

**Novagali Pharma presents the results of its pivotal phase III clinical trial with Vekacia® at AACO.**

**June 25, 2007** (Evry France)– Novagali Pharma, an emerging pharmaceutical company specialized in ophthalmology presents positive results of its pivotal phase III clinical trial positive results from the Phase III clinical study of Vekacia® in children suffering from Vernal Keratoconjunctivitis (VKC) at the XIV Afro-Asian Congress of ophthalmology held from June 20 to 25 2007 in Marrakech (Morocco).

VKC is a severe form of chronic allergic conjunctivitis characterized by ocular discomfort, pain, itching and intense photophobia, which severely debilitates the patients. This rare disease affects mostly children and young adults living in warm climates worldwide. In this orphan disease, it was shown that both symptoms and signs of disease improved in patients receiving Vekacia®. Furthermore, the tolerability of Vekacia® was excellent.

The study was designed as a clinical phase II/III, multicenter, randomized parallel group, double masked, dose ranging, controlled study divided in two treatment periods: (I) a four-week prospective, randomized, multicenter, double-masked, three parallel-group, vehicle-controlled treatment period; and (II) a three-month prospective, multicenter, double-masked treatment period.

The primary objective of Vekacia® phase III study was to assess the efficacy of Vekacia® 0.05 % and Vekacia® 0.1%, administered four times daily, versus a vehicle after a four-week treatment period for patients with VKC. The secondary objectives were to compare the safety and ocular tolerance (objective and subjective) and the long-term safety after four months.

One hundred and eighteen patients (mean age: 8.8) with active bilateral VKC (acute or chronic) were enrolled in the study at over 21 sites in Europe and Mediterranean countries from May 2006 to October 2006. Most patients were suffering from perennial VKC (90 patients, 76.3%) and were presented at study entry with a mixed form of VKC (87 patients, 73.7%).

Vekacia® improved both signs and ocular symptoms of VKC in children who received treatment. The superiority of Vekacia® over its vehicle has been demonstrated by the statistically significant improvement of both objective signs of VKC and keratitis in treated patients. Both doses were safe and well tolerated. Local tolerance at instillation was satisfactory and therefore compliance to the recommended dose regimen of four instillations per day was good. Systemic exposure to CsA was negligible in the treated patients. Compliance to the study regimen of four daily instillations of the drug was excellent.

Overall improvement of subjective symptoms (burning/stinging, tearing, itching, pain, sticky eyelids, foreign body sensation, mucus discharge and photophobia) was superior to the vehicle for both concentrations of Vekacia®. For objective signs (conjunctival erythema/hyperemia, conjunctival chemosis and discharge, papillae, limbal infiltrates and corneal epithelial disease), there was a statistically significant difference between both concentrations of Vekacia® and the vehicle treatment ( $p=0.0386$  and  $0.0208$  for the Vekacia® 0.05% and Vekacia® 0.1% treatment arms, respectively). Similarly, improvement in superficial keratitis was statistically significant with Vekacia® 0.05% versus vehicle ( $p=0.0176$ ).

At one month of study, only seven patients had withdrawn from the study, which comprised four patients using the vehicle and three patients using Vekacia®, including one case of ocular intolerance following study drug instillation. Few treatment-emergent adverse effects (TEAEs) were reported, the most frequent being eye disorders of mild intensity. The tested formulations were rated as comfortable by 94.4% (vehicle), 79.5%

(Vekacia® 0.05%) and 80.6% (Vekacia® 0.1%). Blood levels of CsA were assayed after one month of treatment in 16 patients treated with Vekacia® and five patients had detectable CsA levels below 0.33ng/ml, a value which is considered as negligible

These results are presented at the occasion of a Symposium chaired by Pr BenEzra, lead coordinator of the study.

**About Novagali Pharma Vekacia®:**

Vekacia® is a Cyclosporine A ophthalmic product intended for patients suffering from vernal keratoconjunctivitis. Vekacia® is a proprietary cationic emulsion enabling an efficient and unmatched-level drug absorption in tissues of the eye leading to optimal therapeutic efficacy.

**About Novagali Pharma:** [www.novagali.com](http://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 and currently has 38 employees.

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