[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR Part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Surgical Tool for Ocular Tissue Transplantation

Description of Technology: The invention pertains to a device for delivering in a precise and controlled way a piece of tissue or sheet of cells into the eye such that manipulation of and damage to the tissue, cells, and eye are minimized. The device features a handle with actuating means, a stationary needle extending from the handle to the distal tip, and a pair of grasping arms at the distal tip configured for holding tissue or a sheet of cells. An outer tip needle is slidably disposed along a length the stationary needle. When the outer tip needle is disposed over the pair of grasping arms, the arms are collapsed. When the outer tip needle is withdrawn away from the grasping arms, the arms are expanded. The outer tip needle, when disposed over the grasping arms, also allows for protection of the tissue or sheet of cells during surgical manipulation.

Potential Commercial Applications:

• Ocular transplantation

• Ocular surgery

Competitive Advantages: Can perform transplantation of micron-sized tissue or cell grafts.

Development Stage: Prototype

Inventor: Arvydas Maminishkis (NEI)

Intellectual Property: HHS Reference No. E-105-2013/0 – US Provisional Application No. 61/845,598 filed 12 July 2013

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov

High-Affinity Dopamine D3 Receptor Antagonists and Partial Agonists

Description of Technology: Investigators at the National Institute on Drug Abuse (NIDA) have synthesized a novel class of dopamine D3 receptor ligands using click chemistry. These novel compounds contain a triazole instead of an amide group between the primary and secondary pharmacophore. Although the amide linker has been shown to be essential for high affinity and selectivity in certain D3 receptor ligands, NIDA investigators have determined that the triazole linker maintains desired D3 receptor-binding functionality, and may improve bioavailability because of its resistance to metabolic amidases.

Potential Commercial Applications:

• Therapeutic agent for substance abuse (such as alcohol, nicotine, cocaine, methamphetamine, opioids)

• Therapeutic agent for cognitive disorders (such as schizophrenia, Parkinson's disease, dyskinesia, depression)

• Therapeutic agent for restless legs syndrome

Competitive Advantages:

• Higher affinity for the dopamine D3 receptor

• Improved bioavailability

Development Stage: Early-stage

Inventors: Amy H. Newman, Ashwini Banala, Thomas M. Keck (all of NIDA)

Intellectual Property: HHS Reference No. E-086-2013/0 – US Application No. 61/788,167 filed 15 March 2013

Related Technologies:

• HHS Reference No. E-251-2002 – US Provisional Application No. 60/410,715

• HHS Reference No. E-128-2006 – PCT Application No. PCT/US2007/071412

Licensing Contact: Charlene Sydnor, Ph.D.; 301-435-4689; sydnorc@mail.nih.gov

Collaborative Research Opportunity: The National Institute on Drug Abuse is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize D3 receptor selective antagonists/agonists. For collaboration opportunities, please contact Michelle Kim Leff, MD, MBA at mleff@mail.nih.gov.

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

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Date

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