[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: Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov. Licensing information and copies of the U.S. patent application 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

Novel Multivalent Nanoparticle Vaccines

Description of Technology:

Current seasonal influenza vaccines are designed to elicit immunity to circulating strains of influenza each year. The targeted strains are selected based on predictions of

which strains are likely to be predominant in the human population for a given year. This prediction must be made well ahead of the influenza season to allow time for vaccine production and can be inaccurate.

Scientists at NIAID's Vaccine Research Center are developing an alternative approach for design and production of seasonal influenza vaccines. The design includes recombinant fusion proteins that self-assemble into nanoparticles with influenza antigenic proteins displayed on the nanoparticle surface (*Nature* **499,** 102-106 (2013)). Further engineering these recombinant fusion proteins, the scientists have developed nanoparticles that simultaneously display multiple strains of influenza viral protein antigens (the receptor-binding domain of hemagglutinin) on their surface. Due to the heterogeneity of the antigenic protein derived from multiple strains, these nanoparticles are referred to as mosaic nanoparticles.

Upon immunization of mice with mosaic nanoparticles displaying antigens from eight different H1N1 strains, the elicited antibodies neutralized a panel of H1N1 strains from 1918 through 2009 including the strains that had not been displayed on the mosaic nanoparticle. However, mice immunized with a mixture of the eight types of nanoparticles, each displaying a single antigenic protein, did not elicit a similar breadth of neutralizing antibody response.

NIAID is continuing development of these vaccine candidates through animal studies and moving toward clinical evaluation.

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:

- Vaccine platform for seasonal influenza with broader protection coverage

Competitive Advantages:

- Nucleic acid or recombinant protein-based vaccine
- Increased ease of production compared to current seasonal influenza vaccines

Development Stage:

- In vivo (animal studies)

Inventors: Barney S. Graham, Hadi Yassine, Masaru Kanekiyo (all from NIAID).

Publications: Kanekiyo, M, et al. *Manuscript under revision.*

Intellectual Property: HHS Reference Number E-060-2015 includes U.S. Patent Application No. 15/540,898 filed June 29, 2017 (Pending); Canada Patent Application No. 2,974,346 filed December 31, 2015 (Pending); China Patent Application No. 201580076324.6 filed December 31, 2015 (Pending); Europe Patent Application No. 15825772.5 filed July 7, 2017 (Pending); India Patent Application No 201717026077 filed July 21, 2017 (Pending); Australia Patent Application No. 2015373928 filed July 21, 2017; Brazil Patent Application No. BR112017014219-8 filed June 29, 2017; Israel Patent Application No. 253187 filed December 31, 2015; Japan Patent Application No. 2017-534796 filed June 28, 2017; South Korean Patent Application No. 10-2017-7021112 filed July 27, 2017; Singapore Patent Application No. 11201705264W filed June 23, 2017.

Related Intellectual Property: HHS Reference Number E-293-2011

Licensing Contact: Dr. Amy Petrik, 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 influenza monoclonal antibody technologies**.** For collaboration opportunities, please contact Dr. Amy Petrik, 240-627-3721; amy.petrik@nih.gov.

Dated: April 5, 2018

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Suzanne M. Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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