Dianthus Therapeutics Announces Positive Data for Claseprubart (DNTH103) from the Phase 2 MaGic Trial in Generalized Myasthenia Gravis, Supporting Its Potential Best-In-Class Profile

September 08, 2025

Claseprubart 300mg and 600mg Q2W doses both achieved statistically significant and clinically meaningful improvements in Myasthenia Gravis Activities of Daily Living (MG-ADL) and Quantitative Myasthenia Gravis (QMG) scores at Week 13

Claseprubart demonstrated a rapid and sustained onset of action, with both doses achieving statistically significant improvements in MG-ADL and QMG scores at Week 1

Claseprubart 300mg Q2W dose was also statistically significant and clinically meaningful across other key efficacy endpoints, including Minimal Symptom Expression (MSE), Myasthenia Gravis Composite (MGC) Score and the Myasthenia Gravis Quality of Life Scale (MG-QoL-15r)

Both 300mg and 600mg doses of claseprubart were comparable across key efficacy endpoints, supporting its target product profile of a single, convenient 300mg/2mL self-administered, subcutaneous autoinjector dosed once every two weeks

Claseprubart had a favorable safety profile with no related serious infections, clinical symptoms of emergent autoimmune disease, or drug-related serious adverse events or discontinuations, supporting its target product profile of no Boxed Warning or REMS for meningococcal infections

Phase 3 gMG trial evaluating 300mg/2mL Q2W and Q4W vs. placebo anticipated to initiate in 2026

Investor conference call and webcast to be held today, September 8, 2025 at 8:00 a.m. ET

NEW YORK and WALTHAM, Mass., Sept. 08, 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 positive top-line data from the Phase 2 MaGic trial evaluating the safety and efficacy of claseprubart (DNTH103) in adults with acetylcholine receptor antibody positive (AChR+) generalized Myasthenia Gravis (gMG).

“The results from MaGic mark a significant milestone for Dianthus and are an important step forward for people living with gMG. These results are also a reflection of the commitment and talent of the entire Dianthus team, and I want to thank them for their outstanding execution of this clinical trial,” said Marino Garcia, President and Chief Executive Officer of Dianthus Therapeutics. “The concordance of the efficacy and safety data from the MaGic trial strongly support our best-in-class target product profile for claseprubart 300mg/2mL Q2W in gMG and bolsters our confidence in our execution of the CIDP and MMN clinical programs.”

About the Phase 2 MaGic Trial
The MaGic trial is a global, randomized, double-blind, placebo-controlled Phase 2 trial that enrolled 65 AChR+ participants with gMG. Following an initial loading dose, claseprubart was administered every two weeks (Q2W) via subcutaneous (S.C.) injection at a dose of 300mg/2mL or 600mg/4mL. The initial randomized treatment duration was 13 weeks, followed by a 52-week open-label extension. The primary endpoint of the study was safety and tolerability. Secondary and exploratory efficacy endpoints included Myasthenia Gravis Activities of Daily Living Scale (MG-ADL) and Quantitative Myasthenia Gravis (QMG) score assessments, as well as Minimal Symptom Expression (MSE), Myasthenia Gravis Composite (MGC) score and the Myasthenia Gravis Quality of Life Scale (MG-QOL-15r).

Summary Results from the Phase 2 MaGic Trial
Claseprubart 300mg and 600mg demonstrated rapid, 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 Q2W dose was also statistically significant and clinically meaningful across other key efficacy endpoints, including Minimal Symptom Expression (MSE), Myasthenia Gravis Composite (MGC) Score and the Myasthenia Gravis Quality of Life Scale (MG-QoL-15r).

Claseprubart was generally well tolerated with no drug-related Serious Adverse Events (SAEs) or discontinuations due to any related adverse event. Claseprubart had a favorable clinical safety profile comparable to placebo with no treatment-related serious bacterial infections and no clinical symptoms of emergent autoimmune disorders observed.

“I would like to thank the MaGic investigators and site staff who made the seamless execution of this study possible,” said Simrat Randhawa, MD, Chief Medical Officer of Dianthus Therapeutics. “The consistent and meaningful treatment effect seen in both treatment arms across multiple standard MG efficacy metrics in this Phase 2 trial gives me and my team great confidence in our ability to execute a successful Phase 3 trial.”

“gMG is a chronic condition that can be treated with complement and FcRn inhibitors. The ideal drug should provide continuous symptom control and have low infection risks, infrequent side effects, convenient dosing schedule, and minimal administration burden,” said Dr. Tuan Vu, a Professor of Neurology at the University of South Florida Morsani College of Medicine. “If these impressive results were replicated in a Phase 3 trial, claseprubart may be a differentiated treatment option for patients with gMG.”

Efficacy Results

MG-ADL

- Claseprubart dosed at 300mg S.C. Q2W achieved a statistically significant and clinically meaningful mean improvement from baseline of 4.6 points in MG-ADL score at Week 13 (placebo-adjusted improvement: 1.8 points; P=0.0113). A statistically significant improvement in the MG-ADL was also seen as early as Week 1 with 300mg.

- Claseprubart dosed at 600mg S.C. Q2W achieved a statistically significant and clinically meaningful mean improvement from baseline of 5.4 points in MG-ADL score at Week 13 (placebo-adjusted improvement: 2.6 points; P=0.0006). A statistically significant improvement in the MG-ADL was also seen as early as Week 1 with 600mg.
- As expected, there was no statistically significant difference between the claseprubart 300mg and 600mg arms in MG-ADL score at any time point.

QMG

- Claseprubart dosed at 300mg S.C. Q2W achieved a statistically significant and clinically meaningful mean improvement from baseline of 4.4 points in QMG score at Week 13 (placebo-adjusted improvement: 2.4; P=0.0144). A statistically significant improvement in QMG was also seen as early as Week 1 with 300mg.
- Claseprubart dosed at 600mg S.C. Q2W achieved a statistically significant and clinically meaningful mean improvement from baseline of 4.5 points in QMG score at Week 13 (placebo-adjusted improvement: 2.5; P=0.0111). A statistically significant improvement in QMG was also seen as early as Week 1 with 600mg.
- As expected, there was no statistically significant difference between the claseprubart 300mg and 600mg arms in QMG score at any time point.

Efficacy Summary at Week 13

	Placebo N=22	**Claseprubart 300mg Q2W N=21**		**Claseprubart 600mg Q2W N=22**	
		Absolute	**Placebo-Adjusted**	**Absolute**	**Placebo-Adjusted**
MG-ADL mean change from baseline	-2.8	-4.6	-1.8 *(P=0.0113)**	-5.4	-2.6 *(P=0.0006)**
QMG mean change from baseline	-2.0	-4.4	-2.4 *(P=0.0144)**	-4.5	-2.5 *(P=0.0111)**
MSE	14%	37%	23% *(P=0.0550)**	27%	13% *(P=0.1031)*
MGC mean change from baseline	-3.1	-8.7	-5.6 *(P=0.0008)**	-8.6	-5.5 *(P=0.0008)**
MG-QoL-15r mean change from baseline	-3.9	-6.1	-2.2 *(P=0.0414)**	-5.4	-1.5 *(P=0.1122)*

*One-sided p-values are presented for comparisons of claseprubart vs placebo, with any p-value below 0.1 considered nominally statistically significant.

Safety and Tolerability Results

- Claseprubart was generally well tolerated and demonstrated a clinical safety profile in both treatment arms comparable to placebo.
- No infection signal was observed, including no related serious bacterial infections in the treatment arms; the only related serious adverse event (SAE) of infection occurred in the placebo arm.
- There were no symptoms indicative of autoimmune activation.
- Injection site reactions (ISRs) were infrequent and generally mild, and there were no claseprubart discontinuations from RCT due to related AEs.

Next Steps
“Based on the comparable efficacy data demonstrated in MaGic by the 300mg and 600mg Q2W doses, as well as encouraging early data from the open-label extension, we are planning for an end-of-Phase 2 meeting with the FDA to align on the proposed design of a Phase 3 trial for claseprubart in Myasthenia Gravis that investigates both 300mg Q2W and 300mg Q4W doses vs. placebo,” said Marino Garcia, President and Chief Executive Officer of Dianthus Therapeutics. “2026 will be a catalyst-rich year, with the initiation of the Phase 3 gMG trial followed by results from the interim responder analysis of the Phase 3 CAPTIVATE trial in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and top-line results from the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy (MMN), both in 2H’26.”

Investor Conference Call & Webcast to be Held at 8:00 a.m. ET Today
Dianthus Therapeutics will host an investor call and webcast to discuss the Phase 2 MaGic results today, September 8, 2025 at 8:00 a.m. ET. Please click here to register for this event.

The live webcast may be accessed via the Investors section of the Dianthus Therapeutics website at https://investor.dianthustx.com/. A replay of the webcast will be available following the call.

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-class pipeline-in-a-product across a range of autoimmune disorders with high unmet need. Dianthus is building a neuromuscular franchise with claseprubart and expects to initiate a Phase 3 trial in gMG in 2026, 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.

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 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 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 design for the Phase 3 trial for claseprubart in gMG; 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 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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