



A RANDOMIZED STUDY OF LAPATINIB ALONE OR IN COMBINATION WITH TRASTUZUMAB IN HEAVILY PRETREATED HER2+ METASTATIC BREAST CANCER PROGRESSING ON TRASTUZUMAB THERAPY.

[1015]

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Author(s): J. O'Shaughnessy, K. L. Blackwell, H. Burstein, A. M. Storniolo, G. Sledge, J. Baselga, M. Koehler, S. Laabs, A. Florance, D. Roychowdhury

Background

Lapatinib (L) is an oral, small-molecule inhibitor of EGFR and HER2 with a mechanism of action distinct from that of trastuzumab (T). Preclinical data suggest synergy between L and T. We studied L alone and in combination with T in pts with HER2+ MBC who progressed on T.

Methods

Eligible women had received prior anthracycline and taxane therapy, had MBC with measurable lesions or bone-only disease, and had progressed on prior T-containing therapy. Pts were stratified by hormone receptor status and visceral/nonvisceral disease, then randomized to

receive either L (1,500 mg QD) or L (1,000 mg QD) plus T (2 mg/kg weekly after 4 mg/kg loading dose). If pts progressed on the L arm, they could cross over to the L+T arm. The primary endpoint was PFS (investigator assessment), and secondary endpoints were clinical benefit rate (CBR) at 24 wks, RR, and OS.

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