**Results of bevacizumab biosimilar compared with RMP for the treatment of metastatic colorectal cancer.**

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* [**Abstract**](http://ascopubs.org/doi/abs/10.1200/JCO.2017.35.15_suppl.e14065)

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**Background:** BEVZ92 has being developed as a proposed biosimilar approved reference medicine product (RMP). BEVZ92 has an identical amino acid sequence and highly similar physicochemical and *in vitro* functional properties to RMP. The aim of this study was to demonstrate pharmacokinetics (PK) similarity of BEVZ92 to RMP, in combination in combination with FOLFOX or FOLFIRI, as first-line treatment in patients with mCRC (NCT02069704). **Methods:** PK analysis for multiple dose studies was conducted, as per guidelines, measuring the total exposure area under the concentration-time profile (AUC0-336) at cycle 1, and to the end of the dosing interval at steady-state (AUCss) at cycle 7. PK similarity was achieved if 90% confidence interval (CI) for the test-to-reference ratios of AUC0-336h and AUCss were within 80.00–125.00% bioequivalence acceptance window. Secondary endpoints included other PK parameters, safety profile, immunogenicity and objective response rate (ORR). **Results:** A total of 142 patients were randomized and treated. Bevacizumab serum concentrations showed a ratio (90% CI) of geometric means for BEVZ92 and RMP were 99.4% (90.5%-109%) and 100% (90.2%–112%) for AUC0-336h and AUCss, respectively. All secondary PK endpoints which include Cmax, Ctrough, Tmax, t1/2, Kel, CL, Vd, and RA-AUC were also similar between the two arms. The ORR was 45% (95% CI, 33% to 57%) for BEVZ92, and 52% (95% CI, 40% to 64%) for RMP. Immunogenicity results showed a low incidence in the anti-drug antibodies *de novo* development and similar between both arms. Safety profile in terms of nature, frequency and severity was similar to the RMP and according to what is expected given the underlying disease and concurrent use of chemotherapy. **Conclusions:** These study results confirm the bioequivalence of BEVZ92 and the RMP in a real and common clinical setting, and translates the high similarity demonstrated in the *in vitro* and *in vivo* characterization into the clinical outcomes such as efficacy, immunogenicity and safety profile. [Clinical trial information: NCT02069704.](http://clinicaltrials.gov/show/NCT02069704%22%20%5Ct%20%22_blank)