Leads Biolabs And Dianthus Therapeutics Announce Initiation of Phase 1 Trial Of LBL-047 (DNTH212) In Healthy Volunteers and Patients With Systemic Lupus Erythematosus (SLE)

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LBL-047 (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

Top-line results in healthy volunteers anticipated in 2H'26

Dianthus to provide update on indication prioritization in 1H'26

LBL-047 (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

NANJING, China and NEW YORK and WALTHAM, Mass., Dec. 23, 2025 (GLOBE NEWSWIRE) -- Nanjing Leads Biolabs Co., Ltd. ("Leads Biolabs") (9887.HK), a clinical-stage biotechnology company focused on developing innovative therapies in oncology, autoimmune, and other severe diseases, and 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 the first subject has been successfully dosed in the Phase 1 clinical trial of LBL-047 (DNTH212), a potential first- and best-in-class anti-BDCA2/TACI bifunctional fusion protein developed by Leads Biolabs.

This two-part, double-blind, randomized, placebo-controlled, dose-escalation (single ascending dose) Phase 1 trial is designed to evaluate the safety, tolerability and PK/PD of LBL-047 (DNTH212) in healthy volunteers (Part A) and patients with systemic lupus erythematosus (Part B). The healthy volunteer part of the study is led by Professor Meng Xianmin at Shanghai Public Health Clinical Center, while the SLE part is led by Professors Ye Shuang and Chen Sheng at Renji Hospital, Shanghai Jiaotong University School of Medicine.

By targeting both the innate and adaptive immune systems via two clinically validated pathways that are known drivers of autoimmune disease, this complementary and differentiated approach has the potential to address multiple autoimmune indications with improved outcomes. LBL-047 (DNTH212) has the potential to be a first-line biologic with patient-friendly, S.C. self-administration and Q4W or less frequent dosing.

On October 16, 2025, Leads Biolabs entered into an exclusive global partnership with Dianthus, with the total potential deal value reaching up to $1 billion. Under the agreement, Dianthus licensed exclusive global rights from Leads Biolabs to research, develop, manufacture and commercialize LBL-047 outside Greater China, where it is known as DNTH212, jointly advancing its global development to maximize clinical and commercial potential. Dianthus expects to provide an update on prioritized indications for DNTH212 in the first half of 2026.

"We are pleased to announce the successful dosing of the first subject in our Phase 1 trial of LBL-047. By simultaneously targeting multiple pathways, LBL-047 is designed to address the limitations of single-target therapies. We look forward to advancing this program in collaboration with Dianthus Therapeutics to deliver potentially transformative options for patients worldwide," said Dr. Charles Cai, Chief Medical Officer of Leads Biolabs.

"Initiating this Phase 1 study is the first step to realizing the much anticipated by physicians outcome of targeting multiple pertinent dysfunctional pathways in several autoimmune indications," said Dr. Simrat Randhawa, Head of Research & Development at Dianthus Therapeutics.

About LBL-047 (DNTH212)
LBL-047 (DNTH212) is an investigational bifunctional fusion protein composed of a humanized anti-blood dendritic cell antigen 2 (BDCA2) antibody and an engineered transmembrane activator and CAML interactor (TACI) ectodomain. It is designed to selectively deplete pDCs to reduce type 1 interferon production, while simultaneously inhibiting B-cell activating factor (BAFF) and a proliferation-inducing ligand (APRIL) signaling pathways to suppress B-cell activation, differentiation, and antibody production. By targeting two key drivers of autoimmune disease pathogenesis, this differentiated approach has the potential to address multiple autoimmune indications. Additionally, LBL-047 (DNTH212) has also been optimized with Fc engineering to extend its half-life, offering the potential for a patient-friendly subcutaneous self-administration regimen with a dosing frequency of Q4W or less, supporting its potential as a first-line biologic therapy.

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 dedicated to the discovery, development, and commercialization of innovative therapies to address unmet medical needs in oncology, autoimmune, and other severe diseases both in China and globally. As a front-runner in next-generation immuno-oncology treatments, the company has a differentiated pipeline of 14 innovative drug candidates, including six clinical-stage drug candidates, of which four lead products are among the top-tier clinically advanced candidates globally.

Leads Biolabs adopts a science-driven R&D approach and has successfully established comprehensive R&D capabilities spanning antibody discovery and engineering, in vivo and in vitro efficacy evaluation, as well as druggability assessment. The company has also developed multiple proprietary technology platforms, including LeadsBody platform (a CD3 T-cell engager platform), X-body platform (a 4-1BB engager platform), TOPiKinectics (ADC platform), which serve as the cornerstone for continued innovation and have been validated by the clinical outcomes of bispecific antibody

portfolios.

Leads Biolabs has established integrated capabilities across early discovery, translational medicine, clinical development, CMC and business development. The innovative nature and competitive strengths of drug candidates, coupled with global perspectives, proactive strategy, and efficient clinical validation, have made the company an attractive partner for leading industry players and investment institutions. For more information, please visit https://en.leadsbiolabs.com/

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