A. Background

GSA Bulletin FMR B–12 was signed on January 18, 2006, and became effective on May 25, 2006. The Bulletin provided a list of agencies for which GSA granted unlimited exemptions from the display of U.S. Government license plates and motor vehicle identification. 41 CFR part 102–34 was amended on March 20, 2009 (74 FR 11870). It revised the unlimited exemption from the requirement to display motor vehicle identification to exempt motor vehicles used primarily for investigative, law enforcement, intelligence, or security duties. The change recognizes the need for protecting agency missions and occupant safety and reduces the administrative burden of processing exemptions while maintaining the objective that Federal motor vehicles are required to be conspicuously identified unless exempted (see 40 U.S.C. 609). Therefore, GSA is canceling this Bulletin as unlimited exemptions are covered in 41 CFR 102–34.175.

B. Procedures

Bulletins regarding motor vehicle management are located on the Internet at *http://www.gsa.gov/fmrbulletin* as Federal Management Regulation (FMR) bulletins.

Dated: November 4, 2009.

James Vogelsinger,

Director, Motor Vehicle Management Policy.

[FR Doc. E9–27163 Filed 11–10–09; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

President's Advisory Council for Faith-based and Neighborhood Partnerships

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the President's Advisory Council for Faith-based and Neighborhood Partnerships announces the following meetings:

Name: President's Advisory Council for Faith-based and Neighborhood Partnerships Council Meetings.

Times and Dates:

Tuesday, November 17th, 4 p.m. Eastern.
Tuesday, December 15th, 4 p.m. Eastern.
Tuesday, January 19th, 4 p.m. Eastern.

Place: Meetings will by conference call. Please RSVP to receive the call-in information.

Status: Open to the public, limited only by the space available. Conference call line will be available.

Purpose: The Council brings together leaders and experts in fields related to the work of faith-based and neighborhood organizations in order to: Identify best practices and successful modes of delivering social services; evaluate the need for improvements in the implementation and coordination of public policies relating to faith- based and other neighborhood organizations; and make recommendations for changes in policies, programs, and practices.

Contact Person for Additional Information: Mara Vanderslice, 202–260–1931, *mara.vanderslice@hhs.gov.*

Supplementary Information: Please contact Mara Vanderslice for more information about how to join via conference call line.

Agenda: Topics to be discussed include deliberation on draft recommendations for Council report.

Dated: November 1, 2009.

Mara Vanderslice,

Special Assistant.

[FR Doc. E9–27097 Filed 11–10–09; 8:45 am]

BILLING CODE 4154–07–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.

Simpler Is Better: The Production of Young Cell Cultures From Tumor Infiltrating Lymphocytes (TIL) Yields More Effective Adoptive Cell Transfer (ACT) Immunotherapies

Description of Technology: Available for licensing is an improved method of adoptive cell transfer (ACT) immunotherapy that can be utilized to treat a variety of infectious diseases and cancers, most notably melanoma.

At its foundation, ACT involves isolating lymphocytes with high affinity for a particular antigen, expanding those cells *in vitro* to produce a greater quantity of reactive cells, and infusing the product cells into patients to attack cells expressing the antigen, such as tumor cells, bacterial cells, or viral particles. Previously utilized ACT procedures have been plagued by technical, regulatory, and logistical problems that have prevented consistently successful clinical outcomes. Through years of research, scientists at the National Institutes of Health (NIH) have made great strides in developing ACT into a viable approach to treat cancer patients. Of note, the ACT protocols developed by NIH scientists have successfully treated patients with refractory metastatic melanoma who started with very few effective treatment options. These NIH scientists have found that isolating cells from the tumor infiltrating lymphocytes (TIL) of a patient tumor sample provides a suitable initial lymphocyte culture for further *in vitro* manipulations. They have also discovered that taking the isolated cells through one cycle of rapid expansion (including exposure to IL–2), rather than multiple cycles, yields lymphocyte cultures with higher affinity and longer persistence in patients. Also, they have found that administering nonmyeloablative lymphodepleting chemotherapy prior to the reinfusion of lymphocytes creates a more favorable environment within patients for the transferred cells to execute target cell killing. These scientists envision that, for an ACT immunotherapy to gain regulatory approval and successfully treat a wide array of patients, it will need to be rapid, reliable, and technically simple. One of the most critical factors to this approach is the generation of effective lymphocyte cultures that will rapidly and repeatedly attack the target cells when infused into patients.

Scientists at the NIH have developed a method of generating CD8+ selected ''young'' lymphocyte cultures for infusion into cancer patients. Lymphocytes that spend fewer days *in vitro* between their initial isolation from TIL and their ultimate reinfusion into patients compared to lymphocytes cultured by previous ACT protocols are considered young lymphocyte cultures. Young lymphocytes, typically 19–35 days old when reinfused into patients, exhibit improved proliferation, survival, and enhanced anti-tumor activity within patients to yield greater tumor regression compared to older

lymphocytes, typically 44+ days old. Furthermore, the generation of young lymphocyte cultures is more rapid, reliable, and technically easier than previous ACT culturing methods. Young lymphocytes are isolated from TIL, directed against a single isolated tumor cell suspension, enriched for CD8 expression, and rapidly expanded once using autologous feeder cells without testing the culture for antigen specificity.

This approach to ACT offers a potentially significant improvement and a valuable new immunotherapeutic tool for attacking tumors many types of tumors. For diseases, such as metastatic melanoma, where patients may only have weeks or months of life expectancy, this technology, which provides for improved cell cultures prepared in less time, can make a difference between life and death. In addition, this method might be applicable in treating other diseases such as AIDS, immunodeficiency, or other autoimmunity for which immune effector cells can impact the clinical outcome.

Applications:

• An improved immunotherapy methodology to treat and/or prevent the recurrence of a variety of human cancers, such as melanomas and glioblastomas, infectious diseases, and autoimmune diseases by transferring young lymphocyte cultures engineered into cancer patients.

• A technically simpler, more rapid, more clinically reliable ACT procedure with greater potential to overcome the technical, regulatory, and logistical hurdles of past ACT methods. This technology could be broadly transferrable to a wide array of institutions to treat a wide array of patients.

• The immunotherapy component of a combination therapy regimen aimed at targeting the specific tumor-associated antigens expressed by the cancer cells of individual patients.

Advantages:

• *Technically simpler than previous ACT methods:* Decreased number of steps in the procedure and less analysis of the cell cultures prior to reinfusion into patients.

• *More rapid than previous ACT methods:* Adoptively transferred lymphocytes spend fewer days undergoing *in vitro* culturing, so they are introduced to patients with potentially short life expectancies more quickly.

• *Reliable, life-saving technology:* This technology is anticipated by the inventors to yield greater tumor regression and more objective clinical responses in patients compared to previous ACT protocols and all previously attempted treatments for metastatic melanoma.

Development Status: This technology is being utilized in a clinical protocol for adoptive cell transfer. The technology is a critical component of the successful immunotherapy regimen being used by the inventors and other clinicians at the NCI. Patients enrolled in ACT protocols are expected to show enhanced tumor regression and more objective responses compared to results obtained with previous protocols.

Market: Cancer continues to be a medical and financial burden on U.S. public health. According to U.S. estimates, cancer is the second leading cause of death with over 565,000 deaths reported in 2008 and almost 1.5 million new cases were reported (excluding some skin cancers) in 2008. In 2007, the NIH estimated that the overall cost of cancer was $219.2 billion dollars and $89 billion went to direct medical costs. Despite our increasing knowledge of oncology and cancer treatment methods, the fight against cancer will continue to benefit from the development of new therapeutics aimed at treating individual patients.

Inventors: Mark E. Dudley and Steven A. Rosenberg (NCI).

Related Publications:

1. KQ Tran et al. Minimally cultured tumor-infiltrating lymphocytes display optimal characteristics for adoptive cell therapy. J Immunother. 2008 Oct;31(8):742–751.

2. SA Rosenberg and ME Dudley. Adoptive cell therapy for the treatment of patients with metastatic melanoma. Curr Opin Immunol. 2009 Apr;21(2):233–240

Patent Status: HHS Reference No. E–273–2009/0—U.S. Provisional Application No. 61/237,889 filed 28 Aug 2009

Related Technologies: HHS Reference No. E–275–2002/1—U.S. Patent Application No. 10/526,697 filed 05 May 2005 (foreign counterparts in Europe, Canada, and Australia)

Licensing Status: Available for licensing.

Licensing Contact: Samuel E. Bish, Ph.D.; 301–435–5282; *bishse@mail.nih.gov*

Collaborative Research Opportunity: The Center for Cancer Research, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize cell and gene therapy technologies, and personalized medicines. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Treating Cancer With Anti-Angiogenic Chimeric Antigen Receptors

Description of Technology: Metastasis, the growth and spread of cancer from a localized tumor to other sites in the body, is promoted by the formation of new blood vessels through angiogenesis to ''feed'' the tumor. There is an urgent need to develop new therapeutic strategies that combine fewer side-effects and more specific anti-tumor activity in order to block cancer metastasis in patients. Adoptive immunotherapy is a promising new approach to cancer treatment that engineers an individual's innate and adaptive immune system to fight against specific diseases, including the spread of cancer.

Chimeric antigen receptors (CARs) are hybrid proteins consisting of the portion of an antibody that recognizes a tumor-associated antigen (TAA) fused to protein domains that signal to activate the CAR-expressing cell. Human cells that express CARs, most notably T cells, can recognize specific tumor antigens in an MHC-unrestricted manner with high reactivity. CARs are able to mediate an immune response that promotes robust tumor killing in targeted cells.

Scientists at the National Institutes of Health (NIH) have developed CARs with high affinity for the vascular endothelial growth factor receptor 2 (VEGFR2) (also known as kinase domain region (KDR) in humans and fetal liver kinase-1 (Flk-1) in mice) to utilize as an antiangiogenic tumor therapy. VEGFR2 is expressed on non-cancerous vascular endothelia cells, but is overexpressed on tumor endothelial cells in a variety of cancers, especially solid tumors. VEGFR2 overexpression promotes tumor vasculature, growth, and metastasis. The VEGFR2-specific CARs feature the antigen binding domain of the KDR–1121 or DC101 antibody, which recognize portions of the human and mouse VEGFR2, respectively. This antibody component is fused to the transmembrane and intracellular signaling domains of a T cell receptor (TCR). These CARs combine high affinity recognition of VEGFR2 provided by the antibody portion with the target cell killing activity of a cell expressing an activated TCR. Infusion of these VEGFR2-specific CARs into patients could prove to be a powerful new immunotherapeutic tool for blocking angiogenic cancer metastasis by killing VEGFR2+ tumor cells.

Applications:

• Immunotherapeutics to treat and/or prevent the reoccurrence of a variety of

human cancers that overexpress human VEGFR2 by introducing anti-VEGFR2 CAR expressing T cells into patients with metastatic cancer.

• A possible prophylactic therapy to prevent the spread of cancer in patients whose cancer is predicted to metastasize.

• A drug component of a combination immunotherapy regimen aimed at targeting the specific tumor-associated antigens expressed by cancer cells within individual patients.

Advantages:

• *This discovery is widely applicable to many different cancers:* VEGFR2 is overexpressed in many metastatic cancers that utilize angiogenesis to spread from their initial site of development. An immunotherapy protocol using anti-VEGFR2 CAR could treat a variety of cancer types.

• *Antiangiogenic tumor therapy is anticipated to generate fewer side-effects compared to other treatment approaches:* These CARs can be delivered directly to the bloodstream to gain easy access to the targeted tumor vascular endothelial cells with minimal effects to normal tissues. Furthermore, destroying tumor blood vessels could accelerate tumor cell death so that the therapy can be administered for a shorter period of time. A reduced therapeutic timeframe and minimal access to normal tissues should contribute to reduced side-effects and lowered toxicity for this treatment.

• *The technology is anticipated to be highly effective and killing metastatic cells:* Most angiogenic tumor epithelial cells are believed to overexpress VEGFR2 to a similar degree. Administering a therapeutically effective amount of anti-VEGFR2 CARs to patients may leave no or little tumor cells remaining with an opportunity to metastasize. Many current angiogenesis therapies do not kill tumors, but rather stabilize the tumor, so they require long periods of administration.

Development Status: This technology could soon be ready for clinical development since the inventors plan to initiate clinical trials using CAR engineered lymphocytes for adoptive immunotherapy of cancer.

Market: The Food and Drug Administration (FDA) has approved eight therapies with antiangiogenic properties, including Avastin®, Erbitux®, Vectibix®, Herceptin®, Tarceva®, Nexavar®, Sutent®, Torisel™, Velcade®, and Thalomid®. The majority of these drugs produced worldwide sales exceeding an estimated $500 million in 2007. The fight against cancer and its spread will continue to benefit from the development of new therapeutics aimed at treating individual patients.

Cancer continues to be a medical and financial burden on U.S. public health. Statistically, in the U.S. cancer is the second leading cause of death with over 565,000 deaths reported in 2008 and almost 1.5 million new cases were reported (excluding some skin cancers) in 2008, many with the potential to metastasize. In 2007, the NIH estimated that the overall cost of cancer was $219.2 billion dollars and $89 billion went to direct medical costs.

Inventors: Steven A. Rosenberg et al. (NCI).

Patent Status: HHS Reference No. E–205–2009/0—U.S. Provisional Application No. 61/247,625 filed 01 Oct 2009.

Related Technologies:

• E–045–2009/0—U.S. Provisional Application No. 61/154,080 filed 20 Feb 2009

• E–312–2007/1—PCT Application No. PCT/US2008/077333 filed 23 Sep 2008

• E–059–2007/2—PCT Application No. PCT/US2008/050841 filed 11 Jan 2008, which published as WO 2008/089053 on 24 Jul 2008

• E–304–2006/0—U.S. Provisional Patent Application No. 60/847,447 filed 26 Sep 2006; PCT Application No. PCT/US2007/079487 filed 26 Sep 2007, which published as WO 2008/039818 on 03 Apr 2008

• E–093–1995/0—PCT Application No. PCT/US1996/04143 filed 27 Mar 1996, which published as WO 1996/30516 on 03 Oct 1996

• E–093–1995/2—U.S. Non-Provisional Application No. 08/084,994 filed 02 Jul 1993

Licensing Status: Available for licensing.

Licensing Contact: Samuel E. Bish, Ph.D.; 301–435–5282; *bishse@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: November 3, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–27199 Filed 11–10–09; 8:45 am]

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.

A Method of Identifying Cdk5/p35 Modulators, and Possible Diagnostic or Therapeutic Uses for Neurodegenerative Diseases

Description of Invention: Cyclin-dependent kinase 5 (Cdk5) is a serine/threonine cyclin-dependent kinase that is highly expressed in the central nervous system and controls many biological processes that impact learning and memory, as well as pain and drug addiction. Studies have indicated that abnormal Cdk5 activity may be associated with the onset of neurodegenerative diseases, such as Alzheimer's disease, Parkinson's disease, and amyotrophic lateral sclerosis (ALS). The kinase activity of Cdk5 is turned on when it binds to one of the two proteins considered to be neuronal activators, p35 and p39.

Scientists at the NIH designed a cell-based assay to screen for p35 transcriptional regulators that work as upstream regulators of Cdk5. This technology may be useful for assessing the presence and risk of conditions associated with atypical Cdk5 kinase activity or for finding drug modulators that could be promising drug targets.

Applications: