

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 U.S. 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.

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of

Technology Transfer on or before October 30, 2012 will be considered.

ADDRESSES: 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; Email: 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.

Dated: October 9, 2012.

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

[FR Doc. 2012-25170 Filed 10-12-12; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2012-0056]

National Infrastructure Advisory Council

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Committee Management; Notice of an open Federal Advisory Committee Meeting.

SUMMARY: The National Infrastructure Advisory Council (NIAC) will meet Tuesday, October 16, 2012, at the United States Access Board, 1331 F Street NW., Suite 800, Washington, DC 20004. The meeting will be open to the public.

DATES: The NIAC will meet Tuesday, October 16, 2012, from 1:30 p.m. to 4:30 p.m. The meeting may close early if the committee has completed its business. For additional information, please consult the NIAC Web site, www.dhs.gov/NIAC, or contact the NIAC Secretariat by phone at (703) 235-2888 or by email at NIAC@hq.dhs.gov.

ADDRESSES: United States Access Board, 1331 F Street NW., Suite 800, Washington, DC 20004.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed under **FOR FURTHER INFORMATION CONTACT**, below as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Council as listed in the **SUMMARY** section below. Comments must be submitted in writing no later than October 11, 2012, and must be identified by "DHS-2012-0056" and may be submitted by any one of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting written comments.
- *Email:* NIAC@hq.dhs.gov. Include the docket number in the subject line of the message.
- *Fax:* (703) 603-5098.
- *Mail:* Nancy Wong, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane SW., Mail Stop 0607, Arlington, VA 20598-0607.

Instructions: All written submissions received must include the words "Department of Homeland Security" and the docket number for this action. Written comments received will be posted without alteration at www.regulations.gov, including any personal information provided.