ACN 090 987 250

ASX Release

SUDA SIGNS EXCLUSIVE AGREEMENT FOR SUD-001H FOR THE US MARKET

- **Development, licence and supply agreement for treatment of migraine in US market**
- **Agreement with major pharmaceutical company**
- **Upfront and milestone payments**
- **Funded development project**
- **Royalty plus handling fee on supply of product**

PERTH, AUSTRALIA – 8 November 2018: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery today announces that it has entered into an exclusive product development, licence and supply agreement with Strides Pharma Global Pte Ltd, a fully-owned subsidiary of Strides Pharma Science Ltd, ("Strides") for the development and commercialisation of SUDA's novel SUD-001H fast acting oral spray of sumatriptan to treat migraine headache for the United States.

The product, SUD-001H, will be a formulation of sumatriptan utilising the Company's proprietary OroMist® hydrotrope technology. Once approved by the US Food and Drug Administration (FDA), SUD-001H would be the first novel fast-acting oral spray of sumatriptan in the US market.

Key terms of the agreement

- SUDA will provide, and Strides will fund, product development services for SUD-001H,
- SUDA to receive an upfront cash payment of US$0.4 Mn (approx. AU$0.56 Mn) and a further payment of US$0.6 Mn (approx. AU$0.83 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,
- SUDA to work with Strides team through joint committees to achieve successful US FDA approval for the product.

Mr. Stephen Carter, Chairman & CEO of SUDA, said: “There is a significant unmet medical need for a better treatment modality for patients with migraine headache, particularly patients that have rapid onset of pain and those with the co-morbidity of severe nausea and vomiting. For these patients, SUD-001H offers an attractive treatment option with rapid absorption of the drug through the oral mucosa using our novel OroMist® platform.

“SUDA commissioned a primary marketing assessment of the US market to assess the potential for SUD-001H for the treatment of adult migraine. The market assessment confirmed the need for a product that could demonstrate a faster onset of action and a lower dosage. The assessment further confirmed that the response from medical practitioners was highly supportive.

“We are delighted to have entered into an agreement with a major pharmaceutical company. We are looking forward to working with Strides to ensure the success of SUD-001H in the world’s largest pharmaceutical market.”

SUDA acknowledges that the Company remains on track to achieve further deals as previously described.

Further information:
STEPHEN CARTER
CHIEF EXECUTIVE OFFICER/MANAGING DIRECTOR
SUDA Pharmaceuticals Ltd
Tel: +61 8 6142 555
sjcarter@sudapharma.com

NOTES TO EDITORS:

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 (i.e. cheeks, tongue, gums and palate) include ease of use, lower dosage, reduced side effects and faster response time. SUDA's product pipeline includes ZolpiMist™, a first-in-class oral spray of zolpidem for insomnia. ZolpiMist is marketed in the USA and SUDA has rights to the product outside of the US and Canada. ZolpiMist is partnered with Eddingpharm in China and Teva Pharmaceuticals in Latin America. SUDA has submitted a Marketing Authorisation Application to the Australian Therapeutic Goods Administration for ArTiMist®, its novel sublingual malaria treatment for children. In a Phase III trial, ArTiMist was shown to be superior to intravenous quinine. Other products in development include oral sprays for the treatment of migraine headache, chemotherapy-induced nausea and vomiting, erectile dysfunction, PAH, epileptic seizures and pre-procedural anxiety. For more information, visit www.sudapharma.com

About Strides

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is a 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.

About SUD-001H

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®). Sumatriptan is one of the most widely used drugs for the treatment of acute migraine in adults.

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.

Key Agreement Terms

The agreement is for SUDA to develop an oral spray of sumatriptan and provide an exclusive perpetual licence to Strides to distribute, market and sell SUD-001H sumatriptan oral spray for the treatment of migraine headache in the USA. In addition to the upfront fee of approx. A$560,000, SUDA could receive a further approx. A$830,000 in milestone payments. On commercial sales, SUDA will receive royalties on gross profit (net sales less supply price less handling fee) on sales in the territory. SUDA will supply the product to Strides at cost of goods plus a handling fee.

Strides will fund the development program. SUDA has also granted its partner a right of first refusal to license the product in Europe, Japan, Canada, Australia, New Zealand and/or South Africa. Under the terms of the agreement, SUDA will perform product development services, funded by Strides, to achieve regulatory approval from the FDA. SUDA will supply the product to Strides for an anticipated minimum period of ten years and both parties will work together through Joint Committees to complete the development and maximise the commercial opportunity for SUD-001H in the US market. SUDA is also able to license the product outside of the US, subject to ROFR by Strides, and would pay a royalty to Strides for the use of the intellectual property. The agreement is subject to standard termination clauses.