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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for License: Synergistic Interactions for Improved Cancer Treatment

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees to develop hetIL-15 in combination with other agents, such as PPARa agonists (Fenofibrate), FLT3 inhibitors (quizartinib), IL-12, or chemotherapy into a therapeutic for cancer.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Rose Freel, Ph.D., Unit Supervisor, NCI, Technology Transfer Center, Email: *rose.freel@nih.gov* or Phone: 301-624-1257.

SUPPLEMENTARY INFORMATION: Immunotherapy has emerged as a promising treatment strategy for many types of cancer. However, a major challenge is “exhausted” tumor-infiltrating immune cells, which lose their ability to effectively eliminate cancer cells. To address this issue, researchers are exploring ways to reverse immune exhaustion and improve treatment outcomes. One potential approach involves interleukin-15 (IL-15), a cytokine that promotes the growth and killing ability of tumor-specific CD8+ T cells and NK cells. IL-15, either alone or in combination with other agents, has shown some promise in clinical trials. However, its use is hindered by toxicity at effective doses. Therefore, there is a critical need for safer and more effective combinations to improve patient outcomes.

Inventors at the NCI previously developed heterodimeric IL-15 (hetIL-15), composed of IL-15 and IL-15 receptor alpha (NIH Reference # E-254-2005, E-257-2009, E-141-2008, E-054-2013, and E-070-2015). The inventors now demonstrate novel combinations of hetIL-15 with other

active agents to enhance the metabolic fitness of intratumoral lymphocytes to provide therapeutic improvement. Specifically, the combination of hetIL-15 and Fenofibrate, a cholesterol-lowering drug, increased cytotoxic T cell activity and provided an almost complete eradication of triple negative breast cancer tumors, including metastatic lesions. Similar results occurred in a mouse pancreatic cancer model. Using a mouse orthotopic breast cancer model, hetIL-15 combined with quizartinib – a potent Fms-like tyrosine kinase 3 (Flt3) inhibitor – resulted in a significant tumor growth delay and complete eradication of tumors in 50% of mice after 16 days of treatment. Additionally, the inventors constructed a fusion protein of IL-15 and IL-12 that controls metastatic disease in a mouse melanoma model. These novel combinations would be particularly useful for the treatment of triple negative breast or pancreatic cancer.

This Notice is in accordance with 37 CFR 404.4 - Authority to grant licenses.

NIH Reference Number: E-174-2022.

Product Type: Therapeutic.

Therapeutic Area(s): Oncology | Immunology.

Potential Commercial Applications:

- Treatment for triple negative breast cancer.
- Treatment for pancreatic cancer.
- Treatment of solid tumors for which cellular immunotherapy outcomes are diminished due to T or NK cell exhaustion.
- Treatment of solid tumors for which IL-15-based therapy is diminished due to toxicity at clinically relevant doses.

Competitive Advantages:

- Novel combination showing improved therapeutic potential in several solid cancers, including breast cancer and melanoma.
- Combination of hetIL-15 with agents already approved (Fenofibrate, Flt-3) decreases regulatory risk and thus expedites commercialization.

- Overcoming IL-15 toxicity at clinically relevant doses.

Dated: May 13, 2026.

Richard U. Rodriguez,

Associate Director,

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National Cancer Institute.

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