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LATE-BREAKING ABSTRACTS

COLON CANCER

LBA1 Pembrolizumab in combination with xelox and bevacizumab in patients with microsatellite stable (pMMR/MSS) metastatic colorectal cancer (mCRC) and a high immune infiltrate: A proof of concept study - Preliminary results of FFCD 1703 POCHI trial

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Background: Immune checkpoint inhibitors (ICI) are currently considered ineffective in pMMR/MSS mCRC. However, about 15% of pMMR/MSS CRCs are highly infiltrated by tumor infiltrating lymphocytes and may be sensitive to ICIs. Some immune scores based on CD3+ and/or CD8+ T-cells infiltration are validated to assess lymphocyte infiltration in CRCs.

Methods: POCHI is a multicentre, single-arm phase II trial aiming to evaluate efficacy of Pembrolizumab (anti-PD1) in combination with CAPOX and bevacizumab as first-line treatment of unresectable pMMR/MSS mCRC patients (pts) with a high immune infiltrate defined by at least one positive immune score (Immunoscore® and/or TuLIS) on primary tumor resection specimens. Primary objective was to increase progression-free survival (PFS) at 10 months from 50% to 70%. Main secondary objectives were overall survival, disease control rate (DCR), safety and duration of response (DoR). With a one-sided type one error α of 5%, a power of 85%, 55 pts were required.

Results: Between April 2021 and May 2024, 182 pts were screened in 40 active centres and 28 had at least one positive immune score (15%) and were included in the POCHI trial. Median age was 66 years, 61% were men and 86/14% were ECOG PS 0/1. Most pts had right-sided primary tumour (43%), *RAS*-mutated tumour (65%) and lung (29%) and liver metastases (46%). At the time of this preliminary analysis (cut-off date May 27, 2024), median follow-up was 19 months and 13/28 pts (46%) were still on treatment. Complete response (21%), partial response (54%) or stable disease (21%) led to a DCR of 96%. Median DoR was 10 months. 25/28 pts were still alive and 12-month PFS was 68%. At least one grade 3-4 treatment related adverse event was observed in 64% of pts. No toxic death was observed.

Conclusions: These preliminary results of the POCHI trial demonstrate a good safety profile and a high efficacy of Pembrolizumab combined to a standard therapeutic regimen. The impressive CR rate and DCR observed justify further evaluation of the quadruplet treatment combination in a randomized phase III trial dedicated pMMR/MSS mCRC pts with a high immune infiltrate.

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RECTAL CANCER

LBA2 Interim efficacy analysis of REGINA, a phase II trial of neoadjuvant regorafenib (Rego), nivolumab (Nivo), and short-course radiotherapy (SCRT) in stage II-III rectal cancer (RC)

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Background: Effective strategies to tackle the immune resistance of pMMR/MSS tumors are lacking. Studies suggest a synergistic effect between immune checkpoint inhibitors, multi-kinase inhibitors and radiotherapy. We report the interim efficacy analysis of REGINA, a multicenter, single-arm, phase II trial of neoadjuvant Rego, Nivo, and SCRT for patients (pts) with stage II-III rectal adenocarcinoma (NCT04503694).

Methods: Treatment included an induction phase with 2 infusions of Nivo 240 mg IV q14 and Rego 80 mg/day PO for 2 weeks (W), followed by SCRT (25 Gy), and a consolidation phase with 3 infusions of Nivo 240 mg IV q14 and Rego 80 mg/day PO for 3W. Surgery was carried out 7-8W after SCRT (watch & wait [w&w] allowed). Adjuvant chemotherapy was optional. Rectal biopsies and DCE-DWI MRI were done at baseline, W2 and after treatment. Blood/stool samples were collected. The primary endpoint was complete response (CR) (pathological [p] or clinical [c] CR at 1 year). The Simon 2-stage design was used (1^{st} stage n=36; if $\geq$5 CR, 2^{nd} stage n=24). The null hypothesis (true CR rate of 12%, based on the Stockholm III trial) was tested against a 1-sided alternative and rejected if $\geq$12 CR (α=5%, β=20% for a true CR rate of $\geq$24%).

Results: 36 pts were recruited at 9 Belgian centers. Baseline characteristics: males (50%), median age 64.5 yrs, ECOG PS 0 (89%), low rectum (22%), pMMR/MSS (83%), cT3 (92%), cN+ (72%), MRF+ (25%), latero-pelvic N+ (17%). Treatment completion: induction (83%), SCRT (97%), consolidation (61%). Overall and treatment-related grade ≥3 adverse events occurred in 61% and 56% of pts, respectively. Surgery was done in 27 pts (1 withdrew prior to surgery). 8 (30%) had pCR, and 16 (59%) major pathological response (mPR, Dworak TRG ≥3). A further 8 pts opted for w&w due to cCR. Among the 24 pts with resected pMMR/MSS tumors, 6 (25%) had pCR, 2 (8%) ypTisN0, and 14 (58%) mPR. A further 5 pts opted for w&w due to cCR.

Conclusions: The predefined statistical criteria were met, supporting further investigation of the combination of Rego, Nivo and SCRT as neoadjuvant therapy for locally advanced RC. In the 2nd stage of the study, the Rego dose will be reduced to 60 mg/day to improve safety.

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Legal entity responsible for the study: Institut Jules Bordet.

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UPPER DIGESTIVE – ESOPHAGEAL AND GASTRIC CANCERS

LBA3 Final analysis of the phase III KEYNOTE-585 study of pembrolizumab plus chemotherapy vs chemotherapy as perioperative therapy in locally-advanced gastric and gastroesophageal junction cancer

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Background: At third interim analysis (IA3) of KEYNOTE-585 (NCT03221426), perioperative pembrolizumab (pembro) + chemotherapy (chemo) vs placebo (pbo) + chemo did not show significant improvement of event-free survival (EFS) in patients (pts) with untreated locally-advanced, resectable G/GEJ cancer, although pathCR rate improved. A separate cohort evaluated pembro + FLOT. We present results of the final analysis (FA) of overall survival.

Methods: Eligible pts with untreated, locally advanced, resectable G/GEJ cancer were randomized 1:1 to neoadjuvant pembro 200 mg IV Q3W or pbo + chemo (cisplatin + capecitabine or cisplatin + 5-FU) for 3 cycles. After surgery, pts received adjuvant pembro or pbo + chemo Q3W for 3 cycles, then adjuvant pembro or pbo Q3W for 11 cycles (main cohort). In the FLOT cohort, pts were randomized 1:1 to pembro or pbo + docetaxel, oxaliplatin, leucovorin, and 5-FU, Q2W. Primary end points were pathCR (BICR), EFS (RECIST 1.1, INV), OS (main cohort), and safety (FLOT cohort). OS was not tested statistically at FA as EFS was not positive at IA3.

Results: 804 pts were randomized to the main (402 pembro; 402 pbo) and 1007 to main + FLOT (502 pembro; 505 pbo) cohorts. At data cut-off (Feb 16, 2024), median follow-up was 59.9 mo and 58.6 mo respectively. In the main cohort, the pathCR rate was 13.4% (95% CI, 10.3-17.2) with pembro + chemo vs 2.0% (95% CI, 0.9-3.9) with pbo + chemo (Δ (11.4% [95% CI, 8.0-15.3]). At FA, median EFS was 44.4 vs 25.5 mo (HR 0.81; 95% CI, 0.67-0.99) and median OS was 71.8 vs 55.7 mo (HR 0.86; 95% CI, 0.71-1.06) with pembro + chemo vs pbo + chemo, respectively. Grade ≥3 drug-related AE rates were 65% vs 63%. Outcomes in the main + FLOT cohort are in the table.

Conclusions: Efficacy and safety outcomes with neoadjuvant/adjuvant pembro + chemo followed by adjuvant pembro in pts with untreated, locally advanced resectable G/GEJ cancer at final analysis, were consistent with the prior analysis.

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Table: LBA3 Outcomes in main + FLOT cohort

Efficacy	Pembro + chemo N = 502	Pbo + chemo N = 505	Treatment difference (95% CI)
PathCR[a], % (95% CI)	14.2 (11.3-17.6)	2.8 (1.6-4.7)	11.4 (8.1-15.0)
Median EFS, mo (95% CI)	47.0 (36.2-NR)	26.9 (22.1-34.7)	HR 0.80 (0.67-0.95)
Median OS, mo (95% CI)	NR (59.2-NR)	55.7 (42.8-NR)	HR 0.86 (0.71-1.03)
Safety	Pembro + chemo N = 498	Pbo + chemo N = 503	NA
Grade ≥ 3 drug-related AEs, %	67%	63%	NA

[a]In first 987 pts randomized; HR, hazard ratio; NA, not applicable; NR, not reached