



## **Novagali Pharma launches Phase I clinical trial in oncology for its oral formulation of paclitaxel**

**This proprietary oral micro-emulsifying paclitaxel dosage form, developed by Novagali's in-house R&D team, paves the way for a new approach in the treatment of several types of cancer**

Evry, France, May 31 2005 - Novagali Pharma, a biopharmaceutical company developing innovative drug delivery systems principally in ophthalmology and oncology, announced today the launch of a Phase I clinical trial in patients with advanced cancer for its oral formulation of paclitaxel. The study is being conducted at the Netherlands Kancer Institute, Amsterdam, in order to assess patient tolerance and pharmacokinetic properties in patients with cancer.

Paclitaxel is active against a broad range of cancers but generally has to be used in intravenous form and administered once every three weeks. Novagali Pharma has designed a new oral formulation which improves the treatment, limits patient discomfort and eliminates the need for staying at the hospital. The company has developed a self-micro-emulsifying oily formulation which allows oral administration of the chemotherapy while maintaining efficacy and safety of use.

"Starting clinical trials for a product which enables oral administration of paclitaxel and other taxanes offers a major opportunity to explore new ways of treating cancer," says Jérôme Martinez, President and CEO of Novagali Pharma. "The preclinical results have been extremely promising and we are eager to get the first Phase I results, which we expect before the end of the summer."

"The availability of an oral formulation of paclitaxel with a good tolerance profile is a major therapeutic breakthrough for ambulatory treatment of patients with cancer," explains Dr. Florence Binlich, VP development and medical affairs for Novagali. "It will also allow combination with other oral chemotherapies and should enable the prevention of long-term relapse. Paclitaxel belongs to the taxane class of major chemotherapy agents. They have been used for many years in intravenous forms for the treatment of breast and ovarian cancer or non-small cell lung carcinoma (NSCLC)."

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

Novagali Pharma, localized in the campus of Genopole, Evry, near Paris, develops innovative drug delivery technologies focused on ophthalmology and oncology. Created in 2000, Novagali already has a number of products in Phase I and II clinical trials. These include ophthalmic emulsions to treat dry eye syndrome and orally administered anti-cancer drugs. Since its creation, Novagali Pharma has raised close to EUR18 million from investors including 1.2.3. Multinova, Auriga Partners, CDC Entreprises Innovation, Fonds de co-investissement J.E., Rothschild Investment Partners, Siparex Ventures et Tech Invest.

The technology is based on cationic emulsions. The originality of this approach lies in creating emulsion droplets with positive charges on their surface (whereas these droplets usually have

negative charges). Thanks to this, the positive emulsion droplets are attracted to all biological membranes as the latter are negatively charged. Novagali's nano-emulsion droplets are about 150 nanometers in size and allow the formulation of a wide range of molecules while enhancing their absorption and effectiveness. This technology platform can be applied in many delivery applications, including ocular, oral, injectable and dermatological, and also across a variety of therapeutic areas.

**About Genopole Campus:**

<http://www.genopole.org>

Genopole Campus, dedicated to genetic and post-genomic research, and related sciences, comprises 25 academic research laboratories with strong educational links to the University of Evry-Val d'Essone, and 50 innovative biotechnology companies.

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