Patent Status: PCT Application PCT/US2023/085725 filed on December 22, 2023.

Development Stage: Clinical Phase I.

Dated: November 8, 2024.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024–26451 Filed 11–13–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for Licensing or Collaboration: Methods of Detecting Loss of Heterozygosity and Damaging Mutations in Immune-Related Genes Using Liquid Biopsies

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the licensing or collaboration opportunities for the inventions listed below, which are owned by an agency of the U.S. Government and are available for licensing or collaboration to achieve expeditious commercialization of results of federally funded research and development.

FOR FURTHER INFORMATION CONTACT: Inquiries related to these licensing and collaboration opportunities 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: The technology is a liquid biopsy diagnostic assay capable of detecting loss of heterozygosity (LOH) and somatic mutations in genes important for antigen processing and presentation and interferon-γ (IFN) response pathways. Immunotherapy is an effective cancer treatment utilizing T cells to recognize and eliminate cancer cells. Antigen processing and presentation machinery (APM) and IFN response pathways play an important role for T cells to target cancer cells. To evade immunotherapy, cancer cells can develop somatic mutations in genes important for APM and IFN.

Liquid biopsy is a non-invasive tool that can diagnose and monitor cancer by analyzing circulating tumor DNA. The ability to detect somatic mutations and predict response to immunotherapies using liquid biopsy would be critical to provide more personalized cancer treatment. However, currently marketed liquid biopsies cannot predict response to cellular immunotherapies. As a result, patients with relapsed or recurrent disease lose valuable time and resources on ineffective treatments.

The inventors at the NCI developed a novel method to detect somatic mutations from liquid biopsy samples. Combined with NCI's method to detect loss of heterozygosity in HLA genes—another mechanism for immunotherapy evasion—this invention allows for improved patient selection and non-invasive prediction of response. This novel precision medicine method will allow patient-tailored treatment by targeting treatment based on genetic mutations and prediction of immunotherapy response. This invention could potentially deliver better patient satisfaction, lower healthcare costs and better outcomes.

This invention will be used to select optimal patients and monitor efficacy of treatments—such as TCR–T cell therapy. There are no liquid biopsy assays on the market designed as companion diagnostics for cellular immunotherapy—such as TCR–T cell therapy. Therefore, this technology may be particularly appealing to co-development partners who are developing proprietary cellular immunotherapies.

This Notice is in accordance with 35 U.S.C. 209 and 37 CFR part 404.

NIH Reference Number: E–027–2024–0.

Related Technologies: E–045–2022–0.

Product Type: Diagnostic.

Therapeutic Area(s): Oncology or Immunology.

Potential Commercial Applications:

- Companion diagnostic for cellular immunotherapies.
- Companion diagnostic for monitoring the effectiveness of TCR-based immunotherapies.
- Companion diagnostic for T cell-based immunotherapies, including certain immune checkpoint inhibitors.
- Research use in labs studying and developing new pre-clinical therapeutic candidates.
- Research use in basic research labs studying immunotherapy resistance mechanisms, antigen processing and presentation, IFN response pathways, mutations in cancer cells, basic immunology and basic oncology.

Competitive Advantages

- First method to predict response to immunotherapies by detecting damaging mutations using liquid biopsy samples.
- Non-invasive test not requiring surgery.
- Easy to administer.
- Allows patient-tailored treatment and monitor the effectiveness of TCR-based immunotherapies in a simple and cost-effective manner.
- Potential improvement in patient survival.
- Potential time and money savings for patients, physicians and hospitals.

Patent Status: US Provisional Application 63/572,760 filed on April 4, 2024.

Development Stage: Prototype.

Dated: November 8, 2024.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2024–26446 Filed 11–13–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Council for Complementary and Integrative Health, January 24, 2025, 10:00 a.m. to January 24, 2025, 4:00 p.m., National Institutes of Health, DEM 2, 6707 Democracy Boulevard, Bethesda, MD, 20892 which was published in the **Federal Register** on September 25, 2024, 89 FR 78318.

The notice is being amended to change the start and end times of the open session portion of the meeting. The open session start time has changed from 12:30 p.m. to 1:00 p.m. and the end time has changed from 4:00 p.m. to 5:00 p.m. This meeting is partially closed to the public.

Dated: November 8, 2024.

David W Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–26527 Filed 11–13–24; 8:45 am]

BILLING CODE 4140–01–P