

# ASX Release

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## **SUDA LTD AND EDDINGPHARM ENTER LICENSING AGREEMENT FOR ZOLPIMIST™ IN CHINA**

**PERTH, AUSTRALIA – 9 November 2016:** SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, and Eddingpharm (Asia) Macao Commercial Offshore Limited (Eddingpharm), a leading Chinese pharmaceutical company, today announce that the companies have entered into an exclusive license agreement for the development and commercialisation of SUDA's novel ZolpiMist™ oral spray of zolpidem tartrate to treat insomnia in China. Once approved by the Chinese Food and Drug Administration (CFDA), ZolpiMist would be the first imported fast-acting oral spray of zolpidem tartrate available in China.

Under the terms of the agreement, SUDA receives an upfront cash payment of US\$300,000 (approx. A\$400,000) and is entitled to receive a further milestone payment of US\$200,000 (approx. A\$260,000) following registration of the product in China. In addition, once Zolpimist is registered for sale in China, SUDA will receive escalating tiered royalties on net sales in the territory. The total value of the deal could exceed US\$26 million (approx. A\$34 million) based on Eddingpharm's forecast sales for the first 15 years from launch.

Under the terms of the agreement, Eddingpharm will assume responsibility for development, regulatory and commercialisation activities for ZolpiMist in China. SUDA will supply the product to Eddingpharm and both parties will work together through a Joint Governance Committee to maximise the commercial opportunity for ZolpiMist in China.

Mr Stephen Carter, CEO of SUDA, said: "There is still a significant unmet need for insomnia patients, particularly patients that want rapid onset of sleep, have problems swallowing tablets or gastrointestinal complications. For these patients, ZolpiMist offers an attractive treatment option with rapid absorption of the drug through the oral mucosa.

"We are delighted to have entered into this development and commercialisation agreement with Eddingpharm, an ideal partner for us in China. They are a leading pharmaceutical company in the region and have an excellent track record in launching novel pharmaceutical products with experienced registration and market access professionals as well as an extensive sales and marketing team. We are looking forward to working with our new Chinese partner to ensure the success of ZolpiMist in the world's most populous country."

Mr Ni Xin, CEO of Eddingpharm, commented: “This innovative oral spray has demonstrated rapid absorption and onset of drowsiness in clinical trials. In China, it is estimated that more than 45% of the population, approximately 590 million people, have problems with sleep. The demand amongst Chinese patients for chemical-based pharmaceuticals continues to grow strongly, hence, we are excited to have an exclusive license to this first-in-class FDA-approved treatment for insomnia. ZolpiMist is an excellent fit with our current commercial infrastructure and our strategy for expanding our portfolio.”



**Further information:**

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## **NOTES TO EDITORS:**

### **About SUDA LTD**

SUDA 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 novel formulations of existing off-patent pharmaceuticals. The many potential benefits of administering drugs through the oral mucosa (ie: 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 North America. SUDA's most advanced development-stage product, ArTiMist®, is a 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 and pre-procedural anxiety. For more information, visit [www.sudaltd.com.au](http://www.sudaltd.com.au)

### **About Eddingpharm**

Eddingpharm is a fast-growing Chinese specialty pharmaceutical company, committed to bringing to the Chinese healthcare market high-quality medicines from all over the world, providing patients with more treatment options and better healthcare opportunities. We promote the communication and collaboration between Chinese clinical experts and leading international medical research institutes, and provide academic support to Chinese clinical doctors. The Company has a strong footprint in top tier cities – the core healthcare market in China – and is growing rapidly in lower tier cities. Eddingpharm's wide and expanding coverage includes more than 3,000 hospitals in 29 provinces with a sales force of over 600 professional personnel. The Company has successfully expanded its product portfolio through in-licensing, joint ventures, strategic alliances, exclusive distribution, and other forms of collaboration with multinational pharmaceutical companies, specialty pharmaceutical companies, and biotech companies in the US and Europe. For more information, visit [www.eddingpharm.com](http://www.eddingpharm.com)

### **About ZolpiMist™**

ZolpiMist™ is a first-in-class, US-approved, cherry-flavoured, fast-acting oral spray 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. Additionally, it can be used in patient populations experiencing difficulties in swallowing and/or suffering with gastrointestinal (GI) disorders that restrict the absorption of drugs via the GI mucosa.

### **Key Agreement Terms**

The agreement is an exclusive license to commercialise Zolpimist™ oral spray for the treatment of Insomnia in the territory of mainland China. Under the terms of the agreement, Eddingpharm will assume responsibility for development, regulatory and commercialisation activities for ZolpiMist™ in China. SUDA will supply the product to Eddingpharm and both parties will work together through a Joint Governance Committee to maximise the commercial opportunity for ZolpiMist™ in China. For any improvements to the product generated by Eddingpharm, all rights outside the territory remain with SUDA whilst within the territory they remain with Eddingpharm. The term of the agreement is perpetual. The agreement is subject to standard termination clauses. If the agreement is terminated, then all product rights and registrations are returned to SUDA and there is a 1 year non-compete within the territory and 5 years outside the territory.