IMUNON Announces 11.1 Month Increase in Overall Survival in Patients with Newly Diagnosed, Advanced Ovarian Cancer Treated with IMNN-001

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- **Phase 2 OVATION 2 Study of IMNN-001 administered with standard-of-care chemotherapy as first-line treatment demonstrates a hazard ratio of 0.74 in overall survival (OS) in the intent-to-treat patient population compared with the standard-of-care control arm**
- **OS was extended by 15.7 months in patients receiving three or more doses of IMNN-001 in the 17-dose protocol**
- **Patients also receiving maintenance PARP inhibitor therapy demonstrated an OS hazard ratio of 0.41 in the IMNN-001 trial arm with median OS not yet reached at the time of data lock**
- **Robust and durable benefit of IMNN-001 observed in OS supported by a three-month improvement in the primary endpoint of progression-free survival (PFS)**
- **IMUNON expects to initiate a registrational study in Q1 2025**

Conference call begins today at 8:30 a.m. Eastern time

LAWRENCEVILLE, N.J., July 30, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNA-mediated immunotherapy, announces positive topline results from the Phase 2 OVATION 2 Study with IMNN-001 in patients with advanced ovarian cancer. OVATION 2 is a randomized study of IMNN-001 in combination with neoadjuvant and adjuvant chemotherapy (NACT) inclusive of interval debulking or cytoreductive surgery compared with a control arm of standard-of-care NACT alone. IMNN-001 is the Company's interleukin-12 (IL-12) immunotherapy based on its TheraPlas ™ technology.

Highlights from patients treated with IMNN-001 plus standard-of-care in a first-line treatment setting include:

- An 11.1 month increase in median OS compared with standard-of-care alone in the intent-to-treat population (ITT).
- A hazard ratio in the ITT population of 0.74, which indicates a 35% improvement in survival.
- Among the approximately 90% of trial participants who received at least 20% of specified treatments per-protocol in both study arms, patients in the IMNN-001 arm had a 15.7 month increase in median OS, representing a further extension of life with a hazard ratio of 0.64, a 56% improvement in survival.
- For the nearly 40% of trial participants treated with a poly ADP-ribose polymerase (PARP) inhibitor, the hazard ratio decreased further to 0.41, with median OS in the IMNN-001 treatment arm not yet reached at the time of database lock, compared with median OS of 37.1 months in the standard-of-care treatment arm.

The PFS results, the trial's primary endpoint, support the OS results with:

- A three-month improvement in PFS compared with standard-of-care alone.
- A hazard ratio in the intent-to-treat population of 0.79, indicating a 27% improvement in delaying progression for the IMNN-001 treatment arm.

"These strong and clinically meaningful Phase 2 results are highly encouraging, suggesting that IMNN-001 may improve the outcomes for women with advanced ovarian cancer. In the near term, we look forward to advancing our therapeutic into a Phase 3 pivotal study as soon as possible," said Stacy Lindborg, Ph.D., President and Chief Executive Officer of IMUNON. "Advancements in treatment options for advanced ovarian cancer in women who require neoadjuvant treatment have been limited over the years, and these patients continue to have poor prognoses. Our goal is for IMNN-001 to play an important role in the treatment regimen for the more than 300,000 women diagnosed with this deadly disease. On behalf of IMUNON, I extend heartfelt thanks to the women who participated in this trial, their families and the investigators."

OVATION 2 evaluated the dosing, safety, efficacy and biological activity of intraperitoneal administration of IMNN-001 in combination with 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.

Sebastien Hazard, M.D., Chief Medical Officer of IMUNON, added, "It is highly gratifying to witness the extraordinary overall survival benefit that IMNN-001 showed in this Phase 2 study further supported by consistency across data, including in progression-free survival and in the patients who received three doses or more of IMNN-001 gaining an additional 15.7 months of life, while the safety profile was tolerable. It suggests that IMUNON's IL-12 gene therapy has a long-term impact on the disease."

Commenting on the study results, 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, said, “Typically an increase in survival of six months is considered to be clinically meaningful, and extending survival from 29 months with standard-of-care treatment to 40 months with the addition of IMNN-001 is compelling. Importantly, the extension of survival among IMNN-001 patients also exposed to the new standard that includes PARP inhibitors is even greater. If confirmed in a Phase 3 clinical trial, IMNN-001 could reset the standard of care for women with ovarian cancer.”

Charles A. “Trey” Leath, III, M.D., Director, Division of Gynecologic Oncology, Ellen Gregg Shook Culverhouse Chair in Gynecologic Oncology, Professor, Department of Obstetrics and Gynecology at University of Alabama Medical Center, and OVATION 2 Principal Investigator, said, “I (We) have been investigating IMNN-001 since the Phase 1 OVATION 1 Study and continue to be frustrated by the lack of substantial progress in primary treatment options available to treat this disease. The results from this trial demonstrating that IMNN-001 could extend life by one year or longer are provocative and powerful. I believe that should efficacy be confirmed in a pivotal study, IMNN-001 will be quickly incorporated into the care regimen.”

IMUNON plans to hold an End-of-Phase 2 meeting with the U.S. Food and Drug Administration as soon as possible to discuss the protocol for a Phase 3 study, which is anticipated to begin in the first quarter of 2025. IMUNON also plans to present full OVATION 2 Study results at an upcoming medical conference and to submit the results for publication in a peer-reviewed medical journal.

Conference Call and Webcast

IMUNON is hosting a conference call at 8:30 a.m. Eastern time today to discuss OVATION 2 Study results, next steps and to answer questions. Dr. Thaker will be joining management on the call. To participate in the conference call, please dial 833-816-1132 (Toll-Free/North America) or 412-317-0711 (International/Toll) and ask for the IMUNON call. A live webcast of the call will be available here.

Participants are encouraged to preregister for the call here.

The call will be archived for replay through August 13, 2024. The replay can be accessed at 877-344-7529 (U.S. Toll-Free), 855-669-9658 (Canada Toll-Free) or 412-317-0088 (International Toll), using the replay access code 7783601. A webcast of the call will be available here for 90 days.

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 tumor 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 coding 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 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 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 IL-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, and to further strengthen IMUNON’s balance sheet through attractive business development opportunities. 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 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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