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An open-label trial to assess the safety of regorafenib in Turkish patients with metastatic colorectal cancer (mCRC) that progressed on standard therapy (REGARD)

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Introduction: Regorafenib is an oral multikinase inhibitor that significantly improved overall survival vs placebo in patients with mCRC refractory to available standard

therapies in two randomized phase III trials (Grothey, *et al. Lancet* 2013;381:303–312; Li, *et al. Ann Oncol* 2014 [suppl 2]:iii114). The aim of this open-label phase III study is to characterize the safety profile of regorafenib in Turkish patients with mCRC whose disease has progressed on standard therapies.

Methods: REGARD (ClinicalTrials.gov NCT01853319) is an ongoing, open-label trial. Eligible patients are ≥ 18 years of age with confirmed metastatic adenocarcinoma of the colon or rectum who have progressed during or within 3 months following the last administration of approved standard therapies (a fluoropyrimidine, oxaliplatin, irinotecan, bevacizumab, and an EGFR inhibitor if KRAS wild-type). Patients received regorafenib 160 mg orally once daily for weeks 1–3 of each 4-week cycle. Predefined treatment interruptions and dose reductions were permitted to manage adverse events (AEs). The primary objective is to assess safety. Planned recruitment was 100 patients.

Results: Patients were enrolled between July 2013 and July 2014 in 11 centers in Turkey. A total of 100 patients have received regorafenib treatment: 58% men; 42% women; median age at enrollment was 57 years (range 31–78) and 22% were 65 years of age or older. Baseline ECOG performance status was 0 in 54% of patients and 1 in 46% of patients; 53% of patients had tumors with KRAS mutations and 78% had liver metastasis. Time from first diagnosis of metastatic disease to regorafenib treatment assignment was ≥ 18 months in 83% of patients. Four patients are currently on treatment. The final analysis will be conducted when all patients complete the study.

Conclusion: REGARD is the first study assessing regorafenib in a large number of Turkish patients with mCRC that progressed on standard therapy.