01 improves the efficacy of gemcitabine in treating pancreatic carcin

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Author(s): M. Haenel, D. Quietzsch, V. Heinemann, S. Boeck, R. M. Schmid, A. Liebert, R. Fahrig

Background: (E)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU, RP101), was initially tested in a phase 1 pilot study in pancreatic cancer. Patients (n=13) received gemcitabine (1000 mg/m2), cisplatin (50 mg/m2) and RP101 (500 mg/day). The median survival was 447 days and the TTP was 280 days. Ten of the 13 pts lived longer than one year, 4 nearly two years. Based on these promising results a phase 2 study was initiated to explore varying doses of RP101 used with a fixed dose of GEM.

Methods: Pts with advanced pancreatic adenocarcinoma were eligible for treatment in this single arm study. 22 pts (16 stage IV and 5 stage III) received GEM 1000 mg/m2 on days 1, 8 and 15 of a 28-day schedule. RP101 treatment, at doses of 500, 625, 750, 875 or 1000 mg/day, was on the same day and for three days after chemotherapy. The mean age was 60 years and 73% of pts were males.

Results: The results are based on interim data from an ongoing study and patients at the 2 highest dose groups are still being treated. All RP101 dose groups were combined for analyses, which included all enrolled pts. The data on the 6-month survival status show that 41% are alive; 23% dead; and 36% followed less than 6 months. The median survival (95% CI) is 7.1 months (5.9, not calculated) and 14/22 pts (64%) are still alive. The 6 month survival rate (95% CI) is 0.69 (0.52, 0.85). This compares very favorably with a large recent randomized trial in which pts who received GEM alone had a median survival (95%CI) of 5.9 months (5.1-6.7). PFS and TTP continue to be assessed in this ongoing trial. There appears to be a dose dependent increase in peak GEM levels as a function of the dose of RP101. To date, adverse events are consistent with those observed with GEM or the underlying disease.

Conclusion: RP101 may improve treatment of advanced pancreatic cancer when used with gemcitabine. Updated data on survival, PFS, and safety will be presented based on available data.

RESprotect GmbH
Geschäftsführer: Prof. Dr. Rudolf Fahrig
Fiedlerstr. 34
01307 Dresden - Germany

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Geschäftsführer: Prof. Dr. Rudolf Fahrig
Fiedlerstr. 34
01307 Dresden - Germany