Janssen-Cilag International NV

Turnhoutseweg 30
B-2340 Beerse, Belgium

13 December 2022

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

Subject: Withdrawal of IMBRUVICA®, ibrutinib, 140mg capsule, 140-, 280-, 420- and 560 mg film-coated tablet **EMEA/H/C/003791/II/0073**

Dear Dr. Enzmann,

I would like to inform you that, at this point of time, Janssen-Cilag International NV has taken the decision to withdraw the application for a new indication for IMBRUVICA® in the frontline treatment of Mantle Cell Lymphoma.

This withdrawal is based on the reason that the submitted study data are considered insufficient at this time by CHMP to support the approval for the use of Imbruvica in the proposed indication.

This withdrawal does not have any impact on any ongoing clinical trials.
The benefit-risk balance of Imbruvica remains positive in the approved indications.

Janssen-Cilag International NV would like to sincerely thank the (Co-)Rapporteurs, EMA, PRAC and CHMP members for their time dedicated to reviewing this application and the support provided during the review process.

We reserve 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.