

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, HHS.

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 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, 2001, 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 MacroGenics, Inc., having a place of business in Rockville, Maryland. 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 June 7, 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; E-mail:

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 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 the United States, the European Union, Japan, and Canada.

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 31, 2004.

Steven M. Ferguson,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Substance Abuse and Mental Health Services Administration****Notice of Request for Applications for Cooperative Agreements for Ecstasy and Other Club Drugs Prevention Services (SP 04-004)**

Authority: Section 506B of the Public Health Service Act.

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of request for applications for Cooperative Agreements for Ecstasy and Other Club Drugs Prevention Services (SP 04-004).

SUMMARY: The United States Department of Health and Human Services (HHS), Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) is accepting applications for fiscal year (FY) 2004 Cooperative Agreements for Agreements for Ecstasy and Other Club Drugs Prevention Services (SP 04-004). These cooperative agreements will expand and strengthen effective, culturally appropriate ecstasy and other club drugs prevention services at the State and local levels. The services implemented through these grants must incorporate the best objective information available regarding effectiveness and acceptability. SAMHSA/CSAP expects that the services funded through these grants will be sustained by the grantee beyond the term of the grant.

DATES: Applications are due on June 18, 2004.

FOR FURTHER INFORMATION CONTACT: For questions on program issues, contact: Tom DeLoo, Ph.D., SAMHSA/CSAP, 5600 Fishers Lane, Rockwall II, Suite 1075, Rockville, MD 20857, 301-443-9110, E-mail: *tdeloo@samhsa.gov*.

For questions on grants management issues, contact: Edna Frazier, Office of Program Services, Division of Grants Management, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockwall II, Suite 630, Rockville, MD 20857, (301) 443-6816, *efrazier@samhsa.gov*.

SUPPLEMENTARY INFORMATION: