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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 National Institute of Allergy and Infectious Diseases (NIAID), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the invention listed below, which 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: Inquiries related to this licensing opportunity should be directed to: Benjamin Hurley at 240-276-5489, or benjamin.hurley@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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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:

Human antibodies with anti-lymphocyte specificities and lytic activity.

Description of Technology:

Antibody therapies that target human B cells are a promising way to treat diseases like B-cell cancers and autoimmune conditions like lupus and multiple sclerosis. Traditionally, these antibodies are made in animals and modified to resemble human

antibodies to reduce immune rejection. Researchers in the Laboratory of Immunoregulation (LIR) at the National Institute of Allergy and Infectious Diseases (NIAID) have developed a new approach of using blood plasma from a patient with the rare immune disorder idiopathic CD4 lymphocytopenia (ICL) to find naturally occurring human antibodies.

By using advanced genetic sequencing, the researchers discovered and reproduced several new antibodies that could effectively attack and kill B-cell tumors, normal B cells, and T cells, demonstrating potential for eliminating cancerous or disease-causing immune cells. One potent antibody, NIH58.9, killed B cells at low concentrations of 0.01 nanomolar. These new antibodies may be used as treatments, combined with other therapies, or engineered into special formats like bispecific antibodies or antibody-drug conjugates.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications:

- Development of monoclonal antibody therapies, bispecific antibodies, and antibody-targeted drugs for use in organ transplantation, B-cell lymphomas, and autoimmune conditions.

Competitive Advantages:

- First fully human IgM antibody that binds to and kills B cells at concentrations as low as 0.01Nm.
- Versatile antibody that may be used directly, engineered as IgG1 antibody, and possibly developed into bispecifics or antibody-drug conjugates.

Development Stage:

- Pre-Clinical

Inventors: Dr. Ainhoa Pérez-Díez, Dr. Irini Sereti, both of NIAID.

Intellectual Property: HHS Reference No. E-025-2025. U.S. Provisional Patent Application 63/787,190, filed on April 11, 2025.

Licensing Contact: To license this technology, please contact Benjamin Hurley at 240-276-5489, or benjamin.hurley@nih.gov, and reference E-025-2025.

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 Benjamin Hurley at 240-276-5489, or benjamin.hurley@nih.gov.

Date: March 31, 2026

Surekha Vathyam,

Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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