[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Start-up Commercial License for the Development of Fenoterol and Fenoterol Analogues for the Treatment of Brain, Liver, and Pancreatic Cancers and Congestive Heart Failure

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 to Mitchell Woods Pharmaceuticals, LLC, of an exclusive commercialization license to practice the inventions embodied in the following U.S. Patent Applications (and all continuing applications and foreign counterparts): Serial No. 61/651,961, filed May 25, 2012, entitled, "Methods of Regulating Cannabinoid Receptor Activity-related Disorders and Diseases" [HHS Reference E-139-2012/0-US-1]; Serial No. 61/789,629, filed March 15, 2013, entitled, "Methods of Regulating Cannabinoid Receptor Activity-related Disorders and Diseases" [HHS Reference E-139-2012/1-US-1]; Serial No. 61/312,642, filed March 10, 2010, entitled, "The Use of Fenoterol and Fenoterol Analogues in the Treatment of Glioblastomas and Astrocytomas" [HHS Reference E-013-2010/0-US-01]; Serial No. 60/837,161, filed August 10, 2006, entitled, "Preparation of *R,R*-Fenoterol and *R,R*-Fenoterol Analogues and Their Use in Congestive Heart Failure" [HHS Reference E-205-2006/0-US-1]; and Serial No. 60/927,825, filed May 3, 2007, entitled "Preparation of *R,R*-Fenoterol and *R,R*-

Fenoterol Analogues and Their Use in Congestive Heart Failure" [HHS Reference E-205-2006/1-US-1]. The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive commercialization license territory may be worldwide, and the scope may be limited to the following two fields of use:

> Licensed Field of Use I: An exclusive license to the Patent Rights for research, development, manufacture, distribution, sale, and use in humans for the treatment of brain cancer, liver cancer, or pancreatic cancer within the Licensed Territory of (*R,R'*)-4'-methoxy-1-napthylfenoterol (MNF), (*R,S'*)-4'-methoxy-1-napthylfenoterol, (*R,R'*)-ethylMNF, (*R,R'*)-napthylfenoterol, (*R,S'*) napthylfenoterol, (*R,R'*)-ethyl-napthylfenoterol, and (*R,R'*)-4'-amino-1-napthylfenoterol, (*R,R'*)-4'-hydroxy-1-napthylfenoterol, (*R,R'*)-4-methoxy-ethylfenoterol, (*R,R'*)-methoxyfenoterol, (*R,R'*)-ethylfenoterol, (*R,R'*)-fenoterol; and their respective stereoisomers.
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> Licensed Field of Use II: An exclusive license to the Patent Rights for research, development, and manufacture of Licensed Products incorporating the Licensed Patent Rights; and distribution, sale, and use of such Licensed Products in humans for the treatment of congestive heart failure within the Licensed Territory.

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 exclusive evaluation option license should be directed to: Patrick McCue, 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) 435-5560; Facsimile: (301) 402-0220; E-mail: mccuepat@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns the use of fenoterol analogues in treatments for tumors expressing a cannabinoid receptor, and in treatments for congestive heart failure.

The prospective exclusive commercialization 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 exclusive commercialization license may be granted unless 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 404.7 within fifteen (15) days from the date of this published notice.

Complete 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 commercialization 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.

June 14, 2013
Date

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

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