

Moderna mRNA Vaccine Helps Prevent Cancer Recurrence

A personalized cancer vaccine plus Keytruda lowered the risk of melanoma coming back after surgery.

December 15, 2022 By [Liz Highleyman](#)

A customized mRNA cancer vaccine combined with the checkpoint inhibitor Keytruda (pembrolizumab) reduced the risk of disease recurrence or death in people with high-risk advanced melanoma, according to a [joint announcement from Moderna and Merck](#). In a randomized clinical trial, the vaccine combination significantly reduced the likelihood of cancer recurrence after surgical removal compared with Keytruda alone.

“Today’s results are highly encouraging for the field of cancer treatment,” said Moderna CEO Stéphane Bancel. “mRNA has been transformative for COVID-19, and now, for the first time ever, we have demonstrated the potential for mRNA to have an impact on outcomes in a randomized clinical trial in melanoma.”

The Moderna and Pfizer-BioNTech [messenger RNA \(mRNA\) COVID-19 vaccines](#) use lipid nanoparticles, or fat bubbles, to deliver bits of genetic material that encode instructions for making the SARS-CoV-2 spike protein. When the vaccine is injected into a muscle, cells produce the protein, which triggers an immune response.

Moderna and BioNTech are among several companies working on vaccines to help the immune system fight cancer. In fact, the mRNA technology was [first developed for use in cancer immunotherapy](#). Experimental cancer vaccines contain blueprints for tumor antigens that stimulate an immune response. To create personalized vaccines, a sample from a patient’s tumor is sequenced, and scientists identify which neoantigens—abnormal proteins expressed by cancer cells—are most likely to elicit a robust immune response.

Combining cancer vaccines with checkpoint inhibitors—monoclonal antibodies that restore T-cell activity—could have the effect of letting up on the brakes and stepping on the accelerator at the same time.

Moderna’s customized cancer vaccine candidate mRNA-4157 contains up to 34 different neoantigens selected by an algorithm. In 2020, researchers reported findings from [a small Phase I trial](#) showing that mRNA-4157 plus Keytruda shrank tumors in 50% of people with head and neck

cancer, though no responses were seen in patients with colorectal cancer.

Based on promising early results, a version of the vaccine, dubbed mRNA4157/V940, was evaluated in a Phase IIb study as a treatment for advanced melanoma. New types of immunotherapy are often tested in people with melanoma, which tends to be a [“hot” tumor](#) with many mutations that can stimulate immune responses.

The KEYNOTE-942 trial ([NCT03897881](#)) enrolled 157 people with Stage III or IV cutaneous melanoma. Their cancer could be surgically removed, but it had spread to a lymph node, and they were at high risk for recurrence. At study entry, their cancer had been completely removed, they had not experienced local relapse or distant metastasis and the cancer had not spread to the brain.

After surgery, participants in this open-label trial were randomly assigned to receive nine doses of mRNA-4157 plus Keytruda or Keytruda alone for about a year or until they experienced disease recurrence or unacceptable side effects.

The mRNA-4157/V940 plus Keytruda combination “demonstrated a statistically significant and clinically meaningful improvement” in recurrence-free survival compared with Keytruda alone, according to the joint press release. The combination reduced the risk for recurrence or death after surgical removal by 44%. The companies said this is “the first demonstration of efficacy for an investigational mRNA cancer treatment in a randomized clinical trial.” These results have not yet been peer reviewed and published.

The treatment was generally safe and well tolerated. Side effects were consistent with those observed in previous studies of Keytruda, and the vaccine did not appear to add much. Serious treatment-related adverse events occurred in 14% of patients on the combination regimen versus 10% of those who received Keytruda alone.

Moderna and Merck plan to discuss these results with regulators and start a Phase III melanoma trial in 2023, which they hope to rapidly expand to other tumor types. Moderna is also exploring other cancer vaccine candidates, including mRNA-5671, which targets tumors with KRAS mutations.

BioNTech, too, is working on mRNA vaccines. Earlier this year, researchers reported that the vaccine candidate BNT122 plus a different checkpoint inhibitor, Tecentriq (atezolizumab), [reduced the risk of pancreatic cancer recurrence](#) after surgery. Another BioNTech candidate dubbed CARVac [might help CAR-T therapy](#) work better against solid tumors.

While custom-made cancer vaccines may be more effective, they are labor-intensive and costly, thereby limiting their use. Scientists are also working on off-the-shelf mRNA vaccines targeting common cancer antigens that could potentially offer wider access.

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