Conclusions: Pulmonary resection for metastases from colorectal cancer does produce longer survival, even in patients with multiple lesions and recurrent metastases.

Oral presentations (Thu, 27 Sep, 09.00−11.00)
Gastrointestinal malignancies – non colorectal cancer

3500 ORAL

Preliminary results from a phase II, randomized, double-blind study of sorafenib plus doxorubicin versus placebo plus doxorubicin in patients with advanced hepatocellular carcinoma

G.K. Abou Alfa[1], P. Johnson[2], J. Knox[3], J. Lacava[4], T. Leung[5], A. Mori[6], M.A. Leberre[6], D. Voliotis[7], L. Saltz[1]. *[1]Memorial Sloan-Kettering Cancer Center, Internal Medicine, New York, USA; [2]The University of Birmingham, Division of Cancer Studies, Birmingham, United Kingdom; [3]Princess Margaret Hospital, Medical Oncology, Toronto, Canada; [4]Unidad Oncologica de Neuquen, Medical Oncology, Neuquen, Argentina; [5]Hong Kong Sanatorium & Hospital, Medical Oncology, Hong Kong, Hong Kong; [6]Bayer Schering Pharmaceuticals, Medical Oncology, Puteaux, France; [7]Bayer Schering Pharmaceuticals, Medical Oncology, Wuppertal, Germany*

Background: Sorafenib, a tyrosine kinase inhibitor with multiple targets, including Raf kinase and the vascular endothelial growth factor receptor (VEGFr), has demonstrated modest single agent activity in hepatocellular carcinoma (HCC) (Abou-Alfa et al: JCO 2006:24; 4293–4300) Here we report the findings of an unplanned interim analysis, requested by the external data safety monitoring board, of a phase II, randomized, double–blind study, conducted to assess sorafenib plus doxorubicin (dox) versus placebo plus dox in patients with advanced HCC.
Material and Methods: Patients with advanced HCC, ECOG Performance Status (PS) of
0–2, Child–Pugh A only and no prior systemic therapy, received dox 60 mg/m^2 i.v. every 21 days plus either sorafenib 400 mg orally twice daily or placebo, for a maximum of six cycles (18 weeks) of dox. Patients could continue on single-agent sorafenib or placebo beyond 18 weeks until disease progression. The primary efficacy endpoint was time to progression (TTP) by external review. Secondary endpoints included overall survival (OS), response rate according to RECIST criteria, and toxicity. Twenty-six progression events have occurred at this analysis.
Results: A total of 96 patients were randomized (sorafenib plus dox, n = 47; placebo plus dox, n = 49); 76% were male, 91% had an ECOG PS of 0–1, and the median patient age was 65 years. Baseline patient characteristics were balanced between treatment arms. Data are presented in the table. The TTP and OS of the placebo/dox control arm fall within the range of the historically reported data for dox alone.
Conclusions: In this preliminary analysis, TTP and OS in the sorafenib/dox arm appear to be encouraging, and toxicity appears tolerable. Per the external DSMB recommendation, the trial has been unblinded and remaining patients on the control arm have been crossed over to sorafenib. Updated analyses will be presented at the meeting.

	Time to progression	Overall survival	Response rate (CR+PR) %	Grade 3/4 fatigue	Grade 3/4 neutropenia
Sorafanib/dox	8.5 mo	14.0 mo	4.3	10.6%	36.2%
Placebo/dox	2.8 mo	5.6 mo	2.0	6.3%	41.7%

3501 ORAL

Capecitabine/cisplatin vs. continuous infusion of 5-FU/cisplatin as first-line therapy in patients (pts) with advanced gastric cancer (AGC): a randomised phase III trial

Y. Kang[1], W. Kang[2], D. Shin[3], J. Chen[4], J. Xiong[5], J. Wang[6], M. Lichinitser[7], M. Philco[8], T. Suarez[9], J. Santamaría[10]. *[1]Asan Medical Center, Department of Internal Medicine, Seoul, Korea; [2]Samsung Medical Center, Department of Internal Medicine, Ilwon-dong, Korea; [3]Gachon Medical School Gill Medical Center, Department of Internal Medicine, Incheon-shi, Korea; [4]Jiangsu Cancer Hospital, Department of Oncology, Nanjing, China; [5]1st Affiliated Hospital of Jianxi Medical College, Department of Oncology, Nanchang, China; [6]Shanghai Changzheng Hospital, Department of Oncology, Shanghai, China; [7]Russian Cancer Research Center Blokhin Cancer Research Center, Department of Oncology, Moscow, Russian Federation; [8]Alberto Sabogal Sologuren Hospital, Research Unit, Bellavista Callao, Peru; [9]Centro Medico Pensiones, Department of Oncology, Yucatan, Mexico; [10]Instituto Oncológico Nacional, Department of Medical Oncology, Ancón, Panama*

Background: Capecitabine has proven efficacy and safety in a number of tumours, particularly colorectal, breast and gastric cancers. A phase II study in AGC suggested that capecitabine plus cisplatin (XP) has comparable efficacy to the standard 5-fluorouracil/cisplatin (FP) regimen, with potential safety and convenience advantages. We compared XP and FP as first-line treatment for AGC.
Materials and Methods: In this randomised, open-label, multicentre study, pts with previously untreated AGC received either oral capecitabine (1000 mg/m^2 bid days 1–14) plus cisplatin (80 mg/m^2 i.v. day 1) every 3 weeks (XP arm) or 5-FU (800 mg/m^2/day continuous infusion, days 1–5) plus cisplatin (80 mg/m^2 i.v. day 1) every 3 weeks (FP arm). Pts were treated until disease progression or unacceptable toxicity. Primary endpoint: non-inferiority in progression-free survival (PFS), defined as upper limit for 95% CI of the hazard ratio (HR) of
Results: 316 pts were randomised. Median number of treatment cycles per arm was 5. Median follow-up was 21.2 months (range 13–34) for XP, and 21.0 (14–33) for FP. In the per protocol population, median PFS for XP was 5.6 months (95% CI 4.9–7.3) vs. 5.0 months for FP (95% CI 4.2–6.3). Primary endpoint was met with HR of 0.81 (95% CI 0.63–1.05, p < 0.001 vs. non-inferiority margin of 1.25); non-inferiority was highly significant. Median overall survival (OS) for XP was 10.7 months (95% CI 9.5–11.5) vs. 9.5 months for FP (95% CI 7.5–11.4). For OS, XP was significantly non-inferior vs. FP (HR = 0.89, 95% CI 0.68–1.17, p = 0.0146 vs. non-inferiority margin of 1.25 in per protocol population). XP was significantly superior to FP in terms of objective response rate (ORR, RECIST: 41% vs. 29%; p = 0.0295 in ITT population). Both treatments were well tolerated and had similar safety. Most common treatment-related grade 3/4 adverse events: neutropenia (occurring in 16% of XP vs. 19% of FP pts), vomiting (7% vs. 8%), stomatitis (2% vs. 6%), diarrhoea (5% vs. 5%), anaemia (3% vs. 2%). Rate of hand–foot syndrome was low (22% vs. 4%) relative to other studies.
Conclusions: XP showed highly significant non-inferiority for PFS and OS vs. FP and had similar safety. XP was also significantly superior to FP in terms of ORR.

3502 ORAL

Final results of a randomized phase III trial in patients with advanced adenocarcinoma of the stomach receiving first-line chemotherapy with fluorouracil, leucovorin and oxaliplatin (FLO) versus fluorouracil, leucovorin and cisplatin (FLP)

S.E. Al-Batran[1], J.T. Hartmann[2], S. Probst[3], R. Hofheinz[4], J. Stoehlmacher[5], C. Pauligk[1], S. Hollerbach[6], G. Schuch[7], N. Homann[8], E. Jäger[1]. *[1]Krankenhaus Nordwest, Oncology and Hematology, Frankfurt am Main, Germany; [2]Eberhard-Karls-University, Oncology and Hematology, Tuebingen, Germany; [3]Städtische Kliniken Bielefeld, Oncology and Hematology, Bielefeld, Germany; [4]Universitätsklinikum Mannheim, Oncology and Hematology, Mannheim, Germany; [5]University Hospital Carl Gustav Carus, Oncology and Hematology, Dresden, Germany; [6]Allgemeines Krankenhaus Celle, Oncology and Hematology, Celle, Germany; [7]University Hospital Hamburg – Eppendorf, Oncology and Hematology, Hamburg, Germany; [8]Universitätsklinikum Schleswig-Holstein Campus, Oncology and Hematology, Luebeck, Germany*

Background: Cisplatin-based chemotherapy is a standard option in advanced gastric cancer. However, treatment results have been unsatisfactory so far, with a progression-free survival (PFS) of 3 to 4 months and an overall survival (OS) of 6 to 9 months. In addition, treatment regimens are too intense and toxicity is considerable. The aim of this trial was to determine whether FLO prolongs PFS and reduces toxicity as compared to FLP.