

Results: Amongst 69 patients treated with IO, there were 21 leiomyosarcomas (LMS), 9 well-differentiated/dedifferentiated liposarcomas (WD/DDLPS), 5 undifferentiated pleomorphic sarcomas (UPS) and 7 synovial sarcomas (SS). IO drugs included an anti-PD1/PDL1 for 62 patients. Other IO drugs were other checkpoint inhibitors (N=6) and modified TCR lymphocyte infusion (N=1). Median number of prior lines was 3 (IQR=2-4). Patients with LIPI good (N=30), intermediate (N=26) and poor (N=13) had median PFS of 4.2, 2.6 and 0.7 months, respectively ($p<0.0001$). LIPI remained significantly associated with PFS in multivariate analysis including age, number of prior lines, performance status and albumin level (HR poor=5.97; HR intermediate=2.21; $p=0.0001$). Amongst 131 patients treated with non-IO drugs, there were 32 LMS, 40 WD/DDLPS, 11 UPS and 16 SS. In this cohort, median number of prior lines was 2 (IQR=1-3). Patients with LIPI good (N=78), intermediate (N=39) and poor (N=14) had median PFS of 3.4, 4.3 and 1.8 months, respectively ($p=0.03$). LIPI was not associated with PFS in multivariate analysis for the non-IO cohort ($p=0.71$).

Conclusions: LIPI identifies STS patients most likely to benefit from IO drugs but not other drugs. LIPI may serve as a screening tool for stratification at inclusion in early phase trial.

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84P Predicting longer-term progression-free survival (PFS) with durvalumab after chemoradiotherapy (CRT) in unresectable stage III NSCLC using a mixture cure model (MCM)

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Background: Five-year results from the placebo-controlled phase 3 PACIFIC trial (NCT02125461) demonstrated robust and sustained overall survival (OS) and durable PFS benefit with durvalumab (given every 2 weeks up to 12 months) in pts with unresectable Stage III non-small-cell lung cancer (NSCLC) and no disease progression after platinum-based concurrent CRT. Given the potential for longer-term PFS gain in this curative-intent setting, we used MCM analysis, a common statistical model in such settings, to predict the potential longer-term PFS benefit with durvalumab.

Methods: Pt-level data from 5 years follow-up in PACIFIC were used. MCMs were fitted to PFS data (BICR; RECIST v1.1) to estimate the proportion of pts who are 'long-term survivors' (the statistical cure fraction, defined as the proportion of pts with no risk of disease progression) in each arm. Treatment benefit for the non-cured proportion was also modelled. Model estimates were then used to predict 10-year PFS probabilities ('rates'), while adjusting for background mortality. Models assuming no cure were fitted as sensitivity analyses.

Results: The MCM reported a consistent benefit with durvalumab versus placebo at 10 years with different parametric models and fitted better than non-cure models. The best fitting model used log-normal distribution for pts at risk of progression. Using this model, the estimated statistical cure fraction for PFS was 36.0% (95% CI, 30.2–42.3) with durvalumab and 19.4% (13.7–26.6) with placebo. When accounting for background mortality, the estimated 10-year PFS rate (95% CI) was 28.7% (24.3–33.5) and 15.4% (11.1–21.0), respectively. Similar analysis applying 5-year OS data to both cure and non-cure models also demonstrated longer-term benefit with durvalumab.

Conclusions: MCMs had a good statistical fit with PACIFIC 5-year PFS data. The best fitting cure model estimated a 10-year PFS rate of >25% with durvalumab, almost twice the rate estimated with best supportive care only (i.e. placebo). These analyses, while modelled predictions based on PFS, may assist oncologists with understanding longer-term outcomes in unresectable, Stage III NSCLC.

Clinical trial identification: NCT02125461.

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85P The association between diabetes and survival in patients treated with immunotherapy

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Background: Diabetes frequently accompanies the diagnosis of cancer and has been associated with significantly lower overall and cancer-specific survivals. However, the data on the effect of diabetes on survival is extremely limited in patients treated with immunotherapy. From this point, we aimed to evaluate the relationship between diabetes and survival in patients treated with immunotherapy.

Methods: We retrospectively evaluated the data of 343 relapsed or metastatic cancer patients treated with immunotherapy in Hacettepe University Oncology Hospital. The relationship between the presence of diabetes and overall survival (OS) was evaluated by Kaplan-Meier and Cox regression analyzes. Hazard ratios (HR) and 95% confidence intervals (CI) were reported.

Results: The median age was 61 (IQR 52-68), and 63.3% of the patients were male. Renal cell carcinoma was the most common primary (19.5%), followed by melanoma (17.8%) and non-small cell lung cancer (16.6%). Most of the patients had an ECOG performance score of 0 or 1 (85.7%). At the start of immunotherapy, 30% of the patients had liver metastases, while 45.2% had lung metastases. During a median follow-up of 8.25 (IQR 4.14-18.63) months, 193 patients died (56.3%). In univariate analyses, the OS was significantly lower in patients with higher ECOG performance score (0-1 vs. 2 and above, p=0.001), higher LDH levels (normal vs. >ULN, p=0.004), and diabetes (p=0.005), while no significant association was found between the presence of liver metastases (p=0.213) and the presence of lung metastases (p=0.141) and obesity (p=0.212) with OS. In multivariate analyses, higher ECOG performance score (HR: 1.915, 95% CI: 1.296-2.830, p=0.001), higher LDH levels (HR:

1.510, 95% CI: 1.125-2.027, p=0.006) and diabetes (HR: 1.547, 95% CI: 1.112-2.153, p=0.010) were associated with decreased OS.

Conclusions: We observed a significantly lower OS in diabetic patients treated with immunotherapy, and the negative effect on survival was independent of obesity. Further research is needed to determine the pathophysiological mechanisms of negative survival outcomes in immunotherapy-treated patients with diabetes.

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86P Adjusting ORIENT-11 trial (O-11) results to a US patient population

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Background: O-11 demonstrated that adding sintilimab, a highly selective fully human IgG4 mAb that blocks the binding site of PD-1, to pemetrexed+platinum (SPP) improved progression free survival (PFS) in Chinese patients (pts) with advanced/metastatic nonsquamous NSCLC. To estimate the applicability of O-11 results to US pts, this post hoc retrospective study assesses the effect of SPP v placebo+pemetrexed+platinum (PPP) on PFS, after adjusting the O-11 population to reflect a target US population that would have been eligible for O-11.

Methods: The target US population (n=577) was identified in Flatiron Health EHR derived database based on key O-11 eligibility criteria. Patient level data from O-11 (n=397) and Flatiron datasets were combined. Using inverse probability weighting (IPW), each O-11 patient was assigned a weight based on baseline characteristic data from the target US population. O-11 pts who are more representative of eligible US pts received higher weight, whereas O-11 pts who are less representative were discounted. Prognostic variables including PD-L1 status, ECOG, gender, BMI, smoking history, and age were accounted for in the weights. Minimum effective sample size for PFS after IPW was 156, based on a priori power analysis.

Results: Before IPW, some differences in baseline characteristics of prognostic variables above were observed between O-11 and target US pts (data to be presented). After IPW, the total adjusted O-11 cohort comprised 714 pts and baseline characteristics were balanced (std difference ≤0.20) between adjusted arms. The table shows primary and secondary outcomes results before and after IPW. The trend of PFS benefit with SPP was observed in all specified subgroups (data to be presented).

Conclusions: The effect of SPP on PFS remained superior after adjusting O-11 trial pts to reflect a target US population. Other efficacy and safety outcomes were consistent before and after IPW. These findings may help inform implementation of SPP in the US. Sensitivity analysis is warranted and ongoing.

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Table: 86P

	Before IPW*					After IPW#				
	SPP n = 266		PPP n = 131		HR (95% CI)	SPP n = 362		PPP n = 352		HR (95% CI)
	Median/%	95% CI	Median/%	95% CI		Median/%	95% CI	Median/%	95% CI	
PFS, m	8.9	7.1, 11.3	5.0	4.8, 6.2	0.48 (0.36, 0.64)	8.1	7.0, NR	4.9	4.7, 6.6	0.42 (0.34, 0.53)
OS, m	NR	NR, NR	NR	11.4, NR	0.61 (0.40, 0.93)	NR	NR, NR	NR	10.0, NR	0.65 (0.47, 0.89)
ORR, %	51.9	45.7, 58.0	29.8	22.1, 33.4		51.1	45.7, 56.2	30.1	25.4, 35.2	
DCR, %	86.8	82.2, 90.7	75.6	67.3, 82.7		86.4	82.5, 89.8	72.9	68.1, 77.6	
Grade ≥3 TEAE, %	61.7		58.8			59.4		57.5		

DCR, disease control rate; m, months; NR, not reached; ORR, objective response rate; OS, overall survival; TEAE, treatment emergent adverse event

*Yang et al. 2020

#Outcomes assessed per O-11 protocol, using weighted data