CÁNCER DE MAMA

Efficacy and safety of lapatinib as first-line therapy for ErbB2-amplified locally advanced or metastatic breast cancer.

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Abstract

PURPOSE: This study (EGF20009) assessed the efficacy and tolerability of two lapatinib administration schedules as first-line monotherapy in women with ErbB2-amplified locally advanced or metastatic breast cancer. PATIENTS AND METHODS: Patients with ErbB2-amplified, locally advanced or metastatic breast cancer previously untreated in the metastatic setting were randomly assigned to one of two lapatinib dose cohorts and received either 1,500 mg once daily or 500 mg twice daily. Clinical response was assessed at weeks 8 and 12 and every 12 weeks thereafter. RESULTS: A total of 138 patients were treated with lapatinib for a median of 17.6 weeks. The overall response rate (complete response [CR] plus partial response [PR]) was 24% in the intent-to-treat population, and 31% of patients derived clinical benefit (CR, PR, or stable disease for >or= 24 weeks). The median time to response was 7.9 weeks, and the progression-free survival rates at 4 and 6 months were 63% and 43%, respectively. The most common lapatinib-related adverse events (AEs) were diarrhea, rash, pruritus, and nausea, and these events were primarily grade 1 or 2. There were no significant differences in clinical activity or the AE profile between the dosing schedules. CONCLUSION: Lapatinib demonstrated clinical activity and was well tolerated as first-line therapy in ErbB2-amplified locally advanced or metastatic breast cancer. This study supports further evaluation of lapatinib in first-line and early-stage ErbB2-overexpressing breast cancer.