Nurix Therapeutics Receives U.S. FDA Fast Track Designation for NX-5948 for the Treatment of Relapsed or Refractory Waldenstrom's Macroglobulinemia

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Fast track designation follows positive Phase 1 data presented at the 12th International Workshop on Waldenstrom's Macroglobulinemia

SAN FRANCISCO, Dec. 19, 2024 (GLOBE NEWSWIRE) -- Nurix Therapeutics, Inc. (Nasdaq: NRIX), a clinical stage biopharmaceutical company developing targeted protein modulation drugs designed to treat patients with cancer and inflammatory diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for NX-5948, a highly selective degrader of Bruton's tyrosine kinase (BTK), for the treatment of adult patients with relapsed or refractory Waldenstrom's macroglobulinemia (WM) after at least two lines of therapy, including a BTK inhibitor.

"Fast Track designation for NX-5948 is an important recognition of the unmet patient need in Waldenstrom's macroglobulinemia, particularly in the growing number of patients whose cancer has progressed following BTK inhibitor therapy," said Arthur T. Sands, M.D., Ph.D., president and chief executive officer of Nurix. "This designation follows encouraging safety and efficacy data from our ongoing Phase 1 clinical trial, demonstrating early promise of clinical benefit with potential for durable outcomes. We continue to enroll Waldenstrom's macroglobulinemia patients in the ongoing Phase 1b expansion cohort and anticipate sharing additional clinical data in 2025."

In addition to the Fast Track designation announced today for Waldenstrom's macroglobulinemia, NX-5948 previously received Fast Track designation in January 2024 for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) after at least two lines of therapy, including a BTK inhibitor and a B-cell lymphoma 2 (BCL2) inhibitor. In November 2024, the European Medicines Agency (EMA) granted NX-5948 PRIME designation for the treatment of adult patients with relapsed or refractory CLL/SLL after at least a BTK inhibitor and a BCL2 inhibitor.

About Waldenstrom's Macroglobulinemia

WM is a rare, slow growing type of non-Hodgkin's lymphoma that is characterized by the replacement of normal bone marrow cells by malignant lymphocytic cells that produce monoclonal IgM. This replacement leads to anemia, bleeding, and impaired immune function, while the elevated IgM levels may cause neurologic symptoms. The incidence of Waldenstrom's macroglobulinemia ranges from 0.36 [1,2] to 0.57[3] per 100,000 people in the United States or approximately 1,200 to 1,900 annually. With a median disease duration approaching 10 years,[4] approximately 12,000 to 19,000 patients are living with Waldenstrom's macroglobulinemia in the United States. Recommended first-line treatments including chemoimmunotherapy and BTK inhibitor therapy. There are no therapies approved to treat WM patients after BTKi.

About Fast Track Designation

The FDA's Fast Track designation is intended to facilitate and expedite the development and review of drug candidates to treat serious conditions and fulfill an unmet medical need. To qualify, available clinical and non-clinical data need to demonstrate a therapeutic candidate's potential to address this unmet medical need. A therapeutic candidate that receives Fast Track designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan and, if relevant criteria are met, eligibility for Accelerated Approval and Priority Review.

About PRIME Designation

The PRIME initiative, launched by the EMA in 2016, offers early, proactive and enhanced support to developers of promising medicines to optimize development plans and accelerate evaluation so these medicines can reach patients faster. To be eligible for PRIME, medicines must target an unmet medical need and show potential benefit for patients based on early clinical data.

About NX-5948

NX-5948 is an investigational, orally bioavailable, brain penetrant, small molecule degrader of BTK. NX-5948 is currently being evaluated in a Phase 1 clinical trial in patients with relapsed or refractory B cell malignancies. Nurix has previously reported that NX-5948 is highly potent against a range of tumor cell lines that are resistant to current BTK inhibitor therapies, an important consideration in heavily pretreated CLL/SLL patient populations. Additional information on the ongoing clinical trial can be accessed at clinicaltrials.gov (NCT05131022).

About Nurix

Nurix Therapeutics is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of innovative small molecules and antibody therapies based on the modulation of cellular protein levels as a novel treatment approach for cancer, inflammatory conditions, and other challenging diseases. Leveraging extensive expertise in E3 ligases together with 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, clinical stage 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 activation of multiple immune cell types including T cells and NK cells. Nurix is headquartered in San Francisco, California. For

additional information visit http://www.nurixtx.com.

Forward-Looking Statements

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 Nurix's plans and strategies with respect to NX-5948, the potential advantages and therapeutic benefits of NX-5948, including its potential role in the treatment of B-cell malignancies, including Waldenstrom's macroglobulinemia, the planned timing for the provision of updates from the NX-5948 clinical trial, and the potential benefits of Fast Track designation. Forward-looking statements reflect Nurix's current beliefs, expectations, and assumptions. 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) the risks inherent in the drug development process, including the unexpected emergence of adverse events or other undesirable side effects during clinical development; (ii) uncertainties related to the timing and results of clinical trials; (iii) whether Nurix will be able to fund its research and development activities and achieve its research and development goals; (iv) the impact of economic and market conditions and global and regional events on Nurix's business, clinical trials, financial condition, liquidity and results of operations; (v) whether Nurix will be able to protect intellectual property and (vi) other risks and uncertainties described under the heading "Risk Factors" in Nurix's Quarterly Report on Form 10-Q for the fiscal period ended August 31, 2024, 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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