

Non-interventional study (NIS) information

Title / acronym	Encorafenib and cetuximab in patients with metastatic, BRAF ^{V600E} -mutated, colorectal carcinoma: a multi-centric, multi-national, prospective, longitudinal, non-interventional study in Germany and Austria / B RAF inhibitor E ncorafenib and C etuximab R ead life I nvestigation of N ext G eneration C RC treatment / BERING ^{CRC}	
Version identifier	Final 2.0	
Date of current version	08 July 2022	
Active substances	Encorafenib: ATC-code L01XE46 Cetuximab: ATC-code L01XC06	
Medicinal products	Encorafenib: Braftovi® 50/75 mg hard capsules Cetuximab: Erbitux® 5mg/ml solution for infusion (or Cetuximab-biosimilar, if available and used)	
Product references	Encorafenib marketing authorization nos.: EU/1/18/1314/001 EU/1/18/1314/003 EU/1/18/1314/002 EU/1/18/1314/004 Cetuximab marketing authorization nos.: EU/1/04/281/003 EU/1/04/281/005	
Marketing authorization holders	<u>Encorafenib</u> : Pierre Fabre Médicament; Boulogne-Billancourt, France <u>Cetuximab</u> : Merck KGaA; Darmstadt, Germany	
Research question and main objectives	Data from a pivotal clinical trial are usually based on a selected patient population in order to provide standardized results in the given indication. However, after marketing authorization usage in a broader patient population is to be expected. European approval of the doublet therapy encorafenib and cetuximab for patients with pretreated metastatic colorectal cancer (mCRC) harboring a BRAF ^{V600E} mutation is applied for based on the pivotal clinical trial BEACON CRC: When compared to standard chemotherapy the doublet therapy showed favorable efficacy results in terms of overall response rate (ORR) and overall survival (OS). BERING ^{CRC} NIS – designed as a prospective, longitudinal, non-interventional study – will investigate the real-world effectiveness, quality of life, safety and tolerability of encorafenib and cetuximab in a broad patient population with mCRC harboring a BRAF ^{V600E} mutation, who have received prior systemic therapy.	
Countries	Germany (ca. 70-80 centers) & Austria (ca. 10-20 centers)	
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