IMUNON Presents Positive Data from Phase 2 OVATION 2 Clinical Trial of IMNN-001 in Advanced Ovarian Cancer at SITC 39th Annual Meeting

November 7, 2024

IMNN-001 immunotherapy plus standard-of-care chemotherapy resulted in 35% improvement in overall survival and 25% improvement in progression-free survival versus standard-of-care alone

Treatment was generally well tolerated, with no reports of cytokine release syndrome or any other serious immune related adverse events

Company plans to initiate Phase 3 pivotal trial of IMNN-001 in Q1 2025

LAWRENCEVILLE, N.J., Nov. 07, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNA-mediated immunotherapy, today announced the presentation of new clinical data from the recently completed Phase 2 OVATION 2 Study of IMNN-001, its investigational interleukin-12 (IL-12) immunotherapy for the treatment of advanced ovarian cancer based on the company's proprietary TheraPlas ® technology. Results will be highlighted in a late-breaking poster session at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting, taking place November 6-10, 2024, in Houston, Texas and virtually.

IMNN-001 is an IL-12 DNA plasmid vector encased in a nanoparticle delivery system that enables cell transfection followed by persistent, local production and secretion of the IL-12 protein. IL-12 is one of the most active pluripotent cytokines for the induction of strong anti-cancer immunity acting through the induction of T-lymphocyte and natural killer cell proliferation, inhibiting tumor mediated immune suppression.

A total of 112 patients with newly diagnosed advanced ovarian cancer (intent-to-treat population) were enrolled in the Phase 2 OVATION 2 Study with a median follow-up of 24 months. Study participants 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 (NACT) of paclitaxel and carboplatin compared to standard-of-care NACT alone. The results being presented at the SITC Annual Meeting, as of June 21, 2024, demonstrated:

- Patients treated with IMNN-001 plus standard-of-care NACT lived 11.1 months (35%) longer than patients treated with NACT alone with a median overall survival (OS) of 40.5 months and 29.4 months, respectively (hazard ratio 0.74).
- IMNN-001 treatment was associated with better surgical outcomes compared to NACT alone with a surgical response rate of 64.6% and 52.1%, respectively. The chemotherapy response score, another measure of treatment benefit, was 26.1% in the IMNN-001 treatment group versus 13.0% in the control group.
- IMNN-001 was also associated with an improvement in progression-free survival (PFS) with a median PFS of 14.9 months in the IMNN-001 treatment group compared to 11.9 months in the control group (hazard ratio 0.79).
- The rate of complete response for best overall response, a measure of tumor shrinkage, was comparable across all study participants (n=1 in both groups, or 1.7% in IMNN-001 treatment group, 1.9% in the control group) when measured early in the study at debulking surgery.
- In a subgroup analysis of patients who received a PARP inhibitor as maintenance therapy, patients in the IMNN-001 treatment arm had a median PFS of 33.8 months versus 22.1 months in the control arm (hazard ratio 0.80) and median OS was not reached for the treatment arm versus 37.1 months for the control arm.
- IMNN-001 was generally well tolerated, with the most common adverse events (AEs) primarily gastrointestinal events (abdominal pain, nausea, vomiting). Pain management protocols were found to be effective. There were no reports of cytokine release syndrome or any other serious immune related AEs.

"These results from OVATION 2, including overall survival and progression-free survival among women with advanced ovarian cancer treated with IMNN-001 and NACT compared to standard-of-care NACT alone, reflect a meaningful improvement and show consistency across various endpoints and patient subgroups," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "This consistency brings great hope and excitement that these results can be replicated in Phase 3, and that IMNN-001 may offer a significant advancement in the treatment landscape for ovarian cancer. We look forward to our end-of-Phase 2 in-person meeting with the FDA to discuss plans for the Phase 3 pivotal trial, which we expect to start in the first quarter of next year."

"IMNN-001 is the first immunotherapy to achieve a clinically effective response in ovarian cancer, including benefits in both progression-free and overall survival, let alone in a first-line treatment setting," said study investigator and presenter Jennifer Scalici, M.D., Professor, Division of Gynecological Oncology, Emory University School of Medicine. "It is also especially encouraging that IMNN-001 offers benefits when used alongside PARP inhibitors, which have been very important in the treatment of advanced ovarian cancer but still present limitations in terms of OS benefits. There is a significant unmet need in treating women with ovarian cancer, which is the second deadliest gynecologic malignancy, and the promising results from the OVATION 2 Study represent the potential of IMNN-001 to offer a much-needed treatment option."

The details of the SITC poster presentation are as follows:

Abstract Title: Phase I/II study of Safety and Efficacy of Intraperitoneal IMNN-001 with Neoadjuvant Chemotherapy of Paclitaxel and Carboplatin in Patients Newly Diagnosed with Advanced Epithelial Ovarian Cancer
Presenting Author: Jennifer Scalici, M.D., Professor, Division of Gynecological Oncology, Emory University School of Medicine

Date: Friday, November 8, 2024
Time: 12:15-1:45 p.m. and 5:30 - 7:00 p.m. CST
Abstract Number: 1505

As previously announced, IMUNON plans to hold an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in person to discuss the design for a Phase 3 pivotal study of IMNN-001 in advanced ovarian cancer, with the trial expected to start in the first quarter of 2025.

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.

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. Additionally, the Company has entered a first-in-human study of its COVID-19 booster vaccine (IMNN-101). 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. 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 of a Phase 3 trial of IMNN-001, the timing and outcome of the Company's End-of-Phase 2 meeting with the FDA, 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 of 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.

Contacts:

Media
CG Life
Jenna Urban
212-253-8881
jurban@cglife.com

Investors
ICR Healthcare
Peter Vozzo
443-213-0505
peter.vozzo@westwicke.com

Source: Imunon, Inc.