Aytu BioPharma Announces Addition of Fourth Patent License for AR101/Enzastaurin

This Fourth Patent for AR101/Enzastaurin Strengthens and Broadens the Intellectual Property Portfolio Surrounding the Treatment of Inherited Vascular Disorders Including Vascular Ehlers-Danlos Syndrome (VEDS).

Multiple Patent Families Filed in Key Global Markets

ENGLEWOOD, CO / September 14, 2022 / Aytu BioPharma, Inc. (the Company or "Aytu") (Nasdaq:AYTU), a pharmaceutical company focused on developing and commercializing novel therapeutics, with a development pipeline addressing rare, pediatric-onset disorders, today announced the addition of a fourth patent to the intellectual property suite surrounding AR101/Enzastaurin. This fourth patent, also licensed from Johns Hopkins University, is titled "Pathway Targets for the Treatment of Vascular Ehlers-Danlos Syndrome," expands the scientific evidence of the pathophysiology of Vascular Ehlers-Danlos Syndrome (VEDS) and is highly confirmatory of the therapeutic approach for AR101/Enzastaurin. The patent has an expiry date of September 2041, assuming no patent term extensions.

"We're excited about the continued evidence being generated in support of AR101/Enzastaurin for the treatment of VEDS," remarked Josh Disbrow, Chief Executive Officer of Aytu BioPharma. "Adding this fourth patent to the portfolio deepens and broadens the intellectual property surrounding AR101/Enzastaurin for the treatment of inherited vascular disorders, including VEDS, for which we are advancing AR101 as an initial indication. We expect to advance the PREVEnt Trial in VEDS for AR101 and dose the first patient by early 2023."

About Vascular Ehlers-Danlos Syndrome (VEDS)

Vascular Ehlers-Danlos Syndrome 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. 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 currently no approved therapies for VEDS.

About AR101 (enzastaurin)

AR101 (enzastaurin) is an orally available investigational first-in-class small molecule, serine/threonine kinase inhibitor of the PKC beta, PI3K and AKT pathways. AR101 has been studied in more than 3,300 patients across a range of solid and hematological tumor types. Dr. Hal Dietz, professor of genetic medicine and director of the William S. Smilow Center for

Marfan Syndrome at The Johns Hopkins University School of Medicine, developed the first preclinical model that mimics the human condition and recapitulates VEDS. This knock-in mouse model has the same genetic mutation most prevalent in VEDS patients and is representative of the human condition in both the timing and location of vascular events. The model has generated identical structural histology and mechanical characteristics, and unbiased findings demonstrated that structure alone does not lead to vascular events. Objective comparative transcriptional profiling by high-throughput RNA sequencing of the aorta displayed a molecular signature for excessive PKC/ERK cell signaling that is the driver of disease. PKC inhibition proved efficacious in multiple pre-clinical models and prevented death due to vascular rupture.

AR101 has received Orphan Drug Designation in both the United States and in Europe, allowing for seven years of marketing exclusivity in the United States and ten years in Europe. The United States FDA has granted AR101 Fast Track designation. AR101 is protected by a suite of patents being pursued in major markets globally which have been licensed from The Johns Hopkins University and have an earliest priority date of March 2017.

Dr. Dietz is a consultant to Aytu BioPharma and is the chair of its scientific advisory board. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflict-of-interest policies.

About the PREVEnt Trial in VEDS

The PREVEnt Trial is a global registrational study that will study enzastaurin as a daily treatment of COL3A1-confirmed VEDS and assess the safety and efficacy in a randomized controlled study across approximately 34 sites across the United States and Europe. We expect approximately 260 patients to be enrolled and randomized 1:1 versus standard of care over approximately 30 months. The primary endpoint will be time to a VEDS-related medical intervention. We expect to dose the first patient by early 2023.

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 strength of our intellectual property portfolio, 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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