurrent/Metastatic Endometrial and Renal Cell Cancers, University Health Network-Princess Margaret Hospital. Oza, Amit M. (416) 946-2818.

8508 Addition of the Gamma-Secretase Inhibitor RO4929097 to Erlotinib in Patients with Advanced Non-Small Cell Lung Cancer, M D Anderson Cancer Center. Stewart, David J. (713) 792-6363.

8522 A Neoadjuvant Pharmacodynamic Study Of RO4929097 in Pancreas Cancer, University of Chicago. Khan, Gazala N. (734) 615-4762.

8554 A Phase Ib Neoadjuvant Study of the Gamma Secretase Inhibitor (RO4929097) in Combination with the Aromatase Inhibitor Letrozole in Post-Menopausal Women with Stage II/III Hormone Receptor-Positive Breast Cancer, University of Pittsburgh Cancer Institute. Puhalla, Shannon L. (412) 641-3494.

8784 A Phase 1 Study of 1-Methyl-D-tryptophan in Combination with Docetaxel in Metastatic Solid Tumors, Moffitt Cancer Center and Research Institute. Soliman, Hatem H. (813) 745-4933.

N2008-02 Phase I Study of Vorinostat in Combination with 13-Cis-Retinoic Acid in Patients with Refractory/Recurrent Neuroblastoma, New Approaches to Neuroblastoma Treatment. Park, Julie Ruggieri (206) 987-1947.

#### Phase I/II

8491 Phase Ib/II Study of the Gamma-Secretase Inhibitor (GSI) RO4929097 in Combination with Cisplatin, Vinblastine, and Temozolomide (CVT) in Patients with Metastatic Melanoma, Memorial Sloan Kettering Cancer Center. Schwartz, Gary K. (212) 639-5720.

ACNS0927 A Phase I/II Study of Suberoylanilide Hydroxamic Acid (SAHA, Vorinostat) and Local Irradiation, Followed by Maintenance SAHA in Children with Newly Diagnosed Diffuse Intrinsic Pontine Gliomas, COG Phase 1 Consortium. Su, Jack Meng-Fen (832) 822-4306.

AMC-075 Sequential Phase I/Randomized Phase II Trial of Vorinostat and Risk-Adapted Chemotherapy with Rituximab in HIV-Related B-cell Non-Hodgkin's Lymphoma, AIDS-Associated Malignancies Clinical Trials Consortium. Ramos, Juan Carlos (305) 243-6611.

#### Phase II

8506 Phase II/Pharmacodynamic Study of the

Gamma-Secretase Inhibitor RO4929097 in Patients who are Progression-Free at Completion of Front-Line Chemotherapy for Advanced Non-Small Cell Lung Cancer, MD Anderson Cancer Center. Stewart, David J. (713)792-6363.

8576 A Randomized Phase II Study of Peripheral Androgen Blockade with Bicalutamide Followed by Placebo or Treatment with the Gamma Secretase Inhibitor RO4929097 in Men with Rising PSA after Definitive Local Therapy for Adenocarcinoma of the Prostate, Cancer Institute of New Jersey. Stein, Mark Nathan (732) 235-7278.

E2408 A 3-Arm Randomized Phase II Trial of Bendamustine-Rituximab Followed by Rituximab vs Bortezomib-BR Followed by Rituximab vs BR Followed by Lenalidomide/Rituximab in High Risk Follicular Lymphoma, Eastern Cooperative Oncology Group. Evens, Andrew M. (312) 695-6180.

GOG-0186H A Randomized Phase II Evaluation of Weekly Paclitaxel Versus Weekly Paclitaxel with Oncolytic Reovirus in the Treatment of Recurrent or Persistent Ovarian, Fallopian Tube or Primary Peritoneal Cancer, Gynecologic Oncology Group. Cohn, David Elliot (614) 366-9090.

GOG-0268 A Phase II Evaluation of Temsirolimus in Combination with Carboplatin and Paclitaxel

Followed by Temsirolimus Consolidation as First-Line Therapy in the Treatment of Stage III-IV Clear Cell Carcinoma of the Ovary, Gynecologic Oncology Group. Farley, John Hall (301) 295-3430.

#### Phase III

AALL0932 Treatment of Patients with Newly Diagnosed Standard Risk B-Precursor Acute Lymphoblastic Leukemia, Children's Oncology Group. Angiolillo, Anne (202) 476-2800.

CALGB-90802 Randomized Phase III Trial Comparing Everolimus Plus Placebo Versus Everolimus plus Bevacizumab for Advanced Renal Cell Carcinoma Progressing After Treatment with Tyrosine Kinase Inhibitors, Cancer and Leukemia Group B. Philips, George K. (802)656-5487.

NCCTG-N08C9 Phase III, Randomized, Double-Blind Study of Sulfasalazine versus Placebo in the Prevention of Acute Diarrhea in Patients Receiving Pelvic Radiation Therapy, North Central Cancer Treatment Group. Miller, Robert C. 507-284-4827.

RTOG-1010 A Phase III Trial Evaluating the Addition of Trastuzumab to Trimodality Treatment of HER2-Overexpressing Esophageal Adenocarcinoma, Radiation Therapy Oncology Group. Safran, Howard (401) 444-6217.

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