Friday, 23 March 2012 15:00–17:00

KEYNOTE SYMPOSIUM

Key Messages to Take Back to Your Practice on Monday Morning

1BA Best abstract

Subcutaneous Administration of Trastuzumab in Patients with HER2-positive Early Breast Cancer: Results From the Phase III Randomised, Open-label, Multi-centre Neoadjuvant-adjuvant HannaH Study

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Background: Treatment with trastuzumab (Herceptin®) is the standard of care (SoC) for patients (pts) with HER2-positive breast cancer (BC). The initial loading dose is administered intravenously (IV) over 90 min followed by subsequent maintenance infusions over 30 min. Trastuzumab subcutaneous formulation (SC) utilises recombinant human hyaluronidase (rHuPH20), allowing rapid subcutaneous administration (<5 min), potentially improving convenience and compliance.

HannaH is a trial designed to demonstrate non-inferiority between the trastuzumab SC and IV formulations. Co-primary endpoints are pre-surgery serum trough concentration (C_{trough}) of trastuzumab and pathological complete response (pCR) rate.

Methods: Pts with HER2-positive, operable, locally-advanced or inflammatory BC were randomised to receive 8 cycles of chemotherapy (4x docetaxel 75 mg/m^2 followed by 4x FEC 600/75/600 mg/m^2) concurrently with either 3-weekly trastuzumab SC (600 mg fixed dose) or trastuzumab IV (8 mg/kg->6 mg/kg). After surgery, pts continued trastuzumab SC or IV to complete 1 year of treatment, with a further 2 years follow-up. The main analysis was performed when all pts had completed surgery (unless prematurely withdrawn) and when $\geqslant$ 100 pts had completed 1 year of treatment.

Results: 596 pts were enrolled. Surgery data were available from 274 pts (SC arm) and 278 pts (IV arm). In total, 116 pts had completed adjuvant treatment at the time of the analysis. Baseline demographics and tumour characteristics were well balanced. Non-inferiority of trastuzumab SC was demonstrated for both co-primary endpoints: C_{trough} and pCR. The geometric mean of C_{trough} was 69.0 μg/mL (coefficient of variation [CoV]: 55.8%) in the SC arm compared with 51.8 μg/mL (CoV 52.5%) in the IV arm. Point estimates for pCR in the per-protocol set were 45.4% (SC arm) vs. 40.7% (IV arm), implying a difference of 4.7% in favour of SC (95% CI: −3.99–13.39), with similar results seen in the ITT population. The overall safety profile of trastuzumab SC was consistent with the known safety profile of trastuzumab IV. Immunogenicity data (occurrence and titers of anti-trastuzumab antibodies [ADA]) will be presented.

Conclusions: Results of the HannaH trial have established the non-inferiority of trastuzumab SC compared with the IV formulation. Trastuzumab SC offers potential to provide more convenient, time- and resource-saving administration of the SoC, although its role remains to be fully determined.

All abstracts were reviewed by relevant experts on the scientific committee. Each abstract was scored by five scientific committee members. Following the scoring, the Executive Scientific Committee met and ranked the abstracts by their total score, reviewing any abstracts where there were significant discrepancies between individual reviewers' scores.

The Executive Scientific Committee selected 5% abstracts for oral. These were deemed to have new, exciting, unpublished data. 4% were selected for poster discussion to highlight the most interesting studies in breast cancer. 76% were selected as poster presentation; these were deemed to either have interesting new data, or in some cases, very important data that even though recently previously presented was felt to be sufficiently important to warrant inclusion in the EBCC.