



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and commercialization of Caspase Inhibitors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Center for Advancing Translational Sciences, 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 Patents and Patent Applications listed in the Supplementary Information section of this Notice to Elgia Therapeutics Inc. (“Elgia”), headquartered in La Jolla, CA.

DATES: Only written comments and/or applications for a license which are received by the National Center for Advancing Translational Sciences’ Office of Strategic Alliances 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 Exclusive Patent License should be directed to: Sury Vepa, Ph.D., J.D., Senior Licensing and Patenting Manager, Office of Strategic Alliances, Telephone: (301)-642-0460; E-mail: sury.vepa@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Application No. 61/299,790, filed January 29, 2010 which is entitled “Caspase Inhibitors” (HHS Ref. No. E-308-2009-0-US-01);
2. International Patent Application No. PCT/US2011/02274 filed on January 27, 2011 which is entitled “Caspase Inhibitors” (HHS Ref. No. E-308-2009-0-PCT-02); and

3. US Patent Application No. 13/575,273 filed on July 25, 2012 which is entitled “Caspase Inhibitors” and issued as U.S. Patent No. 9,365,612 (HHS Ref. No. E-308-2009-0-US-03).

The patent rights in these inventions have been either 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 following:

“Development, manufacture, use and commercialization of Caspase Inhibitors disclosed and claimed in the prospective licensed patent rights, for the treatment of inflammatory diseases, such as hidradenitis suppurativa (HS) in humans and animals.”

The subject technology discloses potent and selective caspase 1 inhibitors that target the active site of the enzyme. Several cyanopropanate containing small molecules were synthesized, including one based upon the optimized peptidic scaffold of the prodrug VX-765. A number of these compounds were potent inhibitors of caspase 1 ($IC_{50}s \leq 1$ nM). Examination of these small molecules versus a caspase panel demonstrated an impressive degree of selectivity for caspase 1 inhibition. The small molecular probe ML132 (CID-4462093; NCGC-00183434) is the most potent caspase 1 inhibitor reported to date. It also possesses a unique selectivity pattern relative to other reported caspase inhibitors. A number of these compounds were assessed for their hydrolytic stability and selected absorption, distribution, metabolism and elimination (ADME) properties. Some of the compounds of this invention could be developed as effective therapeutics for diseases such as inflammatory diseases such as hidradenitis suppurativa (HS), ischemic disorders, Huntington’s disease, amyotrophic lateral sclerosis (ALS), rheumatoid arthritis, osteoarthritis, inflammatory bowel disease and sepsis.

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 Center for Advancing Translational Sciences 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 from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: July 16, 2023.

Joni L. Rutter,

Director, Office of the Director,

National Center for Advancing Translational Sciences.

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