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Pfizer Announces Results from Trial of AROMASIN in Postmenopausal Women with Hormone Sensitive Early Breast Cancer

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Results Presented During the CTRC-AACR San Antonio Breast Cancer Symposium (SABCS)

(BUSINESS WIRE)--Pfizer today announced results from a first planned analysis of the TEAM (Tamoxifen, Exemestane, Adjuvant, Multicenter) trial. TEAM was originally designed in 2001 as a comparison of 5 years of upfront AROMASIN® (exemestane tablets) vs. tamoxifen. In 2004, based on results of Intergroup Exemestane Study (IES) the TEAM trial design was revised; the tamoxifen arm was converted into a tamoxifen/AROMASIN sequencing arm. This analysis presented at SABCS represents the first of two co-primary endpoints that will be reported from this trial. The first co-primary endpoint compares early events by measuring disease-free survival (DFS: disease progression or death) at 2.75 years in 9,775 patients randomized to initial therapy with either tamoxifen or AROMASIN.

The analysis of DFS at 2.75 years demonstrated an 11 percent reduction in the risk of DFS events in favor of AROMASIN (HR=0.89; 95% CI, 0.77-1.03). This difference was not statistically significant (p=0.118). A second planned analysis of DFS after five years of therapy is expected in late 2009. Results from TEAM trial sub-studies were also presented at SABCS.

“The TEAM data contribute to the growing knowledge of the role of aromatase inhibitors in the treatment of early breast cancer,” said Dr. Steve Jones, medical director, U.S. Oncology Research, Houston and Texas Oncology, Dallas, TX. “Clinicians take into account patient profile, clinical evidence and guidelines when determining the optimal treatment regimen for patients, and should consider these new data as treatment strategies are evaluated.”

Additional TEAM Study Results

- Additional secondary analyses demonstrated a:
  - 15 percent reduction in the risk of recurrence-free survival(RFS) events in favor of AROMASIN (HR=0.85; 95 percent CI, 0.72-1.00; p=0.049)
  - 19 percent improvement in the time-to-distant metastasis in favor of AROMASIN (HR=0.81; 95 percent CI, 0.67-0.98; p=0.026)
- When adjusting the primary DFS analysis accounting for discontinuation rates and patients who switched prior to 2.5 years, an analysis showed a 17 percent reduction in the risk of DFS events at 2.75 years in favor of AROMASIN (HR=0.83; 95 percent CI, 0.71-0.97; p=0.021)
  - Treatment discontinuation rates for tamoxifen and AROMASIN were 29.5 percent and 18.9 percent, respectively

    - 754 patients in the tamoxifen arm switched prior to 2.5 years
- The most common side effects reported in the TEAM trial were consistent with the expected safety profile of these agents. Side effects were coded by NCI CTC (version 2), and included for tamoxifen and AROMASIN (all grades), respectively: hot flashes (33 percent, 28.5 percent); arthralgias (9.2 percent, 18.4 percent); fatigue (16 percent, 16.8 percent); pain (13.2 percent, 14.6 percent); infection (13 percent, 11.9 percent)
- The incidence of bone-related side effects for tamoxifen and Aromasin, respectively, were:
    - Osteoporosis (2.2 percent, 4.9 percent)
    - Spine/wrist/hip fractures (0.5 percent, 0.6 percent)

TEAM Sub-studies

- Data from the TEAM Pathology study support the prognostic value of PgR in ER+ early breast cancer
- Results from additional TEAM sub-studies (bone, cognitive function, quality of life and physical activities) were also presented

About the TEAM Trial

TEAM is a randomized, open-label, multinational trial in 9,775 postmenopausal women with hormone sensitive early breast cancer. The TEAM trial represents an international collaboration of investigators in 9 countries who conducted the trial following protocols representative of local clinical practice.

TEAM was originally designed in 2001 as a comparison of 5 years of upfront AROMASIN® (exemestane tablets) 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 5 years versus patients who received sequential therapy of tamoxifen for 2.5-3 years followed by AROMASIN for a total of 5 years

Secondary endpoints included overall survival, time to new primary breast cancer, recurrence-free survival, time to new primary cancers (other than breast) and safety and tolerability. The TEAM trial includes 19 prospectively planned observational and translational research sub-studies.

“Aromasin has had an important impact on the treatment of women with breast cancer since its approval,” said Dr. Ray Urbanski, senior medical director/Oncology Group Lead. “We are proud of our heritage in breast cancer, and continued commitment to develop new treatment options to meet the unmet needs of these patients.”

About Aromasin® (exemestane tablets)

Aromasin is the only aromatase inhibitor indicated for sequential therapy in postmenopausal women with HR positive early breast cancer after 2-3 years of tamoxifen for a total of 5 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.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of treatments and currently has 22 innovative compounds in clinical development across four platforms. By leveraging the strength of our resources and scientific talent, Pfizer Oncology strives to discover and develop novel treatment options to improve the outlook for oncology patients. Pfizer currently devotes more than 22 percent of its total R&D budget to the field of oncology, investing annually in worldwide research initiatives. We also partner with healthcare providers, governments and local communities around the world to provide better quality healthcare and health system support. For more information on the above information, please visit http://www.Pfizer.com.

For more information on AROMASIN and Pfizer Oncology, including full prescribing information for AROMASIN, please visit www.pfizer.com.

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