



Dr. Harald Enzmann

European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

11 August 2023

**Subject: Iclusig, (ponatinib), 15 mg, 30 mg, 45 mg, film-coated tablets -
EMA/H/002695/II/0064 - Withdrawal of the application for a new indication**

Dear Dr. Enzmann,

I would like to inform you that, at this point of time, Incyte Biosciences Distribution B.V. has taken the decision to withdraw the application to add a new indication for Iclusig, in the treatment of newly diagnosed adult patients with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL), either in combination with chemotherapy, or in monotherapy after corticosteroid induction in patients not eligible to receive chemotherapy-based regimens.

This withdrawal is based on the feedback from the CHMP which indicates that Committee will not be able to conclude that the benefits outweigh the risks on the basis of the data provided. The MAH, Incyte Biosciences Distribution B.V., is not in a position to satisfactorily address the list of questions raised by the CHMP and has therefore made the decision to withdraw the application.

There are no ongoing clinical trials that will be affected by the withdrawal of the extension application.

The MAH reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

We would like to take this opportunity to thank the (Co)-Rapporteurs and EMA for their time reviewing this application.

Iclusig (ponatinib)
EMA/H/C/00002695

The MAH agrees for this letter to be published on the EMA website.

