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IMvigor130: a phase III study of atezolizumab with or without platinum-based chemotherapy in previously untreated metastatic urothelial carcinoma

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Disclosures

Dr Enrique Grande has the following financial relationships to disclose:

- Honoraria for advisory boards and/or lectures:
  - Pfizer, Bristol-Myers Squibb, Ipsen, Roche, Eisai, EUSA Pharma, MSD, Sanofi Genzyme, Adacap, Novartis, Pierre Fabre, Lexicon, Celgene, Astellas, Janssen, Bayer
- Research grants:
  - Pfizer, AstraZeneca, Roche, Ipsen, Lexicon, Molecular Templates
- Leadership roles in medical societies:
  - ENETS, GETNE and GETHI
- Stocks or ownership interest:
  - None

Metastatic urothelial carcinoma (mUC)

- Cisplatin-based chemotherapy has been standard 1L treatment in mUC for > 30 years, during which time no further advancements have been reported[1,2]
  - ≈ 50% of patients with mUC are ineligible for cisplatin, and they generally receive inferior carboplatin-based regimens[3,4]
- PD-L1 and PD-1 inhibitors are the first new systemic therapies for mUC, both for 1L treatment of cisplatin-ineligible patients and for patients experiencing disease progression despite platinum-based chemotherapy (plt/gem)[5-12]
- In July 2018, the FDA and EMA revised the 1L label for atezolizumab (anti–PD-L1) and pembrolizumab (anti–PD-1) based on IDMC assessments[13-16]
- Here we report final PFS and interim OS results for IMvigor130, assessing atezolizumab alone or in combination with plt/gem vs placebo + plt/gem in 1L mUC

plt/gem, cisplatin or carboplatin plus gemcitabine.

1. Loehrer *JCO* 1992; 2. von der Maase *JCO* 2005; 3. Bamias *Ann Oncol* 2018; 4. Galsky *Ann Oncol* 2012; 5. Gartrell *Urol Oncol* 2017; 6. Balar *Lancet* 2017; 7. Balar *Lancet Oncol* 2017; 8. Powles *Lancet* 2018; 9. Rosenberg *Lancet* 2016; 10. Massard *J Clin Oncol* 2016; 11. Sharma *Lancet Oncol* 2017; 12. Apolo *J Clin Oncol* 2017; 13. TECENTRIQ USPI 2019; 14. TECENTRIQ SmPC 2019; 15. KEYTRUDA USPI 2019; 16. KEYTRUDA SmPC 2019.

IMvigor130: Key protocol amendments

Arms	Randomization	Platinum eligibility	Monotherapy	Enrolment (n)
2	2:1	Cisplatin-ineligible only	No	129

Rationale: IMvigor210 results provided proof-of-concept for testing atezo monotherapy and including cisplatin-eligible patients

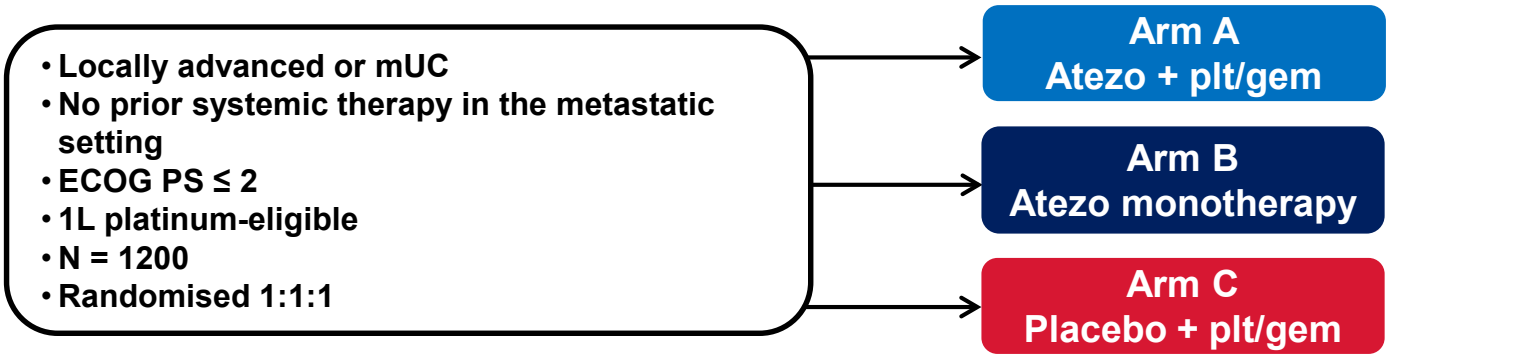
3	1:1:1	Cisplatin-ineligible/ Cisplatin-eligible	Yes	1078

Rationale: IDMC recommended change based on early assessment of the atezo monotherapy arm

3	1:1:1	Cisplatin-ineligible/ Cisplatin-eligible	Only PD-L1 IC2/3[a]	6

[a] PD-L1 status in the monotherapy arm was unblinded in the final protocol amendment per IDMC recommendation, such that IC0/1 patients received atezo + plt/gem and IC2/3 patients received atezo monotherapy.

IMvigor130 study design



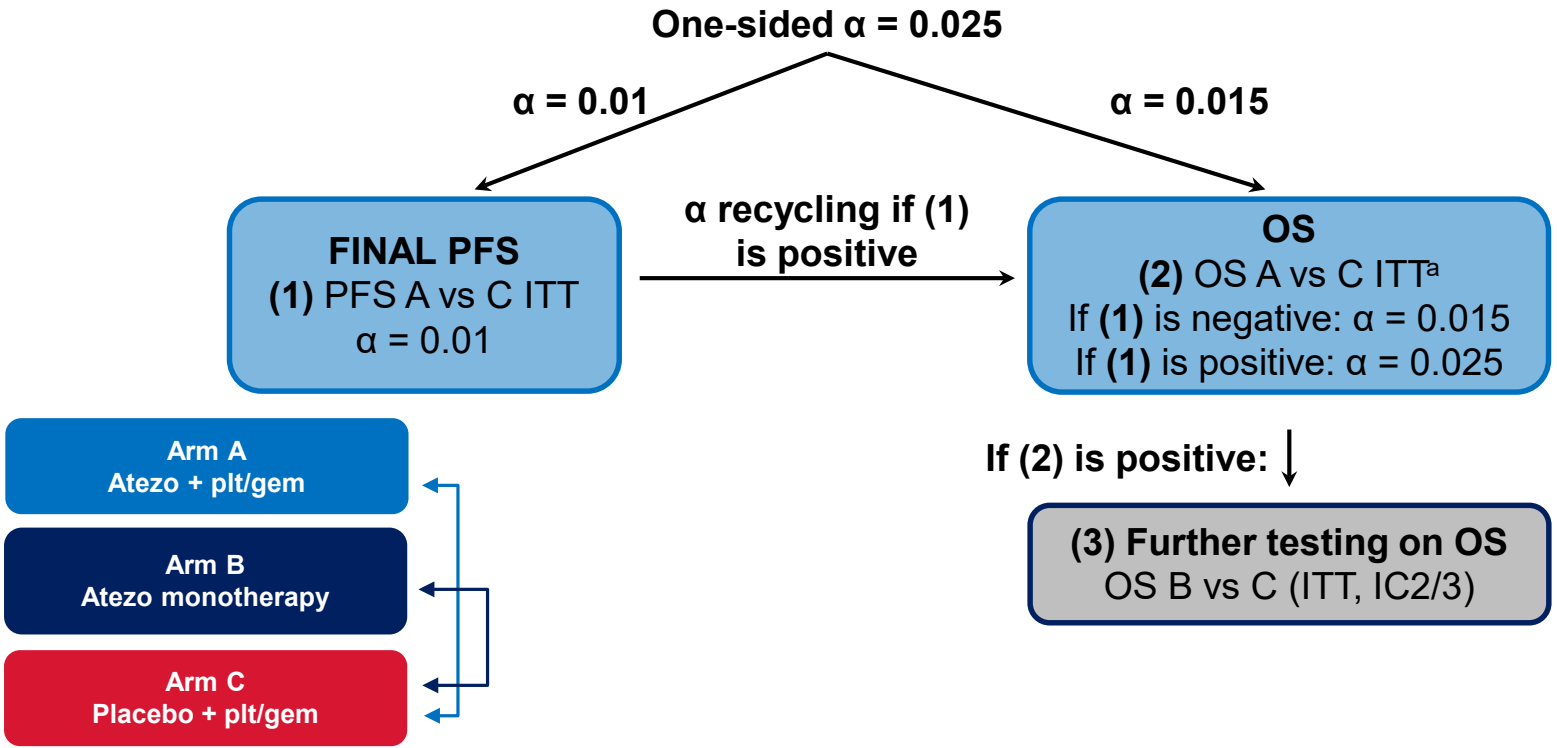
Stratification factors:
- PD-L1 IC status (IC0 vs IC1 vs IC2/3)
- Bajorin risk factor score including KPS < 80% vs ≥ 80% and presence of visceral metastases (0 vs 1 vs 2 and/or patients with liver metastases)
- Investigator choice of plt/gem (cisplatin + gem or carboplatin + gem)

Co-primary endpoints:
- INV-assessed PFS[a] and OS (Arm A vs C)
- OS (Arm B vs C, hierarchical approach)

Key secondary endpoints:
- INV-ORR[a] and DOR
- PFS[a] and OS (Arm B vs C; PD-L1 IC2/3 subgroup)
- Safety

[a] per RECIST 1.1.

IMvigor130 statistical testing hierarchy



ITT, intent to treat.

[a] Timing of this final PFS and interim OS analysis was planned after ≈ 667 PFS events were observed in ITT (Arms A + C). Final OS analysis will be triggered by number of OS events observed in ITT (Arms A + C). The efficacy boundaries at interim and final OS analyses were determined based on the O'Brien Fleming alpha spending function.

IMvigor130 baseline characteristics

Characteristic	Atezo + plt/gem (n = 451)	Placebo + plt/gem (n = 400)[a]	Atezo (n = 362)
Median age (range), y	69 (31-87)	67 (33-89)	67 (36-87)
ECOG PS, n (%)			
0	182 (40)	173 (43)	157 (43)
1	209 (46)	187 (47)	174 (48)
2	60 (13)	40 (10)	31 (9)
Bajorin risk factor score, n (%)			
0	176 (39)	162 (41)	151 (42)
1	169 (37)	149 (37)	134 (37)
2 and/or liver mets	106 (24)	89 (22)	77 (21)
PD-L1 status on IC, n (%)			
IC2/3	108 (24)	91 (23)	88 (24)
IC1	195 (43)	179 (45)	160 (44)
IC0	148 (33)	130 (33)	114 (31)
Cisplatin ineligibility[b]	204 (45)	140 (35)	107 (30)
Renal impairment	113 (25)	94 (24)	65 (18)
Investigator choice of chemotherapy[c]			
Carboplatin	314 (70)	264 (66)	227 (63)
Cisplatin	137 (30)	136 (34)	135 (37)

[a] n = 359 for comparisons to atezo monotherapy arm. [b] Per Galsky criteria per protocol, excluding New York Heart Association functional classification.
[c] Of the patients considered cisplatin eligible at study entry, 52% received carboplatin, while 10% of patients who were cisplatin ineligible received cisplatin.

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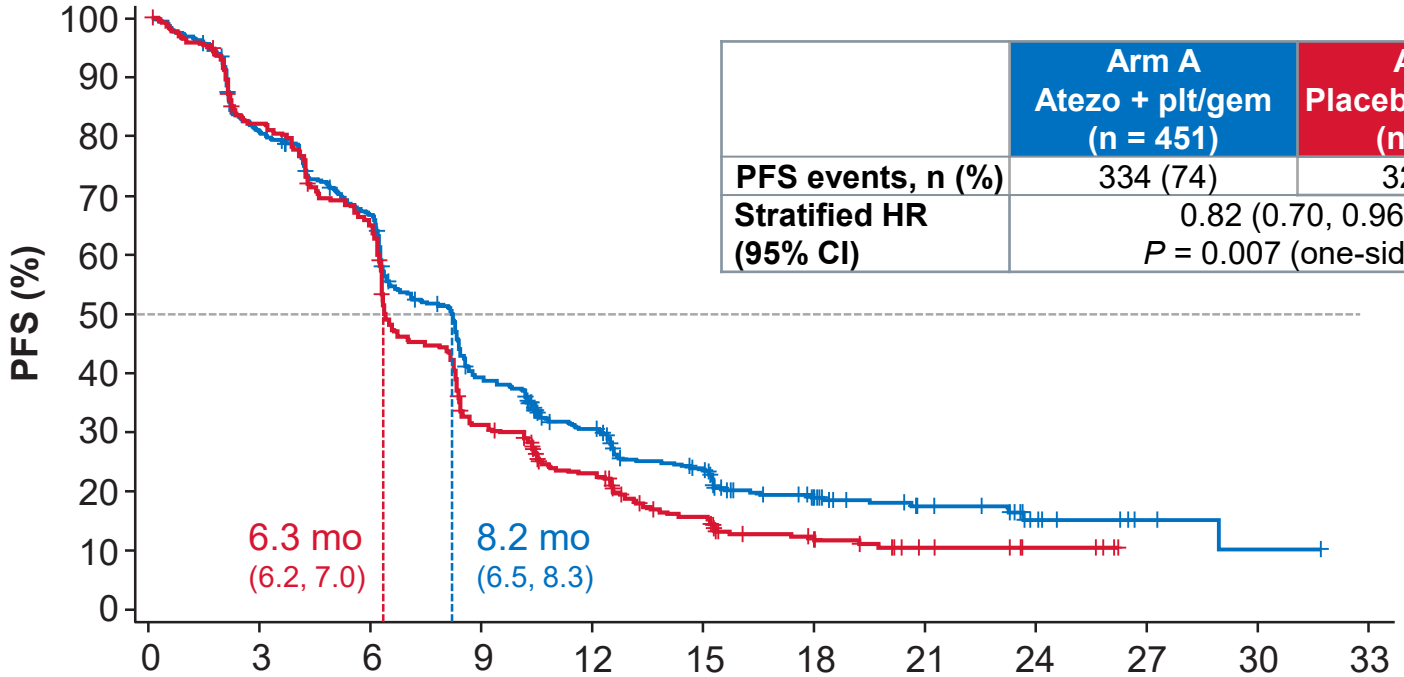
Final PFS: ITT (Arm A vs Arm C)



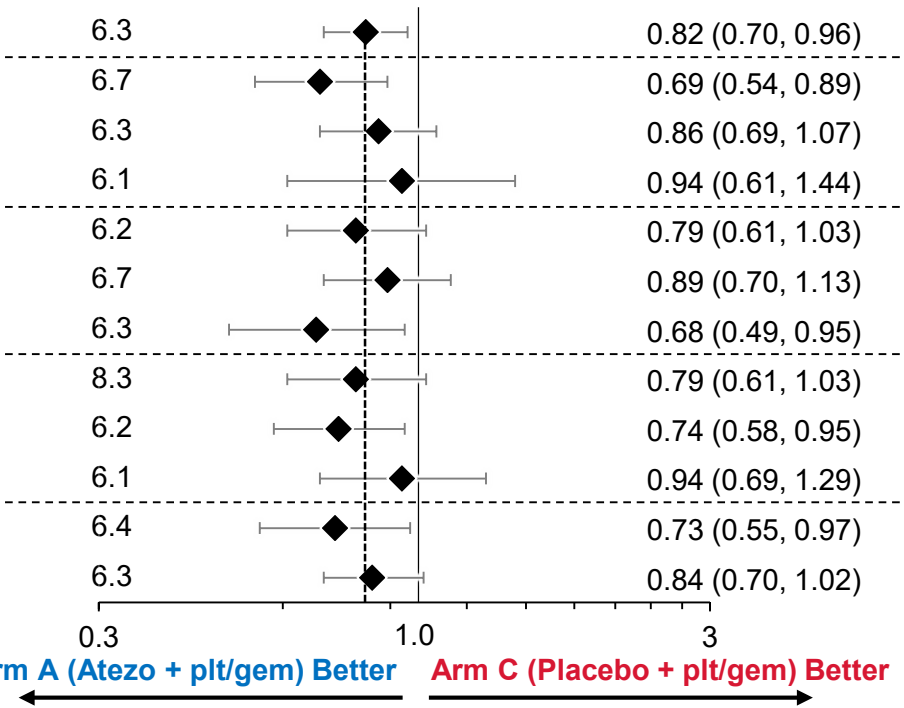
	Arm A Atezo + plt/gem (n = 451)	Arm C Placebo + plt/gem (n = 400)
PFS events, n (%)	334 (74)	326 (82)
Stratified HR (95% CI)	0.82 (0.70, 0.96) *P* = 0.007 (one-sided)	

No. at Risk												
Atezo + plt/gem	451	345	282	160	111	74	42	22	10	4	2	NE
Placebo + plt/gem	400	317	246	116	73	40	18	11	4	NE	NE	NE

NE, not estimable. Data cutoff 31 May 2019; median survival follow-up 11.8 months (all patients).

PFS subgroups: ITT (Arm A vs Arm C)

Characteristic		Patients (n)	Arm A mPFS, mo (n = 451)	Arm C mPFS, mo (n = 400)	HR (95% CI)[a]
All patients		851	8.2	6.3	0.82 (0.70, 0.96)
ECOG PS	0	355	9.4	6.7	0.69 (0.54, 0.89)
	1	396	6.8	6.3	0.86 (0.69, 1.07)
	2	100	4.8	6.1	0.94 (0.61, 1.44)
PD-L1 status	0	278	6.5	6.2	0.79 (0.61, 1.03)
	1	374	8.1	6.7	0.89 (0.70, 1.13)
	2/3	199	8.6	6.3	0.68 (0.49, 0.95)
Bajorin risk factor score	0	338	9.8	8.3	0.79 (0.61, 1.03)
	1	318	8.2	6.2	0.74 (0.58, 0.95)
	2 and/or liver mets	195	5.0	6.1	0.94 (0.69, 1.29)
Investigator choice of chemo	Cisplatin	273	8.8	6.4	0.73 (0.55, 0.97)
	Carboplatin	578	7.1	6.3	0.84 (0.70, 1.02)



[a] Unstratified HR shown for all characteristics except for 'All Patients', where stratified HR is shown.

PFS subgroups: ITT (Arm A vs Arm C)

Characteristic		Patients (n)	Arm A mPFS, mo (n = 451)	Arm C mPFS, mo (n = 400)	HR (95% CI)[a]
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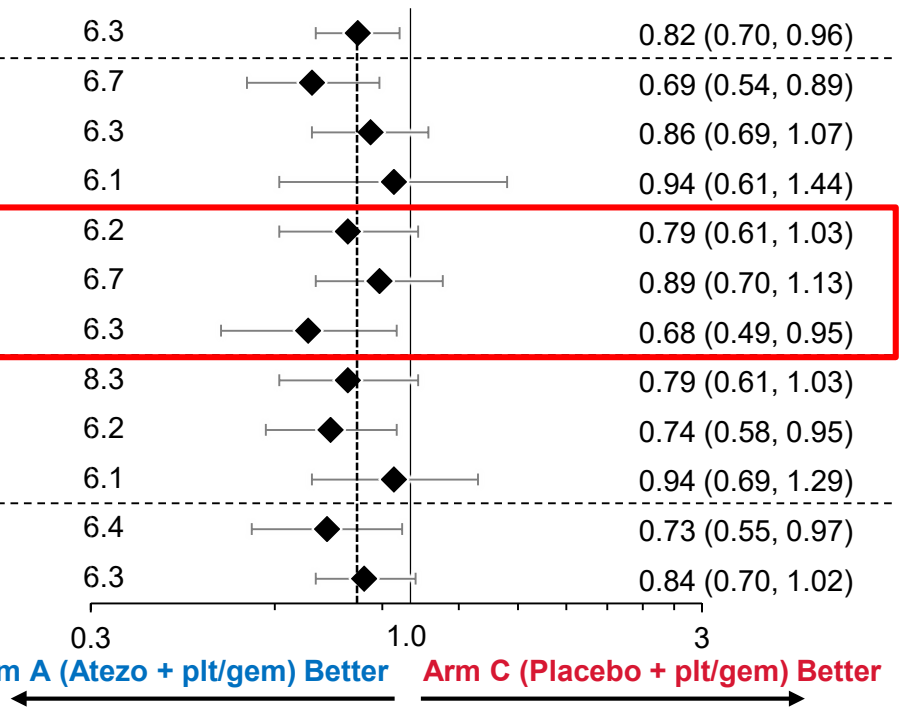

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PFS subgroups: ITT (Arm A vs Arm C)

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	1	396	6.8	6.3	0.86 (0.69, 1.07)
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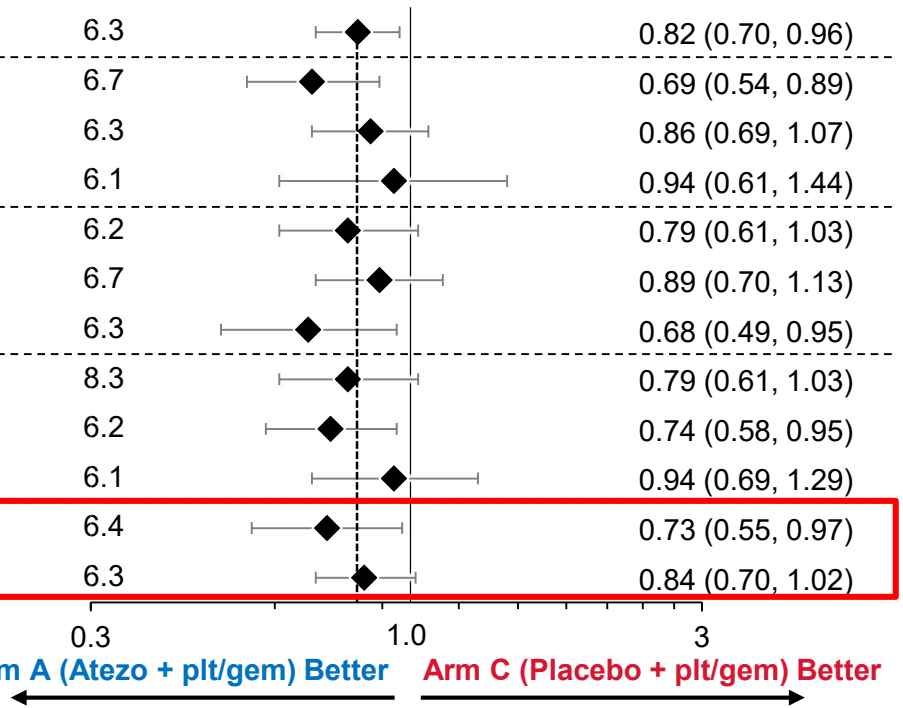
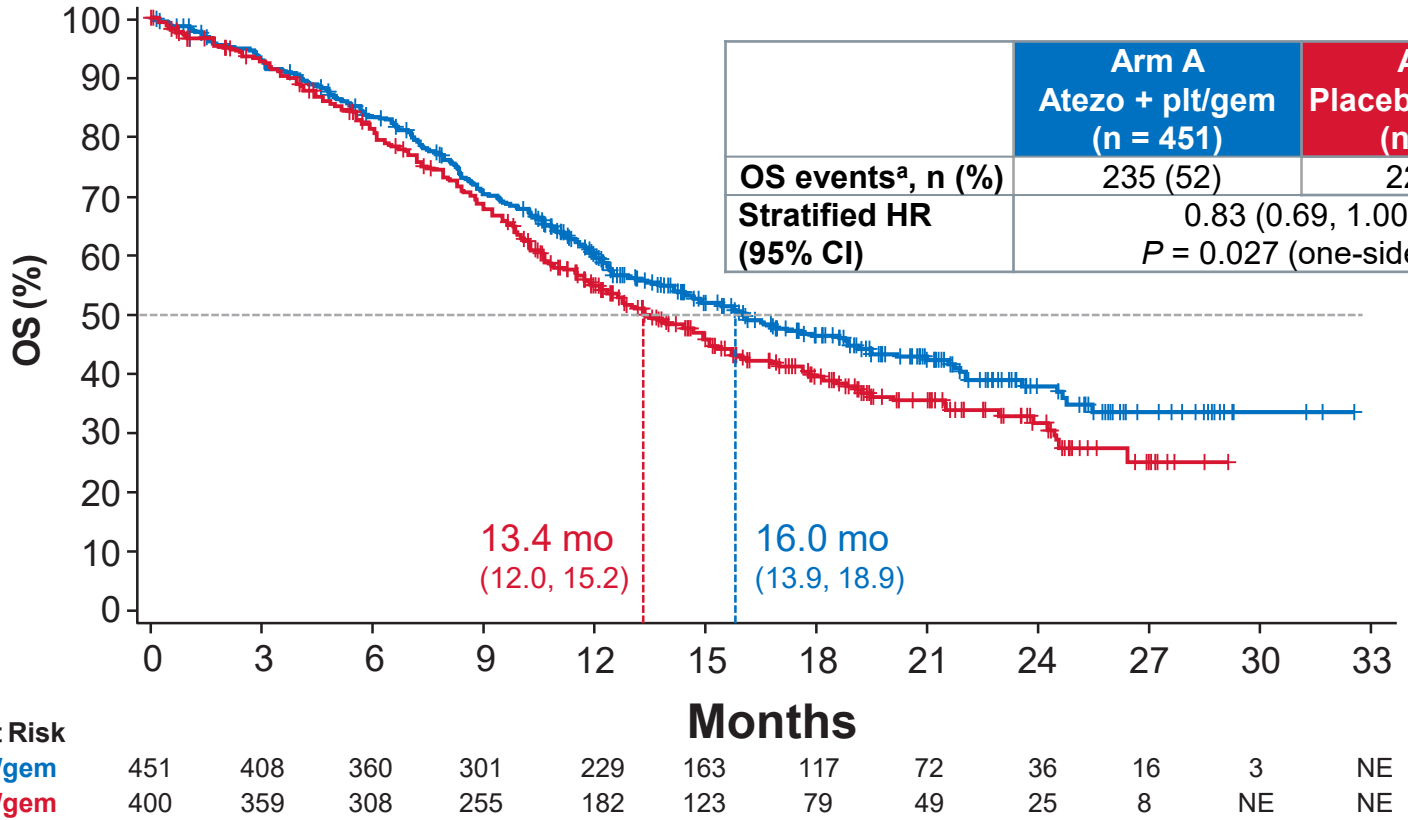


[a] Unstratified HR shown for all characteristics except for 'All Patients', where stratified HR is shown.

Interim OS: ITT (Arm A vs Arm C)



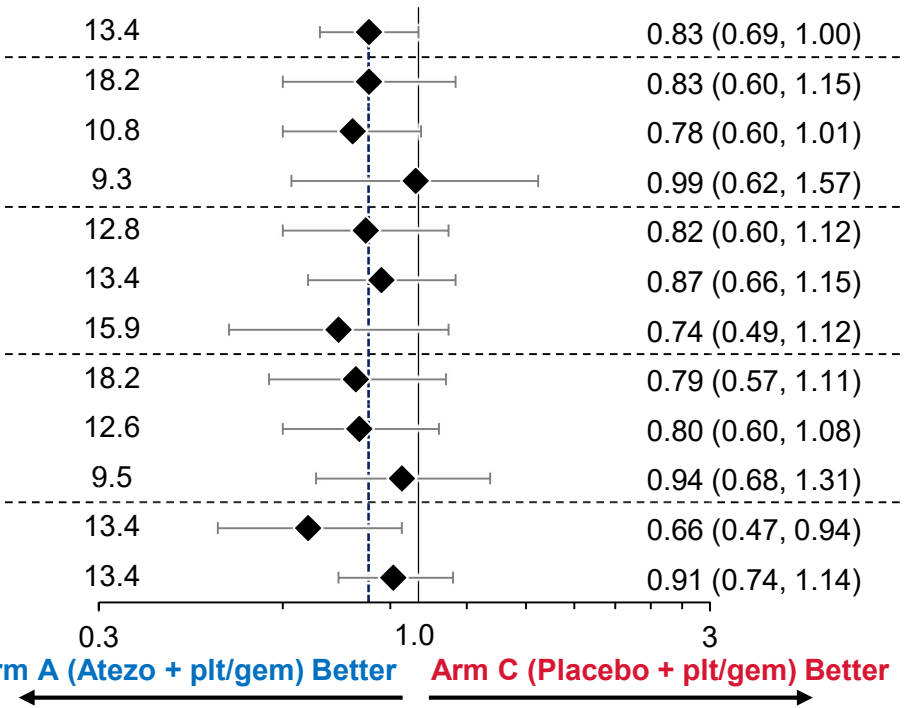
	Arm A Atezo + plt/gem (n = 451)	Arm C Placebo + plt/gem (n = 400)
OS events[a], n (%)	235 (52)	228 (57)
Stratified HR (95% CI)	0.83 (0.69, 1.00) *P* = 0.027 (one-sided)[b]	

No. at Risk												
Atezo + plt/gem	451	408	360	301	229	163	117	72	36	16	3	NE
Placebo + plt/gem	400	359	308	255	182	123	79	49	25	8	NE	NE

Data cutoff 31 May 2019; median survival follow-up 11.8 months (all patients). [a] 5% of patients from Arm A and 20% of patients from Arm C received non-protocol immunotherapy. [b] Did not cross the interim efficacy boundary of 0.007 per the O'Brien-Fleming alpha spending function.

Interim OS subgroups: ITT (Arm A vs Arm C)

Characteristic		Patients (n)	Arm A mOS, mo (n = 451)	Arm C mOS, mo (n = 400)	HR (95% CI)[a]
All patients		851	16.0	13.4	0.83 (0.69, 1.00)
ECOG PS	0	355	22.0	18.2	0.83 (0.60, 1.15)
	1	396	14.2	10.8	0.78 (0.60, 1.01)
	2	100	7.4	9.3	0.99 (0.62, 1.57)
PD-L1 status	0	278	14.2	12.8	0.82 (0.60, 1.12)
	1	374	14.9	13.4	0.87 (0.66, 1.15)
	2/3	199	23.6	15.9	0.74 (0.49, 1.12)
Bajorin risk factor score	0	338	24.5	18.2	0.79 (0.57, 1.11)
	1	318	15.8	12.6	0.80 (0.60, 1.08)
	2 and/or liver mets	195	9.5	9.5	0.94 (0.68, 1.31)
Investigator choice of chemo	Cisplatin	273	21.7	13.4	0.66 (0.47, 0.94)
	Carboplatin	578	14.2	13.4	0.91 (0.74, 1.14)



[a] Unstratified HR shown for all characteristics except for 'All Patients', where stratified HR is shown.

Interim OS subgroups: ITT (Arm A vs Arm C)

Characteristic		Patients (n)	Arm A mOS, mo (n = 451)	Arm C mOS, mo (n = 400)	HR (95% CI)[a]
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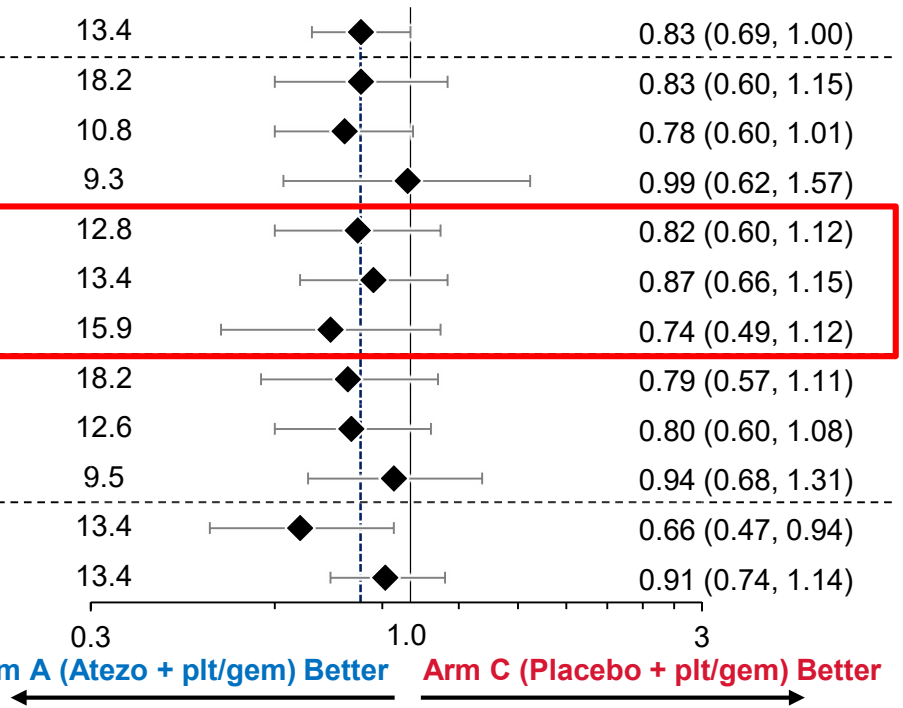

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Interim OS subgroups: ITT (Arm A vs Arm C)

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All patients		851	16.0	13.4	0.83 (0.69, 1.00)
ECOG PS	0	355	22.0	18.2	0.83 (0.60, 1.15)
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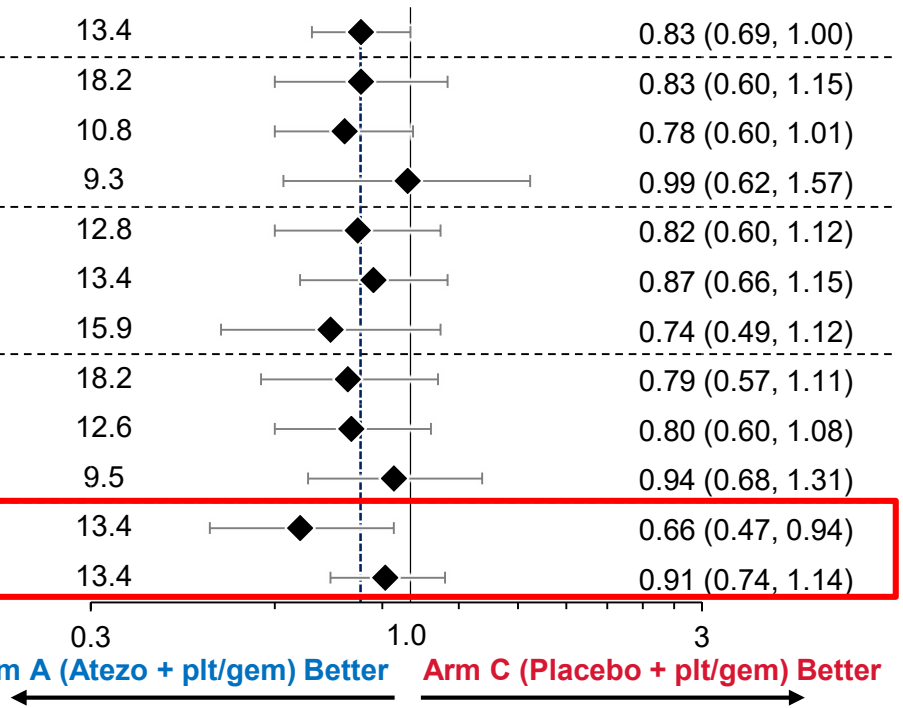
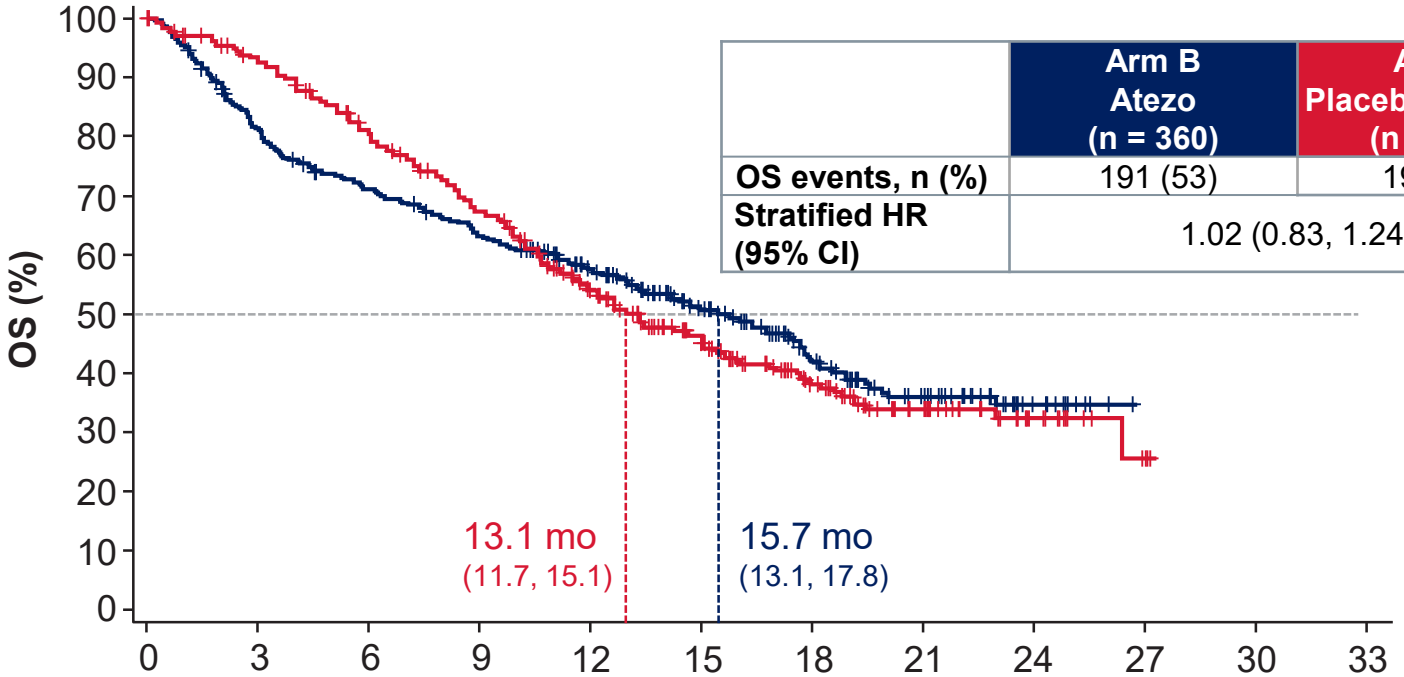


[a] Unstratified HR shown for all characteristics except for 'All Patients', where stratified HR is shown.

Interim OS for Monotherapy: ITT (Arm B vs Arm C)

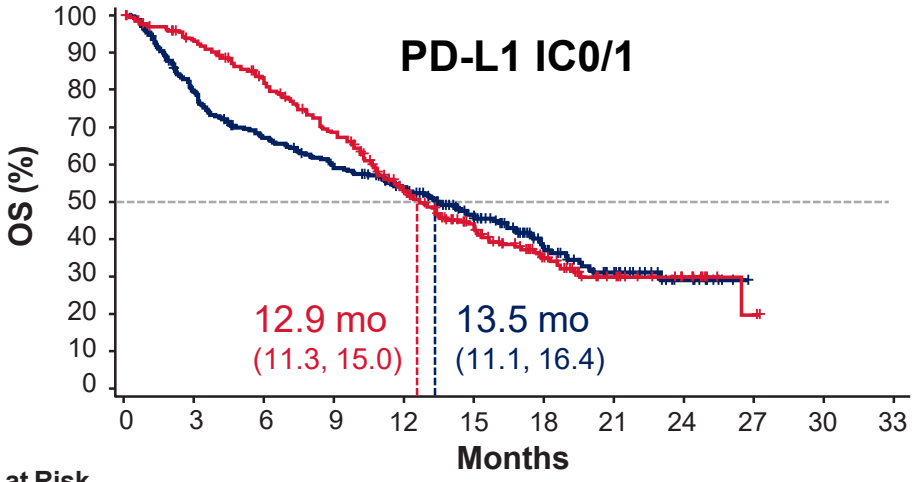


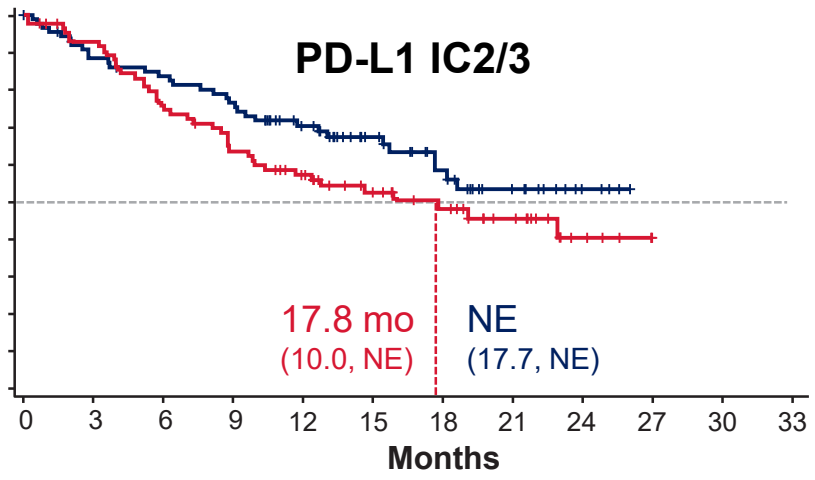
	Arm B Atezo (n = 360)	Arm C Placebo + plt/gem (n = 359)[a]
OS events, n (%)	191 (53)	198 (55)
Stratified HR (95% CI)	1.02 (0.83, 1.24)	

No. at Risk												
Atezo	360	285	245	216	173	120	72	42	16	NE	NE	NE
Placebo + plt/gem	359	322	274	224	158	103	62	35	15	3	NE	NE

Data cutoff 31 May 2019; median survival follow-up 11.8 months (all patients). [a] Comparison only includes patients concurrently enrolled with Arm B.

Interim OS: PD-L1 status (Arm B vs Arm C)





No. at Risk												
Atezo	272	210	175	152	124	85	48	28	11	NE	NE	NE
Placebo + plt/gem	274	246	212	173	116	73	41	21	10	2	NE	NE

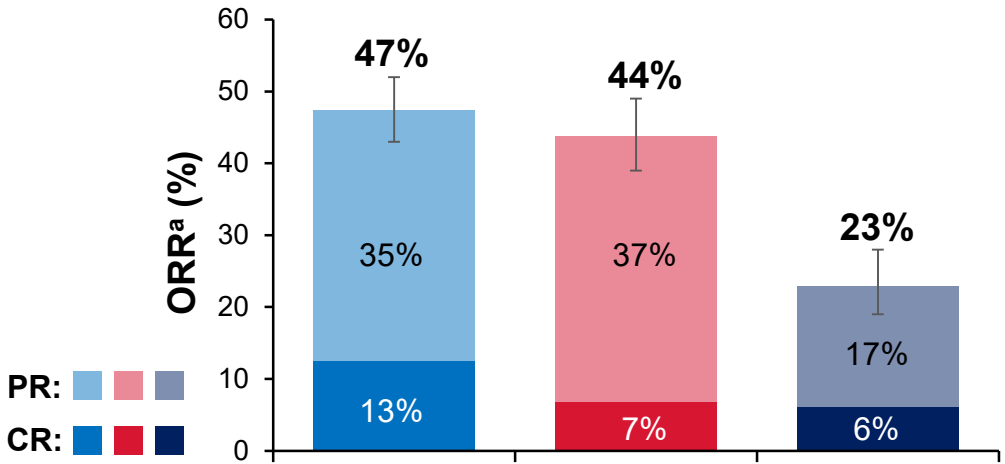
No. at Risk												
Atezo	88	75	70	64	49	35	24	14	5	NE	NE	NE
Placebo + plt/gem	85	76	62	51	42	30	21	14	5	1	NE	NE

	Arm B Atezo (n = 272)	Arm C Placebo + plt/gem (n = 274)
OS events, n (%)	158 (58)	156 (57)
Unstratified HR (95% CI)	1.07 (0.86, 1.33)	

	Arm B Atezo (n = 88)	Arm C Placebo + plt/gem (n = 85)
OS events, n (%)	33 (38)	42 (49)
Stratified HR (95% CI)	0.68 (0.43, 1.08)	

Data cutoff 31 May 2019; median survival follow-up 11.8 months (all patients).

Confirmed ORR and DOR



	Atezo + plt/gem	Placebo + plt/gem	Atezo
DOR[b], median (95% CI), mo	8.5 (7.2,10.4)	7.6 (6.3, 8.5)	NE (15.9, NE)

Data cutoff 31 May 2019; median survival follow-up 11.8 months (all patients).
[a] Objective response–evaluable patients: n = 447 in atezo + plt/gem, n = 397 in placebo + plt/gem, n = 359 in atezo.
[b] n = 212 in atezo + plt/gem, n = 174 in placebo + plt/gem, n = 82 in atezo.

Safety summary

AE, n (%)	Atezo + plt/gem (n = 453)	Placebo + plt/gem (n = 390)	Atezo (n = 354)
Any grade, all cause	451 (100)	386 (99)	329 (93)
Grade 3-4	383 (85)	334 (86)	148 (42)
Grade 5	29 (6)	20 (5)	28 (8)
Any grade, treatment related	434 (96)	373 (96)	211 (60)
Grade 3-4	367 (81)	315 (81)	54 (15)
Grade 5	9 (2)	4 (1)	3 (1)
Any grade, serious	234 (52)	191 (49)	152 (43)
Treatment-related serious AEs	144 (32)	101 (26)	44 (12)
Any grade leading to any treatment discontinuation	156 (34)	132 (34)	22 (6)
Atezo or placebo discontinuation	50 (11)	27 (7)	21 (6)
Cisplatin discontinuation	53 (12)	52 (13)	0
Carboplatin discontinuation	90 (20)	79 (20)	1 (< 1)[a]
Gemcitabine discontinuation	117 (26)	100 (26)	1 (< 1)[a]
Any grade leading to any dose reduction or interruption	363 (80)	304 (78)	112 (32)

AE, adverse event. Safety-evaluable population.
Data cutoff, 31 May 2019; median survival follow-up 11.8 months (all patients).
[a] This patient was randomised to atezo + plt/gem and received atezo; they had an AE of pyrexia that day, and gemcitabine and carboplatin were marked as 'drug withdrawn'. Since no chemotherapy was given, this patient was included in the atezo monotherapy arm for safety analysis.

AESIs suggestive of potential immune-related aetiology

Any grade AESIs ≥ 1% in any arm[a], n (%)	Atezo + plt/gem (n = 453)	Placebo + plt/gem (n = 390)	Atezo (n = 354)
Rash	137 (30)	74 (19)	45 (13)
Hepatitis (diagnosis and laboratory abnormalities)[b]	82 (18)	49 (13)	50 (14)
Hepatitis (laboratory abnormalities)	79 (17)	44 (11)	46 (13)
Hepatitis (diagnosis)	6 (1)	8 (2)	6 (2)
Hypothyroidism	48 (11)	15 (4)	36 (10)
Hyperthyroidism	31 (7)	7 (2)	17 (5)
Pneumonitis	12 (3)	6 (2)	12 (3)
Infusion-related reactions	6 (1)	3 (1)	5 (1)
Pancreatitis	3 (1)	2 (1)	6 (2)

AESI, adverse event of special interest.

Safety-evaluable population.

[a] Based on medical concept category, not the requirement of systemic corticosteroid use; AESIs requiring the use of systemic corticosteroids: atezo + plt/gem, n = 55 (12%); placebo + plt/gem, n = 22 (6%); atezo, n = 29 (8%).

[b] Some patients were captured in both categories.

IMvigor130—ESMO 2019 (LBA14): presented by Dr Enrique Grande

http://bit.ly/2Z1bPbD

IMvigor130 conclusions

- IMvigor130 is the first immune checkpoint inhibitor study to demonstrate an improvement in PFS over standard of care in 1L mUC
- At this interim analysis, clinically meaningful improvement in OS was observed with atezolizumab + plt/gem vs placebo + plt/gem but did not cross the pre-specified interim efficacy boundary; follow-up will continue to final analysis
- OS benefit of atezolizumab monotherapy vs placebo + plt/gem was greater in PD-L1-selected patients (IC2/3) than in ITT patients, although not formally tested
- Atezolizumab + plt/gem was well tolerated, with a safety profile consistent with each individual agent
- The results from IMvigor130 support atezolizumab + plt/gem as an important new treatment option for patients with untreated mUC

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