

TABLE 1—ESTIMATES FOR ANNUAL BURDEN HOURS

Type of data collection instrument	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Focus Groups	500	1	1	500
Pre/Post Test	2,500	1	15/60	625
Survey	2,500	1	15/60	625
Interview	500	1	1	500
Tracking/Feedback Form	1,500	1	30/60	750
Total	7,500	3,000

Dated: March 21, 2014.

Sarah L. Glavin,

Deputy Director, Office of Science Policy, Analysis, and Communications, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.

[FR Doc. 2014-07105 Filed 3-28-14; 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 a Single Domain Human Anti-Mesothelin Monoclonal Antibody 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 start-up option license to practice the inventions embodied in U.S. Patent Application 61/706,396 entitled “Mesothelin Antibodies and Methods for Eliciting Potent Antitumor Activity” [HHS Ref. E-236-2012/0-US-01], PCT Application PCT/US2013/059883 entitled “Mesothelin Antibodies and Methods for Eliciting Potent Antitumor Activity” [HHS Ref. E-236-2012/0-PCT-02], and all related continuing and foreign patents/patent applications for the technology family, to H2Bio, 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 start-up option licensed territory may be worldwide, and the field of use may be limited to:

The use of the monoclonal antibody SD1 (and glycoengineered variants thereof) as an antibody therapy for the treatment of mesothelioma, pancreatic cancer, ovarian cancer and lung adenocarcinoma. The

Licensed Field of Use explicitly excludes the use of the antibody in the form of an immunoconjugate, including, but not limited to, immunotoxins.

Upon the expiration or termination of the exclusive start-up option license, H2Bio, Inc. will have the exclusive right to execute an exclusive commercialization license which will supersede and replace the exclusive start-up option license with no greater field of use and territory than granted in the exclusive start-up option license.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before April 15, 2014 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: lambertsond@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns a monoclonal antibody and methods of using the antibody for the treatment of mesothelin-expressing cancers, including mesothelioma, lung cancer, ovarian cancer and pancreatic cancer. The specific antibody covered by this technology is designated SD1, which is a single domain, fully human monoclonal antibody against mesothelin.

Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer cells. The SD1 antibody can selectively bind to these cancer cells and induce cell death 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 start-up option 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 start-up option 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 fifteen (15) days from the date of this published notice.

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 start-up option 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: March 27, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development & Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014-07022 Filed 3-28-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Multivalent Vaccines for Rabies Virus and Ebola and Marburg (Filoviruses)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR 404, that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of an exclusive license to practice the following invention as embodied in the following patent applications: E-032-2011/0, Blaney *et al.*, “Multivalent Vaccines for Rabies Virus and Filoviruses,” U.S. Patent Application Number 61/439,046, filed

on February 3, 2011, PCT Application Number PCT/US2012/23575, filed on February 2, 2012, U.S. Patent Application Number 13/983,545, filed on August 2, 2013, European Patent Application Number 12702953.6, filed on February 2, 2012, and Canadian Patent Application Number 2826594, filed on February 2, 2012, to Excell BIO, Inc., having a place of business in Shoreview, Minnesota, United States of America. The patent rights in these inventions have been assigned to the United States of America and Thomas Jefferson University.

DATES: Only written comments and/or application for a license which are received by the NIH Office of Technology Transfer on or before April 30, 2014 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Peter Soukas, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Email: ps193c@nih.gov; Telephone: (301) 435-4646; Facsimile: (301) 402-0220.

SUPPLEMENTARY INFORMATION: No vaccine candidates against Ebola virus (EBOV) or Marburg virus (MARV) are nearing licensure, and the need to develop a safe and efficacious vaccine against filoviruses continues. Whereas several preclinical and clinical vaccine candidates against EBOV or MARV exist (please see below for further elaboration), their further development is a major challenge based on safety concerns, pre-existing vector immunity, issues such as manufacturing, dosage, and marketability, and funding for development. The inventors have developed a new platform based on live or chemically inactivated (killed) rabies virus (RABV) virions containing EBOV glycoprotein (GP) in their envelope. In preclinical trials, immunization with such recombinant RABV virions provided excellent protection in mice against lethal challenge with the mouse adapted EBOV and RABV. More specifically, the inventors have developed a trivalent filovirus vaccine based on killed rabies virus virions for use in humans to confer protection from all medically relevant filoviruses and RABV. Two additional vectors containing EBOV Sudan GP or MARV GP are planned to be constructed in addition to the previously developed EBOV Zaire GP containing vaccine. Live attenuated vaccines have been developed for use in at risk nonhuman primate populations in Africa and

inactivated vaccines have been developed for use in humans.

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 404. The prospective exclusive license may be granted unless, within thirty (30) days from the date of this published Notice, 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 404.

The fields of use may be limited to (1) inactivated vaccines against rabies virus and filoviruses for use in humans and (2) live attenuated vaccines against rabies virus and filoviruses for use in non-human animals.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: March 26, 2014.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2014-07023 Filed 3-28-14; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special

Emphasis Panel; NIH Loan Repayment Program (Clinical and Pediatric Researchers).

Date: April 24, 2014.

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

Agenda: To review and evaluate contract proposals.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Room 3094, Morrisville, NC 27560; (Virtual Meeting).

Contact Person: RoseAnne M. McGee, Associate Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, (919) 541-0752, mcgee1@niehs.nih.gov.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Career Grant Applications Review in Environmental Health Sciences.

Date: April 24, 2014.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Room 3118, Morrisville, NC 27560, (Telephone Conference Call).

Contact Person: Leroy Worth, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30/Room 3171, Research Triangle Park, NC 27709, (919) 541-0670, worth@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: March 25, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014-07021 Filed 3-28-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of meetings of the National Center for Advancing Translational Sciences.