Intravacc.
Innovating vaccines

Press Release

Intravacc announces additional favorable preclinical and toxicology data for Avacc 10®, an intranasal SARS-CoV-2 candidate vaccine

- Additional pre-clinical data of Avacc 10®indicate reduction in upper respiratory tract viral load and cross neutralization of variants of concern
- Avacc 10® toxicology data support the start of a phase I clinical trial in Q4 2022

Bilthoven, The Netherlands, 12 September 2022 – **Intravacc,** a world leader in translational research and development of preventive and therapeutic vaccines, today announced additional favorable preclinical and toxicology data for Avacc 10®, the company's SARS-CoV-2 intranasal candidate vaccine. These results demonstrate a reduction in upper respiratory tract viral load, broad cross protection against circulating variants of concern. and a good safety profile, allowing progression towards a phase I clinical study.

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

"Based on our additional pre-clinical data, Avacc 10® has the potential to reduce the spreading of the virus as well as providing broad protection against circulation variants. Combined with the favorable toxicological safety data, this puts us a good position for our Phase I clinical trial, which will commence in Q4 2022."

The first set of pre-clinical studies of Avacc 10®, published in *Frontiers of Immunology* in December 2021, demonstrated high levels of spike-binding immunoglobulin G (IgG) and A (IgA) antibodies in serum, and the nose and lungs after two intranasal vaccinations 3 weeks apart. Avacc 10® vaccinated hamsters challenged with SARS-CoV-2 were protected from weight loss and viral replication in the lungs and histopathology showed no lesions in lungs 7 days after challenge.

The objectives of the additional pre-clinical and toxicology study of Avacc 10® were to study the dosing, cross neutralization and safety of the intranasal vaccine. For the dosing study, mice were vaccinated intranasally with two doses of various concentrations of OMV and Spike protein. Three weeks after the last vaccination neutralizing antibodies against the SARS-CoV-2 Wuhan strain and variants of concern Delta, Gamma and Omicron were determined in the sera. High virus neutralizing antibody titers were detected against all the variant viruses. Syrian hamsters were used to study viral replication after challenge with SARS-CoV-2. A reduced viral load in throat and lungs and highly reduced lung lesions were observed in Avacc 10® vaccinated animals exposed to placebo vaccinated, challenged animals. Furthermore, delayed transmission of Avacc 10® vaccinated, challenged animals to placebo vaccinated animals was observed.

The purpose of the repeated dose toxicity study was to assess the safety and tolerability of Avacc 10® when administered through the intranasal route in New Zealand White Rabbits. Animals were vaccinated 3 times with Avacc 10®, and control animals with OMV only, or saline buffer. Toxicity was monitored until 2 weeks after the final vaccination. No clinical signs of toxicity nor morbidity/mortality were found in any of the groups, and no gross pathological changes were observed, demonstrating the safety of OMV based vaccine. All Avacc 10® vaccinated animals showed high IgG antibodies levels against Spike as well as virus neutralizing antibodies.

Based on the outcome of the Phase I trial, Intravacc will seek manufacturing and commercialization license partners.

=== 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 adjuvant 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 OMVs, reduce the toxicity and achieve the desired antigenic composition. Intravacc's OMV platform is fully 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 contract development and manufacturing organization 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. Around 40% 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 universities, public health organizations (WHO, Bill & Melinda Gates Foundation), biotech and pharmaceutical companies. For more information, please visit www.intravacc.nl.

Contact info

Intravacc
Dr. Jan Groen, CEO
P: +31 30 7920 454

Mirjam Hartman, Media relations
P: +31 6 115 969 94
E: press.office@intravacc.nl

LifeSpring Life Sciences Communication, Amsterdam
Leon Melens
P: +31 6 538 16427
E: lmelens@lifespring.nl