Drug ComboApproved for Advanced BreastCa

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The Food and Drug Administration has approved lapatinib in combination with letrozole for the treatment of postmenopausal women with advanced breast cancer that is hormone receptor and HER2 positive and for whom hormonal therapy is indicated. A kinase inhibitor, lapatinib (Tykerb) targets the HER2 protein that is overexpressed in HER2-positive breast cancer. Letrozole (Femara), an aromatase inhibitor, is used in patients with hormone-dependent breast cancer.

In a study sponsored by lapatinib manufacturer GlaxoSmithKline, progression-free survival was more than two-fold higher among the women treated with the all-oral combination of these two agents, compared with those who received letrozole alone. “It is too early to determine whether an improvement in overall survival will be observed in the clinical trial,” the FDA statement said.

In the trial, median progression-free survival was 35.4 weeks among the 111 women who received lapatinib (1,500 mg/day) plus letrozole (2.5 mg/day), and 13.8 weeks among the 110 women who received letrozole alone, according to the revised label for lapatinib. The safety profile of lapatinib was similar to that observed in previous studies of women with advanced breast cancer. Diarrhea, rash, nausea, and fatigue were the most common side effects, according to the FDA. Treatment with lapatinib has been associated with decreased left ventricular ejection fraction and increased risk of cardiac, pulmonary, and renal complications.