OncoPep Announces Initiation of Phase 1b Clinical Trial of PVX-410 in Smoldering Multiple Myeloma and Upcoming Presentation of Positive Results from Phase 1/2a Clinical Trial at ASH

-- Multi-Peptide Cancer Vaccine to be Evaluated in Investigator-Sponsored Clinical Trial --

-- Final Results of Phase 1/2a Study of PVX-410 to be Presented at ASH2016 –

BOSTON – November 28, 2016 -- OncoPep, Inc. today announced the initiation of a Phase 1b clinical trial evaluating PVX-410, a multi-peptide therapeutic cancer vaccine, in patients with moderate or high-risk for progression smoldering multiple myeloma (SMM), an asymptomatic precursor to multiple myeloma, which is a cancer of the plasma cells. The study, led by Noopur Raje, M.D. at Massachusetts General Hospital, will assess the safety and tolerability of PVX-410 in combination with durvalumab with or without lenalidomide. The trial initiation follows the successful completion of a Phase 1/2a dose escalation study of PVX-410 in patients with SMM, the results of which will be presented at the 58th Annual Meeting of the American Society of Hematology (ASH), being held from December 3-6, 2016 in San Diego, California.

"We are encouraged by the results of the Phase 1/2a clinical trial, which demonstrated that PVX-410 is well-tolerated and may elicit a memory T cell response in patients with smoldering multiple myeloma," said Dr. Raje, Director of the Center for Multiple Myeloma at the Massachusetts General Hospital Cancer Center and Associate Professor of Medicine at Harvard Medical School. "In the Phase 1b trial, we are looking to further evaluate the safety and tolerability of PVX-410 in combination with the checkpoint inhibitor, durvalumab, and the immunomodulatory drug, lenalidomide, in hopes that the combination will further augment a targeted immune-mediated attack against SMM cells and ultimately prevent progression to multiple myeloma."

The open label Phase 1b study is designed to evaluate the safety and tolerability of PVX-410 and durvalumab with and without lenalidomide in patients with SMM. Patients will receive either durvalumab alone, PVX-410 + durvalumab, or PVX-410 + durvalumab + lenalidomide over a three-month treatment phase. The study is expected to enroll approximately 26 patients at multiple trial sites, including Massachusetts General Hospital. More information on the trial can be found at clinicaltrials.gov, identifier number NCT02886065.

Details of the Phase 1/2a data presentation at ASH are as follows:

Title: "Final Results of a Phase 1/2a, Dose Escalation Study of PVX-410 Multi-Peptide Cancer Vaccine in Patients with Smoldering Multiple Myeloma (SMM)"
Session: Myeloma: Therapy, excluding Transplantation: Poster I
Date: Saturday, December 3, 2016

Time: 5:30pm – 7:30pm PST
Location: Hall GH, San Diego Convention Center

Results of the Phase 1/2a clinical trial demonstrated that PVX-410 was well-tolerated, with a treatment-emergent adverse event (TEAE) profile that was consistent with that expected. PVX-410 was immunogenic as a monotherapy and in combination with lenalidomide, with the immune response to PVX-410 being enhanced by the addition of lenalidomide.

A total of 22 patients with moderate or high-risk SMM received six bi-weekly subcutaneous injections of PXV-410 at either a low dose, target dose, or target dose plus lenalidomide. All patients experienced at least one TEAE, the majority of which were Grade 1 in intensity and occurred within 2 days of PVX-410 injection. No deaths or study drug-related serious adverse events were reported.

An immune response to PVX-410 was demonstrated by an increase in the percentage of tetramer- and interferon-gamma-positive cells in the $CD3^{+}CD8^{+}$ T cell population and increases from baseline in interleukin-2-, tumor necrosis factor-alpha-, and CD137-positive $CD8^{+}$ T cells. Moreover, an increase in the effector memory T cell population was seen post-vaccination, a response that was enhanced by the addition of lenalidomide.

Among the 12 monotherapy patients, five (two low-dose, three target-dose) experienced progression to active disease within nine months post-treatment, and seven had stable disease (SD) at follow-up month 12. Among the nine evaluable PVX-410 + lenalidomide patients, five achieved at least a minimal response, with 1 patient achieving a partial response. One of these five patients then progressed to multiple myeloma by month five post-treatment. Four patients had SD at follow-up month 12.

About Smoldering Multiple Myeloma
Smoldering multiple myeloma (SMM) is a plasma cell proliferative disorder with a high risk of progression to multiple myeloma (MM). It is estimated that SMM accounts for approximately 15% of all newly diagnosed cases of MM, and the annual risk of progression from SMM to symptomatic MM requiring treatment is estimated to be 10%. The current standard of care for SMM is watchful waiting, and approaches that intend to delay or prevent progression to symptomatic MM are needed.

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 multiple myeloma-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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