

management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 8, 2010.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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BILLING CODE 4163-18-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.

Prevention and Treatment of Herpes Virus Infection by Inhibition of the JMJD2 Family of Histone Demethylases

Description of Invention: Investigators at the NIH have discovered a potential means for preventing or treating a herpes virus infection by inhibiting the activity of the host cell's histone demethylases. When herpesviruses enter a cell, they are inactivated by cellular defense mechanisms that wrap the viral genome in repressive chromatin structures. In order for viral replication to progress, the host's own histone demethylases are recruited to the viral genome to reverse this repression. In a preceding invention, the laboratory disclosed that viral replication and reactivation can be significantly reduced through inhibition

of the histone demethylase LSD1 using Mono-Amino Oxidase Inhibitors (MAOIs); drugs that are in clinical use. The current invention further discloses that inhibition of a second set of histone demethylases (JMJD2 family) using a specific JMJD2 inhibitor, dimethyloxaloylglycine (DMOG), also results in significant repression of herpes viral replication.

Either alone or in combination, small molecule inhibition of LSD1 and the JMJD2 family present novel approaches for preventing herpes virus infection and halting viral reactivation that can lead to a disease that ranges from mild core sores to herpesvirus keratitis and life-threatening encephalitis. Additionally, chromatin-mediated repression of viral genomes and the requirement to de-repress these genomes for productive infection appears to be general to herpesviruses. Therefore, this treatment could also be applicable to chicken pox, shingles, CMV disease, mononucleosis, and Kaposi's sarcoma.

Applications: Prevention or treatment of infection by herpes simplex virus and other diseases caused by herpesviruses (i.e. Epstein-Barr virus, cytomegalovirus, varicella zoster, and Kaposi's sarcoma-associated herpesvirus).

Advantage: Inhibition of histone demethylases provides an alternative pathway for repressing herpes virus infection as compared to purine analog antivirals. While purine analogs are the most widely prescribed treatment for herpes infection, drug resistance is prevalent. Additionally, inhibition of histone demethylases results in no expression of viral gene products; in contrast to DNA replication inhibitors.

Development Status:

- Early-stage development
- Pre-clinical data available for mice
- Further pre-clinical and clinical development is needed

Market:

- Genital herpes can result from infection with either HSV type 2 or type 1, mainly by HSV type 2 in the U.S., which typically causes more recurrent and severe manifestations of the disease.
- According to the Centers for Disease Control and Prevention, nationwide, 16.2%, or about one out of six, people 14 to 49 years of age have genital HSV-2 infection.
- HSV keratitis is the most frequent cause of corneal blindness in the United States.

Inventors: Thomas Kristie et al. (NIAID)

Publications: None related to this invention available at this time.

Patent Status: U.S. Provisional Application No. 61/366,563 filed 22 Jul 2010 (HHS Reference No. E-184-2010/0-US-01).

Related Technologies: "Use of Mono-Amine Oxidase Inhibitors to Prevent Herpes Virus Infections and Reactivation from Latency"—HHS Reference No. E-275-2008/2-PCT-02.

Licensing Status: Available for licensing.

Licensing Contacts:

- Eric W. Odom, PhD; 301-435-5009; odome@mail.nih.gov.
- Susan O. Ano, PhD; 301-435-5515; anos@mail.nih.gov.

Collaborative Research Opportunity: The NIAID Laboratory of Viral Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize prevention and treatment of viral diseases. Please contact Thomas Kristie, PhD at 301.496.3854 or tkristie@niaid.nih.gov for more information.

Treatment of Inflammatory Bowel Disease (IBD) Using IL-13 Modulators and Inhibitors

Description of Invention: Ulcerative colitis (UC), a chronic inflammatory disease of the colorectum, affects approximately 400,000 people in the United States. The cause of UC is not known, although an abnormal immunological response to bacterial antigens in the gut microflora is thought to be involved. Available for licensing are broad claims covering (1) treatments preventing the inflammatory response of colitis by modulating IL-13 and Natural Killer T cell (NKT) activity and (2) methods for screening for therapeutic compounds effective for colitis. NIH scientists and their collaborators have used a mouse model of experimental colitis (oxazolone colitis, OC) to show that IL-13, a Th2 cytokine, is a significant pathologic factor in OC and that neutralizing IL-13 in these animals effectively prevents colitis. Inflammation in this mouse model has also been shown to be effectively blocked by neutralizing IL-13 or by inhibiting the activation of NK-T cells through CD1.

Oxazolone colitis (OC) is a colitis induced by intrarectal administration of a relatively low dose of the haptening agent oxazolone subsequent to skin sensitization with oxazolone. A highly reproducible and chronic colonic inflammation is obtained that is histologically similar to human ulcerative colitis. Studies show that NKT cells, rather than conventional CD4+T cells, mediate oxazolone colitis,

are the source of IL-13, and are activated by CD1 expressing intestinal epithelial cells. Tissue removed from UC patients were also shown to contain increased numbers of nonclassical NKT cells that produce markedly increased amounts of IL-13. In addition, these NKT cells are cytotoxic for epithelial cells, supporting the concept that epithelial damage is a key factor in UC.

Applications: Development of IL-13 and CD1 based therapeutics to treat or prevent ulcerative colitis.

Development Status: Small animal model studies.

Inventors: Warren Strober, Ivan Fuss, Frank Heller, Richard Blumberg (NIAID).

Related Publications:

1. IJ Fuss et al. Nonclassical CD1d-restricted NK T cells that produce IL-13 characterize an atypical Th2 response in ulcerative colitis. *J Clin Invest.* 2004 May;113(10):1490-1497. [PubMed: 15146247].

2. F Heller et al. Oxazolone colitis, a Th2 colitis model resembling ulcerative colitis, is mediated by IL-13-producing NK-T cells. *Immunity* 2002 Nov;17(5):629-638. [PubMed: 12433369].

Patent Status:

- U.S. Patent No. 7,666,411 issued 23 Feb 2010 (HHS Reference No. E-131-2002/0-US-02).

- U.S. Patent Application No. 12/709,029 filed 19 Feb 2010 (HHS Reference No. E-131-2002/0-US-10).

- International patent/patent application filings.

Related Technologies: Related IBD technologies also available for licensing include IL-13 mutant and chimeric molecules (HHS Reference No. E-003-2005/0) and NF-kappa B decoy oligonucleotides (HHS Reference No. E-108-2005/0).

Licensing Status: Available for licensing.

Licensing Contact: Sury Vepa, PhD, J.D.; 301-435-5020; vepas@mail.nih.gov.

Dated: October 12, 2010.

Richard U. Rodriguez,

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

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Mouse Anti-Mouse CXCL9 (Mig) Monoclonal Antibodies

Description of Invention: This technology describes monoclonal antibodies against mouse chemokine (C-X-C motif) ligand 9 (CXCL9), also known as Monokine induced by gamma interferon (Mig). CXCL9 is a secreted protein that functions to attract white cells and increased expression of CXCL9 has been linked to several diseases. The inventors at the NIH generated over 100 anti-mouse CXCL9 antibodies from a CLXL9/Mig knockout mouse and further characterized several antibodies to show neutralization of CXCL9. As such, these antibodies could be used to measure concentrations of mouse CLXL9 in laboratory samples and block the activity of CXCL9 in injected mice. These antibodies are suitable for ELISA and Western blot. The antibodies have not been tested in flow cytometry or immunohistochemistry, but may also be useful for these applications.

Applications

- ELISA assays for detection and measurement of CXCL9.
- Neutralization of CXCL9 activity in mouse models and *in vitro* assays to study the role of CXCL9 in immune response and disease.

Advantages: Can be used in mice without eliciting endogenous antibodies reacting against the injected anti-CXCL9.

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

Inventors: Joshua M. Farber and Hongwei H. Zhang (NIAID).

Patent Status: HHS Reference No. E-198-2009/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status

Available for licensing.

Licensing Contact: Whitney A. Hastings; 301-451-7337; hastingw@mail.nih.gov.

Signal-to-Noise Enhancement in Imaging Applications Using a Time-Series of Images

Description of Invention: The invention offered for licensing relates to the field of imaging and specifically to the field of medical imaging. The apparatus and method of the invention provide for noise reduction in imaging applications that use a time-series of images. In one embodiment of the invention, a time-series of images is acquired using a same imaging protocol of the same subject area, but the images are spaced in time by one or more time intervals (e.g., 1, 2, 3 * * * seconds apart). A sub-region is projected across all of the images to perform a localized analysis (corresponding X-Y pixels or X-Y-Z voxels are analyzed across all images) that identifies temporal components within each sub-region. Subsequently, within the sub-regions, only those temporal components are selected whose amplitude is above a predetermined amplitude threshold. The images are then reconstructed using the sub-regions with reduced components. A maximal-intensity-projection (MIP) is applied in the temporal domain (tMIP) in order to obtain a single image with reduced noise (this can be done either at the sub-region level or at the reconstructed image level). The technology can be applied to a broad spectrum of medical imaging technologies such as MRI, X-Ray, CT and others.

Applications: Medical imaging and diagnostics applied to MRI, X-Ray, CT scans or other imaging modalities including PET, SPECT, ultrasound or optical.

Advantages: Enhancing signal-to-noise of medical imaging techniques.

Development Status

- Proof of concept has been demonstrated. Data is available.