Intravacc.
Innovating vaccines

Press Release

Intravacc announces positive data of first in human intranasal OMV based vaccine for SARS-CoV-2

- First in human phase I clinical study using OMV as an adjuvant for intranasal vaccination
- Avacc 10® intranasal booster vaccine induces a mucosal response and no adverse events
- Data will be presented at the World Vaccine Conference on April 3rd 2024 in Washington, DC

Bilthoven, The Netherlands, 27 March 2024 – Intravacc, a world leader in translational research and development of preventive and therapeutic vaccines, today announced positive clinical data of a first in human (FIH) study of Avacc 10®, an intranasal outer membrane vesicles (OMV) based booster vaccine for SARS-CoV-2. The main objectives of the FIH clinical study were to demonstrate safety, tolerability and immunogenicity of intranasally administered Avacc 10®.

Phase I clinical trial

The phase I clinical trial, which was conducted in Australia, assessed the tolerability, safety and immunogenicity of the Avacc 10® vaccine. In a randomized, double-blinded, placebo and OMV controlled study, 36 healthy 18-55 year-old, male and female volunteers, received two intranasal doses, 3 weeks apart. One group received a low dose and the second group a high dose of Avacc 10®. Both groups were followed for a period of 6 months post vaccination. The study also evaluated the ability of Avacc 10® to induce an immune response, by measuring IgA and IgG antibodies and virus neutralizing antibodies in volunteers with existing high levels of IgG antibodies against SARS-CoV-2.

Administration of the Avacc 10® vaccine was well tolerated with no vaccine related adverse events (AEs) leading to participant study discontinuation. Immunogenicity data of the group that received the high dose of Avacc 10® demonstrated the induction of a mucosal immune response.

Dr. Dinja Oosterhoff, Intravacc's VP of Research & Development stated:

> *"The very encouraging immune response results from our Avacc 10® Phase 1 trial clearly demonstrates that we can use an OMV based vaccine to booster the immune response."*

Dr. Jan Groen, Intravacc's Chairman & CEO, says:

> *"This FIH intranasal vaccine study marks a significant milestone for Intravacc's flagship OMV based vaccine platform. Now Intravacc is also developing an intranasal vaccine for Gonorrhea targeting the FIH in Q4 2025. The company has already licensed other OMV based vaccines to large pharma companies."*

Oral Presentation

- Title: Avacc 10: An intranasal OMV based subunit vaccine for COVID-19
- Session: COVID & beyond
- Date April 3, 4.40-4.55 PM
- Presenter: Dr. Dinja Oosterhoff

=== E N D S ===

About Intravacc's OMV platform technology

For the development of vaccines, Intravacc has designed and developed a platform based on outer membrane vesicles (OMVs) - spherical particles with intrinsic immune-stimulating properties. The OMVs can be rigged with immunogenic peptides and/or proteins that stimulate effective adaptive immunity. The OMV carrier has been optimized to induce a more effective immune response against these newly

introduced antigens. Intravacc has also developed genetic tools to increase the yield of the OMVs, reduce the toxicity and achieve the desired antigenic composition. Intravacc's OMV platform is scalable and allows rapid and efficient modification of the antigen composition, either through genetic modification of the bacterial host or by associating antigens with stored OMVs.

About Intravacc

Intravacc, located at Utrecht Science Park Bilthoven in the Netherlands, is a leading global CDMO for infectious diseases and therapeutic vaccines. As an established independent CDMO with many years of experience in the development and optimization of vaccines and vaccine technologies, Intravacc has transferred its technology world-wide for many vaccines including polio, measles, DPT, Hib and influenza. Approximately 30% of childhood disease vaccines are based on Intravacc's know-how and proprietary technology. Intravacc offers a wide range of expertise for independent vaccine development, from concept to Phase I/II clinical studies for partners around the world, including biotech and pharmaceutical companies, governmental agencies and NGOs. With its innovative vaccine platforms OMV-Vacc, Cell-Vacc, Con-Vacc, E.co-Vacc and good manufacturing procedures (GMP) facilities the company is well positioned to address the unmet needs in the vaccine and immune therapy market.

Contact info

Intravacc
Dr. Jan Groen, CEO
P: +31 30 7920 454
E: press.office@intravacc.nl