

Types of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Researchers, Physicians, Other Health Care Providers, Librarians, Students, General Public	27,910	1	.129	3,607

The annualized cost to respondents for each year of the generic clearance is estimated to be \$23,126. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: David Sharlip, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number 301-402-9680 or E-mail your request to sharlipd@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: March 23, 2009.

Betsy L. Humphreys, M.L.S.,

Deputy Director, National Library of Medicine, National Institutes of Health.

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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.

Method of Making a Vaccine

Description of Technology: Current invention describes the methods to prepare vaccines, and to use such vaccines in the vaccination and treatment of human disease, e.g., the human immunodeficiency virus (HIV) infections and cancer. More specifically, the present invention provides a vaccine and method for making same which is effective to elicit a desired antibody against a target antigen comprising a primary immunogen and a secondary immunogen, wherein the primary immunogen is effective to elicit B cell receptors (BCRs) that are on the maturational pathway of the desired antibody and have an intermediate degree of somatic mutational diversity, and the secondary immunogen comprises an epitope of the desired target antibody and is effective to further diversify the BCRs sufficient to form mature BCRs having the identical

or substantially identical sequence as the desired antibody.

Applications: Treatment and prevention of HIV infection.

Advantages: Novel methods to design vaccines for HIV treatment and prevention; May also be used for designing vaccines for cancer treatment.

Development Status: *In vitro* data available.

Market: HIV therapeutics and preventatives.

Inventor: Dimiter S. Dimitrov (NCI).

Publications:

1. MY Zhang, Y Shu, S Phogat, X Xiao, F Cham, P Bouma, A Choudhary, YR Feng, I Sanz, S Rybak, CC Broder, GV Quinnan, T Evans, DS Dimitrov. Broadly cross-reactive HIV neutralizing human monoclonal antibody Fab selected by sequential antigen panning of a phage display library. *J Immunol Methods*. 2003 Dec;283(1-2):17-25.

2. MY Zhang, X Xiao, IA Sidorov, V Choudhry, F Cham, PF Zhang, P Bouma, M Zwick, A Choudhary, DC Montefiori, CC Broder, DR Burton, GV Quinnan Jr, DS Dimitrov. Identification and characterization of a new cross-reactive human immunodeficiency virus type 1-neutralizing human monoclonal antibody. *J Virol*. 2004 Sep;78(17):9233-9242.

3. Z Zhu, AS Dimitrov, KN Bossart, G Crameri, KA Bishop, V Choudhry, BA Mungall, YR Feng, A Choudhary, MY Zhang, Y Feng, LF Wang, X Xiao, BT Eaton, CC Broder, DS Dimitrov. Potent neutralization of Hendra and Nipah viruses by human monoclonal antibodies. *J Virol*. 2006 Jan;80(2):891-899.

4. MY Zhang, V Choudhry, IA Sidorov, V Tenev, BK Vu, A Choudhary, H Lu, GM Stiegler, HW Katinger, S Jiang, CC Broder, DS Dimitrov. Selection of a novel gp41-specific HIV-1 neutralizing human antibody by competitive antigen panning. *J Immunol Methods*. 2006 Dec 20;317(1-2):21-30.

5. V Choudhry, MY Zhang, IA Sidorov, JM Louis, I Harris, AS Dimitrov, P Bouma, F Cham, A Choudhary, SM Rybak, T Fouts, DA Montefiori, CC Broder, GV Quinnan Jr, DS Dimitrov. Cross-reactive HIV-1 neutralizing monoclonal antibodies selected by screening of an immune human phage library against an envelope glycoprotein (gp140) isolated

from a patient (R2) with broadly HIV-1 neutralizing antibodies. *Virology*. 2007 Jun 20;363(1):79–90.

6. Z Zhu, S Chakraborti, Y He, A Roberts, T Sheahan, X Xiao, LE Hensley, P Prabakaran, B Rockx, IA Sidorov, D Corti, L Vogel, Y Feng, JO Kim, LF Wang, R Baric, A Lanzavecchia, KM Curtis, GJ Nabel, K Subbarao, S Jiang, DS Dimitrov. Potent cross-reactive neutralization of SARS coronavirus isolates by human monoclonal antibodies. *Proc Natl Acad Sci USA*. 2007 Jul 17;104(29):12123–12128.

7. Z Zhu, KN Bossart, KA Bishop, G Cramer, AS Dimitrov, JA McEachern, Y Feng, D Middleton, LF Wang, CC Broder, DS Dimitrov. Exceptionally potent cross-reactive neutralization of Nipah and Hendra viruses by a human monoclonal antibody. *J Infect Dis*. 2008 Mar 15;197(6):846–853.

8. MY Zhang, BK Vu, A Choudhary, H Lu, M Humbert, H Ong, M Alam, RM Ruprecht, G Quinnan, S Jiang, DC Montefiori, JR Mascola, CC Broder, BF Haynes, DS Dimitrov. Cross-reactive human immunodeficiency virus type 1-neutralizing human monoclonal antibody which recognizes a novel conformational epitope on gp41 and lacks reactivity against self antigens. *J Virol*. 2008 Jul;82(14):6869–6879.

Patent Status: U.S. Provisional Application No. 61/104,706 filed 11 Oct 2008 (HHS Reference No. E-322-2008/0-US-01).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this method. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Anti-Hepatitis C Virus Activity of the Protein Scytovirin (SVN)

Description of Technology: The invention provides compositions and methods of use for potent anti-HCV protein scytovirin to prevent and treat HCV infections. Currently there is neither effective treatment nor vaccine against HCV infection and chronic HCV infection may lead to liver cancer and death. Scytovirin can be used alone or in combination with other anti-HCV drugs for HCV treatment and prevention.

Applications: The treatment and prevention of HCV infections.

Advantages: Potent anti-HCV activity; Can be applied both systematically or locally.

Development Status: *In vitro* data available.

Market: HCV therapeutics and preventatives.

Inventors: Barry R. O'Keefe et al. (NCI).

Publications: Data collection and manuscripts may be submitted in 2009.

Patent Status: U.S. Provisional Application No. 61/137,511 filed 31 Jul 2008 (HHS Reference No. E-161-2008/0-US-01).

Related Technology: HHS Reference No. E-017-2002/0—Scytovirins and Related Conjugates, Antibodies, Compositions, Nucleic Acids, Vectors, Host Cells, Methods of Production and Methods of Using Scytovirin.

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The National Cancer Institute CCR Molecular Targets Development Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

Dated: March 19, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9-6933 Filed 3-27-09; 8:45 am]

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Treatment of Schistosomiasis Using Substituted Oxadiazole 2-Oxides

Description of Technology: Available for licensing and commercial development are pharmaceutical compositions and methods for the treatment of schistosomiasis in mammals. The various compositions are based on a number of compounds derived from 1,2,5-oxadiazole that are potent inhibitors of thioredoxin glutathione reductase (TGR), a critical parasite redox protein.

Schistosomiasis is a chronic disease caused by trematode flatworms of the genus *Schistosoma*, including *S. mansoni*, *S. japonicum* and *S. haematobium*. Adult schistosome parasites live in an aerobic environment within human hosts, and therefore must have effective mechanisms to maintain cellular redox balance. Additionally, the worms must be able to evade reactive oxygen species generated by the host's immune response. In most eukaryotes there are two major systems to detoxify reactive oxygen species, one based on the tripeptide glutathione and the other based on the protein thioredoxin. Glutathione reductase (GR) reduces glutathione disulfide, whereas thioredoxin reductases (TrxR) are pivotal in the Trx-dependent system. It was recently discovered that specialized TrxR and GR enzymes are absent in schistosomes. Instead, they are replaced by the unique multifunctional enzyme TGR. This reliance on a single enzyme for both glutathione disulfide and thioredoxin reduction suggests that the parasite's redox systems are subject to a bottleneck dependence on TGR, and that TGR represents a potentially important drug target.

Schistosomiasis remains a major and neglected health problem in many tropical areas. The health burden resulting from schistosomiasis is estimated to include more than 200 million people infected, 779 million at risk of infection, 280,000 deaths annually, and more than 20 million individuals experiencing high morbidity. Clinical manifestations of schistosomiasis infection include abdominal pain, cough, diarrhea,