

An estimated 180,510 new cases of breast cancer and 40,060 deaths due to breast cancer in the United States in 2007.

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

*Inventors:* Nima Sharifi *et al.* (NCI).

*Patent Status:* U.S. Provisional Application No. 60/958,351 filed 03 Jul 2007 (HHS Reference No. E-163-2007/0-US-01).

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

*Licensing Contact:* Jennifer Wong; 301-435-4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov).

*Collaborative Research Opportunity:* The Medical Oncology Branch, National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize—treatments of resistant prostate cancer. Please contact John D. Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

**A Clinically Proven Therapeutic Treatment and Diagnostic Tool for Mesothelin Expressing Cancers: A Novel Recombinant Immunotoxin SS1P (anti-mesothelin dsFv-PE38)**

*Description of Technology:* Mesothelin is a glycoprotein, whose expression has been largely restricted to mesothelial cells in normal tissues. Mesothelin has been shown to be expressed in several cancers including mesothelioma, lung cancer, pancreatic cancers, gastric cancers and ovarian cancers, and has the potential of being used as a novel target for the development of new treatments.

The technology relates to the SSIP immunotoxin that can be used to kill cells expressing mesothelin on their surfaces, such as mesothelioma, ovarian cancer, lung cancer, ovarian cancer and stomach cancer. Additionally, it can be used for the detection of mesothelin expressing cells present in a biological sample.

The SSIP immunotoxin is a recombinant immunotoxin generated by the fusion of a high affinity anti-mesothelin Fv (SS1) with a 38 kDa portion of *Pseudomonas Exotoxin A* (PE38).

*Applications:* SS1P can be used as a therapy for mesothelin expressing cancers.

The immunotoxin can be used as a stand alone treatment and in combination with standard chemotherapy.

*Advantage:* SS1P immunotoxin is available for use and has been successfully tested clinically for the

treatment of mesothelioma and ovarian cancer with low side effects.

*Development Status:* Phase 1 studies have been completed for mesothelin expressing cancers such as mesothelioma, ovarian cancer and pancreatic cancer.

Phase 2 studies to begin shortly for combination therapy using SS1P and standard chemotherapy.

*Inventors:* Ira Pastan (NCI) *et al.*

*Relevant Publications:* 1. R Hassan *et al.* Phase I study of SS1P, a recombinant anti-mesothelin immunotoxin given as a bolus I.V. infusion to patients with mesothelin-expressing mesothelioma, ovarian, and pancreatic cancers. Clin Cancer Res. 2007 Sep 1;13 (17):5144-5149.

2. Y Zhang *et al.* Synergistic antitumor activity of taxol and immunotoxin SS1P in tumor-bearing mice. Clin Cancer Res. 2006 Aug 1;12(15):4695-4701.

*Patent Status:* U.S. Patent No. 7,081,518 issued 25 Jul 2006, entitled "Anti-Mesothelin Antibodies Having High Binding Affinity" (HHS Reference No. E-139-1999/0-US-07)

*Related Intellectual Property:* 1. U.S. Patent No. 4,892,827 entitled "Recombinant Pseudomonas Exotoxin: Construction of an Active Immunotoxin with Low Side Effects" [HHS Ref. No. E-385-1986/0];

2. U.S. Patent Nos. 6,051,405, 5,863,745, and 5,696,237 "Recombinant Antibody-Toxin Fusion Protein" [HHS Ref. No. E-135-1989/0];

3. U.S. Patents 5,747,654, 6,147,203, and 6,558,672 entitled "Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity" [HHS Ref. No. E-163-1993/0];

4. U.S. Patent No. 6,153,430, and U.S. Patent Application No. 09/684,599 "Nucleic Acid Encoding Mesothelin, a Differentiation Antigen Present on Mesothelium, Mesotheliomas and Ovarian Cancers" [HHS Ref. No. E-002-1996/0];

5. U.S. Patent 6,083,502 entitled "Mesothelium Antigen and Methods and Kits for Targeting It" [HHS Ref. No. E-002-1996/1];

6. U.S. Patent Application 09/581,345: "Antibodies, Including Fv Molecules, and Immunoconjugates Having High Binding Affinity for Mesothelin and Methods for Their Use" [HHS Ref. No. E-021-1998/0];

7. PCT Application No. PCT/US01/18503, "Pegylation of Linkers Improves Antitumor Activity and Reduces Toxicity of Immunoconjugates" [HHS Ref. No. E-216-2000/2];

8. PCT Application No. PCT/US2006/018502 and U.S. Patent Application No. 60/681,104, entitled "Anti-Mesothelin

Antibodies Useful For Immunological Assays" [HHS Ref. No. E-015-2005/0-US-01]; and

9. Any related foreign filed national stage applications claiming priority to such patent applications and patents listed above.

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

*Licensing Contact:* David A. Lambertson, Ph.D.; 301-435-4632; [lambertsond@mail.nih.gov](mailto:lambertsond@mail.nih.gov).

*Collaborative Research Opportunity:* The National Cancer Institute Laboratory of Molecular Biology is seeking statements of capability or interest from parties interested in collaborative research to further develop, immunotoxin SS1P. Please contact John D. Hewes, Ph.D. at 301-435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: November 16, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-23194 Filed 11-29-07; 8:45 am]

BILLING CODE 4140-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Human Genome Research 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 meetings 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:* Center for Inherited Disease Research Access Committee.

*Date:* January 10-11, 2008.

*Time:* 7 a.m. to 3:45 p.m.

*Agenda:* To review and evaluate grant applications and/or proposals.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Jerry Roberts, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, National Institutes of Health, 5635

Fishers Lane, Suite 4076, MSC 9305, Bethesda, MD 20892-9306, 301 402-0838, jr39m@nih.gov.

*Name of Committee:* Center for Inherited Disease Research Access Committee, CIDR Access Committee B.

*Date:* January 11, 2008.

*Time:* 4 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Rudy Pozzatti, PhD., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, 5635 Fishers Lane, Suite 4076, MSC 9306, Bethesda, MD 20852, (301) 402-0838, pozzatrr@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: November 26, 2007.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-5883 Filed 11-29-07; 8:45 am]

BILLING CODE 4140-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute on Drug Abuse; 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 meetings 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 Drug Abuse Special Emphasis Panel, B/ START Review.

*Date:* December 14, 2007.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

*Contact Person:* Mark Swieter, PhD, Chief, Training and Special Projects Review Branch, Office of Extramural Affairs, National Institutes on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Suite 220, Bethesda,

MD 20892-8401, (301) 435-1389, ms80x@nih.gov.

*Name of Committee:* National Institute on Drug Abuse Special Emphasis Panel, B/ START Review.

*Date:* December 14, 2007.

*Time:* 1 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

*Contact Person:* Mark Swieter, PhD, Chief, Training and Special Projects Review Branch, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, 6101 Executive Boulevard, Suite 220, Bethesda, MD 20892-8401, (301) 435-1389, ms80x@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: November 19, 2007.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-5878 Filed 11-29-07; 8:45 am]

BILLING CODE 4140-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of General Medical Sciences; 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 of General Medical Sciences Special Emphasis Panel, NIH Pathway to Independence Awards (K99/R00).

*Date:* December 6-7, 2007.

*Time:* 7 p.m. to 3:30 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:* Meredith D. Temple-O'Connor, PhD, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45

Center Drive, Room 3AN12C, Bethesda, MD 20892, 301-594-2772, templeocm@mail.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: November 19, 2007.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 07-5879 Filed 11-29-07; 8:45 am]

BILLING CODE 4140-01-M

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Institute of Allergy and Infectious Diseases; 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 of Allergy and Infectious Diseases Special Emphasis Panel, Immune Pathogenesis in Chronic HIV Infection.

*Date:* December 17, 2007.

*Time:* 9 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge 6700, 6700B Rockledge Drive, Room 3133, Bethesda, MD 20817 (Telephone Conference Call).

*Contact Person:* Peter R. Jackson, PhD, Chief, ACERB, Scientific Review Program, Division of Extramural Activities, NIAID, NIH, DHHS, 6700-B Rockledge Drive, Room 3140, MSC 7616, Bethesda, MD 20892-7616, 301-496-2550, pjackson@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology,