



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development, Production, and Commercialization of Ebola Neutralizing Single Monoclonal Antibody for the Treatment of Ebola Virus Disease in Humans

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the U.S. and European Patents and Patent Applications listed in the Supplementary Information section of this Notice to Ridgeback Biotherapeutics, L.P., located in Miami, Florida.

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

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Daniel Lee, J.D., Technology Transfer and Patent Specialist, National Institute of Allergy and Infectious Diseases Technology Transfer and Intellectual Property Office by email (daniel.lee5@nih.gov) or phone (301-761-6327).

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-045-2015: Neutralizing Antibodies to Ebolavirus Glycoprotein and Their Use

1. United States Provisional Patent Application No. 62/087,087, filed 3 December 2014 (HHS Reference No. E-045-2015-0-US-01);
2. International Patent Application No. PCT/US2015/060733, filed 13 November 2015 (HHS Reference No. E-045-2015-0-PCT-02);
3. European Patent Application No. 15797815.6, filed 13 November 2015 (HHS Reference No. E-045-2015-0-EP-03); and
4. United States Patent No. 10,273,288, issued 30 April 2019 (HHS Reference No. E-045-2015-0-US-05).

The patent and patent application rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the fields of use may be limited to the following: development, production, and commercialization of Ebola neutralizing monoclonal antibody mAb114, as a single antibody not in combination with other monoclonal antibodies, for the treatment of Ebola virus disease in humans.

This technology discloses the discovery, isolation, production, and advancement in the development of recombinant neutralizing antibodies specific to the Ebola virus glycoprotein, varying Ebola virus glycoprotein recognition profiles, and increasing neutralization potency for a therapeutic in a patient diagnosed with Ebola virus.

This Notice is made in accordance with 35 U.S.C. § 209 and 37 C.F.R. § 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license 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 C.F.R. § 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.

Dated: February 26, 2021.

Surekha Vathyam,

Deputy Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021-05235 Filed: 3/12/2021 8:45 am; Publication Date: 3/15/2021]