IMUNON Announces Database Lock for Phase 2 OVATION 2 Study with IMNN-001 in Advanced Ovarian Cancer

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Novel IL-12 Immunotherapy Administered with Standard of Care as First-Line Treatment

Expects topline results by the end of July

LAWRENCEVILLE, N.J., June 24, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in advanced development of its non-viral DNA-mediated immunotherapy, announces database lock for its Phase 2 OVATION 2 Study evaluating the safety and efficacy of IMNN-001 in patients with advanced ovarian cancer. Median Overall Survival (OS) and Progression Free Survival (PFS) have been reached and all patients in the open-label study have achieved treatment observation duration of 16 months, as required per protocol to evaluate efficacy. The independent statisticians have received the raw trial data and will follow the statistical analysis plan as they analyze the data from the trial. IMUNON expects to report topline results including hazard ratios before the end of July 2024.

OVATION 2 is evaluating the dosing, safety, efficacy and biological activity of intraperitoneal administration of IMNN-001 in combination with neoadjuvant chemotherapy (NACT) in patients newly diagnosed with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. Treatment in the neoadjuvant period is designed to shrink the tumors as much as possible for optimal surgical removal after three cycles of chemotherapy. Following NACT, patients undergo interval debulking surgery, followed by three additional cycles of adjuvant chemotherapy to treat any residual tumor. Patients were randomized 1:1 and evaluated for safety and efficacy to compare NACT plus IMNN-001 versus standard-of-care NACT. Patients randomized to the IMNN-001 treatment arm received up to 17 doses of 100 mg/m^2, in addition to NACT. Full enrollment of 110 patients was reached in September 2022.

The OVATION 2 Study is meant to inform the design of the intended Phase 3 trial and was not powered for statistical significance. Per the Statistical Analysis Plan (SAP), the primary efficacy analysis will be based on the Intent to Treat (ITT) population. The primary efficacy endpoint is PFS, with secondary endpoints including OS, Objective Response Rate, Chemotherapy Response Score and Surgical Response.

Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON, said, “Reaching data lock for the OVATION 2 Study is a significant achievement for our team and a step forward in our mission to bring an innovative treatment to patients battling ovarian cancer. With the last patient enrolled in September 2022, the analyses generated using the ITT population, an industry gold standard, will now have sufficient data maturity to analyze both PFS and OS endpoints with a good level of confidence. We are hopeful that IMNN-001 will offer improved outcomes and a much-needed alternative to those affected by this deadly disease.”

Sebastien Hazard, M.D., Ph.D., chief medical officer of IMUNON, added, “Given the maturity of our data, OS will be important in the readout of the trial and in planning the Phase 3 trial. As the definitive endpoint, OS has been observed across all tumor types as most reflective of the long-term benefit of immunotherapies. We look forward to the trial readout and sharing learnings from the trial with the patient and medical community.”

About IMNN-001 Immunotherapy

Designed using IMUNON's proprietary TheraPlas® platform technology, IMNN-001 is an interleukin-12 (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. IMUNON 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.

About Epithelial Ovarian Cancer

Epithelial ovarian cancer is the fifth deadliest malignancy among women in the United States. There are approximately 22,000 new cases of ovarian cancer every year and approximately 70% are diagnosed in advanced Stage III/IV. Epithelial ovarian cancer is characterized by dissemination of tumor in the peritoneal cavity with a high risk of recurrence (75% in Stage III/IV) after surgery and chemotherapy. Since the five-year survival rates of patients with Stage III/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 IMUNON

IMUNON is a 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 its modalities. The first modality, TheraPlas®, is developed for the coding of cytokines and other therapeutic proteins in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine®, is developed for the delivery of DNA-coded viral antigens that can elicit a strong immunological response.

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. IMUNON will continue to leverage this novel technology and to advance the therapeutic

potential of plasmid DNA to better serve patients with difficult-to-treat conditions. For more information, please 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. All statements, other than statements of historical fact, including, but not limited to, statements regarding the Company's IND application, expectations regarding the Phase 1 clinical study of IMNN-101, including with respect to enrollment for the study and reporting of data, the potential efficacy and safety profile of our PlaCCine platform, potential partnering opportunities, and the Company's plans and expectations with respect to its development programs more generally, are forward-looking statements. We generally identify forward-looking statements by using words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances). Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, uncertainties relating to 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 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, except to the extent required by law, to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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