

## NOVAGALI P H A R M A

### NOVAGALI PHARMA REPORTS POSITIVE RESULTS IN PHASE II STUDY FOR CATIOPROST® VS. TRAVATAN Z® IN PATIENTS WITH GLAUCOMA AND OCULAR SURFACE DISEASE

**Evry (France), September, 8 2011.** Novagali Pharma announced today US phase II positive results on the efficacy and safety of Catioprost® in patients with glaucoma and presenting concomitant ocular surface disease (OSD). The study met its objectives demonstrating intraocular pressure (IOP) reduction and OSD signs and symptoms improvement compared to Travatan Z® control group.

The multicenter, phase II, investigator-masked, randomized study was designed to evaluate the safety and efficacy of Catioprost® compared to Travatan Z®, both BAK-free prostaglandin analogue products, in subjects with glaucoma or ocular hypertension and OSD. Efficacy endpoints were the reduction of IOP and improvement in signs and symptoms of OSD including corneal fluorescein staining (CFS) and conjunctival hyperemia (eye redness). 105 patients were enrolled and results were evaluated after one month and three months of treatment. The results will be presented at upcoming international conferences.

Catioprost® was shown to be as effective as Travatan Z® in lowering IOP. At month three, the mean of diurnal IOP reduction from baseline was 29% vs 24% at 8am, 29% vs 27% at 10am, 26% vs 24% at 4pm respectively for Catioprost® vs. Travatan Z®.

On the OSD endpoints, Catioprost® showed an improvement over Travatan Z® at one and three months. There was a statistically significant improvement in corneal damage from baseline assessed by CFS (30% vs. 5% reduction,  $p=0.0461$ ) at month three for Catioprost® vs. Travatan Z®. Catioprost® treated patients demonstrated symptoms improvement with a greater reduction in concomitant use of artificial tears compared to Travatan Z®.

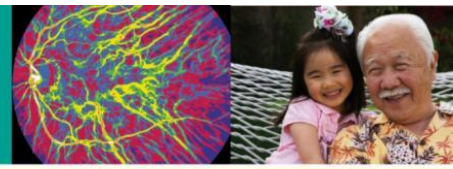
While having a similar safety and tolerability profile Catioprost® showed a clinically important strong trend toward less worsening of conjunctival hyperaemia than Travatan Z® (26% vs 43%).

This Phase II clinical study confirms pre-clinical investigation outcomes at Mount Sinai Hospital in New York and Quinze-Vingts Hospital in Paris. These pre-clinical studies have shown the efficacy of Catioprost® in controlling IOP and its potential for limiting and reversing damage to the ocular surface relative to other prostaglandin therapies for glaucoma<sup>1,2</sup>.

Ronald Buggage, CSO of Novagali Pharma says: *"While preservative-free anti-glaucoma therapy is becoming the new treatment paradigm to avoid long-term deleterious effects of preservatives on the eye, there is a real need for glaucoma products that not only reduce the risk of iatrogenic toxicity but that additionally can maintain and restore the ocular surface. With the promising Catioprost® results better protection for ocular surface and long-term patient compliance can be expected for the million of patients that suffer from glaucoma and OSD"*

Jérôme Martinez, CEO of Novagali Pharma, comments: *"These excellent results are further confirmation of our unique Novasorb® technological platform's medical value in treating the ocular surface providing substantial advantages for patients. We look forward to initiating a Phase III clinical program and making Catioprost® available to the many patients suffering glaucoma and OSD. We are proud of these results which confirm Novagali as a leading innovator in the field of ophthalmology"*

[About Glaucoma](#)



Glaucoma is an eye disease that affects over 70 million people worldwide with 60% presenting symptoms and signs similar to what is experienced by patients with dry eye disease<sup>3</sup>. The most common therapeutic approach is the daily instillation of anti-glaucoma eye drops to control the intraocular pressure (IOP). However, patient ageing and the long-term use of formulations containing preservatives may lead to damage to the ocular surface of varying degrees of severity<sup>4</sup>. Such damage impacts vision-related quality of life, undermines patient compliance and compromises the efficacy of IOP lowering treatments increasing the risk for gradual loss of peripheral vision or even irreversible blindness. The global glaucoma market was estimated to be USD 5.8 billion in 2010<sup>5</sup>.

## About Catioprost®

Catioprost®, a preservative-free cationic emulsion containing 0.005% latanoprost, is intended for glaucoma therapy while treating damage of the ocular surface. Worldwide, latanoprost is the leading prescribed compound to control IOP. Catioprost® combines latanoprost with Novagali Pharma's patented Novasorb® technology which has been demonstrated to improve ocular surface damage in patients dry eye disease and vernal keratoconjunctivitis.

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

Founded in 2000, Novagali Pharma SA is a pharmaceutical company that develops and commercializes ophthalmic innovative 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 are have ongoing undergoing phase III clinical trial programs.

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

Novagali Pharma carried out a successful IPO in July 2010. This entailed a €22 million capital increase.



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This press release contains certain forward-looking statements. Although the company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. For a discussion of risks and uncertainties which could cause the company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risques") section of the Document de Référence (annual report) filed on April 29, 2011 with the AMF under number R. 11-0021 and of the Rapport Financier Semestriel (half year financial report) published on August 31, 2011, which are available on the AMF website (<http://www.amf-france.org>) or on Novagali Pharma's website ([www.novagali.com](http://www.novagali.com)). This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to securities of Novagali Pharma in any country.

<sup>1</sup> Garrigue et al. A Comparative Study of Latanoprost Cationic Emulsion (Catioprost®) and Latanoprost Aqueous Solution (Xalatan®) in Preclinical Efficacy and Safety Models. 2011 ARVO proceedings

<sup>2</sup> Liang et al. In vitro and in vivo evaluation of newly developed cationic emulsion formulations in corneal wound healing models. 2010 ARVO proceedings

<sup>3</sup> Leung et al. Prevalence of Ocular Surface Disease in Glaucoma Patients, Journal of Glaucoma 2008

<sup>4</sup> Baudouin C, et al.. 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>5</sup> Allergan conference analysts Q2 2011