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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

Prospective Grant of Exclusive Patent License: Development of an antibody-drug conjugate for use in PhotoImmunoTherapy

**AGENCY:** National Institutes of Health

**ACTION:** Notice.

**SUMMARY:** The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the U.S. Patents and Patent Applications listed in the Summary Information section of this notice to Aspyrian Therapeutics, Inc. (“Aspyrian”) located in **San Diego, California USA.**

**DATES:** Only written comments and/or applications for a license which are received by the National Cancer Institute’s Technology Transfer Center 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, and comments relating to the contemplated exclusive license should be directed to: Thomas Clouse, J.D., Senior Licensing and Patenting Manager,  
NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504 E-mail: [thomas.clouse@nih.gov](mailto:thomas.clouse@nih.gov).

**SUPPLEMENTARY INFORMATION:**

## **Intellectual Property**

United States Provisional Patent Application No. 62/202,252, filed August 7, 2015 “Near Infrared PhotoImmunoTherapy (NIR-PIT) of Suppressor Cells to Treat Cancer” [HHS Reference No. E-231-2015/0-US-01]; and

PCT Patent Application PCT/US2016/045090, filed August 2, 2016 “Near Infrared PhotoImmunoTherapy (NIR-PIT) of Suppressor Cells to Treat Cancer” [HHS Reference No. E-231-2015/0-PCT-02].

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following: “Use of photosensitizing antibody-fluorophore conjugate defined by the Licensed Patent Rights by itself for PhotoImmunoTherapy (PIT), or in combination with cancer therapeutic agents, to treat cancer or hyperplasia.”

This technology discloses the concept of binding an anti-foxp3+ antibody to IR700 to bind to foxp3+ T-cells. When irradiated with near infrared light localized at the site of the solid tumor, controlled local knockdown of foxp3+ negative regulatory T-cells in tumors results in rapid tumor death without the severe autoimmune response that is induced by systemic knock-down of foxp3+ T-cells. Theoretically, this technology can be used in a broad spectrum of patients with a variety of solid cancers including those with multiple distant metastasis as foxp3+ T-cells are generally believed to be critical to immunotolerance found in cancers. By treating a single local site with this technology, systemic host immunity against in situ cancers can be dramatically activated, leading to

rapid tumor regression at the treated lesion as well as distant metastatic lesions untreated with the near infrared light while inducing minimal side effects.

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

Complete applications for a license in the prospective field of use that are filed in response to this notice will be treated as objections to the grant of the contemplated Exclusive Patent License Agreement. 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.

September 16, 2016

Dated

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Richard U. Rodriguez, M.B.A.

Associate Director

Technology Transfer Center

National Cancer Institute

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