SUDA PHARMACEUTICALS LTD

ACN 090 987 250

ASX Release

SUDA SUBMITS MARKETING AUTHORISATION APPLICATION FOR ZOLPIMIST

- **SUDA submitted its Marketing Authorisation file for ZolpiMist™ to the TGA**
- **The TGA has considered and accepted the file for evaluation**

PERTH, AUSTRALIA – 4 April 2019: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, today announces that that the Australian Therapeutic Goods Administration (TGA) has accepted for review the Marketing Authorisation Application (MAA) for ZolpiMist Oral spray for the treatment of insomnia.

In early 2019, SUDA made a submission to the TGA and based on that submission the TGA has advised that the filing has been found to have passed preliminary assessment and the TGA has accepted the dossier for full evaluation.

The evaluation process involves a number of stages and the TGA now has 255 days to complete its review and provide an opinion, including potential approval, of the ZolpiMist Marketing Authorisation.

SUDA has agreements for ZolpiMist in Brazil, Chile, Mexico, China, Philippines, Malaysia, Singapore with options over Thailand, Indonesia, Vietnam, Myanmar, Cambodia, Laos and Brunei. SUDA is in negotiations with pharmaceutical companies for other countries in South America as well as for Korea, Middle East and North Africa, UAE, Kuwait, Spain, Italy, France and Germany.

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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

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. 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.