than 2 business days before the meeting. If FDA is unable to post the background 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/RiskCommunicationAdvisoryCommittee.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: 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 June 1, 2015. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3:30 p.m. on June 8, 2015. 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 May 22, 2015. 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 May 26, 2015. Interested persons can also log on to *http://www.fda.gov/AdvisoryCommittees/RiskCommunicationAdvisoryCommittee.htm* to see and hear the proceedings.

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 Luis G. Bravo 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.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: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10024 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 10, 2015, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel phone number is 301–977–8900.

Contact Person: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of biologics license application (BLA) 125522, proposed trade name REPATHA (established name: Evolocumab) for injection, submitted by Amgen Inc., as adjunct to diet to reduce low-density lipoprotein cholesterol (LDL–C), total cholesterol (TC), apolipoprotein B (ApoB), non-high-density lipoprotein cholesterol (non-HDL–C), TC/HDL–C, ApoB/ApoA1, very low-density lipoprotein cholesterol, triglyceride, and lipoprotein A, and to increase HDL–C and ApoA1, in adults with hyperlipidemia or mixed dyslipidemia, either in combination with a statin or statin with other lipid-lowering therapies (*e.g.,* ezetimibe), or alone, or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or alone or in combination with other lipid-lowering therapies in patients for whom a statin is not considered clinically appropriate. In addition, the committee will discuss the safety and efficacy of evolocumab to reduce LDL–C, TC, ApoB, and non-HDL–C, in combination with other lipid-lowering therapies (*e.g.* statins, LDL apheresis) in patients at least 12 years of age with homozygous familial hypercholesterolemia.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background 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: 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 May 27, 2015. Oral presentations from the public will be scheduled between approximately 1:15 p.m. to 2:15 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 May 18,

2015. 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 May 19, 2015.

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 Philip Bautista 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: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10022 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–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.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

A Novel T Cell Therapy Against Patient-Specific Cancer Mutations

Description of Technology: This invention is a novel T cell therapy against cancer mutations that are patient specific. Scientists at the National Institutes of Health have developed a method to identify T cells that specifically recognize immunogenic mutations expressed only by cancer cells. Human cancers contain genetic mutations that are unique to each patient. Some of the mutated peptides are immunogenic, can be recognized by T cells, and therefore, may serve as therapeutic targets. The inventors identified cancer-specific mutations from a patient with widely metastatic cholangiocarcinoma by sequencing tumor samples and comparing with normal cells. Using tandem minigene constructs encoding all of the mutations expressed by a patient's tumor, the inventors identified T cells that recognized the immunogenic mutations from the same patient. These mutation-reactive T cells have the potential to eliminate the cancer cells while sparing normal tissues since normal tissues do not express the mutations. The inventors expanded these mutation-reactive T cells in vitro, and infused a highly pure population of these T cells back into the same patient. The patient experienced tumor regression when she was treated with this approach.

Potential Commercial Applications

- Personalized immunotherapy with mutation-reactive T cells for mediating tumor regression in patients with immunogenic mutations.
- Mutation-reactive T cell therapy especially beneficial for cancer patients refractory to other therapies.
- A research tool to identify patient-specific immunogenic mutations in the tumor.

Competitive Advantages

- This patient-specific therapy has the potential application to most epithelial cancers, which account for about 90% of cancer deaths in the United States.
- Personalized mutation-specific T cells recognize mutations harboring tumor cells only and spare normal tissues. This therapy has no tissue toxicities comparing to traditional chemotherapy and radiotherapy.
- The infusion of a highly pure population of these mutation-specific T cells may maximize therapy and result in regression of all target lesions.

Development Stage

- Early-stage
- *In vitro* data available
- *In vivo* data available (human)
- *Ex vivo* data available

Inventors: Eric Tran, Yong-Chen W. Lu, Paul F. Robbins, Steven A. Rosenberg (all of NCI).

Publications

1. Tran E, et al. Cancer immunotherapy based on mutation-specific CD4+ T cells in a patient with epithelial cancer. Science. 2014 May 9; 344(6184):641–5. [PMID 24812403]

2. Robbins P, et al. Mining exomic sequencing data to identify mutated antigens recognized by adoptively transferred tumor-reactive T cells. Nat Med. 2013 Jun;19(6):747–52. [PMID 23644516]

3. Tran E, et al. T-cell therapy against cancer mutations. Oncotarget. 2014 Jul 15;5(13):4579–80. [PMID 25046408]

Intellectual Property: HHS Reference No. E–229–2014/0—PCT Application No. PCT/US2014/058805 filed October 2, 2014.

Related Technology: HHS Reference No. E–233–2014/0—PCT Application No. PCT/US2014/058796 filed October 2, 2014.

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

Collaborative Research Opportunity: The National Cancer Institute, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize T-cell therapy against cancer mutations. For collaboration opportunities, please contact Steven A. Rosenberg, M.D., Ph.D. at *sar@nih.gov.*

A Novel, Personalized T Cell Therapy: T-Cell Receptor Engineered T Cells Targeting Tumor Specific Mutations

Description of Technology: This invention is a novel T cell therapy against cancer mutations that are patient specific. Scientists at the National Institutes of Health have developed a method to identify and generate T-cell receptor (TCR) engineered T cells for personalized cancer therapy. The TCR is a complex of integral membrane proteins that recognizes antigens and activates T cells. Human cancers