tumors against checkpoint-responsive wild-type MC38 tumors.

Competitive Advantages:

- Uniquely models a clinically relevant checkpoint-resistance mechanism.
- Uses the MC38 colon cancer model, which is well-established and regulatorily de-risked.
- Unique model permitting the interrogation of abrogated response to anti-PD-1 and anti-PD-1 treatment.

Collaboration Opportunity: Licensing.

Dated: August 7, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–16449 Filed 8–11–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Owned Invention Available for License: Drug-Regulatable, Inducible Expression of Membrane-Bound Interleukin 12 (DRIM-IL-12) for Use in Adoptive Cell Therapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: Scientists at the National Cancer Institute (NCI) have developed a novel tightly regulated drug-responsive, membrane-bound IL-12 cytokine platform, that enhances anti-tumor efficacy in adoptive cell therapy (ACT) with engineered T-cells (CAR, TCR, TILs) while improving safety. The NCI seeks research co-development partners and/or licensees to advance this technology toward clinical translation.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license/co-development opportunity should be directed to: Andrew Burke, Ph.D., Senior Technology Transfer Manager, Email: *burkear@mail.nih.gov* or Phone: 240–276–5484.

SUPPLEMENTARY INFORMATION: ACT offers hope for patients with refractory or metastatic cancers, but effectiveness is frequently undermined by the immunosuppressive tumor microenvironment and T-cell dysfunction. Interleukin-12 (IL-12), a powerful cytokine with strong anti-tumor properties, has long been recognized for its potential to invigorate T-cell responses within tumors. However, systemic administration of IL-12 results in severe toxicity. Further, prior gene therapy strategies failed to provide sufficient control over IL-12 expression. These two factors compromise safety and therapeutic performance.

This invention introduces a Nuclear Factor of Activated T cells (NFAT)-inducible, drug-regulatable, membrane-bound IL-12 (DRIM-IL-12) system that delivers spatiotemporally controlled cytokine expression within the engineered T cell therapy product. This platform ensures IL-12 is expressed only upon T-cell activation. Concurrently, the degron (D) sequence confers lenalidomide-dependent proteasome-mediated degradation—serving as a drug-controlled safety switch to limit systemic toxicity. A transmembrane (TM) domain anchors IL-12 in the plasma membrane, preventing unintended secretion and promoting localized immune modulation. When paired with tumor-specific TCRs or CARs (*e.g.,* anti-mutant p53 or KRAS TCRs, or CD19 CAR), this platform enhances tumor cell killing and long-term survival in preclinical models. In a mouse model, DRIM-IL-12 demonstrated substantially improved safety compared to the previous generation of NFAT-inducible IL-12. The inventors also demonstrate that DRIM-IL-12 expression can be dialed down or fine-tuned to prevent T-cell exhaustion or differentiation, which can occur with uncontrolled IL-12 expression.

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

NIH Reference Number: E–217–2023.

Related Technologies: N/A.

Product Type: Therapeutic.

Therapeutic Area(s): Immunology | Oncology.

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

Publications:

- Kim SP, et al. Drug-regulatable, inducible, and membrane-bound interleukin 12 (IL-12TM-D) for use in adoptive cell therapies against advanced cancers. *https://doi.org/10.1136/jitc-2024-SITC2024.0344.*

Patents: PCT/US2025/031121, filed May 28,2025.

Potential Commercial Applications:

- Solid tumors expressing p53 or KRAS mutations.
- Hematologic malignancies.
- Melanoma.

Competitive Advantages:

- Versatile platform for inducible cytokine regulation.
- Superior survival in mouse models compared with TCR-only T-cells.
- Enhanced tumor cell killing and long-term survival in murine models.
- Decreased IL-12-associated toxicity.
- Maintenance of higher IL-12 expression.
- Improved sensitivity to lenalidomide-mediated degradation.

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for developing a novel tightly regulated drug-responsive, membrane-bound IL-12 cytokine platform, that enhances anti-tumor efficacy in adoptive cell therapy (ACT) with engineered T-cells (CAR, TCR, TILs).

Dated: August 7, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–16438 Filed 8–11–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: DNA Methylation-Based Cancer Diagnostics for Accurate Tumor Classification

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This technology encompasses a DNA methylation-based diagnostic platform designed to improve the accuracy and consistency of cancer classification, with demonstrated utility for tumors of the central nervous system, kidney, and hematopoietic system. By identifying disease-specific methylation signatures, the approach reduces interobserver variability and enhances diagnostic confidence. The central nervous system (CNS) classifier is built from a curated reference set of 16,567 methylation profiles and organizes tumors into 22 families and 133 clinically relevant diagnostic classes, including 21 newly developed methylation classes not represented in other existing tools. Across multiple independent validation cohorts (n = 5,875), the classifier demonstrated robust performance, and in a clinical-impact analysis of 1,204 NIH validation cases, methylation profiling materially influenced final diagnosis in 74.4% of cases by refining, increasing precision, or reclassifying. The CNS classifier was deployed as a user-facing software tool, MethylScape Analysis, which streamlines methylation-based classification workflows for CNS tumors, *https://methylscape.ccr.cancer.gov/*. The development of multiple specialized classifiers supports a more granular

understanding of tumor biology and informed clinical decision-making.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Jaime Greene, M.S., Senior Technology Transfer Manager, NCI, Technology Transfer Center, Email: *greenejaime@mail.nih.gov* or Phone: 240–276–6633.

SUPPLEMENTARY INFORMATION: Accurate CNS tumor classification can be challenging when tumors show overlapping histology, limited tissue or atypical features. A meaningful fraction of cases remains unclassified or assigned with limited confidence with current molecular tools. These diagnostic ambiguities directly affect subtype and grade assignment which, in turn, influence treatment planning, prognosis, and clinical trial eligibility. Variability across observers and institutions can lead to additional testing, delays, and inconsistent diagnoses.

The NCI/Bethesda classifier addresses this gap using DNA methylation patterns as a robust molecular fingerprint. It applies a stratified machine learning framework to extend diagnostic coverage and improve assignment confidence for CNS tumors. The classifier was developed from a rigorously curated reference set of over 16k methylation profiles, structured into 22 tumor families and 133 clinically relevant diagnostic classes and includes 21 recently developed methylation classes not represented in existing tools. The approach has been validated across multiple independent cohorts (n = 5,875) and supports deployment through MethylScape, a public web-based portal that streamlines classifier execution for broad accessibility. In an NIH validation cohort analysis of 1,204 high-confidence matches with pre-methylation diagnoses available, methylation profiling confirmed the initial diagnosis in 25.6% of cases while driving clinically meaningful diagnostic evolution in the remainder, including refined diagnosis (subtyping) in 14.6%, new diagnosis with increased precision in 54.7%, and substantial diagnostic reclassification in 5.0%—changes that are expected to affect patient management in the reclassification subset.

Renal neoplasms present a parallel diagnostic challenge due to morphologic and molecular heterogeneity, overlapping microscopic features, and interobserver variability. As a result, a subset of cases are unclassifiable even after immunohistochemical, mutation and cytogenetic workups. To address this, the Kidney Classifier component of this platform leverages genome-wide DNA methylation profiling (feasible on formalin-fixed paraffin-embedded tissue using robust array-based methods). It was developed through examination of methylation signatures from over 2,000 renal neoplasms, identifying 23 coherent methylation groups that correlate with known tumor types and reveal clinically relevant novel subtypes. A machine learning classifier trained on 1,284 samples was externally tested on 287 renal neoplasms, demonstrating >90% concordance between expected neoplasm type and high-score methylation-based classification, with discordant cases highlighting opportunities for diagnostic reclassification and improved precision in challenging renal tumor evaluations.

Licensing and collaboration opportunities include commercial development of methylation-based diagnostic tests and/or software-enabled classification solutions for clinical laboratories, reference labs, and diagnostic companies. Partners may engage in external validation (retrospective and prospective), assay standardization, integration into pathology workflows and reporting systems, and extension of classifier coverage to additional tumor types and multi-institutional datasets. Consistent with consensus recommendations for complementary classifiers, the inventors are also interested in collaborations that: (1) operationalize multi-classifier strategies (concordant/complementary prediction to increase confidence, (2) leverage discordance to trigger orthogonal follow-up) and (3) accelerate clinical translation through scalable deployment models- including CLIA laboratory workflows and regulated diagnostic pathways.

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

≤*NIH Reference Number:* E–105–2023–0.

Related Technologies: N/A.

Product Type: Oncology.

Therapeutic Area(s): Diagnostic.

Development Stage: Prototype.

Publications:

- Aldape K., et.al. cIMPACT–NOW update 9: Recommendations on utilization of genome-wide DNA methylation profiling for central nervous system tumor diagnostics. Neurooncol Adv. 2025 Jan 3;7(1):vdae228. PMID: 39902391.

Patents: PCT/US2024/054179, filed November 1,2024.

Potential Commercial Applications:

- Molecular classification and diagnosis of CNS and kidney tumors, including difficult-to-classify and low-confidence cases.
- Diagnostic subtyping aligned to WHO-guided entities.
- Reference-lab and hospital-lab deployment.
- Clinical trial stratification and translational research cohort harmonization.
- Multi-classifier diagnostic decision support.
- Cancer treatment development.

Competitive Advantages:

- Developed from a rigorously curated, large reference set of methylation profiles.
- Clinically relevant CNS diagnostic.
- CNS tumor methylation classes not represented in existing tools, expanding diagnostic coverage.
- Clinical-impact analysis creating superior diagnostic precision.
- Superior classifier for kidney cancer.
- Superior classifiers for multiple solid, difficult-to-diagnose tumors.
- Integrative into clinical workflows, improving diagnostic practices and enhancing patient care.

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations to further develop and possibly expand the classification capabilities of the software.

Dated: August 7, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–16441 Filed 8–11–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Monoclonal Antibody (RO4) That Reacts With the Juxta-Membrane Region of Mesothelin

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees for a novel monoclonal antibody (mAb), RO4, that can be used to treat mesothelin (MSLN) expressing cancers.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Laurie Whitney, Ph.D., Unit Supervisor, NCI, Technology Transfer Center, Email: *WhitneyL@mail.nih.gov* or Phone: 240–276–5505.

SUPPLEMENTARY INFORMATION: Mesothelin (MSLN) is a surface antigen