Nurix Therapeutics Doses First Patient in Phase 1 Clinical Trial of DeTIL-0255, a Drug-Enhanced Cell Therapy for the Treatment of Patients with Solid Tumors

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First in human study of drug-enhanced tumor infiltrating lymphocyte therapy in patients with gynecological malignancies

SAN FRANCISCO, April 05, 2022 (GLOBE NEWSWIRE) -- Nurix Therapeutics, Inc. (Nasdaq: NRIX), a clinical stage biopharmaceutical company developing targeted protein modulation drugs, today announced that the first patient has been dosed in its Phase 1 clinical trial of DeTIL-0255, a drug-enhanced tumor infiltrating lymphocyte therapy and the lead candidate in its cellular therapy portfolio. The trial is designed to evaluate the safety and efficacy of DeTIL-0255 in patients with advanced gynecological malignancies including ovarian cancer, cervical cancer, and endometrial cancer.

DeTIL-0255 is a cell therapy derived via ex-vivo treatment of patient-derived tumor infiltrating lymphocytes (TILs) with a potent, small-molecule inhibitor of Casitas B-lineage lymphoma proto-oncogene-B (CBL-B) called NX-0255, which was identified using Nurix's proprietary DELigase platform.

"The initiation of our first cell therapy study is a major milestone for Nurix and the culmination of significant efforts across our clinical, regulatory and manufacturing teams. It is also the first time targeted protein modulation has been combined with cell therapy, marking the beginning of what we believe will be an important step forward in the treatment of solid tumors," said Robert J. Brown, M.D., executive vice president of clinical development of Nurix. "Within the rubric of targeted protein modulation, Nurix has now moved three treatment modalities into the clinic including oral targeted protein degraders, an oral CBL-B inhibitor, and now a drug-enhanced cell therapy."

CBL-B is an E3 ligase that is expressed in immune cells, and in the context of cancer functions as an intracellular checkpoint that negatively regulates T cell activation, NK cell activity, and immune response through the degradation of specific intracellular signalling proteins. Inhibition of CBL-B with NX-0255 increases those protein levels and is used to generate a drug-enhanced cell therapy product with superior anti-tumor activity in animal models of adoptive cell therapy. Nurix expects to provide a clinical update from the safety run-in portion of the Phase 1 study in the second half of 2022.

"Our preclinical models of adoptive T-cell therapy demonstrate that NX-0255 treatment of cells provides improved characteristics that have the potential to increase the success of manufacturing durable cells that can deliver significant anti-tumor effects," said Michael T. Lotze, M.D., chief cellular therapy officer of Nurix. "DeTIL-0255 is an autologous TIL product that is designed to overcome the major limitations of current TIL therapy which include T cell exhaustion post expansion, suboptimal manufacturing success rates, and poor persistence of anti-tumor cells in the patient."

About DeTIL-0255
The DeTIL-0255 investigational product under development is an autologous cell therapy consisting of T cells derived from a patient's tumor expanded in culture with recombinant interleukin-2 and the small molecule CBL-B inhibitor NX-0255. DeTIL-0255 is designed to be a single administration autologous TIL therapy infused following non-myeloablative chemotherapy. Given the improved phenotypes of T cells produced with CBL-B inhibition, DeTIL-0255 could allow a broader application of TIL therapy, potentially providing long term benefit to patients with multiple types of cancer. Nurix is conducting the open label Phase 1 trial of DeTIL-0255 at multiple sites in the United States. Additional information on the clinical trial can be accessed at www.clinicaltrials.gov (NCT05107739).

About Nurix Therapeutics, Inc.
Nurix Therapeutics is a clinical stage biopharmaceutical company focused on the discovery, development, and commercialization of small molecule and cell therapies based on the modulation of cellular protein levels as a novel treatment approach for cancer and other challenging diseases. Leveraging Nurix's extensive expertise in E3 ligases together with its proprietary DNA-encoded libraries, Nurix has built DELigase, an integrated discovery platform to identify and advance novel drug candidates targeting E3 ligases, a broad class of enzymes that can modulate proteins within the cell. Nurix's drug discovery approach is to either harness or inhibit the natural function of E3 ligases within the ubiquitin proteasome system to selectively decrease or increase cellular protein levels. Nurix's wholly owned pipeline includes targeted protein degraders of Bruton's tyrosine kinase, a B-cell signaling protein, and inhibitors of Casitas B-lineage lymphoma proto-oncogene B, an E3 ligase that regulates T cell activation. Nurix is headquartered in San Francisco, California. For more information, please visit http://www.nurixtx.com/.

Forward Looking Statement
This press release contains statements that relate to future events and expectations and as such constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When or if used in this press release, the words "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "outlook," "plan," "predict," "should," "will," and similar expressions and their variants, as they relate to Nurix, may identify forward-looking statements. All statements that reflect Nurix's expectations, assumptions or projections about the future, other than statements of historical fact, are forward-looking statements, including, without limitation, statements regarding our future financial or business performance, conditions, plans, prospects, trends or strategies and other financial and business matters; our current and prospective drug candidates; the planned timing and conduct of our clinical trial programs for our drug candidates; the planned timing for the provision of clinical updates and initial findings from our clinical studies; the potential advantages of our DELigase™ platform and drug candidates; and the extent to which our scientific approach and DELigase™ platform may potentially address a broad range of diseases Forward-looking statements reflect Nurix's current beliefs, expectations, and assumptions regarding the future of Nurix's business, future plans and strategies, its development plans, its preclinical and clinical results, future conditions and other factors Nurix believes are appropriate in the circumstances. Although Nurix believes the expectations and assumptions reflected in such forward-looking statements are reasonable, Nurix can give no assurance that they will prove to be correct. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and changes in circumstances that are difficult to predict, which could cause Nurix's actual activities and results to differ materially from those expressed in any forward-looking statement. Such risks and uncertainties include, but are not limited to: (i) risks and uncertainties related to Nurix's ability to advance its drug candidates, obtain regulatory approval of and ultimately commercialize its drug candidates; (ii) the timing and results of preclinical studies and clinical trials; (iii) Nurix's ability to fund development activities and achieve development goals; (iv) the impact of the COVID-19 pandemic on Nurix's business, clinical trials, financial condition, liquidity and results of operations; (v) Nurix's ability to protect intellectual property and (vi) other risks and uncertainties described under the heading "Risk Factors" in Nurix's Annual Report on Form 10-K for the fiscal year ended November 30, 2021 and other SEC filings. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements. The statements in this press release speak only as of the date of this press release, even if subsequently made available by Nurix on its website or otherwise. Nurix disclaims any intention or obligation to update publicly any forward-looking statements, whether in response to new information, future events, or otherwise, except as required by applicable law.

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