IMUNON Files IND Application to Begin Human Testing of IMNN-101

March 13, 2024

Company expects enrollment in Phase 1 proof-of-concept study of DNA-based vaccine technology to begin in Q2
The application follows guidance provided to IMUNON in Pre-IND meeting with the FDA

LAWRENCEVILLE, N.J., March 13, 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 it has filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for IMNN-101 for a Phase 1 clinical study with a seasonal COVID-19 booster vaccine. Following acceptance by the FDA, enrollment in this human proof-of-concept study is expected to begin in the second quarter of 2024.

IMNN-101 utilizes the company's PlaCCine platform, a proprietary mono- or multi-valent DNA plasmid that controls the expression of pathogen antigens and is delivered via a non-viral synthetic DNA delivery system. The primary objectives of the Phase 1 study are to evaluate the vaccine safety, tolerability and neutralizing antibody response and its durability in healthy adults. The secondary objectives of the study are to evaluate the ability of the IMNN-101 vaccine to elicit IgG and T-cell responses and their durability. Based on reported preclinical data, durability of immune expression is expected to demonstrate superiority over published mRNA vaccine data.

As currently planned, the Phase 1 study will enroll 24 subjects evaluating three escalating doses of IMNN-101. IMMN-101 for this study 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.

"We are delighted to have completed the work necessary to file this IND application and look forward to demonstrating proof-of-concept for our PlaCCine platform in COVID-19. We selected this initial evaluation for our platform because of the significant amount of published comparator data that is readily available, and because mRNA vaccines have established a new standard for vaccine development," said Michael H. Tardugno, IMUNON's executive chairman. "We believe that upon completion of a successful Phase 1 study, we will attract the interest of potential partners for further development of this platform."

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 suggest superior commercial handling and distribution properties compared with mRNA vaccines, as well as greater manufacturing flexibility.
- 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 of immunity, we believe these attributes are key to attracting potential partners for future development of the PlaCCine modality in many other infectious diseases where there are limited options or drawbacks to the use of those available. We're looking forward to generating the proof-of-concept data necessary to begin these dialogues," Mr. Tardugno added.

About IMUNON

IMUNON is a fully integrated, 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 four modalities. The first modality, TheraPlas®, is developed for the coding of proteins and cytokines in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine®, is developed for the coding of 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 third modality, FixPlas®, concerns the application of our DNA technology to produce universal cancer vaccines, also called tumor associated antigen cancer vaccines. The fourth modality, IndiPlas®, is in the discovery phase and will focus on the development of personalized cancer vaccines, or neoepitope cancer vaccines.

The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of newly diagnosed 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 conducting IND-enabling preclinical studies for the development of a COVID-19 booster vaccine (IMNN-101) and a treatment for the LASSA virus (IMNN-102). The Company has also initiated preclinical work to develop a Trp2 tumor associated antigen cancer vaccine in melanoma (IMNN-201). 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 FDA acceptance of our IND application; 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 acquisitions or licenses of other technologies, assets or businesses; 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:

IMUNON
Jeffrey W. Church
Executive Vice President, CFO
and Corporate Secretary
609-482-2455
jchurch@imunon.com

LHA Investor Relations
Kim Sutton Golodetz
212-838-3777
Kgolodetz@lhai.com

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