Abstract 1666

Adjuvant FOLFOX4 plus or minus cetuximab (Cmab) in patients (pts) with KRAS mutant (mKRAS) resected stage III colon cancer (CC). Results from the PETACC8 intergroup trial.

Type: Abstract

Category: Gastrointestinal tumors, colorectal

Authors: R. Salazar[1], E. Mini[2], G. Folprecht[3], F. Subtil[4], J.-L. van Laethem[5], J. Thaler[6], J.A. Bridgewater[7], E. van Cutsem[8], C. Lepage[4], J. Taieb[9]; [1]Barcelona/ES, [2]Firenze/IT, [3]Dresden/DE, [4]Dijon Cedex/FR, [5]Brussels/BE, [6]Wels/AT, [7]London/UK, [8]Leuven/BE, [9]Paris/FR

Body

Background: FOLFOX4 is standard adjuvant therapy for resected stage III CC. PETACC 8 assessed the potential benefit of Cmab added to FOLFOX4 in resected stage III CC. Initially PETACC 8 enrolled pts regardless of KRAS status; here we report efficacy and tolerability results in mKRAS pts prior to an amendment restricting enrolment to pts with KRAS wild-type tumors.

Methods: Pts with informed consent were randomized 28-56 days following resection to 12 biweekly cycles of oxaliplatin 85 mg/m^2 d1, with leucovorin 200 mg/m^2, 5FU 400 mg/m^2 bolus IV, then 22-hr IV 5FU 600 mg/m^2 on d1and2 (FOLFOX4), without (arm A) or with Cmab (arm B) 250 mg/m^2 weekly (400 mg/m^2, cycle1). Tumors were centrally tested for KRAS. This analysis focuses on pts with mKRAS CC. The primary endpoint was disease free survival (DFS) time. Secondary endpoints included overall survival (OS), treatment compliance and toxicity. Subgroup analysis were performed.

Results: 742 pts with mKRAS CC were enrolled prior to the restriction to pts with KRASwild-type tumors (Arm A, 374; Arm B, 368). Median follow-up is 45.4 months. No difference was seen between the arms for DFS (HR 1.06, 95% CI 0.82-1.37; p=0.65). 3-yr DFS was 71.0% (95% CI 66.0-75.3) in Arm A and 70.7% (95% CI 65.6-75.1) in Arm B. No statistical benefit of Cmab was observed in any of the subgroups analysed. The frequency of any AE grade ≥ 3 was significantly increased in Arm B (68.4% Arm A vs 81.0% Arm B; RR: 1.18, 95% CI 1.09-1.29). Diarrhea, asthenia, mucositis, skin disorders (grade ≥ 3) and failure to complete 12 cycles were also significantly higher in Arm B.

Conclusions: The analysis of this randomized phase III trial has not shown a benefit for adding cetuximab to FOLFOX4 in patients with resected stage III mKRAS CC with global results very close to those observed in KRAS wild type pts.

Supported by Merck-Serono, Sanofi-Aventis.

Print