Aytu BioPharma Announces AR101 Granted Orphan Designation in Europe for the Treatment of Ehlers-Danlos Syndrome

ENGLEWOOD, CO / March 2, 2022 / Aytu BioPharma, Inc. (NASDAQ:AYTU), a pharmaceutical company focused on developing and commercializing novel therapeutics, today announced that the European Commission granted orphan designation to AR101 (enzastaurin), a PKCβ inhibitor, for the treatment of Ehlers-Danlos Syndrome (EDS), a group of rare inherited connective tissue disorders that includes the severe subtype vascular EDS (VEDS). This designation is based on a positive opinion from the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA COMP). The U.S. Food and Drug Administration (FDA) previously granted orphan drug designation to AR101 for the treatment of Ehlers-Danlos Syndrome, including VEDS. Aytu plans to initiate its PREVEnt Trial to assess the safety and efficacy of AR101 in patients with COL3A1-confirmed VEDS by mid-2022.

“We are very excited to have been granted orphan designation by the European Commission. VEDS is a devastating inherited connective tissue disorder for which there are no approved treatments, and we are pleased to see the regulatory community recognize the urgent need to bring therapies to the people with rare diseases who need them,” said Josh Disbrow, chief executive officer of Aytu BioPharma. “We are preparing to initiate our PREVEnt registrational study in the middle of this year, which will evaluate AR101 as a first-in-class treatment for VEDS in patients across study sites in both the U.S. and Europe.”

Orphan designation in the EU is granted by the European Commission based on a positive opinion issued by the EMA COMP. To qualify, an investigational medicine must be intended to treat a seriously debilitating or life-threatening condition that affects fewer than five in 10,000 people in the EU, and there must be sufficient non-clinical or clinical data to suggest the investigational medicine may produce clinically relevant outcomes. EMA orphan designation provides companies with certain benefits and incentives, including clinical protocol assistance, differentiated evaluation procedures for Health Technology Assessments in certain countries, access to a centralized marketing authorization procedure valid in all EU member states, reduced regulatory fees and 10 years of market exclusivity.

About vascular Ehlers-Danlos Syndrome (VEDS)

Vascular Ehlers Danlos Syndrome (VEDS) is the severe subtype of Ehlers-Danlos Syndrome, affecting 1 in 50,000 people worldwide and results from pathogenic variants in the COL3A1 gene, which encodes the chains of type III procollagen, a major protein in vessel walls and hollow organs. VEDS is typically diagnosed in childhood and is characterized by arterial aneurysm, dissection and rupture, bowel rupture and rupture of the gravid uterus. Twenty-five percent of VEDS patients have a first complication by the age of 20 years, and more than eighty percent have at least one complication by the age of 40. VEDS is a devastating condition, and VEDS patients have a median lifespan of 51 years. There are no FDA-approved

therapies for VEDS.

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 from the U.S. Food and Drug Administration and 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 financial results and statements 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 ability to attract and retain key management team members, the future growth potential of our commercial portfolio, the anticipated start dates, durations and completion dates and the potential safety and efficacy of our product candidates AR101 and Healight. 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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