Vaccsheet

Avacc® 2: A first-in-class prophylactic quadrivalent vaccine against hand, foot, and mouth disease (HFMD)

At a glance

Technology
Quadrivalent vaccine produced on proprietary Vero and HEK293 cell lines.

Status
Finalizing pre-clinical development, including toxicology and dose response studies.

Unmet need
Outbreaks in Asia-Pacific upwards of 10 million cases.[1] Small, localized outbreaks common in European countries.

> 10 million
cases in Asia-Pacific

Target
Enteroviruses EV71_C4, CVA10, CVA16, and CVA6.

Route of administration & schedule
Intramuscular injection; likely 3 doses.

Vaccsheet

Disease: Hand, foot, and mouth disease (HFMD)

Hand, foot, and mouth disease is a viral infection that commonly occurs in toddlers, causing fever and a rash in the mouth, hands, and feet. Rare and severe cases may include painful blisters and difficulty swallowing and can lead to paralysis. Although the disease typically resolves itself, larger outbreaks in the Asia-Pacific region have numbered in the tens of millions[1] and pose a considerable socioeconomic burden[2]. Currently, only China has approved monovalent vaccines as prophylactic treatment.[1, 3] However, because the disease is caused by a group of entero-viruses, only a multivalent vaccine can effectively prevent future outbreaks.

Therapeutic concept: A first-in-class prophylactic quadrivalent vaccine

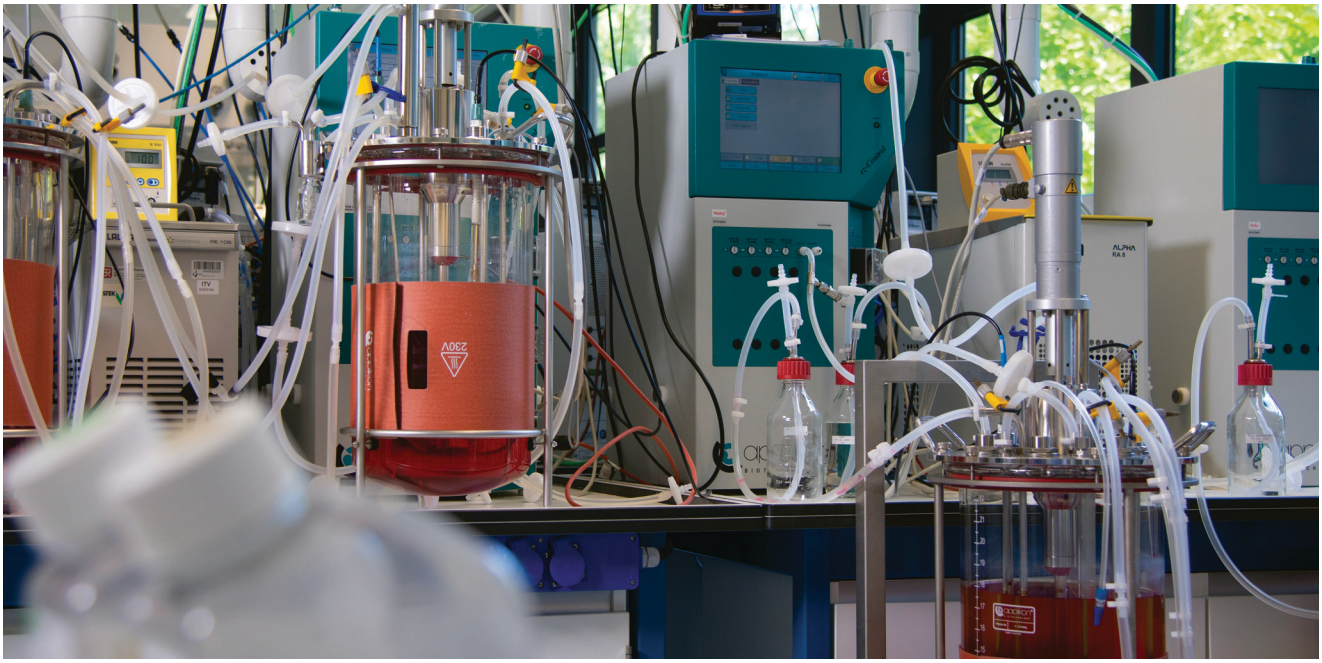
The majority of HFMD cases are caused by the enteroviruses EV71, CVA16, CVA10, and CVA6. Intravacc is developing a vaccine that targets all four enteroviruses. The cell-based vaccine combines inactivated viruses cultured in Vero and HEK293 cell lines.

Technology: A time-tested cell platform

The HFMD vaccine uses Intravacc's cell-based platform (Cell-Vacc). Three of the 4 HFMD viruses are 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 fourth enterovirus of the vaccine is cultured on a novel cGMP-grade HEK293 cell line that grows in suspension.

Current status: Pre-clinical studies show promising results

Monovalent vaccines against the individual targets EV71, CVA10, and CVA6 induced high virus neutralizing titers (VNT) in mouse models, evidence of protective responses. Figure 1 shows the positive VNT observed for the EV71_C4 and CVA10 vaccines, with CVA10 reaching the upper limit of detection. Furthermore, IgG was observed in serum of the immunized treatment groups (data not shown). The quadrivalent vaccine is in active



High levels of virus neutralizing antibodies are induced by vaccination in preclinical mouse models

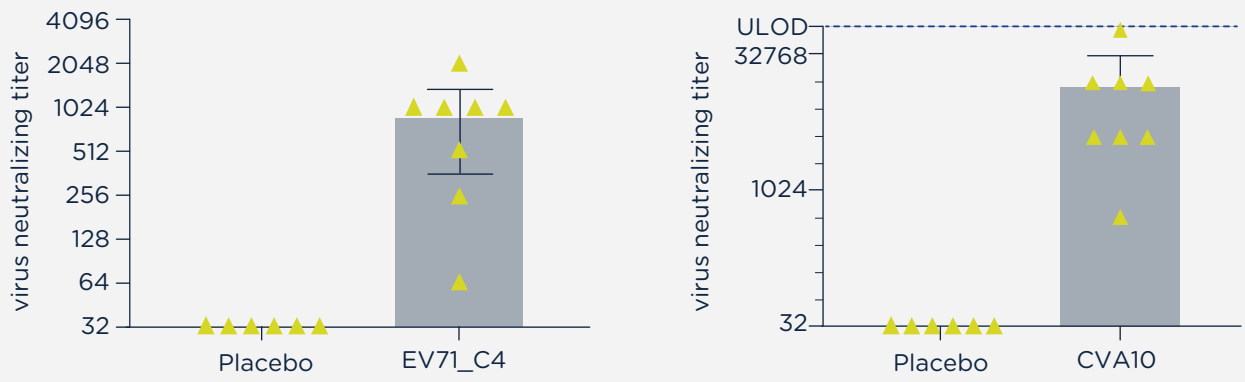


Figure 1. Mouse models treated with monovalent vaccines against the individual target enteroviruses exhibit a multi-fold increase in neutralizing antibodies. ULOD = upper limit of detection.

development and slated to enter clinical stages under partnerships or licensing. Such agreements include access to GMP master seed lots, a scalable production process, a pre-clinical data package with developed assay panels, and tailored transfer packages for monovalent or combination vaccine candidates. Current development steps include:

Manufacturing

The master seed lot for CVA6 is slated for production at end of 2023.

Characterization

Efficacy experiments in mouse models are nearing completion. A pre-clinical toxicology study and a dose study are planned.

Regulatory affairs

The pre-clinical data package will be completed.

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

[1] Zhu et al. 2023. J Biomed. Sci. doi: https://doi.org/10.1186/s12929-023-00908-4

[2] Wang et al. 2016. Epidemiol. Infect. doi: 10.1017/S0950268815001569

[3] Brewer et al. 2021. Vaccines. doi: 10.3390/vaccines9030199

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