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Abstract CT131: A randomized, double-blind, phase III study comparing trifluridine/tipiracil (FTD/TPI) versus placebo in patients with molecular residual disease following curative resection of colorectal cancer (CRC): The ALTAIR Study FREE

Hideaki Bando; Jun Watanabe; Masahito Kotaka; Nobuhisa Matsuhashi; Eiji Oki; Yoshito Komatsu; Manabu Shiozawa; Keiji Hirata; Yuji Miyamoto; Kun-Huei Yeh; Shruti Sharma; Vasily Aushev; Adham Jurdi; Minetta C. Liu; Alexey Aleshin; Ichiro Takemasa; Daisuke Kotani; Akihito Sato; Toshihiro Misumi; Yoshiaki Nakamura; Qian Shi; Hiroya Taniguchi; Takeshi Kato; Takayuki Yoshino

+ Author & Article Information

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Abstract

Background:

Tumor-informed circulating tumor (ct) DNA testing is recognized as a powerful predictor of CRC recurrence. However, the benefit of systemic therapy to prevent or delay clinical recurrence in patients (pts) with molecular recurrence after curative surgery remains uncertain.

Methods:

Pts with CRC who had undergone curative resection of primary and/or metastatic sites + standard of care (SoC) adjuvant treatment, if applicable, were enrolled in ALTAIR study if they (1) prospectively tested positive for ctDNA using a clinically validated, personalized assay (Signatera™, Natera, Inc.) within 3 months before enrollment and (2) had no recurrence on radiological (CT) imaging. Pts were randomized to receive FTD/TPI or placebo for 6 months. CT scans and ctDNA analyses were conducted every 2 months in the first year, every 3 months in the second year, and every 6 months in the third year. The primary endpoint was disease-free survival (DFS), with secondary endpoints including ctDNA clearance, overall survival (OS), and adverse events. The study assumed a median DFS of 8 months in the placebo group, an HR of 0.667 for the FTD/TPI group, 0.05 significance level, 0.80 power, 2-year enrollment, and 1-year follow-up, requiring 240 pts and 190 DFS events. Baseline ctDNA levels were evaluated by mean tumor molecules (MTM)/ml.

Results:

Between July 2020 and June 2023, 243 pts were enrolled and randomized to FTD/TPI (n=122) or placebo (n=121). Baseline characteristics were balanced, and 96.3% of pts received SoC treatment postoperatively. FTD/TPI group had a median DFS of 9.30 months vs. 5.55 months in the placebo group, which did not reach statistical significance in the primary population (HR, 0.79; 95% CI, 0.60-1.05; *P* = 0.107). The benefit was highly pronounced, however, in stage IV pts (HR: 0.53, P = 0.012). In addition, after excluding pts with low ctDNA levels (<0.179 MTM/mL, threshold determined by ROC analysis) from both arms, significant benefit with FTD/TPI was observed in the primary population, resulting in an improved DFS (N=154, HR: 0.61 95% CI: 0.43-0.85; P = 0.003) with a median DFS of 8.12 months for FTD/TPI vs. 3.89 months for placebo; consistent with these findings, a trend toward higher ctDNA clearance rate was observed for the FTD/TPI group (8.33%), compared to placebo (4.05%).OS data remain immature, with 24 events reported across both arms. Grade ≥3 adverse events occurred in 73.0% of the FTD/TPI arm versus 3.3% in the placebo arm, with no new safety signals.

Conclusions:

Although statistical significance was not reached in the primary population, FTD/TPI showed benefit in pts with high molecular tumor burden and/ or Stage IV disease, resulting in improved DFS.

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