IMUNON to Present Phase 3 Ovarian Cancer Study of IMNN-001 at ESMO Congress

October 14, 2025

Prestigious European Society for Medical Oncology Conference “trials-in-progress” session

Pivotal OVATION 3 trial of its DNA-mediated immunotherapy in newly diagnosed patients underway

Company on track with established plans to accelerate patient recruitment

LAWRENCEVILLE, N.J., Oct. 14, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (Nasdaq: IMNN), a clinical-stage company in Phase 3 development with its DNA-mediated immunotherapy, today announced that a trials-in-progress abstract on the ongoing Phase 3 OVATION 3 clinical trial of IMNN-001, its investigational therapy for the treatment of women with newly diagnosed advanced ovarian cancer, was accepted for poster presentation at the European Society for Medical Oncology (ESMO) Congress 2025, being held October 17-21, 2025 in Berlin, Germany.

IMNN-001, based on IMUNON’s proprietary TheraPlas ® technology platform, is an interleukin-12 (IL-12) DNA plasmid vector incorporated 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 therapy to achieve a clinically effective response in advanced (stage IIIC/IV) ovarian cancer including benefits in both progression-free survival and overall survival in a first-line treatment setting when used with standard of care chemotherapy.

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, with up to 46 additional sites being considered for activation.

Details of the ESMO virtual poster presentation are as follows:

> **Abstract Title:** OVATION-3: A randomized phase III trial evaluating the safety and efficacy of intraperitoneal IL-12 gene therapy administered in combination with standard neoadjuvant and adjuvant chemotherapy (N/ACT) in newly-diagnosed patients with advanced epithelial ovarian cancer (EOC)
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> **Presenting Author:** Premal H. Thaker, M.D., Chief of Gynecologic Oncology, David & Lynn Mutch Distinguished Professor of Obstetrics & Gynecology, Director of Gynecologic Oncology Clinical Research at Washington University School of Medicine, Study Chair of OVATION 2 and Phase 3 OVATION 3 trials
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> **Poster Number:** 1234eTiP

Following the conference, the poster presentation will be available on the “Scientific Presentations” page of the IMUNON website at **https://investors.imunon.com/scientific-presentations**.

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 stage epithelial ovarian cancer. The study is supported with unprecedented overall survival (OS) data from a large, 112-patient, randomized Phase 2 OVATION 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 median OS of 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***.

The OVATION-3 trial is a robustly designed clinical study with at least 95% statistical power on the primary endpoint of overall survival. The trial design includes two planned interim analyses of the primary endpoint, designed to allow for an accelerated timeline for FDA submission of an IMNN-001 BLA if the primary endpoint reaches statistical significance. OVATION 3 is currently enrolling patients at four clinical 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 neoadjuvantly 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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