Dianthus Therapeutics Completes Enrollment of Phase 2 MaGic Trial of DNTH103 in Generalized Myasthenia Gravis With Top-Line Results Expected in September

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MaGic trial exceeded enrollment target of 60 patients

Top-line results anticipated this September will be the first of three DNTH103 catalysts by YE'26

Building a neuromuscular franchise with DNTH103 in gMG, CIDP and MMN with a potential best-in-class, potent classical pathway inhibitor intended as a self-administered autoinjector dosed once every two weeks

NEW YORK and WALTHAM, Mass., May 05, 2025 (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 completion of enrollment in the Phase 2 MaGic trial of DNTH103 in patients with generalized Myasthenia Gravis (gMG). 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. Initial top-line results from the MaGic trial are anticipated in September 2025.

MaGic is a global, randomized, double-blind, placebo-controlled Phase 2 trial that enrolled 65 patients with acetylcholine receptor (AChR) antibody positive gMG, exceeding the enrollment target of 60 patients. The primary endpoint of the trial is safety and tolerability, and key secondary endpoints include Myasthenia Gravis Activities of Daily Living Scale (MG-ADL) and Quantitative Myasthenia Gravis (QMG) score assessments.

“We are pleased to have reached this important milestone in the development of DNTH103 for gMG, which is well understood to be a classical pathway-driven disease,” said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. “Latest estimates indicate that the gMG market in the U.S. exceeds 100,000 patients, approximately 85% of whom have AChR autoantibody-driven disease, with growing first-line biologic use. Despite currently approved treatment options, a significant unmet need exists for patients seeking continuous symptom control, lower risk for infections, and more convenient dosing and administration, which we believe DNTH103 has the potential to address as a first-line therapy.”

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 designed to enable a more convenient subcutaneous, self-administered injection dosed as infrequently as once every two weeks. DNTH103 has the potential to be a best-in-class pipeline-in-a-product across a range of autoimmune disorders with high unmet need and is also being evaluated in the ongoing Phase 3 CAPTIVATE trial in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and the ongoing Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy (MMN). The Company is on track for the interim responder analysis of the Phase 3 CAPTIVATE trial in CIDP and top-line data from the Phase 2 MoMeNtum trial in MMN in 2H’26.

About the Phase 2 MaGic Trial
The MaGic trial is a global, randomized, double-blind, placebo-controlled Phase 2 study in 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 in September 2025.

About Generalized Myasthenia Gravis (gMG)
Generalized Myasthenia Gravis (gMG) is a chronic autoimmune disorder driven by the classical pathway that causes progressive muscle weakness. Over 100,000 people in the U.S. are living with gMG and approximately 85% have AChR autoantibody-driven disease. Despite availability of current treatment options, a significant number of patients remain uncontrolled and are seeking better treatment options which may offer sustained efficacy, lower potential risk for infections, and convenient dosing and administration.

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 is building a neuromuscular franchise with DNTH103 and anticipates reporting top-line data from the Phase 2 MaGic trial in generalized Myasthenia Gravis in September 2025, the interim responder analysis of the Phase 3 CAPTIVATE trial in Chronic Inflammatory Demyelinating Polyneuropathy in 2H’26, and top-line data from the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy in 2H’26.

DNTH103 is an investigational agent that is not approved as a therapy in any indication in any jurisdiction worldwide.

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.

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 and administration of DNTH103; the anticipated timing of the initiation and results from those studies and trials; expectations regarding the time period over which the Company’s capital resources are expected to be sufficient to fund its anticipated operations; 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 the Company’s Annual Report on Form 10-K for the period ended December 31, 2024, 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.

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