Nurix Therapeutics Receives U.S. FDA Fast Track Designation for NX-5948 for the Treatment of Relapsed or Refractory CLL and SLL

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Fast track designation follows positive Phase 1 data presented at the American Society of Hematology that supports strategy to broadly develop NX-5948 in CLL and other non-Hodgkin lymphoma indications

SAN FRANCISCO, Jan. 16, 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 chronic lymphocytic leukemia or small lymphocytic lymphoma (r/r CLL/SLL) after at least two lines of therapy, including a BTK inhibitor (BTKi) and a B-cell lymphoma 2 (BCL2) inhibitor.

"Fast Track designation for NX-5948 is an important recognition of the unmet patient need in CLL, particularly in the growing number of patients whose cancer has progressed following BTK and BCL2 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. The receipt of Fast Track designation is especially timely given our plans to accelerate enrollment in the Phase 1 trial of NX-5948 with the goal of enabling a pivotal study for NX-5948 as rapidly as possible."

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 an 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.

Nurix recently reported positive clinical data from the dose escalation stage of its Phase 1a/1b clinical trial evaluating daily oral dosing of BTK degrader NX-5948 in patients with r/r B-cell malignancies at the American Society of Hematology (ASH) meeting held in December 2023. In the ASH presentation, six of seven patients in the CLL population that received doses ranging from 50 to 200 mg demonstrated clinical benefit with three partial responses (PR) that were all ongoing as of the October 17, 2023 data cut. NX-5948 was well-tolerated across all doses tested with no dose limiting toxicities (DLTs) or treatment-related serious adverse events (SAEs) and no treatment emergent adverse events (TEAEs) that resulted in drug discontinuation. Importantly, there were no incidences of atrial fibrillation or hypertension. Dose escalation continues across all indications and the study is actively enrolling patients in the United States, the United Kingdom, and the Netherlands. Additional data with higher dose levels and longer treatment duration are expected in 2024.

About NX-5948
NX-5948 is an investigational, orally bioavailable, 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 medicines based on the modulation of cellular protein levels as a novel treatment approach for cancer and other challenging diseases including inflammatory conditions. 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 cell 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 for NX-5948, including Nurix's plans to accelerate enrollment in the NX-5948 clinical trials; the tolerability, safety profile, therapeutic potential and other advantages of NX-5948, including its potential to address a range of BTKi mutations; the planned timing and conduct of the clinical trial for NX-5948; the planned timing for the provision of updates and findings 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 regarding the future. Although Nurix believes these expectations and assumptions 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) whether Nurix will be able to successfully conduct the Phase 1 clinical trial for NX-5948 and receive results on its expected timelines, or, at all; (ii) the unexpected emergence of adverse events or other undesirable side effects during clinical development; (iii) whether Nurix will be able to successfully complete clinical development for NX-5948; (iv) the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; (v) whether regulatory authorities will be satisfied with the results from Nurix's clinical studies; (vi) whether Nurix will be able to obtain regulatory approval of and ultimately commercialize its drug candidates; (vii) whether Nurix will be able to fund development activities and achieve development goals; (viii) the impact of macroeconomic conditions and global events on Nurix's clinical trials and operations; and (ix) other risks and uncertainties described under the heading "Risk Factors" in Nurix's Quarterly Report on Form 10-Q for the fiscal quarter ended August 31, 2023, 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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