



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Brian Bailey at 240-669-5128, or bbailey@mail.nih.gov. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852: tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

EV-D68 Monoclonal Antibodies Isolated from Immunized Rhesus Macaques

Description of Technology:

Enterovirus D68 (EV-D68) has been linked to the widespread outbreaks of respiratory illness and acute flaccid myelitis (AFM) in the United States and Europe in 2014, 2016, and 2018. Although EV-D68 is now the most frequently encountered enterovirus (41.1% of cases), with an estimated global prevalence of 4%, there are no specific, FDA-approved therapeutic interventions targeting this virus.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Disease (NIAID) have identified four monoclonal antibodies that potently bind and neutralize multiple subclades of EV-D68, including B3 and A2 variants. Animal studies have indicated that these Rhesus macaque-derived monoclonal antibodies (mAbs) are likely to confer protection against respiratory illness in young children (particularly those under age 5) and in individuals with respiratory or immunocompromising conditions. Analyses conducted using standard techniques such as cryo-EM have enabled the inventors to further characterize the epitopes of two unique EV-D68-specific antibodies, suggesting the value of this technology for developing multi-specific approaches that confer broad protection against EV-D68.

Humanization and combination of these mAbs with other antibodies exhibiting unique epitope specificities may prove beneficial for therapeutic or prophylactic purposes, especially within the context of a broader pandemic preparedness program. Further, these antibodies could be incorporated into diagnostic assays/kits for the rapid and accurate detection of EV-D68 in clinical or non-clinical settings.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR part 404.

Potential Commercial Applications:

- Prevention or treatment of EV-D68 infection
- Development of diagnostic assays for rapid, accurate EV-D68 detection in clinical and non-clinical settings

Competitive Advantages:

- Development of prophylactic or therapeutic interventions against EV-D68 that effectively induce broad protection against multiple circulating subclades

Development Stage: Preclinical

Inventors: Tracy Ruckwardt, Daniel Moss, Peter Krug, Masaru Kanekiyo (all of NIAID VRC)

Relevant Publications: Krug et al. EV-D68 virus-like particle vaccines elicit cross-clade neutralizing antibodies that inhibit infection and block dissemination. *Sci. Adv.*

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Intellectual Property: HHS Reference No. E-041-2024; Provisional Patent Application 63/640,619, filed on April 30, 2024, and PCT Patent Application No.

PCT/US2025/027110, filed on April 30, 2025.

Licensing Contact: To license this technology, please contact Brian Bailey at 240-669-5128, or bbailey@mail.nih.gov and reference E-041-2024.

Dated: June 20, 2025.

Surekha Vathyam,

Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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