Introduction: Combination chemotherapy regimens including fluoropyrimidines as well as albumin-bound paclitaxel have shown promising results in patients with metastatic pancreatic adenocarcinoma (mPC). Based on the recently described excellent therapeutic index of capecitabine plus nab-paclitaxel in metastatic breast cancer, the present phase II trial was initiated.

Methods: Patients with previously untreated mPC were treated with capecitabine (825 mg/m² orally bid on days 1-15) and nab-paclitaxel (125 mg/m² intravenously on days 1 and 8) every 3 weeks. In patients without clinically relevant adverse reactions after the 1st treatment course (≤ grade 2 toxicities according to NCI-CTC vs. 4.0, exuding alopecia and fatigue of any degree) and adequate bone marrow function, the nab-paclitaxel dose was escalated to 100 mg/m² on days 1, 8 and 15 of each cycle; this intra-individual dose escalation was maintained during subsequent treatment courses if tolerated. The primary endpoint was objective response rate (ORR) according to RECIST criteria, assessed by an independent radiological review committee with evaluation performed every 2 months.

Results: Between 12/2013 and 01/2015, 30 patients were entered in this monocentric academic phase II trial. All patients had an ECOG performance status of 0-1, 66% had liver metastases and 23% had biliary stents in place at time of study initiation. Median CA19-9 was 807,5 U/mL (0,9-100.000 U/mL). In all patients except 2, a dose escalation of nab-paclitaxel after the 1st treatment course could be accomplished. The most common grade 3 adverse events included transient sensory neuropathy (42,1%), (afebrile) neutropenia (26,3%), hand-foot-syndrome (15,8%), and phototoxic skin reaction (15,8%). Among 28 RECIST-response assessable patients, the ORR was 43% and stable disease (SD) was noted in 39%, resulting in a disease control rate (DCR) of 82%. CA19-9 declines of >50% occurred in 58% of patients with pre-treatment pathological levels. After a median follow-up of 8,6 months (1,6-20,8 months) 19/30 patients (63%) are presently alive.

Conclusion: The combination of capecitabine + nab-paclitaxel at these doses and scheduling was well tolerated and showed substantial antitumor efficacy.