establishment of novel therapies in pretreated disease where there are few treatment options (Heiman et al. *Value Health*, 2014). The efficacy and safety of trifluridine/tipiracil (TAS-102) has been evaluated in the pivotal, phase 3, randomized, double-blind placebo-controlled in 800 pretreated mCRC patients (RECOURSE, Mayer et al, *NEJM* 2015). In 2016, trifluridine/tipiracil received European approval for the management of mCRC patients previously treated with, or not considered candidates for, available therapies. In order to confirm the established safety and efficacy profile in everyday practice, we designed a phase IIIb international, open-label, single-arm, early access program for trifluridine/tipiracil in mCRC patients.

Methods: Patients eligible for the study are men or women aged $\geq$18 years with histologically confirmed metastatic colorectal adenocarcinoma previously treated with, or not considered candidates for, available therapies including fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, anti-VEGF, and anti-EGFR agents. Other inclusion criteria are Eastern Cooperative Oncology Group performance status 0 or 1, and adequate organ function. Patients who have already received trifluridine/tipiracil, with known hypersensitivity to the active substances or excipients, or who have other serious illness or medical condition are ineligible. Trifluridine/tipiracil (35 mg/m^2 bid) is administered orally on days 1 to 5 and days 8 to 12 of each 28-day cycle. The primary study objective is to collect safety data, and all adverse events will be graded using the National Cancer Institute Common Terminology Criteria for Adverse Events (version 4.03). The treatment efficacy will be recorded on the basis of tumour assessments made by investigators according to standard of care. Other measurements will include quality of life (EQ-5D and EORTC QLQ-C30 questionnaires at baseline and every 4 weeks) and medical resource utilization data (inpatient stays, outpatient treatments, key concomitant medications, home care visits, and radiation therapy). The study is planned to include 20 countries (excluding North America and Asia) and has a target of 1000 patients. Due to the descriptive nature of the study, there is no formal sample size calculation. The first patient was enrolled in October 2016. The results will inform on the efficacy and safety of trifluridine/tipiracil in the context of daily practice. Interim results are expected in the summer of 2018.

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Results:

Conclusion:

P – 355 The international open-label early-access study of trifluridine/tipiracil (TAS-102) in patients with pretreated metastatic colorectal cancer (phase IIIb)

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Introduction: There have been many advances in the treatment of metastatic colorectal cancer (mCRC) over the last three decades. Despite this, there is a need for