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Adjuvant Pertuzumab and Trastuzumab in Early Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer in the APHINITY Trial: Third Interim Overall Survival Analysis With Efficacy Update

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Abstract

Clinical trials frequently include multiple end points that mature at different times. The initial report, typically based on the primary end point, may be published when key planned co-primary or secondary analyses are not yet available. Clinical Trial Updates provide an opportunity to disseminate additional results from studies, published in JCO *or elsewhere, for which the primary end point has already been reported.*The APHINITY trial (ClinicalTrials.gov identifier: NCT01358877) previously demonstrated that pertuzumab added to adjuvant trastuzumab and chemotherapy improved invasive disease-free survival (iDFS) for patients with early human epidermal growth factor receptor 2-positive (HER2+) breast cancer (BC). Here, we report the preplanned third interim analysis of overall survival (OS) and a descriptive updated iDFS analysis with 8.4 years of median follow-up of 4,804 patients in the intent-to-treat population. The 8-year OS was 92.7% in the pertuzumab versus 92.0% in the placebo group (hazard ratio [HR], 0.83 [95% CI, 0.68 to 1.02]; *P* = .078, above the 0.006 significance threshold). The HR was 0.80 [95% CI 0.63 to 1.00] in the node-positive cohort and 0.99 [95% CI, 0.64 to 1.55] in the node-negative cohort. Updated results of 8-year iDFS in the node-positive cohort showed an absolute improvement of 4.9% favoring pertuzumab (86.1% *v* 81.2%; HR, 0.72 [95% CI, 0.60 to 0.87]). The node-negative cohort did well without adding pertuzumab (8-year iDFS and OS in the placebo group were 93.3% and 96.4%, respectively). The iDFS benefit was seen in the hormone receptor-negative (HR, 0.82 [95% CI, 0.64 to 1.06]) and HR+ cohorts (HR of 0.75 [95% CI, 0.61 to 0.92]). Despite improvement in overall iDFS, the addition of pertuzumab did not improve OS at this third interim analysis.

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