

Clinical Trials:

**Long-Term Effect Of One Phase III Trial:
Benefit For Thousands Of Patients**

Data collected in a single large comparative clinical trial testing combination chemotherapy for metastatic colorectal cancer has been used not only to benefit the patients that enrolled but also patients who subsequently developed the disease, according to a review article published in *The Oncologist*.

According to the article by Richard Goldberg, of University of North Carolina, the study also helped to refine the clinical trials process and move forward the potential for individualized therapy for patients. The benefits of this collaboration between patients, physicians across the U.S. and Canada, the National Cancer Institutes of the U.S. and Canada, and two pharmaceutical
(Continued to page 2)

Lung Cancer:

**High Dose Radiotherapy Plus Chemo
Encouraging For Small Cell Lung Cancer**

Treating limited stage small cell lung cancer with a combination of accelerated high-dose radiotherapy and chemotherapy has shown encouraging results, opening the door to larger scale investigation, according to research from the University of Texas M.D. Anderson Cancer Center.

The phase II study was presented Nov. 3 in an oral session at the annual meeting of the American Society for Radiation Oncology, in Chicago, by Ritsuko Komaki, professor and program director of Lung Cancer Research and Thoracic Radiation Oncology at M. D. Anderson.

“While still early, these may be the most important study findings for limited stage small cell lung cancer in the past decade,” said Komaki, the study’s lead author. “This research is important because it achieved a high level of control of the disease while minimizing damage to the esophagus.”

Small cell lung cancer is an aggressive cancer that accounts for about 20 percent of lung cancers; approximately 20 percent of these cases are classified as LSCL, defined as cancer present in one lung and possible lymph node involvement, but has not metastasized.

“Over the past few years, we have made significant progress by giving concurrent chemotherapy and thoracic radiotherapy (radiation to the chest), as well as prophylactic cranial radiotherapy (radiation to the head to prevent cancer),” said Komaki, who also holds the Gloria Lupton Tennison Distinguished Professorship in Lung Cancer Research at M. D. Anderson.

(Continued to page 3)

© Copyright 2009
The Cancer Letter Inc.
All rights reserved.

Clinical Trials:

**A Chronicle Of One
Large Phase III Trial**

... Page 2

Lung Cancer:

**ASCO Updates
Treatment Guideline**

... Page 3

**Nicotine Patch-Lozenge
Combination Is Best
For Smoking Cessation**

... Page 4

Prevention:

**Higher HDL Associated
With Decreased
Risk of Cancer**

... Page 5

NCI-Approved Trials

... Page 8

Trial Changed Treatment For Colorectal Cancer

(Continued from page 1)

companies (Pharmacia and sanofi-aventis) are still being realized five years after the original trial concluded.

Not only did the phase III trial, which ran from 1997-2004, prove that combination chemotherapies adding new drugs to the standard treatment in use for 50 years are effective in treating metastatic colorectal cancer, but it also provided data for more than 25 additional scientific papers. This ongoing research has helped to improve the prognosis and change the standard of care for patients with this diagnosis.

"The history of this study shows how patients' decisions to enroll in clinical trials can benefit thousands of others, even years down the road," said Goldberg, physician-in-chief of the N.C. Cancer Hospital and associate director for clinical research at UNC Lineberger Comprehensive Cancer Center.

"These individuals have helped doctors and scientists change the way we treat metastatic colorectal cancer and simplify the way we run clinical trials in cancer patients," he said.

Based on the trial, FDA approved a new agent, oxaliplatin, administered with 5-fluorouracil for the indication "treatment of previously untreated patients with colorectal cancer that had spread to other organs" in 2004.

As one of the first clinical trials to monitor chemotherapy toxicity in real-time, the study allowed

researchers to quickly eliminate drug combinations that were more likely to result in negative outcomes for patients.

Over the course of the study, as the field of pharmacogenetics evolved, researchers were able to use the individual patient's DNA collected with a simple blood test to better pinpoint which were most likely to have severe side effects. The DNA analysis also helps doctors determine which patients derive greater benefits from a particular drug and adjust their chemotherapy to minimize risk, while maximizing the chances that their cancer would respond to therapy.

"Over time, the fact that this study collected DNA and plasma with patient permission has been important to our ability to make significant progress in understanding how patients' genetic profiles interact with anti-cancer drugs," said Goldberg.

Data from the study was also used to examine how patients did with a combination of surgery and drug therapy, to study how the combination drug therapy worked in patients with different risk profiles based on the type and progression of their cancer, and to assess the economic cost-benefit of combination therapies.

"The original data collected has also been combined with data from other clinical trials to examine overall survival rates and to explore differences in outcomes based on patient age and symptom profiles so that we could understand the risks and benefits when we treat older and sicker patients with the more intensive treatments" Goldberg said. "The data was also used to simplify how we follow tumor measurements and side effect profiles in clinical trials speeding the pace and reducing the cost of research."

"The history of this study demonstrates how sharing data among groups of scientists and doctors and asking questions that span scientific disciplines can help us make progress that is meaningful for patients over the relatively short time frame of approximately a decade," he added.

Other investigators on the review study were Hanna Sanoff, clinical assistant professor of medicine and Howard McLeod, professor of pharmacy and UNC Lineberger member; Daniel Sargent, Erin Green and Jan Buckner, from the Mayo School of Medicine in Rochester, Minnesota; and Roscoe Morton, from the Iowa Oncology Research Association CCOP.

The original clinical trial was a partnership between the enrolled patients, the National Cancer Institutes of the US and Canada, NCI sponsored cooperative groups, industry, and investigators at academic centers, Community Clinical Oncology

THE CLINICAL CANCER LETTER

To purchase a subscription,
call 800-513-7042 or visit
www.cancerletter.com

Publisher: Kirsten Boyd Goldberg

Editorial: 202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
Customer Service FAQ at www.cancerletter.com

Customer Service: 800-513-7042
PO Box 40724, Nashville TN 37204-0724

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

Programs and private practices. The review study was supported by the North Central Cancer Treatment Group and NCCTG Biospecimen Resource, sanofi-aventis and Pharmacia now a part of Pfizer.

The article, "NCCTG Study N9741: Leveraging Learning from an NCI Cooperative Group Phase III Trial," is available online at <http://theoncologist.alphamedpress.org/cgi/content/full/14/10/970>.

Lung Cancer: **Treatment Adapted For New Randomized Intergroup Trial**

(Continued from page 1)

"However, five-year survival in limited stage small cell lung cancer is still only 26 percent, and the likelihood of recurrence and metastasis is still too high."

A previous phase III study conducted at M. D. Anderson and other sites through the North America Intergroup, showed accelerated fractionated radiotherapy (treatment in which radiation levels are increased over time) with concurrent VP-16 (etoposide) and cisplatin (platinum-based drugs) improved five-year survival rates. But this treatment often causes other side effects.

"Severe inflammation of the lining of the esophagus, also known as acute esophagitis, is a significant risk in this type of treatment," Komaki said. "Therefore, despite its long-term survival benefit, this modality has not been popular in community hospitals."

Researchers at M. D. Anderson and their colleagues developed this new study to find a way to increase the level of radiation during concurrent chemotherapy without increasing damage to normal tissue. Supported by NCI grant, this clinical study was then proposed to the Radiation Therapy Oncology Group.

Patients with LSCL were treated with thoracic radiotherapy that was accelerated slowly over three weeks. The next step included two weeks of higher radiation levels twice daily, for a total of five weeks. During radiotherapy, patients received four cycles of chemotherapy.

"We gave the patients boosts of radiation twice a day in the last two weeks of treatment, when resistant cells often start to proliferate," Komaki said.

During the median follow-up time of 19 months, 41 percent of patients experienced complete response, and another 39 percent had partial response. Despite the higher radiation dose, the rate of acute severe esophagitis was significantly lower than the previous study, 18 percent, vs. 27 percent, respectively.

However, at 36.6 percent, the two-year survival rate did not improve. In addition, while local control of the disease was excellent, 80 percent, the majority of patients still developed distant metastasis, Komaki said.

Komaki said further study is needed, possibly including a cycle of induction chemotherapy before concurrent treatment. Improved systemic treatment and staging work-ups are needed too, she said.

This study has been adapted by a new randomized intergroup trial (CALGB/RTOG/ECOG/SWOG) that will enroll 700 patients in multiple sites across the country. This research will compare three radiation dose levels and treatment duration times.

Age Shouldn't Determine Lung Cancer Treatment, ASCO Says In New Guideline

New recommendations on the use of chemotherapy to treat patients with stage 4 non-small cell lung cancer were issued earlier this month by the American Society of Clinical Oncology.

The evidence-based clinical practice guideline indicates a patient's physical age should not determine the cancer treatment he/she is given. Instead, ASCO recommends oncologists take other factors into account including physiological age and performance status when determining appropriate treatment for stage 4 NSCLC patients.

The new guideline also makes specific recommendations for first-line treatment of NSCLC including:

- Cisplatin or carboplatin may be used for first-line chemotherapy in combination with a second drug, such as docetaxel, gemcitabine, irinotecan, paclitaxel, pemetrexed or vinorelbine.
- Bevacizumab is recommended with carboplatin plus paclitaxel in particular circumstances.
- Physicians may consider adding cetuximab to cisplatin plus vinorelbine in first-line therapy in patients with a tumor which tests positive for EGFR protein.
- Gefitinib may be used as first-line therapy in patients with a tumor which tests positive for an activating EGFR gene mutation.

Recommendations for second-line and third-line treatment include:

- For second-line treatment, the guideline recommends the use of a single drug, either docetaxel, erlotinib, gefitinib or pemetrexed.
- For third-line treatment, the guideline recommends

erlotinib if a patient's performance status is 0 to 3 and he/she has not previously received erlotinib or gefitinib.

While patients with a tumor that tests positive for an EGFR mutation may receive certain drugs which target EGFR earlier in the course of their disease, the guideline does not recommend the routine use of molecular markers to choose treatment for patients with NSCLC because there is not enough evidence that doing so extends patients' lives.

"The use of molecular markers in treating people with cancer is a rapidly developing field with interesting potential," said Giuseppe Giaccone, co-chair of the guideline expert panel and a physician and researcher with the National Cancer Institute. "ASCO is diligently monitoring clinical research involving the use of biomarkers to personalize the treatment of patients with NSCLC to ensure that its guidelines reflect all available high quality evidence."

The updated guideline also highlights disparities in treating members of minority populations who are diagnosed with lung cancer. Research has shown that only 36 percent of African Americans with stage 4 NSCLC receive first-line chemotherapy. Reasons for these disparities include socio-economic status, access to health services, other existing medical conditions and ineffectual communication between health care providers and patients.

"Ethnic and racial minorities experience worse outcomes compared to whites in all stages of lung cancer, and these disparities are frequently due to communication barriers between doctors and their patients," said Christopher Azzoli, co-lead author of the guideline and physician at the Memorial Sloan-Kettering Cancer Center. "When patients receive uniform clinical care, these disparities are minimized."

The updated guideline, decision aid tools, and other resources are available at www.asco.org/guidelines/nsclc.

Patch-Lozenge Combination Best For Smoking Cessation

In the largest study to date comparing smoking cessation therapies, the use of the nicotine lozenge in combination with the nicotine patch provided the greatest benefit for smokers trying to quit, resulting in over a two-fold better smoking cessation outcome 6 months after quitting compared to smokers who received placebo medication.

The study also showed that this combination improved initial cessation and end of treatment quit

rates compared to using just one therapy. This three-year project was supported by the National Cancer Institute and the National Institute on Drug Abuse. The study appears in the November issue of the Archives of General Psychiatry.

Many smokers have quit successfully using a variety of smoking cessation aids, but there has been little research on the relative effectiveness of these therapies.

What makes this study unique is that it compared three different medications (the nicotine patch; the nicotine lozenge; and the oral medication bupropion) with placebo and each other.

The study also compared two different combination therapies (the lozenge plus the patch and the lozenge plus bupropion) with placebo and with a composite group combining all of the individual therapies. In addition to medication, smokers received six one-on-one counseling sessions provided by trained case managers.

More than 1,500 smokers participated in the study, with treatment lasting from eight to 12 weeks. Investigators looked at initial cessation and quit rates at several intervals, including at the end of a week, at eight weeks, and at six months.

To view the study online, go to: <http://archpsyc.ama-assn.org>.

Myeloma:

Lower Dose Dexamethasone Can Be Used To Treat Newly Diagnosed Myeloma

High-dose dexamethasone is a mainstay of therapy for multiple myeloma. However, a study published online and in the November edition of The Lancet Oncology concludes that lenalidomide plus low-dose dexamethasone is associated with better short-term overall survival and lower toxicity than lenalidomide plus high-dose dexamethasone in patients with newly diagnosed myeloma; and is thus a viable treatment option for these patients.

"High-dose dexamethasone in a community-setting seems more toxic than low-dose dexamethasone, with more early deaths in the first 4 months, increased risk of thromboembolic complications, and higher overall risk of serious adverse events, particularly in patients older than 65 years," said S. Vincent Rajkumar, consultant, Mayo Clinic, and the lead author on the study.

The researchers found that 79% of 214 patients

receiving high-dose therapy and 68% of 205 patients on low-dose therapy had complete or partial response within four cycles.

However, at the second interim analysis at 1 year, overall survival was 96% in the low-dose dexamethasone group compared with 87% in the high dose group. As a result, the trial was stopped and patients on high dose therapy were crossed over to low-dose therapy.

As far as safety, 117 (52%) patients on the high-dose regimen had grade 3 or worse toxic effects in the first four months, compared with 35% of the 220 on the low-dose regimen for whom toxicity data were available.

Preliminary findings of this study were previously reported in abstract form at American Society of Hematology's annual meeting in December 2007.

Cancer Prevention:

Low Total Cholesterol Linked To Higher Risk Of Cancer; Higher HDL Associated With Decreased Risk Of Cancer

A pair of studies in Cancer Epidemiology, Biomarkers & Prevention lay to rest the decades-long concern that lower total cholesterol may lead to cancer, and in fact lower cholesterol may reduce the risk of high-grade prostate cancer.

Demetrius Albanes, a senior investigator at the National Cancer Institute, said early studies suggested that low cholesterol could increase the risk of certain types of cancer.

"Our study affirms that lower total cholesterol may be caused by undiagnosed cancer. In terms of public health message, we found that higher levels of 'good cholesterol' (HDL) seem to be protective for all cancers, which is in line with recommendations for cardiovascular health," said Albanes.

The researchers observed 29,093 men from the Alpha-Tocopherol, Beta-Carotene Cancer Prevention Study cohort for 18 years, making it the largest and longest study of its kind. In that follow-up period, they noted 7,545 cancer cases.

Low total cholesterol blood levels were associated with an 18 percent higher risk of cancer overall, similar to the increases seen in previous studies, but this risk disappeared when the researchers excluded cases that occurred in the early years after the original blood draw.

This finding suggests that the low total cholesterol levels did not cause cancer, but rather were the result of underlying cancer, said Albanes.

Higher levels of HDL cholesterol were associated with a 14 percent decreased risk of cancer even after excluding nine years of early cases.

In an accompanying study that looked specifically at risk for high-grade prostate cancer, Elizabeth Platz, associate professor in the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health and co-director of the Cancer Prevention and Control Program at the Sidney Kimmel Comprehensive Cancer Center at the Johns Hopkins University, found a link between low cholesterol and decreased risk of high-grade prostate cancer among 5,586 men older than 55 years.

Specifically, if men had total cholesterol of less than 200 mg/dL they had a 59 percent reduced risk of high-grade prostate cancer, defined as a Gleason score eight to 10. No association was seen for prostate cancer overall or for prostate cancer with a lower Gleason score.

Platz said that the study supports another benefit of keeping cholesterol low among men in this age group.

"High-grade prostate cancer is less common than prostate cancer overall, but it is a subset of prostate cancer that is more likely to progress," said Platz.

Discussion of the benefits of lower cholesterol inevitably leads to the discussion of the role of statins, which have produced one of the great public health success stories of the past few decades as cholesterol and, subsequently, heart disease rates have both fallen.

Statins have been enormous money makers for their industry manufacturers and with two already off patent, and the largest seller, Lipitor, scheduled to go off patent next year, researchers did leave open the possibility that industry leaders may seek a new indication for these blockbuster drugs.

"Until there is evidence from randomized trials, men should not take statins in order to prevent high-grade prostate cancer," said Eric Jacobs, strategic director of pharmacoepidemiology at the American Cancer Society, who wrote an accompanying editorial. He said a randomized trial among men without prostate cancer would need to be very large and might not be feasible.

"One possibility, however, would be a randomized trial among early stage prostate cancer patients opting for surveillance rather than immediate treatment, to see if statins could lower risk of prostate cancer progression," Jacobs said.

Cancer Disparities: **Black-White Disparity Seen In End Of Life Treatment**

A study of racial disparities in end-of-life care revealed that black cancer patients' treatment preferences were less likely to be observed than were white patients' preferences, according to researchers from Dana-Farber Cancer Institute.

Some black patients who had opted not to be resuscitated or put on a ventilator in a life-or-death crisis received the treatment anyway, and died in an intensive care unit. Conversely, white patients who had expressed a preference for aggressive care in end-of-life discussions with a doctor were three times more likely to receive it than were black patients who had voiced the same wishes.

"End-of-life care discussions appeared to be more effective in ensuring that white patients' treatment preferences were honored," said Holly Prigerson, senior author of the report in *The Journal of Clinical Oncology*. "We are not saying that black treatment preferences were ignored. Black patients did want, and did receive, more aggressive care than whites. The disparity was in the effect of treatment preferences on care received—not that black preferences didn't matter."

The study, which Prigerson and colleagues undertook to explore previously reported racial disparities in end-of-life care, such as the use of hospice and desire to undergo intensive treatments in hope of prolonging life.

"None of the white patients who reported the completion of a do-not-resuscitate order, or a DNR, order at baseline subsequently received intensive care in the last week of life," said Prigerson. "This did not prove to be the case for black patients. DNR orders did not significantly protect black patients from intensive end-of-life care in this study."

The black-white disparity in adherence to advance directives may be linked to gaps in communication, some of which resulted from discontinuities in care that may have been more prevalent in the treatment of black patients, she said.

For example, the researchers identified a few instances where DNR orders completed for black patients fell through the cracks because their informal caregivers (friend or family member) changed over the course of their illness, or because a critically ill patient was treated at a different hospital from the one that normally provided their care. In such cases where documentation was lacking, doctors forced into quick

decisions felt obligated to do everything possible for the patient, even if the situation seemed hopeless, said Prigerson.

The researchers, including lead author Elizabeth Trice Loggers, of Dana-Farber and scientists at several other institutions, interviewed 234 white and 68 black patients with advanced cancer. The initial interview included questions about the patients' preference for end-of-life care; the level of trust in their physicians; whether they had had an end-of-life care discussion with a doctor; and whether they had completed a DNR order. The patients' informal caregivers were interviewed separately. Each patient was monitored until their death, which on average was 3.5 months later. A patient was considered to have received intensive end-of-life care if he or she had undergone cardiopulmonary resuscitation and/or been placed on a ventilator in the last week of life, followed by death in an intensive care unit.

Prigerson said the study's findings highlight the need to improve clinical communication between black patients and their oncology care providers.

Breast Cancer: **HER2+ Tumors Increase Risk Of Recurrence, Study Finds**

Early-stage breast cancer patients with HER2 positive tumors one centimeter or smaller are at significant risk of recurrence of their disease, compared to those with early-stage disease who do not express the aggressive protein, according to a study led by researchers at the University of Texas M.D. Anderson Cancer Center.

The findings, published online in the *Journal of Clinical Oncology*, is the first large study to analyze this cohort and represents a shift in the way women with early-stage HER2 positive breast cancer should be assessed for risk of recurrence and considered for treatment, said the study's senior author, Ana Gonzalez-Angulo, associate professor in M. D. Anderson's Departments of Breast Medical Oncology and Systems Biology.

The research was first presented at the CRTC-AACR San Antonio Breast Cancer Symposium in December 2008.

Herceptin, (trastuzumab) was approved for use in 1998 for women whose advanced breast cancer expresses Human Epidermal growth factor Receptor 2, or HER2. Approximately 15-20 percent of breast cancer cells produce an excess amount of the HER2 growth protein on their surface, which makes the cancer more

aggressive. Herceptin is a monoclonal antibody that latches on to these proteins and inhibits tumor growth.

"This study represents a current debate within clinical practice - the risk of recurrence for early-stage breast cancer patients with HER2 positive tumors one centimeter or smaller," said Gonzalez-Angulo. "Our findings show that women with early stage HER2 positive breast cancer have a 23 percent chance of recurrence. In contrast, the five-year survival rate of all women with such early-stage breast cancer is more than 90 percent.

"The findings indicate that physicians need to consider offering these women Herceptin-based therapy in the post-operative, or adjuvant setting," Gonzalez-Angulo continued.

Current guidelines call for no additional therapy after surgery and radiation if tumors are less than five millimeters and Herceptin-based adjuvant therapy should be discussed with patients if the tumors are from six to 10 millimeters, Gonzalez-Angulo explained.

According to Gonzalez-Angulo, the number of patients with HER2 positive tumors smaller than one centimeter continues to increase as breast cancer surveillance and early detection become increasingly sophisticated.

"Before now, there's been no data regarding how to treat these women because they were excluded from all the definitive trials confirming Herceptin's benefit. This data strongly suggests that we need to rethink how we treat early-stage breast cancer patients with HER2 positive tumors and likely offer anti-HER2 therapy in the adjuvant setting."

For the retrospective study, Gonzalez-Angulo, and her team used M. D. Anderson's Breast Cancer Research Database to analyze 965 patients treated between 1990 and 2002. All of the patients' tumors were smaller than one centimeter; patients whose receptor status could not be analyzed and/or had received adjuvant chemotherapy or Herceptin at any time were excluded. The median age of the women at diagnosis was 57 years. To validate the findings, a second cohort of 350 patients from European institutions was also analyzed.

Of the M. D. Anderson patient population, more than 10 percent, or 98 patients, had HER2 positive tumors. In addition, 77 percent were hormone-receptor positive and 13 percent were triple receptor-negative.

In those analyzed with HER2 positive tumors, the five-year, recurrence-free survival was 77.1 percent; in contrast, HER2 negative patients' recurrence-free survival was 93.7 percent. Five-year distant recurrence-free survival was 86.4 percent in women with HER2

positive tumors compared to 97.2 percent in women with HER2-negative tumors. Patients with HER2-positive tumors had 2.68 times higher risk of recurrence and 5.3 times higher risk of distant recurrence than those with HER2-negative tumors.

In addition, women with HER2-positive tumors had 5.09 times the risk of recurrence and 7.81 times risk of distant recurrence than women with hormone receptor-positive tumors.

The European subset confirmed the M. D. Anderson findings and showed reproducibility, said Gonzalez-Angulo.

"The risk of recurrence was much higher than we suspected. With this study, we now have concrete evidence to discuss with our HER2 positive patients with even the smallest of tumors, and Herceptin alone or combined with chemotherapy should be strongly considered as adjuvant therapy," said Jennifer Litton, assistant professor in M. D. Anderson Department of Breast Medical Oncology, and also an author on the study. "This data should also encourage this subset of patients to be included in ongoing clinical trials with HER2-targeted therapies."

Gonzalez-Angulo and Litton hope that a specific, three-arm clinical trial can be designed comparing observation, Herceptin, and Herceptin combined with chemotherapy.

Currently, M. D. Anderson is a study site for BETH (BEvacizumab and Trastuzumab Adjuvant Therapy in HER2-positive Breast Cancer), an international phase III trial investigating the benefits of combining Avastin and Herceptin, together with chemotherapy for early stage HER2-positive breast cancer. Vincente Valero, professor in the Department of Breast Medical Oncology and also an author on the JCO research, is the study's institutional PI.

The Clinical Cancer Letter To End Print Edition In 2010

The Clinical Cancer Letter will cease production of a print edition in 2010.

All subscribers will receive the newsletter via email as of February 2010.

Subscribers to the print edition will begin to be moved to the online edition in December and January.

Print subscribers will receive a letter via regular mail with instructions on providing an email address and accessing the online newsletter.

The change is necessary due to increased printing, mailing, and postage costs.

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

8215 A Phase I Study of Poly IC:LC and NY-ESO-1/gp100/MART-1 Peptides Emulsified with Montanide ISA 51 with Escalating Doses of CP 870,893 in the Treatment of Subjects with Resected Stage III or Stage IV Melanoma, Moffitt Cancer Center and Research Institute. Weber, Jeffrey S. (813) 745-2007.

8269 A Phase I, Single-Institution Open Label, Dose-Escalation Trial with an Expansion Cohort Evaluating the Safety and Tolerability of AZD6244 and IMC-A12 in Subjects with Advanced Solid Malignancies, Johns Hopkins University. Azad, Nilofer S. (410) 614-9169.

8321 Phase I Study of 5-Azacytidine and Oxaliplatin in Patients with Advanced Cancers Relapsed or Refractory to Any Platinum Therapy, M D Anderson Cancer Center. Tsimberidou, Apostolia-Maria (713) 792-4259.

8472 ABT-888 as Monotherapy and in Combination with Mitomycin C in Patients with Solid Tumors with Deficiency in Homologous Recombination Repair, Ohio State University Medical Center. Villalona-Calero, Miguel Angel (614) 293-9424.

Phase I/II

8147 Phase I/II Trial of Anti-IGF-IR Monoclonal Antibody IMC-A12 Plus mTOR Inhibitor Temsirolimus (CCI-779) in Metastatic Castration-Resistant Prostate Cancer, Memorial Sloan Kettering Cancer Center. Rathkopf, Dana E. (646) 422-4379.

8329 A Phase I/II Trial of ABT-888, an Inhibitor of Poly(ADP-ribose) Polymerase (PARP), and Topotecan in Patients with Solid Tumors (Phase I) and Relapsed or Refractory Ovarian Cancer or Primary Peritoneal Cancer (Phase II) After Prior Platinum Containing First-Line Chemotherapy, Mayo Clinic Rochester. Menefee, Michael E. (904) 953-7290.

Phase II

E1908 A Phase II Randomized Trial Comparing Standard and Low Dose Rituximab: Initial Treatment of Progressive Chronic Lymphocytic Leukemia in Elderly Patients Using Alemtuzumab, and Rituximab, Eastern Cooperative Oncology Group. Zent, Clive S. (507) 266-1154.

RTOG-0921 A Phase II Study of Postoperative

Intensity Modulated Radiation Therapy with Concurrent Cisplatin and Bevacizumab Followed by Carboplatin and Paclitaxel for Patients with Endometrial Cancer, Radiation Therapy Oncology Group. Viswanathan, Akila N. (617) 732-6331.

Phase III

E1208 A Phase III Randomized, Double-Blind Trial of Chemoembolization with or without Sorafenib in Unresectable Hepatocellular Carcinoma (HCC) in Patients with and without Vascular Invasion, Eastern Cooperative Oncology Group. Kauh, John Sae Wook (404) 778-2407.

GOG-0250 A Randomized Phase III Evaluation of Docetaxel and Gemcitabine Plus G-CSF with Bevacizumab Versus Docetaxel and Gemcitabine Plus G-CSF with Placebo in the Treatment of Recurrent or Advanced Leiomyosarcoma of the Uterus, Gynecologic Oncology Group. Hensley, Martee Leigh (212) 639-6902.

RTOG-0848 A Phase III Trial Evaluating Both Erlotinib and Chemoradiation as Adjuvant Treatment for Patients with Resected Head of Pancreas Adenocarcinoma, Radiation Therapy Oncology Group. Abrams, Ross Allen (312) 942-5771.

Phase Other

AALL08B2 Genome-Wide Interrogations in Childhood Acute Lymphoblastic Leukemia, Children's Oncology Group. Loh, Mignon Lee-Cheun (415) 514-0853.

AAML09B2 Genomic and Proteomic Profiling of Childhood AML, Children's Oncology Group. Lacayo, Norman James (650) 723-5535.

AAML09B2 Genomic and Proteomic Profiling of Childhood AML, Children's Oncology Group. Lacayo, Norman James (650) 723-5535.

ACOSOG-Z4091 Next-Generation Sequencing-Based Characterization of Lung Adenocarcinoma Genomes, American College of Surgeons Oncology Trials Group. Mardis, Elaine R. (314) 286-1805.

ACOSOG-Z4097 CK19/P-cadherin Ratio as Predictor of Recurrence in Early Stage Adenocarcinoma of Lung, American College of Surgeons Oncology Trials Group. Reed, Carolyn Elaine (843) 876-4845.

AREN10B1 Validation of Prognostic Markers for Very Low Risk Wilms Tumors, Children's Oncology Group. Perlman, Elizabeth Jones (773) 880-4306.

Pilot

8313 Pilot Biomarker Study of the Integrin AlphaV Beta3 Antagonist Cilengitide (EMD121974) in Combination with Sunitinib, University of Chicago. Maitland, Michael L. (773) 834-8981.