



August 3, 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 Cyclosporine Softgel Capsules”**

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

**Manjula Ramamurthy**  
**Company Secretary**

Encl. As above

**Strides Pharma Science Limited**

CIN: L24230MH1990PLC057062

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Regd Off: 201, Devavrata, Sector 17, Vashi, Navi Mumbai – 400 703, India | Tel: +91 22 2789 2924 / 3199 Fax: +91 22 2789 2942

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## Strides receives USFDA approval for Cyclosporine Softgel Capsules

***Approval strengthens Strides immunosuppressant portfolio for the US markets  
Product to be launched immediately  
To be marketed by Strides Pharma Inc. in the US market***

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**Bengaluru, August 3, 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 **Cyclosporine Softgel Capsules USP (Modified), 25 mg, 50 mg, and 100 mg** from the United States Food & Drug Administration (USFDA). The product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Neoral Capsules 25 mg, 50 mg, and 100 mg, of Novartis Pharmaceuticals Corporation (Novartis). Cyclosporine Softgel Capsules is part of Strides niche product portfolio with limited competition in the US market. Strides is the first Indian company to get approval for the product. The approval further strengthens Strides immunosuppressant portfolio for the US markets which now comprises of Mycophenolate Mofetil tablets and capsules, Tacrolimus capsules and Cyclosporine Softgel Capsules.

According to IQVIA MAT data, the US market for Cyclosporine Capsules USP, 25 mg, 50 mg, and 100 mg is approximately US\$ 91Mn. 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 279 cumulative ANDA filings (including recently acquired portfolio from Endo at Chestnut Ridge) with USFDA of which 259 ANDAs have been approved and 20 are pending approval. The company has set a target to launch ~ 20 new products every year in the US.

### About Cyclosporine Capsules

Cyclosporine is used as an immunosuppressant medication. It is prescribed for the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants. Cyclosporine is also used to treat severe rheumatoid arthritis and psoriasis.

### 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](http://www.strides.com)

### **For further information, please contact:**

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**Strides Pharma Science Limited**

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