



DIANTHUS THERAPEUTICS

Dianthus Therapeutics Announces Initiation of Phase 3 Emerge Trial of Claseprubart in Generalized Myasthenia Gravis

June 29, 2026

EMERGE is a global, randomized, multicenter, placebo-controlled Phase 3 trial that will evaluate claseprubart 300mg/2mL S.C. dosed Q2W and Q4W vs. placebo, with top-line results anticipated in 2H'28

Advancing a neuromuscular franchise with claseprubart, a highly potent investigational classical pathway inhibitor, across generalized Myasthenia Gravis (gMG), Multifocal Motor Neuropathy (MMN) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), with best-in-disease, pipeline-in-a-product potential

NEW YORK and WALTHAM, Mass., June 29, 2026 (GLOBE NEWSWIRE) -- Dianthus Therapeutics, Inc. (Nasdaq: DNTH), a clinical-stage biotechnology company dedicated to developing next-generation therapies to transform the treatment of severe autoimmune diseases, today announced initiation of the [Phase 3 EMERGE trial](#) of claseprubart in generalized Myasthenia Gravis (gMG).

"Given the impressive Phase 2 MG results, the medical team has been eagerly anticipating the initiation of this important study and the opportunity to implement important Phase 2 learnings," said Simrat Randhawa, M.D., Executive Vice President and Head of R&D of Dianthus Therapeutics. "Our internal enthusiasm has been matched by site and principal investigator interest globally so far."

EMERGE is a global, randomized, multicenter, placebo-controlled Phase 3 trial in approximately 195 participants with generalized Myasthenia Gravis who are acetylcholine receptor antibody positive (AChR+). Following an initial loading dose, claseprubart 300mg/2mL will be administered every two or four weeks (Q2W or Q4W) via subcutaneous (S.C.) injection. The primary endpoint of this trial is the change from baseline in the Myasthenia Gravis Activities of Daily Living Scale (MG-ADL) in the treatment arms vs. the placebo arm. A similar evaluation is used for secondary efficacy endpoints such as the Quantitative Myasthenia Gravis (QMG) scale, Minimal Symptom Expression (MSE), Myasthenia Gravis Composite (MGC) Score and the Myasthenia Gravis Quality of Life Scale (MG-QoL-15r). Top-line results from this trial are anticipated to be available in 2H'28.

[Results](#) from the [MaGic trial](#), a global, randomized, double-blind, placebo-controlled Phase 2 trial in patients with gMG who are acetylcholine receptor (AChR) antibody positive, were reported in September 2025 and [presented](#) at the Myasthenia Gravis Foundation of America (MGFA) Scientific Session held during the 2025 American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) Annual Meeting. Claseprubart 300mg/2mL Q2W S.C. demonstrated rapid, sustained, statistically significant and clinically meaningful improvements over placebo as measured by both MG-ADL and QMG, including at Week 1 and at Week 13. The claseprubart 300mg/2mL Q2W dose was also statistically significant and clinically meaningful across other key efficacy endpoints, including MSE, MGC and MG-QoL-15r. Claseprubart was generally well tolerated with no drug-related Serious Adverse Events (SAEs) or discontinuations due to any related adverse event.

About Claseprubart (DNTH103)

Claseprubart 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. Claseprubart is enhanced with YTE half-life extension technology designed to enable a more convenient subcutaneous, infrequently dosed, self-administered injection. 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, claseprubart has the potential to be a best-in-disease pipeline-in-a-product across a range of autoimmune disorders with high unmet need. Claseprubart was granted Orphan Drug Designation by the FDA for the treatment of Myasthenia Gravis in May 2026.

Dianthus is building a neuromuscular franchise with claseprubart and expects to report top-line data from the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy in Q4'26, to provide an update on timing of top-line data from Part B of the Phase 3 CAPTIVATE trial in Chronic Inflammatory Demyelinating Polyneuropathy by YE'26, and to report top-line results from the Phase 3 EMERGE trial in generalized Myasthenia Gravis in 2H'28.

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

About Generalized Myasthenia Gravis

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 Dianthus Therapeutics

Dianthus Therapeutics, Inc. is a clinical-stage biotechnology company dedicated to developing next-generation therapies to transform the treatment of severe autoimmune diseases. Based in New York City and Waltham, Mass., Dianthus is comprised of an experienced team of biotech and pharma executives who aim 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 claseprubart, and any developments or results in

connection therewith, including the target product profile and administration of claseprubart; the anticipated timing of the initiation and results from those studies and trials; expectations regarding the clinical trial designs or indications; 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 market size, patient population size, and potential opportunities for complement therapies, in particular with respect to claseprubart. Claseprubart is an investigational agent that is not approved as a therapy in any indication in any jurisdiction worldwide. 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 claseprubart and data from clinical trials may not be predictive of the results or success of ongoing or later clinical trials, that the development of claseprubart may take longer and/or cost more than planned, that the Company or its partner may be unable to successfully complete the clinical development of the Company's compounds, that the Company or its partner 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, 2025, 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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