[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Production of Live Respiratory Syncytial Virus and Parainfluenza Virus Vaccines

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Summary Information section of this notice to Medigen Vaccines Biologics Corp. (Medigen), having a place of business in Zhubei, Taiwan.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Allergy and Infectious Diseases' Technology Transfer and Intellectual Property Office on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Commercialization Patent License should be directed to: Peter Soukas, Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Suite 6D, Rockville, MD 20852-9804; Email: ps193c@nih.gov; Telephone: (301) 496-2644; Facsimile: (240) 627-3117.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application Number 62/661,320, filed April 23, 2018 and entitled "Chimeric Vaccines," [HHS Reference No. E-018-2018-0]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive licensed territory may be worldwide, and the field of use may be limited to: "Live Respiratory Syncytial Virus (RSV) and Parainfluenza Virus (PIV) vaccines."

Human respiratory syncytial virus (RSV) continues to be the leading viral cause of severe acute lower respiratory tract disease in infants and children worldwide. A licensed vaccine or antiviral drug suitable for routine use remains unavailable. This invention relates to the use of murine pneumonia virus (MPV), a virus to which humans normally are not exposed and that is not cross-protected with RSV, as a vector to express the RSV fusion (F) glycoprotein as an RSV vaccine candidate. The RSV F ORF was

codon optimized. The RSV F ORF was placed under the control of MPV transcription signals and inserted at the first (rMPV-F1), third (rMPV29 F3), or fourth (rMPV-F4) gene position of a version of the MPV genome that contained a codon pair optimized L polymerase gene. The recovered viruses replicated in vitro as efficiently as the empty vector, with stable expression of RSV F protein. Replication and immunogenicity of rMPV-F1 and rMPV-F3 were evaluated in rhesus macaques following administration by the combined intranasal and intratracheal routes. Both viruses replicated at low levels in the upper and lower respiratory tract, maintained stable RSV F expression, and induced similar high levels of RSV-neutralizing serum antibodies that reached peak titers by fourteen (14) days post-vaccination. rMPV provides a highly attenuated yet immunogenic vector for the expression of RSV F protein, with potential application in RSV-naïve and RSV experienced populations. The technology relates to live, chimeric non-human Mononegavirales vectors that allow a cell to express at least one protein from at least one human pathogen as well as compositions comprising the vectors, methods and kits for eliciting an immune response in a host, and methods of making the vectors.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization license. In response to this Notice, the

public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License applications submitted in response to this Notice will be presumed to contain business confidential information, and any release of information in these license applications will be made only as required and upon a request under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: December 11, 2018.

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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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