Madison Vaccines Incorporated Expands Clinical Trial of MVI-118 for Prostate Cancer to University of Washington

-- MVI-118, Gene-based Immunotherapy, Is Intended to Delay Disease Progression in Men with Metastatic Prostate Cancer --

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MADISON, Wis. & SEATTLE--(BUSINESS WIRE)--Madison Vaccines Incorporated (MVI), a clinical stage company developing gene-based immunotherapies, today said that the Phase 1 clinical trial of MVI-118 for metastatic prostate cancer, is expanding to a third clinical site - The University of Washington-Seattle. MVI-118 is being explored for use in combination with androgen deprivation therapy (ADT), to delay resistance and prolong duration of disease control in men with metastatic prostate cancer. The Phase 1 clinical study, to determine safety and detect a response by the immune system, is already underway at the University of Wisconsin-Madison and at the Rutgers Cancer Institute in New Jersey.

"Many patients are reluctant to start chemotherapy treatment, especially if they are feeling well," said Michael Schweizer, MD, principle investigator at the University of Washington School of Medicine. "This study will provide vital information about the safety as well as the clinical and immunologic effects of a novel approach to treatment, that may move us toward an effective alternative to chemotherapy for these men."

MVI-118 uses plasmid DNA (genetically engineered material encoding a human antigen) to activate the body's own immune system to target specific features of prostate cancer cells. In this case the target is the human androgen receptor that drives the progression of prostate cancer and, in many cases, is responsible for the resistance to current treatments. This gene-based immunotherapy works in concert with the androgen deprivation therapy the men are already receiving. The combination provides a powerful dual attack on the cancer – the androgen deprivation depletes the fuel supply of male hormones that drives the cancer, while MVI-118 limits the ability to use remaining hormone by stimulating a response against cancer cells that express more androgen receptors.
Richard R. Lesniewski, PhD, President and CEO of MVI, said, “Although commonly referred to as ‘vaccines,’ our products are actually forms of gene-based immunotherapy. They are taken up by cells to stimulate specific responses using the body’s natural mechanisms to fight the cancer.”

This plasmid DNA immunotherapy can be rapidly manufactured, is more stable in storage relative to many forms of vaccines, and represents off-the-shelf therapies that do not have to be individually engineered for each individual patient. They are easily administered with simple intradermal injections under the skin.

Dr. Lesniewski added, “Reimbursement potential is always part of our strategy. Developing agents with low costs of goods, that use simple delivery mechanisms, is critical to the long-term success of immune activating agents as affordable and sustainable therapies.”

Preclinical data suggest repeat injections of MVI-118 in combination with ADT can produce a potent immune response against the tumor. Based on other preclinical findings, MVI is planning additional drug combinations with MVI-118, including addition of a PD-1 inhibitor, also known as a checkpoint inhibitor, and other androgen receptor blocking agents that help make the cancer cells more vulnerable to the immune attack driven by MVI-118.

A second MVI immune-activating therapy, MVI-816, is being explored in a clinical trial with a checkpoint inhibitor (pembrolizumab), in men with metastatic, castrate-resistant prostate cancer. Early data from a 12-week pilot study show consistent signals of anti-tumor activity. MVI-816 induces immune responses to cells expressing prostatic acid phosphatase (PAP), an antigen specific to prostate cells.

MVI-816 is also being evaluated in a fully enrolled Phase 2 clinical trial, as a single agent, in men with earlier stage prostate cancer. In this trial, men with rising PSA after primary surgery or radiation, but before these patients have detectable metastases (tumor spread), are being dosed with MVI-816 for up to 2 years. This trial will inform MVI whether metastases can be delayed or prevented by immunotherapy, which may have the added benefit of delaying the need for androgen deprivation therapy.

Taken together, this means MVI is developing immune-activating therapies for men throughout the entire spectrum of prostate cancer progression, from premetastatic (MVI-816), to newly metastatic (MVI-118) to late stage metastatic disease (MVI-816 + checkpoint inhibitor). MVI-816 and MVI-118 were developed in the laboratory of Douglas McNeel, MD, PhD, at the University of Wisconsin-Madison.

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