Three DB102 (Enzastaurin) Presentations at ASCO and the 15th International Conference on Malignant Lymphoma (ICML)

Novel Genomic Biomarker of Response to Enzastaurin in Glioblastoma Identified

SAN DIEGO, May 17, 2019 -- Denovo Biopharma LLC, a pioneer in applying precision medicine to develop innovative therapies, today announced three presentations on DB102 (Enzastaurin). Two posters at the American Society of Oncology (ASCO) conference in Chicago, Illinois, USA, and an oral presentation at the 15th International Conference on Malignant Lymphoma (ICML) in Lugano, Switzerland, are being presented.

Poster 2023 at ASCO describes retrospective identification of novel Denovo Genomic Marker 1 (DGM1) that is correlated and potentially predictive of response to DB102 from a Phase 3 DLBCL maintenance clinical study and its replication in an independent first-line DLBCL Phase 2 clinical study. In both studies, DGM1+ patients had significantly increased overall survival (OS) compared to DGM1- patients. The same biomarker was evaluated for predictability in a glioblastoma (GBM) clinical study and the data are supportive of DGM1 as a potentially predictive biomarker for enzastaurin response in both DLBCL and GBM. DB102 guided by DGM could be valuable to patients since both indications have high unmet need--no new therapy has been approved for either indication in two decades.

ASCO Poster TPS7569 and oral presentation OT03 at ICML report on the design of the ongoing ENGINE Phase III clinical trial in frontline high risk patients with DLBCL.

About DB102

DB102 (Enzastaurin) is an orally available investigational first-in-class small molecule, serine/threonine kinase inhibitor of the PKC-beta and AKT pathways studied in over 3,000 patients across a range of solid and hematological tumor types. DB102 was originally developed by Eli Lilly and Co. and for which Denovo has acquired worldwide rights. DB102 received orphan drug designation in DLBCL and glioblastoma multiforme (GBM) from the FDA and EMA.

About ENGINE Pivotal Clinical Study

The ENGINE trial is a global, randomized, double-blind, registrational study evaluating the efficacy of DB102 in combination with R-CHOP versus R-CHOP alone in patients with high-risk DLBCL with or without the biomarker DGM1. The study is to enroll 235 patients and the primary outcome measure is overall survival in patients with DGM1. For information on the

DB102 ENGINE Phase 3 study,
visit https://clinicaltrials.gov/ct2/results?cond=&term=NCT03263026

About Denovo Biopharma
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 for its lead product candidate, DB102, which was in-licensed from Eli Lilly. The company has two additional late stage programs: DB103, for schizophrenia, and DB104, for depression. For additional information please visit www.denovobiopharma.com.

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