Vaccsheet

Avacc® 12: A vaccine against gonorrhea based on *Neisseria meningitidis* Outer Membrane Vesicles expressing *N. gonorrhoeae* antigens

At a glance

Technology
Proprietary heterologous Outer Membrane Vesicle (OMV) technology.

Status
Pre-clinical phase.

Unmet need
Estimated global annual incidence is 86.9 million adults. Highest rates in Africa and South America.[1]

Annual adult incidence
86.9 million

Target
Neisseria gonorrhoeae.

Route of administration & schedule
Intramuscular injection; likely 2 doses.

Vaccsheet

Disease: Gonorrhea (*Neisseria gonorrhoeae*)

The second most common bacterial sexually transmitted disease (STD), gonorrhea, has been a public health concern for centuries. Today, roughly 86–88 million adults are infected worldwide every year.[1] Treatment consists of a single dose of systemic antibiotics. Nevertheless, the pathogen's rapid and repeated development of antimicrobial resistance, the lack of exposure-based immunity, and the stigma associated with STDs have made infection control elusive.[1] The World Health Organization (WHO) has highlighted the urgency for alternative therapies and a vaccine.[2]

Therapeutic concept: a heterologous OMV of *N. meningitidis* plus recombinant *N. gonorrhoeae* antigens

Evidence has accumulated that the 4CMenB vaccine licensed against group B meningococcal infections also affords some protection against gonorrhea.[3,4] Its use was associated with reduced diagnoses and hospitalizations.[5] Avacc 12 leverages this protective mechanism. The vaccine uses Intravacc's *Neisseria meningitidis* serogroup B platform – which has 90% overall homology and shares many outer membrane antigens with *N. gonorrhoeae* – to induce cross-protection against gonorrhea. The *N. meningitidis* bacteria are additionally engineered to replace meningitidis antigens with their gonococcal counterpart, which further increases the effectiveness of the vaccine.

Technology: A platform designed for infectious diseases

Intravacc's OMV platform, OMV-Vacc, is a highly versatile technology that has demonstrated efficient performance in prophylactic vaccines for bacterial and viral infections. The naturally secreted bacterial vesicles are safe in humans. OMVs enable flexible vaccine concepts and are highly stable, requiring only a standard cold chain. Avacc 12 consists of *N. meningitidis* OMV expressing *N. gonorrhoeae* antigens (Figure 1).

Current status: Pre-clinical studies show Avacc 12 elicits IgG response

Studies in mice have provided proof-of-concept for the pre-clinical utility of Avacc 12. Mice injected intramuscularly three times with *N. meningitidis* OMV had elevated IgG titers compared to controls injected with phosphate buffer saline (PBS). The response was comparable to titer levels induced by the 4CMenB vaccine. Including selected recombinant *N. gonorrhoeae* antigens on the OMV increases the response (Figure 2).

Elevated serum antibody response against gonococci after vaccination with Avacc 12

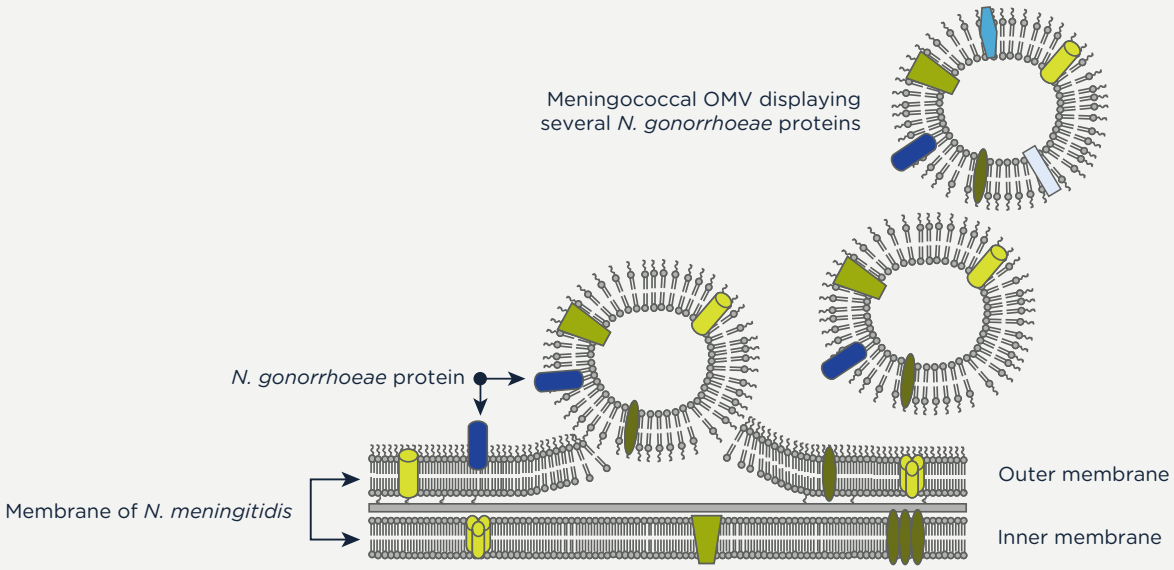

Figure 1. Intravacc's *Neisseria meningitidis* serogroup B platform induces cross-protection against gonorrhea. Expressing selected gonococcal antigens in the *N. meningitidis* OMV further increases effectiveness.

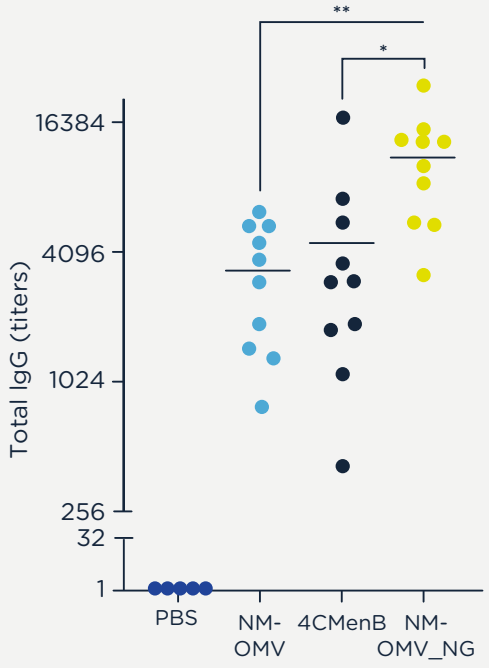

Figure 2. Vaccinating mice 3 times with the *N. meningitidis* OMV via intramuscular injection elevated serum IgG to comparable levels as the 4CMenB vaccine. Avacc 12 includes *N. gonorrhoeae* antigens in the *N. meningitidis* OMV, which further increased the response (NM-OMV_NG). PBS = phosphase buffer saline.

Avacc 12 will be developed toward a phase I clinical trial with the possibility of partnerships or licensing. Further development steps include:

Manufacturing

A GMP-compliant production process is in place. Establish the corresponding analytical assays.

Characterization

Extend the pre-clinical data package.

Regulatory affairs

Continue development towards phase I clinical studies.

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

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[1] Unemo *et al.* 2019. Nature. doi: 10.1038/s41572-019-0128-6

[2] WHO. 2021. Gonorrhoea: latest antimicrobial global surveillance results and guidance for vaccine development published. https://www.who.int/news/item/22-11-2021-gonorrhoea-antimicrobial-resistance-results-and-guidance-vaccine-development (accessed July 2023)

[3] Petousis-Harris et al. 2017. Lancet 390: 1603. doi: 10.1016/S0140-6736(17)31449-6

[4] Petousis-Harris. 2018. Hum. Vaccin. Immunother. 14: 1058. doi: 10.1080/21645515.2017.1381810

[5] Paynter et al. 2019. Vaccines 7: E5. doi: 10.3390/vaccines7010005

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