Celldex Therapeutics Presents Positive Preclinical Data from TSLP/SCF Bispecific Antibody Program CDX-622 at IMMUNOLOGY2023™

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HAMPTON, N.J., May 15, 2023 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced preclinical data from CDX-622, the Company's bispecific antibody with dual targeting of the alarmin TSLP and stem cell factor (SCF), also known as KIT receptor ligand, developed from its bispecific antibody platform. TSLP and SCF have been shown to contribute to the pathophysiology of various inflammatory, fibrotic and allergic disorders. These data were presented in a poster session as part of IMMUNOLOGY2023™, the annual meeting of the American Association of Immunologists (AAI).

The preclinical data show CDX-622 potently neutralizes the alarmin TSLP, a potent mediator of inflammation, and blocks SCF/KIT interaction required for mast cell function and survival. CDX-622 was well tolerated and demonstrated a favorable pharmacokinetic profile as well as robust evidence of skin mast cell depletion in preclinical models. The biophysical and functional characteristics of CDX-622 support the initiation of development activities including manufacturing and IND-enabling studies.

"Clinical studies with our KIT antibody, barzolvolimab, have demonstrated the significant potential of mast cell depletion through the inhibition of KIT. CDX-622 builds on this understanding and adds a second critical inflammatory pathway—TLSP mediated inflammation," said Tibor Keler, Ph.D., Executive Vice President and Chief Scientific Officer of Celldex Therapeutics. "The data presented at AAI demonstrate that we have successfully combined blockade of these two complementary inflammatory pathways into one molecule and support the further advancement of CDX-622, which we believe provides a unique opportunity to target multiple pathways in disease settings where using combination therapies is challenging."

In the preclinical data presented at IMMUNOLOGY 2023, CDX-622 demonstrated potent inhibition of TSLP and SCF with a similar potency as comparator monoclonal antibodies *in vitro*. CDX-622 was shown to have monoclonal antibody-like biophysical and pharmacokinetic characteristics. The data also demonstrated strong evidence of skin mast cell depletion, consistent with the expected role of SCF/KIT in mast cell survival. Simultaneous inhibition of TSLP and mast cells with CDX-622 may result in improved efficacy over approaches targeting single pathways in inflammatory, fibrotic and allergic disorders.

The poster presented at IMMUNOLOGY2023™ can be viewed on the "Publications" page of the "Science" section of the Celldex website.

About CDX-622
CDX-622 is a bispecific antibody developed from novel humanized antibodies specific for TSLP and SCF. CDX-622 combines blockade of the alarmin TSLP with mast cell inhibition through SCF neutralization. Combined blockade of these non-redundant pathways that drive inflammation may lead to enhanced clinical activity in certain inflammatory, fibrotic and allergic disorders.

About Celldex's Bispecific Antibody Platform
Celldex's deep antibody experience and in-house manufacturing capabilities support efficient development of next generation bispecific antibody programs for inflammatory/autoimmune diseases and oncology. Bispecific antibodies can engage two independent pathways involved in controlling immune reactions and can overcome challenges associated with combination treatment approaches. Targets are being selected based on new science as well as their compatibility to be used in bispecific antibody formats with Celldex's existing antibody programs.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company dedicated to developing monoclonal and bispecific antibodies that address devastating diseases for which available treatments are inadequate. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with inflammatory diseases and many forms of cancer. Visit www.celldex.com.

Forward Looking Statement
This release contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct or that those goals will be achieved, and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to successfully complete research and further development and commercialization of Company drug candidates, including barzolvolimab (also referred to as CDX-0159), in current or future indications; the uncertainties inherent in clinical testing and accruing patients for clinical trials; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage and successfully complete multiple clinical trials and the research and development efforts for our multiple products at varying stages of development; the effects of the outbreak of COVID-19 on our business and results of operations; the availability, cost, delivery and quality of clinical materials produced by our own manufacturing facility or supplied by contract manufacturers, who may be our sole source of supply; the timing, cost and uncertainty of obtaining regulatory approvals; the failure of the market for the Company's programs to continue to develop; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; our ability to continue to obtain capital to meet our long-term liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we have initiated or plan to initiate; and other factors listed under "Risk Factors" in our annual report on Form 10-K and quarterly reports on Form 10-Q.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

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