



## NOVAGALI P H A R M A

### NOVAGALI PHARMA COMPLETES PATIENTS RECRUITMENT FOR ITS US PHASE II CLINICAL TRIAL OF CATIOPROST®

**Evry (France), 14 April 2011.** Novagali Pharma, a pharmaceutical company that develops innovative ophthalmic products, announces today the completion of enrolment for its phase II clinical trial of Catioprost® in patients with glaucoma and presenting concomitant damage to the ocular surface.

The randomized phase II trial is a safety and efficacy study of Catioprost® compared to Travatan Z® to treat glaucoma and ocular surface disease. It has enrolled 105 patients in the United States.

Glaucoma is a chronic eye disease that can lead to a gradual loss of peripheral vision or even irreversible blindness. It is thought to affect over 70 million people worldwide with 60% also suffering from damage to the ocular surface which manifests itself with signs and symptoms similar to those experienced by patients with dry eye disease<sup>1</sup>. The global glaucoma market was estimated to be worth USD 5.3bn in 2009.

Daily administration of topical medication to control intraocular pressure is the most common therapeutic approach in glaucoma patients. However, patient age and the long-term use of formulations containing preservatives, particularly BAK which has been shown to be toxic to the cornea and the conjunctiva<sup>2</sup>, may lead to ocular surface damage of varying degrees of severity. Such damage may undermine the compliance and efficacy of anti-glaucoma treatments.

Catioprost® is a preservative-free cationic emulsion containing 0.005% latanoprost, formulated to reduce intraocular pressure while simultaneously treating damage to the ocular surface. Worldwide, latanoprost is the compound most often prescribed to control intraocular pressure. Catioprost® combines latanoprost with Novagali Pharma's patented Novasorb® technology which has been shown to improve ocular surface damage in patients with dry eye disease.

The Phase II clinical study follows preclinical studies at Mount Sinai Hospital in New York and Quinze-Vingts Hospital in Paris. These studies have shown the efficacy of Catioprost® in controlling intraocular pressure, the superiority of its safety profile<sup>3</sup> and its potential for limiting and reversing damage to the ocular surface relative to other prostaglandin therapies for glaucoma<sup>4</sup>.

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<sup>1</sup> Leung et al. Prevalence of Ocular Surface Disease in Glaucoma Patients. *Journal of Glaucoma* 2008

<sup>2</sup> Baudouin C, Labbé A, Liang H, Pauly A, Brignole-Baudouin F. Preservatives in eyedrops: the good, the bad and the ugly. *Prog Retin Eye Res.* 2010 Jul;29(4):312-34. Epub 2010 Mar 17.

<sup>3</sup> Liang et al. Comparison of the ocular tolerability of a latanoprost cationic emulsion versus conventional formulations of prostaglandins: an in vivo toxicity assay. *Molecular Vision* 2009; 15:1690-1699

<sup>4</sup> Liang et al. In vitro and in vivo evaluation of newly developed cationic emulsion formulations in corneal wound healing models. 2010 ARVO proceedings.



## [About NOVAGALI Pharma \(www.novagali.com\)](http://www.novagali.com)

Founded in 2000, Novagali Pharma SA is a pharmaceutical company that develops innovative ophthalmic products for all segments of the eye. Thanks to its three proprietary technology platforms, the Company has an advanced portfolio of highly innovative products, one of which is already on sale and two of which are in phase III clinical trials.

In 2009, Frost & Sullivan recognised Novagali with the Award of the Year for Industry Innovation & Advancement, for its proprietary emulsion technology platforms, and Siemens awarded the company the Grand Prix de l'Innovation "Health Award" for Novasorb®. In April 2010, Novagali Pharma and its partners in the Vitrena project obtained €9.4 million in funding from OSEO for this diabetic retinopathy project.

Novagali Pharma successfully carried out an IPO in July 2010 raising 22 million euros.



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