SUDA LTD

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# ASX Release

## SUDA GRANTED SCIENTIFIC ADVICE MEETING WITH UK MHRA FOR EUROPEAN APPROVAL OF ZOLPIMIST™

**PERTH, AUSTRALIA – 25 May 2017:** SUDA LTD (ASX: SUD), a leader in oro-mucosal drug delivery, today announces that that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has granted SUDA a meeting on 21 June 2017 to discuss the proposed plan for registration of SUDA's novel ZolpiMist™ oral spray of zolpidem tartrate to treat insomnia in the UK and European Union.

The MHRA provides scientific advice to applicants on all aspects of development and registration of pharmaceuticals. SUDA is seeking advice on the suitability of its regulatory strategy which is to file for approval of ZolpiMist in Europe based on the data that successfully resulted in the product's US FDA approval, together with a small pharmacokinetic study to compare ZolpiMist with Sanofi's European brand-leading tablet of zolpidem tartrate, Stilnoct®, in healthy adults.

The proposed regulatory dossier is intended to support a marketing authorisation application to either the MHRA or the European Medicines Agency. Furthermore, SUDA will be seeking advice from the MHRA on the acceptability of the excipients used in the ZolpiMist oral spray formulation which are all listed in the US pharmacopeia.

Mr Stephen Carter, SUDA's CEO and Managing Director, commented: "It is estimated that about 100 million people suffer from some sort of insomnia in the EU (*source: EFPIA*). There remains a significant unmet need for new treatment options, particularly for patients that want rapid onset of sleep, have problems swallowing tablets or have gastrointestinal complications. For these patients, ZolpiMist offers an attractive alternative with rapid absorption of the drug through the oral mucosa. We look forward to the feedback from the MHRA and to bringing ZolpiMist to market in this key territory."

**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 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 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

**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.