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Celldex Therapeutics Announces Initiation of Phase 1 Clinical Trial of CDX-301

NEEDHAM, Mass.--(BUSINESS WIRE)--Jan. 17, 2012-- Celldex Therapeutics, Inc. (Nasdaq: CLDX) today announced that dosing has initiated in a Phase 1 study of its hematopoietic growth factor, CDX-301, in healthy subjects. The study is being conducted in collaboration with Rockefeller University. CDX-301 is soluble, recombinant human FMS-like tyrosine kinase 3 ligand (Flt3L) and previous experience has shown that it increases the numbers and activity of blood stem cells and immune cells. CDX-301 is a potent stem cell mobilizer and dendritic cell growth factor. While there are multiple possible indications for CDX-301, Celldex's first priority is to develop this molecule for hematopoietic stem cell transplant, where it has demonstrated improvement of blood cell reconstitution in preclinical *in vivo* models.

The Phase 1 study of CDX-301 is a dose-escalating clinical trial aimed at determining the appropriate dose for further development based on safety, tolerability and biological activity. The trial will evaluate seven different dosing regimens of CDX-301 and will accrue approximately 30 healthy subjects at Rockefeller University.

"This clinical trial represents the first step in the continued clinical development of this biologically active molecule," said Thomas Davis, M.D., Chief Medical Officer of Celldex Therapeutics. "In particular, we believe that CDX-301 has significant potential to be developed in a number of indications in cancer, inflammatory and infectious diseases."

About CDX-301 (Flt3L)

CDX-301 or Flt3L is a potent hematopoietic cytokine that stimulates the expansion and differentiation of hematopoietic progenitor and stem cells. Flt3L has demonstrated a unique capacity to increase the number of circulating dendritic cells in both laboratory and clinical studies. In addition, Flt3L has shown impressive results in models of cancer, infectious diseases and inflammatory/autoimmune diseases. Celldex believes this ligand may hold significant opportunity for synergistic development in combination with other proprietary molecules in the Company's portfolio.

About Celldex Therapeutics, Inc.

Celldex 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, 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 TechnologyTM 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.

Source: Celldex Therapeutics, Inc.

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