Aytu BioScience Announces Positive Clinical Results from Healight(TM) Pilot Study in SARS-CoV-2 Patients

Data indicate endotracheal UVA light catheter therapy reduces SARS-CoV-2 viral load and improves clinical outcomes in mechanically ventilated SARS-CoV-2 patients

ENGLEWOOD, CO / March 8, 2021 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, announced today that data from a first in-human, open label, clinical trial in SARS-CoV-2 patients has been released.

The pre-print publication titled "Endotracheal application of ultraviolet A light in critically ill severe acute respiratory syndrome coronavirus-2 patients: A first-in-human study" 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 UVA light therapy for five consecutive days. The UVA light catheter was inserted into an endotracheal tube (ETT) and illuminated for 20 minutes during 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 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 clinical severity scores improved by 4.75 points on day 30. Importantly, no serious adverse device effects were observed, and no early treatment discontinuation occurred.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "We believe the Healight technology can become an important tool for fighting the global COVID-19 pandemic, and we look forward to continuing discussions with the FDA on the advancement of this technology. There may be additional anti-infective applications for Healight beyond COVID-19, so having this initial proof of concept data gives us a great deal of enthusiasm for the potential of this investigational device. I would like to thank the team and our collaborators for the work that went into conducting this study and generating this data."

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

The data have been published in MedRxiv, an online archive for health science pre-print manuscripts that are not yet peer reviewed. The manuscript has been submitted for peer review.

The complete study manuscript can be accessed at:

https://www.medrxiv.org/content/10.1101/2021.03.05.21252997v1.article-metrics

About Aytu BioScience, Inc.

Aytu BioScience is a commercial-stage specialty pharmaceutical company focused on commercializing novel products that address significant patient needs. Aytu currently markets a portfolio of prescription products addressing large primary care and pediatric markets. The portfolio includes Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"), ZolpiMist®, the only FDA-approved oral spray prescription sleep aid, Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup, Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency. Aytu also distributes a COVID-19 IgG/IgM rapid antibody test and a rapid COVID-19 antigen test. These tests are used separately in the rapid, qualitative diagnostic assessment of the 2019 Novel Coronavirus. Additionally, Aytu has licensed worldwide rights to develop the Healight™ technology platform. Healight is an investigational medical device being studied as a prospective treatment for COVID-19 and other respiratory infections.

Aytu operates a consumer health subsidiary, Aytu Consumer Health that licenses and develops safe and effective consumer healthcare products designed to improve men's and women's health and vitality. Aytu Consumer Health commercializes numerous novel consumer health products competing in large healthcare categories including diabetes, men's health, sexual wellness, respiratory health, and general wellness. The Aytu Consumer Health 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.

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 results of the Healight clinical studies, the effectiveness of Healight in treating SARS-CoV-2, the effectiveness of Healight as compared to other treatments of SARS-CoV-2, the safety of Healight as compared to other treatments of SARS-CoV-2, the outcomes of discussions relating to Healight with regulators including the Food & Drug Administration (FDA), the commercial plans involving Healight, and other forward-looking aspects related to the Healight program. 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: our future financial results, the results of the Healight clinical program and outcomes of regulatory discussions, failure to obtain the required votes of Neos’ shareholders or Aytu’s shareholders to approve the recently announced Neos merger transaction and related matters, the risk that a condition to closing of the proposed transaction may not be satisfied, that either party may terminate the merger agreement or that the closing of the proposed transaction might be delayed or not occur at all, potential adverse reactions or changes to business or employee relationships, including those resulting from the announcement or completion of the transaction, the diversion of management time on transaction-related issues, the ultimate timing, outcome and results of integrating the operations of Aytu and Neos, the effects of the business combination of Aytu and Neos, 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, regulatory approval of the transaction, risks relating to gaining market acceptance of our products, obtaining reimbursement by third-party payors, the potential future commercialization of the combined company’s product candidates, the anticipated start dates, durations and completion dates, as well as the potential future results, of the combined company’s ongoing and future clinical trials, the anticipated designs of the combined company’s future clinical trials, anticipated future regulatory submissions and events, the combined company’s anticipated future cash position and future events under current and potential future collaboration, the regulatory and commercial risks associated with the Company’s distributed COVID-19 rapid tests, the accuracy of the COVID-19 rapid tests as compared to other COVID-19 tests, market acceptance of the tests, the ability to obtain FDA approval or authorization for the tests, our ability to obtain sufficient tests to meet consumer demand, if any, the manufacturers’ ability to meet customer demand, if any, reputation risks if the tests are not as effective as anticipated, and that the current regulatory environment continues to

permit the sale of the tests.

Contact for Media and Investors:

Sarah McCabe
Stern Investor Relations
sarah.mccabe@sternir.com

SOURCE: Aytu BioScience, Inc.

View source version on accesswire.com:
https://www.accesswire.com/634168/Aytu-BioScience-Announces-Positive-Clinical-Results-from-HealightTM-Pilot-Study-in-SARS-CoV-2-Patients