material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: On August 2, 2013, from 10 a.m. to approximately 1 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before July 26, 2013. Oral presentations from the public will be scheduled between approximately 12 noon and 1 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before July 18, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by July 19, 2013.

Closed Committee Deliberations: On August 2, 2013, from approximately 1 p.m. to 1:30 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the site visit report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Bryan Emery or Pearl Muckelvene at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: June 21, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–15239 Filed 6–25–13; 8:45 am]

BILLING CODE 4160–01–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 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.

Predicting Age of Onset of Niemann-Pick Disease

Description of Technology: Niemann-Pick disease (NPD) refers to a group of fatal inherited metabolic disorders. Children with type A or B NPD usually die within the first few months or years of life, while NPD type C progresses more slowly, and affected individuals may survive into their seventies. The lifespan of patients with NPD is related to the age of onset. At present, however, there is no effective diagnostic method to predict the age of NPD disease onset.

The instant invention presents diagnostic compositions and efficient methods for predicting the age of onset of a lysosomal storage disease (e.g., NPD) and of diseases associated with lysosomal of autophagic defects (e.g., Parkinson's disease and Alzheimer's disease) in patients. It can also be used to screen for agents useful in treating NPD patients.

Potential Commercial Applications:

- Predicting the age of disease onset in patients with Niemann-Pick disease, and other diseases associated with lysosomal or autophagic defects.
- Identifying agents for treating NPD patients.

Competitive Advantages: A new method for predicting the age of NPD disease onset.

Development Stage:

- Early-stage.
- Pre-clinical.
- In vitro data available.

Inventors: William J. Pavan, et al. (NHGRI).

Intellectual Property: HHS Reference No. E–060–2013/0—U.S. Provisional Application No. 61/781,807 filed 14 Mar 2013.

Licensing Contact: Betty B. Tong, Ph.D.; 301–594–6565; *tongb@mail.nih.gov*.

Collaborative Research Opportunity: The National Human Genome Research Institute (NHGRI) is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize diagnostic methods for predicting the age of onset of lysosomal disorders, such as NPD and Parkinson's. For collaboration opportunities, please contact Dr. William J. Pavan at *bpavan@nhgri.nih.gov*.

Rat Model for Alzheimer's Disease

Description of Technology: The present invention is directed to a transgenic rat model of Alzheimer's Disease (AD) termed TgF344–19+/−. The invention rat overexpresses two human genes (APPswe and PS1ΔE9 genes), each of which are believed to be independent dominant causes of early-onset AD. The hemizygote exhibits major features of AD pathology (i.e., dense and diffuse amyloid plaques, neurofibrillary tangles, cerebral amyloid angiopathy, hyperphosphorylated tau, paired-helical filaments, Hirano bodies, granulovacuolar degeneration, cognitive impairment, and cortical neuronal loss).

The invention rat is superior to AD mice models because the rat has a larger sized brain to accommodate *in vivo* imaging studies and complex behavioral

testing. Further, the invention rat has a longer life span so that studies of longer duration or studies involving serial sampling can be conducted. The invention rat can be used to evaluate potential treatments for AD and to further investigate AD physiology.

Potential Commercial Applications:

• In vivo validation of AD therapeutics.

• Development and validation of imaging methods to diagnose AD.

• Detailed investigation of AD pathology and physiology.

Competitive Advantages:

• Rat model in contrast to available mice models.

• Rat model based on over-expression of genes responsible for early onset AD.

Development Stage:

• Prototype.

• In vivo data available (animal).

Inventors: Robert M. Cohen, et al. (NIMH).

Publication: Borchelt DR, et al. Familial Alzheimer's disease-linked presenilin 1 variants elevate Abeta1–42/1–40 ratio in vitro and in vivo. Neuron. 1996 Nov; 17(5):1005–13. [PMID 8938131]

Intellectual Property: HHS Reference No. E–211–2012/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Lauren Nguyen-Antczak, Ph.D., J.D.; 301–435–4074; *nguyenantczakla@mail.nih.gov*.

Prognostic Biomarkers for Patients With Early Stage Lung Cancer

Description of Technology: Investigators at the National Cancer Institute have discovered a set of biomarkers that can identify patients with early stage lung cancer who have a high risk of relapse. Available for licensing are prognostic assays based on these biomarkers, which can enable clinicians to select more effective therapy and post-operative follow-up strategies.

Surgery is the standard care for patients with stage I lung cancer. Despite successful surgery, 20–30% of patients will relapse. Chemotherapy can improve patient survival; however, it is controversial if early stage cancer patients should be treated with chemotherapy since, for many cases, it will harm quality of life with little therapeutic benefit. Utilizing patient samples, the investigators conducted a retrospective study in eight patient cohorts that validated the gene classifier set. These prognostic methods can guide physicians to select appropriate treatment and follow-up while sparing other patients of unnecessary treatment and negative side-effects of chemotherapy.

Potential Commercial Applications:

• Method to determine the prognosis of patients with lung cancer.

• Method to select more effective treatment and post-operative follow-up for patients with early stage lung cancer.

Competitive Advantages: Assays were validated in human tissue samples and eight different patient cohorts.

Development Stage:

• Early-stage.

• In vivo data available (human).

Inventors: Curt Harris (NCI), Aaron Schetter (NCI), Ichiro Akagi (Nippon Medical School), and Hirokazu Okayama (Fukushima Medical University).

Publication: Akagi I, et al. Combination of protein coding and non-coding gene expression as a robust prognostic classifier in stage I lung adenocarcinoma. Cancer Res. 2013 May 2; Epub ahead of print. [PMID 23639940]

Intellectual Property: HHS Reference No. E–048–2012/0—U.S. Provisional Application No. 61/691,118 filed 20 Aug 2012.

Related Technology: HHS Reference No. E–181–2006/0—U.S. Patent Nos. 7,943,318 and 8,377,637 and Australian Patent No. 2007205234, and related patent applications pending in Australia, Canada, China, Europe, Japan and the U.S.

Licensing Contact: Jennifer Wong, M.S.; 301–435–4633; *wongje@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize an early detection test for lung cancer. For collaboration opportunities, please contact John Hewes, Ph.D. at *hewesj@mail.nih.gov*.

Retroviral and Lentiviral Vectors To Increase Efficiency of Inducible Pluripotent Stem Cell (iPSC) Production

Description of Technology: Researchers at the National Cancer Institute have discovered that modulating a specific p53 isoform increases the number of inducible pluripotent stem cells that can be obtained from cells that are being re-programmed to obtain pluripotent cells. It is known that the activity of p53 regulates the self-renewal and pluripotency of normal and cancer stem cells, and also affects re-programming efficiency of iPS cells. This p53 isoform-based technology provides a more natural process of increasing iPS cell production than previous methods of decreasing p53.

Potential Commercial Applications:

• Stem cell-based regenerative medicine.

• Cancer therapeutic that targets cancer stem cells.

Competitive Advantages: The retroviral and lentiviral vectors in this invention allow more selective control of p53 activities than siRNA or mutant p53 methods.

Development Stage: Early-stage.

Inventors: Curtis C. Harris (NCI) et al.

Intellectual Property: HHS Reference No. E–239–2010/0—

• U.S. Provisional Patent Application No. 61/389,134 filed 01 Oct 2010.

• International Patent Application PCT/US2011/054304 filed 30 Sep 2011, which published as WO/2012/044979 on 05 Apr 2012.

• Australian Patent Application 2011308567 filed 30 Sep 2011.

• US Patent Application No. 13/877,100 filed 29 Mar 2013.

• Applications also pending in CA, EP, JP (filing nos. unknown).

Related Technologies:

• HHS Reference No. E–033–2008/0—Therapeutic Applications of a p53 Isoform in Regenerative Medicine, Aging, and Cancer.

• HHS Reference No. E–137–2010/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Contact: Patrick McCue, Ph.D.; 301–435–5560; *mccuepat@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Human Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize Retroviral and Lentiviral Vectors. For collaboration opportunities, please contact John D. Hewes, Ph.D. at *hewesj@mail.nih.gov*.

Dated: June 20, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–15204 Filed 6–25–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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.