Dianthus Therapeutics Announces Initiation of Phase 2 MaGic Trial of DNTH103 In Generalized Myasthenia Gravis (gMG)

February 26, 2024

Top-line results from gMG MaGic trial anticipated in 2H 2025

Building a neuromuscular franchise with DNTH103 through additional planned Phase 2 trials in Multifocal Motor Neuropathy (MMN) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

DNTH103 is a potential best-in-class, potent classical pathway inhibitor planned for self-administration as a low volume, subcutaneous injection once every two weeks

NEW YORK and WALTHAM, Mass., Feb. 26, 2024 (GLOBE NEWSWIRE) -- Dianthus Therapeutics, Inc. (Nasdaq: DNTH), a clinical-stage biotechnology company dedicated to advancing the next generation of antibody complement therapeutics to treat severe autoimmune diseases, today announced the initiation of the Phase 2 MaGic trial of DNTH103 in patients with generalized Myasthenia Gravis. The initiation follows U.S. Food and Drug Administration (FDA) clearance of the Phase 2 Investigational New Drug (IND) application for DNTH103. Top-line results from this trial are anticipated in the second half of 2025.

“Following our encouraging Phase 1 data demonstrating a 60-day half-life and potent, specific classical pathway inhibition, we are excited to rapidly advance DNTH103, our investigational active C1s inhibitor, into a Phase 2 study in generalized Myasthenia Gravis,” said Simrat Randhawa, M.D., Chief Medical Officer of Dianthus Therapeutics. “DNTH103 provides a unique approach to complement inhibition in gMG, which could result in a more convenient and safer alternative for patients versus current options.”

The MaGic trial is a global, randomized, double-blind, placebo-controlled Phase 2 study in up to 60 patients with generalized Myasthenia Gravis who are acetylcholine receptor (AchR) antibody positive. Following an initial loading dose, DNTH103 will be administered every two weeks (Q2W) via subcutaneous (S.C.) injection. The S.C. treatment duration will initially be 12 weeks with a 52-week open label extension. The primary endpoint of the study is safety and tolerability. Secondary endpoints include Myasthenia Gravis Activities of Daily Living Scale (MG-ADL) and Quantitative Myasthenia Gravis (QMG) score assessments. Initial top-line results from this trial are anticipated to be available in the second half of 2025.

“For patients with AchR-positive gMG, inappropriate activation of the complement classical pathway is a major driver of disease pathology and therefore patient symptoms,” said Mazen M. Dimachkie, M.D., Professor of Neurology and Director of Neuromuscular Division at the University of Kansas Medical Center. “I am excited to collaborate with Dianthus to evaluate this investigational, highly specific classical pathway inhibitor that could fill the need for a more convenient and safe complement inhibitor for my gMG patients.”

About DNTH103
DNTH103 is an investigational, clinical-stage, potent monoclonal antibody engineered to selectively target the classical pathway by inhibiting only the active form of the C1s protein, a clinically validated complement target. DNTH103 is enhanced with YTE half-life extension technology designed to enable a more convenient subcutaneous, self-administered injection dosed as infrequently as once every two weeks. Additionally, selective inhibition of the classical complement pathway may lower patient risk of infection from encapsulated bacteria by preserving immune activity of the lectin and alternative pathways. As the classical pathway plays a significant role in disease pathology, DNTH103 has the potential to be a best-in-class pipeline-in-a-product across a range of autoimmune disorders with high unmet need. Dianthus has initiated a Phase 2 trial in generalized Myasthenia Gravis and plans to initiate additional Phase 2 trials in other neuromuscular indications, including Multifocal Motor Neuropathy and Chronic Inflammatory Demyelinating Polyneuropathy, in 2024.

About Dianthus Therapeutics
Dianthus Therapeutics is a clinical-stage biotechnology company dedicated to designing and delivering novel, best-in-class monoclonal antibodies with improved selectivity and potency. Based in New York City and Waltham, Mass., Dianthus is comprised of an experienced team of biotech and pharma executives who are leading the development of next-generation antibody complement therapeutics, aiming to deliver transformative medicines for people living with severe autoimmune and inflammatory diseases.

Dianthus has initiated a Phase 2 trial of DNTH103, a potential best-in-class active C1s inhibitor, in generalized Myasthenia Gravis and plans to initiate additional Phase 2 trials in other neuromuscular indications, including Multifocal Motor Neuropathy and Chronic Inflammatory Demyelinating Polyneuropathy, in 2024.

To learn more, please visit www.dianthustx.com and follow us on LinkedIn.

Cautionary Statement Regarding Forward-Looking Statements
Certain statements in this press release, other than purely historical information, may constitute “forward-looking statements” within the meaning of the federal securities laws, including for purposes of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995, express or implied statements regarding future plans and prospects, including statements regarding the expectations or plans for discovery, preclinical studies, clinical trials and research and development programs, in particular with respect to DNTH103, and any developments or results in connection therewith, including the target product profile of DNTH103; the anticipated timing of the initiation and results from those studies and trials; and expectations regarding the market and potential opportunities for complement therapies, in particular with respect to DNTH103. The words “opportunity,” “potential,” “milestones,” “runway,” “will,” “anticipate,” “achieve,” “near-term,” “catalysts,” “pursue,” “pipeline,” “believe,” continue,” “could,” “estimate,” “expect,” “ intend,” “may,” “might,” “plan,” “possible,” “predict,” “project,” “ should,” “strive,” “would,” “aim,” “target,” “commit,” and similar expressions (including the negatives of these terms or variations of them) generally identify forward-looking statements, but the absence of these words does not mean that statement is not forward looking.

Actual results could differ materially from those included in the forward-looking statements due to various factors, risks and uncertainties, including, but not limited to, that preclinical testing of DNTH103 and data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that the development of DNTH103 or the Company's other compounds may take longer and/or cost more than planned, that the Company may be unable to successfully complete the clinical development of the Company's compounds, that the Company may be delayed in initiating, enrolling or completing its planned clinical trials, and that the Company's compounds may not receive regulatory approval or become commercially successful products. These and other risks and uncertainties are identified under the heading "Risk Factors" included in Exhibit 99.1 to the Company's Current Report on Form 8-K filed with the SEC on September 12, 2023 (as amended on September 21, 2023), and other filings that the Company has made and may make with the SEC in the future. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved.

The forward-looking statements in this press release speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Dianthus undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

Contact
Jennifer Davis Ruff
Dianthus Therapeutics
jdavisruff@dianthustx.com