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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 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 and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications related to this invention.

SUPPLEMENTARY INFORMATION: Technology description follows.

Novel VAR2CSA immunogens and methods of use thereof

Description of Technology:

The invention provides immunogen polypeptides comprising fragments of VAR2CSA protein expressed by *P. falciparum* as potential second-generation placental malaria vaccine candidates. VAR2CSA is the leading antigen target for a placental malaria vaccine, where associated antibody titers are correlated with protection. Aspects of the inventive immunogen polypeptides comprise all or portions of the chondroitin sulfate A (CSA) binding regions of VAR2CSA, as identified by a structural study of VAR2CSA conducted by the inventors, that

possess great sequence conservation among P. falciparum strains when compared to competing clinical vaccine candidates PRIMVAC and PAMVAC. Also provided are methods of using the immunogen polypeptides for vaccination and treatment of disease.

Oncology Application

The VAR2CSA immunogens bind to oncofetal CSA, a putative therapeutic target for multiple cancers, including NSCLC, breast, bladder and 40-50% of all pediatric solid tumors. Oncofetal CSA is only expressed solely in the placenta, except in several cancerous tissues, making it an ideal target for targeted therapeutics such as immunogens that are cross linked to cytotoxic agents.

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:

- Placental malaria vaccine
- CSA-binding proteins for cancer therapeutics

Competitive Advantages:

- Strain-transcending immunogens for vaccination
- Improved immunogen production through expression of key protein regions

Development Stage:

- Immunogens successfully tested in a small animal model

Inventors: Dr. Niraj Tolia and Dr. Rui Ma, both of NIAID.

Publications: Ma, R. et al., "Structural basis for placental malaria mediated by Plasmodium falciparum VAR2CSA", Nat Microbiol 6, 380–391, 2021.

Intellectual Property: HHS Reference No. E-021-2021-0-US-01 - U.S. Provisional Application No. 63/115,729, filed November 19, 2020.

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

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 the invention. For collaboration opportunities, please contact Peter Tung at 240-669-5483; peter.tung@nih.gov.

Dated: October 15, 2021.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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