OncoPep Announces Initiation of Phase 1b Clinical Trial of PVX-410 in Triple Negative Breast Cancer

-- Multi-Center Investigator-Sponsored Clinical Trial to Evaluate Safety and Tolerability of Multi-Peptide Cancer Vaccine --

BOSTON – November 28, 2016 -- OncoPep, Inc. announced that a Phase 1b clinical trial is underway to evaluate PVX-410, a multi-peptide therapeutic cancer vaccine, as an adjuvant treatment in patients who have completed all planned therapy for stage II or III triple negative breast cancer (TNBC). The study, led by Steven Isakoff, M.D., Ph.D. at Massachusetts General Hospital, will assess the safety and tolerability of PVX-410 in combination with the checkpoint inhibitor durvalumab.

"In this Phase 1b clinical trial, we are looking to evaluate the safety of PVX-410 alone and in combination with durvalumab, and to determine whether the vaccine and durvalumab can work together to assist immune system recognition of TNBC," said Dr. Isakoff, Associate Director for Breast Cancer Clinical Research at the Massachusetts General Hospital Cancer Center and Assistant Professor in Medicine at Harvard Medical School. "We are hopeful that this approach will allow immune system recognition of cancer-associated antigens and result in a targeted immune response that can be utilized as a possible adjuvant treatment for stage II or III TNBC."

"The initiation of this Phase 1b clinical trial of PVX-410 in TNBC marks an important milestone in OncoPep's development," said Doris Peterkin, Chief Executive Officer of OncoPep. "We are now developing PVX-410 in two oncology indications, TNBC and smoldering multiple myeloma, in which we are hopeful that the vaccine will provide enhanced immune targeting of cancer cells for improved patient outcomes."

The multi-center, open label Phase 1b study is designed to evaluate the safety, tolerability, and immune response to PVX-410 alone and in combination with durvalumab in an adjuvant setting in patients who have completed all planned therapy for stage II or III TNBC. Patients will receive six bi-weekly intramuscular injections of PVX-410, which will be given in combination with an intravenous infusion of durvalumab on the day of the 4^{th} and 6^{th} PVX-410 injection. The study is expected to enroll approximately 20 patients at multiple treatment centers, including Massachusetts General Hospital, Beth Israel Deaconess Medical Center, and Dana-Farber Cancer Institute. More information on the trial can be found at clinicaltrials.gov, identifier number NCT02826434.

About Triple Negative Breast Cancer

Triple negative breast cancer (TNBC) is a form of breast cancer that lacks the three receptors found most commonly on breast cancer cells: estrogen receptor (ER), progesterone receptor (PR), and hormone epidermal growth factor receptor 2 (HER-2). TNBC accounts for

approximately 15-20% of all breast cancer cases and is more likely to spread and recur than other forms of breast cancer.

About PVX-410
PVX-410 is a novel therapeutic cancer vaccine currently in Phase 1b clinical trials in smoldering multiple myeloma and triple negative breast cancer. PVX-410 consists of four peptides from unique regions of three cancer-associated antigens and is designed to elicit an immune response to the targeted tumor antigens. PVX-410 was granted orphan drug designation from the U.S. Food and Drug Administration in 2013.

About OncoPep
OncoPep is developing targeted immunotherapeutics to prevent the progression of cancer, prolong survival and restore the quality of life of patients. OncoPep's lead program is a multi-peptide therapeutic vaccine for use in treating smoldering multiple myeloma.
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