



## **IMUNON Reports Independent Data Monitoring Committee Recommends Continued Phase 2 Development of IMNN-001 Following Favorable Safety Review**

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Independent Data Monitoring Committee recommends the ongoing Phase 2 MRD study continue without modification following its review of all safety data to date

No cytokine release syndrome, systemic toxicities or serious immune-related adverse events observed to date, reinforcing IMNN-001's differentiated safety profile as an IL-12-based immunotherapy

MRD study has now demonstrated the safety and tolerability of IMNN-001 both in combination with bevacizumab and in the maintenance setting

Recommendation follows encouraging preliminary Phase 2 MRD data reported in July demonstrating evidence of deeper anti-tumor activity and immune activation

**LAWRENCEVILLE, N.J., Sept. 22, 2026 (GLOBE NEWSWIRE)** -- IMUNON, Inc. (Nasdaq: IMNN), a clinical-stage biotechnology company developing DNA-mediated immunotherapies, today announced that the Independent Data Monitoring Committee (IDMC) overseeing its ongoing Phase 2 minimal residual disease (MRD) translational study of IMNN-001 has reviewed all safety data to date and recommended that the study continue without modification after identifying no new safety signals and confirming comparable safety across both treatment arms.

The IDMC is comprised of independent medical experts in gynecologic cancers. The Phase 2 MRD study is a randomized, controlled translational study assessing minimal residual disease following treatment with standard-of-care chemotherapy and bevacizumab, with or without IMNN-001, in women with newly diagnosed advanced ovarian cancer. The multi-site study is being conducted in collaboration with Break *Through* Cancer and is led by investigators at The University of Texas MD Anderson Cancer Center.

"The IDMC's recommendation to continue our Phase 2 MRD study without modification provides important independent validation of the favorable safety profile we have consistently observed across our clinical development program," said Stacy Lindborg, Ph.D., President and Chief Executive Officer of IMUNON. "Across our completed and ongoing clinical studies, we have observed no cytokine release syndrome, no systemic toxicities and no serious immune-related adverse events—an important distinction for an IL-12-based immunotherapy. Combined with the encouraging biological and clinical activity reported from this study in July, these findings further strengthen our confidence as we continue advancing our pivotal Phase 3 OVATION 3 trial."

Consistent with this experience, the latest IDMC review identified no new safety concerns in the ongoing pivotal Phase 3 OVATION 3 trial. The MRD study has also achieved two important safety objectives by demonstrating the safety and tolerability of IMNN-001 both in combination with bevacizumab and in the maintenance setting.

In July 2026, the Company reported encouraging preliminary data from the MRD study, which is designed both to evaluate clinical activity and to better understand how IMNN-001 remodels the tumor immune microenvironment following frontline treatment. Among patients who reached the study's primary assessment at second-look laparoscopy, treatment with IMNN-001 was associated with:

- A lower rate of MRD positivity compared with the control arm (44% versus 67%);
- Higher clearance of circulating tumor DNA (ctDNA) (87.5% versus 62.5%); and
- A higher proportion of patients achieving "no evidence of disease" following frontline therapy (100% versus 56%).

While preliminary and based on a limited number of patients, these findings provide encouraging evidence that IMNN-001 may drive deeper anti-tumor responses while maintaining the highly favorable safety profile consistently observed across the Company's clinical development program. These clinical findings are supported by translational analyses that demonstrated robust IL-12 expression within macrophages, activation of downstream cytokines including interferon-gamma, and evidence of both macrophage and T-cell activation, consistent with remodeling the tumor immune microenvironment from an immunologically "cold" state to one that is immunologically active, or "hot."

### **About the Translational Phase 2 MRD Study**

The Phase 2 MRD study (NCT05739981) is evaluating IMNN-001 in combination with standard-of-care neoadjuvant and adjuvant chemotherapy plus bevacizumab in women with newly diagnosed advanced ovarian cancer, conducted through the Break *Through* Cancer Targeting Minimal Residual Disease in Ovarian Cancer TeamLab. Patients in the experimental arm receive IMNN-001, administered intraperitoneally, in combination with N/ACT plus bevacizumab, followed by interval cytoreductive surgery and additional cycles of adjuvant chemotherapy plus IMNN-001. Patients then undergo second-look laparoscopy (SLL) to assess for minimal residual disease, followed by maintenance therapy assigned according to homologous recombination deficiency (HRD) status. The primary endpoint of the study is MRD-positive rate at SLL; the secondary endpoint is progression-free survival (PFS). The study also includes serial translational analyses of tumor tissue, circulating tumor DNA (ctDNA), microbiome, and intraperitoneal fluid, to further characterize IMNN-001's impact on the tumor immune microenvironment.

### **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 neoadjuvantly in patients with newly diagnosed ovarian cancer. IMUNON previously reported positive results from the completed Phase 2 OVATION 2 Study, which assessed IMNN-001 (100 mg/m<sup>2</sup> administered intraperitoneally weekly) plus neoadjuvant and adjuvant chemotherapy (N/ACT) of paclitaxel and carboplatin compared to standard-of-care N/ACT alone in 112 patients with newly diagnosed advanced 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-based gene therapy technology across its modalities. The first modality, TheraPlas<sup>®</sup>, 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 Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy being developed for the localized treatment of advanced ovarian cancer. IMNN-001 has been evaluated in multiple clinical trials including one Phase 2 clinical trial (OVATION 2) and is currently being studied in the ongoing Phase 3 clinical trial (OVATION 3). 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 completed dosing in a first-in-human study of its COVID-19 booster vaccine (IMNN-101). The Company will continue to leverage these modalities and to advance, either directly or through partnership, the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions. For more information, please visit [www.imunon.com](http://www.imunon.com).

### About Break Through Cancer

Founded in 2021, Break Through Cancer empowers outstanding researchers and physicians to both intercept and find cures for several of the deadliest cancers by stimulating radical collaboration among outstanding cancer research institutions, including its founding partners: Dana-Farber Cancer Institute, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Memorial Sloan Kettering Cancer Center, MIT's Koch Institute for Integrative Cancer Research, and The University of Texas MD Anderson Cancer Center.

The Foundation is supported by a Board of Directors from the five partner institutions and a Scientific Advisory Board of U.S. cancer experts. The Foundation was launched with an extraordinary challenge pledge of \$250 million from Mr. and Mrs. William H. Goodwin, Jr. and their family, and the estate of William Hunter Goodwin III.

For further information, please visit the Foundation's website at [www.breakthroughcancer.org](http://www.breakthroughcancer.org).

### Forward-Looking Statements

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