Celldex Announces First Patient Dosed in Phase 1 Study of CDX-585 in Patients with Advanced Malignancies

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HAMPTON, N.J., May 31, 2023 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced that the first patient has been dosed in a Phase 1 study of CDX-585. CDX-585 combines highly active PD-1 blockade with anti-ILT4 blockade to overcome immunosuppressive signals in T cells and myeloid cells. Celldex plans to develop CDX-585 for the treatment of solid tumors either as monotherapy or in combination with other oncologic treatments. CDX-585 is the first compound from Celldex's research and collaboration agreement with Biosion, Inc. and combines Celldex's ILT4 mAb with Biosion's PD-1 mAb.

"We are excited to advance CDX-585 into clinical development as we continue to build our experience with our bispecific platform," said Diane C. Young, M.D, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. "Targeting both myeloid and T cell checkpoints with a bispecific is a novel approach that we believe could provide benefit for patients that are either refractory to or not likely to benefit from PD-1 blockade alone."

This open-label, multi-center, intravenous study of CDX-585 is being evaluated in patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy. The dose-escalation phase of the study (n=~30 patients) is designed to determine a maximum tolerated dose (MTD) and to select CDX-585 dose(s) for future evaluation in tumor specific expansion cohorts. In the first phase, increasing doses of CDX-585 will be administered intravenously (0.03 mg/kg up to 10.0 mg/kg) every 2 weeks until confirmed disease progression, intolerance, or for a maximum of 2 years. In the second phase, potential expansion cohorts will evaluate the safety, tolerability and biologic effects, including anti-tumor activity, of selected dose level(s) of CDX-585 in specific tumor types.

Preclinical data recently presented at the American Association of Cancer Research (AACR) Annual Meeting 2023 demonstrated that CDX-585 is a potent antagonist of both PD-1 and ILT4, and CDX-585 is more potent than the combination of PD-1 and ILT-4 mAbs in several model systems. CDX-585 also demonstrated a good pharmacokinetic profile and no evidence of toxicity supporting initiation of clinical development.

For additional information on this trial (NCT05788484), please visit www.clinicaltrials.gov.

About CDX-585
CDX-585 is a dual targeting PD-1/ILT4 bispecific antibody from Celldex's bispecific antibody platform. Expression of ILT4 in several tumor types is associated with poor outcome and in preclinical models, antagonist antibodies to ILT4 have demonstrated immune enhancing and antitumor effects. Preclinical studies have shown that CDX-585 is a potent antagonist of both PD-1 and ILT4, and CDX-585 is more potent than the combination of PD-1 and ILT-4 mAbs in several model systems. CDX-585 is being developed as part of a research and collaboration agreement with Biosion, Inc. and combines Celldex's ILT4 mAb with Biosion's PD-1 mAb.

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 combining these into one molecule can result in stronger activity than a combination of the independent antibodies. 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. Lead targets in development are emerging as important pathways controlling inflammatory diseases or immunity to tumors.

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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