Atezolizumab Monotherapy in Cisplatin-Ineligible Patients With Previously Untreated Metastatic Urothelial Carcinoma: 5-Year Response and Survival Analysis From the Phase II IMvigor210 Study (Cohort 1)

Jonathan E. Rosenberg,¹ Matthew D. Galsky,² Arjun V. Balar,³ Yohann Loriot,⁴ Andrea Necchi,⁵ Jean Hoffman-Censits,⁶ Sandy Srinivas, Alexandra Drakaki, Apurva Javery, 9 Yi Shi,¹⁰ Hannah (Xinhui) Huang,¹⁰ Xiaodong Shen,¹⁰ Michiel S. van der Heijden¹¹

¹ Memorial Sloan Kettering Cancer Center, New York, NY, USA; ² Icahn School of Medicine at Mount Sinai/Tisch Cancer Institute, New York, NY, USA; 3 Perlmutter Cancer Center, NYU Langone Health, New York, NY, USA;⁴ Université Paris-Sud, Université Paris-Saclay, Gustave Roussy, Villejuif, France; ⁵ Vita-Salute San Raffaele University and IRCCS San Raffaele Hospital, Milan, Italy; ⁶ Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, Baltimore, MD, USA; ⁷ Stanford University Medical Center, Stanford, CA, USA; 8 University of California, Los Angeles, Los Angeles, CA, USA; 9 Syneos Health, Raleigh, NC, USA; 10 Genentech Inc, South San Francisco, CA, USA; 11 Netherlands Cancer Institute, Amsterdam, the Netherlands



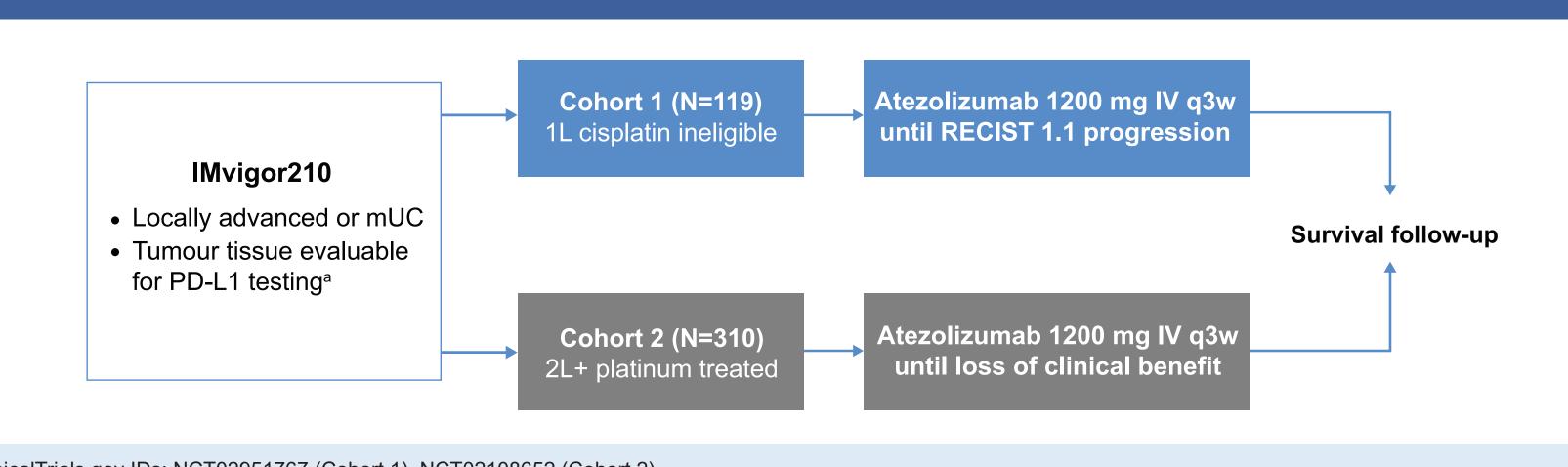
BACKGROUND

- Cisplatin-based chemotherapy is the standard of care for first-line (1L) treatment of metastatic urothelial carcinoma (mUC), although many patients are ineligible for cisplatin
- Atezolizumab (anti-PD-L1) is recommended for the treatment of several types of locally advanced or mUC, including cisplatin-ineligible patients whose tumours express PD-L1 (PD-L1-expressing immune cells [IC] covering ≥5% of the tumour area [IC2/3])¹⁻³
- Cohort 1 of the pivotal, single-arm, Phase II, IMvigor210 study demonstrated the tolerability of and durable responses to 1L atezolizumab in patients with cisplatin-ineligible mUC,4 with sustained responses observed with additional follow-up⁵
- The ongoing Phase III IMvigor130 study has also demonstrated prolonged efficacy with 1L atezolizumab monotherapy vs platinum-based chemotherapy in exploratory analyses in patients with PD-L1 IC2/3 tumours, including those ineligible for cisplatin^{6,7}
- To evaluate the long-term efficacy of atezolizumab in patients with cisplatinineligible previously untreated mUC, here, we report updated data from IMvigor210 Cohort 1, based on over 5 years of follow-up



IMvigor210 is an ongoing, global, single-arm, Phase II trial investigating the efficacy and safety of atezolizumab monotherapy in 1L cisplatin-ineligible mUC and previously platinum-treated mUC

Figure 1. IMvigor210 study design⁴



- Primary endpoint (Cohort 1) was objective response rate (ORR) per RECIST 1.1 as assessed by independent review facility (IRF)
- Key secondary endpoints reported here: duration of response (DOR) as assessed by IRF and overall survival (OS)
- In this poster, efficacy was descriptively evaluated in the all-comer patients and subgroups defined by PD-L1 status on IC (IC2/3 or PD-L1–expressing IC covering <5% of the tumour area [IC0/1])



RESULTS

Durable responses and long-term survival with 1L atezolizumab monotherapy were observed in this 5-year clinical update

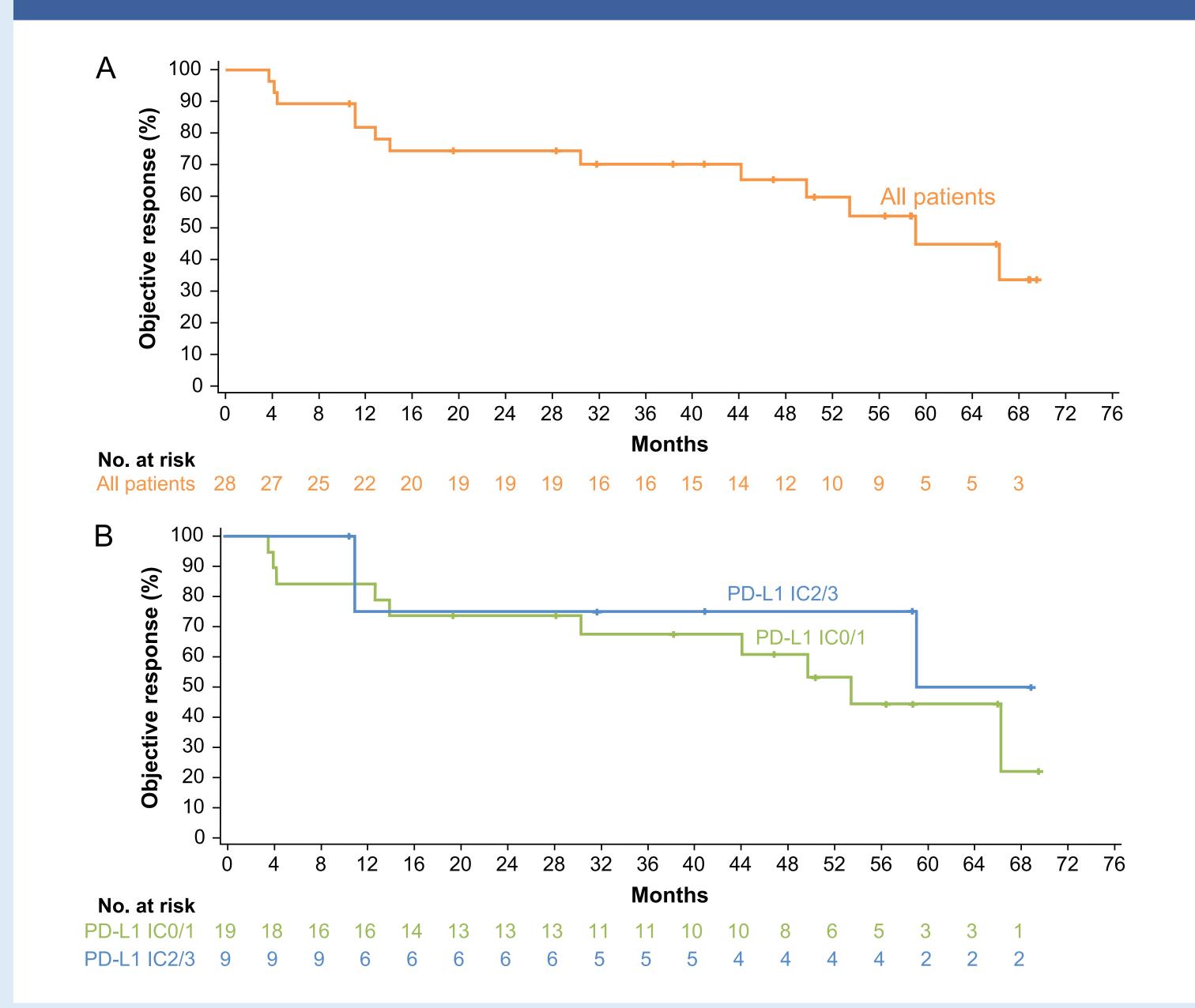
Table. Efficacy summary	All comers	PD-L1 IC0/1	PD-L1 IC2/3
Tablet Efficacy Sammary	(N=119)	(n=87)	(n=32)
Objective response ^a			
ORR, n (%) [95% CI]	28 (23.5) [16.2, 32.2]	19 (21.8) [13.7, 32.0]	9 (28.1) [13.8, 46.8]
CR, n (%)	12 (10.1)	7 (8.0)	5 (15.6)
Ongoing responses, n/n (%)b	15/28 (53.6)	9/19 (47.4)	6/9 (66.7)
Median DOR (95% CI), mo	59.1 (44.2, NE)	53.5 (30.4, NE)	NE (11.1, NE)
os			
OS events, n (%)	92 (77.3)	68 (78.2)	24 (75.0)
Median OS (95% CI), mo	16.3 (10.4, 24.5)	19.1 (10.4, 25.2)	12.3 (6.0, 49.8)
24-mo OS (95% CI), %	41.1 (32.1, 50.2)	41.8 (31.1, 52.5)	39.3 (22.1, 56.5)
60-mo OS (95% CI), %	21.6 (13.7, 29.5)	19.6 (10.8, 28.5)	27.0 (10.3, 43.7)
Clinical cutoff, 31 January 2021.			

Response was per IRF in objective response-evaluable patients.

- ^b Refers to no death or progressive disease only in patients who achieved an objective response.
- As of the data cutoff, the median follow-up duration was 70.8 months (range, 0.2-77.5)
- There were no new responders since the 14 March 2016 data cutoff

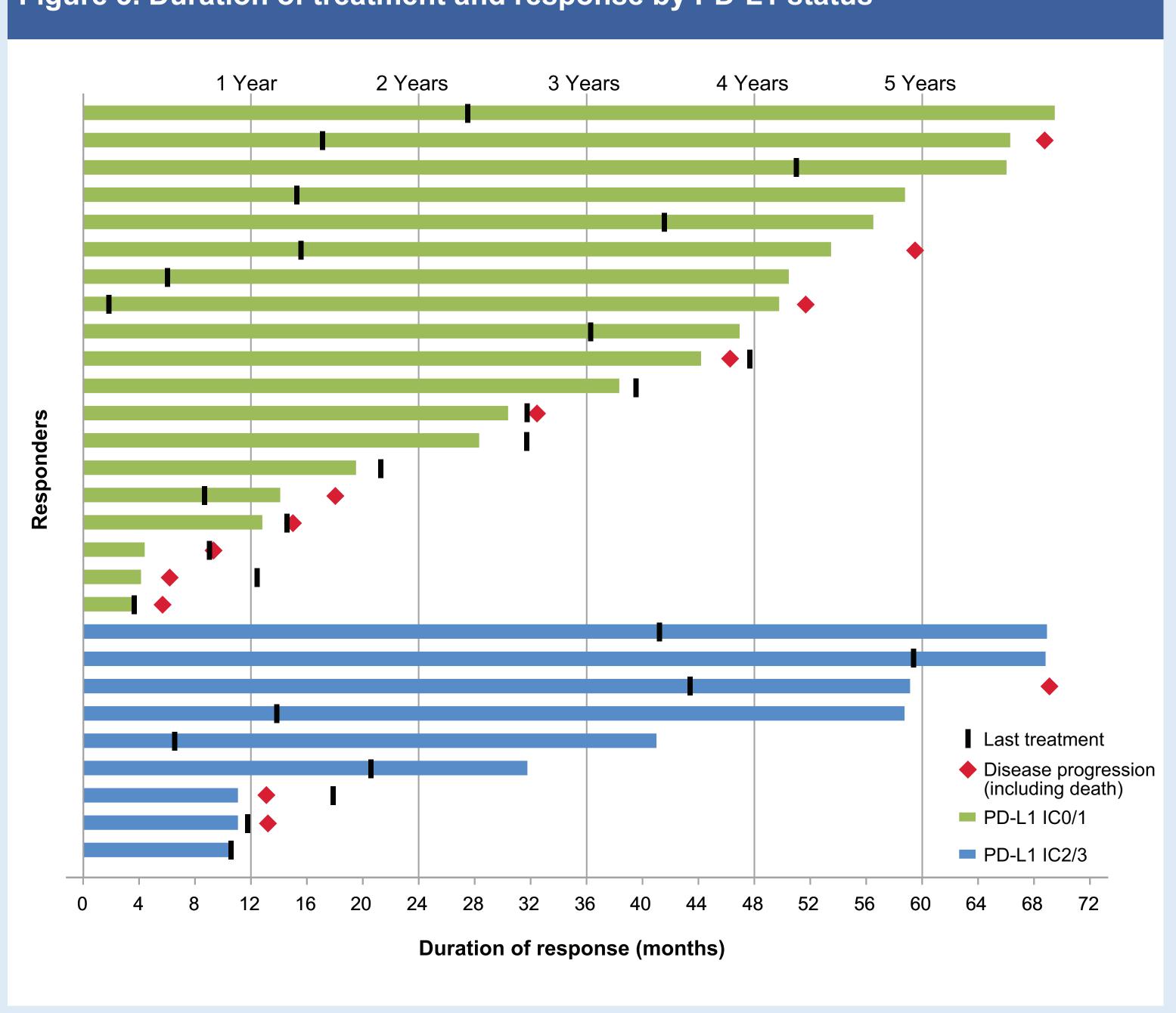
Median DOR has not been reached in the PD-L1 IC2/3 subgroup of patients

Figure 2. Kaplan-Meier curves for DOR (A) in all comers and (B) by PD-L1 status



Clinical cutoff, 31 January 2021

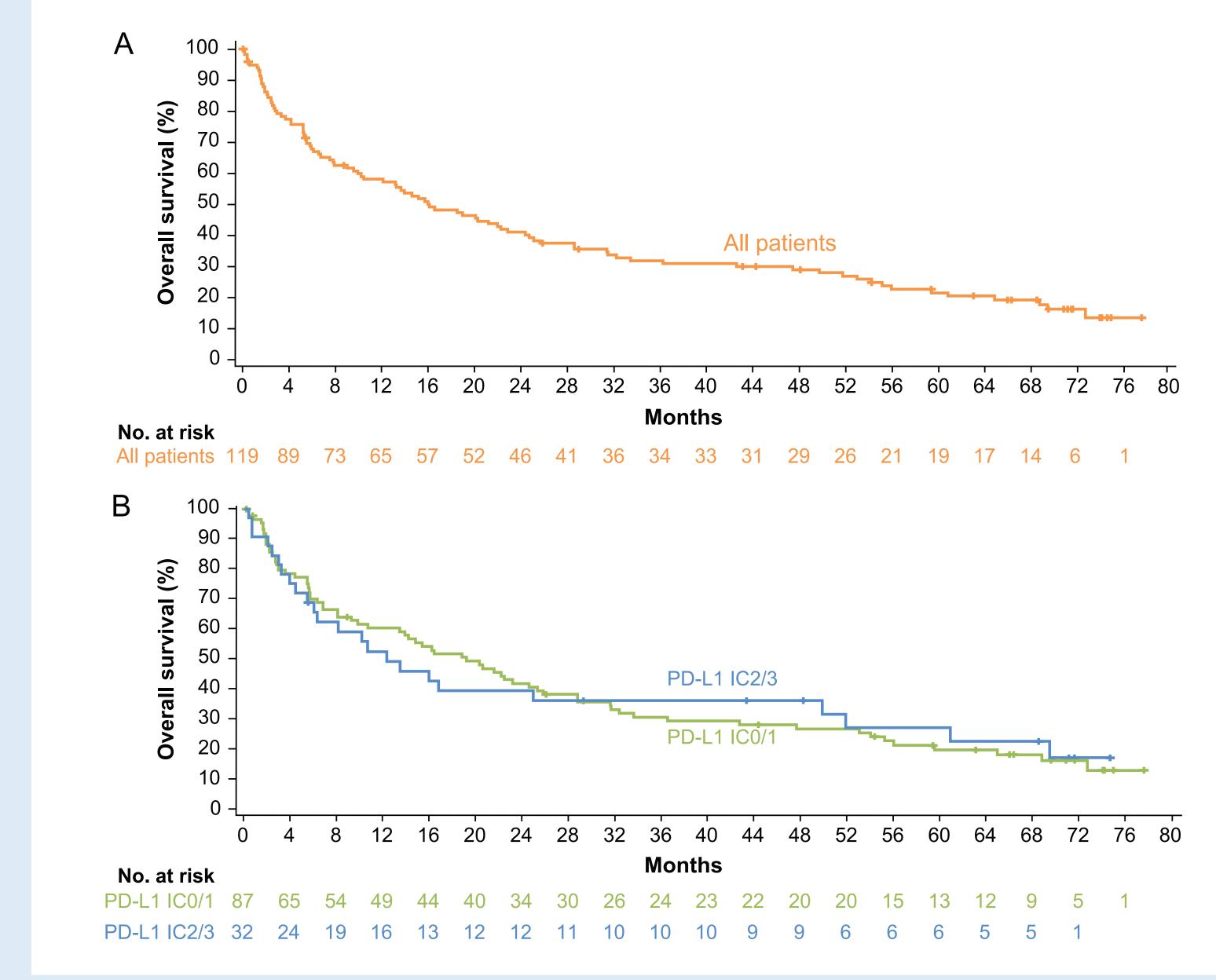
Figure 3. Duration of treatment and response by PD-L1 status



Clinical cutoff, 31 January 2021

Prolonged survival was seen in the all-comer population, including patients with PD-L1 IC0/1 and IC2/3 tumours





Clinical cutoff, 31 January 2021

CONCLUSIONS

Durable responses and long-term survival with 1L atezolizumab monotherapy in cisplatin-ineligible mUC were observed in this 5-year clinical update from the Phase II IMvigor210 study (Cohort 1)

Median DOR was not reached in patients with PD-L1 IC2/3 mUC

The 5-year OS rate seen in the overall all-comer population (≈22%) compares favourably with historic data,8 including gemcitabine/carboplatin in cisplatin-ineligible patients9

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For questions or comments on this poster, please conta Dr Jonathan E. Rosenberg at rosenbj1@mskcc.org

AUTHOR EMAIL