2026 ESMO GASTROINTESTINAL CANCERS

Annual Congress

Health-related quality of life with zanidatamab + chemotherapy ± tislelizumab for first-line HER2-positive advanced/metastatic gastro-oesophageal adenocarcinoma: Results from HERIZON-GEA-01

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Declaration of Interests

Kohei Shitara reports consulting fees from Abbvie; ALX Oncology; Amgen; Arcus Biosciences; Astellas Pharma; AstraZeneca; Bayer; Boehringer Ingelheim; Bristol-Myers Squibb; CMIC Co., Ltd; Daiichi Sankyo; eChainaHealth, Inc.; Elevation Oncology; Gilead Sciences; GlaxoSmithKline K.K.; Guardant Health; Healios; Janssen; Leap Therapeutics; Levolution Medicines, Inc.; MSD; Moderna Therapeutics; Novartis; Oncolys BioPharma; Ono Pharmaceutical; Phanes Therapeutics; Sanofi; Scandion Oncology; Suzuhou Liangyihui Network Technology Co.; Takeda; and Zymeworks; honoraria from Astellas Pharma, AstraZeneca, Bristol-Myers Squibb, Janssen, Lilly, and Ono Pharmaceutical; and research funding from Amgen, Astellas Pharma, AstraZeneca, Chugai Pharma, Daiichi Sankyo, Eisai, Insyte Biosciences G.K., Medpace Japan K.K., MSD, Ono Pharmaceutical, PPD-SNBL, PRA Health Sciences, Syneos Health, Taiho Pharmaceutical, and Toray Industries.

Background

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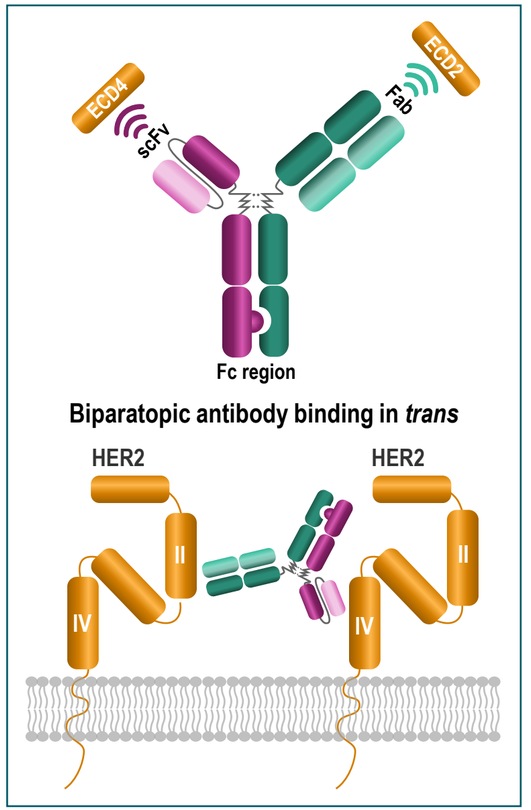
- In the primary analysis of PFS and first interim analysis of OS from the phase 3 HERIZON-GEA-01 trial, **zanidatamab + chemotherapy ± tislelizumab significantly prolonged PFS**, and **+ tislelizumab, yielded a significant OS benefit** vs trastuzumab + chemotherapy in 1L HER2-positive mGEA[1]
  - The safety profile was consistent with the known profiles of each individual treatment
- **Zanidatamab** is a **HER2-directed bispecific antibody** that binds to the **HER2 ECD 2 and 4** in a ***trans* configuration**, facilitating the formation of **distinct HER2 clusters** on the cell surface. It has several key mechanisms of action[2]
  - Increasing **HER2 internalization**
  - Reducing **phosphorylation of EGFR, HER2, and HER3** and blocking **downstream signalling**
  - Inducing immune-mediated effects (**CDC, ADCC, and ADCP**)
- **Tislelizumab** is a **high-affinity immune checkpoint inhibitor targeting PD-1** and is specifically **engineered to minimise Fcγ receptor binding on macrophages**[3,4]



Here we report results of prespecified secondary endpoints and post-hoc exploratory analyses of PROs measuring HRQoL for patients in HERIZON-GEA-01

1L, first-line; ADCC, antibody-dependent cellular cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; CDC, complement-dependent cytotoxicity; ECD, extracellular domain; EGFR, epidermal growth factor receptor; Fab, fragment antigen binding; Fc, fragment crystallizable; HER2, human epidermal growth factor receptor 2; HER3, human epidermal growth factor receptor 3; HRQoL, health-related quality of life; mGEA, advanced or metastatic gastro-oesophageal adenocarcinoma; OS, overall survival; PD-1, programmed cell death protein 1; PFS, progression-free survival; PRO, patient-reported outcome; scFv, single-chain variable fragment.

1. Shitara K, et al. *N Engl J Med.* 2026;394:2022-14. 2. Weisser NE, et al. *Nat Commun.* 2023;14(1):1394. 3. Hong Y, et al. *FEBS Open Bio.* 2021;11(3):782-92. 4. Zhang T, et al. *Cancer Immunol Immunother.* 2018;67(7):1079-90.

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HERIZON-GEA-01 Study Design

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Global phase 3 trial of zanidatamab + chemotherapy ± tislelizumab vs trastuzumab + chemotherapy in previously untreated patients with HER2+ mGEA

ClinicalTrials.gov: NCT05152147

Key Eligibility Criteria

- Age ≥18 years
- Unresectable, locally advanced, recurrent, or metastatic GEA
- HER2 IHC 3+ or IHC 2+/ISH+ per central testing
- ECOG PS 0 or 1
- No prior treatment for locally advanced or metastatic disease
- No prior HER2-targeted agents or immunotherapy in any setting

Stratification Factors

- Geographic region
- HER2 status
- ECOG PS

R 1:1:1

N = 914

Arm A: Trastuzumab + chemotherapy[a]

Arm B: Zanidatamab 1800 mg (<70 kg) or 2400 mg (≥70 kg) IV Q3W + chemotherapy[a]

Arm C: Zanidatamab 1800 mg (<70 kg) or 2400 mg (≥70 kg) IV Q3W + tislelizumab[b] + chemotherapy[a]

Computed tomography/ MRI[c] Q6W

Prophylaxis to prevent IRR and diarrhoea was mandatory in the zanidatamab-containing arms

Treatment until disease progression/death/unacceptable toxicity
Chemotherapy could be discontinued after 6 cycles

Dual Primary Endpoints

- PFS (per BICR)
- OS

Select Secondary Endpoints

- Frequency and severity of AEs
- Change from baseline in PRO parameters
  - EORTC QLQ-C30
  - EORTC QLQ-OG25
  - EQ-5D 5L (limited to pharmacoeconomic analyses)

PRO Outcomes Analysed

- **EORTC QLQ-C30** (Core cancer symptoms, functional outcomes, and global health/QoL)
- **EORTC QLQ-OG25** (Tumour-specific symptoms and nutritional outcomes)

Notable differences between arms were observed for select EORTC QLQ-C30 outcomes and are reported here

[a]Physician's choice of capecitabine plus oxaliplatin or 5-fluorouracil plus cisplatin. Chemotherapy was administered for at least 6 cycles or until disease progression, unacceptable toxicity, or another criterion for treatment discontinuation was met.
[b]Tislelizumab 200 mg was administered IV Q3W. [c]Computed tomography/MRI scans were performed every 6 weeks for the first 54 weeks, then every 9 weeks.
AE, adverse event; BICR, blinded independent central review; cORR, confirmed objective response rate; ECOG PS, Eastern Cooperative Oncology Group performance status; EORTC QLQ-OG25, European Organisation for Research and Treatment of Cancer Oesophago-Gastric Cancer questionnaire; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; EQ-5D 5L, EuroQoL 5-dimensions 5-levels questionnaire; GEA, gastro-oesophageal adenocarcinoma; HER2, human epidermal growth factor receptor 2; HRQoL, health-related QoL; IHC, immunohistochemistry; IRR, infusion-related reaction; ISH, in situ hybridisation; IV, intravenously; mGEA, advanced or metastatic GEA; MRI, magnetic resonance imaging; OS, overall survival; PFS, progression-free survival; PRO, patient-reported outcome; Q3W, every 3 weeks; Q6W, every 6 weeks; QoL, quality of life; R, randomisation.

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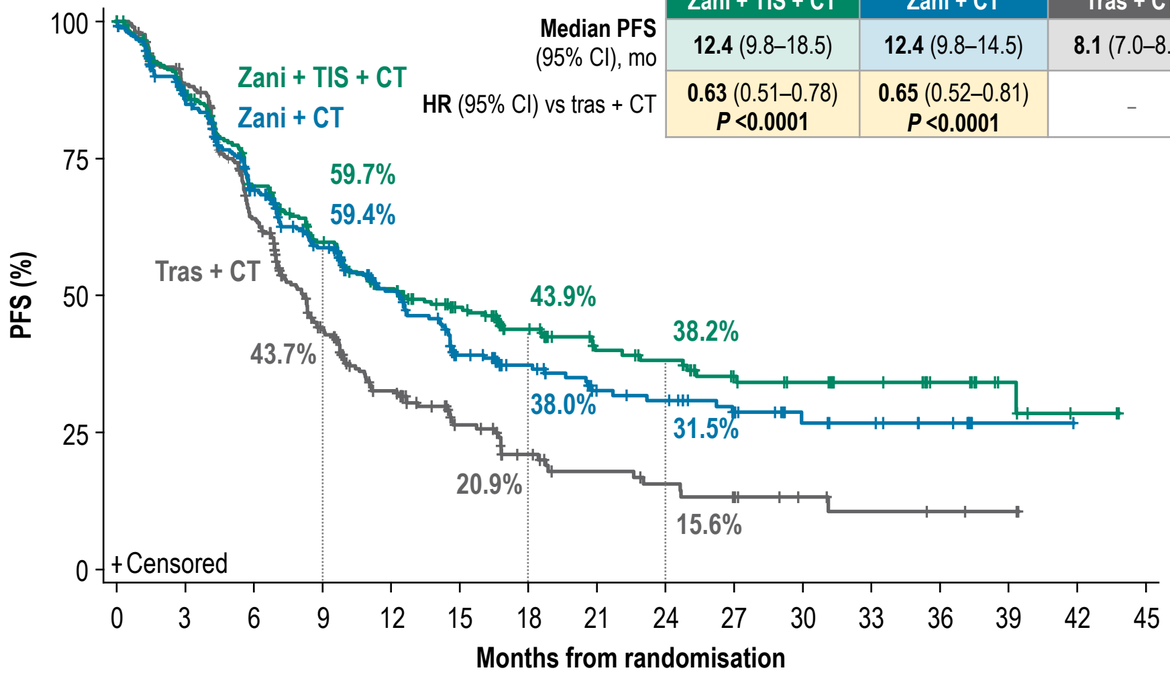
Primary Endpoints: PFS per BICR and OS

Significant and clinically meaningful improvement for PFS occurred in both zanidatamab-containing arms and for OS in the zanidatamab + tislelizumab + chemotherapy arm vs trastuzumab + chemotherapy[1,2]

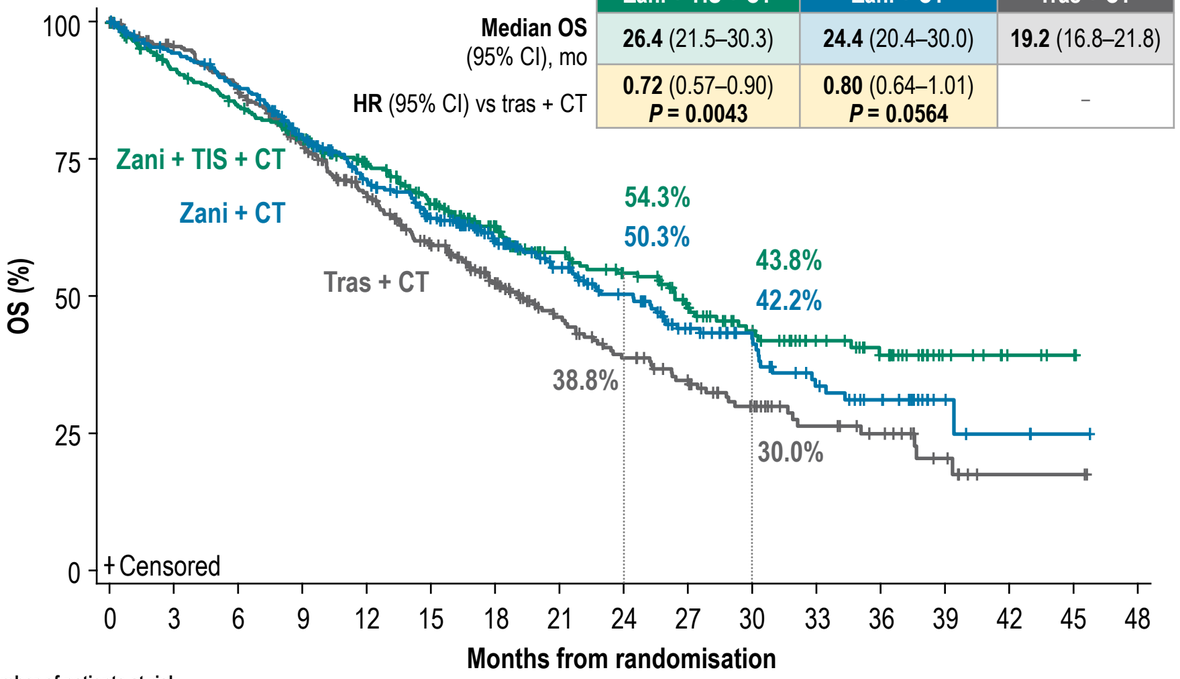
	Zani + TIS + CT	Zani + CT	Tras + CT
Median PFS (95% CI), mo	**12.4** (9.8–18.5)	**12.4** (9.8–14.5)	**8.1** (7.0–8.9)
HR (95% CI) vs tras + CT	**0.63** (0.51–0.78) ***P*** **<0.0001**	**0.65** (0.52–0.81) ***P*** **<0.0001**	–



Number of patients at risk

Zani + TIS + CT	302	240	183	147	113	90	65	46	42	30	27	20	13	6	2	0
Zani + CT	304	231	175	137	105	70	53	37	34	26	14	12	8	1	0	
Tras + CT	308	247	168	97	63	37	23	16	13	10	6	4	3	2	0	

	Zani + TIS + CT	Zani + CT	Tras + CT
Median OS (95% CI), mo	**26.4** (21.5–30.3)	**24.4** (20.4–30.0)	**19.2** (16.8–21.8)
HR (95% CI) vs tras + CT	**0.72** (0.57–0.90) ***P*** **= 0.0043**	**0.80** (0.64–1.01) ***P*** **= 0.0564**	–



Number of patients at risk

Zani + TIS + CT	302	267	246	222	190	157	125	96	82	64	49	36	27	10	4	2	0
Zani + CT	304	277	257	222	187	156	121	98	78	56	41	28	21	6	3	1	0
Tras + CT	308	284	261	219	178	140	106	77	61	50	33	22	17	8	2	2	0

Data cutoff: October 1, 2025.

BICR, blinded independent central review; CT, chemotherapy; OS, overall survival; PFS, progression-free survival; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

1. Elimova E, et al. *J Clin Oncol.* 2026;44:LBA285. 2. Shitara K, et al. *N Engl J Med.* 2026;394:2022-14.

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Common TRAEs (≥20% of Patients in Any Arm)

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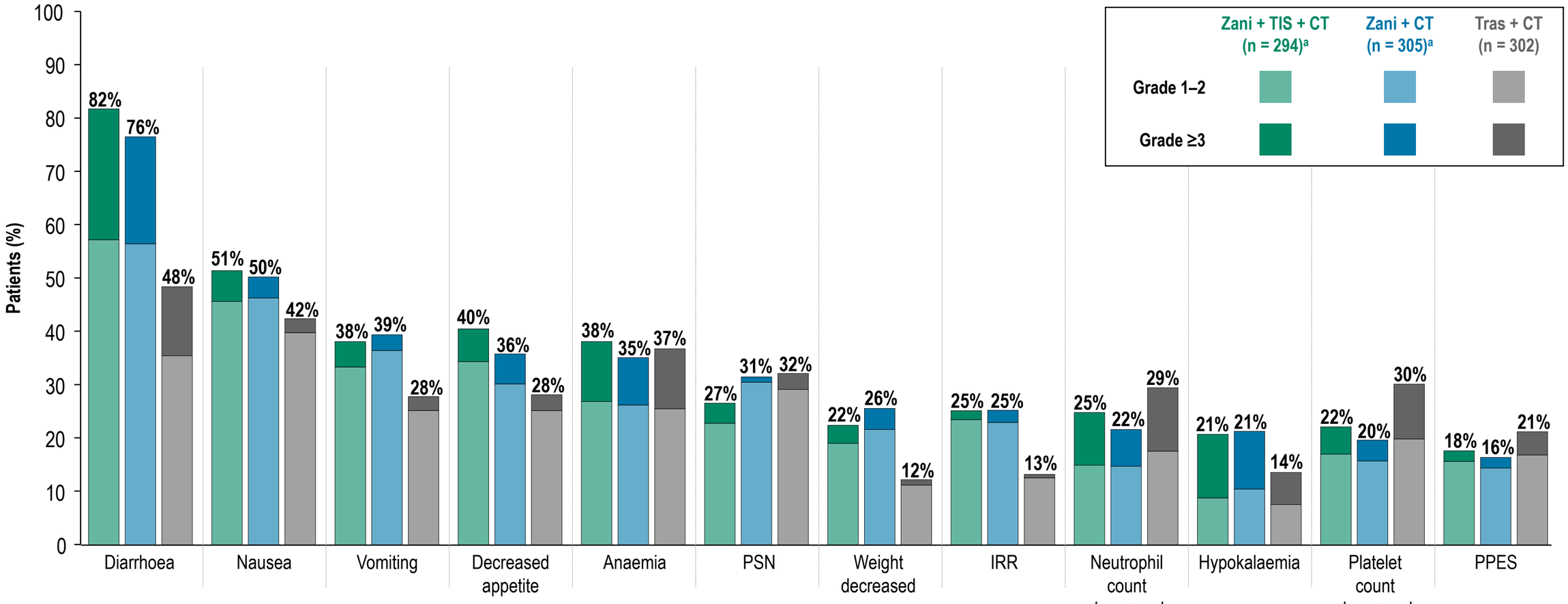
Diarrhoea was the most common TRAE in all treatment arms[1,2]



Data cutoff: October 1, 2025.

[a]Five patients who were assigned to the zanidatamab-tislelizumab-chemotherapy arm did not receive tislelizumab. Data from these patients are summarised in the zanidatamab-chemotherapy arm.

CT, chemotherapy; IRR, infusion-related reaction; PPES, palmar-plantar erythrodysesthesia syndrome; PSN, peripheral sensory neuropathy; TIS, tislelizumab; TRAE, treatment-related adverse event; tras, trastuzumab; zani, zanidatamab.

1. Elimova E, et al. *J Clin Oncol.* 2026;44:LBA285. 2. Shitara K, et al. *N Engl J Med.* 2026;394:2022-14.

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EORTC QLQ-C30 Completion Rates

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Completion rates for EORTC QLQ-C30 during the on-treatment period remained high throughout the study

Completion rate[a], % (n/N)	Zanidatamab + tislelizumab + CT	Zanidatamab + CT	Trastuzumab + CT
Start-of-treatment visit	96.7 (292/302)	97.4 (296/304)	95.8 (295/308)
While on treatment, min–max[b]	97.0–100.0	97.0–100.0	98.3–100.0
End-of-treatment visit[c]	60.7 (128/211)	65.4 (151/231)	70.2 (186/265)

- All PRO assessments were administered once every cycle for the first 12 cycles, then every other cycle thereafter

Data cutoff: October 1, 2025.
[a]Completion is defined as completing ≥1 scale within the questionnaire based on the EORTC scoring derivation. [b]On-treatment range is from C2D1 to C24D1. [c]Completion rate at the end-of-treatment visit is defined as the percentage of patients who completed a PRO assessment at the end-of-treatment visit out of the patients who discontinued study treatment.
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; PRO, patient-reported outcome.

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EORTC QLQ-C30 Global Health Status/Quality of Life

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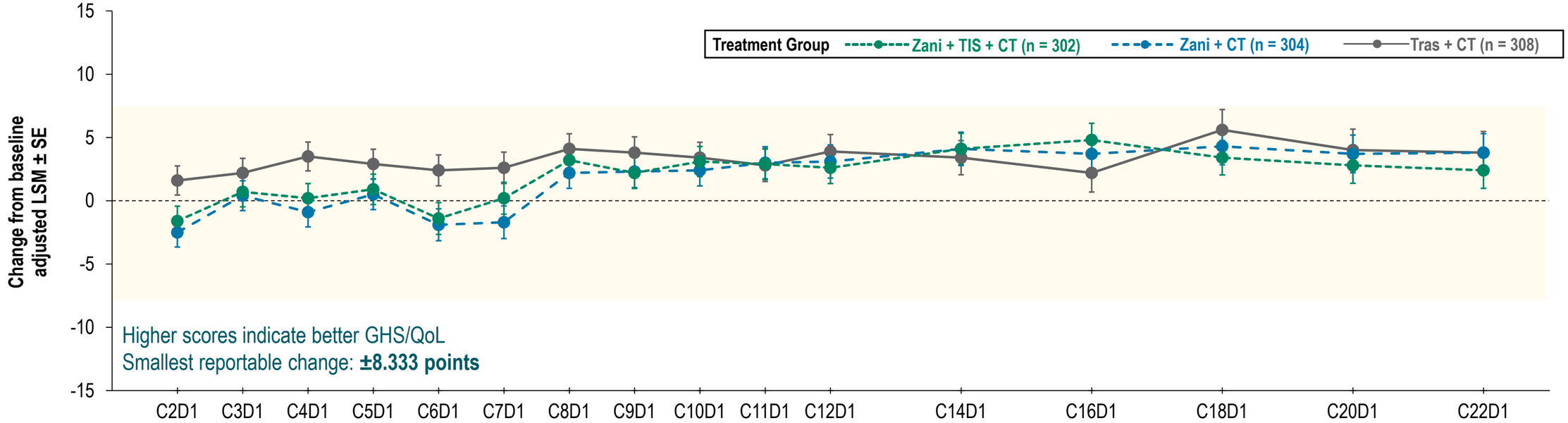
There were no substantive changes in GHS/QoL from baseline across treatment arms over time



Number of patients:	C2D1	C3D1	C4D1	C5D1	C6D1	C7D1	C8D1	C9D1	C10D1	C11D1	C12D1	C14D1	C16D1	C18D1	C20D1	C22D1
Zani + TIS + CT	266	247	239	223	213	205	196	183	176	163	160	140	130	113	96	86
Zani + CT	269	243	234	225	217	189	178	170	162	145	134	113	106	94	87	75
Tras + CT	276	259	250	239	230	207	187	166	152	133	118	98	78	67	61	52

- Baseline mean scores were balanced across arms: 63.6 (tras + CT), 65.2 (zani + CT), and 65.1 (zani + TIS + CT)
- Changes in the treatment arms were not substantive as they were less than the smallest reportable change of ±8.333 points
- After C8D1, among patients that remained on treatment, mean LSM were slightly above baseline for the remaining treatment duration

Data cutoff: October 1, 2025.
Shaded area represents smallest reportable change of ±8.333 points. Patients could discontinue CT at the discretion of the treating physician (after completion of cycle 6).
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; GHS/QoL, global health status/quality of life; LSM, least-squares mean; PF, physical functioning; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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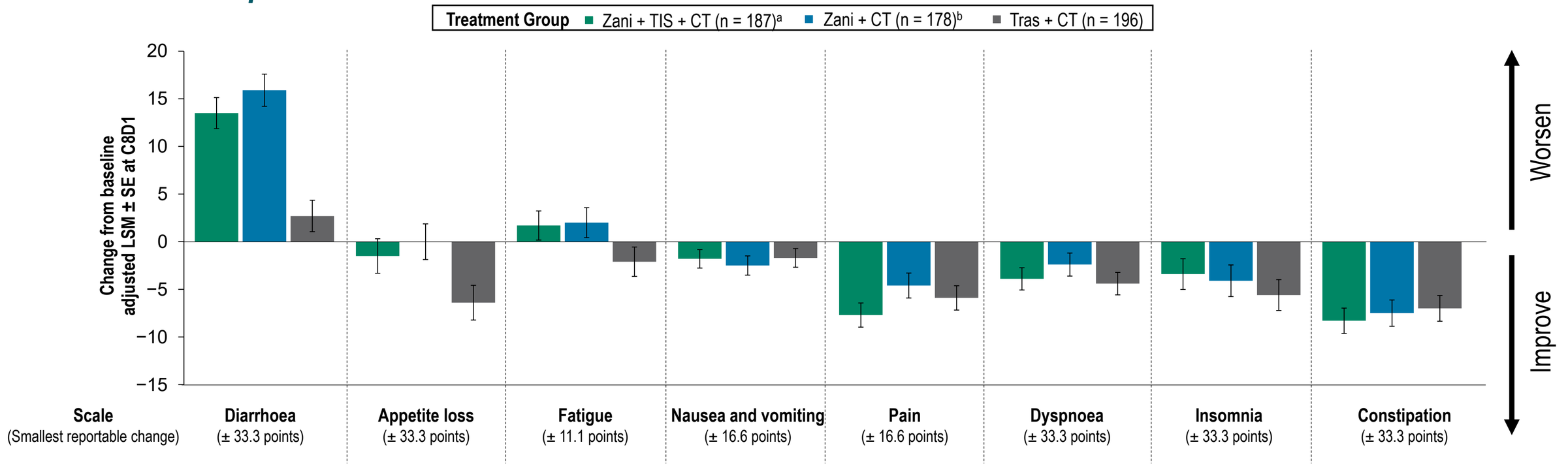
EORTC QLQ-C30 Symptom Scales at C8D1

Across symptom scales at C8D1, few notable differences in change from baseline were observed between the control arm and experimental arms



- At C8D1, change from baseline in diarrhoea scores showed the greatest decline of all symptoms and the greatest difference between zani-containing arms and the control arm
- Symptom scales per EORTC QLQ-OG25 were similar across arms throughout the study (data not shown)

Data cutoff: October 1, 2025. Patients could discontinue CT at the discretion of the treating physician (after completion of cycle 6).
[a]For diarrhoea, n = 179. [b]For appetite loss, n = 195.
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; EORTC QLQ-OG25, European Organisation for Research and Treatment of Cancer Oesophago-Gastric Cancer questionnaire; LSM, least-squares mean; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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EORTC QLQ-C30 Symptom: Diarrhoea

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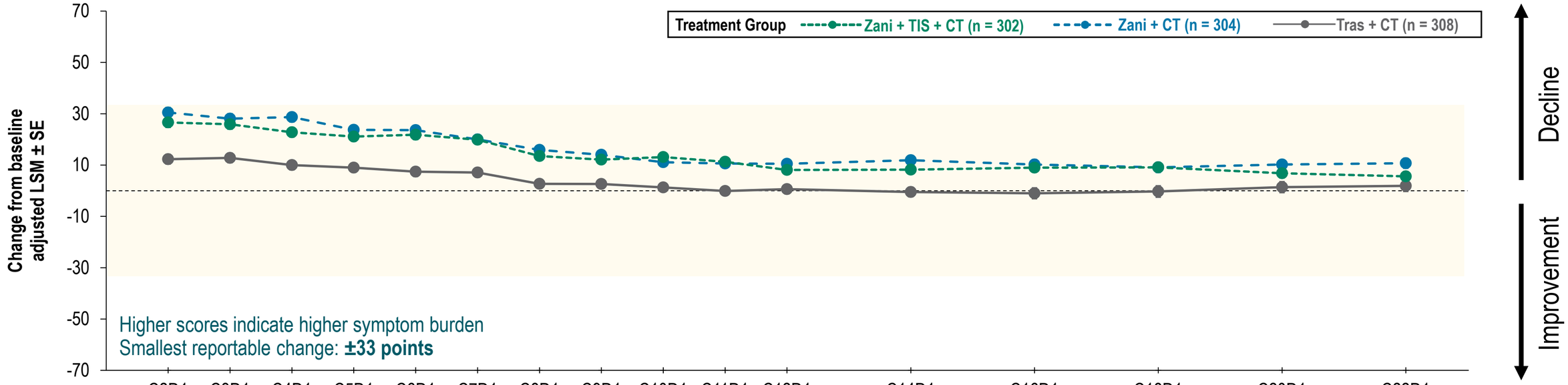
Patient-reported diarrhoea was consistent with the safety profile; the severity of diarrhoea improved across all arms at C8D1 and remained stable through subsequent time points



Number of patients:	C2D1	C3D1	C4D1	C5D1	C6D1	C7D1	C8D1	C9D1	C10D1	C11D1	C12D1	C14D1	C16D1	C18D1	C20D1	C22D1
Zani + TIS + CT	266	247	239	223	213	205	196	183	175	163	160	140	130	113	96	86
Zani + CT	270	244	235	226	218	190	179	171	162	146	135	114	107	95	87	75
Tras + CT	276	259	250	239	230	207	187	166	152	133	117	98	78	67	61	52

- Baseline diarrhoea scores were low across all arms; patients in all 3 treatment arms reported an increase in the severity of diarrhoea following the initiation of study treatment, but to a greater degree in the zani + TIS + CT and zani + CT arms than in the control arm, however, this improved after C8D1

Data cutoff: October 1, 2025.
Shaded area represents smallest reportable change of ±33 points. Patients could discontinue CT at the discretion of the treating physician (after completion of cycle 6).
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; LSM, least-squares mean; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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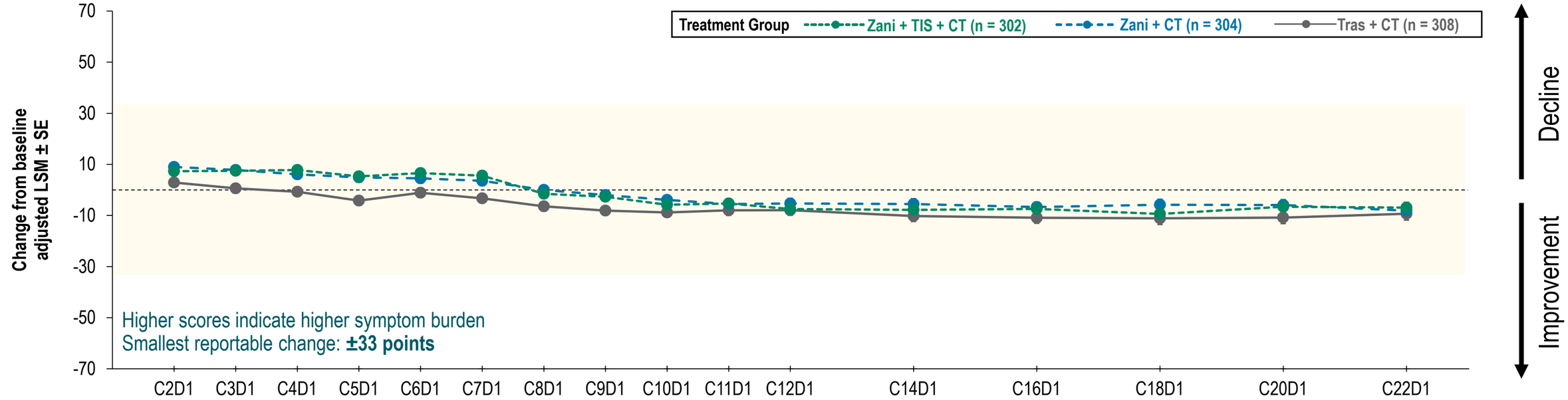
EORTC QLQ-C30 Symptom: Appetite Loss

Patients in all 3 treatment arms reported an improvement at C8D1, which remained stable throughout the remaining treatment duration



Number of patients:	C2D1	C3D1	C4D1	C5D1	C6D1	C7D1	C8D1	C9D1	C10D1	C11D1	C12D1	C14D1	C16D1	C18D1	C20D1	C22D1
Zani + TIS + CT	267	247	238	224	212	204	195	183	174	162	160	140	129	113	96	86
Zani + CT	267	241	232	224	216	186	178	168	161	143	133	114	106	96	87	74
Tras + CT	276	258	250	238	229	207	187	165	152	133	118	97	78	67	61	52

- Across treatment arms, patient-reported appetite loss scores were low at baseline, improved at C8D1, and were comparable at subsequent time points

Data cutoff: October 1, 2025.
Shaded area represents smallest reportable change of ±33 points. Patients could discontinue CT at the discretion of the treating physician (after completion of cycle 6).
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; LSM, least-squares mean; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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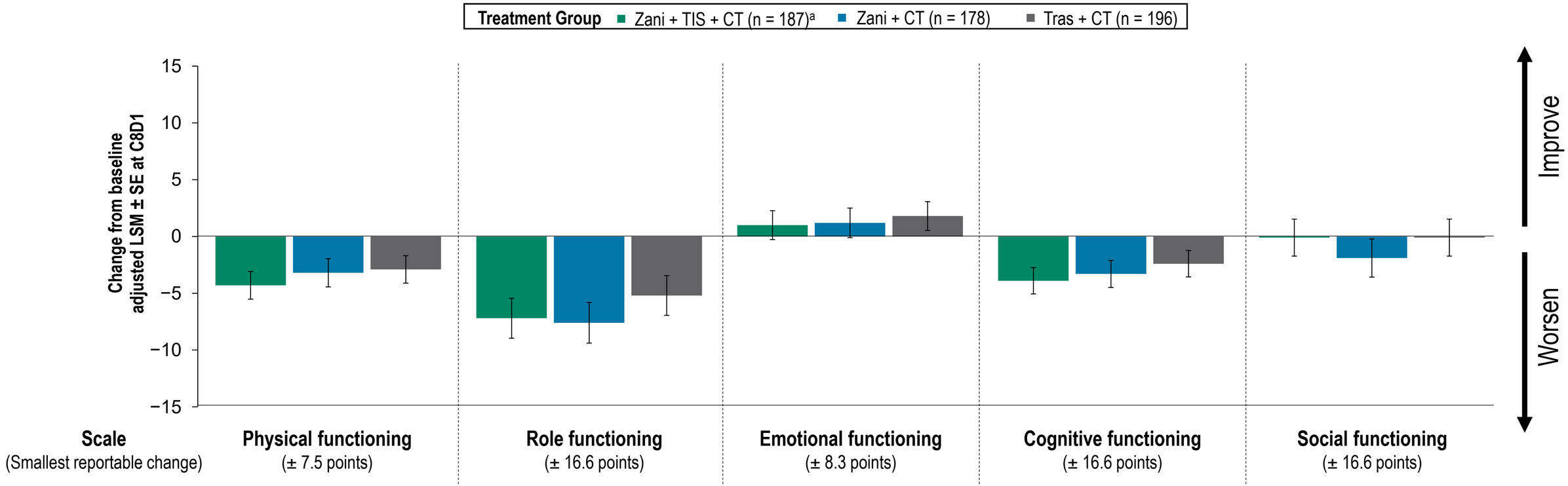
EORTC QLQ-C30 Functional Scales at C8D1

Across functional scales at C8D1, changes from baseline were generally similar across groups, indicating minimal impact on patient functioning



Data cutoff: October 1, 2025. Patients could discontinue CT at the discretion of the treating physician (after completion of cycle 6).

[a]For physical functioning.

C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; GHS, global health status; LSM, least-squares mean; QoL, quality of life; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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EORTC QLQ-C30 Physical Functioning

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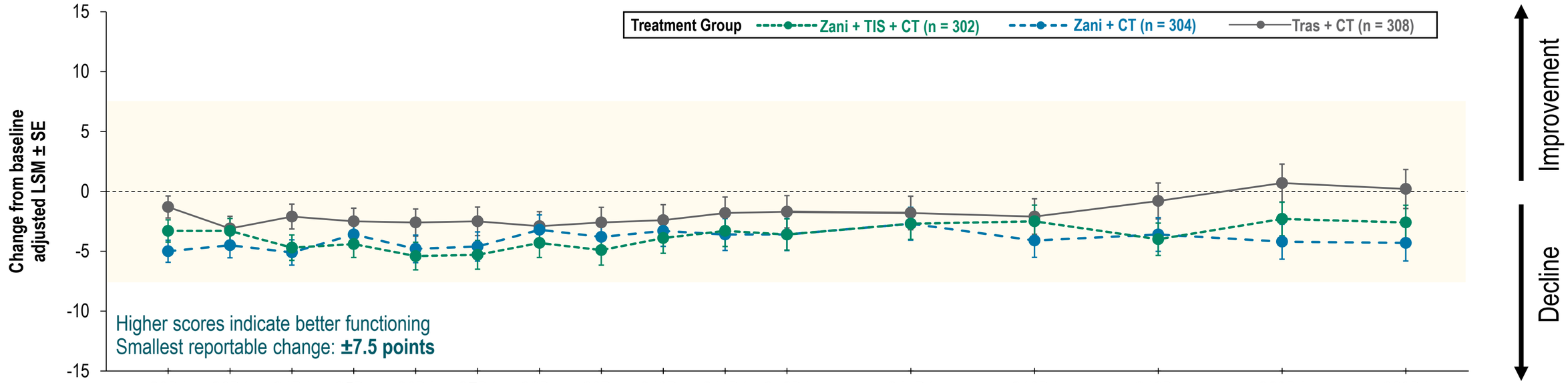
Physical functioning scores declined slightly after treatment initiation, but improved over time



Number of patients:	C2D1	C3D1	C4D1	C5D1	C6D1	C7D1	C8D1	C9D1	C10D1	C11D1	C12D1	C14D1	C16D1	C18D1	C20D1	C22D1
Zani + TIS + CT	268	247	236	224	212	205	196	183	174	162	159	140	130	113	96	86
Zani + CT	270	243	235	226	218	188	179	170	163	144	134	114	106	96	87	74
Tras + CT	276	258	250	239	229	207	187	165	152	133	118	97	76	67	61	52

- Mean physical function scores at baseline were similar across treatment arms
- Differences in adjusted mean scores between the treatment arms were not substantive, as they were less than the smallest change of ±7.5 points

Data cutoff: October 1, 2025.
Shaded area represents smallest reportable change of ±7.5 points. Patients could discontinue CT at the discretion of the treating physician (after completion of cycle 6).
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; LSM, least-squares mean; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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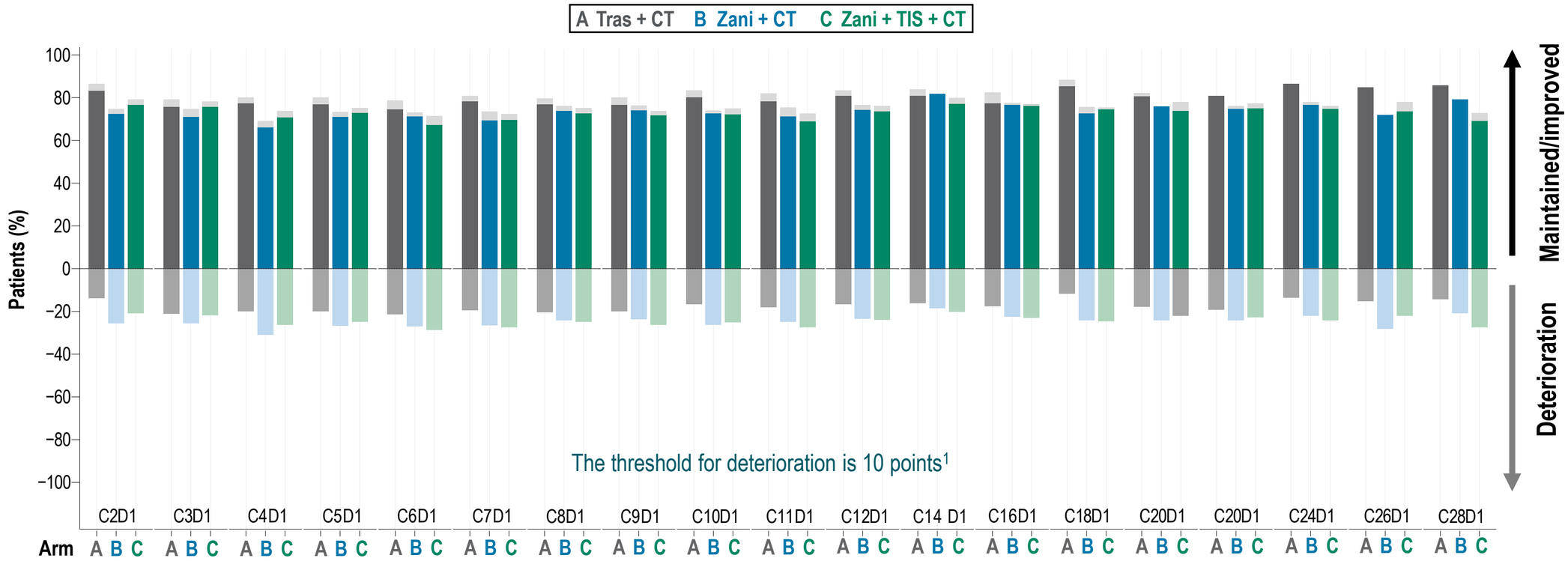
EORTC QLQ-C30 Maintenance of Physical Function

In a post hoc analysis, most patients across all arms maintained their physical function relative to baseline



- During CT treatment (between C2D1 and C8D1) the percentage of patients that maintained or improved physical function relative to baseline was high in all 3 treatment arms (range: zani + TIS + CT, 67.4%–76.7%; zani + CT, 66.1%–73.8%; tras + CT, 74.5%–83.2%)

Data cutoff: October 1, 2025. Patients could discontinue CT at the discretion of the treating physician (after completion of cycle 6).
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.
1. Osoba D, et al. *J Clin Oncol*. 1998;16:139-44.

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Discussion

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- In HERIZON-GEA-01, clinically meaningful and statistically significant improvements were observed for PFS in both zanidatamab-containing arms and for OS in the zanidatamab + tislelizumab + chemotherapy arm vs trastuzumab + chemotherapy
- Zanidatamab-containing regimens improved survival outcomes relative to trastuzumab + chemotherapy with minimal detriment to HRQoL
- Overall, there were no substantive changes in GHS/QoL, functional outcomes, or symptom scores in any of the treatment arms
  - Patient-reported diarrhoea was consistent with the known safety profiles of the agents administered

A copy of these slides be accessed via the QR code above

These data support the use of zanidatamab + chemotherapy with and without tislelizumab as a new standard of care in the 1L treatment of patients with HER2-positive mGEA

1L, first-line; GHS, global health status; HER2, human epidermal growth factor receptor 2; HRQoL, health-related QoL; mGEA, advanced or metastatic gastro-oesophageal adenocarcinoma; OS, overall survival; PFS, progression-free survival; QoL, quality of life.

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Lay Summary

Why did we perform this research?

- Current treatments for people with locally advanced or metastatic gastroesophageal adenocarcinoma (or mGEA) only provide modest benefit
- Some of these tumours have too much of a protein called human epidermal growth factor receptor 2 (or HER2) on the cell surface (also known as HER2-positive)
- In the HERIZON-GEA-01 study, people who received zanidatamab plus chemotherapy with and without tislelizumab survived longer without their cancer getting worse than people treated with trastuzumab plus chemotherapy
  - There were no new concerning side effects with either zanidatamab or tislelizumab
- It is important to learn the quality of life reported by patients taking certain medicines to understand the overall risks vs benefits of that medication

How did we perform this research?

- The HERIZON-GEA-01 study looked at whether a medicine called zanidatamab, which targets HER2, could help people with previously untreated HER2-positive mGEA
- People in this study could receive one of three possible treatments:
  1) Zanidatamab combined with a medicine called tislelizumab, which targets a protein called PD-1, plus standard chemotherapy
  2) Zanidatamab plus standard chemotherapy
  3) Trastuzumab, which is the current standard medicine for targeting HER2 in mGEA, plus standard chemotherapy
- Patients filled out questionnaires throughout treatment to indicate their level of wellbeing for various symptoms and types of functioning (physical, emotional, social, etc.)

What were the results of this research?

- People who received zanidatamab plus chemotherapy with and without tislelizumab did not experience any concerning impacts to their quality of life during treatment
  - Patients reported slightly worsened physical functioning, health-related quality of life, and symptoms of diarrhoea and appetite loss at the beginning of the trial
  - Diarrhoea and appetite loss are known side effects of zanidatamab and tislelizumab with chemotherapy
  - These symptoms, along with physical functioning and quality of life, improved over the course of the trial, specifically from the time that patients could discontinue chemotherapy

HER2, human epidermal growth factor receptor 2; mGEA, advanced or metastatic gastroesophageal adenocarcinoma; PD-1, programmed cell death protein 1.

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