developed metachronous EC and local recurrence, respectively. Apart from one, they could be retreated endoscopicaly.
Conclusions: EMR is a very useful therapeutic modality for cSt I EC, not only for local control but also as a clinically sufficient treatment; especially in pts. with severe concurrent disease.

6575 POSTER

Bevacizumab combined with chemotherapy in the treatment of advanced/metastatic gastro-entero-pancreatic tumours: interim safety results from the phase II BETTER study

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Background: Gastro-entero-pancreatic (GEP) tumours are known to be highly vascular with elevated expression levels of vascular endothelial growth factor (VEGF). The aim of this study was to assess the efficacy and safety of adding bevacizumab (BV), a VEGF inhibitor, to two chemotherapy regimens in patients (pts) with previously untreated, progressive locally advanced/metastatic well-differentiated GEP tumours (pancreatico-duodenal and gastrointestinal [GI] tract).
Materials and Methods: Prospective, open-label, two-arm, non-comparative, multicentre phase II trial (EUDRACT 2007–003381−18). Pts with pancreatico-duodenal tumours received 5-FU 400 mg/m^2/day + streptozotocin 500 mg/m^2/day every 6 weeks + BV 7.5 mg/kg i.v. every 3 weeks (Arm 1); pts with GI tract tumours received capecitabine 1000 mg/m^2 per day on days 1−14 + BV 7.5 mg/kg i.v. every 3 weeks (Arm 2). After 6 months of treatment the physicians judged whether further chemotherapy was required. BV was administered until disease progression, unacceptable toxicity, or pt or physician decision to discontinue. The primary endpoint was progression-free survival. Secondary endpoints included response rate, overall survival and safety. The trial was funded by Roche France.
Results: Here we report interim safety findings on the first 40 pts enrolled (from a planned total of 81 pts) between June 07 and May 08. These findings relate to the first 6 months of treatment. Baseline characteristics are as follows: 21 male, 19 female; median age 59 years (range 37−82); 20 pancreatico-duodenal, 20 GI tract tumours. Grade 3/4 adverse events (AEs) were observed in 10 pts (50%) in Arm 1 and 12 pts (60%) in Arm 2. Main grade 3/4 AEs included hypertension (2 pts in Arm 1, 5 pts in Arm 2), asthenia (1 in Arm 1, 2 in Arm 2), embolism (1 in each Arm), haemorrhage (1 in each Arm), abdominal pain (1 in Arm 1), nausea (1 in Arm 1), diarrhea (2 in Arm 2) and febrile neutropenia (1 in Arm 2). Grade 3/4 BV-related AEs were observed in 3 pts in Arm 1 and 5 pts in Arm 2. Serious AEs were reported in 3 pts in each arm (1 BV-related SAE in Arm 1 and 2 in Arm 2). Treatment discontinuation due to toxicity was reported in 2 pts in Arm 1 and 1 pt in Arm 2. One pt died due to BV-related haemorrhagic stroke.
Conclusions: These results showed no unanticipated toxicity with BV plus standard chemotherapy for pts with previously untreated, progressive locally advanced/metastatic well-differentiated GEP tumours.

6576 POSTER

Irinotecan and low-dose capecitabine combination as first-line chemotherapy in advanced or metastatic gastric cancer: results of a phase II study

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Background: Chemotherapy has a proven palliative role in advanced or metastatic gastric cancer. However, none of the currently explored regimens have shown compelling improvements without an impact on patients' quality of life. This phase II pilot study investigated the combination of irinotecan (CPT11) plus low-dose capecitabine as first-line therapy in advanced or metastatic gastric cancer.
Materials and Methods: For a period of 3 years patients with advanced or metastatic gastric cancer were enrolled to receive a combination of irinotecan 80 mg/m^2 on days 1, 8 and 15 plus capecitabine 625 mg/m^2 twice daily on days 1−14 every 4 weeks for a maximum of 8 cycles. Outcomes included response rate, time to progression, overall survival and safety. Outcomes were evaluated every 2 cycles.
Results: 32 patients, with a median age of 55 years, were evaluable. A total of 153 cycles were administered with a median of 4.7 cycles per patient. The objective response rate was 47%, with 9 patients having stable disease. The overall tumour control rate was 75%. Median time to progression and overall survival were 5 months and 8 months, respectively. Treatment was well tolerated with only 7 reported cases of grade 3/4 toxicities. No treatment-related deaths or hand-foot syndrome were observed during the study. Grade 3/4 toxicities were neutropenia (2 patients), diarrhoea (2 patients), nausea and vomiting (2 patients), asthenia (1 patient). Dose reduction was required for at least one cycle in 7 cases (22%).
Conclusion: The monthly regimen of low-dose capecitabine plus irinotecan appears to be active with a good toxicity profile in the treatment of advanced or metastatic gastric cancer. In cases where there is contraindication of platinum-based therapy, the more recent oxaliplatin- or docetaxel-based chemotherapies can be applied to this regimen.

6577 POSTER

A randomized phase II trial of weekly docetaxel plus either cisplatin or oxaliplatin in patients with previously untreated advanced gastric cancer: Preliminary results

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Background: Docetaxel, in combination with cisplatin or oxaliplatin, has demonstrated efficacy against advanced gastric cancer (AGC). This randomized phase II trial evaluated two weekly docetaxel-based regimens to see which would be most promising according to objective response rate (ORR) as first-line therapy in AGC.
Methods: Chemotherapy-naïve patients with measurable unresectable and/or metastatic gastric adenocarcinoma and a performance status $\leqslant 2$ were randomly assigned to receive docetaxel (35 mg/m^2) weekly on days 1 and 8 of a 21-day cycle plus either cisplatin (60 mg/m^2 on day 1) (arm A) or oxaliplatin (120 mg/m^2 on day 1) (arm B). Toxicity was assessed on days 1, 8, and 21 of each cycle, and response was evaluated every 2 cycles.
Results: Between March 2007 and April 2009, 75 eligible patients entered. In Arm A, 35 patients were evaluable for objective response and 36 for safety. In Arm B, 37 patients were evaluable for objective response and 37 for safety. Median age was 57 years and disease status was comparable for both arms. Fourteen of 35 (40.0%) patients had a confirmed objective response in the arm A (95% confidence interval [CI] 23.7−56.2%) and 16 of 37 (43.2%) patients had a confirmed objective response in the arm B (95% CI 27.2−59.2%). No significant difference was noted between the arms both for ORR ($p = 0.641$) or for disease control (62.9% and 81.1%, respectively, $p = 0.116$). Median progression free survival time was 4.8 month in the arm A and 4.3 months in the arm B (Hazard ratio = 1.040; 95% CI, 0.602−1.797; $p = 0.889$). Median overall survival time was 9.6 months in the arm A and not reached in the arm B (Hazard ratio = 0.501; 95% CI, 0.243−1.036; $p = 0.062$). There was no relevant difference in the occurrence of overall grade 3/4 toxicity between the two arms (58.3% vs. 54.1%, respectively; $p = 0.815$). Neutropenia was the most common grade 3/4 toxicity (33.3% vs. 37.8%, respectively). There was one treatment related death in each arm.
Conclusions: The preliminary results showed that both treatment arms have similar clinical efficacy as front-line treatment in AGC. Each regimen has a manageable tolerability profile. The accrual is ongoing.

6578 POSTER

A randomized phase II study of irinotecan monotherapy versus irinotecan plus 5-fluorouracil/leucovorin combination as a salvage chemotherapy in previously treated patients with advanced/metastatic gastric cancer

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Background: The purpose of this study was to compare the efficacy and toxicity of adding 5-fluorouracil/leucovorin to irinotecan in locally advanced/metastatic gastric cancer as a salvage chemotherapy.
Materials and Methods: Eligible patents had performance status 0 to 2, measurable unresectable and/or metastatic gastric adenocarcinoma,