

February 21, 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 Amantadine Hydrochloride Softgel Capsules"

Thanks & Regards,

For Strides Pharma Science Limited,

Manjula Ramamurthy Company Secretary

Manjula R.

Encl. As above



# Strides receives USFDA approval for Amantadine Hydrochloride Softgel Capsules

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

**Bengaluru, February 21, 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 *Amantadine Hydrochloride Softgel Capsules USP,100 mg* from the United States Food & Drug Administration (USFDA). The product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Symmetrel Capsules, 100 mg, of Endo Pharmaceuticals, Inc (Endo).

According to IQVIA MAT December 2021 data, the US market for Amantadine Hydrochloride Capsules USP,100 mg is approximately US\$ 11 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 also has approval for Amantadine Hydrochloride tablets and the combined market size of Tablets and Capsules together is approximately US\$ 21 Mn as per IQVIA MAT December 2021 data.

The company has 271 cumulative ANDA filings with USFDA of which 244 ANDAs have been approved and 27 are pending approval.

## About Amantadine Hydrochloride Capsules

Amantadine hydrochloride capsules are indicated for the prophylaxis and treatment of signs and symptoms of infection caused by various strains of influenza A virus. Amantadine hydrochloride capsules are also indicated in the treatment of parkinsonism and drug-induced extrapyramidal reactions.

## **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 <a href="https://www.strides.com">www.strides.com</a>

#### For further information, please contact:

## <u>Strides</u>

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# Strides Pharma Science Limited

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