[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, 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. 209 and 37 CFR Part 404 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.

FOR FURTHER INFORMATION: 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.

Peptide Inhibitor of p38 Mapk Signaling for the Treatment of Inflammatory Autoimmune Diseases and Inflammatory Cancers

Description of Technology: This invention relates to a peptide fragment of GADD45A growth arrest and DNA-damage-inducible, alpha (Gadd45a), a protein involved in the p38 Map kinase signaling pathway. Although the fragment is only 15 amino acids in length, it retains the functionality of Gadd45a by inhibiting enzymatic activity of tyrosine-323-phosphorylaled p38 *in vitro*. The peptide fragment is tagged to render it cell-permeable and, according to *in vitro* studies, it exhibits minimal toxicity. The inventors have found that the fragment readily penetrates T cells to inhibit (a) proliferation in response to T cell receptor-mediated stimulation; (b) skewing of T cells to Th I and Th 17 cells; and (c) inflammatory cytokine production. As a result, this fragment has anti-inflammatory properties and has potential as a therapeutic for inflammatory autoimmune conditions or inflammatory cancers, such as pancreatic cancer.

Potential Commercial Applications: Treatment for inflammatory autoimmune conditions or inflammatory cancers, such as pancreatic cancer.

Competitive Advantages: Minimal cellular toxicity.

Development Stage: In vitro data available.

Inventors: Jonathan D. Ashwell, Mohammed S. Alam, Paul R. Mittelstadt (all of NCI).

Intellectual Property:

• HHS Reference No. E-281-2012/0 – US Provisional Application No. 61/728,368 filed 20 Nov 2012.

• HHS Reference No. E-281-2012/1 – US Provisional Application No. 61/774,066 filed 07 Mar 2013.

Licensing Contact: Jaime M. Greene; 301-435-5559; greenejaime@mail.nih.gov

Cannabinoid Receptor 1 (CB1) Inverse Agonists for the Treatment of Diabetes, Obesity and their Complications

Description of Technology: Endocannabinoids are lipid signaling molecules that act on the same cannabinoid receptors – CB1 and CB2 – that recognize and mediate the effects of marijuana. Activation of CB1 receptors increases appetite and the biosynthesis and storage of lipids, inhibits the actions of insulin and leptin, and promotes tissue inflammation and fibrosis. This has led to the development of CB1 receptor blocking drugs (inverse agonists) for the treatment of obesity and its metabolic complications, referred to as the metabolic syndrome. However, many CB1 inverse agonists can cross the blood-brain barrier, causing psychiatric side effects.

Researchers at NIH have now developed a novel strategy to structurally modify CB1 inverse agonists with the goals of (1) limiting their brain penetrance without losing their metabolic efficacy due to CB1 inverse agonism, and (2) generating compounds whose primary metabolite directly targets enzymes involved in inflammatory and fibrotic processes associated with metabolic disorders. These modified CB1 inverse agonists can be used to effectively treat metabolic syndrome and its complications without the risk of the psychiatric side effects, and have improved antiinflammatory and antifibrotic efficacy due to acting on more than one molecular target.

Potential Commercial Applications:

• Treatment for obesity

• Treatment for metabolic syndrome

• Treatment of diabetes

• Treatment of fibrosis

Competitive Advantages:

• Inhibits metabolic activity without causing psychiatric side effects

• Offers improved antiinflammatory and antifibrotic efficacy

Development Stage:

• In vitro data available

• In vivo data available (animal)

Inventors: George Kunos (NIAAA), Milliga Iyer (NIAAA), Resat Cinar (NIAAA), Kenner Rice (NIDA)

Intellectual Property: HHS Reference No. E-282-2012/0 – US Provisional Application No. 61/725,949 filed 11 Nov 2012

Licensing Contact: Jaime M. Greene; 301-435-5559; greenejaime@mail.nih.gov

Collaborative Research Opportunity: The National Institute on Alcohol Abuse and Alcoholism, Laboratory of Physiologic Studies, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize peripherally restricted CB1 receptor blockers with improved efficacy. For collaboration opportunities, please contact George Kunos, M.D., Ph.D. at George.Kunos@nih.gov or 301-443-2069.

Software Method for 2-D NMR Tissue Compartment Analysis

Description of Technology: The invention pertains to a method for improving the accuracy of compartment characterization using NMR. Conventional methods use Laplace transformation analyzed one dimensional transverse NMR relaxometry to investigate spin-lattice decay of water in diverse body compartments using. This method, although used extensively, is inaccurate and limited by signal-to-noise obscurities and when the materials and compartments to be analyzed vary in size or have disparate relaxation characteristics.

The improved method of this invention utilizes the detection of a 2-dimensional (2-D) NMR signal, created through use of a standard pulse sequence and variations, analysis of the signal using inverse Laplace transform, followed by projection of the resultant 2-D data onto a single axis corresponding to the parameter of original interest. The method can be extended to analyses for 3-D or higher dimensional experiments and inverse Laplace transforms.

Potential Commercial Applications:

- Compartment analysis
- Petroleum discovery
- Multiple sclerosis

Competitive Advantages: Compartment resolution

Development Stage: Prototype

Inventors: Richard G. Spencer and Hasan Celik (NIA)

Intellectual Property: HHS Reference No. E-734-2013/0 – Software. Patent protection is not being pursued for this technology.

Licensing Contact: Michael Shmilovich; 301-435-5019; shmilovm@mail.nih.gov

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

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