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Posted February 1, 2010

## FDA approves lapatinib plus letrozole for HER-2–positive, HR-positive, metastatic breast cancer

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The FDA has announced its accelerated approval of the combination of lapatinib plus the aromatase inhibitor letrozole for the treatment of hormone-receptor–positive, *HER-2*–positive, metastatic breast cancer in postmenopausal women for whom hormonal therapy is indicated.

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Lapatinib (Tykerb, GlaxoSmithKline) plus letrozole (Femara, Novartis) is a first-line, oral treatment for the disease.

"This drug combination of [lapatinib] plus [letrozole] provides women being treated for advanced breast cancer with an important treatment option. This entirely oral treatment regimen works by targeting both *HER-2* and the hormone receptors, thereby slowing the cancer cells' ability to grow or spread," said **Richard Pazdur, MD**, director of the Office of Oncology Drug Products at the FDA.

The approval was based on **PFS results of a study** that compared lapatinib plus letrozole vs. letrozole alone. The double blind, placebo-controlled trial included 219 postmenopausal women with hormone-receptor–positive, *HER-2*–positive metastatic breast cancer.

Patients assigned to the drug combination had a median PFS of 8.2 months vs. three months in women assigned letrozole alone.

According to the FDA, it is too early to determine if the drug combination will also result in an improvement in OS.

The most commonly reported adverse effects of the drug combination were diarrhea, rash, nausea and fatigue.

Lapatinib was initially approved in combination with capecitabine (Xeloda, Roche) in 2007 for the treatment of advanced *HER-2*–positive breast cancer in women who failed on prior treatments.

**PERSPECTIVE**

This approval addresses a relatively uncommon subgroup of patients: the "triple positive." Preclinical data support the idea that one of the reasons patients do not benefit from endocrine therapy is due to activation of growth factor signaling pathways, like *HER-2*. Thus, the trial and FDA approval support the idea that targeting two pathways has benefit over targeting just one pathway. Like any advance, this study raises additional questions. Should patients first get letrozole and wait until the disease progresses before adding lapatinib, or is targeting both pathways from day one the most beneficial? This trial showed an improvement in PFS for the combination, but a cross-over was not mandated and OS was not improved in this initial report. Would co-targeting of *HER-2* with trastuzumab and lapatinib be equal or superior to co-targeting the estrogen receptor and *HER-2*? Despite these questions, we cannot underestimate the value of this translation of laboratory research into improved clinical strategies. The next agenda item will be to refine the strategy to identify the best sequence, and identify individual patients who will receive most benefit from this targeting.

- Douglas Yee, MD  
HemOnc Today Editorial Board member

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