First Patient Dosed in Biomarker-Guided Phase 3 Study of DB102 (Enzastaurin) in Patients with Newly-Diagnosed Glioblastoma (GBM)

SAN DIEGO, January 7, 2021 -- Denovo Biopharma LLC, a pioneer in applying precision medicine to development of innovative therapies, today announced dosing of the first patient in its biomarker guided Phase 3 clinical study evaluating the DB102 (enzastaurin) in combination with temozolomide and radiation as first line therapy to treat newly-diagnosed glioblastoma multiforme (GBM). This randomized, double-blind, placebo-controlled global study is to enroll more than 300 patients and the primary outcome measure is overall survival in patients with Denovo Genomic Marker 1 (DGM1). This GBM stuty has received Phase 3 permission from regulatory agencies from US, Canada, and China, and also gained FDA's Fast Track designation last year.

"This GBM study is the second global Phase 3 trial of DB102 for patients with cancer following our first global Phase 3 trial of DB102 for patients with diffuse large B-cell lymphoma (DLBCL). In both trials, we use DGM1 to identify the patients who will receive the most benefits from DB102 therapy in combination regimens," said Zane Yang, M.D., Denovo's Chief Medical Officer. "GBM remains to be one of the deadliest cancers and the first line drug treatment still relies on temozolomide as the backbone -- many promising anticancer drugs, including anti-PD-1 drugs, have failed to improve upon temozolomide's efficacy. I am hopeful that our innovative approach can bring new hope to patients with this difficult-to-treat condition that continues to have a significant unmet need."

For more information on the DB102 ENGAGE clinical study, visit https://clinicaltrials.gov/ct2/show/NCT03776071

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 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 Glioblastoma
Glioblastoma Multiforme (GBM) is the most common type of adult primary malignant brain cancer, with 18,000 newly-diagnosed patients in the US and 13,000 deaths annually. Standard treatment for patients with newly diagnosed GBM can include surgery followed by radiation and chemotherapy, but treatment options are limited. The five-year survival rate of patients with GBM is less than five percent.

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 is enrolling patients in the U.S. and China with diffuse large B-cell lymphoma (DLBCL) in a Phase 3 clinical trial and will start 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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