Albireo
AN IPSEN COMPANY

Date: 22-10-2023

[redacted]
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of extension of indication application package for Bylvay, (odevixibat), 200, 400, 600 and 1 200 µg Hard capsules - EMEA/H/C/004691/II/0011

Dear [redacted]

For the withdrawal of an application to extend the therapeutic indication

I would like to inform you that, at this point in time, Albireo AB has taken the decision to withdraw the application package of 29 November 2022 for the extension of indication for Bylvay to treat cholestatic pruritus in Alagille syndrome (ALGS) in patients aged 6 months or older.

This withdrawal is based on the following reason:

Feedback from the Committee for Orphan Medicinal Products (COMP) on 5 October 2023, indicates that the Committee will not recommend maintenance of the orphan designation and thus the market exclusivity for Bylvay in ALGS. Bylvay is currently authorised as an orphan medicinal product for the treatment of progressive familial intrahepatic cholestasis (PFIC) and it is not possible under EU law for a medicine to be authorised for an orphan and a non-orphan condition at the same time. Since the final COMP opinion will lead to a negative European Commission (EC) decision for the extension of indication, Albireo has decided to withdraw the application package.

The ongoing open-label extension study A4250-015 in ALGS will be completed as planned. Beyond the initial 72 weeks of treatment, the study contains an optional extension period during which patients can continue to receive treatment until the drug is commercially available. The ongoing compassionate use programme in ALGS is currently not affected by this withdrawal.

We reserve the right to make further marketing authorisation application/variation application submissions at a future date in this or other therapeutic indications.

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

Yours sincerely,

[redacted]

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