IMUNON Announces Translational Data from Phase 1/2 OVATION 2 Study of IMNN-001 in Advanced Ovarian Cancer

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Data reinforce dose-dependent mechanism with IMNN-001 100mg/m^2 dose associated with 20% increase in IL-12 levels compared to 79mg/m^2 dose

Results from OVATION 2 Study continue to validate TheraPlas® technology, demonstrating DNA-mediated production of key anti-cancer immune cytokines following treatment

IMNN-001 continues to show favorable safety profile, with no reports of serious immune-related adverse events

LAWRENCEVILLE, N.J., Feb. 19, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company entering a pivotal Phase 3 trial of its DNA-mediated immunotherapy, today announced new translational 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 based on the company's proprietary TheraPlas ® technology, for the treatment of newly diagnosed advanced ovarian cancer. Results demonstrated a 20% increase in IL-12 levels in women treated with IMNN-001 (100 mg/m^2 administered intraperitoneally weekly) plus standard-of-care (SoC) neoadjuvant and adjuvant chemotherapy (NACT) compared to IL-12 levels in women treated with IMNN-001 (79 mg/m^2).

"These new data from the OVATION 2 Study confirm what we saw in the Phase 1 study and build on the robust body of evidence supporting the safety and strong overall survival results achieved with IMNN-001. These data also give us new levels of insight confirming the potential of our TheraPlas technology platform," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "We are especially pleased that we continue to observe a highly positive benefit-risk profile of IMNN-001, the first immunotherapy to achieve clinically effective progression-free and overall survival in advanced ovarian cancer in conjunction with chemotherapy. We look forward to advancing this program to a Phase 3 pivotal trial, which remains on track to start this quarter."

In this analysis increases in IL-12 levels were sampled in the peritoneal fluid cavity, which is the primary tumor microenvironment. Little to no changes were observed in the systemic blood stream of treated patients. In addition, the rise in IL-12 levels was accompanied by local increases in interferon-gamma (IFN-γ) and tumor necrosis factor-alpha (TNF-α), key downstream anti-cancer immune cytokines. Results showed no reports of serious immune-related adverse events including cytokine release syndrome.

"The increases in levels of IL-12 and positive downstream effects on IFN-γ and TNF-α indicate that IMNN-001 treatment is having a broad impact on important cancer-fighting cytokines and effectively targeting the tumor microenvironment with limited to no systemic toxicities," 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. "I look forward to hopefully seeing these remarkable results from the OVATION 2 Study replicated in a Phase 3 trial, which would further validate the significant potential of IMNN-001 to be transformative for the current standard of care for women with newly diagnosed advanced ovarian cancer."

In December 2024, IMUNON reported continued strong improvement in overall survival data from the Phase 2 OVATION 2 Study, demonstrating an improvement in median overall survival of 13 months following treatment with IMNN-001 (100 mg/m^2) plus SoC NACT compared to 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. More than 10% of trial participants have reached 48 months or beyond.

Also in December 2024, IMUNON announced the outcome of an End-of-Phase 2 in-person meeting with the U.S. Food and Drug Administration (FDA), supporting the advancement of IMNN-001 for the treatment of advanced ovarian cancer into a Phase 3 pivotal study. IMUNON remains on track to initiate a Phase 3 pivotal trial of IMNN-001 using the selected 100 mg/m^2 dose 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. 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. 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 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 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
jurban@cglife.com

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

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