

Intas Biopharma & Kwizda Complete Phase I Clinical Trial of Neukine in Europe

Intas Biopharmaceuticals Limited (IBPL) and European pharmaceutical major Kwizda Pharma GmbH has jointly completed Phase I clinical trial study of NEUKINE®, biosimilar form of recombinant GCSF.

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Intas Biopharmaceuticals Limited (IBPL) and European pharmaceutical major **Kwizda Pharma GmbH** has jointly completed Phase I clinical trial study of **Neukine®**, biosimilar form of recombinant GCSF. As per results of study conducted by European counterpart, **Neukine®**, IBPL's registered trademark for Filgrastim, is safe and exhibits an identical pharmacokinetic and pharmacodynamic profile compared to a reference product. Neukine® promotes growth of white blood cells, which help to fight infections after cancer chemotherapy treatment. Upon completion of an upcoming clinical phase III trial, both companies, IBPL and Kwizda, will lodge an application to get the product approved for European market. The market launch is planned for early 2010.

As part of European application process, Kwizda and IBPL are working jointly on the clinical trials of Neukine®. Announcing phase I results of clinical trials, **Dr. Helmut Brunar, VP (Research & Business Development), Kwizda Pharma GmbH**, said, "Neukine® exhibits identical efficacy to the EU-approved reference product. Not only was Neukine® cleared from the patients' blood plasma just as quickly as the reference, but the number of neutrophils also increased with identical kinetics after treatment. We are very pleased with these results."

The study was a single-dose, randomised, double blind, two-way crossover trial and used an active control. The trial involved 36 patients and was carried out by Prof. Bernd Jilma, MD, of the Medical University of Vienna (Department of Clinical Pharmacology). The trial confirms data from the Indian market, where Neukine® has been approved since 2004. **Filgrastim** is in a class of drugs known as growth factors; it promotes the growth of white blood cells, which help to fight infections. Filgrastim has been used to increase white blood cell counts in people who have cancer, follow chemotherapy and take medications that lower white blood cell counts.

Dr. Dhananjay Patankar, Chief Technical Officer, IBPL, explains: "Over 3,000 cancer patients have already been treated with Neukine® in India. No severe adverse reactions were reported, other than those commonly associated with Filgrastim. We are very confident that our joint clinical trials with Kwizda Pharma will demonstrate the quality of Neukine® to the European authorities."

Neukine® (rHu GCSF) was the first drug introduced by IBPL in India and subsequently **Erykine®** (rHu EPO), **Intalfa®** (rHu IFN) and **Neupeg®**; (Peg GCSF) in domestic market and few international markets. IBPL has also entered into several distribution and marketing agreements with reputed international companies in regulated and semi-regulated markets of Europe, Asia-Pacific, Middle East, Russia & CIS, South and Central America and Africa.

Commenting on the development, **Mr. Mani Iyer, Director, IBPL**, said, 'The initial results of the study are very encouraging and it has given a strong advantage to IBPL as the company is looking to strengthen its presence in Europe. As part of its business strategy, IBPL is working with Kwizda Pharma, which is helping to secure EU approval and will provide support with marketing logistics.

Kwizda Pharma has a well-established clinical background and extensive experience with regulatory procedures.

As far as IBPL is concerned, Europe is an ideal market to serve the goal of developing innovative research technologies/new molecules related to biopharmaceuticals; evaluate technology platforms; identify partnership opportunities, in-licensable IPs; and to build up Novel Drug Delivery System. IBPL has also scheduled clinical trials of **Erythropoietin** and **Interferon Alpha** in the European market next year.'

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About Intas Biopharmaceuticals Limited:

Since launch of biotechnology operations in May 2000, Research & Development, Manufacturing and Marketing of biopharmaceutical products, with a special focus on Oncology (Cancer), are major thrust areas for IBPL. The company is India's first and only biopharmaceuticals manufacturing company to receive **European Union - Good Manufacturing Practice (EU-GMP)** certification. Today, Intas Biopharmaceuticals Limited is the sole manufacturer of **Pegylated GCSF** in India and markets under the brand name '**Neupeg**'.

About Kwizda Pharma GmbH:

Kwizda GmbH is a privately owned group of companies and has been operating since 1853 (pharmaceutical division). Kwizda Pharma is a leading European manufacturer and wholesaler of proprietary, in-licensed and third party pharmaceuticals, OTC drugs and hospital infusions. In 2007, the company recorded sales of approximately EUR 50 million.

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