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Celldex Therapeutics Announces Positive Three-Year Survival Data for Rindopepimut Phase 2 Clinical Program

--Data Strongly Support Ongoing Phase 3 Clinical Program--

--Data Presented at Society for Neuro-Oncology's (SNO) 17th Annual Scientific Meeting and Education Day--

NEEDHAM, Mass.--(BUSINESS WIRE)-- Celldex Therapeutics, Inc. (NASDAQ: CLDX) announced today the presentation of three-year survival data from the Phase 2 rindopepimut clinical program in EGFRvIII-positive glioblastoma—a more aggressive form of glioblastoma typically associated with reduced long-term survival in comparison to the glioblastoma population as a whole. Across three Phase 2 studies of rindopepimut, survival data remains consistent and suggests a substantial and continuing survival benefit in comparison to independent control datasets (see chart below) at the median and at three years. In the multi-center Phase 2 ACT III study, the median overall survival is 24.6 months from diagnosis (21.8 months from study entry) and overall survival is 26% at three years. In the Phase 2 ACT II study, the median overall survival is 24.4 months from diagnosis (20.5 months from study entry) and overall survival is 23% at three years. In the Phase 2 ACTIVATE study, the median overall survival is 24.6 months from diagnosis (20.4 months from study entry) and overall survival is 33% at three years.

Rindopepimut Overall Survival (OS) Across Three Phase 2 Studies in EGFRvIII-Positive Glioblastoma vs Independent Control Datasets

Rindopepimut Phase 2 Studies (all data from study entry)	Median (months)	OS 3 years
ACT III (n=65)	21.8	26%
ACT II (n=22)	20.5	23%
ACTIVATE (n=18)	20.4	33%
Independent Control Datasets (all data from study entry)		
MD Anderson EGFRvIII-positive patients matched[1] to ACTIVATE patient population (n=17) *(contemporary with ACTIVATE)*	12.2[2]	6%
Radiation Therapy Oncology Group (RTOG) 0525 study - all EGFRvIII-positive patients (n=142) *(contemporary with ACT III)*	15.1	18%
RTOG 0525 study - all EGFRvIII-positive patients treated with standard dose temozolomide (n=62) *(contemporary with ACT III)*	14.2	7%
RTOG 0525 study - EGFRvIII-positive patients matched[1] to ACT III/IV patient population (n=29) *(contemporary with ACT III)*	16	13%

[1]Controls are closely matched to rindopepimut patient criteria including gross total resection of patient tumor and ~3 months without disease progression at time of study entry; [2]In order to provide comparable timeframes across datasets, data have been estimated assuming study entry at three months from diagnosis.

"The long-term survival data across all three rindopepimut Phase 2 clinical trials are consistent and suggest that rindopepimut is providing long-term survival beyond what is historically seen in this subset of EGFRvIII-expressing glioblastoma patients—a group that typically has more aggressive disease associated with a worse prognosis than the general glioblastoma patient population," said John Sampson, MD, PhD, Dr. Robert H. Wilkins and Gloria Wilkins Professor of Neurosurgery & Associate Deputy Director, The Preston Robert Tisch Brain Tumor Center Duke University Medical Center, Durham, NC and lead investigator of the ACT II and ACTIVATE studies. "Based on the results to date, I am hopeful that with continued success in the clinic, rindopepimut has the potential to be a much needed treatment option for patients with EGFRvIII-positive glioblastoma."

In addition to the presentation of updated survival data, Celldex also announced the presentation of data from a retrospective analysis of EGFRvIII expression status and associated clinical outcome in the Phase 3 Radiation Therapy Oncology Group's (RTOG) 0525 study. This analysis was conducted by The University of Texas MD Anderson Cancer

Center in cooperation with RTOG to provide an assessment of the prognosis for patients with EGFRvIII-positive disease contemporary with the ACT III data.

"The RTOG 0525 data continue to demonstrate that patients with EGFRvIII-positive glioblastoma fare worse than the general glioblastoma patient population, particularly when it comes to long-term survival," said Thomas Davis, MD, Senior Vice President and Chief Medical Officer of Celldex Therapeutics. "In line with our expectations given improvements in both the overall standard of care and in best supportive care, the updated historical control data demonstrate a modest improvement in outcome compared to previous data. This improvement is well within the bounds of what we anticipated when we designed our ongoing Phase 3 randomized ACT IV study and provides further confidence in the ACT IV study design."

"The results presented at SNO provide further validation for the rindopepimut clinical program," said Anthony Marucci, President and Chief Executive Officer of Celldex Therapeutics. "The median and long-term survival rates are impressive in comparison to both the MD Anderson and RTOG historical control datasets, with 23% to 33% of patients on rindopepimut surviving to the three year mark versus 6% to 18% of patients in the historical control datasets. In addition, while the ACT II and ACT III data continue to mature, across all three Phase 2 rindopepimut studies, approximately 15% of patients are alive at five years compared to an expectation of 0%. These results support our belief that rindopepimut has the potential to dramatically alter the prognosis for patients with EGFRvIII-positive glioblastoma. To that end, we continue to actively enroll patients in the pivotal ACT IV study with more than 150 clinical sites around the world selected to participate and, to date, 118 of these sites actively screening patients."

The data announced today were presented at the Society for Neuro-Oncology's (SNO) 17th Annual Scientific Meeting and Education Day in Washington, DC. Duane A. Mitchell, MD, PhD, Assistant Professor of Surgery (Neurosurgery), Duke University Medical Center presented the updated overall survival data from the rindopepimut Phase 2 ACT III, ACT II and ACTIVATE studies in an educational session entitled "Immunotherapy of Malignant Brain Tumors" and Michael Weller, MD, Professor, Department of Neurology, University Hospital Zurich presented data from a cohort of patients with EGFRvIII-positive glioblastoma that were included in the Phase 3 Radiation Therapy Oncology Group's (RTOG) 0525 study (closed to accrual in 2008) in an educational session called "Biomarkers and Clinical Care: are we there yet?"

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 is expressed in approximately 30% of glioblastoma tumors. Celldex is actively enrolling two clinical studies of rindopepimut—a Phase 3 international study called ACT IV in patients with newly diagnosed EGFRvIII-positive glioblastoma and a Phase 2 study called ReACT in patients with recurrent EGFRvIII-positive glioblastoma. Drs. Sampson and Mitchell have a patent that has been licensed by Celldex and may receive royalties related to sales of this immunotherapeutic vaccine.

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 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, 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 limited cash reserves and 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 have initiated or plan to initiate; 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 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.

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.

Celldex Therapeutics, Inc.
Sarah Cavanaugh, 781-433-3161
Vice President of IR & Corp Comm
scavanaugh@celldextherapeutics.com
or
For Media:
BMC Communications
Brad Miles, 646-513-3125
bmiles@bmccommunications.com

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