AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: **Arimidex® Tablets 1mg**
ACTIVE INGREDIENT: **Anastrozole**

Study No:	NIS-OJP-ARI-2007/1 (NCT00859560)
Study Title:	Retrospective survey of bone fracture in patients with Arimidex 1mg

Developmental phase: N/A
Study Completion Date: December 26, 2008
Date of Report: July 16, 2009

OBJECTIVES:

Primary objective
Evaluate effects of anastrozole on bone fracture in post-menopausal breast cancer patients with anastrozole as adjuvant therapy.

Secondary objective
Investigate the followings:

- Incidence of bone density assessment in actual medical practice
- Breast cancer recurrence
- Overall survival

METHODS:

This study was a special post-marketing surveillance (PMS, also called clinical experience investigation) in Japan and conducted by AstraZeneca KK in accordance with relevant Japanese regulation.

The study included patients who were previously registered in another PMS conducted from Jan. 2001 to Feb. 2004. The purpose of the previous PMS was to confirm safety and efficacy of anastrozole. In this current PMS, bone fracture episodes after the previous PMS were retrospectively collected in post-menopausal breast cancer patients with anastrozole as adjuvant therapy. It was also investigated whether these patients received regular bone density assessment during the administration of anastrozole. The information for breast cancer recurrence and all causes of death after the previous PMS was collected.

For statistical analyses, data for bone fracture episodes, breast cancer recurrence, and all causes of death were combined with the date collected in the previous PMS. All bone fracture episodes while a patient was receiving anastrozole, and up to 30 days after anastrozole treatment ended, were included to calculate bone fracture rate. The data for 5-year event free survival rate and 5-year overall survival rate were analyzed by Kaplan-Meier method with an intention-to-treat approach.

RESULTS:

Of 2,416 patients in the previous PMS, 2,193 patients were included in the analyses. Mean (±S.D.) treatment duration was 1,200 (±685) days and annual bone fracture rate was 1.1%/year (95% confidence interval: 0.9-1.4 %/year). Treatment duration with anastrozole was not associated with annual bone fracture rate (0-1 year: 1.0%; 1-2 year 1.3%; 2-3 year 0.9%; 3-4 year: 1.3%). Age and history of arthritis and joint pain were statistically significant factors to increase the bone fracture rate. Bone density assessment rate during anastrozole treatment was increased especially in 2007 and 2008.

Five-year recurrence free survival rate for patients without history of endocrine therapy was 86.8% (95% confidence interval: 85.0-88.5%) and 5-year overall survival rate for all patients was 94.8% (95% confidence interval: 93.8-95.8%).