

New drug shows promise in treating early-stage breast cancer

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Early results from a UCLA-led clinical trial found treating women with estrogen receptor (ER)-positive and human epidermal growth factor receptor-2 (HER2)-negative early breast cancers with a novel type of

anti-hormonal therapy, called an oral selective estrogen receptor degrader (SERD), led to clinically meaningful reductions in tumor activity prior to surgery. The activity was assessed by measuring the levels of Ki67, which is a protein that is expressed when the cancer cell is dividing. Reduction in levels of Ki67 gives researchers information about the likelihood of a good outcome.

Women treated with two weeks of the oral SERD giredestrant had more than an 80% drop in their tumor Ki67, compared to a 67% reduction in patients who were treated with the standard care aromatase inhibitor (AI) anastrozole, which are pills that lower estrogen levels.

"These are encouraging data from the first reported trial comparing an oral SERD to an AI," said lead author Dr. Sara Hurvitz, director of the Breast Cancer Clinical Research Program at the UCLA Jonsson Comprehensive Cancer Center. "Our results provide an early indication that giredestrant may reduce [cancer](#) cell division to a greater extent than our standard of care treatment. And we know from other studies that when a tumor drops its Ki67 after two weeks of anti-hormonal therapy, the patient has a lower chance of disease recurrence long-term. These data provide solid rationale to further evaluate giredestrant in larger randomized trials in the curative or late-stage settings."

ER-positive breast cancer comprises over two-thirds of all breast cancer diagnosed; more than 180,000 women are diagnosed with this subtype annually in the United States. Up to half of women with ER-positive disease will end up developing treatment resistance to current therapies.

Oral SERDs, which are [estrogen receptor](#) downregulators that are taken in pill form instead of injection, are becoming a more widely studied alternative to aromatase inhibitors, which are currently the standard care treatment for women with ER-positive early breast cancer, but do not always work long-term. Researchers are continuing to develop new

generations of oral SERDs to better overcome drug resistance.

Researchers enrolled 202 postmenopausal women with untreated, ER-positive and HER2-negative early breast cancer to evaluate the efficacy, safety and pharmacokinetic properties of giredestrant. Half the patients received two weeks of giredestrant and the other half received two weeks of anastrozole in the window of opportunity phase. After two weeks, palbociclib was given in combination with either giredestrant or anastrozole for the 14-week neoadjuvant phase prior to surgery. Biopsies were done prior to starting the therapy and at the two-week time point to see if the percentage of cells expressing Ki67 dropped. Data from the interim analysis were presented which comprised 108 safety-evaluable patients and 83 efficacy-evaluable patients.

The interim analysis shows giredestrant may be another treatment option for women with ER positive [breast](#) cancer. The data also gives researchers evidence that they should move forward with the full primary analysis and that giredestrant should be studied in larger randomized trials.

More information: Conference:

www.esmo.org/meetings/esmo-congress-2021

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