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.

Rational HIV Therapeutic Design

Description of Technology: This technology describes the structural nature of a highly conserved tyrosine-sulfate binding pocket on the HIV–1 gp120 envelope glycoprotein and the use of this information to design HIV-entry inhibitors that target it. The binding pocket was characterized by structural determinations of the N-terminus of CCR5 with gp120 as well as of the complex of 412d (a tyrosine-sulfated antibody) with gp120 and CD4. The N terminus of CCR5, like the 412d antibody, is tyrosine-sulfated. In spite of structural differences between these molecules, gp120 recognizes both tyrosine-sulfated molecules in similar ways, indicating that this specificity can be exploited in the design of HIV-entry inhibitors.

Applications: HIV therapeutic design.

Inventors: Peter D. Kwong et al. (NIAID).

Patent Status: U.S. Provisional Application No. 60/923,498 filed 13 Apr 2007 (HHS Reference No. E–181–2007/0–US–01).

Licensing Contact: Susan Ano, PhD; 301/435–5515; *anos@mail.nih.gov.*

Collaborative Research Opportunity: The Vaccine Research Center of the National Institute of Allergy and Infectious Diseases as well as the Laboratory of Bioorganic Chemistry of the National Institute of Diabetes and Digestive and Kidney Diseases are seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize tyrosine-sulfated CCR5-based inhibitors of HIV–1 infection. Please contact Susan Ano for more information.

Viral Entry or Replication Inhibitors

Description of Technology: The Tec family of tyrosine kinases, consisting of five family members Tec, Btk, Itk, Rlk, and BMX, are key regulators of signaling pathways of T lymphocytes. Many existing antiviral therapies rely on inhibition of viral replication, which leads to emergence or selection of resistant viruses. The current technology provides an alternative method for prevention or treatment of viral infection through administration of a Tec tyrosine kinase inhibitor. Such inhibitors can be siRNA, small chemical compounds, antisense or antibody. The current technology describes the inhibition of Itk (also known as Emt and Tsk) and the resulting decrease in HIV infectivity, replication, and transcription for exemplary purposes. Importantly, these inhibitors do not affect the expression of HIV co-receptors CCR5, CXCR4, or CD4. The current technology could be used in combination with therapeutics that target virus replication.

Application: Treatment of viral infection.

Development Status: In vitro data available.

Inventors: Julie Readinger et al. (NHGRI).

Patent Status: U.S. Provisional Application No. 60/786,245 filed 29 Mar 2006 (HHS Reference No. E–151–2006/0–US–01); PCT Application No. PCT/US2007/007711 filed 29 Mar 2007 (HHS Reference No. E–151–2006/1–PCT–01).

Licensing Contact: Susan Ano, Ph.D.; 301/435–5515; *anos@mail.nih.gov.*

Dual Expression DNA Influenza Vaccine

Description of Technology: The NIH is pleased to announce a single vector DNA vaccine against influenza as available for licensing. The single vector expresses both hemagglutinin (HA) and matrix (M) proteins, generating both humoral and cellular immune responses. The vaccine candidate completely protected mice against homologous virus challenge and significantly improved survival against heterologous virus challenge. A robust and reliable vaccine supply is widely recognized as critical for seasonal or pandemic influenza preparedness. The advantages offered by this vaccine make it an excellent candidate for further development.

Advantages: (1) DNA vaccines easy to produce and store; (2) Vaccine candidate improved survival against heterologous virus challenge; (3) No risk of reversion to pathogenic strain as with live-attenuated virus vaccines; (4) Can be administered to immuno-compromised individuals, increasing potential market size; (5) HA and M proteins encoded by single vector, ensuring uniform delivery of immunogen; (6) More efficient to boost synergistic effects on both HA and M specific immune responses than a mixture of individual plasmids; (7) M protein not subject to antigenic drift, which allows advanced manufacturing and overcomes the need for strain monitoring; (8) DNA vaccines elicit cellular immune response, essential for efficient virus clearance.

Application: Influenza vaccine.

Inventors: Zhiping Ye *et al.* (CBER/FDA).

Patent Status: U.S. Provisional Application No. 60/786,747 filed 27 Mar 2006 (HHS Reference No. E–300–2005/0–US–01); PCT Application No. PCT/US2007/007529 filed 27 Mar 2007 (HHS Reference No. E–300–2005/1–PCT–01).

Licensing Contact: Susan Ano, Ph.D.; 301/435–5515; *anos@mail.nih.gov.*

Collaborative Research Opportunity: The CBER/FDA Division of Viral Products is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the HA/M single vector DNA vaccine. Please contact Zhiping Ye at 301–435–5197 or *zhiping.ye@fda.hhs.gov* for more information.

Peptide Mimotope Candidates for Otitis Media Vaccine

Description of Technology: This technology describes peptide mimotopes of lipooligosaccharides (LOS) from nontypeable *Haemophilus influenzae* (NTHi) and *Moraxella catarrhalis* that are suitable for developing novel vaccines against the respective pathogens, for which there are currently no licensed vaccines. The mimotopes not only immunologically mimic LOSs from NTHi and *M. catarrhalis* but will also bind to antibodies specific for the respective LOS. NTHi and *M. catarrhalis* are common pathogens that cause otitis media in children and lower respiratory tract infections in adults. The

effectiveness of a vaccine could be increased by substitution of a LOS epitope with a peptide mimic. Preliminary experiments have shown that some of the mimic peptides conjugated to a carrier were as effective as their respective LOS-based vaccine in stimulating a humoral immune response in rabbits. A single consensus amino acid sequence was identified for *M. catarrhalis,* while four such sequences were identified for NTHi. Thus, the identified peptides are promising candidates for developing novel vaccines for NTHi or *M. catarrhalis.*

Applications: Otitis media vaccine.

Development Status: In vivo data available.

Inventor: Xin-Xing Gu (NIDCD).

Patent Status: U.S. Patent Application No. 11/187,419 filed 22 Jul 2005 (HHS Reference No. E–344–2002/0–US–03).

Licensing Contact: Susan Ano, Ph.D.; 301/435–5515; *anos@mail.nih.gov.*

Collaborative Research Opportunity: The NIDCD Vaccine Research Section is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Peptide vaccines derived from LOS of NTHi or *M. catarrhalis.* Please contact Marianne Lynch, a technology development specialist, at 301–594–4094 or *lynchm2@mail.nih.gov* for more information.

Dated: July 17, 2007.

Steven M. Ferguson,

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

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

State-of-the-Science Conference: Prevention of Fecal and Urinary Incontinence in Adults; Notice

Notice is hereby given of the National Institutes of Health (NIH) ''State-of-the-Science Conference: Prevention of Fecal and Urinary Incontinence in Adults'' to be held December 10–12, 2007, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8:30 a.m. on December 10 and 11, and at 9 a.m. on December 12, and will be open to the public.

Fecal and urinary incontinence—the inability to control bowel movements or urination, respectively—are conditions with ramifications that extend well beyond their physical manifestations. Many people find themselves withdrawing from their social lives and attempting to hide the problem from their families, friends, and even their doctors. The embarrassing nature of these conditions poses a significant barrier to seeking professional treatment, resulting in a large number of unreported, untreated individuals. Therefore, it is difficult to determine the accurate prevalence of these conditions, as well as any associated medical history trends. Incontinence is more likely to affect the aging population, although it is not considered a normal consequence of aging. As baby boomers approach their 60s, the incidence and public health burden of incontinence are likely to increase.

Fecal incontinence is a serious and embarrassing problem that affects up to 5 percent of the general population and up to 39 percent of nursing home residents. It affects people of all ages but is more common in women and the elderly. Bowel function is controlled by three factors: rectal sensation, rectal storage capacity, and anal sphincter pressure. If any of these are compromised, fecal incontinence can occur. This condition can have many causes, including constipation, diarrhea, complicated childbirth, muscular or nerve damage, reduced storage capacity due to scarring or irritation, or pelvic dysfunction.

Although urinary incontinence can affect people at all stages of life, it has been estimated that urinary incontinence affects 38 percent of women and 17 percent of men 60 years of age and older. Urinary incontinence can occur if muscles in the wall of the bladder suddenly contract or if muscles surrounding the urethra suddenly relax. Women who have undergone childbirth are the most commonly associated at-risk population for urinary incontinence. Pregnancy and delivery can weaken pelvic muscles, and reduced levels of the hormone estrogen following menopause can cause reduced muscle tone around the urethra, increasing the chance of leakage. Additionally, neurologic injury, birth defects, strokes, multiple sclerosis, and physical problems associated with aging have been reported to contribute.

Because incontinence is likely widely underdiagnosed and underreported, it has been difficult to identify both at-risk and affected populations. Also, because the biological mechanisms that cause both fecal and urinary incontinence are not well understood, it has been difficult to develop robust prevention and management strategies. Toward that end, the National Institute of Diabetes and Digestive and Kidney Diseases and the Office of Medical Applications of Research of the NIH will convene a State-of-the-Science Conference from December 10 to 12, 2007, to assess the available scientific evidence relevant to the following questions:

- What are the prevalence, incidence, and natural history of fecal and urinary incontinence in the community and long-term care settings?
- What is the burden of illness and impact of fecal and urinary incontinence on the individual and society?
- What are the risk factors for fecal and urinary incontinence?
- What can be done to prevent fecal and urinary incontinence?
- What are the strategies to improve the identification of persons at risk and patients who have fecal and urinary incontinence?
- What are the research priorities in reducing the burden of illness in these conditions?

An impartial, independent panel will be charged with reviewing the available published literature in advance of the conference, including a systematic literature review commissioned through the Agency for Healthcare Research and Quality. The first day and a half of the conference will consist of presentations by expert researchers and practitioners and open public discussions. On Wednesday, December 12, the panel will present a statement of its collective assessment of the evidence to answer each of the questions above. The panel will also hold a press conference to address questions from the media. The draft statement will be published online later that day, and the final version will be released approximately six weeks later. The primary sponsors of this meeting are the National Institute of Diabetes and Digestive and Kidney Diseases and the NIH Office of Medical Applications of Research.

Advance information about the conference and conference registration materials may be obtained from American Institutes for Research of Silver Spring, Maryland, by calling 888–644–2667, or by sending e-mail to *consensus@mail.nih.gov.* American Institutes for Research's mailing address is 10720 Columbia Pike, Silver Spring, MD 20901. Registration information is also available on the NIH Consensus Development Program Web site at *http://consensus.nih.gov.*

Please Note: The NIH has instituted security measures to ensure the safety of NIH employees and property. All visitors must be prepared to show a photo ID upon request. Visitors may be required to pass through a metal detector and have bags, backpacks, or