DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: 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, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, 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, Whitehead *et al.*, ''Development of Mutations Useful for Attenuating Dengue Viruses and Chimeric Dengue Viruses'', U.S. Provisional Patent Application 60/293,049, filed May 22, 2001, PCT/US02/16308, filed May 22, 2002, U.S. Patent Application 10/719,547, filed November 21, 2003, European Patent Application 02739358.6, filed May 22, 2002, Canadian Patent Application 2448329, filed May 22, 2002, Indian Patent Application 2814DELNP2003, filed May 22, 2002, Australian Patent Application 2002312011, filed May 22, 2002, and Brazilian Patent Application PI0209943.8, filed May 22, 2002, and (2) E–089–2002, ''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'', U.S. Provisional Applications 60/377,860, filed May 3, 2002, 60/436,500, filed December 23, 2002, PCT/US03/13279, filed April 25, 2003, to Fundaco Butantan, having a place of business in Sao Paulo, Brazil. The patent rights in this invention have been assigned to the United States of America.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before December 28, 2004, 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) 496–7056, ext. 268; 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 404.7. The prospective exclusive license may be granted unless, within 60 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 404.7.

The field of use may be limited to live attenuated vaccines against dengue infections in humans. The Licensed Territory may be limited to Brazil.

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: October 22, 2004.

Steven M. Ferguson,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 04–24167 Filed 10–28–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Public Health Service; Notice of Listing of Members of the Substance Abuse and Mental Health Services Administration's Senior Executive Service Performance Review Board (PRB)

The Substance Abuse and Mental Health Services Administration (SAMHSA) announces the persons who will serve on the Substance Abuse and Mental Health Services Administration's Performance Review Board. This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4), which requires that members of performance review boards be appointed in a manner to ensure consistency, stability, and objectivity in performance appraisals, and requires that notice of the appointment of an individual to serve as a member be published in the Federal Register.

The following persons will serve on the SAMHSA Performance Review Board, which oversees the evaluation of performance appraisals of SAMHSA's Senior Executive Service (SES) members: James L. Stone, Chairperson; Daryl W. Kade; Douglas Morgan; Kathryn Power.

For further information about the SAMHSA Performance Review Board, contact the Division of Management Systems, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 3–1017, Rockville, Maryland 20857, telephone (240) 276–1124 (not a toll-free number).

Dated: October 4, 2004.

Charles G. Curie,

Administrator, SAMHSA.

[FR Doc. 04–24155 Filed 10–28–04; 8:45 am]

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