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Subject: Withdrawal of Xiidra (lifitegrast) 50 mg/ml eye drops solution in single-dose container

EMA product reference: EMEA/H/C/004653

Date: June 18, 2020

Dear Madam, Sir,

Novartis Europharm Ltd would like to inform you of the decision to withdraw the application for Marketing Authorisation of Xiidra (lifitegrast) 50 mg/ml eye drops solution in single-dose container, which is intended for:

- Treatment of moderate to severe dry eye disease in adults for whom prior use of artificial tears has been insufficient.

This withdrawal is based on the following reason:

- Novartis Europharm Ltd had decided to discontinue this application since the major objections raised cannot be resolved within the available time frame.

There are no ongoing clinical trials with lifitegrast.

Novartis Europharm Ltd will continue to support the EU approved ongoing compassionate use program.

Novartis Europharm Ltd reserves the right to make further submissions at a future date in this or other therapeutic indication(s).

Novartis Europharm Ltd would like to sincerely thank the (Co) Rapporteurs, EMA, PRAC and CHMP for their time dedicated to reviewing this application and the valuable support and helpful guidance provided during the review process.

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

Should you need any further information or clarification, please do not hesitate to contact us.

Yours sincerely,