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Exploring the EMERALD Trial: What the Subgroup Analyses of Advanced Breast Cancer Patients Found

Announcer:
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Host:
For patients with metastatic ER-positive, HER2-negative breast cancer, short for estrogen receptor-positive/human epidermal growth factor receptor 2-negative breast cancer, current treatment guidelines recommend the use of endocrine therapy with either an aromatase inhibitor or fulvestrant, plus a cyclin-dependent kinase 4/6 inhibitor, also called a CDK4/6i, as first-line treatment. But while the guidelines then recommend sequential endocrine therapy for disease progressions, mutations to estrogen receptor 1, or ESR1, can occur with progression to advanced disease, leading to resistance to endocrine therapy.

Elacestrant, a novel, oral selective ER degrader, has been investigated as a potential therapeutic option for patients with previously treated advanced or metastatic hormone receptor-positive breast cancer, including ESR1-mutant breast cancers associated with endocrine resistance. Three subgroup analyses stemming from the EMERALD Trial evaluated the efficacy of this investigational agent.

To recap, the EMERALD trial was a multicenter randomized, controlled, open-label, phase III study conducted in patients with ER-positive/HER2-negative advanced breast cancer who developed progression of disease after first- or second-line treatment with endocrine therapy and a CDK4/6i. 239 patients were randomized to receive 400 milligrams of elacestrant orally once daily, while 238 patients received standard-of-care endocrine monotherapy. Almost half of all patients had an ESR1 mutation.

The EMERALD trial found that elacestrant significantly reduced the risk of disease progression or death by 30 percent in all patients, and by 45 percent in patients with an ESR1 mutation.

The first subgroup analysis, presented at the American Society of Clinical Oncology's 2022 meeting, compared progression-free survival between elacestrant and standard of care endocrine therapy in patients without prior chemotherapy. Among patients enrolled in the EMERALD trial, 77.8% had not received prior chemotherapy for advanced or metastatic breast cancer. Within this subgroup, treatment with elacestrant was associated with significantly prolonged progression-free survival compared to standard of care in both the overall population and patients with ESR1 mutations.

A second subgroup analysis, presented at the European Society for Medical Oncology 2022 Congress, compared elacestrant versus fulvestrant or aromatase inhibitors to better distinguish efficacy regardless of type of endocrine therapy. A subgroup analysis presented at the ESMO 2022 congress compared elacestrant versus fulvestrant or an aromatase inhibitor to better distinguish efficacy regardless of endocrine therapy. The results once again demonstrated improved progression free survival with elacestrant compared with fulvestrant or an aromatase inhibitor in all patients including those with ESR1 mutations.

And most recently, a subgroup analysis presented at the 2022 San Antonio Breast Cancer Symposium examined the impact of duration of therapy with prior CDK4/6i on progression-free survival. The study results determined that the longer the duration of prior CDK4/6i therapy, the longer progression-free survival benefited elacestrant versus standard of care, and this response was even more pronounced in patients with ESR1 mutations.

The authors note that taken together, these findings from the EMERALD trial and subgroup analyses highlight the superior efficacy of elacestrant over standard-of-care endocrine therapy in ER-positive/HER2-negative advanced or metastatic breast cancer patients, suggesting a promising new option for second- or third-line therapy.

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