



This document is scheduled to be published in the Federal Register on 11/17/2016 and available online at <https://federalregister.gov/d/2016-27613>, and on [FDsys.gov](https://fdsys.gov)

BILLING CODE: 4140-01-P

DEPARTMENT: DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

**Government-Owned Inventions; Availability for Licensing and/or Co-Development**

AGENCY: National Institutes of Health

ACTION: Notice

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S. to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

ADDRESSES: Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702.

FOR FURTHER INFORMATION CONTACT: Information on licensing and co-development research collaborations, and copies of the U.S. patent applications listed below may be obtained by contacting: Attn. Invention Development and Marketing Unit, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, Mail Stop 9702, Rockville, MD, 20850-9702, Tel. 240-276-5515 or email [ncitechtransfer@mail.nih.gov](mailto:ncitechtransfer@mail.nih.gov). A signed Confidential Disclosure Agreement may be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Title of invention:

Gene Signature Predictive of Hepatocellular Carcinoma Response to Transcatheter Arterial Chemoembolization (TACE)

Keywords: Diagnostic, Biomarker, Prognostic, Hepatocellular Carcinoma, Patient Stratification, TACE, HCC

Description of Technology:

Hepatocellular Carcinoma (HCC) is one of the most common cancers worldwide with largely unfavorable outcomes due to a lack of effective treatment options for patients in the later state of disease. The gold standard of care for HCC patients with intermediate to locally advanced tumors is transcatheter arterial chemoembolization (TACE), a procedure whereby the tumor is targeted both with local chemotherapy and restriction of local blood supply. TACE procedures are often not effective, however, and a need exists to identify patients that will respond to TACE.

Scientists in NCI's Laboratory of Human Carcinogenesis have identified a 14-gene signature that is predictive of response to TACE. The "TACE Navigator Gene Signature Assay," based on a Nanostring Technologies platform, is useful in identifying those HCC patients, prior to treatment, who will respond to and have the greatest survival benefit following TACE. The signature can also identify patients who need additional/alternative therapeutic modalities.

This invention is owned by an agency of the U.S. Government and is available for licensing and/or co-development in the U.S., in accordance with 35 U.S.C. 209 and 37 CFR part 404, to achieve expeditious commercialization of results of federally-funded

research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing and/or co-development.

Potential Commercial Applications:

- Prognostic test for HCC patient response to TACE procedure
- Companion diagnostic for TACE procedure

Value Proposition:

- First in class prognostic diagnostic for frontline therapy in highly prevalent HCC

Development Stage:

Basic (Target ID)

Inventor(s):

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Intellectual Property:

HHS Reference No. E-101-2016

US Provisional Application 62/292,789 (HHS Reference No. E-101-2016/0-US-01) filed February 8, 2016 entitled “Gene Signature Predictive of Hepatocellular Carcinoma Response to Transcatheter Arterial Chemoembolization (TACE)”

Related Technologies: NIH Reference No. E-024-2009 entitled “Gene Signature for Predicting Solid Tumors Patient Response”

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for the commercialization of a companion diagnostic for HCC patients undergoing TACE procedures.

Contact Information:

Requests for copies of the patent application or inquiries about licensing, research collaborations, and co-development opportunities should be sent to John D. Hewes, Ph.D., email: john.hewes@nih.gov.

Date: November 8, 2016

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[FR Doc. 2016-27613 Filed: 11/16/2016 8:45 am; Publication Date: 11/17/2016]