

and Child Health Coordinator, Maternal and Child Health Program, Indian Health Service, 801 Thompson Avenue, Suite 300, Rm 313, Rockville, Maryland 20852, *voice*: 301-443-5070, *fax*: 301-594-6213 or *judith.thierry@ihs.gov*.

For general information regarding this announcement: Ms. Orié Platero, IHS Headquarters, Office of Clinical and Preventive Services, 801 Thompson Avenue, Room 326, Rockville, MD 20852, (301) 443-2522 or *orie.platero@ihs.gov*.

3. For specific grant-related and business management information: Martha Redhouse, Grants Management Specialist, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, 301-443-5204 or *Martha.redhouse@ihs.gov*.

### VIII. Other Information

The IHS is focusing efforts on three health initiatives that linked together, have the potential to achieve positive improvements in the health of American Indian and Alaska Native (AI/AN) people. These three initiatives are Health Promotion/Disease Prevention, Management of Chronic Disease, and Behavioral Health. Further information is available at the Health Initiatives Web site: <http://www.ihs.gov/nonMedical/Programs/DirInitiatives/index.cfm>.

This agreement supports the Department of Health and Human Services' objective in FY 2006 to transform the health care system as well as the FY 2007 objective to emphasize prevention and healthy living as well as to accelerate personalized health care.

Dated: April 19, 2007.

**Robert G. McSwain,**

*Deputy Director, Indian Health Service.*

[FR Doc. 07-2051 Filed 4-25-07; 8:45 am]

BILLING CODE 4165-16-M

## 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.

#### Apparatus for Brachytherapy

*Description of Technology:* Available for licensing and commercial development is a device for delivering targeted radiation brachytherapy to a portion of tissue in the cavity of a patient. The device includes an applicator with a balloon where in a deflated state is inserted into the body cavity and in an inflated state enlarges to fill the body cavity. The balloon moves from the deflated state into the inflated state upon introduction of pressurized fluid to the interior of the balloon. The apparatus also includes a catheter extending over at least a portion of the balloon for delivering treatment to the adjacent cavity (e.g., radiation or heat). A tracking device (e.g., a camera) is included in the apparatus for helping track the positioning of the balloon within the body cavity prior to inflation. The apparatus can be alternatively configured with a second balloon containing a therapeutic agent which is inflated after positioning and expansion with a first balloon first.

*Applications:* Brachytherapy; Radiation dosing; Cancer therapy.

*Development Status:* Early-stage; Pre-clinical data available; Prototype.

*Inventor:* Anurag K. Singh (NCI).

*Patent Status:* U.S. Provisional Application No. 60/811,762 filed 08 Jun 2006 (HHS Reference No. E-314-2005/0-US-01).

*Licensing Status:* Available for licensing non-exclusively or exclusively to qualified applicants that satisfy the criteria set forth in 37 CFR 404.7.

*Licensing Contact:* Michael A. Shmilovich, Esq.; 301/435-5019; *shmilovm@mail.nih.gov*.

Dated: April 18, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-7927 Filed 4-25-07; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

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#### Biotinylated Alkylating Acridine for Pull-downs of Viral Pre-integration Complexes (PIC) or Other Cytosol Localized DNAs

*Description of Technology:* The invention describes a DNA-binding molecule that allows recovery of viral DNA and associated proteins. An acridine orange based molecule was modified and the resulting alkylating acridine molecule intercalates with viral pre-integration complexes (PIC) or other DNAs localized in cytosol. Because the molecule is also biotinylated, streptavidin beads can be used to purify the molecule and the bound DNA and associated protein can subsequently be eluted and analyzed. The invention provides a useful tool to facilitate the studies for viral PIC and other cytosol DNAs.

*Applications:* Research Tool.

*Development Status:* *In vitro* data available.

*Inventors:* Gunnar Thor Gunnarsson and Rafal Wierzchoslawski (NCI).

*Patent Status:* HHS Reference No. E-131-2007/0—Research Tool.

*Licensing Status:* Available for non-exclusive licensing as biological material and research tool.

*Licensing Contact:* Sally Hu, Ph.D.; 301/435-5606; *HuS@mail.nih.gov*.

### Structure of TIM Family Members

*Description of Technology:* Available for licensing and commercial development are methods to produce and/or enhance therapeutic agents based on models of the three-dimensional structures of the Ig-like domains of various TIM family members to a) develop agonists and antagonists of the T-cell immunoglobulin mucin (TIM) family of receptors and b) design specific TIM receptor-mutants with altered binding capabilities. The TIM receptors are involved in the regulation of immune responses, tissue regeneration, cancer, and viral cell entry. The invention provides models of the three-dimensional structures of the Ig-like domains of TIM family members developed after several crystal structures were resolved. The structures were further validated by mutagenesis and biochemical analysis.

The TIM family comprises type 1 integral membrane glycoproteins containing a characteristic six-cysteine Ig-like domain extended above the cell surface by a mucin-like domain. The crystal structures revealed diverse homophylic interactions between TIM family members. The three-dimensional structure of all TIM family members can be used in the making of agonists and antagonists of homophilic, heterophilic, and ligand interactions of these receptors.

#### *Applications:*

1. Therapies that target the interaction of TIM family members with their ligands, such as small molecules or monoclonal antibodies, can control immune responses and the development of a variety of diseases.

2. TIM receptor-mutants with enhanced, reduced, or destroyed binding capabilities to ligands and TIM family receptors can control TIM receptor-functions.

3. Furthermore, the homophylic, heterophylic, and ligand interactions between the TIM receptors and the TIM receptor-mutants can be used as targets to develop therapeutic agents for medical and veterinary purposes, to prevent viral infection, regulate immune responses, modulate cell adhesion and tissue regeneration, treat and prevent cancer, and treat autoimmune and atopic diseases.

*Development Status:* The technology is in early stages of development.

*Inventors:* Gerardo Kaplan (CBER/FDA), et al.

#### *Related Publications:*

1. C Santiago, A Ballesteros, C Tami, L Martínez-Muñoz, GG Kaplan, JM Casanovas. Structures of T cell immunoglobulin mucin receptors 1 and

2 reveal mechanisms for regulation of immune responses by the TIM receptor family. *Immunity*. 23 Mar 2007;26(3):299–310.

2. A Anderson, S Xiao, VK Kuchroo. Tim protein structures reveal a unique face for ligand binding. *Immunity*. 23 Mar 2007;26(3):273–275.

*Patent Status:* U.S. Provisional Application No. 60/865,642 filed 13 Nov 2006 (HHS Reference No. E-098-2006/0-US-01)

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

*Licensing Contact:* Cristina Thalhammer-Reyero, Ph.D., M.B.A.; 301/435-4507; [thalhamc@mail.nih.gov](mailto:thalhamc@mail.nih.gov).

### A Method With Increased Yield for Production of Polysaccharide-Protein Conjugate Vaccines Using Hydrazide Chemistry

*Description of Technology:* Current methods for synthesis and manufacturing of polysaccharide-protein conjugate vaccines employ conjugation reactions with low efficiency (about twenty percent). This means that up to eighty percent of the added activated polysaccharide (PS) is lost. In addition, inclusion of a chromatographic process for purification of the conjugates from unconjugated PS is required.

The present invention utilizes the characteristic chemical property of hydrazide groups on one reactant to react with aldehyde groups or cyanate esters on the other reactant with an improved conjugate yield of at least sixty percent. With this conjugation efficiency the leftover unconjugated protein and polysaccharide would not need to be removed and thus the purification process of the conjugate product can be limited to diafiltration to remove the by-products of small molecules. The new conjugation reaction can be carried out within one or two days with reactant concentrations between 1 and 25 mg/mL at PS/protein ratios from 1:2 to 3:1, at temperatures between 4 and 40 degrees Centigrade, and in a pH range of 5.5 to 7.4, optimal conditions varying from PS to PS.

*Application:* Cost effective and efficient manufacturing of conjugate vaccines.

*Inventors:* Che-Hung Robert Lee and Carl E. Frasch (CBER/FDA)

*Patent Status:* U.S. Patent Application No. 10/566,899 filed 01 Feb 2006, claiming priority to 06 Aug 2003 (HHS Reference No. E-301-2003/0-US-10); U.S. Patent Application No. 10/566,898 filed 01 Feb 2006, claiming priority to 06 Aug 2003 (HHS Reference No. E-

301-2003/1-US-02); International rights available.

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

*Licensing Contact:* Peter A. Soukas, J.D.; 301/435-4646; [soukasp@mail.nih.gov](mailto:soukasp@mail.nih.gov).

### Identification of Anti-HIV Compounds Inhibiting Virus Assembly and Binding of Nucleocapsid Protein to Nucleic Acid

*Description of Technology:* The subject invention identified two groups of active anti-viral compounds. The first group comprises aromatic, antimony-containing compounds, while the second group comprises aromatic tricarboxylic acid. Both groups were shown to inhibit viral particle assembly and inhibit the binding of nucleocapsid protein to nucleic acid. Recently, the first group also demonstrated the capability of blocking HIV-1 viral entry into CD4+ cells through binding to CD4 and inhibiting gp120-CD4 interaction, and they are well tolerated *in vivo*. Hence, these compounds are potent inhibitors of HIV and act via a novel mechanism, ideal for developing a new generation of anti-HIV medicine.

*Applications:* HIV treatment and prevention.

*Development Status:* *In vivo* preclinical data available, including data from efficacy, pharmacokinetics and preliminary toxicity studies.

*Inventors:* Robert H. Shoemaker (NCI), Michael J. Currens (NCI), Alan R. Rein (NCI), Ya-xiong Feng (NCI), Robert J. Fisher (SAIC/NCI), Andrew G. Stephen (SAIC/NCI), Karen Worthy (SAIC/NCI), Shizuko Sei (SAIC/NCI), Bruce Crise (SAIC/NCI), Louis E. Henderson (SAIC/NCI).

*Related Publication:* QE Yang et al. Discovery of small-molecule human immunodeficiency virus type 1 entry inhibitors that target the gp120-binding domain of CD4. *J Virol*. 2005 May;79(10):6122–6133.

*Patent Status:* U.S. Patent Application No. 10/528,747 filed 22 Mar 2005 (HHS Reference No. E-121-2002/0-US-03); European Patent Application No. 03773233.6 filed 08 May 2005 (HHS Reference No. E-121-2002/0-EP-04).

*Licensing Status:* Available for exclusive and non-exclusive licensing.

*Licensing Contact:* Sally Hu, Ph.D.; 301/435-5606; [HuS@mail.nih.gov](mailto:HuS@mail.nih.gov).

*Collaborative Research Opportunity:* The NCI HIV DRP Retroviral Replication Laboratory is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize these active anti-viral compounds. Please contact John D. Hewes, Ph.D. at 301-435-3121 or

[hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

### Monoclonal Antibodies Specific for the E2 Glycoprotein of Hepatitis C Virus and Their Use in the Diagnosis, Treatment and Prevention of Hepatitis C

**Description of Technology:** Hepatitis C virus is an enveloped, single-stranded RNA virus, approximately 50 nm in diameter, that has been classified as a separate genus in the Flaviviridae family. Most persons infected with hepatitis C virus develop chronic infection. These chronically infected individuals have a relatively high risk of developing chronic hepatitis, liver cirrhosis and hepatocellular carcinoma. There is currently no vaccine to prevent the hepatitis C virus infection. The present invention relates to human monoclonal antibodies which exhibit immunological binding affinity for the hepatitis C virus E2 glycoprotein and are cross-reactive against different hepatitis C virus strains. These antibodies may be used in passive immunoprophylaxis for the prevention of hepatitis C virus infection and/or in passive immunotherapy for the treatment of hepatitis C.

**Applications:** In vitro diagnostic assay for identifying patients infected with hepatitis C virus and contaminated blood samples; method of preventing infection using monoclonal antibodies that neutralize E2 glycoproteins from different genotypes of hepatitis C virus.

**Market:** Over 4 million people in the U.S. are infected with hepatitis C virus. An estimated 150 to 200 million people are infected with hepatitis C virus worldwide.

**Inventors:** Suzanne U. Emerson (NIAID), Robert H. Purcell (NIAID), Harvey J. Alter (NIAID), *et al.*

**Related Publication:** DJ Schofield *et al.* Human monoclonal antibodies that react with the E2 glycoprotein of hepatitis C virus and possess neutralizing activity. *Hepatology*. 2005 Nov;42(5):1055-1062.

**Patent Status:** U.S. Provisional Application No. 60/250,561, filed 01 Dec 2000 (HHS Reference No. E-017-2001/0-US-01); PCT Application No. PCT/US01/45221, filed 30 Nov 2001, published as WO 02/055560 on 18 Jul 2002 (HHS Reference No. E-017-2001/0-PCT-02); U.S. Patent Application No. 10/432,006 filed 16 May 2003, issued as U.S. Patent No. 6,924,362 on 02 Aug 2005 (HHS Reference No. E-017-2001/0-US-03)

**Licensing Contact:** Chekesha S. Clingman, Ph.D.; 301/435-5018; [clingmac@mail.nih.gov](mailto:clingmac@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 these monoclonal antibodies. For more information, please contact Robert H. Purcell, M.D., Co-chief, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 50 South Drive, Bldg. 50, Rm. 6523, Bethesda, MD 20892-8009; Phone (301) 496-5090; Fax (301) 402-0524.

### Major Neutralization Site of Hepatitis E Virus and Use of This Neutralization Site in Methods of Vaccination

**Description of Technology:** Hepatitis E is endemic in many countries throughout the developing world, in particular on the continents of Africa and Asia. The disease generally affects young adults and has a very high mortality rate, up to 20%, in pregnant women. This invention relates to the identification of a neutralization site of hepatitis E virus (HEV) and neutralizing antibodies that react with it. The neutralization site is located on a polypeptide from the ORF2 gene (capsid gene) of HEV. This neutralization site was identified using a panel of chimpanzee monoclonal antibodies that are virtually identical to human antibodies. Since this neutralization site is conserved among genetically divergent strains of HEV, the neutralizing monoclonal antibodies may be useful in the diagnosis, treatment and/or prevention of hepatitis E. Furthermore, immunogens that encompass this neutralization site may be used in vaccination to effectively prevent, and/or reduce the incidence of HEV infection. Polypeptides containing this neutralization site may be useful in evaluating vaccine candidates for the production of neutralizing antibodies to HEV.

**Inventors:** Suzanne U. Emerson (NIAID), Robert H. Purcell (NIAID), *et al.*

#### Related Publications:

1. YH Zhou *et al.* A truncated ORF2 protein contains the most immunogenic site on ORF2: antibody responses to non-vaccine sequences following challenge of vaccinated and non-vaccinated macaques with HEV. *Vaccine* 2005 May 2;23(24):3157-3165.

2. DJ Schofield *et al.* Monoclonal antibodies that neutralize HEV recognize an antigenic site at the carboxyterminus of an ORF2 protein vaccine. *Vaccine* 2003 Dec 12;22(2):257-267.

3. YH Zhou *et al.* An ELISA for putative neutralizing antibodies to hepatitis E virus detects antibodies to genotypes 1, 2, 3, and 4. *Vaccine* 2004 Jun 30;22(20):2578-2585.

**Patent Status:** U.S. Patent No. 6,930,176, issued 16 Aug 2005 (HHS Reference No. E-043-2000/0-US-04); EP Application 00982311.3, filed on 03 Nov 2000, published as 1235862 on 04 Sept 2002 (HHS Reference No. E-043-2000/0-EP-03); U.S. Patent No. 7,148,323, issued 12 Dec 2006 (HHS Reference No. E-043-2000/0-US-05)  
**Licensing Contact:** Chekesha S. Clingman, Ph.D.; 301/435-5018; [clingmac@mail.nih.gov](mailto:clingmac@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 these antibodies or structures they interact with. For more information, please contact Robert H. Purcell, M.D., Co-chief, Laboratory of Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 50 South Drive, Bldg. 50, Rm. 6523, Bethesda, MD 20892-8009; Phone (301) 496-5090; Fax (301) 402-0524.

Dated: April 17, 2007.

**Steven M. Ferguson,**

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

[FR Doc. E7-7930 Filed 4-25-07; 8:45 am]

**BILLING CODE 4140-01-P**

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