IMUNON Finalizes Phase 3 Study Design with FDA for IMNN-001 in Newly Diagnosed Advanced Ovarian Cancer

March 24, 2025

First and only immunotherapy to show meaningful overall survival benefit in a Phase 2 trial in patients with advanced ovarian cancer

Initiation of trial sites underway for ground-breaking Phase 3 pivotal trial of DNA-mediated IL-12 therapeutic

Company to hold conference call on Tuesday, March 25, 2025, at 2:00 p.m. ET

LAWRENCEVILLE, N.J., March 24, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in Phase 3 development with its DNA-mediated immunotherapy, today announced that the U.S. Food and Drug Administration (FDA) is aligned with the protocol for the Phase 3 pivotal trial, called OVATION 3, of its lead candidate IMNN-001 in development for the treatment of women with newly diagnosed advanced ovarian cancer. The company is currently initiating trial sites and working with trial investigators to begin enrolling study participants.

"We are grateful for the ongoing guidance and support from the FDA and are very pleased that the agency is fully aligned on our plans related to the Phase 3 trial," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "The Phase 2 OVATION 2 study data are highly encouraging, demonstrating that IMNN-001 is the first immunotherapy to achieve a clinically effective response in ovarian cancer, including benefits in both progression-free and overall survival in frontline treatment, and we continue to observe strong improvements with additional monitoring and follow-up of patients. We look forward to potentially replicating these unprecedented results in the Phase 3 OVATION 3 study. We are currently initiating trial sites and are focused on enrolling study participants as quickly as possible as we work towards our goal of bringing thousands of women with advanced ovarian cancer a first-in-class and much-needed treatment option."

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 (NACT) of paclitaxel and carboplatin compared to standard of care (SoC) NACT alone. Study participants will be randomized 1:1 and include women with newly diagnosed advanced ovarian cancer (stage 3 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, IMNN-001 plus NACT boosted median overall survival to 46 months—outpacing standard-of-care NACT by 13 months—up 2 months from the prior 11-month mark after 7 additional months of follow-up, with an excellent safety profile showing no cytokine release syndrome or serious adverse events. In the same month, the company also announced a positive outcome from a Type C Chemistry, Manufacturing, and Controls (CMC) meeting with the FDA regarding current good manufacturing practice (cGMP) production of IMNN-001 for the Phase 3 trial and potential commercialization. Production of IMNN-001 is conducted at IMUNON's in-house manufacturing facility located in Huntsville, Alabama.

Conference Call and Webcast

IMUNON is hosting a conference call to discuss the Phase 3 OVATION 3 pivotal trial of IMNN-001 on Tuesday, March 25, 2025, at 2:00 p.m. ET. Company management will be joined by:

- 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 the OVATION 2 Study Chair
- L.J. Wei, Ph.D., Professor of Biostatistics, Harvard T.H. Chan School of Public Health

To participate in the call, please dial 833-816-1132 (Toll-Free/North America) or 412-317-0711 (International/Toll) and ask for the IMUNON Phase 3 protocol call. A live webcast of the call will also be available here.

The call will be archived for replay until April 8, 2025. The replay can be accessed at 877-344-7529 (U.S. Toll-Free), 855-669-9658 (Canada Toll-Free) or 412-317-0088 (International Toll), using the replay access code 9074731. An audio replay of the call will also be available here for 90 days.

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 Phase 2 development. 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. The Company has completed enrollment for a first-in-human study of its COVID-19 booster vaccine (IMNN-101) which remains ongoing. IMUNON will continue to leverage these modalities and to advance the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions, and to further strengthen IMUNON's balance sheet through attractive business development opportunities. 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 for commencement and potential outcome of a Phase 3 trial of IMNN-001, 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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