

Novagali Pharma Announces FDA Clearance of IND for US Pivotal Phase III Trial of Nova22007 for Treatment of Dry Eye Syndrome

EVRY- April 26, 2007 – Novagali Pharma, an emerging ophthalmic pharmaceutical company that develops innovative products for all segments of the eye, announced today that the Company's Investigational New Drug Application (IND) to conduct a pivotal Phase III clinical trial of its Cyclosporine A ocular product, Nova22007, has been granted by the U.S. Food and Drug Administration (FDA).

Nova22007 is a Cyclosporine A ophthalmic product intended to be used to treat patients suffering from moderate-to-severe Dry Eye Syndrome. Nova22007 is a proprietary cationic emulsion enabling an optimal penetration of Cyclosporine A in tissues of the eye surface that benefit from Novasorb[®] cationic emulsion technology features.

As part of this IND, the FDA has agreed that Novagali may proceed directly into pivotal Phase III clinical trials in the United States in patients with moderate-to-severe Dry Eye Syndrome. This IND follows a pre-IND/end of Phase II meeting held with the FDA in July 2006. The FDA has reviewed the quality, safety and efficacy data generated by Novagali in European Phase II clinical study of Nova22007 in patients suffering from Sjögren syndrome associated with keratoconjunctivitis sicca (dry keratitis). In addition, the FDA has provided written guidance on the U.S. Phase III trial protocol. The planned, double-masked randomized vehicle-controlled study will evaluate the efficacy of Nova22007 in relieving dry eye objective and subjective symptoms.

"FDA clearance of Nova22007 IND for a pivotal Phase III study represents an important milestone for Novagali, validating our ocular technology platform Novasorb[®]" said Jerome Martinez, president and CEO of Novagali Pharma. "With our upcoming phase III trial in the EU, the two pivotal studies would enable to register the Product in both US and EU, and provide patients with a novel and uniquely-improved dry eye prescription product".

This ethical product is complementary to Cationorm[®], a cationic emulsion dedicated to dry eye relief benefiting from Novasorb[®] features. Cationorm[®] received CE mark in Europe and complies with US ocular OTC monograph as an eye lubricant product.

About Novagali Pharma: www.novagali.com

Novagali Pharma SA is an emerging ophthalmic pharmaceutical company based in the Genopole 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 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 marking product for dry eye relief; and Nova22007, a product for the treatment of moderate-to-severe dry eye syndrome. Founded in 2000, the firm has raised a total amount of Euro 44 million in 3 series of financing.

Press Contact: Genevieve Garrigos
+33(0)1.69.87.40.20
genevieve.garrigos@novagali.com