

interpretation or other reasonable accommodations, should indicate the special accommodation when registering online or by notifying Jennifer Gillissen at jennifer.gillissen@kauffmaninc.com by October 25.

Authority: The National Clinical Care Commission is required under the National Clinical Care Commission Act (Pub. L. 115–80). The Commission is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C., App.) which sets forth standards for the formation and use of federal advisory committees.

Dated: October 1, 2018.

Don Wright,

Deputy Assistant Secretary for Health (Disease Prevention and Health Promotion).

[FR Doc. 2018–21854 Filed 10–5–18; 8:45 am]

BILLING CODE 4150–32–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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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.

Dated: September 25, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2018–21768 Filed 10–5–18; 8:45 am]

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.

Hybridoma Cell Lines Producing Antibodies to RSV NS1

Description of Technology: This technology provides a new set of hybridoma cell lines each expressing a single monoclonal antibody against human respiratory syncytial virus (RSV) nonstructural protein 1 (NS1). These antibodies have variously been shown to detect NS1 protein in an enzyme-linked immunosorbent assay (ELISA), Western blot assay, immunofluorescence microscopy of paraformaldehyde-fixed cells, and flow cytometry. The various antibodies can vary in their efficiency in each of these assays. This technology provides a unique set of qualified monoclonal antibodies against RSV NS1 protein which currently do not exist. These antibodies and cell lines may be of interest to any persons investigating RSV infection processes, particularly as it relates to the activity of NS1 in such an infection process.

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
- Unique research tool

Development Stage:

- *In vitro* data assessment

Inventors: Thomas McCarty (NIAID), Joseph Marcotrigiano (NIAID), Peter Collins (NIAID).

Publications: None.

Intellectual Property: HHS Reference No. E-018-2018/0—U.S. Provisional Application No. 62/661,320, filed April 23, 2018 (pending).

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.

Dated: September 25, 2018.

Suzanne M. Frisbie,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

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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:

Barry Buchbinder, Ph.D., 240-627-3678; barry.buchbinder@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.

HIV-1 Env Fusion Peptide Immunogens and Their Use

Description of Technology: Millions of people are infected with HIV-1 worldwide, and 2.5 to 3 million new infections have been estimated to occur yearly. Although effective antiretroviral therapies are available, millions succumb to AIDS every year, especially in Sub-Saharan Africa, underscoring the need to develop measures to prevent the spread of this disease.

HIV-1 is an enveloped virus, which hides from humoral recognition behind a wide array of protective mechanisms. During infection, the major envelope protein of HIV-1 is cleaved by host cell proteases into two smaller versions (gp120 and gp41). Together gp120 and gp41 make up the HIV-1 Env spike, which is a target for neutralizing antibodies. It is believed that immunization with an effective immunogen based on the HIV-1 Env glycoprotein can elicit a neutralizing response, which may be protective against HIV-1 infection.

Researchers at the Vaccine Research Center (VRC) of the National Institute of Allergy and Infectious Diseases used knowledge from the crystal structure of an HIV-1 neutralizing antibody, VRC34.01, in complex with its epitope on the HIV-1 Env trimer, to develop novel immunogens. HIV-1 uses a fusion peptide, located at the N-terminus of the gp41 subunit, to fuse with a target cell to infect the cell. The crystal structure revealed the epitope recognized by VRC34.01 to be composed primarily of the exposed 8 residues of the fusion peptide at the N-terminus of the gp41 subunit. Researchers designed fusion peptide immunogens that were comprised of the exposed residues of the fusion peptide coupled to highly immunogenic carrier proteins to focus the immune response to this conserved site of vulnerability. The fusion peptide can be displayed on scaffold proteins and—when coupled to HIV-1 Env trimer boosts—has the potential to elicit antibodies capable of neutralizing diverse HIV-1 strains in mice, guinea pigs and rhesus macaques, and might therefore serve as the basis for an effective HIV vaccine.

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:

HIV-1 vaccine

Competitive Advantages:

Potential to be a broadly neutralizing HIV-1 vaccine

Development Stage: *In vivo* testing (rodents and non-human primates).

Inventors: Peter Kwong (NIAID), John Mascola (NIAID), Kai Xu (NIAID), Rui Kong (NIAID), Tongqing Zhou (NIAID), Li Ou (NIAID), Cheng Cheng (NIAID), Wing-Pui Kong (NIAID), Gwo-Yu Chuang (NIAID), Kevin Liu (NIAID), Michael Gordon Joyce (NIAID), Yongping Yang (NIAID), Baoshan Zhang (NIAID)

Publications:

(a) Kong, Rui, et al. “Fusion peptide of HIV-1 as a site of vulnerability to