# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## **National Institutes of Health**

Prospective Grant of Exclusive License: Photosensitizing Antibody-Fluorophore Conjugates for Photo-Immunotherapy

**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 404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is contemplating the grant of a worldwide exclusive evaluation option license, to practice the inventions embodied in US patent application 13/180,111, filed July 11, 2011 (HHS Reference# E-205-2010/ 0-US-02), originated from provisional application 61/363,079 filed July 09, 2010, and entitled "Photosensitizing Antibody Fluorophore Conjugates for Photo-Immunotherapy" to Aspyrian Therapeutics, Inc., a company incorporated under the laws of the State of Delaware, having its headquarters in San Diego, California. The United States of America is the assignee of the rights of the above inventions.

The field of use may be limited to "use of photosensitizing antibody-fluorophore conjugate for imaging and photo-immunotherapy of cancer" and may be further limited to certain types of cancer and/or specific platforms.

Upon the expiration or termination of the exclusive evaluation option license, Aspyrian Therapeutics, Inc. will have the right to execute an exclusive worldwide patent commercialization license which will supersede and replace the exclusive evaluation option license with the same field of use.

DATES: Only written comments and/or applications for a license received by the NIH Office of Technology Transfer on or before March 5, 2012 will be

considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Uri Reichman, Ph.D., M.B.A., Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852–3804; Telephone: (301) 435–4616; Facsimile: (301) 402–0220; Email: Reichmau@mail.nih.gov. A signed confidentiality nondisclosure agreement will be required to receive copies of any patent applications that have not been published or issued by the United States

Patent and Trademark Office or the World Intellectual Property Organization.

SUPPLEMENTARY INFORMATION: The present technology provides a novel method for cancer therapy which may offer improved specificity and sensitivity in cancer treatment. The method is based on molecular targeting. More specifically, it is based on photoimmunotherapy (PIT). The therapeutic agent is a targeted photosensitizer composed of a tumor specific antibody conjugated to IR700 dve, where the dve is sensitive to a near infrared light. Upon administration of the conjugated antibody to a subject, it specifically binds to the targeted cancerous tissue. Upon subsequent irradiation with a near infrared light, the dye releases energy that leads to the killing of the targeted cells. The concept was proven by the inventors in vitro and in vivo with mouse models, using humanized anti-HER1 (Panitumumab, for colon cancer), anti-HER2 (Trastuzumab, for breast cancer) and anti-PSMA antibody (huJ591, for prostate cancer). Targeted cells were completely killed while normal cells were not noticeably affected. The technology provides also for wearable LED systems that can be used to irradiate the photosensitizer.

The prospective exclusive evaluation option license will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive evaluation option license may be granted unless, within fifteen (15) days from the date of this published notice, 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 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response 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: February 13, 2012.

## Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, 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 Human Anti-CD22 Monoclonal Antibodies for the Treatment of Human Cancers and Autoimmune Disease

**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 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 61/042,239 entitled "Human Monoclonal Antibodies Specific for CD22" [HHS Ref. E-080-2008/0-US-01], PCT Application PCT/ US2009/124109 entitled "Human and Improved Murine Monoclonal Antibodies Against CD22" [HHS Ref. E-080-2008/0-PCT-02], U.S. patent application 12/934,214 entitled "Human Monoclonal Antibodies Specific for CD22" [HHS Ref. E-080-2008/0-US-03], 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 m971 and m972 (SMB–002) monoclonal antibodies as therapies for the treatment of B cell cancers and autoimmune disease. The Licensed Field of Use includes the use of the antibodies in the form of an immunoconjugate, including 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.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before March 5, 2012 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the