IMUNON Presents Positive Phase 2 Translational Data of IMNN-001 in Advanced Ovarian Cancer at ESMO Gynaecological Cancers Congress 2025

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ASCO 2025 overall survival data bolster IMNN-001's potential in advanced ovarian cancer, supported by robust translational results at ESMO

Results from OVATION 2 Study reinforce IMNN-001 mechanism of action, producing IL-12 and key anti-cancer immune cytokines in the tumor-microenvironment post-treatment

Company currently advancing Phase 3 pivotal trial of IMNN-001, with first two sites initiated

LAWRENCEVILLE, N.J., June 18, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in Phase 3 development of its DNA-mediated immunotherapy, today announced the presentation of new positive translational data from the Phase 2 OVATION 2 Study of IMNN-001, its investigational gene-based interleukin-12 (IL-12) immunotherapy based on the Company's proprietary TheraPlas ® technology platform, for the treatment of newly diagnosed advanced ovarian cancer. Results are being highlighted in a poster presentation at the ESMO Gynaecological Cancers Congress 2025, taking place June 19-21, 2025, in Vienna, Austria.

The Phase 2 OVATION 2 Study assessed 112 participants treated with IMNN-001 (100 mg/m^2 administered intraperitoneally weekly) plus standard-of-care (SoC) neoadjuvant and adjuvant chemotherapy (N/ACT). IL-12 levels were sampled in the peritoneal fluid cavity, which is the primary tumor micro-environment. Results being presented at the ESMO Congress showed that treatment with IMNN-001 induced substantial increases in IL-12 and interferon-gamma (IFN-γ) and tumor necrosis factor-alpha (TNF-α), key downstream anti-cancer immune cytokines. Increases in IL-12, IFN-γ and TNF-α levels in the peritoneal cavity were approximately 27-, 62- and 36-fold following treatment, respectively, demonstrating the tumor-localized effect of IMNN-001 in women with advanced ovarian cancer. IMNN-001 continues to show a favorable safety profile.

"We are encouraged by these translational data being presented at the ESMO Gynaecological Cancers Congress 2025, which strongly complement the compelling overall survival results from the OVATION 2 trial presented at ASCO 2025," said Douglas V. Faller, M.D., Ph.D., Chief Medical Officer of IMUNON. "The clinical outcomes, showing a robust increase in overall survival for women with advanced ovarian cancer treated with IMNN-001 plus standard-of-care chemotherapy, align with these pharmacological and immunopathological findings. These results validate that IMNN-001 induces IL-12 and its downstream anti-tumor effectors, IFN-γ and TNF-α, exclusively at the tumor site with minimal systemic exposure, supporting our ongoing Phase 3 OVATION 3 trial."

At the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting and in a peer-reviewed article in Gynecologic Oncology, IMUNON presented unprecedented overall survival data from the Phase 2 OVATION 2 Study. Treatment with IMNN-001 plus SoC chemotherapy in women with newly diagnosed advanced ovarian cancer demonstrated consistent, clinically meaningful improvements in overall survival, progression-free survival, chemotherapy response score, and surgical response, with a favorable safety profile. IMUNON is advancing the pivotal Phase 3 OVATION 3 Study of IMNN-001, with the first two trial sites initiated in May 2025.

About the Phase 2 OVATION 2 Study

OVATION 2 evaluated the dosing, safety, efficacy and biological activity of intraperitoneal administration of IMNN-001 in combination with neoadjuvant and adjuvant chemotherapy (N/ACT) of paclitaxel and carboplatin 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 N/ACT, patients undergo interval debulking surgery, followed by three additional cycles of adjuvant chemotherapy 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 N/ACT plus IMNN-001 versus standard-of-care N/ACT. In accordance with the study protocol, patients randomized to the IMNN-001 treatment arm could receive up to 17 weekly doses of 100 mg/m2 in addition to N/ACT. 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/m2 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 multiple clinical trials including one Phase 2 clinical trial (OVATION 2). 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 has completed dosing in a first-in-human study of its COVID-19 booster vaccine (IMNN-101). The Company will continue to leverage these modalities and to advance, either directly or through partnership, the technological frontier 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 timing of 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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