



**Billing Code 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Prospective Grant of an Exclusive Patent License: AAV Mediated exendin-4 gene Transfer to Salivary Glands to Protect Subjects from Diabetes or Obesity**

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

**ACTION:** Notice.

**SUMMARY:** The National Institute of Diabetes and Digestive and Kidney Disease and National Institute of Dental and Craniofacial Research, institutes of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the United States, European and Canadian Applications listed in the Supplementary Information section of this notice to Kriya Therapeutics, Inc., located in Palo Alto, California, USA.

**DATES:** Only written comments and/or applications for a license which are received by the National Institute of Diabetes and Digestive and Kidney Disease's Technology Advancement Office 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 applications, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Vladimir Knezevic, MD, (Senior) Advisor for Commercial Evaluation, Technology Advancement Office, Building 12A, Room 3011, Bethesda, MD 20817-5632 (for business mail), Telephone: (301)-435-5560; E-mail: [vlado.knezevic@nih.gov](mailto:vlado.knezevic@nih.gov).

## **SUPPLEMENTARY INFORMATION:**

### **Intellectual Property**

- I. U.S. Pat: 9,511,103 issued 2016-12-06, entitled “AAV mediated exendin-4 gene transfer to salivary glands to protect subjects from diabetes or obesity” (HHS Reference Number E-142-2011-0-US-05)
- II. U.S. Divisional Pat: 10,300,095 issued 2019-05-28, entitled “AAV mediated exendin-4 gene transfer to salivary glands to protect subjects from diabetes or obesity” (HHS Reference Number E-142-2011-0-US-6)
- III. European Patent National Stage: EP2709653 granted 2017-11-22, entitled “AAV mediated exendin-4 gene transfer to salivary glands to protect subjects from diabetes or obesity” (HHS Reference Number E-142-2011-0EP-04), validated in Great Britain, France and Germany.
- IV. U.S. Patent Application No. 16/396,262 filed 2019-04-26, entitled “AAV Mediated Exendin-4 Gene Transfer to Salivary Glands to Protect Subjects from Diabetes or Obesity” (HHS Reference Number E-142-2011-0-US-10).
- V. Canadian Application No. 2,833,623 filed 2012-04-19, entitled “AAV Mediated Exendin-4 Gene Transfer to Salivary Glands to Protect Subjects from Diabetes or Obesity” (HHS Reference Number E-142-2011-0-CA-03).

The patent rights in these inventions have been assigned or exclusively licensed to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to prevention and treatment of type-2 diabetes and obesity.

The above-listed patent portfolio covers inventions directed to gene therapy and specifically, expression vectors and therapeutic methods of using such vectors in the treatment of type-2 diabetes and obesity.

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. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Diabetes and Digestive and Kidney Disease 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: April 1, 2020.

**Vladimir Knezevic,**

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