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First-line trastuzumab deruxtecan (T-DXd)–based regimens in advanced HER2-expressing gastric cancer, gastroesophageal junction adenocarcinoma, or esophageal adenocarcinoma: Safety results from DESTINY-Gastric03 Part 2 Arms D and F, and Part 4

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Objective

- To investigate the safety of 1L T-DXd in combination with an ICI (pembrolizumab or rilvegostomig) and a fluoropyrimidine in patients with HER2-expressing GC, GEJA, or EA treated as part of the Phase Ib/II DESTINY-Gastric03 trial

Conclusions

- Rates of Grade ≥3 all-cause and treatment-related AEs were numerically lower among patients receiving T-DXd 5.4 mg/kg in combination with an ICI and a lower-dose fluoropyrimidine than in those treated with a regimen containing T-DXd 6.4 mg/kg and a higher-dose fluoropyrimidine
- The safety profiles of all three regimens were generally consistent with those of each component agent,[1–5] with no new safety signals identified
- These results support the continued investigation of T-DXd 5.4 mg/kg in combination with pembrolizumab or rilvegostomig as 1L treatment in patients with advanced HER2-expressing GC, GEJA, or EA

Plain language summary

Why did we perform this research?

- Human epidermal growth factor receptor 2 (HER2) is a protein found at higher-than-normal levels in some cancers of the digestive system, including gastric cancer (GC), gastroesophageal junction adenocarcinoma (GEJA), and esophageal adenocarcinoma (EA).[1–3] Most cancers with increased levels of HER2 are referred to as either HER2-positive or HER2-low, depending on how much HER2 is present
- Trastuzumab deruxtecan (T-DXd) is an antibody-drug conjugate that is made up of a chemotherapy drug and a linker (together called deruxtecan) joined to an antibody (trastuzumab). T-DXd binds to HER2 on tumor cells and kills them.[4,5] T-DXd is approved for patients with HER2-positive GC or GEJA that has spread from its original site (advanced cancer) and who have previously received trastuzumab[6,7]
- We performed this research to find out more about the side effects of T-DXd given with chemotherapy and a type of drug called an immune checkpoint inhibitor (ICI) in people with advanced HER2-positive or HER2-low GC, GEJA, or EA who have not received any prior treatment

How did we perform this research?

- We used results from three groups of people who were treated in a clinical trial called DESTINY-Gastric03:
  1) Part 2 Arm D: People treated with T-DXd 6.4 mg/kg, pembrolizumab, and higher-dose chemotherapy
  2) Part 2 Arm F: People treated with T-DXd 5.4 mg/kg, pembrolizumab, and lower-dose chemotherapy
  3) Part 4: People treated with T-DXd 5.4 mg/kg, a different ICI called rilvegostomig, and lower-dose chemotherapy

What were the findings of this research?

- The results of this research show that side effects were generally less severe in people treated with lower doses of T-DXd and chemotherapy, given with either pembrolizumab or rilvegostomig, than in those treated with higher doses of T-DXd and chemotherapy, given with pembrolizumab
  - When they occurred, side effects could be managed by delaying treatment or reducing the dose of T-DXd and/or chemotherapy
- Side effects from treatment commonly affected the digestive system (for example, nausea and diarrhea) or the blood (for example, low levels of red blood cells)

What are the implications of this research?

- These results support further research into the use of T-DXd with ICIs and chemotherapy as a treatment for people with advanced HER2-positive or HER2-low GC, GEJA, or EA who have not received any previous treatment

Where can I access more information?

- To learn more about the DESTINY-Gastric03 trial, please visit https://clinicaltrials.gov/study/NCT04379596

1. Gravalos C, Jimeno A. *Ann Oncol.* 2008;19:1523–1529. 2. Plum PS, et al. *BMC Cancer.* 2019;19:38. 3. Jørgensen JT, Hersom M. *J Cancer.* 2012;3:137–144. 4. Nakada T, et al. *Chem Pharm Bull (Tokyo).* 2019;67:173–185. 5. Ogitani Y, et al. *Clin Cancer Res.* 2016;22:5097–5108. 6. ENHERTU® (fam-trastuzumab deruxtecan-nxki). United States Prescribing Information. Accessed May 5, 2026. https://daiichisankyo.us/prescribing-information-portlet/getPIContent?productName=Enhertu&inline=true. 7. Enhertu (trastuzumab deruxtecan). European Medicines Agency Summary of Product Characteristics. Accessed May 5, 2026. https://www.ema.europa.eu/en/documents/product-information/enhertu-epar-product-information_en.pdf.

Poster

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Introduction

- The addition of pembrolizumab to trastuzumab plus chemotherapy (fluoropyrimidine and platinum) has improved clinical outcomes for patients with HER2-positive GC and GEJA[6]
- However, this regimen is associated with high rates of Grade ≥3 treatment-related AEs and its use is limited to patients with HER2-positive and programmed cell death ligand-1–positive tumors[3,4,6]
- T-DXd, a HER2-directed antibody-drug conjugate, is approved as monotherapy at a dose of 6.4 mg/kg in the 2L+ setting for patients with locally advanced or metastatic HER2-positive GC or GEJA who have received a prior trastuzumab-based regimen[1,2]
- Previous results from Part 2 Arms D and F of the Phase Ib/II DESTINY-Gastric03 trial demonstrated the promising antitumor activity of 1L T-DXd 6.4 and 5.4 mg/kg triplet combination regimens in patients with unresectable, locally advanced or metastatic GC, GEJA, or EA,[7] with the 5.4-mg/kg dose selected for continued investigation in the 1L setting
- We present detailed safety data from patients who received T-DXd in combination with an ICI (pembrolizumab or rilvegostomig) and a fluoropyrimidine in Part 2 Arm D, Part 2 Arm F, and Part 4 of DESTINY-Gastric03

Methods

- DESTINY-Gastric03 (NCT04379596) is a Phase Ib/II global, multicenter, open-label, dose-escalation and expansion study (**Figure 1**)
- The study enrolled adult patients with HER2-expressing (IHC 3+, IHC 2+/ISH+, IHC 2+/ISH−, or IHC 1+) unresectable, locally advanced or metastatic GC, GEJA, or EA, with no prior treatment for metastatic disease
- For this analysis, three data cutoffs were selected to allow presentation of data with similar treatment durations in each group:
  - Part 2 Arm D: February 15, 2023
  - Part 2 Arm F: August 19, 2024
  - Part 4: October 16, 2025

Figure 1. Design of DESTINY-Gastric03 Part 2 Arm D, Part 2 Arm F, and Part 4

Phase Ib/II open-label multicenter study (NCT04379596)

Key enrollment criteria
- Adults ≥18 years of age
- Unresectable, locally advanced or metastatic GC, GEJA, or EA
- HER2-expressing tumors
  - Part 2 Arms D and F: IHC 3+ or IHC 2+/ISH+
  - Part 4: IHC 3+, IHC 2+/ISH+, IHC 2+/ISH−, or IHC 1+
- No prior treatment for metastatic disease
- ECOG PS of 0 or 1

Part 2 Arm D (n=43)
T-DXd 6.4 mg/kg* + pembrolizumab + 5-FU† (n=8) or higher-dose capecitabine† (n=35)

Part 2 Arm F (n=32)
T-DXd 5.4 mg/kg* + pembrolizumab + 5-FU† (n=6) or lower-dose capecitabine† (n=26)

Part 4 (n=62)
T-DXd 5.4 mg/kg* + rilvegostomig + 5-FU† (n=18) or lower-dose capecitabine† (n=45)

Endpoints for Parts 2 and 4‡

Primary endpoint
- Confirmed ORR by investigator assessment per RECIST 1.1

Secondary endpoints
- Safety
- DCR, DOR, and PFS, all by investigator assessment per RECIST 1.1
- OS
- Pharmacokinetics
- Immunogenicity
- Association between HER2 expression and efficacy

Overall, DESTINY-Gastric03 includes five parts and six arms within Part 2; only Part 2 Arm D, Part 2 Arm F, and Part 4 are shown here.
*IV Q3W. †Treatment with 5-FU or capecitabine was decided by the investigator. ‡Listed endpoints may also apply to other parts of the study.

Results

Patient characteristics

- At the respective data cutoffs, 43 patients in Part 2 Arm D, 32 patients in Part 2 Arm F, and 62 patients in Part 4 had received at least one dose of study treatment and were included in the safety analysis population
  - Thirty-one (72.1%), 27 (84.4%), and 48 (77.4%) patients, respectively, remained on any study treatment at data cutoff
- Patient demographics and clinical characteristics are presented in **Table 1**

Table 1. Patient demographics and clinical characteristics

	Part 2 Arm D (n=43) T-DXd 6.4 mg/kg + fluoropyrimidine + pembrolizumab	Part 2 Arm F (n=32) T-DXd 5.4 mg/kg + fluoropyrimidine + pembrolizumab	Part 4 (n=62) T-DXd 5.4 mg/kg + fluoropyrimidine + rilvegostomig
Age, median (range), years	65.0 (41–80)	61.0 (20–78)	62.5 (27–84)
≥75 years, n (%)	6 (14.0)	2 (6.3)	11 (17.7)
Sex, n (%)			
Male	33 (76.7)	29 (90.6)	43 (69.4)
Female	10 (23.3)	3 (9.4)	19 (30.6)
Race, n (%)			
Asian	19 (44.2)	15 (46.9)	18 (29.0)
Black or African American	1 (2.3)	0	1 (1.6)
White	23 (53.5)	17 (53.1)	39 (62.9)
Not reported	0	0	4 (6.5)
ECOG PS, n (%)			
0	23 (53.5)	17 (53.1)	28 (45.2)
1	20 (46.5)	15 (46.9)	34 (54.8)
Primary tumor site, n (%)			
Gastric	27 (62.8)	21 (65.6)	32 (51.6)
Gastroesophageal junction	8 (18.6)	7 (21.9)	18 (29.0)
Esophageal	8 (18.6)	4 (12.5)	10 (16.1)
Missing	0	0	2 (3.2)

Safety summary

- In Part 2 Arm D, median treatment duration was 6.1 months (range, 0.5–13.3) for both T-DXd and pembrolizumab
- In Part 2 Arm F, median treatment duration was 6.9 months (range, 0.7–10.3) for T-DXd and 7.5 months (range, 0.7–10.3) for pembrolizumab
- In Part 4, median treatment duration was 6.5 months (range, 0.7–14.7) for both T-DXd and rilvegostomig
- Rates of Grade ≥3 AEs, serious AEs, and AEs leading to dose modifications were numerically lower in Part 2 Arm F and Part 4 (T-DXd 5.4 mg/kg–based regimens) than in Part 2 Arm D (T-DXd 6.4 mg/kg–based regimen; **Table 2**)

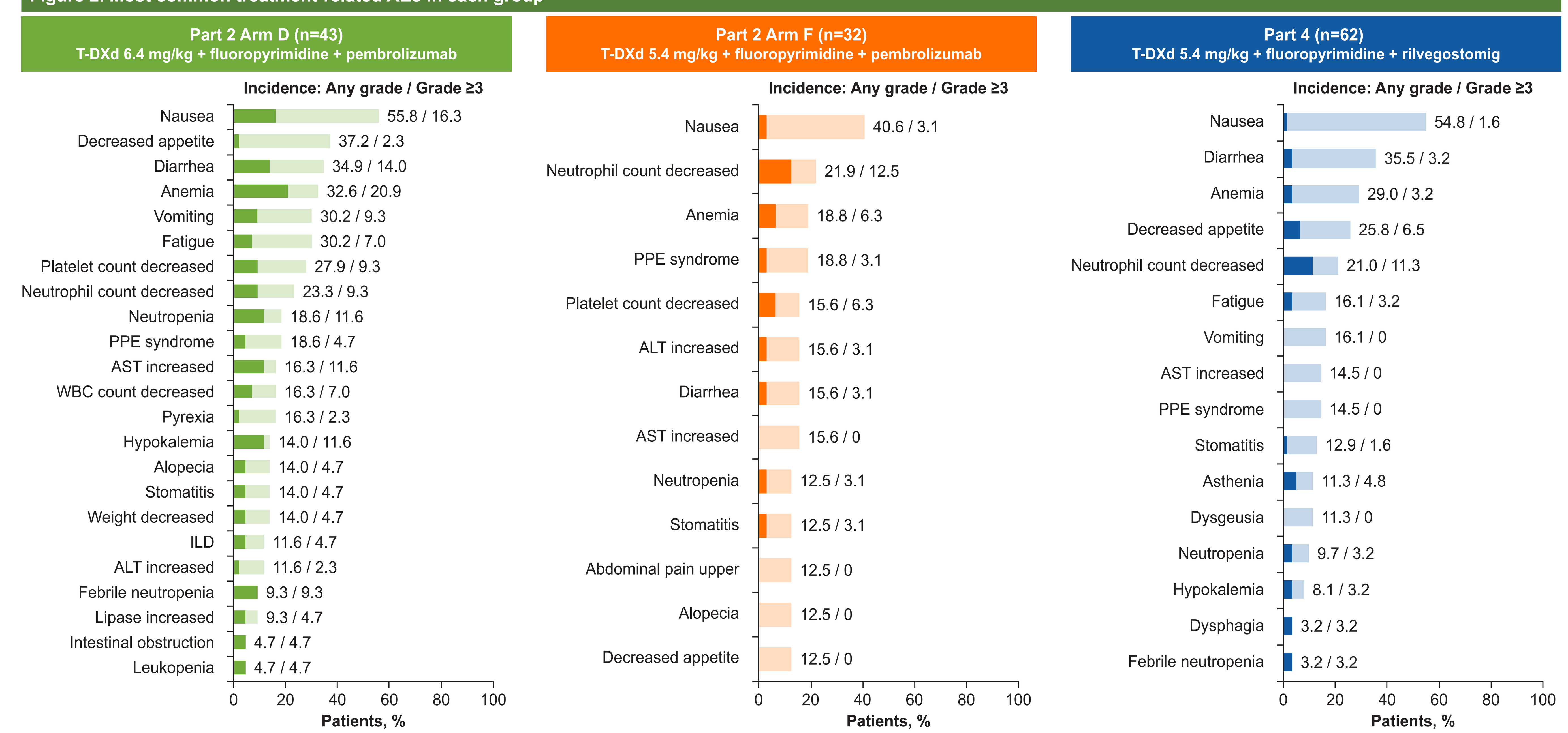
Table 2. Safety summary

Patients, n (%)	Part 2 Arm D (n=43) T-DXd 6.4 mg/kg + fluoropyrimidine + pembrolizumab	Part 2 Arm F (n=32) T-DXd 5.4 mg/kg + fluoropyrimidine + pembrolizumab	Part 4 (n=62) T-DXd 5.4 mg/kg + fluoropyrimidine + rilvegostomig
All-causality AEs	43 (100)	31 (96.9)	60 (96.8)
Treatment related*	40 (93.0)	27 (84.4)	55 (88.7)
Grade ≥3 AEs	38 (88.4)	15 (46.9)	31 (50.0)
Treatment related*	33 (76.7)	11 (34.4)	24 (38.7)
Serious AEs†	25 (58.1)	12 (37.5)	22 (35.5)
Treatment related*†	19 (44.2)	5 (15.6)	12 (19.4)
AEs associated with death	4 (9.3)	0	2 (3.2)
Treatment related*	4 (9.3)‡	0	1 (1.6)§
AEs leading to discontinuation of any investigational product	16 (37.2)	7 (21.9)	7 (11.3)
Treatment related*	15 (34.9)ǁ	6 (18.8)¶	6 (9.7)**
AEs leading to discontinuation of T-DXd	10 (23.3)	2 (6.3)	2 (3.2)
AEs leading to discontinuation of pembrolizumab (Part 2) or rilvegostomig (Part 4)	9 (20.9)	2 (6.3)	2 (3.2)
AEs leading to dose reduction of T-DXd	13 (30.2)	5 (15.6)	13 (21.0)
AEs leading to dose interruption of T-DXd††	23 (53.5)	9 (28.1)	24 (38.7)
AEs leading to dose interruption of pembrolizumab (Part 2) or rilvegostomig (Part 4)††‡‡	26 (60.5)	12 (37.5)	25 (40.3)

*Assessed by the investigator as possibly related to any of the investigational products. †Including events with an outcome of death. ‡Primary cause of death: ILD (n=2); febrile neutropenia (n=1); and respiratory failure due to pneumonitis (n=1). §Primary cause of death: Pneumonia (n=1). ǁILD (n=4); nausea (n=2); diarrhea (n=1); febrile neutropenia (n=1); herpes zoster (n=1); leukopenia (n=1); myocarditis (n=1); neutropenia (n=1); platelet count decreased (n=1); pneumonitis (n=1); and upper gastrointestinal hemorrhage (n=1). ¶Asthenia (n=1); back pain (n=1); diarrhea (n=1); PPE syndrome (n=1); platelet count decreased (n=1); and thrombocytopenia (n=1). **ALT increased and AST increased (n=1; both events reported in the same patient); asthenia (n=1); fatigue (n=1); ILD (n=1); malaise (n=1); and pneumonia (n=1). ††Dose interruptions include dose delays. ‡‡Dose reductions were not permitted for pembrolizumab and rilvegostomig.

- The most common any-grade treatment-related AEs reported in each group were mainly gastrointestinal or hematologic in nature; nausea was the most frequently reported in all three groups (Part 2 Arm D, n=24 [55.8%]; Part 2 Arm F, n=13 [40.6%]; and Part 4, n=34 [54.8%]; **Figure 2**)
- The most common Grade ≥3 treatment-related AEs in each group were:
  - Part 2 Arm D: Anemia (n=9 [20.9%]), nausea (n=7 [16.3%]), diarrhea (n=6 [14.0%]), and AST increased, neutropenia, and hypokalemia (all n=5 [11.6%])
  - Part 2 Arm F: Neutrophil count decreased (n=4 [12.5%]), anemia (n=2 [6.3%]), and platelet count decreased (n=2 [6.3%])
  - Part 4: Neutrophil count decreased (n=7 [11.3%]) and decreased appetite (n=4 [6.5%])

Figure 2. Most common treatment-related AEs in each group*



*AEs assessed by the investigator as possibly related to any of the investigational products that were reported in ≥10% of patients at any grade severity or in two or more patients at Grade ≥3 severity in each group.

AESIs

- AESIs related to T-DXd are presented in **Table 3**
  - Adjudicated treatment-related ILD/pneumonitis was reported in 6 (14.0%) patients in Part 2 Arm D (Grade 1/2, n=4 [9.3%]) and 2 (3.2%) patients in Part 4 (both Grade 2); no events were reported in Part 2 Arm F
- AESIs related to rilvegostomig are presented in **Table 4**
  - The most common AESIs were diarrhea/colitis and hepatic events (both n=9 [14.5%]); most were Grade 1 or 2 in severity

Table 3. AESIs related to T-DXd

Patients, n (%)	Part 2 Arm D (n=43) T-DXd 6.4 mg/kg + fluoropyrimidine + pembrolizumab	Part 2 Arm F (n=32) T-DXd 5.4 mg/kg + fluoropyrimidine + pembrolizumab	Part 4 (n=62) T-DXd 5.4 mg/kg + fluoropyrimidine + rilvegostomig
Any-grade adjudicated treatment-related ILD/pneumonitis*	6 (14.0)	0	2 (3.2)
Grade 1	1 (2.3)	0	0
Grade 2	3 (7.0)	0	2 (3.2)
Grade 3	0	0	0
Grade 4	0	0	0
Grade 5	2 (4.7)	0	0
Left ventricular dysfunction†	0	0	1 (1.6)‡

*Assessed by the independent ILD Adjudication Committee; causality was determined by the ILD Adjudication Committee. †Assessed by the investigator as possibly related to T-DXd. ‡Grade 2 event that was recovering/resolving at data cutoff.

Table 4. AESIs related to rilvegostomig in Part 4*

Patients, n (%)	Part 4 (n=62) T-DXd 5.4 mg/kg + fluoropyrimidine + rilvegostomig	
	Any grade	Grade ≥3
Diarrhea/colitis	9 (14.5)	1 (1.6)
Hepatic events	9 (14.5)	1 (1.6)
Dermatitis/rash	6 (9.7)	1 (1.6)
ILD/pneumonitis†	4 (6.5)	0
Hypothyroid events	3 (4.8)	0
Pancreatic events	2 (3.2)	1 (1.6)
Hyperthyroid events	2 (3.2)	0
Infusion/hypersensitivity reactions	1 (1.6)	0
Myocarditis	1 (1.6)	0
Myositis	1 (1.6)	0

*Assessed by the investigator as possibly related to rilvegostomig. †Four patients had ILD or pneumonitis events assessed as possibly related to rilvegostomig by the investigator, of whom two had events subsequently adjudicated as ILD/pneumonitis and related to T-DXd by the ILD Adjudication Committee (shown in Table 3). Relationship of ILD/pneumonitis events with rilvegostomig was not evaluated by the ILD Adjudication Committee.

Abbreviations

1L, first line; 2L+, second line and beyond; 5-FU, 5-fluorouracil; AE, adverse event; AESI, adverse event of special interest; ALT, alanine aminotransferase; AST, aspartate aminotransferase; DCR, disease control rate; DOR, duration of response; EA, esophageal adenocarcinoma; ECOG PS, Eastern Cooperative Oncology Group performance status; GC, gastric cancer; GEJA, gastroesophageal junction adenocarcinoma; HER2, human epidermal growth factor receptor 2; ICI, immune checkpoint inhibitor; IHC, immunohistochemistry; ILD, interstitial lung disease; ISH, *in situ* hybridization; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PPE, palmar-plantar erythrodysesthesia; Q3W, every 3 weeks; RECIST 1.1, Response Evaluation Criteria in Solid Tumors, version 1.1; T-DXd, trastuzumab deruxtecan; WBC, white blood cell.

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Disclosures

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References

1. ENHERTU® (fam-trastuzumab deruxtecan-nxki). United States Prescribing Information. Accessed May 5, 2026. https://daiichisankyo.us/prescribing-information-portlet/getPIContent?productName=Enhertu&inline=true
2. Enhertu (trastuzumab deruxtecan). European Medicines Agency Summary of Product Characteristics. Accessed May 5, 2026. https://www.ema.europa.eu/en/documents/product-information/enhertu-epar-product-information_en.pdf
3. KEYTRUDA® (pembrolizumab). United States Prescribing Information. Accessed May 5, 2026. https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf
4. Keytruda (pembrolizumab). European Medicines Agency Summary of Product Characteristics. Accessed May 5, 2026. https://www.ema.europa.eu/en/documents/product-information/keytruda-epar-product-information_en.pdf
5. Shitara K, et al. *N Engl J Med.* 2020;382:2419–2430.
6. Janjigian YY, et al. *Lancet.* 2023;402:2197–2208.
7. Janjigian YY, et al. *J Clin Oncol.* 2025;43(4 Suppl):Abstract 448.