IMUNON Makes the Frontline Case for Phase 3 IMNN-001 Study: 14.7-Month OS Signal, Historical IL-12 Safety Barriers Overcome, Enrolling Ahead of Plan

September 24, 2026

2026 R&D Day presentation highlights include:

- Review of final Randomized Phase 2 overall survival results
- Supportive Preliminary MRD Study Data and translational findings
- Pathway to confirmatory readout in OVATION 3
- Testimonial conversation with an OVATION 1 participant now 10 years from diagnosis

LAWRENCEVILLE, N.J., Sept. 24, 2026 (GLOBE NEWSWIRE) -- IMUNON, Inc. (Nasdaq: IMNN), a clinical-stage biotechnology company developing DNA-mediated immunotherapies, today is presenting an update on its IMNN-001 development program for women with newly diagnosed advanced ovarian cancer. The program reviews final overall survival results from the randomized Phase 2 OVATION 2 Study, preliminary clinical and translational findings from the Phase 2 minimal residual disease (MRD) study conducted in partnership with Break *Through* Cancer and led by investigators at The University of Texas MD Anderson Cancer Center, and enrollment and operational progress in the ongoing pivotal Phase 3 OVATION 3 trial.

“A 14.7-month median overall survival difference observed in a 112-patient randomized Phase 2 study represents an important clinical signal that we believe warrants confirmation in a pivotal Phase 3 trial,” said Stacy R. Lindborg, Ph.D., President and Chief Executive Officer of IMUNON. “For women newly diagnosed with advanced ovarian cancer, it represents the potential for meaningful additional survival at a time when the frontline standard of care has changed very little in more than 25 years.”

Dr. Lindborg added, “If confirmed in Phase 3, IMNN-001 has the potential to become the first locally delivered IL-12 immunotherapy for frontline advanced ovarian cancer. In OVATION 2, women who received IMNN-001 plus neoadjuvant and adjuvant chemotherapy achieved a median overall survival of 45.1 months compared with 30.4 months for standard of care alone. Importantly, this survival signal was observed without the historical systemic safety challenges that limited earlier IL-12 programs. While OVATION 2 was not powered for overall survival, confirming that signal in OVATION 3, where overall survival is the primary endpoint, is the work in front of us.”

R&D Day Program Highlights

Dr. Lindborg opened the event by framing three questions the Company planned to present answers to: why systemic IL-12 failed historically, why IMNN-001 is different, and why the next stretch of OVATION 3 is the value-defining chapter of the program. Dr. Lindborg also closed the event by describing the Company’s near-term catalysts, including two pre-planned event-driven interim analyses in OVATION 3 designed to create a path to an earlier biologics license application for full approval if the survival signal crosses the pre-specified threshold.

Douglas V. Faller, M.D., Ph.D., Chief Medical Officer, IMUNON, reviewed why recombinant IL-12 programs were abandoned after dose-limiting systemic toxicity, and how IMNN-001 — an IL-12 DNA plasmid formulated with IMUNON’s proprietary TheraPlas® nanoparticle and administered intraperitoneally — is designed to produce durable, local IL-12 in the peritoneal cavity where advanced ovarian cancer lives and spreads. Key points presented included:

- IMNN-001 is not recombinant IL-12 cytokine injected into the bloodstream. Instead, it instructs the patient’s own cells to produce IL-12 locally, activating both innate and adaptive immunity and remodeling a “cold” tumor microenvironment toward a “hot” antitumor state.
- Immune biomarker work from OVATION 1 and OVATION 2 showed increased recruitment of CD8+ T cells, myeloid dendritic cells and M1 macrophages, with decreases in immunosuppressive markers, consistent with the intended mechanism of action.
- The OVATION 2 safety profile did not cause the toxicities that closed earlier systemic IL-12 programs: no cytokine release syndrome, no serious systemic immune-related adverse events of the type that historically halted development, and a consistent, manageable profile dominated by gastrointestinal events, including abdominal pain in a minority of patients associated with intraperitoneal administration.
- Independent data monitoring committees recommended continuation without modification for both OVATION 3 (mid-2026) and the MRD study (August 2026).

Premal H. Thaker, M.D., David & Lynn Mutch Distinguished Professor, Chief of Gynecologic Oncology and Director of Gynecologic Oncology Clinical Research at Washington University School of Medicine, and study chair of OVATION 2 and OVATION 3, while noting that OVATION 2 was not powered for survival, placed the survival results for OVATION 2 and plans for OVATION 3 in the context of a frontline standard that has been essentially unchanged for more than 25 years. Highlights included:

- In the intent-to-treat population of the randomized, 112-patient OVATION 2 study, median overall survival was 45.1 months with IMNN-001 plus neoadjuvant and adjuvant chemotherapy versus 30.4 months with standard of care alone, a 14.7-month difference. The benefit widened as the data matured from the July 2024 readout (11.1 months) to the December 2025 final analysis.
- In the PARP inhibitor maintenance subgroup, median overall survival was 65.6 months versus 41.4 months, a 24.2-month improvement.
- Primary and secondary endpoints and the safety profile in OVATION 2 favored IMNN-001, with translational evidence of local immune activation at the tumor site.
- OVATION 3 is a randomized, 1:1, approximately 500-patient pivotal trial in newly diagnosed Stage IIIB/C or IV epithelial ovarian, fallopian tube or primary peritoneal cancer recommended for neoadjuvant chemotherapy. Overall survival is the primary endpoint. The design includes two pre-planned, event-driven interim analyses intended to support a potential earlier submission for full approval.
- Operational progress: protocol submission to site activation in approximately six months; protocol approval to first patient randomized in approximately two months; observed study-level enrollment of about 0.5 patients per site per month versus a 0.3 planning assumption. The Company is targeting completion of enrollment in the first quarter of 2029.

Amir Jazaeri, M.D., Vice Chair for Clinical Research and Director of the Gynecologic Cancer Immunotherapy Program at MD Anderson Cancer Center, and lead principal investigator of the Phase 2 MRD study, presented preliminary clinical and translational findings, noting that while the sample size is still too small to evaluate efficacy, early results appear encouraging. Among patients who have reached second-look laparoscopy to date:

- Residual Disease (MRD)-positive rate: 44.4% (4/9) in the IMNN-001 arm versus 66.7% (6/9) in the control arm.
- Circulating tumor DNA (ctDNA) clearance: 87.5% (7/8) with IMNN-001 versus 62.5% (5/8) in control.
- No evidence of disease after frontline therapy: 9 of 9 evaluable patients (100%) in the experimental arm versus 5 of 9 (56%) in control.
- Biomarker data indicates IMNN-001 is preferentially taken up by macrophages in peritoneal fluid and tumor tissue, driving local IL-12 expression, remodeling of the tumor microenvironment, and expanding T-cell receptor clones consistent with induction of anti-cancer immunity. These findings are preliminary and based on patients who have reached the SLL assessment point.

William Bradley, M.D., Professor and Vice Chair for Clinical Research in the Division of Gynecologic Oncology at the Medical College of Wisconsin, and a principal investigator across OVATION 1, 2 and 3, joined an OVATION 1 participant in a prerecorded conversation on what diagnosis, successful treatment with IMNN-001, and the years that followed have meant to her in clinic and at home. The participant, treated with IMNN-001 on the Phase 1b OVATION 1 study, is now almost 10 years from diagnosis and reports remaining free of cancer recurrence.

Webcast
A replay webcast of the event and presentation materials will be available on the “Scientific Presentations” page of the IMUNON website at https://investors.imunon.com/scientific-presentations.

About the Phase 3 OVATION 3 Trial
The pivotal Phase 3 OVATION 3 trial is evaluating intraperitoneal IMNN-001 at 100 mg/m² in combination with standard-of-care neoadjuvant and adjuvant chemotherapy versus chemotherapy alone in patients with newly diagnosed Stage IIIB/C or IV epithelial ovarian, fallopian tube or primary peritoneal cancer. The trial is enrolling an all-comers population that includes both homologous recombination-deficient and homologous recombination-proficient patients; eligible patients who respond to first-line platinum-based chemotherapy will proceed to PARP inhibitor maintenance according to applicable guidelines and prescribing information. The primary endpoint is overall survival, with secondary endpoints including chemotherapy response score, surgical response score at interval debulking surgery, time to second-line treatment or death, and objective response rate.

About IMNN-001 Immunotherapy
Designed using IMUNON’s proprietary TheraPlas ® platform technology, IMNN-001 is an IL-12 DNA plasmid encased in a nanoparticle delivery system that enables cell transfection followed by persistent, local production 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. IMNN-001 has been evaluated as monotherapy and in combination regimens, including the completed Phase 1b OVATION 1 study and the randomized Phase 2 OVATION 2 study of IMNN-001 (100 mg/m² administered intraperitoneally weekly) plus neoadjuvant and adjuvant paclitaxel and carboplatin compared with standard-of-care chemotherapy alone in 112 women with newly diagnosed advanced ovarian cancer. IMNN-001 is now being studied in the pivotal Phase 3 OVATION 3 trial. The program has received Fast Track and Orphan Drug designation in the United States and orphan status in Europe.

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 being studied in 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 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 expectations regarding 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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