CARCINOMES DES GLANDES SALIVAIRES
NISCAHN ANTI-PD1 MONOTHERAPIE
Fayette et al., ASCO 2019

		ACC (N = 46)	Non-ACC (N = 52)
Gender	M (%)	26 (56.5%)	29 (55.8%)
	- (%)	20 (43.5%)	23 (44.2%)
Age median (range)		59 (36-80)	63 (29-81)
Metastatic Disease at inclusion	Yes	42 (91.3%)	49 (94.2%)
	No	4 (8.7%)	3 (5.8%)
Locoregional relapse at inclusion	Yes	11 (23.9%)	16 (30.8%)
	No	35 (76.1%)	36 (69.2%)
Prior Treatments		46 (100%)	52 (100%)
Surgery		39 (84.8%)	47 (90.4%)
Radiotherapy		42 (91.3%)	47 (90.4%)
Metastatic Chemotherapy		23 (50%)	34 (65.4%)
Histology for non-ACC (as per local review)			
Mucoepidermoid carcinoma			6 (11.5%)
Adenocarcinoma			28 (53.8%)
Salivary duct carcinoma			2 (3.8%)
Other			16 (30.8%)

ACC	Primary Endpoint	Non-ACC
33.3% (95%CI: 21.8-45.6)	NPR_{6m}	14% (95%CI: 6.8-24.7)
N = 15 / 45	Pts alive without progression at 6 months	N = 7 / 50
N = 46	Secondary Endpoints	N = 52
4.9 (95%CI: 3.4-6.8)	Median PFS (months)	1.8 (95%CI: 1.7-3.5)
18.1 (95%CI: 11.6-NR)	Median OS (months)	9.5 (95%CI: 7.2-NR)
10.77 (1.14-12.61)	Median FU (months) (min - max)	8.35 (1.12-14.49)
8.7% (95%CI: 2.4-20.8)	Overall Response Rate	3.8% (95%CI: 0.5-13.2)

BEST OVERALL RESPONSE	ACC (N = 46)	Non-ACC (N = 52)
Complete Response	0 (0%)	0 (0%)
Partial Response	4 (8.7%)	2 (3.8%)
Stable Disease	25 (55.5%)	22 (42.3%)
Progressive Disease	15 (34.8%)	28 (53.8%)

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ANTI-PD1 MONOTHERAPIE
PHASE II KN158 Even et al., ICHNO 2021

Key Eligibility Criteria

- Progression on or intolerance to ≥1 line of standard treatment for unresectable and/or metastatic disease
- Measurable disease per RECIST v1.1
- ECOG PS 0 or 1
- Provision of a tumor sample for biomarker assessment
  - Any PD-L1 status permitted[b]
    - PD-L1–positive defined as PD-L1 CPS ≥1
    - PD-L1–negative defined as PD-L1 CPS <1

Pembrolizumab
200 mg IV Q3W

For 35 cycles (approximately 2 years) or until disease progression,[c] intolerable toxicity, investigator decision, or patient withdrawal

109 patients with salivary gland carcinoma enrolled

Completed treatment	9 (8.3%)
Discontinued treatment	100 (91.7%)
Disease progression*	85 (78.0%)
Consent withdrawal	10 (9.2%)
AE	5 (4.6%)

Primary endpoint: ORR (RECIST v1.1, independent central review), including in biomarker-selected subgroups
Secondary endpoints: DOR, PFS (RECIST v1.1, independent central review), OS, and safety

CARCINOMES DES GLANDES SALIVAIRES ANTI-PD1 MONOTHERAPIE PHASE II KN158 Even et al., ICHNO 2021

	Patients N = 109
Age, years, median (range)	60.0 (22–82)
<65 years	77 (70.6)
Men	54 (49.5)
ECOG PS 1	51 (46.8)
PD-L1–positive tumor	28 (25.7)
No. of prior lines of systemic therapy[a]	
0	15 (13.8)
1	46 (42.2)
2	26 (23.9)
≥3	22 (20.2)
Prior radiation therapy	94 (86.2)

CARCINOMES DES GLANDES SALIVAIRES
ANTI-PD1 MONOTHERAPIE
PHASE II KN158 Even et al., ICHNO 2021

	All Patients N = 109[a]	PD-L1 Positive N = 28	PD-L1 Negative N = 77
ORR, % (95% CI)	4.6 (1.5–10.4)	10.7 (2.3–28.2)	2.6 (0.3–9.1)
Best overall response			
CR	1 (0.9)	0	1 (1.3)
PR	4 (3.7)	3 (10.7)	1 (1.3)
SD	53 (48.6)	9 (32.1)	43 (55.8)
Non-CR/non-PD	1 (0.9)	0	1 (1.3)
PD	42 (38.5)	11 (39.3)	29 (37.7)
Nonevaluable	5 (4.6)	4 (14.3)	0
No assessment	3 (2.8)	1 (3.6)	2 (2.6)