GEMCITABINE + CISPLATIN (GEM+CIS) IN COMBINATION WITH REGIONAL HYPERTHERMIA (RHT) IN SECOND-LINE THERAPY OF GEMCITABINE-REFRACTORY METASTATIC PANCREATIC CANCER

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Background
Our completed phase III trial comparing GEM + CIS vs. GEM alone showed good efficacy for the combination arm in 1st-line therapy (ASCO abstr. No. 1003, 2003). Based on the rationale of chemosensitization of CIS by RHT we are performing a prospective phase II study with GEM + CIS combined with RHT.

Methods
Until 8/2005 12 pts with metastatic pancreatic adenocarcinoma who failed GEM-based 1st-line-therapy were enrolled in this study. One cycle consisted of GEM (1000mg/m²) on d1 followed by CIS (25mg/m²) on d2 and d4 combined with RHT (BSD system). A total of 2 blocks each of 4 cycles were given biweekly. The main endpoints were time to second progression (TTP2) and 1-year event free survival (1-yr-EFS). TTP2 and EFS were defined as time from start of 2nd-line therapy until progression of disease or death. Response (RECIST) was evaluated after 4 and 8 cycles of therapy.

Results
Pt characteristics: median age 60; M:F=8:4. Median time to first progression (TTP1) was 6 months (95% CI:2-7). 8/12 pts received all 8 cycles. No toxic death and no grade 4 toxicity occurred. In 12/2005 10/12 pts were evaluable for this study. Control of disease (1CR, 2MR, 4NC) and progression (3PD) occurred in 70% and 30%, respectively. The median TTP2 is 8 months (95% CI: 2-13) and the 1-yr-EFS is 32% (95% CI:3-61). 7 pts are alive at 12/2005.

Conclusions
Our ongoing study (EudraCT-No 2005-003855-11) using RHT combined with GEM + CIS shows promising antitumor activity with an encouraging TTP2 and median 1-yr-EFS in the 2nd-line treatment of GEM-refractory metastatic pancreatic cancer.