Dianthus Therapeutics Announces DNTH312, a First-In-Class, Next-Generation Bifunctional Fusion Protein Combining Claseprubart and TACI, for Severe Autoimmune Diseases

August 04, 2026

DNTH312 is an internally developed bifunctional fusion protein targeting potent inhibition of active C1s (aC1s) and BAFF/APRIL, two validated pathways with complementary disease modifying mechanisms

DNTH312 demonstrated comparable in vitro potency and aC1s inhibition to claseprubart, with a comparable non-human primate (NHP) half-life

DNTH312 showed similar depth of Ig reductions vs. povetacicept following a single dose in NHPs

By building on claseprubart's best-in-class profile, DNTH312 strengthens Dianthus' leadership in neuromuscular disease, while expanding into additional autoimmune diseases where both B cell modulation and Classical Pathway inhibition could provide additional benefits to more patients

DNTH312 aims to be Phase 1 ready by YE'27

NEW YORK and WALTHAM, Mass., Aug. 04, 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 DNTH312, an investigational, first-in-class, extended half-life bifunctional fusion protein that combines claseprubart and TACI. DNTH312 is designed to deliver robust Classical Pathway inhibition via aC1s and inhibition of B cell activity via BAFF/APRIL, two validated pathways with complementary disease modifying mechanisms.

"We're excited to announce DNTH312 as a new pipeline candidate that originated from our internal research team efforts. DNTH312 combines upstream and downstream inhibition of pathways often responsible for the morbidity seen in autoantibody mediated diseases such as MG, CIDP and MMN, and targets pathways the Dianthus medical team is already expert at evaluating," said Simrat Randhawa, MD, Executive Vice President and Head of Research and Development of Dianthus Therapeutics.

DNTH312: Goal to Drive Superior Clinical Efficacy by Targeting Both aC1s and BAFF/APRIL

Combining upstream (B-cell) and downstream (classical pathway) inhibition in a single molecule is a very attractive approach in indications where morbidity is largely driven by autoantibodies that can drive inappropriate immune activity including Classical Complement Pathway activation. For example, in MG, targeting B cells via BAFF/APRIL inhibition should reduce autoantibodies that attract local inflammation to the neuromuscular junction, while blocking the Classical Pathway prevents local deposition of pro inflammatory complement components such as C3a and especially the Membrane Attack Complex (MAC).

DNTH312 demonstrated comparable *in vitro* potency and aC1s inhibition to claseprubart across several functional assays of Classical Pathway inhibition. Additionally, DNTH312 is enhanced with YTE half-life extension technology, and has a similar NHP half-life (22 days) to claseprubart, which has an approximately 60-day half-life in humans. DNTH312 also demonstrated a similar depth of IgM, IgA, and IgG reduction following a single dose in NHPs compared to povetacicept, a late-stage, clinically validated BAFF/APRIL inhibitor.

This dual mechanism is intended to result in deeper responses, broader symptom control and ability to reach larger target populations of patients with severe autoimmune diseases.

Key potential benefits of DNTH312 include:

- **Comparable NHP half-life to claseprubart:** DNTH312 has a similar NHP half-life (22 days) to claseprubart, which has an approximately 60-day half-life in humans
- **Comparable aC1s inhibition and potency to claseprubart:** Demonstrated across multiple complement *in vitro* pharmacodynamic functional assays
- **Comparable Ig reductions to povetacicept, with a longer half-life in NHPs:** DNTH312 is targeting infrequent, S.C. self-administration
- **Clinically validated MoAs combined have the potential superior clinical efficacy:** Inhibition of the Classical Pathway or aC1s has been clinically validated in generalized Myasthenia Gravis, Chronic Inflammatory Demyelinating Polyneuropathy, Multifocal Motor Neuropathy, and more. BAFF/APRIL has been clinically validated in generalized Myasthenia Gravis, Sjögren's Disease, Systemic Lupus Erythematosus, IgA Nephropathy, Rheumatoid Arthritis, and more
- **DNTH312 extends our neuromuscular leadership position with new IP protection expected through at least 2047**, beyond claseprubart IP protection expected through at least 2043, excluding extensions

"With the expertise and knowledge gained from claseprubart, DNTH312 is a natural and highly synergistic fit for Dianthus," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "DNTH312 is intended to have wide utility across several therapeutic areas as we continue to expand our leadership in severe autoimmune diseases with our potentially best-in-class, pipeline-in-a-product therapies."

DNTH312 aims to be Phase 1 ready by YE'27.

About DNTH312
DNTH312 is an internally developed, investigational, first-in-class, next-generation bifunctional fusion protein combining claseprubart and TACI to target potent inhibition of aC1s and BAFF/APRIL. DNTH312 is enhanced with YTE half-life extension technology, similar to claseprubart. By targeting

two validated pathways with complementary disease modifying mechanisms, DNTH312 is designed to expand Dianthus' leadership position in autoimmune diseases with potential for best-in-disease efficacy by targeting deeper responses and broader symptom control, while also addressing larger patient populations. DNTH312 aims to be Phase 1 ready by YE'27.

DNTH312 is an investigational agent that is not approved as a therapy in any indication in any jurisdiction worldwide.

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 DNTH312, and any developments or results in connection therewith, including the target product profile and administration of claseprubart and DNTH312; 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 market opportunities, in particular with respect to claseprubart and DNTH312. Claseprubart and DNTH312 are investigational agents that are not approved as therapies 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 DNTH312 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 DNTH312 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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