A.12–1—ESTIMATES OF HOUR BURDEN—Continued

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Clinical Evaluation	100	1	30/60	50
Survey Instrument	100	1	1	100
Device Training	100	2	1	200
Health Data Monitoring	100	2	10	2,000
Device Return	15	1	18/60	5

Dated: March 3, 2014.

Robert S. Balaban,

Scientific Director, Dir, NHLBI, NIH.

Dated: March 3, 2014.

Lynn Susulske,

NHLBI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2014–05698 Filed 3–13–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Evaluation License Agreement: Pre-Clinical Evaluation and Commercial Development of Anti-Tyrosine Kinase-Like Orphan Receptor 1 Antibody-Drug Conjugates 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. Patent Application 61/172,099 entitled ''Anti-human ROR1 Antibodies'' [HHS Ref. E–097–2009/0–US–01], PCT Application No. PCT/US2010/032208 entitled ''Anti-human ROR1 Antibodies'' [HHS Ref. E–097–2009/0–PCT–02], U.S. Patent Application 61/418,550 entitled, ''Chimeric Rabbit/Human ROR1 Antibodies'' [HHS Ref. No. E–039–2011/0–US–01], and PCT Application No. PCT/US2011/062670 entitled, ''Chimeric Rabbit/Human ROR1 Antibodies'', and all related continuing and foreign patents/patent applications for the technology family, to Ardeagen Corporation. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective start-up exclusive evaluation option license territory may be worldwide and the field of use may be limited to pre-clinical evaluation and commercial development of an antibody-drug conjugate comprising an anti-tyrosine protein kinase transmembrane receptor (ROR1) antibody for the treatment of human ROR1 expressing cancers, wherein the antibody moiety comprises the anti-ROR1 antibodies designated as 2A2, 2D11, R11, R12, or R31. For avoidance of doubt, this Agreement explicitly excludes the development of an immunotoxin comprising 2A2 and *Pseudomonas* exotoxin A targeted immunotoxins for the treatment of human ROR1 expressing cancers. Upon expiration or termination of the start-up exclusive evaluation option license, Ardeagen Corporation will have the right to execute a start-up exclusive patent commercialization license which will supersede and replace the start-up exclusive evaluation option license with no broader territory than granted in the start-up exclusive evaluation option license and the field of use will be commensurate with the commercial development plan at the time of conversion.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before March 31, 2014 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 start-up exclusive evaluation option license is being considered under the small business initiative launched on October 1, 2011 and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective start-up exclusive evaluation option license, and a subsequent start-up exclusive patent commercialization license, may be granted unless within fifteen (15) 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 evaluation 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 12, 2014.

Richard U. Rodriguez,

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

[FR Doc. 2014–05678 Filed 3–13–14; 8:45 am]

BILLING CODE 4140–01–P