of 63 was required to identify a clinical meaningful ORR ⩾15% based on Simon's Minimax 2-stage design.
Results: As of Apr 05, 64 pts (median age 51 years) were enrolled. Of these, 56% and 16% were ER+ and HER2+, respectively, and 82% had visceral disease. Fifty-two pts had prior adjuvant chemotherapy (A = 90%; T = 56%), and in the MBC setting, 62 pts were previously treated with A (26%), T (69%), capecitabine (66%), vinorelbine (23%), platinum (16%) and gemcitabine (15%). Preliminary efficacy data are available for 51 pts, seven (14%) of whom achieved partial responses and one had stable disease for 11 months. Grade 2/3 treatment-related adverse events (AEs) are listed below. No grade 4 AEs were reported.

Table 1: Most common AEs

	Percentage (N = 41)	
	Grade 2	Grade 3
Fatigue	32	5
Diarrhoea	20	7
Anorexia	17	0
Hypertension	10	5
Mouth pain	12	0
Hand–foot syndrome	5	7
Neutropenia*	15	39
Thrombocytopenia	17	15
Anaemia	12	2

*No patients with neutropenic fever

Seven (17%) of 41 pts required toxicity-related dose-reduction, and 13 (31%) required dose-interruption. Currently, 21 pts remain on treatment and only two have discontinued for toxicity.
Conclusions: This Phase II study demonstrates the clinical activity of sunitinib as a monotherapy in MBC pts unresponsive to prior chemotherapy or radiotherapy. Sunitinib has acceptable toxicity. Further studies should include pts with exposure to fewer prior regimens and sunitinib in combination therapy.

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A single institution randomized trial of taxotere (T) and xeloda (X) given in combination vs. taxotere (t) followed by xeloda (x) after progression as first line chemotherapy (CT) for metastatic breast cancer (MBC)

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Purpose: Xeloda and Taxotere have demonstrated preclinical antitumor synergy mediated by upregulation of thymidine phosphorylase. XT combination gave significantly superior overall survival, tumor response and TTP compared with T alone in patients with MBC (JCO 20: 2812, 20), but just one third of the patients receiving T continued with X after progression of the disease. We designed this study to evaluate the efficacy and toxicity of the combination of Taxotere and Xeloda compared with Taxotere followed by Xeloda after progression for Metastatic Breast Cancer (MBC).
Materials and methods: 100 patients (pts) with measurable MBC, prior adjuvant anthracyclines (100%) but no prior chemotherapy for MBC and KPS ⩾ 70 were randomized to receive: arm A = X 1,250 mg/m^2 twice daily d1–14 plus + T 75 mg/m^2 day 1; arm B = T 100 mg/m^2 day 1 followed after progression by X 1250 mg/m^2 twice daily d1–14, both given on a q3 week cycle. The two arms were well balanced for known prognostic factors: median age 58 (26–75) vs 51 (25–75) yrs, median KP 100 (70–100) both arms; hormone responsive disease 20% vs. 16%, dominant metastatic sites: viscera 70% vs. 68%, soft tissue 16% vs 13, bone 21% vs. 23%; number of involved organs: 1 = 58% vs. 52%, 2 = 30% vs. 34%, > 2 = 12% vs. 14%. We did not translate the results obtained from the use of Xeloda monotherapy into analysis of response rate and time to progression but we use them in analysis of overall survival and toxicity.
Results: See the table.
Grade 3 toxicity was more present in arm A: 70% vs. 56%; grade 4 was similarly distributed. The main toxicities were: Fatigue; 10% for both groups, Alopecia; 6% vs. 8%, Hand and foot syndrome; 24% vs. 2%, Nausea; 6% vs., 4%, Diarrhea; 16% vs. 8%, Stomatitis; 20% vs. 6%, Neutropenia; 14% for both groups, Neutropenic fever; 14% vs. 16%. We have had to reduce the dose for the 52% of the patients from the Arm A (Xeloda; 4%, Taxotere; 8%, both; 40%) and for the 30% patients from the Arm B.
Conclusion: XT provides significant TTP and OS advantage over T even after the 75% of the patient progressed on Taxotere had been cross-overed to Xeloda monotherapy.

	Group A	Group B	P value
Complete responses (%)	14	6	
Partial responses	54	34	
Overall responses	68	40	0.004
Time to progression (months)	9.3	7.66	0.0017
95%CI	(8.49–10.17)	(6.33–8.99)	
Overall survival (months)	22.00	19.00	0.006
95%CI	(20.85–23.15)	(17.85–20.15)	

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Safety comparison of oral ibandronate and intravenous zoledronic acid in metastatic breast cancer patients: Phase III data

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Background: Bisphosphonates are the standard of care for metastatic bone disease. Ibandronate is a third-generation, single-nitrogen bisphosphonate available in intravenous and oral formulations. In Phase III trials, both ibandronate formulations were well tolerated and had safety profiles comparable to placebo. In this study, oral ibandronate was compared directly with zoledronic acid in terms of safety assessments.
Materials and methods: This head-to-head, multicenter, randomized, open-label, parallel-group study recruited breast cancer patients with advanced disease and at least one confirmed osteolytic or mixed bone lesion. Patients were randomly assigned to receive oral ibandronate 50 mg/day (n = 137) or intravenous zoledronic acid 4 mg via 15-minute infusion every 4 weeks for 12 weeks (n = 137). All adverse events (AEs) were recorded throughout the study.
Results: In general, both bisphosphonates were well tolerated. However, the proportion of patients who experienced AEs was higher in the zoledronic acid group than the ibandronate group (76% versus 65%). In particular, there was a higher incidence of AEs during the first 3 days of the study for zoledronic acid than ibandronate (47% versus 8%). This was composed predominantly of acute-phase response AEs, including pyrexia, chills, flu-like illness, arthralgia, and myalgia, that were probably or possibly treatment-related. Throughout the entire study, a higher proportion of patients reported bone pain in the zoledronic acid group (21%) than the ibandronate group (12%), although the incidence of gastrointestinal (GI) AEs was slightly higher for ibandronate (23% compared with 18% for zoledronic acid). The incidence of serious AEs (ibandronate 5.8%; zoledronic acid 8.0%) and withdrawals (ibandronate 2.9%; zoledronic acid 5.1%) was lower for ibandronate.
Conclusion: In this first direct comparison of safety profiles, more patients treated with intravenous zoledronic acid experienced AEs than those treated with oral ibandronate. In particular, zoledronic acid was associated with a high incidence of an acute-phase response following initial treatment, a known side-effect with a disproportionate risk among intravenous bisphosphonates. The frequency of GI AEs was only slightly higher for oral ibandronate than intravenous zoledronic acid. Oral ibandronate represents an effective and well-tolerated treatment for metastatic bone disease with apparent AE advantages over intravenous zoledronic acid.

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Incidence and implications of HER2 and hormonal receptor overexpression in newly diagnosed metastatic breast cancer

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Background: Overexpression of the HER2 receptor protein predicts a worse prognosis and higher metastatic risk in patients (pts) with breast cancer. HER2 positivity also has a strong predictive value for the clinical benefit of trastuzumab (Herceptin®, H). The aim of this study was to assess the incidence of HER2 and ER/PR overexpression in patients with newly diagnosed metastatic breast cancer (MBC) and to compare the