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; eChinaHealth, Inc.; Elevation Oncology; Gilead Sciences; GlaxoSmithKline K.K.; Guardant Health; Healios; Janssen; Leap Therapeutics; Merck Sharp & Dohme; Moderna Therapeutics; Novartis; Oncolys BioPharma; Ono Pharmaceutical; Phanes Therapeutics; Revolution Medicines, Inc.; 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, Medpace Japan K.K., Merck Sharp & Dohme, Ono Pharmaceutical, PPD-SNBL, PRA Health Sciences, Syneos Health, Taiho Pharmaceutical, and Toray Industries.*

Background

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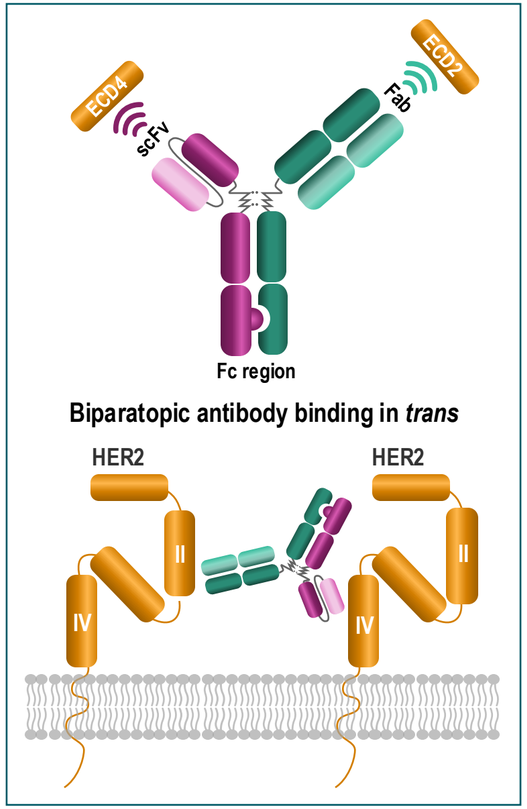
- *In the primary analysis of PFS and the first interim analysis of OS from the phase 3 HERIZON-GEA-01 trial,* **zanidatamab + chemotherapy ± tislelizumab significantly prolonged PFS**, *and* **+ tislelizumab yielded a significant OS benefit** *vs trastuzumab + chemotherapy in 1L HER2-positive mGEA*[1]
  - *The safety profile was consistent with the known profiles of each individual treatment*
- **Zanidatamab** *is a* **HER2-directed bispecific antibody** *that binds to* **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 internalisation**
  - *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 crystallisable; 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 status/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

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

[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; ECOG PS, Eastern Cooperative Oncology Group performance status; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; EORTC QLQ-OG25, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Oesophago-Gastric Cancer Module (25 Items); EQ-5D 5L, EuroQoL 5-Dimensions 5-Levels questionnaire; GEA, gastro-oesophageal adenocarcinoma; HER2, human epidermal growth factor receptor 2; 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

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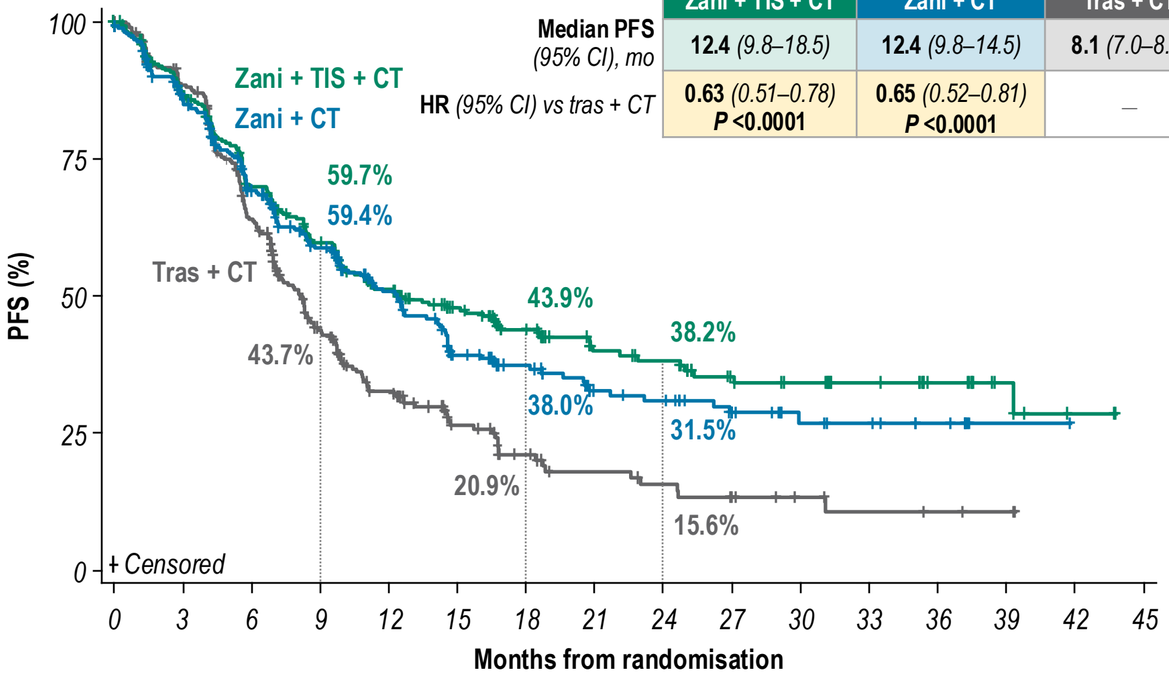
Significant and clinically meaningful improvement for PFS occurred in both zanidatamab-containing arms and for OS in the zanidatamab + tislelizumab + chemotherapy arm vs trastuzumab + chemotherapy[1,2]

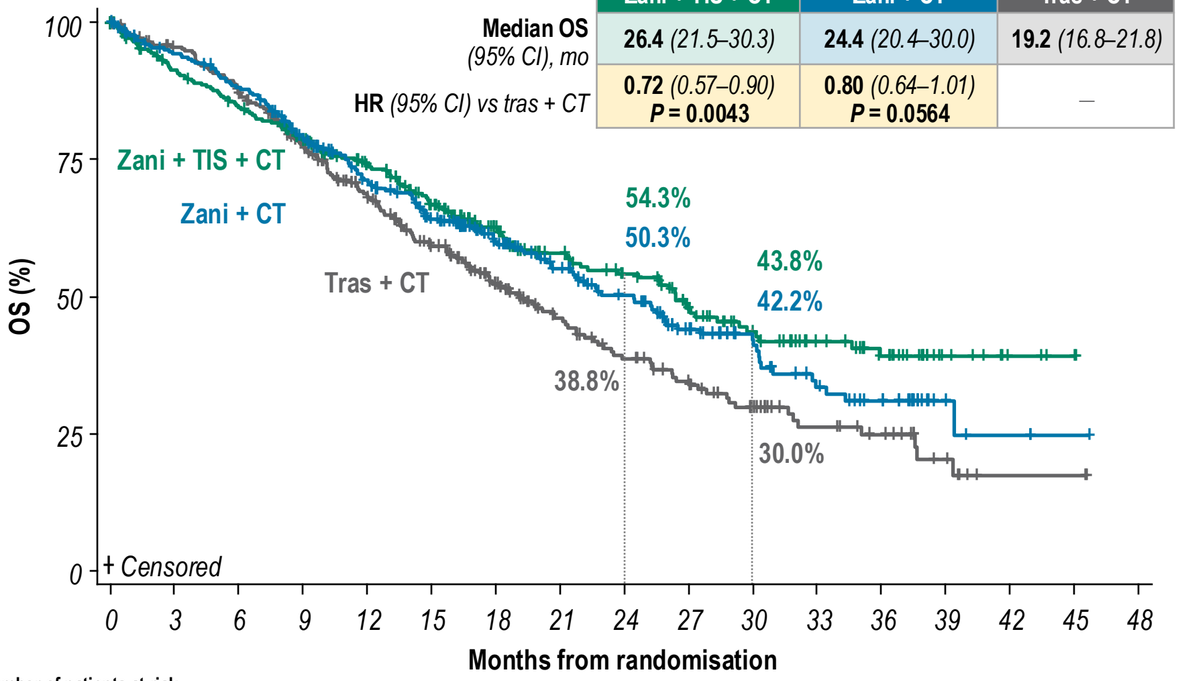
	Zani + TIS + CT	Zani + CT	Tras + CT
Median PFS *(95% CI), mo*	**12.4** *(9.8–18.5)*	**12.4** *(9.8–14.5)*	**8.1** *(7.0–8.9)*
HR *(95% CI) vs tras + CT*	**0.63** *(0.51–0.78)* ***P*** **<0.0001**	**0.65** *(0.52–0.81)* ***P*** **<0.0001**	—



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; HR, hazard ratio; 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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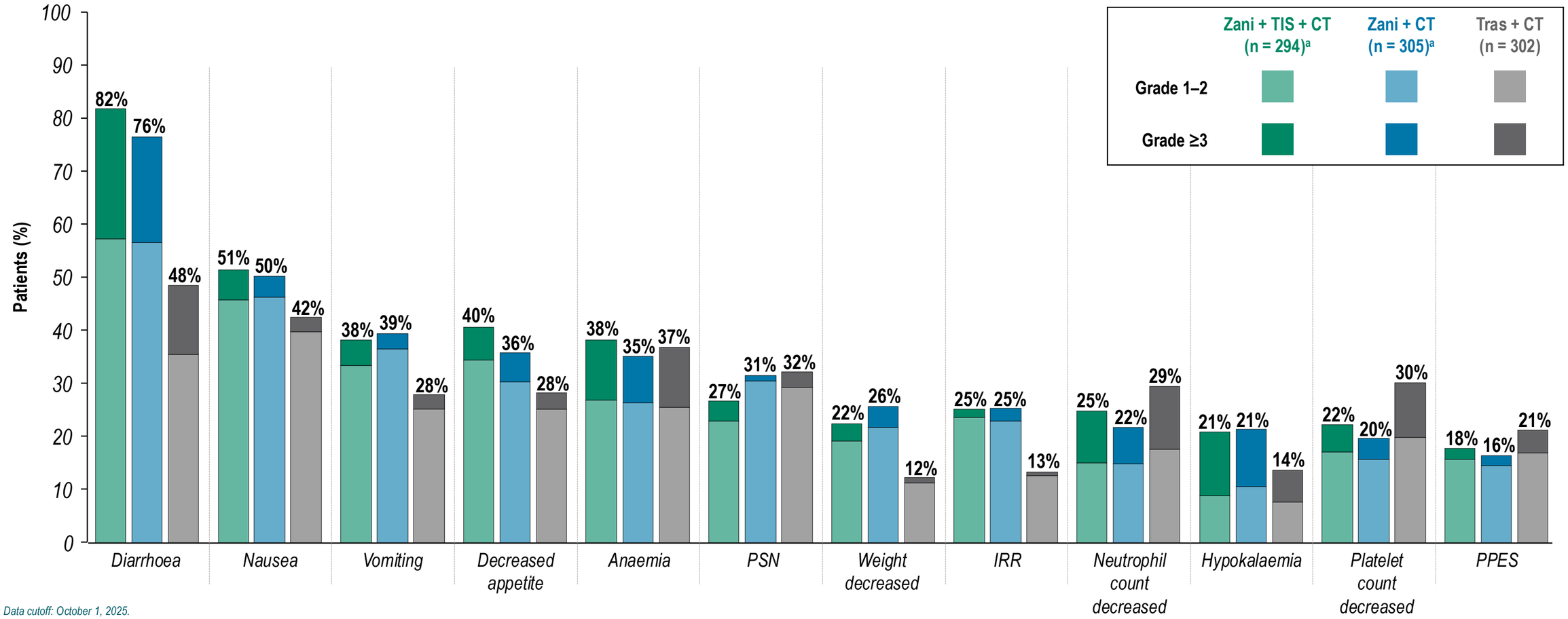
Common TRAEs (≥20% of Patients in Any Arm)

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)

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–Core 30; max, maximum; min, minimum; PRO, patient-reported outcome.

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EORTC QLQ-C30 Global Health Status/Quality of Life

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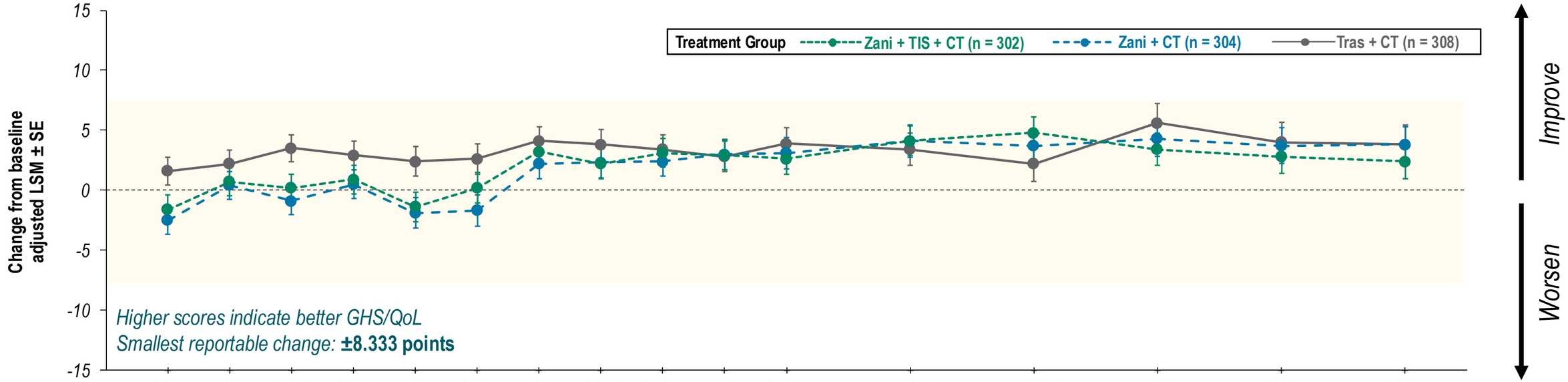
There were no substantive changes in GHS/QoL from baseline across treatment arms over time



Number of patients[a]	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 who 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 C6).
[a]Reflects the number of patients included in the analysis at each time point.
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; GHS/QoL, global health status/quality of life; LSM, least-squares mean; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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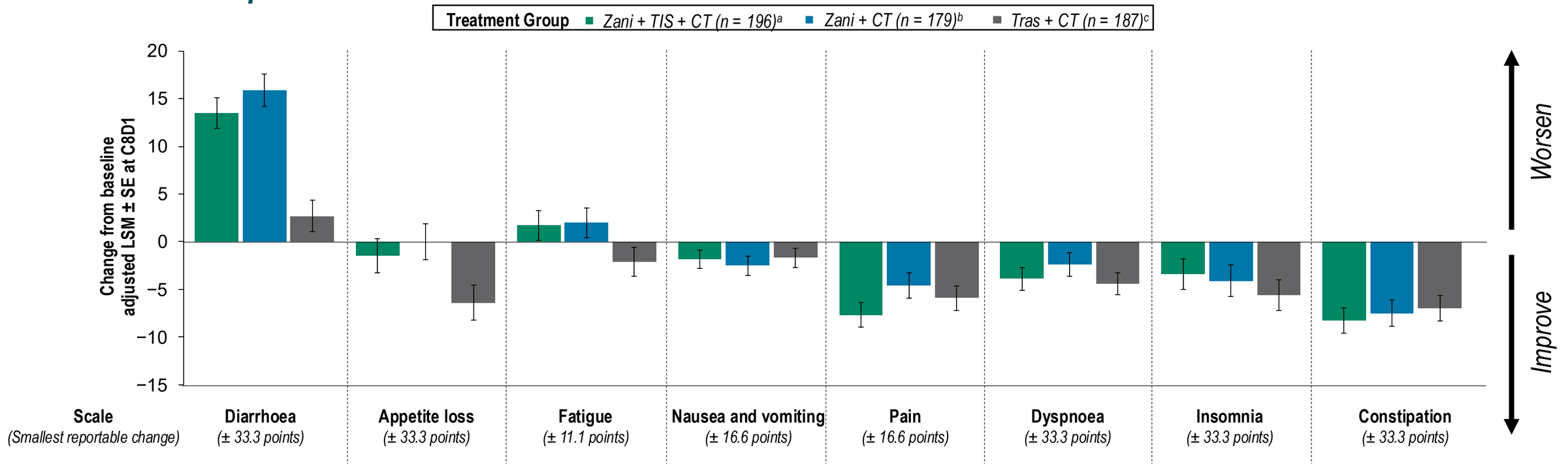
EORTC QLQ-C30 Symptom Scales at C8D1

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; across all treatment arms, patients reported improvement in nausea and vomiting, pain, dyspnoea, insomnia, and constipation*
- *Disease-specific symptoms 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 appetite loss, n = 195; for pain, n = 197. [b]For appetite loss and insomnia, n = 178. [c]For insomnia, n = 186.
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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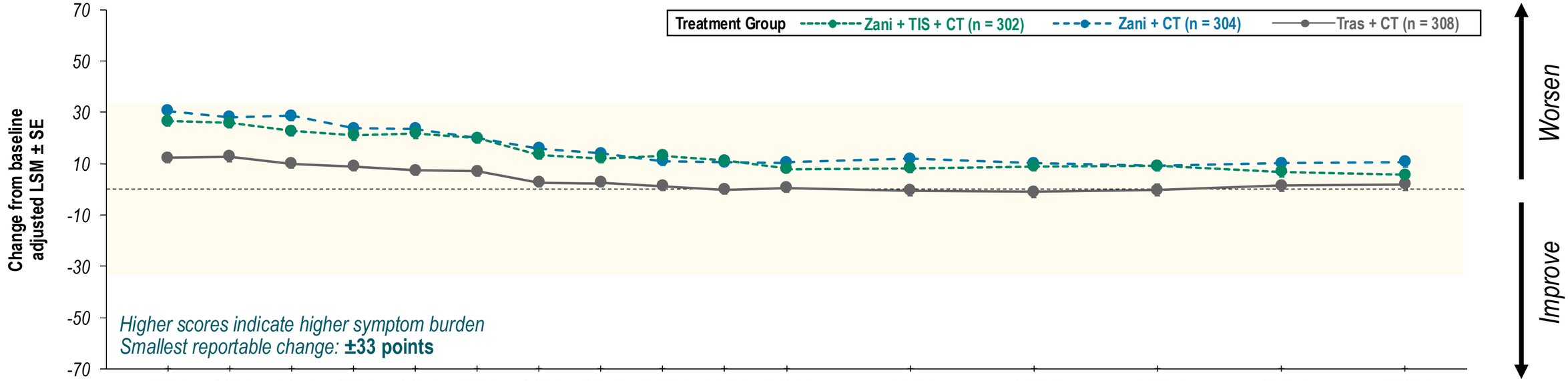
Patient-reported diarrhoea was consistent with the safety profile; the severity of diarrhoea improved across all arms at C8D1 and remained stable through subsequent time points



Number of patients[a]															
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 C6).
[a]Reflects the number of patients included in the analysis at each time point.
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; LSM, least-squares mean; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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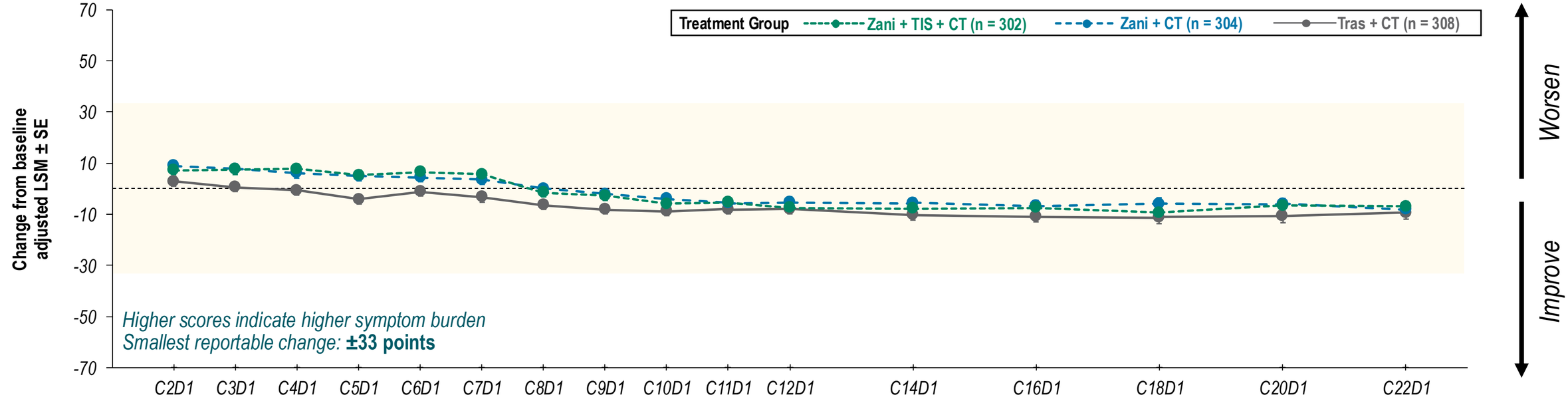
EORTC QLQ-C30 Symptom: Appetite Loss

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



Number of patients[a]															
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 C6).
[a]Reflects the number of patients included in the analysis at each time point.
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; LSM, least-squares mean; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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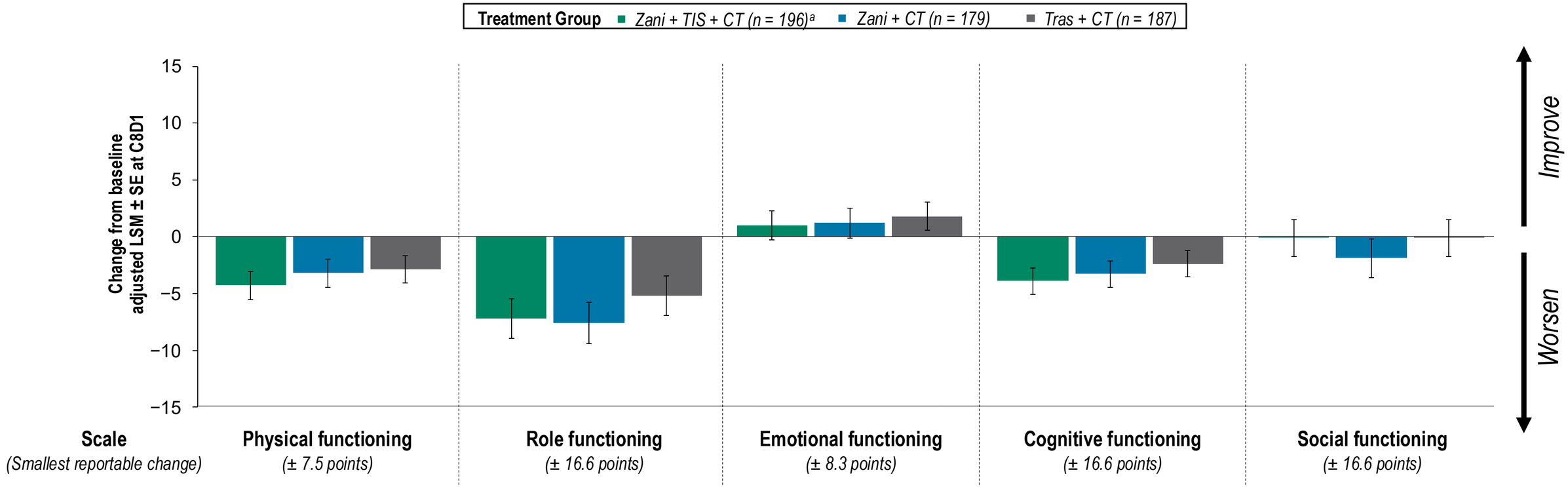
EORTC QLQ-C30 Functional Scales at C8D1

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 C6).
[a]For role functioning, n = 197.
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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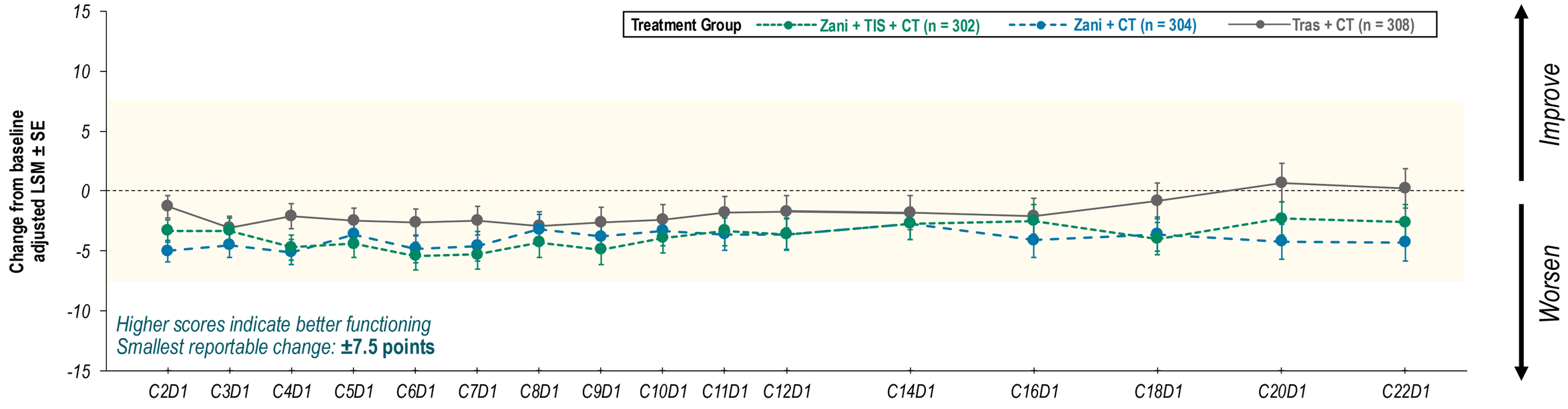
EORTC QLQ-C30 Physical Functioning

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



Number of patients[a]	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 C6).
[a]Reflects the number of patients included in the analysis at each time point.
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; LSM, least-squares mean; SE, standard error; TIS, tislelizumab; tras, trastuzumab; zani, zanidatamab.

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EORTC QLQ-C30 Maintenance of Physical Function

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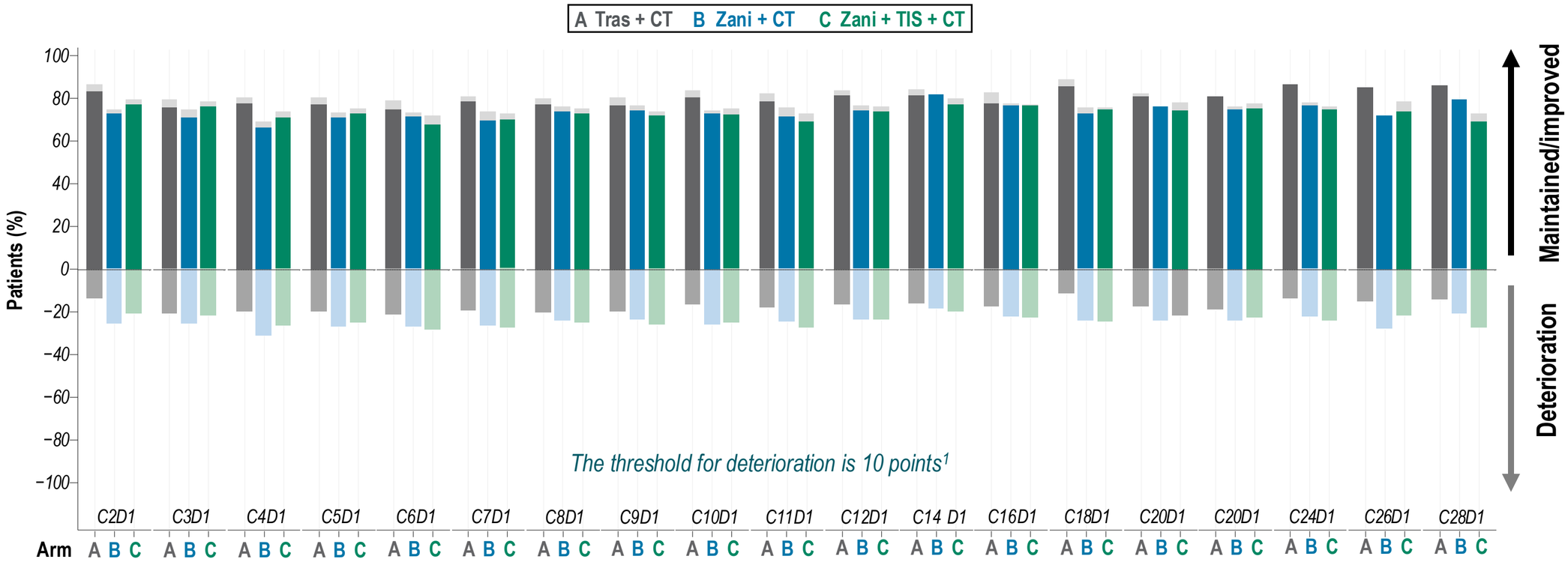
In a post hoc analysis, most patients across all arms maintained their physical function relative to baseline



- *Between C2D1 and C8D1, the percentage of patients that maintained or had 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 C6).
C, cycle; CT, chemotherapy; D, day; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; 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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Acknowledgements

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Lay Summary

Why did we perform this research?

- *Current treatments for people with locally advanced or metastatic gastro-oesophageal 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 compared with people treated with trastuzumab plus chemotherapy*
  - *There were no new concerning side effects with either zanidatamab or tislelizumab*
- *It is important to measure 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 well-being 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 on 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 gastro-oesophageal adenocarcinoma; PD-1, programmed cell death protein 1.

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