[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Multivalent Vaccines for Rabies Virus and Ebola and Marburg (Filoviruses)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a an exclusive license to practice the following invention as embodied in the following patent applications: E-032-2011/0, Blaney et al., "Multivalent Vaccines for Rabies Virus and Filoviruses," U.S. Patent Application Number 61/439,046, filed on February 3, 2011, PCT Application Number PCT/US2012/23575, filed on February 2, 2012, U.S. Patent Application Number 13/983,545, filed on August 2, 2013, European Patent Application Number 12702953.6, filed on February 2, 2012, and Canadian Patent Application Number 2826594, filed on February 2, 2012, to Exxell BIO, Inc., having a place of business in Shoreview, Minnesota, United States of America. The patent rights in these inventions have been assigned to the United States of America and Thomas Jefferson University.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE THIRTY (30) DAYS FROM DATE OF PUBLICATION OF NOTICE 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 license should be directed to: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: ps193c@nih.gov; Telephone: (301) 435-4646; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: No vaccine candidates against Ebola virus (EBOV) or Marburg virus (MARV) are nearing licensure, and the need to develop a safe and efficacious vaccine against filoviruses continues. Whereas several preclinical and clinical vaccine candidates against EBOV or MARV exist (please see below for further elaboration), their further development is a major challenge based on safety concerns, pre-existing vector immunity, issues such as manufacturing, dosage, and marketability, and funding for development. The inventors have developed a new platform based on live or chemically inactivated (killed) rabies virus (RABV) virions containing EBOV glycoprotein (GP) in their envelope. In preclinical trials, immunization with such recombinant RABV virions provided excellent protection in mice against lethal challenge with the mouse adapted EBOV and RABV. More specifically, the inventors have

developed a trivalent filovirus vaccine based on killed rabies virus virions for use in humans to confer protection from all medically relevant filoviruses and RABV. Two additional vectors containing EBOV Sudan GP or MARV GP are planned to be constructed in addition to the previously developed EBOV Zaire GP containing vaccine. Live attenuated vaccines have been developed for use in at risk nonhuman primate populations in Africa and inactivated vaccines have been developed for use in humans.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, NIH 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 404.

The fields of use may be limited to (1) inactivated vaccines against rabies virus and filoviruses for use in humans and (2) live attenuated vaccines against rabies virus and filoviruses for use in non-human animals.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: March 26, 2014.

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Richard U. Rodriguez,
Director,
Division of Technology Development and Transfer,

Office of Technology Transfer,
National Institutes of Health.

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