Sponsor

Novartis

Generic Drug Name

Nilotinib

Therapeutic Area of Trial

Glivec® (imatinib)-resistant or Glivec® (imatinib)-intolerant chronic myeloid leukemia (CML) and relapsed/refractory Ph+ ALL

Approved Indication

Adult patients with Philadelphia chromosome (Bcr-Abl) positive CML in chronic phase and CML in accelerated phase who are resistant or intolerant to at least one prior therapy including imatinib

Study Number

CAMN107A1101E1

An extension study to the CAMN107A1101 study.

Title

A phase I/II multicenter, dose-escalation study of oral AMN107 on a continuous daily dosing schedule in adult patients with Glivec® (imatinib)-resistant or Glivec®(imatinib)-intolerant CML, or relapsed/refractory Ph+ ALL (Extension Study).

Phase of Development

Phase I/II (Phase IV after the approval)

Study Start/End Dates

Phase I part: 25/Aug/2005 to 02/Dec/2009

Phase II part: 27/Jan/2006 to 02/Dec/2009

Study Design/Methodology

This was an open-label, multicenter, extension study of a phase I/II dose-escalation study (CAMN107A1101) in patients who completed the phase I and phase II component of CAMN107A1101. Treatment in this extension study was started with the same dosage and administration as used at the end of the phase I and phase II component of CAMN107A1101 in each patient, and allowed to continue until unacceptable toxicity occurred, until progression of disease was identified, or until the investigator determined that continuation of treatment was not in the best interest of the patient. After the date of approval of AMN107, the treatment was continued until its duration exceeded 3 years, or its marketed product became available in each study

centers, whichever came later.

One treatment cycle was defined as 28 days of daily administration of AMN107. If there was a dose delay of > 21 days (> 42 days in the case of hematologic toxicity) in the administration of AMN107 from the previous dose, the patient was to be withdrawn from the study.

Centres

19 centers in Japan

Publication

Tojo A, Usuki K, Urabe A, et al. (2009) A Phase I/II study of nilotinib in Japanese patients with imatinib-resistant or -intolerant Ph+ CML or relapsed/refractory Ph+ ALL. Int J Hematol; 89:679-88

Date of Clinical Trial Report

30 Jul 2010

Date Inclusion on Novartis Clinical Trial Results Database

14-Mar-2011

Date of Latest Update