

# IMUNON Enters into Technology Evaluation Agreement with Acuitas Therapeutics to Evaluate IMUNON's PLACCINE Plasmid DNA with Acuitas' Lipid Nanoparticle Delivery System

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Successful combination of technologies will expand the opportunities for IMUNONs DNA-based modality and broaden applications for the PLACCINE nucleic acid vaccine platform as an alternative to mRNA and protein vaccines

LAWRENCEVILLE, N.J. and VANCOUVER, B.C., Nov. 10, 2022 (GLOBE NEWSWIRE) -- IMUNON, Inc. (NASDAQ: IMNN), a clinical-stage drug development company, and Acuitas Therapeutics, a private biotechnology company focused on the development of delivery systems for nucleic acid vaccines and therapeutics based on lipid nanoparticles (LNP), today announced the signing of an agreement to evaluate the combination of IMUNON's PLACCINE nucleic acid vaccine constructs formulated with Acuitas' proprietary lipid delivery technology. Under the agreement, IMUNON will evaluate administration of its vector constructs formulated in various Acuitas LNP formulations for gene expression and immunogenicity in murine models.

"We are delighted to enter into this technology evaluation agreement with Acuitas Therapeutics, an organization renowned for its delivery technology capabilities, particularly with its LNP systems for mRNA vaccines," said Corinne Le Goff, Ph.D., President and Chief Executive Officer of IMUNON. "In light of the recent successes with our PLACCINE technology and promising proof-of-concept SARS CoV-2 data in non-human primates, we believe the time is right to explore the expansion of our technology to other types of delivery systems as we position our nucleic acid-based modality as the future of vaccinology."

IMUNON has demonstrated initial proof-of-concept of its PLACCINE nucleic acid vaccine platform in rodent and non-human primate models through intramuscular (IM) administration of PLACCINE plasmid DNA constructs expressing single or multiple SARS-CoV-2 antigens in combination with the PLACCINE delivery system. In October 2022, IMUNON reported partial results from an ongoing non-human primate study that examined a single plasmid DNA vector containing the SARS-CoV-2 Alpha variant spike antigen formulated with a synthetic DNA delivery system. In the study, Cynomolgus monkeys were vaccinated with the PLACCINE vaccine or a commercial mRNA vaccine on Day 1, 28 and 84.

Analysis of blood samples for IgG and neutralizing antibodies showed evidence of immunogenicity in both PLACCINE- and mRNA-vaccinated subjects. PCR analysis of bronchoalveolar lavage showed viral clearance by >90% of the non-vaccinated controls. In a majority of vaccinated animals, viral clearance from nasal swab followed a similar pattern and a similar clearance profile was observed when viral load was analyzed by the tissue culture infectious dose method. In an ongoing stability study, the physio-chemical properties and immunogenicity of PLACCINE vaccine did not change during storage at 4° C for up to six months.

Thomas Madden, Ph.D., President and Chief Executive Officer and co-founder of Acuitas Therapeutics, said, "We are excited to collaborate with IMUNON to evaluate nucleic acid-based vectors delivered using our LNP technology."

Acuitas Therapeutics was founded by Drs. Pieter Cullis, Michael Hope and Thomas Madden, who in September 2022 received Canada's Governor General's Innovation Award. This prestigious award recognized their work in developing LNP systems to deliver cancer drugs to tumors and to enable RNA- and DNA-based drugs for therapeutic use. Among other achievements, their work resulted in the LNP system that enables COMRINATY®, the Pfizer/BioNTech COVID-19 mRNA vaccine.

## About the PLACCINE Platform

PLACCINE, part of IMUNON's proprietary nucleic acid technology with synthetic delivery systems platform, is the subject of multiple patent applications that cover a broad range of next-generation nucleic acid vaccines. An adaptation of the Company's TheraPlas technology for therapeutic proteins, PLACCINE is a modality for prophylactic vaccines characterized by a single nucleic acid vector with multiple coding regions. The vaccine vector is designed to express multiple pathogen antigens along with the option to include a potent immune modifier. PLACCINE has potential to be easily modified to create vaccines against a multitude of infectious diseases, with benefits including:

- Durability of protection Durable antigen expression induces robust immunological response
- Breadth of protection Multi-cistronic vectors increase the breadth of immune response and allows for combination vaccines
- Transmission advantage Option for co-expression of potent immune modifiers increases the immune response and lowers the risk of viral shedding
- Safe and convenient Synthetic delivery systems present no risk of genotoxicity (i.e., no virus or cytotoxicity) and require no device; it also allows for convenient handling for pandemic control
- Flexible manufacturing Versatile platform enables rapid response to changing pathogens; stability at normal refrigerator temperatures simplifies handling and distribution

## **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 has two platform technologies: the TheraPlas<sup>®</sup> platform for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and the PLACCINE platform for the development of nucleic acid vaccines for infectious diseases and cancer. The company's lead clinical program, GEN-1, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase II development. GEN-1 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 preclinical proof-of-concept studies on a nucleic acid vaccine candidate targeting the SARS-CoV-2 virus to validate its PLACCINE platform. IMUNON's platform technologies are based on the delivery of nucleic acids with novel synthetic delivery systems that are independent of viral vectors or devices. IMUNON will continue to leverage these platforms and to advance the technological frontier of nucleic acid-based products to better serve patients with difficult-to-treat conditions. For more information on IMUNON, visit www.imunon.com.

#### **About Acuitas Therapeutics**

Founded in February 2009, Vancouver-based Acuitas Therapeutics (<a href="https://www.acuitastx.com">www.acuitastx.com</a>) is a private biotechnology company that specializes in the development of delivery systems for nucleic acid therapeutics based on lipid nanoparticles. The company partners with pharmaceutical and biotechnology companies and academic institutes to advance nucleic acid therapeutics into clinical trials and to the marketplace. The team works with partners to develop new therapies to address unmet clinical needs based on its internationally recognized capabilities in delivery technology. Acuitas Therapeutics has agreements in place with several partners to use its proprietary lipid nanotechnology in the development of COVID-19 vaccines. These include Pfizer/BioNTech for COMIRNATY®, which has received full approval in the U.S. and Canada and is authorized for Emergency Use in Europe, the UK and many other countries. The Acuitas team is currently working on therapeutics focused on addressing cancer, HIV/AIDS, tuberculosis, malaria, rabies, and other serious diseases.

## **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. Readers are cautioned that such forward-looking statements involve risks and uncertainties including, without limitation, 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 IMUNONs periodic reports and prospectuses filed with the Securities and Exchange Commission. IMUNON assumes no obligation to update or supplement forward-looking statements that become untrue because of subsequent events, new information or otherwise.

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