4646 - Adjuvant Nivolumab in High-Risk Muscle-Invasive Urothelial Carcinoma: Real-World Evidence from the PrInCIS-NIADY Study of the Spanish Oncology Genitourinary Group (SOGUG)

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Background

- Adjuvant nivolumab significantly improved disease-free survival (DFS) in patients (pts) with high-risk muscle-invasive urothelial carcinoma (MIUC) after radical surgery in the phase III CheckMate-274 trial.
  (*DF. Bajorin et al. N Engl J Med: 2021;384;2102-14*)
- Based on these results, since august 2023, the Spanish National Health System reimburses postoperative nivolumab in high-risk, positive programmed death ligand 1 (PDL1) MIUC.

Methods

- **PrInCIS**: Nationwide multicentre, **non-interventional epidemiological study** with retrospective patient inclusion and prospective follow-up.
- The **NIADY cohort** included pts. with **high-risk PDL1+ MIUC treated with adjuvant nivolumab in routine practice** across **65 hospitals** in **16 Spanish regions.**
- Baseline characteristics, treatment patterns, safety, and outcomes were analysed and compared against CheckMate-274.

Aim

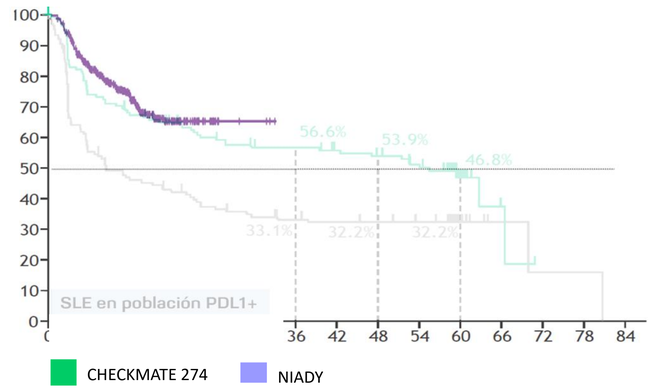
- To assess the **effectiveness** and **safety** of **adjuvant nivolumab** in **real-world clinical practice** after its approval in Spain

Results

Baseline Characteristics: Patients Treated with Nivolumab	CHECKMATE 274	NIADY
Nº patients	353	402
Male/Female (%)	75.1/24.9	81.8/18.2
Mean Age (range yr.)	65.3 (30-92)	69.5 (35-88)
≥ 65 yr. (%)	56.1	74.9
PS (%) - 0-1	98	96.7
- ≥ 2	2	3.3
Tumor origin at initial diagnosis (%)		
- Urinary bladder	79	91.4
- Renal pelvis or ureter	21	8.6
Histology (%)		
- Urothelial carcinoma	59.7	79.2
- Urothelial carcinoma variants	40.3	7.8
- Non-urothelial component	..	12.9
Neoadjuvant ChT (%)		
- Cisplatin based	43.3	48.9
- Carboplatin based	..	2.3
Pathological Tumor Stage at Resection (%)		
- pT2-4 a N0	52.2	64.3
- pT4b o N+	47.3	35.7
- LVI	..	44.1
- Positive margins	..	12.9
PDL1 expression level ≥1% (%)	39.7	95.7
Reason for adjuvant Nivolumab (%)		
- Residual Disease after neoadjuvant ChT	43.3	49.6
- No neoadjuvant ChT	56.7	44.1
- Physician`s decision	..	6.3

PS: Performance Status. LVI: Lymphovascular invasion. ChT: Chemotherapy. DFS: Disease Free Survival. OS: Overal Survival.

DFS. Patients with PDL1 ≥ 1%: CHECKMATE 274 vs NIADY



DFS & OS	NIADY
No Evidence of Disease	**57.0 %**
Alive with Disease	28.3 %
Exitus	14.7 %
Median DFS	NR
DFS estimate at 18 months	**65.6 %**
Median OS	NR
OS estimate at 18 months	**78.3 %**

Safety	NIADY
Treatment delay	37.3 %
AEs G1-2 > 10%	Asthenia. Rash. Diarrhea.
AEs G3-4 > 1%	> ALT/AST, > blood creatinine level

NIADY			
Median follow-up: 13 months		**Treatment After Recurrence**	
Recurrence: Metastases, 2nd tumor, Exitus	**27.3 %**	- None	5.3 %
- Lymph nodes	20 %	- Platinum based ChT	8.8 %
- Soft tissue	7.6 %	- Platinum based ChT -Avelumab	1.1 %
- Lung	5.3 %	- AntiPD1-PDL1	1.0 %
- Liver	3.8 %	- Enfortumab-vedotin	6.6 %
- Bone	6.6 %	- Taxanes-Vinflunine	0.8 %
- 2nd utothelial tumor	2 %	- Radiotherapy-Surgery	0.3 %
Response After Recurrence			
- Complete response	7.5%		
- Stable disease, partial response, on treatment	60.2%		
- Disease progession	34.3 %		

Conclusion

- With a median follow-up of 13 months, **our real-world data validates the results of the pivotal trial** with a manegeable safety profile despite an older population.
- The **PrInCIS-NIADY study reinforces the role of adjuvant nivolumab in daily clinical practice** for high-risk MIUC as defined in the Checkmate-274 trial.

Conflicts of interest: *The presenting author has no conflict of interest regarding this communication.*

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