

Nurix Therapeutics Announces Partial Clinical Hold For NX-2127 Phase 1 Trial

November 1, 2023

Currently enrolled patients may continue receiving NX-2127

SAN FRANCISCO, Nov. 01, 2023 (GLOBE NEWSWIRE) -- Nurix Therapeutics, Inc. (Nasdaq: NRIX), a clinical stage biopharmaceutical company developing targeted protein modulation drugs designed to treat patients with hematologic malignancies and solid tumors, today announced that the U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on U.S. Phase 1 NX-2127-001 study evaluating NX-2127 in various B-cell malignancies. Screening and enrollment of new study participants has been paused. Patients currently enrolled in the clinical study who are deriving clinical benefit may continue to receive treatment in accordance with the ongoing study protocol. Nurix is working with the FDA to resolve the partial clinical hold as soon as possible.

The partial clinical hold follows the company's communication to the FDA of its intention to transition to an improved manufacturing process. Nurix's other drug programs are not affected by the NX-2127 manufacturing process improvement.

"The initial NX-2127 manufacturing process produced a Phase 1 drug product that has yielded important proof-of-concept results with meaningful clinical responses in patients with advanced B-cell malignancies," said Arthur T. Sands, M.D., Ph.D., president and chief executive officer of Nurix. "While the partial hold is in effect, we will supply the current drug product for patients who continue on therapy in the Phase 1 study and will work expeditiously with FDA to introduce the improved NX-2127 manufacturing process and drug product into our clinical development plan."

About NX-2127

NX-2127 is a novel bifunctional molecule that degrades BTK and cereblon neosubstrates Ikaros (IKZF1) and Aiolos (IKZF3). NX-2127 is currently being evaluated in a Phase 1 clinical trial in patients with relapsed or refractory B cell malignancies. Additional information on the ongoing clinical trial can be accessed at www.clinicaltrials.gov (NCT04830137).

About Nurix Therapeutics, Inc.

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. 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 ability to resolve the partial clinical hold, including the likelihood that the partial clinical hold will be lifted and the timing of any such resolution; Nurix's plans and expectations for discussions with the FDA and the outcomes from such discussions; Nurix's plans to transition to an improved manufacturing process for NX-2127 drug product; Nurix's plans to supply current drug product to patients currently enrolled in the NX-2127 clinical trial; and the impact of the partial clinical hold on Nurix's other drug programs. Forward-looking statements reflect Nurix's current beliefs, expectations, and assumptions regarding the future of Nurix's business, its future plans and strategies, 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) the risk that the FDA may require Nurix to collect additional data or information beyond what Nurix currently expects; (ii) the risk that Nurix may not be able to adequately address the FDA's concerns with respect to the NX-2127 clinical trial; (iii) uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that the FDA may not remove the partial clinical hold; (iv) uncertainties regarding Nurix's ability to comply with regulatory requirements; (v) the risk that ongoing regulatory obligations and continued regulatory review may result in significant additional expense to Nurix or penalties for failure to comply; and (vi) 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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