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Celldex Initiates a Phase 2 Study of Rindopepimut in Patients with Recurrent Glioblastoma including Avastin® Naive and Refractory Populations

Vaccine Targets Patients with EGFRvIII-positive Recurrent Glioblastoma

NEEDHAM, Mass.--(BUSINESS WIRE)--Jan. 4, 2012-- Celldex Therapeutics, Inc. (NASDAQ: CLDX) today announced that patient screening has initiated in a Phase 2 trial of rindopepimut in combination with Avastin® in patients with recurrent epidermal growth factor variant III (EGFRvIII)-positive glioblastoma, called the “ReACT Study.” This new study will run in parallel with Celldex’s Phase 3 trial (ACT IV) evaluating rindopepimut in patients with newly diagnosed EGFRvIII-expressing glioblastoma (GB).

“We believe the combination of rindopepimut and Avastin in EGFRvIII-positive recurrent glioblastoma holds promise for a patient population that has very few treatment options,” commented Anthony S. Marucci, President and CEO of Celldex. “Based on our exciting Phase 2 results in front-line EGFRvIII GB patients, promising data in this patient population would be very compelling in expanding treatment options for the future.”

“We have experience with patients who received rindopepimut under a compassionate use program and did quite well, despite significant residual tumors, supporting the potential for a beneficial effect in patients with recurrent disease,” stated Thomas Davis, M.D., Chief Medical Officer of Celldex. “Evidence of an improved response rate or delay in disease progression would provide additional support for rindopepimut approval,” added Dr. Davis.

The study will enroll approximately 95 patients in a first or second relapse of glioblastoma following receipt of standard therapy and will be conducted at approximately 20 sites across the United States. Approximately 70 Avastin (bevacizumab) naive patients will be randomized to receive either rindopepimut or a control injection of Keyhole Limpet Hemocyanin (KLH) in a blinded fashion; all patients will also receive Avastin. KLH is a component of rindopepimut and was selected due to its ability to generate a similar injection site reaction to that observed with the rindopepimut vaccine.

Additionally, 25 patients refractory to Avastin®, having received Avastin in either the frontline or recurrent setting with subsequent progression, will receive rindopepimut plus Avastin in a single treatment arm. Patients in all three arms will be evaluated for the Progression Rate at six months (PFS6), objective response rate (ORR), overall survival (OS), and progression free survival (PFS).

Clinical Data Supporting Rindopepimut in Glioblastoma

Rindopepimut has been evaluated in three successful clinical studies of patients with EGFRvIII-positive glioblastoma to date: the ACTIVATE, ACT II and ACT III studies. Notably, rindopepimut demonstrated consistent and statistically significant increased PFS and OS rates across all three studies compared to a cohort of patients (historical controls) treated at M.D. Anderson Cancer Center and matched for eligibility (including having glioblastoma expressing the EGFRvIII oncogene). In ACTIVATE, ACT II and ACT III, median PFS from diagnosis was 14.2, 15.3 and 12.3 months compared to 6.4 months in the control cohort, while median OS from diagnosis was 24.6, 24.4, 24.6 and 15.2 months, respectively. Mature data from the ACT III study were recently presented at the Society for Neuro-Oncology conference and indicated that 52% of the patients were alive at two years, which is consistent with data from the ACTIVATE and ACT II studies, where 50% of the enrolled patients were also alive at two years from diagnosis. In addition, the four-year survival rate for ACTIVATE is 22%, while follow-up in ACT II and ACT III is ongoing.

In ACT III, the results for the predefined primary endpoint, 66% Progression Free Rate (PFR) at approximately 8.5 months post-diagnosis, show a statistically significant improvement (p=0.0168) over a predetermined estimate of 53%, which is beyond the range of expected progression-free survival for glioblastoma patients receiving standard of care. Published results for standard of care and from matched historical controls are 45% and 29%, respectively, for PFR at 8.5 months post-diagnosis.

In all clinical trials to date, rindopepimut has been generally well tolerated with injection site reaction being the most frequently observed side effect.

About Rindopepimut

Rindopepimut is an investigational immunotherapeutic vaccine that targets the tumor-specific molecule epidermal growth factor receptor variant III (EGFRvIII). EGFRvIII is a mutated form of the epidermal growth factor receptor (EGFR) that is only expressed in cancer cells and not in normal tissue and is a transforming oncogene that can directly contribute to cancer cell growth. Expression of EGFRvIII is linked to poor long term survival regardless of other factors such as extent of resection and age. EGFRvIII has been shown by polymerase chain reaction (PCR) analysis to be expressed in approximately 31% of glioblastoma tumors.

About Celldex Therapeutics, Inc.

Celldex Therapeutics is the first antibody-based combination immunotherapy company. Celldex has a pipeline of drug candidates in development for the treatment of cancer and other difficult-to-treat diseases based on its antibody focused Precision Targeted Immunotherapy (PTI) Platform. The PTI Platform is a complementary portfolio of monoclonal antibodies, antibody-targeted vaccines and immunomodulators used in optimal combinations to create novel disease-specific drug candidates. For more information, please visit http://www.celldextherapeutics.com.

Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995: *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 (CDX-110), CDX-011, CDX-1135 (formerly TP10), CDX-1401, CDX-1127, CDX-301, Belinostat and other products. 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 obtain additional capital on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that we plan to initiate in 2011; our ability to adapt APC Targeting Technology™ to develop new, safe and effective vaccines against oncology and infectious disease indications; our ability to successfully complete product research and further development of our programs; the uncertainties inherent in clinical testing; our limited experience in bringing programs through Phase 3 clinical trials; our ability to manage research and development efforts for multiple products at varying stages of development; the timing, cost and uncertainty of obtaining regulatory approvals; the failure of the market for the Company's programs to continue to develop; our limited cash reserves and our ability to obtain additional capital on acceptable terms, or at all; 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 risks detailed from time to time in the Company's filings with the Securities and Exchange Commission, including the Company's Form 10-K for the fiscal year ended December 31, 2010, and its Forms 10-Q and 8-K.*

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.

Avastin is a registered trademark of Genentech.

Source: Celldex Therapeutics, Inc.

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