

Novagali Announces Achievement of Targeted Patient Enrolment in Phase III Clinical Trial for Nova22007 in Vernal Keratoconjunctivitis

This pivotal study follows orphan drug designation in Europe

October 4, 2006 (Evry, France): Novagali Pharma, a biopharmaceutical company specialized in ophthalmology, announces today it has completed enrollment of patients in a pivotal multi-center phase III program to evaluate the efficacy and safety of Nova22007 for the treatment of vernal keratoconjunctivitis (VKC) well ahead of schedule. Lead by Pr David Ben Ezra, Hadassah Hebrew University Hospital, Jerusalem, who first reported use and efficacy of Cyclosporine A for treatment of VKC, the study involves key experts and opinion leaders in the field of ocular allergy throughout Europe.

VKC is a severe form of chronic allergic conjunctivitis characterized by painful ocular discomfort and intense photophobia, which severely debilitates patients. This rare disease affects mostly children and young adults living in warm climates worldwide. In March 2006, Novagali received European Medicines Agency (EMA) orphan drug designation for Nova22007 in the treatment of VKC.

Severe forms of VKC are currently treated with topical steroids which often induce serious ocular complications and visual impairment in patients. Cyclosporine A should be a safe and effective alternative to steroids.

Nova22007 is a topical Cyclosporine A cationic emulsion enabling an efficient and unmatched level drug absorption in tissues of the eye leading to optimal therapeutic efficacy. This proprietary ophthalmic emulsion of Cyclosporine A will be the first therapeutic product dedicated to treatment of such a severe ocular condition.

"Our ability to enroll a large number of patients in our VKC study, at a rate faster than expected, indicates the high unmet medical need in this pediatric and adolescent population," declares Dr Florence Binlich, Novagali's Medical Director who adds "This will help us advance the development of Nova22007 for VKC treatment which should become the reference product in such indication". Novagali aims to complete the study within the next months and then apply for registration in Europe mid 2007. Novagali expects to receive European marketing approval so that it can begin to provide patients with Nova22007 Orphan Medical Product in 2008.

"With the completion of the enrollment in this first multi-country study, the company has entered into the era of late-stage pharmaceutical clinical development and has demonstrated its ability to manage full development programs for ophthalmic products", says Jerome Martinez, President and CEO of Novagali, proudly, "and supported by a prestigious international clinical advisory board, our clinical team is about to initiate phase III clinical trials in Europe and USA with Nova22007 for the much larger clinical indication of dry eye".

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

Novagali Pharma SA, a biopharmaceutical company specializing in ophthalmology, develops innovative products for all segments of the eye. Founded in 2000, the firm has raised a total amount of €44 million from 1.2.3. Multinova, AGF Private Equity, Auriga Partners, Bernard Chauvin, CDC Entreprises Innovation, Crédit Agricole Private Equity, Edmond de Rothschild Investment Partners, FCJE and Siparex Ventures.

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