SpringWorks Therapeutics Reports First Quarter 2021 Financial Results and Recent Business Highlights

May 6, 2021

– Reported Interim Data from Phase 2b ReNeu Trial of Mirdametinib in NF1-PN Demonstrating Encouraging Clinical Activity and Tolerability in the First 20 Adult Patients Enrolled –

– Announced Achievement of First Patient Dosed in Allogene and Janssen Phase 1 Trials Evaluating Nirogacestat in Combination with BCMA Therapies –

– Expanded Targeted Oncology Pipeline with Exclusive Worldwide License to TEAD Inhibitor Portfolio –

STAMFORD, Conn., May 06, 2021 (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, 2021 and provided an update on recent company developments.

"In the first quarter of 2021 we continued to execute on our 10 clinical programs and grew our portfolio of opportunities aimed at serving a broad group of patients across our three distinct oncology segments: late-stage rare oncology, hematological cancers and biomarker-defined metastatic solid tumors," said Saqib Islam, Chief Executive Officer of SpringWorks. "We are poised for multiple important data readouts this year, including topline data from our Phase 3 DeFi trial, initial clinical data from our BCMA combination trial of nirogacestat with GSK's BLENREP in multiple myeloma and initial clinical data from our metastatic solid tumor trials being conducted in collaboration with BeiGene. I look forward to reporting on our continued progress throughout 2021."

Recent Business Highlights and Upcoming Milestones

Late-Stage Rare Oncology

- In February 2021, SpringWorks reported interim data from the adult stratum of the ongoing potentially registrational Phase 2b ReNeu trial evaluating mirdametinib in pediatric and adult patients with NF1-associated plexiform neurofibromas. Of the first 20 adult patients enrolled, 50% had achieved an objective response, the primary endpoint of the study, as assessed by blinded independent central review, and 16 of these 20 patients (80%) remained on study as of the January 22, 2021 data cutoff. In addition, mirdametinib was generally well tolerated, with the majority of treatment-related adverse events (TRAE) being Grade 1 or 2 and only one Grade 3 TRAE reported; there have been no Grade 4 or 5 TRAEs reported. The Company expects to report additional clinical data from the ReNeu trial at a medical conference this year and to complete enrollment of the trial in the second half of 2021.
- SpringWorks expects to report topline data from the Phase 3 DeFi trial in the second half of 2021, as previously disclosed.
- Recruitment is ongoing in a Phase 2 study sponsored by the Children's Oncology Group evaluating nirogacestat in pediatric patients with desmoid tumors.

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

- Enrollment is ongoing in three Phase 1 studies evaluating nirogacestat in combination with anti-B-cell maturation antigen (BCMA) therapies in adult patients with relapsed or refractory multiple myeloma: a Phase 1b trial sponsored by GSK evaluating nirogacestat in combination with BLENREP (belantamab mafodotin-blmf), a Phase 1 study sponsored by Allogene evaluating nirogacestat in combination with ALLO-715, and a Phase 1 study sponsored by Janssen Research & Development, LLC (Janssen) evaluating nirogacestat in combination with teclistamab. Initial data from the GSK-sponsored study are expected in 2021. SpringWorks also expects that two additional collaborator-sponsored trials will initiate in the first half of 2021, as previously disclosed: nirogacestat + Pfizer's elranatamab and nirogacestat + Precision Biosciences' PBCAR269A.
- In March 2021, SpringWorks entered into a services agreement with ONCOtracker, Inc., a leading innovation center for novel cancer treatment and testing with a focus on the diagnosis and treatment of multiple myeloma, other B-cell malignancies, and related disorders, to explore the effect of nirogacestat on soluble BCMA release and membrane-bound BCMA receptor density in primary bone marrow samples collected from multiple myeloma patients. This research is intended to further confirm nirogacestat's ability to potentiate BCMA by using *ex vivo* patient-derived models with associated longitudinal clinical characterization for each sample.

Biomarker-Defined Metastatic Solid Tumors

- In May 2021, SpringWorks entered into an exclusive worldwide license agreement with Katholieke Universiteit Leuven (KU

Leuven) and the Flanders Institute for Biotechnology (VIB) for the in-license of a portfolio of novel small molecule inhibitors of the TEA Domain (TEAD) family of transcription factors, designed for the potential treatment of biomarker-defined solid tumors driven by aberrant Hippo pathway signaling. The licensed portfolio includes advanced lead compounds and multiple backup compounds from diverse chemical series, which were discovered at KU Leuven's Center for Drug Design and Discovery (CD3) in collaboration with Professor Georg Halder of the VIB-KU Leuven Center for Cancer Biology. SpringWorks expects to nominate a development candidate from this portfolio and move into IND-enabling studies in 2022.
- Enrollment is ongoing in a Phase 1b/2 trial evaluating mirdametinib with BeiGene's RAF dimer inhibitor, lifirafenib, in adult patients with *RAS/RAF* mutant and other MAPK pathway aberrant solid tumors. BeiGene is sponsoring this trial and SpringWorks and BeiGene expect to report initial clinical data in 2021, as previously disclosed.
- Enrollment is ongoing in a Phase 1 trial of BGB-3245 in adult patients with RAF mutant solid tumors. BGB-3245 is a selective RAF dimer inhibitor being developed by MapKure, LLC, a joint venture between SpringWorks and BeiGene. Initial clinical data from the MapKure-sponsored Phase 1 trial are expected in 2021, as previously disclosed.
- In March 2021, SpringWorks entered into a research collaboration agreement with Inserm Transfert, the private subsidiary of Inserm, acting as a delegatee of the French National Institute of Health and Medical Research (Inserm) to explore the ability of nirogacestat to delay the development of resistance to the EGFR inhibitor osimertinib in preclinical models of non-small cell lung cancer (NSCLC) driven by the *EGFR* C797S gatekeeper mutation. This research, which will be led by Antonio Maraver, Ph.D. at Montpellier Cancer Research Institute (IRCM U1194), is intended to build on previous in vivo work from Dr. Maraver's lab demonstrating the potential for gamma secretase inhibition to enhance the activity of osimertinib in EGFR-driven models of NSCLC.[1]

General Corporate

- In March 2021, Bhavesh Ashar was appointed Chief Commercial Officer of SpringWorks. Mr. Ashar has more than 20 years of global pharmaceutical and biotechnology experience, most recently having served as Senior Vice President, General Manager of U.S. Oncology at Bayer Healthcare where he was responsible for a broad portfolio in prostate, liver, colorectal, GIST, hematologic and tumor-agnostic biomarker driven cancers.

First Quarter 2021 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were $17.4 million for the first quarter, compared to $9.7 million for the comparable period of 2020. The increases in R&D expenses were primarily attributable to an increase in external costs related to drug manufacturing and trial costs, and an increase in internal costs driven by the growth in employee costs associated with increases in the number of R&D personnel and an increase in stock-based compensation expense.
- **General and Administrative (G&A) Expenses**: G&A expenses were $12.4 million for the first quarter, compared to $6.4 million for the comparable period of 2020. The increases in G&A expenses were primarily attributable to the hiring of additional personnel in G&A functions supporting the growth of the organization, as well as an increase in stock-based compensation expense.
- **Net Loss Attributable to Common Stockholders:** SpringWorks reported net loss of $29.8 million, or $0.62 per share, for the first quarter of 2021. This compares to a net loss of $15.3 million, or $0.37 per share, for the comparable period of 2020.
- **Cash Position:** Cash, cash equivalents and marketable securities were $541.0 million as of March 31, 2021.

COVID-19 Update

To date, the COVID-19 pandemic has had a relatively modest impact on SpringWorks' business operations, in particular on SpringWorks' clinical trial programs, and SpringWorks is undertaking considerable efforts to mitigate the various challenges presented by this crisis. For further details and descriptions of the risks associated with the COVID-19 pandemic, please see the Risk Factors in SpringWorks' periodic filings with the Securities and Exchange Commission and refer to the Forward-Looking Statements section in this press release.

About SpringWorks Therapeutics

SpringWorks is a clinical-stage biopharmaceutical company applying a precision medicine approach to acquiring, developing and commercializing life-changing medicines for underserved patient populations suffering from devastating rare diseases and cancer. SpringWorks has a differentiated portfolio of small molecule targeted oncology product candidates and is advancing two potentially registrational clinical trials in rare tumor types, as well as several other 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 industry leaders to expand its portfolio. 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 press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding SpringWorks' clinical trials and its strategy, business plans and focus. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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, those related to SpringWorks' financial results, the timing for initiation, progress and completion of SpringWorks' clinical trials or third-party clinical trials of its product candidates, the timing for expected data readouts from partners and partners' clinical trials, the fact that interim results from a clinical study may not be predictive of the final results of such study or the results of other ongoing or future studies, whether and when, if at all, SpringWorks' product candidates will receive approval from the U.S. Food and Drug Administration, or FDA, or other foreign regulatory authorities, uncertainties and assumptions regarding the impact of the COVID-19 pandemic on SpringWorks' business, operations, clinical trials involving its product candidates, supply chain, strategy, goals and anticipated timelines, competition from other biopharmaceutical companies, and other risks identified in SpringWorks' SEC filings. SpringWorks cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. SpringWorks disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent SpringWorks' views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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

	Three Months Ended March 31,	
(in thousands, except share and per-share data)	**2021**	**2020**
Operating expenses:		
Research and development	$ 17,375	$ 9,727
General and administrative	12,381	6,403
Total operating expenses	29,756	16,130
Loss from operations	(29,756)	(16,130)
Interest and other income:		
Other income	3	—
Interest income, net	227	936
Total interest and other income	230	936
Equity investment loss	(261)	(100)
Net loss	$ (29,787)	$ (15,294)
Net loss per share, basic and diluted	$ (0.62)	$ (0.37)
Weighted average common shares outstanding, basic and diluted	48,229,539	41,789,120

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

	March 31, 2021	December 31, 2020
(in thousands)		
Cash, cash equivalents and marketable securities	$ 541,042	$ 561,820
Working Capital (1)	462,785	495,788
Total assets	554,588	576,191
Total liabilities	19,891	19,133
Accumulated deficit	(148,390)	(118,603)
Total stockholders' equity	534,697	557,058

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

Contact:
Kim Diamond
Vice President, Communications and Investor Relations
Phone: 203-561-1646
Email: kdiamond@springworkstx.com

References

[1] Bousquet E, Quantin X, Pujol J, et al. Notch Inhibition Overcomes Resistance to Tyrosine Kinase Inhibitors Promoted by Gate-Keeper Mutations in EGFR-Driven Lung Adenocarcinoma. J Clin Invest. 2020;130(2):612-624. //doi.org/10.1172/JCI126896.