HonorHealth Research Institute patient with advanced skin cancer in remission for more than a year following clinical trial of Werewolf Therapeutics' investigational novel conditionally activated IL-2 pro-drug WTX-124

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There are nearly 40,000 U.S. cases of cutaneous squamous cell carcinoma each year that advance to stages that are difficult to treat and life-threatening

Skin Cancer Awareness Month in May shines a spotlight on the growing burden of advanced skin cancers

The investigational drug is designed to be activated in the tumor microenvironment, including in cutaneous squamous cell carcinoma

SCOTTSDALE, Ariz., May 20, 2025 (GLOBE NEWSWIRE) -- A common and unsightly skin cancer that can turn deadly has been undetectable for more than a year in a patient treated with a new targeted immune-therapy in a clinical trial at HonorHealth Research Institute.

Wayne Futch, 73, of Phoenix, developed a type of skin cancer known as cutaneous squamous cell carcinoma, following a career in pool-maintenance that regularly exposed him to hours of strong sunlight. Despite wearing sunscreen and protective clothing, Mr. Futch's face was disfigured by skin cancer. He lost his right eye following more than 60 radiation treatments that ultimately failed to rid him of the malignancy. "It disfigured my face," Mr. Futch said of the cancer and radiation treatment. "I knew I needed to take some different action, because the radiation was not getting rid of it."

It was then that Mr. Futch said he learned of a new clinical trial for his type of skin cancer at HonorHealth Research Institute. He enrolled in the clinical trial in September 2023. Mr. Futch was infused with a new type of drug that substantially shrunk his tumor in just 8 weeks and left him with no detectable cancer after 12 weeks.

"I haven't had any cancer since (the trial). I don't have any pain, other than the nerve damage done by the radiation," said Mr. Futch, who after high school hitchhiked to Phoenix from southern California, married and has remained in the Valley of the Sun ever since. "I feel confident that if (the cancer) ever comes back again, that they'll detect it and get rid of it, because they did it once already."

The investigational drug is an engineered derivative of the long-proven, but highly toxic, anti-cancer drug known as Interleukin-2 (IL-2). The drug is designed to remain inactive in the periphery until it selectively releases fully potent IL-2 in the tumor microenvironment to stimulate antitumor immunity with reduced toxicity.

The clinical trial (NCT05660384) is evaluating the investigational drug as a monotherapy and in combination with pembrolizumab in patients with immunotherapy sensitive advanced or metastatic solid tumors who have failed standard of care treatment, including checkpoint inhibitor therapy.

"This drug is designed to be inactive upon infusion and only activated within the tumor, which means that we have the potential to get all of the benefit of IL-2 with much better safety," said Justin Moser, M.D., an associate clinical investigator in HonorHealth Research Institute's Cancer Research Division and Associate Research Professor at Arizona State University School of Medicine and Advanced Medical Engineering. "We are overjoyed with the benefit that this patient received, especially given the very limited treatment options available for patients with immunotherapy refractory squamous cell carcinoma."

1 million Americans diagnosed annually

Cutaneous squamous cell carcinoma is a cancer of the outer layer of skin, though it can also develop in other parts of the body. More than 1 million U.S. patients across all stages are diagnosed annually, and nearly 7,000 succumb to this disease when it becomes advanced or metastatic. When detected early, cases of cutaneous squamous cell cancer can be treated effectively with surgery, radiation, curettage (scraping), or cryotherapy (freezing with liquid nitrogen). For cases that progress to advanced disease, systemic therapy is required. Checkpoint inhibitors are approved for these cases, but for patients whose disease fails this treatment, there are currently no consistently effective therapies.

Incidence tripled in three decades

The incidence of cutaneous squamous cell carcinoma has tripled over the past three decades, owing to an aging population and cumulative sun damage, but also because of improved methods of skin cancer screening and detection.

HonorHealth Research Institute in Scottsdale is one of 10 national clinical trial sites for this new drug. Other sites are: Tampa; Atlanta; Chicago; Indianapolis; Hackensack, N.J.; Buffalo; Portland; Dallas and San Antonio. Patients, caregivers, and healthcare providers can learn more about the clinical trial by visiting clinicaltrials.gov.

As Skin Cancer Awareness Month in May shines a spotlight on the growing burden of this disease, as well as other forms of skin cancer, like cutaneous melanoma, this clinical trial offers new hope to patients who previously had few or no remaining treatment options.

For more about HonorHealth Research Institute clinical trials: call 833-354-6667; or email clinicaltrials@HonorHealth.com.

For more about Werewolf Therapeutics clinical trials: call 617-675-1865; or email clinicaltrials@werewolftx.com.

About the HonorHealth Research Institute
HonorHealth Research Institute is an international destination that is at the forefront of providing patients with a better quality of life through its clinical trials and innovative treatment options. Headquartered in Scottsdale, Arizona, the institute's team of physicians and researchers collaborate with experts from across the nation to offer life-changing therapies, drugs and devices. At HonorHealth Research Institute, patients have access to tomorrow's health innovations, today. Learn more at: HonorHealth.com/research.

About Werewolf Therapeutics
Werewolf Therapeutics, Inc., is a 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. 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; 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; 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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