SpringWorks Therapeutics Reports Preliminary Fourth Quarter and Full Year 2024 Financial Results and Provides Business Updates at 43rd Annual J.P. Morgan Healthcare Conference

January 13, 2025

– Achieved $61.5 million and $172.0 million in preliminary fourth quarter and full year 2024 OGSIVEO® (nirogacestat) U.S. net product revenues, respectively –

– Ended 2024 with approximately $462 million in cash, cash equivalents, and marketable securities –

– Additional updates across Company's commercial portfolio and investigational pipeline to be provided during J.P. Morgan Healthcare conference presentation today at 11:15 a.m. PT –

STAMFORD, Conn., Jan. 13, 2025 (GLOBE NEWSWIRE) -- SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a commercial-stage biopharmaceutical company focused on severe rare diseases and cancer, today announced its preliminary fourth quarter and full year 2024 U.S. net product revenue for OGSIVEO® (nirogacestat) and provided additional company updates ahead of its presentation at the 43rd Annual J.P. Morgan Healthcare conference.

Preliminary Fourth Quarter and Full Year 2024 Financial Results* and Recent Business Highlights

- Preliminary fourth quarter and full-year 2024 U.S. net product revenue for OGSIVEO were $61.5 million and $172.0 million, respectively.
- As of December 31, 2024, total preliminary cash, cash equivalents, and marketable securities was $461.9 million. SpringWorks expects its cash position to fund operations through profitability, which the Company anticipates achieving in the first half of 2026.
- Presented long-term follow-up data from the Phase 3 DeFi trial of nirogacestat in adults with progressing desmoid tumors in the fourth quarter of 2024. These results showed that longer-term treatment with nirogacestat (median duration of treatment: 34 months) was associated with further reductions in tumor size, increase in objective response rate with additional partial responses and complete responses, sustained improvements in desmoid tumor symptoms including pain, and a consistent safety profile.
- Obtained an exclusive, global license from Rappta Therapeutics Oy for a first-in-class molecular glue of specific Protein Phosphatase 2A (PP2A) complexes. PP2A mutations represent a class of targetable oncogenic drivers in molecularly defined subsets of uterine cancer patients with high unmet need. In preclinical models of PP2A mutant uterine cancer, SW-3431 (formerly RPT04402) showed rapid, deep and durable tumor regressions as a monotherapy. In exchange for the license, Rappta received a $13 million upfront payment and is eligible to receive further clinical, regulatory and commercial milestone payments, and tiered single digit royalties on net sales.

* The preliminary fourth quarter and full year 2024 financial results are unaudited and do not present all information necessary for an understanding of the Company's results of operations and financial position for the fourth quarter and full year 2024. Such financial results are subject to adjustment and could differ from the Company's announcement of complete financial results in February 2025.

2025 Priorities and Anticipated Milestones

OGSIVEO (nirogacestat)

- Continue strong commercial execution of the OGSIVEO launch in the U.S.
- Secure regulatory approval for OGSIVEO in the European Union (EU) and launch OGSIVEO following reimbursement authorization in individual EU countries, beginning with Germany in mid-2025.
- Publish long-term follow-up data from the Phase 3 DeFi trial of nirogacestat in adults with desmoid tumors in a peer-reviewed journal by the end of 2025.
- Report initial data from the Phase 2 trial evaluating nirogacestat as a monotherapy in patients with ovarian granulosa cell tumors in the first half of 2025.
- Continue to support several industry and academic collaborator studies evaluating nirogacestat as part of B-cell maturation antigen (BCMA) combination therapy regimens across treatment lines in patients with multiple myeloma.

Mirdametinib (NF1-PN)

- Secure FDA approval in adults and children with NF1-associated plexiform neurofibromas, or NF1-PN (PDUFA: February 28, 2025), and launch in the U.S.
- Obtain regulatory approval in the EU for mirdametinib for the treatment of adults and children with NF1-PN and begin initial launch in 2025.

Emerging Pipeline

- SpringWorks expects additional data to be presented by MapKure from the brimarafenib monotherapy trial in the second half of 2025.
- Continue enrolling patients in Phase 1 trial of SW-682 in Hippo-mutant solid tumors.
- File an Investigational New Drug (IND) application for SW-3431 by the end of 2025.

"2025 is set up to be another transformative year for SpringWorks. With the potential launch of our second medicine and global expansion to serve patients with two devastating diseases, we are energized by the opportunity to continue delivering on the commitments we have made to the patient communities we are dedicated to serving," said Saqib Islam, Chief Executive Officer of SpringWorks. "In parallel with our commercial launches, we are advancing our pipeline of oncology programs for heavily underserved patient populations and are confident that our strong foundation will drive our long-term growth and success."

Presentation at the 43rd Annual J.P. Morgan Healthcare Conference

SpringWorks will webcast its presentation from the 43rd Annual J.P. Morgan Healthcare Conference today, Monday, January 13, 2025 at 11:15 a.m. PT (2:15 p.m. ET). To access the live webcast, please visit the Events & Presentations page within the Investors & Media section of the company's website at https://ir.springworkstx.com. A replay of the webcast will be available on SpringWorks' website for a limited time following the conference.

About SpringWorks Therapeutics

SpringWorks is a commercial-stage biopharmaceutical company applying a precision medicine approach to developing and delivering life-changing medicines for people with severe rare diseases and cancer. OGSIVEO® (nirogacestat), approved in the United States for the treatment of adult patients with progressing desmoid tumors who require systemic treatment, is the Company's first FDA-approved therapy. SpringWorks also has a diversified targeted therapy pipeline spanning solid tumors and hematological cancers, with programs ranging from preclinical development through advanced clinical trials. In addition to its wholly owned programs, SpringWorks has also entered into multiple collaborations with innovators in industry and academia to unlock the full potential for its portfolio and create more solutions for patients in need.

For more information, visit www.springworkstx.com and follow @SpringWorksTx on X (formerly Twitter), LinkedIn, and YouTube.

SpringWorks uses its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Such disclosures will be included on SpringWorks' website in the Investors & Media section. Accordingly, investors should monitor such portions of the SpringWorks website, in addition to following press releases, SEC filings and public conference calls and webcasts.

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 our preliminary financial results for the fourth quarter and full year 2024, current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our development and commercialization plans, the timing of and results from our preclinical studies and clinical trials, the potential for mirdametinib to become an important new treatment for adult and pediatric NF1-PN patients, expectations regarding the timing and results of the reviews by the FDA and the EMA, as applicable, of each of the NDA and the MAA for mirdametinib for the treatment of adult and pediatric NF1-PN patients, including the FDA's PDUFA target action date for the NDA, expectations regarding the timing and results of the MAA for OGSIVEO and our plans to make OGSIVEO commercially available in individual countries in the European Union following required approvals beginning in mid-2025, our plans to present additional data from the Phase 3 DeFi trial of nirogacestat at upcoming conferences, our plans for seeking regulatory approval for and making mirdametinib available for NF1-PN patients, if approved, expectations regarding the timing and initial data from the Phase 2 trial evaluating nirogacestat in patients with recurrent ovarian granulosa cell tumors, our expectations and timing for additional data for *brimarafenib in the second half of 2025,* our *expectations and the timing of the Phase 1 trial of SW-682, our plans to file an IND for SW-3431 by the end of 2025, 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 press release 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 press release, including, without limitation, risks relating to: (i) the success of our commercialization efforts with respect to OGSIVEO, (ii) our limited experience as a commercial company, (iii) our ability to obtain or maintain adequate coverage and reimbursement for OGSIVEO, (iv) the success and timing of our product development activities, including the initiation and completion of our clinical trials, (v) our expectations regarding the potential clinical benefit of OGSIVEO for adult patients with desmoid tumors who require systemic treatment, (vi) estimates regarding the number of adult patients who are diagnosed with desmoid tumors annually per year in the U.S. and the potential market for OGSIVEO, (vii) the fact that topline or interim data from clinical studies may not be predictive of the final or more detailed results of such study or the results of other ongoing or future studies, (viii) the success and timing of our collaboration partners' ongoing and planned clinical trials, (ix) the timing of our planned regulatory submissions and interactions, including the timing and outcome of decisions made by the FDA, EMA, and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies, (x) whether FDA, 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 and mirdametinib, (xi) our ability to obtain regulatory approval of any of our product candidates or maintain regulatory approvals granted for our products, (xii) our plans to research, discover and develop additional product candidates, (xiii) our ability to enter into collaborations for the development of new product candidates and our ability to realize the benefits expected from such collaborations, (xiv) our ability to maintain adequate patent protection and successfully enforce patent claims against third parties, (xv) the adequacy of our cash position to fund our operations through any time period indicated herein, (xvi) our ability to establish manufacturing capabilities, and our and our collaboration partners' abilities to manufacture our product candidates and scale production, and (xvii) 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 II of SpringWorks' Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, as well as discussions of potential risks, uncertainties and other important factors in SpringWorks' subsequent filings.

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