SpringWorks Therapeutics Reports First Quarter 2023 Financial Results and Recent Business Highlights

May 3, 2023

– NDA for Nirogacestat in Adults with Desmoid Tumors Accepted by the FDA and Granted Priority Review; PDUFA Action Date Set for August 27, 2023 –

– Phase 3 DeFi Trial Evaluating Nirogacestat in Adults with Desmoid Tumors Published in the New England Journal of Medicine –

– Encouraging Clinical Data on MAPK Solid Tumor Programs Presented at the American Association for Cancer Research Annual Meeting 2023 –

STAMFORD, Conn., May 03, 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, today reported first quarter financial results for the period ended March 31, 2023 and provided an update on recent company developments.

"In the first quarter of 2023 we continued to deliver strong results across our diversified oncology pipeline. We were very pleased that our New Drug Application for nirogacestat in desmoid tumors was accepted with Priority Review by the FDA, and that our Phase 3 DeFi trial was published in the *New England Journal of Medicine.* Our team is energized by the opportunity to deliver the first FDA-approved therapy for this devastating disease and continues to work expeditiously to serve the desmoid tumor patient and physician communities following potential FDA approval later this year," said Saqib Islam, Chief Executive Officer of SpringWorks. "In parallel, we are advancing our Phase 2b ReNeu trial and believe that mirdametinib has the opportunity to address a substantial unmet need that remains for patients with NF1-associated plexiform neurofibromas. We are on track to report topline data from the trial later this year, with the goal of submitting an NDA in the first half of 2024. We look forward to sharing our continued progress throughout the year."

Recent Business Highlights and Upcoming Milestones

Rare Oncology

- In February 2023, the U.S. Food and Drug Administration (FDA) accepted SpringWorks' New Drug Application (NDA) for nirogacestat, an investigational oral, small molecule gamma secretase inhibitor, in development as a monotherapy for the treatment of adults with desmoid tumors. The application has been granted Priority Review and given a Prescription Drug User Fee Act (PDUFA) action date of August 27, 2023. SpringWorks also expects to file a Marketing Authorization Application for nirogacestat with the European Medicines Agency in 2024.
- Data from the Phase 3 DeFi trial of nirogacestat in adult patients with progressing desmoid tumors were published in the March 9, 2023 edition of the *New England Journal of Medicine*.
- SpringWorks expects to present topline data from the pediatric and adult cohorts of the Phase 2b ReNeu trial evaluating mirdametinib, an investigational MEK inhibitor, in NF1-PN in the second half of 2023. Pending these data, SpringWorks anticipates submitting an NDA to the FDA for mirdametinib as a treatment for NF1-PN in the first half of 2024.
- Patients continue to be enrolled in a Phase 2 trial evaluating nirogacestat in ovarian granulosa cell tumors.

B-cell Maturation Antigen (BCMA) Combinations in Multiple Myeloma

- SpringWorks continues to evaluate nirogacestat as part of several BCMA combination therapy regimens across treatment lines in collaboration with industry leaders. In 2023, SpringWorks expects that additional clinical data of nirogacestat in combination with BCMA-directed therapies will be presented and that additional planned Phase 1 collaborator studies will be initiated.

Biomarker-Defined Metastatic Solid Tumors

- 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 were presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2023. The combination showed antitumor activity in patients with various KRAS, NRAS, and BRAF mutations across several solid tumor types, including low-grade serous ovarian cancer (LGSOC), non-small cell lung cancer (NSCLC), and endometrial cancer. These data support the advancement of this combination into the dose-expansion portion of the study, which will focus on a biomarker selected patient population with a tumor agnostic approach. The expansion is expected to start in the second half of 2023.
- Updated clinical data from the Phase 1a/1b study of brimarafenib (BGB-3245), an investigational, selective RAF dimer inhibitor, in adult patients with advanced or refractory solid tumors harboring MAPK pathway aberrations were presented at AACR in April 2023. Objective responders included patients with tumors harboring BRAF V600E that had progressed on

prior BRAF/MEK inhibitors with or without checkpoint inhibitor treatment, BRAF Class II mutation, BRAF fusion, NRAS and KRAS mutations. These data supported the advancement of brimarafenib into the Phase 1b dose expansion portion of the study, which has been enrolling patients since October 2022 in defined cohorts.
- Patients continue to be enrolled in the SpringWorks-sponsored Phase 1/2a combination study of brimarafenib and mirdametinib.
- New preclinical data for SW-682, SpringWorks' TEAD inhibitor, were presented at AACR in April 2023. The data provide promising evidence of SW-682's anti-tumor activity, a favorable pharmacokinetics profile and good tolerability in mice, and further support SpringWorks' thesis that TEAD palmitoylation represents a rational point of intervention for Hippo-driven cancers. SpringWorks expects to file an Investigational New Drug Application for SW-682 in 2023.

General Corporate

- SpringWorks continues to expand and strengthen its intellectual property portfolio. In March 2023, the United States Patent and Trademark Office issued U.S. Patent No. 11,612,588, which is directed to the treatment of desmoid tumors with pharmaceutical compositions of nirogacestat and expires in 2042. SpringWorks now has eight Orange Book-listable patents for nirogacestat.

First Quarter 2023 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were $33.5 million for the first quarter of 2023, compared to $34.1 million for the comparable period of 2022. The decrease in R&D expense was primarily attributable to a decrease in external costs related to drug manufacturing, clinical trial and other research, as well as facility-related costs, offset by an increase in internal costs driven by the growth in employee costs associated with increases in the number of personnel, including an increase in stock-based compensation expense.
- **General and Administrative (G&A) Expenses:** G&A expenses were $44.2 million for the first quarter of 2023, compared to $27.4 million for the comparable period of 2022. The increase in G&A expense was largely attributable to commercial readiness activities to support the potential U.S. launch of nirogacestat for the treatment of adults with desmoid tumors. The increase in G&A included an increase in both internal costs and in consulting and professional services. The increase in internal costs was attributable to the growth in employee costs associated with increases in the number of personnel, including an increase in stock-based compensation expense, driven by the growth of our commercial organization, which included establishing certain sales, marketing, and commercialization functions. The increase in consulting and professional services was also primarily attributable to commercial readiness activities as we expand the capabilities of the organization.
- **Net Loss Attributable to Common Stockholders:** SpringWorks reported a net loss of $73.4 million, or $1.18 per share, for the first quarter of 2023. This compares to a net loss of $61.8 million, or $1.26 per share, for the comparable period of 2022.
- **Cash Position:** Cash, cash equivalents and marketable securities were $528.1 million as of March 31, 2023.

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 living 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 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 the Company's 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.

Forward-Looking Statements

This presentation 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 nirogacestat to become an important new treatment for adult patients with desmoid tumors, the potential for Marketing Authorization Application for nirogacestat, expectations regarding the timing and results of the FDA's review of the NDA for nirogacestat, including the FDA's PDUFA target action date for the NDA, and the adequacy of the data contained in the NDA to serve as the basis for an approval of nirogacestat for the treatment of adults with desmoid tumors, 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 about the timing of the commencement of the dose-expansion phase of the Phase 1b/2 trial evaluating mirdametinib with lifirafenib, our plans to file an Investigational New Drug Application for SW-682 in 2023, our plans to report additional clinical data of nirogacestat in combination with BCMA-directed therapies and initiate additional planned Phase 1 collaborator studies, our plans to begin dosing a Phase 1/2a combination study of brimarafenib and mirdametinib, 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 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) the fact that topline data or interim data from our 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, (iii) the success and timing of our collaboration partners' ongoing and planned clinical trials, (iv) the timing of our planned regulatory submissions and interactions and the timing and outcome of decisions made by the FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; (v) 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, (vi) our ability to obtain and maintain regulatory approval of any of our product candidates, (vii) our plans to research, discover and develop additional product candidates, (viii) our ability to enter into collaborations for the development of new product candidates and our ability to realize the benefits expected from such collaborations, (ix) our ability to maintain adequate patent protection and successfully enforce patent claims against third parties, (x) the adequacy of our cash position to fund our operations through any time period indicated herein, (xi) our ability to establish manufacturing capabilities, and our and our collaboration partners' abilities to manufacture our product candidates and scale production, (xii) our ability to meet any specific milestones set forth herein, and (xiii) 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 II of SpringWorks' Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, as well as discussions of potential risks, uncertainties and other important factors in SpringWorks' subsequent filings.

SpringWorks Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three Months Ended March 31,	
(in thousands, except share and per-share data)	**2023**	**2022**
Operating expenses:		
Research and development	$ 33,524	$ 34,103
General and administrative	44,175	27,366
Total operating expenses	77,699	61,469
Loss from operations	(77,699)	(61,469)
Interest and other income (expense):		
Other expense	(199)	(193)
Interest income, net	5,756	198
Total interest and other income	5,557	5
Equity investment loss	(1,278)	(337)
Net loss	$ (73,420)	$ (61,801)
Net loss per share, basic and diluted	$ (1.18)	$ (1.26)
Weighted average common shares outstanding, basic and diluted	62,326,992	48,937,756

SpringWorks Therapeutics, Inc.
Selected Balance Sheet Data
(Unaudited)

	March 31, 2023	December 31, 2022
(in thousands)		
Cash, cash equivalents and marketable securities	$ 528,141	$ 597,006
Working Capital (1)	499,904	548,711
Total assets	569,197	630,242
Total liabilities	62,273	72,050
Accumulated deficit	(643,350)	(569,930)
Total stockholders' equity	506,924	558,192

(1) We define working capital as current assets less current liabilities.

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