**Gastrointestinal Tumours, Colorectal**

**MAINTENANCE STRATEGY WITH FLUOROPYRIMIDINES (FP) PLUS BEVACIZUMAB (BEV), BEV ALONE OR NO TREATMENT, FOLLOWING A 24-WEEK FIRST-LINE INDUCTION WITH FP, OXALIPLATIN (OX) AND BEV FOR PATIENTS WITH METASTATIC COLORECTAL CANCER: MATURE DATA AND SUBGROUP ANALYSIS OF THE AIO KRK 0207 PHASE III STUDY**


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**Aim:** AIO KRK 0207 investigates which maintenance strategy, no treatment or Bev alone, is non-inferior to FP plus Bev, following a 24-week induction with FP/Ox/Bev.

**Methods:** Following registration pts received induction treatment with FP/Ox/Bev. Pts without progression after 24 weeks were randomized into arms: A) standard maintenance with FP plus Bev; B) Bev alone; or C) observation. At first progression, re-induction of the initial treatment was planned. Primary endpoint was the "time to failure of strategy" (TFS), including maintenance plus re-induction after first progression. Secondary endpoints included time to first progression (PFS1) and overall survival (OS).

**Results:** 837 pts were enrolled, 473 randomized. Primary tumor was resected in 74% of pts, 56% had involvement of >1 site. Median PFS1 in arms A, B, C were 6.2 vs 4.8 vs 3.6 mos., respectively (logrank p value: <0.0001). After PFS1, only 21%, 43% and 45% were re-induced. For TFS, arm C is slightly inferior compared to arm A (median: 6.8 vs. 6.1 mos., HR 1.22, 95% CI 0.96-1.57, p = 0.11), but without difference between arms A and B (HR 0.98, 95% CI 0.76-1.26, p = 0.85). With currently limited follow up and 203 documented events, OS does not differ between treatment arms (median: 23.8, 26.2 and 23.1 mos., p = 0.75). 60% of pts had CR/PR after induction, 40% SD. TFS of pts with CR/PR is superior to pts with SD (median 7.5 vs. 4.6 mos., p < 0.0001). In pts with SD, arm A seems to be superior to B (and C), whereas there is no difference between all arms in pts with CR/PR. "All RAS" status was centrally assessed in 337 (71%) of pts; 42% were wild-type (wt) and 58% mutant (mut). TFS of pts with RAS wt is marginally superior to pts with RAS mut (median 8.5 vs. 7.1 mos., p = 0.047). In pts with RAS wt, A and B are superior to C, whereas there is no difference between all arms in pts with RAS mut. Global quality of life did not differ between arms.

**Conclusions:** With respect to the primary endpoint TFS, our findings suggest that maintenance with Bev mono is non-inferior to FP/Bev. Updated results including OS, multivariate analyses and sequential treatment data will be presented.

**Disclosure:** S. Hegewisch-Becker: Advisory role: Merck, Roche. Updated results including OS, multivariate analyses and sequential treatment data will be presented.

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Abstracts

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