

ASX Release

SUDA and STADA Australia Enter a Licence and Distribution Agreement for ZolpiMist

- SUDA grants an exclusive Licence for the rights to ZolpiMist® for commercialisation in Australia to STADA Pharmaceuticals, part of the international Pharmaceutical Company, STADA Group
- SUDA to receive an upfront payment of \$170,000 and a milestone fee of \$40,000 on the regulatory approval of a specific spray unit enhancement
- SUDA to receive a 10% royalty on the sales of the enhanced product
- STADA to leverage the TGA approval and commercialise ZolpiMist in Australia

PERTH, AUSTRALIA – 24 August 2021: SUDA Pharmaceuticals Ltd (ASX: SUD), a biotechnology company focused on developing therapies to treat cancer and conditions that affect the central nervous system, has entered into an exclusive License and Distribution Agreement for ZolpiMist® in Australia with STADA Pharmaceuticals Australia Pty Ltd, a member of the global, German-based STADA Group.

SUDA obtained approval from the Therapeutic Goods Administration (TGA) for ZolpiMist as announced 29 July 2020¹ and continues to work closely with its current licensees. SUDA will submit a further application to the TGA for a modification to the current spray unit, incorporating in the application a more economical, elegant, and user-friendly child resistant lock (CRL). It is anticipated that the new CRL will be implemented from the second batch of product produced for STADA onward.

According to a survey conducted by the University of Southampton, the incidence of people suffering from sleep problems rose from one in six to one in four during the COVID-19 pandemic.² Clinical data supports the faster onset of action of ZolpiMist over conventional tablet forms of the drug³, which is a critical factor for an effective anti-insomnia medication.

Mr David Phillips, SUDA's Executive Director of Business Development, commented: "We are very excited about developing the partnership with STADA, who have strong

¹ Refer to ASX announcement 29 July 'TGA Approval Granted for ZolpiMist'

² <https://www.southampton.ac.uk/news/2020/08/sleeploss-lockdown.page>

³ Raffa *et al.*, (2019). More Rapid Sleep Onset with Lingual-Spray vs Oral-Tablet Delivery Zolpidem.

credentials to successfully market ZolpiMist in Australia and potentially in other territories. By completing an agreement in Australia, we continue to make progress for the commercial build out of ZolpiMist. This partnership is anticipated to lead to SUDA's first revenue stream from the commercialisation of a product from our portfolio."

STADA has advised SUDA that commercial sales are expected to commence in Q3 CY2022.

Ms Helen Tye, STADA Australia's General Manager for Australia and New Zealand commented: "At STADA Australia, our people strive to be fully committed to STADA's purpose of caring for people's health as a trusted partner. STADA is committed to providing medicines that may provide relief for patients suffering with various conditions. Sleep problems can impact on people's overall health both mentally and physically, with insomnia sufferers reporting a lower quality of life compared with people who are sleeping well. STADA believes that nobody should have to compromise their quality of life or give up what they would like to do because of a medical condition. We are pleased to licence this product from SUDA and look forward to facilitating patients, who suffer from short-term insomnia, having access to a convenient oral-mucosal spray. This agreement serves as further evidence that STADA is increasingly a go-to-partner for specialty pharmaceuticals in Australia."

Key terms of the Agreement:

- i. The Agreement is a perpetual, exclusive Licence for ZolpiMist® for Australia;
- ii. STADA has the option to distribute the product in New Zealand;
- iii. SUDA will receive an upfront fee of \$170,000 plus a milestone payment of \$40,000;
- iv. The milestone payment is linked to the approval of the enhanced CRL;
- v. SUDA will receive a 10% royalty based on net sales of the enhanced product;
- vi. SUDA to manufacture and supply the product at agreed supply prices;
- vii. STADA is responsible for commercialisation of the product in Australia;
- viii. The agreement is subject to standard termination clauses.

For and on behalf of the Board and for further information please contact:

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NOTES TO EDITORS:

About SUDA Pharmaceuticals Ltd

SUDA Pharmaceuticals Ltd (ASX: SUD) is a biotechnology company focused on developing therapies to treat human disease. SUDA's two focus areas are oncology and conditions that impact the central nervous system. SUDA is developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers. The Company is also developing low-risk oral sprays to reformulate existing pharmaceuticals. The 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 an oral spray for the platelet-lowering drug anagrelide to treat metastatic disease in the background of high platelets, and ZolpiMist™, a first-in-class oral spray of zolpidem tartrate to treat short-term insomnia. ZolpiMist is approved by the FDA and the TGA and is marketed in the USA. SUDA has rights to the product outside of the US and Canada. Other products in development include oral sprays to treat migraine headaches, motion sickness, and drug-resistant epilepsy.

For more information, visit www.sudapharma.com

About STADA

For more than 120 years, STADA has been dedicated to supplying high-quality, innovative pharmaceutical products that help to improve the quality of life of patients. STADA is a global pharmaceutical company with offices in more than 30 countries, including Germany, UK, Central Europe, Eastern Europe, Asia, Australia, and New Zealand.

STADA Australia is a speciality pharmaceutical company with a product focus on infusion therapies in Neurology and Pain Management and works closely with Britannia Pharmaceuticals in the UK, a wholly owned subsidiary of STADA, to ensure the latest innovative therapies and advancements in Europe are brought to Australia and New Zealand for Parkinson's disease.

STADA is committed to improving the quality of life of patients, and supporting carers, through the provision of specialty products and support delivered by a compassionate, caring team of professionals and continues to build partnerships with healthcare professionals to deliver patient outcomes.

About ZolpiMist™

ZolpiMist™ is a first-in-class, US-approved, cherry-flavoured, fast-acting oral spray version of zolpidem tartrate (marketed under the brand name of Ambien® or Stilnox®), a non-benzodiazepine prescribed for the treatment of insomnia. It provides a convenient and easy-to-use alternative route of administration, by delivering a therapeutic dose with one or two actuations of the spray into the oral cavity. The pivotal studies demonstrated bioequivalence of ZolpiMist 5mg and 10mg doses with the respective Ambien tablets. The time to therapeutic levels of both ZolpiMist doses were significantly shorter than the corresponding Ambien tablets and ZolpiMist showed a faster onset of drowsiness. ZolpiMist advantages include reduced sleep latency, patient convenience, and ease of use as it is administered without the need of water, unlike conventional tablets. Also, it can benefit patients experiencing difficulties in swallowing and/or suffering with gastrointestinal (GI) disorders that restrict the absorption of drugs via the GI mucosa.