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Efficacy and Safety Outcomes for Adjuvant Immunotherapy Driving Guideline Recommendations for Stage IIB/IIC Melanoma

Announcer:

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Dr. Ascierto:

Hello everybody, and good morning. This is CME on ReachMD, and I'm Dr. Paolo Ascierto. In this episode, I relay efficacy and safety outcomes for adjuvant immunotherapy, driving guidelines' recommendation for stage IIB/IIC melanoma.

We know that in the field of melanoma stage IIB/IIC, we got data from 2 important randomized trials, the CheckMate 76K and the KEYNOTE-716.

The CheckMate 76K was a phase 3 randomized trial, which randomized 709 patients in 2 arms. One arm with the nivolumab as treatment, dosage 480 mg for 12 months every 4 weeks. And the control arm was placebo. The main endpoint was the relapse-free survival.

So now we have important data about this trial and in terms of relapse-free survival, we have seen better outcomes for the patients treated with the nivolumab compared to the placebo with an observation of 0.42. So that is really good. What is more important is that the distant metastasis-free survival, it is surrogate and put more close to the overall survival, still in favor of the treatment with the nivolumab. From a safety point of view, the safety was consistent with all the data that we have seen in the other settings, and also in other diseases. The classic safety profile of nivolumab.

The KEYNOTE-716 was another phase 3 trial, which compared the pembrolizumab, another anti-PD-1, to the placebo. The patients enrolled were 976 patients in these 2 arms; one with the pembrolizumab with classical dosage of 200 mg/kg for 1 year, every 3 weeks, and the control arm, the placebo still. Relapse-free survival main endpoint. We have more mature data compared to CheckMate 76K, because in the first trial that I mentioned, the follow-up is less than 36 months. Here, now we have the data with the 40.5 months.

Still, relapse-free survival showed a better impact with pembrolizumab compared with placebo. And the hazard ratio was with a more mature follow-up of 0.62. That means 38% of risk reduction for recurrence. And again, here, the distant metastasis-free survival showed a better outcome for the patients treated with pembrolizumab compared to placebo. And again, safety profile consistent with all the previous data.

What is the impact of this data on the clinical practice? So we know that melanoma IIB and IIC are patients with a high risk to develop a recurrence. And mainly in the IIC patients, the outcome of these patients, generally, it's something like the IIIB. And for this reason, these patients should be really considered for this treatment.

So in general, in the guidelines, what we use is the sentence, can we treat it, or should we treat it? Surely, IIC patients should be treated with anti-PD-1 in this case. Stage IIB patients, still, are patients at high-risk. For these patients, probably not a really must. We can use the sentence, can we treat? And this should be discussed with the patients because there is still a high percentage of IIB patients in the placebo arm that can reach a good outcome even without any treatment.

So this is what we usually do in clinical practice for the IIB patients. We discuss with the patients we can use this treatment for the IIC. It's a strong recommendation to treat these patients due to the high risk.

So, well, that's all the time we have today. And I hope this review will be useful in your practice and good-bye, everybody.

Announcer:

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