



Nurix Therapeutics Announces Positive Dose Finding Data in Chronic Lymphocytic Leukemia and Advances NX-2127 to Next Phase of Clinical Development

May 26, 2022

Data to be discussed at Nurix R&D Day at 8:00 a.m. ET today May 26

SAN FRANCISCO, May 26, 2022 (GLOBE NEWSWIRE) -- [Nurix Therapeutics, Inc.](#) (Nasdaq: NRIX), a biopharmaceutical company developing targeted protein modulation drugs, today announced that it has initiated the first of several potential Phase 1b expansion cohorts in its ongoing Phase 1 trial of NX-2127, an orally administered degrader of Bruton's tyrosine kinase (BTK) with immunomodulatory activity. The first expansion cohorts will focus on patients with chronic lymphocytic leukemia (CLL).

The expansion into CLL is based on recent positive data from Nurix's ongoing Phase 1a dose escalation study of NX-2127, including:

- Meaningful clinical benefit including multiple confirmed responses by IWCLL criteria observed in highly pre-treated relapsed/refractory CLL patients with a median of 6 prior therapies
- Clinical responses in patients with BTK mutations that confer resistance to current BTK targeted therapies including both covalent and noncovalent BTK inhibitors
- All patients show robust and durable BTK degradation
- All patients show Immunomodulatory activity mediated through the E3 ligase cereblon
- Overall biologic activity in all patients at the 100 mg dose with a favorable safety profile

"Our decision to advance NX-2127 in patients with CLL is based on the promising efficacy, safety, pharmacokinetic, and pharmacodynamic data from the ongoing Phase 1a dose escalation trial. There is a significant unmet need for a therapeutic approach with the potential to address the growing problem of relapse due to the development of BTK inhibitor resistance. We aim to meet that need and are encouraged by the emerging data demonstrating the potential of BTK degradation to treat acquired resistance mutations for both standard of care and newly developed BTK inhibitors," said Robert J. Brown, M.D., executive vice president of clinical development at Nurix. "We look forward to highlighting the biomarker data and preliminary safety and efficacy data that guided our decision to expand the trial for CLL patients at Nurix's R&D Day, scheduled for May 26th in New York City, and will provide a full clinical update at a future medical conference in the second half of 2022."

The Phase 1b expansion cohorts will include up to 40 CLL patients enrolled across multiple clinical sites in the United States. Patients will have received two or more prior regimens including a BTK inhibitor. All patients will be dosed at 100 mg orally once daily. The Phase 1a dose escalation portion of the trial will continue to enroll non-CLL patients at doses ranging from 50mg to 300mg orally once daily.

Nurix R&D Day

Nurix will host a research & development (R&D) day for analysts and investors that will be held today May 26, 2022 from 8:00 a.m. to 11:00 a.m. ET in New York City. The R&D Day will feature a presentation by guest speaker, Anthony Mato, M.D., MSCE, director of the chronic lymphocytic leukemia (CLL) Program at Memorial Sloan Kettering Cancer Center, who will provide a perspective on the clinical experience and unmet need in hematologic malignancies. The event will include presentations from Nurix's management team, who will provide a comprehensive update on Nurix's four clinical programs, DELigase® discovery platform and future development plans.

A live webcast, as well as a replay, will be available in the [Investors](#) section of the Nurix website under Events and Presentations.

About NX-2127

Nurix's lead drug candidate from its protein degradation portfolio, NX-2127, is an orally bioavailable degrader of BTK with immunomodulatory activity for the treatment of relapsed or refractory B-cell malignancies. NX-2127 harnesses the normal cellular protein degradation mechanism, the E3 ligase-mediated ubiquitin-proteasome pathway, to catalyze degradation of BTK. BTK is an enzyme involved in B-cell development, differentiation and signaling that is critical for proliferation and survival of lymphoma and leukemia cells in many B-cell malignancies. Inhibitors of BTK, such as ibrutinib, are approved for treatment of B-cell cancers, however certain patients cannot tolerate them and in other patients, specific mutations can arise in the BTK protein that confer resistance to these agents, thereby reducing their efficacy. Degradation of BTK has the potential to overcome resistance in patients harboring such mutations in BTK. In addition, NX-2127 catalyzes degradation of transcription factors including Ikaros and Aiolos involved in regulating T-cell function, resulting in immunomodulatory activity.

About the Phase 1, Study of NX-2127

The multicenter Phase 1 study is designed to evaluate safety, pharmacokinetics, pharmacodynamics and preliminary clinical activity of orally administered NX-2127 in adult patients with relapsed or refractory B-cell malignancies. The study is being conducted in two parts. The Phase 1a element is a dose-escalation study in which cohorts of patients will receive ascending oral doses of NX-2127 once daily to determine the maximum tolerated dose (MTD) and/or the optimal Phase 1b dose based on safety and tolerability. The second portion of the study, Phase 1b, is a dose expansion phase in which cohorts of patients with specific cancers will receive NX-2127 to further evaluate the safety and clinical activity of the

recommended dose. The study is expected to enroll eligible patients with the following cancers: chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), Waldenstrom macroglobulinemia (WM), mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), follicular lymphoma (FL), and diffuse large B-cell lymphoma (DLBCL), who have required and received prior systemic therapies. Additional information on the clinical trial can be accessed at ClinicalTrials.gov ([NCT04830137](https://clinicaltrials.gov/ct2/show/study/NCT04830137)).

About Nurix Therapeutics, Inc.

Nurix Therapeutics is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of small molecule therapies designed to modulate 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 the development and regulatory status of Nurix's drug candidates; the tolerability, safety profile, therapeutic potential and other potential advantages of Nurix's drug candidates; the planned timing and conduct of the clinical trials for Nurix's drug candidates; and the planned timing for the provision of updates and initial findings from Nurix's clinical trials and programs. 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) whether Nurix will be able to successfully conduct Phase 1 clinical trials for NX-2127 and its other drug candidates and receive results on its expected timelines, or at all; (ii) whether Nurix will be able to successfully complete clinical development for NX-2127 and its other drug candidates; (iii) the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; (iv) whether regulatory authorities will be satisfied with the design of and results from Nurix's clinical studies; (v) whether Nurix will be able to obtain regulatory approval of and ultimately commercialize its drug candidates; (vi) whether Nurix will be able to fund development activities and achieve development goals; (vii) the impact of the COVID-19 pandemic on Nurix's operations and clinical trials; and (viii) other risks and uncertainties described under the heading "Risk Factors" in Nurix's Quarterly Report on Form 10-Q for the fiscal period ended February 28, 2022, 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.

Contacts:

Investors:

Elizabeth Wolffe, Ph.D.
Wheelhouse Life Science Advisors
lwolffe@wheelhousesa.com

Media:

Brett Whelan
LifeSci Communications
bwhelan@lifescicomms.com