Celldex Presents Preliminary Data from Ongoing CDX-527 Phase 1 Dose Escalation Trial at the 2021 ASCO Annual Meeting

June 4, 2021

HAMPTON, N.J., June 04, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced preliminary data from the Company's Phase 1 dose escalation study of PD-L1xCD27 bispecific antibody CDX-527 in patients with advanced malignancies. These data were presented in a poster session as part of the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting taking place June 4-8, 2021.

These are the first-in-human data of CDX-527, the first candidate developed from Celldex's bispecific platform which utilizes the Company's proprietary highly active anti-PD-L1 and CD27 human antibodies to couple CD27 co-stimulation with blockade of the PD-L1/PD-1 pathway.

"We are encouraged by this emerging initial data where we have observed a good safety profile along with promising pharmacodynamic and pharmacokinetic activity, which are important key hurdles for the development of bispecific antibodies," said Tibor Keler, Ph.D., Executive Vice President and Chief Scientific Officer of Celldex Therapeutics. "While we are still early in the dose escalation phase, we are excited to advance into higher dose cohorts and evaluate the data further as the study progresses. We believe this preliminary data provides further validation of our preclinical studies and demonstrates the potential of our bispecific platform to produce next generation candidates."

Summary of preliminary data from ongoing Phase 1 Trial of CDX-527:

As of the data cut-off on April 16, 2021, 11 patients were enrolled in the first 5 dose escalation cohorts, 0.03 mg/kg through 3 mg/kg.

- CDX-527 was well tolerated, with no dose-limiting toxicities or treatment related serious adverse events observed.
- Pharmacokinetics and receptor occupancy demonstrate good exposure starting at the 1 mg/kg dose and no evidence of significant anti-drug antibodies impact.
- Pharmacodynamic parameters demonstrate biological activity consistent with immune activation including: transient increase in pro inflammatory cytokines/chemokines, upregulation of activation marker on T cells and particularly NK cells and a decrease in regulatory T cells.
- Patients continue to be enrolled in the dose escalation phase of the trial.

The Phase 1 study is an open label dose-escalation and expansion study (0.03 mg/kg to 10 mg/mg) in 40 patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy. The study is designed to determine an MTD during the dose-escalation phase and to recommend a dose level for further study in a subsequent expansion phase. The expansion is designed to further evaluate the tolerability, and biologic and anti-tumor effects of selected dose level(s) in specific tumor types. For additional information on this trial (NCT04440943), please visit www.clinicaltrials.gov.

Celldex expects to report additional safety, PK, PD and clinical activity data from this study during 2022.

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

About CDX-527
Celldex's deep antibody experience and in-house manufacturing capabilities support efficient development of bispecific antibody targets. Targets are selected based on new science as well as their compatibility to be used in bispecific antibody formats with existing Celldex antibody programs. CDX-527, which combines CD27 activation and PD-1 blockade, was the first candidate to enter the clinic from the platform and is currently enrolling patients in a Phase 1 dose escalation study. Celldex is also exploring important targets controlling inflammation and auto-immune pathways.

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; the effects of the outbreak of COVID-19 on our business and results of operations; 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 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.

Company Contact
Sarah Cavanaugh
Senior Vice President, Corporate Affairs & Administration
(508) 864-8337
scavanaugh@celldex.com

Patrick Till
Senior Director, Investor Relations & Corporate Communications
(484) 788-8560
ptill@celldex.com

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