



**[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, HHS.

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S.

Government and is available for licensing.

**FOR FURTHER INFORMATION CONTACT:** Dr. Vince Contreras, 240-669-2823; vince.contreras@nih.gov. Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301-496-2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

**SUPPLEMENTARY INFORMATION:** Technology description follows.

**Optimized variants of the broadly neutralizing HIV-1 gp41 antibody, 10E8**

**Description of Technology:**

Scientists at the National Institute of Allergy and Infectious Diseases (NIAID) recently discovered a human neutralizing antibody, 10E8, that binds to the GP41 protein of HIV-1 and prevents infection by HIV-1. 10E8 potently neutralizes up to 98% of genetically diverse HIV-1 strains.

By engineering the 10E8 antibody, NIAID scientists have improved the properties of 10E8 that affect manufacturability, such as solubility, while preserving its neutralizing breadth and potency.

10E8 variants are useful for passive protection from infection, as therapeutics, and as a tool for vaccine development.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR Part 404.

**Potential Commercial Applications:**

- Passive protection to prevent HIV infection
- Passive protection to prevent mother-to-infant HIV transmission
- Gene-based vectors for anti-gp41 antibody expression
- Therapeutics for elimination of HIV infected cells that are actively producing virus

**Competitive Advantages:**

- Among the most potent and broadly neutralizing human antibodies isolated to date
- Broad reactivity and high affinity to most HIV-1 strains
- Improved manufacturability relative to the natural 10E8 antibody

**Development Stage:**

- In vivo data available (animal)

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**Publications:** Kwon, Y.D. et al. (2016) Optimization of the Solubility of HIV-1-Neutralizing Antibody 10E8 through Somatic Variation and Structure-Based Design. *J Virol.* 90(13): 5899-914. [PMID: 27053554]

**Intellectual Property:** HHS Reference Number E-133-2015 includes Patent Cooperation Treaty Application Number PCT/US2016/060390 filed November 3, 2016; Canadian Patent Application Number 3003878 filed May 1, 2018; China Patent Application Number TBD filed May 1, 2018; European Patent Application Number 16801639.2 filed June 1, 2018; India Patent Application Number 20187016184 filed 30 April 2018; U.S. Patent Application Number 15/772,443 filed 30 April 2018; South

Africa Patent Application Number 2018/02875 filed 2 May 2018; Australia Patent Application Number 2016349392 filed 4 May 2018.

**Related Intellectual Property:** HHS Reference Number E-253-2011

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