TPS3637 Poster Session

An observational/translational study to conduct real-world evidence and develop biomarkers of fruquintinib for patients with metastatic colorectal cancer (mCRC): FruBLOOM trial (JACCRO CC-19).

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Background: The FRESCO-1/2 trials demonstrated a survival benefit of fruquintinib (FRU) in mCRC after 3rd-line therapy. FRU can be considered as one of the standard treatments for mCRC. The FRESCO-2 trial was conducted in patients (pts) treated with FTD/TPI and/or regorafenib (Rego) and did not include pts who were not using either agent. Although FTD/TPI + bevacizumab (Bev) is currently one of 3rd-line standard treatments for mCRC, there are few data regarding the efficacy and safety of FRU in pts after FTD/TPI + Bev. Therefore, this study will accumulate real-world-data of FRU in clinical practice and evaluate the efficacy and safety of FRU after FTD/TPI + Bev. Also, we will evaluate clinical outcomes of FRU as 3rd- or later-line treatment after both FTD/TPI + Bev and Rego. The predictive biomarkers of FRU in the later-line setting hold significant clinical promise, for choosing personalized treatment plans (e.g., FRU vs. FTD/TPI + Bev / Rego) and enhancing the prognosis of mCRC pts. Therefore, this translational study approaches developing biomarkers for predicting FRU efficacy by analyzing pre-treatment blood samples. Furthermore, we will explore treatment resistance mechanisms using post-treatment blood samples. **Methods:** This is a multicenter observational/translational study to prospectively evaluate the efficacy and safety of FRU as a 3rd- or later-line treatment, mainly after FTD/TPI + Bev in mCRC pts in clinical practice. We will enroll 200 pts receiving FRU after FTD/TPI + Bev to the cohort A, and 100 pts receiving FRU as 3rd-line or after both FTD/TPI + Bev and Rego to the cohort B. Eligibility criteria are (1) pts with CRC confirmed as adenocarcinoma, (2) pts planning to receive FRU monotherapy as 3rd- or later-line treatment, (3) prior treatments with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, an anti-EGFR therapy (if *RAS*/*BRAF* wild-type), BRAF therapy (if *BRAF* mutant), and immune checkpoint inhibitor (if MSI-high), (4) pts with ECOG Performance Status of 0-2, (5) pts must be at least 18 years of age at the time of consent, and (5) pts have measurable or evaluable lesions in RECIST v1.1. The primary endpoint is overall survival in pts of the cohort A. The secondary endpoints are clinical outcomes including response rate, progression-free survival, duration of response, and safety in pts of the cohort A and B. In the biomarker study, blood samples will be prospectively collected before and after treatment, for translational research including genomic alteration analysis in circulating tumor-DNA by DNA exome sequencing, gene expression measurement in cfRNA by tumor-educated blood platelets (TEP)-Seq RNA analysis, and plasma proteins analysis by multiplex immunoassay panels. Enrollment opens in February 2025 (UMIN000056813). Clinical trial information: UMIN000056813. Research Sponsor: Takeda.