IMUNON Presents IMNN-001 Phase 2 Translational Data in Advanced Ovarian Cancer Demonstrating 13-Month OS Extension via Tumor Micro-Environment Shift

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Results from OVATION 2 Study reinforce IMNN-001 efficacy benefits observed in the clinic and unique mechanism of action, producing key anti-cancer immune cytokines post-treatment

Pivotal Phase 3 trial of IMNN-001 underway, with four trial sites activated to date and on plan for site expansion to accelerate patient recruitment

LAWRENCEVILLE, N.J., Sept. 22, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (Nasdaq: IMNN), a clinical-stage company in Phase 3 development with 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 were highlighted in a presentation at the American Association for Cancer Research (AACR) Special Conference in Cancer Research: Advances in Ovarian Cancer Research held in Denver, Colorado.

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). IMUNON reviewed translational data on the changes induced by the local administration of IL-12 and its downstream effectors in the tumor micro-environment (TME) from paired samples (pre- and post-treatment) from study participants. Results presented at the AACR Special Conference demonstrated:

- Positive shift in the local TME to favorable immune stimulatory T cell ratios in the majority of participants treated with IMNN-001, including favorable ratios of CD8+/T regulatory (Treg) cells, CD8+/IDO+ cells, and CD8+/CD4+ cells.
- TME shift in favor of decreased immunosuppression cells (IDO+, PDL1+, Treg, CD4+) and increased immunostimulatory cells (CD8+, CD8+ effector, myeloid dendritic cells) in the majority of participants post-treatment.
- IMNN-001 treatment creates a "hot" anti-TME by increasing the recruitment of anti-tumor CD8+ and myeloid dendritic cells in 50-80% of the paired samples and decreasing immunosuppressive markers (IDO, PDL1, Treg cells) in 65-80% of the samples.
- IMNN-001 continues to show a favorable safety profile.

"These new translational data are very encouraging and strongly reinforce and are consistent with the unprecedented positive overall survival results previously reported from the OVATION 2 Study," said Douglas V. Faller, M.D., Ph.D., Chief Medical Officer of IMUNON and study presenter at the AACR conference. "Results from the study continue to validate our TheraPlas® technology and the broad impact of IMNN-001 on important cancer-fighting cytokines, effectively turning the tumor microenvironment from "cold" to 'hot' by activating both innate and adaptive immune systems, with limited to no systemic toxicities. IMNN-001 has shown significant therapeutic potential in clinical trials thus far, and the robust survival benefits and favorable safety profile observed align with these translational findings, supporting our ongoing Phase 3 OVATION 3 trial. We look forward to advancing the Phase 3 trial as quickly as possible for the many women with advanced ovarian cancer who are in urgent need of new, innovative treatment options."

The OVATION 2 Study poster presentation is available on the "Scientific Presentations" page of IMUNON's website at **https://investors.imunon.com/scientific-presentations**.

In July 2025, the Company announced treatment of the first patient in the pivotal Phase 3 OVATION 3 Study and is working with trial investigators to expand clinical sites and accelerate enrollment. Four sites have been activated to date and are open for patient enrollment.

About the OVATION 3 Study

OVATION 3 is IMUNON's pivotal Phase 3 study of IMMN-001, an IL-12 gene-mediated immunotherapy, in women with advanced epithelial ovarian cancer. The study is supported with unprecedented overall survival (OS) data from a large, 112-patient, randomized Phase 2 study showing the following:

- Median 13-month increase in OS (HR 0.70) and median 3-month increase in PFS (HR 0.79) in IMNN-001 treatment arm compared to standard of care alone.
- Better therapeutic effect observed with IMNN-001 treatment compared to the control arm (p=0.0375), as shown by mean 6.5-month extension of time free of progression or death (PFS + OS) captured in totality of treatment effect.
- Use of poly ADP-ribose polymerase (PARP) inhibitors as part of maintenance therapy further enhanced outcomes, with median OS not yet reached in the IMNN-001 treatment arm as patients surpass >5 years since randomization in the trial compared to 37 months on standard of care (HR 0.42).

The results from the OVATION 2 Study have resulted in invitations to present data from the Phase 2 Study at both the ASCO and ESMO annual

meetings and in the peer-reviewed journal Gynecologic Oncology.

OVATION 3 is currently enrolling patients at four trial sites with up to 46 additional sites being considered for activation.

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/m^2 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 score.

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 multiple clinical trials including one Phase 2 clinical trial (OVATION 2) and is currently conducting a Phase 3 clinical trial (OVATION 3). 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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