Celldex Presents Positive Preclinical Data from PD-1/ILT4 Bispecific Antibody Program CDX-585 at SITC 2021

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HAMPTON, N.J., Nov. 12, 2021 (GLOBE NEWSWIRE) -- Celldex Therapeutics, Inc. (NASDAQ:CLDX) today announced positive preclinical data from CDX-585, the Company's bispecific antibody with dual targeting of ILT4 and PD-1 checkpoint pathways, developed from its bispecific antibody platform. These data were presented in a poster session as part of the Society for Immunotherapy of Cancer's 36th Annual Meeting (SITC 2021).

The data show CDX-585 effectively combines the blockade of ILT4 and PD-1 into one molecule, with favorable biophysical and functional characteristics, supporting the initiation of development activities including manufacturing and IND-enabling studies. CDX-585 is the first compound from Celldex's research and collaboration agreement with Biosion, Inc. and combines Celldex's ILT4 mAb with Biosion's PD-1 mAb.

"We are pleased with this data which demonstrate we have successfully combined two important pathways into one molecule and support the further advancement of CDX-585," said Tibor Keler, Ph.D., Executive Vice President and Chief Scientific Officer of Celldex Therapeutics. "We believe that co-targeting ILT4 and PD-1, which are both critical checkpoint pathways, has the potential to produce significant immune enhancing and antitumor effects. We are excited to move forward with CDX-585 in addition to the continued generation of other candidates from our bispecific antibody platform for oncology and inflammatory diseases."

In the preclinical data presented at SITC, the simultaneous inhibition of ILT4 and PD-1 checkpoints with CDX-585 led to myeloid and T cell activation which may potentially demonstrate clinical utility, particularly in the T cell checkpoint inhibitor refractory setting. CDX-585 promoted T cell activation as measured by mixed lymphocyte reactions superior to that achieved by the combination of ILT4 and PD-1 monoclonal antibodies. CDX-585 also demonstrated anti-tumor activity in a humanized mouse model of melanoma and had a favorable pharmacokinetic profile in pilot studies, without adverse effects of treatment noted in clinical observations or clinical chemistry.

The poster presented at SITC can be viewed on the "Publications" page of the "Science" section of the Celldex website.

About CDX-585
CDX-585 is a dual targeting PD-1/ILT4 bispecific antibody from Celldex's bispecific antibody platform, currently in preclinical studies including manufacturing and IND-enabling studies. Expression of ILT4 in several tumor types is associated with poor outcome and in preclinical models, antagonist antibodies to ILT4 have demonstrated immune enhancing and antitumor effects. CDX-585 is being developed as part of a research and collaboration agreement with Biosion, Inc.

About Celldex's Bispecific Antibody Platform
Celldex's deep antibody experience and in-house manufacturing capabilities support efficient development of next generation bispecific antibody programs for inflammatory/autoimmune diseases and oncology. Bispecific antibodies can engage two independent pathways involved in controlling immune reactions and combining these into one molecule can result in stronger activity than a combination of the independent antibodies. Targets are being selected based on new science as well as their compatibility to be used in bispecific antibody formats with Celldex's existing antibody programs. Lead targets in development are emerging as important pathways controlling inflammatory diseases or immunity to tumors.

About Celldex Therapeutics, Inc.
Celldex is a clinical stage biotechnology company dedicated to developing monoclonal and bispecific antibodies that address devastating diseases for which available treatments are inadequate. Our pipeline includes antibody-based therapeutics which have the ability to engage the human immune system and/or directly affect critical pathways to improve the lives of patients with inflammatory diseases and many forms of cancer. Visit www.celldex.com.

About Biosion, Inc.
Biosion is a global clinical stage biotechnology company developing innovative therapeutics to address resistant, refractory, relapsed and residual disease for patients worldwide. The company is building its innovative pipeline through internally-derived proprietary technologies, including its H^3 hybridoma platform, SynAb™ synergistic antibody evaluation, SynTracer™ HT-endocytosis screening and Flexibody™ bispecific platforms. Biosion is actively seeking global partners who are interested in licensing, partnership or co-development opportunities. For more information and full pipeline details, please visit www.biosion.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, including CDX-0159, in current or future indications; 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 effects of the outbreak of COVID-19 on our business and results of operations; the availability, cost, delivery and quality of clinical 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; our ability to continue to obtain 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; 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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