Per protocol analysis and final OS update of the FIRE-3 (AIO KRK-0306) study comparing FOLFIRI plus cetuximab vs. FOLFIRI plus bevacizumab. First Author: Sebastian Stintzing, Ludwig Maximilian University of Munich, Munich, Germany

**Background:** FIRE-3 compared 1st-line therapy with FOLFIRI plus either cetuximab or bevacizumab in 592 KRAS exon 2 wt mCRC patients (pts). Extended RAS analysis showed RAS wild-type (RASwt) in tumors of 400 pts.

*J Clin Oncol 36, 2018 (suppl; abstr 3508)*

Polymorphism in the circadian clock pathway to predict outcome in patients (pts) with metastatic colorectal cancer (mCRC): Data from TRIBE and FIRE-3 phase III trials. First Author: Francesca Battaglin, Division of Medical Oncology, USC Norris Comprehensive Cancer Center, Keck School of Medicine, Los Angeles, CA

**Conclusions:** Our results provide the first evidence that CLOCKrs3749474 polymorphism may have a predictive value in mCRC pts treated with first-line FOLFIRI/bev. This finding supports a possible role of clock genes in contributing to resistance to anti-VEGF treatment.
Abstract 3591 Poster Session (Board #84), Sun, 8:00 AM-11:30 AM Somatic

**Somatic DNA mutations, tumor mutational burden (TMB), and MSI Status: Association with efficacy in patients (pts) with metastatic colorectal cancer (mCRC) of FIRE-3 (AIO KRK-0306).** First Author: Volker Heinemann, Department of Medicine III, University Hospital, LMU Munich, Munich, Germany

**Conclusions:** NGS analysis revealed distinct subgroups of mCRCs with different prognosis. MSI status had prognostic impact, but TMB could not be validated as a prognostic or predictive marker.

Abstract e15711 - Publication Only

**Cost-effectiveness of FOLFIRI + cetuximab vs FOLFIRI + bevacizumab in the first-line treatment of RAS wild-type (wt) metastatic colorectal cancer (mCRC) in Germany: Data from the FIRE-3 (AIO KRK-0306) study.**


**Conclusions:** Based on our analyses, FOLFIRI + cet is cost-effective compared with FOLFIRI + bev in pts treated in Germany with RAS wt mCRC. The cost-effectiveness of FOLFIRI + cet improves for
Abstract 3534 Poster Session (Board #27), Sun, 8:00 AM-11:30 AM

Impact of primary tumor side on outcomes of every-2-weeks (q2w) cetuximab + first-line FOLFOX or FOLFIRI in patients with RAS wild-type (wt) metastatic colorectal cancer (mCRC) in the phase 2 APEC trial. First Author: Timothy Jay Price, Queen Elizabeth Hospital, University of Adelaide, Woodville, Australia

Conclusions: Consistent with prior first-line pivotal studies with weekly cetuximab, a prognostic effect of tumor side in patients receiving first-line q2w cetuximab was confirmed in APEC. In patients with R-sided mCRC, ORR remained ≥ 50%, and resection rate was comparable to that of L-sided patients, in line with prior evidence showing that use of cetuximab may be appropriate when rapid tumor shrinkage is the goal. These hypothesis-generating data raise the possibility of a synergy between cetuximab and irinotecan in patients with R-sided tumors, although numbers are small. Clinical trial information: NCT00778830

J Clin Oncol 36, 2018 (suppl; abstr 3534)
Final overall survival (OS) analysis of first-line (1L) FOLFOX-4 cetuximab (cet) in patients (pts) with RAS wild-type (wt) metastatic colorectal cancer (mCRC) in the phase 3 TAILOR trial. First Author: Shukui Qin, Nanjing Bayi Hospital, Nanjing, China

Conclusions: The TAILOR study met all its endpoints, confirming cet in combination with FOLFOX-4 as an effective standard-of-care 1L treatment regimen for pts with RAS wt mCRC. We acknowledge that OS findings for the mITT population are likely influenced by the low percentage of pts who received further lines of treatment after progression on their 1L regimen, suggesting regional differences in access to anticancer therapy. Clinical trial information: NCT01228734

J Clin Oncol 36, 2018 (suppl; abstr 3521)