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https://reachmd.com/programs/cme/rwe-supporting-cdk46-inhibitor-use-in-hr-metastatic-breast-cancer/16599/

Released: 12/08/2023
Valid until: 12/08/2024
Time needed to complete: 51m

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RWE Supporting CDK4/6 Inhibitor Use in HR+ Metastatic Breast Cancer

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

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Dr. Gallagher:
Hi, my name is Dr. Christopher Gallagher, Medical Oncologist, and I'm going to be speaking today on Real-World Evidence Supporting CDK 4/6 Inhibitor Use in Hormone Receptor-Positive Metastatic Breast Cancer.

The first study I'll talk about is the P-Reality X study, a study where they obtained data from the Flatiron database, mostly from community oncology practices. Almost 3,000 records were used in this study. They collected data from 2015 to 2020. The women were – and the median age was 70, 68% were non-Hispanic white, and 30% had visceral disease. And the median follow-up was pretty similar between the aromatase inhibitor with palbociclib versus aromatase inhibitor alone. And the primary endpoints were real-world progression-free survival and overall survival.

Looking at the graphs below and looking at the real-world progression-free survival and overall survival, whether it was with the median unadjusted or the inverse probability weighting or propensity score matching, two different ways to measure real-world data, the progression-free survival and overall survival were very similar to the randomized clinical trial in PALOMA-2.

Looking at another study looking at real-world use of palbociclib, this is the POLARIS trial. This was a prospective, observational study where they had 1,242 women enrolled, 902 received first-line therapy with palbociclib, and 340 second-line therapy or later. Women were on average 64 years, majority were non-Hispanic white, 68% had recurrent disease, approximately 40% visceral metastatic disease, and 34% bone only disease. The median follow-up was 35.7 months, and their endpoints were real-world progression-free survival, response rate, clinical benefit rate, and overall survival.

And looking at the data here presented in ESMO 2022, the real-world progression-free survival and overall survival, especially in the first-line setting, again, were very similar to the data from the randomized clinical trial looking at palbociclib.

Turning now to ribociclib being used with an aromatase inhibitor, this data source comes from a registry called the KARMA registry from Australia, collected on women receiving first-line ribociclib with an aromatase inhibitor, slightly less patients, 160 collected data from 2017 to 2018. The women were younger at 54 age on average, 24% were premenopausal, 31% had bone only disease, and 36% visceral disease. They had relatively good median follow-up of 36.4 months and their primary endpoint was progression-free survival.

And they compared their data to that of the MONALEESA study. Then when this was published in 2022, median progression-free survival was not yet reached. The 12-month and 18-month progression-free survival, the women in the KARMA registry did better than those in the MONALEESA-2 study. But when looking at who these women were, they tended to be younger, 54 versus 62. They had higher rates of bone only metastatic disease, less visceral disease, and fewer metastatic sites. So, the KARMA register, although it had superior progression-free survival to MONALEESA-2, it was more likely due to the more favorable baseline characteristics, and possibly

less frequent scheduling of assessments and diagnostic imaging.

Turn next to abemaciclib, which was the third CDK 4/6 to receive FDA approval and look at some real-world evidence with abemaciclib. This comes from pharmacy claims. They were the IBM Market Scan Data Research Base, 454 patients, records from 2017 to 2019. You can see the demographics there, but what's a little different is the endpoints. The first endpoint is time to discontinuation, time to chemotherapy, medication adherence, and medication wastage.

About ¾ of the patients started abemaciclib at the index full dose 150 mg twice daily. Those who received prior CDK 4/6 inhibitor, were less likely to start at full dose, 31% had a dose reduction within the first 90 days, lower than that in the randomized clinical trials. This was the drug wastage that was calculated, and 86% of the patients refilled abemaciclib at least once, looking at drug adherence. When you looked at time-to-event outcomes, the women who received prior CDK 4/6 inhibitor, their time to discontinuing the drug and their time to chemotherapy was shorter.

Thank you for your participation and listening today. Hope you appreciated it.

Announcer:
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