AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Iressa
ACTIVE INGREDIENT: Gefinitib

Study No: 1839/0067

Gefitinib treatment in hormone resistant and hormone receptor negative advanced breast cancer.

Developmental phase: Phase II
Study Completion Date: November 2005
Date of Report: February 2009

OBJECTIVES:

The trial comprised two separate phase II study groups designed to detect activity of gefitinib in patients with advanced breast cancer. The phase II study for group I was in women with tumors that were hormone receptor positive while the phase II study for group II was in women with tumors that were hormone receptor negative. The measure of treatment activity was clinical benefit (complete response, partial response or stable disease for at least 24 weeks).

METHODS:

A two-arm multicentre phase II trial of oral gefitinib
500mg/day was planned in two separate groups of 45 patients with advanced breast cancer for whom chemotherapy was not currently indicated.
Group 1 had hormone resistant breast cancer defined as hormone receptor positive breast cancer with disease progression after treatment with both tamoxifen and an aromatase inhibitor.
Group 2 had hormone receptor negative breast cancer.

Tumour response was assessed every 8 weeks. The primary end-point was the clinical benefit rate (CBR).

RESULTS:

Gefitinib treatment in hormone-resistant and hormone receptor-negative advanced breast cancer.

Green MD, Francis PA, Gebski V, Harvey V, Karapetis C, Chan A, Snyder R, Fong A, Basser R, Forbes JF; on behalf of the Australian New Zealand Breast Cancer Trials Group.
Ann Oncol. 2009 Jun 24. [Epub ahead of print]
PMID: 19553291