# Aytu BioScience and Validus Pharmaceuticals Announce ZolpiMist Co-Promotion Agreement and Launch Into the \$163 Million Psychiatry Market

Co-Promotion Expands Physician Promotion of Aytu's Prescription Sleep Aid with Dedicated Specialty Sales Force, into Psychiatry Market, Which Accounted for Over 2.7 Million Zolpidem Tartrate Prescriptions for The Twelve Months Ending August 2019

Aytu's third announced product co-promotion and has expanded Natesto®,
Tuzistra® XR, and ZolpiMist promotional efforts to over 100 sales representatives
nationwide

ENGLEWOOD, CO and PARSIPPANY, NJ / October 2, 2019 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs and Validus Pharmaceuticals LLC ("Validus"), a privately-held specialty pharmaceutical company focused on acquiring, reformulating, and marketing prescription products in specialty therapeutic areas, today announced the signing of a co-promotion agreement to exclusively commercialize ZolpiMist™ to psychiatrists in the United States. For the twelve months ending August 2019, U.S. psychiatrists wrote over 2.7 million zolpidem tartrate prescriptions, representing \$163 million in wholesale revenue.

This represents Aytu's third announced product co-promotion and has expanded Natesto®, Tuzistra® XR, and ZolpiMist promotional efforts to over 100 sales representatives nationwide.

Validus is a commercial-stage, private equity-backed specialty pharmaceutical company with a focused psychiatry sales force. Validus began ZolpiMist promotion October 1, 2019.

Through this co-promotion, Validus gains exclusive promotional rights to ZolpiMist to psychiatrists and will receive a fixed percentage commission payment based on total psychiatrist prescriptions written. The agreement term is three years and allows for Validus' expansion of promotion to all U.S. psychiatrists.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "Validus is an ideal partner with which to expand our promotional efforts for ZolpiMist. Their established commercial capability and strong relationships with psychiatrists, who are prolific prescribers of sleep aids, make Validus an excellent fit to grow ZolpiMist prescriptions in a specialty we don't currently reach. Further, this partnership enables our sales force to focus on primary care and provides for promotion by an experienced sales team in this high-prescribing specialty in key markets around the country."

John Kinney, Chief Executive Officer of Validus, stated, "We are excited to bring ZolpiMist to psychiatrists and look forward to a long, successful relationship with Aytu. Psychiatrists are

the primary focus of our specialty sales team and we're pleased to leverage our capabilities to educate the market on a novel product like ZolpiMist along with our established psychiatry product portfolio."

## 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<sup>™</sup>, 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 extendedrelease 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.

#### **About Validus Pharmaceuticals**

Validus Pharmaceuticals is a Parsippany, New Jersey-based specialty pharmaceutical company focused on the acquisition, reformulation, and marketing of FDA-approved prescription products that satisfy unmet clinical needs. To fulfill this mission, Validus acquires and partners on marketed products that have well-established safety profiles and clinical benefits. Validus' marketed psychiatry portfolio includes Equetro®, Marplan®, and ZolpiMist™.

## **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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