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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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

Recombinant RSV B1 expressing eGFP as a reporter gene

Description of Technology:

The inventors have created a reverse genetics system for RSV strain B1 of antigenic subgroup B encoding a replication-competent recombinant RSV that contains a codon-optimized G ORF and expresses enhanced green fluorescence protein (GFP). There are two antigenic subgroups of RSV, subgroups A and B, and most of the available information and reagents are for subgroup A. Immunity against either subgroup has reduced effectiveness in restricting the heterologous subgroup, suggesting that an effective RSV vaccine might need to contain both subgroups. The sequence of the wild type G gene was refractory to cloning into full-length antigenomic cDNA in *E. coli*, and so the inventors made and successfully used a codon optimized version. In addition, the inventors inserted an eGFP gene into the first gene position (promoter proximal). The resulting virus is replication-competent and efficiently expresses GFP in infected cells. This virus can be used as a tool to detect RSV-neutralizing antibodies to RSV subgroup B in a plaque-reduction assay. It also can be used to evaluate RSV infection in vitro and in vivo using GFP fluorescence to track infection. The antigenomic cDNA clone also provides the starting material for making live-attenuated subgroup B-specific RSV vaccine candidates containing defined mutations. These defined mutations can include ones that we previously developed for RSV subgroup A, and include stabilized point mutations, stabilized codon-deletions, and gene-deletions.

The present invention provides a reverse genetics system encoding strain B1 of RSV subgroup B containing a codon-optimized G ORF and encoding eGFP. This provides a tool for RSV subgroup B serology assays, for tracking RSV infection, and a starting point for making attenuated subgroup B strains for vaccine purposes.

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
- Serology assays
- Vaccine manufacture

Competitive Advantages:

- Ease of manufacture
- Unique research tool

Development Stage:

- *In vitro* data assessment

Inventors: Ursula Buchholz (NIAID), Peter Collins (NIAID).

Publications: None.

Intellectual Property: HHS Reference No. E-159-2018-0

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.

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