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# The EMERALD Trial: Comparing an Oral SERD vs. Endocrine Therapy for Advanced Breast Cancer

**Announcer:**
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**Host:**
Endocrine therapy is the standard of care recommended for locally advanced or metastatic ER-positive, HER2-negative breast cancer, short for estrogen receptor-positive, human epidermal growth factor receptor 2-negative breast cancer. But mutations such as estrogen receptor 1, also known as ESR1, can lead to disease progression, including endocrine therapy resistance. For this reason, estrogen receptor inhibitors and selective estrogen receptor degraders have become the focus of increasing research into ESR1-mutant breast cancers. And one such investigational agent, an oral selective estrogen receptor degrader called elacestrant, may offer a promising therapeutic option for patients with ESR1-mutant breast cancers.

To evaluate the efficacy of this agent, a randomized phase III study known as the EMERALD trial was conducted in patients with ER-positive/HER2-negative advanced breast cancer. These patients had progression of disease after first- or second-line treatment with combination endocrine therapy and cyclin-dependent kinase 4/6 inhibitor. 239 patients were randomly assigned to receive 400 milligrams of elacestrant orally once daily and compared with 238 patients who received standard-of-care endocrine monotherapy.

Looking at the study population baseline characteristics, the median age was 63 years, and almost half of all patients had a detectable ESR1 mutation. Just over 40 percent of patients had received two prior endocrine therapies, and 22 percent received one prior round of chemotherapy.

Progression-free survival in all patients and progression-free survival in patients with detectable ESR1 mutation were the study's two primary endpoints. Elacestrant met both primary endpoints and showed significant improvement in progression-free survival versus the standard of care arm, with reduced risk of progression or death by 30 percent in all patients and by 45 percent in patients with an ESR1 mutation.

Adverse events were generally reported with similar frequency in both treatment groups, and the most commonly reported adverse events with elacestrant versus standard of care were nausea, fatigue, vomiting, decreased appetite, and arthralgias. Adverse events led to treatment discontinuation in 6.3 percent of patients receiving elacestrant and 4.4 percent of patients receiving standard-of-care endocrine therapy. No deaths were assessed as treatment-related in either arm.

The authors suggest the safety and efficacy data in the EMERALD trial represent an opportunity to offer ER-positive/HER2-negative advanced or metastatic breast cancer patients an option for second- or third-line oral monotherapy, and further clinical trials will continue to shed light on the impact of treatment regimens incorporating elacestrant.

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