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Neoadjvuant Versus Adjuvant Pembrolizumab for Resected Stage III-IV Melanoma (SWOG S1801)

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

Prior to beginning the activity, please be sure to review the faculty and commercial support disclosure statements as well as the learning objectives.

Dr. Patel:
My name is Sapna Patel, I'm a medical oncologist at MD Anderson, and it is my pleasure to present results of SWOG S1801, neoadjuvant versus adjuvant pembrolizumab for resectable stage III to IV melanoma.

To test the hypothesis that a neoadjuvant anti-PD-1 regimen would improve event-free survival compared to the adjuvant regimen of the same treatment, we designed the S1801 study. The study was a 1:1 randomized phase II trial where participants received the exact same surgery and the same number of doses of pembrolizumab, just sequenced differently, as shown here.

The primary endpoint of the study was event-free survival, defined here, and to account for differences in time to adjuvant therapy and owing to the difference in timing of radiographic assessments, and to avoid biasing in favor of the neoadjuvant arm where radiographic assessments occurred at a later time point on study. Participants who did not register to adjuvant therapy were assigned an event-free survival of 84 days.

This is the disposition of participants on S1801. 345 participants entered the study and 313 were randomized.

At a median follow-up of 14.7 months, we reached the trigger for analysis at 104 events. Event-free survival was significantly longer in the neoadjuvant arm compared to the adjuvant arm with a hazard ratio of 0.58 and a two-sided p-value of 0.004. Landmark two-year event-free survival was 72% in the neoadjuvant arm versus 49% in the adjuvant arm.

Event-free survival favored the neoadjuvant arm in all key subgroups shown here.

Radiographic response was assessed on the neoadjuvant arm before surgery. Nine participants achieved a complete radiographic response, and 59 participants a partial response. 42 participants had an increase in target lesions, but 30 were still able to go on to receive surgery. And one study participant with a complete radiographic response declined surgery and has not had a recurrence after 31-1/2 months of follow-up.

This is a description of events that occurred on S1801. In red are disease progression or recurrence events, as opposed to toxicity or compliance events.

This is a graphical representation of the different periods of time on each arm. There were a similar proportion of participants on each arm who made it to surgery and adjuvant therapy without an event. One key takeaway to note is that the majority of events in S1801 occurred in the adjuvant period in the adjuvant arm.

Treatment-related adverse events were similar on both study arms. Neoadjuvant pembrolizumab did not increase adverse events in the

peri-operative period.

In summary, event-free survival was significantly longer in the neoadjuvant arm than in the adjuvant arm. In two-year event-free survival was 72% versus 49%. Events occurring before adjuvant therapy occurred similarly on both arms, but events occurring after the initiation of adjuvant therapy occurred more frequently in the adjuvant arm. S1801 demonstrated no new safety signals with the use of neoadjuvant pembrolizumab.

In conclusion, compared to the same treatment given entirely in the adjuvant setting, neoadjuvant pembrolizumab followed by adjuvant pembrolizumab improves event-free survival in resectable melanoma. I'd like to thank and acknowledge the 90 sites across the United States who enrolled participants on S1801, nearly half of which were community oncology practices. Thank you.

Announcer:
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