Pfizer Logo

Pfizer To Present Clinical Data From Expanded Breast Cancer Portfolio At The San Antonio Breast Cancer Symposium

Thursday, December 03, 2009 - 04:30pm

Results from Studies in Early Breast Cancer and Advanced Disease to be Presented

(BUSINESS WIRE)--Pfizer Oncology announced today that it will be presenting study findings evaluating several compounds including those from its newly expanded breast cancer portfolio following the recent acquisition of Wyeth, focusing on the needs of multiple breast cancer patient populations at the CTRC-AACR San Antonio Breast Cancer Symposium (SABCS) being held December 9 – 13. Presentations will highlight results from long-term follow-up of Aromasin® (exemestane tablets) in an adjuvant switch study of postmenopausal women with early breast cancer; data on neratinib, an investigational, orally administered, pan-ErbB inhibitor in patients with HER2 (also known as ErbB2) positive breast cancer; as well as findings on Sutent® (sunitinib malate) in metastatic breast cancer.

“As the needs of the breast cancer community continue to evolve, we are working diligently to develop novel treatment options to help a variety of patient populations,” said Maria Koehler MD, PhD, Vice President, Women’s Cancers Strategy for Pfizer Oncology. “At this important meeting, we are pleased to share research from our expanded pipeline, including neratinib and sunitinib, which builds upon our strong heritage in breast cancer research with Aromasin.”

Pfizer will present an exploratory analysis from the updated 91-month median follow-up data of the Intergroup Exemestane Study (IES) study (Oral #12; December 10). IES, a landmark trial with the longest follow-up of endocrine treatment in the adjuvant switch setting, is a randomized, double-blind, multinational trial of postmenopausal women with early breast cancer. IES evaluates the clinical benefits of switching 2,352 patients to Aromasin after two to three years of tamoxifen versus continuing 2,372 patients on tamoxifen for a full five years of therapy.

Pfizer will also present data relating to the efficacy and safety of neratinib, an orally administered, irreversible inhibitor of the ErbB-1 (EGFR), ErbB-2 (HER2) and ErbB-4 (HER4) kinases. Data presentations at the meeting include the evaluation of the safety and efficacy of neratinib in combination with paclitaxel in HER2 positive metastatic breast cancer (Poster #5081; December 12), as well as data on gastrointestinal and cardiovascular safety profiles based on a Phase 2 study of neratinib monotherapy in patients with advanced HER2 positive breast cancer (Poster #5096; December 12).

Final results will be presented from the Phase 3 SUN 1107 trial evaluating single-agent sunitinib versus single-agent capecitabine in patients with HER2 negative advanced breast cancer after failure of standard treatment. Earlier this year, at the recommendation of an independent Data Monitoring Committee (DMC), the trial was

stopped after the DMC determined that sunitinib would be unable to reach the primary endpoint of improved progression-free survival compared to capecitabine, in the study population.

“We are working to improve our understanding of the mechanisms and biology of breast cancer to facilitate better matching of patients to treatments, with the goal of increased benefits from selected therapies,” added Dr. Koehler. “Whether it is through studying the addition of new compounds into existing regimens, or pursuing novel treatment strategies, we strive to improve outcomes for breast cancer patients worldwide.”

In ongoing support of the breast cancer community, new data from the BRIDGE (Bridging Gaps, Expanding Outreach – Metastatic Breast Cancer Patient) survey, a wide-reaching assessment of the needs, experiences and attitudes of women living with metastatic breast cancer (Poster #3085; December 12) will be presented. The survey was expanded to include 392 additional participants from four additional countries - Brazil, Venezuela, Canada and Australia. The survey now spans 13 countries across five continents, with a total of 1,342 respondents.

Additional Pfizer Data Presentations

- New analyses from the TEAM (Tamoxifen, Exemestane, Adjuvant, Multicenter) trial will also be presented at SABCS, comparing five years of exemestane as initial therapy to tamoxifen followed by exemestane for five years: The TEAM trial, a prospective, randomized, Phase 3 trial in postmenopausal women with hormone-sensitive early breast cancer (Oral #11; December 10).
- Safety and efficacy of neratinib in combination with vinorelbine in ErbB2+ metastatic breast cancer (Poster #5095; December 12)
- Safety of neratinib in combination with capecitabine in patients with solid tumors: a phase 1/2 study (Poster #5108; December 12)

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers, including breast, lung, prostate, sarcoma, melanoma, and various hematologic cancers. Pfizer Oncology has more than 25 biologics and small molecules in clinical development and more than 200 clinical trials underway.

By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for the right patient at the right time.

For more information please visit www.Pfizer.com.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world’s best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world’s leading biopharmaceutical company, we also collaborate with

health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

About Aromasin® (exemestane tablets)

Aromasin is the only aromatase inhibitor indicated for sequential therapy in postmenopausal women with HR positive early breast cancer after two to three years of tamoxifen for a total of five years of adjuvant therapy. The use of Aromasin in this setting is supported by the landmark IES trial. Aromasin is also indicated for the treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.

Important Aromasin (exemestane tablets) Safety Information

Aromasin should not be used in women who are premenopausal, are nursing or pregnant, have a known hypersensitivity to the drug, or are taking estrogen-containing agents. Dose modification is recommended for patients who are receiving certain medications, including strong CYP 3A4 inducers. In patients with early breast cancer, elevations in bilirubin, alkaline phosphatase, and creatinine were more common in those receiving Aromasin than either tamoxifen or placebo. Reductions in bone mineral density over time are seen with the use of Aromasin.

About Sutent® (sunitinib malate)

Sutent is an oral multi-kinase inhibitor approved for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate and for advanced / metastatic renal cell carcinoma (RCC).

Sutent works by blocking multiple molecular targets implicated in the growth, proliferation and spread of cancer. Two important Sutent targets, vascular endothelial growth factor receptor (VEGFR) and platelet-derived growth factor receptor (PDGFR), are expressed by many types of solid tumors and are thought to play a crucial role in angiogenesis, the process by which tumors acquire blood vessels, oxygen and nutrients needed for growth. Sutent also inhibits other targets important to tumor growth, including KIT, FLT3 and RET.

Important Sutent (sunitinib malate) Safety Information

Women of child bearing age who are (or become) pregnant during therapy should be informed of the potential for fetal harm while on Sutent.

Decreases in left ventricular ejection fraction (LVEF) to below the lower limit of normal (LLN) have been observed. Patients with concomitant cardiac conditions should be carefully monitored for clinical signs and symptoms of congestive heart failure.

Patients should be monitored for hypertension and treated as needed with standard antihypertensive therapy. Complete blood counts (CBCs) with platelet count and serum chemistries should be performed at the beginning of each treatment cycle for patients receiving treatment with Sutent.

The most common adverse reactions in advanced RCC and GIST clinical trials were fatigue, asthenia, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspepsia, abdominal pain, constipation, hypertension, rash, hand-foot syndrome, skin discoloration, altered taste, anorexia and bleeding.

For more information on Pfizer Oncology, including full prescribing information for Aromasin (exemestane tablets) and Sutent (sunitinib malate), please visit www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release Is as of December 4, 2009. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about neratinib, a product candidate, and potential additional indications for Sutent and Aromasin that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for neratinib and for such additional indications for Sutent and Aromasin as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of neratinib and such additional indications for Sutent and Aromasin; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K.

Pfizer Inc. Media: Chris Loder, O: 212-733-7897 M: 347-453-8199 OR Investors: Jennifer Davis, O: 212-733-0717 M: 347-237-7947