[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 and A Broadly Neutralizing Human Anti-HIV Monoclonal Antibody (10E8) Capable of Neutralizing Most HIV-1 Strains

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 RNAceuticals, Inc. located at 12 Indian Trail Road, Woodbridge, CT, USA 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 240-627-3705; E-mail: chris.kornak@nih.gov.

SUPPLEMENTARY INFORMATION:

The following represents the intellectual property to be licensed under the prospective agreement.

N6: To date, NIAID has filed the following patent applications for this matter: two U.S. Provisionals (E-131-2015-0-US-01, 62/136,228, filed on 03/20/2015 and E-131-2015-1-US-01, 62/250,378 filed on 11/03/2015) that were combined into one PCT Application (E-131-2015-2-PCT-01, PCT/US2016/023145, filed on 03/18/2016), and entered the national stage in the United States (E-131-2015-2-US-07, 15/559,791, filed on 09/19/2017 and E-131-2015-2-US-09, 16/786,267, filed on 02/10/2020), Europe (E-131-2015-2-EP-05, 16716979.6 and E-131-2015-2-EP-10, 20156388.9), Canada (E-131-2015-2-CA-03, 2,980,005), Australia (E-131-2015-2-AU-02, 2016235541), China (E-131-2015-2-CN-04, 201680028822.8), South Africa (E-131-2015-2-ZA-08, 2017/06155), and India (E-131-2015-2-IN-06, 201737032671).

10E8: NIAID has filed the following patent applications for this matter, three U.S. Provisionals (E-253-2011-0-US-01, 61/556,660, filed on 11/07/2011, E-253-2011-1-US-01, 61/672,708, filed on 07/17/2012, and E-253-2011-2-US-01, 61/698,480, filed on

09/07/2012) that were combined into one PCT application (E-253-2011-3-PCT-01, PCT/US2012/063958, filed on 11/07/2012), and entered the national stage, in seven countries: United States (E-253-2011-3-US-05, 14/356,557, filed on 05/06/2014, E-253-2011-4-US-01, 14/450,773, filed on 08/04/2014, E-253-2011-3-US-09, 15/226,744, filed on 08/02/2016, E-253-2011-3-US-13, 15/699,902, filed on 09/08/2017), Europe (E-253-2011-3-EP-03, 12847241.2), China (E-253-2011-3-CN-02, 201280065580.1), India (E-253-2011-3-IN-04, 3678/DELNP/2014), South Africa (E-253-2011-3-ZA-06, 2014/03264), Brazil (E-253-2011-3-BR-07, BR112014010823-4), and Russia (E-253-2011-3-RU-08, 2014118462).

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: (1) Administration to humans of DNA and/or RNA including without limitation modified RNA encoding a protein or proteins, containing all or some of the CDRs of N6 and (2) Administration to humans of DNA and/or RNA including without limitation modified RNA encoding a protein or proteins, containing all or some of the CDRs of 10E8.

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 for this invention was published in the Federal Register on March 13, 2017.

The other invention, 10E8, has great potential to provide passive protection from infection, as a therapeutic, or as a tool for the development of vaccine immunogens. 10E8 is one of the most potent HIV-neutralizing antibodies isolated thus far and it can potently neutralize up to 98% of genetically diverse HIV-1 strains. 10E8 is specific to the membrane-proximal external region (MPER) of the HIV envelope protein, GP41. An abstract for this invention was published in the Federal Register on April 24th, 2012 and June 24th, 2014.

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. In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available. License

applications submitted in response to this notice will be presumed to contain business confidential information. and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

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Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

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