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Celldex Therapeutics Initiates Phase 1/2 Study of Varlilumab in Combination with Sunitinib in Metastatic Clear Cell Renal Cell Carcinoma

HAMPTON, N.J., May 28, 2015 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today announced the initiation of an open-label, Phase 1/2 safety and tolerability study examining the investigational combination of varlilumab and sunitinib (SUTENT®) in patients with metastatic clear cell renal cell carcinoma (CC-RCC). Varlilumab is Celldex's fully human monoclonal agonist antibody that binds and activates CD27, a critical co-stimulatory molecule in the immune activation cascade. Sunitinib is approved by the FDA as monotherapy for the treatment of advanced renal cell carcinoma (RCC), as well as certain advanced gastrointestinal stromal tumors and pancreatic neuroendocrine tumors. Varlilumab is currently being studied in four Phase 1/2 combination studies, and additional combination studies will be initiated in 2015.

Sunitinib blocks the function of receptor tyrosine kinases (RTKs), of which several are implicated in tumor growth, angiogenesis and metastasis. Sunitinib was selected for an investigational combination with varlilumab because it has demonstrated the potential to modulate anti-tumor immunity and reverse immune suppression in the tumor microenvironment. Varlilumab strengthens or creates an immune response against a new antigen, or target; therefore, a synergistic combination of sunitinib and varlilumab may elicit stronger responses in the immune system to fight CC-RCC and potentially other cancers. In Celldex's Phase 1 study of varlilumab in multiple solid tumors, promising signs of clinical activity in patients with refractory CC-RCC were observed, including a durable partial response (13.0+ months) that has continued to decrease in tumor volume over time and prolonged stable disease (4 patients with a range of 5.3 to 33.0+ months).

"A growing understanding of renal cell carcinoma tumor biology has suggested that sunitinib's mechanism of action may result in immune system stimulation in this indication," said Thomas Davis, M.D., Executive Vice President and Chief Medical Officer of Celldex Therapeutics. "We think we may be able to build on this potential effect in clear cell renal cell carcinoma because varlilumab can both enhance immune responses and may have a therapeutic effect through T cell signaling mechanisms. This study furthers our commitment to expanding the applicability of varlilumab across several cancers and approaches with immunotherapy in novel combinations."

The Phase 1 portion of the study will assess the safety and tolerability of varlilumab at 0.3, 1.0 and 3.0 mg/kg combined with sunitinib at 50 mg in order to identify a recommended dose for the Phase 2 portion of the study. In both phases of the trial, varlilumab will be administered once every three weeks for up to eight six-week cycles (a total of up to 16 varlilumab doses). In each six-week cycle, sunitinib 50mg will be administered orally once daily for four weeks followed by two weeks without administration. The primary objective of the Phase 2 portion of the study is to assess the preliminary anti-tumor efficacy of the varlilumab/sunitinib combination measured by the overall response rate (ORR). Secondary objectives include safety and tolerability, pharmacokinetics, immunogenicity and further assessment of anti-tumor activity across a broad range of endpoints. The study is anticipated to include up to 10 sites in the United States and enroll approximately 60 patients.

About Varlilumab

Varlilumab is a fully human monoclonal agonist antibody that binds and activates CD27, a critical co-stimulatory molecule in the immune activation cascade. 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.

SUTENT® is a registered trademark of Pfizer, Inc.

About Celldex Therapeutics, Inc.

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.

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 RINTEGA, 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; our ability to maintain and derive benefit from the Breakthrough Therapy Designation for RINTEGA, 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.

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