European Medicines Agency Grants Bexobrutideg (NX-5948) Orphan Drug Designation for the Treatment of Lymphoplasmacytic Lymphoma, also Known as Waldenström Macroglobulinemia

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Regulatory momentum builds for bexobrutideg with multiple designations across the United States and EU, Including EMA PRIME and FDA Fast Track for CLL/SLL

SAN FRANCISCO, July 07, 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, today announced that the European Medicines Agency (EMA) has granted Orphan Drug Designation (ODD) to bexobrutideg (NX-5948) for the treatment of lymphoplasmacytic lymphoma. Bexobrutideg is an orally bioavailable, brain penetrant degrader of Bruton's tyrosine kinase (BTK) which is being evaluated in an ongoing Phase 1a/b clinical trial in adults with relapsed or refractory B-cell malignancies, including lymphoplasmacytic lymphoma, also known as Waldenström macroglobulinemia (WM).

The EMA's Orphan Drug Designation program grants orphan status to therapies intended for the treatment, diagnosis, or prevention of rare diseases that affect fewer than 5 in 10,000 people in the European Union. This designation provides several incentives to encourage the development of treatments for rare conditions, including 10 years of market exclusivity in the EU upon approval, access to protocol assistance, eligibility for centralized marketing authorization, and significant reductions in regulatory fees.

"The EMA's Orphan Drug Designation for bexobrutideg represents an important milestone in our regulatory strategy and underscores the significant unmet medical need for improved treatments for Waldenström macroglobulinemia," said Arthur T. Sands, M.D., Ph.D., president and chief executive officer of Nurix. "Granting of the designation highlights bexobrutideg's potential to provide patients with WM a promising new therapeutic option."

Waldenström macroglobulinemia is a rare type of blood cancer that affects B lymphocytes, a form of white blood cell. In this disease, B cells grow and survive abnormally, leading to their accumulation in the bone marrow, lymph nodes, and spleen. Early symptoms often include fatigue and weakness. It is characterized by the overproduction of IgM paraprotein—a blood protein that can cause the blood to thicken and lead to complications such as vision issues, heart problems, hemolytic anemia, and neurological symptoms.

Bexobrutideg previously received the U.S. Food and Drug Administration's Fast Track designation in December 2024 for the treatment of WM and Fast Track designation in January 2024 for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) after at least two lines of therapy, including a BTK inhibitor and a B-cell lymphoma 2 (BCL2) inhibitor. In November 2024, the EMA granted PRIME designation to bexobrutideg for the treatment of adult patients with relapsed or refractory CLL/SLL after treatment with at least a BTK inhibitor and a BCL2 inhibitor.

About Bexobrutideg (NX-5948)

Bexobrutideg is an investigational, orally bioavailable, brain penetrant, small molecule degrader of BTK currently being evaluated in a Phase 1 clinical trial in patients with relapsed or refractory B cell malignancies. Nurix previously has reported encouraging safety and efficacy data in patients with WM treated in the ongoing Phase 1a/b clinical trial of bexobrutideg, demonstrating early promise of clinical benefit with potential for durable outcomes. Nurix continues to enroll patients with WM in an ongoing Phase 1b expansion cohort and anticipates sharing additional clinical data in 2025. Additional information on the ongoing clinical trial can be accessed at clinicaltrials.gov (NCT05131022). Nurix is also developing bexobrutideg for the potential treatment of inflammatory diseases.

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. All statements that reflect Nurix's expectations, assumptions or projections about the future are forward-looking statements, including, without limitation, statements regarding the potential benefits of Orphan Drug Designation, the therapeutic potential of bexobrutideg, and the planned timing for the provision of updates and findings from Nurix's clinical trials. 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 advance, obtain regulatory approval of and ultimately commercialize bexobrutideg; (ii) whether Nurix will be able to fund development activities and achieve development goals; (iii) whether Nurix will be able to protect intellectual property and (iv) 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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