



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive, Inter-Institutional Agreement-Institution Lead: Generation of Antigen-Specific T and B Cells Using Engineered Commensals.

AGENCY: National Institutes of Health, National Institute of Allergy and Infectious Diseases, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Allergy and Infectious Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive, Inter-Institutional Agreement-Institution Lead to CZ Biohub SF, LLC (“CZB”), located in San Francisco, California, in its rights to the technologies and 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 Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 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, Inter-Institutional Agreement-Institution Lead should be directed to: Jonathan Motley, Ph.D., Technology Transfer and Patent Specialist, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, 6D29, MSC9804, Rockville, MD 20852-9804, phone number 240-669-5209, or jonathan.motley@nih.gov.

SUPPLEMENTARY INFORMATION: The following and all continuing U.S. patents/patent applications thereof are the intellectual properties to be licensed under the prospective agreement to CZB: United States Provisional Patent Application Serial No. 63/588,398, filed October 6, 2023, the title of which is “Generation Of Antigen-Specific T And B Cells Using Engineered Commensals” (HHS Reference No. E-047-2024-0-US-01); and PCT Application Number PCT/US24/50039, filed October 4, 2024 (HHS Reference No. E-047-2024-0-PC-01), the title of which is “Generation Of Antigen-Specific T And B Cells Using Engineered Commensals”.

The patent rights to this technology have been assigned to CZB, The Board Of Trustees Of The Leland Stanford Junior University, and the Government of the United States of America as represented by the Secretary, Department of Health & Human Services.

The prospective patent license will be for the purpose of consolidating the patent rights to CZB, for the development and commercialization of the technology.

Consolidation of these co-owned rights is intended to expedite development of the technology, consistent with the goals of the Bayh-Dole Act codified as 35 U.S.C. 200–212.

The prospective interinstitutional agreement may include an exclusive license for NIAID’s rights in these jointly owned patents. It will be sublicensable, and any sublicenses granted by CZB will be subject to the provisions of 37 CFR part 404.

In the subject technology, the inventors describe a method of modifying commensal bacteria to carry heterologous antigenic fragments and the use of these modified bacterial cells to specifically stimulate or reduce a host’s immune response by modulating the response of T- and B-cells or antigen-presenting cells (APCs). To modify the bacterial cells, the inventors describe the use of genetic tools and fusion proteins, transpeptidases,

or by using covalent bonding of the antigenic fragment to extracellular proteins found on the surface. The modified bacteria are then applied to the skin or mucosal membranes of a target mammal (including humans). Other applications could include the delivery of molecules encased in lipid nanoparticles by adhering them to the surface of the commensal bacteria via the modification methods described above.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice the National Institute of Allergy and Infectious Diseases 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.

Complete 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 U.S.C. 552.

Dated: June 30, 2025.

Surekha Vathyam,

Director,

Technology Transfer and Intellectual Property Office,

National Institute of Allergy and Infectious Diseases.