Subject name	Address	Effective date
DIRICO	BERKLEY, MA	1/5/2006
MOUNTAIN VISTA CHIROPRACTIC CENTER, INC	LONGMONT, CO	3/20/2006
ROLANDO ROZAS, MD, PA	MIAMI, FL	3/20/2006
RURAL HEALTH NETWORKS OF FLORIDA	CITRA, FL	3/20/2006
TWILIGHT YEARS ADULT CARE, INC	MINNEAPOLIS, KS	3/20/2006
UNIVERSAL MEDICAL ASSOCIATION OF USA, INC	ROSEMEAD, CA	3/20/2006
DEFAULT ON HEAL LOAN		
COLE, MARIA	WEST PALM BEACH, FL	3/20/2006
DENSMORE, ROBERT	TAMPA, FL	3/20/2006
ETIENNE, FERNANDE	ROSELLE, NJ	3/20/2006
FENTON, MARK	VAN NUYS, CA	3/20/2006
FERNANDEZ, OCTAVIO	MIAMI, FL	3/20/2006
HUDSON, DONALD	LANSING, MI	3/20/2006
KEOSHIAN, CRAIG	VALENCIA, CA	3/20/2006
KYCYNKA, DREW	SPRING HILL, FL	3/20/2006
LARA-FULLER, ADRIENNE	OXNARD, CA	2/2/2006

Dated: March 8, 2006.

Maureen Byer,

Acting Director, Exclusions Staff, Office of Inspector General.

[FR Doc. E6–3803 Filed 3–15–06; 8:45 am]

BILLING CODE 4152–01–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.

Use of CYP1B1*3 Genotyping To Predict Survival to Docetaxel Treatment in Androgen-Independent Prostate Cancer

William D. Figg et al. (NCI).

U.S. Provisional Application No. 60/716,439 filed September 12, 2005 (HHS Reference No. E–307–2005/0–US–01).

Licensing Contact: Mojdeh Bahar; 301/435–2950; *baharm@mail.nih.gov.*

Androgen-independent prostate cancer (AIPC) remains the second leading cause of cancer death in men in developed nations, and it is estimated that one in six men will be diagnosed with prostate cancer. The use of docetaxel has been shown to prolong survival rate and improve the quality of life in patients suffering from AIPC.

Scientists at NIH have identified a genetic marker called CYP1B1*3 (4326C>G; L432V) that can predict survival in patients with prostate cancer prior to treatment with docetaxel. In a study of 25 patients suffering from AIPC, patients that were homozygous or heterozygous wild-type for the 4326C>G transition had an increased mean survival time after docetaxel treatment when compared to patients carrying the homozygous variant. These patients showed a survival rate of 15.3 months compared to 7.5 months for those homozygous with the variant CYP1B1*3.

This genetic marker (CYP1B1*3) can be measured in DNA obtained from a blood sample. This technology can be potentially used as a diagnostic tool to predict the patient's propensity to respond to docetaxel treatment when being treated for AIPC.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Adoptive Immunotherapy With Enhanced T Lymphocyte Survival

Steven A. Rosenberg et al. (NCI).

PCT Application No. PCT/US05/3640 filed October 7, 2005 (HHS Reference No. E–340–2004/2–PCT–01);

U.S. Provisional Application No. 60/617,340 filed October 8, 2004 (HHS Reference No. E–340–2004/0–US–01).

Licensing Contact: Michelle A. Booden; 301/451–7337; *boodenm@mail.nih.gov.*

Adoptive immunotherapy strategies have existed for several years now and many have proven to be highly successful in a limited subset of patients. This limited response rate among a diverse patient population may not be surprising, given the complexity of the immune system and the complicated evolution of a normal cell to a immune evading malignancy. A common observation amongst most patients that did not respond to adoptive therapy strategies is that the immune response to the cancer was not sustained.

A number of cytokines have been shown to sustain a T-cell response when administered systemically with autologous isolated T-cells. However, the systemic delivery of many cytokines, such as IL–2, will cause significant toxicity before the beneficial immunologic effects of the autologous T-cells can occur. This invention describes a method of transfecting isolated autologous T-Lymphocytes with endogenous cytokines, for example IL–7 and IL–15, to sustain an adoptive T-lymphocyte response without systemic toxicity. The invention also describes a method for improving expression of transfected cytokines via a codon optimized IL–15 vector. Applications of this technology beyond cancer include the potential use of cytokine expressing cells in treating

infectious and autoimmune diseases and vaccination.

This invention was developed at the NCI Surgery Branch. The Surgery Branch plans to initiate clinical studies utilizing this technology and collaborative opportunities may be available. Publications which may provide background information for this technology include:

1. Hsu C, Hughes MS, Zheng Z, Bray RB, Rosenberg SA, Morgan RA. Primary human T lymphocytes engineered with a codon-optimized IL–15 gene resist cytokine withdrawal-induced apoptosis and persist long-term in the absence of exogenous cytokine. *J Immunol. 2005 Dec 1;*175(11):7226–34.

2. Rosenberg, SA and Dudley, ME. Cancer regression in patients with metastatic melanoma after the transfer of autologous antitumor lymphocytes. Proc Natl Acad Sci USA 2004 Oct 5;101 Suppl 2:14639–45. Epub 2004 Sep 20.

3. Klebanoff CA, Finkelstein SE, Surman DR, Lichtman MK, Gattinoni L, Theoret MR, Grewal N, Spiess PJ, Antony PA, Palmer DC, Tagaya Y, Rosenberg SA, Waldmann TA, Restifo NP. IL–15 enhances the in vivo antitumor activity of tumor-reactive CD8+ T cells. Proc Natl Acad Sci USA 2004 Feb 17;101(7):1969–74. Epub 2004 Feb 04.

4. Dudley ME, Rosenberg SA. Adoptive-cell-transfer therapy for the treatment of patients with cancer. Nat Rev Cancer. 2003 Sep;3(9):666–75. Review.

5. Liu K, Rosenberg SA. Interleukin-2-independent proliferation of human melanoma-reactive T lymphocytes transduced with an exogenous IL–2 gene is stimulation dependent. J Immunother. 2003 May-Jun;26(3):190–201.

6. Liu K, Rosenberg SA. Transduction of an IL–2 gene into human melanoma-reactive lymphocytes results in their continued growth in the absence of exogenous IL–2 and maintenance of specific antitumor activity. J Immunol. 2001 Dec 1;167(11):6356–65.

Gene Therapy by Administration of Genetically Engineered CD34+ Obtained by Cord Blood

Robert M. Blaese (NCI), et al.
U.S. Patent No. 6,984,379 issued January 10, 2006 (HHS Reference No. E–045–1995/0–US–01).
Licensing Contact: John Stansberry, Ph.D.; 301/435–5236; *stansbej@mail.nih.gov.*

This invention provides a method of providing a therapeutic effect in human patients by administering to the patient CD34+ cells obtained from umbilical cord blood. The CD34+ cells have been engineered with at least one nucleic acid sequence encoding a therapeutic agent. Such CD34+ cells could be engineered by transducing the cells with a retroviral vector including the nucleic acid sequence encoding the therapeutic agent. This method has been applied in treating new born infants suffering from adenosine deaminase (ADA) deficiency. This application was filed pre-GATT and is therefore valid 17 years from issued date of January 10, 2006.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Dated: March 8, 2006.

Steven M. Ferguson,

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

[FR Doc. E6–3764 Filed 3–15–06; 8:45 am]
BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Evaluation of the Policy Academies on Chronic Homelessness—New

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) and the Health Resources and Services Administration (HRSA) will fund an evaluation of the Policy Academies on Chronic Homelessness held in 2002, 2003, and 2004. These Policy Academies were sponsored by the U.S. Department of Human Services (HHS) in partnership with the U.S. Department of Veterans Affairs, U.S. Department of Labor and the U.S. Department of Housing and Urban Development. The Policy Academies were 3–4 day meetings designed to help teams of State, Territory and local policymakers develop Action Plans intended to improve access to mainstream services for people who are homeless.

This evaluation will assess the effectiveness of the Policy Academies in helping States and Territories address the problem of chronic homelessness. This evaluation has been conceptualized in two parts. The process evaluation will focus on the activities related to conducting the Policy Academies. The process evaluation interviews will focus on: (1) How the Policy Academy concept was developed, (2) how the Federal Partners implemented the Policy Academies, (3) what factors influenced the effectiveness of each step of the intervention (i.e., pre-Academy site visits, Policy Academy meetings, and post-Academy technical assistance), (4) what changes in the Policy Academy process occurred over time, (5) what challenges/barriers Federal Partners faced in the development and implementation of the Policy Academies, and (6) how future Policy Academies could be improved to better meet the needs of States and Territories. The process evaluation will include all 45 States and Territories that participated in one of the Policy Academies on Chronic Homelessness, as well as the three Pacific Territories (American Samoa, Commonwealth of the Northern Marianas Islands, and Guam,) that participated in a special series of Policy Academies on Homelessness held in American Samoa and Guam.

The second part, the outcome evaluation, will assess how successful State, Territory, and local policymakers have been in implementing the Action Plans that were developed at the Policy Academies. The outcome evaluation interviews will focus on: (1) How States and Territories put together their Policy Academy teams, (2) the content and overall quality of the Action Plans these teams developed, (3) to what extent States and Territories have been able to increase access to coordinated housing and mainstream services for persons experiencing homelessness, (4) what challenges/barriers States and Territories faced in trying to achieve short- and long-term goals, and (5) to what extent relationships among the Governor's office, legislators, key program administrators, and public and private stakeholders were created or strengthened. In order to reduce burden on informants, the outcome evaluation will focus on a sample of States and Territories (the 19 States and Territories participating in the last two Policy Academies on Chronic Homelessness and the three Pacific Territories).