

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:

Dawn Taylor-Mulneix at 301-767-5189, or dawn.taylor-mulneix@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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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 Monoclonal Antibodies That Target Plasmodium Falciparum Sporozoites

Description of Technology

Malaria is one of the world's deadliest infectious diseases, causing an estimated 249 million cases and 608,000 deaths annually, with children in the regions of Africa and South Asia being most vulnerable. Approx 2,000 cases of malaria are reported in the United States each year, by travelers from malaria-risk countries. Malaria is a mosquito-borne parasitic disease transmitted through the bite of infected female mosquitoes, which introduces *Plasmodium* sporozoites into the bloodstream of the human host. There are five *Plasmodium* parasite species that cause malaria in humans, of which, the vast majority of life-threatening cases are caused by infection with *Plasmodium falciparum* parasites.

Researchers at NIAID have developed 11 human monoclonal antibodies that bind to a unique site on the circumsporozoite protein (CSP) on *Plasmodium falciparum* sporozoites that is not targeted by any known monoclonal antibodies. These

antibodies do not bind to recombinant forms of CSP and as such bind to a processed or post-translational form of the protein processed by the sporozoites. In vivo studies have shown several of these antibodies can substantially reduce liver parasite burden in a mouse model of malaria. These antibodies can work cooperatively with known antibodies that target the repeat region of CSP. Some of these novel antibodies have shown enhanced protection in an animal model when combined with known protective monoclonal antibodies against sporozoites, suggesting that together they may form an effective cocktail to prevent malaria.

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

- Prophylactic and preventative treatment against malaria.

Competitive Advantages

- These antibodies bind to a unique site on the circumsporozoite protein (CSP) on *Plasmodium falciparum* sporozoites that is distinct from the targets of pre-existing mAbs.
- These monoclonal antibodies can be used alone or in combination with existing antibodies.

Development Stage

- Pre-Clinical
Inventors: Joshua Tan, Ph.D., Cherrille Dacon, Ph.D., both of NIAID.
Publications: n/a.

Intellectual Property: HHS Reference No. E-212-2022-0. U.S. Provisional Patent Application No. 63/409,016, filed on September 22, 2022, and PCT Patent Application No. PCT/US2023/074791, filed on September 21, 2023.

Licensing Contact: To license this technology, please contact Dawn Taylor-Mulneix at 301-767-5189, or dawn.taylor-mulneix@nih.gov, and reference E-212-2022.

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. Areas of specific interest include (a) testing developability of these antibodies (e.g., biophysical characteristics, cross-reactivity, pharmacokinetics, toxicity), (b) pre-clinical model assessment, and (c) human clinical trials. For collaboration opportunities, please

contact Dawn Taylor-Mulneix at 301-767-5189, or dawn.taylor-mulneix@nih.gov.

Dated: April 8, 2024.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0014]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Declaration of Financial Support

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (i.e. the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until June 17, 2024.

ADDRESSES: All submissions received must include the OMB Control Number 1615-0014 in the body of the letter, the agency name and Docket ID USCIS-2006-0072. Submit comments via the Federal eRulemaking Portal website at <https://www.regulations.gov> under e-Docket ID number USCIS-2006-0072.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721-3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this