[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Flavivirus Vaccines

AGENCY: National Institute of Allergy and Infectious Diseases, National Institutes of Health, Public Health Service, DHHS.

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.

DATE: Only written comments and/or application for a license which are received by the NIAID Technology Transfer and Intellectual Property Office on or before [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials 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 62/307,170, filed March 11, 2016 and entitled "Live Attenuated Zika Virus Vaccines," Whitehead et al., and PCT Patent Application Number PCT/US2017/0021989, filed March 11, 2017 and entitled "Live Attenuated Zika Virus Vaccines," Whitehead et al. [HHS Reference E-118-2016/0]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned to the government of the United States of America.

The field of use may be limited to monovalent live attenuated Zika vaccines and multivalent live attenuated flavivirus vaccines. The Licensed Territory may be limited to Europe, China, South Korea, Japan, India, Australia and New Zealand.

Zika virus (ZIKV) is an emerging infectious disease that was first identified in 1947, and that has more recently become a major public health threat around the world. ZIKV has recently been shown to cause devastating neurological damage in infants and serious complications in adults in some cases, and may have other effects that have not yet been identified or definitively

linked to the virus. There are no treatments or vaccines for this insidious virus. Recommendations that women who live in or travel to endemic areas avoid pregnancy for long periods of time are unrealistic, particularly in contexts where access to reproductive services is limited, and threaten to leave those most likely to suffer the devastating consequences of Zika without effective protection. There is therefore urgent need to develop biomedical interventions in parallel with ongoing public health efforts against ZIKV.

No vaccine exists today to prevent ZIKV infections. The methods and compositions of this invention provide a means for prevention of ZIKV infection by immunization with live attenuated, immunogenic viral vaccines against ZIKV and/or Dengue virus.

Many entities, governmental, academic, and commercial, are actively pursuing development of ZIKV vaccines each using a different approach to address this public health need. The U.S. Government is coordinating its vaccine development response to ZIKV and has published this plan at https://www.phe.gov/Preparedness/planning/Pages/zika-white-paper.aspx.

Vaccine development approaches for ZIKV include but are not limited to inactivated virus (dead virus), live attenuated virus (weakened virus), recombinant viral vectors (weakened virus with target genes added), and subunit (portion of a virus) as well as mRNA- and DNA-based (gene-targeted). These various strategies provide multiple redundancies, expanded choice, and ensure short and long term maximal benefits to the public.

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 thirty (30) 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 filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Commercialization Patent License Agreement. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the *Freedom of Information Act*, 5 U.S.C. 552.

Dated: May 14, 2018

_____

Suzanne M. Frisbie

Deputy Director

Technology Transfer and Intellectual Property Office

National Institute of Allergy and Infectious Diseases

[FR Doc. 2018-11258 Filed: 5/24/2018 8:45 am; Publication Date: 5/25/2018]