Validation of a genomic assay in early-stage HER2+ breast cancer treated with trastuzumab and pertuzumab (HP): a correlative analysis from PHERGain phase II trial

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Background
- HER2DX is a 27-gene test for patients with early-stage HER2+ breast cancer.
- HER2DX was evaluated retrospectively on baseline pre-treatment Formalin-Fixed Paraffin-Embedded (FFPE) tumor biopsies from the PHERGain phase II clinical trial (NCT03161353) (Figure 1).

Methods
- HER2DX was evaluated prospectively on baseline pre-treatment Formalin-Fixed Paraffin-Embedded (FFPE) tumor biopsies from the PHERGain phase II clinical trial (NCT03161353) (Figure 1). This was an unplanned exploratory analysis. Primary objective was the association of HER2DX with pCR when HP was a continuous variable.
- The association of HER2DX risk score with 3-year invasive disease-free survival (iDFS) was an exploratory objective.
- HER2DX was evaluated in 292 of 356 patients with HER2+ breast cancer.

Results
- HER2DX was evaluated in 292 of 356 (82.0%) tumors (Table 1).
- Median patient follow-up was 3.6 years.
- HER2DX pCR score as a continuous and categorical variable was significantly associated with pCR in univariate and multivariate logistic regression analyses (Table 2).
- 3-year iDFS data was available for 272 patients. Eleven out of 12 iDFS events (92%) occurred in patients with RD (Figure 3).
- Within patients with RD, HER2DX low-risk showed a numerically better 3-year iDFS (100%) with an event had HER2DX high-risk disease (Figure 4).

Conclusions
- HER2DX pCR score reliably predicts pCR after HP-based therapy.
- HER2DX risk score identifies patients with RD and a low risk of recurrence.
- HER2DX offers personalized insights for HER2+ breast cancer treatment, especially with HP-based therapy.

References:

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Conflicts of interest of the presenting author:

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