

January 25, 2021

BSE Limited Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001 <u>Scrip code: 532531</u> **The National Stock Exchange of India Limited** Exchange Plaza, Bandra-Kurla Complex Bandra (E) Mumbai - 400 051 <u>Scrip code: STAR</u>

Dear Madam/ Sir,

Sub: Press Release

Please find attached Press Release issued by the Company titled:

"Strides receives USFDA approval for Ursodiol Capsules"

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

Manjula R.

Manjula Ramamurthy Company Secretary

Encl. As above





Strides receives USFDA approval for Ursodiol Capsules

To be marketed by Strides Pharma Inc. in the US market

Bengaluru, January 25, 2021 – Strides Pharma Science Limited (Strides) today announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received approval for *Ursodiol Capsules USP, 300 mg* from the United States Food & Drug Administration (USFDA). The product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Actigall[®] Capsules, 300 mg, of Allergan Sales, LLC.

According to IQVIA MAT November 2020 data, the US market for Ursodiol Capsules USP, 300 mg is approximately US\$ 45 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 127 cumulative ANDA filings with USFDA of which 96 ANDAs have been approved and 31 are pending approval.

About Ursodiol Tablets

Ursodiol tablets are indicated for the treatment of patients with Primary Biliary Cirrhosis (PBC).

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 (Florida). 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 <u>www.strides.com</u>

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