



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: c-Abl tyrosine kinase inhibitory compound embodiments and methods of making and using the same

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 Neurala Bio, Inc. (Neurala), headquartered in Delaware.

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 AFTER DATE OF PUBLICATION 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: Jasmine Kalsi, M.S., Licensing and Patenting Manager, Office of Strategic Alliances, Telephone: 301-435-0129; E-mail: jasmine.kalsi@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

“C-Abl Tyrosine Kinase Inhibitory Compound Embodiments and Methods of Making and Using the Same”

- 1) U.S. Patent Application No. 16/976,012, HHS Ref. No. E-253-2017-0-US-03, which was issued as Patent Number 11,649,218 on May 16, 2023
- 2) Chile Patent Application No. 2317-2020, HHS Ref. No. E-253-2017-0-CL-04, which was issued as Patent Number CL67.840 on August 2, 2023
- 3) U.S. Patent Application No. 18/128,603, HHS Ref. No. E-253-2017-0-US-02, filed on March 30, 2023 (Pending)

The patent rights in these inventions have been either assigned and/or exclusively licensed to the government of the United States of America and Pontificia Universidad Catolica de Chile.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

“Use of NCGC00373060, also known as “NEUROTINIB” and its analogs for the treatment of central nervous system disorders, including Epilepsy, Parkinson’s Disease, Lysosomal Storage Disorders (Niemann Pick C and A, Tay-Sachs, Gaucher’s Disease), and Alzheimer’s Disease.”

The inventions relate to a series of novel compounds that inhibit c-Abl tyrosine kinase by binding to an allosteric site of the c-Abl tyrosine kinase. These compounds have favorable tolerability, high potency, high selectivity, good brain penetration, and robust efficacy. All of this allows them to potentially treat diseases such as cancers or neurodegenerative disease.

The compounds of the subject inventions can be used individually or in combination to develop new therapies to treat diseases involving the c-Abl tyrosine kinase, specifically

diseases resulting from overexpression of c-Abl tyrosine kinase. The diseases resulting from overexpression of c-Abl tyrosine kinase include frontal temporal dementia associated with ALS, primary lateral sclerosis, Sly syndrome, glioblastoma, neuroblastoma and viral pathogenesis resulting from HIV.

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: May 12, 2025.

Joni L. Rutter,

Director, Office of the Director,

National Center for Advancing Translational Sciences

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