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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, PhD, 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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

Substitutions-modified Prefusion RSV F Proteins and their Use

Description of Technology:

The respiratory syncytial virus (RSV) fusion (F) glycoprotein is the primary target of neutralizing antibodies. The F glycoprotein exists in at least two conformations, a meta-stable prefusion state, and an extremely stable postfusion state. Both states share several

epitopes targeted by neutralizing antibodies, but it has been demonstrated that the prefusion conformation of F contains at least one epitope not present in the postfusion conformation. Natural infection results in neutralizing antibodies that are primarily directed against the prefusion conformation of F, not its postfusion conformation. The instability of the prefusion form of F has hindered both its characterization and its use as a vaccine antigen.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases have overcome technical obstacles to produce a homogeneous, soluble RSV F glycoprotein vaccine which is stabilized in the prefusion conformation and has improved stability and immunogenicity compared to the native protein. Additionally, several modifications were introduced to remove the requirement for furin during production, resulting in an increase in expression levels of the immunogen. Stability of the immunogen was increased 20-fold as compared to DS-CAV1 (a prefusion-stabilized RSV F glycoprotein vaccine candidate that is currently being assessed in clinical trials) upon incubation at 60 ºC. In mice, these immunogens elicited neutralization titers that were 2 to 5-fold higher than DS-CAV1.

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: RSV vaccine for human use.
- Probe: B cell-sorting probe to isolate potent neutralizing monoclonal antibodies
- Diagnostics: To assess the titer of prefusion-specific antibodies in sera.

Competitive Advantages:

- Increased stability compared to the current leading RSV vaccine candidate (DS-Cav1).
- Elicits increased neutralization titers in mice.

Development Stage:

- *In vivo* testing (mice)

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Publications: Joyce, M. Gordon, et al., Nature structural & molecular biology, 23.9 (2016): 811; PMID: 27478931

Intellectual Property: HHS Reference Number E-064-2016: U.S. Patent Application \ No. 62/314,946 filed 03/29/2016; PCT Application Number PCT/US2017/024714 filed 03/29/2017 (pending)

Related Intellectual Property: HHS Reference Number E-081-2013

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