Aytu BioScience Announces Emergency Use Authorization of COVID-19 IgG/IgM Rapid Test

Fourth FDA Emergency Use Authorization of a COVID-19 IgG/IgM Lateral Flow Rapid Test

1.4 Million Rapid Tests Available for Distribution at Company's Warehouse

ENGLEWOOD, CO / June 1, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company (the "Company") focused on commercializing novel products that address significant medical needs, today announced the U.S. Food and Drug Administration (the "FDA") has granted Emergency Use Authorization (EUA) for the COVID-19 IgG/IgM Rapid Test Cassette distributed by the Company. This is only the fourth lateral flow COVID-19 rapid serology test authorized by the FDA.

Additionally, more than 1.4 million COVID-19 IgG/IgM rapid tests have been delivered to the Company's warehouse in San Diego and are available for distribution.

Emergency Use Authorization of the COVID-19 IgG/IgM Rapid Test Cassette was granted by the FDA on May 29, 2020 to Healgen Scientific, LLC, the U.S. subsidiary of manufacturer Zhejiang Orient Gene Biotech, Limited. Aytu BioScience announced a U.S. distribution agreement to distribute the Zhejiang Orient Gene rapid test on March 10, 2020.

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative test for the detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in whole blood, plasma (Li+-heparin, K2-EDTA and sodium citrate), and serum. The product is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, stated, "This Emergency Use Authorization is an important milestone for the Company in its fight against the COVID-19 pandemic. This EUA establishes the clinical utility of the COVID-19 IgG/IgM Rapid Test in helping to identify individuals demonstrating an immune response to the COVID-19 virus. This test may serve as an important clinical tool as the U.S. and other countries work to reopen businesses and schools and we collectively work to re-establish normalcy in our everyday lives. Further, with more than 1.4 million tests now in stock at our San Diego warehouse, we look forward to serving the medical professionals in need of serology testing. We are proud to be playing a role to help in the COVID-19 health crisis."

The FDA authorization letter for the COVID-19 IgG/IgM Rapid Test Cassette can be found in the link below:

https://www.fda.gov/media/138435/download

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 exclusive 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. The Company also recently signed an exclusive worldwide licensing agreement with Cedars-Sinai to develop the Healight™ technology platform, which is being studied as a potential treatment for COVID-19 and other severe respiratory infections.

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: market and other conditions, 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, the regulatory and commercial risks associated with introducing the COVID-19 rapid tests, any delays in shipment that may impact our ability to distribute the COVID-19 rapid tests, any reputational harm we may incur if there are delays in receiving the shipment of the COVID-19 rapid tests, our ability to enforce various 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 tests, 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 manufacturers 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, and their potential future commercialization.

Contact for Investors:

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

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