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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of a Start-Up Exclusive Patent License Agreement: Treatment of Graves' Disease, Hyperthyroidism and Thyroid Cancer

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), 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:

1. PCT Application No.: PCT/US2011/031752 filed 08 Apr 2011
HHS Ref. No.: E-067-2010/0-PCT-02
Titled: Inverse Agonists and Neutral Antagonists for the TSH Receptor
Inventors: Marvin Gershengorn (NIDDK), Susanne Neumann (NIDDK), Wenwei Huang (NCATS), Craig Thomas (NCATS)
2. Australian Application No.: 2011237421 filed 15 Aug 2012
HHS Ref. No.: E-067-2010/0-AU-03
3. Canadian Application No.: 2,789,818 filed 15 Aug 2012
HHS Ref. No.: E-067-2010/0-CA-04
4. Chinese Application No.: 201180013235.9 filed 15 Aug 2012
HHS Ref. No.: E-067-2010/0-CN-05

5. European Application No.: 11766807.9 filed 15 Aug 2012
HHS Ref. No.: E-067-2010/0-EP-06
6. Indian Application No.: 2055/KOLNP/2012 filed 15 Aug 2012
HHS Ref. No.: E-067-2010/0-IN-07
7. Japanese Application No.: 2013-503984 filed 15 Aug 2012
HHS Ref. No.: E-067-2010/0-JP-08
8. U.S. Application No.: 13/579,251 filed 15 Aug 2012
HHS Ref. No.: E-067-2010/0-US-09

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: Treatment of Graves' Disease, hyperthyroidism and thyroid cancer.

DATE: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: 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., 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; E-mail: 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 antagonize the activity of the thyroid stimulating hormone receptor (“TSHR”). These antagonists are classified into two functional categories: (a) neutral antagonists that prevent TSHR from being turned on, and (b) inverse agonists that turn off active TSHR. Both categories of antagonists may be useful in treating hyperthyroidism and Graves’ disease, an autoimmune disease that is commonly associated with hyperthyroidism. In addition, certain small molecule compounds that function as inverse agonists of TSHR may be effective in reducing the recurrence of thyroid cancer.

The prospective Start-Up Exclusive Patent License is being considered under the small business initiative launched on 1 October 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. 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 404.7.

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.

May 20, 2013

Date

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

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