[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Cripto-1 Point of Care (POC) Tests and Kits for the Detection of Colon and Rectal Cancer, Breast Cancer, and Lung Cancer

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Beacon Biomedical LLC ("Beacon") located in Scottsdale, AZ, USA.

> Intellectual Property: U.S. Patent No.7,078,176 issued July 18, 2006 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-US-03] and foreign equivalents thereof.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use will be limited to the use of Licensed Patent Rights to develop FDA approved and/or

510K cleared Point of Care (POC) tests and kits for the purpose of disease state recognition, detection, diagnosis, monitoring, association and risk-stratification of colon and rectal cancer, breast cancer, and lung cancer.

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 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Eggerton Campbell, Ph.D. Licensing and Patenting Manager, Cancer Branch, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5282; Facsimile: (301) 435-4013; E-mail: Eggerton.Campbell@.nih.gov.

SUPPLEMENTARY INFORMATION:

Cripto-1 (CR1) is a member of the epidermal growth factor (EGF)-related families of peptides and is involved in the development and progression of various human carcinomas. In particular, CR1 overexpression has been detected in 50-90% of carcinomas of the colon, pancreas, stomach, gallbladder, breast, lung, endometrium and cervix. Current methodologies of cancer detection, e.g. immunohistochemistry, can be time consuming, inconvenient and oftentimes, inaccurate, and therefore, a need exists for more efficient, reliable and less time consuming methods of detection. The invention

relates to such a method of detection. This test could be used to more effectively screen and perhaps stage cancers. Additionally, should particular tumor cells, e.g. breast tumor cells, express a sufficiently high level of CR1, it may be possible to use the disclosed assay to detect and measure CR1 in human serum and/or plasma and possibly other physiological fluids.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, 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.

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 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.

December 2, 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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