was 44 weeks (range 1–104). Most notably, antibody treatment was continued beyond disease progression in 56 pts. Response rates are summarized in table 1.

Table 1

Objective response	T (n=60)	T+CT (n=179)	Pre-treated* (n=123)	Chemo-naïve* (n=112)
CR+PR	50%	62%	58%	65%
CR	17%	15%	11%	18%
PD	18%	16%	20%	14%

*In the metastatic setting.

Toxicity was a rare event in the T alone group with one case each of grade 3/4 nausea, cardiotoxicity and allergic reaction. In the T+CT group, the antibody effects cannot be separated from those of the cytostatic drugs, with only 3 cases of cardiotoxicity (none of grade 3/4) reported so far.

Conclusions: T proved to be effective and tolerable both as a single drug or part of a chemotherapy combination in the community-based routine treatment of advanced BC. In clinical use the administration of T+/−CT or endocrine treatment is safe and widespread. Notably, although lacking evidence, physicians continue to use T beyond progression of disease in advanced BC.

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Prospective multicenter randomized phase III studies of weekly vs standard docetaxel (D2) plus doxorubicin (D4) for 1st line treatment of metastatic breast cancer (MBC)

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Background: Previous phase II studies indicated a greatly reduced hematotoxicity of taxane based regimens given on weekly schedules. Presently, two trials have been initiated which compare the efficacy and toxicity of weekly applied docetaxel to its standard 3-weekly application. In the D2 trial, elderly and unfit patients are randomized to receive single-agent 1st-line treatment with either weekly or 3-weekly docetaxel, while in the D4 trial younger and fit patients receive either a weekly or 3-weekly regimen of docetaxel in combination with doxorubicin.

Patients and Methods: Patients previously untreated with chemotherapy for metastatic disease can be recruited. Eligible for the D2 study are pts >60 yrs or with a Karnofsky performance status (KPS) of 60–80%. Pts are randomized to receive docetaxel either on a 3-weekly (75 mg/m^2 q3wks, arm A) or on a weekly schedule (30 mg/m^2 d1, 8, 15 q4wks, arm B). Inclusion criteria for the D4 study are age <65 yrs or KPS 70–100%. All pts in the D4 study receive doxorubicin (50 mg/m^2) on the first day of treatment in addition to docetaxel given either at a 3-weekly dose of 75 mg/m^2 q3wks (arm C) or at a weekly dose of 35 mg/m^2 (days 1, 8, 15, q4wks, arm D). Treatment is continued until a maximum of 8 cycles, unacceptable toxicity or disease progression. All pts receive standard corticosteroid prophylaxis.

Results: Presently, 38 pts were recruited for each study (D2 median age 70 yrs, KPS 80%; D4 median age 48 yrs, KPS 90%). In the D2 study, 19 pts are evaluable (A 9, B 10). Grade 3/4 leukopenia was observed in 2/1 pts (A). Grade 3/4 non-hematological toxicity included alopecia (8/0), pulmonary toxicity (2/1) as well as nausea, stomatitis, neurotoxicity and fluid retention (1/0 pt each). In the D4 study, 17 pts are evaluable (C 9, D 8). Severe leukopenia (grade 3/4) was observed in 3/2 pts (C) and 5/2 pts (D). Neutropenia-related complications >grade 2 as infection and/or fever occurred in 2 pts (C) and 1 pt (D). Grade 3/4 non-hematological toxicities included alopecia (6/0), pulmonary toxicity and pain (1/1 each), stomatitis and nausea (2/0 each) as well as neurotoxicity and fluid retention (1/0 each).

Conclusion: Preliminary data support the feasibility of both, the weekly and the 3-weekly regimen of docetaxel application either as a single-agent or in combination with doxorubicin. More complete data will be presented at the meeting.

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Letrozole (LE)–Vinorelbine (VIN) as first-line treatment in advanced breast cancer (ABC) patients: Preliminary results of a multicentre Phase II study

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Therapeutic options for ABC consist of chemotherapy (CHT) and hormonal therapy (HT), but site and number of metastases often limit the use of HT in receptor-positive (RE+) patients (pts). Previous studies investigated the possibility of a synergism between the two options, even if considering old drugs. VIN is a semi-synthetic vinca alcaloid with a well documented activity in ABC pts, as well as LE, a second generation, non steroidal aromatase inhibitor which demonstrated an interesting activity, both as first and second line therapy. Aim of the present study was to evaluate the activity of the LE–VIN combination (objective response, OR) as well as the toxicity. One cycle consisted of VIN 20 mg/mq/week iv for 8 consecutive times, followed by 1 week rest, with the simultaneous administration of LET 2.5 mg/day po, without interruption. In the case of OR or stable disease (SD) 1 or 2 other cycles were planned. Till now, 41 RE+ pts have been enrolled. Median age was 67.5 years (53–96). Twenty pts (48.8%) had received tamoxifen as adjuvant therapy and median DFI was 38 months (0–248). Metastatic sites were viscera (29, 70.7%), bone (34.1%) and soft tissue (20, 48.8%). All pts were PS 0/1 at the start of CHT. A total of 424 administrations were delivered, of which 26 were 1-week delayed mainly due to granulocytopenia. G-CSF were administered in 17 pts. At the end of 1st cycle, 33 pts were evaluable for activity: 1 CR (3%), 4 PR (12.1%) and 19 SD (46.3%) were obtained. 22 pts completed the 2nd cycle: 1 CR (4.5%), 10 PR (45.5%) and 11 SD (50%) were observed. Till now, only 18 pts completed also the 3rd cycle: 2 CR, 12 PR (OR 77.7%) and 4 SD were obtained. LE–VIN combination was well tolerated and few Grade 3–4 toxicities were observed: anemia: G3=1, G4=1; flebitis: G3=1; leucopenia: G4=2; granulocytopenia: G3=1, G4=2. No deterioration in PS was observed. At the present, more than half pts are still taking LE as maintenance therapy.

In conclusion, LE–VIN is a feasible and very well tolerated option for ABC pts. OR are most frequently observed after at least two cycles, probably due to pts hormonal status. Low incidence of adverse events allows its use also in elderly pts with visceral metastatic disease.

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Videothoracoscopic talc pleurodesis for the treatment of malignant pleural effusion in breast cancer

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Background: Malignant pleural effusion secondary to breast cancer is a locoregional disease, caused by lymphatic spread. Talc pleurodesis is an effective technique for the management of symptomatic malignant pleural effusion. The aim of this report is to evaluate the results and follow-up in patients undergone videothoracoscopic talc pleurodesis for malignant pleural effusion secondary to breast cancer.

Methods: Forty-four patients underwent videothoracoscopy for malignant pleural effusion secondary to breast cancer. Either cytology on pleural fluid or histology on pleural biopsy obviated final diagnosis of malignancy in all patients. All of these patients were treated with talc pleurodesis performed under general anaesthesia, once the possibility of a complete re-expansion of the lung on the treated side had been ascertained. Five grams of sterile asbestos-free purified talc were insufflated in the pleural space under direct vision at time of the procedure. One chest tube was left in place until the fluid drainage was less than 100 mL per postoperative day. Quality of life was assessed before surgery and at 1 month after procedure by short form health survey (SF-36) and Nottingham Health Profile questionnaires.

Results: No perioperative mortality was observed. Videothoracoscopic talc pleurodesis was effective in controlling recurrence in all patients at 1 month. Two episodes of respiratory distress syndrome were observed. Overall survival at 6, 12 and 24 months was 91%, 73% and 41% respectively. Moreover quality of life was significantly improved in all patients.

Conclusions: Videothoracoscopic talc pleurodesis represents the procedure of choice for treatment of malignant pleural effusion secondary to breast cancer.