Werewolf Therapeutics Receives Fast Track Designation from the U.S. FDA for WTX-124, an Investigational Therapy for the Treatment of Cancer

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Fast Track Designation underscores the promise of Werewolf's INDUKINE™ platform

WATERTOWN, Mass., Oct. 08, 2025 (GLOBE NEWSWIRE) -- Werewolf Therapeutics, Inc. (the "Company" or "Werewolf") (Nasdaq: HOWL), pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer and other immune-mediated conditions, today announced that the Company has received Fast Track Designation for the use of WTX-124 for the potential treatment of patients with locally advanced or metastatic cutaneous melanoma after standard of care immunotherapy. WTX-124 is a conditionally activated interleukin 2 (IL-2) INDUKINE therapy. Fast Track Designation is intended to expedite the development of drugs to address a serious unmet medical need and provide opportunities for frequent FDA interactions.

Werewolf is evaluating WTX-124 in a Phase 1/1b open-label, multicenter study including single-agent and combination arms with pembrolizumab for the treatment of multiple advanced solid tumors (NCT05479812). WTX-124 was designed to stimulate a powerful anti-tumor immune response by providing IL-2 selectively to the tumor microenvironment while decreasing the systemic toxicities that have been observed with other IL-2 immune therapies.

"At Werewolf we are focusing on efforts to address the high unmet need of cancer patients, and we believe there is significant opportunity with WTX-124 for the potential treatment of advanced cancers," said Daniel J. Hicklin, PhD, President and Chief Executive Officer of Werewolf. "We are encouraged by this Fast Track Designation as an important milestone for the WTX-124 program and because it underscores the urgent need for patients with relapsed/refractory melanoma where treatment options are limited. In the fourth quarter, we anticipate sharing preliminary data from the ongoing WTX-124 Phase 1/1b clinical trial, including in patients with cutaneous melanoma, and engaging with the FDA regarding the potential registration strategy for this agent."

The FDA's Fast Track program is designed to facilitate the development and expedite the review of investigational drugs that demonstrate the potential to address unmet medical needs in serious or life-threatening conditions. Product candidates with Fast Track designation are eligible for priority review, the opportunity for a rolling Biologics License Application (BLA), and accelerated approval if relevant criteria are met. The Fast Track designation for WTX-124 was granted based on data in cutaneous melanoma patients previously treated with immune checkpoint inhibitor therapy who demonstrated clinically meaningful anti-tumor activity with a tolerable safety profile. The designation could enable Werewolf to interact more frequently with the FDA to discuss WTX-124's development path.

A description of the Fast Track criteria and process is available on the FDA website:
https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

About Werewolf Therapeutics

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 and other immune-mediated conditions. The Company is leveraging its proprietary PREDATOR ® platform to design conditionally activated INDUKINE™ and INDUCER™ molecules that stimulate both adaptive and innate immunity with the goal of addressing the limitations of conventional proinflammatory immune therapies. Werewolf's INDUKINE molecules are intended to remain inactive in peripheral tissue yet activate selectively in the tumor microenvironment. The Company's most advanced clinical stage 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. Werewolf is advancing WTX-124 in multiple tumor types as a single agent and in combination with an immune checkpoint inhibitor and WTX-330 in multiple solid tumor types as a single agent. Werewolf is leveraging positive data from its INDUKINE molecules to advance the development of INDUCER molecules. Werewolf's first INDUCER development candidate, WTX-1011, targets STEAP1 for prostate cancer. To learn more visit www.werewolftx.com.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Werewolf's strategy, future operations, prospects, plans, and objectives of management; the expected timeline for the preclinical and clinical development of product candidates and the availability of data from such preclinical and clinical development; the timing of anticipated regulatory engagement; the potential benefits of Fast Track Designation for WTX-124 for the potential treatment of advanced or metastatic cutaneous melanoma, including the potential to expedite development and enable frequent interactions with the FDA; the potential activity and efficacy of product candidates in preclinical studies and clinical trials; and the anticipated safety profile of product candidates constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "aim," "anticipate," "believe," "contemplate," "continue," "could," "design," "designed to," "engineered," "estimate," "expect," "goal," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "promise," "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, and the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; whether preliminary or interim data from a clinical trial will be predictive of the future results of the trial and future clinical trials; the Company's ability to manage cash resources and obtain additional cash resources to fund the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in the "Risk Factors" section of the Company's most recent Form 10-Q filed with the Securities and Exchange Commission (SEC), 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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