controls leading to a successful investigational new drug (IND) application. Collaborators should have experience in the pre-clinical development of small molecules and a track record of successful submission of IND applications to the FDA for rare and neglected diseases.

The full CRADA proposal should include a capability statement with a detailed description of (1) collaborator's chemistry expertise in the areas of modulation of small molecule physical properties and formulation of small molecules, and its ability to manufacture sufficient quantities of chemical compounds according to FDA guidelines and under Good Manufacturing Practice (GMP); (2) expertise with Gaucher disease and/or expertise with disorders such as Parkinson disease which might benefit from increases in GCase activity; (3) expertise in regulatory affairs, particularly at the IND filing and early clinical trials stages; (4) collaborator's ability to support, directly or through contract mechanisms, and ability, upon the successful completion of relevant milestones, to support the ongoing pharmacokinetics and biological studies, long term toxicity studies, process chemistry and other pre-clinical development studies needed to obtain regulatory approval of a given molecule so as to ensure a high probability of eventual successful commercialization; and, (5) collaborator's ability to provide adequate funding to support some of the project's pre-clinical studies.

Publications:

1. ''A High Throughput Glucocerebrosidase Assay Using the Natural Substrate Glucosylceramide,'' Motobar O, Goldin E, Leister W, Liu K, Southall N, Huang W, Marugan JJ, Sidransky E, Zheng W, *Anal Bioanal Chem,* 402(2), 731–9, 2012.

2. ''A Novel High Throughput Screening Assay for Small Molecule Therapy for Gaucher Disease Using N370S Mutant Glucocerebrosidase from Patient Tissue,'' Goldin E, Zheng W, Motabar O, Southall N, Marugan JJ, Austin CP and Sidransky E, *PLoS One,* 7(1), e29861, 2012

3. Discovery, SAR and Biological evaluation of Non Inhibitory Small Molecule Modulators of Glucocerebrosidase with Chaperone Activity,'' Patnaik, S, Zheng W, Choi J, Motabar O, Southall N, Westbroek W, Lea W, Velayati A, Goldin E, Sidransky E, Leister W, Marugan J, *J. Med. Chem,* 55(12), 5734–48, 2012.

4. ''A non-inhibitory chaperone reverses impaired function and lipid storage in a patient derived-Gaucher macrophage model,'' Aflaki E, Stubblefield B, Maniwang E, Lopez G, Goldin E, Westbroek W, Marugan JJ, Southall N, Patnaik S, Zheng W, Tayebi N, and Sidransky E, *Blood,* Submitted.

5. ''An induced pluripotent stem cell model that recapitulates the pathologic hallmarks of Gaucher disease,'' Panicker LM, Miller D, Park TS, Patel B, Azevedo JL, Awad O, Masood AM, Veenstra TM, Goldin E, Polumuri SK, Vogel SN, Sidransky E, Zambidis ET, Feldman RA, *Proc Nat Acad Sci USA,* 109(44):18054–9, 2012

Background Technology Available for Licensing:

1. ''Salicylic acid derivatives useful as glucocerebrosidase activators,'' Juan Jose Marugan et al., U.S. Provisional Patent Application No. 61/616,758, HHS Ref. No. E–144–2012/0–US–01.

2. ''Salicylic acid derivatives and additional compounds useful as glucocerebrosidase activators,'' Juan Jose Marugan et al., U.S. Provisional Patent Application No. 61/616,773, HHS Ref. No. E–144–2012/1–US–01.

Dated: January 30, 2013.

Christopher P. Austin,

Director, National Center for Advancing Translational Sciences, National Institutes of Health.

[FR Doc. 2013–02609 Filed 2–5–13; 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, Public Health Service, 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. 207 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 Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION:

Mutations in the G Protein Coupled Receptor (GPCR) Gene Family in Melanoma

Description of Technology: Using exon capture and next generation sequencing approaches to analyze the entire G protein coupled receptor (GPCR) gene family in melanoma, the researchers at the NIH have identified several novel somatic (e.g., tumor-specific) alterations. GPCRs play an integral part in regulating physiological functions and the importance of these molecules is evident by the fact that approximately half of the current FDA approved therapeutics target GPCRs or their direct downstream signaling components.

Many of the GPCR gene mutations identified by the NIH researchers were mutated in a large portion of melanoma patients and already have inhibitors, the most notable being the Glutamate Receptor Metabotropic 3 (GRM3) mutation which could be functionally signification for melanoma tumorigenesis. Therefore, this technology could aid in the development of specific inhibitors of GRM3 as well as the pathway it activates, mitogen-activated protein kinase (MEK), for the treatment of melanoma patients with these mutations. To complement these findings, human melanoma metastatic cell lines harboring GRM3 mutations are also available for licensing.

Potential Commercial Applications:

- Diagnostic array for the detection of GRM3 mutations.
- Method of identifying GRM3 inhibitors as therapeutic agents to treat malignant melanoma patients.
- In vitro and in vivo cell model for the GRM3 mutation in melanoma. This is a useful tool for investigating GRM3 phenotype biology, including growth, motility, invasion, and metabolite production.

Competitive Advantages:

- GPCR mutations, GRM3 in particular, are frequent in melanomas.
- Several inhibitors to GPCR and MEK are already in clinical trials, thus this technology may prove useful for the development of novel diagnostic tests and therapeutics.
- Associated cell lines derived from melanoma patients are available.

Development Stage: Pre-clinical.

Inventors: Yardena Samuels (NHGRI), Todd Prickett (NHGRI), and Steven Rosenberg (NCI).

Publication: Prickett TD, et al. Exon capture analysis of G-protein coupled receptors reveals activating mutations in GRM3 in melanoma. Nat Genet. 2011 Sep 25;43(11):1119–26. [PMID 21946352].

Intellectual Property:

• HHS Reference No. E–244–2010/0—U.S. Provisional Application No. 61/462,471 filed 23 Sep 2010; PCT Application No. PCT/US2011/052032 filed 16 Sep 2011.

• HHS Reference No. E–029–2012/0—Research Tool. Patent protection is not being pursued for the GRM3 melanoma metastatic cell lines.

Related Technologies: HHS Reference Nos.—E–013–2011/0 (patent app: PCT); E–024–2012/0 (research tool); E–272–2008/0 (patent app: US, EP); E–229–2010/0 (research tool); E–232–2010/0 (research tool).

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov.*

Collaborative Research Opportunity: The NHGRI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Claire Driscoll, Director, NHGRI Technology Transfer Office, at *cdriscol@mail.nih.gov* or 301–594–2235.

Human Melanoma Metastasis Cell Lines Harboring GRM3 Mutations

Description of Technology: Using exon capture and next generation sequencing approaches to analyze the entire G protein coupled receptor (GPCR) gene family in melanoma, the researchers at the NIH have identified several novel somatic (e.g., tumor-specific) alterations. GPCRs play an integral part in regulating physiological functions and the importance of these molecules is evident by the fact that approximately half of the current FDA approved therapeutics target GPCRs or their direct downstream signaling components. Many of the GPCR gene mutations identified by the NIH researchers were mutated in a large portion of melanoma patients and already have inhibitors, the most notable being the Glutamate Receptor Metabotropic 3 (GRM3) mutation which could be functionally signification for melanoma tumorigenesis.

Available for licensing are several melanoma cell lines that harbor GRM3 mutations. These cell lines provide useful and efficient tools for studying melanoma and can be used in the development of specific inhibitors of GRM3 as well as the pathway it activates, mitogen-activated protein kinase (MEK), for the treatment of melanoma patients with these mutations.

Potential Commercial Applications:

• Diagnostic array for the detection of GRM3 mutations

• Method of identifying GRM3 inhibitors as therapeutic agents to treat malignant melanoma patients.

• In vitro and in vivo cell model for the GRM3 mutation in melanoma. This is a useful tool for investigating GRM3 phenotype biology, including growth, motility, invasion, and metabolite production.

• Tool for testing the activity of GRM3 inhibitors and generating GRM3 mutation knock-outs.

Competitive Advantages:

• Cell lines are derived from melanoma patients.

• GRM3 mutations are highly frequent and/or highly mutated in melanomas.

• Several inhibitors to GPCR and MEK are already in clinical trials, thus this technology may prove useful for the development of novel diagnostic tests and therapeutics.

Development Stage: Pre-clinical

Inventors: Yardena Samuels (NHGRI), Todd Prickett (NHGRI), and Steven Rosenberg (NCI)

Publication: Prickett TD, et al. Exon capture analysis of G-protein coupled receptors reveals activating mutations in GRM3 in melanoma. Nat Genet. 2011 Sep 25;43(11):1119–26. [PMID 21946352]

Intellectual Property: HHS Reference No. E–029–2012/0—Research Tool. Patent protection is not being pursued for the GRM3 melanoma metastatic cell lines.

Related Technologies: HHS Reference Nos.—E–244–2010/0 (patent app: PCT); E–013–2011/0 (patent app: PCT); E–024–2012/0 (research tool); E–272–2008/0 (patent app: US, EP); E–229–2010/0 (research tool); E–232–2010/0 (research tool)

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov*

Collaborative Research Opportunity: The NHGRI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Claire Driscoll, Director, NHGRI Technology Transfer Office, at *cdriscol@mail.nih.gov* or 301–594–2235.

Human Melanoma Metastasis Cell Lines Harboring MITF Mutations

Description of Technology: Researchers at the NIH have found recurrent somatic mutations in the microphthalmia-associated transcription factor (MITF). Previous studies have linked the MITF pathway to the progression of melanoma, however, little is known about somatic gene mutations in the MITF pathway that could contribute to this progression. The NIH researchers evaluated primary and metastatic melanoma samples for the presence of somatic mutations in two genes of the MITF pathway, MITF and SRY (sex determining region Y)-box 10 (SOX10). They identified 16 previously unidentified somatic mutations in these genes. These studies suggest that MITF and SOX10 genes could be used as diagnostic markers in human metastatic melanoma. Consequently, these cell lines could be used to further investigate the effects of MITF and SOX10 in melanoma and to develop therapeutics targeting this gene and protein.

Potential Commercial Applications:

• Diagnostic array for the detection of MITF mutations.

• In vitro and in vivo cell model for the MITF mutations in melanoma. This is a useful tool for investigating MITF phenotype biology, including growth, motility, invasion, and metabolite production.

Competitive Advantages:

• Cell lines are derived from melanoma patients.

• The MITF mutation is frequent in melanomas.

Development Stage: Pre-clinical

Inventors: Yardena Samuels (NHGRI) and Steven Rosenberg (NCI)

Publication: Cronin JC, et al. Frequent mutations in the MITF pathway in melanoma. Pigment Cell Melanoma Res. 2009 Aug;22(4):435–44. [PMID 19422606]

Intellectual Property: HHS Reference No. E–023–2012/0—Research Tool. Patent protection is not being pursued for the MITF melanoma metastatic cell lines.

Related Technologies: HHS Reference Nos.—E–029–2012/0 (research tool); E–013–2011/0 (patent app: PCT); E–024–2012/0 (research tool); E–272–2008/0 (patent app: US, EP); E–229–2010/0 (research tool); E–232–2010/0 (research tool)

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov*

Collaborative Research Opportunity: The NHGRI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Claire Driscoll, Director, NHGRI Technology Transfer Office, at *cdriscol@mail.nih.gov* or 301–594–2235.

Human Melanoma Metastasis Cell Lines Harboring TRRAP, GRIN2A, and PLCB4 Mutations

Description of Technology: Researchers at the NIH have identified

several novel somatic (e.g., tumor-specific) alterations, many of which have not previously been known to be genetically altered in tumors or linked to melanoma. In particular, the researchers identified a recurrent ''hotspot'' mutation in the transformation/transcription domain-associated protein (TRRAP) gene, identified the glutamate receptor ionotropic N-methyl D-aspartate 2A (GRIN2A) gene as a highly mutated in melanoma, and have shown that the majority of melanoma tumors have alternations in genes encoding members of the glutamate signaling pathway, such as phospholipase C, beta 4 (PLCB4). Therefore, this technology not only provides a comprehensive map of genetic alterations in melanoma, but has important diagnostic and therapeutic applications.

Available for licensing are several melanoma cell lines that harbor TRRAP, GRIN2A, and PLCB4 mutations. These cell lines provide useful and efficient tools for studying melanoma and can be used in the development of specific therapeutics for patients harboring these mutations. Specifically, these cell lines could be used to develop inhibitors to limit tumor growth and further understand melanoma and the biology of these genes.

Potential Commercial Applications:

• Diagnostic array for the detection of TRRAP, GRIN2A, and PLCB4 mutations.

• Method of identifying TRRAP, GRIN2A, and PLCB4 inhibitors as therapeutic agents to treat malignant melanoma patients.

• In vitro and in vivo cell model for understanding the biology of TRRAP, GRIN2A, and PLCB4, including growth, motility, invasion, and metabolite production.

Competitive Advantages:

• Cell lines are derived from melanoma patients.

• TRRAP, GRIN2A, and PLCB4 mutations are highly frequent and/or highly mutated in melanomas.

• Glutamate antagonists have already been shown to inhibit tumor growth. Thus, this technology may prove useful for the development of novel diagnostic tests and therapeutics.

Development Stage: Pre-clinical

Inventors: Yardena Samuels (NHGRI) and Steven Rosenberg (NCI)

Publication: Wei X, et al. Exome sequencing identifies GRIN2A as frequently mutated in melanoma. Nat Genet. 2011 May; 43(5):442–6. [PMID 21499247]

Intellectual Property: HHS Reference No. E–024–2012/0—Research Tool. Patent protection is not being pursued for the TRRAP, GRIN2A, PLCB4 melanoma metastatic cell lines.

Related Technologies: HHS Reference Nos.—E–013–2011/0 (patent apps. PCT); E–272–2008/0 (patent apps. US, EP); E–229–2010/0 (research tool); E–232–2010/0 (research tool); E–029–2012/0 (research tool); E–244–2012/0 (patent app: PCT)

Licensing Contact: Whitney Hastings; 301–451–7337; *hastingw@mail.nih.gov*

Collaborative Research Opportunity: The NHGRI is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Claire Driscoll, Director, NHGRI Technology Transfer Office, at *cdriscol@mail.nih.gov* or 301–594–2235.

Dated: January 31, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–02516 Filed 2–5–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Arthritis and Musculoskeletal and Skin Diseases Initial Review Group; Arthritis and Musculoskeletal and Skin Diseases Clinical Trials Review Committee.

Date: March 12–13, 2013.

Time: 8:00 a.m. to 4:00 PM.

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Gaithersburg Washingtonian Ctr, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Charles H Washabaugh, Ph.D., Scientific Review Officer, National Institute of Arthritis, Musculoskeletal and Skin Diseases, National Institutes of Health, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (301) 496–9568, *washabac@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: January 30, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–02517 Filed 2–5–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Clinical Trial Cobre.

Date: February 27, 2013.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Lisa A. Newman, SCD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3As.19K, Bethesda, MD 20892–4874, 301–594–2704, *newmanla2@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)