

An exploratory analysis based on tumor location of REACHIN, a randomized double-blinded placebo-controlled phase II trial of regorafenib after failure of gemcitabine and platinum-based chemotherapy for locally advanced (nonresectable) and metastatic biliary tract tumors.

Background: The REACHIN trial met its primary endpoint of improving PFS for patients with biliary tract cancer (BTC) treated with regorafenib (R) as compared to placebo (P): Median (m) PFS for R was 3.0 months (mo) (95% CI: 2.3-4.9) and 1.5 mo (95% CI : 1.2-2.0) for P with an HR= 0.49 (95% CI: 0.29-0.81), $p=0.005$ (Demols A et al, ASCO-GI 2019, Abstr 345). We exploratory analyzed the benefit of R according to tumor location: intra-hepatic (ICC), extra-hepatic (ECC), gallbladder (GB) or peri-hilar (PH). **Methods:** Tumor locations were recorded at randomization of patients in REACHIN (NCT02162914), a multicenter double-blinded P-controlled randomized phase II study to evaluate the safety and efficacy of R in patients with locally advanced (non resectable) and metastatic histologically proven BTC, progressing after gemcitabine-platinum. We analyzed mPFS according to tumor location and their respective 95% CI. **Results:** 66 patients were randomized and the mPFS data are summarized in the table. **Conclusions:** Most of the patients had ICC location (64%). The mPFS in the P arm is similar according to the tumor location. Despite its exploratory value and the small number of patients per tumor location, R seems superior to P in ICC, GB and PH. Data in ECC are not conclusive. Additional biomarkers (FGFR, NGS analysis) are ongoing and will be presented at the meeting. [Clinical trial information: NCT02162914.](https://clinicaltrials.gov/ct2/show/study/NCT02162914)

	R			P		
	N	mPFS (mo)	95% CI	N	mPFS (mo)	95% CI
ICC	23	3.0	(1.5–4.9)	19	1.5	(1.1–2.1)
ECC	3	1.4	(0.5–5.3)	6	1.5	(0.6–4.7)
GB	4	4.7	(0.0–8.8)	5	1.6	(0.4–2)
PH	3	2.6	(1.1–4.5)	3	0.5	(0.0–3.0)

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