SUDA PHARMACEUTICALS LTD

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ASX Release

SUDA CONTINUES TO EXPAND PATENT COVERAGE FOR SUD-003/004 SILDENAFIL SPRAYS

- **Patents granted in Europe and China for PAH and SSRI ED; and**
- **UK, France and Germany for Erectile Dysfunction**

PERTH, AUSTRALIA – 18th February 2019: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, today announces that the European and Chinese Intellectual Property Offices have accepted SUDA's patent applications for its sildenafil-based products: SUD-004 for pulmonary arterial hypertension (PAH); and Selective Serotonin Reuptake Inhibitor (SSRI) anti-depressant induced erectile dysfunction (SSRI-ED). The patents (European Patent Application 2787967 and Chinese Patent Application CN 104822368B) are titled: *Oral Spray Formulations and Methods for Administration of Sildenafil* (PAH & SSRI-ED).

Further, the European Patent Office has also accepted SUDA's patent application for its sildenafil-based products, SUD-003 for erectile dysfunction (ED). The patent (European Patent Application 2575765) is titled: *Oral Spray Formulations and Methods for Administration of Sildenafil* (ED). The patent has been validated in the United Kingdom, France and Germany.

SUDA has had similar patents granted in the USA, Japan, Russia, Australia, New Zealand, Canada, South Africa and Singapore, and patent applications are pending in other jurisdictions. Sildenafil is the active drug in Pfizer's Viagra® tablet for erectile dysfunction and Revatio® for PAH.

The ED patent family provides protection until December 2032. The claims of these patents cover the administration of sildenafil, being the active pharmaceutical ingredient in SUD-003, via an oral spray for the treatment of erectile dysfunction.

The PAH & SSRI-ED patent family provides protection until December 2032. The claims of these patents cover the administration of sildenafil, being the active pharmaceutical ingredient in SUD-004, via an oral spray for the treatment of erectile dysfunction induced by Selective Serotonin Reuptake Inhibitor (SSRI) anti-depressants and for the treatment of pulmonary arterial hypertension.

The global erectile dysfunction drugs market is expected to reach an estimated US$3.4 billion in 2019. It affects about 150 million men worldwide and about 50% of men aged 40-88 suffer from the disorder with the prevalence increasing with age.

SSRI-induced erectile dysfunction is a common condition, affecting up to 75% of patients taking SSRIs such as Prozac®, Zoloft® and Paxil®.

PAH is a disease that affects blood pressure between the heart and the lungs. PAH occurs at all ages; however, the incidence of it increases with age. It is more common among women and people over 75 years of age and is often linked to heart failure. The PAH market is estimated to be growing at a CAGR of 5% and reached US$ 3.6 billion in 2015.

Mr Stephen Carter, SUDA's Executive Chairman, commented: "We are delighted to have this patent applications accepted in Europe and China. It reinforces our proprietary position covering the oral spray delivery of sildenafil for erectile dysfunction and pulmonary arterial hypertension. Both products are the subject of licensing discussions in various countries. With granted patents, the value of our novel oral sprays is significantly enhanced."

Further information:
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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. 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; and cancer.

For more information, visit www.sudapharma.com