

## **Aytu BioScience Confirms Export and Incoming Delivery of COVID-19 IgG/IgM Rapid Tests**

***Chinese Officials Confirm China Won't Restrict Exports of Medical Products Needed to Fight Coronavirus***

***Company in Late-Stage Negotiations to Secure Distribution Agreement for Additional COVID-19 IgG/IgM Rapid Test Which is Approved by China's National Medical Products Administration (NMPA)***

**ENGLEWOOD, CO / April 17, 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 export and delivery of the Company's incoming COVID-19 rapid tests remains on track as previously announced.

Additionally, the Company is in late-stage negotiations to secure rights to distribute a second COVID-19 IgG/IgM rapid test, which is approved by China's National Medical Products Administration (NMPA).

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "Since the Company began taking the fight to COVID-19, we have continued to aggressively search for and evaluate diagnostic tests and other novel technologies that may complement our current product offering and benefit COVID-19 patients. Also, given the nationwide shortage of tests, we believe we are obligated to secure as many additional tests as we can to help with this shortage. To that end, I am excited to say we're in the final stages of securing yet another IgG/IgM antibody rapid test for U.S. distribution. This test is already approved by China's NMPA, is being regularly exported from China, and has strong clinical performance. By securing this additional antibody test, we expect to have an even greater supply to fulfill the substantial demand we're experiencing. We all need to continue to do the very best we can to help COVID-19 patients and those medical professionals for whom they care."

Mr. Disbrow continued, "On March 31, an announcement was made by China's Ministry of Commerce restricting the export of medical materials that have not obtained approval from the NMPA. It is important to note that just yesterday the Associated Press released an article titled, '**China says no plans to limit export of anti-virus supplies.**' The article states: 'Commerce Ministry spokesman Gao Feng said Beijing has taken steps to speed up customs clearance while ensuring the quality of exported epidemic-prevention goods. Gao said Thursday, 'China has not and will not restrict the export of epidemic prevention materials.' These statements provide us with confidence and are consistent with the information we continue to receive from our test kit licensor. We remain confident about the timely delivery of the Company's incoming order of COVID-19 IgG/IgM tests," commented Mr. Disbrow.

Mr. Disbrow concluded, “We have received further confirmation that the COVID-19 IgG/IgM Rapid Test manufactured by Zhejiang Orient Gene is in the approval process with NMPA. We remain highly confident in the test’s clinical performance as recently demonstrated in a published, third-party peer-reviewed study and believe that the Zhejiang Orient Gene COVID-19 IgG/IgM Rapid Test is a reliable test in detecting COVID-19 antibodies. The independent study demonstrates test accuracy of 98.0% and 94.1% for IgG and IgM, respectively, when using PCR-positive cases as true positives, which we believe establishes strong clinical utility of the test.”

The Company will continue to inform our stakeholders about our continuing developments relating to our COVID-19 fight and the progress of the Aytu BioScience business.

### **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](http://aytubio.com) and visit [innovuspharma.com](http://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 Zhejiang Orient Gene's COVID-19 Rapid Test (the "COVID-19 Rapid Test"), shipping delays or regulatory processes and their impact on our ability to introduce the COVID-19 Rapid Test, the ability of the COVID-19 Rapid Test to accurately and reliably test for COVID-19, Zhejiang Orient Gene's ability to manufacture the COVID-19 Rapid Test on a high volume scale, manufacturing problems, customs 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 Kit, the demand or lack thereof for the COVID-19 Rapid Test Kit, Zhejiang Orient Gene's ability to obtain approval from China's National Medical Product Administration ("NMPA") to continue to manufacture and export the COVID-19 Rapid Test, the impact the ongoing disputes surrounding COVID-19 between the People's Republic of China and the United States of America may have on our ability to import additional COVID-19 Rapid Tests from Zhejiang Orient Gene, our ability to successfully identify and enter into an agreement with an alternative manufacture of a COVID-19 rapid test that is approved by the NMPA, the timing of any agreement with an alternative manufacture of a COVID-19 rapid test, any reputational or business harm that we may incur in the event the COVID-19 Rapid Test is not reliable or accurate in testing for COVID-19, any reputational or business harm that we may incur for selling the COVID-19 Rapid Test from a manufacture that is not currently approved by the NMPA, whether the testing standards of the NMPA are comparable to the FDA's standards and any market inference whether positive or negative that may be derived from selling rapid tests that are or are not manufactured by companies approved by the NMPA, scientific and market acceptance of antibody tests as acceptable tests for the detection of COVID-19, the reliability of independent third-party study as it relates to the measure of effectiveness of the COVID-19 Rapid Test, our ability to obtain COVID-19 rapid tests from NMPA approved manufactures on acceptable terms, our ability to meet the demand for COVID-19 rapid tests, unfavorable media coverage related to the COVID-19 Rapid Test, 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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