DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, 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. 207 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.

ADDRESSES: 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.

Vaccines for Protection Against Mucosatropic Infections

Description of Invention: The invention offered for licensing and commercial development relates to the field of Vaccines. More specifically, the invention describes novel compositions, strategy and methods that can effectively induce local mucosal immune response (*e.g.* in a female genital tract that is infected with a mucosatropic pathogen), as well as systemic immune response. The method comprises administrating to the treated subject at least two (2) immunogenic compositions in a prime-boost regimen, each comprising an effective amount of an immunogen derived from the pathogen. The first composition is administered to the epithelial surface of the subject in combination with one or more agents or treatment to disrupt the epithelial surface (*e.g.*nonoxobol-9 or depot medroxyprogesterone acetate). The second immunogenic composition is administered systemically. The first composition is typically a papillomavirus pseudovirion (PsV) comprising a polynucleotide that encodes proteins on the mucosatropic pathogen. The PsV has shown to confer tropism for the basal epithelium and is uniquely capable of eliciting strong immune response at this environment. The immunogenic composition that is administered systemically is typically selected from one of the following groups: (a) A live attenuated virus (*e.g.* poxivirus) expressing a protein or proteins of the infecting pathogen, (b) a DNA vector encoding proteins of the pathogen, or (c) an immunogenic polypeptide from the pathogen.

Applications: Vaccines against infectious pathogens, particularly against mucosatropic pathogens and pathogens such as HIV, HCV, HSV or HPV that initiate infection at mucosal sites including the female genital tract.

Advantages:

• The unique properties of the PsV vaccine vectors have shown to confer tropism for the basal epithelium, and are several folds more effective as mucosal vaccines compared with other DNA vaccines such as naked or vectored DNA.

• The use of epithelial disruptive agent enhances the effectiveness of the PsV vaccines in mucosal tissues.

• The unique vaccine compositions and the prime-boost vaccination strategy assure both local (*i.e.* vaginal track) and systemic immunity.

Development Status: Proof of principle has been demonstrated. Animal efficacy data in mice and primates is available.

Market: The market for vaccines against infectious diseases is huge. The present invention is unique as it can be used as a vaccine platform with diverse number of applications and in multiple vaccines. The technology can provide mucosal/local and systemic immunization simultaneously and thus it may prove to be extremely powerful against mucosatropic pathogens. The commercial potential of the present invention is thus vast.

Inventors: Genoveffa Franchini, Christopher B. Buck, John T. Schiller, *et al.* (NCI)

Relevant Publications:

1. Barney S. Graham, John T. Schiller, Christopher B. Buck, Jeffrey N. Roberts, Teresa R. Johnson, John D. Nicewonger, Rhonda C. Kines, and Man Chen. Use of HPV Virus-like Particles to Deliver Gene-based Vaccines. USPA 12/863,572 filed July 19, 2010. Priority date January 19, 2008 (USPA 61/022,324) and PCT/US2009/031600, filed January 21, 2009 (HHS Reference No. E–077–2008/0).

2. CB Buck, DV Pastrana, DR Lowy, JT Schiller. Efficient intracellular assembly of papillomaviral vectors. J Virol. 2004 Jan;78(2):751–757. [PubMed: 14694107].

3. BS Graham, RC Kines, KS Corbett, J Nicewonger, TR Johnson, M Chen, D LaVigne, JN Roberts, N Cuburu, JT Schiller, and CB Buck. Mucosal delivery of human papillomavirus pseudovirus-encapsidated plasmids improves the potency of DNA vaccination. Mucosal Immunol. 2010 Sep;3(5):475–486. [PubMed: 20555315].

Patent Status: U.S. Provisional Application No. 61/447,499 filed 28 Feb 2011 (HHS Reference No. E–112–2011/0–US–01), entitled "Cervicovaginal Vaccination With Papillomavirus Pseudovirions for Protection Against Mucosatropic Infection".

Licensing Status: Available for licensing and commercial development.

Licensing Contacts:

• Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@nih.gov.*

• John Stansberry, PhD; 301–435–5236; *js852e@nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Vaccine Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Vaccines for Protection Against Mucosatropic Infections. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Peptide Therapeutics for Cardiac Failure

Description of Invention: Available for licensing are therapeutic peptides that induce heart contractions without affecting blood pressure during cardiac failure. During cardiac failure, the heart suffers a decrease in contraction force, which weakens the heart's ability to deliver blood. Interestingly, the failing heart also retains an ability to increase its contraction force. This represents the theoretical basis for treatment of heart failure with positive inotropic agents, which increase heart contractility. Currently available positive inotropic agents include catecholamines such as epinephrine, Milrinone, and beta-receptor agonists. However, these treatments demonstrate negative side effects including increased blood pressure as well as heart attack.

Investigators at the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development have developed therapeutic peptides designated as Serpinin and its derivative pGlu-Serpinin. These peptides act via a signaling pathway independent from the classical receptor-mediated adrenergic pathway and as a result, they can increase heart contractility without affecting blood pressure. These peptides represent a novel pharmacological approach in the treatment of cardiac failure.

Applications: Treatment for cardiac failure.

Advantages: Therapies that increase heart contractions without affecting blood pressure.

Development Status: The technology is currently in the pre-clinical stage of development.

Market:

• In the U.S., cardiac failure affects an estimated 5.7 million people and there are approximately 550,000 newly diagnosed cases per year.

• Cardiac failure was estimated to result in direct and indirect costs of $37.2 billion in the United States in 2009.

• Heart failure is responsible for 11 million physician visits each year, and more hospitalizations than all forms of cancer combined.

Inventors: Y. Peng Loh (NICHD) and Bruno Tota (University of Calabria).

Relevant Publications: None. Future publications are being contemplated.

Patent Status: U.S. Provisional Application No. 61/427,243 filed 27 Dec 2010 (HHS Reference No. E–001–2011/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, Section on Cellular Neurobiology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of serpinin and pyroglu-serpinin in treatment of heart failure. Please contact Joseph Conrad at 301–435–3107 or *jmconrad@mail.nih.gov* for more information.

Alpha-Glucosidase Chaperones and Inhibitors for Treatment of Pompe Disease and Type 2 Diabetes

Description of Invention: Scientists at the NIH have discovered small molecules that can act as chaperones and correct the misfolding of mutated alpha-glucosidase enzyme. Pompe disease is caused by deficiency or dysfunction of alpha-glucosidase. The only FDA-approved treatment of Pompe disease is enzyme replacement, which in this case costs approximately $300,000 per year and elicits an immune reaction in most patients that limits clinical utility.

In addition, scientists at the NIH have discovered small molecule inhibitors of alpha glucosidase enzyme. Alpha glucosidase converts carbohydrates into monosaccharides. Inhibition of this conversion is useful for type 2 diabetes. Three FDA-approved inhibitors of alpha glucosidase exist but all have low efficacy:side effect ratios.

Applications:

• Therapeutic for Pompe disease.

• Therapeutic for type 2 diabetes.

Advantages:

• Potentially more affordable and less immunogenic than the current therapeutic for Pompe disease.

• Potentially better efficacy:side effect ratios than existing type 2 diabetes therapeutics.

Development Status: Early stage.

Market: Pompe disease occurs in 1 in every 40,000 births (*http://www.ninds.nih.gov/disorders/pompe/pompe.htm*).

Inventors: Juan J. Marugan, Ehud M. Goldin, Noel T. Southall, Wei Zheng, Jingbo Xiao, Ellen Sidransky, and Omid Motabar (NHGRI).

Patent Status: U.S. Provisional Patent Application No. 61/409/697 filed 03 November 2010 (HHS Reference No. E–256–2010/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Steve Standley, PhD; 301–435–4074; *sstand@od.nih.gov.*

Mouse IL–12p40 Expressing Cell Line

Description of Invention: The subject invention is a recombinant human 293T cell line that expresses mouse IL–12p40 protein to high levels. IL–12p40 is a subunit of both Interleukin-12 (IL–12) and IL–23; however, it can also be expressed as a monomer (IL–12p40) and as a homodimer (IL–12p80). IL–12p40 is produced mainly by antigen presenting cells such as macrophages, neutrophils, microglia, and dendritic cells in response to pathogens or inflammatory agents. It is an immunostimulatory messenger molecule that can disseminate in the body and signal the presence of a pathogen. The role of IL–12p40 is still being elucidated. This cell line produces and secretes mouse IL–12p40 proteins that have post-translational modifications similar to native IL–12p40 protein, overcoming an issue that is seen with IL–12p40 protein expressed in bacterial, insect, or hamster cells.

Applications: Production of mouse IL–12p40 for research applications.

Advantages: IL–12p40 protein is expressed in human cell line, so post-translational modifications are similar to native protein.

Development Status: In vitro data can be provided upon request.

Market: Research reagent.

Inventors: Nevil J. Singh (NIAID).

Patent Status: HHS Reference No. E–247–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

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

Dated: May 20, 2011.

Richard U. Rodriguez,

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

[FR Doc. 2011–13084 Filed 5–25–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

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 meeting.

The meeting 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 Child Health and Human Development Initial Review Group; Function, Integration, and Rehabilitation Sciences Subcommittee.

Date: June 24, 2011.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Hotel, 4300 Military Road, Washington, DC 20015.

Contact Person: Anne Krey, PhD, Scientific Review Officer, Division of Scientific Review, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, 301–435–6908, *Ak41o@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)