potent against virions produced from PBMC, perhaps due to differences in glycosylation. Importantly, the bifunctional protein is composed of almost entirely human sequences. It potentially can be linked to other functional moieties to achieve desired properties (longer plasma half-life, selective killing of HIV-infected cells, imaging of viral reservoirs, etc.). The chimeric protein of this invention has considerable potential for prevention of HIV–1 infection, both as a topical microbicide and as a systemic treatment for HIV infection. It also has potential utility for treatment of chronic infection, including gene therapy strategies involving hematopoietic stem cells and/or viral vectors. Such proteins, nucleic acid molecules encoding them, and their production and use in preventing or treating viral infections are claimed in the patents issued for this invention.

Applications:
• Prophylactic and/or therapeutic treatment for HIV infection.
• Topical microbicide treatment to prevent against HIV infection.
• Imaging of HIV infected cells in tissues.

Advantages:
• High neutralization efficiency due to unique bifunctional binding characteristics.
• Potentially minimally immunogenic or toxic (human sequences and possibly low treatment doses).
• Broad neutralizing activity.
• Mechanism of action less susceptible to resistance.

Development Status:
• Reproducible production and scale-up of chimeric protein has been demonstrated.
• Potent and broad neutralization of genetically diverse HIV–1 clinical isolates has been demonstrated.

Market: The race to develop effective antiviral strategies against HIV infection is ongoing. The problems exhibited by conventional drugs such (i.e. toxicity and resistance) have triggered the pursuit of alternative approaches to HIV/AIDS prevention and treatment. One of the new approaches is the development of neutralizing antibodies against the HIV envelope proteins. This approach has not yet yielded any commercially viable treatment. It is believed that the approach presented in the subject invention will circumvent many of the shortcomings of the existing drugs and other pursued approaches. If this approach is successful the commercial rewards will be huge because of the global magnitude of HIV epidemics.

Inventor: Edward A. Berger (NIAID).
Related Publications:

Patent Status:
HHS Reference No. E–039–1999/0—
• European Patent No. 1161445, issued 03 Sep 2008 for France, Germany, Great Britain, Italy.
• Applications pending in Canada, Japan.

Licensing Status: Available for licensing.
Licensing Contacts: Uri Reichman, PhD, MBA; 301–435–4616; ur7o@nih.gov; or Susan Ano, PhD, 301–435–5515; anos@mail.nih.gov.

Collaborative Research Opportunity: The NIAID, Office of Technology Development, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize “A Novel Chimeric Protein for Prevention and Treatment of HIV Infection.” Please contact Marguerite J. Miller at 301–435–8619 for more information.
Richard U. Rodriguez, Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2010–12794 Filed 5–26–10; 8:45 am]
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, 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.

UOK 257, the First BHD Tumor Cell Line, and UOK257–2 Wild Type FLCN- Restored Renal Cell Line as In Vitro and In Vivo Models of Energy/Nutrient Sensing through the AMPK and mTOR Signaling Pathways

Description of Invention: Scientists at the National Institutes of Health (NIH) have developed a novel renal cell carcinoma (RCC) cell line designated UOK257, which was derived from the surgical kidney tissue of a patient with hereditary Birt-Hogg-Dube’ (BHD) syndrome and companion cell line UOK257–2 in which FLCN expression has been restored by lentivirus infection. These cell lines harbors a germine mutation of FLCN gene (alias BHD) and displays loss of heterozygosity, can grow as xenograft in nude mice. Patients affected with BHD develop skin papules (fibrofolliculomas), lung cysts, spontaneous pneumothorax and an increased risk for bilateral multifocal renal tumors. Loss of both copies of the FLCN gene has been documented in BHD renal tumors; however, the molecular mechanisms by which inactivation of the encoded protein, folliculin, leads to the BHD phenotype are currently unknown. They have developed an important research tool for in vitro folliculin functional studies. The companion cell line will be extremely useful for comparative biochemical analyses of cell culture systems in which the FLCN gene is either expressed or inactivated, including identification of renal tumor biomarkers, alteration of biochemical pathways resulting from loss of FLCN...
function, tumorigenicity of FLCN null versus FLCN restored cells, preclinical therapeutic drug testing in xenograft animal models produced from injection of these cell lines, etc. UOK 257 and UOK257–2 are thus useful cell models for studying the underlying molecular derangements associated with mTOR pathways and other biogenesis pathways in human kidney cancer and for evaluating novel therapeutic approaches for this disease. UOK257 is also one of the 40-member renal cancer cell lines in the Tumor Cell Line Repository of the Urologic Oncology Branch (UOB), National Cancer Institute (NCI).

Related Publications

In situ Hybridization Assay To Detect Endometrial Cancer

Description of Invention: Investigators at the National Cancer Institute have developed a sensitive, specific and robust human microRNA in situ hybridization (ISH) assay that can detect, quantify, and identify cancer biomarkers. Currently available microRNA (miRNA) markers can be detected by microarray, Northern Blot, real time RT–PCR, and sequencing analysis. However, these assays cannot specify tissue and cell types that contain miRNAs without laser microdissection (LMD). LMD has severe limitations as it requires expensive equipment and its miRNA yields are too low to be detected by the aforementioned techniques.

Available for licensing is an optimized ISH assay to detect miRNAs. ISH represents an efficient and specific assay to detect miRNA of interest due to direct interaction with specific tissue and cell types. This ISH assay utilized fresh cell lines and it can be adapted to frozen cells and tissue samples. Utilizing the assay, the investigators have found that miRNA–31 is decreased in cancerous endometrial cells in comparison to controls. This ISH assay provides for a less expensive, more efficient and highly sensitive assay to detect and quantify microRNAs.

Applications
- Method to detect and quantify miRNAs.
- Method and kits to diagnose endometrial cancer.

Advantages: Cost effective, highly sensitive assay to detect miRNAs.

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

Market
- U.S. microRNA revenues were $20 million in 2008 will increase to more than an estimated $98 million in 2015.
- Global cancer market is worth more than eight percent of total global pharmaceutical sales.
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration


Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products.”


ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.


SUPPLEMENTARY INFORMATION:

I. Background

The guidance documentamends the January 2002 guidance document of the same title by: Incorporating donor deferral recommendations for donors who have received a transfusion of blood or blood components in France since 1980, providing updated scientific information on CJD and vCJD, revising labeling recommendations for Whole Blood and blood components intended for transfusion, and recognizing AABB’s full Donor History Questionnaire Version 1.3 as an acceptable mechanism for collection of donor history information. The guidance document amends the January 2002 guidance finalized in August 2006 (2006 draft guidance). The 2006 draft guidance was intended to amend the 2002 guidance by adding a donor deferral recommendation for donors who have received a transfusion of blood or blood components in France since 1980.

Specifically, in the 2006 draft guidance, we stated that we intended to incorporate the new donor deferral recommendation into the guidance document. The 2006 draft guidance reissues the revised 2002 guidance as a level 2 guidance document for immediate implementation (71 FR 46484, August 14, 2006). Upon further consideration, however, we believe it appropriate to issue the guidance document as a level 1 guidance document.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the...