Press release

NOVAGALI PHARMA

Novagali Pharma receives positive Scientific Advice from the European Medicines Agency for the Phase III clinical trial of Cyclokat® for the treatment of Dry Eye Disease

Evry (France), January 5th, 2011: **Novagali Pharma** (NYSE Euronext Paris: FR0010915553), a pharmaceutical company that develops innovative ophthalmic products, today announced that it has received positive Scientific Advice from the European Medicines Agency (EMA) regarding the Phase III clinical trial of Cyclokat®, its proprietary cationic emulsion of Ciclosporin, for the treatment of Dry Eye Disease (DED).

Following its review, the EMA has agreed with the design of the proposed final pivotal Phase III study in patients with severe DED intended to be supportive of the Marketing Authorisation Application of Cyclokat® .

This multicenter, double masked pivotal study, will involve approximately 250 patients. Novagali Pharma expects to obtain regulatory clearance, to initiate this study, before the end of H1 2011. Results are expected to become available by mid 2012.

Jérôme Martinez, Chief Executive Officer of Novagali Pharma, concludes: « *No effective treatment for dry eye disease is currently marketed in Europe, leaving a major unsatisfied medical need in 18 million patients*[1]*. In view of this market opportunity, we choose to focus our efforts on developing our product Cyclokat® in Europe. These efforts have already begun to produce results as we have now received positive Scientific Advice from the EMA for the Phase III clinical trial of Cyclokat® in the treatment of patients with severe dry eye disease. This major milestone in the final development phase of Cyclokat® substantially improves its medical value and attractiveness to potential partners*».

For the US market a similar Phase III clinical trial will be conducted.

About Scientific Advice

Scientific Advice is a procedure offered by the EMA to stakeholders for clarification of questions arising during development of medicinal products. The scope of Scientific Advice is limited to scientific issues, i.e. to quality, non-clinical and clinical aspects of the concerned medicinal product not yet unequivocally covered by published scientific guidelines. Scientific Advice focuses on development strategies rather than pre-evaluation of data to support a Marketing Authorization Application. Scientific Advice is legally non-binding and is based on the current scientific knowledge which may be subject to future changes

About NOVAGALI Pharma (www.novagali.com)

Founded in 2000, Novagali Pharma SA is a pharmaceutical company that develops ophthalmic innovative products for all segments of the eye. Thanks to its three proprietary technology platforms, the Company has an advanced portfolio of highly innovative products, one of which is already on sale and two of which are undergoing phase III clinical trials.
In 2009, Frost & Sullivan recognised Novagali with the Award for Industry Innovation & Advancement of the Year, for its proprietary emulsion technology platforms, and Siemens awarded the company the "Health Award" Grand Prix de l'Innovation for Novasorb®. In April 2010, Novagali Pharma and its partners in the Vitrena project obtained €9.4 million in funding from Oséo for this diabetic retinopathy project.
Novagali Pharma carried out a successful IPO in July 2010. This entailed a €22 million capital increase, making it the largest round of fundraising on the stock market in the biotechnology industry in the first half of 2010 in France.

[1] Prevalence of Dry Eye for Top 5 EU countries - Datamonitor 2010

Contacts

Novagali
Geneviève Garrigos
VP RH & Communication
Tel: +33 (0)6 65 54 60 19

*New***Cap.**
Investor relations
Axelle Vuillermet / Emmanuel Huynh
Tel: +33 (0) 1 44 71 94 93
E-mail: novagali@newcap.fr

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