TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

Type of information collection	Respondents	Number of respondents	Number of responses per respondents	Average burden per response (minutes)	Total burden hours
Total		249,940			12,580

HHS OMH estimates the total annual burden for this collection of information is 12,580 hours. The estimated burden for the information collection reflects an overall annual increase of 10,576 hours. We attribute this adjustment to an increase in the number of respondents utilizing the TCH e-learning program(s) and/or e-resource(s).

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2026–03313 Filed 2–19–26; 8:45 am]

BILLING CODE 4150–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for License: Gait Assistance Systems and Methods of Control Thereof; Correction

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; correction.

SUMMARY: The Clinical Center (CC), an institute/center of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), published a Notice in the **Federal Register** on February 13, 2026. That notice requires a correction in the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Tedd Fenn, J.D., M.S., Technology Transfer Manager, NCI, Technology Transfer Center, Email: *Edward.Fenn@nih.gov* or Phone: 240–276–6833.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 13, 2026, in FR Doc. 2026–02906, on page 6865, as found within the **SUPPLEMENTARY INFORMATION** section. Currently reads:

NIH Reference Number: E–121–2013.

and is corrected to read:

NIH Reference Number: E–241–2023.

Alycia Booth,

NIH Federal Register Certifying Official, National Institutes of Health.

[FR Doc. 2026–03406 Filed 2–19–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Inventions Available for License: Novel Human Immunogenic Epitopes of the Human Endogenous Retrovirus ERVMER34–1

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI), an institute/center of the National Institutes of Health (NIH), Department of Health and Human Services (HHS), is giving notice of the license opportunity for the invention listed below, which is owned by an agency of the U.S. Government and is available to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Michael Pollack, Ph.D., Unit Supervisor, NCI, Technology Transfer Center, Email: *michael.pollack@nih.gov* or Phone: 240–276–5519.

SUPPLEMENTARY INFORMATION: The NCI seeks research co-development partners and/or licensees for the clinical translation of novel peptide-based therapeutic cancer vaccines derived from ERVMER34–1, a human endogenous retrovirus (HERV) antigen, offering a unique opportunity to address a significant unmet need in the treatment of various carcinomas.

HERVs, remnants of ancient retroviral germline infections that comprise ~8% of the human genome, represent a promising yet underexplored frontier in targeted cancer therapy. Although typically epigenetically silenced in normal adult tissues, select HERV components, including RNAs and envelope proteins, are frequently overexpressed in various carcinomas due to epigenetic dysregulation—a hallmark of cancer. The challenge lies in identifying specific, highly immunogenic HERV targets that elicit potent anti-tumor immune responses without triggering autoimmunity. Addressing this need is critical to advancing broadly applicable cancer immunotherapies.

Inventors at the NCI have developed and characterized a novel cancer immunotherapy platform targeting ERVMER34–1, a specific HERV envelope protein that is highly expressed across multiple human carcinomas while exhibiting minimal expression in normal tissues. Using transcriptomic and proteomic datasets, the team confirmed the tumor-selective expression profile of ERVMER34–1. To improve safety and specificity, they engineered an artificial antigen-presenting cell line to express the full-length ERVMER34–1 protein, HLA–A2 and CD80 to facilitate efficient priming and expansion of ERVMER34–1-reactive CD8+ T cells. To therapeutically target ERVMER34–1, they modified the ERVMER34–1 protein by removing the signal peptide, cleavage site, predicted immunosuppressive domain, transmembrane domain and a 170-amino acid region homologous to human proteins. These modifications prevent surface trafficking, antigen shedding, immune dampening, and off-target reactivity. This modified sequence was incorporated into a recombinant adenoviral vector as a therapeutic cancer vaccine. In preclinical murine models (*e.g.,* MC38 colon cancer, EMT6 breast cancer), vaccination with this construct alone or in combination with immune checkpoint blockade or an IL–15 superagonist elicited robust, multifunctional $CD4^+$ and $CD8^+$ T cell responses. Those enhanced T cell responses induced tumor clearance, increased intratumoral lymphocyte infiltration, broadened neoantigen spreading and prolonged tumor control. ERVMER34–1-reactive T cells could be expanded from both healthy donor and cancer patient Peripheral Blood Mononuclear Cells (PBMCs) and demonstrated specific cytolytic activity against ERVMER34–1^+ human carcinoma cell lines in vitro. To support peptide-based approaches, researchers

developed an overlapping 15-mer peptide library spanning the modified ERVMER34–1 protein sequence. These peptides elicited strong, polyfunctional T cell responses in vitro—including both $CD4^+$ and HLA–A2-restricted $CD8^+$ T cell activation, enabling precise epitope mapping and facilitating future peptide vaccine design and adoptive T cell receptor (TCR)-based therapies.

NIH Reference Number: E–159–2019–0.

Therapeutic Area(s): Oncology/Immunology.

Related Invention: E–056–2023–0.

Potential Commercial Applications:

- Peptide-based therapeutic cancer vaccines.
- Adenoviral vector-based therapeutic cancer vaccines.
- Liposome- or nanoparticle-formulated therapeutic cancer vaccines.
- Artificial Antigen-Presenting Cell platforms expressing ERVMER34–1 with HLA–A2 and CD80 to expand antigen-specific T cells for adoptive cell therapies.
- Adoptive T cell therapies using ERVMER34–1-specific TCRs isolated from PBMCs or engineered T cells redirected against shared HERV antigens.
- Combination immunotherapies pairing the ERVMER34–1 vaccine with checkpoint inhibitors and/or epigenetic modifiers to boost response breadth and tumor infiltration.
- Cytokine or immuno-cytokine-enhanced combination regimens incorporating immune-oncology agents to amplify tumor-specific T cell activation.
- Companion diagnostic tools to identify ERVMER34–1-expressing tumors for patient selection and treatment stratification.

Competitive Advantages:

- Broad tumor coverage across ~62% of carcinomas.
- Minimal expression in normal tissues reduces toxicity risk and expands market potential.
- Engineered antigen design in vaccine eliminates immunosuppressive and off-target domains, improving safety and therapeutic precision.
- Elicits potent, multifunctional T cell responses with cytokine production and broad epitope recognition, enhancing anti-tumor efficacy.
- Selectively clears tumor cells based on ERVMER34–1 expression, enabling precise targeting across variable antigen levels.
- Demonstrates remarkable synergistic efficacy with immune checkpoint inhibitors, achieving ~89% tumor clearance in established large tumors in mouse models.
- Exhibits synergistic interaction with cytokine agonists such as N–803 (Anktiva), significantly enhancing neoepitope-reactive T cell responses and improving tumor control in combination therapies.
- Potential for use in combination with epigenetic modulators to enhance expression of targeted antigen in human carcinomas.

Patent Applications:

- Australia National Stage 2021210915; filed on 2022–08–18; Status: Pending.
- Canada National Stage 3165251; filed on 2022–07–19; Status: Pending.
- European Patent National Stage 21705769.4; filed on 2022–08–18; Status: Pending.
- US National Stage 17/793,753; filed on 2022–07–19; Status: Pending.
- Hong Kong: European patent (EP) 62023070659.5; filed on 2023–03–27; Status: Pending.

Development Stage: Pre-clinical (*in vivo*).

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for the clinical translation of novel peptide-based therapeutic cancer vaccines derived from ERVMER34–1, a human endogenous retrovirus (HERV) antigen, offering a unique opportunity to address a significant unmet need in the treatment of various carcinomas.

Publications:

- Maldonado MDM, et al. Combination of a therapeutic cancer vaccine targeting the endogenous retroviral envelope protein ERVMER34–1 with immune-oncology agents facilitates expansion of neoepitope-specific T cells and promotes tumor control (PMID: 40360436).
- Gracia-Hernandez M, et al. Combination Therapy Approaches to Enhance the Efficacy of ERV-Targeting Vaccines in Cancer (PMID: 40387511).

Dated: February 17, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–03338 Filed 2–19–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: In Vivo Manufactured Anti-CD19 Chimeric Antigen Receptor (CAR) Products for the Treatment or Prevention of B Cell Mediated Autoimmune Diseases

AGENCY: National Institutes of Health, HHS.

ACTION: Notice; correction.

SUMMARY: The Department of Health and Human Services, National Institutes of Health published a Notice in the **Federal Register** on August 5, 2025. That notice requires a correction in the **SUPPLEMENTARY INFORMATION** section.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before March 9, 2026 will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)–276–5484; Email: *andy.burke@nih.gov.*

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of February 13, 2026, in FR Doc. 2026–02907, on page 6864, as found within the **SUPPLEMENTARY INFORMATION** section. Currently reads:

''The development, production, and commercialization of an anti-CD19 targeting chimeric antigen receptor (CAR)-based immunotherapy using a:

1. non-viral synthetic nanoparticle-based system, or
2. viral system (excluding lentiviral)

that encapsulates mRNA or DNA encoding a CAR having the complementary determining region (CDR) sequences of the anti-CD19 scFv known as Hu19, for the treatment or prevention of autoimmune diseases.

And is corrected to read:

''The development, production, and commercialization of an anti-CD19 targeting chimeric antigen receptor (CAR)-based immunotherapy using a:

3. non-viral synthetic nanoparticle-based system, or
4. viral system

that encapsulates mRNA or DNA encoding a CAR having the complementary determining region