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Celldex Therapeutics Initiates Phase 2 Combination Study of CDX-3379 and Cetuximab in Head and Neck Squamous Cell Carcinoma

HAMPTON, N.J., Nov. 17, 2017 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today that enrollment has opened in its open-label Phase 2 study of CDX-3379 in combination with cetuximab in patients with cetuximab-refractory, advanced head and neck squamous cell carcinoma (HNSCC). CDX-3379 is Celldex's human monoclonal antibody that selectively binds and inhibits the activity of ErbB3, also known as HER3. ErbB3 may be an important receptor regulating cancer cell growth and survival as well as resistance to targeted therapies, and it is expressed in many cancers, including HNSCC. Cetuximab, which is marketed under the brand name Erbitux®, is a monoclonal antibody that specifically binds EGFR and inhibits its signaling pathway.

"ErbB3 is a central enabler for known oncogenic drivers, including EGFR, a validated target with approved targeted therapeutics, such as cetuximab. Unfortunately, resistance to targeted treatments often develops, and we believe CDX-3379 may play an important role in overcoming it. CDX-3379 specifically blocks ErbB3 with potent binding affinity and locks it into a deactivated state, blocking both its mechanisms of interacting with its ligand and also with other oncogenic drivers," said Christopher Turner, M.D., Vice President, Clinical Science at Celldex Therapeutics. "In a Phase 1b study, we saw evidence of antitumor activity among the nine patients with HNSCC who were treated with CDX-3379 in combination with cetuximab, including a durable complete response in a patient who had previously progressed on single-agent cetuximab."

Study Overview
This multicenter, open-label, Phase 2 study of CDX-3379 in combination with cetuximab will enroll approximately 30 patients with cetuximab-resistant, advanced HNSCC who have previously been treated with an anti-PD1 checkpoint inhibitor, a population with limited options and a particularly poor prognosis. CDX-3379 (12 mg/kg) will be administered once every three weeks, and cetuximab (400 mg/m^2 initial dose, then 250 mg/m^2) will be administered every week. Treatment will continue until disease progression or intolerance, and assessments will occur every six weeks.

Using a Simon two-stage design, the first stage of study will enroll 13 patients, and if at least one patient achieves a partial response or complete response, enrollment will progress to the second stage. The primary objective is to assess the anti-tumor efficacy of CDX-3379 in combination with cetuximab as measured by objective response rate. Secondary objectives of the study include analyses of safety, pharmacokinetics, immunogenicity and further assessment of anti-tumor activity across a broad range of endpoints, such as clinical benefit rate, duration of response, progression-free survival and overall survival, for the combination. Tumor response assessments will be performed by the investigator according to standardized, objective response criteria (RECIST 1.1).

More information about this study is available on www.clinicaltrials.gov (Identifier: NCT03076372).

About CDX-3379
CDX-3379 is a human immunoglobulin G1 lambda (IgG1λ) monoclonal antibody that selectively binds and inhibits ErbB3 activity. ErbB3 may be an important receptor regulating cancer cell growth and survival as well as resistance to targeted therapies, and it is expressed in many cancers, including head and neck, thyroid, breast, lung and gastric cancers, as well as melanoma. The proposed mechanism of action for CDX-3379 sets it apart from other drugs in development in this class due to its ability to block both ligand-independent and ligand-dependent ErbB3 signaling by binding to a unique epitope. It has a favorable pharmacologic profile, including a longer half-life and slower clearance relative to other drug candidates in this class. CDX-3379 also has potential to enhance anti-tumor activity and/or overcome resistance in combination with other targeted and cytotoxic therapies to directly kill tumor cells.

Erbitux® is a registered trademark of Eli Lilly & Co.

About Celldex Therapeutics, Inc.
Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline includes antibodies, antibody-drug conjugates and other protein-based therapeutics 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 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 glembatumumab vedotin and other Company drug candidates; our ability to obtain additional 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; our ability to realize the anticipated benefits from the acquisition of Kolltan and to operate the combined business efficiently; 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; our ability to maintain and derive benefit from the Fast Track designation for glembatumumab vedotin which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; 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; 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
Celldex Therapeutics, Inc.
(781) 433-3161
scavanaugh@celldex.com

Charles Liles
Associate Director, Investor Relations & Corp Communications
Celldex Therapeutics, Inc.
(617) 383-3433
cliles@celldex.com

Dan Budwick
Founder, 1AB Media
(973) 271-6085
dan@1abmedia.com