Aytu BioScience Announces Regulatory Approval of ZolpiMist(R) by Australian Therapeutic Goods Administration

Aytu BioScience's Sublicensee SUDA Pharmaceuticals Secures TGA Approval, Enabling Near-Term Commercialization of ZolpiMist

ENGLEWOOD, CO / July 30, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company (the "Company") focused on commercializing novel products that address significant patient needs, today announced the approval of ZolpiMist® (zolpidem tartrate oral spray) by the Therapeutic Goods Administration (TGA) in Australia. This approval, which was secured by the Company's ZolpiMist sublicensee SUDA Pharmaceuticals Ltd ("SUDA"), enables near-term commercialization of ZolpiMist in Australia. SUDA (ASX:SUD) is a publicly-listed drug delivery company focused on oro-mucosal administration and is headquartered in Perth, Western Australia.

With this approval by Australia's TGA, ZolpiMist will be included on the Australian Register of Therapeutic Goods and can now be commercialized and supplied within Australia. Further, this approval will assist SUDA's current ZolpiMist sublicensees, Teva Pharmaceuticals, Mitsubishi Tanabe Pharma Singapore and MTP Korea, in their submissions in their respective territories.

On March 9, 2010 Aytu BioScience announced a global distribution agreement for ZolpiMist with SUDA whereby the Company assumed a milestone and royalty-based licensing agreement with SUDA. As specified in the companies' global licensing agreement, SUDA will pay Aytu a portion of each upfront and milestone payment received from sublicensees, and Aytu will receive ongoing royalty payments on sales generated by SUDA's sublicensees as ZolpiMist is launched in each territory.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, stated, "We congratulate the SUDA team for obtaining TGA approval for ZolpiMist and look forward to SUDA and their partners moving ZolpiMist closer to commercialization in Australia and elsewhere. This is an exciting time for SUDA and represents an important milestone for Aytu as we move closer to realizing ex-US licensing revenue for ZolpiMist."

Dr. Michael Baker, Chief Executive Officer and Managing Director of SUDA, commented, "The TGA submission was a combined effort by SUDA's technical team as well as our regulatory consultant, Pharma To Market. Obtaining the approval indicates the calibre of our staff and is also 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."

The global sleep aid market is currently estimated at almost $50 billion in annual revenue, and annual revenue is estimated to reach nearly $80 billion in 2022.

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 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 also distributes a 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.

Aytu also operates a subsidiary focused on consumer health, Innovus Pharmaceuticals, Inc. ("Innovus"), 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 Rx and consumer health products, leveraging its focused commercial team and expertise to build leading brands within large therapeutic markets. For more information visit aytubio.com and visit 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 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

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, the regulatory and commercial risks associated with introducing the COVID-19 rapid test, the effectiveness of the COVID-19 rapid rest, market acceptance of the National Cancer Institute or other independently conducted studies' testing results, the regulatory, clinical, and commercial risks associated with the investigational Healight device, effects of the business combination of Aytu and the Commercial Portfolio and the 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, including the risks associated with ZolpiMist's commercial success in Australia and elsewhere, 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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