

Novagali Pharma successfully completes Phase II clinical study with its ophthalmic formulation of Cyclosporine A

Nova22007, the Cationic Emulsion of Cyclosporine A developed by Novagali, is an innovative product indicated for the treatment of dry eye syndrome

Evry, France, January 10, 2006 - Novagali Pharma, a biopharmaceutical company specializing in ophthalmology, announces today the successful completion of a Phase II clinical study of its formulation of Cyclosporine A. The results demonstrate the safety of Nova22007 in patients suffering from Sjögren syndrome associated with keratoconjunctivitis sicca, and indicate trends towards efficacy, which will be validated during Phase III studies.

Nova22007 is a proprietary cationic emulsion enabling an optimal penetration of Cyclosporine A in tissues of the eye surface. "The results of this Phase II trial are consistent with our preclinical data," says Dr Florence Binlich, Novagali's Medical Director.

"These results confirm the safety of our formulation in patients suffering from moderate-to-severe keratitis," Dr Binlich enthusiastically adds. "Confirmation of the efficacy trends during future Phase III trials would establish Nova22007 as a truly significant therapeutic advance for dry eye patients". Novagali plans to start Phase III studies in 2006.

Cyclosporine A is the reference molecule for treatment of keratoconjunctivitis sicca with immune and inflammatory etiologies. Its sales are predicted to reach US\$300 million in 2008 in the United States.

Dry eye syndrome is a common ophthalmic disease affecting an estimated 90 million people worldwide. The market, valued at close to US\$700 million in 2005, is expected to reach US\$1 billion by 2008.

Dry eye syndrome is linked to a quantitative or qualitative deficit of tears and characterized by a lasting and painful ocular discomfort, which severely debilitates sufferers. In moderate and severe cases, the eye surface is altered (keratoconjunctivitis sicca) leading to vision disorders. This keratoconjunctivitis is often associated with auto-immune diseases such as Sjögren syndrome.

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

Novagali Pharma, a biopharmaceutical company specializing in ophthalmology, develops innovative treatments for all segments of the eye.

Founded in 2000, the firm has raised 18 million Euros from 1.2.3. Multinova, Auriga Partners, CDC Entreprises Innovation, Fonds de co-investissement J.E., Rothschild Investment Partners, Siparex Ventures and Crédit Agricole Private Equity.

Press Contact: Genevieve Garrigos
+33(0)6.82.85.58.99
genevieve.garrigos@novagali.com