SUDA PHARMACEUTICALS LTD

ACN 090 987 250

ASX Release

TGA Approval Granted For ZolpiMist™

Highlights:

- **TGA approval achieved ahead of projected Q4 2020 deadline**
- **TGA approval enables ZolpiMist™ to be sold in Australia**
- **TGA approval enables more competitive supply price**
- **TGA approval supports corresponding submissions in additional territories**

PERTH, AUSTRALIA – 29 July 2020: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, is pleased to announce that the Therapeutics Goods Administration (TGA) has approved the registration of the Company's lead product ZolpiMist (zolpidem tartrate) for the treatment of short-term insomnia in adults.

As outlined on 12 May 2020, SUDA had submitted a Marketing Authorisation Application (MAA) to the TGA for ZolpiMist in April 2019. SUDA, subsequent to the submission, made a strategic decision to register a supplemental active pharmaceutical ingredient (API) supplier and final product manufacturer which required an amendment to the TGA submission. Completion of the TGA review was expected Q4 2020.

The TGA approval includes the supplemental API supplier and final product manufacturer which allows SUDA to supply the product at a more competitive supply price and potentially allows the Company to target additional territories.

The benefits of TGA approval are:

i. ZolpiMist will be included on the Australian Register of Therapeutic Goods and can be commercialised and supplied within Australia;

ii. Demonstrates SUDA's compliance with Good Manufacturing Practice and an ability to obtain regulatory approvals for its products; and

iii. It will assist our current partners, TEVA, Mitsubishi Tanabe Pharma Singapore and MTP Korea, in their submissions in their respective territories with the amended API supplier and manufacturer.

Dr Michael Baker commented: "The TGA submission was a combined effort by SUDA's technical team as well as our regulatory consultant, Pharma To Market. Obtaining the approval indicates the calibre of our staff and is also a key benefit to our partners for ZolpiMist. We are delighted by the outcome and look forward to seeing the commencement of commercial sales in the foreseeable future."

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 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. Other products in development include oral sprays for the treatment of: migraine headache; chemotherapy-induced nausea and vomiting; erectile dysfunction; pulmonary hypertension; epileptic seizures and pre-procedural anxiety and cancer.

For more information, visit www.sudapharma.com