

**Collaborative Research Opportunity:** The NIDCD Otolaryngology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology as well as collaborate on further pre-clinical and clinical studies with the TMC2 gene mutations. Please contact Ms. Marianne Lynch at 301-402-5579 or via e-mail at [lynchm@nhlbi.nih.gov](mailto:lynchm@nhlbi.nih.gov) for more information.

Dated: April 30, 2007.

**Steven M. Ferguson,**

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

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## 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.

#### Influenza Vaccines and Antiviral Agents

**Description of Technology:** The subject invention offers candidate DNA vaccines to target H5N1, H1N1, H3N2 and other subtypes of influenza. These candidates are designed primarily to elicit neutralizing antibodies. The candidate vaccines express hemagglutinin (H/HA) or neuramidase

(N/NA) protein that has been codon optimized and/or modified at the protease cleavage site. The modified genes could be used in DNA vaccines, in viral vectors, recombinant proteins/particles or combination. The studies use proprietary expression systems that increase protein expression relative to commonly used alternatives. This invention potentially provides a vaccine strategy for controlling influenza epidemics, including avian flu, should it cross over to humans; the 1918 strain of flu; and seasonal flu strains. In addition, this invention is designed to lead to a combination vaccine to provide a broadly protective vaccine. The incorporation of specific cleavage site types to facilitate preparation of pseudotypes from a variety of strains is an important aspect of this invention.

In addition, HA pseudotyped lentiviral vectors are being tested to screen for neutralizing abs in patients and to screen for diagnostic and therapeutic monoclonal abs.

**Applications and Advantages:** Influenza vaccine for pandemic or epidemic application; Potential for combination vaccine for broad protection, removing need for seasonal strain monitoring; DNA vaccines are easy to produce and store; No risk of reversion to pathogenic strain as with live-attenuated virus vaccines.

**Development Status Highlights:** Phase I clinical trials planned for select candidates; DNA vaccine encoding 1918 influenza virus HA protein protects mice against lethal viral challenge; Codon optimized for expression in human cells.

**Inventors:** Gary J. Nabel (VRC/NIAID), Wing-pui Kong (VRC/NIAID), Zhi-yong Yang (VRC, NIAID), *et al.*

**Publication:** Certain aspects of this technology were published in WP Kong *et al.* Protective immunity to lethal challenge of the 1918 pandemic influenza virus by vaccination. *Proc Natl Acad Sci USA.* 2006 Oct 24;103(43):15987-15991. Epub 2006 Oct 16, doi: 10.1073/pnas.0607564103.

**Patent Status:** U.S. Provisional Application No. 60/774,923 filed 16 Feb 2006 (HHS Reference No. E-116-2006/0-US-01) and PCT Application No. PCT/US2007/004506 filed 16 Feb 2007 (influenza) (HHS Reference No. E-116-2006/1-PCT-01); U.S. Patent No. 7,094,598 issued 22 Aug 2006 (CMV/R) (HHS Reference No. E-241-2001/1-US-01) and associated foreign rights.

**Licensing Status:** Available for exclusive or non-exclusive licensing.

**Licensing Contact:** Susan Ano, Ph.D.; 301/435-5515; [anos@mail.nih.gov](mailto:anos@mail.nih.gov).

#### Enhanced, Targeted Delivery for DNA Vaccines

**Description of Technology:** Available for licensing from the NIH is a fusion protein for enhanced gene delivery. Exemplary proteins for achieving this improvement comprise an adenovirus serotype 5 fiber, penton base and core protein V fused to the DNA binding domain of HMG. In vitro studies have shown the effectiveness of the chimeric protein-DNA vaccine co-administration by an increase in uptake of ten to twenty fold. In particular, the plasmid with the chimeric core protein V was delivered efficiently to dendritic cells (DC) as well as 293T cells. The utilization of this chimeric protein could further enhance the immune response elicited by DNA vaccines.

**Potential Applications:** Improved DNA vaccine delivery and uptake.

**Inventors:** Gary J. Nabel and Wataru Akahata (VRC/NIAID).

**Patent Status:** U.S. Provisional Application No. 60/737,896 filed 18 Nov 2005 (HHS Reference No. E-043-2006/0-US-01); U.S. Provisional Application No. 60/795,529 filed 26 Apr 2006 (HHS Reference No. E-043-2006/1-US-01); PCT Application No. PCT/US2006/044525 filed 20 Nov 2006 (HHS Reference No. E-043-2006/3-PCT-01)

**Licensing Status:** Available for non-exclusive or exclusive licensing.

**Licensing Contact:** Susan Ano, Ph.D.; 301/435-5515; [anos@mail.nih.gov](mailto:anos@mail.nih.gov).

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.