Recombinant NIE Antigen From *Strongyloides stercoralis*

Description of Technology: *Strongyloides stercoralis* is an intestinal nematode endemic that affects an estimated 30 to 100 million people worldwide. Many of these individuals may be asymptomatic for decades. The present invention discloses a NIE recombinant antigen that can be used in improved assays and diagnostics for *S. stercoralis* infection. The NIE antigen is the only one that is non-cross-reactive with sera from humans with other related filaria infections. The NIE antigen can be utilized as a skin test antigen for immediate hypersensitivity as well as for use in ELISA or other assays.

Potential Commercial Applications: Assays and diagnostics for *S. stercoralis* infection.

Competitive Advantages:

- Only non-cross-reactive *Strongyloides* antigen
- Use in a variety of formats

Development Stage:

- Prototype
- Pilot
- Pre-clinical
- In vitro data available
- In vivo data available (human).

Inventors: Thomas B. Nutman, Ravi Varatharajalu, Franklin A. Neva (all of NIAID).

Publications:

1. Krolewiecki AJ, et al. Improved diagnosis of Strongyloides stercoralis using recombinant antigen-based serologies in a community-wide study in northern Argentina. Clin Vaccine Immunol. 2010 Oct;17(10):1624–30. [PMID 20739501]
2. Ramanathan R, et al. A luciferase immunoprecipitation systems assay enhances the sensitivity and specificity of diagnosis of Strongyloides stercoralis infection. J Infect Dis. 2008 Aug 1;198(3):444–51. [PMID 18558872]
3. Ravi V, et al. Strongyloides stercoralis recombinant NIE antigen shares epitope with recombinant Ves v 5 and Pol a 5 allergens of insects. Am J Trop Med Hyg. 2005 May;72(5):549–53. [PMID 15891128]
4. Ravi V, et al. Characterization of a recombinant immunodiagnostic antigen (NIE) from Strongyloides stercoralis L3-stage larvae. Mol Biochem Parasitol. 2002 Nov–Dec;125(1–2):73–81. [PMID 12467975]

Intellectual Property: HHS Reference No. E–081–2012/0—Research Material. Patent protection is not being pursued for this technology.

Licensing Contact: Edward (Tedd) Fenn, J.D.; 424–500–2005; *tedd.fenn@nih.gov.*

Therapeutic Hepatitis C Virus Antibodies

Description of Technology: Therapeutic antibodies against Hepatitis C Virus (HCV) have not been very effective in the past and there is evidence that this may result in part from interfering antibodies generated during infection that block the action of neutralizing antibodies. These neutralizing antibodies prevent HCV infection of a host cell.

The subject technologies are monoclonal antibodies against HCV that can neutralize different genotypes of HCV. Both antibodies bind to the envelope (E2) protein of HCV found on the surface of the virus. One of the monoclonal antibodies neutralizes HCV genotype 1a, the most prevalent HCV strain in the U.S., infection and *in vitro* data show that it is not blocked by interfering antibodies. The second antibody binds a conserved region of E2 and can cross neutralize a number of genotypes including genotypes 1a and 2a. The monoclonal antibodies have the potential to be developed either alone or in combination into therapeutic antibodies that prevent or treat HCV infection. These antibodies may be particularly suited for preventing HCV re-infection in HCV patients who undergo liver transplants; a population of patients that is especially vulnerable to the side effects of current treatments for HCV infection.

Potential Commercial Applications: Therapeutic antibodies for the prevention and/or treatment of HCV infection.

Competitive Advantages:

- Therapeutic antibodies have generally fewer side effects than current treatments for HCV infection.
- Potential to be developed into an alternative treatment for HCV infected liver transplant patients, who often cannot tolerate the side effects of current drug treatments.

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: Stephen M. Feinstone, Hongying Duan, Pei Zhang, Marian E. Major, Alla V. Kachko (all of FDA)

Publications:

1. Kachko A, et al. New neutralizing antibody epitopes in hepatitis C virus envelope glycoproteins are revealed by dissecting peptide recognition profiles. Vaccine. 2011 Dec 9;30(1):69–77. [PMID 22041300]
2. Duan H, et al. Amino acid residue-specific neutralization and nonneutralization of hepatitis C virus by monoclonal antibodies to the E2 protein. J Virol. 2012 Dec;86(23):12686–94. [PMID 22973024]

Intellectual Property:

- HHS Reference No. E–002–2012/0—US Provisional Patent Application No. 61/648,386 filed 17 May 2012; International PCT Application No. PCT/US13/41352 filed 16 May 2013
- HHS Reference No. E–167–2012/0—International PCT Application No. PCT/US12/62197 filed 26 October 2012

Licensing Contact: Kevin W. Chang, Ph.D.; 301–435–5018; *changke@mail.nih.gov.*

Dated: November 13, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–27739 Filed 11–19–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Synthetic and Biological Chemistry B Study Section, October 17, 2013, 08:00 a.m. to October 17, 2013, 08:00 p.m., Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037 which was published in the **Federal Register** on September 23, 2013, 78 FR 58323.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 on December 11, 2013, from 12:00 p.m. to 06:00 p.m. The meeting is closed to the public.

Dated: November 14, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–27740 Filed 11–19–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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