Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 801 are approved under OMB control number 0910–0485; the collection of information in 21 CFR part 803 are approved under OMB control number 0910–0437; the collections of information in 21 CFR part 806 are approved under OMB control number 0910–0350; the collections of information in 21 CFR part 807 Subpart B are approved under OMB control number 0910–0387; the collections of information in 21 CFR part 814 Subparts B and E are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0311; and the collections of information in 21 CFR part 820 are approved under OMB control number 0910–0073.

V. Comments

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number listed in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.


Leslie Kux,
Assistant Commissioner for Policy.
[FR Doc. 2013–23939 Filed 9–24–13; 8:45 am]
BILLING CODE 4160–01–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 CONTACT: 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 20852–3004; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Small Interfering RNA Knock-Down of Cannabinoid-1 Receptor (CB1R) for the Treatment or Prevention of Type-2 Diabetes

Description of Technology: Endocannabinoids (EC) are lipid signaling molecules that act on the same cannabinoid receptors that recognize and mediate the effects of marijuana. Activation of the EC receptor CB1R has been shown to play a key role in the development of obesity and its metabolic consequences, including insulin resistance and type 2 diabetes. Researchers at NIH have now demonstrated in the Zucker diabetic fatty (ZDF) rat model of type-2 diabetes that beta-cell loss is caused by the CB1R-mediated activation of a macrophage-mediated inflammatory response. They have further demonstrated that treatment of ZDF rats with a peripheral CB1R antagonist restores normoglycemia and preserves beta-cell function and that similar results were seen following selective in vivo knockdown of macrophage CB1R by daily treatment of ZDF rats with D-glucan-encapsulated CB1R Small interfering RNA (siRNA). Therefore, knock-down of CB1R with siRNA may represent a new method of treating type-2 diabetes or preventing the progression of insulin resistance to overt diabetes.


Competitive Advantages: A new means of inhibiting the endocannabinoid receptor CB1R.

Development Stage: In vivo data available (animal).

Inventors: George Kunos (NIAAA), Tony Jourdan (NIAAA), Michael P. Czech (UMass Medical School), Myriam Aouadi (UMass Medical School).


Licensing Contact: Jaime M. Greene; 301–435–5595; greenejaime@mail.nih.gov.

Methods for the Treatment of AIDS and Other Retroviral Diseases Using Plant-Derived Compounds

Description of Technology: Human immunodeficiency virus-1 (HIV–1) affects 1.4 million patients in the U.S. and over 33 million worldwide. While highly active antiretroviral therapy (HAART), the current standard of care, is effective in suppressing retroviral activity, cure has not been achieved due to the persistence of latently infected T cells in treated patients. An agent capable of sensitizing this T cell subpopulation concordant with HAART may add significant benefit to individuals with retroviral diseases.

Researchers at the NIH have identified Englerin A and its derivatives as potent and specific activators of viral replication in infected T cells. Use of these compounds in conjunction with existing antiviral therapies has been described for the treatment of AIDS, adult T cell leukemia/lymphoma and other retroviral diseases.

Intellectual property assets available for license include novel compositions of Englerin A along with methods of their use in the treatment of retroviral diseases.

Potential Commercial Applications

• Novel adjuvant therapy for the treatment of retroviral diseases such as AIDS or HTLV-induced leukemia/lymphoma.
• Therapeutic for the management of T lymphocytopenia.

Competitive Advantages

• Englerin A and its derivatives are potent and selective activator of protein kinase C theta in immune cells.
• Compounds are anticipated to have fewer off-target toxicities relative to currently available PKC activators (e.g., interleukins-2 and 7).
• Compounds are optimized for use in combination with clinically available antiviral agents.

Development Stage

• Pre-clinical.
• In vitro data available.
• In vivo data available (animal).

Inventors: Leonard Neckers, Marston Lineham, Carole Sourbier, Jane Trepel, Min-jung Lee, Bradley Scroggins, John Beutler (all of NCI).

Publications


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


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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel, PAR Panel: Tobacco Control Regulatory Research.

Date: October 15–16, 2013.
Time: 8:00 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.
Contact Person: Mark P Rubert, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301–435–1775, rubertm@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Drug Discovery for the Nervous System Study Section.

Date: October 17, 2013.
Time: 8:30 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Pier 5 Hotel, 711 Eastern Avenue, Baltimore, MD 21202.
Contact Person: Mary Custer, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892, (301) 435–1164, custerm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Academic Research Enhancement Award.

Date: October 18, 2013.
Time: 8:00 a.m. to 10:30 a.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.