IMUNON Announces Positive CMC Meeting with FDA for IMNN-001 in Treatment of Advanced Ovarian Cancer

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Company aligned with FDA on CMC strategy and requirements in preparation of Phase 3 pivotal trial of IMNN-001

Vertical integration of major components assures a high-quality, commercially viable future manufacturing capability

On track to initiate Phase 3 pivotal trial of IMNN-001 in first quarter of 2025

LAWRENCEVILLE, N.J., Dec. 19, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNA-mediated immunotherapy, today announced the positive outcome of a Type C Chemistry, Manufacturing, and Controls (CMC) meeting with the U.S. Food and Drug Administration (FDA) regarding production of IMNN-001 for the treatment of women with newly diagnosed advanced ovarian cancer. The goal of the meeting was to seek alignment and agreement with the FDA on key CMC topics to support IMNN-001 production for the planned Phase 3 pivotal trial and a potential future new biologic license application (BLA) submission. IMUNON remains on track to initiate the 500-patient Phase 3 trial of IMNN-001 in the first quarter of 2025.

"We are very pleased with our recent FDA interactions as we continue to work collaboratively with the Agency to align on the most expeditious path to advance IMNN-001 into Phase 3 and toward potential commercialization for the thousands of women with newly diagnosed advanced ovarian cancer in need of additional treatment options," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "The FDA's agreement with our plan to meet key CMC requirements is highly encouraging, establishing our ability to produce our gene-mediated therapeutic for our Phase 3 pivotal trial as well as creating a highly cost-efficient framework for potential commercialization."

The meeting with the FDA included a review of IMUNON's current good manufacturing practice (cGMP) clinical-scale and commercial manufacturing process for IMNN-001, conducted at the company's manufacturing facility based in Huntsville, Alabama. The Agency agreed that the company's potency assay which measures interferon-gamma (IFN-γ) is acceptable for the Phase 3 clinical study and for use in a commercial setting for release of drug product. The FDA also agreed with the company's strategy to establish comparability of the core components of IMNN-001 produced by IMUNON with product previously produced through an external contract development and manufacturing organization (CDMO).

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 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.

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