Celldex Therapeutics, Inc. Logo

Celldex Initiates Phase 1 Study of KIT Inhibitor CDX-0159

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CDX-0159 to be studied in chronic idiopathic urticaria after completing healthy volunteer study

HAMPTON, N.J., Nov. 18, 2019 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today that a Phase 1a study of CDX-0159 has initiated in healthy volunteers. CDX-0159 is a humanized monoclonal antibody that specifically binds the KIT receptor and potently inhibits its activity. The KIT receptor tyrosine kinase is expressed in a variety of cells, including mast cells. In certain inflammatory diseases, such as chronic idiopathic urticaria (CIU), also known as chronic spontaneous urticaria (CSU), mast cell degranulation plays a central role in the onset and progression of the disease. Following completion of the study in healthy volunteers, Celldex plans to further study CDX-0159 in CIU.

“CDX-0159 is a potent KIT inhibitor that we believe has significant potential in diseases driven by mast cells via KIT,” said Diane C. Young, MD, Senior Vice President and Chief Medical Officer. “We look forward to completing this study in healthy volunteers and moving into chronic idiopathic urticaria, an indication where mast cells play a central role in disease pathophysiology and which we believe offers a rapid development pathway.”

This first in-human study is a randomized, double-blind, placebo-controlled, Phase 1 study designed to evaluate the safety of single ascending doses in up to 32 healthy subjects. Secondary objectives of the study include analyses of pharmacokinetic and pharmacodynamics, as assessed by measuring changes in stem cell factor and tryptase, and assessments of the immunogenicity of CDX-0159. More information about this study is available on www.clinicaltrials.gov (Identifier: NCT04146129).

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.

About CDX-0159
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), also known as chronic spontaneous urticaria (CSU), mast cell activation plays a central role in the onset and progression of the disease. In a Phase 1 clinical study with our 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. CDX-0159 is currently in a Phase 1a study designed to evaluate the safety profile, pharmacokinetics and pharmacodynamics of single ascending doses in healthy subjects. Following completion of this study, the Company 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.

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.

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