Dianthus Therapeutics Announces Exclusive License Agreement with Leads Biolabs for DNTH212, a First and Potentially Best-In-Class, Phase 1 Ready Bifunctional BDCA2 & BAFF/APRIL Inhibitor for Severe Autoimmune Diseases

October 16, 2025

DNTH212 is a bifunctional fusion protein targeting plasmacytoid dendritic cell (pDC) BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function

Demonstrated superior inhibition of pDCs vs. litifilimab in vitro and superior Ig reductions vs. povetacicept in NHPs highlight the potential for improved clinical benefit in severe autoimmune diseases

DNTH212 has the potential to be a first line biologic in multiple autoimmune disorders with patient-friendly S.C. self-administration and Q4W or less frequent dosing

IND cleared by FDA in September 2025 and expected to clear in China in Q4'25. Phase 1 study of DNTH212 expected to initiate in Q4'25 with top-line results in healthy volunteers in 2H'26

Pro forma estimated cash of ~$525 million; reaffirms runway into 2028

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

NEW YORK and WALTHAM, Mass., Oct. 16, 2025 (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 it has entered into an exclusive licensing agreement with Nanjing Leads Biolabs Co., Ltd. ("Leads" (9887.HK) for DNTH212 (being developed in China by Leads Biolabs as LBL-047), a first and potentially best-in-class bifunctional BDCA2 and BAFF/APRIL inhibitor.

DNTH212 is an investigational, extended half-life bifunctional fusion protein targeting plasmacytoid dendritic cell (pDC) BDCA2 to reduce Type 1 interferon production, while simultaneously inhibiting BAFF/APRIL to suppress B cell function. By targeting both the innate and adaptive immune systems via two clinically validated pathways that are known drivers of autoimmune disease pathogenesis, this complementary and differentiated approach has the potential to address multiple autoimmune indications with improved outcomes.

"We are excited to partner with Leads Biolabs and build upon our vision of becoming a leading autoimmune-focused biopharmaceutical company with the addition of DNTH212 to our pipeline," said Marino Garcia, Chief Executive Officer of Dianthus Therapeutics. "Both claseprubart and DNTH212, with their validated mechanisms of action and patient friendly convenience of infrequent S.C. self-administration, have the potential to significantly improve the lives of patients suffering from a range of severe autoimmune disorders. We look forward to leveraging the pipeline-in-a-product potential of DNTH212."

pDCs are specialized immune cells that produce large amounts of Type 1 interferons (IFN- and IFN-). High levels of Type 1 interferon drive chronic inflammation and tissue damage, making Type 1 interferon inhibition a promising therapeutic strategy in multiple autoimmune diseases. DNTH212 demonstrated comparable IFNα inhibition and superior pDC depletion in-vitro compared to litifilimab, a late-stage clinically validated BDCA2 monoclonal antibody.

BAFF/APRIL activation of B cells generate autoantibodies against tissues that trigger inflammation and tissue damage. Inhibiting BAFF/APRIL has been shown to be a clinically validated therapeutic strategy in numerous autoimmune diseases. DNTH212 demonstrated superior inhibition of immunoglobulins (i.e. IgM, IgA, and IgG) in non-human primates compared to povetacicept, a late-stage clinically validated BAFF/APRIL inhibitor.

"The medical team is ready to exploit the full potential of this unique asset targeting both the innate and adaptive immune systems," said Dr. Simrat Randhawa, Head of Research & Development of Dianthus Therapeutics. "Autoimmune experts have been asking for combination biologic approaches for years so we expect an enthusiastic reception from them as we roll out our target indications."

A two-part Phase 1 study in China in healthy volunteers (Part A) and patients with systemic lupus erythematosus (Part B) is expected to initiate by year end 2025, with top-line results in healthy volunteers expected in the second half of 2026.

"We are pleased to partner with Dianthus, a leading biotechnology company with a proven track record of executing complex global clinical trials and delivering meaningful results for patients," said Dr. Xiaoqiang Kang, Founder, Chairman and CEO of Leads Biolabs. "This collaboration reinforces our commitment to advancing highly innovative drug candidates into the clinic to address serious autoimmune conditions, while further diversifying our pipeline and positioning Leads Biolabs for long-term growth. Dianthus' deep experience and expertise in this space will be invaluable as we work to bring LBL-047 to patients worldwide."

License Overview:

Under the terms of the agreement, Dianthus will pay Leads Biolabs up to $38 million, comprised of $30 million in upfront and near-term milestone payments plus an additional $8 million milestone upon the initiation of a Dianthus-led Phase 1 study, for exclusive rights to develop and commercialize DNTH212 globally outside of Greater China. Leads Biolabs will also be eligible to receive up to an additional $962 million in total development and regulatory approval milestones and sales-based milestones across multiple indications, as well as tiered royalties from mid-single digits up to a low double-digit on ex-Greater China net sales.

Dianthus will have an estimated pro forma cash balance of approximately $525 million following the in-licensing of DNTH212. Estimated pro forma cash includes preliminary and unaudited cash, cash equivalents and investments as of September 30, 2025 of approximately $555 million less $30 million of upfront and near-term milestone payments made to Leads Biolabs as part of the in-licensing.

Dianthus is reaffirming its guidance of cash runway into 2028, including the planned development of DNTH212.

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 licensing agreement today, October 16, 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 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.

About Leads Biolabs
Founded in 2012, Leads Biolabs is a clinical-stage biotechnology company developing innovative therapies for underserved medical needs in oncology, autoimmune, and other severe diseases in China and globally. A front-runner in next-generation immuno-oncology, the company has a pipeline of 14 drug candidates, including six clinical-stage programs, four of which are among the most advanced in their class. Leads Biolabs leverages proprietary platforms, including LeadsBody™ (CD3 T-cell engager) and X-body™ (4-1BB engager), along with integrated capabilities across discovery, translational medicine, clinical development, CMC, and business development. The innovative nature and competitive strengths of its drug candidates, combined with a proactive strategy, efficient clinical validation, and global perspective, position Leads Biolabs as a preferred partner for leading biopharmaceutical companies and venture capital investors.

For more information, please visit https://en.leadsbiolabs.com/.

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 DNTH212, and any developments or results in connection therewith, including the target product profile and administration of claseprubart and DNTH212; 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 and DNTH212. Claseprubart and DNTH212 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 DNTH212 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 DNTH212 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, 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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