First Participants Vaccinated in IMUNON's IMNN-101 Phase 1 Clinical Trial

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DNA vaccine proof-of-concept study expected to demonstrate an "mRNA better" platform

LAWRENCEVILLE, N.J., June 05, 2024 (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, announces that the first participants have been treated in the IMNN-101 Phase 1 clinical trial. This proof-of-concept study of IMUNON's proprietary PlaCCine ® platform is being conducted in healthy volunteers as a seasonal COVID-19 vaccine.

Two participants were inoculated at DM Clinical Research in Philadelphia and topline data are anticipated by year-end 2024. IMNN-101 utilizes the company's PlaCCine platform, a proprietary mono- or multi-valent DNA plasmid that regulates the expression of key pathogen antigens and is delivered via a novel synthetic DNA delivery system.

"Enrollment of these first participants is an important milestone for IMUNON," said Stacy R. Lindborg, Ph.D., president and chief executive officer of IMUNON. "We look forward to completing this study with the goal of demonstrating proof-of concept with our 'mRNA better' PlaCCine technology and, if successful, partnering the technology. Along with PlaCCine's improved durability, we expect to demonstrate the platform's attributes and competitive advantages to support our strategy to attract potential partners for further development."

This U.S. Phase 1 study is expected to enroll 24 participants to evaluate three escalating doses of IMNN-101 with eight participants at each dose. For this study, IMMN-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.

Based on reported preclinical data, durability of immune protection is expected to be superior to published mRNA vaccine data. IMUNON's preclinical work with prototype PlaCCine vaccines has shown:

- Immunogenicity and protection in non-human primates exceeding 95%, which is comparable to mRNA vaccines. These characteristics and stability of the vaccine at workable temperatures (up to one year at 4°C and one month at 37°C) suggest superior commercial handling and distribution properties compared with mRNA vaccines.
- Expected increased durability of protection, better compliance and manufacturing flexibility compared with viral or other DNA or protein vaccines.

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 Company's IND application, expectations regarding the Phase 1 clinical study of IMNN-101, including with respect to enrollment for the study and reporting of data, the potential efficacy and safety profile of our PlaCCine platform, 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; 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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