were to characterize the safety and effectiveness of regorafenib for the treatment of mCRC in real-world clinical practice. Here we present the results of the final analysis.

Methods: This prospective, observational study was conducted in 13 countries across Europe, Latin America, and Asia and recruited patients with mCRC who were previously treated with approved therapies, and for whom the decision to treat with regorafenib was made by the treating physician prior to enrollment, according to the local health authority approved label. Dose interruptions and reductions were permitted for the management of adverse events (AEs). The primary endpoint was the incidence of treatment-emergent AEs (TEAEs; NCI-CTCAE v4.03). Secondary endpoints included OS, progression-free survival (PFS), and disease control rate (DCR).

Results: A total of 1037 patients (61% male, 39% female) received treatment. At study entry, the median age was 65 years (range: 24–93), most patients were ECOG PS 0–1 (87%) versus PS 2–4 (6%), 56% had KRAS mutations and 37% did not, and the most common metastatic sites were the liver (72%) and the lung (57%). The median treatment duration was 2.5 months (range: 0.03–29.5). The initial daily regorafenib dose was 160 mg in 57% of patients, 120 mg in 30%, and 80 mg in 12%. Overall, 40% of patients had dose reductions; 48% had an interruption/delay, and 35% had no dose modifications. TEAEs of any grade occurred in 95% of patients, and were considered regorafenib related in 80% of patients. Grade $\geq$3 TEAEs occurred in 62% of patients, and in 36% of patients they were attributed to regorafenib. The most common grade $\geq$3 TEAEs were fatigue (10%), hypertension (8%), and hand–foot skin reaction (HFSR; 7%), with most being regorafenib related (fatigue 9%; HFSR 7%; hypertension 6%). Grade 5 TEAEs occurred in 17% of patients, and were considered regorafenib related in 1% of patients. Median OS was 7.6 months (95% confidence interval [CI]: 7.1–8.2) and median PFS was 2.8 months (95% CI: 2.6–2.8). DCR was 21.0% by radiologic assessment, with a partial response in 3.1% of patients as best response.

Conclusion: In this real-world, observational study, AEs were generally consistent with the known safety profile of regorafenib in mCRC, although reported incidence rates of some AEs were lower than in clinical trials. The starting dose for almost half of patients was less than 160 mg/day. Median OS and PFS were in the range observed in phase 3 trials in this setting.

O – 012 Safety and effectiveness of regorafenib in patients with metastatic colorectal cancer (mCRC) in routine clinical practice: Final analysis from the prospective, observational CORRELATE study

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Introduction: In the randomized, phase 3 CORRECT and CONCUR trials, regorafenib significantly improved overall survival (OS) versus placebo in patients with mCRC who progressed on standard therapies. The approved dose of regorafenib is 160 mg daily administered 3 weeks on/1 week off. The aims of CORRELATE (NCT02042144)