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Meeting Abstract | 2019 ASCO Annual Meeting I

GASTROINTESTINAL (NONCOLORECTAL) CANCER

DOI: 10.1200/JCO.2019.37.15_suppl.4038

Trifluridine/tipiracil (FTD/TPI) in patients (pts) with metastatic gastroesophageal junction cancer (mGEJC): Subgroup analysis from TAGS.

Background: The incidence of GEJC is increasing in North America and Europe, especially among white men. Many pts present with metastatic disease or relapse locally or systemically after resection of early-stage disease. The global phase 3 study TAGS (NCT02500043) demonstrated the efficacy and safety of FTD/TPI in previously treated pts with metastatic gastric cancer (mGC)/mGEJC. Here we report results in the mGEJC subgroup from TAGS. **Methods:** Pts with mGC/mGEJC treated with ≥2 prior chemotherapy regimens were randomized (2:1) to receive FTD/TPI (35 mg/m^2 BID on days 1–5 and 8–12 of each 28-day cycle) or placebo, plus best supportive care. A preplanned efficacy and safety analysis was performed in pts with mGEJC. **Results:** Of 507 randomized pts, 145 (29%) had GEJC as the sole primary disease site (FTD/TPI, 98/337; placebo, 47/170). Of pts with mGEJC, 85% were male and 83% were white (overall population, 73% and 70%). Baseline characteristics were generally balanced for pts with mGEJC across treatment groups, except for fewer pts having prior gastrectomy (40% vs 55%) and more pts having received ≥3 prior regimens (74% vs 66%) in the FTD/TPI group than in the placebo group. FTD/TPI had an efficacy benefit in pts with mGEJC, and the FTD/TPI safety profile was similar in this subgroup and the overall population (table). **Conclusions:** FTD/TPI showed a manageable safety profile and efficacy benefit in pts with mGEJC in the TAGS trial, despite heavier pretreatment of the FTD/TPI than the placebo group. Clinical trial information: NCT02500043.

	Overall population[1]		mGEJC	
	FTD/TPI	Placebo	FTD/TPI	Placebo
ITT population, n	337	170	98	47
Median OS, mo	5.7	3.6	4.8	3.5
HR (95% CI)	0.69 (0.56–0.85)		0.75 (0.50–1.11)	
Median PFS, mo	2.0	1.8	1.9	1.8
HR (95% CI)	0.57 (0.47–0.70)		0.60 (0.41–0.88)	
Safety population, n	335	168	97	46
Grade ≥3 AEs of any cause, %				
Any	80	58	77	59
Most common[a]				
Neutropenia[b]	34	0	25	0
Anemia[c]	19	8	13	4

	Overall population[1]		mGEJC	
	FTD/TPI	Placebo	FTD/TPI	Placebo
Fatigue	7	6	10	0
Abdominal pain	4	9	4	15
AEs of any grade or cause, %				
Leading to dosing modification	58	22	54	24
Leading to treatment discontinuation	13	17	9	11

[a]Occurring in ≥10% of pts in any group. [b]Includes decreased neutrophil count. [c]Includes decreased hemoglobin level. 1. Shitara K, et al. *Lancet Oncol* 2018.