[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development of a Gene Signature Predictive of Hepatocellular Carcinoma (HCC) Patient Response to Transcatheter Arterial Chemoembolization (TACE)

AGENCY: National Institutes of Health

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of 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 Patents and Patent Applications listed in the Supplementary Information section of this notice to 3D Medicines ("3DMed") located in Shanghai, China**.**

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

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Jim Knabb, Ph.D., Technology Transfer and Patent Specialist, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: jim.knabb@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 62/292,789, filed February 8, 2016 entitled "Gene Signature Predictive of Hepatocellular Carcinoma Response to Transcatheter Arterial Chemoembolization" [HHS Reference No. E-101-2016/0-US-01]; PCT Patent Application PCT/US2017/016851, filed February 7, 2017 and entitled "GENE SIGNATURE PREDICTIVE OF HEPATOCELLULAR CARCINOMA RESPONSE TO TRANSCATHETER ARTERIAL CHEMOEMBOLIZATION (TACE)" [HHS Reference No. E-101-2016/0-PCT-02]; (and U.S. and foreign patent applications claiming priority to the aforementioned applications).

The patent rights in these inventions have been assigned and/or exclusively licensed 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 Development and commercialization of the transcatheter arterial chemoembolization (TACE) gene signature as a diagnostic device predictive of TACE response in patients with hepatocellular carcinoma (HCC). The field of use may be further limited to companion diagnostic tests that are sold following Premarket Approval by the FDA or equivalent regulatory agency in foreign jurisdictions".

This technology discloses a gene expression signature that is predictive of HCC patient response to TACE. TACE therapy is a procedure whereby the tumor is targeted with both local chemotherapy and restriction of local blood supply, and is employed in the treatment of locally advanced hepatocellular carcinoma (HCC). Patient biopsies are analyzed by Next-Generation Sequencing (NGS) and expression analysis of the gene

signature can be used to stratify patients for TACE therapy. Through the commercialization of this gene signature for TACE efficacy, HCC patients can be identified as candidates for TACE therapy, or as needing alternative treatment strategies.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute 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.

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 Exclusive Patent 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.

Dated: February 15, 2017 _____

Richard U. Rodriguez,

Associate Director

Technology Transfer Center

National Cancer Institute

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