Denali Therapeutics Announces Data Presentations on Enzyme TransportVehicle™ Programs for Hunter Syndrome, Sanfilippo Syndrome Type A and Pompe Disease at Upcoming 2026 WORLDSymposium™

January 29, 2026

- Hunter syndrome (MPS II) presentations will include analysis from continued follow-up of Phase 1/2 data for tividenofusp alfa (DNL310), currently under FDA Priority Review
- Preliminary data from Phase 1/2 study of DNL126 (ETV:SGSH) for Sanfilippo syndrome type A (MPS IIIA) to be featured in oral presentation
- Phase 1 study design of DNL952 (ETV:GAA) for Pompe disease and supporting preclinical data will appear in poster session

SOUTH SAN FRANCISCO, Calif., Jan. 29, 2026 (GLOBE NEWSWIRE) -- Denali Therapeutics Inc. (Nasdaq: DNLI) today announced the presentation of clinical and preclinical data from its Enzyme TransportVehicle™ (ETV) programs at the upcoming 22nd Annual WORLD*Symposium* ™ to be heldFebruary 2-6, 2026, in San Diego, California. These presentations will demonstrate the broad potential of the ETV to enable the delivery of enzyme replacement therapies to the whole body, including the brain.

Two oral presentations will discuss continued follow-up data from the Phase 1/2 clinical study of tividenofusp alfa (DNL310) for Hunter syndrome (mucopolysaccharidosis type II, or MPS II) and preliminary clinical data from the ongoing Phase 1/2 study of DNL126 (ETV:SGSH) for Sanfilippo syndrome type A (MPS IIIA). In addition, three posters will highlight a case study with a non-neuronopathic sibling pair from the Phase 1/2 study of tividenofusp alfa; a community survey conducted in partnership with patient advocacy organization Project Alive examining unmet needs among individuals living with MPS II and their caregivers; and a health outcomes analysis evaluating the clinical and economic burden among individuals treated for MPS II. The U.S. Food and Drug Administration (FDA) is conducting a Priority Review of the Biologics License Application (BLA) for tividenofusp alfa, with a decision expected by April 5, 2026. Denali will also detail the design of the Phase 1 study of DNL952 (ETV:GAA) for Pompe disease and supporting preclinical data in two posters.

Details on the WORLD*Symposium* presentations are below:

Platform Presentations

Title: Phase I/II Study of Intravenous Tividenofusp Alfa for Mucopolysaccharidosis Type II
Presentation #258
Date: Thursday, February 5, 2026
Session Time: 11:00 AM-noon PST

Title: Preliminary Results From Phase I/II, First-in-Human, Open-Label Study of DNL126 in Children With Mucopolysaccharidosis Type IIIA (MPS IIIA)
Presentation #183
Date: Thursday, February 5, 2026
Session Time: 11:00 AM-noon PST

Poster Presentations

Title: Persistent Clinical Burden and Unmet Needs in Hunter Syndrome (MPS II) in the United States: A Retrospective Cohort Study
Poster #052
Date: Tuesday, February 3, 2026
Time: 3:30-5:30 PM PST

Title: Enhanced Correction of Skeletal Muscle and Brain Pathology in a Pompe Mouse Model Using Transferrin Receptor-Mediated Delivery of GAA
Poster #290
Date: Wednesday, February 4, 2026
Time: 3:30-5:30 PM PST

Title: Tividenofusp Alfa Treatment in a Male Sibling Pair with Non-neuronopathic Mucopolysaccharidosis Type II (MPS II)
Poster #065
Date: Thursday, February 5, 2026
Time: 3:30-5:30 PM PST

Title: Quality of Life (QoL), Unmet Needs, and Treatment Experience of People Living with Mucopolysaccharidosis Type II (MPS II) and Their Caregivers: A Community Survey

Poster #248
Date: Thursday, February 5, 2026
Session Time: 3:30-5:30 PM PST

Title: A Phase 1, Multi-center, Open-label Study Design to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of DNL952 in Adult Participants with Late-Onset Pompe Disease
Poster #034
Date: Thursday, February 5, 2026
Time: 3:30-5:30 PM PST

PDFs of the presentations will be available on the Events page in the Investor section of Denali's corporate website once the WORLD*Symposium* embargo lifts.

Denali will sponsor a satellite symposium event titled "Transforming Patient Care in MPS II" on Thursday, February 5, 2026, from 6:45-7:45 AM PST. Featured speakers are Barbara Burton, M.D.; Gwen Gunn, Ph.D., M.S. and Paul Harmatz, M.D.

About the Denali TransportVehicle™ Platform

The blood-brain barrier (BBB) is essential in maintaining the brain's microenvironment and protecting it from harmful substances and pathogens circulating in the bloodstream. Historically, the BBB has posed significant challenges to drug development for central nervous system diseases by preventing most drugs from reaching the brain in therapeutically relevant concentrations. Denali's TransportVehicle™ (TV) platform is a proprietary technology designed to effectively deliver large therapeutic molecules such as antibodies, enzymes and oligonucleotides throughout the whole body, including the brain, by crossing the BBB after intravenous administration. The TV platform is based on engineered Fc domains that bind to specific natural transport receptors, such as transferrin receptor and CD98 heavy chain amino acid transporter, which are expressed at the BBB and deliver the TV and its therapeutic cargo to the brain through receptor-mediated transcytosis. In animal models, antibodies and enzymes engineered with the TV platform demonstrate more than 10- to 30-fold greater brain exposure than similar antibodies and enzymes without this technology. Oligonucleotides engineered with the TV platform demonstrate more than a 1,000-fold greater brain exposure in primates than systemically delivered oligonucleotides without this technology. Improved exposure and broad distribution in the brain may increase therapeutic efficacy by enabling widespread achievement of therapeutically relevant concentrations of product candidates. The TV platform has been clinically validated and five TV-enabled programs are currently in clinical development.

About Denali Therapeutics

Denali Therapeutics Inc. is a biotechnology company pioneering a new class of biotherapeutics designed to cross the blood-brain barrier using its proprietary TransportVehicle™ platform. With a clinically validated delivery platform and a growing portfolio of therapeutic candidates across all stages of development, Denali is advancing toward its goal of delivering effective medicines to transform the lives of people living with neurodegenerative, lysosomal storage and other serious diseases. For more information, please visit www.denalitherapeutics.com.

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 2026 WORLDS*ymposium* ™; expectations related to Denali's TransportVehicle™ (TV) platform; the timing and availability of data from the ongoing Phase 1/2 study in DNL126 and data analysis from the Phase 1/2 study in DNL310; plans and expectations regarding the ongoing Phase 1 study in DNL952 and the availability of preclinical data for this study; and timelines and expectations related to the potential approval of DNL310. 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: uncertainties related to the FDA's policies and accelerated approval program, including risks that the PDUFA action date may be extended and the FDA may not approve DNL310; the possibility of events or changes that could lead to the termination of Denali's collaboration agreements; Denali's dependence on successful development and commercialization 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 and commercial products; 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 27, 2025, and November 6, 2025,

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.

Investor Contact:
Laura Hansen, Ph.D.
hansen@dnli.com

Media Contact:
Erin Patton
epatton@dnli.com

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