

Aytu BioScience Announces Completion of Healight(TM) Safety Study in Critically Ill COVID-19 Patients

First Safety Study Utilizing Ultraviolet A Light Catheter as a Prospective Anti-Infective in Critically Ill, Intubated SARS-Cov-2 Patients

ENGLEWOOD, CO / December 28, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company (the "Company") focused on commercializing novel products that address significant patient needs announced the completion of the safety study evaluating the Healight™ ultraviolet A light catheter technology. This single center, U.S.-based study evaluated the safety and proof of principle of the Healight device in newly intubated critically ill patients on mechanical ventilation diagnosed with COVID-19.

The data collected from this clinical investigational-use-only study will be presented to the U.S. Food & Drug Administration (FDA) as part of the review process for Healight as a COVID-19 treatment. The results from this study will also be submitted for publication.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "This is an important milestone, and we look forward to continuing discussions with the FDA on the advancement of the Healight technology."

The Healight technology platform employs proprietary methods of administering intermittent ultraviolet (UV) A light via a novel respiratory tract device. Pre-clinical findings indicate the technology's significant impact on reducing a wide range of viral and bacterial loads, including the coronavirus HCoV-229E, which is associated with the common cold. Recently published pre-clinical data have been the basis of discussions with the FDA for a path to enable human use for the potential treatment of SARS-CoV-2 in intubated patients in the intensive care unit (ICU).

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 primary care portfolio includes (i) Natesto®, the only FDA-approved nasal formulation of testosterone for men with hypogonadism (low testosterone, or "Low T"), (ii) ZolpiMist®, the only FDA-approved oral spray prescription sleep aid, and (iii) Tuzistra® XR, the only FDA-approved 12-hour codeine-based antitussive syrup. The pediatric portfolio includes (i) Cefaclor, a second-generation cephalosporin antibiotic suspension; (ii) Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions; and (iii) 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 recently 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, Innovus Pharmaceuticals, Inc. (“Innovus”), a specialty pharmaceutical company commercializing, licensing and developing safe and effective consumer healthcare products designed to improve men’s and women’s health and vitality. Innovus commercializes numerous novel consumer health products competing in large healthcare categories including diabetes, men’s health, sexual wellness, respiratory health, and general wellness. The Innovus 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 and visit innovuspharma.com to learn about Aytu’s consumer healthcare products.

Forward-Looking Statement

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 outcomes of discussions relating to Healight with regulators including the Food & Drug Administration (FDA), the commercial potential of 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: the results of the Healight clinical program and outcomes of regulatory discussions, the intended use of net proceeds from the recently completed public offering, 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 introducing 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 scale up manufacturing 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:

James Carbonara
Hayden IR
(646) 755-7412
james@haydenir.com

SOURCE: Aytu BioScience, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/622381/Aytu-BioScience-Announces-Completion-of-HealightTM-Safety-Study-in-Critically-Ill-COVID-19-Patients>