



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: Brian Bailey, PhD, at 240-669-5128 or 301-201-9217, or by email at bbailey@mail.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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.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:

SARS-CoV-2 Spike Fused to Hepatitis B Surface Antigen.

Description of Technology:

The emergence of the SARS-CoV-2 virus and its immune-escaping variants have led to global COVID-19 pandemic/endemic, underscoring the urgent need for effective vaccines with strong and durable immune responses.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) used a novel approach to SARS-CoV-2 vaccine development by leveraging hepatitis B surface antigen (HBsAg), which has a proven

track record of safety and efficacy in hepatitis B vaccines. They designed fusion protein constructs comprised of HBsAg linked by a series of glycine-serine residues to the prefusion stabilized spike protein of SARS-CoV-2. These constructs can self-assemble into nanoparticles in mammalian cells and bind monoclonal antibodies (mAbs) that are specific to different domains of the SARS-CoV-2 spike. The nanoparticles elicit potent and durable immune responses including neutralizing antibody response. *In vitro* and *in vivo* experiments demonstrate that this nanoparticle platform has the potential for use as a robust SARS-CoV-2 vaccine.

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:

- Novel SARS-CoV-2 vaccine and universal vaccines against coronavirus
- Vaccine development against other viral pathogens such as HIV and flu

Competitive Advantages:

- Higher potency, potentially longer protection compared to other SARS-CoV-2 vaccine formulations.
- Potent immune response via genetic delivery, including DNA and RNA immunization.
- Improved immunogenicity compared to other nanoparticle or virus-like-particle (VLP)-based vaccines for SARS-CoV-2 spike protein.

Development Stage:

- Pre-Clinical

Inventors: Drs. John Mascola, Cuiping Liu, Wei Shi, Amarendra Pegu, Lingshu Wang, Wing-Pui Kong, all of NIAID.

Publication: Liu, C., Wang, L., Merriam, J.S. *et al.* Self-assembling SARS-CoV-2 spike-HBsAg nanoparticles elicit potent and durable neutralizing antibody responses via genetic delivery. *npj Vaccines* 8, 111 (2023). <https://doi.org/10.1038/s41541-023-00707-w>

Intellectual Property: HHS Reference No. E-171-2021-0- EIR-00 U.S. Patent Application No. 63/278,956 filed on November 12, 2021; HHS Reference No. E-171-2021-0- EIR-00 U.S. Patent Application No WO 2023/086961; PCT/US2022/079750, filed on November 11, 2022.

Licensing Contact: To license this technology, please contact Brian Bailey, PhD; 240-669-5128 or 301-201-9217; bbailey@mail.nih.gov, and reference E-171-2021.

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. Areas of specific interest include (a) testing developability of the antibodies elicited by SARS-CoV-2 spike-HBsAg nanoparticles (e.g., biophysical characteristics, cross-reactivity, pharmacokinetics, toxicity), (b) pre-clinical model assessment, and (c) human clinical trials. For collaboration opportunities, please contact Brian Bailey, PhD; 240-669-5128 or 301-201-9217, bbailey@mail.nih.gov.

Dated: February 15, 2024.

Surekha Vathyam,

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Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.