



## Press Release

November 09, 2018

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# Strides enters into a strategic partnership with SUDA Pharmaceuticals for the US market

## Exclusive agreement for novel and first fast-acting oral spray of sumatriptan in the US market

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**Bangalore, November 09, 2018** Strides Pharma Science Limited (Strides) today announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte Limited, Singapore has entered into an exclusive product development, licensing and supply agreement with SUDA Pharmaceuticals Ltd (ASX: SUD) for its novel drug SUD-001H, an oral spray of sumatriptan to treat migraine headache for the US market.

Execution of Strides' generic product pipeline for the US is nearing completion and is expected to have 150+ ANDA filings by 2021. The company is now focusing on developing a portfolio of complex and specialty products including products filed under the 505B (2) regulatory pathway. The company through inhouse development and partnerships will build a portfolio of limited competition products offering exclusivity for a sustainable period. Today's announcement of partnership with SUDA is part of company's specialty portfolio buildout for the US market.

Sumatriptan is one of the most widely used drugs for the treatment of acute migraine in adults. SUD-001H is a first-in-class mint-flavoured oral spray formulation of sumatriptan (marketed in tablet form and in a nasal spray by GlaxoSmithKline under the brand name Imitrex®). The product will be filed with the USFDA under the 505B (2) regulatory pathway and on approval is expected to be the first fast-acting oral spray of sumatriptan in the US market. The product will utilize SUDA's recently developed proprietary OroMist® hydrotrope technology that significantly improves the rate of absorption and the quantity of drug that is absorbed across the mucosal membranes. A primary market assessment on the potential for SUD-001H for the treatment of adult migraine confirmed the need for a product that could demonstrate a faster onset of action and the same was supported by medical practitioners.

### Terms of the agreement

- SUDA will provide product development services for SUD-001H funded by Strides
- SUDA to work with Strides team through joint committees to achieve successful USFDA approval for the product
- SUDA to receive an upfront cash payment of US\$ 0.4 Mn and a further payment of

US\$ 0.6 Mn on reaching certain milestones including the pilot first-in-man clinical study, submission and approval of the product in the US.

- On commercial sales, SUDA will receive royalties plus a handling fee
- Strides to have a right of first refusal for additional territories including the European Union, Australia and New Zealand, Canada, South Africa and Japan.

### About Migraine

Migraines are headaches that typically last from 4-72 hours. Patients may experience nausea and vomiting as well as sensitivity to light or sound. Migraine sufferers frequently report throbbing pain that worsens with normal activity. According to the National Headache Foundation, more than 36 Mn Americans suffer from migraine. The drug market value of migraine treatments in the US was estimated to be ~US\$1.2 Bn in 2017.

### 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 facilities for Regulated Markets 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)

### About SUDA Pharmaceuticals Ltd

SUDA Pharmaceuticals Ltd (ASX: SUD) is a drug delivery company focused on oro-mucosal administration, headquartered in Perth, Western Australia. The Company is developing low-risk oral sprays using its OroMist® technology to reformulate existing pharmaceuticals. The many potential benefits of administering drugs through the oral mucosa include ease of use, lower dosage, reduced side effects and faster response time. For more information, visit [www.sudapharma.com](http://www.sudapharma.com)

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

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