

## 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 the 505 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](https://clinicaltrials.gov/ct2/show/study/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)
<b>Median age, yrs (range)</b>	61 (22–82)	61 (34–82)
<b>ECOG PS, %</b>		
0	52	63
1	48	37
<b>Primary tumor, %</b>		
Colon	64	52
Rectum	30	37
<b>Tumor sites, %</b>		
1	19	30
2	36	38
3	27	16
<b>KRAS status, %</b>		
Mutant	54	47
Wild-type	41	44