



FOR IMMEDIATE RELEASE

Two Posters on DB102 (Enzastaurin) Presented at the American Society of Hematology Annual Meeting

- Improved Survival in Patients with Genetic Biomarker Identified from Late-Stage Clinical Studies;
- Combination of DB102 with the BTK Inhibitor Provides Synergistic Efficacy in Preclinical Models

SAN DIEGO, November 26, 2018 -- Denovo Biopharma LLC, a pioneer in applying precision medicine to develop innovative therapies, today announced the presentation of two posters on DB102 (Enzastaurin) at the American Society of Hematology conference that takes place from Saturday, December 1, 2018 through Tuesday, December 4, in San Diego.

The first poster describes retrospective identification of a novel genetic biomarker 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 a first-line DLBCL Phase 2 clinical study. In both studies, DGM1+ patients had highly significantly increased overall survival (OS) compared to DGM1- patients. Based on these results, Denovo Biopharma initiated and is currently enrolling a biomarker driven Phase 3 pivotal study (ENGINE trial) in patients with newly diagnosed DLBCL.

The second poster reports that the combination of DB102, a PKC- β inhibitor, with ibrutinib, a BTK inhibitor, led to synergistic antitumor activity in DLBCL preclinical studies. When used in combination, DB102 and ibrutinib produced a lasting, synergistic effect on the survival and proliferation of ABC and GCB DLBCL cell lines as compared to each agent used separately. The combination treatment also synergistically inhibited tumor cell migration and invasion as well as key related signal transduction pathways. These results provide a sound foundation for a novel strategy to treat DLBCL patients by combining DB102 with BTK inhibitors such as ibrutinib.

Further information about these two posters is below.

Poster Name: Improved Survival with Enzastaurin Treatment in Diffuse Large B-Cell Lymphoma Patients with the Novel Genetic Biomarker, DGM1

Session Name: 627. Aggressive Lymphoma (Diffuse Large B-Cell and Other Aggressive B-Cell Non-Hodgkin Lymphomas)—Results from Retrospective/Observational Studies: Poster III
Date: Monday, December 3, 2018

Presentation Time: 6:00 PM - 8:00 PM
Location: San Diego Convention Center, Hall GH

Poster Name: Combination of Enzastaurin and Ibrutinib Synergistically Induces Anti-tumor Effects in Diffuse Large B Cell Lymphoma

Session Name: 625. Lymphoma: Pre-Clinical—Chemotherapy and Biologic Agents: Poster I
Date: Saturday, December 1, 2018
Presentation Time: 6:15 PM - 8:15 PM
Location: San Diego Convention Center, Hall GH

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 and 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 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 the 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 more information on the DB102 ENGINE Phase 3 study, visit <https://clinicaltrials.gov/ENGINE>

About Denovo Biopharma

Denovo Biopharma is a clinical stage biopharmaceutical company that applies novel biomarker approaches to precision drug development to re-evaluate medicines that have failed in broad patient populations. The company applies its expertise to archived clinical samples 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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