

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 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.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before August 19, 2013 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: 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.

Dated: July 15, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013-17318 Filed 7-18-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2013 Funding Opportunity

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

ACTION: Notice of intent to award a Single Source Grant to the current grantee of the Suicide Prevention Resource Center program.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award a programmatic supplement of approximately \$583,330 (total costs) for up to one year to the current grantee of the Suicide Prevention Resource Center program. The current grantee is Education Development Center, Inc., Waltham, Massachusetts. This is not a formal request for applications. Assistance will be provided only to the Education Development Center, Inc. based on receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SM-13-008.

Catalog of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 520A and 520C of the Public Health Service Act, as amended.

Justification: The purpose of this 1-year supplement is to support implementation of the National Strategy for Suicide Prevention (NSSP) and to support the infrastructure of the National Action Alliance (Action Alliance) for Suicide Prevention, with the overall goal of reducing suicides and suicidal behaviors in the country.

Funds will be used to support implementation of the Action Alliance high priority area, to transform health care systems to significantly reduce suicide and suicide attempts.

This will also build on the momentum of the 2011 report released by the Action Alliance's Clinical Care and Intervention Task Force, *Suicide Care in Systems Framework*, including the informal "zero suicide" learning

collaborative, which currently involves six states and health care systems.

Funds will also be used to directly support the infrastructure of the Action Alliance such as funding staff support for key Alliance initiatives, including the Action Alliance Executive Committee and task forces, and for direct meeting expenses of the Executive Committee and select task forces.

SAMHSA funds only one Suicide Prevention Resource Center, SAMHSA's primary vehicle for providing technical assistance to the field. Therefore, this program supplement will be awarded to the grantee that manages the SPRC, specifically to the Education Development Center, Inc., Waltham, Massachusetts. There are no other sources with the available resources and expertise to successfully complete the tasks of this proposal within the one-year grant period.

Contact: Cathy Friedman, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8-1097, Rockville, MD 20857; Telephone: (240) 276-2316; Email: cathy.friedman@samhsa.hhs.gov.

Cathy J. Friedman,

Public Health Analyst, SAMHSA.

[FR Doc. 2013-17276 Filed 7-18-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2013 Funding Opportunity

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

ACTION: Notice of intent to award a Single Source Grant to Link2Health Solutions, Inc.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) intends to award approximately \$200,000 (total costs) for up to one year to Link2Health Solutions, Inc. the current grantee for the National Suicide Prevention Lifeline. This is not a formal request for applications. Assistance will be provided only to Link2Health Solutions, Inc based on the receipt of a satisfactory application that is approved by an independent review group.

Funding Opportunity Title: SM-13-012.

Catalog Of Federal Domestic Assistance (CFDA) Number: 93.243.

Authority: Section 520A of the Public Health Service Act, as amended.

Justification: Only an application from Link2Health Solutions will be considered for funding under this announcement. It is considered most cost-effective and efficient to supplement the existing grantee for the National Suicide Prevention Lifeline and to build on the existing capacity and infrastructure.

Link2Health Solutions is in the unique position to carry out the activities of this grant announcement because it is the current recipient of SAMHSA's cooperative agreement to manage the National Suicide Prevention Lifeline. The purpose of this program is to manage, enhance, and strengthen the National Suicide Prevention Lifeline (referred to as the Lifeline).

Supplemental funding is being provided for the National Suicide Prevention Lifeline as a result of increased need for services through non-traditional telephonic means (e.g. chat and text-based intervention services). Priorities and awareness raising activities will also be directed towards ensuring that the prevention needs of diverse populations will be addressed.

Contact: Cathy Friedman, Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Room 8-1097, Rockville, MD 20857; Telephone: (240) 276-2316; Email: cathy.friedman@samhsa.hhs.gov.

Cathy J. Friedman,

Public Health Analyst, SAMHSA.

[FR Doc. 2013-17269 Filed 7-18-13; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[Docket No. USCBP-2013-0027]

Advisory Committee on Commercial Operations of Customs and Border Protection (COAC)

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security (DHS).

ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The Advisory Committee on Commercial Operations of Customs and Border Protection (COAC) will meet on August 7, 2013, in Washington, DC. The meeting will be open to the public.

DATES: COAC will meet on Wednesday, August 7, from 1:00 p.m. to 5:00 p.m. e.s.t. Please note that the meeting may