Dianthus Therapeutics Announces Early GO Decision Following Interim Responder Analysis in Phase 3 CAPTIVATE Trial of Claseprubart in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

March 09, 2026

Early GO decision reached ahead of Q2'26 guidance based on GO criteria of 20 confirmed responders achieved with less than 40 planned participants completing open-label Part A

Key objectives achieved: Company will maintain the Part A dose of 300mg/2mL S.C. Q2W, plans to engage with regulators to remove the 600mg/4mL S.C. Q2W dose arm from Part B, and expects to enroll up to 256 patients in Part A to randomize 128 patients in Part B

Independent DSMB review confirmed GO decision; no related serious infections, no clinical symptoms of autoimmune activation, and no related serious adverse events or discontinuations

GO decision supports continued development of claseprubart 300mg/2mL Q2W S.C. in CIDP, targeting a potentially best-in-disease biologic profile across a broad population of CIDP patients, including those refractory to standard-of-care

Investor conference call and webcast to be held today, March 9, 2026 at 8:00 a.m. ET

NEW YORK and WALTHAM, Mass., March 09, 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 an early GO decision based on an interim responder analysis in the Phase 3 CAPTIVATE trial of claseprubart in Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

"We are excited to announce an early GO decision based on results from less than 40 planned participants completing Part A of the CAPTIVATE Phase 3 trial. These interim responder analysis results, in addition to the robust Phase 2 data from our MaGic trial in generalized Myasthenia Gravis, bolster our confidence in the best-in-class target profile for claseprubart and its potential to become a best-in-disease, first-line biologic of choice across a range of large and growing neuromuscular indications," said Marino Garcia, Chief Executive Officer of Dianthus. "Classical pathway inhibition could replace the standard of care in the multi-billion-dollar CIDP market with the potential for improved efficacy, differentiated safety, and lower patient burden. We expect our planned study design changes to streamline the CAPTIVATE trial and support even faster execution."

Interim Responder Analysis Results Summary

- The target for the Part A interim responder analysis was a response rate of 50% or greater (i.e., ≥20 confirmed responders out of first 40 participants to complete Part A) based on precedent set with aC1s inhibition.
- This GO decision was reached early, after 20 confirmed responders were achieved with less than 40 planned participants completing Part A of the trial.
- There have been no related serious infections, no clinical symptoms of autoimmune activation, no related serious adverse events or discontinuations.
- The GO decision was confirmed by an independent DSMB review.

Next Steps: Planned CAPTIVATE Trial Design Updates
Dianthus anticipates the following:

- Maintain the claseprubart 300mg/2mL S.C. Q2W dose in Part A;
- Engage with regulators to remove the claseprubart 600mg/4mL S.C. Q2W arm from Part B;
- Enroll up to 256 patients (previously up to 480) in Part A to randomize 128 patients in Part B (previously 192); and
- Provide CAPTIVATE Part B top-line guidance by the end of 2026.

"As a neurologist who specialized in and treated many patients with neuromuscular diseases including CIDP, it is encouraging to see consistency across multiple clinically meaningful measures including INCAT, MRC-SS, Grip Strength, and IRODS in Part A of the CAPTIVATE study," said James K. Sheffield, MD, Vice President and Head of CIDP Development of Dianthus. "These initial findings motivate the CIDP team to get to primary results as soon as possible."

About CAPTIVATE
CAPTIVATE is a single, two-part, randomized withdrawal Phase 3 trial of claseprubart in CIDP. In open-label Part A of this trial, participants are administered a loading dose followed by 300mg claseprubart administered every 2 weeks (Q2W) via subcutaneous (S.C.) injection for up to 13 weeks. Part A included an interim responder analysis of a pre-defined number of participants. The primary endpoint in Part A is response as measured as ≥1 point decrease (improvement) in adjusted INCAT score compared to Part A baseline. Only participants who respond to claseprubart in Part A will be randomized into Part B, a double-blind, placebo-controlled treatment period of up to 52 weeks, where they will be assessed for prevention of relapse, safety and tolerability, followed by an open-label extension period. The primary endpoint in Part B is efficacy (time to relapse) as measured as ≥1 point increase in adjusted INCAT. The Company believes this single pivotal trial will support Biologics License Application filing in adult patients with CIDP and expects to provide CAPTIVATE Part B top-line guidance by the end of 2026.

CAPTIVATE 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 CAPTIVATE trial interim responder analysis today, March 9, 2026 at 8:00

a.m. ET. To access the live conference call by phone, please register here. Conference call participants in the question and answer session should pre-register to receive the dial-in number and personal PIN.

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. The presentation that will be used on this webcast is available here.

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 generalized Myasthenia Gravis in mid-2026, with top-line results expected in the second half of 2028, report top-line data from the Phase 2 MoMeNtum trial in Multifocal Motor Neuropathy in the second half of 2026, and provide an update on timing of top-line data from Part B of the Phase 3 CAPTIVATE trial in Chronic Inflammatory Demyelinating Polyneuropathy by the end of 2026.

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

About CIDP
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) is an autoimmune and inflammatory disorder affecting the myelin that insulates and protects peripheral nerves. CIDP is estimated to affect more than 40,000 people in the United States. Common symptoms of the disease include weakness, loss of balance, and sensation changes in the arms or legs. In the classic or typical CIDP, there is symmetric involvement of both upper and lower limbs, characterized by weakness in the proximal (for example, shoulder region or hip region) as well as distal (for example, wrist or ankle) muscle groups. In addition, there is sensory involvement. There are several atypical forms of CIDP, characterized by varying levels of motor and sensory involvement with overlap. CIDP follows a relapsing-remitting or a progressive clinical course, which can result in substantial disability, loss of motor and sensory function, and negative impact on quality of life.

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; 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 preliminary interim analysis based on a limited number of patients from the Part A open-label portion of the claseprubart CAPTIVATE study in patients with CIDP may not be predictive of the results or success of the remaining patients treated in Part A or patients treated in Part B of the CAPTIVATE study, 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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