[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive Option 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 a co-exclusive (or exclusive, if the other party declines to move forward with an agreement) 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 MesoPharm Therapeutics, 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 co-exclusive (or 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, breast 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 co-exclusive start-up option license, MesoPharm Therapeutics, Inc. will have the co-exclusive right to execute a co-exclusive (or exclusive, if the other party declines their option) commercialization license which will supersede and replace the co-exclusive start-up option license with no greater field of use and territory than granted in the co-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 [Insert date 15 days from date of publication of notice in the FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated co-exclusive start-up option 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; E-mail: 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 co-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 co-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 co-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: July 14, 2014

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Richard U. Rodriguez, M.B.A.
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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