



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Certain Fusion Proteins and Their Use for the Treatment of Humans with Short Stature

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Cancer Institute, both 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 Patents and Patent Applications listed in the Supplementary Information section of this Notice to EpifiZa Inc. of Montreal, QC (Canada).

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 FIFTEEN (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 Exclusive Patent License should be directed to: Richard T. Girards, Jr., Esq., MBA, Senior Technology Transfer Manager, National Institutes of Health, NCI Technology Transfer Center by email (richard.girards@nih.gov) or phone (240-276-6825).

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-003-2014: AGENTS THAT SPECIFICALLY BIND MATRILIN-3 AND THEIR USE / CARTILAGE TARGETING AGENTS AND THEIR USE

1. United States Provisional Patent Application No. 61/927,904, filed 15 January 2014 (HHS Reference No. E-003-2014-0-US-01);
2. United States Patent No. 10,323,083, issued 18 June 2019 (HHS Reference No. E-003-2014-0-US-06);
3. United States Patent Application No. 16/391,101, filed 22 April 2019 (HHS Reference No. E-003-2014-0-US-07);
4. International Patent Application No. PCT/US2015/011433, filed 14 January 2015 (HHS Reference No. E-003-2014-0-PCT-02);
5. Australia Patent No. 2015206515, issued 26 March 2020 (HHS Reference No. E-003-2014-0-AU-03);
6. Canada Patent Application No. 2931005, filed 14 January 2015 (HHS Reference No. E-003-2014-0-CA-04);
7. European Patent No. 3 094 350 B1, issued 04 March 2020 (HHS Reference No. E-003-2014-0-EP-05) and all of its national validations;
8. European Patent Application No. 19219282.1, filed 14 January 2015 (HHS Reference No. E-003-2014-0-EP-11); and
9. any and all other U.S. and ex-U.S. patents and patent applications claiming priority to any one of the foregoing, now or in the future.

The patent and patent application 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 fields of use may be limited to the following: the development, manufacture, distribution, sale and use of one or more fusion proteins for the treatment of humans with short stature associated with one or more genetic conditions.

These technologies disclose, e.g., monoclonal antibodies and antibody fragments that specifically bind to matrilin-3, conjugates including these molecules, and nucleic acid

molecules encoding the antibodies, antigen binding fragments and conjugates. Also disclosed are compositions including the disclosed antibodies, antigen binding fragments, conjugates, and nucleic acid molecules. Methods of treating or inhibiting a cartilage disorder in a subject, as well as methods of increasing chondrogenesis in cartilage tissue are further provided. The methods can be used, for example, for treating or inhibiting a growth plate disorder in a subject, such as a skeletal dysplasia or short stature.

This Notice is made in accordance with 35 U.S.C. § 209 and 37 C.F.R. § 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 C.F.R. § 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 from 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: January 11, 2021.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.