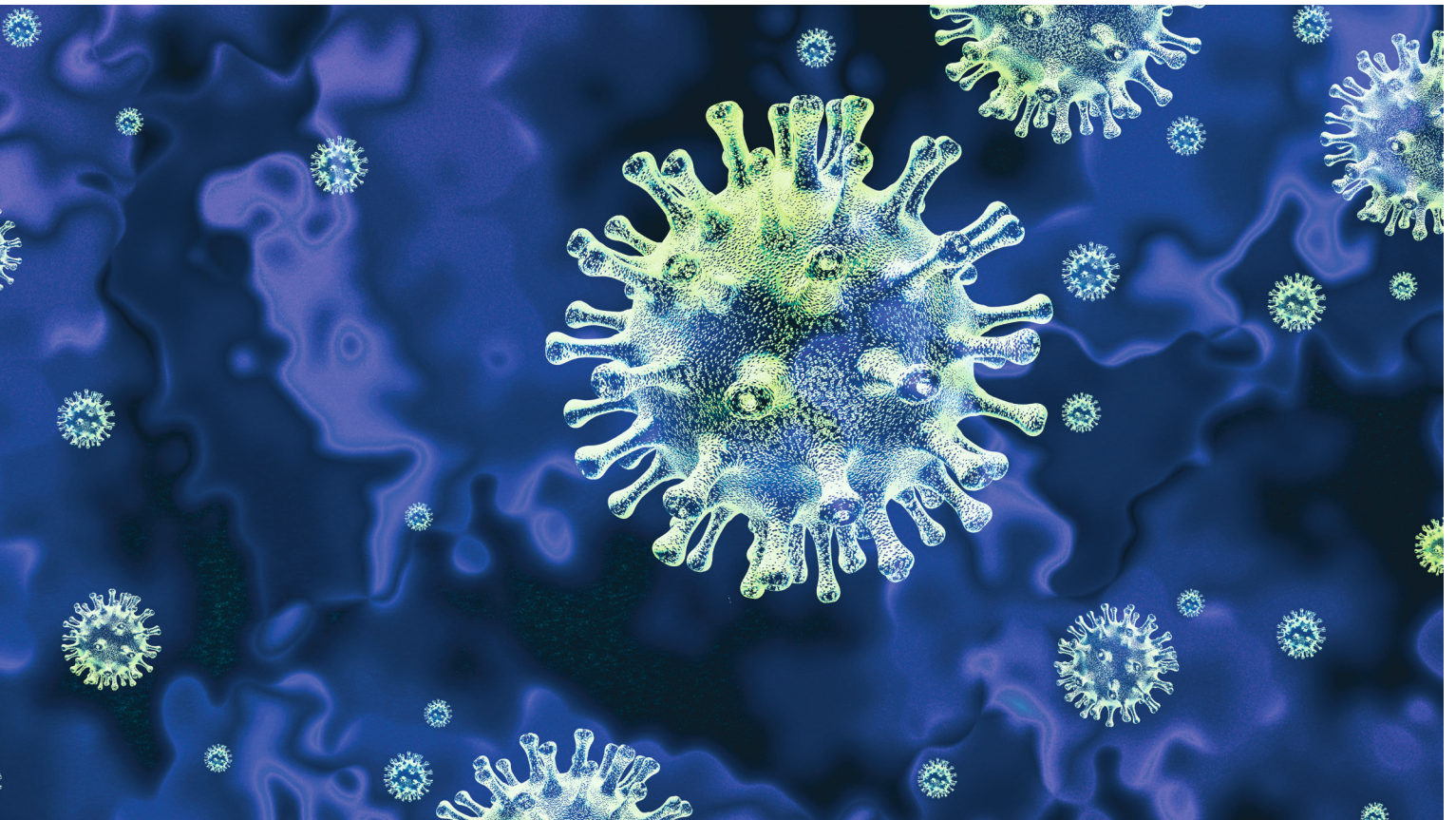


**Avacc® 10:** An intranasal vaccine against COVID-19 based on *Neisseria meningitidis* Outer Membrane Vesicles mixed with stabilized spike protein



## At a glance



### Technology

Proprietary Outer Membrane Vesicle technology (OMV-Vacc).



### Status

Clinical phase.



### Unmet need

Over 770 million cases reported to the WHO as of September 2023<sup>1</sup>.

Reported cases  
**>770 million**



### Target

SARS-CoV-2.



### Route of administration & schedule

Intranasal spray; a 2-dose booster vaccine.



# Vaccsheet

## **Disease: Coronavirus disease 2019 (COVID-19)**

COVID-19 is a contagious viral disease caused by the coronavirus SARS-CoV-2. Infection often, but not always, leads to flu-like symptoms (fever, cough, headache, fatigue),<sup>2,3</sup> and loss of smell and taste.<sup>4</sup> The most severe cases develop dyspnea, hypoxia, respiratory failure, or multiorgan dysfunction. Some patients continue to experience symptoms for years after infection (long COVID).<sup>5</sup> As of September 2023, over 770 million people worldwide have been affected by and 6.9 million people have died from COVID-19.<sup>1</sup>

## **Concept: a safe, intranasal vaccine to build a first line of defense**

Avacc 10 consists of Outer Membrane Vesicles (OMV) derived from the bacterium *N. meningitidis* that are mixed with the stabilized spike protein of SARS-CoV-2. Like other intranasal vaccines, Avacc 10 triggers the mucosal system in the nose and upper airways to secrete immunoglobulin A (IgA). As a result, both local and systemic immunity can provide more robust protection against initial infection and transmission of SARS-CoV-2. The intranasal route of administration is non-invasive, making it ideal for low- and middle-income countries.

## **Technology: A platform designed for infectious diseases**

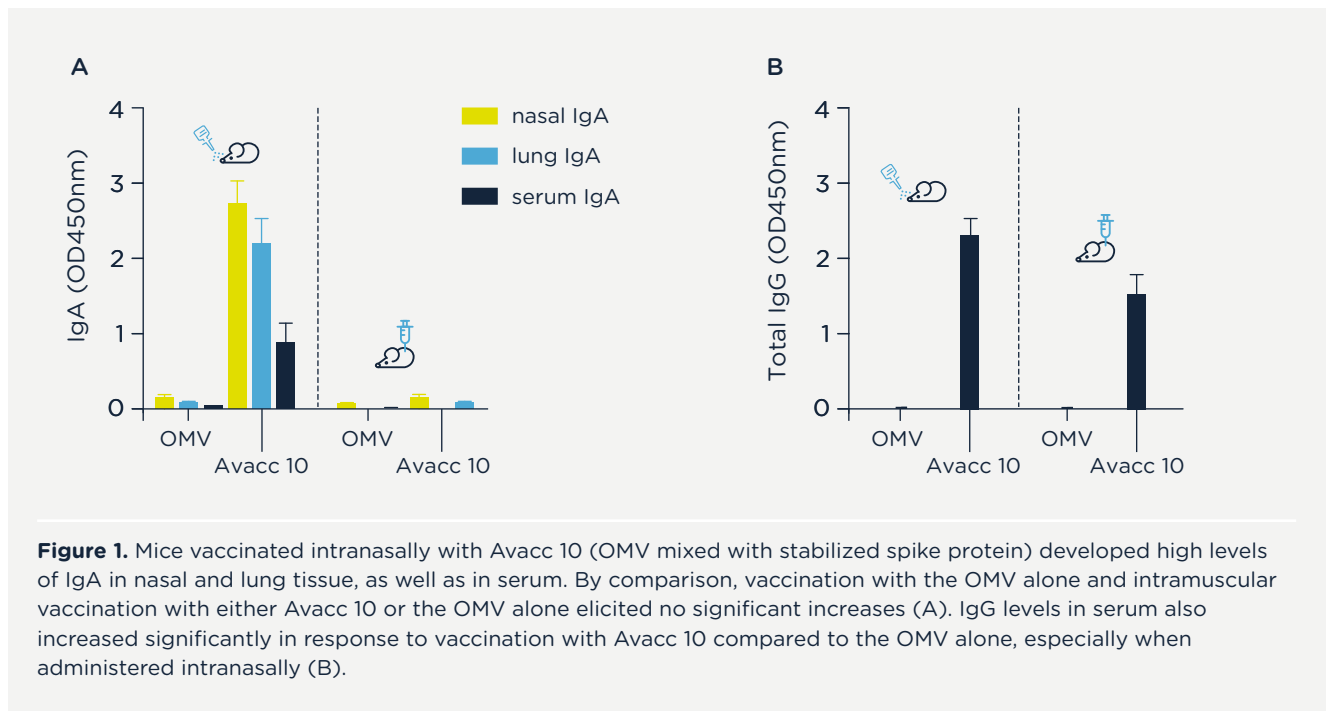
Avacc 10 is based on Intravacc's OMV platform, OMV-Vacc. This highly versatile technology has demonstrated efficient performance in prophylactic vaccines for bacterial and viral infections. The naturally secreted bacterial vesicles are mixed with the spike proteins as antigens. These OMVs are safe in both adults and children and highly stable, requiring only a standard cold chain.

## **Current status: Avacc 10 induced high IgA and IgG titers and prevented lung lesions in challenge studies**

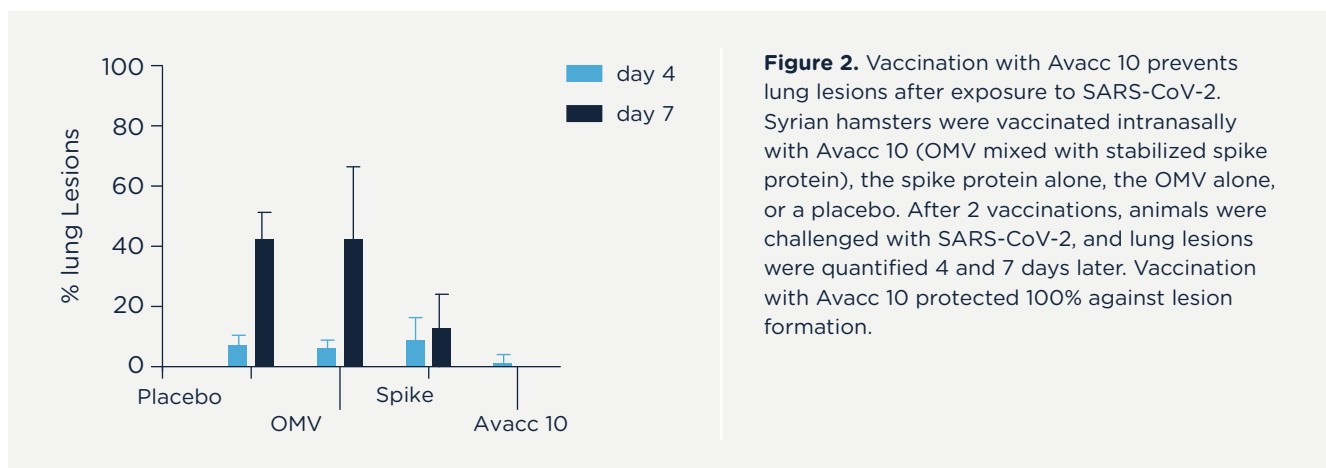
In preclinical studies, intranasal vaccination with Avacc 10 induced high levels of spike-binding immunoglobulin G (IgG) in serum, and high levels of IgA in the nose and lungs of mice (Figure 1). These antibodies also exhibited cross-neutralization against various SARS-CoV-2 variants of concern (data not shown). In challenge studies with Syrian hamsters, intranasal vaccination with Avacc 10 induced 100% protection against lung lesions after animals were exposed to SARS-CoV-2 intranasally (Figure 2) and delayed virus transmission among immunized animal groups (data not shown).



**Intranasal vaccination with Avacc 10 induces high levels of IgA and IgG in animal models**



**Vaccination with Avacc 10 prevents lung lesions from SARS-CoV-2 infection in animal models**





Toxicology studies have also demonstrated the safety, tolerability, and immunogenicity of Avacc 10 in rabbits (data not shown). Avacc 10 is currently being tested in a phase I clinical study as a booster vaccine in healthy volunteers.

With funding from the Coalition for Epidemic Preparedness Innovations (CEPI), Intravacc is also working to develop a vaccine that provides broad protection against SARS-CoV-2, including its variants, and other Betacoronaviruses.

Further development of Avacc 10 is planned under partnerships or licensing. We offer a complete technology transfer package with a scalable production process, a pre-clinical, clinical, and toxicology data package, GMP master seed lots, and comprehensive documentation.



### Manufacturing

The GMP process has been developed.



### Characterization

Pre-clinical studies with mice and hamsters, as well as toxicology studies with rabbits are completed.



### Regulatory affairs

A phase I clinical trial is ongoing.

Other supportive data and structures for partnership or licensing are available and can be presented in a confidential follow-up meeting.

<sup>1</sup> WHO Coronavirus Dashboard. <https://covid19.who.int/>

<sup>2</sup> Islam *et al.* 2021. PLOS ONE 16: e0249788. doi:10.1371/journal.pone.0249788

<sup>3</sup> Islam *et al.* 2020. Front Neurol. 11: 562634. doi:10.3389/fneur.2020.562634

<sup>4</sup> Agyeman *et al.* 2020. Mayo Clin. Proc. 95: 1621. doi:10.1016/j.mayocp.2020.05.030

<sup>5</sup> Davis *et al.* 2023. Nature Rev. Microbiol. 21: 133. doi:10.1038/s41579-022-00846-2

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