Intravacc
Innovating vaccines

Press Release

Intravacc announces positive preclinical data for its SARS-CoV-2 nose spray vaccine

- Intranasal administration of OMV-Spike protected against challenge with SARS-CoV-2
- Intranasal vaccine administration has significant advantages over injectables
- OMV technology is a powerful vaccine platform for future pandemics

Bilthoven, The Netherlands, 7 April 2021 – Intravacc, a global leader in translational research and development of viral and bacterial vaccines, today announced that it has obtained positive preclinical results for its SARS-CoV-2 Outer Membrane Vesicle (OMV) based recombinant Spike protein (rSp) candidate nose spray vaccine.

For the preclinical study four groups of mice and four groups of hamsters received two intranasal immunizations on day one and day 21. One group of mice and hamsters received a vaccine based on OMV's mixed with rSp (CovOMV) and the other a vaccine based on OMV's coupled to rSp based on Intravacc's proprietary OMV click technology (CovOMVclick). Control animals received respectively only OMV's or only rSp. On day 35 the mice blood samples were tested for virus neutralizing antibodies. The hamsters were challenged with SARS-CoV-2 on day 42 after blood collection. Over a period of seven days after challenges, their bodyweight loss was measured and on day seven the animals were pathologically examined for lung lesions.

In the mice that received the CovOMV- and CovOMVclick vaccines, respectively 30% and 90% virus neutralizing antibodies were detected. In all the hamsters both candidate vaccines induced neutralizing antibodies, but the level of antibodies in hamsters that received CovOMVclick was slightly higher compared to the other group. In the group receiving rSp only, one animal showed a low virus neutralizing antibody titer. Intranasal vaccination with both OMV-rSp vaccine candidates resulted in complete protection after challenge, as no lung lesions were detected by histopathology, seven days after the hamsters were challenged. Furthermore, all hamsters that received the CovOMV- and CovOMVclick vaccines showed reduced systemic weight loss after challenge, whereas unvaccinated animals or animals vaccinated with OMV's or rSp lost more than 10% of their bodyweight.

Dr. Dinja Oosterhoff, Director Program Management at Intravacc, says:

> *"Our focus is to develop an intranasal COVID-19 vaccine that can induce both a systemic and a mucosal immune response. Mucosal immunity is the first line of defense for respiratory infections and plays an important role in the prevention of transmission of SARS-CoV-2. The preclinical data provides evidence supporting the efficacy potential of our OMV platform for intranasal applications."*

Mid 2020, Intravacc announced the start of it's SARS-CoV-2 intranasal vaccine development program using its proprietary OMV vaccine technology platform. Earlier studies at Intravacc had already demonstrated the safety of OMV's as a vaccine platform. The SARS-CoV-2 vaccines that are currently approved are all based on intramuscular immunization. Intravacc's intranasal OMV SARS-CoV-2 vaccine candidates not only induce high mucosal and systemic immune responses, but they are also cheap to manufacture and stay stable at 4°C for many years. OMV's can be used for developing both viral and bacterial vaccines. High quantities of OMV can be produced and stored at 4°C. In case of a pandemic, synthetic or recombinant peptides and/or proteins derived from sequence analysis of the

pathogen can be quickly produced and coupled to the OMV's, making them an ideal candidate platform for future pandemics.

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

"We are very pleased with this pre-clinical data of our intranasal SARS-CoV-2 candidate vaccine. This allows us to move quickly towards an in human combined phase I and II clinical trial. Based on historical scientific- and clinical data generated at Intravacc, I am convinced that we are well-positioned for the further development of this vaccine. This and previous data clearly demonstrate the value of our OMV-vaccine technology for future development of other preventive and therapeutic vaccines."

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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 of innovative vaccines against infectious diseases. As an established independent CDMO with over 100 years of experience in the development and optimization of vaccines and vaccine technologies, Intravacc has transferred its technology related to polio vaccines, measles vaccines, DPT vaccines, Hib vaccines and influenza vaccines around the world. Around 40% of childhood disease vaccines are based on Intravacc's 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.

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