Memorial Sloan Kettering Cancer Center Now Enrolling Patients in Phase 1/2 Clinical Trial of IMUNON's IMNN-001 in Combination with Bevacizumab in Advanced Ovarian Cancer

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Trial will evaluate the effect of this combination therapy on minimal residual disease

LAWRENCEVILLE, N.J., Feb. 27, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage drug-development company focused on developing non-viral DNA-mediated immunotherapy and next-generation vaccines, announces that Memorial Sloan Kettering Cancer Center has joined MD Anderson Cancer Center in enrolling patients in a Phase 1/2 clinical trial evaluating IMUNON's IMNN-001 in combination with bevacizumab in patients with advanced ovarian cancer. IMNN-001 is a DNA-based interleukin-12 (IL-12) immunotherapy currently in the Phase 2 OVATION 2 Study for the localized treatment of advanced ovarian cancer.

Dr. Corinne Le Goff, President and Chief Executive Officer of IMUNON, said, "We are delighted that such a prestigious institution as Memorial Sloan Kettering has joined this trial, which is testing the combination of IMNN-001 and bevacizumab, known as Avastin ™, in ovarian cancer. We believe this combination therapy holds promise based on our preclinical animal studies, which showed strong synergies between IMNN-001 and bevacizumab. As an innovative immunotherapy, IMNN-001 may transform the first-line treatment of ovarian cancer and provide new options to women diagnosed with Stage III/IV disease who face cure rates of 15% or less."

This Phase 1/2 trial is designed to enroll 50 patients with Stage III/IV advanced ovarian cancer. Patients undergoing frontline neoadjuvant therapy will be randomized 1:1 to receive standard chemotherapy plus bevacizumab vs. chemotherapy plus bevacizumab and IMNN-001. The trial's primary endpoint is detection of minimal residual disease (MRD) by second-look laparoscopy (SLL), and the secondary endpoint is progression-free survival (PFS).

Initial SLL data are expected within one year following the completion of enrollment and final PFS data are expected approximately three years following the completion of enrollment. This trial will also include a wealth of translational endpoints aimed at understanding the clonal evolution and immunogenomic features of the MRD phase of ovarian cancer that is currently undetectable by imaging or tumor markers.

The trial's principal investigator is Amir Jazaeri, M.D., Professor of Gynecologic Oncology and Reproductive Medicine at The University of Texas MD Anderson Cancer Center. The Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology will also be involved in translational analyses using trial samples and animal models of ovarian cancer MRD, including biomarker and genomic analyses, which is expected to expand the Company's knowledge of the treatment paradigm. These initiatives are a part of the Break *Through* Cancer Targeting Ovarian Cancer Minimal Residual Disease Using Immune and DNA Repair Directed Therapies TeamLab collaboration.

Dr. Le Goff added, "We are excited about the potential for IMNN-001 in ovarian cancer, in particular following our recently announced encouraging interim PFS and overall survival data for our OVATION 2 Study evaluating the benefits of IMNN-001 in the neoadjuvant setting."

About Epithelial Ovarian Cancer

Epithelial ovarian cancer (EOC) is the fifth deadliest malignancy among women in the United States. There are approximately 22,000 new cases of ovarian cancer every year and the majority (approximately 70%) are diagnosed in advanced Stages III and IV. EOC is characterized by dissemination of tumor in the peritoneal cavity with a high risk of recurrence (75%, Stages III and IV) after surgery and chemotherapy. Since the five-year survival rates of patients with Stages III and IV disease at diagnosis are poor (41% and 20%, respectively), there remains a need for a therapy that not only reduces the recurrence rate, but also improves overall survival. The peritoneal cavity of advanced ovarian cancer patients contains the primary tumor environment and is an attractive target for a regional approach to immune modulation.

About IMNN-001 Immunotherapy

Designed using IMUNON's proprietary TheraPlas ® platform technology, IMNN-001 (formerly GEN-1) is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system that enables cell transfection followed by persistent, local secretion of the IL-12 protein. IL-12 is one of the most active cytokines for the induction of potent anticancer immunity acting through the induction of T-lymphocyte and natural killer cell proliferation. The Company previously reported positive safety and encouraging Phase 1 results with IMNN-001 administered as monotherapy or as combination therapy in patients with advanced peritoneally metastasized primary or recurrent ovarian cancer and completed a Phase 1b dose-escalation trial (the OVATION 1 Study) of IMNN-001 in combination with carboplatin and paclitaxel in patients with newly diagnosed ovarian cancer. It announced full enrollment in the OVATION 2 Study in September 2022, interim data in September 2023 and expects to report topline data in the second quarter of 2024.

About IMUNON

IMUNON is a fully integrated, clinical-stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms to generate safe, effective and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. IMUNON is developing its non-viral DNA technology across four modalities. The first modality, TheraPlas®, is developed for the coding of proteins and cytokines in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine®, is developed for the coding of viral antigens that can elicit a strong immunological response. This technology may represent a promising platform for the development of vaccines in infectious diseases. The third modality, FixPlas®, concerns the application of our DNA technology to produce universal cancer vaccines, also called tumor associated antigen cancer vaccines. The fourth modality, IndiPlas®, is in the discovery phase and will focus on the development of personalized cancer vaccines, or neoepitope cancer vaccines.

The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase 2 development. IMNN-001 works by instructing the body to produce safe and durable levels of powerful cancer-fighting molecules, such as interleukin-12 and interferon gamma, at the tumor site. Additionally, the Company is conducting IND-enabling preclinical studies for the development of a COVID-19 booster vaccine (IMNN-101) and a treatment for the LASSA virus (IMNN-102). The Company has also initiated preclinical work to develop a Trp2 tumor associated antigen cancer vaccine in melanoma (IMNN-201). We will continue to leverage these modalities and to advance the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions. For more information on IMUNON, visit www.imunon.com.

Forward-Looking Statements

IMUNON wishes to inform readers that forward-looking statements in this news release are made pursuant to the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; the uncertainties of and difficulties in analyzing interim clinical data; the significant expense, time and risk of failure of conducting clinical trials; the need for IMUNON to evaluate its future development plans; possible acquisitions or licenses of other technologies, assets or businesses; possible actions by customers, suppliers, competitors or regulatory authorities; and other risks detailed from time to time in IMUNON's filings with the Securities and Exchange Commission. IMUNON assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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