do not win will not receive payment for services provided to beneficiaries residing in the CBA for the duration of the demonstration period.

A non-required bidder is:

• A small business laboratory, which we are defining as one that will supply less than $100,000 annually in demonstration tests to Medicare FFS beneficiaries residing in the CBA during each year of the demonstration. These laboratories may choose to be a ''passive'' laboratory. A passive-small business laboratory will have a $100,000 ceiling on annual payment from Medicare for demonstration tests for the duration of the demonstration.

• A laboratory that exclusively serves beneficiaries entitled to Medicare because they have end-stage renal disease (ESRD) residing in the CBA may choose to be a ''passive'' laboratory under the demonstration. A passive-ESRD laboratory may continue to provide services to ESRD beneficiaries residing in the CBA and receive payment from Medicare for demonstration tests paid under the competitively set Part B Clinical Laboratory Fee Schedule (demonstration fee schedule) for the duration of the demonstration.

• A laboratory that exclusively serves beneficiaries residing in nursing homes or receiving home health services in the CBA may choose to be a ''passive'' laboratory under the demonstration. A passive-nursing home laboratory may continue to provide services to beneficiaries residing in nursing homes or receiving home health services in the CBA and receive payment from Medicare for demonstration tests paid under the demonstration fee schedule for the duration of the demonstration.

This notice announces a ''Bidder's Conference'' to be held in the San Diego-Carlsbad-San Marcos, California MSA on October 31, 2007 for potential bidders to learn about the demonstration rules and ask questions about the bidding process. A Bidder's Package provides information about the demonstration project and is available to the public on the CMS project Web site. There will be a single bidding competition covering demonstration tests for each CBA. Bidders will be required to submit a bid price for each Health Care Procedure Coding System (HCPCS) code in the demonstration test menu. Bidding laboratories will be asked to identify demonstration tests that they do not perform, and will be asked to explain their plans for responding to requests for demonstration tests that they do not perform in house (for example, subcontracting and referrals). As part of their bid, laboratories will provide information on ownership, location of affiliated laboratories and specimen collection sites, CLIA certification, laboratory finances, and quality.

III. Collection of Information Requirements

This information collection requirement is subject to the Paperwork Reduction Act of 1995 (PRA). The collection is currently approved under OMB control number 0938–1008 entitled ''Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project Application Form'' with a current expiration date of January 31, 2009.

Authority: Section 302(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 4, 2007.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–20499 Filed 10–16–07; 8:45 am]

BILLING CODE 4120–01–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.

Novel Roles of a DNA Repair Protein, DNA-PKcs, in Obesity, Neurological Function, and Aging

Description of Technology: The catalytic subunit of the DNA-dependent protein kinase complex (DNA-PKcs) has been shown to be important in DNA repair and VDJ recombination in lymphocytes. The inventors have discovered that DNA-PKcs also plays novel, important roles in energy regulation and neurological function. The inventors observed that mature DNA-PKcs-deficient mice (also known as SCID mice) have a lower proportion of fat, resist obesity, and have significantly greater physical endurance than wild-type control mice, particularly with increasing age. The inventors also observed that DNA-PKcs-deficient mice have better memory and less anxiety. One potential explanation for this is that they express higher levels of brain-derived neurotrophic factor (BDNF), which is associated with neurogenesis, memory formation and suppression of anxiety and depression. Moreover, DNA-PKcs-deficient cells produce less oxidative stress. Thus, inhibition of DNA-PKcs may have unexpected utility in the treatment of a wide range of diseases and conditions.

The invention discloses methods of inhibiting DNA-PKcs activity to decrease adiposity, improve physical endurance and increase insulin sensitivity and the number of mitochondria. Also claimed are methods directed to improved neurological function, such as methods for protection from neurodegenerative disease, improving memory and learning ability, and for reducing depression and anxiety. Additionally, the invention discloses methods for reducing inflammation and for treating heart disease.

Applications:

Development of therapeutics targeting obesity, insulin-resistant diabetes, and age-related loss of physical endurance.

Development of therapeutics to treat neurological disorders such as depression and memory loss.

Market:

Obesity is a large and growing therapeutic market; over thirty percent of Americans are obese, and over sixty percent are overweight.

Similarly, the market for therapeutics directed to insulin-resistant, or Type 2, diabetes is rapidly expanding; the market for such drugs is expected to top $12 billion in 2012.

Loss of endurance and muscle mass is common in the elderly; the average

adult loses thirty percent of his muscle mass between the ages of 20 and 70.

Development Status: Early stage.

Inventors: Jay H. Chung et al. (NHLBI).

Publication: In preparation.

Patent Status: U.S. Provisional Application No. 60/958,714 filed 06 July 2007 (HHS Reference No. E–068–2007/0-US–01).

Licensing Status: This technology is available for exclusive, co-exclusive, or nonexclusive licensing.

Licensing Contact: Tara L. Kirby, Ph.D.; 301/435–4426; *tarak@mail.nih.gov*.

Collaborative Research Opportunity: The National Heart Lung and Blood Institute, Laboratory of Biochemical Genetics, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize DNA-PKcs inhibitors for treatment or prevention of metabolic and degenerative diseases. Please contact Jay Chung (*chungj@nhlbi.nih.gov*) for more information.

Predictive Diagnostic Test for Anti-Depressant Related Suicide Risk

Description of Technology: A number of studies have reported a potential link between antidepressant treatment and suicides. Although the scientific basis for this phenomenon is not known, the Food and Drug Administration (FDA) required a black box warning of worsening depression and/or emergence of suicidality (i.e., development of suicidal thoughts or behavior) in both adult and pediatric patients taking several antidepressants. While use of antidepressants fell subsequent to the black box warning, recent studies suggest that pediatric suicides may actually be rising. This has led to concerns that untreated depression due to the black box warning could potentially result in an overall increase in suicides.

To determine whether a genetic basis for suicidal risk exists for a sub-group of depressed patients, NIH researchers genetically screened patients with major depression treated with the serotonin selective reuptake inhibitor (SSRI) citalopram (Celexa) in the NIMH-funded Sequenced Treatment Alternatives for Depression (STAR*D) trial. Versions of two genes coding for components of the brain's glutamate chemical messenger system were linked to suicidal thinking associated with antidepressant use. Having both implicated versions increased risk of such thoughts more than 14-fold. By identifying those patients who need close monitoring, alternative treatments and/or specialty care, these genetic tests should prevent the under prescribing of anti-depressant drugs and the resulting possibility of suicide due to sub-optimal treatment.

Applications: Diagnostic tests predicting the likelihood of suicide during anti-depressant treatment.

Market: Depression ranks among the ten leading causes of disability and will become the second-largest cause of the global health burden by 2020. An estimated 121 million people worldwide suffer from a depressive disorder for which they require treatment. It is estimated that 5.8% of all men and 9.5% of all women will suffer from a depressive disorder in any given year and that 17% of all men and women will suffer from a depressive disorder at some point in their lives.

Development Status: Clinical data.

Inventors: Francis J. McMahon et al. (NIMH).

Patent Status: U.S. Provisional Application No. 60/854,978 Filed 27 Oct 2006 (HHS Reference No. E–157–2006/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Norbert Pontzer, Ph.D., J.D.; 301/435–5502; *pontzern@mail.nih.gov*.

Collaborative Research Opportunity: The National Institute of Mental Health Mood and Anxiety Disorders Program Genetics Unit is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the Predictive Diagnostic Test for Anti-Depressant Related Suicide. Please contact Dr. Francis McMahon at *mcmahonf@mail.nih.gov* for more information.

Dated: October 11, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–20483 Filed 10–16–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

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HIV–1 Integrase Inhibitors for the Treatment of Retroviral Infections

Description of Technology: This technology describes the structure and activity of N-benzyl derivatives of 2,3-dihydro-6,7-dihydroxy-1H-isoindol-1-ones and 2,3-dihydro-6,7-dihydroxy-1H-isoindole-1,3(2H)-diones as new HIV–1 integrase inhibitors. HIV, as well as other retroviruses, requires three key viral enzymes for replication: Reverse transcriptase, protease and integrase (IN). A significant number of patients fail to respond to combination therapies consisting of reverse transcriptase and protease inhibitors, due to the development of viral resistance. IN functions by initial processing of viral cDNA in a cleavage step termed 3′-processing (3′-P). This is followed by insertion of the cleaved cDNA into the host genome in a reaction known as ''strand transfer'' (ST). Certain agents covered under the subject technology have been shown to exhibit selective inhibition of ST reactions relative to 3′-P reactions. These compounds inhibit purified IN *in vitro* and are also active against HIV–1 derived vectors in cell-based assay. These inhibitors may have a potential therapeutic value for retroviral infections, including AIDS, especially for patients exhibiting drug resistance to current therapy regimes.

Applications: The treatment and prevention of HIV infections.

Development Status: In vitro data available.

Inventors: Terrence R. Burke Jr., Xue Zhi Zhao, Yves Pommier, and Elena Semenova (NCI).

Related Publication: WG Verschueren et al. Design and optimization of tricyclic phtalimide analogue as novel inhibitors of HIV–1 integrase. J Med Chem 2005 Mar 24;48(6):1930–1940.