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.

DESCRIPTION OF INVENTION:

**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 administering 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. nonoxynol-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. poxvirus) 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 agents 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:**


**Licensing Status:** Available for licensing and commercial development.

**Licensing Contacts:**

- Uri Reichman, PhD, MBA; 301–435–4616; URT@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.
Inhibitors for Treatment of Pompe Disease and Type 2 Diabetes

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 (NICHID) and Bruno Tota (University of Calabria).

Relevant Publications: None. Future publications are being contemplated.


Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633 or wongj@email.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. 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).


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. Sinha (NIAID).


Licensing Status: Available for licensing.

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

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

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