

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Faslodex
ACTIVE INGREDIENT: Fulvestrant

Study No: NIS-OFR-FAS-2007/1

Observational usage study of Faslodex in patients suffering from initial breast cancer in France

Developmental phase: -

Study Completion Date: September 2007

Date of Report: May 2008

OBJECTIVES:

The purpose of this study was to describe the way Faslodex is used in France, in patients suffering from initial breast cancer, that is to evaluate Faslodex treatment duration and to determine patients profile.

METHODS:

Data were retrospectively collected from oncologists managing patients suffering from initial breast cancer, treated by Faslodex, treatment which was stopped during 2007. The study was conducted from 10th April 2007 (screening stage beginning) and 5th June 2007 (last patient inclusion).

RESULTS:

A total of 217 patients suffering from initial breast cancer and treated by Faslodex, treatment which was stopped during 2007, were included in the analysis from 50 physicians, that is an average of 4,3 patients per doctor. Almost the entire population of patients were menopausal, suffering from tumours having estrogen receptors and had metastases or local recurrences. Overall, 94% (N = 205) had received previous endocrine therapy :130 patients (60%) had received at least once tamoxifen, others previous aromatase inhibitor treatment without tamoxifen. Among the patients whose Faslodex treatment is over at the time of the study, 89% (N = 182) have not received or are not going to receive another line of endocrine therapy, after the stop of Faslodex treatment. The average Faslodex treatment duration is 7 months, the median is 6 months.

The findings confirm fulvestrant is correctly used in France, according to the guidelines. The duration of treatment median, which was not clearly defined, is 6 months. Faslodex is used as a last resort, after previous endocrine therapy.