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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Exceptionally Selective D2 Dopamine Receptor Antagonists as Therapeutics

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Neurological Disorders and Stroke and the National Center for Advancing Translational Sciences, 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 Psycala Bio, Inc. (Psycala), incorporated in Delaware.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Neurological Disorders and Stroke Technology Transfer on or before [INSERT DATE 45 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: Susan Ano, Ph.D., Chief, Technology Transfer Branch, Telephone: 301-435-5515; E-mail: *susan.ano@nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

"2,4-Diphenyl-3,4-Dihydroquinazoline Derivatives and Related Compounds as D2 Dopamine Receptor-Selective Antagonists''

U.S. Patent Application No. 63/666,563, filed July 1, 2024 (HHS Reference E-119-2021-0-US-01)

The patent rights in this invention have been assigned 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:

> NCGC-1360 ((s)-4-(6-chloro-2-(5-methoxypyridin-2-yl)-4-phenylquinazolin-3(4h)-yl)-2-methylbutan-2-ol) and related analogs for the treatment of central nervous system disorders, including but not limited to schizophrenia spectrum and other psychotic disorders, bipolar disorder and related disorders, and depressive disorders as classified by the Diagnostic and Statistical Manual of Mental Disorders (DSM V).

Researchers at NINDS and NCATS have developed a new class of therapeutic agents that may significantly advance the treatment of CNS disorders. These compounds are antagonists with high selectivity for the dopamine D2 receptor (D2R), showing over 1,000-fold selectivity compared to D3R and D4R. Promising in vitro ADME (Absorption, Distribution, Metabolism, and Excretion) data and in vivo pharmacokinetics indicate effective brain penetration, positioning these molecules as potential treatments for schizophrenia, bipolar disorder, and depression. Designed to minimize off-target side effects, particularly extrapyramidal motor side effects (EPS), these compounds maintain therapeutic efficacy. These compounds exhibit atypical antipsychotic properties without typical off-target effects and are expected to have reduced overall side effects. These molecules can be administered in various pharmaceutical forms, either alone or in combination with other therapeutic agents.

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 forty-five (45) days from the date of this published Notice, the National Institute of Neurological Disorders and Stroke 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.

Susan E. Ano,

Chief,

Technology Transfer Branch,

National Institute of Neurological Disorders and Stroke.

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