



AdJane Reports First Clinical Validation of its OMV Vaccine Platform Inducing Mucosal Immunity in Humans

Descrizione

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Phase I results provide platform-level validation supporting AdJane's broader development programs in pandemic preparedness, respiratory infectious diseases and antimicrobial resistance

DELFT, Netherlands, July 1, 2026 /PRNewswire/ - AdJane, a clinical-stage vaccine platform company developing intranasal and intramuscular vaccines based on native Outer Membrane Vesicles (nOMVs), today announces the publication of first-in-human Phase I clinical data in the peer-reviewed journal *Vaccines*, demonstrating the ability of its proprietary nOMV platform to induce both mucosal and systemic immune responses in humans.

The first-in-human randomized, double-blind, placebo- and OMV-controlled trial in 40 healthy adults demonstrated that AdJane's platform, combined with a SARS-CoV-2 Spike protein and administered intranasally, was safe and well tolerated and induced both systemic and mucosal immune responses. The combination triggered dose-dependent systemic immune responses across multiple measures, including virus-neutralizing antibodies. Importantly, the study showed induction of immune activity at the nasal mucosa - the primary entry site for many respiratory pathogens.

The findings provide clinical proof-of-concept for AdJane's nOMV platform and support its broader application across respiratory pathogens, pandemic preparedness scenarios, and other infectious disease targets currently under development.

"This publication represents an important validation milestone for AdJane and our mucosal nOMV platform," said Anita Gashi, Managing Director of AdJane. "Current injectable vaccines are highly effective at preventing severe disease but have shown limited ability to interrupt infection and transmission at the mucosal level. Our Phase I data demonstrate that intranasal OMV-based vaccination can safely induce both systemic and mucosal immunity in humans, supporting the potential

of our platform as a next-generation approach for respiratory infectious diseases and pandemic preparedness.â?•

Addressing the Mucosal Immunity Gap in Vaccines for Respiratory Infections

The COVID-19 pandemic highlighted a major challenge in infectious disease control: while injectable vaccines can provide strong protection against severe disease and death, they generally induce limited immune protection in the upper respiratory tract, where many airborne pathogens initiate infection and transmission. This gap reduces the ability of conventional vaccines to limit person-to-person spread.

Mucosal vaccination approaches aim to address this limitation by generating immune responses directly at the site of pathogen entry, while also inducing broader systemic protection. As interest in transmission-blocking immunity and pandemic preparedness strategies continues to grow globally, mucosal vaccination is increasingly recognized as an important emerging modality in vaccine development.

AdJaneâ??s nOMV platform is designed to support rapid adaptation against emerging respiratory pathogens while enabling scalable and practical deployment strategies.

About the OMV Platform

AdJaneâ??s nOMV platform is based on more than three decades of scientific research originating from leading Dutch governmental research institutions. The platform utilizes native outer membrane vesicles derived from *Neisseria meningitidis* bacteria, which naturally stimulate the immune system while closely mimicking bacterial surface structures.

The platform incorporates four proprietary genetic modifications designed to improve safety, manufacturing performance, and deployment flexibility, while preserving the intrinsic immunostimulatory properties of the vesicles. AdJaneâ??s platform is designed as a modular plug-and-play technology that enables incorporation of multiple antigens through several engineering approaches, supporting rapid vaccine development against newly emerging pathogens and other infectious disease targets.

The platform is being applied across multiple programs, including pandemic preparedness collaborations targeting broad-spectrum respiratory viral protection in partnership with CEPI, and antimicrobial resistance applications including a CARB-X-supported program against multidrug-resistant *Neisseria gonorrhoeae*, one of the most commonly reported sexually transmitted bacterial infections responsible for over 80 million new infections annually.

In addition, the platform has demonstrated stability under standard refrigeration conditions for more than 2.5 years, supporting stockpiling and broader global deployment without reliance on ultra-cold supply chains.

About AdJane

AdJane is a clinical-stage vaccine platform company developing next-generation intranasal and intramuscular vaccines based on its native Outer Membrane Vesicle (nOMV) platform technology. The company focuses on pandemic preparedness, antimicrobial resistance, and global infectious disease challenges.

AdJane's platform has been scientifically developed over more than 30 years by leading Dutch governmental research institutions and supports multiple deployment modalities for both prophylactic and therapeutic applications.

AdJane's platform is protected by a layered intellectual property portfolio covering antigen presentation and display technologies, as well as proprietary manufacturing processes and specific applications.

For more information, contact:

Anita Gashi, Managing Director anita.gashi@adjane.com +31 6 20 97 90 90 www.adjane.com

About the Study

The Phase I study was a first-in-human, randomized, double-blind, placebo- and OMV-controlled clinical trial conducted in 40 healthy SARS-CoV-2 seropositive adults aged 18-55 years.

Full study results are published in *Vaccines* and are available at <https://www.mdpi.com/3957576>. The trial is registered at [ClinicalTrials.gov](https://clinicaltrials.gov) under identifier NCT05604690.

View original content to download multimedia: <https://www.prnewswire.co.uk/news-releases/adjane-reports-first-clinical-validation-of-its-omv-vaccine-platform-inducing-mucosal-immunity-in-humans-302815790.html>

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