Arrangements in lieu of other, potentially clinically superior, laboratories. OIG recognizes that whether any particular Registry Arrangement violates the anti-kickback statute depends on the intent of the parties to the arrangement. Payments from a laboratory to a physician to compensate the physician for services related to data collection and reporting may be reasonable in certain limited circumstances. However, the anti-kickback statute prohibits the knowing and willful payment of such compensation if even one purpose of the payments is to induce or reward referrals of Federal health care program business.

Characteristics of a Registry Arrangement that may be evidence of such unlawful purpose include, but are not limited to, the following:

- The laboratory requires, encourages, or recommends that physicians who enter into Registry Arrangements perform the tests with a stated frequency (*e.g.,* four times per year) to be eligible to receive, or to not receive a reduction in, compensation.
- The laboratory collects comparative data for the Registry from, and bills for, multiple tests that may be duplicative (*e.g.,* two or more tests performed using different methodologies that are intended to provide the same clinical information) or that otherwise are not reasonable and necessary.
- Compensation paid to physicians pursuant to Registry Arrangements is on a per-patient or other basis that takes into account the value or volume of referrals.
- Compensation paid to physicians pursuant to Registry Arrangements is not fair market value for the physicians' efforts in collecting and reporting patient data.
- Compensation paid to physicians pursuant to Registry Arrangements is not supported by documentation, submitted by the physicians in a timely manner, memorializing the physicians' efforts.
- The laboratory offers Registry Arrangements only for tests (or disease states associated with tests) for which it has obtained patents or that it exclusively performs.
- When a test is performed by multiple laboratories, the laboratory collects data only from the tests it performs.
- The tests associated with the Registry Arrangement are presented on the offering laboratory's requisition in a manner that makes it more difficult for the ordering physician to make an independent medical necessity decision with regard to each test for which the laboratory will bill (*e.g.,* disease-related panels).

Other characteristics not listed above may increase the risk of fraud and abuse associated with a Registry Arrangement or provide evidence of unlawful intent. For example, the risk of fraud and abuse would be particularly high if a laboratory were to pay, and collect data for its Registry from, only a subset of physicians who were selected on the basis of their prior or anticipated referral volume, rather than their specialty, sub-specialty, or other relevant attribute.

The anti-kickback statute does not prohibit laboratories from engaging in, or paying compensation for, legitimate research activities. However, claims that Registries are intended to promote and support clinical research and treatment are not sufficient to disprove unlawful intent. Even legitimate actions taken to substantiate such claims, including, for example, retaining an independent Institutional Review Board to develop study protocols and participation guidelines, will not protect a Registry Arrangement if one purpose of the arrangement is to induce or reward referrals. Furthermore, for the reasons set forth in section II.A above, OIG's concerns regarding Registry Arrangements are not abated when those arrangements apply only to data collected from tests performed on non-Federal health care program patients' specimens.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible ''kickback'' arrangement, physicians who enter into Registry Arrangements with laboratories also may be at risk under the statute.

III. Conclusion

OIG is concerned about the risks that Specimen Processing Arrangements and Registry Arrangements pose under the anti-kickback statute. This Special Fraud Alert reiterates our longstanding concerns about payments from laboratories to physicians in excess of the fair market value of the physicians' services and payments that reflect the volume or value of referrals of Federal health care program business. Should interested parties continue to have questions about the structure of a particular Specimen Processing Arrangement or Registry Arrangement, the OIG Advisory Opinion process remains available. Information about the process may be found at: *http://oig.hhs.gov/faqs/advisory-opinions-faq.asp.*

To report suspected fraud involving Registry Arrangements, Specimen Processing Arrangements, or similar arrangements, contact the OIG Hotline at *https://forms.oig.hhs.gov/hotlineoperations/or* by phone at 1–800–447–8477 (1–800–HHS–TIPS).

Dated: June 7, 2014.

Daniel R. Levinson,

Inspector General.

[FR Doc. 2014–16219 Filed 7–10–14; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Evaluation Option Exclusive License: Development of Granulysin Immunotherapy

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 Patent Application. No. 61/250,601, filed October 12, 2009, HHS Ref. No.: E–158–2009/0–US–01, Titled: ''Granulysin Immunotherapy''; International Application No. PCT/US2010/052036, filed October 8, 2010, HHS Ref. No.: E–158–2009/0–PCT–02, Titled: ''Granulysin Immunotherapy''; U.S. Patent Application No. 13/501,726, filed April 12, 2012, HHS Ref. No.: E–158–2009/0–US–06, Titled: ''Granulysin Immunotherapy'', and foreign equivalents thereof to Orpheden Therapeutics, Inc. (''Orpheden''), a Delaware corporation doing business principally in the state of Illinois. 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 development of 15kD granulysin as set forth in the Licensed Patent Rights for the treatment of human cancers.

Upon the expiration or termination of the exclusive evaluation option license, Orpheden 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: 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