

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 the United States of America, Canada, Mexico, Brazil and Argentina.

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. While important, current measures for mosquito control are insufficient in most settings to prevent the spread of the 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Summer Research Education Experience Programs (R25).

Date: June 21, 2018.

Time: 12:00 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Hiromi Ono, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National

Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Boulevard, Room 4238, MSC 9550, Bethesda, MD 20892, 301-827-5820, hiromi.ono@nih.gov.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; NIH Pathway to Independence Award (K99/R00).

Date: June 25, 2018.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Susan O. McGuire, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, National Institute on Drug Abuse, National Institutes of Health, DHHS, 6001 Executive Blvd., Room 4245, Rockville, MD 20852, (301) 827-5817, mcguireso@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: May 21, 2018.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meetings

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The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; SBIR Phase II "Analytical Tools for Scholarly Research Assessment and Decision in the Biomedical Enterprise" (1214, 1217).

Date: May 31, 2018.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).