# Aytu BioScience Announces China Export Clearance of Company's COVID-19 IgG/IgM Rapid Test

## 500,000 Rapid Tests Cleared for Shipment to Company's Warehouse

**ENGLEWOOD, CO / April 30, 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 it has received confirmation of export approval for product shipment by China's Ministry of Commerce for the Company's COVID-19 IgG/IgM Rapid Test.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "The backlog of medical products being exported from China created a shipment delay, but Aytu's next 500,000 rapid tests have now been cleared for shipment to the U.S. This export clearance from China, along with the additional supply we have secured through our new relationship with Biolidics, gives us great confidence in our supply chain and ability to provide these needed test kits to the U.S. medical community. Our shipments remain on track for delivery and, upon receipt, will be distributed to U.S. customers."

### **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<sup>™</sup>, 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<sup>™</sup>, 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. This point-of-care test has been validated in a 126 patient clinical trial in China and has received CE marking.

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 regulatory and commercial risks associated with introducing the COVID-19 Rapid Test, any delays in shipment that may impact our ability to distribute the COVID-19 Rapid Test, any reputational harm we may incur if there are delays in receiving the shipment of the COVID-19 Rapid Test, our ability to enforce the exclusivity provisions of the distribution agreement, the reliability of serological testing in detecting COVID-19, shipping delays 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, the manufacturer of the COVID-19 Rapid Test's 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 Kit, the demand or lack thereof for the COVID-19 Rapid Test Kit, our ability to obtain additional COVID-19 Rapid Tests to meet demand, our ability to secure additional tests if the manufacture of the COVID-19 Rapid Tests is 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.

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