

## **Novagali Pharma Announces FDA Clearance of IND for US Clinical Trial of Nova63035 in patients with Diabetic Macular Edema**

**EVRY- January 18, 2007** – Novagali Pharma, an emerging ophthalmic pharmaceutical company announced today that the Company's Investigational New Drug Application (IND) to conduct a Phase I clinical trial of its Nova63035, an ophthalmic injectable emulsion based on EYEJECT® technology containing a corticosteroid prodrug for the treatment of Diabetic Macular Edema (DME), has been granted by the U.S. Food and Drug Administration (FDA).

DME is a severe form of diabetic retinopathy, a common complication of diabetes. In diabetic retinopathy, the blood vessels in the retina are damaged and can become blocked causing oxygen-deprivation in the retina; serious complications, such as retinal detachment and neovascular glaucoma may then occur. The modification of vessels can also lead to accumulation of fluid (edema) in the central area of the retina (macula) and can damage central vision leading to severe vision loss and even blindness.

It is forecasted that the number of patients with diabetes worldwide will reach 215 million by 2010<sup>(1)</sup>. Nearly 50% of patients with diabetes develop some degree of diabetic retinopathy and the risk increases with age. The only approved method for treating DME involves laser photocoagulation therapy, which can leave irreversible blind spots in the retina. Due to such significant limitations, there is a need for more effective treatments. While there are no drugs yet approved by the FDA for DME, there is clinical evidence that corticosteroids reduce edema associated with DME (off-label ITV injection of triamcinolone, a molecule normally used in other indications).

Nova63035 is a unique injectable emulsion allowing the sustained release of the prodrug over six to nine months thanks to EYEJECT® technology features. The prodrug is converted into the drug by the presence of enzymes which are present in the targeted tissues, in the present case, retina and choroid. These enzymes are not present in the vitreous or in the aqueous humor. This specific distribution of the enzymes could allow for avoidance of the common corticosteroid side effects such as the increase of the intraocular pressure (glaucoma) and the opacification of the lens (cataract).

The FDA has agreed that Novagali may proceed with Phase I clinical trials in the United States in patients with DME aiming to evaluate the safety and to observe the efficacy trend of the injection of Nova63035. The patients will be monitored for a period of twelve months following injection.

*"It is the first FDA clearance for a clinical trial with a Novagali product addressing a retinal pathology"* said Jerome Martinez, president and CEO of Novagali Pharma. *"This step is very encouraging for the research teams that have developed this first product candidate based on our innovative proprietary EYEJECT® technology designed to allow the administration of drugs to the back of the eye"*.

<sup>(1)</sup> Source: Amos A., McCarty D., and Zimmet P. *"The Rising Global Burden of Diabetes and its complications: Estimates and Projections to the Year 2010"* Diabete Med 1997, 14 S7 – 85.

**About Novagali Pharma:** <http://www.novagali.com>

Novagali Pharma is an emerging ophthalmic pharmaceutical company based in the *Génopôle* biocluster in Evry (France), that develops innovative products for all segments of the eye. Thanks to its proprietary technology platforms Novasorb® and Eyeject®, the company has developed a broad pipeline of 8 innovative products addressing main ocular conditions as well as orphan diseases. Most advanced products include Vekacia®, an orphan product for treatment of vernal keratoconjunctivitis, Cationorm®, a CE mark product for dry eye relief, and Nova22007, a product



for the treatment of moderate-to-severe dry eye syndrome. Founded in 2000, Novagali Pharma has 50 employees.

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