Santen Oy

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20 May 2016

Dr. Tomas Salmonson
European Medicines Agency,
7 Westferry Circus,
Canary Wharf,
London, E14 4HB
United Kingdom

Re: Withdrawal of OPSIRIA (sirolimus) 22 mg/ml Solution for injection
EMA product reference number – EMA/H/C/003978/0000

Dear Dr. Salmonson,

I would like to inform you that Santen has taken the decision to withdraw the Marketing Authorisation Application for Opsiria 22 mg/ml solution for injection (INN: sirolimus), which was intended to be used for the treatment of chronic non-infectious uveitis of the posterior segment of the eye.

The withdrawal is based on the following rationale:

In order to allow early access for patients to Opsiria as a new treatment option for the orphan disease of chronic non-infectious uveitis of the posterior segment of the eye, the application was filed based on the data of a single phase III study. Santen acknowledges the need to submit data from the currently ongoing second phase III study prior to review for marketing authorization approval.

Upon completion of the second phase III study, Santen intends to resubmit the application for Opsiria.

Please do not hesitate to contact us if you have questions concerning the content of this letter.

Yours sincerely,