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

August 4, 2021

– Entered into Clinical Collaboration with Seagen to Evaluate Nirogacestat in Combination with SEA-BCMA and Dosed First Patients in Three Phase 1 Clinical Trials Evaluating Nirogacestat in Combination with BCMA Therapies Across Modalities in Patients with Relapsed or Refractory Multiple Myeloma –

– Announced Issuance of New U.S. Composition of Matter Patent to Polymorphic Form of Mirdametinib, Extending Patent Protection into 2041 –

– Announced Several New Clinical Trials for Mirdametinib, Including a Phase 1/2 Trial in Children and Young Adults with Low-Grade Glioma and a Phase 1b/2a Trial in Patients with Advanced Solid Cancers Harboring Selected MAPK-Activating Mutations –

– Expanded Targeted Oncology Pipeline with Exclusive Worldwide License to TEA Domain (TEAD) Inhibitor Portfolio –

– Strengthened Leadership Team with Appointments of Dr. Mike Burgess as Head of Research and Development and Dr. Jim Cassidy as Chief Medical Officer –

STAMFORD, Conn., Aug. 04, 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 financial results for the second quarter and year-to-date periods ended June 30, 2021 and provided an update on recent company developments.

“We are very pleased with our execution in the second quarter of 2021, which included continuing to advance our strategy to evaluate nirogacestat as a BCMA potentiator across modalities, building upon our intellectual property portfolio by extending the patent protection for mirdametinib into 2041, and expanding our targeted oncology pipeline through collaborations with leading cancer centers as well as the in-license of a TEAD inhibitor portfolio,” said Saqib Islam, Chief Executive Officer of SpringWorks. “In the second half of the year we expect important data readouts across our late-stage rare oncology, BCMA combinations in multiple myeloma and metastatic solid tumor programs, including topline data from our Phase 3 DeFi study. In parallel, we will continue to advance our 15 development programs on behalf of oncology patients."

Recent Business Highlights and Upcoming Milestones

Late-Stage Rare Oncology

- SpringWorks expects to report topline data from the Phase 3 DeFi trial evaluating nirogacestat in adult patients with progressing desmoid tumors 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.
- Updated 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 were presented at the 2021 Children’s Tumor Foundation NF Conference in June 2021. These updated data were based on a cut-off date of March 23, 2021 and showed durable efficacy in the same 20 patients reported in February 2021, with the median time on treatment now having reached 13 cycles (approximately 12 months); the objective response rate remained at 50%, and 80% of these patients remained on study at the data cutoff. In addition, mirdametinib remained generally well tolerated; the majority of treatment-related adverse events (TRAE) in these patients were Grade 1 or 2, with only one Grade 3 TRAE observed and no Grade 4 or 5 adverse events (AE) reported in these 20 patients as of the data cutoff. The Company expects to complete enrollment of the trial in the second half of 2021.
- In June 2021, SpringWorks entered into a collaboration to conduct a Phase 1/2 clinical trial evaluating mirdametinib in children and young adults with low-grade glioma. Patients are being dosed in this study, which is sponsored by St. Jude Children’s Research Hospital.

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

- In June 2021, SpringWorks entered into a clinical trial collaboration agreement with Seagen Inc. to evaluate nirogacestat in combination with SEA-BCMA, Seagen’s investigational monoclonal antibody targeting B-cell maturation antigen (BCMA) in patients with relapsed or refractory multiple myeloma.
- Enrollment is ongoing in four clinical trials evaluating nirogacestat in combination with 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, a Phase 1 study sponsored by Janssen evaluating nirogacestat in combination with teclistamab, and a Phase 1/2a study sponsored by Precision BioSciences evaluating nirogacestat in combination with PBCAR269A. Initial data from the GSK-sponsored study are expected in 2021. SpringWorks also expects that two additional collaborator-sponsored trials will initiate enrollment in the second half of 2021, as previously disclosed:

nirogacestat + Pfizer's elranatamab and nirogacestat + Seagen's SEA-BCMA.

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 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 commence 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. Initial clinical data from the BeiGene-sponsored trial are expected 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 trial are expected in 2021, as previously disclosed.
- In August 2021, SpringWorks announced a platform study sponsored by Memorial Sloan Kettering Cancer Center to evaluate mirdametinib both as a monotherapy and as a combination therapy in advanced solid tumors harboring selected MAPK-activating mutations. This trial is planned to initially explore mirdametinib in two patient cohorts: the first in combination with fulvestrant, a selective estrogen receptor degrader, in patients with estrogen receptor-positive metastatic breast cancer with MAPK alterations (particularly inactivating mutations in *NF1*) and the second as a monotherapy in advanced solid tumors harboring oncogenic *MEK1* or *MEK2* mutations.
- In May 2021, SpringWorks entered into a research collaboration with the University of Zurich to further explore the activity of mirdametinib and lifirafenib combination therapy in preclinical patient-derived NRAS-mutant solid tumors models. The research, which is being led by Reinhard Dummer, M.D., builds upon previous translational work presented by SpringWorks and BeiGene and is intended to support ongoing and future patient selection strategies and to further define the competitive differentiation of the MAPK pathway vertical inhibition strategy supported by the combination of mirdametinib and lifirafenib.

General Corporate

- In July 2021, the United States Patent and Trademark Office issued a new composition of matter patent that covers the polymorphic form of mirdametinib that is currently in clinical development. This patent expires in 2041.
- SpringWorks appointed Mike Burgess, M.B.Ch.B., Ph.D. as Head of Research and Development and Jim Cassidy, M.D., Ph.D. as Chief Medical Officer. Drs. Burgess and Cassidy each bring decades of experience in oncology drug discovery and development as physician-scientists and R&D leaders at leading biotech and pharmaceutical companies.

Second Quarter 2021 Financial Results

- **Research and Development (R&D) Expenses:** R&D expenses were $32.1 million for the second quarter, compared to $12.9 million for the comparable period of 2020. The increases in R&D expenses were primarily attributable to a nonrefundable upfront payment to KU Leuven and VIB for the in-licensing of the TEAD inhibitor program, 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 $14.9 million for the second quarter, compared to $6.9 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 $47.0 million, or $0.97 per share, for the second quarter of 2021. This compares to a net loss of $19.9 million, or $0.47 per share, for the comparable period of 2020.
- **Cash Position:** Cash, cash equivalents and marketable securities were $507.5 million as of June 30, 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 patients living with severe rare diseases and cancer. SpringWorks has a differentiated targeted oncology portfolio of small molecule product candidates and is advancing 15 development programs, including two potentially registrational 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 expand 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 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 expected benefits of collaborations, 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 June 30,		Six Months Ended June 30,	
(in thousands, except share and per-share data)	**2021**	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 32,091	$ 12,947	$ 49,466	$ 22,674
General and administrative	14,930	6,874	27,311	13,277
Total operating expenses	47,021	19,821	76,777	35,951
Loss from operations	(47,021)	(19,821)	(76,777)	(35,951)
Interest and other income:				
Other income	(41)	—	(38)	—
Interest income, net	211	157	438	1,093
Total interest and other income	170	157	400	1,093
Equity investment loss	(159)	(229)	(420)	(329)
Net loss	$ (47,010)	$ (19,893)	$ (76,797)	$ (35,187)
Net loss per share, basic and diluted	$ (0.97)	$ (0.47)	$ (1.59)	$ (0.84)
Weighted average common shares outstanding, basic and diluted	48,422,921	41,945,058	48,326,764	41,867,089

SpringWorks Therapeutics, Inc.

Selected Balance Sheet Data
(Unaudited)

	June 30, 2021	December 31, 2020

(in thousands)				
Cash, cash equivalents and marketable securities	$	507,483	$	561,820
Working capital (1)		443,978		495,788
Total assets		520,428		576,191
Total liabilities		23,845		19,133
Accumulated deficit		(195,400)		(118,603)
Total stockholders' equity		496,583		557,058

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

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