SpringWorks Therapeutics Announces Expected CHMP Opinion in Q2 2025 for Nirogacestat for the Treatment of Adults with Desmoid Tumors in the European Union

April 27, 2025

STAMFORD, Conn., April 27, 2025 (GLOBE NEWSWIRE) -- SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a commercial-stage biopharmaceutical company focused on severe rare diseases and cancer, announced today that the Company anticipates the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) will adopt an opinion on the marketing authorization application (MAA) for nirogacestat, an oral gamma secretase inhibitor, for the treatment of adults with desmoid tumors in the second quarter of 2025.

About SpringWorks Therapeutics

SpringWorks is a commercial-stage biopharmaceutical company dedicated to improving the lives of patients with severe rare diseases and cancer. We developed and are commercializing OGSIVEO® (nirogacestat) as the first and only FDA-approved medicine for adults with desmoid tumors and GOMEKLI™ (mirdametinib) as the first and only FDA-approved medicine for both adults and children with neurofibromatosis type 1 associated plexiform neurofibromas (NF1-PN). We are also advancing a diverse portfolio of novel targeted therapy product candidates for patients with both solid tumors and hematological cancers.

For more information, visit www.springworkstx.com and follow @SpringWorksTx on X, LinkedIn, Facebook, Instagram and YouTube.

SpringWorks Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, relating to our business, operations, and financial conditions, including but not limited to current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our development and commercialization plans, expectations regarding the timing and outcome of a decision from the CHMP on the marketing authorization application for nirogacestat, as well as relating to other future conditions. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Any forward-looking statements in this presentation are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this presentation, including, without limitation, risks relating to: (i) the timing of our planned regulatory submissions and interactions, including the timing and outcome of decisions made by the EMA and other regulatory authorities, (ii) whether EMA or other regulatory authorities will require additional information or further studies, or may fail or refuse to approve or may delay approval of our product candidates, including nirogacestat, (iii) our ability to obtain regulatory approval of any of our product candidates or maintain regulatory approvals granted for our products, and (iv) our ability to meet any specific milestones set forth herein.

Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements.

For further information regarding the risks, uncertainties and other factors that may cause differences between SpringWorks' expectations and actual results, you should review the "Risk Factors" in Item 1A of Part I of SpringWorks' Annual Report on Form 10-K for the year ended December 31, 2024, as well as discussions of potential risks, uncertainties and other important factors in SpringWorks' subsequent filings.

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