

*Intellectual Property:* HHS Reference No. E-208-2003/0—U.S. Patent No. 7,655,752 issued 02 Feb 2010.

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

### Human Antibodies and Fusion Proteins With Potent and Broad HIV-1 Neutralizing Activity

*Description of Technology:* The inventions listed below provide multiple novel human anti-HIV-1 domain antibodies (m36 and its affinity-matured versions) and their fusion proteins with two-domain or single-domain human soluble CD4 (sCD4) that can potentially be used alone or synergistically with other anti-HIV-1 antibodies and antiretroviral drugs as therapeutics and/or preventatives for infection by different HIV-1 strains.

Some of the inventions listed below also describe some fusion proteins as vaccine immunogens that could elicit broadly neutralizing antibodies against HIV-isolates from different clades. One invention also describes the methods to prepare and use the immunogens in the vaccination for prevention of HIV-1 infections. More specifically, the later invention provides a vaccine composed of a primary immunogen and a secondary immunogen, and a method for making the vaccine which could be effective in eliciting desired broadly neutralizing antibodies. The primary immunogen could be effective in activating B cell receptors (BCRs) that are on the maturational pathways of the desired antibodies and have an intermediate degree of somatic mutational diversity. The secondary immunogen contains epitopes of the desired antibodies and could be effective in further diversifying the BCRs sufficiently to form mature BCRs that have the identical or substantially identical sequence as the desired antibodies.

*Potential Commercial Applications:* Treatment and prevention of HIV-1 infections.

#### *Competitive Advantages:*

- Elicits broadly neutralizing antibodies against HIV-1 isolates from different clades.
- Potentially elicits antibodies that are not regulated by tolerance mechanisms.
- Novel methods to design vaccines for HIV-1 treatment and prevention.
- May also be used for designing vaccines for cancer treatment.
- Relatively small size allows for potential penetration into lymphoid tissues.

#### *Development Stage:*

- In vitro data available.
- In vivo data available (animal).

*Inventors:* Dimiter Dimitrov and Weizao Chen (NCI).

#### *Publications:*

1. Chen W, *et al.* Human domain antibodies to conserved sterically restricted regions on gp120 as exceptionally potent cross-reactive HIV-1 neutralizers. *Proc Natl Acad Sci USA*. 2008 Nov 4;105(44):17121-6. [PMID 18957538].

2. Chen W, *et al.* Engineered single human CD4 domains as potent HIV-1 inhibitors and components of vaccine immunogens. *J Virol*. 2011 Sep;85(18):9395-405. [PMID 21715496].

3. Chen W, *et al.* Bifunctional fusion proteins of the human engineered antibody domain m36 with human soluble CD4 are potent inhibitors of diverse HIV-1 isolates. *Antiviral Res*. 2010 Oct;88(1):107-15. [PMID 20709110].

4. Chen W, Dimitrov DS. Human monoclonal antibodies and engineered antibody domains as HIV entry inhibitors. *Curr Opin HIV AIDS*. 2009 Mar;4(2):112-7. [PMID 19339949].

#### *Intellectual Property:*

- HHS Reference No. E-043-2008/0—U.S. Patent Application No. 12/811,998 filed 07 Jul 2010; related international applications.

- HHS Reference No. E-322-2008/0—U.S. Patent Application No. 13/123,659 filed 11 Apr 2011.

- HHS Reference No. E-103-2010/1—PCT Application No. PCT/US2011/037439 filed 20 May 2011, which published as WO 2011-146891 on 31 May 2012.

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

*Collaborative Research Opportunity:* The NCI CCR Nanobiology Program is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize m36, single domain sCD4, and related fusion proteins as candidate therapeutics against HIV-1. For collaboration opportunities, please contact John Hewes, Ph.D. at [hewesj@mail.nih.gov](mailto:hewesj@mail.nih.gov).

Dated: September 27, 2012.

**Richard U. Rodriguez,**

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

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**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of General Medical Sciences Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 General Medical Sciences Special Emphasis Panel; Phase III Antibiotic Clinical Trials.

*Date:* November 1, 2012.

*Time:* 11 a.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Natcher Building, 45 Center Drive, Room 3An18K, Bethesda, MD 20892.

*Contact Person:* Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An18, Bethesda, MD 20892, 301-594-3907, [pikbr@mail.nih.gov](mailto:pikbr@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: September 27, 2012.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as