SUDA PHARMACEUTICALS LTD

ACN 090 987 250

ASX Release

Chile Ministry of Health Approval Granted to Teva Pharmaceuticals for ZolpiMist®

Highlights:

- **Chile approval achieved for SUDA's ZolpiMist®**
- **This approval enables ZolpiMist to be marketed in Chile by SUDA's partner, Teva Pharmaceuticals**
- **This is the first of Teva's territories to achieve approval**
- **This approval supports corresponding submissions in additional territories**

PERTH, AUSTRALIA – 21 October 2021: SUDA Pharmaceuticals Ltd (ASX: SUD), a biotechnology company focused on developing therapies to treat cancer and conditions that affect the central nervous system, is pleased to announce that the Ministry of Health, Chile, has approved the registration of the Company's lead product ZolpiMist (zolpidem tartrate) by Teva Pharmaceuticals for the treatment of short-term insomnia in adults.

SUDA's partner, Teva Pharmaceuticals, submitted a Marketing Authorisation Application (MAA) with the new supplemental API supplier and the Australian final product manufacturer to the Chilean authority for ZolpiMist in May 2021. Approval was granted significantly sooner than the expected date of April 2022.

The improved supply chain allows SUDA to supply the product at a more competitive supply price.

The benefits of the Chile approval are:

i. ZolpiMist can be commercialised and supplied within Chile;

ii. It demonstrates compliance with international Good Manufacturing Practice and an ability to obtain regulatory approvals with partners.

Dr Michael Baker commented: “The Chile submission was a combined effort by SUDA and Teva Pharmaceuticals. Obtaining the approval indicates the calibre of SUDA’s team as well as that of our partner, Teva Pharmaceuticals and is 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 biotechnology company focused on developing therapies to treat human disease. SUDA’s two focus areas are oncology and conditions that impact the central nervous system. SUDA is developing its invariant natural killer T (iNKT) cell therapy platform from Imperial College London to treat blood cancers. The Company is also developing low-risk oral sprays to reformulate existing pharmaceuticals. The 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 an oral spray for the platelet-lowering drug anagrelide to treat metastatic disease in the background of high platelets, and ZolpiMist™, a first-in-class oral spray of zolpidem tartrate to treat short-term insomnia. ZolpiMist is approved by the FDA and the TGA and is marketed in the USA. SUDA has rights to the product outside of the US and Canada. Other products in development include oral sprays to treat migraine headaches, motion sickness, and drug-resistant epilepsy.

For more information, visit www.sudapharma.com

This announcement contains certain statements which may constitute forward-looking statements or information (‘’forward-looking statements”), including statements regarding negotiations with third parties and regulatory approvals. These forward-looking statements are based on certain key expectations and assumptions, including assumptions regarding actions of third parties and financial terms. These factors and assumptions are based upon currently available information and the forward-looking statements contained herein speak only as of the date hereof. Although the expectations and assumptions reflected in the forward-looking statements are reasonable in the view of the Company’s directors and management, reliance should not be placed on such statements as there is no assurance that they will prove correct. This is because forward-looking statements are subject to known and unknown risks, uncertainties and other factors that could influence actual results or events and cause actual results or events to differ materially from those stated, anticipated or implied in the forward-looking statements. These risks include, but are not limited to: uncertainties and other factors that are beyond the control of the Company; global economic conditions; risk associated with foreign currencies; and risk associated with securities market volatility. The Company assumes no obligation to update any forward-looking statements or to update the reasons why actual results could differ from those reflected in the forward-looking statements, except as required by Australian securities laws and ASX Listing Rules.