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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]

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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