the individual response of metastatic breast cancers to docetaxel and trastuzumab, however, the clinical responses were observed in all patients with Bcl-2-negative tumors.

Conclusion: weekly docetaxel and trastuzumab is safe and effective combination method for HER-2-overexpressing metastatic breast cancer.

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An exploratory analysis examining proportion of patients responding for 1 year or more in two phase III studies of fulvestrant versus anastrozole

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Background: Fulvestrant ('Faslodex') is an estrogen receptor (ER) antagonist that has no agonist effects. Two Phase III trials have shown fulvestrant to be at least as effective as anastrozole and associated with a longer median duration of response (DOR; 16.7 months vs 13.7 months, respectively) in patients with advanced breast cancer who had progressed on prior endocrine therapy. This abstract reports an exploratory combined analysis of DOR by categorical time period (⩾1 year), in the patients who experienced an objective response (OR; complete [CR] or partial response [PR]) or clinical benefit (CB; CR + PR + stable disease [SD] ⩾24 weeks) in these two trials.

Methods: Duration of OR and CB was calculated from the date of randomisation until disease progression and percentages were calculated using the total number of patients per treatment group as the denominator (fulvestrant n=428; anastrozole n=423).

Results: A total of 186 patients gained CB with fulvestrant treatment (CR: n=20; PR: n=62; SD ⩾24 weeks: n=104) compared with 173 patients receiving anastrozole (CR: n=11; PR: n=59; SD ⩾24 weeks: n=103). Table 1 shows the proportion of patients with OR or CB in these studies who maintained their response ⩾1 year.

	Fulvestrant 250mg [n=428] (%)	Anastrozole 1mg [n=423] (%)
Total number of patients with OR	82 (19.2)	70 (16.5)
Number of patients with OR ⩾1 yr	43 (10.0)	30 (7.1)
Total number of patients with CB	186 (43.5)	173 (40.9)
Number of patients with CB ⩾1 yr	82 (19.2)	59 (13.9)

OR, objective response; CB, clinical benefit.

A greater proportion of patients on fulvestrant achieved OR and CB for ⩾1 year, these data being supportive of previously reported increased median DOR observed with fulvestrant in these trials.

Conclusion: Fulvestrant is as effective as anastrozole in terms of all major efficacy endpoints evaluated and may have advantages with respect to proportion of patients with prolonged DOR.

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Breast cancer with synchronous metastases: trends in survival over a 14-year period

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Purpose: Although new drugs have been approved during the 1990s for the treatment of metastatic breast cancer, it is not clear whether or not their use has changed the outcome of patients in daily practice. This study sought to determine whether survival has improved over time for breast cancer patients who had metastases at diagnosis.

Methods: 724 patients have been treated in 3 French Cancer centers for an initially metastatic breast cancer between 1987 and 2000. 343 have been diagnosed between 1987 and 1993, and 381 have been diagnosed between 1994 and 2000. Tumor characteristics, treatments and outcome of these patients were compared by χ^2 test, log rank test and Cox regression analysis.

Results: Characteristics were not different between the patients diagnosed between 1987–93 and those diagnosed between 1994–2000. Ten percent of patients treated between 1987 and 1994, and 58% of patients treated between 1994 and 2000 have received either a taxane or a new aromatase inhibitor. The 3 year overall survival rates were 27% for patients treated between 1987–1993 and 44% for patients treated between 1994–2000 (p<0.001). The treatment period (1994–2000 versus 1987–1993) was a prognostic factor in multivariate analysis (relative risk: 0.6, p<0.001).

Conclusion: The survival of breast cancer patients presenting with metastases at diagnosis has improved over the time. This study highly suggests that this improvement is related to treatment.

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Intravenous and oral ibandronate reduce the risk of skeletal-related events (SREs) in patients with breast cancer and bone metastases

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Background: Ibandronate is a highly potent aminobisphosphonate that has recently been approved in Europe for the treatment of metastatic bone disease. Phase III clinical trials have investigated the impact of intravenous and oral ibandronate on the occurrence of SREs in women diagnosed with breast cancer and bone metastases.

Methods: Three multicenter, randomized, double-blind, placebo-controlled trials were conducted. In a trial of intravenous ibandronate, a 6 mg dose (n=154) was compared with placebo (n=158) infused over 1–2 hours every 3–4 weeks. In two trials of oral ibandronate, a 50 mg daily dose (n=287) was compared with placebo (n=277). Data from the oral trials were pooled for analysis, as pre-specified in the study protocols. The primary efficacy endpoint was the Skeletal Morbidity Period Rate (SMPR), defined as the number of 12-week periods with new bone complications. Secondary analysis of SREs was conducted using a multivariate Poisson regression model. A post-hoc analysis using the Andersen-Gill method (time to multiple SREs) was also performed, as used to assess SREs in a 2-year trial of zoledronic acid in patients with metastatic bone disease [1].

Results: Mean SMPR was significantly reduced with ibandronate (6 mg dose, 1.19 versus 1.45 with placebo, p=0.004; 50 mg dose, 0.95 versus 1.18 with placebo, p=0.004). The multivariate Poisson regression analysis demonstrated that intravenous ibandronate 6 mg led to a statistically significant 40% reduction in the risk of SREs compared with placebo (RR 0.60, 95% CI = 0.43, 0.85; p=0.0033). The effect of oral ibandronate 50 mg on the risk of SREs was similar (38% reduction versus placebo, RR 0.62, 95% CI =0.48, 0.79; p<0.0001). The Andersen-Gill analysis showed a 29% reduction in SREs for intravenous ibandronate (RR 0.71, p=0.018) and a 35–42% reduction for oral ibandronate (p<0.005) compared with placebo.

Conclusions: In patients with metastatic breast cancer, intravenous ibandronate 6 mg and oral ibandronate 50 mg similarly reduced the occurrence of SREs. The risk reductions reported with intravenous and oral ibandronate for the prevention of bone events appear to be comparable to zoledronic acid [1], warranting further investigation in comparative studies. As an effective alternative to intravenous bisphosphonates, oral ibandronate offers the choice of convenient at-home dosing to eliminate time-consuming hospital visits for bisphosphonate therapy.

References

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Longitudinal changes in serum her-2/neu oncoprotein levels in trastuzumab-treated metastatic breast cancer patients

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Background. To evaluate longitudinal variations of serum HER-2/neu extracellular domain (sHER-2) in metastatic breast cancer patients receiving combined trastuzumab treatment.

Patients and methods. 33 patients were monitored by serial sHER-2 ELISA (Oncogene Science) before and during treatment. Results were compared to time to progression (TTP) and survival from treatment initiation. Non parametric statistical tests were used.

Results. Median sHER-2 before 1st injection was 41.37 ng/ml (range 7.54–1597.00 ng/ml, n=32). Mean sHER-2 levels differed significantly between responders (n=20) and non responders (n=13) (P<0.0001). Median TTP (266 days, range 35–1000 days) was unrelated to clinico-biological variables at diagnostic or number and site of metastases before trastuzumab-based treatment. Patients with sHER-2 levels ⩽30 ng/ml