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Health-related quality of life (HRQoL) in patients (pts) treated with pembrolizumab (pembro) vs chemotherapy as first-line treatment in microsatellite instability-high (MSI-H) and/or deficient mismatch repair (dMMR) metastatic colorectal cancer (mCRC): Phase III KEYNOTE-177 study

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Background

Pembro monotherapy significantly improved PFS vs standard of care (SOC) chemotherapy as first-line treatment in pts with MSI-H or dMMR mCRC in the phase III KEYNOTE-177 (NCT02563002) study. HRQoL results are reported.

Methods

Pts with confirmed MSI-H/dMMR mCRC with no prior systemic therapy for mCRC were randomized 1:1 to pembro 200 mg Q3W for up to 2 y or investigator's SOC choice of mFOLFOX6 or FOLFIRI Q2W ± bevacizumab or cetuximab. EORTC QLQ-C30, EORTC QLQ-CR29, and EQ-5D-3L were administered at baseline and at various time points up to 1 y or end of treatment, whichever came first, and at 30 days after treatment discontinuation. Data from pts receiving ≥1 dose of study treatment and completing ≥1 HRQoL assessment were analyzed. Least-squares mean (LSM) score change from baseline to prespecified wk 18, 95% CI, and nominal 2-sided *P* values were calculated. Time to deterioration (TTD; ≥10-point decline from baseline) was assessed by Kaplan-Meier method and Cox regression model. HRs, 95% CIs, and nominal 1-sided *P* values are provided.

Results

Data for 294 pts (152, pembro; 142 SOC) were available for HRQoL analyses. Compliance at baseline was >90% in pembro and SOC arms for all 3 questionnaires and remained high at wk 18 (>85% and >75%, respectively). LSM change from baseline to wk 18 showed clinically meaningful improvement in QLQ-C30 global health status (GHS)/QoL (LSM difference: 8.96; 95% CI, 4.24-13.69; *P*=0.0002) and EQ-5D VAS (LSM difference: 7.38; 95% CI, 2.82-11.93; *P*=0.0016) for pts receiving pembro vs SOC. Prolonged TTD for pts receiving pembro vs SOC was observed for GHS/QoL (HR, 0.61; 95% CI, 0.38-0.98; *P*=0.0195), physical functioning (HR, 0.50; 95% CI, 0.32-0.81; *P*=0.0016), social functioning (HR, 0.53; 95% CI, 0.32-0.87; *P*=0.0050), and fatigue (HR, 0.48; 95% CI, 0.33-0.69; *P*≤0.0001).

Conclusions

Pembro monotherapy demonstrated clinically meaningful improvements in HRQoL vs SOC chemotherapy in pts with previously untreated MSI-H/dMMR mCRC.

Clinical trial identification

NCT02563002.

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