



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

Prospective Grant of Co-Exclusive Patent License: Production of Monovalent Live Attenuated Zika Vaccines and Multivalent Live Attenuated Zika and Dengue 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 a Co-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, and Panacea Biotec Ltd., having a place of business in New Delhi, India.

**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 30 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 Co-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,” [HHS Reference No. E-118-2016-0-US-01]; PCT Patent Application Number PCT/US2017/0021989, filed March 11, 2017 and entitled “Live Attenuated Zika Virus Vaccines,” [HHS Reference No. E-118-2016-0-PCT-02]; Indian Patent Application Number 201817036778 filed September 28, 2018 and entitled “Live Attenuated Zika Virus Vaccines,” [HHS Reference No. E-118-2016-0-IN-09]; 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 co-exclusive licensed territory may be limited to India, and the field of use may be limited to: “Monovalent live attenuated Zika vaccines and multivalent live attenuated flavivirus vaccines.”

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 co-exclusive license will be royalty bearing, and the prospective co-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 licenses 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 co-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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