SUDA PHARMACEUTICALS LTD

ACN 090 987 250

ASX Release

ZolpiMist Clinical Results Published

PERTH, AUSTRALIA – 6th August 2019: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oro-mucosal drug delivery, is pleased to announce ZolpiMist Clinical Study Results Demonstrating Lingual Spray Delivers More Rapid Sleep Onset Compared to Tablet Form of Zolpidem Based on Efficacy Parameters and Pharmacokinetics.

Aytu BioScience, Inc. the ZolpiMist marketing authorisation holder in the USA, announced today the publication of a clinical study in the journal Pharmacy and Pharmacology, demonstrating that ZolpiMist, SUDA's lingual spray formulation of zolpidem, achieves sleep onset more quickly than the oral tablet form of zolpidem (brand name Ambien®) in patients seeking short-term treatment for insomnia.

This new scientific report describes a post-hoc analysis of data from the pivotal Phase 3 study of ZolpiMist. The four-arm crossover study compares 5 and 10 mg doses of the lingual spray (LS) and tablet formulations of zolpidem in 43 adults (N = 20 males, 23 females). The generally accepted blood serum therapeutic threshold for zolpidem in treatment of insomnia is a blood plasma concentration of 20 ng/mL. On average, ZolpiMist achieved this threshold more quickly than tablet zolpidem. The lingual spray (ZolpiMist) formulation achieved this threshold at 7.0 and 10.5 minutes, for the 10 mg and 5 mg doses, respectively. Tablet zolpidem achieved this threshold at 15.0 and 17.2 minutes, for the 10 mg and 5 mg doses, respectively.

An additional measure to quantify sedation that was utilized in this study was the Digit Symbol Substitution Test (DSST), which is an assessment of attention, perceptual speed, motor speed, visual scanning and memory. The average time to achieve a 5-point change (from baseline) in DSST for ZolpiMist was 4.8 minutes and 8.0 minutes, for the 10 mg and 5 mg doses, respectively. Conversely, for tablet zolpidem, the time to achieve a 5-point change (from baseline) in DSST was 14.0 minutes and 16.2 minutes, for the 10 mg and 5 mg doses, respectively.

These analyses help illustrate the differences in administration modality and absorption of two formulations of zolpidem tartrate. The oral tablet formulation is relatively slow compared to the lingual spray and subjects a drug to a first-pass metabolism effect. Thus, bioavailability is generally low and slow comparatively. This, in turn, results in ZolpiMist lingual spray enabling a more than two-fold faster onset of sedation over zolpidem tablets.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "We are pleased with the reported results of this new analysis that demonstrate a more rapid onset of sleep and increased bioavailability of ZolpiMist when compared to zolpidem tablets. The novel oral spray form embodied in ZolpiMist may present patients with a more convenient form and a simple way to achieve rapid sleep onset. For the first time this study has established the clinical proof

demonstrating fast sleep onset and the distinct pharmacokinetics of ZolpiMist that support its use in the short-term treatment of insomnia."

Further information:
STEPHEN CARTER
CHIEF EXECUTIVE OFFICER / MANAGING DIRECTOR
SUDA Pharmaceuticals Ltd
Tel: +61 8 6142 555
sjcarter@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; PAH; epileptic seizures and pre-procedural anxiety; and cancer. For more information, visit www.sudapharma.com

About Aytu BioScience, Inc.

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant patient needs. The company currently markets Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"). Aytu also has exclusive U.S. and Canadian rights to ZolpiMist™, an FDA-approved, commercial-stage prescription sleep aid indicated for the short-term treatment of insomnia characterized by difficulties with sleep initiation. Aytu recently acquired exclusive U.S. commercial rights to Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup. Tuzistra XR is a prescription antitussive consisting of codeine polistirex and chlorpheniramine polistirex in an extended-release oral suspension. Additionally, Aytu is developing MiOXSYS®, a novel, rapid semen analysis system with the potential to become a standard of care for the diagnosis and management of male infertility caused by oxidative stress. MiOXSYS is commercialized outside of the U.S. where it is a CE Marked, Health Canada cleared, Australian TGA approved, Mexican COFEPRAS approved product. Aytu is planning U.S.-based clinical trials in pursuit of 510k de novo medical device clearance by the FDA. Aytu's strategy is to continue building its portfolio of revenue-generating products, leveraging its focused commercial team and expertise to build leading brands within large therapeutic markets. For more information visit aytubio.com.