IMUNON Announces IMNN-001 Abstract Accepted for Oral Presentation at 2025 ASCO Annual Meeting

April 21, 2025

Highly promising survival data from OVATION 2 Study of treatment of newly diagnosed advanced ovarian cancer to be presented

Initiation of Phase 3 trial sites underway for pivotal study of IMNN-001 following alignment on protocol with FDA

LAWRENCEVILLE, N.J., April 21, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in Phase 3 development of its DNA-mediated immunotherapy, today announced that an abstract highlighting new, highly encouraging, Overall Survival data from the Phase 2 OVATION 2 Study of IMNN-001 to treat women with newly diagnosed advanced ovarian cancer was accepted for oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting. The meeting is being held May 30 - June 3, 2025, in Chicago, Illinois and virtually. IMUNON recently announced alignment with the U.S. Food and Drug Administration (FDA) on the study protocol for the Phase 3 OVATION 3 clinical trial of IMNN-001 and has initiated trial site activation.

IMNN-001, based on the company's proprietary TheraPlas ® technology platform, is an interleukin-12 (IL-12) DNA plasmid vector encased in a nanoparticle delivery system, enabling cell transfection followed by persistent, local production and secretion of the IL-12 protein in the tumor microenvironment. IL-12 is a powerful pluripotent cytokine known for inducing strong anti-cancer immunity by promoting T-lymphocyte and natural killer cell proliferation while inhibiting tumor-mediated immune suppression. IMNN-001 is the first and only IL-12 immunotherapy to achieve a clinically effective response including overall survival benefit in frontline treatment in patients with advanced (Stage III/IV) ovarian cancer.

“We are pleased to have the opportunity to present new data from the Phase 2 OVATION 2 Study of IMNN-001 in an oral presentation at ASCO’s Annual Meeting,” said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. “This recognition underscores the significant potential of IMNN-001 to transform the treatment of women with newly diagnosed advanced ovarian cancer, an underserved population that has not seen treatment innovation in over 25 years, as we advance our Phase 3 program. We look forward to sharing more about our progress during this pivotal stage of development.”

About the OVATION 2 Study

OVATION 2 evaluated the dosing, safety, efficacy and biological activity of intraperitoneal administration of IMNN-001 in combination with neoadjuvant (NACT) and adjuvant chemotherapy (ACT) of paclitaxel and carboplatin (N/ACT) 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 ACT to treat any residual tumor. This open-label study enrolled 112 patients who were randomized 1:1 and evaluated for safety and efficacy to compare NACT plus IMNN-001 versus standard-of-care NACT. In accordance with the study protocol, patients randomized to the IMNN-001 treatment arm could receive up to 17 weekly doses of 100 mg/m^2 in addition to NACT. As a Phase 2 study, OVATION 2 was not powered for statistical significance. Additional endpoints included objective response rate, chemotherapy response score and surgical response.

About IMNN-001 Immunotherapy

Designed using IMUNON's proprietary TheraPlas® platform technology, IMNN-001 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. 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. IMUNON previously reported positive results from the recently completed Phase 2 OVATION 2 Study, which assessed IMNN-001 (100 mg/m^2 administered intraperitoneally weekly) plus neoadjuvant and adjuvant chemotherapy (N/ACT) of paclitaxel and carboplatin compared to standard-of-care N/ACT alone in 112 patients with newly diagnosed advanced ovarian cancer.

About Epithelial Ovarian Cancer

Epithelial ovarian cancer is the sixth deadliest malignancy among women in the U.S. There are approximately 20,000 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 tumors in the peritoneal cavity with a high risk of recurrence (75%, 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 gene-based delivery 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 gene delivery of 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 that has completed 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. The Company has completed enrollment for a first-in-human study of its COVID-19 booster vaccine (IMNN-101) which remains ongoing. IMUNON will continue to leverage these modalities and to advance the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions, and to further strengthen IMUNON's balance sheet through attractive business development opportunities. 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 timing for commencement and potential outcome of a Phase 3 trial of IMNN-001, the timing and enrollment of the Company's clinical trials, the potential of any therapies developed by the Company to fulfill unmet medical needs, the market potential for the Company's products, if approved, the potential efficacy and safety profile of our product candidates, 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, including the fact that interim results are not necessarily indicative of final results; the uncertainties of and difficulties in analyzing interim clinical data; the significant expense, time and risk of failure in 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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