

## **Study: Vaccine helps drug keep melanoma patients cancer-free**

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Adding a personalized cancer vaccine to the blockbuster drug Keytruda kept more melanoma patients in remission than the immune therapy alone, co-developers Moderna Inc. and Merck & Co. said in their first



detailed presentation of a key study.

About 79% of people who received both treatments stayed cancer-free 18 months later in a mid-stage trial, compared with 62% of people who received only Merck's Keytruda, the companies said Sunday at the American Association for Cancer Research's annual meeting in Orlando, Florida. Side effects with the vaccine were generally mild, such as fatigue, they said.

The <u>cancer</u> vaccine is an important part of Moderna's post-pandemic strategy as the need for COVID-19 vaccines cools. The results suggest the combination works, and the companies will likely need to prove the effect in a much larger final-stage trial before seeking US approval, Merck Chief Medical Officer Eliav Barr said in an interview. While Moderna executives had earlier suggested the companies might pursue accelerated approval based on the mid-stage results, Barr said they are preparing to first complete the phase 3 study that should begin later this year.

With novel therapies like this one, patients, doctors, guideline writers, payers and regulators will want to see a larger body of data so they can understand the new medicine and its potential role in practice, Barr said.

Since the companies released initial results from the <u>cancer vaccine</u> combination treatment in December, analysts and doctors have debated the magnitude of the effect and the methods used to quantify it. The detailed data being presented at the conference indicate that the treatment should be studied in more patients, said Sapna Patel, a melanoma medical oncologist at MD Anderson Cancer Center in Houston.

"It looks more effective than just the standard of care and will take a phase 3 study to say it's truly effective," Patel said.



In the trial, patients received the two drugs after the melanoma was surgically removed. Moderna analyzed the genetic sequence of each patient's tumor to create a vaccine that teaches the <u>immune system</u> to recognize markers of the abnormal growth. People received it every three weeks for a total of nine doses. They also received Keytruda every three weeks for up to 18 treatments.

Merck and Moderna plan to test the combination in other cancers where Keytruda is already used. They're aiming to start a study in <u>lung cancer</u> shortly after starting the next melanoma trial, Barr said.

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