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FOLFOX plus PANITUMUMAB (Pmab) according to a “stop-and-go” strategy in first-line in patients (pts) with non-mutated RAS/BRAF metastatic colorectal cancer (mCRC): Results of the FFCD 1605 – OPTIPRIME phase II trial

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Background

Anti-EGFR treatments may lead to cumulative skin and nail limiting toxicities and to the emergence of resistance clones. The OPTIPRIME phase II trial assesses the interest of using Oxaliplatin and Pmab in a “stop-and-go” strategy to improve treatment tolerability and efficacy by increasing the duration of disease control (DDC).

Methods

Pts received induction FOLFOX plus Pmab for 6 cycles then a maintenance therapy with fluoropyrimidine in case of disease control. At progression, Pmab +/- Oxaliplatin were re-introduced for 6 cycles and so-on. The primary endpoint was DDC defined as radiological progression under EGFR with chemotherapy or death. Patients with R0/R1 metastases surgery were censored at the date of surgery; patients who did not have metastases resection and who were alive without progression were censored at last news or at the beginning of second-line in case of switch without progression under Pmab. With a H0 of 14 months (mo), a H1 of 20 mo (1-sided α of 5%, a power of 80%, and 10% lost to follow-up), 118 pts were to be included using one-arm non-parametric method. With a 36 mo of enrolment and a 24 mo of follow-up, the upper critical value for H0 rejection was 17.84 m.

Results

Between April 2018 and May 2023, 36 centers enrolled 118 pts; mITT population was of 115 pts (3 *KRAS* or *BRAF* mutations excluded). Main characteristics at inclusion were: median age 68 y, male 79%, ECOG PS 0-1 94%, right sided colon cancer 12%, synchronous metastases 44%, liver metastases 74%, and median number of metastatic sites 2. After a median follow-up of 47.9 mo, median DDC was 24.9 mo (90%CI: 19.3-28.3). ORR was 74.8%. Ninety-six pts (83.5%) had at least one maintenance treatment (LV5FU2 83%, capecitabine 17%); 22%, 30% and 12% of pts had one, two and three reintroduction loops, respectively. Thirteen (11%) pts had surgery of their metastases. Eighty pts (69.6%) received a second-line treatment. Median OS was 36.1 mo (95%CI: 27.5-39.9).

Conclusions

The OPTIPRIME trial met its primary objective, validating the value of Pmab’s use in a “stop-and-go” strategy. These findings further support the use of fluoropyrimidine-alone maintenance therapy.

Clinical trial identification

NCT03584711.

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Legal entity responsible for the study

FFCD (Fédération Francophone de Cancérologie Digestive).

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Disclosure

J. Bachet: Financial Interests, Personal, Advisory Board: AbbVie, Bayer, BMS, Incyte, GSK, Merck Serono, MSD, Nutricia, Servier, Takeda; Financial Interests, Personal, Financially compensated role: Amgen, Pierre Fabre. F. Hocine: Financial Interests, Personal, Other: Sanofi, Pfizer, Ipsen, BMS, Kapa, Servier, Pierre Fabre, Leo Pharma, Amgen, Janssen, AstraZeneca, Gilead. J. Taieb: Financial Interests, Personal, Advisory Board: MSD, Astellas, Merck, Servier, Pierre Fabre, Amgen, BMS, Novartis, Pfizer, Sanofi, Rotta pharm, Takeda, Boehringer Ingelheim; Financial Interests, Personal, Invited Speaker: Amgen, Merck, MSD, Novartis; Financial Interests, Personal, Invited Speaker, symposia: Astellas; Financial Interests, Personal, Other, steering committee of clinical trial: Novartis; Non-Financial Interests, Leadership Role, President of the scientific committee of the ARCAD foundation until end 2022: ARCAD Foundation; Non-Financial Interests, Leadership Role, Chair of the ARCAD pancreas research group: ARCAD Foundation; Non-Financial Interests, Leadership Role, Member of the administrative council, the scientific committee, the executive board and responsible for the international relationships /partnership for FFCD in the prodige intergroup: Federation Francophone de Cancerologie Digestive (FFCD); Non-Financial Interests, Other, steering committee of clinical trials: Pfizer, Servier. J.M. Phelip: Financial Interests, Personal, Advisory Board: Amgen, BMS, Merck Serono, MSD, Pierre Fabre, Roche, Servier, Takeda. All other authors have declared no conflicts of interest.

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