ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
CTSU IBCSG Drug Accountability Form	Health Care Practitioner	11	12	10/60	22
CTSU IBCSG Transfer of Investigational Agent Form.	Health Care Practitioner	3	12	20/60	12
Site Initiated Data Update Form	Health Care Practitioner	10	12	10/60	20
Data Clarification Form	Health Care Practitioner	341	12	20/60	1,364
RTOG 0834 CTSU Data Transmittal Form	Health Care Practitioner	60	12	10/60	120
MC0845(8233) CTSU Data Transmittal	Health Care Practitioner	50	12	10/60	100
CTSU Generic Data Transmittal Form	Health Care Practitioner	500	12	10/60	1,000
CTSU Patient Enrollment Transmittal Form	Health Care Practitioner	200	12	10/60	400
CTSU P2C Enrollment Transmittal Form	Health Care Practitioner	15	12	10/60	30
CTSU Transfer Form	Health Care Practitioner	20	12	10/60	40
CTSU System Account Request Form	Health Care Practitioner	20	12	20/60	80
CTSU Request for Clinical Brochure	Health Care Practitioner	75	12	10/60	150
CTSU Supply Request Form	Health Care Practitioner	75	12	10/60	150
CTSU Web Site Customer Satisfaction Survey	Health Care Practitioner	275	1	15/60	69
CTSU Helpdesk Customer Satisfaction Survey	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey	Health Care Practitioner	60	1	15/60	15
PIO Customer Satisfaction Survey	Health Care Practitioner	100	1	5/60	8
Concept Clinical Trial Survey	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey	Health Care Practitioner	1,000	1	5/60	83
Low Accrual Clinical Trial Survey	Health Care Practitioner	1,000	1	5/60	83

Dated: November 7, 2013.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2013–27554 Filed 11–18–13; 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 Modified T-cells for the Treatment of Multiple Myeloma

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 to Thirsty Brook Bioscience, Inc., of an exclusive evaluation option license to practice the inventions embodied in the following US Patent Applications (and all continuing applications and foreign counterparts): Serial No. 61/622,6008 entitled, ''Chimeric Antigen Receptors Targeting B-cell Maturation Antigen'' [HHS Ref. E–040–2012/0–US–01]. The patent rights in these inventions have been assigned to the Government of the United States of America.

The prospective exclusive evaluation option license territory may be worldwide, and the field of use may be limited to:

''The research, development, and manufacture of chimeric antigen receptor (CAR)-expressing human T-cells directed against B-cell Maturation Antigen (BCMA) for the treatment of multiple myeloma.''

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

DATES: Only written comments or applications for a license (or both) which are received by the NIH Office of Technology Transfer on or before December 4, 2013 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation option license should be directed to: Patrick McCue, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–5560; Facsimile: (301) 402–0220; Email: *mccuepat@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The invention concerns a series of CARs that specifically target BCMA (a.k.a. CD269), a protein that is highly expressed on the surface of multiple myeloma cells. The patent rights include claims to vectors incorporating the CARs, as well as methods of destroying multiple myeloma cells using T-cells engineered to express a CAR.

The prospective exclusive evaluation option license is being considered under the small business initiative launched on 1 October 2011, and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive evaluation option license, and a subsequent exclusive commercialization 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 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: November 13, 2013.

Richard U. Rodriguez,

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

[FR Doc. 2013–27601 Filed 11–18–13; 8:45 am]

BILLING CODE 4140–01–P