

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Casodex

ACTIVE INGREDIENT: Bicalutamide

Study No: D6874L00016

A study with a new tablet of Casodex (ICI176, 334-1) to confirm if bicalutamide is not absorbed via oral mucosa in Japanese Healthy volunteers.

Developmental Phase: Post Market

Study Completion Date: LSLV, 16 August 2010

Date of Report: NA (CSR will not be prepared because this study was conducted as a preliminary study before a BE study with a new tablet.)

OBJECTIVES:

To confirm if bicalutamide is not absorbed via oral mucosa after ICI176,334-1 is given to healthy volunteers.

METHODS:

To measure bicalutamide in the saliva and in blood after a new tablet of Casodex (ICI176,334-1) is disintegrated in the oral cavity.

RESULTS:

Bicalutamid was not absorbed via oral mucosa.