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Session E. Gastrointestinal (colorectal) cancer

E13 Subgroup analysis of patients with metastatic colorectal cancer (mCRC) treated with regorafenib (REG) in the CORRECT trial who had progression-free survival (PFS) longer than 4 months

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Background: In the CORRECT phase III trial (NCT01103323), the multikinase inhibitor REG significantly improved overall survival (OS) and PFS *vs* placebo in patients with mCRC who had disease progression after other standard therapies (HR for OS: 0.77; 1-sided p = 0.0052; Grothey 2013). A post-hoc exploratory subgroup analysis was conducted to evaluate patients in the REG treatment group who had a PFS longer than 4 months (long-PFS) defined as patients who progressed, died, or discontinued treatment for other reasons after 4 months.

Methods: Of the505 patients randomized to REG in CORRECT, 98 (19.4%) were classified as having a long-PFS benefit. Baseline characteristics, safety, and dosing parameters were analyzed descriptively.

Results: The long-PFS subpopulation was representative of the overall study population (Table). Long-PFS patients received a median of 6 cycles of REG (1-12), 92% received ≥5 cycles, and 20% had > 8 cycles. Overall 34% of patients had dose reductions and 87% had dose interruptions. The actual mean daily dose was 139 mg and the mean percent of the planned dose was 81%. Adverse events (AE) of any grade were experienced by all long-PFS patients, and the most common grade ≥3 AEs were hand-foot skin reaction (20%), hypertension (17%), diarrhea (17%), and fatigue (16%).

Conclusions: A subset of 98 (19.4%) patients treated with REG in the CORRECT study had a PFS > 4 months, confirming the clinical benefit and tolerability of REG as a treatment option for patients with mCRC. Prospective validation of these findings in conjunction with biomarker analysis from real-life clinical experience is needed.

Clinical trial information: NCT01103323

Table: E13

Baseline characteristics of all REG-treated patients and the long-PFS subgroup in CORRECT.

		All patients (n=505)	Long-PFS (n=98)
Median age, yrs (range)		61 (22–82)	61 (34–82)
ECOG PS, %	0	52	63
	1	48	37
Primary tumor, %	Colon	64	52
	Rectum	30	37
Tumor sites, %	1	19	30
	2	36	38
	3	27	16
***KRAS* status, %**	Mutant	54	47
	Wild-type	41	44

abstracts