

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: 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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:

Vaccinia Virus Strain WR With Deletion of Growth Factor Genes ("vSC20")

Description of Technology:

This technology relates to mutant vaccinia virus expression vectors. Researchers at NIAID have developed a recombinant vaccinia virus in which the growth factor genes were deleted from both ends of the genome. The recombinant vaccinia virus is attenuated and can replicate efficiently in rapidly dividing cells such as tumors.

The mutation in the recombinant virus was confirmed through various tests, including Southern blot analysis and growth factor assays. The mutant expression vectors show diminished virus replication in non-dividing cells and attenuation in animal models compared to other vaccinia virus expression vectors. They may have use as vaccines, cancer therapies as well as for gene delivery.

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:

- Recombinant vaccinia virus with deletion of growth factor genes can be used for cancer therapeutics and diagnostics.

Competitive Advantages:

- The recombinant vaccinia virus is attenuated and can replicate efficiently in rapidly dividing cells, such as tumors.

- Applications include use in tumor-directed gene therapy, given the enhanced safety profile, tumor selectivity, and the oncolytic effects after systemic delivery.

Development Stage:

- Pre-Clinical.

Inventors: Bernard Moss, M.D., Ph.D. and Sekhar Chakrabarti, Ph.D., both of NIAID.

Publications: Buller, R M et al. "Deletion of the vaccinia virus growth factor gene reduces virus virulence." *Journal of virology* vol. 62,3 (1988): 866-74. doi:10.1128/JVI.62.3.866-874.1988; McCart, J A et al. "Systemic cancer therapy with a tumor-selective vaccinia virus mutant lacking thymidine kinase and vaccinia growth factor genes." *Cancer research* vol. 61,24 (2001): 8751-7.

Intellectual Property: HHS Reference No. E-028-2021. U.S. Patent 8506947B2, issued on August 13, 2013.

Licensing Contact: To license this technology, please contact Benjamin Hurley at 240-276-5489 or benjamin.hurley@nih.gov and reference E-028-2021.

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.

Dated: February 14, 2024.

Surekha Vathyam,

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

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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