

ASX Release

SUDA ANNOUNCES UPDATE ON ZOLPIMIST™ IN USA AND CANADA

PERTH, AUSTRALIA – 15 June 2018: SUDA Pharmaceuticals Ltd (ASX: SUD), a leader in oromucosal drug delivery, today announced that Magna Pharmaceuticals, Inc., the global owner of ZolpiMist™ (zolpidem tartrate oral spray), has exclusively licensed the product in the USA and Canada to Englewood, Colorado-based, Aytu BioScience, Inc. (NASDAQ: AYTU). Aytu is an emerging specialty pharmaceutical company and will add ZolpiMist to its current commercial portfolio which includes a testosterone replacement nasal gel, Natesto®.

ZolpiMist is an FDA-approved, proprietary, oral spray formulation of zolpidem tartrate and is indicated for the short-term treatment of insomnia characterised by difficulties with sleep initiation. SUDA has an exclusive global licence to ZolpiMist, excluding the USA and Canada.

Josh Disbrow, Aytu BioScience's CEO commented: "We are excited to add another approved product to our portfolio. Given the substantial overlap in prescribers of testosterone replacement therapies, and Natesto in particular, and anti-insomnia treatments, the company plans to market both Natesto and ZolpiMist to the primary care physicians we already call on. Our prescribers have embraced the novel nasal delivery of Natesto for the treatment of hypogonadism, and likewise, we believe that ZolpiMist's uniquely-delivered oral spray will present a unique, complementary clinical story in a similarly large, adjacent therapeutic category."

Insomnia is the most common specific sleep disorder, with short-term sleep issues reported by about 30% of US adults. For the twelve months ending February 2018, sales in the US prescription sleep aid category were US\$1.8 billion. Over this period, there were over 43 million prescriptions of non-benzodiazepine sleep aids written in the USA, and zolpidem tartrate tablets (brand name Ambien®) was the most commonly prescribed. More than 30 million prescriptions of various forms of zolpidem tartrate are prescribed annually in the USA.

ZolpiMist's unique oral spray formulation enables high bioavailability via rapid absorption through the oral mucosa and no first-pass metabolism through the liver, resulting in a rapid onset of sleep.

SUDA's CEO, Mr Stephen Carter, commented: "We are pleased that Magna Pharmaceuticals has licensed ZolpiMist to Aytu BioScience in the USA and Canada. Aytu is well placed to build further awareness of this novel oral spray for insomnia and to grow prescription demand in the US market through its direct sales force. The success of ZolpiMist in the USA enhances our efforts to secure partners and commercialise the product in the rest of the world. We look forward to working with the team at Aytu."



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

About Aytu BioScience, Inc.

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on global commercialisation of novel products addressing significant medical needs. The Company currently markets Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"). 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. Aytu recently licensed exclusive U.S. rights to ZolpiMist™, an FDA-approved, commercial-stage prescription sleep aid indicated for the short-term treatment of insomnia characterised by difficulties with sleep initiation. 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, growing markets. For more information visit www.aytubio.com