Denovo Biopharma and QIAGEN partner to develop companion diagnostic test for the treatment of Diffuse Large B-Cell Lymphoma (DLBCL)

- QIAGEN's blood-based test will help to identify patients with Diffuse Large B-Cell Lymphoma (DLBCL) likely to respond to Denovo's new investigational cancer treatment DB102
- The partners seek FDA premarket approval (PMA) of the companion diagnostic test in tandem with the new drug application (NDA) approval.

San Diego, California, Germantown, Maryland, and Hilden, Germany, December 9, 2021 - Denovo Biopharma LLC and QIAGEN (NYSE: QGEN; Frankfurt Prime Standard: QIA) today announced a collaboration to develop a blood-based companion diagnostic (CDx) test to identify patients expressing Denovo Genomic Marker 1 (DGM1™) who are likely to respond to Denovo's investigational cancer drug DB102™ for treatment of diffuse large B-cell lymphoma (DLBCL), one of the most common lymphoid cancers.

Under the agreement, QIAGEN will develop a diagnostic assay that can detect the Denovo Genomic Marker 1 (DGM1™) in DLBCL patients, a biomarker discovered by Denovo that predicts the responsiveness to DB102. Also known as enzastaurin, Denovo's drug is a first-in-class investigational small molecule inhibitor of PKC-beta, a protein whose presence has been compellingly linked to DLBCL cases.

"As our ENGINE trial nears completion, we are pleased to be working with QIAGEN on commercial development of our DB102 program to enable patients and physicians to potentially benefit from DB102 treatment," said Xiao-Xiong Lu, Denovo's Chief Technology Officer. "As a pioneer in precision medicine QIAGEN brings extensive experience in companion diagnostics, including ten FDA-approved tests."

QIAGEN will develop a real-time qualitative PCR companion diagnostic for the QIAGEN Rotor-Gene Q MDx instrument and apply for premarket approval (PMA) with the US-based Food and Drug Administration (FDA). The goal is to get the PMA for the test contemporaneously with Denovo receiving new drug application (NDA) approval for its DB102. The drug and the DGM1 marker are currently in a phase III trial, called ENGINE, on newly diagnosed, high-risk DLBCL patients.

"We are proud to be at the cutting edge of precision medicine, a quantum leap from traditional one-drug-fits all medicine," said Jonathan Arnold, Vice President, Head of Oncology and Precision Diagnostics at QIAGEN. "Our molecular testing expertise will help Denovo to develop the use of the DGM1 marker with the DB102 drug for patients with DLBCL."

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 & Co., 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 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 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 in the US and China with DLBCL in a Phase 3 clinical trial and has an ongoing 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 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.

About QIAGEN

QIAGEN N.V., a Netherlands-based holding company, is the leading global provider of Sample to Insight solutions that enable customers to gain valuable molecular insights from samples containing the building blocks of life. Our sample technologies isolate and process DNA, RNA and proteins from blood, tissue and other materials. Assay technologies make these biomolecules visible and ready for analysis. Bioinformatics software and knowledge bases interpret data to report relevant, actionable insights. Automation solutions tie these together in seamless and cost-effective workflows. QIAGEN provides solutions to more than 500,000 customers around the world in Molecular Diagnostics (human healthcare), Applied Testing (primarily forensics), Pharma (pharma and biotech companies) and Academia (life sciences research). As of September 30, 2021, QIAGEN employed approximately 6,000 people in over 35 locations worldwide. Further information can be found at www.qiagen.com.

Forward-Looking Statement QIAGEN

Certain statements contained in this press release may be considered forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended. To the extent that any of the statements contained herein relating to QIAGEN's products, collaborations markets, strategy or operating results, including without limitation its expected adjusted net sales and adjusted diluted earnings results, are forward-looking, such statements are based on current expectations and assumptions that involve a number of uncertainties and risks. Such uncertainties and risks include, but are not limited to, risks associated with management of growth and international operations (including the effects of currency fluctuations, regulatory processes and dependence on logistics), variability of operating results and allocations between customer classes, the commercial development of markets for our products to customers in academia, pharma, applied testing and molecular diagnostics; changing relationships with customers, suppliers and strategic partners; competition; rapid or unexpected changes in technologies; fluctuations in demand for QIAGEN's products (including fluctuations due to general economic conditions, the level and timing of customers' funding, budgets and other factors); our ability to obtain regulatory approval of our products; difficulties in successfully adapting QIAGEN's products to integrated solutions and producing such products; the ability of QIAGEN to identify and develop new products and to differentiate and protect our products from competitors' products; market acceptance of QIAGEN's new products and the integration of acquired technologies and businesses. For further information, please refer to the discussions in reports that QIAGEN has filed with, or furnished to, the U.S. Securities and Exchange Commission (SEC).

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Contacts:

Denovo Biopharma LLC

Michael F. Haller, Ph.D.
Chief Business Officer and Head of US Finance

e-mail: mhaller@denovobiopharma.com

QIAGEN

Investor Relations		**Public Relations**	
John Gilardi	+49 2103 29 11711	Thomas Theuringer	+49 2103 29 11826
Phoebe Loh	+49 2103 29 11457		
e-mail: ir@QIAGEN.com		e-mail: pr@QIAGEN.com	