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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Live Attenuated Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in the 3'-UTR of Dengue Types 1, 2, 3, and 4

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 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: (1) E-120-2001/0, Whitehead et al., "Development of Mutations Useful for Attenuating Dengue Viruses and Chimeric Dengue Viruses", European Patent Application Number 02739358.6 (now European Patent Number 1402075, validated in Austria, Belgium, Switzerland/Liechtenstein, Germany, Denmark, Spain, Finland, France, the United Kingdom, Ireland, Italy, the Netherlands, Sweden and Turkey), filed May 22, 2002, United States Patent Application Number 10/719,547 (now U.S. Patent Number 7,226,602), filed November 21, 2003, Canadian Patent Application Number 2448329

(now Canadian Patent Number 2448329), filed May 22, 2002, Australian Patent Application Number 20022312011 (now Australian Patent Number 20022312011), filed May 22, 2002, Australian Patent Application Number 2008203275 (now Australian Patent Number 2008203275), filed May 22, 2002, Australian Patent Application Number 2012200637, filed May 22, 2002, United States Patent Application Number 11/446,050, filed June 2, 2006, now U.S. Patent Number 7,560,118, issued July 14, 2009, United States Patent Application Number 12/396,376 (now United States Patent Number 8,039,003), filed March 2, 2009, United States Patent Application Number 13/240,849, filed September 22, 2011, European Patent Application Number 10181776.5, filed May 22, 2002, European Patent Application Number 10181786.4, filed May 22, 2002, and European Patent Application Number 10181804.5, filed May 22, 2002 (2) E-089-2002/0,1, Whitehead et al., "Dengue Tetravalent Vaccine Containing a Common 30 Nucleotide Deletion in The 3'-UTR of Dengue Types 1,2,3, And 4, or Antigenic Chimeric Dengue Viruses 1,2,3, And 4", United States Patent Application Number 10/970,640 (now United States Patent Number 7,517,531), filed October 21, 2004, Canadian Patent Application Number 2483653, filed April 25, 2003, European Patent Application Number 03724319.3 (now European Patent Number 1554301, validated in Austria, Belgium, Bulgaria, Switzerland/Liechtenstein, Estonia, Finland, France, the United Kingdom, Ireland, Iceland, Italy, Lithuania, Malta, the Netherlands, Poland, Portugal, Romania, Sweden, Slovenia, Slovakia, Turkey, Cyprus, Croatia, Czech Republic, Denmark, Germany, Greece, Hungary, Latvia, Luxembourg, and Monaco), filed April 25, 2003, Japanese Patent Application Number 2004-50077, filed April 25, 2003, Australian Patent Application 2003231185 (now Australian Patent Number

2003231185), filed April 25, 2003, United States Patent Application Number 12/398,043 (now United States Patent Number 8,075,903), filed March 4, 2009, United States Patent Application Number 13/305,639, filed November 28, 2011, European Patent Application Number 10177735.7, filed April 25, 2003, and European Patent Application Number 10177740.7, filed April 25, 2003, and (3) E-139-2006/0, Whitehead et al., "Development of Dengue Vaccine Components", Australian Patent Application 2007285929, filed August 15, 2007, Canadian Patent Application Number 2661296, filed August 15, 2007, Chinese Patent Application Number 200780031489.4, filed August 15, 2007, European Patent Application Number 07840969.5, filed August 15, 2007, United States Patent Application Number 12/376,756 (now U.S. Patent Number 8,337,860), filed February 6, 2009, and United States Patent Application Number 13/692,557, filed December 3, 2012 to Merck Sharp & Dohme Corp., having a place of business in Whitehouse Station, New Jersey, U.S.A. The patent rights in this invention have been assigned to the United States of America.

DATE: 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.

ADDRESS: 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: The global prevalence of dengue has grown dramatically in recent decades. The disease is now endemic in more than 100 countries in Africa, North and South America, the Eastern Mediterranean, Southeast Asia and the Western Pacific. Southeast Asia and the Western Pacific are most seriously affected. Before 1970 only nine countries had experienced Dengue Hemorrhagic Fever (DHF) epidemics, a number that had increased more than four-fold by 1995. WHO currently estimates there may be 50 million cases of dengue infection worldwide every year.

The methods and compositions of this invention provide a means for prevention of dengue infection and dengue hemorrhagic fever (DHF) by immunization with attenuated, immunogenic viral vaccines against dengue. The vaccine is further described in Blaney JE et al., "Mutations which enhance the replication of dengue virus type 4 and an antigenic chimeric dengue virus type 2/4 vaccine candidate in Vero cells." *Vaccine*. 2003 Oct 1;21(27-30):4317-27 and Whitehead SS et al., "A live, attenuated dengue virus type 1 vaccine candidate with a 30-nucleotide deletion in the 3' untranslated region is highly attenuated and immunogenic in monkeys." *J. Virol*. 2003 Jan;77(2):1653-7.

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 Part 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 field of use may be limited to live attenuated vaccines against dengue infections in humans.

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.

July 15, 2013
Date

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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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