ESMO VIRTUAL PLENARY

KEYNOTE-522: Phase 3 Study of Neoadjuvant Pembrolizumab + Chemotherapy versus Placebo + Chemotherapy, Followed by Adjuvant Pembrolizumab versus Placebo for Early-Stage Triple-Negative Breast Cancer

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Declaration of Interests

Peter Schmid

- Advisory/consultancy: Pfizer, AZ, Novartis, Roche, Merck, BI, Bayer, Eisai, Puma, Celgene
- Honoraria (self): Pfizer, AZ, Novartis, Roche, Merck, BI, Bayer, Eisai, Puma, Celgene
- Funding to institution for research support: AZ, Genentech, Roche, Oncogenex, Novartis, Astellas
- Spouse is an employee of Genentech/Roche
- Study funding, medical writing, and editorial support: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA

Triple-Negative Breast Cancer (TNBC)

- TNBC accounts for 15% to 20% of breast cancers[1,2]
- At diagnosis
  - Majority of tumors (~70%) are histologically grade 3 and highly proliferative[3]
  - Majority diagnosed at stage II (43%) or stage III (19%)
- Associated with early recurrences
- Neoadjuvant chemotherapy is the current standard-of-care treatment approach for early-stage disease[4-8]
- Patients who experience pCR following neoadjuvant chemotherapy have longer EFS and OS; however, increased risk for disease recurrence and death remains[9]
- High unmet need for novel therapies that can augment effectiveness of chemotherapy
- Strong rationale for combination of immunotherapy and chemotherapy in TNBC[10]

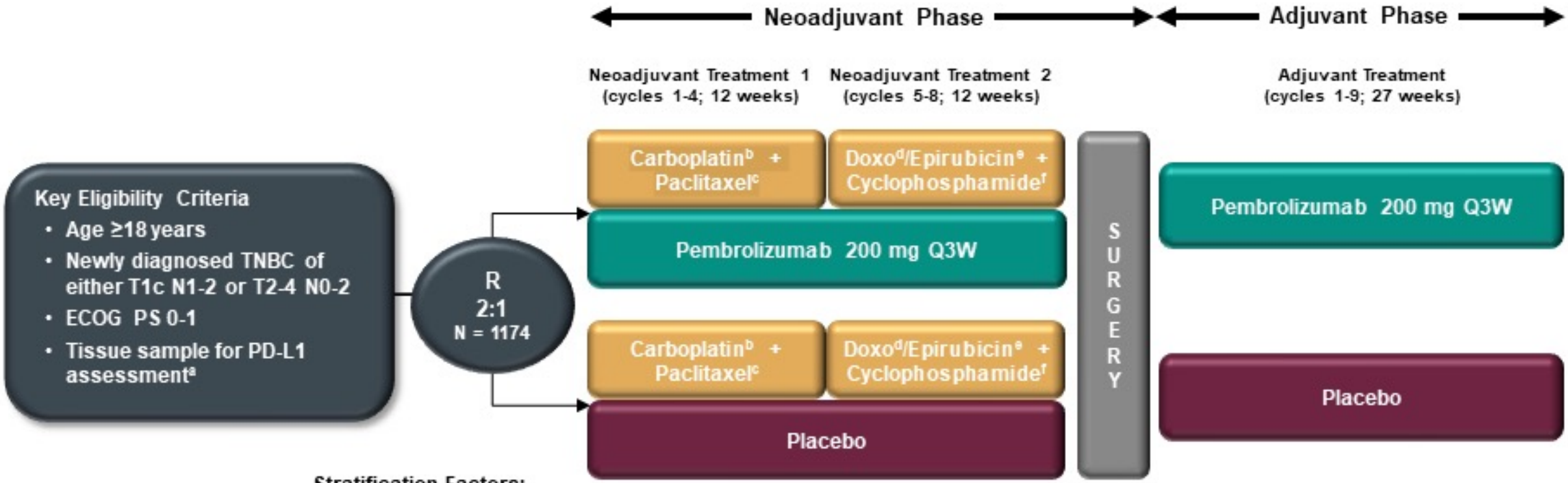
1. Arnedos M, et al. *Ther Adv Med Oncol* 2012;4:195-210; 2. Bauer KR, et al. *Cancer* 2007;109:1721-8; 3. Urru SAM, et al. *BMC Cancer* 2018;18:56. 4. Cardoso F, et al. *Ann Oncol* 2019;30:1194-220; 5. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Breast Cancer. Version 3.2020. March 6, 2020; 6. Cardoso F, et al. *Ann Oncol* 2018;29:1634-57; 7. Curigliano G, et al. *Ann Oncol* 2017;28:1700-12; 8. Burstein HJ, et al. *Ann Oncol* 2019;30:1541-57; 9. Cortazar P, et al. *Lancet* 2014;384:164-72; 10. Liu J, et al. *Cancer Discov* 2016;6:1382-99.

Pembrolizumab in TNBC

- Pembrolizumab showed antitumor activity and manageable safety in metastatic TNBC, especially the first-line setting[1-3]
- Neoadjuvant pembrolizumab + chemotherapy showed manageable safety and antitumor activity in early TNBC in KEYNOTE-173[4] and I-SPY2[5]
  - Based on these results[4,5], pembrolizumab + chemotherapy was granted Breakthrough Therapy Designation by the US FDA for the neoadjuvant treatment of patients with high-risk, early-stage TNBC
- Prior analyses from KEYNOTE-522[6] showed that the addition of pembrolizumab to platinum-containing neoadjuvant chemotherapy resulted in a statistically significant improvement in pCR and a favorable trend in EFS

1. Adams S, et al. *Ann Oncol* 2019;30:405-11; 2. Adams S, et al. *Ann Oncol* 2019;30:397-404; 3. Nanda R, et al. *J Clin Oncol* 2016;34:2460-7; 4. Schmid P, et al. *Ann Oncol* 2020;31:569-81; 5. Nanda R, et al. *JAMA Oncol* 2020;6:676-84; 6. Schmid P, et al. *N Engl J Med* 2020;382:810-21.

KEYNOTE-522 Study Design (NCT03036488)



Stratification Factors:
- Nodal status (+ vs -)
- Tumor size (T1/T2 vs T3/T4)
- Carboplatin schedule (QW vs Q3W)

Neoadjuvant phase: starts from the first neoadjuvant treatment and ends after definitive surgery (post treatment included)

Adjuvant phase: starts from the first adjuvant treatment and includes radiation therapy as indicated (post treatment included)

[a]Must consist of at least 2 separate tumor cores from the primary tumor.
[b]Carboplatin dose was AUC 5 Q3W or AUC 1.5 QW.
[c]Paclitaxel dose was 80 mg/m² QW.
[d]Doxorubicin dose was 60 mg/m² Q3W.
[e]Epirubicin dose was 90 mg/m² Q3W.
[f]Cyclophosphamide dose was 600 mg/m² Q3W.

Study Endpoints

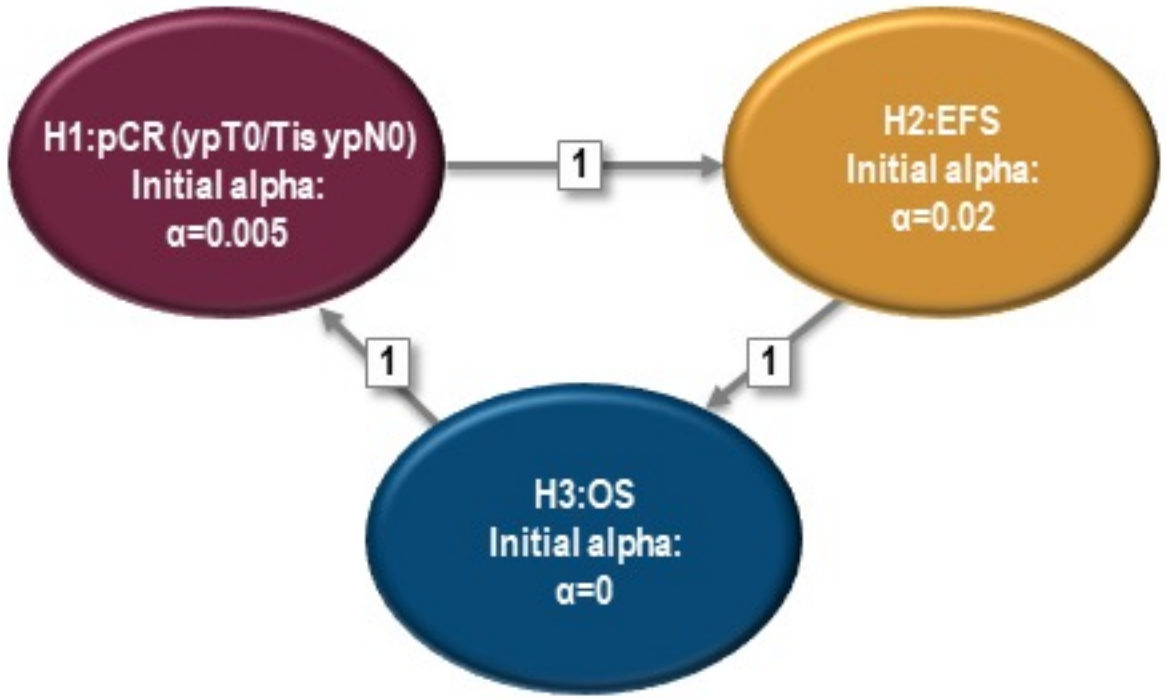
- Primary Endpoints
  - pCR (ypT0/Tis ypN0) assessed by local pathologist in ITT population[a]
  - Event-free survival (EFS) assessed by investigator in ITT population
- Secondary Endpoints
  - pCR as per alternative definitions (ypT0 ypN0 and ypT0/Tis)[a]
  - Overall survival (OS)
  - pCR[a], EFS and OS[b] in the PD-L1–positive population[c]
  - Safety in all treated patients
- Exploratory Analyses
  - EFS in patient subgroups
  - EFS by pCR (ypT0/Tis ypN0)
  - Distant Progression- or Distant Recurrence-Free Survival

[a]Subjects without pCR data due to any reason or who received neoadjuvant chemotherapy not specified in the protocol were counted as non-pCR; definitive pCR analysis presented previously. [b]To be presented later. [c]PD-L1 assessed at a central laboratory using the PD-L1 IHC 22C3 pharmDx assay and measured using the combined positive score (CPS; number of PD-L1–positive tumor cells, lymphocytes, and macrophages divided by total number of tumor cells x 100); PD-L1–positive = CPS ≥1.

Statistical Considerations

- Primary Hypotheses
  - H1: pCR (ypT0/Tis ypN0)
  - H2: EFS
- Secondary Hypothesis
  (only tested when EFS succeeds)
  - H3: overall survival (OS)

- Multiplicity:



Summary of Analysis Populations

1174 patients randomized 2:1 from Mar 2017 to Sep 2018

Pembrolizumab + Chemotherapy Arm

- 784 allocated
- 778 (99.2%) started Carboplatin/Paclitaxel
- 726 (92.6%) started AC or EC
- 768 (98.0%) had documented surgery[b]
- 588 (75.0%) started adjuvant treatment

Analysis Populations

- ITT: N = 784
- Safety-evaluable: N = 783[c]

Median (range) follow-up[d]: 39.1 mo (30.0-48.0)

Placebo + Chemotherapy Arm

- 390 allocated
- 389 (99.7%) started Carboplatin/Paclitaxel
- 369 (94.6%) started AC or EC
- 381 (97.7%) had documented surgery[b]
- 331 (84.9%) started adjuvant treatment

Analysis Populations

- ITT: N = 390
- Safety-evaluable: N = 389[c]

Median (range) follow-up[d]: 39.1 mo (30.1-47.6)

[a]Includes radiographic and clinical PD. [b]Patients did not have to complete all neoadjuvant therapy to undergo surgery. [c]Includes all patients who received ≥1 dose of study treatment or underwent surgery.
[d]Defined as the time from randomization to the data cutoff date of March 23, 2021.

Baseline Characteristics, ITT Population

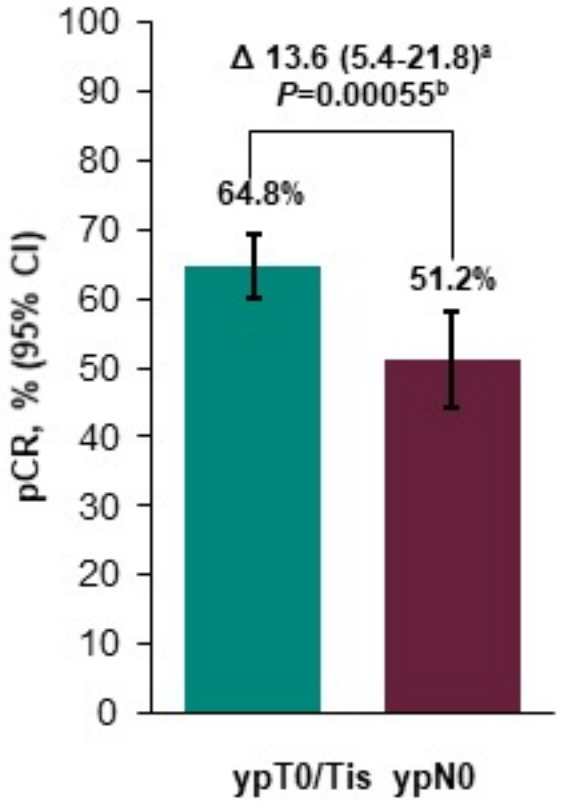
Characteristic, n (%)	All Subjects, N = 1174	
	Pembro + Chemo N = 784	Pbo + Chemo N = 390
Age, median (range), yrs	49 (22-80)	48 (24-79)
ECOG PS 1	106 (13.5)	49 (12.6)
PD-L1–positive[a]	656 (83.7)	317 (81.3)
Carboplatin schedule		
QW	449 (57.3)	223 (57.2)
Q3W	335 (42.7)	167 (42.8)
Tumor size		
T1/T2	580 (74.0)	290 (74.4)
T3/T4	204 (26.0)	100 (25.6)
Nodal involvement		
Positive	405 (51.7)	200 (51.3)
Negative	379 (48.3)	190 (48.7)

[a]PD-L1 assessed at a central laboratory using the PD-L1 IHC 22C3 pharmDx assay and measured using the combined positive score (CPS; number of PD-L1–positive tumor cells, lymphocytes, and macrophages divided by total number of tumor cells x 100); PD-L1–positive = CPS ≥1. Data cutoff date: March 23, 2021.

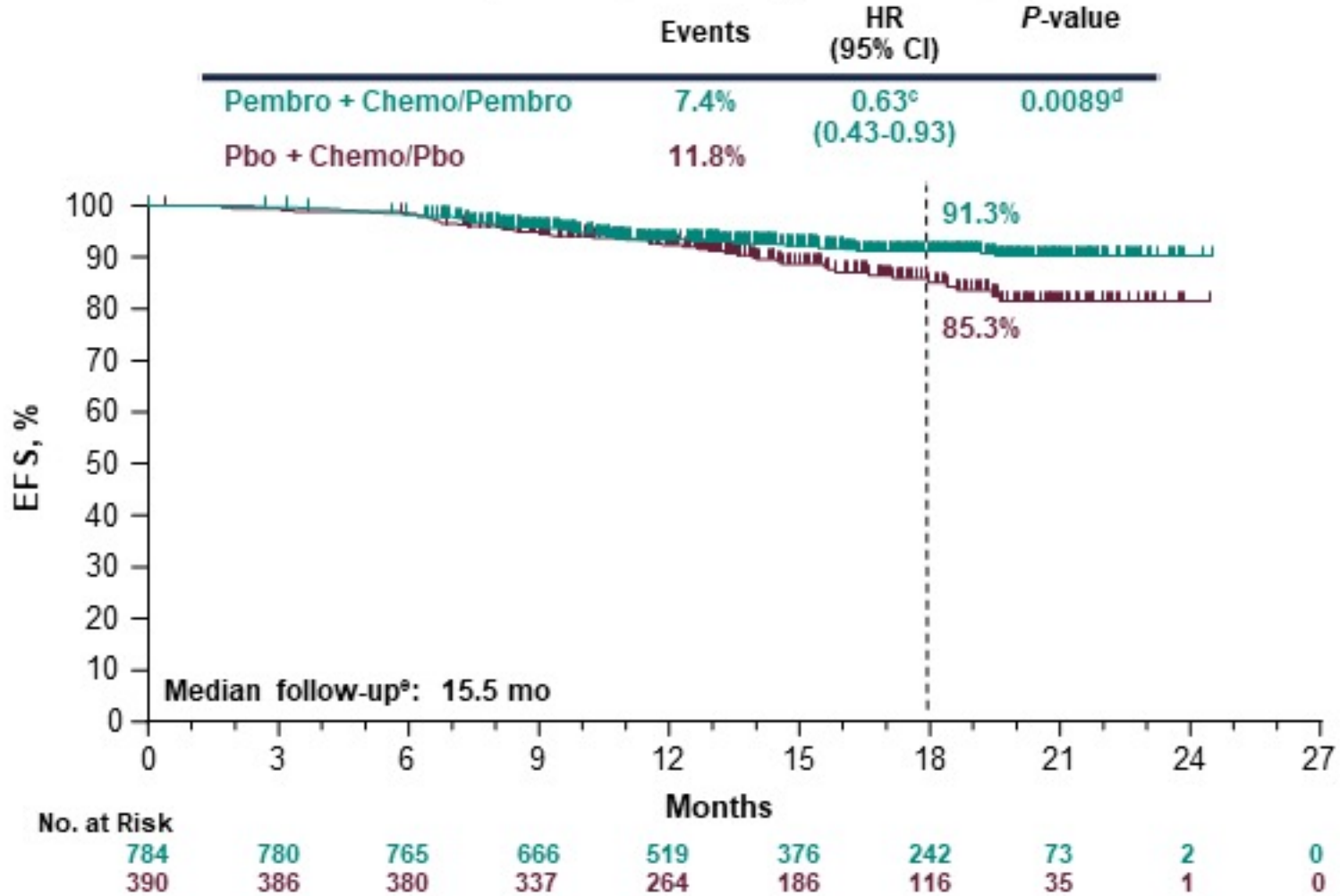
Prior Analyses of KEYNOTE-522

Primary pCR Endpoint at IA1[1]

Pembro + Chemo (N = 401)
Pbo + Chemo (N = 201)

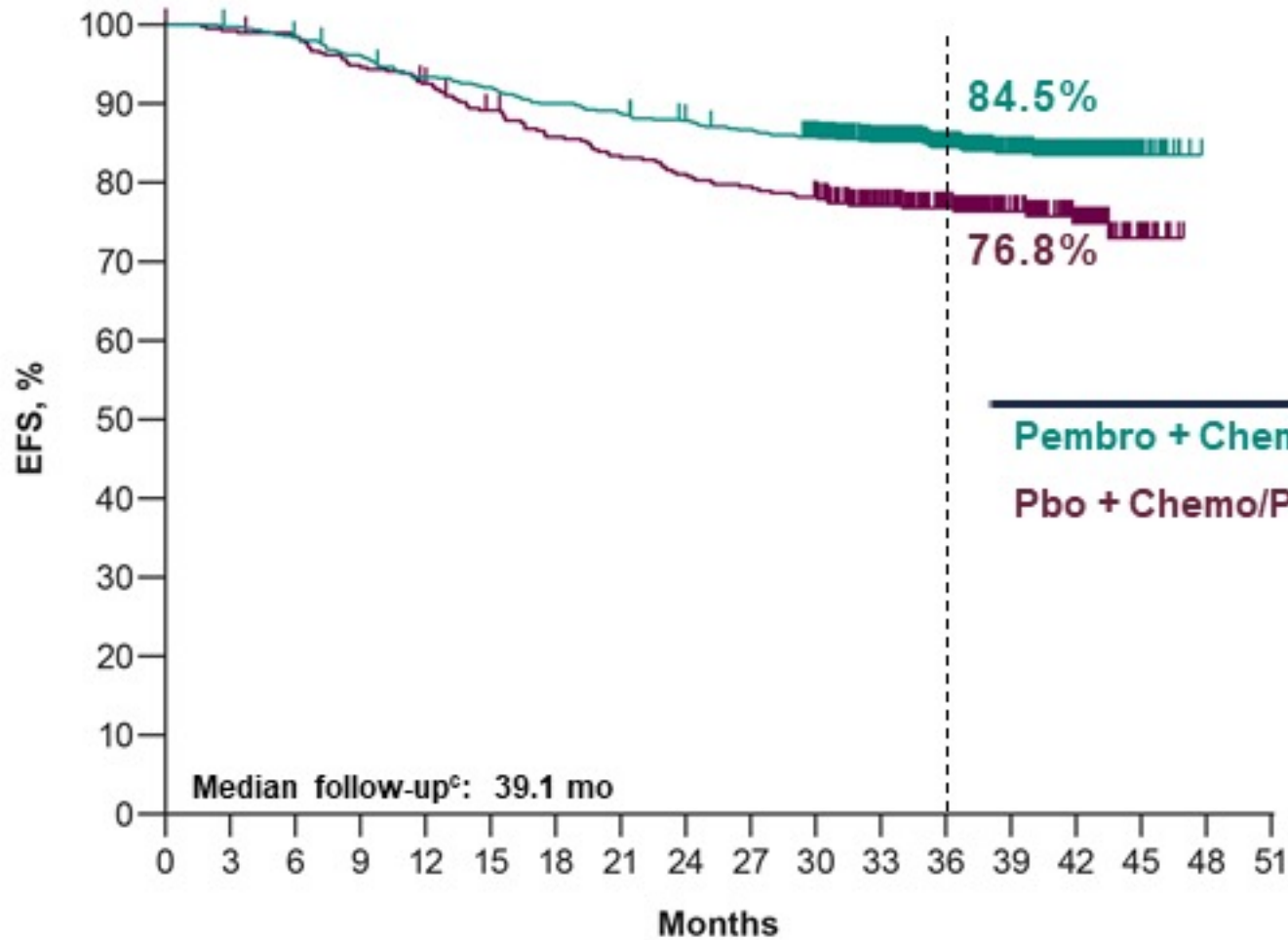


First EFS Analysis at IA2[1]



[a]Estimated treatment difference based on Miettinen & Nurminen method stratified by randomization stratification factors. [b]Prespecified *P*-value boundary for significance of 0.003 was crossed; data cutoff date: September 24, 2018. [c]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. [d]Prespecified *P*-value boundary for significance of 0.000051 not reached at this analysis. [e]Defined as the time from randomization to the date of death or data cutoff date of April 24, 2019, if the patient was alive. 1. Schmid P, et al. *N Engl J Med* 2020;382:810-21.

Statistically Significant and Clinically Meaningful EFS at IA4



	Events	HR (95% CI)	*P*-value
Pembro + Chemo/Pembro	15.7%	0.63[a] (0.48-0.82)	0.00031[b]
Pbo + Chemo/Pbo	23.8%		

No. at Risk

Pembro + Chemo/Pembro	784	781	769	751	728	718	702	692	681	671	652	551	433	303	165	28	0	0
Pbo + Chemo/Pbo	390	386	382	368	358	342	328	319	310	304	297	250	195	140	83	17	0	0

[a]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. [b]Prespecified *P*-value boundary of 0.00517 reached at this analysis.
[c]Defined as the time from randomization to the data cutoff date of March 23, 2021.

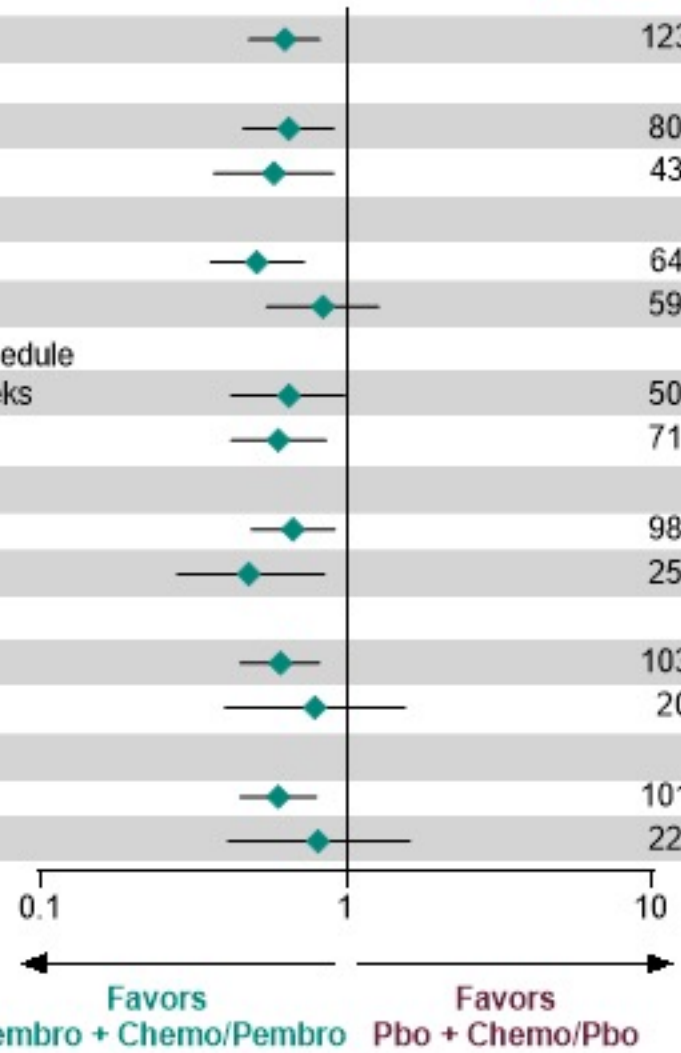
Summary of First EFS Events by Category

Event	All Subjects, N = 1174	
	Pembro + Chemo/Pembro N = 784	Pbo + Chemo/Pbo N = 390
Any EFS event	123 (15.7%)	93 (23.8%)
Progression of disease that precludes definitive surgery	14 (1.8%)	15 (3.8%)
Local recurrence[a]	28 (3.6%)	17 (4.4%)
Distant recurrence	60 (7.7%)	51 (13.1%)
Secondary primary malignancy[b]	6 (0.8%)	4 (1.0%)
Death	15 (1.9%)	6 (1.5%)

[a]13 patients in the pembro group and 9 patients in the pbo group had subsequent distant recurrence. [b]Sites include blood, bone marrow, chest wall, colon, endometrium, ovaries, stomach, and tongue.
Data cutoff date: March 23, 2021.

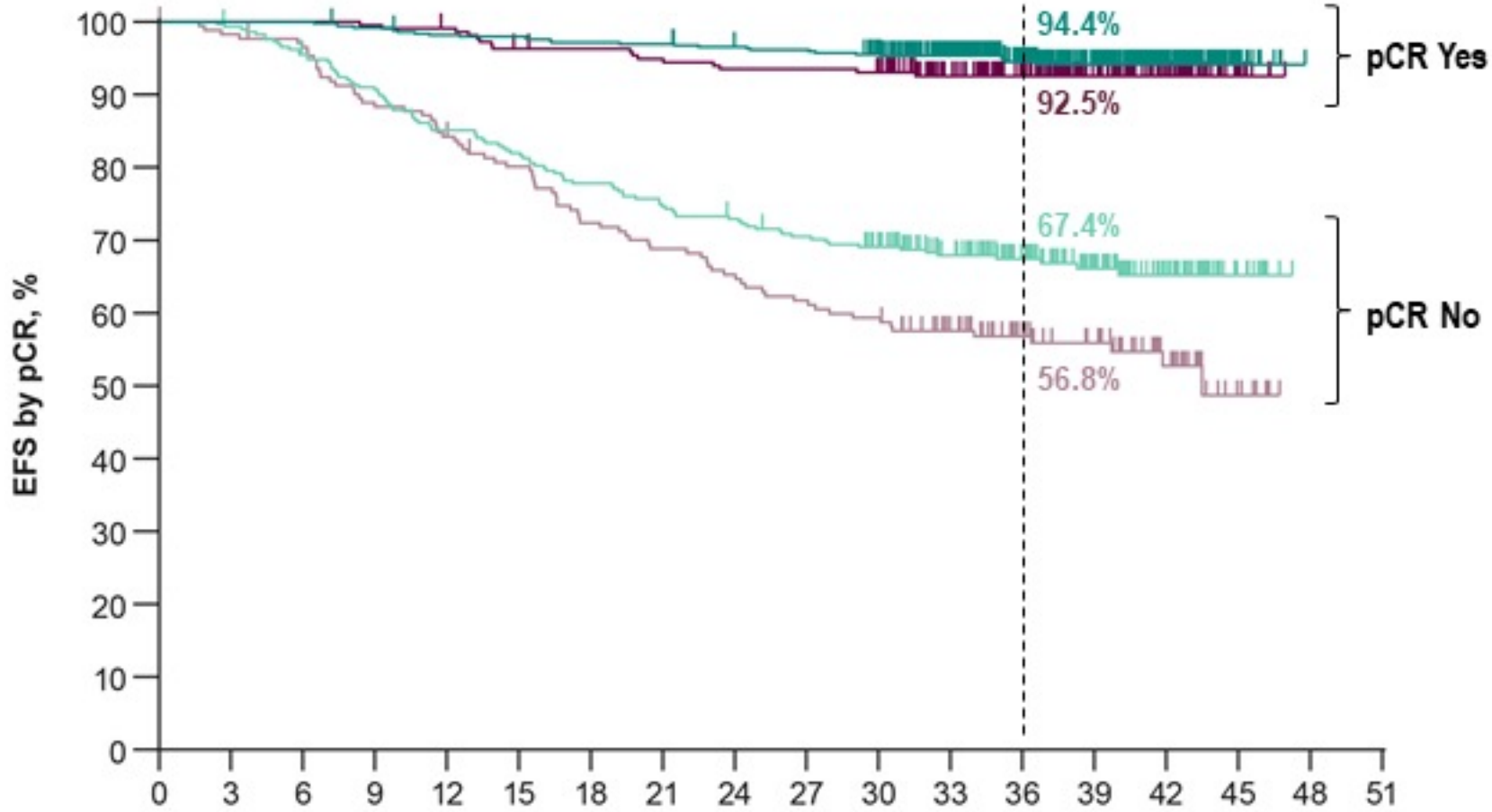
EFS in Patient Subgroups

Subgroup	No. Events/No. Patients (%) Pembro + Chemo/Pembro	Pbo + Chemo/Pbo	Hazard Ratio (95% CI)
Overall	123/784 (15.7)	93/390 (23.8)	0.63 (0.48 to 0.82)
Nodal status			
Positive	80/408 (19.6)	57/196 (29.1)	0.65 (0.46 to 0.91)
Negative	43/376 (11.4)	36/194 (18.6)	0.58 (0.37 to 0.91)
Tumor size			
T1/T2	64/581 (11.0)	59/290 (20.3)	0.51 (0.36 to 0.73)
T3/T4	59/203 (29.1)	34/100 (34.0)	0.84 (0.55 to 1.28)
Carboplatin schedule			
Every 3 weeks	50/334 (15.0)	37/167 (22.2)	0.65 (0.42 to 0.99)
Weekly	71/444 (16.0)	56/220 (25.5)	0.60 (0.42 to 0.86)
PD-L1 status			
Positive	98/656 (14.9)	68/317 (21.5)	0.67 (0.49 to 0.92)
Negative	25/128 (19.5)	25/69 (36.2)	0.48 (0.28 to 0.85)
Age category			
<65 years	103/700 (14.7)	79/342 (23.1)	0.61 (0.45 to 0.82)
≥65 years	20/84 (23.8)	14/48 (29.2)	0.79 (0.40 to 1.56)
ECOG PS			
0	101/678 (14.9)	80/341 (23.5)	0.60 (0.45 to 0.80)
1	22/106 (20.8)	13/49 (26.5)	0.81 (0.41 to 1.62)



For overall population and PD-L1 subgroups, analyses based on Cox regression model with Efron's method of tie handling with treatment as a covariate and stratified by nodal status (positive vs negative), tumor size (T1/T2 vs T3/T4), and frequency of carboplatin (once weekly vs once every 3 weeks); for other subgroups, analysis based on unstratified Cox model. Data cutoff date: March 23, 2021.

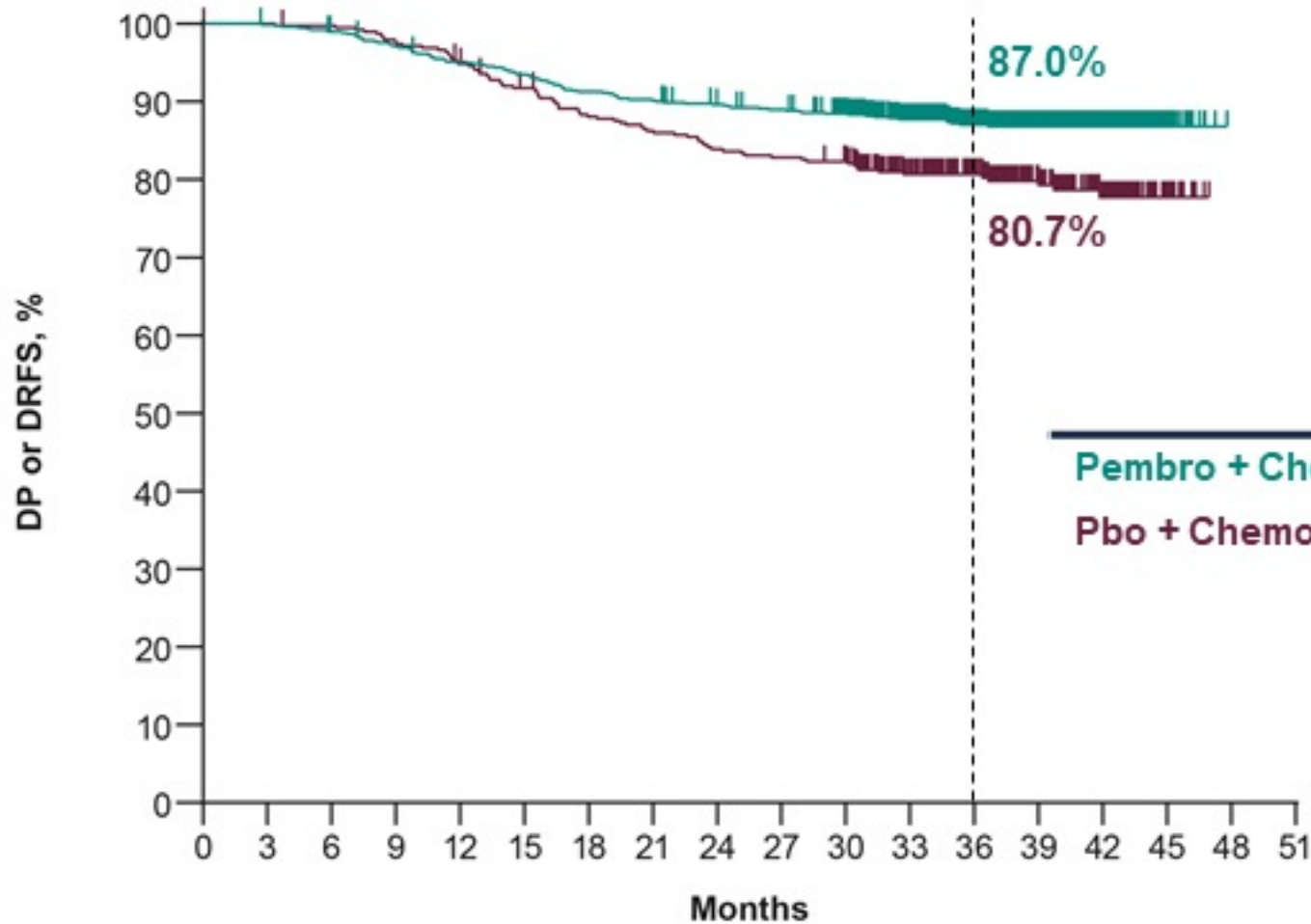
EFS by pCR (ypT0/Tis ypN0)



No. at Risk																		
Pembro + Chemo/Pembro Responder	494	494	494	489	483	482	478	477	472	470	460	387	307	220	122	18	0	0
Pbo + Chemo/Pbo Responder	217	217	217	216	214	207	206	203	200	200	197	165	130	87	56	9	0	0
Pembro + Chemo/Pembro Non-Responder	290	287	275	262	245	236	224	215	209	201	192	164	126	83	43	10	0	0
Pbo + Chemo/Pbo Non-Responder	173	169	165	152	144	135	122	116	110	104	100	85	65	53	27	8	0	0

Data cutoff date: March 23, 2021.

Distant Progression- or Distant Recurrence-Free Survival



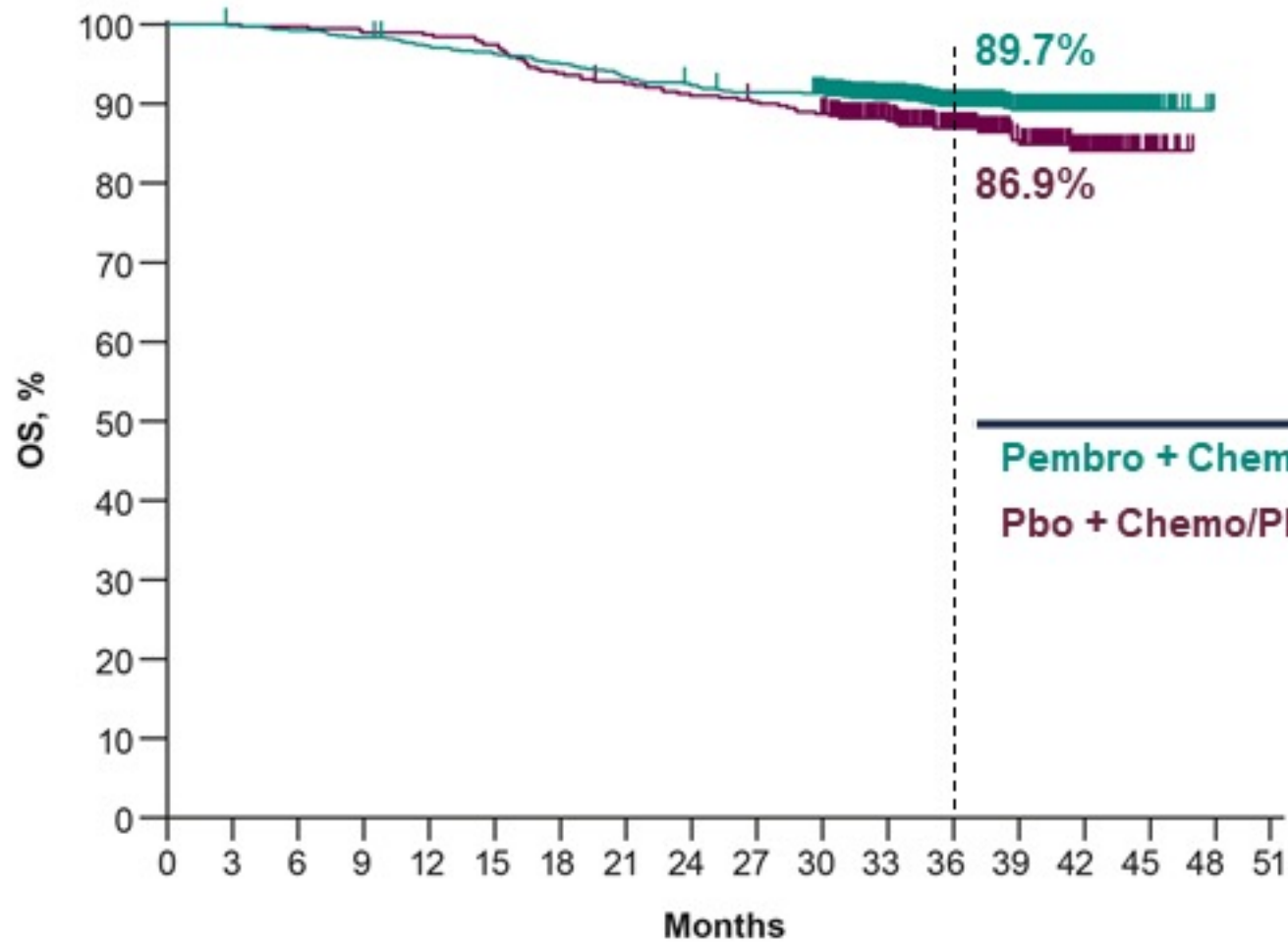
	Events	HR (95% CI)
Pembro + Chemo/Pembro	12.8%	0.61[a] (0.46-0.82)
Pbo + Chemo/Pbo	20.3%	

No. at Risk

Pembro + Chemo/Pembro	784	782	773	758	741	728	711	702	692	685	663	561	439	308	167	29	0	0
Pbo + Chemo/Pbo	390	389	387	379	367	352	337	330	321	317	312	259	202	143	84	17	0	0

[a]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. Data cutoff date: March 23, 2021.

Overall Survival



	Events	HR (95% CI)	*P*-value
Pembro + Chemo/Pembro	10.2%	0.72[a] (0.51-1.02)	0.03214[b]
Pbo + Chemo/Pbo	14.1%		

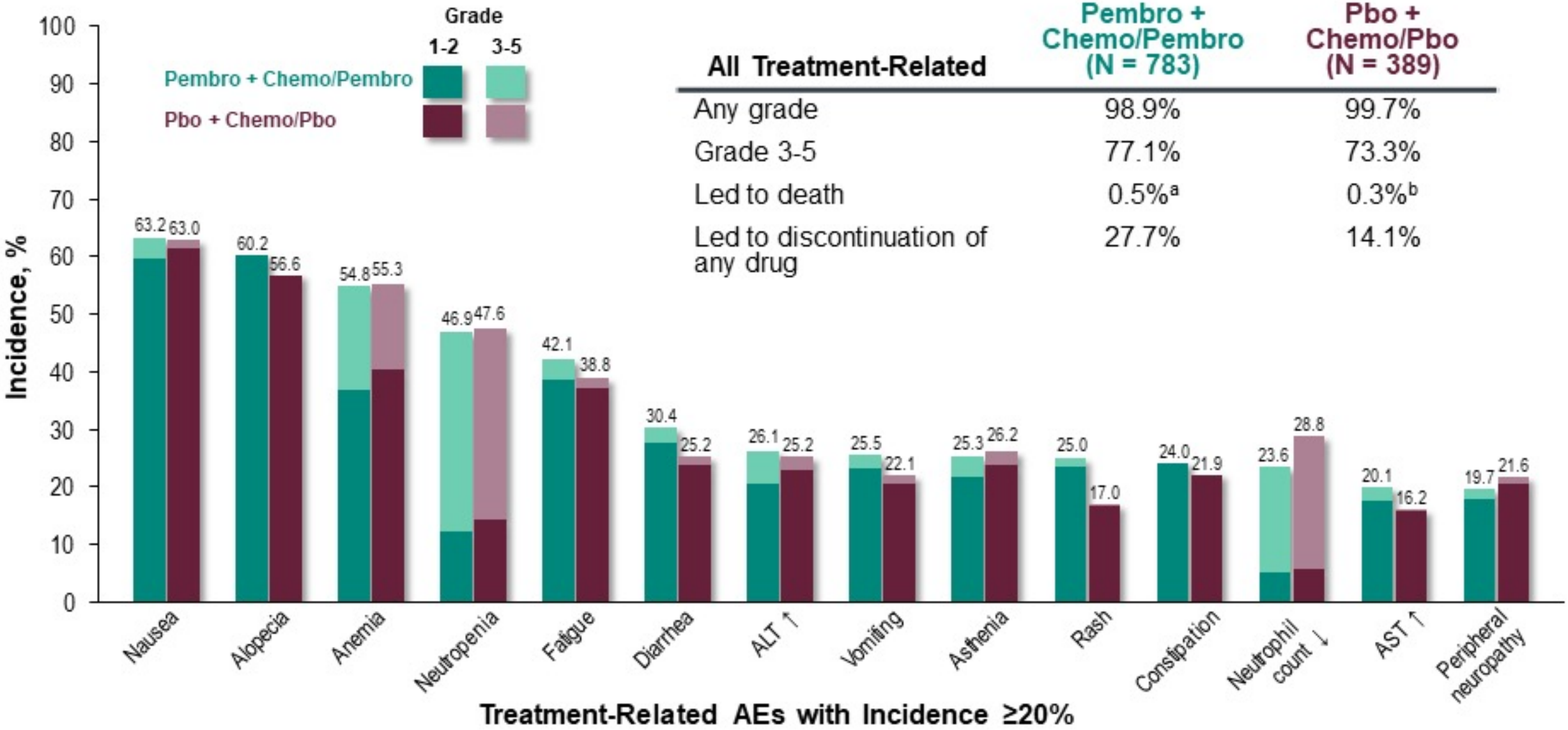
No. at Risk

Pembro + Chemo/Pembro	784	782	777	770	759	752	742	729	720	712	701	586	461	323	178	30	0	0
Pbo + Chemo/Pbo	390	390	389	386	385	380	366	360	354	350	343	286	223	157	89	17	0	0

[a]Hazard ratio (CI) analyzed based on a Cox regression model with treatment as a covariate stratified by the randomization stratification factors. [b]Prespecified *P*-value boundary of 0.00086 not reached at this analysis.
Data cutoff date: March 23, 2021.

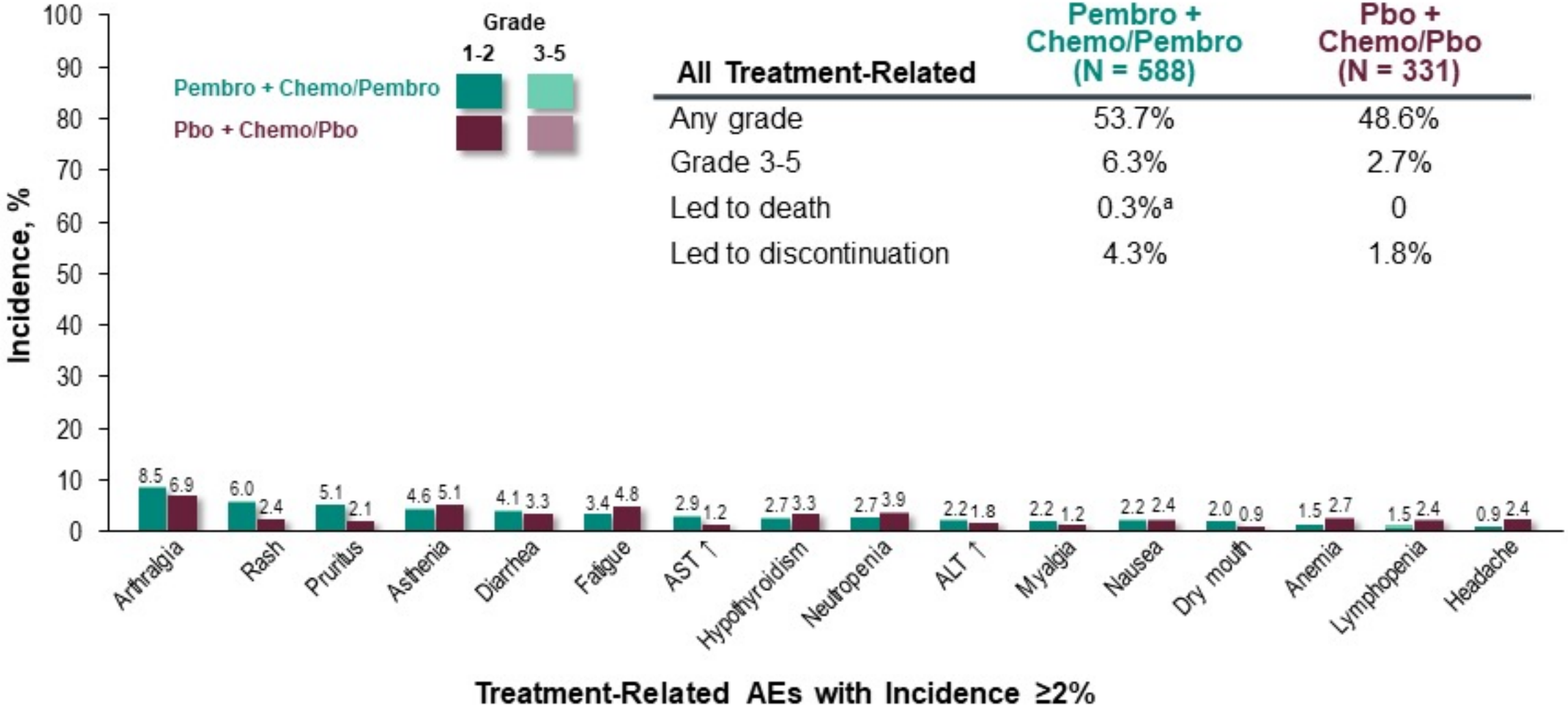
Treatment-Related AEs in Combined Phases

All Treatment-Related	Pembro + Chemo/Pembro (N = 783)	Pbo + Chemo/Pbo (N = 389)
Any grade	98.9%	99.7%
Grade 3-5	77.1%	73.3%
Led to death	0.5%[a]	0.3%[b]
Led to discontinuation of any drug	27.7%	14.1%



[a]1 patient from sepsis and multiple organ dysfunction syndrome; 1 patient from pneumonitis; 1 patient from pulmonary embolism; 1 patient from autoimmune encephalitis. [b]1 patient from septic shock.
Data cutoff date: March 23, 2021.

Treatment-Related AEs in Adjuvant Phase

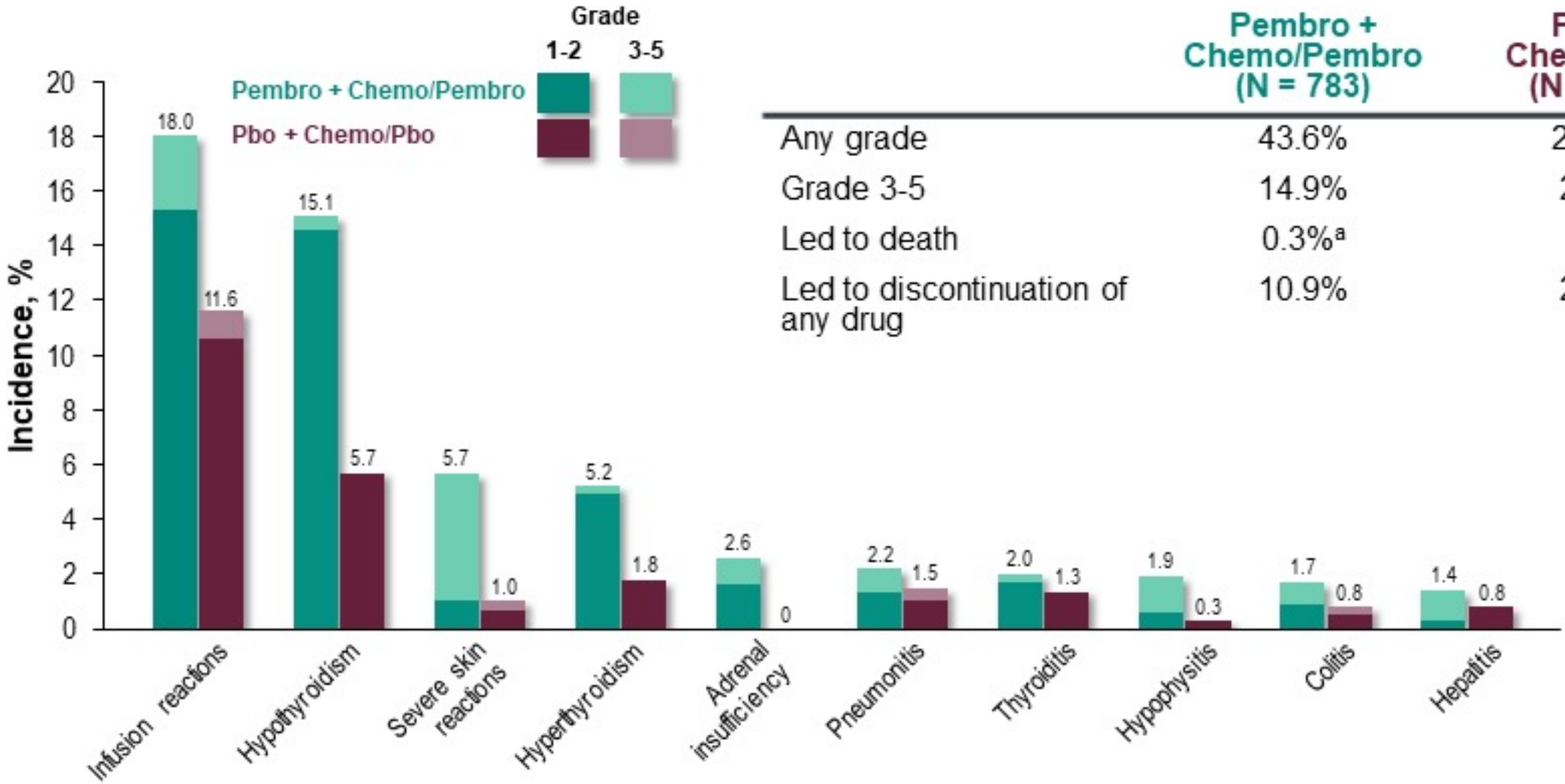


All Treatment-Related	Pembro + Chemo/Pembro (N = 588)	Pbo + Chemo/Pbo (N = 331)
Any grade	53.7%	48.6%
Grade 3-5	6.3%	2.7%
Led to death	0.3%[a]	0
Led to discontinuation	4.3%	1.8%

Treatment-Related AEs with Incidence ≥2%

[a]1 patient from pulmonary embolism and 1 patient from autoimmune encephalitis.
Data cutoff date: March 23, 2021.

Immune-Mediated AEs and Infusion Reactions in Combined Phases

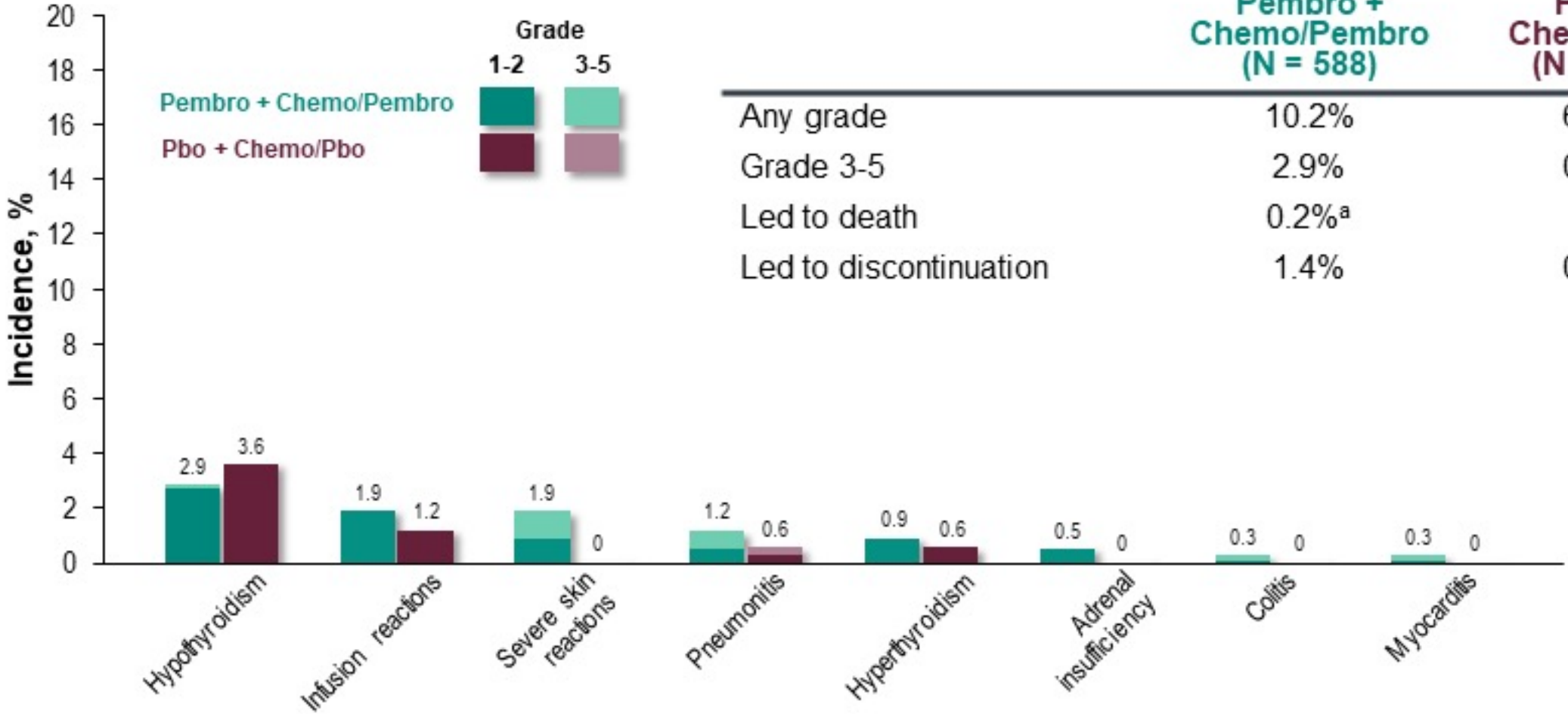


	Pembro + Chemo/Pembro (N = 783)	Pbo + Chemo/Pbo (N = 389)
Any grade	43.6%	21.9%
Grade 3-5	14.9%	2.1%
Led to death	0.3%[a]	0
Led to discontinuation of any drug	10.9%	2.6%

Immune-Mediated AEs and Infusion Reactions with Incidence ≥10 Patients

[a]1 patient from pneumonitis and 1 patient from autoimmune encephalitis. Considered regardless of attribution to treatment or immune relatedness by the investigator. Related terms included in addition to preferred terms listed. Data cutoff date: March 23, 2021.

Immune-Mediated AEs and Infusion Reactions in Adjuvant Phase



	Pembro + Chemo/Pembro (N = 588)	Pbo + Chemo/Pbo (N = 331)
Any grade	10.2%	6.0%
Grade 3-5	2.9%	0.3%
Led to death	0.2%[a]	0
Led to discontinuation	1.4%	0.3%

Immune-Mediated AEs and Infusion Reactions with Incidence ≥2 Patients

[a]1 patient from autoimmune encephalitis. Considered regardless of attribution to treatment or immune relatedness by the investigator. Related terms included in addition to preferred terms listed.
Data cutoff date: March 23, 2021.

Summary and Conclusions

- KEYNOTE-522 is the first prospective randomized placebo-controlled phase 3 trial of pembrolizumab in early TNBC in the neoadjuvant and adjuvant settings
- KEYNOTE-522 met its dual primary endpoints:
  - Neoadjuvant pembrolizumab + chemotherapy resulted in a statistically significant and clinically meaningful increase in pCR (ypT0/Tis ypN0) ($P = 0.00055$)
  - Neoadjuvant pembrolizumab + chemotherapy followed by adjuvant pembrolizumab showed a statistically significant and clinically meaningful improvement in EFS ($P = 0.00031$)
- At this early timepoint, there was a favorable trend for OS in the pembrolizumab group; follow-up is ongoing
- Safety was consistent with the known profiles of each regimen, with no new safety concerns
- Most immune-mediated AEs occurred in the neoadjuvant phase, were low-grade and manageable with treatment interruption, steroid administration, and/or hormone replacement
- These results support pembrolizumab plus platinum-containing neoadjuvant chemotherapy, followed by adjuvant pembrolizumab after surgery, as a new standard-of-care treatment regimen for patients with high-risk, early-stage TNBC

Acknowledgements

PATIENTS AND THEIR FAMILIES

Investigators and site personnel from 181 sites (plus 2 satellite sites) in 21 countries

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