

Leiden Medical Center and Intravacc to start clinical trial with new intranasal corona vaccine

- Nasal spray vaccine based on soluble nano-spheres with synthetic corona proteins
- No use of mRNA or vector technology
- Better and direct immunization of mucosa against multiple corona viruses
- Intravacc focuses on preclinical and process development research and GMP vaccine production
- Financing of clinical trial study made possible in part by Dutch governmental body Top Consortium for Knowledge and Innovation (TKI)

Bilthoven, The Netherlands, 5 January 2022 – **Intravacc**, a global leader in translational research and development of therapeutic vaccines and vaccines against infectious diseases, today announced a partnership with Dutch Leiden University Medical Center (LUMC) to develop and evaluate a new nasal spray corona vaccine in a clinical phase I/II study. This new vaccine, NANO-VAC, is based on microscopic soluble nano-spheres, containing synthetic mini proteins that, when administered as a nasal spray, directly protects the upper respiratory tract including nasal passages and throat (mucosa) before the virus reaches the lungs. The design of this type of vaccine thereby makes the vaccine broadly protective, harnessing both arms of the immune system, against SARS-2 (COVID19) but also SARS-1, MERS, and other beta coronaviruses. Intravacc also develops AVACC-10, a nasal spray corona vaccine based on Outer Membrane Vesicles. Nasal spray vaccines are ideal to prevent and stop transmission to other people and are a perfect solution for people with a fear of needles.

The planned clinical phase I/II study is made possible in part by the Top Consortium for Knowledge and Innovation (TKI) of Health~Holland, part of the Dutch top sector Life Sciences & Health. Health~Holland plays a connecting role between the business community, government, research institutes, patients and social organizations.

Dr. Luis Cruz's team, responsible for LUMC's Translational Nanobiomaterials and Imaging department, spent more than a year working on the new, sustainable and simple nasal spray vaccine. The preclinical studies in animals showed surprisingly positive results. The phase I/II clinical study is led by Dr Leo Visser of the Infectious Diseases Department of the LUMC. Intravacc will focus on a number of additional and preliminary preclinical exercises and the process development research of the vaccine through a scalable vaccine production process using its expertise in GMP vaccine production. The nasal spray vaccine will be tested on healthy volunteers to evaluate safety and tolerability. This phase I/II clinical trial is expected to start at the end of 2022 and the first study data is expected in the first half of 2023.

Dr. Luis J. Cruz, head of LUMC's Translational Nanobiomaterials and Imaging department, said:
"Intravacc and LUMC create major synergy by combining distinct complimentary expertises and competencies. A promising collaboration!"

Mode of action

NANO-VAC is intended to protect humans against current and future COVID-19 variants. The nano vaccine candidate is not only based on spike protein but also other target proteins in the coronavirus. It consists of a nanoparticle formulation containing multi-epitopes polypeptides of the immunogenic spike (S) protein of SARS-CoV-2 (COVID19), as well as other 100% conserved epitopes derived from distinct coronavirus proteins of which important targeting has already been identified for inducing a complete



humoral systemic and mucosal immune response, and cellular immunity response, both neutralizing antibodies and T cells, both for immediate immunization, and for a longer-term defense.

To enhance the effectiveness, the adjuvant hepatitis B core antigen HBcAg is used, which already has a proven effect in a nasal spray vaccine against liver inflammation. The HBcAG particle has been safely administered intranasally, serving as a carrier for nasal route and an immunostimulant for the mucosal immune cells of the nasal passages and upper respiratory tract. The vaccine does not apply the more recently used mRNA technique or inactivated cold viruses (vectors).

The other COVID nasal spray vaccine that Intravacc is working on, AVACC-10, uses OMVs, vesicles that bacteria communicate with and that serve as a platform to transport a protein that can (eventually) fight COVID.

Platform-technology for NANOVAAC and AVACC-10

In addition to COVID-19, the platform technologies on which these vaccines are based can also be used for the development of vaccines against a variety of other diseases. Several clinical studies with vaccine candidates developed on these platforms and administered by nasal spray or injection, have demonstrated safety for use in humans. NANOVAAC and AVACC 10 can be quickly adapted to new COVID virus variants and then produced rapidly in large quantities and cheaper than existing vaccines. In addition, they can be stored at room temperature, which simplifies transport over longer distances. This makes these vaccines an ideal solution for lower-income countries with a more limited medical infrastructure.

Jan Groen PhD, Intravacc's Chief Executive Officer comments:

"I am particularly pleased with Intravacc's input in the development of this new nasal spray vaccine. This concept and Intravacc's own AVACC-10 vaccine are potential game-changers in the fight against COVID. According to renowned immunologist Professor Ed Lavelle, of Trinity College Dublin, transmission of the virus is best blocked where it enters the body. It is therefore preferable to administer the vaccine via a spray in the nose for direct immunization of the throat and nasal mucosa ([2022 nasal spray interview](#))."

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About Intravacc

Intravacc, located Dutch Utrecht Science Park in Bilthoven, is a leading global contract developer and producer of innovative vaccines for infectious diseases and immunotherapy. As an established independent CDMO organization with over 100 years of experience in developing and optimizing 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 vaccines targeting childhood diseases are based on Intravacc technology. Intravacc provides a broad range of expertise for independent vaccine development from concept to Phase I/II clinical trials for partners worldwide, including universities, public health organizations (WHO, Bill & Melinda Gates Foundation) and biotech and pharmaceutical companies.

For more information, visit: www.intravacc.nl.



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