Off-the-Shelf Cancer Vaccine Elicits Strong Immune Response in Patients With Pancreatic and Colorectal Cancer

The ELI-002 2P vaccine can trigger powerful immune responses and may delay recurrence in patients with tumors driven by KRAS mutations.

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A novel cancer vaccine that stimulates the immune system to target one of the most common cancer-driving mutations has shown encouraging early results in patients with pancreatic and colorectal cancer, two of the most difficult-to-treat malignancies, according to a study led in part by investigators at the UCLA Health Jonsson Comprehensive Cancer Center.

The findings, published in Nature Medicine, show that the vaccine, called ELI-002 2P, can trigger powerful and lasting immune responses and may help prevent or delay cancer recurrence in high-risk patients whose tumors are driven by KRAS mutations. After an extended follow-up of 19.7 months, the researchers found that median relapse-free survival was 16.33 months and median overall survival was 28.94 months—both exceeding historical norms— with the greatest benefit seen in patients who developed strong mKRAS-specific T cell responses. For example, median relapse-free survival was not reached versus 3.02 months, and median overall survival was not reached versus 15.98 months comparing the above versus below T cell threshold groups.

“This is an exciting advance for patients with KRAS-driven cancers, particularly pancreatic cancer, where recurrence after standard treatment is almost a given and effective therapies are limited,” said first author of the study Zev Wainberg, MD, professor of medicine at the David Geffen School of Medicine at UCLA and researcher in the UCLA Health Jonsson Comprehensive Cancer Center. “We observed that patients who developed strong immune responses to the vaccine remained disease-free and survived for much longer than expected.”

The study, which included follow-up data from the AMPLIFY 201 Phase 1 trial, evaluated the safety and efficacy of a lymph node-directed vaccination that targets KRAS mutations. These mutations are found in about 25% of solid tumors and drive about 90% of pancreatic cancers and 50% of colorectal cancers.

Unlike some other cancer treatments that may need to be personalized for each patient based on their specific characteristics and mutations, ELI-002 2P is an “off-the-shelf” vaccine that is

designed to be a standardized product that can stimulate the immune system to recognize and attack cancer cells in a general way, without the need for the time-consuming and complex process of creating a unique vaccine for each patient.

The study followed 25 patients with either pancreatic ductal adenocarcinoma (20) or colorectal cancer (5) who had undergone surgery and showed signs of minimal residual disease, or traces of cancer DNA in the blood that often signal relapse.

Each patient received a series of injections with ELI-002 2P, which uses an amphiphile technology developed by Elicio Therapeutics that helps shuttle antigens directly to the lymph nodes, where immune responses are activated.

Among the findings:

- 84% of patients (21 out of 25) generated KRAS-specific T cells, including both CD4+ helper cells and CD8+ killer cells. Importantly, many of these T cells persisted over time.
- In 24% of patients (3 pancreatic, 3 colorectal), the biomarkers associated with the tumor were completely cleared.
- Patients with higher (above threshold) T-cell responses had a longer relapse-free survival compared to those with lower T-cell responses. In patients with higher responses, the median relapse-free survival was not reached, meaning so many patients were still cancer-free, a median time to relapse could not be calculated, versus 3.02 months ($p=0.0002$) in those with lower responses, and the median overall survival was not reached versus 15.98 months ($p=0.0099$) among those without strong T cell responses.
- 67% of tested patients developed immune responses to additional tumor-associated mutations, suggesting potential for broader anti-tumor activity.

“Targeting KRAS has long been considered one of the difficult challenges in cancer therapy,” said Wainberg. “This study shows that the ELI-002 2P vaccine can safely and effectively train the immune system to recognize and fight cancer-driving mutations. It offers a promising approach to generating precise and durable immune responses without the complexity or cost of fully personalized vaccines.”

The research team has completed enrollment in a larger Phase 2 study of ELI-002 7P, a next-generation version of the vaccine that targets a broader set of KRAS mutations.

The study’s senior authors are Shubham Pant from the MD Anderson Cancer Center and Eileen O’Reilly from Memorial Sloan Kettering Cancer Center. A full list of authors can be found in the study.

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