SpringWorks Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Highlights Recent Business Updates

February 27, 2024

– Reported OGSIVEO™ (nirogacestat) net product revenue of $5.4 million in first partial quarter of launch following FDA approval on November 27, 2023 –

– Submitted Marketing Authorization Application to the European Medicines Agency for nirogacestat for the treatment of desmoid tumors –

– Presented positive topline data from Phase 2b ReNeu trial of mirdametinib in patients with NF1-PN; on track to submit New Drug Application in first half of 2024 –

– Submitted IND for SW-682 and received FDA clearance to proceed with Phase 1a trial –

– Ended 2023 with $662.6 Million in Cash, Cash Equivalents and Marketable Securities –

STAMFORD, Conn., Feb. 27, 2024 (GLOBE NEWSWIRE) -- SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a commercial-stage biopharmaceutical company focused on severe rare diseases and cancer, today reported financial results for the fourth quarter and full year periods ended December 31, 2023 and provided an update on recent company developments.

“In 2023, OGSIVEO became the first FDA-approved therapy for adults with desmoid tumors with our approval in November and we are very pleased with the initial progress of our launch. We are also very excited by our opportunity in NF1-PN based on the positive topline data from our pivotal Phase 2b ReNeu trial, which demonstrated mirdametinib's best-in-class potential for both children and adults with these devastating tumors. In addition, we made strong progress across our broader pipeline and continued to strengthen our financial position and our intellectual property protection for our lead assets,” said Saqib Islam, Chief Executive Officer of SpringWorks. “Our focus for 2024 is to continue delivering a successful U.S. launch for OGSIVEO in desmoid tumors, to file our NDA for mirdametinib with the goal of having our second approval by 2025, to make progress towards expanding the reach of OGSIVEO into additional geographies outside of the U.S., and to unlock additional opportunities across our emerging portfolio.”

Recent Business Highlights and Upcoming Milestones

OGSIVEO™ (Nirogacestat)

- Received U.S. Food and Drug Administration (FDA) approval for OGSIVEO, an oral gamma secretase inhibitor, for the treatment of adult patients with progressing desmoid tumors who require systemic treatment on November 27, 2023.
- Launched OGSIVEO in the U.S. and achieved net product revenue of $5.4 million in the first partial quarter of the launch. To date, OGSIVEO has been reimbursed by payers representing over 98% of commercial lives, as well as by Medicare and Medicaid, with coverage aligned to the FDA-approved label.
- Highlighted the update of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) in December 2023 which recommend nirogacestat as an NCCN Category 1, Preferred treatment option for desmoid tumors.
- Submitted a Marketing Authorization Application (MAA) for nirogacestat for the treatment of adult patients with desmoid tumors to the European Medicines Agency (EMA) in February 2024.
- Presented additional patient-reported outcome data from the Phase 3 DeFi trial at the 2023 Connective Tissue Oncology Society Annual Meeting.
- On track to report initial data from the Phase 2 trial evaluating nirogacestat as a monotherapy in patients with recurrent ovarian granulosa cell tumors in the second half of 2024.
- Continuing 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

- Presented positive 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 November 2023. The confirmed objective response rate was 52% in pediatric patients and 41% in adult patients, as assessed by Blinded Independent Central Review, which was the primary endpoint of the study. Mirdametinib treatment also showed deep and durable responses and demonstrated significant improvements in key secondary patient-reported outcome measures. Mirdametinib was generally well tolerated in the trial, with the majority of adverse events (AEs) being Grade 1 or Grade 2. The most frequently reported AEs were rash, diarrhea, and vomiting in the pediatric cohort and rash, diarrhea, and nausea in the adult cohort.
- On track to submit an 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.
- Expect to present data from the pediatric and adult cohorts of the ReNeu trial at a medical congress in the first half of 2024 and to submit the trial results for publication in a peer-reviewed journal in 2024.

Emerging Pipeline

- On track to present additional data from the dose expansion portion of the Phase 1b trial evaluating brimarafenib (BGB-3245) in adult patients with RAF mutant solid tumors in the second half of 2024. Brimarafenib is an investigational, selective RAF dimer inhibitor being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene, Ltd.
- Patients continue to be enrolled in the dose escalation phase of the SpringWorks-sponsored Phase 1/2a combination study of brimarafenib and mirdametinib.
- The FDA cleared the Investigational New Drug (IND) application submitted by 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. MapKure expects to initiate a Phase 1b trial in the first quarter of 2024.
- Dose expansion cohort is ongoing in the BeiGene-sponsored Phase 1b/2 trial evaluating mirdametinib in combination with BeiGene's RAF dimer inhibitor, lifirafenib, in adult patients with NRAS mutant solid tumors.
- The FDA cleared the IND application for SW-682, a novel, oral, potent, and selective TEA Domain inhibitor designed to treat tumors driven by Hippo pathway mutations. SpringWorks plans to initiate a Phase 1a trial of SW-682 in Hippo mutant solid tumors in the first half of 2024.

General Corporate

- Strengthened balance sheet with upsized public offering in December 2023; gross proceeds from the offering, before deducting underwriting discounts and commissions and offering expenses, were approximately $316.2 million.
- The United States Patent and Trademark Office has recently issued four new patents for OGSIVEO and one new patent for mirdametinib, extending protection for both products into 2043. The U.S. patent portfolio for OGSIVEO includes 16 Orange Book listed patents; the U.S. patent portfolio for mirdametinib includes 10 patents that are expected to be Orange Book listed.

Fourth Quarter and Full Year 2023 Financial Results

- **Revenues:** OGSIVEO net product revenues were $5.4 million in the fourth quarter of 2023, the first partial quarter of the U.S. launch.
- **Research and Development (R&D) Expenses:** R&D expenses were $43.7 million and $150.5 million for the fourth quarter and full year 2023, respectively, compared to $37.9 million and $146.1 million for the comparable periods of 2022. The increase in R&D expense for the fourth quarter and year ended 2023 was primarily attributable to an increase in employee costs associated with head count growth, partially offset by a decrease in costs related to drug manufacturing, clinical trials and other research.
- **Selling, General and Administrative (SG&A) Expenses:** SG&A expenses were $59.8 million and $197.6 million for the fourth quarter and full year 2023, respectively, compared to $40.5 million and $134.6 million for the comparable periods of 2022. The increase in SG&A expense for the fourth quarter and the full year 2023 were largely attributable to commercial readiness activities to support the U.S. launch of OGSIVEO.
- **Net Loss Attributable to Common Stockholders:** SpringWorks reported a net loss of $94.3 million, or $1.44 per share, for the fourth quarter of 2023 and a net loss of $325.1 million, or $5.15 loss per share, for the year ended December 31, 2023. This compares to a net loss of $74.2 million, or $1.19 per share, for the fourth quarter of 2022 and a net loss of $277.4 million, or $5.21 per share for the year ended December 31, 2022.
- **Cash Position:** Cash, cash equivalents and marketable securities were $662.6 million as of December 31, 2023.

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.

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, expectations regarding timing and results of the EMA's review of the MAA for nirogacestat, including its ongoing validation of our submission package, and the adequacy of the data contained in the MAA to serve as the basis for marketing approval of nirogacestat for the treatment of desmoid tumors in the European Union, the potential for the results of the Phase 2b ReNeu clinical trial to support an NDA submission for mirdametinib in first half of 2024, our plans to report additional data from the Phase 2b ReNeu clinical trial at an upcoming medical conference and submit for publication data from such clinical trial in a peer-reviewed medical journal in 2024, 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, our plans to initiate a Phase 1a trial of SW-682 in Hippo mutant solid tumors 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, our plans to present additional data for brimarafenib monotherapy in MAPK-mutant solid tumors in second half of 2024, our plans to support MapKure's initiation of a Phase 1b trial of brimarafenib with panitumumab in CRC and pancreatic cancer patients in first quarter of 2024, 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 our clinical trials, (v) our expectations regarding the potential clinical benefit of OGSIVEO for adult patients with desmoid tumors who require systemic treatment, (vi) the potential for OGSIVEO to become the new standard of care for adult 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) 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, (ix) the success and timing of our collaboration partners' ongoing and planned clinical trials, (x) 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, (xi) 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, (xii) our ability to obtain regulatory approval of any of our product candidates or maintain regulatory approvals granted for our products, (xiii) our plans to research, discover and develop additional product candidates, (xiv) our ability to enter into collaborations for the development of new product candidates and our ability to realize the benefits expected from such collaborations, (xv) our ability to maintain adequate patent protection and successfully enforce patent claims against third parties, (xvi) the adequacy of our cash position to fund our operations through any time period indicated herein, (xvii) our ability to establish manufacturing capabilities, and our and our collaboration partners' abilities to manufacture our product candidates and scale production, and (xviii) 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 I of SpringWorks' Annual Report on Form 10-K for the year ended December 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)

	Year Ended December 31,		
(in thousands, except share and per-share data)	**2023**	**2022**	**2021**
Revenue:			
Product revenue, net	$ 5,447	$ —	$ —
Total revenue	5,447	—	—
Operating expenses:			
Cost of product revenue	422	—	—
Research and development	150,487	146,122	101,676
Selling, general and administrative	197,551	134,552	71,792
Total operating expenses	348,460	280,674	173,468
Loss from operations	(343,013)	(280,674)	(173,468)
Interest and other income:			
Interest and other income, net	22,947	6,147	546
Total interest and other income	22,947	6,147	546
Equity method investment loss	(5,038)	(2,890)	(988)
Net loss	$ (325,104)	$ (277,417)	$ (173,910)

Net loss per share, basic and diluted	$ (5.15)	$ (5.21)	$ (3.59)
Weighted average common shares outstanding, basic and diluted	63,123,936	53,290,528	48,497,790

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

	As of December 31,	
	2023	**2022**
(in thousands)		
Cash, cash equivalents and marketable securities	$ 662,588	$ 597,006
Working Capital (1)	422,742	548,711
Total assets	725,788	630,242
Total liabilities	99,569	72,050
Accumulated deficit	(895,034)	(569,930)
Total stockholders' equity	626,219	558,192

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

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