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Trastuzumab deruxtecan for pretreated patients with HER2-expressing solid tumors: DESTINY-PanTumor02 Part 1 final analysis

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Objective

- To present the final analysis results from DESTINY-PanTumor02 (NCT04482309) Part 1, evaluating the efficacy and safety of trastuzumab deruxtecan (T-DXd) in patients with human epidermal growth factor receptor 2 (HER2)-expressing, locally advanced, metastatic, or unresectable solid tumors

Conclusions

- Consistent with the primary and post-hoc analyses,[1,2] T-DXd continued to show durable and clinically meaningful antitumor activity in patients with HER2-expressing tumors (immunohistochemistry [IHC] 3+/2+), irrespective of whether HER2 IHC status was determined by central or local testing
  - The greatest benefit was observed in patients with HER2 IHC 3+ tumors
  - With extended follow up, safety remained consistent with the known profile of T-DXd, with no new safety signals observed compared with the primary analysis[1]
- These results further reinforce T-DXd as a recommended treatment for pretreated patients with HER2-positive (IHC 3+) tumors[3–5]
  - Part 2 of the study is currently ongoing and is expected to provide further insights into the antitumor activity of T-DXd in pretreated patients with HER2-expressing/amplified solid tumors[6]

Plain language summary

Why did we perform this research?

Trastuzumab deruxtecan (T-DXd) is an antibody-drug conjugate, which is a chemotherapy with a linker (together called deruxtecan) joined to an antibody (trastuzumab). T-DXd binds to human epidermal growth factor receptor 2 (HER2) on the surface of cancer cells. Once inside the cell, it releases the chemotherapy to kill these cells.[1,2] Based, in part, on the primary analysis (the main planned assessment of the data) of Part 1 of the DESTINY-PanTumor02 clinical study,[3] T-DXd is a recommended treatment in multiple countries for people with solid tumors that have the highest level of HER2 (HER2-positive, also known as immunohistochemistry [IHC] 3+) that have spread or cannot be completely removed with surgery and who have received prior systemic treatment and/or have no satisfactory alternative treatment options available.[4–6] A final analysis (the last assessment of the data) of Part 1 of DESTINY-PanTumor02 was planned to further evaluate the benefit of T-DXd for people with tumors that have high levels of HER2.

How did we perform this research?

This study included people with HER2-expressing (known as IHC 3+ or IHC 2+) tumors that have spread or cannot be completely removed with surgery. Participants had received prior systemic treatment or had no satisfactory alternative treatment options available before receiving T-DXd in Part 1 of the DESTINY-PanTumor02 study.

What were the findings of this research?

Overall, 100 out of 267 people (37.5%) who participated in Part 1 had a response to T-DXd (ie their tumors reduced in size). The greatest responses to T-DXd were seen in those with the highest tumor level of HER2 (IHC 3+). The most common severe side effects (Grade 3 or higher) related to T-DXd, seen in more than 5% of people, were neutropenia / reduced neutrophil count, anemia, and fatigue. Overall, the observed side effects were consistent with those expected in people receiving T-DXd and no new safety concerns were found compared with the primary analysis.[3]

What are the implications of this research?

Results from the final analysis of Part 1 of DESTINY-PanTumor02 reaffirm the use of T-DXd as a treatment for people with HER2-positive (IHC 3+) cancers that have spread or cannot be completely removed with surgery and who have received prior systemic treatment and/or have no satisfactory alternative treatment options available.[4–6]

Where can I access more information?

For information about DESTINY-PanTumor02, please visit https://www.clinicaltrials.gov/study/NCT04482309. Primary results from DESTINY-PanTumor02 Part 1 have been published in the *Journal of Clinical Oncology* at https://ascopubs.org/doi/10.1200/JCO.23.02005. You can also speak to your doctor about this and other clinical studies.

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Poster

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Introduction

- T-DXd (HER2-directed antibody-drug conjugate) is approved for HER2-positive, HER2-low, and HER2-ultralow breast cancer; HER2-positive gastric or gastroesophageal junction adenocarcinoma; and *HER2*-mutant non-small cell lung cancer[3–5,7]
- Primary results (data cutoff June 8, 2023) from DESTINY-PanTumor02 Part 1 demonstrated clinically meaningful activity for T-DXd in pretreated advanced HER2-expressing solid tumors, with the greatest benefit observed in HER2 IHC 3+ tumors, irrespective of local or central HER2 IHC test results[1,2]
  - Based, in part, on this primary analysis, T-DXd is approved in multiple countries for adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior treatment and/or have no satisfactory alternative therapies[3–5]
- Here, we present the final analysis of DESTINY-PanTumor02 Part 1

Methods

Patient population

- Adults with histologically confirmed locally advanced, metastatic, or unresectable solid tumors (excluding breast, colorectal, gastric, and non-small cell lung cancer)
- Disease progression following ≥1 prior systemic treatment or without alternative treatment options; prior HER2-directed therapy was allowed
- HER2-expressing tumors with IHC 3+/2+ scored using current American Society of Clinical Oncology / College of American Pathology (ASCO/CAP) guidelines for scoring HER2 in gastric cancer[8]
- HER2 expression at enrollment was based on local testing; however, if local testing was not available, enrollment was determined by central HER2 testing (HercepTest [DAKO])
  - Retrospective central HER2 testing was performed for patients enrolled based on a local HER2 test result

*Investigator assessed per RECIST 1.1; †included patients with salivary gland cancer (n=19), malignant neoplasm of unknown primary site (n=5), extramammary Paget disease (n=3), cutaneous melanoma (n=2), oropharyngeal neoplasm (n=2), adenoid cystic carcinoma, head and neck cancer, lip and/or oral cavity cancer, esophageal adenocarcinoma, intestinal adenocarcinoma, appendiceal adenocarcinoma, esophageal squamous cell carcinoma, testicular cancer, and vulvar carcinoma (all n=1). DCR, disease control rate; DOR, duration of response; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumours; T-DXd, trastuzumab deruxtecan

Study type

Open label, multicenter, multicohort, Phase 2

Treatment

T-DXd 5.4 mg/kg IV Q3W

Trial registration

NCT04482309

Data cutoff

October 10, 2024

Endpoints

Primary:
- Confirmed ORR*

Secondary:
- DOR*
- DCR*
- PFS*
- OS
- Safety and tolerability

Exploratory:
- Subgroup analyses by HER2 status
- Subgroup analyses by biomarker status

Cohorts

- Endometrial
- Cervical
- Ovarian
- Bladder
- Other tumors†
- Biliary tract
- Pancreatic

Results

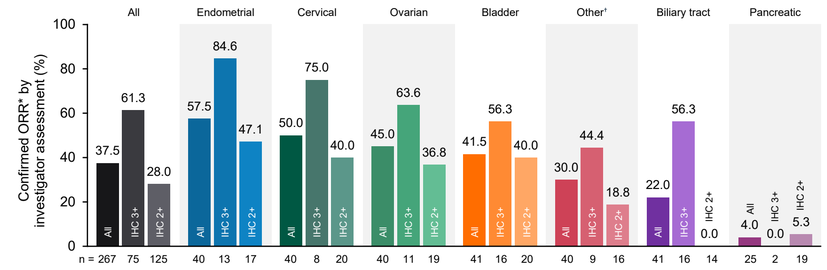
- At final data cutoff (October 10, 2024), 267 patients across seven tumor cohorts (endometrial [n=40], cervical [n=40], ovarian [n=40], bladder [n=41], biliary tract [n=41], pancreatic [n=25], and other tumors [n=40]) had received T-DXd
- By central test results, 75 (28.1%) patients had HER2 IHC 3+ tumors and 125 (46.8%) patients had HER2 IHC 2+ tumors (**Table 1**)
- Median number (range) of prior lines of therapy among patients was 2 (0–12); 40.8% of all patients had received at least three prior lines of therapy (**Table 1**)
- Ten (3.7%) patients were ongoing treatment at data cutoff; the most common reason for treatment discontinuation was objective disease progression (57.3%)
- Median (range) follow up for all patients was 12.98 (0.4–47.7) months
- Median number of treatment cycles received was 8.0 (21.7% of patients received ≥18 cycles [~12 months of treatment])

Table 1. Baseline demographics and clinical characteristics

	All patients (N=267)
Median age, years (range)	62 (23–85)
Sex, female, n (%)	178 (66.7)
Race, n (%)	
White	163 (61.0)
Black or African American	6 (2.2)
Asian	87 (32.6)
Other	6 (2.2)
Not reported	5 (1.9)
ECOG performance status, n (%)*	
0	126 (47.2)
1	140 (52.4)
HER2 testing at enrollment, n (%)	
Local	202 (75.7)
Central	65 (24.3)
HER2 IHC status at enrollment, n (%)	
IHC 3+	111 (41.6)
IHC 2+	151 (56.6)
IHC 1+	5 (1.9)
HER2 IHC status by central testing, n (%)	
IHC 3+	75 (28.1)
IHC 2+	125 (46.8)
IHC 1+	25 (9.4)
IHC 0	30 (11.2)
Unknown	12 (4.5)
No. of prior lines of therapy, n (%)†	
0	3 (1.1)
1	71 (26.6)
2	84 (31.5)
3	55 (20.6)
4	21 (7.9)
≥5	33 (12.4)

*One patient within the ovarian cancer cohort had an ECOG performance score of 2;
†one patient from each of the bladder, endometrial, and other tumors cohorts received no prior treatment regimens (prior radiotherapy was not considered)
ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry

Figure 1. Investigator-assessed confirmed ORRs by tumor cohort and central HER2 IHC status



Investigator-assessed ORR analyses were performed for patients who received ≥1 dose of T-DXd (n=267). *Confirmed ORR per RECIST 1.1; †included patients with salivary gland cancer (n=19), malignant neoplasm of unknown primary site (n=5), extramammary Paget disease (n=3), cutaneous melanoma (n=2), oropharyngeal neoplasm (n=2), adenoid cystic carcinoma, head and neck cancer, lip and/or oral cavity cancer, esophageal adenocarcinoma, intestinal adenocarcinoma, appendiceal adenocarcinoma, esophageal squamous cell carcinoma, testicular cancer, and vulvar carcinoma (all n=1)
HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ORR, objective response rate; RECIST, Response Evaluation Criteria in Solid Tumours; T-DXd, trastuzumab deruxtecan

Table 2. Investigator-assessed median PFS by tumor cohort and HER2 IHC status

Median PFS, months (95% CI) [n]*	All patients	HER2 IHC status by central testing		HER2 IHC status at enrollment‡	
		IHC 3+	IHC 2+	IHC 3+	IHC 2+
All	6.9 (5.6, 8.0) [267]	11.9 (8.2, 13.0) [75]	5.4 (4.2, 6.0) [125]	9.7 (7.0, 12.5) [111]	5.1 (4.1, 6.0) [151]
Endometrial	11.1 (7.1, 25.8) [40]	28.1 (7.3, NE) [13]	8.5 (4.6, 15.1) [17]	24.8 (4.5, 35.7) [16]	11.0 (6.0, 19.5) [24]
Cervical	7.0 (4.2, 11.1) [40]	NE (3.9, NE) [8]	4.8 (2.7, 5.7) [20]	NE (3.9, NE) [10]	4.6 (1.4, 8.1) [25]
Ovarian	5.9 (4.0, 8.3) [40]	12.5 (3.1, NE) [11]	4.1 (2.3, 12.6) [19]	12.6 (4.1, NE) [15]	4.4 (2.3, 7.1) [25]
Bladder	7.0 (4.2, 9.7) [41]	7.4 (3.0, 11.9) [16]	7.8 (2.6, 11.6) [20]	7.0 (3.9, 11.5) [27]	7.0 (2.6, 13.0) [14]
Other†	8.8 (5.5, 12.5) [40]	22.3 (5.6, NE) [9]	5.5 (2.8, 8.7) [16]	13.0 (6.3, 23.4) [16]	6.6 (2.9, 8.8) [24]
Biliary tract	4.6 (3.1, 6.0) [41]	7.4 (2.8, 12.5) [16]	4.2 (2.8, 6.0) [14]	6.9 (3.0, 8.0) [22]	3.7 (2.8, 5.1) [19]
Pancreatic	3.2 (1.8, 7.2) [25]	5.4 (2.8, NE) [2]	2.8 (1.4, 9.1) [19]	8.0 (1.2, NE) [5]	3.2 (1.4, 4.9) [20]

Discrepancies in n numbers are owing to patients with central HER2 IHC status of 1+/0/unknown enrolled as IHC 3+/2+ by local testing
*Investigator assessed per RECIST 1.1; †included patients with salivary gland cancer (n=19), malignant neoplasm of unknown primary site (n=5), extramammary Paget disease (n=3), cutaneous melanoma (n=2), oropharyngeal neoplasm (n=2), adenoid cystic carcinoma, head and neck cancer, lip and/or oral cavity cancer, esophageal adenocarcinoma, intestinal adenocarcinoma, appendiceal adenocarcinoma, esophageal squamous cell carcinoma, testicular cancer, and vulvar carcinoma (all n=1); ‡HER2 expression for enrollment was based on local assessment, where available, otherwise enrollment was based on central testing
CI, confidence interval; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; NE, not evaluable; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumours

Table 3. Median OS by tumor cohort and HER2 IHC status

Median OS, months (95% CI) [n]	All patients	HER2 IHC status by central testing		HER2 IHC status at enrollment†	
		IHC 3+	IHC 2+	IHC 3+	IHC 2+
All	13.4 (11.9, 15.3) [267]	21.1 (16.0, 26.0) [75]	12.2 (10.7, 13.6) [125]	17.7 (12.8, 23.4) [111]	12.0 (9.6, 13.5) [151]
Endometrial	24.2 (12.8, 33.7) [40]	33.7 (18.9, NE) [13]	16.4 (8.0, 34.7) [17]	29.0 (4.5, NE) [16]	20.3 (8.1, 33.1) [24]
Cervical	13.6 (11.1, 19.7) [40]	35.8 (3.9, NE) [8]	11.6 (5.1, 18.0) [20]	35.8 (3.9, NE) [10]	11.7 (8.0, 13.6) [25]
Ovarian	13.2 (8.0, 17.7) [40]	20.0 (3.8, NE) [11]	13.0 (4.7, 21.9) [19]	20.0 (7.2, NE) [15]	10.7 (5.9, 14.8) [25]
Bladder	12.8 (11.2, 15.1) [41]	13.4 (6.7, 19.8) [16]	13.1 (11.0, 19.9) [20]	12.6 (6.7, 17.2) [27]	13.5 (8.0, 19.9) [14]
Other*	21.0 (12.9, 25.1) [40]	25.1 (11.1, NE) [9]	14.6 (6.8, 22.4) [16]	25.2 (11.1, 40.0) [16]	15.5 (9.6, 22.4) [24]
Biliary tract	7.0 (4.6, 10.2) [41]	12.4 (2.8, 26.3) [16]	6.0 (3.7, 11.7) [14]	7.6 (4.6, 23.7) [22]	5.3 (3.1, 10.2) [19]
Pancreatic	5.0 (3.8, 14.2) [25]	12.4 (8.8, NE) [2]	4.9 (2.4, 15.7) [19]	8.8 (2.4, NE) [5]	4.7 (3.2, 14.2) [20]

Discrepancies in n numbers are owing to patients with central HER2 IHC status of 1+/0/unknown enrolled as IHC 3+/2+ by local testing
*Included patients with salivary gland cancer (n=19), malignant neoplasm of unknown primary site (n=5), extramammary Paget disease (n=3), cutaneous melanoma (n=2), oropharyngeal neoplasm (n=2), adenoid cystic carcinoma, head and neck cancer, lip and/or oral cavity cancer, esophageal adenocarcinoma, intestinal adenocarcinoma, appendiceal adenocarcinoma, esophageal squamous cell carcinoma, testicular cancer, and vulvar carcinoma (all n=1); †HER2 expression for enrollment was based on local assessment, where available, otherwise enrollment was based on central testing
CI, confidence interval; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; NE, not evaluable; OS, overall survival

Efficacy

- Investigator-assessed confirmed objective response rates (ORRs) were highest for patients with HER2 IHC 3+ tumors by central testing (**Figure 1**)
  - Compared with the primary analysis,[1] one additional patient with bladder cancer (HER2 IHC 2+ by central testing) achieved a confirmed objective response by investigator assessment
- According to the local or central HER2 test result used for enrollment, investigator-assessed confirmed ORRs were also greatest for patients with HER2 IHC 3+ tumors (52.3% [95% confidence interval (CI) 42.6, 61.8]; n=111) versus those with IHC 2+ tumors (26.5% [95% CI 19.6, 34.3]; n=151)
- Longer investigator-assessed median progression-free survival (PFS) and median overall survival was observed in patients with HER2 IHC 3+ tumors versus those with IHC 2+ tumors by central testing and according to the HER2 test result used for enrollment (**Tables 2 and 3**)
- Results by investigator assessment were consistent with those by independent central review (ICR); across all patients:
  - Confirmed ORR by ICR was 37.5% (95% CI 31.6, 43.6)
  - Median PFS by ICR was 7.0 months (95% CI 6.0, 8.5)

Safety

- Drug-related Grade ≥3 adverse events (AEs) occurred in 111 (41.6%) patients (**Table 4**)
  - The most common (>5%) Grade ≥3 drug-related AEs were neutropenia (11.2%), anemia (10.9%), decreased neutrophil count (8.6%), and fatigue (6.0%)
- Adjudicated drug-related interstitial lung disease / pneumonitis occurred in 31 (11.6%) patients; the majority of cases were either Grade 1 (n=8, 3.0%) or Grade 2 (n=19, 7.1%)
  - One (0.4%) patient with biliary tract cancer had a Grade 3 event
  - Three (1.1%) Grade 5 events were reported (one patient in the biliary tract cancer cohort, one patient in the endometrial cancer cohort, and one patient in the other tumors cohort)

Table 4. Safety summary

AE category, n (%)	All patients (N=267)
Any AE	261 (97.8)
Any drug-related AE	226 (84.6)
Grade ≥3	111 (41.6)
Drug-related serious AEs	36 (13.5)
Drug-related AEs associated with dose interruptions	55 (20.6)
Drug-related AEs associated with dose reductions	56 (21.0)
Drug-related AEs associated with discontinuations	27 (10.1)
Drug-related AEs associated with deaths	4 (1.5)
Adjudicated drug-related ILD/pneumonitis	31 (11.6)
Grade ≥3	4 (1.5)

Analyses include all patients who received ≥1 dose of T-DXd (n=267); median total treatment duration was 5.6 months (range: 0.4–41.9)
AE, adverse event; ILD, interstitial lung disease; T-DXd, trastuzumab deruxtecan

Limitations

- It was not possible to include a comparator arm given the range of tumor types included
- ASCO/CAP guidelines[8] for scoring HER2 for gastric cancer were used, per the study protocol; however, these guidelines are not specific to the tumor types evaluated

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