

Aflibercept (Zaltrap®) in addition to FOLFIRI for the 2nd line therapy of metastatic colorectal cancer

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Aflibercept (Zaltrap®) is an angiogenesis inhibitor administered in combination with a FOLFIRI regimen (5-fluorouracil, leucovorin and irinotecan) for the 2nd line treatment of therapy-resistant metastatic colorectal cancer. Aflibercept has been approved for this indication by the EMA in February 2013 and in March 2012 by the FDA.

The marketing authorisation was based on the results of VELOUR trial, a multinational, randomised, double-blind study with 1,226 participating patients. All patients had received an oxaliplatin-containing chemotherapy prior to aflibercept and some had been pretreated with bevacizumab. Within the study, patients received either aflibercept+FOLFIRI or placebo+FOLFIRI. Analyses showed that adding aflibercept to FOLFIRI led to a significantly improved median overall survival – 13.50 vs. 12.07 months (HR 0.817, $p = .0032$) in the aflibercept group compared to control group. For progression free survival and response rate, better results were reported for the aflibercept group than for the control group.

In the aflibercept/FOLFIRI arm, treatment-emergent adverse events occurred in 99.2% of patients compared to 97.9% of control arm patients. There were more patients affected by adverse events of grade 3 and grade 4 in the aflibercept arm than in the control arm. Adverse events led to discontinuation from study treatment in 26.8% (aflibercept group) and 12.1% (control group) respectively.

The effects of aflibercept on overall survival and progression free survival have to be balanced against the high incidence of adverse events. An ongoing study evaluates the quality of life in patients receiving aflibercept; its results could provide more information about this essential parameter.

The full German version is available

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