# IMUNON Announces 2025 ASCO Annual Meeting Oral Presentation Highlighting Unprecedented Survival Data from Phase 2 Trial of IMNN-001 in Treatment of Newly Diagnosed Advanced Ovarian Cancer

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*Data show continuous* clinically significant improvement, with median 13-month and 3-month increases in overall and progression-free survival, respectively, in treatment group

Women treated with IMNN-001 and standard of care chemotherapy plus PARP inhibitors achieved nearly 12-month increase in PFS compared to standard of care; median OS in IMNN-001 treatment arm not yet reached after more than five years

Phase 2 OVATION 2 Study results also published in peer-reviewed journal Gynecologic Oncology

**LAWRENCEVILLE, N.J., May 23, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN)**, a clinical-stage company in Phase 3 development of its DNA-mediated immunotherapy, today announced new positive data from the Company's Phase 2 OVATION 2 Study of IMNN-001, an investigational therapy for the treatment of advanced ovarian cancer. Results are being highlighted in an oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, being held May 30 - June 3, 2025, in Chicago, Illinois and virtually, and are also being published simultaneously in the peer-reviewed journal *Gynecologic Oncology*.

Based on the highly encouraging Phase 2 OVATION 2 Study results and following alignment with the U.S. Food and Drug Administration (FDA), IMUNON recently initiated the first two sites for its pivotal Phase 3 OVATION 3 Study of IMNN-001 in newly diagnosed advanced ovarian cancer.

"We are very encouraged by these remarkable results and the fact that they are being presented in two of the most prestigious platforms in oncology research – the ASCO Annual Meeting and *Gynecologic Oncology,*" said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "As we continue to evaluate findings from our Phase 2 OVATION 2 Study, the data show consistently strong improvement in overall and progression-free survival, suggesting that IMNN-001 may drive positive outcomes that can truly make a difference in the lives of women with ovarian cancer, even for those with advanced and very difficult to treat stages of disease."

"The results from this Phase 2 trial are powerful and highly encouraging. Typically, an increase in survival of six months is considered clinically meaningful. The data being presented at ASCO indicate that IMNN-001 could extend the lives of women with newly diagnosed with advanced ovarian cancer by one year or longer, representing a potentially historic advance in standard of care," said Premal H. Thaker, M.D., Interim 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. "This is the first immunotherapy with a favorable safety profile to demonstrate survival benefits when used in conjunction with standard of care chemotherapy in a frontline setting. The fact that IMNN-001 has the potential to be used in conjunction with PARP inhibitors and in women with HRD and BRCA mutations is also particularly exciting. I look forward to helping enroll the Phase 3 trial in the months ahead."

Participants with newly diagnosed advanced epithelial ovarian cancer in the Phase 2 OVATION 2 Study (n=112) were randomized 1:1 to evaluate the safety and efficacy of IMNN-001 (100 mg/m$^2$ administered intraperitoneally weekly) plus neoadjuvant and adjuvant chemotherapy (N/ACT) compared to standard of care (SoC) N/ACT alone, with a median follow-up of 31 months. Among the findings being presented at the ASCO Annual Meeting:

- Patients in the intent-to-treat (ITT) population administered IMNN-001 plus SoC N/ACT achieved a median increase in overall survival (OS) of 13 months compared to SoC N/ACT alone (46 vs. 33 months), with a hazard ratio of 0.69.
- Increased therapeutic activity was observed among patients treated with poly ADP-ribose polymerase (PARP) inhibitors as part of standard maintenance therapy, with the median OS not yet reached in the IMNN-001 treatment arm after more than five years (vs. 37 months in the control arm), with a hazard ratio of 0.38.
- Increased therapeutic activity was also observed in women positive for homologous recombination deficiency (HRD+), including BRCA1 or BRCA2 mutations, with a hazard ratio of 0.42.
- For the ITT population, patients treated with IMNN-001 plus SoC N/ACT achieved a median 3-month increase in progression-free survival (PFS) compared to SoC N/ACT alone (14.9 vs. 11.9 months), with a hazard ratio of 0.79.
- Patients also receiving PARP inhibitors achieved a median 11.7-month increase in PFS when treated with IMNN-001 and SoC N/ACT compared to SoC N/ACT alone (33.8 vs. 22.1 months), with a hazard ratio of 0.8.
- IMNN-001 was well tolerated, with the most common adverse events (AEs) primarily including abdominal pain, nausea and vomiting. There were no reports of cytokine release syndrome, systemic toxicity or serious immune-related AEs.

The details of the ASCO oral presentation are as follows:

- **Abstract Title:** A phase I/II study of the safety and efficacy of intraperitoneal IMNN-001 in combination with neoadjuvant chemotherapy (NACT) of paclitaxel and carboplatin in patients newly diagnosed with advanced epithelial ovarian cancer (EOC): Updated survival analysis from OVATION-2 trial.
- **Presenting Author:** Premal H. Thaker, M.D., Washington University School of Medicine, OVATION 2 Study Chair
- **Date:** Tuesday, June 3, 2025

- **Session Time:** 8:00-9:30 a.m. CT
- **Session Title:** Gynecologic Cancer
- **Abstract Number:** 5516

“These data also further validate our TheraPlas technology platform on which IMNN-001 is based and its potential to harness the powerful immunological properties of IL-12 to target the tumor micro-environment and treat ovarian cancer effectively, while alleviating side effects often seen with other immunotherapies. We look forward to advancing our Phase 3 pivotal trial of IMNN-001 as quickly as possible in efforts to bring this novel therapy to the many women in desperate need of new treatment options,” added Dr. Lindborg.

In the pivotal Phase 3 OVATION 3 Study of IMNN-001, study participants will be randomized 1:1 and include women with newly diagnosed advanced ovarian cancer (stage IIIC or IV) who are eligible for N/ACT (the ITT population), with a sub-group of HRD+ women including those with BRCA1 or BRCA2 mutations. The primary endpoint of the study is OS, and secondary endpoints are surgical response score, chemotherapy response score, clinical response and time to second-line treatment. The study will also assess several exploratory endpoints.

**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 (NACT) 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 NACT, 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 NACT plus IMNN-001 versus standard-of-care NACT. 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 NACT. 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 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 (NACT) of paclitaxel and carboplatin compared to standard-of-care NACT 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). 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 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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