

whose chemical properties are such that they spontaneously aggregate in vitro or in vivo, assuming parallel or antiparallel beta sheet configurations. Amyloid proteins can arise from peptides which, though differing in primary amino acid sequences, assume the same tertiary and quaternary structures. The amyloid structure presents a regular array of accessible N-termini of the peptide molecules.

Claimed in this application are compositions and methods for use of amyloid proteins as vaccine scaffolds, on which peptide determinants from microorganisms or tumors may be presented to more efficiently generate and produce a sustained neutralizing antibody response to prevent infectious diseases or treat tumors. The inventors have arrayed peptides to be optimally immunogenic on the amyloid protein scaffold by presenting antigen using three different approaches. First, the N-terminal ends of the amyloid forming peptides can be directly modified with the peptide antigen of interest; second, the N-termini of the amyloid forming peptides are modified with a linker to which the peptide antigens of interest are linked; and third, the scaffold amyloid may be modified to create a chimeric molecule.

Aside from stability and enhanced immunogenicity, the major advantages of this approach are the synthetic nature of the vaccine and its low cost. Thus, concerns regarding contamination of vaccines produced from cellular substrates, as are currently employed for some vaccines, are eliminated; the robust stability allows the amyloid based vaccine to be stored at room temperature for prolonged periods of time; and the inexpensive synthetic amino acid starting materials, and their rapid spontaneous aggregation in vitro should provide substantial cost savings over the resource and labor-intensive current vaccine production platforms.

**Application:** Immunization to prevent infectious diseases or treat chronic conditions or cancer.

**Developmental Status:** Vaccine candidates have been synthesized and preclinical studies have been performed.

**Inventors:** Amy Rosenberg (CDER/FDA), James E. Keller (CBER/FDA), Robert Tycko (NIDDK).

**Patent Status:** U.S. Provisional Application No. 60/922,131 filed 06 Apr 2007 (HHS Reference No. E-106-2007/0-US-01).

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

**Licensing Contact:** Peter A. Soukas, J.D.; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

**Collaborative Research Opportunity:** The FDA, Division of Therapeutic Proteins (CDER) and Office of Vaccines, Division of Bacterial Products (CBER) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize amyloid based vaccines for prevention of infectious disease or treatment of malignant states. Please contact Amy Rosenberg at [amy.rosenberg@fda.hhs.gov](mailto:amy.rosenberg@fda.hhs.gov) or (301) 827-1794 for more information.

Dated: July 19, 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

#### 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.

#### Transgenic Mouse Model for Lupus and Other Autoimmune Diseases

**Description of Technology:** The inventors have developed a series of transgenic mice that overexpress Toll-Like Receptor 7 (TLR7) at different levels. Overexpression of TLR7 in these mice results in a lupus-like syndrome, the intensity of which correlates with

the level of overexpression. As the pathology in these mice results from the overexpression of a single gene, it represents a superior model for lupus and other autoimmune diseases compared to other existing mouse models that dysregulate multiple genes to achieve the same pathologic syndrome.

Two strains are currently available. The TLR7.Tg1 strain overexpresses TLR7 at approximately 16 times the wild-type level. The TLR7.Tg6 strain overexpresses TLR7 at approximately 4 times the level of a wild-type mouse; additionally, the transgene for this strain is located on the Y chromosome, which would be advantageous for cross-breeding to other mouse lines.

**Inventors:** Jonathan Deane *et al.* (NIAID).

**Related Publication:** P. Pisitkun *et al.* Autoreactive B cell responses to RNA-related antigens due to TLR7 gene duplication. *Science* 2006 Jun 16;312(5780):1669-1672.

**Patent Status:** HHS Reference No. E-128-2007/0—Research Tool.

**Licensing Status:** This technology is available for nonexclusive licensing.

**Licensing Contact:** Tara L. Kirby, Ph.D.; 301/435-4426; [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov).

#### Dysphagia Rehabilitation (Swallowing Recovery): Vibro-Tactile Stimulation Device and Method for Motor Control Recovery

**Description of Technology:** Available for licensing and/or commercial development under a scientific collaboration, are device and method patents for volitional swallowing with a substitute sensory system. The inventions are potentially applicable to a wide variety of indications, including recovery post-stroke and post extubation for example, after coronary bypass surgery. The device is being tested in dysphagic patients in two, ongoing clinical trials at the National Institutes of Health. A collaborator or licensee is needed to support further clinical trials, validation studies, and final package development.

**Device:** For the device patent, upon activation a vibrator moves and vibrates the larynx. Patients can initiate sensory stimulation immediately prior to the patient's own initiation of a swallow. Specifically, the device allows the patient to coordinate muscular movement with a button press to permit volitional swallowing. The device can also include a movement sensor for monitoring pressure on the patient's larynx and a swallowing detector. The swallowing detector includes a piezoelectric stretch receptor and a

stimulator, coupled to the movement sensor, for applying pressure to a patient's larynx prior to swallowing. The device can also be used to automatically trigger and retrain swallowing to prevent aspiration pneumonia post stroke or post extubation.

**Method:** For the method patent, the instant device has also been claimed in a patent application asserting rights for improving voluntary initiation of swallowing in neurologically impaired patients. Swallowing recovery alleviates the risk of aspiration by augmenting volitional control using a simultaneous motor act (e.g., such as pressing a button to indicate when they are ready to swallow). It is believed that such motor training also initiates sensory stimulation, immediately preceding the motor act, and that such sensory stimulation enhances excitation of a central pattern generator in the brain stem that augments the volitional control of swallowing. This principle is applicable to other neurological impairments; their associated enhancement of voluntary motor act control by the patient initiating immediately concurrent and related sensory stimulations. Neurological impairments that are contemplated include reflex actions involving interactions between afferent and efferent paths (at the spinal cord or in the brain stem) as well as higher order interactions. This invention includes methods for treating neurologically impaired humans using devices such as those that produce vibratory stimulation, pressure stimulation, auditory stimulation, temperature stimulation, visual stimulation, olfactory stimulation, taste stimulation, or a combination of these. Combinations of two or more stimulation types are particularly useful. For example, the combined use of button press training with simultaneous vibratory and pressure stimulation on the neck to augment feedback to the brain stem swallowing centers to facilitate voluntary control of swallowing (thought to be largely an involuntary brain stem function) is particularly useful for treating dysphagic patients. Alternatively automatic cycles of stimulation at intervals during the day can be used for intensive retraining of swallowing post stroke or post-extubation to prevent aspiration.

**Inventors:** Christy Ludlow (NINDS), Christopher Poletto (NINDS), Janessa Humbert (NINDS), Newlin Morgan (NIMH).

**Patent Status:** PCT Application No. PCT/US2006/025535 (HHS Reference No. E-251-2005/1-PCT-02).

**Licensing Contact:** Michael A. Shmilovich, Esq.; 301/435-5019; [shmilovm@mail.nih.gov](mailto:shmilovm@mail.nih.gov).

**Collaborative Research Opportunity:** For research and development collaborations with inventors, contact Heather Gunas at 301-435-3944 or e-mail at [gunash@mail.nih.gov](mailto:gunash@mail.nih.gov).

Dated: July 19, 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

#### National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Mentored Patient Oriented Research Career Development Award (K23's).

**Date:** August 23, 2007.

**Time:** 11 a.m. to 12 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, Rockledge Center 2, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Mark Roltsch, PhD, Scientific Review Administrator, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7192, Bethesda, MD 20892-7924, 301-435-0287, [roltschm@nhbi.nih.gov](mailto:roltschm@nhbi.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 92.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: July 19, 2007.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-3668 Filed 7-26-07; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), 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 on Alcohol Abuse and Alcoholism Special Emphasis Panel, Review of SBIR/STTR Applications; RFA AA-07-009/10.

**Date:** August 13, 2007.

**Time:** 2 p.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Philippe Marmillot, PhD, Scientific Review Administrator, National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 5635 Fishers Lane, RM 3045, Bethesda, MD 20892, 301-443-2861, [marmillotp@mail.nih.gov](mailto:marmillotp@mail.nih.gov). (Catalogue of Federal domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: July 20, 2007.

**Anna Snouffer,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-3667 Filed 7-26-07; 8:45 am]

**BILLING CODE 4140-01-M**