# Aytu BioScience Announces Receipt of Initial Shipment of 100,000 COVID-19 IgG/IgM Point-of-Care Rapid Tests; Additional 500,000 Tests on Order

## Initial Shipment of 2-10 Minute COVID-19 Rapid Tests Received at Company's Englewood, Colorado Facility

**ENGLEWOOD, CO / April 1, 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 its first Coronavirus Disease 2019 ("COVID-2019") IgG/IgM Rapid Test shipment containing 100,000 tests from the manufacturer. The Company is now in the process of relabeling the test kits to comply with Food and Drug Administration (FDA) requirements relating to labeling of COVID-19 serology test kits and expects to begin filling current backorders and additional incoming orders shortly thereafter.

Additionally, the Company expects to receive another 500,000 rapid tests from the manufacturer in the next two to three weeks in order to fulfill additional customer orders.

Josh Disbrow, Chief Executive Officer of Aytu BioScience, commented, "We're pleased to have the first 100,000 tests now in stock at our facility in Englewood, Colorado. The Company is now preparing the kits for shipment to customers. Following the completion of the labeling process and final clearance by FDA, we'll be shipping this initial inventory to healthcare professionals across the country. While preparing these kits for distribution, we are also preparing to receive our next shipment of 500,000 tests."

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 been validated in a 126 patient clinical trial and is CE marked. The COVID-19 IgG/IgM Rapid Test is registered with the FDA and listed on the FDA website as one of the serology tests allowed by the agency to be commercialized in the United States. The COVID-19 IgG/IgM Rapid Test is intended for professional use and delivers results between 2 and 10 minutes at the point-of-care.

### **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. This point-of-care test has been validated in a 113 patient clinical trial 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 IgG/IgM Rapid Test, shipping delays and their impact on our ability to introduce the COVID-19 IgG/IgM Rapid Test, our ability to enforce our exclusive rights to distribute the COVID-19 IgG/IgM Rapid Test

in the jurisdictions set forth in the distribution agreement, the ability of the COVID-19 IgG/IgM Rapid Test to accurately and reliably test for COVID-19, the manufacture of the COVID-19 IgG/IgM Rapid Test's ability to manufacture such testing kits on a high volume scale, manufacturing problems or delays related to the COVID-19 IgG/IgM Rapid Test, our ability to satisfy any labelling conditions or other FDA or other regulatory conditions to sell the COVID-19 IgG/IgM Rapid Test Kit, the ability to obtain a sufficient number of COVID-19 IgG/IgM Rapid Test kits to meet demand if any, the demand or lack thereof for the COVID-19 IgG/IgM Rapid Test Kit, 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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