



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

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

Prospective Grant of an Exclusive Patent License: Manufacturing and Testing of PVSRIPO in the Treatment of Solid, Non-lymphoid Tumors expressing Poliovirus Receptor CD155

**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 Commercialization Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Istari Oncology Incorporated located in North Carolina, U.S.A.

**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 Commercialization Patent License should be directed to: Lauren Nguyen-Antczak, Ph.D., 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: [lauren.nguyen-antczak@nih.gov](mailto:lauren.nguyen-antczak@nih.gov).

**SUPPLEMENTARY INFORMATION:**

**Intellectual Property**

United States Provisional Patent Application No. 62/173,777, filed June 10, 2015 and entitled “Processes for Production and Purification of Nucleic Acid Containing Compositions” [HHS Reference No. E-267-2014/0-US-01];

PCT Patent Application PCT/US2016/036888, filed E-267-2014/0-PCT-02 and entitled “Processes for Production and Purification of Nucleic Acid Containing Compositions” [HHS Reference No. E-267-2014/0-PCT-02];

United States Provisional Patent Application No. 62/199,663, filed July 31, 2015 and entitled “Methods of Analyzing Virus-Derived Therapeutics” [HHS Reference No. E-240-2015/0-US-01];

PCT Patent Application PCT/US2016/044788, filed July 29, 2016 and entitled “Methods of Analyzing Virus-Derived Therapeutics” [HHS Reference No. E-240-2015/1-PCT-01]; and U.S. and foreign patent applications claiming priority to the aforementioned applications.

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: “Manufacturing and Testing of PVSRIPO in the Treatment of Solid, Non-lymphoid Tumors expressing Poliovirus Receptor CD155, wherein PVSRIPO is genetically recombinant, non-pathogenic poliovirus:rhinovirus chimera that consists of the genome of the live attenuated poliovirus serotype 1 (SABIN) vaccine (PV1S) with its cognate IRES element replaced with that of HRV2.”

The E-267-2014 technology discloses improved methods for large scale production of highly purified, therapeutic grade, oncolytic polioviruses. Invention processes provide industrial scale, and cGMP compliant manufacturing of PVSRIPO. The E-240-2015 technology discloses improved methods for detecting genetic micro-heterogeneity in manufactured batches of RNA virus-derived therapeutics, such as PVSRIPO.

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.

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 Commercialization 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.

Dated: May 12, 2017

Richard U. Rodriguez

Associate Director

Technology Transfer Center

National Cancer Institute

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