

Biol., in press (available online 2008 Sep 16, doi:10.1016/j.jmb.2008.09.008).

**Patent Status:** U.S. Provisional Application No. 61/086,027 filed 04 Aug 2008 (HHS Reference No. E-211-2008/0-US-01).

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

**Licensing Contact:** Jennifer Wong; 301-435-4633; wongje@mail.nih.gov.

**Collaborative Research Opportunity:** The Experimental Transplantation and Immunology Branch, Center for Cancer Research, National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the fully human anti-human NKG2D monoclonal antibody KYK-2.0 IgG1. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

### Methods for the Detection and Treatment of Lung Cancer

**Description of Technology:** Lung cancer is the third most common malignant disease and the first leading cause of cancer death in the western world. Non-small cell lung cancer (NSCLC) is one of the leading causes of death accounting for nearly 30% of all cancer deaths. Despite considerable research, lung cancer remains difficult to diagnose and treat effectively. Current chemotherapeutic regimens provide poor survival benefits and the unmet clinical need among lung cancer patients is very high. The prognosis is very bleak since most patients are diagnosed with lung cancer at a late stage.

The inventors have discovered that approximately 20% of common adult NSCLC have an aberrant activation of CRTC gene members with marked induction of CRTC regulated genes. CRTC activation is linked with the loss of LKB1/STK11 kinases which results in CRTC underphosphorylation and enhanced nuclear localization. As the LKB1/STK11 signaling pathways has been exploited in potential cancer therapeutic treatments, this novel unrecognized consequence the loss of LKB1/STK11 function associated with aberrant CRTC activation in cancer offers new candidate diagnostic and therapeutic targets for NSCLC.

#### Applications:

- Novel cancer diagnostics and therapeutic treatments.
- Method to detect and treat lung cancer.

**Development Status:** The technology is currently in the pre-clinical stage of development.

#### Market:

- Lung cancer is the leading cause of cancer deaths among both men and women in the U.S.

- The NSCLC market was estimated to be worth US\$3.7 billion in 2006 and will increase by 17% by 2012.

**Inventors:** Frederic Kaye and Amy Coxon (NCI).

**Patent Status:** U.S. Provisional Application No. 61/036,830 filed 13 Mar 2008 (HHS Reference No. E-069-2008/0-US-01).

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

**Licensing Contact:** Jennifer Wong; 301-435-4633; wongje@mail.nih.gov.

### Human Perilipin Proteins

**Description of Technology:** Perilipins are important regulators of lipid storage in fat cells. These proteins stabilize fat droplets and control their breakdown by controlling access of lipid-degrading enzymes. Since these proteins are central to the storage and breakdown of body fat it very likely that they are crucial for the regulation of body weight. Perilipin expression is elevated in obese animals and humans. Mutations in the perilipin gene are associated with increased risk of obesity in women. Importantly, when the perilipin gene is inactivated the obesity of model mice is reversed. Therefore, perilipin could be a good candidate for therapeutic targeting to treat obesity in humans.

This NIH invention claims DNA sequences of splice variants that code for human perilipin protein isoforms and methods of expressing the recombinant protein in bacteria or mammalian cells. It also claims substantially purified perilipin proteins and methods for detecting their presence in a biological sample.

#### Applications:

- Drug development for obesity.
- Diagnostics for detection of perilipins.
- Antigens for antibody production.
- Markers for identifying true adipocytes.

#### Advantages:

- Cloned DNA sequences ready for protein expression.
- Isoforms allow greater flexibility in designing therapeutics.

#### Development Status:

**Inventors:** Constantine Londos, Andrew S. Greenberg, Alan R. Kimmel, John J. Egan (NIDDK).

**Related Publication:** AS Greenberg et al. Perilipin, a major hormonally regulated adipocyte-specific phosphoprotein associated with the periphery of lipid storage droplets. J Biol Chem. 1991 Jun 15;266(17):11341-11346.

#### Patent Status:

- U.S. Patent No. 6,074,842 issued 13 Jun 2000 (HHS Reference No. E-111-1991/0-US-03).

- U.S. Patent No. 5,585,462 issued 17 Dec 1996 (HHS Reference No. E-111-1991/1-US-01).

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

**Licensing Contact:** Surekha Vathyam, PhD; 301-435-4076; vathyams@mail.nih.gov.

Dated: September 29, 2008.

**Richard U. Rodriguez,**

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.

### Murine Monoclonal Antibodies Effective To Treat Respiratory Syncytial Virus

**Description of Technology:** Available for licensing through a Biological Materials License Agreement are the murine MAbs described in Beeler et al, "Neutralization epitopes of the F glycoprotein of respiratory syncytial virus: effect of mutation upon fusion function," J Virol. 1989 Jul;63(7):2941-

2950. The MAbs that are available for licensing are the following: 1129, 1153, 1142, 1200, 1214, 1237, 1112, 1269, and 1243. One of these MAbs, 1129, is the basis for a humanized murine MAb (see U.S. Patent 5,824,307 to humanized 1129 owned by MedImmune, Inc.), recently approved for marketing in the United States. MAbs in the panel reported by Beeler *et al.* have been shown to be effective therapeutically when administered into the lungs of cotton rats by small-particle aerosol. Among these MAbs several exhibited a high affinity (approximately  $10^9\text{M}^{-1}$ ) for the RSV F glycoprotein and are directed at epitopes encompassing amino acid 262, 272, 275, 276 or 389. These epitopes are separate, nonoverlapping and distinct from the epitope recognized by the human Fab of U.S. Patent 5,762,905 owned by The Scripps Research Institute.

**Applications:** Research and drug development for treatment of respiratory syncytial virus.

**Inventors:** Robert M. Chanock, Brian R. Murphy, Judith A. Beeler, and Kathleen L. van Wyke Coelingh (NIAID).

**Patent Status:** HHS Reference No. B-056-1994/1—Research Tool. Patent protection is not being pursued for this technology.

**Licensing Status:** Available for non-exclusive licensing under a Biological Materials License Agreement.

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

### Neutralizing Monoclonal Antibodies to Respiratory Syncytial Virus

**Description of Technology:** Respiratory syncytial virus (RSV) is the most common cause of bronchiolitis and pneumonia among infants and children under 1 year of age. Illness begins most frequently with fever, runny nose, cough, and sometimes wheezing. During their first RSV infection, between 25% and 40% of infants and young children have signs or symptoms of bronchiolitis or pneumonia, and 0.5% to 2% require hospitalization. Most children recover from illness in 8 to 15 days. The majority of children hospitalized for RSV infection are under 6 months of age. RSV also causes repeated infections throughout life, usually associated with moderate-to-severe cold-like symptoms; however, severe lower respiratory tract disease may occur at any age, especially among the elderly or among those with compromised cardiac, pulmonary, or immune systems.

This invention is a human monoclonal antibody fragment (Fab) discovered utilizing phage display technology. The neutralizing

monoclonal antibody was isolated and its binding site was identified. Fab F2-5 is a broadly reactive fusion (F) protein-specific recombinant Fab generated by antigen selection from a random combinatorial library displayed on the surface of filamentous phage. In an *in vitro* plaque-reduction test, the Fab RSVF2-5 neutralized the infectivity of a variety of field isolates representing viruses of both RSV subgroups A and B. The Fab recognized an antigenic determinant that differed from the only other human anti-F monoclonal antibody (RSV Fab 19) described thus far. A single dose of 4.0 mg of Fab RSVF2-5/kg of body weight administered by inhalation was sufficient to achieve a 2000-fold reduction in pulmonary virus titer in RSV-infected mice. The antigen-binding domain of Fab RSVF2-5 offers promise as part of a prophylactic regimen for RSV infection in humans.

**Application:** Respiratory Syncytial Virus prophylaxis/therapeutic.

**Development Stage:** The antibodies have been synthesized and preclinical studies have been performed.

**Inventors:** Brian Murphy (NIAID), Robert Chanock (NIAID), James Crowe (NIAID), *et al.*

**Publication:** JE Crowe *et al.* Isolation of a second recombinant human respiratory syncytial virus monoclonal antibody fragment (Fab RSVF2-5) that exhibits therapeutic efficacy *in vivo*. *J Infect Dis.* 1998 Apr;177(4):1073-1076.

**Patent Status:** HHS Reference No. E-001-1996/0—U.S. and Foreign Rights Available.

**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).

### Human Neutralizing Monoclonal Antibodies to Respiratory Syncytial Virus and Human Neutralizing Antibodies to Respiratory Syncytial Virus

**Description of Technology:** This invention is a human monoclonal antibody fragment (Fab) discovered utilizing phage display technology. It is described in Crowe *et al.*, *Proc Natl Acad Sci USA.* 1994 Feb 15;91(4):1386-1390 and Barbas *et al.*, *Proc Natl Acad Sci USA.* 1992 Nov 1;89(21):10164-10168. This MAb binds an epitope on the RSV F glycoprotein at amino acid 266 with an affinity of approximately  $10^9\text{M}^{-1}$ . This MAb neutralized each of 10 subgroup A and 9 subgroup B RSV strains with high efficiency. It was effective in reducing the amount of RSV in lungs of RSV-infected cotton rats 24 hours after treatment, and successive

treatments caused an even greater reduction in the amount of RSV detected.

**Applications:** Research and drug development for treatment of respiratory syncytial virus.

**Inventors:** Robert M. Chanock (NIAID), Brian R. Murphy (NIAID), James E. Crowe Jr. (NIAID), *et al.*

**Patent Status:** U.S. Patent 5,762,905 issued 09 Jun 1998 (HHS Reference No. E-032-1993/1-US-01); U.S. Patent 6,685,942 issued 03 Feb 2004 (HHS Reference No. E-032-1993/1-US-02); U.S. Patent Application No. 10/768,952 filed 29 Jan 2004 (HHS Reference No. E-032-1993/1-US-03).

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

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

Dated: September 26, 2008.

**Richard U. Rodriguez,**

*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 Cancer 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

**Name of Committee:** National Cancer Institute Special Emphasis Panel; Early Diagnosis Using Nanotechnology-Based Imaging and Sensing.

**Date:** October 23, 2008.

**Time:** 1 p.m. to 3 p.m.

**Agenda:** To review and evaluate contract proposals.

**Place:** National Institutes of Health, 6116 Executive Boulevard, Room 406, Rockville, MD 20852, (Telephone Conference Call).

**Contact Person:** Joyce C. Pegues, PhD, Scientific Review Officer, Special Review