

speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 25, 2007.

Closed Committee Deliberations: On May 16, 2007 from 3:50 p.m. to 4:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the review of internal research programs in the Office of Bacterial Parasitic and Allergenic Products, Office of Vaccines Research and Review, CBER.

Person's attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Christine Walsh or Denise Royster at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 6, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7-7090 Filed 4-13-07; 8:45 am]

BILLING CODE 4160-01-S

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.

New Mouse T Cell Receptors as Potential Therapeutic Agents for the Treatment of Metastatic Cancer

Description of Technology: Adoptive immunotherapy is one of the most promising new therapeutic approaches to treat cancer.

T cell receptors (TCR) are the proteins responsible for the T cell's ability to recognize infected or transformed cells. A TCR consists of two domains, one variable domain that recognizes the antigen and one constant region that helps the TCR anchor to the membrane and transmit the recognition signal by interacting with other proteins.

This invention describes the identification of two mouse TCRs that target a common and highly expressed melanoma antigen, gp100, expressed by human cancers. These TCRs, have superior (100-1000 times) biological function compared to other human tumor-specific TCR that are currently in use in experimental trials using genetically engineered T cells. Therefore, these new TCRs represent potential therapeutic agents that can be used in the treatment of metastatic cancers, especially melanomas.

Applications: New mouse TCRs have been identified that recognize human gp100; The mouse TCRs have 100-1000 times superior biological function compared to their human counterpart in recognizing gp100 when expressed in human lymphocytes; Human T cells genetically engineered to express new TCRs can serve as potential therapeutic agents in the treatment of patients with metastatic cancers; Clinical trials with these novel TCRs are currently being planned.

Development Status: Pre-clinical work has been completed and clinical studies are forthcoming.

Inventors: Nicholas P. Restifo *et al.* (NCI).

Relevant Publications:

1. A manuscript relating to this invention is under preparation and will be available once accepted.

2. RA Morgan *et al.* Cancer regression in patients after transfer of genetically engineered lymphocytes. *Science*. 2006 Oct 6;314(5796):126-129.

Patent Status: U.S. Provisional Application No. 60/884,732 filed 12 Jan

2007 (HHS Reference No. E-059-2007/0-US-01); U.S. Provisional Application No. 60/885,724 filed 19 Jan 2007 (HHS Reference No. E-059-2007/1-US-01).

Licensing Status: This technology is available for licensing under an exclusive or non-exclusive patent license.

Licensing Contact: Michelle Booden, Ph.D.; 301/451-7337; boodenm@mail.nih.gov.

Collaborative Research Opportunity: The Surgery Branch, NCI, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this T cell receptor that is specific for human tumors. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

A Novel DNA Vaccine for the Treatment of Malignancies Expressing Immature Laminin Receptor Protein

Description of Technology: This invention describes a new potent chemoattractant-based DNA vaccine to evoke therapeutic anti-tumor responses against tumors. The vaccine targets the antigen presenting cells (APCs) to efficiently present an antigen to MHC class I and class II molecules to induce tumor specific CD4 and CD8 T cell responses.

The antigen tested is a highly conserved oncofetal antigen named immature laminin receptor protein (OFA-iLRP) that is preferentially expressed in malignant tissues. The vaccine construct consists of novel fusion proteins with enhanced binding affinities to augment antigen processing and antitumor responses.

Applications and Modality:

1. *In vivo* laboratory data shows that OFA-iLRP can be used as a potential immunotherapeutic antigen for the treatment of several malignancies including lymphoma, breast, lung, and ovarian.

2. The vaccine construct is a novel fusion protein designed to enhance immunogenicity of OFA-iLRP via delivering it to chemokine receptors expressed on antigen presenting cells.

3. The vaccine formulation will be most effective if used for treatment of cancer patients with minimal residual disease to protect from the disease relapse.

4. The vaccine potentially could be effective as a preventive measure for people with cancer predisposition by eliciting long term anti-OFA-iLRP humoral and cellular memory.

5. Very simple and less invasive vaccine that can be easily delivered to the skin, muscle or other tissues.

Market: Previous attempts to produce a vaccine construct with OFA-iLRP antigen have been laborious, expensive and non-reproducible showing no definitive demonstrations on the efficacy use of OFA-iLRP as a cancer vaccine. This simple chemoattractant based DNA vaccine is effective, potential cancer therapy with extensive *in vivo* data. It can be a valuable addition to the fast growing cancer vaccine market.

Development Status: The technology is currently in the pre-clinical stage of development and planned for clinical tests in patients with NSCLC (tentative start date 2008).

Inventors: Arya Biragyn *et al.* (NIA)

Related Publications:

1. A manuscript directly related to this technology will be available as soon as it is accepted for publication.

2. A Biragyn *et al.* Genetic fusion of chemokines to a self tumor antigen induces protective, T-cell dependent antitumor immunity. *Nat Biotechnol.* 1999 Mar;17(3):253–258.

3. A Biragyn *et al.* Mediators of innate immunity that target immature, but not mature, dendritic cells induce antitumor immunity when genetically fused with nonimmunogenic tumor antigens. *J Immunol.* 2001 Dec 1;167(11):6644–6653.

Patent Status: U.S. Provisional Application No. 60/841,927 filed 01 Sep 2006, entitled “Methods and Compositions for the Treatment and Prevention of Cancer” (HHS Reference No. E–271–2006/0–US–01).

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

Licensing Contact: Thomas P. Clouse, J.D.; 301/435–4076; clousetp@mail.nih.gov.

Collaborative Research Opportunity: The National Institute on Aging, Immunotherapeutics Unit, Laboratory of Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize simple and potent vaccines that target embryonic antigens expressed in tumors. Please contact John D. Hewes, Ph.D. at (301) 435–3121 or hewesj@mail.nih.gov for more information.

Preparation of (R,R)-Fenoterol and (R,R)-or (R,S)-Fenoterol Analogues and Their Use in Treating Congestive Heart Failure

Description of Technology: This technology is directed to the discovery of (R,R)- and (R,S)-fenoterol analogues which are highly effective and selective at binding B2-adrenergic receptors. The patent application includes methods of

using such compounds and compositions for the treatment of cardiac disorders such as congestive heart failure and pulmonary disorders such as asthma or chronic obstructive pulmonary disease.

Market: Approximately 5 million individuals are diagnosed with congestive heart failure in the United States and an estimated 3.5 million hospitalizations are attributed to heart failure each year.

Inventors: Irving W. Wainer *et al.* (NIA).

Patent Status: U.S. Provisional Application No. 60/837,161 filed 10 Aug 2006 (HHS Reference No. E–205–2006/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301/435–4521; sayyidf@mail.nih.gov.

Collaborative Research Opportunity: The National Institute on Aging, Laboratory of Clinical Investigation, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of fenoterol analogues in the treatment of cardiac disorders. Please contact John D. Hewes, Ph.D. at 301–435–3121 or hewesj@mail.nih.gov for more information.

Transgenic Mouse Model that has Defective Innate and Adaptive Immunity

Description of Technology: The present research tool is a transgenic mouse model (C57BL/6 H–2^b) that has defective innate and adaptive immunity. The mouse model harbors adaptive immunity cells, but lacks normal cellular responses and has an altered pattern of antibody production. The cells of the innate immune system (NK and NKT cells) are also nearly absent.

The mouse model lacks lymph nodes. The mouse model also lacks the ability to reject autologous, allogeneic, and presumably xenogeneic cells. The mouse model also has a defective antibody production mechanism, making only early antibodies (IgM) and little, if any, mature isotypes (G2a, G2b).

Applications and Modality:

1. New mouse model to study human tumors.
2. New mouse model to study immune function reconstitution.
3. New mouse model to study the development of lymph nodes and role of lymph nodes in the disease process.
4. Most mouse or human progenitor cells can be transferred to and engraft in the mouse model.

Market:

1. In 2006, 600,000 estimated deaths from cancer related diseases.

2. Immunotherapy market is expected to double in the next 5 years.

3. Research tool useful for adoptive immunotherapy studies.

Development Status: The technology is a research tool.

Inventor: John R. Ortaldo (NCI).

Related Publications:

1. JJ Subleski, VL Hall, TC Back, JR Ortaldo, RH Wilttrout. Enhanced antitumor response by divergent modulation of natural killer and natural killer T cells in the liver. *Cancer Res.* 2006 Nov 15;66(22):11005–11012.

2. JR Ortaldo, A Mason, J Willette-Brown, FW Ruscetti, J Wine, T Back, T Stull, EW Bere, L Feigenbaum, R Winkler-Pickett, and HA Young. Modulation of lymphocyte function with inhibitory CD2: Loss of NK and NKT function. Submitted to *Blood* (2/2007).

Patent Status: HHS Reference No. E–290–2005/0—Research Tool. This technology is not patented. The mouse model will be transferred through a Material Transfer Agreement (for not-for-profit institutions) or through a Biological Materials License (commercial entities).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact for Commercial Entities: Thomas P. Clouse; 301/435–4076; clousetp@mail.nih.gov.

Material Transfer Agreement Contact for Not-For-Profit Institutions: Kathy Higinbotham; 301/846–5465; higinbok@mail.nih.gov.

Dissection Tools and Methods of Use

Description of Technology: Available for licensing is a dissection tool for cutting cell aggregates into smaller portions for further colony propagation. It is comprised of a handle attached to a rotatable shaft fitted with a cutting blade. The technology describes a safe and practical device that provides maximum product yield by preventing material from accumulating between the cutting surfaces. It also provides for more uniform cut colonies using lesser number of cuts than existing stem cell cutting instruments.

Applications: Makes possible the sectioning of cultured embryonic stem cells into smaller fractions for their transfer to new culture medium and subsequent incubation.

Market: Researchers worldwide who utilize cultured embryonic stem cells.

Inventors: Soojung Shin (NIA).

Patent Status: U.S. Provisional Application No. 11/531,972 filed 14 Sep 2006 (HHS Reference No. E–272–2005/0–US–01).

Licensing Status: Available for non-exclusive licensing.

Licensing Contact: Fatima Sayyid, M.H.P.M.; 301/435-4521; sayyidf@mail.nih.gov.

Dated: April 9, 2007.

Steven M. Ferguson,

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

[FR Doc. E7-7108 Filed 4-13-07; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

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 meetings.

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 Cancer Institute Special Emphasis Panel, SPORE in GI and Head & Neck Cancers.

Date: June 11-12, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Shamala K. Srinivas, PhD, Scientific Review Administrator, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8123, Bethesda, MD 20892, 301-594-1224, ss537t@nih.gov.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee G—Education.

Date: June 26-27, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Sonya Roberson, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8109,

Bethesda, MD 20892, 301-594-1182, robersos@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, R25 Special Emphasis Panel (SEP).

Date: June 26, 2007.

Time: 5 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Robert Bird, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8113, Bethesda, MD 20892-8328, 301-496-7978, birdr@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel, Cancer Prevention Research Small Grant Program (R03).

Date: June 28-29, 2007.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Irina V. Gordienko, PhD, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7073, MS 2829, Bethesda, MD 20892, 301-594-1566, gordienkoiv@mail.nih.gov.

Name of Committee: National Cancer Institute Initial Review Group, Subcommittee H—Clinical Groups.

Date: July 9-10, 2007.

Time: 1 p.m. to 11 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Mirage I & II, Washington, DC 20007.

Contact Person: Timothy C. Meeker, MD, PhD, Scientific Review Administrator, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8103, Bethesda, MD 20892, (301) 594-1279, meekert@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 5, 2007.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-1848 Filed 4-13-07; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, March 5, 2007, 12 p.m. to March 5, 2007, 4 p.m. National Institutes of Health, 6130 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on January 11, 2007, 72 FR1335.

The meeting notice is changed to reflect the date change from March 5, 2007 to April 13, 2007. The meeting is closed to the public.

Dated: April 5, 2007.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 07-1849 Filed 4-13-07; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood 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 the following meeting of the Sickle Cell Disease Advisory Committee.

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.

Name of Committee: Sickle Cell Disease Advisory Committee.

Date: June 4, 2007.

Time: 8:30 a.m. to 4 p.m.

Agenda: Discussion of Programs and Issues.

Place: National Institutes of Health, Rockledge 6700, 6700A Rockledge Drive, Room 354, Bethesda, MD 20817.

Contact Person: Robert B. Moore, PhD, Health Scientist Administrator, Blood Diseases Program, Division of Blood Disease and Resources, National Heart, Lung, and Blood Institute, NIH, 6701 Rockledge Drive, Room 10162, Bethesda, MD 20892, 301/435-0050.

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