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ALCON LABORATORIES (U.K.) LIMITED,
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ENGLAND HP2 7UD

Direct Line:

Date: 28th February 2006

Subject: Withdrawal of RETAANE 30mg/ml suspension for depot injection, EMEA/H/C/000635

Dear Dr Brasseur,

I would like to inform you that Alcon Laboratories (UK) Ltd has taken the decision to withdraw the application for Marketing Authorisation of RETAANE 30mg/ml suspension for depot injection, which was intended to be used for the treatment of exudative age-related macular degeneration (wet AMD), at this point of time.

This withdrawal is based on the following reasons:

- Alcon's research and development and marketing strategies

It is confirmed that there are ongoing clinical trials and compassionate use programmes with RETAANE 30mg/ml suspension for depot injection in the EU.

The details of those trials, and the compassionate use is attached to this correspondence as Appendix A.

RETAANE 30mg/ml suspension is approved in Australia for exudative AMD lesions that have a classic component. We intend to supply this commercial product for compassionate use in Member States that allow such imports for named/compassionate use. In Members States that do have this provision we will continue to supply the investigational product consistent with local legislation.

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 EMEA website.

Yours sincerely,

Appendix A

Clinical protocol entitled "An Evaluation of Efficacy and Safety of Posterior Juxtascleral Administrations of Anecortave Acetate for Depot Suspension (15 mg or 30 mg) versus Sham Administration in Patients (Enrolled in Study "A" or Study "B") at Risk for Developing Sight-Threatening Choroidal Neovascularization (CNV) Due to Exudative Age-Related Macular Degeneration (AMD)" (C-02-60)

Countries in which study is being conducted:

Australia
Austria
Belgium
Brazil
Denmark
France
Germany
Hungary
Italy
Netherlands
New Zealand
Poland
Portugal
Spain
Sweden
Switzerland
UK

Clinical protocol entitled "An Evaluation of Efficacy and Safety of Posterior Juxtascleral Injections of Anecortave Acetate 15 mg (0.5 ml of 30 mg/ml Anecortave acetate sterile suspension) versus Vehicle in Patients with Subfoveal Choroidal Neovascularization (CNV) Due to Exudative Age-Related Macular Degeneration (AMD)" (C-02-27)

Countries in which study is being conducted:

France
Germany
Hungary
New Zealand
Poland
Portugal
Sweden
Turkey
UK

Clinical protocol entitled: "An Open Label Evaluation of Long Term Efficacy and Safety of Posterior Juxtascleral Injections of Anecortave Acetate 15 mg in Patients with Subfoveal Exudative Age-Related Macular Degeneration (AMD)" (C-03-15)

Countries in which study is being conducted or planned:

Austria
Belgium
Denmark
France
Germany
Hungary
Italy
Netherlands
New Zealand
Poland
Portugal
Spain
Sweden
Switzerland
UK

Ongoing Compassionate Use:

Austria
Argentina
Australia
Belgium
Brazil
Denmark
Germany
Greece
Italy
Netherlands
New Zealand
Portugal
Sweden
Switzerland
UK