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Strides receives USFDA tentative approval for Roflumilast

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

The product received approval in 15 months under the new GDUFA goal date regime.

The product will be launched earliest by January 2020.

According to IMS data, the US market for Roflumilast Tablets 500 mcg is approximately $174 million.

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.