

heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014-29035 Filed 12-10-14; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of a Start-Up Exclusive Patent License Agreement: Use of Compounds Covered by Patent Rights for Diagnosis of Human Thyroid Cancer Requiring FDA Premarket Approval or an Equivalent Authority Outside of the United States, and Treatment of Human Thyroid Cancer

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 a Start-Up Exclusive Patent License to Nova Therapeutics LLC, a company having a place of business in Delaware, to practice the inventions embodied in the following patent applications:

- (a) PCT Patent Application No. PCT/US2008/11958, Filed: October 20, 2008, HHS Ref. No.: E-284-2008/0-PCT-01
- (b) Australian Patent No. 2008-363295, Filed: October 20, 2008, HHS Ref. No.: E-284-2008/0-AU-02
- (c) Canadian Patent Application No. 2,741,030, Filed: October 20, 2008, HHS Ref. No.: E-284-2008/0-CA-03
- (d) European Patent Application No. 08876356.0, Filed: October 20, 2008, HHS Ref. No.: E-284-2008/0-EP-04
- (e) Indian Patent Application No. 3684/DELNP/2011, Filed: October 20, 2008, HHS Ref. No.: E-284-2008/0-IN-05
- (f) Japanese Patent Application No. 2011-532048, Filed: October 20, 2008, HHS Ref. No.: E-284-2008/0-JP-06

(g) U.S. Patent No. 8,741,259 U.S. Patent Application No. 13/125,045, Filed: October 20, 2008, HHS Ref. No.: E-284-2008/0-US-07

(h) U.S. Patent Application No. 13/897,330, Filed: October 20, 2008, HHS Ref. No.: E-284-2008/0-US-08
Current status: pending

(i) U.S. Patent Application No. 14/243,821, Filed: October 20, 2008, HHS Ref. No.: E-284-2008/0-US-10

The patent rights in this invention have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Patent License Agreement may be worldwide and the field of use may be limited to: Use of compounds covered by Patent Rights for diagnosis of human thyroid cancer requiring FDA premarket approval or an equivalent authority outside of the United States, and treatment of human thyroid cancer.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before December 26, 2014 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Patent License Agreement should be directed to: Lauren Nguyen-Antczak, Ph.D., J.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4074; Facsimile: (301) 402-0220; Email: Lauren.Nguyen-antczak@nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent application(s) that have not been published or issued by the United States Patent and Trademark Office of the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: This invention concerns small molecule compounds that agonize the activity of the thyroid stimulating hormone receptor ("TSHR"). These TSHR agonists enhance or activate the thyroid stimulating hormone ("TSH") signaling pathway by directly binding to the transmembrane domain of TSHR. Invention compounds may be administered alone or in combination with radioactive iodine to detect thyroid cancer cells. Additionally, invention compounds may be administered in combination with radioactive iodine to treat thyroid cancer, such as to ablate thyroid remnants in patients after a thyroidectomy.

The prospective Start-Up Exclusive Patent License that is being considered

can be found at <http://www.ott.nih.gov/forms-model-agreements#SUMLA>, which complies with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective Start-Up Exclusive Patent License is being provided under the small business initiative launched on 1 October 2011. The prospective Start-Up Exclusive Patent License may be granted unless the NIH receives written evidence and argument, within fifteen (15) days from the date of this published notice, 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.

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Start-Up Exclusive Patent 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: December 4, 2014.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014-29017 Filed 12-10-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meetings will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meetings 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 Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: January 28, 2015.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Closed: 3:45 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 715, MSC 5452, Bethesda, MD 20892, (301) 594-8843, stanfibr@nidk.nih.gov.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: January 28, 2015.

Open: 1:00 p.m. to 2:30 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Closed: 2:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 715, MSC 5452, Bethesda, MD 20892, (301) 594-8843, stanfibr@nidk.nih.gov.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: January 28, 2015.

Open: 1:00 p.m. to 3:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, Conference Room 7, 31 Center Drive, Bethesda, MD 20892.

Closed: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 7, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 715, MSC 5452, Bethesda, MD 20892, (301) 594-8843, stanfibr@nidk.nih.gov.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory

Council; Digestive Diseases and Nutrition Subcommittee.

Date: January 28, 2015.

Open: 1:00 p.m. to 2:30 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Closed: 2:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Conference Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 715, MSC 5452, Bethesda, MD 20892, (301) 594-8843, stanfibr@nidk.nih.gov.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: www.nidk.nih.gov/fund/divisions/DEA/Council/coundesc.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 5, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-29020 Filed 12-10-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (R13/U13).

Date: January 6, 2015.

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

Agenda: To review and evaluate grant applications.

Place: 5601 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Vasundhara Varthakavi, DVM, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, Room 3E70B, 5601 Fishers Lane, Rockville, MD 20852, 240-669-5020, varthakaviv@niaid.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 5, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-29019 Filed 12-10-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

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 meetings.

The meetings 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: Neurological Sciences Training Initial Review Group; NST-1 Subcommittee.

Date: February 9-10, 2015.