NOVARTIS

Tomas Salmonson
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB

21 May 2014

Subject: Withdrawal of the type II variation to add a new indication for Tasigna® (nilotinib), 200 mg hard capsules (EMEA/H/C/798/II/0061)

Dear Dr Salmonson,

I would like to inform you that Novartis Europharm Ltd. is withdrawing the application for Tasigna 200 mg hard capsules for the following new indication: "Adult patients with Philadelphia chromosome positive CML in the chronic phase who have not achieved a molecular response greater than or equal to a 4.5-log reduction with imatinib treatment".

This withdrawal is based on the following reason:

The CHMP considers that the data provided to support the new indication at this time are not sufficient to allow the committee to recommend approval of this type II variation application.

This decision will not have consequences for any patients enrolled in any ongoing Novartis sponsored Tasigna clinical trials or for any patients treated with Tasigna in current indications.

As noted in the CHMP assessment report, with respect to the potential benefits of deep molecular response, data from ongoing treatment-free remission studies are not available at present. Therefore, Novartis reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

Yours sincerely,

On behalf of Novartis Europharm Limited