REATA

9 November 2022

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

[redacted]

Subject: Withdrawal of Imbarkyd (bardoxolone methyl), 5 and 15 mg, hard capsules – EMA/CHMP/109166/2022

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Dear [redacted]

I would like to inform you that, at this point, Reata Ireland Limited has taken the decision to withdraw the application for Marketing Authorisation of Imbarkyd (bardoxolone methyl), 5 and 15 mg hard capsules, which was intended to be used for the treatment of chronic kidney disease (CKD) caused by Alport syndrome is adults and adolescents aged 12 years and above.

This withdrawal is based on the view that the CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance at the present time.

The withdrawal of the application has no consequences for the ongoing bardoxolone methyl clinical trials.

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.

Reata wishes to thank the CHMP and the 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]

Reata Swiss International

[redacted]

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