

Resources/inputs	Activities	Outputs	Outcomes
Identified via proposal	5. Assess feasibility of establishing priority EPHS functions.	Selection and testing of at least one pilot program or demonstration project addressing the selected EPHS.	Improved capacity to develop and/or offer public health programs and services to address prioritized public health activities in AI/AN communities.

[FR Doc. 2024-05826 Filed 3-19-24; 8:45 am]

BILLING CODE 4166-14-P

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: Peter Tung at 240-669-5483 or peter.tung@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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

Licensing information and copies of the patent applications listed below 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 by contacting Peter Tung at 240-669-5483 or peter.tung@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Enhanced Stability and Efficacy of Pfs48/45 Domain III Protein Variants for Malaria Vaccine Development Using SPEEDesign Technology

Description of Technology

The technology includes modifying the Plasmodium falciparum Pfs48/45 Domain III protein sequence to enhance its stability and efficacy to aid in malaria vaccine development. This approach successfully overcomes previous production challenges by increasing the thermostability of the antigen and eliminating the need for additional modifications that could impair vaccine effectiveness. Crucially, the technology maintains the essential neutralizing epitope of Pfs48/45, ensuring its effectiveness in preventing malaria transmission as a transmission-blocking vaccine. Developed using the SPEEDesign program, these novel protein variants show increased stability and a more robust transmission blocking response than wild-type proteins. The potential applications of this technology are providing a more stable and effective vaccine, potentially reducing the incidence of malaria and leading to improved health outcomes.

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

- This malaria vaccine technology offers competitive advantages by providing increased thermostability and enhanced immune response without the need for efficacy-reducing modifications, potentially revolutionizing malaria prevention with more effective and stable vaccine options.

Competitive Advantages

- The development of more effective and stable malaria vaccines offers improved prevention strategies in regions affected by this disease and significantly contributing to global health initiatives.

Development Stage

Pre-Clinical

Inventors: Niraj Tolia, Ph.D., Thayne Dickey, Ph.D., all of NIAID.

Publications

Intellectual Property: HHS Reference No. E-030-2023-0-US-01, US Provisional Application No. 63/476,897, filed on December 22, 2022; HHS Reference No. E-030-2023-0-PC-01, PCT Application No. PCT/US2023/085849, filed on December 22, 2023

Licensing Contact: To license this technology, please contact Peter Tung at 240-669-5483 or peter.tung@nih.gov, and reference E-030-2023.

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 Peter Tung at 240-669-5483 or peter.tung@nih.gov.

Dated: March 14, 2024.

Surekha Vathyam,

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

[FR Doc. 2024-05880 Filed 3-19-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Manufacturing of Anti-Malaria Monoclonal Antibody L9LS in Transgenic Cows and Sheep

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Taurgen Malaria, Inc. ("Taurgen"), headquartered in Logan, UT. Taurgen Malaria, Inc. is a wholly-owned subsidiary of Taurgen Therapeutics, LLC, which is also headquartered in Logan, UT.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before April 4, 2024 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Wade Green, Ph.D., Lead Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases Telephone: (301) 761-7505; Email: wade.green@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 62/842,590, filed May 03, 2019, titled "Neutralizing antibodies to *Plasmodium falciparum* circumsporozoite protein and their use" [HHS Reference No. E-087-2019-0-US-01];

2. International Patent Application No. PCT/US2020/031345, filed May 04, 2020, titled "Neutralizing antibodies to *Plasmodium falciparum* circumsporozoite protein and their use" [HHS Reference No. E-087-2019-0-PCT-01];

3. European Patent Application No. 20727798.9, filed May 04, 2020, titled "Neutralizing antibodies to *Plasmodium falciparum* circumsporozoite protein and their use" [HHS Reference No. E-087-2019-0-EP-02]; and

4. United States Patent Application No. 17/608,381, filed October 02, 2021, titled "Neutralizing antibodies to *Plasmodium falciparum* circumsporozoite protein and their use" [HHS Reference No. E-087-2019-0-US-03].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

"Production of the L9LS monoclonal antibody in transgenic bovine and ovine species."

The E-087-2019 patent family is primarily directed to (1) compositions of matter of the L9LS monoclonal antibody, (2) methods of treating and preventing infection with *Plasmodium falciparum* using the L9LS monoclonal antibody, and (3) methods of manufacturing the L9LS monoclonal antibody. The exclusive field of use

which may be granted to Taurgen applies to only manufacturing of the L9LS monoclonal antibody in transgenic bovine and ovine species. Accordingly, the proposed scope of rights which may be conveyed under the license covers only a portion of total scope of the E-087-2019 patent family and only a subset of the possible methods of manufacturing the L9LS monoclonal antibody.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially and may be made publicly available.

Complete license applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: March 14, 2024.

Surekha Vathyam,

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

[FR Doc. 2024-05878 Filed 3-19-24; 8:45 am]

BILLING CODE 4140-01-P

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:

Peter Tung at 240-669-5483 or peter.tung@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.

Licensing information and copies of the patent applications listed below 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 by contacting Peter Tung at 240-669-5483 or peter.tung@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Next-Generation MSP1-Targeted Malaria Immunotherapy: Enhanced Vaccine Candidates and Monoclonal Antibodies

Description of Technology

This technology encompasses the development of highly advanced malaria vaccine candidates and human monoclonal antibodies, both centered on targeting the Merozoite Surface Protein 1 (MSP1) of the *Plasmodium falciparum* malaria parasite. The innovation lies in utilizing a novel computational design and in vitro screening process, which has created MSP1 vaccine candidates that are significantly more immunogenic, stable, and cost-effective than existing alternatives. These vaccines focus on the 19 kDa carboxy-terminus fragment of MSP1. They contain engineered amino acid changes and are displayed on self-assembling nanoparticles to elicit a more potent immune response, potentially offering more robust and durable protection against malaria. Additionally, the technology includes the production of enhanced human monoclonal antibodies with improved affinity for the same fragment of MSP1, designed to overcome the parasite's immune evasion tactics. These advancements hold immense promise for significantly improving malaria prevention and treatment. They could lead to the development of more