diarrhoea (5% vs 5%), dyspnoea (4% vs 5%), neutropaenia (3% vs 5%), mucositis (4% vs 1%), and others less frequently. The no. of pts discontinuing treatment due to adverse events in the CAP+PL arm was 9 (8%) and in the CAP+SOR arm was 15 (13.4%). The most common reasons for discontinuation (CAP+PL vs CAP+SOR) include HFSR (2 vs 8) and diarrhoea (3 vs 1).
**Conclusions:** In this randomised double-blind phase 2 trial, the oral combination of CAP+SOR demonstrated significant improvement in PFS in pts with locally adv or met BC. The regimen was tolerable and exhibited a clinically manageable toxicity profile. No new or unexpected side effects were observed with this combination. These results represent the first randomised study to demonstrate the efficacy of SOR in the treatment of adv BC.

**4LBA** LATE BREAKING ABSTRACT

**Final results of the randomized phase III CHARTWEL-trial (ARO 97-1) comparing hyperfractionated-accelerated vs conventionally fractionated radiotherapy in non-small cell lung cancer (NSCLC)**

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**Background:** Accelerated radiotherapy counteracts repopulation of tumor cells during treatment and may significantly improve local control and survival in patients with locally advanced NSCLC (CHART-trial, Saunders 1997). Nevertheless local failure rates $\geqslant$80% call for radiation dose escalation, using conformal techniques. We report here the final results of the CHARTWEL trial (CHART weekend less).
**Patients and Methods**: Between 1997 and 2005 406 pts. with NSCLC were randomized by 15 centres in Germany, Poland and Czech Republic. Inclusion criteria: UICC stage (I: 10%, II: 6%, IIIA:38% IIIB:46%), WHO performance 0−1. Randomization was stratified according to stage, histology, neoadjuvant chemotherapy (CTx; no = 300/yes = 106) and center. All patients were treated with 3D RT using a linear accelerator to 60 Gy/40 f/2.5 w (CHARTWEL) or 66 Gy/33 f/6.5 w (CF). The trial was carried out within the Arbeitsgemeinschaft Radioonkologie (trial # ARO 97-1) of the Deutschen Krebsgesellschaft and sponsored by the Deutsche Krebshilfe.
**Results**: Intent-to-treat analysis did not reveal significant differences of overall survival (primary endpoint) at 2, 3 and 5 yrs after CHARTWEL (31%, 22% and 11%) vs CF (32%, 18% and 7%; HR 0.92, 95% CI 0.75–1.13, p = 0.43). Also local tumor control rates (LC; HR 0.86; 0.68–1.09; p = 0.22) and distant metastasis rates (HR 1.06; 0.78–1.44; p = 0.71) did not significantly differ between the arms. Acute dysphagia was more pronounced after CHARTWEL. Pneumonitis determined by imaging was increased after CHARTWEL, without clinical differences. Exploratory analysis revealed a significant trend for improved LC after CHARTWEL vs CF with increasing UICC, T or N stage (p = 0.006–0.025) and after CTx (HR 0.48, 0.26–0.89, p = 0.019).
**Conclusions**: OS and LC were not significantly different after CHARTWEL and CF in the overall trial population. The impact of higher total dose in CF on LC was compensated by the shorter overall treatment time in CHARTWEL. This confirms a time factor of fractionated radiotherapy in NSCLC, and cautions treatment prolongation. The efficacy of CHARTWEL vs CF was higher in advanced stages and after CTx. From this we hypothesize that CHARTWEL after neoadjuvant CTx is a promising avenue to intensify treatment of locally advanced NSCLC which may overcome current limitations by toxicity of simultaneous radiochemotherapy.

**5LBA** LATE BREAKING ABSTRACT

**First efficacy findings from a randomized phase III trial of capecitabine + oxaliplatin vs. bolus 5-FU/LV for stage III colon cancer (NO16968/XELOXA study)**

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**Background:** Adjuvant capecitabine is at least equivalent to bolus i.v. 5-FU/LV in disease-free survival (DFS) and overall survival (OS) in stage III colon cancer [Twelves et al. NEJM 2005; ASCO GI 2008]. Phase III clinical trials in 1st- and 2nd-line metastatic colorectal cancer have shown that capecitabine + oxaliplatin (XELOX) is as effective and safe as oxaliplatin + infusional 5-FU/LV [Cassidy et al. JCO 2008; Rothenberg et al, Ann Oncol 2008; Ducreux et al. ASCO 2007; Diaz-Rubio et al. JCO 2007; Porschen et al. JCO 2007]. NO16968 was designed to compare the efficacy and safety of XELOX with bolus i.v. 5-FU/LV (the standard regimen at study start) for stage III colon cancer. In a planned safety analysis, XELOX had an acceptable safety profile in this setting [Schmoll et al. JCO 2007].
**Materials and Methods:** Patients were randomized to receive either XELOX (capecitabine 1000 mg/m$^2$ orally bid d1−14 + oxaliplatin 130 mg/m$^2$ i.v. d1, q3w for 8 cycles) or bolus i.v. 5-FU/LV according to the Mayo Clinic (LV 20 mg/m$^2$ + 5-FU 425 mg/m$^2$ d1−5, q4w for 6 cycles) or Roswell Park (LV 500 mg/m$^2$ + 5-FU 500 mg/m$^2$ d1, w1−6 in 8w cycles $\times$4) regimens, as both had shown nearly identical efficacy in a prior trial [Haller et al. JCO 2005]. Each participating center's preferred 5-FU/LV regimen was selected at study start and used in all patients treated at that center.
**Results:** 1886 patients were recruited and randomized between April 2003 and October 2004. Of these, 1864 were evaluable in the previously reported safety analysis. After a median follow-up of 57 months, 1886 patients are evaluable for the primary study endpoint, DFS, which was significantly superior for XELOX at 3 and 4 years.

| | 3-year DFS | 4-year DFS |
|---|---|---|
| XELOX | 71.0% | 68.4% |
| 5-FU/LV | 67.0% | 62.3% |
| | HR 0.80, p = 0.0045 | |

**Conclusions:** XELOX is superior to i.v. bolus 5-FU/LV in DFS as adjuvant treatment for stage III colon cancer. The results with XELOX in the adjuvant setting confirm the benefits shown with oxaliplatin plus 5-FU combinations in stage III patients enrolled in the MOSAIC (FOLFOX vs. LV5FU2) and NSABP C-07 (5-FU/LV vs. FLOX) trials, and may provide a potential additional option for patients with stage III disease. OS data are currently immature; follow-up is ongoing, and updates will be reported when available.

**6LBA** LATE BREAKING ABSTRACT

**Addition of cetuximab to oxaliplatin-based combination chemotherapy (CT) in patients with KRAS wild-type advanced colorectal cancer (ACRC): a randomised superiority trial (MRC COIN)**

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**Background:** Cetuximab (C) has proven efficacy in *KRAS* wild-type (wt) advanced colorectal cancer (ACRC). One of the two questions posed by the COIN trial (ISRCTN27286448) was whether the addition of cetuximab to continuous oxaliplatin-based chemotherapy (CT) improves overall survival