Aytu BioScience Announces First ZolpiMist(TM) Clinical Study Results Demonstrating More Rapid Sleep Onset with Lingual Spray Zolpidem versus Oral Tablet

ZolpiMist Clinical Study Results Demonstrating Lingual Spray Delivers More Rapid Sleep Onset Compared to Tablet Form of Zolpidem Based on Efficacy Parameters and Pharmacokinetics

ENGLEWOOD, CO / August 5, 2019 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, announced today the publication of a clinical study in the journal *Pharmacy and Pharmacology,* demonstrating that ZolpiMist, Aytu BioScience'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."

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.

Forward-Looking Statements

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: risks relating to gaining market acceptance of our products, obtaining or maintaining reimbursement by third-party payors, 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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