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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: *In Vivo* Manufactured Anti-CD19 Chimeric Antigen Receptor (CAR) Products for the Treatment or Prevention of B Cell Mediated Autoimmune Diseases

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 Kyverna Therapeutics, Inc. ("Kyverna"), a company located in Emeryville, California, the United States of America.

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 FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-5484; E-mail: *andy.burke@nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. U.S. Provisional Patent Application 62/006,313 (HHS Reference E-042-2014-0-US-01), filed 2 June 2014;
2. PCT Application PCT/US2015/033473 (HHS Reference E-042-2014-0-PCT-02), filed 1 June 2015;

3. Australian Patent 2015270912 (HHS Reference E-042-2014-0-AU-03), issued 17 December 2020;
4. Canadian Patent Application 2951045 (HHS Reference E-042-2014-0-CA-04), filed 1 June 2015;
5. Chinese Patent ZL201580033802.5 (HHS Reference E-042-2014-0-CN-05), issued 31 August 2021;
6. European Patent 3149044 (HHS Reference E-042-2014-0-EP-06), issued 21 October 2020 and validated in the following jurisdictions:
    a. Germany (HHS Reference E-042-2014-0-DE-19);
    b. Spain (HHS Reference E-042-2014-0-ES-20);
    c. France (HHS Reference E-042-2014-0-FR-21);
    d. The United Kingdom (HHS Reference E-042-2014-0-GB-22);
    e. Italy (HHS Reference E-042-2014-0-IT-23); and
    f. Ireland (HHS Reference E-042-2014-0-IE-24);
7. Israeli Patent 249305 (HHS Reference E-042-2014-0-IL-07), issued 1 October 2021;
8. Indian Patent 406961 (HHS Reference E-042-2014-0-IN-08), filed 19 May 2022;
9. Japanese Patent 6797693 (HHS Reference E-042-2014-0-JP-09), issued 20 November 2020;
10. South Korean Patent 2016-7036828 (HHS Reference E-042-2014-0-KR-10), issued 20 May 2024;
11. Mexican Patent 383150 (HHS Reference E-042-2014-0-MX-11), issued 3 June 2021;
12. New Zealand Patent 727167 (HHS Reference E-042-2014-0-NZ-12), issued 8 October 2024;
13. Saudi Arabian Patent 8651 (HHS Reference E-042-2014-0-SA-13), issued 15 September 2021;
14. Singapore Patent 11201609960Q (HHS Reference E-042-2014-0-SG-14), issued 28

September 2021;

15. United States Patent 10,287,350 (HHS Reference E-042-2014-0-US-15), issued 14 May 2019;
16. Hong Kong Patent HK 1234420 (HHS Reference E-042-2014-0-HK-16), issued 4 June 2021;
17. United States Patent 11,236,161 (HHS Reference E-042-2014-0-US-17), issued 1 February 2022;
18. New Zealand Patent 764530 (HHS Reference E-042-2014-0-NZ-18), issued 8 October 2024;
19. European Patent Application 20197459.9 (HHS Reference E-042-2014-0-EP-25), filed 22 September 2020;
20. Australian Patent 2020267211 (HHS Reference E-042-2014-0-AU-26), issued 15 August 2024;
21. Japanese Patent 7004470 (HHS Reference E-042-2014-0-JP-27), issued 6 January 2022;
22. Mexican Patent Application MX/a/2021/006239 (HHS Reference E-042-2014-0-MX-28), filed 27 May 2021;
23. Israeli Patent 283423 (HHS Reference E-042-2014-0-IL-29), issued 2 July 2022;
24. Hong Kong Patent Application 42021038427.7 (HHS Reference E-042-2014-0-HK-30), filed 8 September 2021;
25. United States Patent Application 17/557,845 (HHS Reference E-042-2014-0-US-31), filed 21 December 2021;
26. Japanese Patent 7485650 (HHS Reference E-042-2014-0-JP-32), issued 6 January 2022;
27. United States Patent 12,473,359 (HHS Reference E-042-2014-0-US-33), issued 18 November 2025;
28. Israeli Patent Application 291292 (HHS Reference E-042-2014-0-IL-34), filed 13 March 2022;

29. Indian Patent Application 202248047256 (HHS Reference E-042-2014-0-IN-35), filed 19 August 2022;
30. South Korean Patent Application 10-2024-7016401 (HHS Reference E-042-2014-0-KR-01), filed 17 May 2024;
31. Japanese Patent Application 2024-074954 (HHS Reference E-042-2014-0-JP-01), filed 2 May 2024;
32. Australian Patent Application 2024205043 (HHS Reference E-042-2014-0-AU-01), filed 24 July 2024;
33. European Patent Application 25209657.3 (HHS Reference E-042-2014-0-EP-01), filed 20 October 2025;
34. Israeli Patent Application 324883 (HHS Reference E-042-2014-0-IL-01), filed 24 November 2025; and
35. Japanese Patent Application 2025-283967 (HHS Reference E-042-2014-0-JP-02), filed 26 December 2025.

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:

“The development, production, and commercialization of an anti-CD19 targeting chimeric antigen receptor (CAR)-based immunotherapy using a:

1. non-viral synthetic nanoparticle-based system, or
2. viral system (excluding lentiviral)

that encapsulates mRNA or DNA encoding a CAR having the complementary determining region (CDR) sequences of the anti-CD19 scFv known as Hu19, for the treatment or prevention of autoimmune diseases.

The following are specifically excluded from the Licensed Field of Use:

1. Anti-CD19 targeting CAR-based immunotherapy using CRISPR/Cas9-edited allogeneic (where the donor and recipient are different) T lymphocytes.
2. Anti-CD19 targeting CAR-based immunotherapy using autologous T lymphocytes engineered by lentivirus."

The E-042-2014-0 invention family generally discloses CARs which recognize the cell surface protein CD19. CD19 is expressed primarily on B cells, including autoreactive B cells which drive the development of certain autoimmune disorders. For many autoimmune diseases there are limited therapeutic options. The development of a new anti-CD19 CAR-based therapy has the potential to meet the needs of patients who are poorly served by existing standards of care.

It is noted that the exclusive field of use which may be granted to Kyverna applies to only a subset of CAR constructs claimed in the patent rights and does not include, for example, any constructs which exclusively utilize the FMC63-based antigen binding domain. Accordingly, the scope of rights which may be conveyed under the proposed license covers a portion of the possible applications of E-042-2014.

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: February 10, 2026

Richard U. Rodriguez,

Supervisory Technology Transfer and Patent Specialist,

Technology Transfer Center,

National Cancer Institute.

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