Aytu BioPharma Announces Fast Track Designation Granted to AR101 for the Treatment of Vascular Ehlers-Danlos Syndrome

ENGLEWOOD, CO / April 19, 2022 / Aytu BioPharma, Inc. (NASDAQ:AYTU), a pharmaceutical company focused on developing and commercializing novel therapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to AR101 (enzastaurin), a protein kinase C (PKC) β inhibitor, for the treatment of patients with Vascular Ehlers-Danlos Syndrome (VEDS).

“We are pleased that AR101 has received FDA Fast Track designation as it highlights the significant need for new treatment options for patients diagnosed with VEDS, a serious, life-shortening condition for which there are no approved treatments today,” stated Josh Disbrow, Chief Executive Officer of Aytu BioPharma. “Receipt of Fast Track designation enables more frequent interaction with the FDA throughout the AR101 development process, along with a shorter review timeframe. With this important designation now in hand, we are focused on getting the operational elements of the pivotal PREVEnt study of AR101 in place such that we can initiate it as quickly as possible, with plans to begin patient dosing by late 2022 or early 2023.”

The PREVEnt Trial is designed to enroll approximately 260 COL3A1-positive VEDS patients in order to assess time to arterial events leading to intervention among patients treated with AR101 compared to patients treated with standard of care. Including the planned enrollment period, the study is expected to last approximately thirty months.

AR101 has received Orphan Drug designation in the United States and Europe, and the AR101 Investigational New Drug application has been accepted by the U.S. FDA to begin a registrational study.

About Fast Track Designation

Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious conditions and fill an unmet medical need. Fast Track addresses a broad range of serious conditions, and the request can be initiated by a pharmaceutical company at any time during the development process. FDA reviews the request and decides based on whether or not the drug fills an unmet medical need in a serious condition. Once a drug receives Fast Track designation, early and frequent communication between the FDA and the sponsor is encouraged throughout the entire drug development and review process.

About Aytu BioPharma, Inc.

Aytu BioPharma is a pharmaceutical company with a portfolio of commercial prescription therapeutics and consumer health products, and a growing therapeutics pipeline focused on treating rare, pediatric-onset disorders. The company’s prescription products include Adzenys XR-ODT® (amphetamine) extended-release orally disintegrating tablets (see Full Prescribing

Information, including Boxed WARNING) and Cotempla XR-ODT® (methylphenidate) extended-release orally disintegrating tablets (see Full Prescribing Information, including Boxed WARNING) for the treatment of attention deficit hyperactivity disorder (ADHD), as well as Karbinal® ER (carbinoxamine maleate), an extended-release carbinoxamine (antihistamine) suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines containing combinations of fluoride and vitamins in various formulations for infants and children with fluoride deficiency. Aytu is also building a therapeutic pipeline, which includes AR101 (enzastaurin), a PKCβ inhibitor in development for the treatment of vascular Ehlers-Danlos Syndrome (VEDS). VEDS is a rare genetic disease typically diagnosed in childhood resulting in high morbidity and a significantly shortened lifespan, and for which there are no currently approved treatments. AR101 has received Orphan Drug designation and Fast Track designation from the U.S. Food and Drug Administration and has received Orphan Drug designation from the European Medicines Agency. To learn more, please visit aytubio.com.

Forward-Looking Statements

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 press release, 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. Forward-looking statements, including but not limited to any statements regarding the intellectual property and product information presented in this press release. 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: the future growth potential of our commercial portfolio and the anticipated start dates, durations and completion dates and the potential safety and efficacy of our product candidates. We also refer you to the risks described in ‘Risk Factors’ in Aytu’s Annual and Quarterly Reports on Form 10-K and 10-Q and in the other reports and documents it files with the Securities and Exchange Commission.

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