**INTRODUCTION**

- The addition of cetuximab to first-line standard irinotecan-5-fluorouracil (FOLFIRI) or oxaliplatin (FOLFOX) improved clinical outcomes in patients with RAS wild-type metastatic colorectal cancer (mCRC), as shown in the randomized CRYSTAL and OPUS trials.1,2
- These results have led to the formulation of combination chemotherapy with cetuximab or panitumumab plus FOLFOX or FOLFOX as a standard-of-care first-line treatment for mCRC patients with mCRC.
- CRYSTAL and OPUS enrolled predominantly Caucasian patients.1,2
- The randomized CRYSTAL and OPUS trials demonstrated the superiority of combination chemotherapy with cetuximab plus FOLFOX over FOLFOX alone in terms of response rate, survival, and safety/tolerability.
- Based on emerging scientific evidence, the protocol was amended to consider only patients with RAS wild-type mCRC, who comprised the modified intent-to-treat (mITT) population.

**METHODS**

- **TAILOR** (EMR22023-007, NCT01893784) is an open-label, randomized, multicenter phase 3 trial that includes an mITT population of 380 patients from China with RAS wild-type mCRC (Figure 1).

**RESULTS**

- **Patient characteristics**
  - The mITT population comprised 380 patients from China with RAS wild-type mCRC:
    - 194 patients in the cetuximab plus FOLFOX-4 arm and 196 patients in the FOLFOX-4 arm.
  - The modified safety population includes 380 patients from China with RAS wild-type mCRC.
  - 194 patients were treated with cetuximab plus FOLFOX-4, and 196 patients received FOLFOX-4.
  - Baseline characteristics were reasonably balanced between treatment arms (Table 1).

- **Treatment exposure**
  - Cumulative data, number of courses, and relative dose intensity (RDI) data are presented in Table 2.
  - Higher cumulative chemotherapy doses in the cetuximab plus FOLFOX-4 vs FOLFOX-4 arm likely reflect longer dosing duration due to the longer PFS.

- **Efficacy**
  - Adding cetuximab to FOLFOX-4 significantly improved the primary endpoint of median PFS by 5.6-7.9 months (HR: 0.70, 95% CI: 0.61-0.89; p = .004) compared to patients in the FOLFOX-4 arm (Table 3).
  - ORR was also significantly higher in the cetuximab plus FOLFOX-4 vs FOLFOX-4 arm (Table 3).
  - After 300 events (76.3% of the mITT population), current assessment of median OS suggests it is 11.7 vs 13.0 months (HR: 0.76, 95% CI: 0.61-0.96; p = .004) compared to patients in the FOLFOX-4 arm (Table 4).

**CONCLUSIONS**

- **The TAILOR study** met its primary endpoint and confirms cetuximab in combination with chemotherapy as a standard-of-care first-line treatment regimen for patients with RAS wild-type mCRC.
- **The addition of cetuximab to first-line FOLFOX chemotherapy significantly improved PFS, ORR, and OS in patients from China with RAS wild-type mCRC; an observation that is consistent with previous pivotal studies.**
- **There were no new or unexpected safety findings.**
- **Safety**
  - All adverse events during treatment were managed as per protocol, and no deaths specifically related to cetuximab were observed.

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**DISCLOSURES**

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