

Novagali Pharma completes a Phase I clinical trial in oncology with its oral formulation of Paclitaxel

Nova12005, a proprietary oral self micro-emulsifying Paclitaxel dosage form developed by Novagali's in-house R&D team, paves the way for a novel alternative in the treatment of taxane-sensitive tumours.

Evry, France, September 19 2005 - Novagali Pharma, a biopharmaceutical company developing innovative drug delivery systems principally in ophthalmology and oncology, announced today the successful completion of a Phase I clinical trial in patients with advanced cancer with its oral formulation of Paclitaxel. The study, lead by Pr. Jan Schellens, was carried out at the Netherlands Kancer Institute in Amsterdam. The primary objectives were to assess safety, tolerance and pharmacokinetic properties of Nova12005 in patients with cancer.

Paclitaxel is highly active against a broad range of cancers. It is administered per infusion once every three weeks. Novagali Pharma has designed a new oral formulation which would allow outpatient treatment and improve patient quality of life.

"The trial showed that Novagali's oral Paclitaxel was safe and well tolerated in patients with advanced cancer," said Dr. Florence Binlich, Vice-President Development and Medical affairs at Novagali Pharma. "Thanks to Novagali's proprietary formulation, the drug was quickly absorbed and the bioavailability was high. Repeated oral schedules of Nova12005 should enable appropriate patient exposure and maintenance of therapeutic levels for at least eight hours after administration."

"These results obtained with Paclitaxel, one of the most challenging molecules when it comes to oral delivery of chemotherapy, validate Novagali Pharma's proprietary oral micro-emulsifying technology," said Dr. Grégory Lambert, Novagali's Vice-President Research & Development. "We believe this formulation concept could be extended to deliver other poorly absorbed drugs by the oral route."

This oral formulation of Paclitaxel constitutes a promising alternative to the intravenous delivery of taxanes. Novagali Pharma is seeking a partner for further development of the product.

About Novagali Pharma

Novagali Pharma, based on the Genopole campus at 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.

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