IMUNON Presents New Translational Data at SITC 2026 Demonstrating How IMNN-001 Activates and Sustains Anti-Tumor T-Cell Immunity in Advanced Ovarian Cancer

November 6, 2026

Analysis of paired patient biopsies from the randomized Phase 2 OVATION 2 study shows IMNN-001 increased CD8+/Treg, CD8+/CD4+ and CD8+/IDO+ ratios in both tumor and stroma

Findings provide an immunological mechanism for the 14.7-month improvement in final median overall survival reported with IMNN-001 in OVATION 2

Data reinforces the ongoing pivotal Phase 3 OVATION 3 trial, which will extend IMUNON's translational research program

LAWRENCEVILLE, N.J., Nov. 06, 2026 (GLOBE NEWSWIRE) -- IMUNON, Inc. (Nasdaq: IMNN), a clinical-stage biotechnology company developing DNA-mediated immunotherapies, today announced new translational data from its randomized Phase 2 OVATION 2 study of IMNN-001 in newly diagnosed advanced ovarian cancer. The data are being presented in a poster at the Society for Immunotherapy of Cancer (SITC) 41st Annual Meeting (SITC 2026), being held November 4-8, 2026, at the Phoenix Convention Center in Phoenix, Arizona.

The analysis evaluated paired tumor biopsies collected at screening laparoscopy and at interval debulking surgery from patients in both arms of OVATION 2, using 21 immune markers assessed by cyclic immunofluorescence. The results show that the addition of IMNN-001 to standard-of-care neoadjuvant and adjuvant chemotherapy (N/ACT) was primarily responsible for increased anti-tumoral T-cell activity, as measured by increases in the CD8+/Treg, CD8+/CD4+ and CD8+/IDO+ ratios in both the tumor and the stroma. Higher CD8+/Treg and CD8+/CD4+ ratios have been associated with improved patient outcomes in other studies. The chemotherapy component of the regimen contributed a complementary effect, supporting proinflammatory macrophage polarization and decreasing myeloid infiltration, particularly in the tumor.

These findings provide additional evidence that the combination of IMNN-001 with N/ACT favors the switch of the tumor microenvironment from immunologically “cold” to “hot,” supporting both the activation and the persistence of a T-cell immune response while suppressing pro-tumor myeloid cells. The findings corroborate translational results previously reported from the Phase 1 OVATION 1 study and provide a mechanistic rationale for the clinical benefit observed in OVATION 2, in which IMNN-001 improved final median overall survival by 14.7 months (45.1 months versus 30.4 months) compared with the standard-of-care control arm and median progression-free survival by three months.

“This data provides a compelling immunological explanation for the survival benefit we observed in OVATION 2,” said Stacy R. Lindborg, Ph.D., president and chief executive officer of IMUNON. “Seeing a consistent, treatment-driven shift in the tumor immune microenvironment in patient biopsies, rather than in a preclinical model, is an important validation of our TheraPlas platform. Presenting this work at SITC, the premier forum for cancer immunotherapy, reflects the growing scientific interest in our approach as we advance the pivotal Phase 3 OVATION 3 trial.”

“The central challenge in epithelial ovarian cancer has been its highly immunosuppressive tumor microenvironment, which has limited the effectiveness of immune therapies such as checkpoint inhibitors,” said Douglas V. Faller, M.D., Ph.D., chief medical officer of IMUNON. “What these paired serial patient biopsies show is that IMNN-001 delivers IL-12 where it is needed and dramatically remodels local immune balance in favor of the patient (from “cold” to immunologically “hot”), with minimal systemic IL-12 exposure and a highly favorable safety and tolerability profile. The complementary contributions of IMNN-001 and chemotherapy observed in this analysis help explain why this combination has translated into a survival benefit in the clinic.”

The Phase 3 OVATION 3 trial (NCT06915025) is currently enrolling and is designed to confirm the safety and survival benefit of IMNN-001 in frontline advanced ovarian cancer. The trial will also extend the immunological translational research program described in the poster.

Presentation Details

IMNN-001-mediated therapeutic delivery of IL-12 plasmid to tumor tissue and tumor microenvironment, promotes activation and persistence of T-cells which translates to a survival benefit in the clinic
Presenting author: Dr. Douglas Faller, IMUNON, Inc.
Abstract/Poster number: 478
Session: Poster Session 2, Saturday, November 7, 2026, 10 a.m.–2 p.m. and 6–8:10 p.m. MST
Location: Phoenix Convention Center, Phoenix, Arizona
The poster will be available on the Scientific Presentations section of the IMUNON website at www.imunon.com following the presentation.

About the OVATION 2 Study

The OVATION 2 Study (NCT03393884) was a randomized, controlled Phase 1/2 trial evaluating IMNN-001 (100 mg/m2 administered intraperitoneally weekly) in combination with standard-of-care neoadjuvant and adjuvant chemotherapy (N/ACT) of paclitaxel and carboplatin, compared with N/ACT alone, in 112 patients with newly diagnosed Stage III/IV epithelial ovarian cancer. The study included the collection of paired tumor tissue at screening laparoscopy and at interval debulking surgery to support translational research.

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 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 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-based gene therapy technology across its modalities. The lead 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 Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy being developed for the localized treatment of advanced ovarian cancer. IMNN-001 has been evaluated in multiple clinical trials including one Phase 2 clinical trial (OVATION 2) and is currently being studied in an ongoing 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. The Company will continue to leverage its 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 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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