SpringWorks Therapeutics Highlights 2022 Accomplishments and Anticipated Milestones for 2023 at the 41st Annual J.P. Morgan Healthcare Conference

January 9, 2023

STAMFORD, Conn., Jan. 09, 2023 (GLOBE NEWSWIRE) -- SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a clinical-stage biopharmaceutical company focused on developing life-changing medicines for patients with severe rare diseases and cancer, will present today at the 41st 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 2022 accomplishments and announced its anticipated key milestones for 2023.

2022 Accomplishments

- Presented positive Phase 3 DeFi data of nirogacestat, an investigational oral gamma secretase inhibitor, in adult patients with desmoid tumors at the European Society for Medical Oncology (ESMO) Congress.
- Submitted a New Drug Application (NDA) to the United States Food and Drug Administration (FDA) for nirogacestat for the treatment of adults with desmoid tumors, which is being reviewed under the FDA's Real-Time Oncology Review (RTOR) program.
- Expanded and strengthened its intellectual property portfolio, including a new patent issued by the United States Patent and Trademark Office in the fourth quarter of 2022 directed to pharmaceutical compositions of nirogacestat (U.S. Patent No. 11,504,354), which expires in 2042 and represents what is expected to be the seventh Orange Book-listable patent for nirogacestat.
- Participated in a Type C meeting with the FDA to align on the statistical analysis plan for the Phase 2b ReNeu trial evaluating mirdametinib, an investigational MEK inhibitor, in adult and pediatric patients with NF1-associated plexiform neurofibromas (NF1-PN) and expectations for an anticipated NDA submission in this indication.
- Initiated a Phase 2 trial evaluating nirogacestat in patients with ovarian granulosa cell tumors (OvGCT).
- Expanded global, non-exclusive license and collaboration agreement with GSK plc (GSK) to evaluate nirogacestat in combination with belantamab mafodotin in patients with multiple myeloma, including in earlier lines of treatment.
- Demonstrated clinical proof of concept for BGB-3245, a selective RAF dimer inhibitor being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene, as well as for the combination of mirdametinib and BeiGene's RAF dimer inhibitor, lifirafenib.
- Advanced BGB-3245 monotherapy into dose expansion cohorts and announced plans for a new Phase 1/2a study evaluating BGB-3245 in combination with mirdametinib.
- Nominated TEAD inhibitor development candidate (SW-682).
- Strengthened financial position to over $650 million in cash, cash equivalents and marketable securities, as of September 30, 2022, which is expected to provide runway into 2026.
- Established commercial infrastructure to support anticipated first U.S. product launch for nirogacestat in patients with desmoid tumors.

Anticipated 2023 Key Milestones

- Obtain regulatory approval from the FDA for nirogacestat in adults with desmoid tumors and launch nirogacestat as the first approved therapy for these patients in the second half of 2023.
- Highlight publication of Phase 3 DeFi trial data in a peer-reviewed journal and present additional analyses from the study at upcoming medical meetings.
- Present topline data from the pediatric and adult cohorts of the Phase 2b ReNeu trial in NF1-PN in the second half of 2023. Pending these data, SpringWorks anticipates submitting an NDA for mirdametinib as a treatment for NF1-PN in the first half of 2024.
- Continue enrollment in the Phase 2 trial of nirogacestat in patients with OvGCT.
- Expand data set with additional clinical data of nirogacestat in combination with BCMA-directed therapies and initiate additional planned Phase 1 collaborator studies.
- Present additional clinical data from the Phase 1 trial evaluating BGB-3245 in adult patients with RAF mutant solid tumors at a medical conference in the first half of 2023.
- Present additional data from BeiGene-sponsored Phase 1b/2 trial evaluating mirdametinib in combination with lifirafenib in adult patients with RAS/RAF mutant and other MAPK pathway aberrant solid tumors at a medical conference in the first half of 2023.
- Dose first patient in BGB-3245 + mirdametinib combination study in MAPK-mutant solid tumors in the first half of 2023.

- File Investigational New Drug Application for TEAD inhibitor SW-682.

"We expect 2023 to not only mark SpringWorks' transition into a commercial-stage company, but also to be a year of continued development execution and value-creating data readouts across our portfolio," 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 overwhelmingly positive Phase 3 DeFi data for nirogacestat in desmoid tumors that were disclosed last year and our expectations for a successful topline readout for the Phase 2b ReNeu trial in children and adults with NF1-PN. Our strong execution in 2022, coupled with a financial position that funds us well into 2026 and durable IP protections for our lead assets, positions us well for continued performance on behalf of patients with devastating diseases."

Presentation at the 41st Annual J.P. Morgan Healthcare Conference
SpringWorks will webcast its presentation from the 41st Annual J.P. Morgan Healthcare Conference today, Monday, January 9, 2023 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 clinical-stage biopharmaceutical company applying a precision medicine approach to acquiring, developing and commercializing life-changing medicines for patients with severe rare diseases and cancer. SpringWorks has a differentiated targeted oncology pipeline spanning solid tumors and hematological cancers, including two late-stage clinical trials in rare tumor types as well as several programs addressing highly prevalent, genetically defined cancers. SpringWorks' strategic approach and operational excellence in clinical development have enabled it to rapidly advance its two lead product candidates into late-stage clinical trials while simultaneously entering into multiple shared-value partnerships 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 Twitter and LinkedIn.

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 plans, our preclinical and clinical results, the potential for the results of the Phase 3 DeFi clinical trial to support an NDA submission for nirogacestat, the potential for nirogacestat to become an important new treatment for patients with desmoid tumors, our plans for seeking regulatory approval for and making nirogacestat available to desmoid tumor patients, if approved, 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, 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 and timing of our product development activities, including the initiation and completion of SpringWorks' clinical trials, (ii) our expectations regarding the potential clinical benefit to patients with desmoid tumors based upon the results of our DeFi trial, (iii) the fact that topline or interim data from a clinical study may not be predictive of the final or more detailed results of such study, or the results of other ongoing or future studies, (iv) the success and timing of our collaboration partners' ongoing and planned clinical trials, (v) 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) and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; (vi) whether FDA or other regulatory authorities will require additional information or further studies, or may fail or refuse to approve or may delay approval of our drug candidates, including nirogacestat and mirdametinib, (vii) our ability to obtain and maintain regulatory approval of any of our product candidates, (viii) our plans to research, discover and develop additional product candidates, (ix) our ability to enter into collaborations for the development of new product candidates, (x) our ability to establish manufacturing capabilities, and our and our collaboration partners' abilities to manufacture our product candidates and scale production, (xi) our ability to meet any specific milestones set forth herein, and (xii) uncertainties and assumptions regarding the impact of the COVID-19 pandemic on SpringWorks' business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines.

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' Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, as well as discussions of potential risks, uncertainties and other important factors in SpringWorks' subsequent filings.

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