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SERENA-6: Acting on ESR1 Mutations in Advanced Breast Cancer

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Dr. Mayer:
Hello from ASCO 2026 here in Chicago. I'm Dr. Erica Mayer. Today, I'm reviewing final progression-free survival 2 results from the phase 3 SERENA-6 trial, evaluating first-line camizestrant for patients with advanced breast cancer and emergent ESR1 mutations.

SERENA-6 is a very important trial that is evaluating the concept of monitoring for the detection of resistance in cancers and then applying the correct therapy for patients whose tumors have resistance mutations, in this case using an oral SERD.

SERENA-6 is a 2-step trial. Step 1 of SERENA-6 was a surveillance step in which over 3,000 patients who had initiated first-line therapy for metastatic hormone receptor-positive HER2-negative breast cancer using an aromatase inhibitor and a CDK4/6 inhibitor were monitored for the development of an ESR1 mutation. What was being looked for was finding the mutation in the absence of clinical progression.

Over 3,000 patients were screened, and 315 patients were identified who were able to move on to step 2 of the SERENA-6 trial, in which those patients were randomized to switch their endocrine therapy from aromatase inhibitor to the oral SERD camizestrant with continuation of CDK4/6 inhibitor and a placebo versus staying on their aromatase inhibitor and their CDK4/6 inhibitor and a placebo.

The primary endpoint of the study was progression-free survival. This data was originally presented at last year's ASCO in a plenary session, showing a prolongation in progression-free survival. So this is a positive trial.

This year at ASCO, we are seeing updated data from SERENA-6, including updated results for progression-free survival. This confirms the benefit of making that switch to camizestrant at time of emergence of the ESR1 mutation. And we see that there is a prolongation in progression-free survival from 9 months to almost 17 months in those who make the change.

Importantly, with prolonged follow-up, we see that at a time point of over 2 and a half years out from randomization, there's about 30% of patients who remain on the camizestrant arm without evidence of disease progression, which is really quite remarkable.

Another important finding from the SERENA-6 study is that quality of life was prolonged in patients who make the switch, with a substantial prolongation in time to deterioration of quality of life, and that has been confirmed.

This year at ASCO, we are also seeing results from progression-free survival 2, which is looking at time until second progression. This has been closely monitored for this study, and now we are able to say that this is significantly prolonged in patients who make the switch to camizestrant, with a prolongation of almost 7 months, and this was statistically significant.

Importantly, there was also a significant prolongation until time to chemotherapy, which is a very important and clinically relevant endpoint for our patients.

So overall, we see that with prolonged follow-up of the SERENA-6 trial, we see confirmation of the primary endpoint of progression-free survival, support for the very important endpoint of prolongation in quality of life. We now see that PFS2 is statistically significant, with a 7-month improvement in PFS2, and we also see a prolongation in time to patient receipt of chemotherapy.

We will continue to monitor the SERENA-6 trial closely, but we are very grateful for these updates this year at ASCO.

Thank you.

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