[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of Therapeutic Agents for the Treatment of Metastatic Breast Cancer and T-cell Lymphoma.

AGENCY: National Institutes of Health, Public Health Service, 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 Birich Technologies, Inc., of an exclusive evaluation option license to practice the inventions embodied in the following US Patent Applications (and all continuing applications and foreign counterparts): Serial No. 61/045,088 entitled, "COMPOSITIONS AND METHODS FOR DELIVERING INHIBITORY OLIGONUCLEOTIDES" [HHS Ref. E-051-2008/0-US-01]; Serial No. 61/333,512 entitled, "Peptide Inhibitors of Interferon Gamma and Interleukin 10 Signaling" [HHS Ref. E-167-2010/0-US-01]; and Serial No. 60/987,340 entitled, "Diagnostic and Therapeutic Applications of a p53 Isoform in Regenerative Medicine, Aging and Cancer" [HHS Ref. E-033-2008/0-US-01]. The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide, and the field of use may be limited to:

The use in humans of the peptide-based antisense delivery technology (ChemoArp) in conjunction with either (i) a peptide-based interleukin-10 (IL-10) inhibitor as a dual-biologic therapy to treat metastatic breast cancer, or ii) incorporating a *p53* isoform antisense oligonucleotide as a single biologic therapy to treat T-cell lymphoma.

Upon the expiration or termination of the exclusive evaluation option license, Birich Technologies, Inc. will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive evaluation option license with no greater field of use and territory than granted in the exclusive evaluation option license.

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: These inventions concern i) compositions and methods for targeted delivery of inhibitory nucleic acids to cells using a cell surface receptor ligand targeting domain and an inhibitory oligonucleotide-binding domain to efficiently deliver the antisense nucleic acid to cells that expresses the cell surface receptor that binds the ligand, ii) compositions that potently and selectively interfere with dimerization of interleukin-10 and binding of this protein to its receptor, and iii) compositions that inhibit *delta133p53*, a natural variant nucleic acid of tumor suppressor protein 53 (p53) that inhibits p53-dependent cell senescence.

The prospective exclusive evaluation option 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 evaluation option license, and a subsequent 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 evaluation option 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.

October 9, 2012
Date

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

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