Patent Status: PCT Application No. PCT/US2009/66867 filed 04 Dec 2009 (HHS Reference No. E–054–2009/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Charlene Sydnor, Ph.D.; 301–435–4689; *sydnorc@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Mental Health Clinical Brain Disorders Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the development of PIK3CD inhibitors for the treatment of CNS disorders including schizophrenia, psychosis, and cognitive deficiency. Please contact Amanda Law at *lawa@mail.nih.gov* for more information.

Fast Electron Paramagnetic Resonance Imaging (EPRI) Using CW–EPR Spectrometer With Sinusoidal Rapid-Scan and Digital Signal Processing

Description of Invention: Electron Paramagnetic Resonance (EPR) Imaging is an indispensable tool that may be applied to a variety of disciplines for evaluation of chemical species having unpaired electrons such as free radicals and transition metal ions. In Continuous Wave (CW)–EPR the sample is continuously irradiated with weak RF radiation while sweeping the magnetic field relatively slowly. Existing CW–EPR techniques utilize a signal detection method known as phase-sensitive detection which results in data acquisition times that are too long for in vivo applications. The present technology represents significant improvements on conventional CW–EPR.

The subject technology includes three approaches to collecting image data with increased spatial, temporal and spectral resolution and improved sensitivity. Spectral data acquisition is performed by a direct detection strategy involving mixing a signal to base-band and acquiring data with a fast-digitizer. Projection data is acquired using a sinusoidal magnetic field sweep under gradient magnetic fields. Data collection times are decreased with the utility of rotating gradients.

Further improvement to the present technology includes optimized DSP (digital signal processing) transmit and receive systems that decrease the analog background noise and allow optimizing the extent of signal averaging for improved image quality.

Increased speed and sensitivity make CW–EPR a potentially useful and complementary tool to proton Magnetic Resonance Imaging for in vivo imaging. The presently described improvements to CW–EPR will allow changes of blood perfusion and oxygenation in tumors to be observed in nearly real-time, while improved resolution will permit angiogenesis in and around tumors to be monitored in a non-invasive manner. Additionally, rapid scan imaging provides excellent temporal resolution and will help quantify pharmaco-kinetics and metabolic degradation kinetics of bioactive and redox sensitive free radicals such as nitroxides.

Applications

- Enhanced spatial, temporal, and spectral resolution of Continuous Wave-Electron Paramagnetic Resonance Imaging.
- Real-time assessment of changes in blood perfusion and oxygenation.

Development Status: Preliminary experiments have been conducted and the technology has been tested for feasibility.

Inventors: Sankaran Subramanian *et al.* (NCI).

Relevant Publication: Subramanian S, Koscielniak JW, Devasahayam N, Pursley RH, Pohida TJ, Krishna MC. A new strategy for fast radiofrequency CW EPR imaging: Direct detection with rapid scan and rotating gradients. J Magn Reson. 2007 Jun; 186(2):212–219. [PubMed: 17350865].

Patent Status

- U.S. Provisional Application No. 60/818,052 filed 30 Jun 2006 (HHS Reference No. E–221–2005/0–US–01).
- PCT Application No. PCT/US07/00072371 filed 02 Jul 2007, which published as WO 2008/091365 on 31 Jul 2008 (HHS Reference No. E–221–2005/1–PCT–01).
- U.S. Patent Application No. 12/306,514 filed 23 Dec 2008 (HHS Reference No. E–221–2005/1–US–02).
- U.S. Patent Application No. 12/564,006 filed 21 Sep 2009 (HHS Reference No. E–221–2005/2–US–01).

Licensing Status: Available for licensing.

Licensing Contacts

- Uri Reichman, PhD, MBA; 301–435–4616; *UR7a@nih.gov.*
- John Stansberry, PhD; 301–435–5236; *js852e@nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Radiation Biology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop improved hardware in terms of higher gradient & sweep frequencies and compatible AC amplifiers and evaluate, or commercialize the above rapid scan-rotating gradients strategy for performing routine in vivo radiofrequency CW EPR imaging in small animals. Please contact John D. Hewes, PhD, at 301–435–3121 or *hewesj@mail.nih.gov for* more information.

Dated: August 20, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–21347 Filed 8–26–10; 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.

An XMRV Tool Box: Expression Plasmids, Genes, and Proteins for All Components of the Xenotropic Murine Leukemia Virus-Related Virus (XMRV)

Description of Invention: The xenotropic murine leukemia virus-related virus (XMRV) has been implicated as a possible causative agent of prostate cancer and chronic fatigue syndrome (CFS). Scientists at the National Institutes of Health (NIH) and Science Applications International Corporation in Frederick, MD (SAIC–Frederick) have developed sixty four (64) protein expression plasmids for components of XMRV. One or more

XMRV proteins made available through these expression plasmids could have clinical relevance to diagnosing or treating human disease. The work to develop this technology was performed in the Protein Expression Laboratory at SAIC–Frederick in collaboration with expert retrovirologists from the National Cancer Institute's Frederick, MD campus, a site well-positioned to develop these expression plasmids from initial cloning to final validations. The development of these XMRV tools is expected to save researchers months in laboratory production time and thousands of dollars in labor costs.

The XMRV strain utilized to generate these expression plasmids is a reference strain isolated from a human patient. Each expression plasmid encodes one of the ten proteins that comprise the XMRV retrovirus (matrix, p12, capsid, nucleocapsid, protease, reverse transcriptase, integrase, surface, transmembrane, and envelope). Nine of the ten XMRV proteins expressed by these clones have been successfully purified in large quantities using scale-up processes. The expression vectors were generated utilizing the Gateway® cloning system and consist of Gateway® entry clones, bacterial (*Escherichia coli*) expression clones, baculovirus expression clones, and mammalian expression clones. Expression of the appropriate XMRV protein from its corresponding expression clone has been confirmed. The entry clones have been validated for Gateway® subcloning and the baculovirus clones have been validated for baculovirus production and can be transposed into baculoviral genomes. The plasmids have been fully mapped and sequenced and contain one or more elements to facilitate laboratory use, such as antibiotic resistance genes, specialized promoter sequences, maltose-binding protein and His tags, TEV protease sites, Kozak-ATG sequences, signal peptides, and other elements.

Applications:

• Research tool whose large-scale production capability can be utilized to develop serological assays for detecting XMRV and other retroviruses to possibly establish these viruses as causative agents for CFS, prostate cancer, and other diseases with unknown origins.

• Collection of research tools that could be utilized to develop a complete set of diagnostic assays for detecting each of these XMRV proteins in patient samples.

• Research tool to serve as a platform for developing therapeutic moieties, such as neutralizing antibodies and other biologics, for treating prostate cancer, chronic fatigue syndrome, and any other disease where XMRV is later identified as the causative agent.

• A logical starting point for generating clinical-grade XMRV constructs for use in clinical vaccine, immunotherapy, and gene therapy studies.

Advantages:

• *First complete set of plasmids available for the expression of each XMRV protein individually:* Researchers looking to study XMRV can save months of time and thousands of dollars by using this set of XMRV tools. The plasmids have been fully-mapped and validated for protein expression. This plasmid portfolio offers a variety of vectors for expressing these XMRV proteins including Gateway® entry clones, bacterial vectors, baculoviral vectors, and mammalian expression systems.

• *Clones were developed from an XMRV isolate taken from a patient with a confirmed XMRV infection:* The proteins produced by these expression plasmids are anticipated to have direct clinical applicability to human XMRV diseases.

• *Launching pad for any commercial entity desiring to develop diagnostics or therapeutics for XMRV:* This technology is likely to give companies in the prostate cancer arena or the emerging chronic fatigue syndrome market a competitive advantage for developing anti-XMRV products faster than competitors. The molecular targets needed as a starting point for therapeutic development are provided by this technology.

Market: Apart from cancers of the skin, prostate cancer is the most common form of cancer found in men, especially in men over the age of 65. In the United States, an estimated 200,000 men are diagnosed with prostate cancer each year and around 100 men die of the disease daily. About $5 billion dollars is spent annually on treatments for prostate cancer.

The Center for Disease Control (CDC) estimates that over 1 million Americans are living with chronic fatigue syndrome and approximately 80% of these individuals are undiagnosed. This debilitating disease likely affects over 17 million people worldwide and the cause of CFS is currently unknown. Those individuals diagnosed with CFS are a vocal patient group desiring expanded research into the cause of CFS and possible treatments and/or cures. In the United States alone, an estimated $9 billion dollars is lost annually due to CFS-induced decreases in worker productivity.

Inventors: Dominic Esposito (SAIC), Alan Rein (NCI), Stuart Le Grice (NCI), James Hartley (SAIC), William Gillette (SAIC), Ralph Hopkins III (SAIC), Troy Taylor (SAIC).

Selected Publications:

1. VC Lombardi, *et al.* Detection of an infectious retrovirus, XMRV, in blood cells of patients with chronic fatigue syndrome. Science 2009 Oct 23;326(5952):585–589. [PubMed: 19815723]

2. A Urisman, *et al.* Identification of a novel Gammaretrovirus in prostate tumors of patients homozygous for R462Q RNASEL variant. PLoS Pathog. 2006 Mar;2(3):e25. [PubMed: 16609730]

Patent Status: HHS Reference No. E–155–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

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

Tempol: A Commercially Available Nitroxide as Cancer Therapeutics

Description of Invention: The invention is the discovery that a commercially available stable nitroxide, namely TEMPOL can effectively reduce the level of hypoxia-inducible transcription factor (HIF)–2α. Elevated HIF–2α is associated with clear cell kidney cancer characterized by mutation of the VHL tumor suppressor gene and with many other cancers. Therefore, TEMPOL can potentially be developed into a cancer drug to treat patients with elevated HIF–2α, whether due to compromised VHL function or not.

Applications: Known compound (TEMPOL) found to be effective in treating several cancers.

Advantages: Animal data confirms effectiveness of TEMPOL against cancer support.

Development Status: Pre-clinical, *In vivo* animal data available.

Target Market: The potential drug will target a population that suffers from genetic diseases such as inherited von Hippel-Lindau (VHL) disease, which is associated with elevated expression of HIF–2α and patients with kidney and other cancers characterized by elevation of HIF–2α. Inherited VHL disease is a cancer syndrome caused by germ line mutations of the VHL tumor suppressor gene. VHL is characterized by angiomas and hemangioblastomas of the brain, spinal cord, and retina. These can lead to cysts and/or tumors of the kidney, pancreas, and adrenal glands (*e.g.,*

pheochromocytoma and endolymphatic sac tumors).

Renal clear cell carcinoma (RCC) develops in approximately 75% of VHL patients by age 60 and is a leading cause of death in this population. Inactivation (mutation or methylation) of the VHL gene is associated with greater than 90% of all clear cell RCC (including sporadic cases) (Nickerson *et al.* Clin Cancer Res 2008;14:4726–34). Thus, subjects with compromised VHL function represent a significant population that has or is at risk for developing cancer, including RCC. There is data that HIF–2α may be important in all or most cancers (Franovic *et al.* Proc Natl Acad Sci U S A 2009;106:21306–11).

Inventors: W. Marston Linehan (NCI), Tracey A. Rouault (NICHD), James B. Mitchell (NCI), Murali K. Cherukuri (NCI).

Patent Status: U.S. Provisional Application No. 61/265,194 filed 30 Nov 2009 (HHS Reference No. E–133–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Sabarni Chatterjee, Ph.D.; 301–435–5587; *chatterjeesa@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Urologic Oncology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of Tempol to target HIF–2α in cancer. Please contact John Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Chimeric Anti-human ROR1 Monoclonal Antibodies

Description of Invention: Available for licensing are mouse anti-human receptor tyrosine kinase-like orphan receptor 1 (ROR1) monoclonal antibodies (mAbs). ROR1 is a signature cell surface antigen for B-cell chronic lymphocytic leukemia (B–CLL) and mantle cell lymphoma (MCL) cells, two incurable B-cell malignancies that are newly diagnosed in approximately 15,000 and 3,500 patients per year, respectively, in the United States. Currently, there are no therapeutic mAbs that specifically target B–CLL or MCL cells. Anti-ROR1 mAbs may be linked to chemical drugs or biological toxins thus providing cytotoxic delivery to malignant B-cells and not normal cells. Additionally, these antibodies can be fused to radioisotopes and can be used to diagnose B–CLL and MCL malignancies.

Applications:

• B–CLL and MCL antibody therapeutics.

• Method to diagnose B–CLL and MCL.

Advantages: Selective targeting to malignant B–CLL and MCL cells.

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

Market:

• The monoclonal antibody market is one of the fastest growing sectors of the pharmaceutical industry with a 48.1% growth between 2003 and 2004 and the potential to reach $30.3 billion in 2010. This growth rate is driven by the evolution of chimeric and humanized to fully humanized antibody therapeutics.

• Approximately 18,500 patients with ROR1-expressing B-cell malignancies are newly diagnosed annually in the United States.

Inventors: Christoph Rader and Sivasubramanian Baskar (NCI).

Related Publications:

1. S Baskar *et al.* Unique cell surface expression of receptor tyrosine kinase ROR1 in human B-cell chronic lymphocytic leukemia. Clin Cancer Res. 2008 Jan 15;14(2):396–404. [PubMed: 18223214]

2. M Hudecek *et al.* The B-cell tumor associated antigen ROR1 can be targeted with T-cells modified to express a ROR1-specific chimeric antigen receptor. Blood. 2010 Aug 11; Epub ahead of print. [PubMed: 20702778]

Patent Status:

• U.S. Provisional Application No. 61/172,099 filed 23 Apr 2009 (HHS Reference No. E–097–2009/0–US–01).

• PCT Application No. PCT/US10/32208 filed 23 Apr 2010 (HHS Reference No. E–097–2009/0–PCT–02).

Licensing Status: Available for licensing.

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Experimental Transplantation and Immunology Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize anti-ROR1 mAbs, antibody-drug conjugates, radioimmunoconjugates, bispecific antibodies, and other therapeutic or diagnostic modalities. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: August 23, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–21349 Filed 8–26–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–0031–N]

Medicare Program; Listening Session Regarding the Implementation of Section 10332 of the Patient Protection and Affordable Care Act, Availability of Medicare Data for Performance Measurement

DATE: September 20, 2010.

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a listening session to receive comments regarding implementation of section 10332 of the Patient Protection and Affordable Care Act (the Affordable Care Act), which amended section 1874 of the Social Security Act: Availability of Medicare Data for Performance Measurement. The purpose of the listening session is to solicit input from potential stakeholders on key components of the design of the program. We are soliciting input on the types of organizations that may be interested in receiving data as qualified entities under this provision; the criteria such organizations will have to meet for participation; procedures for CMS to approve interested organizations for participation; provider communities and geographic areas that might be served by these entities; data elements required, and the sources and types of other data that these organizations might match to Medicare claims; challenges in calculating performance measures from the data, and issues related to the identification, selection, and reporting of the performance measures.

DATES: *Meeting Date:* The listening session will be held on Monday, September 20, 2010 from 9 a.m. until 1 p.m. Eastern Daylight Time (e.d.t.).

Deadline for Meeting Registration and Request for Special Accommodations: Registration opens on August 27, 2010. Registration must be completed by 5 p.m. e.d.t. on September 16, 2010. Requests for special accommodations