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Innovating vaccines

Press Release

Intravacc launches phase I clinical trial of Avacc 10®, an intranasal subunit booster vaccine for SARS-CoV-2

- Randomized, double blinded, placebo-controlled trial
- Evaluation of two doses in 36 volunteers
- Mid-term data expected by end Q1 2023

Bilthoven, The Netherlands, 30 November 2022 – **Intravacc,** a world leader in translational research and development of preventive and therapeutic vaccines, today announced that it enrolled the first participant in a phase I first in-human clinical trial of Avacc 10®, the company's SARS-CoV-2 intranasal subunit vaccine, as a booster to previous COVID-19 vaccinations. Avacc 10® is based on Intravacc's proprietary outer membrane vesicles (OMV) platform.

The phase I clinical trial has just commenced in a clinical center in Australia, and will assess the tolerability, safety and immunogenicity of the intranasal Avacc 10® vaccine. In a randomized, double-blind placebo and OMV control study, 36 healthy male and female volunteers aged 18-55, who are IgG seropositive for SARS-CoV-2, will receive two intranasal doses, three weeks apart. One group will receive a low dose and the second group a high dose. Both groups will be followed for a period of 6 months post vaccination. In addition, the study will evaluate the ability of Avacc 10® to induce an immune response, by measuring IgA and IgG antibodies, neutralizing antibodies, mucosal immunity, and cellular immunity. The trial will run from September 2022 through June 2023. The first interim results of the trial are expected end Q1 2023. Learn more about the trial at *Clinicaltrials.gov*

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

> *"This is a very important milestone in the development of our intranasal OMV-based vaccine. We strongly believe that intranasal vaccines offer major advantages over injectable vaccines, and we are excited to take our vaccine concept to the next stage, supporting our CDMO business."*

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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 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 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