

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

Dated: January 6, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-00157 Filed 1-8-14; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Cardiovascular and Renal 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: Cardiovascular and Renal 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 February 12, 2014, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/default.htm>; under the heading "Resources for You," click on "Public Meetings at the FDA White Oak Campus." Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Kristina Toliver, 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, email: CRDAC@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 new drug application (NDA) 204958, cangrelor injection, submitted by The Medicines Company, for the proposed indication of reduction of thrombotic cardiovascular events including stent thrombosis (events related to blood clots in a stent, a device inserted to keep the artery open) in patients with coronary artery disease undergoing percutaneous coronary intervention (PCI). PCI refers to the opening of narrowed blood vessels supplying the heart muscle by a balloon inserted through an artery puncture with or without a stent. The applicant is also proposing that cangrelor be indicated to maintain P2Y12 inhibition in patients with acute coronary syndromes or patients with stents who are at increased risk for thrombotic events (such as stent thrombosis) when oral P2Y12 therapy is interrupted due to surgery. P2Y12 is a protein involved in blood clotting; inhibiting this protein is a key mechanism of action of cangrelor.

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 January 29, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 January 21, 2014. 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 January 22, 2014.

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 Kristina Toliver 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.

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BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of a Veterinary Rabies Vaccine Based on the ERAG3m Virus Strain

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Provisional Patent Application No. 60/727,038, entitled "Method of Sequencing Whole Viral Genomes, Related Compositions, and Genome Sequences", filed October 14, 2005 (HHS Ref. No. E-326-2013/0-

US-01); PCT Patent Application No. PCT/US2006/040134, entitled "Rabies Virus Compositions and Methods", filed October 13, 2006, (E-326-2013/0-PCT-02); and Chinese Patent Application No. 200680038314.4, entitled "Rabies Virus Compositions and Methods", filed October 13, 2006 (HHS Ref. No. E-326-2013/0-CN-06). The patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive license territory is China, and the field of use may be limited to "Rabies vaccines based on the ERAg3m virus strain for veterinary use only."

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before February 10, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application(s), inquiries, and comments relating to the contemplated exclusive license should be directed to: Whitney Blair, J.D., M.P.H., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4937; Facsimile: (301) 402-0220; Email: whitney.blair@nih.gov.

SUPPLEMENTARY INFORMATION: This license specifically concerns a highly attenuated rabies virus, ERAg3m, with a mutation in the glycoprotein (G) gene and a switch of the G gene with the matrix protein gene in the viral genome. After a one-dose intramuscular vaccination, the ERAg3m virus protected 100% of mice and hamsters from lethal challenge. ERAg3m also may offer better protection than traditional inactivated vaccinations, as demonstrated in co-infection studies. This technology is capable of being developed into a one-dose rabies vaccine for human or veterinary use.

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 the 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.

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: January 2, 2014.

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

[FR Doc. 2014-00126 Filed 1-8-14; 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 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.

New Compounds for Treating or Preventing Obesity

Description of Technology: Available for licensing are new compounds developed for the treatment or prevention of obesity. The compounds act to block the absorption of dietary fats in the gut by interfering with signaling through the farnesoid X receptor. There is correlative evidence that inhibition of the farnesoid X receptor can reduce obesity resulting from high fat-based diets. While many farnesoid X receptor agonists are known, until now there have been no known therapeutic agents that can inhibit this receptor.

Also available for licensing are methods of synthesizing the compounds

and methods of using the compounds to treat or prevent obesity.

Potential Commercial Applications:

- Pharmaceutical treatments for obesity.
 - Pharmaceutical agents to reduce weight gain.
- Competitive Advantages:
- There are no known therapeutic agents to inhibit the farnesoid X receptor; thus, agents developed from the present technology could be first-to-market.

• Compounds stay in the intestine and are not toxic.

Development Stage:

- Early-stage.
- In vitro data available.
- In vivo data available (animal).

Inventors: Frank Gonzalez, Fei Li, Changtao Jiang, James Mitchell (all of NCI).

Intellectual Property: HHS Reference No. E-508-2013/0—US Provisional Application No. 61/861,109 filed 01 August 2013.

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

Chimeric Antigen Receptors to CD276 (B7-H3) for Treatment of Cancer

Description of Technology: Chimeric antigen receptors (CARs) are hybrid proteins consisting of an antibody binding fragment fused to protein signaling domains. When CARs are expressed in T-cells, the T-cells become cytotoxic towards cells expressing the proteins that the CAR recognizes. By developing a CAR that is specific for a cell surface protein that is selectively expressed on diseased cells, it is possible to selectively target those cells for destruction, thereby treating the disease.

Solid tumors are typically treated with a non-specific approach of surgical resection, followed by chemotherapy or radiation therapy. Unfortunately, such an approach is traumatic for the patient, and leads to numerous side-effects. This suggests that a more specific approach to treating solid tumors is needed. CD276 (B7-H3) is a tumor-associated antigen that is expressed on several solid tumors, making it a promising therapeutic target. This technology concerns the generation of three high-affinity CARs (CD276.1, CD276.6 and CD276.17) that target CD276. These CARs can potentially be used in the treatment of cancers associated with CD276 expression.

Potential Commercial Applications:

- Treatment of diseases associated with increased or preferential expression of CD276.
- Specific diseases include neuroblastoma, Ewing's sarcoma,