IMUNON Announces Six-Month Data Showing Durability of Protection for Next-Generation DNA Vaccine Platform in Phase 1 Clinical Trial in COVID-19

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Company's PlaCCine ® technology platform demonstrates better durability and other advantages compared to mRNA vaccines

Results further validate PlaCCine as a novel vaccine platform with potential applications in COVID-19 and other infectious diseases with epidemic implications

LAWRENCEVILLE, N.J., May 15, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company focused on developing non-viral DNA-mediated immunotherapies and evaluating an adaptation of the platform's potential as a next-generation vaccine, today announced new data from its first Phase 1 proof-of-concept clinical trial of IMNN-101, an investigational DNA plasmid vaccine based on the Company's proprietary PlaCCine® technology platform, for protection against COVID-19. Results in 24 healthy volunteers demonstrated IMNN-101's durability of protection at six months after a single dose targeting the SARS-CoV-2 Omicron XBB1.5 spike antigen variant. IMNN-101 induced up to a 3-fold median increase in the serum neutralizing antibody (NAb) titers from baseline at six months, with initial evidence of a stronger immune response in two higher dose cohorts (2.0 mg and 1.0 mg) compared to a lower dose cohort (0.5 mg). The highest observed increase among the participating volunteers was 8-fold from baseline. IMNN-101 continues to be safe and well tolerated, with no serious adverse effects reported.

"It is very encouraging to see strong evidence supporting the favorable immunogenicity, durability and safety of IMNN-101 at six months in trial participants, all of whom were previously vaccinated or infected multiple times, further validating the significant potential of our PlaCCine technology platform to support development of an effective treatment for COVID-19, new variants and emerging pathogens with epidemic potential," said Stacy Lindborg, Ph.D., President and Chief Executive Officer of IMUNON. "Our platform is designed to support development of vaccines with several competitive advantages, including vaccine stability at workable temperatures and ease of manufacturing compared to available mRNA vaccines. We are currently involved in discussions about the further development of our PlaCCine platform for prophylactic vaccines, which we hope will lead to a long-term strategic partnership to advance these promising technologies as efficiently as possible."

In the Phase 1 trial, designed to demonstrate the advantages of IMUNON's technology compared to approved messenger RNA (mRNA) vaccines, IMNN-101 was administered as a single dose vaccine without a booster dose in study participants who were previously vaccinated against the Omicron XBB1.5 variant. Study participants had high baseline immune characteristics, presumably from prior infection and multiple previous vaccinations against COVID-19, and ongoing infection. Modest increases in T-cell responses were observed in trial participants who received multiple immunizations prior to the study.

"I have seen firsthand how COVID-19 continues to impact patients, especially those with underlying health conditions. While existing vaccines have saved countless lives, there is a need for more updated and widely available options to keep pace with potential variants, and particularly with applications in unaddressed and emerging infectious diseases. Expanding our vaccine toolkit is essential to reduce hospitalizations and prevent long-term complications. These latest data indicate that IMNN-101 may offer a safe, effective and advantageous treatment option for patients in the future," said Ai-ris Collier, M.D., Co-Director of the Clinical Trials Unit, Center for Virology and Vaccine Research Center, Beth Israel Deaconess Medical Center.

Results from the Phase 1 trial build on data previously announced in February 2025, which showed IMNN-101 induced a persistent 2- to 4-fold increase in serum NAb titers from baseline through Week 4, further increasing NAb titers between Week 2 and Week 4. The immune response was also observed against the XBB1.5 variant and many newer variants following treatment, demonstrating the IMNN-101 vaccine's cross-reactivity. The Phase 1 clinical data of IMNN-101 is consistent with strong evidence of immunogenicity and protection for the PlaCCine platform in rodents and non-human primates, with prior preclinical results showing comparable protection efficiency (>95%) to a commercial mRNA vaccine in non-human primates.

About PlaCCine® and IMNN-101

IMNN-101 utilizes the Company's PlaCCine ® technology platform, a proprietary composition of a DNA plasmid that regulates the expression of key pathogen antigens and a novel synthetic DNA delivery system. The plasmid-based expression vector accommodates single or multiple antigens through its flexible vector design, offers manufacturing flexibility compared to viral, mRNA or protein vaccines, and the synthetic delivery system protects DNA from degradation and facilitates DNA uptake after injection with acceptable safety.

About the Phase 1 PoC Clinical Trial

This U.S. Phase 1 proof-of-concept (PoC) study enrolled 24 participants to evaluate three escalating doses of IMNN-101 with eight participants at each dose. All participants were treated at DM Clinical Research in Philadelphia. For this study, IMNN-101 has been designed to protect against the SARS-CoV-2 Omicron XBB1.5 variant, in accordance with the FDA's Vaccines and Related Biological Products Advisory Committee's June 2023 announcement of the framework for updated COVID-19 doses. The primary objectives of the study are to evaluate safety and tolerability in healthy adults. Secondary objectives include evaluating IMNN-101's immunogenicity and associated durability.

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

gene-based delivery 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 gene delivery of 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 multiple clinical trials including one Phase 2 clinical trial (OVATION 2). 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**.

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 of enrollment of the Company's clinical trials, the potential of any therapies or vaccines 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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