[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent Commercialization License: N6, A Novel, Broad, Highly Potent HIV-Specific Antibody

AGENCY: National Institutes of Health.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases (NIAID), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent commercialization license to GlaxoSmithKline Intellectual Property Development Ltd (GSK) located at 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom, to practice the inventions embodied in the patent applications listed in the Supplementary Information section of this notice.

DATES: Only written comments and/or applications for a license which are received by the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated exclusive patent commercialization license should be directed to: Chris Kornak, Lead Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Suite 6D, MSC 9804, Rockville, MD 20852-9804, phone number 301-496-2644, or chris.kornak@nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement: HHS Reference No. E-131-2015/0-US-01, United States Provisonal Patent Application Serial No. 62/136,228, filed on 03/20/2015; HHS Reference No. E-131-2015/1-US-01, United States Provisional Patent Application Serial No. 62/250,378 filed on 11/03/2015; HHS Reference No. E-131-2015/2-PCT-01, PCT Patent Application Serial No. PCT/US2016/023145, filed on 03/18/2016; HHS Reference No. E-131-2015/2-US-07, United States Patent Application Serial No 15/559,791, filed on 09/19/2017; HHS Reference No. E-131-2015/2-EP-05, European Patent Application Serial No. 16716979.6, filed on 10/19/2017; HHS Reference No. E-131-2015/2-CA-03, Canadian Patent Application Serial No. 2,980,005, filed on 09/15/2017; HHS Reference No. E-131-2015/2-AU-02, Australian Patent Application Serial No. 2016235541, filed on 09/08/2017; HHS Reference No. E-131-2015/2-CN-04, filing in process, HHS Reference No. E-131-2015/2-ZA-08, South African Patent Application Serial No. 2017/06155, filed on 09/11/2017; and HHS Reference No. E-131-2015/2-IN-06, Indian Patent Application Serial No. 201737032671, filed on 09/14/2017.

All rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive patent commercialization license territory may be worldwide and the field of use may be limited to: "Administration to humans of a GP120-binding protein or proteins, containing the 6 CDRs of the N6 antibody, all as described in the Licensed Patent Rights. This field of use does not include bi-specific/multi-specific constructs utilizing the Licensed Patent Rights."

The N6 antibody has evolved a unique mode of binding that depends less on a variable area of the HIV envelope known as the V5 region and focuses more on conserved regions, which change relatively little among HIV strains. This allows N6 to tolerate changes in the HIV envelope, including the attachment of sugars in the V5 region, a major mechanism by which HIV develops resistance to other VRC01-class antibodies. N6 was shown in pre-clinical studies to neutralize approximately 98 percent of HIV isolates tested. The studies also demonstrate that N6 neutralizes approximately 80 percent of HIV isolates which were resistant to other antibodies of the same class, and does so very potently. Its breadth and potency makes N6 a highly desirable candidate for development in therapeutic or prophylactic strategies. An abstract of the subject invention was published in the Federal Register on March 13, 2017.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive patent commercialization license will be royalty bearing and may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Allergy and Infectious Diseases 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.

Complete applications for a license in the prospective field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent commercialization 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.

_____

Suzanne Frisbie,
Deputy Director,
Technology Transfer and Intellectual Property Office,
National Institute of Allergy and Infectious Diseases.

[FR Doc. 2017-25745 Filed: 11/28/2017 8:45 am; Publication Date: 11/29/2017]