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1104P Efficacy of immune checkpoint inhibition in metastatic or non-resectable melanoma after failure of adjuvant anti-PD1 treatment: A EUMelareg real-world evidence study

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Background: Adjuvant immune checkpoint inhibition (ICI) with anti-PD1 antibodies in high-risk resected melanoma has been shown to improve recurrence-free survival by about 50 percent. It is unclear, whether adjuvant pre-treatment with anti-PD1 antibodies would impair response to ICI in metastatic patients with recurrence after adjuvant ICI.

Methods: From the adjuvant study platform of the European Melanoma Treatment Registry (EUMelaReg) we analysed cases with recurrence following adjuvant anti-PD1 ICI. In those, receiving ICI in the first-line setting, response rates and progression-free survival were compared to patients selected from the EMelaReg database by matching for relevant prognostic factors in the first-line non-adjuvant setting.

Results: A total of 389 melanoma patients with first-line ICI after failure from adjuvant anti-PD1 antibody treatment could be matched 1:1 for several prognostic covariates to first-line ICI cases without adjuvant pre-treatment. Overall response rate was significantly lower after adjuvant anti-PD1 treatment failure (32.9% vs. 40.0%) and progression free survival was 4.6 months for patients with adjuvant pre-treatment as compared to 10.1 months for PD1-naive patients ($p<0.0001$). This contrast was independent from usage of single agent anti-PD1 or combined ICI with anti-PD1 and anti-CTLAE4 in the first-line setting.

Conclusions: Adjuvant pre-treatment with anti-PD1 antibodies was related to an inferior response and progression-free survival in patients with metastatic or non-resectable melanoma receiving ICI in the first-line setting.

Legal entity responsible for the study: The European Melanoma Treatment Registry.

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1105P First-line nivolumab plus ipilimumab in advanced melanoma patients previously treated with adjuvant systemic therapy

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Background: The combination of nivolumab and ipilimumab (NIVO+IPI) is associated with the most durable responses and the highest overall survival rates in patients (pts) with advanced melanoma. However, this regimen is increasingly being used in a different patient population than in clinical trials, namely after prior adjuvant treatment. The objective of this study is to evaluate the efficacy and safety of NIVO+IPI in pts who have relapsed despite adjuvant treatment.

Methods: This retrospective analysis included pts with unresectable stage III and stage IV melanoma treated with NIVO+IPI between 01/2021-10/2022 at 5 cancer centers in Poland according to uniform criteria. All pts received prior adjuvant therapy (immunotherapy or BRAF/MEK inhibitors) for stage III/IV melanoma.

Results: A total of 70 pts were identified. The median age was 53 years, 32% of pts were female, 46% had *BRAF* mutation. At baseline, 18.5% of pts had unresectable stage III disease, 21.2% had stage M1a, 18.2% M1b, 34.8% M1c and 7.6% M1d. Most pts (81.4%) received anti-PD1 in the adjuvant setting. In 70% of pts, the disease relapsed during adjuvant therapy. Median follow-up time was 12.6 months. The objective response rate was 24%. A higher response rate was observed in pts who were immunotherapy-naive (33%) than in pts who received anti-PD1 in the adjuvant setting (22%). Median progression-free survival (mPFS) was 3.9 (95%CI 3.0—9.7) months. Although not statistically significant, a higher median PFS of NIVO+IPI was observed in patients who received BRAF/MEK inhibitors as compared to those who were treated with anti-PD1 antibodies in the adjuvant setting (11.1 vs 3.7 months, p=0.53). Overall survival rate at 12 months was 59% (95%CI 47—74). Treatment-related adverse events (TRAEs) of any grade were observed in 97% of pts and grade 3/4 TRAEs occurred in 24% of pts.

Conclusions: NIVO+IPI shows lower efficacy in advanced melanoma pts who have relapsed despite adjuvant treatment comparing to clinical trial data. The population of pts with a particularly poor prognosis are those previously treated with adjuvant anti-PD-1 antibodies, as disease recurrence indicates some resistance to immunotherapy difficult to overcome by adding anti-CTLA4 antibody to anti-PD-1 therapy.

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1106P Anti-PD-1 (PD1) monotherapy or in combination with anti-CTLA-4 for metastatic melanoma (MM) patients (pts) with liver metastases (mets)

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Background: Liver mets have been associated with poor response and survival in pts with MM treated with PD1 alone or in combination with anti-CTLA-4 (ipilimumab; PD1+IPI). Whether these pts benefit from PD1+IPI over PD1 is unknown. In MM pts with liver metastases, we sought to: a) determine objective response rate (ORR), progression-free survival (PFS) and overall survival (OS) to PD1 vs PD1+IPI, and b) identify clinical predictors of response and survival to PD1+/-IPI.

Methods: MM pts with liver mets treated with 1st line PD1 or PD1+IPI were included. Demographics, patient and disease characteristics, baseline blood parameters and clinical outcomes were examined. Univariate and multivariate (MVA) analyses were performed to identify clinical predictors of response and survival.

Results: Of 533 MM pts treated with 1st line PD1 or PD1+IPI; 284 (53%) had PD1 and 249 (47%) had PD1+IPI. PD1 group had more ECOG PS $\geq$1 (53% vs 34%), but less BRAF V600 mutation (15% vs 33%) and stage M1D (15% vs 31%). Median follow-up from commencement of PD1+/-IPI was 47 months (42—51); ORR was 41%, higher in PD1+IPI (47%) vs PD1 (35%) (p=0.0027). PFS and OS at 1 year were 68% and 40%, respectively; non statistically higher with PD1+IPI (69%/43%) vs PD1 (67%/38%) (p>0.05). However, on MVA with multiple imputation for missing values and adjusting for predefined variables including age, gender, melanoma subtype (cutaneous non-acral, acral and mucosal), mutation status, ECOG PS, LDH and M1 substage

Efficacy of immune checkpoint inhibition in metastatic or nonresectable melanoma after failure of adjuvant anti PD1 treatment - A EUMelaReg real world evidence study -

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Background

Adjuvant immune checkpoint inhibition (ICI) with anti-PD1 antibodies in high-risk resected melanoma has improved recurrence-free survival by about 50 percent, but there is still a proportion of patients who develop recurrence despite adjuvant anti-PD1 treatment, many of them unresectable or metastatic disease. Overall, in stage IIIA to IIID around 40% of patients may develop a recurrence according to the long-term result of the KEYNOTE-054 trial. This may occur while still on the 12 months of adjuvant treatment or later in the course of the disease and is referred to as early and late ICI resistance.

Available data on the efficacy of ICI therapy in advanced patients who have relapsed after adjuvant anti-PD1 therapy are sparse, and it is unclear, whether adjuvant pre-treatment with anti-PD1 antibodies would impair response to ICI in patients with metastatic recurrence. This study was performed to evaluate the clinical outcomes of patients with metastatic or non-resectable melanoma treated with or without upfront anti-PD1 monotherapy treatment in the adjuvant setting.

Methods

Cases with non-resectable stage III or stage IV melanoma who were treated with non-adjuvant immune checkpoint inhibition after failure from adjuvant anti-PD1 treatment were selected from the EUMelaReg database. Patients were excluded if they had a uveal or mucosal type of melanoma, while acral and melanoma of unknown primary were included. Both, 1st line single anti-PD1 therapy (pembrolizumab or nivolumab) and combined anti-PD1/CTLA4 (Ipi/Nivo) therapy were included.

Primary outcomes of interest were (1) the overall response rate (ORR) of 1st line ICI treatment and (2) progression-free survival (PFS) from start of non-adjuvant ICI.

Further analysis included stratifications for the time of the preceding recurrence ('early': up to 3 months after end of adjuvant treatment) and the impact of several prognostic covariates.

In order to prevent statistical bias from selection of patients, matching was performed with a nearest neighbour algorithm using mahalanobis distance as distance metric. Samples were matched for ECOG, AJCC stage, baseline serum LDH, number of metastatic sites, sex, BRAF status, age and Charlson comorbidity score. The type of 1st line ICI was included as exact 1:1 match.

Results

389 cases with 1st line ICI after failure from adjuvant anti-PD1 therapy were successfully matched with metastatic cases receiving 1st line ICI without adjuvant anti-PD1 treatment (anti-PD1 naïve cohort). The goodness of matching is demonstrated by only non-significant differences in key prognostic variables (Table 1) as well as by only small standardized differences in the respective parameters (Figure 3).

Response rates in cases after adjuvant anti-PD1 failure were significantly lower (ORR: 31.6% vs. 49.9%; p<0.0001) than in treatment naïve cases (Table 2), which was also reflected in a shorter PFS (4.0 months vs. 15.5 months; p < 0.0001; Figure 1).

The results were influenced by the time of the preceding recurrence (ORR: 28.8% in early vs. 38.5% in late recurrences; Figure 4A). For the early recurrences, this was most pronounced in recurrence during the first 6 months of adjuvant treatment (Figure 4B).

The effect of decreased response rate in 1st line after failure of adjuvant anti-PD1 could be seen in both, combined anti-PD1/CTLA4 treatment as in single agent anti-PD1 re-treatment (Figure 6).

Figure 1: PFS of patients treated with 1st line ICI stratified by adjuvant anti-PD1 pre-treatment

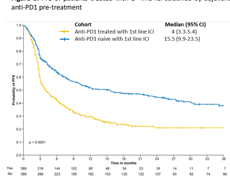


Table 2: Response rates with 1st line ICI in stratified by adjuvant anti-PD1 pre-treatment

	Anti-PD1 treated (N = 389)	Anti-PD1 naïve (N = 389)	P-value
Best response			
CR	62 (15.9%)	86 (22.1%)	< 0.0001
PR	61 (15.7%)	108 (27.8%)	
SD	54 (13.9%)	51 (13.1%)	
PD	154 (39.6%)	93 (23.9%)	
Unknown	58 (14.9%)	51 (13.1%)	
ORR	123 (31.6%)	194 (49.9%)	< 0.0001
DCR	177 (45.5%)	245 (63.0%)	< 0.0001
Survival			
Median PFS (95% CI)	4.0 (3.3-5.5)	15.5 (10.1-24.2)	< 0.0001

PFS was 4.0 months in the adjuvant anti-PD1 pre-treated cohort compared to 15.5 months in anti-PD1 naive patients (p<0.0001; Figure 1; Table 2). Response rates were accordingly lower in patients after adjuvant anti-PD1 failure, affecting both partial responses (PR) and compete responses (CR) (Table 2).
The median follow-up time was significantly shorter in pre-treated patients than in anti-PD1 naive cases due to the relative recent introduction of adjuvant anti-PD1 treatment into routine practice (Table 1).

Figure 2: Graphical illustration of the analyzed polulation

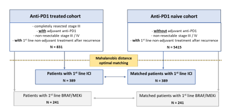
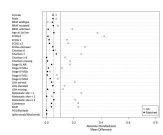

Anti-PD1 treated cohort
- completely resected stage III
- with adjuvant anti-PD1
- non-resectable stage III / IV
- with 1st line non-adjuvant treatment after recurrence
N = 831
Anti-PD1 naive cohort
- without adjuvant anti-PD1
- non-resectable stage III / IV
- with 1st line non-adjuvant treatment after recurrence
N = 5415
Mahalanobis distance optimal matching
Patients with 1st line ICI
N = 389
Matched patients with 1st line ICI
N = 389
Patients with 1st line BRAF/MEKi
N = 241
Matched patients with 1st line BRAF/MEKi
N = 241

Figure 3: Love plot of matched population



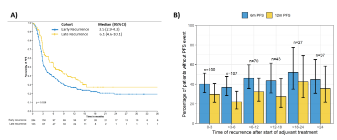
Matching was performed with an optimal matching algorithm using mahalanobis distance as distance metric. Samples were matched for ECOG, AJCC stage, LDH, Number of metastatic sites, Sex, BRAF status, Age and Charlson comorbidity score. Additionally, an exact matching on the type of immunotherapy was performed. The love plot (Figure 3) shows good matching of all covariates indicated by absolute standardized mean differences below 0.1 (a generally accepted threshold).

Table 1: Clinical characteristics of matched patients treated with ICI in 1st line

	Anti-PD1 treated (N=389)	Anti-PD1 naive (N=389)	P-value
Sex			
Female	139 (35.7%)	148 (38.0%)	0.552
Male	250 (64.3%)	241 (62.0%)	
Age at start of 1st line (years)			
Mean (SD)	61.5 (14.6)	62.2 (12.5)	0.442
Median [Min, Max]	63.0 [19.0, 89.0]	63.0 [30.0, 93.0]	
BRAF			
Wildtype	241 (62.0%)	233 (59.9%)	0.78
Mutated	112 (28.8%)	121 (31.1%)	
Unknown	36 (9.3%)	35 (9.0%)	
ECOG at start of 1st line			
0	285 (73.3%)	283 (72.8%)	0.798
1	63 (16.2%)	60 (15.4%)	
>= 2	10 (2.6%)	8 (2.1%)	
Missing/Unknown	31 (8.0%)	38 (9.8%)	
Charlson comorbidity score			
6	249 (64.0%)	258 (66.3%)	0.872
7	64 (16.5%)	56 (14.4%)	
>=8	25 (6.4%)	25 (6.4%)	
Missing/Unknown	51 (13.1%)	50 (12.9%)	
AJCC stage at start of 1st line			
Stage III, NR	52 (13.4%)	48 (12.3%)	0.987
Stage IV M1a	54 (13.9%)	52 (13.4%)	
Stage IV M1b	69 (17.7%)	70 (18.0%)	
Stage IV M1c	156 (40.1%)	157 (40.4%)	
Stage IV M1d	58 (14.9%)	62 (15.9%)	
LDH at start of 1st line			
Normal	260 (66.8%)	253 (65.0%)	0.795
Elevated	87 (22.4%)	95 (24.4%)	
Missing	42 (10.8%)	41 (10.5%)	
Number of metastatic sites at start of 1st line			
1	174 (44.7%)	164 (42.2%)	0.69
2	108 (27.8%)	108 (27.8%)	
>= 3	107 (27.5%)	117 (30.1%)	
Type of melanoma			
Cutaneous	363 (93.3%)	358 (92.0%)	0.582
MUP	26 (6.7%)	31 (8.0%)	
Type of 1st line therapy			
PD1 blockade	81 (20.8%)	81 (20.8%)	1
Ipi/Nivo	308 (79.2%)	308 (79.2%)	
Median Follow-up (95% CI)	17.5 (15.5-19.3)	36.5 (32.7-38.9)	< 0.0001

N: number of patients, MUP: melanoma with unknown primary, ECOG: Eastern Cooperative Oncology Group, LDH: Lactate dehydrogenase; AJCC: American Joint Committee on Cancer, anti-PD1: PD-1, Programmed cell death protein 1.

Figure 4: A) Kaplan Meier curves of PFS of patients treated with 1st line ICI stratified by early and late resistance. B) 6 and 12 months PFS stratified by timing of recurrence after start of adjuvant treatment.



Progression-free survival (PFS) in metastatic 1st line was significantly longer in patients who had experienced late recurrences from adjuvant treatment (> 3 months after end of adjuvant treatment) than those with early recurrences.

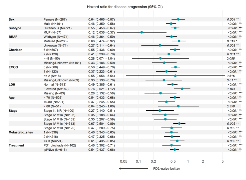
Six months (6m) and 12 months (12m) PFS for cases treated with anti-PD1 single agent or combined anti-PD1/CTLA4 showing lower progression-survival (PFS) for very early recurrences.

Table 3: Clinical outcome of patients with IO in 1st line grouped by reason for end of adjuvant treatment

	Disease Progression (N = 231)	Regularly Ended (N = 85)	Toxicity (N = 38)	Other* (N = 35)	Total (N = 389)	P-value
Best response						
CR	30 (13.0%)	14 (16.5%)	10 (26.3%)	8 (22.9%)	62 (15.9%)	0.61
PR	33 (14.3%)	19 (22.4%)	5 (13.2%)	4 (11.4%)	61 (15.7%)	
SD	34 (14.7%)	12 (14.1%)	4 (10.5%)	4 (11.4%)	54 (13.9%)	
PD	97 (42.0%)	30 (35.3%)	13 (34.2%)	14 (40.0%)	154 (39.6%)	
Unknown	37 (16.0%)	10 (11.8%)	6 (15.8%)	5 (14.3%)	58 (14.9%)	
ORR	63 (27.3%)	33 (38.8%)	15 (39.5%)	12 (34.3%)	123 (31.6%)	0.14
DCR	97 (42.0%)	45 (52.9%)	19 (50.0%)	16 (45.7%)	177 (45.5%)	0.34
Survival						
Median PFS (95% CI)	3.5 (3-4.4)	6.0 (3-8.7)	8.3 (3.4-14.5)	4 (2.6-8.1)	4 (3.3-5.5)	0.1827

N: Number of patients; CR: Complete response; PR: Partial remission, SD: Stable disease, PD: Progressive disease, ORR: Overall response rate, DCR: Disease control rate, CI: Confidence interval; PFS: Progression-free survival, FU: follow-up. *Patients ended adjuvant therapy due to investigators decision/patient´s wish/other

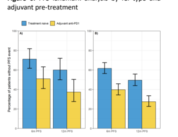
Figure 5: Multivariable cox regression for PFS for patients treated with 1st line ICI.


Hazard ratio for disease progression (95% CI)
Sex Female (N=287) 0.64 (0.466 - 0.87) 0.004 **
Male (N=491) 0.46 (0.359 - 0.58) <0.001 ***
Subtype Cutaneous (N=721) 0.55 (0.456 - 0.67) <0.001 ***
MUP (N=57) 0.12 (0.036 - 0.37) <0.001 ***
BRAF Wildtype (N=474) 0.46 (0.364 - 0.59) <0.001 ***
Mutated (N=233) 0.66 (0.474 - 0.92) 0.013 *
Unknown (N=71) 0.27 (0.114 - 0.64) 0.003 **
Charlson 6 (N=507) 0.55 (0.436 - 0.69) <0.001 ***
7 (N=120) 0.41 (0.239 - 0.70) 0.001 **
>=8 (N=50) 0.28 (0.074 - 1.04) 0.058
Missing/Unknown (N=101) 0.33 (0.186 - 0.59) <0.001 ***
ECOG 0 (N=568) 0.56 (0.449 - 0.70) <0.001 ***
1 (N=123) 0.37 (0.223 - 0.61) <0.001 ***
>= 2 (N=18) 0.55 (0.056 - 5.54) 0.616
Missing/Unknown (N=69) 0.33 (0.138 - 0.76) 0.01 **
LDH Normal (N=513) 0.49 (0.385 - 0.61) <0.001 ***
Elevated (N=182) 0.76 (0.521 - 1.12) 0.163
Missing (N=83) 0.28 (0.132 - 0.58) <0.001 ***
Age < 70 (N=526) 0.54 (0.433 - 0.68) <0.001 ***
70-80 (N=201) 0.37 (0.245 - 0.55) <0.001 ***
> 80 (N=51) 0.64 (0.245 - 1.66) 0.358
Stage Stage III, NR (N=100) 0.27 (0.140 - 0.51) <0.001 ***
Stage IV M1a (N=106) 0.35 (0.188 - 0.64) <0.001 ***
Stage IV M1b (N=139) 0.35 (0.207 - 0.59) <0.001 ***
Stage IV M1c (N=313) 0.67 (0.504 - 0.89) 0.005 **
Stage IV M1d (N=120) 0.47 (0.289 - 0.75) 0.002 **
Metastatic_sites 1 (N=338) 0.46 (0.343 - 0.63) <0.001 ***
2 (N=216) 0.47 (0.325 - 0.68) <0.001 ***
>= 3 (N=224) 0.61 (0.435 - 0.85) 0.003 **
Treatment PD1 blockade (N=162) 0.46 (0.302 - 0.71) <0.001 ***
Ipi/Nivo (N=616) 0.54 (0.437 - 0.66) <0.001 ***
PD1-naive better

Hazard ratios for PFS grouped by different prognostic covariates and adjusted in a multivariable Cox regression model for the effect of all other covariates showing general homogenous effect of pre-treatment with adjuvant anti-PD1 on PFS outcome in the metastatic situation.

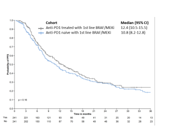
N: number of patients, MUP: melanoma with unknown primary, ECOG: Eastern Cooperative Oncology Group, LDH: Lactate dehydrogenase; Stage: American Joint Committee on Cancer V8 clinical stage.

Figure 6: PFS landmark analysis by ICI type and adjuvant pre-treatment



Six months (6m) and 12 months (12m) PFS for cases treated with anti-PD1 single agent (A) or combined anti-PD1/CTLA4 (B) showing similar PFS decrease for both treatment approaches. PFS: progression-free survival.

Figure 7: Kaplan Meier analysis 1st line BRAF/MEKi therapy after failure of adjuvant anti-PD1



BRAF-V600 mutated cases matched by the same algorithm as for the main study and comparing PFS for ant-PD1 naive ('No') cases vs. those with anti-PD1 failure in adjuvant treatment ('Yes') showing no outcome bias from different follow-up times in both cohorts. PFS: progression-free survival.

Conclusions

Adjuvant pre-treatment with anti-PD1 antibodies was related to an inferior response and progression-free survival in patients with metastatic or non-resectable melanoma receiving ICI in the 1st line setting after failure from adjuvant anti-PD1 treatment. This effect was seen irrespective of whether combined ICI or single agent anti-PD1 re-treatment was used. While there is no general direct impact of these results on clinical practise, it underscores the need for further developments of immune based treatments but may also impact treatment decisions in BRAF V600 mutated cases.
A major limitation of our study is the observational nature of our database and despite matching a major differences persisted in follow-up times of both cohorts (Figure 1). In order to check whether this difference could introduce bias, we reproduced the procedure for patients with 1st line BRAF/MEKi therapy. Notably, there was no evidence of bias due to different follow-up times as shown by the analogous Kaplan-Meier analysis with unimpaired efficacy of BRAK/MEK inhibition after adjuvant anti-PD1 failure (Figure 7).
In conclusion, the potential of ICI in metastatic disease may be impaired by preceding adjuvant ICI in high-risk melanoma.

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