melanoma patients. Diagnostic tests specifically directed at NUAK2 are anticipated to be highly predictive of the progression level and course of disease in individual patients. Gaining information about melanoma before late-stage symptoms are observed should give clinicians more opportunity to treat patients before the cancer metastasizes out of control.

- Few therapies exist for melanoma and the treatments utilized by clinicians are prone to toxic side effects. Targeted therapies such as shRNAs directed against NUAK2 could combine more effective inhibition of melanoma with fewer harsh side effects.

**Development Status:** This technology is in a preclinical stage of development.

**Market:** There remains a long-felt public health need to develop new therapies and diagnostics for treating melanoma. Melanoma is the most serious type of skin cancer, accounting for the majority of skin cancer deaths, and the percentage of people who develop melanoma has more than doubled in the past 30 years. With the increase in Hispanic and Asian populations in the United States, the incidence of acral melanoma has risen to become a major public health problem as it accounts for between 30%–70% of melanoma cases in dark-skinned individuals. In the United States alone in 2009, it is estimated that 68,720 new cases of melanoma were diagnosed and 8,650 people were expected to die of the disease. In 2003, the American Academy of Dermatology and the Society for Investigative Dermatology released a comprehensive study that quantified the estimated total direct cost associated with the treatment of melanoma in 2004 at $291 million in the United States. Currently, there are more than 200 therapeutics in active development to target melanoma—from early pre-clinical to marketed drugs. Clearly, a sizable portion of the melanoma diagnostic and therapeutic markets is available, since no one course of treatment is effective for all patients and very few diagnostic tools exist to identify melanoma at early stages.

**Availability for Licensing**

**Licensing Contact:** Jennifer Wong; 301–435–4633; wongj@mail.nih.gov; Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Cell Biology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Prolonging Survival in Melanoma Patients. Please contact John Hewes, PhD, at 301–435–3121 or hewesj@mail.nih.gov for more information.

**Immortalized Human Bronchial Epithelial Cell Line**

**Description of Invention:** Normal cells can be cultured in vitro for a limited period of time before they exhibit a “cancer” or senescence, wherein they display abnormal cell morphology and significant reduction or cessation of cell proliferation. Investigators at the National Cancer Institute developed immortalized cell line by isolating bronchial epithelial cells from non-cancerous individuals and subsequent infection with an adenovirus 12–SV40 virus hybrid. Unlike normal cells, the immortalized cells can be cultured continuously in vitro in suitable medium and retain features of normal human bronchial epithelial cells, including the absence of invasive behavior in vitro or in vivo. These cells can also be transfected with oncogenes and used as a model for multistage carcinogenesis, or employed to assay a biological or chemical agent’s ability to induce differentiation and carcinogenesis as well as test potential chemotherapeutic agents.

**Applications:**

- Model to study multistage bronchial carcinogenesis.
- Identification of potential chemotherapeutic drugs.
- Identification of carcinogenic agents.

**Advantages:** Immortalized cells that retain normal human bronchial characteristics.

**Market:**

- Global cancer market is worth more than eight percent of total global pharmaceutical sales.
- Cancer industry is predicted to expand to $85.3 billion by 2010.

**Inventors:** Curtis C. Harris (NCI) et al.

**Licensing**

- **Publications:**


**Licensing Status:** Available for licensing.
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 underived 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 hydrophobicity 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.


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 diseases associated with CNV.

Advantages:

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

Development Status: In clinical trials.


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


Licensing Contact: Norbert Pontzer, J.D., Ph.D.; 301–496–5502; pontzerR@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 hubbso@mail.nih.gov for more information.

Dated: July 22, 2010.

Jennifer Spaeth,
Director, Office of Federal Advisory Committee Policy.

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.

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.

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

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