



## **Denovo Biopharma LLC Announces Breakthrough Discovery of a Novel Genetic Biomarker for DB107 for a Gene Therapy-Based Medicine**

**SAN DIEGO**, December 14, 2021 -- Denovo Biopharma LLC (“Denovo”), a pioneer in applying precision medicine to the development of innovative therapies, today announced it discovered a novel genetic biomarker, Denovo Genomic Marker 7 (DGM7™), using its proprietary biomarker discovery platform. DGM7 has been shown to be associated with response to treatment of recurrent high grade glioma (HGG) with an investigational gene therapy combination treatment, DB107, via retrospective analysis. DB107 is an investigational combination product consisting Toca 511 (vocimagene amiretrorepvec) in combination with Toca FC (extended-release flucytosine, [5-FC]), which is part of the retroviral replicating vector (RRV) platform that was acquired from Tocagen in 2020.

In addition to potentially being useful for selecting patients who may respond to DB107 therapy, the utility of this genetic biomarker may extend to the broader RRV platform. This RRV platform has the capability of carrying a wide variety of genes, in addition to the gene carried by DB107. Furthermore, this finding demonstrates that Denovo’s biomarker discovery platform has broad utility for such disparate drug modalities as small molecules and viral vectors.

“Biomarker-guided DB107 treatment brings a much needed treatment option to patients with recurrent high-grade glioma, a major unmet medical need with median survival less than a year,” said Wen Luo, PhD, Denovo’s Chief Executive Officer and Chief Scientific Officer. “Denovo now has three biomarker-guided programs in active development using biomarkers discovered using its biomarker platform, which once again shows that it can deliver repeatable success.”

### **About Denovo’s RRV Platform and DB107**

DB107 is an innovative approach utilizing a proprietary gene therapy platform, RRV, combined with a prodrug, to selectively infect and kill cancer cells while stimulating a robust and durable anti-cancer immune response against a tumor with minimal toxicity. DB107 has been tested clinically in solid tumors including recurrent high-grade GBM and colorectal cancer, most recently in a randomized 403-patient Phase 3 trial. DB107 received Orphan Drug Designation in GBM from the FDA and EMA, and Fast Track Designation from the FDA.

### **About HGG and Glioblastoma**

Most common type of HGG is Glioblastoma multiforme (GBM), which is also 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**

Denovo Biopharma LLC 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 with diffuse large B-cell lymphoma (DLBCL) in a Phase 3 clinical trial in the US and China, and enrollment is ongoing in a Phase 3 trial in 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 medical 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 GBM, DB108 (endostatin) for non-small cell lung cancer (NSCLC), and DB109 (idalopirdine) for Alzheimer's Disease. For additional information please visit [www.denovobiopharma.com](http://www.denovobiopharma.com).

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