Denali Therapeutics Announces Upcoming Presentations on Hunter Syndrome (MPS II) and TransportVehicle™ Enabled Investigational Therapeutic Tividenofusp Alfa at the 2025 WORLDSymposium™

January 30, 2025 1:00 PM PST

SOUTH SAN FRANCISCO, Calif., Jan. 30, 2025 (GLOBE NEWSWIRE) -- Denali Therapeutics Inc. (NASDAQ: DNLI), today announced upcoming oral (platform) and poster presentations at the 21st Annual WORLD*Symposium* ™, which will be held February 3-7, 2025, in San Diego, California. The oral presentation includes clinical results related to its Hunter syndrome (MPS II) investigational therapeutic, tividenofusp alfa (DNL310). Tividenofusp alfa is enabled by the Denali TransportVehicle™ platform, which is designed to effectively deliver enzyme, oligonucleotide, or antibody therapeutics to all tissues in the body, including the brain by crossing the blood-brain barrier.

The presentation schedule at WORLD*Symposium* ™ 2025 is as follows:

Title: Interim Analysis of Efficacy and Safety of Weekly Intravenous Tividenofusp Alfa in Mucopolysaccharidosis Type II (MPS II) – Platform Presentation
Session: Clinical Applications Platform Presentations
Date: Thursday, February 6, 2025
Session Time: 8:30 AM Pacific Time

Title: Unmet Needs in the Treatment and Care of Somatic Manifestations in People with Mucopolysaccharidosis Type II (Hunter Syndrome): A Targeted Literature Review – Poster #44
Session: Translational Research – Poster Session II
Date: Thursday, February 6, 2025
Session Time: 3:30 – 5:30 PM Pacific Time

Title: Age-Dependent Reference Intervals for Cerebrospinal Fluid (CSF) and Urine Heparan Sulfate (HS) and Dermatan Sulfate (DS) and CSF Gangliosides – Poster #132
Session: Clinical Applications – Poster Session III
Date: Thursday, February 6, 2025
Session Time: 3:30 – 5:30 PM Pacific Time

Denali is also sponsoring the following satellite symposium event at WORLD*Symposium* ™ 2025:

Title: Voices in Unison – Insights into the Unmet Needs in MPS II from Patient Community and Physician Perspectives (Chair: Barbara K. Burton, M.D.; Speakers: Joseph Muenzer, M.D., Ph.D. and Kristin McKay, President and Executive Director of Project Alive)
Date: Wednesday, February 5, 2025
Time: 6:45 – 7:45 AM Pacific Time

About Denali Therapeutics
Denali Therapeutics is a biopharmaceutical company developing a broad portfolio of product candidates engineered to cross the blood-brain barrier for neurodegenerative diseases and lysosomal storage diseases. Denali pursues new treatments by rigorously assessing genetically validated targets, engineering delivery across the blood-brain barrier and guiding development through biomarkers that demonstrate target and pathway engagement. Denali is based in South San Francisco. For additional information, please visit www.denalitherapeutics.com.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements by Denali Therapeutics Inc. (“Denali” or the “Company”) regarding Denali’s planned presentations and events at the 2025 WORLD*Symposium* ™ and expectations related to Denali's TransportVehicle™ (TV) platform. Actual results are subject to risks and uncertainties and may differ materially from those indicated by these forward-looking statements as a result of these risks and uncertainties, including but not limited to: Denali’s dependence on successful development of its BBB platform technology and TV-enabled product candidates; Denali’s ability to initiate and enroll patients in its current and future clinical trials; Denali’s ability to conduct or complete clinical trials on expected timelines; Denali’s reliance on third parties for the manufacture and supply of its product candidates for clinical trials; the potential for clinical trial results to differ from preclinical, early clinical, preliminary or expected results; the risk of significant adverse events, toxicities, or other undesirable side effects; the risk that results from early clinical biomarker studies will not translate to clinical benefit in late clinical studies; the risk that product candidates may not receive regulatory approval necessary to be commercialized; developments relating to Denali’s competitors and its industry, including competing product candidates and therapies; Denali’s ability to obtain, maintain, or protect intellectual property rights;

and other risks and uncertainties. In light of these risks, uncertainties, and assumptions, the forward-looking statements in this press release are inherently uncertain and may not occur, and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Accordingly, you should not rely upon forward-looking statements as predictions of future events. Denali's product candidates are investigational, and their safety and efficacy profiles have not yet been established. No Denali product candidates have been approved by any health authority for any use. Information regarding additional risks and uncertainties may be found in Denali's Annual and Quarterly Reports filed on Forms 10-K and 10-Q filed with the Securities and Exchange Commission (SEC) on February 28, 2024, and November 6, 2024, respectively, and Denali's future reports to be filed with the SEC. Denali does not undertake any obligation to update or revise any forward-looking statements, to conform these statements to actual results or to make changes in Denali's expectations, except as required by law.

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