North American Subgroup Results From VELOUR: Ziv-Aflibercept vs Placebo Plus FOLFIRI in mCRC That Is Resistant to or Has Progressed After an Oxaliplatin-Containing Regimen
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ABSTRACT

Background: The North American subgroup analysis from the phase 3 VELOUR trial was conducted to evaluate the safety and efficacy of Ziv-aflibercept + FOLFIRI vs placebo plus FOLFIRI in patients with metastatic colorectal cancer (mCRC) who were naïve to oxaliplatin or had progression after an oxaliplatin-containing regimen. The study was designed and powered to demonstrate a statistically significant difference between the Ziv-aflibercept plus FOLFIRI and placebo plus FOLFIRI treatment groups in overall survival (OS), based on the multinational phase 3 VELOUR trial (N=1226) that showed statistically significant improvements in overall survival (OS), progression-free survival (PFS), and response rate; OS, overall survival; PFS, progression-free survival.

Methods: The North American subgroup analysis included patients in the 50 US states plus Puerto Rico (n=612). Patients were randomized to receive Ziv-aflibercept (4 mg/kg) + FOLFIRI or placebo plus FOLFIRI every 2 weeks for up to 6 cycles. The primary endpoint was OS for the North American subgroup. The North American subgroup was similar in terms of prior bevacizumab use, but more patients in the placebo arm had liver-only metastases compared with the Ziv-aflibercept arm. Overall survival by geographic region is compared in Table 1 and Figure 1. The North American subgroup included patients in the US states plus Puerto Rico (n=73). The subgroup was generally well balanced in terms of the number of metastatic organs involved, % metastatic organ involvement, and number of cycles received.

Results: Median OS and PFS in the North American subset from VELOUR were consistent with the global study. The addition of ziv-aflibercept to FOLFIRI resulted in a statistically significant improvement in median OS: 13.50 months with placebo (95% CI, 11.072-13.109) vs 15.67 months with ziv-aflibercept (95% CI, 14.404-16.936) (P<0.0001). The addition of ziv-aflibercept to FOLFIRI also resulted in a statistically significant improvement in median PFS: 6.01 months with placebo (95% CI, 4.170-7.848) vs 7.46 months with ziv-aflibercept (95% CI, 5.980-9.936) (P=0.0002). The addition of ziv-aflibercept to FOLFIRI resulted in a statistically significant improvement in overall response rate: 30% ORR with placebo vs 43% ORR with ziv-aflibercept (P<0.0001). There was no grade 4 AEs associated with the addition of ziv-aflibercept to FOLFIRI.

The North American subgroup was included patients in the US states plus Puerto Rico (n=73). The subgroup was generally well balanced in terms of the number of metastatic organs involved, % metastatic organ involvement, and number of cycles received.

Conclusions: The North American subgroup analysis from the phase 3 VELOUR trial showed that the addition of ziv-aflibercept to FOLFIRI resulted in statistically significant improvements in overall survival (OS), progression-free survival (PFS), and overall response rate; OS, overall survival; PFS, progression-free survival.

INTRODUCTION

The North American subgroup analysis from the phase 3 VELOUR trial was conducted to evaluate the safety and efficacy of Ziv-aflibercept + FOLFIRI vs placebo plus FOLFIRI in patients with metastatic colorectal cancer (mCRC) who were naïve to oxaliplatin or had progression after an oxaliplatin-containing regimen. The study was designed and powered to demonstrate a statistically significant difference between the Ziv-aflibercept plus FOLFIRI and placebo plus FOLFIRI treatment groups in overall survival (OS), based on the multinational phase 3 VELOUR trial (N=1226) that showed statistically significant improvements in overall survival (OS), progression-free survival (PFS), and response rate; OS, overall survival; PFS, progression-free survival.

Patients were included if they were ≥18 years old who were naïve to oxaliplatin or had progression after an oxaliplatin-containing regimen. The North American subgroup was included in patients in the 50 US states plus Puerto Rico (n=612). The primary endpoint was OS for the North American subgroup. The North American subgroup was similar in terms of prior bevacizumab use, but more patients in the placebo arm had liver-only metastases compared with the Ziv-aflibercept arm. Overall survival by geographic region is compared in Table 1 and Figure 1. The North American subgroup was included patients in the US states plus Puerto Rico (n=73). The subgroup was generally well balanced in terms of the number of metastatic organs involved, % metastatic organ involvement, and number of cycles received.

RESULTS

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DISCUSSION

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LIMITATIONS

The North American subgroup analysis from the phase 3 VELOUR trial showed that the addition of ziv-aflibercept to FOLFIRI resulted in statistically significant improvements in overall survival (OS), progression-free survival (PFS), and overall response rate; OS, overall survival; PFS, progression-free survival.

REFERENCES


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