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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Size-Dependent Brain and Lymphatic Distribution of Macromolecular Drug Delivery Platform

AGENCY: National Institutes of Health, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Cancer Institute, 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 applications listed in the Supplementary Information section of this notice to Sangam Lifesciences, Inc. (Sangam), a company located in Denver, Colorado.

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 an Exclusive Patent License should be directed to: Whitney Hastings, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (301)-624-1286; E-mail: *whitney.hastings2@nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. US Provisional Patent Application No. 63/037,058 filed June 10, 2020, and entitled "Size-Dependent Brain and Lymphatic Distribution of Macromolecular Drug Delivery Platform" [HHS Reference No. E-078-2020-0-US-01];

2. US Patent Cooperation Treaty Application No. PCT/US2021/036548 filed June 9, 2021, and entitled “Size-Dependent Brain and Lymphatic Distribution of Macromolecular Drug Delivery Platform” [HHS Reference No. E-078-2020-0-PCT-02];
3. U.S. National Stage Application No. 18/009,710 filed December 9, 2022, and entitled “Size-Dependent Brain and Lymphatic Distribution of Macromolecular Drug Delivery Platform” [HHS Reference No. E-078-2020-0-US-06];
4. Australia National Stage Application No. 2021289443 filed January 3, 2023, and entitled “Size-Dependent Brain and Lymphatic Distribution of Macromolecular Drug Delivery Platform” [HHS Reference No. E-078-2020-0-AU-03];
5. Canada National Stage Application No. 3186654 filed June 9, 2021, and entitled “Size-Dependent Brain and Lymphatic Distribution of Macromolecular Drug Delivery Platform” [HHS Reference No. E-078-2020-0-CA-04]; and
6. European Patent National Stage Application No. 21822452.5 filed January 5, 2023, and entitled “Size-Dependent Brain and Lymphatic Distribution of Macromolecular Drug Delivery Platform” [HHS Reference No. E-078-2020-0-EP-05].

The patent rights in these inventions 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:

“Use of the Patent Rights to develop, manufacture and commercialize a poly (L-lysine succinylated) (PLS) alpha-galactosylceramide prodrug for human and veterinary uses in the treatment of cancer.”

This technology describes a drug delivery platform comprising a negatively charged, synthetic polymer, PLS, which specifically targets scavenger receptor A1 (SR-

A1). The PLS polymer contains side chains with pendant carboxylic acids that facilitate conjugation of therapeutically active ingredients through hydrolysable ester bonds, allowing for the delivery and controlled release of drugs to SR-A1 expressing cells and tissues. Depending on the nature of the therapeutic agent conjugated to the PLS, this drug delivery platform has the potential to be widely applicable across a range of psychiatric, oncology, infections, inflammatory and neurological disorders. To date, this drug platform technology has been tested with several therapeutic agents including alpha-galactosylceramide, breflate, LD10, and HCQ.

The scope of exclusivity for this license will be limited to the PLS- alpha-galactosylceramide prodrug for the treatment of cancers. Other fields of use will still be available if this license is granted, including use of the PLS-alpha-galactosylceramide prodrug for non-oncology indications and the PLS platform conjugated to 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 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: April 14, 2025.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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