

- Shigella vaccines, therapeutics and diagnostics.

Competitive Advantages

- Vector is well-characterized.
- Simple manufacturing process.
- Potential low-cost vaccine.
- Oral vaccine—avoids need for needles.
- Temperature-stable formulation allows for vaccine distribution without refrigeration.

Development Stage

- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Dennis J. Kopecko and De Qi Xu (FDA/CBER)

Publication

Xu DQ, et al. Core-linked LPS expression of Shigella dysenteriae serotype 1 O-antigen in live Salmonella typhi vaccine vector Ty21a: preclinical evidence of immunogenicity and protection. Vaccine. 2007 Aug 14;25(33):6167–75. [PMID 17629369]

Intellectual Property: HHS Reference No. E-214-2004/0—

- EP Application No. 05754091.6 filed 24 May 2005
- EP Application No. 12186545.5 filed 24 May 2005
- US Patent No. 8,071,113 issued 06 Dec 2011
- US Patent No. 8,337,831 issued 25 Dec 2012
- US Application No. 13/687,797 filed 28 Nov 2012

Licensing Contact: Peter A. Soukas; 301-435-4646; soukasp@mail.nih.gov

Collaborative Research Opportunity: The FDA Center for Biologics Evaluation and Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize combination typhoid-shigellosis oral vaccine. For collaboration opportunities, please contact Dr. Dennis J. Kopecko at dennis.kopecko@fda.hhs.gov or 301-661-8839.

Oral Shigellosis Vaccine

Description of Technology: This application claims a *Salmonella typhi* Ty21a construct comprising a *Shigella sonnei* O-antigen biosynthetic gene region inserted into the *Salmonella typhi* Ty21a chromosome, where heterologous *Shigella sonnei* form 1 O-antigen is stably expressed together with homologous *Salmonella typhi* O-antigen. The constructs of this invention elicit immune protection against virulent *Shigella sonnei* challenge, as well as *Salmonella Typhi* challenge.

Also claimed in this application are methods of recombinering a large antigenic gene region into a bacterial chromosome.

Bacillary dysentery and enteric fevers continue to be important causes of morbidity in both developed and developing nations. *Shigella* cause greater than one hundred and fifty million cases of dysentery and enteric fever occurs in greater than twenty-seven million people annually. Currently, there is no licensed vaccine to prevent the occurrence of shigellosis. Increasing multiple resistance in *Shigella* commonly thwarts local therapies.

Potential Commercial Applications

- One component of a multivalent Shigellosis vaccine under development
- Research tool

Competitive Advantages

- Low cost production
- Lower cost vaccine
- Oral vaccine—no needles required
- Temperature-stable manufacturing process—avoids need for refrigeration during vaccine distribution

Development Stage

- Pre-clinical
- In vitro data available
- In vivo data available (animal)

Inventors: Dennis J. Kopecko and Madushini N. Dharmasena (FDA/CBER)

Publication

Dharmasena MN, et al. Stable Expression of Shigella sonnei Form I O-Polysaccharide Genes Recombineered into the Chromosome of Live Salmonella Oral Vaccine Vector Ty21a. Int J Med Microbiol. 2013 (accepted).

Intellectual Property: HHS Reference No. E-168-2012/0—US Application No. 61/701,939 filed 17 Sep 2012

Licensing Contact: Peter A. Soukas; 301-435-4646; soukasp@mail.nih.gov

Collaborative Research Opportunity: The FDA Center for Biologics Evaluation and Research is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize oral Shigellosis vaccine. For collaboration opportunities, please contact Dr. Dennis J. Kopecko at dennis.kopecko@fda.hhs.gov or 301-661-8839.

Dated: February 1, 2013.

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

[FR Doc. 2013-02834 Filed 2-7-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Beta-Cell Function and Cognition.

Date: March 4, 2013.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Barbara A. Woynarowska, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 402-7172, woynarowskab@nidk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK R24 SEP.

Date: March 4, 2013.

Time: 12:30 p.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Xiaodu Guo, MD, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 761, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-4719, guox@extra.nidk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Liver Related Ancillary Studies.

Date: March 13, 2013

Time: 1:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Paul A. Rushing, Ph.D., Scientific Review Officer, Review Branch,

DEA, NIDDK, National Institutes of Health, Room 747, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8895, rushingp@extra.niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Limited Competition for the Continuation of Look AHEAD (Action for Health in Diabetes) Consortium (U01-RFA-DK12-502).

Date: March 14, 2013.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK Ancillary Studies.

Date: March 15, 2013.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 760, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-3993, tathamt@mail.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Limited Competition Acute Kidney Injury.

Date: March 20, 2013.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Robert Wellner, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-4721, rw175w@nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Collaborative Interdisciplinary Team Science-3.

Date: March 27, 2013.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes Of Health,

Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, jerkinsa@niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Collaborative Interdisciplinary Team Science-8.

Date: April 1, 2013.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, jerkinsa@niddk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; R24 Collaborative Interdisciplinary Team Science-1.

Date: April 2, 2013.

Time: 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ann A. Jerkins, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 759, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, 301-594-2242, jerkinsa@niddk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: February 1, 2013.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-02836 Filed 2-7-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other

reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group

Date: March 18-19, 2013

Time: 9:00 a.m. to 1:00 p.m.

Agenda: March 18, 2013—Informed Consent for Genomic Research; March 19, 2013, March 18, 2013—Informed Consent for Genomic Research;

Place: National Institutes of Health, Building 31, C Wing, 6th Floor, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Kelli Marciel, Director, Office of Advocacy Relations, National Cancer Institute, National Institutes of Health, 31 Center Drive, Building 31, Room 10A28, Bethesda, MD 20892, 301-594-3194.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: deainfo.nci.nih.gov/advisory/dclg/dclg.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 4, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013-02837 Filed 2-7-13; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health; Disparities Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is