Celldex Therapeutics Initiates Phase 1 Study of New Bispecific Product Candidate CDX-527 in Solid Tumors

Aug 24, 2020

HAMPTON, N.J., Aug. 24, 2020 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today that enrollment has opened in its open-label, Phase 1 study of CDX-527 in patients with advanced or metastatic solid tumors that have progressed during or after standard of care therapy. CDX-527 is the first candidate from Celldex's bispecific antibody platform. It uses Celldex's proprietary highly active anti-PD-L1 and CD27 human antibodies to couple CD27 costimulation with blockade of the PD-L1/PD-1 pathway to help prime and activate anti-tumor T cell responses through CD27 costimulation, while preventing PD-1 inhibitory signals that subvert the immune response.

"CDX-527 builds on our prior clinical experience where the combination of CD27 activation and PD-1 blockade was well tolerated and demonstrated biological and clinical activity when the individual agents were dosed together," said Tibor Keler, Ph.D., Executive Vice President and Chief Scientific Officer of Celldex Therapeutics. "We believe this bodes well for the potential safety and activity profile of CDX-527, which incorporates the two mechanisms into one molecule. Importantly, preclinical studies of CDX-527 also demonstrated greater activity than the combination of individual antibodies, adding to our enthusiasm that this next-generation checkpoint inhibitor could be an important addition to the Celldex pipeline."

This study, which is expected to enroll up to approximately 90 patients with solid tumors, is designed to determine the maximum tolerated dose, or MTD, during a dose-escalation phase and to recommend a dose level for further study in a subsequent expansion phase. The expansion phase is designed to further evaluate the tolerability and biologic effects of selected dose level(s) of CDX-527 in specific tumor types. Secondary objectives of the study include analyses of safety and tolerability, pharmacokinetics, immunogenicity and assessment of anti-tumor activity across a broad range of endpoints, such as objective response rate, clinical benefit rate, duration of response, progression-free survival and overall survival. More information about this study is available on www.clinicaltrials.gov (Identifier: NCT04440943).

About CDX-527
CDX-527 is a bispecific antibody composed of Celldex's proprietary PD-L1 and CD27 human antibodies. CDX-527 combines blockade of the PD-1 pathway with T cell costimulation through CD27 into one molecule using an IgG1-ScFv format. Preclinical data demonstrate CDX-527 is more potent than the combination of anti-PD-L1 and anti-CD27 antibodies in T cell activation and anti-tumor activity. CDX-527 has direct antibody-dependent cellular cytotoxicity (ADCC) against CD27 or PD-L1 expressing tumor cells. In addition, CDX-527 exhibits an antibody-like pharmacokinetic profile without concerning toxicity in preclinical models. Prior clinical data with Celldex's CD27 antibody as monotherapy and in combination with PD-1 inhibitors supports combining these pathways in patients with cancer. The Company believes that the potential for CDX-527 will include both monotherapy and combination studies with other immunotherapies or conventional cancer treatments.

About Celldex Therapeutics, Inc.
Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline includes immunotherapies and other targeted biologics derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. Visit https://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; our ability to realize the cost benefits of consolidating our office and laboratory space and to retain key personnel after that consolidation; 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 and commercial grade 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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Source: Celldex Therapeutics, Inc.