Final overall survival (OS) analysis of PHEREXA: A randomized phase III trial of trastuzumab (H) + capcitabine (X) ± pertuzumab (P) in patients with HER2-positive metastatic breast cancer (MBC) who experienced disease progression during or after H-based therapy

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Methods

Study design

PHEREXA was a multicenter, open-label, randomized phase III study—the design of which is shown in Figure 1. Figure 1. Study design.

Background

H + X is chemotherapy + P is highly effective for the first-line treatment of HER2-positive MBC and for high-risk HER2-positive early BC.

The PHEREXA study (NCT01626614) randomized H + X vs. P with trastuzumab (H) who received a prior treatment in another arm during or after H-based therapy.

The study rationale was based on the German Breast Group 26 trial, which showed that continuing H + X after progressing on an H-containing regimen increased response rate and time to progression compared with X alone, without an increase in toxicity.

In the primary analysis of PHEREXA (clinical cutoff May 2013, adding P to H + X to show a 3-month improvement in response rate), the study achieved its primary endpoint, with a statistically significant difference in the median time to treatment failure (TTF) favoring H + X over P (H + X: 15.6 months vs. P: 13.2 months).

The study was conducted in full accordance with the guidelines for Good Clinical Practice and the Declaration of Helsinki.

Stratification was by prior central nervous system disease, measurable vs. nonmeasurable disease, and response to first-line H.

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