Nurix Announces FDA Clearance of IND Application for GS-6791/NX-0479 - a Novel IRAK4 Degrader for Inflammatory Conditions

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Collaboration partner, Gilead Sciences, to begin *Phase 1 single ascending dose (SAD) and multiple ascending dose (MAD) study in healthy volunteers in Q2 2025*

GS-6791/NX-0479 has potential clinical applications across multiple blockbuster markets in inflammation, in both rheumatology and dermatology, including rheumatoid arthritis and atopic dermatitis

Nurix to receive a $5 million milestone payment from Gilead for FDA clearance of the IND, bringing the total amount received under the 2019 collaboration agreement to $135 million

Nurix is eligible for an additional $420 million in development, regulatory and commercial milestones associated with the IRAK4 degrader program as well as potential future royalties and retains an option to co-develop and co-detail in the United States with the parties splitting U.S. profits and losses

SAN FRANCISCO, April 17, 2025 (GLOBE NEWSWIRE) -- Nurix Therapeutics, Inc. (Nasdaq: NRIX), a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of targeted protein degradation medicines, announced today that the U.S. Food and Drug Administration (FDA) has cleared the IND for the IRAK4 degrader GS-6791/NX-0479, enabling the initiation of a Phase 1 trial, which is anticipated to begin in Q2 2025.

“GS-6791/NX-0479 is a highly optimized, selective, oral degrader of IRAK4, a master regulator of IL-1R/TLR signaling pathways that plays a crucial role in inflammatory processes. IRAK4 has both kinase and scaffolding functions, thus complete pathway blockade requires an innovative approach like targeted protein degradation,” said Gwenn M. Hansen, Ph.D., chief scientific officer of Nurix. “In preclinical studies, GS-6791/NX-0479 has demonstrated rapid and potent IRAK4 degradation across multiple human cell types in vitro, as well as rapid and sustained degradation in non-human primates. The ability to achieve complete IRAK4 degradation and cytokine suppression in disease-relevant tissues such as synovial fibroblasts and keratinocytes supports GS-6791/NX-0479’s potential as a best-in-class therapeutic. Additionally, GS-6791/NX-0479 has shown robust efficacy in rodent models of arthritis, supporting its potential to deliver superior therapeutic benefits for chronic inflammatory diseases including rheumatoid arthritis and atopic dermatitis.”

“Today’s announcement highlights the continuing success and productivity of our collaboration with Gilead and demonstrates Nurix’s ability to advance potential best-in-class degrader-based medicines for patients suffering from inflammation and autoimmune diseases,” said Arthur T. Sands, M.D., Ph.D., president and chief executive officer of Nurix. “GS-6791/NX-0479 is one drug candidate emerging from Nurix’s growing pipeline of degrader-based medicines designed to treat inflammation and autoimmune diseases, including our STAT6 degrader in collaboration with Sanofi and our proprietary BTK degrader NX-5948, which we plan to evaluate in patients with inflammation and autoimmune diseases.”

In June 2019, Gilead and Nurix entered into a global strategic collaboration to discover, develop and commercialize a pipeline of up to five innovative targeted protein degradation therapies for patients with cancer and other challenging diseases. Under the terms of the agreement, Nurix received an upfront payment of $45 million and was eligible to receive success-based preclinical milestones totaling $15 million, along with a licensing fee of $20 million and $425 million in potential clinical, regulatory, and commercial milestones payments per program as well as up to low double-digit tiered royalties on net sales. Following the receipt of $5 million for the IND clearance, Nurix remains eligible for $420 million in potential future milestones for the IRAK4 program. Nurix retains the option to co-develop and co-detail up to two programs in the United States, following completion of an applicable Phase 1 clinical trial, subject to certain restrictions. For those programs that Nurix opts in to co-develop and co-detail, the parties will split development costs as well as profits and losses 50/50 for the United States, and Nurix will be eligible to receive royalties on ex-U.S. sales and reduced milestone payments. Gilead has the right to veto up to one co-development option, in which case the option will revert back to Nurix for use on potential future licensed products.

About GS-6791/NX-0479

GS-6791/NX-0479 is a potent, selective, oral IRAK4 degrader. IRAK4 plays a critical role in toll-like receptor (TLR) and interleukin-1 family receptor (IL-1R) signaling and has both scaffold and kinase functions, making it an ideal target for disruption by targeted protein degradation. Degradation of IRAK4 by GS-6791/NX-0479 has potential applications in the treatment of rheumatoid arthritis and other inflammatory diseases. Nurix’s collaboration partner, Gilead Sciences, licensed the program in 2023 and is

responsible for advancing this program through clinical development.

About Nurix Therapeutics, Inc.

Nurix Therapeutics is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of targeted protein degradation medicines, the next frontier in innovative drug design aimed at improving treatment options for patients with cancer and inflammatory diseases. Nurix's wholly owned, clinical stage pipeline includes degraders of Bruton's tyrosine kinase (BTK), a B-cell signaling protein, and inhibitors of Casitas B-lineage lymphoma proto-oncogene B (CBL-B), an E3 ligase that regulates activation of multiple immune cell types including T cells and NK cells. Nurix also is advancing multiple potentially first-in-class or best-in-class degraders and degrader antibody conjugates (DACs) in its preclinical pipeline. Nurix's partnered drug discovery pipeline consists of preclinical stage degraders of IRAK4 and STAT6, as well as multiple additional programs under collaboration agreements with Gilead Sciences, Inc., Sanofi S.A. and Pfizer Inc., within which Nurix retains certain options for co-development, co-commercialization and profit sharing in the United States for multiple drug candidates. Powered by a fully AI-integrated discovery engine capable of tackling any protein class, and coupled with unparalleled ligase expertise, Nurix's dedicated team has built a formidable advantage in translating the science of targeted protein degradation into clinical advancements. Nurix aims to establish degrader-based treatments at the forefront of patient care, writing medicine's next chapter with a new script to outmatch disease. 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 expectations with respect to GS-6791/NX-0479; the therapeutic potential and other advantages of GS-6791/NX-0479, including its potential to address chronic inflammatory diseases such as rheumatoid arthritis and atopic dermatitis; and the potential benefits of and Nurix's expectations with respect to its strategic collaborations, including the achievement of research milestones. 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 ability of each party to perform its obligations under the Nurix-Gilead collaboration; (ii) whether the parties will be able to successfully conduct and complete preclinical development, clinical development and commercialization of any drug candidates under the Nurix-Gilead collaboration; (iii) the unexpected emergence of adverse events or other undesirable side effects during preclinical and clinical development; (iv) whether Nurix will be able to fund development activities and achieve development goals, including those under the Nurix-Gilead collaboration; (v) risks and uncertainties relating to the timing and receipt of payments from Nurix's collaboration partners, including milestone payments and royalties on future potential product sales; 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 February 28, 2025, 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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