breast cancer, early stage

DISEASE-FREE SURVIVAL (DFS) IN THE LAPATINIB ALONE ARM AND EXPANDED RESULTS OF THE PHASE III ALTTO TRIAL (BIG 2-06; NCCTG ALLIANCE N063D) IN THE ADJUVANT TREATMENT OF HER2-POSITIVE EARLY BREAST CANCER (EBC)


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Aim: The Adjuvant Lapatinib and/or Trastuzumab Treatment Optimisation (ALTTO) Trial is a randomised phase III adjuvant breast cancer trial comparing 3 oral lapatinib (L)-containing regimens with trastuzumab (T), each given for 1 year. DFS results of L + T and T —> L compared to T, presented at ASCO 2014, showed a non-significant DFS benefit. Results of L vs T and key secondary analyses are presented for the first time.

Methods: 8381 patients (pts) were randomised to receive either T (N = 2097), L (N = 2100), T —> L (N = 2091), or L + T (N = 2093) from 2007-2011. Primary comparison of L vs T evaluated non-inferiority at a margin of 1.11 and the futility boundary for this arm was crossed resulting in premature arm closure (Aug 2011). Pts in the L arm who were free of disease recurrence at that time were offered T as adjuvant treatment. Key secondary analyses including DFS by hormone receptor status and CNS endpoints are now presented.

Results: In 4197 pts and at a median follow-up of 4.5 years, 366 (17%) DFS events in the L and 301 (14%) DFS events in the T arms were observed. 1090 (52%) pts in the L arm received at least one T dose. In post-hoc analysis, there was evidence that these pts benefited from receiving T [hazard ratio (HR) = 0.67; 95% CI 0.49-0.91 from a time-dependent Cox model of DFS]. The non-inferiority HR was 1.34 (95% CI 1.15-1.56) in the ITT population; 1.45 for hormone receptor negative, 1.23 for hormone receptor positive. CNS as first site of metastases occurred in 2% of cases in all arms. AEs of any grade were more common with L than T: diarrhoea (64% vs 20%), rash or erythema (54% vs 20%) and hepatobiliary (25% vs 16%). Any cardiac events were infrequent in

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