

Effects of Regorafenib Therapy on Health-Related Quality of Life in Patients With Metastatic Colorectal Cancer in the Phase III CONCUR Trial

Abstract 697

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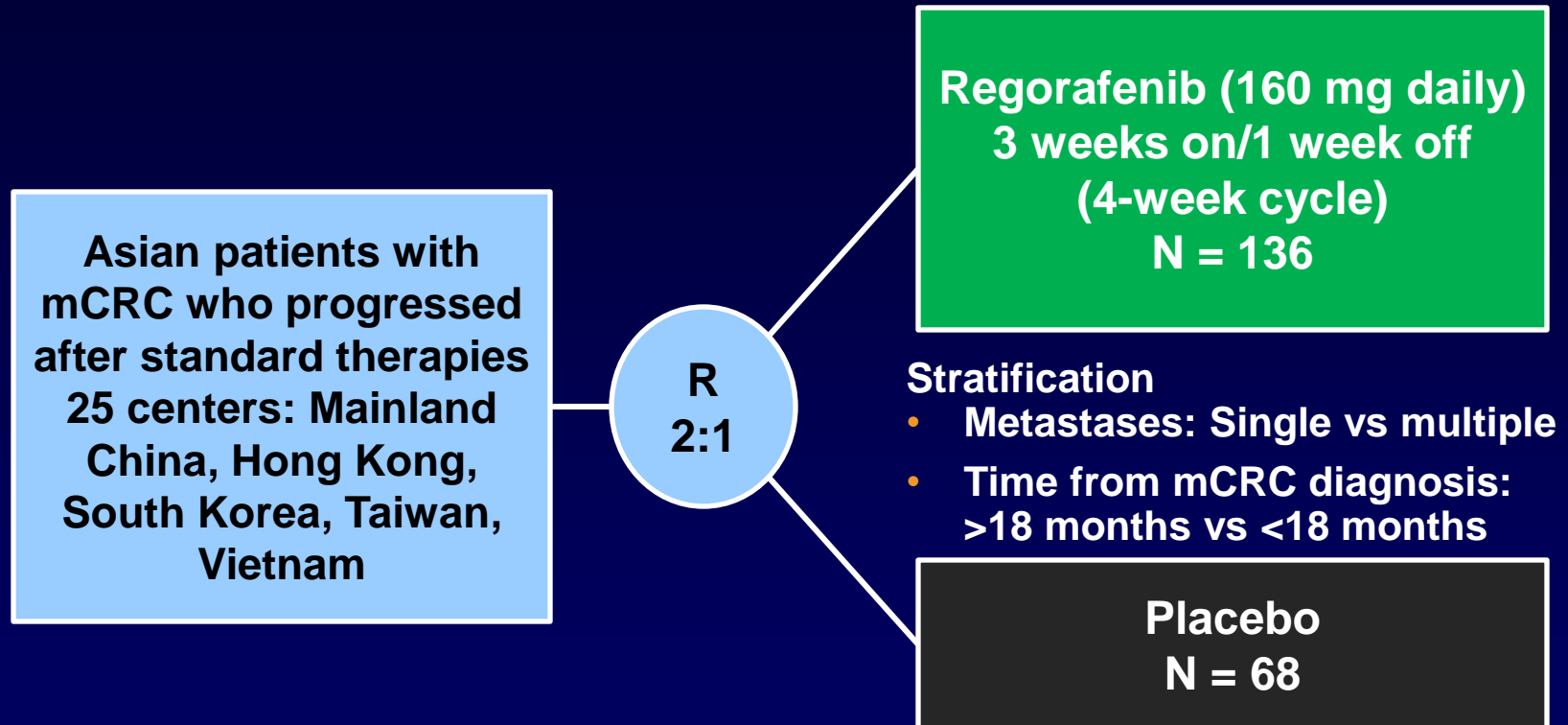
Background

- Regorafenib (REG) is an oral multikinase inhibitor that blocks the activity of multiple protein kinases that are involved in the regulation of angiogenesis, oncogenesis, and the tumor microenvironment
- Two phase III trials have shown that regorafenib significantly improves overall survival (OS) versus placebo (PBO) in patients with mCRC whose disease had progressed on standard treatments
 - CONCUR: HR 0.55 (95% CI 0.40-0.77; $P = .0002$)¹
 - CORRECT: HR 0.77 (95% CI 0.64-0.94; $P = .0052$)²
- The objective of this current study is to report the effects of regorafenib on health-related quality of life (HRQoL) in patients enrolled in the CONCUR trial

1. Grothey A, et al. *Lancet*. 2013;381:303-312. 2. Li Q, et al. *Ann Oncol*. 2014;25(Suppl 2): Abstract O-0023.

Qin S, et al. *J Clin Oncol*. 2015;33(suppl 3): Abstract 697.

Trial Design



Primary endpoint: OS

Secondary endpoints:

**Progression-free survival (PFS),
response rate, disease control rate (DCR)**

All patients received BSC

Treat until progression, unacceptable toxicity, or withdrawal

Key Inclusion Criteria

- Pathologically proven mCRC
- Measurable or nonmeasurable disease (RECIST v1.1)
- Failed ≥ 2 prior CRC treatment regimens, which included a fluoropyrimidine, oxaliplatin, and irinotecan
- Progression during or within 3 months after the last approved standard therapy or during or within 6 months of completing adjuvant oxaliplatin-based therapy
- Prior anti-VEGF or anti-EGFR targeted therapy allowed, but not mandatory
- ECOG performance status 0 or 1

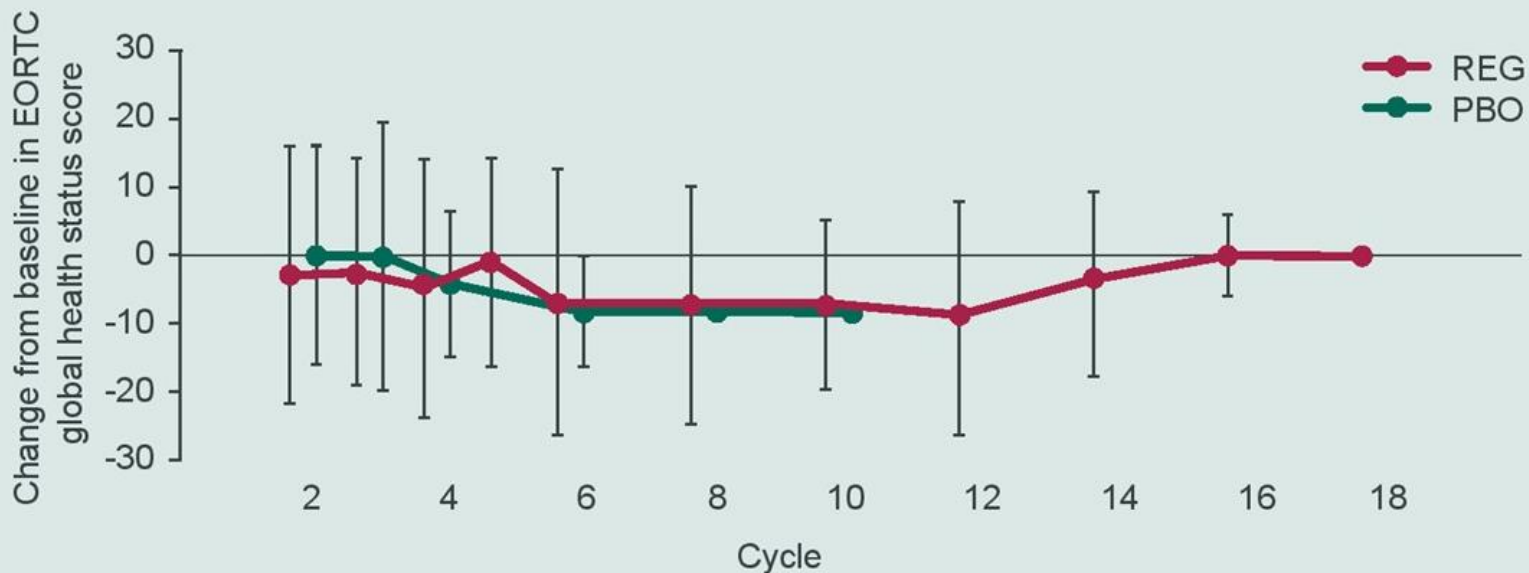
HRQoL Assessment

- HRQoL was assessed in all 204 patients in prespecified analyses using the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and the Euro-QoL five dimension questionnaire (EQ-5D) index and visual analog scale (VAS)
- HRQoL outcomes were expressed as least squares mean (LSM) time-adjusted area under the curve (AUC) to allow descriptive evaluation of HRQoL for both REG and PBO groups across the entire treatment period
 - Longitudinal change from baseline in scores on individual domains were also compared using descriptive statistics
- For both domains, higher scores represent better quality of life; a change in score of 10 points was considered the minimal clinically important difference

LSM Time-Adjusted AUC of HRQoL Scales

| LSM Time-Adjusted AUC (95% CI) | Reg (n = 131) | PBO (n = 63) |
|------------------------------------|---------------------------|---------------------------|
| EORTC QLQ-C30 global health status | 60.76 (58.81 to 62.71) | 61.16 (58.48 to 63.83) |
| Difference from placebo | -0.40 (-3.53 to 2.72) | |
| EQ-5D index | 0.70 (0.67 to 0.73) | 0.74 (0.70 to 0.78) |
| Difference from placebo | -0.03 (-0.08 to 0.01) | |
| EQ-5D VAS | 69.28 (67.48 to 71.08) | 70.46 (68.01 to 72.91) |
| Difference from placebo | -1.18 (-4.01 to 1.66) | |

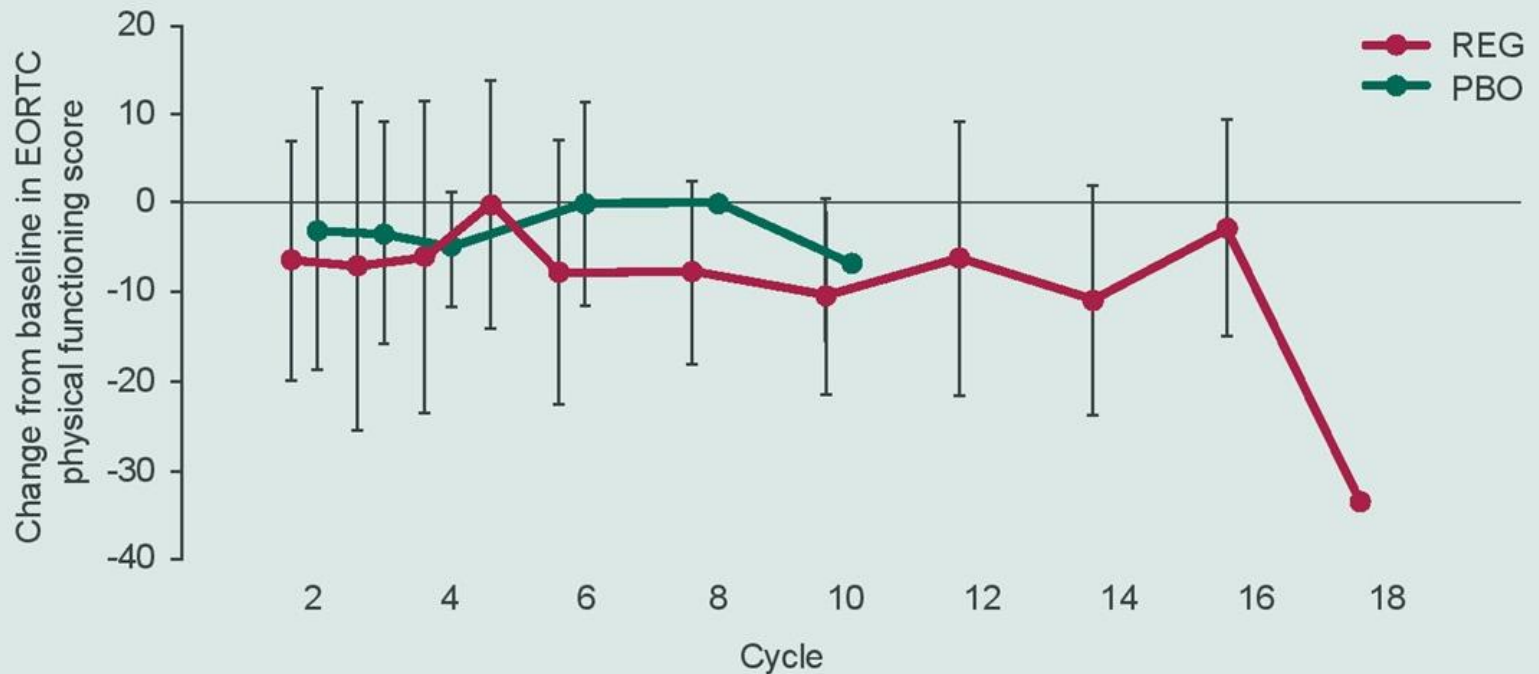
EORTC QLQ-C30 Global Health Status



Patients with completed questionnaires, n

| | | | | | | | | | |
|-----|-----|----|----|----|----|----|---|---|---|
| REG | 124 | 65 | 45 | 23 | 15 | 11 | 8 | 5 | 1 |
| PBO | 53 | 4 | 3 | 1 | 1 | 0 | 0 | 0 | 0 |

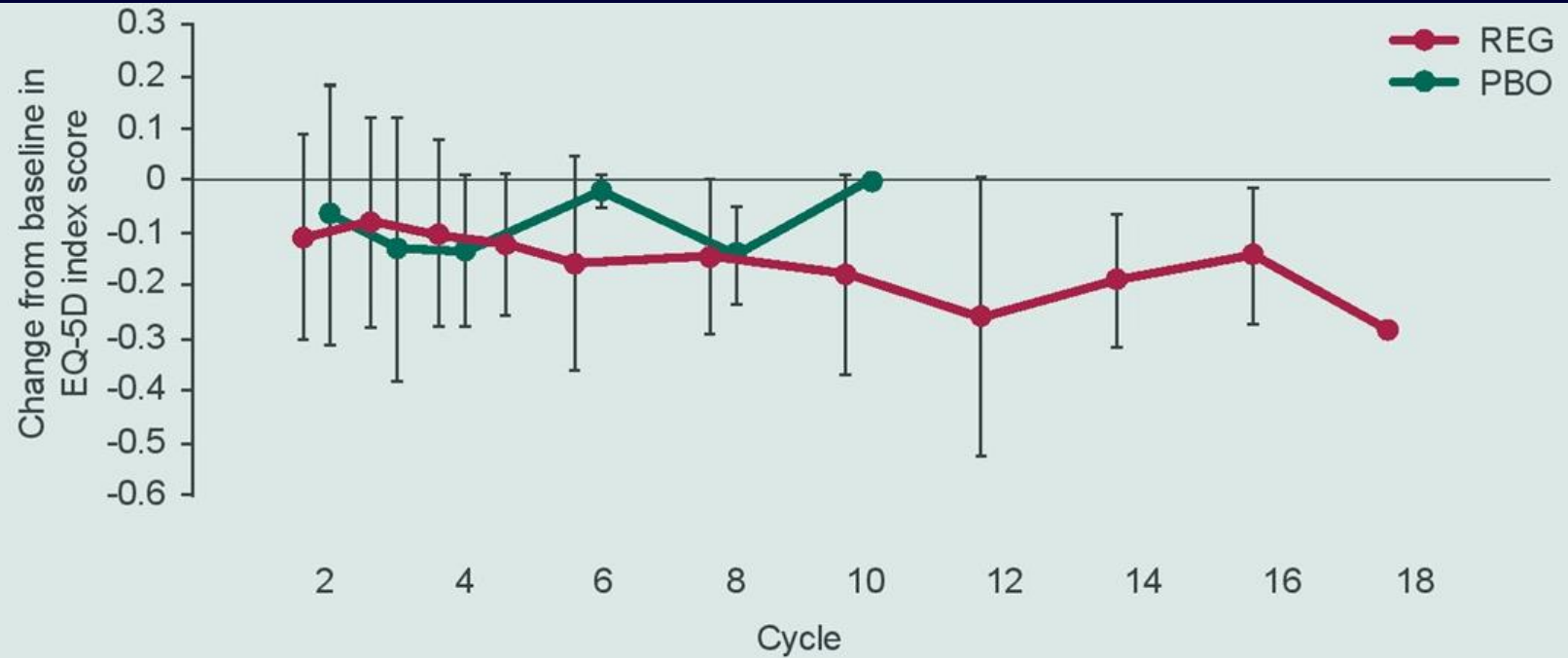
EORTC QLQ-C30 Physical Function Scores



Patients with completed questionnaires, n

| | | | | | | | | | |
|-----|-----|----|----|----|----|----|---|---|---|
| REG | 124 | 65 | 45 | 23 | 15 | 11 | 8 | 5 | 1 |
| PBO | 53 | 4 | 3 | 1 | 1 | 0 | 0 | 0 | 0 |

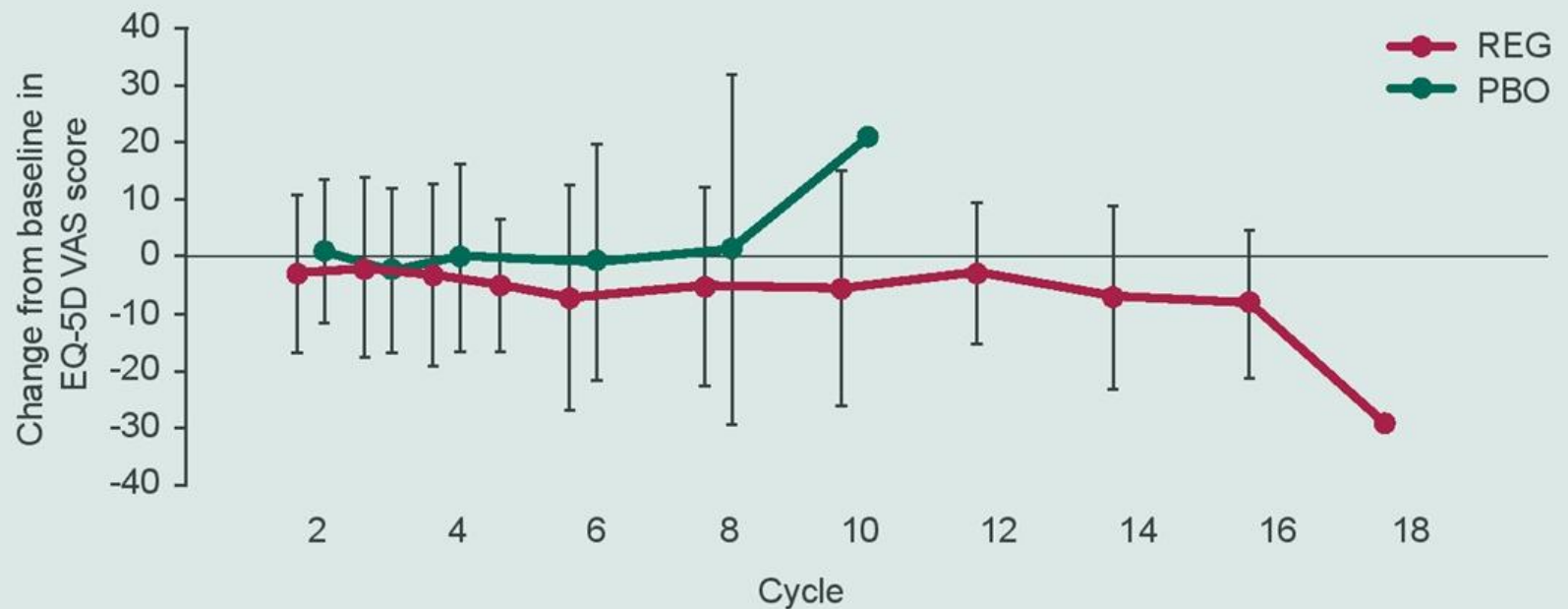
EQ-5D Index



Patients with completed questionnaires, n

| | | | | | | | | | |
|-----|-----|----|----|----|----|----|---|---|---|
| REG | 123 | 63 | 45 | 23 | 15 | 11 | 8 | 5 | 1 |
| PBO | 53 | 4 | 3 | 2 | 1 | 0 | 0 | 0 | 0 |

EQ-5D VAS Scores



Patients with completed questionnaires, n

| | | | | | | | | | |
|-----|-----|----|----|----|----|----|---|---|---|
| REG | 123 | 64 | 45 | 23 | 15 | 11 | 8 | 5 | 1 |
| PBO | 53 | 4 | 3 | 2 | 1 | 0 | 0 | 0 | 0 |

Conclusions

- HRQoL did not appear to differ in REG-treated patients compared with PBO recipients, as assessed by LSM time-adjusted AUC of EORTC global health status scores and EQ-5D index and VAS scores
- Longitudinal changes from baseline in EORTC QLQ-C30 global health status and physical functioning scores and EQ-5D index and VAS scores appeared generally similar in the REG and PBO groups
 - EORTC QLQ-C30 global health status and physical functioning appeared to be reduced from baseline in both the REG and PBO groups
- These findings indicate that REG significantly prolongs survival while maintaining comparable HRQoL versus PBO in Asian patients with mCRC, consistent with findings from the global CORRECT trial