



June 10, 2022

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai – 400 001
Scrip code: 532531

The National Stock Exchange of India Limited
Exchange Plaza, Bandra-Kurla Complex
Bandra (E) Mumbai - 400 051
Scrip code: STAR

Dear Madam/ Sir,

Sub: Press Release

Please find attached Press Release issued by the Company titled:

“Strides receives USFDA approval for Ibuprofen OTC Oral Suspension”

Thanks & Regards,
For **Strides Pharma Science Limited,**

A handwritten signature in blue ink that reads 'Manjula R.'.

Manjula Ramamurthy
Company Secretary



Encl. As above

Strides Pharma Science Limited

CIN: L24230MH1990PLC057062

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Strides receives USFDA approval for Ibuprofen OTC Oral Suspension

*Product approval under the Competitive Generic Therapy route
Strides to have 180-day exclusivity for the product*

Bengaluru, June 10, 2022 – Strides Pharma Science Limited (Strides) today announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received approval for **Ibuprofen Oral Suspension USP, 50 mg/1.25 mL (40 mg/mL) (OTC)** from the United States Food & Drug Administration (USFDA). The product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Infants' Advil[®] Concentrated Drops, 50 mg/1.25 mL (40 mg/mL) (OTC), of GlaxoSmithKline Consumer Healthcare Holdings (US) LLC. The Product approval further strengthens Strides Ibuprofen franchise for the US markets.

Strides was granted a Competitive Generic Therapy (CGT) designation for its ANDA and is the **“first approved applicant”** for Ibuprofen Oral Suspension USP, 50 mg/1.25 mL (40 mg/mL) (OTC). **Strides will have a 180 days of Competitive Generic Therapy (CGT) exclusivity for the product**, under section 505(j)(5)(B)(v) of the FD&C Act.

The US OTC market for Ibuprofen Oral Suspension USP, 50 mg/1.25 mL (40 mg/mL) is approximately ~US\$ 41 Mn. The product will be manufactured at the company's facility at Bengaluru and will be marketed by Strides Pharma Inc. in the US market.

The company has 274 cumulative ANDA filings (including recently acquired portfolio from Endo at Chestnut Ridge) with USFDA of which 251 ANDAs have been approved and 23 are pending approval. The company currently has ~60 commercialized products in the US and has set a target to launch ~ 20 new products every year from the combined portfolio.

About Ibuprofen Oral Suspension

Ibuprofen is a nonsteroidal anti-inflammatory drug (NSAID) used to relieve pain from various conditions such as headache, dental pain, menstrual cramps, muscle aches, or arthritis. It is also used to reduce fever and to relieve minor aches and pain due to the common cold or flu.

About Strides

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is a global pharmaceutical company headquartered in Bengaluru, India. The Company mainly operates in the regulated markets and has an “in Africa for Africa” strategy along with an institutional business to service donor-funded markets. The Company's global manufacturing sites are located in India (Chennai, Puducherry and two locations in Bengaluru), Singapore, Italy (Milan), Kenya (Nairobi) and the United States (New York). The Company focusses on “difficult to manufacture” products that are sold in over 100 countries. Additional information is available at the Company's website at www.strides.com

For further information, please contact:

Strides

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