

## **NOVAGALI PHARMA Successfully Enrolls First Patient in U.S. Phase I Clinical Study with CORTIJECT® for Diabetic Macular Edema**

**Evry - France April 23, 2008:** Novagali Pharma, an emerging ophthalmic pharmaceutical company today announced that it has successfully injected the first patient in a Phase I clinical trial using CORTIJECT®, an ophthalmic injectable emulsion based on EYEJECT® technology platform containing a corticosteroid prodrug for the treatment of Diabetic Macular Edema (DME). This trial, which will enroll a total of 15 patients, is designed to evaluate the safety and to observe the efficacy trend of CORTIJECT®. The patients will be monitored for a period of twelve months following injection.

Company's Investigational New Drug Application (IND) to conduct this Phase I clinical trial has been granted by the U.S. Food and Drug Administration (FDA) in January 2008 (cf. Novagali Pharma Press Release issued on January 18th, 2008).

"This first injection in patient is a crucial step toward the clinical development of our state-of-the-art technology for the posterior segment of the eye that can be used to develop new treatments for retinopathies" said Jerome Martinez, Pharm.D., Novagali Pharma Chief Executive Officer. "Thanks to EYEJECT® technology, CORTIJECT® is a major move with the optimized use of corticosteroids for the back of the eye expected to combine ease of use, sustained release and ocular safety. Administering this emulsion through a single injection can offer real medical value to both physicians and patients."

Investigators for this open-label, dose-escalation study will treat patients suffering from DME with a single intravitreal injection (inside the eye) of CORTIJECT® formulation. The trial will include 3 treatment arms with patients receiving one of three doses of Novagali Corticosteroid prodrug. Each administration of CORTIJECT® will provide the patient with exposure to the compound for approximately nine months.

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

Novagali Pharma is an ophthalmic pharmaceutical company based in the Gépôle biocluster in Evry (France) that develops and commercializes innovative products. Thanks to its proprietary technology platforms Novasorb® and Eyeject®, the company has developed a broad pipeline of 7 innovative products addressing main ocular conditions as well as orphan diseases. Most advanced products include Vekacia®, an orphan product for treatment of vernal keratoconjunctivitis, Cyclokat®, a product for the treatment of moderate-to-severe dry eye syndrome and Cortiject® for the treatment of diabetic retinopathies. Cationorm®, indicated for dry eye symptoms is commercialized in France since April 2008. Founded in 2000, Novagali Pharma has 50 employees.

For further information:

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