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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Monospecific 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 Syncopation Life Sciences Inc., ("Syncopation"), located in Palo Alto, California**.**

DATES: Only written comments and/or complete 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: 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, at at Telephone: (240)-276-7856; or at E-mail: jim.knabb@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

E-080-2012-0: Human Monoclonal Antibodies Specific for CD22

1. US Provisional Patent Application 61/042,329, filed April 4, 2008 (E-080-2008-0-US-01);
2. International Patent Application PCT/US2009/039,080, Filed April 1, 2009 (E-080-2008/0-PCT-02);
3. US Patent Application: 12/934,214, filed September 23, 2010 (E-080-2008-0-US-03);
4. US Patent Application 13/959,061, filed August 5, 2015 (E-080-2008-0-US-04);
5. US Patent Application 15/012,023, filed February 1, 2016 (E-080-2008-0-US-05);
6. US Patent Application 15/424,238, filed February 3, 2017 (E-080-2008-0-US-06).

<u>E-291-2012-0: M971 Chimeric Antigen Receptors</u>

1. US Provisional Patent Application 61/717,960, filed October 24, 2012 (E-291-2012-0-US-01);
2. International Patent Application PCT/US2013/060332, filed September 18, 2013 (E-291-2012-0-PCT-02);
3. Australia Application No: 2019235926, filed September 2, 2020 (E-291-2012-0-AU-03);
4. Brazil Patent Application BR112015009003-6, filed April 22, 2015 (E-291-2012-0-BR-04);
5. Canada Application No: 2889055, filed September 18, 2013 (E-291-2012-0-CA-05);
6. China Application No: 201380061387.5, filed May 25, 2015 (E-291-2012-0-CN-06);
7. European Patent Application No: 13773468.7, filed September 18, 2013 (E-291-2012-0-EP-07);
8. India Patent Application No: 2344/CHENP/2015, filed September 18, 2013 (E-291-2012-0-IN-08);

9. Japan Application No: 539602/2015, filed April 24, 2015 (E-291-2012-0-JP-09);
10. Russia Patent Application: 2015117237, filed May 7, 2015 (E-291-2012-0-RU-10);
11. US Patent Application: 14/437,889, filed April 23, 2015 (E-291-2012-0-US-11);
12. Hong Kong Patent Application: 16101891.0, filed February 19, 2016 (E-291-2012-0-HK-12);
13. Russia Patent Application: 2018116582, filed May 4, 2018 (E-291-2012-0-RU-13);
14. Japan Patent Application: 2018-088908, filed May 2, 2018, (E-291-2012-0-JP-14);
15. Australia Patent Application: 2018204257, filed June 14, 2018 (E-291-2012-0-AU-16);
16. US Patent Application: 16/107,271, filed August 21, 2018 (E-291-2012-0-US-17);
17. Germany Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-DE-18);
18. Spain Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-ES-19);
19. France Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-FR-20);
20. Great Britain Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-GB-21);
21. Italy Patent Application: 13773468.7, filed April 22, 2015 (E-291-2012-0-IT-22);
22. China Patent Application: 201910500128.7, filed June 11, 2019 (E-291-2012-0-CN-23);
23. US Patent Application: 16/869,792, filed May 8, 2020 (E-291-2012-0-US-24).

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:

"Development, manufacture and commercialization of chimeric antigen receptor T cell (CAR-T) immunotherapies (both autologous and allogeneically derived) for the treatment of B cell malignancies that express CD22 wherein:

1. The T cells are engineered to be monospecific for CD22; and

2. The chimeric antigen receptor is specific for CD22 via the m971 scFv".

This technology discloses CAR therapies that target CD22 by utilizing the anti-CD22 binder known as m971. CD22 is expressed on the surface of B cells in B cell malignancies and CD22-targeting CAR-T has shown 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: June 9,2021.

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Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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