IMUNON Announces Results from its End-of-Phase 2 Meeting with the FDA for its Lead IMNN-001 Clinical Program in Advanced Ovarian Cancer

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FDA Project Team supports the company's proposed Phase 3 trial strategy, including overall trial design, target patient population, treatment schedule, and primary endpoint

Final Protocol submission on track for December, supporting initiation of Phase 3 registrational trial in Q1 2025

LAWRENCEVILLE, N.J., Nov. 25, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNA-mediated immunotherapy, today announced the outcome of its recent End-of-Phase 2 in-person meeting with the U.S. Food and Drug Administration (FDA), supporting the advancement of its investigational interleukin-12 (IL-12) immunotherapy IMNN-001 for the treatment of advanced ovarian cancer into a Phase 3 pivotal study. IMUNON remains on track to initiate the 500-patient Phase 3 trial in the first quarter of 2025.

"The collaborative End-of-Phase 2 meeting with the FDA represents another important milestone in our IMNN-001 clinical program, and we are very pleased that the Agency is aligned with the potential for IMNN-001 to address a significant unmet need in ovarian cancer treatment and our Phase 3 plans," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "We are encouraged by the robust safety and efficacy data from our Phase 2 OVATION 2 Study, including the positive survival results recently presented in a late-breaking session at the SITC Annual Meeting. IMNN-001 is the first immunotherapy to achieve a clinically effective response in ovarian cancer, including benefits in both progression-free and overall survival in frontline treatment."

"Our goal is to replicate these remarkable results in a Phase 3 trial, which would be transformative for the current standard of care, substantially improving overall survival and giving hope to thousands of women with advanced ovarian cancer who continue to experience disease progression," Dr. Lindborg added.

The interaction with the FDA included an extensive review of data generated to date, including 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. The OVATION 2 Study results demonstrated that IMNN-001 immunotherapy plus standard-of-care chemotherapy resulted in approximately a one-year (35%) improvement in overall survival compared to treatment with standard-of-care chemotherapy alone. Treatment was also generally well tolerated, with no reports of cytokine release syndrome or any other serious immune related adverse events.

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.

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