

## 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.*

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**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](mailto: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**