Intellectual Property

E–109–2020: High-Throughput Generation of iPSC Carrying Antigen Specific TCRs From Tumor Infiltrating Lymphocytes

1. US Provisional Patent Application 63/068,458 filed August 21, 2020 (E–109–2020–0–US–01).

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:

''Manufacture and commercialization of adoptive T cell therapy products generated from autologously-derived, induced pluripotent stem cells for the treatment of cancer in humans.''

E–109–2020 generally discloses methods of producing induced pluripotent stem cells from isolated tumor infiltrating lymphocytes which express antigen-specific T cell receptors.

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 which 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 U.S.C. 552.

Dated: April 29, 2021.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Amy F. Petrik, Ph.D., 240–627–3721; *amy.petrik@nih.gov.* Licensing information and copies of the U.S. patent application listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows:

Antibodies With Potent and Broad Neutralizing Activity Against Antigenically Diverse and Highly Transmissible SARS–CoV–2 Variants

Emergence of highly transmissible SARS–CoV–2 variants of concern that are resistant to current therapeutic antibodies highlights the need for continuing discovery of broadly reactive antibodies.

Scientists at the Vaccine Research Center of the National Institute of Allergy and Infectious Diseases discovered and characterized a group of human monoclonal antibodies that target unique epitopes on the receptor binding domain of SARS–CoV–2 spike protein. These antibodies ultra-potently neutralize >12 variants of SARS–CoV–2, including P1, B.1.429, B.1.1.7 and B.1.351, as shown in a pseudovirus neutralization assay. These antibodies target 3 distinct epitopes in the receptor binding domain of the spike protein and function by blocking ACE2 binding. These antibodies are not impacted by spike mutations that knockout binding to other therapeutic antibodies, including E484K, N439K, Y453F, L452R and K417N. Several antibodies are able to simultaneously bind to the spike protein and are compatible for use in combination therapies. In *in vitro* assays, these combinations were shown to decrease the appearance of escape mutants suggesting the potential to mitigate resistance development when used as combination therapy.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404.

Potential Commercial Applications

- Treatment of SARS–CoV–2 infection

Competitive Advantages

- Ultra-potent neutralization of currently identified SARS–CoV–2 variants
- Combinations show the potential to mitigate resistance
- Mechanism of Action—These antibodies bind to block ACE2 receptor binding to the SARS–CoV–2 spike protein

Development Stage: Preclinical Research.

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Publications: Wang, L. *et al.,* (2021). Antibodies with potent and broad neutralizing activity against antigenically diverse and highly transmissible SARS–CoV–2 variants. *BioRxiv.*

Intellectual Property: HHS Reference Number E–037–2021 includes U.S. Provisional Patent Application Number 63/147,419 filed February 9, 2021.

Licensing Contact: To license this technology, please contact Amy F. Petrik, Ph.D., 240–627–3721; *amy.petrik@nih.gov.*

Dated: April 27, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

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