

INTAS Plans Filgrastim launch in North America, Europe

Intas Biopharma is a part of Cooperation between three continents for Biosimilar GCSF

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Intas Biopharmaceuticals Limited (IBPL) signed business agreement with Canada-based **Apotex Inc.** for co-development and supply of its Filgrastim brand, Neukine® in North America (US and Canada). European pharmaceutical major Kwizda Pharma, who is working with IBPL to develop G-CSF for the European market, has transferred all of its rights in IBPL's G-CSF to Apotex. Both, Apotex and IBPL, jointly, plan to launch Neukine® in US market.

Speaking on the development, **Mr. Mani Iyer, Executive Director, IBPL**, said, 'This business deal brings together two companies having respective expertise in niche areas of operations. IBPL and Apotex have complementary strengths, which will help in launching the first GCSF generic in North America. IBPL and Apotex are eyeing a significant share of total G-CSF market in North America and Europe, which is currently estimated to be around \$1.4 billion annually. Although guidelines for biosimilar product registration in North America are not yet finalized, the companies anticipate that there would be a clear pathway for biotech companies, once the legislation is in place.

As far as IBPL is concerned, North America and Europe are ideal markets 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 and Apotex are keen to explore prospective business opportunities for more biosimilar products in the coming years.'

Dr. Jeremy B Desai, Executive Vice President, Research & Development, Apotex adds 'This agreement represents an important milestone for Apotex, as it strengthens the organization's development in Europe and will offer support for entering this important market with future biosimilar products currently in the Apotex development pipeline'.

Dr. Helmut Brunar, VP Research and Business Development, Kwizda Pharma explains mutual benefits of the agreement: 'It is part of Kwizda Pharma's current business strategy to work together with non-European pharmaceutical companies to break into the European market. That is why we worked with IBPL to successfully complete a phase I clinical trial and have transferred our rights in IBPL's G-CSF to Apotex including initiation of a phase III trial for the approval of G-CSF in Europe'.

Amongst top five leaders in generic market, Apotex has a strong registration, marketing & distribution team whereas IBPL offers a unique competitive advantage in terms of R&D and Manufacturing of biopharmaceuticals. The deal offers immense growth opportunities for both, Apotex and IBPL, as they look to consolidate their presence in the global biogenerics market. **Neukine® (rHu GCSF)** is 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.

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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 GmbH

Kwizda GmbH is a privately owned group of companies and has been operating since 1853 (pharmaceutical division). Kwizda Pharma is a leading Austrian 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.

About Apotex Inc.

Apotex Inc. is the largest Canadian-owned pharmaceutical company, employing over 6,800 people in research, development, manufacturing and distribution facilities world-wide. Apotex produces more than 300 generic molecules in a variety of different presentations, which, in Canada, are used to fill over 75 million prescriptions a year - the largest amount of any pharmaceutical company in this country. In the next 10 years, Apotex will spend \$2 Billion in R&D and has presently over 600 products under development.

For more information, Please contact:

Jayshree Sanadhya

Sr. Account Executive - Imprimis PR