Prior (neo)adjuvant CT is permitted if completed ⩾6 months before randomisation (⩾12 months for taxane-containing therapy). Pts receive either Bev+X (21 d cycles: X 1000 mg/m^2 bid d1−14 + Bev 15 mg/kg d1) or Bev+Pac (28 d cycles: Pac 90 mg/m^2 d1, 8, 15 + Bev 10 mg/kg d1, 15). In both arms, treatment is continued until progressive disease (PD), unacceptable toxicity or withdrawal of consent. If one agent is discontinued before PD, the other is continued. The primary objective is to demonstrate non-inferior overall survival with Bev+X versus Bev+Pac (upper limit ⩽1.33 for the 2-sided confidence interval for hazard ratio). Secondary objectives include comparison of overall response rate (RECIST), PFS, time to response, duration of response, time to treatment failure, safety (CTCAE v3) and QoL (EORTC QLQ-30). The recruitment target is 560 pts within 18 months. Assuming 12.5% dropout, a sample size of 490 eligible pts provides 80% power to reject the null-hypothesis of inferiority, assuming 24-month median overall survival with Bev+Pac.

Results: By 31st March 2009, 84 pts from 8 countries had been randomised.

	Bev+X (n = 45)	Bev+Pac (n = 39)
Median age, years (range)	61 (35−77)	60 (36−84)
Post menopausal, n (%)	39 (87)	31 (79)
ECOG PS, n (%)		
0	33 (73)	31 (79)
1	12 (27)	5 (13)
2	0	3 (8)
Stage, n (%)		
I	6 (13)	3 (8)
II	19 (42)	9 (23)
III	11 (25)	11 (28)
IV	9 (20)	13 (33)
n/a	0	3 (8)
ER negative, n (%)	14 (31)	9 (23)
PgR negative, n (%)	15 (33)	13 (33)
Metastatic sites, n (%)		
Liver	16 (36)	15 (38)
Lung	25 (56)	16 (41)
Lymph nodes	24 (53)	21 (54)
Bone	20 (44)	16 (41)
Endocrine therapy, n (%)		
Adjuvant only	18 (40)	15 (38)
LR/MBC only	5 (11)	4 (10)
Both	2 (4)	3 (8)
Adjuvant CT, n (%)	27 (60)	22 (56)
Anthracycline and taxane	6 (13)	4 (10)
Anthracycline, no taxane	18 (40)	14 (36)
Taxane, no anthracycline	0	2 (5)
Other	3 (7)	2 (5)
Mean DFI, months*	59	56

*Excluding 22 pts with primary metastatic disease.

Conclusions: This is the first trial designed to compare two different Bev-containing regimens in LR/MBC. A planned interim safety analysis will be performed when 150 eligible pts have completed 2 cycles of therapy. Updated information will be presented. Trial NCT00600340 is sponsored by CECOG.

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Epoetin beta therapy in anaemic breast cancer patients receiving chemotherapy: results of a subgroup from a large prospective cohort study

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Background: Anaemia is the most frequent haematological complication in cancer patients (Pts) receiving chemotherapy (CT). Epoetin beta (E) is an Erythropoiesis Stimulating Agent (ESA) approved for the treatment of symptomatic anaemia in adult Pts with non-myeloid malignancies receiving CT. This study is addressing the daily practice of E in anaemic cancer Pts receiving CT and was conducted to assess E use, efficacy, safety and impact on quality of life (QoL).

Material and Methods: This is an analysis of a subgroup (breast cancer Pts) from a large (n = 3265) prospective, multicentric, observational French study in oncology. Eligible Pts were 18 yrs or older, received CT for a solid tumour or a non myeloid haematological malignancy, and treated with E for anaemia. Pts were enrolled between Dec. 2004 and Mar. 2006. Planned follow-up was 4 months. Response to E (i.e. Hb increase of ⩾2 g/dl and/or an achievement of Hb level ⩾12 g/dl without any blood transfusion after E treatment initiation) was the primary endpoint. Data on treatment administration, QoL (FACT-F subscale), transfusions, safety were collected.

Results: 420 Pts with breast cancer were enrolled. Baseline characteristics in this subgroup (mean±SD): age 57.2±11.9 yrs, weight 64.3±13.8 kg, Hb level 10.2±1.0 g/dl. WHO PS 0 (18%), 1 (50%), ⩾2 (32%). Baseline Hb (g/dl): <9 (13.4%), [9−11[(64.4%), [11−12[(21%), ⩾12 (1.2%). Presenting stages were III-IV in 46% of Pts. Median time from initial diagnosis to inclusion: 22.1 months. Pts received first line (43.4%), second line (20.9%), third line or more (35.7%) CT. PolyCT was administered in 72.4% of the Pts: taxanes (42%), anthracyclins (45.1%), platinum-based CT (8.3%), targeted therapy (13.4%). At inclusion, prior radiotherapy was given in 54.1%, prior ESA in 13.9% and iron supplementation in 42.3% (1.9% intravenously). Almost all Pts (99.5%) were treated on a once weekly E regimen at a median starting dose of 30.000 IU, i.e. about 450 UI/kg. Response rate to E was 63.3% at the end of the study [95%CI: 58.1−68.2]. Mean FACT-F score improved from 27.1±11.3 at inclusion [95%CI: 25.6−28.6] to 33.5±10.5 at the end of study [95%CI: 32.1−34.9]. Only 15.2% of Pts required red blood cell transfusions. Epoetin beta was well tolerated. Thromboembolic events were reported only in 5 pts (1.3%).

Conclusions: This study conducted in routine practice confirms that epoetin beta is effective and well-tolerated to treat CT-induced anaemia in breast cancer Pts.

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Comparable efficacy of low-dose (1,000 mg/m^2 b.i.d.) capecitabine and standard-dose (1,250 mg/m^2 b.i.d.) capecitabine administered for ⩾6 weeks in older women with advanced breast cancer

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Background: Capecitabine (X) is a tumour activated oral fluoropyrimidine that generates 5-FU preferentially in tumour tissue. In patients with metastatic breast cancer, X has demonstrated consistently high efficacy with a favourable safety profile. This phase II, open-label, single-centre, sequential study (M66106) evaluated the safety and efficacy of X in older women with advanced breast cancer (ABC).

Methods: Patients were aged ⩾65 years, had a confirmed diagnosis of ABC, with measureable or evaluable disease in at least one non-irradiated site, ECOG performance status 0−2, a life expectancy ⩾3 months and adequate bone marrow, renal and hepatic function. Patients were previously untreated or had received ⩽1 prior chemotherapy and/or ⩽2 hormonal regimens for metastatic disease. Previous 5-FU-based chemotherapy was only permitted if completed ⩾1 year before study enrolment. X was initially administered at a standard dose of 1,250 mg/m^2 b.i.d. on days 1−14 every 21 days, with the treatment cycle repeated at least once. Due to the poor tolerability of standard-dose X in this population, the starting dose of X for all patients enrolled after 27 October 2000 was reduced to 1,000 mg/m^2 b.i.d. (low-dose X). The primary study endpoint was tolerability, while secondary endpoints included response rate and time to disease progression (TTP). Tumour assessments (WHO criteria) were made at 6-weekly intervals and at study withdrawal. Safety and efficacy data for the ITT population (all patients who received ⩾1 course of study treatment) have been published previously [Bajetta et al. JCO 2005;23:2155−61]. Here we report efficacy results for the standard population (all patients who received ⩾6 weeks of X at ⩾50% of the planned dose).

	Low-dose X (1,000 mg/m^2 b.i.d.) [n = 38]	Standard-dose X (1,250 mg/m^2 b.i.d.) [n = 24]
Complete response, n (%)	1 (3)	1 (4)
Partial response, n (%)	15 (39)	12 (50)
Progressive disease, n (%)	1 (3)	1 (4)
Stable disease, n (%)	21 (55)	10 (42)
Median TTP, days (range)	151 (64–244)	140 (46–252)