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**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of Start-Up Exclusive Evaluation Option License Agreement: *In***

*Vitro* Diagnostics for Prediction of Therapeutic Efficacy in Cancer and Other

Angiogenesis-Mediated Diseases

**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 Evaluation Option License Agreement to Advanced Personalized Diagnostics, LLC, a company having a place of business in Alexandria, Virginia, to practice the inventions embodied in U.S. Provisional Patent Application No. 60/976,732, entitled “Stably Transfected Multicolored Fluorescent Cells”, filed October 1, 2007 (HHS Ref. No. E-281-2007/0-US-01); U.S. Patent Application No. 12/060,752, entitled “Multiplex Assay Method for Mixed Cell Populations”, filed April 1, 2008, (HHS Ref. No. E-281-2007/0-US-02); and U.S. Patent Application No. 12/802,666, entitled “Methods of Monitoring Angiogenesis and Metastasis in Three Dimensional Co-Cultures”, filed June 10, 2010 (HHS Ref. No.

E-281-2007/1-US-01). The patent rights in these inventions have been assigned to the Government of the United States of America. The territory of the prospective Start-Up Exclusive Evaluation Option License Agreement may be worldwide, and the field of use may be limited to “The use of the Licensed Patent Rights limited to an FDA-approved Class III *in vitro* diagnostic device for prediction of therapeutic efficacy in cancer and other angiogenesis-mediated diseases.”

Upon the expiration or termination of the Start-up Exclusive Evaluation Option License Agreement, Advanced Personalized Diagnostics, LLC will have the exclusive right to execute a Start-Up Exclusive Patent License Agreement which will supersede and replace the Start-up Exclusive Evaluation Option License Agreement, with no greater field of use and territory than granted in the Start-up Exclusive Evaluation Option License Agreement.

**DATE:** Only written comments and/or applications for a license 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(s), inquiries, comments, and other materials relating to the contemplated Start-Up Exclusive Evaluation Option License Agreement should be directed to: Tara L. Kirby, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4426; Facsimile: (301) 402-0220; E-mail: [tarak@mail.nih.gov](mailto:tarak@mail.nih.gov). A signed confidentiality

nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States Patent and Trademark Office or the World Intellectual Property Organization.

**SUPPLEMENTARY INFORMATION:** This technology relates to a three-dimensional co-culture system that can be used to assay cellular activity relating to angiogenesis (formation of new blood vessels) and metastasis (spread of cancer). The co-culture system is designed to mimic the *in vivo* environment of a tumor and consists of fluorescently-labeled tumor cells, endothelial cells, and other component cell types (e.g. macrophages, mast cells, fibroblasts, adipocytes, and pericytes). The co-culture system can be used to identify, monitor, and measure changes in morphology, migration, proliferation, and apoptosis of cells involved in angiogenesis and/or metastasis. The co-cultures are developed in 96-well plates to allow rapid and efficient screening for angiogenic agents and/or therapeutic agents for cancer. This technology may be used to develop diagnostic tests for personalized therapies for cancer and other angiogenesis-mediated diseases.

The prospective Start-Up Exclusive Evaluation Option License Agreement is being considered under the small business initiative launched on October 1, 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 Evaluation Option License Agreement and a subsequent Start-Up Exclusive Patent License Agreement 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 contemplated Start-Up Exclusive Evaluation

Option License Agreement 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 Evaluation Option License Agreement. 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 10, 2013  
Date

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

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