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European Medicines Agency (EMA)
Domenico Scarlattilaan 6
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27 June 2022

To the attention of the CHMP chairman

Subject: Parsaclisib Incyte Biosciences Distribution B.V. (parsaclisib) tablet – EMEA/H/C/005893: Withdrawal of Marketing Authorisation Application

Dear Dr Enzmann,

We would like to inform you that, at this point in time, we have decided to withdraw the Marketing Authorisation Application for Parsaclisib Incyte Biosciences Distribution B.V. (parsaclisib) tablet (EMEA/H/C/005893) which was intended for the treatment of adult patients with relapsed or refractory marginal zone lymphoma (MZL).

Following the CHMP Day 120 List of Questions and the clarification meeting with the (Co)-Rapporteurs and EMA, we determined that we were not in a position to address satisfactorily the CHMP concerns, namely in regards to the conditional MA confirmatory study design and the feasibility issues encountered to conduct a randomized Phase 3 study with time to event endpoints.

The applicant reserves the right to submit further Marketing Authorisation Applications for this medicinal product at a future date in this or other therapeutic indication(s).

The withdrawal does not have any impact on ongoing clinical trials.

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

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

Should you need further information, please do not hesitate to contact us.