[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: Amy Petrik., Ph.D., 240-627-3721; amy.petrik@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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

PREFUSION CORONAVIRUS SPIKE PROTEINS AND THEIR USE

Description of Technology:

Coronaviruses (CoVs) can cause severe respiratory disease with high fatality rates in humans. The 2002-2003 SARS-CoV epidemic resulted in 8098 cases and 744 deaths, and

MERS-CoV, which emerged in 2012, has resulted in 2144 cases and over 750 deaths as of March 2018. Currently, there are no effective prophylactic or therapeutic measures, and because other CoVs are poised to emerge as new human pathogens, there is a need to define a general CoV vaccine solution. Past efforts to develop CoV vaccines have used whole-inactivated virus, live-attenuated virus, recombinant protein subunit, or genetic approaches.

CoV spike (S) proteins mediate cellular attachment and membrane fusion and are therefore the target of protective antibodies. Inventors at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases have developed a novel CoV S protein vaccine antigen. This technology employs protein engineering to stabilize S in its prefusion conformation, preventing structural rearrangement, and exposing antigenically preferable surfaces. The technology has been applied to several CoV spikes, including those from human-relevant viruses, such as HKU1-CoV, SARS-CoV, and MERS-CoV. Particularly for MERS-COV, stabilized S proteins have been shown to elicit superior neutralizing antibody responses up to 10-fold higher in animal models and protect mice against lethal MERS-CoV infection. This technology is applicable for delivery via other platforms, such as mRNA.

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:

The stabilized prefusion coronavirus spike protein can be used as a vaccine antigen to elicit robust neutralizing antibody responses.

Competitive Advantages:

- Improved immunogenicity compared to other coronavirus S vaccine formulations.
- Increased protein expression, stability, and manufacturability compared to wild-type CoV S.

Development Stage:

- In vivo data available (animal).

Inventors:

Barney Graham (NIAID), Masaru Kanekiyo (NIAID), M. Gordon Joyce (NIAID), Kizzmekia Corbett (NIAID), Hadi Yassine (NIAID), Andrew Ward (Scripps), Robert Kirchdoefer (Scripps), Christopher Cottrell (Scripps), Jesper Pallesen (Scripps), Hannah Turner (Scripps), Nianshuang Wang (Dartmouth), Jason McLellan (Dartmouth),

Intellectual Property: HHS Reference No. E-234-2016/0, U.S. Provisional Patent Application Number 62/412,703, filed October 25, 2016, PCT Patent Application PCT/US2017/058370 filed October 25, 2017.

Licensing Contact: Amy Petrik, Ph.D., 240-627-3721; amy.petrik@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 norovirus diagnostics or vaccines. For collaboration opportunities, please contact Amy Petrik, Ph.D., 240-627-3721; amy.petrik@nih.gov.

Dated: April 5, 2018

_____

Suzanne M. Frisbie.

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018-07822 Filed: 4/13/2018 8:45 am; Publication Date: 4/16/2018]