[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: Peter Soukas, J.D., 301-594-8730; peter.soukas@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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

Attenuated Human Parainfluenza Virus Type 1 Expressing Ebola Virus Glycoprotein GP as an Intranasal Ebola Vaccine

Description of Technology:

Ebola virus (EBOV) hemorrhagic fever is one of the most lethal viral infections and lacks a licensed vaccine. EBOV is transmitted by contact with body fluids from infected individuals including droplets or aerosols. Aerosolized EBOV could also be exploited for intentional virus spread. Therefore, vaccines that protect against mucosal and systemic exposure are needed.

The NIH/NIAID has developed recombinant human parainfluenza virus type 1 (rHPIV1) bearing a stabilized attenuating mutation in the P/C gene to express the membrane-anchored form of EBOV glycoprotein GP as an intranasal (IN) EBOV vaccine. GP was codon optimized and expressed either as a full-length protein or a chimeric form in which its transmembrane and cytoplasmic tail (TMCT) domains were substituted with those of the HPIV1 F protein in an effort to increase packaging into the vector particle and enhance immunogenicity. GP was inserted either preceding the N gene (pre-N) or between the N and P genes (N-P) of rHPIV1. All vectors replicated to high titers in vitro and had stable GP expression. Viruses were attenuated and replicated at low titers in the respiratory tract of African green monkeys. Two doses of candidates expressing GP from the pre-N position elicited higher GP neutralizing serum antibody titers than the N-P viruses, and unmodified GP induced higher levels than its TMCT counterpart. Unmodified EBOV GP was packaged into the HPIV1 particle, and the TMCT modification did not increase packaging or immunogenicity. Overall, the candidate expressing full-length GP from the Pre-N position was the most immunogenic.

This invention relates to an attenuated and immunogenic IN vaccine candidate expected to be well tolerated in humans and is available for 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:

- Viral diagnostics
- Vaccine research

Competitive Advantages:

- Ease of manufacture
- Bivalent or Multivalent live attenuated vaccines
- B cell and T cell activation
- Low-cost vaccines
- Intranasal administration/needle-free delivery

Development Stage:

- In vivo data assessment (animal)

Inventors: Shirin Munir (NIAID), Matthias Lingemann (NIAID), Ursula Buchholz (NIAID), Peter Collins (NIAID).

Publications: "Attenuated Human Parainfluenza Virus Type 1 Expressing **Ebola** Virus Glycoprotein GP Administered Intranasally Is Immunogenic in African Green Monkeys," Lingemann M, Liu X, Surman S, Liang B, Herbert R, Hackenberg AD, Buchholz UJ, Collins PL, Munir S. J Virol. 2017 Apr 28;91(10). pii: e02469-16. doi: 10.1128/JVI.02469-16. Print 2017 May 15. PMID: 28250127

Intellectual Property: HHS Reference No. E-142-2018/0

Licensing Contact: Peter Soukas, J.D., 301-594-8730; peter.soukas@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 for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301-594-8730; peter.soukas@nih.gov.

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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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