

ASX Release

ZolpiMist™ Update

PERTH, AUSTRALIA – 12 May 2020: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oromucosal drug delivery, is providing an update relating to its ZolpiMist™ Oral spray for the treatment of insomnia.

SUDA submitted a Marketing Authorisation Application (MAA) to the Therapeutic Goods Administration (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 manufacturer which required an amendment to the TGA submission.

The outcome of the strategic decision is a reduction of the costs of raw material and finished product which will enable SUDA to create additional value over the medium to long-term from its existing partnerships and to establish additional partnerships across more territories.

The API will now be sourced from a well-known, global generics manufacturer and ZolpiMist will be manufactured and packaged by the Australian subsidiary of a well-known global manufacturer of over-the-counter and generic prescription pharmaceuticals.

To support this amendment, SUDA was required to submit additional data to the TGA supporting the quality of the product being generated using the new API supplier and manufacturer. Additional data requested by the TGA has been submitted and the TGA are continuing with their review of the submission.

Given the change of manufacturer and based on feedback from the TGA, completion of the TGA review is expected Q4 2020.

Importantly, the data submitted to the TGA will also be shared with our current and future partners to support their regulatory submissions.

SUDA continues to make progress, securing additional license and supply agreements for ZolpiMist. The most recent being with Mitsubishi Tanabe Pharma Korea for the territory of South Korea, announced in March 2020. SUDA is continuing discussions with parties covering a range of territories in line with the strategy for global commercialisation of the product.

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

Paul Hopper
Executive Chairman
SUDA Pharmaceuticals Ltd
Tel: +61 (0) 406 671 515
phopper@sudapharma.com

Dr Michael Baker
Chief Executive Officer
SUDA Pharmaceuticals Ltd
Tel +61 (0) 403 468 187
mbaker@sudapharma.com

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