Denovo's Licenses DB102 (Enzastaurin) for Rare Genetic Pediatric Onset Disorders to Aytu BioPharma

- Program targeting vascular Ehlers-Danlos Syndrome (vEDS), a rare inherited connective tissue disorder resulting in high morbidity and a significantly shortened life span with no FDA-approved treatments

SAN DIEGO, April 13, 2021 -- Denovo Biopharma LLC, a pioneer in applying precision medicine to development of innovative therapies, today announced that Aytu BioPharma has acquired substantially all the assets of Rumpus Therapeutics, including Rumpus' option to license DB102 for rare genetic pediatric onset or congenital disorders outside of oncology from Denovo Biopharma LLC. Furthermore, Aytu Biopharma has exercised this option so it now has an exclusive worldwide license from Denovo Biopharma LLC for these indications. Terms of the license were not disclosed.

Rumpus has focused its development of DB102 on 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. There are currently no U.S. Food and Drug Administration (FDA)-approved treatments for vEDS. Preclinical studies conducted by Dr. Hal Dietz, Professor of Genetic Medicine at Johns Hopkins University School of Medicine and an Investigator at the Howard Hughes Medical Institute have shown that PKC inhibition proved efficacious in multiple pre-clinical models and prevented death due to vascular rupture. Aytu BioPharma expects that this development program for DB102 will progress directly to a single pivotal study.

"DB102 has the potential to treat a variety of disorders, both inside and outside of the oncology field. Rumpus Therapeutics has been actively pursuing development of DB102 in select rare genetic onset non-oncology indications, such as vEDS, since signing the option agreement, and we welcome the interest of Aytu BioPharma in accelerating these efforts," said Michael F. Haller, Ph.D., Denovo's Chief Business Officer. "As these indications are outside Denovo's core development areas for DB102 in DLBCL, GBM, and pulmonary arterial hypertension (PAH), this represents a validation of Denovo's business model of acquiring drugs for all indications and developing them with newly-discovered biomarkers in parallel with out-licensing non-core indications. We are pleased that DB102 is generating economic value to Denovo prior to read-out of our pivotal clinical studies in oncology."

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. 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 DB102
DB102 (enzastaurin) is an orally available investigational first-in-class small molecule, serine/threonine kinase inhibitor of the PKC beta, PI3K, and AKT pathways that has been studied in more than 3,000 patients across a range of solid and hematological tumor types. DB102 was originally developed by Eli Lilly and Company for which Denovo has acquired worldwide rights. DB102 received Orphan Drug Designation in DLBCL and glioblastoma multiforme (GBM) from the FDA and EMA and Fast Track Designation from the FDA.

About Denovo Biopharma LLC
Denovo Biopharma is a clinical-stage biopharmaceutical company that applies 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 in the U.S. and China with diffuse large B-cell lymphoma (DLBCL) in a Phase 3 clinical trial and has started a Phase 3 trial in Glioblastoma (GBM) for its lead product candidate, DB102 (enzastaurin), which was in-licensed from Eli Lilly. The company has six additional late-stage programs targeting major unmet needs: DB103 (pomaglumetad methionil) for schizophrenia, DB104 (liafensine) for depression, DB105 (formerly ORM-12741) for Alzheimer's Disease, DB106 (vosaroxin) for acute myeloid leukemia (AML), DB107 (formerly Toca 511 and Toca FC) for recurrent high grade glioma, and DB108 (endostatin) for non-small cell lung cancer (NSCLC). For additional information please visit www.denovobiopharma.com.

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