MADISON VACCINES ANNOUNCES FIRST PATIENT DOSED IN AN EXPANDED COMBINATION TRIAL OF MVI-816 PLUS KEYTRUDA® FOR METASTATIC, TREATMENT-RESISTANT PROSTATE CANCER

MADISON, WI– August 2, 2017 - Madison Vaccines Incorporated (MVI) today announced the first patient has been dosed in an expanded clinical trial to further extend the potential benefits of checkpoint inhibitors to men with advanced prostate cancer. Known PD-1 and PDL-1 checkpoint inhibitors work well as monotherapy in many cancers, but not very well by themselves in prostate cancer. MVI is exploring the use of its gene based immune-activator MVI-816 in combination with checkpoint inhibitors to extend their use to treatment of prostate cancer. Now, based on initial findings from a Phase 1b pilot study of MVI-816 plus Keytruda® (pembrolizumab), MVI has begun dosing an expanded cohort of 20 patients with metastatic, castrate-resistant prostate cancer, who will be offered the combination regimen for up to 48 weeks.

Madison Vaccines' immune activator in expanded combo trial with checkpoint inhibitor for advanced prostate cancer

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"Observations in the Phase 1b trial include declines in PSA, a common blood-based indicator of prostate cancer, evidence of tumor regressions on CT scan, and an increase in the relevant immune-system T cells in patients' blood," said Glenn Liu, MD, Principle Investigator at the University of Wisconsin-Madison Carbone Cancer Center, where the trial is being conducted. "As an oncologist, I am pleased to be able to further explore the combination of MVI-816 and pembrolizumab in 20 additional patients."

Richard R. Lesniewski, PhD, President and CEO of MVI, added, "The Phase 1b trial data confirm our preclinical hypothesis regarding dose and scheduling of MVI-816 in combination with a checkpoint inhibitor to obtain optimum clinical response. MVI is encouraged by these early clinical signals."

MECHANISM OF ACTION

Checkpoint inhibitors have captured the attention of oncologists with their ability to fight many forms of cancer by blocking PD-1 and PDL-1, a regulatory mechanism that dampens the immune system's ability

to fight the cancer. However, they have not been as affective in prostate tumors, possibly because prostate tumors do not elicit a large enough immune response, leaving too few immune cells to be activated by checkpoint inhibitors alone.

“That’s where MVI-816 comes in,” said Douglas McNeel, MD, PhD, the Chief Scientific Founder and Medical Officer for MVI. “MVI-816 induces immune responses to cells expressing prostatic acid phosphatase (PAP), an antigen specific to prostate cells. We believe the addition of MVI-816 activates and increases the number of immune system T cells in the prostate tumor, and then the PD-1 inhibitor enables these T-cells to more efficiently kill the cancer.”

MVI-816, and a second immunological agent, MVI-118, were developed in Dr. McNeel’s laboratory at the University of Wisconsin-Madison. Although commonly referred to as “vaccines,” they do not use protein antigens to prevent or treat the cancer. Rather, they use plasmid DNA (genetically engineered material encoding a human antigen) to induce the immune system to attack cancer cells. Proper timing and sequencing of the plasmid DNA and the checkpoint inhibitor appear to be critical for optimum response. Plasmid DNA immunotherapies can be rapidly manufactured, represent off-the-shelf therapies that do not have to be individually engineered for each patient, and they are easily administered with simple injections under the skin.

<u>Contacts</u>

Corporate:
Madison Vaccines Incorporated
Richard Lesniewski, PhD, President 610-850-4697

Media:
Deanne Eagles, Initiate PR, 917-837-5866
Deanne.eagle@initiatePR.com