[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive License: Biomarkers for Acute Ischemic Stroke

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 co-exclusive patent license to practice the inventions embodied in U.S. Patent Application No. 13/580,571 filed 22 August, 2012 and entitled "Biomarkers for Acute Ischemic Stroke" [HHS Ref. No. E-023-2010/0-US-03] to CereDx, Inc., which is located in West Virginia. The patent rights in this invention have been assigned to the United States of America.

The prospective co-exclusive license territory may be worldwide and the field of use may be limited to the use of the diagnostics of ischemic stroke.

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 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered. This notice updates the Federal Register Notice published in 80 FR 28633, Tuesday May 19, 2015.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated co-exclusive license should be directed to: Uri Reichman, Ph.D, MBA, Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD. 20852-3804. Telephone: (301) 435-4616; Facsimile: (301) 402-0220; E-mail: reichmau@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This technology is directed to gene biomarkers for the diagnosis and potential treatment of acute ischemic stroke. Stroke is the third leading cause of death in the United States, of which 87% are ischemic stroke and result in death within 30 days in 8-12% of the cases. Currently, recombinant tissue plasminogen activator (rtPA, trade name alteplase), is the only FDA approved ischemic stroke treatment, and it is only effective when administered to patients within three hours from the onset of symptoms. Unfortunately, the median time from stroke symptom onset to presentation to the emergency department is 3-6 hours. Although advances in neuroimaging and clinical management have helped with patient survival rates, these techniques are not infallible and at times result in misdiagnosis. The biomarkers

identified in this technology may be used to develop a diagnostic testing device for determining stroke subtype in the field.

The prospective co-exclusive 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 co-exclusive license may be granted unless within thirty (30) 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 co-exclusive 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: August 28, 2015.

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Richard U. Rodriguez,
Acting Director,
Office of Technology Transfer,
National Institutes of Health.

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