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Immunomic Therapeutics Announces Clinical Trial of ITI-3000 for the Treatment of Merkel Cell Carcinoma

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ROCKVILLE, Md.--(BUSINESS WIRE)--Feb 7, 2022--

Immunomic Therapeutics, Inc., (“ITI”), a privately-held clinical-stage biotechnology company pioneering the study of LAMP (Lysosome Associated Membrane Protein) -mediated nucleic acid-based immunotherapy, today announced its first Phase 1 clinical study evaluating ITI-3000 in patients with Merkel cell carcinoma (MCC), a rare but aggressive form of skin cancer that is typically caused by the Merkel cell polyomavirus (MCPyV). The single-center study will be conducted at the University of Washington School of Medicine and the Fred Hutchinson Cancer Center in Seattle, Washington and will be led by Drs. Paul Nghiem, Song Park and David Koelle.

The trial is a Phase 1, open label, First in Humans (FIH) study to evaluate the safety, tolerability and immunogenicity of 4 mg of ITI-3000 in patients with Merkel polyomavirus-positive Merkel cell carcinoma (MCC) patients who have undergone surgery. The study’s primary endpoints include Dose Limiting Toxicities (DLTs), Adverse Events/Serious Adverse Reactions, (AEs/SARs) standard clinical assessments and safety laboratory parameters.

ITI-3000 leverages the company’s investigational UNiversal Intracellular Targeted Expression (UNITE) platform, powered by LAMP, which fuses a mutated form of the large T antigen (LT) of Merkel cell polyomavirus (MCPγV) with LAMP1. This lysosomal targeting technology has been shown to result in enhanced antigen presentation and a balanced immune response, including, of

note, ITI-3000 activated antigen-specific CD4+ T cells *in vivo*. The plasmid DNA vaccine will be administered utilizing PharmaJet's well established Stratis ® Needle-free Injection System that precisely targets delivery to the intramuscular tissue layer.

"This therapeutic vaccine trial is the first of its kind in the world and may help address the fact that MCC recurs in 40% of cases after initial treatment, but no adjuvant therapy is approved for these patients," noted Dr. Paul Nghiem, co-lead of the clinical study, and Head of Dermatology at University of Washington.

"This Phase 1 clinical trial of ITI-3000 in MCC is an important milestone, as it expands the reach of our immuno-oncology program beyond our ongoing phase 2 study of ITI-1000 (Umitrelimorgene autodencel) in glioblastoma multiforme, to a second potential indication," stated Dr. William Hearl, Chief Executive Officer of Immunomic Therapeutics, Inc. "Based on the strength of our UNITE platform and strong pre-clinical data generated, to date, we believe ITI-3000 has the potential to address the urgent unmet medical need for therapies to treat this aggressive form of skin cancer."

The majority of MCCs are associated with MCPγV infection, making LT an attractive target for therapeutic cancer vaccines. MCPγV integrates into the host genome, resulting in expression of a truncated form of the viral LT in infected cells. While induction of tumor-reactive CD8+ T cells is a major goal of cancer therapy, CD4+ T cells provide essential support to CD8+ T cells by promoting their expression of cytotoxic effector molecules and increasing their proliferation and durability. Cytokines secreted by CD4+ T cells, such as IFNγ, can also exert desirable effects on the tumor microenvironment. Therefore, a cancer vaccine that promotes potent, antigen-specific CD4+ T cell responses to MCPγV-LT may drive robust anti-tumor immune responses.

About Immunomic Therapeutics, Inc.

Immunomic Therapeutics, Inc. (ITI) is a privately held, clinical stage biotechnology company pioneering the development of vaccines through its proprietary technology platform, UNiversal Intracellular Targeted Expression (UNITE), which is designed to utilize the body's natural biochemistry to develop vaccines that generate broad immune responses. UNITE has a robust

history of applications in various therapeutic areas, including infectious diseases, oncology, allergy and autoimmune diseases. ITI is primarily focused on applying the UNITE platform to oncology, where it could potentially have broad applications, including antigen-derived antibodies as biologics. The Company has built a pipeline leveraging UNITE with programs in oncology, animal health, infectious disease and allergy. ITI maintains its headquarters in Rockville, Maryland. For more information, please visit www.immunomix.com.

About PharmaJet

PharmaJet's mission is to improve people's lives through needle-free technology. PharmaJet Needle-free Systems provide increased vaccine effectiveness, a preferred patient and caregiver experience, and a proven path to commercialization. They are also safe, fast and easy-to-use. The Tropis ® System has CE Mark and WHO PQS certification for intradermal injections. The Stratis ® System has U.S. FDA 510(k) marketing clearance, CE Mark, and WHO PQS certification to deliver medications and vaccines either intramuscularly or subcutaneously. Visit www.pharmajet.com for more information. Follow PharmaJet on LinkedIn.

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