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Cancer research news for clinicians

2009 Year In Review:

ASCO Annual Report Names Significant Clinical Research Advances Of Past Year

The American Society of Clinical Oncology released its annual report, an independent assessment of the most significant clinical cancer research studies of the past year, including 15 major advances.

The report also makes policy recommendations for increasing investment in cancer research funding, accelerating progress in clinical cancer research, and ensuring that Americans with cancer receive high-quality care.

"These continuing research advances should encourage people with

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Multiple Myeloma:

Revlimid Extends Time To Progression Compared To Placebo In Phase III Trial

Initial results from a large, randomized clinical trial for patients with multiple myeloma showed that patients who received the oral drug lenalidomide (Revlimid, also known as CC-5013) following a blood stem cell transplant had their cancer kept in check longer than patients who received a placebo.

The clinical trial, for patients ages 18 to 70, was sponsored by the National Cancer Institute and conducted by a network of researchers led by the Cancer and Leukemia Group B in collaboration with the Eastern Cooperative Oncology Group and the Blood and Marrow Transplant Clinical Trials Network (BMT CTN). The BMT CTN is co-sponsored by NCI and the National Heart, Lung, and Blood Institute, both parts of the National Institutes of Health.

The independent data and safety monitoring committee overseeing the trial (known as CALGB-100104) found that the study demonstrated a longer time before the cancer progressed following autologous blood stem cell transplantation for those patients on the study drug than those on placebo and so the trial was stopped early.

Autologous blood stem cell transplantation is a procedure in which a patient's own blood stem cells are removed, the patient is then treated with high doses of chemotherapy and/or radiation therapy to kill the cancer, after which the blood stem cells are returned to the patient. It is a common procedure for patients with multiple myeloma.

A total of 568 patients with multiple myeloma, who had received no more than 12 months of prior therapy and no prior transplant, were enrolled

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ASCO Lists 15 Advances In Cancer Research In 2009

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cancer and those who care for them," said ASCO President Douglas Blayney. "As this report demonstrates, investment in clinical cancer research is paying off. Since 1990, cancer death rates have declined 15 percent. Today, two-thirds of patients survive at least five years after diagnosis, compared to just half 40 years ago, and they have a dramatically higher quality of life."

This year, ASCO identified 15 major cancer research advances in four key areas.

Advances in Personalized Medicine And Targeted Therapies

Multiple trials this year demonstrated that oncology is no longer "one size fits all" medicine. Rather, increased understanding of the biology of cancer is enabling researchers to develop highly targeted drugs and personalized treatment regimens for patients. Advances in this category include:

• The targeted drug trastuzumab (Herceptin), which has been successful against breast tumors that overexpress the HER2 protein, was found to improve survival for HER2+ gastric cancer.

• Researchers identified the first effective immunotherapy for neuroblastoma—chimeric anti-GD2 antibody ch.14.18.

• For the first time in 30 years, a randomized trial identified a regimen—initial chemotherapy combined with the EGFR-targeted drug cetuximab (Erbitux)—that increases survival for people with metastatic head and neck cancer.

• Researchers identified a specific subset of patients with non-small cell lung cancer who benefit from first-line treatment with the targeted drug gefitinib (Iressa).

• FDA approved new indications for targeted drugs to treat glioblastoma and advanced kidney cancer, both highly challenging forms of cancer. Bevacizumab (Avastin) was approved as a single agent for treatment of glioblastoma and when combined with interferon, for treatment of advanced kidney cancer. Everolimus (Afinitor) was approved for kidney cancer in patients whose disease has progressed despite treatment with other targeted drugs.

New Standards of Care

Results from several long-awaited clinical trials this year affirmed the superiority of certain treatment regimens for biliary, lung, and prostate cancers. These include:

• The first-ever standard of care for advanced biliary cancer (cancers of the gallbladder and bile ducts). Results from the largest clinical trial to date for this disease stage showed that combination gemcitabine (Gemzar) and cisplatin treatment increases survival and slows cancer progression, compared with gemcitabine treatment alone.

• Data from a late-stage trial reporting that maintenance therapy with pemetrexed (Alimta) extends survival for patients with nonsquamous forms of advanced NSCLC—a finding that establishes a new standard and gives patients a long-term, easily-administered treatment option with low toxicity.

• Practice-changing findings showing that radiation following prostatectomy improves survival and reduces risk of metastasis for men with early-stage prostate cancer.

Cancer Prevention and Screening

This year, findings from large trials shed new light on widely used cancer detection, monitoring and prevention tools. Major research advances in this category include:

• Interim results from two large trials showing that routine PSA testing has a minimal effect on reducing prostate cancer mortality—findings that add new insight to a long-time debate.

• A large trial showing that treating relapsed ovarian cancer based on rising levels of a protein in

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the blood called CA125 does not improve outcomes, compared with monitoring for physical symptoms of ovarian cancer relapse. These findings will help spare women from the anxiety and costs of frequent CA125 testing, as well as the toxicity of earlier treatment.

• Research suggesting that more women may benefit from HPV vaccination than previously thought, based on findings showing that Gardasil reduces the risk of HPV infection, cervical cancer and other HPV-related disease in women aged 25 to 45.

Large Trials Settle Key Debates in Colon, Breast Cancer Treatment

The results of two closely watched studies settled major debates in the treatment of colon and breast cancers. These include:

• In the first trial to examine bevacizumab in the adjuvant setting, researchers demonstrated that adjuvant bevacizumab treatment does not prevent colon cancer recurrence in patients who have undergone surgery for their disease.

• Standard three-drug chemotherapy is more effective and less toxic than single-drug treatment with capecitabine (Xeloda) in women age 65 and older undergoing adjuvant treatment for early-stage breast cancer. Researchers had thought that single-drug treatment may be more tolerable for older women, but this was not found to be the case.

ASCO's Recommendations

In the report, ASCO also makes three key recommendations for accelerating progress in clinical cancer research and ensuring that people with cancer have access to high-quality care.

"To achieve new breakthroughs, the scale of our nation's response must match the scale of the problem," Blayney said. "The cancer community has a long road ahead before we reach President Obama's goal of finding 'a cure for cancer in our time.' Long-term federal investment in our nation's clinical research infrastructure and health care reform that ensures that all Americans have access to high-quality care are important first steps."

ASCO's recommendations include:

• Increase Federal Investment in Cancer Research Funding: Breakthroughs in cancer treatment cannot emerge without consistent federal investment in cancer research. While Congress and the Obama administration increased cancer research funding for the first time in five years through the 2009 stimulus package and FY 2010 budget, sustained and reliable funding increases are needed to achieve major advances. ASCO calls on Congress and the presidential administration build upon recent investments by increasing federal funding for NIH and NCI in FY 2011 and beyond.

• Strengthen the Nation's Clinical Research System: Clinical trials are the engine that drives cancer research, but today very few patients participate. Doctors are not reimbursed for the full cost of trial participation, and current regulatory requirements for clinical trials can be confusing, burdensome, and contradictory. ASCO urges policymakers to support the nation's clinical research system by requiring insurance providers to cover clinical trials participation, increasing funding to cover the cost of patient participation, and reducing regulatory burdens to conducting clinical trials.

• Ensure Patients Receive High-Quality Care: ASCO has become a leading innovator in developing and encouraging the adoption of high-quality standards for cancer care. In this report, ASCO calls on health care systems and providers to implement quality programs that ensure all patients receive high-quality care, and calls on policymakers to support legislation that fairly covers the cost of providing high-quality, comprehensive cancer care to patients.

The report, "Clinical Cancer Advances 2009: Major Research Advances in Cancer Treatment, Prevention and Screening," is available at www.cancer.net.

Multiple Myeloma:
Phase III Trial Finds Revlimid Extends Time To Progression

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between December 2004 and July 2009. All patients received autologous transplantation following a high dose of a drug called melphalan, which is commonly used to treat multiple myeloma.

Ultimately, 460 patients who had adequate organ function and no evidence of progressive disease, were randomized between 90 and 100 days after transplant to receive lenalidomide or placebo. Patients began lenalidomide or placebo between day 100 to 110 and continued until they had evidence of progressive disease.

Among the patients who received placebo, half had their myeloma progress (worsen) within an estimated 778 days. In contrast, for those patients taking lenalidomide, a median time to progression cannot be defined because fewer than half the patients had worsening of their myeloma. This represents a 58 percent reduction in the risk of disease progression for

the group taking lenalidomide. This difference in time to progression was highly statistically significant.

This is the first randomized phase III trial to demonstrate a clinical benefit of lenalidomide following transplant for multiple myeloma. However, the trial has not yet shown evidence of an overall survival benefit.

The types of side effects observed in this trial were similar to those observed in other clinical trials with lenalidomide. Detailed results from this trial will be presented at a future scientific meeting.

"This study answers the important question for multiple myeloma patients regarding maintenance lenalidomide therapy starting at 100 days following transplant," said Philip McCarthy Jr., associate professor of medicine at Roswell Park Cancer Institute and principal investigator of this study. "We now know that prolonged maintenance therapy with lenalidomide when compared to placebo will delay disease progression. This is an exciting advance in the field of multiple myeloma therapy and occurred due to the willingness of multiple myeloma patients to participate in this study and to the cooperation of the many physicians and study groups involved."

Lenalidomide, a derivative of thalidomide, was approved by the U.S. Food and Drug Administration in 2006 to be used in combination with dexamethasone, a steroid, for the treatment of multiple myeloma in patients who received at least one prior therapy for their disease. Celgene Corp. provided lenalidomide for this trial under a clinical trials agreement with NCI.

Breast Cancer:

Tykerb Plus Herceptin Better Than Monotherapy, Study Says

In a clinical study, women with an aggressive form of breast cancer experienced a median survival of 14 months when treated with an investigational combination of Tykerb (lapatinib) plus Herceptin (trastuzumab).

The results of the phase III study in HER2-positive metastatic breast cancer were presented during the 32nd Annual CTRC-AACR San Antonio Breast Cancer Symposium earlier this month.

The study included 296 women with HER2-positive disease, characterized by an overexpression of the HER2 protein in the cancer cells. Patients enrolled in the study experienced recurrence of breast cancer despite a median of three prior trastuzumab-based therapies. The data presented at the San Antonio congress showed that patients overcame resistance to trastuzumab with the introduction of the lapatinib-trastuzumab combination.

"The clinical benefits brought forth by the lapatinib and trastuzumab combination are quite compelling and lead me to believe the agents may be acting together to form a sort of 'dual blockade' to obstruct the HER2 pathway necessary for the tumor to thrive," said primary investigator, Kimberly Blackwell, of Duke University Medical Center.

Patients in the study were randomized to receive single agent lapatinib (1500 mg/daily) or a combination of lapatinib (1000 mg p.o. daily) plus trastuzumab (2 mg/kg). For those patients treated with monotherapy lapatinib, cross-over to the combination was allowed if the disease progressed after at least four weeks of therapy. Final analysis showed clinical activity for lapatinib in the control arm. Women treated with monotherapy lapatinib experienced a median overall survival of 9.5 months compared with 14 months when treated with the combination (median HR: 0.74, p=0.026).

"It's possible that, by lapatinib working inside the cell and trastuzumab working outside the cell, the combination of agents is able to provide a more complete anti-tumor attack," said Blackwell. "To achieve a survival advantage of greater than one year for this aggressive form of breast cancer is very encouraging."

Final safety analysis showed the incidence of adverse events were similar among both treatment groups with the exception of the incidence of grade 1 and 2 diarrhea, which was significantly higher in the combination group (P = 0.03). The incidence of grade 3 or higher AEs was similar among treatment groups (7%). The most common adverse events (incidence greater than or equal to 10%) were diarrhea, nausea, rash, fatigue and vomiting. Of the Grade 3/4 adverse events observed, cardiac events were reported in three patients on the combination arm and in one patient on the monotherapy arm. One patient in the combination arm experienced cardiac failure and later died due to pulmonary thromboembolism that was caused by disease progression and/or study medication.

Bisphosphonates May Reduce Recurrent Breast Cancer

Bisphosphonates are routinely given to women with postmenopausal breast cancer, but new data presented earlier this month at the CTRC-AACR San Antonio Breast Cancer Symposium suggests that these agents may play a role in reducing recurrent breast cancer as

well. Following are highlights of the studies:

The Z-FAST Study 5-Year Final Follow-Up

Zoledronic acid is both safe and effective in preventing bone loss in postmenopausal women with breast cancer who are treated with aromatase inhibitors, according to data presented at the symposium.

"Women who take aromatase inhibitors need some sort of bone protection, and this five-year data show that zoledronic acid is a viable option," said Adam Brufsky, associate professor of medicine, associate chief of hematolgy-oncology, and associate director for clinical investigation, University of Pittsburgh Cancer Institute.

Brufsky estimates that between 20,000 to 30,000 women a year will benefit from this therapy and that number is growing. Anastrozole, currently sold as Arimidex by AstraZeneca, is scheduled to go off patent within the next few years.

"Women who are on Medicare tend to go with tamoxifen because the cost of anastrozole puts them squarely in the donut hole of Medicare Part D, but once the cost barrier is removed there will likely be a mass switch to the aromatase inhibitor, which will necessitate the need for bone protection," said Brufsky.

Beyond the aging population, use of zoledronic acid could increase even further if the signs that it prevents breast cancer recurrence continue in larger studies.

Brufsky's study, Z-FAST (Zometa-Femara Adjuvant Synergy Trial), focused on 602 postmenopausal women with stage I to IIIa estrogen or progesterone receptor-positive breast cancer. The researchers randomized patients to immediate zoledronic acid or delayed zoledronic acid. The delayed group received it only if the T-score dropped below two or a clinical fracture occurred.

After five years, patients in the immediate treatment arm had a bone mineral density increase of 6.2 percent in their lumbar spine area, while those in the delayed arm had a decrease of 2.4 percent. In the hip area, the increase was 2.6 percent with immediate treatment compared with a 4.1 percent decrease with delayed treatment.

Fractures occurred in 10.7 percent of the patients treated immediately and 12.4 percent of the patients who received delayed treatment.

There were no serious renal events and no osteonecrosis of the jaw, which confirmed that the drug was safe and well tolerated.

Results from the Women's Health Initiative

Results of a new analysis of data from the Women's Health Initiative observational study showed that women who used bisphosphonates, which are commonly prescribed bone-strengthening pills, had significantly fewer invasive breast cancers than women who did not use bisphosphonates.

In the 150,000-plus cohort of generally healthy postmenopausal women, the researchers found that women who used bisphosphonates, mostly alendronate, which is sold as Fosamax by Merck, had 32 percent fewer cases of invasive breast cancer compared to women who did not use such drugs.

"The idea that bisphosphonates could reduce breast cancer incidence is very exciting because there are about 30 million prescriptions for these agents written annually in the United States targeting bone health, and more could easily be used to counteract both osteoporosis and breast cancer," said the study's lead investigator, Rowan Chlebowski, medical oncologist at the Los Angeles Biomedical Research Institute at Harbor-University of California, Los Angeles Medical Center.

The concept arose from findings in a report on an adjuvant breast cancer trial where use of the bisphosphonate zoledronic acid given intravenously every six months resulted in fewer contralateral breast cancers.

"It appeared to make bone less hospitable to breast cancer," Chlebowski said.

However, since bisphosphonates are prescribed for women with low bone mineral density and low bone mineral density has been associated with lower breast cancer incidence, a means to control for potential differences between women prescribed bisphosphonate and those not prescribed bisphosphonate in the cohort was needed.

Given that, Chlebowski and colleagues devised a way to control for use of bisphosphonates in the WHI. About 10,000 of the participants had bone mineral density analysis as part of the study, and for the rest they used a 10-item hip fracture predictive score to measure bone density. The researchers were able to correlate the findings from the women who had bone mineral density tests to findings from the predictive score in order to correct for any potential difference in bone density in women using bisphosphonates compared to non-users. Studying 2,216 WHI participants who were using bisphosphonates when they entered the study, the researchers found that only 64 women developed breast cancer, and most of those cases (50) were estrogen receptor positive. Overall, there was a mean 32 percent

fewer breast cancers in women using bisphosphonates compared to women who did not. There were 30 percent fewer estrogen receptor-positive cancers and 34 percent fewer entry receptor-negative cancers in bisphosphonate users. The latter finding was not statistically significant as there were very few receptor-negative cases.

"Bisphosphonates reduce angiogenesis and stimulate immune cells responsible for tumor cell surveillance as potential mediators," Chlebowski said. "This association needs to be studied further.Wwhile we currently have several options for reducing receptor-positive breast cancers, none are available for receptor-negative cancers."

Several ongoing adjuvant breast cancer trials evaluating oral and intravenous bisphosphonate will be available in the near future to provide randomized clinical trial evidence regarding their influence on new contralateral breast cancer risk, Chlebowski said.

Bisphosphonates and Postmenopausal Disease

The use of bisphosphonates for more than one year was associated with a 29 percent reduction in the risk of postmenopausal breast cancer, according to results presented at the symposium.

Lead researcher Gad Rennert, chairman of the Department of Community Medicine and Epidemiology at the Carmel Medical Center of Clalit Health Services and a faculty member at the Technion-Israel Institute of Technology in Israel, said these data help shed light on a possible new pathway for breast cancer prevention.

"We have identified a new class of drugs that is associated with a reduced risk of breast cancer, and if proven in randomized trials, we may be able to recommend it to postmenopausal women for this purpose," said Rennert.

Rennert and colleagues extracted data from the Breast Cancer in Northern Israel Study, which is a population-based, case-control study. They evaluated the use of bisphosphonates for at least five years in 4,575 postmenopausal study participants using a structured interview.

The self-reported, long-term use of bisphosphonates prior to diagnosis was associated with a significant reduced relative risk for breast cancer by approximately 34 percent.

This reduction remained significant, at 29 percent, even after adjusting for a large variety of risk factors for breast cancer such as age, fruit and vegetable consumption, sports activity, family history of breast cancer, ethnic group, body mass index, calcium supplement and hormone replacement therapy use, number of pregnancies, months of breastfeeding and age at first pregnancy.

Moreover, the breast tumors identified among patients who used bisphosphonates were more often estrogen receptor positive and less often poorly differentiated.

Combination of Letrozole and Zoledronic Acid

Preoperative combination therapy with letrozole and zoledronic acid is safe and effective, but more research is needed to verify the impact on overall survival or reduced morbidity.

Nigel Bundred, professor in surgical oncology at the University Hospital of South Manchester and the University of Manchester, United Kingdom, and colleagues conducted this study to determine whether the addition of the bisphosphonate zoledronic acid to treatment with letrozole increased cell death or lowered proliferation.

Letrozole is an oral, non-steroidal aromatase inhibitor used for treatment of local or metastatic breast cancer that is hormone receptor-positive. Zoledronic acid, also known as zoledronate, is used to prevent bone fractures in patients with cancers like prostate cancer and multiple myeloma, or for treatment of bone metastases.

Researchers conducted the study in 109 postmenopausal women with early, invasive hormone receptor-positive breast cancer. Patients were randomized and treated for 14 days with placebo, letrozole 2.5 mg per day, or to letrozole with adjuvant use of zoledronic acid 4 mg intravenously two to four days before surgery.

While the addition of zoledronic acid was safe, results showed no other benefits compared with letrozole use alone.

"Letrozole significantly lowered proliferation," said Bundred. "A combination of letrozole and a bisphosphonate, while lowering proliferation, did not do significantly greater than letrozole on its own."

Study Finds High-Risk Women Reluctant To Take Tamoxifen

Even when women at high-risk of breast cancer are well-informed about the risks and benefits of using the drug tamoxifen for prevention, only 6 percent said they were likely to take it.

Researchers at the University of Michigan Comprehensive Cancer Center created a decision aid designed to inform women about the risks and benefits associated with tamoxifen. The study targeted women who were at high risk of developing breast cancer within

the next five years; 632 women participated.

After viewing the decision aid, 41 percent of women could correctly answer six questions about the risks and benefits of tamoxifen, while 63 percent correctly answered at least five of the six questions.

Despite this understanding, only 29 percent of women said they were likely to seek out more information about tamoxifen, and only 29 percent said they would ask their doctor about it. A scant 6 percent of women said they were likely to take tamoxifen.

Results of the study appear online in the journal Breast Cancer Research and Treatment.

Cancer Screening:

Cervical Cancer Screening Can Be Done Later, Less Often

Women can be screened less frequently for cervical cancer with the Pap test (cervical cytology) than previously recommended, according to newly updated evidence-based guidelines issued Nov. 20 by the American Congress of Obstetricians and Gynecologists.

Previously, adolescents were advised to begin screening within three years of becoming sexually active or at age 21 (whichever was younger) and to continue annually.

Now, AGOG recommends that women wait until age 21 and then be screened every two years until age 30. Thereafter, following three consecutive negative tests, women should be screened once every three years.

Women 30 and older can be screened with Pap tests and human papillomavirus (HPV) DNA tests every three years if their results are negative. The new recommendations appear in the December issue of Obstetrics & Gynecology.

These guidelines do not take into account whether a woman has been vaccinated against HPV, which is the cause of most cervical cancers. (Vaccinated women might be shown eventually to need even less frequent screening.)

More frequent screening might be needed for women with certain risk factors, including those with weakened immune systems.

Women who have had a total hysterectomy and no history of high-grade cervical intraepithelial neoplasia should discontinue cervical cancer screening altogether.

This change to a more conservative approach is designed to "avoid unnecessary treatment of adolescents, which can have economic, emotional, and future childbearing implications," the organization said.

"Although the rate of HPV infection is high among sexually active adolescents, invasive cancer is very rare in women under age 21," the statement said.

Also, while HPV infections occur more often in younger women, their immune systems nearly always clear the infections and the associated cervical intraepithelial neoplasia within one to two years. If, however, these lesions are treated with surgery, adolescents who have most of their childbearing years ahead of them face an increased risk of premature births, as well as a greater need for caesarean sections.

Colon Cancer:

No Benefit For Cetuximab In Early-Stage Colon Cancer

A Data Monitoring Committee determined that in a phase III clinical trial for early-stage colon cancer, no group of patients benefited from the addition of the monoclonal antibody cetuximab (Erbitux) to a standard chemotherapy regimen known as FOLFOX.

Monoclonal antibodies are a type of protein designed in the laboratory that can locate and bind to substances in the body, including tumor cells. There was some initial evidence that the addition of cetuximab to FOLFOX may have been harmful, particularly in patients age 70 or older. Approximately 1,760 patients with stage III colon cancer (cancer that has spread to the lymph nodes surrounding the colon but not to other parts of the body) after compete surgical removal of the cancerous portions of the colon were randomized between the two treatment arms. All patients had their tumors tested and only those patients with tumors that did not contain mutations in the KRASgene (called KRAS wild-type) were included in the analysis. Detailed results from the study will be presented at a future scientific meeting.

This study (N0147: A Randomized Phase III Trial of Oxaliplatin Plus 5-Fluorouracil/Leucovorin With or Without Cetuximab After Curative Resection for Patients with Stage III Colon Cancer) was conducted by a network of researchers led by the North Central Cancer Treatment Group and sponsored by the National Cancer Institute under a Cooperative Research and Development Agreement with Sanofi-Aventis and in collaboration with Imclone Systems, a wholly owned subsidiary of Eli Lilly and Co. and Bristol- Myers Squibb under a Clinical Supply Agreement. Current recommendations limit cetuximab therapy to patients with metastatic colorectal tumors that do not contain mutations in the KRAS gene.

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

8420 A Phase I Dose-Escalation Study of the Hedgehog Smoothened Antagonist GDC-0449 Plus Pan-Notch Inhibitor RO4929097 Administered in Patients with Advanced Breast Cancer, Barbara Ann Karmanos Cancer Institute. LoRusso, Patricia Mucci (313) 576-8716.

8614 Adoptive Transfer of Cord Blood T cells to Prevent and Treat CMV and Adenovirus Infections after Transplantation, Baylor College of Medicine. Bollard, Catherine Mary (832) 824-4781.

Phase I/II

RTOG-0929 A Randomized Phase I/II Study of ABT-888 in Combination with Temozolomide in Recurrent (Temozolomide Resistant) Glioblastoma, Radiation Therapy Oncology Group. Robins, H. Ian (608) 263-1416.

RTOG-0932 A Phase I/II Study of Induction AMG 655 and Gemcitabine, Followed by AMG 655, Capecitabine and 3-D Conformal Radiation Therapy with Subsequent Maintenance Therapy for Locally Advanced Pancreatic Cancer, Radiation Therapy Oncology Group. Crane, Christopher H. (713) 563-2340.

Phase II

8121 A Phase II Study of Temsirolimus and IGF-1 Receptor Antibody IMC-A12 in Patients with Metastatic Sarcomas, Memorial Sloan Kettering Cancer Center. Maki, Robert G. (212) 639-5720.

CALGB-100701 Phase II Study of Reduced-Intensity Allogeneic Stem Cell Transplant for High-Risk Chronic Lymphocytic Leukemia, Cancer and Leukemia Group B, Alyea, Edwin Pascal (617) 632-3903.

N0923 A Randomized Double-Blinded Phase II Study of NTX-010, a Replication-Competent Picornavirus, After Standard Platinum-Containing Cytoreductive Induction Chemotherapy in Patients with Extensive Stage Small Cell Lung Cancer, North Central Cancer Treatment Group. Molina, Julian R. (507) 284-9265.

NCIC-199 A Phase II Study of Temsirolimus, an mTOR Inhibitor, in Patients with Recurrent, Unresectable, Locally Advanced or Metastatic Carcinoma of the Cervix, National Cancer Institute of Canada Clinical Trials Group. Tinker, Anna (604) 877-6000.

PBTC-030 A Phase II Trial of Capecitabine Rapidly Disintegrating Tablets and Concomitant Radiation Therapy in Children with Newly Diagnosed Brainstem Gliomas, Pediatric Brain Tumor Consortium, Kilburn, Lindsay B. (832) 824-4615.

S0916 A Phase II, Window Trial of the Anti-CCR2 Antibody MLN1202 in Patients with Bone Metastases, Southwest Oncology Group. Pienta, Kenneth James (734) 647-3421.

Phase III

AHOD0831 A Non-Randomized Phase III Study of Response Adapted Therapy for the Treatment of Children with Newly Diagnosed High Risk Hodgkin Lymphoma, Children's Oncology Group. Kelly, Kara M. (212) 305-5808.

CALGB-80802 Phase III Randomized Study of Sorafenib Plus Doxorubicin Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma, Cancer and Leukemia Group B. Abou-Alfa, Ghassan (212) 639-3112.

E2906 Phase III Randomized Trial of Clofarabine as Induction and Post-Remission Therapy vs. Standard Daunorubicin & Cytarabine Induction and Intermediate Dose Cytarabine Post-Remission Therapy, Followed by Decitabine Maintenance vs. Observation in Newly-Diagnosed Acute Myeloid Leukemia in Older Adults (Age >/= 60 Years), Eastern Cooperative Oncology Group. Foran, James Macleod (205) 934-2721.

Other

AAML10B11 Genetic Predictors of AML Treatment Response, Children's Oncology Group. Aplenc, Richard (267) 426-7252.

AOST10B2 Tissue Factor Expression in Bone Sarcomas, Children's Oncology Group. Ranalli, Mark Anthony (614) 722-3563.

NCIC-PR.3A Evaluating Tissue Biomarkers of Outcome: Secondary Analyses of MRC RT01 and PR07, National Cancer Institute of Canada Clinical Trials Group. Parker, Christopher C. 020-8661-3425.

Pilot: AMC-063 Single-Arm, Dose-Finding Pilot Trial of Single-Agent Bortezomib in Patients with Relapsed/Refractory AIDS-Associated Kaposi Sarcoma with Correlative Assessments of KSHV and HIV, AIDS-Associated Malignancies Clinical Trials Consortium. Reid, Erin Gourley (858) 822-6276.