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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 Human Anti-Mesothelin Monoclonal Antibodies for the Treatment of Human Cancers.

**AGENCY:** National Institutes of Health, Public Health Service, HHS

**ACTION:** Notice

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR Part 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive evaluation option license to practice the inventions embodied in U.S. Patent Application 61/040,005 entitled “Human Monoclonal Antibodies Specific for Mesothelin” [HHS Ref. E-079-2008/0-US-01], PCT Application PCT/US2009/038228 entitled “Human Monoclonal Antibody Against Mesothelin” [HHS Ref. E-079-2008/0-PCT-02], Australian patent application AU 2009228361 entitled “Human Monoclonal Antibody Against Mesothelin” [HHS Ref. E-079-2008/0-AU-03], Canadian patent application CA 2718321 entitled “Human Anti-Mesothelin Monoclonal Antibodies” [HHS Ref. E-079-2008/0-CA-04], European patent application EP 09726082.2 entitled “Human Monoclonal Antibody Against Mesothelin” [HHS Ref. E-079-2008/0-EP-05], US patent application 12/934,060 entitled “Human Anti-Mesothelin Monoclonal Antibodies” [HHS Ref. E-079-2008/0-US-06], and all related continuing and foreign patents/patent applications for the technology family, to Sanomab, Ltd. 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 evaluation option license territory may be worldwide, and the field of use may be limited to:

The use of the monoclonal antibody m912 (SM-101) as an antibody therapy for the treatment of pancreatic cancer, ovarian cancer, lung cancer, mesothelioma, and stomach/gastric cancer. 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 evaluation option license, Sanomab, Ltd. 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.

**DATE:** 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.

**ADDRESS:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive evaluation 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@od.nih.gov](mailto:lambertsond@od.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, stomach/gastric cancer, ovarian cancer and pancreatic cancer. The

specific antibody covered by this technology is designated m912 (SM-101), which is a fully human monoclonal antibody against mesothelin.

Mesothelin is a cell surface antigen that is preferentially expressed on certain types of cancer cells. The m912 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 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 404.7. 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 404.7 within fifteen (15) days from the date of this published notice. A previous notice for this license was published on 12 October 2011.

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.

January 24, 2012

Date

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

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