Denovo Biopharma LLC Announces Multiple Presentations at Major Conferences

- Use of a Pharmacogenomic to Retarget a Failed Clinical Trial with Liafensine in Depression
- Case Study of an Exceptional Responder: Enzastaurin Long Term Efficacy in a Patient with Primary and Recurrent Glioblastoma Multiforme (GBM)
- DB102-01 ENGAGE Study: A biomarker-guided, randomized, double-blind, placebo-controlled, multi-center phase 3 clinical trial of DB102 in patients with newly diagnosed glioblastoma multiforme (GBM)
- Extended benefits in patients with recurrent high grade glioma that continuously receive Toca FC after Toca 511 Treatment
- A novel precision medicine approach to advance Toca 511 gene therapy

SAN DIEGO, November 2, 2021 – Denovo Biopharma LLC (Denovo), a pioneer in using biomarker-guided precision medicine to develop innovative therapies, today announced presentations at several conferences: one on DB104 (liafensine) at the CNS Summit (November 7-10, 2021, Boston, MA, USA), two on DB102 (enzastaurin) and one on DB107 (Toca 511/Toca FC) at the Society for NeuroOncology (SNO) Annual Meeting (November 18-21, 2021, Boston, MA, USA), and one on DB107 at the International Oncolytic Virus Conference (IOVC) (November 5-7, 2021, Sedona, AZ, USA).

Podium presentation titled "Use of a Pharmacogenomic Biomarker to Retarget a Failed Clinical Trial with Liafensine in Depression" at the CNS Summit describes how Denovo identified the DGM4 pharmacogenomic biomarker that is predictive of efficacy of DB104 in patients with treatment-resistant depression, and also shows that DGM4 did not predict efficacy in patients receiving standard of care treatments and as such was specific to liafensine.

Poster # CTNI-25 titled "Case Study of an Exceptional Responder: Enzastaurin Long Term Efficacy in a Patient with Primary and Recurrent Glioblastoma Multiforme (GBM)" at SNO is a case study of a patient with primary and recurrent GBM who is an exceptional (15-year) responder to DB102. This patient was found to have DGM1, the pharmacogenomic biomarker discovered by Denovo that is associated with an increased survival in patients with GBM who are treated with DB102.

Poster # CTNI-08 titled "DB102-01 ENGAGE Study: A biomarker-guided, randomized, double-blind, placebo-controlled, multi-center phase 3 clinical trial of DB102 in patients with newly diagnosed glioblastoma multiforme (GBM)" at SNO describes the Denovo-sponsored ENGAGE clinical trial in patients with newly-diagnosed GBM who are DGM1-positive, and who will receive DB102 in combination with standard of care treatment.

Invited podium presentation titled “A novel precision medicine approach to advance Toca 511 gene therapy” at IOVC covers the results of the Phase 3 Toca5 clinical trial, and how a pharmacogenomic approach may guide future treatments of GBM with DB107.

Poster #CTNI-03 titled “Extended benefits in patients with recurrent high grade glioma that continuously receive Toca FC after Toca 511 Treatment” at SNO covers seven patients with recurrent high grade glioma who have an extended benefit (ranging from 29 months to 7 years and 5 months) upon treatment with DB107 with six still remaining in treatment having either complete responses or stable disease.

About DB102
DB102 (enzastaurin) is an orally available first-in-class investigational small molecule, as a serine/threonine kinase inhibitor of the PKC beta, PI3K, and AKT pathways, that has been studied in over 3,000 patients with a range of solid and hematological tumor types. Enzastaurin was originally developed by Eli Lilly, and for which Denovo has acquired worldwide rights. Denovo discovered the novel pharmacogenomic biomarker DGM1™ and is conducting a Phase 3 trial in patients with newly-diagnosed diffuse large B-cell lymphoma (DLBCL) and another Phase 3 trial in newly-diagnosed glioblastoma multiforme (GBM). Enzastaurin received Fast Track Designation for GBM from the FDA, Orphan Drug Designation for DLBCL and GBM from the FDA, and Orphan Medicinal Product Designation for DLBCL and GBM from the EMA.

About DB104
DB104 (liafensine) is an orally available first-in-class investigational small molecule, as a serotonin-norepinephrine-dopamine triple reuptake inhibitor (SNDRI), that has been studied in over 2,000 patients with treatment-resistant depression (TRD). Liafensine was originally developed by Albany Molecular Research, Inc. (AMRI) and Bristol-Myers Squibb (BMS), and for which Denovo has acquired worldwide rights. Denovo discovered the novel pharmacogenomic biomarker DGM4™ and is planning a Phase 2b clinical trial.

About DB107
DB107 (Toca 511/Toca FC), acquired from Tocagen, is a two-part cancer-selective immunotherapy comprising an investigational gene therapy (Toca 511) and an investigational small molecule (Toca FC). Toca 511 is a retroviral replicating vector that selectively infects cancer cells and delivers a gene for the enzyme, cytosine deaminase (CD). Toca FC is an orally administered prodrug that is converted to an anti-cancer drug, 5-fluorouracil (5-FU), when it encounters CD. 5-FU kills cancer cells and immune-suppressive myeloid cells resulting in anti-cancer immune activation and subsequent tumor killing. The Toca 511/Toca FC regimen has been tested clinically in recurrent high-grade glioma, most recently in a 403-patient Phase 3 trial.

About Denovo Biopharma LLC
Denovo Biopharma 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 in the US and China with diffuse large B-cell lymphoma (DLBCL) in a Phase 3 clinical trial and has an ongoing Phase 3 trial in glioblastoma (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 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 glioma, 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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