Werewolf Therapeutics Provides Business Update and Highlights 2025 Strategic Outlook

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– Data from expansion arms in Phase 1/1b clinical trial evaluating WTX-124 as monotherapy expected in first half of 2025 to guide regulatory engagement on potential registrational pathways –

– Data from expansion arms in Phase 1/1b clinical trial evaluating WTX-124 in combination with pembrolizumab anticipated in fourth quarter of 2025 –

– Initiation of Phase 1/2 dose and regimen-finding clinical trial of WTX-330 expected in first quarter of 2025 –

– Cash guidance provides runway through at least the second quarter of 2026 –

WATERTOWN, Mass., Jan. 13, 2025 (GLOBE NEWSWIRE) -- Werewolf Therapeutics, Inc. (the "Company" or "Werewolf") (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 and other immune-mediated conditions, today provided a business update and outlined its strategic outlook and expected milestones for 2025.

"2024 was a year of execution for Werewolf in which we reported data from both of our clinical programs, highlighting promising durable anti-tumor activity with unprecedented tolerability for cytokine therapeutics. These data reinforced our INDUKINE^{TM} design, establishing that we could reproducibly improve the therapeutic index in an outpatient setting with a potentially best-in-class profile for WTX-124," said Daniel J. Hicklin, Ph.D., President and Chief Executive Officer of Werewolf. "We continue to advance WTX-124 as a monotherapy and in combination with pembrolizumab in expansion arms and anticipate sharing preliminary monotherapy data in one or more expansion arms in the first half of 2025. We expect these data to guide the next steps of the development program, and pending additional insight from the data, we intend to engage with regulators to discuss potential registrational pathways. We further anticipate sharing data from combination expansion arms in the fourth quarter of 2025."

Dr. Hicklin added, "In addition, WTX-330, our IL-12 INDUKINE molecule, has the potential to be a first-in-class therapy for immunotherapy-resistant cancers. We plan to initiate a Phase 1/2 dose- and regimen- finding clinical trial of WTX-330 in the first quarter of 2025 which includes expansion arms in specific indications."

Anticipated Milestones

Werewolf has provided the following program guidance for 2025:

WTX-124: *a systemically delivered, conditionally activated IL-2 INDUKINE molecule being developed as monotherapy and in combination with pembrolizumab in multiple solid tumor types.*

Werewolf continues to evaluate WTX-124 as a monotherapy and in combination with pembrolizumab through the ongoing Phase 1/1b clinical trial evaluating the INDUKINE molecule in multiple solid tumor types. WTX-124 has shown promising monotherapy activity and an improved tolerability profile versus high dose IL-2 in heavily pretreated patients refractory to all standard-of-care therapies, including immune checkpoint inhibitors. The Company has selected 18 mg administered intravenously every two weeks (IV Q2W) as the recommended dose for monotherapy expansion arms in metastatic melanoma, renal cell carcinoma (RCC) and cutaneous squamous cell carcinoma (CSCC), as well as combination expansion arms in metastatic melanoma, RCC, and non-small cell lung cancer (NSCLC). In 2025, the Company plans to:

- Report interim data from monotherapy expansion arms evaluating WTX-124 in more homogeneous, less heavily pre-treated patient populations;
- Engage with regulators to discuss potential registrational pathways for WTX-124, including strategies for accelerated approval as a monotherapy, pending additional insight into its clinical profile; and
- Report interim data from combination expansion arms in the fourth quarter of 2025.

WTX-330: *a systemically delivered, conditionally activated IL-12 INDUKINE molecule being developed in advanced or metastatic solid tumors.*

At the Society for Immunotherapy of Cancer's (SITC) 39 th annual meeting in November 2024, Werewolf presented an interim update from the Phase 1 clinical trial highlighting the tolerability profile and monotherapy efficacy signals of WTX-330. In 2025, the Company plans to:

- Initiate a Phase 1/2 dose- and regimen-finding clinical trial in the first quarter of 2025 to optimize the delivery of WTX-330 to the tumor microenvironment; and
- Pending data, open expansion arms in selected tumor types.

Preclinical Portfolio: *includes development candidates WTX-712 and WTX-518, our IL-21 and binding protein resistant IL-18 INDUKINE molecules, respectively, for treatment of cancer, and WTX-921, an IL-10 INDUKINE molecule for treatment of inflammatory bowel disease (IBD) and potentially other inflammatory diseases.*

In 2025, Werewolf plans to complete ongoing pre-clinical work to support IND-stage programs and seek strategic partnerships to advance these programs.

Cash Position and Financial Guidance:

Werewolf continues to expect that its cash and cash equivalents will fund operational expenses and capital expenditure requirements through at least the second quarter of 2026.

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 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 tumor types or Non-Hodgkin Lymphoma as a single agent. 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 projection of the cash runway; the expected timeline for the preclinical and clinical development of product candidates and the availability of data from such preclinical and clinical development; 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; the timing of and the Company's 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; 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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