Celldex Therapeutics, Inc. Logo

Celldex Presents Promising Data from CDX-0159 and CDX-527 Programs

November 11, 2019

-CDX-0159 IND accepted; Phase 1 study to start by YE 2019-
-CDX-527 on track for IND filing in 1H 2020-

HAMPTON, N.J., Nov. 11, 2019 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) presented data from the Company's preclinical pipeline this weekend. A review of the CDX-0159 early development program was presented at the American College of Allergy, Asthma & Immunology Annual Scientific Meeting on November 9, 2019 in the Distinguished Industry Oral Abstract Session. Preclinical data supporting the continued development of the Company's CDX-527 bispecific candidate were also presented at the Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting (SITC 2019), including both a poster presentation on November 9, 2019 and a talk during the preconference program session "Novel Multi-Targeted Therapeutic Platforms" on Wednesday, November 6, 2019.

"Our preclinical development efforts have yielded two very exciting candidates for continued advancement," said Tibor Keler, PhD, Executive Vice President and Chief Scientific Officer. "Our KIT inhibitor, CDX-0159, is poised to enter the clinic before year end—first in healthy volunteers and then in patients with chronic idiopathic urticaria, an indication we believe could offer an opportunity for a rapid development pathway. CDX-527, the first candidate from our bispecific platform, builds on our prior clinical experience combining CD27 activation and PD-1 blockade. CDX-527 showed greater activity than the combination of individual antibodies, adding to our optimism that this next-generation checkpoint inhibitor will be an important addition to the Celldex pipeline. We look forward to filing an IND for CDX-527 in the first half of 2020."

CDX-0159 Presentation Highlights:

CDX-0159 is a humanized monoclonal antibody that specifically binds the receptor tyrosine kinase KIT and potently inhibits its activity. KIT is expressed in a variety of cells, including mast cells, and its activation by its ligand SCF regulates mast cell functions including activation and survival. In certain inflammatory diseases, such as chronic idiopathic urticaria (CIU), mast cell activation plays a central role in the onset and progression of the disease.

In a Phase 1 clinical study with Celldex's KIT antagonist monoclonal antibody, CDX-0158, robust inhibition of mast cell activity was observed supporting the concept that targeting KIT can modulate mast cell activity and potentially provide clinical benefit in mast cell related diseases. CDX-0158 was re-engineered and replaced with CDX-0159, a New Molecular Entity (NME), to ablate Fc receptor interactions and effector function and improve its safety profile, while preserving full KIT inhibitory activity. In addition, CDX-0159 was modified to provide extended half-life following administration.

Celldex's Investigational New Drug (IND) Application for CDX-0159 has been accepted by the Food and Drug Administration and the Company plans to initiate a Phase 1a study of CDX-0159 by year-end 2019. The study is designed to evaluate the safety profile, pharmacokinetics and pharmacodynamics of single ascending doses of CDX-0159 in healthy subjects. Following completion of this study, Celldex plans to further study CDX-0159 in CIU, a mast cell-related disease. CIU presents as itchy hives, angioedema or both for at least six weeks without a specific trigger; multiple episodes can play out over years or even decades. The prevalence of CIU is estimated to be 0.5% to 1% of the total population or up to 3.2 million cases in the United States. About 50% of patients with CIU achieve symptomatic control with antihistamines or leukotriene receptor antagonists. Omalizumab, an IgE inhibitor, provides relief for roughly half of the remaining antihistamine/leukotriene refractory patients. Consequently, there is a need for more effective later line therapies.

CDX-527 Presentation Highlights:

Bispecific antibodies that engage two independent pathways involved in controlling immune responses to tumors are a rapidly growing area for the development of next generation PD-1 inhibitors. CDX-527 is the first candidate from Celldex's bispecific platform and uses Celldex'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. Celldex's prior clinical experience with combining CD27 activation and PD-1 blockade provide the rationale for linking these two pathways into one molecule. The data presented at SITC demonstrate that CDX-527 is more potent at T cell activation and anti-tumor immunity than the combination of parental monoclonal antibodies. Celldex is currently completing CDX-527 GMP manufacturing activities and IND-enabling studies and plans to file an IND in the first half of 2020. The Company believes that CDX-527 supports development of combination studies across the Celldex pipeline without needing to access competitor checkpoint inhibitors, allowing for quicker and more cost-effective studies.

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 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; 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 maintain compliance with Nasdaq listing requirements; our ability to realize the cost benefits of consolidating our office and laboratory space and to retain key personnel after that consolidation; our ability to realize the anticipated benefits from the acquisition of Kolltan; 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; 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

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