Pts received 3-weekly cycles of NVBo 80 mg/m^2 (after a first cycle at 60 mg/m^2 in the absence of G3/4 neutropenia) days 1 and 8; X 1000 mg/m^2 bid (750 if ⩾65 years) days 1−14; H 4 mg/kg day 1 as a loading dose then 2 mg/kg i.v. weekly starting on day 8. Treatment was continued until progression or unacceptable toxicity.
Results: Baseline characteristics: median age 53.5 years (18% ⩾65); prior (neo)adjuvant CT in 54%; type of CT: anthracycline 55%, anthracycline + taxane 30%, CMF 11%, taxane 4%; visceral involvement in 82%, >2 metastatic sites in 34%. Treatment administered: median 9 cycles, median relative dose intensity: NVBo 75%, X 77%, H 96%; NVBo dose escalation to 80 mg/m^2 in 87% of pts. Safety (n = 50, G3/4 NCI CTC v2 adverse events): neutropenia 69% of pts, hand–foot syndrome 18%, diarrhoea 16%, vomiting 12%, febrile neutropenia 8%, asthenia 8%, infection with G3/4 neutropenia 4%, LVEF decline 4%, stomatitis 4%. Efficacy (n = 46 evaluable pts): objective response (OR) rate (RECIST) 74% (95% CI [59−86]), CR 13%, PR 61%, SD 20%, PD 6%. OR for visceral metastases: 68%. Disease control (CR+PR+ SD for ⩾6 months) 91%. After a median follow-up of 17.6 months, median progression-free survival and overall survival have not been reached. 12 patients are still receiving treatment.
Conclusions: NVBo + X is an effective first-line chemotherapy option in combination with H in pts with HER2-positive MBC, with an acceptable safety profile.

2125 POSTER

Phase I-II study of IV vinorelbine (VRL) and oxaliplatin (OXP) every two weeks (q2w) in metastatic breast cancer (MBC): Interim results of the phase II trial

A. Guerrero[1], A. Rodriguez-Lescure[2], L. Calvo[3], A. Llombart[1], S. Servitja[4], V. Pons[2], S. Antolin[3], G. Gutierrez[5], J. Gayo[5], I. Tusquets[4]. *[1]Instituto Valenciano de Oncologia, Servicio de Oncologia Medica, Valencia, Spain; [2]Hospital General Universitario de Elche, Servicio de Oncologia Medica, Elche, Spain; [3]Complejo Hospitalario Universitario Juan Canalejo, Servicio de Oncologia Medica, A Coruña, Spain; [4]Hospital del Mar, Servicio de Oncologia Medica, Barcelona, Spain; [5]Pierre Fabre Iberica, Division de Oncologia, Barcelona, Spain*

Background: The combination of VRL and OXP was shown to be effective for the treatment of NSCLC. We designed a scheme for first line MBC consisting of administering IV VRL and OXP q2w to determine the maximal tolerated dose (MTD), recommended doses (RDs) and safety. The phase II part was planned to confirm the clinical efficacy and safety of the combination.
Materials: 30 chemonaive patients (pts) with MBC were accrued in the phase II part of the study (recruitment still ongoing). As previously reported for the phase I part, RDs consisted of VRL 30 mg/m^2 with OXP 90 mg/m^2 both administered every 2 weeks.
Results: Median age 58 y (range; 33−83), 24 pts (80%) received prior (neo)adjuvant CT. Karnofsky performance status 100%, 63%; 90%, 29.6%; 80%, 7.4%. Sites of metastasis included liver (33.3%), lung (44.3%), bone (46.7%), soft tissue (13.3%). Local relapse in 8 pts (26.6%). 2 pt were not evaluable for efficacy. Among the 28 pts evaluable, 20 pts achieved objective responses (OR 71.4%, 95% CI, 51.3% to 86.8%) among them 14.3% with complete response; 17.9% pts had a stable disease and 10.7% presented progressive disease. With a median follow up of 4 months (range 1.2−11.9), median survival has yet to be reached. All patients were evaluable for safety. A total of 207 cycles (cy) were administered. This regimen was well tolerated with neutropenia WHO grade 3−4 observed in 11% cy (40% pts). Non-hematological toxicity was mild and manageable, with fatigue grade 3 reported in 6 cy (3 pts), constipation grade 3 in 2 cy (1 pt) and neurotoxicity grade 3 in 2 cy (2 pt).
Conclusions: The combination of VRL and OXP as first-line treatment is a highly active, well-tolerated and convenient regimen in pts with MBC.

2126 POSTER

Activity of fulvestrant in patients with visceral metastases: result from EFECT

G. Romieu[1], J. Bines[2], L. Mauriac[3]. *[1]Centre Val D Aurelle P Lamarque, Dept of Oncology, Montpellier, France; [2]Instituto Nacional de Cancer, Dept of Oncology, Rio de Janeiro, Brazil; [3]Institut Bergonie, Dept of Oncology, Bordeaux, France*

Background: Patients with visceral metastases are often regarded as being less likely to respond to hormonal therapy than those without visceral metastases.
Methods: EFECT is a randomised, double-blind, double-dummy, multicentre, Phase III trial, comparing the efficacy and tolerability of fulvestrant (Faslodex®) vs exemestane (Aromasin®) in postmenopausal women with hormone receptor-positive advanced breast cancer (ABC) progressing/recurring after prior non-steroidal aromatase inhibitor (AI) therapy. Fulvestrant (IM) was used in a loading-dose regimen: 500 mg on Day 0, 250 mg on Days 14 and 28, and 250 mg every 28±3 days thereafter. Exemestane 25 mg PO was given once daily.
Results: The overall analysis from EFECT demonstrated the effectiveness of fulvestrant vs exemestane in this trial population. Overall, 693 women were randomised to fulvestrant (n = 351) or exemestane (n = 342). Of these, 56.1% of patients receiving fulvestrant and 57.9% of patients receiving exemestane had visceral involvement (lung and/or liver). Here, efficacy data from EFECT were analysed in evaluable patients with and without visceral metastases.

	Fulvestrant		Exemestane	
	VM	No VM	VM	No VM
Objective response, %	7.1	8.0	4.4	11.6
Clinical benefit, %	29.1	38.6	27.2	40.7
Median time to progression, months	3.1	4.1	2.8	5.2
Median duration of clinical benefit[a], months	9.9	8.0	8.1	8.6

[a]Retrospective analysis; VM, visceral metastases.

Conclusion: In EFECT, both fulvestrant and exemestane demonstrated clinical benefit in patients with visceral metastases. This builds on similar Phase III data for fulvestrant in the post-tamoxifen setting.

2127 POSTER

Activity of Fulvestrant in patients with HER2-positive advanced breast cancer

J.F.R. Robertson[1], G. Steger[2], P. Neven[3], S. Barni[4], B. Kaufman[5], F. Gieseking[6]. *[1]City Hospital Nottingham, Professorial Unit of Surgery, Nottingham, United Kingdom; [2]Medical University of Vienna, Dept of Internal Medicine I, Vienna, Austria; [3]University of Leuven, Dept of Oncology, Leuven, Belgium; [4]Treviglio-Caravaggio Hospital, Division of Medical Oncology, Treviglio, Italy; [5]Sheba Medical Center, Dept of Oncology, Tel Hashomer, Israel; [6]University of Eppendorf, Dept of Oncology, Eppendorf, Germany*

Background: Although endocrine therapy is commonly used to treat advanced breast cancer (ABC), patients with HER2-positive (HER2+) disease are generally regarded as being less responsive to such treatments. Fulvestrant (FaslodexTM), a novel estrogen receptor (ER) antagonist with no agonist effects, is licensed for the treatment of postmenopausal women with ABC after progression on prior chemotherapy. Here we examine pooled clinical experience data from patients with HER2+ disease who received fulvestrant treatment.
Methods: Postmenopausal women with HER2+ disease were treated with fulvestrant 250 mg/month IM until progression or another reason for discontinuation. Clinical response was assessed monthly using RECIST or UICC criteria, or the clinical judgment of the treating physician. Clinical benefit (CB) was defined as the proportion of patients experiencing a response (complete response [CR] or partial response [PR]) or stable disease (SD) lasting ⩾6 months.
Results: Seventy patients with HER2+ ABC and a median age of 61 years (range 30−85 years) received fulvestrant. Patients had received a median of 2 prior endocrine therapies (range 0−3) and 2 chemotherapies (range 0−4) for ABC. ER and/or progesterone receptor (PgR) status was assessed in 69 patients. Twenty-eight patients experienced CB (5 PR and 23 SD ⩾6 months) with fulvestrant, giving a CB rate of 40.0%, with activity noted up to the fourth line of endocrine therapy, and the seventh line of overall ABC therapy. The CB rate was 44.4% in ER+/PgR+ patients (n = 36) and 43.5% in ER+/PgR− patients (n = 23).
Conclusion: From these data, fulvestrant appears to demonstrate activity in patients with HER2+ ER+ ABC. The observed activity was independent of PgR status and was consistent with the efficacy of fulvestrant seen in the overall ABC population. These are encouraging data, warranting further exploration of the use of fulvestrant in treating HER2+ disease.