13 September 2024

Dr Harald Enzmann
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Durysta, bimatoprost, 10 micrograms intracameral implant in applicator

Subject: Withdrawal of EMEA/H/C/005916

Dear Dr. Enzmann,

I would like to inform you that, at this point of time, AbbVie Deutschland GmbH & Co. KG (AbbVie) has taken the decision to withdraw the application for Marketing Authorisation of Durysta, bimatoprost, 10 micrograms intracameral implant in applicator, which was intended to be used for the reduction of intraocular pressure (IOP) in adults with open angle glaucoma (OAG) or ocular hypertension (OHT).

This withdrawal is based on the following reason:

AbbVie has decided to discontinue this application because the major objections raised cannot be resolved within the available time frame.

This withdrawal does not have any consequences on the ongoing clinical trials.

AbbVie thanks the (Co) Rapporteurs, EMA, PRAC and the CHMP for their time dedicated to reviewing this application and the valuable support and helpful guidance provided during the review process.

AbbVie reserves the right to make further submissions at a future date on this or other therapeutic indication(s).

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

Yours faithfully,

[redacted]

[redacted]
Regulatory Affairs TA – Europe Region
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