supportive care. The aim of this analysis was to evaluate the effects of FTP/TPI in the European subpopulation of TAGS.

Methods: TAGS enrolled pts with histologically confirmed, non-resectable mGC, Eastern Cooperative Oncology Group (ECOG) performance status 0/1, and ≥2 prior chemotherapy regimens. Pts were randomised 2:1 to FTD/TPI (35 mg/m^2 BID on days 1–5 and 8–12 every 28 days) or placebo. Primary endpoint was OS. Secondary endpoints included PFS, time to deterioration (TTD) of ECOG and safety; 507 pts were randomised to FTD/TPI (n = 337) or placebo (n = 170). Median follow-up was 10.7 months.

Results: 277 pts (mean age 63.0 years; 75% male) were enrolled from 64 sites in Europe. Baseline characteristics were balanced between groups; 120 (67%) and 63 (65%) of pts in FTD/TPI and placebo groups had received ≥3 regimens of prior systemic therapy. FTP/TPI significantly prolonged OS (hazard ratio [HR] 0.59, 95% confidence interval [CI] 0.44-0.78), PFS (HR 0.46, 95% CI 0.35–0.61) and TTD to ECOG (HR 0.59, 95% CI 0.45–0.78; Table) compared with placebo. FTD/TPI had a predictable and manageable safety profile. Treatment-emergent adverse events (TEAEs) were reported in 172/180 (96%) FTD/TPI-treated and 92/97 (96%) placebo-treated pts. Efficacy and safety in European population of TAGS.

Table: 801P

	FTD/TPI (n = 180)	Placebo (n = 97)	HR (95% CI)	P-value (2-sided)
Efficacy outcomes, median (95% CI)				
OS	5.45 (4.34–6.21)	3.15 (2.43–3.58)	0.59 (0.44–0.78)	0.0002
PFS	1.94 (1.91–2.50)	1.77 (1.74–1.87)	0.46 (0.35–0.61)	<0.0001
TTD of ECOG	3.84 (2.89–4.50)	2.10 (1.87–2.53)	0.59 (0.45–0.78)	0.0001
TEAEs, n (%)				
Any	172 (96.1)	92 (95.8)		
Serious	79 (44.1)	49 (51.0)		
Grade ≥3	143 (79.9)	62 (64.6)		
Treatment-related	140 (78.2)	55 (57.3)		
Leading to dose modification	107 (59.8)	26 (27.1)		
Leading to treatment discontinuation	24 (13.4)	19 (19.8)		
Leading to death	19 (10.6)	14 (14.6)		

Conclusions: FTD/TPI was effective and well tolerated in European patients, consistent with the overall population of TAGS.

Clinical trial identification: NCT02500043.

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801P Efficacy and safety of trifluridine/tipiracil (FTD/TPI) in European patients with heavily pretreated metastatic gastric cancer (mGC): An analysis of the TAGS study

M. Alsina[1], J. Tabernero[2], H-T. Arkenau[3], M. Squadroni[4], T. Doi[5], C. Faustino[6], M. Ghidini[7], W. Mansoor[8], K. Shitara[9], E. Van Cutsem[10], N. Causse-Amellal[11], C. Leger[12], D. Skanji[13], D. Ilson[14]

[1]Medical Oncology Department, Vall d'Hebron University Hospital, Barcelona, Spain, [2]Oncology, Vall d'Hebron University Hospital and Vall d'Hebron Institute of Oncology (VHIO), Barcelona, Spain, [3]SCRI, Sarah Cannon Research Institute SCRI UK, London, UK, [4]Oncologia Medica, Humanitas Gavazzeni, Bergamo, Italy, [5]Department of Experimental Therapeutics, National Cancer Center Hospital East, Chiba, Japan, [6]Oncologia Medica, Instituto Portugues de Oncologia Centro do Porto(IPO-Porto), Porto, Portugal, [7]Oncology, Istituti Ospitalieri di Cremona, Cremona, Italy, [8]Medical Oncology, The Christie NHS Foundation Trust, Manchester, UK, [9]Experimental Therapeutics (and Gastrointestinal Oncology), National Cancer Center Hospital, Kashiwa, Japan, [10]Internal Medicine, University Hospitals Gasthuisberg/Leuven and KU Leuven, Leuven, Belgium, [11]Centre for Therapeutic Innovation, Servier, Suresnes, France, [12]Centre for Therapeutic Innovation, Servier, Suresnes, France, [13]Statistics Department, Servier, Suresnes, France, [14]Medical Oncology, Memorial Sloan Kettering, New York City, NY, USA

Background: TAGS, a randomised, double-blind, phase III study, showed that FTD/TPI significantly improved overall survival (OS) and progression-free survival (PFS) compared with placebo in heavily pretreated mGC patients (pts) receiving best

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