

FGK RS GmbH | Heimeranstrasse 35 | 80339 München | Germany

Committee for Medicinal Products for Human Use (CHMP)  
Attn: Dr. Harald Enzmann  
European Medicines Agency  
Domenico Scarlattilaan 6  
1083 HS Amsterdam

The Netherlands

23 August 2021

Subject: Withdrawal of Livmarli 9.5 mg/ml oral solution;  
EMA procedure reference: EMEA/H/C/5551

Dear Dr. Harald Enzmann,

I would like to inform you that, at this point of time, FGK Representative Service GmbH located at Heimeranstrasse 35, 80339 Munich, Germany, who is the EU applicant for a Marketing Authorisation for Livmarli 9.5 mg/ml oral solution (maralixibat chloride) on behalf of Mirum Pharmaceuticals Inc. has taken the decision to withdraw that application for Marketing Authorisation, which was intended to be used for:

- Treatment of Progressive Familial Intrahepatic Cholestasis Type 2 (PFIC2) in patients 1 year of age and older.

The withdrawal is based on a reassessment of Mirum's regulatory and business strategies following the CHMP discussion and anticipated upcoming additional data. The withdrawal is without prejudice to resubmission.

This withdrawal does not have any impact on any ongoing clinical trials with maralixibat.

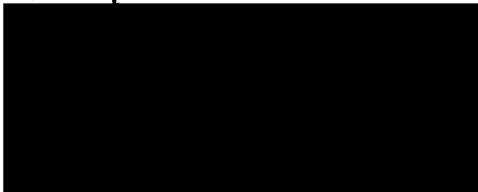
Mirum remains fully committed to the development of maralixibat in PFIC and other indications and reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

FGK Representative Services GmbH would like to sincerely thank the (Co)-Rapporteurs, EMA, CHMP members for the time dedicated to reviewing this application and the support provided during the procedure.

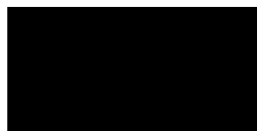
We agree for this letter to be published on the European Medicines Agency website.

Best regards,

**FGK Representative Service GmbH**



FGK Representative Service GmbH



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