Denovo Biopharma LLC Announces Partner Aytu BioPharma Receives FDA Clearance and Orphan Drug Designation for Enzastaurin in Vascular Ehlers-Danlos Syndrome

SAN DIEGO, December 14, 2021 -- Denovo Biopharma LLC ("Denovo"), a pioneer in applying precision medicine to the development of innovative therapies, today announced its partner Aytu BioPharma (Nasdaq: AYTU), has received FDA clearance for its IND application for enzastaurin and also Orphan Drug Designation (ODD) for enzastaurin for the treatment of Vascular Ehlers-Danlos Syndrome (VEDS).

The IND clearance enables Aytu to proceed with initiating a pivotal clinical trial for enzastaurin in VEDS. Aytu plans to initiate the PREVEnt Trial in VEDS in the first half of 2022. The PREVEnt Trial will assess the safety and efficacy of enzastaurin in COL3A1-confirmed VEDS patients.

The FDA grants ODD 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. ODD affords 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. In addition to this ODD for enzastaurin for VEDS, it has ODD for DLBCL and glioblastoma multiforme (GBM) from the FDA and EMA.

"Since licensing enzastaurin for VEDS from Denovo earlier this year, Aytu has made remarkable progress with enzastaurin for patients with VEDS," said Michael F. Haller, PhD, Denovo's Chief Business Officer. "This demonstrates the value of Denovo's strategy of acquiring drugs and developing them itself with novel biomarkers in parallel with licensing non-core indications for partners to develop for the potential benefit of patients, the partner, and Denovo."

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 Denovo Biopharma
Denovo Biopharma LLC is a clinical-stage biopharmaceutical company that uses novel biomarker approaches to re-evaluate medicines that have failed in broad patient populations. The

company seeks to discover genomic biomarkers correlated with patients' responses to drug candidates retrospectively. Denovo then designs and executes efficient clinical trials in targeted patient populations to optimize the probability of a successful trial. Denovo has completed enrollment of patients with diffuse large B-cell lymphoma (DLBCL) in a Phase 3 clinical trial in the US and China, and enrollment is ongoing in a Phase 3 trial in GBM for its lead product candidate, DB102 (enzastaurin), which was in-licensed from Eli Lilly & Co. The company has seven additional late-stage programs targeting major unmet medical needs: DB103 (pomaglumetad methionil) for schizophrenia, DB104 (liafensine) for depression, DB105 (ORM-12741) for Alzheimer's Disease, DB106 (vosaroxin) for acute myeloid leukemia (AML), DB107 (Toca 511/Toca FC) for recurrent high-grade GBM, DB108 (endostatin) for non-small cell lung cancer (NSCLC), and DB109 (idalopirdine) for Alzheimer's Disease. For additional information please visit www.denovobiopharma.com.

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