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GI CONNECT

APPROPRIATE USE OF IMMUNOTHERAPY IN THE PERI-OPERATIVE SETTING FOR GASTRIC & GEJ CANCER

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NOVEMBER 2025

DEVELOPED BY GI CONNECT

This programme is developed by GI CONNECT, an international group of experts in the field of gastrointestinal oncology.

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Acknowledgement and disclosures

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Expert disclosures:

- **Dr Sam Klempner** has received financial support/sponsorship for research support, consultation, or speaker fees from the following companies:
  - Astellas, AstraZeneca, BMS, Coherus, Daiichi-Sankyo, Eli Lilly, Merck, Novartis, Nuvalent Therapuetics and Sanofi

EDUCATIONAL OBJECTIVES

1. Explore the latest clinical insights on the **addition of immunotherapy** to peri-operative FLOT, and the implications for clinical practice

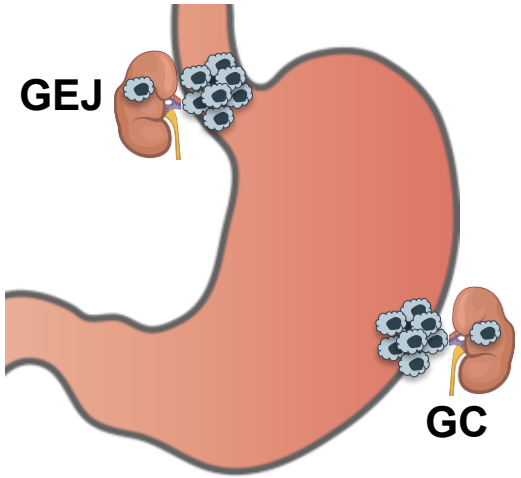
2. Recognise **toxicities** and be able to manage them appropriately

CLINICAL TAKEAWAYS

- **FLOT remains the standard peri-operative regimen** for resectable gastric, GEJ, and esophageal cancers
- **MATTERHORN supports adding durvalumab to FLOT**, with clear improvements in event-free and overall survival, consistent across most subgroups and without added meaningful toxicity
- **Peri-operative feasibility remains high:** over 90% of MATTERHORN participants proceeded to surgery, underscoring that FLOT plus durvalumab is practical in real-world settings
- **Optimal delivery requires MDT coordination** to assess resectability, surgical fitness, and support dose adjustments that preserve neoadjuvant intensity
- **In practice**, most patients can complete neoadjuvant therapy and surgery, and **adding durvalumab is reasonable for the majority of FLOT-eligible patients**

FLOT, fluorouracil plus leucovorin, oxaliplatin and docetaxel; GEJ, gastroesophageal junction; MDT, multidisciplinary team

MANAGEMENT OF OPERABLE GASTRIC/GEJ ADENOCARCINOMAS[1,2]



Neoadjuvant CRT (e.g., CROSS study[3])

Concurrent CRT → +/- Adjuvant PD-1 inhibitor[4] → Surveillance

Peri-operative chemotherapy (e.g., AIO-FLOT4 study[5])

Chemotherapy → Chemotherapy → Surveillance

Adjuvant chemotherapy (e.g., CLASSIC study[6])

Chemotherapy → Surveillance

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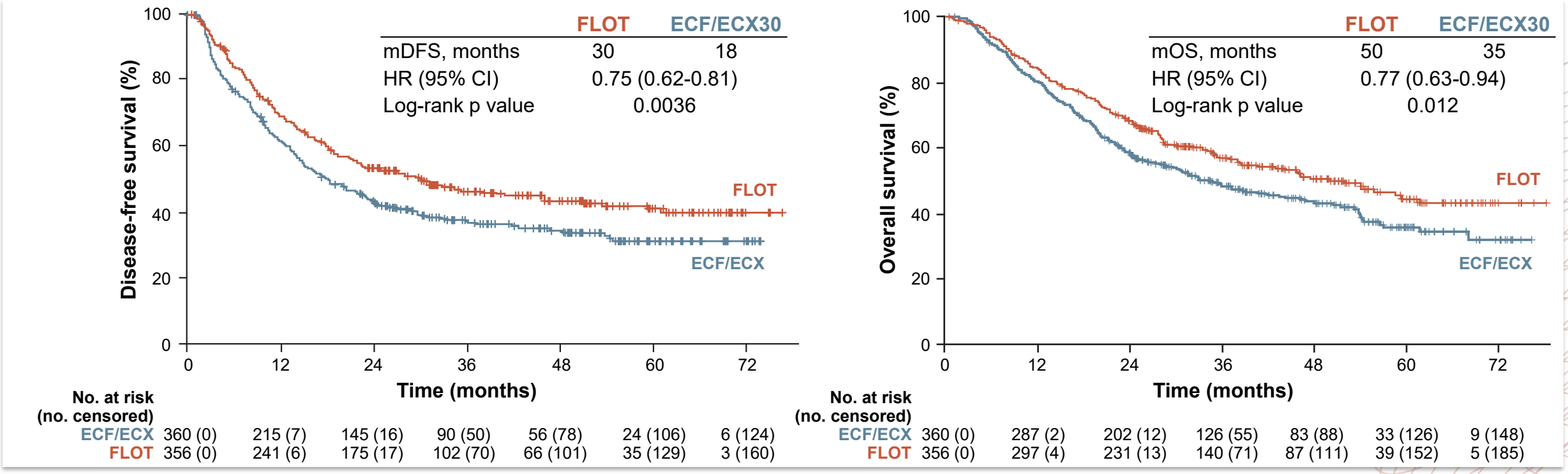
CRT, chemoradiotherapy; GC, gastric cancer; GEJ, gastroesophageal junction

1. NCCN Guidelines for eosphageal/EGJ cancers, Version 4.2025: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf; 2. Obermannová R, et al. ESMO Open. 2025;10:104134; 3. Van Hagen P, et al. N Engl J Med 2012; 366:2074-2084; 4. Kelly RJ, et al. New Engl J Med. 2021;384:1191-203; 5. Al-Batran SE, et al. Lancet. 2019;393:1948-57; 6. Bang Y-J, et al. Lancet 2012, *379*, 315–321

PERI-OPERATIVE THERAPY IS A GLOBAL OPTION

FLOT4 trial[1]



Guideline	Neoadjuvant/Peri-operative population	Preferred Regimens	Key Trials
NCCN[2]	High risk cT2N0,cT1b-T2, N+, cT3-cT4a, any N	**FLOT; FLOT + durvalumab**	AIO-FLOT4,[1] ESOPEC[5], MATTERHORN[6]
ESMO[3]	cT2-T4 or cN1-3 M0	**FLOT**	
Pan-Asian ESMO[4]	Stage >1B resectable/ cT4N+, Bulky lymph nodes	**Doublet [fluoropyrimidine/oxaliplatin/cisplatin] or triplet [FLOT, DOS]**	AIO-FLOT4,[1] PRODIGY,[7] RESOLVE,[8] JCOG0501[9]

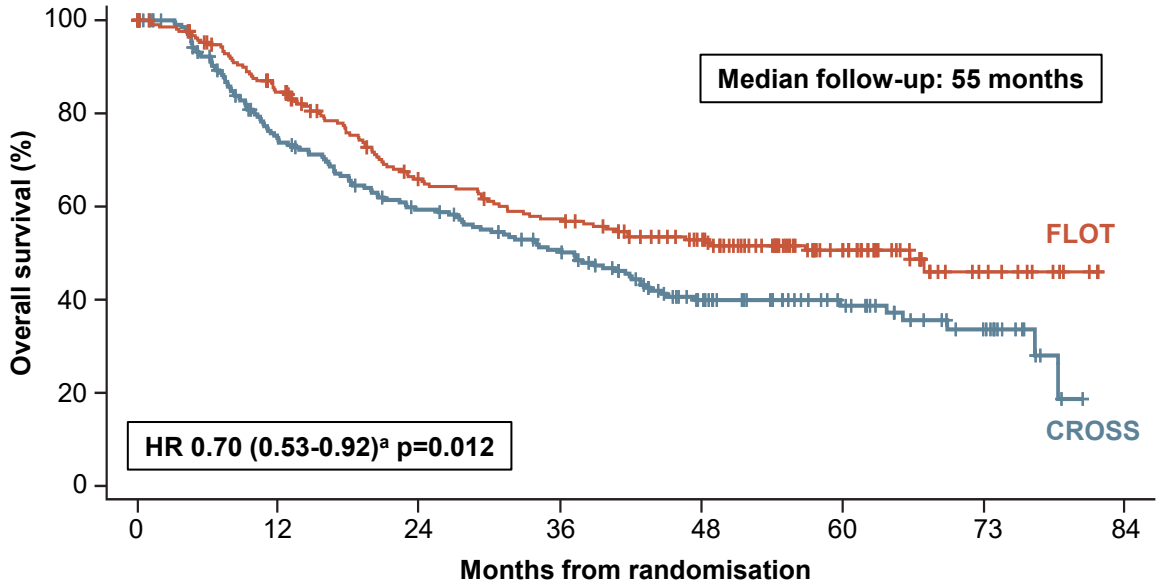
5-FU, fluorouracil; CI, confidence interval; (c)TN, (clinical) Tumour, Nodal (staging); (m)DFS, (median) disease-free survival; DOS, docetaxel, oxaliplatin and S-1; ECF/ECX, epirubicin+cisplatin+5-FU/capecitabine; ESMO, European Society for Medical Oncology; FLOT, fluorouracil plus leucovorin, oxaliplatin and docetaxel; HR, hazard ratio; mOS, (median) overall survival; NCCN, National Comprehensive Cancer Network

1. Al-Batran SE, et al. Lancet. 2019;393:1948-57; 2. NCCN Guidelines for eosphageal/EGJ cancers, Version 4.2025: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf; 3. Obermannová R, et al. ESMO Open. 2025;10:104134; 4. Shitara K, et al. ESMO Open. 2024;9:102226; 5. Hoeppner J, et al. N Engl J Med. 2025;392:323-335; 6. Janjigian YY, et al. N Engl J Med. 2025;393:217-30; 7. Kang YK, et al. J Clin Oncol. 2021;39:2903-2913; 8. Zhang X, et al. Lancet Oncol. 2021;22:1081-1092; 9. Iwasaki Y, et al. Gastric Cancer. 2021;24:492-502

ESOPEC: EFFICACY (ITT POPULATION)

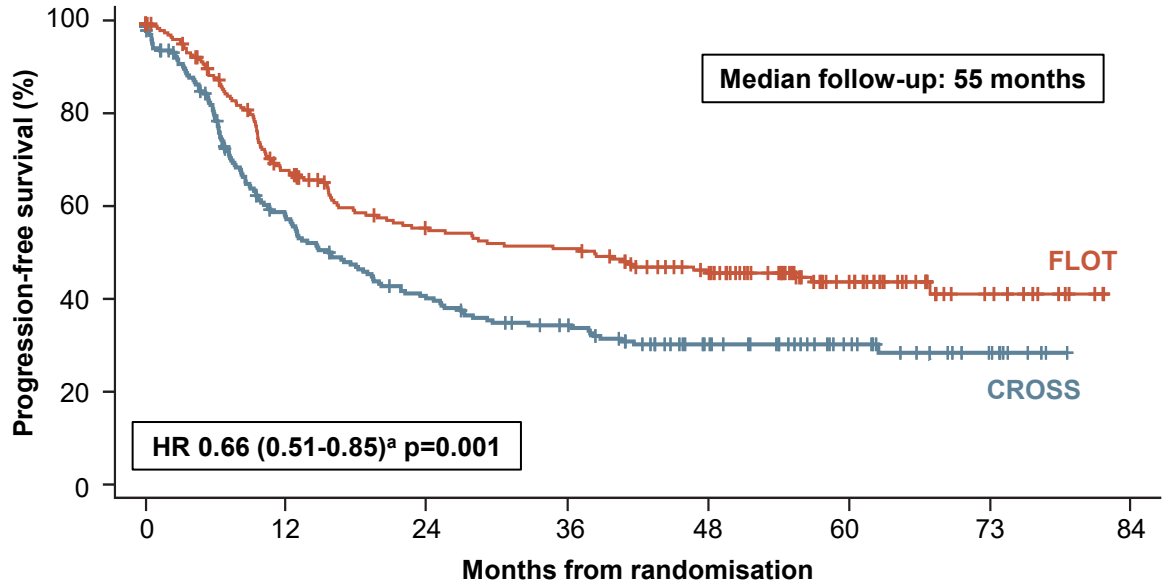
- Peri-operative chemotherapy (FLOT) plus surgery improves overall survival compared to neoadjuvant chemoradiation (CROSS) plus surgery for patients with cT1cN+ and cT2-4a,cN-/+ resectable esophageal adenocarcinoma[1]

OVERALL SURVIVAL (ITT)[2]



FLOT	221	172	124	107	84	44	11	0
CROSS	217	146	113	92	54	32	15	0

PROGRESSION-FREE SURVIVAL (ITT)[2]



FLOT	221	135	101	93	73	39	11	0
CROSS	217	113	78	62	39	22	9	0

[a] Two-sided 95% confidence interval; Cox regression adjusted for N stage and age, stratified for trial site

CROSS, preoperative radiotherapy plus carboplatin and paclitaxel (as used in CROSS study); (c)N, (clinical) Node stage; cT, clinical Tumour stage; FLOT, fluorouracil plus leucovorin, oxaliplatin and docetaxel; HR, hazard ratio; ITT, intention-to-treat

1. Hoeppner J, et al. J Clin Oncol 2024;42(No. 17_Suppl). Abstract LBA1; 2. Hoeppner J, et al. N Engl J Med 2025;392:323-35

THE PERI-OPERATIVE CHEMOTHERAPY-ICI LANDSCAPE

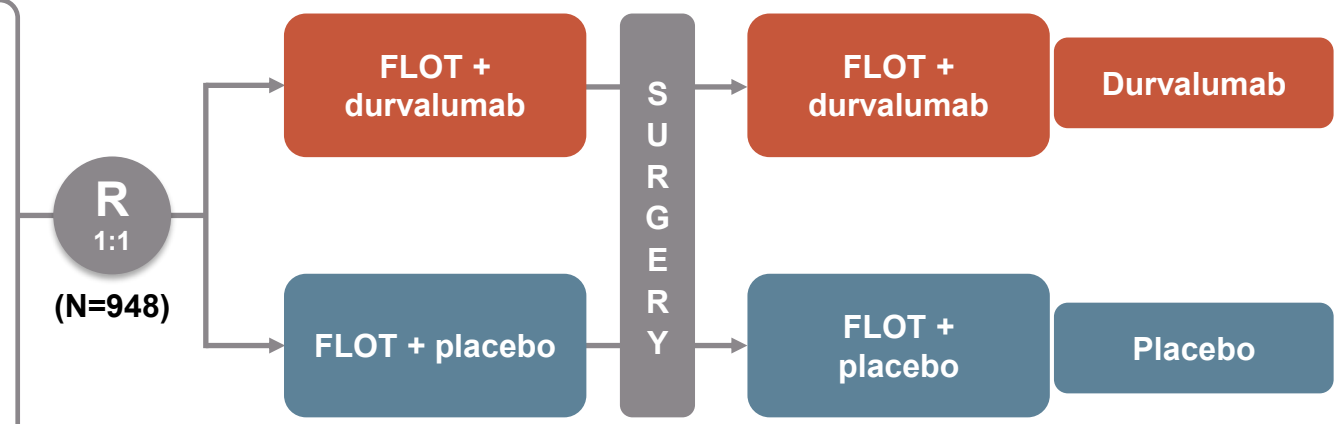
MATTERHORN[1]

Study population:

- G/GEJ adenocarcinoma
- Stage II–IVA
- ECOG 0-1
- No prior therapy

Stratification factors:

- Geographic region
- Clinical N status
- PD-L1 status



Primary = **EFS**
Secondary = pCR, OS

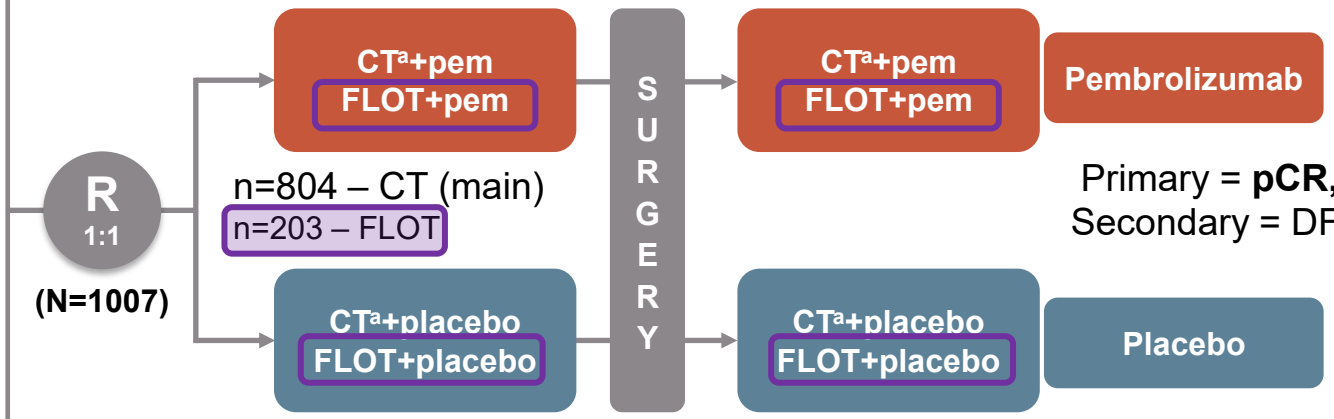
KEYNOTE-585[2,3]

Study population:

- ≥T3 and/or N+
- ECOG PS 0-1
- No prior therapy

Stratification factors:

- Asia vs non-Asia
- Stage II vs III vs IVA
- CT vs FLOT



Primary = **pCR,[b] EFS,[b] OS[b]; safety[c]**
Secondary = DFS,[b] OS,[d] EFS,[d] safety[d]

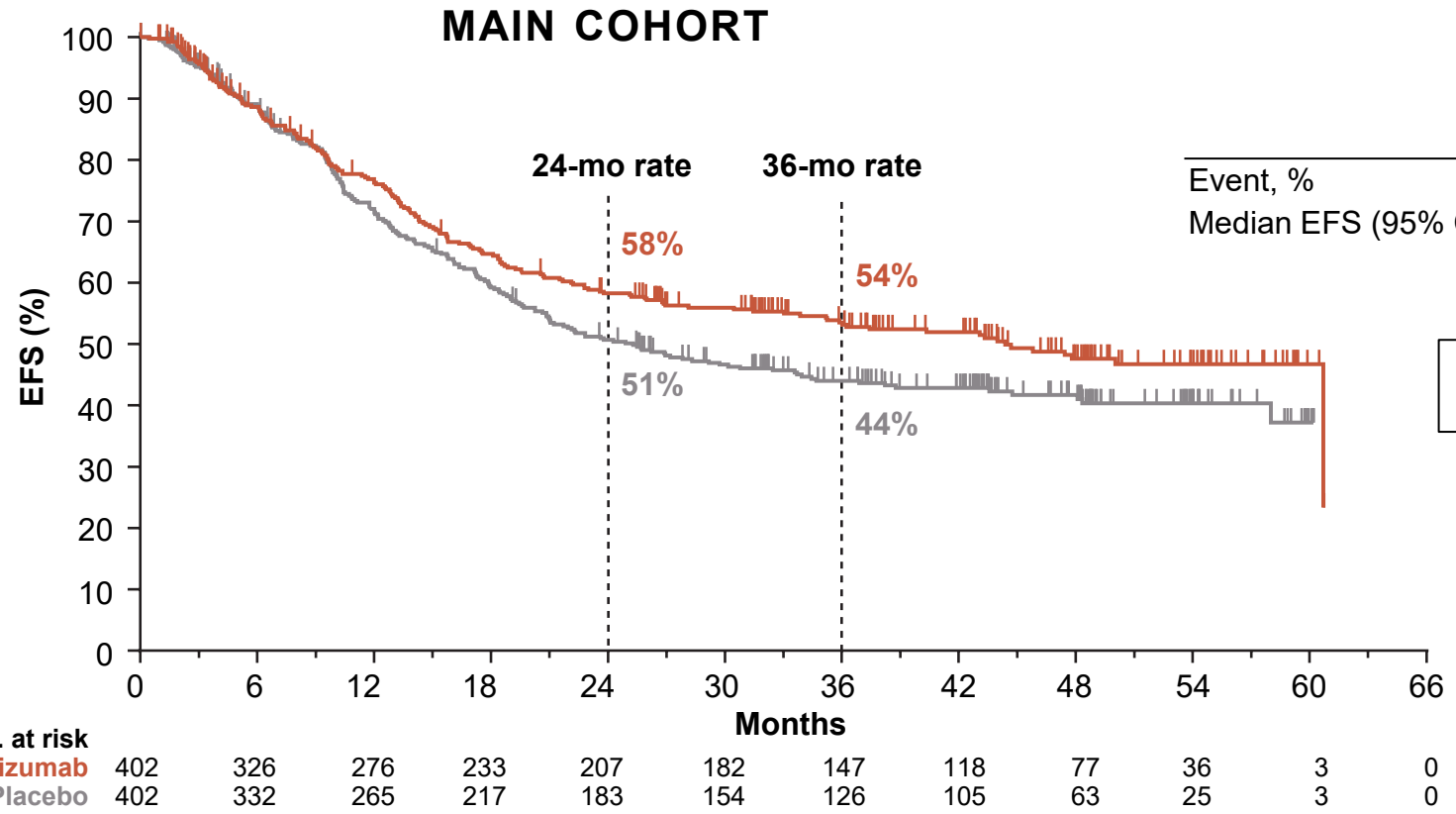
[a] CT: intravenous cisplatin plus oral capecitabine or fluorouracil; [b] Main cohort; [c] FLOT cohort; [d] FLOT+main cohorts (combined)

DFS, disease-free survival; ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; FLOT, 5-fluorouracil, leucovorin, oxaliplatin and docetaxel; N, Nodal (staging); OS, overall survival; pCR, pathological complete response; pem, pembrolizumab; R, randomisation; T, Tumour (staging)

1. Janjigian YY, et al. J Clin Oncol. 2025;43(suppl 17). Presented at ASCO Congress 2025 (Abstract LBA5); 2. Al-Batran S-E, et al. J Clin Oncol 2024;42(No. 3_suppl). Presented at ASCO GI Cancer Symposium 2024 (Abstract 247, oral presentation); 3. Shitara K, et al. J Clin Oncol. 2025;43:3152-3159

KEYNOTE-585: PERI-OPERATIVE CHEMO/FLOT ± PEMBRO

EVENT-FREE SURVIVAL DID NOT MEET STATISTICAL SIGNIFICANCE PER THE PRE-SPECIFIED STATISTICAL ANALYSIS PLAN



	Pembro	Placebo
Event, %	46	53
Median EFS (95% CI), mo	44.4 (33.0-NR)	25.3 (20.6-33.9)

HR 0.81 (95% CI: 0.67-0.99)
p=0.0198[a]

[a] Threshold for significance was one-sided p=0.0178
Data cut-off date: 9 Feb 2023.

EFS defined as time from randomisation to first occurrence of radiographic disease progression per RECIST v1.1, local or distant recurrence assessed by CT scan or biopsy if indicated, clinical progression, or death due to any cause per investigator assessment

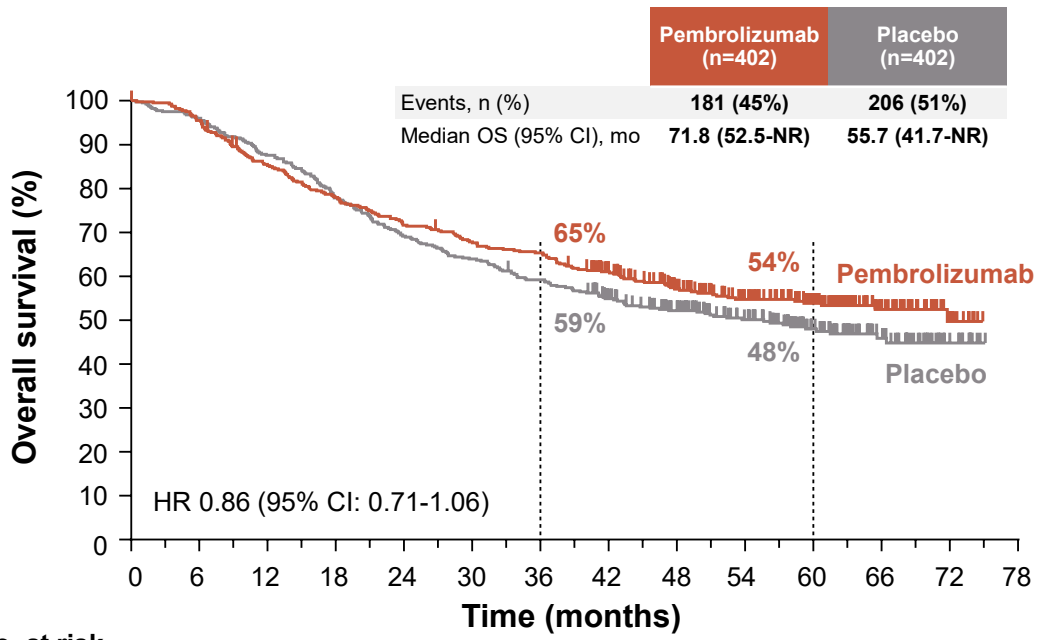
Chemo, chemotherapy; CI, confidence interval; CT, computed tomography; EFS, event-free survival; FLOT, fluorouracil plus leucovorin, oxaliplatin and docetaxel; HR, hazard ratio; mo, months; NR, not reached; pembro, pembrolizumab; RECIST, Response Evaluation Criteria in Solid Tumours

Shitara K, et al. Ann Oncol. 2023;34(suppl_2):S1316. Abstract LBA74

KEYNOTE-585: FINAL OVERALL SURVIVAL

OVERALL SURVIVAL DID NOT MEET STATISTICAL SIGNIFICANCE PER THE PRE-SPECIFIED STATISTICAL ANALYSIS PLAN

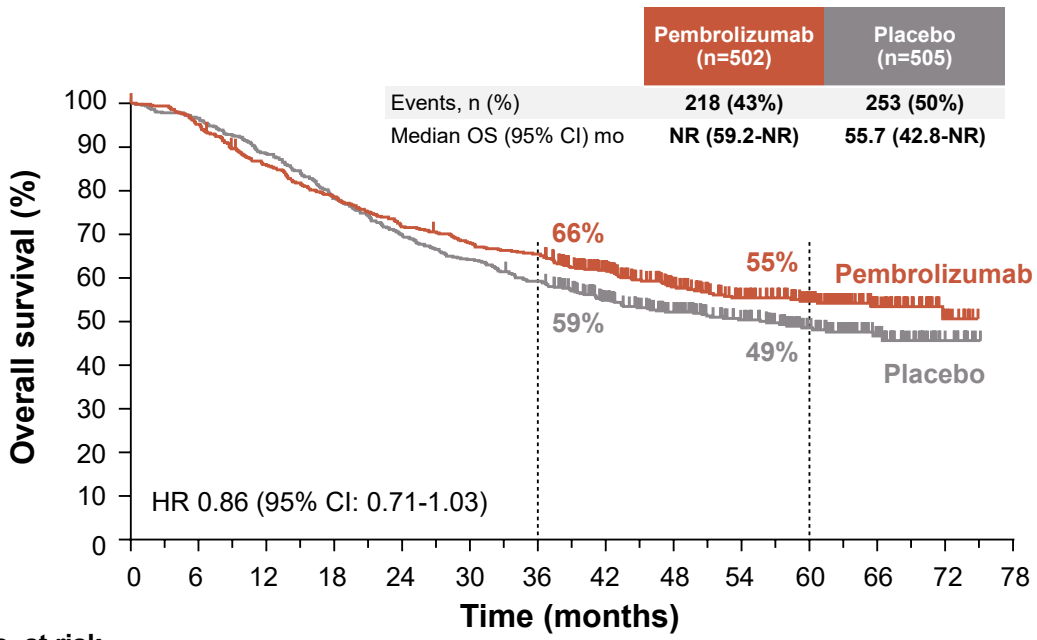
Main cohort



No. at risk

Pembrolizumab	402	383	339	310	285	269	259	226	189	145	111	56	15	0
Placebo	402	386	352	313	278	257	237	209	176	140	90	47	14	0

Main plus FLOT cohorts



No. at risk

Pembrolizumab	502	477	427	391	357	338	325	258	207	162	127	60	15	0
Placebo	505	488	447	395	353	324	298	240	195	159	109	50	14	0

CI, confidence interval; FLOT, fluorouracil plus leucovorin, oxaliplatin and docetaxel; HR, hazard ratio; mo, months; NR, not reached; OS, overall survival

Shitara K, et al. J Clin Oncol. 2025;43:3152-3159

MATTERHORN: STUDY DESIGN[1,2]

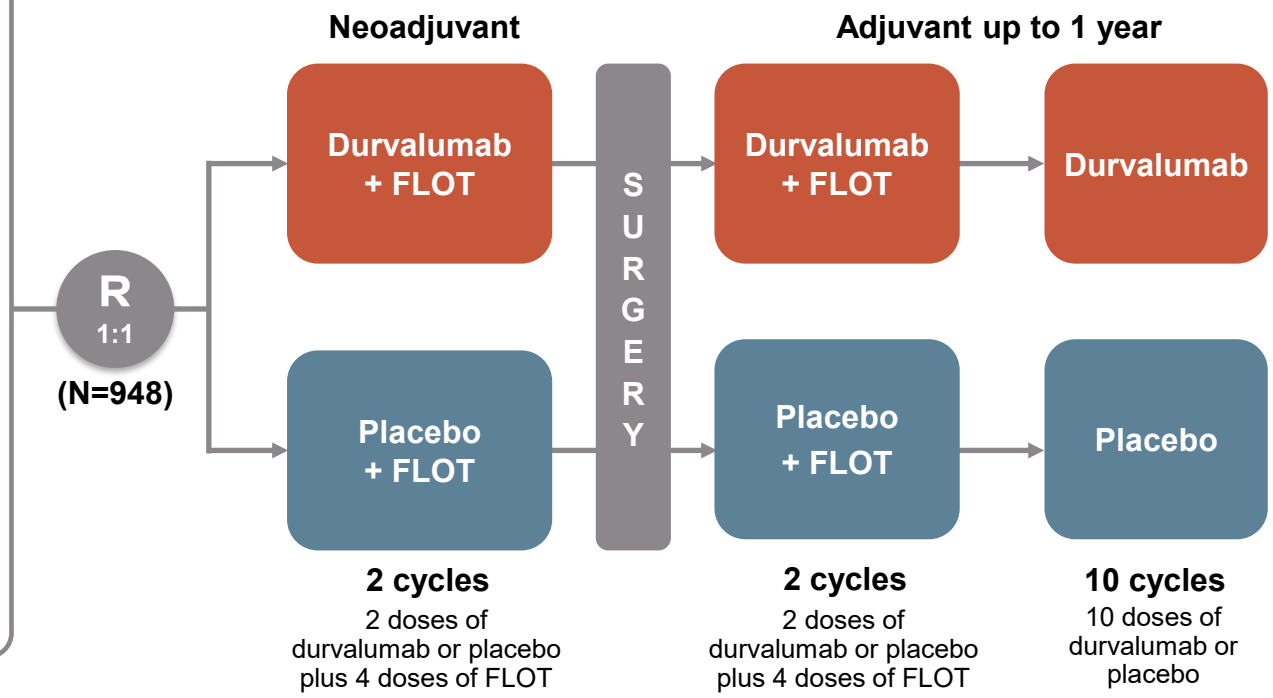
MATTERHORN IS A GLOBAL, PHASE 3, RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY

Study population:

- G/GEJ adenocarcinoma
- Stage II–IVA per American Joint Committee on Cancer 8th edition
- No evidence of metastasis
- No prior therapy
- ECOG PS 0 or 1
- Global enrolment from Asia, Europe, North America and South America

Stratification factors:

- Geographical region: Asia versus non-Asia
- Clinical lymph node status: positive versus negative
- PD-L1 expression: TAP <1% versus TAP ≥1%*



Primary endpoint:

- EFS

Secondary endpoints:

- OS
- pCR (central review by modified Ryan criteria)

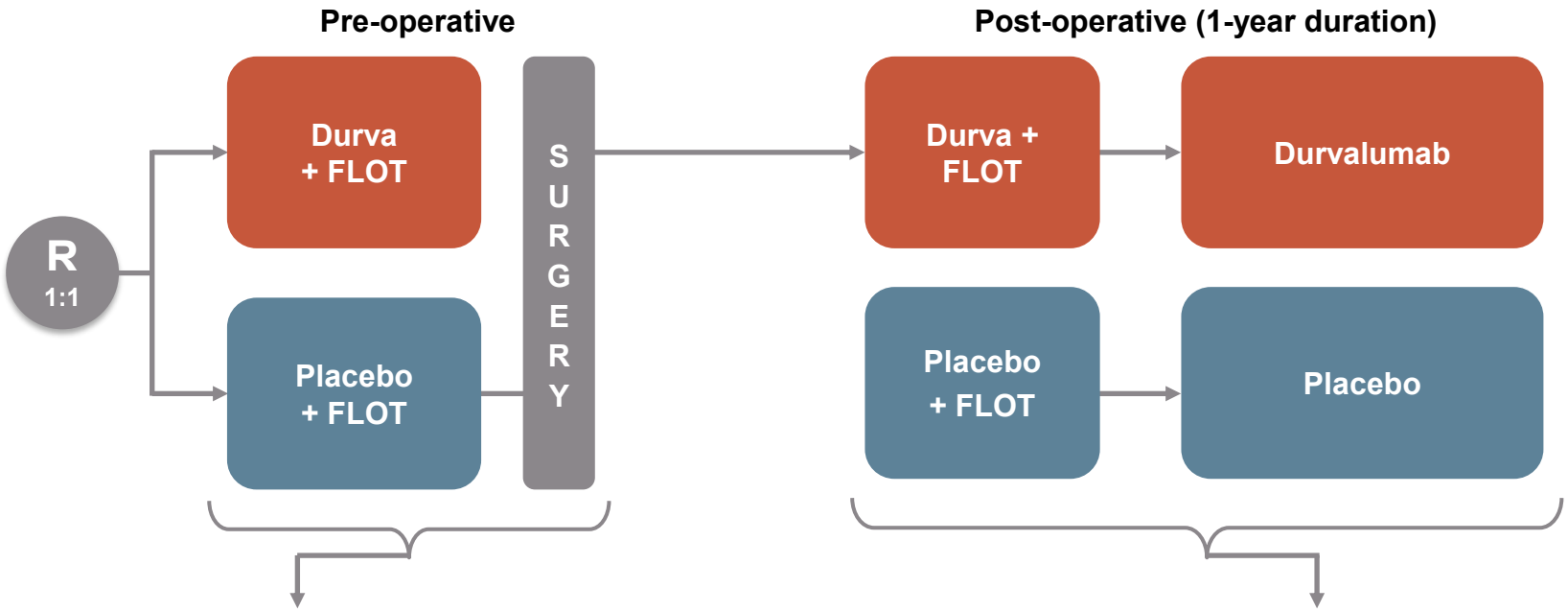
* Measured by immunohistochemistry using VENTANA PD-L1 (SP263) Companion Diagnostic Assay (Roche Diagnostics; investigational use only) and recorded at randomisation on the Interactive Response Technology System, Randomisation and Trial Supply Management, Electronic Case Report Form or from external vendor data from samples collected on or before randomisation

FLOT: 5-fluorouracil 2600 mg/m^2, leucovorin 200 mg/m^2, oxaliplatin 85 mg/m^2, docetaxel 50 mg/m^2, on Days 1 and 15 Q4W, 4 doses (2 cycles) pre- and post-operative; durvalumab: 1500 mg on Day 1 Q4W, 2 doses (2 cycles) of durvalumab or placebo pre- and post-operative, followed by 10 doses of post-operative durvalumab or placebo monotherapy. Participants underwent surgery 4-8 weeks after last dose of neoadjuvant therapy. Adjuvant therapy began 4-12 weeks post-surgery. Durvalumab or placebo monotherapy may be continued if post-operative FLOT is discontinued due to toxicity

ECOG PS, Eastern Cooperative Oncology Group performance status; EFS, event-free survival; FLOT, 5-fluorouracil, leucovorin, oxaliplatin and docetaxel; G / GEJ, gastric / gastroesophageal junction; OS, overall survival; pCR, pathological complete response; PD-L1, programmed cell death ligand-1; Q4W, every 4 weeks; R, randomisation; TAP, tumour area positivity

1. Janjigian YY, et al. N Engl J Med. 2025;393:217-30. 2. Janjigian YY, et al. J Clin Oncol. 2025;43(suppl 17). Abstract LBA5. Presented at: ASCO Congress 2025

DURVALUMAB DOES NOT IMPACT FLOT DELIVERY



NO impact on pre-operative delivery

Feature	Durva + FLOT	Placebo + FLOT
Received All FLOT	**95%**	**92%**
Received All durva/placebo	97%	95%
Went to surgery	**91%**	**90%**

NO impact on post-operative delivery

Feature	Durva + FLOT	Placebo + FLOT
Started FLOT	**74%**	**73%**
Received All FLOT	**48%**	**52%**
Received All durva/placebo	52%	52%

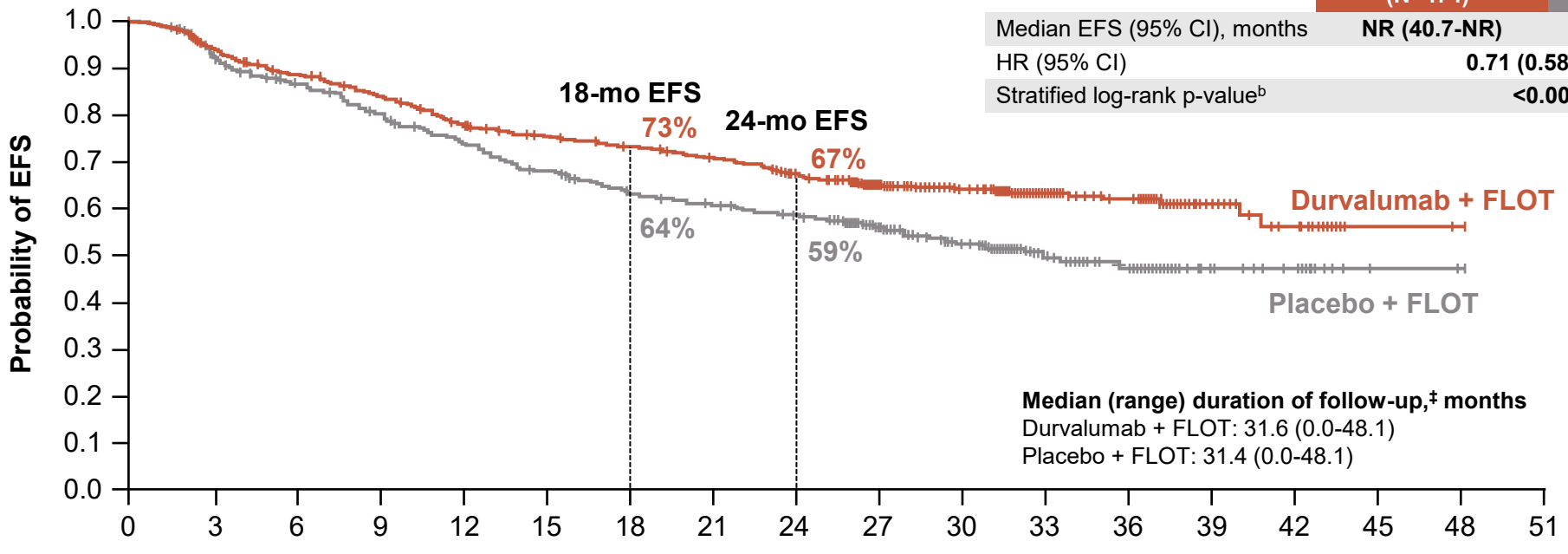
durva, durvalumab; FLOT, 5-fluorouracil, leucovorin, oxaliplatin and docetaxel; R, randomisation

Janjigian YY, et al. J Clin Oncol. 2025;43(suppl 17). Presented at ASCO Congress 2025 (Abstract LBA5); Janjigian Y, et al. N Engl J Med 2025;393:217-230

MATTERHORN: PRIMARY ENDPOINT OF EFS[1,2]

A STATISTICALLY SIGNIFICANT IMPROVEMENT IN EFS WAS OBSERVED WITH DURVALUMAB + FLOT VERSUS PLACEBO + FLOT

	Durvalumab + FLOT (N=474)[a]	Placebo + FLOT (N=474)[a]
Median EFS (95% CI), months	NR (40.7-NR)	32.8 (27.9-NR)
HR (95% CI)	0.71 (0.58-0.86)	
Stratified log-rank p-value[b]	<0.001	



No. of participants at risk																		Total no. of events
Durvalumab + FLOT	474	436	404	381	351	334	320	307	288	234	187	107	88	33	20	2	1	0	167
Placebo + FLOT	474	429	392	360	329	302	278	264	249	202	160	89	65	26	21	2	1	0	218

[a] Full analysis set (all randomised participants, regardless of treatment received); [b] The threshold of significance for this analysis was 0.0239; ‡ In censored participants

Events were defined as the earliest of RECIST v1.1 events, non-RECIST v1.1 events or deaths due to any cause. Analysis was based on BICR assessments and / or locally by pathology testing if clinically required. The HR and its CI were estimated from a Cox proportional hazards model, adjusted for geographical region, clinical lymph node status and PD-L1 expression. The CI for the HR was calculated using a profile likelihood approach. The 2-sided p-value was calculated using a stratified log-rank test adjusted for geographical region, clinical lymph node status and PD-L1 expression

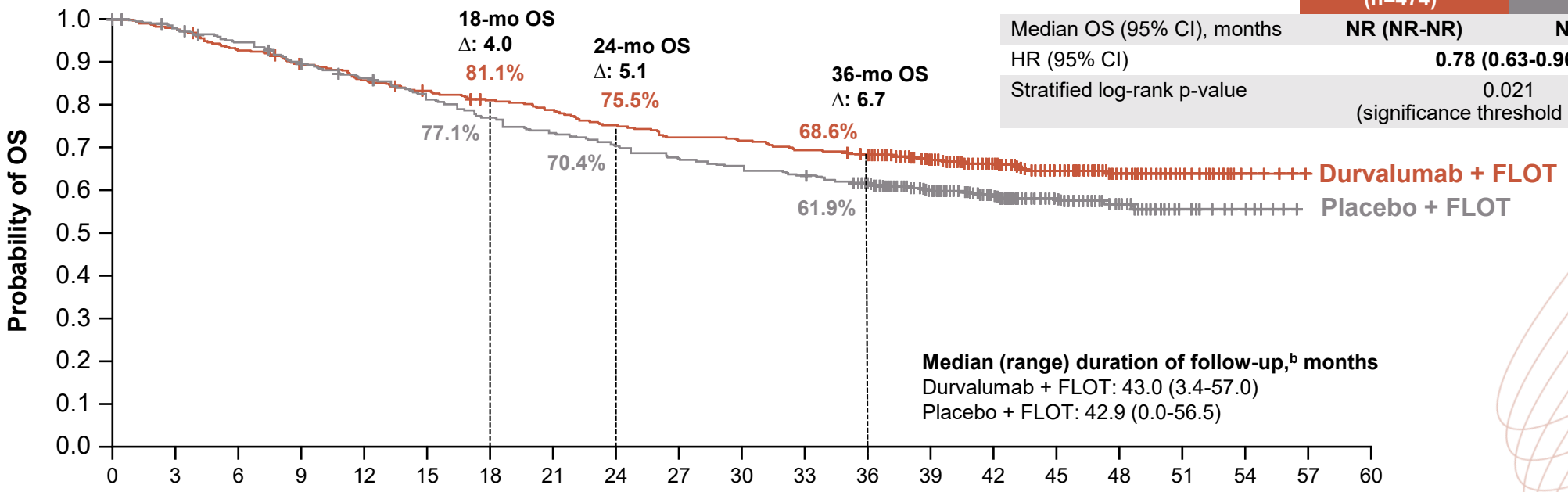
BICR, blinded independent central review; CI, confidence interval; EFS, event-free survival; FLOT, 5-fluorouracil, leucovorin, oxaliplatin and docetaxel; HR, hazard ratio; mo, month; NR, not reached; PD-L1, programmed cell death ligand-1; RECIST v1.1, Response Evaluation Criteria in Solid Tumours, version 1.1

1. Janjigian YY, et al. N Engl J Med. 2025;393:217-30; 2. Janjigian YY, et al. J Clin Oncol. 2025;43(suppl 17). Abstract LBA5. Presented at: ASCO Congress (2025)

MATTERHORN: FINAL OS

A STATISTICALLY SIGNIFICANT AND CLINICALLY MEANINGFUL IMPROVEMENT IN OS WAS OBSERVED WITH DURVALUMAB + FLOT VERSUS PLACEBO + FLOT IN THE INTENTION-TO-TREAT POPULATION

	Durvalumab + FLOT (n=474)[a]	Placebo + FLOT (n=474)[a]
Median OS (95% CI), months	**NR (NR-NR)**	**NR (NR-NR)**
HR (95% CI)	**0.78 (0.63-0.96)**	
Stratified log-rank p-value	0.021 (significance threshold p<0.0499)	



No. of participants at risk																					Total no. of events
Durvalumab + FLOT	474	464	438	422	403	389	377	367	351	338	334	323	316	255	182	112	71	29	6	1	0	160
Placebo + FLOT	474	457	439	414	395	374	355	338	324	310	298	293	278	221	167	99	61	23	7	0	0	192

[a] Intention-to-treat analysis set (all randomised participants, regardless of treatment received). [b] In censored participants

Data cut-off: 01 September 2025. OS maturity: 37.1%. Events were defined as time from randomisation until the date of death due to any cause. The HR and its CI were estimated from a Cox proportional hazards model, adjusted for geographic region, clinical lymph node status, and PD-L1 expression status. The CI for the HR was calculated using a profile likelihood approach. An HR <1 favours durvalumab + FLOT. The two-sided p-value was calculated using a stratified log-rank test adjusting for geographic region, clinical lymph node status, and PD-L1 expression status.

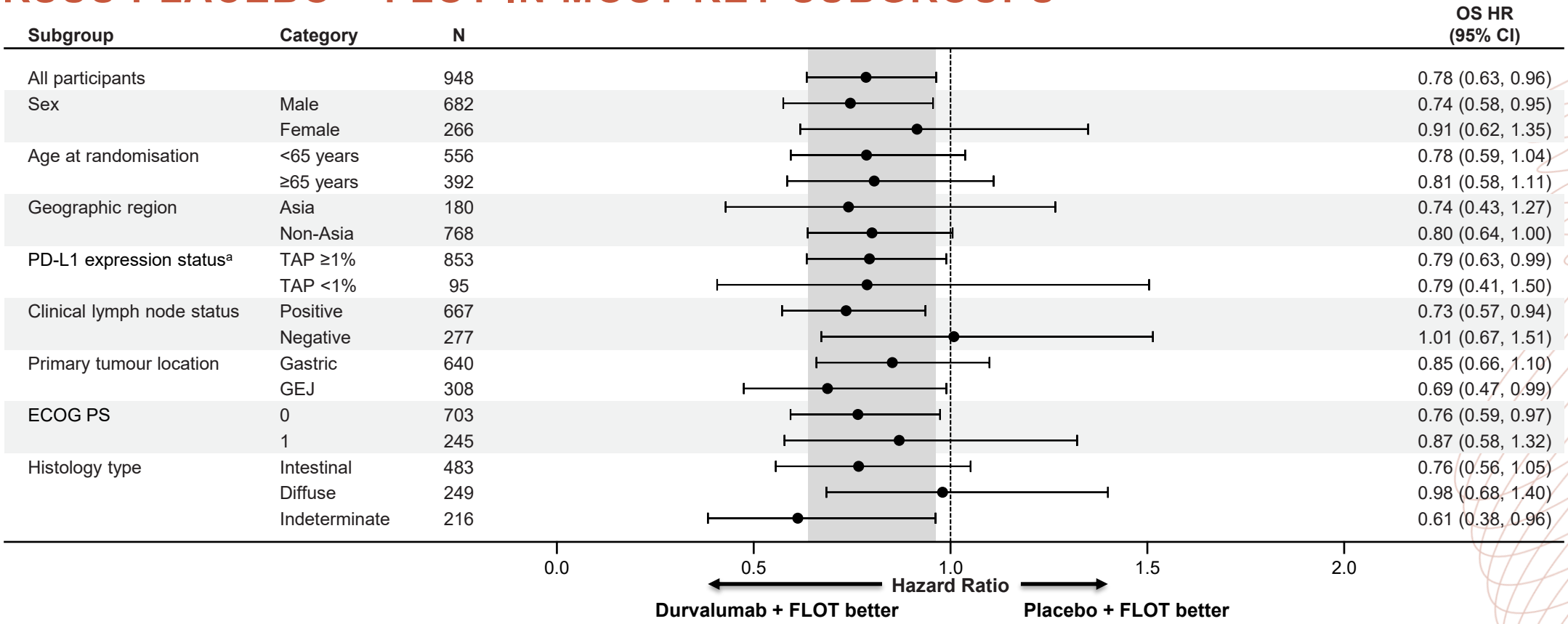
CI, confidence interval; FLOT, 5-fluorouracil, leucovorin, oxaliplatin, and docetaxel; HR, hazard ratio; mo, month; NR, not reached; OS, overall survival

Tabernero J, et al. Ann Oncol. 2025;36(suppl_2):S1-S60. 10.1016/annonc/annonc1965. Presented at ESMO 2025 (Abstract LBA81)

MATTERHORN: OS IN KEY SUBGROUPS

A CONSISTENT BENEFIT IN OS WAS OBSERVED WITH DURVALUMAB + FLOT VERSUS PLACEBO + FLOT IN MOST KEY SUBGROUPS

Subgroup	Category	N	OS HR (95% CI)
All participants		948	0.78 (0.63, 0.96)
Sex	Male	682	0.74 (0.58, 0.95)
	Female	266	0.91 (0.62, 1.35)
Age at randomisation	<65 years	556	0.78 (0.59, 1.04)
	≥65 years	392	0.81 (0.58, 1.11)
Geographic region	Asia	180	0.74 (0.43, 1.27)
	Non-Asia	768	0.80 (0.64, 1.00)
PD-L1 expression status[a]	TAP ≥1%	853	0.79 (0.63, 0.99)
	TAP <1%	95	0.79 (0.41, 1.50)
Clinical lymph node status	Positive	667	0.73 (0.57, 0.94)
	Negative	277	1.01 (0.67, 1.51)
Primary tumour location	Gastric	640	0.85 (0.66, 1.10)
	GEJ	308	0.69 (0.47, 0.99)
ECOG PS	0	703	0.76 (0.59, 0.97)
	1	245	0.87 (0.58, 1.32)
Histology type	Intestinal	483	0.76 (0.56, 1.05)
	Diffuse	249	0.98 (0.68, 1.40)
	Indeterminate	216	0.61 (0.38, 0.96)



[a] Measured by immunohistochemistry using VENTANA PD-L1 (SP263) Companion Diagnostic Assay (Roche Diagnostics; investigational use only) and recorded at randomisation on the Interactive Response Technology System, Randomisation and Trial Supply Management, Electronic Case Report Form or from external vendor data from samples collected on or before randomisation. Participants provided a tumour tissue sample at screening to determine PD-L1 status using the TAP scoring method

Data cut-off: 01 September 2025. The analysis was performed using a Cox proportional hazards model with treatment as the only covariate. An HR <1 favours durvalumab + FLOT. The CI was calculated using a profile likelihood approach. The grey band represents the 95% CI for the intention-to-treat HR

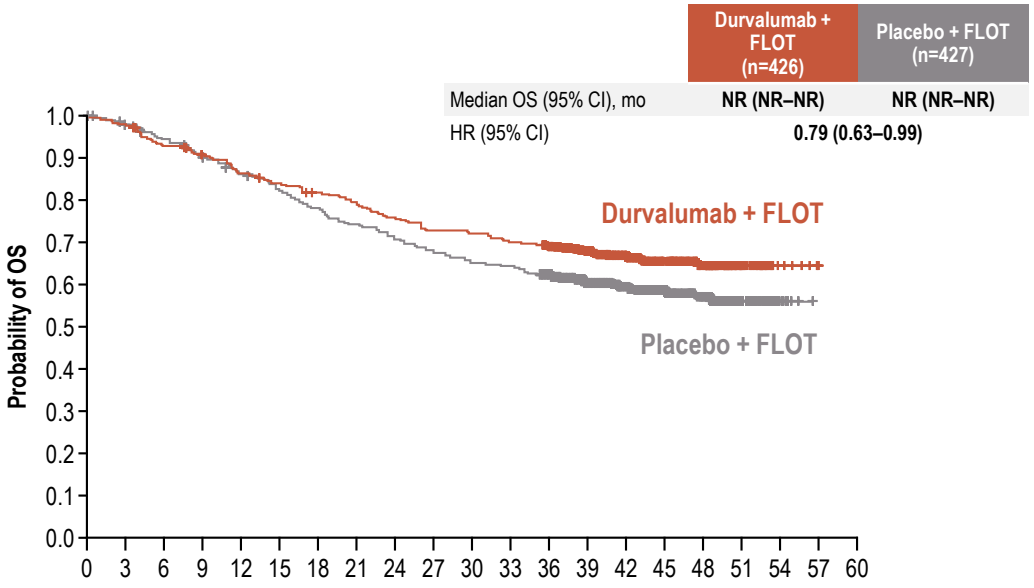
CI, confidence interval; ECOG, Eastern Cooperative Oncology Group performance status; FLOT, 5-fluorouracil, leucovorin, oxaliplatin and docetaxel; GEJ, gastroesophageal junction; HR, hazard ratio; OS, overall survival; TAP, Tumour Area Positivity

Tabernero J, et al. Ann Oncol. 2025;36(suppl_2):S1-S60. 10.1016/annonc/annonc1965. Presented at ESMO 2025 (Abstract LBA81)

MATTERHORN: OS BY PD-L1 STATUS

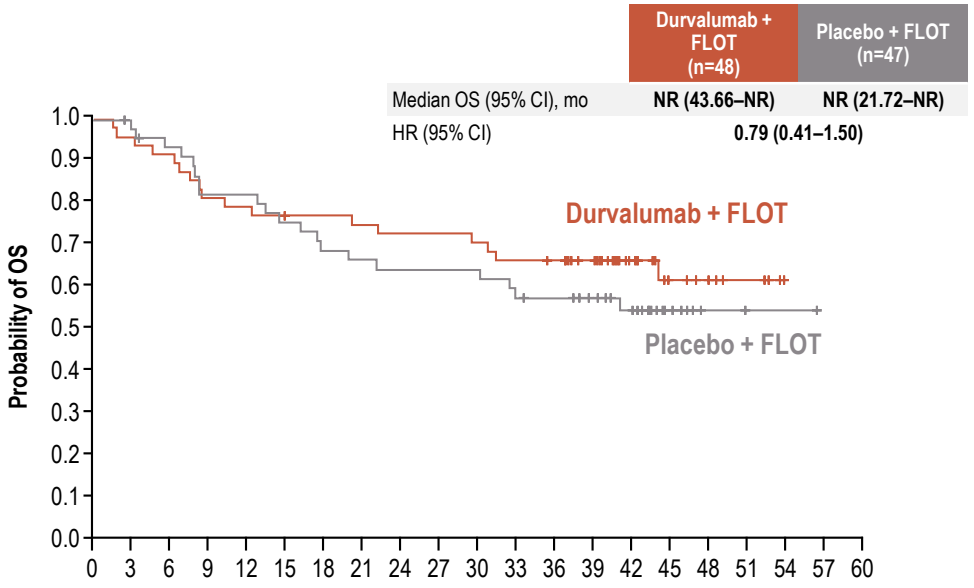
OS WAS IMPROVED WITH DURVALUMAB + FLOT VERSUS PLACEBO + FLOT REGARDLESS OF PD-L1 STATUS

PD-L1 TAP ≥1%[a]



No. of participants at risk																						Total no. of events
Durvalumab + FLOT	426	418	394	383	365	353	341	332	317	304	301	292	286	229	165	101	64	25	6	1	0	143
Placebo + FLOT	427	412	397	377	358	340	324	308	295	281	270	267	253	200	152	91	59	22	6	0	0	172

PD-L1 TAP <1%[a]



No. of participants at risk																										Total no. of events
Durvalumab + FLOT	48	46	44	39	38	36	36	35	34	34	33	31	30	26	17	11	7	4	0	0	0	17
Placebo + FLOT	47	45	42	37	37	34	31	30	29	29	28	26	25	21	15	8	2	1	1	0	0	20

[a] Measured by immunohistochemistry using VENTANA PD-L1 (SP263) Companion Diagnostic Assay (Roche Diagnostics; investigational use only) and recorded at randomisation on the Interactive Response Technology System, Randomisation and Trial Supply Management, Electronic Case Report Form or from external vendor data from samples collected on or before randomisation. Participants provided a tumour tissue sample at screening to determine PD-L1 status using the TAP scoring method

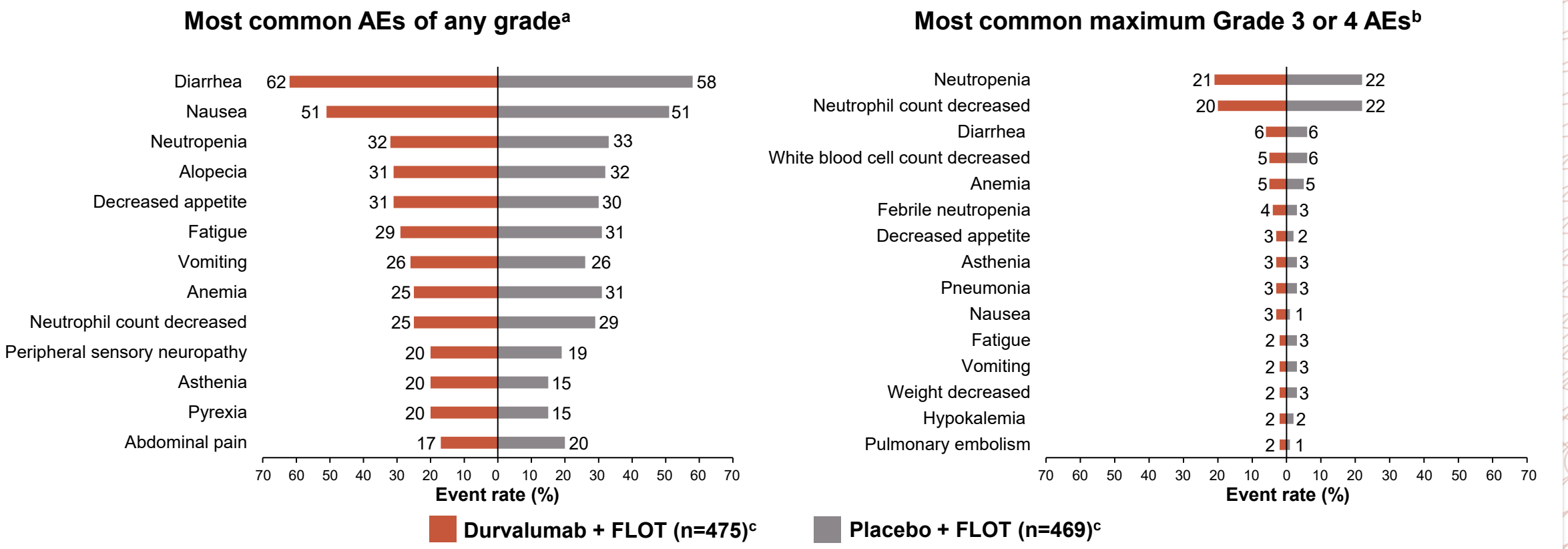
Data cut-off: 01 September 2025. The HR and its CI were estimated from a Cox proportional hazards model. The CI for the HR was calculated using a profile likelihood approach

CI, confidence interval; FLOT, 5-fluorouracil, leucovorin, oxaliplatin and docetaxel; HR, hazard ratio; NR, not reached; OS, overall survival; PD-L1, programmed death ligand – 1; TAP, Tumour Area Positivity

Tabernero J, et al. Ann Oncol. 2025;36(suppl_2):S1-S60. 10.1016/annonc/annonc1965. Presented at ESMO 2025 (Abstract LBA81)

AE RATES SIMILAR BETWEEN DURVALUMAB AND FLOT ARMS

MATTERHORN STUDY



[a] AEs occurring in ≥20% of participants in any treatment group; [b] AEs occurring in ≥2% of participants in any treatment group; [c] Safety analysis set (participants who received at least one dose of study treatment); one participant in the placebo + FLOT group received a single dose of durvalumab and is, therefore, included in the durvalumab + FLOT group for the safety analysis

AE, adverse event; FLOT, 5-fluorouracil, leucovorin, oxaliplatin and docetaxel

Janjigian YY, et al. J Clin Oncol. 2025;43(suppl 17). Presented at ASCO Congress 2025 (Abstract LBA5)

MATTERHORN: CONCLUSIONS

- Durvalumab + FLOT demonstrated a statistically significant and clinically meaningful improvement in OS versus FLOT alone in the intention-to-treat population
- OS improved with durvalumab + FLOT versus placebo + FLOT, regardless of PD-L1 status

- MATTERHORN represents the first successful perioperative IO trial in gastric/GEJ cancer to meet both its primary endpoint (EFS) and its key secondary endpoint (OS), establishing durvalumab as a new global standard of care for these patients
- The FDA have approved durvalumab + FLOT (regardless of PD-L1 status) as neoadjuvant and adjuvant treatment, followed by single agent durvalumab, for adults with resectable gastric/GEJ adenocarcinoma based on the MATTERHORN trial

EFS, event-free survival; FDA, Food and Drug Administration; FLOT, 5-fluorouracil, leucovorin, oxaliplatin and docetaxel; GEJ, gastroesophageal junction; OS, overall survival; PD-L1, programmed death ligand – 1

IMPLEMENTING FLOT IN CLINICAL PRACTICE

- Early surgical involvement for discussions of candidacy and surgical planning
- Dose reductions can be quite effective, limited concern with reductions in oxaliplatin and docetaxel
- Neoadjuvant component quite important, and we do not yet have data to clearly de-escalate adjuvant component unless needed to manage toxicities

FLOT, 5-fluorouracil, leucovorin, oxaliplatin and docetaxel

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