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 dye, where the dye 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.

[FR Doc. 2012–3828 Filed 2–16–12; 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 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

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; Email: *lambertsond@od.nih.gov.*

SUPPLEMENTARY INFORMATION: This invention concerns monoclonal antibodies against CD22 and methods of using the antibodies for the treatment of CD22-expressing cancers, including hematological malignancies such as hairy cell leukemia, chronic lymphocytic leukemia and pediatric acute lymphoblastic leukemia, and autoimmune disease such as lupus and Sjogren's syndrome. The specific antibodies covered by this technology are designated m971 and m972 (SMB–002; applicant designation).

CD22 is a cell surface antigen that is preferentially expressed on certain types of cancer cells, and is involved in the modulation of the immune system. The m971 and m972 antibodies can selectively bind to diseased 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 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 404.7 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: February 13, 2012.

Richard U. Rodriguez,

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

[FR Doc. 2012–3829 Filed 2–16–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Proposed Project: Toolkit Protocol for the Crisis Counseling Assistance and Training Program (CCP)—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) will create a toolkit to be used for the purposes of collecting data on the Crisis Counseling Assistance and Training Program (CCP). The CCP provides supplemental funding to states and territories for individual and community crisis intervention services during a Federal disaster.

The CCP has provided disaster mental health services to millions of disaster survivors since its inception and, as a result of 30 years of accumulated expertise, it has become an important model for Federal response to a variety of catastrophic events. State CCPs, such as the recent 2009 Project A'apa Atu (for the Tsunami in American Samoa), 2010 Tennessee Recovery Project (following devastating flooding), Healing Joplin and Project Rebound (following the 2011 tornadoes in Joplin, Missouri and Alabama), and most recently the multiple CCPs that resulted from 2011 Hurricane Irene, and flooding throughout the summer of 2011 have primarily addressed the short-term mental health needs of communities through (a) Outreach and public education, (b) individual and group counseling, and (c) referral. Outreach and public education serve primarily to normalize reactions and to engage people who might need further care. Crisis counseling assists survivors to cope with current stress and symptoms in order to return to predisaster functioning. Crisis counseling relies largely on ''active listening,'' and crisis counselors also provide psycho-education (especially about the nature of responses to trauma) and help clients build coping skills. Crisis counseling typically continues no more than a few times. Because crisis counseling is time-limited, referral is the third important functions of CCPs. Counselors are expected to refer clients to formal treatment if the person has developed more serious psychiatric problems.

Data about services delivered and users of services will be collected throughout the program period. The data will be collected via the use of a toolkit that relies on standardized forms. At the program level, the data will be entered quickly and easily into a cumulative database to yield summary tables for quarterly and final reports for the program. We have confirmed the feasibility of using scanable forms for most purposes. Because the data will be collected in a consistent way from all programs, they can be uploaded into an ongoing national database that likewise provides CMHS with a way of producing summary reports of services provided across all programs funded.

The components of the tool kit are listed and described below:

- *Encounter Logs.* These forms document all services provided. Completion of these logs is required by the crisis counselors. There are three types of encounter logs: (1) Individual/Family Crisis Counseling Services Encounter Log; (2) Group Encounter Log; and (3) Weekly Tally Sheet.
  - Individual/Family Crisis Counseling Services Encounter Log. Crisis counseling is defined as an interaction that lasts at least 15 minutes and involves participant disclosure. This form is completed by the Crisis Counselor for each service recipient or family, defined as the person or persons who actively participated in the session (e.g., by verbally participating), not someone who is merely present. For families, complete only one form to capture all family members who are actively engaged in the visit. Information collected includes demographics, service characteristics, risk factors, and referral data.
  - Group Encounter Log. This form is used to identify either a group crisis counseling encounter or a group public education encounter. A check at the top identifies the class of activities (i.e., counseling or education). Information collected includes services characteristics, group identity and characteristics, and group activities.