Dr. Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Date: 20 July 2022

Subject: Withdrawal of EXKIVITY (mobocertinib) 40 mg hard capsules, EMEA/H/005621

Dear Dr. Enzmann,

We would like to inform you that, Takeda Pharma A/S has taken the decision to withdraw the application for the Marketing Authorisation of EXKIVITY (mobocertinib) 40 mg hard capsules, which was intended to be used for the treatment of adult patients with epidermal growth factor receptor (EGFR) exon 20 insertion mutation-positive advanced non-small cell lung cancer (NSCLC), who have received prior platinum-based therapy.

This withdrawal is based on interactions with the CHMP indicating that the data provided thus far would not be sufficient to support a positive opinion on the conditional marketing authorisation of EXKIVITY (mobocertinib). We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

Takeda would like to sincerely thank the (Co-)Rapporteurs and the EMA for their time dedicated to reviewing this application and the helpful guidance provided during the review process.

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

Yours sincerely,

Takeda Pharmaceuticals International AG

Takeda Pharmaceuticals International AG
Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Switzerland
Tel: +41-44-555-10-00