

Panel Review of R25 Research Training Grant Applications.

Date: July 17, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815

Contact Person: Lisa A. Dunbar, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.12F, Bethesda, MD 20892, 301-594-2849, dunbar@mail.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: June 22, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-15659 Filed 6-25-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive License Agreement: Development of Bispecific and Multi-Specific Fusion Proteins for the Treatment of ROR1 Expressing Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license agreement to practice the inventions embodied in US Provisional Application No. 61/418,550 entitled, “Chimeric rabbit/human ROR1 antibodies” filed December 1, 2010 [HHS Ref. E-039-2011/0-US-01]; PCT Application No. PCT/US2011/062670 entitled, “Chimeric rabbit/human ROR1 antibodies” filed November 30, 2011 [HHS Ref. E-039-2011/0-PCT-02]; Australian Patent Application No. 2011336650 entitled, “Chimeric rabbit/human ROR1 antibodies” filed November 30, 2011 [HHS Ref. E-039-2011/0-AU-03]; Canadian Patent Application No. 2818992 entitled, “Chimeric rabbit/human ROR1 antibodies” filed November 30, 2011

[HHS Ref. E-039-2011/0-CA-04]; European Patent Application No. 11791733.6 entitled, “Chimeric rabbit/human ROR1 antibodies” filed November 30, 2011 [HHS Ref. E-039-2011/0-EP-05]; and U.S. Patent Application No. 13/990,977 entitled, “Chimeric rabbit/human ROR1 antibodies” filed May 31, 2013 [HHS Ref. E-039-2011/0-US-06] and all related continuing and foreign patents/patent applications for the technology family to Emergent BioSolutions. 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 develop, make, have made, sell, have sold, import and export bi-specific and multi-specific fusion proteins that are capable of eliciting redirected T-cell cytotoxicity for the treatment of human receptor tyrosine kinase-like orphan receptor 1 (ROR1) expressing cancers, wherein said fusion proteins comprise one or more single-chain variable fragment (scFv) ROR1 binding domains from the anti-ROR1 antibodies designated as R11 or R12, one or more of Licensee’s proprietary scFv CD3 binding domains, and optionally a fragment crystallizable (Fc) domain.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before July 27, 2015 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Jennifer Wong, M.S., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4633; Facsimile: (301) 402-0220; Email: wongje@od.nih.gov.

SUPPLEMENTARY INFORMATION: Tyrosine kinase-like orphan receptor 1 (ROR1) is a signature cell surface antigen for B-cell malignancies, most notably, B-cell chronic lymphocytic leukemia (B-CLL) and mantle cell lymphoma (MCL) cells, two incurable diseases. The investigators have developed a portfolio of chimeric anti-ROR1 monoclonal antibodies that selectively target ROR1 malignant B-cells but not normal B-cells. These antibodies may be linked to chemical drugs or biological toxins thus providing targeted cytotoxic delivery to malignant B-cells while sparing normal

cells. Moreover, as these antibodies selectively target ROR1, they can also be used to diagnose B-cell malignancies.

The prospective exclusive license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH 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.

Any additional, properly filed, and complete 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: June 22, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015-15655 Filed 6-25-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: The Development of an Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive license to practice the inventions embodied in U.S. Provisional Patent Application 62/006,313 entitled “Chimeric Antigen Receptors Targeting CD-19” [HHS Ref. E-042-2014/0-US-01], and all related continuing and foreign patents/patent applications for the technology family, to Kite Pharma, Inc. The patent rights in these inventions have been assigned to and/or exclusively licensed to the Government of the United States of America.

The prospective exclusive licensed territory may be worldwide, and the field of use may be limited to: “All prophylactic and therapeutic uses for

CD19-associated diseases, states and conditions in humans.”

DATES: Only applications for a license which are received by the NIH Office of Technology Transfer on or before July 27, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: David A. Lambertson, Ph.D., Senior Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-4632; Facsimile: (301) 402-0220; Email: lambertson@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns an anti-CD19 chimeric antigen receptor (CAR) and methods of using the CAR for the treatment of CD19-expressing cancers, including B cell malignancies.

CD19 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, particularly cancers of B cell origin such as Non-Hodgkin's Leukemia (NHL), acute lymphoblastic leukemia (ALL) and chronic lymphocytic leukemia (CLL). The anti-CD19 CARs of this technology contain (1) antigen recognition sequences that bind specifically to CD19 and (2) signaling domains that can activate the cytotoxic functions of a T cell. The anti-CD19 CAR can be transduced into T cells that are harvested from a cancer patient; from there, T cells expressing the anti-CD19 CAR are selected, expanded and then be reintroduced into the patient. Once the anti-CD19 CAR-expressing T cells are reintroduced into the patient, the T cells can selectively bind to CD19-expressing cancer cells through its antigen recognition sequences, thereby activating the T cell through its signaling domains to selectively kill the cancer cells. Through this mechanism of action, the selectivity of the a CAR allows the T cells to kill cancer cells while leaving healthy, essential cells unharmed. This can result in an effective therapeutic strategy with fewer side effects due to less non-specific killing of cells.

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 the NIH 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 within thirty (30) days from the date of this published notice.

Complete applications for a license in an appropriate field of use that are 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: June 22, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015-15657 Filed 6-25-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615-0023]

Agency Information Collection Activities: Application To Register Permanent Residence or Adjust Status, Form I-485 Supplement A, and Instruction Booklet for Filing Form I-485 and Supplement A, Form I-485; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection notice was previously published in the **Federal Register** on March 10, 2015, at 80 FR 12647, allowing for a 60-day public comment period. USCIS received eight comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until July 27, 2015. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at oir_submission@omb.eop.gov.

omb.eop.gov. Comments may also be submitted via fax at 202-395-5806. (This is not a toll free number.) All submissions received must include the agency name and the OMB Control Number 1615-0023.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information, please read the Privacy Act notice that is available via the link in the footer of <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: If you need a copy of the information collection instrument with instructions or additional information, please contact us at: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529-2140, Telephone number 202-272-8377. (This is not a toll free number.) Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at <http://www.uscis.gov>, or call the USCIS National Customer Service Center at 800-375-5283 (TTY 800-767-1833).

SUPPLEMENTARY INFORMATION:

Comments

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submission of responses).