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Efficacy of combined Trastuzumab and CMF therapy in women with metastatic breast cancer. EORTC protocol 10995

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Background: Efficacy of classical CMF combined with 3-weekly Trastuzumab (T), followed by T alone in metastatic breast cancer (MBC).
Materials and Methods: Patients (pts) with previously treated MBC were enrolled into a Phase II study of T (4 mg/kg then by 2 mg/kg) IV weekly plus CMF, Bonadonna regimen, for a maximum of 8 cycles (cy), followed by T alone (6 mg/kg) IV 3 weekly. Primary objective was the incidence of congestive heart failure and response rate (RR) of the combination of T+CMF. Entry criteria included HER2 overexpression, limited anthracycline (A) exposure, normal baseline LVEF and measurable disease (RECIST).
Results: The trial was closed to recruitment in January 2006, 10 pts are still on treatment. Seventy one pts were entered with a median age of 54 (range 31−75). Forty-one pts had prior CT (32 A), of which 26 adjuvant, 6 MBC, and 9 both adjuvant and MBC. Adjuvant CMF was given in 14 pts. Median PS was 0, 52 pts had visceral disease with a median interval from diagnosis to first relapse of 33.4 months (mo). Out of 70 pts receiving T+CMF (34 pts with 8 cy), 42 continued with T alone for a median duration of 7 cy. Eleven pts discontinued treatment due to toxicity (9 on T+CMF, 2 on T alone). To date, the RR is 54% (32/59 pts): 55% (24/44) 1st line; 53% (8/15) 2nd line. Among pts receiving prior adjuvant CMF, the RR was 6/14 (43%). An independent review of responses is underway. Median time to response was 2 mo, median duration of response was 8.2 mo, with 63% of responders having a remission for more than 6 mo, and a maximum duration of 1.3 yrs in 2 pts. The median progression free survival was 9.5 mo.
Conclusions: Combination of T+CMF regimen is feasible treatment for patients with HER2 positive MBC. Preliminary response data indicate good efficacy of CMF+T in MBC patients.

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MO19391: an open-label safety study of bevacizumab plus taxane monotherapy or in combination as first-line treatment of patients with locally recurrent or metastatic breast cancer (LR or MBC)

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Background: In randomised phase III trial E2100, the addition of bevacizumab to first-line paclitaxel significantly improved progression-free survival in patients with LR or MBC. The MO19391 trial is investigating the safety profile of bevacizumab in LR or MBC in combination with standard first-line taxane therapy. It will also form the basis of a second-line duration trial after progressive disease (PD).
Methods: This open-label, single-arm trial will enrol approximately 2,300 patients from around 510 centres in 50 countries worldwide. The primary endpoint is to assess the safety of first-line bevacizumab plus taxane-based therapy in the treatment of LR or MBC. Secondary endpoints include TTP and OS. Patients must have histologically confirmed, HER2-negative LR or MBC and ECOG PS 0−2. Exclusion criteria include prior chemotherapy for LR or MBC and evidence of CNS metastases. Patients receive bevacizumab (10 mg/kg q2w or 15 mg/kg q3w) in combination with the physician's choice of taxane regimen (or investigator's standard of care [SOC] regimen if taxanes are contraindicated or not SOC of the investigator, although anthracyclines are not permitted). Treatment continues until disease progression or unacceptable toxicity. Patients showing PD will be offered randomisation into a trial testing second-line chemotherapy +/− bevacizumab. All serious and non-serious adverse events that occur will be collected, along with additional information regarding adverse events of special interest (hypertension, proteinuria, wound-healing complications, arterial and venous thromboembolic events, CNS bleeding, other haemorrhages, GI perforations and congestive heart failure).

	ITT population (n = 177)
Median age (years)	52
range	29–76
ECOG PS (%)	
0	57.4
1	33.0
2	9.7
ER status (%)	
+	64.7
−	33.8
unknown	1.4
PR status (%)	
+	55.4
–	39.6
unknown	5.0
Disease stage (%)	
LR	1.7
MBC	98.3
Neo/adjuvant chemotherapy (%)	
yes	83.3
no	16.7
Neo/adjuvant anthracycline (%)	
epirubicin	42.7
doxorubicin	48.2
Neo/adjuvant taxane (%)	
paclitaxel	15.5
docetaxel	20.0
Chemotherapy backbone (%)	
taxane monotherapy	64.4
taxane combination	24.9
other	10.2

Results: Recruitment commenced in 09/06. As of 03/07, 283 patients have been enrolled, from 20 countries. Patient characteristics for the ITT population are presented in the table.
Conclusions: MO19391 is a large ongoing trial that will further elucidate the safety profile of bevacizumab in a community setting. Analysis of safety will be presented.

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Triple combination of oral vinorelbine, capecitabine and trastuzumab as first-line treatment in HER2-positive metastatic breast cancer (MBC): latest results of an international phase II trial

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Background: Chemotherapy (CT) plus trastuzumab (H) is the standard first-line treatment for HER2-positive MBC. H plus vinorelbine is an active and well-tolerated regimen in this setting. The all-oral combination of oral vinorelbine (NVBo) and capecitabine (X) also appears active and well tolerated in MBC. For the first time, we report efficacy and safety results from the full population of 50 patients (pts) entered in an international trial evaluating the NVBo + X + H combination in HER2-positive MBC.
Materials and Methods: In this multicentre trial, main eligibility criteria included: HER2-positive disease (IHC 3+ or FISH+), documented measurable MBC previously untreated by CT, relapse 6 months after completing neoadjuvant or adjuvant CT, Karnofsky PS $\geqslant$70, age $\geqslant$18 years.