

and for identification of agents which cause or reverse immunosuppression.

Development Status: Pre-clinical stage.

Inventors: Augusto C. Ochoa et al. (NCI).

Patent Status: U.S. Patent No. 5,583,002 issued 10 Dec 1996 (HHS Reference No. E-231-1995/1-US-01); U.S. Patent No. 5,556,763 issued 17 Sep 1996 (HHS Reference No. E-231-1995/3-US-01);

U.S. Patent No. 5,889,143 issued 10 Dec 1996 (HHS Reference No. E-231-1995/3-US-02);

U.S. Patent Application No. 09/280,655 filed 29 Mar 1999 (HHS Reference No. E-231-1995/3-US-03);

U.S. Patent No. 5,658,744 issued 19 Aug 1997 (HHS Reference No. E-232-1995/0-US-01);

U.S. Patent No. 5,965,366 issued 12 Dec 1999 (HHS Reference No. E-232-1995/1-US-01); and any foreign equivalent patents and patent applications.

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

Licensing Contact: John Stansberry; 301/435-5236; stansbej@mail.nih.gov.

Dated: November 14, 2007.

Steven M. Ferguson,

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

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 United States 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.

Monoclonal Antibody to a Specific Peptide-MHC Class II Complex

Description of Invention: T lymphocytes play an important role in the immune system by recognizing foreign protein motifs on cells. T lymphocytes are stimulated to recognize these motifs through their interactions with peptide-MHC complexes (pMHC). Thus, studying pMHC is an important aspect of understanding how the immune system works, particularly with regard to the development of vaccines. Unfortunately, the detection of pMHC is largely dependent on indirect assays, due to the difficulty of producing antibodies for specific pMHC.

This invention regards the development of hybridomas (C4H3) for the production of antibodies that are highly specific for a particular pMHC complex consisting of hen egg lysozyme peptide 46-61 (HEL) and the I-A^k MHC class II molecule. These antibodies can be used for a myriad of purposes which include studying how cells form pMHC.

Applications: Discovery of methods for antigen delivery in the development of vaccines.

Quantitation and distribution of pMHC complexes on cells.

Study antigen processing in experimental immunological research systems.

Advantages: High specificity for the pMHC complex of HEL-I-A^k MHC class II molecule.

HEL-I-A^k is widely used in experimental immunological research systems, giving the hybridoma and antibodies great applicability.

Inventors: Ronald N. Germain *et al.* (NIAID).

Publications: 1. G Zhong *et al.* Production, specificity, and functionality of monoclonal antibodies to specific peptide-major histocompatibility complex class II complexes formed by processing of exogenous protein. *Proc Natl Acad Sci U S A.* 1997 Dec 9; 94(25):13856-13861. 2. A Porgador *et al.* Localization, quantitation, and in situ detection of specific peptide-MHC class I complexes using a monoclonal antibody. *Immunity.* 1997 Jun; 6(6):715-726.

Patent Status: HHS Reference No. E-021-2008/0-Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: David A. Lambertson, Ph.D.; 301-435-4632; lambertsond@mail.nih.gov.

Collaborative Research Opportunity: The NIAID Lymphocyte Biology Section, Laboratory of Immunology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize monoclonal antibody C4H3, specific for HEL (46-61) bound to the MHC class II molecule I-A^k. Please contact Ronald N. Germain, M.D., Ph.D., at rgermain@nih.gov for more information.

Bifunctional Compounds that Bind to Hormone Receptors

Description of Technology: The development and progression of prostate cancer is dependent on the androgen receptor (AR), a ligand-dependent transcription factor. In the inactive form AR resides in the cytosolic region of the cell and when activated, AR is imported into the nucleus. Initial hormonal therapy for prostate cancer involves lowering serum levels of testosterone to shut down AR activity. Despite initial patient responses to testosterone-depleting therapies, prostate cancer becomes refractory to hormonal therapy. Notably, AR is reactivated in hormone-refractory prostate cancer and reinstates its proliferative and survival activity.

Available for licensing is a novel chemical compound which is bifunctional and binds to AR. This compound is comprised of tubulin-binding and steroid receptor-binding moieties. This compound is designed to antagonize AR function in a nonclassical manner by several mechanisms and kills hormone-refractory prostate cells better than both functional moieties. This compound is a first-in-class of bifunctional steroid receptor binding agents that can antagonize steroid receptors in a variety of hormone-dependent diseases, such as breast and prostate cancer.

Applications: Therapeutic compounds that selectively target steroid receptor-expressing cancer cells resulting in decreased toxicity.

Method to treat hormone resistant prostate cancer and potentially other steroid receptor dependent diseases such as breast cancer.

Market: Prostate cancer is the second most common type of cancer among men, wherein one in six men will be diagnosed with prostate cancer.

An estimated 218,890 new cases of prostate cancer and 27,050 deaths due to prostate cancer in the United States in 2007.

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.

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 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.

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 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.

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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