[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Methods of Modulating Erythropoiesis with Arginine Vasopressin Receptor 1B Molecules

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Dental and Craniofacial Research, 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 Patent Applications listed in the Supplementary Information section of this notice to ERYTHRYx Therapeutics, located in Los Angeles, California**.**

DATES: Only written comments and/or applications for a license which are received by the Office of Technology Transfer and Innovation Access, National Institute of Dental and Craniofacial Research 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 an Exclusive Patent License should be directed to: Yun Mei, Technology Transfer and Patent Specialist, Office of Technology Transfer and Innovation Access, National Institute of Dental and Craniofacial Research, National Institutes of Health, BLDG 1 DEM, RM667, 6701 Democracy Blvd, Bethesda, MD 20817; Telephone: (301) 827-4639; Facsimile: (301) 496-1005; E-mail: yun.mei@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Patent Application No. 61/885,258, filed October 1, 2013 and entitled "Methods of Modulating Erythropoiesis with Arginine Vasopressin Receptor 1B Molecules" (HHS Reference No. E-619-2013-0-US-01);
2. PCT Application No. PCT/US2014/058613, filed October 1, 2014 and entitled "Methods of Modulating Erythropoiesis with Arginine Vasopressin Receptor 1B Molecules" (HHS Reference No. E-619-2013-0-PCT-02);
3. U.S. Patent Application No. 15/022,531, filed March 16, 2016 and entitled "Methods of Modulating Erythropoiesis with Arginine Vasopressin Receptor 1B Molecules" (HHS Reference No. E-619-2013-0-US-03);

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 the United States and the field of use may be limited to "Use of arginine vasopressin receptor 1B agonists to treat anemia caused by (i) chronic renal failure on dialysis, (ii) receiving myelosuppressive chemotherapy, or (iii) lacking antidiuretic hormone."

The subject technology is a method of using arginine vasopressin receptor 1B (AVPR1B) agonists to increase the number of red blood cells to treat anemia. The inventors discovered that hematopoietic stem cells express AVPR1B receptor, and these receptors play a key role in promoting hematopoietic stem and progenitor cell proliferation. The number of red blood cells and their precursors significantly increased on day 2 following vasopressin administration, an onset time much faster than

erythropoietin (EPO), which is commonly used to stimulate red blood cell production for anemia treatment. EPO takes about a week to manifest its clinical effects. The AVPR1B agonists can be used to jumpstart the hematopoietic system and erythropoietin can be used to sustain the effect.

The subject technology is a repurposing of an existing drug, vasopressin, an AVPR1B agonist, also called antidiuretic hormone. It is a nine-amino acid peptide secreted from the posterior pituitary and used to treat patients with central diabetes insipidus, an uncommon disorder that causes an imbalance of water in the body. This imbalance leads to excretion of large amount of urine (polyuria) and intense thirst even after drinking fluids (polydipsia).

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 Institute of Dental and Craniofacial Research 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 USC 552.

Dated: June 19, 2018.

David W. Bradley,

Director,

Office of Technology Transfer and Innovation Access,

National Institute of Dental and Craniofacial Research,

National Institutes of Health.

[FR Doc. 2018-13443 Filed: 6/21/2018 8:45 am; Publication Date: 6/22/2018]