Dated: March 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–06498 Filed 3–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Theranostic Kits for mTOR Analog-based Chemotherapy

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 to ProVivoX, Inc., of an exclusive evaluation option license to practice the inventions embodied in the following US Patent, US Patent Application, and International Patent Application (and all foreign counterparts): US Provisional Patent Application Serial No. 61/144,501, filed 14 January 2009, entitled: ''Ratio-based Biomarker of Survival Utilizing PTEN and Phospho-AKT'' [HHS Reference No. E–025–2009/0–US–01]; International Application No. PCT/US2010/020944, filed on 13 January 2010, entitled: ''Ratio-based Biomarkers and Methods of Use Thereof'' [HHS Reference No. E–025–2009/0–PCT–02]; US Patent Application Serial No. 13/144,474, filed 13 July 2011 [HHS Reference No. E–025–2009/0–US–02]; and Canadian Patent Application No. 2,749,601, filed on 13 January 2010 [HHS Reference No. E–025–2009/0–CA–05]. The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be United States and Canada, and the field of use may be limited to:

a. ''Exclusive use of the Licensed Patent Rights to develop an immunohistochemistry (IHC)- or tissue microarray-based test kit for use with human tissue samples and approved in the United States and Canada as a Class III medical device, such test kit to be distributed in commerce for the for the purpose of predicting survival, response to therapy, or cancer recurrence in breast cancer patients.''

b. ''Non-exclusive use of the Licensed Patent Rights to develop an immunohistochemistry (IHC)- or tissue microarray-based test kit for use with human tissue samples and for which the United States FDA issues an order, in the form of a letter, which finds Licensee's kit to be a medical device substantially equivalent to one or more similar legally marketed devices, and states that the Licensee's device can be marketed in the U.S. (*i.e.,* 510(k) cleared), such test kit to be distributed in commerce for the purpose of predicting survival, response to therapy, or cancer recurrence in breast cancer patients.''

Upon the expiration or termination of the exclusive evaluation option license, ProVivoX, Inc., will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before April 7, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; Email: *mccuepat@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The technology describes a method of identifying cancer patients that may benefit from mTOR analog-based chemotherapy or agents directed against the AKT pathway.

The prospective exclusive evaluation license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization license, may be granted unless 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 within fifteen (15) days from the date of this published notice.

Complete 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 exclusive evaluation option 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: March 17, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–06487 Filed 3–20–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil (NHLBI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the FR in Volume 79 on December 31, 2014 on page 78876 and allowed 60-days for public comment. One public comment was received that was a personal opinion regarding conducting research about the Brazil blood donation system. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments To Omb: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Simone Glynn, MD, Project Officer/ICD Contact, Two Rockledge