IMUNON Reports Interim Progression-Free Survival and Overall Survival Data in Phase 1/2 OVATION 2 Study in Advanced Ovarian Cancer

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Intent-to-treat population shows 9-month OS improvement over control arm

Subgroup of patients treated with IMNN-001 + PARPi shows meaningful PFS and OS trend compared with control arm

Continued follow-up is indicated to confirm initial observations

LAWRENCEVILLE, N.J., Sept. 28, 2023 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage biotechnology company focused on developing DNA-mediated immunotherapies and next-generation vaccines, announces interim progression-free survival (PFS) and overall survival (OS) data with IMNN-001 in its Phase 1/2 OVATION 2 Study. IMNN-001 is the Company's IL-12 gene-mediated immunotherapy based on its TheraPlas ™ technology. Full enrollment of 110 patients was reached in September 2022.

OVATION 2 is evaluating the dosing, safety, efficacy and biological activity of intraperitoneal IMNN-001 in combination with neoadjuvant chemotherapy (NACT) in patients newly diagnosed with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. NACT 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 chemotherapy to treat any residual tumor.

As expected for a Phase 1/2 study, the study is directional and was designed with an 80% confidence interval to show an approximate 33% improvement in PFS, when comparing the treatment arm (NACT + IMNN-001) with the control arm (NACT only). The secondary endpoints include OS, objective response rate (ORR), pathological response, surgical response and serologic response. The study was not powered for p values of 0.05. The final readout of this study is expected by mid-2024. A positive readout would inform next development steps.

Interim data from the intent-to-treat (ITT) population being reported today show efficacy trends in PFS, demonstrating a delay in disease progression in the treatment arm of approximately 33% compared with the control arm, with the hazard ratio nearing the required value. Preliminary OS data follows a similar trend, showing an approximate 9-month improvement in the treatment arm over the control arm.

Subgroup analyses show patients treated with a PARP inhibitor (PARPi) as maintenance therapy had longer PFS and OS if they were also treated with IMNN-001 compared with patients treated with NACT only. This was not a pre-specified subgroup as PARP inhibitors were approved after the OVATION 2 Study was initiated.

- The median PFS in the PARPi + NACT group and the PARPi + NACT + IMNN-001 group was 15.7 months and 23.7 months, respectively.
- The median OS in the PARPi + NACT group was 45.6 months and has not yet been reached in the PARPi + NACT + IMNN-001 group.

While the data is still preliminary, the Company has concluded at this point that patients treated with a combination of NACT + PARPi + IMNN-001 appear to have the greatest benefit and should be the focus of on-going follow up.

IMUNON also continues to see benefits in other secondary endpoints including an approximately 20% higher R0 tumor resection score and a doubling of the CRS 3 chemotherapy response score to approximately 30% in the treatment arm versus 14% in the control arm. A complete tumor resection (R0) is a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Chemotherapy response score is considered a good prognostic indicator in ovarian cancer. Safety analyses continue to show good tolerability of IMNN-001 in this setting.

Commenting on the interim data, Dr. Corinne Le Goff, IMUNON's president and chief executive officer, said, "We are encouraged by these interim results and are particularly intrigued by the overall survival trends in the subgroup of patients who received PARP inhibitors, neoadjuvant chemotherapy and IMNN-001. While the number of patients in this subgroup is relatively small, this regimen may hold potential in treatment strategies as we continue to monitor patients enrolled in OVATION 2, with expectations to report topline results in mid-2024."

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. The Company 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 (EOC) is the fifth deadliest malignancy among women in the United States. There are approximately 22,000 new cases of ovarian cancer every year and approximately 70% are diagnosed in advanced Stage III/IV. EOC is characterized by dissemination of tumor in the peritoneal cavity with a high risk of recurrence (75% in 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 fully integrated, 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 four modalities. The first modality, TheraPlas ™, is developed for the coding of proteins and cytokines in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine ™, is developed for the coding of viral antigens that can elicit a strong immunological response. This technology may represent a promising platform for the development of vaccines in infectious diseases. The third modality, FixPlas ™, concerns the application of our DNA technology to produce universal cancer vaccines, also called tumor-associated antigen cancer vaccines. The fourth modality, which is in the discovery phase, IndiPlas ™, will focus on the development of personalized cancer vaccines, or neoepitope cancer vaccines.

The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in 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 is conducting IND-enabling preclinical studies for the development of a COVID-19 booster vaccine (IMNN-101) and a treatment for the Lassa virus (IMNN-102). The Company has also initiated preclinical work to develop a Trp2 tumor-associated antigen cancer vaccine in melanoma: IMNN-201. We 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 on IMUNON, 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. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, unforeseen changes in the course of research and development activities and in clinical trials; 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 acquisitions or licenses of other technologies, assets or businesses; possible actions by customers, suppliers, competitors or regulatory authorities; and other risks detailed from time to time in IMUNON's periodic reports and prospectuses filed with the Securities and Exchange Commission. IMUNON assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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