Axitinib or bevacizumab plus FOLFOX or FOLFIRI as second-line therapy in patients with metastatic colorectal cancer

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INTRODUCTION

- The present analysis is a phase II study (NCT00747870) of axitinib in patients with metastatic colorectal cancer (mCRC) who had previously received bevacizumab plus chemotherapy. Patients were randomized 1:1 to axitinib or bevacizumab with either FOLFOX or FOLFIRI. The primary endpoint was median overall survival (OS) in an intention-to-treat (ITT) population.

METHODS

- Study design and objectives: In a double-blind, patients previously treated with chemotherapy containing regimens including bevacizumab plus oxaliplatin (FOLFOX) or fluorouracil/leucovorin plus irinotecan (FOLFIRI), patients aged 18–75 years with at least one measurable lesion were randomized 1:1 to receive axitinib plus FOLFOX or bevacizumab plus FOLFOX (Study design).

OBJECTIVE

- Patients stratified by ECOG PS (0 vs 1) and prior bevacizumab treatment.

RESULTS

- Overall, 171 patients were randomized (axitinib-FOLFOX n=86; bevacizumab-FOLFOX n=85).
- In an ITT analysis, axitinib-FOLFOX was associated with a trend towards a survival benefit compared with bevacizumab-FOLFOX (HR 1.17, 95% CI 0.72–1.92; p=0.46). In a subset analysis of patients without prior bevacizumab treatment, there was an OS benefit in favor of axitinib-FOLFOX (HR 1.49, 95% CI 0.53–4.19; p=0.46).

CONCLUSIONS

- Axitinib plus FOLFOX was associated with a trend towards better overall survival compared with bevacizumab plus FOLFOX.

ACKNOWLEDGMENTS

- The study was supported by Genentech, Inc., South San Francisco, CA, USA.

REFERENCES


Figure 2. Progression-free survival (PFS) by treatment group, with or without prior bevacizumab exposure

Figure 3. Objective response rate by treatment group, with or without prior bevacizumab exposure

Table 1. Patient characteristics

Table 2. Treatment-emergent adverse events

Table 3. Efficacy analyses

Figure 4. Overall survival (OS) by treatment group, with or without prior bevacizumab exposure

Figure 5. Median overall survival (OS) by treatment group, with or without prior bevacizumab exposure

Axitinib/FOLFOX Bevacizumab/FOLFOX Axitinib/FOLFIRI Bevacizumab/FOLFIRI

Study Treatments

- Axitinib was administered orally daily with a starting dose of 5 mg BID. This could be increased to 7.5 mg BID. Axitinib was administered in 21-day cycles. Dose reductions were permitted for toxicity.
- Bevacizumab was administered intravenously (IV) over 90 minutes concurrently with oxaliplatin or leucovorin over 120 minutes; do not exceed 15 mg/m2 IV every 2 weeks.

OBJECTIVE

- Efficacy analyses were performed in the intent-to-treat population.

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