lling Code 4167-05-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Method of Manufacturing Papilloma Infiltrating Lymphocyte (PIL) Cell Therapy Products as a Treatment for Patients with Chronic Viral Infection(s)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees for development of papilloma-infiltrating lymphocytes (PIL) as treatment for patients with chronic human papillomavirus (HPV) 6 or 11 infections.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license 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: Recurrent respiratory papillomatosis (RRP) and anogenital condyloma are caused by chronic infection with human papillomavirus (HPV) types 6 or 11. These conditions lead to the development of papillomatous growths in different regions of the body. RRP affects the upper aerodigestive tract, condylomas the anogenital area. In RRP, growths in the aerodigestive tract can cause dysphonia, dyspnea and – in severe cases – airway obstruction. This may lead to recurrent pneumonia or respiratory failure.

Current treatment for RRP primarily involves repeated surgical debulking or laser ablation to manage symptoms. However, the virus often persists in a latent state, resulting in continual papilloma regrowth. The need for frequent procedures exposes patients to cumulative anesthetic and surgical risks, emotional distress, significantly diminished quality of life and persistent healthcare costs. There are no approved systemic therapies for chronic HPV 6 or 11-related conditions despite progress in localized treatments such as surgery and laser ablation. This highlights a clear unmet need for effective, curative therapies.

Researchers at the NCI have developed a novel adoptive cell therapy approach to target conditions driven by HPV types 6 or 11. They successfully identified and preferentially expanded HPV 6 and/or 11-specific T cells from papilloma tissue obtained from RRP patients. These PILs demonstrated the ability to eliminate papillomatous tissue. Relatedly, a T cell manufacturing method holds promise for developing cell-based therapies for widespread use in chronic HPV 6/11-related conditions – including RRP and anogenital condyloma. Notably, the ability to isolate and expand antigen-specific lymphocytes from non-cancerous growths represents an exciting advancement in the field of adoptive cell therapy – potentially paving the way for treating a broader range of non-malignant diseases.

The Center for Immuno-Oncology and the Surgical Oncology Program of the NCI, Center for Cancer Research are actively seeking industry partners to support the clinical development and commercialization of this approach. It is particularly well-suited for biotech firms focused on T cell therapies or addressing HPV-related diseases. Strategic collaboration could accelerate market entry and unlock significant value in an area with high unmet medical need.

"This Notice is in accordance with 37 C.F.R. § 404.4 Authority to grant licenses."

NIH Reference Number: E-143-2024-0.

Related Technologies: N/A.

Product Type: Infectious Disease | Immunology.

Therapeutic Area(s): Therapeutic.

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

Publications:

- Bai K, Norberg SM, Sievers C, Meyer T, et al. Durable response in a patient with recurrent respiratory papillomatosis treated with immune checkpoint blockade. (https://doi.org/10.1002/hed.27144).

Patents: PCT/US2025/051640, filed October 20,2025.

Potential Commercial Applications:

- Immunotherapy for chronic HPV-related conditions such as RRP and anogenital condyloma.
- Development of personalized T cell therapies targeting HPV 6 or HPV 11 infections.
- Generation of T cell receptor (TCR) libraries for research and therapeutic purposes.

Competitive Advantages:

- Addresses lack of approved systemic therapies for chronic HPV 6 or 11-related conditions.
- Potential to treat both non-cancerous and cancerous HPV-related conditions.
- PILs represent novel therapeutic approach.
- Drug development for RRP may qualify for regulatory incentives due to the rarity of the disease.
- Increased therapeutic efficacy from the ability to produce oligoclonal T cell populations.
- Selective expansion of T cells with high specificity for HPV 6 or HPV 11 antigens.
- Methodology applicable to both therapeutic and preventative treatments for chronic HPV infections.

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for PIL in treatment for chronic HPV6/11-associated diseases

Dated: July 13, 2026.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

[FR Doc. 2026-14347 Filed: 7/15/2026 8:45 am; Publication Date: 7/16/2026]