IMUNON CEO RECAPS A YEAR OF CLINICAL ACHIEVEMENT AND SOLID FUNDAMENTALS

June 2, 2025

Outstanding Phase 2 Results will be discussed at the 2025 ASCO in an Oral Presentation and featured in peer reviewed medical journal Gynecologic Oncology

Phase 3 OVATION 3 Study in progress

LAWRENCEVILLE, N.J. , June 02, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN)

Dear Valued Shareholders,

A Year of Breakthroughs: IMUNON Has Never Been Stronger

As I mark my first year as President and CEO of IMUNON, I am thrilled to share the progress we have made in advancing our mission to transform cancer treatment. With robust fundamentals and groundbreaking clinical data, your company is well positioned to deliver an innovative therapy and to create significant value for you, our shareholders.

Progress with IMNN-001: A Potential Game-Changer for Ovarian Cancer

Over the past year, we have achieved remarkable milestones, most notably with our lead candidate, IMNN-001, which has entered the pivotal Phase 3 OVATION 3 Study for the frontline treatment of women newly diagnosed with advanced ovarian cancer. The Phase 2 OVATION 2 Study (n=112, median follow-up of 31 months) has demonstrated powerful and highly encouraging results, positioning IMNN-001 as a potential advance in the standard of care. Key findings, that will be presented tomorrow, June 3, in an oral presentation at the prestigious American Society of Clinical Oncology (ASCO) Annual Meeting and are also being published simultaneously in Gynecologic Oncology, include:

- Significant Survival Benefits: In the intent-to-treat (ITT) population, IMNN-001 plus standard-of-care neoadjuvant and adjuvant chemotherapy (N/ACT) extended median overall survival (OS) by 13 months (46 vs. 33 months) compared to standard-of-care N/ACT alone, with a hazard ratio of 0.69. As Dr. Premal H. Thaker, OVATION 2 Study Chair and Interim Chief of Gynecologic Oncology at Washington University School of Medicine, noted, “An increase in survival of six months is considered clinically meaningful. The data indicating that IMNN-001 could extend lives by one year or longer represent a potentially historic advance.”

- Enhanced Efficacy with PARP Inhibitors: For patients receiving poly ADP-ribose polymerase (PARP) inhibitors as maintenance therapy, median OS in the IMNN-001 arm has not yet been reached after more than five years (vs. 37 months in the control arm), with a hazard ratio of 0.38.

- Strong Results in HRD+ and BRCA Populations: Increased therapeutic activity was observed in women with homologous recombination deficiency (HRD+), including BRCA1/2 mutations, with a hazard ratio of 0.42.

- Consistency of Clinical Data: Consistency, across multiple endpoints, subgroups and data analyses, suggest that the OS results are real and have great promise to be confirmed in our Phase 3 study, and particularly in the HRD+ and BRCA-mutated population where this important subgroup readout may occur much sooner than in the ITT population.

- Favorable Safety Profile: IMNN-001 was well tolerated, with primarily manageable adverse events (e.g., abdominal pain, nausea, vomiting) and no reports of cytokine release syndrome, systemic toxicity, or serious immune-related adverse events, making it a promising first-in-class immunotherapy.

- Our dialogue with the U.S. Food and Drug Administration (FDA), to date, has not identified any fundamental weaknesses in our data, analyses or assumptions. Their alignment in support of our Phase 3 trial was quick and unambiguous.

With these results, IMNN-001 becomes the first immunotherapy with a favorable safety profile to demonstrate survival benefits in a frontline setting leading to the potential to transform ovarian cancer treatment.

TheraPlas Platform: A Foundation for Broad Impact

The TheraPlas platform, which powers IMNN-001, leverages the immunological properties of interleukin-12 (IL-12) to target the tumor microenvironment effectively. These data further validate TheraPlas’ potential to treat ovarian cancer while alleviating side effects often seen with other immunotherapies. Beyond ovarian cancer, we are exploring IMNN-001 applications in other tumor types and TheraPlas’ ability to carry other therapeutic DNA payloads, both of which could unlock significant opportunities for growth and partnerships.

Growing Momentum and Financial Discipline

Our clinical success has attracted increasing interest from institutional investors, reflecting confidence in our science and strategy. The recent upward trajectory in our share price positions us well to potentially meet the $1 NASDAQ listing requirement in the near term. As we prepare for the Phase 3 OVATION 3 Study, which will evaluate IMNN-001 in women with stage IIIC or IV ovarian cancer (randomized 1:1, with OS as the primary endpoint), we are committed to funding this pivotal trial strategically. We have taken steps to conserve cash and align our critical needs with available capital on hand, while securing the resources needed to advance this potentially transformative therapy through optimal opportunities.

Looking Ahead: A Bright Future for IMUNON

With a pivotal Phase 3 trial on the horizon, compelling data validating our TheraPlas platform, and a clear financial strategy, IMUNON is poised for transformative growth. We are dedicated to bringing IMNN-001 to patients in desperate need of new treatment options while delivering sustainable value to you, our shareholders.

On behalf of the entire IMUNON team, thank you for your continued support and belief in our vision. Together, we are building a company that has the potential to redefine cancer care. I look forward to sharing more milestones as we advance toward our goal.

Sincerely,

Stacy R. Lindborg, Ph.D.
President and Chief Executive Officer
IMUNON, Inc.

Forward-Looking Statements

IMUNON wishes to inform readers that forward-looking statements in this letter 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 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 in 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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