Billing Code 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies.

AGENCY: National Institutes of Health, 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 and Patent Applications listed in the Supplementary Information section of this Notice to CJ Healthcare, ("CJ"), located in Seoul, Republic of Korea**.**

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 applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Jim Knabb, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530, MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702; Telephone: (240)-276-7856; Facsimile: (240)-276-5504; E-mail: jim.knabb@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-016-2015: Chimeric Antigen Receptor Targeting both CD19 and CD22

1. US Provisional Patent Application 62/135,442, filed March 19, 2015 (E-106-2015-0-US-01);
2. International Patent Application PCT/US2016/023055, filed March 18, 2016 (E-106-2015/0-PCT-02)
3. US Patent Application No.: 15/559,485, filed September 19, 2017 (E- E-106-2015/0-US-03)

E-017-2017: CD19/CD22 Bicistronic CAR Targeting Human B-Cell Malignancies

1. US Provisional Patent Application 62/506,268, filed May 15, 2017 (E-017-2017-0-US-01);
2. International Patent Application PCT/ US2018/032,809, filed May 15, 2018 (E-017-2017/0-PCT-02)

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

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

"Treatment of B cell malignancies using autologously-derived, lentiviral vector transduced, T cells expressing chimeric antigen receptor(s) (CAR) dual specific for CD19 and CD22, utilizing the anti-CD19 antigen binding domain of the FM63 antibody and the anti-CD22 antigen binding domain of the M971 antibody"

This technology discloses CAR therapies that target both CD19 and CD22 by utilizing the anti-CD19 binder known as FM63 and the anti-CD22 binder known as M971. CD19 and

CD22 are each expressed on the surface of B cells in B cell malignancies and are hallmark examples of antigen targeting in CAR-T therapies, with CD19-targeting CAR-T therapies being the first FDA approved CAR-T, and CD22-targeting CAR-T showing early promise in clinical trials for ALL and NHL.

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.

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: December 20, 2019.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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