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Committee for Medicinal Products for Human Use (CHMP)
Attn. Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Date: 11th October 2022

Subject: Withdrawal of Infigratinib 25 mg hard capsules and Infigratinib 100 mg hard capsules - EMEA/H/0005361 Marketing Authorisation Application

Dear Dr. Enzmann,

I would like to inform you that Helsinn Birex Pharmaceuticals Ltd. (Helsinn) is withdrawing the application for Marketing Authorisation of Infigratinib 25 mg hard capsules and Infigratinib 100 mg hard capsules, which were intended to be used for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement.

This withdrawal is based on the Applicant's decision not to pursue any further development of the drug following a reassessment of regulatory and business strategies.

The ongoing clinical trial (EUDRACT n. 2018-004004-19) in cholangiocarcinoma will be closed. The patients currently on treatment will be managed according to protocol provisions and applicable legislation, where required.

We reserve the right to make further submissions at a future date.

Helsinn would like to sincerely thank the (Co)-Rapporteurs, EMA, and CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

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

Yours sincerely,

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