Dianthus Therapeutics Announces Positive Top-line Phase 1 Data and Debuts Trading on Nasdaq as DNTH

September 12, 2023

Positive top-line Phase 1 data for lead clinical program DNTH103 confirm potent classical pathway inhibition, extended half-life, and a potentially differentiated safety profile

Results support DNTH103's best-in-class potential to be the first subcutaneous, self-administered injection dosed as infrequently as once every two weeks to treat a range of autoimmune disorders

Company plans to initiate multiple Phase 2 trials targeting neuromuscular indications in 2024, starting with generalized Myasthenia Gravis in Q1 2024, followed by Multifocal Motor Neuropathy in Q2 2024, and Chronic Inflammatory Demyelinating Polyneuropathy in second half of 2024

Dianthus Therapeutics, Inc. will begin trading on Nasdaq as DNTH with approximately $184 million of cash runway expected to fund operations into Q2 2026

NEW YORK and WALTHAM, Mass., Sept. 12, 2023 (GLOBE NEWSWIRE) -- Dianthus Therapeutics, Inc. ("Dianthus"), 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 Phase 1 data for DNTH103 validating its best-in-class potential as a selective classical pathway inhibitor targeting only the active form of the C1s protein. Additionally, Dianthus will begin trading on the Nasdaq Capital Market today as DNTH, following the successful completion on September 11, 2023 of the previously announced merger with Magenta Therapeutics ("Magenta").

The Phase 1 healthy volunteer study was designed to validate the extended half-life, potent classical pathway inhibition, and potentially differentiated safety profile of DNTH103. Top-line data across seven single and multiple ascending dose cohorts with 52 healthy volunteers confirmed its approximately 60-day half-life and highly potent classical pathway inhibition, establishing DNTH103's best-in-class potential to be the first self-administered subcutaneous injection dosed as infrequently as once every two weeks to treat a range of autoimmune disorders. The results also demonstrated DNTH103 was generally well tolerated with no serious adverse events or complement-related infections. Dianthus plans to initiate multiple Phase 2 studies in 2024 in various neuromuscular indications, starting with generalized Myasthenia Gravis (gMG) in the first quarter of 2024 followed by additional Phase 2 trials for Multifocal Motor Neuropathy (MMN) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Additional information about our Phase 1 data and DNTH103 can be found in our corporate presentation at investor.dianthustx.com.

"This is an exciting and transformative time at Dianthus as we announce top-line Phase 1 data for DNTH103 validating its potential to become a new standard of care with a best-in-class profile for multiple classical pathway-driven autoimmune disorders," said Marino Garcia, President and Chief Executive Officer of Dianthus Therapeutics. "These results, combined with our transition to the public markets, represent a major milestone in our growth trajectory. We are now well positioned to execute across multiple Phase 2 trials as we continue to maximize the value of DNTH103 as a pipeline-in-a-product."

"I am very encouraged by the Phase 1 safety and pharmacokinetic/pharmacodynamic data seen with DNTH103, our highly potent and selective upstream classical complement pathway inhibitor. Classical pathway activation plays a significant role in the pathology of various autoimmune disorders such as generalized Myasthenia Gravis, where patients still face significant disease and treatment burden, and we are excited to start the gMG Phase 2 trial early next year," said Simrat Randhawa, M.D., Chief Medical Officer of Dianthus Therapeutics. "We also look forward to starting Phase 2 trials in both MMN and CIDP in 2024, two neuromuscular autoimmune disorders which currently have no approved targeted biologics and where we believe DNTH103 could benefit patients."

Concurrent with the closing of the merger, Dianthus completed a $72 million private investment in its common stock and pre-funded warrants from a syndicate of healthcare investors led by Fidelity Management & Research Company, Catalio Capital Management, 5AM Ventures, Avidity Partners, Wedbush Healthcare Partners and founding investors Fairmount, Tellus BioVentures and Venrock Healthcare Capital Partners. The cash and cash equivalents as of the close of the business combination were approximately $184 million, which is expected to provide cash runway into the second quarter of 2026.

About DNTH103
DNTH103 is a 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 plans to initiate Phase 2 trials in multiple neuromuscular indications in 2024, starting with generalized Myasthenia Gravis in the first quarter of 2024.

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 of DNTH103; the anticipated timing of the results from those studies and trials; expectations regarding the use of proceeds and 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 headings "Risk Factors—Risks related to Dianthus" and “—Risks Related to the Combined Company” included in the Company’s definitive proxy statement/prospectus that was filed with and declared effective by the SEC on August 1, 2023, 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.

Media Contact Peg Rusconi Verge Scientific Communications prusconi@vergescientific.com Investor Relations Contact IR@dianthustx.com