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# STRIDES ARCOLAB ANNOUNCES US FDA APPROVAL FOR GEMCITABINE FOR INJECTION USP

# First Oncology injectable approval for the US market Product to be launched through Pfizer immediately

July 26, 2011 Bangalore: Onco Therapies Limited, a wholly owned subsidiary of Strides Arcolab Limited (Strides) today announced that it has received US FDA approval for Gemcitabine for Injection USP in 200mg, 1 gm and 2 gm dosage forms.

Gemcitabine is the first product to be approved from its Oncology facility at Bangalore, which was certified for compliance by US FDA in May 2011. According to March 2011 data, the U.S. market for Gemcitabine approximated USD 700 Million.

Gemcitabine is part of the Oncology portfolio licensed to Pfizer in January 2010 for the US market and will be launched immediately.

Strides is amongst the first wave players to receive this approval and amongst the few Companies approved for all three dosage forms.

"We are delighted with this milestone approval marking our foray into the US Oncology market. Commercialisation of this product will further strengthen the Pfizer – Strides partnership in the global oncology space" said Venkat Iyer, Executive Director, Strides Arcolab and CEO, Agila Specialties. He further stated that the oncology approval flow is expected to gain momentum in the coming days.

## About Gemcitabine

Gemcitabine for Injection USP, the generic form of the chemotherapy drug Gemzar<sup>®</sup> is a nucleoside metabolite inhibitor that exhibits antitumor activity. It is available as a Lyophilised powder for Injection indicated for ovarian cancer, breast cancer & non-small cell lung cancer in combination with other drugs and in treatment of pancreatic cancer as a single-agent.



#### About Agila Specialties

Agila is the specialties unit of Strides Arcolab which was spun off as a separate division post the Company's restructuring in 2009. It is focused on key domains such as oncolytics, penems, pencillins, cephalosporins, ophthalmics, peptides and biosimilars and operates from 8 worldclass global manufacturing facilities, including one of the largest steriles capacity in India and amongst the largest lyophilization (freeze drying) capacities in the world. Agila's marketing network covers 70 countries and it has partnerships with some of the world's leading pharmaceutical companies for both developed and emerging markets.

### **About Strides Arcolab Limited**

Strides Arcolab, listed on the Bombay Stock Exchange Limited (532531) and National Stock Exchange of India Limited (STAR), is a global pharmaceutical company headquartered in Bangalore, India that develops and manufactures a wide range of IP-led niche pharmaceutical products with an emphasis on sterile injectables.

The company has 14 manufacturing facilities across 6 countries with presence in more than 75 countries in developed and emerging markets. Manufacturing is ably supported by a 350-scientist strong global R&D Centre located in Bangalore.

Additional information is available at the company's website at www.stridesarco.com.

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