Aytu BioScience Secures Exclusive U.S. Distribution Agreement for Coronavirus 2019 (COVID-19) Point-of-Care Rapid Test

Company Expects to Pursue Commercial Use Under FDA's Emergency Use Authorization

ENGLEWOOD, CO / March 10, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that it signed an exclusive distribution agreement for the right to commercialize a clinically validated and commercially used coronavirus 2019 (COVID-19) IgG/IgM Rapid Test. The test has been licensed from L.B. Resources, Limited (a Hong Kong Corporation), which licensed North American rights from product developer Zhejiang Orient Gene Biotech Co., Ltd. The test is intended for professional use and delivers clinical results between 2 and 10 minutes at the point-of-care. This exclusive agreement grants Aytu the exclusive right to distribute the product in the United States for a period of three years, with additional three-year autorenewals thereafter.

The COVID-19 IgG/IgM Rapid Test is a solid phase immunochromatographic assay used in the rapid, qualitative and differential detection of IgG and IgM antibodies to the 2019 Novel Coronavirus in human whole blood, serum or plasma. This point-of-care test has been validated in a 113 patient clinical trial and has received CE marking. It is currently one of only a few tests used for coronavirus screening in China.

Test Features:

- Results reported in 2-10 minutes
- Facilitates patient treatment decisions quickly
- Simple, time-saving procedure
- Small specimens, only 5 µL of serum/plasma or 10 µL of whole blood specimens required
- All necessary reagents provided & no equipment needed
- High sensitivity and specificity

Clinical Results

The COVID-19 IgG/IgM Rapid Test was evaluated with 113 blood samples obtained from patients exhibiting pneumonia or respiratory symptoms. All samples were tested using the Orient Gene diagnostic device, and the results were compared to RT-PCR or clinical diagnosis (including chest Computed Tomography and clinical signs and symptoms) of Novel Coronavirus pneumonia.

Clinical results using the COVID-19 IgG/IgM Rapid Test show:

1. The sensitivity of the IgM test is 87.9% (87/99) and specificity is 100% (14/14) when compared to RT-PCR.
2. The sensitivity of the IgG test is 97.2% (35/36) during patients' convalescence period and specificity is 100% (14/14).

The Company expects to pursue U.S. regulatory clearance and expects to consult with the U.S. Food and Drug Administration about qualifying the test under FDA's Emergency Use Authorization.

The Company expects to receive an initial product shipment in three to four weeks, pending the timing of required regulatory, customs, and importation activities.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "The safety and health of every American is of paramount importance to the company as we face the threat of the coronavirus. We are excited to be able to work with U.S. regulatory authorities, and we will work to make this important test available in the U.S. as soon as possible. Coronavirus is a major global health concern, and we are proud to be in a position to help clinicians address this very serious public health concern."

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 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) AcipHex® Sprinkle™, a granule formulation of rabeprazole sodium, a commonly prescribed proton pump inhibitor; (ii) Cefaclor, a second-generation cephalosporin antibiotic suspension; (iii) Karbinal® ER, an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions; and (iv) Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary prescription fluoride-based supplement product lines containing combinations of fluoride and vitamins in various for infants and children with fluoride deficiency.

Aytu recently acquired Innovus Pharmaceuticals, 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 over thirty-five consumer health products competing in large healthcare categories including diabetes, men's health, sexual wellness and respiratory health. 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 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 the company'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 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: the regulatory and commercial risks associated with introducing the COVID-19 Rapid Test, effects of the business combination of Aytu and the Commercial Portfolio and the previously announced, but not yet consummated, merger ("Merger") with Innovus Pharmaceuticals, 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, the diversion of management time on Merger-related issues and integration of the Commercial Portfolio, the ultimate timing, outcome and results of integrating the operations the Commercial Portfolio and Innovus with Aytu's existing operations, the failure to obtain the required votes of Innovus' shareholders or Aytu's shareholders to approve the Merger and related matters, the risk that a condition to closing of the Merger may not be satisfied, that either party may terminate the merger agreement or that the closing of the Merger might be delayed or not occur at all, the price per share utilized in the formula for the initial $8 million merger consideration in the Merger may not be reflective of the current market price of Aytu's common stock on the closing date, potential adverse reactions or changes to business or employee relationships, including those resulting from the announcement or completion of the Merger, 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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