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ELEVATE: Elacestrant Plus Capivasertib in Advanced Breast Cancer

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Dr. Bardia:
Hello, I'm Aditya Bardia, medical oncologist at UCLA, and I'm excited to talk about the ELEVATE results presented at ASCO 2026 in Chicago.

As a reminder, ELEVATE is an umbrella study. It looked at elacestrant-based combinations for patients with ER-positive, HER2-negative metastatic breast cancer.

At ASCO 2026, we see the results of elacestrant in combination with capivasertib, an AKT inhibitor. The background is that fulvestrant plus capi, or capivasertib, is FDA approved for patients with ER-positive, HER2-negative metastatic breast cancer who have alterations in the PI3K pathway, PIK3CA mutation, PTEN mutation, or AKT mutation. Fulvestrant is given as an intramuscular shot. Elacestrant is an oral SERD that is FDA approved for ESR1-mutant metastatic breast cancer. So this study looked at the combination of elacestrant with capivasertib.

Patients were enrolled in this clinical trial. And three important points to remember related to this study. The first, in terms of drug-drug interaction, there were no drug-drug interactions seen between elacestrant and capivasertib. Second, in terms of the safety profile, there were no surprises. Capivasertib is associated with diarrhea, and that was seen in this clinical trial as well. There was no new unanticipated toxicity seen with elacestrant plus capivasertib. Importantly, no bradycardia or visual disturbance. These are side effects that can be observed with other oral SERDs but were not seen with elacestrant plus capivasertib.

And then finally, in terms of efficacy, the combination was quite effective. We saw a median progression-free survival getting close to 12 months with the combination. We saw responses with a response rate of about 30% with the combination of elacestrant plus capivasertib, duration of response that was not reached yet, and overall a disease control rate of close to 90% with elacestrant plus capi.

And if we compare this to fulvestrant plus capi, the median PFS in the CAPItello trial was about 7 months. Now, there are caveats with cross-trial comparisons, but it is clear that the combination is effective and overall appeared safe.

So to summarize, elacestrant plus capi in this clinical trial was an option that was safe, well tolerated, and demonstrated evidence of clinical activity, as seen in the umbrella ELEVATE study.

The enrollment in Part 2 of this trial with 62 patients has been completed, so we'll have additional data looking at the combination of elacestrant and capivasertib.

So it's great to see this oral SERD in combination with a targeted agent that targets the PI3 kinase/AKT pathway and provides an all-oral option for patients with ER-positive, HER2-negative metastatic breast cancer.

Thank you so much for joining today.

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