[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Anti-Marinobufagenin Antibodies and Methods for Diagnosis and Treatment of Cardiovascular Disease and Fibrotic Disease

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute on Aging, 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. and International Patents and Patent Applications listed in the Supplementary Information section of this notice to CTS Biopharma LLC, located in Sunnyvale, CA**.**

DATES: Only written comments and/or complete 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 an Exclusive Patent License should be directed to: Richard T. Girards, Jr., Esq., MBA, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E508 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 (for overnight courier services); Telephone: (240)-276-6825; Facsimile: (240)-276-5504; E-mail: richard.girards@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 60/694,733 [HHS Ref No. E-092-2004/0-US-01], filed on June 27, 2005 and entitled "Anti-marinobufagenin antibodies and

methods for their use;" Patent Cooperation Treaty Patent Application No. PCT/US2006/024918 [HHS Ref No. E-092-2004/0-PCT-02], filed on June 26, 2006 and entitled "Anti-marinobufagenin antibodies and methods for their use;" and U.S. and foreign patents and/or patent applications claiming priority to the aforementioned applications, including but not limited to United States Patent No. 8,038,997 [HHS Ref No. E-092-2004/0-US-03] entitled "Anti-marinobufagenin antibodies and methods for their use."

Certain rights in the patent and these applications have been assigned 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 the Licensed Patent Rights for the following: (1) the use of anti-marinobufagenin antibodies for one or both of (a) the treatment of fibrotic disease and (b) the treatment of cardiovascular disease, including but not limited to preeclampsia and (2) companion diagnostics associated with the aforementioned treatments.

The patents and applications potentially to be licensed disclose antibodies (mAbs) that specifically bind marinobufagenin. They also disclose use of these mAbs in the diagnosis and treatment of cardiovascular disease such as hypertension. Further, they disclose use of these mAbs in the diagnosis and treatment of fibrotic diseases. The patents and applications potentially to be licensed also disclose technologies useful with respect to companion diagnostics for both fibrotic and cardiovascular diseases. The public substantially will benefit from the clinical and commercial development of these mAbs for the treatment and of cardiovascular as well as fibrotic disorders. The public also will benefit from the clinical and commercial development of companion diagnostics relative to these conditions.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and 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.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a completed license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice must be complete and in acceptable form by the expiration date of this Notice to be considered for a license. License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: March 8, 2018.

Richard U. Rodriguez,

Associate Director

Technology Transfer Center

National Cancer Institute

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