UPDATE - IMUNON's Ovarian Cancer R&D Day to Feature Presentations from IMNN-001 Clinical Study Investigators, Immunology and Biostatistics Experts, and Executive Management

September 9, 2024

September 18th Event in New York City to Include a Review of the Opportunity for Investigational Therapy IMNN-001 (IL-12) to Treat Advanced Ovarian Cancer and Clinical Development Timeline

LAWRENCEVILLE, N.J., Sept. 09, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company in late-stage development with its DNA-mediated immunotherapy, will hold its first Ovarian Cancer R&D Day on September 18, 2024 at the Harvard Club (35 West 44th Street) in New York City. The event will feature presentations and updates on the development program for IMNN-001, Imunon's investigational therapy currently in development for the treatment of ovarian cancer. Presentations from KOLs including clinical study investigators, immunology and biostatistics experts and company management will take place from 10:00 a.m. to 12:00 p.m. Eastern time, followed by lunch and informal conversations with presenters from 12:00 p.m. to 1:00 p.m. Eastern time.

To RSVP for the event, please register here.

Plans for the Ovarian Cancer R&D Day event follow IMUNON's recent announcement of positive topline data from its randomized Phase 2 OVATION 2 Study of IMNN-001 showing that treatment was associated with an 11.1 month increase in median OS in the intent-to-treat population, representing a 35% improvement in survival among patients with advanced disease.

The R&D Day program will include insights from thought leaders with expertise in ovarian cancer and immunology and principal investigators from IMNN-001 clinical studies. The agenda will include a review of the OVATION 2 Study results, assessments of oncology clinical trial endpoints and a discussion of the potential role of IMNN-001 in the treatment of advanced ovarian cancer. In addition, IMUNON management will review next steps in the development program for IMNN-001 and the potential impact treatment could have on standard of care.

Presenters during the R&D Day event will include (listed in order of presentations):

- Sid Kerkar, M.D., T cell biology review editor, *Frontiers in Immunology*. Dr. Kerkar will discuss the important role of IL-12 in treating cancer.
- William Bradley, M.D., Professor, Obstetrics and Gynecology, Gynecologic Oncology, Medical College of Wisconsin. Dr. Bradley will discuss the data highlighting the safety and efficacy of IMNN-001.
- L.J. Wei, Ph.D., Professor of Biostatistics, Harvard T.H. Chan School of Public Health. Dr. Wei will discuss the opportunity to combine PFS and OS to provide a clinically interpretable evaluation of the IMNN-001 treatment effect.
- Amir Jazaeri, M.D., Vice Chair for Clinical Research, Director, Gynecologic Cancer Immunotherapy Program, Department of Gynecologic Oncology and Reproductive Medicine, University of Texas MD Anderson Cancer Center. Dr. Jazaeri will discuss the ongoing Phase 1/2 study of IMNN-001 in combination with bevacizumab in advanced ovarian cancer, for which he serves as principal investigator, including the importance of minimal residual disease and early translational insights.
- Premal Thakker, M.D, David & Lynn Mutch Distinguished Professor of Obstetrics & Gynecology, Chief of Gynecologic Oncology, Interim Director of Gynecologic Oncology Clinical Research, Professor of Gynecologic Oncology, Washington University School of Medicine, and the OVATION 2 Study Chair. Dr. Thaker will discuss the OVATION 2 topline results and their clinical significance beyond the reported topline results.

IMUNON executives at the R&D Day event will include:

- Stacy R. Lindborg, Ph.D., President and CEO, will provide an overview of treatment for women newly diagnosed with ovarian cancer and discuss how IMNN-001 has the potential to change the paradigm as well as planning for a Phase 3 registration study.
- Khursheed Anwar, Ph.D., Chief Scientific Officer, will review the company's TheraPlas technology platform, among other topics.

IMUNON strongly encourages in-person attendance to facilitate networking and direct engagement with speakers and management. For those unable to attend in person, a webcast will be available using the same registration link as above.

OVATION 2 Study Topline Results

OVATION 2 evaluated the dosing, safety, efficacy and biological activity of intraperitoneal administration of IMNN-001 in combination with neoadjuvant and adjuvant chemotherapy (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 announced on July 30, 2024, 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 overall survival (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.

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 that has completed Phase 2 clinical studies. 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 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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