# Aytu BioPharma Receives Orphan Drug Designation from FDA for AR101 for Treatment of Vascular Ehlers-Danlos Syndrome

**ENGLEWOOD, CO / December 8, 2021** / Aytu BioPharma, Inc. (NASDAQ:AYTU), a specialty pharmaceutical company focused on commercializing novel therapeutics and consumer healthcare products, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug designation to AR101 (enzastaurin) for the treatment of Ehlers-Danlos Syndrome. Treatment of vascular Ehlers-Danlos Syndrome (VEDS) is within the scope of this orphan drug designation. The company plans to launch a single pivotal trial, the PREVEnt Trial, of AR101 in patients with VEDS in the first half of 2022. 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.

“Receiving Orphan Drug designation for AR101 underscores the unmet need for patients with VEDS, for which there are currently no FDA-approved treatments,” said Josh Disbrow, Chief Executive Officer of Aytu BioPharma. “This designation is an important milestone, and we look forward to working with the FDA as we advance this potential treatment option with the goal of positively impacting patients diagnosed with this devastating disease.”

The FDA grants Orphan Drug designation status to drugs and biologics that are intended for the safe and effective treatment, diagnosis or prevention of rare diseases, or conditions that affect fewer than 200,000 people in the U.S. Orphan Drug designation affords Aytu certain financial incentives to support clinical development and the potential for up to seven years of market exclusivity in the U.S. upon regulatory approval.

**About Aytu BioPharma, Inc.**

Aytu BioPharma is a specialty pharmaceutical company with a growing commercial portfolio of prescription therapeutics and consumer health products. The company’s primary prescription products treat attention deficit hyperactivity disorder (ADHD) and other common pediatric conditions. Aytu markets ADHD products 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). The company also markets ZolpiMist®, a short-term treatment for insomnia characterized by difficulties with sleep initiation (see Full Prescribing Information, including Boxed WARNING). The company’s other pediatric products include 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. The company’s evolution has been driven by strategic in-licensing, acquisition-based transactions and organic product

growth. Aytu is building a complimentary therapeutic development pipeline including a prospective treatment (AR101/enzastaurin) for vascular Ehlers-Danlos Syndrome (vEDS), a rare genetic disease resulting in high morbidity and a significantly shortened lifespan. There are no currently approved treatments for vEDS. 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 presentation, 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 Part I, Item 1A of Aytu's Annual Report on Form 10-K and in the other reports and documents it files with the Securities and Exchange Commission and (ii) the Risk Factors set forth in Aytu's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the SEC.

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