



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: Carol A. Salata at 240-627-3727; csalata@niaid.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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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-Stabilized Fusion (F) Glycoprotein Vaccine Immunogens For Human

Metapneumovirus

Description of Technology:

Human metapneumovirus (hMPV) infections have been shown as a common cause of upper and lower respiratory diseases such as bronchiolitis and pneumonia in young children, the elderly, and other immunocompromised individuals. Studies show that infections by the non-segmented negative strand RNA virus begin with attachment and entry of viral glycoproteins that mediate fusion with host cellular membranes. Like for the human respiratory syncytial virus (hRSV), a viral entry is initiated by the fusion (F) protein. Given its role in hMPV entry, the F protein has thus been a target for eliciting neutralizing antibodies and development of novel protein-based therapeutic vaccines.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases (NIAID) developed improved recombinant human metapneumovirus (hMPV) F proteins stabilized in the prefusion conformation that can elicit potent neutralizing antibodies against infection. Double and triple stabilized candidates were designed with inter- and intraprotomer disulfide mutations that increase protein production and show improved antigenic recognition by prefusion-specific antibodies. These second-generation immunogens constitute an improvement over the first generation constructs and are characterized by additional stabilization that results in optimal neutralization responses.

The second-generation stabilized prefusion hMPV F immunogens may be an ideal vaccine immunogen to elicit broad potent neutralizing antibodies against metapneumovirus infection, particularly in children and immunocompromised adults.

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:

- A promising vaccine immunogen to elicit broad potent neutralizing antibodies against metapneumovirus infection, particularly in children and immunocompromised adults.

Competitive Advantages:

- There are no approved vaccines or therapeutics against the second leading cause of pediatric viral lower respiratory tract infection in infants and young children.
- Second-generation hMPV F immunogens induce higher titer neutralizing responses than first-generation versions in mice.

Development Stage: Preclinical Research.

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Publications: Liu, P., et al (2013). A live attenuated human metapneumovirus vaccine strain provides complete protection against homologous viral infection and cross-protection against heterologous viral infection in BALB/c mice. *Clinical and Vaccine Immunology*, 20(8), 1246-1254.

Battles, M. B., et al, (2017). Structure and immunogenicity of pre-fusion-stabilized human metapneumovirus F glycoprotein. *Nature communications*, 8(1), 1-11.

Intellectual Property: HHS Reference Number E-131-2019 includes U.S. Provisional Patent Application Number 63/017,581, filed on 04/29/2020.

Licensing Contact: To license this technology, please contact Carol A. Salata at 240-627-3727; csalata@niaid.nih.gov

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