

THE CLINICAL CANCER LETTER

Cancer research news for clinicians

Breast Cancer:

Breast Cancer Survivors Who Take Aspirin Have 50% Reduced Risk Of Metastasis

An analysis of data from the Nurse's Health Study, a large, ongoing prospective observational study, shows that women who have completed treatment for early-stage breast cancer and who take aspirin have a nearly 50 percent reduced risk of breast cancer death and a similar reduction in the risk of metastasis.

"This is the first study to find that aspirin can significantly reduce the risk of cancer spread and death for women who have been treated for early-

(Continued to page 2)

Cost-Effectiveness Research:

Economic Analysis Finds Erlotinib Marginally Cost-Effective For NSCLC

Weighing both magnitude of survival benefit and expense, researchers found that the drug erlotinib, which was found to improve overall survival by two months in patients with advanced non-small cell lung cancer, is marginally cost-effective.

The results of the economic analysis using clinical trial data were reported in a new study published online Feb. 16 in the Journal of the National Cancer Institute.

Natasha Leighl, of the University Health Network in Toronto, and colleagues performed an analysis of erlotinib treatment in the NCIC Clinical Trials Group BR.21 trial to determine the cost-effectiveness of treating various populations with the drug, a tyrosine kinase inhibitor. The researchers also calculated the incremental cost-effectiveness ratio.

The incremental cost-effectiveness ratio for erlotinib treatment in the trial population was \$94,638 (2007 Canadian dollar) per life-year gained (95% confidence interval = \$52,359 to \$429,148).

According to the researchers, this figure exceeds the threshold historically accepted as cost-effective (\$50,000 per quality-adjusted life year). The ratio was in the higher range of cost-effectiveness ratios that high-resource countries may consider acceptable. Thus, it may be possible to enhance the cost-effectiveness of this treatment through the clinical and molecular selection of patients for treatment, the authors report.

Subgroup analyses revealed that erlotinib may be more cost-effective in never-smokers or patients with high EGFR gene copy number.

"Ongoing efforts to identify which patients are most likely to benefit from

(Continued to page 8)

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

Breast Cancer:

Racial Disparities Persist In Diagnosis Of Advanced Breast, Colon Cancers

... Page 3

Breast Cancer Rates Decline Most For Affluent White Women

... Page 4

Ovarian Cancer:

Symptoms Not Useful For Early-Stage Detection

... Page 5

Lung Cancer:

Studies Investigate Balance Of Palliation, Side Effects For RT

... Page 6

NCI-Approved Trials

... Page 7

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

Aspirin Use Cut Breast Cancer Metastasis, Death, By Half

(Continued from page 1)

stage breast cancer,” said Michelle Holmes, associate professor of medicine and epidemiology at Harvard Medical School & Harvard School of Public Health and the study’s lead author. “If these findings are confirmed in other clinical trials, taking aspirin may become another simple, low-cost and relatively safe tool to help women with breast cancer live longer, healthier lives.”

Investigators report it is not yet clear how aspirin affects cancer cells, but they speculate it decreases the risk of cancer metastasis by reducing inflammation, which is closely associated with cancer development. Prior studies have also suggested that aspirin inhibits cancer spread: one study found that people with colon cancer who took aspirin lived longer than those who did not, and laboratory studies have also shown that aspirin inhibited the growth and invasiveness of breast cancer cells.

In this analysis, researchers evaluated data from the Nurses’ Health Study, which included 4,164 female nurses in the U.S. (ages 30 to 55 in 1976) who were diagnosed with stage I, II, or III breast cancer between 1976 and 2002 and were followed through June 2006. They examined patients’ use of aspirin for one or more years after a breast cancer diagnosis (when patients would have completed treatment such as surgery, radiation therapy, and/or chemotherapy) and

the frequency of metastasis and breast cancer death. (The authors emphasized that patients undergoing active treatment should not take aspirin due to potential interactions that can increase certain side effects.)

A total of 400 women experienced metastasis, and 341 of these died of breast cancer. Women who took aspirin two to five days per week had a 60 percent reduced risk of metastasis and a 71 percent lower risk of breast cancer death. Those who took aspirin six or seven days a week had a 43 percent reduced risk of metastasis and a 64 percent lower risk of breast cancer death. The risk of breast cancer metastasis and mortality did not differ between women who did not take aspirin and those who took aspirin once a week.

Researchers also found that women who took non-aspirin non-steroidal inflammatory drugs (NSAIDs) six or seven days a week also had a reduced risk of breast cancer death (a 48 percent reduction), but women who took NSAIDs less frequently and those who used acetaminophen did not experience such a benefit.

While the investigators did not collect data on aspirin dose, they noted that women who took aspirin regularly most likely took it for heart disease prevention; the typical dose for that purpose is 81 mg/day.

Racial Disparities Persist In Diagnosis Of Advanced Breast Cancer, Colon Cancer

The incidence of advanced breast cancer diagnosis among black women remained 30 percent to 90 percent higher compared to white women between 1992 and 2004, according to new findings by researchers at Fred Hutchinson Cancer Research Center.

In addition, the disparity in the incidence of advanced colorectal cancer actually widened over this time period as rates fell among whites but increased slightly among blacks.

The findings are published online in *Hormones and Cancer*, a publication of the Endocrine Society.

“While we could not determine the exact contributors to the trends we saw in this study, it is interesting to note that for breast cancer, mammographic screening rates were quite similar among African American and white women in the United States during the time period we studied,” said senior author Christopher Li, an associate member of the Public Health Sciences Division at the Hutchinson Center. “This suggests that factors other than screening may be contributing to this persistent disparity, including

THE CLINICAL CANCER LETTER

Editor and Publisher: Kirsten Boyd Goldberg

Editorial, Subscriptions, and Customer Service:
202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
Website: <http://www.cancerletter.com>

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

differences in both lifestyle and genetics.”

A potential explanation for this disparity, he said, is that overall, black women have more-aggressive tumors that are more difficult to detect and treat as compared to non-Hispanic white women. Specifically, they have higher rates of hormone-receptor-negative breast cancers. Such tumors, while relatively rare, grow quickly and therefore often are not detected during screening mammograms. These tumors also are more resistant to therapy because they don't respond to estrogen-blocking drugs such as tamoxifen.

The study included data on 7,237 women with newly diagnosed distant-stage breast cancer. Of these women, 1,364 were black and 5,873 were white.

Overall, rates of advanced breast cancer remained essentially constant among women of both races throughout the study period, affecting about 18 out of 100,000 black women and 12 out of 100,000 white women.

The study also looked at rates of advanced-stage colorectal and prostate cancer in an attempt to deduce how screening practices may have impacted the magnitude of racial disparities in these malignancies during this 12-year period, an era of increased use of breast, colorectal and prostate cancer screening in the U.S.

For colorectal cancer, the researchers saw a widening of the racial disparity gap. Distant-stage incidence rates among non-Hispanic whites declined over time but increased somewhat among blacks.

“It is possible that differing rates of colorectal endoscopy screening between African American and non-Hispanic whites could contribute to this widening disparity,” said lead author Jean McDougall, a doctoral student in epidemiology at the University of Washington School of Public Health.

The study looked at data from 8,920 people diagnosed with distant-stage colorectal cancer. Of these, 1,669 were black and 7,251 were white. The black colorectal cancer patients were slightly younger at diagnosis and were more likely to be female as compared to whites.

The relative risk of advanced colorectal cancer was significantly elevated in blacks throughout the study period. In 1992, blacks were 60 percent more likely to be diagnosed with late-stage colorectal cancer as compared to whites, and by 2004 that likelihood had doubled.

However, for prostate cancer, the disparity gap narrowed somewhat over time, as advanced-stage prostate cancer incidence rates declined for both black and non-Hispanic whites.

The study included data from 2,801 men with late-stage cancer, 791 black and 2,010 white. The incidence of distant-stage prostate cancer among black men fell from 50 cases in 100,000 at the start of the study to 19.8 cases in 100,000 at the end of the data collection process. This level was still three times higher than that of white men, but it was a significant decline nonetheless.

“During this time period it became increasingly apparent that prostate cancer was an important public health problem in the African American community and there was a lot of effort to address this issue by raising awareness of screening,” Li said. “I think that maybe we're seeing some of the benefits of that work here.”

For the study, the researchers analyzed data from 12 population-based urban cancer registries throughout the continental U.S. and Hawaii, representing about 14 percent of the population. They focused on distant-stage cancers for which screening tests were widely available.

Data included female breast cancer cases between ages 40 and 64, male prostate cancer cases between ages 50 and 64, and male and female colorectal cancer cases between ages 50 and 64. The age ranges were chosen to reflect American Cancer Society screening guidelines and Medicare eligibility.

The study did not evaluate late-stage cancer rates among Asians/Pacific Islanders, American Indians/Alaska Natives or those of Hispanic ethnicity because of insufficient numbers of cases within each racial/ethnic group to conduct a statistically significant analysis of cancer trends over time.

Because the analysis was based on population-based data on incidence rates of advanced cancer but not on individual data that would reflect tumor biology or screening practices, the authors caution that the findings cannot predict individual risk but should be interpreted as a broad view of cancer trends over time.

“Epidemiologic studies such as this one are an important first step in understanding trends in disease rates on a population level,” McDougall said. “However, we cannot draw strong conclusions regarding the factors contributing to the trends observed from this study, as its goal was to describe trends over time without using detailed data on individual cases and the complex factors that contribute to disease.”

The authors concluded that blacks continue to have a disproportionately high cancer burden, and therefore “continued multipronged efforts aimed at improving access to breast, colorectal and prostate cancer prevention, screening, diagnostics and treatment services are warranted.”

African-Americans Survival Disadvantage

In a different study, researchers found that African-Americans with cancer are less likely to survive it than whites, and residents of poor neighborhoods less likely to survive than are those in wealthier areas of the state.

The racial disadvantage diminishes when socioeconomic status is a consideration, but does not disappear, according to the study in the February issue of the *Journal of Health Care for the Poor and Underserved*.

“Our results are not surprising,” said Xiaoling Niu, a biostatistician at Cancer Epidemiology Services in the New Jersey Department of Health and Senior Services, and lead study author. “Other studies have also revealed poorer survival rates among blacks.” Few, however, relied on such a wealth of data on such a diverse population, she said.

The data come from the New Jersey State Cancer Registry, which records nearly all cases among the 8.6 million residents of the state. The authors looked at cases diagnosed from 1986 to 1999 and analyzed survival rates for breast cancer in women; prostate, colorectal and lung cancer; and all cancers combined.

Having cancer and being black or living in a poorer neighborhood meant higher risk of death, even when researchers adjusted for age and cancer stage at diagnosis. “Disparities occur amid relative poverty as well as absolute poverty,” the authors wrote.

Other minorities fared better than African-Americans: Cancer survival among Hispanics was the same as for whites; among Asians and Pacific Islanders, it was better.

Taken alone, these data cannot explain the observed racial, ethnic and socioeconomic disparities, but “this kind of study can provide background information for more targeted research into underlying behavioral and social factors,” Niu said.

Study co-author Karen Pawlish, an epidemiologist, said, “diet, obesity, physical activity and smoking may affect survival. Biological factors could explain part of the difference, but there may be other factors related to access and quality of care.”

Brian Smedley, vice president and director of the Health Policy Institute at the Joint Center for Political and Economic Studies in Washington, said that “separate but unequal” health care services probably are involved.

“We know that minorities are disproportionately clustered in medically underserved communities, where many health care institutions have fewer resources to

provide high-quality care,” Smedley said. “Research increasingly points to differences in care that patients of color receive compared to whites. Some have called this ‘medical apartheid.’”

The N.J. study “raises more questions than it answers,” Smedley said. “I’d like to see research move away from describing the problem to looking at interventions that level the playing field.”

Breast Cancer Rates Decline Most for Affluent White Women

Breast cancer rates are declining, but some groups have seen a more significant decline than others, with race, ethnicity and economic background playing a part.

According to a new national study, the only significant decline in breast cancer rates occurred among white, non-Hispanic women, 50 and older, who live in affluent countries and who have the kind of tumors that an estrogen-rich environment will nourish. Breast cancer rates declined by as much as 10 percent annually in this group.

The study, which appears online and in the April supplement of the *American Journal of Public Health*, relied on data obtained from 13 U.S. population-based cancer registries for 1992 to 2005, and analyzed trends among 350,000 cases, looking at race/ethnicity and socioeconomic position, as well as age at diagnosis and breast cancer tumor characteristics.

In 2002, the Women’s Health Initiative study prompted many doctors to stop prescribing hormone therapy when the findings contradicted the previously held assumption that estrogen/progestin replacement therapy would lower a woman’s risk of heart disease.

Instead, the findings suggested that hormone therapy actually would increase the risk of heart disease and breast cancer. Although the new study on breast cancer trends did not have access to information on individual women’s hormone therapy use, the same group of women who exhibited the most significant decline in breast cancer rates was also the group most likely to have been taking hormones before the Women’s Health Initiative.

“The fact that it was not a general decline gives further credence to the idea that it was something very specific commonly affecting this group of women,” said lead study author Nancy Krieger. “It looks like the most logical thing was a change in the administration of hormone therapy. The rates didn’t decline among white women living in less affluent countries or black women

in rich or poor countries.” Krieger is a professor in the department of society, human development and health at the Harvard School of Public Health.

Low Prevalence Of Tamoxifen Use For Cancer Prevention

Researchers with the National Cancer Institute have found that the prevalence of tamoxifen use for the prevention of breast cancer among women without a personal history of breast cancer is very low.

Tamoxifen can reduce the risk of developing breast cancer in women who are at increased risk for developing the disease.

Details of this survey are published in the February issue of *Cancer Epidemiology, Biomarkers & Prevention*, a journal of the American Association for Cancer Research.

The low prevalence of tamoxifen use may stem from various sources, which were not investigated in this study, according to the study’s coauthor Andrew Freedman, chief of the Clinical and Translational Epidemiology Branch in the NCI Division of Cancer Control and Population Sciences.

However, he stressed that “counseling individual women about using tamoxifen to prevent breast cancer must include a patient’s discussion with her physician about the drug’s risks and benefits, as well as consideration of the patient’s personal values, preferences, lifestyle and specific medical situation.”

Lead author of this study, Erika Waters, assistant professor at Washington University School of Medicine in St. Louis, and colleagues at the NCI wanted to gain an understanding of how many women aged 40 to 79 years were taking tamoxifen for the prevention of breast cancer. They answered this question using data from the National Health Interview Surveys from years 2000 and 2005, which are nationwide surveys designed to be representative of the entire U.S. The surveys included more than 10,000 women for each year.

“Our results indicated that very few women were using tamoxifen to prevent breast cancer,” said Waters. “However, we don’t know exactly why.”

The researchers found that the prevalence of tamoxifen use in this survey population was very low—0.2 percent in 2000 and 0.08 percent in 2005. The difference between the two years was not statistically meaningful, according to the researchers.

Freedman and Waters speculated that the drug’s low uptake may be linked to many factors including the fact that tamoxifen is associated with several side

effects. These side effects include hot flashes, sexual problems, uterine cancer, blood clots and cataracts. Other possible explanations that the researchers gave for the low uptake may be that physicians are unaware of the drug’s availability, physicians are reluctant to prescribe it, patients are reluctant to take it, there is a lack of patient or physician education about the drug, or skepticism about whether the benefits outweigh the risks. It could also be that physicians and patients are, in fact, very educated and are making very informed decisions, according to the researchers.

“The decision to use a drug like tamoxifen in women at high-risk for, but who do not yet have a diagnosis of breast cancer is not easy. It is dependent upon the woman’s personal choice, which can be influenced by many factors, not just her medical eligibility. There is no right answer,” said Waters, who at the time of the study was a fellow in the Cancer Prevention Fellowship Program, Center for Cancer Training, NCI.

Susan Gapstur, vice president of epidemiology, American Cancer Society, and editorial board member of *Cancer Epidemiology, Biomarkers & Prevention*, said that “overall, these results provide an important snapshot of the very low uptake of tamoxifen for cancer prevention.”

“Although the researchers speculate on a number of possible explanations, it remains unclear to what extent the low uptake might be attributed to physician reluctance to prescribe tamoxifen and/or patient reluctance to take it,” said Gapstur.

Ovarian Cancer: Symptoms Don't Help Detect Early-Stage Ovarian Cancer

Use of symptoms to trigger a medical evaluation for ovarian cancer does not appear to detect early-stage ovarian cancer earlier and would likely result in diagnosis in only 1 out of 100 women in the general population with such symptoms, according to an article published online January 28 in the *Journal of the National Cancer Institute*.

Researchers at Fred Hutchinson Cancer Research Center in Seattle assessed the predictive value of certain symptoms, including abdominal pain or bloating and urinary frequency, which were cited in a recent consensus statement as a way to diagnose ovarian cancer earlier.

Mary Anne Rossing, of the Program in Epidemiology at Fred Hutchinson, and colleagues conducted in-person interviews with 812 patients aged 35-74 years who had

epithelial ovarian cancer that was diagnosed from 2002 through 2005. They compared the results from these case patients with results from interviews with 1,313 population-based control subjects—women who did not have ovarian cancer. The researchers assessed the sensitivity, specificity, and positive predictive value of a proposed symptom index and of symptoms included in the consensus recommendation.

Symptoms appeared in most case patients only about 5 or fewer months before diagnosis. Women with early-stage ovarian cancer were somewhat less likely to have symptoms (except nausea) than those with late-stage cancer. The estimated positive predictive value of the symptoms was 0.6%–1.1% overall and less than 0.5% for early-stage disease.

The authors conclude that 100 symptomatic women would need to be evaluated to detect one woman with ovarian cancer. “The low positive predictive value of symptoms to detect ovarian cancer—particularly at an early stage—argues for a cautious approach to the use of symptom patterns to trigger extensive medical evaluation for ovarian cancer,” the authors write.

In an editorial, Beth Karlan and Ilana Cass, of the Division of Gynecologic Oncology at Cedars-Sinai Medical Center, note the strengths of the study, including in-person interviews and large number of patients, but also point out its limitations: inherent recall bias and survival bias in case patients and control subjects. Recall bias is always a possibility in case-control studies in that case subjects may be more likely to remember symptoms than control subjects.

“Importantly, these findings remind us that wide recognition of symptoms alone will not incrementally improve the overall survival from ovarian cancer,” the editorialists write. “Rather, they highlight the urgent need to develop better molecular markers and improved imaging modalities for ovarian cancer screening.”

Lung Cancer: **Two-Week Break Balances RT Palliation, Side Effects**

Decisions regarding the optimal lung cancer treatment regime are a difficult choice for physicians. Featured in February’s issue of the *Journal of Thoracic Oncology*, researchers investigated the utilization of surgery and the subsequent need for radiotherapy when treating stage I small cell lung cancer.

An additional study reported on the positive outcomes of a two-week break in palliative chest radiotherapy for patients with non-small cell lung

cancer.

In the first study, researchers sought to assess the overall efficacy of split-course palliative chest radiotherapy (RT) for symptom relief in patients with advanced non-small cell lung cancer. They also investigated the impact of a two-week break on survival outcomes.

The majority of lung cancer patients present with locally advanced or stage IV disease. The primary challenge in treating these patients is that most present with poor performance status, and the benefit of treatment may be doubtful because of poor tolerance to any form of therapy. Palliative chest RT for lung malignancies has shown to be effective in relieving serious chest symptoms from tumor bleeding or mass effect on major airways, vessels and nerves. However, there is a lack of consensus for an optimal palliative RT regimen.

Researchers reviewed the medical records of 140 patients in a retrospective analysis. The team evaluated symptom relief and toxicity during and after completion of RT treatment from clinician notes and patient-reported symptom inventory forms. Then, the researchers examined the impact of the treatment regimen on survival rates. Symptomatic relief was observed in all types of chest symptoms with an extent ranging from 52-84 percent. Long-lasting symptom relief was experienced in 58 percent of patients. Therapy was well-tolerated, and toxicity was mild and transient, with grade 1 or 2 treatment-related esophagitis completely resolved during the two-week break. Cancer survival was not adversely affected by a break in treatment.

“Balancing symptomatic relief with the side effects of radiotherapy remains a critical element of patient treatment,” said lead investigator, Su Metcalfe, of the James P. Wilmot Cancer Center at the University of Rochester. “Our selection design represents a viable option for patients who cannot tolerate continuous radiation treatment courses. Furthermore, the study’s finding provides the basis for future large prospective studies that evaluate split-course palliative chest radiotherapy against other regimens.”

The second study investigated the utilization of surgery and the subsequent need for radiotherapy when treating stage I small cell lung cancer. Traditionally, SCLC treatment regimes include chemotherapy and radiotherapy for limited stage disease; however, the study concludes that in selected patients with early stage disease a lobectomy (removal of lung) had an excellent overall survival without additional treatment.

Researchers retrospectively evaluated the outcomes

of 247 stage I SCLC patients who underwent lobectomies; these cases were identified using the National Cancer Institute's Surveillance Epidemiology and End Results database. Results showed the three- and five-year survival rates for the patient group who underwent lobectomies without RT were 58.1 percent and 50.3 percent, respectively. For those who supplemented their surgery with RT, three- and five-year overall survival was 64.9 percent and 57.1 percent.

"Based on our analysis, surgery without RT may offer a reasonable survival in a selected cohort of patients who undergo lobectomy, but this needs to be validated in a prospective setting," said study lead investigator James Yu, of Yale University. "We cannot say conclusively whether patients who endure invasive surgeries can go without additional adjuvant radiation or chemotherapy, but looking forward, the study findings create a platform for advancing the understanding of the role of surgery in therapy."

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

7606 Immunotherapy for Unresectable Pancreas Cancer: A Phase I Study of Intratumoral Recombinant Fowlpox PANVAC (PANVAC-F) plus Subcutaneous Recombinant Vaccinia PANVAC (PANVAC-V), PANVAC-F and Recombinant Granulocyte-Macrophage Colony Stimulating Factor (rH-GM-CSF), Cancer Institute of New Jersey. Poplin, Elizabeth (732) 235-8053.

8342 Autophagic Modulation with Anti-Angiogenic Therapy in Patients with Advanced Malignancies: A Phase I Trial of Sunitinib and Hydroxychloroquine, Cancer Institute of New Jersey. Mehnert, Janice M. (732) 235-6777.

ADV0819 A Phase I Study of SAHA and Temozolomide in Children with Relapsed or Refractory Primary Brain or Spinal Cord Tumors, COG Phase I Consortium. Hummel, Trent Ryan (513) 636-4266.

GOG-9924 A Phase I Pharmacokinetic Study of Intraperitoneal CTEP-Supplied Agent Bortezomib and Carboplatin in Patients with Persistent or Recurrent, Ovarian, Fallopian Tube, or Primary Peritoneal Cancer, Gynecologic Oncology Group. Dizon, Don S. (401) 453-7520.

Phase I/II

AMC-070 A Phase I/II Study of Lenalidomide in Patients with AIDS-Associated Kaposi's Sarcoma, AIDS-Associated Malignancies Clinical Trials Consortium. Shimabukuro, Kelly Anne (858) 822-6276.

RTOG-0913 Phase I/II Trial of Concurrent RAD001 (Everolimus) with Temozolomide/Radiation Followed by Adjuvant RAD001/Temozolomide in Newly Diagnosed Glioblastoma, Radiation Therapy Oncology Group. Chinnaiyan, Prakash (813) 745-3425.

S0905 A Phase I/Randomized Phase II Study of Cediranib Versus Placebo in Combination with Cisplatin and Pemetrexed in Chemonaive Patients with Malignant Pleural Mesothelioma, Southwest Oncology Group Tsao. Anne S. (713) 792-6363.

Phase II

8167 Pilot Phase II Study of Temsirolimus in Patients with Recurrent Mixed Mesodermal and Mullerian Tumors (Carcinosarcoma) of the Uterus, Montefiore Medical Center. Einstein, Mark H. (718) 405-8082.

8468 A Phase 2 Study of Positron Emission Tomography Imaging with [18F]-Fluoromisonidazole (FMISO) and [18F]-Fluorodeoxyglucose (FDG) for Assessment of Tumor Hypoxia in Soft Tissue Sarcoma, University of Washington Medical Center. Eary, Janet F. (206) 598-7567.

CALGB-30803 A Randomized Phase II Study of Insulin-Like Growth Factor Pathway Inhibition Based Neoadjuvant Therapy in Early Resectable Non-Small Cell Lung Cancer, Cancer and Leukemia Group B. Dubey, Sarita (415) 353-7065.

E1308 A Phase II Trial of Induction Chemotherapy Followed by Cetuximab (Erbix) with Low Dose vs. Standard Dose IMRT in Patients with HPV-Associated Resectable Squamous Cell Carcinoma of the Oropharynx, Eastern Cooperative Oncology Group. Marur, Shanthi (410) 502-3820.

E2A08 A Phase II Study of Bortezomib, Liposomal Doxorubicin, Dexamethasone, and Cyclophosphamide in Patients with Multiple Myeloma Relapsing within 12 Months of Autologous Stem Cell Transplant, Eastern Cooperative Oncology Group. Kumar, Shaji K. (507) 266-0523.

RTOG-0837 Randomized, Phase II, Double-Blind, Placebo-Controlled Trial of Conventional Chemoradiation and Adjuvant Temozolomide Plus Cediranib Versus Conventional Chemoradiation and Adjuvant Temozolomide Plus Placebo in Patients with Newly Diagnosed Glioblastoma, Radiation Therapy

Oncology Group. Batchelor, Tracy T. (617) 724-8770.
RTOG-0937 Randomized Phase II Study Comparing Prophylactic Cranial Irradiation Alone to Prophylactic Cranial Irradiation and Consolidative Extra-Cranial Irradiation for Extensive Disease Small Cell Lung Cancer (ED-SCLC), Radiation Therapy Oncology Group. Gore, Elizabeth M. (414) 805-4465.

S0833 Modified Total Therapy 3 (TT3) for Newly Diagnosed Patients with Multiple Myeloma (MM): A Phase II Southwest Oncology Group Trial for Patients Aged ≤ 65 Years, Southwest Oncology Group. Abidi, Muneer Hyder (313) 576-8711.

S0925 A Randomized Phase II Study of Combined Androgen Deprivation Versus Combined Androgen Deprivation with IMC-A12 for Patients with New Hormone-Sensitive Metastatic Prostate Cancer, Southwest Oncology Group. Yu, Evan Ya-Wen (206) 288-6292.

Phase III

E4A08 A Randomized Phase III Trial of Melphalan and Dexamethasone (MDex) Versus Bortezomib, Melphalan and Dexamethasone (BMDex) for Untreated Patients with Systemic Light-Chain (AL) Amyloidosis Ineligible for Autologous Stem-Cell Transplantation, Eastern Cooperative Oncology Group. Dispenzieri, Angela (507) 284-2479.

Other

AAML10B12 Mechanisms of PLAGL2-Induced Leukaemogenesis, Children's Oncology Group. Meshinchi, Soheil (206) 667-4077.

AAML10B13 Critical Role of MicroRNA-34a and MicroRNA-194 in Acute Myeloid Leukemia with CEBPA Mutations, Children's Oncology Group. Meshinchi, Soheil (206) 667-4077.

AAML10B15 EVI-1 Expression in Pediatric AML with 11q23 Abnormalities, Children's Oncology Group. McKenney, Amy Heerema (650) 721-3288.

AAML10B16 Stat3 Activation as a Potential Prognostic Marker and Therapeutic Target in Pediatric AML, Children's Oncology Group. Redell, Michele Simmons (832) 822-4824.

AOST10B3 Genomic Study of Metastatic Osteosarcoma Using Next-Generation Sequencing Technology, Children's Oncology Group. Khan, Javed (301) 435-2937.

CALGB-150905 Natural Killer Cell KIR and HLA Genotypes May Predict Response to Antibody Therapy in Follicular Lymphoma, Cancer and Leukemia Group B. Venstrom, Jeffrey M. (646) 888-2321.

E3200T3 Molecular Predictors of Outcome of FOLFOX4 + Bevacizumab versus FOLFOX4 Alone

versus Bevacizumab Alone in 2nd Line Treatment of Metastatic Colorectal Carcinoma - E3200, Eastern Cooperative Oncology Group. Meropol, Neal Jay (216) 844-5220.

GOG-8006 Development of a Serum Proteomic Profile for Cervical Cancer with Potential Prognostic Value, Gynecologic Oncology Group. Khleif, Samir N. (301) 594-0210.

GOG-8012 ERCC1 Expression as a Predictor of Progression Free and Overall Survival in Patients with Epithelial Ovarian Cancer Treated on GOG Protocols 0172 and 0182, Gynecologic Oncology Group. Krivak, Thomas Carl (412) 641-1153.

S9031-S9126-S9333-S9500-B Topoisomerase 2 Expression and Acute Myeloid Leukemia, Southwest Oncology Group. Advani, Anjali S. (216) 445-9354.

Pilot

ARST08P1 A Pilot Study to Evaluate Novel Agents (Temozolomide and Cixutumumab) in Combination with Intensive Multi-Agent Interval Compressed Therapy for Patients with High-Risk Rhabdomyosarcoma, Children's Oncology Group. Malempati, Suman (503) 494-1543.

Cost-Effectiveness:

Erlotinib May Be More Cost-Effective In Subgroups

(Continued from page 1)

treatment and to make targeted cancer therapies more affordable will serve to make this important treatment option available for lung cancer patients worldwide," the authors write.

In an accompanying editorial, Scott Ramsey, of Fred Hutchinson Cancer Research Center, said the study provided new information to help address some of the questions surrounding the drug's use. Although the study's findings are unlikely to sway any policies, it does provide information on the potential economic impact of biomarker-guided treatment with erlotinib.

"The unwillingness of public and private health systems and providers in the United States to consider costs relative to benefits in decisions about access to these products presents a clear signal to drug manufacturers," he writes. "It also presents the rest of the world with a need for information that identifies patients for whom the amount of benefit of therapies such as erlotinib can support a valid argument for their use."

Study limitations: Some costs were not captured in the database and required modeling. Prospective utility data were not collected in the BR.21 trial.