COVID-19 IgG/IgM Rapid Test Cassette Distributed by Aytu BioScience Featured in Business Insider Article

Article Reports Results from Independent Study Demonstrating Test's 100% Sensitivity and Specificity for IgM Antibodies and 96.7% and 97.5% Sensitivity and Specificity, Respectively, for IgG Antibodies

ENGLEWOOD, CO / July 27, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company (the "Company") focused on commercializing novel products that address significant patient needs, today shared an article published in *Business Insider* reporting on the performance of over sixty COVID-19 antibody tests, including the COVID-19 IgG/IgM rapid test distributed by the Company. The COVID-19 IgG/IgM rapid test cassette distributed by the Company was reported as one of the few tests with 100% sensitivity and 100% specificity in detecting SARS-CoV-2 IgM antibodies.

The *Business Insider* article, published July 23, 2020, is titled "***A new study evaluated the accuracy of more than 60 coronavirus antibody tests. 13 were a cut above the rest.***"

A link to the article can be found below:

https://www.businessinsider.com/best-coronavirus-antibody-tests-ranked-by-accuracy-2020-7

The new, independent review reported in *Business Insider* was peer-reviewed and published in the journal *Diagnostics* and evaluated more than 60 serological antibody tests on the U.S. market.

A link to the *Diagnostics* peer-reviewed study titled "*COVID-19 Serological Tests: How Well Do They Actually Perform?*" can be found below:

https://www.mdpi.com/2075-4418/10/7/453/htm

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "We continue to observe, in independently conducted studies, the robust performance characteristics of the COVID-19 IgG/IgM rapid test we licensed and now distribute. It is important that clinicians and the public remain informed about the disparity in the performance characteristics of the various serology assays. Based on the *Diagnostics* peer-reviewed publication it is clear we are distributing one of the best performing tests in the category and are pleased to see more independent validation of the test's clinical results."

COVID-19 IgG/IgM rapid test cassette product and purchasing information is available at aytubio.com. Product inquiries may be sent to COVID-19@aytubio.com.

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.

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.

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 also distributes a COVID-19 IgG/IgM rapid test. This coronavirus 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.

Aytu also operates a subsidiary focused on consumer health, 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 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 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 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, the regulatory and commercial risks associated with introducing the COVID-19 rapid test, the effectiveness of the COVID-19 rapid rest, market acceptance of the National Cancer Institute or other independently conducted studies' testing results, the regulatory, clinical, and commercial risks associated with the investigational Healight device, effects of the business combination of Aytu and the Commercial Portfolio and the 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 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/598975/COVID-19-IgGIgM-Rapid-Test-Cassette-Distributed-by-Aytu-BioScience-Featured-in-Business-Insider-Article