SpringWorks Therapeutics Highlights 2023 Accomplishments and Anticipated Milestones for 2024 at the 42nd Annual J.P. Morgan Healthcare Conference

January 8, 2024

STAMFORD, Conn., Jan. 08, 2024 (GLOBE NEWSWIRE) -- SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a commercial-stage biopharmaceutical company focused on severe rare diseases and cancer, will present today at the 42nd Annual J.P. Morgan Healthcare Conference at 7:30 a.m. PT (10:30 a.m. ET), and a live webcast will be available at ir.springworkstx.com. Ahead of the presentation, the Company highlighted its 2023 accomplishments and announced its anticipated key milestones for 2024.

2023 Accomplishments

Nirogacestat

- Received approval from the United States Food and Drug Administration (FDA) for OGSIVEO™ (nirogacestat), an oral gamma secretase inhibitor, for the treatment of adult patients with progressing desmoid tumors who require systemic treatment.
- Published data from the Phase 3 DeFi trial of nirogacestat in adult patients with progressing desmoid tumors in the *New England Journal of Medicine*.
- Presented additional data from the Phase 3 DeFi trial at several leading medical conferences. These presentations demonstrated rapid, sustained and consistent improvements in pain and functional status in patients receiving OGSIVEO using multiple assessment tools.
- Completed enrollment in the Phase 2 trial evaluating nirogacestat as a monotherapy in patients with recurrent ovarian granulosa cell tumors (OvGCT).
- Continued to evaluate nirogacestat in patients with multiple myeloma as part of several B-cell maturation antigen (BCMA) combination therapy regimens across treatment lines in collaboration with industry leaders. Clinical data from two BCMA combination studies were presented at the European Hematology Association congress and provided further validation of the mechanistic approach supporting nirogacestat's ability to enhance the activity of BCMA-directed therapies across modalities. In addition, a Regeneron-sponsored study was initiated to evaluate nirogacestat in combination with linvoseltamab, Regeneron's bispecific antibody targeting BCMA and CD3.

Mirdametinib (NF1-PN)

- Presented positive topline data from the pivotal Phase 2b ReNeu trial evaluating mirdametinib, an investigational oral MEK inhibitor, in pediatric and adult patients with neurofibromatosis type 1-associated plexiform neurofibromas (NF1-PN). Data demonstrated a confirmed objective response rate of 52% in pediatric patients and 41% in adult patients, as assessed by Blinded Independent Central Review. Mirdametinib treatment resulted in deep and durable responses and led to significant improvements in key secondary patient-reported outcome measures. Mirdametinib was generally well tolerated in the ReNeu trial, with the majority of adverse events being Grade 1 or Grade 2.

Emerging Pipeline

- Presented updated data from the Phase 1a/1b study of brimarafenib (BGB-3245), an investigational, selective RAF dimer inhibitor being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene, Ltd., in adult patients with advanced or refractory solid tumors harboring MAPK pathway aberrations at the American Association for Cancer Research (AACR) annual meeting. These data supported the advancement of brimarafenib into the Phase 1b cohort expansion portion of the study.
- Shared updated clinical data from the Phase 1b trial evaluating mirdametinib in combination with BeiGene's investigational RAF dimer inhibitor, lifirafenib, in patients with advanced or refractory solid tumors with RAS mutations, RAF mutations and other MAPK pathway aberrations at AACR. The combination showed antitumor activity in patients with various mutations across several solid tumor types and support the advancement of this combination into the dose-expansion portion of the study, which is evaluating the combination in patients with *NRAS*-mutated solid tumors.
- Dosed the first patient in a Phase 1/2a combination study of brimarafenib and mirdametinib.
- The FDA cleared the Investigational New Drug (IND) application submitted through MapKure for a combination study of brimarafenib with panitumumab, a monoclonal antibody targeting EGFR, in colorectal and pancreatic cancer patients with known MAPK pathway mutations. Amgen Inc. is supplying panitumumab pursuant to a clinical trial collaboration agreement with MapKure.

- Submitted an IND application for SW-682, a novel, potent, and selective TEAD inhibitor development candidate targeting tumors driven by Hippo pathway mutations.

General Corporate

- Continued to expand and strengthen the intellectual property portfolios for nirogacestat and mirdametinib, with Orange Book listable patents providing protection past 2040 for both nirogacestat and mirdametinib.
- Strengthened balance sheet with upsized public offering; gross proceeds from the offering, before deducting underwriting discounts and commissions and estimated offering expenses, were approximately $316.25 million. SpringWorks estimates that its cash, cash equivalents and marketable securities as of September 30, 2023 exceeded $700 million on a pro forma basis.

Anticipated 2024 Key Milestones

Nirogacestat

- Continue to advance U.S. launch of OGSIVEO (nirogacestat) as the first and only approved therapy for adult patients with desmoid tumors and establish as standard of care.
- Submit Marketing Authorisation Application (MAA) for nirogacestat for the treatment of adult patients with desmoid tumors to the European Medicines Agency (EMA) in the first half of 2024.
- Report initial data from the Phase 2 trial evaluating nirogacestat as a monotherapy in patients with OvGCT in the second half of 2024.
- Expand data set with additional clinical data of nirogacestat in combination with BCMA-directed therapies.

Mirdametinib (NF1-PN)

- Submit a New Drug Application (NDA) to the FDA for mirdametinib for the treatment of children and adults with NF1-PN in the first half of 2024.
- Present data from the pediatric and adult cohorts of the Phase 2b ReNeu trial of mirdametinib in NF1-PN at a medical congress in the first half of 2024 and submit for publication in a peer-reviewed journal in 2024.

Emerging Pipeline

- Present additional data for brimarafenib as a monotherapy in MAPK-mutant solid tumors in the second half of 2024.
- Support initiation of Phase 1b trial of brimarafenib in combination with panitumumab, a monoclonal antibody targeting EGFR, in colorectal and pancreatic cancer patients with known MAPK pathway mutations in the first quarter of 2024.
- Initiate Phase 1 trial of SW-682, SpringWorks' TEAD inhibitor, in Hippo mutant solid tumors in the first half of 2024.

"Our focus in 2024 is to deliver a successful U.S. launch of OGSIVEO as the first and only FDA-approved therapy for adults with desmoid tumors and to prepare for our second potential FDA approval by filing our NDA for mirdametinib as a treatment for patients with NF1-PN in the first half of the year," said Saqib Islam, Chief Executive Officer of SpringWorks. "We are very pleased with our progress towards our goal of having two marketed products by 2025 given the highly positive topline data from our Phase 2b ReNeu trial and will simultaneously advance our broader pipeline of targeted oncology programs. Our achievements in 2023, our strong financial position and the durable IP protections for our lead assets position us for continued, long-term success as we execute on our mission to improve the lives of patients with devastating diseases."

Presentation at the 42nd Annual J.P. Morgan Healthcare Conference

SpringWorks will webcast its presentation from the 42nd Annual J.P. Morgan Healthcare Conference today, Monday, January 8, 2024 at 7:30 a.m. PT (10:30 a.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.

Founded in 2017, SpringWorks has a diversified targeted oncology pipeline spanning solid tumors and hematological cancers, including clinical trials in rare tumor types and highly prevalent, genetically defined cancers. OGSIVEO™, approved in the United States for the treatment of adult patients with progressing desmoid tumors who require systemic treatment, is SpringWorks' first FDA-approved therapy. SpringWorks' strategic approach and operational excellence in clinical development have enabled it to rapidly advance its lead product candidates into late-stage trials and enter into multiple collaborations with innovators in industry and academia to unlock the full potential for its portfolio and create more solutions for patients with cancer.

For more information, visit www.springworkstx.com and follow @SpringWorksTx on X (formerly Twitter), LinkedIn, 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, our preclinical and clinical results, the market

potential of OGSIVEO for adult patients with desmoid tumors, the potential for a Marketing Authorisation Application for nirogacestat with the European Medicines Agency, the potential for the results of the Phase 2b ReNeu clinical trial to support an NDA submission for mirdametinib, the potential for mirdametinib to become an important new treatment for patients with NF1-PN, 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, expectations regarding the timing and results of topline data from the Phase 2b ReNeu clinical trial, our plans to initiate a Phase 1 trial of SW-682 in the first half of 2024, our plans to report additional clinical data of nirogacestat in combination with BCMA-directed therapies and initiate additional planned Phase 1 collaborator studies, our expectations regarding the potential for the Phase 1b dose expansion phase of brimarafenib, expectations about whether our patents for our lead assets will adequately protect SpringWorks against competition, 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 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 SpringWorks' clinical trials, (v) our expectations regarding the potential clinical benefit of OGSIVEO for patients with desmoid tumors, (vi) the potential for OGSIVEO to become the new standard of care for patients with desmoid tumors, (vii) 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, (viii) our expectations regarding the potential clinical benefit of mirdametinib for NF1-PN patients, (ix) 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, (x) the success and timing of our collaboration partners' ongoing and planned clinical trials, (xi) the timing of our planned regulatory submissions and interactions, including the timing and outcome of decisions made by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies, (xii) 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, (xiii) our ability to obtain regulatory approval of any of our product candidates or maintain regulatory approvals granted for our products, (xiv) our plans to research, discover and develop additional product candidates, (xv) our ability to enter into collaborations for the development of new product candidates and our ability to realize the benefits expected from such collaborations, (xvi) our ability to maintain adequate patent protection and successfully enforce patent claims against third parties, (xvii) the adequacy of our cash position to fund our operations through any time period indicated herein, (xviii) our ability to establish manufacturing capabilities, and our and our collaboration partners' abilities to manufacture our product candidates and scale production, and (xix) 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, 2023, as well as discussions of potential risks, uncertainties and other important factors in SpringWorks' other filings with the Securities and Exchange Commission.

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