[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 cancer

AGENCY: National Institutes of Health, Public Health Service, HHS

ACTION: Notice

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Cancer Institute, 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, Inc. ("Beacon") located in Scottsdale, AZ**,** USA**.** A notice was previously published on December 6, 2013 in Volume 78, Number 235 for a period of thirty (30) days. Herein, the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is proposing a modification to the contents of the previous notice regarding the following intellectual property:

U.S. Provisional Patent Application No. 60/264,643 filed January 26, 2001 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-US-01];

PCT Application No. PCT/US02/02225 filed January 23, 2002 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-PCT-02];

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];

Canada Patent No. 2,434,694 issued September 18, 2012 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-CA-04];

Australian Patent No. 2002236871 issued April 12, 2007 entitled "Detection and Quantification of

Cripto-1" [HHS Ref. No. E-290-2000/0-AU-05];

Europe Patent No. 1370869 issued December 27, 2006 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-EP-06] and validated in Germany [HHS Ref. No. E-290-2000/0-DE-08], France [HHS Ref. No. E-290-2000/0-FR-09], Italy [HHS Ref. No. E-290-2000/0-IT-10], Spain [HHS Ref. No. E-290-2000/0-ES-12], Ireland [HHS Ref. No. E-290-2000/0-IE-12], Great Britain [HHS Ref. No. E-290-2000/0-GB-13] and Switzerland [HHS Ref. No. E-290-2000/0-CH-14];

Japan Patent No. 3821779 issued June 30, 2006 entitled "Detection and Quantification of Cripto-1" [HHS Ref. No. E-290-2000/0-JP-07].

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 may be limited to the use of the Licensed Patent Rights to make, use and sell FDA approved and 510(k) cleared, or foreign equivalent, Point of Care (POC) tests, services and kits for the purpose of disease state recognition, detection, diagnosis, monitoring, association and risk-stratification of cancer.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Rose Freel, Ph.D. Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 8490 Progress Drive, Riverside 5, Suite 400, Frederick, MD 21702; Telephone: (301) 624-1257; E-mail: rose.freel@nih.gov

SUPPLEMENTARY INFORMATION: Cripto-1 (Cr-1) 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, Cr-1 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 Cr-1, it may be possible to use the disclosed assay to detect and measure Cr-1 in human serum and/or plasma and possibly other physiological fluids.

The previous notice published on December 6, 2013 contemplated the prospective grant of an exclusive license in a field of use that was limited to the use of the 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. This notice serves to modify the prospective grant that may be limited to field of use as described in the Summary above.

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

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.

Dated: November 9, 2015.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center, National Cancer Institute.

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