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Pfizer Announces Updated Trial Results for AROMASIN® (exemestane tablets) In Switch And Upfront Settings

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Additional Results from the 91-Month Median Follow-up of the Intergroup Exemestane Study (IES) and the Tamoxifen, Exemestane, Adjuvant, Multicenter (TEAM) Study Demonstrate Benefits of Aromasin in Estrogen-Receptor Positive/Unknown Postmenopausal Early Breast Cancer Patients

(BUSINESS WIRE)--Pfizer today announced results from an exploratory analysis of the Intergroup Exemestane Study (IES) at a median follow-up of 91 months in estrogen-receptor positive (ER+) or estrogen-receptor unknown (ER-unknown) women that looked at breast cancer free survival (BCFS) and censored deaths that occurred prior to breast cancer relapse. These data showed that women who switched to Aromasin® (exemestane tablets) after 2.5 years of tamoxifen experienced a 19 percent reduction in risk of breast cancer recurrence (BCFS) (HR=0.81 95% CI (0.71, 0.92); p<0.001) compared to women who continued on tamoxifen for a full five years of treatment. Separately, results from the Tamoxifen, Exemestane, Adjuvant, Multicenter (TEAM) study did not show a difference in disease free survival (DFS) in women who took Aromasin for five years compared to those who switched from tamoxifen to Aromasin after two to three years (HR=0.97 (95% CI 0.88-1.08); P=0.604). Data from IES and TEAM, presented today at the CTRC-AACR San Antonio Breast Cancer Symposium (SABCS), continue to underscore the benefits of Aromasin for postmenopausal women with hormone-receptor positive/unknown early breast cancer.

About IES

IES is a landmark trial with the longest follow-up of endocrine treatment in the adjuvant switch setting. It is a randomized, double-blind, multinational trial of postmenopausal women with early breast cancer. The trial is run by the International Collaborative Cancer Group in collaboration with the Institute of Cancer Research-Clinical Trials and Statistics Unit (ICR-CTSU), under the auspices of the Breast International group and sponsored by Pfizer. IES evaluates the clinical benefits of switching patients to Aromasin after two to three years of tamoxifen (n=2,352) versus continuing patients on tamoxifen for a full five years of therapy (n=2,372). The primary endpoint of IES was DFS in the intent-to-treat (ITT) population.

The ITT analysis at a median follow-up of 91 months regarding DFS, overall survival (OS), adverse events and other events of interest, including cardiovascular and musculoskeletal, was presented at the joint ECCO 15/ESMO 34 in September 2009. The current analysis of BCFS focuses on the 4,599 patients who are ER+/unknown.

“Using breast cancer free survival as an endpoint focuses on breast cancer events only, which is important in a population of older patients who are likely to have other medical problems,” said Dr. Stephen Jones, Medical Director, U.S. Oncology Research, Houston and Texas Oncology, Dallas, Texas. “We are pleased to see Aromasin’s place within the switch treatment paradigm underscored once again by these additional long-term data.”

About TEAM

TEAM is a randomized, open-label, multinational trial in 9,779 postmenopausal women with hormone sensitive early breast cancer. The TEAM trial represents an international collaboration of investigators in nine countries who conducted the trial following protocols representative of local clinical practice.

TEAM was originally designed in 2001 as a comparison of five years of upfront Aromasin vs. tamoxifen. In 2004, based on results of IES, the TEAM design was revised; the tamoxifen arm was converted into a tamoxifen/Aromasin sequencing arm. The modified design includes two co-primary endpoints comparing DFS in a pre-planned pooled analysis:

- At 2.75 years in patients randomized to initial therapy with either tamoxifen or Aromasin (presented at SABCS 2008)
- In patients treated with Aromasin for five years versus patients who received sequential therapy of tamoxifen for 2.5 to three years followed by Aromasin for a total of five years (presented at SABCS 2009)

The analysis of DFS at a median follow-up of 5.1 years did not show a difference between five years of upfront treatment with Aromasin and switching to Aromasin following two to three years of tamoxifen. Results demonstrate:

- Disease Free Survival (ITT): HR=0.97 (95% CI 0.88-1.08); P=0.604
- Time to Recurrence (ITT): HR=0.94 (95% CI 0.83-1.06); P=0.293
- Overall Survival (ITT): HR=1.00 (95% CI 0.89-1.14); P=0.999

The safety profile reported in the TEAM study is consistent with known side effects of Aromasin and tamoxifen. Upfront Aromasin was associated with increased reported incidence of osteoporosis, fractures, arthralgia, nerve compression, vaginal dryness, hypertension and hyperlipidaemia. Tamoxifen followed by Aromasin was associated with increased reported incidence of hot flushes, vaginal bleeding, vaginal discharge, endometrial abnormalities, endometrial cancer and venous thrombosis.

“We are pleased to have data from both IES and TEAM presented at this year’s SABCS,” said Maria Koehler MD, PhD, Vice President, Women’s Cancers Strategy for Pfizer Oncology. “We believe that results from both studies further support physician and patient confidence in Aromasin.”

About Aromasin® (exemestane tablets)

Aromasin is the only aromatase inhibitor indicated for sequential therapy in postmenopausal women with hormone-receptor (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 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 scientific 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. We have 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.

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For more information on Aromasin, please visit www.Pfizer.com.

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