

## NOVAGALI P H A R M A

### Novagali Pharma Announces Enrollment of the First Patients in a Pivotal Phase III Study of Cyclokát® for Dry Eye Disease

**Evry (France), April 5<sup>th</sup> 2011:** Novagali Pharma, a pharmaceutical company that develops innovative ophthalmic products, today announced enrollment of the first patients in Sansika study, the European multi-national confirmatory pivotal Phase III study of Cyclokát® in patients with severe Dry Eye Disease. The Company received a positive Scientific Advice from the European Medicines Agency (EMA) regarding the final steps in the development of Cyclokát® last December.

Cyclokát® is a cyclosporine ophthalmic formulation intended for the treatment of patients suffering from severe Dry Eye Disease. Cyclokát® is a proprietary cationic emulsion employing the Novasorb® technology that optimizes the absorption of cyclosporine in tissues of the eye surface which makes once-a-day dosing possible.

The Sansika® study is a multicenter, randomized, double-masked, two parallel arms, vehicle-controlled, 6 month phase III trial of Cyclokát® in patients with severe Dry Eye Disease with a 6 month open label treatment safety follow-up period. Approximately 250 patients will be enrolled across 6 European Union member states. This pivotal phase III clinical trial follows two phase II studies performed in Europe and in the US and, the Siccanove study, the first European phase III study of Cyclokát® conducted in patients with moderate to severe Dry Eye Disease.

Ronald R. Buggage, M.D., Chief Scientific Officer of Novagali Pharma, states: *“Dry eye disease is a bilateral chronic inflammatory disease of the ocular surface characterized by inflammation and symptoms of ocular discomfort resulting from an inadequate quantity or quality of tears. In severe cases, there is damage to the cornea (keratitis) as a result of the on-going ocular surface inflammation that can lead to an increased risk of infection, vision loss and impaired quality of life. In patients with severe DED there is an urgent need for a safe and effective anti-inflammatory therapy.”*

Jérôme Martinez, Chief Executive Officer of Novagali Pharma, concludes: *“No effective treatment for dry eye disease is currently marketed in Europe, leaving a major unsatisfied medical need in 18 million patients<sup>1</sup>. Cyclokát® could be the first product approved in Europe for this indication and in view of this market opportunity we choose to focus our efforts on developing our product in this market. This Phase III clinical trial of Cyclokát® is intended to support the Marketing Authorisation Application that we expect to file in the last quarter of 2012. This major milestone in the final clinical development phase of Cyclokát® substantially improves its medical value and attractiveness.”*

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

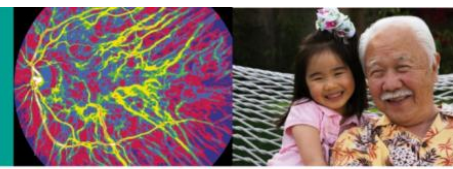
*Founded in 2000, Novagali Pharma SA is a pharmaceutical company that develops ophthalmic innovative products for all segments of the eye. Thanks to its three proprietary technology platforms, the Company has an advanced portfolio of highly innovative products, one of which is already on sale and two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

*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 enabling the Company to raise €22 million.*



<sup>1</sup> Prevalence of Dry Eye for Top 5 EU countries - Datamonitor 2010



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**Next press release:  
2010 annual results on April 26, 2011  
(after market)**

Novagali Pharma is listed on NYSE Euronext Paris - Compartment C  
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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 Base filed with the AMF, which is 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.*