

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.

### **Therapeutics for the Treatment and Prevention of Atherosclerosis and Cardiovascular Disease**

*Description of Invention:* This technology consists of peptides and peptide-analogues that enhance clearance of excess cholesterol in cells and do not exhibit the cytotoxicity that has hampered development of similar potential therapeutics.

Briefly, apolipoprotein A-1 (ApoA-1) promotes cholesterol efflux from cells and its concentration is inversely correlated with atherosclerotic events. The isolated peptidic component of ApoA-1 that acts within the cholesterol secretion pathway is therapeutic towards atherosclerosis but exhibits cytotoxic effects. In contrast, our inventors have derivatized that ApoA-1 peptide which is both less cytotoxic and more active than the underivatized component in initial studies. This potential therapeutic is similar to high density lipoprotein (HDL) therapy and may complement statin-mediated reduction of pro-atherogenic lipoproteins.

#### *Potential Applications:*

- Treatment and prevention of atherosclerosis
  - Treatment and prevention of cardiovascular disease, coronary artery disease, heart attack, stroke, and inflammation
  - Therapeutic or preventative coating for a heart or vascular implant
  - Alternative to HDL therapy
- Potential Advantages:*
- Enhanced cytotoxicity profile
  - Enhanced hydrophilicity profile
  - Complements statin-based therapies
  - Oral delivery approaches in development

*Development Status:* Early stage with *in vitro* proof of concept data.

*Market:* The CDC indicates that heart attacks account for 26% of deaths in the United States of which atherosclerosis is a significant contributing factor or cause. Global sales for cardiovascular therapeutics are expected to exceed \$50b in 2010.

*Inventors:* Amar A. Sethi (NHLBI) *et al.*

*Patent Status:* U.S. Provisional Application No. 61/265,291 filed 30 Nov 2009 (HHS Reference No. E-047-2009/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Fatima Sayyid, M.H.P.M.; 301-435-4521; [Fatima.Sayyid@nih.hhs.gov](mailto:Fatima.Sayyid@nih.hhs.gov).

### **Use of Immunosuppressive Agents for Treatment of Age-related Macular Degeneration (AMD) and Diabetic Retinopathy**

*Description of Invention:* AMD belongs to a group of disorders in which the immune system may play an important role. This invention discloses that patients with AMD gain additional therapeutic benefit from combination treatment of immunosuppressive agents and standard-of-care in comparison to standard-of-care alone. This invention slows the progression of choroidal neovascularization (CNV) and may have implications for related pathologies, including diabetic retinopathy. Clinical data from a small, randomized pilot clinical trial are available.

#### *Applications:*

- A method of treatment for AMD.
- A method of treatment for diabetic retinopathy.
- A method of treatment for diseases associated with CNV.

#### *Advantages:*

- Likely to be synergistic with existing therapeutics.
- May enable repurposing of some existing immunosuppressive agents.

*Development Status:* In clinical trials.

*Market:* An estimated three million individuals in the United States will have an advanced form of AMD by 2020 (Klein R *et al.* The epidemiology of age-related macular degeneration. *Am J Ophthalmol.* 2004;137(3):486-95).

*Inventors:* Robert B. Nussenblatt and Frederick L. Ferris (NEI).

*Publication:* In preparation.

*Patent Status:* U.S. Provisional Application No. 61/254,439 filed 23 Oct 2009 (HHS Reference No. E-198-2008/0-US-01).

*Licensing Status:* Available for licensing.

*Licensing Contact:* Norbert Pontzer, J.D., Ph.D.; 301-435-5502; [pontzern@mail.nih.gov](mailto:pontzern@mail.nih.gov).

*Collaborative Research Opportunity:* The National Eye Institute, Laboratory of Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of immunosuppressive agents in the treatment of age related macular degeneration. This is in light of new findings that immune mechanisms appear to be central to the expression of the clinical disease we know as AMD. Please contact Alan Hubbs, Ph.D. at 301-594-4263 or [hubbsa@mail.nih.gov](mailto:hubbsa@mail.nih.gov) for more information.

Dated: July 22, 2010.

**Richard U. Rodriguez,**

*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**

### **Office of the Director; 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 materials, 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:* Advisory Committee to the Director, NIH.

*Date:* August 9, 2010.

*Time:* 2 p.m. to 3 p.m. e.s.t.

*Agenda:* To review and evaluate grant applications (Telephone Conference Call).

*Place:* National Institutes of Health, Building 31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

*Contact Person:* Lawrence A. Tabak, PhD, DDS, Acting Director, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, National Institutes of Health, 31 Center Drive, Building 31, Room 2C39, Bethesda, MD 20892, 301-496-3571, [lawrence\\_tabak@nih.gov](mailto:lawrence_tabak@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Dated: July 22, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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