



IMUNON Announces Data Monitoring Committee Recommends Continuation of Phase 3 OVATION 3 Study Without Modification

June 23, 2026

On track for enrollment of 80 participants by Q1 2027

Trial is supported by Phase 2 results showing significant improvement in overall survival in women with newly diagnosed advanced ovarian cancer

Novel immunotherapy technology demonstrating unprecedented IL-12 safety profile and extraordinary Phase 2 efficacy

LAWRENCEVILLE, N.J., June 23, 2026 (GLOBE NEWSWIRE) -- IMUNON, Inc. (Nasdaq: IMNN), a clinical-stage company in Phase 3 development with its DNA-mediated immunotherapy, today announced that the independent Data Monitoring Committee (iDMC) has recommended continuation of the pivotal Phase 3 OVATION 3 clinical trial evaluating IMNN-001 in combination with standard of care (SoC) neoadjuvant and adjuvant chemotherapy (N/ACT) in women with newly diagnosed advanced ovarian cancer.

"We are very pleased that the iDMC has recommended continuation of the landmark OVATION 3 clinical trial without modification, representing another important validation of the remarkable efficacy and safety data previously reported and further indicating the potential for IMNN-001 to represent a historic advance in the treatment of ovarian cancer," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "We remain ahead of our anticipated schedule in patient enrollment and this recommendation by the iDMC brings new levels of momentum to our efforts to advance this trial as rapidly as possible."

The pivotal Phase 3 OVATION 3 trial is a robustly designed clinical study with the primary endpoint of overall survival (OS). The trial design includes two planned interim analyses of the primary endpoint, designed to allow for an accelerated timeline for potential submission of a Biologics License Application (BLA) for full approval of IMNN-001 to the U.S. Food and Drug Administration (FDA) if the primary endpoint reaches statistical significance. With 27 patients enrolled to date, the trial remains on track to complete enrollment of approximately 80 patients by the end of Q1 2027. The strong benefit/risk profile, with an advantageous safety profile, has been validated in two successive randomized and controlled clinical trials.

"I want to express our gratitude to all of our investigators and to the patients who have supported this trial thus far, and also to our outstanding leadership team at IMUNON who have showed a remarkable level of dedication to advancing this trial and bringing a new option and new hope to women living with ovarian cancer," Dr. Lindborg added. "We look forward to updating on our progress in the months ahead."

About the Phase 3 OVATION 3 Study

OVATION 3 is an ongoing Phase 3 pivotal study to evaluate 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 activate the patient's immune system to recognize and eliminate tumor cells, while also shrinking the tumor 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 plus IMNN-001 to further stimulate anti-tumor immunity and treat any residual tumor. This randomized controlled study will enroll 500 patients, who will be 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 can receive up to 17 weekly doses of 100 mg/m² in addition to N/ACT. The primary endpoint of the trial is overall survival. Additional endpoints include objective response rate, chemotherapy response score, surgical response score, and time to second line therapy. The trial includes two interim analyses for assessment of efficacy, which could potentially serve as opportunities for early registration. OVATION 3 is currently enrolling at multiple sites throughout the US.

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. The Company reported a median 14.7-month increase in OS (45.1 vs. 30.4 months) in women in the IMNN-001 treatment arm compared to SoC alone, demonstrating continuous improvement in OS (3.6 delta). In addition, women treated with IMNN-001 and SoC chemotherapy plus poly ADP-ribose polymerase (PARP) inhibitors as part of maintenance therapy achieved a median increase in OS of 24.2 months (65.6 vs. 41.4 months) compared to SoC chemotherapy alone. With these efficacy results, IMNN-001 continued to maintain a highly favorable safety and tolerability profile. 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 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/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) 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 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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