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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: High ASS1 Expressing Tumors

Embody a Purine Rich Genomic Signature and Sensitivity to Purine Depletion

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive, sublicensable patent license to Yeda Research & Development Co, Ltd (“YEDA”), the technology transfer company of the Weizmann Institute of Science, a non-profit research institution located in Rehovot, Israel for NCI’s rights to the patent applications listed in the Supplementary Information section of this notice.

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 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive patent license should be directed to: Kevin W. Chang, Ph.D., Senior Licensing and Patenting Manager at Telephone: (240)-276-6910 or at E-mail: changke@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

The following and all continuing U.S. and foreign patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to YEDA: PCT Patent Application PCT/IL2020/050708, filed June 24, 2020 and entitled

“High ASS1 Expressing Tumors Embody A Purine Rich Genomic Signature And Sensitivity To Purine Depletion” [HHS Reference No. E-210-2020-0-PCT-01].

The patent rights in these inventions have been assigned to the Government of the United States of America and YEDA. The prospective license will be for the purpose of consolidating the patent rights to YEDA, one of the co-owners of said rights, for commercial development and marketing. Consolidation of these co-owned rights is intended to expedite development of the invention, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200–212.

The prospective patent license will be worldwide, exclusive, and may be limited to those fields of use commensurate in scope with the patent rights. It will be sublicensable, and any sublicenses granted by YEDA will be subject to the provisions of 37 CFR parts 401 and 404.

This technology discloses methods of treating a high argininosuccinate synthase (ASS1) expressing solid tumor with a combination of a purine synthase inhibitor or an agent that increases the pyrimidine to purine ratio in a cell, and an immune-modulating drug, such as a checkpoint inhibitor.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will include terms for the sharing of royalty income with NCI from commercial sublicenses of the patent rights. 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 CFR part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. 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 : July 6, 2021.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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