

O – 016 First-line FOLFOX plus panitumumab followed by 5-FU/LV plus panitumumab or single-agent panitumumab as maintenance therapy in patients with RAS wild-type metastatic colorectal cancer (mCRC): The VALENTINO study

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Introduction: Since mCRC registration first-line trials scheduled the continuation of doublets plus anti-EGFRs until progressive disease (PD), there is still no evidence if de-escalating treatment intensity after an anti-EGFR-based induction phase might be not inferior in terms of disease control, while reducing toxicity burden and improving quality of life. The MACRO-2 trial suggested that maintenance with cetuximab alone after mFOLFOX + cetuximab achieved a progression-free survival (PFS)% not inferior than mFOLFOX + cetuximab until PD in KRAS exon 2 wild-type patients.

Methods: 229 RAS wild-type unresectable mCRC patients were enrolled and received FOLFOX + panitumumab induction (8 cycles) followed, in absence of PD, by 1:1 randomly-assigned maintenance with panitumumab (arm B) or panitumumab + 5-FU/LV (arm A) until PD/unacceptable toxicity/death. The primary endpoint was to demonstrate the non-inferiority of 10-month (10-m) PFS% of arm B vs A. An overall sample size of 224 subjects (112 in the control group and 112 in the study group) achieved 90% power to detect a 50% 10-m PFS in arm A and a maximum 15% difference in arm B, with a significance level of 0.1 and a 15% drop-out rate. Secondary endpoints were safety, PROs, response rate, duration of response, time to treatment failure and overall survival.

Results: Will be provided after primary analysis with central RAS and BRAF molecular analyses.

Conclusion: NA