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# What Doctors Want You to Know About the New Experimental Melanoma Vaccine

- An experimental vaccine could lower the risk of melanoma coming back after treatment.
- The deadly form of cancer has a high recurrence rate.
- Doctors say the technology may be used in the future to prevent other forms of cancer.

An experimental new vaccine that could help prevent the deadly skin cancer melanoma from coming back after treatment is getting lots of attention: Developers Moderna and Merck shared in a joint press release that phase 3 results for their mRNA-based vaccine called intismeran "met endpoints of recurrence-free survival," though they did not provide exact numbers.

The phase 3 trial builds on results from a phase 2b trial shared at the American Society of Clinical Oncology's annual meeting earlier this year. According to the data, researchers found that a combination of intismeran and the immunotherapy medication Keytruda lowered the risk of melanoma recurrence by 49% at five-year follow-up, and reduced the risk of distant spread of the cancer or dying from melanoma by 59%.

**Meet the experts**: Michael Christopher, M.D., a dermatologist and melanoma specialist at Ironwood Dermatology in Tucson; Kim Margolin, M.D., oncologist and medical director of The Borstein Family Foundation Melanoma Program at Providence Saint John's Cancer Institute in Santa Monica, CA; Ahmad Tarhini, M.D., Ph.D., an investigator on the trial and a medical oncologist in the Cutaneous Oncology Department at Moffitt Cancer Center; Mario Sznol, M.D., a medical oncologist specializing in

melanoma immunotherapy with Sylvester Comprehensive Cancer Center, part of the University of Miami Health System

Melanoma recurrence rates vary by stage. In one Danish study of more than 25,000 people with melanoma, 2% of patients with stage IA disease experienced a recurrence, while 58% of those with stage IIIC disease, in which cancer has spread to nearby lymph nodes, had their cancer return.

"If it comes back, the outcome is typically poor," says Michael Christopher, M.D., a dermatologist and melanoma specialist at Ironwood Dermatology in Tucson, Arizona.

Intismeran is still in clinical trials and more data is needed. However, doctors are excited about what this could mean for the future of melanoma treatment—and cancer care as a whole.

## What is the new melanoma vaccine and how does it work?

The vaccine is called intismeran autogene. If approved by the U.S. Food and Drug Administration (FDA), it will be a first-in-class messenger RNA (mRNA) based individualized neoantigen therapy, per the news release. Meaning, it will be a customized cancer treatment.

The vaccine uses a sample of a patient's tumor to find the unique "fingerprint" of their cancer. This is then used to generate a unique anti-tumor response from the patient's immune system, per the release.

"This approach is essentially a personalized cancer vaccine designed using the molecular characteristics of an individual patient's tumor," says Kim Margolin, M.D., oncologist and medical director of The Borstein Family Foundation Melanoma Program at Providence Saint John's Cancer Institute in Santa Monica, CA. "The vaccine is intended to help the immune system recognize and eliminate those [cancer] cells before they can establish recurrent or metastatic disease," she adds.

## Why is this needed?

If melanoma is caught in its early stages, the risk of recurrence is low, according to Mario Sznol, M.D., a medical oncologist specializing in melanoma immunotherapy with Sylvester Comprehensive Cancer Center, part of the University of Miami Health System.

However, melanoma has a higher rate of recurrence when the cancer is detected at later stages. "This [vaccine] could be particularly useful after surgery because a patient may have microscopic residual melanoma cells that are below the threshold of detection with currently available imaging or other tests," Dr. Margolin says. So it may be able to trigger your immune system to fight off cancer cells that other detection or screening may not yet find.

## Who may be good candidates for this vaccine?

The vaccine isn't designed for everyone with melanoma. Instead, it's meant for patients with melanoma that's been resected (meaning, removed by surgery) and is stage IIB, IIC, III, or IV, according to Ahmad Tarhini, M.D., Ph.D., an investigator on the trial and a medical oncologist in the Cutaneous Oncology Department at Moffitt Cancer Center. These patients are "considered at high-risk for melanoma recurrence and death from melanoma," he says.

## Doctors say there are still unanswered questions.

Intismeran isn't given on its own—it's combined with an immunotherapy treatment called Keytruda (pembrolizumab) that is already used to lower the risk of recurrence in people with stage IIB or higher stages of melanoma. With that, it's difficult to know at this point how much added benefit comes from the vaccine over using Keytruda alone, Dr. Margolin says.

"A statistically significant improvement is important, but the magnitude of the benefit and its durability are ultimately what matter to patients and clinicians," she says.

Safety is also a big concern. “Immune-based treatments can produce immune-related adverse events because activation of the immune system can sometimes result in attacks against normal tissues,” Dr. Margolin says. Adding another treatment designed to bolster the immune system could potentially increase the number or severity of these side effects, she says—but we just don’t know at this point. (In their joint press release, Merck and Moderna shared that the safety profiles of this combination therapy in the latest trial “were consistent with those observed in previously reported studies for the combination, with no new safety signals observed.”)

Certain types of melanomas have characteristics that impact how well they respond to immune-based approaches, and some patients may do well with pembrolizumab or nivolumab (another immunotherapy drug, sold under the brand name Opdivo) without the addition of the vaccine, Dr. Margolin says. “Exposing them to an additional therapy may not provide enough incremental benefit to justify the added complexity or potential toxicity,” she says.

Still, in cancer treatment, many people opt for additional therapy to be safe, says Dr. Sznol. “There are quite a number of people who might have been cured from surgery alone,” he says. “They would also get side effects from a therapy they don’t need. But most people would still prefer to be treated upfront rather than later when they have metastatic disease.”

There are also logistical and economic concerns. “Developing a personalized vaccine requires sufficient tumor tissue and takes time, which could limit its feasibility for some patients,” Dr. Margolin says. “The cost could also be substantial, raising questions about access and the practicality of delivering this approach broadly.”

## Can it be used for other forms of cancer?

That is still to be determined. However, the personalized nature of the vaccine suggests that this could potentially be used to prevent recurrence of other types of cancer, Dr. Christopher says. “The technology is there,” he says. “This may eventually be something we utilize for other cancers.”

Dr. Tarhini says the technology is already being tested on other forms of cancer, including non-small cell lung cancer, bladder cancer, renal cell carcinoma, pancreatic ductal adenocarcinoma, and gastric carcinoma. "We have high hopes that this form of immunotherapy will lead to positive results across other cancers as well," he says.

Dr. Sznol says that the findings are "exciting." "There's a possibility that this could change the field," he says. "It may have implications for other diseases. We just don't know right now."

It's unclear what exactly happens next with the vaccine. However, Merck and Moderna stated in their press release that the latest data will be presented "at an upcoming international medical meeting and shared with regulatory authorities." Then, it would need approval from the FDA before it would be available to U.S. consumers.

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