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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government Owned Inventions Available 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**: Inquiries related to this licensing opportunity should be directed to: Suna Gulay French, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: suna.gulay@nih.gov or Phone: 240-276-7424.

**SUPPLEMENTARY INFORMATION:**

**NIH Reference Number:** E-153-2016-0.

**Title**: T-Cell Immunotherapy that Targets Aggressive Epithelial Tumors

**Intellectual Property**

US Provisional Application 62/327,529 filed April 26, 2016

PCT Application PCT/US2017/027865 filed April 17, 2017

US Patent 11,352,410 issued June 7, 2022

European Patent 3448882 issued November 24, 2021, validated in Switzerland, Germany, Belgium, Denmark, Spain, Finland, France, United Kingdom, Ireland, Italy, The Netherlands, Norway, Sweden

Australian Patent Application 2017258745 filed October 19, 2018

Canadian Patent Application 3021898 filed April 17, 2017

**Technology Summery**

Metastatic cancers cause up to 90% of cancer deaths, yet few treatment options exist for patients with metastatic disease. Adoptive transfer of T cells that express tumor-reactive T-cell receptors (TCRs) has been shown to mediate regression of metastatic cancers in some patients. Unfortunately, identification of antigens expressed solely by cancer cells and not normal tissues has been a major challenge for the development of T-cell based immunotherapies. Thus, it is essential to find novel target antigens differentially expressed in cancer versus normal tissues.

Inventors at the National Cancer Institute (NCI) have developed a TCR that specifically targets the Kita-Kyushu Lung Cancer Antigen 1 (KK-LC-1) 52-60 epitope. KK-LC-1 antigen (encoded by the CT83 gene) is highly expressed by several common and aggressive epithelial tumor types. Importantly, KK-LC-1 is expressed at very low levels in normal tissues and not in those tissues vital for survival. This expression profile makes KK-LC-1 an attractive target for T-cell based, anti-cancer therapies.

Researchers at the NCI seek licensing and/or co-development research collaborations for T-cell immunotherapy that targets KK-LC-1 for use in the treatment of epithelial cancers.

**Therapeutic Area(s):** Cancer.

**Competitive Advantages:** Differential expression profile of KK-LC-1 suggests that therapy with a specific KK-LC-1 TCR could be cancer-specific and would not damage normal tissues; The repertoire of targetable epithelial antigens for TCR-T cell therapy is larger than for CAR-T cells; Increased sensitivity may improve tumor cell detection and killing versus CAR-T cells, due to lower epitope density required for activation; Higher avidity and lower affinity could result in each TCR-T cell destroying numerous antigen-presenting cancer cells; Thousands of cancer patients each year with otherwise untreatable disease may be eligible for immunotherapy with this TCR.

Achieving expeditious commercialization of federally funded research and development is consistent with the goals of the Bayh-Dole Act, codified as 35 U.S.C. 200-212 and 37 CFR 404.4.

**Development Stage**: Clinical Phase I.

Dated: March 5**,** 2024**.**

**Richard U. Rodriguez,**

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