



September 14, 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 tablets”**

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

**Manjula Ramamurthy**  
**Company Secretary**  
**ICSI Membership No. A30515**

Encl. As above

**Strides Pharma Science Limited**

CIN: L24230MH1990PLC057062

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## Strides receives tentative USFDA approval for Dolutegravir tablets

- *Strides' ANDA is tentatively approved under USFDA's expedited review provision for the President's Emergency Plan for AIDS Relief (PEPFAR)*
- *Approval of this product complements Strides' approved range of first-line HIV treatments to now include treatment naïve patients as well*

**Bangalore, India, Sep 14, 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 Dolutegravir 50mg tablets from the United States Food & Drug Administration (USFDA).

The product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Tivicay Tablets of ViiV Healthcare Company. The approval adds to a list of products that Strides has approved under the PEPFAR pathway taking the total to 13 products.

The Dolutegravir 50mg tablet has a market opportunity in the US of ~US\$ 1,345Mn per IQVIA. The products will be manufactured at the company's facility in Bengaluru. The conversion of this tentative approval to a full approval is expected upon expiry of the constraining patents.

The PEPFAR tentative approval for Strides qualifies the Company to participate in global donor funded programs that procure this lifesaving medicine and it is supplied in 126 countries. As of full year 2022, donor procurement for Dolutegravir 50mg tablet is estimated at a value of ~35mn USD. This product further strengthens the available offerings in HIV treatment from Strides.

The company has 260 cumulative ANDA filings (including the recently acquired portfolio from Endo at Chestnut Ridge) with USFDA, of which 230+ ANDAs have been approved. The company has set a target to launch ~ 60 new products over three years in the US.

### About Dolutegravir 50mg tablets

Dolutegravir tablets belong to a class of medication known as antiretrovirals. This medication is the first line of antiretroviral therapy (ART) for treatment naïve patients. It works by preventing the multiplication of the virus in human cells.

### 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 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 focuses on "difficult to manufacture" products sold in over 100 countries. Additional information is available at the Company's website at [www.strides.com](http://www.strides.com).

**For further information, please contact:**

**Strides**

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**Strides Pharma Science Limited**

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