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Overall survival (OS) of patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) treated with first-line (1L) FOLFIRINOX (FFX): Bridging the gap between the NAPOLI 3 trial and real-world practice.

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Background: NALIRIFOX (liposomal irinotecan + 5-fluorouracil/leucovorin + oxaliplatin) demonstrated significantly improved OS compared to 1L gemcitabine + nab-paclitaxel in the phase 3 NAPOLI 3 trial (NCT04083235). The median OS (95% CI) in the NALIRIFOX intention-to-treat population (N= 383) was 11.1 (10.0, 12.1) months. However, the relative efficacy of NALIRIFOX versus FFX (irinotecan + 5-fluorouracil/leucovorin + oxaliplatin), another standard of care for 1L treatment of mPDAC, has not been studied. To further contextualize findings from NAPOLI 3 trial, the current study described OS among patients treated with 1L FFX in the real-world setting. **Methods:** Three cohorts of patients with mPDAC treated with 1L FFX were identified from the Flatiron Health database. The all-comer cohort included all adult patients with mPDAC treated with 1L FFX since January 2014. Among them, the trial-aligned cohort included patients with mPDAC treated with 1L FFX between January 1, 2020 and July 31, 2022 (to align with the time period of NAPOLI 3 trial) who met the eligibility criteria of NAPOLI 3. Finally, a subgroup of patients in the trial-aligned cohort who received modified FFX (mFFX) regimen composed the trial-aligned mFFX cohort. OS was assessed using Kaplan-Meier analysis. **Results:** The all-comer cohort consisted of 3,271 patients. The trial-aligned cohort included 219 patients, of whom 154 (70%) were treated with mFFX. The distribution of baseline characteristics was similar across three cohorts (Table). The median age of the trial-aligned cohort was 65 years old, with 46% of patients being female, 67% being White, and 47% having ECOG score of 1. The median OS (95% CI) in the all-comer cohort and trial-aligned cohort was 9.0 (8.5, 9.3) months and 9.1 (7.8, 10.9) months, respectively; the median OS (95% CI) was 8.6 (7.3, 10.5) months in the trial-aligned mFFX cohort. **Conclusions:** NALIRIFOX regimen in the NAPOLI 3 trial showed numerically improved OS compared to FFX, including mFFX, in the real-world setting. Analysis adjusting for baseline characteristics are warranted and will provide further insights for the comparative efficacy of the two regimens. Research Sponsor: Ipsen Corp.

Characteristics of real-world FOLFIRINOX cohorts.

	All-comer cohort (N=3,271)	Trial-aligned cohort (N=219)	Trial-aligned mFFX cohort (N=154)
Baseline characteristics			
Age, years, mean (SD)	63.5 (9.0)	64.6 (8.2)	65.1 (8.5)
Female, n (%)	1,377 (42.1)	100 (45.7)	68 (44.2)
White, n (%)	2,118 (64.8)	146 (66.7)	100 (64.9)
ECOG score = 1, n (%)	1,327 (48.9)*	103 (47.0)	77 (50.0)
Endpoint			
Median OS, months (95% CI)	9.0 (8.5, 9.3)	9.1 (7.8, 10.9)	8.6 (7.3, 10.5)

Abbreviations: CI, confidence interval; ECOG, Eastern Cooperative Oncology Group; OS, overall survival; SD, standard deviation.
*Proportion calculated based on 2,711 patients with ECOG available at baseline.

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