Strides receives USFDA approval for Polyethylene Glycol 3350 and Electrolytes for Oral Solution

Approval completes Strides PEG 3350 Laxatives portfolio for the US markets
Product to be marketed by Strides Pharma Inc. in the US

Bangalore, 24 December, 2018 Strides Pharma Science Limited (Strides) today announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received approval for Polyethylene Glycol 3350 and Electrolytes for Oral Solution USP, 236 grams/2.97 grams/6.74 grams/5.86 grams/22.74 grams/4 Liter from the United States Food & Drug Administration (US FDA). The product is a generic version of GoLYTELY® of Braintree Laboratories, Inc.

Strides has already garnered an important market share for Polyethylene Glycol 3350, Sodium Chloride, Sodium Bicarbonate and Potassium Chloride for Oral Solution (IMS market share at 22%) and Polyethylene Glycol 3350, Powder for Solution (OTC). With the current approval, Strides now offers a complete range of PEG 3350 Laxatives for the US markets comprising of 3 approved products addressing a combined Rx and OTC opportunity of ~US$ 400 Mn as per IMS and IRi data. The product will be manufactured at flagship facility in Bangalore and will be marketed by Strides Pharma Inc. in the US market.

The company has 80 cumulative ANDA filings with USFDA of which 55 ANDAs have been approved including 11 approvals received in FY 19.

About Polyethylene Glycol 3350 and Electrolytes for Oral Solution

Polyethylene Glycol 3350 and Electrolytes for Oral Solution is a laxative solution that increases the amount of water in the intestinal tract to stimulate bowel movements.

About Strides

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is global pharmaceutical Company headquartered in Bangalore. The Company has two business verticals, viz., Regulated Markets and Emerging Markets. The Company has a global manufacturing footprint with 7 manufacturing facilities spread across three continents including 5 facilities for Regulated Markets and 2 facilities for the Emerging Markets. The Company has strong R&D infrastructure in India with global filing capabilities and a strong commercial footprint across 100 countries. Additional information is available at the Company’s website at www.strides.com
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