SUMMARY

ASTRAZENECA

FINISHED PRODUCT: FASLODEX™

ACTIVE INGREDIENT: fulvestrant

Study title (number): A double blind, double-dummy, randomised, parallel group multicentre trial to compare the efficacy, tolerability, endometrial and bone effects of FASLODEX™ (fulvestrant) 250 mg monthly with NOLVADEX™ (tamoxifen) 20 mg daily when given as neoadjuvant treatment in post menopausal women with primary breast cancer (9238IL/0042)

Clinical Phase: III

First subject enrolled: 2 May 2001
Study termination date: 13 August 2001
AstraZeneca approval date: 9 January 2003

Principal investigator and location (centre no.):

Was the study completed? No
Was the study conducted in a manner compliant with GCP? Yes
Reasons for Abbreviated Report: This Study was terminated mainly on ethical grounds following emerging initial analyses of Study 9238IL/0025.

Termination details: After the enrolment of the 3 patients a decision was taken by the sponsor to terminate the study and for those patients currently ongoing to be withdrawn. This decision resulted from the emerging initial analyses of study 9238IL/0025 (fulvestrant vs. tamoxifen as first line treatment for advanced breast cancer) which suggested that although fulvestrant had shown clinical activity, equivalence to tamoxifen could not be claimed and therefore, mainly on ethical grounds, it was decided not to continue to enrol further patients into the study and to terminate the participation of those patients already enrolled and receiving study. This decision was communicated to the study sites and all three patients who were withdrawn from the study subsequently received treatment with tamoxifen.

Study treatment: A total of 4 study centres were set up prior to the closure of the study. At the time that the study was stopped, 11 patients had been screened and 3 of these were subsequently enrolled and received study treatment. Two patients received a single fulvestrant 250 mg im injection, and one patient received three courses (84 tablets) of tamoxifen 20 mg.

Safety: No serious/unexpected adverse events or adverse drug reactions were reported for any of the three patients enrolled to the study. One patient (fulvestrant 250 mg group) reported headache on the day she began study treatment, and this event subsequently resolved three days later. The same patient subsequently reported pain in the right shoulder and separately in the mammary area where surgery had been performed. All three events were reported as moderate in intensity. The pain reported in the shoulder and mammary areas did not resolve prior to the patient leaving the study, although on follow up period the pain in the right shoulder reduced in intensity to mild.
