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

August 2, 2023

– Presented additional Phase 3 DeFi data at ASCO demonstrating clinically significant reductions in pain and substantial reductions in tumor volume and T2 hyperintensity with nirogacestat treatment –

– Completed enrollment of Phase 2 trial evaluating nirogacestat in patients with ovarian granulosa cell tumors –

– Highlighted encouraging Phase 1 and 2 clinical data from emerging pipeline programs at AACR and EHA –

STAMFORD, Conn., Aug. 02, 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 second quarter financial results for the period ended June 30, 2023 and provided an update on recent company developments.

“Our team continues to work with urgency and is ready to serve patients with desmoid tumors following the anticipated FDA approval of nirogacestat later this year,” said Saqib Islam, Chief Executive Officer of SpringWorks. “We also believe that mirdametinib has the potential to be a best-in-class therapy for patients with NF1-PN and look forward to reporting topline data from our ReNeu trial in the fourth quarter while simultaneously advancing our portfolio of opportunities across our rare oncology, BCMA combinations in multiple myeloma, and biomarker-defined metastatic solid tumors programs."

Recent Business Highlights and Upcoming Milestones

Rare Oncology

- In June 2023, SpringWorks announced that the U.S. Food and Drug Administration (FDA) has updated the Prescription Drug User Fee Act (PDUFA) action date for the New Drug Application (NDA) for nirogacestat for the treatment of adults with desmoid tumors to allow more time to review additional analyses of previously submitted data that had been provided by SpringWorks in response to the FDA’s information requests. No additional data or studies have been requested by the FDA at this time. The new PDUFA action date is November 27, 2023.
- In June 2023, additional data from the Phase 3 DeFi trial assessing the impact of nirogacestat on pain, tumor volume, and T2 hypersensitivity in adults with desmoid tumors were presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting. Statistically significant and clinically meaningful reductions in pain were observed with nirogacestat compared with placebo at Cycle 10 across three prespecified pain assessment tools evaluated in DeFi. Reductions in pain were rapid, becoming evident as early as Cycle 2 (the first post-treatment timepoint evaluated), and these reductions were sustained through to the end of the double-blind phase of the trial. In addition, researchers presented data from the DeFi trial demonstrating that treatment with nirogacestat led to significantly improved median best change from baseline in MRI-assessed tumor volume of the largest target tumor compared with placebo. In addition, significant improvement in the median best percent change in T2 hyperintensity signal ratio of the largest target tumor compared with placebo was also observed with nirogacestat treatment.
- In May 2023, SpringWorks announced full enrollment of the Phase 2 trial evaluating nirogacestat as a monotherapy in patients with recurrent ovarian granulosa cell tumors. SpringWorks expects to report initial data from the trial in 2024.
- 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-associated plexiform neurofibromas (NF1-PN) in the fourth quarter of 2023. If these data are positive, SpringWorks plans to submit an NDA to the FDA for mirdametinib for the treatment of NF1-PN in the first half of 2024.

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 June 2023, updated clinical data from the Phase 1/2 study sponsored by GSK plc evaluating nirogacestat in combination with low-dose belamaf (belantamab mafodotin-blmf, GSK's antibody-drug conjugate) in patients with relapsed or refractory multiple myeloma (RRMM) were presented at the European Hematology Association (EHA) 2023 Congress. These clinical data continue to support that combining nirogacestat with a low dose of belamaf may result in comparable efficacy to a higher monotherapy belamaf dose while simultaneously substantially reducing the frequency of high-grade ocular adverse events.
- In June 2023, new data from the Phase 1b clinical trial sponsored by Janssen Research & Development, LLC (Janssen)

evaluating nirogacestat in combination with teclistamab, Janssen's bispecific antibody targeting BCMA and CD3, were presented at EHA, representing the first clinical data set of nirogacestat in combination with a BCMA bispecific agent. The results demonstrated that high and deep response rates were observed with the nirogacestat plus teclistamab combination across all dose levels assessed and the safety profile was optimized with delayed administration of lower-dose nirogacestat.

Biomarker-Defined Metastatic Solid Tumors

- In April 2023, 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 2023. 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 will evaluate the combination in patients with *NRAS*-mutated solid tumors. The expansion is expected to start in the second half of 2023.
- In April 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. 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.
- In April 2023, SpringWorks presented new preclinical data for SW-682, the Company's TEAD inhibitor development candidate, at AACR. 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 the fourth quarter of 2023.

Second Quarter 2023 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were $35.9 million for the second quarter, compared to $38.0 million for the comparable period of 2022. The decrease in R&D expenses was primarily attributable to a decrease in external costs related to drug manufacturing, clinical trials and other research, partially 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 $47.0 million for the second quarter, compared to $31.0 million for the comparable period of 2022. The increase in G&A expenses was largely attributable to commercial readiness activities to support the U.S. launch of nirogacestat, if approved, for the treatment of adults with desmoid tumors. 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 net loss of $77.9 million, or $1.25 per share, for the second quarter of 2023. This compares to a net loss of $69.1 million, or $1.41 per share, for the comparable period of 2022.
- **Cash Position:** Cash, cash equivalents and marketable securities were $476.7 million as of June 30, 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 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.

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, expectations regarding the timing of 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, 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 the fourth quarter of 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 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 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, and (xii) 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 June 30, 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 June 30,		Six Months Ended June 30,	
(in thousands, except share and per-share data)	**2023**	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 35,858	$ 38,024	$ 69,382	$ 72,127
General and administrative	46,994	30,987	91,169	58,353
Total operating expenses	82,852	69,011	160,551	130,480
Loss from operations	(82,852)	(69,011)	(160,551)	(130,480)
Interest and other income (expense):				
Other expense, net	(98)	(24)	(297)	(217)
Interest income, net	5,926	372	11,682	570
Total interest and other income	5,828	348	11,385	353
Equity investment loss	(901)	(387)	(2,179)	(724)
Net loss	$ (77,925)	$ (69,050)	$ (151,345)	$ (130,851)
Net loss per share, basic and diluted	$ (1.25)	$ (1.41)	$ (2.43)	$ (2.67)
Weighted average common shares outstanding, basic and diluted	62,464,081	49,071,590	62,360,651	48,989,690

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

(in thousands)	June 30, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 476,707	$ 597,006
Working Capital (1)	441,991	548,711
Total assets	517,329	630,242
Total liabilities	65,888	72,050
Accumulated deficit	(721,275)	(569,930)
Total stockholders' equity	451,441	558,192

(1) We define Working Capital as current assets less current liabilities.

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