[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: Vince Contreras, Ph.D., 240-669-2823; vince.contreras@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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

Prefusion HPIV F Immunogens and Their Use.

Description of Technology:

Human parainfluenza virus (hPIV) is an RNA-based paramyxovirus that causes respiratory infections in children and adults. There are four serotypes that can result in a

myriad of diseases of the respiratory tract including croup, bronchitis, and pneumonia (Mao et al., 2012). hPIV is a leading cause of respiratory tract infection and hospitalization among children under 5, only surpassed by the respiratory syncytial virus (RSV). Currently, there are limited treatment options and no approved vaccines. Recently, studies showed that a large proportion of neutralizing antibodies preferentially recognize exposed epitopes in the prefusion conformation of the RSV F protein, which together with other evidence suggests that creation of stabilized prefusion F protein immunogens might be a universal strategy to develop vaccine candidates for inducing protective immune responses in RSV and other related viruses, such as hPIV.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases created immunogenic PIV fusion (F) glycoproteins for types 1,2,3 and 4 (hPIV1, hPIV2, hPIV3 and hPIV4) that have been modified to stabilize the prefusion conformation.

These stabilized prefusion F immunogens, especially hPIV3, induced high titer neutralizing responses in mice and rhesus macaques, and should thus serve as promising candidates for the prevention of PIV infection in humans.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. § 209 and 37 CFR Part 404.

Potential Commercial Applications:

- hPIV vaccines for people of all ages;
- Specific focus on the elderly and young children

Competitive Advantages:

- Use as a multivalent hPIV vaccine;

- Use in combination with influenza or RSV vaccine compositions;
- hPIV3 neutralizing titers induced in both mice and rhesus macaques were substantially higher than the highest PIV3 neutralizing titers observed in a cohort of over 100 humans.

Development Stage:

- *In vivo* testing (primates and mice)

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Intellectual Property: HHS Reference Number E-215-2016 includes U.S. Provisional Patent Application Number 62/412,699 filed 10/25/2016 and PCT Application Number PCT/US2017/058322 filed 10/25/2017 (pending).

Related Intellectual Property: HHS Reference Number: E-064-2016.

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