gastrointestinal tumours, colorectal

A PROSPECTIVE, OBSERVATIONAL TRIAL TO FURTHER ASSESS SAFETY AND EFFICACY OF REGORAFENIB IN PATIENTS WITH METASTATIC COLORECTAL CANCER (MCRC) IN ROUTINE CLINICAL PRACTICE (CORRELATE)


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Background: The oral multikinase inhibitor regorafenib significantly improved overall survival vs placebo (HR 0.77, p = 0.0052) in patients with mCRC that progressed on available treatments in the randomized, double-blind, placebo-controlled CORRECT trial (Grothey, Van Cutsem et al. Lancet 2013). CORRELATE will characterize the safety and efficacy of regorafenib in real-world clinical practice.

Trial design: This prospective, observational, multicenter trial (ClinicalTrials.gov identifier NCT02042144) will be conducted in routine clinical practice settings in more than 25 countries in Europe, Latin America, and the Asia-Pacific region. The trial will recruit 3,000 patients with mCRC previously treated with other approved therapies and for whom a decision has been made to treat with regorafenib. Patients will receive oral regorafenib 160 mg once daily for weeks 1–3 of each 4-week cycle. Dose interruptions and reductions will be permitted for the management of adverse events. The primary endpoint is the incidence of treatment-emergent adverse events, assessed using National Cancer Institute Common Terminology Criteria for Adverse Events. Secondary endpoints are overall survival, progression-free survival, disease control rate, health-related quality of life (assessed using the EQ-5D questionnaire), and healthcare resource use. Data sources will include medical records, routine measurements, and patient-reported outcome questionnaires. All patients receiving ≥1 dose of regorafenib will be included in the overall analysis. Two planned interim assessments will occur after 1,000 and 2,000 patients have been observed for ≥3 months. The final analysis will be performed when all patients have been followed for ≥18 months from the time they discontinue regorafenib (unless they withdrew from the trial early because of death, consent withdrawal, or patient/investigator decision to stop). Recruitment is under way, with the first patient enrolled in April 2014; the estimated primary completion date is July 2017.

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