

September 15, 2023

**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 tentative USFDA approval for Dolutegravir/ Lamivudine/ Tenofovir Disproxil Fumurate tablets"

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

Manjula Ramamurthy Company Secretary ICSI Membership No. A30515

Encl. As above



## Strides receives tentative USFDA approval for Dolutegravir/ Lamivudine/ Tenofovir Disproxil Fumurate tablets

 Strides' NDA 505b2 is tentatively approved under USFDA's expedited review provision for the President's Emergency Plan for AIDS Relief (PEPFAR)

**Bangalore, India, Sep 15, 2023** - Strides Pharma Science Limited (Strides) today announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received tentative approval for its New Drug Application (NDA) 505b2 of Dolutegravir/ Lamivudine/ Tenofovir Disproxil Fumurate 50mg/ 300mg/ 300mg tablets from the United States Food & Drug Administration (USFDA). The Product will be manufactured at the company's facility in Bengaluru.

Approval of this product under the PEPFAR program completes Strides' qualification to all major markets and donor programs including Global Fund and South Africa.

The PEPFAR tentative approval for Strides qualifies the Company to participate in the PEPFAR programs that procure this lifesaving medicine. Through country tenders and donor funded programs it is estimated that the value of procurement for Dolutegravir/ Lamivudine/ Tenofovir Disproxil Fumurate 50mg/ 300mg/ 300mg tablets is ~650mn USD.

The Company has 260+ cumulative NDA/ ANDA filings with USFDA, of which 230+ ANDAs have been approved. The Company has set a target to launch ~ 60 new products over the next three years in the US.

## About Dolutegravir/ Lamivudine/ Tenofovir Disproxil Fumurate 50mg/ 300mg/ 300mg tablets

Dolutegravir/ Lamivudine/ Tenofovir Disproxil Fumurate 50mg/ 300mg/ 300mg tablets is a complete regimen for treatment of HIV-1 infection in adults and pediatric patients weighing at least 35kgs.

## **About Strides**

Strides, a global pharmaceutical company headquartered in Bengaluru, India, is listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR). The Company mainly operates in the regulated markets and has an "in Africa for Africa" strategy and an institutional business to service donorfunded 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 focuses on "difficult to manufacture" products 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:

Strides

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**Strides Pharma Science Limited** 

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