Vol. 34 No. 5
May 2011

THE
CLINICAL CANCER LETTER

Cancer research news for clinicians

ASCO Annual Meeting:

ASCO Highlights Seven of 4,000 Abstracts Submitted for Annual Meeting, June 3-7

The American Society of Clinical Oncology highlighted seven studies from among more than 4,000 abstracts publicly posted online in advance of ASCO's 47th Annual Meeting.

The meeting, which is expected to draw approximately 30,000 cancer specialists, will be held in Chicago, June 3-7. The theme of this year's meeting is "Patients. Pathways. Progress."

"This year marks the 40th anniversary of the signing of the National Cancer Act, a law that led to major new investments in cancer research," said ASCO President George Sledge. "Every day in our offices, and every year at the ASCO meeting, we see the results of those investments. People with cancer are living longer, with a better quality of life, than ever before."

(Continued to page 2)

Glioblastoma:

Analyzing Tumor Tissue In Clinical Trials Can Improve Outcomes, RTOG Trial Finds

Initial results from a phase III trial demonstrated the importance of prospective molecular analysis of tumor tissue of patients with newly diagnosed glioblastoma.

The trial, "RTOG 0525 Phase III Trial Comparing Conventional Adjuvant Temozolomide with Dose-Intensive Temozolomide in Patients with Newly Diagnosed Glioblastoma," found no significant improvement in overall patient survival or disease progression. The study compared patients who received dose-dense TMZ plus radiotherapy to patients who received standard-dose TMZ plus radiotherapy.

However, the trial proved the feasibility of collecting and analyzing tumor tissue prospectively in a multi-center setting.

The international, NCI-supported trial was led by RTOG principal investigator Mark Gilbert, of MD Anderson Cancer Center, and conducted in concert with the European Organization for Research and Treatment of Cancer and NCCTG.

"Given the promising preliminary data of improved patient outcomes using an adjuvant dose-intensive schedule of temozolomide, the trial allowed us to robustly test whether this treatment strategy provides a significant benefit over standard-dose temozolomide treatment," said Gilbert.

"While dose-dense temozolomide did not demonstrate improved efficacy for patients newly diagnosed with a glioblastoma, the study results confirmed the prognostic significance of MGMT gene methylation and

(Continued to page 3)

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

Selected Abstracts from ASCO Annual Meeting in Chicago

(Continued from page 1)

"With our growing understanding of the nature of cancer development and behavior, cancer is becoming a chronic disease that a growing number of patients can live with for many years," said Sledge, the Ballve-Lantero Professor of Oncology and professor of pathology and laboratory medicine at the Indiana University School of Medicine.

"The studies released today are the latest examples of progress against the disease, from new personalized treatments, to new approaches to screening and prevention."

The highlighted studies include:

• First Large Study of HPV and Pap Co-Testing in Routine Clinical Practice Confirms Many Women Can Safely Extend Testing to Every Three Years; HPV Testing Alone Also Appears to be Superior to Pap Testing Alone: The first large-scale study of both human papillomavirus testing and Pap smear for cervical cancer screening in routine clinical practice confirms that women can safely extend their screening intervals from one to three years. The study also found that HPV testing may be more accurate than conventional Pap smear in determining cervical cancer risk.

• Combined Screening with CA-125 and Transvaginal Ultrasound Does Not Reduce Ovarian Cancer Death Rate, Results in High Number of False Positives: Findings from a large, long-term study—the Prostate, Lung, Colorectal and Ovarian Screening Trial—showed that using a CA-125 blood test and transvaginal ultrasound for early detection of ovarian cancer did not reduce the risk of dying from the disease, and resulted in a large number of false positives and related follow-up procedures.

• Novel Screening Approach Suggests PSA Levels Among Men Age 44-50 May Predict Long-Term Risk of Metastatic Prostate Cancer or Prostate Cancer-Related Death: A large, population-based study of Swedish men showed that prostate-specific antigen levels at the time of initial screening among men aged 44 to 50 can accurately predict the risk that a man will die of prostate cancer or develop metastatic prostate cancer up to 30 years later, suggesting half of men could undergo just three PSA tests in a lifetime.

• Genetic Biomarkers Predict Taxane-Induced Neuropathy: This study identified a genetic biomarker for nerve damage caused by paclitaxal, a complication of chemotherapy that can keep patients from functioning normally and interrupt their treatment.

• Randomized Study Shows that Maintenance Therapy and PARP Inhibitors Could Play Important Roles in Treatment of Relapsed Ovarian Cancer: A phase II trial showed that the oral drug olaparib, given after chemotherapy, improved progression-free survival in women with the most common type of relapsed ovarian cancer.

• Novel Multi-targeted Agent Cabozantinib (XL184) Has Significant Effect on Several Advanced Solid Tumors, and Can Shrink or Eliminate Bone Metastases: Cabozantinib demonstrated high rates of disease control in patients with prostate, ovarian and liver cancers. Importantly, it controlled bone metastases in patients with breast and prostate cancers and melanoma.

• Long-Term Smoking, But Not Moderate Alcohol Use, Linked to Increased Risk of Common Cancers Among Women Already at High Risk of Breast Cancer: A prospective study of more than 13,000 healthy women at high risk of breast cancer reported that the risks of invasive breast, lung and colon cancers were significantly higher in women with long smoking histories, compared to women who did not smoke or had shorter smoking histories.

The study did not confirm previous reports of increased risk of cancer among those with moderate alcohol use, though it found that moderate alcohol use was associated with a lower risk of colon cancer. Low physical activity was associated with a significantly higher risk of endometrial cancer.

THE CLINICAL CANCER LETTER

Editor and Publisher: Paul Goldberg
Intern: Conor Hale

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.

Glioblastoma:

Molecular Classification Can Improve Prognostic Prediction

(Continued from page 1)

demonstrated the feasibility of prospective tumor tissue collection, molecular stratification and collection of patient outcomes in a large transatlantic intergroup trial."

The trial enrolled 1,173 study participants at 185 facilities in North America and 24 facilities in Europe.

Study eligibility criteria required that tumor tissue, obtained at the time of biopsy or surgery and with patient consent, be sent for central pathology review to confirm the tumor as a glioblastoma and as adequate to perform MGMT gene methylation analysis and molecular risk classification (to assess whether a correlation exists between these biomarkers and study participant outcomes).

Upon pathology confirmation, eligible patients were enrolled in the trial and randomized into one of two adjuvant treatment arms: Arm 1, the standard arm: TMZ days 1-5 every 28 days for up to 12 cycles/months; or Arm 2, the experimental arm: TMZ days 1-21 every 28 days for up to 12 cycles/months.

Study participants were stratified to assess correlation of their outcome with three major criteria: prognostic recursive partitioning, based upon age, performance status, extent of pretreatment surgery, neurologic function and mental status; MGMT status (methylated, unmethylated, or indeterminate); and radiation therapy treatment (U.S. standard vs. European).

"In this trial we've demonstrated the positive correlation between clinical outcomes and molecular classification of glioblastoma, which will enable improved future prognostic prediction, spur the development of specific therapies based on tumor biology, and ultimately lead to individualization of treatment," said MD Anderson's Kenneth Aldape, trial co-chair for neuropathology and correlative biology.

Aldape will present findings of the tumor tissue profiling at the ASCO Annual Meeting in Chicago.

NSCLC:

Targeting One Specific Protein Can Double PFS; Triple Overall Survival

Final results from a phase II study evaluating investigational personalized medicine in previously treated advanced non-small cell lung cancer showed that by targeting the protein Met, progression-free survival could be doubled, and overall survival could be tripled.

The randomized, multicenter, double-blind study compared Genentech's MetMAb plus Tarceva (erlotinib) against Tarceva alone, in patients whose tumors had high levels of Met as determined by a companion diagnostic. MetMAb is a unique, one-armed, investigational antibody designed to target Met, which is associated with a poor outcome in many cancers.

People with previously treated NSCLC had their tumors analyzed for Met protein levels using an immunohistochemistry test developed by Ventana Medical Systems, a unit of Roche.

Tumors with high Met protein levels were classified as Met diagnostic-positive, and with low Met protein levels as Met diagnostic-negative.

In the overall population of patients with high and low Met expression (n=137), the combination of MetMAb and Tarceva did not show a statistically significant improvement in PFS compared to Tarceva alone (HR=1.09, p=0.687, median PFS: 2.2 months for the combination vs. 2.6 months for Tarceva alone).

In people with high Met tumors, those who received MetMAb plus Tarceva had a statistically significant doubling of PFS compared to those who received Tarceva alone (HR=0.53, p=0.04). The median PFS was improved from 1.5 months to 2.9 months.

The addition of MetMAb to Tarceva also led to a statistically significant improvement in OS compared to Tarceva alone (HR=0.37, p=0.002) in people with high Met tumors. The improvement in median OS was tripled from 3.8 months to 12.6 months.

There were no unexpected safety signals from the combination of MetMAb with Tarceva and the safety profile of Tarceva was consistent with previous studies of the medicine in people with solid tumors.

The most common adverse events of any grade (≥15 percent in any subgroup or study arm, regardless of Met diagnostic status) included rash, diarrhea, fatigue, decreased appetite, nausea, shortness of breath, cough, acne-like rash, infections, dry skin, anemia, vomiting, fever, pain, chest pain, back pain and peripheral edema.

Of these adverse events, only peripheral edema

was seen at a higher rate in the combination group compared with the Tarceva only group (23.2 percent vs. 7.5 percent).

Although PFS and OS were improved in people classified as having high Met tumors, those with low Met tumors had worse outcomes when given MetMAb plus Tarceva as compared to Tarceva alone (PFS: HR=1.82, p=0.050, median PFS: 1.4 months for the combination vs. 2.7 months for Tarceva alone; OS: HR=1.78, p=0.158, median OS: 8.1 months for the combination vs. 15.3 months for Tarceva alone). This result highlights the importance of a companion diagnostic in evaluating the efficacy of experimental therapeutics to distinguish between the people who may potentially benefit from a new medicine as well as those who may not.

"The unique design of MetMAb and the development of a companion diagnostic test allowed us to target a specific pathway that may be driving cancer growth," said Hal Barron, Genentech's chief medical officer and head of global product development. "These results support further investigation of MetMAb as a potential personalized medicine for people with lung cancer and we plan to start a phase III study later this year."

Full results of the OAM4558g study will be presented during an oral abstract session at the ASCO Annual Meeting on June 5, by David Spigel, the principal investigator and program director of lung cancer research at the Sarah Cannon Research Institute in Nashville, Tenn.

Myeloma:

Revlimid Maintenance Therapy Delayed Progression by 90%

A study evaluating Revlimid (lenalidomide) for maintenance therapy following bone marrow stem cell transplants for myeloma demonstrated delayed disease progression and overall survival rates of 90 percent more than two years after transplant, said the International Myeloma Foundation.

The Cancer and Leukemia Group B study showed that Revlimid maintenance resulted in longer remissions, delaying disease progression by a median of four years.

"This clearly validates an important treatment option for patients," said Kenneth Anderson, of the Dana-Farber Cancer Institute. "The development of new, targeted drugs such as Revlimid that are well tolerated allowed us to consider this approach, and with these new survival data we can add long-term maintenance to our arsenal as a new standard of care."

Results demonstrated benefit with progression free survival in a similar study of Revlimid following transplant, from the French Francophone Myeloma Intergroup. Maintenance therapy is being considered as an option with other drugs, including Velcade, when administered in a reduced dose, or as a subcutaneous injection instead of the traditional IV.

There is an issue of a small number of second cancers developing in patients taking Revlimid long-term. Possible factors are being studied including patients' genetic profiles and prior treatments.

"There is a risk/benefit ratio with all potent medications, but overall survival clearly demonstrates that in this case, benefit far outweighs any risk," said Brian Durie, the foundation's chairman, who co-authored a retrospective analysis of Revlimid and second cancers.

Breast Cancer:

Drug Effectiveness Weakens After Three Years, Study Says

Some breast cancer treatments may lose their effectiveness once the patient survives the first three years, suggests a new study published in the Journal of Clinical Oncology.

Researchers examined existing data and hazard curves and came to the conclusion that breast cancer may recur many years after initial diagnosis and treatment, and that drug studies should be redesigned to take that into account, said Ismail Jatoi, chief of surgical oncology at the Cancer Therapy & Research Center at the University of Texas Health Science Center at San Antonio.

"The current paradigm that we have is that these drugs, over the lifetime of the patient, have a constant effect," said Jatoi, the paper's lead author. "What we've suggested in this paper is that's not really the case. What we're seeing is that some drugs have an initial effect. The effect of the drug diminishes after about three years."

There's also some suggestion that immunotherapy, which has not yet been developed for breast cancer treatment, could have a delayed effect, with the benefits not evident for several years. Jatoi said it would make sense to design trials to follow patients for eight or nine years, or possibly begin studies that take patients who are five- or seven-year breast cancer survivors.

"This is important because we're seeing more and more long-term breast cancer survivors," Jatoi said.

Breast Cancer:

Nexavar Improves PFS In HER-2 Negative Breast Cancer

Results from a phase IIb trial evaluating patients with locally advanced or metastatic HER-2 negative breast cancer, previously treated with a bevacizumab-containing regimen, showed that Nexavar tablets were associated with statistically significant improvements in progression-free survival and time-to-progression.

The randomized, double-blind, placebo-controlled study evaluated Nexavar in combination with a chemotherapeutic agent, either gemcitabine or capecitabine in 160 patients.

Patients receiving Nexavar (sorafenib) in addition to standard chemotherapy agents obtained a progression-free survival benefit with median of 3.4 months to progression versus 2.7 (HR=0.65, one-sided p-value=0.01).

Time-to-progression was similarly improved from a median of 3.6 months from 2.7 (HR=0.64; one-sided p-value=0.009) in this pre-treated population, said Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals.

The safety and tolerability profile of the combination was consistent with the previous experience. The most commonly reported treatment-emergent grade 3/4 adverse events were hand-foot skin reaction (39 percent), neutropenia (21 percent) and stomatitis (10 percent).

"These data are similar to those observed in our previous phase II trial evaluating Nexavar in combination with capecitabine," said Ted Love, executive vice president and head of research and development and technical operations for Onyx Pharmaceuticals.

"Onyx and Bayer are continuing to explore Nexavar's potential utility in breast cancer through a Phase 3 trial evaluating Nexavar in combination with capecitabine in advanced breast cancer in the RESILIENCE trial."

The data will be presented on June 6, during the oral abstract session at the ASCO annual meeting in Chicago.

The RESILIENCE phase III study will evaluate Nexavar in combination with capecitabine in patients with locally advanced or metastatic HER-2 negative breast cancer who are resistant to or have failed prior taxane and an anthracycline or for whom further anthracycline is not indicated. The primary endpoint of the study is progression-free survival. Secondary endpoints include overall survival, time to progression, and safety.

Prostate Cancer:

Xgeva Significantly Increases Bone Metastasis-Free Survival

Primary results of a phase III trial demonstrated that Xgeva (denosumab) significantly increased bone metastasis-free survival for more than four months in men with castrate-resistant metastatic prostate cancer that has not yet spread to bone.

The data showed that XGEVA significantly improved median bone metastasis-free survival by 4.2 months, a risk reduction of 15 percent, compared with placebo (29.5 vs. 25.2 months, respectively; HR=0.85; 95% CI: 0.73, 0.98; P=0.028).

Xgeva also significantly delayed the time to first bone metastases by 3.7 months compared with placebo (HR 0.84; 95% CI: 0.71, 0.98; P=0.032; risk reduction of 16 percent). The drug also reduced the risk of bone metastases that were symptomatic by 33 percent (HR 0.67; 95% CI: 0.49, 0.92; P=0.01).

Overall survival was similar between groups (HR 1.01; 95% CI: 0.85, 1.20; P=0.91), and the hazard ratio for progression-free survival was 0.89 (95% CI: 0.78, 1.02, P=0.093).

With effective therapies in place for both early castrate-sensitive prostate cancer and advanced castrate-resistant prostate cancer, there is a gap in the treatment plan for those patients who are castrate-resistant but have not yet developed metastatic disease, said Amgen.

Adverse events were relatively similar between the Xgeva and placebo arms. Hypocalcemia and osteonecrosis of the jaw were reported with increased frequencies in the Xgeva treated patients.

The yearly rate of ONJ in the Xgeva arm was similar to prior Xgeva trial results. Back pain was the most common adverse event reported in the Xgeva arm of the trial.

Xgeva is a RANK Ligand inhibitor, indicated for the prevention of skeletal-related events in patients with bone metastases from solid tumors.

Full results of the '147 study were presented at the American Urological Association annual meeting in Washington, D.C., Amgen said.

Xgeva is not indicated for the prevention of SREs in patients with multiple myeloma. Denosumab is also marketed as Prolia in other indications.

Follow us on Twitter:
@TheCancerLetter

End-of-Life Care:

U.S. Patients Use More Chemotherapy, Less Emergency Care than Canadians

Older patients with advanced lung cancer in the United States make much less use of hospital and emergency room services at the end of life than their counterparts in Ontario, but use far more chemotherapy, according to a study published in JNCI.

In the U.S., Medicare covers hospice care for qualified patients. Ontario has no hospice program comparable to the U.S., but provides palliative care through inpatient acute care units, outpatient services and home health care.

To compare end-of-life care between the two systems, Joan Warren, of NCI, and colleagues used U.S. Surveillance, Epidemiology, and End Results (SEER)-Medicare data and data from the Ontario Cancer Registry. They identified patients age 65 and older who died with non-small cell lung cancer during 1999-2003 and reviewed health claims from their last 5 months of life to collect data on chemotherapy, emergency room use, hospitalizations, and supportive care in both short-term (less than 6 months) and longer-term (6 months or more) survivors.

Patients in both countries used health-care services extensively, particularly in the last month of life. Ontario patients had hospital admissions and used emergency room services at rates that were statistically significantly greater than those of U.S. patients.

More than twice as many Ontario patients died in hospital (e.g., 48.5 percent of short-term survivors compared to 20.4 percent in the U.S.) even though a majority of Ontario patients have reported that they would prefer to die at home. In each of the last 5 months, chemotherapy rates were statistically significantly higher among SEER-Medicare patients than among the Ontario patients.

The authors note that these findings partly support the commonly held view that U.S. physicians have a more aggressive attitude toward treatment and that patients in the U.S. tend to receive more intensive health-care services. However, U.S. patients can also enroll in hospice services.

The authors conclude that the lack of hospice services contributes to higher rates of hospital and emergency room visits and in-hospital deaths among Ontario patients.

The findings, they write, "will inform health planners and policy makers in each country regarding current patterns of end-of-life care and where there may be opportunities for changing practice patterns or programs."

Bladder Cancer:

Urocidin May Provide Alternative To Cystectomy in BCG Cancers

Results from a prospective, ongoing phase III trial of the intravesical formulation of Mycobacterial cell wall-DNA complex, known as Urocidin, indicate that it may provide an alternative to cystectomy for patients with bacillus Calmette-Guerin refractory non-muscle invasive bladder cancer.

Endo Pharmaceuticals and Bioniche Life Sciences presented the findings during a podium presentation at the 2011 American Urological Association annual meeting in Washington, D.C.

The preliminary results were generated from an interim analysis of Urocidin in the treatment of NMIBC that is refractory to BCG and at high risk of progression.

Patients with high grade papillary tumors and/or carcinoma in situ, and having failed to respond to one or more courses of BCG, were administered Urocidin by trans-urethral catheter directly into the bladder. A total of 129 patients were enrolled from 25 centers in the U.S. and Canada.

The overall one-year disease-free survival rate was 25 percent. The one-year DFS rate was 35 percent for patients with only papillary tumors and 21 percent for patients with carcinoma in situ with or without papillary tumors. The preliminary results indicate that intravesical administration of Urocidin was well tolerated.

Clinical Trials Approved By NCI CTEP Last Month

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

8762: A Phase 1 Trial of MK-2206 in Combination with Anastrozole or Letrozole in Postmenopausal Women with Estrogen Receptor Positive Metastatic Breast Cancer. Washington University School of Medicine; Ma, Cynthia Xiuguang. (314) 362-9383.

8876: A Phase 1 Study of Gemcitabine, Carboplatin and Lenalidomide (GCL) for Treatment of Patients with Advanced/Metastatic Urothelial Carcinoma (UC) and Other Solid Tumors. National Cancer Institute Medicine Branch; Apolo, Andrea Borghese. (301) 496-4916.

N1085: A Phase I and Feasibility Study of Everolimus (RAD001) plus R-CHOP for New Untreated Diffuse Large B-Cell Lymphoma (DLBCL). North Central Cancer Treatment Group; Johnston, Patrick Bruce. (507) 284-4642.

Phase II

8729: A Phase II Study of MK-2206 in the Treatment of Recurrent Platinum-Resistant Ovarian, Fallopian Tube, or Peritoneal Cancer. Dana-Farber Cancer Institute; Liu, Joyce Fu. (617) 632-5269.

8735: A Multi-Institutional Phase II Study of the Akt Inhibitor MK-2206 in Refractory Biliary Cancers. Ohio State University Medical Center; Bekaii-Saab, Tanios Sam. (614) 293-9863.

8783: A Phase 2 Study of Pazopanib (GW786034) in Patients with Advanced and Progressive Malignant Pheochromocytoma or Paraganglioma. Mayo Clinic; Sideras, Kostandinos. (507) 284-2511.

8822: Phase II Study of Azacitidine and Entinostat (SNDX-275) in Patients with Advanced Breast Cancer. Mayo Clinic; Stearns, Vered. (443) 287-6489.

8834: Phase II Study of Lenalidomide to Repair Immune Synapse Response and Humoral Immunity in Early-Stage, Asymptomatic Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) with High-Risk Genomic Features. Ohio State University Medical Center; Jones, Jeffrey Alan. (614) 293-3507.

8853: Randomized Phase II, Double-Blind, Placebo-Controlled Trial of Cyclophosphamide Alone or in Combination with Veliparib (ABT-888) in ER and/or PR-Positive and HER2/neu-Negative Metastatic Breast Cancer. Albert Einstein College of Medicine; Andreopoulou, Eleni. (718) 904-2555.

8972: Randomized Phase II Trial of Timed Sequential Therapy (TST) with Alvocidib (Flavopiridol), Ara-C and Mitoxantrone (FLAM) vs. "7+3" for Adults Age 70 and Under with Newly Diagnosed Acute Myelogenous Leukemia (AML). Johns Hopkins University; Karp, Judith E. (410) 502-7726.

8977: Phase 2 Trial of R115777 in Previously Untreated Older Adults with AML and Baseline Presence of a Specific 2-Gene Expression Signature Ratio. Moffitt Cancer Center and Research Institute; Lancet, Jeffrey E. (813) 745-6841.

ANBL1021: Feasibility/Phase II Study of hu14.18-IL2 Immunocytokine + GM-CSF and Isotretinoin in Patients with Relapsed or Refractory Neuroblastoma. Children's Oncology Group; Shusterman, Suzanne. (617) 632-4901.

CALGB-40903: Phase II Study Neoadjuvant Letrozole for Postmenopausal Women with Estrogen Receptor Positive Ductal Carcinoma in SITU (DCIS). Cancer and Leukemia Group B; Hwang, Eun-Sil (Shelley). (415) 353-7908.

CALGB-80803: Randomized Phase II Trial of PET Scan-Directed Combined Modality Therapy in Esophageal Cancer. Cancer and Leukemia Group B; Goodman, Karyn Aalami. (212) 639-3983.

Phase III

ACCL1032: A Randomized Controlled Trial of Acupressure to Control Chemotherapy-Induced Nausea (CIN) in Children Receiving Cisplatin. Children's Oncology Group; McLean, Thomas Williams. (336) 716-4085.

ACOSOG-Z4099: A Randomized Phase III Study of Sublobar Resection (+/- Brachytherapy) versus Stereotactic Body Radiation Therapy in High Risk Patients with Stage I Non-Small Cell Lung Cancer (NSCLC). American College of Surgeons Oncology Trials Group; Fernando, Hiran C. (617) 638-5600.

Other Phases

AHEP11B1: Genetics and Biology of Liver Tumorigenesis in Children. Children's Oncology Group; Tomlinson, Gail E. (210) 562-9116.

ARST11B2: Next Generation Sequencing of Childhood Soft Tissue Sarcomas to Identify Drivers of Primary and Metastatic Disease. Children's Oncology Group; Sorensen, Poul Henrik Bredahl. (604) 675-8202.

CALGB-151101: PIK3CA Mutation Status as a Biomarker in Elderly Women with Breast Cancer. Cancer and Leukemia Group B; Moynahan, Mary Ellen. (646) 888-4561.

GOG-0267: Quality of Life and Care Needs in Patients with Persistent or Recurrent Platinum-Resistant Ovarian, Fallopian Tube, and Peritoneal Cancer. Gynecologic Oncology Group; DiSaia, Philip J. (215) 854-0770.

GOG-8016: Genomic and Proteomic Profiles Associated with Recurrence in Stage I Endometrioid Endometrial Carcinoma. Gynecologic Oncology Group; Maxwell, George Larry. (202) 782-8517.

GOG-8023: The Role of Synuclein-gamma (SNCG) in the Carcinogenesis of Uterine Papillary Serous Carcinoma. Gynecologic Oncology Group. Buttin, Barbara Malalai. (312) 472-4684.

N0147-ICSC-1: Genome Wide Predictors of Survival in Colorectal Cancer. North Central Cancer Treatment Group; Peters, Ulrike. (206) 667-2450.

N9741-ICSC-1: Genome Wide Predictors of Survival in Colorectal Cancer. North Central Cancer Treatment Group; Peters, Ulrike. (206) 667-2450.

S9031-S9333-S0112-S0301-A: Proteomic Signature Associated with Clinical Response to Cytarabine Based Induction Therapy in Patients with AML 56 Years and Older. Southwest Oncology Group; Radich, Jerald Patrick. (206) 667-4118.

FDA Approvals:

Afinitor and Sutent Approved For Pancreatic Neuroendocrine Tumors

FDA approved Afinitor tablets for the treatment of progressive neuroendocrine tumors of pancreatic origin in patients with unresectable, locally advanced or metastatic disease. Pancreatic NET is a rare disease, affecting two to four million people annually worldwide.

This, with Sutent second, marks the first approval of a treatment for pNET patients in the U.S. in nearly 30 years.

The approval was based on phase III data from the RADIANT-3 (RAD001 In Advanced Neuroendocrine Tumors) trial, which showed that treatment with Afinitor (everolimus) more than doubled the time without tumor growth (median 4.6 to 11.0 months) and reduced the risk of cancer progression by 65 percent versus placebo in patients with advanced pancreatic NET (HR=0.35 [95% CI, 0.27 to 0.45]; p<0.001).

A consistent improvement in progression-free survival was seen with Afinitor in all patient subgroups.

The FDA determined that the safety and effectiveness of Afinitor in the treatment of patients with carcinoid tumors has not been established.

FDA also approved Sutent for the treatment of patients with pancreatic NET.

The approval was based on data from the SUN 1111 phase III trial that demonstrated improvement in progression-free survival compared to placebo (10.2 versus 5.4 months, p=0.000146) in this patient population.

Treatment also yielded a statistically significant improvement in tumor response, with an objective response rate of 9.3 percent (95% CI: 3.2, 15.4, p=0.0066).

No objective responses were observed with placebo. While overall survival was not mature at the time of final analysis, nine deaths were observed in patients enrolled in the Sutent arm versus 21 deaths in patients enrolled in the placebo arm.

The most frequently occurring side effects were diarrhea, nausea, vomiting, fatigue, anorexia, high blood pressure, abdominal pain, changes in hair color, stomatitis, and neutropenia.

Abbott PCR Test For HCV Load Sensitive to Within 12 IU/mL

FDA has approved Abbott's RealTime PCR test for measuring the viral load of hepatitis C, the leading cause of liver cancer in the U.S.

The RealTime HCV assay, developed for use on the Abbott m2000 system, measures HCV RNA levels at baseline and during treatment and can be utilized to predict sustained and non-sustained virological response to HCV therapy.

The test offers precise quantitation of HCV in human plasma or serum. It is a highly sensitive HCV viral load test—the limit of detection and the limit of quantitation are the same, 12 IU/mL. This level of sensitivity enables clinicians to gauge success of antiviral drug treatment for eradicating the infection.

The results from the RealTime HCV assay must be interpreted within the context of all relevant clinical and laboratory findings.

The Abbott RealTime HCV assay is not for screening blood, plasma, serum or tissue donors for HCV, or to be used as a diagnostic test to confirm the presence of HCV infection, said Abbott.