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.

ADDRESS: 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: 301/496–7037; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Availability for Licensing

Influenza DNA Vaccine That Protects Against Lethal H5N1 Challenge

Description of Technology: Concerns about a potential influenza pandemic and its prevention dominate health news, with new cases of bird (avian) influenza (H5N1 strain) cases being reported on a daily basis. Vaccination is one of the most effective ways to minimize suffering and death from influenza. Currently, there is not an effective vaccine to protect against the H5N1 strain, thought to be a leading pandemic candidate. The technology described here relates to a DNA influenza vaccine encoding the matrix 2 (M2) protein, which is highly conserved among different influenza strains. The M2 component can be used either alone or in combination with other influenza components. Specifically, mouse studies showed that the use of M2 from H1N1 strain protected against a lethal challenge with H5N1 strain. The current technology offers several advantages over traditional influenza vaccine approaches, including (a) ease and speed of production without need for eggs, (b) no surveillance to determine dominant strain(s), and (c) no potential for antigenic shift as observed for the components (HA and NA) of current influenza vaccines.

Inventors: Suzanne L. Epstein et al. (CBER/FDA).


Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Susan Ano, PhD.; 301/435–5515; anos@mail.nih.gov

Collaborative Research Opportunity: The Food and Drug Administration’s Center for Biologics Evaluation and Research (CBER) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Beatrice Droke at 301/827–7008 or bdroke@oc.fda.gov for more information.

Methods for Inhibiting HIV and Other Viral Infections by Modulating Ceramide Metabolism

Description of Technology: This invention provides methods of inhibiting or preventing HIV–1 infections by inducing either the de novo biosynthesis of ceramide, or by activating enzymes (e.g., sphingomyelinas) involved in the generation of ceramide at the plasma membrane, or by direct incorporation of exogenous ceramide into target cell membranes. The invention describes methods for administration a retinamide compound particularly an N-(aryl) retinamide (4–HPR) resulting in increased plasma membrane ceramide levels, which results in the inhibition of HIV–1 infection in monocyte/macrophages by perturbing membrane organization. In addition, because of its low toxicity in non-tumor cells, 4–HPR and related compounds are particularly suitable for long-term preventative or therapeutic administration to subjects suffering from an HIV infection or who are at risk of contracting an HIV infection. Thus, this invention provides a novel means of treating or inhibiting HIV and other viral infections by administering a retinamide compound to a patient suffering from or susceptible to such a viral infection.

Inventors: Robert P. Blumenthal et al. (NCI).

Publications:


Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Suyi Hu, PhD., M.B.A.; 301/435–5606; hus@mail.nih.gov

Collaborative Research Opportunity: The National Cancer Institute, Center for Cancer Research Nanobiology Program, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the clinical potential of sphingolipid-based antiviral therapies. Please contact Melissa Maderia at maderiam@mail.nih.gov or by phone at 301/846–5465 for more information.

Methods and Compositions for the Inhibition of HIV–1 Replication

Description of Technology: This invention relates to methods and compositions for the attenuation of HIV–1 replication in human cells, and especially in CD4+ human peripheral blood mononuclear cells, such as blood monocyte-derived macrophages by targeting a host cell protein. HIV–1 infected macrophages typically resist cell death, support viral replication, and facilitate HIV–1 transmission. We found that the gene encoding cyclin-dependent kinase inhibitor 1A (CDKN1A) is consistently expressed following virus binding, and reexpressed at the peak of HIV–1 replication. The protein encoded by this gene, also known as p21, is associated with cell cycle regulation, anti-apoptotic response and cell differentiation. Increased levels of p21 may enhance survival and long-term persistence of HIV–1 infected macrophages. Following identification of p21 as a candidate molecule in facilitating viral replication, efforts to curtail its role were investigated as a mode of blunting infection in macrophages. RNA interference (siRNA) represents a tool to regulate gene expression and when siRNA specific for p21 or p21-specific oligonucleotides were transfected into primary macrophages to silence the expression of p21, HIV infection was aborted, thereby validating p21 as a cellular factor essential to productive HIV infection in this population. Extending these observations, a
pharmacologic agent known to
influence p21 expression, the synthetic
triterpenoid and peroxisome
proliferator-activated receptor gamma
([PPAR] ligand, 2-cyano-3,12-
dioxooleana-1,9-dien-28-oic acid
(CDDO) or its derivative di-CDDO, was
shown to moderate virally-induced p21
expression and concurrently dampen
HIV infection. CDDO is part of a class
of synthetic triterpenoids based on
natural products resembling steroids in
their biogenesis and in their pleiotropic
actions. A newly developed CDDO
derivative, which is orally bioavailable,
also suppresses HIV. These results,
coupled with the evidence that
macrophage p21 is a requisite
antiretroviral agents. The anti-retroviral
effect of CDDO was evident when
peripheral blood mononuclear cells
(PBMC) were infected with a T-tropic
(X4) or dual tropic viral (R5X4) strain of
HIV–1. These studies suggest that these
triterpenoids may aid in the control of
retroviral replication. Neither p21
oligonucleotides nor CDDO were toxic
to the cultured macrophages or
peripheral blood mononuclear cells.
Thus, p21 inhibitors could be safe and
effective anti-HIV therapeutic
candidates to be used independently
and/or in conjunction with current anti-
retroviral therapy. In this regard, CDDO
will be entered into human trials for
the first time in the near future for its anti-
cancer indications, thereby determining
its maximally tolerated dose for use in
subsequent HIV/AIDS clinical trials.
Current anti-retroviral therapy, often
characterized by high toxicity and the
emergence of drug resistant virus
strains, may be augmented through the
identification of these and other new
anti-viral agents targeting host cellular
molecules less prone to mutational
events.

Inventors: Sharon M. Wahl, Nancy
Vazquez-Maldonado, Teresa Greenwell-
Wild (NIDCR).

Publication:
1. S.M. Wahl et al., “HIV accomplices
and adversaries in macrophage
infection,” J. Leukoc. Biol. 2006, in
press.
2. N. Vazquez et al., “Human
immunodeficiency virus type 1-induced
macrophage gene expression includes
the p21 gene, a target for viral
regulation.” J. Virol. (2005 Apr)
79(7):4479–4491.

Patent Status: U.S. Provisional
Application No. 60/516,794 filed
November 4, 2003 (HHS Reference No.
E–114–2003/0–US–01); PCT
Application No. PCT/US2004/36492
filed November 3, 2004, which
published as WO 2005/046732 on May
26, 2005 (HHS Reference No. E–114–
2003/0–PCT–02)

Licensed Status: Available for non-
exclusive or exclusive licensing.

Licensed Contact: Sally Hu, PhD.,
M.B.A.; 301/435–5606;
hus@email.nih.gov

Collaborative Research Opportunity:
The National Institute of Dental and
Craniofacial Research, Oral Infection
and Immunity Branch, is seeking
statements of capability or interest from
parties interested in collaborative
research to further develop, evaluate,
or commercialize this technology. Please
contact David W. Bradley, PhD., at
bradleyda@niddcr.nih.gov or by phone at
301/402–0540 for more information.

Dated: May 18, 2006.

David R. Sadowski,
Acting Director, Division of Technology
Development and Transfer, Office of
Technology Transfer, National Institutes of
Health.

[FR Doc. E6–8176 Filed 5–25–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and
Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the
Federal Advisory Committee Act, as
amended (5 U.S.C. Appendix 2), notice is hereby
given of a meeting of the
National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the
public as indicated below, with
attendance limited to space available.

Individuals who plan to attend and
need special assistance, such as sign
language interpretation or other
reasonable accommodations, should
notify the Contact Person listed below
in advance of the meeting.

The meeting 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
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: National Advisory
Council on Minority Health and Health
Disparities.

Date: June 13, 2006.

Closed: 8:30 a.m. to 10 a.m.

Agenda: To review and evaluate grant
applications.

Place: National Institutes of Health, Two
Democracy Plaza, 6707 Democracy
Boulevard, Suite 800, Bethesda, MD 20892.

Open: 10 a.m. to 5 p.m.

Agenda: The agenda will include Opening
Remarks, Administrative Matters, Director’s
Report, NCMHD, IC Strategic Plan Report,
NIMHD Minority Research Training Programs
Update, NCMHD Program Highlights, and
other business of the Council.

Place: National Institutes of Health, Two
Democracy Plaza, 6707 Democracy
Boulevard, Suite 800, Bethesda, MD 20892.

Contact Person: Donna Brooks, Asst.
Director for Administration, National Center
on Minority Health and Health Disparities,
National Institutes of Health, 6707
Democracy Blvd., Suite 800, Bethesda, MD
20892. 301–435–2135.
brooksd@ncmhd.nih.gov.

Any interested person may file written
comments with the committee by forwarding
the statement to the Contact Person listed
on this notice. The statement should include
the name, address, telephone number and when
applicable, the business or professional
affiliation of the interested person.

Dated: May 18, 2006.

Anna Snouffer,
Acting Director, Office of the Federal Advisory
Committee Policy.

[FR Doc. 06–4893 Filed 5–25–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND
HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and
Infectious Diseases; Notice of Closed
Meeting

Pursuant to section 10(d) of the
Federal Advisory Committee Act, as
amended (5 U.S.C. Appendix 2), notice is hereby
given of the following
meeting.

The meeting will be closed to 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: Allergy, Immunology,
and Transplantation Research Committee,
Allergy, Immunology and Transplantation
Research Committee (AITRC).

Date: June 12, 2006.

Time: 8 a.m. to 5 p.m.