

## **U.S. Army Breast Cancer Vaccine Research Achieves Multiple Milestones**

/PRNewswire/ -- If Col. George Peoples has anything to say about it, pink ribbons will one day be obsolete and breast cancer will be a preventable disease. Peoples, chief of surgical oncology at San Antonio Military Medical Center (SAMMC) is the founder, director and principal investigator of the Cancer Vaccine Development Program (CVDP), an Army research network that this month is celebrating a few milestones toward its mission to prevent breast cancer.

Breast cancer is one of the most frequent cancers in the U.S. military, just as it is prevalent in the civilian world. For more than 15 years, the CVDP has been conducting research on vaccines that target human epidermal growth factor receptor 2 (HER2/neu), a protein that is expressed by breast cancer cells.

The Army is an ideal place to conduct medical research, according to Peoples. "Military families want to be of service and help others, so they're more likely to say yes to a clinical trial," he said. "Our acceptance rate [for clinical trials] is nearly 50 percent, while in the civilian world it's in the single digits." Other aspects of Army medicine also facilitate medical research. For example, all major hospitals in the military system are linked through electronic medical records, allowing patients to move among facilities worldwide and resulting in a lower drop-out rate than civilian studies.

The vaccines, made up of peptides, are small pieces of the HER2/neu protein, which the immune system can recognize and attack with T-cells. Army researchers at CVDP have studied several peptides, each of which offer lessons on how to identify and eliminate cancerous cells and are in different stages of development.

E75 Phase II clinical trials complete September 10 was a key date for the CVDP: Phase II of a clinical trial on a peptide called E75 concluded after eleven years. E75 was discovered in the mid-1990s, and Dr. Peoples has taken it through consecutive stages of development - pre-clinical, clinical and human trials. Phase II of the trial studied E75 in preventing recurrence of breast cancer in a control group of cancer survivors vs. a vaccinated group. The final Phase II report will be delivered at the San Antonio Breast Cancer Symposium in December. A Phase III trial began in January and will include between 700 and 1,000 breast cancer patients around the world.

"The Phase II trial data has shown that the rate of breast cancer recurrence in women who received E75 was half the rate observed in the control group," said Peoples. "We look forward to seeing if the Phase III trial will confirm these results."

E75 in combination with trastuzumab (Herceptin) This fall, Dr. Peoples hopes to

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initiate a new clinical trial at the CVDP that uses the E75 vaccine in combination with trastuzumab (Herceptin), an injection used to treat breast cancer, to test for a synergistic effect. Breast cancer patients who express a high level of HER2/neu are indicated for treatment with Herceptin. This study examines whether vaccine therapy combined with Herceptin may be an option for those with lower or moderate rates of HER2/neu expression.

AE37 study presented at American College of Surgeons Clinical Congress On October 2 at the American College of Surgeons Clinical Congress, the CVDP presented a poster on another peptide, AE37, which showed that after completing standard treatment, breast cancer survivors who received injections of AE37 were more likely to survive in remission without recurrence than the control group in the study. While AE37 did not prevent recurrence in all patients, it provoked an immunologic response in patients across the board, including survivors at high risk of recurrence, those with the hard-to-treat "triple negative" form of breast cancer and those with lower levels of HER2 expression.

"Patients with a lower level of expressed HER2 protein, who wouldn't be eligible for the HER2-binding antibody, trastuzumab (Herceptin), had a survival rate of more than 88 percent, compared to 70 percent in the control group," said U.S. Army Capt. John Berry, MD, a research associate. "The vaccine may have benefited patients with less aggressive cancers."

E39 targets a new protein The first patient was enrolled in August of this year as the CVDP moves into an exciting new direction with a new series of trials on a vaccine peptide (E39) that targets a different highly expressed protein, FBP - an abbreviation for folate binding protein - instead of HER2. There are no drugs currently available that target FBP.

A major innovation of the CVDP was its emphasis on reducing recurrence in breast cancer survivors that successfully completed a course of standard treatment prior to being vaccinated. "Our program was one of the first to enroll cancer survivors with healthy immune systems rather than focus on people with end-stage, metastatic cancer," said Peoples. "Enrolling patients with very advanced cancer is a holdover from trials testing toxic chemotherapies. Data has shown that the vaccines, in contrast, are non-toxic."

In the meantime, cancer remains a major threat to human health and Dr. Peoples says there is much work ahead for the CVDP. "The ultimate goal is to vaccinate at-risk patients who have never had cancer," he said. "We are looking at areas of future research in combining vaccines and combining a vaccine with other forms of immunotherapy. HER2/neu is expressed in other cancers, and we hope to one day have vaccines to prevent lung, colon, prostate and ovarian cancers."

Dr. Peoples received his undergraduate degree from the United States Military Academy at West Point in 1984 and graduated from Johns Hopkins School of Medicine. His interest in immunotherapy and cancer research was sparked during his residency in general surgery at Brigham and Women's Hospital in Boston. He continued his education with a research fellowship at the Laboratory of Biologic

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Cancer Therapy at Harvard Medical School, and training in surgical oncology at MD Anderson Cancer Center. He has been working on cancer research ever since.

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