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464P Safety and efficacy of trifluridine/tipiracil (FTD/TPI) in metastatic colorectal cancer (mCRC) patients according to previous treatment with regorafenib in the international phase IIIb PRECONNECT study

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Background: The oral chemotherapy trifluridine/tipiracil (FTD/TPI or TAS-102) is approved for treatment of previously treated mCRC patients (pts) beyond the second line, in the same setting as regorafenib. Optimal treatment sequencing between the two at this stage is not established. Here, a descriptive post hoc sub-group analysis assessed safety and efficacy of FTD/TPI in mCRC pts according to previous treatment with regorafenib in a preliminary analysis of the phase 3b PRECONNECT study (NCT03306394).

Methods: PRECONNECT is enrolling pts with histologically confirmed mCRC previously treated with available therapies, with an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0/1. Pts receive oral FTD/TPI (35 mg/m^2 bid) on days 1–5 and 8–12 of each 28-day cycle. Of the 462 patients who received at least one dose at cutoff (1 Nov 2017), 166 (36%) were pretreated with regorafenib.

Results: Patient subgroups pretreated (n = 166) and non-pretreated (n = 296) with regorafenib were broadly similar, with a slight imbalance for RAS mutant status (61% vs 47%), left-sided tumour (58% vs 65%) and treatment line (12% vs 36% receiving FTD/TPI third line), respectively. There was no difference in rate of emergent or drug-related any grade adverse events (AEs), or drug-related grade $\geq$3 AEs in pts treated with FTD/TPI between the regorafenib pretreated and regorafenib non-pretreated subgroups (98% vs 96%; 77% vs 79%; and 54% vs 51%, respectively). The most common drug-related grade $\geq$3 AEs were neutropenia (43% vs 40%) and anemia (8% vs 7%). Median FTD/TPI treatment duration were 2.7 and 3.1 months, with a median PFS of 2.7 (95% CI 2.2-3.3) and 3.3 months (95% CI 2.8-3.7), disease control rate was 38% (95% CI 30–46) and 43% (95% CI 37-49) and median time to ECOG-PS $\geq$2 was 8.5 and 8.7 months in the regorafenib pretreated and regorafenib non-pretreated, respectively.

Conclusions: FTD/TPI may be used either before or after regorafenib with similar efficacy results making treatment safety profile and patient quality of life major points to determine treatment option in third-line for mCRC patients.

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