KEYNOTE-671: Randomized, double-blind, phase 3 study of pembrolizumab or placebo plus platinum-based chemotherapy followed by resection and pembrolizumab or placebo for early stage NSCLC.

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The impact of response-directed surgery and adjuvant therapy on long-term survival after neoadjuvant ipilimumab plus nivolumab in stage III melanoma: Three-year data of PRADO and OpACIN-neo.

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Background: Neoadjuvant ipilimumab (IPI) + nivolumab (NIVO) has been shown to induce high pathologic response rates associated with an excellent relapse-free survival (RFS) in high-risk stage III melanoma. While OpACIN-neo tested different neoadjuvant IPI + NIVO regimens followed by therapeutic lymph node dissection (TLND) without adjuvant systemic therapy (ST), PRADO tested a personalized approach. In patients (pts) achieving a major pathologic response (MPR; ≥10% viable tumor), TLND and adjuvant ST were omitted, and pts with pathologic non-response (pNR; >50% viable tumor) were treated with adjuvant ST (BRAFi/MEKi or anti-PD1) or radiotherapy after TLND. Here, we address 1) whether omitting TLND in MPR pts had an adverse effect on long-term survival and 2) whether adding adjuvant ST in pNR pts had a favorable effect on survival.

Methods: The 3-year (3y) RFS and distant metastasis-free survival (DMFS) of pts with MPR and pNR from PRADO and OpACIN-neo were analyzed, comparing MPR pts with TLND versus without TLND and pNR pts with adjuvant ST versus without adjuvant ST. Survival rates were calculated and compared with Kaplan-Meier and log-rank methods. Associations between baseline characteristics and RFS or DMFS were examined by Cox regression analysis. Results: Median follow-up was 37.9 months in PRADO (cutoff Jan 8, 2023) and 46.8 months in OpACIN-neo (cutoff Feb 14, 2022). For MPR pts, TLND omission did not affect survival, with a 3y RFS of 93% versus 96% (p=0.47) and 3y DMFS 98% versus 98% (p=0.92) for pts without TLND (n=59) versus with TLND (n=53), respectively. In pNR pts, an indication for a RFS and DMFS benefit was seen favoring pts with adjuvant ST (n=17; n=10 BRAFi/MEKi and n=7 anti-PD1) over pts without adjuvant ST (n=23), with 3y RFS rates being 64% versus 35% (p=0.10) and 3y DMFS rates 70% versus 52% (p=0.24). Baseline clinical characteristics did not differ between PRADO and OpACIN-neo pts or were not associated with RFS and DMFS. Conclusions: Omitting TLND in MPR pts after neoadjuvant IPI + NIVO seems not to affect RFS or DMFS. Given the high survival rates, adjuvant ST is unlikely to give further benefit in these pts. In pts with pNR, addition of adjuvant ST with ongoing anti-PD1 or switch to BRAFi/MEKi appears to improve RFS and DMFS. Clinical trial information: NCT02977052. Research Sponsor: BMS.

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Background: Previously, we showed that in our first PD1-inhibitor (PD1-inh) arm of I-SPY2, pCR associates with high STAT1/chemokine/dendritic signatures in TN and with high B-cell/low mast cell in HR+. From these results, we defined a research-grade Immune classifier incorporated into the RPS (PMID: 35623341), a schema designed to increase pCR if used to prioritize treatment. A clinical-grade version of the Immune (ImPrint) and other RPS biomarkers are now used in I-SPY2.2. Here we evaluate immune markers in 5 Immune-Oncology (IO) therapy arms (2 PD1-inh, 2 PD1-inh combinations, and 1 PDL1-inh combination).

Methods: 343 patients with HER2-negative BC with information on pCR and mRNA in 5 IO arms (n 60-72 pts) plus controls (Ctr: 343) were considered. 32 continuous markers including 30 immune (7 checkpoint genes, 14 immune cell, 3 T/B-cell prognostic, 1 TGFB and 5 tumor-immune) and ESR1/PGR and proliferation signatures were assessed for association with pCR using logistic regression. p-values were adjusted using the Benjamini-Hochberg method (BH p < 0.05). Correlations to multiplex immunofluorescence (mIF) data from our initial arm (immune cell and spatial proximity markers) were calculated. Performance of ImPrint, developed with Agendia Inc, was characterized overall and within HR subsets. Results: A larger number of the research-grade immune markers predict response to IO in HR+ than in TN, with the most for HR+ in combination-IO arms (27/32 biomarkers). Tumor-immune signatures dominated by chemokines/cytokines were most consistently associated with pCR across IO arms and across receptor status. Moreover, we found that these markers correlate to mIF spatial proximity measures reflecting high spatial co-localization of PD1+ immune and PDL1+ tumor cells, in TN especially (r=0.59; p=0.003). The ImPrint classifier was evaluated in the IO arms. In HR+, 28% were ImPrint+; and pCR rates were 76% in ImPrint+ vs. 16% in ImPrint-. In TN, 46% were ImPrint+; and pCR rates were 75% in ImPrint+ and 37% in ImPrint-. Overall (HR+ and TN, in all IO arms), pCR rates were 75% in ImPrint+ and 23% in ImPrint-. Performance varied by arm, with the highest pCR rates for HR+/ImPrint+ >90%; and for TN/ImPrint+ >81%. In contrast, pCR rates in the control arm were 34% for ImPrint+ (HR+:33%; TN: 34%) and 13% for ImPrint- (HR+: 21%; TN:8%). Conclusions: Tumor-immune signaling signatures predict response for IO drug class in both TN and HR+HER2-. The ImPrint single-sample classifier predicts response to a variety of IO regimens in both subsets and may inform prioritization of IO vs other treatments and best balance likely benefit vs risk of serious immune-related adverse events. Clinical trial information: NCT01042379. Research Sponsor: QLHC.
Clinical Science Symposium

Friendly-user score assessing gut dysbiosis and resistance to immune checkpoint inhibitors (ICI).

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Background: Accumulating evidence pointed to the impact of the intestinal microbiota on ICI outcomes across various cancers. Although specific gut microbial species have been associated with beneficial responses (i.e. Akkermansia muciniphila (Akk)), no consensus exists on a gut fingerprint predicting immunoresistance to clinical routine use. Methods: NCT04567446 provided whole genome sequencing (WGS) of longitudinal fecal samples from patients (pts) with advanced non-small cell lung cancer (NSCLC) during ICI (alone or with chemotherapy) in France and Canada. Topological Pearson networks clustered into species interacting groups (SIG) correlating with overall survival (OS; OS<12=NR; OS>12=R). Forty harmful (SIG1) and thirty-four beneficial (SIG2) WGS species were associated with NR and R to ICI. A monodimensional score (TOPOSCORE) based on SIG1/SIG2 ratio combined with Akk relative abundance was calculated and compared to machine-learning (ML) algorithms. Multivariate Cox analysis (MVA) adjusted for established risk factors (ATB, gender, age, ECOG, PD-L1, LIPI score). Intraindividual dynamics of the TOPOSCORE was evaluated in pts with at least two fecal samples. Three independent cohorts of NSCLC and genitourinary (GU) cancers pts validated the data. Results: In n=245 and n=148 NSCLC pts, we could classify pts into dysbiotic (SIG1+, 33%) and eubiotic (SIG2+, 67%), using the TOPOSCORE. Pts falling within the SIG2+ exhibited a significantly prolonged OS than pts falling into SIG1+ (HR: 0.50 (0.36-0.71), p<0.0001). TOPOSCORE also predicted OS in 277 ICI-treated NSCLC and GU pts and compared to the state-of-the-art ML algorithms, held the highest percentage of correct predictions (63%). At MVA, TOPOSCORE was independently associated with OS (HR: 0.56 (0.39-0.81), p=0.002). Analyzing the intraindividual dynamics of the TOPOSCORE (n=67), we found that 74% of SIG2+ and 68% of SIG1+ individuals remained in their initial classification during ICI treatment. We finally scaled the calculation of the TOPOSCORE down to 24WGS (instead 75WGS) and set up a qPCR-based friendly-user test capable of accurately identifying the fecal presence of the bacteria of interest within 48 hrs. We confirmed (n=323) that OS was superior in those pts harboring a 24-bacteria-qPCR-based TOPOSCORE falling within the SIG2+ category (HR: 0.65 (0.48 to 0.87), p=0.0005). Conclusions: TOPOSCORE represents a robust biomarker predicting and following the dynamic of the immunoresistance to ICI across cancers on an individual basis. By converting the WGS TOPOSCORE to a qPCR-based test with a rapid turnaround time, it will be possible to adopt this score in routine clinical practice to improve pts stratification and ICI success rates guiding the selection of dysbiotic pts amenable to microbiota-centered interventions and eubiotic fecal microbiota transplantation donors. Clinical trial information: NCT04567446. Research Sponsor: None.
Effect of CBM588 in combination with cabozantinib plus nivolumab for patients (pts) with metastatic renal cell carcinoma (mRCC): A randomized clinical trial.

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Fecal microbiota transplantation combined with anti-PD-1 inhibitor for unresectable or metastatic solid cancers refractory to anti-PD-1 inhibitor.

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Background: The gut microbiome is emerging as a key regulator of the immune system during immunotherapy. However, the effect of modulating the gut microbiome in patients (pts) with cancer refractory to immunotherapy remains largely unknown. We aimed to evaluate whether the fecal microbiota transplantation (FMT) could help overcome resistance in pts with advanced solid cancer refractory to anti-PD-(L)1 inhibitors and identify specific commensal bacteria that contribute to the efficacy of FMT (NCT04264975).

Methods: This is a prospective, single-arm clinical trial of FMT plus anti-PD-(L)1 inhibitor in pts with advanced solid cancer refractory to anti-PD-(L)1 inhibitors. The key eligibility criteria for donors included ongoing durable complete or partial response ≥ 6 months with anti-PD-(L)1 monotherapy or combination therapy for advanced solid tumors. FMT was performed using colonoscopy, followed by continuation or reintroduction of anti-PD-(L)1 inhibitor until unacceptable toxicity or disease progression. Repeated FMT from the same or different donors was allowed.

Results: From Jan. 2019 to Aug. 2020, 13 pts with metastatic gastric cancer (GC) (n=4), esophageal squamous cell carcinoma (ESCC) (n=5), and hepatocellular carcinoma (HCC) (n=4) were enrolled; male (77%), median age=60 yrs (range, 38-76), and median line of prior systemic therapy=3 (range, 2-5). All had confirmed disease progression on nivolumab monotherapy with primary resistance (46.2%) or secondary resistance (53.8%), and underwent FMT with continued nivolumab. There were six FMT donors (HCC [n=4], GC [n=1], ESCC [n=1], who had maintained (CR; n=4) or (PR; n=2) with nivolumab or pembrolizumab monotherapy. Of the 13 recipients, five showed SD and one achieved PR after FMT with a disease control rate of 46.2% (6/13) and an objective response rate of 7.7% (1/13). Recipient #7 (R7), who had metastatic HCC with primary resistance to nivolumab, initially showed PD to the 1st FMT from donor #1, but achieved PR after the 2nd FMT from donor #5. Clinical response was accompanied by an increase in levels of cytotoxic T cells in the blood and tumor microenvironment, immune cytokines, and the relative abundance of a new species derived from donor #5 showing 97% whole genome nucleotide sequence similarity with Prevotella sp. Marseille-P4119. We isolated this species from feces of R7 and preclinical experiments showed that treatment with this species activated human CD4+ and CD8+ T cells with increased IFN-γ secretion, and suppressed tumor growth in a syngeneic mouse model by enhancing tumor infiltration of cytotoxic T cells. Moreover, the combination treatment with anti-PD-1 and this species reduced the tumor volume more than with anti-PD-1 alone.

Conclusions: FMT containing the effective microbiota could overcome resistance to anti-PD-1 inhibitor by modulating the tumor microenvironment in advanced solid cancer pts. Clinical trial information: NCT04264975. Research Sponsor: grants from National Cancer Centre, Korea (NCC-1911267); a grant (2018-0608) from the Asan Institute for Life Sciences, Asan Medical Center, Korea.
First phase 3 results from CARTITUDE-4: Cilta-cel versus standard of care (PVd or DPd) in lenalidomide-refractory multiple myeloma.

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The full, final text of this abstract will be available at meetings.asco.org on the day of presentation and in the online supplement to the June 10, 2023, issue of the Journal of Clinical Oncology.
Primary overall survival analysis of the phase 3 randomized ZUMA-7 study of axicabtagene ciloleucel versus standard-of-care therapy in relapsed/refractory large B-cell lymphoma.

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