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Celldex Therapeutics Initiates a Phase 2 Study of Glembatumumab Vedotin in Patients with Advanced Melanoma

HAMPTON, N.J., Dec. 4, 2014 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (Nasdaq:CLDX) today announced that it has initiated an open-label Phase 2 study of glembatumumab vedotin (CDX-011) in patients with unresectable Stage III or IV melanoma. Glembatumumab vedotin is a fully-human monoclonal antibody-drug conjugate (ADC) that targets glycoprotein NMB (gpNMB), a protein overexpressed by multiple tumor types, including metastatic melanoma where approximately 85% of patients overexpress the marker. Overexpression of gpNMB has been shown to promote the invasion and metastasis of cancer and has been associated with poor clinical outcome. The study is expected to include up to 10 sites in the United States and will enroll approximately 60 patients. Glembatumumab vedotin was previously evaluated in a Phase 1/2 study in patients with unresectable stage III or stage IV melanoma, a Phase 1/2 study in advanced breast cancer, a Phase 2 study in advanced breast cancer (the EMERGE study) and is currently being evaluated in patients with metastatic triple negative breast cancers that overexpress gpNMB in the METRIC Study.

"Based upon initial studies in breast cancer and melanoma, we believe gpNMB could be a very important target in oncology, especially in melanoma. Despite significant advances in the field, metastatic melanoma has one of the fastest growing incidence rates and large numbers of patients still require additional treatment options," said Thomas Davis, MD, Executive Vice President and Chief Medical Officer of Celldex Therapeutics. "In a previous study of patients with metastatic melanoma that did not select for gpNMB expression, we observed an impressive 15% overall response rate and a progression-free survival of 3.9 months in all-comers. Upon further analysis, the data suggested a trend toward prolonged PFS in patients with high gpNMB expression. Fundamental to this new study and planned future studies of glembatumumab vedotin in additional indications, we will evaluate whether potential clinical benefit is linked to the degree of gpNMB expression."

Study Overview

This study is a Phase 2, open-label study of glembatumumab vedotin in patients with unresectable stage III or IV melanoma. Eligible patients must have received no more than four prior anticancer regimens, including no more than one prior chemotherapy-containing regimen, for advanced disease. Patients will receive glembatumumab vedotin every 3 weeks until disease progression or intolerance and then be followed for survival. Prior treatments must include ipilimumab and BRAF/MEK targeted agents, as applicable. The primary objective is to evaluate the anticancer activity of glembatumumab vedotin in advanced melanoma as measured by the objective response rate (ORR). Secondary endpoints include analyses of progression-free survival (PFS), duration of response (DOR), overall survival (OS), retrospective investigation of whether the anticancer activity of glembatumumab vedotin is dependent upon the degree of gpNMB expression in tumor tissue and safety.

About Glembatumumab vedotin

Glembatumumab vedotin (CDX-011) is a fully-human monoclonal antibody-drug conjugate (ADC) that targets glycoprotein NMB (gpNMB). gpNMB is a protein overexpressed by multiple tumor types, including breast cancer and melanoma. gpNMB has been shown to be associated with the ability of the cancer cell to invade and metastasize and to correlate with reduced time to progression and survival in breast cancer. The gpNMB-targeting antibody, CR011, is linked to a potent cytotoxic, monomethyl auristatin E (MMAE), using Seattle Genetics' proprietary technology. Glembatumumab vedotin is designed to be stable in the bloodstream, but to release MMAE upon internalization into gpNMB-expressing tumor cells, resulting in a targeted cell-killing effect. Glembatumumab vedotin is in development for the treatment of locally advanced or metastatic breast cancer, with an initial focus in triple negative disease, and for the treatment of Stage III and IV melanoma. Additional studies are planned in squamous cell lung cancer, osteosarcoma, uveal melanoma and pediatric sarcoma.

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 rindopepimut ("rindo"; CDX-110), glembatumumab vedotin ("glemba"; CDX-011), varlilumab ("varli"; CDX-1127), CDX-1401, CDX-301 and other products and our goals for 2014. 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 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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