

veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency, European Federation of Animal Health, Committee on Veterinary Medicinal Products, the U.S. FDA, the U.S. Department of Agriculture, the Animal Health Institute, the Japanese Veterinary Pharmaceutical Association, the Japanese Association of Veterinary Biologics, and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Revised Guidance on Impurities in New Veterinary Drug Substances

In the **Federal Register** of January 4, 2006 (71 FR 351), FDA published a notice of availability for a draft revised guidance entitled "Impurities in New Veterinary Drug Substances (Revision)" VICH GL10(R) giving interested persons until February 3, 2006, to comment on the draft revised guidance. No comments were received. The revised guidance announced in this document finalizes the draft revised guidance announced on January 4, 2006. The revised guidance has been amended to add to the glossary a definition for the term "Degradation Products".

The document is intended to provide guidance for new animal drug applicants (referred to in the guidance as registration applicants) on the content and qualification of impurities in new veterinary drug substances intended to be used for new veterinary medicinal products produced by chemical synthesis and not previously registered in a country, region, or member state. The revised guidance is the product of the Quality Expert Working Group of the VICH.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These

collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections 2 through 7 of the guidance have been approved under OMB Control Number 0910–0032.

IV. Significance of Guidance

This revised document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." In addition, guidance documents must not include mandatory language such as "shall," "must," "required," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement.

The revised VICH guidance (guidance for industry #92) is consistent with the agency's current thinking on impurities in new veterinary drug substances. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

V. Comments

Interested persons may, at any time, submit written or electronic comments regarding the revised guidance document to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two copies of written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Electronic Access

Persons with access to the Internet may obtain the guidance from either the CVM home page (<http://www.fda.gov/cvm>) or the Division of Dockets Management Web site (<http://www.fda.gov/ohrms/dockets/default.htm>).

Dated: November 12, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–22902 Filed 11–21–07; 8:45 am]

BILLING CODE 4160–01–S

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.

Inactivation of Enveloped Viruses and Tumor Cells for Infectious Disease and Cancer Vaccines

Description of Invention: The current technology describes the inactivation of viruses, parasites, and tumor cells by the hydrophobic photoactivatable compound 1,5-iodoanthylazide (INA). This non-toxic compound will diffuse into the lipid bilayer of biological membranes and upon irradiation with light will bind to proteins and lipids in this domain, thereby inactivating fusion of enveloped viruses with their corresponding target cells. Furthermore, the selective binding of INA to protein domains in the lipid bilayer preserves the structural integrity and therefore immunogenicity of proteins on the exterior of the inactivated virus. This technology is universally applicable to other microorganisms that are surrounded by biological membranes like parasites and tumor cells. The broad utility of the subject technology has been demonstrated using influenza virus, HIV, SIV, Ebola and equine encephalitis virus (VEE) as representative examples. The inactivation approach for vaccine development presented in this technology provides for a safe, non-

infectious formulation for vaccination against the corresponding agent. Vaccination studies demonstrated that mice immunized with INA inactivated influenza, ebola and VEE mounted a protective immune response against lethal doses of the corresponding virus. A second technology for inactivating HIV and other retroviruses by inactivation of zinc fingers is described in E-174-1993/1,2.

Applications: Vaccines against enveloped viruses, including influenza and HIV; Cancer vaccines.

Development Status: Animal data (mouse) available for influenza.

Inventors: Yossef Raviv *et al.* (NCI).

Publication: Y Raviv *et al.*

Inactivation of retroviruses with preservation of structural integrity by targeting the hydrophobic domain of the viral envelope. *J Virol.* 2005 Oct;79(19):12394-12400.

Patent Status:

PCT application, serial number PCT/US2005/009559 (publication number WO 2005/093049), filed 22 Mar 2005 claiming priority to 22 Mar 2004; National Stage applications pending in Australia, Canada, China, Europe, India, and U.S. (HHS Reference No. E-303-2003/0).

PCT application, serial number PCT/US2007/007338, filed 23 Mar 2007 claiming priority to 24 Mar 2006 (HHS Reference No. E-135-2006/1-PCT-01; influenza-specific inactivation).

U.S. Patent No. 6,001,555, issued 14 Dec 1999 (HHS Reference No. E-174-1993/1); PCT application, serial number PCT/US95/11915 (publication number WO 96/09406), filed 19 Sept 1995 claiming priority to 23 Sept 1994, now EP patent number 0782632, issued 16 April 2003 in Italy, Belgium, Switzerland, Germany, and United Kingdom (HHS Reference No. E-174-1993/2; second HIV inactivation technology).

Licensing Contacts:

For HHS Reference Nos. E-303-2003 and E-135-2006—Susan Ano, PhD; phone: (301) 435-5515; e-mail: anos@mail.nih.gov.

For HHS Reference No. E-174-1993—Sally Hu, PhD, MBA; phone: (301) 435-5606; e-mail: hus@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute's Membrane Structure and Function Section is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize non-infectious formulation for vaccination. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Monoclonal Antibodies That Bind or Neutralize Dengue Virus

Description of Invention: Among the arthropod-borne flaviviruses, the four dengue virus serotypes, dengue type 1 virus (DENV-1), dengue type 2 virus (DENV-2), dengue type 3 virus (DENV-3), and dengue type 4 virus (DENV-4) are most important in terms of human morbidity and geographic distribution. Dengue viruses cause dengue outbreaks and major epidemics in most tropical and subtropical areas where *Aedes albopictus* and *Aedes aegypti* mosquitoes are abundant. Dengue infection produces fever, rash, and joint pain in humans. A more severe and life-threatening form of dengue, characterized by hemorrhagic fever and hemorrhagic shock, has occurred with increasing frequency in Southeast Asia and Central and South America, where all four dengue virus serotypes circulate. A safe and effective vaccine against dengue is currently not available. Passive immunization with monoclonal antibodies from non-human primates or humans represents a possible alternative to vaccines for prevention of illness caused by dengue virus.

The application claims monoclonal antibodies that bind or neutralize dengue type 1, 2, 3, and/or 4 viruses. The application also claims fragments of such antibodies retaining dengue virus-binding ability, fully human or humanized antibodies retaining dengue virus-binding ability, and pharmaceutical compositions including such antibodies. The application also claims isolated nucleic acids encoding the antibodies of the invention. Additionally, application claims prophylactic, therapeutic, and diagnostic methods employing the antibodies and nucleic acids of the invention.

Application: Prophylaxis against dengue serotypes 1, 2, 3 and 4.

Development Status: Antibodies have been synthesized and preclinical studies have been performed.

Inventors: Ching-Juh Lai and Robert Purcell (NIAID).

Publications: The antibodies are further described in:

1. R Men *et al.* Identification of chimpanzee Fab fragments by repertoire cloning and production of a full-length humanized immunoglobulin G1 antibody that is highly efficient for neutralization of dengue type 4 virus. *J Virol.* 2004 May;78(9):4665-4674.

2. AP Goncalves *et al.* Chimpanzee Fab fragments and a derived humanized immunoglobulin G1 antibody that efficiently cross-neutralize dengue type

1 and type 2 viruses. *J Virol.* 2004 Dec;78(23):12910-12918.

3. AP Goncalves *et al.* Epitope determinants of a chimpanzee Fab antibody that efficiently cross-neutralizes dengue type 1 and type 2 viruses map to inside and in close proximity to fusion loop of the dengue type 2 virus envelope glycoprotein. *J Virol.* 2004 Dec;78(23):12919-12928.

4. AP Goncalves *et al.* Monoclonal antibody-mediated enhancement of dengue virus infection in vitro and in vivo and strategies for prevention. *Proc Natl Acad Sci U S A.* 2007 May 29;104(22):9422-9427.

Patent Status: U.S. Patent Application No. 10/582,006 filed 07 Jun 2006 (HHS Reference No. E-066-2003/5-US-02); Canadian Patent Application No. 2548808 filed 03 Dec 2004 (HHS Reference No. E-066-2003/5-CA-03).

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

Licensing Contact: Peter A. Soukas, J.D.; 301/435-4646; soukasp@mail.nih.gov.

Collaborative Research Opportunity: The NIAID Laboratory of Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Ching-Juh Lai at 301-594-2422 for more information.

Novel Non-Nucleoside Agents for the Inhibition of HIV Reverse Transcriptase for the Treatment of HIV-1

Description of Invention: Despite recent developments in drug and compound design to combat the human immunodeficiency virus (HIV), there remains a need for a potent, non-toxic compound that is effective against wild type reverse transcriptase (RT) as well as RTs that have undergone mutations and thereby become refractory to commonly used anti-HIV compounds. There are two major classes of RT inhibitors. The first comprises nucleoside analogues, which are not specific for HIV-RT and are incorporated into cellular DNA by host DNA polymerases. Nucleoside analogues can cause serious side effects and have resulted in the emergence of drug resistance viral strains that contain mutations in their RT. The second major class of RT inhibitors comprises non-nucleoside RT inhibitors (NNRTIs) that do not act as DNA chain terminators and are highly specific for HIV-RT. This technology is a novel class of NNRTIs (substituted benzimidazoles) effective in the inhibition of HIV-RT wild type as well as against variant HIV strains resistant to many non-nucleoside

inhibitors. These NNRTIs are highly specific for HIV-1 RT and do not inhibit normal cellular polymerases, resulting in lower cytotoxicity and fewer side effects than the nucleoside analogues, such as AZT. This novel class of compounds could significantly improve the treatment of HIV by increasing compliance with therapy.

Inventors: Christopher A. Michejda, Marshall Morningstar, Thomas Roth (NCI).

Patent Status: U.S. Patent No. 6,369,235 issued 09 Apr 2002 (HHS Reference No. E-076-1997/1-US-01); U.S. Patent No. 6,894,068 issued 17 May 2005 (HHS Reference No. E-076-1997/1-US-02).

Licensing Contact: Sally Hu, PhD., MBA; 301/435-5606; hus@mail.nih.gov.

Dated: November 9, 2007.

Steven M. Ferguson,

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

[FR Doc. E7-22821 Filed 11-21-07; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Public Teleconference Regarding Licensing and Collaborative Research Opportunities for: "Brother of the Regulator of Imprinted Sites" (BORIS): A Novel Protein That Can Be Used for Diagnosis and as a Therapeutic Target for the Treatment of Several Cancers; Dr. Victor Lobanenkov et al. (NIAID)

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

Technology Summary

The technology describes the discovery of a novel gene encoding the DNA-binding factor, "Brother of the Regulator of Imprinted Sites", BORIS, related to the unique, evolutionarily conserved, CTCF factor involved in regulation of genomic imprinting and cancer. Furthermore, it describes several splice variants of BORIS that translate into different proteins and antibodies of BORIS that can be used for diagnosis and treatment of cancer.

Technology Description

A very recent finding is that protein CTCF (expressed in all somatic tissues) binds, in a methylation-dependent manner, to the imprinting control regions thus allowing somatic cells to distinguish functionally maternal from paternal alleles. The new factor, BORIS,

shares with CTCF the same spectrum of DNA sequence specificity and it is normally expressed only in germ cells of human gonads (when patterns of gene imprinting are re-established), but not in CTCF-expressing somatic cells.

Additionally, since cell-growth controlling CTCF has properties of a tumor suppressor gene, abnormal activation of BORIS upon cancerous transformation of somatic cells results in competition with the normal function of CTCF, thereby promoting tumor growth. The inventors found that antibodies against BORIS are present and can be detected in human blood serum taken from patients with cancer but not from healthy donors.

Additionally, 14 new alternative splice forms of the BORIS polypeptide have been identified which show specificity to specific cancers, suggesting that circulating antibodies for specific BORIS splice variants in cancer patients can be associated with specific types or stages of malignant tumors.

Therefore, BORIS can be used in both diagnostic and therapeutic arenas: First, mutations in BORIS genomic locus or detection of encoded by the BORIS locus mRNAs or polypeptides expressed in any tissue besides normal gonads may be indicative of a pre-cancerous or cancerous state thus serving a diagnostic and/or prognostic purpose; and, second, targeting of abnormally activated BORIS should serve as a novel therapeutic approach to treat cancer.

BORIS Technology Can Have Three Major Applications

1. BORIS can be used as a therapeutic target for anti-cancer treatments.

2. BORIS expression can serve as a diagnostic marker for specific cancers other than testis.

3. Detection of antibodies against BORIS in blood serum samples can also be used as an indicator of pre-cancerous or cancerous condition existing.

Competitive Advantage of Our Technology

Cancer/testis (CT) genes, predominantly expressed in the testis (germ cells) and generally not in other normal tissues, are aberrantly expressed in human cancers. This highly restricted expression provides a unique opportunity to use these CT genes for diagnostics, immunotherapeutic, or other targeted therapies. BORIS is a newly described CT gene shown to be expressed in several cancers including lung, brain, uterine and endometrial among others and thus can be used as a novel diagnostic and therapeutic target.

Patent Estate

This technology consists of the following patents and patent applications:

1. U.S. Patent Application No. 10/505,377 filed October 20, 2004 and all foreign counterparts [E-227-2001/0-US-03];

2. U.S. Patent Application No. 11/575,732 filed March 21, 2007 and all foreign counterparts [E-241-2004/0-US-04]; and

3. PCT Application No. PCT/US2007/7728 filed August 30, 2007 [E-117-2006/0-PCT-02]

Next Step: Teleconference

There will be a teleconference where the principal investigator will explain this technology. Licensing and collaborative research opportunities will also be discussed. If you are interested in participating in this teleconference please call or e-mail Mojdeh Bahar; (301) 435-2950; baharm@mail.nih.gov. OTT will then e-mail you the date, time and number for the teleconference.

Dated: November 9, 2007.

Steven M. Ferguson,

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

[FR Doc. E7-22820 Filed 11-21-07; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; 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 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: National Institute of Environmental Health Sciences Special Emphasis Panel, Genetic Environmental Training.

Date: November 27, 2007.

Time: 8:30 a.m. to 5 p.m.