Werewolf Therapeutics Announces Clinical Trial Collaboration with Merck on its WTX-124 INDUKINE™ Program

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Werewolf Therapeutics to evaluate WTX-124, a systemically-delivered, conditionally activated Interleukin-2 (IL-2) INDUKINE molecule, in combination with KEYTRUDA® (pembrolizumab) as a treatment for patients with solid tumors

CAMBRIDGE, Mass., Aug. 18, 2021 (GLOBE NEWSWIRE) -- Werewolf Therapeutics, Inc. (Nasdaq: HOWL), an innovative biopharmaceutical company pioneering the development of conditionally activated therapeutics engineered to stimulate the body's immune system for the treatment of cancer, today announced that it has entered into a clinical trial collaboration and supply agreement with Merck, known as MSD outside the United States and Canada, to evaluate WTX-124, a systemically-delivered, conditionally activated Interleukin-2 (IL-2) INDUKINE product candidate, in combination with KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy. The planned clinical trial will be conducted by Werewolf Therapeutics and is designed to evaluate the safety and preliminary efficacy of WTX-124 as a monotherapy and in combination with KEYTRUDA in patients with solid tumors.

"Werewolf Therapeutics is delighted to be partnering with Merck to study the combination of KEYTRUDA and WTX-124, a molecule designed to deliver IL-2 preferentially to the tumor microenvironment and the first of Werewolf's INDUKINE portfolio to enter the clinic," said Randi Isaacs, M.D., Chief Medical Officer of Werewolf Therapeutics. "The clinical benefit of targeting IL-2 as a treatment for cancer has long been established; however, its utility has been limited by challenging toxicities. We believe WTX-124 has the potential to enhance therapeutic options for cancer patients as a monotherapy and when combined with checkpoint inhibitors like KEYTRUDA."

WTX-124 is a systemically-delivered, conditionally activated IL-2 INDUKINE molecule that has been engineered to minimize the severe toxicities that have been observed with recombinant IL-2 therapy and maximize clinical benefit when administered as monotherapy or in combination with checkpoint inhibitors in multiple tumor types. Werewolf Therapeutics plans to submit an investigational new drug (IND) application for WTX-124 to the U.S. Food and Drug Administration (FDA) in the first half of 2022. Subject to FDA clearance of the IND application, Werewolf Therapeutics expects to promptly initiate a Phase 1 clinical trial evaluating WTX-124 as a monotherapy and as a combination therapy with KEYTRUDA for the treatment of solid tumors.

About Werewolf Therapeutics, Inc.

Werewolf Therapeutics, Inc. is an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer. We are leveraging our proprietary PREDATOR™ platform to design conditionally activated molecules that stimulate both adaptive and innate immunity with the goal of addressing the limitations of conventional proinflammatory immune therapies. Our INDUKINE™ molecules are intended to remain inactive in peripheral tissue yet activate selectively in the tumor microenvironment. Our most advanced product candidates, WTX-124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2 (IL-2) and Interleukin-12 (IL-12) INDUKINE molecules, respectively, for the treatment of solid tumors. We are continuing preclinical studies for both WTX-124 and WTX-330 and expect to advance each candidate in multiple tumor types as a single agent and in combination with an immune checkpoint inhibitor.

To learn more visit www.werewolftx.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risk and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Werewolf Therapeutics' strategy, future operations, prospects, plans, objectives of management, the expected timeline for submitting investigational new drug applications and its sufficiency of its cash resources constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "aim," "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "target," "will," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. The Company may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the development of product candidates, including the conduct of research activities, the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies; the timing of and our ability to submit and obtain regulatory approval for investigational new drug applications; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; the Company's ability to obtain sufficient cash resources to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; the impact of the COVID-19 pandemic on the Company's business and operations; as well as the risks and uncertainties identified in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on June 10, 2021 and in subsequent filings the Company may make with the SEC. In addition, the forward-looking statements included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this press release.

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