OncoPep Initiates Phase 1/2a Clinical Trial with Multi-Peptide Vaccine to Treat Smoldering Multiple Myeloma

BOSTON -- January 29, 2013 -- OncoPep, Inc. today announced that the Company has initiated a Phase 1/2a clinical trial evaluating PVX-410, a multi-peptide therapeutic cancer vaccine, in patients with smoldering multiple myeloma, an asymptomatic precursor of multiple myeloma, which is an incurable cancer of the plasma cells. PVX-410 is composed of four proprietary, synthetic peptides that target specific antigens found on the surface of multiple myeloma cells. Target enrollment for this study is 13 patients. The trial will assess the safety and tolerability of the cancer vaccine, and early-stage data from the study are expected in late 2013.

"The initiation of our first clinical trial is an important milestone for OncoPep and follows positive preclinical studies with PVX-410 that demonstrated the ability to stimulate a strong immune response against multiple myeloma cell lines and patient cells *in vitro*," said Doris Peterkin, Chief Executive Officer of OncoPep. "Unfortunately, the only treatment option for patients with smoldering multiple myeloma is 'watchful waiting' until they progress to active multiple myeloma, a situation which can be frustrating to both patients and their clinicians. OncoPep hopes PVX-410 will become a treatment option for these patients, which may prevent them from progressing to active disease."

PVX-410 is the first vaccine candidate developed from the Company's multi-peptide therapeutic cancer vaccine portfolio, which was exclusively licensed from Dana-Farber Cancer Institute.

About the PVX-410 Phase 1/2a Clinical Trial

OncoPep's Phase 1/2a clinical trial is designed to evaluate the safety and tolerability of PVX-410 in the treatment of patients with smoldering multiple myeloma. It is an open label, dose escalation study, in which 13 patients with a confirmed clinical diagnosis of smoldering multiple myeloma will receive either a 0.4 mg or 0.8 mg dose over twelve weeks in six, bi-weekly subcutaneous injections. Immune and clinical response will also be evaluated through the treatment period and for 12 months following treatment. The treatment centers include the cancer centers at Massachusetts General Hospital (Boston), MD Anderson Cancer Center (Houston) and Winship Cancer Institute of Emory University (Atlanta). More information on this study can be found at www.clinicaltrials.gov (Identifier: NCT01718899).

About Smoldering Multiple Myeloma

Smoldering multiple myeloma (SMM) is a plasma cell proliferative disorder with a high risk of progression to multiple myeloma (MM). The International Myeloma Working Group defines SMM by serum monoclonal protein (≥3 g/dL) or bone marrow clonal plasma cells (BMPC) (> 10%), or both, along with normal organ and marrow function.[1] The risk of progression to MM is 10 percent per year in the first five years of SMM.[2]

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.
www.oncopep.com

References

[1] Palumbo, *et al. Leukemia*. (2009) 1-15.
[2] Kyle, *et al. Leukemia*. (2010) 1121-1127.

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