
Eli Lilly European Regulatory Team

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Dr. Daniel Brasseur
European Medicines Agency (EMA)
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Canary Wharf
London
E14 4HB
UK

Subject: Withdrawal of ARXXANT™ (ruboxistaurin), 32 mg, film-coated tablets
EMA/H/C/000753

Dear Dr. Brasseur,

I would like to inform you that, at this point of time, Eli Lilly Nederland B.V. has taken the decision to withdraw the application for Marketing Authorisation of ARXXANT™ (ruboxistaurin), 32 mg, film-coated tablets, which was intended to be used for the treatment of diabetic retinopathy in adult patients with moderate to severe non-proliferative diabetic retinopathy.

This withdrawal is based on the request for additional data, which we are not able to provide within the timeframe allowed in the Centralised Procedure.

This decision has no immediate consequences for patients enrolled in ongoing 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.

Yours sincerely,

European Regulatory Affairs