Erbitux™ (Cetuximab) Plus FOLFOX for Colorectal Cancer (EXPLORE): Preliminary efficacy analysis of a randomized phase III trial

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Abstract

Background

The EXPLORE study was designed as a randomised phase III study to evaluate the efficacy and tolerability of the combination of cetuximab with FOLFOX4 in patients with metastatic colorectal cancer (mCRC) in the first-line setting. Patients were randomised to receive FOLFOX4 alone or cetuximab plus FOLFOX4. The primary endpoint of the study was time to progression (TPP). Safety and efficacy data by the arm are presented.

Methods

Eligibility criteria included: ECOG performance status 0-2, EGFR positive, metastatic colorectal cancer, and treatment naïve with respect to irinotecan or fluoropyrimidine. The primary endpoint was time to progression. The randomisation was stratified by study site and ECOG performance status (0-1, 2). Patients received the following: Oxaliplatin 85mg/m² and leucovorin 400mg/m² loading weekly, and 250mg/m² daily and 5-FU 200mg/m² d1 and d2 weekly. Patients also received cetuximab 400mg/m² weekly (FOLFOX4 q 2 weeks). The study is closed to accrual. The study is closed to accrual.

Key Eligibility

- EGFR positive, metastatic colorectal cancer
- ECOG performance status 0-2
- Prior severe infusion reaction to monoclonal antibody therapy
- Prior chemotherapy for treatment of metastatic colorectal carcinoma.

Key Outcomes

- Disease control rate
- Response rate
- Overall survival
- Progression-free survival
- Safety profile

Results

TPP was 20.5 months in the cetuximab plus FOLFOX4 arm compared to 15.2 months in the FOLFOX4 arm (log-rank p-value: 0.0036, 95% CI 1.32-2.72). The median overall survival was not reached in the cetuximab plus FOLFOX4 arm compared to 13.4 months in the FOLFOX4 arm (log-rank p-value: 0.0323, 95% CI 1.16-5.10). The incidence of adverse events was consistent with previous reports of the agent. A total of 102 patients were randomised to the current trial. The study was designed to accrue 1100 pts, but due to changes in the standard of care, enrollment to the EXPLORE study was stopped. The study is closed to accrual.

Conclusions

Due to changes in the standard of care, enrollment to the EXPLORE trial was stopped with a total number of 102 patients.

References


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