

## **Aytu BioScience Announces Exclusive ZolpiMist(TM) License to Commercialize Aytu's Oral Spray Sleep Aid in South Korea**

### ***Aytu BioScience Licensee SUDA Pharmaceuticals Expands ZolpiMist Global Footprint Through Exclusive Licensing Agreement with Mitsubishi Tanabe Pharma Corporation***

**ENGLEWOOD, CO / April 8, 2020** / Aytu BioScience, Inc. (NASDAQ:AYTU) (the "Company"), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that Australia-based SUDA Pharmaceuticals Ltd (ASX: SUD; "SUDA"), a leader in oro-mucosal drug delivery and Aytu's ZolpiMist™ licensing partner outside the U.S. and Canada, has entered into an exclusive license agreement to commercialize ZolpiMist™ in South Korea. The agreement is with Mitsubishi Tanabe Pharma Korea Ltd (MTPK), a wholly owned subsidiary of Mitsubishi Tanabe Pharma Corporation (MTPC) and allows for MTPC to exclusively commercialize ZolpiMist in South Korea.

The agreement between SUDA and MTPC is for an exclusive license for, and supply of, ZolpiMist for a term of ten years from first commercial sale. As part of the agreement SUDA will receive an upfront fee, along with a milestone payment based on MTPK obtaining regulatory approval in South Korea, and commercial milestone payments based on MTPK achieving sales targets. SUDA will also receive a double-digit royalty based on net sales of the product in the territory.

Aytu will receive of portion of the upfront payment, milestone payments, and royalty payments as part of the global sublicensing agreement between Aytu and SUDA as announced on March 6, 2019.

SUDA's obligations include the registration of ZolpiMist with the Australian Therapeutic Goods Administration (TGA) and will be responsible for the supply of ZolpiMist for which SUDA will receive a handling fee.

Josh Disbrow, Aytu BioScience's Chief Executive Officer, commented, "We commend our colleagues at SUDA as they continue to build out the global footprint for ZolpiMist through this licensing agreement in South Korea. Mitsubishi Tanabe is a leading, world-class Japanese pharmaceutical company, and we expect their commercial efforts in South Korea to enable a successful launch and growth of the ZolpiMist brand. We wish both parties well as they pursue regulatory approvals in both Australia and South Korea and, pending such approval, a successful launch of this novel, fast-acting sleep aid."

#### **About Aytu BioScience, Inc.**

Aytu BioScience, Inc. is a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant patient needs. The Company

currently markets a portfolio of prescription products addressing large primary care and pediatric markets. The primary care portfolio includes (i) Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or “Low T”), (ii) ZolpiMist™, the only FDA-approved oral spray prescription sleep aid, and (iii) Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup. The pediatric portfolio includes (i) AcipHex® Sprinkle™, a granule formulation of rabeprazole sodium, a commonly prescribed proton pump inhibitor; (ii) Cefaclor, a second-generation cephalosporin antibiotic suspension; (iii) Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions; and (iv) Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various for infants and children with fluoride deficiency. Aytu recently acquired exclusive U.S. distribution rights to the COVID-19 IgG/IgM Rapid Test. This coronavirus test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. This point-of-care test has been validated in a 126 patient clinical trial in China and has received CE marking.

Aytu recently acquired Innovus Pharmaceuticals, a specialty pharmaceutical company commercializing, licensing and developing safe and effective consumer healthcare products designed to improve men’s and women’s health and vitality. Innovus commercializes over thirty-five consumer health products competing in large healthcare categories including diabetes, men’s health, sexual wellness and respiratory health. The Innovus product portfolio is commercialized through direct-to-consumer marketing channels utilizing the Company’s proprietary Beyond Human® marketing and sales platform.

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](http://aytubio.com) and visit [innovuspharma.com](http://innovuspharma.com) to learn about the Company’s consumer healthcare products.

## **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 by Aytu BioScience, Inc. 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](http://www.sudapharma.com)**

### **About Mitsubishi Tanabe Pharma Corporation (MTPC)**

Mitsubishi Tanabe Pharma Corporation, which was founded in 1678, has its headquarters in Doshomachi, Osaka, Japan, which is the birthplace of Japan's pharmaceutical industry. Mitsubishi Tanabe Pharma Korea (MTPK) is based in Seoul with the parent company MTPC. The Mitsubishi Tanabe Pharma corporate philosophy is to "contribute to the healthier lives of people around the world through the creation of pharmaceuticals." This philosophy expresses how they have returned to the basics of the discovery of pharmaceuticals and puts the fundamental purpose into words. In line with this philosophy, they strive to be a global research-driven pharmaceutical company that is trusted by society. Going forward, in accordance with the Group's shared values that "everything we do is for the patients," we will work to fulfil our social mission as a life sciences company by creating pharmaceuticals that are useful to people around the world and delivering those pharmaceuticals to patients

**For more information, visit <https://www.mt-pharma.co.jp/e/>**

### **About ZolpiMist**

ZolpiMist is a first-in-class, FDA-approved, cherry-flavoured, fast-acting oral spray of zolpidem tartrate (marketed under the brand name of Ambien® in the United States), a non-benzodiazepine prescribed for the treatment of insomnia. It provides a convenient and easy-to-use alternative route of administration, by delivering a therapeutic dose with one or two actuations of the spray into the oral cavity. The pivotal studies demonstrated bioequivalence of ZolpiMist 5mg and 10mg doses with the respective Ambien tablets. ZolpiMist advantages include patient convenience, and ease of use as it is administered without the need of water, unlike conventional tablets. Also, it can benefit patients experiencing difficulties in swallowing and/or suffering with gastrointestinal (GI) disorders that restrict the absorption of drugs via the GI mucosa.

### **Forward-Looking Statement**

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. All statements other than statements of historical facts contained in this presentation, are forward-looking statements. Forward-looking statements are generally written in the future tense and/or are preceded by words such as 'may,' 'will,' 'should,' 'forecast,' 'could,' 'expect,' 'suggest,' 'believe,' 'estimate,' 'continue,' 'anticipate,' 'intend,' 'plan,' or similar words, or the negatives of such terms or other variations on such terms or comparable terminology. These statements are just predictions and are subject to

risks and uncertainties that could cause the actual events or results to differ materially. These risks and uncertainties include, among others: market and other conditions associated with prospective commercialization of ZolpiMist in South Korea, the regulatory and commercial risks associated with introducing the COVID-19 Rapid Test, our ability to enforce the exclusivity provisions of the distribution agreement, the reliability of serological testing in detecting COVID-19, shipping delays and their impact on our ability to introduce the COVID-19 Rapid Test, the ability of the COVID-19 Rapid Test to accurately and reliably test for COVID-19, the manufacturer of the COVID-19 Rapid Test's ability to manufacture such testing kits on a high volume scale, manufacturing problems or delays related to the COVID-19 Rapid Test, our ability to satisfy any labelling conditions or other FDA or other regulatory conditions to sell the COVID-19 Rapid Test Kit, the demand or lack thereof for the COVID-19 Rapid Test Kit, our ability to obtain additional COVID-19 Rapid Tests to meet demand, our ability to secure additional tests if the manufacture of the COVID-19 Rapid Tests is unable to meet demand, the effects of the business combination of Aytu and the Commercial Portfolio and the recently completed merger ("Merger") with Innovus Pharmaceuticals, including the combined company's future financial condition, results of operations, strategy and plans, the ability of the combined company to realize anticipated synergies in the timeframe expected or at all, changes in capital markets and the ability of the combined company to finance operations in the manner expected, the diversion of management time on Merger-related issues and integration of the Commercial Portfolio, the ultimate timing, outcome and results of integrating the operations the Commercial Portfolio and Innovus with Aytu's existing operations, risks relating to gaining market acceptance of our products, obtaining or maintaining reimbursement by third-party payors for our prescription products, the potential future commercialization of our product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results, of our ongoing and future clinical trials, the anticipated designs of our future clinical trials, anticipated future regulatory submissions and events, our anticipated future cash position and future events under our current and potential future collaboration. We also refer you to the risks described in 'Risk Factors' in Part I, Item 1A of the company's Annual Report on Form 10-K and in the other reports and documents we file with the Securities and Exchange Commission from time to time.

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