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New Immunotherapy, MK-3475, Shows Promise for Metastatic Melanoma [1]

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According to the results of a large phase I study, a new drug called MK-3475 may benefit people with melanoma that has spread to other parts of the body. MK-3475 blocks the function of a protein called PD-1 (programmed death-1) found on T-cells, a type of white blood cell that directly helps fight disease. Because PD-1 keeps the immune system from destroying cancer cells, stopping PD-1 from working allows the immune system to better eliminate melanoma.

As part of this study, 411 people with melanoma that had spread to distant parts of skin, the lungs, or other organs received treatment with MK-3475, although it was given using three different dose schedules. Before joining the study, 221 participants had received ipilimumab (Yervoy), while 190 had not.

MK-3475 provided a benefit no matter which dose was given and regardless of a number of other factors, including previous treatment with ipilimumab. Overall, 34% of the participants had tumors that responded to treatment. The response rate was higher in patients who had not had treatment with ipilimumab before the study began (40% compared with 28% of patients whose tumors had gotten worse during or after ipilimumab treatment). After about a year, 88% of the patients whose tumors responded to MK-3475 had not gotten worse. The estimated one-year overall survival rate was 69% for all participants and 74% for people who had not previously received treatment with ipilimumab. The one-year survival rate is the percentage of people who live at least one year after starting treatment.

Overall, 8% of the participants experienced serious treatment-related side effects, and 4% had to stop treatment because them.

What this means for patients

?This is probably the biggest phase I trial ever conducted in oncology,? said lead study author Antoni Ribas, MD, PhD, a professor of medicine at the David Geffen School of Medicine at the University of California in Los Angeles. ?We were excited to see that MK-3475 was effective in

previously untreated patients as well as in those who had multiple prior therapies, including ipilimumab. These are early data, but they tell us we are on to something really important.?

The U.S. Food and Drug Administration has granted MK-3475 a breakthrough therapy designation for metastatic melanoma or melanoma that cannot be removed with surgery, as well as a priority review designation. This helps speed up the review and approval of drugs that offer major advances in treatment or provide a treatment for a condition that does not have an adequate existing treatment.

Additional clinical trials are planned, but eligible patients with advanced melanoma who have been previously treated with ipilimumab and, if indicated, a BRAF inhibitor may be able to receive MK-3475 through an expanded access program. Expanded access programs allow drug manufacturers to provide patients with new investigational drugs under certain conditions. Talk with your doctor about all of your treatment options, including clinical trials.

Dr. Ribas was a recipient of a Conquer Cancer Foundation of ASCO Career Development Award in 2000.

Questions to ask your doctor

- What stage of melanoma do I have?
- What are my treatment options?
- What clinical trials are open to me? Where are they located, and how do I find out more about them?
- What treatment plan do you recommend? Why?
- What is my chance of recovery?
- Where can I get more information about expanded access programs?

More Information

Guide to Melanoma [2]

What is Immunotherapy? [3]

When the First Treatment Doesn?t Work [4]

Drug Approval and Labeling [5]

Links:
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