

preclinical microbicide evaluation studies. CV-N has the potential to become a microbicide useful in preventing sexual transmission of HIV. An effective anti-HIV microbicide could slow down the spread of the virus in the population, especially in the developing world, before an effective vaccine is available.

The field of use may be limited to the topical use of commensal bacteria that express cyanovirin-N.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: February 2, 2007.

**Steven M. Ferguson,**

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

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## 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.

#### Integrase Inhibitors for the Treatment of Retroviral Infection Including Human Immunodeficiency Virus-1

*Description of Technology:* Available for licensing and commercial development are stilbenedisulfonic acid derivatives for treatment of human immunodeficiency virus-1 (HIV-1) and other retroviral infections. Current HIV-1 therapeutic treatments target the viral protease and reverse transcriptase enzymes, which are essential for retroviral infection. However, these drugs often have limitations due to drug resistant variants, which render drugs ineffective. Additionally, such drugs are often toxic when administered in combination therapies. Thus, efficacious inhibitors of retroviral infection that are devoid of toxicity are presently needed.

The subject invention describes stilbenedisulfonic acid derivatives, which target the integrase enzyme of retroviruses. Similar to protease and reverse transcriptase activity, integrase function is essential for retroviral infection. Integrase catalyzes integration of reverse transcribed viral DNA into a host cell's genome. For this reason, integrase is considered a rational therapeutic target for HIV-1 infection. Further, integrase is a favorable target because the enzyme has no human cellular counterpart, which could interact with a potential integrase inhibitor and cause harmful side effects. Recent clinical data with an integrase inhibitor from Merck shows impressive clinical activity. The Merck compound is different from the current invention and is projected for FDA approval mid 2007. Thus, the subject invention is valuable for safe and effective treatment of HIV-1 and other retroviral infections.

*Application:* Treatment of HIV infection.

*Development Status:* The technology is ready for use in drug discovery and development.

*Inventors:* Yves Pommier (NCI), Elena Semenova (NCI), Christophe Marchand (NCI).

*Patent Status:* U.S. Provisional Application No. 60/849,718 filed 04 Oct 2006 (HHS Reference No. E-264-2006/0-US-01).

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

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

#### Broadly Cross-Reactive Neutralizing Antibodies Against Human Immunodeficiency Virus Selected by ENV-CD4-CO-Receptor Complexes

*Description of Technology:* This invention provides a novel anti-HIV human monoclonal antibody named X5.

This antibody demonstrates promise over conventional anti-HIV antibodies because the X5 antibody exhibits a unique binding activity compared to its counterparts. It has been established that the initial stage of HIV-1 entry into cells is mediated by a complex between the viral envelope glycoprotein (Env) such as gp120-gp41, a receptor CD4 and a co-receptor CCR5. The X5 antibody binds to an epitope on gp120 that is induced by interaction between gp120 and the receptor CD4 and enhanced by the co-receptor CCR5. The X5 antibody also shows strong activity at very low levels (in the range from 0.0001-0.1 Mg/ml concentration is dependent on the isolate). Because it is a human antibody, it can be administered directly into patients so that it is an ideal candidate for clinical trials. It also can be easily produced because it was obtained by screening of phage display libraries and its sequence is known. Finally, since it has neutralized all virus envelope glycoproteins, including those from primary isolates of different clades, the epitope is highly conserved and resistance is unlikely to develop. Therefore, this antibody and/or its derivatives including fusion proteins with CD4 are good candidates for clinical development.

Additional information on the current research in Dr. Dimitrov's laboratory may be found at <http://www-lecb.ncifcrf.gov/dimitrov/dimitrov.html>.

*Applications:* Antibody for HIV research, diagnostics and therapeutic development.

*Development Status:* Preclinical data is available at this time.

*Inventors:* Dimitar Dimitrov (NCI), Xiadong Xiao (NCI), Yuuei Shu (NCI), Sanjay Phogat (NIAID), *et al.*

*Patent Status:* Patent Cooperation Treaty Serial No. PCT/US02/33165 filed 16 Oct 2002; National Stage Filing in United States, India, Canada, Australia, Europe (HHS Reference No. E-130-2001/0).

*Availability:* Available for licensing and commercial development, excluding the field of use of the development of the PEGylated X5, PEGylated X5 derivatives, mutants of PEGylated X5 or a derivative.

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

*Collaborative Research Opportunity:* The NCI Center for Cancer Research Nanobiology Program (CCRNBP) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize antibodies for HIV research, diagnostics and therapeutic development. Please contact John D. Hewes, Ph.D. at (301

435-3121 or [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov) for more information.

Dated: February 2, 2007.

**Steven M. Ferguson,**

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

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**National Institutes of Health**

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**Conditional Expression of the Transcription Factor ARNT in a Mouse Model**

*Description of Technology:* The aryl hydrocarbon receptor nuclear translocator (Arnt) protein is a transcription factor that plays an important role in mammalian development and physiological homeostasis. A member of the PAS domain/bHLH family of transcription factors, it is an obligate dimerization partner with other members of this family, such as the aryl hydrocarbon receptor (AHR) and hypoxia-inducible factor 1alpha (HIF1alpha). It was shown to be a critical factor in control of gene expression in a number of tissues including ovary, vascular endothelium, keratinocytes, and T-cells.

Available for licensing is a mouse line homozygous for floxed alleles of the *Arnt* gene. This mouse line can be used to disrupt the *Arnt* gene in different tissues by breeding the *Arnt*-floxed mice with transgenic mice in which the Cre recombinase is under the control of tissue-specific promoters. These mice can be used as a research tool for drug development where PAS/bHLH transcription factors are targeted.

*Applications:* Tool for drug studies targeting PAS/bHLH transcription factors; Tool to probe the role of the Arnt protein in a tissue-specific manner.

*Inventors:* Frank J. Gonzalez (NCL).

*Related Publications:*

1. S. Tomita, C.J. Sinal, S.H. Yim, and F.J. Gonzalez. Conditional disruption of the aryl hydrocarbon receptor nuclear translocator (*Arnt*) gene leads to loss of target gene induction by the aryl hydrocarbon receptor and hypoxia-inducible factor 1alpha. *Mol Endocrinol.* 2000 Oct;14(10):1674-1681.

2. S.H. Yim, Y. Shah, S. Tomita, H.D. Morris, O. Gavrilova, G. Lambert, J.M. Ward, and F.J. Gonzalez. Disruption of the *Arnt* gene in endothelial cells causes hepatic vascular defects and partial embryonic lethality in mice. *Hepatology.* 2006 Sep;44(3):550-560.

*Licensing Status:* This technology is available as a research tool under a Biological Materials License.

*Patent Status:* HHS Reference No. E-047-2007/0—Research Tool.

*Licensing Contact:* Tara L. Kirby, Ph.D.; 301/435-4426; [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov).

**Nanopore Structured Biosensors**

*Description of Technology:* Available for licensing and commercial development is a new glucose monitor system developed for direct glucose measurement without the use of mediators and glucose enzymes. Nanopore structured glucose sensors with special membrane bearing receptors mimic the function of the glucose oxidase and show the ability to directly measure glucose with high precision and accuracy; especially for measuring hypoglycemia and hyperglycemia ranges. These inventions provide improvements for type I and type II diabetes patients over commercial meters which lack the accuracy at the lower glucose range.

*Application:* Diagnostics.

*Market:* Diabetes.

*Development Status:* Early-stage.

*Inventors:* Ellen T. Chen (FDA) et al.

*Related Publications:*

1. E.T. Chen and J. Thornton. Novel nanopore structured glucose biosensors promote reagentless glucose concentration measurements in the

hypoglycemic range. Abstract presented at FDA Science Forum, April 2005, Washington, DC.

2. E.T. Chen. Amperometric biomimetic enzyme sensors based on modified cyclodextrin as electrocatalysts. U.S. Patent No. 6,582,583 issued 24 Jun 2003.

*Patent Status:* U.S. Provisional Application No. 60/792,902 filed 19 Apr 2006 (HHS Reference No. E-185-2006/0-US-01).

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

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

**Human Neutralizing Monoclonal Antibodies to Respiratory Syncytial Virus and Human Neutralizing Antibodies to Respiratory Syncytial Virus**

*Description of Technology:* This invention is a human monoclonal antibody fragment (Fab) discovered utilizing phage display technology. It is described in Crowe et al., *Proc Natl Acad Sci USA.* 1994 Feb 15;91(4):1386-1390 and Barbas et al., *Proc Natl Acad Sci USA.* 1992 Nov 1;89(21):10164-10168. This MAb binds an epitope on the RSV F glycoprotein at amino acid 266 with an affinity of approximately  $10^9 M^{-1}$ . This MAb neutralized each of 10 subgroup A and 9 subgroup B RSV strains with high efficiency. It was effective in reducing the amount of RSV in lungs of RSV-infected cotton rats 24 hours after treatment, and successive treatments caused an even greater reduction in the amount of RSV detected.

*Applications:* Research and drug development for treatment of respiratory syncytial virus.

*Inventors:* Robert M. Chanock (NIAID), Brian R. Murphy (NIAID), James E. Crowe, Jr. (NIAID), et al.

*Patent Status:* U.S. Patent 5,762,905 issued 09 Jun 1998 (HHS Reference No. E-032-1993/1-US-01); U.S. Patent 6,685,942 issued 03 Feb 2004 (HHS Reference No. E-032-1993/1-US-02); U.S. Patent Application No. 10/768,952 filed 29 Jan 2004 (HHS Reference No. E-032-1993/1-US-03).

*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).

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**Steven M. Ferguson,**

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

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