

Celldex Presents Promising Data from CDX-527 Bispecific and TAM Receptor Programs at American Association for Cancer Research (AACR) Annual Meeting 2019

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HAMPTON, N.J., April 01, 2019 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) presented promising data from the Company's growing bispecific and TAM (Tyro3, Axl, MerTK) receptor programs during poster sessions today at the American Association for Cancer Research (AACR) Annual Meeting 2019.

"Our research and discovery efforts have yielded multiple promising candidates that address important needs in cancer immunotherapy and complement our pipeline," said Tibor Keler, Ph.D., Executive Vice President and Chief Scientific Officer of Celldex Therapeutics. "CDX-527 joins two powerful pathways in the immune system, PD-1 blockade and CD27 costimulation. The data we presented at AACR demonstrate that this bispecific antibody candidate has greater activity than the combination of the two individual antibodies and support advancing the program into IND-enabling studies. In addition, we also presented data on our lead candidate antibodies targeting the TAM receptors, which act as checkpoints on myeloid cells. We have uncovered a unique mechanism for antibody-mediated activation of dendritic cells and macrophages and demonstrated that a surrogate MerTK mAb promotes anti-tumor immunity alone and enhances the activity of PD-1 blockade. We look forward to continuing to progress both CDX-527 and our TAM program over the course of the year," concluded Keler.

Presentation Highlights:

[Poster #2392](#): CDX-527: A novel bispecific immune-modulating antibody targeting CD27 and PD-L1 (Vitale, et. al)

- The use of bispecific antibodies provides opportunities to engage two independent pathways involved in controlling immune responses to tumors. Preclinical and clinical studies support the safety and benefit of combining PD-1 blockade with a CD27 agonist.
- The bispecific CDX-527 combines a novel and potent PD-L1 antibody for blocking the PD-1 checkpoint pathway with the binding domains of a CD27 agonist antibody for CD27-mediated costimulation of T cells.
- CDX-527 demonstrated potent inhibition of PD-1 signaling and T cell activation using *in vitro* models with reporter cell lines and human primary cell cultures.
- Anti-tumor activity was tested with a surrogate bispecific molecule that binds mouse PD-L1 and human CD27 in human CD27-expressing transgenic mice. The bispecific demonstrated potent anti-tumor activity in a BCL1 lymphoma model and was significantly more effective than the combination of the CD27 and PD-L1 monoclonal antibodies (mAbs).
- A pilot study in non-human primates suggests that CDX-527 demonstrates good pharmacokinetic properties and no toxicities were observed.
- Based on the promising data observed to date and the PK/PD profiles, Celldex has initiated manufacturing activities and investigational new drug (IND) enabling studies to support clinical studies of CDX-527.

[Poster #1555](#): Monoclonal antibodies targeting the TAM family of receptor tyrosine kinases (Alvarado, et al)

- TAM receptors (Tyro3, Axl, MerTK) are receptor tyrosine kinases (RTKs) expressed in innate immune cells. These receptors have been gaining importance in the immunotherapy field due to their role as checkpoint molecules on macrophages, dendritic cells, and other immune cells, where they can negatively regulate anti-tumor immunity.
- Celldex presented data showing that lead candidate mAbs targeting MerTK, Axl or Tyro-3 activate myeloid cells, including monocytes, macrophages and dendritic cells, enhancing pro-inflammatory cytokine release, increasing expression of costimulatory molecules and enhancing T cell activation in mixed lymphocyte reaction (MLR) assays.
- Celldex demonstrated that the potent activity of the TAM-specific antibodies are dependent on a unique coupling of the TAM receptors with Fc receptors.
- Celldex's most advanced program targets MerTK, where the Company has demonstrated that antibody targeting of MerTK in mice elicits an inflammatory cytokine response similar to that observed in the human cells and in MerTK deficient mice and has anti-tumor activity when dosed alone or in combination with a PD-1 inhibitor in a colon cancer model.
- These data support development of anti-TAM mAbs as therapies to activate innate immune responses with a potential for systemic dosing. The Company intends to advance potential candidates into development activities this year.

About Celldex Therapeutics, Inc.

Celldex is developing targeted therapeutics to address devastating diseases for which available treatments are inadequate. Our pipeline includes immunotherapies and other targeted biologics derived from a broad set of complementary technologies which have the ability to engage the human immune system and/or directly inhibit tumors to treat specific types of cancer or other diseases. 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. These statements are typically preceded by words such as "believes," "expects," "anticipates," "intends," "will," "may," "should," or similar expressions. These 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 or that those goals will be achieved, 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 Company 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; our ability to maintain compliance with Nasdaq listing requirements; our ability to realize the anticipated benefits from the acquisition of Kolltan; 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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