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Abstract:

Background: Regorafenib (BAY 73-4506) is an oral multikinase inhibitor of a broad range of angiogenic, oncogenic, and stromal kinases. The phase III CORRECT trial was conducted to evaluate efficacy and safety of regorafenib in pts with mCRC who had progressed after all approved standard therapies. **Methods:** Enrollment criteria included documented mCRC and progression during or \leq 3 months after last standard therapy. Pts were randomized 2:1 to receive regorafenib (160 mg od po, 3 weeks on/1 week off) plus BSC, or placebo (PL) plus BSC. Pts continued on treatment until progression, death, or unacceptable toxicity. The primary endpoint was overall survival (OS). Secondary endpoints included progression-free survival (PFS), overall response rate (ORR), disease control rate (DCR), safety, and quality of life. **Results:** From May 2010 to March 2011, 760 pts were randomized (regorafenib: 505; PL: 255). Baseline characteristics were balanced between two arms. Preliminary results are available from a pre-planned formal interim analysis. The estimated hazard ratio (HR) for OS was 0.773 (95% CI: 0.635, 0.941; 1-sided $p=0.0051$). Median OS was 6.4 mos (95% CI: 5.9, 7.3) for regorafenib and 5.0 mos (95% CI: 4.4, 5.8) for PL. The estimated HR for PFS was 0.493 (95% CI: 0.418, 0.581; 1-sided $p < 0.000001$). Median PFS was 1.9 mos (95% CI: 1.88, 2.17) for regorafenib and 1.7 mos (95% CI: 1.68, 1.74) for PL. ORR was 1.6% for regorafenib and 0.4% for PL. DCR was 44% for regorafenib and 15% for PL ($p < 0.000001$). Since the prespecified OS efficacy boundary was crossed (nominal α : 0.0093), the Data Monitoring Committee recommended to unblind the study and pts on PL were allowed to cross over to regorafenib. The most frequent grade 3+ AEs in the regorafenib arm were hand-foot skin reaction (17%), fatigue (15%), diarrhea (8%), hyperbilirubinemia (8%), and hypertension (7%). Updated results will be presented. **Conclusions:** Statistically significant benefit in OS and PFS was observed for regorafenib over PL in pts with mCRC who have failed all approved standard therapies. No new or unexpected safety signal was found.