e 4140-01-P

<AGENCY TYPE='S'>DEPARTMENT OF HEALTH AND HUMAN SERVICES

<SUBAGY>National Institutes of Health

<SUBJECT>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 *brian.bailey@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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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:

Pan-GI Norovirus Monoclonal Antibody and Its Use.

Description of Technology:

Norovirus is a leading cause of vomiting, diarrhea, and foodborne illness worldwide, with 700 million cases and 200,000 deaths occurring each year. Despite decades of work in the field, there are no preventive or therapeutic strategies specifically approved for even the most prevalent forms of human norovirus (i.e., GI, GII genogroups), which are highly contagious and carry an increased risk of severe complications in children, older adults, and those with immunocompromising conditions.

Researchers at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases (NIAID) have isolated the first broadly reactive monoclonal antibody against GI genogroup noroviruses (mAbs16E10) using samples from a human blood donor. Results of *in vitro* and *in vivo* analyses further supported the antibody's broad binding and blocking specificity to the entire GI norovirus genogroup, neutralization of the GI.1 type, and abrogation of infection in a non-human primate challenge. These complementary findings highlight the technology as a promising candidate for clinical applications, including prophylaxis for at-risk populations, diagnostics, and the development of candidate vaccines based on the newly discovered epitope.

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:

- Immunotherapy for immunocompromised populations
- Prophylactic treatment for at-risk populations
- Development of novel diagnostic, detection, and isolation methods
- Development of vaccine candidates that effectively induce broadly neutralizing antibodies with the potential to intervene against multiple noroviruses within the GI genogroup

Competitive Advantages:

- First broadly reactive monoclonal antibody against GI genogroup
- Exceptionally large binding epitope with high binding affinity
- Promising preliminary results in non-human primates

Development Stage: Preclinical

Relevant Publications: Rimkute I, et al. A broadly protective human antibody for GI genogroup noroviruses. Nat Microbiol. 2025. https://doi.org/10.1038/s41564-025-01952-6

Inventors: Mario Roederer, Inga Rimkute, Peter Kwong, Adam Olia, Rafaello Verardi (all of NIAID VRC)

Intellectual Property: HHS Reference No. E-025-2024; Provisional Patent Application 63/653,691, filed on May 30, 2024.

Licensing Contact: To license this technology, please contact Brian Bailey at 240-669-5128 or *brian.bailey@nih.gov*, and reference E-025-2024.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. For collaboration opportunities, please contact Brian Bailey at 240-669-5128 or *brian.bailey@nih.gov*, and reference E-025-2024.

<SIG><DATED>Dated: June 9, 2025.

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Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.</SIG>

[FR Doc. 2025-10921 Filed: 6/13/2025 8:45 am; Publication Date: 6/16/2025]