IMUNON Announces Continued Strong Improvement in Overall Survival Data from Randomized Phase 2 OVATION 2 Study of IMNN-001

December 10, 2024

Based on more than six months of additional monitoring, data show continued improvement in overall survival (OS) in intent-to-treat (ITT) population of women newly diagnosed with advanced ovarian cancer

Median OS increased from 11 to 13 months in IMNN-001 treatment group based on latest data analysis

No change in IMNN-001 favorable safety profile including no reports of serious immune-related adverse events

IMUNON remains on track to initiate Phase 3 pivotal trial of IMNN-001 in Q1 2025

LAWRENCEVILLE, N.J., Dec. 10, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNA-mediated immunotherapy, today announced additional clinical data from ongoing analyses of results from the Company's Phase 2 OVATION 2 Study of IMNN-001, its investigational interleukin-12 (IL-12) immunotherapy for the treatment of advanced ovarian cancer based on its proprietary TheraPlas® technology. The updated results, based on an additional seven months of patient monitoring, show the hazard ratio (HR) decreased from 0.74 to 0.69, with an increase in median overall survival (OS) from 11.1 to 13 months following treatment with IMNN-001 plus standard-of-care (SoC) neoadjuvant and adjuvant chemotherapy (NACT) versus SoC alone. More than one-third of patients in the trial survived more than 36 months from the point of study enrollment, with 62% of those surviving patients from the IMNN-001 treatment arm and 38% from the SoC arm. Over 10% of trial participants have reached 48 months or beyond.

"These results indicate that OS benefits are being maintained in the population of patients treated with IMNN-001, providing strong additional validation of the potential for our novel IL-12 immunotherapy to represent a historic advance in the treatment of ovarian cancer," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "We understand the significant challenges that ovarian cancer presents to women and their families, especially women with advanced late-stage disease who are newly diagnosed, and that there is a desperate need for new treatments that can make a meaningful difference. We remain on track to initiate a Phase 3 pivotal clinical trial for IMNN-001 in advanced ovarian cancer in the first quarter of 2025 and look forward to updating on our progress."

The OVATION 2 Study included a total of 112 patients with newly diagnosed advanced ovarian cancer (intent-to-treat population). Study participants were randomized 1:1 to evaluate the safety and efficacy of IMNN-001 (100 mg/m^2 administered intraperitoneally weekly) plus NACT of paclitaxel and carboplatin compared to SoC NACT alone. Initial results from the OVATION 2 Study were reported in July 2024 and results were recently presented in a late-breaking session at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting in November 2024.

"While most research in ovarian cancer in recent years has focused on maintenance therapies for patients who have already responded to chemotherapy, the fact that we are seeing these positive results maintained in a population of newly diagnosed patients with advanced stages of disease requiring neoadjuvant chemotherapy is unprecedented and especially encouraging," 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 the OVATION 2 Study Chair. "As the first immunotherapy to achieve clinically effective progression-free and overall survival in ovarian cancer in conjunction with chemotherapy, we are especially excited to advance this promising program to a pivotal Phase 3 clinical trial."

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 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	**Investors**
CG Life	ICR Healthcare
Jenna Urban	Peter Vozzo
203-218-9180	443-213-0505
jurban@cglife.com	peter.vozzo@icrhealthcare.com

Source: Imunon, Inc.