# IMUNON Announces First Patient Dosed in Phase 3 OVATION 3 Study of IMNN-001 in Newly Diagnosed Advanced Ovarian Cancer

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Initiation of additional trial sites and patient enrollment activities ongoing with multiple patients in screening

**LAWRENCEVILLE, N.J., July 30, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (Nasdaq: IMNN)**, a clinical-stage company in Phase 3 development of its DNA-mediated immunotherapy, today announced that the first patient has been dosed in the pivotal Phase 3 OVATION 3 Study evaluating the Company's lead candidate, IMNN-001, for the treatment of women with newly diagnosed advanced ovarian cancer. The first patient was dosed by Melanie K. Bergman, M.D., FACOG, Gynecologic Oncologist with Providence Medical Group at Providence Health in Spokane, Washington.

"IMNN-001 represents a potentially transformative therapy that, in combination with standard of care chemotherapy, may make a meaningful difference in the lives of women facing a new devastating diagnosis of advanced ovarian cancer," said Dr. Bergman. "IMNN-001 has shown significant therapeutic potential in clinical trials thus far, including consistent overall survival benefit across multiple treatment groups. We are pleased to be involved in the Phase 3 study and support its clinical development to further validate its safety and efficacy for women who currently have no effective options besides chemotherapy and surgery."

"It is very encouraging to see the strong interest and enthusiasm among the scientific community in our novel IMNN-001 program. Dosing the first patient is an important step forward and we expect to build on this momentum in the coming months as patient enrollment activities continue to accelerate in the OVATION 3 Study," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "We have great urgency around this program because patients do not have any other options besides the standard of care, which includes neoadjuvant and adjuvant chemotherapy and surgery. We have the resources in place needed to advance IMNN-001 efficiently and we are well positioned to fulfill our promise to help improve the standard of care for thousands of women worldwide with advanced ovarian cancer."

The Phase 3 OVATION 3 trial is designed to assess the safety and efficacy of IMNN-001 (100 mg/m$^2$ administered intraperitoneally weekly) plus neoadjuvant and adjuvant chemotherapy (N/ACT) of paclitaxel and carboplatin compared to standard of care (SoC) N/ACT alone. Study participants will be randomized 1:1 and include women with newly diagnosed advanced ovarian cancer (stage 3C or 4) who are eligible for neoadjuvant therapy, the intent-to-treat population, with a sub-group of women positive for homologous recombination deficiency (HRD), including BRCA1 or BRCA2 mutations. Participants who are HRD positive will receive poly ADP-ribose polymerase (PARP) inhibitors as part of standard maintenance therapy. The primary endpoint of the study is overall survival, 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.

In June 2025, IMUNON presented unprecedented positive overall survival data from the Phase 2 OVATION 2 Study of IMNN-001 at the American Society of Clinical Oncology (ASCO) Annual Meeting and in the peer-reviewed journal *Gynecologic Oncology.* Published OVATION 2 data showed that treatment with IMNN-001 plus SoC chemotherapy in women with newly diagnosed advanced ovarian cancer resulted in consistent, clinically meaningful improvements in several key endpoints across treatment groups, including overall survival, progression-free survival, chemotherapy response score and surgical response score, with a favorable safety profile. IMUNON also presented new translational data at the ESMO Gynaecological Cancers Congress demonstrating that IMNN-001 creates a "hot" anti-tumor microenvironment by recruiting CD8+ T cells, macrophages and dendritic cells into the tumor microenvironment and decreasing Treg suppressor cells. This biomarker research further validates IMNN-001's mechanism of action and selective immune activation at the tumor site.

**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/m$^2$ 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 score.

**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 (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). 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 of 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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