NEWS RELEASE

UW Medicine
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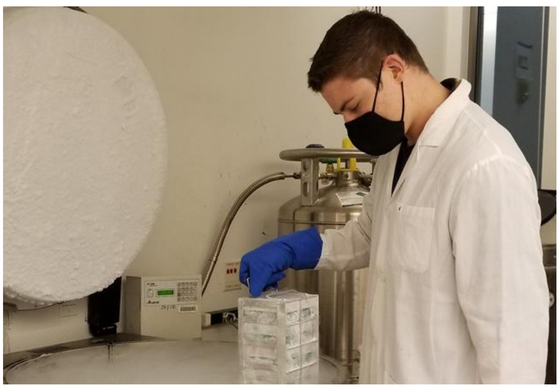
Novel breast cancer therapy candidate enters clinical study

Veana and UW Medicine are evaluating a combination of alpha-TEA and trastuzumab for advanced HER2 positive breast cancer

MEDIA CONTACT: UW Medicine: Leila Gray, 206.475.9809, leilag@uw.edu
Veana Therapeutics, Inc.: info@veana-therapeutics.com



Kiran Dhillon
In a UW Medicine cancer immunotherapy lab, research scientist Nick Drovetto puts a rack of samples into a liquid nitrogen tank.

A Phase 1 patient trial of the novel, oral therapy candidate, alpha-TEA, for advanced HER2 positive breast cancer is now underway. Veana Therpeutics, Inc., and UW Medicine will collaborate on the clinical testing of Veana's lead agent – an alpha TEA lysine salt, in combination with the monoclonal antibody, trastuzumab, brand name Herceptin.

In HER2 positive breast cancer, the tumor cells produce a higher-than-usual level of the HER2 protein that drives cancer growth and spread.

Alpha-TEA lysine salt is a first-in-class, small molecule that destabilizes the energy powerhouses of these proliferating cancer cells. It is an analog of alpha-tocopherol that has been chemically modified to be toxic to tumor cells at doses that are not harmful to normal cells.

By upsetting a cancer cell's mitochondria, it sets off a programmed cell death. As they self-destruct, the fragmenting cancer cells trigger an alarm signal. This signal calls up certain immune cells to seek and destroy other cancer cells.

In this way, alpha-TEA reduces cancer growth by stimulating the body's immune response against the tumor. Trastuzumab is a targeted therapy that attaches to HER2 receptors on the surface of cancer cells. This blocks the signals that tell the cells to grow and might tag the cell for the body's immune system to get rid of it. The hope is that adding alpha-TEA to trastuzumab therapy will work better against HER2+ breast cancer than trastuzumab alone in cases that have that have become resistant to usual treatment.

The Veana-sponsored Phase I, single-site, dose-escalation study at UW Medicine will evaluate the safety of and clinical response to the alpha-TEA lysine salt when used with the HER2-specific monoclonal antibody, trastuzumab. This Phase 1 study will be looking for side effects and for the best dosage.

The oral medication will be given to Stage IV HER2+ breast cancer patients who have been treated with definitive therapy and who have received maintenance targeted antibody therapy. This could be either tratuzumab monotherapy or combination tratuzumab and pertuzumab therapy. The participants will be patients who currently have progressive disease that is refractory to prior treatment and that has appeared in other parts of the body. The patient trial takes place in Seattle.

This study will, secondarily, evaluate other immunological aspects of the body's disease defense system: changes in memory T cells, frequency of HER2-specific T cells, and the function of Natural Killer cells. As an exploratory objective, the study will assess the status of immune cells that destroy cancer cells, Th1 (Tbet+), compared to immune cells that protect cancer cells, Th2 (GATA3+). These T cells can appear in the tumor microenvironment.

The trial brings together university and biotech researchers in advancing cancer immunotherapy

"We are honored to collaborate with the UW Medicine Cancer Vaccine Institute and renowned breast cancer oncologists, Mary "Nora" Disis and William Gwin, who will be leading the study, because of their commitment to bringing new treatment options to the clinic that have the potential to improve clinical outcomes in cancer patients with minimal impact on their quality of life, " said Emmanuel T. Akporiay. He is the founder and chief executive officer of Veana Therapeutics, Inc. and a noted cancer scientist.

Veana Therapeutics, Inc. is a privately held, clinical stage, research and development biotechnology company that is working to develop safer, more effective oral therapies to try to improve and extend the lives of people affected by cancer. The Portland, Ore., company was founded in 2012.

"Alpha-TEA represents a new approach to immunotherapy, acting in concert with standard treatments, to determine if we can improve outcomes for patients," said Disis. She is a professor of medicine, Division of Medical Oncology, at the University of Washington School of Medicine. Disis holds the Helen B. Slonaker Endowed Professorship for Cancer Research.

"We look forward to bringing alpha-TEA into the clinic to provide our patients a new promising immune based therapy, " said Gwin, who is a physician at the Seattle Cancer Care Alliance and an acting instructor in medical oncology at the UW School of Medicine.

The federal clinical trial listing for this study at www.clinicaltrials.gov is reference number NCT04120246

Patients interested in the study can contact:

UW Medicine Cancer Vaccine Institute, Seattle

Study website: https://depts.washington.edu/tumorvac/protocol-146-alpha-tea

Email: cvitrial@medicine.washington.edu

Phone: 1.866.932.8588

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