Results: All patients have progressed at the time of analysis. Five patients (38%) derived clinical benefit (CB) (compete response/partial response/stable disease for ⩾ 6 months) with a median duration of 9 (7–32) months. Details for the different subgroups are shown in the table.

Agents prior to G+E	N	CB(%)	Median duration of response (mo)
G+A	3	0	N/A
G+T, G+A	6	50	9 (9–32)
G+T, G+A, M	4	50	8 (7–9)

G = Goserelin; T = Tamoxifen; A = Anastrozole; E = Exemestane; M = Megestrol acetate.

Therapy was well tolerated and no patients withdrew due to side effects.

Conclusion: A combined use of goserelin and exemestane produces CB with long duration of response in significant proportion of premenopausal women with ER+ advanced breast cancer following prior use of other endocrine agents. The continued use of ovarian function suppression with goserelin alongside available endocrine agents allows further therapeutic opportunities (with much better side-effect profile than chemotherapy) in this setting. Further studies are warranted.

410 Poster

Safety and efficacy of first-line docetaxel–gemcitabine in metastatic breast cancer

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Purpose: New combinations and strategies have been developed over the past 10 years including new drugs such as taxanes and Gemcitabine and this design demonstrates the feasibility of the most effective drugs, while minimizing toxicity.

Docetaxel (DXL) – Gemcitabine (GMZ) has shown significant activity against metastatic breast cancer (MBC) in a lot of studies.

Methods: From November 1998 to January 2000, 42 patients have been enrolled in the study and all patients had previously received adjuvant therapy.

Treatment: Patients received DXL: 75 mg/m^2 Day1 + GMZ: 1250 mg/m^2 Day 1 and Day 8, every 3 weeks without growth factor support. Median age was 57.5 years (range 27–74).

Results: Complete response was observed in 22.5% (9 patients) and partial response in 57.5% (24 patients) with an overall response rate of 80%. The probability of one-year survival was 83.5%. Main grade * toxicities were Neutropenia in 12.5% (5 patients) and Anaemia in 7.5% (3 patients). Nausea and vomiting grade 2–3 were in 19.2%.

Conclusion: DXL + GMZ is an active regimen in MBC. This scheme is of an easy administration, very well tolerated and effective in patients with MBC relapsing after an anthracycline based adjuvant treatment.

411 Poster

Combination of vinorelbine alternating i.v. and oral in combination with docetaxel as 1st line chemotherapy of metastatic breast cancer

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Background: The combination of IV VRL and DTX was shown to be feasible and effective in MBC. In an effort to improve patient convenience a regimen alternating i.v. and oral VRL was investigated.

Methods: A phase II study was designed to evaluate the efficacy and the tolerance of i.v. VRL 20 mg/m^2 with DTX 60 mg/m^2 on day 1 and oral VRL 60 mg/m^2 on day 15 of a three-week cycle in first line treatment MBC for a maximum of 6 cycles (recommended dose established in phase I study, abstract n° 684, ASCO 2004).

Prior adjuvant CT was allowed if completed at least 12 months before study entry. At least one bidimensionnally measurable lesion (WHO criteria) was required.

Results: 49 patients (pts) were treated: with a median age of 53 years; 31 pts (63.3%) had received prior adjuvant chemotherapy; 44 pts (89.9%) had a KPS ⩾80%; and 38 pts (77.6%) had visceral involvement. A total of 261 cycles were given (median 6). Median relative dose intensities (RDI) of i.v. VRL and DTX were ⩾ 99% and median RDI of oral VRL was 76.4%. Neutropenia was the major dose-limiting event (grade (G) 4 in 51% of pts and 22.1% of cycles) but only complicated in 5 pts: 4 febrile neutropenia (8.2%) and one neutropenic infection (2%). In terms of non-haematological related toxicity, the most frequent events reported were alopecia (61.2%), fatigue (22.4%), weight loss (18.4%), stomatitis (16.3%) and constipation, diarrhoea and nausea (14.3% each). G3 events were stomatitis, vomiting and amenorrhea (4.1% each) and fatigue, constipation, diarrhoea, nausea, infection, syncope and abdominal pain (2% each). The single grade 4 event was dehydration. The combination was effective with 24 responses documented and validated by an independent panel review, yielding a response rate of 55.8% [95% CI: 40–71] in the 43 evaluable pts. Median progression-free survival was 5.5 months [95% CI: 4.2–7.2]. Median overall survival has not yet been reached with a median duration of follow-up of 9.7 months.

Conclusions: This combination with oral VRL on day 15 avoiding hospitalisation is effective and manageable. VRL i.v./oral D1/D15-DTX D1 every 3 weeks represents a convenient option to combine DTX and VRL for the palliative treatment of MBC.

412 Poster

Trastuzumab (T) plus oral vinorelbine (OV) in patients with advanced breast cancer (ABC) overexpressing Her2/neu

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Background: Trastuzumab combined with i.v. Vinorelbine (ivV) is an active regimen for pts with ABC. We previously developed two effective chemotherapy (CT) regimens which included day 1 and 3 ivV (FLN, ViFUP). In order to further improve Quality of Life (QoL) of pts undergoing treatment for ABC, a new regimen using oV, day 1 and 3, plus q3wks T was tested (ToV).

Methods: Forty-one pts with ABC, HER2/neu 3+ or FISH positive, were enrolled to receive three different dose level of oV. Thirty-four pts (median age 48 yrs; 28–71) received 271 courses of T, 6 mg/kg (loading dose, 8 mg/kg) on d1, and oV 55 mg/m^2 on day 1 and 3, q3wks. Eight pts received previous CT for ABC. Three pts received 23 courses of oV at a dose of 75 mg/m^2 and 4 pts received 19 courses of oV 60 mg/m^2; for this dose level accrual is ongoing. Pts were treated until disease progression or unacceptable toxicity or treatment refusal.

Results: Thirty-four pts treated with oV 55 mg/m^2 were evaluable for response and toxicity and received a median of 8 courses (range,1–16). Treatment was well tolerated with no G3–4 NCI-CTC non-haematological toxicity but only G3 elevation of SGOT in 1 pt; G2 observed toxicity consisted of nausea (4 pts), diarrhoea (4 pts), mucositis (1 pt) and constipation (3 pts). Five pts had G3–4 neutropenia. Six pts required a ⩾25% oV dose reduction. Two pts had CR, 11 PR, 17 NC and 3 PD. Median TTP was 8.7 mos (1.6–21.4+) and median duration of response was 13 mos (2.4–20+). The combination with oV 75 mg/m^2 appeared unfeasible for G4 neutropenia in 2/3 pts, while the intermediate dose of oV 60 mg/m^2 was then selected to be evaluated and the first 4 treated pts do not show any relevant side effects.

Conclusions: The ToV combination is active and well tolerated. It allows once-every three weeks hospital admission and frees pts and care providers from the unpleasant effect of ivV. ToV 60 mg/m^2 is currently under evaluation with particular attention to QoL parameters and acceptance.

413 Poster

Vinorelbine (V) plus docetaxel (D) followed by Capecitabine (C) as first-line treatment of metastatic breast cancer (MBC)

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Background: Vinorelbine (V), Docetaxel (D) and Capecitabine (C) were found to be active as single agent in metastatic breast cancer. In this trial, we evaluated the efficacy and tolerability of V and D combination followed by C in first line treatment of MBC.

Patients and Methods: Pts were eligible if they had recurrent or metastatic breast cancer, measurable disease, ECOG PS ⩽2, adequate organ function, ability to give informed consent and had received no chemotherapy for metastatic disease. All patients had received anthracycline-based chemotherapy in the adjuvant setting. Patients were treated with 6 cycles of V (25 mg/m^2) on days 1 and 8 and D (75 mg/m^2) on day 1 every 3 weeks. Patients who responded or had stable disease at the end of ND treatment, received 6 cycles of C (1250 mg/m^2 twice daily).

Results: From Feb 2001 to Dec 2002, 25 patients were enrolled. The median age was 41 years (range 34–61). The sites of metastasis were liver in 17 (27%), skin in 15 (24%), lymph nodes in 12 (19%), lung in 10 (16%) and soft tissue in 2 (3%) pts. Number of metastatic sites were: 3 in 13 pts, 2