IMpassion130: Results from a global, randomised, double-blind, Phase III study of atezolizumab + *nab*-paclitaxel vs placebo + *nab*-paclitaxel in treatment-naive locally advanced or metastatic triple-negative breast cancer

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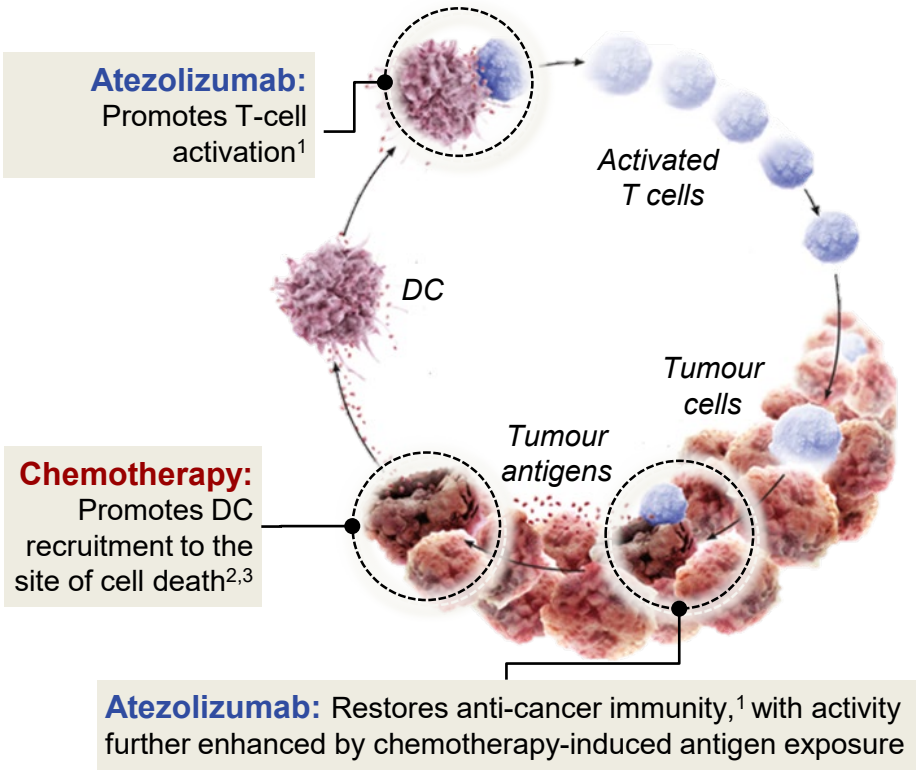
  - Grants, support of parent study, and funding of editorial support from F. Hoffmann-La Roche during the conduct of the study
  - Grants and research support to institution from AstraZeneca, Roche/Genentech, Oncogenex, Novartis, Astellas outside this study
  - Honoraria from Pfizer, AstraZeneca, Novartis, Roche, Merck, Boehringer Ingelheim, Bayer, Eisai, Celgene and Puma outside this study
  - Uncompensated steering committee member for the IMpassion130 trial
  - Spouse is an employee of Roche

Triple-negative breast cancer (TNBC)

- Patients with advanced or metastatic TNBC experience poor outcomes relative to patients with other breast cancer subtypes,[1] with a median OS of ≈ 18 months or less[2-4]
- First-line treatment typically includes single-agent taxane or anthracycline chemotherapy[5,6]
- No targeted therapies have improved OS to date
- Checkpoint inhibition may be a useful approach in the treatment of TNBC
  - PD-L1 can inhibit anti-cancer immune responses[7]
  - PD-L1 in TNBC is expressed mainly on tumour-infiltrating immune cells (IC)[8,9]

1. den Brok *BCRT* 2017. 2. Gobbini *EJC* 2018. 3. Yardley *Ann Oncol* 2018. 4. Miles *Ann Oncol* 2013. 5. NCCN 2018. 6. Cardoso *Ann Oncol* 2018.
7. Chen *Immunity* 2013. 8. Sabatier *Oncotarget* 2015. 9. Mittendorf *CIR* 2014.

Atezolizumab and chemotherapy



- Atezolizumab (anti–PD-L1) monotherapy is approved in the United States, Europe and elsewhere for certain types of metastatic urothelial carcinoma and lung cancer[4]
- In a Phase I study, atezolizumab monotherapy was active in multiple cancers, including TNBC,[5,6] with greater activity in patients whose tumours had PD-L1 IC ≥ 1%[6]
- The addition of chemotherapy can enhance atezolizumab's anti-tumour activity[7,8]
  - In a Phase Ib study in mTNBC, concurrent administration of *nab*-paclitaxel did not inhibit atezolizumab-mediated immunodynamic effects[8]

DC, dendritic cell.

1. Chen *Immunity* 2013. 2. Zitvogel *Immunity* 2013. 3. Emens *CIR* 2015. 4. TECENTRIQ US PI/SmPC 2018. 5. Herbst *Nature* 2014.
6. Emens *JAMA Oncol* 2018. 7. Jotte ASCO 2018. 8. Pohlmann AACR 2018.

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IMpassion130 study design

Key IMpassion130 eligibility criteria[a]:

- Metastatic or inoperable locally advanced TNBC
  - Histologically documented[b]
- No prior therapy for advanced TNBC
  - Prior chemo in the curative setting, including taxanes, allowed if TFI ≥ 12 mo
- ECOG PS 0-1

Stratification factors:

- Prior taxane use (yes vs no)
- Liver metastases (yes vs no)
- PD-L1 status on IC (positive [≥ 1%] vs negative [< 1%])[c]

R 1:1

Atezo + nab-P arm:

Atezolizumab 840 mg IV
- On days 1 and 15 of 28-day cycle

+ *nab*-paclitaxel 100 mg/m^2 IV
- On days 1, 8 and 15 of 28-day cycle

Double blind; no crossover permitted

Plac + nab-P arm:

Placebo IV
- On days 1 and 15 of 28-day cycle

+ *nab*-paclitaxel 100 mg/m^2 IV
- On days 1, 8 and 15 of 28-day cycle

RECIST v1.1
PD or toxicity

- Co-primary endpoints were PFS and OS in the ITT and PD-L1+ populations[d]
  - Key secondary efficacy endpoints (ORR and DOR) and safety were also evaluated

IC, tumour-infiltrating immune cell; TFI, treatment-free interval. [a] ClinicalTrials.gov: NCT02425891. [b] Locally evaluated per ASCO–College of American Pathologists (CAP) guidelines. [c] Centrally evaluated per VENTANA SP142 IHC assay (double blinded for PD-L1 status). [d] Radiological endpoints were investigator assessed (per RECIST v1.1).

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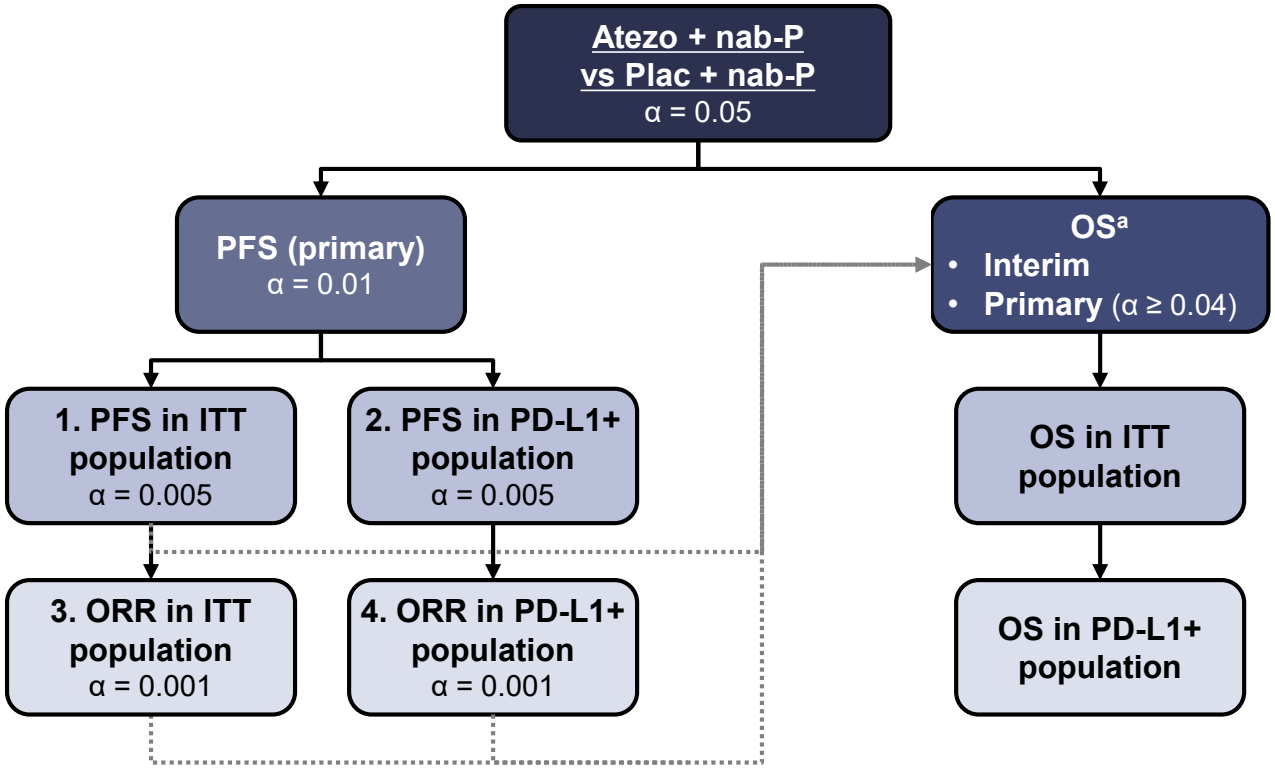
IMpassion130 statistical testing



- Primary PFS analysis (PFS tested in ITT and PD-L1+ populations)
- First interim OS analysis (OS tested in ITT population, then, if significant, in PD-L1+ population)

[a] α recycled if PFS/ORR testing is significant. Hazard ratio (HR)/*P* value–stopping boundaries are dependent on the OS analysis timing.

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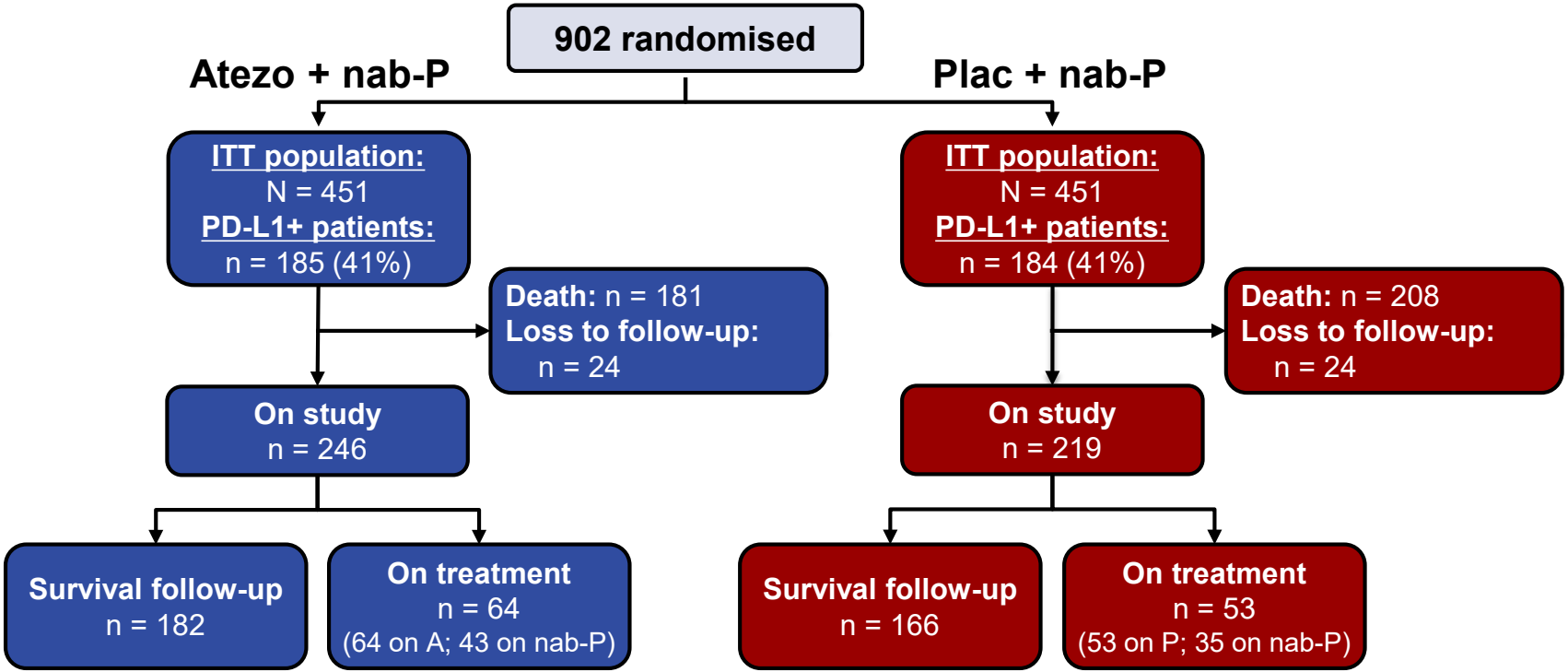
IMpassion130 patient disposition



- Safety-evaluable population: 452[a]
- Safety-evaluable population: 438[a]

Data cutoff: 17 April 2018. [a] 6 patients per arm did not receive study treatment; 7 patients in the Plac + nab-P arm received 1 dose of atezolizumab and were evaluated in the Atezo + nab-P safety population.

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IMpassion130 baseline characteristics

Characteristic	Atezo + nab-P (N = 451)	Plac + nab-P (N = 451)
Median age (range), y	55 (20-82)	56 (26-86)
Female, n (%)	448 (99%)	450 (100%)
Race, n (%)[a]		
White	308 (68%)	301 (67%)
Asian	85 (19%)	76 (17%)
Black/African American	26 (6%)	33 (7%)
Other/multiple	20 (4%)	26 (6%)
ECOG PS, n (%)[b,c]		
0	256 (57%)	270 (60%)
1	193 (43%)	179 (40%)
Prior (neo)adjuvant treatment, n (%)	284 (63%)	286 (63%)
Prior taxane	231 (51%)	230 (51%)
Prior anthracycline	243 (54%)	242 (54%)

Characteristic	Atezo + nab-P (N = 451)	Plac + nab-P (N = 451)
Metastatic disease, n (%)	404 (90%)	408 (91%)
No. of sites, n (%)[d]		
0-3	332 (74%)	341 (76%)
≥ 4	118 (26%)	108 (24%)
Site of metastatic disease, n (%)		
Lung	226 (50%)	242 (54%)
Bone	145 (32%)	141 (31%)
Liver	126 (28%)	118 (26%)
Brain	30 (7%)	31 (7%)
Lymph node only[d]	33 (7%)	23 (5%)
PD-L1+ (IC), n (%)	185 (41%)	184 (41%)

Data cutoff: 17 April 2018. [a] Race was unknown in 12 patients in the Atezo + nab-P arm and 15 in the Plac + nab-P arm. [b] Of n = 450 in each arm. [c] ECOG PS before start of treatment was 2 in 1 patient per arm. [d] Of n = 450 in the Atezo + nab-P arm and n = 449 in the Plac + nab-P arm arm.

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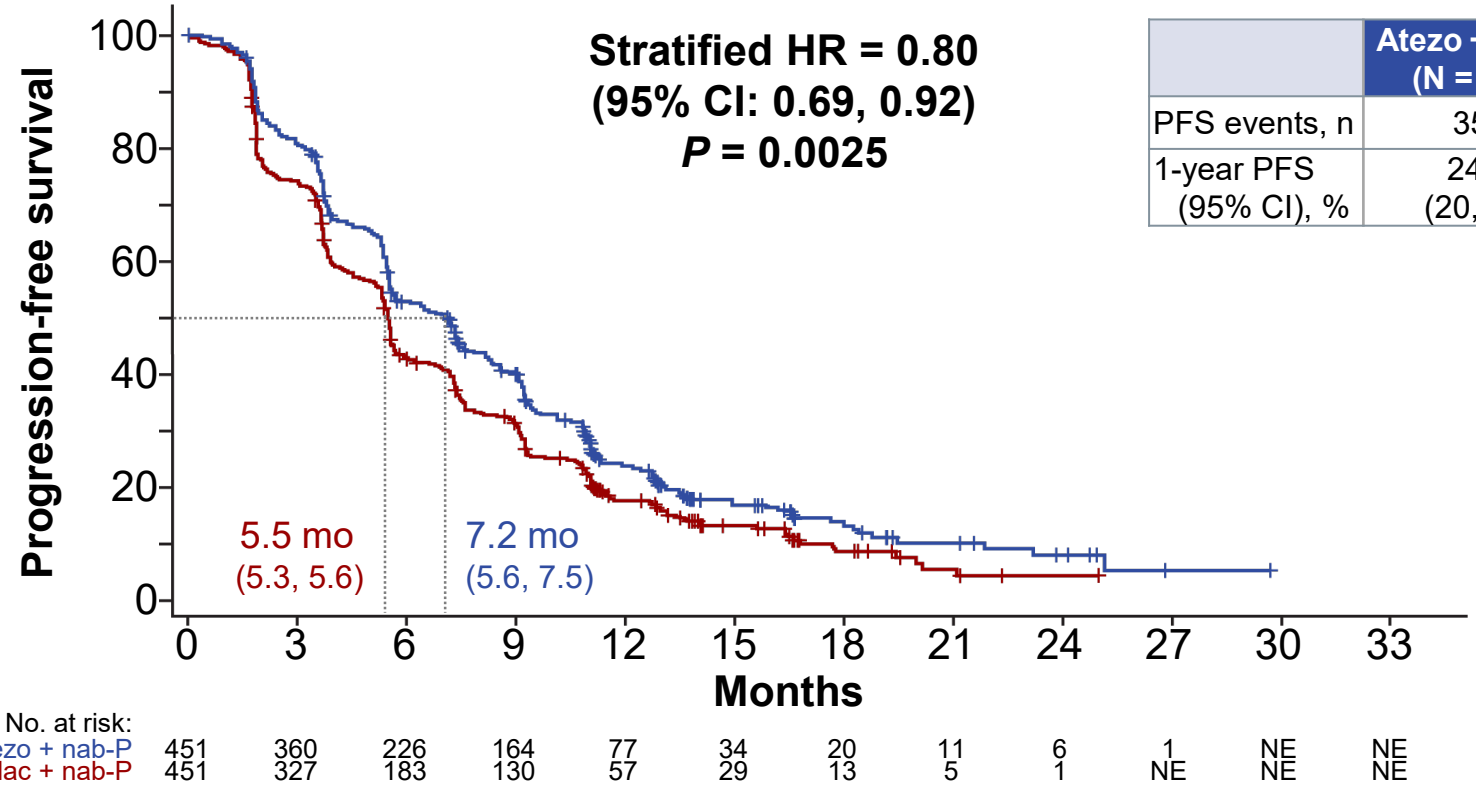
Primary PFS analysis: ITT population



	Atezo + nab-P (N = 451)	Plac + nab-P (N = 451)
PFS events, n	358	378
1-year PFS (95% CI), %	24% (20, 28)	18% (14, 21)

NE, not estimable. Data cutoff: 17 April 2018. Median PFS durations (and 95% CI) are indicated on the plot. Median follow-up (ITT): 12.9 months.

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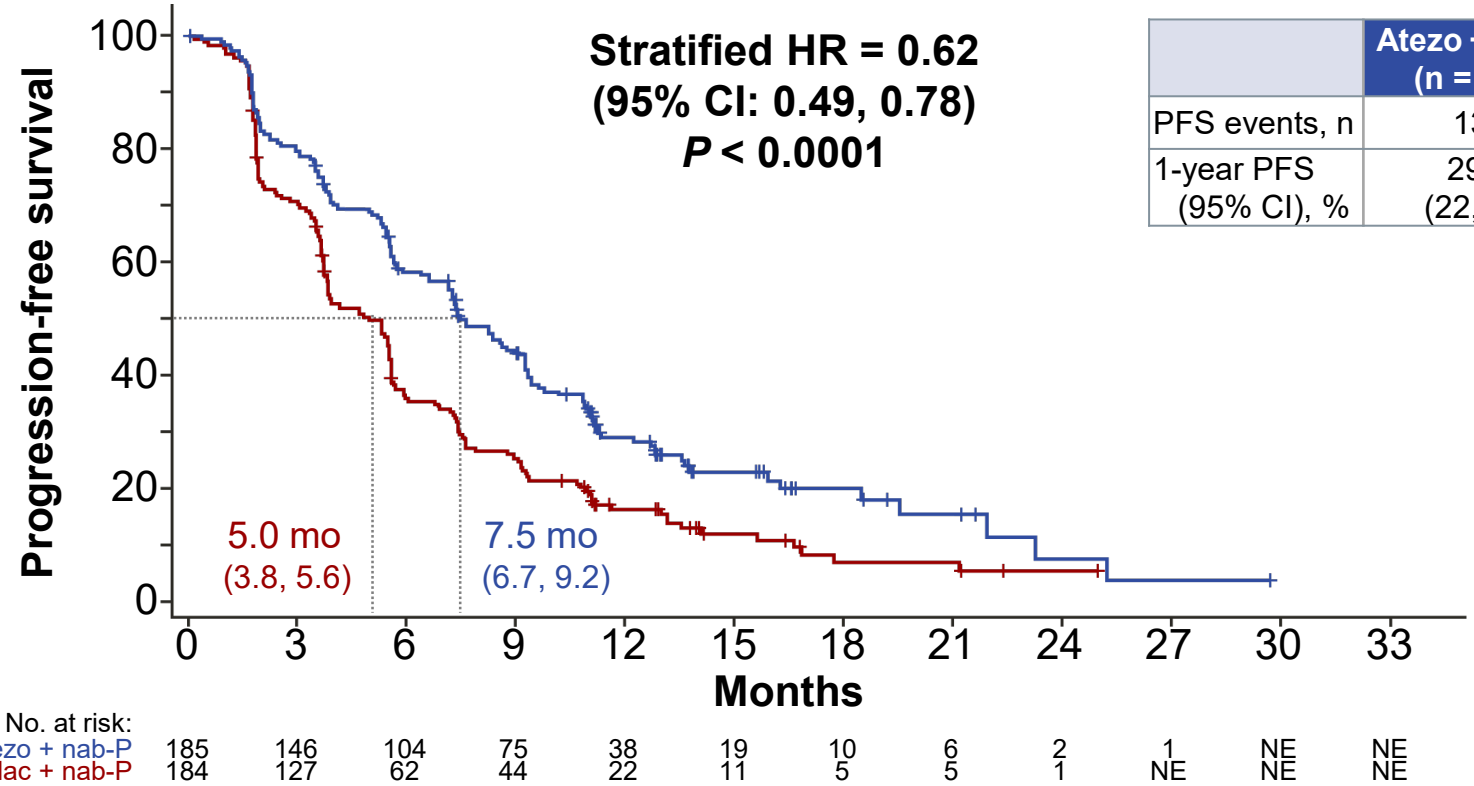
Primary PFS analysis: PD-L1+ population



	Atezo + nab-P (n = 185)	Plac + nab-P (n = 184)
PFS events, n	138	157
1-year PFS (95% CI), %	29% (22, 36)	16% (11, 22)

Data cutoff: 17 April 2018.

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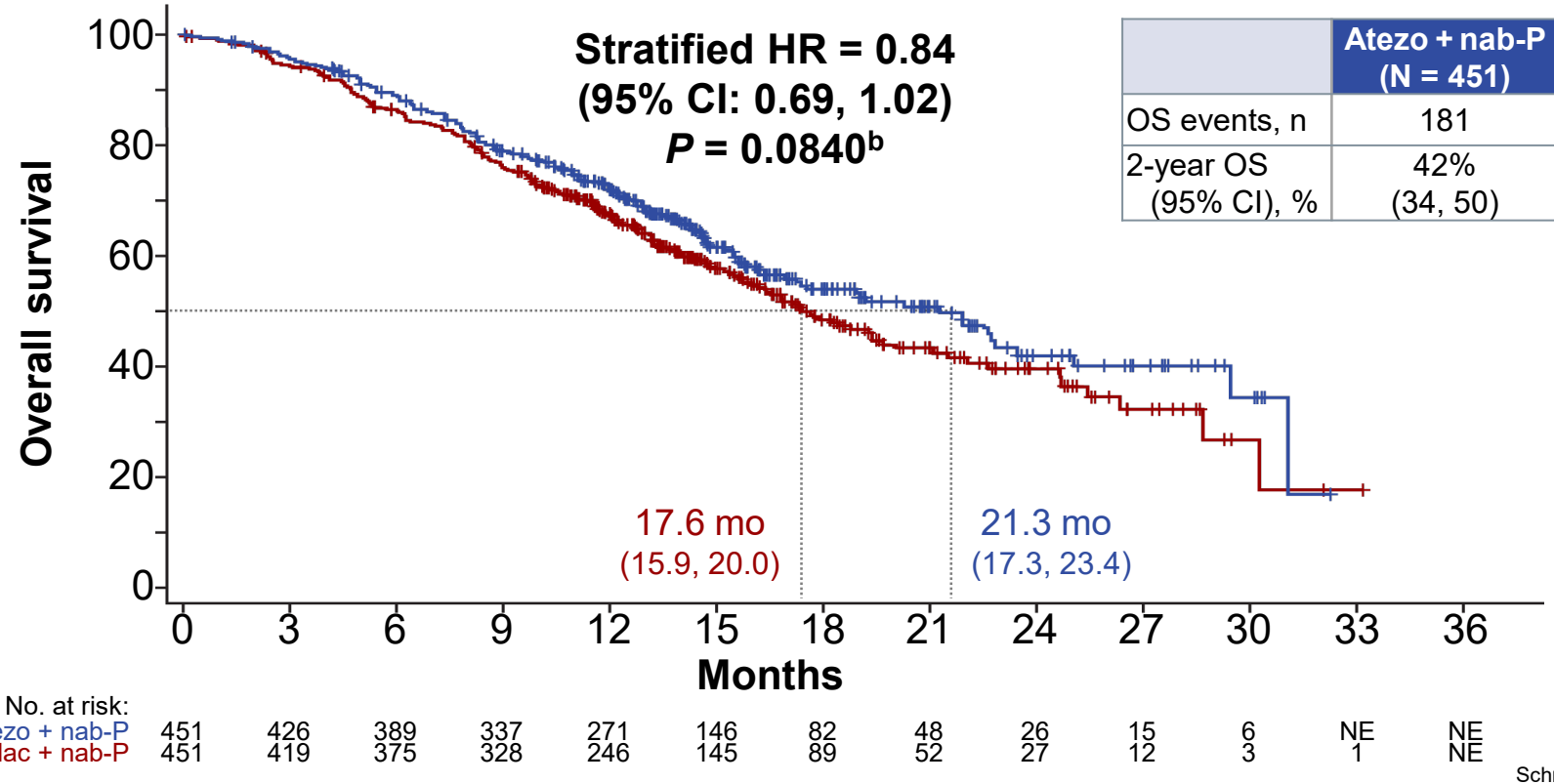
Interim OS analysis: ITT population[a]



	Atezo + nab-P (N = 451)	Plac + nab-P (N = 451)
OS events, n	181	208
2-year OS (95% CI), %	42% (34, 50)	40% (33, 46)

Data cutoff: 17 April 2018. Median OS durations (and 95% CI) are indicated on the plot. Median follow-up (ITT): 12.9 months.
[a] For the interim OS analysis, 59% of events had occurred. [b] Significance boundary was not crossed.

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ESMO 2018 (LBA1_PR)
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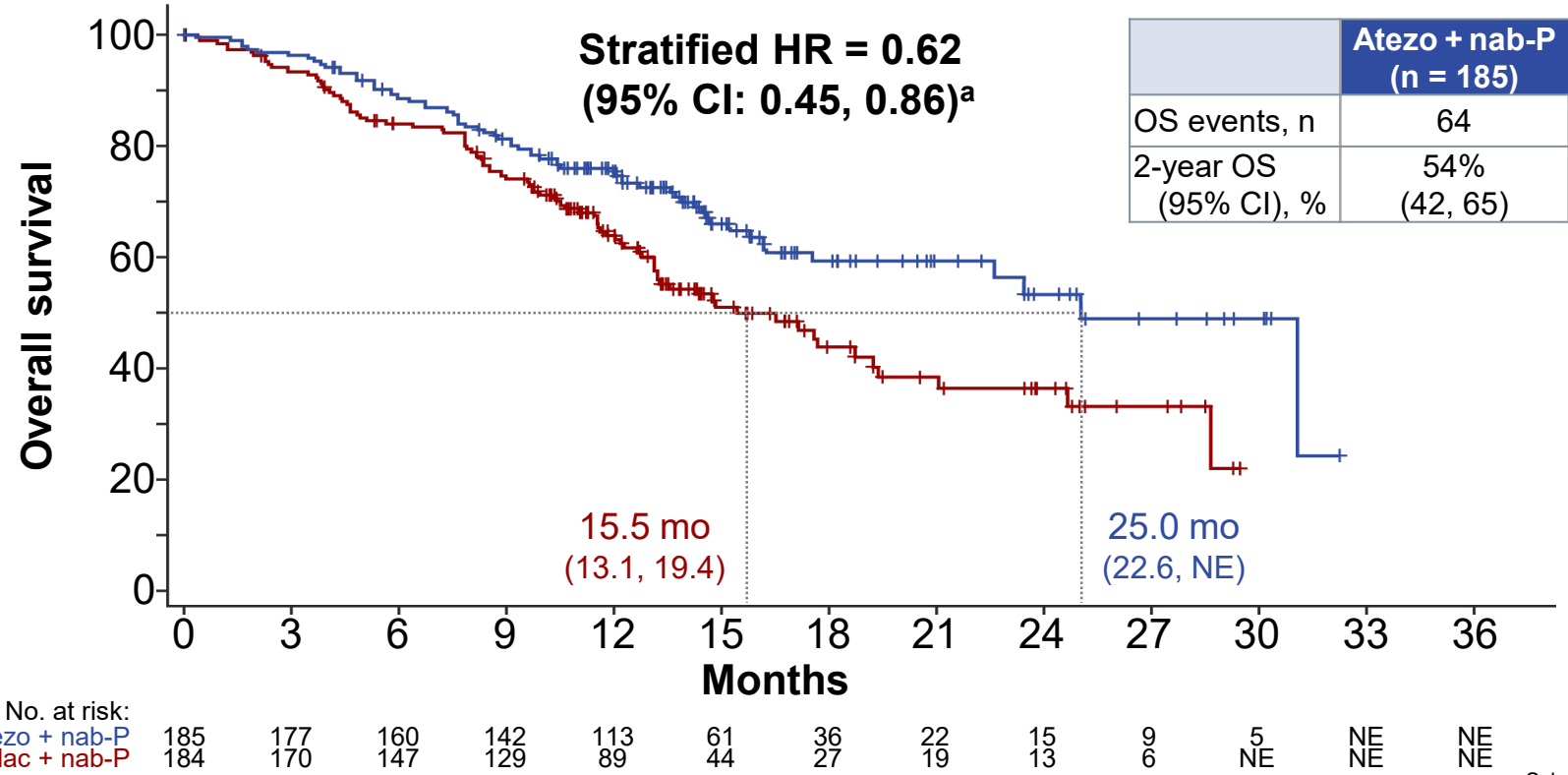
Interim OS analysis: PD-L1+ population



	Atezo + nab-P (n = 185)	Plac + nab-P (n = 184)
OS events, n	64	88
2-year OS (95% CI), %	54% (42, 65)	37% (26, 47)

Data cutoff: 17 April 2018. Median OS durations (and 95% CI) are indicated on the plot. [a] Not formally tested.

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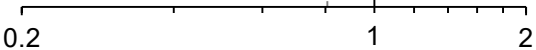
PFS subgroup analysis: ITT population

Characteristic		Patients	Hazard Ratio (95% CI)[a]
All		902	0.81 (0.70, 0.93)
Baseline liver metastases	Yes	244	0.80 (0.62, 1.04)
	No	658	0.79 (0.66, 0.94)
Prior taxane use	Yes	461	0.80 (0.65, 0.97)
	No	441	0.81 (0.66, 1.00)
PD-L1 status	PD-L1+ (IC1/2/3)	369	0.64 (0.51, 0.80)
	PD-L1– (IC0)	533	0.95 (0.79, 1.15)
Age group	18-40 y	114	0.79 (0.53, 1.16)
	41-64 y	569	0.84 (0.70, 1.01)
	≥ 65 y	219	0.69 (0.51, 0.94)
ECOG PS[b]	0	526	0.78 (0.64, 0.94)
	1	372	0.82 (0.66, 1.03)
Baseline disease status	Locally advanced	88	0.66 (0.40, 1.09)
	Metastatic[c]	812	0.82 (0.71, 0.96)
No. of metastatic sites	0-3[c]	673	0.76 (0.64, 0.91)
	> 3[c]	226	0.89 (0.67, 1.17)
Brain metastases	Yes	61	0.86 (0.50, 1.49)
	No	841	0.80 (0.69, 0.93)
Lung metastases	Yes	468	0.87 (0.72, 1.07)
	No	434	0.74 (0.60, 0.91)
Prior (neo)adjuvant chemo	Yes	570	0.85 (0.71, 1.03)
	No	332	0.72 (0.57, 0.92)



A + nab-P better ← → **P + nab-P better**

Stratification factors

Data cutoff: 17 April 2018.
[a] Unstratified HRs are shown; 95% CIs are plotted as error bars. Dashed vertical line represents value in ITT population.
[b] Patients with ECOG PS 2 not plotted.
[c] Excludes patients with unknown/other values.

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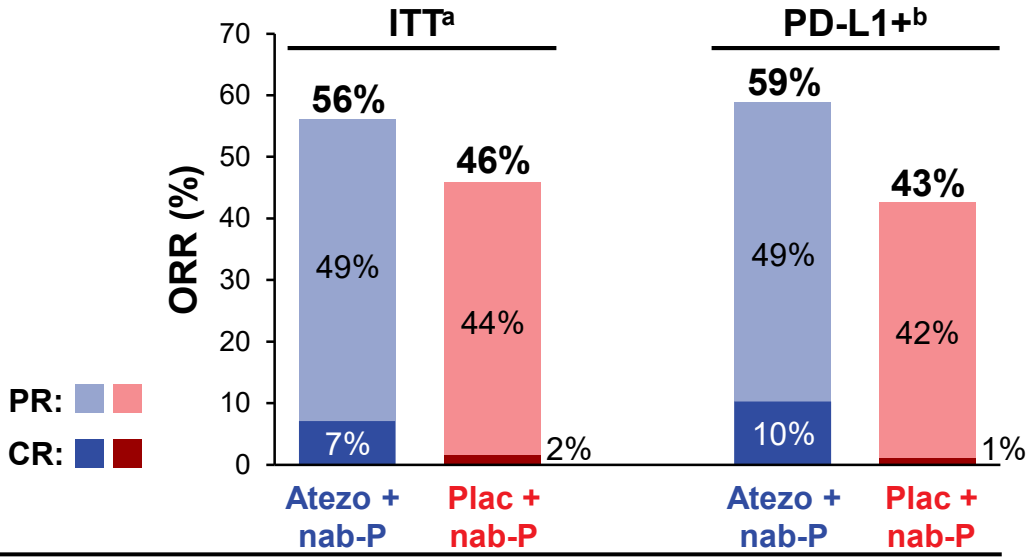
Secondary efficacy endpoints



	ITT[a]		PD-L1+[b]	
	Atezo + nab-P	Plac + nab-P	Atezo + nab-P	Plac + nab-P
DOR, median (95% CI), mo	7.4 (6.9, 9.0)	5.6 (5.5, 6.9)	8.5 (7.3, 9.7)	5.5 (3.7, 7.1)
No. of ongoing responses, n (%)[c]	78 (31%)	52 (25%)	39 (36%)	19 (24%)

- Numerically higher and more durable responses were seen in the Atezo + nab-P arm
  - Differences were not significant based on α level = 0.1% (ITT: *P* = 0.0021; PD-L1+: *P* = 0.0016)
- The CR rate was higher in the Atezo + nab-P arm vs the Plac + nab-P arm
  - ITT population: 7% vs 2%
  - PD-L1+ patients: 10% vs 1%

Data cutoff: 17 April 2018. Objective response–evaluable patients: [a] 450 in Atezo + nab-P arm and 449 in Plac + nab-P arm. [b] 185 in Atezo + nab-P arm and 183 in Plac + nab-P arm. [c] No death or PD.

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Exposure and dose intensity

	nab-P Exposure		Atezo or Plac Exposure	
	Atezo + nab-P (n = 452)	Plac + nab-P (n = 438)	Atezo + nab-P (n = 452)[a]	Plac + nab-P (n = 438)
Treatment duration, weeks				
Median (range)	22.1 (0-137)	21.8 (0-103)	24.1 (0-139)	22.1 (0-109)
Patients with indicated treatment duration, n (%)				
≤ 16 weeks	361 (80%)	316 (72%)	355 (79%)	316 (72%)
≤ 6 months	315 (70%)	257 (59%)	311 (69%)	259 (59%)
≤ 12 months	100 (22%)	75 (17%)	138 (31%)	108 (25%)
≤ 18 months	53 (12%)	44 (10%)	89 (20%)	63 (14%)
> 18 months	12 (3%)	7 (2%)	25 (6%)	15 (3%)
Dose intensity, %				
Mean (SD)	87.7 (18%)	90.4 (15%)	95.8 (10%)	NE
No. of cycles				
Median (range)	6.0 (1-34)	6.0 (1-26)	7.0 (1-35)	6.0 (1-28)

- A higher proportion of patients in the Atezo + nab-P arm compared with the Plac + nab-P arm received nab-P for at least 6 months (70% vs 59%) and at least 12 months (22% vs 17%)
- Atezo did not compromise the dose intensity of *nab*-P

Safety evaluable population. Data cutoff: 17 April 2018. [a] Excludes placebo exposure for 13 patients in the Atezo + nab-P arm.

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Safety summary

AE, n (%)	Atezo + nab-P (n = 452)	Plac + nab-P (n = 438)
All-cause AEs		
Any grade	449 (99%)	429 (98%)
Grade 3-4	220 (49%)	185 (42%)
Grade 5	6 (1%)	3 (1%)
Treatment-related AEs		
Any grade	436 (96%)	410 (94%)
Grade 3-4	179 (40%)	132 (30%)
Grade 5[a]	3 (1%)[a]	1 (< 1%)[a]
Any grade serious AEs		
Serious AEs regardless of attribution	103 (23%)	80 (18%)
Treatment-related serious AEs	56 (12%)	32 (7%)
Any-grade AEs leading to any treatment discontinuation	72 (16%)	36 (8%)
Leading to atezo or plac discontinuation	29 (6%)	6 (1%)
Leading to *nab*-P discontinuation	72 (16%)	36 (8%)
Any-grade AEs leading to any dose reduction or interruption	212 (47%)	177 (40%)
Leading to atezo or plac dose interruption	139 (31%)	103 (24%)
Leading to *nab*-P dose reduction or interruption	195 (43%)	172 (39%)

AE, adverse event. Safety-evaluable population. Data cutoff: 17 April 2018. [a] Treatment-related deaths: autoimmune hepatitis, mucosal inflammation/death, septic shock (n = 1 each, Atezo + nab-P arm); hepatic failure (n = 1, Plac + nab-P arm).

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Most common AEs regardless of attribution

AEs in ≥ 20% (all grade) or ≥ 3% (grade 3-4) of patients in either arm, n (%)	Atezo + nab-P (n = 452)		Plac + nab-P (n = 438)	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4
Alopecia	255 (56%)	3 (1%)	252 (58%)	1 (< 1%)
Fatigue	211 (47%)	18 (4%)	196 (45%)	15 (3%)
Nausea[a]	**208 (46%)**	**5 (1%)**	**167 (38%)**	**8 (2%)**
Diarrhoea	147 (33%)	6 (1%)	150 (34%)	9 (2%)
Anaemia	125 (28%)	13 (3%)	115 (26%)	13 (3%)
Constipation	113 (25%)	3 (1%)	108 (25%)	1 (< 1%)
Cough[a]	**112 (25%)**	**0**	**83 (19%)**	**0**
Headache	105 (23%)	2 (< 1%)	96 (22%)	4 (1%)
Neuropathy peripheral	98 (22%)	**25 (6%)**	97 (22%)	**12 (3%)**
Neutropaenia[a]	**94 (21%)**	**37 (8%)**	**67 (15%)**	**36 (8%)**
Decreased appetite	91 (20%)	3 (1%)	79 (18%)	3 (1%)
Neutrophil count decreased	57 (13%)	21 (5%)	48 (11%)	15 (3%)
Hypertension	22 (5%)	4 (1%)	24 (5%)	11 (3%)

- The most common AEs were generally similar between arms
- Most common Grade 3-4 AEs: neutropaenia, decreased neutrophil count, peripheral neuropathy, fatigue, anaemia
  - Grade 3-4 AEs ≥ 2% higher in the Atezo + nab-P arm included peripheral neuropathy (6% vs 3%)

Data cutoff: 17 April 2018. [a] AEs with ≥ 5% higher incidence in the A + nab-P arm vs P + nab-P arm; others include pyrexia and hypothyroidism (not shown in the table because overall frequency was < 20%).

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Most common serious AEs

SAEs occurring in ≥ 1% of patients in either arm (regardless of attribution)

SAE, n (%)	Atezo + nab-P (n = 452)		Plac + nab-P (n = 438)	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4
All	103 (23%)	78 (17%)[a]	80 (18%)	56 (13%)[b]
Pneumonia	10 (2%)	8 (2%)[c]	5 (1%)	0
Urinary tract infection	5 (1%)	2 (< 1%)	0	0
Dyspnoea	5 (1%)	3 (1%)	2 (< 1%)	2 (< 1%)
Pyrexia	5 (1%)	3 (1%)	3 (1%)	0

- A higher proportion of patients in the Atezo + nab-P arm than in the Plac + nab-P arm reported SAEs (23% vs 18%)
- No SAE was reported with a ≥ 2% difference between treatment arms

SAE, serious adverse event. Data cutoff: 17 April 2018. [a] Six Grade 5 events occurred. [b] Three Grade 5 events occurred. [c] One Grade 5 event occurred.

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AESIs suggestive of potential immune-related aetiology

AESI, n (%)[a]	Atezo + nab-P (n = 452)		Plac + nab-P (n = 438)	
	Any Grade	Grade 3-4	Any Grade	Grade 3-4
All	259 (57%)	34 (8%)	183 (42%)	19 (4%)
Important AESIs				
Hepatitis (all)	69 (15%)	23 (5%)	62 (14%)	13 (3%)
Hepatitis (diagnosis)	10 (2%)	6 (1%)	7 (2%)	1 (< 1%)
Hepatitis (lab abnormalities)	62 (14%)	17 (4%)	58 (13%)	12 (3%)
Hypothyroidism	78 (17%)	0	19 (4%)	0
Hyperthyroidism	20 (4%)	1 (< 1%)	6 (1%)	0
Pneumonitis	14 (3%)	1 (< 1%)	1 (< 1%)	0
Meningoencephalitis[b]	5 (1%)	0	2 (< 1%)	0
Colitis	5 (1%)	1 (< 1%)	3 (1%)	1 (< 1%)
Adrenal insufficiency	4 (1%)	1 (< 1%)	0	0
Pancreatitis	2 (< 1%)	1 (< 1%)	0	0
Diabetes mellitus	1 (< 1%)	1 (< 1%)	2 (< 1%)	1 (< 1%)
Nephritis	1 (< 1%)	0	0	0
Other AESIs[c]				
Rash	154 (34%)	4 (1%)	114 (26%)	2 (< 1%)
Infusion-related reactions	5 (1%)	0	5 (1%)	0

- 1 grade 5 AESI per arm (both treatment related):
  - Atezo + nab-P: autoimmune hepatitis
  - Plac + nab-P: hepatic failure
- All hypothyroidism AESIs were grade 1-2; none led to discontinuation
  - Atezo + nab-P: 17%
  - Plac + nab-P: 4%
- Pneumonitis was infrequent with only 1 grade 3-4 event in the Atezo + nab-P arm
  - Atezo + nab-P: 3%
  - Plac + nab-P: < 1%
- Hepatitis rates were balanced

AESI, adverse event of special interest. Data cutoff: 17 April 2018. [a] Baskets of preferred terms according to medical concepts. [b] All events of photophobia. [c] Includes all AESIs occurring in ≥ 1% of patients in either arm.

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IMpassion130 conclusions

- IMpassion130 is the first Phase III study to demonstrate a benefit with first-line immunotherapy in mTNBC
  - Atezolizumab + *nab*-paclitaxel resulted in statistically significant PFS benefit in the ITT and PD-L1+ populations (ITT HR = 0.80 [95% CI: 0.69, 0.92] and PD-L1+ HR = 0.62 [95% CI: 0.49, 0.78]), which was clinically meaningful in the PD-L1+ population
  - At this first interim OS analysis, clinically meaningful improvement in OS with atezolizumab + *nab*-paclitaxel (vs placebo + *nab*-paclitaxel) was observed in the PD-L1+ population, with a HR of 0.62 and a median OS improvement from 15.5 months to 25.0 months (formal OS testing in PD-L1+ patients not performed per hierarchical study design)
  - No detriment observed for the PD-L1– subgroup
- Atezolizumab + *nab*-paclitaxel was well tolerated, with a safety profile consistent with each agent
- For patients with PD-L1+ tumours,[a] these data establish atezolizumab + *nab*-paclitaxel as a new standard of care

[a] PD-L1 expression on ≥1% of tumour-infiltrating immune cells.

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