

Melanoma drug holding up well after further testing

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Merck's late-stage melanoma drug, pembrolizumab, continues to show great promise in shrinking the deadly tumors, particularly when taken at the highest dosage offered in trials, according to a study published Thursday in the *New England Journal of Medicine*.

At the end of 12 weeks, the [intravenous drug](#) had shrunk tumors in 52 percent of patients when administered every two weeks, at a dosage of 10 milligrams per kilogram of body weight. Even when a lower dosage, and more time in between dosages, were taken into account, the overall tumor-response rate was 38 percent.

In most patients who showed a positive response, the results lasted beyond one year. And a dozen patients showed a "complete response," meaning their cancer was gone altogether.

Considering that melanoma is the deadliest of the skin cancers, killing some 9,000 people each year, discussing survival in terms of years and not months has cancer specialists using words they had rarely ventured to use during the previous three decades of research into the disease.

"This is monumental," said Dr. Jack Jacoub, medical oncologist at the MemorialCare Cancer Institute at Orange Coast Memorial Medical Center in Fountain Valley, Calif., who was not involved in the research. "Things look much more optimistic for this disease."

In recent years, much of scientists' energy, and research funding, has

been focused on using the body's [immune system](#) to fight invading [cancer cells](#). An FDA-approved drug called ipilimumab (brand name Yervoy) acts like a brake on a protein called CTLA-4, allowing the body's own T cells to battle cancerous melanoma tumors. Alone, it has a response rate of 10.9 percent in trials, but when maker Bristol-Myers Squibb combined it with another drug, nivolumab, the response rate jumped to 41 percent, according to data released in May.

Lambrolizumab, which used to be called MK-3475, puts the brakes on a different protein, PD-1, the same one nivolumab works on.

"Most patients think their immune system is weak and wonder why cancer is growing," said Dr. Bartosz Chmielowski, an oncologist at Ronald Reagan UCLA Medical Center who was a co-investigator for the study. "They say, 'I just want to boost my immune system.' Usually, it's not true. It's not that the immune system is weak; the [cancer](#) has found a way around the immune system.

"These results are extremely exciting and encouraging."

A subgroup in the study had taken Yervoy previously, with no improvement; in this study, they enjoyed the same response as other patients.

The most common side effects of the drug were fatigue, rash and diarrhea, but they were low-grade.

One drawback of the study, which was funded by Merck, is that it was not randomized: There was no alternative therapy to compare the [drug](#) with, and no placebo.

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