# Aytu BioPharma Announces Initiation of the AR101 PREVEnt Trial for the Treatment of Vascular Ehlers-Danlos Syndrome

**ENGLEWOOD, CO / July 20, 2022** / Aytu BioPharma, Inc. (NASDAQ:AYTU), a pharmaceutical company focused on developing and commercializing novel therapeutics, today announced the initiation of the global Phase 3 PREVEnt (Prevention of Ruptures with Enzastaurin for Vascular Ehlers-Danlos Syndrome) clinical trial of enzastaurin (AR101) for the treatment of patients with COL3A1-positive Vascular Ehlers-Danlos Syndrome (VEDS). VEDS is a rare genetic disorder typically diagnosed in childhood and characterized by arterial aneurysm, dissection and rupture, bowel rupture and rupture of the gravid uterus. The company has begun patient identification and study site contracting and has received regulatory clearance to initiate this registrational study in the United States and numerous countries in Europe.

“We are excited about the progression of this global clinical trial evaluating a novel pathway for the treatment of VEDS, a devastating rare disease with massive unmet need,” said Josh Disbrow, Chief Executive Officer of Aytu BioPharma. “The PREVEnt Trial is global in nature with an anticipated 30+ sites across the US and Europe. We have received an FDA Safe to Proceed Letter, and in Europe have garnered Regulatory Authority and Ethics Commission approvals to begin clinical work in multiple countries. We anticipate additional country-specific approvals in the coming months.”

Topher Brooke, Executive Vice President of Rare Disease Development of Aytu BioPharma, commented, “We are so grateful to all the clinical trial sites for their efforts in aiding our study start up with the aim of dosing a first patient by early 2023. In coordination with trial sites and patient advocacy organizations in the US and Europe, we plan to make it as easy as possible to participate in the PREVEnt Trial, including allowing patients to continue any VEDS-related therapies they are currently taking for the duration of the study.”

The PREVEnt Trial is a prospective, Phase 3, global, randomized, double-blind, placebo-controlled efficacy trial designed to evaluate enzastaurin in patients with genetically confirmed COL3A1-positive VEDS. The primary measure of the trial is to determine whether enzastaurin reduces the occurrence of VEDS-related arterial events (ruptures, dissections, pseudoaneurysms, carotid-cavernous fistula, aneurysm) requiring medical intervention compared to placebo. The company expects to enroll approximately 260 COL3A1-confirmed VEDS patients in the PREVEnt Trial. Individuals seeking more information on the enzastaurin pivotal clinical trial are invited to visit www.preventvedstrial.com and https://clinicaltrials.gov/ct2/show/NCT05463679?term=Aytu+BioPharma&draw=2&rank=1

**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 antihistamine suspension indicated to treat numerous allergic conditions, and Poly-Vi-Flor® and Tri-Vi-Flor®, two complementary fluoride-based prescription vitamin product lines available 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 Commission. Aytu is also researching and advancing the development of the Healight ultraviolet light A (UVA) endotracheal catheter, a patented, investigational medical device with potential application in the treatment of severe, difficult-to-treat respiratory infections. 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. All statements other than statements of historical facts contained in this press release, are forward-looking statements, including but not limited to any statements regarding the financial results and statements presented in this press release and during the business update call following its 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 anticipated start dates, durations and completion dates and the potential future results of ongoing and future AR101 clinical trials, the effectiveness of AR101 in treating VEDS and the anticipated future regulatory submissions and events related to AR101. We also refer you to (i) the risks described in 'Risk Factors' in Aytu's Annual Report on Form 10-K, in Quarterly Reports filed on Form 10-Q, and in the other reports and documents it files with the Securities and Exchange Commission.

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