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 A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.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

Genomic sequence of avian paramyxovirus type 2 and uses thereof

Description of Technology:

As a first step towards characterizing the molecular genetics and pathogenesis of avian paramyxovirus type 2 (APMV-2), the biological activities and growth characteristics of APMV-2 were investigated. The present inventors found that APMV-2 is different than Newcastle Disease Virus (NDV, AMPV-1) in several characteristics: (I) APMV-2 does not require trypsin or allantoic fluid to grow in cell culture; (II) previous RNA-RNA hybridization studies showed APMV-2 is genetically different than NDV; (III) APMV-2 is the only paramyxovirus serotype which causes single-cell infection foci in cell culture, and does not induce cell fusion, which is a hallmark of paramyxovirus infection; (IV) APMV-2 does not kill chicken embryos; and (V) APMV-2 does not grow in the brain of chickens.

These results suggested that APMV-2 is significantly different biologically and genetically from NDV. These differences provide certain advantages over other viruses considered for use as a vaccine, as a virus vector, or as a therapeutic. For example, unlike the current NDV vaccine such as LaSota and Hitchner B1 that can cause disease due to reversion to virulence, since AMPV-2 is not an agricultural pathogen, it is not a concern for the poultry industry. Unlike many strains of NDV, APMV-2 is not a Select Agent.

However, in order to develop a recombinant APMV-2 virus for use as a vector, vaccine, or cancer therapy, the complete genome sequence was needed, and a reverse genetic system needed to be developed. Sequence analysis proved to be difficult since primers based on NDV were not useful because the two viruses are genetically different. Therefore, different strategies had to be used for primer design, including the design and testing of consensus primers from other paramyxoviruses, primers based on gene start and gene end sequences of other paramyxoviruses, and primer walking.

This invention covers the complete genomic sequence of avian paramyxovirus type 2, strains Yucaipa, England, Kenya and Bangor. The genomic sequence of strain Yucaipa was used to develop a reverse genetic system for AMPV-2. This produced cDNA-derived AMPV-2 with the same properties as biologically-derived AMPV-2, confirming the authenticity of the genomic sequence. The sequence and reverse genetic system are useful for production of recombinant infective virus, a virus vector, for vaccine development and for therapeutic compositions. The sequences are also useful for development of viral diagnostics. The recombinant APMV-2 was used to express a foreign antigen, the green fluorescent protein (GFP), and can be used as a vaccine vector. Recombinant APMV-2 can also be used in cancer treatment, similar to NDV.

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 therapeutics
- Viral diagnostics
- Vaccine research

Competitive Advantages:

- Ease of manufacture
- Low-cost vaccine
- Adjuvants unnecessary

Development Stage:

- In vivo data assessment (animal)

Inventors: Siba Samal (EM), Peter Collins (NIAID).

Intellectual Property: HHS Reference No. E-019-2018-0 —U.S. Provisional Application No. 61/218,851, filed June 19, 2009, HHS Reference No. E-019-2018-1 – U.S. Patent Application No. 12/803165, filed June 21, 2010, now U.S. Patent No. 9,937,196.

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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Wade W. Green,

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Technology Transfer and Intellectual Property Office,

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