Aytu BioPharma Announces Positive Preclinical Data in Ventilator-Associated Pneumonia with its Novel, Proprietary Healight™ Delivery Technology

Preclinical Proof-of-Concept Study Demonstrates Effectiveness of Healight in Delaying Time to Development of Ventilator-Associated Pneumonia

ENGLEWOOD, CO / April 25, 2022 / Aytu BioPharma, Inc. (NASDAQ:AYTU), a pharmaceutical company focused on developing and commercializing novel therapeutics, today announced positive results from a preclinical pilot study showing that administration of its Healight™ ultraviolet light A (UVA) endotracheal catheter delayed the time to development of ventilator-associated pneumonia (VAP) in a novel porcine model. Healight is the company's patented, investigational medical device technology employing proprietary methods of administering intermittent UVA light delivered via a novel respiratory endotracheal catheter.

VAP has a reported mortality rate approaching 50% in some patient populations, making it one of the most difficult-to-treat and deadly infections affecting hospitalized patients. Approximately 86% of nosocomial pneumonias are associated with mechanical ventilation and result in VAP. Between 250,000 and 300,000 VAP cases per year occur in the United States alone, which is an incidence rate of 5 to 10 cases per 1,000 hospital admissions. VAP afflicts up to 15% of mechanically ventilated patients in intensive care units.

Aytu's proof-of-concept study with Healight was conducted at Hospital Clinic de Barcelona under the supervision of principal investigator Antonio Torres, M.D., Ph.D., FERS, FCCP, ATSF, Senior Consultant, Pulmonology Department – one of the only centers in the world with access to this well-characterized porcine model of VAP caused by oropharyngeal secretions colonized by *Pseudomonas aeruginosa*. In the study, administration of the Healight UVA endotracheal catheter resulted in a 46% reduction in multidrug-resistant *Pseudomonas aeruginosa* (PA C1-17) versus controls following two separate 20-minute treatments. Based on these positive data, Hospital Clinic de Barcelona and Aytu have initiated a second, larger porcine VAP study to guide the future development of Healight for patients with VAP.

"Data from this study are critically important as they establish proof-of-concept for Healight as a potential treatment for VAP, a frequently occurring and life-threatening infection that develops in severely ill ventilated patients, which results in poor clinical outcomes and high rates of mortality," said Josh Disbrow, chief executive officer of Aytu BioPharma. "VAP is an area of tremendous clinical need, and our mission is to bring therapeutic solutions to patients with complex diseases. We're very encouraged by these positive data that demonstrate the effectiveness of Healight in a well-established and validated model. We look forward to advancing Healight into the next phase of development in VAP and evaluating potential additional indications that could benefit from our novel delivery technology."

Aytu plans to report data from the ongoing, larger preclinical study of Healight in VAP later in 2022, which will guide the company's development plans in VAP and potential additional indications.

About Healight

Healight is a patented, investigational medical device technology employing proprietary methods of administering intermittent ultraviolet (UV)-A light via a novel respiratory endotracheal catheter. Originally developed at Cedars-Sinai Medical Center, Aytu BioPharma owns an exclusive worldwide license for all respiratory applications of the Healight UV-A light-based technology. Proof of concept clinical findings for Healight demonstrated significant reductions in SARS-CoV-2 viral load and improvement in clinical outcomes in a small number of mechanically ventilated SARS-CoV-2 patients. Earlier published preclinical findings indicated the technology's significant impact on eradicating a wide range of viruses and bacteria, inclusive of human coronavirus. Pre-clinical studies are now underway to assess the safety and efficacy of Healight in ventilator-associated pneumonia.

About Aytu BioPharma, Inc.

Aytu BioPharma is a pharmaceutical company with a portfolio of commercial prescription therapeutics and consumer health products, and a growing therapeutics pipeline focused on treating rare, pediatric-onset disorders. The company's prescription products include Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) and Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) for the treatment of attention deficit hyperactivity disorder (ADHD), as well as Karbinal® ER (carbinoxamine maleate), an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency. Aytu is also building a therapeutic pipeline, which includes AR101 (enzastaurin), a PKCβ inhibitor in development for the treatment of vascular Ehlers-Danlos Syndrome (VEDS). VEDS is a rare genetic disease typically diagnosed in childhood resulting in high morbidity and a significantly shortened lifespan, and for which there are no currently approved treatments. AR101 has received Orphan Drug designation and Fast Track designation from the U.S. Food and Drug Administration and has received Orphan Drug designation from the European Medicines Agency. Aytu is also researching and advancing the development of the Healight ultraviolet light A (UVA) endotracheal catheter, a patented, investigational medical device with potential application in the treatment of severe, difficult-to-treat respiratory infections. To learn more, please 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 press release, 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. Forward-looking statements, including but not limited to any statements regarding the intellectual property and product information presented in this press release. 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: the future growth potential of our commercial portfolio and the anticipated start dates, durations and completion dates of the pre-clinical and clinical studies associated with our product candidates and the potential safety and efficacy of our product candidates. We also refer you to the risks described in ‘Risk Factors’ in Aytu’s Annual and Quarterly Reports on Form 10-K and 10-Q and in the other reports and documents it files with the Securities and Exchange Commission.

Contact:

Chelcie Lister
THRUST Strategic Communications
chelcie@thrustsc.com

SOURCE: Aytu BioPharma, Inc.

View source version on accesswire.com:
https://www.accesswire.com/698448/Aytu-BioPharma-Announces-Positive-Preclinical-Data-in-Ventilator-Associated-Pneumonia-with-its-Novel-Proprietary-HealightTM-Delivery-Technology