

New breast cancer combination approved

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Although Tykerb has already been approved for HER2-positive metastatic breast cancer, most patients must wait until they progress on other therapies before they are offered the targeted agent. But late Friday, the Food and Drug Administration granted Tykerb (lapatinib) accelerated approval as a first-line treatment in combination with Femara (letrozole).

The regimen is approved for postmenopausal women with ER-positive, HER2-positive metastatic breast cancer. It pairs Tykerb, which targets EGFR and HER2, with Femara, an aromatase inhibitor approved for ER-positive breast cancer.

The FDA based its approval on a study that included 219 women with ER-positive, HER2-positive cancer. Researchers found that Tykerb/Femara increased median progression-free survival by more than five months compared with Femara alone (8.2 months compared with 3 months). The most common side effects noted in the trial were diarrhea, rash, nausea, and fatigue.

For more information, read [A Winning Combination](#), which covers the study presented at the 2008 San Antonio Breast Cancer Symposium. During the meeting, several researchers and oncologists noted the significance of the study results.

"This is huge improvement. This is very important information," said Edith Perez, MD, a professor of medicine at the Mayo Clinic and HER2-positive breast cancer researcher, during the 2008 meeting. There was also evidence that suggested the Tykerb and Femara combination could have the potential to benefit patients who relapsed on tamoxifen.

Tykerb was originally approved in 2007 in combination with Xeloda (capecitabine) for women with advanced or metastatic HER2-positive breast cancer, but only after they progressed on chemotherapy and Herceptin (trastuzumab). However, it is not known if the recently approved regimen is better than Herceptin (trastuzumab) in this patient population.