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

proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Intramural Continuing Umbrella of Research Experiences (iCURE) Application, 0925–XXXX, Exp., Date XX/XXXX, EXISTING COLLECTION IN USE WITHOUT OMB APPROVAL, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The new Intramural Continuing Umbrella of Research Experiences (iCURE) program supports mentored research experiences for qualified post-baccalaureate (including post masters) individuals, graduate students, and postdoctoral fellows in the multidisciplinary National Cancer Institute (NCI) intramural research environment. This information collection request are applications and a reference letter to help evaluate the merits of the candidates and their potential match for the iCURE program. iCURE is an extension of the highly successful NCI Center to Reduce Cancer Health Disparities' (CRCHD) Continuing Umbrella of Research Experiences (CURE) program which helps support the career progress of its scholars toward research independence, as well as fosters and sustains diversity in the biomedical research pipeline. Like the CURE program, iCURE strongly encourages the participation of individuals from underrepresented populations and is aligned with NCI's interest in diversity. The benefit of collecting this information is to enable the selection of the best matching candidates for the iCURE program. The iCURE program aims to, 1. Enhance the diversity of the NCI Intramural Research Program (IRP), and 2. Promote the career progress of the iCURE scholars in cancer research.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated burden hours are 305.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Postbac Supplemental Application	Post-Baccalaureate (Including Post-Master's) Individuals.	50	1	30/60	25
Graduate Student Application	Graduate Students	30	1	2	60
Postdoctoral Fellowship Application	Postdoctoral Candidates	50	1	2	100
Reference Letter	PIs, professors, supervisors	240	1	30/60	120
Total		370	370		305

Patricia M. Busche,

Project Clearance Liaison, National Cancer Institute, National Institutes of Health.

[FR Doc. 2018–16053 Filed 7–26–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke, Muscular Dystrophy Coordinating Committee Call for Committee Membership Nominations

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The Office of the Secretary of the Department of Health and Human Services (HHS) is seeking nominations for an individual to serve as a nonfederal public member on the Muscular Dystrophy Coordinating Committee.

DATES: Nominations are due by 5 p.m. EDT on August 31, 2018.

ADDRESSES: Nominations must be sent to Glen Nuckolls, Ph.D., by email to *nuckollg@ninds.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Glen Nuckolls, Ph.D., by email to *nuckollg@ninds.nih.gov.* or (301) 496–5745.

SUPPLEMENTARY INFORMATION: The Muscular Dystrophy Coordinating Committee (MDCC) is a federal advisory committee established in accordance with the Muscular Dystrophy Community Assistance, Research, and Education Amendments of 2001 (MD–CARE Act; Pub. L. 107–84). The MD–CARE Act was reauthorized in 2008 by Public Law 110–361, and again in 2014 by Public Law 113–166. The MD–CARE Act specifies that the committee membership be composed of ⅔ governmental agency representatives and ⅓ public members. We are seeking nominations for two non-federal, public members at this time, due to turnover of committee membership. Nominations will be accepted between July 31 and August 31, 2018.

Who is Eligible: Nominations are encouraged for new or reappointment of non-federal public members who can provide the public and/or patient perspectives to discussions of issues considered by the Committee. Self-nominations and nominations of other individuals are both permitted. Only one nomination per individual is required. Multiple nominations for the same individual will not increase likelihood of selection. Non-federal, public members may be selected from the pool of submitted nominations or other sources as needed to meet statutory requirements and to form a balanced committee that represents the diversity within the muscular dystrophy communities. Nominations are especially encouraged from leaders or representatives of muscular dystrophy research, advocacy, or service organizations, individuals with muscular dystrophy or their parents or guardians. In accordance with White House Office of Management and Budget guidelines (FR Doc. 2014–19140), federally-registered lobbyists are not eligible.

Committee Composition: The Department strives to ensure that the membership of HHS Federal advisory committees is fairly balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that the views of all genders, all ethnic and racial groups, and people with disabilities are