Survival Benefit Maintained in Long Term Follow-up of IES with Pfizer’s AROMASIN® (Exemestane Tablets)

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91-Month Follow-up of the Intergroup Exemestane Study (IES) Demonstrated a Significant Disease-Free Survival Benefit in Favor of Switching to AROMASIN After 2 to 3 Years of Tamoxifen Compared to Continuing on Tamoxifen for 5 Years in Oestrogen-Receptor Positive/Unknown Postmenopausal Early Breast Cancer Patients

(BUSINESS WIRE)--Pfizer Inc today announced new, longer-term data from the Intergroup Exemestane Study (IES) showing that women who switched to AROMASIN® (exemestane tablets) after taking tamoxifen for two to three years experienced a significant reduction (18%) in the risk of disease-free survival (DFS) events (HR=0.82; 95% CI: 0.73-0.92; P=0.0009), compared to women who continued on tamoxifen for a full five years of treatment.1 In addition, IES showed that AROMASIN prolonged overall survival (OS) in the ER+/unknown population with a 14% reduction in the risk of dying (HR=0.86; 95% CI: 0.75-0.99; P=0.04).1 These results demonstrate that the benefits of treatment are maintained in long term follow-up. These results were presented at the joint ECCO 15/ESMO 34 meeting in Berlin, Germany.1

“These new, long-term follow-up data of the IES demonstrate a significant survival benefit for patients who switched to AROMASIN compared to those who stayed on tamoxifen,” said Charles Coombes, head of the oncology department at Imperial College, London, UK and principal investigator of the IES. “These findings are important to patients and physicians alike as they reaffirm their confidence in switching to AROMASIN after two to

three years of tamoxifen.”

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.2 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. The primary endpoint of the study was DFS in the intent-to-treat (ITT)i population. Within the IES, 97% of the study population was oestrogen-receptor positive/unknown.1

In postmenopausal women with early breast cancer at a median follow-up of 91 months, switching to AROMASIN after two to three years of tamoxifen, for a total of five years of treatment, was shown to result in a:

16% reduction in the risk of DFS events, defined as local or distant recurrence of breast cancer, contralateral breast cancer, or death from any cause, compared to staying on tamoxifen for five years (HR=0.84; 95% CI: 0.75-0.94; P=0.002) in the ITTi population.1
For the secondary endpoint of overall survival in the ITT population, there was an 11% relative risk reduction of death. There was a statistically significant 14% reduction in the risk of death noted in the ER+/unknownii population (HR=0.86: 95% CI: 0.75-0.99 P=0.04).1
These DFS and OS data are consistent with the previous IES update at 55.7 months. Additionally, AROMASIN’s safety profile at 91 months was similar to that shown previously. An analysis of events of interest including cardiovascular and musculoskeletal showed no new serious adverse events in comparison to the previous analysis.1

“AROMASIN has proven to be an effective treatment for postmenopausal women with oestrogen-receptor positive early breast cancer after 2-3 years of tamoxifen treatment,” said Mace Rothenberg, MD, senior vice president, clinical development and medical affairs, Pfizer Oncology. “The extraordinarily long-term follow up of patients enrolled in this study adds to the body of data supporting AROMASIN’s benefits and further underscores Pfizer’s commitment to oncology.”

About AROMASIN® (exemestane tablets)3

In Europe, AROMASIN is indicated for the adjuvant treatment of postmenopausal women with oestrogen receptor positive invasive early breast cancer, following two to three years of initial adjuvant tamoxifen therapy. AROMASIN is indicated for the treatment of

advanced breast cancer in women with natural or induced postmenopausal status whose disease has progressed following anti-oestrogen therapy. Efficacy has not been demonstrated in patients with oestrogen receptor negative status.

In the United States, AROMASIN is indicated for the adjuvant treatment of postmenopausal women with oestrogen-receptor positive early breast cancer who have received two to three years of tamoxifen and are switched to AROMASIN for completion of a total of five consecutive years of adjuvant hormonal therapy. 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 Information3

AROMASIN should not be used in women who are premenopausal, are nursing or pregnant, have a known hypersensitivity to the drug, or are taking oestrogen-containing agents. Dose modification is recommended for patients who are receiving certain medications, including strong CYP 3A4 inducers such as rifampicin and phenytoin. 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 for cancer patients worldwide. Our robust pipeline consists of 21 biologics and small molecules in clinical development. Pfizer Oncology has over 200 clinical trials including robust Phase 3 clinical trial programs in renal cell carcinoma, prostate cancer, non-small cell lung cancer, metastatic breast cancer, and hepatocellular carcinoma.

By working collaboratively with academic institutions, researchers, governments, and licensing partners, Pfizer Oncology strives to transform treatment by targeting the right drug for the right patient at the right time.

For more information please visit www.Pfizer.com.

1. Coombes RC, et al. Survival and safety post study treatment completion: an updated analysis of the Intergroup Exemestane Study (IES). Results presented at ECCO/ESMO

September 22, 2009. Abstract 5.010.

2. Coombes, RC, et al. Survival and safety of exemestane versus tamoxifen after 2-3 years' tamoxifen treatment (Intergroup Exemestane Study): a randomized controlled trial. The Lancet. 2007: 369: 559-70

3. Data on File.

i ITT: Intent-to-treat population is generally interpreted as including all patients in a study population, regardless of whether they actually satisfied the entry criteria, the treatment actually received, and subsequent withdrawal or deviation from the protocol.

ii ER+/unknown: Oestrogen-receptor positive breast cancer needs the hormones oestrogen or progesterone to grow. Cancer whose receptor status is unknown is referred to as "ER unknown."

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