Moderna, Merck breakthrough could usher in wave of cancer vaccines

Merck and Moderna's success with a personalized cancer vaccine designed to keep melanoma at bay opens a new avenue of treatment that doctors hope will work against many types of tumors.

Unlike chemotherapy, which kills both healthy and cancerous cells, or immunotherapy, which revs up the immune system, personalized cancer vaccines train the immune system to specifically target mutations found only on a person's tumor.

Merck and Moderna said on Wednesday their vaccine helped prevent the return and spread of disease in a large trial involving more than 1,000 melanoma patients. They had localized tumors that were removed surgically, but had a high risk of recurrence. Moderna expects that thousands of melanoma patients could benefit within the first few years of approval.

"It is a big deal for the field in general," said Dr. Ryan Sullivan, director of the Center for Melanoma at Mass General Brigham Cancer Institute. "With this positive study, there is hope (and likely investment to follow) that these approaches may change the way we treat cancer more broadly."

The trial result is "a monumental leap forward," validating mRNA technology as a cancer treatment, said Dr. Julie Gralow, chief medical officer of the American Society of Clinical Oncology.

Beyond melanoma, personalized cancer vaccines are in late-stage development for a host of tumor types. Merck and Moderna have several large trials underway in non-small cell lung cancers that have been surgically removed.

They are also studying the combination in mid-stage trials in patients with bladder and kidney cancers as well as in early-stage trials in pancreatic and stomach cancers, with numerous trial results expected in the next year or two, Moderna President Stephen Hoge said.

Roche and BioNTech, whose mRNA technology was used in the Pfizer COVID vaccines, are testing a similar treatment called autogene cevumeran in mid-stage studies in colon and pancreatic cancer patients who have undergone surgery.

Results of the colon cancer trial are expected in 2027, with pancreatic trial results to follow in 2031.

“We should be hearing results from multiple studies over the next few years and there’s every reason to hope now, with this news, that many of them will be positive,” said Dr. Robert Vonderheide, director of Penn Medicine’s Abramson Cancer Center and president-elect of the American Association for Cancer Research.

Merck and Moderna’s treatment, known as intismeran autogene, involves activating the immune system with up to nine doses of Merck’s immunotherapy drug Keytruda, infused every six weeks, plus up to nine doses of a customized mRNA vaccine that instructs the immune system to attack the patient’s specific cancer cells.

When used alone after surgery to reduce the risk that melanoma returns, Keytruda is given every three to six weeks for up to a year.

In melanoma patients, Keytruda treatment can result in fatigue, diarrhea, rash and inflammation of joints and muscles, as well as of healthy organs in some cases. The companies said they saw no new side effects with the addition of the vaccine.

The trial is ongoing and the companies have not released full results. They will continue to follow volunteers to determine whether the drug extends overall survival.

Five-year data from a previous mid-stage trial presented in June showed the vaccine had cut the risk that the cancer would return by half, and reduced the risk that it would spread to new locations by 59% compared with Keytruda alone.

In that trial, the addition of an mRNA vaccine also showed no new increase in the rate of serious side effects.

“What we saw in the (mid-stage trial) were the kinds of reactions people were having when they got a flu or COVID shot or any other vaccine,” Hoge said.

Dr. Elizabeth Buchbinder, a melanoma specialist at the Mass General Brigham Cancer Institute, said doctors treating patients whose cancer has been surgically removed often weigh the benefits of treating with Keytruda against the risk of side effects, especially for patients with only a 20% risk of cancer recurrence.

The added benefit of the vaccine, however, “may change that math,” she said.

Buchbinder said a key reason to select melanoma to test in combination with Keytruda was that it is a tumor that produces a lot of mutations, making it easier for the immune system to spot.

Many other cancer types also produce multiple mutations, she said, suggesting it may have broad applicability.

“We’ll see, but it’s definitely an area that is going to be exploding, especially with these results coming out,” she said.

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