

Novagali Pharma receives US FDA Orphan Drug Designation for Vekacia® for the treatment of Vernal Keratoconjunctivitis

EVRY- May 24, 2007 – Novagali Pharma, an emerging ophthalmic pharmaceutical company, announced today orphan drug designation granted by the U.S. Food and Drug Administration (FDA) to Cyclosporine A drug Vekacia®, a patented cationic emulsion, for the treatment of Vernal Keratoconjunctivitis (VKC).

VKC is a rare and severe form of chronic allergic conjunctivitis affecting mostly children and young adults. It is characterized by painful ocular discomfort, itching and intense photophobia, which severely debilitates patients and virtually forces them to live in the dark with the obvious consequences on school attendance and learning.

In March 2006, the Committee for Orphan Medical Products (COMP), a division of the European Medicines Agency (EMA), has granted orphan drug designation in the European Union to Vekacia® and in April 2007, Novagali has announced the positive results from the phase III pivotal clinical study in children suffering from VKC. It was shown that both symptoms and signs of disease improved in patients receiving Vekacia®. Furthermore, product was safe and well tolerated. Novagali plans to file European Marketing Authorization mid-2007.

Today, Vekacia has been granted orphan drug designation for treatment of VKC by the Food and Drug Administration (FDA). Drugs that receive orphan drug designation obtain seven years of marketing exclusivity from the date of drug approval as well as tax credits for clinical trial costs, marketing application filing fee waivers and assistance from the FDA in the drug development process.

“This US orphan designation is an important milestone for patients suffering from VKC. There are currently no approved therapies for the treatment of this debilitating condition in US and in Europe and it is satisfying to know that our product has the potential to allow children to resume daily activities such as attending school” Said Jerome Martinez, president and CEO of Novagali Pharma who adds “this is a key step for our future development in the US”.

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

Novagali
Genevieve Garrigos
+33 6 65 54 60 19
genevieve.garrigos@novagali.com

Euro RSCG
Estelle Griffe
+ 33 1 58 47 95 25 / + 33 6 23 75 09 23
estelle.griffe@eurorscg.fr