



IMUNON Reports Strong Enrollment Momentum in Phase 3 OVATION 3 Trial of IMNN-001 in Advanced Ovarian Cancer

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- Enrollment momentum exceeding expectations is based on highly promising survival (OS) data and well tolerated safety profile demonstrated in the Company's large, randomized Phase II study, OVATION 2
- Strong enrollment demonstrates the confidence of principal investigators from prestigious cancer institutions in the trial design and its potential for a successful outcome
- Enrollment ahead of plan across all study sites. Additional sites opening on pace with projections

LAWRENCEVILLE, N.J., July 30, 2026 (GLOBE NEWSWIRE) -- IMUNON, Inc. (Nasdaq: IMNN) ("IMUNON" or "the Company"), a clinical-stage biotechnology company developing its novel DNA-mediated immunotherapies, today is providing a progress update on its pivotal Phase 3 OVATION 3 trial of IMNN-001 in patients with newly diagnosed advanced ovarian cancer. Since initiating the trial, the Company has observed rapid site activation and an enrollment rate that is exceeding its forecast. The trial advanced from protocol submission to site activation in approximately 6 months and from protocol approval to first patient randomized in approximately 2 months, a third of the time of the external industry benchmark.

The currently observed study-level enrollment rate of approximately 0.5 patients per site per month meaningfully exceeds the assumed rate of 0.3 patients per site per month used in the trial plan. That planning assumption was already set at a premium relative to the Company's OVATION 2 experience and to historical industry ovarian cancer trials, which have generally enrolled at approximately 0.2 patients per site per month. The strong OVATION 3 enrollment is supported by highly promising clinical and biomarker data, most notably the overall survival (OS) evidence from the large, randomized Phase 2 OVATION 2 study and a high rate of conversion from pre-screening to randomization underscores strong interest in the trial by investigators and patients. More than 70% of sites are currently meeting or exceeding the assumed average enrollment rate of 0.3 patients per month. The Company now projects enrollment to be completed in the second quarter of 2029. Two pre-planned interim analyses are expected with the goal of early BLA filing for full regulatory approval if they achieve the pre-specified threshold.

"The early momentum we are seeing in OVATION 3 reflects the strength of our clinical data, the quality of our sites and the commitment of the investigators and patients participating in the trial," said Stacy Lindborg, Ph.D., President and Chief Executive Officer of IMUNON. "We've seen enrollment build quarter after quarter, including through the early summer months when trials typically slow down, a trend we view as a strong signal of investigator and patient engagement. The consistent safety profile we've now observed across multiple studies further re-enforces our confidence in IMNN-001, uniquely designed to safely exploit the pluripotent capability of IL-12 to recruit the entirety of the patient's own immune system to fight cancer, as we continue to advance our pivotal Phase 3 OVATION 3 trial."

IMNN-001 has continued to demonstrate a highly favorable safety and tolerability profile, with no observed episodes of cytokine release syndrome, systemic toxicities or serious immune-related adverse events that have historically foiled the use of IL-12 to effectively treat cancer patients. Safety profiles have been comparable between the two arms of the study (IMNN-001 plus neoadjuvant and adjuvant chemotherapy {N/ACT} versus N/ACT alone), consistent with observations from the Company's ongoing Phase 2 Minimal Residual Disease (MRD) study. No safety issues have been raised in recent Independent Data Monitoring Committee (IDMC) reviews of either ongoing study.

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 advanced epithelial ovarian 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 encased in a nanoparticle delivery system that enables cell transfection followed by persistent, local production 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-based gene therapy 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 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 the 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. 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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