

# IMUNON to Present Phase 2 Data of IMNN-001 in Treatment of Newly Diagnosed Ovarian Cancer at SITC 39th Annual Meeting

October 30, 2024

## Results from OVATION 2 Study of IMNN-001 to be highlighted in late-breaking acceptance

Company also announces FDA End-of-Phase 2 in-person meeting to discuss Phase 3 trial of IMNN-001

#### Phase 3 trial is expected to begin in Q1 2025

**LAWRENCEVILLE, N.J., Oct. 30, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN)**, a clinical-stage company in late-stage development with its DNA-mediated immunotherapy, today announced the acceptance of a late-breaking presentation featuring new clinical data from the Phase 2 OVATION 2 Study of IMNN-001, its investigational therapy for the treatment of advanced ovarian cancer, at the Society for Immunotherapy of Cancer (SITC) 39<sup>th</sup> Annual Meeting, being held November 6-10, 2024, in Houston, Texas and virtually. The company also announced 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.

The company's lead clinical program IMNN-001, designed using IMUNON's proprietary TheraPlas <sup>®</sup> platform technology, 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, inhibition of tumor mediated immune suppression.

"We are pleased to have the opportunity to present new data from the Phase 2 OVATION 2 Study of IMNN-001 in a late-breaking session at SITC's Annual Meeting," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "The growing body of evidence supporting IMNN-001 in the treatment of women with advanced ovarian cancer thus far is very encouraging, including the incredibly positive topline data we recently reported showing an 11.1-month increase in median overall survival among patients treated with IMNN-001 compared to patients treated with standard of care, representing a 35% improvement in survival. We look forward to sharing additional data from the OVATION 2 Study, including during our in-person meeting with the FDA to align on the trial design for our planned Phase 3 pivotal study. We are hopeful that the FDAs interest in meeting in person, as these discussions are often held virtually, suggests a deep interest in IMNN-001 and its promise as demonstrated in the Phase 2 study."

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., Adjunct Professor, Department of Gynecology & Obstetrics, 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: 9299

**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<sup>®</sup>, is developed for the coding of cytokines and other therapeutic proteins in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine<sup>®</sup>, is developed for the delivery of DNA-coded 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 <a href="https://www.imunon.com">www.imunon.com</a>.

# 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.

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