

awardees to evaluate and report performance and outcome information. This information will be used by the U.S. Department of Health and Human Services (HHS) to evaluate the effectiveness and outcomes of the BTCDP. HRSA will use standard data collection forms to record the number of healthcare providers trained by profession and by course category, qualitative information on progress being achieved on approved objectives

within the cooperative agreement, and performance outcomes of healthcare providers participating in training. The data collection forms do not duplicate other data collection efforts.

The BTCDP is the only Federal program solely committed to the preparedness training of healthcare providers. As such, BTCDP awardees share curriculum, accomplishments, and lessons learned through an established network on a regular basis,

a network vital to the development of a prepared healthcare workforce. Awardees stand uniquely prepared to respond to Congressional demand for efficient and effective training within the fiscal and time constraints of this program. Collecting data from awardees regarding their performance is the first step in meeting this demand.

The estimated annual burden is as follows:

Submission type	Number of respondents	Responses per respondent	Total number of responses	Hours per response	Total burden hours
Performance and Outcome Data .....	32	1	32	16	512

Send comments to Susan G. Queen, PhD, HRSA Reports Clearance Officer, Room 10-33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 3, 2006.

**Cheryl R. Dammons,**

Director, Division of Policy Review and Coordination.

[FR Doc. E6-19087 Filed 11-9-06; 8:45 am]

BILLING CODE 4165-15-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.

**A Simian Immunodeficiency Virus Expressing HIV-1 Reverse Transcriptase for the Study of Antiviral Drug Resistance in Macaques**

*Description of Technology:* Antiviral drug-resistance is the primary source for the decreased efficacy of currently available human immunodeficiency virus-1 (HIV-1) therapies. The available material provides a model system in which to test new antiviral treatment efficacy as well as the development of multi-drug-resistance to HIV-1 reverse transcriptase inhibitors, which is a widespread obstacle of existing antiretroviral therapies. This invention describes a simian immunodeficiency virus (SIV) that expresses HIV-1 reverse transcriptase. The available virus infects and replicates in macaques and has demonstrated use in the study of drug-resistance in an animal model. This technology represents an advantage over traditional SIVs, which are not susceptible to FDA-approved antiretroviral drugs and as a result cannot be used to study HIV drug-resistance in animals. Thus, the current research tool provides a novel resource for advancing the study of drug-resistance to antiretroviral therapy and has the potential to contribute to the development of innovative therapeutic agents that are successful against drug-resistant HIV strains.

*Application:* Research and development of novel therapeutics for the treatment of drug-resistant HIV.

*Development Status:* Biological Material is sufficient for use as a research tool.

*Inventors:* Vineet N. KewalRamani and Zandra Ambrose (NCI).

*Related Publication:* Z Ambrose, V Boltz, S Palmer, JM Coffin, SH Hughes, VN KewalRamani. *In vitro*

characterization of a simian immunodeficiency virus-human immunodeficiency virus (HIV) chimera expressing HIV type 1 reverse transcriptase to study antiviral resistance in pigtail macaques. *J Virol.* 2004 Dec;78(24):13553-13561.

*Patent Status:* HHS Reference No. E-315-2006/0—Biological Material.

*Licensing Status:* Available for non-exclusive licensing under a Biological Materials License Agreement.

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

*Collaborative Research Opportunity:* The National Cancer Institute's HIV Drug Resistance Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize animal models in which to evaluate anti-HIV-1 therapy. Please contact Betty Tong, PhD at 301-594-4263 or [tongb@mail.nih.gov](mailto:tongb@mail.nih.gov) for more information.

**Anti-H5N1 Influenza Activity of the Antiviral Protein Cyanovirin**

*Description of Technology:* Influenza A viral subtype H5N1 causes avian influenza and is currently the subject of increasing international attention. Usually, avian influenza infection is limited to birds and pigs; however H5N1 has the unique capacity to bring about severe illness and death in humans. H5N1 is highly contagious, fast spreading and rapidly evolving and therefore has the potential to cause a worldwide health epidemic.

The available technology embodies methods of using a cyanovirin-N (CV-N) peptide, protein, or nucleic acid in the prevention and/or treatment of infection. Methods, which utilize CV-N in the treatment of certain influenza strains, have previously been demonstrated. However, the novel use of CV-N to treat the H5N1 strain is

unique and development of prophylactics and/or therapeutics against the virus represents a significant contribution to agriculture and public health sectors throughout the world.

**Application:** Novel therapeutics for the treatment and prevention of avian influenza.

**Development Status:** In vitro and early-stage animal studies have been performed.

**Inventors:** Barry R. O'Keefe and James B. McMahon (NCI).

**Patent Status:** U.S. Provisional Application No. 60/838,712 filed 18 Aug 2006 (HHS Reference No. E-198-2006/0-US-01).

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

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

**Collaborative Research Opportunity:** The NCI Molecular Targets Development Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize cyanovirin-N for use against H5N1 influenza. Please contact Betty Tong, PhD at 301-594-4263 or [tongb@mail.nih.gov](mailto:tongb@mail.nih.gov) for more information.

#### Methods for Treating Drug-Resistant HIV-1 Infection

**Description of Technology:** Drug-resistance is a critical factor contributing to the loss of clinical benefit of currently available human immunodeficiency virus-1 (HIV-1) therapies. Accordingly, combination therapies have evolved to address the rapidly evolving virus. However, there has been great concern regarding the growing resistance of HIV-1 strains to current therapies as multi-drug resistance to protease inhibitors is becoming more common. The current technology embodies a breakthrough against this immense obstacle of existing HIV-1 treatments.

Compositions and methods of inhibiting the protease of multi-drug resistant retroviruses such as HIV-1 are available for non-exclusive licensing and commercial development. The antiviral activity of the compound described by the current invention has been established against multi-protease inhibitor-resistant HIV-1 variants and demonstrated effective in patients with widespread resistance to currently available protease inhibitors. In addition, commercial development of this composition has resulted in the production of a novel drug that has recently been granted accelerated approval by the U.S. Food and Drug Administration (FDA) for the treatment

of HIV-1 in patients who are non-responsive to existing antiretroviral therapies.

The available composition retains the unique ability to inhibit drug resistant mutants due to its distinctive points of interaction with the enzyme: the agent tightly binds to the part of the protease substrate binding site, which the virus cannot easily change. Other "conventional" protease inhibitors bind to other parts of the protease substrate binding site, which the virus can relatively easily change, rendering these drugs ineffective after repeated use. Therefore, the current technology represents a highly effective method of targeting drug resistant HIV-1 strains.

**Applications:** (1) Novel therapeutics for the treatment of drug-resistant HIV; (2) Safe and effective methods for administration of anti-HIV/AIDS drugs.

**Development Status:** Clinical trials have been performed with Prezista™ (darunavir), a drug resulting from development of the present technology, which has received accelerated approval from the FDA.

**Inventors:** John W. Erickson (SAIC/NCI), Sergei V. Gulnik (SAIC/NCI), Hiroaki C. Mitsuya (NCI), and Arun K. Ghosh.

#### Related Publications:

1. K Yoshimura, R Kato, MF Kavlick, A Nguyen, V Maroun, K Maeda, KA Hussain, AK Ghosh, SV Gulnik, JW Erickson, H Mitsuya. A potent human immunodeficiency virus type 1 protease Inhibitor, UIC-94003 (TMC 126), and selection of a novel (A28S) mutation in the protease active site. *J Virol.* 2002 Feb;76(3):1349-1358.

2. Y Koh, K Maeda, H Ogata, G Bilcer, T Devasamudram, JF Kincaid, P Boross, Y-F Wang, Y Tie, P Volarath, L Gaddis, JM Louis, RW Harrison, IT Weber, AK Ghosh, H Mitsuya. Novel bis tetrahydrofuran-urethane-containing nonpeptidic protease inhibitor (PI) UIC-94017 (TMC114) potent against multi-PI-resistant human immunodeficiency virus in vitro. *Antimicrob Agents Chemother.* 2003 Oct;47(10):3123-3129.

3. AK Ghosh, PR Sridhar, S Leshchenko, AK Hussain, J Li, AY Kovalevsky, DE Walters, JE Wedekind, V Grum-Tokars, D Das, H Mitsuya. Structure-based design of novel HIV-1 protease inhibitors to combat drug resistance. *J Med Chem.* 2006 Aug 24; 49(17):5252-5261.

4. AK Ghosh, P Ramu Sridhar, N Kumaragurubaran, Y Koh, IT Weber, H Mitsuya. Bis-tetrahydrofuran: a privileged ligand for darunavir and a new generation of HIV protease inhibitors that combat drug resistance. *ChemMedChem.* 2006 Sep;1(9):939-950.

**Patent Status:** U.S. Patent Application No. 09/720,276 filed 07 Mar 2001 (HHS Reference No. E-200-1998/0-US-02); European Patent Application No. 99931861.1 filed 23 Jun 1999 (HHS Reference No. E-200-1998/0-EP 08).

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

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

Dated: November 3, 2006.

#### Steven M. Ferguson,

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

[FR Doc. E6-19050 Filed 11-9-06; 8:45 am]

BILLING CODE 4140-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of the Director, National Institutes of Health, Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, NIH.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

**Name of Committee:** Advisory Committee to the Director, NIH.

**Date:** December 1, 2006.

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

**Agenda:** Among the topics proposed for discussion are: (1) NIH Director's Report; (2) NIH Director's Council of Public Representatives Liaison Report; (3) Institute Director's Report; and (4) Work Group on Outside Awards for NIH Employees.

**Place:** National Institutes of Health, Building 31, C Wing, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892.

**Contact Person:** Shelly Pollard, ACD Coordinator, National Institutes of Health, 9000 Rockville Pike, Building 31, Room 5B64, Bethesda, MD 20892. (301) 496-0959.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a