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## Continued US FDA approval status for Sterile Products Division at Bangalore

### One more Oncology product approval from USFDA Approval for Fludarabine Phosphate Injection

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**December 22, 2011, Bangalore:** Strides Arcolab today announced the following US FDA approvals:

1. **The Sterile Products manufacturing facility (SPD 1) in Bangalore**, the principal sterile facility of Agila, which was recently inspected by the US FDA as part of the routine GMP compliance audit and the facility has been classified as acceptable.

This facility manufactures lyophilized, liquid, dry powder injectables and pre-filled syringes. The last inspection and approval of this site was in March 2009.

V.S.Iyer, Executive Director and CEO – Agila said “this approval endorses our commitment to continued compliance with cGMP.

2. **Fludarabine Phosphate Injection USP 25 mg/mL, packaged in 50 mg/ 2 mL Single-dose vials. Approval for Onco Therapies Limited (a wholly owned subsidiary of Strides).**

According to IMS data, the US market for Fludarabine is approximately USD 15 Million. Fludarabine is part of the Oncology portfolio licensed to Pfizer in January 2010 for the US market and expected to be launched shortly.



### **About Fludarabine**

Fludarabine injection is used to treat chronic lymphocytic leukemia (CLL; a type of cancer of the white blood cells) in adults who have already been treated with at least one other medication and have not gotten better.

### **About Agila Specialties**

Agila Specialties Private Limited 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 world class 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](http://www.stridesarco.com). For further information, please contact:

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