AFLIBERCEPT + FOLFIRI FOR TREATMENT OF METASTATIC COLORECTAL CANCER AFTER OXALIPLATIN FAILURE: 4TH INTERIM SAFETY DATA FROM THE GLOBAL AFLIBERCEPT SAFETY AND QUALITY-OF-LIFE PROGRAM (ASQoP/AFEQT STUDIES)


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Aim: In VELOUR, aflibercept (ziv-aflibercept in the US) + FOLFIRI demonstrated a statistically significant improvement in overall survival vs placebo + FOLFIRI in metastatic colorectal cancer (mCRC) patients (pts) previously treated with an oxaliplatin-containing regimen. Results supported initiation of the global Aflibercept Safety and Quality-of-Life (QoL) Program composed of 2 clinical studies (ASQoP; AFEQT) to capture utility values from QoL instruments and collect safety data from a population similar to that in VELOUR in a real-life setting. We report safety data from the 4th interim analysis of these ongoing studies.

Methods: ASQoP and AFEQT are single-arm, open-label trials in mCRC pts previously treated with an oxaliplatin-containing regimen. Eligible pts received aflibercept 4 mg/kg every 2 weeks on day 1 of each cycle followed by FOLFIRI. FOLFIRI starting dose and subsequent additional dose modifications are at discretion of the treating physician.

Results: At data cut-off for this interim analysis, the safety population (n = 688) was compared with VELOUR. In 44% of ASQoP vs 33.5% of VELOUR, pts were ≥65 years; 10.8% of ASQoP vs 5.4% of VELOUR were ≥75 years. ASQoP pts received a median of 6 treatment cycles while VELOUR pts received a median of 9. Grade (G) 3/4 adverse events (AEs) were experienced by 72.2% of ASQoP pts vs 83.5% in VELOUR. Most were G3. G4 hypertension or diarrhea was not reported. Table shows selected G3/4 AEs.

Conclusions: Interim safety analysis from ASQoP/AFEQT has identified no new safety signals. Despite a greater % of elderly pts in ASQoP/AFEQT, reported incidence of toxicity is generally similar or less than VELOUR. Differences in AE incidence in ASQoP/AFEQT vs VELOUR may be related to the VELOUR protocol requirement of full-dose FOLFIRI initiation and current overall exposure differences.

Disclosure: J. Taieb: has conflicts of interest related to advisory boards for Sanofi and for corporate-sponsored research for Sanofi; Y. Moore: formerly held a leadership position at Sanofi at the time this study was conducted and has stock ownership in Sanofi; C. Zilocchi: is an employee of Sanofi and has stock ownership; S. Brette: is an employee (biostatistician) of Lincoln, which is a consultant for Sanofi. A. Sobrero: has received honoraria for participating in advisory boards for Bayer, Roche, Sanofi, Celgene, Merck, and Amgen. All other authors have declared no conflicts of interest.