

**Press Release**

Wednesday, June 1, 2016

Strides Shasun Limited  
Strides House, Bannerghatta Road,  
Bangalore – 560076.

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**Strides Shasun receives USFDA Tentative Approval for  
Roflumilast Tablets**

First FTF Tentative Approval

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**Bangalore, June 1, 2016** Strides Shasun Limited today announced that it has received tentative approval from the United States Food & Drug Administration (USFDA) for **Roflumilast Tablets, 500 mcg**. The product received approval in 15 months under the new GDUFA goal date regime. The product can be launched earliest by January 2020.

According to IMS data, the US market for Roflumilast Tablets 500 mcg is approximately USD 174 Mn. Roflumilast tablets registered a healthy growth of 16% in value terms and 5% in volume terms in US (IMS March 2016 MAT data). Based upon available information, company believes it is amongst the first wave of ANDA applicants for Roflumilast with a Paragraph IV certification, which is under litigation as per the provisions of the Hatch-Waxman Act. On receiving full approval, the product will be manufactured at the company's Oral dosage facility at Bangalore and marketed by Strides Shasun in the US Market.

**About Roflumilast**

Roflumilast is used to prevent worsening of symptoms in people with severe chronic obstructive pulmonary disease (COPD)

**About Strides Shasun Limited**

Strides Shasun, listed on the Bombay Stock Exchange 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 14 manufacturing facilities spread across three continents including 6 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:**

<p><b><u>Strides Shasun</u></b></p> <p>Badree Komandur, Group CFO +91 80 6784 0747</p> <p>Vikesh Kumar +91 80 6784 0827 Kannan. N: +91 98450 54745 Sandeep Baid: +91 80 6784 0791</p>	<p><b><u>PR Consultancy</u></b></p> <p><b>Fortuna PR</b> K Srinivas Reddy: +91 9000527213 srinivas@fortunapr.com</p> <p>K Priya: +91 9535425418 priya@fortunapr.com</p>
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