Madison Vaccines Says Clinical Trial Begins for Its 2nd Prostate Cancer Vaccine, MVI-118, Intended to Delay Disease Progression in Men with Metastatic Disease

--MVI-118 Represents a Novel Approach to Prostate Cancer Vaccine: Targeting the Androgen Receptor, the Primary Driver of Prostate Cancer Growth and Progression--

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MADISON, Wis.--(BUSINESS WIRE)--Madison Vaccines Incorporated (MVI), today announced dosing has begun in a Phase 1 clinical trial for MVI-118 (pTVG-AR) in men with metastatic prostate cancer who are initiating androgen deprivation therapy (ADT). MVI-118 targets the human androgen receptor, the critical biological target responsible for driving prostate cancer progression and, in many cases, resistance to current therapies. It is being developed to prolong the duration of disease control gained from standard androgen deprivation therapies. The trial will be conducted at the University of Wisconsin – Madison Carbone Cancer Center and two additional Medical Centers.

This is MVI's second prostate cancer vaccine, along with MVI-816 (pTVG-HP), MVI's lead vaccine that has demonstrated clinical evidence of safety, immune activation and biological signals (PSA changes) of activity. Both MVI-816 and MVI-118 are plasmid DNA vaccines that differ from other vaccines because they can be rapidly and inexpensively manufactured, can be administered by simple intradermal injection, and are relatively more stable in storage. MVI-118 is intended to provide persistent activation of $CD8^+$ T-cells that target the androgen receptor, a key tumor cell protein that is frequently and highly overexpressed as resistance to ADT emerges.

"Our objective is to deliver safe, effective and economical vaccine therapies for men at all stages of prostate cancer," said Richard Lesniewski, PhD, President of MVI. "MVI-118 represents a first-in-class immunotherapy approach to the androgen receptor, intended to provide a potent immunological attack on tumors to delay ADT resistance and ensuing disease progression. Initiation of our Phase 1 trial with MVI-118, strategically positions MVI with two vaccines, in three distinct clinical settings, for men with malignant prostate cancer."

MVI-118 is being developed to address a critical need. As many as a third of patients initially treated for prostate cancer will experience disease recurrence, and approximately half of these men will progress to bone metastases and reach a stage where it cannot be cured. In pre-clinical models, MVI-118 demonstrated evidence of safety, T-cell activation, and survival benefit.

MVI's lead vaccine, MVI-816, is in a Phase 2 clinical trial in patients with early biochemically recurrent prostate cancer intended to delay the onset of metastatic disease after primary therapy. MVI-816 is also in a second clinical trial that began this past summer pairing it with an immunomodulatory PD-1 inhibitor to render cancer cells more susceptible to attack by the immune system; this second clinical trial is in patients with metastatic castration-resistant prostate cancer. Both MVI-816 and MVI-118 are intended to address the anticipated surge in prostate cancers over the next two decades as "Baby Boomers" reach the age when men are most commonly diagnosed with the disease.

About MVI

Wisconsin-based MVI is developing two plasmid DNA vaccines to treat men with prostate cancer. MVI has licensed patented technologies that were developed in the laboratory of Dr. Douglas McNeel at the University of Wisconsin-Madison. More information is available at www.madisonvaccines.com.