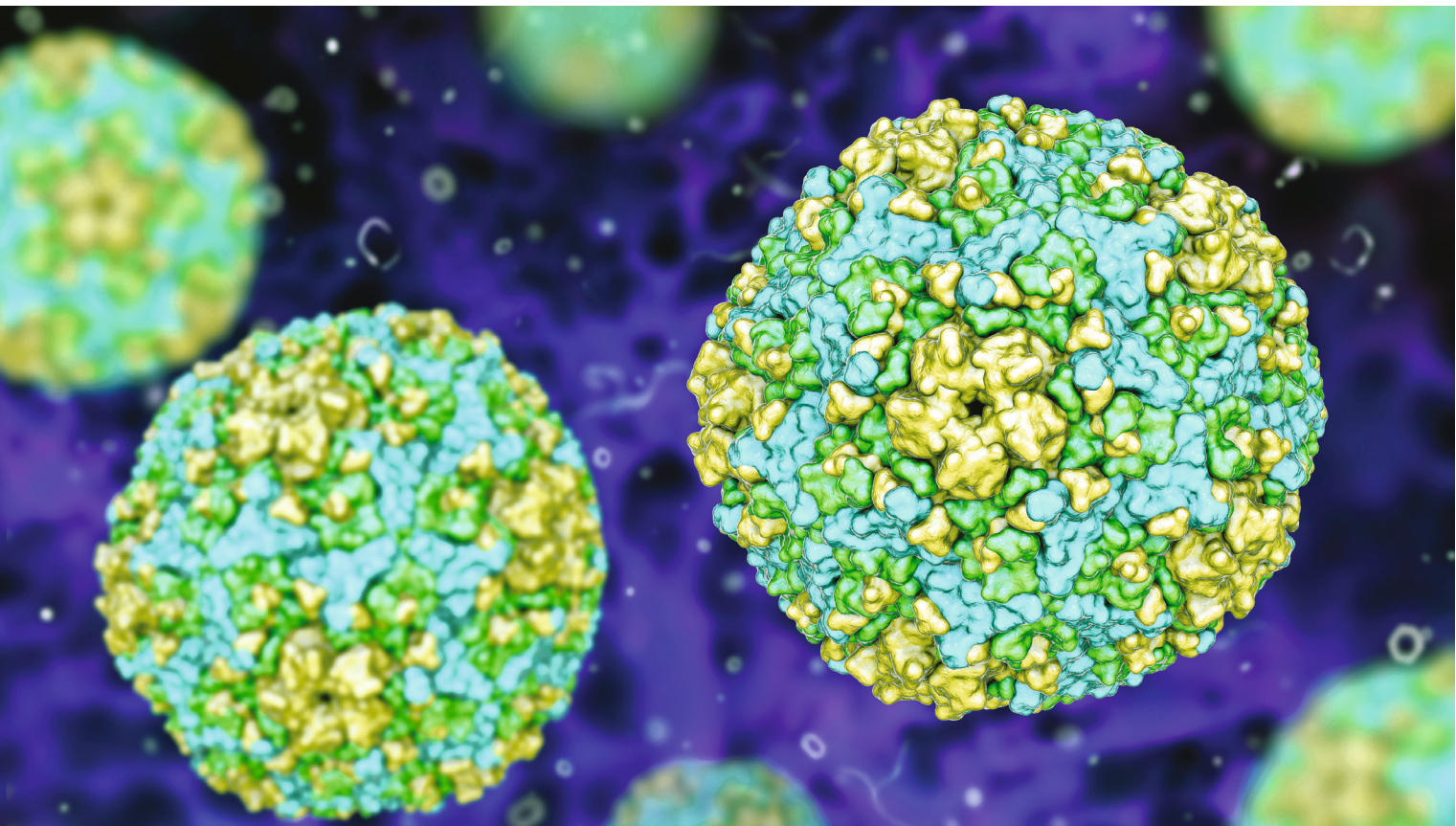


Avacc® 5: A first-in-class inactivated-virus vaccine against enterovirus D68



At a glance



Technology
Inactivated virus produced in a well-established Vero cell system (Cell-Vacc).



Status
Pre-clinical studies in mice and dose-response studies are completed.



Unmet need
Current global infection prevalence is estimated at 4%, though this varies widely by season and region.¹

4%

Worldwide infection prevalence



Target
Enterovirus D68 (EV D68)



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

Enterovirus D68 infection

In 2014, an outbreak of respiratory illness and neurological impairment in North America drew global attention to infections by enterovirus D68.² Though the virus was not new – it was first described in 1962³ – its association with severe illness, mainly in children, led to surveillance programs in many countries.¹ Since then, several countries have reported a biennial cyclical rise in EV D68 infections, which are temporally associated with rises in confirmed cases of acute flaccid myelitis (AFM)⁴ and influenza-like illness.⁵ EV D68 infection is a global public health concern. The estimated infection prevalence varies widely by region and study, but a meta-analysis puts the combined global prevalence at 4%.¹

Therapeutic concept: A first-in-class inactivated-virus vaccine

Avacc 5 is a concept vaccine against EV D68 infection. Based on an inactivated virus, the vaccine is designed for intramuscular administration.

Technology: A safe and well-established production platform

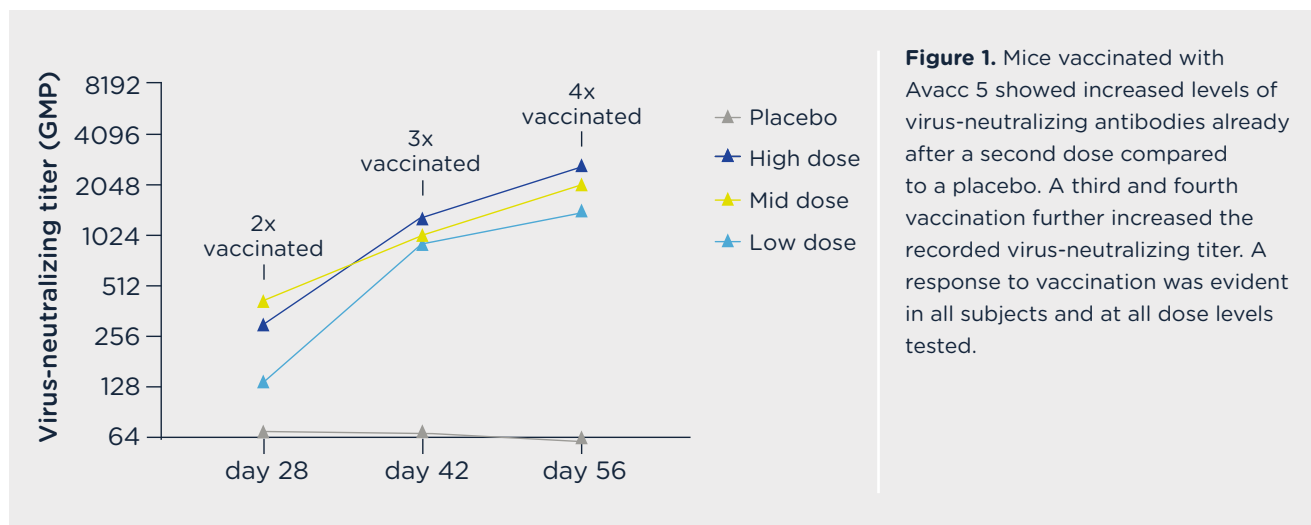
The EV D68 vaccine is produced on Intravacc's cell-based platform (Cell-Vacc), cultured on our proprietary, cGMP-grade, regulatory-approved Vero cells. Successfully used in viral vaccine development and large-scale production since 1987, this mature cell-based platform also includes ready-to-use cell banks, downstream purification processes, and full technology transfer. The platform allows fast-track development and generates high-quality, high-yield viral output, which is then purified and inactivated.

Current status: Strong results from immunogenicity studies

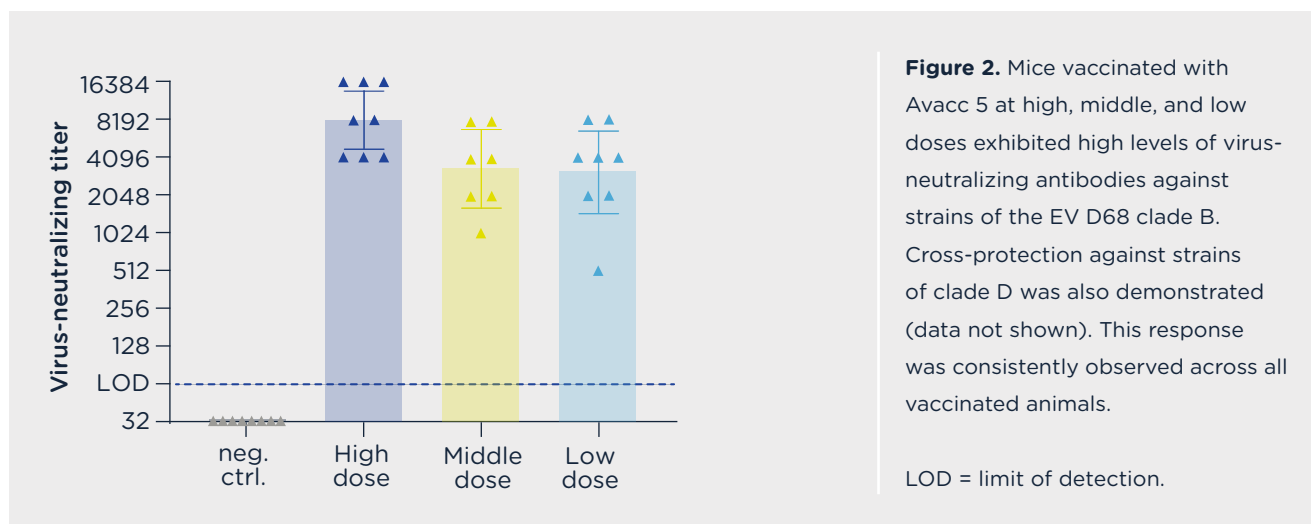
Avacc 5 is being developed through to phase I clinical trials in partnership with the U.S. National Institutes of Health (NIH). Vaccine dose, vaccination schedule, and the requirement for an adjuvant have been evaluated in a series of immunogenicity studies. The results showed that Avacc 5 induces high levels of virus-neutralizing antibodies in all vaccinated animals and for all doses tested. The observed protective responses occurred already after two doses and without need for an adjuvant (Figure 1). Furthermore, Avacc 5 elicits cross-protection against different clade B and clade D⁶ EV D68 viruses (Figure 2).



Vaccination with Avacc 5 results in high levels of virus-neutralizing antibodies



Vaccination with Avacc 5 induces cross-protection against other clades of EV D68



Further clinical stages will advance under other partnerships or licensing. Such agreements include access to GMP master seed lots, a scalable and high-yield production process, a pre-clinical data package with full assay panels, and a tailored transfer package. Next development steps include:



Manufacturing

A GMP master seed lot has been produced and released.



Characterization

Toxicology studies are planned in 2024.



Regulatory affairs

A phase I clinical trial is planned for end of 2024/beginning of 2025.

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

¹ Fall, A. *et al.* (2022) PLOS Neglected Tropical Diseases. doi: 10.1371/journal.pntd.0010073

² Brown, B.A. *et al.* (2014) Genome Announc. doi: 10.1128/genomeA.01201-14

³ Schieble, J.H. *et al.* (1967) J. Virol. doi: 10.1128/jvi.1.3.494-499.1967

⁴ Fang, X. and Huda, R. (2020) J. Clin. Neurol. doi: 10.3988/jcn.2020.16.3.376

⁵ Fall, A. (2022) J. Clin. Virol. doi: 10.1016/j.jcv.2023.105379

⁶ Elrick, M.J. *et al.* (2021) J. Biol. Chem. 296: 100317. doi: 10.1016/j.jbc.2021.100317

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