[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Production of Attenuated West Nile Virus Vaccines

AGENCY: National Institutes of Health, Department of Health and Human Services.

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 the International Medica Foundation located in Shoreview, Minnesota, U.S.A.

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) 594-8730; Facsimile: (240) 627-3117.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-357-2001/0,1, Pletnev et al., "Construction of West Nile Virus and Dengue Virus Chimeras for use in a Live Virus Vaccine to Prevent Disease Cause by West Nile Virus," U.S. Provisional Patent Application Number 60/347,281, filed January 10, 2002, PCT Patent Application Number PCT/US2003/00594, filed January 9, 2003, U.S. Patent Application Number 10/871,775 filed June 18, 2004 (now U.S. Patent Number 8,778,671), U.S. Patent Application Number 14/305,572, filed June 16, 2014, European Patent Application Number 03729602.7, filed January 9, 2003, Israeli Patent Application Number 162949, filed January 9, 2003 (now Israeli Patent Number 162949), Canadian Patent Application Number 2472468, filed January 9, 2003 (now Canadian Patent Number 2472468), Australian Patent Application Number 2003216046, filed January 9, 2003 (now Australian Patent Number 2003216046), Japanese Patent Application Number 2003-559545, filed January 9, 2003 (now Japanese Patent Number 4580650), Australian Patent Application Number 2008203442 filed July 31, 2008 (now Australian Patent Number 2008203442), Israeli Patent Application Number 209342, filed January 9, 2003

(now Israeli Patent Number 209342), European Patent Application Number 11000126.0, filed January 9, 2003 (now European Patent Number 2339011, validated in Belgium, Great Britain, the Netherlands, Norway, Germany, Denmark and France), Australian Patent Application Number 2011250694, filed November 10, 2011 (now Australian Patent Number 2011250694), Australian Patent Application Number 2013213749, filed August 9, 2013, European Patent Application Number 15163537.2, filed April 14, 2015, and Canadian Patent Application Number 2903126, filed August 27, 2015, and U.S. and foreign patent applications claiming priority to the aforementioned applications.

E-006-2007/0, Pletnev et al., "Synergistic Internal Ribosome Entry Site/MicroRNA Based Approach for Attenuation of Flaviviruses and Live Vaccine Development," U.S. Provisional Patent Application Number 62/443,214, filed January 6, 2017, 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 prospective exclusive license territory may be worldwide and the field of use may be limited to live attenuated West Nile Virus vaccines for use in humans or animals.

West Nile virus (WNV) is a positive-strand RNA virus of the family Flaviviridae, part of the Japanese encephalitis virus serocomplex that includes important human pathogens such as Murray Valley encephalitis, Japanese encephalitis, and St. Louis encephalitis viruses. WNV has been present in Africa and Asia for decades and has usually been associated with mild illness that includes symptoms of low-grade fever, headache, rash, myalgia, and arthralgia. Recently, WNV has spread rapidly across the

Western hemisphere and is now the major vector-borne cause of viral encephalitis in the United States. By 2010, 3 million adults were estimated to have been infected with WNV in the United States, with nearly 13,000 cases of neuroinvasive disease, almost half of which occurred in adults greater than 60 years of age. In this age group, WNV infection can cause hepatitis, meningitis, and encephalitis, leading to paralysis, coma, and death. WNV is considered an emerging infection in the United States and presents a significant public health threat. This epidemiological trend of WNV suggests that the United States can expect periodic WNV outbreaks, underscoring the need for a safe and effective vaccine to protect at-risk populations, especially older adults.

WNV is also a significant worldwide public health threat. Starting in the mid-1990s, the frequency, severity, and geographic range of WNV outbreaks increased, and outbreaks of WNV meningitis and encephalitis affecting primarily adults struck Bucharest, Romania, in 1996, Volgograd, Russia, in 1999, and Israel, in 2000. WNV crossed the Atlantic and reached the Western hemisphere in the summer of 1999 when a cluster of patients with encephalitis was reported in the metropolitan area of New York City, New York, in the United States, and within 3 years the virus had spread to most of the contiguous U.S. and the neighboring countries of Canada and Mexico. In addition, although few human cases have been reported, WNV has also been found in Central and South America through surveillance studies in field specimens, suggesting a potential risk for an outbreak in humans. In the approximately eighty (80) years since its discovery, the virus has propagated to a vast region of the globe and is now considered the most important causative agent of viral encephalitis worldwide.

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

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 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 24, 2017.

Suzanne Frisbie,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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