(95% CI: 23−37) and 61 (95% CI: 44−77) weeks (wks), respectively. The ORR for 1st line treatment was 51% compared with 35% for 2nd and 3rd line treatment (p = 0.03). There was no significant difference between 1st and 2nd/3rd line treatment for duration of response (41 vs 55 wks; p = 0.8), TTP (31 vs 21; p = 0.4) or OS (74 vs 52 wks; p = 0.1). No significant difference was seen between pts receiving the full planned dose versus reduced dose for ORR (48% vs 42%; p = 0.9), OS (72 vs 62 wks; p ⩾ 0.9), TTP (27 vs 30 wks; p = 0.5) or duration of response (43 vs 44 wks; p = 0.3). The median OS was 93 (95% CI: 66–120) wks for soft tissue and/or bone metastases vs 49 (95% CI: 39−58) wks for visceral disease (p = 0.03). No significant difference in ORR, TTP or duration of response was seen between these 2 groups. Cap was generally well tolerated, although 35% had treatment delays and 57% required dose reductions. Grade 3−4 hand-foot syndrome toxicity occurred in 11%, lethargy 9% and diarrhoea 2%. No grade 3−4 haematological toxicity was seen except in 5 pts with bone marrow infiltration.

Conclusion: Capecitabine is an effective and well tolerated drug in elderly pts with LA or MBC including for 1st line treatment. Dose reduction is frequently required but does not appear to affect outcome.

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A phase II trial of oral combination chemotherapy with capecitabine and cyclophosphamide (XC) in metastatic breast cancer

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Background: A phase II multicenter trial in patients with metastatic breast cancer (MBC) was conducted to evaluate oral combination chemotherapy (XC) comprising capecitabine (X) and cyclophosphamide (C). We report the results from this trial.

Material and Methods: Patients received XC therapy as follows: 1657 mg/m^2/day (X) plus 65 mg/m^2/day (C), days 1−14, q3w. Patients must have received none or one prior chemotherapy regimen for MBC. The primary endpoint was response rate, secondary endpoints were progression-free survival (PFS) and incidence of adverse events (AEs).

Results: A total of 51 patients (median age 61 years; range 32−82) were enrolled between May 2007 and April 2009. An interim efficacy analysis in 35 patients, showed tumor response to therapy in 16 patients (complete response [CR] in four patients, partial response [PR] in 12 patients), an additional 12 patients achieved stable disease. Progression of disease (PD) was seen in six patients and one patient was non-evaluable (NE). The response rate (RR) was 45.7% with a 54.2% clinical benefit rate (CR + PR + SD ⩾24 weeks). The median PFS was 373 days (range 178–474). A subset analysis suggests that XC therapy is effective even for triple-negative or luminal A (ER+ & HER2−) type breast cancers. An interim safety analysis was conducted in 49 patients. The number of patients who experienced AEs ⩾ grade 3 was: leukocytopenia, 11 patients (22.4%); neutropenia, five patients (10.2%); hemoglobin reduction, one patient (2.0%) and ALP reduction, one patient (2.0%). Grade 2 Hand-foot syndrome (HFS) was reported in 7 patients (14.3%), no grade 3 HFS was reported.

Conclusions: Interim results from this trial demonstrated efficacy of XC oral combination chemotherapy in MBC. In addition, high efficacy of XC was suggested in luminal A type breast cancers and also in triple-negative breast cancers. Adverse drug reactions with XC were mild and the regimen is convenient for patients. Final efficacy and safety results of the trial will be reported at EBCC based on the full follow-up data.

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Quality of life in women with metastatic breast cancer during nine months after randomization in the TEX trial (epirubicin and paclitaxel w/o capecitabine)

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Background: Women with metastatic breast cancer have a relatively short expected survival. Therefore, the impact of treatment on quality of life is an important factor to consider. In the TEX trial, two first line treatment regimens were compared in patients with metastatic breast cancer.

The aim of this paper is to compare the effects of two treatment regimens in the TEX trial on HRQOL at two assessment points (2 and 9 months after random assignment).

Material and Methods: A total of 287 patients at ten Swedish hospitals were randomized to treatment with either epirubicin plus paclitaxel (ET, 143 patients) or epirubicin, paclitaxel and capecitabine (TEX, 144 patients). Treatment was given in 3-week cycles.

Health related quality of life (HRQOL) was assessed by the EORTC-QLQ C30 and EORTC QLQ-BR23 questionnaire at 3 points during nine months from randomization.

Results: 163 patients (70%) completed the questionnaire at baseline, and 2 and 9 months after random assignment. There were no statistical significant differences between the TEX group and the ET group on any of the subscales two months after randomization. Small clinical differences (5 to 10 points difference) were found for Global quality of life, Role functioning, Social functioning and Insomnia, favouring patients treated with ET. This group also scored lower on Fatigue, Dyspnoea, and Diarrhoea than patients who received TEX, although the differences were small. At the nine months assessment, the TEX group scored statistically significantly higher on Global quality of life and Physical functioning. No other statistically significant differences were found for any of the subscales analyzed. In contrast to the findings at the two months assessment, small clinically significant differences were found for Global health related quality of life, Physical functioning, Role functioning, Emotional functioning, Dyspnoea, and Insomnia, all in favor of the TEX group.

Conclusions: At the time when side-effects of chemotherapy were present, patients treated with the combination TEX appeared to fare a bit worse than those receiving ET. However, after nine months, when the patients had adapted to treatment, the TEX group seemed to have a slightly better quality of life.

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First results of an international, retrospective observational study of metastatic breast cancer patients treated with oral vinorelbine based-chemotherapy

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Background: Full oral Chemotherapy (CT) is an active and convenient therapeutic option for metastatic breast cancer (MBC) patients (pts). In this retrospective analysis, we reviewed the characteristics and the outcome of pts treated by oral vinorelbine either as a single-agent or in combination with capecitabine as a first or second line chemotherapy in the metastatic setting.

Materials and Methods: We analysed 216 MBC pts who started treatment with a full oral CT in 13 centres and 7 countries between 2006 and 2008. To be eligible, pts must have received either as a 1st (56%) or 2nd (44%) line oral vinorelbine as a single agent (54%) or in combination with capecitabine (46%).

Results: Main pts characteristics in the full population (n = 216): median age (range): 61 years (32−87); categories of age: <50: 18%, 50−65: 44%, ⩾65: 38%; hormone receptor positive: 63%; ⩾2 metastatic sites: 58%; visceral metastases: 49%; prior CT: 86%; prior CT for MBC: 44%; prior anthracycline: 69%; prior taxane: 43%; prior anthracycline + taxane: 38%; prior hormone therapy: 63%. Median number of cycles: 6 (range:1−54); 52% of pts received more than 6 cycles. G3/4 toxicities: neutropenia 8%, anaemia 2%, thrombocytopenia 1%, febrile neutropenia/neutropenic infection 2%, nausea 6%, vomiting 4%, diarrhoea 6%, fatigue 6%, hand-foot syndrome 14% (combination with capecitabine), neuropathy 1%, alopecia (grade 2) 1%. Efficacy: disease control rate 77% (95% CI [71−83]), 74% as single-agent, 81% in combination, 82% in 1st line, 71% in 2nd line. Median progression-free survival was 9.7 months (95% CI [8.2–12.6]) in 1st line and 6.6 months (95% CI [5.5−8.5]) in 2nd line. With a median follow up of 17.5 months (1st line) and 14.5 months (2nd line), 128 patients were alive, 34 pts were lost to follow-up and 54 pts were dead at the time of