[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of 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 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive license, to practice the inventions embodied in the following patent applications:

1. U.S. Provisional Patent Application No. 61/307,233, filed 23 February 2010
   HHS Ref. No.: E-023-2010/0-US-01
   Titled: Biomarkers for Acute Ischemic Stroke

2. PCT Patent Application No. PCT/US2011/025748, filed 22 February 2011
   HHS Ref. No.: E-023-2010/0-PCT-02
   Titled: Biomarkers for Acute Ischemic Stroke

3. U.S. Patent Application No. 13/580,571, filed 22 August 2012
   HHS Ref. No.: E-023-2010/0-US-03
   Titled: Biomarkers for Acute Ischemic Stroke

to VuEssence, Inc., a company incorporated under the laws of the State of Florida having its headquarters in Odessa, Florida. The patent rights in these inventions have been assigned to the United States of America.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for a copy of the patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Jaime M. Greene, M.S., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5559; E-mail: greenejaime@mail.nih.gov; Facsimile: (301) 402-0220. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

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 exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published notice, 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 404.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated 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.

Dated: May 12, 2015.

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

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