

Novagali Pharma withdraws its marketing authorization application for Vekacia®

Novagali Pharma announces that it has notified the European Medicines Agency (EMA) of its decision to withdraw its application for a marketing authorization for the medicine Vekacia® intended to treat vernal keratoconjunctivitis (VKC), an ophthalmic orphan disease affecting mostly children.

This decision follows the Agency's Committee for Medicinal Products for Human Use (CHMP) view that the data provided did not allow to conclude at that time on a positive benefit-risk balance for Vekacia® long term use in children suffering from this chronic and seasonal disease.

On the basis of currently available clinical data and identified strong medical need, the company considers presenting further data in order to respond to the Agency's expectations.

Novagali is still convinced by the high therapeutic value of this innovative product and maintains its efforts in this indication and other ocular surface diseases. Moreover, the company pursues the development of all its major products in Europe and USA.

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

Novagali Pharma is an ophthalmic pharmaceutical company that develops and commercializes innovative products. Thanks to its proprietary technology platforms Novasorb® and Eyeject®, the company has developed a pipeline of innovative products addressing main ocular conditions as well as orphan diseases. Cationorm®, indicated for the treatment of dry eye symptoms is the first product to be commercialized. Most advanced products include Vekacia®, an orphan product for treatment of vernal keratoconjunctivitis, Cyclokate® (phase III) for the treatment of moderate-to-severe dry eye syndrome, Cortiject® (phase I) for the treatment of diabetic macular edema and Nova21027 for the treatment of glaucoma.

For further information

Novagali Pharma
VP RH & Communication
Geneviève Garrigos
+33 6 65 54 60 19
genevieve.garrigos@novagali.com

Euro RSCG C&O

Emilie Dhélens
+ 33 1 58 47 95 62
emilie.dhelens@eurorscg.fr