Aytu BioScience Announces Exclusive Distribution Agreement for COVID-19 IgG/IgM Rapid Test with Singapore-Based Biolidics Limited

ENGLEWOOD, CO / April 23, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU) (the "Company"), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs, announced the signing of a definitive agreement (the "Agreement") with Singapore-based Biolidics, Limited (SGX: 8YY; "Biolidics") to exclusively distribute Biolidics' COVID-19 IgG/IgM Rapid Test in the United States.

Under the terms of the Agreement, Aytu will exclusively distribute Biolidics' COVID-19 IgG/IgM rapid antibody test in the United States. Aytu has committed to purchase 500,000 tests within one business day from the date of signing of the Agreement. As an additional component of Aytu's exclusivity, the Company has committed to purchase a minimum of 1,250,000 tests within the first three months of the Agreement.

Biolidics' COVID-19 IgG/IgM Rapid Test has been issued Provisional Authorization for distribution by Singapore's Health Science's Authority (HSA), and the product has been authorized for export from Singapore. Biolidics' COVID-19 IgG/IgM Rapid Test will be supplied from Biolidics' facility in Singapore.

Aytu will collaborate with Biolidics and lead the U.S. clinical trials processes and plans to complete and obtain U.S. Food and Drug Administration ("FDA") 510k regulatory filing clearance of the COVID-19 IgG/IgM rapid test kits.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "We are pleased to be partnering with Biolidics in distributing this COVID-19 rapid test in the U.S. With the continued call in the United States for increased COVID-19 testing, we are entering this distribution Agreement at an excellent time. We have experienced significant demand for our current COVID-19 rapid test, so adding this test to our product offering will enable us to better meet the high demand in the U.S. We look forward to a productive working relationship with Biolidics and thank them for their confidence in allowing Aytu to take this product to market in the United States."

Incorporated in 2009 and listed on the Singapore Stock Exchange, Biolidics Limited is a Singapore-based precision medicine medical technology company with a focus in developing a portfolio of innovative diagnostic solutions to lower healthcare costs and improve clinical outcomes.

About Aytu BioScience, Inc.

Aytu BioScience, Inc. 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 U.S. distribution rights to two COVID-19 IgG/IgM rapid tests. These coronavirus tests are solid phase immunochromatographic assays 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.

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: our ability to successfully commercialize Healight Platform Technology, our ability to obtain FDA approval for the Healight Platform Technology, the effectiveness of the Healight Platform Technology in treating patients with

COVID-19 or other illnesses, our ability to adequately protect the intellectual property associated with the Healight Platform Technology, regulatory delays, the reliability of the Healight Platform Technology in killing viruses and bacteria, market acceptance of UV based medical devices, risks associated with the our COVID-19 rapid tests including our ability to enforce the exclusivity provisions of the distribution agreements, the reliability of serological testing in detecting COVID-19, shipping delays and their impact on our ability to introduce the COVID-19 rapid tests, the ability of the COVID-19 rapid tests to accurately and reliably test for COVID-19, the manufacturers of the COVID-19 rapid tests' ability to manufacture such testing kits on a high volume scale, manufacturing problems or delays related to the COVID-19 Rapid Test, our ability to satisfy any labelling conditions or other FDA or other regulatory conditions to sell the COVID-19 rapid test kits, the demand or lack thereof for the COVID-19 rapid test kits, our ability to obtain additional COVID-19 rapid tests to meet demand, our ability to secure additional tests if the manufactures of the COVID-19 rapid tests are unable to meet demand, the effects of the business combination of Aytu and the Commercial Portfolio and the recently completed 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, risks relating to gaining market acceptance of our products, obtaining or maintaining reimbursement by third-party payors for our prescription products, 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.

Contact for Media and Investors:

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

Contact for COVID-19 IgG/IgM Rapid Test and Healight-Related Inquiries:

COVID-19@aytubio.com

SOURCE: Aytu BioScience, Inc.

View source version on accesswire.com:
https://www.accesswire.com/586556/Aytu-BioScience-Announces-Exclusive-Distribution-Agreement-for-COVID-19-IgGIgM-Rapid-Test-with-Singapore-Based-Biolidics-Limited