



August 22, 2018

**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 Sirs,

**Sub: Press Release**

Please find attached press release issued by the Company titled:

**“Strides receives acceptance from USFDA for two key ANDAs under newly introduced  
Competitive Generic Therapy”**

Thanks and Regards

For **Strides Pharma Science Limited**

**Sd/-**

**Manjula Ramamurthy  
Company Secretary**

**Strides Pharma Science Limited**

(Formerly Strides Shasun Limited)

CIN: L24230MH1990PLC057062

Corp Off: Strides House, Bilekahalli, Bannerghatta Road, Bangalore – 560076, India

Tel: +91 80 6784 0000 Fax: +91 80 6784 0700

Regd. Off: 201, Devavrata, Sector 17, Vashi, Navi Mumbai – 400703, India

Tel: +91 22 2789 2924 / 3199 Fax: +91 22 2789 2942

[info@strides.com](mailto:info@strides.com); [www.strides.com](http://www.strides.com)

## Strides receives acceptance from USFDA for two key ANDAs under newly introduced Competitive Generic Therapy

**Combined market for the two products is US\$ 550 Mn  
The two products could be eligible for a potential 180-day exclusivity**

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**Bangalore, August 22, 2018** Strides Pharma Science Limited (Strides) today announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, received ANDA “acceptable for filing” correspondence from the USFDA for two key ANDAs that met the prioritization factors as a potential First Generic with a 10-month GDUFA II review goal date. As per IQVIA MAT data, the US market for these products cumulatively is US\$ 550 Mn.

The USFDA also granted Strides’ request to designate the drug product under these ANDAs as a Competitive Generic Therapy (CGT). If Strides is the first approved applicant with such competitive generic therapies, these products could be eligible for a **potential 180-day CGT exclusivity**, which functions in a similar manner to the Patent Challenge exclusivity for ANDAs.

Approval of the CGT designated ANDAs will be contingent on certain conditions including continued USFDA approval status for the manufacturing plant, API supplier, and CRO. While the CGT designated ANDAs will be eligible for a 180-day CGT exclusivity as subsequent generic will not be approved to market for 180 days after launch, the exclusivity will not preclude the marketing of product that receives approval prior to Strides commercializing the product.

### About Competitive Generic Therapy

With the newly implemented Section 506H of the Food, Drug, and Cosmetic Act, a drug is eligible for designation as a competitive generic therapy if FDA determines that there is “inadequate generic competition”. Inadequate generic competition means there is not more than one approved drug listed in the Orange Book (excluding discontinued section) that is the RLD, or a generic drug with the same RLD as the drug for which designation as a competitive generic therapy is sought. The CGT designation benefits include involvement of senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review of a CGT designated ANDA. The product could also be eligible for **potential 180-day CGT exclusivity** if the application is for a drug, which is considered the “first approved applicant” with such competitive generic therapies.

## Disclaimer Regarding Forward-Looking Statements

This press release contains forward-looking statements, which are based on management's current beliefs and expectations and are subject to substantial risks and uncertainties, both known and unknown that could cause the future results, performance or achievements to differ significantly from that expressed or implied by such forward-looking statements.

## About Strides

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is global pharmaceutical Company headquartered in Bangalore. The Company has two business verticals, viz., Regulated Markets and Emerging Markets. The Company has a global manufacturing footprint with 7 manufacturing facilities spread across three continents including 5 US FDA approved facilities and 2 facilities for the emerging markets. The Company has strong R&D infrastructure in India with global filing capabilities and a strong commercial footprint across 100 countries. Additional information is available at the Company's website at [www.strides.com](http://www.strides.com)

### For further information, please contact:

<p><b><u>Strides</u></b> Badree Komandur, Executive Director - Finance +91 80 6784 0747</p> <p><b><u>Investor Relations:</u></b> Kannan. N: +91 98450 54745 Vikesh Kumar: +91 80 6784 0827 Sandeep Baid : +91 80 6784 0791</p> <p><b><u>Strides Pharma Science Limited</u></b> (Formerly Strides Shasun Limited) CIN : L24230MH1990PLC057062 Regd. Office: 201, 'Devavrata', Sector – 17, Vashi, Navi Mumbai – 400 703 Corp. Office: Strides House, Bannerghatta Road, Bangalore – 560076 Email: <a href="mailto:investors@strides.com">investors@strides.com</a></p>	<p><b><u>PR Consultancy</u></b></p> <p>Fortuna PR K Srinivas Reddy: +91 90005 27213 <a href="mailto:srinivas@fortunapr.com">srinivas@fortunapr.com</a></p> <p>K Priya: +91 95354 25418 <a href="mailto:priya@fortunapr.com">priya@fortunapr.com</a></p>
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