



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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications related to the invention.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 Single-Component AMA1-RON2 Vaccine Candidates: A Breakthrough in Malaria Immunization.

Description of Technology:

This technology focuses on the creation of single-component AMA1-RON2 (Apical membrane antigen 1-rhoptry neck protein 2) vaccine candidates. These candidates are based on a novel composition of matter designed to elicit a more effective immune response against the malaria parasite *Plasmodium falciparum*. The standout aspect of this technology is the Structure-Based Design 1 (SBD1) immunogen, engineered through a structure-based design that significantly enhances its ability to produce potent, strain-transcending neutralizing antibodies. This approach not only surpasses the efficacy of traditional AMA1-RON2 complexes and other insertion fusion designs but also boasts higher thermal stability, indicating better preservation and longevity of the vaccine. The technology's increased stability and efficiency in production present an opportunity to lower vaccine manufacturing costs and simplify logistics, especially in regions where malaria is endemic. Additionally, the adaptability of these immunogens for integration with nanoparticle platforms could further amplify their immunogenicity, paving the way for more robust and lasting protection against malaria. This innovation can potentially transform malaria prevention and control, offering a more effective, stable, and cost-efficient solution to a disease that continues to impact millions worldwide.

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:

- Stable single-component AMA1-RON2 immunogens hold promise for improving malaria prevention and control efforts in endemic regions around the world.

Competitive Advantages:

- No blood-stage malaria vaccine has been approved. This technology offers a competitive edge over other vaccine candidates in development through its easily

manufactured single-component AMA1-RON2 design that elicits a potent broadly neutralizing response that is better than competing candidates.

Development Stage:

- The efficacy of stable single-component AMA1-RON2 immunogens has been validated in rat and rabbit models. Following identification of the most cost-effective platform for vaccine production, the immunogens will be advanced for virulent parasite challenge studies in *Aotus* monkeys and towards human trials.

Inventors: Niraj Tolia, PhD., Thayne Dickey, PhD., Palak Patel, PhD., all of NIAID.

Publications: Patel, P. N. et. al., Structure-based design of a strain transcending AMA1-RON2L malaria vaccine. Nat. Commun. 14, 5345 (2023)

Intellectual Property: HHS Reference No. E-096-2023-0-US-01US-01

US Provisional Application No. 63/524,522, filed on June 30, 2023.

Licensing Contact: To license this technology, please contact Peter Tung at 240-669-5483 or peter.tung@nih.gov, and reference E-096-2023.

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.

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