

OIRA_submission@omb.eop.gov, or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Jamelle E. Banks, Public Health Analyst, Office of Science Policy, Analysis and Communication, National Institute of Child Health and Human Development, 31 Center Drive Room 2A18, Bethesda, Maryland, 20892, or call a non-toll free number (301) 496-1877 or E-mail your request, including your address to banksj@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: October 20, 2011.

Jamelle E. Banks,

Public Health Analyst, Office of Science Policy, Analysis and Communications, National Institute of Child Health and Human Development, 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.

New Non-HLA-A2 Restricted Human T Cell Receptors (TCRs) That Could Be Used To Treat a Broader Cancer Patient Population Via TCR Adoptive Immunity

Description of Technology: NIH scientists have developed T cell receptors (TCRs) that recognize melanoma antigen family A3 (MAGE-A3) or MAGE-A12 peptide antigens. The TCRs recognize these antigens in the context of major histocompatibility complex (MHC) class I molecules, HLA-A1 and HLA-Cw7, respectively. Since these TCRs are not HLA-A2 restricted, their therapeutic use would expand the number of treatable cancer patients using MAGE-A3 or A12-specific TCR adoptive immunotherapy.

There are twelve MAGE-A superfamily antigens designated A1-A12. Their normal function is not well defined, but in cancer cells they block the functions of tumor suppressor proteins to mediate tumor growth and spreading. The MAGE-A proteins are some of the most widely expressed cancer testis antigens expressed on human tumors. Other than non-MHC expressing germ cells of the testis, normal cells do not express these antigens, which make them ideal targets for cancer immunotherapies anticipated to generate less toxic side effects than conventional cancer treatments. These TCRs deliver a robust immune response against MAGE-A3 or A12 expressing cells and could prove to be a powerful approach for selectively attacking tumors without generating toxicity against healthy cells.

Potential Commercial Applications:

- Personalized immunotherapy for a variety of cancers using human T cells expressing these TCRs
- Component of a combination immunotherapy regimen aimed at targeting specific tumor-associated antigens, including MAGE-A3 and MAGE-A12, expressed by cancer cells.
- A research tool to investigate signaling pathways in MAGE-A3 or MAGE-A12 antigen expressing cancer cells.
- An *in vitro* diagnostic tool to screen for cells expressing MAGE-A3 or MAGE-A12 antigens.

Competitive Advantages:

- Highly expressed targets: MAGE-A proteins (especially MAGE-A3) are some of the most highly expressed cancer testis antigens on human tumors
- Limited side effects: MAGE-A proteins are only expressed on tumor cells and non-MHC expressing testis germ cells. Infused cells expressing these TCRs should target MAGE-A3 or A12 expressing tumor cells with little or no toxicity to the patient's normal cells.

- Not HLA-A2 restricted: Expands patient population treatable with MAGE-A TCRs since they recognize antigen in the context of HLA-A1 or HLA-Cw7.

Development Stage:

- Pre-clinical
- *In vitro* data available

Inventors: Steven A. Rosenberg, Paul F. Robbins, Richard A. Morgan, Steven A. Feldman, and Shiqui Zhu (NCI).

Publication: Chinnasamy N, *et al.* A TCR targeting the HLA-A*0201-restricted epitope of MAGE-A3 recognizes multiple epitopes of the MAGE-A antigen superfamily in several types of cancer. *J Immunol.* 2011 Jan 15;186(2):685-696. [PMID 21149604].

Intellectual Property: HHS Reference No. E-266-2011/0—U.S. Patent Application No. 61/535,086 filed 15 September 2011.

Related Technology: HHS Reference No. E-236-2010/0—U.S. Patent Application No. 61/405,668 filed 22 October 2010.

Licensing Contact: Samuel E. Bish, Ph.D.; (301) 435-5282; bishse@mail.nih.gov.

Collaborative Research Opportunity: The Surgery Branch of the National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize T cell receptors that target cancer/testis antigens for use in cancer adoptive immunotherapy. For collaboration opportunities, please contact John Hewes, Ph.D. at hewesj@mail.nih.gov.

Antiandrogen Small Molecules for the Treatment of Prostate Cancer

Description of Technology: The present licensing opportunity is for a new class of small molecule compounds, and the method of using them to treat prostate cancer. This year it is estimated there will be over 32,000 deaths from prostate cancer showing an unmet need for a more effective treatment particularly for castrate-resistant prostate cancer (CRPC). CRPC is characterized by androgen-independent cancer cells that have adapted to the depletion of hormones and continue to grow. Abnormal androgen receptor signaling is known to drive advanced castrate-resistant prostate cancer. The small molecule compounds of the instant invention are antiandrogens that target androgen receptor signaling in both androgen-independent and androgen-sensitive androgen receptor activity, and androgen receptors that are resistant to the current antiandrogens available. Unlike the currently available

antiandrogens, the new small molecules induce androgen receptor degradation and cell death in prostate cancer cells. Further, these compounds and methods can also induce degradation of other steroid hormone receptors demonstrating the possibility of treating a wider range of cancers.

Potential Commercial Applications:

- Series of steroid receptor compounds that cause cancer cell death
- Method of using the compounds in cancer treatment

Competitive Advantages:

- First small molecule antiandrogen treatment
- Causes cell death, not just loss of function
- Potential to treat other cancers through degradation of other steroid hormone receptors

Development Stage: *In vitro* data available.

Inventors: Jane B. Trepel, Yeong Sang Kim, Sunmin Lee, Vineet Kumar, and Sanjay V. Malhotra (NCI).

Intellectual Property: HHS Reference No. E-015-2011/0—U.S. Patent Application No. 61/497,129 filed 15 Jun 2011.

Licensing Contact: Whitney Hastings; (301) 451-7337; hastingw@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Small Molecules for the Treatment of Prostate Cancer. For collaboration opportunities, please contact John Hewes, PhD at hewesj@mail.nih.gov or (301) 496-0477.

Dated: October 21, 2011.

Richard U. Rodriguez,

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

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Protease Deficient *Bacillus anthracis* With Improved Recombinant Protein Yield Capabilities

Description of Technology: Species of *Bacillus*, such as *Bacillus anthracis*, *Bacillus cereus*, and *Bacillus subtilis*, are attractive microorganisms for recombinant protein production in view of their fast growth rate, high yield, and ability to secrete produced products directly into the medium. *Bacillus anthracis* is also attractive in view of its ability to produce anthrax toxin and ability to fold proteins correctly. This application claims a *B. anthracis* strain in which more than one secreted protease is inactivated by genetic modification. Such a protease-deficient *B. anthracis* has an improved ability to produce recombinant secreted proteins compared to other bacteria, particularly other *Bacillus*. Improvements include production of intact (i.e., mature full-length) proteins, often at high yield.

Potential Commercial Applications:

- Vaccine production
- Recombinant protein production
- *B. anthracis* vaccine production

Competitive Advantages:

- Highly efficient production of recombinant proteins
- Low cost production of recombinant proteins

Development Stage:

- Early-stage
- *In vitro* data available

Inventors: Andrei Pomerantsev and Stephen Leppla (NIAID).

Publication: Pomerantsev A, *et al.* A *Bacillus anthracis* strain deleted for six proteases serves as an effective host for production of recombinant proteins. *Protein Expr Purif.* 2011 Nov;80(1):80-90. [PMID 21827967].

Intellectual Property:

- HHS Reference No. E-202-2011/0—U.S. Provisional Application No. 61/514,384 filed 02 Aug 2011

- HHS Reference No. E-202-2011/1—U.S. Provisional Application No. 61/521,617 filed 09 Aug 2011

Licensing Contact: Peter Soukas, J.D.; (301) 435-4646; soukasp@mail.nih.gov.

Collaborative Research Opportunity:

The NIAID is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize *B. anthracis* vaccines, *B. anthracis* protein production. For collaboration opportunities, please contact Charles Rainwater at (301) 435-8617.

Parvovirus B19 Codon Optimized Structural Proteins for Vaccine and Diagnostic Applications

Description of Technology: Parvovirus B19 (B19V) is the only known pathogenic human parvovirus. Infection by this viral pathogen can cause transient aplastic crisis in individuals with high red cell turnover, pure red cell aplasia in immunosuppressed patients, and hydrops fetalis during pregnancy. In children, B19V most commonly causes erythema infectiosum, or fifth's disease. Infection can also cause arthropathy and arthralgia. The virus is very erythrotropic, targeting human erythroid (red blood) progenitors found in the blood, bone marrow, and fetal liver. Currently, there are no approved vaccines or antiviral drugs for the treatment or prevention of B19V infection.

The subject technology is a series of plasmid constructs with codon optimized B19 viral capsid genes (VP1 and VP2) that can be expressed in mammalian cells. Transfection of vectors encoding these optimized VP1 and VP2 genes into different mammalian cell lines, including 293, Cos7, and HeLa cells produce virus-like particles (VLPs). The vectors include bicistronic plasmids expressing the VP1 and VP2 proteins at different ratios to produce B19V VLPs with optimal antigenicity for vaccine applications. This technology can also be used for diagnostic applications and development of a viral packaging system for producing infectious B19V virus.

Applications:

- VLPs based vaccines for the prevention and/or treatment of B19V infection
- DNA based vaccines for the prevention and/or treatment of B19V infection
- B19V diagnostics
- Viral packaging system

Advantages: