Werewolf Therapeutics' Clinical Data for WTX-124 and WTX-330 Presented at the Society for Immunotherapy of Cancer's (SITC) 2026 Annual Meeting

November 9, 2026

- *In a Phase 1/1b clinical trial, WTX-124 was administered safely at its recommended Phase 2 dose of 18 mg IV Q2W in the outpatient setting as monotherapy and in combination with pembrolizumab, with durable antitumor activity in patients with relapsed/refractory immunotherapy-sensitive solid tumors -*
- *Aligned with FDA on a recommended Phase 2 dose of 18 mg IV Q2W for WTX-124 as monotherapy and in combination with pembrolizumab -*
- *In a Phase 1b/2 clinical trial, WTX-330 was well tolerated using an optimized drug product and demonstrated monotherapy antitumor activity in patients with advanced, treatment refractory solid tumors -*

WALTHAM, Mass., Nov. 09, 2026 (GLOBE NEWSWIRE) -- Werewolf Therapeutics, Inc. (the "Company" or "Werewolf") (Nasdaq: HOWL), a biopharmaceutical company that has developed conditionally activated therapeutics engineered to stimulate the body's immune system for the treatment of cancer, today announced new clinical data from its Phase 1/1b clinical trial of WTX-124 and its Phase 1b/2 clinical trial of WTX-330, its conditionally activated Interleukin-2 (IL-2) and Interleukin-12 (IL-12) INDUKINE™ molecules, respectively, for the treatment of solid tumors, as presented by posters at the Society for Immunotherapy of Cancer's (SITC) 2026 Annual Meeting from November 6-8, 2026.

"Werewolf is extremely proud of the team that designed the WTX-124 and WTX-330 molecules and shepherded them through their first-in-human clinical trials. The data presented at SITC demonstrated that both molecules were administered in the outpatient setting with no evidence of vascular leak syndrome or recurrence of prior immune-related adverse events, and each molecule showed evidence of clinical activity in patients with advanced, treatment refractory disease. We would like to express our gratitude to the patients who participated in both of these clinical studies, as well as to the investigators and their study teams. Werewolf continues to explore opportunities for the further clinical development of the WTX-124 and WTX-330 programs," said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf.

The Phase 1/1b clinical trial of WTX-124 evaluated WTX-124 as a monotherapy and in combination with pembrolizumab in patients with relapsed/refractory, immunotherapy-sensitive locally advanced or metastatic solid tumors who were refractory to or intolerant of standard of care treatment. The presentation at SITC reported data from 155 patients: 65 patients treated in Part 1 (dose escalation), 42 with 1-28 mg WTX-124 IV Q2W monotherapy and 23 with WTX-124 1-23 mg IV Q2W combined with pembrolizumab 400 mg IV Q6W; and an additional 90 patients treated in Part 2 (dose expansion) with the WTX-124 recommended phase 2 dose as monotherapy (n=49) or in combination with pembrolizumab (n=41). All patients had previously received standard of care immune-checkpoint inhibitor (ICI) regimens.

monotherapy dose of WTX-124, ranging from 1 mg to 28 mg; and 64 patients treated with WTX-124 at doses ranging from 3 mg to 23 mg in combination with pembrolizumab.

Data for the Phase 1/1b clinical trial of WTX-124, as of the June 4, 2026, clinical database lock date, are summarized as follows:

- In dose escalation, WTX-124 as a monotherapy produced three objective responses in dose escalation, including one durable confirmed complete response (CR) in a patient with primary immune checkpoint inhibitor (ICI)-resistant cutaneous squamous cell carcinoma (CSCC) that has remained ongoing without any additional anticancer therapy for approximately three years, and two partial responses in patients with cutaneous melanoma and gastroesophageal junction (GEJ) adenocarcinoma per immune RECIST. Additional patients with non-small cell lung cancer (NSCLC), mucosal melanoma and GEJ adenocarcinoma showed evidence of durable target lesion regression spanning 3-13 months.
- In dose escalation, WTX-124 in combination with pembrolizumab produced a confirmed CR and a confirmed partial response ongoing at the end of the study (i.e., 24 months), in patients with cutaneous melanoma, including a patient with secondary ICI-resistant disease.
- In dose expansion, WTX-124 in combination with pembrolizumab produced a 37.5% response rate in NSCLC for patients who had prior chemoimmunotherapy, as well as a 15.8% response rate in cutaneous melanoma for patients with prior ICI and targeted therapy, as well as a 33% response rate in patients with non-primary ICI resistant disease.
- WTX-124 was administered safely in the outpatient setting as a monotherapy or in combination with a standard-of-care immune checkpoint inhibitor. Analysis of paired tumor biopsies from 43 patients showed that WTX-124 increased expression of T cell and T cell activation genes, consistent with increased tumor-infiltrating T cells and T cell activation, while expression of the regulatory T cell marker FOXP3 did not appear to change with WTX-124 dose.

These findings are summarized in a poster titled, "A Phase 1/1b study of the tumor-activated IL-2 prodrug WTX-124 alone or in combination with pembrolizumab in adults with relapsed/refractory, advanced/metastatic, immunotherapy-sensitive solid tumors." The late-breaking abstract was presented by Justin Moser, M.D., HonorHealth Research Institute, at SITC on Saturday, November 7, 2026.

Werewolf has aligned with the U.S. Food and Drug Administration (FDA) on a WTX-124 recommended phase two dose (RP2D) of 18 mg IV Q2W for both monotherapy and combination with pembrolizumab. The Company believes the data support compelling opportunities for further development of WTX-124 in non-small cell lung cancer, melanoma, CSCC and gastroesophageal junction adenocarcinoma.

The Phase 1b/2 clinical trial of WTX-330 was designed to evaluate WTX-330, administered intravenously every two weeks in fixed-dose and step-up regimens, in patients with relapsed/refractory, locally advanced or metastatic solid tumors. The presentation at SITC reported data from 24 patients treated at doses ranging from 0.016 mg/kg to 0.032 mg/kg.

Data for the Phase 1b/2 clinical trial of WTX-330 as of the May 14, 2026, clinical database lock date are summarized as follows:

- WTX-330 was well tolerated and was administered primarily in the outpatient setting.
- WTX-330 showed high systemic prodrug exposure with low exposure to free (active) IL-12.
- The frequency of treatment-related adverse events was dramatically reduced at equivalent dose levels compared to what was observed with first-in-human WTX-330 material.
- WTX-330 produced evidence of intratumoral IL-12/STAT4 signaling in 7 of 9 patients contributing paired tumor biopsies.
- WTX-330 produced a confirmed partial response per RECIST 1.1 in a patient with gallbladder cancer whose best response to all prior standard-of-care therapy had been progressive disease, as well as multiple additional tumor regressions in patients with late-line refractory solid tumors.

These findings are summarized in a poster titled, “A Phase 1b/2 study of the tumor-activated IL-12 prodrug WTX-330 in patients with relapsed/refractory solid tumors." The poster was presented at SITC on November 7, 2026.

Werewolf believes WTX-330 is poised for further development as a monotherapy, in combination with an ICI, or in a sequenced combination with WTX-124.

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 has designed conditionally activated INDUKINE™ 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 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. 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 availability of data from such clinical development; the potential activity and efficacy of product candidates in preclinical studies and clinical trials; the anticipated safety profile of product candidates; and the potential further development of WTX-124 and WTX-330, including in specific tumor types and in combination with other therapies, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words “aim,” “anticipate,” “approach,” “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: risks and uncertainties inherent in the development of Werewolf’s product candidates, including the conduct, timing, progress and results of preclinical studies and clinical trials; Werewolf’s ability to successfully advance the clinical development of WTX-124 and WTX-330; whether preliminary or interim clinical will be predictive of final results or results from subsequent clinical trials; whether the safety, tolerability and antitumor activity observed in clinical trials of WTX-124 and WTX-330 will be observed in additional patients or with longer follow-up; Werewolf’s ability to obtain regulatory approvals for its product candidates; Werewolf’s ability to obtain sufficient funding to continue the development of its product candidates; and Werewolf’s ability to obtain and maintain intellectual property rights and regulatory exclusivities; 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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