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# Celldex Therapeutics Announces Clinical Trial Collaboration with Roche to Evaluate the Combination of Varlilumab and MPDL3280A

HAMPTON, N.J., March 17, 2015 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) announced today that it has entered into a clinical trial collaboration with Roche to evaluate the safety, tolerability and preliminary efficacy of varlilumab, Celldex's CD27 targeting investigational antibody, and MPDL3280A (anti-PDL1), Roche's investigational cancer immunotherapy in a Phase 1/2 study in renal cell carcinoma.

Varlilumab and MPDL3280A are part of a new class of investigational medicines known as cancer immunotherapies that are designed to harness the body's own immune system to fight cancer through separate yet complementary mechanisms of action that may enable the activation of T cells, restoring their ability to effectively detect and attack tumor cells. Preclinical data suggest the combination of these two mechanisms are synergistic and may enhance anti-tumor immune response compared to either agent alone. In Celldex's Phase 1 study of varlilumab in multiple solid tumors, promising signs of clinical activity in patients with refractory renal cell carcinoma were observed, including a durable partial response (11.0+ months) that has continued to decrease in tumor volume over time and prolonged stable disease (4 patients with a range of 5.3 to 30.7+ months).

"This collaboration with Roche furthers our ongoing initiative to investigate varlilumab's potential in combination with a broad range of mechanisms and across multiple tumor types," said Thomas Davis, MD, Executive Vice President and Chief Medical Officer of Celldex Therapeutics. "Varlilumab is currently being studied in two Phase 1/2 combination studies and we expect it will enter at least another four combination studies this year. This latest trial is supported by promising signs of single-agent activity observed in our Phase 1 study in patients with renal cell carcinoma. We believe combining an immune activator with a checkpoint inhibitor in this disease setting may augment this activity and the synergy demonstrated in our preclinical varlilumab/anti-PDL1 combination models provide further support for this approach."

Under the terms of this agreement, Roche will provide study drug and Celldex will be responsible for conducting and funding the study, which is expected to begin in 2015.

**About Varlilumab**

Varlilumab is a fully human monoclonal antibody that targets CD27, a critical molecule in the activation pathway of lymphocytes. CD27 can be effectively manipulated with activating antibodies to induce potent anti-tumor responses and may result in fewer toxicities due to its restricted expression and regulation. Varlilumab is a potent anti-CD27 agonist that induces activation and proliferation of human T cells when combined with T cell receptor stimulation. In lymphoid malignancies that express CD27 at high levels, varlilumab may have an additional mechanism of action through a direct anti-tumor effect. Varlilumab has completed a Phase 1 dose-escalation study, demonstrating potent immunologic activity consistent with its mechanism of action and anti-tumor activity in patients with advanced, refractory disease. No maximum tolerated dose was reached and minimal toxicities were observed. Celldex has initiated a broad development program for varlilumab to explore its role as an immune activator in combination with a number of complementary investigational and approved oncology drugs. Varlilumab is currently being studied in two Phase 1/2 combination studies and several additional combination studies will be initiated in 2015.

**About MPDL3280A (anti-PDL1)**

MPDL3280A (also known as anti-PDL1 and RG7446) is an investigational monoclonal antibody designed to interfere with a protein called PD-L1. MPDL3280A is designed to target PD-L1 expressed on tumor cells and tumor-infiltrating immune cells, preventing it from binding to PD-1 and B7.1 on the surface of T cells. By inhibiting PD-L1, MPDL3280A may enable the activation of T cells, restoring their ability to effectively detect and attack tumor cells.

**About Celldex**

Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline is built from a proprietary portfolio of antibodies and immunomodulators used alone and in strategic combinations to create novel, disease-specific therapies that induce, enhance or suppress the body's immune response. Visit www.celldex.com.

**Celldex 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, including those related to the Company's strategic focus and the future development and commercialization (by Celldex and others) of Rintega® ("rindopepimut"; "rindo"; CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2015. 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 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 rindopepimut, glembatumumab vedotin and other 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; 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 our 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.

CONTACT: Celldex

Investors & Company:

Sarah Cavanaugh, (508) 864-8337 or scavanaugh@celldex.com

Media:

Dan Budwick (973)-271-6085 or dan@purecommunicationsinc.com

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