



**[Billing Code 4140-01-P]**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of an Exclusive Patent License: RP2 AAV Vectors for Treating X-Linked Retinitis Pigmentosa**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice

**SUMMARY:** The National Eye 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. and foreign Patents and Patent Applications listed in the Supplementary Information section of this notice to IVERIC bio, Inc. located in New York, NY.

**DATES:** Only written comments and/or applications for a license which are received by the National Eye Institute c/o National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Alan Hubbs,

Ph.D., Senior Technology Transfer Manager, NCITechnology 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, Email:  
hubbsa@mail.nih.gov.

#### **SUPPLEMENTARY INFORMATION:**

The following represents the intellectual property to be licensed under the  
prospective agreement:

#### **Intellectually Property**

1. US Provisional Patent Application No. 62/131,661, filed March 11, 2015 [HHS  
Reference No. E-050-2015/0-US-01];
2. PCT Patent Application No. PCT/US2016/022072 filed March 11, 2016 [HHS  
Reference No. E-050-2015-0-PCT-03];
3. Australian Patent Application No. AU2016228751A, filed on March 11, 2016  
[HHS Reference No. E-050-2015-0-AU-04];
4. Canadian Patent Application No. CA2979229A, filed on March 11, 2016 [HHS  
Reference No. E-050-2015-0-CA-05];
5. European Patent Application No. EP16762623.3A, filed on March 11, 2016 [HHS  
Reference No. E-050-2015-0-EP-06];
6. Japanese Patent Application No. JP2017547425A, filed on March 11, 2016 [HHS  
Reference No. E-050-2015-0-JP-07];
7. United States Patent Application No. US15/556,746, filed on March 11, 2016  
[HHS Reference No. E-050-2015-0-US-08]

With respect to persons who have an obligation to assign their right, title and interest to the Government of the United States of America, the patent rights in these inventions have been assigned to the Government of the United States of America. The prospective exclusive license territory may be world-wide, and the field of use may be limited to the use of Licensed Patent Rights for the following: “Human therapeutics for treating x-linked retinitis pigmentosa: The license will also be limited by licensed products covered by patent rights that pertain to AAV-mediated gene therapy delivering an RP2 transgene.”

This technology discloses adeno-associated virus (AAV) vectors comprising nucleotide sequences encoding RPGR-ORF15 or RP2 and related pharmaceutical compositions. It also discloses methods of treating or preventing x-linked retinitis pigmentosa, increasing photoreceptor number in the retina of a mammal, and increasing visual acuity of a mammal using the vectors and pharmaceutical compositions.

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 Eye 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 license application, will not be treated confidentially, and may be made publicly available.

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 U.S.C. 552.

**Dated:** May 9, 2019.

**Richard U. Rodriguez,**

*Associate Director,*

*Technology Transfer Center,*

*National Cancer Institute.*

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