IMUNON Announces First Site Initiated for Pivotal Phase 3 OVATION 3 Study of IMNN-001 in Newly Diagnosed Advanced Ovarian Cancer

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Company currently initiating additional trial sites and working with study investigators to enroll participants

IMNN-001 is the first and only immunotherapy to show meaningful overall survival benefit in a Phase 2 trial in women with advanced ovarian cancer

Data from Phase 2 OVATION 2 Study are encouraging, with new IMNN-001 data to be highlighted in oral presentation at 2025 ASCO Annual Meeting

LAWRENCEVILLE, N.J., May 08, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in Phase 3 development with its DNA-mediated immunotherapy, today announced that the first trial site has been initiated for the Company's Phase 3 pivotal study, called OVATION 3, of its lead candidate IMNN-001 in development for the treatment of women with newly diagnosed advanced ovarian cancer. The first trial site is Washington University School of Medicine, and IMUNON is currently initiating additional trial sites and working with investigators to begin enrolling study participants.

"This represents a significant step forward for the IMNN-001 development program as we work toward bringing patients this novel IL-12 immunotherapy, the first and only product to show meaningful overall survival benefit in women newly diagnosed with advanced ovarian cancer who have not seen changes in standard of care treatment in more than 25 years," 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, and study-level principal investigator of the OVATION 3 trial. "It has been rewarding to be part of IMNN-001's development for more than a decade and see the progress being made, with highly encouraging data from the Phase 2 study including in women treated with PARP inhibitors as maintenance therapy. I look forward to helping advance the OVATION 3 trial and seeing the results."

The Phase 3 OVATION 3 trial will 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 (ITT) 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 (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.

In December 2024, the Company reported additional clinical data from ongoing analyses of results from the Phase 2 OVATION 2 Study of IMNN-001. IMUNON will highlight new IMNN-001 data from OVATION 2 in an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting, being held May 30 - June 3, 2025, in Chicago, Illinois.

"Initiating the first site for our Phase 3 pivotal trial is an important milestone in our efforts to make IMNN-001 available to women who receive the devastating diagnosis of advanced ovarian cancer and are in urgent need of additional treatment options," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "We are grateful for the continued dedication and support of our team, the investigators and, most importantly, the participants in our clinical trials and their families to help get us to where we are today. Together, we look forward to this next stage of development for IMNN-001, with the latest results bringing new hope that this therapy may make a meaningful difference in people's lives."

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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