Aytu BioPharma Announces Peer-Reviewed Publication of Clinical Results from Healight(TM) Pilot Study

Results Indicate That Endotracheal UVA Light Catheter Therapy is Associated with Significant Reduction in SARS-CoV-2 Viral Load and Improvement in Clinical Outcomes in Mechanically Ventilated COVID-19 Patients

ENGLEWOOD, CO / June 28, 2021 / Aytu BioPharma, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, announced today that data from the first in-human, open label, clinical trial studying the safety and effectiveness of ultraviolet A (UVA) light endotracheal catheter therapy was published online on June 26, 2021 in the peer-reviewed journal *Advances In Therapy*. The UVA light catheter technology utilized in this study is the basis of Aytu BioPharma's Healight™ medical device which has been exclusively licensed worldwide for all endotracheal and nasopharyngeal applications.

The study titled, "*Endotracheal application of ultraviolet A light in critically ill patients infected with severe acute respiratory syndrome coronavirus-2: A first-in-human study of internal ultraviolet A therapy"* concluded that endotracheal UVA light treatment was associated with a significant reduction of SARS-CoV-2 viral load and improvement in WHO clinical severity scores. Additionally, the endotracheal UVA light treatment did not result in any serious adverse device effects and was well tolerated.

A total of five critically ill, mechanically ventilated COVID-19 patients underwent daily UVA light therapy for five consecutive days at a single U.S. center. The UVA light catheter was inserted into the patients' endotracheal tube (ETT) and illuminated for 20 minutes with each treatment. The endotracheal (ET) treatment resulted in significant logarithmic reduction of the SARS-CoV-2 viral load of the ET aspirate, which was the study's primary endpoint. Average log changes from baseline to day five and day six were -2.41 (>99%, p=0.0018) and -3.2 (>99.9%, p=0.0005), respectively. WHO 10-point clinical severity scores improved by an average of 1.6 and 3.6 points on day 15 and day 30, respectively. Excluding subject two who had undetectable viral load, WHO severity scores improved by 4.75 points on day 30. Importantly, no serious adverse device effects or early treatment discontinuation was observed in the study.

Josh Disbrow, Chief Executive Officer of Aytu BioPharma, commented, "These important proof-of-concept first-in-human clinical trial data for the technology underpinning the Healight technology have now been peer-reviewed and published. This pilot study shows the potential clinical utility in treating mechanically ventilated SARS-CoV-2 patients and sets the stage for a larger, sham-controlled clinical study soon to be underway in Europe. That study will include significantly more patients in a well-controlled, randomized clinical trial, and we expect that study to begin in the first quarter of fiscal 2022."

Aside from coronavirus, utilization of internal UVA light may have numerous other clinical applications. Aytu BioPharma will continue to engage with researchers in all therapeutic areas to continue to build on this technology platform.

The peer-reviewed publication can be accessed via the link below:

https://link.springer.com/article/10.1007/s12325-021-01830-7

About Aytu BioPharma, Inc.

Aytu BioPharma is a specialty pharmaceutical company with a growing commercial portfolio of prescription therapeutics and consumer health products. The company's primary prescription products treat attention deficit hyperactivity disorder (ADHD) and other common pediatric conditions. Aytu markets ADHD products Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING), Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING), and Adzenys-ER® (amphetamine) extended-release oral suspension (see Full Prescribing Information, including Boxed WARNING). The company's other pediatric products include 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. The company's evolution has been driven by strategic in-licensing, acquisition-based transactions and organic product growth. Aytu is building a complimentary therapeutic development pipeline including a prospective treatment (AR101/enzastaurin) for vascular Ehlers-Danlos Syndrome (vEDS), a rare genetic disease resulting in high morbidity and a significantly shortened lifespan. There are no currently approved treatments for vEDS. 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. All statements other than statements of historical facts contained in this presentation, are forward-looking statements, including but not limited to any statements regarding the financial results and statements presented in this press release and during the business update call following its 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 anticipated start dates, durations and completion dates and the potential future results of ongoing and future Healight clinical trials, the effectiveness of Healight on treating COVID-19, the accuracy of the results of the study, Healight's potential uses for ventilator assisted patients, potential other clinical uses for Healight and the anticipated future regulatory submissions and events related to Healight. We also refer you to (i) the risks described in 'Risk Factors' in Part I, Item 1A of Aytu's Annual Report on Form 10-K and in the other reports and documents it files with the Securities and Exchange Commission and (ii) the Risk Factors set forth in Aytu's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC.

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https://www.accesswire.com/653324/Aytu-BioPharma-Announces-Peer-Reviewed-Publication-of-Clinical-Results-from-HealightTM-Pilot-Study