SUDA PHARMACEUTICALS LTD

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ASX Release

SUDA PHARMACEUTICALS: SHAREHOLDER UPDATE

PERTH, AUSTRALIA – 21 June 2018: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, today announced an update on its pipeline and business development activities.

ZolpiMist™ zolpidem tartrate oral spray (insomnia)

Magna Pharmaceuticals, Inc., the global owner of ZolpiMist, has exclusively licensed the product in the USA and Canada to Colorado-based, Aytu BioScience, Inc. (NASDAQ: AYTU). Aytu is an emerging specialty pharmaceutical company and will add ZolpiMist to its current commercial portfolio which includes a testosterone replacement nasal gel, Natesto®.

Aytu is well placed to build further awareness of this novel oral spray for insomnia and to grow prescription demand in the US market through its direct sales force. The success of ZolpiMist in the USA enhances SUDA's efforts to secure partners and commercialise the product in the rest of the world.

SUDA's licensee in Latin America, Teva Pharmaceuticals, anticipates first approval in late 2018, which will trigger a milestone payment to SUDA and then royalties on sales.

In China, SUDA's licensee, Eddingpharm, anticipates submitting a Clinical Trial Application in the next few months. This has required substantial work by the teams at both Eddingpharm and SUDA. Eddingpharm is required to conduct a small pharmacokinetic study to demonstrate that ZolpiMist is bioequivalent to the Chinese branded tablet. With the successful completion of this study, Eddingpharm will be in a position to submit its New Drug Application to the Chinese FDA.

SUDA is on track to file a Marketing Authorisation Application (MAA) for ZolpiMist with the Australian Therapeutic Goods Administration in Q4 CY2018. The Company is firstly required to conduct an *in-vitro* dissolution study to show that the US-branded reference drug, Ambien®, is the same as the Australian brand, Stilnox®. Both products are manufactured by Sanofi and are the same according to the literature.

Licensing discussions are progressing in several other territories, including multiple Asian countries, Europe and the Middle East.

ArTiMist® artemether sublingual spray (malaria)

The Australian Therapeutic Goods Administration (TGA) is continuing its review of SUDA's MAA. In the last few weeks, the TGA approved the clinical section of the dossier. SUDA is finalising its responses to some other items that have been raised by the TGA and anticipates approval of ArTiMist before the end of CY2018.

SUDA is scheduling a meeting with the World Health Organisation (WHO) to discuss the addition of ArTiMist to the WHO's Guidelines for the treatment of children with severe malaria.

The decision to meet with the WHO prior to the anticipated regulatory approval of ArTiMist by the TGA was stimulated by SUDA's discussions with a prospective acquirer/licensee of the product. As part of the negotiation, the pharmaceutical company is seeking to know whether any further data is required by the WHO prior to adopting ArTiMist into the Guidelines.

SUD-001 sumatriptan oral spray (migraine)

SUDA is in advanced negotiations with a pharmaceutical company for SUD-001 in the US. The prospective partner is interested in developing SUDA's second-generation formulation of SUD-001, which includes the Company's proprietary permeation-enhancing technology.

Licensing discussions in other territories, including Europe, are progressing.

SUD-003 sildenafil oral spray (erectile dysfunction)

The Canadian Intellectual Property Office has granted SUDA's first patent application in Canada for its sildenafil-based products, SUD-003 and SUD-004. The patent (Canadian Patent Application 2,858,364) is titled: *Oral Spray Formulations and Methods for Administration of Sildenafil*.

SUDA has had similar patents granted in the USA, Japan, Russia, Australia, New Zealand and Singapore, and patent applications are pending in other jurisdictions. These patents provide protection until December 2032.

SUDA is working with the University of Western Australia, supported by grant funding, to investigate the transport of sildenafil across the mucosal membrane at a cellular level. In parallel, SUDA's formulation chemists are continuing to optimise SUD-003 utilising the Company's permeation-enhancing technology with the objective of enhancing the bioavailability and speed of absorption of the active drug.

Several deal discussions are ongoing based on the first-generation formulation of SUD-003, covering Asia, Europe and the Middle East.

SUD-004 sildenafil oral spray (pulmonary arterial hypertension)

The product profile of SUDA's first-generation oral spray formulation of sildenafil, which was successfully evaluated in a pilot pharmacokinetic study, is well suited for the treatment of pulmonary arterial hypertension. SUDA is discussing the development programme for this product with a number of prospective partners.

SUD-005 midazolam oral spray (epileptic seizures)

Formulation work on SUD-005 is ongoing utilising SUDA's permeation-enhancing technology to provide extended patent protection. The current formulation is flavoured strawberry-mint to appeal to infants and as well as older children.

There is strong interest in midazolam as a treatment for epileptic seizures within the pharmaceutical industry. In April 2018, UCB, a global pharmaceutical company, acquired the rights to Proximagen's nasal spray of midazolam for US$150 million upfront and contingent payments of up to US$220 million.

SUDA has multiple partnering discussions ongoing regarding a global licence to SUD-005.

SUD-018 anagrelide oral spray (cancer)

There is a compelling body of published data describing the underlying mechanisms by which the platelet-tumour interaction is mediated and how the reduction of platelets can help prevent tumour growth and metastasis. Anagrelide is a powerful anti-thrombotic agent that reduces elevated levels of platelets.

Anagrelide has the potential to be developed as an effective anti-cancer agent but is fundamentally limited in its current formulation by cardio-stimulatory side-effects. An oro-mucosal spray formulation of anagrelide could minimise these side-effects by avoiding first-pass generation of a highly potent cardio-excitatory metabolite of the drug in the liver.

SUDA's technical team is working on the anagrelide formulation and has been able to significantly enhance the solubility of this highly insoluble molecule.

Co-development opportunities

SUDA is exploring multiple co-development opportunities to apply the OroMist® platform to a broad range of small-molecule and biological drugs. These drugs have significant sales or sales potential but are limited by their poor bioavailability or route of administration.

Pfizer is evaluating next steps to advance one or both of the over-the-counter oral sprays that SUDA formulated in 2017 under a feasibility and option agreement. The delay in Pfizer's decision follows news in October 2017 that Pfizer was seeking to sell its consumer healthcare business, which led to budget constraints within the unit.

Mr. Stephen Carter, SUDA's CEO, commented: "We are making progress towards several key operational goals, including more commercial deals and regulatory approvals. These milestones will add significant value to our product portfolio. Furthermore, I am pleased to report that following extensive negotiations with the HC Berlin Pharma Estate, we anticipate reaching a final settlement, which will remove the uncertainty associated with the claim against SUDA. I am confident in our future success and look forward to updating the market in due course."

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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. For more information, visit www.sudapharma.com