



IMUNON Reports Updated Phase 2 Data Showing Continued Improvement in Median Overall Survival with IMNN-001 in Women with Newly Diagnosed Advanced Ovarian Cancer

March 25, 2026

The increase in median overall survival among women treated with IMNN-001 in the OVATION 2 trial rose from the previously reported 11.1 months to 14.7 months following final data analysis

Patients treated with PARP inhibitor therapy in addition to IMNN-001 and standard of care chemotherapy demonstrated median increase in OS of 24.2 months

Enrollment in IMUNON's Phase 3 pivotal trial for IMNN-001 remains ahead of plan, supported by continued strong interest from investigators and medical community

LAWRENCEVILLE, N.J., March 25, 2026 (GLOBE NEWSWIRE) -- **IMUNON, Inc. (Nasdaq: IMNN)**, a clinical-stage company in Phase 3 development with its DNA-mediated immunotherapy, today announced final clinical data from the completed Phase 2 OVATION 2 clinical trial evaluating IMNN-001 in combination with standard of care (SoC) neoadjuvant and adjuvant chemotherapy (N/ACT). The large randomized 112-patient study evaluated IMNN-001 in women with newly diagnosed advanced ovarian cancer. IMNN-001, the company's lead drug candidate, utilizes its proprietary non-viral DNA delivery platform, TheraPlas[®], the only nucleic acid nanoparticle technology showing promise in treating cancer. This novel immunotherapy is designed to recruit the entirety of the immune system by enabling locoregional secretion of the powerful cancer-fighting cytokine interleukin 12 (IL-12), altering the tumor microenvironment.

Based on prior data assessments, IMUNON previously reported a median 11.1-month increase in OS (40.5 vs. 29.4 months) in the IMNN-001 treatment arm compared to SoC chemotherapy alone. Following the most recent data assessment, the company is now reporting 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, the new IMNN-001 data showed that 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.

"It is very encouraging to see results from the OVATION 2 trial indicating that treatment with IMNN-001 was associated with an overall survival benefit of more than a year in patients treated with IMNN-001 plus chemotherapy and more than two years in women also receiving PARP inhibitors as part of maintenance therapy. These new findings are especially exciting given that there have been no meaningful advances in standard of care in ovarian cancer in the last 30 years," said 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, OVATION 2 Study Chair and Study Chair of Phase 3 OVATION 3 trial. "Importantly, with these new efficacy results, IMNN-001 continues to maintain a highly favorable safety and tolerability profile, further reinforcing the potential of this IL-12 immunotherapy to represent a landmark advance in treatment for women who are in desperate need of new and improved treatment options."

"With each new assessment of the findings from the OVATION 2 study, IMNN-001 has continued to show that it can improve overall survival in women with newly diagnosed advanced ovarian cancer while maintaining an advantageous safety profile," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "The strong response from our current trial investigators and the broader medical community supports our belief in the significant potential of IMNN-001 to make a meaningful difference in women's lives. We remain focused on executing our Phase 3 trial and advancing this promising therapy to the final stage of regulatory review as quickly as possible."

The pivotal Phase 3 OVATION 3 trial is a robustly designed clinical study with the primary endpoint of 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. OVATION 3 is currently enrolling patients at seven clinical sites with up to 43 additional sites being considered for activation. IMUNON anticipates enrolling approximately 80 patients (~20%) of the total target of 500 participants within the next year.

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. 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 letter 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.

Contacts:

Media

Jenna Urban
CG life
212-253-8881
jurban@cglife.com

Investors

Peter Vozzo
ICR Healthcare
443-213-0505
peter.vozzo@icrhealthcare.com



Source: Imunon, Inc.