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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Start-up Exclusive Evaluation Option License: A Novel HIV-1 Entry Inhibitor**

**AGENCY:** National Institutes of Health, HHS

**ACTION:** Notice

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of a start-up exclusive evaluation option license agreement to practice the inventions embodied in U.S. Provisional Patent Application No. 61/791,885 (NIH Ref. No. E-033-2013/0-US-01), filed March 15, 2013; International PCT Application No. PCT/US2014/024120 (NIH Ref. No. E-033-2013/1-PCT-01), filed March 12, 2014; all entitled, “Stabilized Single Human CD4 Domains and Fusion Proteins;” and all continuing applications and foreign counterparts to Absino Co., Ltd, a company having a place of business in Beijing, China.

The patent rights in these inventions have (a) been assigned to the United States of America, as represented by the Secretary, Department of Health and Human Services who has delegated authority for the licensing of inventions to the National Institutes of Health or (b) been exclusively licensed to the National Institutes of Health.

The prospective start-up exclusive evaluation option license territory may be China, the U.S., and Europe, and the field of use may be limited to the development of bispecific multivalent human immunodeficiency virus type 1 (HIV-1) neutralizing fusion proteins as HIV entry inhibitors for the treatment of HIV infections.

Upon the expiration or termination of the start-up exclusive evaluation option license, Absino Co., Ltd will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the start-up exclusive evaluation option license with no greater field of use and territory than granted in the start-up exclusive evaluation option license.

**DATES:** Only written comments and /or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date fifteen (15) days from date of publication of notice in the FEDERAL REGISTER] will be considered.

**ADDRESS:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated start-up exclusive evaluation option license should be directed to: Sally Hu, Ph.D., M.B.A., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard,

Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5606; Facsimile: (301) 402-0220; E-mail: [hus@mail.nih.gov](mailto:hus@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The subject technology is HIV-1 entry inhibitors that can neutralize many subtypes of HIV-1 isolates including clade A-E and tropism R5 and X4 (using either CCR5 or CXCR4 co-receptor for entry). These entry inhibitors are fusion proteins and have a potency about 10-fold higher than that of the broadly neutralizing antibody VRC01 that is in Phase I clinical trial, or 50-fold higher than that of the FDA approved HIV entry inhibitor Fuzeon. Therefore, these fusion proteins are promising drug candidates for HIV/AIDS prevention and treatment.

The prospective start-up exclusive evaluation option license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404. The prospective start-up exclusive evaluation option license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated start-up exclusive evaluation option license. Comments and objections submitted 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: June 16, 2015

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Richard U. Rodriguez, M.B.A.

Acting Director

Office of Technology Transfer

National Institutes of Health

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