DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cancer Immunotherapy

AGENCY: National Institutes of Health, Department of Health and Human Services.

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 U.S. Patents and Patent Applications listed in the Supplementary Information section of this notice to Midissia Therapeutics (''Midissia'') located in San Francisco, CA.

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 August 13, 2018 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: Ricquita Pollard, Technology Transfer Manager, 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; Email: *pollardrd@mail.nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. United States Provisional Patent Application No. 62/248,964 filed Oct. 30, 2015 for ''Compositions and Methods for the Treatment of HER2-Expressing Solid Tumor ''[HHS Ref. No. E–187–2015/0US–01];
2. International Patent Application No. PCT/US2016/059680 filed October 31, 2016 for ''Compositions and Methods for Treatment of HER2-Expressing Solid Tumor'' [HHS Reference No. E–187–2015/0–PCT–02];
3. Canadian National Stage Patent Application (*No. not yet assigned*), filed April 30, 2018 [HHS Ref. No. E–187–2015/0–CA–03];
4. Japanese National Stage Patent Application No. 2018–521518, filed April 30, 2018 [HHS Ref. No. E–187–2015/0–JP–04];
5. Australian National Stage Patent Application No. 2016343845, filed April 30, 2018 [HHS Ref. No. E–187–2015/0–AU–05];
6. European National Stage Patent Application. (*No. not yet assigned*), filed April 30, 2018 [HHS Ref. No. E–187–2015/0–EP–06];
7. U.S. National Stage Patent Application No. 15/771,932, filed April 30, 2018 [HHS Ref. No. E–187–2015/0–US–07];

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 ''development and commercialization of Ad-HER2 vaccines as a therapeutic against HER2-positive cancers as covered within the scope of the Licensed Patent Rights, excluding uses in combination with vectors/adjuvants, checkpoint inhibitors or other immune modulators.''

This technology describes a recombinant adenoviral vector that expresses the extracellular (EC) and transmembrane (TM) domains of the human HER2 protein and is designed to induce a polyclonal anti-tumor response. HER2 is a member of the epidermal growth factor family and is overexpressed in subsets of breast, ovarian, gastric, colorectal, pancreatic and endometrial cancers. This vaccine encodes for the entire EC and TM domains of human HER2neu and is specifically contained within a recombinant adenoviral vector that has the knob of Adenovirus 5 and substituted fiber of Adenovirus 35. The substitution of the knob of Adenovirus 35 whose receptor is CD46 allows for efficient and maximal transduction of human dendritic and hematopoietic cells.

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.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 19, 2018.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2018–16058 Filed 7–26–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Intramural Continuing Umbrella of Research Experiences (iCURE) Application (National Cancer Institute)

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Alison Lin, 9609 Medical Center Drive, Rockville, MD 20850 or call non-toll-free number (240) 276–6177 or Email your request, including your address to: *linaj@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the