Nurix Therapeutics Presents Positive Results from Ongoing Clinical Trial of NX-5948 in Patients with Relapsed Refractory Chronic Lymphocytic Leukemia (CLL) at the European Hematology Association Congress (EHA2024)

June 16, 2024

Objective response rate of 69.2% observed in heavily pretreated patient population including patients with BTK inhibitor resistance mutations

Clinical responses in CLL patients were rapid and deepening with longer time on treatment

Nurix intends to advance NX-5948 into pivotal trial(s) in 2025

Company will host a webcast conference today, June 16, 2024, at 9:00 a.m. ET (3:00 p.m. CEST)

SAN FRANCISCO, June 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 the presentation of updated clinical data for NX-5948, an orally bioavailable degrader of Bruton's tyrosine kinase (BTK), being evaluated in an ongoing Phase 1a/b clinical trial in adults with relapsed or refractory B-cell malignancies, including CLL and non-Hodgkin lymphoma (NHL). Dr. Kim Linton, M.B.Ch.B, MRCP, Ph.D., FRCP, senior lecturer at the University of Manchester, a consultant at The Christie NHS Foundation Trust and an investigator on the clinical trial, presented the data in an oral session at the European Hematology Association Congress, which is being held from June 13–16, 2024, in Madrid, Spain.

"The current results from this study of advanced patients are very impressive for this early stage of development and we are optimistic that NX-5948 has the potential to be an exciting breakthrough for patients with relapsed CLL, particularly in light of the emerging patterns of resistance to the currently available targeted therapies," said Dr. Linton. "As a clinical investigator, it is highly gratifying to be able to offer patients who are refractory to other therapies a once daily, oral drug that can address a range of CLL disease states."

The data presented at EHA include safety findings for all patients in the Phase 1a dose escalation study regardless of diagnosis (n=79) and include efficacy findings for those patients with relapsed or refractory CLL (n=31). Patients were treated with NX-5948 at doses ranging from 50 mg to 600 mg once daily by oral administration. NX-5948 was well tolerated across all doses evaluated with most common treatment emergent adverse events of purpura/contusion, thrombocytopenia and neutropenia. Among the efficacy evaluable patients with CLL (n=26), NX-5948 treatment resulted in a robust objective response rate (ORR) of 69.2% across all doses tested with responses observed as early as the first scan (8 weeks) and with many patients experiencing deepening of their response with longer time on treatment. All responses remained ongoing as of the April 17 data cutoff. This cohort of CLL patients was a heavily pretreated population that had received a median of four prior lines of therapy (range = 2–14) including prior covalent BTK inhibitors (96.8%), prior BCL2 inhibitors (90.3%), and prior non-covalent BTK inhibitors (25.8%). At baseline, a large number of patients had mutations associated with BTK inhibitor resistance including mutations in BTK (43.3%) and PLC2G (20.0%). Poor prognostic features were common including TP53 mutations (46.7%), and two patients (6.5%) had central nervous system (CNS) involvement. Responses were observed across all populations regardless of prior treatment, baseline mutations, or CNS involvement.

Dr. Linton also presented an updated case report that detailed the response of one patient who entered the study with CLL with CNS involvement after having undergone three prior therapies, including treatment with a BTK inhibitor. After daily treatment with 100 mg, and later 300 mg, of NX-5948, the patient exhibited a deepening response approaching complete response criteria by 36 weeks, with elimination of malignant cells in the cerebrospinal fluid (CSF) by 24 weeks.

Another case report presented by the company involved a patient who had received eleven prior lines of therapy, including all available BTK inhibitors (ibrutinib, acalabrutinib, zanubrutinib, and pirtobrutinib). After daily treatment with 200 mg of NX-5948, the patient achieved a response by week 8 which deepened over time and was ongoing with over 6 months of follow up.

"The responses we are observing across the entire CLL cohort at all dose levels are extremely encouraging. As a next step, we will expand the Phase 1b portion of the trial across a range of CLL subpopulations to prepare for initiation of pivotal, registration-directed clinical evaluation in 2025," said Paula G. O'Connor, M.D., chief medical officer of Nurix. "While we did not cover the clinical activity data from the NX-5948 study in the various subtypes of NHL in this presentation, we have observed responses across subtypes including complete responses in patients with advanced DLBCL, MCL, MZL, and PCNSL, as well as consistent

responses in advanced WM. We look forward to presenting additional data from the study for both CLL and NHL as it matures and to providing further details around our plans for the next stage of development of NX-5948."

"With a growing body of positive clinical data, demonstrated activity in the CNS and a favorable safety profile, NX-5948 is emerging as a best-in-class medicine that has the potential to provide an important treatment option for patients with CLL and NHL," said Arthur T. Sands, M.D., Ph.D., president and chief executive officer of Nurix "We intend to move rapidly forward with the goal of initiating pivotal trial(s) with NX-5948 in 2025."

Conference Call Details

On June 16, 2024, at 9:00 a.m., ET (3:00 p.m., CEST), Nurix will host a conference call and webcast to discuss data from the NX-5948 clinical trial and plans for the program. The live webcast, with an accompanying presentation, will be accessible under the Events and Presentations page in the Investors section of the company's website here. To participate in the live conference call please pre-register online here. A replay of the webcast and call will be archived on the Nurix website for approximately 30 days after the event.

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 including chronic lymphocytic leukemia / small lymphocytic lymphoma (CLL / SLL), diffuse large B cell lymphoma (DLBCL), follicular lymphoma (FL), mantle cell lymphoma (MCL), marginal zone lymphoma (MZL), primary central nervous system lymphoma (PCNSL) and Waldenström's macroglobulinemia (WM). 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 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 with respect to NX-5948, including Nurix's plans with respect to presenting additional data from the NX-5948 clinical trial, Nurix's plans to expand the Phase 1b portion of the NX-5948 clinical trial across a range of CLL subpopulations, and Nurix's intention to advance NX-5948 into pivotal trial(s) in 2025; and the potential advantages and therapeutic benefits of NX-5948, including its potential role in the treatment B-cell lymphomas and CLL involving the CNS. 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 February 29, 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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