

Transcript Details

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Pembrolizumab Versus Placebo After Complete Resection of High-Risk Stage III Melanoma: Long-Term Quality of Life Analysis Results of the EORTC 1325-MG/Keynote-054 Double-Blinded Phase 3 Trial

Announcer:

Welcome to CME on ReachMD. This episode is part of our MinuteCME curriculum.

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Dr. Ascierto:

My name is Paolo Ascierto. I'm a medical oncologist and I'd like to discuss with you the data from the Keynote-054 about the long-term quality of life analysis results.

Here, the trial design of Keynote-054, that patient population where high-risk resected, stage three cutaneous melanoma that were randomized in one-to-one, to Pembrolizumab to mean 200 milligrams intravenous every two weeks for one year or in the placebo arm. As you can see, the primary endpoint was relapsed and survival and quality of life assessment was part of the secondary endpoints.

Just few information about study background. We have an approximately five-year median follow-up. We have seen in previous report that the relapse-free survival was 55% in Pembrolizumab R versus 30% in the present one at five years. We also seen the distant metastasis free survival. 61% of patients, distant metastasis is free, versus 44 at five year. And so, there was clear evidence that relapse-free survival and distant metastasis-free survival was better than patients who were treated with Pembrolizumab. At moment, we still don't have overall severe data because are still immature. There was a previous report of the quality-of-life analysis with no clinical relevant different between the two group of patients treated with the Pembrolizumab or placebo and the compliance to the questionnaire for the quality of life was 92% of baseline and about 70% post-baseline. The primary objective of this evaluation of the quality of life in this case of treatment effect long-term global health status.

So this was the primary objective, you have seen, and we already discussed, the data that were already published about relapse free survival. Distant metastasis free survival.

And here the results from these analysis on the long-term quality of life, as you can see, there is no meaningful difference between the two arm, the placebo and the Pembro arm, in the global health quality of life and also the physical functioning and also looking the additional scales. Again, not clinically meaningful different is clear from this graphic.

Also, looking at this two-forest plot about the distant metastasis stages and the immune-related adverse event and impact on the long-term quality of life. As you can see looking at distant metastasis no significant difference between the treatment arms even if there is a trend versus the deterioration. While for the immune-related adverse event, as you can see, really no evidence of an association between immune-related adverse event and treatment in terms of long-term quality of life.

In conclusion, as you have seen from the graphics, there is no relevant differences between the treatment arms in the long-term quality-of-life assessment. The occurrence of distant metastasis was associated with a deterioration of quality of life but in the Pembrolizumab arm, no evidence of impact of immune-related adverse event on the long-term quality of life. Thank you for your attention.

Announcer:

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