SpringWorks Therapeutics Announces Issuance of New U.S. Composition of Matter Patent to Polymorphic Form of Mirdametinib, Extending Patent Protection Into 2041

July 20, 2021

STAMFORD, Conn., July 20, 2021 (GLOBE NEWSWIRE) -- SpringWorks Therapeutics, Inc. (Nasdaq: SWTX) announced today that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 11,066,358 (the '358 patent), directed to mirdametinib, the Company's product candidate in development for several oncology indications, including as a monotherapy for patients with neurofibromatosis type 1-associated plexiform neurofibromas (NF1-PN). The '358 patent, assigned to Warner-Lambert Company LLC (a subsidiary of Pfizer), expires in 2041. The '358 patent is a composition of matter patent that covers the polymorphic form of mirdametinib that is currently in clinical development. SpringWorks has exclusive rights to the '358 patent pursuant to an existing worldwide license with Pfizer.

"We are very pleased that the USPTO has issued this patent, which extends patent protection for mirdametinib into 2041," said Saqib Islam, Chief Executive Officer of SpringWorks. "This new patent is part of our ongoing intellectual property strategy to expand protections across our portfolio of targeted oncology product candidates as we seek to provide new advances and better outcomes for patients with devastating cancers."

About Mirdametinib

Mirdametinib is an oral, potent, allosteric, brain-penetrant small molecule designed to inhibit MEK1 and MEK2, which are proteins that occupy pivotal positions in the MAPK pathway and that play a central role in multiple oncology indications. To date, over 250 subjects have been exposed to treatment with mirdametinib across clinical trials, with preliminary evidence of clinical activity against tumors driven by overactivated MAPK signaling.[1]

Mirdametinib is being evaluated as a monotherapy in a Phase 2b trial for pediatric and adult patients with NF1-associated plexiform neurofibromas (NF1-PN), and in a Phase 1/2 trial for patients with pediatric low-grade gliomas. In addition, mirdametinib is being evaluated in a Phase 1b/2 trial in combination with BeiGene's RAF dimer inhibitor, lifirafenib, in patients with advanced or refractory solid tumors harboring *RAS* mutations, *RAF* mutations, and other MAPK pathway aberrations.

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 two potentially registrational clinical trials in rare tumor types as well as eight 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 http://www.springworkstx.com and follow @SpringWorksTx on Twitter and LinkedIn.

SpringWorks Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 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, and 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 interim data from a clinical study may not be predictive of the final 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) our ability to obtain and maintain regulatory approval of any of our product candidates, (v) our plans to research, discover and develop additional product candidates, (vi) our ability to enter into collaborations for the development of new product candidates, (vii) our ability to establish manufacturing capabilities, and our and our collaboration partners' abilities to manufacture our product candidates and scale production, (viii) our ability to meet any specific milestones set forth herein, and (ix) 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 I of SpringWorks' Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, as well as discussions of potential risks, uncertainties and other important factors in SpringWorks' subsequent filings.

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References:

[1] Weiss B, Wolters P, Plotkin S et al. NF106: A Neurofibromatosis Clinical Trials Consortium Phase II Trial of the MEK Inhibitor Mirdametinib (PD-0325901) in Adolescents and Adults With NF1-Related Plexiform Neurofibromas. *Journal of Clinical Oncology*. 2021;39(7):797-806. doi:10.1200/jco.20.02220.