Sequential treatment with Nab-paclitaxel plus Gemcitabine and Folarinox in metastatic pancreatic adenocarcinoma: GABRINOX phase II results.

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Abstract Disclosures

Background: Folarinox (FFX) and Nab-paclitaxel/Gemcitabine (AG) showed significant efficacy improvement compared to Gemcitabine alone in metastatic pancreatic cancer (mPC). Alternating AG and FFX may overcome resistance and delay tumor progression. We designed a multicenter phase I-II trial to evaluate a sequential treatment with AG followed by FFX in 1-line. Phase I established the recommended doses and confirmed the feasibility in a 12-patient expansion cohort (Assenat et al, ESMO 2016). Phase II assessed the efficacy of the recommended doses.

Methods: During phase II, AG and FFX were administered sequentially, each AG cycle followed by 2 FFX cycles. All chemotherapeutic agents were administered according to standard practice. The primary endpoint was the objective response rate (ORR).

Results: 58 patients were included in 3 centers, between 2014 and 2016. Patients were 50% male, median age 60 years (34-72), ECOG PS 0 (37.9%) or 1 (62.1%). A median of 4 (1-9) cycles were administered, during 34.2 weeks (2.1-79.4). Neurotoxicity rate was low (gr3: 5.2%). Main grade 3/4 toxicities were thrombosis (17.2%/0%), thrombopenia (31%/1.7%), neutropenia (34.5%/22.4%), febrile neutropenia (1.7%/1.7%), nausea (17.2%/0%), diarrhea (25.9%/1.7%), weight loss (1.7%/0%) and asthenia (31%/0%). No toxic death was reported. Efficacy analysis included 57 patients. Response was complete in 3.5% patients; partial in 59.7%; disease was stable in 21% patients, progressive in 15.8%. The primary objective was met with an ORR of 63.2% (95% CI: 49.3-75.5). After a median follow-up of 18.6 months (95% CI: 14.5-25.6), the median progression-free and overall survival were 9.6 months (95% CI: 6.012.3) and 17.8 (95% CI: 11.7-21.3) months.

Conclusions: This phase II study confirmed the phase I data with an acceptable toxicity and a high response rate for this alternating AG and FFX treatment. Survival results are promising and justify considering further randomized trials in these setting. Clinical trial information: NCT01964287

Time (months) PFS rate (%) 95% CI OS rate (%) 95% CI
9 51.6 [37.8-63.8] 70.3 [56.6-80.4] 12 41.2 [27.3-54.7] 61.5 [47.6-72.7] 15 (PFS) / 18 (OS) 29.2 [16.2-43.4] 47.9 [33.3-61.0]

Survival analyses: n = 58
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