



## Press Release

Thursday, February 2, 2017

Strides Shasun Limited  
(Formerly Strides Arcolab Limited)  
Strides House, Bannerghatta Road,  
Bangalore – 560076.

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# Strides Shasun receives USFDA Tentative Approval for Fingolimod Capsules

Second FTF Approval For the company

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**Bangalore, February 2, 2017:** Strides Shasun Limited today announced that its subsidiary Strides Pharma Global Pte Limited, Singapore has received tentative approval from the United States Food & Drug Administration (USFDA) for its Para IV filing of **Fingolimod Capsules, 0.5 mg**. The product can be launched on generic market formation expected in February 2019, with a potential 180 day exclusivity.

According to IMS data, the US market for Fingolimod Capsules is approximately USD 2 Bn. Fingolimod Capsules registered a healthy CAGR of 10 % over last 5 years (IMS December 2016 MAT data). Based upon available information, Company believes it is amongst the first wave of ANDA applicants for Fingolimod with a Paragraph IV certification. On receiving full approval, the product will be manufactured at the Company's Oral dosage facility at Bangalore and marketed by its subsidiary in USA, Strides Pharma Inc.

## About Fingolimod Capsules

Fingolimod Capsules is used for treatment of adult patients with relapsing forms of multiple sclerosis. The product is currently sold by Novartis under the brand name GILENYA®

## About Strides Shasun Limited

Strides Shasun, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is a vertically integrated global pharmaceutical Company headquartered in Bangalore. The Company has four business verticals, viz., Regulated Markets, Emerging Markets, Institutional Business and Pharmaceutical Services & Active Ingredients.

The Company has global manufacturing foot print with 13 manufacturing facilities spread across three continents including 5 US FDA approved facilities and 8 facilities for the emerging markets. The Company has three dedicated R&D facilities in India with global filing capabilities and a strong commercial footprint across 85 countries. 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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