Intercept

09 December 2021

[redacted]

European Medicines Agency (EMA)
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of Zektayos-Hepjuvo (obeticholic acid) 25 mg tablets EMEA/H/C/005249

Dear [redacted]

I would like to inform you that, at this point of time, Intercept Pharma International has taken the decision to withdraw the application for Conditional Marketing Authorisation of Zektayos-Hepjuvo, obeticholic acid, 25 mg tablets which was intended to be used for improvement of liver fibrosis and resolution of steatohepatitis in adult patients with significant liver fibrosis due to nonalcoholic steatohepatitis (NASH), without clinical signs or symptoms of cirrhosis.

This withdrawal is based on the view that CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance at the present time and the company has been unable to complete and provide the analyses of additional data that were being proposed to address CHMP questions in an acceptable timeframe.

The withdrawal of the application has no consequences for the ongoing clinical trials, the results from which are expected to potentially contribute to a future submission in the EU.

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 EMEA website.

Intercept wishes to thank the CHMP and PRAC rapporteurs, CHMP members and EMA staff for their time and dedication in reviewing this application and the support provided throughout the procedure.

Yours sincerely,

[redacted]