IMUNON Announces Data Presented at ASCO Reinforces Unprecedented Overall Survival in Ovarian Cancer Phase 2 Study

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Consistent OS Efficacy Benefit Across Multiple Treatment Subgroups Demonstrates IMNN-001's Ability to Recruit a Powerful Anti-Cancer Immune Response

Results, presented simultaneously in oral presentation at ASCO 2025 and in peer-reviewed Gynecologic Oncology, suggest very meaningful survival effect of IMNN-001 in women HRP and HRD positive, including those with BRAC1 and BRCA2 mutations

LAWRENCEVILLE, N.J., June 03, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in Phase 3 development of its DNA-mediated immunotherapy, today announced positive data from the Company's Phase 2 OVATION 2 Study showing that treatment with IMNN-001 in women with newly diagnosed advanced ovarian cancer resulted in consistent, clinically meaningful improvements in several key endpoints across treatment groups, including overall survival (OS), progression-free survival (PFS), chemotherapy response score and surgical response. Treatment with IMNN-001 also showed a favorable safety profile, with no reports of serious immune-related adverse events. The full results are being presented today in an oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois, and simultaneously published in the peer-reviewed journal *Gynecologic Oncology*.

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. The data being presented today highlight the consistent results achieved across all treatment groups, demonstrating:

- Median 13-month increase in OS (46 vs. 33 months) and median 3-month increase in PFS (14.9 vs. 11.9 months) in IMNN-001 treatment arm compared to standard of care alone.
- Better therapeutic effect observed with IMNN-001 treatment compared to the control arm (p=0.0375), as shown by mean 6.5-month extension of time free of progression or death (PFS + OS) captured in totality of treatment effect.
- Use of poly ADP-ribose polymerase (PARP) inhibitors as part of maintenance therapy further enhanced outcomes, with median OS not yet reached in IMNN-001 treatment arm after >5 years compared to 37 months on standard of care.
- Chemotherapy response score highlights double the response rate of a complete or near complete histopathological response following treatment with 26.1% in the IMNN-001 treatment arm compared to 13.0% in the control arm.
- Surgical response rate of no macroscopic residual tumor left after surgery 64.6% in the IMNN-001 treatment arm compared to 52.1% in the control arm.
- Hazard ratio of 0.78 in study participants who are homologous recombination proficient (HRP) and hazard ratio of 0.42 in women positive for homologous recombination deficiency (HRD+), including BRCA1 or BRCA2 mutations, suggesting increased therapeutic activity.
- IMNN-001 was generally safe and well tolerated, with no reports of cytokine release syndrome, systemic toxicity or serious immune-related adverse events (AEs). The most common AEs primarily included abdominal pain, nausea and vomiting.

"These data highlighting the consistency of results across all treatment groups are a true testament to the power of our TheraPlas technology and the potential of IMNN-001 to transform the treatment paradigm of women who are newly diagnosed with advanced ovarian cancer and in desperate need of new treatment options," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "Results were consistent across a variety of participants, including women who receive PARP inhibitors, who are HRP and HRD positive, and who have BRCA1 and BRCA2 mutations. We are grateful for the continued support and participation of study participants and investigators and look forward to advancing our pivotal Phase 3 OVATION 3 trial of IMNN-001, with the first two trial sites recently initiated."

The OVATION 2 Study oral presentation and journal manuscript will both be available on the "Scientific Presentations" page of IMUNON's website at https://investors.imunon.com/scientific-presentations.

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.

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 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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