



## Press Release

May 2, 2011



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# STRIDES ANNOUNCES US FDA APPROVAL FOR ITS ONCOLOGY FACILITY IN BANGALORE

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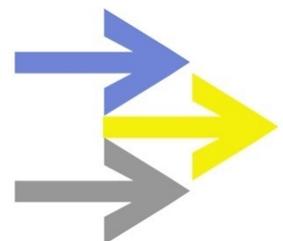
**May 2, 2011, Bangalore:** Onco Therapies Limited (OTL), a division of Agila (a wholly owned subsidiary of Strides Arcolab Limited, 'Strides') today announced that it has received approval from the US FDA for its Oncology facility in Bangalore, a much awaited decision that will enable Strides to play a more significant role in the global oncology industry. Consequent to the approval, Strides expects to begin receiving ANDA approvals for oncology products for which filings have already been made.

Commenting on this milestone achievement, Venkat Iyer, CEO, Agila Specialties, said, "This approval is a testimony to the high standards of quality, compliance and containment practices put in place by Strides. With this approval and the recently announced approval for the Sterile Complex, we now look forward to scaling up our specialty business through the launch of highly specialised products for the US market."

With a world-class sterile injectables platform, robust product pipeline and record regulatory filings, hi-tech manufacturing capacities across countries, an impeccable record of quality and marquee customers and partners across the healthcare industry, the specialty business of Strides is well positioned to build a distinct identity for itself in the industry. Strategic partnerships with the big pharma companies including Pfizer and GlaxoSmithKline, continuing licensing income and new product launches in regulated markets have been key growth drivers for the Company.

"This approval is an important step in strengthening our specialty business and intent to be a global sterile powerhouse," said Arun Kumar, Vice Chairman & Group CEO, Strides Arcolab. "It is a matter of great pride for all of us at Strides and a significant achievement for the Indian pharmaceutical industry," he added.

The state-of-the-art Oncology facility which was established in 2009 manufactures injectables, oral products (tablets and softgels) in the oncology domain. It has been built to the most exacting standards, meeting the requirements of regulatory authorities in the most stringent global markets and is already approved by all other major regulatory authorities allowing the Company to sell globally.



The Company has recently announced US FDA approval for its Sterile Facility (non-oncology) in Bangalore. With these approvals, all of Strides' 5 sterile plants in India are now US FDA approved.

The Company reaffirms its guidance for Year 2011 which factors an aggressive growth of 25% over the previous year, with the Specialties business guided to grow at 45%.

### **Global Partnerships from this Facility:**

In January 2010, the Company announced a licensing and supply collaboration with Pfizer Inc for 40 generic products for the US market. The Company expects to commercialize its first Oncology product for the US market in the beginning of H2 '2011.

In May 2010, the partnership with Pfizer Inc was strengthened by extending the Oncology agreement to Europe, Canada, Australia, New Zealand, Japan and Korea for 38 generic oncology products.

In July 2008, the Company announced an out-licensing deal between OTL and GlaxoSmithKline Pharma for licensing and supply of Injectable products for the 95 emerging markets. The Oncology products for this partnership will be manufactured from the newly approved plant.

The local market value of the products under Strides' partnership with these big pharma companies is estimated at USD 20 Billion.

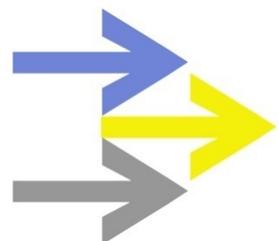
### **Oncology Regulatory Updates**

The Company has already filed 31 Oncology ANDAs (with a local market value of USD 4 Billion) for US FDA approval from this facility.

In Europe, there are 18 Oncology product filings with a local market value of more than USD 3.2 Billion. In addition, the Company has made significant filings in other established and emerging markets.

### **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 7 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).

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