SUDA PHARMACEUTICALS LTD

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ASX Release

ZolpiMist™ Insomnia Product Development Market Update

PERTH, AUSTRALIA – 13 November 2018: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, is pleased to provide this market update for its lead product ZolpiMist™. ZolpiMist is the SUDA first-in-class oral spray of zolpidem tartrate for insomnia.

SUDA's directors and management are buoyed by the strong interest in ZolpiMist and by its potential to be a significant value generator. The company is striving to create ZolpiMist into a future long-term recurring revenue stream.

SUDA has two licence and supply agreements in place for ZolpiMist.

The first with Eddingpharm is for the exclusive sale and distribution of ZolpiMist in mainland China. SUDA is discussing the current progress of the CFDA application with its partner and will provide further updates as progress occurs.

The second is with Teva Pharmaceuticals for Brazil, Chile and Mexico. Teva has already lodged its marketing approval in Chile and is working closely with the SUDA team to progress the application in the large market of Brazil. Teva is continuing to evaluate the Mexican market. Teva had an option on the territories of Argentina, Israel and Australia but has decided not to exercise it. SUDA has a number of potential partners for these regions and will reinvigorate discussions in these markets.

Further to these deals, SUDA has received considerable interest in ZolpiMist from companies ranging from multinationals to specialised pharmaceutical companies covering diverse territories.

SUDA is able to provide a breakdown of developments with ZolpiMist by region:

ASEAN/Asia: agreement signed with Eddingpharm for China; advanced multi-territory negotiations with large pharma companies for Philippines, Malaysia, Singapore, Thailand, Indonesia, Vietnam, Myanmar, Cambodia, Laos, Brunei, South Korea and India.

MENA (Middle East and North Africa): discussions in various stages with companies for the full MENA region as well as specific talks for the United Arab Emirates and Kuwait.

South America: agreement signed with Teva for Brazil, Chile and Mexico; advanced negotiations for other countries in the region including Argentina, Peru, Ecuador, Columbia, Uruguay, Bolivia, Central America, Dominican Republic, Paraguay and Venezuela.

Europe: advanced negotiations with pharma companies for Spain, Italy, France and Germany.

Eastern Europe: specific talks for the regions of Turkey and Russia.

In Australia, SUDA is working with its regulatory consultants to finalise its Marketing Application to the Australian Therapeutic Goods Administration for the approval of ZolpiMist in the Australian market. It is anticipated that the application should be lodged with the TGA in January 2019. SUDA is now looking for a partner for the Australian market.

SUDA's current agreements and all negotiations are based on SUDA's standard business model where SUDA will supply the product and receive an upfront payment followed by payments for achieving regulatory and sales milestones. Further to these payments, SUDA will receive a handling fee as well as double digit royalties on sales (current 10-year forecast (after approvals) on signed deals is approximately US$60Mn as previously reported). Furthermore, based on the current agreements only, SUDA has already received US$0.7Mn in upfront fees and will potentially receive a further US$1.5Mn (approx. A$2Mn) in milestone payments.

Further information:
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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. 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.