Aytu BioScience Announces Positive Results from an Independently Conducted Clinical Study of the Company's Licensed COVID-19 IgG/IgM Point-of-Care Rapid Test

Independent clinical study demonstrates test accuracy of 98.0% and 94.1% for IgG and IgM, respectively, when using PCR-positive cases as true positives

ENGLEWOOD, CO / April 16, 2020 / Aytu BioScience, Inc. (NASDAQ:AYTU), (the "Company"), a specialty pharmaceutical company focused on commercializing novel products that address significant patient needs announced today that results from an independent clinical study using the Company's licensed Coronavirus Disease 2019 ("COVID-19") IgG/IgM Rapid Test were published in the journal Infection Ecology & Epidemiology, further validating the accuracy, specificity and performance of the antibody rapid test.

In this recently published clinical study which included 29 COVID-19 positive cases confirmed by PCR and 124 healthy donors, the rapid test showed an overall specificity of 100% and 99.2% for IgM and IgG, respectively. The authors note, "The high negative predictive value indicates that the rapid test will be useful for detecting past infections and possible immunity, which may be crucial for restoring social functions after lockdown."

Capillary blood samples or serum from PCR-confirmed COVID-19 patients were analyzed with results from the COVID-19 IgG/IgM Rapid Test. Sixty-nine percent of samples from PCR-confirmed COVID-19 patients tested IgM positive, and 93.1% tested IgG positive. These results are well in line with the previously reported specificity of 91.9% for IgG and IgM. The authors note that variability in samples obtained during COVID-19 disease or convalescence period means that in the PCR-confirmed cases, antibodies may not yet have had time to develop. If this were the case, sensitivities of the test could actually be higher.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented "This independently conducted study, which was peer-reviewed and published earlier this week, demonstrates the clinical performance of this COVID-19 IgG/IgM rapid test and establishes the test's utility in understanding a patient's past exposure to COVID-19 and its potential to assess patient immunity as we move past this pandemic and get our society back to work. We are happy to see a leading clinical institution further establish the clinical utility of this important serological test."

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 now been validated in multiple independent trials and is CE marked.

https://www.tandfonline.com/doi/full/10.1080/20008686.2020.1754538

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 exclusive U.S. distribution rights to the 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 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, the completion of the registered direct offering, the satisfaction of customary closing conditions related to the registered direct offering and the intended use of net proceeds from the registered direct offering, 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 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.

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SOURCE: Aytu BioScience, Inc.

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