**Results:** Sixty two patients were included in the standard population, of which 38 received low-dose X, with an objective response rate of 42% (16/38), and 24 received standard-dose X, with a response rate of 54% (13/24). Median TTP was 151 and 140 days, respectively.
**Conclusions:** These results suggest that lower-dose X (1,000 mg/m$^2$ b.i.d.) has comparable efficacy to standard-dose X (1,250 mg/m$^2$ b.i.d.) when administered for $\geqslant$6 weeks to older patients with ABC.

**5061** POSTER

**Gemcitabine and carboplatin in heavily pretreated metastatic breast cancer: predictive value of breast cancer subtypes**

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**Background:** Patients (pts) with breast cancer (BC) are increasingly exposed to anthracyclines and taxanes either as adjuvant treatment or during initial therapy of metastatic disease. This trial studied the efficacy and safety of gemcitabine and carboplatin (GC) in unfavorable subgroup of pts affected by heavily pretreated metastatic BC.
**Patients and Methods:** We included HER-2 negative metastatic BC refractory or resistant to previous anthracycline- and taxane-based chemotherapy, and HER-2 positive metastatic BC with at least two progressions of disease during protracted trastuzumab-based therapy. Other inclusion criteria were: age $\geqslant$18 years, ECOG PS of 0−2, RECIST-defined measurable MBC. Treatment consisted of gemcitabine (1000 mg/m$^2$ iv on days 1 and 8 and carboplatin (AUC 5 iv on day 1) applied every 3 weeks.
**Results:** Forty-two pts were registered. The 1-year disease control rate (PR + CR + SD) was 62%, with a median time to progression (TTP) of 7.0 mos (range 1−12 mos) and a median overall survival (OS) of 10.5 mos (range 1−34 mos). Overall, grade $\geqslant$3 toxicities included neutropenia (45%), and thrombocytopenia (7%). Other non-hematologic toxicities were irrelevant. We performed a subgroup analysis in order to evaluate the prognostic and predictive significance of immunohistochemically defined subsets of pts. According to the definition proposed by BCIRG trialists (Hugh J, et al. J Clin Oncol 2009; 27: 1168–1176), pts were grouped as triple negative (ER negative, PR negative, HER-2 negative), HER-2 (HER-2 positive, ER negative, PR negative), Luminal B (LB) (ER positive and/or PR positive and either HER-2 positive and/or Ki67$^{high}$), and Luminal A (LA) (ER positive and/or PR positive and HER-2 negative and Ki67$^{low}$). LA pts had lower 1-year disease control rate than other subtypes (LA 34% vs others 74%; Fisher's exact p = 0.02), shorter PFS (LA 2.4 mos vs others 6.3 mos, HR = 0.62; 95% CI = 0.28−1.39; Log-rank test p = 0.015), and shorter OS (LA 7.5 mos vs others 11.7 mos, HR = 0.52, 95% CI = 0.23−1.16; p = 0.034).
**Conclusions:** Chemotherapy with GC is an effective and generally well-tolerated treatment option for intensively pretreated pts with metastatic BC. Pts affected by LA subtype BC seem to fare poorly as compared to others subtypes. Specific gene-expression signature between LA and other subtypes might explain the different outcome.

**5062** POSTER

**Fulvestrant in heavily pre-treated ER-positive post-menopausal metastatic breast cancer patients: final update of a phase II study**

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**Background**: Fulvestrant (F), an estrogen receptor down-regolator drug, is effective in ER +ve post-menopausal metastatic breast cancer (MBC) progressing on Tamoxifen (Howell A., 1995) and has demonstrated overall response rates (OORR), time to progression (TTP) and overall survival (OS) comparable with Anastrozole (Howell A., 2000 and Mauriac L., 2003). The aim of the study was to evaluate efficacy and toxicity of F in ER+ve post-menopausal metastatic breast cancer patients (pts) heavily pre-treated both with hormonal agents and chemotherapy.
**Materials and Methods:** From 5/2006 to 12/2008, F 250 mg i.m. q 28 days was administered to 27 ER+ve post-menopausal MBC pts, median age 64 (range 39−81). Fifteen pts (55.5%) had received prior chemotherapy for MBC, and all pts had received prior hormonal therapy (median 2 drugs: range 1−4). Metastatic sites were: 20 bone, 8 liver, 8 lung, 9 nodes, 5 skin, 5 breast. A total of 186 cycles of F were delivered, median 6 cycles/pt. (range 2−24). All pts were valuable for toxicity and for efficacy.
**Results:** Overall response rate (OORR) was 13.7% (0/27CR, 4/27PR) and stable disease (SD) was observed in 9 pts (33.3%); clinical benefit (OORR + SD) was obtained in 13/27 pts. (48.1%). Median TTP in all pts was 7+ mos (range 2−30+ mos.) and in pts obtaining clinical benefit was 9+ mos (range 4−30+ mos). Median OS was 14 mos. (range 3−41+ mos) and 20 mos. (range 9−41+) in pts obtaining clinical benefit. No G3−4 toxicities were observed: G1−2 coetaneous rash occurred in 3/27 (11.1%) pts. and G1−2 asthenia in 3/27 (11.1%) pts.
**Conclusions:** This phase II study demonstrated that F is safe and effective in heavily pre-treated ER+ve post-menopausal MBC pts. Results from this phase II trial are comparable with those observed in pivotal trials, when F was used as 2$^{nd}$ line treatment, suggesting F has comparable efficacy in heavily pretreated MBC pts.

**5063** POSTER

**Paclitaxel combined with ifosfamide in anthracycline- and docetaxel-pretreated metastatic breast cancer**

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**Background:** The aim of this study was to evaluate the efficacy and tolerability of paclitaxel and ifosfamide in anthracycline-/docetaxel-pretreated breast cancer.
**Materials:** Advanced breast cancer patients who had received prior anthracycline- and docetaxel-based chemotherapy were eligible. Paclitaxel (175 mg/m$^2$ i.v. in a 3-hour infusion) on day 1 and ifosfamide (1.5 g/m$^2$ i.v. in a 15-min infusion) on days 1−3 were given every 3 weeks for a maximum of 9 cycles. Tumor response was assessed by using RECIST criteria every 2 cycles.
**Results:** Thirty-four patients (33 with metastatic and 1 with locoregional disease) were enrolled. Anthracycline- and docetaxel-based chemotherapy were previously given to 1/17/13 and 1/12/21 patients in neoadjuvant/adjuvant/metastatic settings, respectively. Three patients did not previously receive anthracycline due to abnormal cardiac function. The response rate under the intent-to-treat analysis was 27.6% (8/34; all partial responses) with the median response duration of 14 months. The median disease control rate was 70.6%. The median progression-free and overall survival was 5.9 and 8.5 months, respectively. A total of 174 cycles of chemotherapy were delivered with median 6 cycles. In terms of toxicities, grade III/IV neutropenia was 46.6% (81/174 cycles) with febrile neutropenia of only 1.7% (3/174 cycles). Grade III/IV nonhematological toxicities were peripheral neuropathy (17.6%; 6/34 patients), infection (11.8%; 4/34 patients) and liver enzyme elevation (2.9%; 1/34 patients). There was one treatment-related death from sepsis.
**Conclusions:** Paclitaxel combined with ifosfamide was effective and tolerable in anthracycline-/docetaxel-pretreated advanced breast cancer. Overcoming docetaxel resistance by using paclitaxel in combination with ifosfamide needs to be addressed via further investigation.

**5064** POSTER

**Zoledronic acid in breast cancer patients with bone metastasis**

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**Background:** Zoledronic acid is a nitrogen containing bisphosphonate that has been proven to reduce oestoprosis and cancer induced osteolysis. Zometa has been the treatment of choice for the prevention of skeletal complication of bone metastasis (pain, pathological fracture) in patients with breast cancer, which have a significant impact on the quality of life of patients. The aim of the study is to evaluate the efficacy and tolerability of Zometa in improving pain scores and quality of life in patients with bone metastasis secondary to breast cancer.
**Material & Methods:** 150 patients with bone metastasis and pathologically confirmed carcinoma of the breast during the period between January 2004 and January 2006 were enrolled, ECOG PS 0−2, and adequate renal function. Treatment consisted of Zometa 4 mg IV over 15 minutes repeated every 3−4 weeks concurrently with chemotherapy and/or hormonal therapy or radiotherapy if treatment was needed. Zometa administered continuously until impairment in the performance status, progression of the disease or severe adverse events. Pain was evaluated by present pain intensity from McGill Melzack (PPI) questionnaire, quality of life (QOL) was assessed with functional assessment of cancer therapy (FACT) questionnaire.
**Results:** The median age was 48 years (range 30−65 years), median PS 1, extent of disease (metastasis): 60 patients (40%) had only one bone