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What Dermatologists & Surgeons Need To Know: Adjuvant Treatment for Resectable Stage II Melanoma

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Dr. Weber:
Hello. I'm Dr Jeffrey Weber. I'm a Medical Oncologist at the Laura and Isaac Perlmutter Cancer Center here at NYU Langone Health in New York City. Today, about key adjuvant clinical trials in melanoma, particularly stage IIB and IIC resected disease.

There have been two significant, large, randomized registration trials for patients with stage IIB/IIC resected melanoma. The first one that came along was the so-called KEYNOTE-716, trial, which was a large, randomized trial of the PD-1 antibody, pembrolizumab, versus placebo. Placebo, of course, was the choice, because at the time the trial started, there was no approved therapy for resected stage IIB/IIC melanoma. And the updated and important data from this trial are shown here. The primary endpoint of that large, randomized, 900+ patient trial with a 1:1 randomization to pembrolizumab for 1 year or placebo was recurrence-free survival. And as you can see with the updated data, I would much rather be on that blue curve than on that red curve. Blue is pembrolizumab for 1 year, red is placebo for 1 year. The hazard ratio for the improvement in recurrence-free survival is 0.61, which is very nice. That's a 39% reduction in the risk of recurring or dying. And again, the curves break apart at the first evaluation at 6 months. That's when you had your first scans on that trial, and they've stayed apart all the way through with now something like 27 months of follow-up. And there's plenty of data at 3 years, and again, suggesting clear benefit for pembrolizumab compared to doing nothing, meaning a placebo, for resected stage IIB/IIC melanoma.

The secondary endpoint was DMFS, or distant metastasis-free survival. And again, if you look at the bottom here, you'd much rather be on the red curve than the blue curve. Here, it's flipped. Red is pembrolizumab, blue is placebo. And the hazard ratio is a very nice 0.64, 36% reduction in the risk of distant metastases, which many of us think is a surrogate for survival. And again, the curves break apart at the first evaluation with first scans in this trial at 6 months, and they stay apart all the way across again, 27 months of follow-up. And again, very impressive data suggesting that there's clear benefit, where we believe that adjuvant pembrolizumab statistically significantly reduces the risk of recurrence or development of distant metastases or death compared to placebo. So again, this led to the approval last year of pembrolizumab as adjuvant therapy for 1 year for resected stage IIB/IIC melanoma.

Not to be outdone, nivolumab, which is the other PD-1 antibody that's been approved and has activity in melanoma, was also tested in an adjuvant study in stage IIB/IIC resected disease. This was CheckMate 76K. And what we see here in this large, randomized, more than 750 patient registrational study is that there was clearly, with shorter follow-up than we've seen with prior trials, only about 16 months, there was clearly benefit in terms of recurrence-free survival, where there was a break in the curve at the first evaluation at about 6 months, the curves stay apart through the years of follow-up. And the hazard ratio was a very nice 0.42, reflecting a 58% reduction in the risk of recurrence or death. And look at that P value, 0.0001, so very significant benefit in terms of recurrence-free

survival for nivolumab in resected stage IIB/IIC melanoma. And if you look at the distant metastasis-free survival, which many of us think is a surrogate for overall survival, you see a similar break in the curve at 6 months. You'd obviously rather be on the blue curve than the black curve. The blue curve is nivolumab, the black curve is placebo. And again, hazard ratio very similar to that for recurrence-free survival at 0.47, reflecting a 53% reduction in the risk of distant metastasis-free survival or death. Again, very nice-looking data in this randomized phase 3 study.

What do we conclude? Well, adjuvant single agent PD-1, either nivolumab or pembrolizumab, prolong recurrence-free and distant metastasis-free survival in patients with resected stage IIB/IIC melanoma. This leads me to believe that dermatologists and surgeons should refer all stage IIB/IIC patients with melanoma to a medical oncologist to have a conversation about possible adjuvant therapy after a complete resection. And again, as always, we need to have biomarkers to choose the patients most likely to relapse to, because we'd rather treat only a few patients to benefit one, and I think that's an important goal.

Thank you for your attention.

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