IMUNON Announces New Immunogenicity Data from Phase 1 Clinical Trial of Its DNA Vaccine in Treatment of COVID-19

February 26, 2025

Results of IMNN-101 Proof-of-Concept study demonstrate persistent immunogenicity in trial participants and further validate PlaCCine® technology

IMNN-101 induced 2- to 4-fold increase in neutralizing antibody (NAb) titers from baseline through Week 4

IMNN-101 continues to show an acceptable safety profile

LAWRENCEVILLE, N.J., Feb. 26, 2025 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage company focused on developing non-viral DNA-mediated immunotherapy and evaluating an adaptation of the platform's potential as a next-generation vaccine, today announced new safety and immunogenicity data from ongoing analyses of results from the Company's first Phase 1 proof-of-concept clinical trial of IMNN-101, its investigational DNA plasmid vaccine based on the Company's proprietary PlaCCine ® technology platform. The Phase 1 study was conducted in 24 healthy volunteers as a seasonal COVID-19 vaccine, targeting the SARS-CoV-2 Omicron XBB1.5 spike antigen. 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. Results demonstrated that IMNN-101 is safe and well-tolerated with no serious adverse effects. IMNN-101 induced a persistent 2- to 4-fold increase in serum neutralizing antibody (NAb) titers from baseline through Week 4, further increasing NAb titers between Week 2 and Week 4. The immune response was observed against the XBB1.5 variant and many newer variants following treatment, demonstrating the IMNN-101 vaccine's cross-reactivity.

"We have strong evidence of vaccine immunogenicity based on the neutralizing antibody response against the Omicron XBB.1.5 strain in this trial, and expect partnering interest in our proof-of-concept data from the PlaCCine platform," said Stacy Lindborg, Ph.D., president and chief executive officer of IMUNON. "These data demonstrate that our first-in-human vaccine based on our PlaCCine platform is safe and immunogenic and is well-suited to developing vaccine candidates for protecting the population against a potential future exposure to a pathogen or controlling a rising pathogen. Given proof of immunogenicity, early indications of durability of protection, and competitive advantages in the stability of our vaccine at workable temperatures compared with available mRNA vaccines, we believe that IMNN-101 has significant potential as a superior next-generation vaccine and will seek potential partners for further development."

The participants in the Phase 1 trial had high baseline immune characteristics presumably from prior infection and multiple previous vaccinations against COVID-19 and ongoing infection as evidenced by the rise in viral nucleocapsid antigen during the study period. Modest increases in T cell responses were observed in this setting of trial participants having received multiple immunizations prior to the study.

"Data from this trial is of high quality and show that IMUNON's DNA vaccine is immunogenic in humans. Following immunization, participants' NAb titers increased through Week 4 with a 2- to 4-fold increase from baseline, a clear and convincing response to the vaccination," 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.

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 that protection exceeded 95% in non-human primates, which is comparable to mRNA vaccines. The robust immunogenicity profile, expected durability of protection, comparative ease of manufacturing, and stability at workable temperatures (up to one year at 4°C and one month at 37°C) suggest that our vaccine based on the PlaCCine technology platform may be a potential viable alternative to available messenger RNA (mRNA) vaccines.

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 with viral or other DNA 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 inoculated 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 ability to elicit neutralizing antibody responses, cellular responses and their 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 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. This

technology may represent a promising platform for the development of vaccines in infectious diseases.

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 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). We 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 on IMUNON, 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 and potential outcome of a Phase 3 trial of IMNN-001, 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, the potential partnering opportunities, 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.

Contacts:

Media	**Investors**
CG Life	ICR Healthcare
Jenna Urban	Peter Vozzo
jurban@cglife.com	443-213-0505
	peter.vozzo@icrhealthcare.com

Source: Imunon, Inc.