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Cancer research news for clinicians

Cancer Risk:

Alcohol Consumption Increases Risk Of Lobular And HR+ Breast Cancer

Alcohol increases the risk of lobular and hormone receptor-positive breast cancer, but not necessarily invasive ductal carcinomas, according to a study published August 23 online in The Journal of the National Cancer Institute.

Although alcohol intake is an established risk factor for overall breast cancer, few studies have looked at the relationship between alcohol use and breast cancer risk by subtype of breast cancer. While some studies have shown (Continued to page 2)

Ovarian Cancer:

Olaparib, A PARP Inhibitor, Can Reduce Tumor Size In Advanced Ovarian Cancer

An international consortium of researchers has shown that an investigational drug, Olaparib, can reduce the size of tumors in women with advanced hereditary ovarian cancer with BRCA gene mutations.

The phase II ovarian cancer study results, as well as another phase II trial that evaluated the drug's effectiveness in the treatment of hereditary breast cancer, were published in a recent issue of Lancet. The two trials showed similar levels of response to the genetically-targeted drug in both breast and ovarian cancers with BRCA mutations.

"These are significant new studies. Olaparib is the first single-agent, non-chemotherapy treatment to show benefit to patients with cancers that result from BRCA1 or BRCA2 gene mutations," said William Audeh, an oncologist specializing in cancer genetics at Cedars-Sinai's Samuel Oschin Comprehensive Cancer Institute and first author on the ovarian cancer study. "Until now, treatments for cancer have been selected based upon where in the body the cancer originated. These two studies suggest that it is the underlying genetic weakness of a cancer, not the organ of origin, that is the key to selecting effective therapy."

The first author of the breast cancer study and the principal investigator for both studies was Andrew Tutt, of the Breakthrough Breast Cancer Research Unit, King's College London School of Medicine.

Olaparib, a poly ADP ribose polymerase (PARP) inhibitor made by AstraZeneca, represents a "targeted therapy" approach to cancer treatment anticancer drugs that interfere with specific pathways involved in cancer growth or survival. The PARP enzyme plays a role in DNA repair, including (Continued to page 4)

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One Or More Drink A Day Associated With Lobular BC

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alcohol use is more strongly related to risk of hormone receptor-positive (estrogen receptor and/or progesterone receptor-positive) breast cancer, not many have looked at breast cancer risk by histology, or whether a tumor is ductal—in the milk ducts—or lobular—in the milk-producing lobules.

To understand how alcohol may influence subtypes of breast cancer, Christopher Li and colleagues at Fred Hutchinson Cancer Research Center conducted an observational study of a subset of patients in the Women's Health Initiative study, conducted between 1993 and 1998, which included 87,724 postmenopausal women aged 50-79 years.

The researchers looked at the following data from the 2,944 women in the WHI study who developed invasive breast cancer: tumor subtypes and hormone status, alcohol consumption, demographic and lifestyle characteristics, family history of diseases and reproductive history. Women were categorized as those who never drank, those who formerly drank and those who currently drank. Drinkers were grouped into six categories according to the average number of drinks per week, starting from less than one drink per week to more than 14 drinks per week.

The researchers found that alcohol use is more strongly related to the risk of lobular carcinoma than ductal carcinoma, and more strongly related to hormone-

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

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receptor-positive breast cancer than hormone-receptornegative breast cancer. These results confirm previous findings of an association of alcohol consumption with hormone-positive breast cancer risk, as well as three previous case control studies that identified a stronger association of alcohol with lobular carcinoma. The risks observed did not vary by the type of alcohol women consumed.

The authors write, "We found that women who drank one or more drinks per day had about double the risk of lobular type breast cancer, but no increase in their risk of ductal type breast cancer. It is important to note that ductal cancer is much more common than lobular cancer accounting for about 70 percent of all breast cancers whereas lobular cancer accounts for only about 10-15 percent of cases."

The study's primary limitation, the authors say, is that alcohol usage was only assessed at the beginning of the study, so the researchers had no information on womens' past alcohol usage, nor their subsequent usage.

Brothers Of Prostate Cancer Patients At Risk Of Diagnosis

The brothers of men with prostate cancer are at an increased risk of prostate cancer diagnosis because of increased diagnostic activity and not necessarily because they carry a genetic mutation that increases risk of the disease, according to a study published online August 19 in The Journal of the National Cancer Institute.

Family history is a stronger risk for prostate cancer than for many other cancers and many epidemiological studies have shown an increased risk of the disease for brothers and sons of men with the disease. Since the introduction and wide-spread usage of the prostate-specific antigen (PSA) test in the early 1990s, the sons and brothers of men with prostate cancer have undergone more diagnostic activity.

To determine whether or not estimates of the familial risk of prostate cancer may be at least partially inflated by detection bias from increased diagnostic activity, Ola Bratt, of the urology department at the Helsingborg Hospital in Sweden, and colleagues, looked at data from the Prostate Cancer Database Sweden for patients who were diagnosed with prostate cancer between 1996 and 2006 and who were registered in the National Prostate Cancer Registry.

Their analysis included 22,511 brothers of 13,975 "index patients," who were prostate cancer patients with one or more brother and their fathers registered in

Sweden's Multi-Generation Register, which includes family information for Swedish residents born starting in 1932.

The researchers found that incidence of prostate cancer was higher among brothers of prostate cancer patients than men of the same age in Sweden and that the incidence was higher still among men with both a brother and father with prostate cancer. Incidence was highest among men who had two brothers with prostate cancer. However, the type of cancer most often detected was early-stage prostate cancer, which is typically detected by a PSA test and may or may not become clinically relevant.

The researchers also found that incidence of prostate cancer diagnosis among brothers of index patients was highest during the first year after the index patient's diagnosis.

Overall incidence of prostate cancer increased sharply in Sweden between 1999 and 2006, and a higher socio-economic status was associated with statistically significant increased risk of a prostate cancer diagnosis.

The authors conclude: "The increased diagnostic activity among men with a family history of prostate cancer, which we observed, will inflate family history as a risk factor for prostate cancer in populations of men who commonly receive PSA testing."

This finding could have clinical relevance, they report. "When counseling men about their risk of hereditary predisposition to prostate cancer, one should consider the possibility that a familial aggregation of prostate cancer may be at least partially caused by increased diagnostic activity," the authors write.

In an accompanying editorial, Ian Thompson of The University of Texas, and colleagues, writes that assessments of variables affecting prostate cancer risk run the risk of unknown biases in most studies. They write: "Perhaps the best tactic would be to change our approach from seeking risk factors for prostate cancer to an assessment of factors related to biologically consequential prostate cancer."

Estrogen Alone Didn't Increase Lung Cancer Mortality In WHI

Use of estrogen alone did not increase lung cancer mortality in postmenopausal women, according to a study published online August 13 in The Journal of the National Cancer Institute.

In the Women's Health Initiative (WHI) trial, which consisted of several clinical trials on postmenopausal

women, one study showed women with previous hysterectomy taking combined estrogen plus progestin therapy had a statistically significant increase in lung cancer mortality, but not incidence. Other studies with combined hormone therapy have had conflicting results. But the influence of estrogen alone was unclear.

To determine whether use of estrogen alone was associated with lung cancer incidence and increased lung cancer mortality, Rowan Chlebowski, of the Los Angeles Biomedical Research Institute, and colleagues, in a post-hoc analysis examined data from a previous randomized, double-blind, placebo-controlled trial in the WHI. This trial was conducted in 40 centers in the U.S., in which 10,739 postmenopausal women aged 50-79 years with a hysterectomy were randomly assigned to groups receiving estrogen alone or placebo.

The researchers found there was only one more death from lung cancer in the estrogen group (34 deaths) compared with the placebo group (33 deaths). Their conclusion was that use of estrogen alone was not associated with lung cancer incidence or death from lung cancer in women with hysterectomies.

The researchers also found that although the effects of combined estrogen and progestin and estrogen alone on coronary heart disease were similar, there were differences in the two therapies' effect on various types of cancer. Combined therapy showed a statistically significant increase of breast cancer incidence, whereas estrogen alone showed a reduced incidence. However, combined therapy showed a statistically significant reduction in colorectal cancer, whereas estrogen alone was not associated with colorectal cancer.

The authors say that a limitation of the study was the small sample size and that further investigation comparing combined therapy to estrogen alone is needed. However, they write, "These findings should be reassuring for women with previous hysterectomy, who use estrogen alone for climacteric symptom management."

Tumors Harder To Detect In Women In Their Forties

The reduced effectiveness of mammographic screening in women in their forties is primarily due to lower detectability instead of faster tumor growth rate, according to a study published online July 27 in The Journal of the National Cancer Institute.

Mammography screening outcomes, measured in terms of tumor size, lifetime gained and mortality, have typically been poorer in women in their forties than women in their fifties, partly because tumors of younger women tend to grow more quickly, so by the time they grow to a detectable size, they would have likely already been detected by a routine examination. Younger women also tend to have denser breast tissue, which can mask tumors, reducing their detectability on mammograms.

To investigate which factor—faster tumor growth rates, or reduced mammographic detectability—contributes to poorer mammography screening outcomes in younger women, Sylvia Plevritis of the Department of Radiology at the Stanford University School of Medicine, and colleagues, used a computer simulated model to estimate the relative effect of biology and technology on mammograms of women in their forties, compared to women in their fifties and sixties.

The researchers used the Breast Cancer Screening Simulator to create hypothetical screening scenarios whereby they could estimate the median tumor size detectable on a mammogram and the mean tumor growth rate in women aged 40-49 and 50-69.

The researchers concluded from their simulation model that lowered mammographic tumor detectability accounted for 79% and faster tumor volume doubling time accounted for 21% of the poorer sensitivity in mammography screening among younger women, compared with older women.

The authors write, "The age-specific differences in mammographic tumor detection contribute more than age-specific differences in tumor growth rates to the lowered performance of mammography screening in younger women."

One limitation of the analysis, according to the authors, is that it did not take into account that low mammographic tumor detectability could be considered a breast cancer risk factor. They write: "More research is needed to not only establish a better relationship between mammographic breast density and breast cancer risk but also understand the differences in tumor characteristics in dense vs non-dense breast tissue."

Ovarian Cancer:

PARP Inhibitor Shrunk Tumors In Phase II Ovarian Cancer Trial

(Continued from page 1)

the repair of DNA damage from chemotherapy. Drugs that inhibit this enzyme appear to contribute to cancer cell death as well as increase their sensitivity to chemotherapy. Of the 57 patients enrolled in the ovarian cancer study worldwide, 33 percent of participants showed a significant shrinkage in the size of their tumors, and in some cases, complete disappearance of their tumors. Toxicities from the drug were relatively mild, including nausea, fatigue and anemia.

"Women with advanced BRCA-mutated ovarian cancer have often been through several chemotherapy regimens, making it difficult to offer effective treatments," said Audeh. "PARP inhibitors may be a promising new option for this heavily 'pre-treated' population."

Approximately 10 percent of ovarian cancer cases have an inherited mutation in the BRCA 1 or 2 genes, the type of cases treated in this trial. Since it is often difficult to diagnose, many women present with advanced disease, which is especially challenging to treat.

The study was supported by AstraZeneca. Audeh has received honoraria as a consultant to AstraZeneca and Myriad Genetics Laboratories as well as financial support for travel to investigator meetings. Many of the other investigators had similar relationships with AstraZeneca.

Lung Cancer:

Two Avastin Trials Show OS Benefit In Advanced Disease

New data from two studies published separately in The Journal of Thoracic Oncology and The Lancet Oncology showed that Avastin-based therapy provided a median overall survival benefit beyond 14 months in people with advanced lung cancer.

E4599: Updated data from a preplanned analysis of the phase III pivotal Avastin E4599 lung cancer trial was published online in The Journal of Thoracic Oncology. These data showed first-line treatment with Avastin plus paclitaxel and carboplatin chemotherapy improved overall survival in patients with adenocarcinoma, the most common form of NSCLC, and helped form the basis of the FDA's approval of Avastin in NSCLC.

- Results demonstrated that first-line Avastinbased therapy provided the longest median OS shown in a Phase III trial of patients with advanced non-small cell adenocarcinoma of the lung to date, at 14.2 months compared to 10.3 months with chemotherapy alone (HR = 0.69 [95% CI: 0.58-0.83]).
- Patients with adenocarcinoma who received Avastin-based therapy had a 45% improvement in overall survival (based on a HR = 0.69 [95% CI:

0.58-0.83]) and a 54% improvement in the likelihood of living without the disease worsening ([HR = 0.65, 95% CI: 0.54-0.78]) compared to those who received chemotherapy alone.

• The results are consistent with those of the phase IV observational SAiL trial.

SAiL Trial: New data from the observational phase IV SAiL study of more than 2,000 patients receiving Avastin in combination with commonly used chemotherapies were published in The Lancet Oncology. The majority of patients in this study were diagnosed with adenocarcinoma.

SAiL confirms the well-established and manageable safety profile of first-line bevacizumab in combination with a range of standard chemotherapy regimens for advanced non-squamous NSCLC.

- Results showed Avastin, in combination with commonly used chemotherapies for lung cancer, provided a median OS benefit of 14.6 months in a community-based population of patients with NSCLC.
- In the study, a median survival of 14.3 or 14.7 months was observed when patients received an Avastin-based regimen that included either carboplatin or cisplatin, respectively.

HRT Use:

Risk-Benefit Analysis Advised Prior To Hormone Therapy

A new analysis of the California Teachers Study, which analyzed hormone replacement therapy use among 2,857 women for almost 10 years, underscores the need for personalized risk-benefit discussions before women begin hormone therapy.

"This is evidence that the story is complicated," said Tanmai Saxena, of the Keck School of Medicine at the University of Southern California. "The benefits of hormone therapy for relief of postmenopausal symptoms among women are clear, but the risks are more complicated than we had previously thought."

In a report published in Cancer Epidemiology, Biomarkers & Prevention, a journal of the American Association for Cancer Research, Saxena and colleagues found that compared with women who had never used hormone therapy, women who used estrogen therapy for more than 15 years had a 19 percent greater risk of developing breast cancer.

Women who used combined therapy with estrogen plus progestin for 15 or more years had an 83 percent greater risk. Breast cancer risk was highest among

women who used the combination regimen.

Breast cancer risk seemed dependent on body mass index (BMI). Those with a BMI less than 30 appeared to have an increased risk of breast cancer with combined hormone therapy; the risk was strongest among women with BMI less than 25. In contrast, obese women (i.e., BMI of 30 or more) had no further increase in risk associated with using combined hormone therapy.

The risk of breast cancer was confined to tumors that were positive for both estrogen and progestin receptors. The risk was somewhat weaker for HER2 negative tumors.

Susan Hankinson, professor of medicine at Harvard Medical School, said the findings underscore the reality that even following the Women's Health Initiative trial and large prospective studies including the California Teachers Study, there are still questions that remain.

"These results add new evidence that risk does vary by other personal characteristics. However, for now, the public health message remains essentially the same. There is an increased risk of breast cancer from hormone use, and further studies will address the question of how specific that risk is," said Hankinson, who is a senior editor of Cancer Epidemiology, Biomarkers & Prevention.

Leukemias:

Elderly Patients Fail To Receive New Cancer Therapy For CML

Researchers from the University of New Mexico Cancer Center have found that elderly patients with chronic myeloid leukemia did not receive an effective new therapy for that cancer nearly as much as younger patients.

CML is a slow growing cancer of the bone marrow for which highly effective new therapy, imatinib (Gleevec) was released in 2001. The National Cancer Institute Patterns of Care study, published in the July 28 edition of The American Journal of Medicine, showed that use of this newer and more effective treatment of CML decreased significantly as the age of the patient increased. The study found that the decreased use of imatinib in older patients resulted in a marked decrease in their survival.

"The 'Patterns of Care' study shows that there is a significant treatment disparity in elderly cancer patients," said Cheryl Willman, director and CEO of the UNM Cancer Center.

Statistics from this Patterns of Care study show

only 46 percent of CML patients aged 80 years-old or older received imatinib, which is considered the most effective treatment of this cancer. The study showed a considerable increase in the amount of younger patients who received imatinib. Nearly 90 percent of patients between the ages of 20- and 50-years-old received imatinib, and 75 percent of patients between the ages of 60- 79-years-old were prescribed the drug. The results of the study showed that failure to receive imatinib resulted in poorer survival among Patterns of Care study elderly patients.

"We found that elderly patients who did not receive imatinib had a very poor survival rate. The older the patient was at the time of his/her diagnosis, the less likely the physician is to prescribe this very effective treatment," said Robert Hromas, deputy director of the UNM Cancer Center and researcher and author of the Patterns of Care study. "We hope that this study will shed light on this disparity, and help to educate physicians on effective cancer treatment options for the elderly. We also hope it encourages elderly patients to become more proactive in their cancer care by discussing treatment options with their physicians."

According to the study, this treatment disparity in elderly chronic myeloid leukemia patients may be caused in part by a lack of clinical trials reporting on possible toxicities in elderly patients. However, this study reports, physician behavior seemed to play a significant role in the lack of use of imatinib in elderly patients. This study recommends several remedies to improve the use of new cancer drugs in the elderly, including mandatory inclusion of older patients in clinical trials, and mandatory reporting of results in those patients, in order to improve physician education on benefits in these patients.

Prevention:

Rising Obesity May Result In Higher Cancer Incidence

According to recent figures from the Centers for Disease Control and Prevention, 2.4 million more Americans became obese between 2007 and 2009. Approximately 26.7 percent of the US adult population, or 72.5 million people, are now obese.

Experts at the American Institute for Cancer Research said this increase may well result in a corresponding increase in the national cancer rate in years to come.

"Obesity plays a central role in many cancers," said Susan Higginbotham, AICR director of research. "Its links to heart disease and diabetes are well-known, but Americans need to understand that more obesity today means more cancer tomorrow."

AICR currently estimates that excess body fat causes approximately 103,600 cases of cancer in the US every year, and warns that as the percentage of the population who are obese continues to increase, this number will rise.

The 103,600 estimate was calculated by combining projected cancer incidence for 2010 with data on the prevalence of obesity and its impact on cancer risk found in the AICR/WCRF report, "Policy and Action for Cancer Prevention," released last year. That report estimated the percentage of various kinds of cancer that are attributable to such risk factors as poor diet, lack of physical activity and excess body fat.

According to AICR, the estimated number of US cancers that are currently linked to excess body fat include:

- 49% of endometrial cancers: 21,300 cases/year
- 35% of esophageal cancers: 5,824 cases/year
- 28% of pancreatic cancers: 12,079 cases/year
- 24% of kidney cancers: 13,978 cases/year
- 21% of gallbladder cancers: 2,050 cases/year
- 17 % of breast cancers: 35,540 cases/year
- 9% of colorectal cancers: 12,831 cases/year

Study Finds Relationship Between Meat Intake, Cancer

A new study suggests that consuming specific compounds in meat related to processing methods may be associated with an increased risk of developing bladder cancer. Published early online in CANCER, a peer-reviewed journal of the American Cancer Society, the findings may be relevant for understanding the role of dietary exposures in cancer risk.

Eating red and processed meats has been linked to an increased risk of developing several different types of cancer. Animal studies have identified a number of compounds in meat that might account for this association. These include heterocyclic amines, polycyclic aromatic hydrocarbons, and N-nitroso compounds. Nitrate and nitrite are added to processed meats and are known precursors to N-nitroso compounds.

Amanda Cross, of the National Cancer Institute, and colleagues conducted one of the first prospective studies—the NIH-AARP Diet and Health Study—to assess the relationship between intake of these meat-related compounds and the risk of developing bladder cancer. They used information gathered through

questionnaires to assess the types of meat consumed as well as how meat was prepared and cooked to estimate the intake of these meat-related compounds.

The investigators had information from approximately 300,000 men and women aged 50 to 71 years from eight US states. At the start of the study (1995 to 1996), all participants completed lifestyle and dietary questionnaires about their usual consumption of foods and drinks. The participants were followed for up to eight years, during which time 854 people were diagnosed with bladder cancer.

People whose diets had the highest amount of total dietary nitrite (from all sources and not just from meat), as well as those whose diets had the highest amount of nitrate plus nitrite from processed meats had a 28 percent to 29 percent increased risk of developing bladder cancer compared with those who consumed the lowest amount of these compounds. This association between nitrate/nitrite consumption and bladder cancer risk may explain why other studies have observed an association between processed meats and increased bladder cancer risk.

Brain Tumors:

Radiation To Stem Cell Niche Improved PFS In Glioblastoma

Patients with deadly glioblastomas who received high doses of radiation that hit a portion of the brain that harbors neural stem cells had double the progression-free survival time as patients who had lower doses or no radiation targeting the area, a study from the Radiation Oncology Department at UCLA's Jonsson Comprehensive Cancer Center has found.

Patients who underwent high doses of radiation that hit the specific neural stem cell site, known as the stem cell niche, experienced 15 months of progression-free survival, while patients receiving lower or no doses to this region experienced 7.2 months of progression-free survival, said Dr. Frank Pajonk, an associate professor of radiation oncology, a cancer center researcher and senior author of the study.

Pajonk said the study, published in the early online edition of the journal BMC Cancer, could result in changes in the way radiation therapy is given to patients with these deadly brain cancers.

"Our study found that if you irradiated a part of the brain that was not necessarily part of the tumor the patients did better," Pajonk said. "We have been struggling for years to come up with new combinations of drugs and targeted therapies that would improve survival for patients with glioblastoma. It may be that by re-shaping our radiation techniques we can extend survival for these patients."

The retrospective study focused on the cases of 55 adult patients with grade 3 or grade 4 glioblastomas who received radiation at UCLA between February 2003 and May 2009. Pajonk said a prospective study is needed to confirm the results.

There is some evidence that many if not all cancers may spring from stem cells or progenitor cells that normally repair damage to the body, but that somehow become mutated and transform into cancer. In this case, Pajonk said the neural stem cell niche, called the periventricular region of the brain, may also be harboring stem cells that have transformed into brain cancer stem cells. However, the niche serves as a sort of safe harbor for the cancer stem cells, keeping them away from the site of the tumor but able to re-grow it once it's removed and the malignant areas of the brain have been treated.

Pajonk theorizes that the brain cancer stem cells in the patients whose niches were irradiated with higher doses may have been damaged or eliminated, giving these patients more time before their cancer recurred.

"This suggests that the neural stem cell niche in the brain may be harboring cancer stem cells, thus providing novel therapy targets," the study states. "We hypothesize that higher radiation doses to these niches improve patient survival by eradicating the cancer stem cells."

The radiation therapy could damage neural stem cells as well as the cancer stem cells, Pajonk said, but those may be replaceable at some future date using induced pluripotent stem cells made from the patient's own cells. The induced pluripotent stem cells, which like embryonic stem cells can make every cell in the body, could be induced into becoming neural stem cells to replace those damaged or eradicated by the radiation to the niche.

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

7997 A Pilot Trial of a Vaccine Combining

Multiple Class I Peptides and Montanide ISA 51 VG with Escalating Doses of Anti-PD-1 Antibody BMS-936558 for Patients with Unresectable Stages III/IV Melanoma, Moffitt Cancer Center and Research Institute. Weber, Jeffrey S. (813) 745-2007.

8316 A Phase I Trial of a Vaccine Combining Multiple Class I Peptides and Montanide ISA 51 VG with Escalating Doses of Anti-PD-1 Antibody BMS-936558 for Patients with Resected Stage IV Melanoma, Moffitt Cancer Center and Research Institute. Weber, Jeffrey S. (813) 745-2007.

Phase I/II

ABTC-1002 Phase I/II Study of R04929097 with Bevacizumab in Patients with Recurrent Malignant Glioma, Adult Brain Tumor Consortium. Pan, Edward (813) 745-3871.

Phase II

8474 A Phase 2 Study of Suberoylanilide Hydroxamic Acid (SAHA) in Subjects with Locally Advanced, Recurrent or Metastatic Adenoid Cystic Carcinoma (ACC) (IND 71976), Barbara Ann Karmanos Cancer Institute. LoRusso, Patricia Mucci (313) 576-8716.

8489 A Phase II Evaluation of SJG-136 in Women with Cisplatin-Refractory or Resistant Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Carcinoma, Moffitt Cancer Center and Research Institute. Crispens, Marta Ann (615) 322-2114.

8635 A Phase II Study of RO4929097 (IND 105994) in Advanced Platinum Resistant Ovarian Cancer, University Health Network-Princess Margaret Hospital. Oza, Amit M. (416) 946-2818.

CALGB-50901 A Phase II Trial of Ofatumumab in Previously Untreated Follicular Non-Hodgkin's Lymphoma, Cancer and Leukemia Group B. Rosenbaum, Cara A. (773) 702-0167.

GOG-0130F A Phase II Evaluation of Ixabepilone (IND #59699) in the Treatment of Recurrent or Persistent Carcinosarcoma of the Uterus, Gynecologic Oncology Group. McCourt, Carolyn Kay (401) 453-7520.

Phase III

8214 Pilot / Phase III Randomized Trial Comparing Standard Systemic Therapy to Cytoreduction + Hyperthermic Intraperitoneal Mitomycin C + Standard Systemic Therapy in Patients with Limited Peritoneal Dissemination of Colon Adenocarcinoma, Walter Reed Army Medical Center. Stojadinovic, Alexander (202) 782-9696. AMC-076 A Randomized Clinical Trial of Infrared Coagulation (IRC) Ablation versus Expectant Management of Intra-Anal High Grade Intraepithelial Neoplasia (HGAIN) in HIV-infected subjects, AIDS-Associated Malignancies Clinical Trials Consortium. Goldstone, Stephen Elliot (212) 242-6500.

E3A06 Randomized Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma, Eastern Cooperative Oncology Group. Lonial, Sagar (404) 727-5572.

GOG-0262 A Randomized Phase III Trial of Every-3-Weeks Paclitaxel Versus Dose Dense Weekly Paclitaxel in Combination with Carboplatin with or without Concurrent and Consolidation Bevacizumab (IND #7921) in the Treatment of Primary Stage III or IV Epithelial Ovarian, Peritoneal or Fallopian Tube Cancer, Gynecologic Oncology Group. Chan, John K. (415) 885-7561.

NSABP-C-11 A Phase III Study Evaluating the Role of Perioperative Chemotherapy and Bevacizumab in Patients with Potentially Resectable Hepatic Colorectal Metastases, National Surgical Adjuvant Breast and Bowel Project. Choti, Michael Andrew (410) 995-7113.

Other

ANBL10B1 Therapeutically Applicable Research to Generate Effective Treatments (TARGET) for Neuroblastoma, Children's Oncology Group. Maris, John M. (215) 590-5244.

E1L09T1 Validation of AML Proteomic Signature Associated with Clinical Response to Ara-C Based Induction Therapy in Patients 60 Years of Age or Older Using Samples from ECOG Studies 3999, 3993 and 1490, Eastern Cooperative Oncology Group. Paietta, Elisabeth (718) 920-9992.

GOG-8013 Topoisomerase 2-Alpha (TOPO2A) Genomic Alterations And Immunohistochemical Expression as Well as Chromosome 17 Polysomy In Advanced or Recurrent Endometrial Carcinoma Treated with Anthracycline-Based Therapy, Gynecologic Oncology Group. Grushko, Tatyana A. (773) 834-3518.

Pilot

ANBL09P1 A COG Pilot Study of Intensive Induction Therapy and 131I-MIBG with Myeloablative Carboplatin, Etoposide and Melphalan (CEM) for Newly Diagnosed High-Risk Neuroblastoma, Children's Oncology Group. Weiss, Brian David (513) 636-9863.