DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 28, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, 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) 451–7337; Facsimile: (301) 402–0220; Email: *hastingw@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: Granulysin is a cytolytic and proinflammatory molecule expressed by activated human cytotoxic T lymphocytes (CTLs) and natural killer (NK) cells when they are attached to disease cells including infection, cancer, transplantation, autoimmunity, skin and reproductive maladies. Granulysin is made in a 15-kDa form that is cleaved into a 9-kDa form at both the amino and the carboxy termini. Granulysin is broadly cytolytic against tumors and microbes. It has been implicated in many of diseases and studies suggest that granulysin may be a useful therapeutic directly contributing to immunity against foreign molecules for a wide variety of diseases.

This technology describes the use of 15 kD granulysin for enhancing immune responses.

Investigators at the NIH have discovered that 15 kD granulysin activates monocytes and induces them to differentiate into mature dendritic cells and activates allospecific T cells.

The proof of this principle was demonstrated by mice expressing granulysin *in vivo* showing markedly improved anti-tumor responses, with increased numbers of activated dendritic cells and cytokine-producing T cells. Furthermore, current data suggest that dendritic cells matured with 15 kD granulysin are superior to the well-established GM–CSF induction. There appears to be a significant market opportunity for use of the 15 kD granulysin for the *ex vivo* dendritic cell maturation and adoptive immunotherapy.

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: July 10, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–16267 Filed 7–10–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Evaluation Option Exclusive License: Development of a Diagnostic and Prognostic for Breast and Prostate Cancer Using Spatial Genome Organization

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, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions embodied in U.S. Provisional Application 61/094,318 filed September 4, 2008 entitled ''Method for detection of cancer based on spatial genome organization'' (HHS Ref No. E–283–2008/0–US–01); International Application PCT/US2009/055857 filed September 3, 2009 entitled ''Method for detection of cancer based on spatial genome organization'' (HHS Ref No. E–283–2008/0–PCT–02); U.S. Patent Application 13/062,247 filed March 4, 2011 entitled ''Method for detection of cancer based on spatial genome organization'' (HHS Ref No. E–283–2008/0–US–0; and foreign equivalents thereof to Radial Genomics, Ltd. (''RG''), a company located in Cambridge, U.K. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive evaluation option license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights for the diagnosis, prognosis, and prediction of cancer.

Upon the expiration or termination of the exclusive evaluation option license, RG 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 and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 28, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, 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) 451–7337; Facsimile: (301) 402–0220; Email: *hastingw@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The successful treatment of cancer is correlated with the early detection of the cancerous cells. Conventional cancer diagnosis is largely based on qualitative morphological criteria, but more accurate quantitative tests could greatly increase early detection of malignant cells. It has been observed that the spatial arrangement of DNA in the nucleus is altered in cancer cells in comparison to normal cells. Therefore, it is possible to distinguish malignant cells by mapping the position of labeled marker genes in the nucleus. This NIH invention provides methods of detecting abnormal cells in a sample using the spatial position of one or more genes within the nucleus of a cell, as well as a kit for detecting abnormal cells using such methods. It also provides methods of identifying gene markers for abnormal cells using the spatial position of one or more genes within the nucleus of a cell. Therefore, this invention could be used as a very effective cancer diagnostic from tumor biopsies after non-invasive techniques such as a mammogram or PSA assay have suggested cancer.

The primary product arising from this technology would be a diagnostic for cancer using tumor biopsies after non-invasive techniques such as a mammogram or PSA assay have suggested the presence of cancer. This novel in vitro diagnostic test for cancer has use in oncology laboratories of hospitals and commercial clinical laboratories. It has several advantages

over other diagnostics including sensitive cancer detection, small sample size (100–200 cells), probes to all genomic regions are available, and it does not require mitotic chromosomes. Additionally, it is applicable to both solid tumors and blood cancers, allows analysis of subpopulations from biopsy, measures metastatic potential of cancer cells, determines tumor type, and can be alternative to or complementary to conventional diagnostics.

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: July 10, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–16268 Filed 7–10–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Molecular-Based Cancer Diagnostic and Prognostic

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, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Heragen, Inc., which is located in Benicia, California to practice the inventions embodied in the following patent applications:

1. U.S. Provisional Application 61/152,597 filed February 13, 2009 entitled ''Molecular-Based Method of Cancer Diagnosis and Prognosis'' (HHS Ref No. E–023–2009/0–US–01).

2. International Application PCT/US2010/024026 filed February 12, 2010 entitled ''Molecular-Based Method of Cancer Diagnosis and Prognosis'' (HHS Ref No. E–023–2009/0–PCT–02).

3. U.S. Patent No. 8,715,928 issued May 6, 2014 entitled ''Molecular-Based Method of Cancer Diagnosis and Prognosis'' (HHS Ref No. E–023–2009/0–US–03).

4. U.S. Patent Application No. 14/215,574, filed March 17, 2014 entitled ''Molecular-Based Method of Cancer Diagnosis and Prognosis'' (HHS Ref No. E–023–2009/0–US–04).

The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to develop FDA approved and/or 510K cleared tests and kits for the diagnosis and prognosis of breast and lung cancer.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before August 11, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, 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) 451–7337; Facsimile: (301) 402–0220; Email: *hastingw@mail.nih.gov*.

SUPPLEMENTARY INFORMATION: Molecular profiling with high throughput assays has gained utility in the management of select cancer patients and several gene expression-based assays are now marketed for improved prognostic accuracy for patients with cancer.

This technology describes a genomics based diagnostic assay for the diagnosis and prognosis of cancer patients. Using a mouse model of breast cancer, the inventors identified a gene expression signature that can predict the outcome for human breast cancer patients with as few as six genes. The gene signature includes a total of 79 cancer survival factor-associated genes and was validated using available genomic test sets that were based on previously conducted human clinical trials. More recently, the six-gene-model was validated for cancers other than breast using multiple, independent, publicly-available human lung cancer data sets. In addition to predicting the outcome of cancer patients, this technology could also be used to stratify patients for further therapy and treat patients by administering therapeutic agents that alter the activity of one of the aforementioned cancer survival factor-associated genes.

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 part 404. The prospective 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.

Any additional 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 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: July 10, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014–16266 Filed 7–10–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive