Bausch & Lomb

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16 July 2007

Dr. Eric Abadie,
Chairman of CHMP
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of RETISERT® (fluocinolone acetonide) 590 microgram Intravitreal Implant EMEA/H/C/787

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Bausch & Lomb Ireland acting as applicant, has taken the decision to withdraw the application for Marketing Authorisation for RETISERT (fluocinolone acetonide) 590 microgram Intravitreal Implant, an orphan medicinal product, which was intended to be used for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.

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 consequences for patients who have previously received a RETISERT implant in clinical trials. There are no ongoing clinical trials in Europe. RETISERT is approved in the United States for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. Due to limited treatment options for this orphan disease, Bausch & Lomb intends to continue to supply the U.S. commercial product in Member States that allow such imports for named patient use.

We reserve the right to resubmit an application for Marketing Authorisation in this and/or other indications at a future date.

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

Yours sincerely,

On behalf of Bausch & Lomb Ireland