# IMUNON's IND Application Cleared to Begin Human Testing of IMNN-101

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**Company expects enrollment in Phase 1 proof-of-concept study of DNA-based vaccine technology to begin in the second quarter**

**LAWRENCEVILLE, N.J., April 18, 2024 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN)**, a clinical-stage drug-development company focused on developing non-viral DNA-mediated immunotherapy and next-generation vaccines, announces receipt of clearance from the U.S. Food and Drug Administration (FDA) to begin a Phase 1 clinical trial with a seasonal COVID-19 booster vaccine. The company filed an Investigational New Drug (IND) application for IMNN-101 in late February, and pending resolution of limited comments from the FDA, expects to commence patient enrollment in the second quarter of 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 unique synthetic DNA delivery system. The primary objectives of the Phase 1 study are to evaluate safety, tolerability, neutralizing antibody response, and the vaccine's durability (duration of immunogenicity) in healthy adults. Secondary objectives of the study include evaluating the ability of the IMNN-101 vaccine to elicit binding antibodies and 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.

As currently planned, the Phase 1 study will enroll 24 subjects evaluating three escalating doses of IMNN-101 at two U.S. clinical trial sites. 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.

"I congratulate the hard-working team at IMUNON that developed the PlaCCine modality on reaching this regulatory milestone. We look forward to demonstrating platform proof-of-concept in COVID-19, as well as a favorable comparison against established vaccines, in particular mRNA vaccines," said Michael Tardugno, IMUNON's executive chairman. "We believe that a successful study outcome will create interest among potential partners as we continue development."

IMUNON's preclinical work with prototype PlaCCine vaccines showed:

- Immunogenicity and protection in non-human primates exceeding 95%, which is comparable to mRNA vaccines. These characteristics and excellent 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.
- PlaCCine vaccines have advantages in T-cell responses, safety, compliance and manufacturing flexibility compared with viral or other DNA or protein vaccines.

Along with improved durability, PlaCCine's attributes and competitive advantages are key to attracting potential partners for other infectious diseases where there are limited options or significant drawbacks to current options.

**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 is entering 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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