



BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development, Commercial Application and Use of Fulvestrant in Combination Therapy for the Treatment of Cancers

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 U.S. Patents and Patent Applications listed in the Supplementary Information section of this notice to NantBioScience, Inc., located in, 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 AFTER 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: Sabarni K. Chatterjee, Ph.D., M.B.A., 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

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SUPPLEMENTARY INFORMATION:

Intellectual Property

- United States Provisional Patent Application No. 62/290,117 filed February 02, 2016, and entitled “Fulvestrant Improves Immune-mediated Cytotoxic Lysis of Cancer Cells.” [HHS Reference No. E-066-2016/0-US-01];
- International PCT Application No. PCT/US2017/015829 filed January 31, 2017, entitled “Fulvestrant Improves Immune-mediated Cytotoxic Lysis of Cancer Cells.” [HHS Reference No. E-066-2016/0-PCT-02]; 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: “Development, commercial application and use of fulvestrant in estrogen receptor positive cancers, in combination with other products and therapies, excluding poxvirus-based vaccines.” For avoidance of doubt, the field of use specifically excludes the use of fulvestrant in combination with poxvirus-based vaccines.

This technology discloses the use of fulvestrant, an estrogen receptor antagonist, as an immune modulating agent that enhances the effects of immunotherapy and/or chemotherapy in cancer cells. Fulvestrant treatment of mesenchymal-like lung carcinoma cells increases immune-mediated lysis by reversing epithelial mesenchymal

transition (EMT), potentially repairing defective cell death mechanisms driven by EMT, and restoring immune-mediated lysis to chemo-resistant cells. Overall, treatment of cancer cells with fulvestrant in combination with immunotherapy or chemotherapy agents results in increased cancer cell death. Although immunotherapy is leading the charge in cancer treatments, its efficacy is limited by patient resistance to immunotherapy and/or non-responsiveness. Combination therapy with fulvestrant that enhances the therapeutic effects of immunotherapy and chemotherapy, is a promising strategy to improve the clinical outcome for patients with resistant or unresponsive tumors.

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: July 6, 2017.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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