Dokumentvorlage, Version vom 16.12.2021

Dossier zur Nutzenbewertung gemäß § 35a SGB V

Trastuzumab-Deruxtecan (Enhertu®)

Daiichi Sankyo Deutschland GmbH

Modul 4 A, Anhang G

Erwachsene Patienten mit fortgeschrittenem HER2-positivem Adenokarzinom des Magens oder des gastroösophagealen Übergangs (GEJ), die bereits ein vorhergehendes Trastuzumab-basiertes Therapieschema erhalten haben

Medizinischer Nutzen und medizinischer Zusatznutzen, Patientengruppen mit therapeutisch bedeutsamem Zusatznutzen

Stand: 31.01.2023

Inhaltsverzeichnis

Anhang 4-G 1: Ergänzende Analysen DESTINY-Gastric01

Anhang 4-G 1.1: Datenschnitt 08. November 2019

Anhang 4-G 1.1.1: Behandlungs- und Beobachtungsdauer

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Study duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Study duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	9.04 (4.688)	7.44 (4.221)
	Median	8.08	6.97
	Q1, Q3	5.62, 12.12	4.14, 10.38
	Min, Max	1.0, 23.1	0.3, 20.3

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to participation end date.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Treatment duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Treatment duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.74 (4.245)	3.12 (2.204)
	Median	4.60	2.76
	Q1, Q3	2.79, 7.13	1.51, 4.17
	Min, Max	0.7, 22.3	0.5, 13.1

Duration of follow-up (months) was derived applying descriptive statistics.
DS-8201a: Time from treatment start to last date of treatment + 21; Phys. Choice (Irinotecan): Time from treatment start to last date of treatment + 14; Phys. Choice (Paclitaxel): Time from treatment start to last date of treatment + 28, 21 or 14 for 1st, 2nd or 3rd dose in the last cycle, respectively.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Survival Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Overall Survival Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	9.04 (4.688)	7.44 (4.221)
	Median	8.08	6.97
	Q1, Q3	5.62, 12.12	4.14, 10.38
	Min, Max	1.0, 23.1	0.3, 20.3

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the date of death due to any cause or censoring of Overall Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Progression-free Survival Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Progression-free Survival Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.47 (4.131)	2.70 (1.865)
	Median	4.37	2.25
	Q1, Q3	2.76, 6.93	1.38, 4.11
	Min, Max	0.0, 22.4	0.0, 6.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the earliest date of the first objective documentation of disease progression, death due to any cause or censoring of Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Duration of Confirmed Response Follow-up duration (months) - for responders only
Full Analysis Set

		DS-8201a (N=51)	Phys. Choice (N=7)
Duration of Confirmed Response Follow-up duration (months)	n (missing)	51 (0)	7 (0)
	Mean (SD)	6.60 (4.456)	3.44 (1.166)
	Median	5.49	3.94
	Q1, Q3	2.96, 9.36	2.63, 4.21
	Min, Max	1.4, 21.0	1.4, 4.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression, death due to any cause or censoring of Duration of Confirmed Response.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Duration of Response Follow-up duration (months) - for responders only
Full Analysis Set

		DS-8201a (N=61)	Phys. Choice (N=8)
Duration of Response Follow-up duration (months)	n (missing)	61 (0)	8 (0)
	Mean (SD)	5.72 (4.568)	3.01 (1.616)
	Median	4.21	3.48
	Q1, Q3	2.76, 7.98	2.02, 4.07
	Min, Max	0.0, 21.0	0.0, 4.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression, death due to any cause or censoring of Duration of Response.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Time to Confirmed Response Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Time to Confirmed Response Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	2.79 (1.877)	2.32 (1.617)
	Median	2.66	1.68
	Q1, Q3	1.45, 3.52	1.38, 2.83
	Min, Max	0.0, 12.0	0.0, 6.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR or censoring the same way as for Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Time to Response Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Time to Response Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	2.69 (1.872)	2.32 (1.617)
	Median	2.23	1.68
	Q1, Q3	1.41, 3.02	1.38, 2.83
	Min, Max	0.0, 12.0	0.0, 6.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR or censoring the same way as for Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Measureable Tumors based on ICR Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Measureable Tumors based on ICR Follow-up duration (months)	n (missing)	119 (6)	56 (6)
	Mean (SD)	5.43 (4.205)	2.70 (1.757)
	Median	4.37	2.63
	Q1, Q3	2.76, 6.90	1.38, 4.09
	Min, Max	0.0, 22.4	0.0, 6.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing tumor assessment. Subjects with assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
EQ-5D VAS score Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
EQ-5D VAS score Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.40 (4.247)	2.86 (2.105)
	Median	4.27	2.76
	Q1, Q3	2.76, 6.93	1.41, 4.17
	Min, Max	0.0, 22.3	0.0, 11.2

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Fact-Ga Total Score Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Fact-Ga Total Score Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.38 (4.252)	2.88 (2.082)
	Median	4.21	2.76
	Q1, Q3	2.76, 6.93	1.41, 4.17
	Min, Max	0.0, 22.3	0.0, 11.2

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Physical Well-being Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Physical Well-being Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.40 (4.247)	2.88 (2.082)
	Median	4.27	2.76
	Q1, Q3	2.76, 6.93	1.41, 4.17
	Min, Max	0.0, 22.3	0.0, 11.2

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Social/Family Well-being Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Social/Family Well-being Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.38 (4.252)	2.88 (2.082)
	Median	4.21	2.76
	Q1, Q3	2.76, 6.93	1.41, 4.17
	Min, Max	0.0, 22.3	0.0, 11.2

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Emotional Well-being Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Emotional Well-being Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.38 (4.252)	2.88 (2.082)
	Median	4.21	2.76
	Q1, Q3	2.76, 6.93	1.41, 4.17
	Min, Max	0.0, 22.3	0.0, 11.2

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Functional Well-being Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Functional Well-being Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.38 (4.252)	2.88 (2.082)
	Median	4.21	2.76
	Q1, Q3	2.76, 6.93	1.41, 4.17
	Min, Max	0.0, 22.3	0.0, 11.2

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Gastric Cancer Symptom (GaCS) Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Gastric Cancer Symptom (GaCS) Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.38 (4.252)	2.88 (2.082)
	Median	4.21	2.76
	Q1, Q3	2.76, 6.93	1.41, 4.17
	Min, Max	0.0, 22.3	0.0, 11.2

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Fact-G Total Score Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Fact-G Total Score Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	5.38 (4.252)	2.88 (2.082)
	Median	4.21	2.76
	Q1, Q3	2.76, 6.93	1.41, 4.17
	Min, Max	0.0, 22.3	0.0, 11.2

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Safety Follow-up duration (months)
Safety Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Safety Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.07 (4.046)	3.49 (2.100)
	Median	5.03	3.15
	Q1, Q3	3.48, 7.20	1.87, 4.50
	Min, Max	1.0, 23.0	0.1, 12.5

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to death date, last date of treatment (last dose of study drug) + 47 days, start of new anti-cancer therapy or last contact date, whichever occured earlier.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Anhang 4-G 1.1.2: Mortalität

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Overall Survival
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	62 (49.6)	39 (62.9)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	12.5 (9.6, 14.3)	8.4 (6.9, 10.7)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	92.7 (86.5, 96.2)	90.0 (79.1, 95.4)
6 Months (95% CI)	80.3 (72.1, 86.4)	66.4 (52.9, 76.9)
9 Months (95% CI)	62.6 (52.5, 71.1)	47.0 (32.9, 59.9)
12 Months (95% CI)	52.1 (41.4, 61.7)	28.9 (16.4, 42.7)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.59 (0.39, 0.88)	
p-value [c]	0.0097	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.59 (0.39, 0.88)	
p-value [c]	0.0088	

Overall Survival (OS) is defined as the time from the date of randomization to the date of death due to any cause. See SAP for the handling of censored cases.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Overall Survival - Subgroup analysis
Full Analysis Set

Subgroup	DS-8201a (N=125)		Phys. Choice (N=62)		Analysis DS-8201a vs. Phys. Choice		Interaction
Level	n/ N (%)	Median (95% CI) [a]	n/ N (%)	Median (95% CI) [a]	Hazard Ratio (95% CI) [b]	p-Value [c]	p-value [d]
Region							0.7127
Japan	48/ 99 (48.5)	12.5 (9.6, 14.3)	33/ 50 (66.0)	8.4 (5.8, 10.8)	0.57 (0.36, 0.89)	0.0121	
Korea	14/ 26 (53.8)	12.0 (5.9, 16.4)	6/ 12 (50.0)	9.3 (3.6, NE)	0.69 (0.25, 1.88)	0.4660	
Lines of prior systemic therapy							0.1163
2	34/ 66 (51.5)	10.8 (8.1, 13.0)	21/ 38 (55.3)	9.3 (5.8, 14.3)	0.85 (0.49, 1.47)	0.5694	
3	16/ 34 (47.1)	16.6 (8.2, 21.2)	13/ 18 (72.2)	7.9 (4.9, 9.2)	0.39 (0.18, 0.85)	0.0136	
>=4	12/ 25 (48.0)	12.5 (8.3, NE)	5/ 6 (83.3)	6.9 (1.6, NE)	0.38 (0.13, 1.11)	0.0655	
Age							0.1408
<65 years	30/ 55 (54.5)	11.5 (8.3, 16.6)	15/ 27 (55.6)	10.7 (7.0, 14.3)	0.82 (0.44, 1.53)	0.5294	
>=65 years	32/ 70 (45.7)	12.8 (10.8, 14.4)	24/ 35 (68.6)	7.3 (4.9, 9.2)	0.44 (0.26, 0.76)	0.0026	
Sex							0.3449
female	18/ 30 (60.0)	10.1 (5.8, 14.4)	12/ 15 (80.0)	8.9 (3.3, 10.8)	0.78 (0.37, 1.66)	0.5244	
male	44/ 95 (46.3)	13.0 (11.5, 16.6)	27/ 47 (57.4)	8.1 (6.4, 13.6)	0.53 (0.33, 0.87)	0.0101	
ECOG PS							0.9050
0	29/ 62 (46.8)	13.0 (10.1, 18.0)	19/ 30 (63.3)	8.6 (6.9, 13.6)	0.57 (0.32, 1.02)	0.0539	
1	33/ 63 (52.4)	11.5 (7.3, 14.3)	20/ 32 (62.5)	8.1 (4.2, 10.4)	0.59 (0.33, 1.04)	0.0650	
HER2 Status in central laboratory							0.0563
IHC 3+	41/ 96 (42.7)	12.8 (10.3, 18.0)	29/ 47 (61.7)	8.6 (6.4, 10.7)	0.47 (0.29, 0.77)	0.0019	
IHC 2+/ISH +	21/ 29 (72.4)	10.1 (5.4, 13.1)	10/ 15 (66.7)	8.4 (3.9, 20.0)	1.14 (0.52, 2.50)	0.7473	
Primary tumor location							0.9576
Gastric	55/108 (50.9)	12.5 (9.1, 14.4)	34/ 55 (61.8)	8.1 (6.4, 10.4)	0.59 (0.38, 0.91)	0.0163	
GEJ	7/ 17 (41.2)	13.0 (7.6, NE)	5/ 7 (71.4)	13.6 (3.4, 14.3)	0.68 (0.21, 2.15)	0.5080	
Histological subtype							0.0632
intestinal	45/ 89 (50.6)	12.5 (10.1, 14.3)	24/ 38 (63.2)	8.6 (6.9, 13.6)	0.65 (0.39, 1.07)	0.0903	
diffuse	12/ 28 (42.9)	14.4 (6.5, NE)	13/ 18 (72.2)	7.1 (3.4, 10.4)	0.38 (0.17, 0.86)	0.0154	
others	5/ 8 (62.5)	5.9 (1.0, NE)	2/ 6 (33.3)	NE (3.0, NE)	2.21 (0.42, 11.75)	0.3411	
Number of metastatic sites							0.6065
<2	9/ 24 (37.5)	17.6 (11.5, NE)	6/ 10 (60.0)	7.9 (3.0, NE)	0.40 (0.13, 1.23)	0.0984	
>= 2	53/101 (52.5)	12.1 (8.6, 14.3)	33/ 52 (63.5)	8.6 (6.4, 10.4)	0.61 (0.39, 0.95)	0.0272	
Previous total gastrectomy							0.0032
yes	6/ 22 (27.3)	NE (13.1, NE)	9/ 9 (100.0)	8.4 (1.6, 10.7)	0.16 (0.05, 0.47)	0.0002	
no	56/103 (54.4)	10.8 (8.6, 13.0)	30/ 53 (56.6)	9.2 (6.4, 13.6)	0.77 (0.49, 1.20)	0.2453	
Prior adjuvant/ neoadjuvant therapy							0.0065
yes	7/ 30 (23.3)	18.0 (12.5, NE)	8/ 10 (80.0)	7.3 (1.6, 11.7)	0.11 (0.03, 0.38)	<.0001	
no	55/ 95 (57.9)	10.3 (8.2, 13.0)	31/ 52 (59.6)	8.6 (6.9, 10.8)	0.78 (0.50, 1.21)	0.2628	
Prior ramucirumab contained treatment							0.8601
yes	46/ 94 (48.9)	12.1 (8.6, 14.3)	27/ 41 (65.9)	8.1 (5.7, 10.7)	0.57 (0.35, 0.92)	0.0196	
no	16/ 31 (51.6)	12.8 (9.1, 18.0)	12/ 21 (57.1)	9.3 (6.4, 14.3)	0.55 (0.25, 1.22)	0.1357	

Overall Survival (OS) is defined as the time from the date of randomization to the date of death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Overall Survival - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.0379
yes	14/ 33 (42.4)	16.6 (10.8, 21.2)	13/ 15 (86.7)	8.6 (3.4, 10.7)	0.27 (0.12, 0.60)	0.0006	
no	48/ 92 (52.2)	10.8 (8.3, 13.1)	26/ 47 (55.3)	8.4 (6.9, 13.6)	0.76 (0.47, 1.24)	0.2734	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0233
yes	18/ 44 (40.9)	16.6 (12.1, 21.2)	14/ 17 (82.4)	8.6 (3.6, 10.7)	0.31 (0.15, 0.63)	0.0007	
no	44/ 81 (54.3)	10.3 (8.1, 13.0)	25/ 45 (55.6)	8.4 (6.9, 13.6)	0.83 (0.50, 1.35)	0.4460	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.5946
yes	12/ 22 (54.5)	10.8 (6.3, 17.6)	4/ 7 (57.1)	7.9 (6.9, NE)	0.75 (0.23, 2.43)	0.6343	
no	50/103 (48.5)	12.8 (9.6, 16.4)	35/ 55 (63.6)	8.4 (5.7, 10.8)	0.56 (0.36, 0.86)	0.0076	
Presence of liver metastasis at baseline							0.9340
yes	35/ 67 (52.2)	10.8 (8.2, 13.0)	24/ 34 (70.6)	7.1 (4.6, 10.4)	0.56 (0.33, 0.95)	0.0284	
no	27/ 58 (46.6)	13.9 (11.5, 16.6)	15/ 28 (53.6)	10.7 (7.9, 13.6)	0.52 (0.26, 1.02)	0.0531	
Renal impairment at baseline							0.6708
normal	14/ 33 (42.4)	13.0 (8.6, NE)	8/ 13 (61.5)	10.4 (3.4, 14.3)	0.48 (0.20, 1.16)	0.0971	
mild	32/ 53 (60.4)	11.5 (8.1, 14.3)	17/ 28 (60.7)	7.1 (4.1, 13.6)	0.69 (0.38, 1.26)	0.2256	
moderate	16/ 39 (41.0)	13.1 (8.2, NE)	13/ 20 (65.0)	8.4 (5.7, 11.7)	0.57 (0.27, 1.20)	0.1347	
severe	0	NE (NE , NE)	1/ 1 (100.0)	3.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.2997
normal	43/ 88 (48.9)	13.0 (10.3, 14.4)	28/ 47 (59.6)	9.2 (7.1, 11.7)	0.62 (0.38, 1.01)	0.0520	
mild	18/ 36 (50.0)	10.8 (6.3, NE)	11/ 15 (73.3)	5.7 (2.0, 10.4)	0.50 (0.23, 1.08)	0.0708	
moderate	1/ 1 (100.0)	7.5 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9518
yes	5/ 8 (62.5)	12.0 (5.8, NE)	3/ 5 (60.0)	14.3 (2.0, 14.3)	0.81 (0.19, 3.48)	0.7722	
no	57/117 (48.7)	12.8 (9.6, 14.4)	36/ 57 (63.2)	8.4 (6.9, 10.4)	0.58 (0.38, 0.89)	0.0119	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.4742
yes	2/ 3 (66.7)	12.0 (9.1, 12.0)	2/ 4 (50.0)	14.3 (3.4, 14.3)	2.51 (0.22, 29.14)	0.4480	
no	60/122 (49.2)	12.5 (9.6, 14.4)	37/ 58 (63.8)	8.4 (6.4, 10.4)	0.57 (0.37, 0.86)	0.0065	

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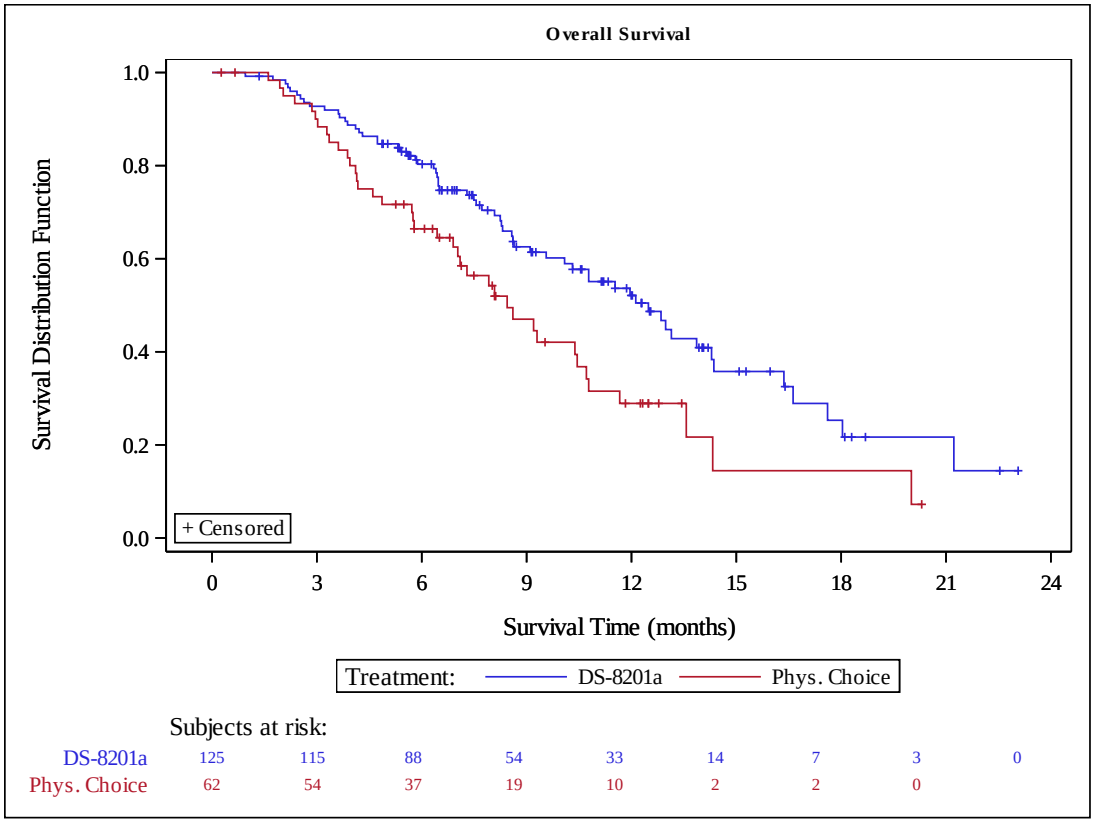
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

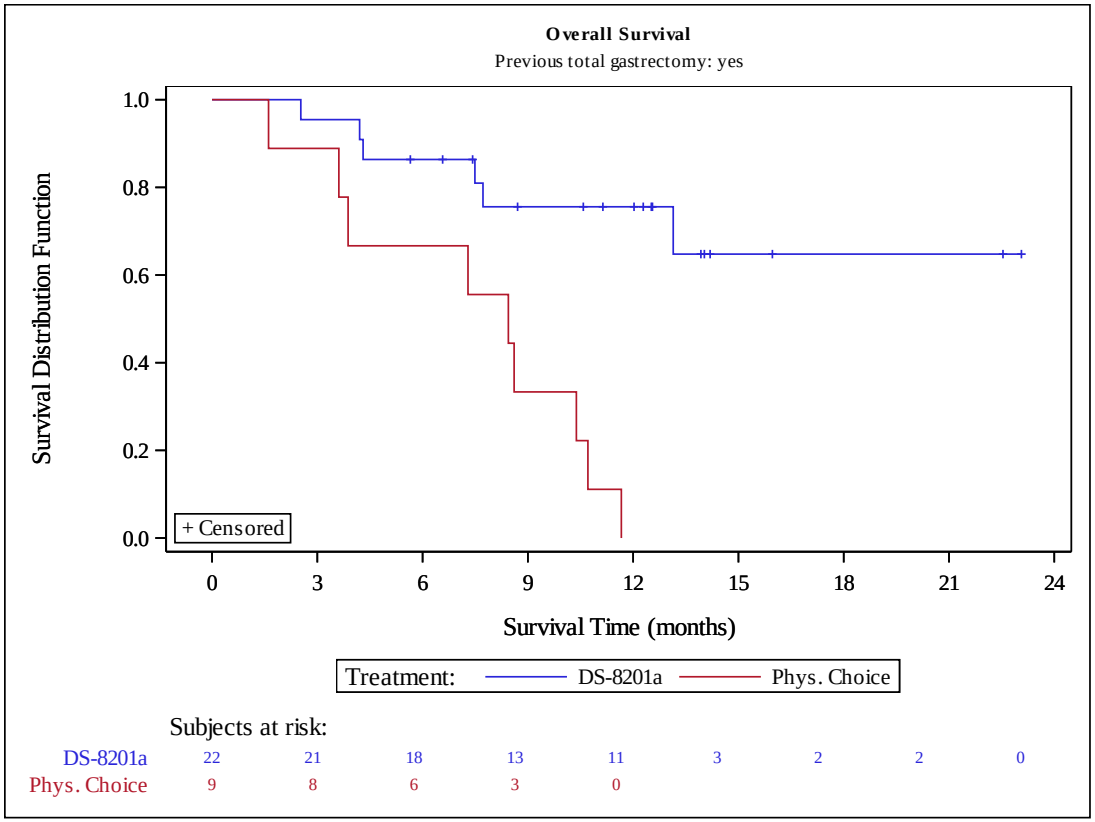
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



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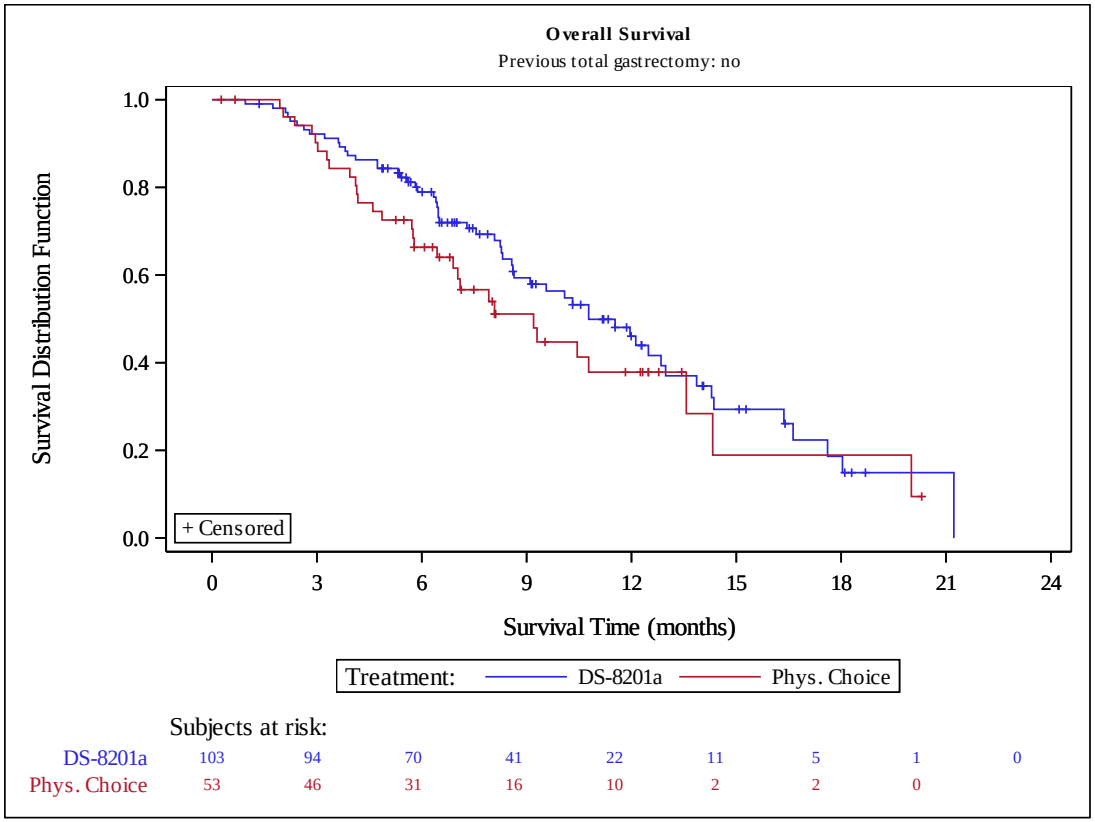
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



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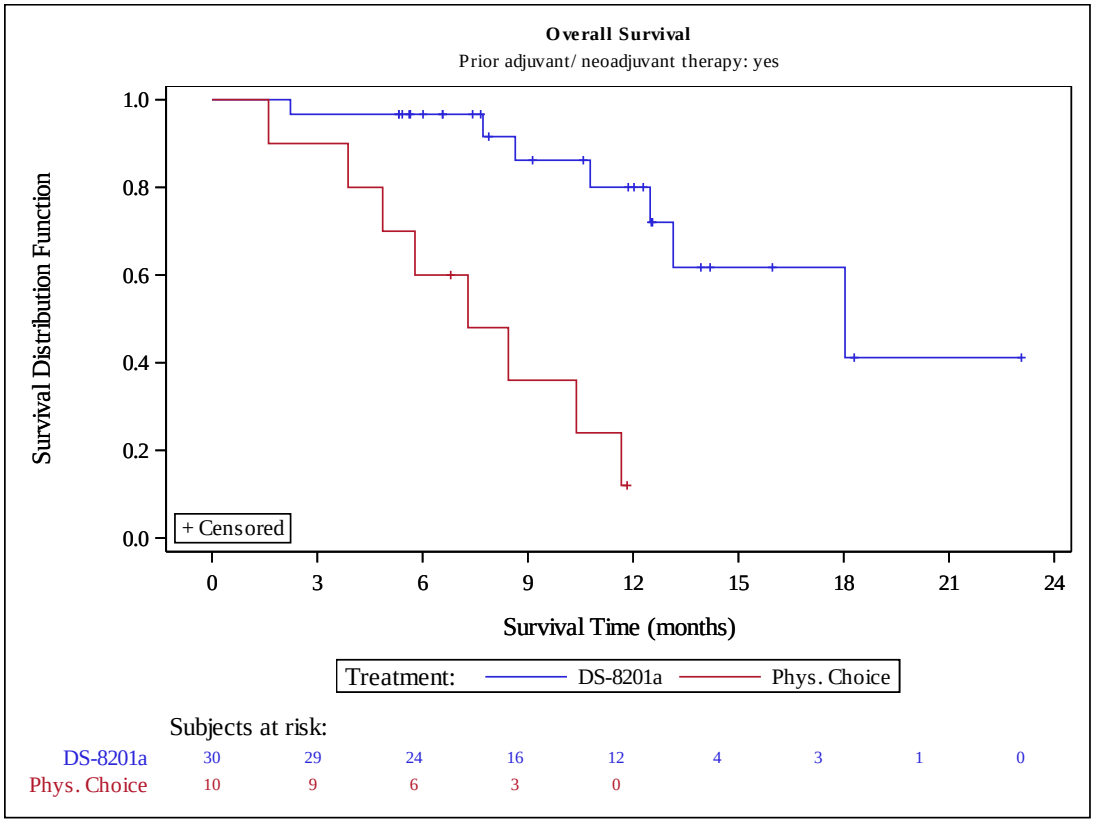
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



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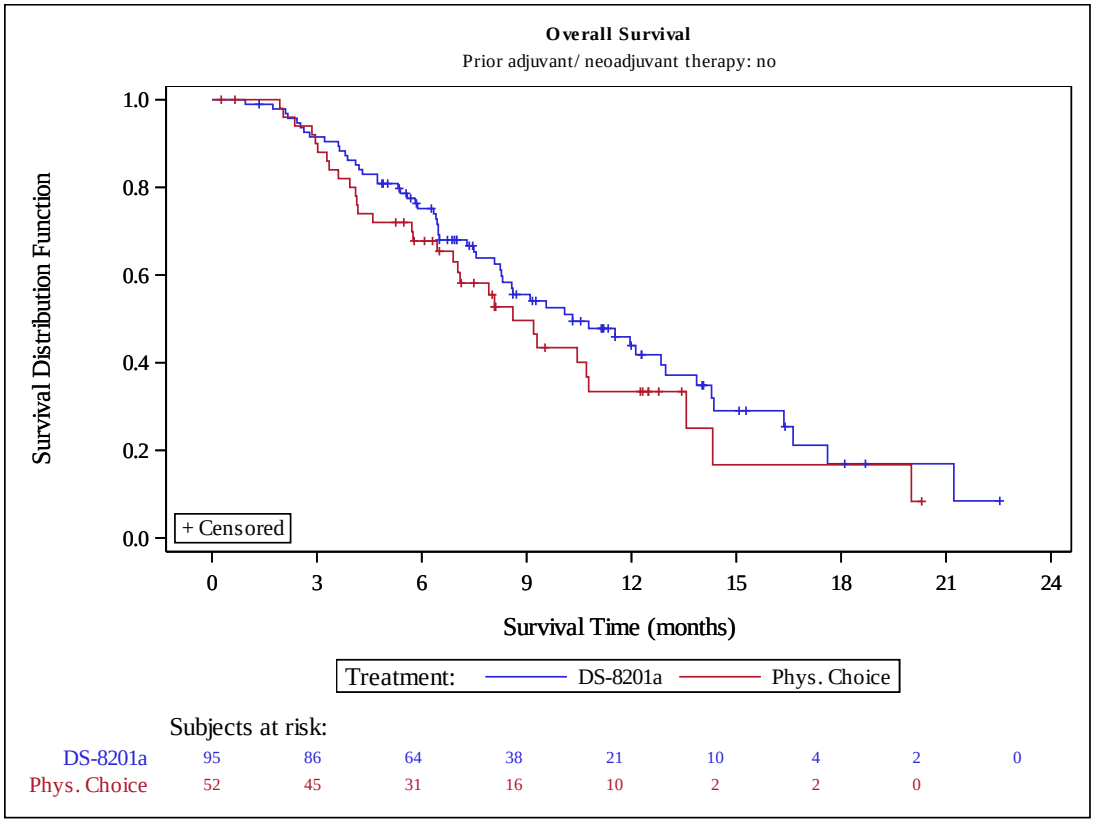
Full Analysis Set



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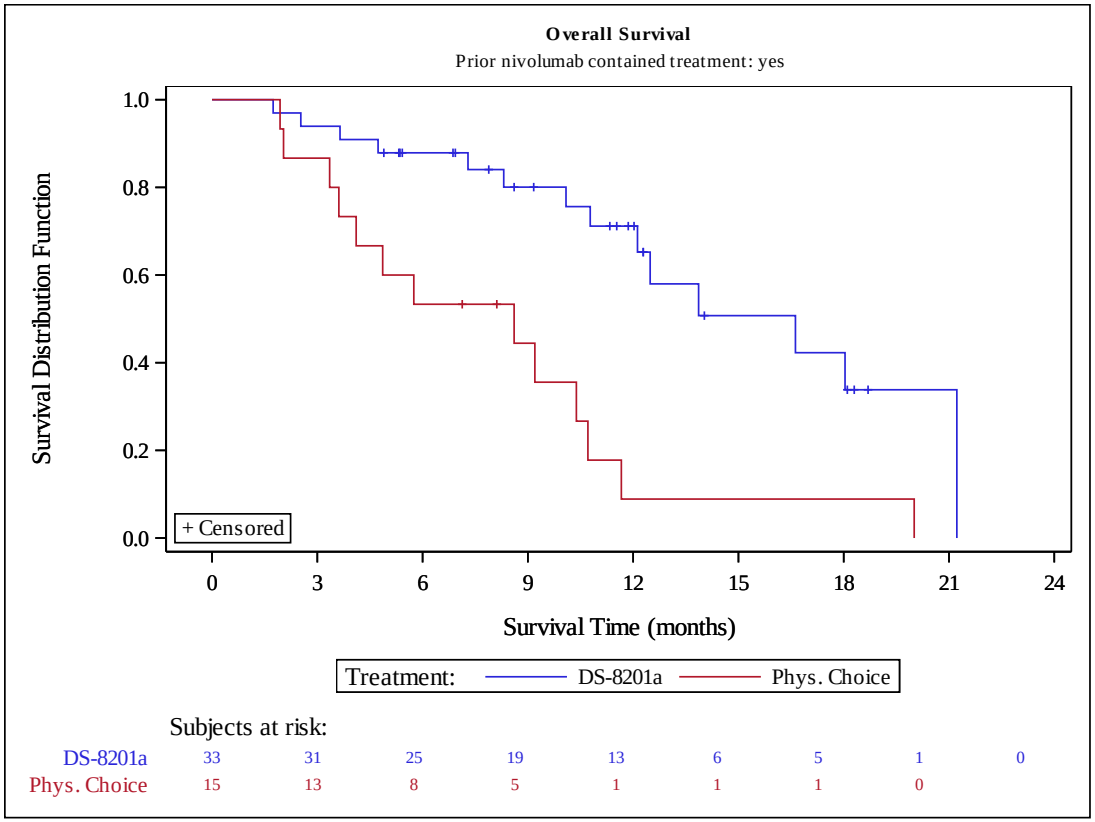

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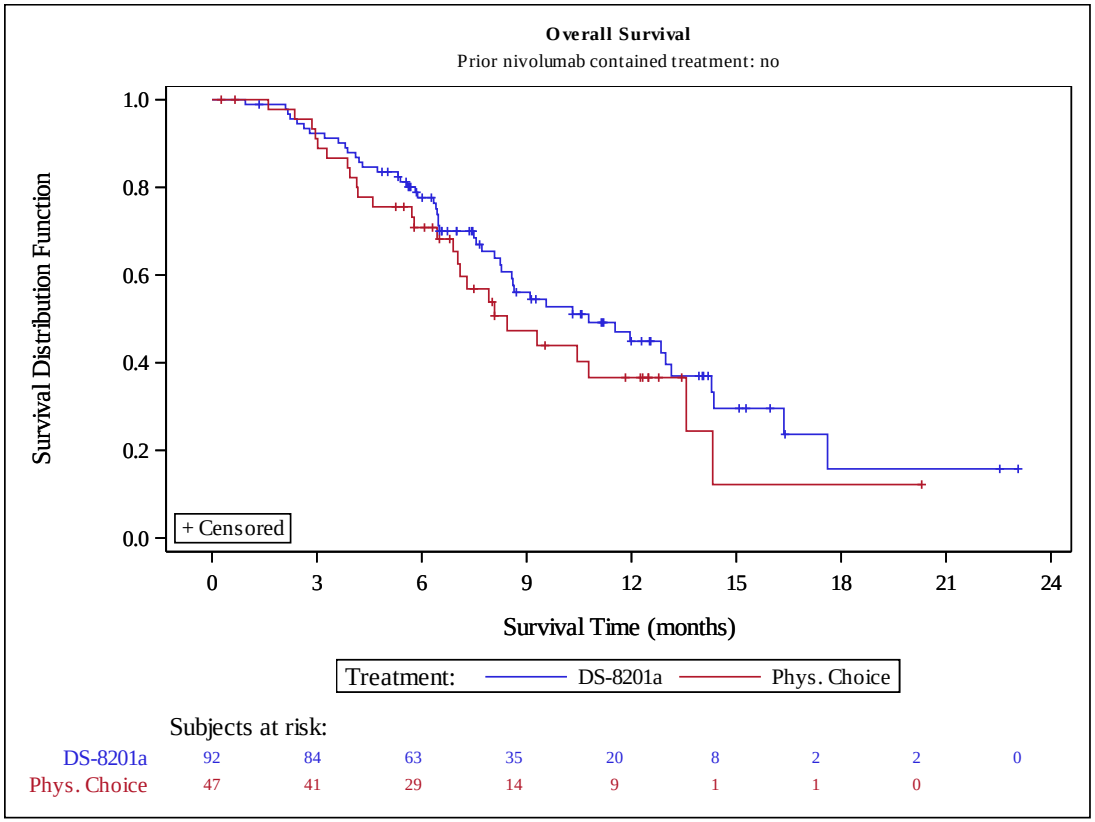

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Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

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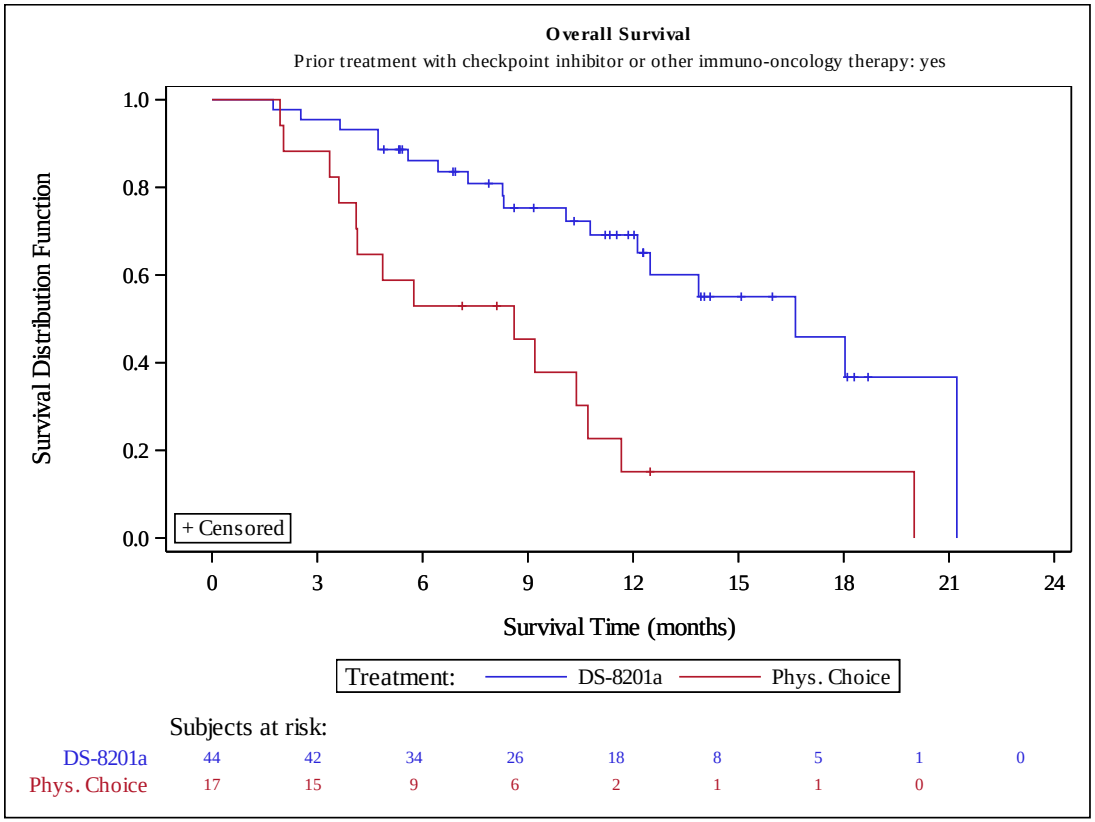

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
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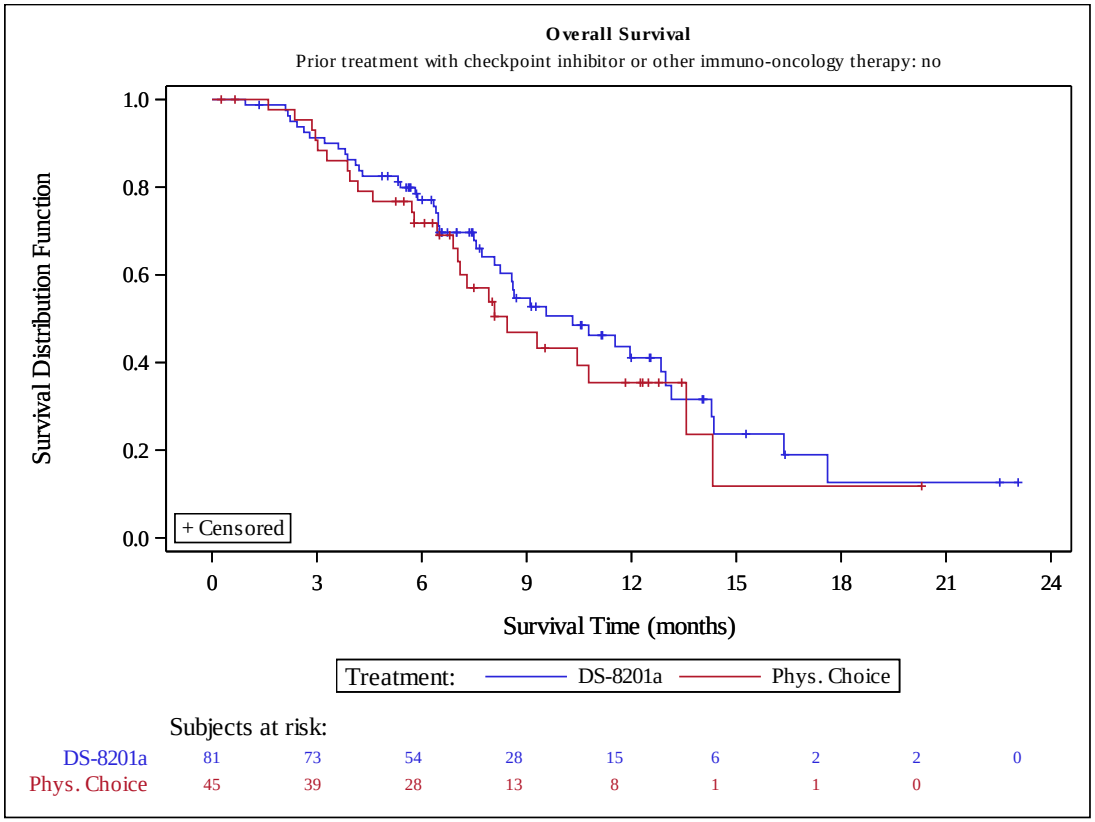
Kaplan Meier Plot of Overall Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Anhang 4-G 1.1.3: Morbidität

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Confirmed Objective Response Rate (ORR) based on ICR
Response Evaluable Set

	DS-8201a (N=119)	Phys. Choice (N=56)
Number of subjects with events, n (%)	51 (42.9)	7 (12.5)
95% CI [a]	33.8, 52.3	5.2, 24.1
Analysis DS-8201a vs. Phys. Choice (stratified)		
Relative Risk (95% CI) [b]	3.43 (1.67, 7.07)	
p-value	0.0008	
Odds Ratio (95% CI) [b]	5.29 (2.21, 12.66)	
p-value	0.0002	
Risk Difference (95% CI) [c]	30.39 (18.00, 42.78)	
p-value	<.0001	
CMH test [d]		
p-value	<.0001	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Relative Risk (95% CI) [e]	3.43 (1.66, 7.07)	
p-value	0.0008	
Odds Ratio (95% CI) [e]	5.25 (2.20, 12.55)	
p-value	0.0002	
Risk Difference (95% CI) [f]	30.36 (16.63, 44.08)	
p-value	<.0001	
CMH test [d]		
p-value	<.0001	

Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Mantel-Haenszel estimators for Common Odds Ratio and Relative Risks. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the common risk difference of two proportions.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[f] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Confirmed Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Region										0.8377
Japan	42/ 95 (44.2) [34.0, 54.8]	6/ 45 (13.3) [5.1, 26.8]	3.32 (1.52, 7.22)	0.0025	5.15 (1.99, 13.32)	0.0007	30.88 (15.16, 46.60)	0.0001	0.0003	
Korea	9/ 24 (37.5) [18.8, 59.4]	1/ 11 (9.1) [0.2, 41.3]	4.13 (0.59, 28.67)	0.1520	6.00 (0.65, 55.00)	0.1129	28.41 (-3.98, 60.80)	0.0856	0.0887	
Lines of prior systemic therapy										0.8072
2	21/ 60 (35.0) [23.1, 48.4]	4/ 33 (12.1) [3.4, 28.2]	2.89 (1.08, 7.70)	0.0342	3.90 (1.21, 12.61)	0.0228	22.88 (4.11, 41.65)	0.0169	0.0179	
3	17/ 34 (50.0) [32.4, 67.6]	3/ 17 (17.6) [3.8, 43.4]	2.83 (0.96, 8.35)	0.0589	4.67 (1.13, 19.24)	0.0331	32.35 (3.23, 61.48)	0.0295	0.0272	
>=4	13/ 25 (52.0) [31.3, 72.2]	0/ 6 (0.0) [0.0, 45.9]	7.27 (0.49, 107.78)	0.1493	14.04 (0.71, 275.74)	0.0820	52.00 (22.08, 81.92)	0.0007	0.0226	
Age										0.1616
<65 years	24/ 52 (46.2) [32.2, 60.5]	1/ 22 (4.5) [0.1, 22.8]	10.15 (1.46, 70.47)	0.0190	18.00 (2.25, 143.92)	0.0064	41.61 (22.27, 60.95)	<.0001	0.0006	
>=65 years	27/ 67 (40.3) [28.5, 53.0]	6/ 34 (17.6) [6.8, 34.5]	2.28 (1.04, 4.99)	0.0386	3.15 (1.15, 8.63)	0.0257	22.65 (3.05, 42.25)	0.0235	0.0225	
Sex										0.3894
female	10/ 30 (33.3) [17.3, 52.8]	2/ 12 (16.7) [2.1, 48.4]	2.00 (0.51, 7.81)	0.3188	2.50 (0.46, 13.65)	0.2900	16.67 (-16.17, 49.50)	0.3198	0.2859	
male	41/ 89 (46.1) [35.4, 57.0]	5/ 44 (11.4) [3.8, 24.6]	4.05 (1.72, 9.54)	0.0013	6.66 (2.40, 18.48)	0.0003	34.70 (19.04, 50.37)	<.0001	<.0001	
ECOG PS										0.4431
0	28/ 59 (47.5) [34.3, 60.9]	3/ 29 (10.3) [2.2, 27.4]	4.59 (1.52, 13.85)	0.0069	7.83 (2.13, 28.72)	0.0019	37.11 (17.65, 56.57)	0.0002	0.0007	
1	23/ 60 (38.3) [26.1, 51.8]	4/ 27 (14.8) [4.2, 33.7]	2.59 (0.99, 6.76)	0.0522	3.57 (1.10, 11.66)	0.0347	23.52 (2.64, 44.39)	0.0272	0.0292	
HER2 Status in central laboratory										0.0189
IHC 3+	45/ 91 (49.5) [38.8, 60.1]	4/ 44 (9.1) [2.5, 21.7]	5.44 (2.09, 14.17)	0.0005	9.78 (3.23, 29.59)	<.0001	40.36 (25.34, 55.37)	<.0001	<.0001	
IHC 2+/ISH +	6/ 28 (21.4) [8.3, 41.0]	3/ 12 (25.0) [5.5, 57.2]	0.86 (0.26, 2.87)	0.8028	0.82 (0.17, 4.00)	0.8044	-3.57 (-38.35, 31.21)	0.8405	0.8066	
Primary tumor location										0.9228
Gastric	43/104 (41.3) [31.8, 51.4]	6/ 49 (12.2) [4.6, 24.8]	3.38 (1.54, 7.39)	0.0023	5.05 (1.98, 12.92)	0.0007	29.10 (14.42, 43.79)	0.0001	0.0003	
GEJ	8/ 15 (53.3) [26.6, 78.7]	1/ 7 (14.3) [0.4, 57.9]	3.73 (0.57, 24.35)	0.1686	6.86 (0.66, 71.72)	0.1080	39.05 (-7.61, 85.71)	0.1010	0.0900	
Histological subtype										0.3688
intestinal	35/ 86 (40.7) [30.2, 51.8]	7/ 37 (18.9) [8.0, 35.2]	2.15 (1.05, 4.39)	0.0355	2.94 (1.16, 7.44)	0.0228	21.78 (3.50, 40.05)	0.0195	0.0200	
diffuse	15/ 27 (55.6) [35.3, 74.5]	0/ 14 (0.0) [0.0, 23.2]	16.61 (1.07, 258.60)	0.0449	35.96 (1.95, 664.08)	0.0160	55.56 (31.39, 79.72)	<.0001	0.0005	
others	1/ 6 (16.7) [0.4, 64.1]	0/ 5 (0.0) [0.0, 52.2]	2.57 (0.13, 52.12)	0.5384	3.00 (0.10, 90.96)	0.5280	16.67 (-31.49, 64.82)	0.4975	0.3613	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Confirmed Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Number of metastatic sites										0.9739
<2	12/ 21 (57.1) [34.0, 78.2]	1/ 6 (16.7) [0.4, 64.1]	3.43 (0.55, 21.31)	0.1863	6.67 (0.66, 67.46)	0.1082	40.48 (-6.81, 87.76)	0.0934	0.0859	
>= 2	39/ 98 (39.8) [30.0, 50.2]	6/ 50 (12.0) [4.5, 24.3]	3.32 (1.51, 7.30)	0.0029	4.85 (1.89, 12.46)	0.0010	27.80 (13.06, 42.54)	0.0002	0.0005	
Previous total gastrectomy										0.3991
yes	11/ 21 (52.4) [29.8, 74.3]	0/ 8 (0.0) [0.0, 36.9]	9.41 (0.62, 143.28)	0.1067	18.62 (0.95, 363.77)	0.0538	52.38 (22.39, 82.37)	0.0006	0.0107	
no	40/ 98 (40.8) [31.0, 51.2]	7/ 48 (14.6) [6.1, 27.8]	2.80 (1.36, 5.78)	0.0054	4.04 (1.65, 9.91)	0.0023	26.23 (10.74, 41.73)	0.0009	0.0015	
Prior adjuvant/ neoadjuvant therapy										0.3287
yes	17/ 29 (58.6) [38.9, 76.5]	0/ 8 (0.0) [0.0, 36.9]	10.50 (0.70, 157.91)	0.0891	23.80 (1.25, 451.58)	0.0348	58.62 (32.72, 84.52)	<.0001	0.0037	
no	34/ 90 (37.8) [27.8, 48.6]	7/ 48 (14.6) [6.1, 27.8]	2.59 (1.24, 5.40)	0.0111	3.56 (1.43, 8.81)	0.0062	23.19 (7.45, 38.93)	0.0039	0.0047	
Prior ramucirumab contained treatment										0.7481
yes	38/ 89 (42.7) [32.3, 53.6]	5/ 37 (13.5) [4.5, 28.8]	3.16 (1.35, 7.39)	0.0080	4.77 (1.70, 13.38)	0.0030	29.18 (12.21, 46.16)	0.0008	0.0017	
no	13/ 30 (43.3) [25.5, 62.6]	2/ 19 (10.5) [1.3, 33.1]	4.12 (1.04, 16.25)	0.0434	6.50 (1.27, 33.29)	0.0247	32.81 (6.04, 59.57)	0.0163	0.0163	
Prior nivolumab contained treatment										0.6886
yes	20/ 33 (60.6) [42.1, 77.1]	3/ 14 (21.4) [4.7, 50.8]	2.83 (1.00, 8.00)	0.0501	5.64 (1.32, 24.17)	0.0198	39.18 (6.89, 71.47)	0.0174	0.0151	
no	31/ 86 (36.0) [26.0, 47.1]	4/ 42 (9.5) [2.7, 22.6]	3.78 (1.43, 10.02)	0.0074	5.35 (1.75, 16.42)	0.0033	26.52 (11.27, 41.78)	0.0007	0.0016	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy										0.8545
yes	25/ 44 (56.8) [41.0, 71.7]	3/ 16 (18.8) [4.0, 45.6]	3.03 (1.06, 8.68)	0.0389	5.70 (1.42, 22.89)	0.0141	38.07 (9.72, 66.41)	0.0085	0.0095	
no	26/ 75 (34.7) [24.0, 46.5]	4/ 40 (10.0) [2.8, 23.7]	3.47 (1.30, 9.24)	0.0129	4.78 (1.53, 14.89)	0.0070	24.67 (8.52, 40.81)	0.0027	0.0043	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug										0.7327
yes	8/ 22 (36.4) [17.2, 59.3]	0/ 6 (0.0) [0.0, 45.9]	5.17 (0.34, 78.84)	0.2369	7.62 (0.38, 152.83)	0.1843	36.36 (5.66, 67.07)	0.0203	0.0861	
no	43/ 97 (44.3) [34.2, 54.8]	7/ 50 (14.0) [5.8, 26.7]	3.17 (1.54, 6.52)	0.0018	4.89 (2.00, 11.95)	0.0005	30.33 (15.02, 45.64)	0.0001	0.0002	
Presence of liver metastasis at baseline										0.7682
yes	25/ 67 (37.3) [25.8, 50.0]	4/ 33 (12.1) [3.4, 28.2]	3.08 (1.17, 8.12)	0.0230	4.32 (1.36, 13.72)	0.0132	25.19 (6.87, 43.52)	0.0071	0.0094	
no	26/ 52 (50.0) [35.8, 64.2]	3/ 23 (13.0) [2.8, 33.6]	3.83 (1.29, 11.40)	0.0156	6.67 (1.76, 25.20)	0.0052	36.96 (14.48, 59.43)	0.0013	0.0026	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Confirmed Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Renal impairment at baseline										0.3891
normal	16/ 32 (50.0) [31.9, 68.1]	0/ 12 (0.0) [0.0, 26.5]	13.00 (0.84, 201.19)	0.0665	25.00 (1.36, 457.96)	0.0300	50.00 (26.95, 73.05)	<.0001	0.0024	
mild	20/ 52 (38.5) [25.3, 53.0]	3/ 26 (11.5) [2.4, 30.2]	3.33 (1.09, 10.20)	0.0349	4.79 (1.27, 18.05)	0.0206	26.92 (5.99, 47.85)	0.0117	0.0146	
moderate	15/ 35 (42.9) [26.3, 60.6]	4/ 18 (22.2) [6.4, 47.6]	1.93 (0.75, 4.96)	0.1732	2.63 (0.72, 9.61)	0.1448	20.63 (-8.82, 50.09)	0.1698	0.1417	
Hepatic impairment at baseline										0.6692
normal	37/ 84 (44.0) [33.2, 55.3]	6/ 43 (14.0) [5.3, 27.9]	3.16 (1.45, 6.89)	0.0039	4.85 (1.85, 12.73)	0.0013	30.09 (13.50, 46.68)	0.0004	0.0007	
mild	13/ 34 (38.2) [22.2, 56.4]	1/ 13 (7.7) [0.2, 36.0]	4.97 (0.72, 34.28)	0.1036	7.43 (0.86, 64.03)	0.0681	30.54 (3.39, 57.69)	0.0275	0.0427	
moderate	1/ 1 (100.0) [2.5, 100.0]	0 [NE, NE]	NE	NE	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors										0.4610
yes	3/ 7 (42.9) [9.9, 81.6]	1/ 4 (25.0) [0.6, 80.6]	1.71 (0.26, 11.47)	0.5784	2.25 (0.15, 33.93)	0.5580	17.86 (-57.86, 93.58)	0.6439	0.5723	
no	48/112 (42.9) [33.5, 52.6]	6/ 52 (11.5) [4.4, 23.4]	3.71 (1.70, 8.12)	0.0010	5.75 (2.27, 14.56)	0.0002	31.32 (17.29, 45.35)	<.0001	<.0001	
Most recently treatment with irinotecan or other topoisomerase I inhibitors										0.4228
yes	1/ 2 (50.0) [1.3, 98.7]	1/ 3 (33.3) [0.8, 90.6]	1.50 (0.18, 12.46)	0.7074	2.00 (0.05, 78.25)	0.7110	16.67 (-100.00, 100.00)	0.7795	0.7389	
no	50/117 (42.7) [33.6, 52.2]	6/ 53 (11.3) [4.3, 23.0]	3.77 (1.73, 8.25)	0.0009	5.85 (2.32, 14.75)	0.0002	31.41 (17.67, 45.16)	<.0001	<.0001	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Objective Response Rate (ORR) based on ICR
Response Evaluable Set

	DS-8201a (N=119)	Phys. Choice (N=56)
Number of subjects with events, n (%)	61 (51.3)	8 (14.3)
95% CI [a]	41.9, 60.5	6.4, 26.2
Analysis DS-8201a vs. Phys. Choice (stratified)		
Relative Risk (95% CI) [b]	3.59 (1.84, 6.99)	
p-value	0.0002	
Odds Ratio (95% CI) [b]	6.28 (2.74, 14.41)	
p-value	<.0001	
Risk Difference (95% CI) [c]	36.97 (24.13, 49.82)	
p-value	<.0001	
CMH test [d]		
p-value	<.0001	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Relative Risk (95% CI) [e]	3.59 (1.85, 6.98)	
p-value	0.0002	
Odds Ratio (95% CI) [e]	6.31 (2.75, 14.48)	
p-value	<.0001	
Risk Difference (95% CI) [f]	36.97 (22.83, 51.12)	
p-value	<.0001	
CMH test [d]		
p-value	<.0001	

Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Mantel-Haenszel estimators for Common Odds Ratio and Relative Risks. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the common risk difference of two proportions.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[f] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Region										0.5585
Japan	48/ 95 (50.5) [40.1, 60.9]	7/ 45 (15.6) [6.5, 29.5]	3.25 (1.60, 6.60)	0.0011	5.54 (2.25, 13.65)	0.0002	34.97 (18.73, 51.21)	<.0001	<.0001	
Korea	13/ 24 (54.2) [32.8, 74.4]	1/ 11 (9.1) [0.2, 41.3]	5.96 (0.89, 40.02)	0.0663	11.82 (1.30, 107.40)	0.0283	45.08 (12.26, 77.90)	0.0071	0.0128	
Lines of prior systemic therapy										0.9266
2	29/ 60 (48.3) [35.2, 61.6]	4/ 33 (12.1) [3.4, 28.2]	3.99 (1.53, 10.36)	0.0045	6.78 (2.12, 21.67)	0.0012	36.21 (17.01, 55.41)	0.0002	0.0005	
3	18/ 34 (52.9) [35.1, 70.2]	3/ 17 (17.6) [3.8, 43.4]	3.00 (1.02, 8.79)	0.0451	5.25 (1.27, 21.66)	0.0218	35.29 (6.19, 64.40)	0.0175	0.0168	
>=4	14/ 25 (56.0) [34.9, 75.6]	1/ 6 (16.7) [0.4, 64.1]	3.36 (0.54, 20.79)	0.1925	6.36 (0.65, 62.69)	0.1128	39.33 (-6.61, 85.27)	0.0933	0.0885	
Age										0.0987
<65 years	30/ 52 (57.7) [43.2, 71.3]	1/ 22 (4.5) [0.1, 22.8]	12.69 (1.84, 87.36)	0.0098	28.64 (3.58, 229.25)	0.0016	53.15 (33.91, 72.38)	<.0001	<.0001	
>=65 years	31/ 67 (46.3) [34.0, 58.9]	7/ 34 (20.6) [8.7, 37.9]	2.25 (1.11, 4.57)	0.0251	3.32 (1.27, 8.67)	0.0143	25.68 (5.37, 45.99)	0.0132	0.0122	
Sex										0.6776
female	14/ 30 (46.7) [28.3, 65.7]	2/ 12 (16.7) [2.1, 48.4]	2.80 (0.75, 10.50)	0.1268	4.38 (0.82, 23.45)	0.0849	30.00 (-3.46, 63.46)	0.0789	0.0739	
male	47/ 89 (52.8) [41.9, 63.5]	6/ 44 (13.6) [5.2, 27.4]	3.87 (1.79, 8.36)	0.0006	7.09 (2.72, 18.44)	<.0001	39.17 (22.97, 55.38)	<.0001	<.0001	
ECOG PS										0.3685
0	31/ 59 (52.5) [39.1, 65.7]	3/ 29 (10.3) [2.2, 27.4]	5.08 (1.69, 15.24)	0.0037	9.60 (2.62, 35.20)	0.0006	42.20 (22.74, 61.66)	<.0001	0.0001	
1	30/ 60 (50.0) [36.8, 63.2]	5/ 27 (18.5) [6.3, 38.1]	2.70 (1.18, 6.20)	0.0191	4.40 (1.47, 13.15)	0.0080	31.48 (9.44, 53.52)	0.0051	0.0059	
HER2 Status in central laboratory										0.0382
IHC 3+	53/ 91 (58.2) [47.4, 68.5]	5/ 44 (11.4) [3.8, 24.6]	5.13 (2.21, 11.91)	0.0001	10.88 (3.92, 30.17)	<.0001	46.88 (31.39, 62.37)	<.0001	<.0001	
IHC 2+/ISH +	8/ 28 (28.6) [13.2, 48.7]	3/ 12 (25.0) [5.5, 57.2]	1.14 (0.36, 3.58)	0.8187	1.20 (0.26, 5.61)	0.8168	3.57 (-32.05, 39.19)	0.8442	0.8189	
Primary tumor location										0.8577
Gastric	52/104 (50.0) [40.0, 60.0]	7/ 49 (14.3) [5.9, 27.2]	3.50 (1.72, 7.14)	0.0006	6.00 (2.47, 14.58)	<.0001	35.71 (20.49, 50.94)	<.0001	<.0001	
GEJ	9/ 15 (60.0) [32.3, 83.7]	1/ 7 (14.3) [0.4, 57.9]	4.20 (0.65, 27.01)	0.1307	9.00 (0.85, 94.90)	0.0675	45.71 (-0.63, 92.06)	0.0532	0.0500	
Histological subtype										0.2902
intestinal	41/ 86 (47.7) [36.8, 58.7]	8/ 37 (21.6) [9.8, 38.2]	2.20 (1.15, 4.23)	0.0175	3.30 (1.36, 8.04)	0.0085	26.05 (7.17, 44.94)	0.0069	0.0070	
diffuse	18/ 27 (66.7) [46.0, 83.5]	0/ 14 (0.0) [0.0, 23.2]	19.82 (1.28, 306.40)	0.0325	56.47 (3.03,1053.10)	0.0069	66.67 (43.46, 89.87)	<.0001	<.0001	
others	2/ 6 (33.3) [4.3, 77.7]	0/ 5 (0.0) [0.0, 52.2]	4.29 (0.25, 72.90)	0.3142	6.11 (0.23, 162.73)	0.2797	33.33 (-22.72, 89.39)	0.2438	0.1736	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Number of metastatic sites										0.9522
<2	13/ 21 (61.9) [38.4, 81.9]	1/ 6 (16.7) [0.4, 64.1]	3.71 (0.60, 22.93)	0.1577	8.13 (0.80, 82.73)	0.0768	45.24 (-1.82, 92.29)	0.0595	0.0549	
>= 2	48/ 98 (49.0) [38.7, 59.3]	7/ 50 (14.0) [5.8, 26.7]	3.50 (1.71, 7.16)	0.0006	5.90 (2.42, 14.38)	<.0001	34.98 (19.67, 50.29)	<.0001	<.0001	
Previous total gastrectomy										0.7782
yes	12/ 21 (57.1) [34.0, 78.2]	1/ 8 (12.5) [0.3, 52.7]	4.57 (0.70, 29.67)	0.1113	9.33 (0.97, 90.03)	0.0534	44.64 (4.82, 84.47)	0.0280	0.0338	
no	49/ 98 (50.0) [39.7, 60.3]	7/ 48 (14.6) [6.1, 27.8]	3.43 (1.68, 6.99)	0.0007	5.86 (2.40, 14.32)	0.0001	35.42 (19.80, 51.03)	<.0001	<.0001	
Prior adjuvant/ neoadjuvant therapy										0.6820
yes	18/ 29 (62.1) [42.3, 79.3]	1/ 8 (12.5) [0.3, 52.7]	4.97 (0.78, 31.75)	0.0905	11.45 (1.24, 106.05)	0.0318	49.57 (12.66, 86.48)	0.0085	0.0143	
no	43/ 90 (47.8) [37.1, 58.6]	7/ 48 (14.6) [6.1, 27.8]	3.28 (1.60, 6.72)	0.0012	5.36 (2.17, 13.21)	0.0003	33.19 (17.24, 49.15)	<.0001	0.0001	
Prior ramucirumab contained treatment										0.3559
yes	42/ 89 (47.2) [36.5, 58.1]	6/ 37 (16.2) [6.2, 32.0]	2.91 (1.35, 6.25)	0.0062	4.62 (1.75, 12.16)	0.0020	30.97 (13.29, 48.66)	0.0006	0.0012	
no	19/ 30 (63.3) [43.9, 80.1]	2/ 19 (10.5) [1.3, 33.1]	6.02 (1.58, 22.95)	0.0086	14.68 (2.84, 75.88)	0.0013	52.81 (26.42, 79.19)	<.0001	0.0003	
Prior nivolumab contained treatment										0.2789
yes	22/ 33 (66.7) [48.2, 82.0]	4/ 14 (28.6) [8.4, 58.1]	2.33 (0.98, 5.53)	0.0542	5.00 (1.27, 19.62)	0.0210	38.10 (4.40, 71.79)	0.0267	0.0175	
no	39/ 86 (45.3) [34.6, 56.5]	4/ 42 (9.5) [2.7, 22.6]	4.76 (1.82, 12.44)	0.0015	7.88 (2.59, 24.02)	0.0003	35.83 (20.29, 51.36)	<.0001	<.0001	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy										0.4691
yes	29/ 44 (65.9) [50.1, 79.5]	4/ 16 (25.0) [7.3, 52.4]	2.64 (1.10, 6.32)	0.0299	5.80 (1.59, 21.11)	0.0077	40.91 (11.22, 70.59)	0.0069	0.0052	
no	32/ 75 (42.7) [31.3, 54.6]	4/ 40 (10.0) [2.8, 23.7]	4.27 (1.62, 11.21)	0.0032	6.70 (2.16, 20.73)	0.0010	32.67 (16.20, 49.13)	0.0001	0.0003	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug										0.6614
yes	9/ 22 (40.9) [20.7, 63.6]	1/ 6 (16.7) [0.4, 64.1]	2.45 (0.38, 15.74)	0.3436	3.46 (0.34, 34.84)	0.2919	24.24 (-22.58, 71.06)	0.3102	0.2807	
no	52/ 97 (53.6) [43.2, 63.8]	7/ 50 (14.0) [5.8, 26.7]	3.83 (1.88, 7.80)	0.0002	7.10 (2.91, 17.34)	<.0001	39.61 (24.27, 54.94)	<.0001	<.0001	
Presence of liver metastasis at baseline										0.5337
yes	30/ 67 (44.8) [32.6, 57.4]	5/ 33 (15.2) [5.1, 31.9]	2.96 (1.26, 6.91)	0.0125	4.54 (1.56, 13.19)	0.0054	29.62 (10.29, 48.96)	0.0027	0.0037	
no	31/ 52 (59.6) [45.1, 73.0]	3/ 23 (13.0) [2.8, 33.6]	4.57 (1.55, 13.44)	0.0058	9.84 (2.59, 37.36)	0.0008	46.57 (24.27, 68.87)	<.0001	0.0002	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Renal impairment at baseline										0.4350
normal	19/ 32 (59.4) [40.6, 76.3]	0/ 12 (0.0) [0.0, 26.5]	15.36 (1.00, 236.22)	0.0501	36.11 (1.97, 663.30)	0.0157	59.38 (36.63, 82.12)	<.0001	0.0005	
mild	24/ 52 (46.2) [32.2, 60.5]	4/ 26 (15.4) [4.4, 34.9]	3.00 (1.16, 7.74)	0.0231	4.71 (1.42, 15.60)	0.0111	30.77 (8.50, 53.04)	0.0068	0.0080	
moderate	18/ 35 (51.4) [34.0, 68.6]	4/ 18 (22.2) [6.4, 47.6]	2.31 (0.92, 5.82)	0.0746	3.71 (1.02, 13.52)	0.0472	29.21 (-0.36, 58.77)	0.0528	0.0429	
Hepatic impairment at baseline										0.6264
normal	46/ 84 (54.8) [43.5, 65.7]	6/ 43 (14.0) [5.3, 27.9]	3.92 (1.82, 8.45)	0.0005	7.46 (2.85, 19.57)	<.0001	40.81 (24.20, 57.42)	<.0001	<.0001	
mild	14/ 34 (41.2) [24.6, 59.3]	2/ 13 (15.4) [1.9, 45.4]	2.68 (0.70, 10.19)	0.1489	3.85 (0.74, 20.13)	0.1102	25.79 (-5.18, 56.77)	0.1027	0.0987	
moderate	1/ 1 (100.0) [2.5, 100.0]	0 [NE, NE]	NE	NE	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors										0.4351
yes	3/ 7 (42.9) [9.9, 81.6]	1/ 4 (25.0) [0.6, 80.6]	1.71 (0.26, 11.47)	0.5784	2.25 (0.15, 33.93)	0.5580	17.86 (-57.86, 93.58)	0.6439	0.5723	
no	58/112 (51.8) [42.1, 61.3]	7/ 52 (13.5) [5.6, 25.8]	3.85 (1.89, 7.84)	0.0002	6.90 (2.87, 16.62)	<.0001	38.32 (23.81, 52.84)	<.0001	<.0001	
Most recently treatment with irinotecan or other topoisomerase I inhibitors										0.4040
yes	1/ 2 (50.0) [1.3, 98.7]	1/ 3 (33.3) [0.8, 90.6]	1.50 (0.18, 12.46)	0.7074	2.00 (0.05, 78.25)	0.7110	16.67 (-100.00, 100.00)	0.7795	0.7389	
no	60/117 (51.3) [41.9, 60.6]	7/ 53 (13.2) [5.5, 25.3]	3.88 (1.90, 7.92)	0.0002	6.92 (2.89, 16.58)	<.0001	38.07 (23.85, 52.29)	<.0001	<.0001	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Confirmed Disease Control Rate (DCR) based on ICR
Response Evaluable Set

	DS-8201a (N=119)	Phys. Choice (N=56)
Number of subjects with events, n (%)	102 (85.7)	35 (62.5)
95% CI [a]	78.1, 91.5	48.5, 75.1
Analysis DS-8201a vs. Phys. Choice (stratified)		
Relative Risk (95% CI) [b]	1.37 (1.11, 1.70)	
p-value	0.0040	
Odds Ratio (95% CI) [b]	3.62 (1.71, 7.64)	
p-value	0.0007	
Risk Difference (95% CI) [c]	23.24 (9.11, 37.38)	
p-value	0.0013	
CMH test [d]		
p-value	0.0005	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Relative Risk (95% CI) [e]	1.37 (1.11, 1.70)	
p-value	0.0041	
Odds Ratio (95% CI) [e]	3.60 (1.71, 7.59)	
p-value	0.0008	
Risk Difference (95% CI) [f]	23.21 (7.75, 38.68)	
p-value	0.0033	
CMH test [d]		
p-value	0.0005	

Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Mantel-Haenszel estimators for Common Odds Ratio and Relative Risks. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the common risk difference of two proportions.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[f] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Confirmed Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Region										0.6742
Japan	82/ 95 (86.3) [77.7, 92.5]	29/ 45 (64.4) [48.8, 78.1]	1.34 (1.06, 1.69)	0.0133	3.48 (1.49, 8.11)	0.0038	21.87 (4.63, 39.11)	0.0129	0.0030	
Korea	20/ 24 (83.3) [62.6, 95.3]	6/ 11 (54.5) [23.4, 83.3]	1.53 (0.87, 2.70)	0.1439	4.17 (0.84, 20.64)	0.0805	28.79 (-10.83, 68.40)	0.1544	0.0746	
Lines of prior systemic therapy										0.7867
2	49/ 60 (81.7) [69.6, 90.5]	20/ 33 (60.6) [42.1, 77.1]	1.35 (1.00, 1.82)	0.0514	2.90 (1.11, 7.54)	0.0294	21.06 (-0.62, 42.74)	0.0569	0.0272	
3	31/ 34 (91.2) [76.3, 98.1]	12/ 17 (70.6) [44.0, 89.7]	1.29 (0.93, 1.79)	0.1218	4.31 (0.89, 20.88)	0.0699	20.59 (-7.49, 48.67)	0.1507	0.0592	
>=4	22/ 25 (88.0) [68.8, 97.5]	3/ 6 (50.0) [11.8, 88.2]	1.76 (0.78, 3.97)	0.1730	7.33 (0.99, 54.40)	0.0513	38.00 (-14.32, 90.32)	0.1546	0.0374	
Age										0.4232
<65 years	44/ 52 (84.6) [71.9, 93.1]	12/ 22 (54.5) [32.2, 75.6]	1.55 (1.04, 2.31)	0.0309	4.58 (1.48, 14.16)	0.0081	30.07 (3.83, 56.31)	0.0247	0.0062	
>=65 years	58/ 67 (86.6) [76.0, 93.7]	23/ 34 (67.6) [49.5, 82.6]	1.28 (1.00, 1.64)	0.0540	3.08 (1.13, 8.42)	0.0281	18.92 (-1.02, 38.86)	0.0629	0.0249	
Sex										0.7862
female	26/ 30 (86.7) [69.3, 96.2]	8/ 12 (66.7) [34.9, 90.1]	1.30 (0.85, 1.99)	0.2252	3.25 (0.66, 16.04)	0.1479	20.00 (-15.15, 55.15)	0.2647	0.1407	
male	76/ 89 (85.4) [76.3, 92.0]	27/ 44 (61.4) [45.5, 75.6]	1.39 (1.08, 1.79)	0.0095	3.68 (1.58, 8.57)	0.0025	24.03 (6.18, 41.88)	0.0083	0.0019	
ECOG PS										0.9816
0	53/ 59 (89.8) [79.2, 96.2]	19/ 29 (65.5) [45.7, 82.1]	1.37 (1.04, 1.81)	0.0259	4.65 (1.49, 14.53)	0.0082	24.31 (2.80, 45.83)	0.0267	0.0057	
1	49/ 60 (81.7) [69.6, 90.5]	16/ 27 (59.3) [38.8, 77.6]	1.38 (0.99, 1.93)	0.0606	3.06 (1.12, 8.40)	0.0296	22.41 (-1.24, 46.05)	0.0633	0.0270	
HER2 Status in central laboratory										0.2925
IHC 3+	78/ 91 (85.7) [76.8, 92.2]	26/ 44 (59.1) [43.2, 73.7]	1.45 (1.12, 1.88)	0.0050	4.15 (1.79, 9.62)	0.0009	26.62 (8.73, 44.52)	0.0035	0.0006	
IHC 2+/ISH +	24/ 28 (85.7) [67.3, 96.0]	9/ 12 (75.0) [42.8, 94.5]	1.14 (0.80, 1.64)	0.4672	2.00 (0.37, 10.75)	0.4192	10.71 (-22.95, 44.38)	0.5328	0.4197	
Primary tumor location										0.5727
Gastric	88/104 (84.6) [76.2, 90.9]	31/ 49 (63.3) [48.3, 76.6]	1.34 (1.06, 1.68)	0.0126	3.19 (1.45, 7.02)	0.0039	21.35 (4.67, 38.03)	0.0121	0.0031	
GEJ	14/ 15 (93.3) [68.1, 99.8]	4/ 7 (57.1) [18.4, 90.1]	1.63 (0.85, 3.15)	0.1425	10.50 (0.84, 130.66)	0.0676	36.19 (-13.06, 85.44)	0.1498	0.0452	
Histological subtype										0.6249
intestinal	76/ 86 (88.4) [79.7, 94.3]	24/ 37 (64.9) [47.5, 79.8]	1.36 (1.06, 1.75)	0.0150	4.12 (1.60, 10.58)	0.0033	23.51 (4.77, 42.25)	0.0140	0.0023	
diffuse	23/ 27 (85.2) [66.3, 95.8]	8/ 14 (57.1) [28.9, 82.3]	1.49 (0.92, 2.41)	0.1031	4.31 (0.96, 19.31)	0.0561	28.04 (-6.56, 62.65)	0.1122	0.0502	
others	3/ 6 (50.0) [11.8, 88.2]	3/ 5 (60.0) [14.7, 94.7]	0.83 (0.28, 2.44)	0.7392	0.67 (0.06, 7.35)	0.7406	-10.00 (-87.02, 67.02)	0.7991	0.7518	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Confirmed Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Number of metastatic sites										0.8572
<2	20/ 21 (95.2) [76.2, 99.9]	4/ 6 (66.7) [22.3, 95.7]	1.43 (0.80, 2.54)	0.2231	10.00 (0.72, 138.68)	0.0861	28.57 (-20.95, 78.09)	0.2581	0.0539	
>= 2	82/ 98 (83.7) [74.8, 90.4]	31/ 50 (62.0) [47.2, 75.3]	1.35 (1.07, 1.71)	0.0120	3.14 (1.44, 6.87)	0.0042	21.67 (4.85, 38.50)	0.0116	0.0034	
Previous total gastrectomy										0.3962
yes	18/ 21 (85.7) [63.7, 97.0]	6/ 8 (75.0) [34.9, 96.8]	1.14 (0.74, 1.77)	0.5488	2.00 (0.27, 14.98)	0.4999	10.71 (-31.45, 52.88)	0.6184	0.5023	
no	84/ 98 (85.7) [77.2, 92.0]	29/ 48 (60.4) [45.3, 74.2]	1.42 (1.11, 1.81)	0.0048	3.93 (1.75, 8.83)	0.0009	25.30 (8.27, 42.32)	0.0036	0.0006	
Prior adjuvant/ neoadjuvant therapy										0.6673
yes	27/ 29 (93.1) [77.2, 99.2]	6/ 8 (75.0) [34.9, 96.8]	1.24 (0.82, 1.87)	0.3038	4.50 (0.52, 38.65)	0.1704	18.10 (-21.26, 57.47)	0.3674	0.1499	
no	75/ 90 (83.3) [74.0, 90.4]	29/ 48 (60.4) [45.3, 74.2]	1.38 (1.08, 1.77)	0.0107	3.28 (1.47, 7.30)	0.0037	22.92 (5.49, 40.35)	0.0100	0.0030	
Prior ramucirumab contained treatment										0.3584
yes	75/ 89 (84.3) [75.0, 91.1]	21/ 37 (56.8) [39.5, 72.9]	1.48 (1.11, 1.99)	0.0087	4.08 (1.72, 9.70)	0.0014	27.51 (7.94, 47.09)	0.0059	0.0010	
no	27/ 30 (90.0) [73.5, 97.9]	14/ 19 (73.7) [48.8, 90.9]	1.22 (0.91, 1.64)	0.1824	3.21 (0.67, 15.45)	0.1450	16.32 (-10.51, 43.14)	0.2332	0.1362	
Prior nivolumab contained treatment										0.3542
yes	31/ 33 (93.9) [79.8, 99.3]	11/ 14 (78.6) [49.2, 95.3]	1.20 (0.90, 1.59)	0.2224	4.23 (0.62, 28.74)	0.1405	15.37 (-12.70, 43.44)	0.2833	0.1221	
no	71/ 86 (82.6) [72.9, 89.9]	24/ 42 (57.1) [41.0, 72.3]	1.44 (1.09, 1.91)	0.0098	3.55 (1.55, 8.12)	0.0027	25.42 (6.66, 44.17)	0.0079	0.0021	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy										0.2015
yes	41/ 44 (93.2) [81.3, 98.6]	13/ 16 (81.3) [54.4, 96.0]	1.15 (0.89, 1.47)	0.2800	3.15 (0.57, 17.57)	0.1900	11.93 (-12.85, 36.72)	0.3454	0.1767	
no	61/ 75 (81.3) [70.7, 89.4]	22/ 40 (55.0) [38.5, 70.7]	1.48 (1.09, 2.00)	0.0107	3.56 (1.52, 8.35)	0.0034	26.33 (6.66, 46.01)	0.0087	0.0028	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug										0.6929
yes	18/ 22 (81.8) [59.7, 94.8]	4/ 6 (66.7) [22.3, 95.7]	1.23 (0.67, 2.23)	0.5029	2.25 (0.30, 16.85)	0.4299	15.15 (-36.47, 66.78)	0.5651	0.4311	
no	84/ 97 (86.6) [78.2, 92.7]	31/ 50 (62.0) [47.2, 75.3]	1.40 (1.11, 1.76)	0.0045	3.96 (1.75, 8.96)	0.0010	24.60 (8.02, 41.18)	0.0036	0.0006	
Presence of liver metastasis at baseline										0.0432
yes	55/ 67 (82.1) [70.8, 90.4]	16/ 33 (48.5) [30.8, 66.5]	1.69 (1.17, 2.45)	0.0052	4.87 (1.93, 12.28)	0.0008	33.60 (11.98, 55.23)	0.0023	0.0005	
no	47/ 52 (90.4) [79.0, 96.8]	19/ 23 (82.6) [61.2, 95.0]	1.09 (0.89, 1.35)	0.3953	1.98 (0.48, 8.18)	0.3457	7.78 (-12.80, 28.35)	0.4589	0.3425	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Confirmed Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Renal impairment at baseline										0.1039
normal	27/ 32 (84.4) [67.2, 94.7]	9/ 12 (75.0) [42.8, 94.5]	1.13 (0.79, 1.61)	0.5203	1.80 (0.36, 9.08)	0.4765	9.38 (-23.89, 42.64)	0.5807	0.4778	
mild	45/ 52 (86.5) [74.2, 94.4]	12/ 26 (46.2) [26.6, 66.6]	1.88 (1.22, 2.88)	0.0041	7.50 (2.48, 22.72)	0.0004	40.38 (16.21, 64.56)	0.0011	0.0002	
moderate	30/ 35 (85.7) [69.7, 95.2]	14/ 18 (77.8) [52.4, 93.6]	1.10 (0.83, 1.46)	0.4988	1.71 (0.40, 7.38)	0.4693	7.94 (-18.70, 34.58)	0.5593	0.4704	
Hepatic impairment at baseline										0.9063
normal	75/ 84 (89.3) [80.6, 95.0]	28/ 43 (65.1) [49.1, 79.0]	1.37 (1.09, 1.73)	0.0074	4.46 (1.76, 11.35)	0.0017	24.17 (6.71, 41.63)	0.0067	0.0010	
mild	26/ 34 (76.5) [58.8, 89.3]	7/ 13 (53.8) [25.1, 80.8]	1.42 (0.83, 2.43)	0.2002	2.79 (0.72, 10.72)	0.1363	22.62 (-13.31, 58.56)	0.2172	0.1334	
moderate	1/ 1 (100.0) [2.5, 100.0]	0 [NE, NE]	NE	NE	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors										0.6559
yes	6/ 7 (85.7) [42.1, 99.6]	2/ 4 (50.0) [6.8, 93.2]	1.71 (0.61, 4.78)	0.3030	6.00 (0.34, 107.42)	0.2235	35.71 (-39.36, 100.00)	0.3511	0.2225	
no	96/112 (85.7) [77.8, 91.6]	33/ 52 (63.5) [49.0, 76.4]	1.35 (1.08, 1.68)	0.0073	3.45 (1.59, 7.49)	0.0017	22.25 (6.24, 38.27)	0.0065	0.0013	
Most recently treatment with irinotecan or other topoisomerase I inhibitors										0.8342
yes	2/ 2 (100.0) [15.8, 100.0]	2/ 3 (66.7) [9.4, 99.2]	1.50 (0.67, 3.34)	0.3206	3.00 (0.08, 115.34)	0.5552	33.33 (-61.68, 100.00)	0.4917	0.4142	
no	100/117 (85.5) [77.8, 91.3]	33/ 53 (62.3) [47.9, 75.2]	1.37 (1.10, 1.71)	0.0053	3.57 (1.67, 7.60)	0.0010	23.21 (7.31, 39.11)	0.0042	0.0007	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Disease Control Rate (DCR) based on ICR
Response Evaluable Set

	DS-8201a (N=119)	Phys. Choice (N=56)
Number of subjects with events, n (%)	103 (86.6)	35 (62.5)
95% CI [a]	79.1, 92.1	48.5, 75.1
Analysis DS-8201a vs. Phys. Choice (stratified)		
Relative Risk (95% CI) [b]	1.39 (1.12, 1.72)	
p-value	0.0030	
Odds Ratio (95% CI) [b]	3.86 (1.81, 8.20)	
p-value	0.0005	
Risk Difference (95% CI) [c]	24.07 (9.98, 38.16)	
p-value	0.0008	
CMH test [d]		
p-value	0.0003	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Relative Risk (95% CI) [e]	1.38 (1.12, 1.72)	
p-value	0.0030	
Odds Ratio (95% CI) [e]	3.86 (1.82, 8.22)	
p-value	0.0005	
Risk Difference (95% CI) [f]	24.05 (8.66, 39.45)	
p-value	0.0022	
CMH test [d]		
p-value	0.0003	

Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Mantel-Haenszel estimators for Common Odds Ratio and Relative Risks. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the common risk difference of two proportions.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[f] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Region										0.5597
Japan	82/ 95 (86.3) [77.7, 92.5]	29/ 45 (64.4) [48.8, 78.1]	1.34 (1.06, 1.69)	0.0133	3.48 (1.49, 8.11)	0.0038	21.87 (4.63, 39.11)	0.0129	0.0030	
Korea	21/ 24 (87.5) [67.6, 97.3]	6/ 11 (54.5) [23.4, 83.3]	1.60 (0.92, 2.81)	0.0983	5.83 (1.07, 31.76)	0.0414	32.95 (-5.94, 71.85)	0.0968	0.0336	
Lines of prior systemic therapy										0.7833
2	50/ 60 (83.3) [71.5, 91.7]	20/ 33 (60.6) [42.1, 77.1]	1.38 (1.02, 1.85)	0.0359	3.25 (1.23, 8.61)	0.0177	22.73 (1.23, 44.23)	0.0383	0.0156	
3	31/ 34 (91.2) [76.3, 98.1]	12/ 17 (70.6) [44.0, 89.7]	1.29 (0.93, 1.79)	0.1218	4.31 (0.89, 20.88)	0.0699	20.59 (-7.49, 48.67)	0.1507	0.0592	
>=4	22/ 25 (88.0) [68.8, 97.5]	3/ 6 (50.0) [11.8, 88.2]	1.76 (0.78, 3.97)	0.1730	7.33 (0.99, 54.40)	0.0513	38.00 (-14.32, 90.32)	0.1546	0.0374	
Age										0.3690
<65 years	45/ 52 (86.5) [74.2, 94.4]	12/ 22 (54.5) [32.2, 75.6]	1.59 (1.07, 2.36)	0.0224	5.36 (1.68, 17.04)	0.0045	31.99 (5.98, 58.01)	0.0159	0.0030	
>=65 years	58/ 67 (86.6) [76.0, 93.7]	23/ 34 (67.6) [49.5, 82.6]	1.28 (1.00, 1.64)	0.0540	3.08 (1.13, 8.42)	0.0281	18.92 (-1.02, 38.86)	0.0629	0.0249	
Sex										0.9027
female	27/ 30 (90.0) [73.5, 97.9]	8/ 12 (66.7) [34.9, 90.1]	1.35 (0.89, 2.05)	0.1589	4.50 (0.83, 24.44)	0.0815	23.33 (-11.25, 57.92)	0.1861	0.0701	
male	76/ 89 (85.4) [76.3, 92.0]	27/ 44 (61.4) [45.5, 75.6]	1.39 (1.08, 1.79)	0.0095	3.68 (1.58, 8.57)	0.0025	24.03 (6.18, 41.88)	0.0083	0.0019	
ECOG PS										0.9088
0	53/ 59 (89.8) [79.2, 96.2]	19/ 29 (65.5) [45.7, 82.1]	1.37 (1.04, 1.81)	0.0259	4.65 (1.49, 14.53)	0.0082	24.31 (2.80, 45.83)	0.0267	0.0057	
1	50/ 60 (83.3) [71.5, 91.7]	16/ 27 (59.3) [38.8, 77.6]	1.41 (1.01, 1.96)	0.0445	3.44 (1.23, 9.58)	0.0182	24.07 (0.59, 47.55)	0.0445	0.0158	
HER2 Status in central laboratory										0.3751
IHC 3+	78/ 91 (85.7) [76.8, 92.2]	26/ 44 (59.1) [43.2, 73.7]	1.45 (1.12, 1.88)	0.0050	4.15 (1.79, 9.62)	0.0009	26.62 (8.73, 44.52)	0.0035	0.0006	
IHC 2+/ISH +	25/ 28 (89.3) [71.8, 97.7]	9/ 12 (75.0) [42.8, 94.5]	1.19 (0.84, 1.69)	0.3302	2.78 (0.47, 16.35)	0.2586	14.29 (-18.71, 47.28)	0.3962	0.2522	
Primary tumor location										0.5944
Gastric	89/104 (85.6) [77.3, 91.7]	31/ 49 (63.3) [48.3, 76.6]	1.35 (1.08, 1.70)	0.0092	3.45 (1.55, 7.65)	0.0024	22.31 (5.72, 38.91)	0.0084	0.0018	
GEJ	14/ 15 (93.3) [68.1, 99.8]	4/ 7 (57.1) [18.4, 90.1]	1.63 (0.85, 3.15)	0.1425	10.50 (0.84, 130.66)	0.0676	36.19 (-13.06, 85.44)	0.1498	0.0452	
Histological subtype										0.8508
intestinal	76/ 86 (88.4) [79.7, 94.3]	24/ 37 (64.9) [47.5, 79.8]	1.36 (1.06, 1.75)	0.0150	4.12 (1.60, 10.58)	0.0033	23.51 (4.77, 42.25)	0.0140	0.0023	
diffuse	23/ 27 (85.2) [66.3, 95.8]	8/ 14 (57.1) [28.9, 82.3]	1.49 (0.92, 2.41)	0.1031	4.31 (0.96, 19.31)	0.0561	28.04 (-6.56, 62.65)	0.1122	0.0502	
others	4/ 6 (66.7) [22.3, 95.7]	3/ 5 (60.0) [14.7, 94.7]	1.11 (0.45, 2.77)	0.8209	1.33 (0.11, 15.70)	0.8192	6.67 (-68.82, 82.15)	0.8626	0.8273	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Number of metastatic sites										0.8873
<2	20/ 21 (95.2) [76.2, 99.9]	4/ 6 (66.7) [22.3, 95.7]	1.43 (0.80, 2.54)	0.2231	10.00 (0.72, 138.68)	0.0861	28.57 (-20.95, 78.09)	0.2581	0.0539	
>= 2	83/ 98 (84.7) [76.0, 91.2]	31/ 50 (62.0) [47.2, 75.3]	1.37 (1.08, 1.72)	0.0086	3.39 (1.53, 7.49)	0.0025	22.69 (5.96, 39.43)	0.0079	0.0020	
Previous total gastrectomy										0.3704
yes	18/ 21 (85.7) [63.7, 97.0]	6/ 8 (75.0) [34.9, 96.8]	1.14 (0.74, 1.77)	0.5488	2.00 (0.27, 14.98)	0.4999	10.71 (-31.45, 52.88)	0.6184	0.5023	
no	85/ 98 (86.7) [78.4, 92.7]	29/ 48 (60.4) [45.3, 74.2]	1.44 (1.13, 1.83)	0.0034	4.28 (1.88, 9.74)	0.0005	26.32 (9.39, 43.25)	0.0023	0.0003	
Prior adjuvant/ neoadjuvant therapy										0.6280
yes	27/ 29 (93.1) [77.2, 99.2]	6/ 8 (75.0) [34.9, 96.8]	1.24 (0.82, 1.87)	0.3038	4.50 (0.52, 38.65)	0.1704	18.10 (-21.26, 57.47)	0.3674	0.1499	
no	76/ 90 (84.4) [75.3, 91.2]	29/ 48 (60.4) [45.3, 74.2]	1.40 (1.09, 1.79)	0.0075	3.56 (1.58, 8.01)	0.0022	24.03 (6.70, 41.36)	0.0066	0.0017	
Prior ramucirumab contained treatment										0.3258
yes	76/ 89 (85.4) [76.3, 92.0]	21/ 37 (56.8) [39.5, 72.9]	1.50 (1.12, 2.02)	0.0065	4.45 (1.85, 10.71)	0.0008	28.64 (9.15, 48.12)	0.0040	0.0005	
no	27/ 30 (90.0) [73.5, 97.9]	14/ 19 (73.7) [48.8, 90.9]	1.22 (0.91, 1.64)	0.1824	3.21 (0.67, 15.45)	0.1450	16.32 (-10.51, 43.14)	0.2332	0.1362	
Prior nivolumab contained treatment										0.3186
yes	31/ 33 (93.9) [79.8, 99.3]	11/ 14 (78.6) [49.2, 95.3]	1.20 (0.90, 1.59)	0.2224	4.23 (0.62, 28.74)	0.1405	15.37 (-12.70, 43.44)	0.2833	0.1221	
no	72/ 86 (83.7) [74.2, 90.8]	24/ 42 (57.1) [41.0, 72.3]	1.47 (1.11, 1.93)	0.0071	3.86 (1.67, 8.91)	0.0016	26.58 (7.93, 45.23)	0.0052	0.0012	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy										0.1727
yes	41/ 44 (93.2) [81.3, 98.6]	13/ 16 (81.3) [54.4, 96.0]	1.15 (0.89, 1.47)	0.2800	3.15 (0.57, 17.57)	0.1900	11.93 (-12.85, 36.72)	0.3454	0.1767	
no	62/ 75 (82.7) [72.2, 90.4]	22/ 40 (55.0) [38.5, 70.7]	1.50 (1.11, 2.03)	0.0075	3.90 (1.65, 9.25)	0.0020	27.67 (8.11, 47.22)	0.0056	0.0015	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug										0.6662
yes	18/ 22 (81.8) [59.7, 94.8]	4/ 6 (66.7) [22.3, 95.7]	1.23 (0.67, 2.23)	0.5029	2.25 (0.30, 16.85)	0.4299	15.15 (-36.47, 66.78)	0.5651	0.4311	
no	85/ 97 (87.6) [79.4, 93.4]	31/ 50 (62.0) [47.2, 75.3]	1.41 (1.12, 1.78)	0.0031	4.34 (1.89, 9.97)	0.0005	25.63 (9.15, 42.11)	0.0023	0.0003	
Presence of liver metastasis at baseline										0.0532
yes	55/ 67 (82.1) [70.8, 90.4]	16/ 33 (48.5) [30.8, 66.5]	1.69 (1.17, 2.45)	0.0052	4.87 (1.93, 12.28)	0.0008	33.60 (11.98, 55.23)	0.0023	0.0005	
no	48/ 52 (92.3) [81.5, 97.9]	19/ 23 (82.6) [61.2, 95.0]	1.12 (0.91, 1.37)	0.2844	2.53 (0.57, 11.15)	0.2210	9.70 (-10.54, 29.93)	0.3475	0.2127	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Renal impairment at baseline										0.1221
normal	27/ 32 (84.4) [67.2, 94.7]	9/ 12 (75.0) [42.8, 94.5]	1.13 (0.79, 1.61)	0.5203	1.80 (0.36, 9.08)	0.4765	9.38 (-23.89, 42.64)	0.5807	0.4778	
mild	45/ 52 (86.5) [74.2, 94.4]	12/ 26 (46.2) [26.6, 66.6]	1.88 (1.22, 2.88)	0.0041	7.50 (2.48, 22.72)	0.0004	40.38 (16.21, 64.56)	0.0011	0.0002	
moderate	31/ 35 (88.6) [73.3, 96.8]	14/ 18 (77.8) [52.4, 93.6]	1.14 (0.87, 1.50)	0.3528	2.21 (0.48, 10.15)	0.3063	10.79 (-15.32, 36.91)	0.4179	0.3032	
Hepatic impairment at baseline										0.9415
normal	76/ 84 (90.5) [82.1, 95.8]	28/ 43 (65.1) [49.1, 79.0]	1.39 (1.10, 1.75)	0.0050	5.09 (1.95, 13.31)	0.0009	25.36 (8.03, 42.68)	0.0041	0.0005	
mild	26/ 34 (76.5) [58.8, 89.3]	7/ 13 (53.8) [25.1, 80.8]	1.42 (0.83, 2.43)	0.2002	2.79 (0.72, 10.72)	0.1363	22.62 (-13.31, 58.56)	0.2172	0.1334	
moderate	1/ 1 (100.0) [2.5, 100.0]	0 [NE, NE]	NE	NE	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors										0.6699
yes	6/ 7 (85.7) [42.1, 99.6]	2/ 4 (50.0) [6.8, 93.2]	1.71 (0.61, 4.78)	0.3030	6.00 (0.34, 107.42)	0.2235	35.71 (-39.36, 100.00)	0.3511	0.2225	
no	97/112 (86.6) [78.9, 92.3]	33/ 52 (63.5) [49.0, 76.4]	1.36 (1.10, 1.70)	0.0053	3.72 (1.70, 8.15)	0.0010	23.15 (7.21, 39.08)	0.0044	0.0007	
Most recently treatment with irinotecan or other topoisomerase I inhibitors										0.8526
yes	2/ 2 (100.0) [15.8, 100.0]	2/ 3 (66.7) [9.4, 99.2]	1.50 (0.67, 3.34)	0.3206	3.00 (0.08, 115.34)	0.5552	33.33 (-61.68, 100.00)	0.4917	0.4142	
no	101/117 (86.3) [78.7, 92.0]	33/ 53 (62.3) [47.9, 75.2]	1.39 (1.11, 1.73)	0.0039	3.83 (1.78, 8.23)	0.0006	24.06 (8.23, 39.89)	0.0029	0.0004	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Progression-free Survival
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	73 (58.4)	36 (58.1)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	5.6 (4.3, 6.9)	3.5 (2.0, 4.3)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	71.7 (62.7, 78.9)	50.3 (35.5, 63.5)
6 Months (95% CI)	42.8 (33.1, 52.1)	20.6 (8.9, 35.6)
9 Months (95% CI)	34.5 (24.9, 44.2)	NE (NE, NE)
12 Months (95% CI)	29.9 (20.1, 40.4)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.47 (0.31, 0.71)	
p-value [c]	0.0003	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.47 (0.31, 0.71)	
p-value [c]	0.0003	

Progression-free survival (PFS) is defined as the time from the date of randomization to the earliest date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Progression-free Survival - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.8942
Japan	58/ 99 (58.6)	5.6 (4.4, 7.0)	30/ 50 (60.0)	4.1 (2.0, 4.9)	0.46 (0.29, 0.72)	0.0007	
Korea	15/ 26 (57.7)	4.4 (2.9, 12.0)	6/ 12 (50.0)	2.8 (1.3, NE)	0.52 (0.19, 1.39)	0.1803	
Lines of prior systemic therapy							0.4036
2	40/ 66 (60.6)	4.3 (3.6, 8.2)	22/ 38 (57.9)	3.5 (1.7, 5.5)	0.60 (0.35, 1.03)	0.0622	
3	18/ 34 (52.9)	5.7 (4.5, NE)	11/ 18 (61.1)	4.1 (1.6, 5.6)	0.23 (0.10, 0.55)	0.0004	
>=4	15/ 25 (60.0)	5.6 (3.6, NE)	3/ 6 (50.0)	2.8 (0.7, NE)	0.43 (0.12, 1.54)	0.1813	
Age							0.7060
<65 years	35/ 55 (63.6)	5.4 (3.6, 7.1)	13/ 27 (48.1)	2.8 (1.4, NE)	0.56 (0.29, 1.09)	0.0810	
>=65 years	38/ 70 (54.3)	5.7 (4.4, 8.2)	23/ 35 (65.7)	4.1 (2.0, 5.5)	0.41 (0.24, 0.70)	0.0009	
Sex							0.4793
female	20/ 30 (66.7)	4.5 (2.8, 7.0)	8/ 15 (53.3)	3.5 (1.6, NE)	0.55 (0.23, 1.30)	0.1645	
male	53/ 95 (55.8)	5.7 (4.3, 7.1)	28/ 47 (59.6)	4.1 (2.0, 5.5)	0.44 (0.27, 0.71)	0.0005	
ECOG PS							0.4156
0	35/ 62 (56.5)	5.6 (4.7, 12.0)	18/ 30 (60.0)	4.3 (1.6, 5.6)	0.39 (0.21, 0.71)	0.0014	
1	38/ 63 (60.3)	4.4 (3.6, 6.9)	18/ 32 (56.3)	2.8 (1.8, 4.3)	0.55 (0.31, 0.99)	0.0422	
HER2 Status in central laboratory							0.0268
IHC 3+	51/ 96 (53.1)	5.8 (4.4, 12.0)	29/ 47 (61.7)	2.8 (1.8, 4.3)	0.36 (0.22, 0.58)	<.0001	
IHC 2+/ISH +	22/ 29 (75.9)	4.3 (2.7, 5.6)	7/ 15 (46.7)	4.3 (1.6, NE)	0.99 (0.41, 2.38)	0.9916	
Primary tumor location							0.8930
Gastric	64/108 (59.3)	5.4 (4.1, 6.9)	33/ 55 (60.0)	2.8 (2.0, 4.9)	0.49 (0.32, 0.75)	0.0010	
GEJ	9/ 17 (52.9)	6.9 (5.4, 14.2)	3/ 7 (42.9)	4.3 (1.4, 4.3)	0.22 (0.04, 1.14)	0.0493	
Histological subtype							0.2124
intestinal	52/ 89 (58.4)	5.6 (4.4, 7.0)	26/ 38 (68.4)	4.1 (2.0, 4.9)	0.44 (0.27, 0.72)	0.0008	
diffuse	15/ 28 (53.6)	5.7 (3.6, NE)	7/ 18 (38.9)	2.6 (1.4, NE)	0.33 (0.12, 0.90)	0.0242	
others	6/ 8 (75.0)	2.9 (1.0, NE)	3/ 6 (50.0)	5.6 (1.4, NE)	1.46 (0.36, 5.89)	0.5904	
Number of metastatic sites							0.8296
<2	12/ 24 (50.0)	12.0 (3.9, NE)	5/ 10 (50.0)	4.2 (1.3, NE)	0.45 (0.15, 1.31)	0.1321	
>= 2	61/101 (60.4)	5.6 (4.3, 6.9)	31/ 52 (59.6)	3.5 (2.0, 4.3)	0.48 (0.30, 0.75)	0.0011	
Previous total gastrectomy							0.1267
yes	8/ 22 (36.4)	NE (4.0, NE)	5/ 9 (55.6)	2.8 (0.7, 4.9)	0.22 (0.06, 0.78)	0.0122	
no	65/103 (63.1)	5.4 (4.2, 6.9)	31/ 53 (58.5)	3.5 (2.0, 5.5)	0.51 (0.33, 0.80)	0.0030	
Prior adjuvant/ neoadjuvant therapy							0.7578
yes	12/ 30 (40.0)	7.0 (5.6, NE)	5/ 10 (50.0)	2.8 (0.7, NE)	0.40 (0.14, 1.19)	0.0921	
no	61/ 95 (64.2)	4.6 (4.1, 5.8)	31/ 52 (59.6)	3.5 (2.0, 4.3)	0.50 (0.32, 0.78)	0.0020	
Prior ramucirumab contained treatment							0.6663
yes	55/ 94 (58.5)	5.4 (4.2, 6.9)	25/ 41 (61.0)	2.8 (1.8, 4.3)	0.45 (0.28, 0.74)	0.0012	
no	18/ 31 (58.1)	5.7 (3.6, 12.0)	11/ 21 (52.4)	4.3 (1.7, 6.4)	0.44 (0.20, 0.99)	0.0418	

Progression-free survival (PFS) is defined as the time from the date of randomization to the earliest date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

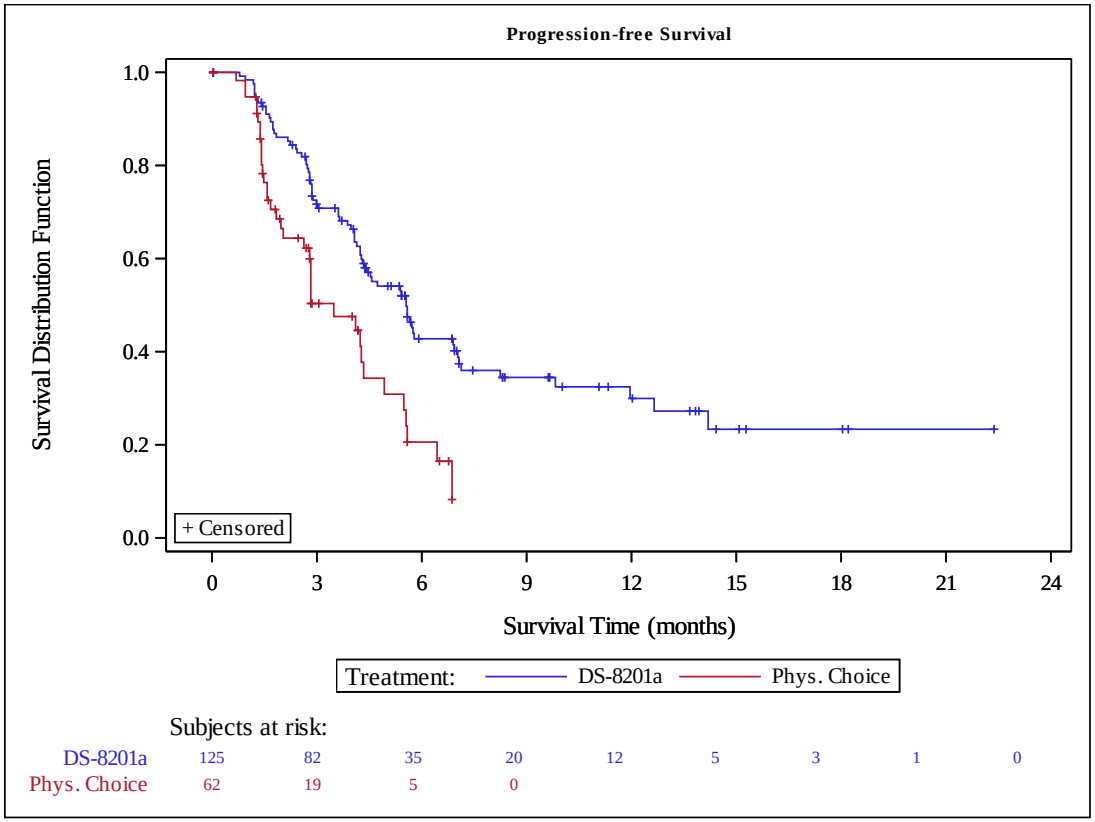
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Progression-free Survival - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.2386
yes	20/ 33 (60.6)	6.9 (5.4, 14.2)	9/ 15 (60.0)	2.8 (2.0, 4.3)	0.20 (0.08, 0.52)	0.0003	
no	53/ 92 (57.6)	4.4 (4.1, 6.9)	27/ 47 (57.4)	3.5 (1.7, 5.5)	0.58 (0.36, 0.93)	0.0215	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.3208
yes	25/ 44 (56.8)	6.9 (5.4, 14.2)	9/ 17 (52.9)	2.8 (2.6, 5.6)	0.25 (0.11, 0.60)	0.0009	
no	48/ 81 (59.3)	4.5 (4.0, 6.9)	27/ 45 (60.0)	3.5 (1.6, 5.5)	0.57 (0.35, 0.93)	0.0239	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.1741
yes	13/ 22 (59.1)	4.3 (2.8, NE)	2/ 7 (28.6)	NE (1.3, NE)	1.38 (0.31, 6.15)	0.6696	
no	60/103 (58.3)	5.7 (4.4, 7.1)	34/ 55 (61.8)	2.8 (2.0, 4.3)	0.40 (0.26, 0.62)	<.0001	
Presence of liver metastasis at baseline							0.1423
yes	41/ 67 (61.2)	4.7 (3.6, 6.9)	26/ 34 (76.5)	2.0 (1.4, 4.2)	0.38 (0.23, 0.63)	0.0001	
no	32/ 58 (55.2)	5.8 (4.4, 12.6)	10/ 28 (35.7)	4.9 (2.8, NE)	0.70 (0.33, 1.46)	0.3377	
Renal impairment at baseline							0.6233
normal	20/ 33 (60.6)	5.6 (3.9, 14.2)	5/ 13 (38.5)	3.5 (1.4, 4.3)	0.45 (0.15, 1.31)	0.1344	
mild	31/ 53 (58.5)	4.5 (3.6, 7.1)	19/ 28 (67.9)	2.0 (1.4, 5.5)	0.43 (0.24, 0.77)	0.0037	
moderate	22/ 39 (56.4)	5.8 (4.2, 12.0)	11/ 20 (55.0)	4.3 (2.8, 6.9)	0.52 (0.24, 1.13)	0.0974	
severe	0	NE (NE , NE)	1/ 1 (100.0)	2.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.4618
normal	51/ 88 (58.0)	5.6 (4.4, 7.0)	26/ 47 (55.3)	3.5 (2.0, 4.9)	0.39 (0.24, 0.64)	0.0001	
mild	22/ 36 (61.1)	3.6 (2.6, 7.1)	10/ 15 (66.7)	2.8 (1.4, NE)	0.71 (0.33, 1.52)	0.3792	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.6352
yes	5/ 8 (62.5)	6.9 (1.2, NE)	3/ 5 (60.0)	4.3 (2.0, 5.5)	0.17 (0.03, 1.08)	0.0356	
no	68/117 (58.1)	5.6 (4.2, 6.9)	33/ 57 (57.9)	2.8 (2.0, 4.9)	0.49 (0.32, 0.75)	0.0010	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.7583
yes	3/ 3 (100.0)	6.9 (5.6, 12.0)	2/ 4 (50.0)	4.9 (4.3, 5.5)	0.00 (0.00, NE)	0.0389	
no	70/122 (57.4)	5.6 (4.3, 7.0)	34/ 58 (58.6)	2.8 (2.0, 4.3)	0.47 (0.31, 0.73)	0.0005	

Progression-free survival (PFS) is defined as the time from the date of randomization to the earliest date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

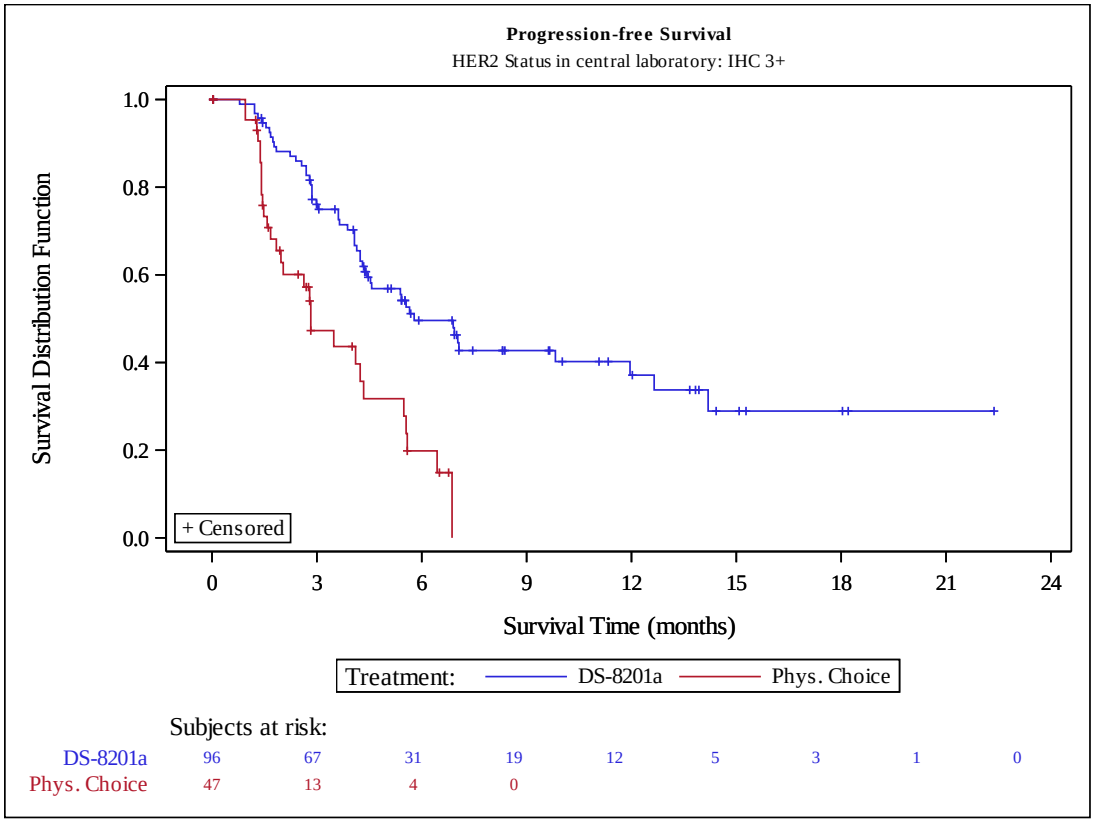
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Progression-free Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

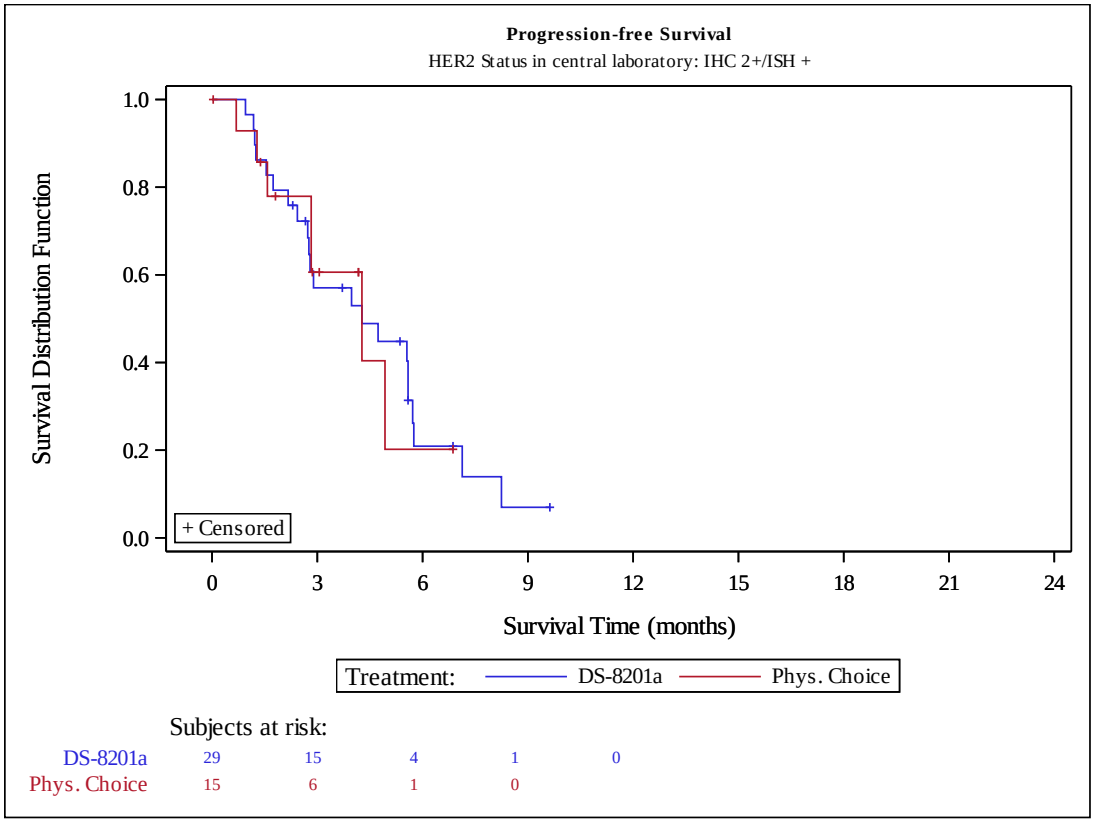
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Progression-free Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Progression-free Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Duration of Confirmed Response
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with confirmed response (CR+PR), N*	51	7
Number of subjects with events, n (%)	18 (35.3)	5 (71.4)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	11.3 (5.6, NE)	3.9 (3.0, 4.9)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	86.9 (73.0, 93.9)	100.0 (100.0, 100.0)
6 Months (95% CI)	61.0 (43.2, 74.7)	NE (NE, NE)
9 Months (95% CI)	56.6 (38.2, 71.5)	NE (NE, NE)
12 Months (95% CI)	49.5 (29.0, 67.1)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.19 (0.06, 0.57)	
p-value [c]	0.0009	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.17 (0.06, 0.53)	
p-value [c]	0.0005	

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Duration of Confirmed Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N* (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N* (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.8418
Japan	15/ 42 (35.7)	11.3 (5.6, NE)	4/ 6 (66.7)	4.1 (3.0, 4.9)	0.17 (0.05, 0.58)	0.0013	
Korea	3/ 9 (33.3)	NE (3.0, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.29 (0.03, 3.19)	0.2801	
Lines of prior systemic therapy							0.6240
2	8/ 21 (38.1)	11.3 (5.5, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.25 (0.05, 1.11)	0.0574	
3	5/ 17 (29.4)	12.7 (4.1, NE)	2/ 3 (66.7)	3.6 (3.0, 4.2)	0.19 (0.03, 1.15)	0.0430	
>=4	5/ 13 (38.5)	NE (4.1, NE)	0	NE (NE , NE)	NE	NE	
Age							0.9932
<65 years	11/ 24 (45.8)	11.3 (5.5, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	7/ 27 (25.9)	NE (5.6, NE)	5/ 6 (83.3)	3.9 (3.0, 4.9)	0.15 (0.04, 0.56)	0.0015	
Sex							0.8466
female	5/ 10 (50.0)	5.6 (2.5, NE)	1/ 2 (50.0)	3.0 (NE , NE)	0.11 (0.01, 1.80)	0.0610	
male	13/ 41 (31.7)	12.7 (5.6, NE)	4/ 5 (80.0)	4.1 (3.9, 4.9)	0.18 (0.05, 0.62)	0.0024	
ECOG PS							0.1595
0	9/ 28 (32.1)	NE (5.7, NE)	3/ 3 (100.0)	3.9 (3.0, 3.9)	0.06 (0.01, 0.36)	<.0001	
1	9/ 23 (39.1)	5.6 (5.5, 11.3)	2/ 4 (50.0)	4.6 (4.2, 4.9)	0.30 (0.06, 1.56)	0.1305	
HER2 Status in central laboratory							0.6821
IHC 3+	14/ 45 (31.1)	12.7 (5.7, NE)	4/ 4 (100.0)	4.1 (3.9, 4.9)	0.17 (0.05, 0.57)	0.0015	
IHC 2+/ISH +	4/ 6 (66.7)	5.6 (2.9, NE)	1/ 3 (33.3)	3.0 (NE , NE)	0.18 (0.01, 2.93)	0.1768	
Primary tumor location							0.9931
Gastric	13/ 43 (30.2)	NE (5.6, NE)	5/ 6 (83.3)	3.9 (3.0, 4.9)	0.17 (0.05, 0.54)	0.0008	
GEJ	5/ 8 (62.5)	8.4 (4.1, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	13/ 35 (37.1)	11.3 (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.19 (0.06, 0.61)	0.0022	
diffuse	5/ 15 (33.3)	NE (5.5, NE)	0	NE (NE , NE)	NE	NE	
others	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.3941
<2	2/ 12 (16.7)	12.7 (12.7, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.11 (0.01, 1.72)	0.0543	
>= 2	16/ 39 (41.0)	8.4 (5.6, NE)	4/ 6 (66.7)	4.1 (3.0, 4.9)	0.21 (0.06, 0.70)	0.0050	
Previous total gastrectomy							NE
yes	2/ 11 (18.2)	NE (4.1, NE)	0	NE (NE , NE)	NE	NE	
no	16/ 40 (40.0)	11.3 (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.18 (0.06, 0.58)	0.0015	
Prior adjuvant/ neoadjuvant therapy							NE
yes	4/ 17 (23.5)	NE (4.1, NE)	0	NE (NE , NE)	NE	NE	
no	14/ 34 (41.2)	11.3 (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.21 (0.06, 0.66)	0.0040	
Prior ramucirumab contained treatment							0.6948
yes	12/ 38 (31.6)	12.7 (5.6, NE)	3/ 5 (60.0)	3.9 (3.0, 4.2)	0.18 (0.05, 0.72)	0.0060	
no	6/ 13 (46.2)	11.3 (5.5, NE)	2/ 2 (100.0)	4.4 (3.9, 4.9)	0.15 (0.02, 1.11)	0.0330	

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Duration of Confirmed Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N* (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N* (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.9152
yes	9/ 20 (45.0)	5.7 (5.5, NE)	2/ 3 (66.7)	3.6 (3.0, 4.2)	0.16 (0.03, 0.89)	0.0151	
no	9/ 31 (29.0)	11.3 (5.6, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.20 (0.05, 0.86)	0.0202	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8196
yes	10/ 25 (40.0)	12.7 (5.5, NE)	2/ 3 (66.7)	3.6 (3.0, 4.2)	0.17 (0.03, 0.88)	0.0154	
no	8/ 26 (30.8)	11.3 (5.5, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.20 (0.04, 0.91)	0.0255	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	2/ 8 (25.0)	NE (2.4, NE)	0	NE (NE , NE)	NE	NE	
no	16/ 43 (37.2)	11.3 (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.15 (0.05, 0.47)	0.0002	
Presence of liver metastasis at baseline							0.5727
yes	12/ 25 (48.0)	8.4 (4.1, NE)	4/ 4 (100.0)	4.1 (3.0, 4.9)	0.27 (0.08, 0.93)	0.0243	
no	6/ 26 (23.1)	NE (5.6, NE)	1/ 3 (33.3)	3.9 (NE , NE)	0.10 (0.01, 1.10)	0.0196	
Renal impairment at baseline							0.9469
normal	8/ 16 (50.0)	10.6 (4.1, NE)	0	NE (NE , NE)	NE	NE	
mild	4/ 20 (20.0)	NE (5.7, NE)	3/ 3 (100.0)	4.2 (3.9, 4.9)	0.19 (0.04, 0.96)	0.0251	
moderate	6/ 15 (40.0)	11.3 (5.6, NE)	2/ 4 (50.0)	3.5 (3.0, 3.9)	0.14 (0.02, 1.04)	0.0258	
severe	0	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7902
normal	13/ 37 (35.1)	11.3 (5.6, NE)	4/ 6 (66.7)	3.9 (3.0, 4.9)	0.14 (0.04, 0.52)	0.0008	
mild	5/ 13 (38.5)	NE (2.9, NE)	1/ 1 (100.0)	4.2 (NE , NE)	0.30 (0.03, 2.88)	0.2661	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.5855
yes	1/ 3 (33.3)	NE (5.5, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.00 (0.00, NE)	0.0833	
no	17/ 48 (35.4)	11.3 (5.6, NE)	4/ 6 (66.7)	4.1 (3.0, 4.9)	0.20 (0.06, 0.66)	0.0033	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.5205
yes	1/ 1 (100.0)	5.5 (NE , NE)	1/ 1 (100.0)	3.9 (NE , NE)	NE	NE	
no	17/ 50 (34.0)	12.7 (5.6, NE)	4/ 6 (66.7)	4.1 (3.0, 4.9)	0.19 (0.06, 0.63)	0.0022	

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NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

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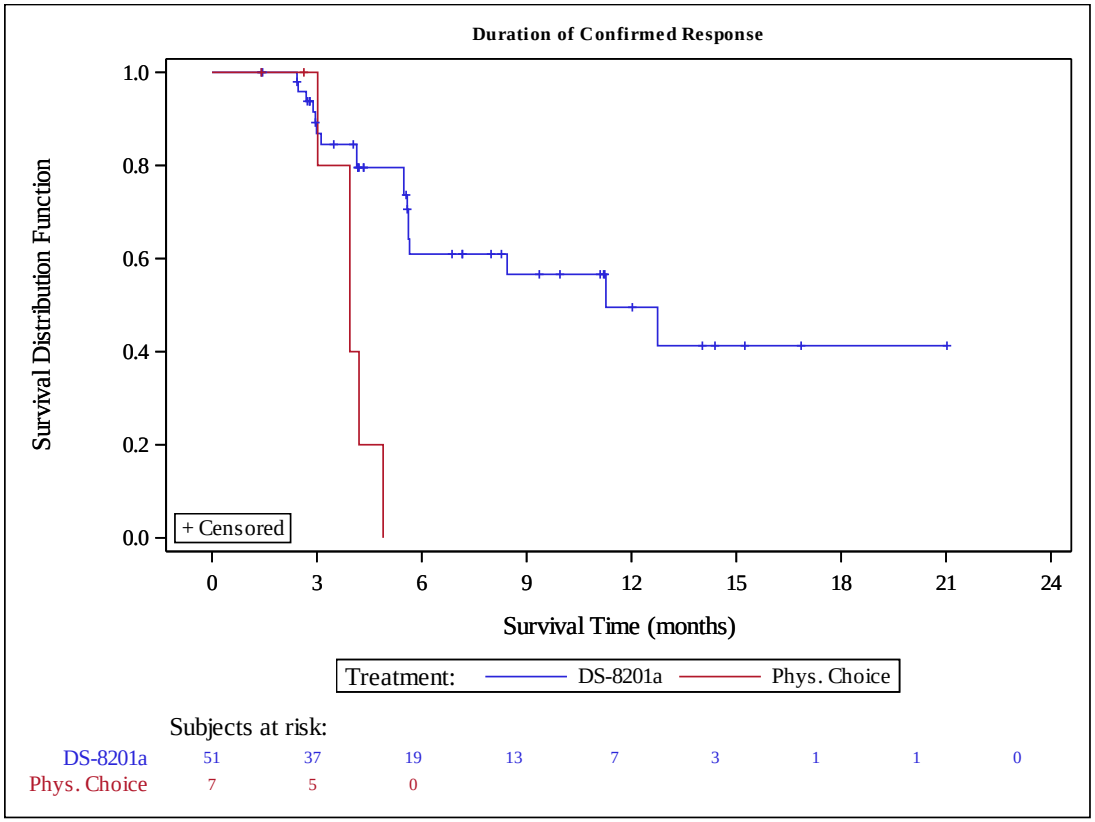
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Duration of Confirmed Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Duration of Response
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with response (CR+PR), N*	61	8
Number of subjects with events, n (%)	25 (41.0)	5 (62.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	8.4 (5.5, NE)	3.9 (3.0, 4.9)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	78.1 (64.5, 87.0)	100.0 (100.0, 100.0)
6 Months (95% CI)	53.1 (37.2, 66.7)	NE (NE, NE)
9 Months (95% CI)	49.3 (33.0, 63.7)	NE (NE, NE)
12 Months (95% CI)	43.1 (25.4, 59.7)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.33 (0.12, 0.90)	
p-value [c]	0.0232	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.32 (0.12, 0.88)	
p-value [c]	0.0208	

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Duration of Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N* (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N* (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.9244
Japan	19/ 48 (39.6)	11.3 (5.5, NE)	4/ 7 (57.1)	4.1 (3.0, 4.9)	0.27 (0.08, 0.85)	0.0157	
Korea	6/ 13 (46.2)	5.6 (1.3, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.59 (0.07, 5.08)	0.6255	
Lines of prior systemic therapy							0.6513
2	14/ 29 (48.3)	5.6 (3.0, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.57 (0.16, 2.10)	0.4227	
3	5/ 18 (27.8)	12.7 (4.1, NE)	2/ 3 (66.7)	3.6 (3.0, 4.2)	0.19 (0.03, 1.15)	0.0430	
>=4	6/ 14 (42.9)	5.6 (4.2, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9921
<65 years	16/ 30 (53.3)	5.6 (4.1, 12.7)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	9/ 31 (29.0)	NE (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.23 (0.07, 0.76)	0.0102	
Sex							0.7294
female	8/ 14 (57.1)	5.6 (1.3, NE)	1/ 2 (50.0)	3.0 (NE , NE)	0.57 (0.06, 5.12)	0.6097	
male	17/ 47 (36.2)	11.3 (5.5, NE)	4/ 6 (66.7)	4.1 (3.9, 4.9)	0.27 (0.08, 0.85)	0.0174	
ECOG PS							0.1610
0	12/ 31 (38.7)	12.7 (5.5, NE)	3/ 3 (100.0)	3.9 (3.0, 3.9)	0.12 (0.03, 0.54)	0.0015	
1	13/ 30 (43.3)	5.6 (3.0, 11.3)	2/ 5 (40.0)	4.6 (4.2, 4.9)	0.58 (0.12, 2.70)	0.4819	
HER2 Status in central laboratory							0.4615
IHC 3+	20/ 53 (37.7)	11.3 (5.6, NE)	4/ 5 (80.0)	4.1 (3.9, 4.9)	0.28 (0.09, 0.87)	0.0207	
IHC 2+/ISH +	5/ 8 (62.5)	5.5 (0.0, NE)	1/ 3 (33.3)	3.0 (NE , NE)	0.47 (0.04, 5.40)	0.5378	
Primary tumor location							0.9922
Gastric	19/ 52 (36.5)	8.4 (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.32 (0.11, 0.91)	0.0269	
GEJ	6/ 9 (66.7)	5.5 (4.1, 12.7)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	16/ 41 (39.0)	11.3 (4.2, NE)	5/ 8 (62.5)	3.9 (3.0, 4.9)	0.26 (0.09, 0.79)	0.0114	
diffuse	8/ 18 (44.4)	5.6 (2.8, NE)	0	NE (NE , NE)	NE	NE	
others	1/ 2 (50.0)	NE (0.0, NE)	0	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.4043
<2	3/ 13 (23.1)	12.7 (2.7, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.19 (0.02, 2.15)	0.1352	
>= 2	22/ 48 (45.8)	5.6 (4.2, NE)	4/ 7 (57.1)	4.1 (3.0, 4.9)	0.37 (0.12, 1.14)	0.0710	
Previous total gastrectomy							0.9944
yes	2/ 12 (16.7)	NE (4.1, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
no	23/ 49 (46.9)	5.6 (4.2, 12.7)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.36 (0.13, 1.02)	0.0473	
Prior adjuvant/ neoadjuvant therapy							0.9942
yes	4/ 18 (22.2)	NE (4.1, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
no	21/ 43 (48.8)	5.7 (4.1, 12.7)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.41 (0.15, 1.16)	0.0873	
Prior ramucirumab contained treatment							0.5894
yes	15/ 42 (35.7)	12.7 (5.5, NE)	3/ 6 (50.0)	3.9 (3.0, 4.2)	0.25 (0.07, 0.95)	0.0276	
no	10/ 19 (52.6)	8.4 (2.4, NE)	2/ 2 (100.0)	4.4 (3.9, 4.9)	0.43 (0.09, 2.13)	0.2854	

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

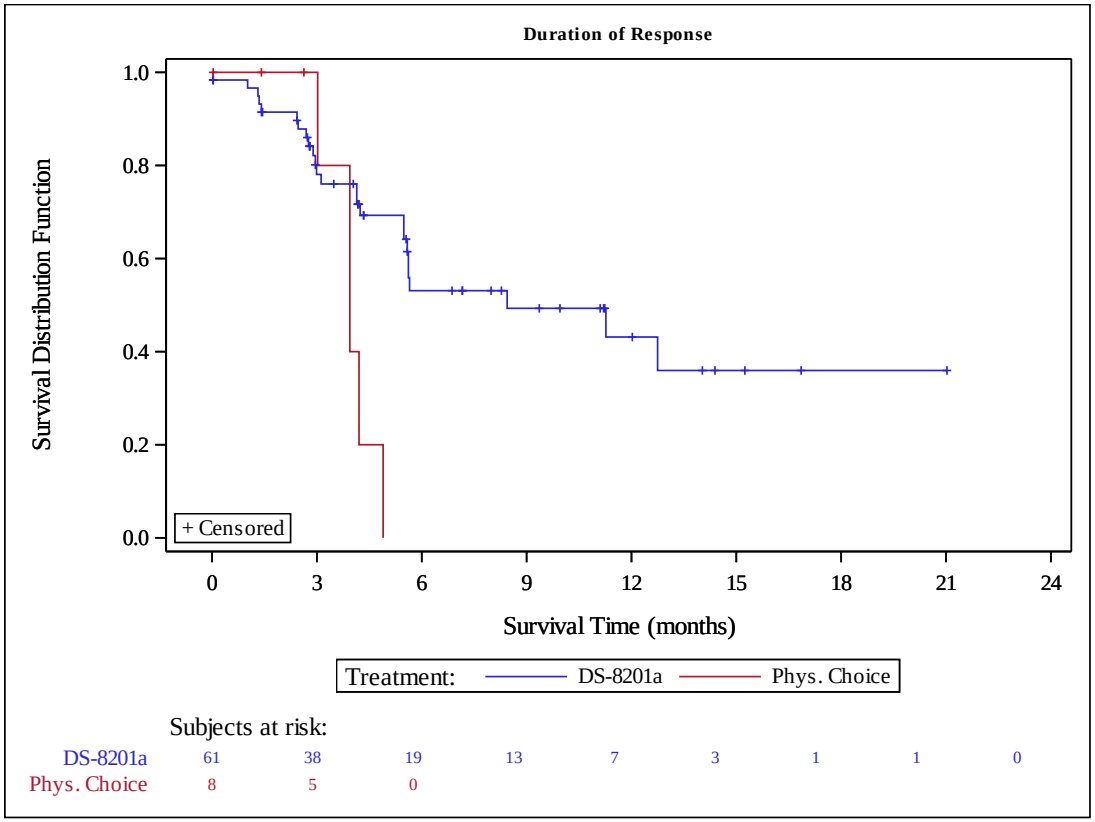
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Duration of Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N* (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N* (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.9646
yes	11/ 22 (50.0)	5.7 (4.2, NE)	2/ 4 (50.0)	3.6 (3.0, 4.2)	0.21 (0.04, 1.09)	0.0383	
no	14/ 39 (35.9)	11.3 (5.5, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.39 (0.11, 1.44)	0.1589	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9126
yes	14/ 29 (48.3)	5.7 (4.2, NE)	2/ 4 (50.0)	3.6 (3.0, 4.2)	0.29 (0.06, 1.40)	0.0997	
no	11/ 32 (34.4)	8.4 (5.5, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.34 (0.09, 1.34)	0.1207	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9940
yes	2/ 9 (22.2)	NE (2.4, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
no	23/ 52 (44.2)	8.4 (5.5, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.31 (0.11, 0.87)	0.0204	
Presence of liver metastasis at baseline							0.9907
yes	15/ 30 (50.0)	5.7 (4.1, NE)	4/ 5 (80.0)	4.1 (3.0, 4.9)	0.35 (0.11, 1.12)	0.0634	
no	10/ 31 (32.3)	11.3 (5.5, NE)	1/ 3 (33.3)	3.9 (NE , NE)	0.48 (0.06, 4.03)	0.4881	
Renal impairment at baseline							0.9461
normal	11/ 19 (57.9)	5.5 (4.1, NE)	0	NE (NE , NE)	NE	NE	
mild	7/ 24 (29.2)	NE (3.1, NE)	3/ 4 (75.0)	4.2 (3.9, 4.9)	0.35 (0.09, 1.41)	0.1223	
moderate	7/ 18 (38.9)	5.6 (3.0, NE)	2/ 4 (50.0)	3.5 (3.0, 3.9)	0.24 (0.04, 1.45)	0.0903	
severe	0	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9914
normal	19/ 46 (41.3)	8.4 (5.5, NE)	4/ 6 (66.7)	3.9 (3.0, 4.9)	0.31 (0.10, 0.98)	0.0381	
mild	6/ 14 (42.9)	NE (2.9, NE)	1/ 2 (50.0)	4.2 (NE , NE)	0.37 (0.04, 3.37)	0.3611	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4613
yes	1/ 3 (33.3)	NE (5.5, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.00 (0.00, NE)	0.0833	
no	24/ 58 (41.4)	8.4 (5.5, NE)	4/ 7 (57.1)	4.1 (3.0, 4.9)	0.37 (0.12, 1.10)	0.0623	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.7350
yes	1/ 1 (100.0)	5.5 (NE , NE)	1/ 1 (100.0)	3.9 (NE , NE)	NE	NE	
no	24/ 60 (40.0)	11.3 (5.6, NE)	4/ 7 (57.1)	4.1 (3.0, 4.9)	0.35 (0.12, 1.05)	0.0497	

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Duration of Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Confirmed Response
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	51 (40.8)	7 (11.3)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	4.1 (2.8, NE)	NE (NE, NE)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	54.0 (43.3, 63.5)	79.0 (57.5, 90.5)
6 Months (95% CI)	44.6 (31.9, 56.6)	79.0 (57.5, 90.5)
9 Months (95% CI)	44.6 (31.9, 56.6)	NE (NE, NE)
12 Months (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	3.10 (1.40, 6.83)	
p-value [c]	0.0031	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	3.06 (1.39, 6.75)	
p-value [c]	0.0033	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Confirmed Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.9626
Japan	42/ 99 (42.4)	3.4 (2.8, NE)	6/ 50 (12.0)	NE (NE , NE)	3.13 (1.33, 7.36)	0.0057	
Korea	9/ 26 (34.6)	5.5 (2.7, NE)	1/ 12 (8.3)	NE (3.0, NE)	2.92 (0.37, 23.15)	0.2879	
Lines of prior systemic therapy							0.9377
2	21/ 66 (31.8)	NE (2.8, NE)	4/ 38 (10.5)	NE (3.0, NE)	2.79 (0.96, 8.13)	0.0480	
3	17/ 34 (50.0)	2.9 (1.7, NE)	3/ 18 (16.7)	NE (1.7, NE)	2.12 (0.62, 7.27)	0.2159	
>=4	13/ 25 (52.0)	3.0 (1.5, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.1510
<65 years	24/ 55 (43.6)	2.9 (2.7, NE)	1/ 27 (3.7)	NE (NE , NE)	9.53 (1.29, 70.56)	0.0067	
>=65 years	27/ 70 (38.6)	NE (2.9, NE)	6/ 35 (17.1)	NE (3.0, NE)	1.95 (0.80, 4.73)	0.1336	
Sex							0.5762
female	10/ 30 (33.3)	NE (2.7, NE)	2/ 15 (13.3)	NE (1.7, NE)	2.08 (0.45, 9.49)	0.3340	
male	41/ 95 (43.2)	3.4 (2.8, NE)	5/ 47 (10.6)	NE (NE , NE)	3.47 (1.37, 8.79)	0.0050	
ECOG PS							0.5850
0	28/ 62 (45.2)	3.2 (2.7, NE)	3/ 30 (10.0)	NE (3.0, NE)	3.80 (1.15, 12.50)	0.0180	
1	23/ 63 (36.5)	5.5 (2.8, NE)	4/ 32 (12.5)	NE (NE , NE)	2.44 (0.84, 7.06)	0.0885	
HER2 Status in central laboratory							0.0466
IHC 3+	45/ 96 (46.9)	3.0 (2.7, NE)	4/ 47 (8.5)	NE (NE , NE)	4.77 (1.72, 13.27)	0.0009	
IHC 2+/ISH +	6/ 29 (20.7)	NE (2.9, NE)	3/ 15 (20.0)	NE (1.6, NE)	0.81 (0.20, 3.23)	0.7620	
Primary tumor location							0.9181
Gastric	43/108 (39.8)	4.1 (2.9, NE)	6/ 55 (10.9)	NE (NE , NE)	3.06 (1.30, 7.19)	0.0068	
GEJ	8/ 17 (47.1)	2.8 (1.4, NE)	1/ 7 (14.3)	NE (1.6, NE)	2.59 (0.32, 20.71)	0.3441	
Histological subtype							0.9999
intestinal	35/ 89 (39.3)	5.5 (2.9, NE)	7/ 38 (18.4)	NE (3.0, NE)	1.96 (0.87, 4.41)	0.0966	
diffuse	15/ 28 (53.6)	2.7 (1.7, 2.9)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	1/ 8 (12.5)	NE (1.4, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.7394
<2	12/ 24 (50.0)	3.4 (1.6, NE)	1/ 10 (10.0)	NE (1.6, NE)	4.21 (0.55, 32.41)	0.1334	
>= 2	39/101 (38.6)	4.1 (2.8, NE)	6/ 52 (11.5)	NE (NE , NE)	2.84 (1.20, 6.72)	0.0125	
Previous total gastrectomy							0.9855
yes	11/ 22 (50.0)	2.8 (1.6, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	40/103 (38.8)	5.5 (2.9, NE)	7/ 53 (13.2)	NE (NE , NE)	2.47 (1.11, 5.52)	0.0220	
Prior adjuvant/ neoadjuvant therapy							0.9887
yes	17/ 30 (56.7)	2.8 (1.6, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	34/ 95 (35.8)	5.5 (2.9, NE)	7/ 52 (13.5)	NE (3.0, NE)	2.11 (0.93, 4.77)	0.0643	
Prior ramucirumab contained treatment							0.6271
yes	38/ 94 (40.4)	4.1 (2.8, NE)	5/ 41 (12.2)	NE (3.0, NE)	2.68 (1.05, 6.81)	0.0305	
no	13/ 31 (41.9)	3.4 (1.7, NE)	2/ 21 (9.5)	NE (NE , NE)	4.13 (0.93, 18.31)	0.0425	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Confirmed Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.5012
yes	20/ 33 (60.6)	2.8 (1.5, 4.1)	3/ 15 (20.0)	NE (1.4, NE)	1.95 (0.57, 6.63)	0.2747	
no	31/ 92 (33.7)	NE (2.9, NE)	4/ 47 (8.5)	NE (NE , NE)	3.54 (1.25, 10.04)	0.0106	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7182
yes	25/ 44 (56.8)	2.8 (1.6, 4.1)	3/ 17 (17.6)	NE (1.7, NE)	2.35 (0.71, 7.79)	0.1500	
no	26/ 81 (32.1)	NE (2.9, NE)	4/ 45 (8.9)	NE (NE , NE)	3.17 (1.11, 9.10)	0.0224	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9857
yes	8/ 22 (36.4)	3.2 (1.7, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	43/103 (41.7)	4.1 (2.8, NE)	7/ 55 (12.7)	NE (NE , NE)	2.66 (1.19, 5.91)	0.0124	
Presence of liver metastasis at baseline							0.5334
yes	25/ 67 (37.3)	3.2 (2.8, NE)	4/ 34 (11.8)	NE (3.0, NE)	2.38 (0.83, 6.85)	0.0955	
no	26/ 58 (44.8)	4.1 (1.7, NE)	3/ 28 (10.7)	NE (NE , NE)	4.07 (1.23, 13.48)	0.0123	
Renal impairment at baseline							0.9758
normal	16/ 33 (48.5)	2.8 (1.6, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	20/ 53 (37.7)	NE (2.8, NE)	3/ 28 (10.7)	NE (NE , NE)	2.38 (0.71, 8.05)	0.1457	
moderate	15/ 39 (38.5)	5.5 (2.7, NE)	4/ 20 (20.0)	NE (3.0, NE)	1.88 (0.62, 5.67)	0.2559	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.3831
normal	37/ 88 (42.0)	NE (2.8, NE)	6/ 47 (12.8)	NE (3.0, NE)	2.51 (1.06, 5.97)	0.0300	
mild	13/ 36 (36.1)	2.9 (2.8, NE)	1/ 15 (6.7)	NE (NE , NE)	7.29 (0.95, 56.20)	0.0264	
moderate	1/ 1 (100.0)	1.6 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3421
yes	3/ 8 (37.5)	NE (1.4, NE)	1/ 5 (20.0)	NE (1.6, NE)	1.26 (0.13, 12.43)	0.8454	
no	48/117 (41.0)	4.1 (2.8, NE)	6/ 57 (10.5)	NE (NE , NE)	3.41 (1.46, 7.97)	0.0025	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.2154
yes	1/ 3 (33.3)	NE (1.4, NE)	1/ 4 (25.0)	NE (1.6, NE)	0.82 (0.05, 13.24)	0.8864	
no	50/122 (41.0)	4.1 (2.8, NE)	6/ 58 (10.3)	NE (NE , NE)	3.46 (1.48, 8.06)	0.0022	

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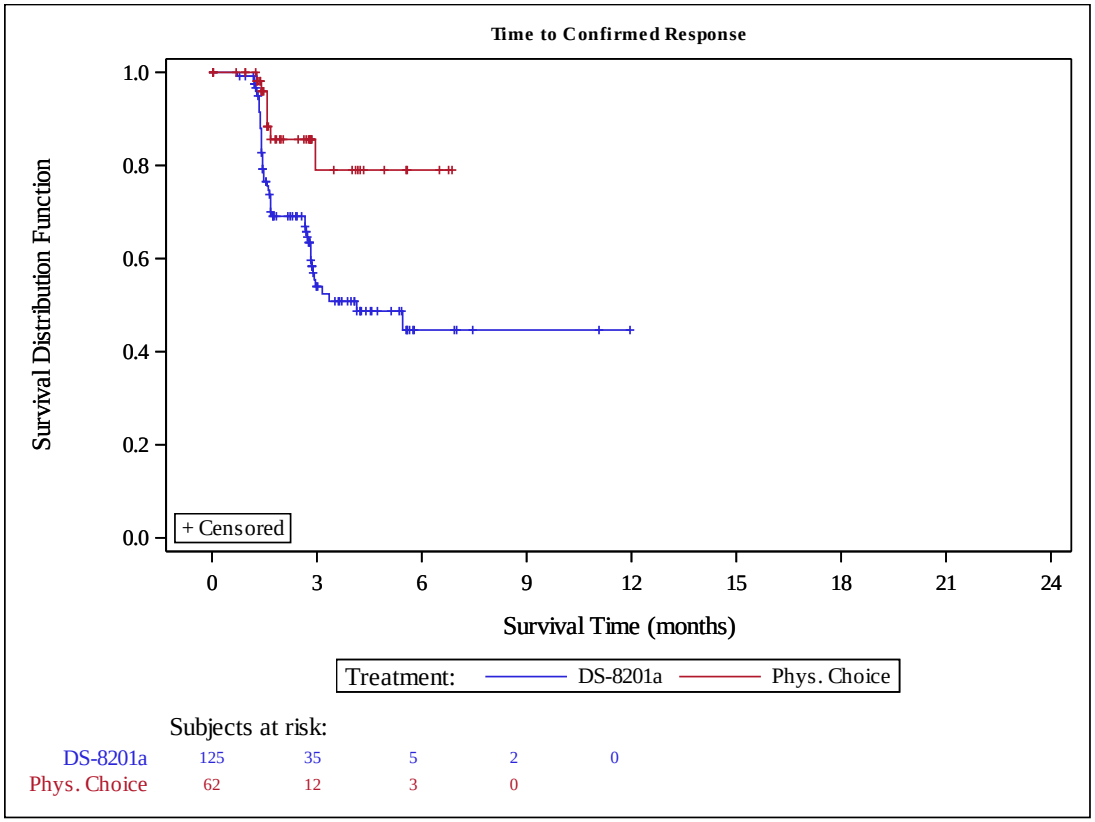
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

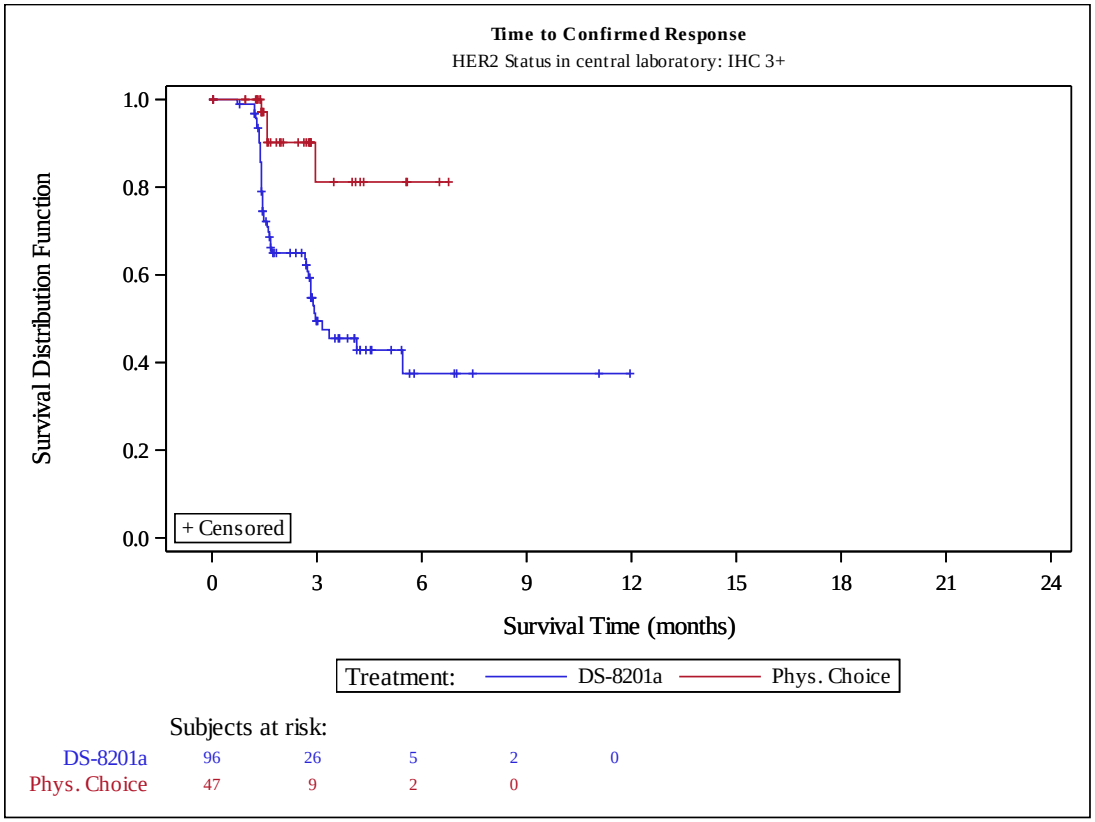
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Time to Confirmed Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

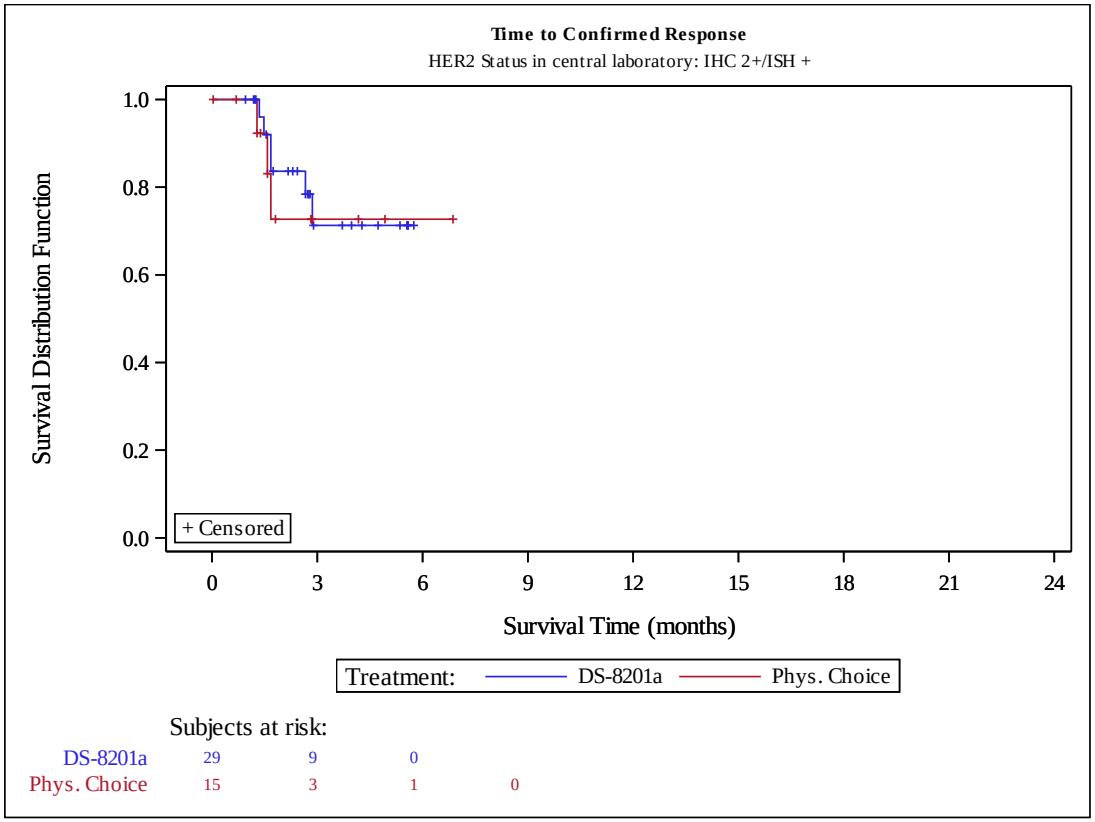
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Time to Confirmed Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Time to Confirmed Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Response
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	61 (48.8)	8 (12.9)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	2.9 (2.7, 5.5)	NE (NE, NE)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	47.8 (37.5, 57.3)	76.6 (55.6, 88.6)
6 Months (95% CI)	33.2 (21.1, 45.9)	76.6 (55.6, 88.6)
9 Months (95% CI)	33.2 (21.1, 45.9)	NE (NE, NE)
12 Months (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	3.33 (1.59, 6.97)	
p-value [c]	0.0007	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	3.34 (1.60, 6.99)	
p-value [c]	0.0006	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.7186
Japan	48/ 99 (48.5)	3.0 (2.7, 5.6)	7/ 50 (14.0)	NE (NE , NE)	3.14 (1.42, 6.93)	0.0027	
Korea	13/ 26 (50.0)	2.8 (1.4, NE)	1/ 12 (8.3)	NE (3.0, NE)	4.68 (0.61, 35.86)	0.1017	
Lines of prior systemic therapy							0.7439
2	29/ 66 (43.9)	5.5 (2.7, NE)	4/ 38 (10.5)	NE (3.0, NE)	4.06 (1.43, 11.55)	0.0042	
3	18/ 34 (52.9)	2.9 (1.7, NE)	3/ 18 (16.7)	NE (1.7, NE)	2.17 (0.64, 7.43)	0.1994	
>=4	14/ 25 (56.0)	2.9 (1.4, 3.4)	1/ 6 (16.7)	NE (1.6, NE)	2.71 (0.36, 20.65)	0.3167	
Age							0.0759
<65 years	30/ 55 (54.5)	2.8 (1.6, 3.0)	1/ 27 (3.7)	NE (NE , NE)	13.04 (1.78, 95.70)	0.0010	
>=65 years	31/ 70 (44.3)	4.1 (2.8, NE)	7/ 35 (20.0)	NE (3.0, NE)	1.89 (0.83, 4.31)	0.1225	
Sex							0.8721
female	14/ 30 (46.7)	3.0 (1.6, NE)	2/ 15 (13.3)	NE (1.7, NE)	2.96 (0.67, 13.05)	0.1322	
male	47/ 95 (49.5)	2.9 (2.7, 5.5)	6/ 47 (12.8)	NE (3.0, NE)	3.48 (1.49, 8.14)	0.0021	
ECOG PS							0.4986
0	31/ 62 (50.0)	2.9 (1.7, NE)	3/ 30 (10.0)	NE (3.0, NE)	4.43 (1.35, 14.51)	0.0069	
1	30/ 63 (47.6)	2.9 (2.7, 5.6)	5/ 32 (15.6)	NE (NE , NE)	2.62 (1.02, 6.77)	0.0375	
HER2 Status in central laboratory							0.0753
IHC 3+	53/ 96 (55.2)	2.8 (1.7, 3.4)	5/ 47 (10.6)	NE (NE , NE)	4.75 (1.90, 11.90)	0.0002	
IHC 2+/ISH +	8/ 29 (27.6)	5.6 (2.9, NE)	3/ 15 (20.0)	NE (1.6, NE)	1.07 (0.28, 4.04)	0.9178	
Primary tumor location							0.9820
Gastric	52/108 (48.1)	3.0 (2.7, 5.5)	7/ 55 (12.7)	NE (NE , NE)	3.29 (1.49, 7.24)	0.0017	
GEJ	9/ 17 (52.9)	1.6 (1.4, NE)	1/ 7 (14.3)	NE (1.6, NE)	3.24 (0.41, 25.64)	0.2298	
Histological subtype							0.9998
intestinal	41/ 89 (46.1)	4.1 (2.8, NE)	8/ 38 (21.1)	NE (3.0, NE)	2.03 (0.95, 4.33)	0.0607	
diffuse	18/ 28 (64.3)	2.7 (1.4, 2.8)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	2/ 8 (25.0)	NE (1.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.7332
<2	13/ 24 (54.2)	2.8 (1.5, NE)	1/ 10 (10.0)	NE (1.6, NE)	4.68 (0.61, 35.81)	0.1015	
>= 2	48/101 (47.5)	2.9 (2.7, 5.6)	7/ 52 (13.5)	NE (NE , NE)	3.14 (1.42, 6.95)	0.0027	
Previous total gastrectomy							0.7369
yes	12/ 22 (54.5)	2.8 (1.6, 4.4)	1/ 9 (11.1)	NE (1.6, NE)	4.54 (0.59, 35.08)	0.1119	
no	49/103 (47.6)	3.2 (2.7, NE)	7/ 53 (13.2)	NE (NE , NE)	3.19 (1.44, 7.04)	0.0023	
Prior adjuvant/ neoadjuvant therapy							0.4067
yes	18/ 30 (60.0)	2.8 (1.6, 4.4)	1/ 10 (10.0)	NE (1.6, NE)	6.81 (0.90, 51.19)	0.0303	
no	43/ 95 (45.3)	3.2 (2.7, NE)	7/ 52 (13.5)	NE (3.0, NE)	2.82 (1.27, 6.27)	0.0077	
Prior ramucirumab contained treatment							0.2585
yes	42/ 94 (44.7)	3.2 (2.8, NE)	6/ 41 (14.6)	NE (3.0, NE)	2.52 (1.07, 5.92)	0.0280	
no	19/ 31 (61.3)	2.7 (1.4, 4.4)	2/ 21 (9.5)	NE (NE , NE)	6.71 (1.56, 28.84)	0.0030	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

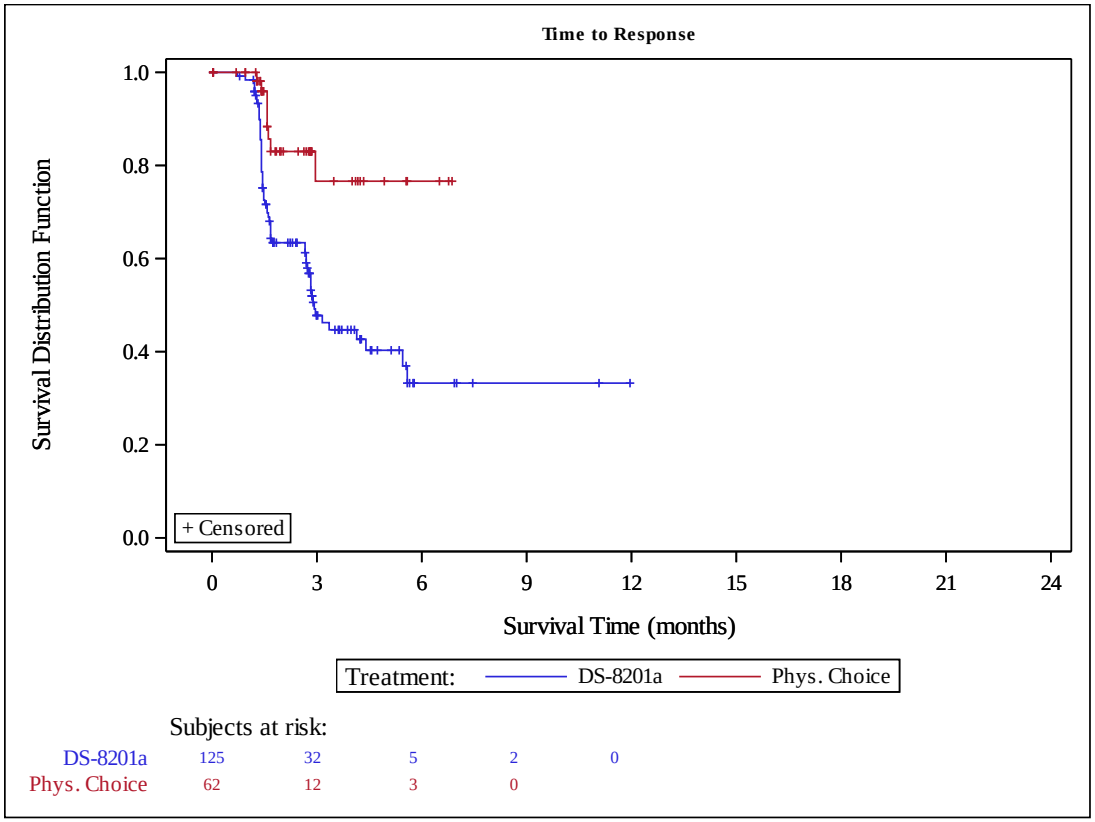
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.2064
yes	22/ 33 (66.7)	2.7 (1.5, 3.4)	4/ 15 (26.7)	NE (1.4, NE)	1.76 (0.60, 5.17)	0.2953	
no	39/ 92 (42.4)	4.4 (2.8, NE)	4/ 47 (8.5)	NE (NE , NE)	4.64 (1.66, 13.00)	0.0012	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.4516
yes	29/ 44 (65.9)	2.7 (1.5, 3.2)	4/ 17 (23.5)	NE (1.6, NE)	2.29 (0.81, 6.54)	0.1090	
no	32/ 81 (39.5)	5.5 (2.8, NE)	4/ 45 (8.9)	NE (NE , NE)	3.97 (1.40, 11.22)	0.0048	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9802
yes	9/ 22 (40.9)	3.2 (1.7, NE)	1/ 7 (14.3)	NE (1.6, NE)	3.04 (0.38, 23.98)	0.2683	
no	52/103 (50.5)	2.9 (2.7, 5.5)	7/ 55 (12.7)	NE (NE , NE)	3.37 (1.53, 7.41)	0.0013	
Presence of liver metastasis at baseline							0.3773
yes	30/ 67 (44.8)	2.9 (2.7, NE)	5/ 34 (14.7)	NE (3.0, NE)	2.44 (0.95, 6.30)	0.0553	
no	31/ 58 (53.4)	2.9 (1.7, NE)	3/ 28 (10.7)	NE (NE , NE)	5.00 (1.53, 16.38)	0.0030	
Renal impairment at baseline							0.9973
normal	19/ 33 (57.6)	2.7 (1.5, 3.0)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	24/ 53 (45.3)	3.4 (1.7, NE)	4/ 28 (14.3)	NE (1.6, NE)	2.16 (0.75, 6.26)	0.1412	
moderate	18/ 39 (46.2)	4.1 (2.7, NE)	4/ 20 (20.0)	NE (3.0, NE)	2.24 (0.76, 6.63)	0.1351	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9021
normal	46/ 88 (52.3)	3.0 (1.7, 5.6)	6/ 47 (12.8)	NE (3.0, NE)	3.28 (1.40, 7.69)	0.0037	
mild	14/ 36 (38.9)	2.9 (2.7, 5.5)	2/ 15 (13.3)	NE (1.6, NE)	3.84 (0.87, 17.06)	0.0579	
moderate	1/ 1 (100.0)	1.6 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.2790
yes	3/ 8 (37.5)	NE (1.4, NE)	1/ 5 (20.0)	NE (1.6, NE)	1.26 (0.13, 12.43)	0.8454	
no	58/117 (49.6)	2.9 (2.7, 4.4)	7/ 57 (12.3)	NE (NE , NE)	3.72 (1.70, 8.15)	0.0004	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.1693
yes	1/ 3 (33.3)	NE (1.4, NE)	1/ 4 (25.0)	NE (1.6, NE)	0.82 (0.05, 13.24)	0.8864	
no	60/122 (49.2)	2.9 (2.7, 5.5)	7/ 58 (12.1)	NE (NE , NE)	3.73 (1.71, 8.17)	0.0004	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Time to Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Results (mm)		
n	117	52
Mean (SD)	40.3 (37.08)	60.0 (54.40)
Median	31.0	42.5
Q1, Q3	14.0, 57.0	26.0, 72.5
Min, Max	0.0, 183.0	0.0, 302.0
Change from Baseline (mm)		
n	117	52
Mean (SD)	-19.8 (24.87)	-2.0 (19.34)
Median	-14.0	-3.0
Q1, Q3	-31.0, -3.0	-10.5, 3.0
Min, Max	-86.0, 29.0	-58.0, 74.0
Percent Change from Baseline (%)		
n	117	52
Mean (SD)	-35.2 (36.69)	-9.0 (29.63)
Median	-32.2	-5.3
Q1, Q3	-62.4, -6.5	-26.6, 6.8
Min, Max	-100.0, 34.0	-100.0, 65.0
LSMean (95% CI) [a]	-35.12 (-41.36, -28.88)	-9.20 (-18.55, 0.16)
Difference of LSMeans (95% CI)	-25.93 (-37.17, -14.68)	
p-value	<.0001	
Hegdes' g (95% CI)	-0.75 (-1.09, -0.42)	
p-value	<.0001	

[a] LSMean obtained from a linear model adjusting for treatment and baseline value.
Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N	Mean (SD)	LSMean (95% CI) [a]	Phys. Choice (N=62) N	Mean (SD)	LSMean (95% CI) [a]	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region											0.5900
Japan	94	-34.6 (37.49)	-34.48 (-41.47, -27.48)	43	-9.8 (27.97)	-10.07 (-20.41, 0.28)	-24.41 (-36.90, -11.92)	0.0001	-0.71 (-1.08, -0.34)	0.0002	
Korea	23	-37.6 (33.89)	-37.71 (-52.07, -23.35)	9	-5.5 (38.34)	-5.16 (-28.13, 17.81)	-32.55 (-59.64, -5.46)	0.0185	-0.93 (-1.73, -0.12)	0.0239	
Lines of prior systemic therapy											0.9556
2	59	-31.4 (36.95)	-31.02 (-39.90, -22.15)	32	-4.7 (32.29)	-5.46 (-17.52, 6.60)	-25.56 (-40.55, -10.57)	0.0008	-0.73 (-1.18, -0.29)	0.0012	
3	33	-36.1 (34.98)	-36.08 (-47.08, -25.07)	15	-14.1 (23.44)	-14.10 (-30.43, 2.23)	-21.98 (-41.67, -2.28)	0.0287	-0.68 (-1.31, -0.06)	0.0327	
>=4	25	-42.9 (38.44)	-43.11 (-57.76, -28.45)	5	-21.4 (27.38)	-20.52 (-53.37, 12.32)	-22.59 (-58.58, 13.41)	0.2188	-0.60 (-1.58, 0.37)	0.2234	
Age											0.0341
<65 years	52	-40.0 (37.00)	-40.22 (-49.46, -30.99)	19	0.0 (25.84)	0.64 (-14.65, 15.94)	-40.87 (-58.74, -22.99)	<.0001	-1.20 (-1.76, -0.64)	<.0001	
>=65 years	65	-31.4 (36.27)	-31.00 (-39.37, -22.62)	33	-14.2 (30.77)	-14.94 (-26.72, -3.17)	-16.05 (-30.54, -1.57)	0.0298	-0.47 (-0.89, -0.04)	0.0313	
Sex											0.7675
female	30	-29.9 (34.86)	-29.67 (-41.34, -18.01)	12	-5.7 (24.94)	-6.39 (-24.87, 12.09)	-23.28 (-45.18, -1.39)	0.0372	-0.71 (-1.40, -0.03)	0.0416	
male	87	-37.0 (37.33)	-37.02 (-44.43, -29.61)	40	-10.0 (31.11)	-9.99 (-20.93, 0.94)	-27.03 (-40.23, -13.82)	<.0001	-0.77 (-1.15, -0.38)	0.0001	
ECOG PS											0.3391
0	58	-37.3 (38.59)	-37.89 (-47.24, -28.54)	28	-7.5 (31.91)	-6.29 (-19.79, 7.21)	-31.60 (-48.08, -15.12)	0.0002	-0.87 (-1.34, -0.40)	0.0003	
1	59	-33.1 (34.93)	-32.62 (-41.04, -24.19)	24	-10.8 (27.29)	-12.05 (-25.35, 1.25)	-20.56 (-36.41, -4.72)	0.0110	-0.62 (-1.11, -0.14)	0.0118	
HER2 Status in central laboratory											0.0546
IHC 3+	89	-38.9 (37.38)	-38.59 (-45.82, -31.37)	40	-6.0 (29.32)	-6.75 (-17.54, 4.04)	-31.84 (-44.84, -18.84)	<.0001	-0.92 (-1.30, -0.53)	<.0001	
IHC 2+/ISH +	28	-23.4 (32.23)	-23.31 (-35.20, -11.42)	12	-19.0 (29.67)	-19.14 (-37.42, -0.86)	-4.17 (-26.13, 17.79)	0.7097	-0.13 (-0.81, 0.55)	0.7072	
Primary tumor location											0.4918
Gastric	102	-34.2 (36.51)	-33.99 (-40.68, -27.30)	46	-9.3 (30.55)	-9.65 (-19.62, 0.32)	-24.34 (-36.35, -12.33)	<.0001	-0.71 (-1.06, -0.35)	0.0001	
GEJ	15	-42.2 (38.43)	-42.58 (-60.68, -24.48)	6	-7.2 (23.45)	-6.33 (-35.02, 22.37)	-36.25 (-70.27, -2.24)	0.0367	-1.01 (-2.01, -0.02)	0.0460	
Histological subtype											0.1791
intestinal	85	-34.3 (37.33)	-34.14 (-41.68, -26.61)	36	-14.2 (32.57)	-14.56 (-26.14, -2.98)	-19.59 (-33.40, -5.77)	0.0055	-0.55 (-0.95, -0.16)	0.0062	
diffuse	26	-39.7 (31.69)	-39.73 (-50.55, -28.90)	12	4.7 (15.39)	4.71 (-11.24, 20.66)	-44.44 (-63.73, -25.14)	<.0001	-1.58 (-2.35, -0.81)	<.0001	
others	6	-28.1 (51.14)	-27.52 (-64.67, 9.63)	4	-4.0 (23.80)	-4.89 (-50.68, 40.91)	-22.63 (-82.49, 37.23)	0.4587	-0.49 (-1.77, 0.80)	0.4575	
Number of metastatic sites											0.4450
<2	21	-49.2 (42.17)	-49.91 (-66.31, -33.50)	6	-12.9 (25.23)	-10.30 (-41.11, 20.51)	-39.61 (-74.60, -4.62)	0.0265	-1.03 (-1.98, -0.08)	0.0329	
>= 2	96	-32.1 (34.88)	-32.14 (-38.83, -25.44)	46	-8.5 (30.36)	-8.53 (-18.20, 1.13)	-23.60 (-35.36, -11.84)	<.0001	-0.71 (-1.07, -0.34)	0.0001	
Previous total gastrectomy											0.3793
yes	20	-42.5 (36.36)	-41.64 (-56.49, -26.79)	8	-6.0 (32.00)	-8.21 (-31.76, 15.34)	-33.43 (-61.35, -5.50)	0.0190	-0.99 (-1.85, -0.13)	0.0246	
no	97	-33.7 (36.77)	-33.48 (-40.24, -26.71)	44	-9.6 (29.53)	-10.04 (-20.08, 0.00)	-23.44 (-35.55, -11.33)	0.0001	-0.69 (-1.05, -0.32)	0.0002	
Prior adjuvant/ neoadjuvant therapy											0.1188
yes	27	-50.5 (37.42)	-50.89 (-64.40, -37.38)	8	-6.8 (31.15)	-5.38 (-30.26, 19.50)	-45.51 (-73.86, -17.15)	0.0017	-1.27 (-2.11, -0.43)	0.0032	
no	90	-30.6 (35.41)	-30.55 (-37.48, -23.61)	44	-9.4 (29.70)	-9.57 (-19.49, 0.35)	-20.97 (-33.08, -8.87)	0.0007	-0.62 (-0.99, -0.26)	0.0009	
Prior ramucirumab contained treatment											0.4319
yes	88	-33.3 (38.65)	-33.24 (-40.95, -25.52)	33	-9.8 (31.90)	-9.97 (-22.57, 2.63)	-23.26 (-38.04, -8.49)	0.0020	-0.63 (-1.04, -0.22)	0.0025	
no	29	-40.9 (29.82)	-40.72 (-50.73, -30.71)	19	-7.7 (25.97)	-8.02 (-20.39, 4.35)	-32.70 (-48.62, -16.78)	<.0001	-1.19 (-1.81, -0.56)	0.0002	
Prior nivolumab contained treatment											0.7638
yes	33	-46.7 (34.96)	-46.81 (-57.83, -35.78)	13	-18.8 (23.18)	-18.60 (-36.17, -1.02)	-28.21 (-48.96, -7.46)	0.0077	-0.87 (-1.54, -0.21)	0.0102	
no	84	-30.7 (36.56)	-30.51 (-37.91, -23.10)	39	-5.8 (31.05)	-6.12 (-16.99, 4.76)	-24.39 (-37.55, -11.23)	0.0003	-0.70 (-1.09, -0.31)	0.0004	

[a] LSMean obtained from a linear model adjusting for treatment and baseline value.
[b] P-value obtained from the same linear model plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 07JUN2022

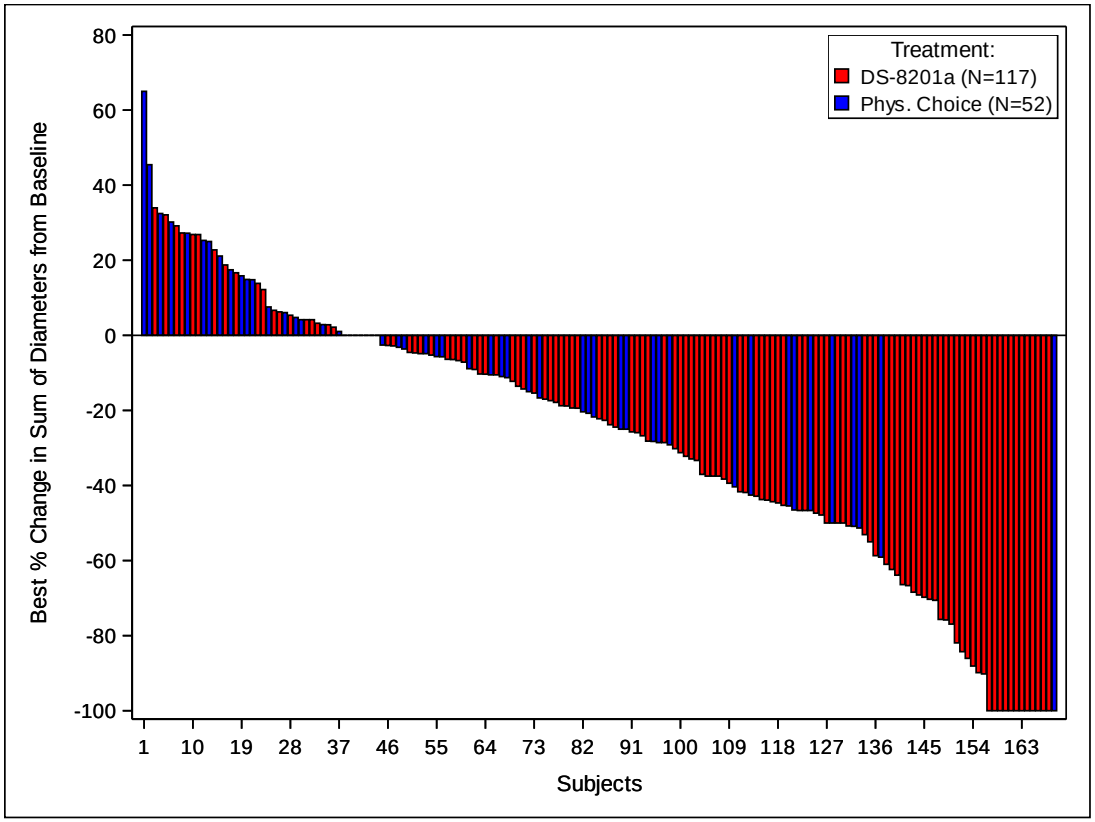
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N	Mean (SD)	LSMean (95% CI) [a]	Phys. Choice (N=62) N	Mean (SD)	LSMean (95% CI) [a]	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy											0.4887
yes	43	-47.3 (33.98)	-47.56 (-56.90, -38.21)	15	-17.9 (22.15)	-17.29 (-33.13, -1.45)	-30.27 (-48.67, -11.86)	0.0013	-0.97 (-1.58, -0.35)	0.0020	
no	74	-28.1 (36.57)	-27.86 (-35.79, -19.93)	37	-5.4 (31.72)	-5.98 (-17.20, 5.24)	-21.88 (-35.64, -8.12)	0.0018	-0.63 (-1.03, -0.23)	0.0022	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug											0.4304
yes	21	-27.3 (34.00)	-27.09 (-41.17, -13.01)	5	-14.4 (24.06)	-15.12 (-44.03, 13.79)	-11.97 (-44.16, 20.22)	0.4661	-0.36 (-1.34, 0.62)	0.4673	
no	96	-36.9 (37.20)	-36.81 (-43.73, -29.89)	47	-8.5 (30.32)	-8.71 (-18.60, 1.19)	-28.10 (-40.18, -16.03)	<.0001	-0.81 (-1.17, -0.45)	<.0001	
Presence of liver metastasis at baseline											0.7020
yes	65	-29.5 (33.84)	-29.48 (-37.78, -21.18)	30	-5.3 (34.29)	-5.40 (-17.62, 6.82)	-24.08 (-38.86, -9.30)	0.0014	-0.71 (-1.15, -0.26)	0.0018	
no	52	-42.3 (39.16)	-42.43 (-51.89, -32.98)	22	-14.2 (21.43)	-13.75 (-28.30, 0.80)	-28.68 (-46.04, -11.32)	0.0012	-0.82 (-1.34, -0.31)	0.0017	
Renal impairment at baseline											0.1912
normal	32	-39.4 (38.58)	-39.18 (-51.14, -27.23)	10	-1.9 (15.96)	-2.44 (-23.83, 18.96)	-36.74 (-61.26, -12.23)	0.0033	-1.06 (-1.81, -0.32)	0.0051	
mild	51	-34.4 (36.52)	-33.91 (-43.36, -24.46)	25	-2.3 (30.22)	-3.29 (-16.82, 10.24)	-30.63 (-47.18, -14.07)	0.0003	-0.89 (-1.39, -0.39)	0.0005	
moderate	34	-32.5 (35.88)	-32.14 (-43.89, -20.39)	17	-23.1 (31.15)	-23.79 (-40.53, -7.06)	-8.35 (-29.00, 12.30)	0.4281	-0.24 (-0.82, 0.35)	0.4239	
severe	0	-	NE	0	-	NE	NE	NE	NE	NE	
Hepatic impairment at baseline											0.6324
normal	82	-38.4 (35.45)	-38.43 (-45.78, -31.07)	39	-10.9 (30.88)	-10.83 (-21.50, -0.16)	-27.60 (-40.56, -14.64)	<.0001	-0.81 (-1.21, -0.42)	<.0001	
mild	34	-26.5 (38.87)	-25.87 (-37.80, -13.94)	13	-3.3 (25.77)	-5.07 (-24.45, 14.31)	-20.80 (-43.64, 2.05)	0.0744	-0.59 (-1.24, 0.06)	0.0776	
moderate	1	-68.4 (-)	-68.42 (-70.38, -66.46)	0	-	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors											0.3729
yes	7	-35.6 (43.48)	-33.24 (-65.56, -0.93)	3	-26.3 (29.18)	-31.69 (-83.06, 19.68)	-1.55 (-64.70, 61.59)	0.9615	-0.04 (-1.39, 1.32)	0.9592	
no	110	-35.2 (36.45)	-35.17 (-41.57, -28.77)	49	-8.0 (29.62)	-7.98 (-17.57, 1.60)	-27.19 (-38.71, -15.66)	<.0001	-0.79 (-1.14, -0.45)	<.0001	
Most recently treatment with irinotecan or other topoisomerase I inhibitors											0.4596
yes	2	-45.2 (30.30)	-36.67 (-78.34, 5.00)	2	-37.9 (30.00)	-46.44 (-88.12, -4.77)	9.77 (-52.73, 72.28)	0.7593	0.33 (-1.65, 2.30)	0.7468	
no	115	-35.0 (36.88)	-35.00 (-41.31, -28.69)	50	-7.9 (29.32)	-7.93 (-17.50, 1.65)	-27.07 (-38.54, -15.61)	<.0001	-0.78 (-1.13, -0.44)	<.0001	

[a] LSMean obtained from a linear model adjusting for treatment and baseline value.
[b] P-value obtained from the same linear model plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

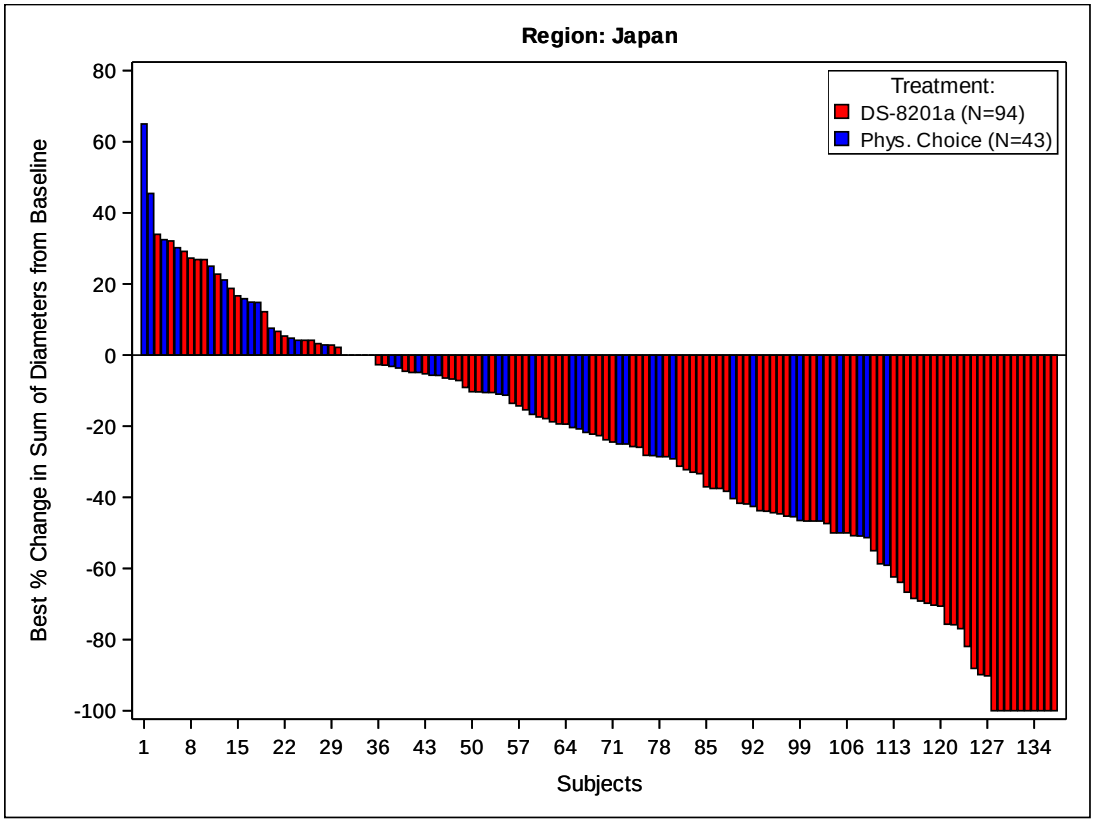
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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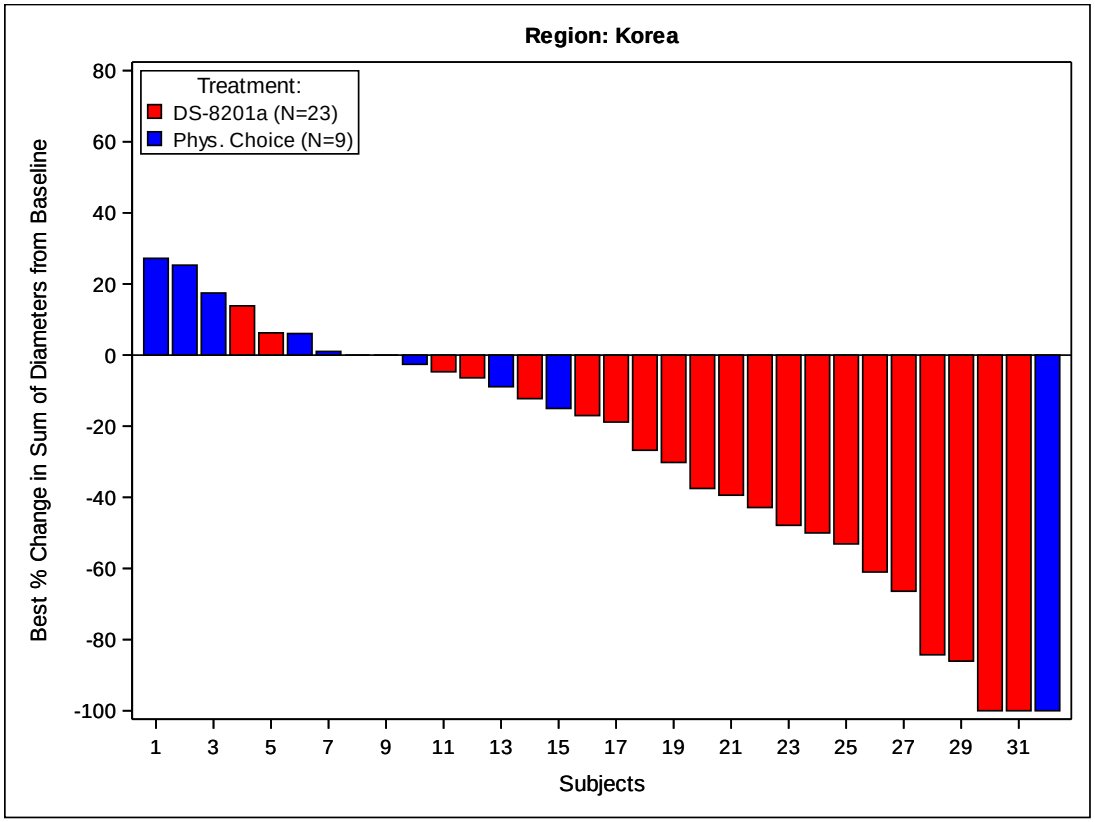

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Protocol DS8201-A-J202
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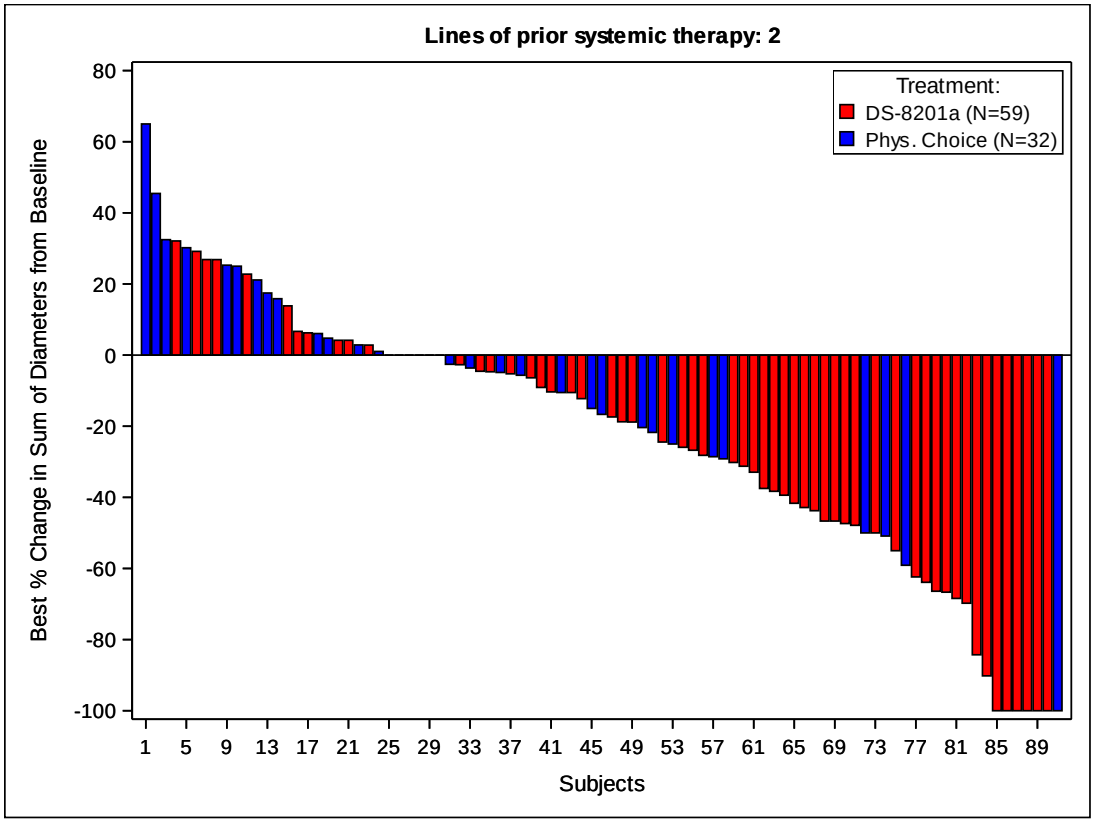

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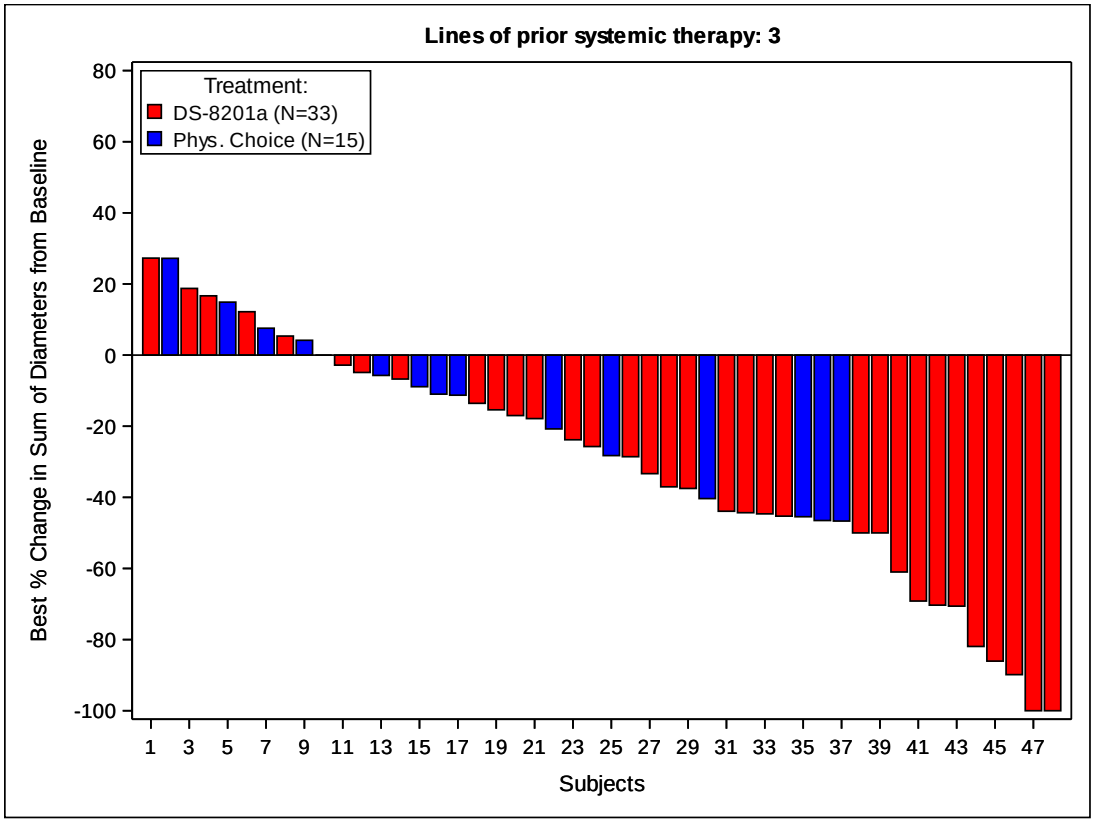

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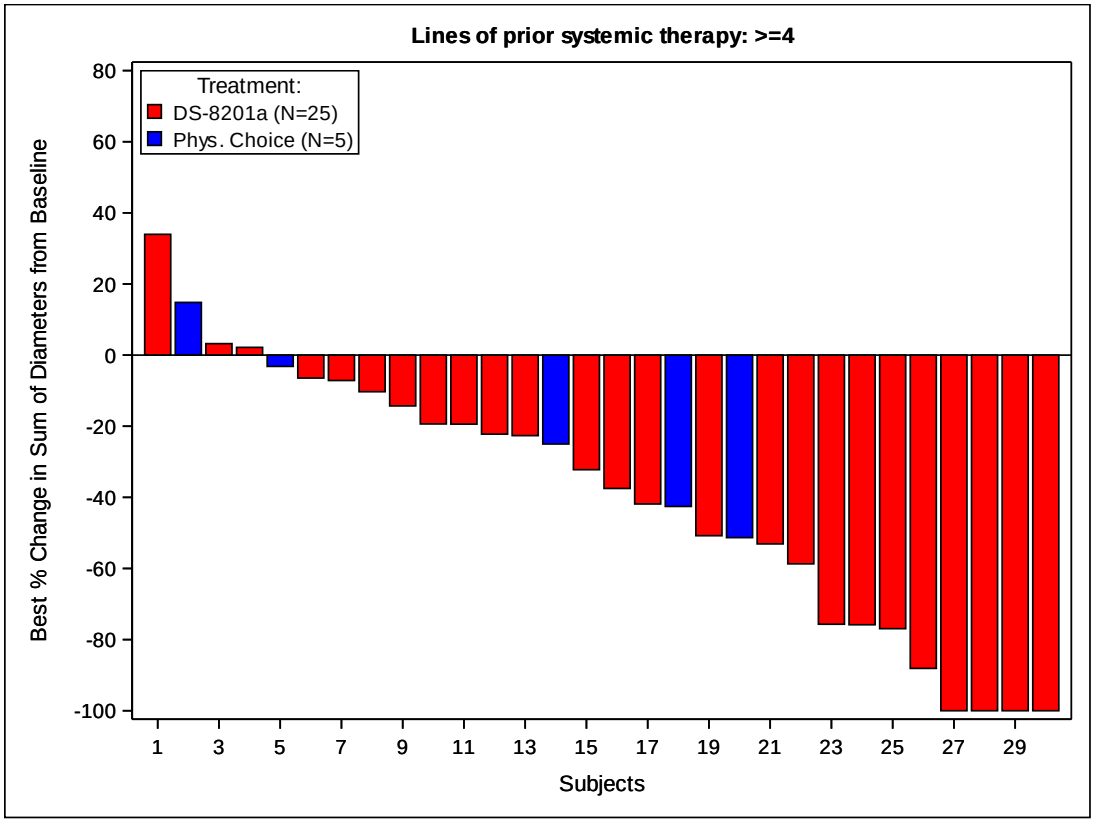

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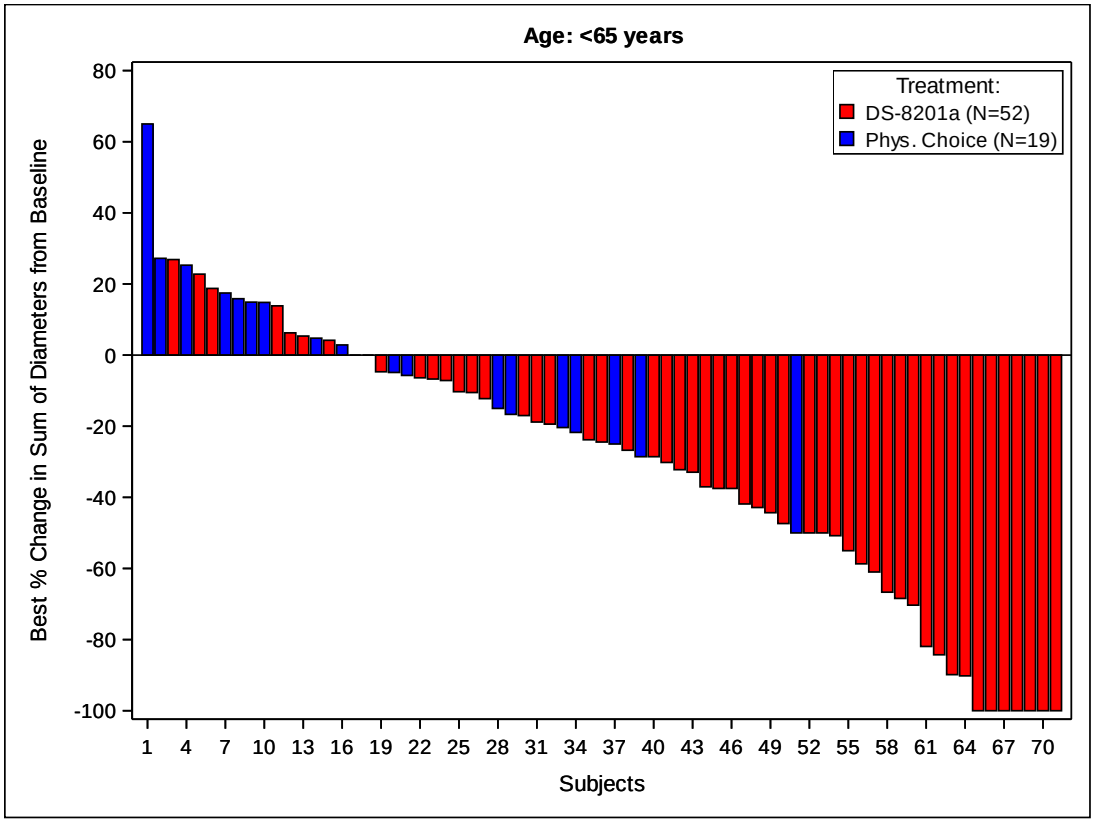

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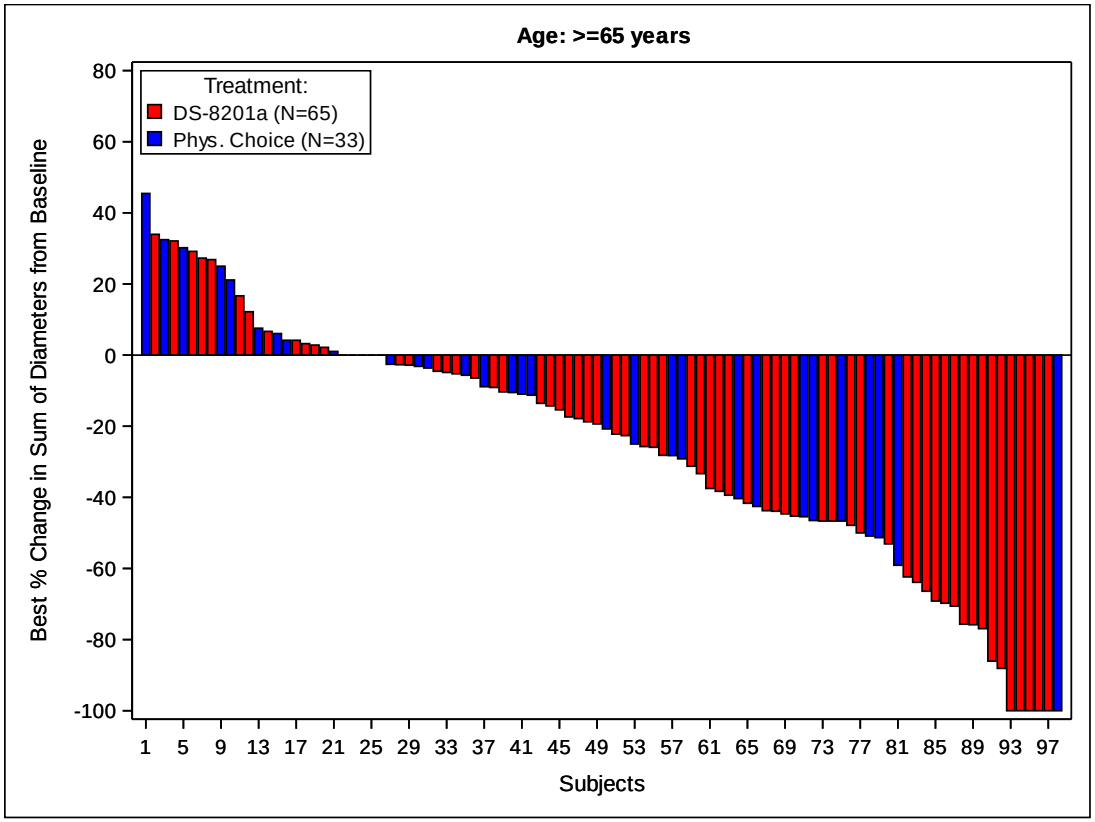

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Protocol DS8201-A-J202
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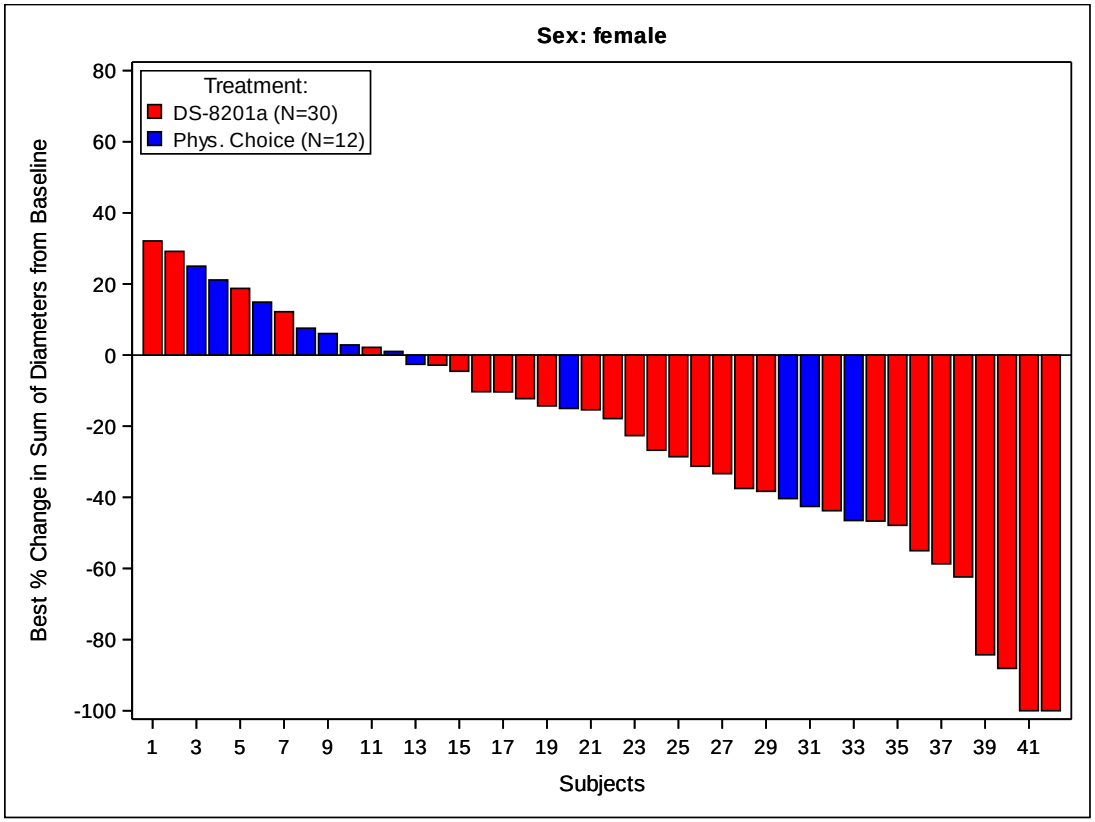

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Protocol DS8201-A-J202
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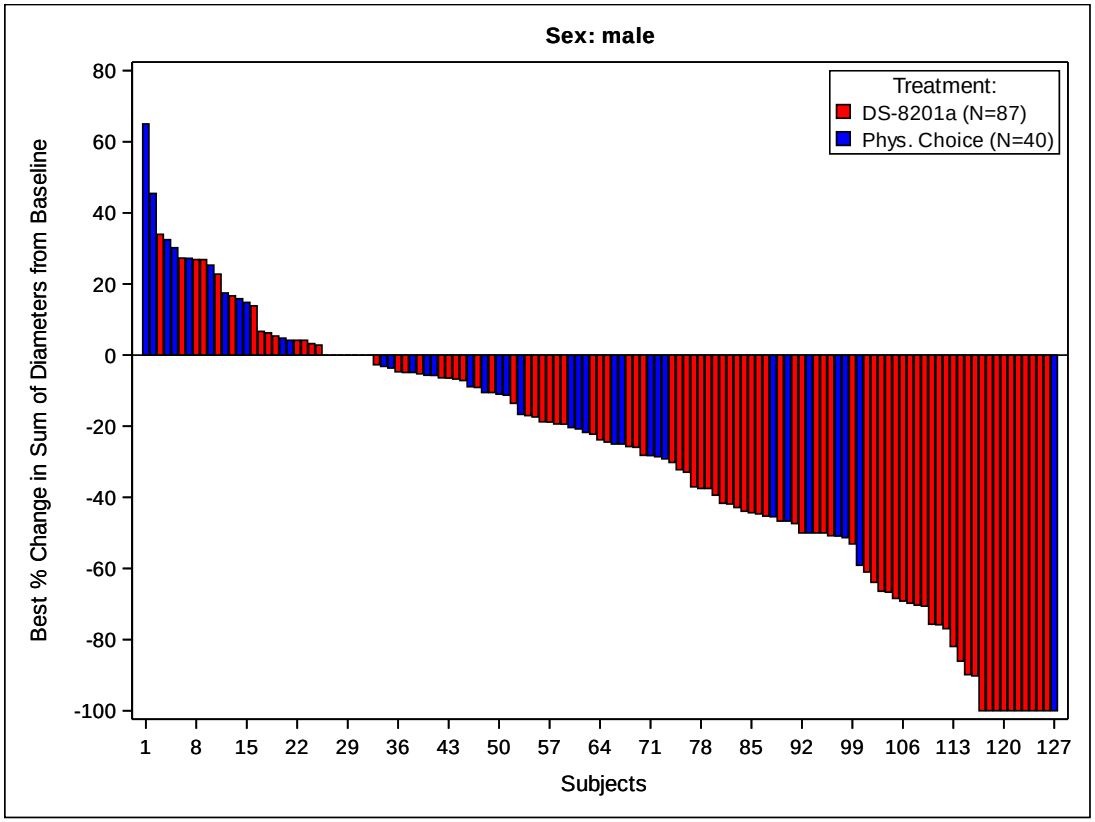

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Protocol DS8201-A-J202
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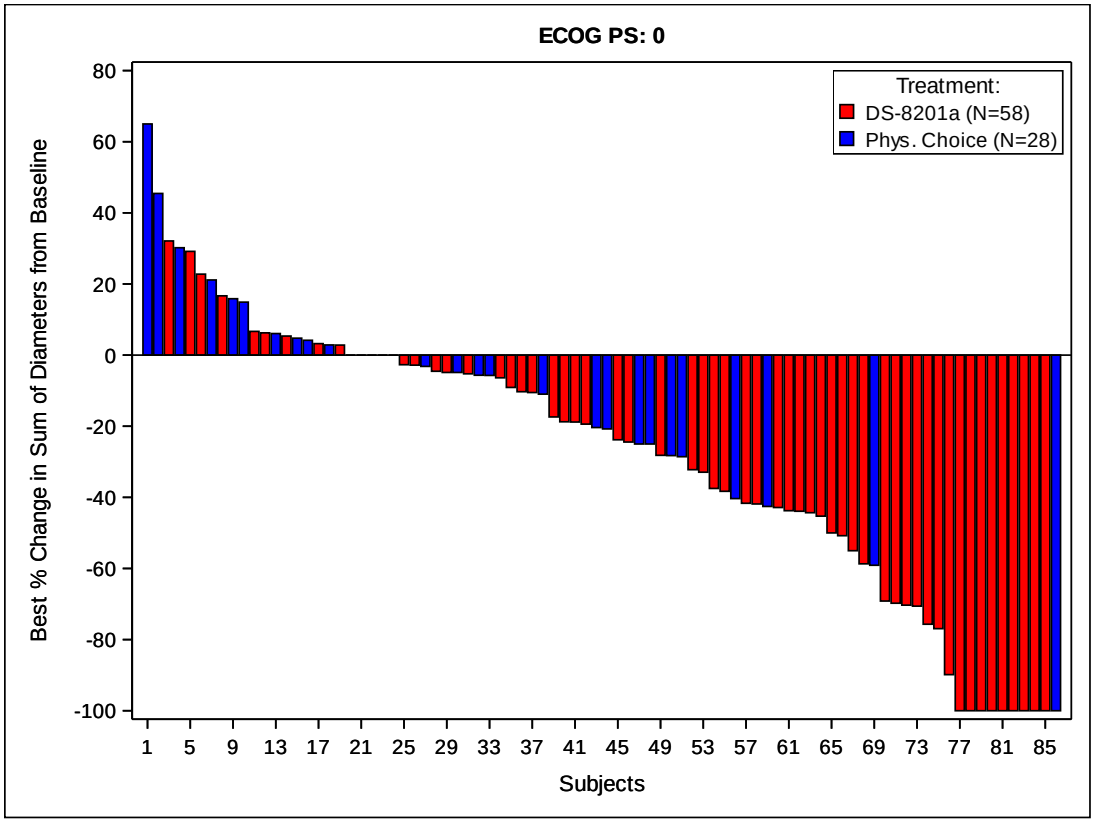

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Protocol DS8201-A-J202
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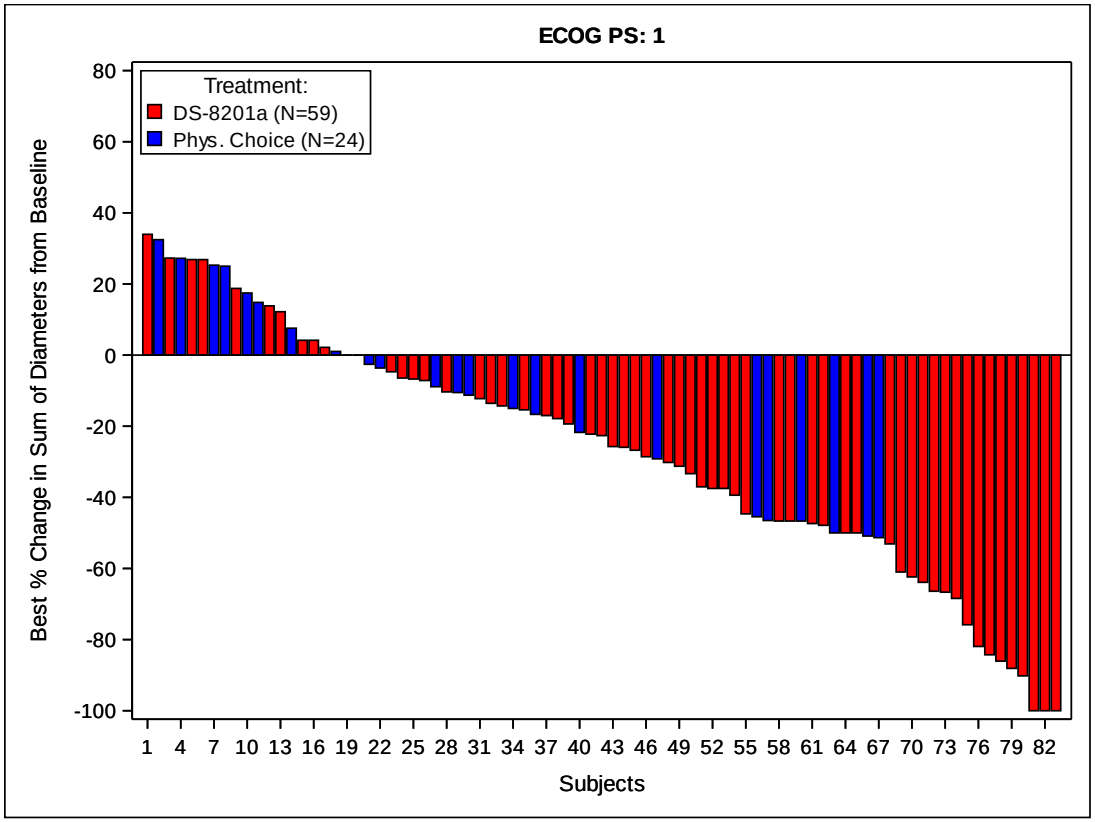

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Protocol DS8201-A-J202
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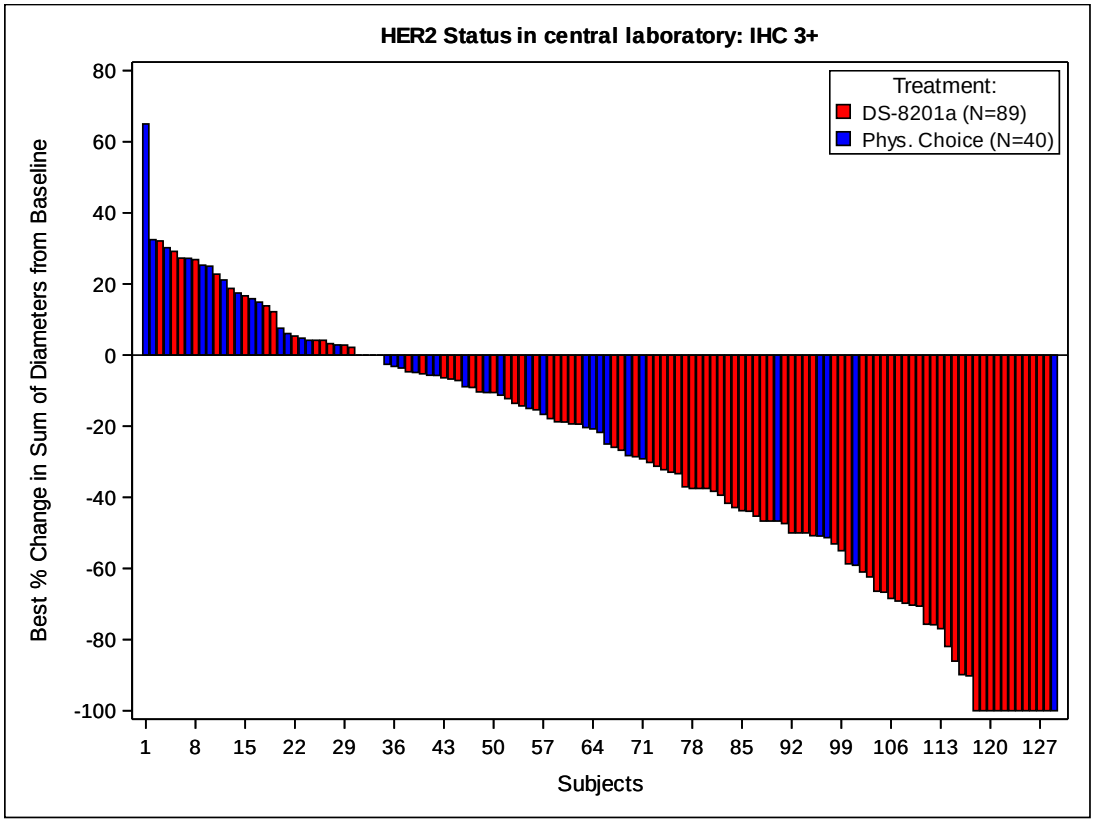

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Protocol DS8201-A-J202
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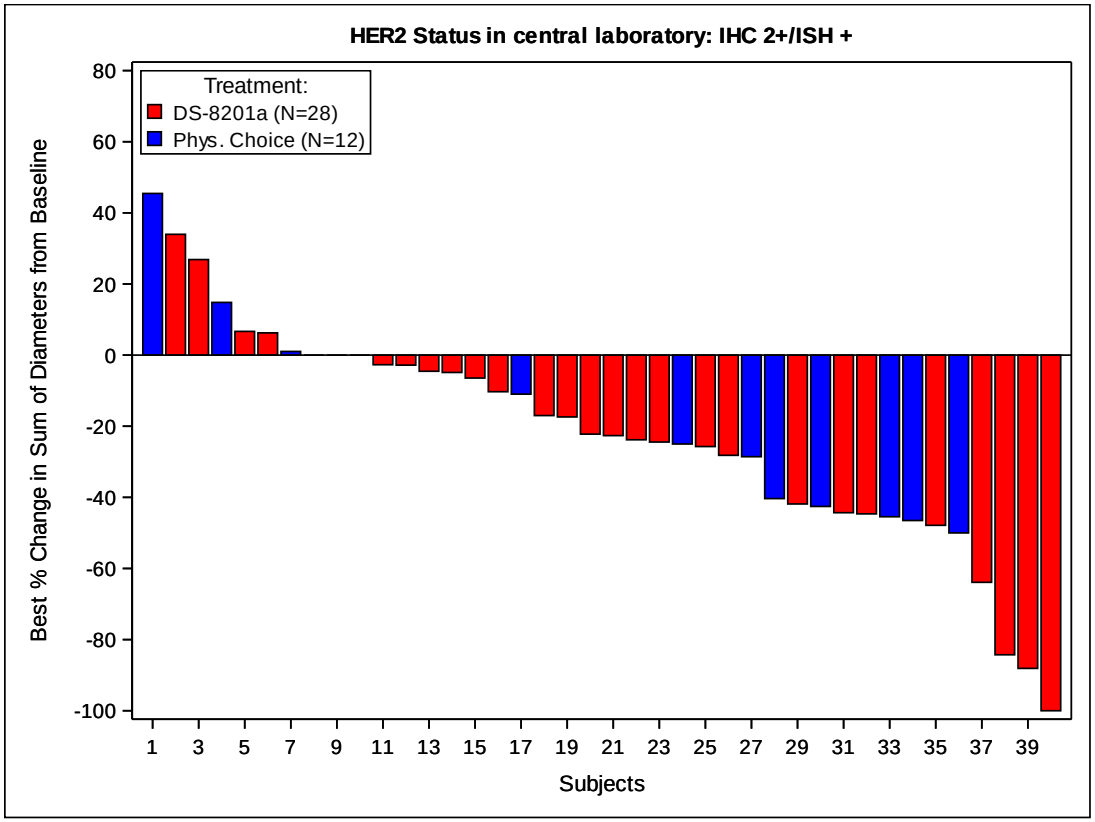

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Protocol DS8201-A-J202
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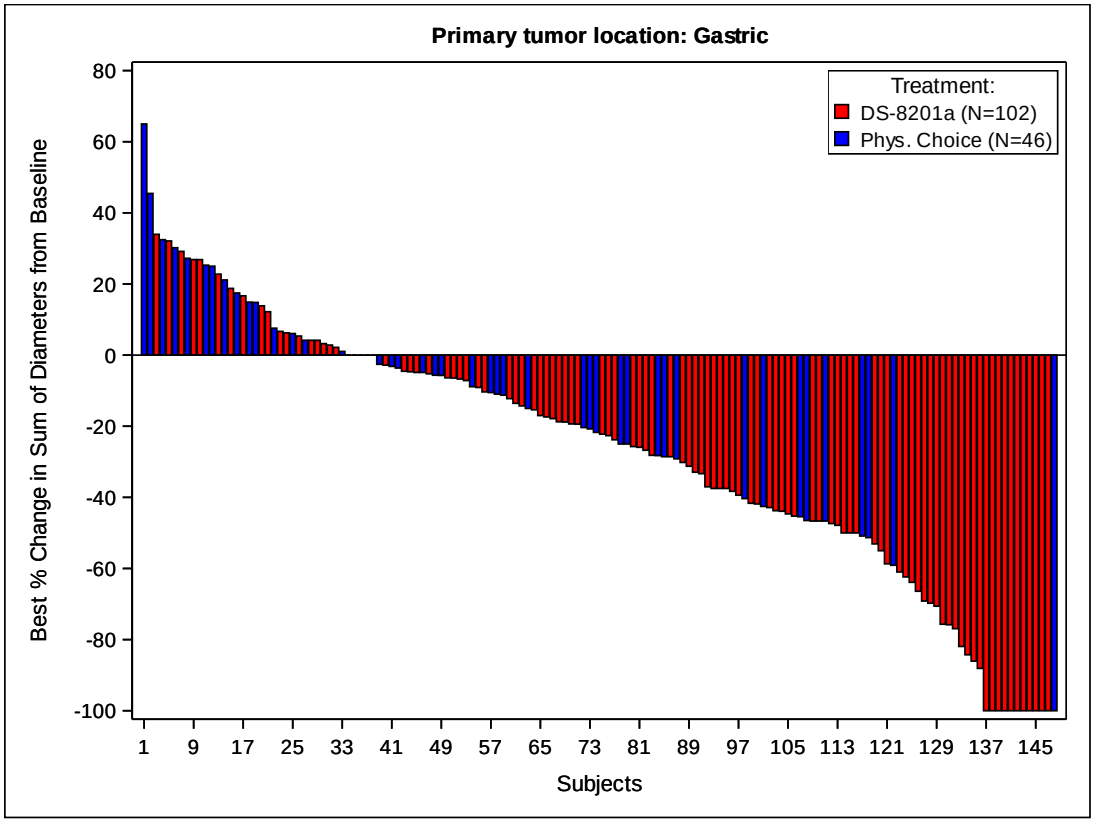

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Protocol DS8201-A-J202
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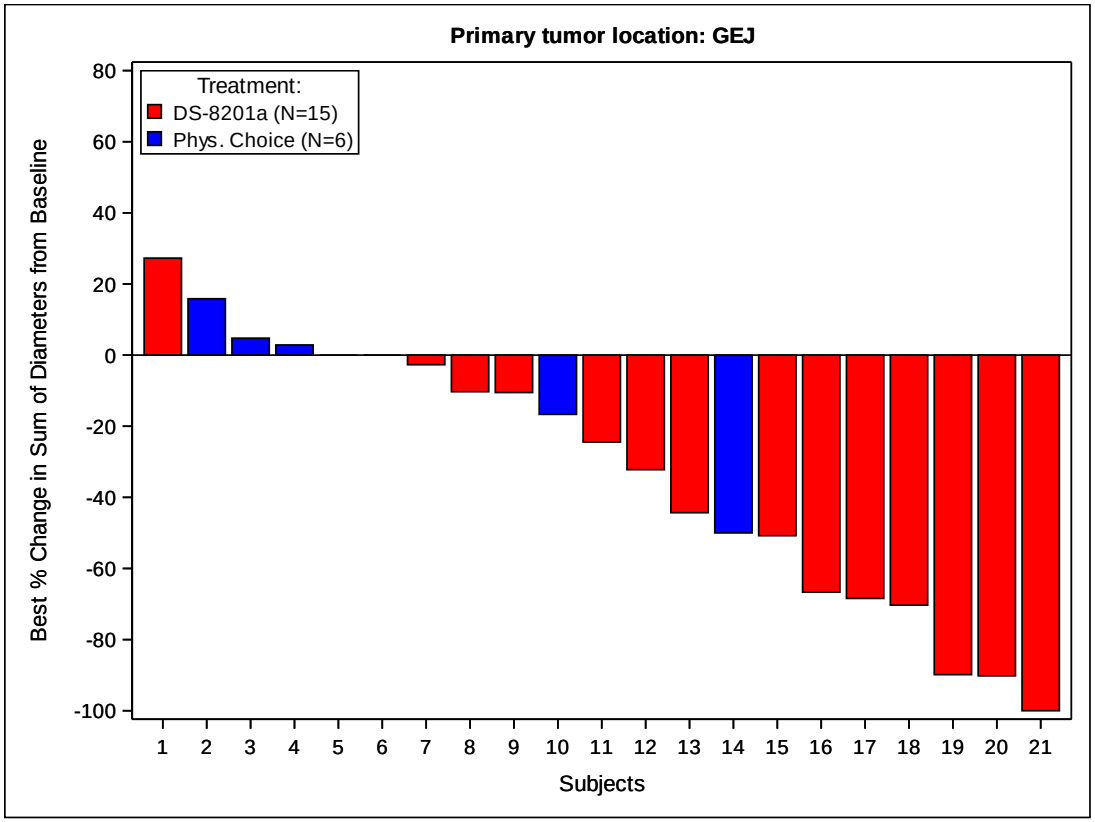

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
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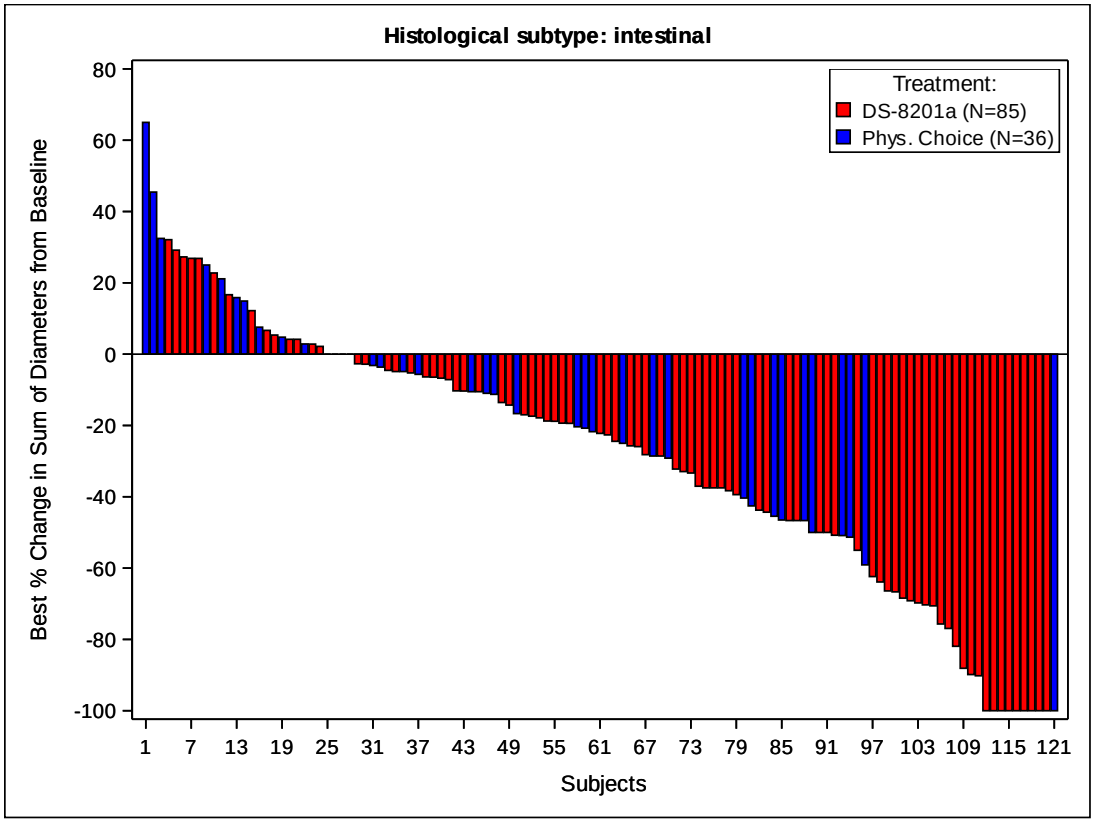
Full Analysis Set



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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
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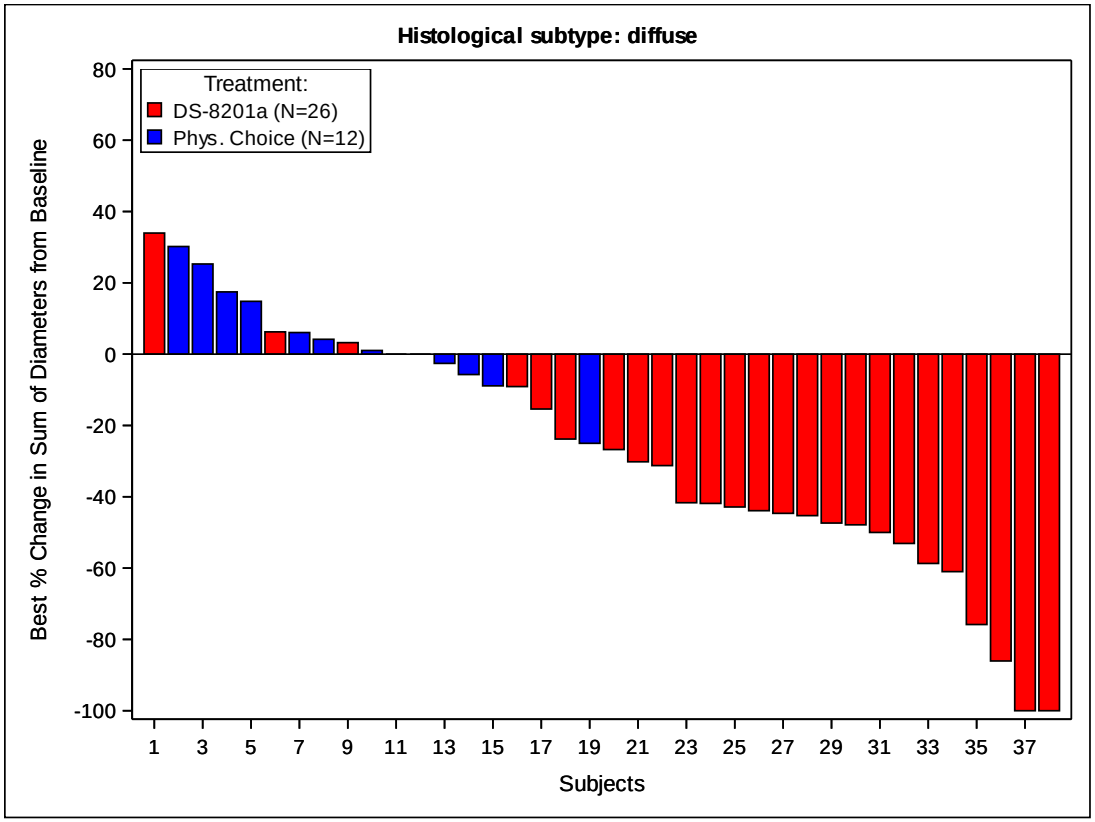

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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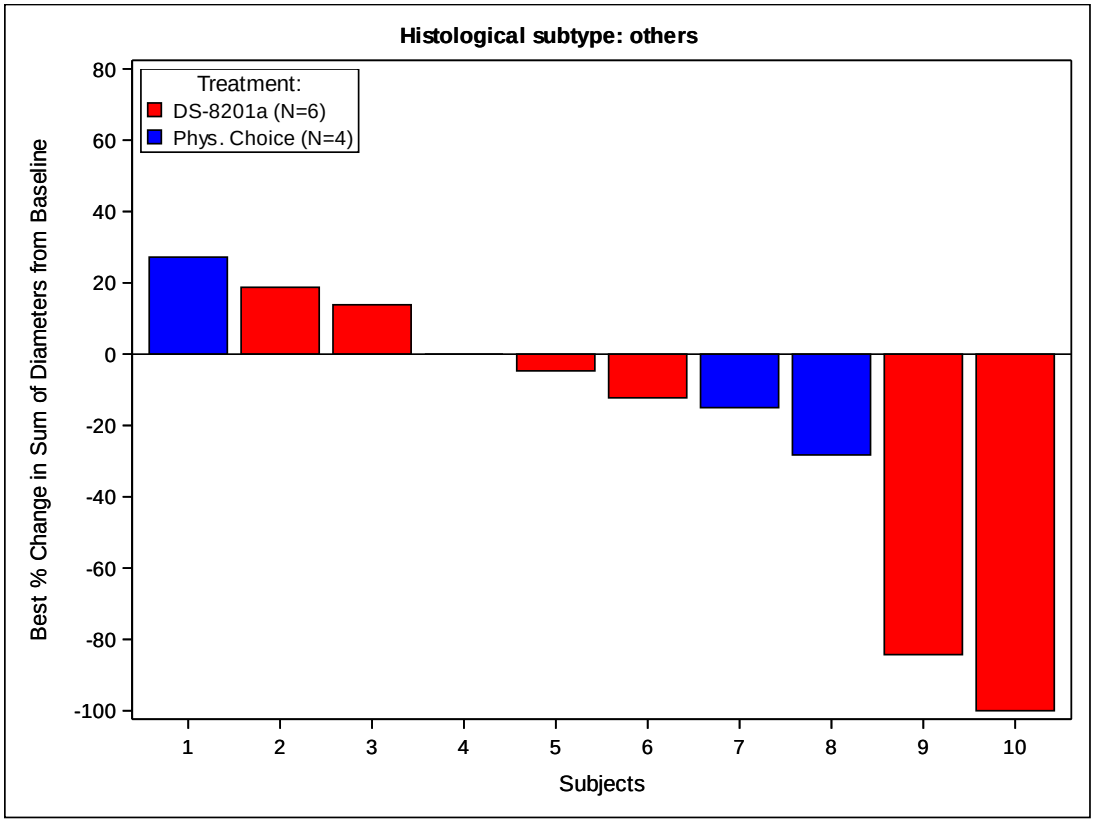
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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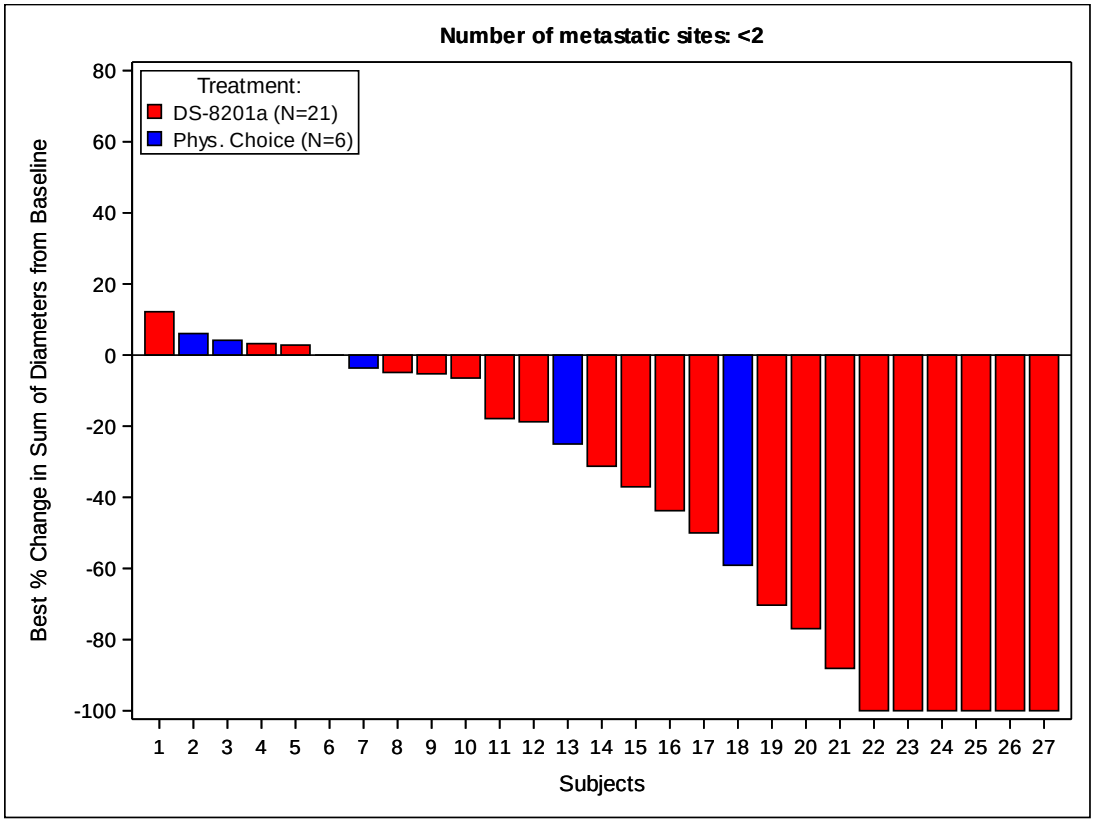

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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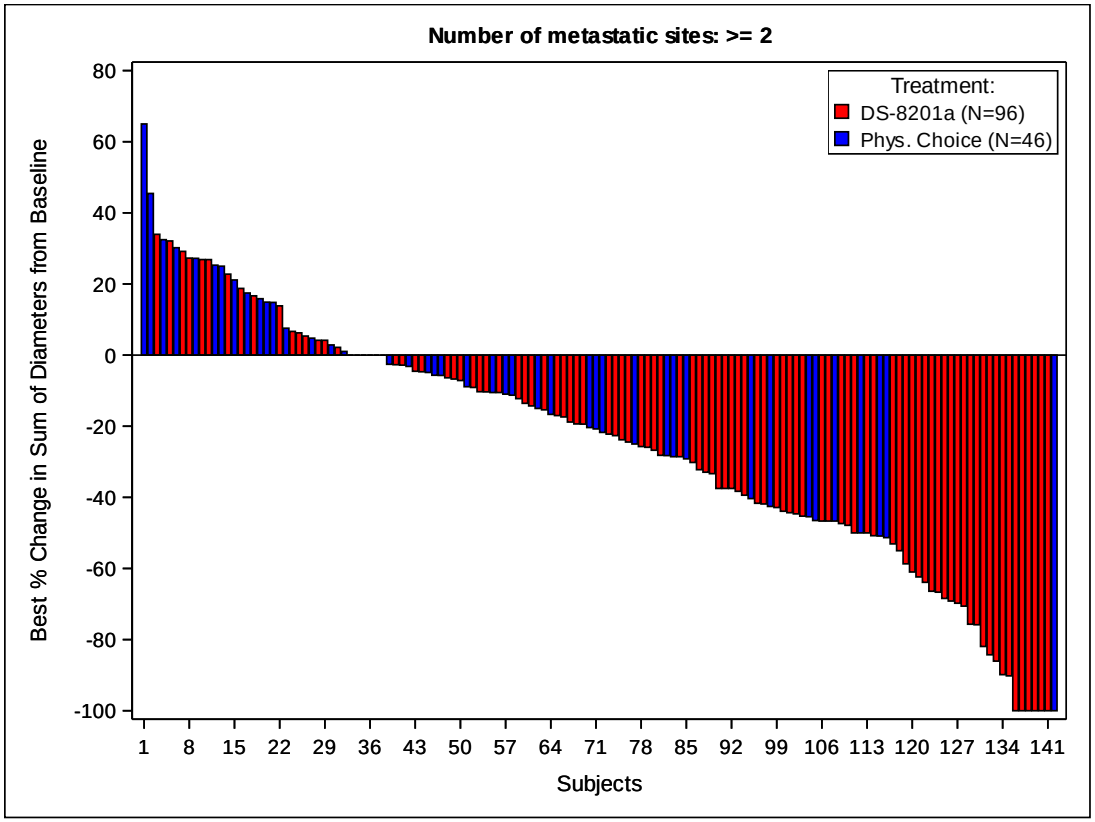

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Protocol DS8201-A-J202
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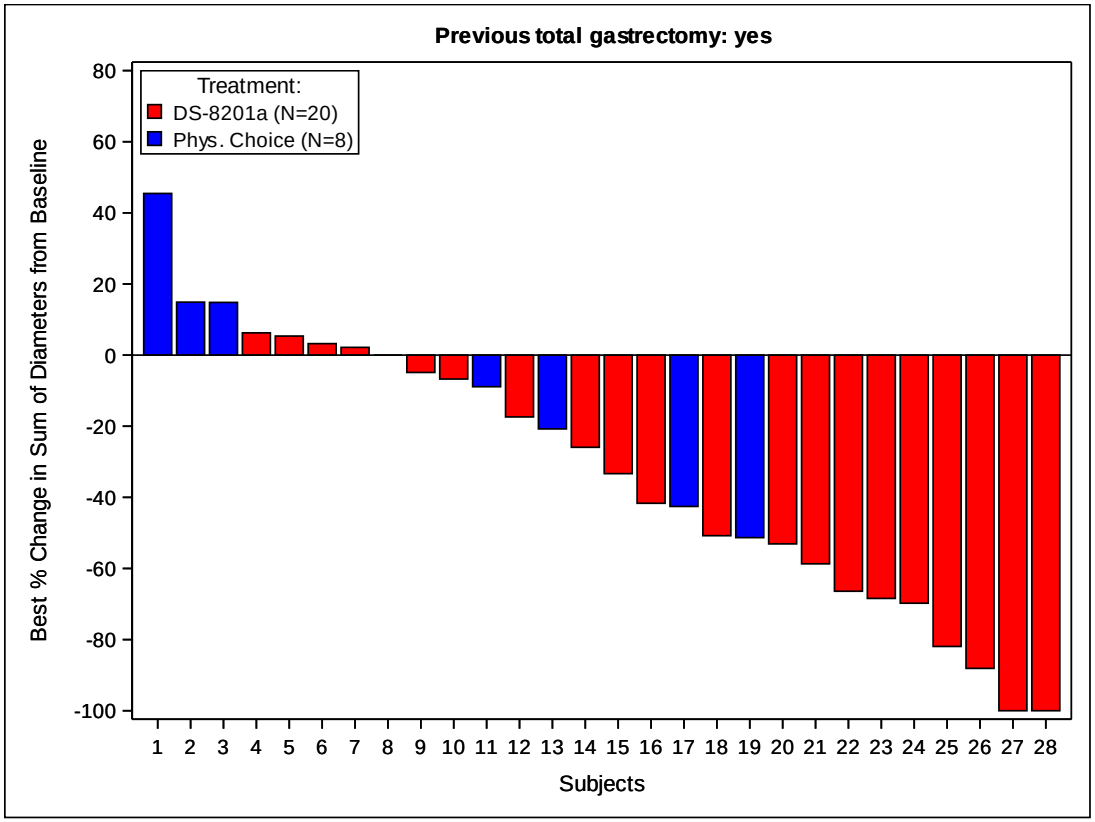

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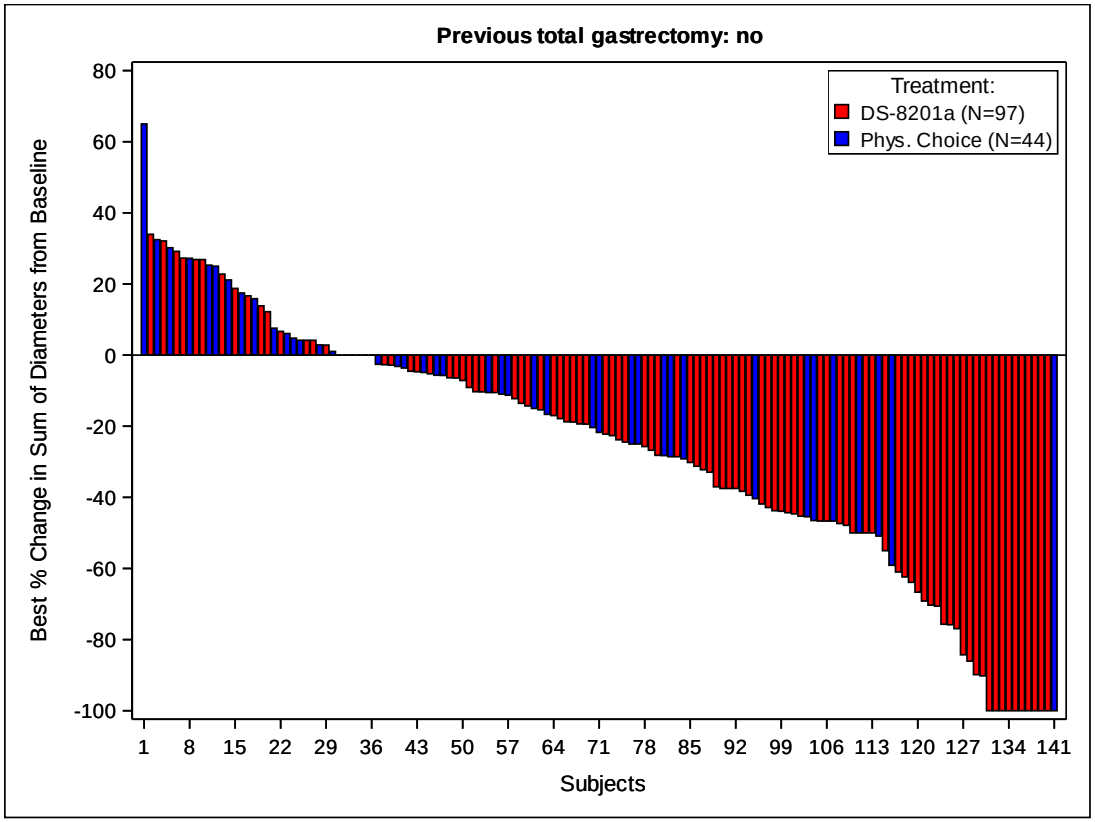

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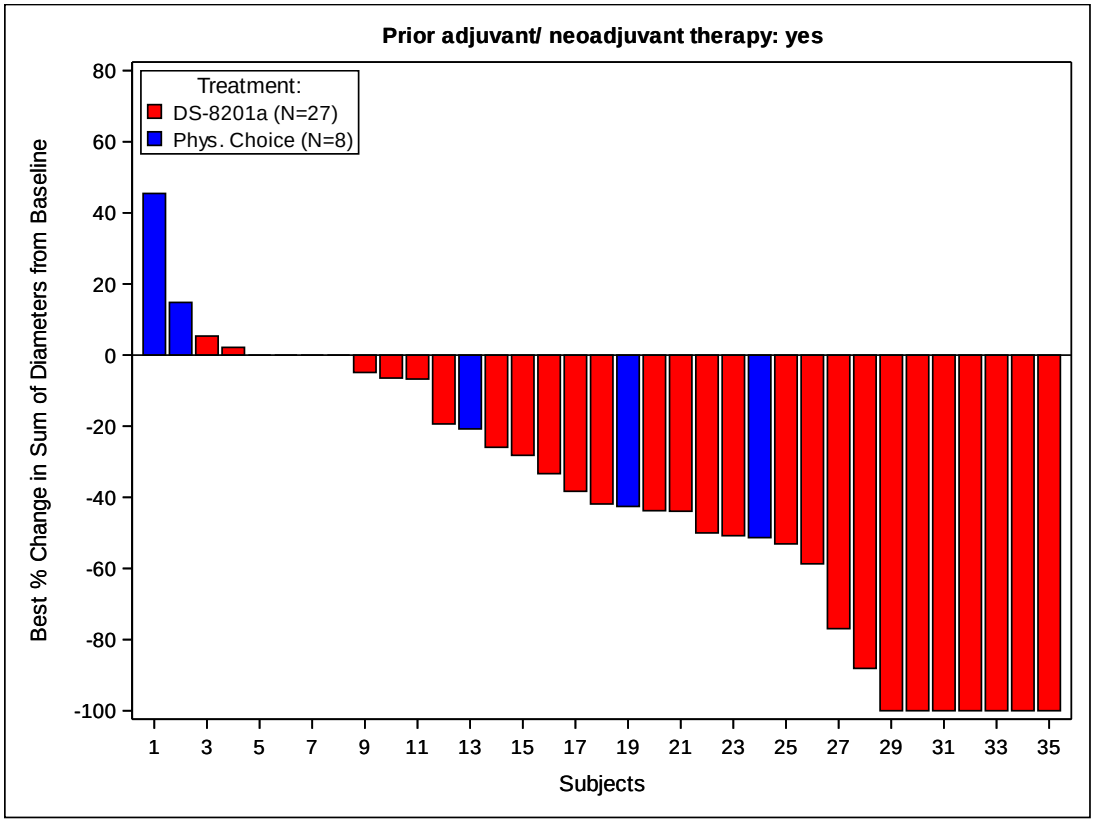
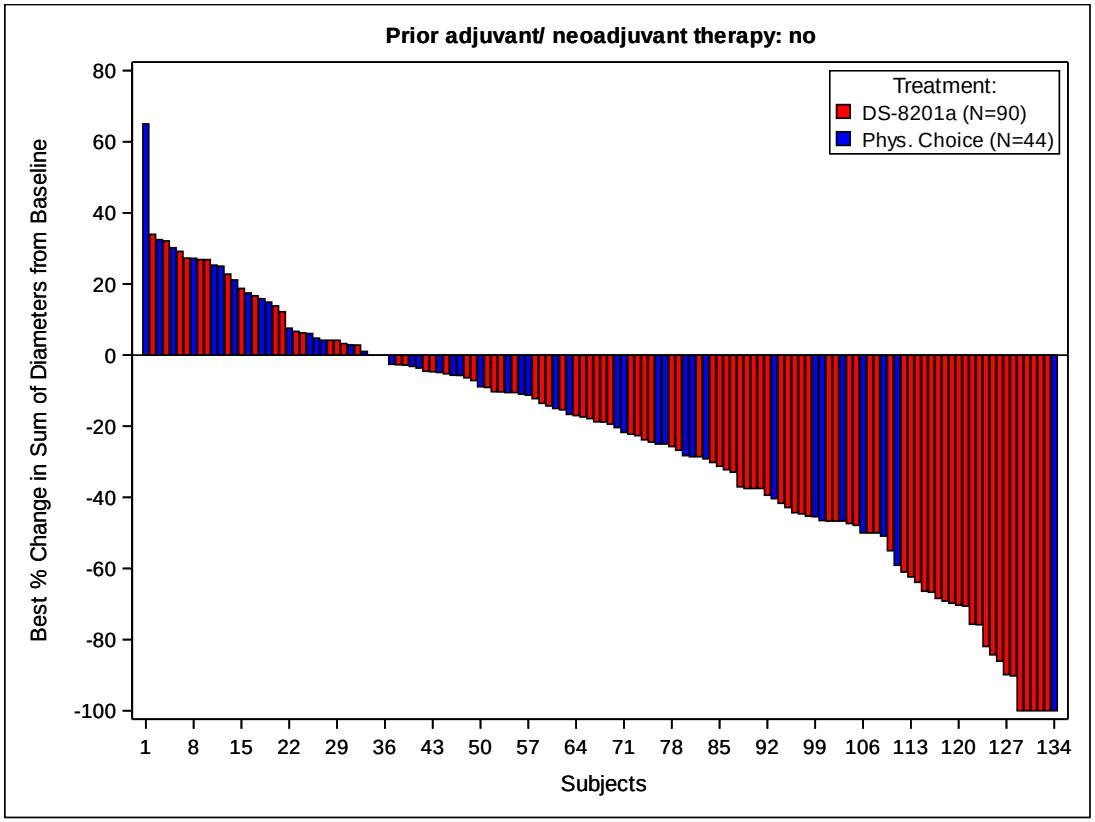
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



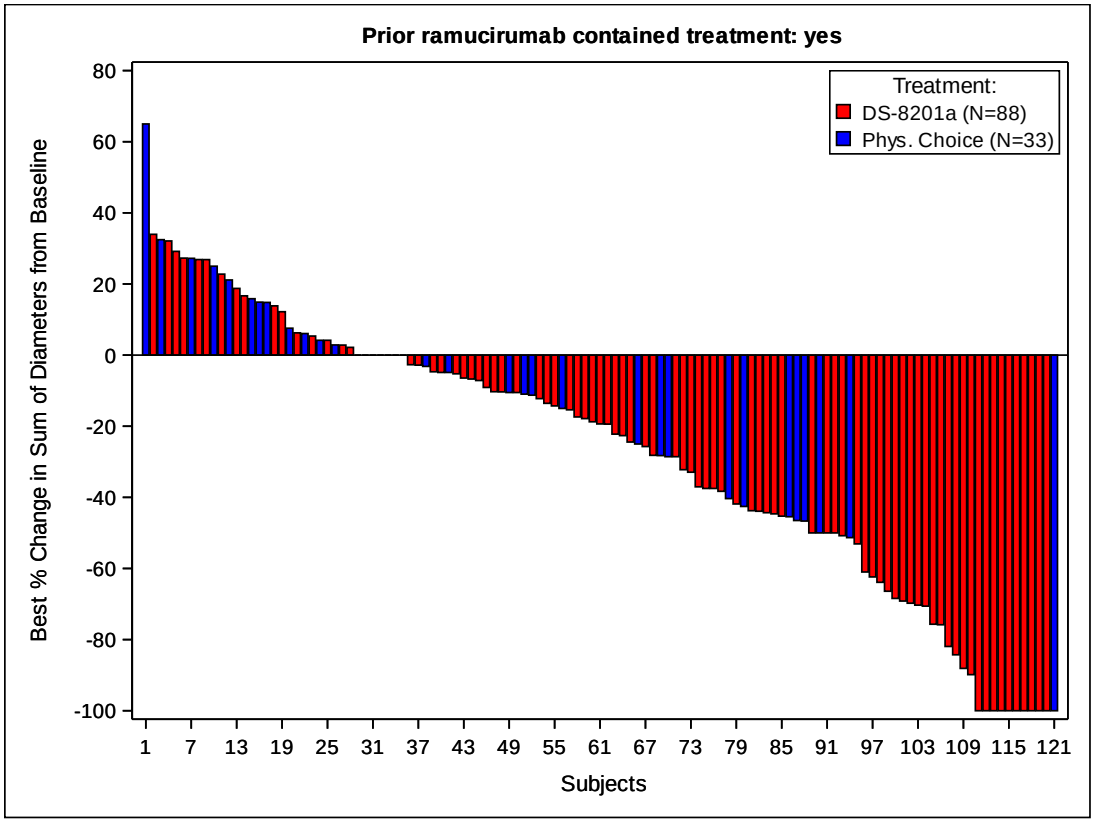
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



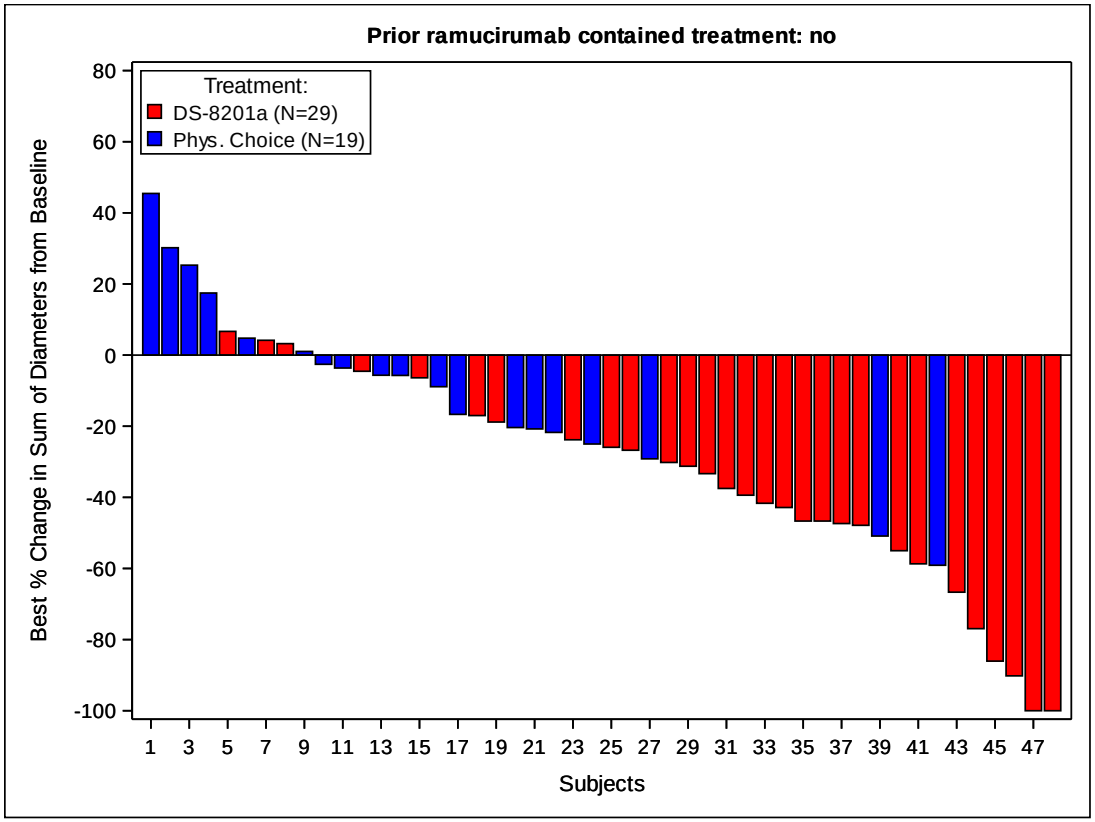
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



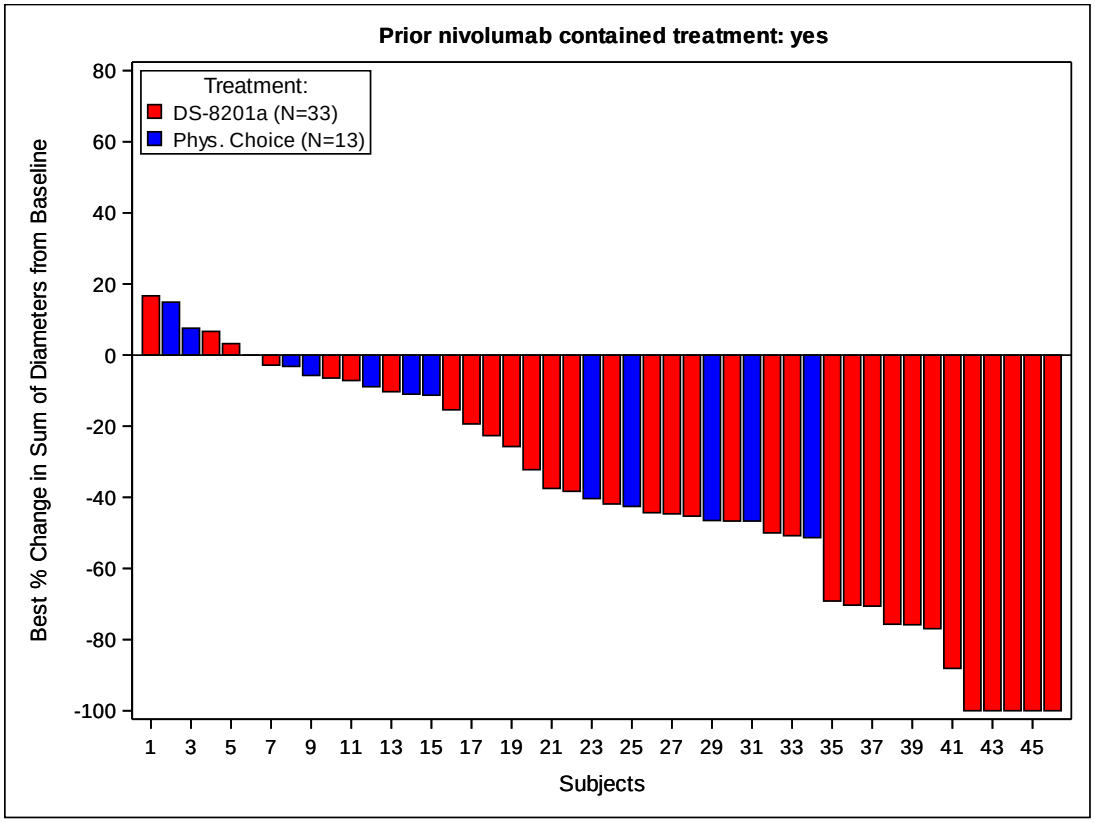
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



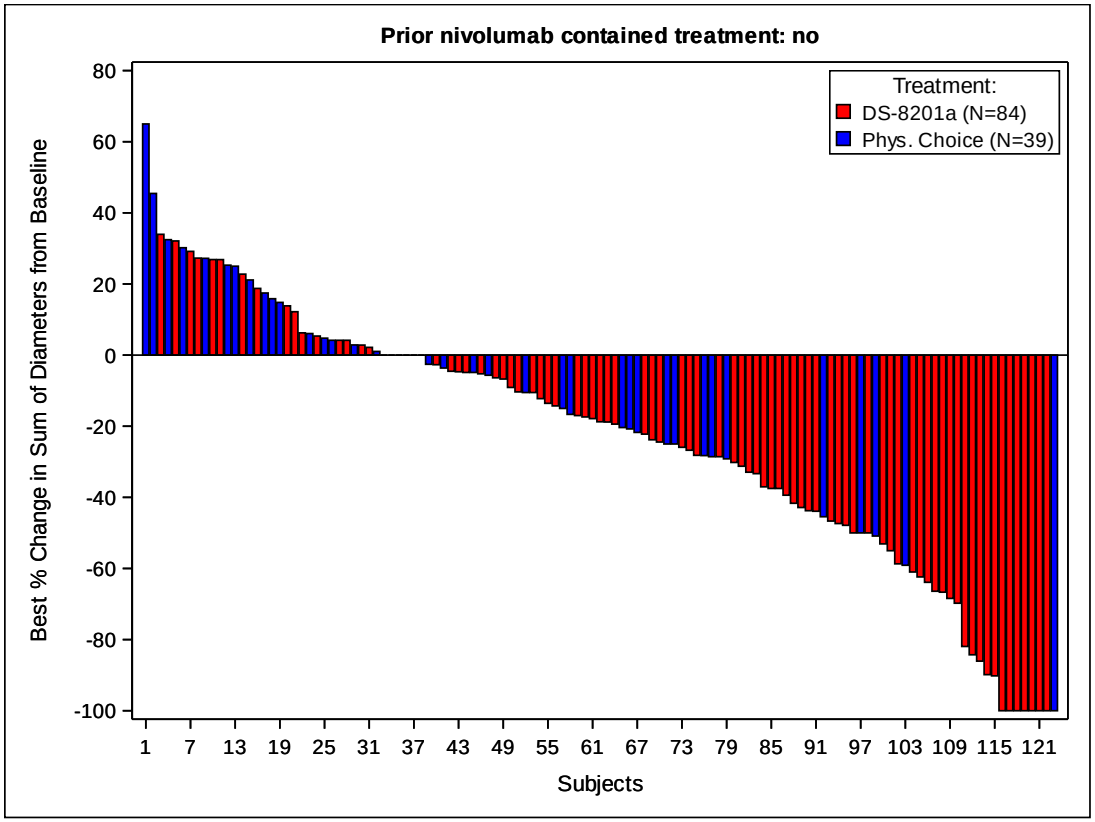
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



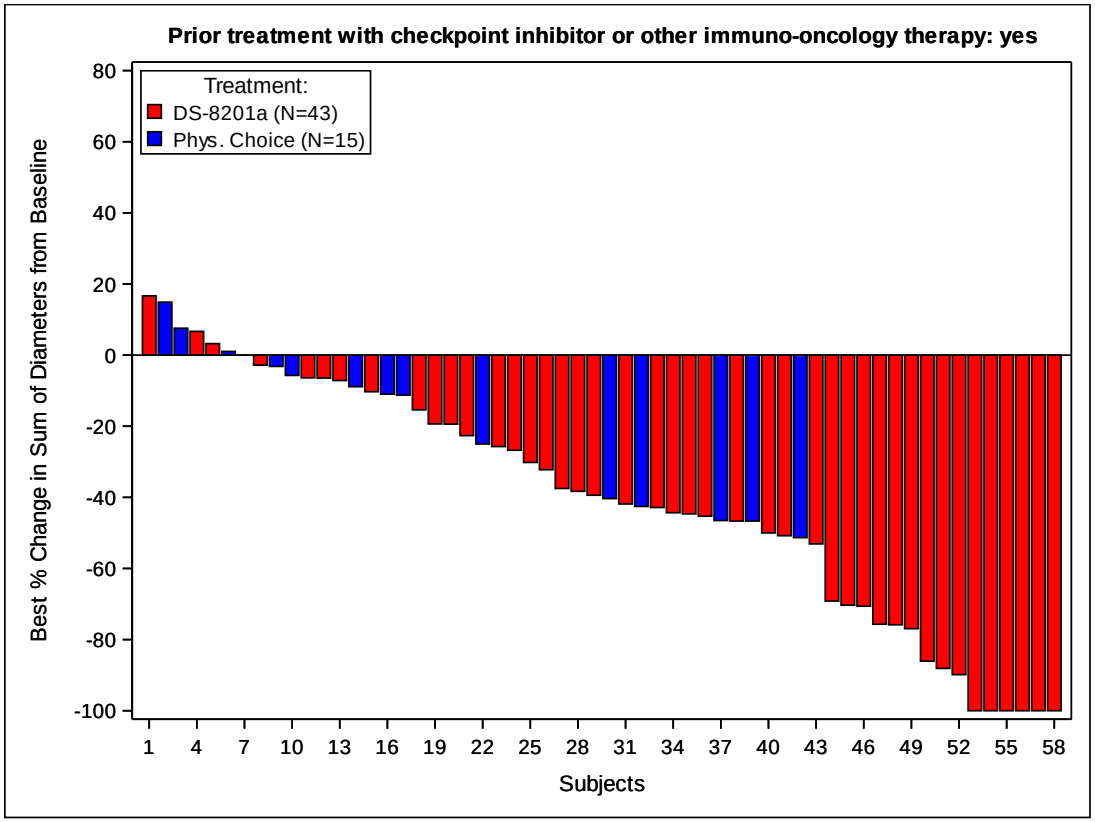
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



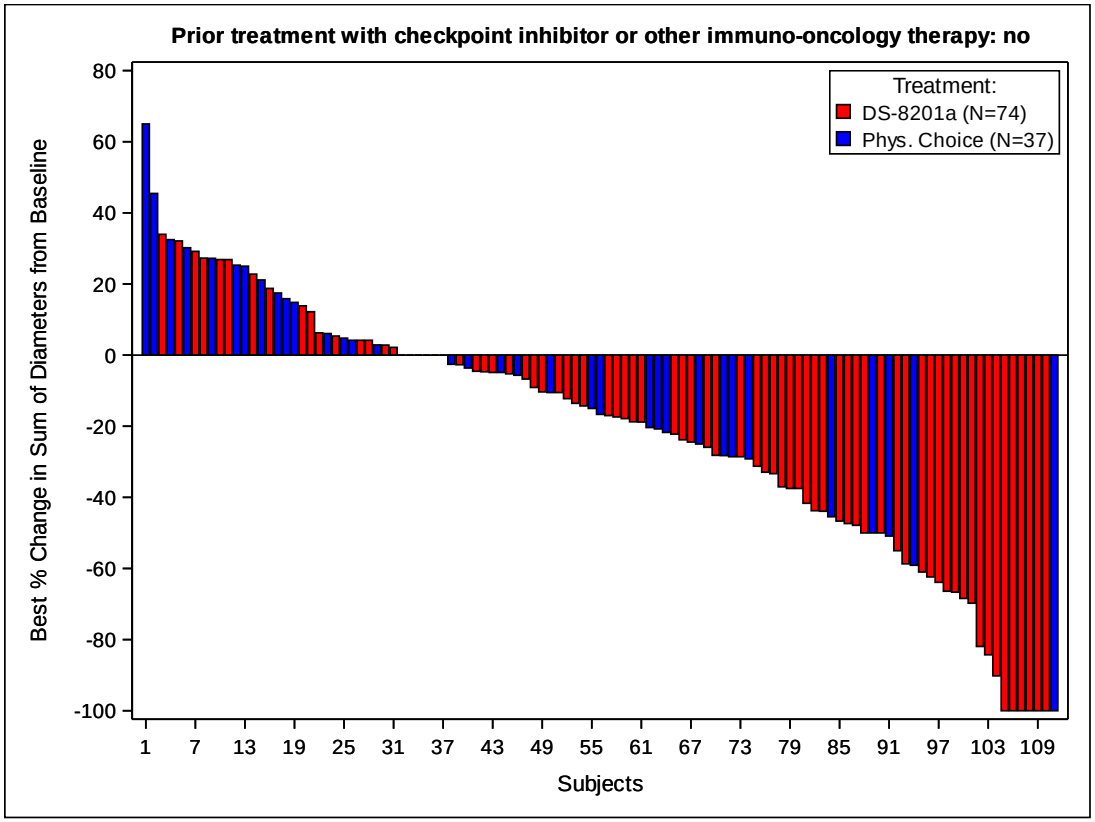
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



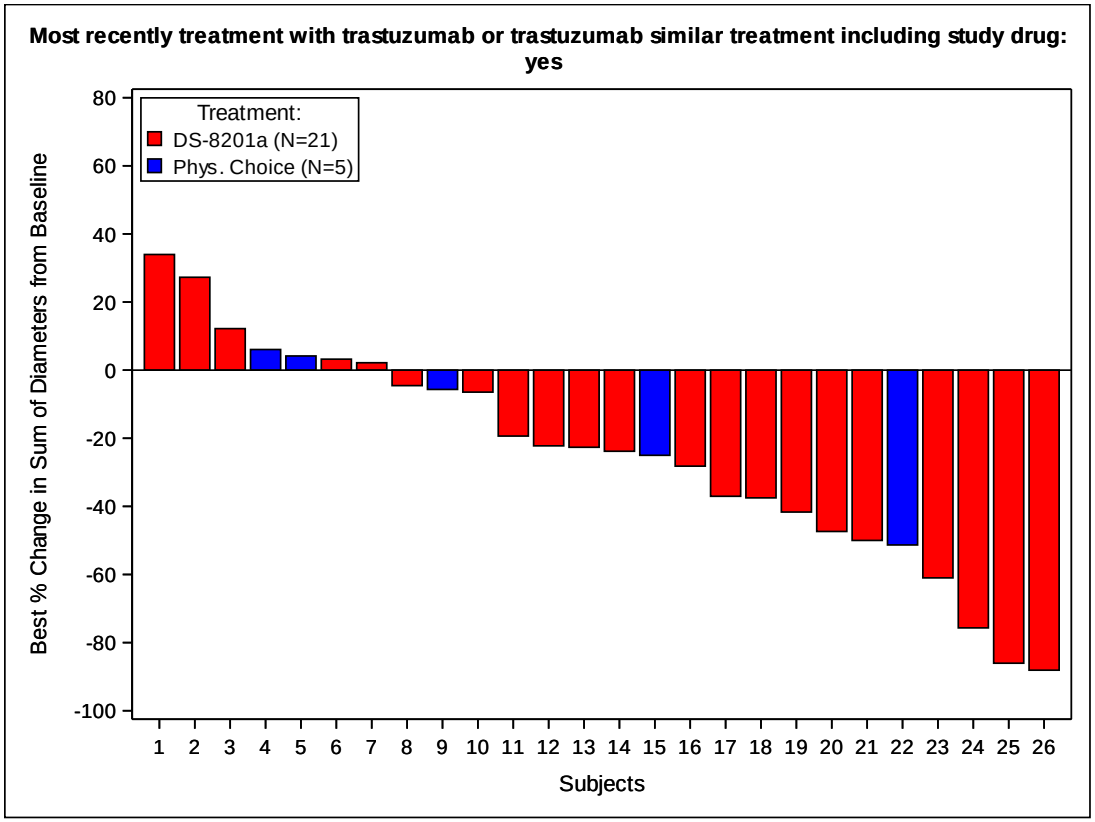
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



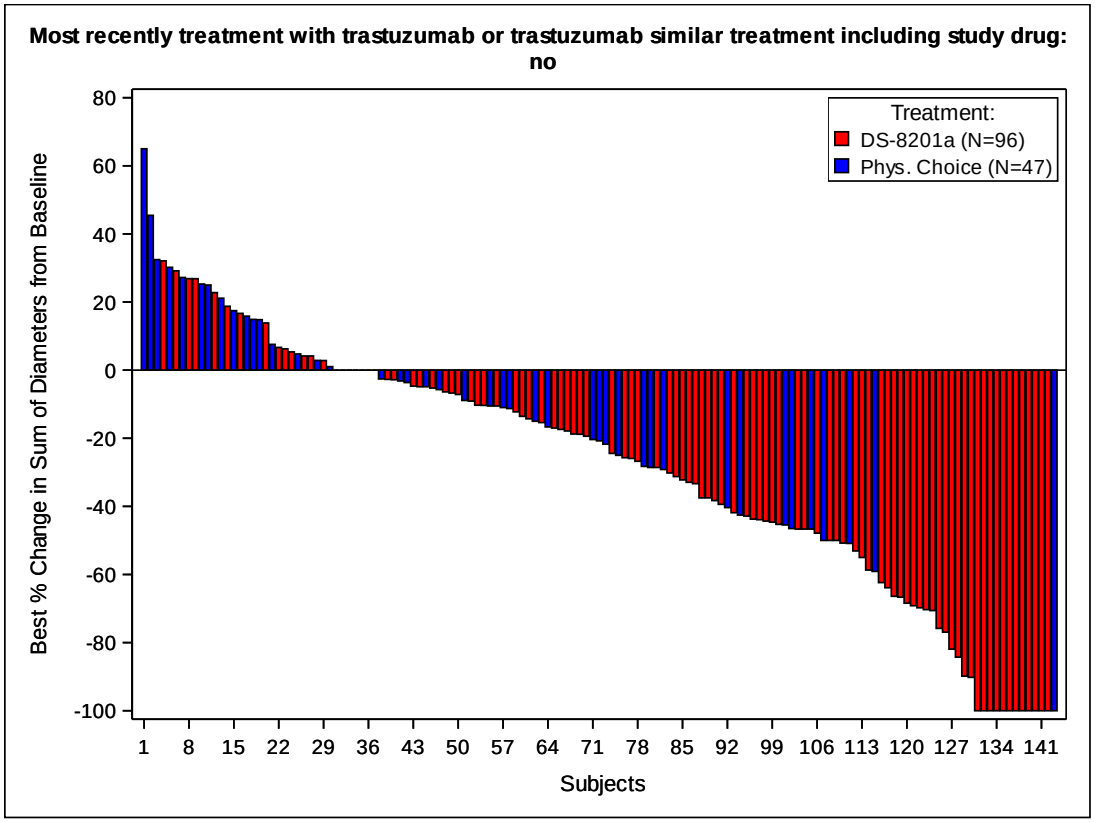
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



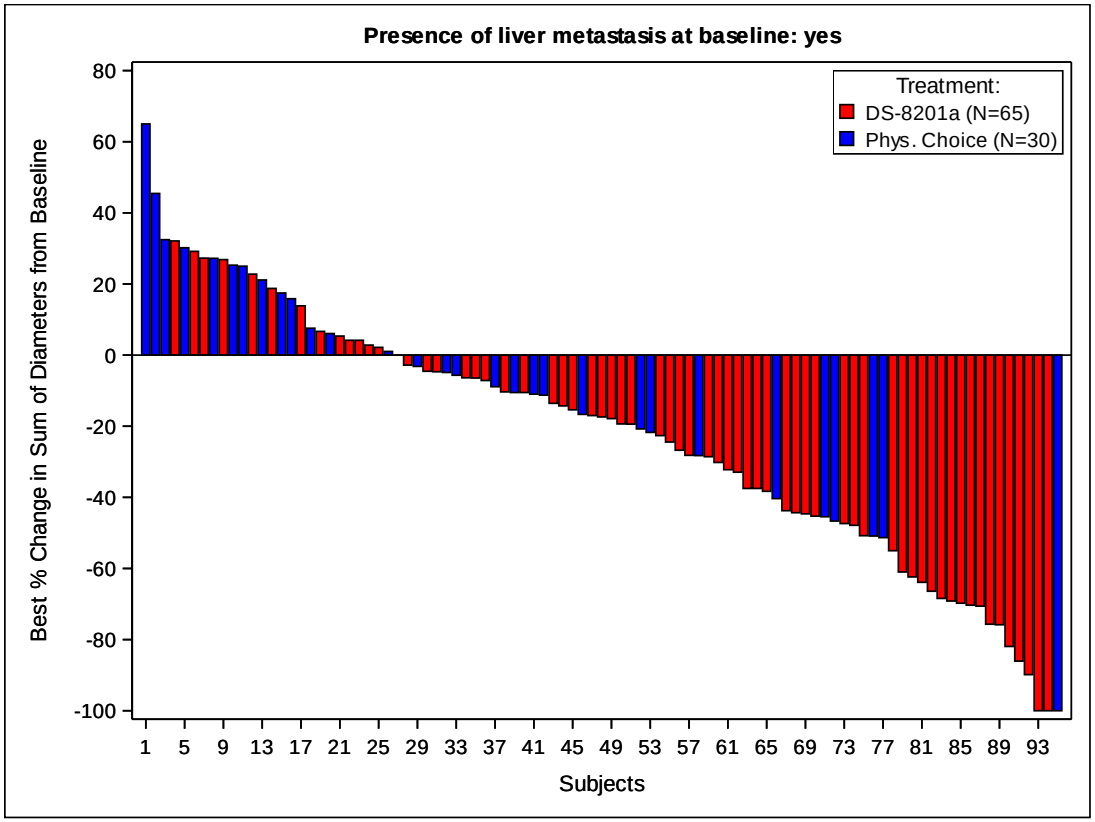
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



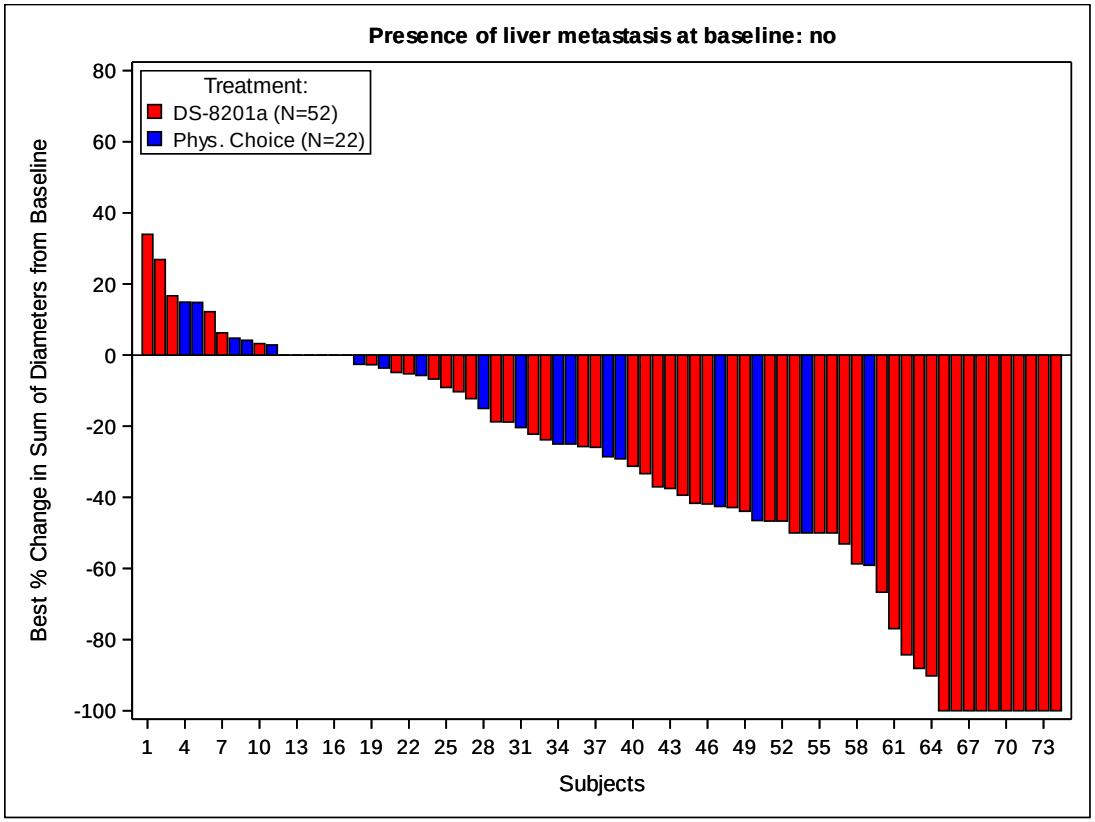
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



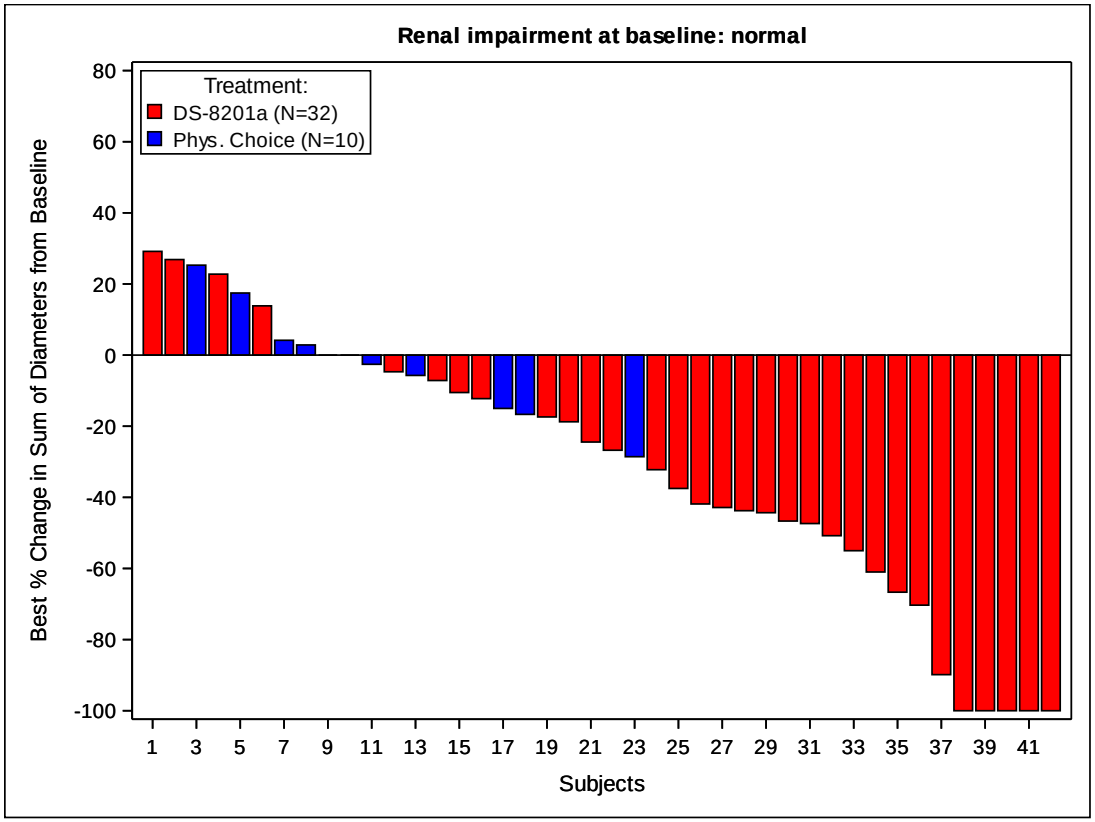
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



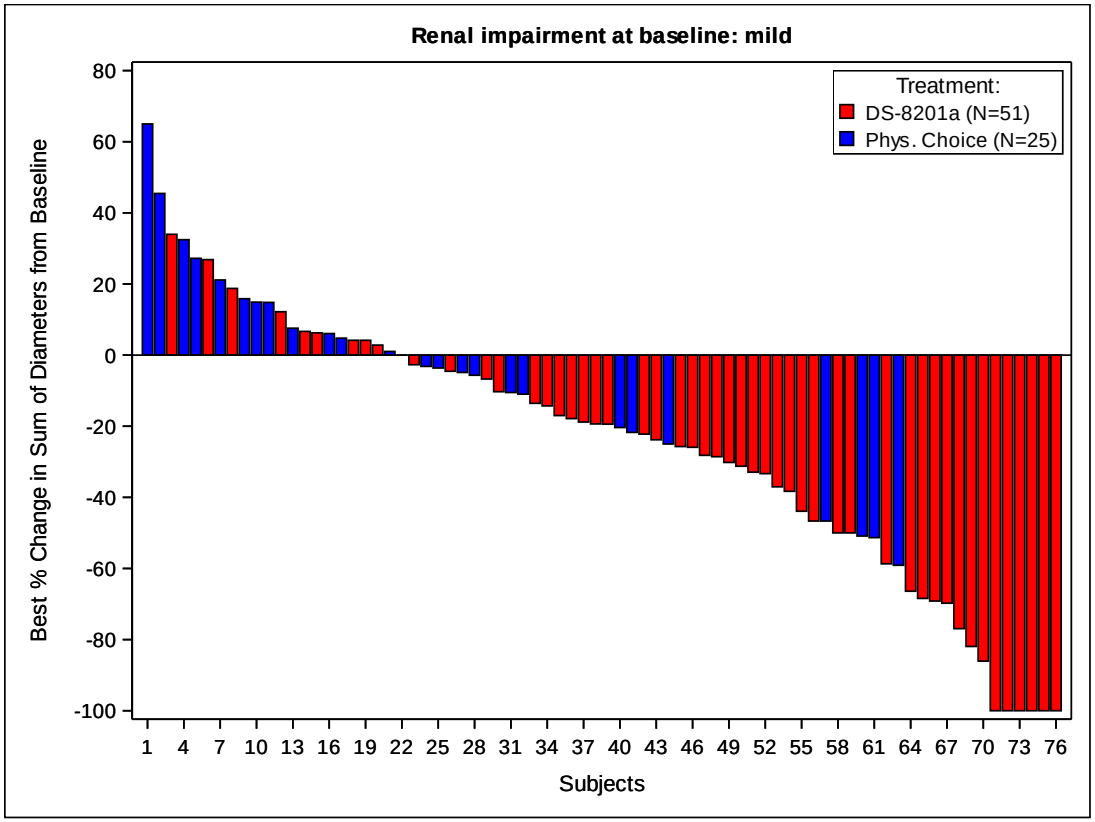
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



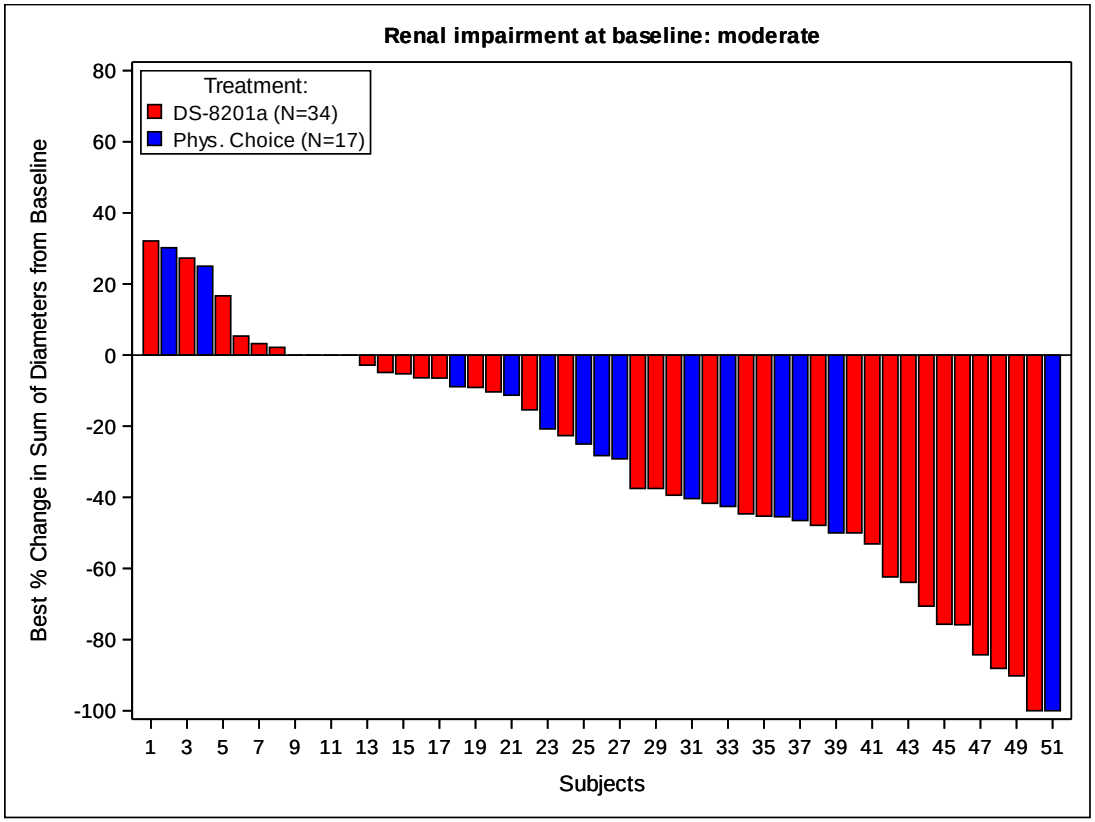
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



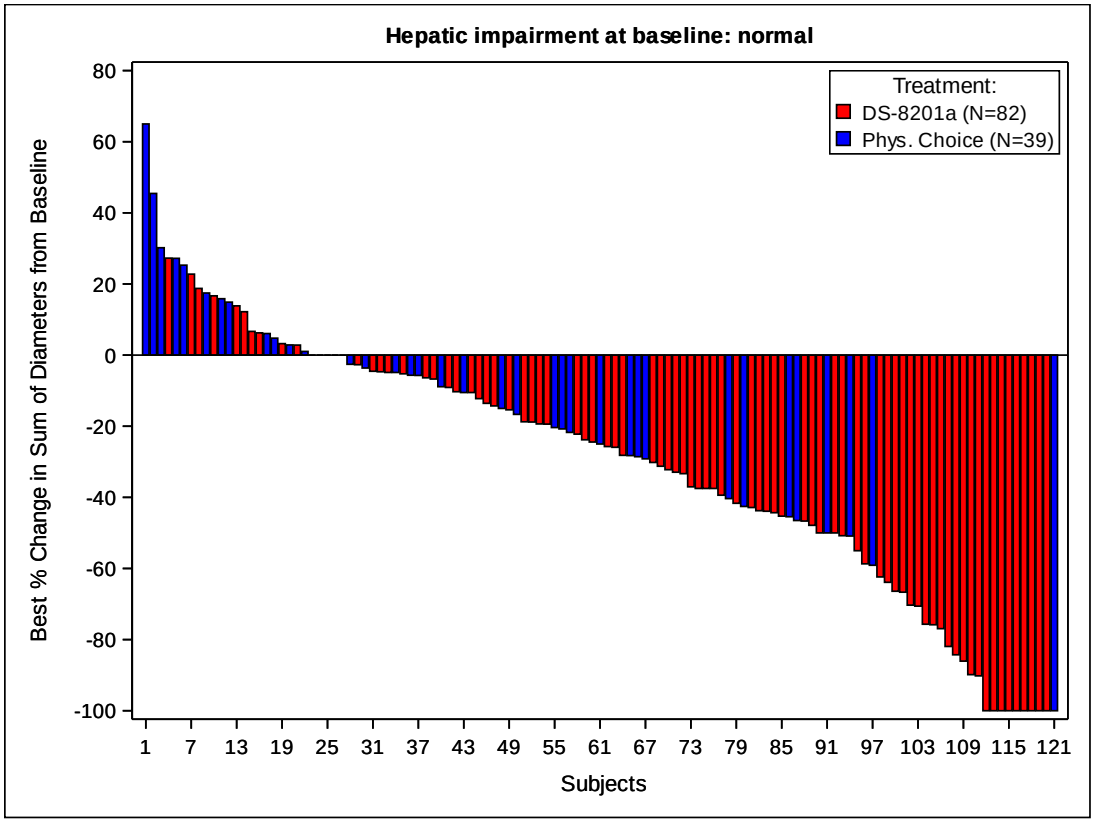
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



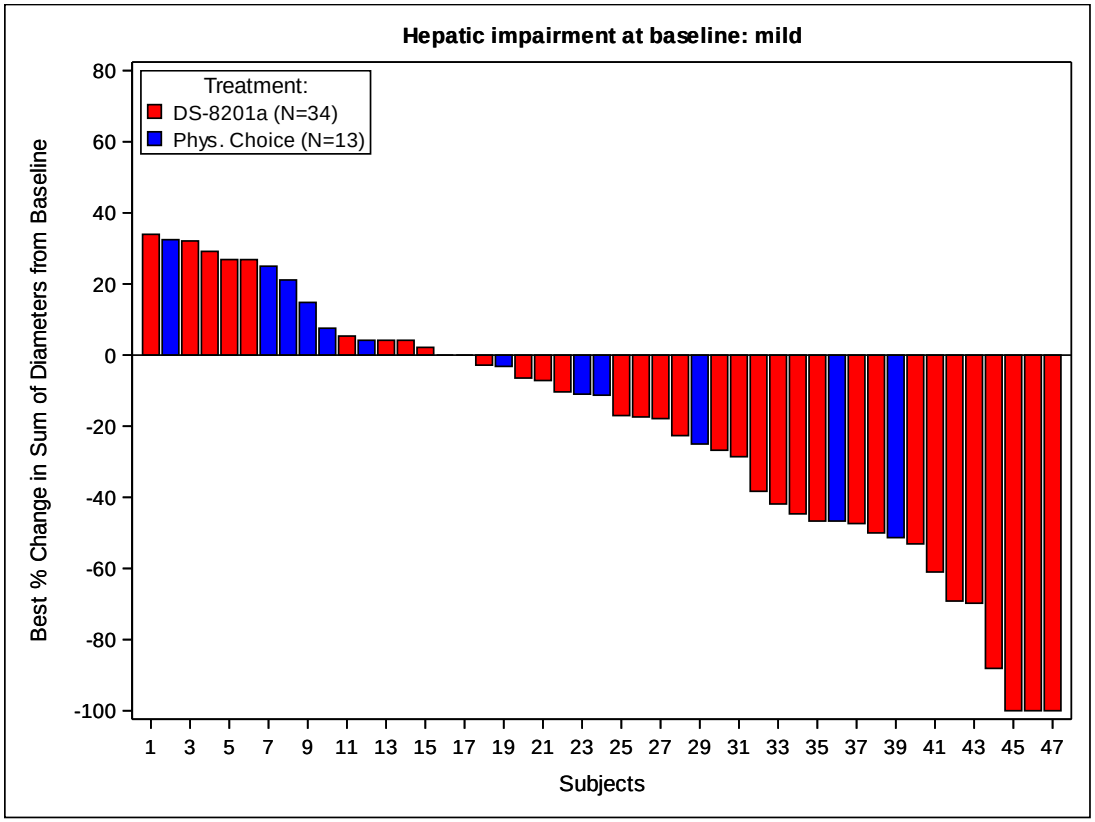
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



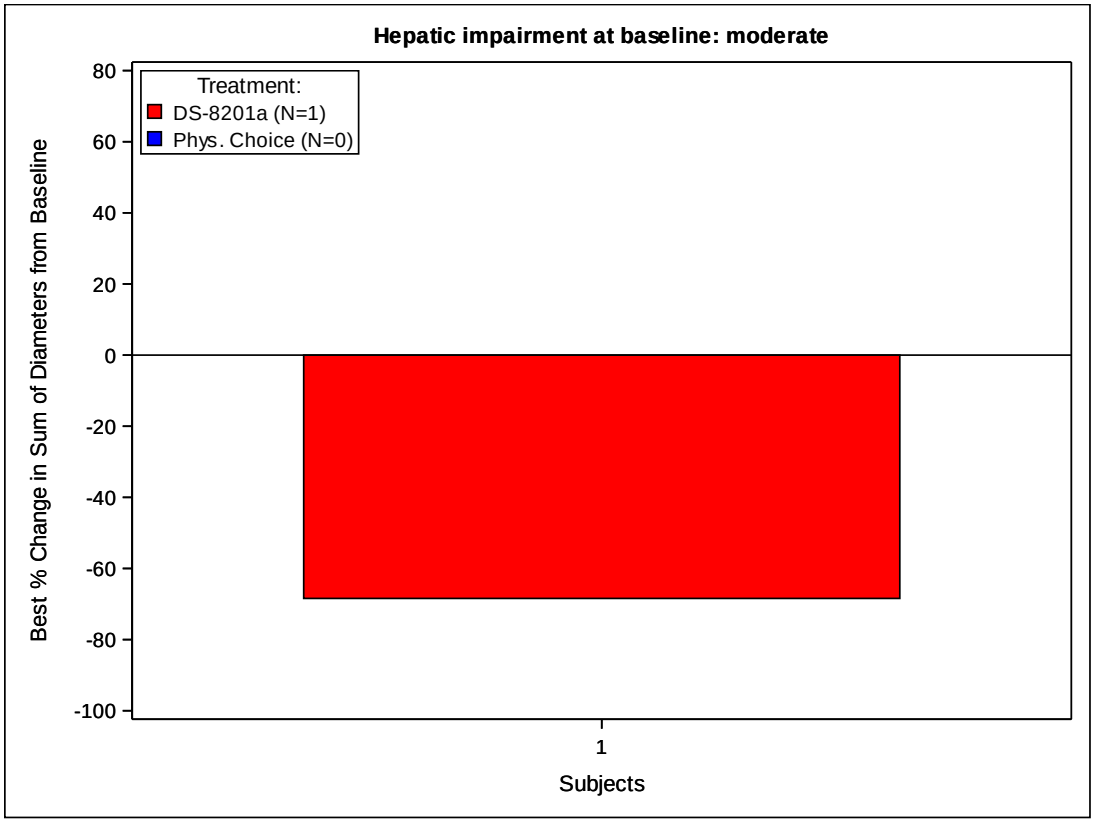
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



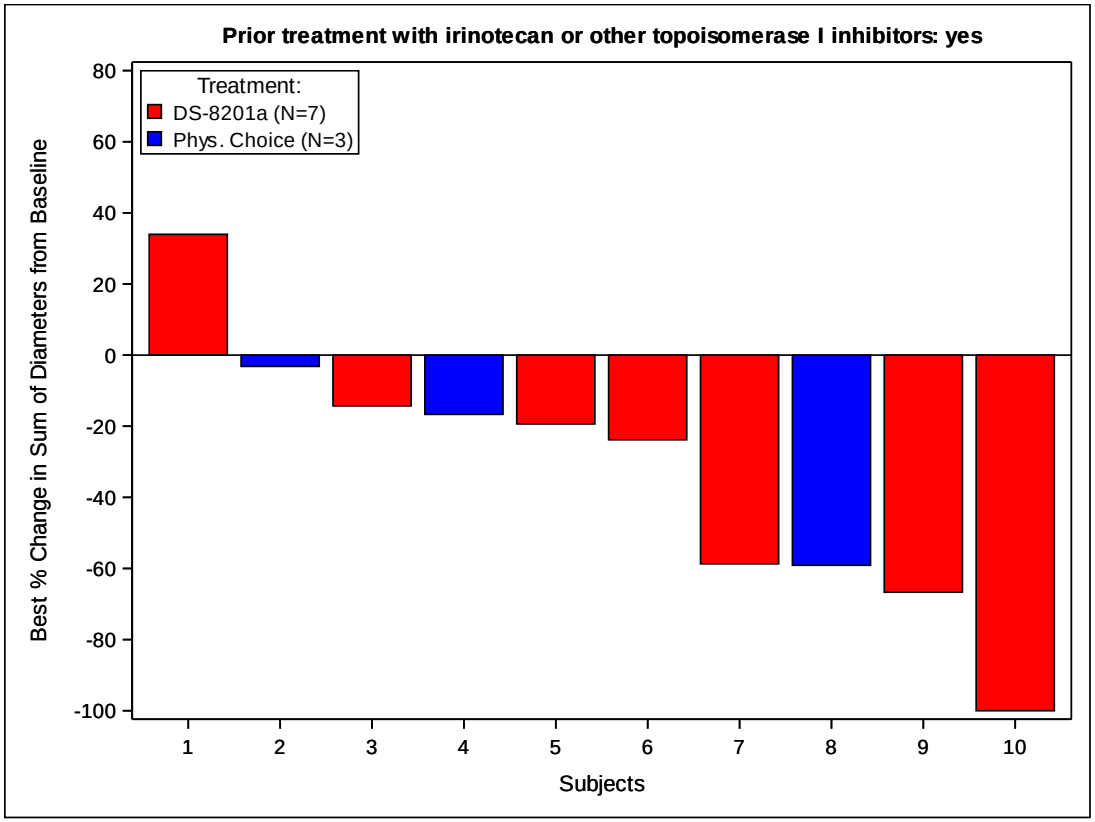
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



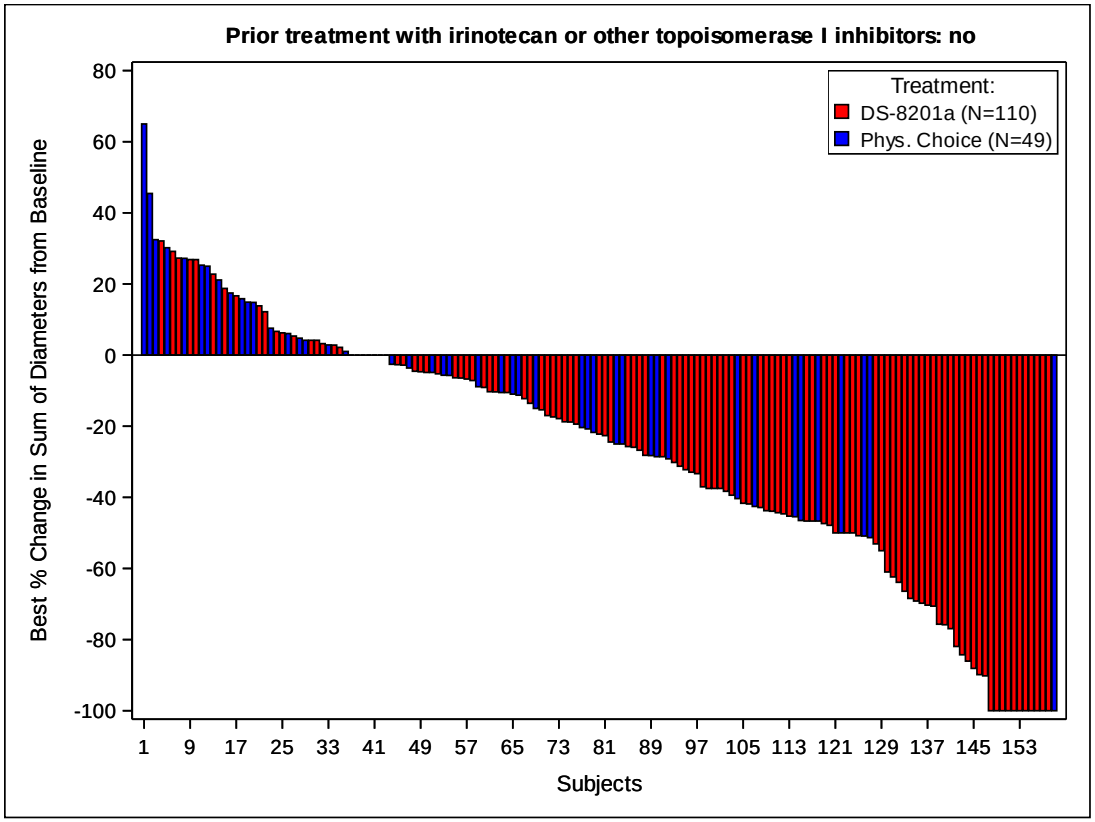
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



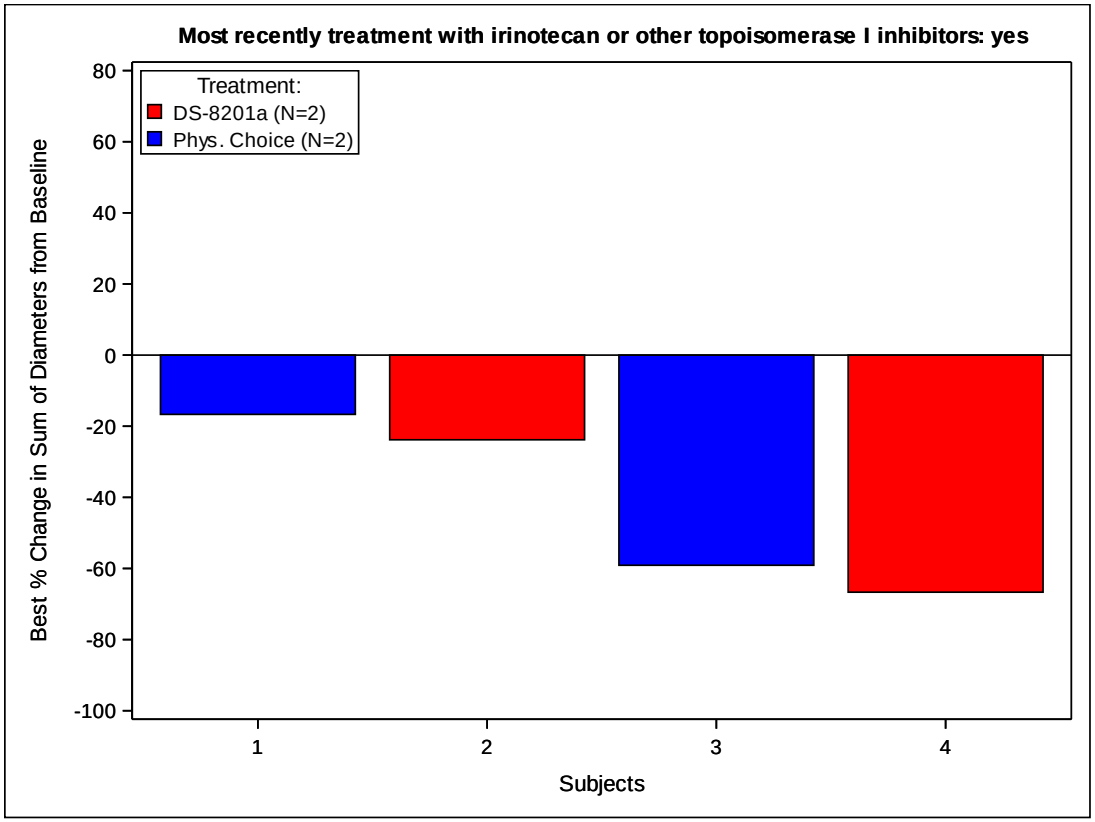
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



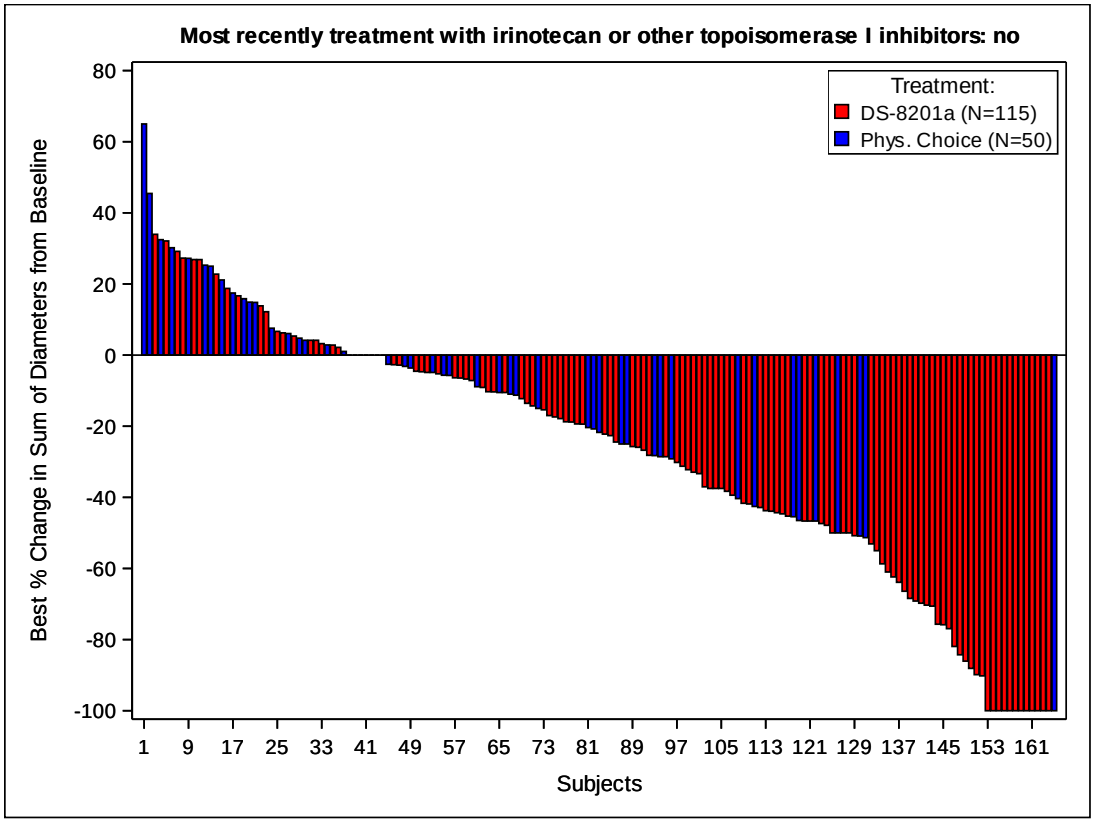
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of EQ-5D VAS score Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	125 (100.0)	62	60 (96.8)
Day 15	125	120 (96.0)	62	53 (85.5)
Day 43	124	118 (95.2)	62	52 (83.9)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	75 (67.6)	50	19 (38.0)
Day 169	105	52 (49.5)	45	11 (24.4)
Day 211	81	34 (42.0)	35	3 (8.6)
Day 253	62	24 (38.7)	26	1 (3.8)
Day 295	51	19 (37.3)	19	1 (5.3)
Day 337	45	15 (33.3)	14	1 (7.1)
Day 379	33	11 (33.3)	10	0 (0.0)
Day 421	22	11 (50.0)	3	0 (0.0)
Day 463	14	7 (50.0)	2	0 (0.0)
Day 505	11	3 (27.3)	2	0 (0.0)
Day 547	6	3 (50.0)	2	0 (0.0)
Day 589	4	1 (25.0)	2	0 (0.0)
Day 631	3	1 (33.3)	0	0 (0.0)
Day 673	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of EQ-5D VAS score by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	125	69.5 (17.24)			60	74.8 (14.76)		
Day 15	120	66.0 (18.35)	120	-3.5 (18.36)	53	71.6 (20.49)	51	-3.5 (16.12)
Day 43	118	70.1 (18.16)	118	0.8 (17.35)	52	71.3 (18.31)	51	-4.3 (14.93)
Day 85	99	71.1 (16.60)	99	1.3 (16.60)	36	74.4 (21.71)	36	-3.6 (19.72)
Day 127	75	71.2 (16.96)	75	0.5 (18.58)	19	80.3 (11.24)	19	0.3 (12.85)
Day 169	52	74.2 (16.06)	52	4.4 (17.58)	11	82.4 (12.16)	11	-3.1 (7.45)
Day 211	34	75.8 (15.29)	34	3.2 (16.93)	3	91.3 (10.02)	3	3.0 (3.46)
Day 253	24	76.4 (14.04)	24	6.0 (17.43)	1	80.0 (-)	1	5.0 (-)
Day 295	19	77.4 (12.62)	19	4.7 (16.30)	1	85.0 (-)	1	10.0 (-)
Day 337	15	76.0 (16.06)	15	-0.1 (22.44)	1	85.0 (-)	1	10.0 (-)
Day 379	11	76.8 (14.88)	11	0.5 (25.34)	0	-	0	-
Day 421	11	75.5 (14.74)	11	-1.0 (23.73)	0	-	0	-
Day 463	7	73.6 (21.93)	7	-0.7 (14.56)	0	-	0	-
Day 505	3	81.7 (7.64)	3	-1.7 (15.28)	0	-	0	-
Day 547	3	85.0 (5.00)	3	1.7 (12.58)	0	-	0	-
Day 589	1	85.0 (-)	1	0.0 (-)	0	-	0	-
Day 631	1	85.0 (-)	1	0.0 (-)	0	-	0	-
Day 673	1	80.0 (-)	1	-5.0 (-)	0	-	0	-
End of Treatment	84	62.5 (20.20)	84	-8.3 (18.79)	52	62.3 (24.68)	50	-11.6 (22.50)

Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of EQ-5D VAS score by Visit
Full Analysis Set

Visit	DS-8201a (N=125) N [a]	N_MISS [b]	LSMean (95% CI)	Phys. Choice (N=62) N [a]	N_MISS [b]	LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
Day 15			-2.74 (-5.60, 0.12)			-2.65 (-7.01, 1.70)	-0.09 (-4.88, 4.71)	0.9710		
Day 43			-2.41 (-5.08, 0.25)			-2.35 (-6.23, 1.52)	-0.06 (-4.30, 4.18)	0.9777		
Day 85			-1.92 (-4.41, 0.56)			-1.91 (-5.83, 2.02)	-0.02 (-4.19, 4.15)	0.9934		
Day 127			-1.44 (-3.90, 1.03)			-1.46 (-6.29, 3.37)	0.03 (-4.99, 5.04)	0.9921		
Day 169			-0.95 (-3.55, 1.66)			-1.01 (-7.24, 5.21)	0.07 (-6.35, 6.49)	0.9834		
Day 211			-0.46 (-3.33, 2.42)			-0.57 (-8.43, 7.29)	0.11 (-7.99, 8.21)	0.9786		
Day 253			0.03 (-3.22, 3.29)			-0.12 (-9.73, 9.49)	0.15 (-9.77, 10.07)	0.9758		
Day 295			0.52 (-3.18, 4.23)			0.33 (-11.10, 11.75)	0.20 (-11.62, 12.01)	0.9740		
Day 337			1.01 (-3.19, 5.21)			0.77 (-12.50, 14.05)	0.24 (-13.51, 13.99)	0.9728		
OVERALL	124	1	-1.60 (-4.05, 0.85)	55	7	-1.61 (-6.06, 2.84)	0.01 (-4.64, 4.66)	0.9963	0.00 (-0.32, 0.32)	0.9964

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of EQ-5D VAS score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.2047
Japan	99	-2.39 (-4.70, -0.07)	47	-1.73 (-6.34, 2.88)	-0.65 (-5.84, 4.54)	0.8045	-0.05 (-0.40, 0.30)	0.7805	
Korea	25	0.61 (-3.20, 4.42)	8	-3.02 (-12.32, 6.28)	3.63 (-6.44, 13.69)	0.4720	0.35 (-0.45, 1.15)	0.3888	
Lines of prior systemic therapy									0.4123
2	65	-0.49 (-3.23, 2.25)	34	-1.13 (-5.65, 3.40)	0.63 (-4.69, 5.96)	0.8138	0.05 (-0.36, 0.47)	0.8015	
3	34	-2.05 (-6.04, 1.94)	16	-1.56 (-10.19, 7.07)	-0.49 (-10.06, 9.08)	0.9194	-0.04 (-0.63, 0.56)	0.9060	
>=4	25	-4.74 (-9.94, 0.46)	5	-5.59 (-24.39, 13.20)	0.85 (-18.69, 20.40)	0.9304	0.06 (-0.90, 1.02)	0.9011	
Age									0.8657
<65 years	54	-0.07 (-3.12, 2.98)	24	-0.02 (-7.10, 7.07)	-0.05 (-7.87, 7.77)	0.9896	-0.00 (-0.48, 0.48)	0.9875	
>=65 years	70	-3.28 (-5.99, -0.56)	31	-3.35 (-8.50, 1.80)	0.07 (-5.76, 5.90)	0.9798	0.01 (-0.42, 0.43)	0.9779	
Sex									0.9524
female	29	-4.29 (-9.24, 0.65)	14	-4.16 (-12.90, 4.59)	-0.14 (-10.24, 9.97)	0.9782	-0.01 (-0.65, 0.63)	0.9762	
male	95	-1.20 (-3.44, 1.04)	41	-1.30 (-6.05, 3.44)	0.11 (-5.17, 5.38)	0.9684	0.01 (-0.36, 0.37)	0.9638	
ECOG PS									0.2469
0	62	-1.26 (-3.41, 0.90)	28	1.04 (-3.93, 6.02)	-2.30 (-7.75, 3.15)	0.4049	-0.22 (-0.67, 0.22)	0.3257	
1	62	-2.41 (-6.00, 1.19)	27	-5.24 (-11.80, 1.31)	2.84 (-4.69, 10.36)	0.4566	0.19 (-0.27, 0.64)	0.4184	
HER2 Status in central laboratory									0.4995
IHC 3+	96	-1.01 (-3.21, 1.19)	41	-1.72 (-6.62, 3.17)	0.71 (-4.69, 6.11)	0.7951	0.06 (-0.31, 0.42)	0.7617	
IHC 2+/ISH +	28	-4.84 (-9.99, 0.30)	14	-2.82 (-10.81, 5.16)	-2.02 (-11.51, 7.48)	0.6699	-0.15 (-0.79, 0.50)	0.6571	
Primary tumor location									0.8459
Gastric	107	-2.83 (-4.98, -0.67)	50	-2.65 (-6.82, 1.52)	-0.18 (-4.90, 4.53)	0.9399	-0.01 (-0.35, 0.32)	0.9332	
GEJ	17	4.21 (-1.54, 9.95)	5	4.53 (-14.54, 23.59)	-0.32 (-20.34, 19.70)	0.9742	-0.02 (-1.02, 0.97)	0.9636	
Histological subtype									0.6180
intestinal	89	-2.15 (-4.50, 0.20)	37	-1.67 (-6.62, 3.29)	-0.48 (-5.98, 5.02)	0.8636	-0.04 (-0.42, 0.35)	0.8448	
diffuse	28	0.53 (-3.98, 5.04)	13	-0.15 (-10.19, 9.90)	0.68 (-10.49, 11.84)	0.9039	0.05 (-0.61, 0.71)	0.8857	
others	7	-11.01 (-27.64, 5.63)	5	-8.04 (-27.11, 11.04)	-2.97 (-28.19, 22.25)	0.7952	-0.16 (-1.31, 0.99)	0.7896	
Number of metastatic sites									0.6302
<2	24	-1.89 (-6.38, 2.60)	10	0.09 (-8.65, 8.83)	-1.98 (-11.89, 7.93)	0.6877	-0.17 (-0.91, 0.57)	0.6524	
>= 2	100	-1.86 (-4.18, 0.45)	45	-2.57 (-7.43, 2.30)	0.71 (-4.71, 6.12)	0.7972	0.05 (-0.30, 0.40)	0.7687	
Previous total gastrectomy									0.2098
yes	22	-3.62 (-8.14, 0.90)	9	5.73 (-7.91, 19.38)	-9.35 (-23.71, 5.00)	0.1973	-0.68 (-1.47, 0.12)	0.0953	
no	102	-1.44 (-3.71, 0.83)	46	-2.88 (-7.33, 1.56)	1.44 (-3.59, 6.47)	0.5723	0.11 (-0.24, 0.46)	0.5273	
Prior adjuvant/ neoadjuvant therapy									0.2644
yes	30	-3.10 (-6.41, 0.21)	9	5.50 (-3.78, 14.77)	-8.59 (-18.45, 1.26)	0.0863	-0.84 (-1.61, -0.07)	0.0318	
no	94	-1.31 (-3.75, 1.14)	46	-3.38 (-7.99, 1.23)	2.08 (-3.19, 7.34)	0.4380	0.16 (-0.20, 0.51)	0.3887	
Prior ramucirumab contained treatment									0.7413
yes	93	-3.00 (-5.17, -0.82)	37	-3.42 (-8.80, 1.95)	0.43 (-5.39, 6.25)	0.8854	0.03 (-0.35, 0.41)	0.8617	
no	31	1.43 (-3.31, 6.17)	18	2.85 (-4.47, 10.17)	-1.42 (-10.29, 7.46)	0.7500	-0.10 (-0.68, 0.48)	0.7332	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

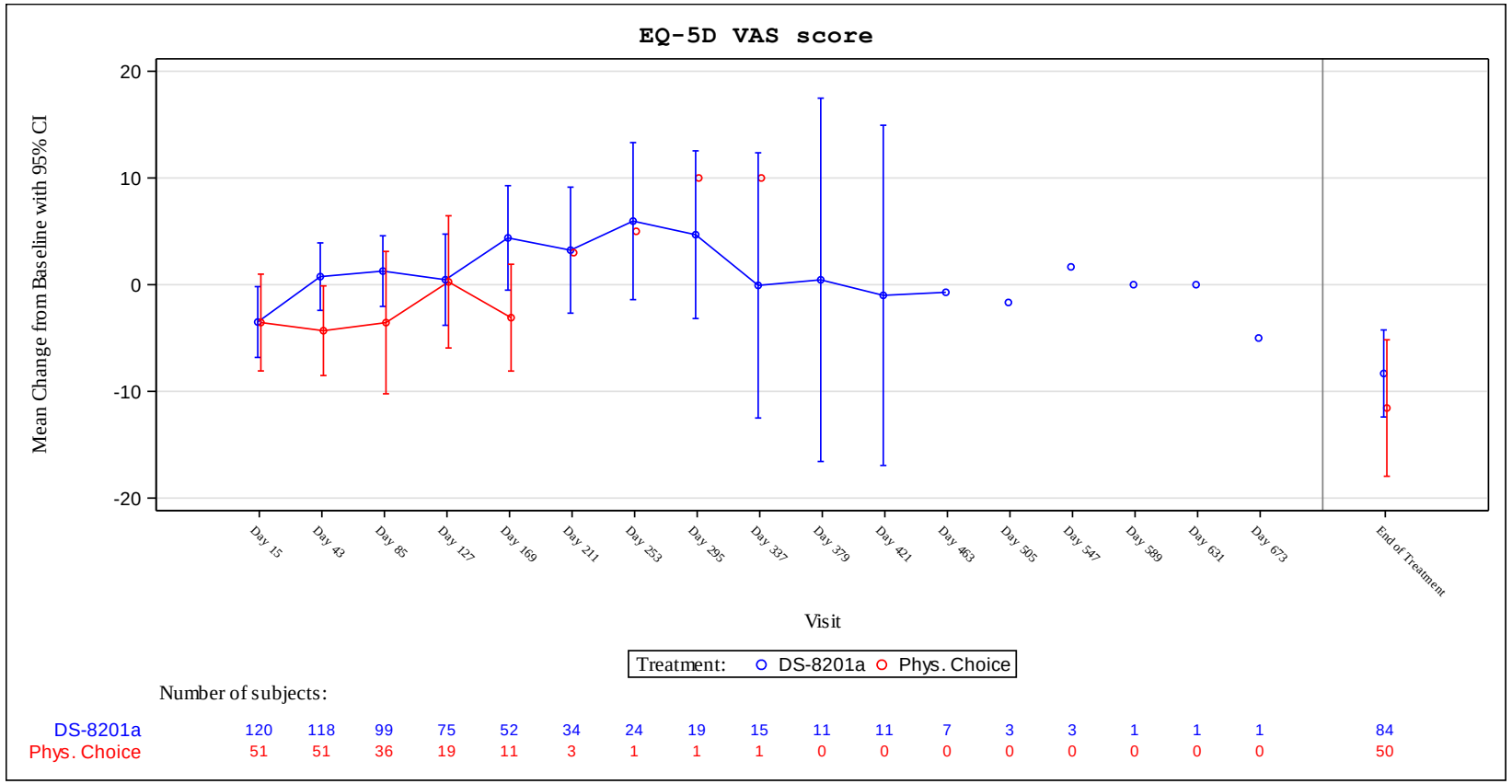
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of EQ-5D VAS score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.6644
yes	33	-4.66 (-8.81, -0.51)	13	-7.21 (-17.91, 3.50)	2.55 (-8.96, 14.06)	0.6612	0.18 (-0.46, 0.82)	0.5866	
no	91	-0.55 (-2.92, 1.82)	42	-0.77 (-5.17, 3.64)	0.22 (-4.82, 5.26)	0.9309	0.02 (-0.35, 0.38)	0.9240	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.5873
yes	44	-3.81 (-7.19, -0.44)	14	-4.99 (-14.80, 4.83)	1.17 (-9.25, 11.60)	0.8240	0.09 (-0.51, 0.69)	0.7729	
no	80	-0.55 (-3.15, 2.05)	41	-1.11 (-5.57, 3.35)	0.56 (-4.64, 5.76)	0.8319	0.04 (-0.33, 0.42)	0.8191	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.1266
yes	22	-1.70 (-7.13, 3.72)	6	5.07 (-6.24, 16.39)	-6.78 (-19.71, 6.16)	0.2928	-0.54 (-1.45, 0.38)	0.2500	
no	102	-1.84 (-4.02, 0.34)	49	-2.92 (-7.48, 1.64)	1.08 (-3.99, 6.15)	0.6741	0.08 (-0.26, 0.42)	0.6315	
Presence of liver metastasis at baseline									0.7843
yes	67	-0.44 (-3.14, 2.26)	29	-0.77 (-6.31, 4.78)	0.33 (-5.86, 6.51)	0.9169	0.03 (-0.41, 0.46)	0.9060	
no	57	-3.33 (-6.37, -0.30)	26	-2.65 (-8.89, 3.58)	-0.68 (-7.68, 6.32)	0.8476	-0.05 (-0.52, 0.41)	0.8261	
Renal impairment at baseline									0.5468
normal	33	2.87 (0.36, 5.38)	11	0.27 (-10.93, 11.47)	2.60 (-8.87, 14.08)	0.6549	0.23 (-0.45, 0.92)	0.5020	
mild	53	-3.24 (-6.82, 0.34)	25	-2.04 (-8.37, 4.29)	-1.20 (-8.56, 6.16)	0.7471	-0.09 (-0.56, 0.39)	0.7251	
moderate	38	-4.09 (-7.96, -0.21)	18	-2.81 (-9.73, 4.12)	-1.28 (-9.23, 6.67)	0.7494	-0.10 (-0.66, 0.46)	0.7289	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.1853
normal	87	-1.76 (-4.15, 0.63)	40	-1.39 (-6.18, 3.39)	-0.37 (-5.73, 5.00)	0.8928	-0.03 (-0.40, 0.35)	0.8796	
mild	36	-1.65 (-5.67, 2.37)	15	-2.88 (-11.56, 5.79)	1.23 (-8.46, 10.93)	0.8000	0.09 (-0.51, 0.69)	0.7662	
moderate	1	NE	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.9801
yes	8	2.05 (-6.15, 10.25)	4	2.46 (-11.78, 16.69)	-0.41 (-17.36, 16.54)	0.9550	-0.04 (-1.24, 1.16)	0.9469	
no	116	-2.19 (-4.32, -0.05)	51	-3.00 (-7.54, 1.54)	0.82 (-4.22, 5.86)	0.7499	0.06 (-0.27, 0.39)	0.7147	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.3268
yes	3	13.02 (2.54, 23.51)	3	0.60 (-10.94, 12.13)	12.43 (-7.83, 32.68)	0.1664	1.77 (-0.12, 3.66)	0.0659	
no	121	-2.06 (-4.14, 0.01)	52	-3.31 (-8.00, 1.39)	1.24 (-3.92, 6.40)	0.6360	0.09 (-0.23, 0.42)	0.5794	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Graphical Summary of EQ-5D VAS score by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADEQ5D

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	51 (40.8)	27 (43.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	11.3 (4.4, NE)	3.8 (1.7, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.67 (0.42, 1.09)	
p-value [c]	0.0969	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.66 (0.41, 1.07)	
p-value [c]	0.0862	

Time to Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.0561
Japan	43/ 99 (43.4)	6.8 (4.0, NE)	21/ 50 (42.0)	4.3 (1.8, NE)	0.84 (0.49, 1.42)	0.4976	
Korea	8/ 26 (30.8)	11.3 (4.2, 11.3)	6/ 12 (50.0)	1.4 (0.5, NE)	0.20 (0.06, 0.64)	0.0029	
Lines of prior systemic therapy							0.3773
2	27/ 66 (40.9)	5.9 (3.6, NE)	15/ 38 (39.5)	4.3 (1.8, NE)	0.79 (0.42, 1.50)	0.4785	
3	13/ 34 (38.2)	12.6 (4.4, NE)	10/ 18 (55.6)	2.2 (1.3, NE)	0.39 (0.16, 0.95)	0.0281	
>=4	11/ 25 (44.0)	11.3 (1.1, NE)	2/ 6 (33.3)	NE (0.5, NE)	0.95 (0.21, 4.36)	0.9511	
Age							0.4700
<65 years	20/ 55 (36.4)	12.6 (4.6, NE)	12/ 27 (44.4)	3.8 (1.4, NE)	0.53 (0.25, 1.12)	0.0850	
>=65 years	31/ 70 (44.3)	5.9 (3.1, NE)	15/ 35 (42.9)	4.0 (1.4, NE)	0.77 (0.42, 1.44)	0.4169	
Sex							0.6394
female	16/ 30 (53.3)	4.4 (2.9, 6.8)	8/ 15 (53.3)	2.8 (0.5, NE)	0.73 (0.31, 1.74)	0.4761	
male	35/ 95 (36.8)	12.6 (5.5, NE)	19/ 47 (40.4)	4.0 (1.8, NE)	0.65 (0.37, 1.15)	0.1346	
ECOG PS							0.5557
0	25/ 62 (40.3)	12.6 (4.0, NE)	11/ 30 (36.7)	4.0 (1.9, NE)	0.81 (0.39, 1.66)	0.5518	
1	26/ 63 (41.3)	4.6 (4.2, 11.3)	16/ 32 (50.0)	1.8 (0.9, NE)	0.57 (0.30, 1.07)	0.0718	
HER2 Status in central laboratory							0.2686
IHC 3+	40/ 96 (41.7)	11.3 (4.5, NE)	22/ 47 (46.8)	3.8 (1.4, NE)	0.56 (0.33, 0.95)	0.0292	
IHC 2+/ISH +	11/ 29 (37.9)	NE (1.4, NE)	5/ 15 (33.3)	NE (0.7, NE)	1.17 (0.41, 3.39)	0.7771	
Primary tumor location							0.6855
Gastric	45/108 (41.7)	5.9 (4.3, NE)	25/ 55 (45.5)	3.8 (1.7, NE)	0.69 (0.42, 1.14)	0.1395	
GEJ	6/ 17 (35.3)	12.6 (1.5, NE)	2/ 7 (28.6)	NE (0.5, NE)	0.62 (0.12, 3.27)	0.5703	
Histological subtype							0.1915
intestinal	39/ 89 (43.8)	5.9 (4.0, NE)	15/ 38 (39.5)	4.3 (1.7, NE)	0.90 (0.49, 1.64)	0.7257	
diffuse	10/ 28 (35.7)	11.3 (3.1, NE)	8/ 18 (44.4)	2.6 (0.9, NE)	0.45 (0.17, 1.18)	0.0951	
others	2/ 8 (25.0)	NE (0.5, NE)	4/ 6 (66.7)	1.4 (0.5, NE)	0.17 (0.02, 1.53)	0.0754	
Number of metastatic sites							0.6366
<2	10/ 24 (41.7)	NE (2.8, NE)	6/ 10 (60.0)	3.1 (0.5, NE)	0.61 (0.22, 1.67)	0.3261	
>= 2	41/101 (40.6)	6.8 (4.4, NE)	21/ 52 (40.4)	4.3 (1.7, NE)	0.69 (0.40, 1.17)	0.1629	
Previous total gastrectomy							0.4332
yes	9/ 22 (40.9)	5.5 (3.1, NE)	3/ 9 (33.3)	NE (0.7, NE)	0.93 (0.24, 3.54)	0.9111	
no	42/103 (40.8)	12.6 (4.3, NE)	24/ 53 (45.3)	3.1 (1.4, NE)	0.63 (0.38, 1.05)	0.0681	
Prior adjuvant/ neoadjuvant therapy							0.4231
yes	13/ 30 (43.3)	5.9 (3.1, NE)	3/ 10 (30.0)	NE (0.5, NE)	1.05 (0.30, 3.74)	0.9389	
no	38/ 95 (40.0)	12.6 (4.3, NE)	24/ 52 (46.2)	3.8 (1.4, NE)	0.62 (0.37, 1.05)	0.0691	
Prior ramucirumab contained treatment							0.2908
yes	40/ 94 (42.6)	6.8 (4.5, NE)	21/ 41 (51.2)	1.9 (1.4, NE)	0.57 (0.33, 0.98)	0.0360	
no	11/ 31 (35.5)	NE (3.6, NE)	6/ 21 (28.6)	NE (2.6, NE)	0.97 (0.36, 2.63)	0.9630	
Prior nivolumab contained treatment							0.4620
yes	14/ 33 (42.4)	NE (1.5, NE)	8/ 15 (53.3)	2.6 (0.6, NE)	0.61 (0.25, 1.48)	0.2540	
no	37/ 92 (40.2)	6.8 (4.3, 12.6)	19/ 47 (40.4)	4.3 (1.8, NE)	0.69 (0.39, 1.21)	0.1940	

Time to Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

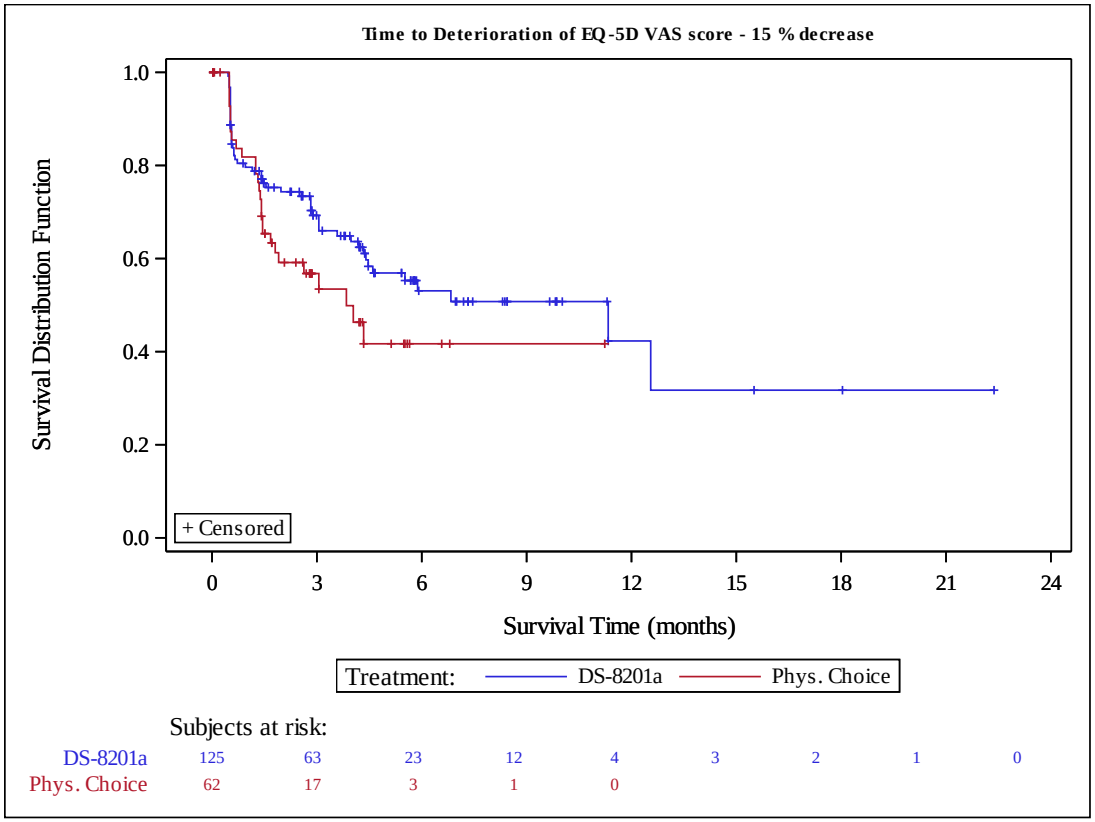
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7079
yes	20/ 44 (45.5)	11.3 (2.9, NE)	8/ 17 (47.1)	3.2 (0.6, NE)	0.61 (0.26, 1.42)	0.2367	
no	31/ 81 (38.3)	6.8 (4.3, NE)	19/ 45 (42.2)	4.0 (1.4, NE)	0.69 (0.39, 1.22)	0.1983	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.4483
yes	7/ 22 (31.8)	NE (0.6, NE)	2/ 7 (28.6)	NE (1.3, NE)	1.15 (0.24, 5.55)	0.8918	
no	44/103 (42.7)	6.8 (4.3, NE)	25/ 55 (45.5)	3.8 (1.7, NE)	0.61 (0.37, 1.01)	0.0516	
Presence of liver metastasis at baseline							0.7556
yes	27/ 67 (40.3)	6.8 (3.6, NE)	13/ 34 (38.2)	4.3 (1.4, NE)	0.71 (0.36, 1.39)	0.3137	
no	24/ 58 (41.4)	11.3 (4.0, NE)	14/ 28 (50.0)	3.1 (1.3, NE)	0.63 (0.32, 1.23)	0.1641	
Renal impairment at baseline							0.1097
normal	8/ 33 (24.2)	NE (4.6, NE)	6/ 13 (46.2)	2.6 (1.2, NE)	0.23 (0.07, 0.74)	0.0074	
mild	28/ 53 (52.8)	4.4 (3.1, 6.8)	11/ 28 (39.3)	4.3 (1.4, NE)	0.95 (0.47, 1.92)	0.8873	
moderate	15/ 39 (38.5)	11.3 (1.4, NE)	9/ 20 (45.0)	4.0 (1.4, NE)	0.81 (0.35, 1.87)	0.5906	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.9 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.2481
normal	38/ 88 (43.2)	12.6 (4.2, NE)	19/ 47 (40.4)	4.0 (1.8, NE)	0.75 (0.43, 1.31)	0.2908	
mild	12/ 36 (33.3)	11.3 (2.9, NE)	8/ 15 (53.3)	1.3 (0.5, NE)	0.43 (0.17, 1.07)	0.0619	
moderate	1/ 1 (100.0)	0.5 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8564
yes	2/ 8 (25.0)	NE (0.5, NE)	1/ 5 (20.0)	NE (0.5, NE)	0.91 (0.08, 10.10)	0.9397	
no	49/117 (41.9)	6.8 (4.3, NE)	26/ 57 (45.6)	3.8 (1.4, NE)	0.64 (0.39, 1.04)	0.0658	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9998
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	51/122 (41.8)	6.8 (4.3, NE)	27/ 58 (46.6)	3.8 (1.4, NE)	0.62 (0.38, 0.99)	0.0427	

Time to Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	36 (28.8)	20 (32.3)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (11.3, NE)	NE (3.8, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.63 (0.36, 1.10)	
p-value [c]	0.1008	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.63 (0.36, 1.09)	
p-value [c]	0.0979	

Time to Definitive Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.1187
Japan	30/ 99 (30.3)	NE (6.9, NE)	15/ 50 (30.0)	NE (3.8, NE)	0.79 (0.42, 1.48)	0.4581	
Korea	6/ 26 (23.1)	11.3 (4.6, NE)	5/ 12 (41.7)	3.2 (1.4, NE)	0.22 (0.06, 0.80)	0.0119	
Lines of prior systemic therapy							0.6106
2	20/ 66 (30.3)	NE (4.6, NE)	12/ 38 (31.6)	NE (3.1, NE)	0.76 (0.37, 1.57)	0.4633	
3	7/ 34 (20.6)	NE (5.5, NE)	6/ 18 (33.3)	NE (1.7, NE)	0.42 (0.14, 1.27)	0.1108	
>=4	9/ 25 (36.0)	11.3 (4.1, NE)	2/ 6 (33.3)	NE (0.5, NE)	0.60 (0.12, 2.90)	0.5272	
Age							0.1416
<65 years	11/ 55 (20.0)	NE (NE , NE)	9/ 27 (33.3)	NE (1.9, NE)	0.40 (0.16, 0.98)	0.0374	
>=65 years	25/ 70 (35.7)	11.3 (4.4, NE)	11/ 35 (31.4)	NE (3.1, NE)	0.84 (0.41, 1.72)	0.6392	
Sex							0.8935
female	13/ 30 (43.3)	4.6 (2.9, NE)	8/ 15 (53.3)	2.4 (0.9, NE)	0.62 (0.25, 1.51)	0.2861	
male	23/ 95 (24.2)	NE (11.3, NE)	12/ 47 (25.5)	NE (4.0, NE)	0.66 (0.32, 1.34)	0.2466	
ECOG PS							0.8772
0	18/ 62 (29.0)	NE (6.9, NE)	9/ 30 (30.0)	NE (3.8, NE)	0.67 (0.30, 1.50)	0.3273	
1	18/ 63 (28.6)	11.3 (4.6, NE)	11/ 32 (34.4)	NE (1.8, NE)	0.60 (0.28, 1.28)	0.1795	
HER2 Status in central laboratory							0.0231
IHC 3+	25/ 96 (26.0)	NE (11.3, NE)	17/ 47 (36.2)	4.3 (2.6, NE)	0.42 (0.22, 0.78)	0.0051	
IHC 2+/ISH +	11/ 29 (37.9)	NE (1.5, NE)	3/ 15 (20.0)	NE (1.8, NE)	2.32 (0.65, 8.35)	0.1859	
Primary tumor location							0.6397
Gastric	34/108 (31.5)	NE (5.9, NE)	19/ 55 (34.5)	NE (3.1, NE)	0.67 (0.38, 1.18)	0.1613	
GEJ	2/ 17 (11.8)	NE (NE , NE)	1/ 7 (14.3)	NE (1.2, NE)	0.57 (0.05, 6.29)	0.6417	
Histological subtype							0.1796
intestinal	27/ 89 (30.3)	NE (5.9, NE)	10/ 38 (26.3)	NE (4.0, NE)	0.90 (0.43, 1.86)	0.7759	
diffuse	7/ 28 (25.0)	NE (11.3, NE)	8/ 18 (44.4)	2.6 (1.4, NE)	0.29 (0.10, 0.83)	0.0148	
others	2/ 8 (25.0)	NE (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	0.88 (0.12, 6.33)	0.8973	
Number of metastatic sites							0.9463
<2	7/ 24 (29.2)	NE (4.2, NE)	4/ 10 (40.0)	NE (0.9, NE)	0.66 (0.19, 2.26)	0.5039	
>= 2	29/101 (28.7)	NE (6.9, NE)	16/ 52 (30.8)	NE (4.0, NE)	0.62 (0.33, 1.16)	0.1303	
Previous total gastrectomy							0.8081
yes	7/ 22 (31.8)	11.3 (4.4, NE)	3/ 9 (33.3)	NE (0.7, NE)	0.61 (0.15, 2.51)	0.4906	
no	29/103 (28.2)	NE (NE , NE)	17/ 53 (32.1)	NE (3.1, NE)	0.63 (0.34, 1.15)	0.1265	
Prior adjuvant/ neoadjuvant therapy							0.1345
yes	10/ 30 (33.3)	11.3 (5.9, NE)	1/ 10 (10.0)	NE (0.7, NE)	2.15 (0.27, 17.29)	0.4605	
no	26/ 95 (27.4)	NE (NE , NE)	19/ 52 (36.5)	4.3 (2.6, NE)	0.55 (0.30, 1.00)	0.0459	
Prior ramucirumab contained treatment							0.6768
yes	27/ 94 (28.7)	NE (6.9, NE)	14/ 41 (34.1)	NE (1.9, NE)	0.59 (0.31, 1.14)	0.1118	
no	9/ 31 (29.0)	NE (4.3, NE)	6/ 21 (28.6)	NE (2.6, NE)	0.73 (0.26, 2.07)	0.5583	
Prior nivolumab contained treatment							0.8476
yes	12/ 33 (36.4)	NE (4.1, NE)	6/ 15 (40.0)	3.8 (1.4, NE)	0.60 (0.22, 1.63)	0.3124	
no	24/ 92 (26.1)	NE (11.3, NE)	14/ 47 (29.8)	NE (3.1, NE)	0.64 (0.33, 1.25)	0.1860	

Time to Definitive Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8447
yes	15/ 44 (34.1)	NE (5.9, NE)	6/ 17 (35.3)	NE (1.4, NE)	0.55 (0.21, 1.45)	0.2221	
no	21/ 81 (25.9)	NE (5.5, NE)	14/ 45 (31.1)	NE (3.1, NE)	0.66 (0.34, 1.31)	0.2319	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.5787
yes	4/ 22 (18.2)	NE (NE , NE)	1/ 7 (14.3)	NE (1.4, NE)	1.16 (0.13, 10.43)	0.8934	
no	32/103 (31.1)	NE (6.9, NE)	19/ 55 (34.5)	NE (3.1, NE)	0.60 (0.33, 1.07)	0.0781	
Presence of liver metastasis at baseline							0.7589
yes	18/ 67 (26.9)	NE (5.9, NE)	9/ 34 (26.5)	NE (4.0, NE)	0.72 (0.32, 1.61)	0.4264	
no	18/ 58 (31.0)	11.3 (6.9, NE)	11/ 28 (39.3)	NE (2.4, NE)	0.57 (0.26, 1.22)	0.1400	
Renal impairment at baseline							0.1062
normal	5/ 33 (15.2)	NE (NE , NE)	5/ 13 (38.5)	NE (1.8, NE)	0.18 (0.05, 0.70)	0.0057	
mild	19/ 53 (35.8)	NE (4.4, NE)	9/ 28 (32.1)	NE (1.4, NE)	0.78 (0.35, 1.74)	0.5472	
moderate	12/ 39 (30.8)	11.3 (4.2, NE)	5/ 20 (25.0)	NE (3.8, NE)	1.10 (0.38, 3.18)	0.8655	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.9 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.6438
normal	27/ 88 (30.7)	NE (6.9, NE)	16/ 47 (34.0)	4.3 (3.1, NE)	0.59 (0.32, 1.11)	0.0983	
mild	9/ 36 (25.0)	11.3 (4.1, NE)	4/ 15 (26.7)	NE (0.5, NE)	0.74 (0.22, 2.47)	0.6213	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7451
yes	1/ 8 (12.5)	NE (3.1, NE)	1/ 5 (20.0)	NE (0.5, NE)	0.46 (0.03, 7.42)	0.5770	
no	35/117 (29.9)	NE (6.9, NE)	19/ 57 (33.3)	NE (3.1, NE)	0.63 (0.36, 1.11)	0.1057	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9997
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	36/122 (29.5)	NE (6.9, NE)	20/ 58 (34.5)	NE (3.1, NE)	0.59 (0.34, 1.02)	0.0574	

Time to Definitive Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
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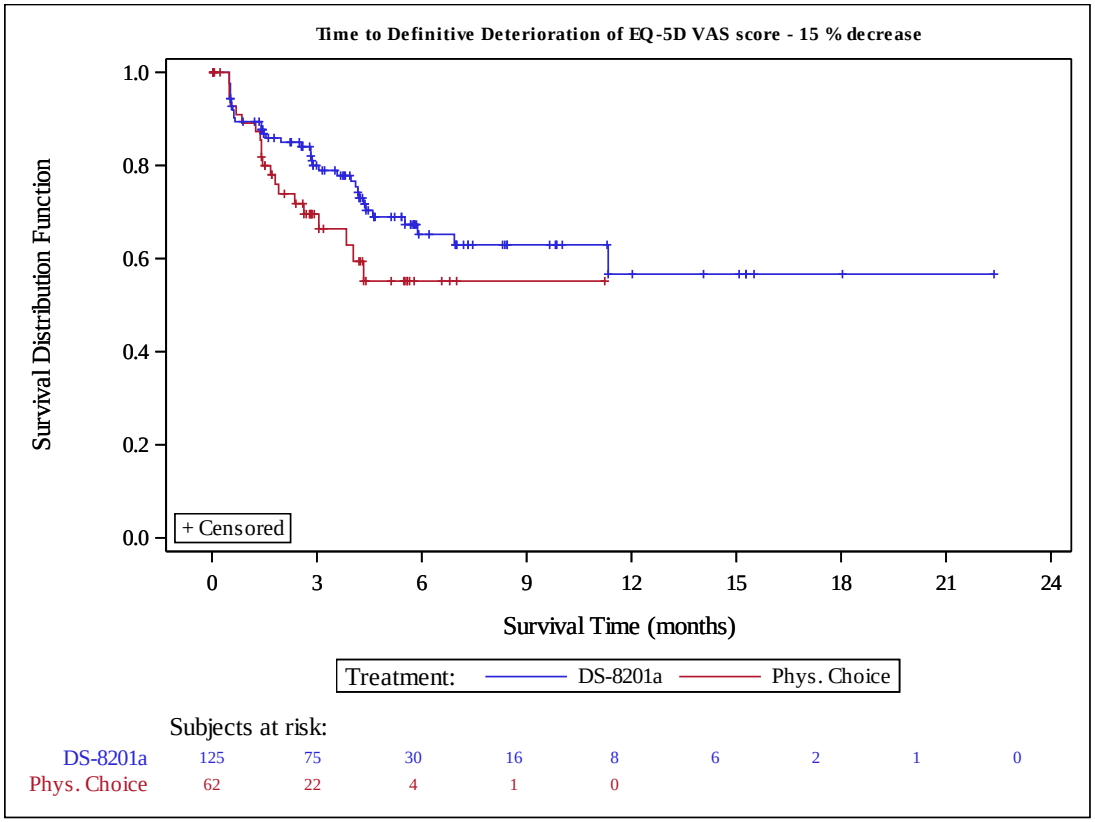
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

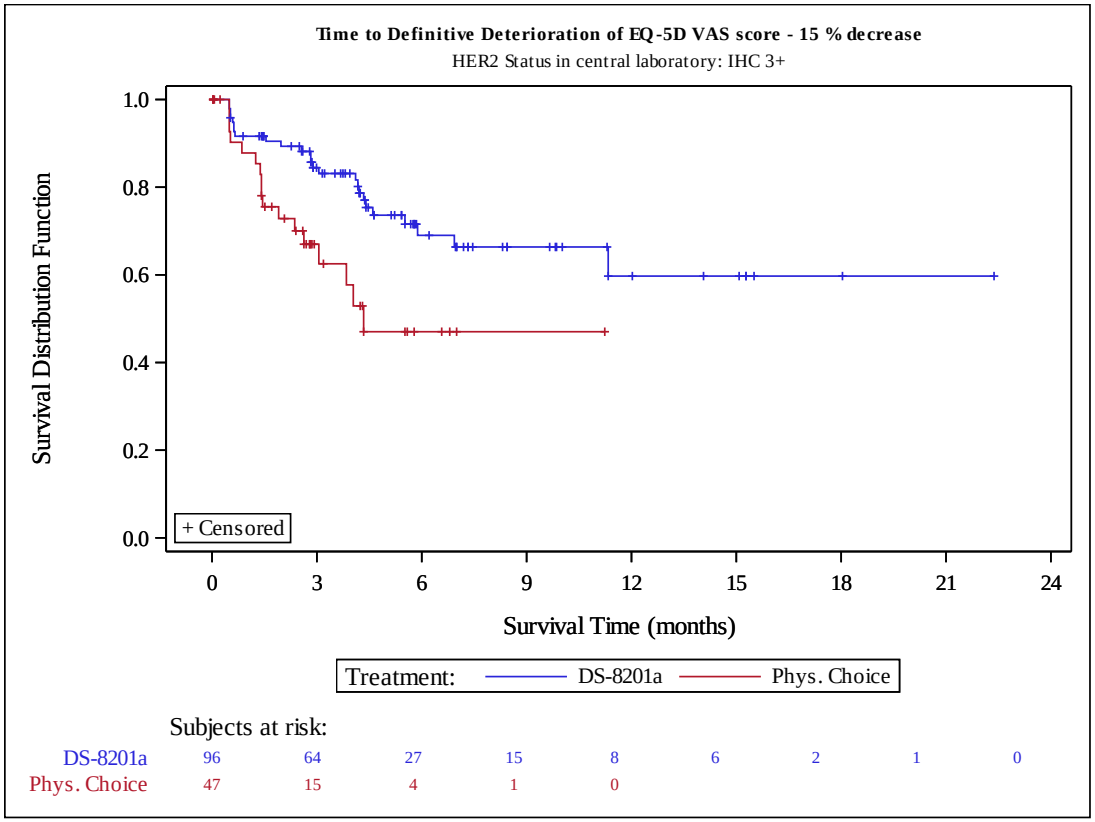
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

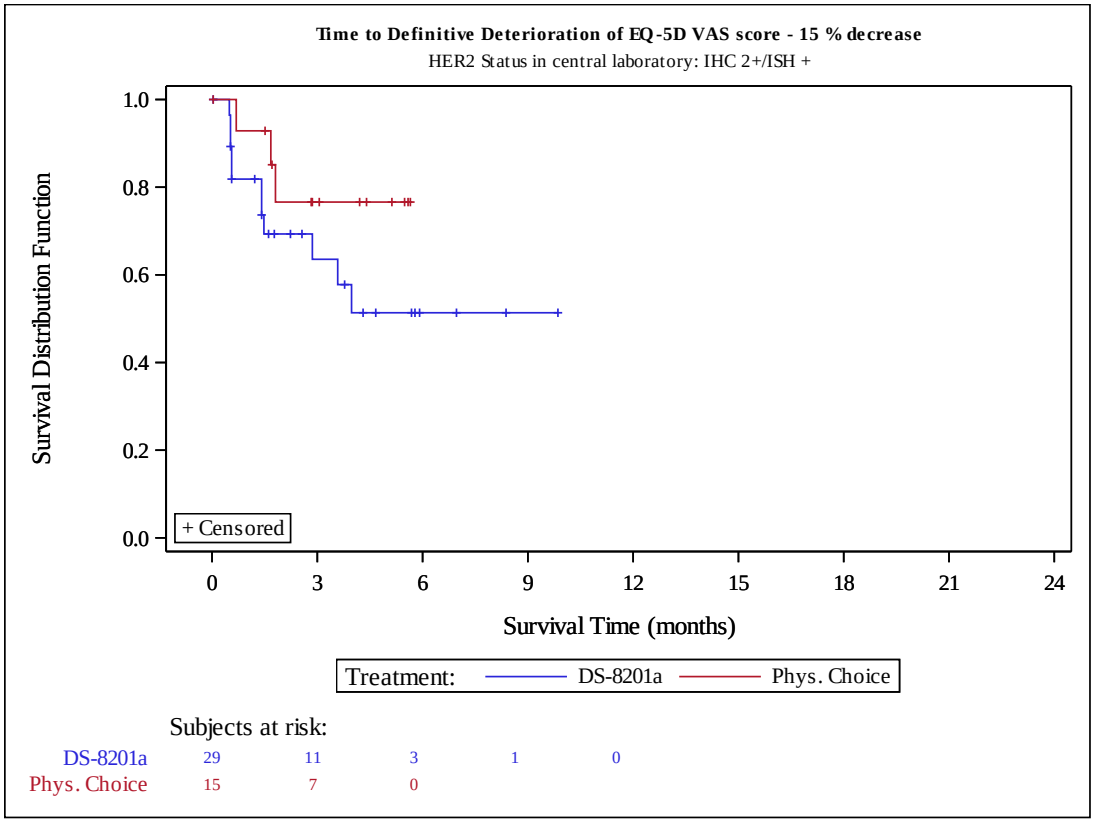
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	120	18 (15.0)	76 (63.3)	26 (21.7)	53	3 (5.7)	40 (75.5)	10 (18.9)
	Day 43	118	23 (19.5)	79 (66.9)	16 (13.6)	52	3 (5.8)	35 (67.3)	14 (26.9)
	Day 85	99	18 (18.2)	63 (63.6)	18 (18.2)	36	4 (11.1)	27 (75.0)	5 (13.9)
	Day 127	75	17 (22.7)	43 (57.3)	15 (20.0)	19	4 (21.1)	12 (63.2)	3 (15.8)
	Day 169	52	12 (23.1)	34 (65.4)	6 (11.5)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	34	6 (17.6)	25 (73.5)	3 (8.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	24	3 (12.5)	19 (79.2)	2 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	19	3 (15.8)	16 (84.2)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	2 (13.3)	10 (66.7)	3 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	2 (18.2)	6 (54.5)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	84	9 (10.7)	48 (57.1)	27 (32.1)	52	4 (7.7)	29 (55.8)	19 (36.5)
Region									
Japan									
	Day 15	98	13 (13.3)	61 (62.2)	24 (24.5)	46	3 (6.5)	35 (76.1)	8 (17.4)
	Day 43	94	16 (17.0)	64 (68.1)	14 (14.9)	43	2 (4.7)	30 (69.8)	11 (25.6)
	Day 85	77	13 (16.9)	50 (64.9)	14 (18.2)	32	3 (9.4)	24 (75.0)	5 (15.6)
	Day 127	61	14 (23.0)	34 (55.7)	13 (21.3)	16	3 (18.8)	11 (68.8)	2 (12.5)
	Day 169	45	10 (22.2)	29 (64.4)	6 (13.3)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 211	28	3 (10.7)	22 (78.6)	3 (10.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	14 (77.8)	2 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	2 (14.3)	12 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	2 (18.2)	7 (63.6)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	66	8 (12.1)	37 (56.1)	21 (31.8)	45	3 (6.7)	28 (62.2)	14 (31.1)
Region									
Korea									
	Day 15	22	5 (22.7)	15 (68.2)	2 (9.1)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 43	24	7 (29.2)	15 (62.5)	2 (8.3)	9	1 (11.1)	5 (55.6)	3 (33.3)
	Day 85	22	5 (22.7)	13 (59.1)	4 (18.2)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 127	14	3 (21.4)	9 (64.3)	2 (14.3)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 169	7	2 (28.6)	5 (71.4)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	3 (50.0)	3 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	11 (61.1)	6 (33.3)	7	1 (14.3)	1 (14.3)	5 (71.4)
Lines of prior systemic therapy									
2									
	Day 15	61	9 (14.8)	40 (65.6)	12 (19.7)	34	2 (5.9)	26 (76.5)	6 (17.6)
	Day 43	62	12 (19.4)	41 (66.1)	9 (14.5)	35	2 (5.7)	25 (71.4)	8 (22.9)
	Day 85	50	8 (16.0)	32 (64.0)	10 (20.0)	21	3 (14.3)	15 (71.4)	3 (14.3)
	Day 127	34	9 (26.5)	16 (47.1)	9 (26.5)	14	3 (21.4)	9 (64.3)	2 (14.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 169	21	7 (33.3)	12 (57.1)	2 (9.5)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	14	3 (21.4)	10 (71.4)	1 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	9 (90.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	2 (28.6)	5 (71.4)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	1 (20.0)	4 (80.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	46	3 (6.5)	27 (58.7)	16 (34.8)	31	3 (9.7)	17 (54.8)	11 (35.5)
Lines of prior systemic therapy									
3									
	Day 15	34	4 (11.8)	23 (67.6)	7 (20.6)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 43	33	5 (15.2)	24 (72.7)	4 (12.1)	14	1 (7.1)	7 (50.0)	6 (42.9)
	Day 85	28	6 (21.4)	20 (71.4)	2 (7.1)	12	1 (8.3)	9 (75.0)	2 (16.7)
	Day 127	23	4 (17.4)	14 (60.9)	5 (21.7)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 169	17	3 (17.6)	11 (64.7)	3 (17.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	12	2 (16.7)	9 (75.0)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	3 (14.3)	13 (61.9)	5 (23.8)	16	1 (6.3)	9 (56.3)	6 (37.5)
Lines of prior systemic therapy									
>=4									
	Day 15	25	5 (20.0)	13 (52.0)	7 (28.0)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 43	23	6 (26.1)	14 (60.9)	3 (13.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	4 (19.0)	11 (52.4)	6 (28.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	4 (22.2)	13 (72.2)	1 (5.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	14	2 (14.3)	11 (78.6)	1 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	3 (17.6)	8 (47.1)	6 (35.3)	5	0 (0.0)	3 (60.0)	2 (40.0)
Age									
<65 years									
	Day 15	52	9 (17.3)	33 (63.5)	10 (19.2)	22	0 (0.0)	18 (81.8)	4 (18.2)
	Day 43	52	15 (28.8)	33 (63.5)	4 (7.7)	23	1 (4.3)	16 (69.6)	6 (26.1)
	Day 85	47	8 (17.0)	34 (72.3)	5 (10.6)	16	2 (12.5)	12 (75.0)	2 (12.5)
	Day 127	34	9 (26.5)	21 (61.8)	4 (11.8)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 169	25	6 (24.0)	18 (72.0)	1 (4.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	16	3 (18.8)	11 (68.8)	2 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	12	1 (8.3)	11 (91.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	11	2 (18.2)	9 (81.8)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	2 (33.3)	3 (50.0)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	5 (13.2)	22 (57.9)	11 (28.9)	21	2 (9.5)	11 (52.4)	8 (38.1)
Age									
>=65 years									
	Day 15	68	9 (13.2)	43 (63.2)	16 (23.5)	31	3 (9.7)	22 (71.0)	6 (19.4)
	Day 43	66	8 (12.1)	46 (69.7)	12 (18.2)	29	2 (6.9)	19 (65.5)	8 (27.6)
	Day 85	52	10 (19.2)	29 (55.8)	13 (25.0)	20	2 (10.0)	15 (75.0)	3 (15.0)
	Day 127	41	8 (19.5)	22 (53.7)	11 (26.8)	11	3 (27.3)	5 (45.5)	3 (27.3)
	Day 169	27	6 (22.2)	16 (59.3)	5 (18.5)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	18	3 (16.7)	14 (77.8)	1 (5.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	1 (12.5)	7 (87.5)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	7	0 (0.0)	4 (57.1)	3 (42.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	46	4 (8.7)	26 (56.5)	16 (34.8)	31	2 (6.5)	18 (58.1)	11 (35.5)
Sex									
female									
	Day 15	28	5 (17.9)	15 (53.6)	8 (28.6)	14	1 (7.1)	9 (64.3)	4 (28.6)
	Day 43	28	5 (17.9)	17 (60.7)	6 (21.4)	13	0 (0.0)	8 (61.5)	5 (38.5)
	Day 85	20	4 (20.0)	10 (50.0)	6 (30.0)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	13	5 (38.5)	4 (30.8)	4 (30.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	9	2 (22.2)	6 (66.7)	1 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	6	1 (16.7)	4 (66.7)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	9 (42.9)	11 (52.4)	14	0 (0.0)	7 (50.0)	7 (50.0)
Sex									
male									
	Day 15	92	13 (14.1)	61 (66.3)	18 (19.6)	39	2 (5.1)	31 (79.5)	6 (15.4)
	Day 43	90	18 (20.0)	62 (68.9)	10 (11.1)	39	3 (7.7)	27 (69.2)	9 (23.1)
	Day 85	79	14 (17.7)	53 (67.1)	12 (15.2)	28	4 (14.3)	21 (75.0)	3 (10.7)
	Day 127	62	12 (19.4)	39 (62.9)	11 (17.7)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	43	10 (23.3)	28 (65.1)	5 (11.6)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	28	5 (17.9)	21 (75.0)	2 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	3 (15.0)	15 (75.0)	2 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	3 (17.6)	14 (82.4)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	9 (64.3)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	8 (12.7)	39 (61.9)	16 (25.4)	38	4 (10.5)	22 (57.9)	12 (31.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS									
0									
	Day 15	61	12 (19.7)	38 (62.3)	11 (18.0)	27	2 (7.4)	23 (85.2)	2 (7.4)
	Day 43	60	13 (21.7)	40 (66.7)	7 (11.7)	26	2 (7.7)	18 (69.2)	6 (23.1)
	Day 85	54	9 (16.7)	34 (63.0)	11 (20.4)	19	2 (10.5)	15 (78.9)	2 (10.5)
	Day 127	42	8 (19.0)	27 (64.3)	7 (16.7)	9	3 (33.3)	4 (44.4)	2 (22.2)
	Day 169	33	8 (24.2)	23 (69.7)	2 (6.1)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	20	3 (15.0)	15 (75.0)	2 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	1 (6.7)	12 (80.0)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	1 (9.1)	10 (90.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	9	1 (11.1)	7 (77.8)	1 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	5 (12.8)	21 (53.8)	13 (33.3)	27	2 (7.4)	17 (63.0)	8 (29.6)
ECOG PS									
1									
	Day 15	59	6 (10.2)	38 (64.4)	15 (25.4)	26	1 (3.8)	17 (65.4)	8 (30.8)
	Day 43	58	10 (17.2)	39 (67.2)	9 (15.5)	26	1 (3.8)	17 (65.4)	8 (30.8)
	Day 85	45	9 (20.0)	29 (64.4)	7 (15.6)	17	2 (11.8)	12 (70.6)	3 (17.6)
	Day 127	33	9 (27.3)	16 (48.5)	8 (24.2)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	19	4 (21.1)	11 (57.9)	4 (21.1)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	14	3 (21.4)	10 (71.4)	1 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	2 (22.2)	7 (77.8)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	4 (8.9)	27 (60.0)	14 (31.1)	25	2 (8.0)	12 (48.0)	11 (44.0)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	93	12 (12.9)	61 (65.6)	20 (21.5)	38	0 (0.0)	31 (81.6)	7 (18.4)
	Day 43	92	17 (18.5)	67 (72.8)	8 (8.7)	39	2 (5.1)	25 (64.1)	12 (30.8)
	Day 85	79	13 (16.5)	55 (69.6)	11 (13.9)	26	3 (11.5)	19 (73.1)	4 (15.4)
	Day 127	60	15 (25.0)	35 (58.3)	10 (16.7)	13	2 (15.4)	8 (61.5)	3 (23.1)
	Day 169	41	12 (29.3)	27 (65.9)	2 (4.9)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	29	6 (20.7)	20 (69.0)	3 (10.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	3 (14.3)	16 (76.2)	2 (9.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	3 (17.6)	14 (82.4)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	10 (71.4)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	5 (7.9)	38 (60.3)	20 (31.7)	38	3 (7.9)	19 (50.0)	16 (42.1)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	6 (22.2)	15 (55.6)	6 (22.2)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 43	26	6 (23.1)	12 (46.2)	8 (30.8)	13	1 (7.7)	10 (76.9)	2 (15.4)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	20	5 (25.0)	8 (40.0)	7 (35.0)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 127	15	2 (13.3)	8 (53.3)	5 (33.3)	6	2 (33.3)	4 (66.7)	0 (0.0)
	Day 169	11	0 (0.0)	7 (63.6)	4 (36.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	4 (19.0)	10 (47.6)	7 (33.3)	14	1 (7.1)	10 (71.4)	3 (21.4)
Primary tumor location									
Gastric									
	Day 15	103	17 (16.5)	63 (61.2)	23 (22.3)	47	3 (6.4)	35 (74.5)	9 (19.1)
	Day 43	101	19 (18.8)	68 (67.3)	14 (13.9)	47	3 (6.4)	31 (66.0)	13 (27.7)
	Day 85	84	15 (17.9)	53 (63.1)	16 (19.0)	33	4 (12.1)	25 (75.8)	4 (12.1)
	Day 127	64	12 (18.8)	37 (57.8)	15 (23.4)	16	4 (25.0)	9 (56.3)	3 (18.8)
	Day 169	42	8 (19.0)	28 (66.7)	6 (14.3)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	29	5 (17.2)	21 (72.4)	3 (10.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	2 (10.0)	16 (80.0)	2 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	2 (13.3)	13 (86.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	0 (0.0)	9 (75.0)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	6 (8.3)	41 (56.9)	25 (34.7)	46	4 (8.7)	23 (50.0)	19 (41.3)
Primary tumor location									
GEJ									
	Day 15	17	1 (5.9)	13 (76.5)	3 (17.6)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 43	17	4 (23.5)	11 (64.7)	2 (11.8)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 85	15	3 (20.0)	10 (66.7)	2 (13.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 127	11	5 (45.5)	6 (54.5)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	4 (40.0)	6 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	2 (66.7)	1 (33.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	2 (66.7)	0 (0.0)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	3 (25.0)	7 (58.3)	2 (16.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	88	11 (12.5)	57 (64.8)	20 (22.7)	36	3 (8.3)	27 (75.0)	6 (16.7)
	Day 43	86	17 (19.8)	57 (66.3)	12 (14.0)	34	2 (5.9)	24 (70.6)	8 (23.5)
	Day 85	73	12 (16.4)	46 (63.0)	15 (20.5)	27	3 (11.1)	20 (74.1)	4 (14.8)
	Day 127	56	13 (23.2)	30 (53.6)	13 (23.2)	14	3 (21.4)	9 (64.3)	2 (14.3)
	Day 169	40	9 (22.5)	25 (62.5)	6 (15.0)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	25	3 (12.0)	19 (76.0)	3 (12.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	16	2 (12.5)	12 (75.0)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	2 (15.4)	11 (84.6)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	2 (20.0)	6 (60.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	64	7 (10.9)	38 (59.4)	19 (29.7)	34	3 (8.8)	22 (64.7)	9 (26.5)
Histological subtype diffuse									
	Day 15	26	6 (23.1)	15 (57.7)	5 (19.2)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 43	26	5 (19.2)	18 (69.2)	3 (11.5)	13	1 (7.7)	8 (61.5)	4 (30.8)
	Day 85	22	5 (22.7)	14 (63.6)	3 (13.6)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 127	15	4 (26.7)	9 (60.0)	2 (13.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	10	3 (30.0)	7 (70.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	3 (37.5)	5 (62.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	16	2 (12.5)	8 (50.0)	6 (37.5)	15	1 (6.7)	6 (40.0)	8 (53.3)
Histological subtype others									
	Day 15	6	1 (16.7)	4 (66.7)	1 (16.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 43	6	1 (16.7)	4 (66.7)	1 (16.7)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 85	4	1 (25.0)	3 (75.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	4	0 (0.0)	4 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	2 (50.0)	2 (50.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	23	4 (17.4)	14 (60.9)	5 (21.7)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	23	4 (17.4)	16 (69.6)	3 (13.0)	10	0 (0.0)	7 (70.0)	3 (30.0)
	Day 85	22	4 (18.2)	13 (59.1)	5 (22.7)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 127	18	5 (27.8)	10 (55.6)	3 (16.7)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	15	5 (33.3)	7 (46.7)	3 (20.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	10	2 (20.0)	8 (80.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	0 (0.0)	6 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	1 (6.7)	10 (66.7)	4 (26.7)	8	0 (0.0)	4 (50.0)	4 (50.0)
Number of metastatic sites >= 2									
	Day 15	97	14 (14.4)	62 (63.9)	21 (21.6)	43	3 (7.0)	32 (74.4)	8 (18.6)
	Day 43	95	19 (20.0)	63 (66.3)	13 (13.7)	42	3 (7.1)	28 (66.7)	11 (26.2)
	Day 85	77	14 (18.2)	50 (64.9)	13 (16.9)	28	4 (14.3)	20 (71.4)	4 (14.3)
	Day 127	57	12 (21.1)	33 (57.9)	12 (21.1)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 169	37	7 (18.9)	27 (73.0)	3 (8.1)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	24	4 (16.7)	17 (70.8)	3 (12.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	3 (16.7)	13 (72.2)	2 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	15	2 (13.3)	13 (86.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	69	8 (11.6)	38 (55.1)	23 (33.3)	44	4 (9.1)	25 (56.8)	15 (34.1)
Previous total gastrectomy									
yes									
	Day 15	20	5 (25.0)	12 (60.0)	3 (15.0)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 43	20	2 (10.0)	16 (80.0)	2 (10.0)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 85	18	2 (11.1)	13 (72.2)	3 (16.7)	6	2 (33.3)	4 (66.7)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	2 (11.8)	10 (58.8)	5 (29.4)	9	2 (22.2)	4 (44.4)	3 (33.3)
Previous total gastrectomy									
no									
	Day 15	100	13 (13.0)	64 (64.0)	23 (23.0)	45	1 (2.2)	35 (77.8)	9 (20.0)
	Day 43	98	21 (21.4)	63 (64.3)	14 (14.3)	44	1 (2.3)	30 (68.2)	13 (29.5)
	Day 85	81	16 (19.8)	50 (61.7)	15 (18.5)	30	2 (6.7)	23 (76.7)	5 (16.7)
	Day 127	64	16 (25.0)	35 (54.7)	13 (20.3)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 169	44	11 (25.0)	30 (68.2)	3 (6.8)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 211	27	4 (14.8)	21 (77.8)	2 (7.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	3 (14.3)	16 (76.2)	2 (9.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	3 (18.8)	13 (81.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	67	7 (10.4)	38 (56.7)	22 (32.8)	43	2 (4.7)	25 (58.1)	16 (37.2)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	6 (20.7)	17 (58.6)	6 (20.7)	9	2 (22.2)	5 (55.6)	2 (22.2)
	Day 43	28	3 (10.7)	22 (78.6)	3 (10.7)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 85	27	5 (18.5)	16 (59.3)	6 (22.2)	7	2 (28.6)	5 (71.4)	0 (0.0)
	Day 127	22	4 (18.2)	14 (63.6)	4 (18.2)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	13	3 (23.1)	8 (61.5)	2 (15.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	8	2 (25.0)	5 (62.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	11 (52.4)	8 (38.1)	9	2 (22.2)	6 (66.7)	1 (11.1)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	91	12 (13.2)	59 (64.8)	20 (22.0)	44	1 (2.3)	35 (79.5)	8 (18.2)
	Day 43	90	20 (22.2)	57 (63.3)	13 (14.4)	44	1 (2.3)	30 (68.2)	13 (29.5)
	Day 85	72	13 (18.1)	47 (65.3)	12 (16.7)	29	2 (6.9)	22 (75.9)	5 (17.2)
	Day 127	53	13 (24.5)	29 (54.7)	11 (20.8)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 169	39	9 (23.1)	26 (66.7)	4 (10.3)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	26	4 (15.4)	20 (76.9)	2 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	3 (15.8)	15 (78.9)	1 (5.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	3 (21.4)	11 (78.6)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	2 (20.0)	7 (70.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	2 (25.0)	5 (62.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	7 (11.1)	37 (58.7)	19 (30.2)	43	2 (4.7)	23 (53.5)	18 (41.9)
Prior ramucirumab contained treatment									
yes									
	Day 15	91	14 (15.4)	55 (60.4)	22 (24.2)	35	2 (5.7)	25 (71.4)	8 (22.9)
	Day 43	90	14 (15.6)	62 (68.9)	14 (15.6)	33	0 (0.0)	21 (63.6)	12 (36.4)
	Day 85	73	11 (15.1)	48 (65.8)	14 (19.2)	23	1 (4.3)	20 (87.0)	2 (8.7)
	Day 127	59	9 (15.3)	39 (66.1)	11 (18.6)	11	2 (18.2)	7 (63.6)	2 (18.2)
	Day 169	41	7 (17.1)	28 (68.3)	6 (14.6)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	25	1 (4.0)	21 (84.0)	3 (12.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	1 (6.7)	12 (80.0)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	1 (7.7)	12 (92.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	7 (11.1)	36 (57.1)	20 (31.7)	35	0 (0.0)	22 (62.9)	13 (37.1)
Prior ramucirumab contained treatment									
no									
	Day 15	29	4 (13.8)	21 (72.4)	4 (13.8)	18	1 (5.6)	15 (83.3)	2 (11.1)
	Day 43	28	9 (32.1)	17 (60.7)	2 (7.1)	19	3 (15.8)	14 (73.7)	2 (10.5)
	Day 85	26	7 (26.9)	15 (57.7)	4 (15.4)	13	3 (23.1)	7 (53.8)	3 (23.1)
	Day 127	16	8 (50.0)	4 (25.0)	4 (25.0)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 169	11	5 (45.5)	6 (54.5)	0 (0.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	9	5 (55.6)	4 (44.4)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	2 (22.2)	7 (77.8)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	2 (33.3)	4 (66.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	3	1 (33.3)	1 (33.3)	1 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	12 (57.1)	7 (33.3)	17	4 (23.5)	7 (41.2)	6 (35.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Prior nivolumab contained treatment									
yes									
	Day 15	33	3 (9.1)	20 (60.6)	10 (30.3)	14	1 (7.1)	10 (71.4)	3 (21.4)
	Day 43	31	5 (16.1)	20 (64.5)	6 (19.4)	10	0 (0.0)	7 (70.0)	3 (30.0)
	Day 85	27	4 (14.8)	15 (55.6)	8 (29.6)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	26	2 (7.7)	20 (76.9)	4 (15.4)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	20	3 (15.0)	15 (75.0)	2 (10.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	13	1 (7.7)	11 (84.6)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	2 (10.0)	12 (60.0)	6 (30.0)	13	0 (0.0)	7 (53.8)	6 (46.2)
Prior nivolumab contained treatment									
no									
	Day 15	87	15 (17.2)	56 (64.4)	16 (18.4)	39	2 (5.1)	30 (76.9)	7 (17.9)
	Day 43	87	18 (20.7)	59 (67.8)	10 (11.5)	42	3 (7.1)	28 (66.7)	11 (26.2)
	Day 85	72	14 (19.4)	48 (66.7)	10 (13.9)	26	4 (15.4)	19 (73.1)	3 (11.5)
	Day 127	49	15 (30.6)	23 (46.9)	11 (22.4)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	32	9 (28.1)	19 (59.4)	4 (12.5)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	21	5 (23.8)	14 (66.7)	2 (9.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	14	2 (14.3)	12 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	2 (18.2)	9 (81.8)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	64	7 (10.9)	36 (56.3)	21 (32.8)	39	4 (10.3)	22 (56.4)	13 (33.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	43	4 (9.3)	28 (65.1)	11 (25.6)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 43	41	8 (19.5)	27 (65.9)	6 (14.6)	12	0 (0.0)	9 (75.0)	3 (25.0)
	Day 85	37	5 (13.5)	22 (59.5)	10 (27.0)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 127	31	3 (9.7)	23 (74.2)	5 (16.1)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	23	5 (21.7)	16 (69.6)	2 (8.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	17	3 (17.6)	13 (76.5)	1 (5.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	13	2 (15.4)	9 (69.2)	2 (15.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	2 (16.7)	10 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	3 (42.9)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	2 (7.1)	17 (60.7)	9 (32.1)	15	0 (0.0)	9 (60.0)	6 (40.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	77	14 (18.2)	48 (62.3)	15 (19.5)	37	2 (5.4)	28 (75.7)	7 (18.9)
	Day 43	77	15 (19.5)	52 (67.5)	10 (13.0)	40	3 (7.5)	26 (65.0)	11 (27.5)
	Day 85	62	13 (21.0)	41 (66.1)	8 (12.9)	25	4 (16.0)	18 (72.0)	3 (12.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 127	44	14 (31.8)	20 (45.5)	10 (22.7)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 169	29	7 (24.1)	18 (62.1)	4 (13.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	17	3 (17.6)	12 (70.6)	2 (11.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	11	1 (9.1)	10 (90.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	1 (14.3)	6 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	1 (20.0)	4 (80.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	56	7 (12.5)	31 (55.4)	18 (32.1)	37	4 (10.8)	20 (54.1)	13 (35.1)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
yes									
	Day 15	22	2 (9.1)	14 (63.6)	6 (27.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	19	4 (21.1)	14 (73.7)	1 (5.3)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 85	16	4 (25.0)	11 (68.8)	1 (6.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 127	12	2 (16.7)	10 (83.3)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	7	1 (14.3)	5 (71.4)	1 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	3	1 (33.3)	2 (66.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	9 (75.0)	2 (16.7)	6	0 (0.0)	5 (83.3)	1 (16.7)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
no									
	Day 15	98	16 (16.3)	62 (63.3)	20 (20.4)	47	3 (6.4)	34 (72.3)	10 (21.3)
	Day 43	99	19 (19.2)	65 (65.7)	15 (15.2)	46	3 (6.5)	31 (67.4)	12 (26.1)
	Day 85	83	14 (16.9)	52 (62.7)	17 (20.5)	31	4 (12.9)	22 (71.0)	5 (16.1)
	Day 127	63	15 (23.8)	33 (52.4)	15 (23.8)	16	4 (25.0)	9 (56.3)	3 (18.8)
	Day 169	45	11 (24.4)	29 (64.4)	5 (11.1)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	31	5 (16.1)	23 (74.2)	3 (9.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	2 (9.1)	18 (81.8)	2 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	2 (11.8)	15 (88.2)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	9 (64.3)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	8 (11.1)	39 (54.2)	25 (34.7)	46	4 (8.7)	24 (52.2)	18 (39.1)
Presence of liver metastasis at baseline									
yes									
	Day 15	65	11 (16.9)	40 (61.5)	14 (21.5)	27	1 (3.7)	22 (81.5)	4 (14.8)
	Day 43	63	14 (22.2)	41 (65.1)	8 (12.7)	27	3 (11.1)	16 (59.3)	8 (29.6)
	Day 85	50	10 (20.0)	33 (66.0)	7 (14.0)	16	3 (18.8)	13 (81.3)	0 (0.0)
	Day 127	36	7 (19.4)	22 (61.1)	7 (19.4)	10	2 (20.0)	5 (50.0)	3 (30.0)
	Day 169	25	7 (28.0)	16 (64.0)	2 (8.0)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	14	2 (14.3)	10 (71.4)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup / Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 253	12	2 (16.7)	9 (75.0)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	2 (22.2)	7 (77.8)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	6 (13.3)	25 (55.6)	14 (31.1)	29	4 (13.8)	16 (55.2)	9 (31.0)
Presence of liver metastasis at baseline									
no									
	Day 15	55	7 (12.7)	36 (65.5)	12 (21.8)	26	2 (7.7)	18 (69.2)	6 (23.1)
	Day 43	55	9 (16.4)	38 (69.1)	8 (14.5)	25	0 (0.0)	19 (76.0)	6 (24.0)
	Day 85	49	8 (16.3)	30 (61.2)	11 (22.4)	20	1 (5.0)	14 (70.0)	5 (25.0)
	Day 127	39	10 (25.6)	21 (53.8)	8 (20.5)	9	2 (22.2)	7 (77.8)	0 (0.0)
	Day 169	27	5 (18.5)	18 (66.7)	4 (14.8)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	20	4 (20.0)	15 (75.0)	1 (5.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	10 (83.3)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	10	1 (10.0)	9 (90.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	1 (20.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	3 (7.7)	23 (59.0)	13 (33.3)	23	0 (0.0)	13 (56.5)	10 (43.5)
Renal impairment at baseline									
normal									
	Day 15	32	6 (18.8)	24 (75.0)	2 (6.3)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 43	33	9 (27.3)	24 (72.7)	0 (0.0)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 85	26	3 (11.5)	20 (76.9)	3 (11.5)	8	1 (12.5)	5 (62.5)	2 (25.0)
	Day 127	19	6 (31.6)	12 (63.2)	1 (5.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	15	4 (26.7)	11 (73.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	0 (0.0)	10 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	8 (88.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	4 (20.0)	12 (60.0)	4 (20.0)	10	1 (10.0)	5 (50.0)	4 (40.0)
Renal impairment at baseline									
mild									
	Day 15	51	9 (17.6)	29 (56.9)	13 (25.5)	25	1 (4.0)	18 (72.0)	6 (24.0)
	Day 43	51	9 (17.6)	33 (64.7)	9 (17.6)	23	1 (4.3)	18 (78.3)	4 (17.4)
	Day 85	45	11 (24.4)	25 (55.6)	9 (20.0)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 127	32	7 (21.9)	19 (59.4)	6 (18.8)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	21	4 (19.0)	15 (71.4)	2 (9.5)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	13	3 (23.1)	7 (53.8)	3 (23.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	8	2 (25.0)	5 (62.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	5 (83.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	40	5 (12.5)	19 (47.5)	16 (40.0)	22	2 (9.1)	11 (50.0)	9 (40.9)
Renal impairment at baseline									
moderate									
	Day 15	37	3 (8.1)	23 (62.2)	11 (29.7)	17	2 (11.8)	13 (76.5)	2 (11.8)
	Day 43	34	5 (14.7)	22 (64.7)	7 (20.6)	17	1 (5.9)	10 (58.8)	6 (35.3)
	Day 85	28	4 (14.3)	18 (64.3)	6 (21.4)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 127	24	4 (16.7)	12 (50.0)	8 (33.3)	7	2 (28.6)	3 (42.9)	2 (28.6)
	Day 169	16	4 (25.0)	8 (50.0)	4 (25.0)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	11	2 (18.2)	9 (81.8)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	0 (0.0)	17 (70.8)	7 (29.2)	19	1 (5.3)	13 (68.4)	5 (26.3)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
Hepatic impairment at baseline									
normal									
	Day 15	84	11 (13.1)	55 (65.5)	18 (21.4)	38	3 (7.9)	31 (81.6)	4 (10.5)
	Day 43	84	16 (19.0)	56 (66.7)	12 (14.3)	40	3 (7.5)	26 (65.0)	11 (27.5)
	Day 85	76	16 (21.1)	46 (60.5)	14 (18.4)	27	4 (14.8)	18 (66.7)	5 (18.5)
	Day 127	59	16 (27.1)	31 (52.5)	12 (20.3)	14	4 (28.6)	7 (50.0)	3 (21.4)
	Day 169	40	10 (25.0)	25 (62.5)	5 (12.5)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	24	5 (20.8)	16 (66.7)	3 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	19	2 (10.5)	15 (78.9)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	2 (13.3)	13 (86.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	2 (18.2)	7 (63.6)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	2 (25.0)	3 (37.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	57	5 (8.8)	32 (56.1)	20 (35.1)	39	4 (10.3)	20 (51.3)	15 (38.5)
Hepatic impairment at baseline									
mild									
	Day 15	35	7 (20.0)	21 (60.0)	7 (20.0)	15	0 (0.0)	9 (60.0)	6 (40.0)
	Day 43	33	7 (21.2)	22 (66.7)	4 (12.1)	12	0 (0.0)	9 (75.0)	3 (25.0)
	Day 85	22	2 (9.1)	16 (72.7)	4 (18.2)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 127	15	1 (6.7)	11 (73.3)	3 (20.0)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 169	12	2 (16.7)	9 (75.0)	1 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	9 (90.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	4 (15.4)	15 (57.7)	7 (26.9)	13	0 (0.0)	9 (69.2)	4 (30.8)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	1 (12.5)	6 (75.0)	1 (12.5)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	3 (37.5)	5 (62.5)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	4 (57.1)	2 (28.6)	1 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	3 (50.0)	3 (50.0)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	5	1 (20.0)	4 (80.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	2 (50.0)	2 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	4 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	5	2 (40.0)	2 (40.0)	1 (20.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	112	17 (15.2)	70 (62.5)	25 (22.3)	49	3 (6.1)	37 (75.5)	9 (18.4)
	Day 43	110	20 (18.2)	74 (67.3)	16 (14.5)	49	3 (6.1)	32 (65.3)	14 (28.6)
	Day 85	92	14 (15.2)	61 (66.3)	17 (18.5)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	69	14 (20.3)	40 (58.0)	15 (21.7)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	47	11 (23.4)	30 (63.8)	6 (12.8)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	30	4 (13.3)	23 (76.7)	3 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	3 (15.0)	15 (75.0)	2 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	17	3 (17.6)	14 (82.4)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	14	2 (14.3)	9 (64.3)	3 (21.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	7 (8.9)	46 (58.2)	26 (32.9)	49	4 (8.2)	27 (55.1)	18 (36.7)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	1 (33.3)	2 (66.7)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	2 (66.7)	1 (33.3)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	2 (66.7)	1 (33.3)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	3	1 (33.3)	2 (66.7)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	117	18 (15.4)	73 (62.4)	26 (22.2)	50	3 (6.0)	37 (74.0)	10 (20.0)
	Day 43	115	22 (19.1)	77 (67.0)	16 (13.9)	49	3 (6.1)	32 (65.3)	14 (28.6)
	Day 85	96	16 (16.7)	62 (64.6)	18 (18.8)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	72	15 (20.8)	42 (58.3)	15 (20.8)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	49	11 (22.4)	32 (65.3)	6 (12.2)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	32	5 (15.6)	24 (75.0)	3 (9.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	3 (13.6)	17 (77.3)	2 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	18	3 (16.7)	15 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	15	2 (13.3)	10 (66.7)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	11	2 (18.2)	6 (54.5)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	9 (10.8)	47 (56.6)	27 (32.5)	50	4 (8.0)	27 (54.0)	19 (38.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Anhang 4-G 1.1.4: Gesundheitsbezogene Lebensqualität

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Fact-Ga Total Score Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	124 (99.2)	62	58 (93.5)
Day 15	125	117 (93.6)	62	52 (83.9)
Day 43	124	117 (94.4)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	52 (49.5)	45	11 (24.4)
Day 211	81	34 (42.0)	35	3 (8.6)
Day 253	62	24 (38.7)	26	1 (3.8)
Day 295	51	19 (37.3)	19	1 (5.3)
Day 337	45	15 (33.3)	14	1 (7.1)
Day 379	33	11 (33.3)	10	0 (0.0)
Day 421	22	11 (50.0)	3	0 (0.0)
Day 463	14	7 (50.0)	2	0 (0.0)
Day 505	11	3 (27.3)	2	0 (0.0)
Day 547	6	3 (50.0)	2	0 (0.0)
Day 589	4	1 (25.0)	2	0 (0.0)
Day 631	3	1 (33.3)	0	0 (0.0)
Day 673	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Fact-Ga Total Score by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	124	125.3 (25.36)			58	128.0 (23.42)		
Day 15	117	117.8 (24.91)	116	-7.9 (20.85)	52	127.1 (27.13)	49	-4.4 (18.92)
Day 43	117	121.0 (27.78)	116	-5.6 (22.66)	53	126.3 (30.44)	50	-4.8 (19.13)
Day 85	99	121.5 (27.79)	98	-6.4 (22.82)	36	129.7 (30.60)	34	-5.6 (17.11)
Day 127	74	126.8 (22.99)	73	-4.0 (21.97)	19	135.5 (26.91)	18	-7.3 (21.04)
Day 169	52	126.6 (25.10)	51	-2.4 (21.87)	11	140.9 (28.11)	10	-5.7 (17.03)
Day 211	34	128.0 (25.73)	33	-3.8 (25.50)	3	166.4 (20.63)	2	5.3 (12.49)
Day 253	24	127.0 (26.40)	24	-1.2 (25.90)	1	175.0 (-)	1	16.2 (-)
Day 295	19	126.5 (25.33)	19	-2.8 (28.19)	1	176.0 (-)	1	17.2 (-)
Day 337	15	123.2 (26.81)	15	-8.2 (31.98)	1	176.0 (-)	1	17.2 (-)
Day 379	11	125.0 (29.28)	11	-11.7 (32.62)	0	-	0	-
Day 421	11	121.5 (30.74)	11	-12.2 (28.39)	0	-	0	-
Day 463	7	135.0 (22.47)	7	0.4 (25.67)	0	-	0	-
Day 505	3	130.1 (33.03)	3	-10.6 (19.96)	0	-	0	-
Day 547	3	125.2 (31.21)	3	-15.4 (14.82)	0	-	0	-
Day 589	1	93.8 (-)	1	-37.2 (-)	0	-	0	-
Day 631	1	89.0 (-)	1	-42.0 (-)	0	-	0	-
Day 673	1	96.5 (-)	1	-34.5 (-)	0	-	0	-
End of Treatment	82	109.9 (31.74)	81	-16.9 (26.31)	53	113.2 (32.10)	49	-16.5 (21.22)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Visit	DS-8201a (N=125) N [a]	N_MISS [b]	LSMean (95% CI)	Phys. Choice (N=62) N [a]	N_MISS [b]	LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
Day 15			-9.72 (-13.81, -5.64)			-6.74 (-12.75, -0.73)	-2.98 (-9.60, 3.63)	0.3755		
Day 43			-9.83 (-13.67, -5.99)			-7.83 (-13.28, -2.38)	-2.00 (-7.96, 3.96)	0.5096		
Day 85			-9.99 (-13.60, -6.37)			-9.47 (-15.03, -3.90)	-0.52 (-6.46, 5.42)	0.8631		
Day 127			-10.15 (-13.75, -6.55)			-11.10 (-17.83, -4.38)	0.96 (-6.08, 8.00)	0.7893		
Day 169			-10.31 (-14.10, -6.51)			-12.74 (-21.26, -4.22)	2.43 (-6.42, 11.29)	0.5893		
Day 211			-10.46 (-14.62, -6.30)			-14.38 (-25.01, -3.74)	3.91 (-7.13, 14.95)	0.4867		
Day 253			-10.62 (-15.29, -5.96)			-16.01 (-28.92, -3.10)	5.39 (-8.03, 18.80)	0.4304		
Day 295			-10.78 (-16.05, -5.51)			-17.65 (-32.92, -2.37)	6.87 (-9.03, 22.76)	0.3965		
Day 337			-10.94 (-16.88, -5.00)			-19.29 (-36.98, -1.59)	8.34 (-10.09, 26.78)	0.3744		
OVERALL	123	2	-10.10 (-13.68, -6.51)	54	8	-10.58 (-16.85, -4.31)	0.49 (-6.11, 7.08)	0.8848	0.02 (-0.30, 0.34)	0.8883

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-Ga Total Score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0097
Japan	98	-8.31 (-11.26, -5.36)	45	-4.73 (-10.56, 1.10)	-3.58 (-10.13, 2.96)	0.2817	-0.22 (-0.57, 0.14)	0.2295	
Korea	25	-6.77 (-15.36, 1.82)	9	-28.03 (-46.94, -9.12)	21.26 (0.47, 42.04)	0.0452	0.92 (0.13, 1.71)	0.0230	
Lines of prior systemic therapy									0.5407
2	64	-5.96 (-10.07, -1.85)	34	-7.91 (-14.58, -1.24)	1.95 (-5.93, 9.83)	0.6242	0.11 (-0.31, 0.53)	0.6026	
3	34	-7.35 (-13.31, -1.39)	16	-11.43 (-23.25, 0.39)	4.08 (-9.15, 17.31)	0.5413	0.21 (-0.39, 0.80)	0.4921	
>=4	25	-14.12 (-20.28, -7.96)	4	3.33 (-21.74, 28.41)	-17.45 (-43.31, 8.41)	0.1817	-1.06 (-2.15, 0.03)	0.0559	
Age									0.5457
<65 years	54	-6.25 (-10.57, -1.93)	25	-9.55 (-19.12, 0.02)	3.30 (-7.30, 13.90)	0.5394	0.17 (-0.30, 0.65)	0.4715	
>=65 years	69	-9.73 (-13.79, -5.67)	29	-7.82 (-15.49, -0.16)	-1.91 (-10.58, 6.76)	0.6632	-0.11 (-0.54, 0.33)	0.6353	
Sex									0.8862
female	29	-4.54 (-10.59, 1.52)	12	-7.83 (-20.59, 4.92)	3.30 (-10.81, 17.41)	0.6420	0.18 (-0.49, 0.86)	0.5940	
male	94	-9.06 (-12.51, -5.61)	42	-8.74 (-15.47, -2.00)	-0.32 (-7.91, 7.26)	0.9330	-0.02 (-0.38, 0.35)	0.9255	
ECOG PS									0.1289
0	61	-9.28 (-12.88, -5.68)	27	-6.40 (-14.21, 1.41)	-2.88 (-11.51, 5.74)	0.5098	-0.18 (-0.63, 0.28)	0.4458	
1	62	-6.34 (-11.08, -1.60)	27	-10.38 (-18.99, -1.76)	4.04 (-5.80, 13.88)	0.4179	0.20 (-0.25, 0.65)	0.3821	
HER2 Status in central laboratory									0.1630
IHC 3+	95	-7.20 (-10.67, -3.73)	41	-9.23 (-16.51, -1.96)	2.03 (-6.05, 10.12)	0.6205	0.11 (-0.26, 0.47)	0.5727	
IHC 2+/ISH +	28	-11.13 (-16.97, -5.28)	13	-4.50 (-13.94, 4.94)	-6.63 (-17.70, 4.45)	0.2346	-0.42 (-1.08, 0.24)	0.2160	
Primary tumor location									0.7418
Gastric	106	-8.47 (-11.70, -5.25)	49	-8.39 (-14.49, -2.29)	-0.09 (-7.01, 6.84)	0.9804	-0.00 (-0.34, 0.33)	0.9785	
GEJ	17	-5.68 (-12.93, 1.56)	5	-7.95 (-29.61, 13.71)	2.27 (-20.53, 25.07)	0.8423	0.14 (-0.86, 1.13)	0.7896	
Histological subtype									0.4172
intestinal	88	-7.78 (-10.87, -4.70)	35	-5.70 (-12.22, 0.82)	-2.08 (-9.30, 5.14)	0.5702	-0.13 (-0.52, 0.26)	0.5198	
diffuse	28	-9.05 (-17.08, -1.02)	14	-13.56 (-29.38, 2.25)	4.51 (-13.38, 22.41)	0.6164	0.19 (-0.46, 0.83)	0.5694	
others	7	-7.09 (-26.28, 12.10)	5	-7.01 (-30.78, 16.77)	-0.08 (-30.91, 30.75)	0.9954	-0.00 (-1.15, 1.14)	0.9951	
Number of metastatic sites									0.0980
<2	23	-10.80 (-17.01, -4.59)	10	2.20 (-9.33, 13.73)	-13.00 (-26.10, 0.11)	0.0519	-0.83 (-1.60, -0.06)	0.0346	
>= 2	100	-7.36 (-10.74, -3.99)	44	-13.00 (-19.91, -6.09)	5.64 (-2.07, 13.34)	0.1510	0.29 (-0.06, 0.65)	0.1055	
Previous total gastrectomy									0.0343
yes	22	-10.58 (-19.00, -2.17)	8	1.28 (-20.09, 22.64)	-11.86 (-34.86, 11.14)	0.3064	-0.53 (-1.35, 0.29)	0.2073	
no	101	-7.42 (-10.55, -4.28)	46	-9.92 (-15.93, -3.91)	2.50 (-4.29, 9.29)	0.4688	0.14 (-0.21, 0.49)	0.4237	
Prior adjuvant/ neoadjuvant therapy									0.4837
yes	30	-6.67 (-12.61, -0.73)	7	-4.06 (-22.39, 14.27)	-2.61 (-21.84, 16.62)	0.7879	-0.15 (-0.97, 0.68)	0.7264	
no	93	-8.45 (-11.85, -5.04)	47	-8.86 (-14.96, -2.75)	0.41 (-6.61, 7.44)	0.9080	0.02 (-0.33, 0.37)	0.8997	
Prior ramucirumab contained treatment									0.0402
yes	92	-10.12 (-13.06, -7.18)	36	-8.47 (-15.47, -1.48)	-1.65 (-9.24, 5.94)	0.6696	-0.10 (-0.49, 0.29)	0.6124	
no	31	-1.96 (-9.41, 5.50)	18	-7.78 (-18.98, 3.43)	5.82 (-7.76, 19.41)	0.3939	0.27 (-0.32, 0.85)	0.3691	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

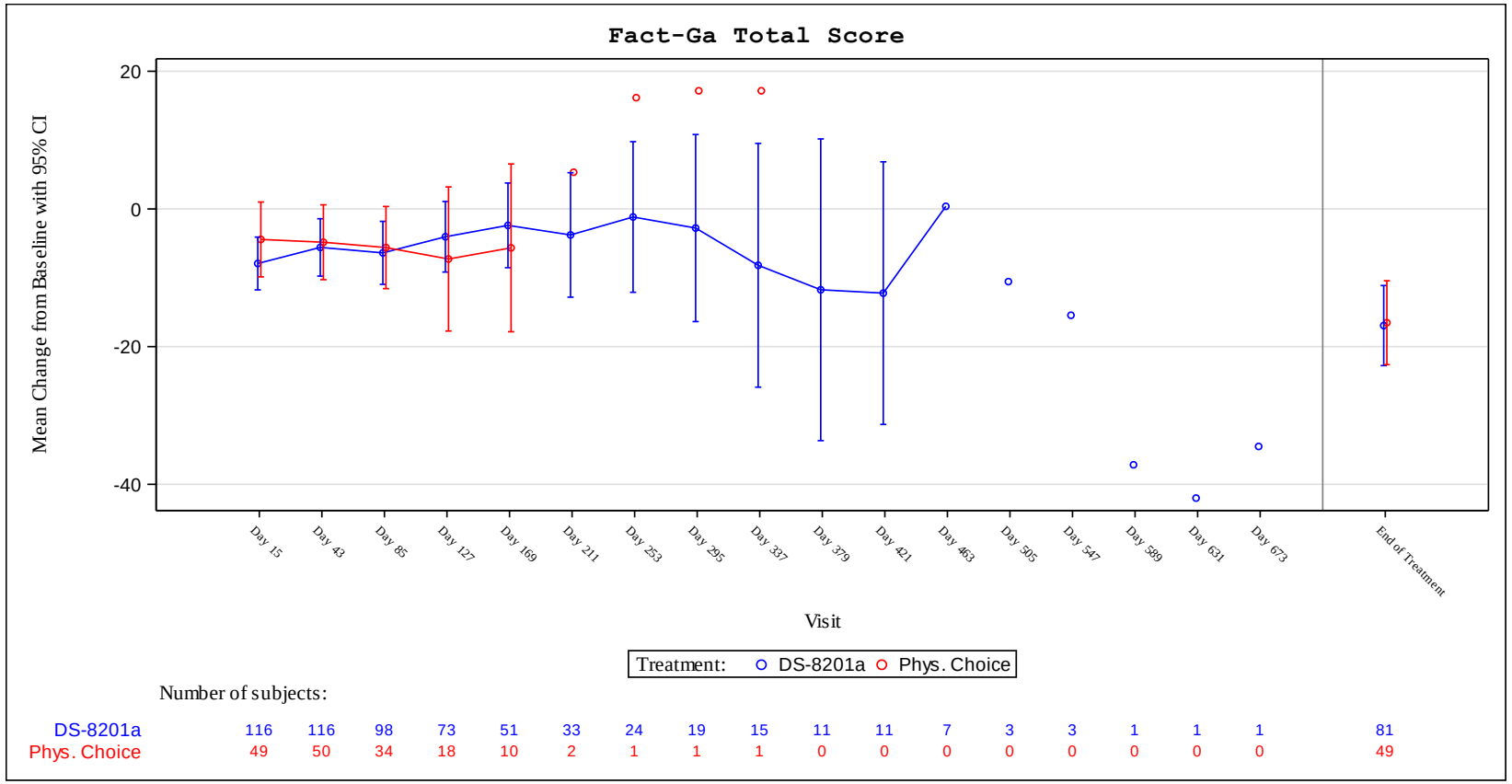
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-Ga Total Score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.2052
yes	33	-11.43 (-16.57, -6.29)	12	-8.65 (-22.64, 5.34)	-2.78 (-17.67, 12.11)	0.7113	-0.16 (-0.82, 0.50)	0.6404	
no	90	-6.66 (-10.33, -2.99)	42	-8.27 (-14.83, -1.72)	1.61 (-5.96, 9.18)	0.6751	0.09 (-0.28, 0.45)	0.6491	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.2237
yes	44	-10.46 (-15.62, -5.29)	13	-8.76 (-23.33, 5.80)	-1.69 (-17.14, 13.75)	0.8286	-0.09 (-0.71, 0.53)	0.7840	
no	79	-6.68 (-10.32, -3.04)	41	-8.38 (-14.46, -2.30)	1.70 (-5.43, 8.83)	0.6388	0.10 (-0.28, 0.47)	0.6154	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.4549
yes	22	-2.99 (-11.24, 5.25)	5	2.69 (-15.98, 21.37)	-5.69 (-26.25, 14.87)	0.5754	-0.30 (-1.27, 0.67)	0.5469	
no	101	-9.03 (-12.23, -5.82)	49	-9.70 (-16.02, -3.37)	0.67 (-6.43, 7.77)	0.8526	0.04 (-0.31, 0.38)	0.8354	
Presence of liver metastasis at baseline									0.2469
yes	67	-6.37 (-10.24, -2.50)	29	-13.00 (-21.17, -4.84)	6.64 (-2.42, 15.69)	0.1496	0.37 (-0.07, 0.81)	0.1006	
no	56	-9.80 (-14.38, -5.22)	25	-4.52 (-13.17, 4.14)	-5.28 (-15.09, 4.53)	0.2882	-0.28 (-0.76, 0.19)	0.2432	
Renal impairment at baseline									0.1690
normal	33	-7.73 (-12.69, -2.78)	12	-27.78 (-44.97, -10.60)	20.05 (2.16, 37.93)	0.0283	1.03 (0.33, 1.72)	0.0037	
mild	53	-7.96 (-13.03, -2.89)	25	-2.24 (-10.84, 6.35)	-5.72 (-15.74, 4.30)	0.2599	-0.29 (-0.77, 0.19)	0.2301	
moderate	37	-8.54 (-13.72, -3.35)	16	-10.21 (-19.76, -0.67)	1.68 (-9.18, 12.54)	0.7590	0.10 (-0.49, 0.69)	0.7387	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.5768
normal	86	-8.02 (-11.63, -4.41)	40	-10.00 (-16.77, -3.23)	1.98 (-5.70, 9.66)	0.6118	0.11 (-0.27, 0.48)	0.5774	
mild	36	-8.49 (-13.71, -3.27)	14	-2.70 (-15.06, 9.67)	-5.79 (-19.28, 7.70)	0.3956	-0.32 (-0.94, 0.30)	0.3093	
moderate	1	NE	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.3399
yes	8	-13.08 (-24.74, -1.42)	4	7.50 (-12.50, 27.49)	-20.58 (-44.71, 3.55)	0.0869	-1.32 (-2.63, -0.01)	0.0489	
no	115	-7.80 (-10.86, -4.74)	50	-11.07 (-17.39, -4.75)	3.27 (-3.75, 10.30)	0.3597	0.18 (-0.16, 0.51)	0.3009	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.4524
yes	3	-8.69 (-39.00, 21.63)	3	4.26 (-26.56, 35.08)	-12.94 (-58.51, 32.62)	0.4366	-0.78 (-2.44, 0.88)	0.3591	
no	120	-8.14 (-11.15, -5.13)	51	-11.67 (-18.22, -5.12)	3.53 (-3.68, 10.75)	0.3364	0.19 (-0.14, 0.51)	0.2688	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Graphical Summary of Fact-Ga Total Score by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	42 (33.6)	13 (21.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	11.2 (5.9, NE)	NE (5.4, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.13 (0.60, 2.13)	
p-value [c]	0.7086	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.13 (0.60, 2.13)	
p-value [c]	0.7131	

Time to Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.0276
Japan	34/ 99 (34.3)	11.2 (5.8, NE)	8/ 50 (16.0)	NE (NE , NE)	1.67 (0.77, 3.64)	0.1932	
Korea	8/ 26 (30.8)	8.4 (4.6, NE)	5/ 12 (41.7)	3.3 (0.5, NE)	0.35 (0.11, 1.14)	0.0666	
Lines of prior systemic therapy							0.5552
2	20/ 66 (30.3)	8.4 (5.9, NE)	7/ 38 (18.4)	NE (5.4, NE)	1.25 (0.52, 3.00)	0.6205	
3	11/ 34 (32.4)	11.2 (5.7, NE)	4/ 18 (22.2)	NE (2.6, NE)	1.03 (0.32, 3.34)	0.9711	
>=4	11/ 25 (44.0)	6.9 (2.0, NE)	2/ 6 (33.3)	NE (0.5, NE)	0.51 (0.11, 2.36)	0.3804	
Age							0.6278
<65 years	18/ 55 (32.7)	NE (5.7, NE)	6/ 27 (22.2)	NE (2.6, NE)	0.98 (0.38, 2.55)	0.9578	
>=65 years	24/ 70 (34.3)	8.4 (5.8, NE)	7/ 35 (20.0)	NE (3.3, NE)	1.30 (0.56, 3.02)	0.5526	
Sex							0.7799
female	9/ 30 (30.0)	8.3 (4.4, NE)	2/ 15 (13.3)	NE (1.6, NE)	1.05 (0.21, 5.21)	0.9473	
male	33/ 95 (34.7)	11.2 (5.9, NE)	11/ 47 (23.4)	NE (5.4, NE)	1.14 (0.57, 2.28)	0.7132	
ECOG PS							0.9111
0	23/ 62 (37.1)	8.3 (5.8, NE)	7/ 30 (23.3)	NE (5.4, NE)	1.02 (0.43, 2.42)	0.9729	
1	19/ 63 (30.2)	11.2 (5.8, NE)	6/ 32 (18.8)	NE (3.3, NE)	1.24 (0.49, 3.15)	0.6493	
HER2 Status in central laboratory							0.9871
IHC 3+	30/ 96 (31.3)	NE (6.9, NE)	13/ 47 (27.7)	NE (3.3, NE)	0.76 (0.39, 1.47)	0.4035	
IHC 2+/ISH +	12/ 29 (41.4)	5.9 (2.8, 11.2)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9884
Gastric	36/108 (33.3)	8.4 (5.8, NE)	13/ 55 (23.6)	NE (5.4, NE)	1.02 (0.54, 1.95)	0.9482	
GEJ	6/ 17 (35.3)	NE (2.8, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.6106
intestinal	28/ 89 (31.5)	8.4 (5.9, NE)	6/ 38 (15.8)	NE (5.4, NE)	1.42 (0.58, 3.48)	0.4416	
diffuse	11/ 28 (39.3)	NE (1.5, NE)	5/ 18 (27.8)	3.3 (0.6, NE)	0.95 (0.33, 2.80)	0.9318	
others	3/ 8 (37.5)	4.6 (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.36 (0.22, 8.23)	0.7372	
Number of metastatic sites							0.9885
<2	6/ 24 (25.0)	NE (8.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	36/101 (35.6)	8.3 (5.8, NE)	13/ 52 (25.0)	NE (3.3, NE)	0.94 (0.49, 1.81)	0.8538	
Previous total gastrectomy							0.5633
yes	6/ 22 (27.3)	NE (1.5, NE)	1/ 9 (11.1)	NE (3.3, NE)	2.46 (0.30, 20.41)	0.3913	
no	36/103 (35.0)	8.4 (5.8, NE)	12/ 53 (22.6)	NE (5.4, NE)	1.02 (0.53, 1.99)	0.9465	
Prior adjuvant/ neoadjuvant therapy							0.9860
yes	9/ 30 (30.0)	6.9 (5.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	33/ 95 (34.7)	11.2 (5.8, NE)	13/ 52 (25.0)	NE (3.3, NE)	1.03 (0.54, 1.99)	0.9289	
Prior ramucirumab contained treatment							0.5061
yes	33/ 94 (35.1)	11.2 (5.8, NE)	8/ 41 (19.5)	NE (5.4, NE)	1.31 (0.60, 2.87)	0.5052	
no	9/ 31 (29.0)	NE (5.7, NE)	5/ 21 (23.8)	NE (2.6, NE)	0.79 (0.26, 2.43)	0.6775	
Prior nivolumab contained treatment							0.8385
yes	14/ 33 (42.4)	11.2 (3.0, NE)	4/ 15 (26.7)	NE (2.6, NE)	1.07 (0.34, 3.32)	0.9080	
no	28/ 92 (30.4)	8.4 (5.8, NE)	9/ 47 (19.1)	NE (5.4, NE)	1.16 (0.54, 2.49)	0.7121	

Time to Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

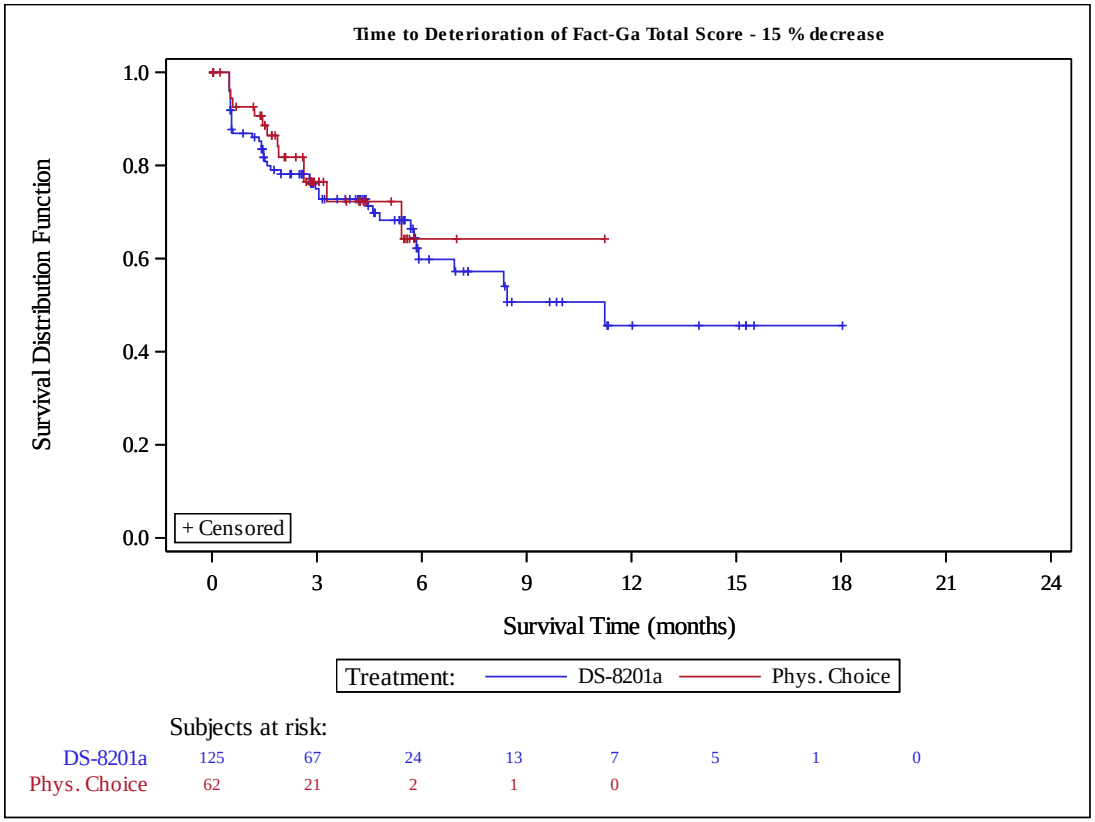
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7071
yes	16/ 44 (36.4)	11.2 (5.8, NE)	4/ 17 (23.5)	NE (2.6, NE)	1.04 (0.34, 3.16)	0.9524	
no	26/ 81 (32.1)	8.3 (5.7, NE)	9/ 45 (20.0)	NE (5.4, NE)	1.17 (0.54, 2.54)	0.6922	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9878
yes	7/ 22 (31.8)	NE (2.8, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	35/103 (34.0)	11.2 (5.9, NE)	13/ 55 (23.6)	NE (5.4, NE)	0.99 (0.52, 1.89)	0.9632	
Presence of liver metastasis at baseline							0.2206
yes	18/ 67 (26.9)	NE (8.3, NE)	8/ 34 (23.5)	NE (3.3, NE)	0.82 (0.35, 1.92)	0.6477	
no	24/ 58 (41.4)	6.9 (4.8, NE)	5/ 28 (17.9)	NE (NE , NE)	1.63 (0.61, 4.35)	0.3224	
Renal impairment at baseline							0.1793
normal	9/ 33 (27.3)	NE (8.3, NE)	4/ 13 (30.8)	NE (0.5, NE)	0.57 (0.17, 1.97)	0.3719	
mild	21/ 53 (39.6)	6.9 (5.7, NE)	4/ 28 (14.3)	NE (NE , NE)	2.20 (0.75, 6.44)	0.1411	
moderate	12/ 39 (30.8)	8.4 (4.8, NE)	5/ 20 (25.0)	5.4 (2.6, NE)	0.80 (0.27, 2.38)	0.6829	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7203
normal	34/ 88 (38.6)	8.4 (5.8, NE)	10/ 47 (21.3)	NE (5.4, NE)	1.17 (0.57, 2.41)	0.6732	
mild	8/ 36 (22.2)	NE (5.8, NE)	3/ 15 (20.0)	NE (1.6, NE)	1.00 (0.26, 3.81)	0.9913	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4413
yes	5/ 8 (62.5)	5.7 (0.5, NE)	1/ 5 (20.0)	NE (0.5, NE)	2.05 (0.24, 17.72)	0.5137	
no	37/117 (31.6)	11.2 (5.9, NE)	12/ 57 (21.1)	NE (5.4, NE)	1.05 (0.54, 2.05)	0.8935	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9877
yes	2/ 3 (66.7)	8.4 (5.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	40/122 (32.8)	11.2 (5.9, NE)	13/ 58 (22.4)	NE (5.4, NE)	1.03 (0.54, 1.96)	0.9292	

Time to Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

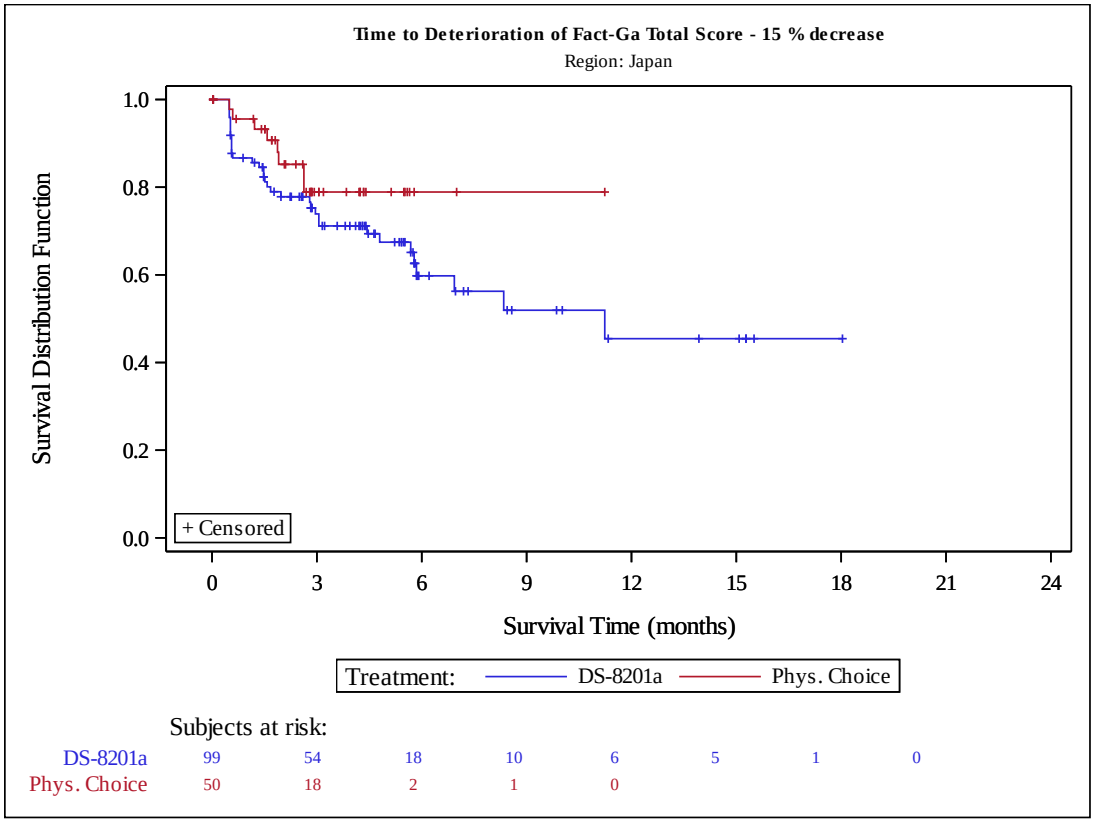
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

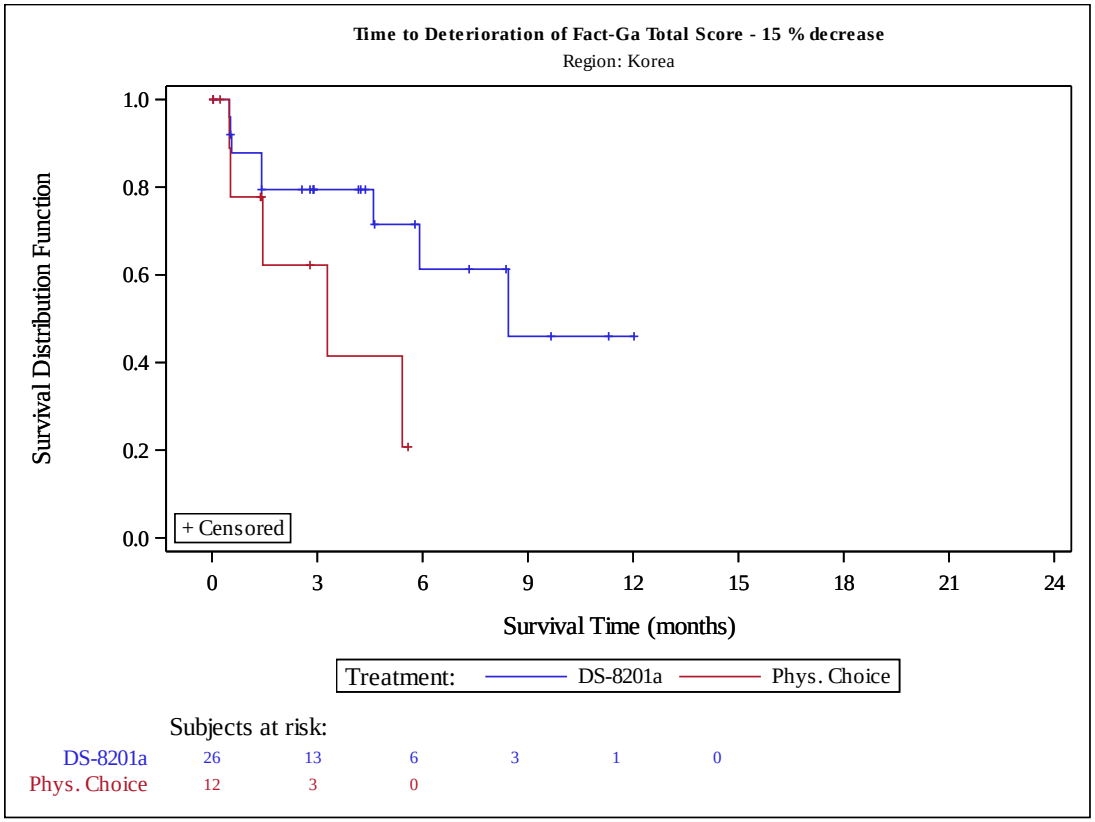
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	31 (24.8)	12 (19.4)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	14.1 (8.4, NE)	NE (5.4, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.76 (0.38, 1.51)	
p-value [c]	0.4261	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.78 (0.39, 1.55)	
p-value [c]	0.4760	

Time to Definitive Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.0801
Japan	23/ 99 (23.2)	NE (8.3, NE)	7/ 50 (14.0)	NE (NE , NE)	1.14 (0.48, 2.70)	0.7621	
Korea	8/ 26 (30.8)	14.1 (4.6, 14.1)	5/ 12 (41.7)	3.3 (0.5, NE)	0.27 (0.08, 0.95)	0.0275	
Lines of prior systemic therapy							0.9133
2	15/ 66 (22.7)	NE (8.3, NE)	7/ 38 (18.4)	NE (5.4, NE)	0.83 (0.33, 2.08)	0.6920	
3	8/ 34 (23.5)	14.1 (11.2, NE)	4/ 18 (22.2)	NE (2.6, NE)	0.55 (0.15, 1.99)	0.3587	
>=4	8/ 25 (32.0)	NE (4.4, NE)	1/ 6 (16.7)	NE (0.5, NE)	0.87 (0.11, 7.12)	0.9106	
Age							0.9468
<65 years	14/ 55 (25.5)	NE (8.3, NE)	5/ 27 (18.5)	NE (NE , NE)	0.81 (0.28, 2.35)	0.6950	
>=65 years	17/ 70 (24.3)	11.2 (7.2, NE)	7/ 35 (20.0)	NE (3.3, NE)	0.79 (0.32, 1.93)	0.6024	
Sex							0.7365
female	7/ 30 (23.3)	8.3 (4.4, NE)	2/ 15 (13.3)	NE (1.6, NE)	0.85 (0.17, 4.38)	0.8512	
male	24/ 95 (25.3)	14.1 (8.4, NE)	10/ 47 (21.3)	NE (5.4, NE)	0.76 (0.36, 1.62)	0.4768	
ECOG PS							0.8681
0	17/ 62 (27.4)	NE (7.2, NE)	6/ 30 (20.0)	NE (5.4, NE)	0.79 (0.30, 2.04)	0.6204	
1	14/ 63 (22.2)	14.1 (11.2, NE)	6/ 32 (18.8)	NE (3.3, NE)	0.78 (0.29, 2.08)	0.6110	
HER2 Status in central laboratory							0.9891
IHC 3+	23/ 96 (24.0)	NE (8.4, NE)	12/ 47 (25.5)	NE (3.3, NE)	0.54 (0.26, 1.12)	0.0937	
IHC 2+/ISH +	8/ 29 (27.6)	11.2 (5.7, 11.2)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9900
Gastric	26/108 (24.1)	14.1 (8.3, NE)	12/ 55 (21.8)	NE (5.4, NE)	0.69 (0.34, 1.39)	0.2952	
GEJ	5/ 17 (29.4)	NE (3.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.8551
intestinal	20/ 89 (22.5)	NE (8.3, NE)	6/ 38 (15.8)	NE (5.4, NE)	0.88 (0.35, 2.24)	0.7895	
diffuse	8/ 28 (28.6)	14.1 (5.7, 14.1)	4/ 18 (22.2)	NE (2.6, NE)	0.73 (0.21, 2.53)	0.6054	
others	3/ 8 (37.5)	4.6 (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.36 (0.22, 8.23)	0.7372	
Number of metastatic sites							0.9900
<2	5/ 24 (20.8)	NE (8.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	26/101 (25.7)	14.1 (8.3, NE)	12/ 52 (23.1)	NE (3.3, NE)	0.62 (0.31, 1.27)	0.1916	
Previous total gastrectomy							0.5182
yes	5/ 22 (22.7)	NE (7.2, NE)	1/ 9 (11.1)	NE (3.3, NE)	1.51 (0.17, 13.51)	0.7157	
no	26/103 (25.2)	14.1 (8.4, NE)	11/ 53 (20.8)	NE (5.4, NE)	0.71 (0.35, 1.48)	0.3625	
Prior adjuvant/ neoadjuvant therapy							0.9880
yes	7/ 30 (23.3)	NE (5.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	24/ 95 (25.3)	14.1 (8.4, NE)	12/ 52 (23.1)	NE (5.4, NE)	0.71 (0.35, 1.45)	0.3436	
Prior ramucirumab contained treatment							0.3805
yes	25/ 94 (26.6)	14.1 (11.2, NE)	7/ 41 (17.1)	NE (5.4, NE)	0.99 (0.42, 2.34)	0.9774	
no	6/ 31 (19.4)	NE (5.7, NE)	5/ 21 (23.8)	NE (2.6, NE)	0.45 (0.13, 1.56)	0.1946	
Prior nivolumab contained treatment							0.2779
yes	8/ 33 (24.2)	NE (11.2, NE)	4/ 15 (26.7)	NE (2.6, NE)	0.50 (0.14, 1.74)	0.2726	
no	23/ 92 (25.0)	14.1 (7.2, NE)	8/ 47 (17.0)	NE (5.4, NE)	0.94 (0.41, 2.15)	0.8783	

Time to Definitive Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

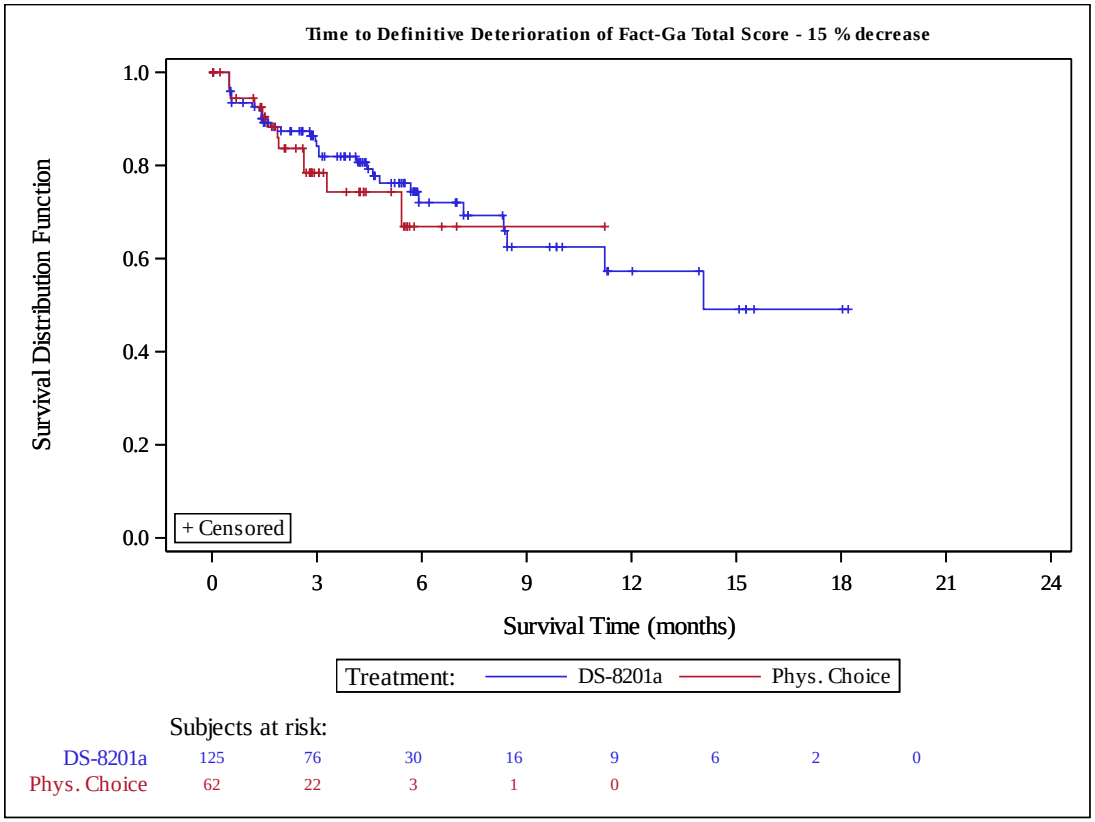
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.2922
yes	10/ 44 (22.7)	NE (11.2, NE)	4/ 17 (23.5)	NE (2.6, NE)	0.58 (0.18, 1.91)	0.3685	
no	21/ 81 (25.9)	8.4 (7.2, NE)	8/ 45 (17.8)	NE (5.4, NE)	0.92 (0.40, 2.12)	0.8359	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9896
yes	5/ 22 (22.7)	14.1 (5.7, 14.1)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	26/103 (25.2)	NE (8.4, NE)	12/ 55 (21.8)	NE (5.4, NE)	0.73 (0.36, 1.47)	0.3712	
Presence of liver metastasis at baseline							0.1006
yes	13/ 67 (19.4)	NE (14.1, NE)	8/ 34 (23.5)	NE (3.3, NE)	0.51 (0.20, 1.26)	0.1347	
no	18/ 58 (31.0)	11.2 (5.9, NE)	4/ 28 (14.3)	NE (NE , NE)	1.39 (0.46, 4.18)	0.5564	
Renal impairment at baseline							0.1821
normal	7/ 33 (21.2)	NE (7.2, NE)	4/ 13 (30.8)	NE (0.5, NE)	0.20 (0.04, 0.92)	0.0226	
mild	15/ 53 (28.3)	11.2 (11.2, NE)	4/ 28 (14.3)	NE (NE , NE)	1.47 (0.48, 4.45)	0.4932	
moderate	9/ 39 (23.1)	NE (5.9, NE)	4/ 20 (20.0)	NE (3.3, NE)	0.73 (0.22, 2.46)	0.6014	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.6202
normal	25/ 88 (28.4)	NE (8.3, NE)	9/ 47 (19.1)	NE (5.4, NE)	0.87 (0.40, 1.90)	0.7198	
mild	6/ 36 (16.7)	14.1 (7.2, NE)	3/ 15 (20.0)	NE (1.6, NE)	0.52 (0.12, 2.31)	0.3755	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4813
yes	4/ 8 (50.0)	8.4 (3.1, NE)	1/ 5 (20.0)	NE (0.5, NE)	1.34 (0.15, 12.22)	0.7942	
no	27/117 (23.1)	NE (11.2, NE)	11/ 57 (19.3)	NE (5.4, NE)	0.76 (0.37, 1.57)	0.4613	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9889
yes	2/ 3 (66.7)	8.4 (5.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	29/122 (23.8)	NE (11.2, NE)	12/ 58 (20.7)	NE (5.4, NE)	0.70 (0.35, 1.40)	0.3066	

Time to Definitive Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	117	6 (5.1)	95 (81.2)	16 (13.7)	52	2 (3.8)	46 (88.5)	4 (7.7)
	Day 43	117	7 (6.0)	94 (80.3)	16 (13.7)	53	2 (3.8)	46 (86.8)	5 (9.4)
	Day 85	99	4 (4.0)	81 (81.8)	14 (14.1)	36	0 (0.0)	32 (88.9)	4 (11.1)
	Day 127	74	7 (9.5)	58 (78.4)	9 (12.2)	19	1 (5.3)	17 (89.5)	1 (5.3)
	Day 169	52	5 (9.6)	40 (76.9)	7 (13.5)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	34	4 (11.8)	25 (73.5)	5 (14.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	24	3 (12.5)	17 (70.8)	4 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	19	3 (15.8)	12 (63.2)	4 (21.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	2 (13.3)	9 (60.0)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	2 (2.4)	59 (72.0)	21 (25.6)	53	0 (0.0)	41 (77.4)	12 (22.6)
Region									
Japan									
	Day 15	95	3 (3.2)	79 (83.2)	13 (13.7)	45	2 (4.4)	41 (91.1)	2 (4.4)
	Day 43	93	6 (6.5)	75 (80.6)	12 (12.9)	43	1 (2.3)	40 (93.0)	2 (4.7)
	Day 85	77	2 (2.6)	64 (83.1)	11 (14.3)	32	0 (0.0)	29 (90.6)	3 (9.4)
	Day 127	60	5 (8.3)	48 (80.0)	7 (11.7)	16	1 (6.3)	15 (93.8)	0 (0.0)
	Day 169	45	3 (6.7)	35 (77.8)	7 (15.6)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 211	28	2 (7.1)	21 (75.0)	5 (17.9)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	1 (5.6)	14 (77.8)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	1 (7.1)	10 (71.4)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	64	1 (1.6)	49 (76.6)	14 (21.9)	45	0 (0.0)	38 (84.4)	7 (15.6)
Region									
Korea									
	Day 15	22	3 (13.6)	16 (72.7)	3 (13.6)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 43	24	1 (4.2)	19 (79.2)	4 (16.7)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 85	22	2 (9.1)	17 (77.3)	3 (13.6)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 127	14	2 (14.3)	10 (71.4)	2 (14.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	7	2 (28.6)	5 (71.4)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	2 (33.3)	3 (50.0)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	10 (55.6)	7 (38.9)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy									
2									
	Day 15	60	4 (6.7)	50 (83.3)	6 (10.0)	34	0 (0.0)	32 (94.1)	2 (5.9)
	Day 43	62	3 (4.8)	50 (80.6)	9 (14.5)	36	1 (2.8)	31 (86.1)	4 (11.1)
	Day 85	50	2 (4.0)	42 (84.0)	6 (12.0)	21	0 (0.0)	19 (90.5)	2 (9.5)
	Day 127	33	3 (9.1)	28 (84.8)	2 (6.1)	14	0 (0.0)	13 (92.9)	1 (7.1)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 169	21	2 (9.5)	18 (85.7)	1 (4.8)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	14	2 (14.3)	12 (85.7)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	10	2 (20.0)	6 (60.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	2 (28.6)	4 (57.1)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	2 (40.0)	3 (60.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	2 (4.5)	32 (72.7)	10 (22.7)	32	0 (0.0)	25 (78.1)	7 (21.9)
Lines of prior systemic therapy 3									
	Day 15	33	1 (3.0)	26 (78.8)	6 (18.2)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 43	33	2 (6.1)	28 (84.8)	3 (9.1)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 85	28	2 (7.1)	23 (82.1)	3 (10.7)	12	0 (0.0)	10 (83.3)	2 (16.7)
	Day 127	23	2 (8.7)	17 (73.9)	4 (17.4)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	17	2 (11.8)	10 (58.8)	5 (29.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	9	1 (11.1)	8 (88.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	0 (0.0)	15 (71.4)	6 (28.6)	16	0 (0.0)	12 (75.0)	4 (25.0)
Lines of prior systemic therapy >=4									
	Day 15	24	1 (4.2)	19 (79.2)	4 (16.7)	4	1 (25.0)	1 (25.0)	2 (50.0)
	Day 43	22	2 (9.1)	16 (72.7)	4 (18.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	0 (0.0)	16 (76.2)	5 (23.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	2 (11.1)	13 (72.2)	3 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	14	1 (7.1)	12 (85.7)	1 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	0 (0.0)	12 (70.6)	5 (29.4)	5	0 (0.0)	4 (80.0)	1 (20.0)
Age <65 years									
	Day 15	51	3 (5.9)	42 (82.4)	6 (11.8)	22	0 (0.0)	20 (90.9)	2 (9.1)
	Day 43	52	4 (7.7)	41 (78.8)	7 (13.5)	24	1 (4.2)	21 (87.5)	2 (8.3)
	Day 85	47	1 (2.1)	38 (80.9)	8 (17.0)	16	0 (0.0)	14 (87.5)	2 (12.5)
	Day 127	34	4 (11.8)	26 (76.5)	4 (11.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	25	1 (4.0)	20 (80.0)	4 (16.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	16	2 (12.5)	11 (68.8)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	12	2 (16.7)	9 (75.0)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	11	2 (18.2)	8 (72.7)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	2 (5.3)	27 (71.1)	9 (23.7)	22	0 (0.0)	17 (77.3)	5 (22.7)
Age									
>=65 years									
	Day 15	66	3 (4.5)	53 (80.3)	10 (15.2)	30	2 (6.7)	26 (86.7)	2 (6.7)
	Day 43	65	3 (4.6)	53 (81.5)	9 (13.8)	29	1 (3.4)	25 (86.2)	3 (10.3)
	Day 85	52	3 (5.8)	43 (82.7)	6 (11.5)	20	0 (0.0)	18 (90.0)	2 (10.0)
	Day 127	40	3 (7.5)	32 (80.0)	5 (12.5)	11	1 (9.1)	10 (90.9)	0 (0.0)
	Day 169	27	4 (14.8)	20 (74.1)	3 (11.1)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	18	2 (11.1)	14 (77.8)	2 (11.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	8 (66.7)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	7	0 (0.0)	3 (42.9)	4 (57.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	0 (0.0)	32 (72.7)	12 (27.3)	31	0 (0.0)	24 (77.4)	7 (22.6)
Sex									
female									
	Day 15	27	1 (3.7)	23 (85.2)	3 (11.1)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 43	28	3 (10.7)	23 (82.1)	2 (7.1)	13	0 (0.0)	11 (84.6)	2 (15.4)
	Day 85	20	1 (5.0)	17 (85.0)	2 (10.0)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 127	13	3 (23.1)	9 (69.2)	1 (7.7)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	9	1 (11.1)	7 (77.8)	1 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	6	0 (0.0)	6 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	0 (0.0)	16 (76.2)	5 (23.8)	14	0 (0.0)	12 (85.7)	2 (14.3)
Sex									
male									
	Day 15	90	5 (5.6)	72 (80.0)	13 (14.4)	39	1 (2.6)	35 (89.7)	3 (7.7)
	Day 43	89	4 (4.5)	71 (79.8)	14 (15.7)	40	2 (5.0)	35 (87.5)	3 (7.5)
	Day 85	79	3 (3.8)	64 (81.0)	12 (15.2)	28	0 (0.0)	24 (85.7)	4 (14.3)
	Day 127	61	4 (6.6)	49 (80.3)	8 (13.1)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 169	43	4 (9.3)	33 (76.7)	6 (14.0)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	28	4 (14.3)	19 (67.9)	5 (17.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	2 (10.0)	15 (75.0)	3 (15.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	3 (17.6)	11 (64.7)	3 (17.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	8 (57.1)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	6 (60.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	61	2 (3.3)	43 (70.5)	16 (26.2)	39	0 (0.0)	29 (74.4)	10 (25.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS									
0									
	Day 15	59	0 (0.0)	53 (89.8)	6 (10.2)	26	0 (0.0)	24 (92.3)	2 (7.7)
	Day 43	59	3 (5.1)	50 (84.7)	6 (10.2)	26	1 (3.8)	24 (92.3)	1 (3.8)
	Day 85	54	1 (1.9)	45 (83.3)	8 (14.8)	19	0 (0.0)	18 (94.7)	1 (5.3)
	Day 127	42	4 (9.5)	36 (85.7)	2 (4.8)	9	1 (11.1)	8 (88.9)	0 (0.0)
	Day 169	33	2 (6.1)	27 (81.8)	4 (12.1)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	20	1 (5.0)	16 (80.0)	3 (15.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	1 (6.7)	10 (66.7)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	0 (0.0)	8 (72.7)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	9	0 (0.0)	7 (77.8)	2 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	0 (0.0)	29 (76.3)	9 (23.7)	27	0 (0.0)	21 (77.8)	6 (22.2)
ECOG PS									
1									
	Day 15	58	6 (10.3)	42 (72.4)	10 (17.2)	26	2 (7.7)	22 (84.6)	2 (7.7)
	Day 43	58	4 (6.9)	44 (75.9)	10 (17.2)	27	1 (3.7)	22 (81.5)	4 (14.8)
	Day 85	45	3 (6.7)	36 (80.0)	6 (13.3)	17	0 (0.0)	14 (82.4)	3 (17.6)
	Day 127	32	3 (9.4)	22 (68.8)	7 (21.9)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 169	19	3 (15.8)	13 (68.4)	3 (15.8)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	14	3 (21.4)	9 (64.3)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	2 (22.2)	7 (77.8)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	3 (37.5)	4 (50.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	2 (33.3)	2 (33.3)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	2 (4.5)	30 (68.2)	12 (27.3)	26	0 (0.0)	20 (76.9)	6 (23.1)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	91	6 (6.6)	72 (79.1)	13 (14.3)	38	1 (2.6)	33 (86.8)	4 (10.5)
	Day 43	91	6 (6.6)	74 (81.3)	11 (12.1)	40	1 (2.5)	34 (85.0)	5 (12.5)
	Day 85	79	3 (3.8)	67 (84.8)	9 (11.4)	26	0 (0.0)	22 (84.6)	4 (15.4)
	Day 127	59	6 (10.2)	45 (76.3)	8 (13.6)	13	0 (0.0)	12 (92.3)	1 (7.7)
	Day 169	41	4 (9.8)	31 (75.6)	6 (14.6)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	29	4 (13.8)	21 (72.4)	4 (13.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	3 (14.3)	14 (66.7)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	3 (17.6)	10 (58.8)	4 (23.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	9 (64.3)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	61	2 (3.3)	44 (72.1)	15 (24.6)	39	0 (0.0)	27 (69.2)	12 (30.8)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	26	0 (0.0)	23 (88.5)	3 (11.5)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 43	26	1 (3.8)	20 (76.9)	5 (19.2)	13	1 (7.7)	12 (92.3)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	20	1 (5.0)	14 (70.0)	5 (25.0)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 127	15	1 (6.7)	13 (86.7)	1 (6.7)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 169	11	1 (9.1)	9 (81.8)	1 (9.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	0 (0.0)	15 (71.4)	6 (28.6)	14	0 (0.0)	14 (100.0)	0 (0.0)
Primary tumor location									
Gastric									
	Day 15	101	6 (5.9)	81 (80.2)	14 (13.9)	46	2 (4.3)	40 (87.0)	4 (8.7)
	Day 43	100	6 (6.0)	80 (80.0)	14 (14.0)	48	2 (4.2)	41 (85.4)	5 (10.4)
	Day 85	84	3 (3.6)	71 (84.5)	10 (11.9)	33	0 (0.0)	29 (87.9)	4 (12.1)
	Day 127	63	6 (9.5)	49 (77.8)	8 (12.7)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	42	4 (9.5)	32 (76.2)	6 (14.3)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	29	3 (10.3)	21 (72.4)	5 (17.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	3 (15.0)	13 (65.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	2 (13.3)	9 (60.0)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	1 (8.3)	7 (58.3)	4 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	4 (50.0)	4 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	70	1 (1.4)	51 (72.9)	18 (25.7)	47	0 (0.0)	35 (74.5)	12 (25.5)
Primary tumor location									
GEJ									
	Day 15	16	0 (0.0)	14 (87.5)	2 (12.5)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	17	1 (5.9)	14 (82.4)	2 (11.8)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 85	15	1 (6.7)	10 (66.7)	4 (26.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	9 (81.8)	1 (9.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	8 (66.7)	3 (25.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	85	4 (4.7)	72 (84.7)	9 (10.6)	35	2 (5.7)	32 (91.4)	1 (2.9)
	Day 43	85	6 (7.1)	72 (84.7)	7 (8.2)	34	0 (0.0)	32 (94.1)	2 (5.9)
	Day 85	73	2 (2.7)	62 (84.9)	9 (12.3)	27	0 (0.0)	25 (92.6)	2 (7.4)
	Day 127	55	5 (9.1)	45 (81.8)	5 (9.1)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 169	40	3 (7.5)	31 (77.5)	6 (15.0)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	25	2 (8.0)	19 (76.0)	4 (16.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	16	1 (6.3)	11 (68.8)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	1 (7.7)	9 (69.2)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	1 (10.0)	6 (60.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	1 (1.6)	47 (75.8)	14 (22.6)	34	0 (0.0)	28 (82.4)	6 (17.6)
Histological subtype diffuse									
	Day 15	26	1 (3.8)	19 (73.1)	6 (23.1)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 43	26	1 (3.8)	18 (69.2)	7 (26.9)	14	0 (0.0)	12 (85.7)	2 (14.3)
	Day 85	22	2 (9.1)	15 (68.2)	5 (22.7)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 127	15	2 (13.3)	9 (60.0)	4 (26.7)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	10	2 (20.0)	7 (70.0)	1 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	2 (25.0)	5 (62.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	7	2 (28.6)	5 (71.4)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	16	1 (6.3)	11 (68.8)	4 (25.0)	16	0 (0.0)	12 (75.0)	4 (25.0)
Histological subtype others									
	Day 15	6	1 (16.7)	4 (66.7)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	0 (0.0)	4 (66.7)	2 (33.3)	5	2 (40.0)	2 (40.0)	1 (20.0)
	Day 85	4	0 (0.0)	4 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	4	0 (0.0)	4 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	1 (25.0)	3 (75.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	23	0 (0.0)	21 (91.3)	2 (8.7)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 43	22	0 (0.0)	21 (95.5)	1 (4.5)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 85	22	0 (0.0)	19 (86.4)	3 (13.6)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 127	18	0 (0.0)	17 (94.4)	1 (5.6)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	15	1 (6.7)	12 (80.0)	2 (13.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	8 (80.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	1 (16.7)	3 (50.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	1 (7.1)	10 (71.4)	3 (21.4)	8	0 (0.0)	8 (100.0)	0 (0.0)
Number of metastatic sites >= 2									
	Day 15	94	6 (6.4)	74 (78.7)	14 (14.9)	42	2 (4.8)	36 (85.7)	4 (9.5)
	Day 43	95	7 (7.4)	73 (76.8)	15 (15.8)	43	1 (2.3)	37 (86.0)	5 (11.6)
	Day 85	77	4 (5.2)	62 (80.5)	11 (14.3)	28	0 (0.0)	24 (85.7)	4 (14.3)
	Day 127	56	7 (12.5)	41 (73.2)	8 (14.3)	15	1 (6.7)	13 (86.7)	1 (6.7)
	Day 169	37	4 (10.8)	28 (75.7)	5 (13.5)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	24	3 (12.5)	17 (70.8)	4 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	14 (77.8)	2 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	15	2 (13.3)	10 (66.7)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	68	1 (1.5)	49 (72.1)	18 (26.5)	45	0 (0.0)	33 (73.3)	12 (26.7)
Previous total gastrectomy									
yes									
	Day 15	20	2 (10.0)	14 (70.0)	4 (20.0)	7	1 (14.3)	6 (85.7)	0 (0.0)
	Day 43	20	1 (5.0)	15 (75.0)	4 (20.0)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 85	18	0 (0.0)	15 (83.3)	3 (16.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 127	11	0 (0.0)	9 (81.8)	2 (18.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	8	0 (0.0)	7 (87.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	0 (0.0)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	0 (0.0)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	13 (76.5)	3 (17.6)	9	0 (0.0)	8 (88.9)	1 (11.1)
Previous total gastrectomy									
no									
	Day 15	97	4 (4.1)	81 (83.5)	12 (12.4)	45	1 (2.2)	40 (88.9)	4 (8.9)
	Day 43	97	6 (6.2)	79 (81.4)	12 (12.4)	45	2 (4.4)	38 (84.4)	5 (11.1)
	Day 85	81	4 (4.9)	66 (81.5)	11 (13.6)	30	0 (0.0)	26 (86.7)	4 (13.3)
	Day 127	63	7 (11.1)	49 (77.8)	7 (11.1)	17	1 (5.9)	15 (88.2)	1 (5.9)
	Day 169	44	5 (11.4)	33 (75.0)	6 (13.6)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 211	27	3 (11.1)	21 (77.8)	3 (11.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	2 (9.5)	16 (76.2)	3 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	2 (12.5)	12 (75.0)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	1 (8.3)	9 (75.0)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	65	1 (1.5)	46 (70.8)	18 (27.7)	44	0 (0.0)	33 (75.0)	11 (25.0)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	2 (6.9)	24 (82.8)	3 (10.3)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 43	27	1 (3.7)	23 (85.2)	3 (11.1)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 85	27	0 (0.0)	24 (88.9)	3 (11.1)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 127	22	0 (0.0)	20 (90.9)	2 (9.1)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	13	1 (7.7)	11 (84.6)	1 (7.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	1 (20.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	1 (20.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	15 (71.4)	5 (23.8)	9	0 (0.0)	9 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	88	4 (4.5)	71 (80.7)	13 (14.8)	44	1 (2.3)	39 (88.6)	4 (9.1)
	Day 43	90	6 (6.7)	71 (78.9)	13 (14.4)	45	1 (2.2)	39 (86.7)	5 (11.1)
	Day 85	72	4 (5.6)	57 (79.2)	11 (15.3)	29	0 (0.0)	25 (86.2)	4 (13.8)
	Day 127	52	7 (13.5)	38 (73.1)	7 (13.5)	15	1 (6.7)	13 (86.7)	1 (6.7)
	Day 169	39	4 (10.3)	29 (74.4)	6 (15.4)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	26	3 (11.5)	21 (80.8)	2 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	2 (10.5)	15 (78.9)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	2 (14.3)	11 (78.6)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	1 (10.0)	8 (80.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	61	1 (1.6)	44 (72.1)	16 (26.2)	44	0 (0.0)	32 (72.7)	12 (27.3)
Prior ramucirumab contained treatment									
yes									
	Day 15	89	3 (3.4)	74 (83.1)	12 (13.5)	34	2 (5.9)	30 (88.2)	2 (5.9)
	Day 43	89	2 (2.2)	74 (83.1)	13 (14.6)	33	2 (6.1)	29 (87.9)	2 (6.1)
	Day 85	73	1 (1.4)	60 (82.2)	12 (16.4)	23	0 (0.0)	22 (95.7)	1 (4.3)
	Day 127	59	4 (6.8)	47 (79.7)	8 (13.6)	11	1 (9.1)	10 (90.9)	0 (0.0)
	Day 169	41	2 (4.9)	34 (82.9)	5 (12.2)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	25	1 (4.0)	19 (76.0)	5 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	1 (6.7)	13 (86.7)	1 (6.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	0 (0.0)	11 (84.6)	2 (15.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	0 (0.0)	44 (71.0)	18 (29.0)	35	0 (0.0)	28 (80.0)	7 (20.0)
Prior ramucirumab contained treatment									
no									
	Day 15	28	3 (10.7)	21 (75.0)	4 (14.3)	18	0 (0.0)	16 (88.9)	2 (11.1)
	Day 43	28	5 (17.9)	20 (71.4)	3 (10.7)	20	0 (0.0)	17 (85.0)	3 (15.0)
	Day 85	26	3 (11.5)	21 (80.8)	2 (7.7)	13	0 (0.0)	10 (76.9)	3 (23.1)
	Day 127	15	3 (20.0)	11 (73.3)	1 (6.7)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	11	3 (27.3)	6 (54.5)	2 (18.2)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	9	3 (33.3)	6 (66.7)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	2 (22.2)	4 (44.4)	3 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	3 (50.0)	1 (16.7)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	3	2 (66.7)	0 (0.0)	1 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	2 (10.0)	15 (75.0)	3 (15.0)	18	0 (0.0)	13 (72.2)	5 (27.8)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Prior nivolumab contained treatment									
yes									
	Day 15	31	0 (0.0)	25 (80.6)	6 (19.4)	13	2 (15.4)	10 (76.9)	1 (7.7)
	Day 43	30	2 (6.7)	24 (80.0)	4 (13.3)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 85	27	1 (3.7)	22 (81.5)	4 (14.8)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	26	1 (3.8)	21 (80.8)	4 (15.4)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	20	2 (10.0)	16 (80.0)	2 (10.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	13	1 (7.7)	10 (76.9)	2 (15.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	0 (0.0)	9 (90.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	0 (0.0)	14 (70.0)	6 (30.0)	13	0 (0.0)	9 (69.2)	4 (30.8)
Prior nivolumab contained treatment									
no									
	Day 15	86	6 (7.0)	70 (81.4)	10 (11.6)	39	0 (0.0)	36 (92.3)	3 (7.7)
	Day 43	87	5 (5.7)	70 (80.5)	12 (13.8)	43	2 (4.7)	36 (83.7)	5 (11.6)
	Day 85	72	3 (4.2)	59 (81.9)	10 (13.9)	26	0 (0.0)	24 (92.3)	2 (7.7)
	Day 127	48	6 (12.5)	37 (77.1)	5 (10.4)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 169	32	3 (9.4)	24 (75.0)	5 (15.6)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	21	3 (14.3)	15 (71.4)	3 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	14	3 (21.4)	8 (57.1)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	3 (27.3)	5 (45.5)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	4 (50.0)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	2 (3.2)	45 (72.6)	15 (24.2)	40	0 (0.0)	32 (80.0)	8 (20.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	41	1 (2.4)	32 (78.0)	8 (19.5)	15	2 (13.3)	12 (80.0)	1 (6.7)
	Day 43	40	2 (5.0)	32 (80.0)	6 (15.0)	12	0 (0.0)	12 (100.0)	0 (0.0)
	Day 85	37	2 (5.4)	29 (78.4)	6 (16.2)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 127	31	3 (9.7)	22 (71.0)	6 (19.4)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	23	3 (13.0)	18 (78.3)	2 (8.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	17	3 (17.6)	12 (70.6)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	13	2 (15.4)	10 (76.9)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	2 (16.7)	8 (66.7)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	1 (3.6)	19 (67.9)	8 (28.6)	15	0 (0.0)	11 (73.3)	4 (26.7)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	76	5 (6.6)	63 (82.9)	8 (10.5)	37	0 (0.0)	34 (91.9)	3 (8.1)
	Day 43	77	5 (6.5)	62 (80.5)	10 (13.0)	41	2 (4.9)	34 (82.9)	5 (12.2)
	Day 85	62	2 (3.2)	52 (83.9)	8 (12.9)	25	0 (0.0)	23 (92.0)	2 (8.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 127	43	4 (9.3)	36 (83.7)	3 (7.0)	15	0 (0.0)	14 (93.3)	1 (6.7)
	Day 169	29	2 (6.9)	22 (75.9)	5 (17.2)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	17	1 (5.9)	13 (76.5)	3 (17.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	11	1 (9.1)	7 (63.6)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	1 (14.3)	4 (57.1)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	54	1 (1.9)	40 (74.1)	13 (24.1)	38	0 (0.0)	30 (78.9)	8 (21.1)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
yes									
	Day 15	22	2 (9.1)	17 (77.3)	3 (13.6)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	19	0 (0.0)	18 (94.7)	1 (5.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 85	16	1 (6.3)	14 (87.5)	1 (6.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 127	12	1 (8.3)	10 (83.3)	1 (8.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	7	1 (14.3)	4 (57.1)	2 (28.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	3	1 (33.3)	1 (33.3)	1 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	10 (83.3)	2 (16.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
no									
	Day 15	95	4 (4.2)	78 (82.1)	13 (13.7)	46	1 (2.2)	41 (89.1)	4 (8.7)
	Day 43	98	7 (7.1)	76 (77.6)	15 (15.3)	47	2 (4.3)	40 (85.1)	5 (10.6)
	Day 85	83	3 (3.6)	67 (80.7)	13 (15.7)	31	0 (0.0)	27 (87.1)	4 (12.9)
	Day 127	62	6 (9.7)	48 (77.4)	8 (12.9)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	45	4 (8.9)	36 (80.0)	5 (11.1)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	31	3 (9.7)	24 (77.4)	4 (12.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	2 (9.1)	16 (72.7)	4 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	2 (11.8)	11 (64.7)	4 (23.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	8 (57.1)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	70	2 (2.9)	49 (70.0)	19 (27.1)	47	0 (0.0)	35 (74.5)	12 (25.5)
Presence of liver metastasis at baseline									
yes									
	Day 15	63	6 (9.5)	48 (76.2)	9 (14.3)	27	1 (3.7)	24 (88.9)	2 (7.4)
	Day 43	63	3 (4.8)	52 (82.5)	8 (12.7)	28	1 (3.6)	24 (85.7)	3 (10.7)
	Day 85	50	3 (6.0)	40 (80.0)	7 (14.0)	16	0 (0.0)	14 (87.5)	2 (12.5)
	Day 127	36	6 (16.7)	26 (72.2)	4 (11.1)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	25	3 (12.0)	20 (80.0)	2 (8.0)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	14	2 (14.3)	11 (78.6)	1 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 253	12	2 (16.7)	9 (75.0)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	0 (0.0)	36 (81.8)	8 (18.2)	30	0 (0.0)	22 (73.3)	8 (26.7)
Presence of liver metastasis at baseline									
no									
	Day 15	54	0 (0.0)	47 (87.0)	7 (13.0)	25	1 (4.0)	22 (88.0)	2 (8.0)
	Day 43	54	4 (7.4)	42 (77.8)	8 (14.8)	25	1 (4.0)	22 (88.0)	2 (8.0)
	Day 85	49	1 (2.0)	41 (83.7)	7 (14.3)	20	0 (0.0)	18 (90.0)	2 (10.0)
	Day 127	38	1 (2.6)	32 (84.2)	5 (13.2)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 169	27	2 (7.4)	20 (74.1)	5 (18.5)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	20	2 (10.0)	14 (70.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	8 (66.7)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	10	2 (20.0)	5 (50.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	2 (25.0)	4 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	1 (20.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	2 (5.3)	23 (60.5)	13 (34.2)	23	0 (0.0)	19 (82.6)	4 (17.4)
Renal impairment at baseline									
normal									
	Day 15	31	1 (3.2)	27 (87.1)	3 (9.7)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	33	2 (6.1)	28 (84.8)	3 (9.1)	12	0 (0.0)	10 (83.3)	2 (16.7)
	Day 85	26	0 (0.0)	23 (88.5)	3 (11.5)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	1 (5.3)	18 (94.7)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	15	0 (0.0)	15 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	17 (85.0)	2 (10.0)	11	0 (0.0)	7 (63.6)	4 (36.4)
Renal impairment at baseline									
mild									
	Day 15	50	2 (4.0)	40 (80.0)	8 (16.0)	25	1 (4.0)	23 (92.0)	1 (4.0)
	Day 43	50	4 (8.0)	38 (76.0)	8 (16.0)	23	1 (4.3)	20 (87.0)	2 (8.7)
	Day 85	45	2 (4.4)	34 (75.6)	9 (20.0)	14	0 (0.0)	14 (100.0)	0 (0.0)
	Day 127	31	4 (12.9)	24 (77.4)	3 (9.7)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 169	21	3 (14.3)	13 (61.9)	5 (23.8)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	13	2 (15.4)	8 (61.5)	3 (23.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	8	2 (25.0)	5 (62.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	4 (66.7)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	0 (0.0)	25 (65.8)	13 (34.2)	22	0 (0.0)	18 (81.8)	4 (18.2)
Renal impairment at baseline									
moderate									
	Day 15	36	3 (8.3)	28 (77.8)	5 (13.9)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 43	34	1 (2.9)	28 (82.4)	5 (14.7)	17	1 (5.9)	15 (88.2)	1 (5.9)
	Day 85	28	2 (7.1)	24 (85.7)	2 (7.1)	14	0 (0.0)	12 (85.7)	2 (14.3)
	Day 127	24	2 (8.3)	16 (66.7)	6 (25.0)	7	1 (14.3)	6 (85.7)	0 (0.0)
	Day 169	16	2 (12.5)	12 (75.0)	2 (12.5)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	11	1 (9.1)	10 (90.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	1 (4.2)	17 (70.8)	6 (25.0)	19	0 (0.0)	15 (78.9)	4 (21.1)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	82	3 (3.7)	67 (81.7)	12 (14.6)	37	1 (2.7)	33 (89.2)	3 (8.1)
	Day 43	83	4 (4.8)	68 (81.9)	11 (13.3)	41	1 (2.4)	36 (87.8)	4 (9.8)
	Day 85	76	3 (3.9)	62 (81.6)	11 (14.5)	27	0 (0.0)	24 (88.9)	3 (11.1)
	Day 127	58	6 (10.3)	45 (77.6)	7 (12.1)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 169	40	4 (10.0)	30 (75.0)	6 (15.0)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	24	3 (12.5)	18 (75.0)	3 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	19	3 (15.8)	13 (68.4)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	3 (20.0)	10 (66.7)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	2 (18.2)	7 (63.6)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	55	2 (3.6)	35 (63.6)	18 (32.7)	40	0 (0.0)	31 (77.5)	9 (22.5)
Hepatic impairment at baseline									
mild									
	Day 15	34	3 (8.8)	27 (79.4)	4 (11.8)	15	1 (6.7)	13 (86.7)	1 (6.7)
	Day 43	33	3 (9.1)	25 (75.8)	5 (15.2)	12	1 (8.3)	10 (83.3)	1 (8.3)
	Day 85	22	1 (4.5)	18 (81.8)	3 (13.6)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 127	15	1 (6.7)	12 (80.0)	2 (13.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	7 (70.0)	2 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	0 (0.0)	23 (88.5)	3 (11.5)	13	0 (0.0)	10 (76.9)	3 (23.1)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	0 (0.0)	6 (75.0)	2 (25.0)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	1 (12.5)	7 (87.5)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	0 (0.0)	6 (85.7)	1 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	0 (0.0)	6 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	0 (0.0)	4 (80.0)	1 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	5	0 (0.0)	3 (60.0)	2 (40.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	109	6 (5.5)	89 (81.7)	14 (12.8)	48	2 (4.2)	43 (89.6)	3 (6.3)
	Day 43	109	6 (5.5)	87 (79.8)	16 (14.7)	50	2 (4.0)	43 (86.0)	5 (10.0)
	Day 85	92	4 (4.3)	75 (81.5)	13 (14.1)	33	0 (0.0)	29 (87.9)	4 (12.1)
	Day 127	68	7 (10.3)	52 (76.5)	9 (13.2)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	47	5 (10.6)	36 (76.6)	6 (12.8)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	30	4 (13.3)	22 (73.3)	4 (13.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	3 (15.0)	15 (75.0)	2 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	17	3 (17.6)	11 (64.7)	3 (17.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	14	2 (14.3)	9 (64.3)	3 (21.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	77	2 (2.6)	56 (72.7)	19 (24.7)	50	0 (0.0)	39 (78.0)	11 (22.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	0 (0.0)	2 (66.7)	1 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	0 (0.0)	1 (100.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors no									
	Day 15	114	6 (5.3)	92 (80.7)	16 (14.0)	49	2 (4.1)	43 (87.8)	4 (8.2)
	Day 43	114	7 (6.1)	91 (79.8)	16 (14.0)	50	2 (4.0)	43 (86.0)	5 (10.0)
	Day 85	96	4 (4.2)	78 (81.3)	14 (14.6)	33	0 (0.0)	29 (87.9)	4 (12.1)
	Day 127	71	7 (9.9)	55 (77.5)	9 (12.7)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	49	5 (10.2)	38 (77.6)	6 (12.2)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	32	4 (12.5)	23 (71.9)	5 (15.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	3 (13.6)	16 (72.7)	3 (13.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	18	3 (16.7)	11 (61.1)	4 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	15	2 (13.3)	9 (60.0)	4 (26.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	81	2 (2.5)	59 (72.8)	20 (24.7)	51	0 (0.0)	39 (76.5)	12 (23.5)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Physical Well-being Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	125 (100.0)	62	59 (95.2)
Day 15	125	121 (96.8)	62	52 (83.9)
Day 43	124	118 (95.2)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	75 (67.6)	50	19 (38.0)
Day 169	105	52 (49.5)	45	11 (24.4)
Day 211	81	34 (42.0)	35	3 (8.6)
Day 253	62	24 (38.7)	26	1 (3.8)
Day 295	51	19 (37.3)	19	1 (5.3)
Day 337	45	15 (33.3)	14	1 (7.1)
Day 379	33	11 (33.3)	10	0 (0.0)
Day 421	22	11 (50.0)	3	0 (0.0)
Day 463	14	7 (50.0)	2	0 (0.0)
Day 505	11	3 (27.3)	2	0 (0.0)
Day 547	6	3 (50.0)	2	0 (0.0)
Day 589	4	1 (25.0)	2	0 (0.0)
Day 631	3	1 (33.3)	0	0 (0.0)
Day 673	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Physical Well-being by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	125	20.4 (5.60)			59	21.4 (5.35)		
Day 15	121	19.2 (5.68)	121	-1.4 (5.82)	52	20.1 (5.84)	50	-1.6 (4.91)
Day 43	118	19.4 (6.11)	118	-1.2 (6.38)	53	20.3 (6.12)	51	-1.2 (5.92)
Day 85	99	19.8 (5.76)	99	-1.1 (5.52)	36	21.9 (5.08)	35	-0.8 (5.38)
Day 127	75	20.8 (4.80)	75	-0.7 (5.26)	19	21.5 (5.22)	19	-2.2 (4.08)
Day 169	52	21.1 (5.02)	52	-0.4 (4.13)	11	22.8 (5.29)	11	-2.4 (5.92)
Day 211	34	20.8 (4.52)	34	-1.4 (4.58)	3	26.3 (1.53)	3	0.0 (0.00)
Day 253	24	20.8 (5.71)	24	-0.9 (5.50)	1	25.0 (-)	1	-1.0 (-)
Day 295	19	20.7 (5.01)	19	-1.7 (5.49)	1	25.0 (-)	1	-1.0 (-)
Day 337	15	20.0 (5.07)	15	-3.0 (6.48)	1	27.0 (-)	1	1.0 (-)
Day 379	11	20.2 (6.35)	11	-2.2 (7.14)	0	-	0	-
Day 421	11	20.0 (6.57)	11	-2.3 (6.40)	0	-	0	-
Day 463	7	22.0 (2.77)	7	0.0 (2.77)	0	-	0	-
Day 505	3	23.3 (3.06)	3	-1.0 (2.00)	0	-	0	-
Day 547	3	22.7 (3.51)	3	-1.7 (2.08)	0	-	0	-
Day 589	1	15.0 (-)	1	-8.0 (-)	0	-	0	-
Day 631	1	14.0 (-)	1	-9.0 (-)	0	-	0	-
Day 673	1	13.0 (-)	1	-10.0 (-)	0	-	0	-
End of Treatment	84	16.7 (6.08)	84	-3.7 (6.45)	53	17.8 (6.95)	50	-3.5 (6.56)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Physical Well-being by Visit
Full Analysis Set

Visit	DS-8201a (N=125) N [a]	N_MISS [b]	LSMean (95% CI)	Phys. Choice (N=62) N [a]	N_MISS [b]	LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
Day 15			-2.36 (-3.27, -1.45)			-2.11 (-3.48, -0.73)	-0.25 (-1.77, 1.26)	0.7416		
Day 43			-2.41 (-3.26, -1.56)			-2.17 (-3.40, -0.94)	-0.24 (-1.59, 1.10)	0.7212		
Day 85			-2.49 (-3.28, -1.69)			-2.26 (-3.51, -1.01)	-0.23 (-1.56, 1.10)	0.7343		
Day 127			-2.56 (-3.35, -1.77)			-2.35 (-3.88, -0.82)	-0.21 (-1.81, 1.38)	0.7916		
Day 169			-2.64 (-3.47, -1.80)			-2.44 (-4.41, -0.47)	-0.20 (-2.23, 1.83)	0.8474		
Day 211			-2.71 (-3.64, -1.79)			-2.53 (-5.01, -0.05)	-0.18 (-2.74, 2.37)	0.8877		
Day 253			-2.79 (-3.84, -1.74)			-2.62 (-5.65, 0.40)	-0.17 (-3.29, 2.96)	0.9156		
Day 295			-2.87 (-4.05, -1.68)			-2.71 (-6.30, 0.88)	-0.15 (-3.87, 3.56)	0.9354		
Day 337			-2.94 (-4.29, -1.59)			-2.80 (-6.97, 1.37)	-0.14 (-4.46, 4.19)	0.9499		
OVERALL	124	1	-2.54 (-3.32, -1.75)	55	7	-2.32 (-3.73, -0.90)	-0.22 (-1.70, 1.26)	0.7707	-0.05 (-0.36, 0.27)	0.7748

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Physical Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0966
Japan	99	-1.56 (-2.28, -0.84)	46	-0.78 (-2.18, 0.62)	-0.78 (-2.36, 0.80)	0.3324	-0.19 (-0.54, 0.16)	0.2808	
Korea	25	-3.08 (-4.71, -1.45)	9	-6.10 (-10.09, -2.12)	3.02 (-1.28, 7.33)	0.1648	0.66 (-0.12, 1.44)	0.0964	
Lines of prior systemic therapy									0.8157
2	65	-2.05 (-2.92, -1.17)	35	-1.71 (-3.13, -0.30)	-0.33 (-2.00, 1.34)	0.6938	-0.09 (-0.50, 0.32)	0.6766	
3	34	-0.76 (-2.26, 0.73)	16	-1.90 (-4.81, 1.01)	1.14 (-2.14, 4.42)	0.4922	0.23 (-0.36, 0.83)	0.4412	
>=4	25	-2.95 (-4.53, -1.38)	4	0.92 (-5.45, 7.29)	-3.87 (-10.45, 2.70)	0.2424	-0.93 (-2.01, 0.16)	0.0933	
Age									0.3613
<65 years	54	-1.39 (-2.31, -0.47)	25	-1.56 (-3.72, 0.61)	0.16 (-2.20, 2.53)	0.8909	0.04 (-0.43, 0.51)	0.8703	
>=65 years	70	-2.25 (-3.22, -1.28)	30	-1.56 (-3.35, 0.24)	-0.70 (-2.74, 1.34)	0.5009	-0.16 (-0.59, 0.27)	0.4658	
Sex									0.8057
female	29	-2.03 (-3.67, -0.38)	13	-1.57 (-4.60, 1.47)	-0.46 (-3.92, 3.00)	0.7909	-0.10 (-0.75, 0.56)	0.7706	
male	95	-1.82 (-2.56, -1.08)	42	-1.53 (-3.03, -0.02)	-0.29 (-1.98, 1.39)	0.7326	-0.07 (-0.43, 0.29)	0.7002	
ECOG PS									0.9112
0	62	-1.42 (-2.27, -0.58)	27	-1.31 (-3.17, 0.56)	-0.11 (-2.18, 1.95)	0.9134	-0.03 (-0.48, 0.42)	0.8988	
1	62	-2.36 (-3.41, -1.32)	28	-1.73 (-3.61, 0.16)	-0.64 (-2.79, 1.52)	0.5593	-0.14 (-0.59, 0.30)	0.5285	
HER2 Status in central laboratory									0.2202
IHC 3+	96	-1.69 (-2.45, -0.93)	42	-1.66 (-3.29, -0.04)	-0.03 (-1.83, 1.77)	0.9779	-0.01 (-0.37, 0.36)	0.9746	
IHC 2+/ISH +	28	-2.57 (-4.09, -1.05)	13	-0.87 (-3.29, 1.55)	-1.69 (-4.55, 1.16)	0.2383	-0.41 (-1.08, 0.25)	0.2207	
Primary tumor location									0.6858
Gastric	107	-1.90 (-2.63, -1.17)	50	-1.49 (-2.88, -0.09)	-0.41 (-2.00, 1.17)	0.6068	-0.10 (-0.43, 0.24)	0.5693	
GEJ	17	-1.59 (-3.19, 0.02)	5	-2.04 (-7.12, 3.04)	0.45 (-4.87, 5.78)	0.8651	0.12 (-0.88, 1.12)	0.8152	
Histological subtype									0.6753
intestinal	89	-1.48 (-2.21, -0.75)	36	-1.00 (-2.52, 0.52)	-0.48 (-2.18, 1.21)	0.5761	-0.12 (-0.51, 0.26)	0.5273	
diffuse	28	-2.94 (-4.70, -1.18)	14	-2.81 (-6.30, 0.68)	-0.13 (-4.04, 3.79)	0.9491	-0.02 (-0.67, 0.62)	0.9424	
others	7	-2.95 (-6.17, 0.26)	5	-0.81 (-5.21, 3.59)	-2.14 (-7.62, 3.33)	0.4039	-0.53 (-1.70, 0.64)	0.3731	
Number of metastatic sites									0.2152
<2	24	-2.95 (-4.39, -1.51)	10	-0.38 (-3.13, 2.37)	-2.57 (-5.68, 0.54)	0.1030	-0.69 (-1.45, 0.07)	0.0733	
>= 2	100	-1.55 (-2.32, -0.79)	45	-2.11 (-3.69, -0.54)	0.56 (-1.20, 2.32)	0.5326	0.13 (-0.23, 0.48)	0.4794	
Previous total gastrectomy									0.0291
yes	22	-2.10 (-3.59, -0.61)	8	1.48 (-2.86, 5.83)	-3.58 (-8.17, 1.00)	0.1234	-0.84 (-1.68, -0.00)	0.0487	
no	102	-1.77 (-2.50, -1.05)	47	-2.06 (-3.45, -0.66)	0.28 (-1.30, 1.86)	0.7249	0.07 (-0.28, 0.41)	0.6966	
Prior adjuvant/ neoadjuvant therapy									0.1315
yes	30	-1.91 (-3.01, -0.81)	8	0.90 (-2.22, 4.01)	-2.81 (-6.11, 0.49)	0.0942	-0.85 (-1.65, -0.05)	0.0385	
no	94	-1.83 (-2.61, -1.04)	47	-2.00 (-3.44, -0.55)	0.17 (-1.48, 1.82)	0.8391	0.04 (-0.31, 0.39)	0.8233	
Prior ramucirumab contained treatment									0.9257
yes	93	-1.92 (-2.64, -1.21)	36	-1.79 (-3.55, -0.02)	-0.14 (-2.05, 1.77)	0.8857	-0.03 (-0.42, 0.35)	0.8628	
no	31	-1.84 (-3.48, -0.20)	19	-0.94 (-3.31, 1.44)	-0.90 (-3.83, 2.02)	0.5377	-0.19 (-0.76, 0.38)	0.5174	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

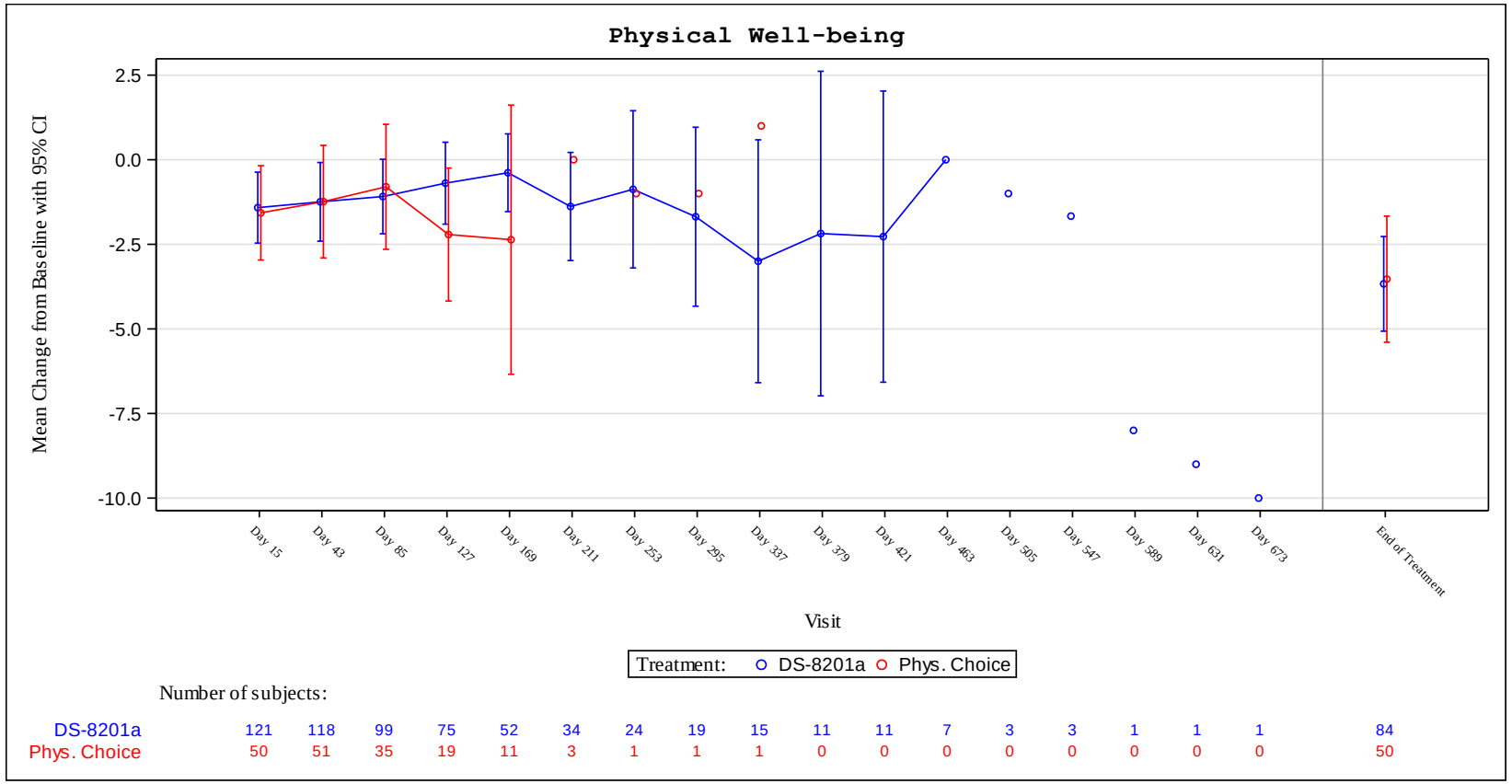
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Physical Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.9739
yes	33	-2.28 (-3.70, -0.86)	12	-2.68 (-6.28, 0.92)	0.40 (-3.47, 4.27)	0.8380	0.08 (-0.58, 0.75)	0.8018	
no	91	-1.76 (-2.53, -0.99)	43	-1.20 (-2.61, 0.20)	-0.55 (-2.17, 1.06)	0.4986	-0.14 (-0.50, 0.23)	0.4601	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.5536
yes	44	-2.55 (-3.78, -1.33)	13	-2.03 (-5.44, 1.37)	-0.52 (-4.14, 3.10)	0.7777	-0.11 (-0.73, 0.51)	0.7221	
no	80	-1.52 (-2.33, -0.71)	42	-1.25 (-2.62, 0.12)	-0.27 (-1.87, 1.34)	0.7414	-0.07 (-0.44, 0.31)	0.7228	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.0737
yes	22	-0.97 (-2.68, 0.74)	6	0.85 (-2.69, 4.39)	-1.82 (-5.88, 2.23)	0.3607	-0.47 (-1.38, 0.45)	0.3162	
no	102	-1.96 (-2.68, -1.24)	49	-2.08 (-3.55, -0.61)	0.12 (-1.52, 1.76)	0.8882	0.03 (-0.31, 0.37)	0.8736	
Presence of liver metastasis at baseline									0.3320
yes	67	-1.16 (-2.11, -0.22)	30	-2.22 (-4.09, -0.35)	1.06 (-1.05, 3.16)	0.3228	0.24 (-0.19, 0.68)	0.2673	
no	57	-2.58 (-3.54, -1.63)	25	-0.95 (-2.89, 0.99)	-1.63 (-3.80, 0.53)	0.1379	-0.40 (-0.88, 0.07)	0.0956	
Renal impairment at baseline									0.0941
normal	33	-2.04 (-3.12, -0.97)	12	-5.82 (-10.26, -1.38)	3.77 (-0.79, 8.34)	0.1045	0.80 (0.12, 1.48)	0.0220	
mild	53	-1.22 (-2.33, -0.11)	25	-0.19 (-2.10, 1.72)	-1.03 (-3.26, 1.20)	0.3596	-0.24 (-0.72, 0.24)	0.3240	
moderate	38	-2.60 (-3.87, -1.33)	17	-1.67 (-3.90, 0.56)	-0.93 (-3.49, 1.64)	0.4726	-0.22 (-0.80, 0.35)	0.4420	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.3035
normal	87	-1.84 (-2.64, -1.04)	40	-2.28 (-3.83, -0.73)	0.44 (-1.31, 2.19)	0.6174	0.11 (-0.27, 0.48)	0.5793	
mild	36	-2.03 (-3.32, -0.75)	15	0.74 (-2.07, 3.55)	-2.77 (-5.89, 0.35)	0.0808	-0.63 (-1.25, -0.02)	0.0432	
moderate	1	0.32 (NE, NE)	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.4347
yes	8	-2.44 (-4.15, -0.74)	4	0.27 (-2.84, 3.38)	-2.71 (-6.41, 0.98)	0.1352	-1.13 (-2.42, 0.15)	0.0832	
no	116	-1.80 (-2.51, -1.09)	51	-1.87 (-3.34, -0.39)	0.06 (-1.57, 1.70)	0.9390	0.01 (-0.31, 0.34)	0.9309	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.4752
yes	3	-1.55 (-5.92, 2.82)	3	-1.07 (-5.50, 3.36)	-0.48 (-7.26, 6.30)	0.8144	-0.23 (-1.84, 1.37)	0.7751	
no	121	-1.84 (-2.53, -1.15)	52	-1.88 (-3.39, -0.37)	0.03 (-1.63, 1.70)	0.9671	0.01 (-0.32, 0.33)	0.9619	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Graphical Summary of Physical Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	65 (52.0)	23 (37.1)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	4.4 (2.8, 6.9)	5.4 (1.6, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.16 (0.72, 1.88)	
p-value [c]	0.5521	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.18 (0.73, 1.91)	
p-value [c]	0.5012	

Time to Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.7282
Japan	51/ 99 (51.5)	4.8 (2.8, 6.9)	18/ 50 (36.0)	NE (1.9, NE)	1.21 (0.70, 2.07)	0.5052	
Korea	14/ 26 (53.8)	1.6 (0.6, NE)	5/ 12 (41.7)	3.4 (0.5, NE)	1.01 (0.36, 2.82)	0.9955	
Lines of prior systemic therapy							0.1481
2	39/ 66 (59.1)	2.9 (1.4, 5.5)	14/ 38 (36.8)	5.4 (1.6, NE)	1.58 (0.86, 2.92)	0.1395	
3	13/ 34 (38.2)	NE (4.0, NE)	6/ 18 (33.3)	NE (1.4, NE)	0.89 (0.33, 2.39)	0.8106	
>=4	13/ 25 (52.0)	6.9 (0.8, NE)	3/ 6 (50.0)	0.6 (0.5, NE)	0.45 (0.12, 1.60)	0.1879	
Age							0.2845
<65 years	28/ 55 (50.9)	5.7 (1.4, NE)	12/ 27 (44.4)	1.9 (1.4, NE)	0.95 (0.48, 1.90)	0.8585	
>=65 years	37/ 70 (52.9)	4.3 (1.7, 6.9)	11/ 35 (31.4)	5.4 (2.6, NE)	1.48 (0.75, 2.90)	0.2506	
Sex							0.9328
female	16/ 30 (53.3)	4.4 (1.4, 9.8)	5/ 15 (33.3)	NE (0.9, NE)	1.16 (0.42, 3.26)	0.7858	
male	49/ 95 (51.6)	4.8 (1.7, NE)	18/ 47 (38.3)	5.4 (1.6, NE)	1.19 (0.69, 2.04)	0.5481	
ECOG PS							0.8184
0	32/ 62 (51.6)	5.7 (2.9, 9.8)	10/ 30 (33.3)	5.4 (1.6, NE)	1.20 (0.58, 2.46)	0.6277	
1	33/ 63 (52.4)	3.1 (1.4, NE)	13/ 32 (40.6)	4.3 (1.4, NE)	1.20 (0.63, 2.28)	0.5938	
HER2 Status in central laboratory							0.4183
IHC 3+	49/ 96 (51.0)	4.4 (1.8, NE)	19/ 47 (40.4)	4.3 (1.6, NE)	1.07 (0.63, 1.83)	0.8186	
IHC 2+/ISH +	16/ 29 (55.2)	4.0 (1.4, 5.7)	4/ 15 (26.7)	NE (0.6, NE)	1.70 (0.56, 5.13)	0.3351	
Primary tumor location							0.1490
Gastric	57/108 (52.8)	4.3 (1.7, 6.8)	20/ 55 (36.4)	5.4 (1.9, NE)	1.32 (0.79, 2.20)	0.2951	
GEJ	8/ 17 (47.1)	NE (0.6, NE)	3/ 7 (42.9)	1.6 (0.5, NE)	0.46 (0.11, 1.96)	0.2788	
Histological subtype							0.8994
intestinal	46/ 89 (51.7)	4.8 (2.8, 9.8)	14/ 38 (36.8)	5.4 (1.6, NE)	1.22 (0.67, 2.23)	0.5213	
diffuse	16/ 28 (57.1)	1.7 (1.2, NE)	7/ 18 (38.9)	1.5 (0.6, NE)	1.02 (0.41, 2.50)	0.9818	
others	3/ 8 (37.5)	NE (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.65 (0.27, 10.04)	0.5796	
Number of metastatic sites							0.0399
<2	16/ 24 (66.7)	2.3 (0.5, NE)	2/ 10 (20.0)	NE (0.6, NE)	4.38 (1.01, 19.09)	0.0320	
>= 2	49/101 (48.5)	5.5 (2.9, 9.8)	21/ 52 (40.4)	4.3 (1.5, NE)	0.89 (0.53, 1.50)	0.6540	
Previous total gastrectomy							0.8070
yes	8/ 22 (36.4)	NE (1.6, NE)	2/ 9 (22.2)	NE (0.7, NE)	1.45 (0.31, 6.85)	0.6298	
no	57/103 (55.3)	4.3 (1.7, 6.8)	21/ 53 (39.6)	4.3 (1.6, NE)	1.17 (0.71, 1.94)	0.5512	
Prior adjuvant/ neoadjuvant therapy							0.4765
yes	14/ 30 (46.7)	6.9 (1.7, NE)	2/ 10 (20.0)	NE (0.6, NE)	1.83 (0.41, 8.12)	0.4183	
no	51/ 95 (53.7)	4.3 (1.5, 6.8)	21/ 52 (40.4)	4.3 (1.6, NE)	1.14 (0.68, 1.91)	0.6218	
Prior ramucirumab contained treatment							0.7232
yes	50/ 94 (53.2)	4.0 (1.7, 6.9)	16/ 41 (39.0)	5.4 (1.4, NE)	1.10 (0.62, 1.94)	0.7632	
no	15/ 31 (48.4)	5.7 (1.4, NE)	7/ 21 (33.3)	NE (1.5, NE)	1.29 (0.52, 3.20)	0.5761	
Prior nivolumab contained treatment							0.6341
yes	19/ 33 (57.6)	4.4 (0.6, NE)	6/ 15 (40.0)	2.6 (0.6, NE)	1.08 (0.42, 2.74)	0.8705	
no	46/ 92 (50.0)	4.8 (2.8, 9.8)	17/ 47 (36.2)	5.4 (1.6, NE)	1.22 (0.70, 2.14)	0.4797	

Time to Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

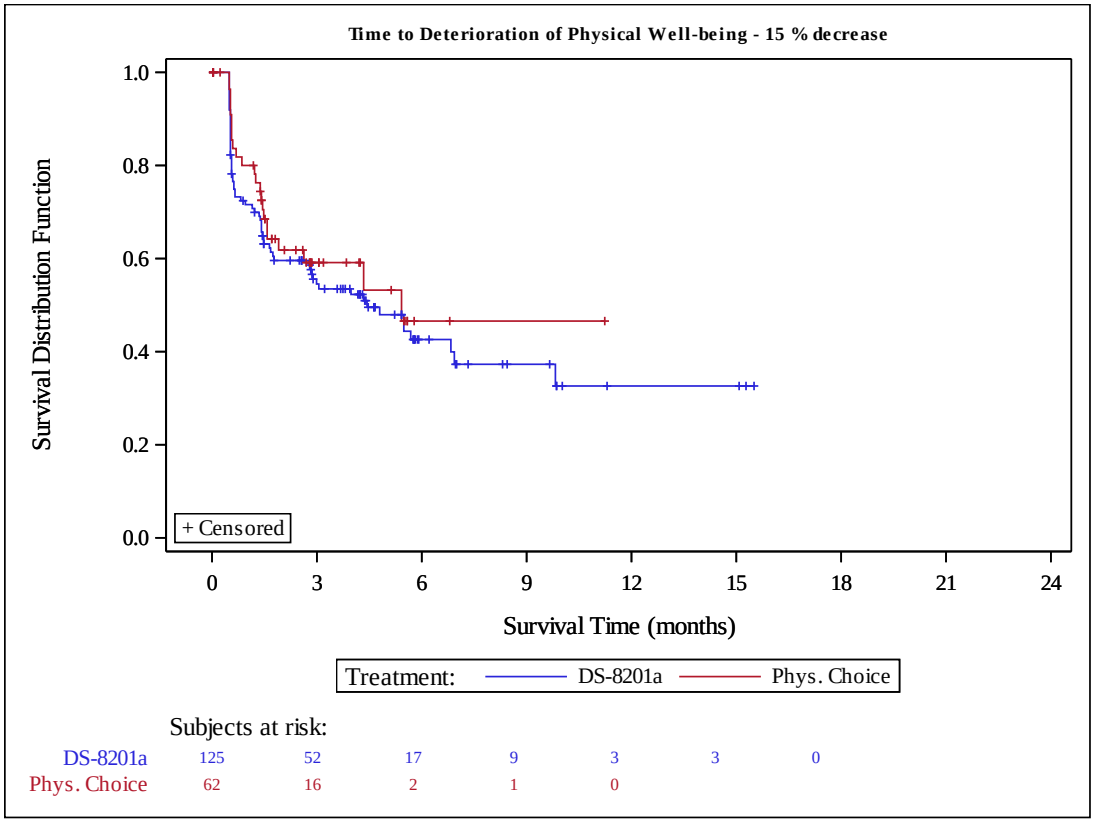
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7256
yes	24/ 44 (54.5)	4.4 (0.7, NE)	6/ 17 (35.3)	NE (0.6, NE)	1.14 (0.46, 2.82)	0.7779	
no	41/ 81 (50.6)	4.3 (2.8, 6.8)	17/ 45 (37.8)	5.4 (1.6, NE)	1.20 (0.68, 2.13)	0.5235	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9806
yes	10/ 22 (45.5)	5.7 (0.6, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	55/103 (53.4)	4.3 (1.7, 6.9)	23/ 55 (41.8)	4.3 (1.5, NE)	1.02 (0.62, 1.67)	0.9474	
Presence of liver metastasis at baseline							0.7635
yes	32/ 67 (47.8)	5.5 (1.7, NE)	12/ 34 (35.3)	4.3 (1.6, NE)	1.09 (0.56, 2.14)	0.8034	
no	33/ 58 (56.9)	4.3 (1.5, 5.7)	11/ 28 (39.3)	NE (1.2, NE)	1.29 (0.65, 2.56)	0.4735	
Renal impairment at baseline							0.4204
normal	19/ 33 (57.6)	2.8 (1.2, NE)	7/ 13 (53.8)	1.6 (0.5, NE)	0.81 (0.34, 1.96)	0.6395	
mild	24/ 53 (45.3)	6.8 (3.1, NE)	7/ 28 (25.0)	NE (4.3, NE)	1.46 (0.62, 3.41)	0.3840	
moderate	22/ 39 (56.4)	2.9 (0.6, 5.5)	8/ 20 (40.0)	5.4 (0.6, NE)	1.45 (0.64, 3.27)	0.3698	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.9 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.5341
normal	46/ 88 (52.3)	5.5 (2.9, 6.9)	17/ 47 (36.2)	5.4 (1.6, NE)	1.06 (0.60, 1.85)	0.8619	
mild	19/ 36 (52.8)	1.7 (0.6, NE)	6/ 15 (40.0)	NE (0.6, NE)	1.59 (0.64, 4.00)	0.3226	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8283
yes	5/ 8 (62.5)	3.1 (0.5, NE)	2/ 5 (40.0)	NE (0.5, NE)	1.22 (0.23, 6.38)	0.8159	
no	60/117 (51.3)	4.4 (1.8, 6.9)	21/ 57 (36.8)	5.4 (1.9, NE)	1.16 (0.70, 1.92)	0.5707	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.5466
yes	2/ 3 (66.7)	5.7 (0.5, NE)	1/ 4 (25.0)	NE (1.6, NE)	1.88 (0.16, 21.86)	0.6076	
no	63/122 (51.6)	4.4 (1.8, 6.9)	22/ 58 (37.9)	5.4 (1.6, NE)	1.13 (0.69, 1.84)	0.6448	

Time to Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

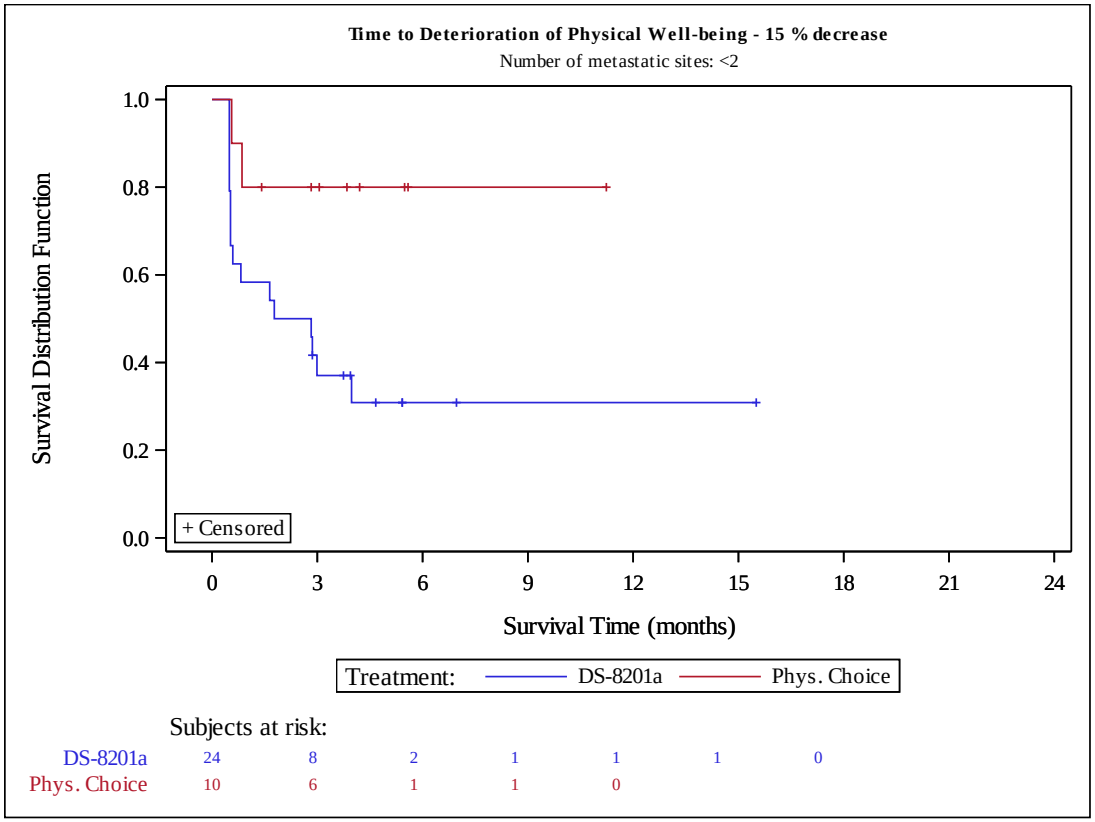
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

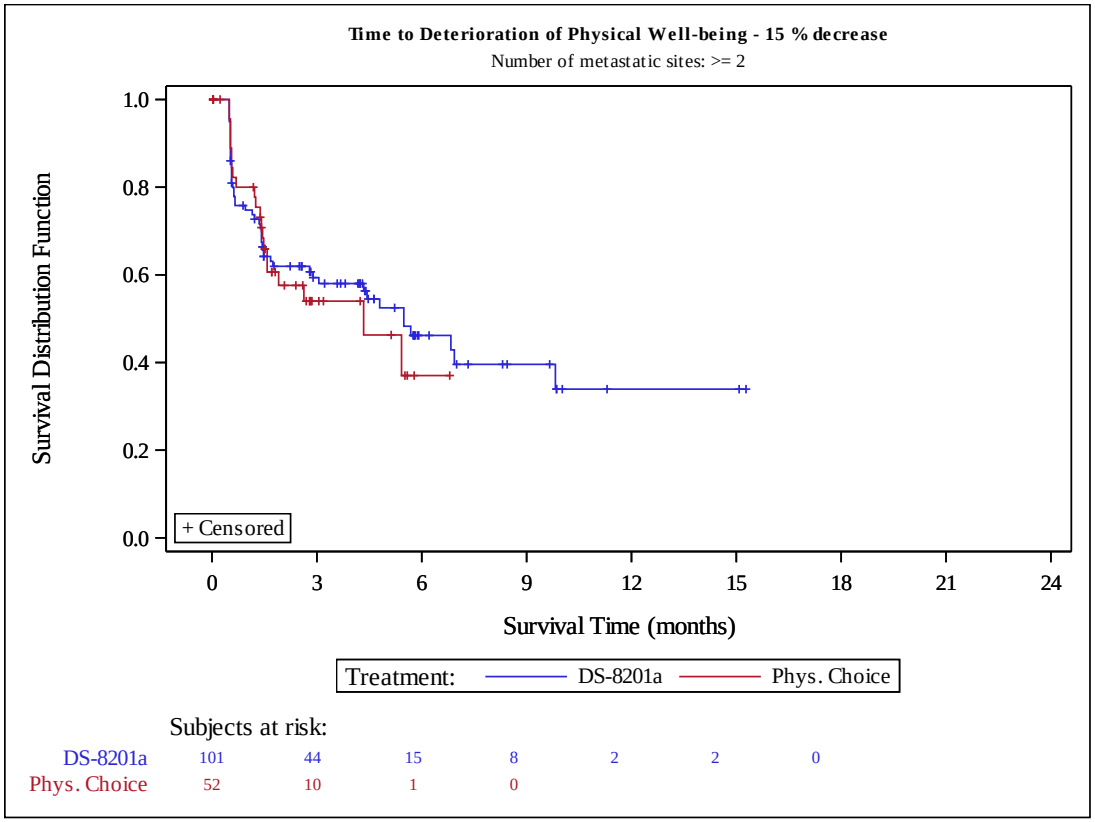
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	50 (40.0)	21 (33.9)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	8.3 (5.5, NE)	5.4 (4.2, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.73 (0.43, 1.23)	
p-value [c]	0.2339	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.77 (0.45, 1.29)	
p-value [c]	0.3152	

Time to Definitive Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.8283
Japan	36/ 99 (36.4)	9.8 (5.7, NE)	16/ 50 (32.0)	NE (4.2, NE)	0.76 (0.42, 1.39)	0.3768	
Korea	14/ 26 (53.8)	5.9 (1.4, 8.4)	5/ 12 (41.7)	3.4 (0.5, NE)	0.63 (0.22, 1.82)	0.3814	
Lines of prior systemic therapy							0.4391
2	29/ 66 (43.9)	7.2 (4.3, 9.8)	13/ 38 (34.2)	5.4 (4.2, NE)	0.93 (0.48, 1.81)	0.8440	
3	10/ 34 (29.4)	NE (5.5, NE)	6/ 18 (33.3)	NE (1.4, NE)	0.38 (0.12, 1.17)	0.0802	
>=4	11/ 25 (44.0)	7.0 (1.0, NE)	2/ 6 (33.3)	NE (0.5, NE)	0.68 (0.15, 3.11)	0.6133	
Age							0.7292
<65 years	22/ 55 (40.0)	9.8 (4.4, NE)	10/ 27 (37.0)	4.3 (1.9, NE)	0.71 (0.32, 1.54)	0.3706	
>=65 years	28/ 70 (40.0)	8.3 (4.3, NE)	11/ 35 (31.4)	5.4 (2.6, NE)	0.82 (0.41, 1.67)	0.5969	
Sex							0.6836
female	14/ 30 (46.7)	8.4 (2.9, NE)	5/ 15 (33.3)	4.2 (1.6, NE)	0.92 (0.32, 2.65)	0.8654	
male	36/ 95 (37.9)	8.3 (5.7, NE)	16/ 47 (34.0)	5.4 (2.6, NE)	0.72 (0.40, 1.32)	0.2930	
ECOG PS							0.6606
0	21/ 62 (33.9)	NE (5.9, NE)	9/ 30 (30.0)	5.4 (4.2, NE)	0.68 (0.30, 1.51)	0.3378	
1	29/ 63 (46.0)	5.5 (4.1, 8.4)	12/ 32 (37.5)	4.3 (1.4, NE)	0.86 (0.43, 1.71)	0.6777	
HER2 Status in central laboratory							0.1548
IHC 3+	36/ 96 (37.5)	9.8 (5.5, NE)	18/ 47 (38.3)	4.3 (2.1, NE)	0.66 (0.37, 1.17)	0.1564	
IHC 2+/ISH +	14/ 29 (48.3)	5.9 (4.1, 8.4)	3/ 15 (20.0)	NE (0.7, NE)	1.24 (0.33, 4.62)	0.7454	
Primary tumor location							0.8154
Gastric	44/108 (40.7)	8.3 (5.5, NE)	19/ 55 (34.5)	NE (2.6, NE)	0.78 (0.45, 1.35)	0.3735	
GEJ	6/ 17 (35.3)	NE (1.5, NE)	2/ 7 (28.6)	4.3 (4.2, NE)	0.72 (0.14, 3.76)	0.7004	
Histological subtype							0.9029
intestinal	34/ 89 (38.2)	8.4 (5.5, NE)	13/ 38 (34.2)	5.4 (4.2, NE)	0.72 (0.37, 1.38)	0.3242	
diffuse	13/ 28 (46.4)	7.0 (1.4, NE)	6/ 18 (33.3)	NE (0.7, NE)	0.81 (0.29, 2.22)	0.6670	
others	3/ 8 (37.5)	NE (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.65 (0.27, 10.04)	0.5796	
Number of metastatic sites							0.1743
<2	11/ 24 (45.8)	7.2 (3.0, NE)	2/ 10 (20.0)	NE (0.6, NE)	1.98 (0.44, 9.00)	0.3675	
>= 2	39/101 (38.6)	8.3 (5.5, NE)	19/ 52 (36.5)	4.3 (2.6, NE)	0.64 (0.36, 1.12)	0.1138	
Previous total gastrectomy							0.6345
yes	7/ 22 (31.8)	NE (4.0, NE)	2/ 9 (22.2)	NE (0.7, NE)	1.16 (0.24, 5.65)	0.8526	
no	43/103 (41.7)	8.3 (5.5, NE)	19/ 53 (35.8)	4.3 (2.6, NE)	0.72 (0.41, 1.25)	0.2486	
Prior adjuvant/ neoadjuvant therapy							0.4397
yes	11/ 30 (36.7)	7.0 (4.0, NE)	2/ 10 (20.0)	NE (0.6, NE)	1.25 (0.27, 5.70)	0.7710	
no	39/ 95 (41.1)	8.4 (5.5, NE)	19/ 52 (36.5)	4.3 (2.6, NE)	0.71 (0.41, 1.25)	0.2380	
Prior ramucirumab contained treatment							0.8343
yes	38/ 94 (40.4)	7.2 (4.8, NE)	14/ 41 (34.1)	5.4 (2.1, NE)	0.75 (0.40, 1.40)	0.3609	
no	12/ 31 (38.7)	8.4 (4.3, NE)	7/ 21 (33.3)	4.3 (1.5, NE)	0.78 (0.30, 2.03)	0.6321	
Prior nivolumab contained treatment							0.0773
yes	12/ 33 (36.4)	NE (4.4, NE)	6/ 15 (40.0)	2.6 (0.6, NE)	0.42 (0.15, 1.20)	0.0961	
no	38/ 92 (41.3)	7.2 (4.8, 9.8)	15/ 47 (31.9)	5.4 (4.2, NE)	0.95 (0.52, 1.75)	0.8854	

Time to Definitive Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

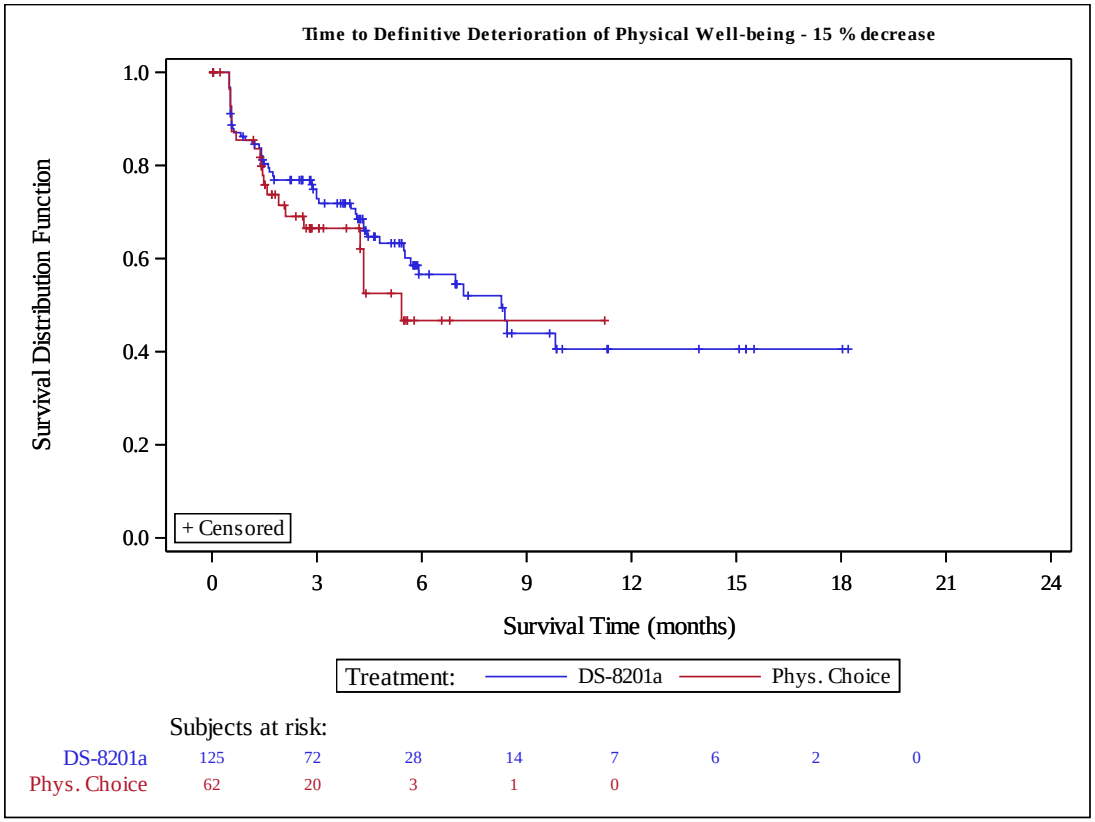
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.2015
yes	17/ 44 (38.6)	NE (4.4, NE)	6/ 17 (35.3)	NE (0.6, NE)	0.59 (0.22, 1.54)	0.2725	
no	33/ 81 (40.7)	7.2 (4.8, 9.8)	15/ 45 (33.3)	5.4 (4.2, NE)	0.89 (0.48, 1.65)	0.7090	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9841
yes	7/ 22 (31.8)	NE (1.8, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	43/103 (41.7)	8.3 (5.5, NE)	21/ 55 (38.2)	4.3 (2.1, NE)	0.65 (0.38, 1.12)	0.1206	
Presence of liver metastasis at baseline							0.2595
yes	23/ 67 (34.3)	9.8 (5.5, NE)	12/ 34 (35.3)	4.3 (2.6, NE)	0.59 (0.29, 1.21)	0.1408	
no	27/ 58 (46.6)	7.0 (4.3, NE)	9/ 28 (32.1)	NE (1.9, NE)	1.02 (0.47, 2.19)	0.9626	
Renal impairment at baseline							0.2521
normal	14/ 33 (42.4)	9.8 (3.0, NE)	7/ 13 (53.8)	4.2 (0.5, 4.3)	0.47 (0.18, 1.21)	0.1063	
mild	18/ 53 (34.0)	8.3 (5.7, NE)	7/ 28 (25.0)	NE (4.3, NE)	0.92 (0.38, 2.23)	0.8551	
moderate	18/ 39 (46.2)	5.5 (4.1, 8.4)	6/ 20 (30.0)	NE (1.4, NE)	1.04 (0.41, 2.68)	0.9219	
severe	0	NE (NE , NE)	1/ 1 (100.0)	2.1 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8322
normal	35/ 88 (39.8)	8.4 (5.5, NE)	15/ 47 (31.9)	5.4 (4.2, NE)	0.73 (0.39, 1.36)	0.3213	
mild	15/ 36 (41.7)	7.0 (2.9, NE)	6/ 15 (40.0)	NE (0.6, NE)	0.84 (0.32, 2.22)	0.7120	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8633
yes	4/ 8 (50.0)	8.4 (0.5, NE)	2/ 5 (40.0)	NE (0.5, NE)	0.83 (0.15, 4.60)	0.8314	
no	46/117 (39.3)	8.3 (5.5, NE)	19/ 57 (33.3)	5.4 (2.6, NE)	0.76 (0.44, 1.31)	0.3199	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.5191
yes	2/ 3 (66.7)	8.4 (5.7, NE)	1/ 4 (25.0)	NE (4.3, NE)	1.14 (0.10, 13.27)	0.9183	
no	48/122 (39.3)	8.3 (5.5, NE)	20/ 58 (34.5)	5.4 (2.6, NE)	0.73 (0.43, 1.25)	0.2468	

Time to Definitive Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	121	15 (12.4)	71 (58.7)	35 (28.9)	52	3 (5.8)	38 (73.1)	11 (21.2)
	Day 43	118	16 (13.6)	73 (61.9)	29 (24.6)	53	6 (11.3)	34 (64.2)	13 (24.5)
	Day 85	99	11 (11.1)	69 (69.7)	19 (19.2)	36	4 (11.1)	27 (75.0)	5 (13.9)
	Day 127	75	10 (13.3)	51 (68.0)	14 (18.7)	19	1 (5.3)	13 (68.4)	5 (26.3)
	Day 169	52	3 (5.8)	40 (76.9)	9 (17.3)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 211	34	2 (5.9)	23 (67.6)	9 (26.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	24	2 (8.3)	15 (62.5)	7 (29.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	19	1 (5.3)	13 (68.4)	5 (26.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	1 (6.7)	9 (60.0)	5 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	1 (9.1)	6 (54.5)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	1 (9.1)	6 (54.5)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	84	7 (8.3)	42 (50.0)	35 (41.7)	53	3 (5.7)	32 (60.4)	18 (34.0)
Region									
Japan									
	Day 15	98	12 (12.2)	59 (60.2)	27 (27.6)	45	3 (6.7)	33 (73.3)	9 (20.0)
	Day 43	94	15 (16.0)	60 (63.8)	19 (20.2)	43	5 (11.6)	29 (67.4)	9 (20.9)
	Day 85	77	9 (11.7)	56 (72.7)	12 (15.6)	32	3 (9.4)	25 (78.1)	4 (12.5)
	Day 127	61	7 (11.5)	44 (72.1)	10 (16.4)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	45	3 (6.7)	34 (75.6)	8 (17.8)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	28	2 (7.1)	18 (64.3)	8 (28.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	13 (72.2)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	1 (7.1)	9 (64.3)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	66	5 (7.6)	38 (57.6)	23 (34.8)	45	3 (6.7)	29 (64.4)	13 (28.9)
Region									
Korea									
	Day 15	23	3 (13.0)	12 (52.2)	8 (34.8)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 43	24	1 (4.2)	13 (54.2)	10 (41.7)	10	1 (10.0)	5 (50.0)	4 (40.0)
	Day 85	22	2 (9.1)	13 (59.1)	7 (31.8)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 127	14	3 (21.4)	7 (50.0)	4 (28.6)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	7	0 (0.0)	6 (85.7)	1 (14.3)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	0 (0.0)	2 (33.3)	4 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	2 (11.1)	4 (22.2)	12 (66.7)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy									
2									
	Day 15	62	4 (6.5)	39 (62.9)	19 (30.6)	34	2 (5.9)	26 (76.5)	6 (17.6)
	Day 43	62	7 (11.3)	39 (62.9)	16 (25.8)	36	3 (8.3)	24 (66.7)	9 (25.0)
	Day 85	50	4 (8.0)	32 (64.0)	14 (28.0)	21	2 (9.5)	17 (81.0)	2 (9.5)
	Day 127	34	4 (11.8)	21 (61.8)	9 (26.5)	14	0 (0.0)	10 (71.4)	4 (28.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 169	21	1 (4.8)	16 (76.2)	4 (19.0)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	14	1 (7.1)	11 (78.6)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	6 (60.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	1 (14.3)	5 (71.4)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	46	2 (4.3)	22 (47.8)	22 (47.8)	32	1 (3.1)	20 (62.5)	11 (34.4)
Lines of prior systemic therapy									
3									
	Day 15	34	7 (20.6)	20 (58.8)	7 (20.6)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 43	33	4 (12.1)	23 (69.7)	6 (18.2)	14	2 (14.3)	8 (57.1)	4 (28.6)
	Day 85	28	5 (17.9)	22 (78.6)	1 (3.6)	12	2 (16.7)	7 (58.3)	3 (25.0)
	Day 127	23	4 (17.4)	16 (69.6)	3 (13.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	17	1 (5.9)	11 (64.7)	5 (29.4)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	12	1 (8.3)	9 (75.0)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	4 (19.0)	10 (47.6)	7 (33.3)	16	2 (12.5)	9 (56.3)	5 (31.3)
Lines of prior systemic therapy									
>=4									
	Day 15	25	4 (16.0)	12 (48.0)	9 (36.0)	4	0 (0.0)	1 (25.0)	3 (75.0)
	Day 43	23	5 (21.7)	11 (47.8)	7 (30.4)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	21	2 (9.5)	15 (71.4)	4 (19.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	2 (11.1)	14 (77.8)	2 (11.1)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 169	14	1 (7.1)	13 (92.9)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	0 (0.0)	3 (37.5)	5 (62.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	10 (58.8)	6 (35.3)	5	0 (0.0)	3 (60.0)	2 (40.0)
Age									
<65 years									
	Day 15	52	8 (15.4)	29 (55.8)	15 (28.8)	22	0 (0.0)	16 (72.7)	6 (27.3)
	Day 43	52	8 (15.4)	29 (55.8)	15 (28.8)	24	2 (8.3)	15 (62.5)	7 (29.2)
	Day 85	47	6 (12.8)	32 (68.1)	9 (19.1)	16	1 (6.3)	13 (81.3)	2 (12.5)
	Day 127	34	7 (20.6)	21 (61.8)	6 (17.6)	8	0 (0.0)	4 (50.0)	4 (50.0)
	Day 169	25	2 (8.0)	18 (72.0)	5 (20.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	16	1 (6.3)	11 (68.8)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	3 (7.9)	19 (50.0)	16 (42.1)	22	0 (0.0)	13 (59.1)	9 (40.9)
Age									
>=65 years									
	Day 15	69	7 (10.1)	42 (60.9)	20 (29.0)	30	3 (10.0)	22 (73.3)	5 (16.7)
	Day 43	66	8 (12.1)	44 (66.7)	14 (21.2)	29	4 (13.8)	19 (65.5)	6 (20.7)
	Day 85	52	5 (9.6)	37 (71.2)	10 (19.2)	20	3 (15.0)	14 (70.0)	3 (15.0)
	Day 127	41	3 (7.3)	30 (73.2)	8 (19.5)	11	1 (9.1)	9 (81.8)	1 (9.1)
	Day 169	27	1 (3.7)	22 (81.5)	4 (14.8)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	18	1 (5.6)	12 (66.7)	5 (27.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	6 (50.0)	5 (41.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	0 (0.0)	4 (50.0)	4 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	7	0 (0.0)	3 (42.9)	4 (57.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	46	4 (8.7)	23 (50.0)	19 (41.3)	31	3 (9.7)	19 (61.3)	9 (29.0)
Sex									
female									
	Day 15	29	3 (10.3)	18 (62.1)	8 (27.6)	13	2 (15.4)	8 (61.5)	3 (23.1)
	Day 43	28	5 (17.9)	15 (53.6)	8 (28.6)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 85	20	2 (10.0)	10 (50.0)	8 (40.0)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 127	13	1 (7.7)	8 (61.5)	4 (30.8)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	9	1 (11.1)	8 (88.9)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	0 (0.0)	5 (83.3)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	11 (52.4)	9 (42.9)	14	1 (7.1)	8 (57.1)	5 (35.7)
Sex									
male									
	Day 15	92	12 (13.0)	53 (57.6)	27 (29.3)	39	1 (2.6)	30 (76.9)	8 (20.5)
	Day 43	90	11 (12.2)	58 (64.4)	21 (23.3)	40	5 (12.5)	25 (62.5)	10 (25.0)
	Day 85	79	9 (11.4)	59 (74.7)	11 (13.9)	28	3 (10.7)	21 (75.0)	4 (14.3)
	Day 127	62	9 (14.5)	43 (69.4)	10 (16.1)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	43	2 (4.7)	32 (74.4)	9 (20.9)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	28	2 (7.1)	18 (64.3)	8 (28.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	1 (5.0)	13 (65.0)	6 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	1 (5.9)	12 (70.6)	4 (23.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	8 (57.1)	5 (35.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	6 (9.5)	31 (49.2)	26 (41.3)	39	2 (5.1)	24 (61.5)	13 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS									
0									
	Day 15	61	8 (13.1)	37 (60.7)	16 (26.2)	26	0 (0.0)	22 (84.6)	4 (15.4)
	Day 43	60	10 (16.7)	41 (68.3)	9 (15.0)	26	1 (3.8)	20 (76.9)	5 (19.2)
	Day 85	54	4 (7.4)	40 (74.1)	10 (18.5)	19	1 (5.3)	16 (84.2)	2 (10.5)
	Day 127	42	5 (11.9)	33 (78.6)	4 (9.5)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 169	33	2 (6.1)	28 (84.8)	3 (9.1)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	20	1 (5.0)	13 (65.0)	6 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	2 (13.3)	10 (66.7)	3 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	0 (0.0)	8 (72.7)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	9	0 (0.0)	7 (77.8)	2 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	1 (2.6)	26 (66.7)	12 (30.8)	27	1 (3.7)	18 (66.7)	8 (29.6)
ECOG PS									
1									
	Day 15	60	7 (11.7)	34 (56.7)	19 (31.7)	26	3 (11.5)	16 (61.5)	7 (26.9)
	Day 43	58	6 (10.3)	32 (55.2)	20 (34.5)	27	5 (18.5)	14 (51.9)	8 (29.6)
	Day 85	45	7 (15.6)	29 (64.4)	9 (20.0)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 127	33	5 (15.2)	18 (54.5)	10 (30.3)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 169	19	1 (5.3)	12 (63.2)	6 (31.6)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	14	1 (7.1)	10 (71.4)	3 (21.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	0 (0.0)	5 (55.6)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	1 (16.7)	2 (33.3)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	0 (0.0)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	0 (0.0)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	6 (13.3)	16 (35.6)	23 (51.1)	26	2 (7.7)	14 (53.8)	10 (38.5)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	93	11 (11.8)	53 (57.0)	29 (31.2)	38	2 (5.3)	29 (76.3)	7 (18.4)
	Day 43	92	13 (14.1)	57 (62.0)	22 (23.9)	40	3 (7.5)	25 (62.5)	12 (30.0)
	Day 85	79	10 (12.7)	53 (67.1)	16 (20.3)	26	2 (7.7)	20 (76.9)	4 (15.4)
	Day 127	60	10 (16.7)	38 (63.3)	12 (20.0)	13	1 (7.7)	7 (53.8)	5 (38.5)
	Day 169	41	3 (7.3)	33 (80.5)	5 (12.2)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	29	2 (6.9)	19 (65.5)	8 (27.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	2 (9.5)	14 (66.7)	5 (23.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	1 (5.9)	12 (70.6)	4 (23.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	9 (64.3)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	1 (9.1)	6 (54.5)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	5 (7.9)	33 (52.4)	25 (39.7)	39	2 (5.1)	21 (53.8)	16 (41.0)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	28	4 (14.3)	18 (64.3)	6 (21.4)	14	1 (7.1)	9 (64.3)	4 (28.6)
	Day 43	26	3 (11.5)	16 (61.5)	7 (26.9)	13	3 (23.1)	9 (69.2)	1 (7.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	20	1 (5.0)	16 (80.0)	3 (15.0)	10	2 (20.0)	7 (70.0)	1 (10.0)
	Day 127	15	0 (0.0)	13 (86.7)	2 (13.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 169	11	0 (0.0)	7 (63.6)	4 (36.4)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	9 (42.9)	10 (47.6)	14	1 (7.1)	11 (78.6)	2 (14.3)
Primary tumor location									
Gastric									
	Day 15	104	14 (13.5)	59 (56.7)	31 (29.8)	46	3 (6.5)	33 (71.7)	10 (21.7)
	Day 43	101	15 (14.9)	61 (60.4)	25 (24.8)	48	5 (10.4)	32 (66.7)	11 (22.9)
	Day 85	84	9 (10.7)	61 (72.6)	14 (16.7)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	64	9 (14.1)	43 (67.2)	12 (18.8)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	42	2 (4.8)	33 (78.6)	7 (16.7)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 211	29	1 (3.4)	19 (65.5)	9 (31.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	2 (10.0)	11 (55.0)	7 (35.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	0 (0.0)	10 (66.7)	5 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	0 (0.0)	7 (58.3)	5 (41.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	4 (50.0)	4 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	4 (50.0)	4 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	7 (9.7)	34 (47.2)	31 (43.1)	47	3 (6.4)	28 (59.6)	16 (34.0)
Primary tumor location									
GEJ									
	Day 15	17	1 (5.9)	12 (70.6)	4 (23.5)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 43	17	1 (5.9)	12 (70.6)	4 (23.5)	5	1 (20.0)	2 (40.0)	2 (40.0)
	Day 85	15	2 (13.3)	8 (53.3)	5 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	8 (66.7)	4 (33.3)	6	0 (0.0)	4 (66.7)	2 (33.3)
Histological subtype									
intestinal									
	Day 15	88	10 (11.4)	52 (59.1)	26 (29.5)	35	3 (8.6)	26 (74.3)	6 (17.1)
	Day 43	86	14 (16.3)	58 (67.4)	14 (16.3)	34	5 (14.7)	21 (61.8)	8 (23.5)
	Day 85	73	9 (12.3)	52 (71.2)	12 (16.4)	27	3 (11.1)	21 (77.8)	3 (11.1)
	Day 127	56	7 (12.5)	39 (69.6)	10 (17.9)	14	1 (7.1)	10 (71.4)	3 (21.4)
	Day 169	40	3 (7.5)	29 (72.5)	8 (20.0)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	25	2 (8.0)	16 (64.0)	7 (28.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	16	2 (12.5)	10 (62.5)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	1 (7.7)	8 (61.5)	4 (30.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	1 (10.0)	6 (60.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	64	6 (9.4)	34 (53.1)	24 (37.5)	34	3 (8.8)	21 (61.8)	10 (29.4)
Histological subtype diffuse									
	Day 15	27	5 (18.5)	14 (51.9)	8 (29.6)	15	0 (0.0)	10 (66.7)	5 (33.3)
	Day 43	26	2 (7.7)	12 (46.2)	12 (46.2)	14	0 (0.0)	10 (71.4)	4 (28.6)
	Day 85	22	1 (4.5)	15 (68.2)	6 (27.3)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 127	15	2 (13.3)	10 (66.7)	3 (20.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	10	0 (0.0)	9 (90.0)	1 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	16	1 (6.3)	7 (43.8)	8 (50.0)	16	0 (0.0)	10 (62.5)	6 (37.5)
Histological subtype others									
	Day 15	6	0 (0.0)	5 (83.3)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	0 (0.0)	3 (50.0)	3 (50.0)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 85	4	1 (25.0)	2 (50.0)	1 (25.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	4	1 (25.0)	2 (50.0)	1 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	1 (25.0)	3 (75.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	23	1 (4.3)	12 (52.2)	10 (43.5)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	23	2 (8.7)	16 (69.6)	5 (21.7)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 85	22	3 (13.6)	13 (59.1)	6 (27.3)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	18	1 (5.6)	12 (66.7)	5 (27.8)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	15	0 (0.0)	11 (73.3)	4 (26.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	10	0 (0.0)	8 (80.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	0 (0.0)	3 (50.0)	3 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	1 (6.7)	7 (46.7)	7 (46.7)	8	0 (0.0)	7 (87.5)	1 (12.5)
Number of metastatic sites >= 2									
	Day 15	98	14 (14.3)	59 (60.2)	25 (25.5)	42	3 (7.1)	30 (71.4)	9 (21.4)
	Day 43	95	14 (14.7)	57 (60.0)	24 (25.3)	43	5 (11.6)	26 (60.5)	12 (27.9)
	Day 85	77	8 (10.4)	56 (72.7)	13 (16.9)	28	3 (10.7)	20 (71.4)	5 (17.9)
	Day 127	57	9 (15.8)	39 (68.4)	9 (15.8)	15	1 (6.7)	9 (60.0)	5 (33.3)
	Day 169	37	3 (8.1)	29 (78.4)	5 (13.5)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	24	2 (8.3)	15 (62.5)	7 (29.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	12 (66.7)	4 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	15	1 (6.7)	10 (66.7)	4 (26.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	69	6 (8.7)	35 (50.7)	28 (40.6)	45	3 (6.7)	25 (55.6)	17 (37.8)
Previous total gastrectomy									
yes									
	Day 15	20	6 (30.0)	11 (55.0)	3 (15.0)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 43	20	4 (20.0)	11 (55.0)	5 (25.0)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 85	18	2 (11.1)	12 (66.7)	4 (22.2)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	0 (0.0)	6 (75.0)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	0 (0.0)	3 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	12 (70.6)	4 (23.5)	9	1 (11.1)	6 (66.7)	2 (22.2)
Previous total gastrectomy									
no									
	Day 15	101	9 (8.9)	60 (59.4)	32 (31.7)	45	3 (6.7)	32 (71.1)	10 (22.2)
	Day 43	98	12 (12.2)	62 (63.3)	24 (24.5)	45	4 (8.9)	29 (64.4)	12 (26.7)
	Day 85	81	9 (11.1)	57 (70.4)	15 (18.5)	30	3 (10.0)	22 (73.3)	5 (16.7)
	Day 127	64	9 (14.1)	43 (67.2)	12 (18.8)	17	0 (0.0)	12 (70.6)	5 (29.4)
	Day 169	44	3 (6.8)	34 (77.3)	7 (15.9)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 211	27	2 (7.4)	19 (70.4)	6 (22.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	2 (9.5)	14 (66.7)	5 (23.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	1 (6.3)	12 (75.0)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	1 (8.3)	9 (75.0)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	67	6 (9.0)	30 (44.8)	31 (46.3)	44	2 (4.5)	26 (59.1)	16 (36.4)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	6 (20.7)	17 (58.6)	6 (20.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 43	28	4 (14.3)	18 (64.3)	6 (21.4)	8	3 (37.5)	4 (50.0)	1 (12.5)
	Day 85	27	3 (11.1)	19 (70.4)	5 (18.5)	7	2 (28.6)	5 (71.4)	0 (0.0)
	Day 127	22	1 (4.5)	16 (72.7)	5 (22.7)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	13	0 (0.0)	11 (84.6)	2 (15.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	8	0 (0.0)	3 (37.5)	5 (62.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	0 (0.0)	1 (20.0)	4 (80.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	13 (61.9)	7 (33.3)	9	1 (11.1)	7 (77.8)	1 (11.1)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	92	9 (9.8)	54 (58.7)	29 (31.5)	44	3 (6.8)	32 (72.7)	9 (20.5)
	Day 43	90	12 (13.3)	55 (61.1)	23 (25.6)	45	3 (6.7)	30 (66.7)	12 (26.7)
	Day 85	72	8 (11.1)	50 (69.4)	14 (19.4)	29	2 (6.9)	22 (75.9)	5 (17.2)
	Day 127	53	9 (17.0)	35 (66.0)	9 (17.0)	15	0 (0.0)	10 (66.7)	5 (33.3)
	Day 169	39	3 (7.7)	29 (74.4)	7 (17.9)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	26	2 (7.7)	20 (76.9)	4 (15.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	2 (10.5)	13 (68.4)	4 (21.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	1 (7.1)	11 (78.6)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	1 (10.0)	8 (80.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	6 (9.5)	29 (46.0)	28 (44.4)	44	2 (4.5)	25 (56.8)	17 (38.6)
Prior ramucirumab contained treatment									
yes									
	Day 15	91	8 (8.8)	56 (61.5)	27 (29.7)	34	3 (8.8)	22 (64.7)	9 (26.5)
	Day 43	90	10 (11.1)	58 (64.4)	22 (24.4)	33	5 (15.2)	21 (63.6)	7 (21.2)
	Day 85	73	8 (11.0)	51 (69.9)	14 (19.2)	23	3 (13.0)	18 (78.3)	2 (8.7)
	Day 127	59	7 (11.9)	40 (67.8)	12 (20.3)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 169	41	2 (4.9)	31 (75.6)	8 (19.5)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	25	1 (4.0)	16 (64.0)	8 (32.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	2 (13.3)	10 (66.7)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	0 (0.0)	10 (76.9)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	4 (6.3)	32 (50.8)	27 (42.9)	35	2 (5.7)	22 (62.9)	11 (31.4)
Prior ramucirumab contained treatment									
no									
	Day 15	30	7 (23.3)	15 (50.0)	8 (26.7)	18	0 (0.0)	16 (88.9)	2 (11.1)
	Day 43	28	6 (21.4)	15 (53.6)	7 (25.0)	20	1 (5.0)	13 (65.0)	6 (30.0)
	Day 85	26	3 (11.5)	18 (69.2)	5 (19.2)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 127	16	3 (18.8)	11 (68.8)	2 (12.5)	8	0 (0.0)	5 (62.5)	3 (37.5)
	Day 169	11	1 (9.1)	9 (81.8)	1 (9.1)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	9	1 (11.1)	7 (77.8)	1 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	0 (0.0)	5 (55.6)	4 (44.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	3 (50.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	3	1 (33.3)	0 (0.0)	2 (66.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	3 (14.3)	10 (47.6)	8 (38.1)	18	1 (5.6)	10 (55.6)	7 (38.9)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Prior nivolumab contained treatment									
yes									
	Day 15	33	2 (6.1)	17 (51.5)	14 (42.4)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 43	31	3 (9.7)	21 (67.7)	7 (22.6)	10	2 (20.0)	5 (50.0)	3 (30.0)
	Day 85	27	2 (7.4)	23 (85.2)	2 (7.4)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 127	26	2 (7.7)	21 (80.8)	3 (11.5)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	20	1 (5.0)	18 (90.0)	1 (5.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	13	1 (7.7)	8 (61.5)	4 (30.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	11 (55.0)	8 (40.0)	13	1 (7.7)	7 (53.8)	5 (38.5)
Prior nivolumab contained treatment									
no									
	Day 15	88	13 (14.8)	54 (61.4)	21 (23.9)	39	2 (5.1)	29 (74.4)	8 (20.5)
	Day 43	87	13 (14.9)	52 (59.8)	22 (25.3)	43	4 (9.3)	29 (67.4)	10 (23.3)
	Day 85	72	9 (12.5)	46 (63.9)	17 (23.6)	26	3 (11.5)	21 (80.8)	2 (7.7)
	Day 127	49	8 (16.3)	30 (61.2)	11 (22.4)	16	0 (0.0)	11 (68.8)	5 (31.3)
	Day 169	32	2 (6.3)	22 (68.8)	8 (25.0)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	21	1 (4.8)	15 (71.4)	5 (23.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	14	1 (7.1)	8 (57.1)	5 (35.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	1 (9.1)	7 (63.6)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	1 (16.7)	2 (33.3)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	64	6 (9.4)	31 (48.4)	27 (42.2)	40	2 (5.0)	25 (62.5)	13 (32.5)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	43	4 (9.3)	22 (51.2)	17 (39.5)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 43	41	4 (9.8)	26 (63.4)	11 (26.8)	12	2 (16.7)	7 (58.3)	3 (25.0)
	Day 85	37	2 (5.4)	28 (75.7)	7 (18.9)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 127	31	3 (9.7)	23 (74.2)	5 (16.1)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	23	1 (4.3)	21 (91.3)	1 (4.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	17	1 (5.9)	11 (64.7)	5 (29.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	13	1 (7.7)	9 (69.2)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	0 (0.0)	6 (60.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	2 (7.1)	14 (50.0)	12 (42.9)	15	1 (6.7)	9 (60.0)	5 (33.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	78	11 (14.1)	49 (62.8)	18 (23.1)	37	2 (5.4)	27 (73.0)	8 (21.6)
	Day 43	77	12 (15.6)	47 (61.0)	18 (23.4)	41	4 (9.8)	27 (65.9)	10 (24.4)
	Day 85	62	9 (14.5)	41 (66.1)	12 (19.4)	25	3 (12.0)	20 (80.0)	2 (8.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 127	44	7 (15.9)	28 (63.6)	9 (20.5)	15	0 (0.0)	10 (66.7)	5 (33.3)
	Day 169	29	2 (6.9)	19 (65.5)	8 (27.6)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	17	1 (5.9)	12 (70.6)	4 (23.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	11	1 (9.1)	6 (54.5)	4 (36.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	1 (14.3)	4 (57.1)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	56	5 (8.9)	28 (50.0)	23 (41.1)	38	2 (5.3)	23 (60.5)	13 (34.2)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
yes									
	Day 15	22	4 (18.2)	12 (54.5)	6 (27.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	19	3 (15.8)	12 (63.2)	4 (21.1)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 85	16	1 (6.3)	14 (87.5)	1 (6.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 127	12	2 (16.7)	10 (83.3)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	7	0 (0.0)	5 (71.4)	2 (28.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	3	0 (0.0)	3 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	10 (83.3)	1 (8.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
no									
	Day 15	99	11 (11.1)	59 (59.6)	29 (29.3)	46	3 (6.5)	32 (69.6)	11 (23.9)
	Day 43	99	13 (13.1)	61 (61.6)	25 (25.3)	47	5 (10.6)	29 (61.7)	13 (27.7)
	Day 85	83	10 (12.0)	55 (66.3)	18 (21.7)	31	4 (12.9)	22 (71.0)	5 (16.1)
	Day 127	63	8 (12.7)	41 (65.1)	14 (22.2)	16	0 (0.0)	11 (68.8)	5 (31.3)
	Day 169	45	3 (6.7)	35 (77.8)	7 (15.6)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	31	2 (6.5)	20 (64.5)	9 (29.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	2 (9.1)	14 (63.6)	6 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	1 (5.9)	11 (64.7)	5 (29.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	8 (57.1)	5 (35.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	6 (8.3)	32 (44.4)	34 (47.2)	47	3 (6.4)	26 (55.3)	18 (38.3)
Presence of liver metastasis at baseline									
yes									
	Day 15	66	10 (15.2)	39 (59.1)	17 (25.8)	27	2 (7.4)	21 (77.8)	4 (14.8)
	Day 43	63	10 (15.9)	38 (60.3)	15 (23.8)	28	3 (10.7)	18 (64.3)	7 (25.0)
	Day 85	50	6 (12.0)	35 (70.0)	9 (18.0)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 127	36	6 (16.7)	26 (72.2)	4 (11.1)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 169	25	2 (8.0)	21 (84.0)	2 (8.0)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	14	1 (7.1)	11 (78.6)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 253	12	2 (16.7)	8 (66.7)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	4 (8.9)	26 (57.8)	15 (33.3)	30	2 (6.7)	17 (56.7)	11 (36.7)
Presence of liver metastasis at baseline									
no									
	Day 15	55	5 (9.1)	32 (58.2)	18 (32.7)	25	1 (4.0)	17 (68.0)	7 (28.0)
	Day 43	55	6 (10.9)	35 (63.6)	14 (25.5)	25	3 (12.0)	16 (64.0)	6 (24.0)
	Day 85	49	5 (10.2)	34 (69.4)	10 (20.4)	20	2 (10.0)	16 (80.0)	2 (10.0)
	Day 127	39	4 (10.3)	25 (64.1)	10 (25.6)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 169	27	1 (3.7)	19 (70.4)	7 (25.9)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	20	1 (5.0)	12 (60.0)	7 (35.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	12	0 (0.0)	7 (58.3)	5 (41.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	10	1 (10.0)	5 (50.0)	4 (40.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	2 (25.0)	5 (62.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	1 (20.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	1 (20.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	3 (7.7)	16 (41.0)	20 (51.3)	23	1 (4.3)	15 (65.2)	7 (30.4)
Renal impairment at baseline									
normal									
	Day 15	32	2 (6.3)	20 (62.5)	10 (31.3)	10	0 (0.0)	7 (70.0)	3 (30.0)
	Day 43	33	4 (12.1)	18 (54.5)	11 (33.3)	12	0 (0.0)	6 (50.0)	6 (50.0)
	Day 85	26	2 (7.7)	17 (65.4)	7 (26.9)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	2 (10.5)	14 (73.7)	3 (15.8)	3	0 (0.0)	0 (0.0)	3 (100.0)
	Day 169	15	1 (6.7)	13 (86.7)	1 (6.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	0 (0.0)	13 (65.0)	7 (35.0)	11	0 (0.0)	5 (45.5)	6 (54.5)
Renal impairment at baseline									
mild									
	Day 15	51	10 (19.6)	30 (58.8)	11 (21.6)	25	1 (4.0)	21 (84.0)	3 (12.0)
	Day 43	51	10 (19.6)	29 (56.9)	12 (23.5)	23	3 (13.0)	16 (69.6)	4 (17.4)
	Day 85	45	8 (17.8)	30 (66.7)	7 (15.6)	14	2 (14.3)	12 (85.7)	0 (0.0)
	Day 127	32	6 (18.8)	23 (71.9)	3 (9.4)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	21	1 (4.8)	16 (76.2)	4 (19.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	13	1 (7.7)	7 (53.8)	5 (38.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	8	2 (25.0)	4 (50.0)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	0 (0.0)	4 (66.7)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	40	6 (15.0)	18 (45.0)	16 (40.0)	22	1 (4.5)	15 (68.2)	6 (27.3)
Renal impairment at baseline									
moderate									
	Day 15	38	3 (7.9)	21 (55.3)	14 (36.8)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 43	34	2 (5.9)	26 (76.5)	6 (17.6)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 85	28	1 (3.6)	22 (78.6)	5 (17.9)	14	2 (14.3)	9 (64.3)	3 (21.4)
	Day 127	24	2 (8.3)	14 (58.3)	8 (33.3)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 169	16	1 (6.3)	11 (68.8)	4 (25.0)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 211	11	1 (9.1)	8 (72.7)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	1 (4.2)	11 (45.8)	12 (50.0)	19	2 (10.5)	12 (63.2)	5 (26.3)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
Hepatic impairment at baseline									
normal									
	Day 15	85	9 (10.6)	54 (63.5)	22 (25.9)	37	2 (5.4)	28 (75.7)	7 (18.9)
	Day 43	84	10 (11.9)	56 (66.7)	18 (21.4)	41	3 (7.3)	28 (68.3)	10 (24.4)
	Day 85	76	7 (9.2)	54 (71.1)	15 (19.7)	27	3 (11.1)	20 (74.1)	4 (14.8)
	Day 127	59	7 (11.9)	42 (71.2)	10 (16.9)	14	0 (0.0)	9 (64.3)	5 (35.7)
	Day 169	40	2 (5.0)	30 (75.0)	8 (20.0)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	24	1 (4.2)	18 (75.0)	5 (20.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	19	1 (5.3)	13 (68.4)	5 (26.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	1 (6.7)	11 (73.3)	3 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	57	2 (3.5)	31 (54.4)	24 (42.1)	40	2 (5.0)	24 (60.0)	14 (35.0)
Hepatic impairment at baseline									
mild									
	Day 15	35	6 (17.1)	16 (45.7)	13 (37.1)	15	1 (6.7)	10 (66.7)	4 (26.7)
	Day 43	33	6 (18.2)	16 (48.5)	11 (33.3)	12	3 (25.0)	6 (50.0)	3 (25.0)
	Day 85	22	3 (13.6)	15 (68.2)	4 (18.2)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 127	15	3 (20.0)	8 (53.3)	4 (26.7)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	5 (50.0)	4 (40.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	5 (19.2)	10 (38.5)	11 (42.3)	13	1 (7.7)	8 (61.5)	4 (30.8)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 85	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	3 (37.5)	2 (25.0)	3 (37.5)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	3 (37.5)	4 (50.0)	1 (12.5)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 85	7	1 (14.3)	5 (71.4)	1 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	0 (0.0)	6 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	5	0 (0.0)	4 (80.0)	1 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	5	1 (20.0)	2 (40.0)	2 (40.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	113	12 (10.6)	69 (61.1)	32 (28.3)	48	3 (6.3)	35 (72.9)	10 (20.8)
	Day 43	110	13 (11.8)	69 (62.7)	28 (25.5)	50	6 (12.0)	32 (64.0)	12 (24.0)
	Day 85	92	10 (10.9)	64 (69.6)	18 (19.6)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	69	10 (14.5)	45 (65.2)	14 (20.3)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	47	3 (6.4)	36 (76.6)	8 (17.0)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	30	2 (6.7)	20 (66.7)	8 (26.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	2 (10.0)	13 (65.0)	5 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	17	1 (5.9)	12 (70.6)	4 (23.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	14	1 (7.1)	9 (64.3)	4 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	6 (7.6)	40 (50.6)	33 (41.8)	50	3 (6.0)	31 (62.0)	16 (32.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	1 (33.3)	1 (33.3)	1 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	3	0 (0.0)	2 (66.7)	1 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	0 (0.0)	1 (100.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors no									
	Day 15	118	14 (11.9)	70 (59.3)	34 (28.8)	49	3 (6.1)	35 (71.4)	11 (22.4)
	Day 43	115	16 (13.9)	70 (60.9)	29 (25.2)	50	6 (12.0)	32 (64.0)	12 (24.0)
	Day 85	96	11 (11.5)	66 (68.8)	19 (19.8)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	72	10 (13.9)	48 (66.7)	14 (19.4)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	49	3 (6.1)	38 (77.6)	8 (16.3)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	32	2 (6.3)	21 (65.6)	9 (28.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	2 (9.1)	14 (63.6)	6 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	18	1 (5.6)	12 (66.7)	5 (27.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	15	1 (6.7)	9 (60.0)	5 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	11	1 (9.1)	6 (54.5)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	1 (9.1)	6 (54.5)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	7 (8.4)	42 (50.6)	34 (41.0)	51	3 (5.9)	31 (60.8)	17 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Social/Family Well-being Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	125 (100.0)	62	59 (95.2)
Day 15	125	121 (96.8)	62	52 (83.9)
Day 43	124	118 (95.2)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	52 (49.5)	45	11 (24.4)
Day 211	81	34 (42.0)	35	3 (8.6)
Day 253	62	24 (38.7)	26	1 (3.8)
Day 295	51	19 (37.3)	19	1 (5.3)
Day 337	45	15 (33.3)	14	1 (7.1)
Day 379	33	11 (33.3)	10	0 (0.0)
Day 421	22	11 (50.0)	3	0 (0.0)
Day 463	14	7 (50.0)	2	0 (0.0)
Day 505	11	3 (27.3)	2	0 (0.0)
Day 547	6	3 (50.0)	2	0 (0.0)
Day 589	4	1 (25.0)	2	0 (0.0)
Day 631	3	1 (33.3)	0	0 (0.0)
Day 673	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Social/Family Well-being by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	125	17.9 (5.67)			59	18.6 (5.74)		
Day 15	121	16.5 (6.76)	121	-1.3 (5.69)	52	18.8 (6.26)	50	0.2 (3.88)
Day 43	118	16.5 (6.33)	118	-1.4 (5.69)	53	18.0 (7.22)	51	-0.9 (5.80)
Day 85	99	16.7 (6.08)	99	-1.2 (4.30)	36	17.5 (7.55)	35	-0.8 (4.85)
Day 127	74	16.4 (6.80)	74	-1.5 (5.65)	19	17.2 (6.36)	19	-2.1 (5.29)
Day 169	52	16.9 (5.97)	52	-0.9 (3.97)	11	17.9 (5.90)	11	-2.0 (4.28)
Day 211	34	17.1 (6.81)	34	-0.8 (6.06)	3	22.8 (5.93)	3	-2.1 (1.86)
Day 253	24	17.3 (7.67)	24	-0.8 (5.70)	1	28.0 (-)	1	1.2 (-)
Day 295	19	17.3 (8.42)	19	-0.7 (4.43)	1	28.0 (-)	1	1.2 (-)
Day 337	15	17.3 (9.03)	15	-0.2 (5.13)	1	28.0 (-)	1	1.2 (-)
Day 379	11	18.8 (8.03)	11	-0.5 (3.11)	0	-	0	-
Day 421	11	18.1 (7.78)	11	-0.7 (3.33)	0	-	0	-
Day 463	7	18.3 (9.75)	7	-0.3 (4.78)	0	-	0	-
Day 505	3	11.4 (12.63)	3	-2.9 (5.00)	0	-	0	-
Day 547	3	12.2 (12.51)	3	-2.1 (3.66)	0	-	0	-
Day 589	1	12.8 (-)	1	-5.2 (-)	0	-	0	-
Day 631	1	14.0 (-)	1	-4.0 (-)	0	-	0	-
Day 673	1	17.5 (-)	1	-0.5 (-)	0	-	0	-
End of Treatment	83	18.1 (5.59)	83	-0.8 (4.45)	53	17.4 (6.98)	50	-1.0 (4.49)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Social/Family Well-being by Visit
Full Analysis Set

Visit	DS-8201a (N=125)			Phys. Choice (N=62)			Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
	N [a]	N_MISS [b]	LSMean (95% CI)	N [a]	N_MISS [b]	LSMean (95% CI)				
Day 15			-1.58 (-2.38, -0.79)			-0.37 (-1.64, 0.90)	-1.21 (-2.60, 0.18)	0.0866		
Day 43			-1.53 (-2.26, -0.80)			-0.55 (-1.64, 0.54)	-0.98 (-2.17, 0.21)	0.1059		
Day 85			-1.45 (-2.13, -0.77)			-0.82 (-1.91, 0.28)	-0.63 (-1.79, 0.52)	0.2809		
Day 127			-1.37 (-2.04, -0.71)			-1.08 (-2.48, 0.31)	-0.29 (-1.73, 1.15)	0.6949		
Day 169			-1.29 (-1.99, -0.59)			-1.35 (-3.21, 0.51)	0.06 (-1.84, 1.96)	0.9503		
Day 211			-1.21 (-1.99, -0.43)			-1.62 (-4.01, 0.77)	0.41 (-2.04, 2.85)	0.7434		
Day 253			-1.13 (-2.02, -0.24)			-1.89 (-4.84, 1.07)	0.75 (-2.27, 3.78)	0.6243		
Day 295			-1.05 (-2.07, -0.03)			-2.15 (-5.68, 1.38)	1.10 (-2.53, 4.73)	0.5508		
Day 337			-0.97 (-2.14, 0.20)			-2.42 (-6.54, 1.70)	1.45 (-2.79, 5.69)	0.5021		
OVERALL	124	1	-1.40 (-2.06, -0.73)	55	7	-0.99 (-2.26, 0.28)	-0.40 (-1.72, 0.91)	0.5466	-0.10 (-0.42, 0.22)	0.5432

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Social/Family Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.3040
Japan	99	-1.20 (-1.79, -0.60)	46	-0.51 (-1.79, 0.76)	-0.68 (-2.09, 0.73)	0.3403	-0.20 (-0.55, 0.16)	0.2752	
Korea	25	-1.29 (-2.54, -0.04)	9	-3.18 (-6.36, 0.01)	1.89 (-1.54, 5.31)	0.2744	0.53 (-0.25, 1.30)	0.1819	
Lines of prior systemic therapy									0.7468
2	65	-0.83 (-1.54, -0.13)	35	-0.50 (-1.69, 0.69)	-0.34 (-1.73, 1.06)	0.6348	-0.11 (-0.52, 0.30)	0.6085	
3	34	-1.24 (-2.53, 0.06)	16	0.02 (-3.00, 3.04)	-1.25 (-4.54, 2.03)	0.4503	-0.27 (-0.87, 0.32)	0.3720	
>=4	25	-2.13 (-3.31, -0.96)	4	-4.92 (-10.51, 0.68)	2.78 (-2.93, 8.50)	0.3338	0.84 (-0.24, 1.92)	0.1255	
Age									0.9028
<65 years	54	-1.57 (-2.38, -0.76)	25	-2.15 (-4.26, -0.03)	0.57 (-1.69, 2.84)	0.6175	0.15 (-0.33, 0.62)	0.5425	
>=65 years	70	-0.94 (-1.69, -0.19)	30	-0.23 (-1.71, 1.25)	-0.71 (-2.37, 0.95)	0.4008	-0.20 (-0.63, 0.22)	0.3496	
Sex									0.3070
female	29	-1.42 (-2.70, -0.15)	13	1.02 (-1.42, 3.46)	-2.45 (-5.20, 0.31)	0.0803	-0.65 (-1.32, 0.01)	0.0550	
male	95	-1.18 (-1.79, -0.57)	42	-1.33 (-2.70, 0.04)	0.15 (-1.36, 1.65)	0.8478	0.04 (-0.32, 0.40)	0.8229	
ECOG PS									0.2246
0	62	-1.15 (-1.87, -0.43)	27	0.19 (-1.52, 1.91)	-1.34 (-3.21, 0.52)	0.1556	-0.39 (-0.85, 0.06)	0.0929	
1	62	-1.40 (-2.21, -0.58)	28	-1.65 (-3.24, -0.07)	0.26 (-1.54, 2.05)	0.7768	0.07 (-0.37, 0.52)	0.7523	
HER2 Status in central laboratory									0.3350
IHC 3+	96	-1.19 (-1.79, -0.58)	42	-0.40 (-1.82, 1.02)	-0.79 (-2.34, 0.76)	0.3191	-0.22 (-0.58, 0.15)	0.2391	
IHC 2+/ISH +	28	-1.38 (-2.67, -0.08)	13	-1.88 (-4.07, 0.32)	0.50 (-2.05, 3.05)	0.6965	0.14 (-0.52, 0.80)	0.6786	
Primary tumor location									0.4632
Gastric	107	-1.34 (-1.96, -0.71)	50	-0.67 (-1.93, 0.60)	-0.67 (-2.08, 0.75)	0.3534	-0.18 (-0.52, 0.16)	0.2951	
GEJ	17	-0.65 (-1.70, 0.39)	5	-3.25 (-7.80, 1.30)	2.60 (-2.07, 7.27)	0.2710	0.88 (-0.15, 1.91)	0.0956	
Histological subtype									0.7485
intestinal	89	-0.95 (-1.57, -0.34)	36	-0.62 (-2.01, 0.76)	-0.33 (-1.85, 1.19)	0.6681	-0.10 (-0.49, 0.29)	0.6178	
diffuse	28	-1.93 (-3.27, -0.59)	14	-0.73 (-3.82, 2.36)	-1.20 (-4.60, 2.20)	0.4832	-0.27 (-0.92, 0.37)	0.4058	
others	7	-2.64 (-4.11, -1.17)	5	-2.15 (-4.28, -0.02)	-0.49 (-3.15, 2.17)	0.7031	-0.24 (-1.39, 0.91)	0.6800	
Number of metastatic sites									0.6218
<2	24	-1.00 (-2.31, 0.31)	10	-0.13 (-2.76, 2.49)	-0.87 (-3.83, 2.10)	0.5584	-0.25 (-0.99, 0.49)	0.5070	
>= 2	100	-1.31 (-1.92, -0.69)	45	-1.12 (-2.54, 0.30)	-0.19 (-1.74, 1.36)	0.8120	-0.05 (-0.40, 0.30)	0.7800	
Previous total gastrectomy									0.4241
yes	22	-0.82 (-2.25, 0.60)	8	-2.16 (-7.28, 2.95)	1.34 (-4.01, 6.70)	0.6176	0.29 (-0.52, 1.10)	0.4806	
no	102	-1.32 (-1.92, -0.72)	47	-0.66 (-1.89, 0.56)	-0.65 (-2.02, 0.71)	0.3464	-0.19 (-0.53, 0.16)	0.2883	
Prior adjuvant/ neoadjuvant therapy									0.2939
yes	30	-1.03 (-2.19, 0.13)	8	-2.72 (-6.30, 0.87)	1.68 (-2.12, 5.48)	0.3798	0.47 (-0.32, 1.25)	0.2453	
no	94	-1.28 (-1.92, -0.65)	47	-0.42 (-1.67, 0.82)	-0.86 (-2.26, 0.54)	0.2262	-0.24 (-0.59, 0.11)	0.1775	
Prior ramucirumab contained treatment									0.1410
yes	93	-1.40 (-1.99, -0.82)	36	-1.18 (-2.78, 0.42)	-0.22 (-1.93, 1.48)	0.7973	-0.06 (-0.45, 0.32)	0.7479	
no	31	-0.72 (-1.95, 0.51)	19	-0.94 (-2.82, 0.95)	0.22 (-2.07, 2.50)	0.8492	0.06 (-0.51, 0.63)	0.8396	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

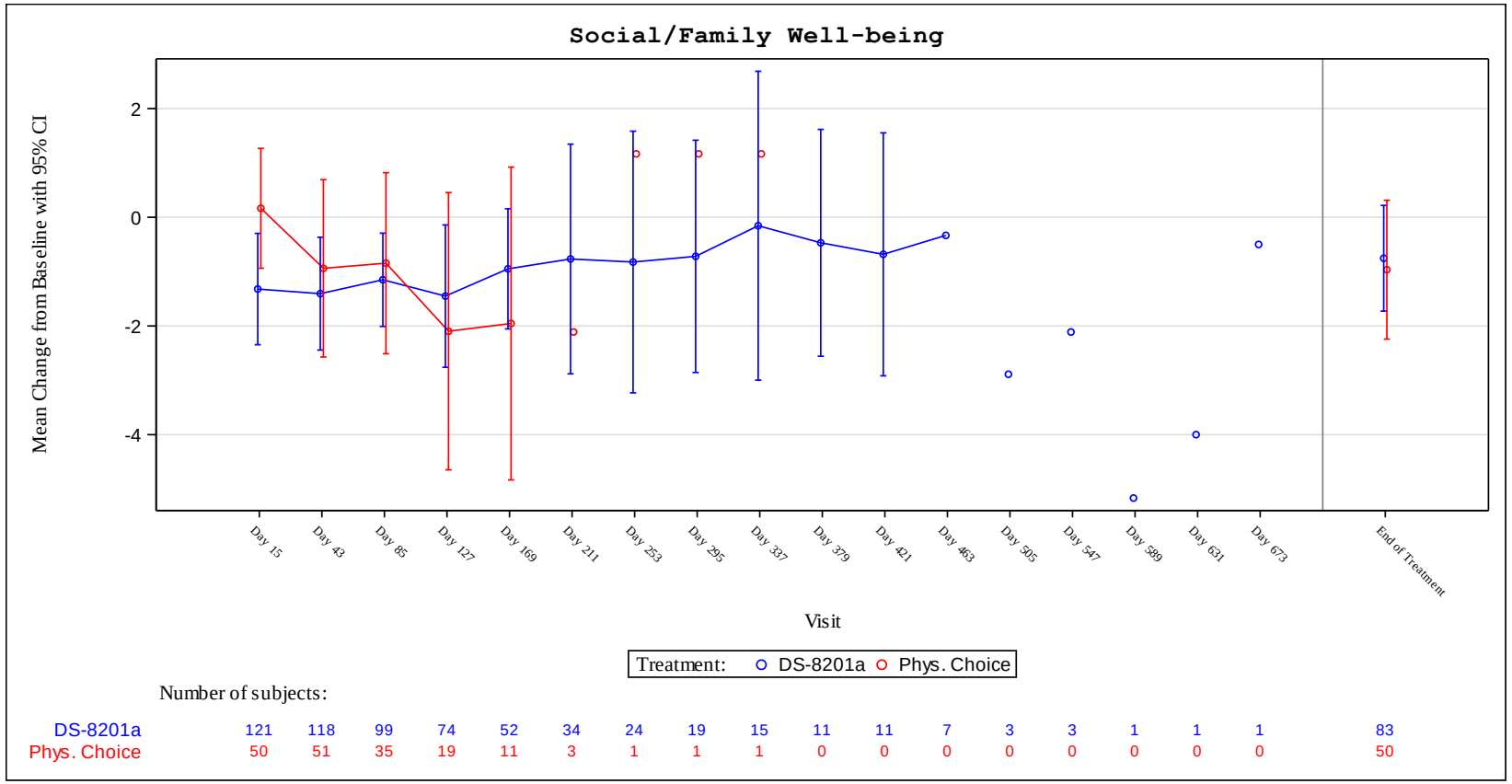
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Social/Family Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.3622
yes	33	-1.90 (-3.01, -0.79)	12	-1.43 (-5.04, 2.17)	-0.46 (-4.24, 3.31)	0.8077	-0.11 (-0.77, 0.55)	0.7436	
no	91	-0.93 (-1.56, -0.31)	43	-0.68 (-1.87, 0.51)	-0.25 (-1.60, 1.10)	0.7132	-0.08 (-0.44, 0.29)	0.6844	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.8282
yes	44	-1.44 (-2.43, -0.45)	13	-2.10 (-5.55, 1.34)	0.67 (-2.92, 4.25)	0.7140	0.16 (-0.46, 0.78)	0.6106	
no	80	-1.09 (-1.73, -0.44)	42	-0.43 (-1.56, 0.70)	-0.66 (-1.97, 0.65)	0.3205	-0.21 (-0.58, 0.17)	0.2814	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.8652
yes	22	-0.91 (-2.45, 0.63)	6	-0.30 (-3.38, 2.79)	-0.61 (-4.07, 2.85)	0.7193	-0.17 (-1.08, 0.73)	0.7086	
no	102	-1.28 (-1.87, -0.69)	49	-0.81 (-2.14, 0.52)	-0.47 (-1.92, 0.99)	0.5291	-0.13 (-0.47, 0.21)	0.4650	
Presence of liver metastasis at baseline									0.1233
yes	67	-1.64 (-2.40, -0.88)	30	-0.80 (-2.46, 0.87)	-0.84 (-2.67, 0.99)	0.3636	-0.23 (-0.66, 0.20)	0.2941	
no	57	-0.82 (-1.60, -0.04)	25	-0.76 (-2.46, 0.93)	-0.06 (-1.93, 1.81)	0.9512	-0.02 (-0.49, 0.45)	0.9435	
Renal impairment at baseline									0.9061
normal	33	-1.82 (-2.79, -0.85)	12	-1.28 (-5.75, 3.19)	-0.55 (-5.12, 4.02)	0.8135	-0.12 (-0.78, 0.54)	0.7263	
mild	53	-1.13 (-1.95, -0.31)	25	-1.11 (-2.61, 0.39)	-0.02 (-1.73, 1.69)	0.9806	-0.01 (-0.48, 0.47)	0.9788	
moderate	38	-0.74 (-1.83, 0.35)	17	0.08 (-1.97, 2.13)	-0.82 (-3.15, 1.51)	0.4858	-0.22 (-0.80, 0.35)	0.4433	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.8278
normal	87	-1.13 (-1.73, -0.53)	40	-0.36 (-1.66, 0.94)	-0.77 (-2.20, 0.66)	0.2908	-0.23 (-0.61, 0.14)	0.2248	
mild	36	-1.50 (-2.71, -0.29)	15	-2.15 (-4.82, 0.53)	0.65 (-2.29, 3.59)	0.6601	0.16 (-0.45, 0.76)	0.6085	
moderate	1	-1.37 (-3.54, 0.79)	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.9322
yes	8	-0.56 (-2.48, 1.36)	4	-1.62 (-5.25, 2.02)	1.05 (-3.29, 5.40)	0.6114	0.38 (-0.83, 1.59)	0.5372	
no	116	-1.24 (-1.81, -0.66)	51	-1.09 (-2.42, 0.25)	-0.15 (-1.60, 1.30)	0.8377	-0.04 (-0.37, 0.29)	0.8095	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.3027
yes	3	2.05 (-0.62, 4.72)	3	-1.84 (-4.61, 0.93)	3.89 (-0.51, 8.30)	0.0734	2.09 (0.10, 4.07)	0.0398	
no	121	-1.29 (-1.85, -0.74)	52	-1.17 (-2.55, 0.21)	-0.12 (-1.61, 1.37)	0.8710	-0.03 (-0.36, 0.29)	0.8449	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Graphical Summary of Social/Family Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	53 (42.4)	17 (27.4)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	5.9 (4.2, NE)	NE (4.1, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.45 (0.84, 2.51)	
p-value [c]	0.1954	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.46 (0.84, 2.52)	
p-value [c]	0.1848	

Time to Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.5122
Japan	42/ 99 (42.4)	5.9 (4.2, NE)	13/ 50 (26.0)	NE (4.1, NE)	1.58 (0.84, 2.94)	0.1545	
Korea	11/ 26 (42.3)	4.6 (1.4, NE)	4/ 12 (33.3)	4.4 (0.5, NE)	1.05 (0.33, 3.32)	0.9716	
Lines of prior systemic therapy							0.5699
2	26/ 66 (39.4)	NE (4.2, NE)	10/ 38 (26.3)	NE (3.0, NE)	1.48 (0.71, 3.07)	0.3027	
3	18/ 34 (52.9)	4.2 (1.4, NE)	5/ 18 (27.8)	NE (1.5, NE)	1.87 (0.69, 5.04)	0.2109	
>=4	9/ 25 (36.0)	NE (0.6, NE)	2/ 6 (33.3)	4.1 (0.7, NE)	0.82 (0.18, 3.80)	0.7814	
Age							0.7262
<65 years	25/ 55 (45.5)	4.2 (1.4, NE)	8/ 27 (29.6)	4.4 (2.6, NE)	1.63 (0.73, 3.62)	0.2399	
>=65 years	28/ 70 (40.0)	NE (4.2, NE)	9/ 35 (25.7)	NE (3.0, NE)	1.34 (0.63, 2.84)	0.4490	
Sex							0.4345
female	11/ 30 (36.7)	NE (1.6, NE)	2/ 15 (13.3)	NE (NE , NE)	2.56 (0.57, 11.59)	0.1933	
male	42/ 95 (44.2)	5.9 (3.2, NE)	15/ 47 (31.9)	4.4 (3.0, NE)	1.32 (0.73, 2.38)	0.3822	
ECOG PS							0.1193
0	25/ 62 (40.3)	NE (4.2, NE)	4/ 30 (13.3)	NE (NE , NE)	2.91 (1.01, 8.37)	0.0380	
1	28/ 63 (44.4)	4.6 (1.4, NE)	13/ 32 (40.6)	4.1 (1.5, NE)	1.02 (0.52, 1.98)	0.9864	
HER2 Status in central laboratory							0.2112
IHC 3+	40/ 96 (41.7)	NE (4.2, NE)	10/ 47 (21.3)	NE (4.1, NE)	1.88 (0.94, 3.77)	0.0729	
IHC 2+/ISH +	13/ 29 (44.8)	4.2 (1.4, NE)	7/ 15 (46.7)	4.4 (0.7, NE)	0.86 (0.34, 2.18)	0.7252	
Primary tumor location							0.5801
Gastric	45/108 (41.7)	5.9 (4.2, NE)	16/ 55 (29.1)	NE (4.1, NE)	1.41 (0.79, 2.50)	0.2503	
GEJ	8/ 17 (47.1)	4.2 (1.4, NE)	1/ 7 (14.3)	4.4 (NE , NE)	2.61 (0.32, 20.97)	0.3487	
Histological subtype							0.4804
intestinal	39/ 89 (43.8)	5.9 (4.2, NE)	10/ 38 (26.3)	NE (4.1, NE)	1.62 (0.81, 3.26)	0.1731	
diffuse	11/ 28 (39.3)	NE (0.6, NE)	6/ 18 (33.3)	NE (0.7, NE)	1.11 (0.41, 3.00)	0.8691	
others	3/ 8 (37.5)	1.4 (1.4, NE)	1/ 6 (16.7)	NE (4.4, NE)	4.00 (0.41, 39.49)	0.2063	
Number of metastatic sites							0.5652
<2	9/ 24 (37.5)	NE (2.8, NE)	3/ 10 (30.0)	4.4 (0.5, NE)	1.05 (0.28, 3.93)	0.9479	
>= 2	44/101 (43.6)	4.6 (1.8, NE)	14/ 52 (26.9)	NE (3.0, NE)	1.60 (0.87, 2.92)	0.1302	
Previous total gastrectomy							0.5653
yes	8/ 22 (36.4)	NE (0.6, NE)	3/ 9 (33.3)	4.1 (0.7, NE)	1.13 (0.30, 4.29)	0.8718	
no	45/103 (43.7)	4.6 (3.2, NE)	14/ 53 (26.4)	NE (4.4, NE)	1.55 (0.85, 2.83)	0.1570	
Prior adjuvant/ neoadjuvant therapy							0.3131
yes	12/ 30 (40.0)	NE (1.4, NE)	4/ 10 (40.0)	4.4 (0.7, NE)	0.88 (0.28, 2.73)	0.8077	
no	41/ 95 (43.2)	5.9 (3.2, NE)	13/ 52 (25.0)	NE (4.4, NE)	1.67 (0.89, 3.13)	0.1074	
Prior ramucirumab contained treatment							0.2917
yes	40/ 94 (42.6)	5.9 (2.8, NE)	9/ 41 (22.0)	NE (4.1, NE)	1.86 (0.90, 3.84)	0.0926	
no	13/ 31 (41.9)	NE (1.4, NE)	8/ 21 (38.1)	NE (1.4, NE)	1.03 (0.42, 2.49)	0.9722	
Prior nivolumab contained treatment							0.7351
yes	19/ 33 (57.6)	4.2 (1.4, NE)	4/ 15 (26.7)	4.1 (0.6, NE)	1.67 (0.56, 4.92)	0.3511	
no	34/ 92 (37.0)	NE (4.2, NE)	13/ 47 (27.7)	NE (4.4, NE)	1.34 (0.70, 2.54)	0.3937	

Time to Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

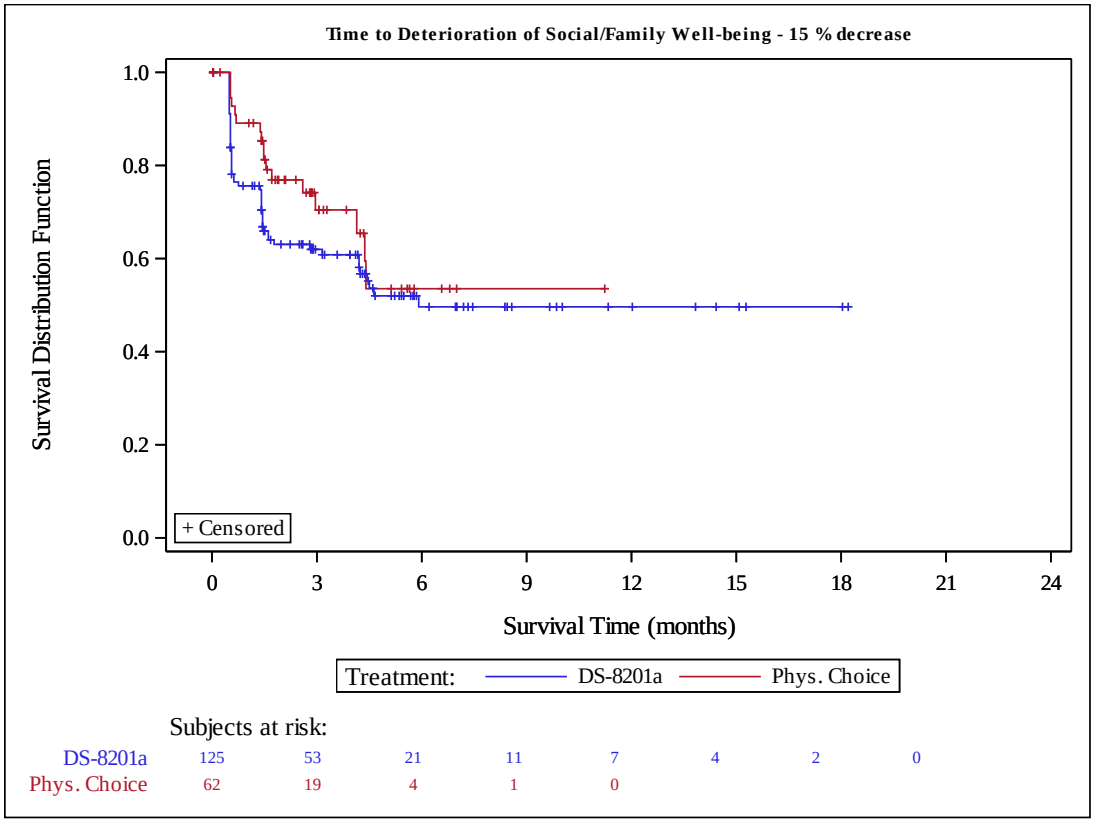
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.6146
yes	22/ 44 (50.0)	4.5 (1.4, NE)	5/ 17 (29.4)	4.1 (0.6, NE)	1.15 (0.43, 3.05)	0.7783	
no	31/ 81 (38.3)	NE (4.2, NE)	12/ 45 (26.7)	NE (4.4, NE)	1.54 (0.79, 3.00)	0.2146	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.5680
yes	7/ 22 (31.8)	5.9 (4.2, NE)	2/ 7 (28.6)	4.1 (0.5, NE)	0.89 (0.18, 4.34)	0.8895	
no	46/103 (44.7)	4.6 (2.8, NE)	15/ 55 (27.3)	NE (4.4, NE)	1.59 (0.89, 2.86)	0.1231	
Presence of liver metastasis at baseline							0.7887
yes	28/ 67 (41.8)	4.5 (1.8, NE)	9/ 34 (26.5)	NE (2.6, NE)	1.56 (0.73, 3.31)	0.2545	
no	25/ 58 (43.1)	NE (2.8, NE)	8/ 28 (28.6)	NE (4.4, NE)	1.34 (0.60, 2.98)	0.4823	
Renal impairment at baseline							0.9464
normal	16/ 33 (48.5)	3.2 (1.4, NE)	4/ 13 (30.8)	NE (1.4, NE)	1.66 (0.56, 4.98)	0.3644	
mild	22/ 53 (41.5)	5.9 (4.2, NE)	8/ 28 (28.6)	4.4 (2.6, NE)	1.22 (0.54, 2.77)	0.6517	
moderate	15/ 39 (38.5)	NE (1.8, NE)	5/ 20 (25.0)	NE (1.7, NE)	1.54 (0.56, 4.24)	0.4096	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7739
normal	39/ 88 (44.3)	5.9 (3.2, NE)	12/ 47 (25.5)	NE (3.0, NE)	1.56 (0.82, 3.00)	0.1814	
mild	14/ 36 (38.9)	NE (1.4, NE)	5/ 15 (33.3)	4.4 (0.7, NE)	1.28 (0.46, 3.56)	0.6513	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3535
yes	1/ 8 (12.5)	NE (0.5, NE)	1/ 5 (20.0)	NE (0.7, NE)	0.53 (0.03, 8.56)	0.6528	
no	52/117 (44.4)	4.6 (3.2, NE)	16/ 57 (28.1)	NE (4.1, NE)	1.53 (0.87, 2.68)	0.1445	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9859
yes	0/ 3 (0.0)	NE (NE , NE)	1/ 4 (25.0)	NE (0.7, NE)	NE	NE	
no	53/122 (43.4)	5.9 (3.2, NE)	16/ 58 (27.6)	NE (4.1, NE)	1.50 (0.86, 2.64)	0.1586	

Time to Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	38 (30.4)	14 (22.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (7.0, NE)	NE (4.4, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.94 (0.50, 1.77)	
p-value [c]	0.8401	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.97 (0.52, 1.80)	
p-value [c]	0.8991	

Time to Definitive Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.4591
Japan	28/ 99 (28.3)	NE (7.2, NE)	10/ 50 (20.0)	NE (4.4, NE)	1.11 (0.53, 2.31)	0.7876	
Korea	10/ 26 (38.5)	5.6 (4.2, NE)	4/ 12 (33.3)	4.4 (0.5, NE)	0.57 (0.17, 1.91)	0.3376	
Lines of prior systemic therapy							0.4178
2	18/ 66 (27.3)	NE (4.6, NE)	9/ 38 (23.7)	5.5 (4.3, NE)	0.87 (0.39, 1.97)	0.7339	
3	13/ 34 (38.2)	9.9 (2.9, NE)	3/ 18 (16.7)	NE (NE , NE)	1.73 (0.49, 6.15)	0.3920	
>=4	7/ 25 (28.0)	NE (5.9, NE)	2/ 6 (33.3)	4.1 (0.7, NE)	0.51 (0.10, 2.55)	0.3933	
Age							0.8760
<65 years	18/ 55 (32.7)	NE (5.6, NE)	7/ 27 (25.9)	4.4 (4.3, NE)	0.85 (0.34, 2.10)	0.7132	
>=65 years	20/ 70 (28.6)	NE (5.9, NE)	7/ 35 (20.0)	NE (4.1, NE)	1.04 (0.44, 2.47)	0.9369	
Sex							0.5162
female	9/ 30 (30.0)	NE (2.9, NE)	2/ 15 (13.3)	NE (NE , NE)	1.55 (0.33, 7.36)	0.5687	
male	29/ 95 (30.5)	NE (7.2, NE)	12/ 47 (25.5)	5.5 (4.3, NE)	0.85 (0.43, 1.69)	0.6331	
ECOG PS							0.0733
0	17/ 62 (27.4)	NE (7.2, NE)	2/ 30 (6.7)	NE (NE , NE)	3.02 (0.69, 13.22)	0.1235	
1	21/ 63 (33.3)	9.9 (4.6, NE)	12/ 32 (37.5)	4.4 (4.1, NE)	0.63 (0.30, 1.29)	0.1970	
HER2 Status in central laboratory							0.2885
IHC 3+	28/ 96 (29.2)	NE (7.2, NE)	7/ 47 (14.9)	NE (4.3, NE)	1.35 (0.58, 3.12)	0.4889	
IHC 2+/ISH +	10/ 29 (34.5)	5.9 (1.8, NE)	7/ 15 (46.7)	4.4 (1.7, NE)	0.64 (0.24, 1.73)	0.3646	
Primary tumor location							0.9236
Gastric	34/108 (31.5)	9.9 (5.9, NE)	13/ 55 (23.6)	NE (4.3, NE)	1.00 (0.52, 1.90)	0.9748	
GEJ	4/ 17 (23.5)	NE (3.2, NE)	1/ 7 (14.3)	4.4 (NE , NE)	0.96 (0.11, 8.73)	0.9701	
Histological subtype							0.5649
intestinal	26/ 89 (29.2)	NE (7.0, NE)	8/ 38 (21.1)	NE (4.1, NE)	1.06 (0.48, 2.37)	0.8912	
diffuse	9/ 28 (32.1)	NE (2.9, NE)	5/ 18 (27.8)	5.5 (1.4, NE)	0.74 (0.24, 2.29)	0.5834	
others	3/ 8 (37.5)	5.6 (1.4, 5.6)	1/ 6 (16.7)	NE (4.4, NE)	2.73 (0.28, 26.42)	0.3657	
Number of metastatic sites							0.6422
<2	7/ 24 (29.2)	NE (4.3, NE)	3/ 10 (30.0)	5.5 (2.8, NE)	0.68 (0.17, 2.65)	0.5754	
>= 2	31/101 (30.7)	9.9 (5.9, NE)	11/ 52 (21.2)	NE (4.3, NE)	1.05 (0.52, 2.12)	0.9011	
Previous total gastrectomy							0.3869
yes	4/ 22 (18.2)	NE (7.2, NE)	2/ 9 (22.2)	4.1 (0.7, NE)	0.51 (0.08, 3.15)	0.4634	
no	34/103 (33.0)	9.9 (5.6, NE)	12/ 53 (22.6)	NE (4.4, NE)	1.09 (0.56, 2.11)	0.8191	
Prior adjuvant/ neoadjuvant therapy							0.2819
yes	7/ 30 (23.3)	NE (7.2, NE)	3/ 10 (30.0)	4.4 (0.7, NE)	0.52 (0.13, 2.07)	0.3376	
no	31/ 95 (32.6)	9.9 (5.6, NE)	11/ 52 (21.2)	NE (4.4, NE)	1.14 (0.57, 2.29)	0.7188	
Prior ramucirumab contained treatment							0.9962
yes	29/ 94 (30.9)	9.9 (5.9, NE)	9/ 41 (22.0)	NE (4.1, NE)	0.95 (0.45, 2.04)	0.8934	
no	9/ 31 (29.0)	NE (4.6, NE)	5/ 21 (23.8)	NE (4.3, NE)	0.93 (0.31, 2.83)	0.8773	
Prior nivolumab contained treatment							0.6144
yes	14/ 33 (42.4)	NE (1.8, NE)	3/ 15 (20.0)	NE (0.6, NE)	1.44 (0.41, 5.07)	0.5698	
no	24/ 92 (26.1)	NE (7.0, NE)	11/ 47 (23.4)	5.5 (4.4, NE)	0.78 (0.38, 1.63)	0.5039	

Time to Definitive Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

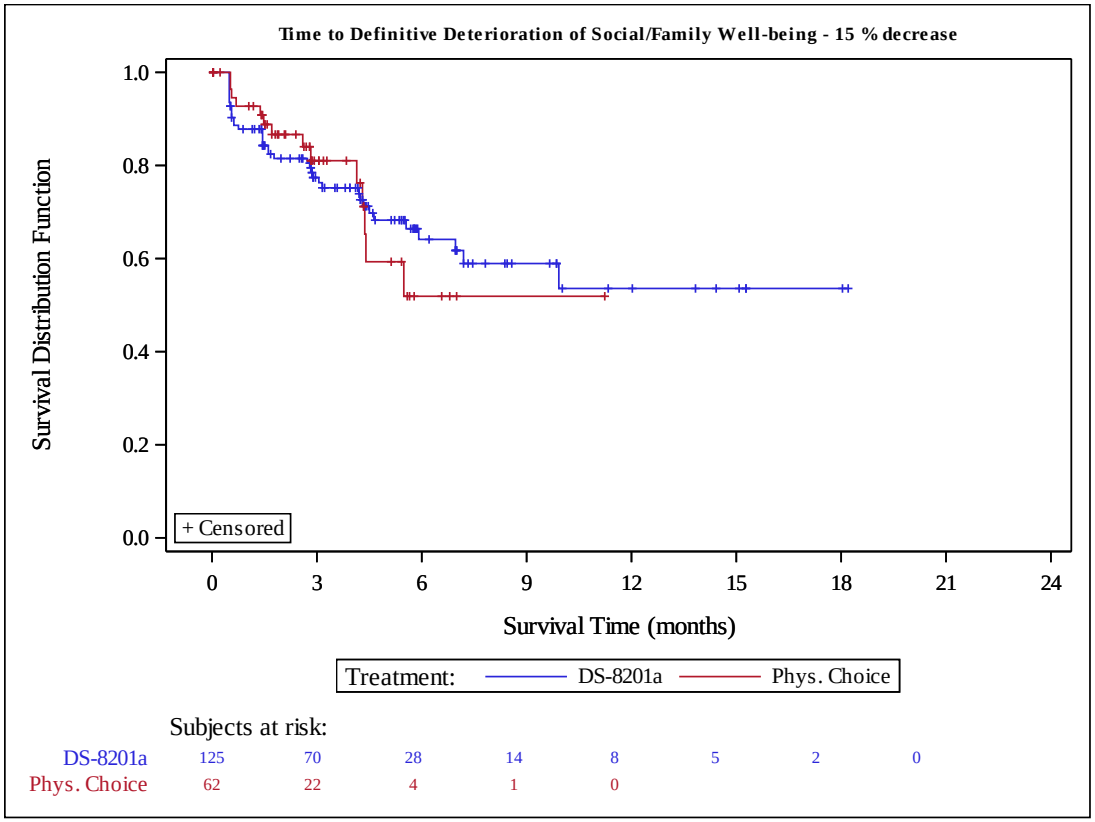
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8985
yes	17/ 44 (38.6)	NE (4.2, NE)	4/ 17 (23.5)	4.1 (2.8, NE)	1.02 (0.34, 3.06)	0.9877	
no	21/ 81 (25.9)	9.9 (7.0, NE)	10/ 45 (22.2)	NE (4.4, NE)	0.87 (0.40, 1.87)	0.7115	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.5483
yes	5/ 22 (22.7)	9.9 (5.9, 9.9)	2/ 7 (28.6)	4.1 (2.8, NE)	0.54 (0.10, 2.98)	0.4731	
no	33/103 (32.0)	NE (7.0, NE)	12/ 55 (21.8)	NE (4.4, NE)	1.07 (0.55, 2.10)	0.8475	
Presence of liver metastasis at baseline							0.5035
yes	22/ 67 (32.8)	9.9 (4.2, NE)	7/ 34 (20.6)	NE (4.1, NE)	1.17 (0.49, 2.76)	0.7298	
no	16/ 58 (27.6)	NE (5.9, NE)	7/ 28 (25.0)	5.5 (4.4, NE)	0.76 (0.31, 1.88)	0.5441	
Renal impairment at baseline							0.5887
normal	14/ 33 (42.4)	7.2 (3.2, NE)	3/ 13 (23.1)	4.3 (1.4, NE)	1.02 (0.28, 3.74)	0.9893	
mild	12/ 53 (22.6)	NE (5.9, NE)	7/ 28 (25.0)	5.5 (2.8, NE)	0.63 (0.24, 1.61)	0.3178	
moderate	12/ 39 (30.8)	NE (4.5, NE)	4/ 20 (20.0)	NE (4.4, NE)	1.40 (0.45, 4.34)	0.5657	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8967
normal	25/ 88 (28.4)	NE (7.0, NE)	9/ 47 (19.1)	NE (4.4, NE)	1.03 (0.47, 2.23)	0.9535	
mild	13/ 36 (36.1)	7.2 (2.9, NE)	5/ 15 (33.3)	4.4 (2.8, NE)	0.88 (0.30, 2.54)	0.8020	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.5643
yes	1/ 8 (12.5)	NE (7.2, NE)	1/ 5 (20.0)	NE (5.5, NE)	0.32 (0.02, 5.15)	0.3940	
no	37/117 (31.6)	NE (5.9, NE)	13/ 57 (22.8)	NE (4.3, NE)	1.02 (0.53, 1.93)	0.9784	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9878
yes	0/ 3 (0.0)	NE (NE , NE)	1/ 4 (25.0)	NE (5.5, NE)	NE	NE	
no	38/122 (31.1)	NE (7.0, NE)	13/ 58 (22.4)	NE (4.3, NE)	0.97 (0.51, 1.85)	0.9214	

Time to Definitive Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	121	17 (14.0)	74 (61.2)	30 (24.8)	52	6 (11.5)	40 (76.9)	6 (11.5)
	Day 43	118	14 (11.9)	77 (65.3)	27 (22.9)	53	6 (11.3)	39 (73.6)	8 (15.1)
	Day 85	99	7 (7.1)	72 (72.7)	20 (20.2)	36	4 (11.1)	26 (72.2)	6 (16.7)
	Day 127	74	10 (13.5)	43 (58.1)	21 (28.4)	19	1 (5.3)	13 (68.4)	5 (26.3)
	Day 169	52	3 (5.8)	39 (75.0)	10 (19.2)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 211	34	7 (20.6)	20 (58.8)	7 (20.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	24	2 (8.3)	15 (62.5)	7 (29.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	19	1 (5.3)	12 (63.2)	6 (31.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	1 (6.7)	11 (73.3)	3 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	8 (9.6)	58 (69.9)	17 (20.5)	53	4 (7.5)	38 (71.7)	11 (20.8)
Region									
Japan									
	Day 15	98	14 (14.3)	60 (61.2)	24 (24.5)	45	6 (13.3)	34 (75.6)	5 (11.1)
	Day 43	94	13 (13.8)	61 (64.9)	20 (21.3)	43	5 (11.6)	33 (76.7)	5 (11.6)
	Day 85	77	6 (7.8)	56 (72.7)	15 (19.5)	32	3 (9.4)	23 (71.9)	6 (18.8)
	Day 127	60	7 (11.7)	37 (61.7)	16 (26.7)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	45	2 (4.4)	36 (80.0)	7 (15.6)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	28	3 (10.7)	19 (67.9)	6 (21.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	0 (0.0)	11 (61.1)	7 (38.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	0 (0.0)	10 (71.4)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	0 (0.0)	10 (90.9)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	65	5 (7.7)	49 (75.4)	11 (16.9)	45	4 (8.9)	33 (73.3)	8 (17.8)
Region									
Korea									
	Day 15	23	3 (13.0)	14 (60.9)	6 (26.1)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 43	24	1 (4.2)	16 (66.7)	7 (29.2)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 85	22	1 (4.5)	16 (72.7)	5 (22.7)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 127	14	3 (21.4)	6 (42.9)	5 (35.7)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	7	1 (14.3)	3 (42.9)	3 (42.9)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	4 (66.7)	1 (16.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	3 (16.7)	9 (50.0)	6 (33.3)	8	0 (0.0)	5 (62.5)	3 (37.5)
Lines of prior systemic therapy									
2									
	Day 15	62	10 (16.1)	39 (62.9)	13 (21.0)	34	3 (8.8)	28 (82.4)	3 (8.8)
	Day 43	62	8 (12.9)	42 (67.7)	12 (19.4)	36	4 (11.1)	28 (77.8)	4 (11.1)
	Day 85	50	2 (4.0)	38 (76.0)	10 (20.0)	21	2 (9.5)	14 (66.7)	5 (23.8)
	Day 127	33	3 (9.1)	20 (60.6)	10 (30.3)	14	0 (0.0)	10 (71.4)	4 (28.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 169	21	0 (0.0)	17 (81.0)	4 (19.0)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	14	5 (35.7)	7 (50.0)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	10	2 (20.0)	7 (70.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	0 (0.0)	5 (71.4)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	5 (11.1)	30 (66.7)	10 (22.2)	32	1 (3.1)	24 (75.0)	7 (21.9)
Lines of prior systemic therapy 3									
	Day 15	34	4 (11.8)	20 (58.8)	10 (29.4)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 43	33	5 (15.2)	18 (54.5)	10 (30.3)	14	2 (14.3)	8 (57.1)	4 (28.6)
	Day 85	28	4 (14.3)	17 (60.7)	7 (25.0)	12	2 (16.7)	9 (75.0)	1 (8.3)
	Day 127	23	4 (17.4)	11 (47.8)	8 (34.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	17	2 (11.8)	12 (70.6)	3 (17.6)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 211	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	9	0 (0.0)	5 (55.6)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	3 (14.3)	12 (57.1)	6 (28.6)	16	3 (18.8)	11 (68.8)	2 (12.5)
Lines of prior systemic therapy >=4									
	Day 15	25	3 (12.0)	15 (60.0)	7 (28.0)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 43	23	1 (4.3)	17 (73.9)	5 (21.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	1 (4.8)	17 (81.0)	3 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	3 (16.7)	12 (66.7)	3 (16.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	14	1 (7.1)	10 (71.4)	3 (21.4)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	0 (0.0)	16 (94.1)	1 (5.9)	5	0 (0.0)	3 (60.0)	2 (40.0)
Age <65 years									
	Day 15	52	5 (9.6)	33 (63.5)	14 (26.9)	22	1 (4.5)	19 (86.4)	2 (9.1)
	Day 43	52	5 (9.6)	34 (65.4)	13 (25.0)	24	3 (12.5)	18 (75.0)	3 (12.5)
	Day 85	47	3 (6.4)	35 (74.5)	9 (19.1)	16	2 (12.5)	12 (75.0)	2 (12.5)
	Day 127	34	4 (11.8)	20 (58.8)	10 (29.4)	8	0 (0.0)	5 (62.5)	3 (37.5)
	Day 169	25	0 (0.0)	20 (80.0)	5 (20.0)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 211	16	2 (12.5)	9 (56.3)	5 (31.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	4 (10.5)	27 (71.1)	7 (18.4)	22	1 (4.5)	15 (68.2)	6 (27.3)
Age									
>=65 years									
	Day 15	69	12 (17.4)	41 (59.4)	16 (23.2)	30	5 (16.7)	21 (70.0)	4 (13.3)
	Day 43	66	9 (13.6)	43 (65.2)	14 (21.2)	29	3 (10.3)	21 (72.4)	5 (17.2)
	Day 85	52	4 (7.7)	37 (71.2)	11 (21.2)	20	2 (10.0)	14 (70.0)	4 (20.0)
	Day 127	40	6 (15.0)	23 (57.5)	11 (27.5)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 169	27	3 (11.1)	19 (70.4)	5 (18.5)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	18	5 (27.8)	11 (61.1)	2 (11.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	6 (50.0)	5 (41.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	1 (12.5)	5 (62.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	7	0 (0.0)	7 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	4 (8.9)	31 (68.9)	10 (22.2)	31	3 (9.7)	23 (74.2)	5 (16.1)
Sex									
female									
	Day 15	29	5 (17.2)	16 (55.2)	8 (27.6)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 43	28	3 (10.7)	19 (67.9)	6 (21.4)	13	2 (15.4)	9 (69.2)	2 (15.4)
	Day 85	20	0 (0.0)	17 (85.0)	3 (15.0)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	13	3 (23.1)	7 (53.8)	3 (23.1)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	9	0 (0.0)	8 (88.9)	1 (11.1)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	6	1 (16.7)	3 (50.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	0 (0.0)	17 (81.0)	4 (19.0)	14	2 (14.3)	11 (78.6)	1 (7.1)
Sex									
male									
	Day 15	92	12 (13.0)	58 (63.0)	22 (23.9)	39	5 (12.8)	30 (76.9)	4 (10.3)
	Day 43	90	11 (12.2)	58 (64.4)	21 (23.3)	40	4 (10.0)	30 (75.0)	6 (15.0)
	Day 85	79	7 (8.9)	55 (69.6)	17 (21.5)	28	3 (10.7)	19 (67.9)	6 (21.4)
	Day 127	61	7 (11.5)	36 (59.0)	18 (29.5)	16	0 (0.0)	11 (68.8)	5 (31.3)
	Day 169	43	3 (7.0)	31 (72.1)	9 (20.9)	9	0 (0.0)	6 (66.7)	3 (33.3)
	Day 211	28	6 (21.4)	17 (60.7)	5 (17.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	2 (10.0)	12 (60.0)	6 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	1 (5.9)	11 (64.7)	5 (29.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	10 (71.4)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	8 (12.9)	41 (66.1)	13 (21.0)	39	2 (5.1)	27 (69.2)	10 (25.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS									
0									
	Day 15	61	10 (16.4)	37 (60.7)	14 (23.0)	26	4 (15.4)	21 (80.8)	1 (3.8)
	Day 43	60	5 (8.3)	42 (70.0)	13 (21.7)	26	2 (7.7)	22 (84.6)	2 (7.7)
	Day 85	54	4 (7.4)	40 (74.1)	10 (18.5)	19	2 (10.5)	15 (78.9)	2 (10.5)
	Day 127	42	7 (16.7)	25 (59.5)	10 (23.8)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	33	2 (6.1)	28 (84.8)	3 (9.1)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 211	20	3 (15.0)	13 (65.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	1 (6.7)	9 (60.0)	5 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	0 (0.0)	7 (63.6)	4 (36.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	9	0 (0.0)	8 (88.9)	1 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	4 (10.3)	31 (79.5)	4 (10.3)	27	2 (7.4)	23 (85.2)	2 (7.4)
ECOG PS									
1									
	Day 15	60	7 (11.7)	37 (61.7)	16 (26.7)	26	2 (7.7)	19 (73.1)	5 (19.2)
	Day 43	58	9 (15.5)	35 (60.3)	14 (24.1)	27	4 (14.8)	17 (63.0)	6 (22.2)
	Day 85	45	3 (6.7)	32 (71.1)	10 (22.2)	17	2 (11.8)	11 (64.7)	4 (23.5)
	Day 127	32	3 (9.4)	18 (56.3)	11 (34.4)	10	0 (0.0)	6 (60.0)	4 (40.0)
	Day 169	19	1 (5.3)	11 (57.9)	7 (36.8)	5	0 (0.0)	2 (40.0)	3 (60.0)
	Day 211	14	4 (28.6)	7 (50.0)	3 (21.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	4 (9.1)	27 (61.4)	13 (29.5)	26	2 (7.7)	15 (57.7)	9 (34.6)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	93	13 (14.0)	56 (60.2)	24 (25.8)	38	3 (7.9)	33 (86.8)	2 (5.3)
	Day 43	92	14 (15.2)	58 (63.0)	20 (21.7)	40	5 (12.5)	28 (70.0)	7 (17.5)
	Day 85	79	7 (8.9)	59 (74.7)	13 (16.5)	26	4 (15.4)	18 (69.2)	4 (15.4)
	Day 127	59	8 (13.6)	35 (59.3)	16 (27.1)	13	0 (0.0)	11 (84.6)	2 (15.4)
	Day 169	41	2 (4.9)	33 (80.5)	6 (14.6)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	29	6 (20.7)	17 (58.6)	6 (20.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	2 (9.5)	13 (61.9)	6 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	1 (5.9)	10 (58.8)	6 (35.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	10 (71.4)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	7 (11.3)	43 (69.4)	12 (19.4)	39	3 (7.7)	30 (76.9)	6 (15.4)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	28	4 (14.3)	18 (64.3)	6 (21.4)	14	3 (21.4)	7 (50.0)	4 (28.6)
	Day 43	26	0 (0.0)	19 (73.1)	7 (26.9)	13	1 (7.7)	11 (84.6)	1 (7.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	20	0 (0.0)	13 (65.0)	7 (35.0)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	15	2 (13.3)	8 (53.3)	5 (33.3)	6	1 (16.7)	2 (33.3)	3 (50.0)
	Day 169	11	1 (9.1)	6 (54.5)	4 (36.4)	3	1 (33.3)	0 (0.0)	2 (66.7)
	Day 211	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	15 (71.4)	5 (23.8)	14	1 (7.1)	8 (57.1)	5 (35.7)
Primary tumor location									
Gastric									
	Day 15	104	15 (14.4)	62 (59.6)	27 (26.0)	46	6 (13.0)	34 (73.9)	6 (13.0)
	Day 43	101	12 (11.9)	65 (64.4)	24 (23.8)	48	5 (10.4)	35 (72.9)	8 (16.7)
	Day 85	84	6 (7.1)	62 (73.8)	16 (19.0)	33	4 (12.1)	23 (69.7)	6 (18.2)
	Day 127	63	9 (14.3)	36 (57.1)	18 (28.6)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	42	3 (7.1)	29 (69.0)	10 (23.8)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 211	29	5 (17.2)	18 (62.1)	6 (20.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	2 (10.0)	12 (60.0)	6 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	1 (6.7)	9 (60.0)	5 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	1 (8.3)	9 (75.0)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	8 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	7 (9.9)	48 (67.6)	16 (22.5)	47	4 (8.5)	33 (70.2)	10 (21.3)
Primary tumor location									
GEJ									
	Day 15	17	2 (11.8)	12 (70.6)	3 (17.6)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	17	2 (11.8)	12 (70.6)	3 (17.6)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 85	15	1 (6.7)	10 (66.7)	4 (26.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	7 (63.6)	3 (27.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	10	0 (0.0)	10 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	10 (83.3)	1 (8.3)	6	0 (0.0)	5 (83.3)	1 (16.7)
Histological subtype									
intestinal									
	Day 15	88	12 (13.6)	55 (62.5)	21 (23.9)	35	5 (14.3)	27 (77.1)	3 (8.6)
	Day 43	86	11 (12.8)	58 (67.4)	17 (19.8)	34	3 (8.8)	27 (79.4)	4 (11.8)
	Day 85	73	5 (6.8)	54 (74.0)	14 (19.2)	27	1 (3.7)	21 (77.8)	5 (18.5)
	Day 127	55	8 (14.5)	33 (60.0)	14 (25.5)	14	1 (7.1)	10 (71.4)	3 (21.4)
	Day 169	40	2 (5.0)	32 (80.0)	6 (15.0)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	25	4 (16.0)	17 (68.0)	4 (16.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	16	1 (6.3)	9 (56.3)	6 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	0 (0.0)	9 (69.2)	4 (30.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	0 (0.0)	9 (90.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	6 (9.5)	46 (73.0)	11 (17.5)	34	3 (8.8)	25 (73.5)	6 (17.6)
Histological subtype diffuse									
	Day 15	27	5 (18.5)	13 (48.1)	9 (33.3)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 43	26	2 (7.7)	17 (65.4)	7 (26.9)	14	1 (7.1)	9 (64.3)	4 (28.6)
	Day 85	22	2 (9.1)	15 (68.2)	5 (22.7)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 127	15	2 (13.3)	8 (53.3)	5 (33.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	10	1 (10.0)	7 (70.0)	2 (20.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	3 (37.5)	3 (37.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	16	1 (6.3)	10 (62.5)	5 (31.3)	16	1 (6.3)	10 (62.5)	5 (31.3)
Histological subtype others									
	Day 15	6	0 (0.0)	6 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	1 (16.7)	2 (33.3)	3 (50.0)	5	2 (40.0)	3 (60.0)	0 (0.0)
	Day 85	4	0 (0.0)	3 (75.0)	1 (25.0)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 127	4	0 (0.0)	2 (50.0)	2 (50.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	2	0 (0.0)	0 (0.0)	2 (100.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	1 (25.0)	2 (50.0)	1 (25.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
Number of metastatic sites <2									
	Day 15	23	5 (21.7)	14 (60.9)	4 (17.4)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	23	3 (13.0)	18 (78.3)	2 (8.7)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 85	22	1 (4.5)	16 (72.7)	5 (22.7)	8	1 (12.5)	5 (62.5)	2 (25.0)
	Day 127	18	3 (16.7)	9 (50.0)	6 (33.3)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 169	15	2 (13.3)	12 (80.0)	1 (6.7)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 211	10	2 (20.0)	7 (70.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	2 (33.3)	3 (50.0)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	3 (20.0)	9 (60.0)	3 (20.0)	8	1 (12.5)	5 (62.5)	2 (25.0)
Number of metastatic sites >= 2									
	Day 15	98	12 (12.2)	60 (61.2)	26 (26.5)	42	6 (14.3)	32 (76.2)	4 (9.5)
	Day 43	95	11 (11.6)	59 (62.1)	25 (26.3)	43	5 (11.6)	30 (69.8)	8 (18.6)
	Day 85	77	6 (7.8)	56 (72.7)	15 (19.5)	28	3 (10.7)	21 (75.0)	4 (14.3)
	Day 127	56	7 (12.5)	34 (60.7)	15 (26.8)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	37	1 (2.7)	27 (73.0)	9 (24.3)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 211	24	5 (20.8)	13 (54.2)	6 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	0 (0.0)	12 (66.7)	6 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	15	1 (6.7)	9 (60.0)	5 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	68	5 (7.4)	49 (72.1)	14 (20.6)	45	3 (6.7)	33 (73.3)	9 (20.0)
Previous total gastrectomy									
yes									
	Day 15	20	6 (30.0)	8 (40.0)	6 (30.0)	7	2 (28.6)	4 (57.1)	1 (14.3)
	Day 43	20	2 (10.0)	14 (70.0)	4 (20.0)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 85	18	1 (5.6)	17 (94.4)	0 (0.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	10 (90.9)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	8	1 (12.5)	7 (87.5)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 211	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	3 (17.6)	13 (76.5)	1 (5.9)	9	0 (0.0)	7 (77.8)	2 (22.2)
Previous total gastrectomy									
no									
	Day 15	101	11 (10.9)	66 (65.3)	24 (23.8)	45	4 (8.9)	36 (80.0)	5 (11.1)
	Day 43	98	12 (12.2)	63 (64.3)	23 (23.5)	45	6 (13.3)	32 (71.1)	7 (15.6)
	Day 85	81	6 (7.4)	55 (67.9)	20 (24.7)	30	4 (13.3)	20 (66.7)	6 (20.0)
	Day 127	63	9 (14.3)	33 (52.4)	21 (33.3)	17	1 (5.9)	12 (70.6)	4 (23.5)
	Day 169	44	2 (4.5)	32 (72.7)	10 (22.7)	10	1 (10.0)	7 (70.0)	2 (20.0)
	Day 211	27	6 (22.2)	15 (55.6)	6 (22.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	1 (4.8)	14 (66.7)	6 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	1 (6.3)	10 (62.5)	5 (31.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	0 (0.0)	9 (75.0)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	66	5 (7.6)	45 (68.2)	16 (24.2)	44	4 (9.1)	31 (70.5)	9 (20.5)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	8 (27.6)	14 (48.3)	7 (24.1)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 43	28	4 (14.3)	17 (60.7)	7 (25.0)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 85	27	2 (7.4)	20 (74.1)	5 (18.5)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 127	22	2 (9.1)	14 (63.6)	6 (27.3)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 169	13	2 (15.4)	10 (76.9)	1 (7.7)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 211	8	1 (12.5)	5 (62.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	3 (14.3)	18 (85.7)	0 (0.0)	9	0 (0.0)	7 (77.8)	2 (22.2)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	92	9 (9.8)	60 (65.2)	23 (25.0)	44	4 (9.1)	35 (79.5)	5 (11.4)
	Day 43	90	10 (11.1)	60 (66.7)	20 (22.2)	45	6 (13.3)	32 (71.1)	7 (15.6)
	Day 85	72	5 (6.9)	52 (72.2)	15 (20.8)	29	4 (13.8)	19 (65.5)	6 (20.7)
	Day 127	52	8 (15.4)	29 (55.8)	15 (28.8)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	39	1 (2.6)	29 (74.4)	9 (23.1)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 211	26	6 (23.1)	15 (57.7)	5 (19.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	1 (5.3)	12 (63.2)	6 (31.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	1 (7.1)	8 (57.1)	5 (35.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	0 (0.0)	7 (70.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	5 (8.1)	40 (64.5)	17 (27.4)	44	4 (9.1)	31 (70.5)	9 (20.5)
Prior ramucirumab contained treatment									
yes									
	Day 15	91	13 (14.3)	56 (61.5)	22 (24.2)	34	3 (8.8)	28 (82.4)	3 (8.8)
	Day 43	90	10 (11.1)	59 (65.6)	21 (23.3)	33	5 (15.2)	25 (75.8)	3 (9.1)
	Day 85	73	5 (6.8)	51 (69.9)	17 (23.3)	23	3 (13.0)	17 (73.9)	3 (13.0)
	Day 127	59	6 (10.2)	36 (61.0)	17 (28.8)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 169	41	2 (4.9)	30 (73.2)	9 (22.0)	7	1 (14.3)	4 (57.1)	2 (28.6)
	Day 211	25	2 (8.0)	17 (68.0)	6 (24.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	0 (0.0)	9 (60.0)	6 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	0 (0.0)	8 (61.5)	5 (38.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	5 (7.9)	47 (74.6)	11 (17.5)	35	3 (8.6)	26 (74.3)	6 (17.1)
Prior ramucirumab contained treatment									
no									
	Day 15	30	4 (13.3)	18 (60.0)	8 (26.7)	18	3 (16.7)	12 (66.7)	3 (16.7)
	Day 43	28	4 (14.3)	18 (64.3)	6 (21.4)	20	1 (5.0)	14 (70.0)	5 (25.0)
	Day 85	26	2 (7.7)	21 (80.8)	3 (11.5)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 127	15	4 (26.7)	7 (46.7)	4 (26.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 169	11	1 (9.1)	9 (81.8)	1 (9.1)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 211	9	5 (55.6)	3 (33.3)	1 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	2 (22.2)	6 (66.7)	1 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	4 (66.7)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	3 (15.0)	11 (55.0)	6 (30.0)	18	1 (5.6)	12 (66.7)	5 (27.8)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Prior nivolumab contained treatment									
yes									
	Day 15	33	4 (12.1)	19 (57.6)	10 (30.3)	13	3 (23.1)	8 (61.5)	2 (15.4)
	Day 43	31	2 (6.5)	18 (58.1)	11 (35.5)	10	0 (0.0)	7 (70.0)	3 (30.0)
	Day 85	27	3 (11.1)	17 (63.0)	7 (25.9)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 127	26	4 (15.4)	12 (46.2)	10 (38.5)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 169	20	1 (5.0)	14 (70.0)	5 (25.0)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 211	13	1 (7.7)	9 (69.2)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	0 (0.0)	5 (50.0)	5 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	15 (75.0)	4 (20.0)	13	2 (15.4)	9 (69.2)	2 (15.4)
Prior nivolumab contained treatment									
no									
	Day 15	88	13 (14.8)	55 (62.5)	20 (22.7)	39	3 (7.7)	32 (82.1)	4 (10.3)
	Day 43	87	12 (13.8)	59 (67.8)	16 (18.4)	43	6 (14.0)	32 (74.4)	5 (11.6)
	Day 85	72	4 (5.6)	55 (76.4)	13 (18.1)	26	4 (15.4)	17 (65.4)	5 (19.2)
	Day 127	48	6 (12.5)	31 (64.6)	11 (22.9)	16	0 (0.0)	12 (75.0)	4 (25.0)
	Day 169	32	2 (6.3)	25 (78.1)	5 (15.6)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	21	6 (28.6)	11 (52.4)	4 (19.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	14	2 (14.3)	10 (71.4)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	1 (9.1)	6 (54.5)	4 (36.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	5 (62.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	7 (11.1)	43 (68.3)	13 (20.6)	40	2 (5.0)	29 (72.5)	9 (22.5)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	43	5 (11.6)	26 (60.5)	12 (27.9)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 43	41	2 (4.9)	27 (65.9)	12 (29.3)	12	0 (0.0)	9 (75.0)	3 (25.0)
	Day 85	37	4 (10.8)	24 (64.9)	9 (24.3)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 127	31	5 (16.1)	15 (48.4)	11 (35.5)	4	1 (25.0)	1 (25.0)	2 (50.0)
	Day 169	23	2 (8.7)	16 (69.6)	5 (21.7)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 211	17	3 (17.6)	11 (64.7)	3 (17.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	13	1 (7.7)	7 (53.8)	5 (38.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	2 (7.1)	19 (67.9)	7 (25.0)	15	2 (13.3)	10 (66.7)	3 (20.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	78	12 (15.4)	48 (61.5)	18 (23.1)	37	3 (8.1)	31 (83.8)	3 (8.1)
	Day 43	77	12 (15.6)	50 (64.9)	15 (19.5)	41	6 (14.6)	30 (73.2)	5 (12.2)
	Day 85	62	3 (4.8)	48 (77.4)	11 (17.7)	25	4 (16.0)	17 (68.0)	4 (16.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 127	43	5 (11.6)	28 (65.1)	10 (23.3)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 169	29	1 (3.4)	23 (79.3)	5 (17.2)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	17	4 (23.5)	9 (52.9)	4 (23.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	11	1 (9.1)	8 (72.7)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	0 (0.0)	3 (42.9)	4 (57.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	0 (0.0)	3 (60.0)	2 (40.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	55	6 (10.9)	39 (70.9)	10 (18.2)	38	2 (5.3)	28 (73.7)	8 (21.1)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
yes									
	Day 15	22	3 (13.6)	14 (63.6)	5 (22.7)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 43	19	2 (10.5)	15 (78.9)	2 (10.5)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 85	16	2 (12.5)	12 (75.0)	2 (12.5)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 127	12	1 (8.3)	9 (75.0)	2 (16.7)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	7	1 (14.3)	5 (71.4)	1 (14.3)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	3	1 (33.3)	2 (66.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	10 (83.3)	2 (16.7)	6	1 (16.7)	3 (50.0)	2 (33.3)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
no									
	Day 15	99	14 (14.1)	60 (60.6)	25 (25.3)	46	5 (10.9)	36 (78.3)	5 (10.9)
	Day 43	99	12 (12.1)	62 (62.6)	25 (25.3)	47	5 (10.6)	34 (72.3)	8 (17.0)
	Day 85	83	5 (6.0)	60 (72.3)	18 (21.7)	31	3 (9.7)	23 (74.2)	5 (16.1)
	Day 127	62	9 (14.5)	34 (54.8)	19 (30.6)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	45	2 (4.4)	34 (75.6)	9 (20.0)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	31	6 (19.4)	18 (58.1)	7 (22.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	2 (9.1)	13 (59.1)	7 (31.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	0 (0.0)	12 (70.6)	5 (29.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	11 (78.6)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	8 (11.3)	48 (67.6)	15 (21.1)	47	3 (6.4)	35 (74.5)	9 (19.1)
Presence of liver metastasis at baseline									
yes									
	Day 15	66	8 (12.1)	40 (60.6)	18 (27.3)	27	6 (22.2)	20 (74.1)	1 (3.7)
	Day 43	63	6 (9.5)	43 (68.3)	14 (22.2)	28	3 (10.7)	20 (71.4)	5 (17.9)
	Day 85	50	3 (6.0)	32 (64.0)	15 (30.0)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 127	36	5 (13.9)	19 (52.8)	12 (33.3)	10	1 (10.0)	7 (70.0)	2 (20.0)
	Day 169	25	1 (4.0)	20 (80.0)	4 (16.0)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 211	14	2 (14.3)	8 (57.1)	4 (28.6)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 253	12	0 (0.0)	7 (58.3)	5 (41.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	4 (44.4)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	3 (6.7)	31 (68.9)	11 (24.4)	30	3 (10.0)	21 (70.0)	6 (20.0)
Presence of liver metastasis at baseline									
no									
	Day 15	55	9 (16.4)	34 (61.8)	12 (21.8)	25	0 (0.0)	20 (80.0)	5 (20.0)
	Day 43	55	8 (14.5)	34 (61.8)	13 (23.6)	25	3 (12.0)	19 (76.0)	3 (12.0)
	Day 85	49	4 (8.2)	40 (81.6)	5 (10.2)	20	2 (10.0)	16 (80.0)	2 (10.0)
	Day 127	38	5 (13.2)	24 (63.2)	9 (23.7)	9	0 (0.0)	6 (66.7)	3 (33.3)
	Day 169	27	2 (7.4)	19 (70.4)	6 (22.2)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 211	20	5 (25.0)	12 (60.0)	3 (15.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	10	0 (0.0)	8 (80.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	5 (13.2)	27 (71.1)	6 (15.8)	23	1 (4.3)	17 (73.9)	5 (21.7)
Renal impairment at baseline									
normal									
	Day 15	32	4 (12.5)	20 (62.5)	8 (25.0)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 43	33	2 (6.1)	23 (69.7)	8 (24.2)	12	2 (16.7)	6 (50.0)	4 (33.3)
	Day 85	26	1 (3.8)	18 (69.2)	7 (26.9)	8	2 (25.0)	6 (75.0)	0 (0.0)
	Day 127	19	3 (15.8)	11 (57.9)	5 (26.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	15	0 (0.0)	13 (86.7)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	10	1 (10.0)	4 (40.0)	5 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	0 (0.0)	4 (44.4)	5 (55.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	1 (14.3)	3 (42.9)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	2 (10.0)	13 (65.0)	5 (25.0)	11	1 (9.1)	7 (63.6)	3 (27.3)
Renal impairment at baseline									
mild									
	Day 15	51	5 (9.8)	34 (66.7)	12 (23.5)	25	4 (16.0)	18 (72.0)	3 (12.0)
	Day 43	51	8 (15.7)	32 (62.7)	11 (21.6)	23	1 (4.3)	21 (91.3)	1 (4.3)
	Day 85	45	3 (6.7)	33 (73.3)	9 (20.0)	14	1 (7.1)	8 (57.1)	5 (35.7)
	Day 127	31	3 (9.7)	19 (61.3)	9 (29.0)	9	0 (0.0)	6 (66.7)	3 (33.3)
	Day 169	21	2 (9.5)	14 (66.7)	5 (23.8)	6	0 (0.0)	3 (50.0)	3 (50.0)
	Day 211	13	1 (7.7)	11 (84.6)	1 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	8	0 (0.0)	6 (75.0)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	5 (83.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	4	0 (0.0)	4 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	1 (2.6)	31 (79.5)	7 (17.9)	22	2 (9.1)	15 (68.2)	5 (22.7)
Renal impairment at baseline									
moderate									
	Day 15	38	8 (21.1)	20 (52.6)	10 (26.3)	16	2 (12.5)	12 (75.0)	2 (12.5)
	Day 43	34	4 (11.8)	22 (64.7)	8 (23.5)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 85	28	3 (10.7)	21 (75.0)	4 (14.3)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 127	24	4 (16.7)	13 (54.2)	7 (29.2)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 169	16	1 (6.3)	12 (75.0)	3 (18.8)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 211	11	5 (45.5)	5 (45.5)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	5 (20.8)	14 (58.3)	5 (20.8)	19	1 (5.3)	15 (78.9)	3 (15.8)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	85	9 (10.6)	56 (65.9)	20 (23.5)	37	4 (10.8)	30 (81.1)	3 (8.1)
	Day 43	84	11 (13.1)	52 (61.9)	21 (25.0)	41	4 (9.8)	30 (73.2)	7 (17.1)
	Day 85	76	5 (6.6)	57 (75.0)	14 (18.4)	27	3 (11.1)	20 (74.1)	4 (14.8)
	Day 127	58	10 (17.2)	33 (56.9)	15 (25.9)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 169	40	3 (7.5)	30 (75.0)	7 (17.5)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	24	7 (29.2)	13 (54.2)	4 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	19	2 (10.5)	12 (63.2)	5 (26.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	1 (6.7)	10 (66.7)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	8 (72.7)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	56	6 (10.7)	41 (73.2)	9 (16.1)	40	2 (5.0)	31 (77.5)	7 (17.5)
Hepatic impairment at baseline									
mild									
	Day 15	35	8 (22.9)	17 (48.6)	10 (28.6)	15	2 (13.3)	10 (66.7)	3 (20.0)
	Day 43	33	3 (9.1)	24 (72.7)	6 (18.2)	12	2 (16.7)	9 (75.0)	1 (8.3)
	Day 85	22	2 (9.1)	14 (63.6)	6 (27.3)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 127	15	0 (0.0)	9 (60.0)	6 (40.0)	5	0 (0.0)	2 (40.0)	3 (60.0)
	Day 169	12	0 (0.0)	9 (75.0)	3 (25.0)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 211	10	0 (0.0)	7 (70.0)	3 (30.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	2 (7.7)	16 (61.5)	8 (30.8)	13	2 (15.4)	7 (53.8)	4 (30.8)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	0 (0.0)	7 (87.5)	1 (12.5)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	0 (0.0)	8 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	0 (0.0)	7 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 127	6	1 (16.7)	5 (83.3)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	0 (0.0)	5 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	5	1 (20.0)	4 (80.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	113	17 (15.0)	67 (59.3)	29 (25.7)	48	6 (12.5)	37 (77.1)	5 (10.4)
	Day 43	110	14 (12.7)	69 (62.7)	27 (24.5)	50	6 (12.0)	36 (72.0)	8 (16.0)
	Day 85	92	7 (7.6)	65 (70.7)	20 (21.7)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	68	9 (13.2)	38 (55.9)	21 (30.9)	16	1 (6.3)	10 (62.5)	5 (31.3)
	Day 169	47	3 (6.4)	34 (72.3)	10 (21.3)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	30	6 (20.0)	18 (60.0)	6 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	1 (5.0)	13 (65.0)	6 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	17	1 (5.9)	11 (64.7)	5 (29.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	14	1 (7.1)	10 (71.4)	3 (21.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	9 (90.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	7 (9.0)	54 (69.2)	17 (21.8)	50	4 (8.0)	36 (72.0)	10 (20.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 127	3	1 (33.3)	2 (66.7)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	0 (0.0)	3 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	1 (50.0)	1 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	1 (100.0)	0 (0.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors no									
	Day 15	118	17 (14.4)	71 (60.2)	30 (25.4)	49	6 (12.2)	38 (77.6)	5 (10.2)
	Day 43	115	14 (12.2)	74 (64.3)	27 (23.5)	50	6 (12.0)	36 (72.0)	8 (16.0)
	Day 85	96	7 (7.3)	69 (71.9)	20 (20.8)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	71	9 (12.7)	41 (57.7)	21 (29.6)	16	1 (6.3)	10 (62.5)	5 (31.3)
	Day 169	49	3 (6.1)	36 (73.5)	10 (20.4)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	32	6 (18.8)	19 (59.4)	7 (21.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	1 (4.5)	14 (63.6)	7 (31.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	18	1 (5.6)	11 (61.1)	6 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	15	1 (6.7)	11 (73.3)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	7 (8.5)	58 (70.7)	17 (20.7)	51	4 (7.8)	37 (72.5)	10 (19.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Emotional Well-being Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	124 (99.2)	62	58 (93.5)
Day 15	125	118 (94.4)	62	52 (83.9)
Day 43	124	117 (94.4)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	52 (49.5)	45	11 (24.4)
Day 211	81	34 (42.0)	35	3 (8.6)
Day 253	62	24 (38.7)	26	1 (3.8)
Day 295	51	19 (37.3)	19	1 (5.3)
Day 337	45	15 (33.3)	14	1 (7.1)
Day 379	33	11 (33.3)	10	0 (0.0)
Day 421	22	11 (50.0)	3	0 (0.0)
Day 463	14	7 (50.0)	2	0 (0.0)
Day 505	11	3 (27.3)	2	0 (0.0)
Day 547	6	3 (50.0)	2	0 (0.0)
Day 589	4	1 (25.0)	2	0 (0.0)
Day 631	3	1 (33.3)	0	0 (0.0)
Day 673	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Emotional Well-being by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	124	16.2 (4.27)			58	16.7 (5.07)		
Day 15	118	16.3 (4.30)	117	0.1 (3.35)	52	17.8 (4.73)	49	0.5 (4.10)
Day 43	117	16.4 (4.69)	116	0.1 (3.52)	53	17.4 (4.97)	50	0.3 (3.91)
Day 85	99	16.5 (4.49)	98	0.0 (3.79)	36	17.2 (5.75)	34	-0.6 (4.04)
Day 127	74	17.6 (3.93)	73	0.3 (3.67)	19	17.9 (4.86)	18	-0.9 (5.10)
Day 169	52	17.4 (4.15)	51	0.0 (3.33)	11	18.9 (4.37)	10	0.0 (4.64)
Day 211	34	17.5 (4.66)	33	-0.0 (3.71)	3	22.7 (0.58)	2	0.0 (2.83)
Day 253	24	17.4 (4.30)	24	0.5 (4.14)	1	23.0 (-)	1	2.0 (-)
Day 295	19	17.2 (3.46)	19	0.9 (3.67)	1	23.0 (-)	1	2.0 (-)
Day 337	15	16.7 (4.42)	15	0.7 (4.03)	1	22.0 (-)	1	1.0 (-)
Day 379	11	17.2 (3.97)	11	0.7 (3.35)	0	-	0	-
Day 421	11	16.4 (4.08)	11	0.5 (3.05)	0	-	0	-
Day 463	7	17.4 (3.99)	7	0.6 (3.26)	0	-	0	-
Day 505	3	19.0 (3.00)	3	1.7 (0.58)	0	-	0	-
Day 547	3	18.3 (1.53)	3	1.0 (1.00)	0	-	0	-
Day 589	1	18.0 (-)	1	3.0 (-)	0	-	0	-
Day 631	1	12.0 (-)	1	-3.0 (-)	0	-	0	-
Day 673	1	14.0 (-)	1	-1.0 (-)	0	-	0	-
End of Treatment	83	15.0 (5.36)	82	-1.3 (4.16)	53	15.0 (6.13)	49	-1.9 (4.91)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Emotional Well-being by Visit
Full Analysis Set

Visit	DS-8201a (N=125)			Phys. Choice (N=62)			Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
	N [a]	N_MISS [b]	LSMean (95% CI)	N [a]	N_MISS [b]	LSMean (95% CI)				
Day 15			-0.36 (-1.00, 0.29)			0.12 (-0.85, 1.09)	-0.48 (-1.55, 0.60)	0.3837		
Day 43			-0.35 (-0.95, 0.25)			-0.16 (-1.03, 0.70)	-0.18 (-1.13, 0.76)	0.7035		
Day 85			-0.33 (-0.89, 0.23)			-0.59 (-1.47, 0.30)	0.25 (-0.69, 1.19)	0.5948		
Day 127			-0.32 (-0.88, 0.24)			-1.01 (-2.11, 0.09)	0.69 (-0.45, 1.83)	0.2342		
Day 169			-0.31 (-0.89, 0.28)			-1.44 (-2.86, -0.01)	1.13 (-0.34, 2.60)	0.1316		
Day 211			-0.29 (-0.94, 0.36)			-1.86 (-3.66, -0.06)	1.57 (-0.29, 3.42)	0.0980		
Day 253			-0.28 (-1.01, 0.45)			-2.28 (-4.49, -0.08)	2.00 (-0.27, 4.28)	0.0840		
Day 295			-0.27 (-1.10, 0.57)			-2.71 (-5.33, -0.09)	2.44 (-0.27, 5.15)	0.0770		
Day 337			-0.25 (-1.20, 0.69)			-3.13 (-6.17, -0.09)	2.88 (-0.27, 6.03)	0.0731		
OVERALL	123	2	-0.32 (-0.88, 0.23)	54	8	-0.87 (-1.89, 0.14)	0.55 (-0.51, 1.61)	0.3068	0.17 (-0.15, 0.49)	0.3113

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Emotional Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0059
Japan	98	-0.04 (-0.48, 0.40)	45	0.17 (-0.75, 1.09)	-0.22 (-1.24, 0.81)	0.6780	-0.08 (-0.44, 0.27)	0.6375	
Korea	25	0.09 (-1.41, 1.59)	9	-4.36 (-7.79, -0.93)	4.45 (0.68, 8.21)	0.0216	1.09 (0.29, 1.89)	0.0079	
Lines of prior systemic therapy									0.0874
2	64	0.20 (-0.43, 0.82)	34	-0.89 (-1.92, 0.13)	1.09 (-0.12, 2.30)	0.0765	0.40 (-0.02, 0.82)	0.0594	
3	34	-0.04 (-1.04, 0.95)	16	-0.87 (-3.00, 1.25)	0.83 (-1.52, 3.18)	0.4832	0.25 (-0.35, 0.84)	0.4191	
>=4	25	-0.40 (-1.26, 0.45)	4	4.95 (1.08, 8.82)	-5.35 (-9.32, -1.38)	0.0091	-2.26 (-3.47, -1.06)	0.0002	
Age									0.7491
<65 years	54	0.29 (-0.36, 0.95)	25	-0.87 (-2.40, 0.66)	1.16 (-0.52, 2.85)	0.1752	0.39 (-0.09, 0.87)	0.1073	
>=65 years	69	-0.27 (-0.92, 0.38)	29	-0.42 (-1.69, 0.85)	0.15 (-1.27, 1.58)	0.8325	0.05 (-0.38, 0.49)	0.8152	
Sex									0.8063
female	29	-0.28 (-1.35, 0.80)	12	-0.70 (-2.98, 1.58)	0.42 (-2.10, 2.95)	0.7380	0.13 (-0.54, 0.81)	0.7002	
male	94	0.08 (-0.43, 0.58)	42	-0.51 (-1.56, 0.54)	0.59 (-0.58, 1.76)	0.3223	0.21 (-0.16, 0.57)	0.2606	
ECOG PS									0.1624
0	61	-0.18 (-0.67, 0.30)	27	-0.14 (-1.27, 1.00)	-0.05 (-1.28, 1.19)	0.9412	-0.02 (-0.47, 0.43)	0.9304	
1	62	0.24 (-0.53, 1.01)	27	-0.80 (-2.26, 0.65)	1.04 (-0.61, 2.69)	0.2141	0.32 (-0.14, 0.77)	0.1739	
HER2 Status in central laboratory									0.1421
IHC 3+	95	0.12 (-0.38, 0.63)	41	-0.70 (-1.85, 0.44)	0.83 (-0.43, 2.08)	0.1948	0.28 (-0.08, 0.65)	0.1308	
IHC 2+/ISH +	28	-0.55 (-1.62, 0.53)	13	0.31 (-1.42, 2.04)	-0.85 (-2.90, 1.19)	0.4042	-0.29 (-0.95, 0.37)	0.3839	
Primary tumor location									0.6045
Gastric	106	-0.06 (-0.56, 0.44)	49	-0.57 (-1.56, 0.43)	0.51 (-0.61, 1.63)	0.3707	0.17 (-0.17, 0.51)	0.3161	
GEJ	17	0.22 (-0.94, 1.38)	5	0.86 (-2.45, 4.16)	-0.63 (-4.13, 2.86)	0.7171	-0.24 (-1.24, 0.76)	0.6369	
Histological subtype									0.1516
intestinal	88	-0.03 (-0.50, 0.45)	35	0.16 (-0.88, 1.20)	-0.19 (-1.33, 0.96)	0.7491	-0.07 (-0.47, 0.32)	0.7124	
diffuse	28	-0.08 (-1.42, 1.26)	14	-3.78 (-6.53, -1.04)	3.70 (0.64, 6.77)	0.0185	0.90 (0.23, 1.57)	0.0085	
others	7	0.43 (-1.60, 2.45)	5	1.53 (-1.21, 4.27)	-1.10 (-4.59, 2.38)	0.4897	-0.44 (-1.60, 0.72)	0.4550	
Number of metastatic sites									0.9744
<2	23	0.11 (-0.69, 0.92)	10	0.04 (-1.52, 1.59)	0.08 (-1.68, 1.83)	0.9311	0.04 (-0.71, 0.78)	0.9235	
>= 2	100	-0.03 (-0.58, 0.51)	44	-0.87 (-2.05, 0.30)	0.84 (-0.46, 2.13)	0.2029	0.27 (-0.09, 0.62)	0.1435	
Previous total gastrectomy									0.0816
yes	22	-0.36 (-1.59, 0.87)	8	3.18 (-0.35, 6.70)	-3.54 (-7.26, 0.19)	0.0628	-1.01 (-1.86, -0.16)	0.0194	
no	101	0.09 (-0.40, 0.57)	46	-0.88 (-1.85, 0.08)	0.97 (-0.11, 2.06)	0.0788	0.35 (0.00, 0.70)	0.0493	
Prior adjuvant/ neoadjuvant therapy									0.3068
yes	30	-0.12 (-0.92, 0.69)	7	1.98 (-0.90, 4.85)	-2.09 (-5.08, 0.90)	0.1677	-0.82 (-1.66, 0.02)	0.0566	
no	93	0.03 (-0.52, 0.58)	47	-0.77 (-1.78, 0.24)	0.80 (-0.35, 1.96)	0.1727	0.27 (-0.08, 0.62)	0.1351	
Prior ramucirumab contained treatment									0.0519
yes	92	-0.13 (-0.59, 0.33)	36	0.15 (-1.00, 1.31)	-0.28 (-1.52, 0.96)	0.6571	-0.11 (-0.49, 0.28)	0.5899	
no	31	0.39 (-0.88, 1.65)	18	-1.62 (-3.54, 0.30)	2.01 (-0.31, 4.32)	0.0878	0.54 (-0.05, 1.13)	0.0728	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

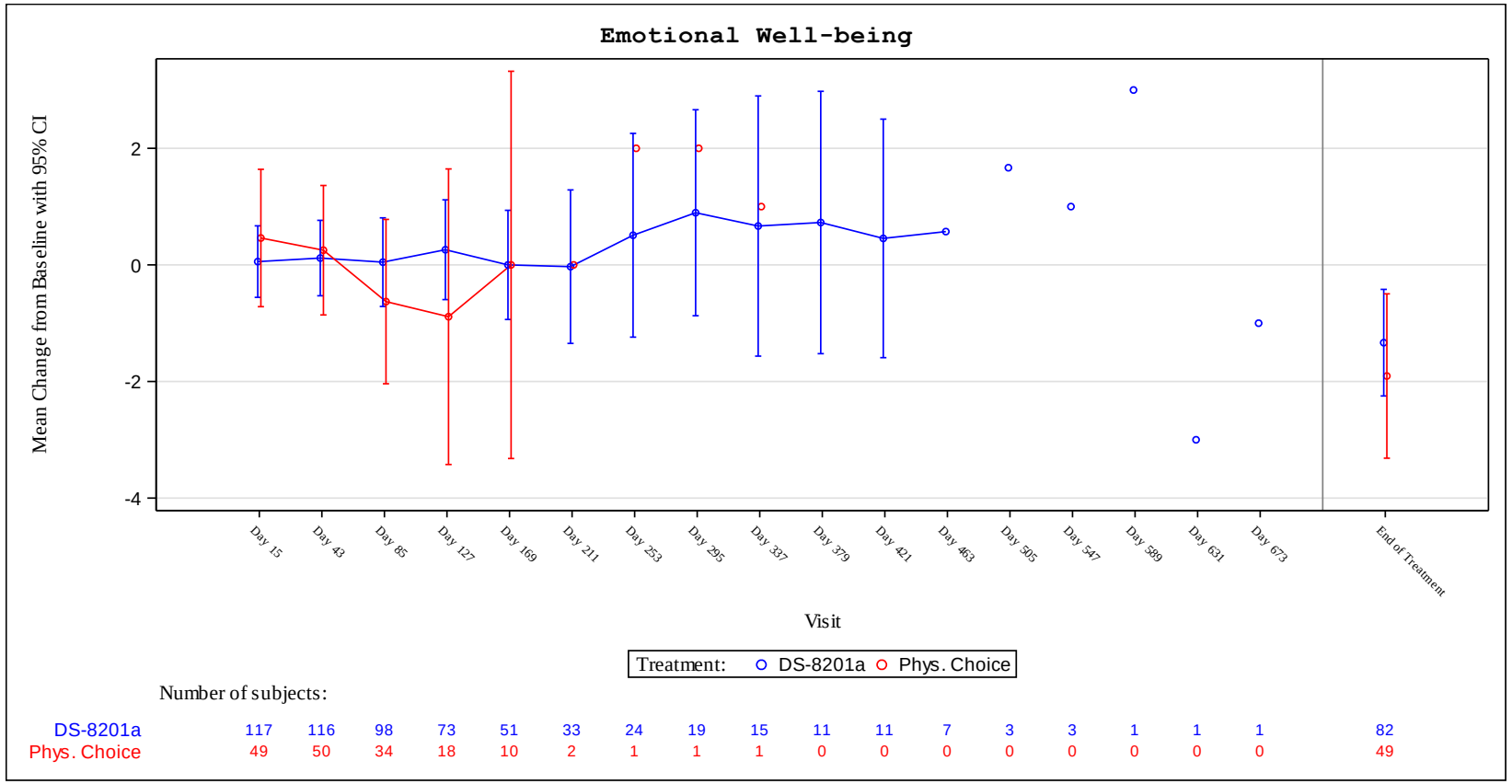
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Emotional Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.1544
yes	33	-0.26 (-1.12, 0.59)	12	0.62 (-1.84, 3.07)	-0.88 (-3.48, 1.72)	0.5036	-0.29 (-0.96, 0.37)	0.3888	
no	90	0.09 (-0.46, 0.64)	42	-0.66 (-1.68, 0.36)	0.75 (-0.42, 1.92)	0.2065	0.26 (-0.11, 0.63)	0.1644	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.0540
yes	44	-0.43 (-1.23, 0.36)	13	0.25 (-2.20, 2.70)	-0.68 (-3.26, 1.89)	0.6005	-0.22 (-0.84, 0.40)	0.4905	
no	79	0.26 (-0.30, 0.82)	41	-0.61 (-1.57, 0.36)	0.87 (-0.25, 1.99)	0.1272	0.32 (-0.06, 0.70)	0.1002	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.7188
yes	22	1.05 (-0.16, 2.26)	5	2.02 (-0.79, 4.83)	-0.97 (-4.04, 2.09)	0.5224	-0.35 (-1.32, 0.63)	0.4864	
no	101	-0.18 (-0.68, 0.32)	49	-0.91 (-1.94, 0.12)	0.73 (-0.41, 1.87)	0.2097	0.25 (-0.09, 0.59)	0.1553	
Presence of liver metastasis at baseline									0.9191
yes	67	0.17 (-0.40, 0.74)	29	-0.59 (-1.88, 0.69)	0.76 (-0.65, 2.17)	0.2869	0.28 (-0.16, 0.71)	0.2145	
no	56	-0.20 (-0.95, 0.54)	25	-0.61 (-2.07, 0.85)	0.40 (-1.24, 2.05)	0.6279	0.13 (-0.34, 0.60)	0.5878	
Renal impairment at baseline									0.0941
normal	33	0.33 (-0.51, 1.18)	12	-4.33 (-7.53, -1.13)	4.66 (1.36, 7.97)	0.0060	1.33 (0.61, 2.04)	0.0003	
mild	53	-0.20 (-0.83, 0.43)	25	0.69 (-0.44, 1.82)	-0.90 (-2.19, 0.40)	0.1733	-0.36 (-0.84, 0.12)	0.1409	
moderate	37	-0.07 (-1.09, 0.94)	16	-1.34 (-3.16, 0.48)	1.27 (-0.81, 3.36)	0.2279	0.39 (-0.20, 0.98)	0.1956	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.3660
normal	86	-0.06 (-0.61, 0.50)	40	-0.98 (-2.06, 0.11)	0.92 (-0.30, 2.14)	0.1403	0.32 (-0.06, 0.69)	0.1014	
mild	36	0.06 (-0.76, 0.87)	14	1.25 (-0.83, 3.34)	-1.20 (-3.45, 1.05)	0.2915	-0.41 (-1.03, 0.21)	0.1945	
moderate	1	0.55 (NE, NE)	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.1380
yes	8	-0.67 (-1.61, 0.26)	4	-0.07 (-1.89, 1.75)	-0.60 (-2.76, 1.55)	0.5612	-0.43 (-1.64, 0.78)	0.4863	
no	115	0.09 (-0.40, 0.57)	50	-0.91 (-1.96, 0.15)	0.99 (-0.17, 2.16)	0.0944	0.33 (-0.01, 0.66)	0.0551	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.3680
yes	3	-0.74 (-2.80, 1.32)	3	-0.08 (-2.18, 2.02)	-0.65 (-3.63, 2.32)	0.5596	-0.53 (-2.16, 1.09)	0.5201	
no	120	0.04 (-0.43, 0.51)	51	-0.95 (-2.04, 0.14)	0.99 (-0.20, 2.18)	0.1025	0.32 (-0.01, 0.65)	0.0551	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Graphical Summary of Emotional Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	42 (33.6)	17 (27.4)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	8.4 (6.9, NE)	NE (3.0, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.83 (0.46, 1.49)	
p-value [c]	0.5162	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.86 (0.48, 1.52)	
p-value [c]	0.5830	

Time to Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.7999
Japan	29/ 99 (29.3)	NE (6.9, NE)	13/ 50 (26.0)	NE (3.0, NE)	0.92 (0.48, 1.79)	0.8006	
Korea	13/ 26 (50.0)	8.4 (2.9, 11.3)	4/ 12 (33.3)	3.3 (0.5, NE)	0.56 (0.17, 1.90)	0.3314	
Lines of prior systemic therapy							0.8777
2	21/ 66 (31.8)	8.4 (5.9, NE)	11/ 38 (28.9)	5.5 (2.9, NE)	0.66 (0.31, 1.40)	0.2703	
3	12/ 34 (35.3)	NE (2.8, NE)	5/ 18 (27.8)	NE (2.6, NE)	1.16 (0.41, 3.31)	0.7872	
>=4	9/ 25 (36.0)	9.7 (2.9, 9.7)	1/ 6 (16.7)	NE (1.1, NE)	1.01 (0.12, 8.22)	0.9960	
Age							0.9467
<65 years	16/ 55 (29.1)	NE (7.0, NE)	6/ 27 (22.2)	NE (2.9, NE)	0.84 (0.32, 2.21)	0.7099	
>=65 years	26/ 70 (37.1)	8.4 (5.9, NE)	11/ 35 (31.4)	4.0 (2.9, NE)	0.88 (0.43, 1.80)	0.7265	
Sex							0.1777
female	13/ 30 (43.3)	5.9 (2.9, 8.4)	2/ 15 (13.3)	NE (1.2, NE)	1.81 (0.39, 8.30)	0.4425	
male	29/ 95 (30.5)	11.3 (8.4, NE)	15/ 47 (31.9)	5.5 (2.9, NE)	0.69 (0.37, 1.31)	0.2499	
ECOG PS							0.3895
0	21/ 62 (33.9)	8.4 (5.9, NE)	6/ 30 (20.0)	NE (4.0, NE)	1.10 (0.44, 2.78)	0.8402	
1	21/ 63 (33.3)	9.7 (4.6, NE)	11/ 32 (34.4)	5.5 (2.9, NE)	0.71 (0.33, 1.51)	0.3603	
HER2 Status in central laboratory							0.3843
IHC 3+	32/ 96 (33.3)	9.7 (6.9, NE)	14/ 47 (29.8)	NE (2.9, NE)	0.74 (0.39, 1.41)	0.3438	
IHC 2+/ISH +	10/ 29 (34.5)	8.4 (2.8, NE)	3/ 15 (20.0)	NE (2.8, NE)	1.45 (0.38, 5.50)	0.5801	
Primary tumor location							0.9875
Gastric	37/108 (34.3)	8.4 (5.9, NE)	17/ 55 (30.9)	5.5 (2.9, NE)	0.78 (0.44, 1.41)	0.4048	
GEJ	5/ 17 (29.4)	NE (2.7, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.7964
intestinal	28/ 89 (31.5)	8.4 (5.9, NE)	11/ 38 (28.9)	NE (2.9, NE)	0.87 (0.43, 1.76)	0.6893	
diffuse	11/ 28 (39.3)	9.7 (2.9, NE)	5/ 18 (27.8)	3.3 (2.6, NE)	0.74 (0.24, 2.22)	0.5622	
others	3/ 8 (37.5)	11.3 (0.5, 11.3)	1/ 6 (16.7)	NE (1.9, NE)	1.57 (0.14, 17.46)	0.7115	
Number of metastatic sites							0.8889
<2	7/ 24 (29.2)	NE (4.2, NE)	3/ 10 (30.0)	5.5 (2.8, NE)	0.76 (0.19, 2.96)	0.6925	
>= 2	35/101 (34.7)	8.4 (5.9, NE)	14/ 52 (26.9)	NE (2.9, NE)	0.87 (0.46, 1.64)	0.6429	
Previous total gastrectomy							0.2229
yes	8/ 22 (36.4)	9.7 (2.8, NE)	1/ 9 (11.1)	NE (3.3, NE)	2.91 (0.36, 23.66)	0.2956	
no	34/103 (33.0)	8.4 (6.9, NE)	16/ 53 (30.2)	5.5 (2.9, NE)	0.73 (0.40, 1.34)	0.2943	
Prior adjuvant/ neoadjuvant therapy							0.3466
yes	11/ 30 (36.7)	5.9 (5.9, NE)	1/ 10 (10.0)	NE (2.9, NE)	1.49 (0.18, 12.10)	0.7121	
no	31/ 95 (32.6)	11.3 (7.0, NE)	16/ 52 (30.8)	5.5 (2.9, NE)	0.81 (0.44, 1.51)	0.4953	
Prior ramucirumab contained treatment							0.4802
yes	29/ 94 (30.9)	11.3 (5.9, NE)	8/ 41 (19.5)	NE (4.0, NE)	1.15 (0.52, 2.56)	0.7383	
no	13/ 31 (41.9)	8.4 (2.9, NE)	9/ 21 (42.9)	3.0 (2.8, NE)	0.68 (0.28, 1.60)	0.3542	
Prior nivolumab contained treatment							0.4489
yes	11/ 33 (33.3)	NE (5.9, NE)	5/ 15 (33.3)	NE (1.2, NE)	0.73 (0.25, 2.12)	0.5411	
no	31/ 92 (33.7)	8.4 (5.9, NE)	12/ 47 (25.5)	5.5 (2.9, NE)	0.93 (0.47, 1.83)	0.8148	

Time to Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

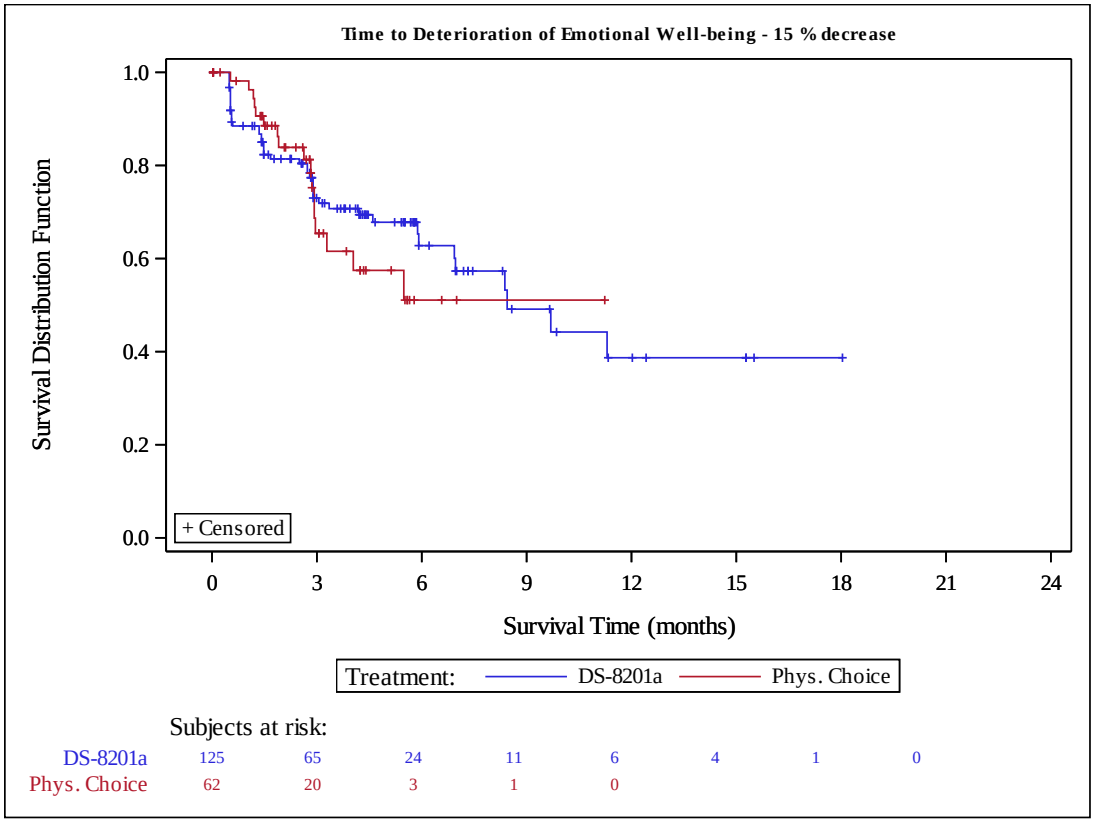
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.4543
yes	17/ 44 (38.6)	9.7 (3.4, NE)	6/ 17 (35.3)	3.3 (1.2, NE)	0.72 (0.28, 1.86)	0.4743	
no	25/ 81 (30.9)	8.4 (5.9, NE)	11/ 45 (24.4)	NE (2.9, NE)	0.91 (0.44, 1.88)	0.7957	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9695
yes	4/ 22 (18.2)	NE (4.2, NE)	1/ 7 (14.3)	NE (2.8, NE)	0.95 (0.10, 8.65)	0.9557	
no	38/103 (36.9)	8.4 (5.9, NE)	16/ 55 (29.1)	5.5 (3.0, NE)	0.87 (0.48, 1.58)	0.6371	
Presence of liver metastasis at baseline							0.4297
yes	20/ 67 (29.9)	8.4 (5.9, NE)	10/ 34 (29.4)	4.0 (2.9, NE)	0.72 (0.33, 1.56)	0.3854	
no	22/ 58 (37.9)	8.4 (4.6, NE)	7/ 28 (25.0)	NE (2.9, NE)	1.07 (0.45, 2.55)	0.8752	
Renal impairment at baseline							0.5008
normal	11/ 33 (33.3)	11.3 (4.6, NE)	4/ 13 (30.8)	NE (1.9, NE)	0.57 (0.17, 1.90)	0.3373	
mild	21/ 53 (39.6)	6.9 (3.4, NE)	7/ 28 (25.0)	NE (2.9, NE)	1.31 (0.55, 3.10)	0.5497	
moderate	10/ 39 (25.6)	8.4 (5.9, NE)	6/ 20 (30.0)	NE (2.9, NE)	0.49 (0.16, 1.49)	0.2005	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.6915
normal	31/ 88 (35.2)	8.4 (5.9, NE)	12/ 47 (25.5)	5.5 (3.3, NE)	0.89 (0.45, 1.76)	0.7241	
mild	11/ 36 (30.6)	9.7 (2.9, NE)	5/ 15 (33.3)	2.9 (1.2, NE)	0.76 (0.26, 2.23)	0.5947	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.1572
yes	6/ 8 (75.0)	2.7 (0.5, 8.4)	2/ 5 (40.0)	5.5 (1.1, NE)	2.24 (0.45, 11.24)	0.3168	
no	36/117 (30.8)	9.7 (6.9, NE)	15/ 57 (26.3)	NE (2.9, NE)	0.76 (0.41, 1.42)	0.3811	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.3813
yes	2/ 3 (66.7)	8.4 (2.7, 8.4)	1/ 4 (25.0)	NE (5.5, NE)	2.00 (0.18, 22.05)	0.5637	
no	40/122 (32.8)	9.7 (6.9, NE)	16/ 58 (27.6)	NE (2.9, NE)	0.81 (0.45, 1.47)	0.4731	

Time to Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	31 (24.8)	14 (22.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	14.4 (8.4, NE)	NE (3.3, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.57 (0.29, 1.12)	
p-value [c]	0.0945	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.60 (0.31, 1.16)	
p-value [c]	0.1261	

Time to Definitive Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.9590
Japan	19/ 99 (19.2)	NE (14.4, NE)	10/ 50 (20.0)	NE (5.5, NE)	0.63 (0.29, 1.38)	0.2390	
Korea	12/ 26 (46.2)	8.4 (4.6, 11.3)	4/ 12 (33.3)	3.3 (0.5, NE)	0.45 (0.13, 1.59)	0.1913	
Lines of prior systemic therapy							0.9796
2	17/ 66 (25.8)	8.4 (5.9, NE)	10/ 38 (26.3)	5.5 (2.9, NE)	0.53 (0.23, 1.21)	0.1252	
3	7/ 34 (20.6)	NE (4.6, NE)	3/ 18 (16.7)	NE (3.3, NE)	0.92 (0.23, 3.64)	0.9093	
>=4	7/ 25 (28.0)	14.4 (5.6, NE)	1/ 6 (16.7)	NE (1.1, NE)	0.59 (0.07, 5.14)	0.6322	
Age							0.6074
<65 years	12/ 55 (21.8)	NE (11.3, NE)	6/ 27 (22.2)	NE (2.9, NE)	0.51 (0.18, 1.45)	0.1964	
>=65 years	19/ 70 (27.1)	9.7 (5.9, NE)	8/ 35 (22.9)	NE (3.3, NE)	0.68 (0.29, 1.60)	0.3719	
Sex							0.2361
female	10/ 30 (33.3)	5.9 (4.6, NE)	2/ 15 (13.3)	NE (1.2, NE)	0.96 (0.19, 4.72)	0.9558	
male	21/ 95 (22.1)	NE (11.3, NE)	12/ 47 (25.5)	NE (2.9, NE)	0.51 (0.24, 1.07)	0.0700	
ECOG PS							0.9271
0	15/ 62 (24.2)	NE (7.0, NE)	6/ 30 (20.0)	NE (4.0, NE)	0.66 (0.25, 1.77)	0.4095	
1	16/ 63 (25.4)	11.3 (8.4, NE)	8/ 32 (25.0)	5.5 (2.9, NE)	0.57 (0.23, 1.38)	0.2065	
HER2 Status in central laboratory							0.1108
IHC 3+	22/ 96 (22.9)	NE (9.7, NE)	12/ 47 (25.5)	NE (2.9, NE)	0.43 (0.21, 0.91)	0.0229	
IHC 2+/ISH +	9/ 29 (31.0)	8.4 (2.8, NE)	2/ 15 (13.3)	NE (2.8, NE)	1.83 (0.38, 8.86)	0.4445	
Primary tumor location							0.9905
Gastric	28/108 (25.9)	11.3 (8.4, NE)	14/ 55 (25.5)	NE (2.9, NE)	0.56 (0.29, 1.09)	0.0844	
GEJ	3/ 17 (17.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.8162
intestinal	20/ 89 (22.5)	NE (8.4, NE)	8/ 38 (21.1)	NE (4.0, NE)	0.68 (0.29, 1.59)	0.3727	
diffuse	9/ 28 (32.1)	9.7 (5.6, NE)	5/ 18 (27.8)	3.3 (2.6, NE)	0.46 (0.14, 1.50)	0.1794	
others	2/ 8 (25.0)	11.3 (4.6, 11.3)	1/ 6 (16.7)	NE (1.9, NE)	0.82 (0.05, 13.24)	0.8864	
Number of metastatic sites							0.7073
<2	5/ 24 (20.8)	14.4 (8.4, NE)	3/ 10 (30.0)	5.5 (2.8, NE)	0.41 (0.09, 1.86)	0.2327	
>= 2	26/101 (25.7)	11.3 (7.0, NE)	11/ 52 (21.2)	NE (3.3, NE)	0.66 (0.32, 1.37)	0.2571	
Previous total gastrectomy							0.3314
yes	6/ 22 (27.3)	9.7 (5.6, NE)	1/ 9 (11.1)	NE (3.3, NE)	1.47 (0.16, 13.19)	0.7277	
no	25/103 (24.3)	14.4 (8.4, NE)	13/ 53 (24.5)	NE (2.9, NE)	0.52 (0.26, 1.05)	0.0642	
Prior adjuvant/ neoadjuvant therapy							0.5300
yes	8/ 30 (26.7)	9.7 (5.9, NE)	1/ 10 (10.0)	NE (2.9, NE)	0.58 (0.06, 5.58)	0.6313	
no	23/ 95 (24.2)	NE (8.4, NE)	13/ 52 (25.0)	NE (3.3, NE)	0.63 (0.31, 1.27)	0.1846	
Prior ramucirumab contained treatment							0.2874
yes	22/ 94 (23.4)	NE (9.7, NE)	6/ 41 (14.6)	NE (4.0, NE)	0.99 (0.39, 2.51)	0.9861	
no	9/ 31 (29.0)	8.4 (5.6, NE)	8/ 21 (38.1)	3.3 (2.8, NE)	0.34 (0.12, 0.96)	0.0314	
Prior nivolumab contained treatment							0.4626
yes	8/ 33 (24.2)	NE (5.9, NE)	4/ 15 (26.7)	NE (1.2, NE)	0.54 (0.16, 1.90)	0.3338	
no	23/ 92 (25.0)	9.7 (8.4, NE)	10/ 47 (21.3)	NE (2.9, NE)	0.65 (0.30, 1.40)	0.2620	

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[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.4702
yes	13/ 44 (29.5)	NE (9.7, NE)	5/ 17 (29.4)	NE (2.6, NE)	0.56 (0.19, 1.65)	0.2849	
no	18/ 81 (22.2)	11.3 (7.0, NE)	9/ 45 (20.0)	NE (4.0, NE)	0.61 (0.27, 1.40)	0.2429	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9000
yes	3/ 22 (13.6)	NE (5.1, NE)	1/ 7 (14.3)	NE (2.8, NE)	0.57 (0.06, 5.70)	0.6297	
no	28/103 (27.2)	14.4 (8.4, NE)	13/ 55 (23.6)	NE (3.3, NE)	0.63 (0.32, 1.25)	0.1798	
Presence of liver metastasis at baseline							0.7203
yes	14/ 67 (20.9)	NE (7.0, NE)	7/ 34 (20.6)	NE (2.9, NE)	0.55 (0.21, 1.40)	0.1998	
no	17/ 58 (29.3)	11.3 (8.4, NE)	7/ 28 (25.0)	NE (2.9, NE)	0.67 (0.27, 1.67)	0.3818	
Renal impairment at baseline							0.3050
normal	7/ 33 (21.2)	NE (7.0, NE)	4/ 13 (30.8)	NE (1.9, NE)	0.25 (0.06, 1.01)	0.0341	
mild	15/ 53 (28.3)	14.4 (5.6, NE)	6/ 28 (21.4)	NE (2.9, NE)	0.87 (0.33, 2.28)	0.7668	
moderate	9/ 39 (23.1)	9.7 (5.9, NE)	4/ 20 (20.0)	NE (2.9, NE)	0.60 (0.16, 2.16)	0.4274	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9514
normal	22/ 88 (25.0)	14.4 (8.4, NE)	10/ 47 (21.3)	NE (4.0, NE)	0.56 (0.25, 1.22)	0.1375	
mild	9/ 36 (25.0)	NE (5.9, NE)	4/ 15 (26.7)	NE (2.8, NE)	0.70 (0.21, 2.35)	0.5568	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8012
yes	4/ 8 (50.0)	8.4 (3.9, NE)	2/ 5 (40.0)	5.5 (1.1, NE)	0.71 (0.13, 3.96)	0.6993	
no	27/117 (23.1)	14.4 (9.7, NE)	12/ 57 (21.1)	NE (3.3, NE)	0.61 (0.30, 1.25)	0.1705	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.8284
yes	1/ 3 (33.3)	NE (8.4, NE)	1/ 4 (25.0)	NE (5.5, NE)	0.58 (0.04, 9.30)	0.6949	
no	30/122 (24.6)	14.4 (8.4, NE)	13/ 58 (22.4)	NE (3.3, NE)	0.59 (0.30, 1.17)	0.1244	

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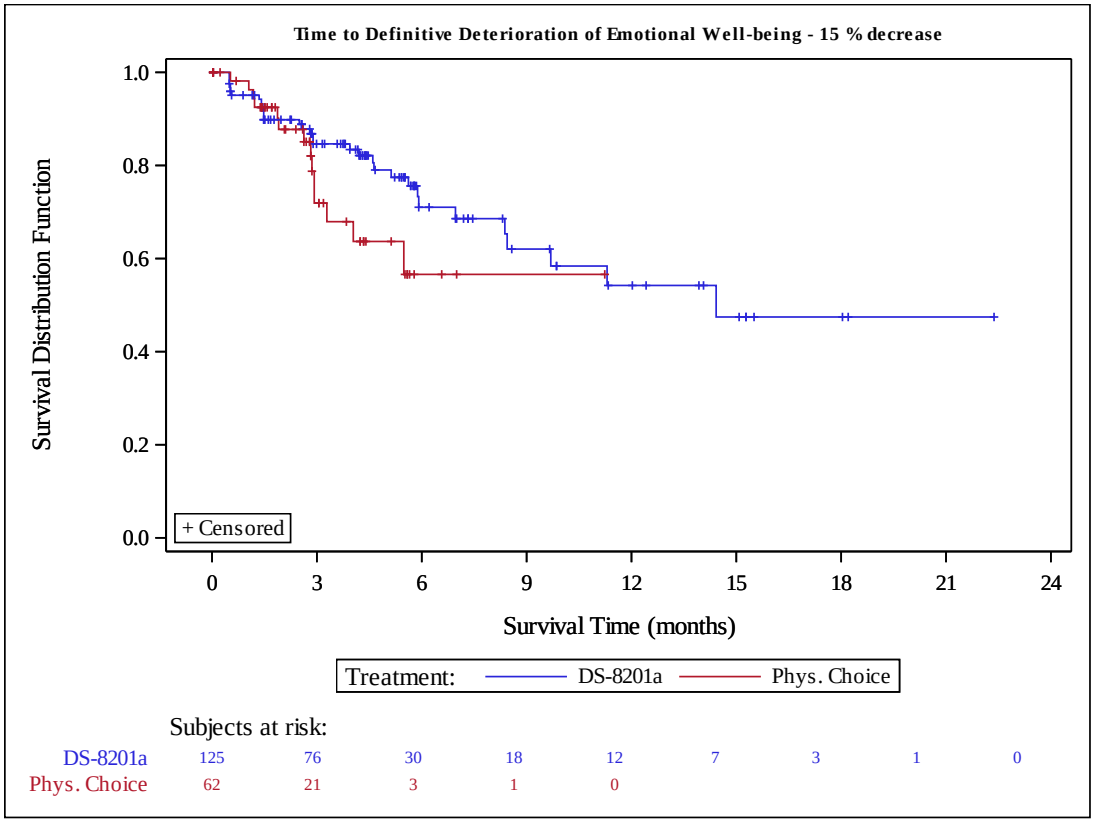
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	118	16 (13.6)	88 (74.6)	14 (11.9)	52	8 (15.4)	43 (82.7)	1 (1.9)
	Day 43	117	17 (14.5)	86 (73.5)	14 (12.0)	53	5 (9.4)	44 (83.0)	4 (7.5)
	Day 85	99	16 (16.2)	65 (65.7)	18 (18.2)	36	4 (11.1)	25 (69.4)	7 (19.4)
	Day 127	74	11 (14.9)	55 (74.3)	8 (10.8)	19	2 (10.5)	14 (73.7)	3 (15.8)
	Day 169	52	6 (11.5)	40 (76.9)	6 (11.5)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 211	34	5 (14.7)	23 (67.6)	6 (17.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	24	5 (20.8)	14 (58.3)	5 (20.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	19	4 (21.1)	13 (68.4)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	3 (20.0)	10 (66.7)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	1 (9.1)	10 (90.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	8 (9.6)	51 (61.4)	24 (28.9)	53	3 (5.7)	36 (67.9)	14 (26.4)
Region									
Japan									
	Day 15	96	12 (12.5)	73 (76.0)	11 (11.5)	45	7 (15.6)	38 (84.4)	0 (0.0)
	Day 43	93	13 (14.0)	70 (75.3)	10 (10.8)	43	5 (11.6)	35 (81.4)	3 (7.0)
	Day 85	77	9 (11.7)	55 (71.4)	13 (16.9)	32	3 (9.4)	23 (71.9)	6 (18.8)
	Day 127	60	6 (10.0)	47 (78.3)	7 (11.7)	16	2 (12.5)	13 (81.3)	1 (6.3)
	Day 169	45	4 (8.9)	35 (77.8)	6 (13.3)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 211	28	3 (10.7)	19 (67.9)	6 (21.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	13 (72.2)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	1 (7.1)	12 (85.7)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	10 (90.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	65	6 (9.2)	45 (69.2)	14 (21.5)	45	3 (6.7)	32 (71.1)	10 (22.2)
Region									
Korea									
	Day 15	22	4 (18.2)	15 (68.2)	3 (13.6)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 43	24	4 (16.7)	16 (66.7)	4 (16.7)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 85	22	7 (31.8)	10 (45.5)	5 (22.7)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 127	14	5 (35.7)	8 (57.1)	1 (7.1)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	7	2 (28.6)	5 (71.4)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	3 (50.0)	1 (16.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	3 (60.0)	1 (20.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	2 (50.0)	0 (0.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	2 (11.1)	6 (33.3)	10 (55.6)	8	0 (0.0)	4 (50.0)	4 (50.0)
Lines of prior systemic therapy									
2									
	Day 15	60	10 (16.7)	45 (75.0)	5 (8.3)	34	5 (14.7)	28 (82.4)	1 (2.9)
	Day 43	62	11 (17.7)	44 (71.0)	7 (11.3)	36	1 (2.8)	33 (91.7)	2 (5.6)
	Day 85	50	6 (12.0)	36 (72.0)	8 (16.0)	21	2 (9.5)	13 (61.9)	6 (28.6)
	Day 127	33	6 (18.2)	26 (78.8)	1 (3.0)	14	0 (0.0)	11 (78.6)	3 (21.4)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 169	21	2 (9.5)	19 (90.5)	0 (0.0)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	14	2 (14.3)	11 (78.6)	1 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	10	2 (20.0)	5 (50.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	2 (28.6)	4 (57.1)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	2 (40.0)	2 (40.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	4 (8.9)	28 (62.2)	13 (28.9)	32	2 (6.3)	20 (62.5)	10 (31.3)
Lines of prior systemic therapy									
3									
	Day 15	34	4 (11.8)	24 (70.6)	6 (17.6)	14	3 (21.4)	11 (78.6)	0 (0.0)
	Day 43	33	5 (15.2)	24 (72.7)	4 (12.1)	14	3 (21.4)	9 (64.3)	2 (14.3)
	Day 85	28	6 (21.4)	16 (57.1)	6 (21.4)	12	1 (8.3)	10 (83.3)	1 (8.3)
	Day 127	23	2 (8.7)	15 (65.2)	6 (26.1)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	17	1 (5.9)	12 (70.6)	4 (23.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	12	3 (25.0)	7 (58.3)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	9	3 (33.3)	5 (55.6)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	3 (14.3)	14 (66.7)	4 (19.0)	16	0 (0.0)	13 (81.3)	3 (18.8)
Lines of prior systemic therapy									
>=4									
	Day 15	24	2 (8.3)	19 (79.2)	3 (12.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 43	22	1 (4.5)	18 (81.8)	3 (13.6)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	21	4 (19.0)	13 (61.9)	4 (19.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	18	3 (16.7)	14 (77.8)	1 (5.6)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	14	3 (21.4)	9 (64.3)	2 (14.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	9 (52.9)	7 (41.2)	5	1 (20.0)	3 (60.0)	1 (20.0)
Age									
<65 years									
	Day 15	51	8 (15.7)	39 (76.5)	4 (7.8)	22	3 (13.6)	19 (86.4)	0 (0.0)
	Day 43	52	10 (19.2)	37 (71.2)	5 (9.6)	24	1 (4.2)	23 (95.8)	0 (0.0)
	Day 85	47	10 (21.3)	28 (59.6)	9 (19.1)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 127	34	7 (20.6)	24 (70.6)	3 (8.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	25	3 (12.0)	19 (76.0)	3 (12.0)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 211	16	2 (12.5)	11 (68.8)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	12	4 (33.3)	5 (41.7)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	11	3 (27.3)	7 (63.6)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	3 (37.5)	4 (50.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
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Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	5 (13.2)	24 (63.2)	9 (23.7)	22	1 (4.5)	15 (68.2)	6 (27.3)
Age									
>=65 years									
	Day 15	67	8 (11.9)	49 (73.1)	10 (14.9)	30	5 (16.7)	24 (80.0)	1 (3.3)
	Day 43	65	7 (10.8)	49 (75.4)	9 (13.8)	29	4 (13.8)	21 (72.4)	4 (13.8)
	Day 85	52	6 (11.5)	37 (71.2)	9 (17.3)	20	3 (15.0)	13 (65.0)	4 (20.0)
	Day 127	40	4 (10.0)	31 (77.5)	5 (12.5)	11	2 (18.2)	7 (63.6)	2 (18.2)
	Day 169	27	3 (11.1)	21 (77.8)	3 (11.1)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	18	3 (16.7)	12 (66.7)	3 (16.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	9 (75.0)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	7	0 (0.0)	6 (85.7)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	3 (6.7)	27 (60.0)	15 (33.3)	31	2 (6.5)	21 (67.7)	8 (25.8)
Sex									
female									
	Day 15	28	5 (17.9)	20 (71.4)	3 (10.7)	13	2 (15.4)	10 (76.9)	1 (7.7)
	Day 43	28	1 (3.6)	23 (82.1)	4 (14.3)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 85	20	3 (15.0)	13 (65.0)	4 (20.0)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 127	13	3 (23.1)	9 (69.2)	1 (7.7)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	9	1 (11.1)	6 (66.7)	2 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	6	0 (0.0)	3 (50.0)	3 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	11 (52.4)	9 (42.9)	14	0 (0.0)	12 (85.7)	2 (14.3)
Sex									
male									
	Day 15	90	11 (12.2)	68 (75.6)	11 (12.2)	39	6 (15.4)	33 (84.6)	0 (0.0)
	Day 43	89	16 (18.0)	63 (70.8)	10 (11.2)	40	4 (10.0)	33 (82.5)	3 (7.5)
	Day 85	79	13 (16.5)	52 (65.8)	14 (17.7)	28	4 (14.3)	17 (60.7)	7 (25.0)
	Day 127	61	8 (13.1)	46 (75.4)	7 (11.5)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	43	5 (11.6)	34 (79.1)	4 (9.3)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	28	5 (17.9)	20 (71.4)	3 (10.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	5 (25.0)	13 (65.0)	2 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	4 (23.5)	12 (70.6)	1 (5.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	3 (21.4)	9 (64.3)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	7 (11.3)	40 (64.5)	15 (24.2)	39	3 (7.7)	24 (61.5)	12 (30.8)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS									
0									
	Day 15	60	7 (11.7)	49 (81.7)	4 (6.7)	26	4 (15.4)	22 (84.6)	0 (0.0)
	Day 43	59	6 (10.2)	48 (81.4)	5 (8.5)	26	2 (7.7)	24 (92.3)	0 (0.0)
	Day 85	54	4 (7.4)	39 (72.2)	11 (20.4)	19	1 (5.3)	16 (84.2)	2 (10.5)
	Day 127	42	4 (9.5)	35 (83.3)	3 (7.1)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 169	33	3 (9.1)	27 (81.8)	3 (9.1)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	20	1 (5.0)	15 (75.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	1 (6.7)	10 (66.7)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	0 (0.0)	10 (90.9)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	9	0 (0.0)	9 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	8 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	2 (5.1)	25 (64.1)	12 (30.8)	27	0 (0.0)	21 (77.8)	6 (22.2)
ECOG PS									
1									
	Day 15	58	9 (15.5)	39 (67.2)	10 (17.2)	26	4 (15.4)	21 (80.8)	1 (3.8)
	Day 43	58	11 (19.0)	38 (65.5)	9 (15.5)	27	3 (11.1)	20 (74.1)	4 (14.8)
	Day 85	45	12 (26.7)	26 (57.8)	7 (15.6)	17	3 (17.6)	9 (52.9)	5 (29.4)
	Day 127	32	7 (21.9)	20 (62.5)	5 (15.6)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	19	3 (15.8)	13 (68.4)	3 (15.8)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 211	14	4 (28.6)	8 (57.1)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	4 (44.4)	4 (44.4)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	4 (50.0)	3 (37.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	3 (50.0)	1 (16.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	6 (13.6)	26 (59.1)	12 (27.3)	26	3 (11.5)	15 (57.7)	8 (30.8)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	91	12 (13.2)	67 (73.6)	12 (13.2)	38	6 (15.8)	31 (81.6)	1 (2.6)
	Day 43	91	14 (15.4)	69 (75.8)	8 (8.8)	40	3 (7.5)	34 (85.0)	3 (7.5)
	Day 85	79	14 (17.7)	52 (65.8)	13 (16.5)	26	3 (11.5)	17 (65.4)	6 (23.1)
	Day 127	59	10 (16.9)	44 (74.6)	5 (8.5)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 169	41	6 (14.6)	31 (75.6)	4 (9.8)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 211	29	4 (13.8)	20 (69.0)	5 (17.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	4 (19.0)	13 (61.9)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	4 (23.5)	11 (64.7)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	3 (21.4)	9 (64.3)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	7 (11.3)	39 (62.9)	16 (25.8)	39	2 (5.1)	25 (64.1)	12 (30.8)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	4 (14.8)	21 (77.8)	2 (7.4)	14	2 (14.3)	12 (85.7)	0 (0.0)
	Day 43	26	3 (11.5)	17 (65.4)	6 (23.1)	13	2 (15.4)	10 (76.9)	1 (7.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	20	2 (10.0)	13 (65.0)	5 (25.0)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 127	15	1 (6.7)	11 (73.3)	3 (20.0)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 169	11	0 (0.0)	9 (81.8)	2 (18.2)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	12 (57.1)	8 (38.1)	14	1 (7.1)	11 (78.6)	2 (14.3)
Primary tumor location									
Gastric									
	Day 15	102	14 (13.7)	74 (72.5)	14 (13.7)	46	7 (15.2)	38 (82.6)	1 (2.2)
	Day 43	100	16 (16.0)	73 (73.0)	11 (11.0)	48	5 (10.4)	39 (81.3)	4 (8.3)
	Day 85	84	15 (17.9)	55 (65.5)	14 (16.7)	33	4 (12.1)	22 (66.7)	7 (21.2)
	Day 127	63	10 (15.9)	45 (71.4)	8 (12.7)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 169	42	5 (11.9)	31 (73.8)	6 (14.3)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 211	29	4 (13.8)	19 (65.5)	6 (20.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	4 (20.0)	12 (60.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	3 (20.0)	10 (66.7)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	8 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	7 (9.9)	42 (59.2)	22 (31.0)	47	3 (6.4)	30 (63.8)	14 (29.8)
Primary tumor location									
GEJ									
	Day 15	16	2 (12.5)	14 (87.5)	0 (0.0)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	17	1 (5.9)	13 (76.5)	3 (17.6)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 85	15	1 (6.7)	10 (66.7)	4 (26.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	10 (90.9)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	9 (75.0)	2 (16.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	86	12 (14.0)	64 (74.4)	10 (11.6)	35	6 (17.1)	29 (82.9)	0 (0.0)
	Day 43	85	13 (15.3)	62 (72.9)	10 (11.8)	34	3 (8.8)	28 (82.4)	3 (8.8)
	Day 85	73	10 (13.7)	51 (69.9)	12 (16.4)	27	2 (7.4)	20 (74.1)	5 (18.5)
	Day 127	55	6 (10.9)	43 (78.2)	6 (10.9)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 169	40	4 (10.0)	31 (77.5)	5 (12.5)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	25	2 (8.0)	18 (72.0)	5 (20.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	16	2 (12.5)	11 (68.8)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	1 (7.7)	11 (84.6)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	1 (10.0)	9 (90.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	5 (7.9)	43 (68.3)	15 (23.8)	34	2 (5.9)	24 (70.6)	8 (23.5)
Histological subtype diffuse									
	Day 15	26	3 (11.5)	20 (76.9)	3 (11.5)	15	2 (13.3)	12 (80.0)	1 (6.7)
	Day 43	26	3 (11.5)	19 (73.1)	4 (15.4)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 85	22	4 (18.2)	12 (54.5)	6 (27.3)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 127	15	3 (20.0)	10 (66.7)	2 (13.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	10	1 (10.0)	8 (80.0)	1 (10.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	3 (37.5)	4 (50.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	7	3 (42.9)	2 (28.6)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	3 (60.0)	1 (20.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	2 (50.0)	1 (25.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	16	3 (18.8)	5 (31.3)	8 (50.0)	16	1 (6.3)	10 (62.5)	5 (31.3)
Histological subtype others									
	Day 15	6	1 (16.7)	4 (66.7)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	1 (16.7)	5 (83.3)	0 (0.0)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 85	4	2 (50.0)	2 (50.0)	0 (0.0)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 127	4	2 (50.0)	2 (50.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	1 (50.0)	1 (50.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	3 (75.0)	1 (25.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Number of metastatic sites <2									
	Day 15	23	2 (8.7)	19 (82.6)	2 (8.7)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 43	22	3 (13.6)	18 (81.8)	1 (4.5)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 85	22	2 (9.1)	16 (72.7)	4 (18.2)	8	2 (25.0)	4 (50.0)	2 (25.0)
	Day 127	18	1 (5.6)	14 (77.8)	3 (16.7)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 169	15	0 (0.0)	12 (80.0)	3 (20.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	10	1 (10.0)	8 (80.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	1 (16.7)	4 (66.7)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	4	1 (25.0)	3 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	2 (13.3)	9 (60.0)	4 (26.7)	8	1 (12.5)	4 (50.0)	3 (37.5)
Number of metastatic sites >= 2									
	Day 15	95	14 (14.7)	69 (72.6)	12 (12.6)	42	7 (16.7)	34 (81.0)	1 (2.4)
	Day 43	95	14 (14.7)	68 (71.6)	13 (13.7)	43	5 (11.6)	34 (79.1)	4 (9.3)
	Day 85	77	14 (18.2)	49 (63.6)	14 (18.2)	28	2 (7.1)	21 (75.0)	5 (17.9)
	Day 127	56	10 (17.9)	41 (73.2)	5 (8.9)	15	2 (13.3)	11 (73.3)	2 (13.3)
	Day 169	37	6 (16.2)	28 (75.7)	3 (8.1)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 211	24	4 (16.7)	15 (62.5)	5 (20.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	4 (22.2)	10 (55.6)	4 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	15	3 (20.0)	10 (66.7)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	2 (18.2)	7 (63.6)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	68	6 (8.8)	42 (61.8)	20 (29.4)	45	2 (4.4)	32 (71.1)	11 (24.4)
Previous total gastrectomy									
yes									
	Day 15	20	5 (25.0)	12 (60.0)	3 (15.0)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 43	20	2 (10.0)	14 (70.0)	4 (20.0)	8	2 (25.0)	6 (75.0)	0 (0.0)
	Day 85	18	2 (11.1)	11 (61.1)	5 (27.8)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 127	11	0 (0.0)	8 (72.7)	3 (27.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	1 (12.5)	3 (37.5)	4 (50.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 211	7	1 (14.3)	3 (42.9)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	3 (17.6)	8 (47.1)	6 (35.3)	9	1 (11.1)	7 (77.8)	1 (11.1)
Previous total gastrectomy									
no									
	Day 15	98	11 (11.2)	76 (77.6)	11 (11.2)	45	8 (17.8)	36 (80.0)	1 (2.2)
	Day 43	97	15 (15.5)	72 (74.2)	10 (10.3)	45	3 (6.7)	38 (84.4)	4 (8.9)
	Day 85	81	14 (17.3)	54 (66.7)	13 (16.0)	30	3 (10.0)	20 (66.7)	7 (23.3)
	Day 127	63	11 (17.5)	47 (74.6)	5 (7.9)	17	1 (5.9)	13 (76.5)	3 (17.6)
	Day 169	44	5 (11.4)	37 (84.1)	2 (4.5)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 211	27	4 (14.8)	20 (74.1)	3 (11.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	4 (19.0)	13 (61.9)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	3 (18.8)	12 (75.0)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	2 (16.7)	9 (75.0)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	66	5 (7.6)	43 (65.2)	18 (27.3)	44	2 (4.5)	29 (65.9)	13 (29.5)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	4 (13.8)	22 (75.9)	3 (10.3)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 43	27	1 (3.7)	24 (88.9)	2 (7.4)	8	2 (25.0)	6 (75.0)	0 (0.0)
	Day 85	27	1 (3.7)	22 (81.5)	4 (14.8)	7	2 (28.6)	4 (57.1)	1 (14.3)
	Day 127	22	1 (4.5)	19 (86.4)	2 (9.1)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	13	1 (7.7)	9 (69.2)	3 (23.1)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 211	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	11 (52.4)	8 (38.1)	9	1 (11.1)	7 (77.8)	1 (11.1)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	89	12 (13.5)	66 (74.2)	11 (12.4)	44	8 (18.2)	35 (79.5)	1 (2.3)
	Day 43	90	16 (17.8)	62 (68.9)	12 (13.3)	45	3 (6.7)	38 (84.4)	4 (8.9)
	Day 85	72	15 (20.8)	43 (59.7)	14 (19.4)	29	2 (6.9)	21 (72.4)	6 (20.7)
	Day 127	52	10 (19.2)	36 (69.2)	6 (11.5)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	39	5 (12.8)	31 (79.5)	3 (7.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	26	4 (15.4)	19 (73.1)	3 (11.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	4 (21.1)	11 (57.9)	4 (21.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	3 (21.4)	10 (71.4)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	2 (20.0)	7 (70.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	6 (9.7)	40 (64.5)	16 (25.8)	44	2 (4.5)	29 (65.9)	13 (29.5)
Prior ramucirumab contained treatment									
yes									
	Day 15	90	10 (11.1)	70 (77.8)	10 (11.1)	34	4 (11.8)	30 (88.2)	0 (0.0)
	Day 43	89	11 (12.4)	67 (75.3)	11 (12.4)	33	4 (12.1)	27 (81.8)	2 (6.1)
	Day 85	73	11 (15.1)	51 (69.9)	11 (15.1)	23	3 (13.0)	19 (82.6)	1 (4.3)
	Day 127	59	7 (11.9)	45 (76.3)	7 (11.9)	11	2 (18.2)	8 (72.7)	1 (9.1)
	Day 169	41	4 (9.8)	32 (78.0)	5 (12.2)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	25	2 (8.0)	19 (76.0)	4 (16.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	2 (13.3)	12 (80.0)	1 (6.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	1 (7.7)	11 (84.6)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	9	0 (0.0)	9 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	4 (6.3)	42 (66.7)	17 (27.0)	35	2 (5.7)	27 (77.1)	6 (17.1)
Prior ramucirumab contained treatment									
no									
	Day 15	28	6 (21.4)	18 (64.3)	4 (14.3)	18	4 (22.2)	13 (72.2)	1 (5.6)
	Day 43	28	6 (21.4)	19 (67.9)	3 (10.7)	20	1 (5.0)	17 (85.0)	2 (10.0)
	Day 85	26	5 (19.2)	14 (53.8)	7 (26.9)	13	1 (7.7)	6 (46.2)	6 (46.2)
	Day 127	15	4 (26.7)	10 (66.7)	1 (6.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 169	11	2 (18.2)	8 (72.7)	1 (9.1)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 211	9	3 (33.3)	4 (44.4)	2 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	3 (33.3)	2 (22.2)	4 (44.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	3 (50.0)	2 (33.3)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	3	2 (66.7)	1 (33.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	4 (20.0)	9 (45.0)	7 (35.0)	18	1 (5.6)	9 (50.0)	8 (44.4)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Prior nivolumab contained treatment									
yes									
	Day 15	32	1 (3.1)	26 (81.3)	5 (15.6)	13	3 (23.1)	10 (76.9)	0 (0.0)
	Day 43	30	5 (16.7)	21 (70.0)	4 (13.3)	10	2 (20.0)	7 (70.0)	1 (10.0)
	Day 85	27	3 (11.1)	18 (66.7)	6 (22.2)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 127	26	1 (3.8)	21 (80.8)	4 (15.4)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 169	20	1 (5.0)	17 (85.0)	2 (10.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 211	13	2 (15.4)	8 (61.5)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	8 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	13 (65.0)	6 (30.0)	13	1 (7.7)	8 (61.5)	4 (30.8)
Prior nivolumab contained treatment									
no									
	Day 15	86	15 (17.4)	62 (72.1)	9 (10.5)	39	5 (12.8)	33 (84.6)	1 (2.6)
	Day 43	87	12 (13.8)	65 (74.7)	10 (11.5)	43	3 (7.0)	37 (86.0)	3 (7.0)
	Day 85	72	13 (18.1)	47 (65.3)	12 (16.7)	26	3 (11.5)	17 (65.4)	6 (23.1)
	Day 127	48	10 (20.8)	34 (70.8)	4 (8.3)	16	0 (0.0)	13 (81.3)	3 (18.8)
	Day 169	32	5 (15.6)	23 (71.9)	4 (12.5)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	21	3 (14.3)	15 (71.4)	3 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	14	4 (28.6)	5 (35.7)	5 (35.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	4 (36.4)	5 (45.5)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	3 (37.5)	3 (37.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	7 (11.1)	38 (60.3)	18 (28.6)	40	2 (5.0)	28 (70.0)	10 (25.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	42	2 (4.8)	33 (78.6)	7 (16.7)	15	3 (20.0)	12 (80.0)	0 (0.0)
	Day 43	40	5 (12.5)	29 (72.5)	6 (15.0)	12	2 (16.7)	9 (75.0)	1 (8.3)
	Day 85	37	4 (10.8)	22 (59.5)	11 (29.7)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 127	31	2 (6.5)	24 (77.4)	5 (16.1)	4	2 (50.0)	1 (25.0)	1 (25.0)
	Day 169	23	2 (8.7)	19 (82.6)	2 (8.7)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 211	17	4 (23.5)	10 (58.8)	3 (17.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	13	3 (23.1)	9 (69.2)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	2 (16.7)	9 (75.0)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	2 (7.1)	16 (57.1)	10 (35.7)	15	1 (6.7)	9 (60.0)	5 (33.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	76	14 (18.4)	55 (72.4)	7 (9.2)	37	5 (13.5)	31 (83.8)	1 (2.7)
	Day 43	77	12 (15.6)	57 (74.0)	8 (10.4)	41	3 (7.3)	35 (85.4)	3 (7.3)
	Day 85	62	12 (19.4)	43 (69.4)	7 (11.3)	25	3 (12.0)	17 (68.0)	5 (20.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 127	43	9 (20.9)	31 (72.1)	3 (7.0)	15	0 (0.0)	13 (86.7)	2 (13.3)
	Day 169	29	4 (13.8)	21 (72.4)	4 (13.8)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	17	1 (5.9)	13 (76.5)	3 (17.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	11	2 (18.2)	5 (45.5)	4 (36.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	2 (28.6)	4 (57.1)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	2 (40.0)	2 (40.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	55	6 (10.9)	35 (63.6)	14 (25.5)	38	2 (5.3)	27 (71.1)	9 (23.7)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
yes									
	Day 15	22	4 (18.2)	15 (68.2)	3 (13.6)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	19	2 (10.5)	16 (84.2)	1 (5.3)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 85	16	6 (37.5)	9 (56.3)	1 (6.3)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 127	12	4 (33.3)	6 (50.0)	2 (16.7)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 169	7	2 (28.6)	3 (42.9)	2 (28.6)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	3	1 (33.3)	1 (33.3)	1 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	2 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	2 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	9 (75.0)	2 (16.7)	6	1 (16.7)	4 (66.7)	1 (16.7)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
no									
	Day 15	96	12 (12.5)	73 (76.0)	11 (11.5)	46	8 (17.4)	37 (80.4)	1 (2.2)
	Day 43	98	15 (15.3)	70 (71.4)	13 (13.3)	47	4 (8.5)	39 (83.0)	4 (8.5)
	Day 85	83	10 (12.0)	56 (67.5)	17 (20.5)	31	3 (9.7)	22 (71.0)	6 (19.4)
	Day 127	62	7 (11.3)	49 (79.0)	6 (9.7)	16	1 (6.3)	13 (81.3)	2 (12.5)
	Day 169	45	4 (8.9)	37 (82.2)	4 (8.9)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	31	4 (12.9)	22 (71.0)	5 (16.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	3 (13.6)	14 (63.6)	5 (22.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	2 (11.8)	13 (76.5)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	10 (71.4)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	7 (9.9)	42 (59.2)	22 (31.0)	47	2 (4.3)	32 (68.1)	13 (27.7)
Presence of liver metastasis at baseline									
yes									
	Day 15	64	12 (18.8)	43 (67.2)	9 (14.1)	27	5 (18.5)	22 (81.5)	0 (0.0)
	Day 43	63	7 (11.1)	49 (77.8)	7 (11.1)	28	3 (10.7)	23 (82.1)	2 (7.1)
	Day 85	50	10 (20.0)	33 (66.0)	7 (14.0)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 127	36	5 (13.9)	27 (75.0)	4 (11.1)	10	2 (20.0)	6 (60.0)	2 (20.0)
	Day 169	25	3 (12.0)	21 (84.0)	1 (4.0)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 211	14	2 (14.3)	10 (71.4)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 253	12	2 (16.7)	7 (58.3)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	3 (6.7)	31 (68.9)	11 (24.4)	30	1 (3.3)	22 (73.3)	7 (23.3)
Presence of liver metastasis at baseline									
no									
	Day 15	54	4 (7.4)	45 (83.3)	5 (9.3)	25	3 (12.0)	21 (84.0)	1 (4.0)
	Day 43	54	10 (18.5)	37 (68.5)	7 (13.0)	25	2 (8.0)	21 (84.0)	2 (8.0)
	Day 85	49	6 (12.2)	32 (65.3)	11 (22.4)	20	2 (10.0)	14 (70.0)	4 (20.0)
	Day 127	38	6 (15.8)	28 (73.7)	4 (10.5)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 169	27	3 (11.1)	19 (70.4)	5 (18.5)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	20	3 (15.0)	13 (65.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	12	3 (25.0)	7 (58.3)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	10	2 (20.0)	7 (70.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	4 (50.0)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	5 (13.2)	20 (52.6)	13 (34.2)	23	2 (8.7)	14 (60.9)	7 (30.4)
Renal impairment at baseline									
normal									
	Day 15	31	4 (12.9)	25 (80.6)	2 (6.5)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 43	33	2 (6.1)	30 (90.9)	1 (3.0)	12	1 (8.3)	10 (83.3)	1 (8.3)
	Day 85	26	5 (19.2)	17 (65.4)	4 (15.4)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	3 (15.8)	16 (84.2)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	15	2 (13.3)	13 (86.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	2 (10.0)	13 (65.0)	5 (25.0)	11	1 (9.1)	6 (54.5)	4 (36.4)
Renal impairment at baseline									
mild									
	Day 15	50	4 (8.0)	37 (74.0)	9 (18.0)	25	5 (20.0)	20 (80.0)	0 (0.0)
	Day 43	50	7 (14.0)	33 (66.0)	10 (20.0)	23	1 (4.3)	22 (95.7)	0 (0.0)
	Day 85	45	5 (11.1)	32 (71.1)	8 (17.8)	14	3 (21.4)	8 (57.1)	3 (21.4)
	Day 127	31	5 (16.1)	22 (71.0)	4 (12.9)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	21	2 (9.5)	16 (76.2)	3 (14.3)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 211	13	2 (15.4)	8 (61.5)	3 (23.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	8	2 (25.0)	5 (62.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	5 (83.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	4	0 (0.0)	4 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	3 (7.7)	24 (61.5)	12 (30.8)	22	2 (9.1)	14 (63.6)	6 (27.3)
Renal impairment at baseline									
moderate									
	Day 15	37	8 (21.6)	26 (70.3)	3 (8.1)	16	2 (12.5)	14 (87.5)	0 (0.0)
	Day 43	34	8 (23.5)	23 (67.6)	3 (8.8)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 85	28	6 (21.4)	16 (57.1)	6 (21.4)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 127	24	3 (12.5)	17 (70.8)	4 (16.7)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 169	16	2 (12.5)	11 (68.8)	3 (18.8)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	11	2 (18.2)	7 (63.6)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	3 (12.5)	14 (58.3)	7 (29.2)	19	0 (0.0)	15 (78.9)	4 (21.1)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	82	9 (11.0)	64 (78.0)	9 (11.0)	37	6 (16.2)	30 (81.1)	1 (2.7)
	Day 43	83	11 (13.3)	63 (75.9)	9 (10.8)	41	4 (9.8)	34 (82.9)	3 (7.3)
	Day 85	76	11 (14.5)	50 (65.8)	15 (19.7)	27	2 (7.4)	20 (74.1)	5 (18.5)
	Day 127	58	10 (17.2)	43 (74.1)	5 (8.6)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 169	40	5 (12.5)	30 (75.0)	5 (12.5)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	24	5 (20.8)	14 (58.3)	5 (20.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	19	4 (21.1)	10 (52.6)	5 (26.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	3 (20.0)	11 (73.3)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	2 (18.2)	8 (72.7)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	56	5 (8.9)	34 (60.7)	17 (30.4)	40	2 (5.0)	28 (70.0)	10 (25.0)
Hepatic impairment at baseline									
mild									
	Day 15	35	7 (20.0)	23 (65.7)	5 (14.3)	15	2 (13.3)	13 (86.7)	0 (0.0)
	Day 43	33	6 (18.2)	22 (66.7)	5 (15.2)	12	1 (8.3)	10 (83.3)	1 (8.3)
	Day 85	22	5 (22.7)	14 (63.6)	3 (13.6)	9	2 (22.2)	5 (55.6)	2 (22.2)
	Day 127	15	1 (6.7)	11 (73.3)	3 (20.0)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 211	10	0 (0.0)	9 (90.0)	1 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	3 (11.5)	16 (61.5)	7 (26.9)	13	1 (7.7)	8 (61.5)	4 (30.8)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	0 (0.0)	6 (75.0)	2 (25.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 43	8	0 (0.0)	7 (87.5)	1 (12.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	0 (0.0)	5 (71.4)	2 (28.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	0 (0.0)	6 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	1 (20.0)	3 (60.0)	1 (20.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	5	0 (0.0)	1 (20.0)	4 (80.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	110	16 (14.5)	82 (74.5)	12 (10.9)	48	8 (16.7)	39 (81.3)	1 (2.1)
	Day 43	109	17 (15.6)	79 (72.5)	13 (11.9)	50	5 (10.0)	41 (82.0)	4 (8.0)
	Day 85	92	16 (17.4)	60 (65.2)	16 (17.4)	33	4 (12.1)	22 (66.7)	7 (21.2)
	Day 127	68	11 (16.2)	49 (72.1)	8 (11.8)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 169	47	5 (10.6)	37 (78.7)	5 (10.6)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 211	30	5 (16.7)	20 (66.7)	5 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	5 (25.0)	12 (60.0)	3 (15.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	17	4 (23.5)	11 (64.7)	2 (11.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	14	3 (21.4)	9 (64.3)	2 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	8 (10.3)	50 (64.1)	20 (25.6)	50	3 (6.0)	35 (70.0)	12 (24.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	2 (66.7)	1 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	0 (0.0)	3 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	0 (0.0)	1 (100.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors no									
	Day 15	115	16 (13.9)	85 (73.9)	14 (12.2)	49	8 (16.3)	40 (81.6)	1 (2.0)
	Day 43	114	17 (14.9)	83 (72.8)	14 (12.3)	50	5 (10.0)	41 (82.0)	4 (8.0)
	Day 85	96	16 (16.7)	63 (65.6)	17 (17.7)	33	4 (12.1)	22 (66.7)	7 (21.2)
	Day 127	71	11 (15.5)	52 (73.2)	8 (11.3)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 169	49	6 (12.2)	37 (75.5)	6 (12.2)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 211	32	5 (15.6)	21 (65.6)	6 (18.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	5 (22.7)	13 (59.1)	4 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	18	4 (22.2)	12 (66.7)	2 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	15	3 (20.0)	10 (66.7)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	11	1 (9.1)	10 (90.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	8 (9.8)	51 (62.2)	23 (28.0)	51	3 (5.9)	35 (68.6)	13 (25.5)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Functional Well-being Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	124 (99.2)	62	58 (93.5)
Day 15	125	118 (94.4)	62	52 (83.9)
Day 43	124	117 (94.4)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	52 (49.5)	45	11 (24.4)
Day 211	81	34 (42.0)	35	3 (8.6)
Day 253	62	24 (38.7)	26	1 (3.8)
Day 295	51	19 (37.3)	19	1 (5.3)
Day 337	45	15 (33.3)	14	1 (7.1)
Day 379	33	11 (33.3)	10	0 (0.0)
Day 421	22	11 (50.0)	3	0 (0.0)
Day 463	14	7 (50.0)	2	0 (0.0)
Day 505	11	3 (27.3)	2	0 (0.0)
Day 547	6	3 (50.0)	2	0 (0.0)
Day 589	4	1 (25.0)	2	0 (0.0)
Day 631	3	1 (33.3)	0	0 (0.0)
Day 673	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Functional Well-being by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	124	17.6 (5.93)			58	17.1 (5.33)		
Day 15	118	15.9 (6.15)	117	-1.8 (5.49)	52	17.1 (6.10)	49	-0.7 (4.54)
Day 43	117	16.6 (6.87)	116	-1.3 (5.67)	53	16.2 (7.29)	50	-1.7 (6.23)
Day 85	99	17.1 (6.32)	98	-1.2 (4.72)	36	16.8 (7.55)	34	-1.3 (4.71)
Day 127	74	17.4 (6.04)	73	-1.4 (5.51)	19	17.1 (7.01)	18	-0.5 (4.44)
Day 169	52	18.2 (5.85)	51	-0.4 (5.94)	11	17.3 (6.39)	10	-1.4 (6.02)
Day 211	34	17.8 (6.13)	33	-1.1 (5.02)	3	24.0 (6.93)	2	0.5 (9.19)
Day 253	24	16.8 (7.19)	24	-1.4 (5.49)	1	28.0 (-)	1	7.0 (-)
Day 295	19	17.5 (7.06)	19	-1.0 (5.29)	1	28.0 (-)	1	7.0 (-)
Day 337	15	16.0 (7.20)	15	-3.1 (6.55)	1	28.0 (-)	1	7.0 (-)
Day 379	11	18.0 (5.55)	11	-2.6 (5.94)	0	-	0	-
Day 421	11	16.1 (6.39)	11	-4.0 (4.63)	0	-	0	-
Day 463	7	18.9 (7.01)	7	-1.7 (3.04)	0	-	0	-
Day 505	3	19.7 (7.09)	3	-2.0 (3.00)	0	-	0	-
Day 547	3	18.0 (7.55)	3	-3.7 (2.08)	0	-	0	-
Day 589	1	15.0 (-)	1	-2.0 (-)	0	-	0	-
Day 631	1	12.0 (-)	1	-5.0 (-)	0	-	0	-
Day 673	1	11.0 (-)	1	-6.0 (-)	0	-	0	-
End of Treatment	83	14.6 (6.56)	82	-3.6 (6.23)	53	14.1 (7.00)	49	-3.5 (4.88)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Functional Well-being by Visit
Full Analysis Set

Visit	DS-8201a (N=125) N [a]	N_MISS [b]	LSMean (95% CI)	Phys. Choice (N=62) N [a]	N_MISS [b]	LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
Day 15			-2.02 (-2.88, -1.16)			-2.14 (-3.50, -0.78)	0.12 (-1.37, 1.60)	0.8779		
Day 43			-2.05 (-2.85, -1.25)			-2.12 (-3.30, -0.93)	0.07 (-1.21, 1.35)	0.9165		
Day 85			-2.09 (-2.83, -1.35)			-2.09 (-3.29, -0.89)	-0.00 (-1.26, 1.26)	0.9960		
Day 127			-2.13 (-2.86, -1.41)			-2.06 (-3.58, -0.53)	-0.07 (-1.64, 1.49)	0.9254		
Day 169			-2.18 (-2.94, -1.41)			-2.03 (-4.05, -0.01)	-0.15 (-2.21, 1.92)	0.8894		
Day 211			-2.22 (-3.07, -1.37)			-2.00 (-4.59, 0.59)	-0.22 (-2.87, 2.43)	0.8717		
Day 253			-2.26 (-3.23, -1.29)			-1.97 (-5.16, 1.22)	-0.29 (-3.56, 2.98)	0.8621		
Day 295			-2.30 (-3.41, -1.20)			-1.94 (-5.75, 1.87)	-0.36 (-4.27, 3.55)	0.8563		
Day 337			-2.34 (-3.60, -1.09)			-1.91 (-6.35, 2.53)	-0.43 (-5.00, 4.14)	0.8526		
OVERALL	123	2	-2.12 (-2.84, -1.40)	54	8	-2.07 (-3.46, -0.67)	-0.05 (-1.49, 1.39)	0.9438	-0.01 (-0.33, 0.31)	0.9433

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Functional Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.2395
Japan	98	-1.48 (-2.09, -0.86)	45	-1.01 (-2.35, 0.33)	-0.47 (-1.94, 1.01)	0.5354	-0.13 (-0.48, 0.22)	0.4761	
Korea	25	-1.96 (-3.47, -0.45)	9	-4.66 (-8.39, -0.92)	2.69 (-1.34, 6.73)	0.1866	0.63 (-0.15, 1.41)	0.1116	
Lines of prior systemic therapy									0.9598
2	64	-0.94 (-1.78, -0.10)	34	-0.72 (-2.13, 0.69)	-0.22 (-1.87, 1.42)	0.7883	-0.06 (-0.48, 0.36)	0.7748	
3	34	-2.83 (-3.94, -1.72)	16	-3.43 (-6.19, -0.66)	0.59 (-2.39, 3.57)	0.6936	0.14 (-0.45, 0.74)	0.6345	
>=4	25	-1.44 (-2.79, -0.09)	4	-1.08 (-7.36, 5.21)	-0.37 (-6.79, 6.06)	0.9096	-0.10 (-1.15, 0.96)	0.8565	
Age									0.3092
<65 years	54	-1.88 (-2.70, -1.05)	25	-1.88 (-3.94, 0.18)	0.00 (-2.22, 2.22)	1.0000	0.00 (-0.47, 0.47)	1.0000	
>=65 years	69	-1.40 (-2.26, -0.55)	29	-1.44 (-3.19, 0.30)	0.04 (-1.90, 1.98)	0.9688	0.01 (-0.42, 0.44)	0.9651	
Sex									0.6093
female	29	-0.86 (-2.15, 0.42)	12	-1.70 (-4.70, 1.29)	0.84 (-2.42, 4.10)	0.6072	0.21 (-0.46, 0.88)	0.5405	
male	94	-1.79 (-2.48, -1.11)	42	-1.42 (-2.90, 0.07)	-0.38 (-2.01, 1.25)	0.6468	-0.10 (-0.46, 0.27)	0.5979	
ECOG PS									0.8176
0	61	-1.55 (-2.31, -0.79)	27	-1.06 (-2.85, 0.74)	-0.50 (-2.44, 1.45)	0.6151	-0.14 (-0.59, 0.32)	0.5513	
1	62	-1.60 (-2.51, -0.69)	27	-1.88 (-3.71, -0.05)	0.28 (-1.76, 2.33)	0.7831	0.07 (-0.38, 0.52)	0.7579	
HER2 Status in central laboratory									0.6176
IHC 3+	95	-1.62 (-2.30, -0.94)	41	-1.60 (-3.19, -0.00)	-0.03 (-1.76, 1.70)	0.9754	-0.01 (-0.37, 0.36)	0.9709	
IHC 2+/ISH +	28	-1.44 (-2.83, -0.06)	13	-1.23 (-3.59, 1.14)	-0.22 (-2.97, 2.54)	0.8758	-0.06 (-0.71, 0.60)	0.8672	
Primary tumor location									0.7849
Gastric	106	-1.65 (-2.34, -0.96)	49	-1.59 (-3.00, -0.18)	-0.06 (-1.63, 1.52)	0.9436	-0.01 (-0.35, 0.32)	0.9364	
GEJ	17	-1.23 (-2.18, -0.29)	5	-1.52 (-5.62, 2.58)	0.29 (-3.92, 4.50)	0.8912	0.11 (-0.89, 1.11)	0.8312	
Histological subtype									0.1309
intestinal	88	-1.38 (-2.04, -0.72)	35	-1.14 (-2.66, 0.37)	-0.24 (-1.89, 1.41)	0.7754	-0.07 (-0.46, 0.33)	0.7385	
diffuse	28	-1.93 (-3.44, -0.42)	14	-3.33 (-6.67, 0.02)	1.40 (-2.27, 5.07)	0.4499	0.29 (-0.36, 0.93)	0.3793	
others	7	-1.74 (-4.83, 1.35)	5	-0.97 (-5.50, 3.56)	-0.77 (-6.70, 5.16)	0.7820	-0.19 (-1.34, 0.96)	0.7478	
Number of metastatic sites									0.0652
<2	23	-1.20 (-2.46, 0.06)	10	1.79 (-0.68, 4.26)	-2.99 (-5.76, -0.22)	0.0353	-0.92 (-1.70, -0.15)	0.0199	
>= 2	100	-1.67 (-2.34, -1.01)	44	-2.92 (-4.49, -1.35)	1.25 (-0.46, 2.95)	0.1506	0.31 (-0.05, 0.66)	0.0904	
Previous total gastrectomy									0.2087
yes	22	-2.45 (-4.19, -0.71)	8	0.74 (-4.33, 5.80)	-3.19 (-8.54, 2.17)	0.2392	-0.64 (-1.46, 0.19)	0.1292	
no	101	-1.38 (-2.02, -0.75)	46	-1.64 (-2.97, -0.30)	0.25 (-1.22, 1.73)	0.7361	0.07 (-0.28, 0.42)	0.7018	
Prior adjuvant/ neoadjuvant therapy									0.7650
yes	30	-0.86 (-2.15, 0.44)	7	0.62 (-3.86, 5.11)	-1.48 (-6.15, 3.19)	0.5306	-0.37 (-1.19, 0.46)	0.3847	
no	93	-1.88 (-2.56, -1.20)	47	-1.60 (-2.92, -0.28)	-0.28 (-1.77, 1.21)	0.7127	-0.07 (-0.42, 0.28)	0.6822	
Prior ramucirumab contained treatment									0.0349
yes	92	-2.13 (-2.76, -1.50)	36	-2.24 (-3.98, -0.50)	0.11 (-1.75, 1.96)	0.9098	0.03 (-0.36, 0.41)	0.8873	
no	31	-0.14 (-1.57, 1.29)	18	-1.36 (-3.57, 0.85)	1.22 (-1.42, 3.87)	0.3584	0.29 (-0.29, 0.87)	0.3320	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

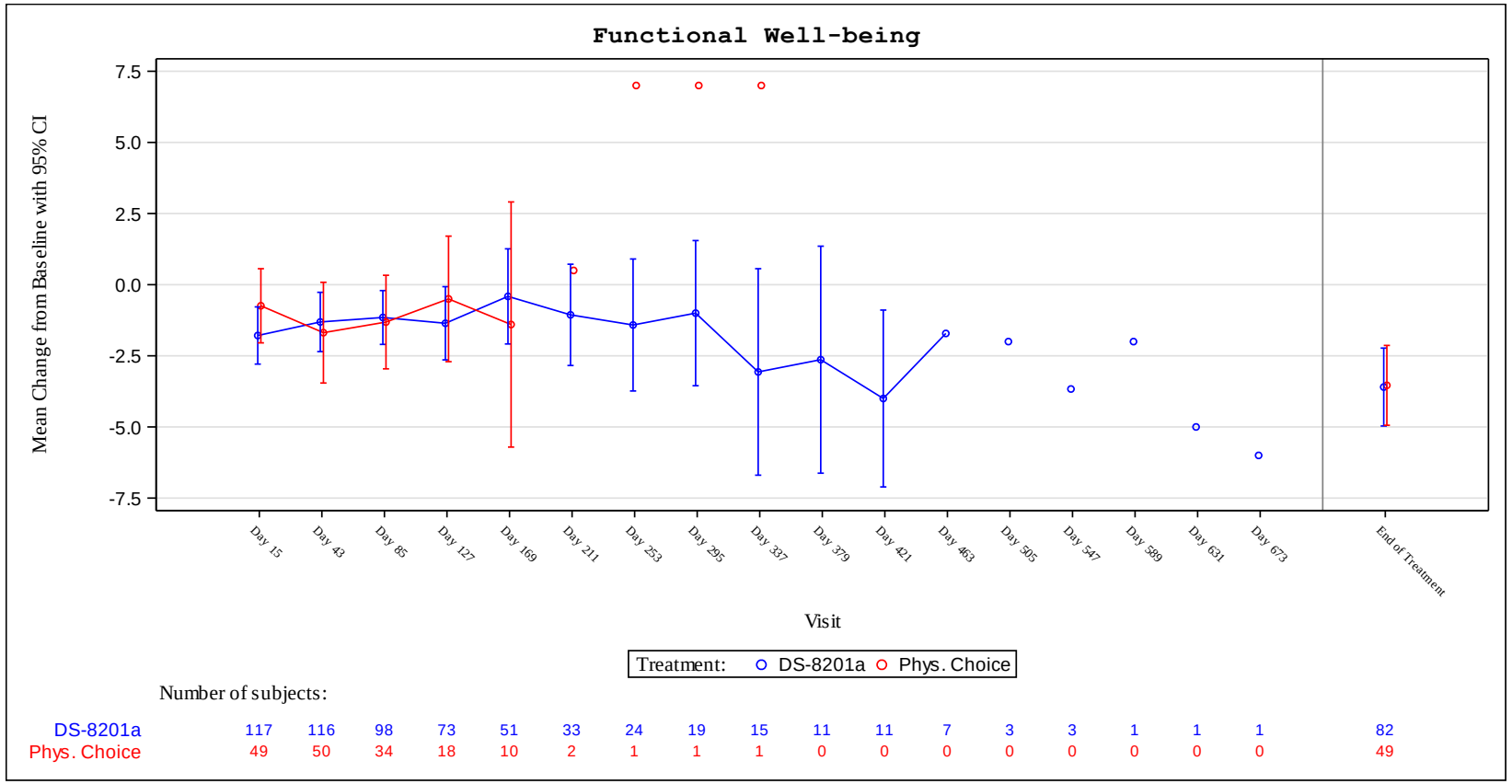
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Functional Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.5737
yes	33	-1.65 (-2.83, -0.46)	12	-3.13 (-6.95, 0.69)	1.48 (-2.51, 5.48)	0.4627	0.33 (-0.33, 1.00)	0.3266	
no	90	-1.60 (-2.31, -0.89)	42	-1.17 (-2.52, 0.18)	-0.44 (-1.96, 1.09)	0.5731	-0.12 (-0.48, 0.25)	0.5352	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.7307
yes	44	-1.61 (-2.70, -0.52)	13	-2.88 (-6.57, 0.81)	1.27 (-2.57, 5.12)	0.5139	0.28 (-0.34, 0.90)	0.3709	
no	79	-1.62 (-2.34, -0.90)	41	-1.13 (-2.40, 0.13)	-0.49 (-1.95, 0.97)	0.5083	-0.14 (-0.52, 0.24)	0.4749	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.4226
yes	22	-0.35 (-1.83, 1.12)	5	-0.32 (-3.77, 3.13)	-0.04 (-3.80, 3.73)	0.9845	-0.01 (-0.98, 0.96)	0.9831	
no	101	-1.81 (-2.46, -1.15)	49	-1.63 (-3.07, -0.20)	-0.17 (-1.75, 1.40)	0.8294	-0.04 (-0.38, 0.30)	0.8039	
Presence of liver metastasis at baseline									0.0203
yes	67	-1.65 (-2.49, -0.80)	29	-3.86 (-5.83, -1.90)	2.22 (0.08, 4.36)	0.0424	0.53 (0.09, 0.98)	0.0178	
no	56	-1.53 (-2.36, -0.70)	25	0.54 (-1.22, 2.31)	-2.08 (-4.02, -0.13)	0.0369	-0.58 (-1.06, -0.10)	0.0180	
Renal impairment at baseline									0.5798
normal	33	-1.56 (-2.60, -0.53)	12	-3.39 (-7.76, 0.98)	1.83 (-2.66, 6.31)	0.4218	0.39 (-0.27, 1.06)	0.2457	
mild	53	-1.25 (-2.34, -0.16)	25	-1.27 (-3.20, 0.66)	0.01 (-2.21, 2.23)	0.9919	0.00 (-0.47, 0.48)	0.9913	
moderate	37	-2.22 (-3.20, -1.23)	16	-2.20 (-4.29, -0.11)	-0.02 (-2.33, 2.30)	0.9879	-0.01 (-0.59, 0.58)	0.9862	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.3043
normal	86	-1.45 (-2.17, -0.73)	40	-1.60 (-3.09, -0.10)	0.15 (-1.51, 1.80)	0.8625	0.04 (-0.34, 0.41)	0.8442	
mild	36	-2.02 (-3.16, -0.88)	14	-1.27 (-4.21, 1.66)	-0.75 (-3.90, 2.40)	0.6376	-0.18 (-0.80, 0.44)	0.5627	
moderate	1	NE	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.1879
yes	8	-1.66 (-3.98, 0.66)	4	2.36 (-1.67, 6.40)	-4.02 (-8.68, 0.64)	0.0836	-1.29 (-2.60, 0.02)	0.0529	
no	115	-1.61 (-2.24, -0.99)	50	-2.55 (-4.02, -1.08)	0.93 (-0.66, 2.53)	0.2510	0.23 (-0.10, 0.56)	0.1753	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.1326
yes	3	-2.39 (-9.25, 4.48)	3	1.72 (-5.28, 8.72)	-4.10 (-13.96, 5.75)	0.2943	-1.02 (-2.72, 0.68)	0.2396	
no	120	-1.61 (-2.21, -1.01)	51	-2.63 (-4.16, -1.10)	1.02 (-0.62, 2.66)	0.2225	0.25 (-0.08, 0.58)	0.1403	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Graphical Summary of Functional Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	69 (55.2)	26 (41.9)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	4.2 (2.8, 6.0)	3.2 (2.6, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.01 (0.64, 1.60)	
p-value [c]	0.9863	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.02 (0.64, 1.61)	
p-value [c]	0.9527	

Time to Deterioration of Functional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.1851
Japan	55/ 99 (55.6)	4.1 (2.8, 6.0)	20/ 50 (40.0)	4.3 (2.6, NE)	1.16 (0.69, 1.94)	0.6037	
Korea	14/ 26 (53.8)	4.2 (1.4, NE)	6/ 12 (50.0)	1.4 (0.5, NE)	0.58 (0.22, 1.54)	0.2596	
Lines of prior systemic therapy							0.2602
2	36/ 66 (54.5)	4.2 (2.6, 6.0)	13/ 38 (34.2)	NE (2.9, NE)	1.43 (0.75, 2.71)	0.2827	
3	21/ 34 (61.8)	2.8 (0.6, 15.5)	11/ 18 (61.1)	2.2 (0.6, 5.7)	0.83 (0.39, 1.73)	0.5770	
>=4	12/ 25 (48.0)	7.0 (2.8, NE)	2/ 6 (33.3)	NE (0.5, NE)	0.55 (0.12, 2.52)	0.4334	
Age							0.0020
<65 years	38/ 55 (69.1)	2.8 (1.4, 4.3)	6/ 27 (22.2)	NE (3.2, NE)	2.74 (1.14, 6.55)	0.0187	
>=65 years	31/ 70 (44.3)	5.6 (3.1, NE)	20/ 35 (57.1)	2.6 (0.7, 4.3)	0.54 (0.31, 0.96)	0.0316	
Sex							0.3064
female	12/ 30 (40.0)	5.5 (2.9, NE)	6/ 15 (40.0)	5.7 (0.5, 5.7)	0.62 (0.23, 1.69)	0.3339	
male	57/ 95 (60.0)	4.1 (1.5, 5.6)	20/ 47 (42.6)	3.2 (2.6, NE)	1.16 (0.69, 1.95)	0.5797	
ECOG PS							0.6387
0	37/ 62 (59.7)	4.3 (2.7, 7.0)	12/ 30 (40.0)	5.7 (1.7, NE)	1.16 (0.60, 2.25)	0.6711	
1	32/ 63 (50.8)	4.1 (2.8, 15.3)	14/ 32 (43.8)	3.1 (1.4, NE)	0.93 (0.49, 1.76)	0.8240	
HER2 Status in central laboratory							0.3109
IHC 3+	54/ 96 (56.3)	4.2 (2.8, 9.8)	21/ 47 (44.7)	3.1 (1.7, NE)	0.91 (0.54, 1.52)	0.6911	
IHC 2+/ISH +	15/ 29 (51.7)	3.8 (1.4, NE)	5/ 15 (33.3)	5.7 (1.7, 5.7)	1.52 (0.55, 4.24)	0.4230	
Primary tumor location							0.9817
Gastric	56/108 (51.9)	4.3 (2.8, 7.0)	26/ 55 (47.3)	3.1 (1.7, 5.7)	0.86 (0.54, 1.38)	0.5141	
GEJ	13/ 17 (76.5)	1.5 (0.5, 15.3)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.3725
intestinal	50/ 89 (56.2)	4.2 (2.8, 6.0)	18/ 38 (47.4)	3.2 (2.6, NE)	0.99 (0.58, 1.72)	0.9597	
diffuse	13/ 28 (46.4)	7.0 (1.4, NE)	6/ 18 (33.3)	NE (0.5, NE)	0.87 (0.32, 2.33)	0.7725	
others	6/ 8 (75.0)	2.8 (0.5, 11.3)	2/ 6 (33.3)	NE (1.4, NE)	2.73 (0.52, 14.23)	0.1904	
Number of metastatic sites							0.1189
<2	13/ 24 (54.2)	12.8 (0.5, 15.5)	2/ 10 (20.0)	NE (1.4, NE)	2.85 (0.63, 12.89)	0.1599	
>= 2	56/101 (55.4)	4.1 (2.8, 5.6)	24/ 52 (46.2)	3.0 (1.7, 5.7)	0.84 (0.51, 1.36)	0.4623	
Previous total gastrectomy							0.5006
yes	13/ 22 (59.1)	2.8 (0.5, NE)	3/ 9 (33.3)	NE (0.5, NE)	1.52 (0.43, 5.38)	0.5192	
no	56/103 (54.4)	4.2 (2.9, 7.0)	23/ 53 (43.4)	3.2 (2.6, NE)	0.92 (0.56, 1.52)	0.7408	
Prior adjuvant/ neoadjuvant therapy							0.8918
yes	13/ 30 (43.3)	12.8 (2.8, NE)	2/ 10 (20.0)	NE (0.6, NE)	1.25 (0.28, 5.66)	0.7855	
no	56/ 95 (58.9)	3.8 (2.6, 4.6)	24/ 52 (46.2)	3.1 (1.7, NE)	1.08 (0.66, 1.75)	0.7677	
Prior ramucirumab contained treatment							0.3065
yes	57/ 94 (60.6)	3.1 (1.5, 4.3)	18/ 41 (43.9)	3.0 (1.7, NE)	1.15 (0.67, 1.97)	0.6254	
no	12/ 31 (38.7)	12.8 (4.3, 15.3)	8/ 21 (38.1)	4.3 (1.4, NE)	0.60 (0.24, 1.55)	0.2781	
Prior nivolumab contained treatment							0.0661
yes	18/ 33 (54.5)	7.0 (0.7, 15.5)	8/ 15 (53.3)	2.2 (0.5, 5.7)	0.53 (0.22, 1.27)	0.1503	
no	51/ 92 (55.4)	4.2 (2.8, 5.6)	18/ 47 (38.3)	4.3 (2.6, NE)	1.26 (0.73, 2.17)	0.4097	

Time to Deterioration of Functional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0765
yes	22/ 44 (50.0)	7.0 (1.4, 15.5)	8/ 17 (47.1)	2.6 (0.5, 5.7)	0.59 (0.26, 1.36)	0.2144	
no	47/ 81 (58.0)	3.8 (2.8, 5.5)	18/ 45 (40.0)	3.2 (2.6, NE)	1.27 (0.74, 2.21)	0.3951	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.8732
yes	8/ 22 (36.4)	NE (2.6, NE)	2/ 7 (28.6)	NE (1.4, NE)	0.96 (0.20, 4.54)	0.9548	
no	61/103 (59.2)	4.1 (2.8, 5.6)	24/ 55 (43.6)	3.1 (1.7, NE)	1.07 (0.66, 1.74)	0.7854	
Presence of liver metastasis at baseline							0.0305
yes	40/ 67 (59.7)	3.1 (1.4, 5.5)	21/ 34 (61.8)	1.7 (0.7, 3.0)	0.71 (0.41, 1.21)	0.2000	
no	29/ 58 (50.0)	6.0 (2.8, 12.8)	5/ 28 (17.9)	NE (3.1, NE)	2.25 (0.86, 5.89)	0.0918	
Renal impairment at baseline							0.4873
normal	23/ 33 (69.7)	3.8 (1.4, 7.0)	4/ 13 (30.8)	3.2 (0.5, NE)	1.62 (0.55, 4.82)	0.3781	
mild	27/ 53 (50.9)	4.6 (2.7, NE)	12/ 28 (42.9)	3.1 (1.4, NE)	0.95 (0.48, 1.88)	0.8632	
moderate	19/ 39 (48.7)	4.2 (2.8, 15.3)	10/ 20 (50.0)	2.8 (1.4, NE)	0.79 (0.36, 1.72)	0.5222	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8145
normal	48/ 88 (54.5)	4.6 (2.8, 11.3)	19/ 47 (40.4)	3.2 (2.6, NE)	0.96 (0.56, 1.66)	0.8742	
mild	20/ 36 (55.6)	2.9 (1.3, 5.6)	7/ 15 (46.7)	2.6 (0.5, NE)	1.05 (0.44, 2.50)	0.9134	
moderate	1/ 1 (100.0)	0.5 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4387
yes	4/ 8 (50.0)	4.3 (0.5, NE)	1/ 5 (20.0)	NE (0.5, NE)	2.18 (0.24, 19.72)	0.4613	
no	65/117 (55.6)	4.2 (2.8, 6.0)	25/ 57 (43.9)	3.1 (1.7, NE)	0.95 (0.59, 1.52)	0.8114	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9831
yes	2/ 3 (66.7)	4.3 (0.5, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	67/122 (54.9)	4.2 (2.8, 6.0)	26/ 58 (44.8)	3.1 (1.7, NE)	0.90 (0.57, 1.44)	0.6492	

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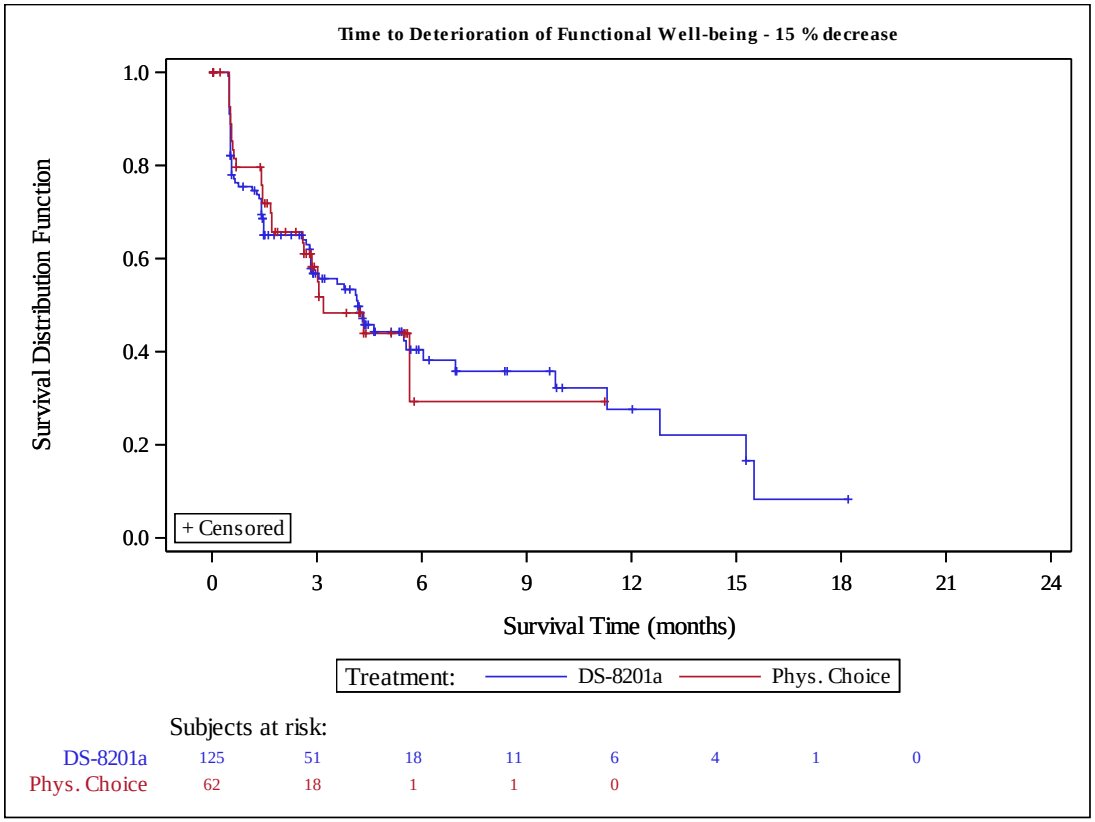
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

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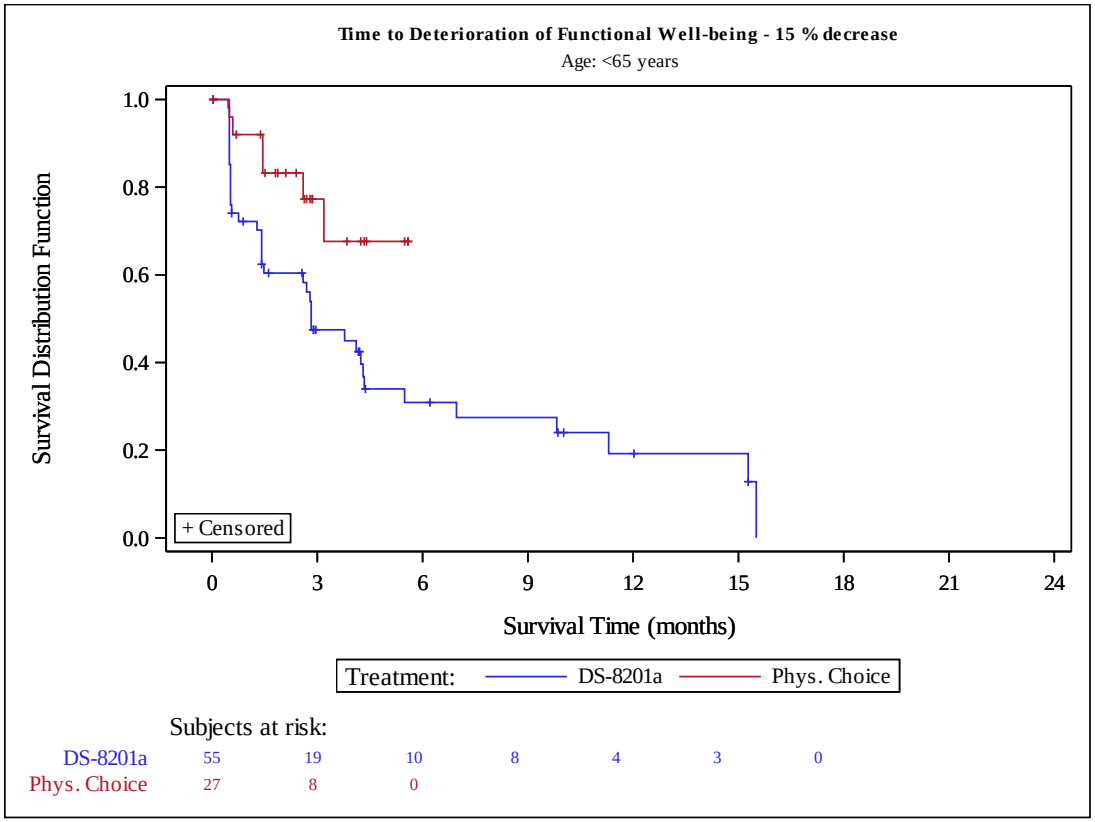

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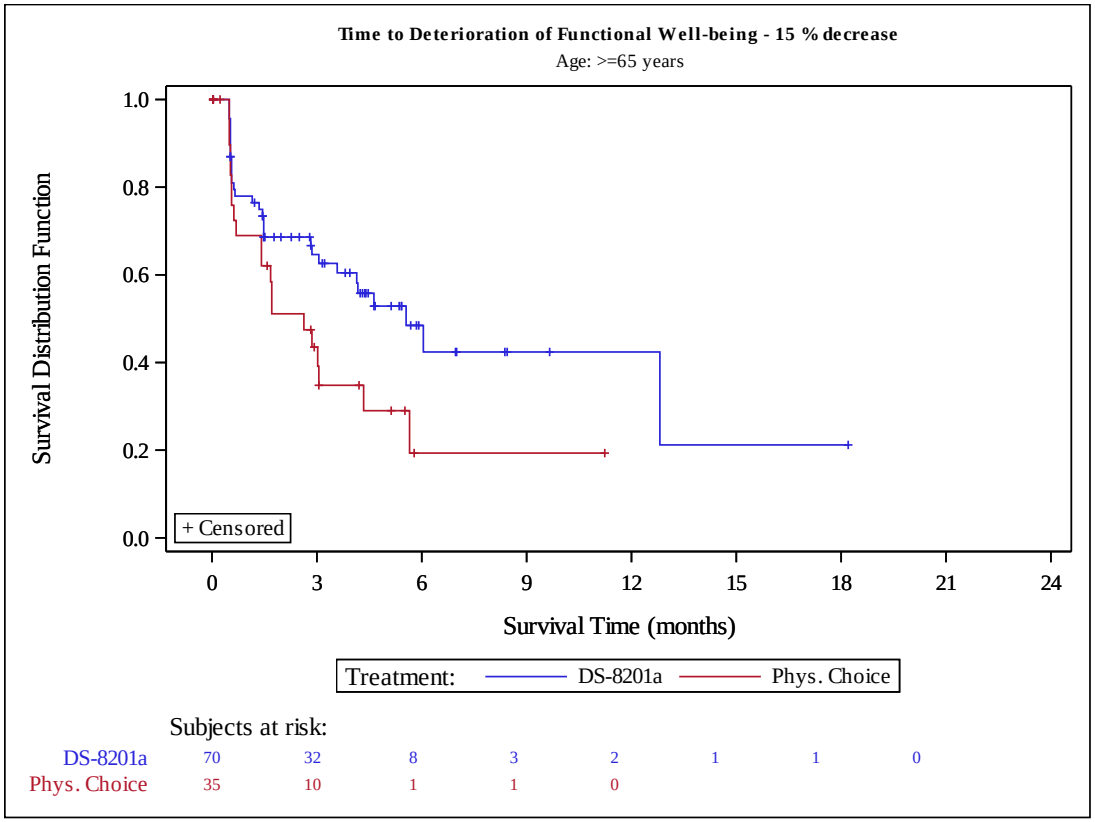

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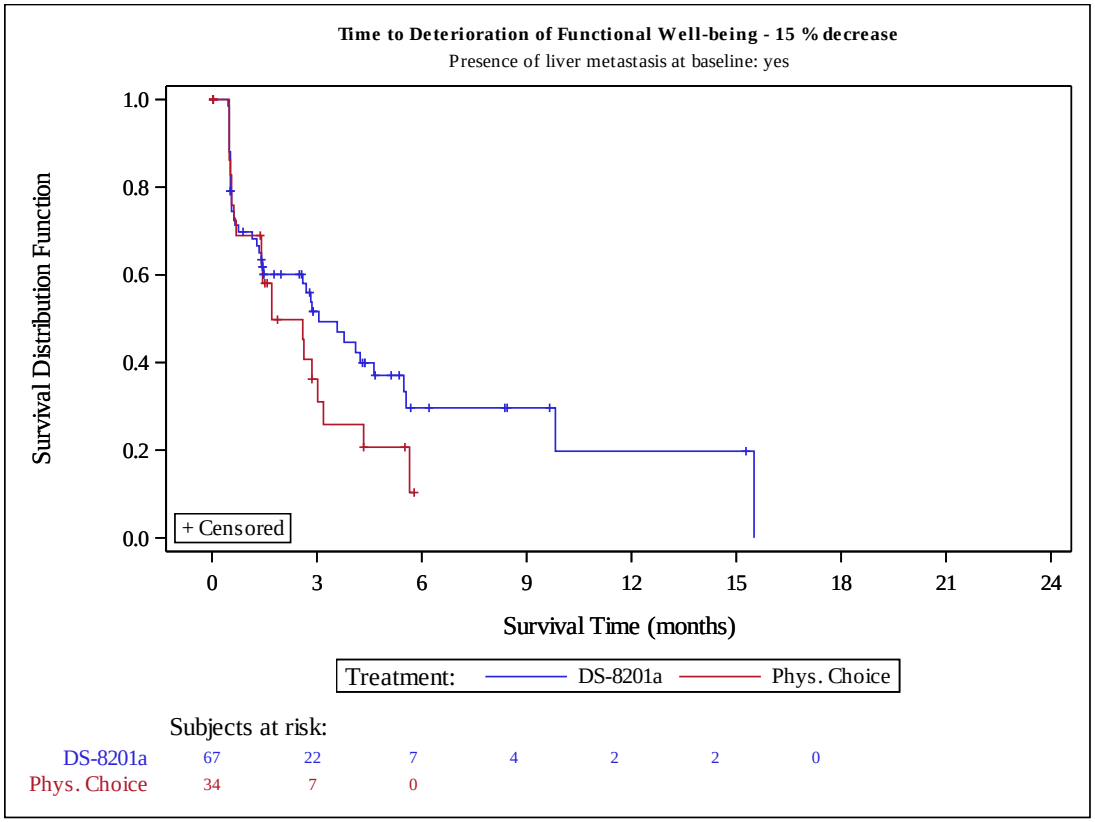

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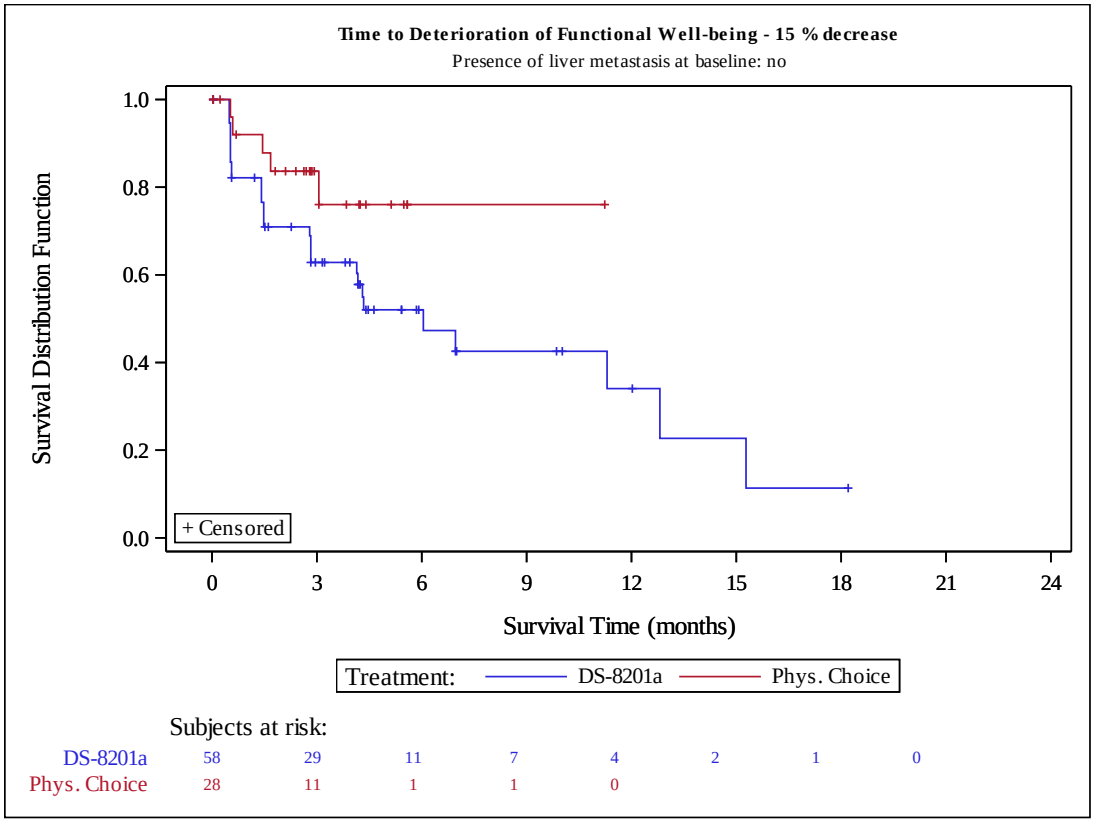

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Source data: ADAM.ADSL and ADAM.ADFACTG
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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	53 (42.4)	22 (35.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	7.3 (5.5, 11.3)	4.3 (3.0, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.60 (0.36, 1.01)	
p-value [c]	0.0554	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.64 (0.38, 1.07)	
p-value [c]	0.0851	

Time to Definitive Deterioration of Functional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.2013
Japan	40/ 99 (40.4)	7.3 (5.5, 15.3)	16/ 50 (32.0)	5.7 (3.2, NE)	0.71 (0.39, 1.30)	0.2627	
Korea	13/ 26 (50.0)	5.7 (2.8, 11.3)	6/ 12 (50.0)	1.4 (0.5, NE)	0.35 (0.12, 0.99)	0.0393	
Lines of prior systemic therapy							0.4645
2	27/ 66 (40.9)	7.3 (4.3, 11.3)	11/ 38 (28.9)	NE (3.0, NE)	0.84 (0.41, 1.74)	0.6489	
3	16/ 34 (47.1)	5.7 (3.1, 15.5)	9/ 18 (50.0)	3.2 (0.6, NE)	0.54 (0.23, 1.25)	0.1397	
>=4	10/ 25 (40.0)	7.2 (4.1, NE)	2/ 6 (33.3)	4.3 (0.5, NE)	0.44 (0.09, 2.12)	0.2979	
Age							0.0793
<65 years	28/ 55 (50.9)	5.7 (4.1, 15.3)	6/ 27 (22.2)	NE (3.2, NE)	1.21 (0.49, 3.02)	0.6759	
>=65 years	25/ 70 (35.7)	7.3 (5.4, 12.8)	16/ 35 (45.7)	3.1 (1.7, NE)	0.44 (0.23, 0.83)	0.0097	
Sex							0.8530
female	11/ 30 (36.7)	5.9 (3.1, NE)	4/ 15 (26.7)	5.7 (0.5, 5.7)	0.64 (0.19, 2.10)	0.4557	
male	42/ 95 (44.2)	7.3 (5.4, 12.8)	18/ 47 (38.3)	4.3 (2.9, NE)	0.64 (0.36, 1.14)	0.1288	
ECOG PS							0.5780
0	26/ 62 (41.9)	8.4 (5.9, 15.5)	11/ 30 (36.7)	4.3 (3.0, NE)	0.53 (0.25, 1.12)	0.0898	
1	27/ 63 (42.9)	5.5 (4.1, 15.3)	11/ 32 (34.4)	4.3 (2.6, NE)	0.78 (0.38, 1.60)	0.5008	
HER2 Status in central laboratory							0.2427
IHC 3+	42/ 96 (43.8)	8.4 (5.5, 12.8)	18/ 47 (38.3)	3.2 (2.9, NE)	0.55 (0.31, 0.97)	0.0384	
IHC 2+/ISH +	11/ 29 (37.9)	7.0 (3.8, NE)	4/ 15 (26.7)	5.7 (1.7, 5.7)	1.06 (0.33, 3.41)	0.9160	
Primary tumor location							0.9866
Gastric	46/108 (42.6)	7.0 (4.6, 9.8)	22/ 55 (40.0)	4.3 (2.9, NE)	0.61 (0.36, 1.03)	0.0606	
GEJ	7/ 17 (41.2)	15.3 (3.8, 15.5)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.2629
intestinal	36/ 89 (40.4)	8.4 (5.5, 15.3)	14/ 38 (36.8)	4.3 (3.0, NE)	0.57 (0.30, 1.09)	0.0868	
diffuse	11/ 28 (39.3)	7.0 (2.7, NE)	6/ 18 (33.3)	4.3 (0.5, NE)	0.58 (0.20, 1.65)	0.3066	
others	6/ 8 (75.0)	2.8 (0.5, 11.3)	2/ 6 (33.3)	NE (1.4, NE)	2.25 (0.43, 11.68)	0.2925	
Number of metastatic sites							0.5245
<2	8/ 24 (33.3)	12.8 (5.5, NE)	2/ 10 (20.0)	NE (1.4, NE)	0.77 (0.15, 3.88)	0.7466	
>= 2	45/101 (44.6)	5.9 (4.2, 9.8)	20/ 52 (38.5)	4.3 (2.6, NE)	0.61 (0.35, 1.05)	0.0737	
Previous total gastrectomy							0.4852
yes	9/ 22 (40.9)	7.2 (2.8, NE)	2/ 9 (22.2)	NE (0.5, NE)	1.10 (0.23, 5.36)	0.9005	
no	44/103 (42.7)	8.4 (4.6, 12.8)	20/ 53 (37.7)	4.3 (2.9, NE)	0.58 (0.34, 1.01)	0.0529	
Prior adjuvant/ neoadjuvant therapy							0.3323
yes	12/ 30 (40.0)	7.0 (5.5, NE)	1/ 10 (10.0)	NE (0.6, NE)	1.52 (0.19, 12.23)	0.6924	
no	41/ 95 (43.2)	7.3 (4.3, 11.3)	21/ 52 (40.4)	4.3 (2.9, NE)	0.63 (0.37, 1.09)	0.1000	
Prior ramucirumab contained treatment							0.6235
yes	43/ 94 (45.7)	5.9 (4.3, 8.6)	15/ 41 (36.6)	4.3 (2.6, NE)	0.66 (0.36, 1.22)	0.1823	
no	10/ 31 (32.3)	12.8 (8.4, 15.3)	7/ 21 (33.3)	NE (1.7, NE)	0.48 (0.17, 1.35)	0.1490	
Prior nivolumab contained treatment							0.0334
yes	13/ 33 (39.4)	12.8 (5.9, NE)	7/ 15 (46.7)	4.1 (0.5, 5.7)	0.28 (0.10, 0.78)	0.0106	
no	40/ 92 (43.5)	7.2 (4.3, 9.8)	15/ 47 (31.9)	4.3 (3.0, NE)	0.83 (0.45, 1.52)	0.5474	

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[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0240
yes	15/ 44 (34.1)	12.8 (5.9, NE)	7/ 17 (41.2)	5.7 (0.5, 5.7)	0.32 (0.12, 0.83)	0.0156	
no	38/ 81 (46.9)	5.5 (4.3, 8.4)	15/ 45 (33.3)	4.3 (3.0, NE)	0.86 (0.46, 1.58)	0.6236	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.8721
yes	6/ 22 (27.3)	NE (4.3, NE)	2/ 7 (28.6)	NE (1.4, NE)	0.50 (0.10, 2.63)	0.4048	
no	47/103 (45.6)	7.2 (4.6, 11.3)	20/ 55 (36.4)	4.3 (2.9, NE)	0.67 (0.39, 1.15)	0.1422	
Presence of liver metastasis at baseline							0.0169
yes	30/ 67 (44.8)	5.7 (3.8, 15.5)	18/ 34 (52.9)	2.6 (1.4, 4.3)	0.40 (0.22, 0.74)	0.0027	
no	23/ 58 (39.7)	8.6 (5.5, 12.8)	4/ 28 (14.3)	NE (4.3, NE)	1.51 (0.51, 4.49)	0.4544	
Renal impairment at baseline							0.7361
normal	16/ 33 (48.5)	7.2 (5.5, 11.3)	4/ 13 (30.8)	3.2 (0.5, NE)	0.34 (0.10, 1.20)	0.0811	
mild	21/ 53 (39.6)	7.3 (4.3, NE)	11/ 28 (39.3)	4.3 (1.4, NE)	0.63 (0.30, 1.33)	0.2164	
moderate	16/ 39 (41.0)	8.4 (2.9, 15.3)	7/ 20 (35.0)	5.7 (2.6, NE)	0.84 (0.34, 2.11)	0.7163	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7942
normal	37/ 88 (42.0)	9.8 (5.4, 15.3)	17/ 47 (36.2)	4.3 (3.0, NE)	0.64 (0.36, 1.17)	0.1453	
mild	16/ 36 (44.4)	5.9 (3.1, 7.3)	5/ 15 (33.3)	NE (0.5, NE)	0.58 (0.20, 1.70)	0.3217	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3599
yes	4/ 8 (50.0)	8.4 (3.1, NE)	1/ 5 (20.0)	NE (0.5, NE)	1.59 (0.18, 14.38)	0.6772	
no	49/117 (41.9)	7.3 (5.4, 12.8)	21/ 57 (36.8)	4.3 (2.9, NE)	0.59 (0.34, 1.01)	0.0494	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9852
yes	2/ 3 (66.7)	8.4 (4.3, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	51/122 (41.8)	7.2 (5.5, 11.3)	22/ 58 (37.9)	4.3 (2.9, NE)	0.55 (0.32, 0.93)	0.0239	

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Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
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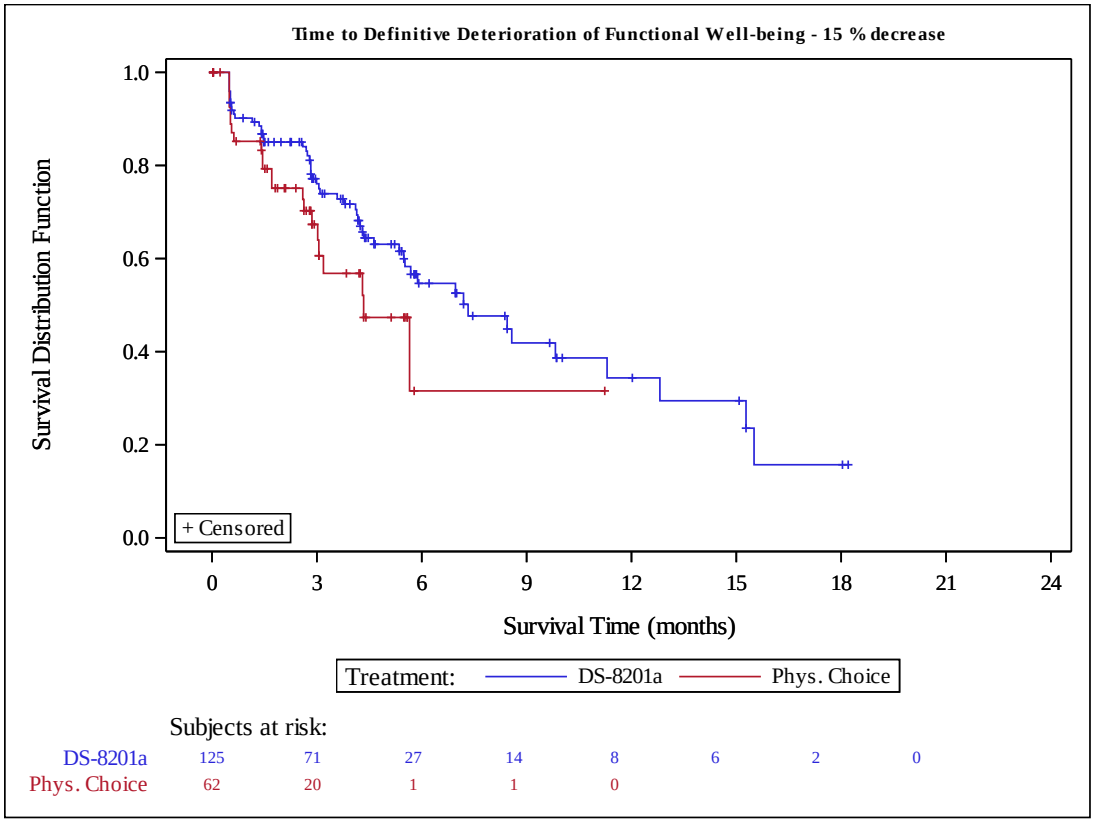
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
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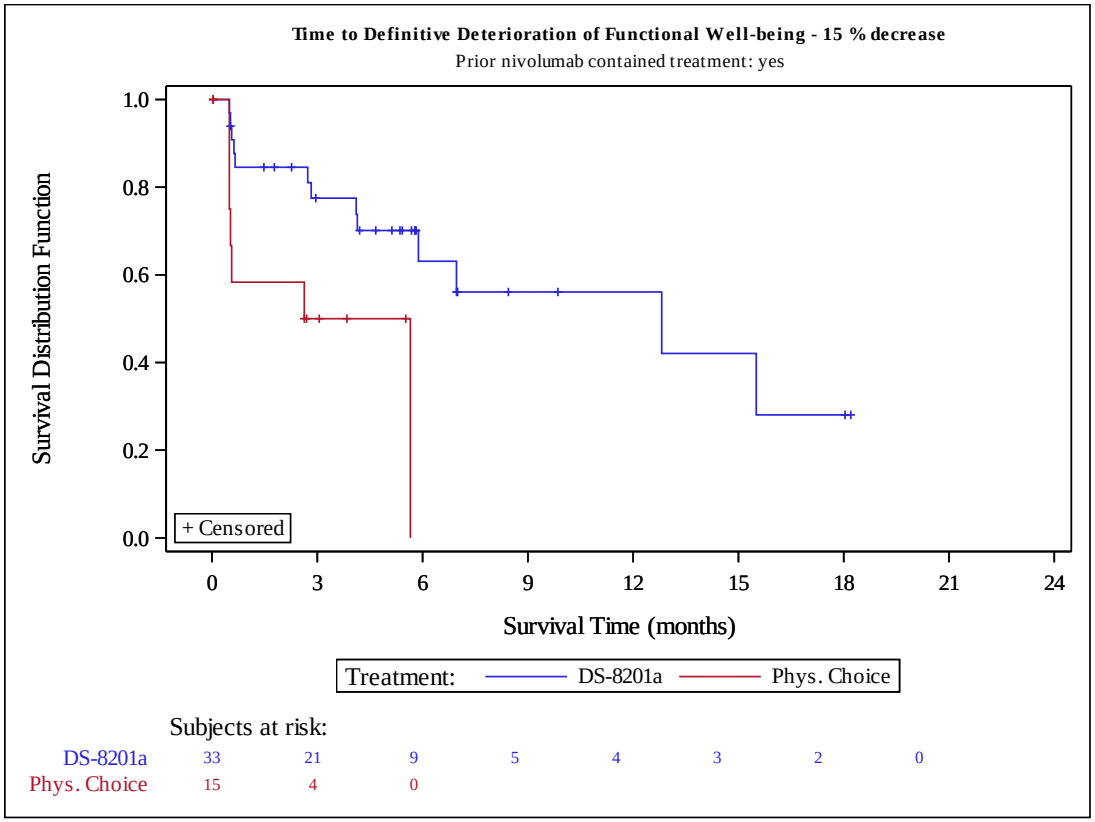

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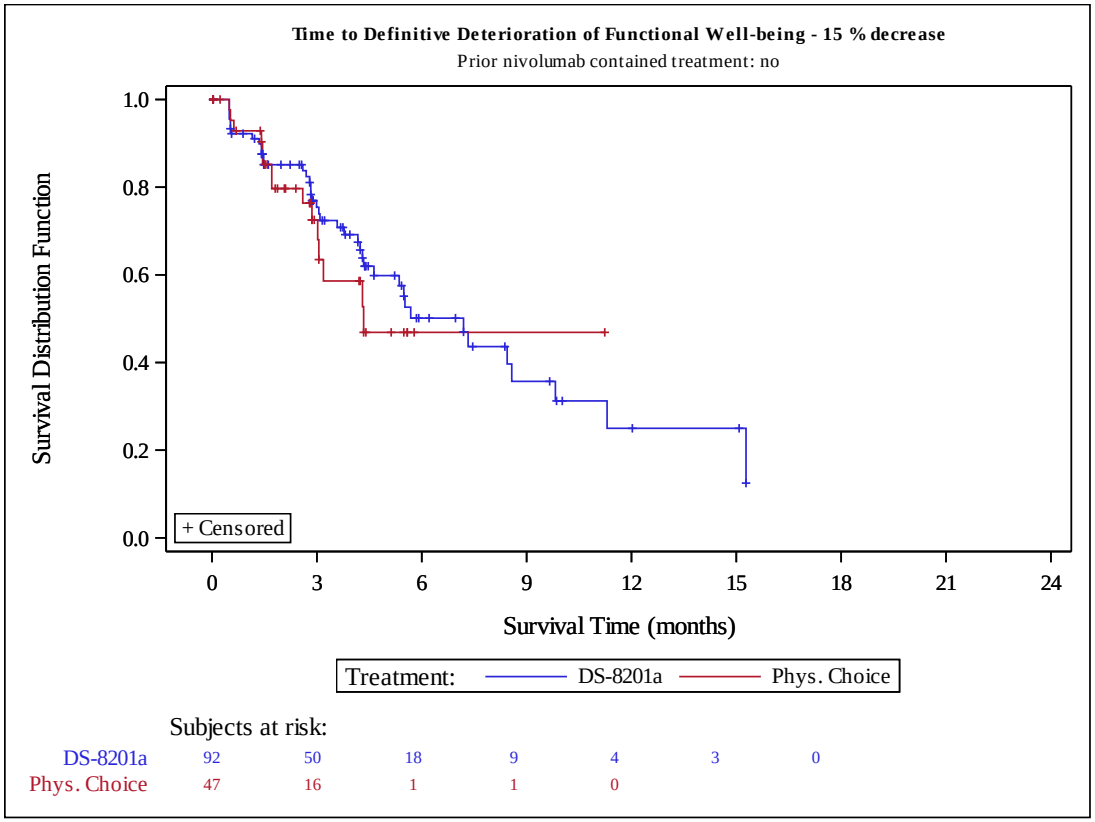
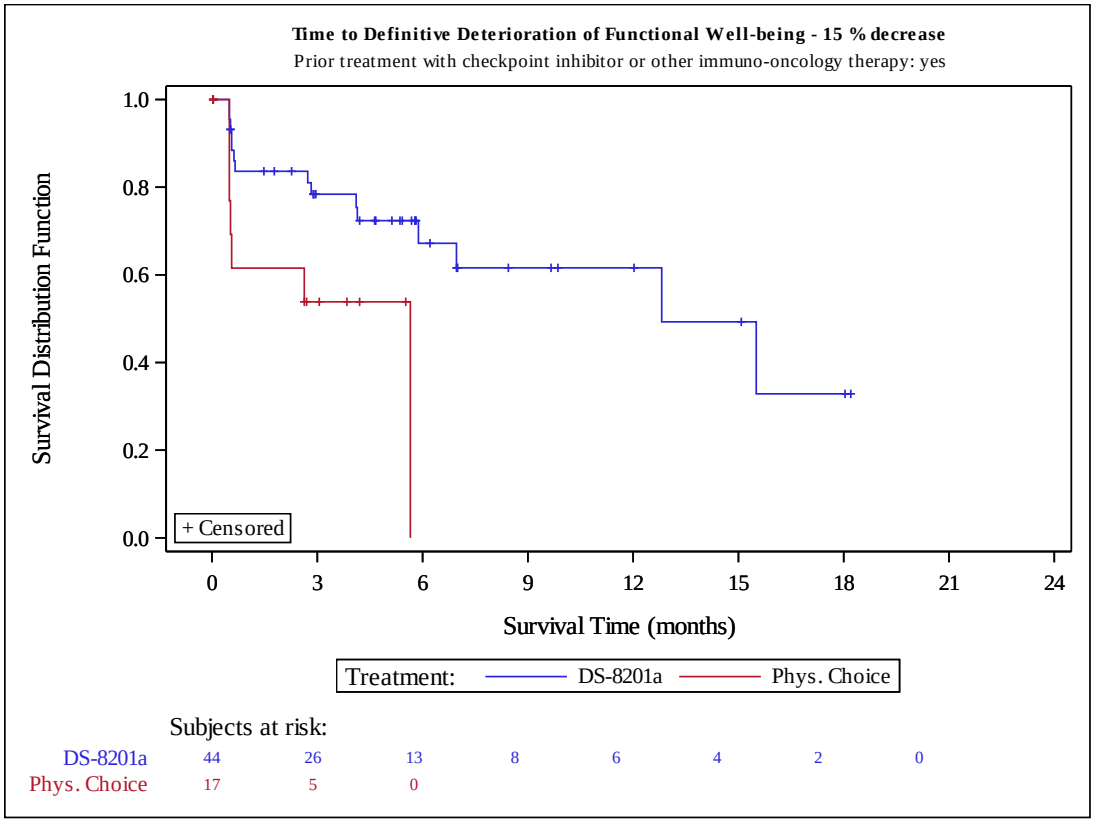
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

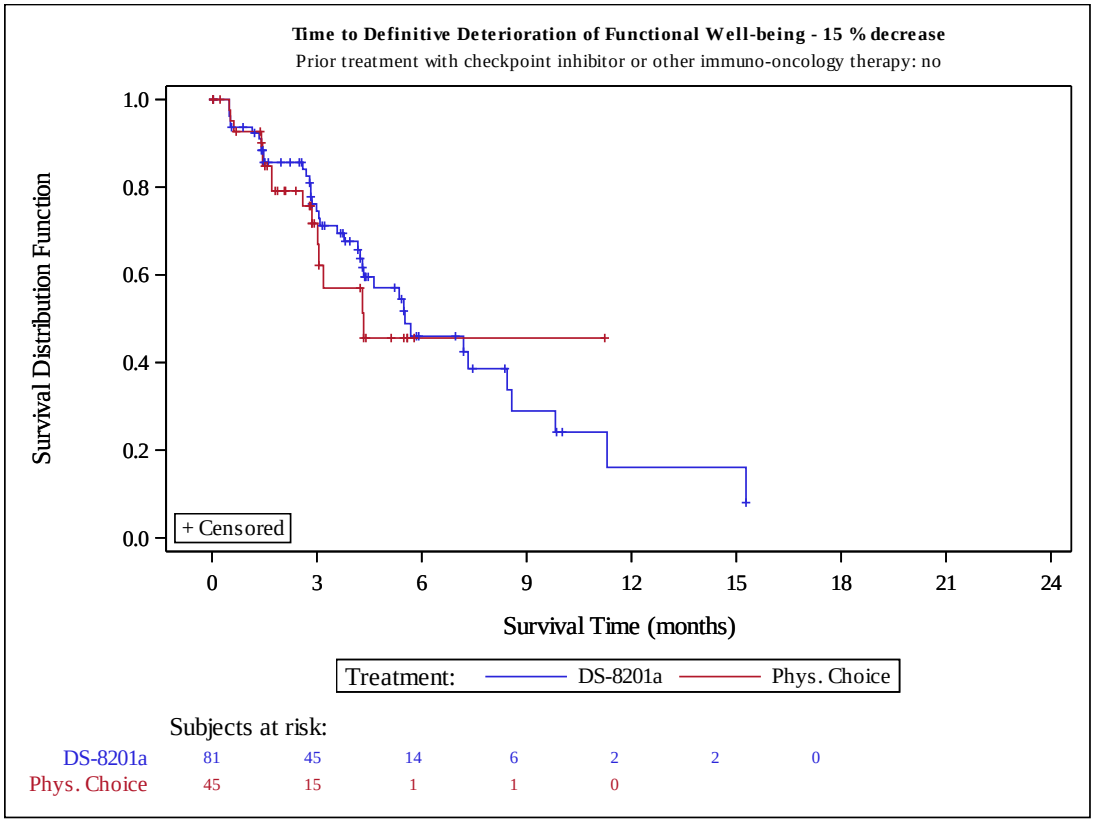
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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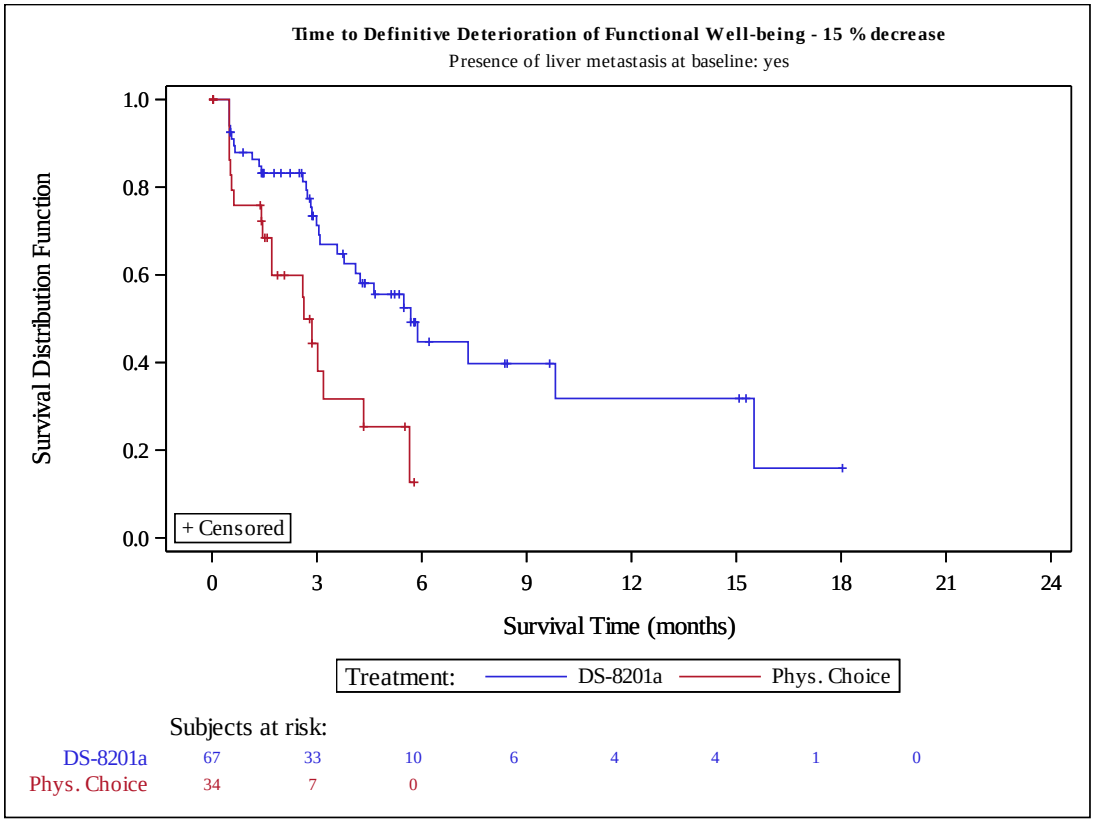
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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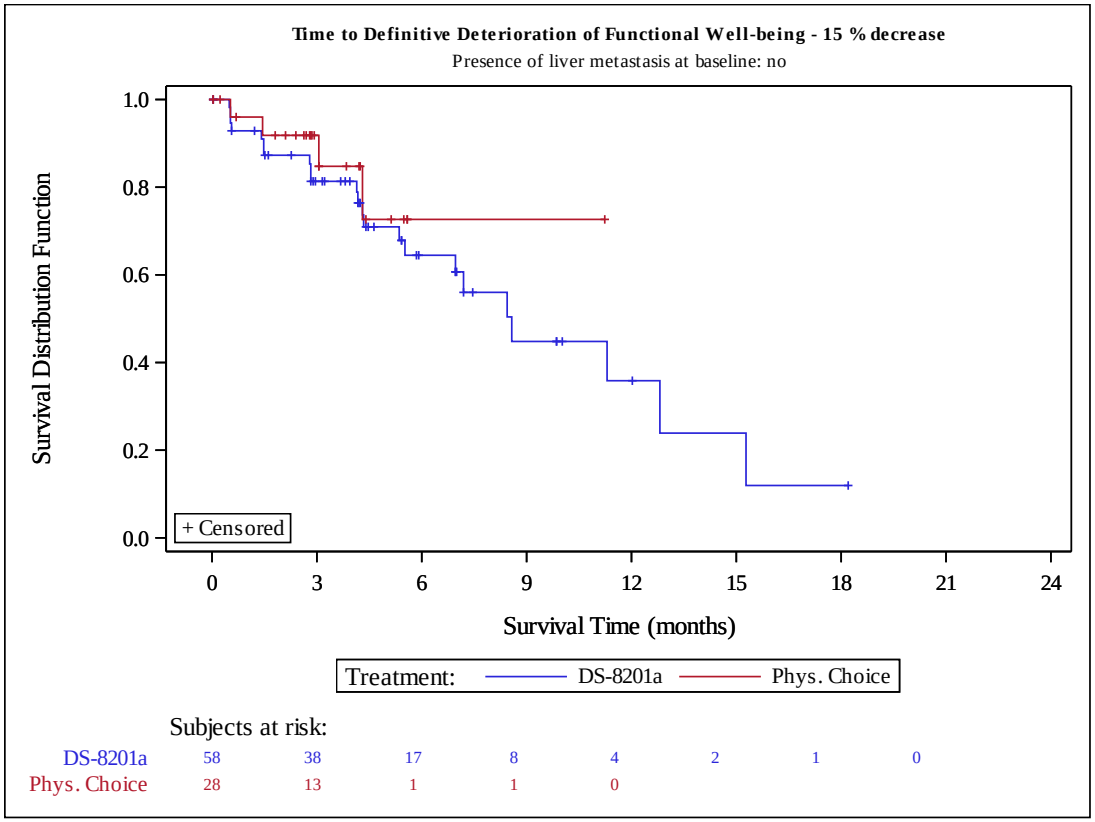
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	118	10 (8.5)	78 (66.1)	30 (25.4)	52	3 (5.8)	38 (73.1)	11 (21.2)
	Day 43	117	10 (8.5)	85 (72.6)	22 (18.8)	53	6 (11.3)	35 (66.0)	12 (22.6)
	Day 85	99	11 (11.1)	63 (63.6)	25 (25.3)	36	3 (8.3)	24 (66.7)	9 (25.0)
	Day 127	74	8 (10.8)	47 (63.5)	19 (25.7)	19	3 (15.8)	12 (63.2)	4 (21.1)
	Day 169	52	9 (17.3)	29 (55.8)	14 (26.9)	11	2 (18.2)	5 (45.5)	4 (36.4)
	Day 211	34	5 (14.7)	22 (64.7)	7 (20.6)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	24	4 (16.7)	13 (54.2)	7 (29.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	19	2 (10.5)	11 (57.9)	6 (31.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	15	1 (6.7)	9 (60.0)	5 (33.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	11	2 (18.2)	6 (54.5)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	7 (8.4)	40 (48.2)	36 (43.4)	53	1 (1.9)	33 (62.3)	19 (35.8)
Region									
Japan									
	Day 15	96	7 (7.3)	65 (67.7)	24 (25.0)	45	2 (4.4)	35 (77.8)	8 (17.8)
	Day 43	93	6 (6.5)	71 (76.3)	16 (17.2)	43	5 (11.6)	31 (72.1)	7 (16.3)
	Day 85	77	10 (13.0)	48 (62.3)	19 (24.7)	32	3 (9.4)	22 (68.8)	7 (21.9)
	Day 127	60	6 (10.0)	42 (70.0)	12 (20.0)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	45	8 (17.8)	26 (57.8)	11 (24.4)	9	1 (11.1)	5 (55.6)	3 (33.3)
	Day 211	28	2 (7.1)	19 (67.9)	7 (25.0)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	18	3 (16.7)	10 (55.6)	5 (27.8)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	14	0 (0.0)	10 (71.4)	4 (28.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	11	0 (0.0)	9 (81.8)	2 (18.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	65	5 (7.7)	34 (52.3)	26 (40.0)	45	1 (2.2)	30 (66.7)	14 (31.1)
Region									
Korea									
	Day 15	22	3 (13.6)	13 (59.1)	6 (27.3)	7	1 (14.3)	3 (42.9)	3 (42.9)
	Day 43	24	4 (16.7)	14 (58.3)	6 (25.0)	10	1 (10.0)	4 (40.0)	5 (50.0)
	Day 85	22	1 (4.5)	15 (68.2)	6 (27.3)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 127	14	2 (14.3)	5 (35.7)	7 (50.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	7	1 (14.3)	3 (42.9)	3 (42.9)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 211	6	3 (50.0)	3 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	1 (20.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	0 (0.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	2 (11.1)	6 (33.3)	10 (55.6)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy									
2									
	Day 15	60	8 (13.3)	40 (66.7)	12 (20.0)	34	2 (5.9)	27 (79.4)	5 (14.7)
	Day 43	62	7 (11.3)	44 (71.0)	11 (17.7)	36	4 (11.1)	26 (72.2)	6 (16.7)
	Day 85	50	5 (10.0)	35 (70.0)	10 (20.0)	21	1 (4.8)	15 (71.4)	5 (23.8)
	Day 127	33	4 (12.1)	21 (63.6)	8 (24.2)	14	1 (7.1)	10 (71.4)	3 (21.4)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 169	21	5 (23.8)	10 (47.6)	6 (28.6)	6	2 (33.3)	3 (50.0)	1 (16.7)
	Day 211	14	3 (21.4)	11 (78.6)	0 (0.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 253	10	3 (30.0)	5 (50.0)	2 (20.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	7	1 (14.3)	4 (57.1)	2 (28.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	3	2 (66.7)	1 (33.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	3 (6.7)	23 (51.1)	19 (42.2)	32	0 (0.0)	22 (68.8)	10 (31.3)
Lines of prior systemic therapy									
3									
	Day 15	34	1 (2.9)	20 (58.8)	13 (38.2)	14	0 (0.0)	10 (71.4)	4 (28.6)
	Day 43	33	2 (6.1)	23 (69.7)	8 (24.2)	14	1 (7.1)	7 (50.0)	6 (42.9)
	Day 85	28	2 (7.1)	15 (53.6)	11 (39.3)	12	2 (16.7)	6 (50.0)	4 (33.3)
	Day 127	23	2 (8.7)	13 (56.5)	8 (34.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	17	1 (5.9)	10 (58.8)	6 (35.3)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 211	12	2 (16.7)	5 (41.7)	5 (41.7)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 253	9	1 (11.1)	4 (44.4)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	3 (14.3)	7 (33.3)	11 (52.4)	16	1 (6.3)	7 (43.8)	8 (50.0)
Lines of prior systemic therapy									
>=4									
	Day 15	24	1 (4.2)	18 (75.0)	5 (20.8)	4	1 (25.0)	1 (25.0)	2 (50.0)
	Day 43	22	1 (4.5)	18 (81.8)	3 (13.6)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	21	4 (19.0)	13 (61.9)	4 (19.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	2 (11.1)	13 (72.2)	3 (16.7)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 169	14	3 (21.4)	9 (64.3)	2 (14.3)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	10 (58.8)	6 (35.3)	5	0 (0.0)	4 (80.0)	1 (20.0)
Age									
<65 years									
	Day 15	51	5 (9.8)	31 (60.8)	15 (29.4)	22	2 (9.1)	18 (81.8)	2 (9.1)
	Day 43	52	3 (5.8)	38 (73.1)	11 (21.2)	24	2 (8.3)	19 (79.2)	3 (12.5)
	Day 85	47	3 (6.4)	29 (61.7)	15 (31.9)	16	0 (0.0)	13 (81.3)	3 (18.8)
	Day 127	34	2 (5.9)	21 (61.8)	11 (32.4)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	25	4 (16.0)	13 (52.0)	8 (32.0)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 211	16	2 (12.5)	11 (68.8)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	12	3 (25.0)	8 (66.7)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	2 (5.3)	17 (44.7)	19 (50.0)	22	0 (0.0)	18 (81.8)	4 (18.2)
Age									
>=65 years									
	Day 15	67	5 (7.5)	47 (70.1)	15 (22.4)	30	1 (3.3)	20 (66.7)	9 (30.0)
	Day 43	65	7 (10.8)	47 (72.3)	11 (16.9)	29	4 (13.8)	16 (55.2)	9 (31.0)
	Day 85	52	8 (15.4)	34 (65.4)	10 (19.2)	20	3 (15.0)	11 (55.0)	6 (30.0)
	Day 127	40	6 (15.0)	26 (65.0)	8 (20.0)	11	3 (27.3)	5 (45.5)	3 (27.3)
	Day 169	27	5 (18.5)	16 (59.3)	6 (22.2)	7	1 (14.3)	3 (42.9)	3 (42.9)
	Day 211	18	3 (16.7)	11 (61.1)	4 (22.2)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	12	1 (8.3)	5 (41.7)	6 (50.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	4 (50.0)	3 (37.5)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	4 (57.1)	3 (42.9)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	5 (11.1)	23 (51.1)	17 (37.8)	31	1 (3.2)	15 (48.4)	15 (48.4)
Sex									
female									
	Day 15	28	4 (14.3)	18 (64.3)	6 (21.4)	13	0 (0.0)	10 (76.9)	3 (23.1)
	Day 43	28	2 (7.1)	24 (85.7)	2 (7.1)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 85	20	2 (10.0)	13 (65.0)	5 (25.0)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	13	1 (7.7)	8 (61.5)	4 (30.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	9	1 (11.1)	6 (66.7)	2 (22.2)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	1 (16.7)	4 (66.7)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	11 (52.4)	8 (38.1)	14	1 (7.1)	9 (64.3)	4 (28.6)
Sex									
male									
	Day 15	90	6 (6.7)	60 (66.7)	24 (26.7)	39	3 (7.7)	28 (71.8)	8 (20.5)
	Day 43	89	8 (9.0)	61 (68.5)	20 (22.5)	40	5 (12.5)	26 (65.0)	9 (22.5)
	Day 85	79	9 (11.4)	50 (63.3)	20 (25.3)	28	2 (7.1)	17 (60.7)	9 (32.1)
	Day 127	61	7 (11.5)	39 (63.9)	15 (24.6)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 169	43	8 (18.6)	23 (53.5)	12 (27.9)	9	2 (22.2)	4 (44.4)	3 (33.3)
	Day 211	28	4 (14.3)	18 (64.3)	6 (21.4)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 253	20	3 (15.0)	10 (50.0)	7 (35.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	17	2 (11.8)	10 (58.8)	5 (29.4)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	14	1 (7.1)	8 (57.1)	5 (35.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	6 (60.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	5 (8.1)	29 (46.8)	28 (45.2)	39	0 (0.0)	24 (61.5)	15 (38.5)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS									
0									
	Day 15	60	2 (3.3)	45 (75.0)	13 (21.7)	26	0 (0.0)	22 (84.6)	4 (15.4)
	Day 43	59	4 (6.8)	45 (76.3)	10 (16.9)	26	3 (11.5)	17 (65.4)	6 (23.1)
	Day 85	54	5 (9.3)	38 (70.4)	11 (20.4)	19	2 (10.5)	13 (68.4)	4 (21.1)
	Day 127	42	5 (11.9)	31 (73.8)	6 (14.3)	9	2 (22.2)	5 (55.6)	2 (22.2)
	Day 169	33	4 (12.1)	23 (69.7)	6 (18.2)	6	1 (16.7)	2 (33.3)	3 (50.0)
	Day 211	20	1 (5.0)	15 (75.0)	4 (20.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 253	15	2 (13.3)	8 (53.3)	5 (33.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	11	0 (0.0)	8 (72.7)	3 (27.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	9	0 (0.0)	8 (88.9)	1 (11.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	2 (5.1)	21 (53.8)	16 (41.0)	27	0 (0.0)	17 (63.0)	10 (37.0)
ECOG PS									
1									
	Day 15	58	8 (13.8)	33 (56.9)	17 (29.3)	26	3 (11.5)	16 (61.5)	7 (26.9)
	Day 43	58	6 (10.3)	40 (69.0)	12 (20.7)	27	3 (11.1)	18 (66.7)	6 (22.2)
	Day 85	45	6 (13.3)	25 (55.6)	14 (31.1)	17	1 (5.9)	11 (64.7)	5 (29.4)
	Day 127	32	3 (9.4)	16 (50.0)	13 (40.6)	10	1 (10.0)	7 (70.0)	2 (20.0)
	Day 169	19	5 (26.3)	6 (31.6)	8 (42.1)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 211	14	4 (28.6)	7 (50.0)	3 (21.4)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	9	2 (22.2)	5 (55.6)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	2 (25.0)	3 (37.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	1 (16.7)	1 (16.7)	4 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	5 (11.4)	19 (43.2)	20 (45.5)	26	1 (3.8)	16 (61.5)	9 (34.6)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	91	10 (11.0)	57 (62.6)	24 (26.4)	38	1 (2.6)	28 (73.7)	9 (23.7)
	Day 43	91	7 (7.7)	67 (73.6)	17 (18.7)	40	5 (12.5)	26 (65.0)	9 (22.5)
	Day 85	79	8 (10.1)	51 (64.6)	20 (25.3)	26	2 (7.7)	16 (61.5)	8 (30.8)
	Day 127	59	6 (10.2)	38 (64.4)	15 (25.4)	13	2 (15.4)	7 (53.8)	4 (30.8)
	Day 169	41	6 (14.6)	24 (58.5)	11 (26.8)	8	1 (12.5)	4 (50.0)	3 (37.5)
	Day 211	29	4 (13.8)	20 (69.0)	5 (17.2)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	21	4 (19.0)	11 (52.4)	6 (28.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	17	2 (11.8)	10 (58.8)	5 (29.4)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	14	1 (7.1)	9 (64.3)	4 (28.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	5 (8.1)	30 (48.4)	27 (43.5)	39	0 (0.0)	24 (61.5)	15 (38.5)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	0 (0.0)	21 (77.8)	6 (22.2)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 43	26	3 (11.5)	18 (69.2)	5 (19.2)	13	1 (7.7)	9 (69.2)	3 (23.1)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	20	3 (15.0)	12 (60.0)	5 (25.0)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 127	15	2 (13.3)	9 (60.0)	4 (26.7)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 169	11	3 (27.3)	5 (45.5)	3 (27.3)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 211	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	10 (47.6)	9 (42.9)	14	1 (7.1)	9 (64.3)	4 (28.6)
Primary tumor location									
Gastric									
	Day 15	102	9 (8.8)	67 (65.7)	26 (25.5)	46	2 (4.3)	33 (71.7)	11 (23.9)
	Day 43	100	10 (10.0)	73 (73.0)	17 (17.0)	48	5 (10.4)	31 (64.6)	12 (25.0)
	Day 85	84	10 (11.9)	52 (61.9)	22 (26.2)	33	3 (9.1)	21 (63.6)	9 (27.3)
	Day 127	63	6 (9.5)	39 (61.9)	18 (28.6)	16	3 (18.8)	9 (56.3)	4 (25.0)
	Day 169	42	7 (16.7)	23 (54.8)	12 (28.6)	11	2 (18.2)	5 (45.5)	4 (36.4)
	Day 211	29	4 (13.8)	18 (62.1)	7 (24.1)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	20	3 (15.0)	10 (50.0)	7 (35.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	15	2 (13.3)	7 (46.7)	6 (40.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	12	1 (8.3)	6 (50.0)	5 (41.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	4 (50.0)	4 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	7 (9.9)	33 (46.5)	31 (43.7)	47	1 (2.1)	27 (57.4)	19 (40.4)
Primary tumor location									
GEJ									
	Day 15	16	1 (6.3)	11 (68.8)	4 (25.0)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	17	0 (0.0)	12 (70.6)	5 (29.4)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 85	15	1 (6.7)	11 (73.3)	3 (20.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	2 (18.2)	8 (72.7)	1 (9.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	7 (58.3)	5 (41.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	86	7 (8.1)	58 (67.4)	21 (24.4)	35	2 (5.7)	26 (74.3)	7 (20.0)
	Day 43	85	6 (7.1)	66 (77.6)	13 (15.3)	34	4 (11.8)	25 (73.5)	5 (14.7)
	Day 85	73	9 (12.3)	47 (64.4)	17 (23.3)	27	2 (7.4)	17 (63.0)	8 (29.6)
	Day 127	55	5 (9.1)	40 (72.7)	10 (18.2)	14	3 (21.4)	8 (57.1)	3 (21.4)
	Day 169	40	8 (20.0)	22 (55.0)	10 (25.0)	7	1 (14.3)	3 (42.9)	3 (42.9)
	Day 211	25	2 (8.0)	18 (72.0)	5 (20.0)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	16	3 (18.8)	8 (50.0)	5 (31.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	13	0 (0.0)	10 (76.9)	3 (23.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	10	0 (0.0)	8 (80.0)	2 (20.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	4 (6.3)	31 (49.2)	28 (44.4)	34	1 (2.9)	20 (58.8)	13 (38.2)
Histological subtype diffuse									
	Day 15	26	2 (7.7)	17 (65.4)	7 (26.9)	15	0 (0.0)	11 (73.3)	4 (26.7)
	Day 43	26	3 (11.5)	16 (61.5)	7 (26.9)	14	0 (0.0)	9 (64.3)	5 (35.7)
	Day 85	22	2 (9.1)	14 (63.6)	6 (27.3)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 127	15	3 (20.0)	6 (40.0)	6 (40.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	10	1 (10.0)	6 (60.0)	3 (30.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	3 (37.5)	3 (37.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	0 (0.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	16	3 (18.8)	9 (56.3)	4 (25.0)	16	0 (0.0)	12 (75.0)	4 (25.0)
Histological subtype others									
	Day 15	6	1 (16.7)	3 (50.0)	2 (33.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 43	6	1 (16.7)	3 (50.0)	2 (33.3)	5	2 (40.0)	1 (20.0)	2 (40.0)
	Day 85	4	0 (0.0)	2 (50.0)	2 (50.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	4	0 (0.0)	1 (25.0)	3 (75.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	1 (50.0)	1 (50.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	0 (0.0)	4 (100.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	23	1 (4.3)	15 (65.2)	7 (30.4)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 43	22	0 (0.0)	21 (95.5)	1 (4.5)	10	2 (20.0)	7 (70.0)	1 (10.0)
	Day 85	22	4 (18.2)	15 (68.2)	3 (13.6)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 127	18	2 (11.1)	15 (83.3)	1 (5.6)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	15	2 (13.3)	9 (60.0)	4 (26.7)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 211	10	1 (10.0)	9 (90.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 253	6	1 (16.7)	3 (50.0)	2 (33.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	3 (75.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	2 (13.3)	7 (46.7)	6 (40.0)	8	0 (0.0)	6 (75.0)	2 (25.0)
Number of metastatic sites >= 2									
	Day 15	95	9 (9.5)	63 (66.3)	23 (24.2)	42	2 (4.8)	29 (69.0)	11 (26.2)
	Day 43	95	10 (10.5)	64 (67.4)	21 (22.1)	43	4 (9.3)	28 (65.1)	11 (25.6)
	Day 85	77	7 (9.1)	48 (62.3)	22 (28.6)	28	2 (7.1)	18 (64.3)	8 (28.6)
	Day 127	56	6 (10.7)	32 (57.1)	18 (32.1)	15	2 (13.3)	9 (60.0)	4 (26.7)
	Day 169	37	7 (18.9)	20 (54.1)	10 (27.0)	8	0 (0.0)	4 (50.0)	4 (50.0)
	Day 211	24	4 (16.7)	13 (54.2)	7 (29.2)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	18	3 (16.7)	10 (55.6)	5 (27.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	15	1 (6.7)	9 (60.0)	5 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	0 (0.0)	6 (54.5)	5 (45.5)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	8	2 (25.0)	4 (50.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	68	5 (7.4)	33 (48.5)	30 (44.1)	45	1 (2.2)	27 (60.0)	17 (37.8)
Previous total gastrectomy									
yes									
	Day 15	20	1 (5.0)	12 (60.0)	7 (35.0)	7	1 (14.3)	4 (57.1)	2 (28.6)
	Day 43	20	0 (0.0)	14 (70.0)	6 (30.0)	8	1 (12.5)	4 (50.0)	3 (37.5)
	Day 85	18	0 (0.0)	11 (61.1)	7 (38.9)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	0 (0.0)	5 (62.5)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	9 (52.9)	7 (41.2)	9	0 (0.0)	7 (77.8)	2 (22.2)
Previous total gastrectomy									
no									
	Day 15	98	9 (9.2)	66 (67.3)	23 (23.5)	45	2 (4.4)	34 (75.6)	9 (20.0)
	Day 43	97	10 (10.3)	71 (73.2)	16 (16.5)	45	5 (11.1)	31 (68.9)	9 (20.0)
	Day 85	81	11 (13.6)	52 (64.2)	18 (22.2)	30	3 (10.0)	18 (60.0)	9 (30.0)
	Day 127	63	7 (11.1)	39 (61.9)	17 (27.0)	17	2 (11.8)	11 (64.7)	4 (23.5)
	Day 169	44	9 (20.5)	24 (54.5)	11 (25.0)	10	2 (20.0)	4 (40.0)	4 (40.0)
	Day 211	27	4 (14.8)	18 (66.7)	5 (18.5)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	21	3 (14.3)	12 (57.1)	6 (28.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	16	1 (6.3)	10 (62.5)	5 (31.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	12	0 (0.0)	8 (66.7)	4 (33.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	66	6 (9.1)	31 (47.0)	29 (43.9)	44	1 (2.3)	26 (59.1)	17 (38.6)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	3 (10.3)	21 (72.4)	5 (17.2)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 43	27	3 (11.1)	21 (77.8)	3 (11.1)	8	2 (25.0)	4 (50.0)	2 (25.0)
	Day 85	27	3 (11.1)	18 (66.7)	6 (22.2)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 127	22	2 (9.1)	17 (77.3)	3 (13.6)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	13	1 (7.7)	10 (76.9)	2 (15.4)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 211	8	1 (12.5)	5 (62.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	9 (42.9)	10 (47.6)	9	0 (0.0)	8 (88.9)	1 (11.1)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	89	7 (7.9)	57 (64.0)	25 (28.1)	44	1 (2.3)	33 (75.0)	10 (22.7)
	Day 43	90	7 (7.8)	64 (71.1)	19 (21.1)	45	4 (8.9)	31 (68.9)	10 (22.2)
	Day 85	72	8 (11.1)	45 (62.5)	19 (26.4)	29	3 (10.3)	17 (58.6)	9 (31.0)
	Day 127	52	6 (11.5)	30 (57.7)	16 (30.8)	15	2 (13.3)	9 (60.0)	4 (26.7)
	Day 169	39	8 (20.5)	19 (48.7)	12 (30.8)	8	1 (12.5)	3 (37.5)	4 (50.0)
	Day 211	26	4 (15.4)	17 (65.4)	5 (19.2)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 253	19	3 (15.8)	10 (52.6)	6 (31.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	14	1 (7.1)	8 (57.1)	5 (35.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	10	0 (0.0)	6 (60.0)	4 (40.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	8	2 (25.0)	4 (50.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	5 (8.1)	31 (50.0)	26 (41.9)	44	1 (2.3)	25 (56.8)	18 (40.9)
Prior ramucirumab contained treatment									
yes									
	Day 15	90	5 (5.6)	59 (65.6)	26 (28.9)	34	3 (8.8)	24 (70.6)	7 (20.6)
	Day 43	89	6 (6.7)	65 (73.0)	18 (20.2)	33	4 (12.1)	23 (69.7)	6 (18.2)
	Day 85	73	8 (11.0)	43 (58.9)	22 (30.1)	23	2 (8.7)	14 (60.9)	7 (30.4)
	Day 127	59	4 (6.8)	38 (64.4)	17 (28.8)	11	2 (18.2)	6 (54.5)	3 (27.3)
	Day 169	41	5 (12.2)	23 (56.1)	13 (31.7)	7	1 (14.3)	2 (28.6)	4 (57.1)
	Day 211	25	1 (4.0)	17 (68.0)	7 (28.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 253	15	2 (13.3)	7 (46.7)	6 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	0 (0.0)	8 (61.5)	5 (38.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	12	0 (0.0)	7 (58.3)	5 (41.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	5 (7.9)	28 (44.4)	30 (47.6)	35	1 (2.9)	21 (60.0)	13 (37.1)
Prior ramucirumab contained treatment									
no									
	Day 15	28	5 (17.9)	19 (67.9)	4 (14.3)	18	0 (0.0)	14 (77.8)	4 (22.2)
	Day 43	28	4 (14.3)	20 (71.4)	4 (14.3)	20	2 (10.0)	12 (60.0)	6 (30.0)
	Day 85	26	3 (11.5)	20 (76.9)	3 (11.5)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 127	15	4 (26.7)	9 (60.0)	2 (13.3)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 169	11	4 (36.4)	6 (54.5)	1 (9.1)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 211	9	4 (44.4)	5 (55.6)	0 (0.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 253	9	2 (22.2)	6 (66.7)	1 (11.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	6	2 (33.3)	3 (50.0)	1 (16.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	2 (10.0)	12 (60.0)	6 (30.0)	18	0 (0.0)	12 (66.7)	6 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Prior nivolumab contained treatment									
yes									
	Day 15	32	2 (6.3)	19 (59.4)	11 (34.4)	13	1 (7.7)	7 (53.8)	5 (38.5)
	Day 43	30	4 (13.3)	21 (70.0)	5 (16.7)	10	1 (10.0)	5 (50.0)	4 (40.0)
	Day 85	27	5 (18.5)	16 (59.3)	6 (22.2)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 127	26	3 (11.5)	17 (65.4)	6 (23.1)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 169	20	3 (15.0)	15 (75.0)	2 (10.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 211	13	1 (7.7)	8 (61.5)	4 (30.8)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 253	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	2 (10.0)	10 (50.0)	8 (40.0)	13	1 (7.7)	6 (46.2)	6 (46.2)
Prior nivolumab contained treatment									
no									
	Day 15	86	8 (9.3)	59 (68.6)	19 (22.1)	39	2 (5.1)	31 (79.5)	6 (15.4)
	Day 43	87	6 (6.9)	64 (73.6)	17 (19.5)	43	5 (11.6)	30 (69.8)	8 (18.6)
	Day 85	72	6 (8.3)	47 (65.3)	19 (26.4)	26	2 (7.7)	18 (69.2)	6 (23.1)
	Day 127	48	5 (10.4)	30 (62.5)	13 (27.1)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	32	6 (18.8)	14 (43.8)	12 (37.5)	8	2 (25.0)	4 (50.0)	2 (25.0)
	Day 211	21	4 (19.0)	14 (66.7)	3 (14.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 253	14	3 (21.4)	7 (50.0)	4 (28.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	11	2 (18.2)	6 (54.5)	3 (27.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	5	2 (40.0)	3 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	5 (7.9)	30 (47.6)	28 (44.4)	40	0 (0.0)	27 (67.5)	13 (32.5)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	42	4 (9.5)	25 (59.5)	13 (31.0)	15	1 (6.7)	9 (60.0)	5 (33.3)
	Day 43	40	5 (12.5)	26 (65.0)	9 (22.5)	12	1 (8.3)	7 (58.3)	4 (33.3)
	Day 85	37	5 (13.5)	24 (64.9)	8 (21.6)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 127	31	5 (16.1)	17 (54.8)	9 (29.0)	4	2 (50.0)	2 (50.0)	0 (0.0)
	Day 169	23	4 (17.4)	17 (73.9)	2 (8.7)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 211	17	3 (17.6)	10 (58.8)	4 (23.5)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 253	13	2 (15.4)	8 (61.5)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	2 (16.7)	6 (50.0)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	3 (10.7)	15 (53.6)	10 (35.7)	15	1 (6.7)	8 (53.3)	6 (40.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	76	6 (7.9)	53 (69.7)	17 (22.4)	37	2 (5.4)	29 (78.4)	6 (16.2)
	Day 43	77	5 (6.5)	59 (76.6)	13 (16.9)	41	5 (12.2)	28 (68.3)	8 (19.5)
	Day 85	62	6 (9.7)	39 (62.9)	17 (27.4)	25	2 (8.0)	17 (68.0)	6 (24.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 127	43	3 (7.0)	30 (69.8)	10 (23.3)	15	1 (6.7)	10 (66.7)	4 (26.7)
	Day 169	29	5 (17.2)	12 (41.4)	12 (41.4)	8	2 (25.0)	4 (50.0)	2 (25.0)
	Day 211	17	2 (11.8)	12 (70.6)	3 (17.6)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 253	11	2 (18.2)	5 (45.5)	4 (36.4)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	7	0 (0.0)	5 (71.4)	2 (28.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	5	0 (0.0)	3 (60.0)	2 (40.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	4	2 (50.0)	2 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	55	4 (7.3)	25 (45.5)	26 (47.3)	38	0 (0.0)	25 (65.8)	13 (34.2)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
yes									
	Day 15	22	1 (4.5)	19 (86.4)	2 (9.1)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	19	1 (5.3)	17 (89.5)	1 (5.3)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 85	16	2 (12.5)	12 (75.0)	2 (12.5)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 127	12	1 (8.3)	10 (83.3)	1 (8.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	7	1 (14.3)	4 (57.1)	2 (28.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	3	1 (33.3)	2 (66.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	9 (75.0)	2 (16.7)	6	0 (0.0)	4 (66.7)	2 (33.3)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
no									
	Day 15	96	9 (9.4)	59 (61.5)	28 (29.2)	46	2 (4.3)	33 (71.7)	11 (23.9)
	Day 43	98	9 (9.2)	68 (69.4)	21 (21.4)	47	5 (10.6)	31 (66.0)	11 (23.4)
	Day 85	83	9 (10.8)	51 (61.4)	23 (27.7)	31	3 (9.7)	20 (64.5)	8 (25.8)
	Day 127	62	7 (11.3)	37 (59.7)	18 (29.0)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 169	45	8 (17.8)	25 (55.6)	12 (26.7)	9	2 (22.2)	3 (33.3)	4 (44.4)
	Day 211	31	4 (12.9)	20 (64.5)	7 (22.6)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 253	22	4 (18.2)	12 (54.5)	6 (27.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	17	1 (5.9)	11 (64.7)	5 (29.4)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	14	1 (7.1)	9 (64.3)	4 (28.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	6 (8.5)	31 (43.7)	34 (47.9)	47	1 (2.1)	29 (61.7)	17 (36.2)
Presence of liver metastasis at baseline									
yes									
	Day 15	64	8 (12.5)	36 (56.3)	20 (31.3)	27	1 (3.7)	17 (63.0)	9 (33.3)
	Day 43	63	6 (9.5)	44 (69.8)	13 (20.6)	28	3 (10.7)	16 (57.1)	9 (32.1)
	Day 85	50	6 (12.0)	29 (58.0)	15 (30.0)	16	1 (6.3)	7 (43.8)	8 (50.0)
	Day 127	36	5 (13.9)	21 (58.3)	10 (27.8)	10	2 (20.0)	5 (50.0)	3 (30.0)
	Day 169	25	4 (16.0)	15 (60.0)	6 (24.0)	6	0 (0.0)	3 (50.0)	3 (50.0)
	Day 211	14	3 (21.4)	7 (50.0)	4 (28.6)	2	0 (0.0)	1 (50.0)	1 (50.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 253	12	2 (16.7)	7 (58.3)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	4 (44.4)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	3 (6.7)	21 (46.7)	21 (46.7)	30	0 (0.0)	14 (46.7)	16 (53.3)
Presence of liver metastasis at baseline									
no									
	Day 15	54	2 (3.7)	42 (77.8)	10 (18.5)	25	2 (8.0)	21 (84.0)	2 (8.0)
	Day 43	54	4 (7.4)	41 (75.9)	9 (16.7)	25	3 (12.0)	19 (76.0)	3 (12.0)
	Day 85	49	5 (10.2)	34 (69.4)	10 (20.4)	20	2 (10.0)	17 (85.0)	1 (5.0)
	Day 127	38	3 (7.9)	26 (68.4)	9 (23.7)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	27	5 (18.5)	14 (51.9)	8 (29.6)	5	2 (40.0)	2 (40.0)	1 (20.0)
	Day 211	20	2 (10.0)	15 (75.0)	3 (15.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 253	12	2 (16.7)	6 (50.0)	4 (33.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	10	1 (10.0)	7 (70.0)	2 (20.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	4 (10.5)	19 (50.0)	15 (39.5)	23	1 (4.3)	19 (82.6)	3 (13.0)
Renal impairment at baseline									
normal									
	Day 15	31	5 (16.1)	18 (58.1)	8 (25.8)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	33	4 (12.1)	23 (69.7)	6 (18.2)	12	1 (8.3)	8 (66.7)	3 (25.0)
	Day 85	26	2 (7.7)	20 (76.9)	4 (15.4)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	0 (0.0)	16 (84.2)	3 (15.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	15	1 (6.7)	10 (66.7)	4 (26.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	5 (55.6)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	3 (15.0)	9 (45.0)	8 (40.0)	11	0 (0.0)	8 (72.7)	3 (27.3)
Renal impairment at baseline									
mild									
	Day 15	50	4 (8.0)	33 (66.0)	13 (26.0)	25	2 (8.0)	17 (68.0)	6 (24.0)
	Day 43	50	5 (10.0)	35 (70.0)	10 (20.0)	23	4 (17.4)	14 (60.9)	5 (21.7)
	Day 85	45	8 (17.8)	24 (53.3)	13 (28.9)	14	1 (7.1)	8 (57.1)	5 (35.7)
	Day 127	31	5 (16.1)	19 (61.3)	7 (22.6)	9	2 (22.2)	5 (55.6)	2 (22.2)
	Day 169	21	6 (28.6)	9 (42.9)	6 (28.6)	6	2 (33.3)	3 (50.0)	1 (16.7)
	Day 211	13	2 (15.4)	8 (61.5)	3 (23.1)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 253	8	2 (25.0)	5 (62.5)	1 (12.5)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	6	1 (16.7)	4 (66.7)	1 (16.7)	1	1 (100.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	4 (10.3)	18 (46.2)	17 (43.6)	22	0 (0.0)	12 (54.5)	10 (45.5)
Renal impairment at baseline									
moderate									
	Day 15	37	1 (2.7)	27 (73.0)	9 (24.3)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 43	34	1 (2.9)	27 (79.4)	6 (17.6)	17	1 (5.9)	12 (70.6)	4 (23.5)
	Day 85	28	1 (3.6)	19 (67.9)	8 (28.6)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 127	24	3 (12.5)	12 (50.0)	9 (37.5)	7	1 (14.3)	4 (57.1)	2 (28.6)
	Day 169	16	2 (12.5)	10 (62.5)	4 (25.0)	5	0 (0.0)	2 (40.0)	3 (60.0)
	Day 211	11	1 (9.1)	8 (72.7)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	0 (0.0)	13 (54.2)	11 (45.8)	19	1 (5.3)	12 (63.2)	6 (31.6)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	82	6 (7.3)	58 (70.7)	18 (22.0)	37	1 (2.7)	31 (83.8)	5 (13.5)
	Day 43	83	6 (7.2)	59 (71.1)	18 (21.7)	41	4 (9.8)	27 (65.9)	10 (24.4)
	Day 85	76	8 (10.5)	50 (65.8)	18 (23.7)	27	3 (11.1)	18 (66.7)	6 (22.2)
	Day 127	58	7 (12.1)	36 (62.1)	15 (25.9)	14	2 (14.3)	8 (57.1)	4 (28.6)
	Day 169	40	7 (17.5)	24 (60.0)	9 (22.5)	7	1 (14.3)	3 (42.9)	3 (42.9)
	Day 211	24	4 (16.7)	16 (66.7)	4 (16.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 253	19	3 (15.8)	12 (63.2)	4 (21.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	15	2 (13.3)	10 (66.7)	3 (20.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	8	2 (25.0)	3 (37.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	56	3 (5.4)	27 (48.2)	26 (46.4)	40	1 (2.5)	24 (60.0)	15 (37.5)
Hepatic impairment at baseline									
mild									
	Day 15	35	4 (11.4)	20 (57.1)	11 (31.4)	15	2 (13.3)	7 (46.7)	6 (40.0)
	Day 43	33	4 (12.1)	25 (75.8)	4 (12.1)	12	2 (16.7)	8 (66.7)	2 (16.7)
	Day 85	22	3 (13.6)	12 (54.5)	7 (31.8)	9	0 (0.0)	6 (66.7)	3 (33.3)
	Day 127	15	1 (6.7)	10 (66.7)	4 (26.7)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 169	12	2 (16.7)	5 (41.7)	5 (41.7)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 211	10	1 (10.0)	6 (60.0)	3 (30.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	5	1 (20.0)	1 (20.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	4 (15.4)	12 (46.2)	10 (38.5)	13	0 (0.0)	9 (69.2)	4 (30.8)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	2 (25.0)	4 (50.0)	2 (25.0)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	1 (12.5)	7 (87.5)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	7	1 (14.3)	5 (71.4)	1 (14.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	6	0 (0.0)	5 (83.3)	1 (16.7)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	5	1 (20.0)	3 (60.0)	1 (20.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	4	1 (25.0)	2 (50.0)	1 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	1 (25.0)	2 (50.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	5	0 (0.0)	3 (60.0)	2 (40.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	110	8 (7.3)	74 (67.3)	28 (25.5)	48	3 (6.3)	35 (72.9)	10 (20.8)
	Day 43	109	9 (8.3)	78 (71.6)	22 (20.2)	50	5 (10.0)	33 (66.0)	12 (24.0)
	Day 85	92	10 (10.9)	58 (63.0)	24 (26.1)	33	2 (6.1)	22 (66.7)	9 (27.3)
	Day 127	68	8 (11.8)	42 (61.8)	18 (26.5)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 169	47	8 (17.0)	26 (55.3)	13 (27.7)	9	1 (11.1)	4 (44.4)	4 (44.4)
	Day 211	30	4 (13.3)	20 (66.7)	6 (20.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	20	3 (15.0)	12 (60.0)	5 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	17	2 (11.8)	9 (52.9)	6 (35.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	14	1 (7.1)	8 (57.1)	5 (35.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	7 (9.0)	37 (47.4)	34 (43.6)	50	1 (2.0)	31 (62.0)	18 (36.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	1 (33.3)	1 (33.3)	1 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	3	0 (0.0)	2 (66.7)	1 (33.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	3	1 (33.3)	1 (33.3)	1 (33.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 253	2	1 (50.0)	0 (0.0)	1 (50.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	0	0 (0.0)	0 (0.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	0 (0.0)	1 (100.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors no									
	Day 15	115	9 (7.8)	77 (67.0)	29 (25.2)	49	3 (6.1)	35 (71.4)	11 (22.4)
	Day 43	114	10 (8.8)	82 (71.9)	22 (19.3)	50	5 (10.0)	33 (66.0)	12 (24.0)
	Day 85	96	11 (11.5)	60 (62.5)	25 (26.0)	33	2 (6.1)	22 (66.7)	9 (27.3)
	Day 127	71	8 (11.3)	45 (63.4)	18 (25.4)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 169	49	8 (16.3)	28 (57.1)	13 (26.5)	9	1 (11.1)	4 (44.4)	4 (44.4)
	Day 211	32	4 (12.5)	21 (65.6)	7 (21.9)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	22	3 (13.6)	13 (59.1)	6 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	18	2 (11.1)	10 (55.6)	6 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	15	1 (6.7)	9 (60.0)	5 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	11	2 (18.2)	6 (54.5)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	7 (8.5)	40 (48.8)	35 (42.7)	51	1 (2.0)	31 (60.8)	19 (37.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Gastric Cancer Symptom (GaCS) Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	125 (100.0)	62	59 (95.2)
Day 15	125	120 (96.0)	62	52 (83.9)
Day 43	124	118 (95.2)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	52 (49.5)	45	11 (24.4)
Day 211	81	34 (42.0)	35	3 (8.6)
Day 253	62	24 (38.7)	26	1 (3.8)
Day 295	51	19 (37.3)	19	1 (5.3)
Day 337	45	15 (33.3)	14	1 (7.1)
Day 379	33	11 (33.3)	10	0 (0.0)
Day 421	22	11 (50.0)	3	0 (0.0)
Day 463	14	7 (50.0)	2	0 (0.0)
Day 505	11	3 (27.3)	2	0 (0.0)
Day 547	6	3 (50.0)	2	0 (0.0)
Day 589	4	1 (25.0)	2	0 (0.0)
Day 631	3	1 (33.3)	0	0 (0.0)
Day 673	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	125	53.3 (13.15)			59	54.6 (13.02)		
Day 15	120	50.2 (12.22)	120	-3.6 (11.20)	52	53.2 (14.20)	50	-2.6 (9.99)
Day 43	118	52.0 (14.27)	118	-1.6 (13.48)	53	54.5 (14.85)	51	-1.1 (10.75)
Day 85	99	51.5 (14.24)	99	-3.0 (13.23)	36	56.3 (14.92)	35	-1.8 (8.64)
Day 127	74	54.4 (11.10)	74	-0.9 (12.07)	19	61.9 (11.44)	19	-1.0 (10.34)
Day 169	52	53.0 (12.68)	52	-0.8 (12.07)	11	64.0 (9.98)	11	0.8 (6.27)
Day 211	34	54.7 (12.40)	34	-0.5 (13.49)	3	70.7 (6.11)	3	7.3 (1.15)
Day 253	24	54.8 (12.77)	24	1.4 (14.65)	1	71.0 (-)	1	7.0 (-)
Day 295	19	53.7 (10.99)	19	-0.3 (15.46)	1	72.0 (-)	1	8.0 (-)
Day 337	15	53.1 (11.63)	15	-2.6 (17.01)	1	71.0 (-)	1	7.0 (-)
Day 379	11	50.8 (14.95)	11	-7.2 (17.34)	0	-	0	-
Day 421	11	51.0 (15.79)	11	-5.7 (16.33)	0	-	0	-
Day 463	7	58.4 (10.16)	7	1.9 (16.66)	0	-	0	-
Day 505	3	56.7 (12.86)	3	-6.3 (10.02)	0	-	0	-
Day 547	3	54.0 (11.53)	3	-9.0 (8.54)	0	-	0	-
Day 589	1	33.0 (-)	1	-25.0 (-)	0	-	0	-
Day 631	1	37.0 (-)	1	-21.0 (-)	0	-	0	-
Day 673	1	41.0 (-)	1	-17.0 (-)	0	-	0	-
End of Treatment	82	45.5 (16.69)	82	-7.5 (14.40)	53	49.0 (16.49)	50	-6.3 (9.54)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Visit	DS-8201a (N=125) N [a]	N_MISS [b]	LSMean (95% CI)	Phys. Choice (N=62) N [a]	N_MISS [b]	LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
Day 15			-3.74 (-5.88, -1.60)			-2.64 (-5.81, 0.53)	-1.10 (-4.57, 2.37)	0.5337		
Day 43			-3.76 (-5.77, -1.75)			-2.48 (-5.34, 0.37)	-1.27 (-4.38, 1.84)	0.4205		
Day 85			-3.78 (-5.67, -1.89)			-2.25 (-5.14, 0.64)	-1.53 (-4.61, 1.54)	0.3268		
Day 127			-3.81 (-5.69, -1.93)			-2.02 (-5.51, 1.48)	-1.80 (-5.45, 1.86)	0.3344		
Day 169			-3.84 (-5.82, -1.86)			-1.78 (-6.23, 2.66)	-2.06 (-6.67, 2.56)	0.3819		
Day 211			-3.87 (-6.05, -1.69)			-1.55 (-7.12, 4.02)	-2.32 (-8.09, 3.46)	0.4313		
Day 253			-3.89 (-6.35, -1.44)			-1.32 (-8.09, 5.46)	-2.58 (-9.62, 4.46)	0.4724		
Day 295			-3.92 (-6.69, -1.15)			-1.08 (-9.11, 6.95)	-2.84 (-11.19, 5.52)	0.5050		
Day 337			-3.95 (-7.08, -0.82)			-0.85 (-10.17, 8.46)	-3.10 (-12.80, 6.61)	0.5309		
OVERALL	124	1	-3.80 (-5.67, -1.93)	55	7	-2.09 (-5.34, 1.15)	-1.71 (-5.11, 1.70)	0.3243	-0.15 (-0.47, 0.16)	0.3426

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Gastric Cancer Symptom (GaCS) - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0085
Japan	99	-4.25 (-5.82, -2.67)	46	-0.66 (-3.74, 2.42)	-3.58 (-7.05, -0.12)	0.0427	-0.40 (-0.76, -0.05)	0.0246	
Korea	25	0.15 (-3.87, 4.17)	9	-7.59 (-16.76, 1.58)	7.74 (-2.28, 17.76)	0.1272	0.71 (-0.07, 1.49)	0.0762	
Lines of prior systemic therapy									0.4066
2	65	-2.62 (-4.72, -0.52)	35	-2.20 (-5.53, 1.14)	-0.42 (-4.37, 3.54)	0.8345	-0.05 (-0.46, 0.36)	0.8256	
3	34	-2.46 (-5.47, 0.55)	16	-3.58 (-9.97, 2.81)	1.12 (-5.96, 8.19)	0.7546	0.11 (-0.49, 0.70)	0.7188	
>=4	25	-6.91 (-9.87, -3.94)	4	6.52 (-6.19, 19.23)	-13.43 (-26.50, -0.35)	0.0443	-1.67 (-2.81, -0.53)	0.0041	
Age									0.2004
<65 years	54	-1.39 (-3.56, 0.77)	25	-1.73 (-6.74, 3.28)	0.34 (-5.19, 5.87)	0.9046	0.03 (-0.44, 0.51)	0.8861	
>=65 years	70	-5.27 (-7.37, -3.17)	30	-1.62 (-5.53, 2.29)	-3.65 (-8.09, 0.79)	0.1061	-0.38 (-0.82, 0.05)	0.0803	
Sex									0.9581
female	29	0.17 (-2.56, 2.90)	13	0.39 (-4.78, 5.57)	-0.22 (-6.10, 5.66)	0.9395	-0.03 (-0.68, 0.63)	0.9329	
male	95	-4.41 (-6.21, -2.60)	42	-2.23 (-5.83, 1.37)	-2.18 (-6.22, 1.85)	0.2879	-0.22 (-0.58, 0.14)	0.2350	
ECOG PS									0.1026
0	62	-5.15 (-7.13, -3.18)	27	-1.64 (-5.95, 2.67)	-3.51 (-8.26, 1.24)	0.1463	-0.39 (-0.85, 0.07)	0.0936	
1	62	-1.45 (-3.84, 0.95)	28	-1.85 (-6.10, 2.39)	0.41 (-4.48, 5.29)	0.8697	0.04 (-0.41, 0.49)	0.8600	
HER2 Status in central laboratory									0.1482
IHC 3+	96	-2.97 (-4.72, -1.22)	42	-1.82 (-5.47, 1.83)	-1.15 (-5.20, 2.91)	0.5781	-0.12 (-0.48, 0.25)	0.5274	
IHC 2+/ISH +	28	-5.27 (-8.48, -2.05)	13	-0.93 (-6.12, 4.27)	-4.34 (-10.47, 1.78)	0.1604	-0.50 (-1.17, 0.17)	0.1421	
Primary tumor location									0.4509
Gastric	107	-3.73 (-5.36, -2.10)	50	-1.70 (-4.77, 1.37)	-2.04 (-5.52, 1.45)	0.2504	-0.22 (-0.55, 0.12)	0.2065	
GEJ	17	-2.07 (-6.29, 2.15)	5	-0.68 (-13.38, 12.02)	-1.39 (-14.80, 12.02)	0.8355	-0.14 (-1.14, 0.85)	0.7786	
Histological subtype									0.4277
intestinal	89	-4.13 (-5.78, -2.48)	36	-0.83 (-4.27, 2.62)	-3.30 (-7.13, 0.52)	0.0899	-0.38 (-0.77, 0.01)	0.0563	
diffuse	28	-2.04 (-5.85, 1.78)	14	-2.84 (-10.46, 4.79)	0.80 (-7.77, 9.38)	0.8527	0.07 (-0.57, 0.71)	0.8328	
others	7	0.16 (-13.13, 13.45)	5	-5.42 (-21.78, 10.95)	5.58 (-16.61, 27.77)	0.5824	0.36 (-0.80, 1.52)	0.5415	
Number of metastatic sites									0.2587
<2	24	-5.56 (-9.03, -2.09)	10	1.49 (-5.00, 7.98)	-7.05 (-14.41, 0.31)	0.0599	-0.79 (-1.55, -0.03)	0.0414	
>= 2	100	-2.98 (-4.70, -1.26)	45	-2.94 (-6.46, 0.57)	-0.04 (-3.97, 3.90)	0.9858	-0.00 (-0.36, 0.35)	0.9839	
Previous total gastrectomy									0.0117
yes	22	-5.52 (-9.33, -1.71)	8	0.42 (-10.35, 11.18)	-5.94 (-17.36, 5.48)	0.3027	-0.55 (-1.37, 0.27)	0.1863	
no	102	-3.04 (-4.69, -1.38)	47	-2.48 (-5.61, 0.64)	-0.55 (-4.10, 2.99)	0.7583	-0.06 (-0.41, 0.29)	0.7347	
Prior adjuvant/ neoadjuvant therapy									0.1755
yes	30	-3.43 (-6.53, -0.32)	8	2.09 (-6.10, 10.28)	-5.52 (-14.27, 3.24)	0.2124	-0.61 (-1.40, 0.19)	0.1333	
no	94	-3.41 (-5.14, -1.68)	47	-2.43 (-5.60, 0.74)	-0.98 (-4.60, 2.65)	0.5955	-0.10 (-0.45, 0.25)	0.5604	
Prior ramucirumab contained treatment									0.2192
yes	93	-4.55 (-6.13, -2.98)	36	-2.56 (-6.37, 1.26)	-2.00 (-6.13, 2.13)	0.3413	-0.22 (-0.61, 0.16)	0.2562	
no	31	-0.04 (-3.51, 3.43)	19	0.43 (-4.67, 5.53)	-0.47 (-6.68, 5.74)	0.8798	-0.05 (-0.62, 0.52)	0.8740	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

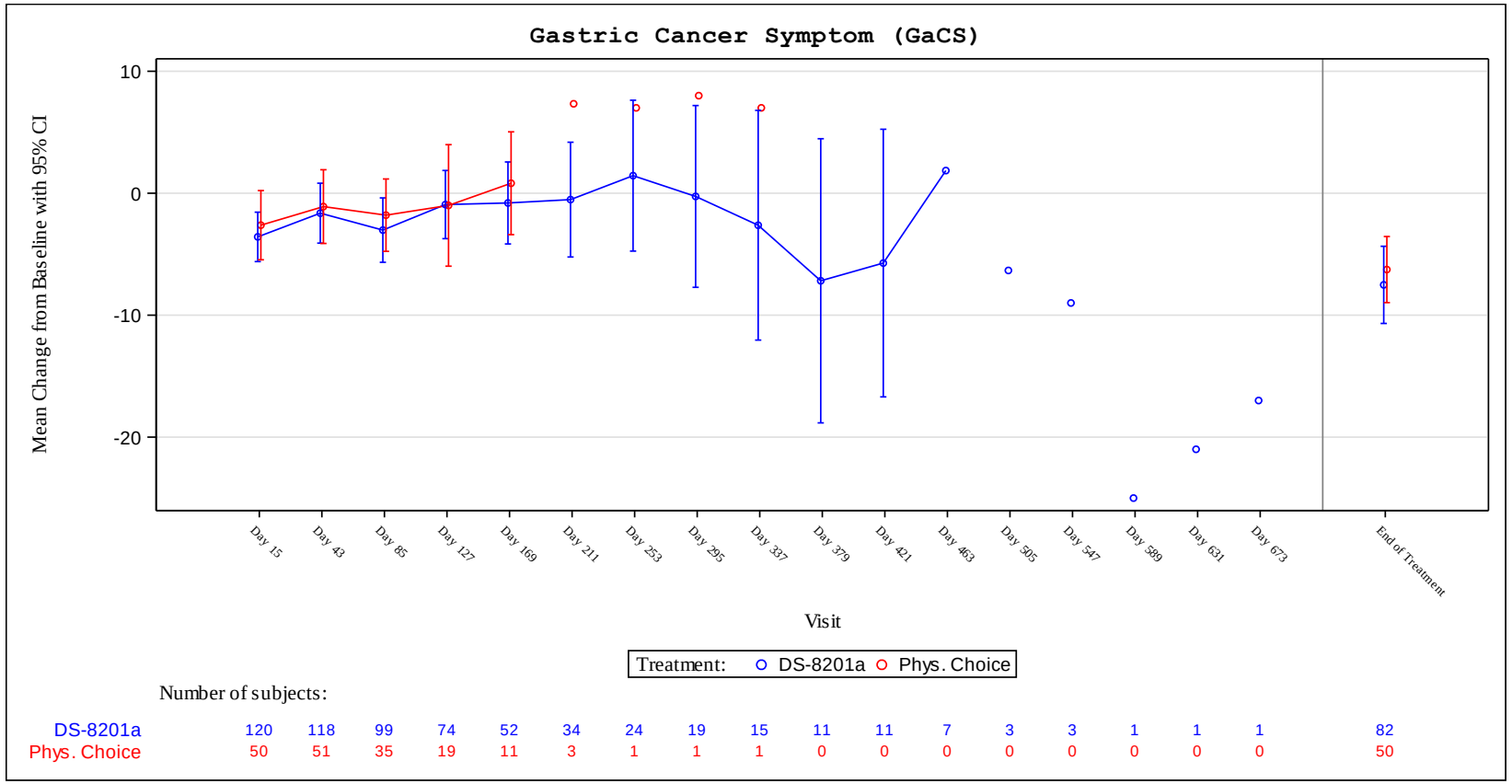
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Gastric Cancer Symptom (GaCS) - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.2460
yes	33	-5.24 (-8.03, -2.45)	12	-1.28 (-8.87, 6.31)	-3.96 (-12.04, 4.13)	0.3336	-0.41 (-1.08, 0.25)	0.2250	
no	91	-2.76 (-4.61, -0.90)	43	-1.82 (-5.14, 1.49)	-0.93 (-4.76, 2.89)	0.6305	-0.10 (-0.46, 0.27)	0.6013	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.2838
yes	44	-4.19 (-6.85, -1.53)	13	-0.63 (-8.19, 6.93)	-3.56 (-11.57, 4.45)	0.3806	-0.35 (-0.97, 0.27)	0.2668	
no	80	-3.10 (-4.96, -1.25)	42	-2.12 (-5.21, 0.98)	-0.99 (-4.62, 2.64)	0.5920	-0.11 (-0.48, 0.26)	0.5660	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.2228
yes	22	-2.31 (-6.44, 1.82)	6	4.82 (-3.55, 13.19)	-7.13 (-16.66, 2.40)	0.1368	-0.75 (-1.67, 0.18)	0.1134	
no	102	-3.74 (-5.39, -2.09)	49	-2.73 (-6.05, 0.60)	-1.02 (-4.73, 2.70)	0.5913	-0.11 (-0.45, 0.24)	0.5457	
Presence of liver metastasis at baseline									0.3160
yes	67	-2.29 (-4.34, -0.23)	30	-2.37 (-6.50, 1.77)	0.08 (-4.57, 4.72)	0.9735	0.01 (-0.42, 0.44)	0.9701	
no	57	-4.70 (-6.99, -2.41)	25	-1.00 (-5.49, 3.49)	-3.70 (-8.75, 1.34)	0.1489	-0.39 (-0.86, 0.09)	0.1095	
Renal impairment at baseline									0.0817
normal	33	-2.46 (-4.92, 0.01)	12	-11.46 (-20.42, -2.51)	9.01 (-0.29, 18.30)	0.0574	0.90 (0.21, 1.59)	0.0102	
mild	53	-4.48 (-7.19, -1.78)	25	1.24 (-3.37, 5.85)	-5.72 (-11.10, -0.34)	0.0374	-0.55 (-1.03, -0.06)	0.0264	
moderate	38	-3.29 (-5.92, -0.66)	17	-2.58 (-7.30, 2.13)	-0.71 (-6.11, 4.69)	0.7943	-0.08 (-0.65, 0.49)	0.7785	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.3892
normal	87	-3.42 (-5.26, -1.57)	40	-3.14 (-6.71, 0.42)	-0.27 (-4.29, 3.75)	0.8938	-0.03 (-0.40, 0.35)	0.8825	
mild	36	-3.41 (-6.10, -0.73)	15	2.17 (-3.56, 7.91)	-5.59 (-12.00, 0.82)	0.0865	-0.62 (-1.23, -0.00)	0.0487	
moderate	1	-13.69 (NE, NE)	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.4141
yes	8	-6.77 (-12.46, -1.07)	4	7.62 (-2.40, 17.63)	-14.38 (-26.30, -2.46)	0.0225	-1.85 (-3.26, -0.44)	0.0100	
no	116	-3.32 (-4.90, -1.75)	51	-2.69 (-5.91, 0.53)	-0.64 (-4.22, 2.95)	0.7274	-0.07 (-0.40, 0.26)	0.6940	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.5952
yes	3	-3.39 (-15.52, 8.74)	3	5.11 (-7.42, 17.64)	-8.50 (-26.83, 9.83)	0.2426	-1.24 (-2.99, 0.51)	0.1646	
no	121	-3.53 (-5.10, -1.97)	52	-2.77 (-6.15, 0.61)	-0.76 (-4.49, 2.96)	0.6869	-0.08 (-0.40, 0.25)	0.6432	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Graphical Summary of Gastric Cancer Symptom (GaCS) by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	57 (45.6)	19 (30.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	5.9 (4.1, 9.8)	NE (3.1, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.19 (0.70, 2.01)	
p-value [c]	0.5265	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.18 (0.70, 1.99)	
p-value [c]	0.5521	

Time to Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.1503
Japan	47/ 99 (47.5)	5.8 (3.0, 9.8)	14/ 50 (28.0)	NE (3.1, NE)	1.42 (0.78, 2.60)	0.2517	
Korea	10/ 26 (38.5)	5.9 (2.9, NE)	5/ 12 (41.7)	3.3 (0.5, NE)	0.58 (0.19, 1.75)	0.3246	
Lines of prior systemic therapy							0.9066
2	30/ 66 (45.5)	5.9 (2.9, NE)	13/ 38 (34.2)	NE (1.6, NE)	1.15 (0.60, 2.22)	0.6763	
3	14/ 34 (41.2)	9.8 (2.8, NE)	5/ 18 (27.8)	3.3 (2.7, NE)	1.13 (0.39, 3.26)	0.8442	
>=4	13/ 25 (52.0)	5.8 (2.8, NE)	1/ 6 (16.7)	NE (0.5, NE)	1.68 (0.22, 12.93)	0.6083	
Age							0.4357
<65 years	24/ 55 (43.6)	5.8 (3.0, NE)	9/ 27 (33.3)	NE (1.4, NE)	0.99 (0.45, 2.18)	0.9803	
>=65 years	33/ 70 (47.1)	5.9 (2.9, 9.8)	10/ 35 (28.6)	5.4 (3.1, NE)	1.39 (0.69, 2.84)	0.3547	
Sex							0.2019
female	9/ 30 (30.0)	8.3 (4.6, NE)	5/ 15 (33.3)	3.1 (1.2, NE)	0.45 (0.14, 1.44)	0.1745	
male	48/ 95 (50.5)	5.8 (2.8, 9.8)	14/ 47 (29.8)	NE (3.3, NE)	1.44 (0.79, 2.62)	0.2331	
ECOG PS							0.6328
0	31/ 62 (50.0)	6.9 (2.8, 9.8)	9/ 30 (30.0)	NE (2.7, NE)	1.34 (0.63, 2.85)	0.4442	
1	26/ 63 (41.3)	5.8 (3.0, NE)	10/ 32 (31.3)	NE (1.4, NE)	1.06 (0.51, 2.22)	0.8757	
HER2 Status in central laboratory							0.6782
IHC 3+	44/ 96 (45.8)	6.9 (4.1, NE)	15/ 47 (31.9)	NE (3.3, NE)	1.14 (0.63, 2.06)	0.6860	
IHC 2+/ISH +	13/ 29 (44.8)	5.7 (2.8, NE)	4/ 15 (26.7)	NE (1.4, NE)	1.35 (0.43, 4.25)	0.6024	
Primary tumor location							0.5413
Gastric	49/108 (45.4)	5.8 (3.1, 9.8)	17/ 55 (30.9)	NE (3.1, NE)	1.22 (0.70, 2.12)	0.5028	
GEJ	8/ 17 (47.1)	NE (0.8, NE)	2/ 7 (28.6)	NE (0.5, NE)	0.93 (0.19, 4.45)	0.9373	
Histological subtype							0.8239
intestinal	43/ 89 (48.3)	5.9 (3.0, 9.8)	12/ 38 (31.6)	NE (3.1, NE)	1.29 (0.68, 2.46)	0.4408	
diffuse	11/ 28 (39.3)	5.8 (1.5, NE)	5/ 18 (27.8)	NE (0.9, NE)	0.97 (0.33, 2.84)	0.9476	
others	3/ 8 (37.5)	4.6 (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.36 (0.22, 8.23)	0.7372	
Number of metastatic sites							0.2742
<2	11/ 24 (45.8)	NE (0.8, NE)	2/ 10 (20.0)	NE (0.6, NE)	2.71 (0.60, 12.22)	0.1805	
>= 2	46/101 (45.5)	5.8 (4.1, 9.8)	17/ 52 (32.7)	5.4 (2.7, NE)	0.96 (0.54, 1.70)	0.8828	
Previous total gastrectomy							0.2990
yes	9/ 22 (40.9)	7.1 (1.5, NE)	1/ 9 (11.1)	NE (3.3, NE)	3.15 (0.39, 25.29)	0.2551	
no	48/103 (46.6)	5.8 (3.0, 9.8)	18/ 53 (34.0)	NE (2.7, NE)	1.07 (0.62, 1.86)	0.8112	
Prior adjuvant/ neoadjuvant therapy							0.5999
yes	9/ 30 (30.0)	6.9 (5.9, NE)	1/ 10 (10.0)	NE (0.6, NE)	1.96 (0.24, 15.71)	0.5143	
no	48/ 95 (50.5)	4.6 (2.9, 8.3)	18/ 52 (34.6)	5.4 (2.7, NE)	1.22 (0.70, 2.11)	0.4958	
Prior ramucirumab contained treatment							0.8843
yes	46/ 94 (48.9)	5.8 (2.9, 9.8)	14/ 41 (34.1)	5.4 (1.9, NE)	1.08 (0.59, 1.99)	0.8223	
no	11/ 31 (35.5)	NE (3.0, NE)	5/ 21 (23.8)	NE (3.3, NE)	1.20 (0.41, 3.50)	0.7283	
Prior nivolumab contained treatment							0.6945
yes	17/ 33 (51.5)	6.9 (0.8, NE)	5/ 15 (33.3)	3.3 (0.6, NE)	0.94 (0.33, 2.63)	0.8822	
no	40/ 92 (43.5)	5.8 (3.1, NE)	14/ 47 (29.8)	NE (5.4, NE)	1.24 (0.67, 2.29)	0.4933	

Time to Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

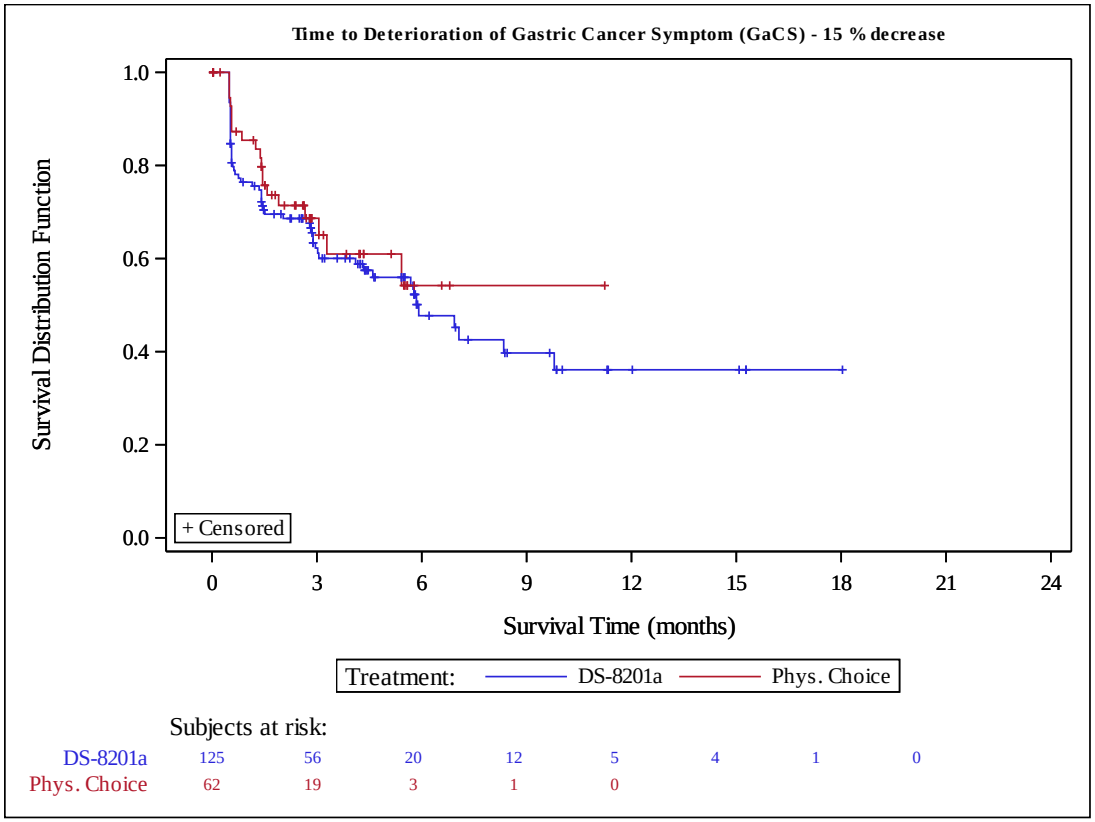
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.6800
yes	21/ 44 (47.7)	6.9 (2.9, NE)	5/ 17 (29.4)	3.3 (2.7, NE)	1.02 (0.38, 2.75)	0.9862	
no	36/ 81 (44.4)	5.8 (3.1, 8.3)	14/ 45 (31.1)	NE (5.4, NE)	1.26 (0.68, 2.34)	0.4756	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9825
yes	9/ 22 (40.9)	5.7 (1.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	48/103 (46.6)	5.9 (3.1, 9.8)	19/ 55 (34.5)	5.4 (2.7, NE)	1.01 (0.59, 1.73)	0.9907	
Presence of liver metastasis at baseline							0.4139
yes	28/ 67 (41.8)	7.1 (4.1, NE)	11/ 34 (32.4)	5.4 (2.7, NE)	0.90 (0.44, 1.85)	0.7806	
no	29/ 58 (50.0)	5.7 (2.8, NE)	8/ 28 (28.6)	NE (1.9, NE)	1.54 (0.70, 3.38)	0.2880	
Renal impairment at baseline							0.1958
normal	13/ 33 (39.4)	8.3 (2.8, NE)	5/ 13 (38.5)	NE (1.2, NE)	0.71 (0.25, 2.07)	0.5250	
mild	26/ 53 (49.1)	5.8 (2.9, NE)	5/ 28 (17.9)	NE (NE , NE)	2.32 (0.88, 6.08)	0.0802	
moderate	18/ 39 (46.2)	5.8 (2.8, NE)	8/ 20 (40.0)	5.4 (0.6, NE)	0.99 (0.43, 2.30)	0.9848	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.9 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9325
normal	43/ 88 (48.9)	5.9 (3.0, NE)	15/ 47 (31.9)	5.4 (3.1, NE)	1.18 (0.65, 2.15)	0.5893	
mild	13/ 36 (36.1)	5.8 (2.9, NE)	4/ 15 (26.7)	NE (0.6, NE)	1.18 (0.38, 3.68)	0.7724	
moderate	1/ 1 (100.0)	4.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3669
yes	5/ 8 (62.5)	3.1 (0.5, NE)	1/ 5 (20.0)	NE (0.5, NE)	2.46 (0.28, 21.31)	0.3901	
no	52/117 (44.4)	5.9 (4.1, 9.8)	18/ 57 (31.6)	NE (3.1, NE)	1.08 (0.62, 1.86)	0.8025	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9853
yes	2/ 3 (66.7)	5.7 (0.5, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	55/122 (45.1)	5.9 (3.1, 9.8)	19/ 58 (32.8)	5.4 (3.1, NE)	1.05 (0.62, 1.79)	0.8648	

Time to Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	43 (34.4)	11 (17.7)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	9.7 (7.0, NE)	NE (5.4, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.35 (0.69, 2.64)	
p-value [c]	0.3869	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.37 (0.70, 2.68)	
p-value [c]	0.3604	

Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%.
Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.0485
Japan	33/ 99 (33.3)	NE (7.0, NE)	6/ 50 (12.0)	NE (NE , NE)	2.17 (0.90, 5.22)	0.0748	
Korea	10/ 26 (38.5)	8.4 (3.0, 14.1)	5/ 12 (41.7)	3.3 (1.4, NE)	0.42 (0.13, 1.34)	0.1275	
Lines of prior systemic therapy							0.8643
2	24/ 66 (36.4)	8.4 (4.3, NE)	7/ 38 (18.4)	NE (5.4, NE)	1.64 (0.70, 3.84)	0.2490	
3	10/ 34 (29.4)	14.1 (5.7, NE)	3/ 18 (16.7)	NE (3.1, NE)	0.97 (0.25, 3.73)	0.9593	
>=4	9/ 25 (36.0)	NE (4.1, NE)	1/ 6 (16.7)	NE (0.5, NE)	1.03 (0.13, 8.29)	0.9635	
Age							0.5503
<65 years	18/ 55 (32.7)	14.1 (7.0, NE)	5/ 27 (18.5)	NE (2.9, NE)	1.07 (0.38, 3.00)	0.8985	
>=65 years	25/ 70 (35.7)	8.4 (5.1, NE)	6/ 35 (17.1)	NE (3.3, NE)	1.64 (0.67, 4.00)	0.2739	
Sex							0.9027
female	7/ 30 (23.3)	NE (4.6, NE)	2/ 15 (13.3)	NE (3.1, NE)	1.05 (0.21, 5.27)	0.9427	
male	36/ 95 (37.9)	9.7 (5.7, NE)	9/ 47 (19.1)	NE (5.4, NE)	1.43 (0.68, 3.01)	0.3368	
ECOG PS							0.8179
0	23/ 62 (37.1)	8.4 (5.9, NE)	5/ 30 (16.7)	NE (5.4, NE)	1.52 (0.57, 4.05)	0.4014	
1	20/ 63 (31.7)	14.1 (4.6, NE)	6/ 32 (18.8)	NE (3.1, NE)	1.25 (0.49, 3.15)	0.6423	
HER2 Status in central laboratory							0.1383
IHC 3+	31/ 96 (32.3)	14.1 (8.3, NE)	10/ 47 (21.3)	NE (5.4, NE)	1.08 (0.52, 2.22)	0.8445	
IHC 2+/ISH +	12/ 29 (41.4)	5.9 (3.0, NE)	1/ 15 (6.7)	NE (3.1, NE)	3.88 (0.48, 31.10)	0.1694	
Primary tumor location							0.9884
Gastric	36/108 (33.3)	9.7 (5.9, NE)	11/ 55 (20.0)	NE (5.4, NE)	1.19 (0.60, 2.38)	0.6131	
GEJ	7/ 17 (41.2)	NE (2.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.8034
intestinal	31/ 89 (34.8)	9.7 (5.9, NE)	6/ 38 (15.8)	NE (5.4, NE)	1.70 (0.71, 4.10)	0.2290	
diffuse	9/ 28 (32.1)	14.1 (5.7, 14.1)	3/ 18 (16.7)	NE (2.9, NE)	1.05 (0.26, 4.15)	0.9643	
others	3/ 8 (37.5)	4.6 (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.36 (0.22, 8.23)	0.7372	
Number of metastatic sites							0.9888
<2	7/ 24 (29.2)	NE (5.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	36/101 (35.6)	9.7 (5.7, NE)	11/ 52 (21.2)	NE (3.3, NE)	1.11 (0.56, 2.22)	0.7577	
Previous total gastrectomy							0.4646
yes	8/ 22 (36.4)	NE (1.5, NE)	1/ 9 (11.1)	NE (3.3, NE)	2.88 (0.36, 23.21)	0.3018	
no	35/103 (34.0)	9.7 (7.0, NE)	10/ 53 (18.9)	NE (5.4, NE)	1.20 (0.59, 2.46)	0.6121	
Prior adjuvant/ neoadjuvant therapy							0.9853
yes	8/ 30 (26.7)	7.0 (5.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	35/ 95 (36.8)	9.7 (4.6, NE)	11/ 52 (21.2)	NE (5.4, NE)	1.29 (0.65, 2.56)	0.4740	
Prior ramucirumab contained treatment							0.9352
yes	33/ 94 (35.1)	14.1 (5.9, NE)	7/ 41 (17.1)	NE (5.4, NE)	1.44 (0.63, 3.29)	0.3884	
no	10/ 31 (32.3)	8.4 (5.7, NE)	4/ 21 (19.0)	NE (2.9, NE)	1.22 (0.37, 3.98)	0.7413	
Prior nivolumab contained treatment							0.4229
yes	11/ 33 (33.3)	NE (5.1, NE)	3/ 15 (20.0)	NE (3.1, NE)	0.82 (0.22, 3.04)	0.7678	
no	32/ 92 (34.8)	8.4 (5.7, NE)	8/ 47 (17.0)	NE (5.4, NE)	1.62 (0.74, 3.56)	0.2224	

Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%.
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NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.5679
yes	15/ 44 (34.1)	NE (5.1, NE)	3/ 17 (17.6)	NE (3.1, NE)	1.09 (0.31, 3.83)	0.8923	
no	28/ 81 (34.6)	8.4 (5.7, NE)	8/ 45 (17.8)	NE (5.4, NE)	1.56 (0.70, 3.46)	0.2703	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9866
yes	7/ 22 (31.8)	14.1 (5.1, 14.1)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	36/103 (35.0)	9.7 (5.9, NE)	11/ 55 (20.0)	NE (5.4, NE)	1.22 (0.61, 2.42)	0.5705	
Presence of liver metastasis at baseline							0.1165
yes	20/ 67 (29.9)	14.1 (8.3, NE)	8/ 34 (23.5)	NE (3.3, NE)	0.88 (0.38, 2.03)	0.7595	
no	23/ 58 (39.7)	8.4 (5.4, NE)	3/ 28 (10.7)	NE (NE , NE)	2.69 (0.80, 9.05)	0.0971	
Renal impairment at baseline							0.6444
normal	11/ 33 (33.3)	14.1 (4.6, NE)	3/ 13 (23.1)	NE (1.9, NE)	0.69 (0.18, 2.73)	0.5926	
mild	18/ 53 (34.0)	NE (5.1, NE)	4/ 28 (14.3)	NE (NE , NE)	1.87 (0.63, 5.55)	0.2535	
moderate	14/ 39 (35.9)	8.4 (3.0, NE)	4/ 20 (20.0)	NE (3.1, NE)	1.47 (0.48, 4.54)	0.4962	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.6222
normal	32/ 88 (36.4)	9.7 (5.9, NE)	9/ 47 (19.1)	NE (5.4, NE)	1.24 (0.58, 2.62)	0.5829	
mild	10/ 36 (27.8)	14.1 (4.1, NE)	2/ 15 (13.3)	NE (NE , NE)	1.76 (0.38, 8.23)	0.4674	
moderate	1/ 1 (100.0)	4.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.6265
yes	5/ 8 (62.5)	5.7 (0.5, NE)	1/ 5 (20.0)	NE (0.5, NE)	1.95 (0.23, 16.81)	0.5367	
no	38/117 (32.5)	14.1 (7.0, NE)	10/ 57 (17.5)	NE (5.4, NE)	1.33 (0.65, 2.69)	0.4374	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9881
yes	2/ 3 (66.7)	8.4 (5.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	41/122 (33.6)	14.1 (7.0, NE)	11/ 58 (19.0)	NE (5.4, NE)	1.26 (0.64, 2.47)	0.5091	

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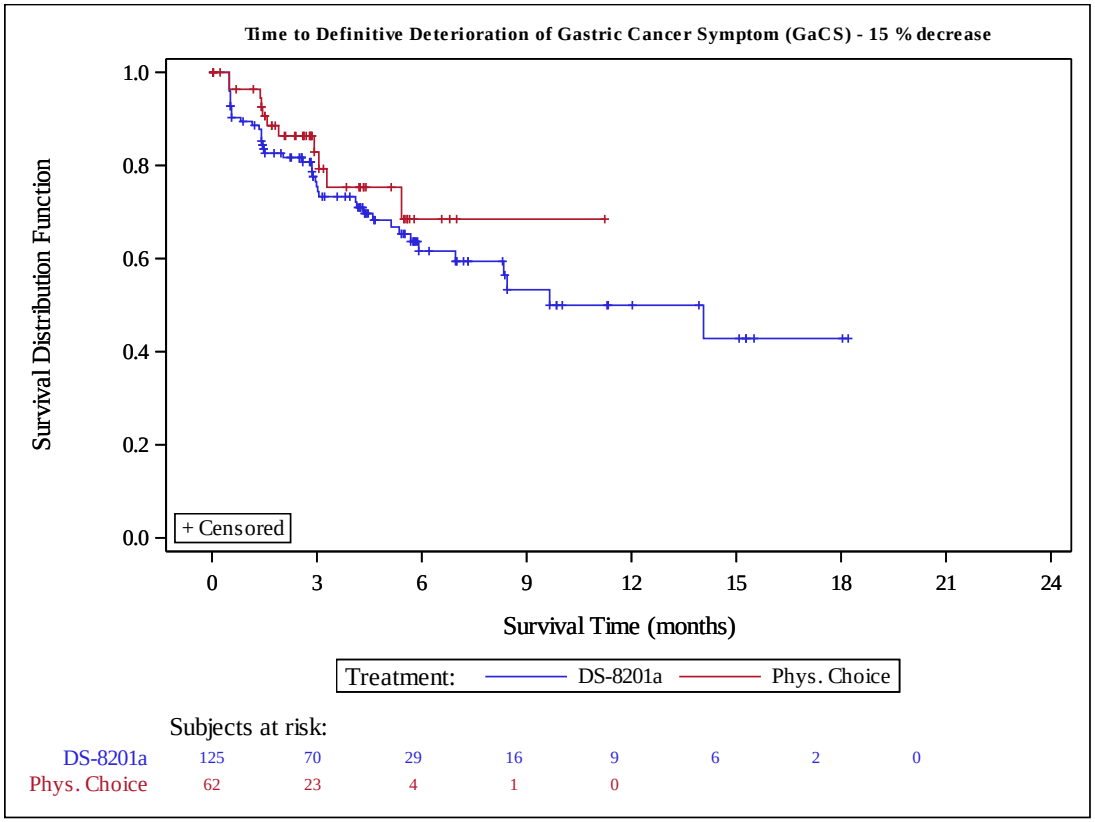
Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

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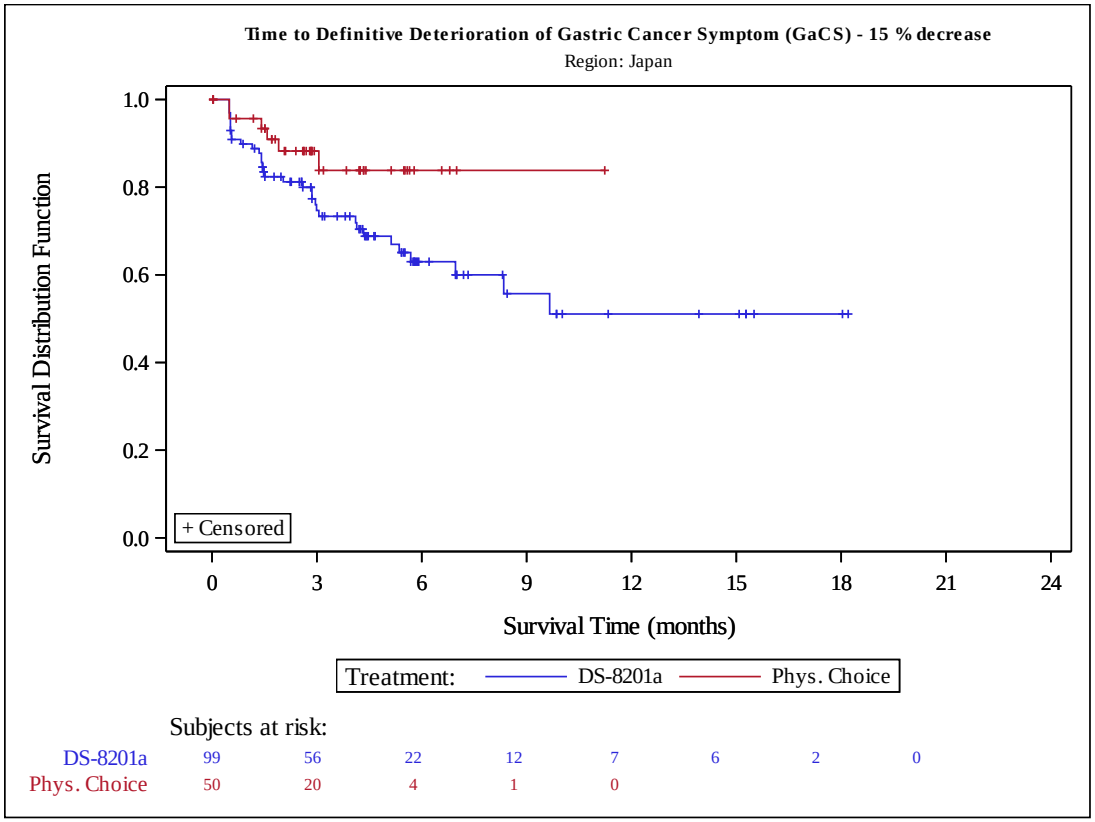
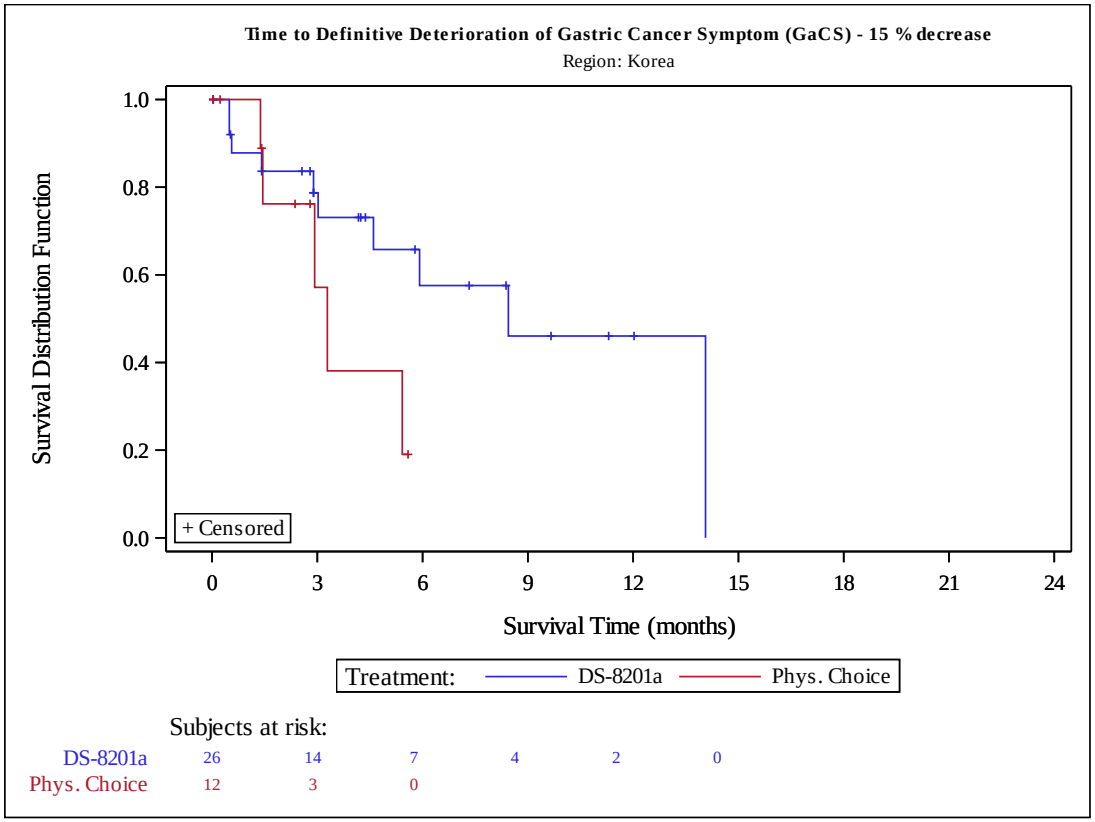
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	120	9 (7.5)	82 (68.3)	29 (24.2)	52	1 (1.9)	43 (82.7)	8 (15.4)
	Day 43	118	17 (14.4)	81 (68.6)	20 (16.9)	53	2 (3.8)	44 (83.0)	7 (13.2)
	Day 85	99	10 (10.1)	65 (65.7)	24 (24.2)	36	1 (2.8)	31 (86.1)	4 (11.1)
	Day 127	74	11 (14.9)	52 (70.3)	11 (14.9)	19	1 (5.3)	17 (89.5)	1 (5.3)
	Day 169	52	7 (13.5)	35 (67.3)	10 (19.2)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	34	7 (20.6)	17 (50.0)	10 (29.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	24	6 (25.0)	13 (54.2)	5 (20.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	19	4 (21.1)	9 (47.4)	6 (31.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	2 (13.3)	9 (60.0)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	1 (9.1)	6 (54.5)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	2 (18.2)	6 (54.5)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	4 (4.9)	49 (59.8)	29 (35.4)	53	1 (1.9)	41 (77.4)	11 (20.8)
Region									
Japan									
	Day 15	97	4 (4.1)	69 (71.1)	24 (24.7)	45	1 (2.2)	37 (82.2)	7 (15.6)
	Day 43	94	11 (11.7)	67 (71.3)	16 (17.0)	43	2 (4.7)	36 (83.7)	5 (11.6)
	Day 85	77	6 (7.8)	52 (67.5)	19 (24.7)	32	1 (3.1)	28 (87.5)	3 (9.4)
	Day 127	60	7 (11.7)	44 (73.3)	9 (15.0)	16	1 (6.3)	15 (93.8)	0 (0.0)
	Day 169	45	5 (11.1)	30 (66.7)	10 (22.2)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 211	28	4 (14.3)	15 (53.6)	9 (32.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	4 (22.2)	11 (61.1)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	2 (14.3)	7 (50.0)	5 (35.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	2 (22.2)	5 (55.6)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	64	3 (4.7)	41 (64.1)	20 (31.3)	45	1 (2.2)	38 (84.4)	6 (13.3)
Region									
Korea									
	Day 15	23	5 (21.7)	13 (56.5)	5 (21.7)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 43	24	6 (25.0)	14 (58.3)	4 (16.7)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 85	22	4 (18.2)	13 (59.1)	5 (22.7)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 127	14	4 (28.6)	8 (57.1)	2 (14.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	7	2 (28.6)	5 (71.4)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	3 (50.0)	2 (33.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	2 (33.3)	2 (33.3)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	8 (44.4)	9 (50.0)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy									
2									
	Day 15	62	4 (6.5)	44 (71.0)	14 (22.6)	34	0 (0.0)	28 (82.4)	6 (17.6)
	Day 43	62	7 (11.3)	42 (67.7)	13 (21.0)	36	0 (0.0)	30 (83.3)	6 (16.7)
	Day 85	50	5 (10.0)	33 (66.0)	12 (24.0)	21	1 (4.8)	18 (85.7)	2 (9.5)
	Day 127	33	6 (18.2)	23 (69.7)	4 (12.1)	14	0 (0.0)	13 (92.9)	1 (7.1)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 169	21	4 (19.0)	16 (76.2)	1 (4.8)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	14	4 (28.6)	8 (57.1)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	10	4 (40.0)	4 (40.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	3 (42.9)	3 (42.9)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	2 (40.0)	3 (60.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	2 (66.7)	1 (33.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	3 (6.8)	25 (56.8)	16 (36.4)	32	1 (3.1)	24 (75.0)	7 (21.9)
Lines of prior systemic therapy									
3									
	Day 15	33	4 (12.1)	20 (60.6)	9 (27.3)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 43	33	5 (15.2)	24 (72.7)	4 (12.1)	14	2 (14.3)	11 (78.6)	1 (7.1)
	Day 85	28	2 (7.1)	22 (78.6)	4 (14.3)	12	0 (0.0)	10 (83.3)	2 (16.7)
	Day 127	23	2 (8.7)	16 (69.6)	5 (21.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	17	2 (11.8)	9 (52.9)	6 (35.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	12	2 (16.7)	7 (58.3)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	0 (0.0)	14 (66.7)	7 (33.3)	16	0 (0.0)	13 (81.3)	3 (18.8)
Lines of prior systemic therapy									
>=4									
	Day 15	25	1 (4.0)	18 (72.0)	6 (24.0)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	23	5 (21.7)	15 (65.2)	3 (13.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	3 (14.3)	10 (47.6)	8 (38.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	3 (16.7)	13 (72.2)	2 (11.1)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	14	1 (7.1)	10 (71.4)	3 (21.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	1 (12.5)	2 (25.0)	5 (62.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	0 (0.0)	3 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	10 (58.8)	6 (35.3)	5	0 (0.0)	4 (80.0)	1 (20.0)
Age									
<65 years									
	Day 15	52	5 (9.6)	36 (69.2)	11 (21.2)	22	0 (0.0)	19 (86.4)	3 (13.6)
	Day 43	52	11 (21.2)	33 (63.5)	8 (15.4)	24	0 (0.0)	19 (79.2)	5 (20.8)
	Day 85	47	6 (12.8)	32 (68.1)	9 (19.1)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 127	34	7 (20.6)	23 (67.6)	4 (11.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	25	3 (12.0)	18 (72.0)	4 (16.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	16	4 (25.0)	9 (56.3)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	12	5 (41.7)	5 (41.7)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	11	3 (27.3)	7 (63.6)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	2 (33.3)	3 (50.0)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

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Primary Cohort
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Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	2 (5.3)	23 (60.5)	13 (34.2)	22	0 (0.0)	17 (77.3)	5 (22.7)
Age									
>=65 years									
	Day 15	68	4 (5.9)	46 (67.6)	18 (26.5)	30	1 (3.3)	24 (80.0)	5 (16.7)
	Day 43	66	6 (9.1)	48 (72.7)	12 (18.2)	29	2 (6.9)	25 (86.2)	2 (6.9)
	Day 85	52	4 (7.7)	33 (63.5)	15 (28.8)	20	1 (5.0)	16 (80.0)	3 (15.0)
	Day 127	40	4 (10.0)	29 (72.5)	7 (17.5)	11	1 (9.1)	10 (90.9)	0 (0.0)
	Day 169	27	4 (14.8)	17 (63.0)	6 (22.2)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	18	3 (16.7)	8 (44.4)	7 (38.9)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	8 (66.7)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	1 (12.5)	2 (25.0)	5 (62.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	7	0 (0.0)	3 (42.9)	4 (57.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	1 (20.0)	4 (80.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	2 (4.5)	26 (59.1)	16 (36.4)	31	1 (3.2)	24 (77.4)	6 (19.4)
Sex									
female									
	Day 15	28	0 (0.0)	25 (89.3)	3 (10.7)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 43	28	5 (17.9)	21 (75.0)	2 (7.1)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 85	20	3 (15.0)	14 (70.0)	3 (15.0)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	13	5 (38.5)	8 (61.5)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	9	3 (33.3)	5 (55.6)	1 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	6	2 (33.3)	4 (66.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	2 (50.0)	1 (25.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	15 (71.4)	5 (23.8)	14	0 (0.0)	12 (85.7)	2 (14.3)
Sex									
male									
	Day 15	92	9 (9.8)	57 (62.0)	26 (28.3)	39	0 (0.0)	32 (82.1)	7 (17.9)
	Day 43	90	12 (13.3)	60 (66.7)	18 (20.0)	40	1 (2.5)	34 (85.0)	5 (12.5)
	Day 85	79	7 (8.9)	51 (64.6)	21 (26.6)	28	1 (3.6)	25 (89.3)	2 (7.1)
	Day 127	61	6 (9.8)	44 (72.1)	11 (18.0)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	43	4 (9.3)	30 (69.8)	9 (20.9)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	28	5 (17.9)	13 (46.4)	10 (35.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	4 (20.0)	12 (60.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	4 (23.5)	8 (47.1)	5 (29.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	8 (57.1)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	61	3 (4.9)	34 (55.7)	24 (39.3)	39	1 (2.6)	29 (74.4)	9 (23.1)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS									
0									
	Day 15	60	1 (1.7)	43 (71.7)	16 (26.7)	26	0 (0.0)	24 (92.3)	2 (7.7)
	Day 43	60	6 (10.0)	44 (73.3)	10 (16.7)	26	1 (3.8)	21 (80.8)	4 (15.4)
	Day 85	54	5 (9.3)	33 (61.1)	16 (29.6)	19	0 (0.0)	18 (94.7)	1 (5.3)
	Day 127	42	6 (14.3)	32 (76.2)	4 (9.5)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 169	33	3 (9.1)	24 (72.7)	6 (18.2)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	20	2 (10.0)	11 (55.0)	7 (35.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	2 (13.3)	9 (60.0)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	0 (0.0)	7 (63.6)	4 (36.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	9	0 (0.0)	7 (77.8)	2 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	1 (2.6)	25 (65.8)	12 (31.6)	27	0 (0.0)	22 (81.5)	5 (18.5)
ECOG PS									
1									
	Day 15	60	8 (13.3)	39 (65.0)	13 (21.7)	26	1 (3.8)	19 (73.1)	6 (23.1)
	Day 43	58	11 (19.0)	37 (63.8)	10 (17.2)	27	1 (3.7)	23 (85.2)	3 (11.1)
	Day 85	45	5 (11.1)	32 (71.1)	8 (17.8)	17	1 (5.9)	13 (76.5)	3 (17.6)
	Day 127	32	5 (15.6)	20 (62.5)	7 (21.9)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	19	4 (21.1)	11 (57.9)	4 (21.1)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	14	5 (35.7)	6 (42.9)	3 (21.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	4 (44.4)	4 (44.4)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	4 (50.0)	2 (25.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	2 (33.3)	2 (33.3)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	3 (6.8)	24 (54.5)	17 (38.6)	26	1 (3.8)	19 (73.1)	6 (23.1)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	93	7 (7.5)	62 (66.7)	24 (25.8)	38	0 (0.0)	31 (81.6)	7 (18.4)
	Day 43	92	14 (15.2)	63 (68.5)	15 (16.3)	40	1 (2.5)	33 (82.5)	6 (15.0)
	Day 85	79	9 (11.4)	53 (67.1)	17 (21.5)	26	1 (3.8)	23 (88.5)	2 (7.7)
	Day 127	59	10 (16.9)	40 (67.8)	9 (15.3)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 169	41	6 (14.6)	27 (65.9)	8 (19.5)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	29	6 (20.7)	14 (48.3)	9 (31.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	6 (28.6)	10 (47.6)	5 (23.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	4 (23.5)	8 (47.1)	5 (29.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	9 (64.3)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	2 (18.2)	6 (54.5)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	61	3 (4.9)	37 (60.7)	21 (34.4)	39	1 (2.6)	28 (71.8)	10 (25.6)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	2 (7.4)	20 (74.1)	5 (18.5)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 43	26	3 (11.5)	18 (69.2)	5 (19.2)	13	1 (7.7)	11 (84.6)	1 (7.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	20	1 (5.0)	12 (60.0)	7 (35.0)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	15	1 (6.7)	12 (80.0)	2 (13.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 169	11	1 (9.1)	8 (72.7)	2 (18.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	12 (57.1)	8 (38.1)	14	0 (0.0)	13 (92.9)	1 (7.1)
Primary tumor location									
Gastric									
	Day 15	103	8 (7.8)	70 (68.0)	25 (24.3)	46	1 (2.2)	38 (82.6)	7 (15.2)
	Day 43	101	14 (13.9)	71 (70.3)	16 (15.8)	48	2 (4.2)	40 (83.3)	6 (12.5)
	Day 85	84	8 (9.5)	57 (67.9)	19 (22.6)	33	1 (3.0)	28 (84.8)	4 (12.1)
	Day 127	63	10 (15.9)	44 (69.8)	9 (14.3)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	42	5 (11.9)	28 (66.7)	9 (21.4)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	29	5 (17.2)	15 (51.7)	9 (31.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	4 (20.0)	11 (55.0)	5 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	2 (13.3)	7 (46.7)	6 (40.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	1 (8.3)	7 (58.3)	4 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	4 (50.0)	4 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	70	3 (4.3)	43 (61.4)	24 (34.3)	47	1 (2.1)	35 (74.5)	11 (23.4)
Primary tumor location									
GEJ									
	Day 15	17	1 (5.9)	12 (70.6)	4 (23.5)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 43	17	3 (17.6)	10 (58.8)	4 (23.5)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 85	15	2 (13.3)	8 (53.3)	5 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	2 (20.0)	7 (70.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	2 (50.0)	2 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	2 (50.0)	2 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	6 (50.0)	5 (41.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	87	5 (5.7)	61 (70.1)	21 (24.1)	35	1 (2.9)	29 (82.9)	5 (14.3)
	Day 43	86	10 (11.6)	63 (73.3)	13 (15.1)	34	2 (5.9)	27 (79.4)	5 (14.7)
	Day 85	73	5 (6.8)	49 (67.1)	19 (26.0)	27	1 (3.7)	23 (85.2)	3 (11.1)
	Day 127	55	7 (12.7)	40 (72.7)	8 (14.5)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 169	40	4 (10.0)	28 (70.0)	8 (20.0)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	25	3 (12.0)	14 (56.0)	8 (32.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	16	3 (18.8)	9 (56.3)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	2 (15.4)	6 (46.2)	5 (38.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	1 (10.0)	6 (60.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	2 (22.2)	5 (55.6)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	2 (3.2)	37 (59.7)	23 (37.1)	34	1 (2.9)	27 (79.4)	6 (17.6)
Histological subtype diffuse									
	Day 15	27	3 (11.1)	17 (63.0)	7 (25.9)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 43	26	5 (19.2)	16 (61.5)	5 (19.2)	14	0 (0.0)	13 (92.9)	1 (7.1)
	Day 85	22	3 (13.6)	14 (63.6)	5 (22.7)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 127	15	3 (20.0)	9 (60.0)	3 (20.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	10	3 (30.0)	5 (50.0)	2 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	4 (50.0)	2 (25.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	7	3 (42.9)	3 (42.9)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	16	2 (12.5)	11 (68.8)	3 (18.8)	16	0 (0.0)	13 (81.3)	3 (18.8)
Histological subtype others									
	Day 15	6	1 (16.7)	4 (66.7)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	2 (33.3)	2 (33.3)	2 (33.3)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 85	4	2 (50.0)	2 (50.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	4	1 (25.0)	3 (75.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	1 (25.0)	3 (75.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	23	0 (0.0)	15 (65.2)	8 (34.8)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	23	1 (4.3)	18 (78.3)	4 (17.4)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 85	22	0 (0.0)	18 (81.8)	4 (18.2)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	18	0 (0.0)	16 (88.9)	2 (11.1)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	15	0 (0.0)	12 (80.0)	3 (20.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	7 (70.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	1 (16.7)	3 (50.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	1 (7.1)	9 (64.3)	4 (28.6)	8	1 (12.5)	7 (87.5)	0 (0.0)
Number of metastatic sites >= 2									
	Day 15	97	9 (9.3)	67 (69.1)	21 (21.6)	42	1 (2.4)	35 (83.3)	6 (14.3)
	Day 43	95	16 (16.8)	63 (66.3)	16 (16.8)	43	2 (4.7)	34 (79.1)	7 (16.3)
	Day 85	77	10 (13.0)	47 (61.0)	20 (26.0)	28	0 (0.0)	24 (85.7)	4 (14.3)
	Day 127	56	11 (19.6)	36 (64.3)	9 (16.1)	15	1 (6.7)	13 (86.7)	1 (6.7)
	Day 169	37	7 (18.9)	23 (62.2)	7 (18.9)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	24	6 (25.0)	10 (41.7)	8 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	5 (27.8)	10 (55.6)	3 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	15	3 (20.0)	7 (46.7)	5 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	2 (25.0)	4 (50.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	68	3 (4.4)	40 (58.8)	25 (36.8)	45	0 (0.0)	34 (75.6)	11 (24.4)
Previous total gastrectomy									
yes									
	Day 15	20	1 (5.0)	14 (70.0)	5 (25.0)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 43	20	2 (10.0)	13 (65.0)	5 (25.0)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 85	18	1 (5.6)	11 (61.1)	6 (33.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	7 (63.6)	3 (27.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	7	2 (28.6)	1 (14.3)	4 (57.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	2 (66.7)	0 (0.0)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	0 (0.0)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	0 (0.0)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	11 (64.7)	5 (29.4)	9	0 (0.0)	8 (88.9)	1 (11.1)
Previous total gastrectomy									
no									
	Day 15	100	8 (8.0)	68 (68.0)	24 (24.0)	45	1 (2.2)	36 (80.0)	8 (17.8)
	Day 43	98	15 (15.3)	68 (69.4)	15 (15.3)	45	1 (2.2)	37 (82.2)	7 (15.6)
	Day 85	81	9 (11.1)	54 (66.7)	18 (22.2)	30	1 (3.3)	25 (83.3)	4 (13.3)
	Day 127	63	10 (15.9)	45 (71.4)	8 (12.7)	17	0 (0.0)	16 (94.1)	1 (5.9)
	Day 169	44	6 (13.6)	31 (70.5)	7 (15.9)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 211	27	5 (18.5)	16 (59.3)	6 (22.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	4 (19.0)	13 (61.9)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	3 (18.8)	9 (56.3)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	1 (8.3)	9 (75.0)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	2 (22.2)	5 (55.6)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	65	3 (4.6)	38 (58.5)	24 (36.9)	44	1 (2.3)	33 (75.0)	10 (22.7)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	1 (3.4)	24 (82.8)	4 (13.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 43	28	3 (10.7)	22 (78.6)	3 (10.7)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 85	27	2 (7.4)	20 (74.1)	5 (18.5)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 127	22	2 (9.1)	18 (81.8)	2 (9.1)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	13	2 (15.4)	8 (61.5)	3 (23.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	8	2 (25.0)	1 (12.5)	5 (62.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	5	2 (40.0)	1 (20.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	1 (20.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	1 (20.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	0 (0.0)	3 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	13 (61.9)	6 (28.6)	9	0 (0.0)	9 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	91	8 (8.8)	58 (63.7)	25 (27.5)	44	1 (2.3)	36 (81.8)	7 (15.9)
	Day 43	90	14 (15.6)	59 (65.6)	17 (18.9)	45	1 (2.2)	37 (82.2)	7 (15.6)
	Day 85	72	8 (11.1)	45 (62.5)	19 (26.4)	29	1 (3.4)	24 (82.8)	4 (13.8)
	Day 127	52	9 (17.3)	34 (65.4)	9 (17.3)	15	0 (0.0)	14 (93.3)	1 (6.7)
	Day 169	39	5 (12.8)	27 (69.2)	7 (17.9)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	26	5 (19.2)	16 (61.5)	5 (19.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	4 (21.1)	12 (63.2)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	3 (21.4)	8 (57.1)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	1 (10.0)	8 (80.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	61	2 (3.3)	36 (59.0)	23 (37.7)	44	1 (2.3)	32 (72.7)	11 (25.0)
Prior ramucirumab contained treatment									
yes									
	Day 15	90	3 (3.3)	64 (71.1)	23 (25.6)	34	1 (2.9)	28 (82.4)	5 (14.7)
	Day 43	90	11 (12.2)	62 (68.9)	17 (18.9)	33	1 (3.0)	27 (81.8)	5 (15.2)
	Day 85	73	6 (8.2)	49 (67.1)	18 (24.7)	23	0 (0.0)	21 (91.3)	2 (8.7)
	Day 127	59	6 (10.2)	45 (76.3)	8 (13.6)	11	1 (9.1)	10 (90.9)	0 (0.0)
	Day 169	41	2 (4.9)	31 (75.6)	8 (19.5)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	25	1 (4.0)	15 (60.0)	9 (36.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	1 (6.7)	12 (80.0)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	0 (0.0)	9 (69.2)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	2 (3.2)	36 (58.1)	24 (38.7)	35	0 (0.0)	28 (80.0)	7 (20.0)
Prior ramucirumab contained treatment									
no									
	Day 15	30	6 (20.0)	18 (60.0)	6 (20.0)	18	0 (0.0)	15 (83.3)	3 (16.7)
	Day 43	28	6 (21.4)	19 (67.9)	3 (10.7)	20	1 (5.0)	17 (85.0)	2 (10.0)
	Day 85	26	4 (15.4)	16 (61.5)	6 (23.1)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 127	15	5 (33.3)	7 (46.7)	3 (20.0)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	11	5 (45.5)	4 (36.4)	2 (18.2)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	9	6 (66.7)	2 (22.2)	1 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	5 (55.6)	1 (11.1)	3 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	4 (66.7)	0 (0.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	3	2 (66.7)	0 (0.0)	1 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	2 (10.0)	13 (65.0)	5 (25.0)	18	1 (5.6)	13 (72.2)	4 (22.2)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Prior nivolumab contained treatment									
yes									
	Day 15	32	1 (3.1)	20 (62.5)	11 (34.4)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 43	31	3 (9.7)	26 (83.9)	2 (6.5)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 85	27	3 (11.1)	18 (66.7)	6 (22.2)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	26	2 (7.7)	19 (73.1)	5 (19.2)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	20	2 (10.0)	15 (75.0)	3 (15.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	13	1 (7.7)	8 (61.5)	4 (30.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	0 (0.0)	9 (90.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	12 (60.0)	7 (35.0)	13	0 (0.0)	10 (76.9)	3 (23.1)
Prior nivolumab contained treatment									
no									
	Day 15	88	8 (9.1)	62 (70.5)	18 (20.5)	39	0 (0.0)	33 (84.6)	6 (15.4)
	Day 43	87	14 (16.1)	55 (63.2)	18 (20.7)	43	1 (2.3)	35 (81.4)	7 (16.3)
	Day 85	72	7 (9.7)	47 (65.3)	18 (25.0)	26	1 (3.8)	23 (88.5)	2 (7.7)
	Day 127	48	9 (18.8)	33 (68.8)	6 (12.5)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 169	32	5 (15.6)	20 (62.5)	7 (21.9)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	21	6 (28.6)	9 (42.9)	6 (28.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	14	6 (42.9)	4 (28.6)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	4 (36.4)	4 (36.4)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	4 (50.0)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	2 (33.3)	2 (33.3)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	3 (4.8)	37 (59.7)	22 (35.5)	40	1 (2.5)	31 (77.5)	8 (20.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	42	3 (7.1)	26 (61.9)	13 (31.0)	15	1 (6.7)	12 (80.0)	2 (13.3)
	Day 43	41	6 (14.6)	31 (75.6)	4 (9.8)	12	1 (8.3)	11 (91.7)	0 (0.0)
	Day 85	37	5 (13.5)	22 (59.5)	10 (27.0)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 127	31	4 (12.9)	20 (64.5)	7 (22.6)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	23	3 (13.0)	17 (73.9)	3 (13.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	17	3 (17.6)	9 (52.9)	5 (29.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	13	2 (15.4)	10 (76.9)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	2 (16.7)	6 (50.0)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	2 (7.1)	15 (53.6)	11 (39.3)	15	0 (0.0)	12 (80.0)	3 (20.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	78	6 (7.7)	56 (71.8)	16 (20.5)	37	0 (0.0)	31 (83.8)	6 (16.2)
	Day 43	77	11 (14.3)	50 (64.9)	16 (20.8)	41	1 (2.4)	33 (80.5)	7 (17.1)
	Day 85	62	5 (8.1)	43 (69.4)	14 (22.6)	25	1 (4.0)	22 (88.0)	2 (8.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 127	43	7 (16.3)	32 (74.4)	4 (9.3)	15	0 (0.0)	14 (93.3)	1 (6.7)
	Day 169	29	4 (13.8)	18 (62.1)	7 (24.1)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	17	4 (23.5)	8 (47.1)	5 (29.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	11	4 (36.4)	3 (27.3)	4 (36.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	2 (28.6)	3 (42.9)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	2 (50.0)	0 (0.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	54	2 (3.7)	34 (63.0)	18 (33.3)	38	1 (2.6)	29 (76.3)	8 (21.1)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
yes									
	Day 15	22	3 (13.6)	15 (68.2)	4 (18.2)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	19	3 (15.8)	14 (73.7)	2 (10.5)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 85	16	1 (6.3)	11 (68.8)	4 (25.0)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 127	12	2 (16.7)	9 (75.0)	1 (8.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	7	1 (14.3)	4 (57.1)	2 (28.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	3	1 (33.3)	1 (33.3)	1 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	8 (66.7)	3 (25.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
no									
	Day 15	98	6 (6.1)	67 (68.4)	25 (25.5)	46	1 (2.2)	37 (80.4)	8 (17.4)
	Day 43	99	14 (14.1)	67 (67.7)	18 (18.2)	47	2 (4.3)	38 (80.9)	7 (14.9)
	Day 85	83	9 (10.8)	54 (65.1)	20 (24.1)	31	1 (3.2)	26 (83.9)	4 (12.9)
	Day 127	62	9 (14.5)	43 (69.4)	10 (16.1)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 169	45	6 (13.3)	31 (68.9)	8 (17.8)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	31	6 (19.4)	16 (51.6)	9 (29.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	5 (22.7)	13 (59.1)	4 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	3 (17.6)	8 (47.1)	6 (35.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	8 (57.1)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	70	3 (4.3)	41 (58.6)	26 (37.1)	47	1 (2.1)	35 (74.5)	11 (23.4)
Presence of liver metastasis at baseline									
yes									
	Day 15	65	7 (10.8)	45 (69.2)	13 (20.0)	27	0 (0.0)	23 (85.2)	4 (14.8)
	Day 43	63	11 (17.5)	43 (68.3)	9 (14.3)	28	1 (3.6)	23 (82.1)	4 (14.3)
	Day 85	50	7 (14.0)	33 (66.0)	10 (20.0)	16	0 (0.0)	14 (87.5)	2 (12.5)
	Day 127	36	8 (22.2)	23 (63.9)	5 (13.9)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	25	4 (16.0)	18 (72.0)	3 (12.0)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	14	3 (21.4)	9 (64.3)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 253	12	2 (16.7)	8 (66.7)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	1 (2.3)	30 (68.2)	13 (29.5)	30	0 (0.0)	22 (73.3)	8 (26.7)
Presence of liver metastasis at baseline									
no									
	Day 15	55	2 (3.6)	37 (67.3)	16 (29.1)	25	1 (4.0)	20 (80.0)	4 (16.0)
	Day 43	55	6 (10.9)	38 (69.1)	11 (20.0)	25	1 (4.0)	21 (84.0)	3 (12.0)
	Day 85	49	3 (6.1)	32 (65.3)	14 (28.6)	20	1 (5.0)	17 (85.0)	2 (10.0)
	Day 127	38	3 (7.9)	29 (76.3)	6 (15.8)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 169	27	3 (11.1)	17 (63.0)	7 (25.9)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	20	4 (20.0)	8 (40.0)	8 (40.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	12	4 (33.3)	5 (41.7)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	10	3 (30.0)	3 (30.0)	4 (40.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	2 (25.0)	4 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	0 (0.0)	4 (80.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	0 (0.0)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	3 (7.9)	19 (50.0)	16 (42.1)	23	1 (4.3)	19 (82.6)	3 (13.0)
Renal impairment at baseline									
normal									
	Day 15	32	2 (6.3)	24 (75.0)	6 (18.8)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 43	33	4 (12.1)	24 (72.7)	5 (15.2)	12	0 (0.0)	9 (75.0)	3 (25.0)
	Day 85	26	2 (7.7)	20 (76.9)	4 (15.4)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 127	19	1 (5.3)	18 (94.7)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	15	1 (6.7)	13 (86.7)	1 (6.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	2 (22.2)	5 (55.6)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	14 (70.0)	5 (25.0)	11	0 (0.0)	8 (72.7)	3 (27.3)
Renal impairment at baseline									
mild									
	Day 15	51	5 (9.8)	32 (62.7)	14 (27.5)	25	0 (0.0)	23 (92.0)	2 (8.0)
	Day 43	51	10 (19.6)	31 (60.8)	10 (19.6)	23	0 (0.0)	20 (87.0)	3 (13.0)
	Day 85	45	6 (13.3)	28 (62.2)	11 (24.4)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 127	31	7 (22.6)	18 (58.1)	6 (19.4)	9	1 (11.1)	8 (88.9)	0 (0.0)
	Day 169	21	4 (19.0)	12 (57.1)	5 (23.8)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	13	3 (23.1)	5 (38.5)	5 (38.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	8	3 (37.5)	4 (50.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	3 (50.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	2 (5.3)	21 (55.3)	15 (39.5)	22	1 (4.5)	17 (77.3)	4 (18.2)
Renal impairment at baseline									
moderate									
	Day 15	37	2 (5.4)	26 (70.3)	9 (24.3)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 43	34	3 (8.8)	26 (76.5)	5 (14.7)	17	2 (11.8)	14 (82.4)	1 (5.9)
	Day 85	28	2 (7.1)	17 (60.7)	9 (32.1)	14	0 (0.0)	11 (78.6)	3 (21.4)
	Day 127	24	3 (12.5)	16 (66.7)	5 (20.8)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 169	16	2 (12.5)	10 (62.5)	4 (25.0)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	11	2 (18.2)	6 (54.5)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	1 (4.2)	14 (58.3)	9 (37.5)	19	0 (0.0)	15 (78.9)	4 (21.1)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	85	5 (5.9)	57 (67.1)	23 (27.1)	37	1 (2.7)	31 (83.8)	5 (13.5)
	Day 43	84	11 (13.1)	59 (70.2)	14 (16.7)	41	2 (4.9)	33 (80.5)	6 (14.6)
	Day 85	76	8 (10.5)	48 (63.2)	20 (26.3)	27	1 (3.7)	22 (81.5)	4 (14.8)
	Day 127	58	9 (15.5)	41 (70.7)	8 (13.8)	14	0 (0.0)	13 (92.9)	1 (7.1)
	Day 169	40	5 (12.5)	27 (67.5)	8 (20.0)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	24	6 (25.0)	12 (50.0)	6 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	19	6 (31.6)	10 (52.6)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	4 (26.7)	7 (46.7)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	2 (18.2)	7 (63.6)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	55	2 (3.6)	30 (54.5)	23 (41.8)	40	1 (2.5)	30 (75.0)	9 (22.5)
Hepatic impairment at baseline									
mild									
	Day 15	34	4 (11.8)	24 (70.6)	6 (17.6)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 43	33	6 (18.2)	21 (63.6)	6 (18.2)	12	0 (0.0)	11 (91.7)	1 (8.3)
	Day 85	22	2 (9.1)	16 (72.7)	4 (18.2)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 127	15	2 (13.3)	11 (73.3)	2 (13.3)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 169	12	2 (16.7)	8 (66.7)	2 (16.7)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	5 (50.0)	4 (40.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	2 (7.7)	19 (73.1)	5 (19.2)	13	0 (0.0)	11 (84.6)	2 (15.4)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	2 (25.0)	3 (37.5)	3 (37.5)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	2 (25.0)	5 (62.5)	1 (12.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	1 (14.3)	4 (57.1)	2 (28.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	1 (16.7)	5 (83.3)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	2 (40.0)	1 (20.0)	2 (40.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	2 (50.0)	1 (25.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	2 (50.0)	0 (0.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	1 (50.0)	0 (0.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	5	1 (20.0)	1 (20.0)	3 (60.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	112	7 (6.3)	79 (70.5)	26 (23.2)	48	1 (2.1)	40 (83.3)	7 (14.6)
	Day 43	110	15 (13.6)	76 (69.1)	19 (17.3)	50	2 (4.0)	41 (82.0)	7 (14.0)
	Day 85	92	9 (9.8)	61 (66.3)	22 (23.9)	33	1 (3.0)	28 (84.8)	4 (12.1)
	Day 127	68	10 (14.7)	47 (69.1)	11 (16.2)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	47	5 (10.6)	34 (72.3)	8 (17.0)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	30	5 (16.7)	16 (53.3)	9 (30.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	4 (20.0)	13 (65.0)	3 (15.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	17	3 (17.6)	9 (52.9)	5 (29.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	14	2 (14.3)	9 (64.3)	3 (21.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	77	3 (3.9)	48 (62.3)	26 (33.8)	50	1 (2.0)	39 (78.0)	10 (20.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	1 (33.3)	1 (33.3)	1 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	1 (33.3)	1 (33.3)	1 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	1 (50.0)	0 (0.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	1	1 (100.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	0 (0.0)	1 (100.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors no									
	Day 15	117	8 (6.8)	81 (69.2)	28 (23.9)	49	1 (2.0)	40 (81.6)	8 (16.3)
	Day 43	115	17 (14.8)	78 (67.8)	20 (17.4)	50	2 (4.0)	41 (82.0)	7 (14.0)
	Day 85	96	10 (10.4)	62 (64.6)	24 (25.0)	33	1 (3.0)	28 (84.8)	4 (12.1)
	Day 127	71	11 (15.5)	49 (69.0)	11 (15.5)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	49	6 (12.2)	34 (69.4)	9 (18.4)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	32	6 (18.8)	16 (50.0)	10 (31.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	5 (22.7)	13 (59.1)	4 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	18	3 (16.7)	9 (50.0)	6 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	15	2 (13.3)	9 (60.0)	4 (26.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	11	1 (9.1)	6 (54.5)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	2 (18.2)	6 (54.5)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	81	4 (4.9)	49 (60.5)	28 (34.6)	51	1 (2.0)	39 (76.5)	11 (21.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Fact-G Total Score Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	124 (99.2)	62	58 (93.5)
Day 15	125	118 (94.4)	62	52 (83.9)
Day 43	124	117 (94.4)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	52 (49.5)	45	11 (24.4)
Day 211	81	34 (42.0)	35	3 (8.6)
Day 253	62	24 (38.7)	26	1 (3.8)
Day 295	51	19 (37.3)	19	1 (5.3)
Day 337	45	15 (33.3)	14	1 (7.1)
Day 379	33	11 (33.3)	10	0 (0.0)
Day 421	22	11 (50.0)	3	0 (0.0)
Day 463	14	7 (50.0)	2	0 (0.0)
Day 505	11	3 (27.3)	2	0 (0.0)
Day 547	6	3 (50.0)	2	0 (0.0)
Day 589	4	1 (25.0)	2	0 (0.0)
Day 631	3	1 (33.3)	0	0 (0.0)
Day 673	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Fact-G Total Score by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	124	72.1 (14.96)			58	73.6 (14.07)		
Day 15	118	67.9 (16.04)	117	-4.4 (12.74)	52	73.9 (15.80)	49	-1.7 (12.41)
Day 43	117	69.0 (16.82)	116	-4.0 (13.24)	53	71.8 (18.69)	50	-3.6 (13.79)
Day 85	99	70.0 (15.98)	98	-3.3 (11.73)	36	73.4 (19.87)	34	-3.6 (12.55)
Day 127	74	72.3 (14.55)	73	-3.1 (12.71)	19	73.6 (17.11)	18	-5.9 (12.50)
Day 169	52	73.6 (14.65)	51	-1.7 (11.81)	11	76.9 (19.38)	10	-6.1 (11.88)
Day 211	34	73.2 (15.24)	33	-3.1 (13.47)	3	95.8 (14.55)	2	-2.7 (12.49)
Day 253	24	72.2 (16.20)	24	-2.6 (12.63)	1	104.0 (-)	1	9.2 (-)
Day 295	19	72.7 (17.14)	19	-2.5 (13.84)	1	104.0 (-)	1	9.2 (-)
Day 337	15	70.1 (17.43)	15	-5.6 (16.19)	1	105.0 (-)	1	10.2 (-)
Day 379	11	74.2 (16.56)	11	-4.6 (16.71)	0	-	0	-
Day 421	11	70.5 (16.46)	11	-6.5 (13.15)	0	-	0	-
Day 463	7	76.6 (15.78)	7	-1.5 (9.71)	0	-	0	-
Day 505	3	73.4 (22.38)	3	-4.2 (10.22)	0	-	0	-
Day 547	3	71.2 (22.33)	3	-6.4 (6.85)	0	-	0	-
Day 589	1	60.8 (-)	1	-12.2 (-)	0	-	0	-
Day 631	1	52.0 (-)	1	-21.0 (-)	0	-	0	-
Day 673	1	55.5 (-)	1	-17.5 (-)	0	-	0	-
End of Treatment	83	64.4 (16.64)	82	-9.3 (13.98)	53	64.3 (19.42)	49	-10.0 (15.61)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-G Total Score by Visit
Full Analysis Set

Visit	DS-8201a (N=125) N [a]	N_MISS [b]	LSMean (95% CI)	Phys. Choice (N=62) N [a]	N_MISS [b]	LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
Day 15			-6.12 (-8.30, -3.93)			-4.43 (-7.79, -1.07)	-1.69 (-5.37, 2.00)	0.3691		
Day 43			-6.13 (-8.17, -4.09)			-5.10 (-8.06, -2.14)	-1.03 (-4.27, 2.20)	0.5292		
Day 85			-6.15 (-8.05, -4.26)			-6.09 (-9.11, -3.08)	-0.06 (-3.26, 3.14)	0.9715		
Day 127			-6.17 (-8.05, -4.30)			-7.09 (-10.87, -3.31)	0.92 (-3.00, 4.84)	0.6451		
Day 169			-6.20 (-8.17, -4.22)			-8.09 (-13.03, -3.15)	1.90 (-3.19, 6.98)	0.4644		
Day 211			-6.22 (-8.41, -4.03)			-9.09 (-15.37, -2.81)	2.87 (-3.59, 9.34)	0.3831		
Day 253			-6.24 (-8.72, -3.76)			-10.09 (-17.80, -2.38)	3.85 (-4.10, 11.79)	0.3415		
Day 295			-6.26 (-9.09, -3.44)			-11.09 (-20.27, -1.90)	4.83 (-4.65, 14.30)	0.3175		
Day 337			-6.29 (-9.49, -3.08)			-12.09 (-22.77, -1.40)	5.80 (-5.24, 16.84)	0.3022		
OVERALL	123	2	-6.17 (-8.03, -4.30)	54	8	-6.77 (-10.24, -3.30)	0.60 (-3.02, 4.23)	0.7431	0.05 (-0.27, 0.37)	0.7433

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-G Total Score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0271
Japan	98	-3.86 (-5.37, -2.35)	45	-2.43 (-5.65, 0.78)	-1.43 (-4.99, 2.13)	0.4303	-0.16 (-0.52, 0.19)	0.3669	
Korea	25	-6.77 (-11.58, -1.96)	9	-18.94 (-29.81, -8.07)	12.17 (0.28, 24.05)	0.0449	0.93 (0.14, 1.72)	0.0215	
Lines of prior systemic therapy									0.6807
2	64	-3.36 (-5.58, -1.13)	34	-4.32 (-8.03, -0.62)	0.97 (-3.39, 5.32)	0.6604	0.10 (-0.32, 0.52)	0.6380	
3	34	-4.51 (-7.61, -1.42)	16	-6.05 (-12.93, 0.83)	1.54 (-6.00, 9.08)	0.6864	0.14 (-0.45, 0.74)	0.6373	
>=4	25	-6.97 (-10.35, -3.58)	4	-0.38 (-15.42, 14.66)	-6.58 (-22.01, 8.85)	0.3960	-0.71 (-1.78, 0.36)	0.1932	
Age									0.9924
<65 years	54	-4.65 (-7.04, -2.26)	25	-6.84 (-12.34, -1.34)	2.19 (-3.82, 8.20)	0.4732	0.21 (-0.27, 0.68)	0.3977	
>=65 years	69	-4.39 (-6.46, -2.33)	29	-3.73 (-7.85, 0.40)	-0.66 (-5.28, 3.95)	0.7759	-0.07 (-0.50, 0.36)	0.7510	
Sex									0.9152
female	29	-4.64 (-8.48, -0.79)	12	-4.49 (-12.69, 3.71)	-0.15 (-9.20, 8.90)	0.9741	-0.01 (-0.69, 0.66)	0.9702	
male	94	-4.41 (-6.16, -2.66)	42	-5.07 (-8.75, -1.38)	0.66 (-3.43, 4.75)	0.7510	0.07 (-0.30, 0.43)	0.7170	
ECOG PS									0.3467
0	61	-3.82 (-5.56, -2.07)	27	-2.89 (-7.01, 1.23)	-0.93 (-5.41, 3.56)	0.6832	-0.11 (-0.57, 0.34)	0.6276	
1	62	-4.93 (-7.50, -2.36)	27	-6.75 (-11.63, -1.86)	1.82 (-3.70, 7.34)	0.5157	0.16 (-0.29, 0.62)	0.4756	
HER2 Status in central laboratory									0.3172
IHC 3+	95	-4.14 (-6.01, -2.28)	41	-5.37 (-9.54, -1.20)	1.23 (-3.35, 5.81)	0.5976	0.12 (-0.25, 0.48)	0.5382	
IHC 2+/ISH +	28	-5.43 (-8.40, -2.46)	13	-2.85 (-7.86, 2.16)	-2.58 (-8.40, 3.24)	0.3783	-0.31 (-0.98, 0.35)	0.3508	
Primary tumor location									0.9854
Gastric	106	-4.61 (-6.35, -2.87)	49	-4.86 (-8.34, -1.38)	0.25 (-3.65, 4.15)	0.9004	0.02 (-0.31, 0.36)	0.8882	
GEJ	17	-3.32 (-6.67, 0.03)	5	-6.16 (-17.56, 5.25)	2.84 (-9.06, 14.73)	0.6344	0.34 (-0.66, 1.35)	0.5011	
Histological subtype									0.1957
intestinal	88	-3.39 (-4.95, -1.82)	35	-3.06 (-6.58, 0.46)	-0.33 (-4.18, 3.53)	0.8682	-0.04 (-0.43, 0.35)	0.8466	
diffuse	28	-6.94 (-11.54, -2.33)	14	-10.39 (-19.96, -0.82)	3.45 (-7.25, 14.16)	0.5217	0.24 (-0.40, 0.89)	0.4602	
others	7	-7.70 (-15.43, 0.03)	5	-1.80 (-12.84, 9.24)	-5.89 (-19.91, 8.12)	0.3672	-0.61 (-1.78, 0.57)	0.3110	
Number of metastatic sites									0.1108
<2	23	-4.57 (-7.43, -1.71)	10	1.32 (-4.28, 6.93)	-5.89 (-12.22, 0.43)	0.0669	-0.80 (-1.56, -0.03)	0.0419	
>= 2	100	-4.30 (-6.13, -2.47)	44	-7.90 (-11.92, -3.88)	3.60 (-0.81, 8.02)	0.1094	0.34 (-0.02, 0.69)	0.0650	
Previous total gastrectomy									0.0997
yes	22	-5.29 (-9.79, -0.80)	8	3.54 (-9.24, 16.32)	-8.84 (-22.41, 4.73)	0.1979	-0.70 (-1.53, 0.13)	0.0989	
no	101	-4.18 (-5.83, -2.52)	46	-5.72 (-9.08, -2.37)	1.55 (-2.20, 5.29)	0.4161	0.16 (-0.19, 0.51)	0.3603	
Prior adjuvant/ neoadjuvant therapy									0.5846
yes	30	-3.61 (-6.73, -0.50)	7	-1.58 (-12.10, 8.94)	-2.04 (-12.99, 8.92)	0.7124	-0.21 (-1.04, 0.61)	0.6139	
no	93	-4.69 (-6.50, -2.88)	47	-5.08 (-8.50, -1.66)	0.38 (-3.50, 4.27)	0.8456	0.04 (-0.31, 0.39)	0.8294	
Prior ramucirumab contained treatment									0.0174
yes	92	-5.42 (-6.96, -3.88)	36	-4.92 (-8.95, -0.89)	-0.50 (-4.81, 3.82)	0.8213	-0.05 (-0.44, 0.33)	0.7812	
no	31	-1.76 (-6.10, 2.58)	18	-6.40 (-12.98, 0.17)	4.65 (-3.34, 12.63)	0.2480	0.37 (-0.22, 0.95)	0.2210	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-G Total Score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.3795
yes	33	-5.61 (-8.16, -3.06)	12	-5.27 (-13.37, 2.83)	-0.34 (-8.83, 8.15)	0.9364	-0.04 (-0.70, 0.62)	0.9151	
no	90	-3.92 (-5.90, -1.94)	42	-4.79 (-8.44, -1.13)	0.86 (-3.32, 5.04)	0.6838	0.08 (-0.28, 0.45)	0.6553	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.3628
yes	44	-5.74 (-8.37, -3.10)	13	-6.28 (-14.80, 2.24)	0.54 (-8.37, 9.46)	0.9046	0.05 (-0.57, 0.67)	0.8714	
no	79	-3.61 (-5.60, -1.63)	41	-4.53 (-7.94, -1.13)	0.92 (-3.04, 4.88)	0.6471	0.10 (-0.28, 0.47)	0.6216	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.4444
yes	22	-0.98 (-5.24, 3.28)	5	1.02 (-8.80, 10.84)	-2.01 (-12.75, 8.74)	0.7047	-0.20 (-1.18, 0.77)	0.6803	
no	101	-5.04 (-6.74, -3.34)	49	-5.61 (-9.19, -2.03)	0.57 (-3.40, 4.53)	0.7789	0.06 (-0.29, 0.40)	0.7486	
Presence of liver metastasis at baseline									0.3660
yes	67	-3.95 (-5.94, -1.95)	29	-8.24 (-12.78, -3.69)	4.29 (-0.67, 9.25)	0.0898	0.44 (0.00, 0.88)	0.0480	
no	56	-4.95 (-7.44, -2.45)	25	-2.37 (-7.35, 2.60)	-2.57 (-8.16, 3.01)	0.3634	-0.25 (-0.72, 0.23)	0.3075	
Renal impairment at baseline									0.2760
normal	33	-5.32 (-8.45, -2.20)	12	-15.53 (-26.47, -4.59)	10.21 (-1.16, 21.58)	0.0782	0.83 (0.14, 1.51)	0.0178	
mild	53	-3.38 (-5.89, -0.88)	25	-1.95 (-6.38, 2.47)	-1.43 (-6.53, 3.67)	0.5790	-0.15 (-0.62, 0.33)	0.5494	
moderate	37	-5.08 (-7.73, -2.43)	16	-5.28 (-10.58, 0.02)	0.20 (-5.73, 6.12)	0.9474	0.02 (-0.56, 0.61)	0.9411	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.4153
normal	86	-4.24 (-6.08, -2.40)	40	-5.28 (-8.98, -1.57)	1.04 (-3.11, 5.18)	0.6222	0.11 (-0.27, 0.48)	0.5793	
mild	36	-5.08 (-8.09, -2.08)	14	-3.55 (-10.90, 3.80)	-1.54 (-9.50, 6.43)	0.7019	-0.15 (-0.76, 0.47)	0.6426	
moderate	1	NE	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.2612
yes	8	-5.77 (-10.75, -0.78)	4	1.19 (-7.78, 10.16)	-6.96 (-17.67, 3.76)	0.1820	-1.01 (-2.27, 0.26)	0.1189	
no	115	-4.31 (-5.94, -2.68)	50	-6.81 (-10.47, -3.15)	2.50 (-1.50, 6.51)	0.2197	0.24 (-0.09, 0.58)	0.1541	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.4704
yes	3	-4.13 (-21.94, 13.68)	3	-1.41 (-19.31, 16.49)	-2.71 (-29.31, 23.88)	0.7649	-0.29 (-1.89, 1.32)	0.7273	
no	120	-4.45 (-6.04, -2.87)	51	-7.14 (-10.92, -3.35)	2.68 (-1.42, 6.79)	0.1991	0.26 (-0.07, 0.58)	0.1276	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631 and Day 673
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Graphical Summary of Fact-G Total Score by Visit - Mean Change from Baseline
Full Analysis Set

95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	42 (33.6)	14 (22.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	11.3 (5.9, NE)	5.7 (4.3, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.03 (0.55, 1.91)	
p-value [c]	0.9397	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.05 (0.57, 1.95)	
p-value [c]	0.8811	

Time to Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.1809
Japan	31/ 99 (31.3)	NE (5.8, NE)	9/ 50 (18.0)	NE (4.3, NE)	1.39 (0.66, 2.95)	0.3870	
Korea	11/ 26 (42.3)	8.4 (4.3, 11.3)	5/ 12 (41.7)	3.3 (0.5, NE)	0.42 (0.13, 1.33)	0.1313	
Lines of prior systemic therapy							0.5853
2	20/ 66 (30.3)	8.4 (5.9, NE)	7/ 38 (18.4)	NE (4.3, NE)	1.13 (0.46, 2.74)	0.7933	
3	11/ 34 (32.4)	NE (4.1, NE)	5/ 18 (27.8)	5.7 (2.6, NE)	0.84 (0.29, 2.47)	0.7371	
>=4	11/ 25 (44.0)	NE (1.6, NE)	2/ 6 (33.3)	1.1 (0.6, NE)	0.54 (0.12, 2.50)	0.4241	
Age							0.8014
<65 years	18/ 55 (32.7)	11.3 (5.5, NE)	6/ 27 (22.2)	NE (2.6, NE)	1.03 (0.40, 2.70)	0.9507	
>=65 years	24/ 70 (34.3)	8.4 (4.6, NE)	8/ 35 (22.9)	5.7 (3.3, NE)	1.11 (0.50, 2.49)	0.7959	
Sex							0.3734
female	12/ 30 (40.0)	7.0 (3.1, NE)	2/ 15 (13.3)	5.7 (NE , NE)	1.49 (0.32, 7.01)	0.6078	
male	30/ 95 (31.6)	NE (5.9, NE)	12/ 47 (25.5)	NE (3.3, NE)	0.95 (0.48, 1.88)	0.8796	
ECOG PS							0.5701
0	19/ 62 (30.6)	NE (7.0, NE)	7/ 30 (23.3)	5.7 (5.4, NE)	0.94 (0.39, 2.28)	0.8881	
1	23/ 63 (36.5)	8.4 (4.3, NE)	7/ 32 (21.9)	NE (3.3, NE)	1.20 (0.51, 2.84)	0.6777	
HER2 Status in central laboratory							0.1313
IHC 3+	33/ 96 (34.4)	11.3 (5.8, NE)	13/ 47 (27.7)	5.4 (3.3, NE)	0.84 (0.44, 1.62)	0.5969	
IHC 2+/ISH +	9/ 29 (31.0)	8.4 (4.0, 8.4)	1/ 15 (6.7)	5.7 (NE , NE)	3.40 (0.41, 27.91)	0.2261	
Primary tumor location							0.9880
Gastric	36/108 (33.3)	8.4 (5.9, NE)	14/ 55 (25.5)	5.7 (4.3, NE)	0.93 (0.50, 1.76)	0.8253	
GEJ	6/ 17 (35.3)	NE (1.5, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.7040
intestinal	28/ 89 (31.5)	NE (5.8, NE)	7/ 38 (18.4)	5.7 (4.3, NE)	1.24 (0.54, 2.88)	0.6146	
diffuse	11/ 28 (39.3)	8.4 (1.6, NE)	5/ 18 (27.8)	3.3 (1.5, NE)	0.94 (0.32, 2.78)	0.9101	
others	3/ 8 (37.5)	11.3 (0.5, 11.3)	2/ 6 (33.3)	NE (1.4, NE)	1.12 (0.15, 8.11)	0.9176	
Number of metastatic sites							0.9882
<2	8/ 24 (33.3)	NE (4.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	34/101 (33.7)	8.4 (5.8, NE)	14/ 52 (26.9)	5.4 (3.3, NE)	0.84 (0.44, 1.60)	0.5914	
Previous total gastrectomy							0.5392
yes	6/ 22 (27.3)	NE (1.4, NE)	1/ 9 (11.1)	NE (3.3, NE)	2.43 (0.29, 20.21)	0.3969	
no	36/103 (35.0)	8.4 (5.8, NE)	13/ 53 (24.5)	5.7 (4.3, NE)	0.95 (0.50, 1.82)	0.8740	
Prior adjuvant/ neoadjuvant therapy							0.9858
yes	9/ 30 (30.0)	NE (5.5, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	33/ 95 (34.7)	8.4 (5.8, NE)	14/ 52 (26.9)	5.7 (3.3, NE)	0.97 (0.51, 1.85)	0.9240	
Prior ramucirumab contained treatment							0.3339
yes	33/ 94 (35.1)	11.3 (5.5, NE)	8/ 41 (19.5)	5.7 (5.4, NE)	1.36 (0.62, 2.98)	0.4457	
no	9/ 31 (29.0)	8.4 (7.0, NE)	6/ 21 (28.6)	4.3 (3.1, NE)	0.61 (0.21, 1.78)	0.3609	
Prior nivolumab contained treatment							0.4308
yes	13/ 33 (39.4)	NE (3.4, NE)	5/ 15 (33.3)	5.7 (1.2, NE)	0.79 (0.28, 2.23)	0.6463	
no	29/ 92 (31.5)	8.4 (5.9, NE)	9/ 47 (19.1)	NE (4.3, NE)	1.16 (0.54, 2.51)	0.7020	

Time to Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

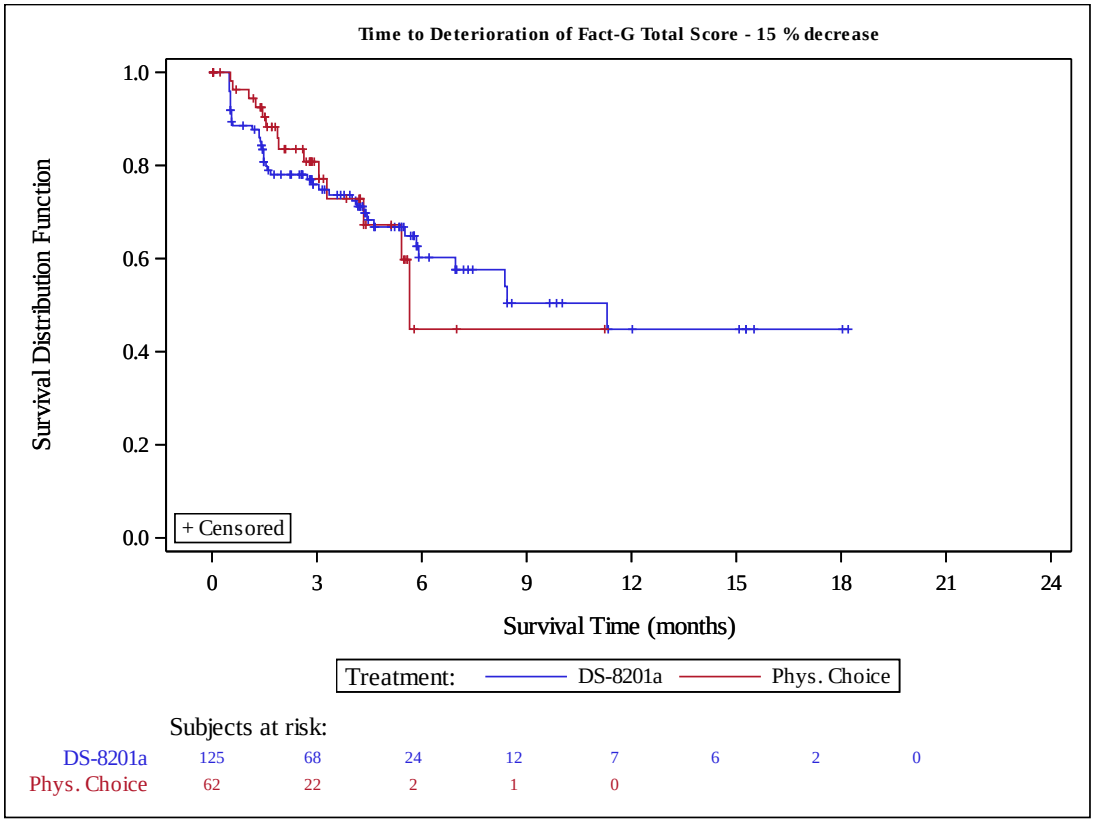
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.4170
yes	16/ 44 (36.4)	NE (4.0, NE)	5/ 17 (29.4)	5.7 (1.2, NE)	0.85 (0.31, 2.33)	0.7430	
no	26/ 81 (32.1)	8.4 (5.8, NE)	9/ 45 (20.0)	NE (4.3, NE)	1.14 (0.52, 2.48)	0.7490	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9884
yes	4/ 22 (18.2)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	38/103 (36.9)	8.4 (5.8, NE)	14/ 55 (25.5)	5.7 (4.3, NE)	1.00 (0.54, 1.88)	0.9956	
Presence of liver metastasis at baseline							0.3917
yes	21/ 67 (31.3)	8.4 (5.8, NE)	9/ 34 (26.5)	5.4 (3.3, NE)	0.83 (0.37, 1.84)	0.6303	
no	21/ 58 (36.2)	11.3 (5.5, NE)	5/ 28 (17.9)	NE (NE , NE)	1.46 (0.54, 3.93)	0.4533	
Renal impairment at baseline							0.2861
normal	10/ 33 (30.3)	11.3 (5.5, NE)	4/ 13 (30.8)	NE (1.5, NE)	0.60 (0.17, 2.06)	0.4086	
mild	19/ 53 (35.8)	NE (4.6, NE)	4/ 28 (14.3)	NE (4.3, NE)	2.12 (0.72, 6.25)	0.1669	
moderate	13/ 39 (33.3)	8.4 (4.3, NE)	6/ 20 (30.0)	5.4 (3.1, NE)	0.68 (0.25, 1.89)	0.4534	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.4557
normal	32/ 88 (36.4)	8.4 (5.9, NE)	12/ 47 (25.5)	5.7 (3.3, NE)	0.91 (0.46, 1.81)	0.7898	
mild	10/ 36 (27.8)	NE (4.3, NE)	2/ 15 (13.3)	NE (1.2, NE)	1.87 (0.41, 8.60)	0.4173	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7917
yes	3/ 8 (37.5)	8.4 (0.5, NE)	1/ 5 (20.0)	NE (1.1, NE)	1.42 (0.15, 13.72)	0.7629	
no	39/117 (33.3)	11.3 (5.8, NE)	13/ 57 (22.8)	5.7 (4.3, NE)	1.02 (0.53, 1.93)	0.9706	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9883
yes	1/ 3 (33.3)	NE (8.4, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	41/122 (33.6)	11.3 (5.8, NE)	14/ 58 (24.1)	5.7 (4.3, NE)	0.97 (0.52, 1.81)	0.9170	

Time to Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	31 (24.8)	13 (21.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	12.8 (8.4, NE)	NE (4.3, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.56 (0.28, 1.11)	
p-value [c]	0.0926	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.60 (0.30, 1.18)	
p-value [c]	0.1322	

Time to Definitive Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.2587
Japan	21/ 99 (21.2)	NE (11.2, NE)	8/ 50 (16.0)	NE (5.7, NE)	0.76 (0.33, 1.78)	0.5252	
Korea	10/ 26 (38.5)	8.4 (5.9, NE)	5/ 12 (41.7)	3.3 (0.5, NE)	0.26 (0.08, 0.92)	0.0254	
Lines of prior systemic therapy							0.3467
2	17/ 66 (25.8)	8.4 (7.0, NE)	7/ 38 (18.4)	NE (4.3, NE)	0.78 (0.31, 1.96)	0.5960	
3	6/ 34 (17.6)	NE (11.2, NE)	5/ 18 (27.8)	5.7 (2.6, NE)	0.32 (0.09, 1.16)	0.0703	
>=4	8/ 25 (32.0)	12.8 (7.0, NE)	1/ 6 (16.7)	NE (1.1, NE)	0.65 (0.08, 5.62)	0.6949	
Age							0.7865
<65 years	15/ 55 (27.3)	NE (7.0, NE)	5/ 27 (18.5)	NE (NE , NE)	0.72 (0.24, 2.13)	0.5455	
>=65 years	16/ 70 (22.9)	11.2 (8.4, NE)	8/ 35 (22.9)	5.7 (3.3, NE)	0.54 (0.22, 1.29)	0.1576	
Sex							0.2604
female	10/ 30 (33.3)	7.0 (4.2, NE)	2/ 15 (13.3)	5.7 (NE , NE)	0.95 (0.19, 4.73)	0.9570	
male	21/ 95 (22.1)	12.8 (11.2, NE)	11/ 47 (23.4)	NE (4.3, NE)	0.50 (0.23, 1.09)	0.0729	
ECOG PS							0.7689
0	14/ 62 (22.6)	NE (7.2, NE)	6/ 30 (20.0)	NE (5.4, NE)	0.54 (0.19, 1.49)	0.2223	
1	17/ 63 (27.0)	11.2 (5.8, NE)	7/ 32 (21.9)	NE (3.3, NE)	0.65 (0.26, 1.66)	0.3655	
HER2 Status in central laboratory							0.0980
IHC 3+	23/ 96 (24.0)	NE (8.4, NE)	12/ 47 (25.5)	NE (3.3, NE)	0.47 (0.22, 0.97)	0.0369	
IHC 2+/ISH +	8/ 29 (27.6)	8.4 (5.9, 11.2)	1/ 15 (6.7)	5.7 (NE , NE)	1.69 (0.18, 15.65)	0.6401	
Primary tumor location							0.9857
Gastric	26/108 (24.1)	11.3 (7.3, NE)	13/ 55 (23.6)	5.7 (4.3, NE)	0.50 (0.25, 1.03)	0.0532	
GEJ	5/ 17 (29.4)	NE (3.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.8660
intestinal	20/ 89 (22.5)	12.8 (7.3, NE)	7/ 38 (18.4)	5.7 (4.3, NE)	0.59 (0.24, 1.46)	0.2460	
diffuse	8/ 28 (28.6)	NE (7.0, NE)	4/ 18 (22.2)	NE (1.5, NE)	0.66 (0.19, 2.38)	0.5158	
others	3/ 8 (37.5)	11.3 (0.5, 11.3)	2/ 6 (33.3)	NE (1.4, NE)	0.82 (0.11, 5.98)	0.8429	
Number of metastatic sites							0.9856
<2	5/ 24 (20.8)	12.8 (7.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	26/101 (25.7)	11.3 (7.0, NE)	13/ 52 (25.0)	5.7 (3.3, NE)	0.52 (0.25, 1.05)	0.0614	
Previous total gastrectomy							0.4798
yes	5/ 22 (22.7)	NE (7.2, NE)	1/ 9 (11.1)	NE (3.3, NE)	1.51 (0.17, 13.51)	0.7157	
no	26/103 (25.2)	11.3 (8.4, NE)	12/ 53 (22.6)	5.7 (4.3, NE)	0.53 (0.26, 1.09)	0.0779	
Prior adjuvant/ neoadjuvant therapy							0.9888
yes	8/ 30 (26.7)	7.2 (5.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	23/ 95 (24.2)	11.3 (8.4, NE)	13/ 52 (25.0)	5.7 (4.3, NE)	0.57 (0.28, 1.16)	0.1124	
Prior ramucirumab contained treatment							0.3990
yes	24/ 94 (25.5)	11.3 (7.2, NE)	7/ 41 (17.1)	NE (5.4, NE)	0.80 (0.33, 1.92)	0.6066	
no	7/ 31 (22.6)	12.8 (7.0, NE)	6/ 21 (28.6)	4.3 (3.1, NE)	0.35 (0.11, 1.15)	0.0715	
Prior nivolumab contained treatment							0.0539
yes	7/ 33 (21.2)	NE (11.2, NE)	5/ 15 (33.3)	5.7 (1.2, NE)	0.23 (0.06, 0.84)	0.0166	
no	24/ 92 (26.1)	8.4 (7.0, NE)	8/ 47 (17.0)	NE (4.3, NE)	0.87 (0.38, 2.00)	0.7453	

Time to Definitive Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

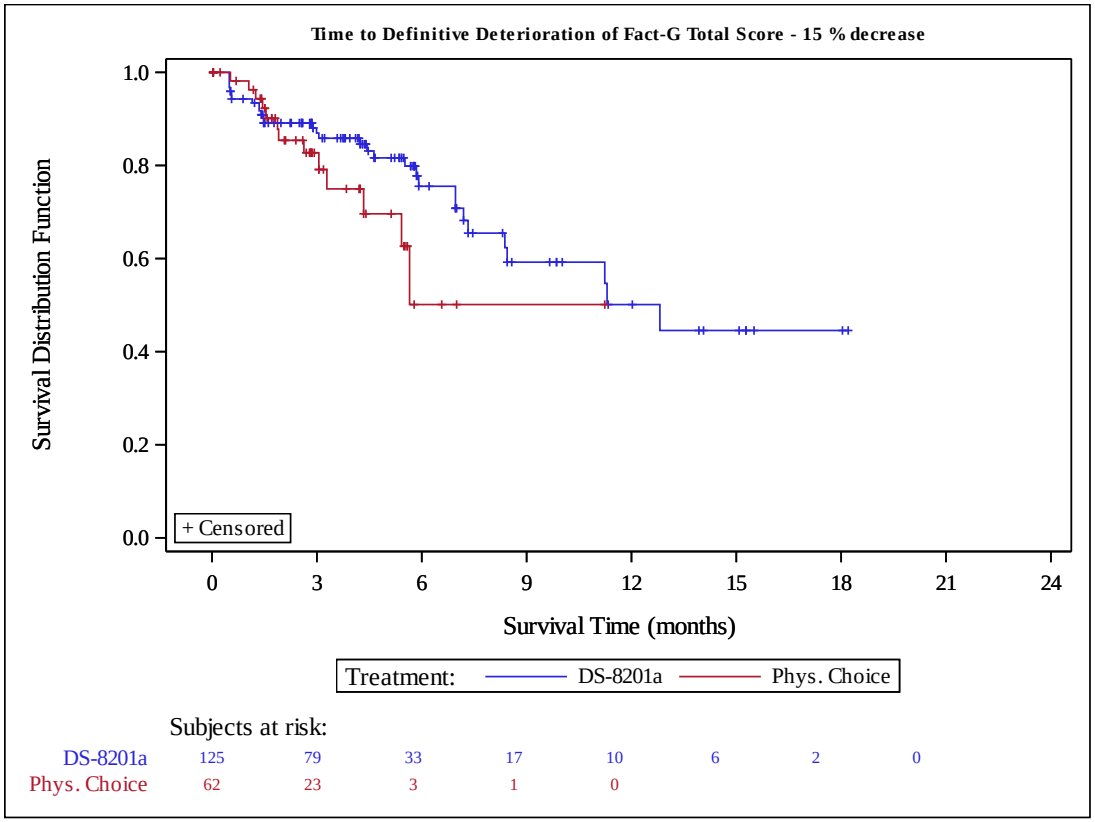
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0873
yes	10/ 44 (22.7)	NE (11.2, NE)	5/ 17 (29.4)	5.7 (1.2, NE)	0.36 (0.11, 1.12)	0.0633	
no	21/ 81 (25.9)	8.4 (7.0, NE)	8/ 45 (17.8)	NE (4.3, NE)	0.80 (0.34, 1.88)	0.6141	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9867
yes	2/ 22 (9.1)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	29/103 (28.2)	11.3 (7.3, NE)	13/ 55 (23.6)	5.7 (4.3, NE)	0.58 (0.29, 1.17)	0.1222	
Presence of liver metastasis at baseline							0.1298
yes	14/ 67 (20.9)	NE (7.0, NE)	9/ 34 (26.5)	5.4 (3.3, NE)	0.44 (0.18, 1.05)	0.0556	
no	17/ 58 (29.3)	11.2 (7.2, NE)	4/ 28 (14.3)	NE (NE , NE)	1.01 (0.32, 3.15)	0.9920	
Renal impairment at baseline							0.2381
normal	8/ 33 (24.2)	11.3 (7.0, NE)	4/ 13 (30.8)	NE (1.5, NE)	0.15 (0.03, 0.70)	0.0061	
mild	14/ 53 (26.4)	12.8 (11.2, NE)	4/ 28 (14.3)	NE (4.3, NE)	1.27 (0.41, 3.93)	0.6831	
moderate	9/ 39 (23.1)	8.4 (7.3, NE)	5/ 20 (25.0)	5.7 (3.1, NE)	0.42 (0.12, 1.41)	0.1417	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.5343
normal	23/ 88 (26.1)	12.8 (8.4, NE)	11/ 47 (23.4)	5.7 (4.3, NE)	0.55 (0.26, 1.17)	0.1133	
mild	8/ 36 (22.2)	NE (7.0, NE)	2/ 15 (13.3)	NE (1.2, NE)	0.87 (0.17, 4.48)	0.8645	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.5231
yes	3/ 8 (37.5)	8.4 (3.1, NE)	1/ 5 (20.0)	NE (1.1, NE)	1.12 (0.11, 10.88)	0.9248	
no	28/117 (23.9)	12.8 (8.4, NE)	12/ 57 (21.1)	5.7 (4.3, NE)	0.56 (0.27, 1.15)	0.1087	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9893
yes	1/ 3 (33.3)	NE (8.4, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	30/122 (24.6)	12.8 (7.3, NE)	13/ 58 (22.4)	5.7 (4.3, NE)	0.52 (0.26, 1.05)	0.0633	

Time to Definitive Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	118	6 (5.1)	98 (83.1)	14 (11.9)	52	2 (3.8)	48 (92.3)	2 (3.8)
	Day 43	117	6 (5.1)	94 (80.3)	17 (14.5)	53	3 (5.7)	46 (86.8)	4 (7.5)
	Day 85	99	3 (3.0)	83 (83.8)	13 (13.1)	36	3 (8.3)	29 (80.6)	4 (11.1)
	Day 127	74	4 (5.4)	60 (81.1)	10 (13.5)	19	1 (5.3)	15 (78.9)	3 (15.8)
	Day 169	52	3 (5.8)	46 (88.5)	3 (5.8)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 211	34	4 (11.8)	25 (73.5)	5 (14.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	24	1 (4.2)	19 (79.2)	4 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	19	3 (15.8)	14 (73.7)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	1 (6.7)	11 (73.3)	3 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	1 (1.2)	60 (72.3)	22 (26.5)	53	1 (1.9)	39 (73.6)	13 (24.5)
Region									
Japan									
	Day 15	96	4 (4.2)	81 (84.4)	11 (11.5)	45	2 (4.4)	42 (93.3)	1 (2.2)
	Day 43	93	6 (6.5)	74 (79.6)	13 (14.0)	43	2 (4.7)	40 (93.0)	1 (2.3)
	Day 85	77	2 (2.6)	66 (85.7)	9 (11.7)	32	3 (9.4)	26 (81.3)	3 (9.4)
	Day 127	60	2 (3.3)	52 (86.7)	6 (10.0)	16	1 (6.3)	13 (81.3)	2 (12.5)
	Day 169	45	3 (6.7)	39 (86.7)	3 (6.7)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	28	2 (7.1)	21 (75.0)	5 (17.9)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	0 (0.0)	16 (88.9)	2 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	1 (7.1)	12 (85.7)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	0 (0.0)	10 (90.9)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	65	0 (0.0)	52 (80.0)	13 (20.0)	45	1 (2.2)	36 (80.0)	8 (17.8)
Region									
Korea									
	Day 15	22	2 (9.1)	17 (77.3)	3 (13.6)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 43	24	0 (0.0)	20 (83.3)	4 (16.7)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 85	22	1 (4.5)	17 (77.3)	4 (18.2)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 127	14	2 (14.3)	8 (57.1)	4 (28.6)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	7	0 (0.0)	7 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	8 (44.4)	9 (50.0)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy									
2									
	Day 15	60	3 (5.0)	52 (86.7)	5 (8.3)	34	0 (0.0)	33 (97.1)	1 (2.9)
	Day 43	62	4 (6.5)	50 (80.6)	8 (12.9)	36	1 (2.8)	33 (91.7)	2 (5.6)
	Day 85	50	2 (4.0)	42 (84.0)	6 (12.0)	21	0 (0.0)	19 (90.5)	2 (9.5)
	Day 127	33	1 (3.0)	28 (84.8)	4 (12.1)	14	0 (0.0)	12 (85.7)	2 (14.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 169	21	1 (4.8)	19 (90.5)	1 (4.8)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	14	2 (14.3)	11 (78.6)	1 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	6 (60.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	2 (28.6)	4 (57.1)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	1 (2.2)	32 (71.1)	12 (26.7)	32	0 (0.0)	25 (78.1)	7 (21.9)
Lines of prior systemic therapy									
3									
	Day 15	34	2 (5.9)	26 (76.5)	6 (17.6)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 43	33	1 (3.0)	29 (87.9)	3 (9.1)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 85	28	1 (3.6)	24 (85.7)	3 (10.7)	12	2 (16.7)	8 (66.7)	2 (16.7)
	Day 127	23	2 (8.7)	18 (78.3)	3 (13.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	17	1 (5.9)	14 (82.4)	2 (11.8)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	9	0 (0.0)	9 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	0 (0.0)	16 (76.2)	5 (23.8)	16	1 (6.3)	10 (62.5)	5 (31.3)
Lines of prior systemic therapy									
>=4									
	Day 15	24	1 (4.2)	20 (83.3)	3 (12.5)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 43	22	1 (4.5)	15 (68.2)	6 (27.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	0 (0.0)	17 (81.0)	4 (19.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	18	1 (5.6)	14 (77.8)	3 (16.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	14	1 (7.1)	13 (92.9)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	0 (0.0)	12 (70.6)	5 (29.4)	5	0 (0.0)	4 (80.0)	1 (20.0)
Age									
<65 years									
	Day 15	51	3 (5.9)	42 (82.4)	6 (11.8)	22	0 (0.0)	21 (95.5)	1 (4.5)
	Day 43	52	3 (5.8)	41 (78.8)	8 (15.4)	24	1 (4.2)	21 (87.5)	2 (8.3)
	Day 85	47	1 (2.1)	40 (85.1)	6 (12.8)	16	0 (0.0)	14 (87.5)	2 (12.5)
	Day 127	34	2 (5.9)	28 (82.4)	4 (11.8)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 169	25	1 (4.0)	21 (84.0)	3 (12.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	16	2 (12.5)	10 (62.5)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	11	2 (18.2)	8 (72.7)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	1 (2.6)	27 (71.1)	10 (26.3)	22	0 (0.0)	17 (77.3)	5 (22.7)
Age									
>=65 years									
	Day 15	67	3 (4.5)	56 (83.6)	8 (11.9)	30	2 (6.7)	27 (90.0)	1 (3.3)
	Day 43	65	3 (4.6)	53 (81.5)	9 (13.8)	29	2 (6.9)	25 (86.2)	2 (6.9)
	Day 85	52	2 (3.8)	43 (82.7)	7 (13.5)	20	3 (15.0)	15 (75.0)	2 (10.0)
	Day 127	40	2 (5.0)	32 (80.0)	6 (15.0)	11	1 (9.1)	9 (81.8)	1 (9.1)
	Day 169	27	2 (7.4)	25 (92.6)	0 (0.0)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	18	2 (11.1)	15 (83.3)	1 (5.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	0 (0.0)	9 (75.0)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	7	0 (0.0)	5 (71.4)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	0 (0.0)	33 (73.3)	12 (26.7)	31	1 (3.2)	22 (71.0)	8 (25.8)
Sex									
female									
	Day 15	28	1 (3.6)	23 (82.1)	4 (14.3)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 43	28	2 (7.1)	22 (78.6)	4 (14.3)	13	0 (0.0)	12 (92.3)	1 (7.7)
	Day 85	20	0 (0.0)	17 (85.0)	3 (15.0)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	13	2 (15.4)	8 (61.5)	3 (23.1)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	9	0 (0.0)	8 (88.9)	1 (11.1)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	6	0 (0.0)	4 (66.7)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	0 (0.0)	14 (66.7)	7 (33.3)	14	1 (7.1)	11 (78.6)	2 (14.3)
Sex									
male									
	Day 15	90	5 (5.6)	75 (83.3)	10 (11.1)	39	1 (2.6)	37 (94.9)	1 (2.6)
	Day 43	89	4 (4.5)	72 (80.9)	13 (14.6)	40	3 (7.5)	34 (85.0)	3 (7.5)
	Day 85	79	3 (3.8)	66 (83.5)	10 (12.7)	28	2 (7.1)	22 (78.6)	4 (14.3)
	Day 127	61	2 (3.3)	52 (85.2)	7 (11.5)	16	0 (0.0)	13 (81.3)	3 (18.8)
	Day 169	43	3 (7.0)	38 (88.4)	2 (4.7)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	28	4 (14.3)	21 (75.0)	3 (10.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	1 (5.0)	17 (85.0)	2 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	3 (17.6)	13 (76.5)	1 (5.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	10 (71.4)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	1 (1.6)	46 (74.2)	15 (24.2)	39	0 (0.0)	28 (71.8)	11 (28.2)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS									
0									
	Day 15	60	2 (3.3)	53 (88.3)	5 (8.3)	26	0 (0.0)	25 (96.2)	1 (3.8)
	Day 43	59	3 (5.1)	49 (83.1)	7 (11.9)	26	2 (7.7)	24 (92.3)	0 (0.0)
	Day 85	54	0 (0.0)	47 (87.0)	7 (13.0)	19	1 (5.3)	17 (89.5)	1 (5.3)
	Day 127	42	1 (2.4)	40 (95.2)	1 (2.4)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	33	2 (6.1)	31 (93.9)	0 (0.0)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	20	1 (5.0)	16 (80.0)	3 (15.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	0 (0.0)	12 (80.0)	3 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	0 (0.0)	10 (90.9)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	9	0 (0.0)	9 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	0 (0.0)	31 (79.5)	8 (20.5)	27	0 (0.0)	21 (77.8)	6 (22.2)
ECOG PS									
1									
	Day 15	58	4 (6.9)	45 (77.6)	9 (15.5)	26	2 (7.7)	23 (88.5)	1 (3.8)
	Day 43	58	3 (5.2)	45 (77.6)	10 (17.2)	27	1 (3.7)	22 (81.5)	4 (14.8)
	Day 85	45	3 (6.7)	36 (80.0)	6 (13.3)	17	2 (11.8)	12 (70.6)	3 (17.6)
	Day 127	32	3 (9.4)	20 (62.5)	9 (28.1)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 169	19	1 (5.3)	15 (78.9)	3 (15.8)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	14	3 (21.4)	9 (64.3)	2 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	3 (37.5)	4 (50.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	6	1 (16.7)	2 (33.3)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	1 (2.3)	29 (65.9)	14 (31.8)	26	1 (3.8)	18 (69.2)	7 (26.9)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	91	6 (6.6)	73 (80.2)	12 (13.2)	38	1 (2.6)	35 (92.1)	2 (5.3)
	Day 43	91	6 (6.6)	73 (80.2)	12 (13.2)	40	2 (5.0)	34 (85.0)	4 (10.0)
	Day 85	79	3 (3.8)	66 (83.5)	10 (12.7)	26	2 (7.7)	20 (76.9)	4 (15.4)
	Day 127	59	3 (5.1)	48 (81.4)	8 (13.6)	13	0 (0.0)	10 (76.9)	3 (23.1)
	Day 169	41	3 (7.3)	35 (85.4)	3 (7.3)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	29	4 (13.8)	21 (72.4)	4 (13.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	1 (4.8)	17 (81.0)	3 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	3 (17.6)	12 (70.6)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	11 (78.6)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	1 (1.6)	46 (74.2)	15 (24.2)	39	0 (0.0)	27 (69.2)	12 (30.8)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	0 (0.0)	25 (92.6)	2 (7.4)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 43	26	0 (0.0)	21 (80.8)	5 (19.2)	13	1 (7.7)	12 (92.3)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	20	0 (0.0)	17 (85.0)	3 (15.0)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 127	15	1 (6.7)	12 (80.0)	2 (13.3)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 169	11	0 (0.0)	11 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	0 (0.0)	14 (66.7)	7 (33.3)	14	1 (7.1)	12 (85.7)	1 (7.1)
Primary tumor location									
Gastric									
	Day 15	102	6 (5.9)	83 (81.4)	13 (12.7)	46	2 (4.3)	42 (91.3)	2 (4.3)
	Day 43	100	5 (5.0)	82 (82.0)	13 (13.0)	48	3 (6.3)	41 (85.4)	4 (8.3)
	Day 85	84	2 (2.4)	72 (85.7)	10 (11.9)	33	3 (9.1)	26 (78.8)	4 (12.1)
	Day 127	63	4 (6.3)	49 (77.8)	10 (15.9)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	42	2 (4.8)	38 (90.5)	2 (4.8)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 211	29	3 (10.3)	21 (72.4)	5 (17.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	1 (5.0)	15 (75.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	2 (13.3)	11 (73.3)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	1 (8.3)	8 (66.7)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	1 (1.4)	51 (71.8)	19 (26.8)	47	1 (2.1)	33 (70.2)	13 (27.7)
Primary tumor location									
GEJ									
	Day 15	16	0 (0.0)	15 (93.8)	1 (6.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	17	1 (5.9)	12 (70.6)	4 (23.5)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 85	15	1 (6.7)	11 (73.3)	3 (20.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	0 (0.0)	11 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	9 (75.0)	3 (25.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	86	4 (4.7)	75 (87.2)	7 (8.1)	35	2 (5.7)	33 (94.3)	0 (0.0)
	Day 43	85	6 (7.1)	70 (82.4)	9 (10.6)	34	0 (0.0)	33 (97.1)	1 (2.9)
	Day 85	73	2 (2.7)	63 (86.3)	8 (11.0)	27	2 (7.4)	23 (85.2)	2 (7.4)
	Day 127	55	2 (3.6)	48 (87.3)	5 (9.1)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 169	40	3 (7.5)	34 (85.0)	3 (7.5)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	25	2 (8.0)	19 (76.0)	4 (16.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	16	0 (0.0)	13 (81.3)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	1 (7.7)	11 (84.6)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	0 (0.0)	9 (90.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	0 (0.0)	49 (77.8)	14 (22.2)	34	1 (2.9)	26 (76.5)	7 (20.6)
Histological subtype diffuse									
	Day 15	26	2 (7.7)	18 (69.2)	6 (23.1)	15	0 (0.0)	13 (86.7)	2 (13.3)
	Day 43	26	0 (0.0)	20 (76.9)	6 (23.1)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 85	22	1 (4.5)	16 (72.7)	5 (22.7)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 127	15	2 (13.3)	9 (60.0)	4 (26.7)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	10	0 (0.0)	10 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	2 (25.0)	5 (62.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	16	1 (6.3)	9 (56.3)	6 (37.5)	16	0 (0.0)	12 (75.0)	4 (25.0)
Histological subtype others									
	Day 15	6	0 (0.0)	5 (83.3)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	0 (0.0)	4 (66.7)	2 (33.3)	5	2 (40.0)	2 (40.0)	1 (20.0)
	Day 85	4	0 (0.0)	4 (100.0)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	4	0 (0.0)	3 (75.0)	1 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	2 (50.0)	2 (50.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	23	0 (0.0)	19 (82.6)	4 (17.4)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 43	22	1 (4.5)	21 (95.5)	0 (0.0)	10	2 (20.0)	8 (80.0)	0 (0.0)
	Day 85	22	0 (0.0)	20 (90.9)	2 (9.1)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 127	18	0 (0.0)	17 (94.4)	1 (5.6)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	15	1 (6.7)	13 (86.7)	1 (6.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	9 (90.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	1 (16.7)	4 (66.7)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	4	1 (25.0)	3 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	1 (6.7)	10 (66.7)	4 (26.7)	8	0 (0.0)	8 (100.0)	0 (0.0)
Number of metastatic sites >= 2									
	Day 15	95	6 (6.3)	79 (83.2)	10 (10.5)	42	2 (4.8)	38 (90.5)	2 (4.8)
	Day 43	95	5 (5.3)	73 (76.8)	17 (17.9)	43	1 (2.3)	38 (88.4)	4 (9.3)
	Day 85	77	3 (3.9)	63 (81.8)	11 (14.3)	28	3 (10.7)	21 (75.0)	4 (14.3)
	Day 127	56	4 (7.1)	43 (76.8)	9 (16.1)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	37	2 (5.4)	33 (89.2)	2 (5.4)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	24	3 (12.5)	16 (66.7)	5 (20.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	0 (0.0)	15 (83.3)	3 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	15	2 (13.3)	11 (73.3)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	68	0 (0.0)	50 (73.5)	18 (26.5)	45	1 (2.2)	31 (68.9)	13 (28.9)
Previous total gastrectomy									
yes									
	Day 15	20	3 (15.0)	13 (65.0)	4 (20.0)	7	1 (14.3)	6 (85.7)	0 (0.0)
	Day 43	20	1 (5.0)	15 (75.0)	4 (20.0)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 85	18	0 (0.0)	15 (83.3)	3 (16.7)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 127	11	0 (0.0)	10 (90.9)	1 (9.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	8	0 (0.0)	7 (87.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	13 (76.5)	3 (17.6)	9	0 (0.0)	8 (88.9)	1 (11.1)
Previous total gastrectomy									
no									
	Day 15	98	3 (3.1)	85 (86.7)	10 (10.2)	45	1 (2.2)	42 (93.3)	2 (4.4)
	Day 43	97	5 (5.2)	79 (81.4)	13 (13.4)	45	3 (6.7)	38 (84.4)	4 (8.9)
	Day 85	81	3 (3.7)	68 (84.0)	10 (12.3)	30	2 (6.7)	24 (80.0)	4 (13.3)
	Day 127	63	4 (6.3)	50 (79.4)	9 (14.3)	17	1 (5.9)	13 (76.5)	3 (17.6)
	Day 169	44	3 (6.8)	39 (88.6)	2 (4.5)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 211	27	3 (11.1)	21 (77.8)	3 (11.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	0 (0.0)	18 (85.7)	3 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	2 (12.5)	13 (81.3)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	0 (0.0)	10 (83.3)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	66	0 (0.0)	47 (71.2)	19 (28.8)	44	1 (2.3)	31 (70.5)	12 (27.3)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	3 (10.3)	24 (82.8)	2 (6.9)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 43	27	1 (3.7)	23 (85.2)	3 (11.1)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 85	27	0 (0.0)	25 (92.6)	2 (7.4)	7	1 (14.3)	6 (85.7)	0 (0.0)
	Day 127	22	0 (0.0)	20 (90.9)	2 (9.1)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	13	1 (7.7)	11 (84.6)	1 (7.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	8	1 (12.5)	5 (62.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	14 (66.7)	6 (28.6)	9	0 (0.0)	9 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	89	3 (3.4)	74 (83.1)	12 (13.5)	44	1 (2.3)	41 (93.2)	2 (4.5)
	Day 43	90	5 (5.6)	71 (78.9)	14 (15.6)	45	2 (4.4)	39 (86.7)	4 (8.9)
	Day 85	72	3 (4.2)	58 (80.6)	11 (15.3)	29	2 (6.9)	23 (79.3)	4 (13.8)
	Day 127	52	4 (7.7)	40 (76.9)	8 (15.4)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	39	2 (5.1)	35 (89.7)	2 (5.1)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	26	3 (11.5)	20 (76.9)	3 (11.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	0 (0.0)	16 (84.2)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	2 (14.3)	11 (78.6)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	10	0 (0.0)	8 (80.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	0 (0.0)	46 (74.2)	16 (25.8)	44	1 (2.3)	30 (68.2)	13 (29.5)
Prior ramucirumab contained treatment									
yes									
	Day 15	90	3 (3.3)	76 (84.4)	11 (12.2)	34	2 (5.9)	31 (91.2)	1 (2.9)
	Day 43	89	3 (3.4)	71 (79.8)	15 (16.9)	33	3 (9.1)	28 (84.8)	2 (6.1)
	Day 85	73	0 (0.0)	63 (86.3)	10 (13.7)	23	3 (13.0)	19 (82.6)	1 (4.3)
	Day 127	59	2 (3.4)	48 (81.4)	9 (15.3)	11	1 (9.1)	9 (81.8)	1 (9.1)
	Day 169	41	2 (4.9)	36 (87.8)	3 (7.3)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	25	1 (4.0)	20 (80.0)	4 (16.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	15	0 (0.0)	14 (93.3)	1 (6.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	0 (0.0)	12 (92.3)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	0 (0.0)	46 (73.0)	17 (27.0)	35	1 (2.9)	27 (77.1)	7 (20.0)
Prior ramucirumab contained treatment									
no									
	Day 15	28	3 (10.7)	22 (78.6)	3 (10.7)	18	0 (0.0)	17 (94.4)	1 (5.6)
	Day 43	28	3 (10.7)	23 (82.1)	2 (7.1)	20	0 (0.0)	18 (90.0)	2 (10.0)
	Day 85	26	3 (11.5)	20 (76.9)	3 (11.5)	13	0 (0.0)	10 (76.9)	3 (23.1)
	Day 127	15	2 (13.3)	12 (80.0)	1 (6.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 169	11	1 (9.1)	10 (90.9)	0 (0.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	9	3 (33.3)	5 (55.6)	1 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	9	1 (11.1)	5 (55.6)	3 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	3 (50.0)	2 (33.3)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	14 (70.0)	5 (25.0)	18	0 (0.0)	12 (66.7)	6 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Prior nivolumab contained treatment									
yes									
	Day 15	32	0 (0.0)	29 (90.6)	3 (9.4)	13	2 (15.4)	11 (84.6)	0 (0.0)
	Day 43	30	1 (3.3)	23 (76.7)	6 (20.0)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 85	27	0 (0.0)	23 (85.2)	4 (14.8)	10	2 (20.0)	6 (60.0)	2 (20.0)
	Day 127	26	1 (3.8)	20 (76.9)	5 (19.2)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	20	2 (10.0)	18 (90.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	13	1 (7.7)	11 (84.6)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	0 (0.0)	10 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	8 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	0 (0.0)	15 (75.0)	5 (25.0)	13	1 (7.7)	7 (53.8)	5 (38.5)
Prior nivolumab contained treatment									
no									
	Day 15	86	6 (7.0)	69 (80.2)	11 (12.8)	39	0 (0.0)	37 (94.9)	2 (5.1)
	Day 43	87	5 (5.7)	71 (81.6)	11 (12.6)	43	3 (7.0)	37 (86.0)	3 (7.0)
	Day 85	72	3 (4.2)	60 (83.3)	9 (12.5)	26	1 (3.8)	23 (88.5)	2 (7.7)
	Day 127	48	3 (6.3)	40 (83.3)	5 (10.4)	16	0 (0.0)	13 (81.3)	3 (18.8)
	Day 169	32	1 (3.1)	28 (87.5)	3 (9.4)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	21	3 (14.3)	14 (66.7)	4 (19.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	14	1 (7.1)	9 (64.3)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	3 (27.3)	6 (54.5)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	5 (62.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	1 (1.6)	45 (71.4)	17 (27.0)	40	0 (0.0)	32 (80.0)	8 (20.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	42	2 (4.8)	35 (83.3)	5 (11.9)	15	2 (13.3)	13 (86.7)	0 (0.0)
	Day 43	40	1 (2.5)	31 (77.5)	8 (20.0)	12	0 (0.0)	11 (91.7)	1 (8.3)
	Day 85	37	1 (2.7)	29 (78.4)	7 (18.9)	11	2 (18.2)	7 (63.6)	2 (18.2)
	Day 127	31	2 (6.5)	22 (71.0)	7 (22.6)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	23	2 (8.7)	21 (91.3)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	17	3 (17.6)	13 (76.5)	1 (5.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	13	1 (7.7)	12 (92.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	2 (16.7)	9 (75.0)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	1 (3.6)	19 (67.9)	8 (28.6)	15	1 (6.7)	9 (60.0)	5 (33.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	76	4 (5.3)	63 (82.9)	9 (11.8)	37	0 (0.0)	35 (94.6)	2 (5.4)
	Day 43	77	5 (6.5)	63 (81.8)	9 (11.7)	41	3 (7.3)	35 (85.4)	3 (7.3)
	Day 85	62	2 (3.2)	54 (87.1)	6 (9.7)	25	1 (4.0)	22 (88.0)	2 (8.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 127	43	2 (4.7)	38 (88.4)	3 (7.0)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 169	29	1 (3.4)	25 (86.2)	3 (10.3)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	17	1 (5.9)	12 (70.6)	4 (23.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	11	0 (0.0)	7 (63.6)	4 (36.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	1 (14.3)	5 (71.4)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	5	0 (0.0)	4 (80.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	55	0 (0.0)	41 (74.5)	14 (25.5)	38	0 (0.0)	30 (78.9)	8 (21.1)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
yes									
	Day 15	22	1 (4.5)	19 (86.4)	2 (9.1)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	19	0 (0.0)	18 (94.7)	1 (5.3)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 85	16	1 (6.3)	15 (93.8)	0 (0.0)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 127	12	1 (8.3)	11 (91.7)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	7	0 (0.0)	7 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	3	1 (33.3)	2 (66.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	11 (91.7)	1 (8.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									
no									
	Day 15	96	5 (5.2)	79 (82.3)	12 (12.5)	46	1 (2.2)	43 (93.5)	2 (4.3)
	Day 43	98	6 (6.1)	76 (77.6)	16 (16.3)	47	2 (4.3)	41 (87.2)	4 (8.5)
	Day 85	83	2 (2.4)	68 (81.9)	13 (15.7)	31	2 (6.5)	25 (80.6)	4 (12.9)
	Day 127	62	3 (4.8)	49 (79.0)	10 (16.1)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	45	3 (6.7)	39 (86.7)	3 (6.7)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	31	3 (9.7)	23 (74.2)	5 (16.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	1 (4.5)	17 (77.3)	4 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	2 (11.8)	13 (76.5)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	10 (71.4)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	1 (1.4)	49 (69.0)	21 (29.6)	47	1 (2.1)	33 (70.2)	13 (27.7)
Presence of liver metastasis at baseline									
yes									
	Day 15	64	5 (7.8)	50 (78.1)	9 (14.1)	27	1 (3.7)	26 (96.3)	0 (0.0)
	Day 43	63	3 (4.8)	51 (81.0)	9 (14.3)	28	1 (3.6)	24 (85.7)	3 (10.7)
	Day 85	50	1 (2.0)	41 (82.0)	8 (16.0)	16	2 (12.5)	12 (75.0)	2 (12.5)
	Day 127	36	3 (8.3)	29 (80.6)	4 (11.1)	10	1 (10.0)	7 (70.0)	2 (20.0)
	Day 169	25	1 (4.0)	22 (88.0)	2 (8.0)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	14	2 (14.3)	9 (64.3)	3 (21.4)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 253	12	0 (0.0)	10 (83.3)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	0 (0.0)	35 (77.8)	10 (22.2)	30	0 (0.0)	21 (70.0)	9 (30.0)
Presence of liver metastasis at baseline									
no									
	Day 15	54	1 (1.9)	48 (88.9)	5 (9.3)	25	1 (4.0)	22 (88.0)	2 (8.0)
	Day 43	54	3 (5.6)	43 (79.6)	8 (14.8)	25	2 (8.0)	22 (88.0)	1 (4.0)
	Day 85	49	2 (4.1)	42 (85.7)	5 (10.2)	20	1 (5.0)	17 (85.0)	2 (10.0)
	Day 127	38	1 (2.6)	31 (81.6)	6 (15.8)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 169	27	2 (7.4)	24 (88.9)	1 (3.7)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	20	2 (10.0)	16 (80.0)	2 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	9 (75.0)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	10	2 (20.0)	7 (70.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	38	1 (2.6)	25 (65.8)	12 (31.6)	23	1 (4.3)	18 (78.3)	4 (17.4)
Renal impairment at baseline									
normal									
	Day 15	31	1 (3.2)	27 (87.1)	3 (9.7)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 43	33	2 (6.1)	28 (84.8)	3 (9.1)	12	1 (8.3)	9 (75.0)	2 (16.7)
	Day 85	26	0 (0.0)	24 (92.3)	2 (7.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	1 (5.3)	17 (89.5)	1 (5.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	15	0 (0.0)	14 (93.3)	1 (6.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	16 (80.0)	3 (15.0)	11	0 (0.0)	7 (63.6)	4 (36.4)
Renal impairment at baseline									
mild									
	Day 15	50	2 (4.0)	41 (82.0)	7 (14.0)	25	1 (4.0)	24 (96.0)	0 (0.0)
	Day 43	50	2 (4.0)	39 (78.0)	9 (18.0)	23	1 (4.3)	21 (91.3)	1 (4.3)
	Day 85	45	2 (4.4)	35 (77.8)	8 (17.8)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 127	31	2 (6.5)	27 (87.1)	2 (6.5)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 169	21	2 (9.5)	17 (81.0)	2 (9.5)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	13	2 (15.4)	9 (69.2)	2 (15.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	8	0 (0.0)	8 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	5 (83.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	39	0 (0.0)	27 (69.2)	12 (30.8)	22	0 (0.0)	18 (81.8)	4 (18.2)
Renal impairment at baseline									
moderate									
	Day 15	37	3 (8.1)	30 (81.1)	4 (10.8)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 43	34	2 (5.9)	27 (79.4)	5 (14.7)	17	1 (5.9)	15 (88.2)	1 (5.9)
	Day 85	28	1 (3.6)	24 (85.7)	3 (10.7)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 127	24	1 (4.2)	16 (66.7)	7 (29.2)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 169	16	1 (6.3)	15 (93.8)	0 (0.0)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 211	11	1 (9.1)	10 (90.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	0 (0.0)	17 (70.8)	7 (29.2)	19	1 (5.3)	13 (68.4)	5 (26.3)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	82	2 (2.4)	71 (86.6)	9 (11.0)	37	1 (2.7)	34 (91.9)	2 (5.4)
	Day 43	83	4 (4.8)	66 (79.5)	13 (15.7)	41	1 (2.4)	37 (90.2)	3 (7.3)
	Day 85	76	3 (3.9)	63 (82.9)	10 (13.2)	27	2 (7.4)	22 (81.5)	3 (11.1)
	Day 127	58	4 (6.9)	47 (81.0)	7 (12.1)	14	1 (7.1)	10 (71.4)	3 (21.4)
	Day 169	40	2 (5.0)	36 (90.0)	2 (5.0)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	24	3 (12.5)	19 (79.2)	2 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	19	1 (5.3)	15 (78.9)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	3 (20.0)	11 (73.3)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	8 (72.7)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	56	1 (1.8)	38 (67.9)	17 (30.4)	40	1 (2.5)	28 (70.0)	11 (27.5)
Hepatic impairment at baseline									
mild									
	Day 15	35	4 (11.4)	26 (74.3)	5 (14.3)	15	1 (6.7)	14 (93.3)	0 (0.0)
	Day 43	33	2 (6.1)	27 (81.8)	4 (12.1)	12	2 (16.7)	9 (75.0)	1 (8.3)
	Day 85	22	0 (0.0)	19 (86.4)	3 (13.6)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 127	15	0 (0.0)	12 (80.0)	3 (20.0)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	6 (60.0)	3 (30.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	0 (0.0)	21 (80.8)	5 (19.2)	13	0 (0.0)	11 (84.6)	2 (15.4)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	0 (0.0)	7 (87.5)	1 (12.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 43	8	0 (0.0)	8 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	0 (0.0)	6 (85.7)	1 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	0 (0.0)	6 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	0 (0.0)	5 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	5	0 (0.0)	3 (60.0)	2 (40.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	110	6 (5.5)	91 (82.7)	13 (11.8)	48	2 (4.2)	44 (91.7)	2 (4.2)
	Day 43	109	6 (5.5)	86 (78.9)	17 (15.6)	50	3 (6.0)	43 (86.0)	4 (8.0)
	Day 85	92	3 (3.3)	77 (83.7)	12 (13.0)	33	3 (9.1)	26 (78.8)	4 (12.1)
	Day 127	68	4 (5.9)	54 (79.4)	10 (14.7)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	47	3 (6.4)	41 (87.2)	3 (6.4)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	30	4 (13.3)	22 (73.3)	4 (13.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	20	1 (5.0)	17 (85.0)	2 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	17	3 (17.6)	12 (70.6)	2 (11.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	14	1 (7.1)	10 (71.4)	3 (21.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	1 (1.3)	57 (73.1)	20 (25.6)	50	1 (2.0)	37 (74.0)	12 (24.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	0 (0.0)	3 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	0 (0.0)	1 (100.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors no									
	Day 15	115	6 (5.2)	95 (82.6)	14 (12.2)	49	2 (4.1)	45 (91.8)	2 (4.1)
	Day 43	114	6 (5.3)	91 (79.8)	17 (14.9)	50	3 (6.0)	43 (86.0)	4 (8.0)
	Day 85	96	3 (3.1)	80 (83.3)	13 (13.5)	33	3 (9.1)	26 (78.8)	4 (12.1)
	Day 127	71	4 (5.6)	57 (80.3)	10 (14.1)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	49	3 (6.1)	43 (87.8)	3 (6.1)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	32	4 (12.5)	23 (71.9)	5 (15.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	22	1 (4.5)	18 (81.8)	3 (13.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	18	3 (16.7)	13 (72.2)	2 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	15	1 (6.7)	11 (73.3)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	1 (1.2)	60 (73.2)	21 (25.6)	51	1 (2.0)	37 (72.5)	13 (25.5)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Summary of Questionnaires with patients having Baseline and at least one Post-Baseline Visit

	DS-8201a (N=125)		Phys. Choice (N=62)	
	n	(%)	n	(%)
EQ-5D VAS score	124	(99.2)	55	(88.7)
Fact-Ga Total Score	123	(98.4)	54	(87.1)
Physical Well-being	124	(99.2)	55	(88.7)
Social/Family Well-being	124	(99.2)	55	(88.7)
Emotional Well-being	123	(98.4)	54	(87.1)
Functional Well-being	123	(98.4)	54	(87.1)
Gastric Cancer Symptom (GaCS)	124	(99.2)	55	(88.7)
Fact-G Total Score	123	(98.4)	54	(87.1)

Daiichi Sankyo Date of Table Generation: 07JUN2022

Anhang 4-G 1.1.5: Sicherheit

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Subjects with events	125 (100.0)	61 (98.4)
Gastrointestinal disorders	104 (83.2)	47 (75.8)
Nausea	79 (63.2)	29 (46.8)
Diarrhoea	40 (32.0)	20 (32.3)
Constipation	30 (24.0)	14 (22.6)
Vomiting	33 (26.4)	5 (8.1)
Abdominal pain	12 (9.6)	8 (12.9)
Stomatitis	14 (11.2)	3 (4.8)
Ascites	7 (5.6)	2 (3.2)
Dyspepsia	4 (3.2)	3 (4.8)
Abdominal distension	4 (3.2)	2 (3.2)
Abdominal pain upper	5 (4.0)	1 (1.6)
Oesophageal stenosis	2 (1.6)	2 (3.2)
Upper gastrointestinal haemorrhage	4 (3.2)	0
Gastric stenosis	3 (2.4)	0
Haemorrhoids	3 (2.4)	0
Gastric haemorrhage	2 (1.6)	0
Gastrointestinal obstruction	1 (0.8)	1 (1.6)
Gastrooesophageal reflux disease	1 (0.8)	1 (1.6)
Inguinal hernia	2 (1.6)	0
Abdominal discomfort	0	1 (1.6)
Anal haemorrhage	1 (0.8)	0
Anal incontinence	1 (0.8)	0
Anal stenosis	1 (0.8)	0
Colitis	1 (0.8)	0
Glossitis	1 (0.8)	0
Haemorrhoidal haemorrhage	1 (0.8)	0
Large intestine perforation	1 (0.8)	0
Lip dry	1 (0.8)	0
Melaena	1 (0.8)	0
Pancreatitis	1 (0.8)	0
Periodontal disease	1 (0.8)	0
Proctalgia	1 (0.8)	0
Salivary hypersecretion	1 (0.8)	0
Tooth loss	1 (0.8)	0
Investigations	99 (79.2)	33 (53.2)
Neutrophil count decreased	77 (61.6)	21 (33.9)
White blood cell count decreased	47 (37.6)	21 (33.9)
Platelet count decreased	47 (37.6)	4 (6.5)
Lymphocyte count decreased	27 (21.6)	2 (3.2)
Weight decreased	17 (13.6)	5 (8.1)
Aspartate aminotransferase increased	12 (9.6)	3 (4.8)
Alanine aminotransferase increased	9 (7.2)	3 (4.8)
Blood alkaline phosphatase increased	10 (8.0)	2 (3.2)
Blood bilirubin increased	10 (8.0)	0
Blood creatinine increased	1 (0.8)	6 (9.7)
Gamma-glutamyltransferase increased	4 (3.2)	0
C-reactive protein increased	2 (1.6)	0
Electrocardiogram QT prolonged	1 (0.8)	1 (1.6)
Troponin T increased	2 (1.6)	0
Amylase increased	1 (0.8)	0
Blood pressure decreased	1 (0.8)	0
Central venous pressure increased	1 (0.8)	0
Haemoglobin decreased	1 (0.8)	0
Liver function test abnormal	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Troponin I increased	1 (0.8)	0
Vascular resistance systemic increased	1 (0.8)	0
Weight increased	0	1 (1.6)
General disorders and administration site conditions	86 (68.8)	34 (54.8)
Malaise	43 (34.4)	10 (16.1)
Fatigue	27 (21.6)	15 (24.2)
Pyrexia	30 (24.0)	10 (16.1)
Oedema peripheral	13 (10.4)	0
Oedema	6 (4.8)	1 (1.6)
Disease progression	3 (2.4)	2 (3.2)
Asthenia	1 (0.8)	3 (4.8)
Mucosal inflammation	1 (0.8)	1 (1.6)
Pain	2 (1.6)	0
Catheter site pain	1 (0.8)	0
Chest pain	1 (0.8)	0
Condition aggravated	1 (0.8)	0
Face oedema	0	1 (1.6)
General physical health deterioration	1 (0.8)	0
Influenza like illness	0	1 (1.6)
Infusion site erythema	1 (0.8)	0
Swelling	1 (0.8)	0
Metabolism and nutrition disorders	86 (68.8)	34 (54.8)
Decreased appetite	75 (60.0)	28 (45.2)
Hypoalbuminaemia	18 (14.4)	8 (12.9)
Hypokalaemia	8 (6.4)	4 (6.5)
Dehydration	8 (6.4)	2 (3.2)
Hyponatraemia	3 (2.4)	3 (4.8)
Hyperkalaemia	1 (0.8)	4 (6.5)
Hypocalcaemia	1 (0.8)	3 (4.8)
Hyperglycaemia	3 (2.4)	0
Hypophosphataemia	1 (0.8)	2 (3.2)
Hyperuricaemia	2 (1.6)	0
Hypoglycaemia	2 (1.6)	0
Hypomagnesaemia	0	2 (3.2)
Diabetes mellitus	1 (0.8)	0
Hypercalcaemia	1 (0.8)	0
Hypophagia	1 (0.8)	0
Hypovolaemia	1 (0.8)	0
Hypozincaemia	1 (0.8)	0
Blood and lymphatic system disorders	77 (61.6)	20 (32.3)
Anaemia	71 (56.8)	19 (30.6)
Febrile neutropenia	6 (4.8)	2 (3.2)
Neutropenia	3 (2.4)	1 (1.6)
Disseminated intravascular coagulation	2 (1.6)	0
Leukopenia	1 (0.8)	1 (1.6)
Thrombocytopenia	2 (1.6)	0
Anaemia vitamin B12 deficiency	1 (0.8)	0
Iron deficiency anaemia	1 (0.8)	0
Infections and infestations	51 (40.8)	14 (22.6)
Nasopharyngitis	10 (8.0)	5 (8.1)
Pneumonia	7 (5.6)	1 (1.6)
Upper respiratory tract infection	6 (4.8)	2 (3.2)
Lung infection	5 (4.0)	0
Influenza	3 (2.4)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Pharyngitis	3 (2.4)	0
Pneumonia bacterial	3 (2.4)	0
Tinea pedis	3 (2.4)	0
Urinary tract infection	3 (2.4)	0
Device related infection	1 (0.8)	1 (1.6)
Folliculitis	1 (0.8)	1 (1.6)
Gingivitis	2 (1.6)	0
Herpes zoster	1 (0.8)	1 (1.6)
Sepsis	2 (1.6)	0
Bacteraemia	1 (0.8)	0
Biliary sepsis	1 (0.8)	0
Biliary tract infection	1 (0.8)	0
Cholangitis infective	1 (0.8)	0
Conjunctivitis	1 (0.8)	0
Cystitis	1 (0.8)	0
Dermatophytosis of nail	1 (0.8)	0
Enterocolitis infectious	1 (0.8)	0
Infection	1 (0.8)	0
Infectious pleural effusion	0	1 (1.6)
Liver abscess	1 (0.8)	0
Nail infection	1 (0.8)	0
Oesophageal candidiasis	1 (0.8)	0
Oral candidiasis	1 (0.8)	0
Otitis media	0	1 (1.6)
Paronychia	1 (0.8)	0
Pericoronitis	0	1 (1.6)
Peritonitis bacterial	1 (0.8)	0
Pneumonia staphylococcal	0	1 (1.6)
Prostatic abscess	0	1 (1.6)
Pulmonary tuberculosis	1 (0.8)	0
Rhinitis	1 (0.8)	0
Tinea capitis	0	1 (1.6)
Skin and subcutaneous tissue disorders	45 (36.0)	17 (27.4)
Alopecia	28 (22.4)	9 (14.5)
Pruritus	8 (6.4)	2 (3.2)
Rash	6 (4.8)	1 (1.6)
Dry skin	5 (4.0)	0
Decubitus ulcer	2 (1.6)	1 (1.6)
Rash maculo-papular	1 (0.8)	2 (3.2)
Erythema	1 (0.8)	1 (1.6)
Skin ulcer	1 (0.8)	1 (1.6)
Dermal cyst	1 (0.8)	0
Dermatitis	0	1 (1.6)
Dermatitis acneiform	1 (0.8)	0
Eczema	1 (0.8)	0
Erythema multiforme	1 (0.8)	0
Haemorrhage subcutaneous	1 (0.8)	0
Ingrowing nail	0	1 (1.6)
Lichen planus	1 (0.8)	0
Nail disorder	0	1 (1.6)
Onychomadesis	1 (0.8)	0
Seborrhoeic dermatitis	0	1 (1.6)
Urticaria	1 (0.8)	0
Respiratory, thoracic and mediastinal disorders	34 (27.2)	12 (19.4)
Hiccups	6 (4.8)	6 (9.7)
Pneumonitis	8 (6.4)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Cough	6 (4.8)	1 (1.6)
Interstitial lung disease	5 (4.0)	0
Oropharyngeal pain	3 (2.4)	1 (1.6)
Epistaxis	3 (2.4)	0
Productive cough	2 (1.6)	1 (1.6)
Dyspnoea	1 (0.8)	1 (1.6)
Pneumonia aspiration	1 (0.8)	1 (1.6)
Upper respiratory tract inflammation	1 (0.8)	1 (1.6)
Dry throat	0	1 (1.6)
Dysphonia	1 (0.8)	0
Emphysema	1 (0.8)	0
Pharyngeal inflammation	1 (0.8)	0
Pleural effusion	1 (0.8)	0
Pulmonary hypertension	1 (0.8)	0
Rhinitis allergic	1 (0.8)	0
Nervous system disorders	**26 (20.8)**	**17 (27.4)**
Dysgeusia	9 (7.2)	4 (6.5)
Dizziness	5 (4.0)	3 (4.8)
Headache	4 (3.2)	4 (6.5)
Peripheral sensory neuropathy	4 (3.2)	2 (3.2)
Cholinergic syndrome	0	3 (4.8)
Cerebral infarction	0	1 (1.6)
Cognitive disorder	1 (0.8)	0
Diplegia	0	1 (1.6)
Facial spasm	0	1 (1.6)
Head discomfort	1 (0.8)	0
Hemiplegia	1 (0.8)	0
Hypoaesthesia	0	1 (1.6)
Loss of consciousness	1 (0.8)	0
Neuropathy peripheral	0	1 (1.6)
Presyncope	1 (0.8)	0
Somnolence	1 (0.8)	0
Syncope	0	1 (1.6)
Vagus nerve disorder	0	1 (1.6)
Musculoskeletal and connective tissue disorders	**23 (18.4)**	**8 (12.9)**
Back pain	9 (7.2)	3 (4.8)
Myalgia	3 (2.4)	2 (3.2)
Pain in extremity	3 (2.4)	1 (1.6)
Muscle spasms	2 (1.6)	0
Muscular weakness	1 (0.8)	1 (1.6)
Musculoskeletal pain	1 (0.8)	1 (1.6)
Neck pain	2 (1.6)	0
Arthralgia	1 (0.8)	0
Flank pain	1 (0.8)	0
Limb discomfort	1 (0.8)	0
Musculoskeletal chest pain	1 (0.8)	0
Pain in jaw	1 (0.8)	0
Hepatobiliary disorders	**21 (16.8)**	**3 (4.8)**
Hepatic function abnormal	10 (8.0)	1 (1.6)
Jaundice cholestatic	5 (4.0)	0
Liver disorder	3 (2.4)	1 (1.6)
Cholangitis	1 (0.8)	1 (1.6)
Bile duct obstruction	1 (0.8)	0
Bile duct stone	1 (0.8)	0
Cholangitis acute	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Cholelithiasis	1 (0.8)	0
Liver injury	1 (0.8)	0
Psychiatric disorders	13 (10.4)	7 (11.3)
Insomnia	11 (8.8)	5 (8.1)
Delirium	4 (3.2)	1 (1.6)
Agitation	0	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (10.4)	6 (9.7)
Cancer pain	5 (4.0)	3 (4.8)
Tumour pain	2 (1.6)	3 (4.8)
Neoplasm progression	2 (1.6)	1 (1.6)
Tumour haemorrhage	3 (2.4)	0
Tumour associated fever	2 (1.6)	0
Pericarditis malignant	1 (0.8)	0
Injury, poisoning and procedural complications	11 (8.8)	2 (3.2)
Fall	3 (2.4)	1 (1.6)
Infusion related reaction	2 (1.6)	0
Animal bite	0	1 (1.6)
Arthropod bite	1 (0.8)	0
Arthropod sting	1 (0.8)	0
Facial bones fracture	1 (0.8)	0
Foot fracture	1 (0.8)	0
Procedural pain	1 (0.8)	0
Spinal compression fracture	1 (0.8)	0
Vascular access site pain	1 (0.8)	0
Vascular disorders	6 (4.8)	7 (11.3)
Hypotension	3 (2.4)	1 (1.6)
Embolism	1 (0.8)	1 (1.6)
Hypertension	0	2 (3.2)
Deep vein thrombosis	0	1 (1.6)
Hot flush	1 (0.8)	0
Internal haemorrhage	0	1 (1.6)
Jugular vein thrombosis	0	1 (1.6)
Venous thrombosis	1 (0.8)	0
Eye disorders	11 (8.8)	1 (1.6)
Cataract	2 (1.6)	0
Dry eye	1 (0.8)	1 (1.6)
Retinal exudates	2 (1.6)	0
Retinal haemorrhage	2 (1.6)	0
Blepharitis	1 (0.8)	0
Eye haemorrhage	1 (0.8)	0
Keratitis	1 (0.8)	0
Macular fibrosis	1 (0.8)	0
Macular oedema	1 (0.8)	0
Retinal detachment	1 (0.8)	0
Retinopathy	1 (0.8)	0
Cardiac disorders	8 (6.4)	1 (1.6)
Acute coronary syndrome	1 (0.8)	0
Atrial fibrillation	1 (0.8)	0
Bundle branch block right	1 (0.8)	0
Cardiomyopathy	1 (0.8)	0
Pericardial effusion	1 (0.8)	0
Stress cardiomyopathy	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Supraventricular extrasystoles	1 (0.8)	0
Supraventricular tachycardia	0	1 (1.6)
Ventricular extrasystoles	1 (0.8)	0
Renal and urinary disorders	6 (4.8)	3 (4.8)
Hydronephrosis	1 (0.8)	1 (1.6)
Proteinuria	2 (1.6)	0
Acute kidney injury	0	1 (1.6)
Bladder spasm	1 (0.8)	0
Dysuria	1 (0.8)	0
Pollakiuria	1 (0.8)	0
Renal impairment	1 (0.8)	0
Urethral pain	0	1 (1.6)
Urinary retention	1 (0.8)	0
Ear and labyrinth disorders	4 (3.2)	0
Tinnitus	2 (1.6)	0
Deafness	1 (0.8)	0
Hypoacusis	1 (0.8)	0
Immune system disorders	2 (1.6)	1 (1.6)
Contrast media allergy	1 (0.8)	1 (1.6)
Anaphylactic reaction	1 (0.8)	0
Hypersensitivity	1 (0.8)	0
Congenital, familial and genetic disorders	1 (0.8)	0
Pyloric stenosis	1 (0.8)	0
Endocrine disorders	1 (0.8)	0
Adrenal insufficiency	1 (0.8)	0
Reproductive system and breast disorders	1 (0.8)	0
Perineal erythema	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious TEAE by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Subjects with events	55 (44.0)	15 (24.2)
Metabolism and nutrition disorders	18 (14.4)	1 (1.6)
Decreased appetite	13 (10.4)	1 (1.6)
Dehydration	4 (3.2)	0
Hypophagia	1 (0.8)	0
Gastrointestinal disorders	14 (11.2)	1 (1.6)
Diarrhoea	2 (1.6)	0
Gastric stenosis	2 (1.6)	0
Gastrointestinal obstruction	1 (0.8)	1 (1.6)
Abdominal distension	1 (0.8)	0
Abdominal pain	1 (0.8)	0
Anal stenosis	1 (0.8)	0
Gastric haemorrhage	1 (0.8)	0
Inguinal hernia	1 (0.8)	0
Large intestine perforation	1 (0.8)	0
Nausea	1 (0.8)	0
Oesophageal stenosis	1 (0.8)	0
Pancreatitis	1 (0.8)	0
Stomatitis	1 (0.8)	0
Upper gastrointestinal haemorrhage	1 (0.8)	0
Vomiting	1 (0.8)	0
Infections and infestations	12 (9.6)	1 (1.6)
Pneumonia	3 (2.4)	0
Lung infection	2 (1.6)	0
Sepsis	2 (1.6)	0
Bacteraemia	1 (0.8)	0
Biliary sepsis	1 (0.8)	0
Biliary tract infection	1 (0.8)	0
Cholangitis infective	1 (0.8)	0
Device related infection	1 (0.8)	0
Infectious pleural effusion	0	1 (1.6)
Pneumonia bacterial	1 (0.8)	0
General disorders and administration site conditions	7 (5.6)	4 (6.5)
Disease progression	3 (2.4)	2 (3.2)
Pyrexia	3 (2.4)	1 (1.6)
Fatigue	1 (0.8)	1 (1.6)
Asthenia	0	1 (1.6)
Condition aggravated	1 (0.8)	0
General physical health deterioration	1 (0.8)	0
Hepatobiliary disorders	8 (6.4)	3 (4.8)
Jaundice cholestatic	3 (2.4)	0
Cholangitis	1 (0.8)	1 (1.6)
Hepatic function abnormal	1 (0.8)	1 (1.6)
Bile duct obstruction	1 (0.8)	0
Bile duct stone	1 (0.8)	0
Cholangitis acute	1 (0.8)	0
Liver disorder	0	1 (1.6)
Liver injury	1 (0.8)	0
Blood and lymphatic system disorders	6 (4.8)	4 (6.5)
Anaemia	4 (3.2)	2 (3.2)
Febrile neutropenia	1 (0.8)	1 (1.6)

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious TEAE by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Disseminated intravascular coagulation	1 (0.8)	0
Neutropenia	0	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (4.8)	2 (3.2)
Neoplasm progression	2 (1.6)	1 (1.6)
Tumour haemorrhage	3 (2.4)	0
Cancer pain	0	1 (1.6)
Pericarditis malignant	1 (0.8)	0
Respiratory, thoracic and mediastinal disorders	6 (4.8)	1 (1.6)
Pneumonitis	3 (2.4)	0
Interstitial lung disease	2 (1.6)	0
Pneumonia aspiration	1 (0.8)	1 (1.6)
Investigations	1 (0.8)	3 (4.8)
Blood creatinine increased	0	2 (3.2)
Neutrophil count decreased	0	1 (1.6)
Platelet count decreased	1 (0.8)	0
White blood cell count decreased	0	1 (1.6)
Nervous system disorders	2 (1.6)	2 (3.2)
Cerebral infarction	0	1 (1.6)
Dizziness	0	1 (1.6)
Hemiplegia	1 (0.8)	0
Presyncope	1 (0.8)	0
Cardiac disorders	3 (2.4)	0
Acute coronary syndrome	1 (0.8)	0
Pericardial effusion	1 (0.8)	0
Stress cardiomyopathy	1 (0.8)	0
Renal and urinary disorders	1 (0.8)	2 (3.2)
Hydronephrosis	1 (0.8)	1 (1.6)
Acute kidney injury	0	1 (1.6)
Vascular disorders	2 (1.6)	0
Hypotension	2 (1.6)	0
Congenital, familial and genetic disorders	1 (0.8)	0
Pyloric stenosis	1 (0.8)	0
Musculoskeletal and connective tissue disorders	1 (0.8)	0
Neck pain	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Subjects with events	107 (85.6)	35 (56.5)
Investigations	79 (63.2)	18 (29.0)
Neutrophil count decreased	62 (49.6)	14 (22.6)
White blood cell count decreased	26 (20.8)	7 (11.3)
Platelet count decreased	14 (11.2)	2 (3.2)
Lymphocyte count decreased	14 (11.2)	1 (1.6)
Blood alkaline phosphatase increased	4 (3.2)	0
Aspartate aminotransferase increased	3 (2.4)	0
Alanine aminotransferase increased	2 (1.6)	0
Electrocardiogram QT prolonged	1 (0.8)	1 (1.6)
Weight decreased	1 (0.8)	1 (1.6)
Amylase increased	1 (0.8)	0
Blood bilirubin increased	1 (0.8)	0
Blood creatinine increased	0	1 (1.6)
Liver function test abnormal	1 (0.8)	0
Troponin T increased	1 (0.8)	0
Blood and lymphatic system disorders	52 (41.6)	14 (22.6)
Anaemia	47 (37.6)	14 (22.6)
Febrile neutropenia	6 (4.8)	2 (3.2)
Neutropenia	2 (1.6)	1 (1.6)
Disseminated intravascular coagulation	2 (1.6)	0
Leukopenia	1 (0.8)	0
Metabolism and nutrition disorders	28 (22.4)	12 (19.4)
Decreased appetite	21 (16.8)	8 (12.9)
Hypokalaemia	5 (4.0)	4 (6.5)
Hypoalbuminaemia	4 (3.2)	3 (4.8)
Hyponatraemia	3 (2.4)	3 (4.8)
Dehydration	3 (2.4)	1 (1.6)
Hyperglycaemia	2 (1.6)	0
Hyperkalaemia	0	1 (1.6)
Hyperuricaemia	1 (0.8)	0
Hypophosphataemia	0	1 (1.6)
Gastrointestinal disorders	22 (17.6)	5 (8.1)
Nausea	6 (4.8)	1 (1.6)
Ascites	3 (2.4)	1 (1.6)
Diarrhoea	3 (2.4)	1 (1.6)
Abdominal pain	1 (0.8)	2 (3.2)
Abdominal distension	1 (0.8)	1 (1.6)
Gastrointestinal obstruction	1 (0.8)	1 (1.6)
Oesophageal stenosis	1 (0.8)	1 (1.6)
Stomatitis	2 (1.6)	0
Anal stenosis	1 (0.8)	0
Colitis	1 (0.8)	0
Gastric haemorrhage	1 (0.8)	0
Gastric stenosis	1 (0.8)	0
Large intestine perforation	1 (0.8)	0
Pancreatitis	1 (0.8)	0
Upper gastrointestinal haemorrhage	1 (0.8)	0
General disorders and administration site conditions	14 (11.2)	5 (8.1)
Fatigue	9 (7.2)	2 (3.2)
Disease progression	3 (2.4)	2 (3.2)
Asthenia	1 (0.8)	1 (1.6)

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Condition aggravated	1 (0.8)	0
General physical health deterioration	1 (0.8)	0
Malaise	1 (0.8)	0
Hepatobiliary disorders	**11 (8.8)**	**3 (4.8)**
Hepatic function abnormal	4 (3.2)	1 (1.6)
Jaundice cholestatic	4 (3.2)	0
Bile duct obstruction	1 (0.8)	0
Bile duct stone	1 (0.8)	0
Cholangitis	0	1 (1.6)
Cholangitis acute	1 (0.8)	0
Liver disorder	0	1 (1.6)
Liver injury	1 (0.8)	0
Infections and infestations	**13 (10.4)**	**1 (1.6)**
Device related infection	1 (0.8)	1 (1.6)
Lung infection	2 (1.6)	0
Pneumonia	2 (1.6)	0
Sepsis	2 (1.6)	0
Bacteraemia	1 (0.8)	0
Biliary sepsis	1 (0.8)	0
Biliary tract infection	1 (0.8)	0
Cholangitis infective	1 (0.8)	0
Infectious pleural effusion	0	1 (1.6)
Influenza	1 (0.8)	0
Pneumonia bacterial	1 (0.8)	0
Urinary tract infection	1 (0.8)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	**7 (5.6)**	**2 (3.2)**
Neoplasm progression	2 (1.6)	1 (1.6)
Tumour haemorrhage	3 (2.4)	0
Cancer pain	1 (0.8)	0
Pericarditis malignant	1 (0.8)	0
Tumour pain	0	1 (1.6)
Vascular disorders	**3 (2.4)**	**3 (4.8)**
Hypotension	2 (1.6)	1 (1.6)
Hypertension	0	2 (3.2)
Embolism	1 (0.8)	0
Nervous system disorders	**2 (1.6)**	**3 (4.8)**
Cerebral infarction	0	1 (1.6)
Dizziness	0	1 (1.6)
Hemiplegia	1 (0.8)	0
Presyncope	1 (0.8)	0
Syncope	0	1 (1.6)
Cardiac disorders	**3 (2.4)**	**1 (1.6)**
Acute coronary syndrome	1 (0.8)	0
Pericardial effusion	1 (0.8)	0
Stress cardiomyopathy	1 (0.8)	0
Supraventricular tachycardia	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders	**3 (2.4)**	**1 (1.6)**
Pneumonia aspiration	1 (0.8)	1 (1.6)
Interstitial lung disease	1 (0.8)	0
Pneumonitis	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Renal and urinary disorders	1 (0.8)	1 (1.6)
Hydronephrosis	1 (0.8)	1 (1.6)
Immune system disorders	1 (0.8)	0
Anaphylactic reaction	1 (0.8)	0
Musculoskeletal and connective tissue disorders	0	1 (1.6)
Myalgia	0	1 (1.6)
Skin and subcutaneous tissue disorders	0	1 (1.6)
Skin ulcer	0	1 (1.6)

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	125 (100.0)	61 (98.4)
Number of censored subjects, n (%)	0 (0.0)	1 (1.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	0.1 (0.1, 0.1)	0.1 (0.1, 0.2)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.40 (1.03, 1.92)	
p-value [c]	0.0492	
Relative Risk (95% CI) [d]	1.02 (0.98, 1.05)	
p-value	0.3173	
Odds Ratio (95% CI) [d]	6.12 (0.25, 152.47)	
p-value	0.2694	
Risk Difference (95% CI) [e]	1.61 (-2.73, 5.95)	
p-value	0.4666	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.7684
Japan	99/ 99 (100.0)	0.1 (0.1, 0.1)	50/ 50 (100.0)	0.1 (0.1, 0.2)	1.52 (1.06, 2.17)	0.0332	
Korea	26/ 26 (100.0)	0.1 (0.0, 0.2)	11/ 12 (91.7)	0.1 (0.0, 0.4)	1.26 (0.61, 2.59)	0.6321	
Lines of prior systemic therapy							0.8081
2	66/ 66 (100.0)	0.1 (0.1, 0.1)	37/ 38 (97.4)	0.2 (0.1, 0.3)	1.42 (0.94, 2.13)	0.1212	
3	34/ 34 (100.0)	0.1 (0.1, 0.1)	18/ 18 (100.0)	0.1 (0.1, 0.2)	1.20 (0.66, 2.18)	0.5971	
>=4	25/ 25 (100.0)	0.1 (0.1, 0.3)	6/ 6 (100.0)	0.2 (0.0, 0.5)	2.11 (0.76, 5.85)	0.1686	
Age							0.5792
<65 years	55/ 55 (100.0)	0.1 (0.1, 0.1)	27/ 27 (100.0)	0.1 (0.1, 0.2)	1.16 (0.72, 1.85)	0.5930	
>=65 years	70/ 70 (100.0)	0.1 (0.1, 0.1)	34/ 35 (97.1)	0.2 (0.1, 0.3)	1.58 (1.04, 2.41)	0.0497	
Sex							0.4381
female	30/ 30 (100.0)	0.1 (0.1, 0.1)	15/ 15 (100.0)	0.1 (0.0, 0.2)	1.11 (0.58, 2.12)	0.8266	
male	95/ 95 (100.0)	0.1 (0.1, 0.1)	46/ 47 (97.9)	0.2 (0.1, 0.3)	1.48 (1.03, 2.12)	0.0400	
ECOG PS							0.9970
0	62/ 62 (100.0)	0.1 (0.1, 0.1)	30/ 30 (100.0)	0.1 (0.1, 0.3)	1.38 (0.88, 2.16)	0.1807	
1	63/ 63 (100.0)	0.1 (0.1, 0.1)	31/ 32 (96.9)	0.1 (0.1, 0.3)	1.40 (0.90, 2.18)	0.1626	
HER2 Status in central laboratory							0.8946
IHC 3+	96/ 96 (100.0)	0.1 (0.1, 0.1)	46/ 47 (97.9)	0.1 (0.1, 0.2)	1.36 (0.95, 1.94)	0.1193	
IHC 2+/ISH +	29/ 29 (100.0)	0.1 (0.1, 0.2)	15/ 15 (100.0)	0.2 (0.0, 0.3)	1.98 (0.95, 4.10)	0.0810	
Primary tumor location							0.8768
Gastric	108/108 (100.0)	0.1 (0.1, 0.1)	54/ 55 (98.2)	0.2 (0.1, 0.3)	1.39 (1.00, 1.94)	0.0716	
GEJ	17/ 17 (100.0)	0.1 (0.0, 0.1)	7/ 7 (100.0)	0.1 (0.0, 0.2)	1.28 (0.50, 3.27)	0.5960	
Histological subtype							0.0493
intestinal	89/ 89 (100.0)	0.1 (0.1, 0.1)	38/ 38 (100.0)	0.2 (0.1, 0.2)	1.73 (1.15, 2.60)	0.0128	
diffuse	28/ 28 (100.0)	0.1 (0.1, 0.1)	17/ 18 (94.4)	0.1 (0.1, 0.5)	1.40 (0.75, 2.62)	0.3118	
others	8/ 8 (100.0)	0.1 (0.0, 0.3)	6/ 6 (100.0)	0.1 (0.0, 0.1)	0.36 (0.10, 1.34)	0.1114	
Number of metastatic sites							0.4364
<2	24/ 24 (100.0)	0.1 (0.1, 0.2)	10/ 10 (100.0)	0.2 (0.0, 0.5)	2.04 (0.92, 4.54)	0.0737	
>= 2	101/101 (100.0)	0.1 (0.1, 0.1)	51/ 52 (98.1)	0.1 (0.1, 0.2)	1.33 (0.94, 1.88)	0.1396	
Previous total gastrectomy							0.0467
yes	22/ 22 (100.0)	0.2 (0.1, 0.3)	9/ 9 (100.0)	0.1 (0.0, 0.5)	0.69 (0.31, 1.56)	0.3369	
no	103/103 (100.0)	0.1 (0.1, 0.1)	52/ 53 (98.1)	0.2 (0.1, 0.2)	1.62 (1.15, 2.27)	0.0088	
Prior adjuvant/ neoadjuvant therapy							0.1649
yes	30/ 30 (100.0)	0.1 (0.1, 0.3)	10/ 10 (100.0)	0.2 (0.0, 0.3)	0.86 (0.41, 1.81)	0.6739	
no	95/ 95 (100.0)	0.1 (0.1, 0.1)	51/ 52 (98.1)	0.1 (0.1, 0.2)	1.56 (1.10, 2.21)	0.0187	
Prior ramucirumab contained treatment							0.9330
yes	94/ 94 (100.0)	0.1 (0.1, 0.1)	40/ 41 (97.6)	0.1 (0.1, 0.2)	1.44 (0.98, 2.11)	0.0872	
no	31/ 31 (100.0)	0.1 (0.1, 0.2)	21/ 21 (100.0)	0.2 (0.1, 0.3)	1.42 (0.80, 2.51)	0.2692	
Prior nivolumab contained treatment							0.7752
yes	33/ 33 (100.0)	0.1 (0.1, 0.1)	15/ 15 (100.0)	0.1 (0.0, 0.2)	1.40 (0.73, 2.70)	0.2781	
no	92/ 92 (100.0)	0.1 (0.1, 0.2)	46/ 47 (97.9)	0.2 (0.1, 0.3)	1.42 (0.99, 2.04)	0.0760	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

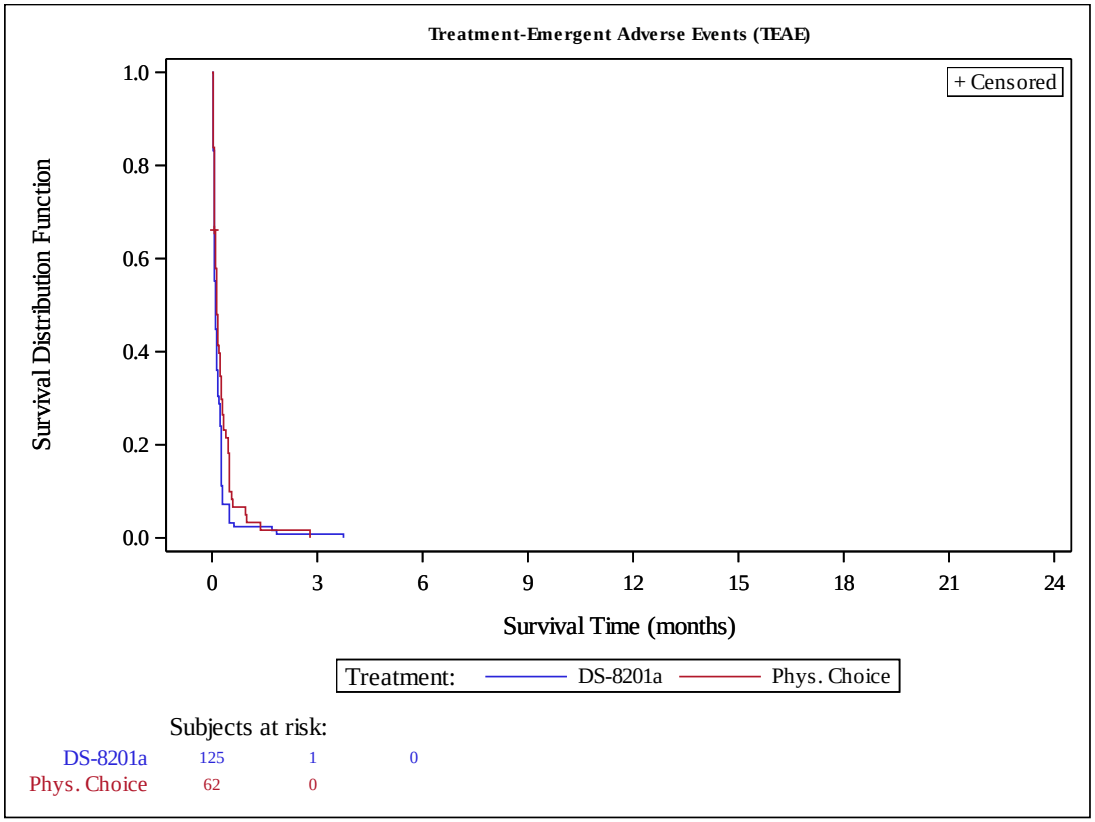
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.4991
yes	44/ 44 (100.0)	0.1 (0.1, 0.1)	17/ 17 (100.0)	0.1 (0.0, 0.2)	1.17 (0.66, 2.08)	0.6218	
no	81/ 81 (100.0)	0.1 (0.1, 0.2)	44/ 45 (97.8)	0.2 (0.1, 0.3)	1.46 (1.00, 2.12)	0.0675	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.3343
yes	22/ 22 (100.0)	0.1 (0.1, 0.2)	7/ 7 (100.0)	0.3 (0.1, 0.5)	2.59 (1.02, 6.59)	0.0417	
no	103/103 (100.0)	0.1 (0.1, 0.1)	54/ 55 (98.2)	0.1 (0.1, 0.2)	1.28 (0.92, 1.79)	0.2145	
Presence of liver metastasis at baseline							0.0661
yes	67/ 67 (100.0)	0.1 (0.1, 0.1)	34/ 34 (100.0)	0.2 (0.1, 0.3)	2.20 (1.40, 3.46)	0.0007	
no	58/ 58 (100.0)	0.1 (0.1, 0.2)	27/ 28 (96.4)	0.1 (0.1, 0.2)	0.98 (0.62, 1.56)	0.8520	
Renal impairment at baseline							0.0682
normal	33/ 33 (100.0)	0.1 (0.1, 0.1)	13/ 13 (100.0)	0.1 (0.0, 0.5)	1.68 (0.85, 3.29)	0.1429	
mild	53/ 53 (100.0)	0.1 (0.1, 0.2)	28/ 28 (100.0)	0.2 (0.1, 0.4)	1.81 (1.12, 2.92)	0.0188	
moderate	39/ 39 (100.0)	0.1 (0.1, 0.2)	19/ 20 (95.0)	0.1 (0.1, 0.2)	0.83 (0.47, 1.46)	0.4899	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9063
normal	88/ 88 (100.0)	0.1 (0.1, 0.1)	46/ 47 (97.9)	0.1 (0.1, 0.2)	1.35 (0.94, 1.95)	0.1229	
mild	36/ 36 (100.0)	0.1 (0.1, 0.2)	15/ 15 (100.0)	0.2 (0.1, 0.3)	1.72 (0.89, 3.34)	0.1429	
moderate	1/ 1 (100.0)	0.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.6151
yes	8/ 8 (100.0)	0.2 (0.1, 0.3)	5/ 5 (100.0)	0.3 (0.1, 2.8)	2.44 (0.63, 9.38)	0.2205	
no	117/117 (100.0)	0.1 (0.1, 0.1)	56/ 57 (98.2)	0.1 (0.1, 0.2)	1.33 (0.96, 1.84)	0.1143	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.2575
yes	3/ 3 (100.0)	0.1 (0.1, 0.2)	4/ 4 (100.0)	0.3 (0.1, 2.8)	3.20 (0.52, 19.89)	0.1886	
no	122/122 (100.0)	0.1 (0.1, 0.1)	57/ 58 (98.3)	0.1 (0.1, 0.2)	1.32 (0.96, 1.82)	0.1281	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

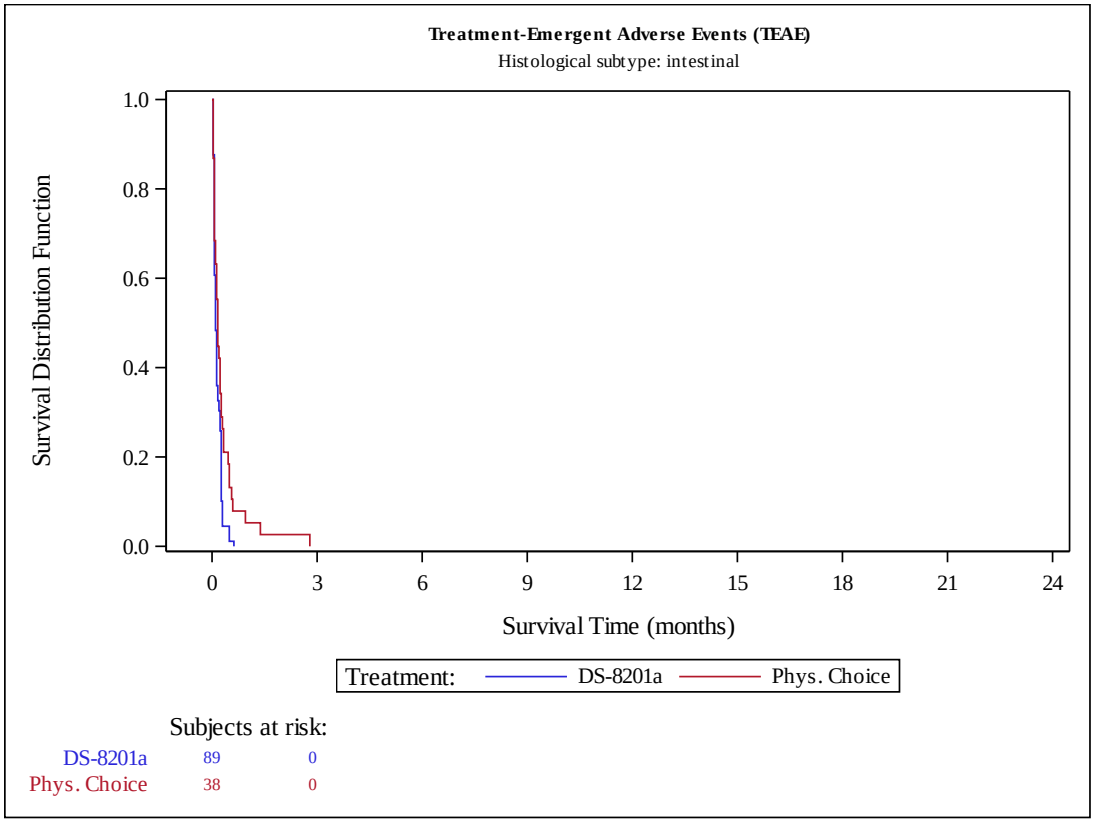
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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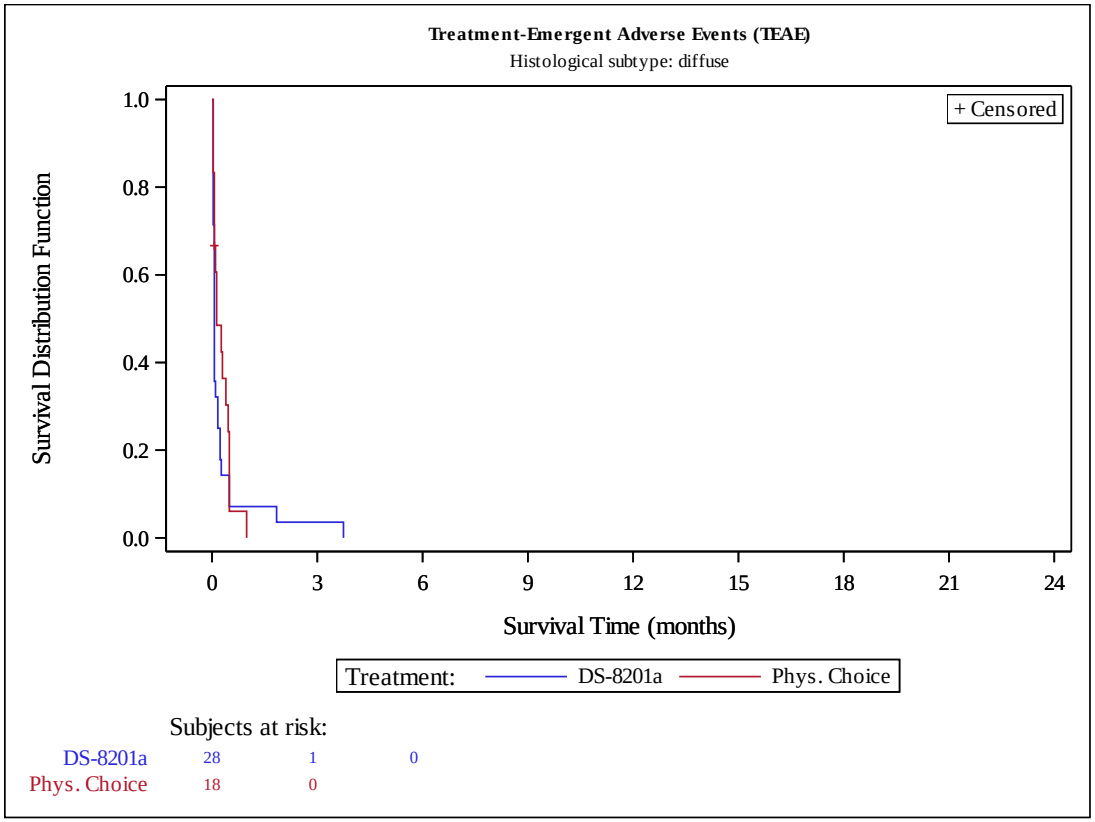
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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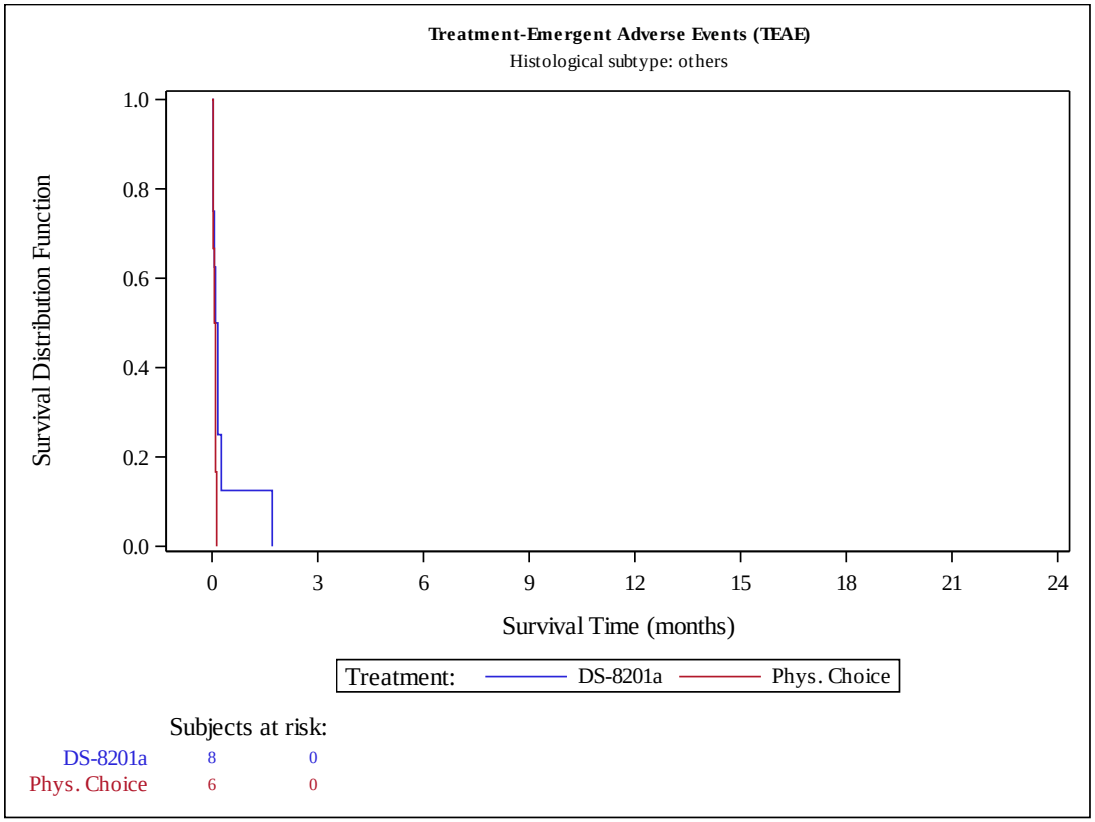
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
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Protocol DS8201-A-J202
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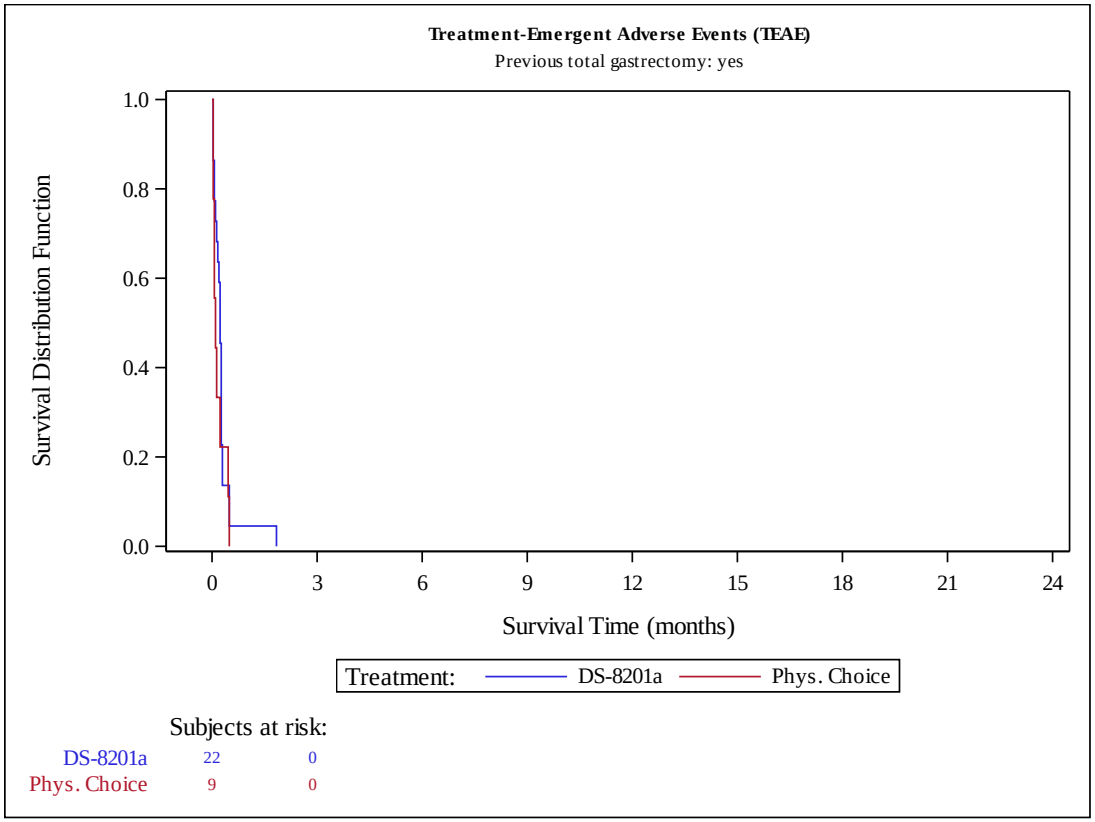
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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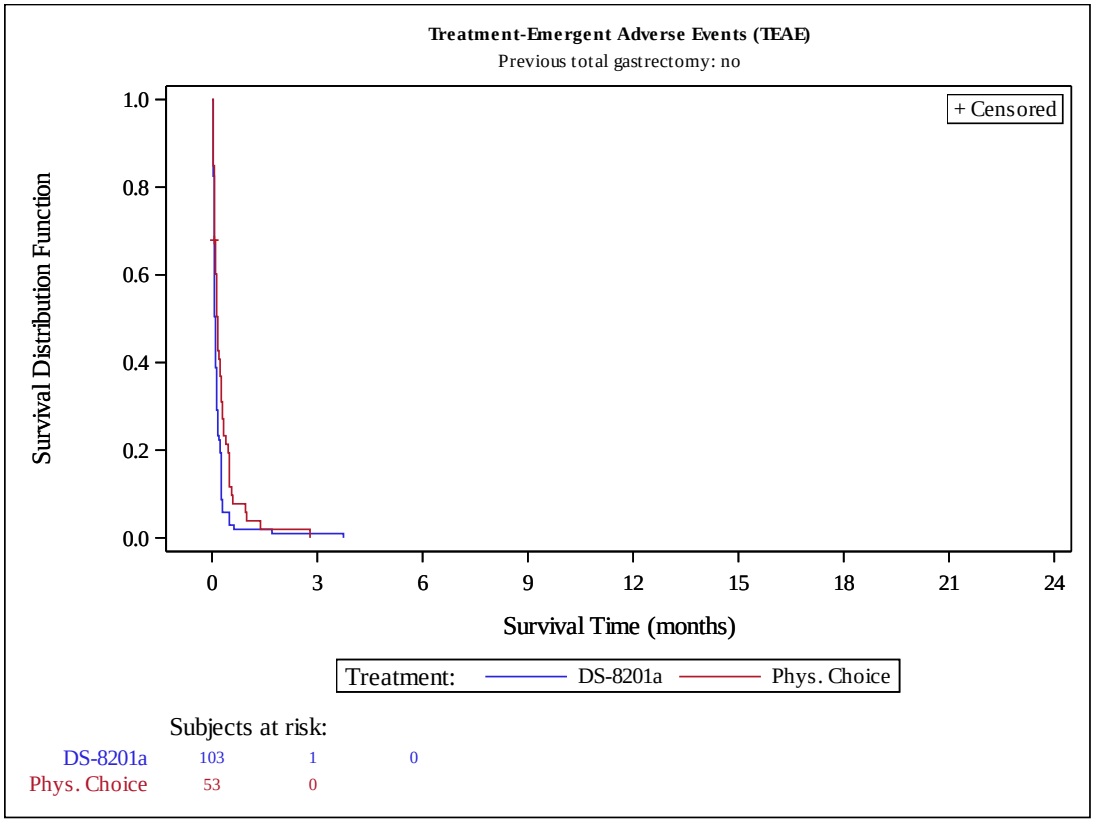
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious TEAE
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	55 (44.0)	15 (24.2)
Number of censored subjects, n (%)	70 (56.0)	47 (75.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	9.9 (5.6, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.43 (0.80, 2.55)	
p-value [c]	0.2222	
Relative Risk (95% CI) [d]	1.82 (1.12, 2.95)	
p-value	0.0152	
Odds Ratio (95% CI) [d]	2.46 (1.25, 4.86)	
p-value	0.0094	
Risk Difference (95% CI) [e]	19.81 (4.84, 34.77)	
p-value	0.0095	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious TEAE - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.6837
Japan	41/ 99 (41.4)	10.3 (5.6, NE)	11/ 50 (22.0)	NE (NE , NE)	1.55 (0.79, 3.04)	0.1970	
Korea	14/ 26 (53.8)	9.6 (2.6, 10.4)	4/ 12 (33.3)	NE (0.5, NE)	1.05 (0.33, 3.34)	0.9288	
Lines of prior systemic therapy							0.7537
2	31/ 66 (47.0)	10.3 (3.5, 15.1)	9/ 38 (23.7)	NE (NE , NE)	1.68 (0.79, 3.55)	0.1715	
3	11/ 34 (32.4)	NE (5.8, NE)	4/ 18 (22.2)	NE (3.0, NE)	0.88 (0.27, 2.92)	0.8365	
>=4	13/ 25 (52.0)	5.4 (1.8, NE)	2/ 6 (33.3)	NE (0.5, NE)	1.34 (0.30, 5.99)	0.7066	
Age							0.8964
<65 years	24/ 55 (43.6)	10.4 (3.5, NE)	6/ 27 (22.2)	NE (NE , NE)	1.42 (0.57, 3.55)	0.4460	
>=65 years	31/ 70 (44.3)	7.8 (4.0, NE)	9/ 35 (25.7)	NE (3.5, NE)	1.46 (0.69, 3.08)	0.3214	
Sex							0.1293
female	17/ 30 (56.7)	3.9 (2.3, NE)	2/ 15 (13.3)	NE (NE , NE)	3.86 (0.89, 16.83)	0.0527	
male	38/ 95 (40.0)	10.4 (5.8, NE)	13/ 47 (27.7)	NE (3.5, NE)	1.09 (0.57, 2.07)	0.7944	
ECOG PS							0.2923
0	20/ 62 (32.3)	NE (5.8, NE)	3/ 30 (10.0)	NE (NE , NE)	2.64 (0.78, 8.94)	0.1062	
1	35/ 63 (55.6)	5.4 (2.7, 9.9)	12/ 32 (37.5)	NE (2.7, NE)	1.11 (0.57, 2.18)	0.7490	
HER2 Status in central laboratory							0.0482
IHC 3+	39/ 96 (40.6)	10.3 (5.8, NE)	14/ 47 (29.8)	NE (3.0, NE)	0.99 (0.53, 1.86)	0.9826	
IHC 2+/ISH +	16/ 29 (55.2)	5.4 (1.7, NE)	1/ 15 (6.7)	NE (NE , NE)	7.65 (1.01, 58.13)	0.0204	
Primary tumor location							0.9854
Gastric	48/108 (44.4)	9.6 (5.6, NE)	15/ 55 (27.3)	NE (NE , NE)	1.31 (0.73, 2.36)	0.3627	
GEJ	7/ 17 (41.2)	15.1 (2.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.9874
intestinal	34/ 89 (38.2)	15.1 (5.8, NE)	8/ 38 (21.1)	NE (NE , NE)	1.48 (0.68, 3.22)	0.3230	
diffuse	15/ 28 (53.6)	9.6 (1.8, NE)	4/ 18 (22.2)	NE (3.0, NE)	1.51 (0.48, 4.76)	0.4731	
others	6/ 8 (75.0)	1.9 (0.1, NE)	3/ 6 (50.0)	NE (0.3, NE)	1.71 (0.43, 6.88)	0.4364	
Number of metastatic sites							0.8631
<2	9/ 24 (37.5)	10.4 (1.8, NE)	2/ 10 (20.0)	NE (0.0, NE)	1.76 (0.38, 8.17)	0.4655	
>= 2	46/101 (45.5)	9.6 (5.4, 15.1)	13/ 52 (25.0)	NE (NE , NE)	1.37 (0.73, 2.56)	0.3264	
Previous total gastrectomy							0.8969
yes	8/ 22 (36.4)	10.4 (3.9, NE)	2/ 9 (22.2)	NE (0.5, NE)	1.15 (0.23, 5.77)	0.8629	
no	47/103 (45.6)	9.6 (5.4, NE)	13/ 53 (24.5)	NE (NE , NE)	1.49 (0.80, 2.77)	0.2085	
Prior adjuvant/ neoadjuvant therapy							0.7421
yes	8/ 30 (26.7)	NE (9.9, NE)	1/ 10 (10.0)	NE (0.5, NE)	1.86 (0.22, 15.55)	0.5612	
no	47/ 95 (49.5)	5.8 (3.5, 15.1)	14/ 52 (26.9)	NE (3.5, NE)	1.47 (0.80, 2.69)	0.2095	
Prior ramucirumab contained treatment							0.7297
yes	38/ 94 (40.4)	9.9 (5.6, NE)	8/ 41 (19.5)	NE (NE , NE)	1.69 (0.78, 3.65)	0.1759	
no	17/ 31 (54.8)	9.6 (2.6, 15.1)	7/ 21 (33.3)	NE (2.8, NE)	1.20 (0.49, 2.97)	0.6893	
Prior nivolumab contained treatment							0.7588
yes	15/ 33 (45.5)	NE (2.4, NE)	3/ 15 (20.0)	NE (2.7, NE)	1.90 (0.54, 6.67)	0.3085	
no	40/ 92 (43.5)	9.9 (5.4, 15.1)	12/ 47 (25.5)	NE (NE , NE)	1.34 (0.70, 2.57)	0.3817	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

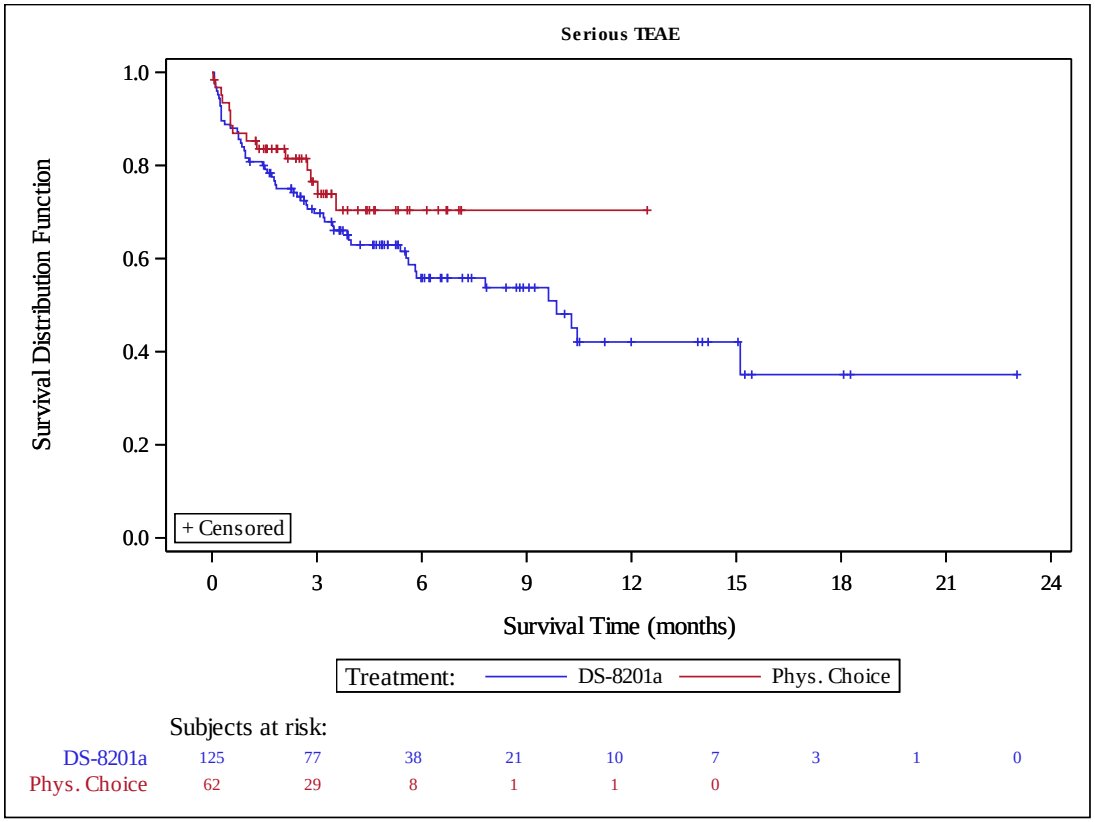
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious TEAE - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.3224
yes	23/ 44 (52.3)	9.6 (2.4, NE)	3/ 17 (17.6)	NE (3.0, NE)	2.43 (0.71, 8.24)	0.1434	
no	32/ 81 (39.5)	10.3 (5.4, NE)	12/ 45 (26.7)	NE (NE , NE)	1.18 (0.60, 2.30)	0.6293	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.2958
yes	12/ 22 (54.5)	5.4 (1.5, NE)	1/ 7 (14.3)	NE (0.6, NE)	3.63 (0.47, 28.16)	0.1866	
no	43/103 (41.7)	10.3 (5.8, NE)	14/ 55 (25.5)	NE (NE , NE)	1.26 (0.68, 2.33)	0.4549	
Presence of liver metastasis at baseline							0.3229
yes	25/ 67 (37.3)	10.3 (5.8, NE)	9/ 34 (26.5)	NE (3.0, NE)	1.07 (0.49, 2.32)	0.8686	
no	30/ 58 (51.7)	7.8 (3.9, 15.1)	6/ 28 (21.4)	NE (NE , NE)	1.91 (0.78, 4.64)	0.1472	
Renal impairment at baseline							0.4291
normal	11/ 33 (33.3)	NE (3.5, NE)	2/ 13 (15.4)	NE (2.1, NE)	1.36 (0.29, 6.36)	0.6937	
mild	25/ 53 (47.2)	5.8 (4.0, NE)	9/ 28 (32.1)	NE (2.8, NE)	1.22 (0.56, 2.63)	0.6174	
moderate	19/ 39 (48.7)	9.9 (1.8, 15.1)	3/ 20 (15.0)	NE (NE , NE)	3.27 (0.96, 11.20)	0.0449	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7963
normal	38/ 88 (43.2)	10.3 (5.6, NE)	11/ 47 (23.4)	NE (NE , NE)	1.32 (0.67, 2.62)	0.4289	
mild	17/ 36 (47.2)	9.9 (1.8, NE)	4/ 15 (26.7)	NE (1.3, NE)	1.70 (0.57, 5.08)	0.3331	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7240
yes	4/ 8 (50.0)	NE (0.3, NE)	1/ 5 (20.0)	NE (1.3, NE)	2.23 (0.24, 20.53)	0.4688	
no	51/117 (43.6)	9.9 (5.6, 15.1)	14/ 57 (24.6)	NE (NE , NE)	1.34 (0.73, 2.45)	0.3358	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9871
yes	1/ 3 (33.3)	NE (5.6, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	54/122 (44.3)	9.9 (5.6, NE)	15/ 58 (25.9)	NE (NE , NE)	1.32 (0.73, 2.36)	0.3548	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Serious TEAE
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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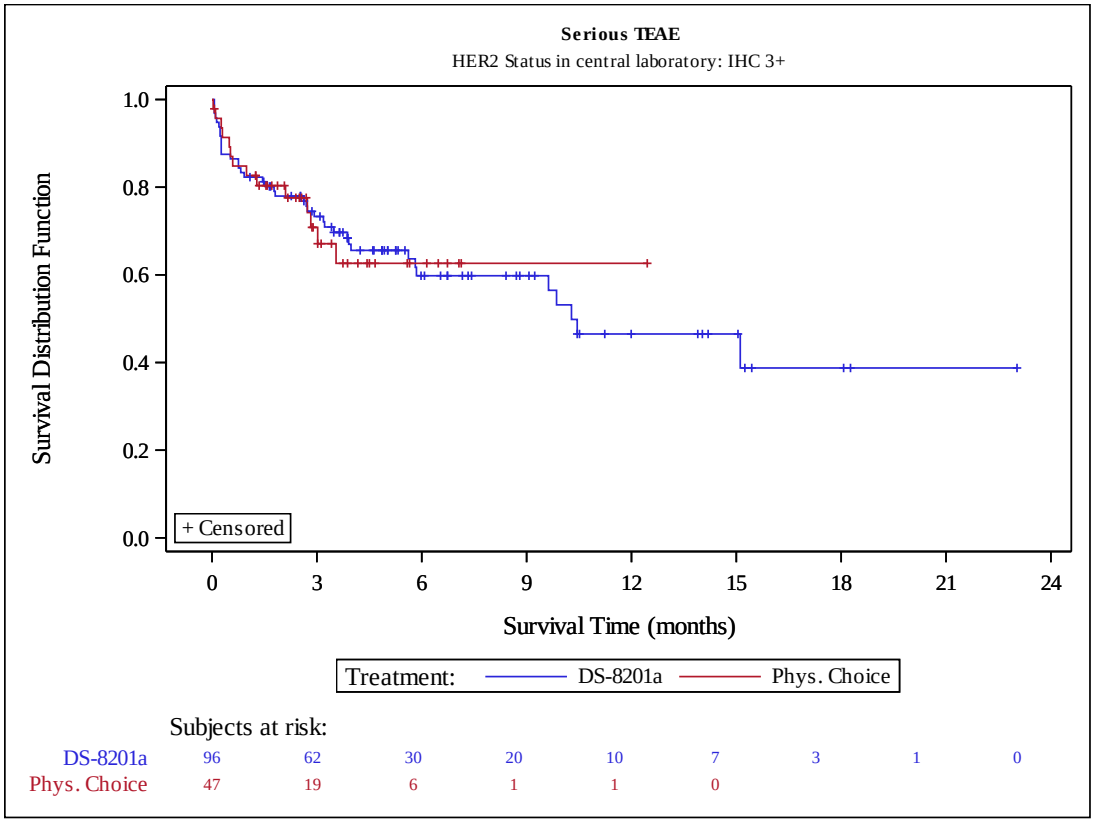

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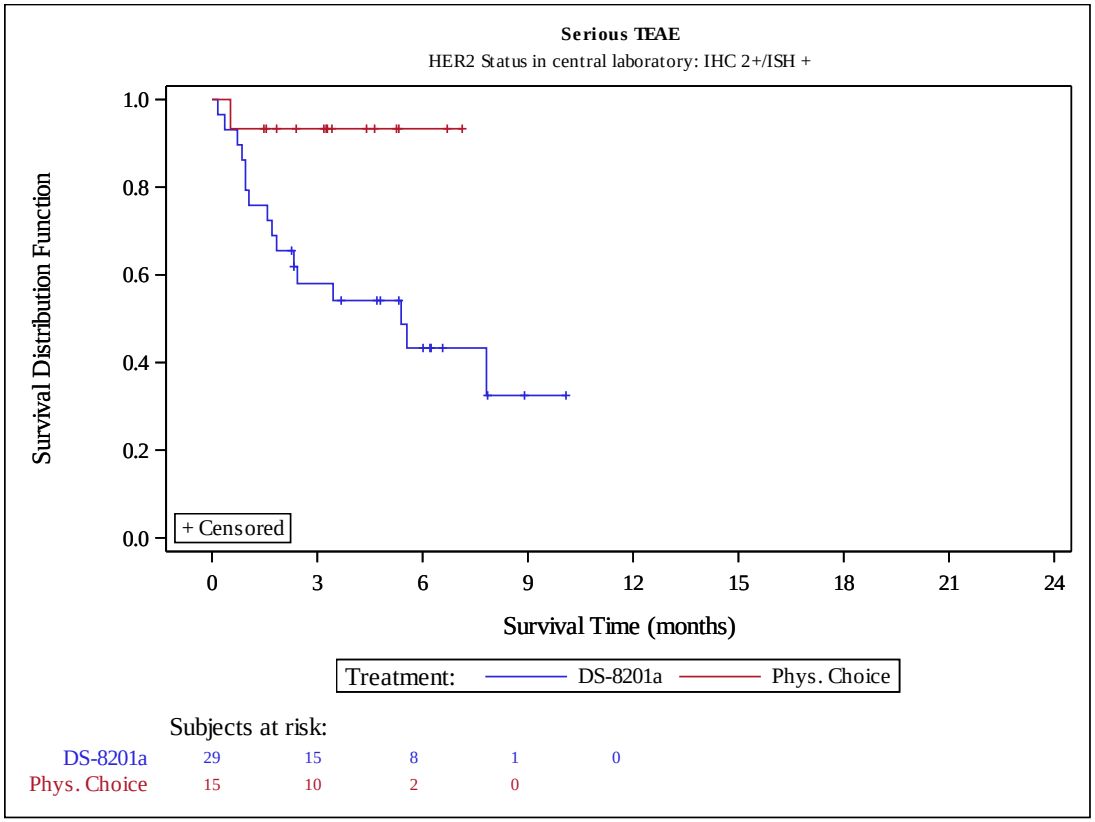

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	107 (85.6)	35 (56.5)
Number of censored subjects, n (%)	18 (14.4)	27 (43.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	0.7 (0.5, 0.7)	1.2 (0.6, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.72 (1.17, 2.52)	
p-value [c]	0.0049	
Relative Risk (95% CI) [d]	1.52 (1.20, 1.91)	
p-value	0.0004	
Odds Ratio (95% CI) [d]	4.59 (2.26, 9.31)	
p-value	<.0001	
Risk Difference (95% CI) [e]	29.15 (14.15, 44.15)	
p-value	0.0001	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.8081
Japan	84/ 99 (84.8)	0.7 (0.5, 0.7)	29/ 50 (58.0)	1.3 (0.5, NE)	1.66 (1.09, 2.54)	0.0176	
Korea	23/ 26 (88.5)	0.7 (0.3, 1.4)	6/ 12 (50.0)	1.0 (0.5, NE)	1.92 (0.78, 4.71)	0.1475	
Lines of prior systemic therapy							0.7202
2	56/ 66 (84.8)	0.7 (0.5, 1.4)	21/ 38 (55.3)	1.2 (0.7, NE)	1.63 (0.99, 2.70)	0.0531	
3	29/ 34 (85.3)	0.5 (0.5, 0.7)	10/ 18 (55.6)	1.4 (0.5, NE)	1.98 (0.96, 4.08)	0.0559	
>=4	22/ 25 (88.0)	0.5 (0.3, 1.4)	4/ 6 (66.7)	0.5 (0.2, NE)	1.27 (0.44, 3.71)	0.6914	
Age							0.7421
<65 years	52/ 55 (94.5)	0.7 (0.5, 1.4)	16/ 27 (59.3)	0.7 (0.5, NE)	1.49 (0.84, 2.63)	0.1564	
>=65 years	55/ 70 (78.6)	0.6 (0.5, 0.7)	19/ 35 (54.3)	1.4 (0.5, NE)	1.80 (1.07, 3.03)	0.0258	
Sex							0.2103
female	26/ 30 (86.7)	0.6 (0.3, 2.7)	6/ 15 (40.0)	NE (0.5, NE)	2.52 (1.03, 6.15)	0.0388	
male	81/ 95 (85.3)	0.7 (0.5, 0.8)	29/ 47 (61.7)	0.7 (0.5, 3.5)	1.51 (0.98, 2.30)	0.0541	
ECOG PS							0.5239
0	50/ 62 (80.6)	0.7 (0.5, 1.4)	15/ 30 (50.0)	2.7 (0.7, NE)	1.98 (1.11, 3.53)	0.0182	
1	57/ 63 (90.5)	0.5 (0.4, 0.7)	20/ 32 (62.5)	0.5 (0.5, NE)	1.52 (0.91, 2.53)	0.1011	
HER2 Status in central laboratory							0.7671
IHC 3+	82/ 96 (85.4)	0.7 (0.5, 0.8)	26/ 47 (55.3)	1.8 (0.5, NE)	1.76 (1.13, 2.74)	0.0109	
IHC 2+/ISH +	25/ 29 (86.2)	0.5 (0.4, 1.4)	9/ 15 (60.0)	1.2 (0.3, NE)	1.52 (0.70, 3.30)	0.2777	
Primary tumor location							0.7785
Gastric	92/108 (85.2)	0.7 (0.5, 0.7)	31/ 55 (56.4)	1.2 (0.5, NE)	1.77 (1.17, 2.66)	0.0053	
GEJ	15/ 17 (88.2)	1.0 (0.5, 2.8)	4/ 7 (57.1)	2.3 (0.3, NE)	1.27 (0.41, 3.92)	0.6870	
Histological subtype							0.2606
intestinal	74/ 89 (83.1)	0.7 (0.5, 1.3)	24/ 38 (63.2)	1.2 (0.5, 3.5)	1.40 (0.88, 2.22)	0.1507	
diffuse	25/ 28 (89.3)	0.5 (0.3, 0.8)	7/ 18 (38.9)	NE (0.5, NE)	3.06 (1.32, 7.13)	0.0059	
others	8/ 8 (100.0)	0.4 (0.0, 1.4)	4/ 6 (66.7)	0.6 (0.3, NE)	2.21 (0.65, 7.45)	0.1626	
Number of metastatic sites							0.7504
<2	20/ 24 (83.3)	0.7 (0.4, 1.3)	6/ 10 (60.0)	0.5 (0.2, NE)	1.40 (0.56, 3.49)	0.4404	
>= 2	87/101 (86.1)	0.7 (0.5, 0.8)	29/ 52 (55.8)	1.4 (0.7, NE)	1.76 (1.15, 2.68)	0.0079	
Previous total gastrectomy							0.1730
yes	17/ 22 (77.3)	1.5 (0.5, 3.4)	6/ 9 (66.7)	0.7 (0.2, NE)	1.02 (0.40, 2.62)	0.9516	
no	90/103 (87.4)	0.5 (0.5, 0.7)	29/ 53 (54.7)	1.3 (0.6, NE)	1.94 (1.28, 2.96)	0.0015	
Prior adjuvant/ neoadjuvant therapy							0.1371
yes	23/ 30 (76.7)	0.7 (0.5, 1.4)	7/ 10 (70.0)	0.6 (0.2, NE)	1.01 (0.43, 2.38)	0.9953	
no	84/ 95 (88.4)	0.5 (0.5, 0.9)	28/ 52 (53.8)	1.4 (0.6, NE)	1.96 (1.28, 3.01)	0.0016	
Prior ramucirumab contained treatment							0.9434
yes	79/ 94 (84.0)	0.7 (0.5, 0.8)	22/ 41 (53.7)	1.2 (0.5, NE)	1.71 (1.07, 2.75)	0.0228	
no	28/ 31 (90.3)	0.5 (0.3, 1.7)	13/ 21 (61.9)	2.3 (0.5, NE)	1.68 (0.86, 3.26)	0.1267	
Prior nivolumab contained treatment							0.1301
yes	31/ 33 (93.9)	0.5 (0.3, 0.5)	8/ 15 (53.3)	1.4 (0.5, NE)	2.89 (1.31, 6.40)	0.0064	
no	76/ 92 (82.6)	0.8 (0.7, 1.5)	27/ 47 (57.4)	1.1 (0.5, NE)	1.47 (0.94, 2.28)	0.0839	

NE: Not estimable.
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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0335
yes	41/ 44 (93.2)	0.5 (0.3, 0.5)	8/ 17 (47.1)	NE (0.5, NE)	3.33 (1.54, 7.18)	0.0011	
no	66/ 81 (81.5)	1.0 (0.7, 1.6)	27/ 45 (60.0)	0.9 (0.5, 3.5)	1.29 (0.82, 2.02)	0.2591	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9690
yes	19/ 22 (86.4)	0.7 (0.3, 1.5)	4/ 7 (57.1)	0.5 (0.1, NE)	1.67 (0.56, 4.97)	0.3407	
no	88/103 (85.4)	0.7 (0.5, 0.8)	31/ 55 (56.4)	1.3 (0.7, NE)	1.71 (1.13, 2.58)	0.0094	
Presence of liver metastasis at baseline							0.3638
yes	59/ 67 (88.1)	0.6 (0.5, 1.3)	19/ 34 (55.9)	1.4 (0.6, NE)	1.96 (1.17, 3.29)	0.0093	
no	48/ 58 (82.8)	0.7 (0.5, 1.0)	16/ 28 (57.1)	0.7 (0.5, NE)	1.44 (0.81, 2.54)	0.2030	
Renal impairment at baseline							0.2231
normal	31/ 33 (93.9)	0.6 (0.5, 0.8)	6/ 13 (46.2)	NE (0.5, NE)	2.52 (1.04, 6.11)	0.0323	
mild	44/ 53 (83.0)	0.7 (0.5, 1.4)	19/ 28 (67.9)	0.7 (0.5, 3.5)	1.23 (0.72, 2.11)	0.4418	
moderate	32/ 39 (82.1)	0.5 (0.3, 1.4)	9/ 20 (45.0)	2.7 (0.4, NE)	2.26 (1.07, 4.78)	0.0278	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.5 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9209
normal	75/ 88 (85.2)	0.7 (0.5, 1.0)	26/ 47 (55.3)	1.8 (0.7, NE)	1.73 (1.11, 2.71)	0.0146	
mild	31/ 36 (86.1)	0.6 (0.4, 0.8)	9/ 15 (60.0)	0.5 (0.5, NE)	1.64 (0.78, 3.46)	0.1785	
moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8152
yes	7/ 8 (87.5)	2.9 (0.1, 8.3)	2/ 5 (40.0)	NE (0.5, NE)	2.13 (0.43, 10.47)	0.3402	
no	100/117 (85.5)	0.7 (0.5, 0.7)	33/ 57 (57.9)	1.2 (0.6, NE)	1.69 (1.14, 2.51)	0.0080	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.3676
yes	3/ 3 (100.0)	4.3 (0.1, 5.6)	1/ 4 (25.0)	NE (0.5, NE)	3.44 (0.34, 34.64)	0.2690	
no	104/122 (85.2)	0.7 (0.5, 0.7)	34/ 58 (58.6)	1.2 (0.5, 3.5)	1.61 (1.09, 2.38)	0.0146	

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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
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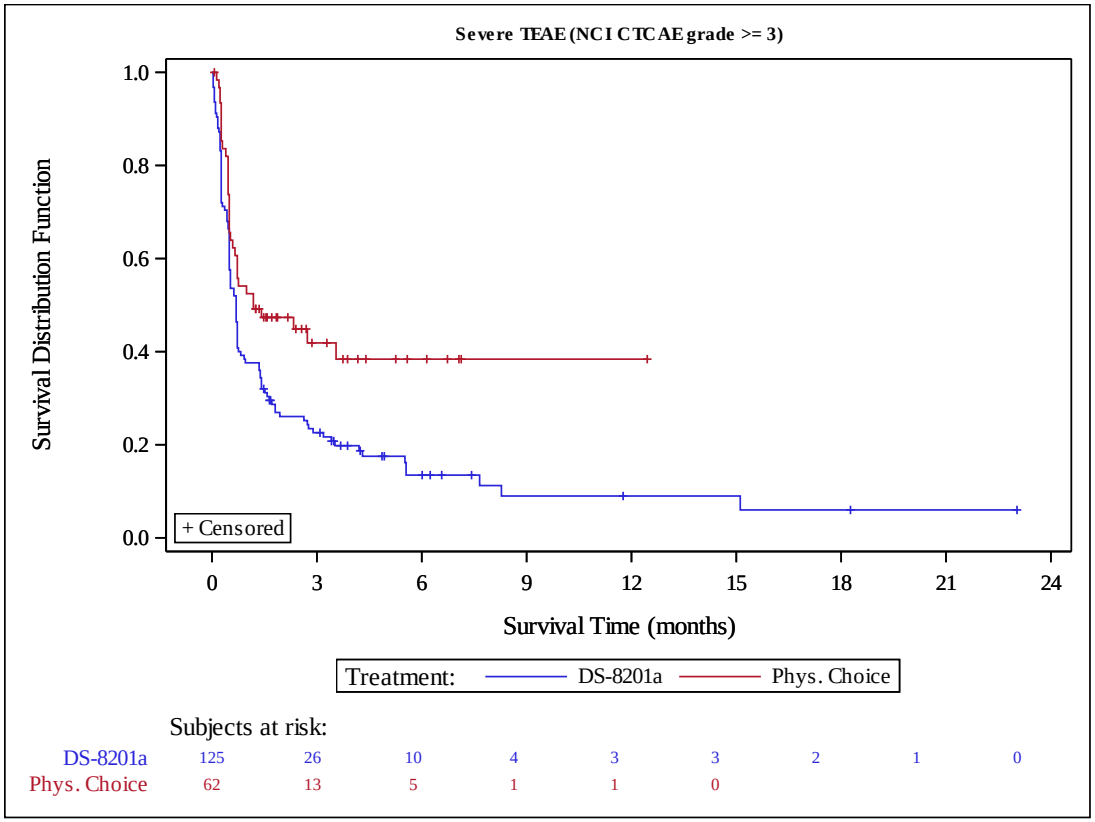
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
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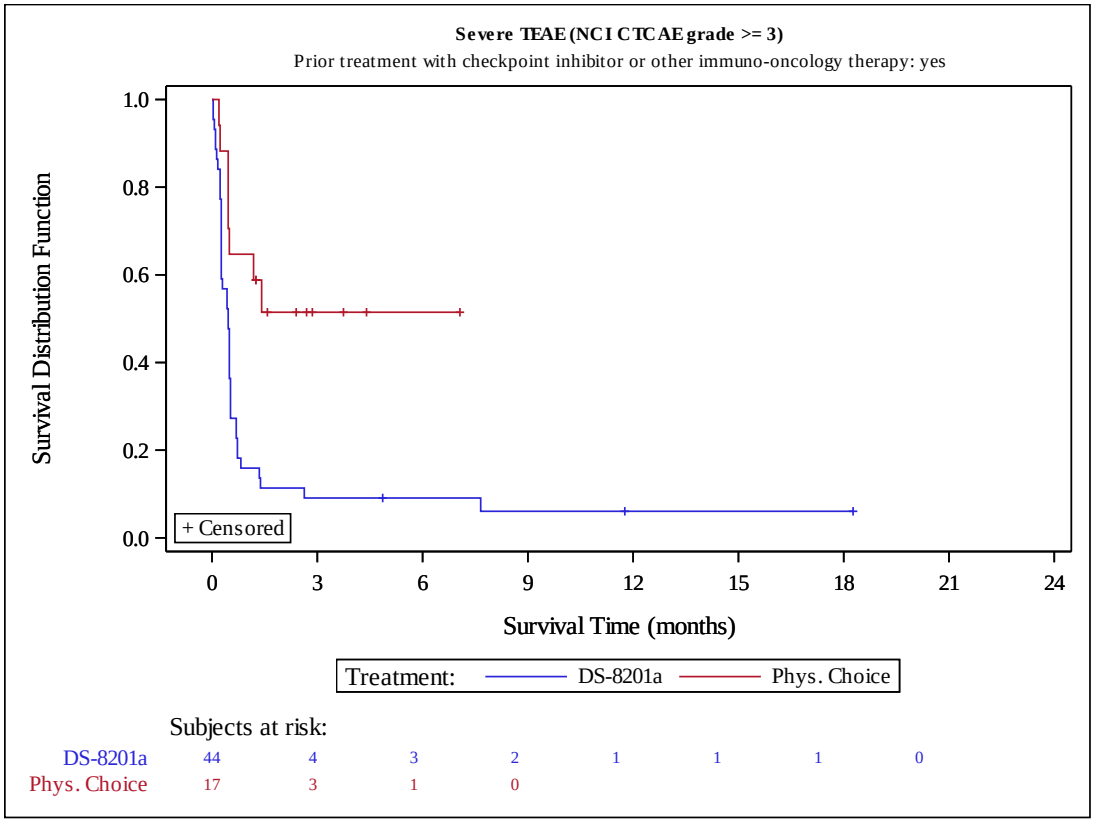

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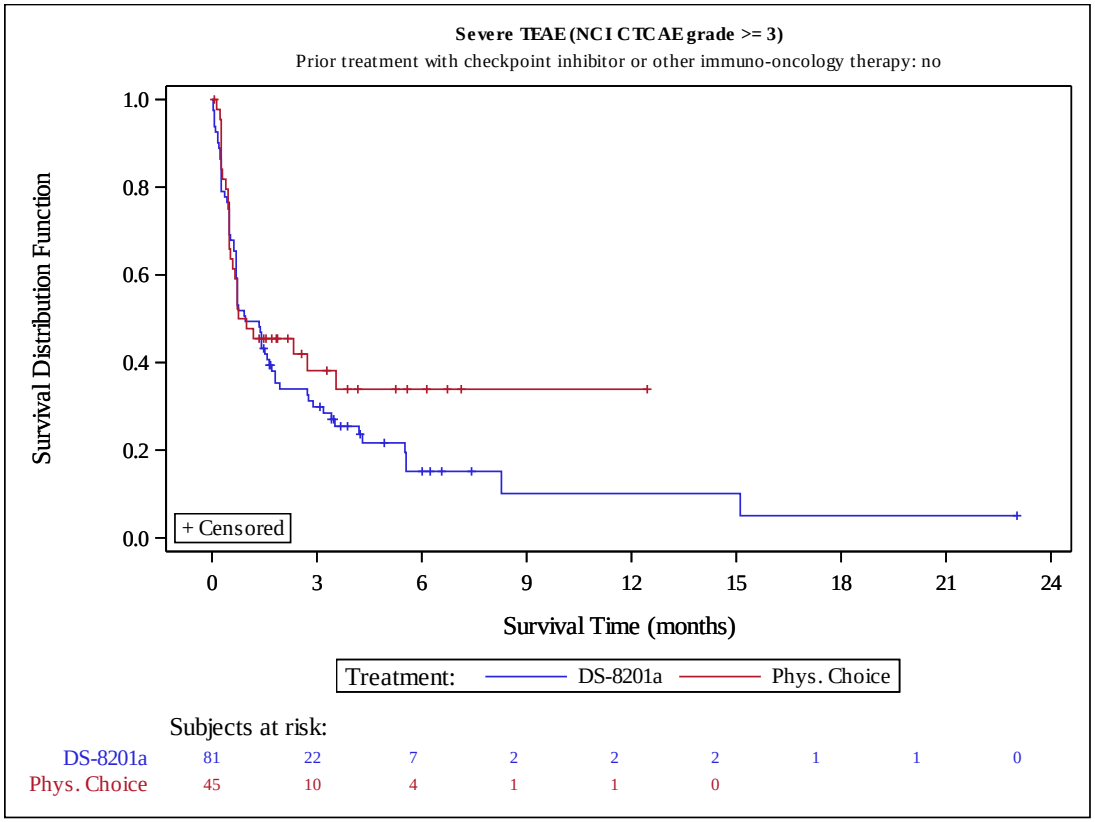
Kaplan Meier Plot of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	124 (99.2)	61 (98.4)
Number of censored subjects, n (%)	1 (0.8)	1 (1.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	0.1 (0.1, 0.1)	0.1 (0.1, 0.2)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.32 (0.97, 1.80)	
p-value [c]	0.1073	
Relative Risk (95% CI) [d]	1.01 (0.97, 1.04)	
p-value	0.6500	
Odds Ratio (95% CI) [d]	2.03 (0.13, 33.05)	
p-value	0.6181	
Risk Difference (95% CI) [e]	0.81 (-3.90, 5.52)	
p-value	0.7351	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.3233
Japan	99/ 99 (100.0)	0.1 (0.1, 0.1)	50/ 50 (100.0)	0.1 (0.1, 0.2)	1.53 (1.07, 2.19)	0.0299	
Korea	25/ 26 (96.2)	0.1 (0.0, 0.3)	11/ 12 (91.7)	0.1 (0.0, 0.4)	0.98 (0.47, 2.03)	0.8801	
Lines of prior systemic therapy							0.7547
2	66/ 66 (100.0)	0.1 (0.1, 0.1)	37/ 38 (97.4)	0.2 (0.1, 0.3)	1.35 (0.90, 2.03)	0.1821	
3	33/ 34 (97.1)	0.1 (0.1, 0.2)	18/ 18 (100.0)	0.1 (0.1, 0.2)	1.06 (0.59, 1.90)	0.9110	
>=4	25/ 25 (100.0)	0.1 (0.1, 0.3)	6/ 6 (100.0)	0.2 (0.0, 0.5)	2.11 (0.76, 5.85)	0.1686	
Age							0.9744
<65 years	55/ 55 (100.0)	0.1 (0.1, 0.1)	27/ 27 (100.0)	0.1 (0.1, 0.2)	1.21 (0.75, 1.94)	0.4613	
>=65 years	69/ 70 (98.6)	0.1 (0.1, 0.2)	34/ 35 (97.1)	0.2 (0.1, 0.3)	1.37 (0.90, 2.08)	0.1824	
Sex							0.4443
female	30/ 30 (100.0)	0.1 (0.1, 0.2)	15/ 15 (100.0)	0.1 (0.0, 0.2)	1.07 (0.56, 2.03)	0.9566	
male	94/ 95 (98.9)	0.1 (0.1, 0.2)	46/ 47 (97.9)	0.2 (0.1, 0.3)	1.39 (0.97, 1.99)	0.0842	
ECOG PS							0.7410
0	62/ 62 (100.0)	0.1 (0.1, 0.1)	30/ 30 (100.0)	0.1 (0.1, 0.3)	1.39 (0.89, 2.17)	0.1725	
1	62/ 63 (98.4)	0.1 (0.1, 0.2)	31/ 32 (96.9)	0.1 (0.1, 0.3)	1.25 (0.80, 1.94)	0.3696	
HER2 Status in central laboratory							0.8450
IHC 3+	95/ 96 (99.0)	0.1 (0.1, 0.2)	46/ 47 (97.9)	0.1 (0.1, 0.3)	1.28 (0.90, 1.83)	0.2138	
IHC 2+/ISH +	29/ 29 (100.0)	0.1 (0.1, 0.2)	15/ 15 (100.0)	0.2 (0.0, 0.3)	1.58 (0.81, 3.07)	0.1964	
Primary tumor location							0.8903
Gastric	107/108 (99.1)	0.1 (0.1, 0.2)	54/ 55 (98.2)	0.2 (0.1, 0.3)	1.31 (0.94, 1.82)	0.1463	
GEJ	17/ 17 (100.0)	0.1 (0.0, 0.1)	7/ 7 (100.0)	0.1 (0.0, 0.2)	1.23 (0.48, 3.16)	0.6535	
Histological subtype							0.0378
intestinal	89/ 89 (100.0)	0.1 (0.1, 0.1)	38/ 38 (100.0)	0.2 (0.1, 0.3)	1.78 (1.18, 2.69)	0.0083	
diffuse	27/ 28 (96.4)	0.1 (0.1, 0.2)	17/ 18 (94.4)	0.1 (0.1, 0.5)	1.13 (0.61, 2.10)	0.7822	
others	8/ 8 (100.0)	0.1 (0.0, 0.3)	6/ 6 (100.0)	0.1 (0.0, 0.1)	0.36 (0.10, 1.34)	0.1114	
Number of metastatic sites							0.2577
<2	24/ 24 (100.0)	0.1 (0.1, 0.2)	10/ 10 (100.0)	0.3 (0.0, 0.5)	2.22 (0.98, 5.01)	0.0583	
>= 2	100/101 (99.0)	0.1 (0.1, 0.1)	51/ 52 (98.1)	0.1 (0.1, 0.2)	1.21 (0.86, 1.71)	0.3186	
Previous total gastrectomy							0.0132
yes	21/ 22 (95.5)	0.3 (0.1, 0.3)	9/ 9 (100.0)	0.1 (0.0, 0.5)	0.52 (0.23, 1.18)	0.0993	
no	103/103 (100.0)	0.1 (0.1, 0.1)	52/ 53 (98.1)	0.2 (0.1, 0.3)	1.60 (1.14, 2.26)	0.0095	
Prior adjuvant/ neoadjuvant therapy							0.1633
yes	29/ 30 (96.7)	0.1 (0.1, 0.3)	10/ 10 (100.0)	0.2 (0.0, 0.4)	0.84 (0.40, 1.76)	0.6074	
no	95/ 95 (100.0)	0.1 (0.1, 0.1)	51/ 52 (98.1)	0.1 (0.1, 0.2)	1.48 (1.04, 2.10)	0.0340	
Prior ramucirumab contained treatment							0.7016
yes	94/ 94 (100.0)	0.1 (0.1, 0.1)	40/ 41 (97.6)	0.1 (0.1, 0.3)	1.43 (0.97, 2.10)	0.0943	
no	30/ 31 (96.8)	0.1 (0.1, 0.2)	21/ 21 (100.0)	0.2 (0.1, 0.3)	1.21 (0.68, 2.14)	0.5668	
Prior nivolumab contained treatment							0.8080
yes	33/ 33 (100.0)	0.1 (0.1, 0.1)	15/ 15 (100.0)	0.1 (0.0, 0.2)	1.35 (0.70, 2.59)	0.3387	
no	91/ 92 (98.9)	0.1 (0.1, 0.2)	46/ 47 (97.9)	0.2 (0.1, 0.3)	1.34 (0.93, 1.92)	0.1455	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

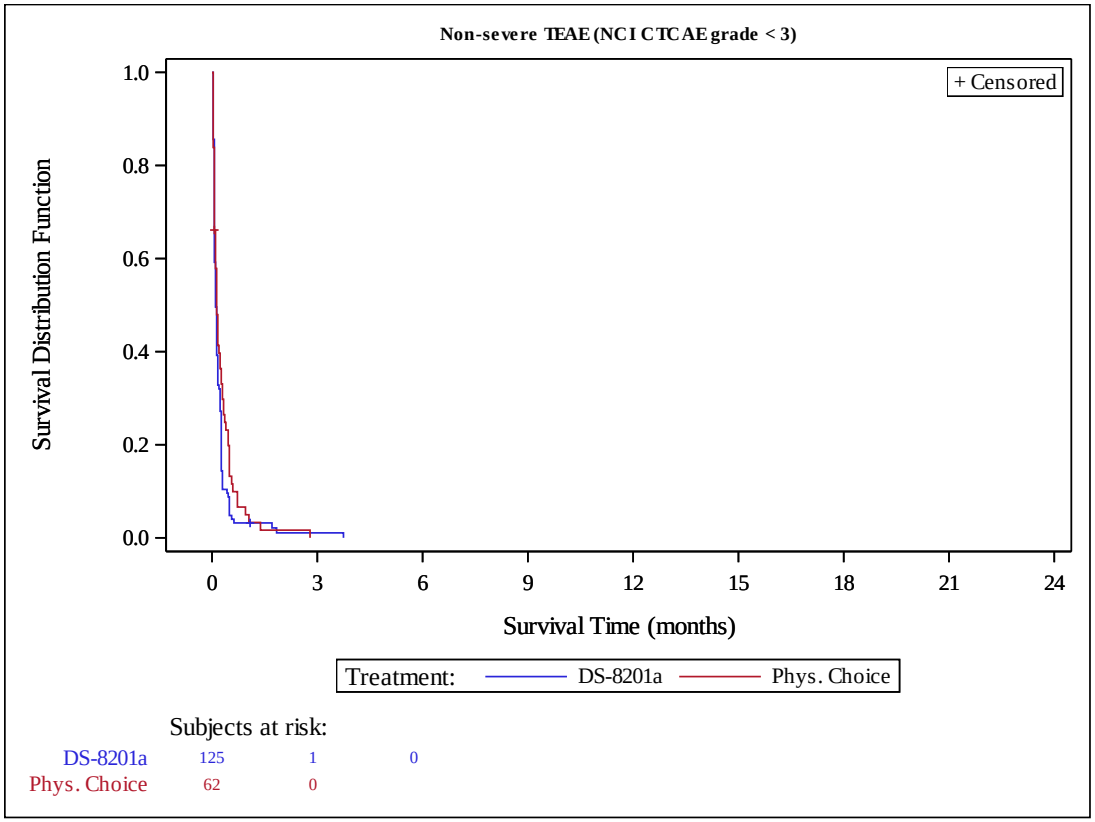
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.1660
yes	43/ 44 (97.7)	0.1 (0.1, 0.1)	17/ 17 (100.0)	0.1 (0.0, 0.2)	0.93 (0.53, 1.65)	0.8122	
no	81/ 81 (100.0)	0.1 (0.1, 0.2)	44/ 45 (97.8)	0.2 (0.1, 0.3)	1.49 (1.02, 2.17)	0.0558	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.1327
yes	22/ 22 (100.0)	0.1 (0.1, 0.2)	7/ 7 (100.0)	0.4 (0.1, 0.5)	3.54 (1.30, 9.68)	0.0110	
no	102/103 (99.0)	0.1 (0.1, 0.1)	54/ 55 (98.2)	0.1 (0.1, 0.2)	1.17 (0.84, 1.63)	0.4622	
Presence of liver metastasis at baseline							0.1990
yes	66/ 67 (98.5)	0.1 (0.1, 0.1)	34/ 34 (100.0)	0.2 (0.1, 0.3)	1.74 (1.13, 2.68)	0.0127	
no	58/ 58 (100.0)	0.1 (0.1, 0.2)	27/ 28 (96.4)	0.1 (0.1, 0.2)	1.01 (0.64, 1.61)	0.9249	
Renal impairment at baseline							0.0218
normal	33/ 33 (100.0)	0.1 (0.1, 0.1)	13/ 13 (100.0)	0.1 (0.0, 0.5)	1.60 (0.82, 3.11)	0.1743	
mild	53/ 53 (100.0)	0.1 (0.1, 0.2)	28/ 28 (100.0)	0.2 (0.1, 0.4)	1.80 (1.11, 2.90)	0.0203	
moderate	38/ 39 (97.4)	0.1 (0.1, 0.2)	19/ 20 (95.0)	0.1 (0.1, 0.2)	0.71 (0.40, 1.25)	0.2113	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9295
normal	87/ 88 (98.9)	0.1 (0.1, 0.1)	46/ 47 (97.9)	0.1 (0.1, 0.2)	1.25 (0.87, 1.79)	0.2658	
mild	36/ 36 (100.0)	0.1 (0.1, 0.3)	15/ 15 (100.0)	0.2 (0.1, 0.3)	1.51 (0.80, 2.82)	0.2261	
moderate	1/ 1 (100.0)	0.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4352
yes	8/ 8 (100.0)	0.2 (0.1, 0.3)	5/ 5 (100.0)	0.3 (0.1, 2.8)	2.76 (0.70, 10.84)	0.1473	
no	116/117 (99.1)	0.1 (0.1, 0.1)	56/ 57 (98.2)	0.1 (0.1, 0.2)	1.24 (0.89, 1.71)	0.2462	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.1764
yes	3/ 3 (100.0)	0.1 (0.1, 0.2)	4/ 4 (100.0)	0.4 (0.1, 2.8)	3.20 (0.52, 19.89)	0.1886	
no	121/122 (99.2)	0.1 (0.1, 0.1)	57/ 58 (98.3)	0.1 (0.1, 0.2)	1.23 (0.90, 1.70)	0.2578	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

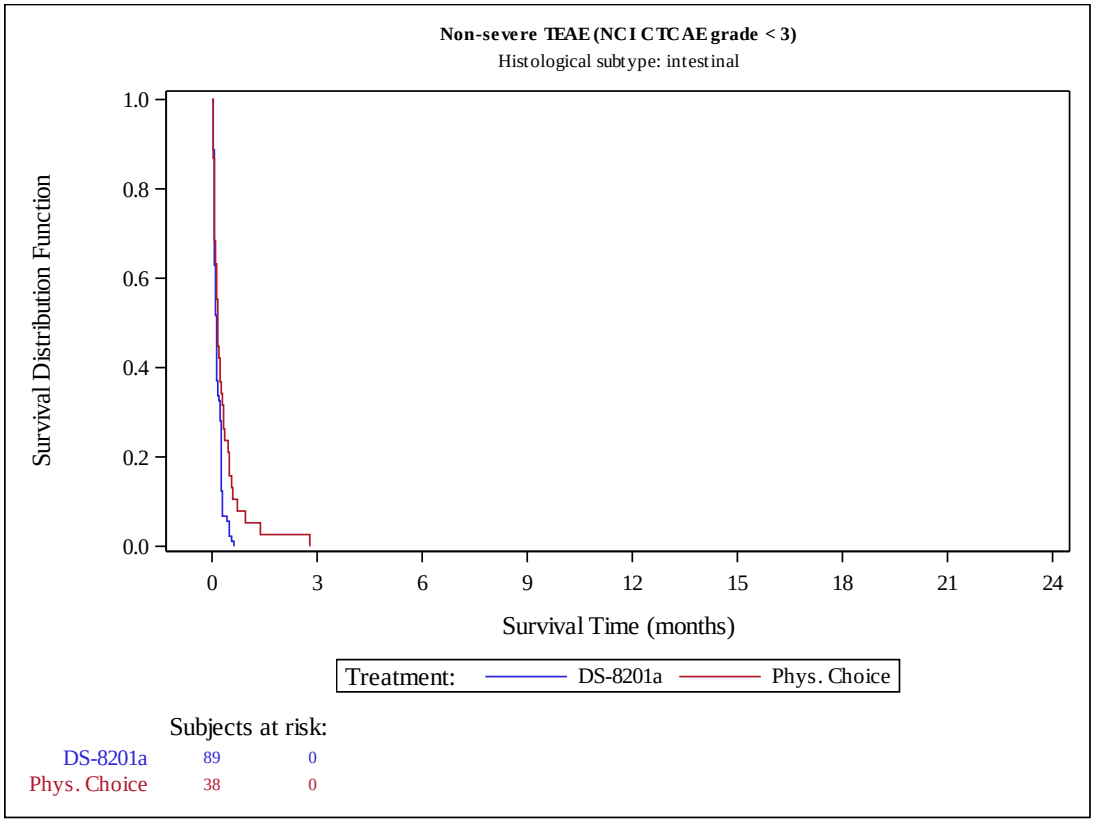
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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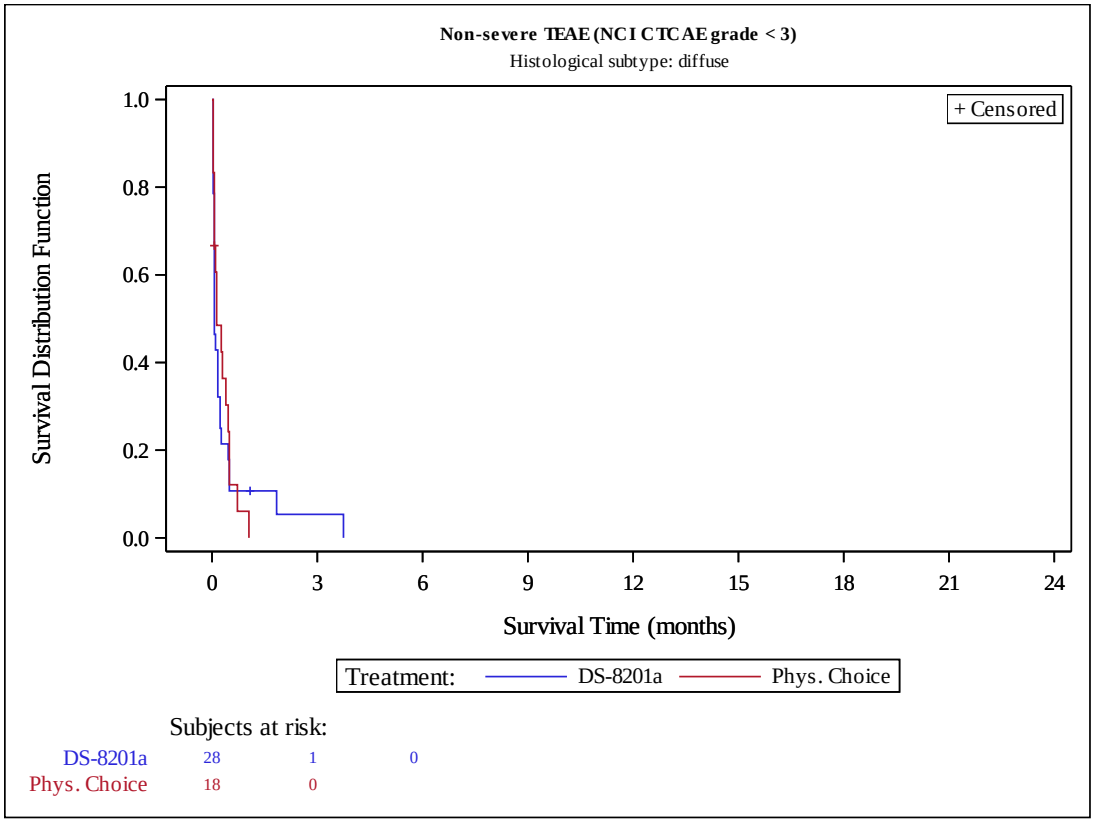
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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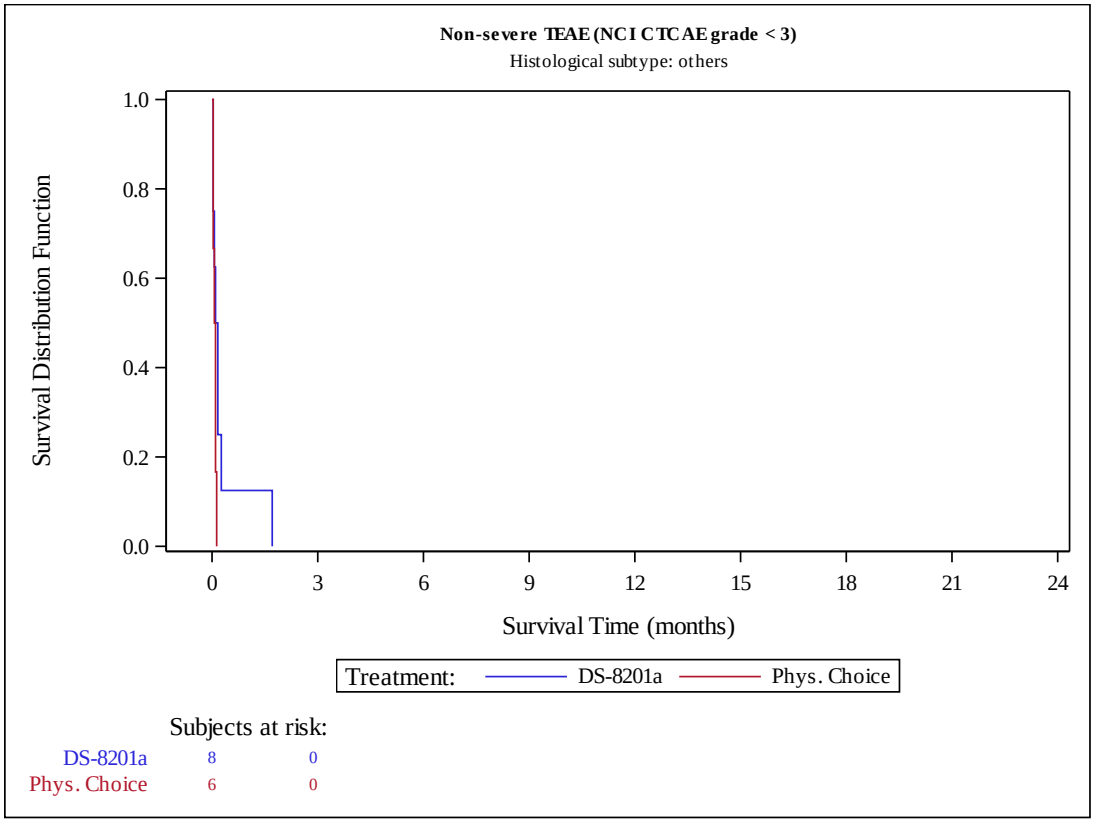
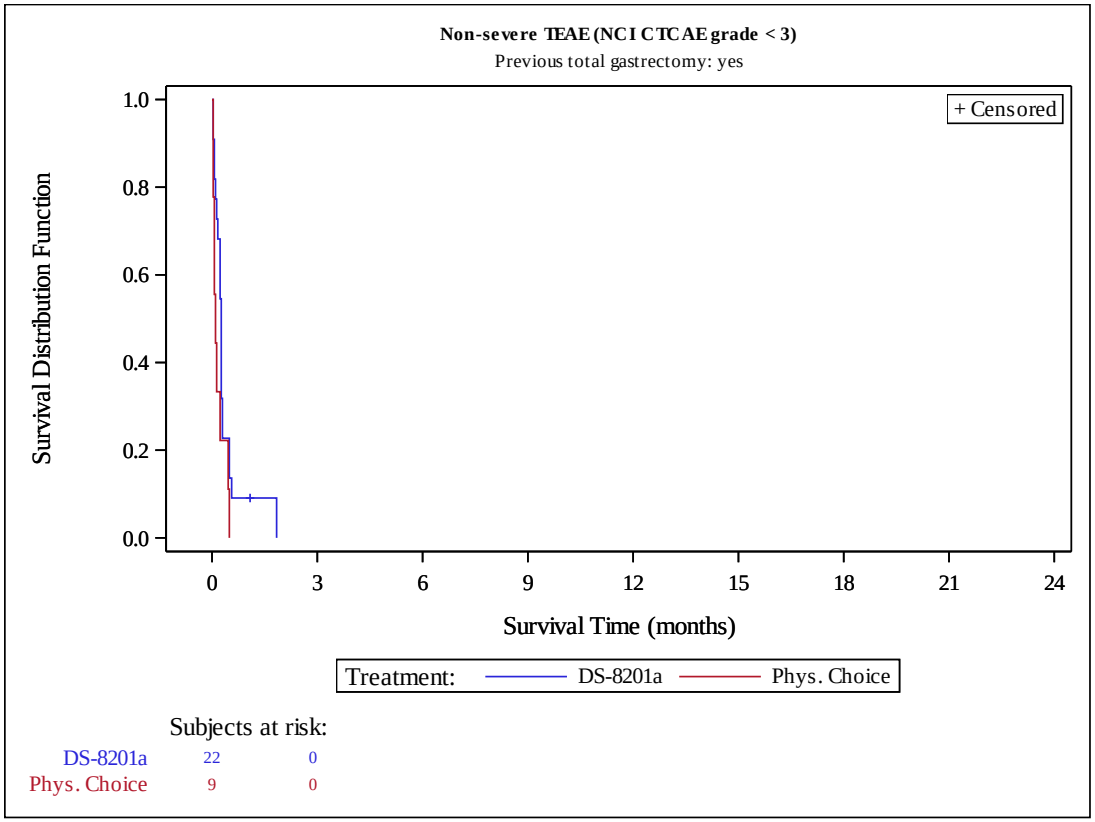
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

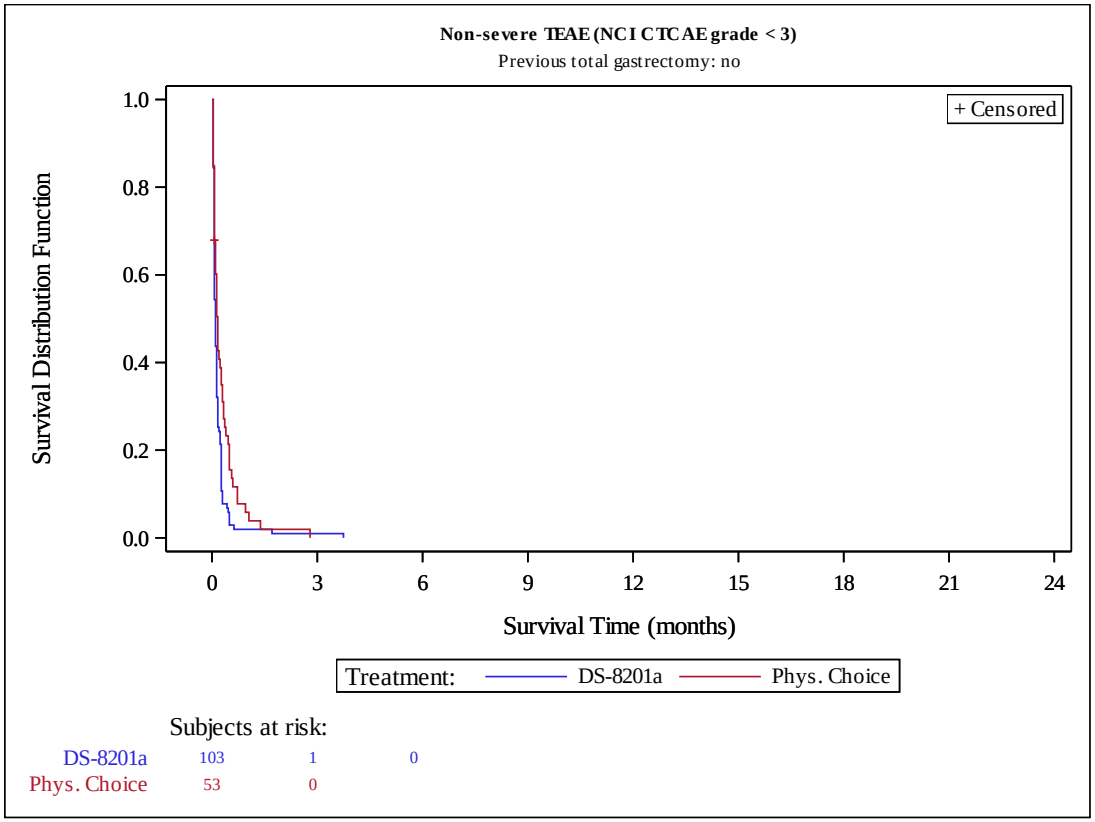
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

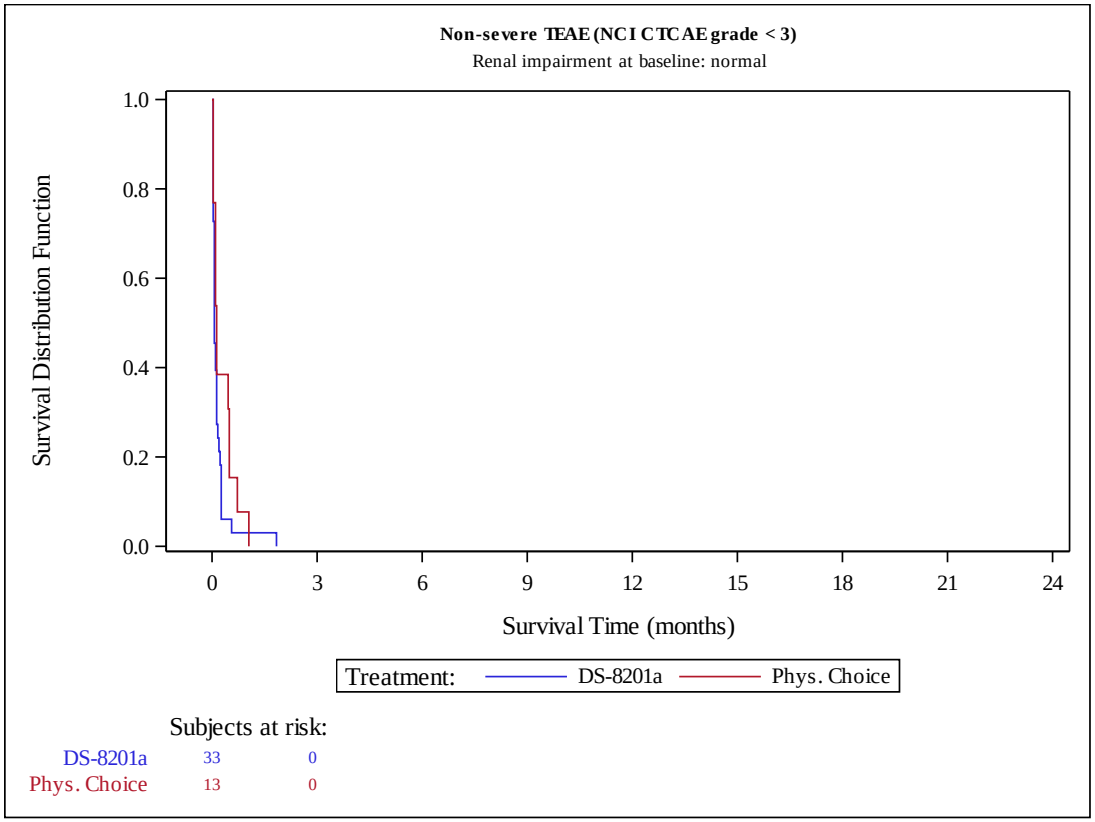
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

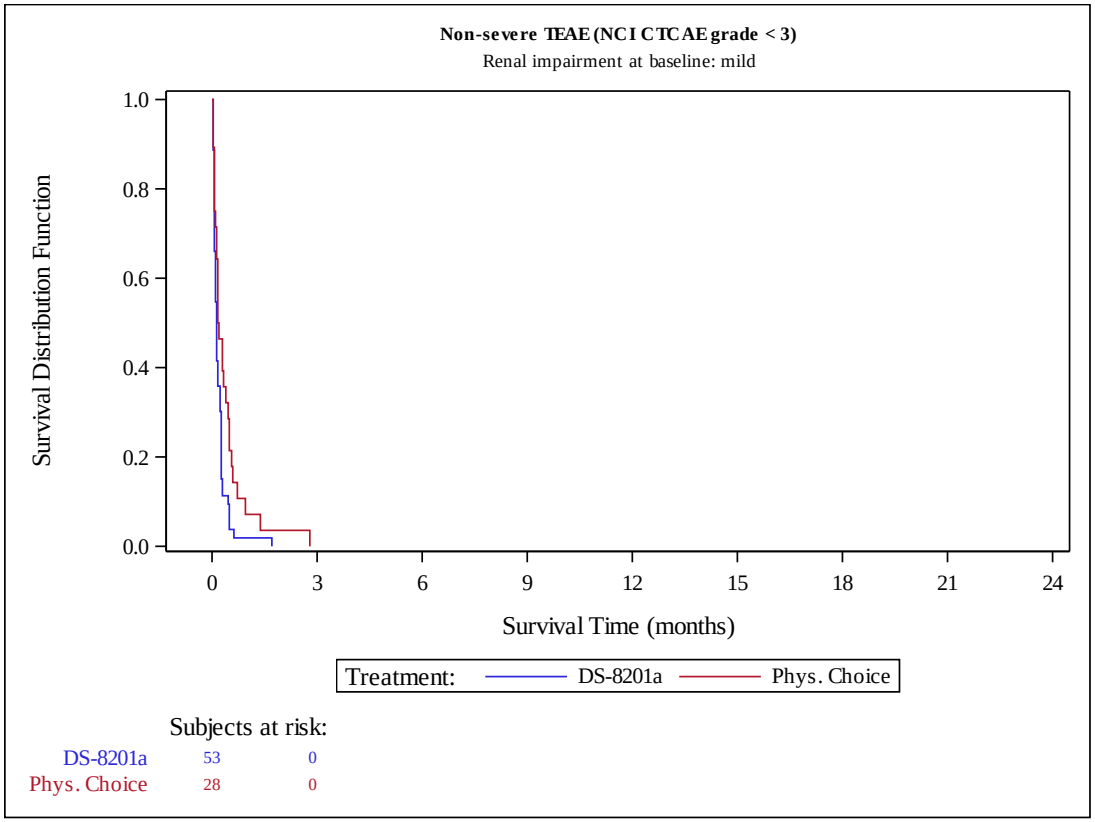
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

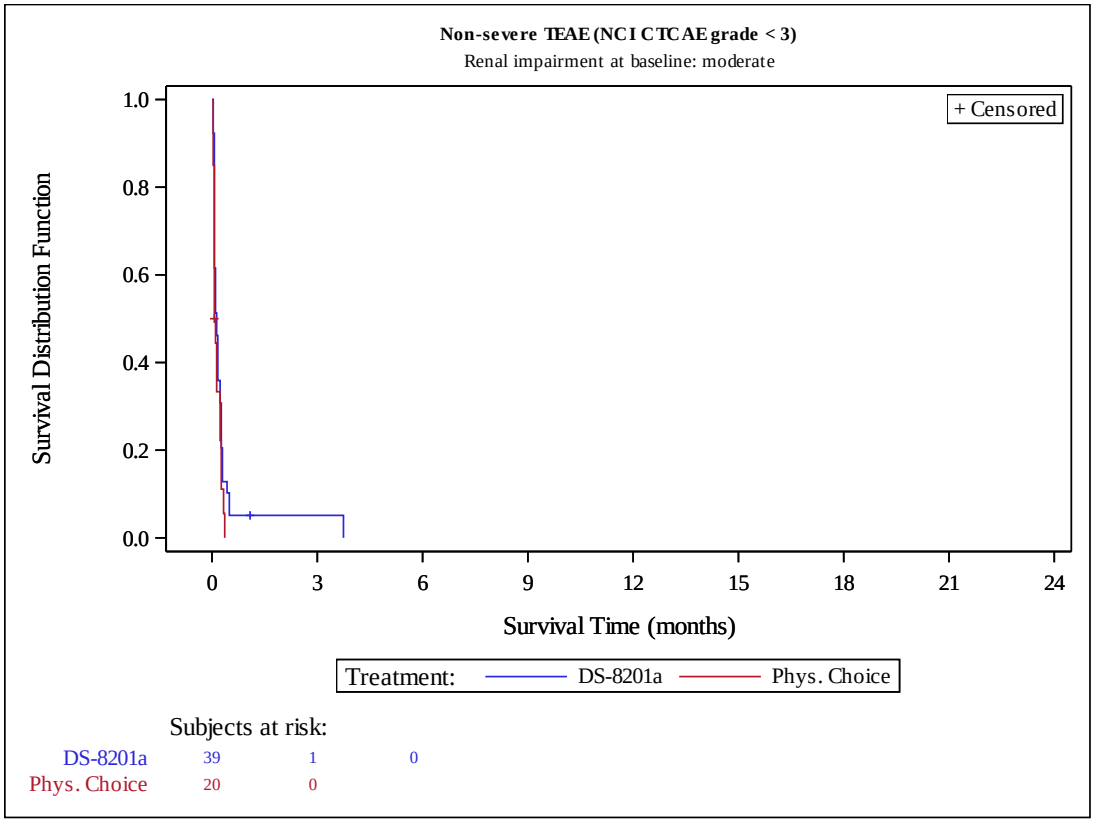
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set

For <<Renal impairment at baseline: severe>> there is only one subject, hence no Kaplan Meier Plot is produced.

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	19 (15.2)	4 (6.5)
Number of censored subjects, n (%)	106 (84.8)	58 (93.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.21 (0.40, 3.63)	
p-value [c]	0.7372	
Relative Risk (95% CI) [d]	2.36 (0.84, 6.63)	
p-value	0.1044	
Odds Ratio (95% CI) [d]	2.60 (0.84, 8.00)	
p-value	0.0960	
Risk Difference (95% CI) [e]	8.75 (-1.23, 18.73)	
p-value	0.0858	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.8418
Japan	14/ 99 (14.1)	NE (NE , NE)	3/ 50 (6.0)	NE (NE , NE)	1.42 (0.40, 5.02)	0.5798	
Korea	5/ 26 (19.2)	10.4 (7.5, NE)	1/ 12 (8.3)	NE (4.5, NE)	0.53 (0.05, 5.99)	0.6034	
Lines of prior systemic therapy							0.5384
2	11/ 66 (16.7)	NE (7.5, NE)	2/ 38 (5.3)	NE (4.5, NE)	1.94 (0.42, 8.86)	0.3877	
3	5/ 34 (14.7)	NE (7.6, NE)	2/ 18 (11.1)	NE (3.0, NE)	0.61 (0.11, 3.52)	0.5814	
>=4	3/ 25 (12.0)	NE (10.4, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9919
<65 years	5/ 55 (9.1)	NE (10.4, NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	14/ 70 (20.0)	NE (10.4, NE)	4/ 35 (11.4)	NE (4.5, NE)	1.10 (0.36, 3.38)	0.8743	
Sex							0.6758
female	6/ 30 (20.0)	NE (5.8, NE)	1/ 15 (6.7)	NE (3.0, NE)	2.26 (0.27, 18.95)	0.4400	
male	13/ 95 (13.7)	NE (10.4, NE)	3/ 47 (6.4)	NE (NE , NE)	0.95 (0.26, 3.46)	0.9377	
ECOG PS							0.6095
0	8/ 62 (12.9)	NE (NE , NE)	2/ 30 (6.7)	NE (4.5, NE)	0.91 (0.19, 4.42)	0.9115	
1	11/ 63 (17.5)	NE (10.4, NE)	2/ 32 (6.3)	NE (NE , NE)	1.51 (0.32, 7.17)	0.5996	
HER2 Status in central laboratory							0.6273
IHC 3+	14/ 96 (14.6)	NE (10.4, NE)	3/ 47 (6.4)	NE (NE , NE)	0.96 (0.27, 3.42)	0.9446	
IHC 2+/ISH +	5/ 29 (17.2)	NE (6.7, NE)	1/ 15 (6.7)	NE (3.0, NE)	2.31 (0.27, 19.87)	0.4322	
Primary tumor location							0.9999
Gastric	19/108 (17.6)	NE (10.4, NE)	4/ 55 (7.3)	NE (NE , NE)	1.29 (0.43, 3.88)	0.6461	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.9999
intestinal	13/ 89 (14.6)	NE (NE , NE)	3/ 38 (7.9)	NE (4.5, NE)	1.09 (0.31, 3.92)	0.8903	
diffuse	5/ 28 (17.9)	10.4 (6.7, NE)	1/ 18 (5.6)	NE (2.8, NE)	0.71 (0.07, 7.18)	0.7773	
others	1/ 8 (12.5)	NE (1.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.7012
<2	3/ 24 (12.5)	NE (7.5, NE)	1/ 10 (10.0)	NE (2.8, NE)	0.79 (0.08, 7.67)	0.8348	
>= 2	16/101 (15.8)	NE (NE , NE)	3/ 52 (5.8)	NE (NE , NE)	1.44 (0.41, 5.07)	0.5651	
Previous total gastrectomy							0.9918
yes	7/ 22 (31.8)	10.4 (7.6, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	12/103 (11.7)	NE (NE , NE)	4/ 53 (7.5)	NE (NE , NE)	0.84 (0.27, 2.65)	0.7634	
Prior adjuvant/ neoadjuvant therapy							0.9905
yes	5/ 30 (16.7)	NE (10.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	14/ 95 (14.7)	NE (NE , NE)	4/ 52 (7.7)	NE (NE , NE)	1.07 (0.34, 3.33)	0.9052	
Prior ramucirumab contained treatment							0.2933
yes	12/ 94 (12.8)	NE (NE , NE)	3/ 41 (7.3)	NE (NE , NE)	0.84 (0.23, 3.08)	0.7896	
no	7/ 31 (22.6)	NE (6.7, NE)	1/ 21 (4.8)	NE (NE , NE)	2.72 (0.33, 22.81)	0.3380	
Prior nivolumab contained treatment							0.9258
yes	6/ 33 (18.2)	NE (NE , NE)	1/ 15 (6.7)	NE (3.0, NE)	1.48 (0.17, 12.66)	0.7204	
no	13/ 92 (14.1)	NE (10.4, NE)	3/ 47 (6.4)	NE (NE , NE)	1.14 (0.32, 4.10)	0.8475	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

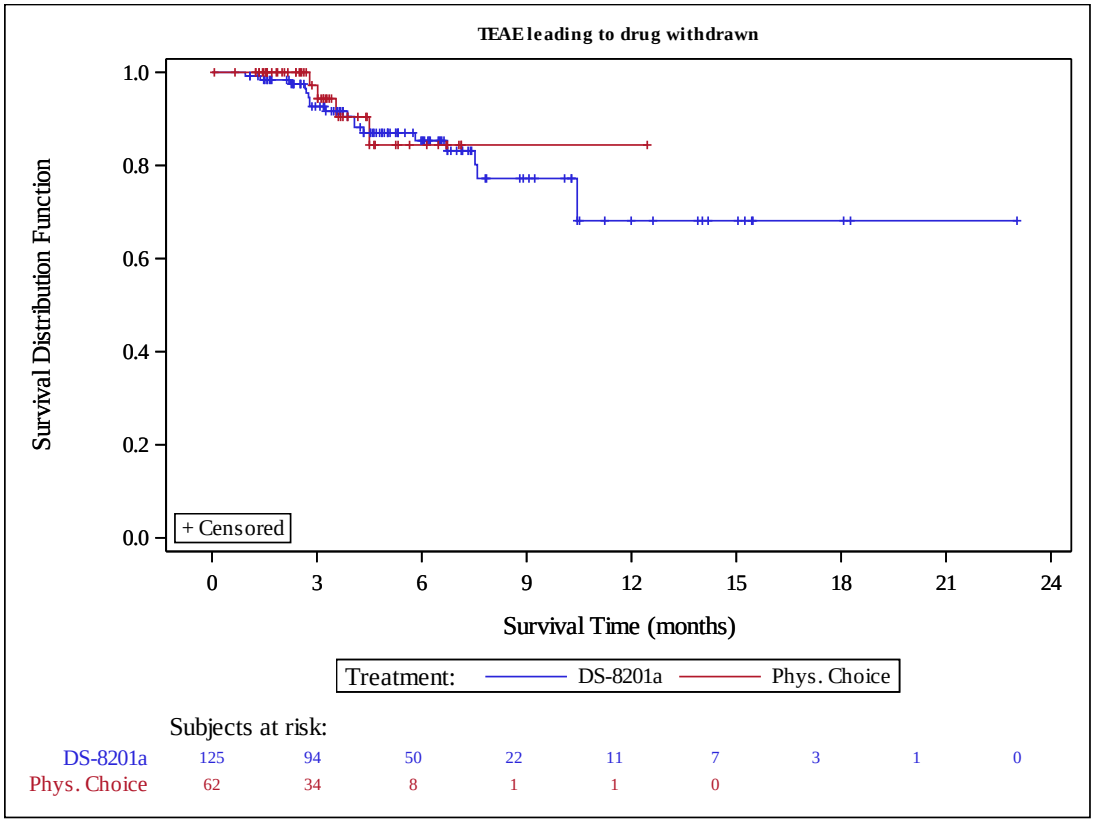
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9724
yes	8/ 44 (18.2)	NE (10.4, NE)	1/ 17 (5.9)	NE (3.0, NE)	1.27 (0.15, 10.84)	0.8250	
no	11/ 81 (13.6)	NE (7.6, NE)	3/ 45 (6.7)	NE (NE , NE)	1.18 (0.32, 4.33)	0.7974	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.3939
yes	2/ 22 (9.1)	NE (6.7, NE)	1/ 7 (14.3)	NE (2.8, NE)	0.50 (0.04, 5.65)	0.5773	
no	17/103 (16.5)	NE (10.4, NE)	3/ 55 (5.5)	NE (NE , NE)	1.48 (0.42, 5.17)	0.5397	
Presence of liver metastasis at baseline							0.7039
yes	8/ 67 (11.9)	NE (NE , NE)	2/ 34 (5.9)	NE (4.5, NE)	0.98 (0.20, 4.77)	0.9815	
no	11/ 58 (19.0)	NE (10.4, NE)	2/ 28 (7.1)	NE (NE , NE)	1.55 (0.33, 7.20)	0.5717	
Renal impairment at baseline							0.5948
normal	3/ 33 (9.1)	NE (10.4, NE)	1/ 13 (7.7)	NE (2.8, NE)	0.67 (0.06, 7.42)	0.7441	
mild	8/ 53 (15.1)	NE (7.6, NE)	1/ 28 (3.6)	NE (NE , NE)	1.96 (0.24, 15.81)	0.5181	
moderate	8/ 39 (20.5)	NE (7.5, NE)	2/ 20 (10.0)	NE (4.5, NE)	1.31 (0.26, 6.54)	0.7422	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7348
normal	13/ 88 (14.8)	NE (NE , NE)	3/ 47 (6.4)	NE (NE , NE)	1.03 (0.28, 3.71)	0.9703	
mild	6/ 36 (16.7)	NE (10.4, NE)	1/ 15 (6.7)	NE (2.8, NE)	1.74 (0.20, 15.01)	0.6080	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9917
yes	3/ 8 (37.5)	NE (2.7, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	16/117 (13.7)	NE (10.4, NE)	4/ 57 (7.0)	NE (NE , NE)	0.98 (0.32, 3.02)	0.9657	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9917
yes	2/ 3 (66.7)	7.5 (6.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	17/122 (13.9)	NE (NE , NE)	4/ 58 (6.9)	NE (NE , NE)	1.03 (0.34, 3.15)	0.9625	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE leading to drug withdrawn
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to death
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	8 (6.4)	2 (3.2)
Number of censored subjects, n (%)	117 (93.6)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.27 (0.27, 6.13)	
p-value [c]	0.7611	
Relative Risk (95% CI) [d]	1.98 (0.43, 9.06)	
p-value	0.3768	
Odds Ratio (95% CI) [d]	2.05 (0.42, 9.96)	
p-value	0.3729	
Risk Difference (95% CI) [e]	3.17 (-4.18, 10.52)	
p-value	0.3974	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to death - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.3897
Japan	6/ 99 (6.1)	NE (NE , NE)	1/ 50 (2.0)	NE (NE , NE)	2.04 (0.24, 17.28)	0.5055	
Korea	2/ 26 (7.7)	NE (NE , NE)	1/ 12 (8.3)	NE (3.6, NE)	0.58 (0.05, 6.47)	0.6537	
Lines of prior systemic therapy							1.0000
2	7/ 66 (10.6)	NE (10.3, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (3.6, NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	1/ 6 (16.7)	NE (2.0, NE)	0.18 (0.01, 2.84)	0.1680	
Age							0.9932
<65 years	4/ 55 (7.3)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	4/ 70 (5.7)	NE (NE , NE)	2/ 35 (5.7)	NE (NE , NE)	0.70 (0.13, 3.86)	0.6818	
Sex							0.9923
female	3/ 30 (10.0)	NE (10.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	5/ 95 (5.3)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.79 (0.15, 4.08)	0.7760	
ECOG PS							0.6671
0	3/ 62 (4.8)	NE (NE , NE)	1/ 30 (3.3)	NE (NE , NE)	0.86 (0.09, 8.74)	0.9018	
1	5/ 63 (7.9)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	1.92 (0.22, 16.47)	0.5459	
HER2 Status in central laboratory							0.9930
IHC 3+	4/ 96 (4.2)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.47 (0.08, 2.70)	0.3867	
IHC 2+/ISH +	4/ 29 (13.8)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9949
Gastric	7/108 (6.5)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	1.13 (0.23, 5.56)	0.8823	
GEJ	1/ 17 (5.9)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.6197
intestinal	6/ 89 (6.7)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	1.82 (0.21, 15.35)	0.5782	
diffuse	1/ 28 (3.6)	NE (NE , NE)	1/ 18 (5.6)	NE (3.6, NE)	0.27 (0.02, 4.32)	0.3211	
others	1/ 8 (12.5)	NE (1.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	8/101 (7.9)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.25 (0.26, 6.04)	0.7849	
Previous total gastrectomy							0.2247
yes	1/ 22 (4.5)	NE (NE , NE)	1/ 9 (11.1)	NE (3.6, NE)	0.19 (0.01, 3.10)	0.1934	
no	7/103 (6.8)	NE (NE , NE)	1/ 53 (1.9)	NE (NE , NE)	2.44 (0.29, 20.15)	0.3931	
Prior adjuvant/ neoadjuvant therapy							0.9943
yes	1/ 30 (3.3)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 95 (7.4)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.23 (0.25, 6.07)	0.7969	
Prior ramucirumab contained treatment							0.7778
yes	6/ 94 (6.4)	NE (NE , NE)	1/ 41 (2.4)	NE (NE , NE)	1.91 (0.23, 15.97)	0.5426	
no	2/ 31 (6.5)	NE (10.3, NE)	1/ 21 (4.8)	NE (NE , NE)	0.67 (0.06, 7.90)	0.7477	
Prior nivolumab contained treatment							0.9923
yes	1/ 33 (3.0)	NE (NE , NE)	2/ 15 (13.3)	NE (3.6, NE)	0.15 (0.01, 1.66)	0.0744	
no	7/ 92 (7.6)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

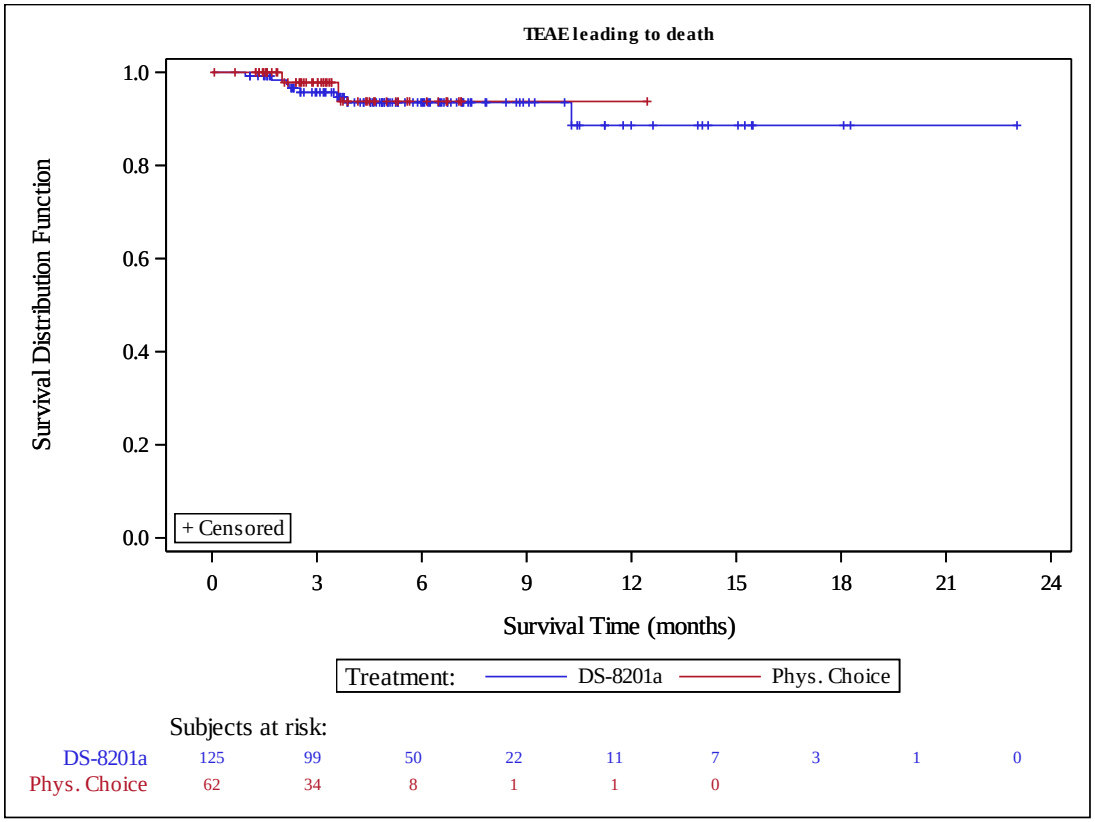
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to death - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9918
yes	1/ 44 (2.3)	NE (NE , NE)	2/ 17 (11.8)	NE (3.6, NE)	0.13 (0.01, 1.48)	0.0545	
no	7/ 81 (8.6)	NE (10.3, NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9948
yes	3/ 22 (13.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	5/103 (4.9)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	0.78 (0.15, 4.21)	0.7757	
Presence of liver metastasis at baseline							0.9930
yes	5/ 67 (7.5)	NE (NE , NE)	2/ 34 (5.9)	NE (NE , NE)	0.62 (0.11, 3.39)	0.5732	
no	3/ 58 (5.2)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							0.9906
normal	3/ 33 (9.1)	NE (10.3, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 53 (5.7)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	1.01 (0.10, 9.69)	0.9963	
moderate	2/ 39 (5.1)	NE (NE , NE)	1/ 20 (5.0)	NE (3.6, NE)	0.89 (0.08, 9.97)	0.9242	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7116
normal	5/ 88 (5.7)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	1.52 (0.17, 13.49)	0.7051	
mild	3/ 36 (8.3)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	1.00 (0.10, 9.67)	0.9996	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9925
yes	0/ 8 (0.0)	NE (NE , NE)	1/ 5 (20.0)	NE (2.0, NE)	NE	NE	
no	8/117 (6.8)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	2.39 (0.29, 19.54)	0.4027	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							1.0000
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	8/122 (6.6)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	1.17 (0.24, 5.68)	0.8458	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE leading to death
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	2 (1.6)	10 (16.1)
Number of censored subjects, n (%)	123 (98.4)	52 (83.9)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	0.08 (0.02, 0.39)	
p-value [c]	<.0001	
Relative Risk (95% CI) [d]	0.10 (0.02, 0.44)	
p-value	0.0023	
Odds Ratio (95% CI) [d]	0.08 (0.02, 0.40)	
p-value	0.0018	
Risk Difference (95% CI) [e]	-14.53 (-25.15, -3.91)	
p-value	0.0073	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9935
Japan	2/ 99 (2.0)	NE (NE , NE)	7/ 50 (14.0)	NE (NE , NE)	0.12 (0.03, 0.60)	0.0021	
Korea	0/ 26 (0.0)	NE (NE , NE)	3/ 12 (25.0)	NE (0.4, NE)	NE	NE	
Lines of prior systemic therapy							0.9496
2	1/ 66 (1.5)	NE (NE , NE)	6/ 38 (15.8)	NE (NE , NE)	0.08 (0.01, 0.69)	0.0032	
3	1/ 34 (2.9)	NE (NE , NE)	3/ 18 (16.7)	NE (NE , NE)	0.17 (0.02, 1.59)	0.0753	
>=4	0/ 25 (0.0)	NE (NE , NE)	1/ 6 (16.7)	NE (0.1, NE)	NE	NE	
Age							0.9933
<65 years	0/ 55 (0.0)	NE (NE , NE)	6/ 27 (22.2)	NE (NE , NE)	NE	NE	
>=65 years	2/ 70 (2.9)	NE (NE , NE)	4/ 35 (11.4)	NE (NE , NE)	0.21 (0.04, 1.14)	0.0465	
Sex							0.8370
female	1/ 30 (3.3)	NE (NE , NE)	4/ 15 (26.7)	NE (0.1, NE)	0.11 (0.01, 0.99)	0.0170	
male	1/ 95 (1.1)	NE (NE , NE)	6/ 47 (12.8)	NE (NE , NE)	0.07 (0.01, 0.56)	0.0010	
ECOG PS							0.5250
0	1/ 62 (1.6)	NE (NE , NE)	7/ 30 (23.3)	NE (NE , NE)	0.05 (0.01, 0.43)	0.0002	
1	1/ 63 (1.6)	NE (NE , NE)	3/ 32 (9.4)	NE (NE , NE)	0.16 (0.02, 1.55)	0.0705	
HER2 Status in central laboratory							0.9942
IHC 3+	2/ 96 (2.1)	NE (NE , NE)	8/ 47 (17.0)	NE (NE , NE)	0.10 (0.02, 0.47)	0.0004	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9994
Gastric	2/108 (1.9)	NE (NE , NE)	10/ 55 (18.2)	NE (NE , NE)	0.08 (0.02, 0.39)	<.0001	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.9873
intestinal	1/ 89 (1.1)	NE (NE , NE)	4/ 38 (10.5)	NE (NE , NE)	0.10 (0.01, 0.93)	0.0127	
diffuse	1/ 28 (3.6)	NE (NE , NE)	4/ 18 (22.2)	NE (0.5, NE)	0.09 (0.01, 0.93)	0.0161	
others	0/ 8 (0.0)	NE (NE , NE)	2/ 6 (33.3)	NE (0.0, NE)	NE	NE	
Number of metastatic sites							0.4625
<2	1/ 24 (4.2)	NE (NE , NE)	2/ 10 (20.0)	NE (0.1, NE)	0.20 (0.02, 2.17)	0.1396	
>= 2	1/101 (1.0)	NE (NE , NE)	8/ 52 (15.4)	NE (NE , NE)	0.05 (0.01, 0.42)	0.0001	
Previous total gastrectomy							0.9949
yes	0/ 22 (0.0)	NE (NE , NE)	1/ 9 (11.1)	NE (0.1, NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	9/ 53 (17.0)	NE (NE , NE)	0.10 (0.02, 0.45)	0.0002	
Prior adjuvant/ neoadjuvant therapy							0.9996
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 95 (2.1)	NE (NE , NE)	10/ 52 (19.2)	NE (NE , NE)	0.09 (0.02, 0.42)	0.0001	
Prior ramucirumab contained treatment							0.9945
yes	2/ 94 (2.1)	NE (NE , NE)	9/ 41 (22.0)	NE (NE , NE)	0.08 (0.02, 0.36)	<.0001	
no	0/ 31 (0.0)	NE (NE , NE)	1/ 21 (4.8)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9948
yes	0/ 33 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
no	2/ 92 (2.2)	NE (NE , NE)	9/ 47 (19.1)	NE (NE , NE)	0.10 (0.02, 0.44)	0.0002	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

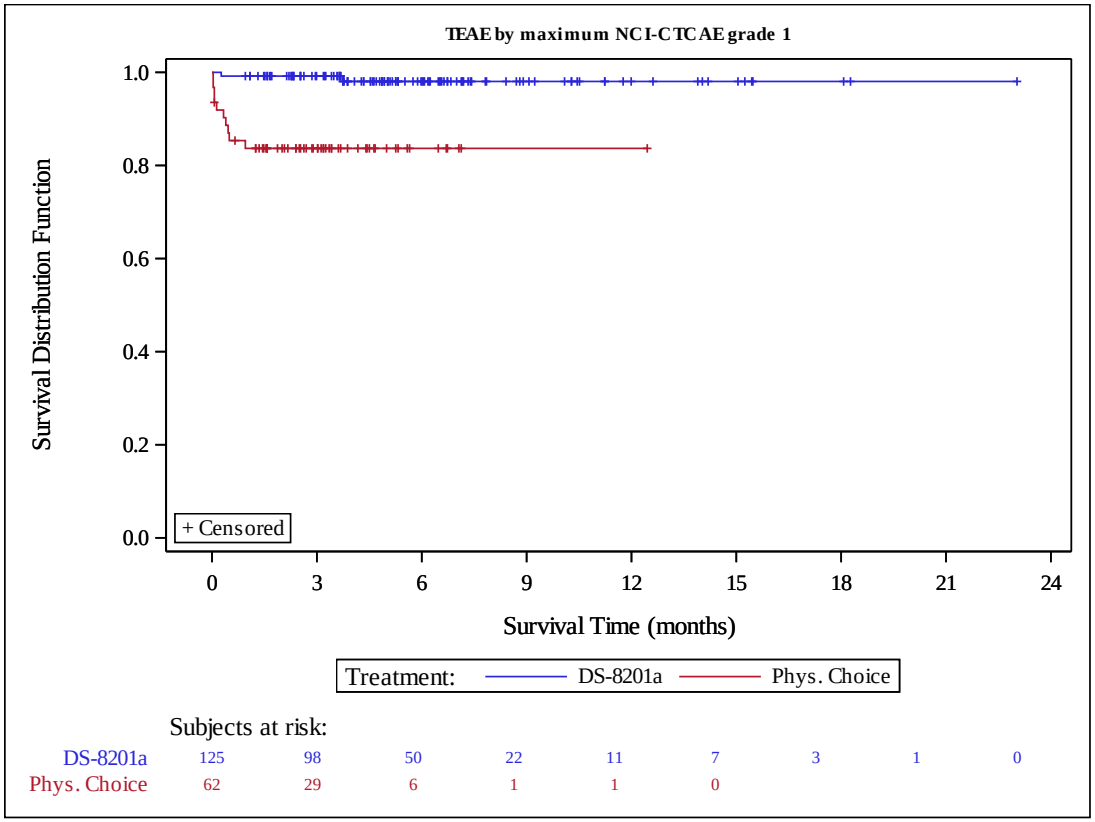
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9944
yes	0/ 44 (0.0)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	NE	NE	
no	2/ 81 (2.5)	NE (NE , NE)	9/ 45 (20.0)	NE (NE , NE)	0.10 (0.02, 0.48)	0.0004	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9948
yes	0/ 22 (0.0)	NE (NE , NE)	1/ 7 (14.3)	NE (0.4, NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	9/ 55 (16.4)	NE (NE , NE)	0.10 (0.02, 0.46)	0.0003	
Presence of liver metastasis at baseline							0.8447
yes	1/ 67 (1.5)	NE (NE , NE)	6/ 34 (17.6)	NE (NE , NE)	0.08 (0.01, 0.65)	0.0024	
no	1/ 58 (1.7)	NE (NE , NE)	4/ 28 (14.3)	NE (NE , NE)	0.09 (0.01, 0.86)	0.0100	
Renal impairment at baseline							0.9598
normal	0/ 33 (0.0)	NE (NE , NE)	3/ 13 (23.1)	NE (0.5, NE)	NE	NE	
mild	1/ 53 (1.9)	NE (NE , NE)	3/ 28 (10.7)	NE (NE , NE)	0.17 (0.02, 1.63)	0.0809	
moderate	1/ 39 (2.6)	NE (NE , NE)	4/ 20 (20.0)	NE (NE , NE)	0.09 (0.01, 0.85)	0.0098	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.2367
normal	1/ 88 (1.1)	NE (NE , NE)	9/ 47 (19.1)	NE (NE , NE)	0.05 (0.01, 0.37)	<.0001	
mild	1/ 36 (2.8)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.40 (0.03, 6.44)	0.5056	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9995
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	2/117 (1.7)	NE (NE , NE)	10/ 57 (17.5)	NE (NE , NE)	0.08 (0.02, 0.37)	<.0001	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9993
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	2/122 (1.6)	NE (NE , NE)	10/ 58 (17.2)	NE (NE , NE)	0.08 (0.02, 0.36)	<.0001	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	16 (12.8)	16 (25.8)
Number of censored subjects, n (%)	109 (87.2)	46 (74.2)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	8.0 (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	0.37 (0.18, 0.76)	
p-value [c]	0.0046	
Relative Risk (95% CI) [d]	0.50 (0.27, 0.92)	
p-value	0.0273	
Odds Ratio (95% CI) [d]	0.42 (0.19, 0.92)	
p-value	0.0289	
Risk Difference (95% CI) [e]	-13.01 (-26.58, 0.57)	
p-value	0.0604	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.7475
Japan	13/ 99 (13.1)	NE (NE , NE)	14/ 50 (28.0)	8.0 (NE , NE)	0.34 (0.16, 0.75)	0.0051	
Korea	3/ 26 (11.5)	NE (NE , NE)	2/ 12 (16.7)	NE (0.3, NE)	0.54 (0.09, 3.26)	0.4917	
Lines of prior systemic therapy							0.8175
2	9/ 66 (13.6)	NE (NE , NE)	10/ 38 (26.3)	8.0 (NE , NE)	0.41 (0.16, 1.04)	0.0519	
3	4/ 34 (11.8)	NE (NE , NE)	5/ 18 (27.8)	NE (1.1, NE)	0.34 (0.09, 1.28)	0.0953	
>=4	3/ 25 (12.0)	NE (6.9, NE)	1/ 6 (16.7)	NE (0.1, NE)	0.52 (0.05, 5.04)	0.5619	
Age							0.4029
<65 years	3/ 55 (5.5)	NE (NE , NE)	5/ 27 (18.5)	NE (NE , NE)	0.26 (0.06, 1.09)	0.0467	
>=65 years	13/ 70 (18.6)	NE (NE , NE)	11/ 35 (31.4)	8.0 (NE , NE)	0.42 (0.18, 0.97)	0.0361	
Sex							0.4418
female	3/ 30 (10.0)	NE (NE , NE)	5/ 15 (33.3)	NE (0.3, NE)	0.27 (0.07, 1.15)	0.0555	
male	13/ 95 (13.7)	NE (NE , NE)	11/ 47 (23.4)	8.0 (NE , NE)	0.42 (0.18, 0.96)	0.0334	
ECOG PS							0.3114
0	11/ 62 (17.7)	NE (NE , NE)	8/ 30 (26.7)	8.0 (NE , NE)	0.47 (0.18, 1.20)	0.1067	
1	5/ 63 (7.9)	NE (NE , NE)	8/ 32 (25.0)	NE (NE , NE)	0.27 (0.09, 0.83)	0.0147	
HER2 Status in central laboratory							0.7678
IHC 3+	12/ 96 (12.5)	NE (NE , NE)	12/ 47 (25.5)	8.0 (NE , NE)	0.34 (0.15, 0.79)	0.0083	
IHC 2+/ISH +	4/ 29 (13.8)	NE (NE , NE)	4/ 15 (26.7)	NE (0.5, NE)	0.46 (0.11, 1.86)	0.2642	
Primary tumor location							0.3540
Gastric	14/108 (13.0)	NE (NE , NE)	13/ 55 (23.6)	8.0 (NE , NE)	0.40 (0.19, 0.88)	0.0186	
GEJ	2/ 17 (11.8)	NE (NE , NE)	3/ 7 (42.9)	NE (0.0, NE)	0.25 (0.04, 1.49)	0.0994	
Histological subtype							0.4032
intestinal	14/ 89 (15.7)	NE (NE , NE)	10/ 38 (26.3)	8.0 (NE , NE)	0.44 (0.19, 1.02)	0.0490	
diffuse	2/ 28 (7.1)	NE (NE , NE)	6/ 18 (33.3)	NE (0.3, NE)	0.17 (0.03, 0.84)	0.0139	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.6917
<2	3/ 24 (12.5)	NE (NE , NE)	2/ 10 (20.0)	8.0 (0.3, 8.0)	0.48 (0.08, 2.94)	0.4207	
>= 2	13/101 (12.9)	NE (NE , NE)	14/ 52 (26.9)	NE (NE , NE)	0.37 (0.17, 0.80)	0.0087	
Previous total gastrectomy							0.2716
yes	5/ 22 (22.7)	NE (4.9, NE)	2/ 9 (22.2)	NE (0.5, NE)	0.64 (0.12, 3.44)	0.6157	
no	11/103 (10.7)	NE (NE , NE)	14/ 53 (26.4)	8.0 (NE , NE)	0.32 (0.14, 0.72)	0.0038	
Prior adjuvant/ neoadjuvant therapy							0.3540
yes	7/ 30 (23.3)	NE (6.9, NE)	3/ 10 (30.0)	NE (0.0, NE)	0.54 (0.14, 2.12)	0.3627	
no	9/ 95 (9.5)	NE (NE , NE)	13/ 52 (25.0)	8.0 (NE , NE)	0.29 (0.12, 0.71)	0.0037	
Prior ramucirumab contained treatment							0.3423
yes	13/ 94 (13.8)	NE (NE , NE)	9/ 41 (22.0)	NE (NE , NE)	0.48 (0.20, 1.14)	0.0902	
no	3/ 31 (9.7)	NE (NE , NE)	7/ 21 (33.3)	8.0 (1.4, 8.0)	0.21 (0.05, 0.84)	0.0159	
Prior nivolumab contained treatment							0.0367
yes	2/ 33 (6.1)	NE (NE , NE)	6/ 15 (40.0)	NE (0.1, NE)	0.06 (0.01, 0.51)	0.0005	
no	14/ 92 (15.2)	NE (NE , NE)	10/ 47 (21.3)	8.0 (NE , NE)	0.57 (0.25, 1.31)	0.1836	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

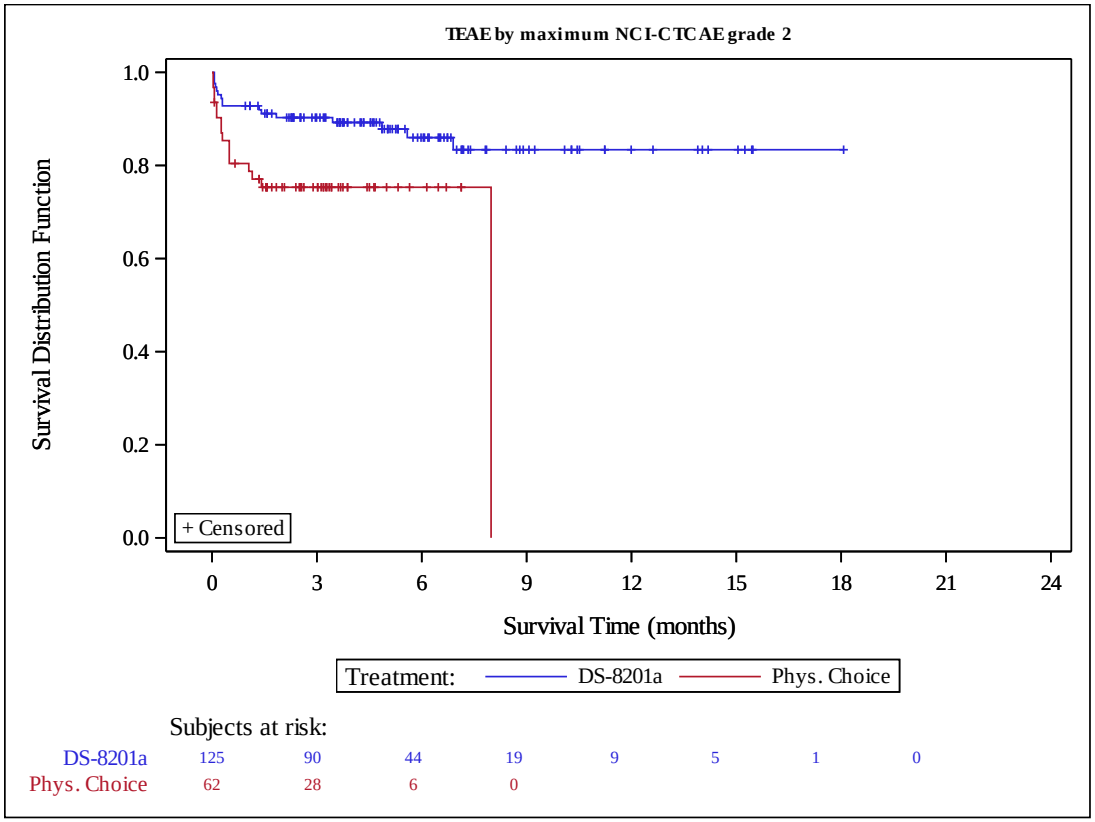
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0057
yes	3/ 44 (6.8)	NE (NE , NE)	8/ 17 (47.1)	NE (0.1, NE)	0.07 (0.02, 0.35)	<.0001	
no	13/ 81 (16.0)	NE (NE , NE)	8/ 45 (17.8)	8.0 (NE , NE)	0.74 (0.30, 1.82)	0.5128	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9946
yes	3/ 22 (13.6)	NE (NE , NE)	2/ 7 (28.6)	NE (0.3, NE)	0.46 (0.08, 2.78)	0.4049	
no	13/103 (12.6)	NE (NE , NE)	14/ 55 (25.5)	8.0 (NE , NE)	0.35 (0.16, 0.77)	0.0064	
Presence of liver metastasis at baseline							0.4989
yes	7/ 67 (10.4)	NE (NE , NE)	9/ 34 (26.5)	NE (NE , NE)	0.33 (0.12, 0.90)	0.0230	
no	9/ 58 (15.5)	NE (NE , NE)	7/ 28 (25.0)	8.0 (NE , NE)	0.45 (0.16, 1.23)	0.1087	
Renal impairment at baseline							0.3212
normal	2/ 33 (6.1)	NE (NE , NE)	4/ 13 (30.8)	NE (1.1, NE)	0.08 (0.01, 0.70)	0.0035	
mild	8/ 53 (15.1)	NE (NE , NE)	6/ 28 (21.4)	8.0 (NE , NE)	0.56 (0.19, 1.65)	0.2861	
moderate	6/ 39 (15.4)	NE (NE , NE)	6/ 20 (30.0)	NE (0.5, NE)	0.42 (0.13, 1.30)	0.1191	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.4290
normal	12/ 88 (13.6)	NE (NE , NE)	11/ 47 (23.4)	8.0 (NE , NE)	0.46 (0.20, 1.06)	0.0620	
mild	4/ 36 (11.1)	NE (NE , NE)	5/ 15 (33.3)	NE (0.3, NE)	0.23 (0.06, 0.88)	0.0204	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4052
yes	1/ 8 (12.5)	NE (4.9, NE)	3/ 5 (60.0)	8.0 (0.1, 8.0)	0.14 (0.01, 1.38)	0.0510	
no	15/117 (12.8)	NE (NE , NE)	13/ 57 (22.8)	NE (NE , NE)	0.45 (0.21, 0.97)	0.0365	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9914
yes	0/ 3 (0.0)	NE (NE , NE)	3/ 4 (75.0)	4.7 (0.1, 8.0)	NE	NE	
no	16/122 (13.1)	NE (NE , NE)	13/ 58 (22.4)	NE (NE , NE)	0.46 (0.22, 0.97)	0.0359	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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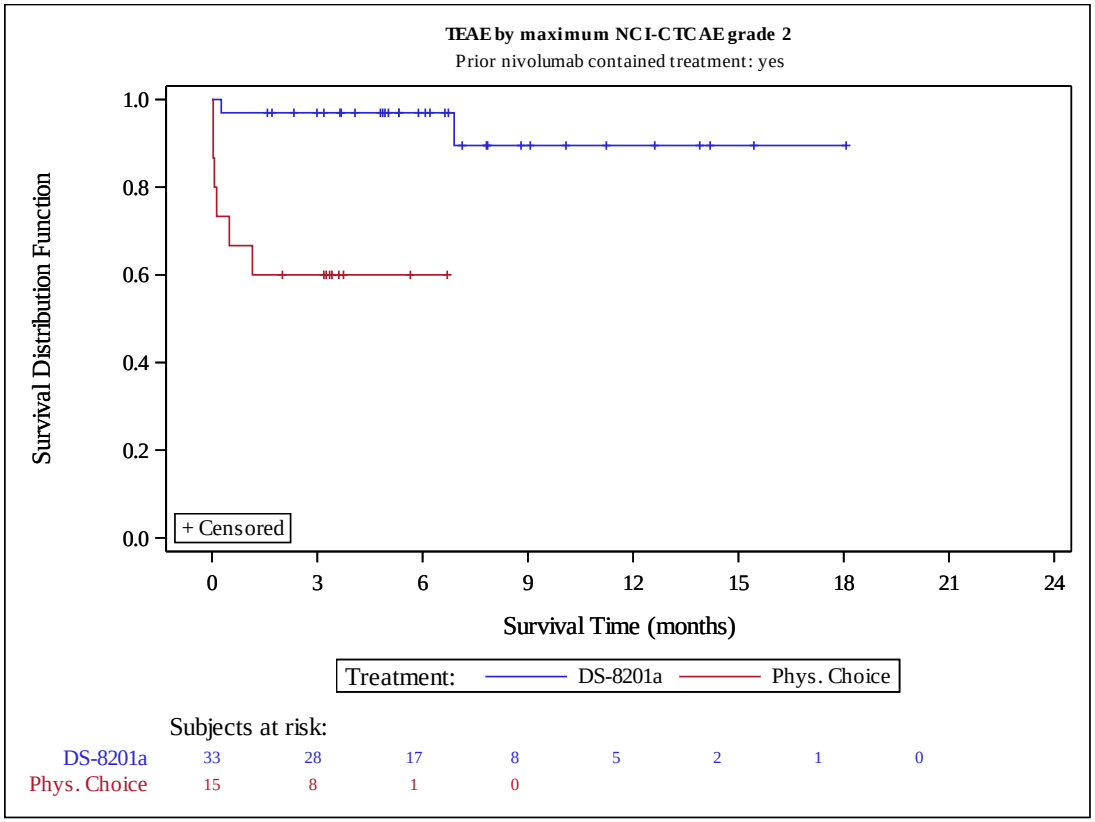
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



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Source data: ADAM.ADSL and ADAM.ADAE
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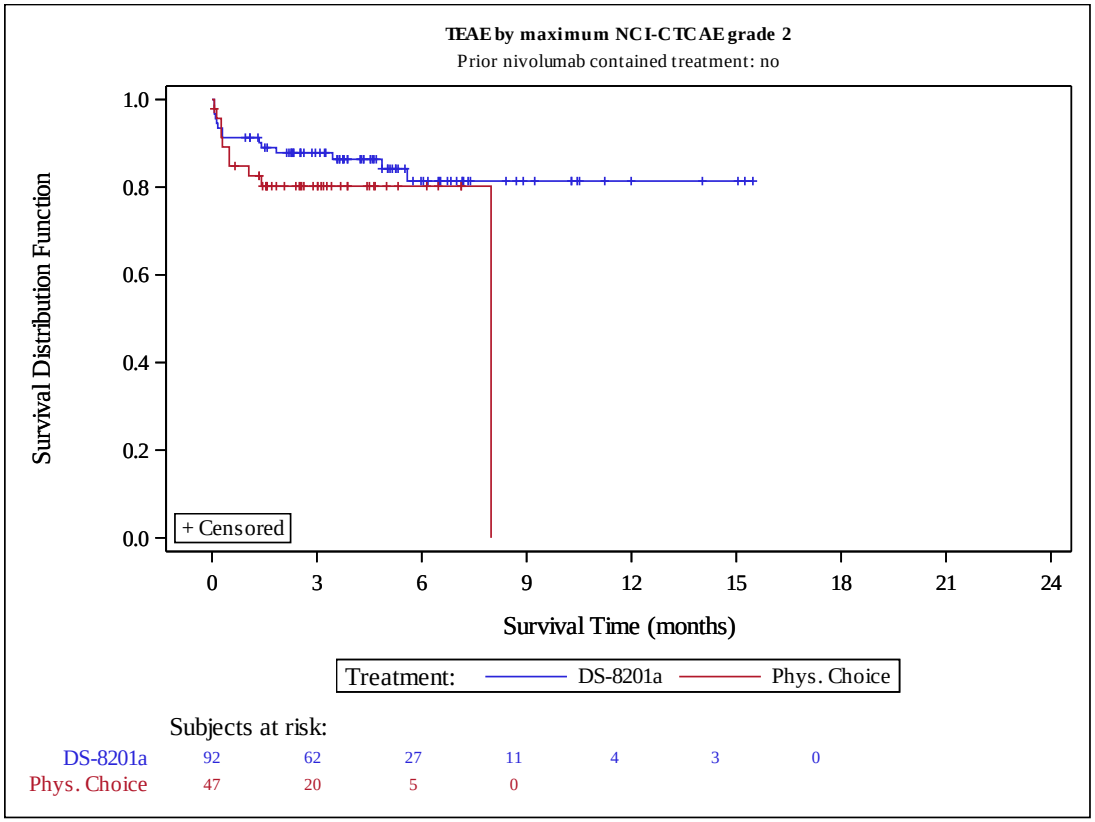
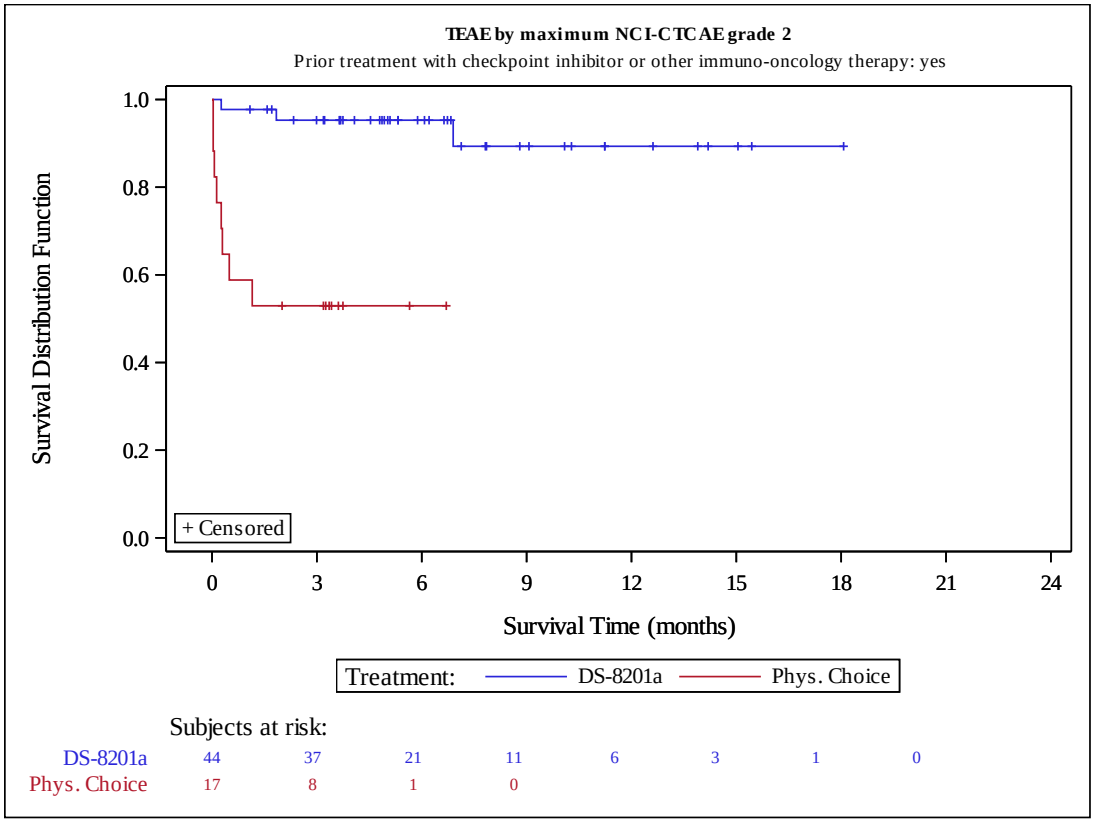
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

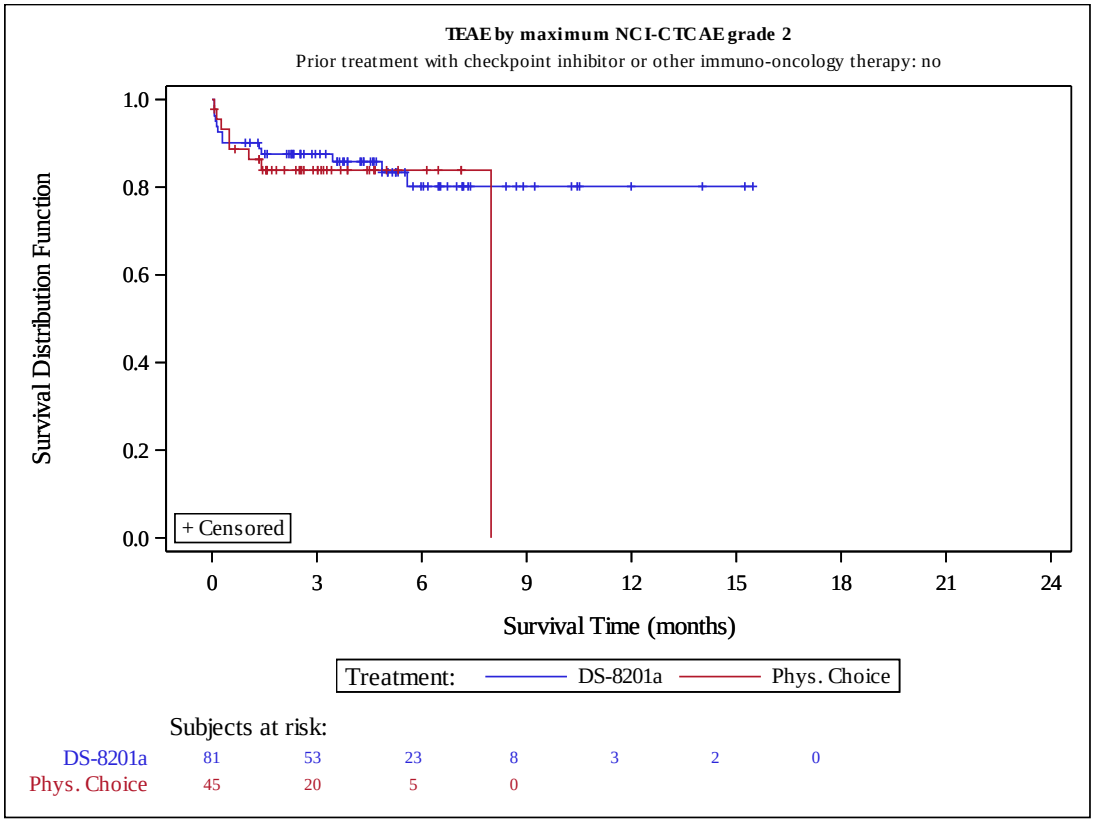
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	76 (60.8)	26 (41.9)
Number of censored subjects, n (%)	49 (39.2)	36 (58.1)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	1.8 (1.3, 4.3)	NE (1.4, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.38 (0.89, 2.17)	
p-value [c]	0.1504	
Relative Risk (95% CI) [d]	1.45 (1.05, 2.01)	
p-value	0.0251	
Odds Ratio (95% CI) [d]	2.15 (1.16, 3.99)	
p-value	0.0155	
Risk Difference (95% CI) [e]	18.86 (2.69, 35.04)	
p-value	0.0223	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.5735
Japan	59/ 99 (59.6)	2.8 (0.9, 5.6)	22/ 50 (44.0)	NE (1.2, NE)	1.29 (0.79, 2.10)	0.3177	
Korea	17/ 26 (65.4)	1.4 (0.7, NE)	4/ 12 (33.3)	NE (0.5, NE)	1.83 (0.61, 5.44)	0.2716	
Lines of prior systemic therapy							0.8842
2	40/ 66 (60.6)	2.7 (1.4, 7.7)	15/ 38 (39.5)	NE (1.2, NE)	1.43 (0.79, 2.59)	0.2393	
3	20/ 34 (58.8)	1.6 (0.5, NE)	8/ 18 (44.4)	2.7 (0.5, NE)	1.31 (0.57, 2.98)	0.5142	
>=4	16/ 25 (64.0)	1.4 (0.5, NE)	3/ 6 (50.0)	NE (0.2, NE)	1.17 (0.34, 4.03)	0.8143	
Age							0.4524
<65 years	37/ 55 (67.3)	2.8 (1.4, 4.3)	10/ 27 (37.0)	NE (0.7, NE)	1.57 (0.78, 3.19)	0.1976	
>=65 years	39/ 70 (55.7)	1.5 (0.7, NE)	16/ 35 (45.7)	3.5 (1.0, NE)	1.24 (0.69, 2.22)	0.4662	
Sex							0.3999
female	16/ 30 (53.3)	3.2 (0.7, NE)	4/ 15 (26.7)	NE (1.0, NE)	2.00 (0.67, 6.01)	0.2102	
male	60/ 95 (63.2)	1.6 (0.8, 4.3)	22/ 47 (46.8)	3.5 (0.7, NE)	1.26 (0.77, 2.05)	0.3570	
ECOG PS							0.7083
0	34/ 62 (54.8)	2.9 (1.3, NE)	11/ 30 (36.7)	NE (2.3, NE)	1.54 (0.78, 3.04)	0.2130	
1	42/ 63 (66.7)	1.4 (0.7, 3.5)	15/ 32 (46.9)	3.5 (0.5, NE)	1.25 (0.69, 2.27)	0.4417	
HER2 Status in central laboratory							0.1249
IHC 3+	59/ 96 (61.5)	1.8 (0.8, 4.2)	17/ 47 (36.2)	NE (2.3, NE)	1.69 (0.98, 2.91)	0.0547	
IHC 2+/ISH +	17/ 29 (58.6)	2.8 (0.7, NE)	9/ 15 (60.0)	1.2 (0.3, NE)	0.74 (0.32, 1.70)	0.4886	
Primary tumor location							0.9960
Gastric	65/108 (60.2)	1.6 (0.8, 5.5)	23/ 55 (41.8)	NE (1.2, NE)	1.41 (0.87, 2.27)	0.1542	
GEJ	11/ 17 (64.7)	3.4 (0.5, 15.1)	3/ 7 (42.9)	2.3 (0.3, NE)	1.22 (0.33, 4.45)	0.7682	
Histological subtype							0.1599
intestinal	51/ 89 (57.3)	2.9 (1.4, 7.7)	19/ 38 (50.0)	2.7 (0.8, NE)	1.02 (0.60, 1.74)	0.9351	
diffuse	19/ 28 (67.9)	1.1 (0.4, 5.6)	5/ 18 (27.8)	NE (0.7, NE)	2.85 (1.06, 7.66)	0.0289	
others	6/ 8 (75.0)	1.1 (0.0, 3.5)	2/ 6 (33.3)	NE (0.5, NE)	2.92 (0.58, 14.78)	0.1514	
Number of metastatic sites							0.6030
<2	19/ 24 (79.2)	0.7 (0.5, 1.4)	5/ 10 (50.0)	NE (0.2, NE)	1.68 (0.62, 4.50)	0.2754	
>= 2	57/101 (56.4)	3.2 (1.5, 5.6)	21/ 52 (40.4)	NE (1.4, NE)	1.29 (0.78, 2.13)	0.3292	
Previous total gastrectomy							0.5905
yes	14/ 22 (63.6)	1.5 (0.7, NE)	5/ 9 (55.6)	2.7 (0.2, NE)	1.17 (0.42, 3.26)	0.7606	
no	62/103 (60.2)	2.7 (1.3, 5.5)	21/ 53 (39.6)	NE (1.4, NE)	1.44 (0.88, 2.38)	0.1409	
Prior adjuvant/ neoadjuvant therapy							0.0766
yes	18/ 30 (60.0)	0.8 (0.7, NE)	7/ 10 (70.0)	0.6 (0.2, NE)	0.70 (0.29, 1.69)	0.3991	
no	58/ 95 (61.1)	2.7 (1.4, 5.5)	19/ 52 (36.5)	NE (2.3, NE)	1.60 (0.95, 2.70)	0.0703	
Prior ramucirumab contained treatment							0.9166
yes	56/ 94 (59.6)	1.8 (0.9, 5.5)	16/ 41 (39.0)	NE (1.2, NE)	1.39 (0.79, 2.42)	0.2436	
no	20/ 31 (64.5)	1.8 (0.5, 15.1)	10/ 21 (47.6)	3.5 (0.7, NE)	1.39 (0.65, 3.00)	0.3983	
Prior nivolumab contained treatment							0.9475
yes	19/ 33 (57.6)	0.7 (0.5, NE)	6/ 15 (40.0)	NE (0.5, NE)	1.56 (0.62, 3.94)	0.3464	
no	57/ 92 (62.0)	2.6 (1.4, 4.2)	20/ 47 (42.6)	NE (1.0, NE)	1.36 (0.81, 2.26)	0.2360	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

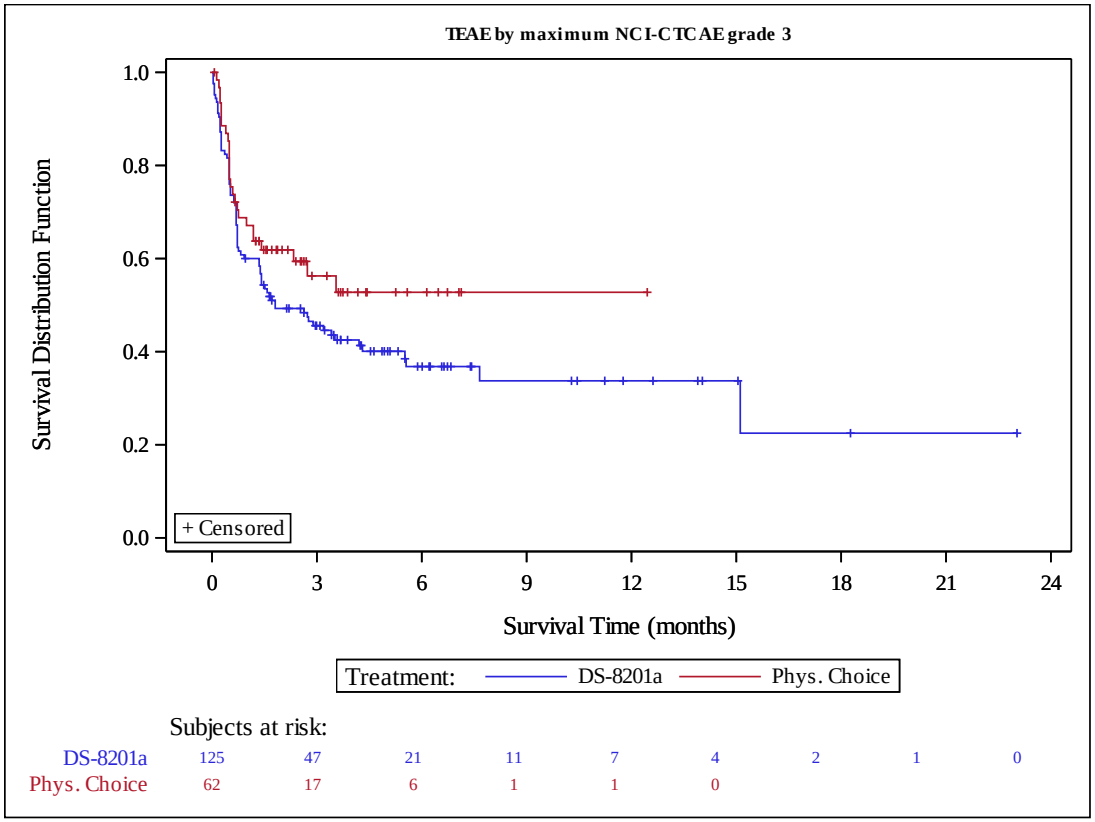
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8318
yes	24/ 44 (54.5)	2.0 (0.5, NE)	6/ 17 (35.3)	NE (0.5, NE)	1.65 (0.67, 4.06)	0.2722	
no	52/ 81 (64.2)	1.8 (1.4, 4.2)	20/ 45 (44.4)	3.5 (0.8, NE)	1.34 (0.80, 2.26)	0.2580	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.2939
yes	13/ 22 (59.1)	1.8 (0.7, NE)	4/ 7 (57.1)	0.5 (0.1, NE)	0.80 (0.26, 2.47)	0.6912	
no	63/103 (61.2)	1.8 (0.8, 4.2)	22/ 55 (40.0)	NE (1.4, NE)	1.50 (0.92, 2.45)	0.0980	
Presence of liver metastasis at baseline							0.6946
yes	37/ 67 (55.2)	2.9 (1.4, NE)	14/ 34 (41.2)	3.5 (1.2, NE)	1.20 (0.64, 2.23)	0.5697	
no	39/ 58 (67.2)	1.1 (0.7, 4.3)	12/ 28 (42.9)	NE (0.5, NE)	1.52 (0.79, 2.91)	0.2015	
Renal impairment at baseline							0.4969
normal	22/ 33 (66.7)	1.4 (0.7, 7.7)	4/ 13 (30.8)	NE (0.7, NE)	2.24 (0.77, 6.54)	0.1290	
mild	31/ 53 (58.5)	3.4 (0.7, 5.6)	14/ 28 (50.0)	3.5 (0.7, NE)	1.06 (0.56, 2.01)	0.8441	
moderate	23/ 39 (59.0)	1.8 (0.7, 15.1)	8/ 20 (40.0)	NE (0.4, NE)	1.45 (0.64, 3.25)	0.3689	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8613
normal	52/ 88 (59.1)	2.6 (1.4, 5.6)	19/ 47 (40.4)	NE (1.2, NE)	1.41 (0.83, 2.38)	0.2070	
mild	23/ 36 (63.9)	1.4 (0.7, 7.7)	7/ 15 (46.7)	NE (0.5, NE)	1.27 (0.54, 2.98)	0.5512	
moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4839
yes	5/ 8 (62.5)	4.9 (0.1, NE)	1/ 5 (20.0)	NE (0.5, NE)	2.73 (0.31, 24.03)	0.3458	
no	71/117 (60.7)	1.8 (0.9, 4.2)	25/ 57 (43.9)	NE (1.2, NE)	1.31 (0.83, 2.08)	0.2400	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.3011
yes	3/ 3 (100.0)	4.3 (0.1, 5.6)	1/ 4 (25.0)	NE (0.5, NE)	3.44 (0.34, 34.64)	0.2690	
no	73/122 (59.8)	1.8 (1.3, 4.2)	25/ 58 (43.1)	NE (1.2, NE)	1.31 (0.83, 2.08)	0.2383	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	23 (18.4)	7 (11.3)
Number of censored subjects, n (%)	102 (81.6)	55 (88.7)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.46 (0.62, 3.42)	
p-value [c]	0.3819	
Relative Risk (95% CI) [d]	1.63 (0.74, 3.59)	
p-value	0.2253	
Odds Ratio (95% CI) [d]	1.77 (0.72, 4.39)	
p-value	0.2167	
Risk Difference (95% CI) [e]	7.11 (-4.50, 18.72)	
p-value	0.2300	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9791
Japan	19/ 99 (19.2)	NE (NE , NE)	6/ 50 (12.0)	NE (NE , NE)	1.48 (0.59, 3.72)	0.4067	
Korea	4/ 26 (15.4)	NE (NE , NE)	1/ 12 (8.3)	NE (NE , NE)	1.44 (0.16, 13.04)	0.7428	
Lines of prior systemic therapy							0.3292
2	9/ 66 (13.6)	NE (NE , NE)	6/ 38 (15.8)	NE (NE , NE)	0.78 (0.28, 2.19)	0.6337	
3	9/ 34 (26.5)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	4.63 (0.58, 36.80)	0.1110	
>=4	5/ 25 (20.0)	NE (8.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.0814
<65 years	11/ 55 (20.0)	NE (NE , NE)	6/ 27 (22.2)	NE (2.7, NE)	0.74 (0.27, 2.05)	0.5623	
>=65 years	12/ 70 (17.1)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	5.68 (0.74, 43.77)	0.0592	
Sex							0.8433
female	7/ 30 (23.3)	NE (8.3, NE)	2/ 15 (13.3)	NE (2.4, NE)	1.59 (0.32, 7.89)	0.5648	
male	16/ 95 (16.8)	NE (NE , NE)	5/ 47 (10.6)	NE (NE , NE)	1.44 (0.52, 3.93)	0.4788	
ECOG PS							0.5230
0	13/ 62 (21.0)	NE (NE , NE)	3/ 30 (10.0)	NE (NE , NE)	1.94 (0.55, 6.86)	0.2964	
1	10/ 63 (15.9)	NE (NE , NE)	4/ 32 (12.5)	NE (NE , NE)	1.13 (0.35, 3.60)	0.8380	
HER2 Status in central laboratory							0.9901
IHC 3+	19/ 96 (19.8)	NE (NE , NE)	7/ 47 (14.9)	NE (NE , NE)	1.11 (0.46, 2.67)	0.8093	
IHC 2+/ISH +	4/ 29 (13.8)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.7463
Gastric	20/108 (18.5)	NE (NE , NE)	6/ 55 (10.9)	NE (NE , NE)	1.51 (0.60, 3.77)	0.3785	
GEJ	3/ 17 (17.6)	NE (NE , NE)	1/ 7 (14.3)	NE (0.5, NE)	1.19 (0.12, 11.41)	0.8739	
Histological subtype							0.3885
intestinal	17/ 89 (19.1)	NE (NE , NE)	4/ 38 (10.5)	NE (NE , NE)	1.75 (0.59, 5.22)	0.3063	
diffuse	5/ 28 (17.9)	NE (8.3, NE)	1/ 18 (5.6)	NE (2.4, NE)	2.06 (0.23, 18.82)	0.5129	
others	1/ 8 (12.5)	NE (0.6, NE)	2/ 6 (33.3)	NE (0.3, NE)	0.39 (0.03, 4.30)	0.4220	
Number of metastatic sites							0.2990
<2	1/ 24 (4.2)	NE (NE , NE)	1/ 10 (10.0)	NE (2.4, NE)	0.40 (0.03, 6.42)	0.5037	
>= 2	22/101 (21.8)	NE (NE , NE)	6/ 52 (11.5)	NE (NE , NE)	1.69 (0.68, 4.21)	0.2497	
Previous total gastrectomy							0.9890
yes	2/ 22 (9.1)	NE (8.3, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	21/103 (20.4)	NE (NE , NE)	7/ 53 (13.2)	NE (NE , NE)	1.43 (0.61, 3.38)	0.4069	
Prior adjuvant/ neoadjuvant therapy							0.9879
yes	4/ 30 (13.3)	NE (8.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	19/ 95 (20.0)	NE (NE , NE)	7/ 52 (13.5)	NE (NE , NE)	1.40 (0.59, 3.35)	0.4433	
Prior ramucirumab contained treatment							0.7570
yes	17/ 94 (18.1)	NE (NE , NE)	5/ 41 (12.2)	NE (NE , NE)	1.38 (0.51, 3.76)	0.5243	
no	6/ 31 (19.4)	NE (8.3, NE)	2/ 21 (9.5)	NE (NE , NE)	1.64 (0.32, 8.31)	0.5484	
Prior nivolumab contained treatment							0.9901
yes	11/ 33 (33.3)	NE (4.4, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	12/ 92 (13.0)	NE (NE , NE)	7/ 47 (14.9)	NE (NE , NE)	0.74 (0.29, 1.91)	0.5382	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

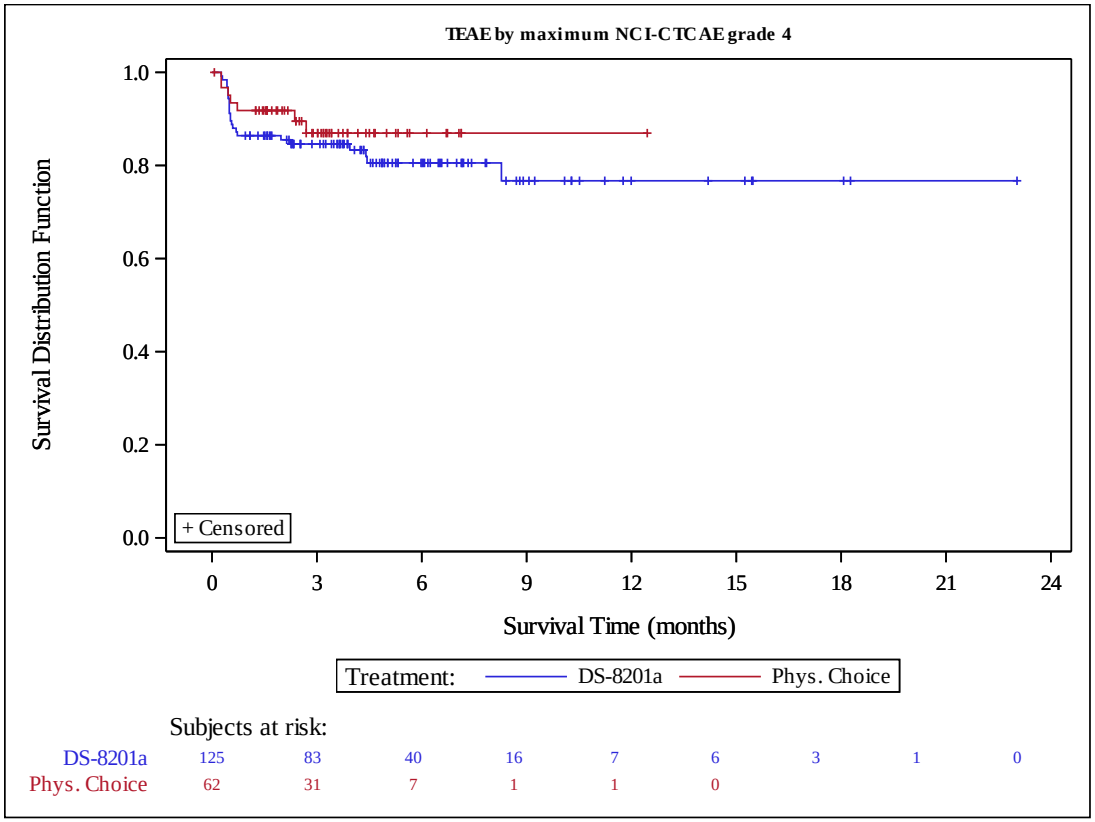
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9899
yes	16/ 44 (36.4)	NE (4.4, NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 81 (8.6)	NE (NE , NE)	7/ 45 (15.6)	NE (NE , NE)	0.45 (0.15, 1.30)	0.1315	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9897
yes	3/ 22 (13.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	20/103 (19.4)	NE (NE , NE)	7/ 55 (12.7)	NE (NE , NE)	1.36 (0.57, 3.24)	0.4852	
Presence of liver metastasis at baseline							0.0903
yes	17/ 67 (25.4)	NE (NE , NE)	3/ 34 (8.8)	NE (NE , NE)	2.87 (0.84, 9.79)	0.0779	
no	6/ 58 (10.3)	NE (NE , NE)	4/ 28 (14.3)	NE (NE , NE)	0.60 (0.16, 2.17)	0.4285	
Renal impairment at baseline							0.9943
normal	6/ 33 (18.2)	NE (NE , NE)	2/ 13 (15.4)	NE (2.7, NE)	1.17 (0.24, 5.81)	0.8463	
mild	10/ 53 (18.9)	NE (8.3, NE)	4/ 28 (14.3)	NE (NE , NE)	1.12 (0.35, 3.60)	0.8472	
moderate	7/ 39 (17.9)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	1/ 1 (100.0)	2.4 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7270
normal	18/ 88 (20.5)	NE (NE , NE)	6/ 47 (12.8)	NE (NE , NE)	1.35 (0.53, 3.44)	0.5245	
mild	5/ 36 (13.9)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	2.14 (0.25, 18.33)	0.4788	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9907
yes	2/ 8 (25.0)	NE (4.4, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	21/117 (17.9)	NE (NE , NE)	7/ 57 (12.3)	NE (NE , NE)	1.38 (0.59, 3.25)	0.4599	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9999
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	23/122 (18.9)	NE (NE , NE)	7/ 58 (12.1)	NE (NE , NE)	1.38 (0.59, 3.24)	0.4575	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	8 (6.4)	2 (3.2)
Number of censored subjects, n (%)	117 (93.6)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.27 (0.27, 6.13)	
p-value [c]	0.7611	
Relative Risk (95% CI) [d]	1.98 (0.43, 9.06)	
p-value	0.3768	
Odds Ratio (95% CI) [d]	2.05 (0.42, 9.96)	
p-value	0.3729	
Risk Difference (95% CI) [e]	3.17 (-4.18, 10.52)	
p-value	0.3974	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.3897
Japan	6/ 99 (6.1)	NE (NE , NE)	1/ 50 (2.0)	NE (NE , NE)	2.04 (0.24, 17.28)	0.5055	
Korea	2/ 26 (7.7)	NE (NE , NE)	1/ 12 (8.3)	NE (3.6, NE)	0.58 (0.05, 6.47)	0.6537	
Lines of prior systemic therapy							1.0000
2	7/ 66 (10.6)	NE (10.3, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (3.6, NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	1/ 6 (16.7)	NE (2.0, NE)	0.18 (0.01, 2.84)	0.1680	
Age							0.9932
<65 years	4/ 55 (7.3)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	4/ 70 (5.7)	NE (NE , NE)	2/ 35 (5.7)	NE (NE , NE)	0.70 (0.13, 3.86)	0.6818	
Sex							0.9923
female	3/ 30 (10.0)	NE (10.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	5/ 95 (5.3)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.79 (0.15, 4.08)	0.7760	
ECOG PS							0.6671
0	3/ 62 (4.8)	NE (NE , NE)	1/ 30 (3.3)	NE (NE , NE)	0.86 (0.09, 8.74)	0.9018	
1	5/ 63 (7.9)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	1.92 (0.22, 16.47)	0.5459	
HER2 Status in central laboratory							0.9930
IHC 3+	4/ 96 (4.2)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.47 (0.08, 2.70)	0.3867	
IHC 2+/ISH +	4/ 29 (13.8)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9949
Gastric	7/108 (6.5)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	1.13 (0.23, 5.56)	0.8823	
GEJ	1/ 17 (5.9)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.6197
intestinal	6/ 89 (6.7)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	1.82 (0.21, 15.35)	0.5782	
diffuse	1/ 28 (3.6)	NE (NE , NE)	1/ 18 (5.6)	NE (3.6, NE)	0.27 (0.02, 4.32)	0.3211	
others	1/ 8 (12.5)	NE (1.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	8/101 (7.9)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.25 (0.26, 6.04)	0.7849	
Previous total gastrectomy							0.2247
yes	1/ 22 (4.5)	NE (NE , NE)	1/ 9 (11.1)	NE (3.6, NE)	0.19 (0.01, 3.10)	0.1934	
no	7/103 (6.8)	NE (NE , NE)	1/ 53 (1.9)	NE (NE , NE)	2.44 (0.29, 20.15)	0.3931	
Prior adjuvant/ neoadjuvant therapy							0.9943
yes	1/ 30 (3.3)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 95 (7.4)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.23 (0.25, 6.07)	0.7969	
Prior ramucirumab contained treatment							0.7778
yes	6/ 94 (6.4)	NE (NE , NE)	1/ 41 (2.4)	NE (NE , NE)	1.91 (0.23, 15.97)	0.5426	
no	2/ 31 (6.5)	NE (10.3, NE)	1/ 21 (4.8)	NE (NE , NE)	0.67 (0.06, 7.90)	0.7477	
Prior nivolumab contained treatment							0.9923
yes	1/ 33 (3.0)	NE (NE , NE)	2/ 15 (13.3)	NE (3.6, NE)	0.15 (0.01, 1.66)	0.0744	
no	7/ 92 (7.6)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

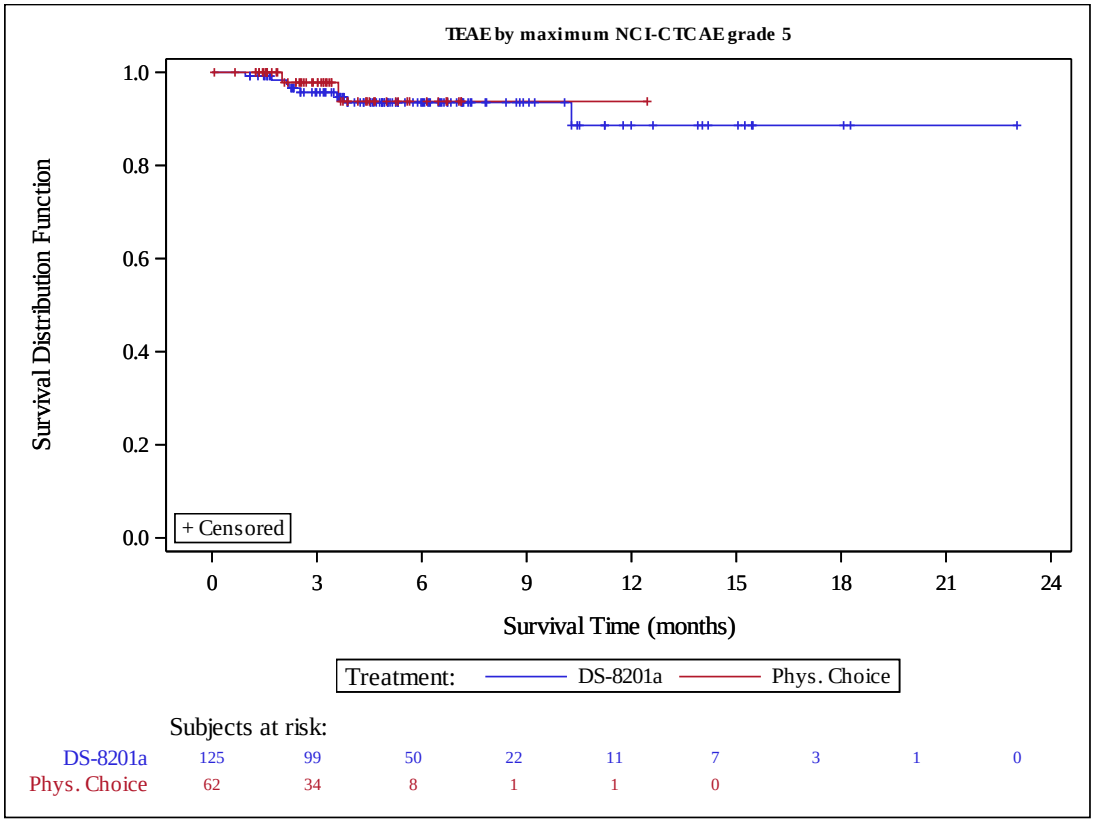
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9918
yes	1/ 44 (2.3)	NE (NE , NE)	2/ 17 (11.8)	NE (3.6, NE)	0.13 (0.01, 1.48)	0.0545	
no	7/ 81 (8.6)	NE (10.3, NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9948
yes	3/ 22 (13.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	5/103 (4.9)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	0.78 (0.15, 4.21)	0.7757	
Presence of liver metastasis at baseline							0.9930
yes	5/ 67 (7.5)	NE (NE , NE)	2/ 34 (5.9)	NE (NE , NE)	0.62 (0.11, 3.39)	0.5732	
no	3/ 58 (5.2)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							0.9906
normal	3/ 33 (9.1)	NE (10.3, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 53 (5.7)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	1.01 (0.10, 9.69)	0.9963	
moderate	2/ 39 (5.1)	NE (NE , NE)	1/ 20 (5.0)	NE (3.6, NE)	0.89 (0.08, 9.97)	0.9242	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7116
normal	5/ 88 (5.7)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	1.52 (0.17, 13.49)	0.7051	
mild	3/ 36 (8.3)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	1.00 (0.10, 9.67)	0.9996	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9925
yes	0/ 8 (0.0)	NE (NE , NE)	1/ 5 (20.0)	NE (2.0, NE)	NE	NE	
no	8/117 (6.8)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	2.39 (0.29, 19.54)	0.4027	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							1.0000
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	8/122 (6.6)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	1.17 (0.24, 5.68)	0.8458	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Investigator)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	13 (10.4)	0 (0.0)
Number of censored subjects, n (%)	112 (89.6)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	22.3 (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	13.50 (0.82, 223.43)	
p-value	0.0691	
Odds Ratio (95% CI) [d]	15.00 (0.88, 256.62)	
p-value	0.0616	
Risk Difference (95% CI) [e]	10.40 (3.84, 16.96)	
p-value	0.0019	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9998
Japan	12/ 99 (12.1)	22.3 (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (10.4, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	8/ 66 (12.1)	NE (10.4, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	1/ 34 (2.9)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	4/ 25 (16.0)	22.3 (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9998
<65 years	3/ 55 (5.5)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	10/ 70 (14.3)	22.3 (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	4/ 30 (13.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	9/ 95 (9.5)	22.3 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9998
0	5/ 62 (8.1)	22.3 (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	8/ 63 (12.7)	NE (10.4, NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	10/ 96 (10.4)	22.3 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	3/ 29 (10.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9982
Gastric	13/108 (12.0)	22.3 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	11/ 89 (12.4)	22.3 (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	2/ 28 (7.1)	NE (10.4, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9999
<2	2/ 24 (8.3)	NE (10.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	11/101 (10.9)	22.3 (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	22.3 (10.4, 22.3)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	9/103 (8.7)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	4/ 30 (13.3)	22.3 (10.4, 22.3)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	9/ 95 (9.5)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9997
yes	7/ 94 (7.4)	22.3 (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 31 (19.4)	NE (10.4, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							1.0000
yes	3/ 33 (9.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	10/ 92 (10.9)	22.3 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

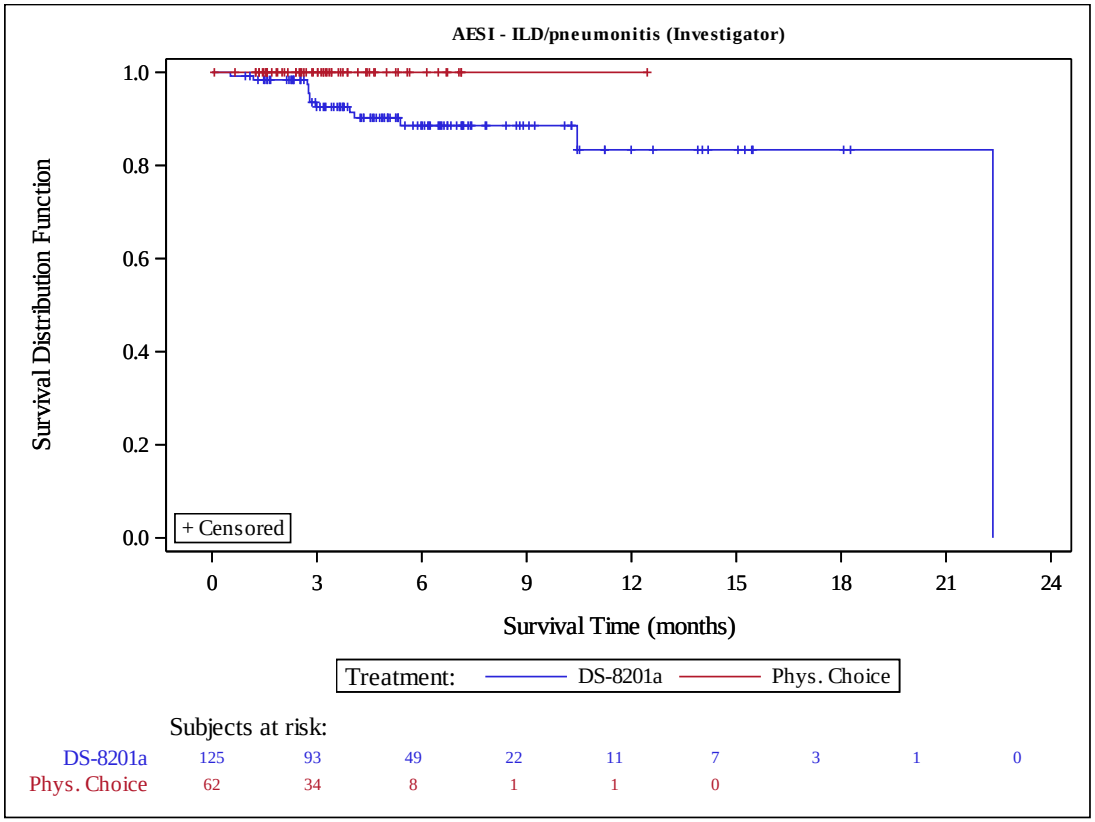
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9999
yes	4/ 44 (9.1)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	9/ 81 (11.1)	22.3 (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	4/ 22 (18.2)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	9/103 (8.7)	22.3 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	5/ 67 (7.5)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 58 (13.8)	22.3 (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	22.3 (10.4, 22.3)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	6/ 53 (11.3)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	5/ 39 (12.8)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							1.0000
normal	9/ 88 (10.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	4/ 36 (11.1)	22.3 (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9982
yes	1/ 8 (12.5)	22.3 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	12/117 (10.3)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9984
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	13/122 (10.7)	22.3 (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of AESI - ILD/pneumonitis (Investigator)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Investigator)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	5 (4.0)	0 (0.0)
Number of censored subjects, n (%)	120 (96.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	5.50 (0.31, 97.90)	
p-value	0.2459	
Odds Ratio (95% CI) [d]	5.71 (0.31, 104.85)	
p-value	0.2410	
Risk Difference (95% CI) [e]	4.00 (-0.64, 8.64)	
p-value	0.0912	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							1.0000
Japan	4/ 99 (4.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (10.4, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	3/ 66 (4.5)	NE (10.4, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	2/ 25 (8.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9999
<65 years	1/ 55 (1.8)	NE (10.4, NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	4/ 70 (5.7)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	3/ 95 (3.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9986
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	5/ 63 (7.9)	NE (10.4, NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9998
IHC 3+	3/ 96 (3.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	2/ 29 (6.9)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9990
Gastric	5/108 (4.6)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	4/ 89 (4.5)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	1/ 28 (3.6)	NE (10.4, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	1/ 24 (4.2)	NE (10.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	4/101 (4.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							1.0000
yes	1/ 22 (4.5)	NE (10.4, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	4/103 (3.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	1/ 30 (3.3)	NE (10.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 95 (4.2)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9999
yes	3/ 94 (3.2)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 31 (6.5)	NE (10.4, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 92 (4.3)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

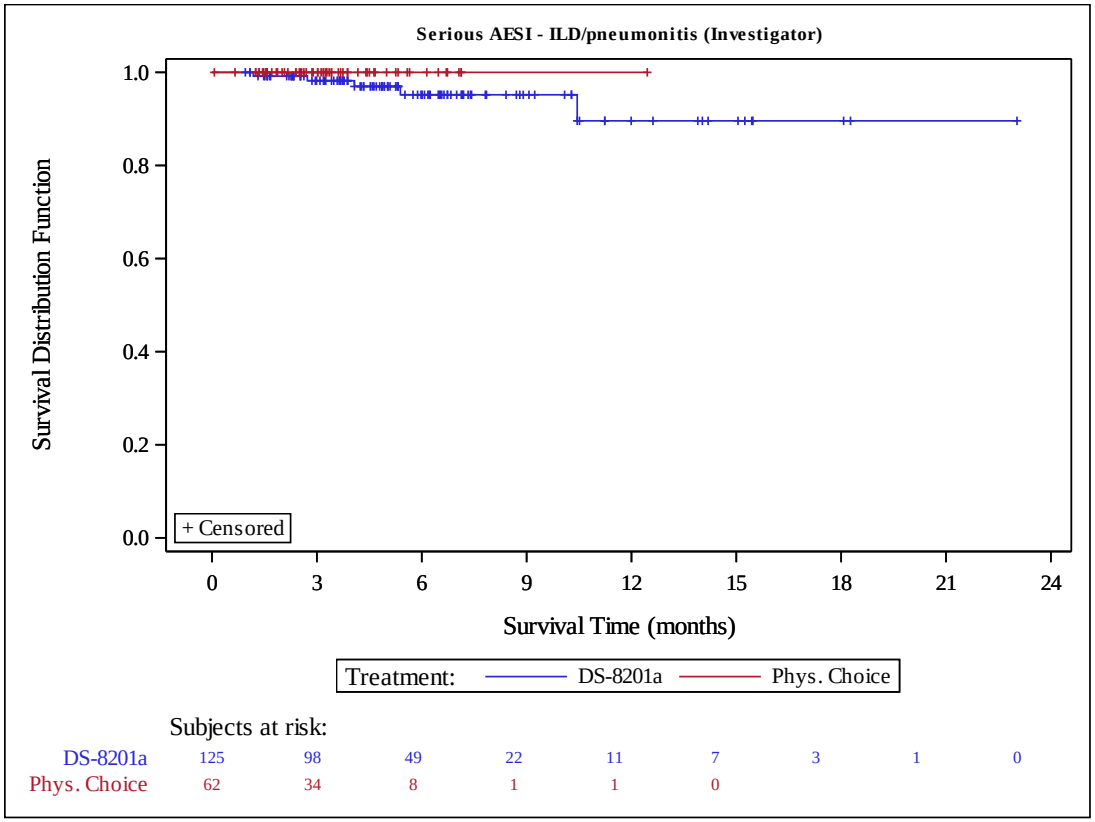
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	2/ 44 (4.5)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 81 (3.7)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	2/ 22 (9.1)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	3/103 (2.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							1.0000
yes	2/ 67 (3.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 58 (5.2)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (10.4, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	2/ 39 (5.1)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	3/ 88 (3.4)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9988
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	5/117 (4.3)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9989
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	5/122 (4.1)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Investigator)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Investigator)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
p-value	0.5522	
Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
p-value	0.5510	
Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
p-value	0.3572	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9991
Japan	2/ 99 (2.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	1/ 66 (1.5)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9989
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	2/ 70 (2.9)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	1/ 30 (3.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9990
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	2/ 63 (3.2)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	1/ 96 (1.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9992
Gastric	2/108 (1.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	2/ 89 (2.2)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9991
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	2/101 (2.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9992
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9991
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 95 (2.1)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9999
yes	1/ 94 (1.1)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 92 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

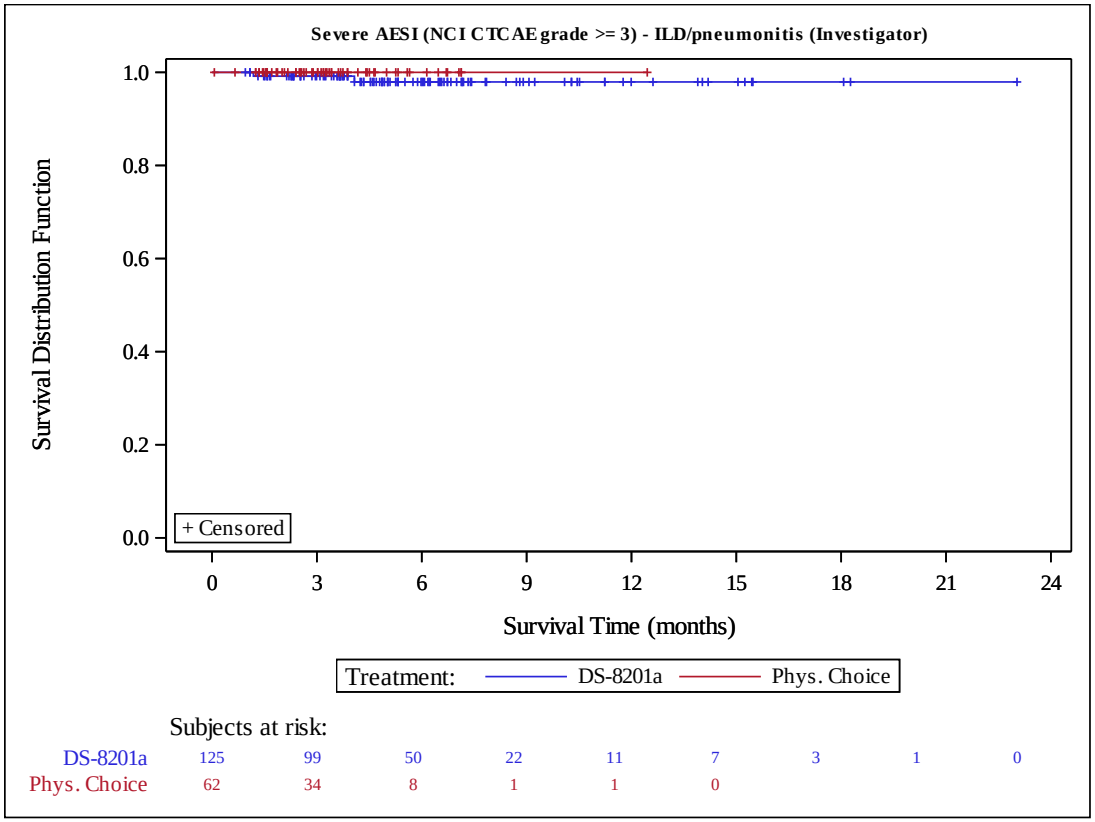
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	1/ 44 (2.3)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 81 (1.2)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	1/ 22 (4.5)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							1.0000
yes	1/ 67 (1.5)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 58 (1.7)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 53 (1.9)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	1/ 39 (2.6)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	1/ 88 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 36 (2.8)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9993
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	2/117 (1.7)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9994
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	2/122 (1.6)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Investigator)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Investigator)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	11 (8.8)	0 (0.0)
Number of censored subjects, n (%)	114 (91.2)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	22.3 (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	11.50 (0.69, 192.01)	
p-value	0.0891	
Odds Ratio (95% CI) [d]	12.55 (0.73, 216.64)	
p-value	0.0817	
Risk Difference (95% CI) [e]	8.80 (2.63, 14.97)	
p-value	0.0052	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9999
Japan	10/ 99 (10.1)	22.3 (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (10.4, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	7/ 66 (10.6)	NE (10.4, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	1/ 34 (2.9)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	3/ 25 (12.0)	22.3 (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9999
<65 years	3/ 55 (5.5)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	8/ 70 (11.4)	22.3 (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	3/ 30 (10.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	8/ 95 (8.4)	22.3 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9999
0	5/ 62 (8.1)	22.3 (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	6/ 63 (9.5)	NE (10.4, NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							1.0000
IHC 3+	9/ 96 (9.4)	22.3 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	2/ 29 (6.9)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9985
Gastric	11/108 (10.2)	22.3 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	9/ 89 (10.1)	22.3 (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	2/ 28 (7.1)	NE (10.4, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	2/ 24 (8.3)	NE (10.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	9/101 (8.9)	22.3 (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	22.3 (10.4, 22.3)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	7/103 (6.8)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	4/ 30 (13.3)	22.3 (10.4, 22.3)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 95 (7.4)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9997
yes	6/ 94 (6.4)	22.3 (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	5/ 31 (16.1)	NE (10.4, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	2/ 33 (6.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	9/ 92 (9.8)	22.3 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

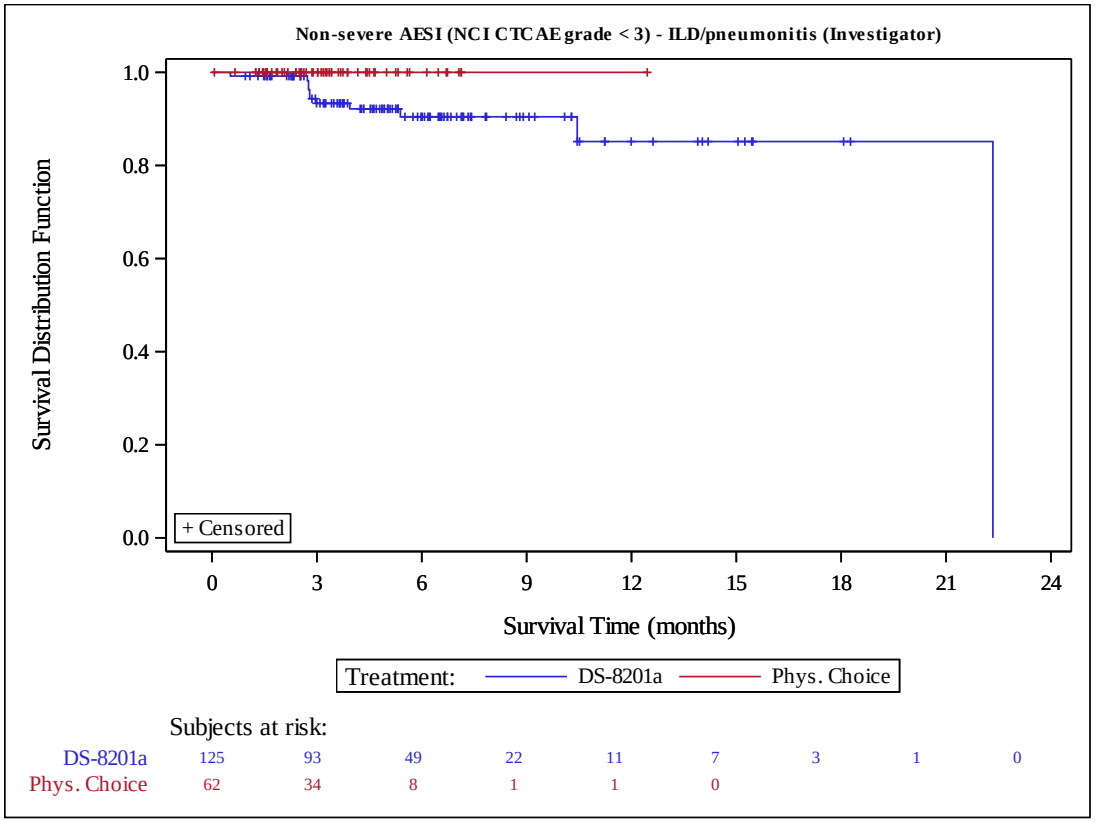
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9999
yes	3/ 44 (6.8)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 81 (9.9)	22.3 (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	3/ 22 (13.6)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	8/103 (7.8)	22.3 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	4/ 67 (6.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 58 (12.1)	22.3 (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	22.3 (10.4, 22.3)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	5/ 53 (9.4)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	4/ 39 (10.3)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							1.0000
normal	8/ 88 (9.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 36 (8.3)	22.3 (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9983
yes	1/ 8 (12.5)	22.3 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	10/117 (8.5)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9986
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	11/122 (9.0)	22.3 (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Investigator)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	12 (9.6)	0 (0.0)
Number of censored subjects, n (%)	113 (90.4)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	21.0 (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	12.50 (0.75, 207.72)	
p-value	0.0782	
Odds Ratio (95% CI) [d]	13.77 (0.80, 236.45)	
p-value	0.0707	
Risk Difference (95% CI) [e]	9.60 (3.23, 15.97)	
p-value	0.0031	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9999
Japan	11/ 99 (11.1)	21.0 (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	7/ 66 (10.6)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	1/ 34 (2.9)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	4/ 25 (16.0)	21.0 (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9998
<65 years	2/ 55 (3.6)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	10/ 70 (14.3)	21.0 (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	4/ 30 (13.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	8/ 95 (8.4)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9999
0	5/ 62 (8.1)	21.0 (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	7/ 63 (11.1)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	9/ 96 (9.4)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	3/ 29 (10.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9983
Gastric	12/108 (11.1)	21.0 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	10/ 89 (11.2)	21.0 (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	2/ 28 (7.1)	NE (8.1, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	2/ 24 (8.3)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	10/101 (9.9)	21.0 (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	21.0 (8.1, 21.0)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	8/103 (7.8)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	4/ 30 (13.3)	21.0 (8.1, 21.0)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 95 (8.4)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9998
yes	7/ 94 (7.4)	21.0 (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	5/ 31 (16.1)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							1.0000
yes	3/ 33 (9.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	9/ 92 (9.8)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

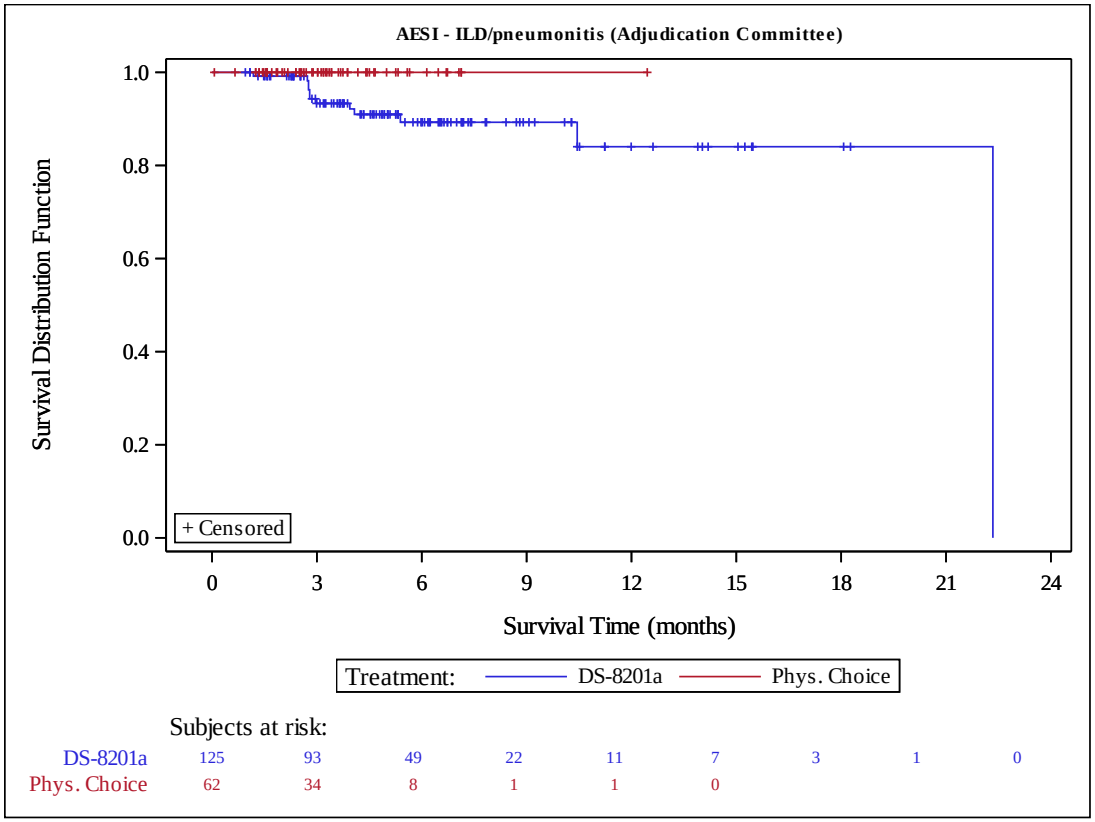
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	4/ 44 (9.1)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 81 (9.9)	21.0 (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	4/ 22 (18.2)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	8/103 (7.8)	21.0 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	4/ 67 (6.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 58 (13.8)	21.0 (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	21.0 (8.1, 21.0)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	5/ 53 (9.4)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	5/ 39 (12.8)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	9/ 88 (10.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 36 (8.3)	21.0 (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9983
yes	1/ 8 (12.5)	21.0 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	11/117 (9.4)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9985
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	12/122 (9.8)	21.0 (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	5 (4.0)	0 (0.0)
Number of censored subjects, n (%)	120 (96.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	5.50 (0.31, 97.90)	
p-value	0.2459	
Odds Ratio (95% CI) [d]	5.71 (0.31, 104.85)	
p-value	0.2410	
Risk Difference (95% CI) [e]	4.00 (-0.64, 8.64)	
p-value	0.0912	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							1.0000
Japan	4/ 99 (4.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	3/ 66 (4.5)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	2/ 25 (8.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9999
<65 years	1/ 55 (1.8)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	4/ 70 (5.7)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9998
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	3/ 95 (3.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9986
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	5/ 63 (7.9)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9998
IHC 3+	3/ 96 (3.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	2/ 29 (6.9)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9990
Gastric	5/108 (4.6)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	4/ 89 (4.5)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	1/ 28 (3.6)	NE (8.1, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	1/ 24 (4.2)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	4/101 (4.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							1.0000
yes	1/ 22 (4.5)	NE (8.1, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	4/103 (3.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	1/ 30 (3.3)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 95 (4.2)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9999
yes	3/ 94 (3.2)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 31 (6.5)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 92 (4.3)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

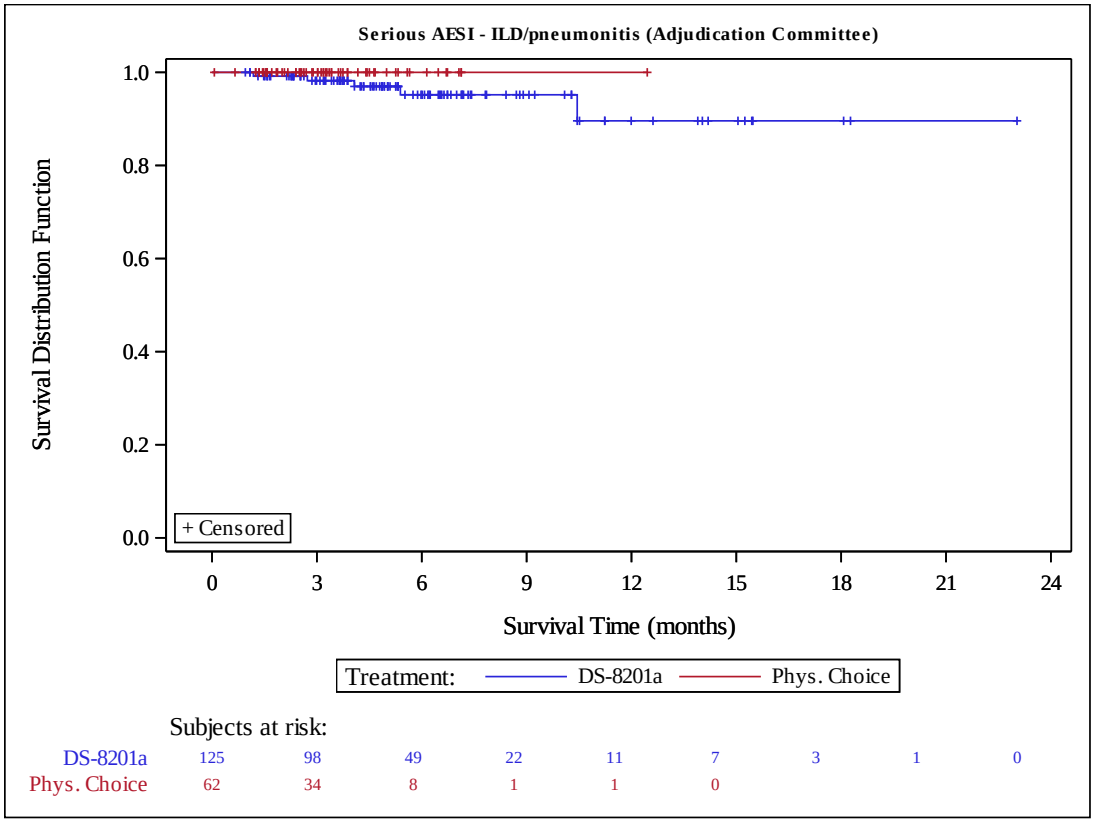
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	2/ 44 (4.5)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 81 (3.7)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	2/ 22 (9.1)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	3/103 (2.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							1.0000
yes	2/ 67 (3.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 58 (5.2)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (8.1, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	2/ 39 (5.1)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	3/ 88 (3.4)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9988
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	5/117 (4.3)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9990
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	5/122 (4.1)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	3 (2.4)	0 (0.0)
Number of censored subjects, n (%)	122 (97.6)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	3.50 (0.18, 66.72)	
p-value	0.4049	
Odds Ratio (95% CI) [d]	3.57 (0.18, 70.23)	
p-value	0.4023	
Risk Difference (95% CI) [e]	2.40 (-1.49, 6.29)	
p-value	0.2265	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9989
Japan	3/ 99 (3.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	2/ 66 (3.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9987
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	3/ 70 (4.3)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9998
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9988
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	3/ 63 (4.8)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	2/ 96 (2.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9990
Gastric	3/108 (2.8)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	3/ 89 (3.4)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9988
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	3/101 (3.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9989
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	3/103 (2.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9988
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 95 (3.2)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							1.0000
yes	2/ 94 (2.1)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							1.0000
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 92 (2.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

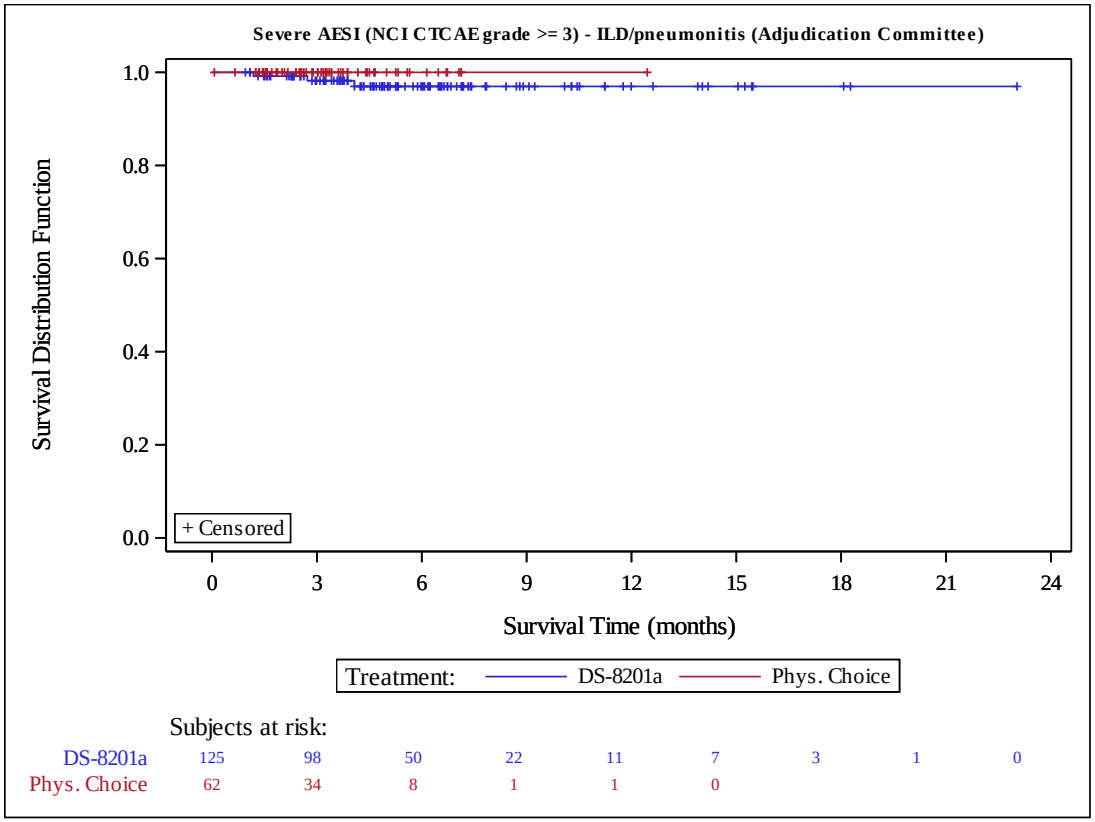
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	1/ 44 (2.3)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 81 (2.5)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	1/ 22 (4.5)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	2/ 67 (3.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 58 (1.7)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 53 (1.9)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	2/ 39 (5.1)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	1/ 88 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9992
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	3/117 (2.6)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9993
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	3/122 (2.5)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	9 (7.2)	0 (0.0)
Number of censored subjects, n (%)	116 (92.8)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	21.0 (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	9.50 (0.56, 160.61)	
p-value	0.1187	
Odds Ratio (95% CI) [d]	10.19 (0.58, 178.05)	
p-value	0.1116	
Risk Difference (95% CI) [e]	7.20 (1.46, 12.94)	
p-value	0.0139	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9999
Japan	8/ 99 (8.1)	21.0 (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	5/ 66 (7.6)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	1/ 34 (2.9)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	3/ 25 (12.0)	21.0 (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9999
<65 years	2/ 55 (3.6)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	7/ 70 (10.0)	21.0 (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							1.0000
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	7/ 95 (7.4)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							1.0000
0	5/ 62 (8.1)	21.0 (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	4/ 63 (6.3)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							1.0000
IHC 3+	7/ 96 (7.3)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	2/ 29 (6.9)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9986
Gastric	9/108 (8.3)	21.0 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	7/ 89 (7.9)	21.0 (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	2/ 28 (7.1)	NE (8.1, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	2/ 24 (8.3)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	7/101 (6.9)	21.0 (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9998
yes	4/ 22 (18.2)	21.0 (8.1, 21.0)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	5/103 (4.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9999
yes	4/ 30 (13.3)	21.0 (8.1, 21.0)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	5/ 95 (5.3)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9998
yes	5/ 94 (5.3)	21.0 (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 31 (12.9)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							1.0000
yes	2/ 33 (6.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 92 (7.6)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

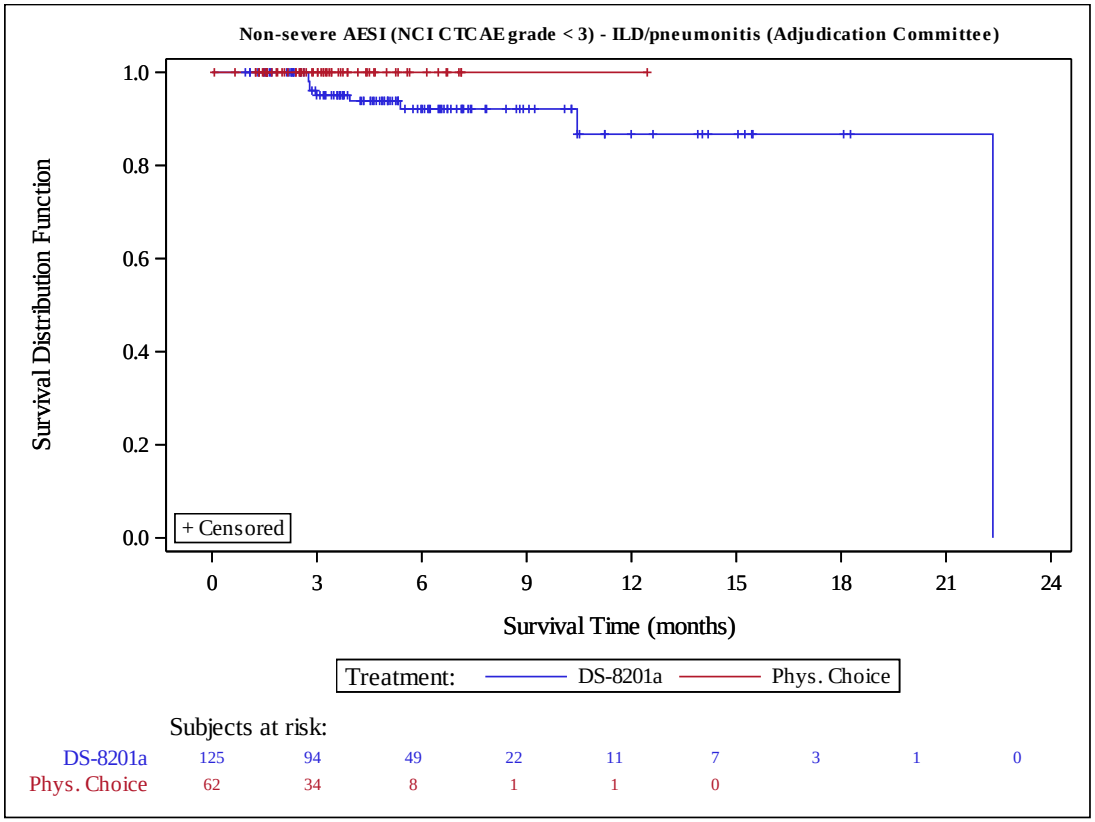
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	3/ 44 (6.8)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 81 (7.4)	21.0 (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	3/ 22 (13.6)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	6/103 (5.8)	21.0 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9998
yes	2/ 67 (3.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 58 (12.1)	21.0 (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	21.0 (8.1, 21.0)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	4/ 53 (7.5)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	3/ 39 (7.7)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9980
normal	8/ 88 (9.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 36 (2.8)	21.0 (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9985
yes	1/ 8 (12.5)	21.0 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	8/117 (6.8)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9987
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	9/122 (7.4)	21.0 (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	12 (9.6)	0 (0.0)
Number of censored subjects, n (%)	113 (90.4)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	21.0 (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	12.50 (0.75, 207.72)	
p-value	0.0782	
Odds Ratio (95% CI) [d]	13.77 (0.80, 236.45)	
p-value	0.0707	
Risk Difference (95% CI) [e]	9.60 (3.23, 15.97)	
p-value	0.0031	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9999
Japan	11/ 99 (11.1)	21.0 (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	7/ 66 (10.6)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	1/ 34 (2.9)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	4/ 25 (16.0)	21.0 (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9998
<65 years	2/ 55 (3.6)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	10/ 70 (14.3)	21.0 (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	4/ 30 (13.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	8/ 95 (8.4)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9999
0	5/ 62 (8.1)	21.0 (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	7/ 63 (11.1)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	9/ 96 (9.4)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	3/ 29 (10.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9983
Gastric	12/108 (11.1)	21.0 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	10/ 89 (11.2)	21.0 (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	2/ 28 (7.1)	NE (8.1, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	2/ 24 (8.3)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	10/101 (9.9)	21.0 (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	21.0 (8.1, 21.0)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	8/103 (7.8)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	4/ 30 (13.3)	21.0 (8.1, 21.0)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 95 (8.4)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9998
yes	7/ 94 (7.4)	21.0 (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	5/ 31 (16.1)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							1.0000
yes	3/ 33 (9.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	9/ 92 (9.8)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

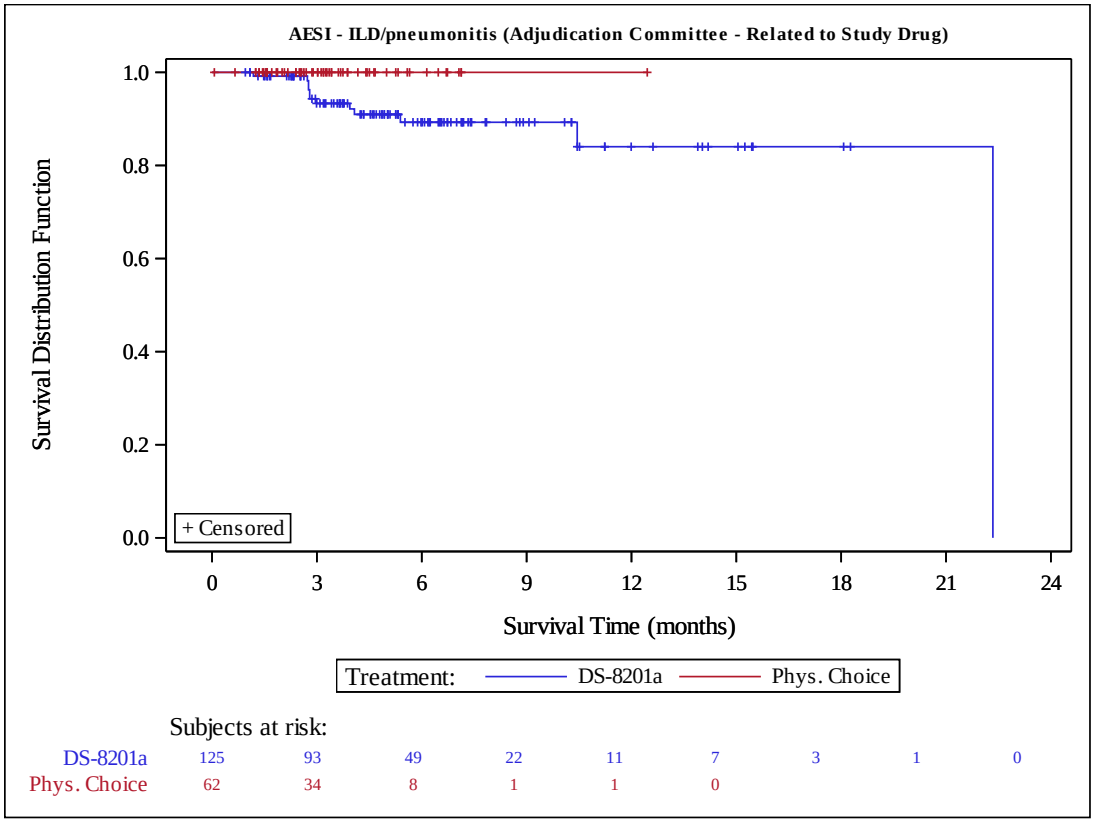
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	4/ 44 (9.1)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 81 (9.9)	21.0 (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	4/ 22 (18.2)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	8/103 (7.8)	21.0 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	4/ 67 (6.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 58 (13.8)	21.0 (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	21.0 (8.1, 21.0)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	5/ 53 (9.4)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	5/ 39 (12.8)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	9/ 88 (10.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 36 (8.3)	21.0 (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9983
yes	1/ 8 (12.5)	21.0 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	11/117 (9.4)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9985
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	12/122 (9.8)	21.0 (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	5 (4.0)	0 (0.0)
Number of censored subjects, n (%)	120 (96.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	5.50 (0.31, 97.90)	
p-value	0.2459	
Odds Ratio (95% CI) [d]	5.71 (0.31, 104.85)	
p-value	0.2410	
Risk Difference (95% CI) [e]	4.00 (-0.64, 8.64)	
p-value	0.0912	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							1.0000
Japan	4/ 99 (4.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	3/ 66 (4.5)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	2/ 25 (8.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9999
<65 years	1/ 55 (1.8)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	4/ 70 (5.7)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9998
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	3/ 95 (3.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9986
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	5/ 63 (7.9)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9998
IHC 3+	3/ 96 (3.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	2/ 29 (6.9)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9990
Gastric	5/108 (4.6)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	4/ 89 (4.5)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	1/ 28 (3.6)	NE (8.1, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	1/ 24 (4.2)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	4/101 (4.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							1.0000
yes	1/ 22 (4.5)	NE (8.1, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	4/103 (3.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	1/ 30 (3.3)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 95 (4.2)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9999
yes	3/ 94 (3.2)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 31 (6.5)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 92 (4.3)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

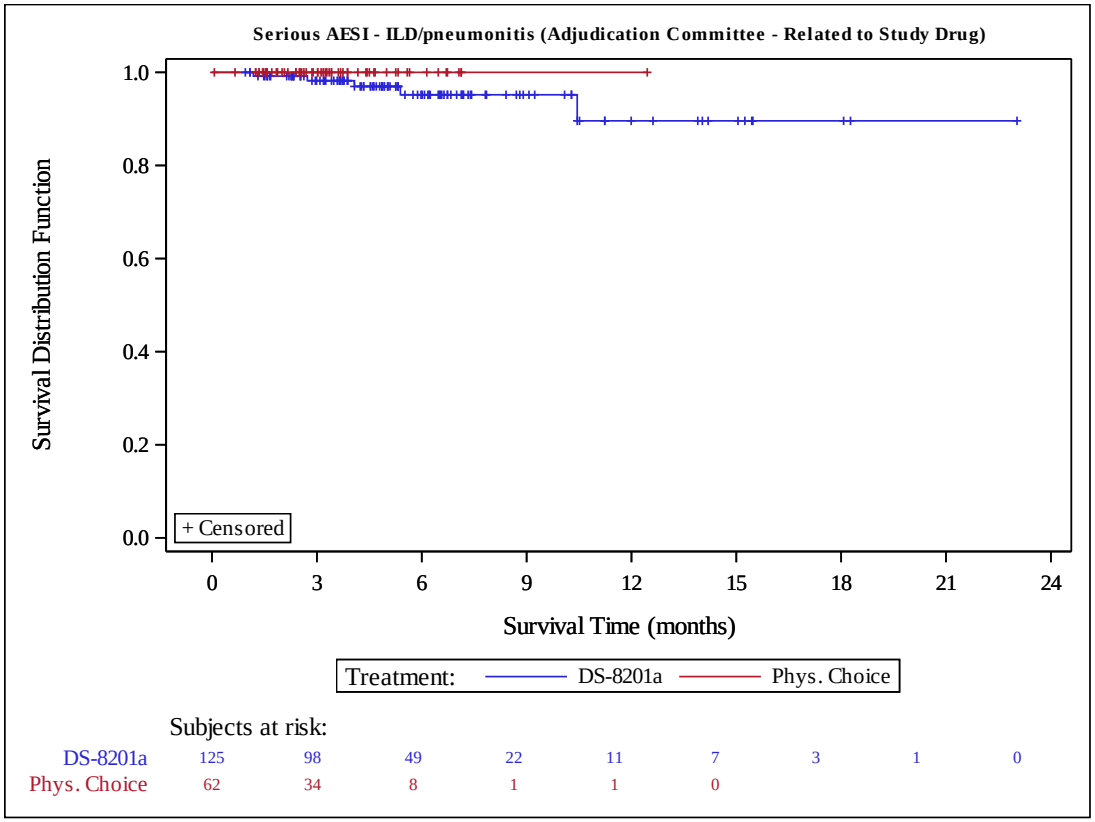
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	2/ 44 (4.5)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 81 (3.7)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	2/ 22 (9.1)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	3/103 (2.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							1.0000
yes	2/ 67 (3.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 58 (5.2)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (8.1, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	2/ 39 (5.1)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	3/ 88 (3.4)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9988
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	5/117 (4.3)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9990
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	5/122 (4.1)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	3 (2.4)	0 (0.0)
Number of censored subjects, n (%)	122 (97.6)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	3.50 (0.18, 66.72)	
p-value	0.4049	
Odds Ratio (95% CI) [d]	3.57 (0.18, 70.23)	
p-value	0.4023	
Risk Difference (95% CI) [e]	2.40 (-1.49, 6.29)	
p-value	0.2265	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9989
Japan	3/ 99 (3.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	2/ 66 (3.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9987
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	3/ 70 (4.3)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9998
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9988
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	3/ 63 (4.8)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	2/ 96 (2.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9990
Gastric	3/108 (2.8)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	3/ 89 (3.4)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9988
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	3/101 (3.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9989
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	3/103 (2.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9988
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 95 (3.2)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							1.0000
yes	2/ 94 (2.1)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							1.0000
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 92 (2.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

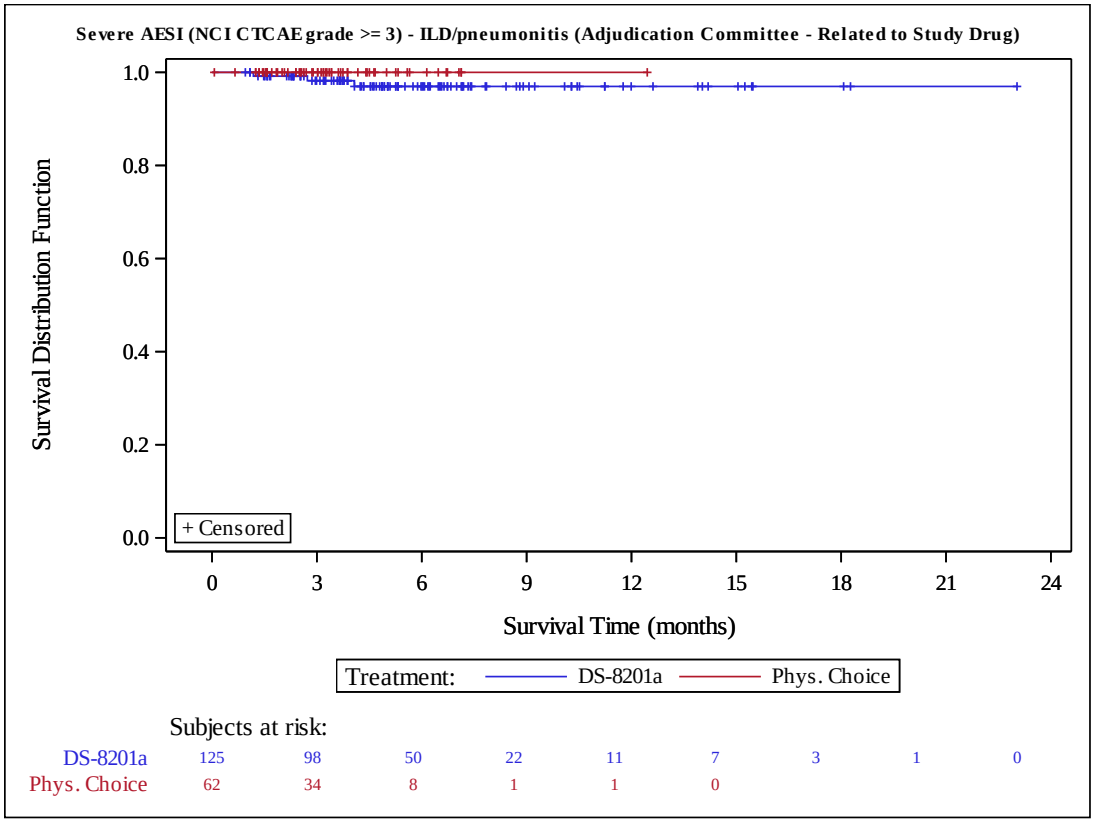
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	1/ 44 (2.3)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 81 (2.5)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	1/ 22 (4.5)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	2/ 67 (3.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 58 (1.7)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 53 (1.9)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	2/ 39 (5.1)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	1/ 88 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9992
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	3/117 (2.6)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9993
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	3/122 (2.5)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	9 (7.2)	0 (0.0)
Number of censored subjects, n (%)	116 (92.8)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	21.0 (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	9.50 (0.56, 160.61)	
p-value	0.1187	
Odds Ratio (95% CI) [d]	10.19 (0.58, 178.05)	
p-value	0.1116	
Risk Difference (95% CI) [e]	7.20 (1.46, 12.94)	
p-value	0.0139	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9999
Japan	8/ 99 (8.1)	21.0 (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	5/ 66 (7.6)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	1/ 34 (2.9)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	3/ 25 (12.0)	21.0 (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9999
<65 years	2/ 55 (3.6)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	7/ 70 (10.0)	21.0 (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							1.0000
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	7/ 95 (7.4)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							1.0000
0	5/ 62 (8.1)	21.0 (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	4/ 63 (6.3)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							1.0000
IHC 3+	7/ 96 (7.3)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	2/ 29 (6.9)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9986
Gastric	9/108 (8.3)	21.0 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	7/ 89 (7.9)	21.0 (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	2/ 28 (7.1)	NE (8.1, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	2/ 24 (8.3)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	7/101 (6.9)	21.0 (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9998
yes	4/ 22 (18.2)	21.0 (8.1, 21.0)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	5/103 (4.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9999
yes	4/ 30 (13.3)	21.0 (8.1, 21.0)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	5/ 95 (5.3)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9998
yes	5/ 94 (5.3)	21.0 (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 31 (12.9)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							1.0000
yes	2/ 33 (6.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 92 (7.6)	21.0 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

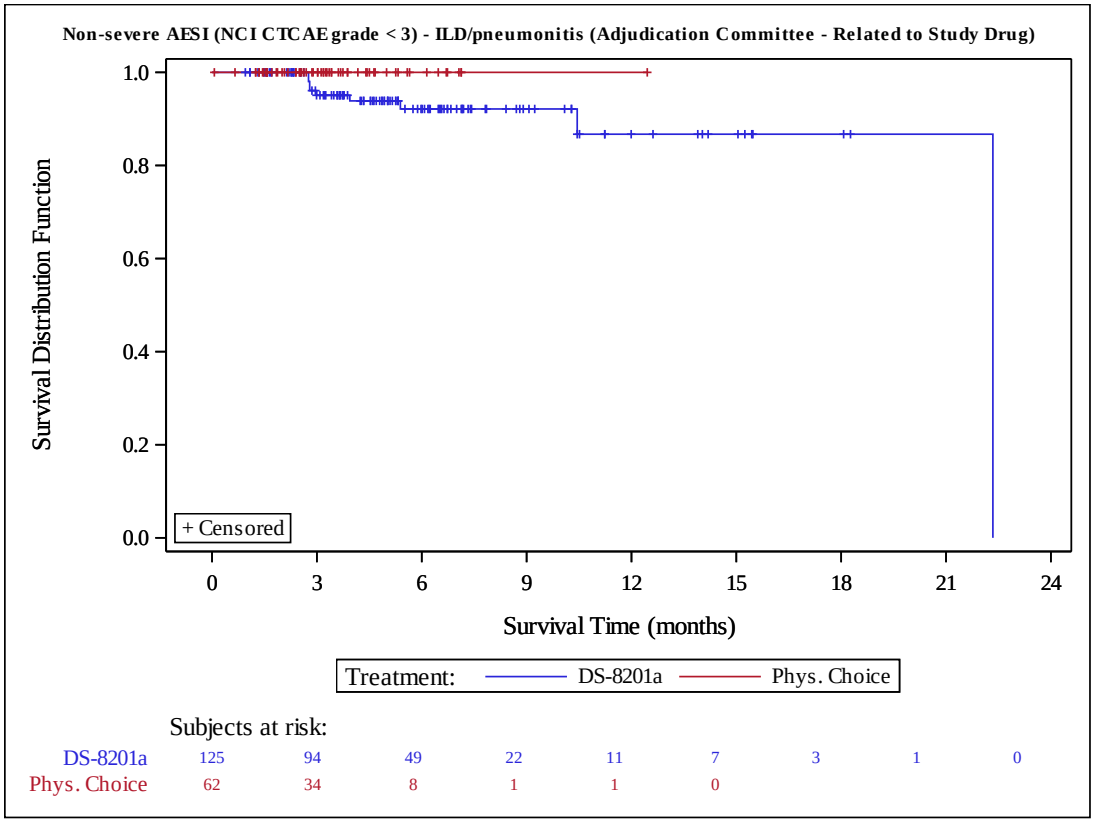
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	3/ 44 (6.8)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 81 (7.4)	21.0 (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	3/ 22 (13.6)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	6/103 (5.8)	21.0 (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9998
yes	2/ 67 (3.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 58 (12.1)	21.0 (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	21.0 (8.1, 21.0)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	4/ 53 (7.5)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	3/ 39 (7.7)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9980
normal	8/ 88 (9.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 36 (2.8)	21.0 (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9985
yes	1/ 8 (12.5)	21.0 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	8/117 (6.8)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9987
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	9/122 (7.4)	21.0 (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - LVEF decrease
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/101 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

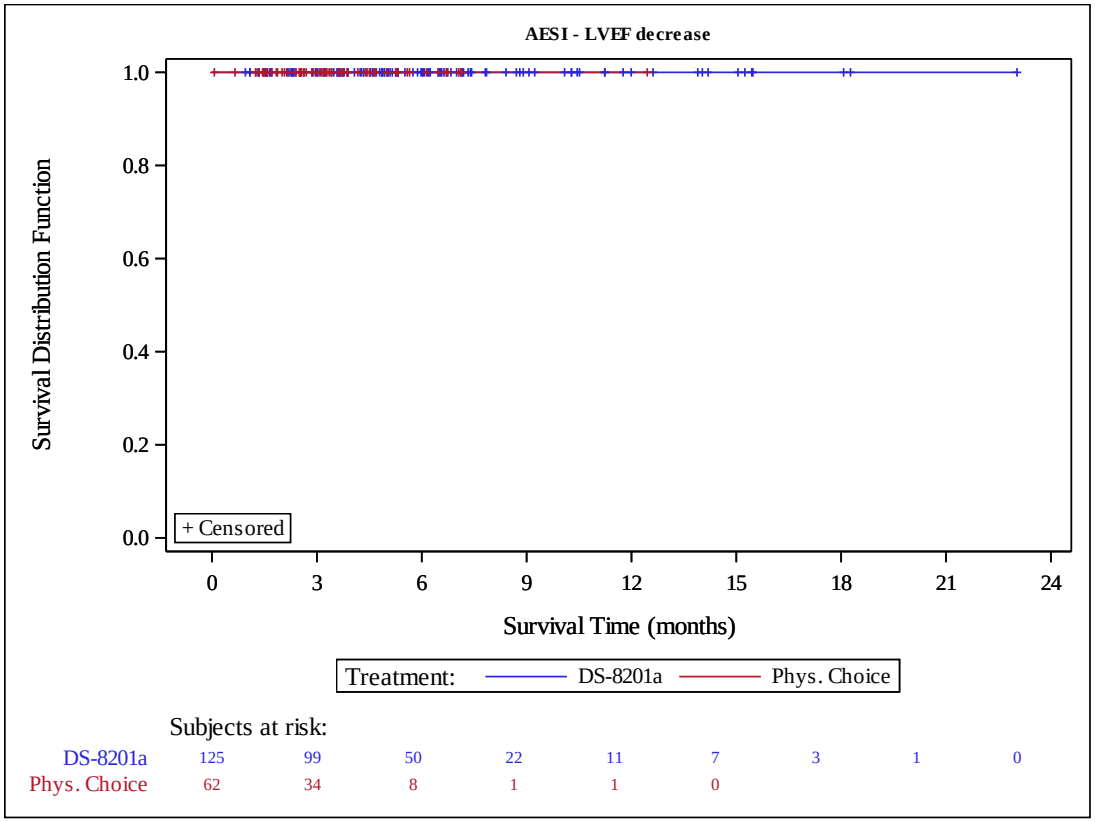
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 67 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 58 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of AESI - LVEF decrease
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - LVEF decrease
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/101 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

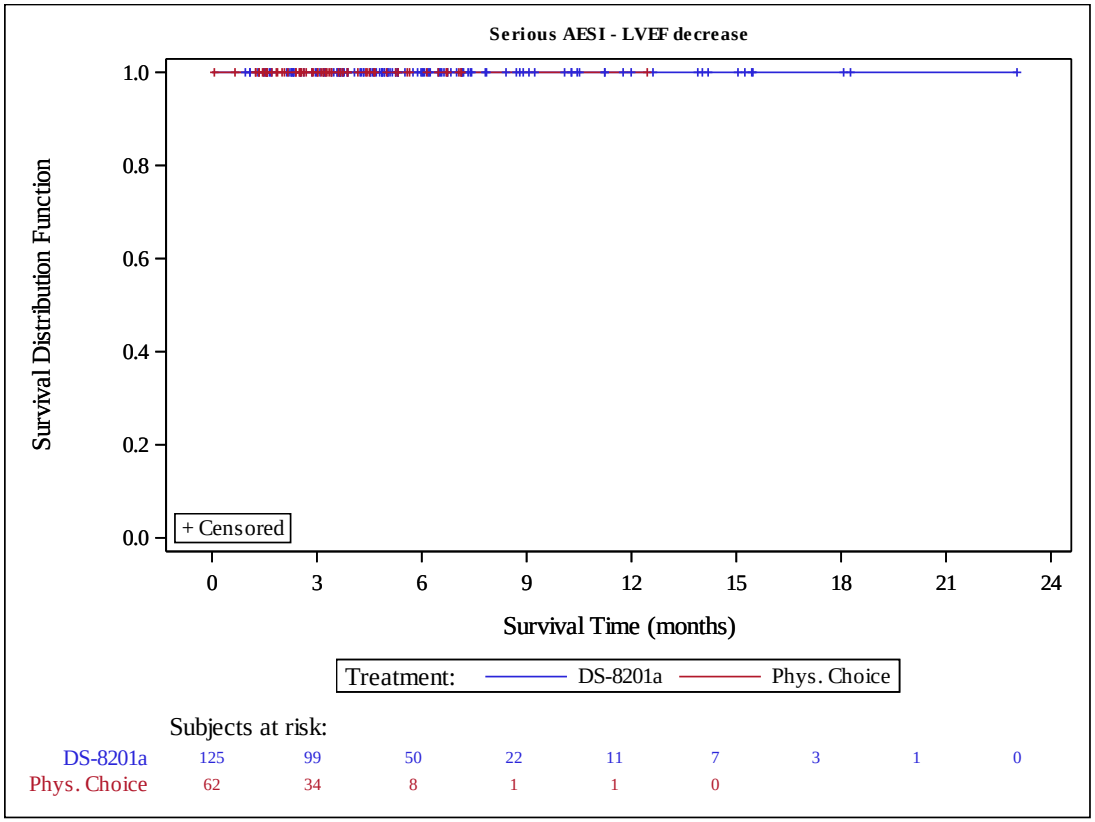
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 67 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 58 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Serious AESI - LVEF decrease
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/101 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

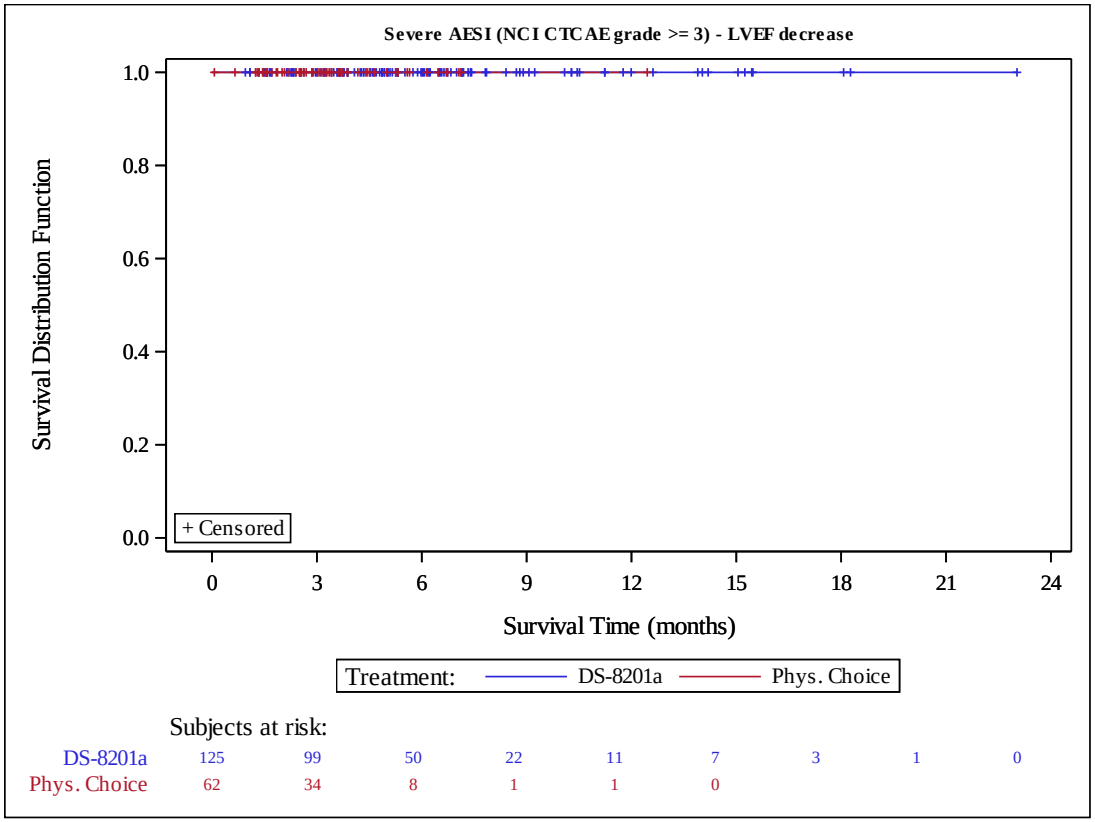
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 67 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 58 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/101 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

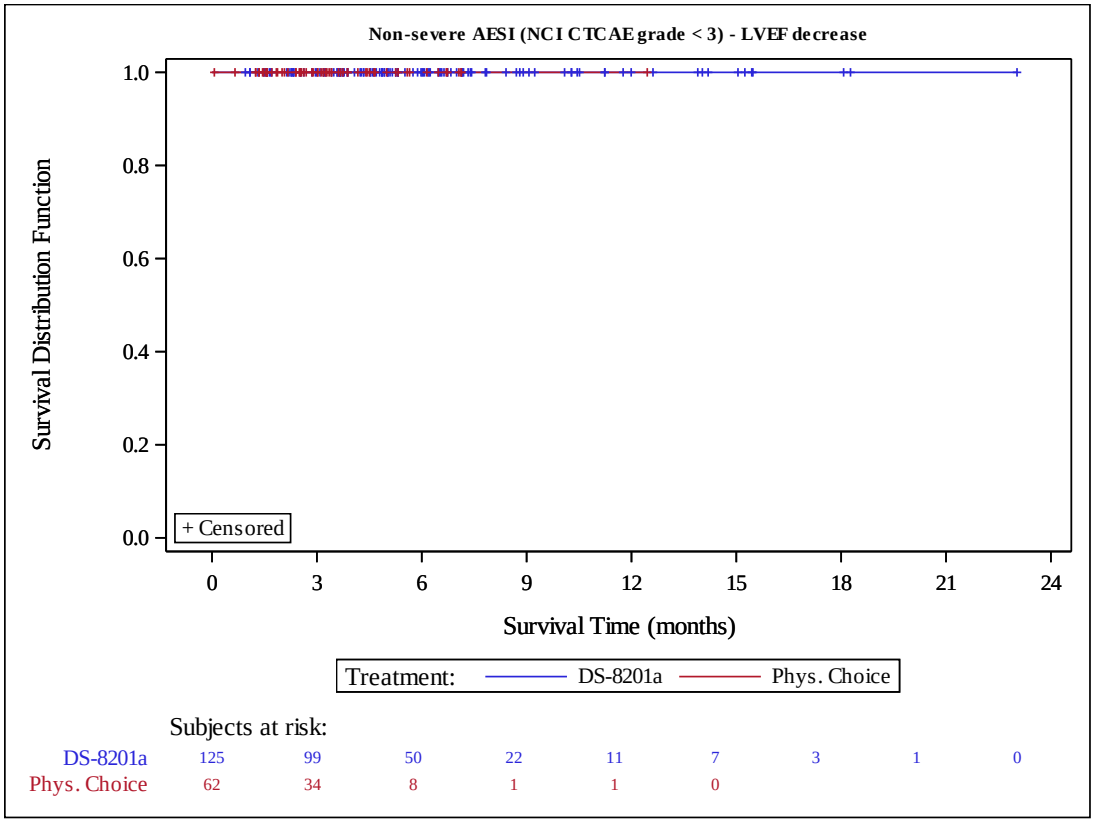
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 67 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 58 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - QT prolongation
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	1 (0.8)	2 (3.2)
Number of censored subjects, n (%)	124 (99.2)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	0.18 (0.02, 2.09)	
p-value [c]	0.1271	
Relative Risk (95% CI) [d]	0.25 (0.02, 2.68)	
p-value	0.2511	
Odds Ratio (95% CI) [d]	0.24 (0.02, 2.72)	
p-value	0.2505	
Risk Difference (95% CI) [e]	-2.43 (-8.30, 3.45)	
p-value	0.4182	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9998
Japan	1/ 99 (1.0)	NE (NE , NE)	2/ 50 (4.0)	NE (NE , NE)	0.19 (0.02, 2.17)	0.1386	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	1/ 66 (1.5)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	0.45 (0.03, 7.32)	0.5647	
3	0/ 34 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9965
<65 years	1/ 55 (1.8)	NE (NE , NE)	1/ 27 (3.7)	NE (NE , NE)	0.30 (0.02, 5.19)	0.3858	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	NE	NE	
Sex							0.9973
female	0/ 30 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9965
0	0/ 62 (0.0)	NE (NE , NE)	1/ 30 (3.3)	NE (NE , NE)	NE	NE	
1	1/ 63 (1.6)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	0.35 (0.02, 5.78)	0.4438	
HER2 Status in central laboratory							0.9970
IHC 3+	1/ 96 (1.0)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	0.30 (0.02, 5.18)	0.3858	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9982
Gastric	0/108 (0.0)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	1/ 89 (1.1)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	0.30 (0.02, 5.01)	0.3749	
diffuse	0/ 28 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9961
<2	0/ 24 (0.0)	NE (NE , NE)	1/ 10 (10.0)	NE (0.7, NE)	NE	NE	
>= 2	1/101 (1.0)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	0.34 (0.02, 5.77)	0.4365	
Previous total gastrectomy							0.9998
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	0.19 (0.02, 2.15)	0.1360	
Prior adjuvant/ neoadjuvant therapy							0.9998
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 95 (1.1)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	0.20 (0.02, 2.28)	0.1524	
Prior ramucirumab contained treatment							0.9977
yes	0/ 94 (0.0)	NE (NE , NE)	2/ 41 (4.9)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9966
yes	0/ 33 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
no	1/ 92 (1.1)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	0.38 (0.02, 6.15)	0.4759	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

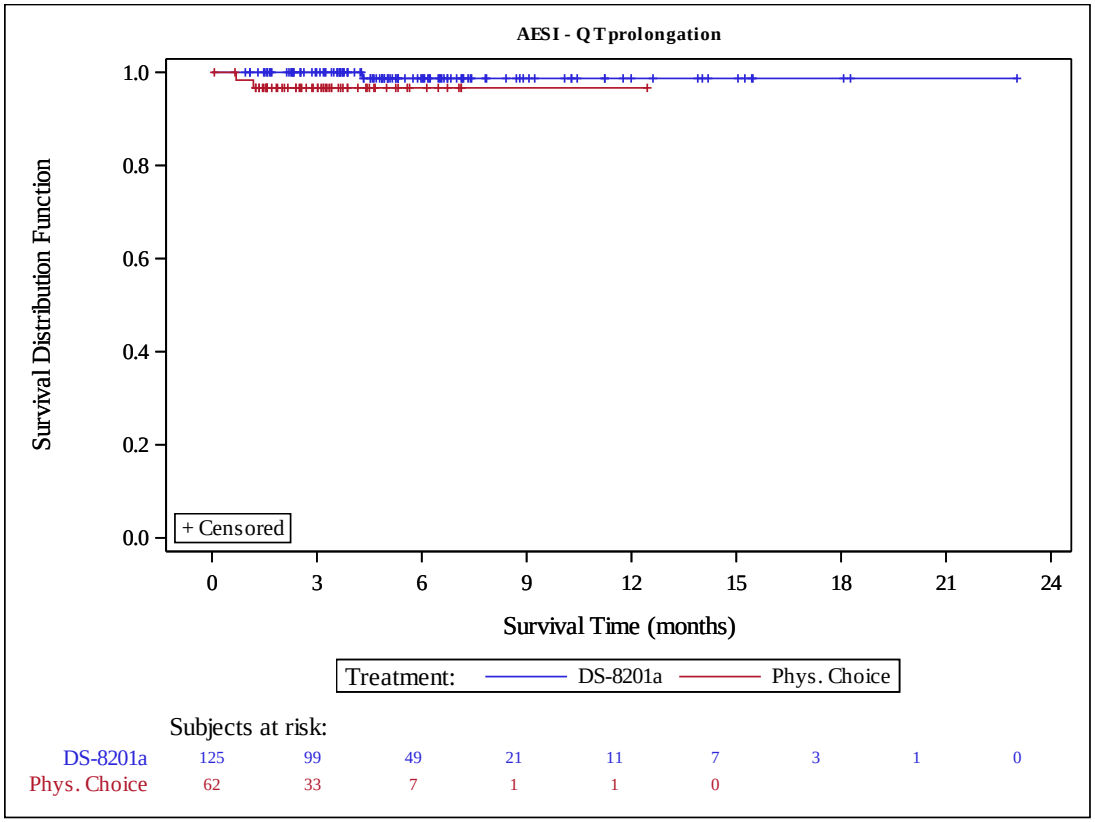
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9958
yes	0/ 44 (0.0)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	NE	NE	
no	1/ 81 (1.2)	NE (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	0.41 (0.02, 6.66)	0.5147	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	0.19 (0.02, 2.19)	0.1404	
Presence of liver metastasis at baseline							0.9965
yes	0/ 67 (0.0)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	NE	NE	
no	1/ 58 (1.7)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	0.32 (0.02, 5.42)	0.4102	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.7 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9998
normal	1/ 88 (1.1)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.18 (0.02, 2.11)	0.1298	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9985
yes	1/ 8 (12.5)	NE (4.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9971
yes	1/ 3 (33.3)	NE (4.3, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of AESI - QT prolongation
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - QT prolongation
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/101 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

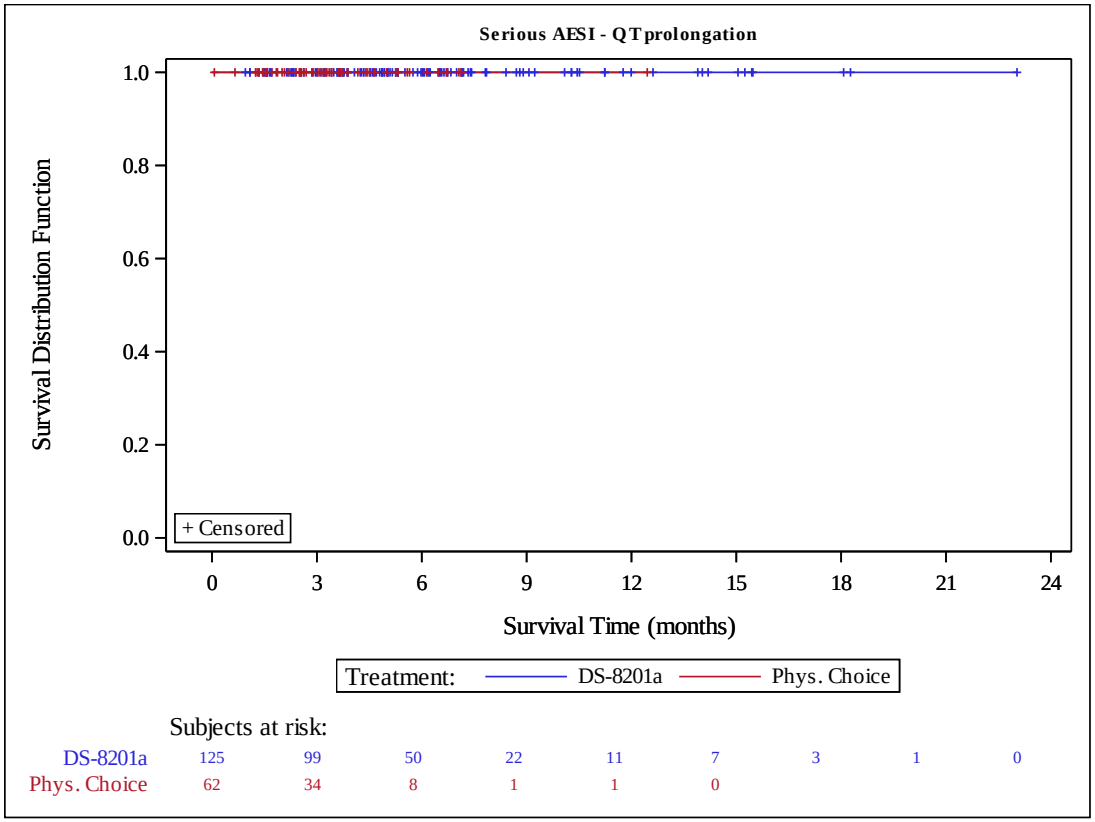
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 67 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 58 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Serious AESI - QT prolongation
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - QT prolongation
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	1 (0.8)	2 (3.2)
Number of censored subjects, n (%)	124 (99.2)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	0.18 (0.02, 2.09)	
p-value [c]	0.1271	
Relative Risk (95% CI) [d]	0.25 (0.02, 2.68)	
p-value	0.2511	
Odds Ratio (95% CI) [d]	0.24 (0.02, 2.72)	
p-value	0.2505	
Risk Difference (95% CI) [e]	-2.43 (-8.30, 3.45)	
p-value	0.4182	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9998
Japan	1/ 99 (1.0)	NE (NE , NE)	2/ 50 (4.0)	NE (NE , NE)	0.19 (0.02, 2.17)	0.1386	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	1/ 66 (1.5)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	0.45 (0.03, 7.32)	0.5647	
3	0/ 34 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9965
<65 years	1/ 55 (1.8)	NE (NE , NE)	1/ 27 (3.7)	NE (NE , NE)	0.30 (0.02, 5.19)	0.3858	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	NE	NE	
Sex							0.9973
female	0/ 30 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9965
0	0/ 62 (0.0)	NE (NE , NE)	1/ 30 (3.3)	NE (NE , NE)	NE	NE	
1	1/ 63 (1.6)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	0.35 (0.02, 5.78)	0.4438	
HER2 Status in central laboratory							0.9970
IHC 3+	1/ 96 (1.0)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	0.30 (0.02, 5.18)	0.3858	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9982
Gastric	0/108 (0.0)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	1/ 89 (1.1)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	0.30 (0.02, 5.01)	0.3749	
diffuse	0/ 28 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9961
<2	0/ 24 (0.0)	NE (NE , NE)	1/ 10 (10.0)	NE (0.7, NE)	NE	NE	
>= 2	1/101 (1.0)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	0.34 (0.02, 5.77)	0.4365	
Previous total gastrectomy							0.9998
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	0.19 (0.02, 2.15)	0.1360	
Prior adjuvant/ neoadjuvant therapy							0.9998
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 95 (1.1)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	0.20 (0.02, 2.28)	0.1524	
Prior ramucirumab contained treatment							0.9977
yes	0/ 94 (0.0)	NE (NE , NE)	2/ 41 (4.9)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9966
yes	0/ 33 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
no	1/ 92 (1.1)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	0.38 (0.02, 6.15)	0.4759	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

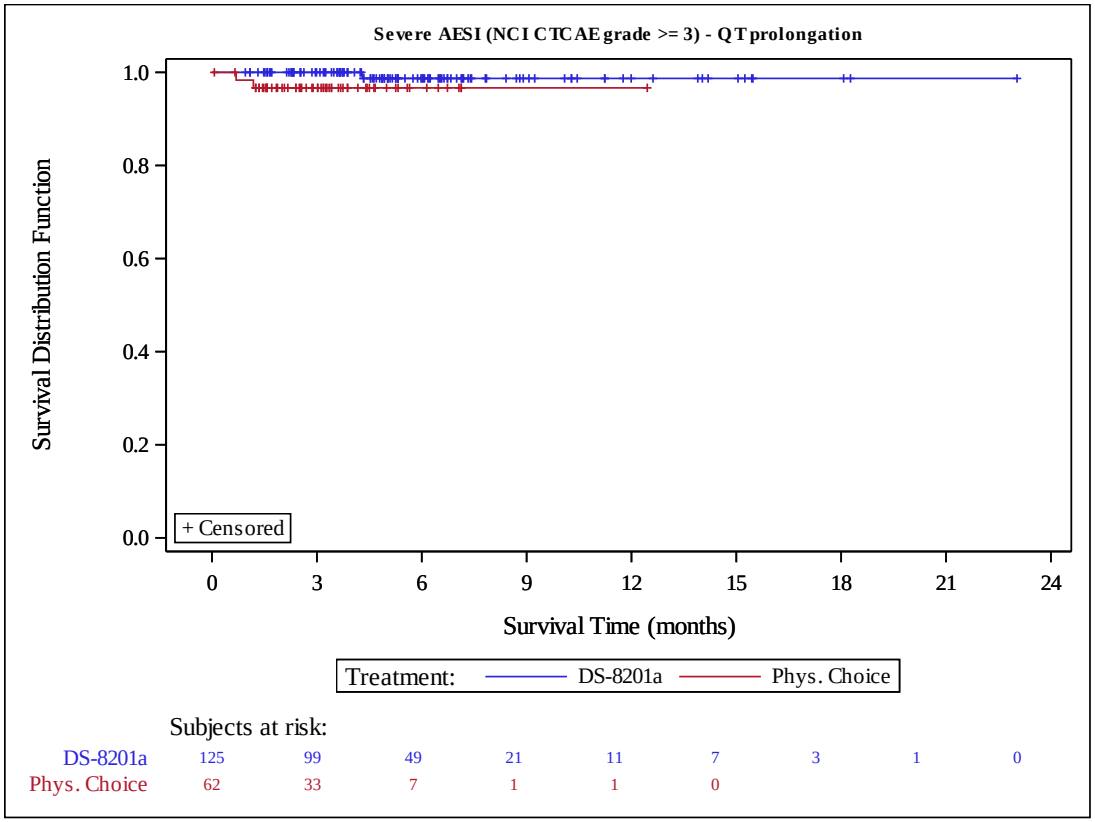
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9958
yes	0/ 44 (0.0)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	NE	NE	
no	1/ 81 (1.2)	NE (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	0.41 (0.02, 6.66)	0.5147	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	0.19 (0.02, 2.19)	0.1404	
Presence of liver metastasis at baseline							0.9965
yes	0/ 67 (0.0)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	NE	NE	
no	1/ 58 (1.7)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	0.32 (0.02, 5.42)	0.4102	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.7 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9998
normal	1/ 88 (1.1)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.18 (0.02, 2.11)	0.1298	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9985
yes	1/ 8 (12.5)	NE (4.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9971
yes	1/ 3 (33.3)	NE (4.3, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - QT prolongation
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - QT prolongation
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/101 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

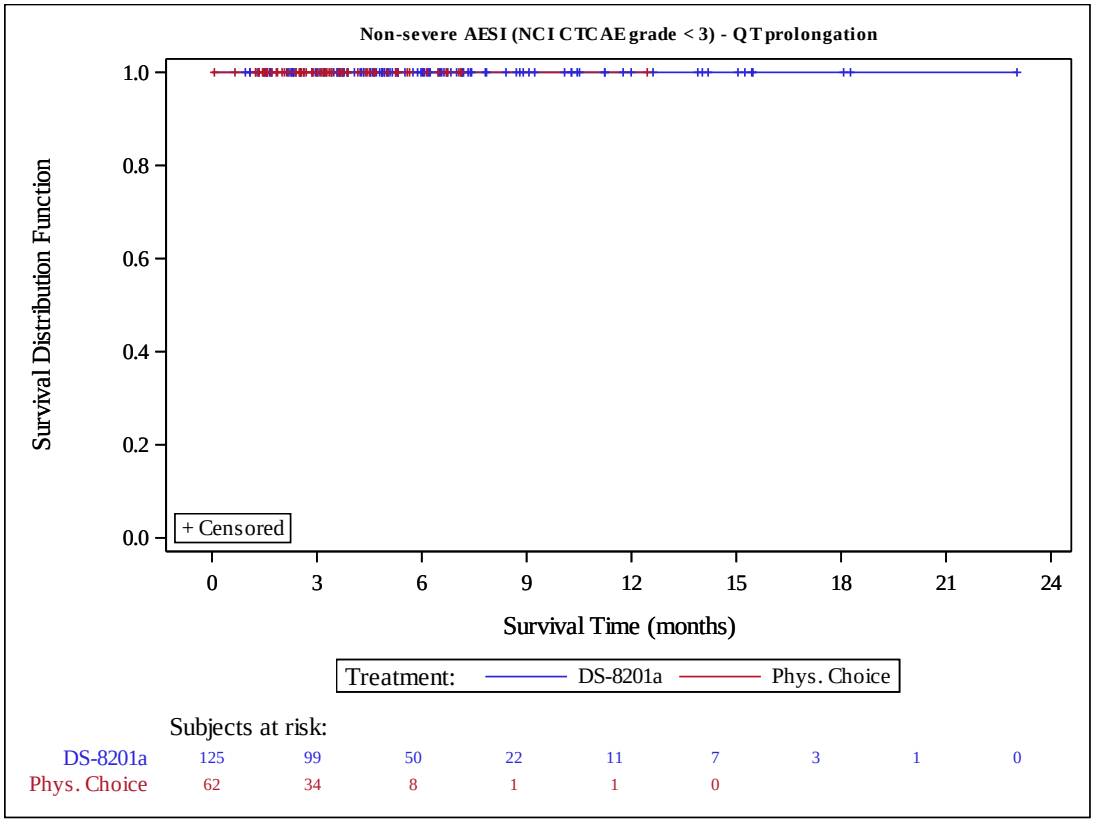
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 67 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 58 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - QT prolongation
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - IRR
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	8 (6.4)	2 (3.2)
Number of censored subjects, n (%)	117 (93.6)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	20.3 (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.34 (0.27, 6.52)	
p-value [c]	0.7175	
Relative Risk (95% CI) [d]	1.98 (0.43, 9.06)	
p-value	0.3768	
Odds Ratio (95% CI) [d]	2.05 (0.42, 9.96)	
p-value	0.3729	
Risk Difference (95% CI) [e]	3.17 (-4.18, 10.52)	
p-value	0.3974	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9932
Japan	6/ 99 (6.1)	20.3 (NE , NE)	2/ 50 (4.0)	NE (NE , NE)	0.96 (0.18, 5.04)	0.9627	
Korea	2/ 26 (7.7)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							0.6764
2	4/ 66 (6.1)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	1.97 (0.22, 17.73)	0.5364	
3	1/ 34 (2.9)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	0.40 (0.02, 6.38)	0.5010	
>=4	3/ 25 (12.0)	20.3 (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.7916
<65 years	3/ 55 (5.5)	NE (NE , NE)	1/ 27 (3.7)	NE (NE , NE)	1.28 (0.13, 12.46)	0.8266	
>=65 years	5/ 70 (7.1)	20.3 (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	1.40 (0.15, 12.81)	0.7621	
Sex							0.9943
female	0/ 30 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
male	8/ 95 (8.4)	20.3 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9939
0	7/ 62 (11.3)	20.3 (NE , NE)	2/ 30 (6.7)	NE (NE , NE)	1.08 (0.21, 5.46)	0.9239	
1	1/ 63 (1.6)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.3735
IHC 3+	7/ 96 (7.3)	20.3 (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	2.25 (0.27, 18.98)	0.4412	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.45 (0.03, 7.26)	0.5668	
Primary tumor location							0.1841
Gastric	7/108 (6.5)	20.3 (NE , NE)	1/ 55 (1.8)	NE (NE , NE)	2.29 (0.27, 19.16)	0.4335	
GEJ	1/ 17 (5.9)	NE (NE , NE)	1/ 7 (14.3)	NE (0.0, NE)	0.40 (0.03, 6.45)	0.5075	
Histological subtype							1.0000
intestinal	8/ 89 (9.0)	20.3 (NE , NE)	2/ 38 (5.3)	NE (NE , NE)	1.22 (0.25, 5.92)	0.8060	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9938
<2	4/ 24 (16.7)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	4/101 (4.0)	20.3 (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	0.57 (0.09, 3.59)	0.5477	
Previous total gastrectomy							0.9940
yes	2/ 22 (9.1)	20.3 (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	6/103 (5.8)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	1.20 (0.24, 6.02)	0.8231	
Prior adjuvant/ neoadjuvant therapy							0.9936
yes	2/ 30 (6.7)	20.3 (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 95 (6.3)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.26 (0.25, 6.35)	0.7787	
Prior ramucirumab contained treatment							0.9935
yes	6/ 94 (6.4)	20.3 (NE , NE)	2/ 41 (4.9)	NE (NE , NE)	0.75 (0.14, 3.95)	0.7290	
no	2/ 31 (6.5)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.4992
yes	2/ 33 (6.1)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.52 (0.04, 6.57)	0.6084	
no	6/ 92 (6.5)	20.3 (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	2.11 (0.25, 18.16)	0.4854	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

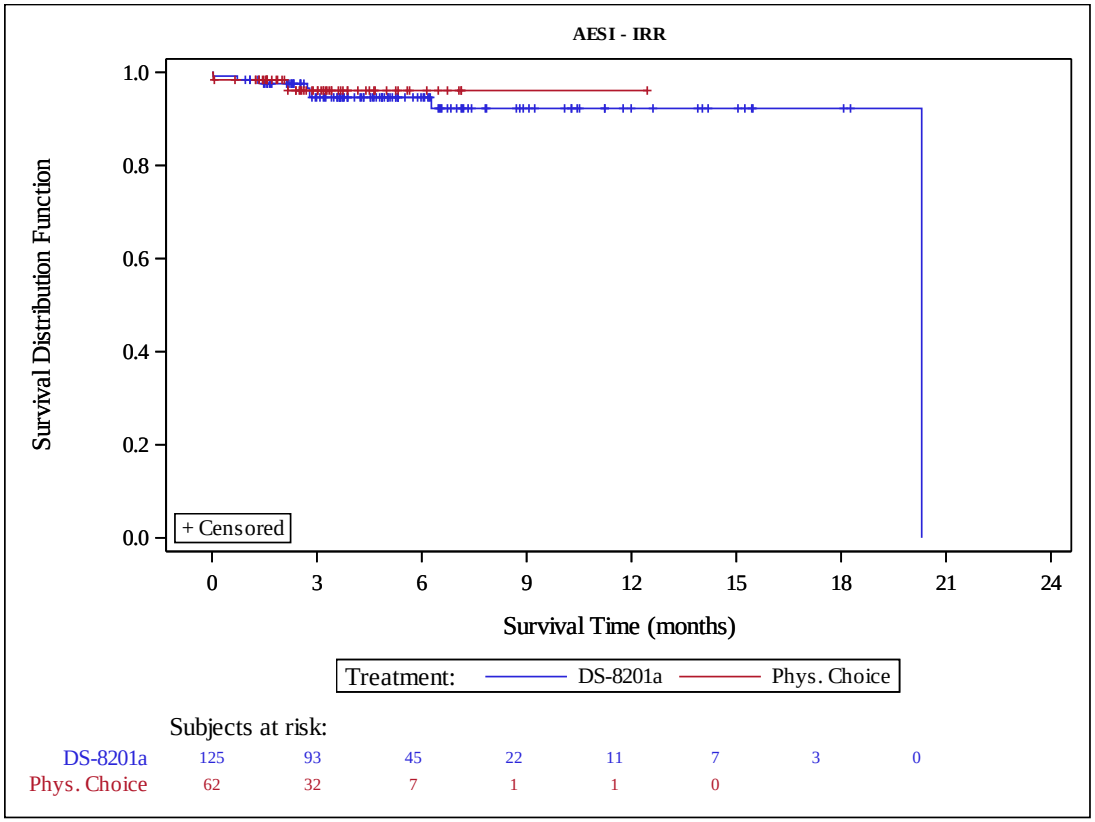
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of AESI - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.3985
yes	2/ 44 (4.5)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	0.44 (0.03, 5.65)	0.5177	
no	6/ 81 (7.4)	20.3 (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	2.33 (0.27, 19.97)	0.4283	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9944
yes	1/ 22 (4.5)	NE (6.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	7/103 (6.8)	20.3 (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	1.32 (0.26, 6.55)	0.7374	
Presence of liver metastasis at baseline							0.5506
yes	2/ 67 (3.0)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	0.59 (0.05, 7.07)	0.6721	
no	6/ 58 (10.3)	20.3 (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	2.14 (0.25, 18.35)	0.4774	
Renal impairment at baseline							0.5928
normal	2/ 33 (6.1)	20.3 (NE , NE)	1/ 13 (7.7)	NE (NE , NE)	0.39 (0.02, 6.23)	0.4899	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	4/ 39 (10.3)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	1.68 (0.18, 15.43)	0.6410	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9951
normal	6/ 88 (6.8)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	1.18 (0.23, 5.99)	0.8392	
mild	2/ 36 (5.6)	20.3 (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9952
yes	2/ 8 (25.0)	20.3 (2.7, 20.3)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	6/117 (5.1)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	1.13 (0.22, 5.69)	0.8820	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9929
yes	1/ 3 (33.3)	NE (2.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	7/122 (5.7)	20.3 (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	1.09 (0.22, 5.51)	0.9132	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of AESI - IRR
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - IRR
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/101 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

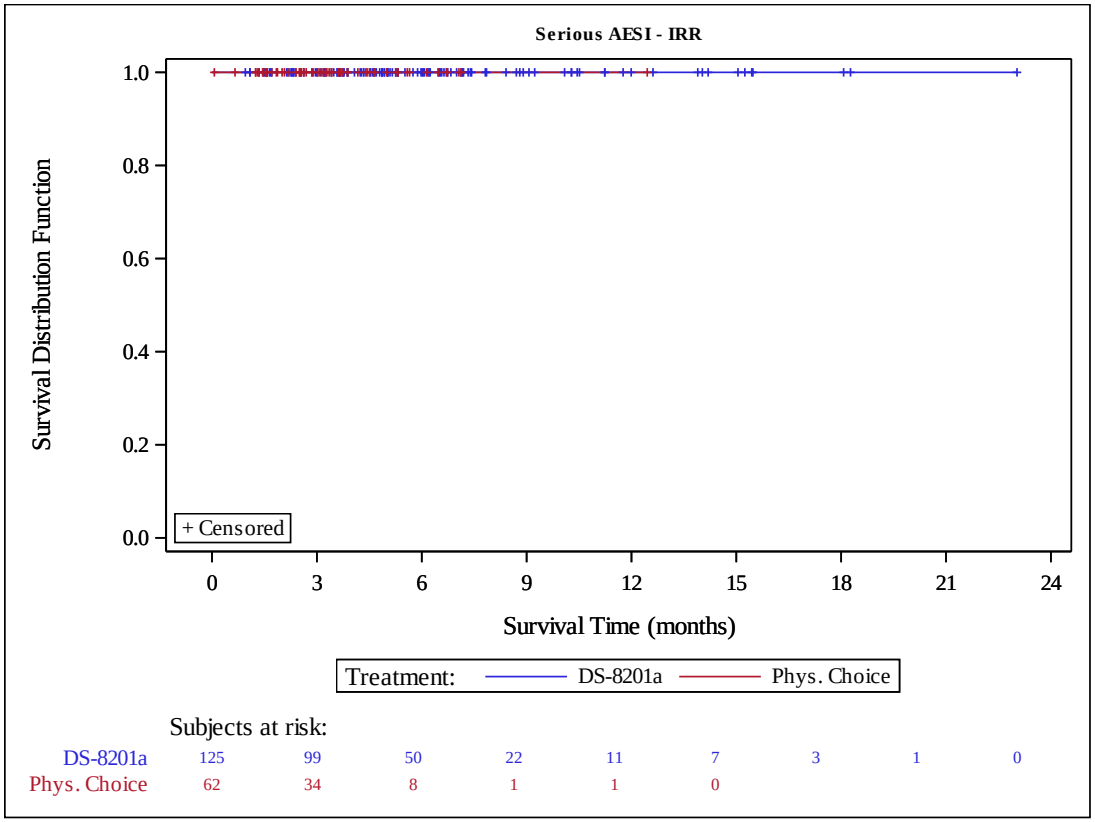
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Serious AESI - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 67 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 58 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Serious AESI - IRR
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - IRR
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 24 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/101 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

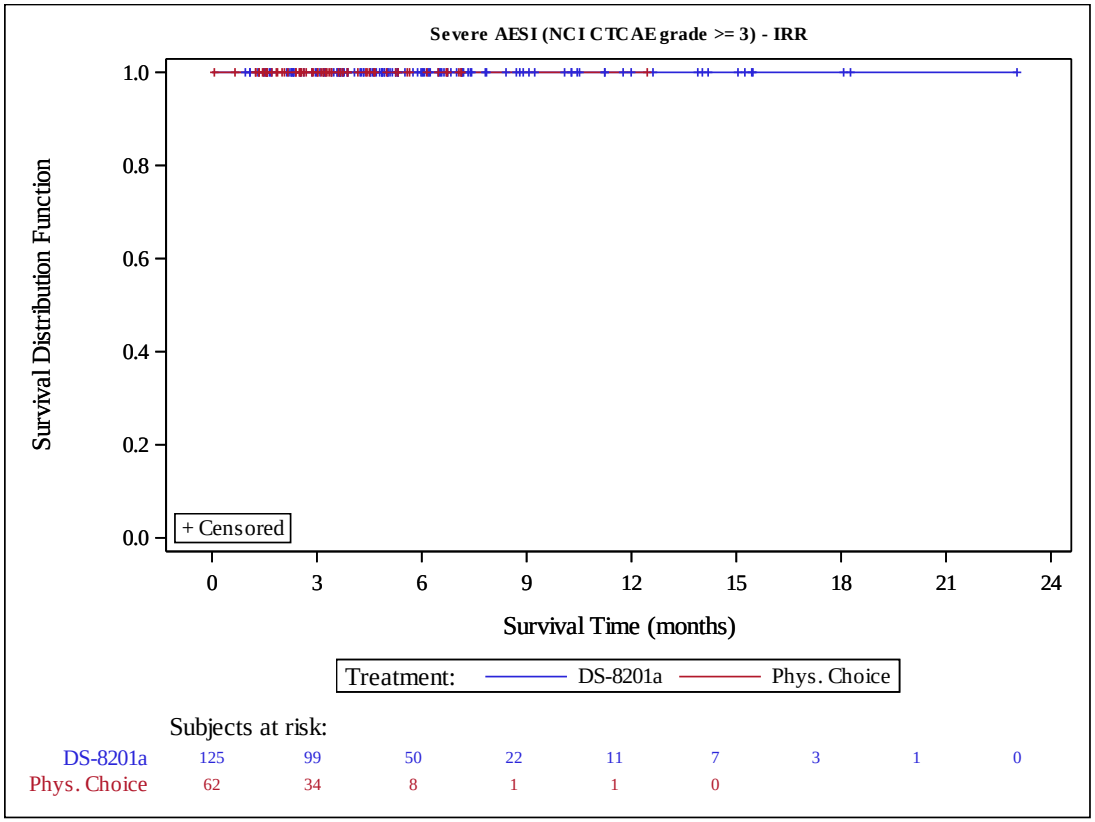
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 67 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 58 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - IRR
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - IRR
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	8 (6.4)	2 (3.2)
Number of censored subjects, n (%)	117 (93.6)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	20.3 (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.34 (0.27, 6.52)	
p-value [c]	0.7175	
Relative Risk (95% CI) [d]	1.98 (0.43, 9.06)	
p-value	0.3768	
Odds Ratio (95% CI) [d]	2.05 (0.42, 9.96)	
p-value	0.3729	
Risk Difference (95% CI) [e]	3.17 (-4.18, 10.52)	
p-value	0.3974	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9932
Japan	6/ 99 (6.1)	20.3 (NE , NE)	2/ 50 (4.0)	NE (NE , NE)	0.96 (0.18, 5.04)	0.9627	
Korea	2/ 26 (7.7)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							0.6764
2	4/ 66 (6.1)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	1.97 (0.22, 17.73)	0.5364	
3	1/ 34 (2.9)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	0.40 (0.02, 6.38)	0.5010	
>=4	3/ 25 (12.0)	20.3 (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.7916
<65 years	3/ 55 (5.5)	NE (NE , NE)	1/ 27 (3.7)	NE (NE , NE)	1.28 (0.13, 12.46)	0.8266	
>=65 years	5/ 70 (7.1)	20.3 (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	1.40 (0.15, 12.81)	0.7621	
Sex							0.9943
female	0/ 30 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
male	8/ 95 (8.4)	20.3 (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9939
0	7/ 62 (11.3)	20.3 (NE , NE)	2/ 30 (6.7)	NE (NE , NE)	1.08 (0.21, 5.46)	0.9239	
1	1/ 63 (1.6)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.3735
IHC 3+	7/ 96 (7.3)	20.3 (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	2.25 (0.27, 18.98)	0.4412	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.45 (0.03, 7.26)	0.5668	
Primary tumor location							0.1841
Gastric	7/108 (6.5)	20.3 (NE , NE)	1/ 55 (1.8)	NE (NE , NE)	2.29 (0.27, 19.16)	0.4335	
GEJ	1/ 17 (5.9)	NE (NE , NE)	1/ 7 (14.3)	NE (0.0, NE)	0.40 (0.03, 6.45)	0.5075	
Histological subtype							1.0000
intestinal	8/ 89 (9.0)	20.3 (NE , NE)	2/ 38 (5.3)	NE (NE , NE)	1.22 (0.25, 5.92)	0.8060	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9938
<2	4/ 24 (16.7)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	4/101 (4.0)	20.3 (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	0.57 (0.09, 3.59)	0.5477	
Previous total gastrectomy							0.9940
yes	2/ 22 (9.1)	20.3 (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	6/103 (5.8)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	1.20 (0.24, 6.02)	0.8231	
Prior adjuvant/ neoadjuvant therapy							0.9936
yes	2/ 30 (6.7)	20.3 (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 95 (6.3)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.26 (0.25, 6.35)	0.7787	
Prior ramucirumab contained treatment							0.9935
yes	6/ 94 (6.4)	20.3 (NE , NE)	2/ 41 (4.9)	NE (NE , NE)	0.75 (0.14, 3.95)	0.7290	
no	2/ 31 (6.5)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.4992
yes	2/ 33 (6.1)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.52 (0.04, 6.57)	0.6084	
no	6/ 92 (6.5)	20.3 (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	2.11 (0.25, 18.16)	0.4854	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

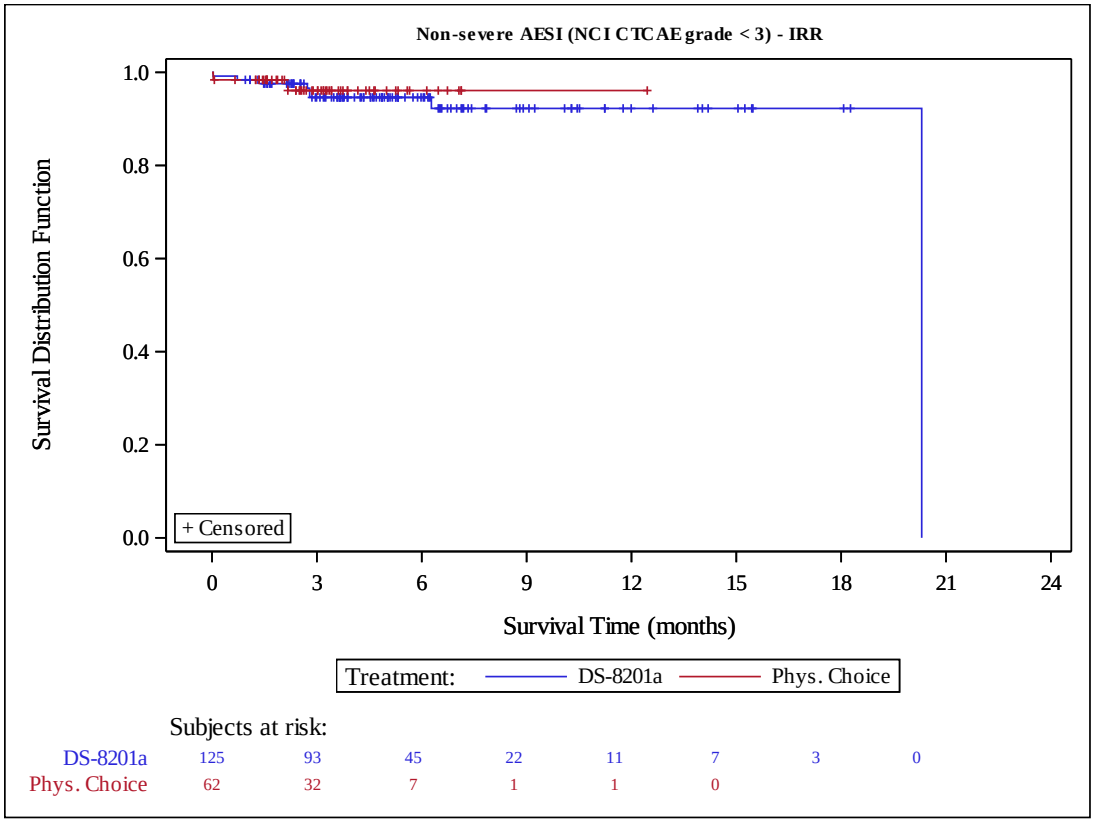
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.3985
yes	2/ 44 (4.5)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	0.44 (0.03, 5.65)	0.5177	
no	6/ 81 (7.4)	20.3 (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	2.33 (0.27, 19.97)	0.4283	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9944
yes	1/ 22 (4.5)	NE (6.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	7/103 (6.8)	20.3 (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	1.32 (0.26, 6.55)	0.7374	
Presence of liver metastasis at baseline							0.5506
yes	2/ 67 (3.0)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	0.59 (0.05, 7.07)	0.6721	
no	6/ 58 (10.3)	20.3 (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	2.14 (0.25, 18.35)	0.4774	
Renal impairment at baseline							0.5928
normal	2/ 33 (6.1)	20.3 (NE , NE)	1/ 13 (7.7)	NE (NE , NE)	0.39 (0.02, 6.23)	0.4899	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	4/ 39 (10.3)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	1.68 (0.18, 15.43)	0.6410	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9951
normal	6/ 88 (6.8)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	1.18 (0.23, 5.99)	0.8392	
mild	2/ 36 (5.6)	20.3 (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9952
yes	2/ 8 (25.0)	20.3 (2.7, 20.3)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	6/117 (5.1)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	1.13 (0.22, 5.69)	0.8820	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9929
yes	1/ 3 (33.3)	NE (2.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	7/122 (5.7)	20.3 (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	1.09 (0.22, 5.51)	0.9132	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - IRR
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	77 (61.6)	20 (32.3)
	Number of censored subjects, n (%)	48 (38.4)	42 (67.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	3.4 (1.8, 4.4)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.93 (1.17, 3.16)	
	p-value [c]	0.0084	
	Relative Risk (95% CI) [d]	1.91 (1.30, 2.81)	
	p-value	0.0010	
	Odds Ratio (95% CI) [d]	3.37 (1.77, 6.41)	
	p-value	0.0002	
	Risk Difference (95% CI) [e]	29.34 (13.71, 44.97)	
	p-value	0.0002	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders, PT: Anaemia	Number of subjects with events, n (%)	71 (56.8)	19 (30.6)
	Number of censored subjects, n (%)	54 (43.2)	43 (69.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	3.9 (2.0, 6.9)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.85 (1.11, 3.08)	
	p-value [c]	0.0165	
	Relative Risk (95% CI) [d]	1.85 (1.24, 2.78)	
	p-value	0.0028	
	Odds Ratio (95% CI) [d]	2.98 (1.56, 5.67)	
	p-value	0.0009	
	Risk Difference (95% CI) [e]	26.15 (10.56, 41.75)	
	p-value	0.0010	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Eye disorders	Number of subjects with events, n (%)	11 (8.8)	1 (1.6)
	Number of censored subjects, n (%)	114 (91.2)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	4.47 (0.57, 34.78)	
	p-value [c]	0.1176	
	Relative Risk (95% CI) [d]	5.46 (0.72, 41.31)	
	p-value	0.1004	
	Odds Ratio (95% CI) [d]	5.89 (0.74, 46.67)	
	p-value	0.0934	
	Risk Difference (95% CI) [e]	7.19 (0.11, 14.27)	
	p-value	0.0466	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	104 (83.2)	47 (75.8)
	Number of censored subjects, n (%)	21 (16.8)	15 (24.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.2 (0.1, 0.3)	0.4 (0.2, 0.9)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.27 (0.90, 1.80)	
	p-value [c]	0.1952	
	Relative Risk (95% CI) [d]	1.10 (0.93, 1.29)	
	p-value	0.2578	
	Odds Ratio (95% CI) [d]	1.58 (0.75, 3.34)	
	p-value	0.2296	
	Risk Difference (95% CI) [e]	7.39 (-6.33, 21.11)	
	p-value	0.2909	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Abdominal pain	Number of subjects with events, n (%)	12 (9.6)	8 (12.9)
	Number of censored subjects, n (%)	113 (90.4)	54 (87.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.46 (0.18, 1.18)	
	p-value [c]	0.0998	
	Relative Risk (95% CI) [d]	0.74 (0.32, 1.73)	
	p-value	0.4908	
	Odds Ratio (95% CI) [d]	0.72 (0.28, 1.86)	
	p-value	0.4929	
	Risk Difference (95% CI) [e]	-3.30 (-14.32, 7.72)	
	p-value	0.5569	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Constipation	Number of subjects with events, n (%)	30 (24.0)	14 (22.6)
	Number of censored subjects, n (%)	95 (76.0)	48 (77.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (10.5, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.85 (0.44, 1.61)	
	p-value [c]	0.6119	
	Relative Risk (95% CI) [d]	1.06 (0.61, 1.85)	
	p-value	0.8300	
	Odds Ratio (95% CI) [d]	1.08 (0.53, 2.23)	
	p-value	0.8295	
	Risk Difference (95% CI) [e]	1.42 (-12.61, 15.45)	
	p-value	0.8428	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	40 (32.0)	20 (32.3)
	Number of censored subjects, n (%)	85 (68.0)	42 (67.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.88 (0.51, 1.51)	
	p-value [c]	0.6385	
	Relative Risk (95% CI) [d]	0.99 (0.64, 1.54)	
	p-value	0.9716	
	Odds Ratio (95% CI) [d]	0.99 (0.52, 1.90)	
	p-value	0.9716	
	Risk Difference (95% CI) [e]	-0.26 (-15.69, 15.17)	
	p-value	0.9738	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	79 (63.2)	29 (46.8)
	Number of censored subjects, n (%)	46 (36.8)	33 (53.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.3 (0.2, 1.7)	NE (0.8, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.64 (1.07, 2.51)	
	p-value [c]	0.0238	
	Relative Risk (95% CI) [d]	1.35 (1.00, 1.82)	
	p-value	0.0473	
	Odds Ratio (95% CI) [d]	1.95 (1.05, 3.62)	
	p-value	0.0334	
	Risk Difference (95% CI) [e]	16.43 (0.20, 32.66)	
	p-value	0.0473	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Stomatitis	Number of subjects with events, n (%)	14 (11.2)	3 (4.8)
	Number of censored subjects, n (%)	111 (88.8)	59 (95.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (16.8, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.82 (0.52, 6.45)	
	p-value [c]	0.3449	
	Relative Risk (95% CI) [d]	2.31 (0.69, 7.76)	
	p-value	0.1737	
	Odds Ratio (95% CI) [d]	2.48 (0.69, 8.98)	
	p-value	0.1663	
	Risk Difference (95% CI) [e]	6.36 (-2.53, 15.26)	
	p-value	0.1610	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Vomiting	Number of subjects with events, n (%)	33 (26.4)	5 (8.1)
	Number of censored subjects, n (%)	92 (73.6)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	3.31 (1.29, 8.49)	
	p-value [c]	0.0085	
	Relative Risk (95% CI) [d]	3.27 (1.34, 7.97)	
	p-value	0.0090	
	Odds Ratio (95% CI) [d]	4.09 (1.51, 11.08)	
	p-value	0.0056	
	Risk Difference (95% CI) [e]	18.34 (6.85, 29.82)	
	p-value	0.0018	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	86 (68.8)	34 (54.8)
	Number of censored subjects, n (%)	39 (31.2)	28 (45.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	1.4 (0.7, 1.9)	2.4 (1.0, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.30 (0.87, 1.93)	
	p-value [c]	0.2042	
	Relative Risk (95% CI) [d]	1.25 (0.97, 1.62)	
	p-value	0.0811	
	Odds Ratio (95% CI) [d]	1.82 (0.97, 3.40)	
	p-value	0.0622	
	Risk Difference (95% CI) [e]	13.96 (-2.06, 29.98)	
	p-value	0.0876	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	27 (21.6)	15 (24.2)
	Number of censored subjects, n (%)	98 (78.4)	47 (75.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.81 (0.43, 1.52)	
	p-value [c]	0.5116	
	Relative Risk (95% CI) [d]	0.89 (0.51, 1.55)	
	p-value	0.6877	
	Odds Ratio (95% CI) [d]	0.86 (0.42, 1.77)	
	p-value	0.6892	
	Risk Difference (95% CI) [e]	-2.59 (-16.67, 11.48)	
	p-value	0.7180	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
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SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Malaise	Number of subjects with events, n (%)	43 (34.4)	10 (16.1)
	Number of censored subjects, n (%)	82 (65.6)	52 (83.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.23 (1.12, 4.44)	
	p-value [c]	0.0192	
	Relative Risk (95% CI) [d]	2.13 (1.15, 3.95)	
	p-value	0.0161	
	Odds Ratio (95% CI) [d]	2.73 (1.26, 5.89)	
	p-value	0.0108	
	Risk Difference (95% CI) [e]	18.27 (4.69, 31.85)	
	p-value	0.0084	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Oedema peripheral	Number of subjects with events, n (%)	13 (10.4)	0 (0.0)
	Number of censored subjects, n (%)	112 (89.6)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	13.50 (0.82, 223.43)	
	p-value	0.0691	
	Odds Ratio (95% CI) [d]	15.00 (0.88, 256.62)	
	p-value	0.0616	
	Risk Difference (95% CI) [e]	10.40 (3.84, 16.96)	
	p-value	0.0019	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
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Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Pyrexia	Number of subjects with events, n (%)	30 (24.0)	10 (16.1)
	Number of censored subjects, n (%)	95 (76.0)	52 (83.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.16 (0.56, 2.39)	
	p-value [c]	0.6933	
	Relative Risk (95% CI) [d]	1.49 (0.78, 2.84)	
	p-value	0.2291	
	Odds Ratio (95% CI) [d]	1.64 (0.74, 3.62)	
	p-value	0.2194	
	Risk Difference (95% CI) [e]	7.87 (-5.16, 20.90)	
	p-value	0.2365	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
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Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders	Number of subjects with events, n (%)	21 (16.8)	3 (4.8)
	Number of censored subjects, n (%)	104 (83.2)	59 (95.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.65 (0.78, 8.97)	
	p-value [c]	0.1036	
	Relative Risk (95% CI) [d]	3.47 (1.08, 11.20)	
	p-value	0.0372	
	Odds Ratio (95% CI) [d]	3.97 (1.14, 13.88)	
	p-value	0.0308	
	Risk Difference (95% CI) [e]	11.96 (2.30, 21.62)	
	p-value	0.0152	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders, PT: Hepatic function abnormal	Number of subjects with events, n (%)	10 (8.0)	1 (1.6)
	Number of censored subjects, n (%)	115 (92.0)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	4.05 (0.51, 31.89)	
	p-value [c]	0.1504	
	Relative Risk (95% CI) [d]	4.96 (0.65, 37.88)	
	p-value	0.1226	
	Odds Ratio (95% CI) [d]	5.30 (0.66, 42.41)	
	p-value	0.1157	
	Risk Difference (95% CI) [e]	6.39 (-0.52, 13.29)	
	p-value	0.0698	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations	Number of subjects with events, n (%)	51 (40.8)	14 (22.6)
	Number of censored subjects, n (%)	74 (59.2)	48 (77.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	9.0 (4.8, NE)	8.0 (4.9, 8.0)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.32 (0.72, 2.42)	
	p-value [c]	0.3602	
	Relative Risk (95% CI) [d]	1.81 (1.09, 3.00)	
	p-value	0.0222	
	Odds Ratio (95% CI) [d]	2.36 (1.18, 4.73)	
	p-value	0.0152	
	Risk Difference (95% CI) [e]	18.22 (3.50, 32.94)	
	p-value	0.0153	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	10 (8.0)	5 (8.1)
	Number of censored subjects, n (%)	115 (92.0)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.59 (0.19, 1.81)	
	p-value [c]	0.3484	
	Relative Risk (95% CI) [d]	0.99 (0.35, 2.78)	
	p-value	0.9878	
	Odds Ratio (95% CI) [d]	0.99 (0.32, 3.04)	
	p-value	0.9878	
	Risk Difference (95% CI) [e]	-0.06 (-9.55, 9.42)	
	p-value	0.9894	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	11 (8.8)	2 (3.2)
	Number of censored subjects, n (%)	114 (91.2)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.18 (0.48, 9.91)	
	p-value [c]	0.3010	
	Relative Risk (95% CI) [d]	2.73 (0.62, 11.93)	
	p-value	0.1825	
	Odds Ratio (95% CI) [d]	2.89 (0.62, 13.49)	
	p-value	0.1758	
	Risk Difference (95% CI) [e]	5.57 (-2.27, 13.41)	
	p-value	0.1635	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations	Number of subjects with events, n (%)	99 (79.2)	33 (53.2)
	Number of censored subjects, n (%)	26 (20.8)	29 (46.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.5 (0.3, 0.7)	2.8 (0.5, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.77 (1.19, 2.63)	
	p-value [c]	0.0045	
	Relative Risk (95% CI) [d]	1.49 (1.16, 1.91)	
	p-value	0.0018	
	Odds Ratio (95% CI) [d]	3.35 (1.73, 6.47)	
	p-value	0.0003	
	Risk Difference (95% CI) [e]	25.97 (10.45, 41.49)	
	p-value	0.0010	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Aspartate aminotransferase increased	Number of subjects with events, n (%)	12 (9.6)	3 (4.8)
	Number of censored subjects, n (%)	113 (90.4)	59 (95.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.29 (0.36, 4.69)	
	p-value [c]	0.6955	
	Relative Risk (95% CI) [d]	1.98 (0.58, 6.77)	
	p-value	0.2742	
	Odds Ratio (95% CI) [d]	2.09 (0.57, 7.69)	
	p-value	0.2682	
	Risk Difference (95% CI) [e]	4.76 (-3.87, 13.40)	
	p-value	0.2799	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Blood alkaline phosphatase increased	Number of subjects with events, n (%)	10 (8.0)	2 (3.2)
	Number of censored subjects, n (%)	115 (92.0)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.47 (0.31, 6.90)	
	p-value [c]	0.6198	
	Relative Risk (95% CI) [d]	2.48 (0.56, 10.97)	
	p-value	0.2314	
	Odds Ratio (95% CI) [d]	2.61 (0.55, 12.29)	
	p-value	0.2253	
	Risk Difference (95% CI) [e]	4.77 (-2.91, 12.46)	
	p-value	0.2233	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Blood bilirubin increased	Number of subjects with events, n (%)	10 (8.0)	0 (0.0)
	Number of censored subjects, n (%)	115 (92.0)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	10.50 (0.63, 176.31)	
	p-value	0.1023	
	Odds Ratio (95% CI) [d]	11.36 (0.65, 197.18)	
	p-value	0.0951	
	Risk Difference (95% CI) [e]	8.00 (2.04, 13.96)	
	p-value	0.0085	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Lymphocyte count decreased	Number of subjects with events, n (%)	27 (21.6)	2 (3.2)
	Number of censored subjects, n (%)	98 (78.4)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	6.05 (1.43, 25.56)	
	p-value [c]	0.0053	
	Relative Risk (95% CI) [d]	6.70 (1.65, 27.25)	
	p-value	0.0079	
	Odds Ratio (95% CI) [d]	8.27 (1.90, 36.01)	
	p-value	0.0049	
	Risk Difference (95% CI) [e]	18.37 (8.72, 28.03)	
	p-value	0.0002	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Neutrophil count decreased	Number of subjects with events, n (%)	77 (61.6)	21 (33.9)
	Number of censored subjects, n (%)	48 (38.4)	41 (66.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	1.3 (0.7, 3.5)	NE (2.8, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.88 (1.16, 3.04)	
	p-value [c]	0.0102	
	Relative Risk (95% CI) [d]	1.82 (1.25, 2.64)	
	p-value	0.0017	
	Odds Ratio (95% CI) [d]	3.13 (1.66, 5.93)	
	p-value	0.0004	
	Risk Difference (95% CI) [e]	27.73 (11.98, 43.48)	
	p-value	0.0006	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Platelet count decreased	Number of subjects with events, n (%)	47 (37.6)	4 (6.5)
	Number of censored subjects, n (%)	78 (62.4)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (9.8, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	6.68 (2.40, 18.56)	
	p-value [c]	<.0001	
	Relative Risk (95% CI) [d]	5.83 (2.20, 15.44)	
	p-value	0.0004	
	Odds Ratio (95% CI) [d]	8.74 (2.98, 25.62)	
	p-value	<.0001	
	Risk Difference (95% CI) [e]	31.15 (19.48, 42.82)	
	p-value	<.0001	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Weight decreased	Number of subjects with events, n (%)	17 (13.6)	5 (8.1)
	Number of censored subjects, n (%)	108 (86.4)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.29 (0.47, 3.53)	
	p-value [c]	0.6214	
	Relative Risk (95% CI) [d]	1.69 (0.65, 4.36)	
	p-value	0.2807	
	Odds Ratio (95% CI) [d]	1.79 (0.63, 5.12)	
	p-value	0.2739	
	Risk Difference (95% CI) [e]	5.54 (-4.73, 15.80)	
	p-value	0.2905	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: White blood cell count decreased	Number of subjects with events, n (%)	47 (37.6)	21 (33.9)
	Number of censored subjects, n (%)	78 (62.4)	41 (66.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (2.8, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.98 (0.59, 1.65)	
	p-value [c]	0.9243	
	Relative Risk (95% CI) [d]	1.11 (0.73, 1.68)	
	p-value	0.6216	
	Odds Ratio (95% CI) [d]	1.18 (0.62, 2.23)	
	p-value	0.6179	
	Risk Difference (95% CI) [e]	3.73 (-12.00, 19.46)	
	p-value	0.6422	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	86 (68.8)	34 (54.8)
	Number of censored subjects, n (%)	39 (31.2)	28 (45.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.5 (0.2, 1.5)	2.1 (0.6, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.39 (0.93, 2.07)	
	p-value [c]	0.1108	
	Relative Risk (95% CI) [d]	1.25 (0.97, 1.62)	
	p-value	0.0811	
	Odds Ratio (95% CI) [d]	1.82 (0.97, 3.40)	
	p-value	0.0622	
	Risk Difference (95% CI) [e]	13.96 (-2.06, 29.98)	
	p-value	0.0876	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Number of subjects with events, n (%)	75 (60.0)	28 (45.2)
	Number of censored subjects, n (%)	50 (40.0)	34 (54.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.8 (0.3, 3.7)	6.0 (1.2, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.47 (0.95, 2.27)	
	p-value [c]	0.0852	
	Relative Risk (95% CI) [d]	1.33 (0.98, 1.81)	
	p-value	0.0719	
	Odds Ratio (95% CI) [d]	1.82 (0.98, 3.37)	
	p-value	0.0560	
	Risk Difference (95% CI) [e]	14.84 (-1.44, 31.12)	
	p-value	0.0740	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Hypoalbuminaemia	Number of subjects with events, n (%)	18 (14.4)	8 (12.9)
	Number of censored subjects, n (%)	107 (85.6)	54 (87.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.83 (0.36, 1.94)	
	p-value [c]	0.6719	
	Relative Risk (95% CI) [d]	1.12 (0.51, 2.42)	
	p-value	0.7814	
	Odds Ratio (95% CI) [d]	1.14 (0.46, 2.78)	
	p-value	0.7807	
	Risk Difference (95% CI) [e]	1.50 (-10.08, 13.07)	
	p-value	0.7999	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	23 (18.4)	8 (12.9)
	Number of censored subjects, n (%)	102 (81.6)	54 (87.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	15.4 (14.5, NE)	8.5 (5.8, 8.5)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.98 (0.42, 2.24)	
	p-value [c]	0.9540	
	Relative Risk (95% CI) [d]	1.43 (0.68, 3.00)	
	p-value	0.3503	
	Odds Ratio (95% CI) [d]	1.52 (0.64, 3.63)	
	p-value	0.3437	
	Risk Difference (95% CI) [e]	5.50 (-6.47, 17.46)	
	p-value	0.3679	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

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Primary Cohort
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	13 (10.4)	6 (9.7)
	Number of censored subjects, n (%)	112 (89.6)	56 (90.3)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.82 (0.31, 2.19)	
	p-value [c]	0.6958	
	Relative Risk (95% CI) [d]	1.07 (0.43, 2.69)	
	p-value	0.8778	
	Odds Ratio (95% CI) [d]	1.08 (0.39, 3.00)	
	p-value	0.8777	
	Risk Difference (95% CI) [e]	0.72 (-9.58, 11.03)	
	p-value	0.8907	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Nervous system disorders	Number of subjects with events, n (%)	26 (20.8)	17 (27.4)
	Number of censored subjects, n (%)	99 (79.2)	45 (72.6)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.63 (0.34, 1.17)	
	p-value [c]	0.1432	
	Relative Risk (95% CI) [d]	0.76 (0.45, 1.29)	
	p-value	0.3070	
	Odds Ratio (95% CI) [d]	0.70 (0.34, 1.41)	
	p-value	0.3125	
	Risk Difference (95% CI) [e]	-6.62 (-21.01, 7.78)	
	p-value	0.3674	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	13 (10.4)	7 (11.3)
	Number of censored subjects, n (%)	112 (89.6)	55 (88.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.75 (0.29, 1.90)	
	p-value [c]	0.5379	
	Relative Risk (95% CI) [d]	0.92 (0.39, 2.19)	
	p-value	0.8527	
	Odds Ratio (95% CI) [d]	0.91 (0.34, 2.42)	
	p-value	0.8529	
	Risk Difference (95% CI) [e]	-0.89 (-11.62, 9.84)	
	p-value	0.8708	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

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Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Psychiatric disorders, PT: Insomnia	Number of subjects with events, n (%)	11 (8.8)	5 (8.1)
	Number of censored subjects, n (%)	114 (91.2)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.85 (0.29, 2.48)	
	p-value [c]	0.7611	
	Relative Risk (95% CI) [d]	1.09 (0.40, 3.00)	
	p-value	0.8658	
	Odds Ratio (95% CI) [d]	1.10 (0.36, 3.32)	
	p-value	0.8656	
	Risk Difference (95% CI) [e]	0.74 (-8.87, 10.34)	
	p-value	0.8807	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	34 (27.2)	12 (19.4)
	Number of censored subjects, n (%)	91 (72.8)	50 (80.6)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	22.3 (12.4, 22.3)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.01 (0.51, 1.97)	
	p-value [c]	0.9802	
	Relative Risk (95% CI) [d]	1.41 (0.78, 2.52)	
	p-value	0.2530	
	Odds Ratio (95% CI) [d]	1.56 (0.74, 3.27)	
	p-value	0.2430	
	Risk Difference (95% CI) [e]	7.85 (-5.91, 21.60)	
	p-value	0.2638	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	45 (36.0)	17 (27.4)
	Number of censored subjects, n (%)	80 (64.0)	45 (72.6)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	20.3 (10.3, 20.3)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.16 (0.66, 2.03)	
	p-value [c]	0.6021	
	Relative Risk (95% CI) [d]	1.31 (0.82, 2.10)	
	p-value	0.2538	
	Odds Ratio (95% CI) [d]	1.49 (0.76, 2.90)	
	p-value	0.2420	
	Risk Difference (95% CI) [e]	8.58 (-6.56, 23.72)	
	p-value	0.2666	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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Primary Cohort
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Skin and subcutaneous tissue disorders, PT: Alopecia	Number of subjects with events, n (%)	28 (22.4)	9 (14.5)
	Number of censored subjects, n (%)	97 (77.6)	53 (85.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.46 (0.69, 3.09)	
	p-value [c]	0.3197	
	Relative Risk (95% CI) [d]	1.54 (0.78, 3.07)	
	p-value	0.2156	
	Odds Ratio (95% CI) [d]	1.70 (0.75, 3.87)	
	p-value	0.2060	
	Risk Difference (95% CI) [e]	7.88 (-4.74, 20.51)	
	p-value	0.2209	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Vascular disorders	Number of subjects with events, n (%)	6 (4.8)	7 (11.3)
	Number of censored subjects, n (%)	119 (95.2)	55 (88.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.37 (0.12, 1.11)	
	p-value [c]	0.0649	
	Relative Risk (95% CI) [d]	0.43 (0.15, 1.21)	
	p-value	0.1094	
	Odds Ratio (95% CI) [d]	0.40 (0.13, 1.23)	
	p-value	0.1102	
	Risk Difference (95% CI) [e]	-6.49 (-16.42, 3.44)	
	p-value	0.2002	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Blood and lymphatic system disorders	Region							0.5050
	Japan	61/ 99 (61.6)	3.6 (1.9, 4.8)	15/ 50 (30.0)	NE (NE , NE)	2.08 (1.18, 3.67)	0.0104	
	Korea	16/ 26 (61.5)	1.8 (0.7, NE)	5/ 12 (41.7)	NE (0.3, NE)	1.43 (0.52, 3.90)	0.4849	
	Lines of prior systemic therapy							0.5061
	2	42/ 66 (63.6)	2.0 (1.0, 4.4)	13/ 38 (34.2)	NE (2.3, NE)	1.96 (1.05, 3.66)	0.0316	
	3	18/ 34 (52.9)	4.1 (2.0, NE)	6/ 18 (33.3)	NE (1.4, NE)	1.30 (0.51, 3.33)	0.5835	
	>=4	17/ 25 (68.0)	2.6 (0.5, 11.7)	1/ 6 (16.7)	NE (1.7, NE)	4.63 (0.61, 34.95)	0.1030	
	Age							0.4486
	<65 years	35/ 55 (63.6)	3.4 (1.4, 5.2)	7/ 27 (25.9)	NE (2.3, NE)	2.39 (1.05, 5.40)	0.0308	
	>=65 years	42/ 70 (60.0)	3.2 (1.0, 5.5)	13/ 35 (37.1)	NE (1.7, NE)	1.66 (0.89, 3.11)	0.1102	
	Sex							0.0597
	female	20/ 30 (66.7)	1.4 (0.5, 10.0)	2/ 15 (13.3)	NE (NE , NE)	6.00 (1.40, 25.80)	0.0060	
	male	57/ 95 (60.0)	3.5 (1.9, 5.2)	18/ 47 (38.3)	NE (1.9, NE)	1.47 (0.86, 2.50)	0.1583	
	ECOG PS							0.5146
	0	33/ 62 (53.2)	4.8 (1.9, 14.6)	7/ 30 (23.3)	NE (NE , NE)	2.41 (1.06, 5.48)	0.0320	
	1	44/ 63 (69.8)	2.0 (1.0, 3.6)	13/ 32 (40.6)	NE (1.2, NE)	1.66 (0.89, 3.09)	0.1022	
	HER2 Status in central laboratory							0.6349
	IHC 3+	60/ 96 (62.5)	3.4 (1.6, 4.4)	16/ 47 (34.0)	NE (2.3, NE)	1.80 (1.03, 3.14)	0.0355	
	IHC 2+/ISH +	17/ 29 (58.6)	2.8 (0.8, 6.9)	4/ 15 (26.7)	NE (1.0, NE)	2.42 (0.81, 7.20)	0.1039	
	Primary tumor location							0.8891
	Gastric	67/108 (62.0)	2.8 (1.5, 4.3)	18/ 55 (32.7)	NE (2.8, NE)	1.97 (1.16, 3.32)	0.0100	
	GEJ	10/ 17 (58.8)	4.3 (1.4, NE)	2/ 7 (28.6)	NE (0.6, NE)	1.65 (0.36, 7.67)	0.5185	
	Histological subtype							0.4419
	intestinal	52/ 89 (58.4)	4.1 (1.9, 10.0)	14/ 38 (36.8)	NE (2.3, NE)	1.58 (0.87, 2.86)	0.1358	
	diffuse	19/ 28 (67.9)	2.0 (0.5, 3.9)	4/ 18 (22.2)	NE (1.1, NE)	2.81 (0.95, 8.31)	0.0506	
	others	6/ 8 (75.0)	1.0 (0.1, 5.2)	2/ 6 (33.3)	NE (0.3, NE)	3.65 (0.71, 18.70)	0.0996	
	Number of metastatic sites							0.6039
	<2	13/ 24 (54.2)	11.7 (0.8, NE)	2/ 10 (20.0)	NE (0.5, NE)	2.56 (0.57, 11.46)	0.2008	
	>= 2	64/101 (63.4)	2.6 (1.5, 4.3)	18/ 52 (34.6)	NE (1.9, NE)	1.87 (1.11, 3.17)	0.0178	
	Previous total gastrectomy							0.3963
	yes	10/ 22 (45.5)	4.8 (1.9, NE)	3/ 9 (33.3)	NE (0.5, NE)	1.13 (0.31, 4.14)	0.8487	
	no	67/103 (65.0)	2.8 (1.0, 4.3)	17/ 53 (32.1)	NE (2.8, NE)	2.13 (1.25, 3.63)	0.0047	
	Prior adjuvant/ neoadjuvant therapy							0.6985
	yes	16/ 30 (53.3)	4.3 (1.8, NE)	2/ 10 (20.0)	NE (0.5, NE)	2.52 (0.57, 11.07)	0.2055	
	no	61/ 95 (64.2)	2.4 (1.4, 4.3)	18/ 52 (34.6)	NE (2.3, NE)	1.91 (1.13, 3.24)	0.0146	
	Prior ramucirumab contained treatment							0.3190
	yes	58/ 94 (61.7)	3.0 (1.4, 4.8)	11/ 41 (26.8)	NE (NE , NE)	2.40 (1.26, 4.59)	0.0063	
	no	19/ 31 (61.3)	3.5 (1.8, 11.7)	9/ 21 (42.9)	NE (0.6, NE)	1.35 (0.61, 3.00)	0.4568	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Blood and lymphatic system disorders	Prior nivolumab contained treatment							0.8736
	yes	23/ 33 (69.7)	2.4 (0.5, 11.7)	5/ 15 (33.3)	NE (1.4, NE)	2.02 (0.75, 5.41)	0.1606	
	no	54/ 92 (58.7)	3.5 (1.8, 4.4)	15/ 47 (31.9)	NE (2.8, NE)	1.88 (1.06, 3.34)	0.0279	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8087
	yes	31/ 44 (70.5)	2.0 (0.5, 4.8)	6/ 17 (35.3)	NE (1.4, NE)	2.05 (0.85, 4.97)	0.1075	
	no	46/ 81 (56.8)	3.7 (1.9, 5.5)	14/ 45 (31.1)	NE (2.8, NE)	1.81 (1.00, 3.30)	0.0488	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.2851
	yes	14/ 22 (63.6)	3.2 (0.5, 5.5)	1/ 7 (14.3)	NE (0.6, NE)	5.67 (0.74, 43.18)	0.0583	
	no	63/103 (61.2)	3.4 (1.5, 4.8)	19/ 55 (34.5)	NE (2.3, NE)	1.75 (1.04, 2.93)	0.0321	
	Presence of liver metastasis at baseline							0.2455
	yes	45/ 67 (67.2)	2.0 (0.5, 3.4)	15/ 34 (44.1)	NE (1.2, NE)	1.60 (0.89, 2.89)	0.1177	
	no	32/ 58 (55.2)	4.4 (2.6, 11.7)	5/ 28 (17.9)	NE (NE , NE)	3.00 (1.17, 7.72)	0.0169	
	Renal impairment at baseline							0.0485
	normal	22/ 33 (66.7)	3.7 (1.4, 4.8)	1/ 13 (7.7)	NE (NE , NE)	7.18 (0.95, 53.95)	0.0254	
	mild	32/ 53 (60.4)	3.6 (1.0, 6.9)	14/ 28 (50.0)	2.3 (1.4, NE)	1.12 (0.60, 2.11)	0.7342	
	moderate	23/ 39 (59.0)	2.0 (0.5, NE)	4/ 20 (20.0)	NE (NE , NE)	3.73 (1.29, 10.80)	0.0090	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.5 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.9520
	normal	54/ 88 (61.4)	3.6 (1.6, 5.2)	15/ 47 (31.9)	NE (2.8, NE)	1.94 (1.09, 3.45)	0.0218	
	mild	22/ 36 (61.1)	2.6 (0.8, 14.6)	5/ 15 (33.3)	NE (1.4, NE)	1.84 (0.69, 4.89)	0.2149	
	moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7948
	yes	4/ 8 (50.0)	NE (0.3, NE)	1/ 5 (20.0)	NE (1.7, NE)	2.31 (0.26, 20.78)	0.4435	
	no	73/117 (62.4)	3.2 (1.8, 4.3)	19/ 57 (33.3)	NE (2.8, NE)	1.86 (1.12, 3.09)	0.0155	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9835
	yes	2/ 3 (66.7)	4.4 (2.8, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	75/122 (61.5)	3.2 (1.8, 4.3)	20/ 58 (34.5)	NE (2.8, NE)	1.76 (1.07, 2.90)	0.0239	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Region							0.4474
	Japan	56/ 99 (56.6)	4.3 (2.4, 10.0)	14/ 50 (28.0)	NE (NE , NE)	2.03 (1.13, 3.66)	0.0171	
	Korea	15/ 26 (57.7)	2.6 (0.7, NE)	5/ 12 (41.7)	NE (0.4, NE)	1.31 (0.47, 3.61)	0.6070	
	Lines of prior systemic therapy							0.6865
	2	37/ 66 (56.1)	3.7 (1.4, 14.6)	13/ 38 (34.2)	NE (2.3, NE)	1.69 (0.89, 3.18)	0.1033	
	3	18/ 34 (52.9)	4.1 (2.0, NE)	5/ 18 (27.8)	NE (1.7, NE)	1.64 (0.60, 4.48)	0.3321	
	>=4	16/ 25 (64.0)	3.9 (0.5, 11.7)	1/ 6 (16.7)	NE (1.7, NE)	4.14 (0.55, 31.37)	0.1376	
	Age							0.6049
	<65 years	32/ 55 (58.2)	4.3 (1.6, 14.6)	7/ 27 (25.9)	NE (2.3, NE)	2.15 (0.94, 4.91)	0.0623	
	>=65 years	39/ 70 (55.7)	3.7 (1.9, 11.7)	12/ 35 (34.3)	NE (1.9, NE)	1.66 (0.87, 3.18)	0.1263	
	Sex							0.0759
	female	19/ 30 (63.3)	2.0 (0.5, 10.0)	2/ 15 (13.3)	NE (NE , NE)	5.52 (1.28, 23.84)	0.0098	
	male	52/ 95 (54.7)	4.3 (2.4, 11.7)	17/ 47 (36.2)	NE (1.9, NE)	1.43 (0.82, 2.48)	0.2083	
	ECOG PS							0.6142
	0	31/ 62 (50.0)	10.0 (2.4, NE)	7/ 30 (23.3)	NE (NE , NE)	2.20 (0.96, 5.04)	0.0574	
	1	40/ 63 (63.5)	2.6 (1.5, 4.3)	12/ 32 (37.5)	NE (1.7, NE)	1.64 (0.86, 3.13)	0.1290	
	HER2 Status in central laboratory							0.5977
	IHC 3+	54/ 96 (56.3)	4.3 (1.9, 10.0)	15/ 47 (31.9)	NE (2.8, NE)	1.72 (0.97, 3.06)	0.0649	
	IHC 2+/ISH +	17/ 29 (58.6)	2.8 (0.8, 6.9)	4/ 15 (26.7)	NE (1.0, NE)	2.39 (0.80, 7.13)	0.1069	
	Primary tumor location							0.7876
	Gastric	62/108 (57.4)	3.7 (1.8, 6.9)	17/ 55 (30.9)	NE (NE , NE)	1.91 (1.11, 3.28)	0.0174	
	GEJ	9/ 17 (52.9)	4.4 (1.4, NE)	2/ 7 (28.6)	NE (0.6, NE)	1.44 (0.30, 6.84)	0.6423	
	Histological subtype							0.4909
	intestinal	48/ 89 (53.9)	4.4 (2.4, 11.7)	13/ 38 (34.2)	NE (2.3, NE)	1.53 (0.83, 2.85)	0.1785	
	diffuse	17/ 28 (60.7)	2.6 (0.5, NE)	4/ 18 (22.2)	NE (1.1, NE)	2.54 (0.85, 7.60)	0.0834	
	others	6/ 8 (75.0)	1.0 (0.1, 5.2)	2/ 6 (33.3)	NE (0.4, NE)	3.78 (0.74, 19.28)	0.0883	
	Number of metastatic sites							0.5595
	<2	13/ 24 (54.2)	11.7 (0.8, NE)	2/ 10 (20.0)	NE (0.5, NE)	2.56 (0.57, 11.46)	0.2008	
	>= 2	58/101 (57.4)	3.2 (1.8, 5.5)	17/ 52 (32.7)	NE (2.3, NE)	1.78 (1.03, 3.07)	0.0363	
	Previous total gastrectomy							0.2494
	yes	8/ 22 (36.4)	NE (2.6, NE)	3/ 9 (33.3)	NE (0.5, NE)	0.89 (0.23, 3.38)	0.8622	
	no	63/103 (61.2)	3.2 (1.4, 5.2)	16/ 53 (30.2)	NE (NE , NE)	2.11 (1.21, 3.66)	0.0071	
	Prior adjuvant/ neoadjuvant therapy							0.7585
	yes	15/ 30 (50.0)	4.8 (1.8, NE)	2/ 10 (20.0)	NE (0.5, NE)	2.24 (0.51, 9.92)	0.2740	
	no	56/ 95 (58.9)	3.2 (1.5, 5.5)	17/ 52 (32.7)	NE (2.8, NE)	1.86 (1.08, 3.21)	0.0245	
	Prior ramucirumab contained treatment							0.1526
	yes	55/ 94 (58.5)	3.7 (1.4, 5.5)	10/ 41 (24.4)	NE (NE , NE)	2.52 (1.28, 4.95)	0.0060	
	no	16/ 31 (51.6)	4.4 (1.9, NE)	9/ 21 (42.9)	NE (0.6, NE)	1.10 (0.48, 2.49)	0.8299	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Protocol DS8201-A-J202
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Primary Cohort
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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Prior nivolumab contained treatment							0.5309
	yes	22/ 33 (66.7)	2.4 (0.5, 11.7)	4/ 15 (26.7)	NE (1.7, NE)	2.41 (0.81, 7.12)	0.1057	
	no	49/ 92 (53.3)	4.1 (2.0, 10.0)	15/ 47 (31.9)	NE (2.8, NE)	1.69 (0.95, 3.02)	0.0735	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.5693
	yes	29/ 44 (65.9)	2.4 (0.5, 6.9)	5/ 17 (29.4)	NE (1.7, NE)	2.27 (0.87, 5.92)	0.0896	
	no	42/ 81 (51.9)	4.3 (2.0, NE)	14/ 45 (31.1)	NE (2.8, NE)	1.66 (0.91, 3.05)	0.0990	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.3653
	yes	12/ 22 (54.5)	4.1 (0.5, NE)	1/ 7 (14.3)	NE (0.6, NE)	4.72 (0.61, 36.36)	0.1005	
	no	59/103 (57.3)	3.9 (1.9, 10.0)	18/ 55 (32.7)	NE (2.8, NE)	1.71 (1.01, 2.91)	0.0465	
	Presence of liver metastasis at baseline							0.3747
	yes	42/ 67 (62.7)	2.0 (0.5, 4.8)	14/ 34 (41.2)	NE (1.4, NE)	1.65 (0.89, 3.03)	0.1107	
	no	29/ 58 (50.0)	5.2 (3.7, NE)	5/ 28 (17.9)	NE (NE , NE)	2.58 (1.00, 6.69)	0.0434	
	Renal impairment at baseline							0.0429
	normal	21/ 33 (63.6)	3.9 (1.4, 10.0)	1/ 13 (7.7)	NE (NE , NE)	6.96 (0.92, 52.43)	0.0287	
	mild	30/ 53 (56.6)	4.3 (1.5, 11.7)	14/ 28 (50.0)	2.3 (1.4, NE)	1.06 (0.56, 2.01)	0.8775	
	moderate	20/ 39 (51.3)	2.4 (0.5, NE)	3/ 20 (15.0)	NE (NE , NE)	4.16 (1.24, 14.03)	0.0124	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.5 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.7373
	normal	51/ 88 (58.0)	4.3 (1.8, 6.9)	15/ 47 (31.9)	NE (2.8, NE)	1.79 (1.00, 3.19)	0.0479	
	mild	20/ 36 (55.6)	3.7 (1.1, NE)	4/ 15 (26.7)	NE (1.7, NE)	2.19 (0.74, 6.43)	0.1468	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7703
	yes	4/ 8 (50.0)	NE (0.3, NE)	1/ 5 (20.0)	NE (1.7, NE)	2.31 (0.26, 20.78)	0.4435	
	no	67/117 (57.3)	3.9 (1.9, 5.5)	18/ 57 (31.6)	NE (NE , NE)	1.78 (1.06, 3.01)	0.0293	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9841
	yes	2/ 3 (66.7)	4.4 (2.8, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	69/122 (56.6)	3.9 (2.0, 6.9)	19/ 58 (32.8)	NE (2.8, NE)	1.70 (1.02, 2.83)	0.0425	

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Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Gastrointestinal disorders, PT: Nausea	Region							0.1910
	Japan	65/ 99 (65.7)	0.3 (0.2, 1.0)	22/ 50 (44.0)	NE (0.9, NE)	1.90 (1.17, 3.09)	0.0085	
	Korea	14/ 26 (53.8)	1.2 (0.1, NE)	7/ 12 (58.3)	0.6 (0.0, NE)	0.93 (0.38, 2.32)	0.8326	
	Lines of prior systemic therapy							0.5204
	2	40/ 66 (60.6)	0.3 (0.1, NE)	16/ 38 (42.1)	NE (0.6, NE)	1.77 (0.99, 3.16)	0.0560	
	3	23/ 34 (67.6)	0.2 (0.1, 5.8)	9/ 18 (50.0)	3.0 (0.3, NE)	1.81 (0.84, 3.93)	0.1294	
	>=4	16/ 25 (64.0)	1.0 (0.1, NE)	4/ 6 (66.7)	1.1 (0.1, NE)	0.87 (0.29, 2.61)	0.8264	
	Age							0.8612
	<65 years	41/ 55 (74.5)	0.2 (0.1, 0.3)	17/ 27 (63.0)	0.8 (0.4, NE)	1.65 (0.93, 2.91)	0.0951	
	>=65 years	38/ 70 (54.3)	1.7 (0.2, NE)	12/ 35 (34.3)	NE (1.9, NE)	1.75 (0.91, 3.34)	0.0846	
	Sex							0.2993
	female	20/ 30 (66.7)	0.3 (0.1, 2.2)	9/ 15 (60.0)	0.8 (0.1, NE)	1.11 (0.51, 2.45)	0.7722	
	male	59/ 95 (62.1)	0.3 (0.2, 2.8)	20/ 47 (42.6)	NE (0.9, NE)	1.87 (1.12, 3.11)	0.0160	
	ECOG PS							0.4347
	0	42/ 62 (67.7)	0.2 (0.2, 0.6)	17/ 30 (56.7)	1.5 (0.3, NE)	1.41 (0.80, 2.49)	0.2291	
	1	37/ 63 (58.7)	0.7 (0.1, NE)	12/ 32 (37.5)	NE (0.6, NE)	1.92 (1.00, 3.68)	0.0507	
	HER2 Status in central laboratory							0.1087
	IHC 3+	57/ 96 (59.4)	0.3 (0.2, 5.8)	24/ 47 (51.1)	1.9 (0.6, NE)	1.34 (0.83, 2.16)	0.2478	
	IHC 2+/ISH +	22/ 29 (75.9)	0.2 (0.1, 1.3)	5/ 15 (33.3)	NE (0.2, NE)	3.32 (1.25, 8.82)	0.0106	
	Primary tumor location							0.2966
	Gastric	65/108 (60.2)	0.4 (0.2, 3.4)	26/ 55 (47.3)	NE (0.6, NE)	1.47 (0.93, 2.32)	0.1000	
	GEJ	14/ 17 (82.4)	0.2 (0.1, 0.3)	3/ 7 (42.9)	NE (0.2, NE)	3.49 (0.99, 12.30)	0.0392	
	Histological subtype							0.2292
	intestinal	57/ 89 (64.0)	0.3 (0.2, 2.2)	15/ 38 (39.5)	NE (1.5, NE)	2.03 (1.15, 3.59)	0.0127	
	diffuse	17/ 28 (60.7)	0.2 (0.1, NE)	9/ 18 (50.0)	1.9 (0.4, NE)	1.63 (0.72, 3.67)	0.2559	
	others	5/ 8 (62.5)	0.4 (0.0, NE)	5/ 6 (83.3)	0.2 (0.0, NE)	0.62 (0.18, 2.18)	0.4462	
	Number of metastatic sites							0.2446
	<2	17/ 24 (70.8)	0.2 (0.1, 1.7)	3/ 10 (30.0)	NE (0.0, NE)	3.15 (0.92, 10.87)	0.0567	
	>= 2	62/101 (61.4)	0.4 (0.2, 2.8)	26/ 52 (50.0)	1.9 (0.6, NE)	1.45 (0.91, 2.29)	0.1217	
	Previous total gastrectomy							0.1146
	yes	10/ 22 (45.5)	NE (0.2, NE)	5/ 9 (55.6)	3.0 (0.1, NE)	0.74 (0.25, 2.18)	0.5759	
	no	69/103 (67.0)	0.2 (0.1, 0.7)	24/ 53 (45.3)	NE (0.6, NE)	1.90 (1.19, 3.03)	0.0067	
	Prior adjuvant/ neoadjuvant therapy							0.9068
	yes	14/ 30 (46.7)	NE (0.2, NE)	3/ 10 (30.0)	NE (0.0, NE)	1.58 (0.45, 5.49)	0.4795	
	no	65/ 95 (68.4)	0.2 (0.1, 0.6)	26/ 52 (50.0)	1.9 (0.6, NE)	1.77 (1.12, 2.79)	0.0141	
	Prior ramucirumab contained treatment							0.3739
	yes	60/ 94 (63.8)	0.3 (0.2, 1.7)	21/ 41 (51.2)	1.9 (0.5, NE)	1.41 (0.86, 2.32)	0.1851	
	no	19/ 31 (61.3)	0.6 (0.1, NE)	8/ 21 (38.1)	NE (0.9, NE)	2.18 (0.95, 4.99)	0.0648	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Gastrointestinal disorders, PT: Nausea	Prior nivolumab contained treatment							0.8193
	yes	23/ 33 (69.7)	0.3 (0.2, 2.8)	8/ 15 (53.3)	1.9 (0.1, NE)	1.51 (0.67, 3.38)	0.3154	
	no	56/ 92 (60.9)	0.3 (0.2, 1.7)	21/ 47 (44.7)	NE (0.6, NE)	1.67 (1.01, 2.76)	0.0477	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8713
	yes	28/ 44 (63.6)	0.6 (0.2, 5.8)	8/ 17 (47.1)	NE (0.2, NE)	1.54 (0.70, 3.38)	0.2816	
	no	51/ 81 (63.0)	0.2 (0.1, 1.0)	21/ 45 (46.7)	NE (0.6, NE)	1.69 (1.02, 2.82)	0.0450	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.1151
	yes	15/ 22 (68.2)	0.2 (0.1, 2.8)	1/ 7 (14.3)	NE (0.1, NE)	7.32 (0.96, 55.74)	0.0235	
	no	64/103 (62.1)	0.3 (0.2, 1.7)	28/ 55 (50.9)	1.9 (0.6, NE)	1.42 (0.91, 2.22)	0.1277	
	Presence of liver metastasis at baseline							0.3393
	yes	43/ 67 (64.2)	0.3 (0.1, 2.8)	15/ 34 (44.1)	NE (0.6, NE)	1.98 (1.10, 3.57)	0.0227	
	no	36/ 58 (62.1)	0.3 (0.2, 5.8)	14/ 28 (50.0)	1.9 (0.2, NE)	1.30 (0.70, 2.41)	0.4155	
	Renal impairment at baseline							0.2761
	normal	23/ 33 (69.7)	0.2 (0.1, 0.3)	7/ 13 (53.8)	0.9 (0.5, NE)	2.03 (0.86, 4.77)	0.1103	
	mild	33/ 53 (62.3)	0.6 (0.1, 3.4)	10/ 28 (35.7)	NE (1.5, NE)	2.21 (1.09, 4.48)	0.0256	
	moderate	23/ 39 (59.0)	0.5 (0.2, NE)	11/ 20 (55.0)	1.5 (0.1, NE)	1.00 (0.49, 2.05)	0.9769	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	1.9 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.1806
	normal	55/ 88 (62.5)	0.2 (0.2, 2.8)	25/ 47 (53.2)	1.5 (0.5, NE)	1.41 (0.88, 2.26)	0.1686	
	mild	23/ 36 (63.9)	0.4 (0.1, NE)	4/ 15 (26.7)	NE (0.1, NE)	2.98 (1.03, 8.66)	0.0320	
	moderate	1/ 1 (100.0)	0.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.5392
	yes	6/ 8 (75.0)	0.6 (0.1, NE)	2/ 5 (40.0)	NE (0.4, NE)	3.23 (0.64, 16.33)	0.1354	
	no	73/117 (62.4)	0.3 (0.2, 1.7)	27/ 57 (47.4)	3.0 (0.6, NE)	1.56 (1.00, 2.44)	0.0489	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.0795
	yes [e]	3/ 3 (100.0)	0.1 (0.1, 0.2)	1/ 4 (25.0)	NE (0.4, NE)	2.72E8 (0.00, NE)	0.0101	
	no	76/122 (62.3)	0.3 (0.2, 1.7)	28/ 58 (48.3)	3.0 (0.6, NE)	1.52 (0.98, 2.34)	0.0628	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Gastrointestinal disorders, PT: Vomiting	Region							0.9909
	Japan	27/ 99 (27.3)	NE (9.6, NE)	5/ 50 (10.0)	NE (NE , NE)	2.72 (1.04, 7.10)	0.0329	
	Korea	6/ 26 (23.1)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
	Lines of prior systemic therapy							0.7601
	2	18/ 66 (27.3)	NE (NE , NE)	4/ 38 (10.5)	NE (NE , NE)	2.70 (0.91, 7.97)	0.0625	
	3	12/ 34 (35.3)	NE (5.9, NE)	1/ 18 (5.6)	NE (NE , NE)	6.20 (0.80, 48.15)	0.0455	
	>=4	3/ 25 (12.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Age							0.3069
	<65 years	18/ 55 (32.7)	NE (5.9, NE)	4/ 27 (14.8)	NE (NE , NE)	2.27 (0.76, 6.72)	0.1303	
	>=65 years	15/ 70 (21.4)	NE (9.6, NE)	1/ 35 (2.9)	NE (NE , NE)	7.59 (1.00, 57.58)	0.0208	
	Sex							0.4247
	female	11/ 30 (36.7)	NE (0.5, NE)	1/ 15 (6.7)	NE (NE , NE)	6.78 (0.87, 52.60)	0.0338	
	male	22/ 95 (23.2)	NE (NE , NE)	4/ 47 (8.5)	NE (NE , NE)	2.51 (0.86, 7.33)	0.0809	
	ECOG PS							0.2390
	0	12/ 62 (19.4)	NE (NE , NE)	3/ 30 (10.0)	NE (NE , NE)	1.86 (0.52, 6.61)	0.3341	
	1	21/ 63 (33.3)	NE (9.6, NE)	2/ 32 (6.3)	NE (NE , NE)	5.59 (1.31, 23.92)	0.0089	
	HER2 Status in central laboratory							0.9890
	IHC 3+	23/ 96 (24.0)	NE (NE , NE)	5/ 47 (10.6)	NE (NE , NE)	2.30 (0.87, 6.07)	0.0834	
	IHC 2+/ISH +	10/ 29 (34.5)	9.6 (5.9, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	Primary tumor location							0.9889
	Gastric	28/108 (25.9)	NE (NE , NE)	5/ 55 (9.1)	NE (NE , NE)	2.89 (1.11, 7.49)	0.0231	
	GEJ	5/ 17 (29.4)	NE (1.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	Histological subtype							0.8323
	intestinal	21/ 89 (23.6)	NE (9.6, NE)	2/ 38 (5.3)	NE (NE , NE)	4.62 (1.08, 19.75)	0.0233	
	diffuse	8/ 28 (28.6)	NE (5.9, NE)	2/ 18 (11.1)	NE (NE , NE)	2.21 (0.46, 10.60)	0.3120	
	others	4/ 8 (50.0)	NE (0.0, NE)	1/ 6 (16.7)	NE (0.1, NE)	3.54 (0.40, 31.77)	0.2275	
	Number of metastatic sites							0.9005
	<2	8/ 24 (33.3)	NE (0.4, NE)	1/ 10 (10.0)	NE (0.6, NE)	3.80 (0.47, 30.45)	0.1771	
	>= 2	25/101 (24.8)	NE (9.6, NE)	4/ 52 (7.7)	NE (NE , NE)	3.12 (1.08, 9.02)	0.0264	
	Previous total gastrectomy							0.9997
	yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
	no	33/103 (32.0)	NE (9.6, NE)	5/ 53 (9.4)	NE (NE , NE)	3.52 (1.37, 9.05)	0.0053	
	Prior adjuvant/ neoadjuvant therapy							0.9889
	yes	2/ 30 (6.7)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	no	31/ 95 (32.6)	NE (9.6, NE)	5/ 52 (9.6)	NE (NE , NE)	3.52 (1.36, 9.07)	0.0056	
	Prior ramucirumab contained treatment							0.5185
	yes	27/ 94 (28.7)	NE (9.6, NE)	3/ 41 (7.3)	NE (NE , NE)	3.96 (1.20, 13.09)	0.0150	
	no	6/ 31 (19.4)	NE (5.9, NE)	2/ 21 (9.5)	NE (NE , NE)	1.95 (0.39, 9.73)	0.4081	

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[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Gastrointestinal disorders, PT: Vomiting	Prior nivolumab contained treatment							0.8506
	yes	9/ 33 (27.3)	NE (9.6, NE)	1/ 15 (6.7)	NE (NE , NE)	3.87 (0.48, 30.95)	0.1675	
	no	24/ 92 (26.1)	NE (NE , NE)	4/ 47 (8.5)	NE (NE , NE)	3.15 (1.09, 9.09)	0.0255	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9588
	yes	10/ 44 (22.7)	NE (9.6, NE)	1/ 17 (5.9)	NE (NE , NE)	3.70 (0.47, 29.25)	0.1811	
	no	23/ 81 (28.4)	NE (NE , NE)	4/ 45 (8.9)	NE (NE , NE)	3.34 (1.15, 9.66)	0.0188	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9887
	yes	6/ 22 (27.3)	NE (5.9, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	27/103 (26.2)	NE (NE , NE)	5/ 55 (9.1)	NE (NE , NE)	2.94 (1.13, 7.65)	0.0208	
	Presence of liver metastasis at baseline							0.1144
	yes	19/ 67 (28.4)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	10.46 (1.40, 78.13)	0.0044	
	no	14/ 58 (24.1)	NE (9.6, NE)	4/ 28 (14.3)	NE (NE , NE)	1.54 (0.50, 4.71)	0.4507	
	Renal impairment at baseline							0.7297
	normal	12/ 33 (36.4)	NE (2.6, NE)	2/ 13 (15.4)	NE (1.4, NE)	2.54 (0.57, 11.35)	0.2074	
	mild	12/ 53 (22.6)	NE (9.6, NE)	1/ 28 (3.6)	NE (NE , NE)	5.88 (0.76, 45.53)	0.0544	
	moderate	9/ 39 (23.1)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	5.06 (0.64, 39.96)	0.0872	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.6 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.9892
	normal	20/ 88 (22.7)	NE (NE , NE)	5/ 47 (10.6)	NE (NE , NE)	2.07 (0.77, 5.55)	0.1408	
	mild	13/ 36 (36.1)	NE (2.6, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9909
	yes	1/ 8 (12.5)	NE (5.9, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
	no	32/117 (27.4)	NE (9.6, NE)	5/ 57 (8.8)	NE (NE , NE)	3.20 (1.24, 8.24)	0.0108	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9910
	yes	1/ 3 (33.3)	NE (5.9, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	32/122 (26.2)	NE (NE , NE)	5/ 58 (8.6)	NE (NE , NE)	3.10 (1.21, 7.99)	0.0134	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
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Daiichi Sankyo

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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: General disorders and administration site conditions, PT: Malaise	Region							0.9997
	Japan	43/ 99 (43.4)	NE (2.1, NE)	10/ 50 (20.0)	NE (NE , NE)	2.42 (1.22, 4.82)	0.0094	
	Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
	Lines of prior systemic therapy							0.3289
	2	19/ 66 (28.8)	NE (NE , NE)	8/ 38 (21.1)	NE (4.6, NE)	1.39 (0.61, 3.17)	0.4432	
	3	12/ 34 (35.3)	NE (2.3, NE)	1/ 18 (5.6)	NE (NE , NE)	6.68 (0.87, 51.44)	0.0351	
	>=4	12/ 25 (48.0)	NE (0.3, NE)	1/ 6 (16.7)	NE (0.2, NE)	2.99 (0.39, 23.04)	0.2696	
	Age							0.3949
	<65 years	19/ 55 (34.5)	NE (2.8, NE)	3/ 27 (11.1)	NE (NE , NE)	3.36 (1.00, 11.37)	0.0385	
	>=65 years	24/ 70 (34.3)	NE (NE , NE)	7/ 35 (20.0)	NE (4.6, NE)	1.73 (0.75, 4.02)	0.1964	
	Sex							0.3435
	female	11/ 30 (36.7)	NE (1.6, NE)	4/ 15 (26.7)	NE (0.6, NE)	1.40 (0.44, 4.39)	0.5643	
	male	32/ 95 (33.7)	NE (NE , NE)	6/ 47 (12.8)	NE (NE , NE)	2.77 (1.16, 6.63)	0.0172	
	ECOG PS							0.4841
	0	26/ 62 (41.9)	NE (2.3, NE)	5/ 30 (16.7)	NE (4.6, NE)	2.73 (1.05, 7.12)	0.0326	
	1	17/ 63 (27.0)	NE (NE , NE)	5/ 32 (15.6)	NE (NE , NE)	1.75 (0.64, 4.74)	0.2681	
	HER2 Status in central laboratory							0.1786
	IHC 3+	32/ 96 (33.3)	NE (NE , NE)	5/ 47 (10.6)	NE (NE , NE)	3.29 (1.28, 8.43)	0.0088	
	IHC 2+/ISH +	11/ 29 (37.9)	NE (1.4, NE)	5/ 15 (33.3)	NE (0.7, NE)	1.22 (0.42, 3.52)	0.7157	
	Primary tumor location							0.3402
	Gastric	33/108 (30.6)	NE (NE , NE)	9/ 55 (16.4)	NE (NE , NE)	1.88 (0.90, 3.94)	0.0875	
	GEJ	10/ 17 (58.8)	1.5 (0.1, NE)	1/ 7 (14.3)	NE (1.4, NE)	5.20 (0.66, 40.80)	0.0804	
	Histological subtype							0.8713
	intestinal	37/ 89 (41.6)	NE (2.8, NE)	9/ 38 (23.7)	NE (4.6, NE)	1.94 (0.93, 4.01)	0.0714	
	diffuse	6/ 28 (21.4)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	3.66 (0.44, 30.42)	0.1978	
	others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Number of metastatic sites							0.2132
	<2	13/ 24 (54.2)	3.4 (0.2, NE)	1/ 10 (10.0)	NE (0.2, NE)	6.66 (0.87, 50.98)	0.0345	
	>= 2	30/101 (29.7)	NE (NE , NE)	9/ 52 (17.3)	NE (NE , NE)	1.74 (0.83, 3.68)	0.1398	
	Previous total gastrectomy							0.0388
	yes	4/ 22 (18.2)	NE (NE , NE)	3/ 9 (33.3)	4.6 (0.2, NE)	0.48 (0.11, 2.18)	0.3263	
	no	39/103 (37.9)	NE (NE , NE)	7/ 53 (13.2)	NE (NE , NE)	3.12 (1.39, 6.97)	0.0035	
	Prior adjuvant/ neoadjuvant therapy							0.3334
	yes	11/ 30 (36.7)	NE (1.9, NE)	3/ 10 (30.0)	NE (0.2, NE)	1.22 (0.34, 4.38)	0.7686	
	no	32/ 95 (33.7)	NE (NE , NE)	7/ 52 (13.5)	NE (NE , NE)	2.68 (1.18, 6.08)	0.0141	
	Prior ramucirumab contained treatment							0.9824
	yes	34/ 94 (36.2)	NE (NE , NE)	7/ 41 (17.1)	NE (4.6, NE)	2.17 (0.96, 4.90)	0.0564	
	no	9/ 31 (29.0)	NE (NE , NE)	3/ 21 (14.3)	NE (NE , NE)	2.17 (0.59, 8.02)	0.2333	

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SOC: General disorders and administration site conditions, PT: Malaise	Prior nivolumab contained treatment							0.0752
	yes	21/ 33 (63.6)	1.4 (0.2, NE)	2/ 15 (13.3)	NE (NE , NE)	6.38 (1.49, 27.24)	0.0040	
	no	22/ 92 (23.9)	NE (NE , NE)	8/ 47 (17.0)	NE (NE , NE)	1.36 (0.60, 3.06)	0.4636	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.1809
	yes	21/ 44 (47.7)	NE (0.7, NE)	2/ 17 (11.8)	NE (NE , NE)	4.84 (1.13, 20.65)	0.0184	
	no	22/ 81 (27.2)	NE (NE , NE)	8/ 45 (17.8)	NE (NE , NE)	1.50 (0.67, 3.37)	0.3292	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9852
	yes	10/ 22 (45.5)	NE (0.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	33/103 (32.0)	NE (NE , NE)	10/ 55 (18.2)	NE (NE , NE)	1.77 (0.87, 3.59)	0.1110	
	Presence of liver metastasis at baseline							0.4999
	yes	25/ 67 (37.3)	NE (2.8, NE)	5/ 34 (14.7)	NE (NE , NE)	2.82 (1.08, 7.38)	0.0268	
	no	18/ 58 (31.0)	NE (NE , NE)	5/ 28 (17.9)	NE (4.6, NE)	1.69 (0.63, 4.55)	0.3010	
	Renal impairment at baseline							0.9610
	normal	13/ 33 (39.4)	NE (1.5, NE)	2/ 13 (15.4)	NE (1.4, NE)	2.71 (0.61, 12.03)	0.1722	
	mild	15/ 53 (28.3)	NE (NE , NE)	4/ 28 (14.3)	NE (NE , NE)	2.15 (0.71, 6.48)	0.1694	
	moderate	15/ 39 (38.5)	NE (2.3, NE)	4/ 20 (20.0)	NE (4.6, NE)	2.01 (0.67, 6.06)	0.2043	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.9164
	normal	32/ 88 (36.4)	NE (NE , NE)	8/ 47 (17.0)	NE (NE , NE)	2.19 (1.01, 4.77)	0.0423	
	mild	11/ 36 (30.6)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	2.42 (0.54, 10.94)	0.2335	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8459
	yes	4/ 8 (50.0)	NE (0.1, NE)	1/ 5 (20.0)	NE (1.4, NE)	2.74 (0.31, 24.61)	0.3471	
	no	39/117 (33.3)	NE (NE , NE)	9/ 57 (15.8)	NE (NE , NE)	2.19 (1.06, 4.53)	0.0298	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.8894
	yes	2/ 3 (66.7)	1.7 (1.5, NE)	1/ 4 (25.0)	NE (1.4, NE)	2.21 (0.20, 24.47)	0.5079	
	no	41/122 (33.6)	NE (NE , NE)	9/ 58 (15.5)	NE (NE , NE)	2.26 (1.10, 4.65)	0.0231	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations	Region							0.1086
	Japan	81/ 99 (81.8)	0.3 (0.3, 0.5)	26/ 50 (52.0)	2.8 (0.5, NE)	2.13 (1.36, 3.31)	0.0007	
	Korea	18/ 26 (69.2)	2.9 (0.7, 4.2)	7/ 12 (58.3)	1.4 (0.5, NE)	0.77 (0.32, 1.88)	0.5699	
	Lines of prior systemic therapy							0.7038
	2	50/ 66 (75.8)	1.3 (0.5, 1.9)	19/ 38 (50.0)	2.8 (0.5, NE)	1.58 (0.93, 2.69)	0.0842	
	3	30/ 34 (88.2)	0.3 (0.3, 0.5)	11/ 18 (61.1)	0.9 (0.5, NE)	2.29 (1.14, 4.62)	0.0184	
	>=4	19/ 25 (76.0)	0.5 (0.3, 1.9)	3/ 6 (50.0)	NE (0.5, NE)	1.89 (0.56, 6.42)	0.3125	
	Age							0.5041
	<65 years	47/ 55 (85.5)	0.7 (0.3, 1.8)	13/ 27 (48.1)	2.8 (0.5, NE)	1.95 (1.05, 3.62)	0.0331	
	>=65 years	52/ 70 (74.3)	0.5 (0.3, 0.7)	20/ 35 (57.1)	1.1 (0.5, NE)	1.58 (0.94, 2.64)	0.0893	
	Sex							0.8088
	female	23/ 30 (76.7)	0.5 (0.3, 2.3)	7/ 15 (46.7)	NE (0.5, NE)	1.96 (0.84, 4.57)	0.1240	
	male	76/ 95 (80.0)	0.5 (0.3, 0.7)	26/ 47 (55.3)	1.4 (0.5, NE)	1.72 (1.10, 2.69)	0.0172	
	ECOG PS							0.1653
	0	50/ 62 (80.6)	0.4 (0.3, 0.7)	14/ 30 (46.7)	NE (0.5, NE)	2.40 (1.33, 4.36)	0.0026	
	1	49/ 63 (77.8)	0.7 (0.4, 1.9)	19/ 32 (59.4)	1.4 (0.5, NE)	1.33 (0.78, 2.27)	0.3144	
	HER2 Status in central laboratory							0.9944
	IHC 3+	75/ 96 (78.1)	0.5 (0.4, 1.4)	24/ 47 (51.1)	2.8 (0.5, NE)	1.78 (1.12, 2.82)	0.0138	
	IHC 2+/ISH +	24/ 29 (82.8)	0.3 (0.3, 1.2)	9/ 15 (60.0)	0.7 (0.3, NE)	1.78 (0.82, 3.84)	0.1527	
	Primary tumor location							0.2034
	Gastric	84/108 (77.8)	0.5 (0.3, 0.7)	31/ 55 (56.4)	1.4 (0.5, NE)	1.60 (1.06, 2.42)	0.0264	
	GEJ	15/ 17 (88.2)	0.7 (0.3, 1.9)	2/ 7 (28.6)	NE (0.5, NE)	4.30 (0.97, 19.04)	0.0369	
	Histological subtype							0.5798
	intestinal	72/ 89 (80.9)	0.5 (0.3, 0.7)	21/ 38 (55.3)	1.4 (0.5, NE)	1.84 (1.13, 3.00)	0.0136	
	diffuse	22/ 28 (78.6)	0.5 (0.3, 2.9)	8/ 18 (44.4)	2.8 (0.5, NE)	1.83 (0.80, 4.15)	0.1440	
	others	5/ 8 (62.5)	3.5 (0.3, NE)	4/ 6 (66.7)	1.1 (0.4, NE)	0.81 (0.22, 3.08)	0.7426	
	Number of metastatic sites							0.2380
	<2	18/ 24 (75.0)	0.7 (0.3, 3.0)	7/ 10 (70.0)	0.5 (0.0, NE)	1.12 (0.46, 2.69)	0.8011	
	>= 2	81/101 (80.2)	0.5 (0.3, 0.7)	26/ 52 (50.0)	2.8 (0.5, NE)	1.99 (1.28, 3.10)	0.0021	
	Previous total gastrectomy							0.0517
	yes	17/ 22 (77.3)	1.3 (0.3, 2.9)	7/ 9 (77.8)	0.5 (0.2, NE)	0.72 (0.29, 1.79)	0.4956	
	no	82/103 (79.6)	0.5 (0.3, 0.7)	26/ 53 (49.1)	2.8 (0.7, NE)	2.08 (1.34, 3.23)	0.0011	
	Prior adjuvant/ neoadjuvant therapy							0.4384
	yes	26/ 30 (86.7)	0.3 (0.3, 0.7)	7/ 10 (70.0)	0.5 (0.2, NE)	1.27 (0.55, 2.94)	0.5836	
	no	73/ 95 (76.8)	0.5 (0.3, 1.4)	26/ 52 (50.0)	2.8 (0.7, NE)	1.85 (1.18, 2.89)	0.0073	
	Prior ramucirumab contained treatment							0.0375
	yes	77/ 94 (81.9)	0.3 (0.3, 0.7)	19/ 41 (46.3)	2.8 (0.5, NE)	2.36 (1.43, 3.91)	0.0007	
	no	22/ 31 (71.0)	1.4 (0.5, 5.6)	14/ 21 (66.7)	1.4 (0.4, 3.7)	0.96 (0.49, 1.88)	0.9285	

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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations	Prior nivolumab contained treatment							0.2671
	yes	30/ 33 (90.9)	0.3 (0.3, 0.3)	9/ 15 (60.0)	0.7 (0.5, NE)	2.73 (1.28, 5.80)	0.0077	
	no	69/ 92 (75.0)	0.7 (0.5, 1.8)	24/ 47 (51.1)	2.8 (0.5, NE)	1.57 (0.99, 2.50)	0.0553	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8707
	yes	38/ 44 (86.4)	0.3 (0.3, 0.5)	11/ 17 (64.7)	0.5 (0.5, NE)	1.87 (0.95, 3.69)	0.0711	
	no	61/ 81 (75.3)	0.7 (0.5, 1.8)	22/ 45 (48.9)	2.8 (0.5, NE)	1.70 (1.04, 2.77)	0.0319	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.5450
	yes	16/ 22 (72.7)	0.6 (0.3, 6.1)	4/ 7 (57.1)	0.5 (0.3, NE)	1.36 (0.45, 4.14)	0.5541	
	no	83/103 (80.6)	0.5 (0.3, 0.7)	29/ 55 (52.7)	2.8 (0.5, NE)	1.85 (1.21, 2.83)	0.0046	
	Presence of liver metastasis at baseline							0.1500
	yes	56/ 67 (83.6)	0.5 (0.3, 0.7)	17/ 34 (50.0)	2.8 (0.5, NE)	2.39 (1.39, 4.13)	0.0012	
	no	43/ 58 (74.1)	0.7 (0.3, 2.9)	16/ 28 (57.1)	0.7 (0.5, NE)	1.31 (0.73, 2.33)	0.4107	
	Renal impairment at baseline							0.9095
	normal	27/ 33 (81.8)	0.7 (0.3, 1.6)	7/ 13 (53.8)	2.8 (0.5, NE)	1.74 (0.75, 4.05)	0.2039	
	mild	45/ 53 (84.9)	0.3 (0.3, 0.7)	16/ 28 (57.1)	1.4 (0.5, NE)	2.03 (1.15, 3.61)	0.0151	
	moderate	27/ 39 (69.2)	1.2 (0.3, 3.1)	9/ 20 (45.0)	NE (0.4, NE)	1.60 (0.75, 3.41)	0.2180	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.0 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.4940
	normal	69/ 88 (78.4)	0.5 (0.3, 1.4)	23/ 47 (48.9)	3.7 (0.7, NE)	1.89 (1.18, 3.03)	0.0082	
	mild	29/ 36 (80.6)	0.4 (0.3, 0.7)	10/ 15 (66.7)	0.5 (0.3, NE)	1.41 (0.68, 2.91)	0.3505	
	moderate	1/ 1 (100.0)	1.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3486
	yes	5/ 8 (62.5)	4.9 (0.3, NE)	3/ 5 (60.0)	1.4 (0.5, NE)	0.88 (0.21, 3.80)	0.8474	
	no	94/117 (80.3)	0.5 (0.3, 0.7)	30/ 57 (52.6)	2.8 (0.5, NE)	1.85 (1.23, 2.80)	0.0031	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.5387
	yes	2/ 3 (66.7)	6.1 (3.6, NE)	2/ 4 (50.0)	NE (0.5, NE)	0.69 (0.09, 5.25)	0.7166	
	no	97/122 (79.5)	0.5 (0.3, 0.7)	31/ 58 (53.4)	2.8 (0.5, NE)	1.78 (1.19, 2.68)	0.0051	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Lymphocyte count decreased	Region							0.9995
	Japan	27/ 99 (27.3)	NE (8.3, NE)	2/ 50 (4.0)	NE (NE , NE)	6.50 (1.54, 27.46)	0.0034	
	Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
	Lines of prior systemic therapy							0.9444
	2	12/ 66 (18.2)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	6.66 (0.86, 51.50)	0.0357	
	3	9/ 34 (26.5)	NE (4.4, NE)	1/ 18 (5.6)	NE (NE , NE)	3.32 (0.41, 26.82)	0.2334	
	>=4	6/ 25 (24.0)	NE (8.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Age							0.5887
	<65 years	9/ 55 (16.4)	NE (8.3, NE)	1/ 27 (3.7)	NE (NE , NE)	3.32 (0.41, 27.09)	0.2357	
	>=65 years	18/ 70 (25.7)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	8.84 (1.18, 66.25)	0.0104	
	Sex							0.6030
	female	8/ 30 (26.7)	NE (8.3, NE)	1/ 15 (6.7)	NE (NE , NE)	3.83 (0.47, 31.12)	0.1761	
	male	19/ 95 (20.0)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	8.34 (1.11, 62.52)	0.0136	
	ECOG PS							0.8082
	0	16/ 62 (25.8)	NE (8.3, NE)	1/ 30 (3.3)	NE (NE , NE)	6.83 (0.90, 51.87)	0.0316	
	1	11/ 63 (17.5)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	5.21 (0.67, 40.46)	0.0780	
	HER2 Status in central laboratory							0.1990
	IHC 3+	24/ 96 (25.0)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	10.41 (1.40, 77.28)	0.0044	
	IHC 2+/ISH +	3/ 29 (10.3)	NE (NE , NE)	1/ 15 (6.7)	NE (2.8, NE)	1.64 (0.17, 15.75)	0.6658	
	Primary tumor location							0.9915
	Gastric	24/108 (22.2)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	5.40 (1.27, 22.97)	0.0105	
	GEJ	3/ 17 (17.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	Histological subtype							0.7736
	intestinal	21/ 89 (23.6)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	8.79 (1.18, 65.49)	0.0104	
	diffuse	6/ 28 (21.4)	NE (8.3, NE)	1/ 18 (5.6)	NE (1.9, NE)	2.65 (0.30, 23.11)	0.3592	
	others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Number of metastatic sites							0.3490
	<2	6/ 24 (25.0)	NE (7.7, NE)	1/ 10 (10.0)	NE (1.9, NE)	2.26 (0.27, 18.98)	0.4403	
	>= 2	21/101 (20.8)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	9.92 (1.33, 73.97)	0.0058	
	Previous total gastrectomy							0.9912
	yes	2/ 22 (9.1)	NE (8.3, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
	no	25/103 (24.3)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	6.06 (1.43, 25.67)	0.0053	
	Prior adjuvant/ neoadjuvant therapy							0.9894
	yes	7/ 30 (23.3)	NE (8.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	no	20/ 95 (21.1)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	4.88 (1.14, 20.98)	0.0184	
	Prior ramucirumab contained treatment							0.9913
	yes	25/ 94 (26.6)	NE (NE , NE)	2/ 41 (4.9)	NE (NE , NE)	5.06 (1.19, 21.43)	0.0145	
	no	2/ 31 (6.5)	NE (8.3, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	

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SOC: Investigations, PT: Lymphocyte count decreased	Prior nivolumab contained treatment							0.8316
	yes	12/ 33 (36.4)	NE (3.8, NE)	1/ 15 (6.7)	NE (2.8, NE)	4.91 (0.63, 38.27)	0.0940	
	no	15/ 92 (16.3)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	6.99 (0.92, 53.11)	0.0289	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7573
	yes	13/ 44 (29.5)	NE (7.7, NE)	1/ 17 (5.9)	NE (NE , NE)	4.51 (0.58, 34.90)	0.1143	
	no	14/ 81 (17.3)	NE (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	7.02 (0.92, 53.61)	0.0288	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9911
	yes	5/ 22 (22.7)	NE (4.2, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	22/103 (21.4)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	5.16 (1.21, 22.10)	0.0137	
	Presence of liver metastasis at baseline							0.4766
	yes	19/ 67 (28.4)	NE (7.7, NE)	1/ 34 (2.9)	NE (NE , NE)	9.25 (1.23, 69.39)	0.0083	
	no	8/ 58 (13.8)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	3.22 (0.40, 26.14)	0.2451	
	Renal impairment at baseline							0.9999
	normal	5/ 33 (15.2)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
	mild	12/ 53 (22.6)	NE (8.3, NE)	1/ 28 (3.6)	NE (NE , NE)	5.69 (0.73, 44.08)	0.0605	
	moderate	10/ 39 (25.6)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	1.9 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.2521
	normal	22/ 88 (25.0)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	10.86 (1.46, 80.87)	0.0035	
	mild	5/ 36 (13.9)	NE (7.7, NE)	1/ 15 (6.7)	NE (2.8, NE)	1.66 (0.18, 14.83)	0.6486	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9918
	yes	3/ 8 (37.5)	NE (0.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
	no	24/117 (20.5)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	5.33 (1.25, 22.66)	0.0111	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9993
	yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	27/122 (22.1)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	5.73 (1.35, 24.23)	0.0073	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Neutrophil count decreased	Region							0.9474
	Japan	67/ 99 (67.7)	0.7 (0.5, 1.4)	19/ 50 (38.0)	NE (0.7, NE)	1.95 (1.17, 3.25)	0.0105	
	Korea	10/ 26 (38.5)	NE (3.0, NE)	2/ 12 (16.7)	NE (2.8, NE)	1.86 (0.40, 8.53)	0.4160	
	Lines of prior systemic therapy							0.1826
	2	35/ 66 (53.0)	3.5 (0.7, NE)	14/ 38 (36.8)	NE (1.4, NE)	1.36 (0.73, 2.54)	0.3293	
	3	25/ 34 (73.5)	0.6 (0.5, 0.7)	4/ 18 (22.2)	NE (NE , NE)	4.12 (1.42, 11.92)	0.0050	
	>=4	17/ 25 (68.0)	0.7 (0.5, 5.0)	3/ 6 (50.0)	NE (0.5, NE)	1.24 (0.36, 4.26)	0.7553	
	Age							0.6110
	<65 years	35/ 55 (63.6)	2.3 (0.7, 5.0)	8/ 27 (29.6)	NE (2.8, NE)	2.03 (0.93, 4.42)	0.0697	
	>=65 years	42/ 70 (60.0)	0.7 (0.5, NE)	13/ 35 (37.1)	NE (0.5, NE)	1.65 (0.88, 3.07)	0.1224	
	Sex							0.1214
	female	20/ 30 (66.7)	0.9 (0.5, 5.6)	3/ 15 (20.0)	NE (0.7, NE)	4.07 (1.20, 13.73)	0.0146	
	male	57/ 95 (60.0)	1.4 (0.7, 5.0)	18/ 47 (38.3)	NE (0.7, NE)	1.51 (0.89, 2.57)	0.1350	
	ECOG PS							0.7622
	0	42/ 62 (67.7)	0.7 (0.5, 2.3)	11/ 30 (36.7)	NE (0.7, NE)	2.06 (1.06, 4.00)	0.0300	
	1	35/ 63 (55.6)	3.0 (0.7, NE)	10/ 32 (31.3)	NE (2.8, NE)	1.72 (0.85, 3.48)	0.1320	
	HER2 Status in central laboratory							0.3779
	IHC 3+	59/ 96 (61.5)	1.4 (0.7, 4.2)	14/ 47 (29.8)	NE (2.8, NE)	2.14 (1.19, 3.83)	0.0101	
	IHC 2+/ISH +	18/ 29 (62.1)	0.6 (0.5, NE)	7/ 15 (46.7)	NE (0.5, NE)	1.34 (0.56, 3.23)	0.5001	
	Primary tumor location							0.6035
	Gastric	65/108 (60.2)	1.2 (0.6, 5.0)	19/ 55 (34.5)	NE (2.8, NE)	1.77 (1.06, 2.95)	0.0279	
	GEJ	12/ 17 (70.6)	1.3 (0.5, 5.0)	2/ 7 (28.6)	NE (0.5, NE)	2.74 (0.60, 12.40)	0.1761	
	Histological subtype							0.3704
	intestinal	56/ 89 (62.9)	1.2 (0.6, 4.2)	16/ 38 (42.1)	NE (0.6, NE)	1.48 (0.85, 2.58)	0.1936	
	diffuse	18/ 28 (64.3)	0.6 (0.5, 6.1)	4/ 18 (22.2)	NE (2.8, NE)	3.19 (1.08, 9.47)	0.0252	
	others	3/ 8 (37.5)	NE (0.3, NE)	1/ 6 (16.7)	NE (0.5, NE)	2.30 (0.24, 22.37)	0.4616	
	Number of metastatic sites							0.2369
	<2	15/ 24 (62.5)	1.0 (0.5, NE)	5/ 10 (50.0)	NE (0.2, NE)	1.09 (0.40, 3.02)	0.8161	
	>= 2	62/101 (61.4)	1.4 (0.5, 5.0)	16/ 52 (30.8)	NE (2.8, NE)	2.13 (1.23, 3.69)	0.0068	
	Previous total gastrectomy							0.1021
	yes	13/ 22 (59.1)	1.9 (0.5, NE)	5/ 9 (55.6)	0.7 (0.2, NE)	0.88 (0.31, 2.47)	0.7904	
	no	64/103 (62.1)	0.7 (0.5, 4.2)	16/ 53 (30.2)	NE (NE , NE)	2.20 (1.27, 3.81)	0.0042	
	Prior adjuvant/ neoadjuvant therapy							0.0441
	yes	22/ 30 (73.3)	0.7 (0.5, 1.9)	7/ 10 (70.0)	0.5 (0.2, NE)	0.79 (0.34, 1.86)	0.5480	
	no	55/ 95 (57.9)	1.9 (0.7, 5.6)	14/ 52 (26.9)	NE (NE , NE)	2.26 (1.26, 4.08)	0.0053	
	Prior ramucirumab contained treatment							0.1072
	yes	60/ 94 (63.8)	0.7 (0.5, 3.0)	11/ 41 (26.8)	NE (NE , NE)	2.52 (1.32, 4.80)	0.0036	
	no	17/ 31 (54.8)	5.0 (0.5, NE)	10/ 21 (47.6)	2.8 (0.5, NE)	1.07 (0.49, 2.34)	0.8771	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Neutrophil count decreased	Prior nivolumab contained treatment							0.0435
	yes	27/ 33 (81.8)	0.5 (0.5, 0.5)	4/ 15 (26.7)	NE (0.5, NE)	4.69 (1.62, 13.58)	0.0019	
	no	50/ 92 (54.3)	3.5 (1.3, 6.1)	17/ 47 (36.2)	NE (1.4, NE)	1.36 (0.79, 2.37)	0.2656	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.1470
	yes	33/ 44 (75.0)	0.5 (0.5, 0.7)	5/ 17 (29.4)	NE (0.5, NE)	3.26 (1.26, 8.39)	0.0105	
	no	44/ 81 (54.3)	3.5 (0.7, NE)	16/ 45 (35.6)	NE (1.4, NE)	1.43 (0.80, 2.53)	0.2209	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.0820
	yes	13/ 22 (59.1)	1.3 (0.5, NE)	4/ 7 (57.1)	0.5 (0.3, NE)	0.75 (0.24, 2.31)	0.5825	
	no	64/103 (62.1)	1.3 (0.6, 3.5)	17/ 55 (30.9)	NE (NE , NE)	2.16 (1.27, 3.70)	0.0041	
	Presence of liver metastasis at baseline							0.1022
	yes	45/ 67 (67.2)	0.7 (0.5, 1.4)	10/ 34 (29.4)	NE (2.8, NE)	2.77 (1.39, 5.52)	0.0027	
	no	32/ 58 (55.2)	3.1 (0.7, NE)	11/ 28 (39.3)	NE (0.5, NE)	1.23 (0.62, 2.44)	0.5514	
	Renal impairment at baseline							0.8350
	normal	21/ 33 (63.6)	0.7 (0.5, NE)	5/ 13 (38.5)	NE (0.5, NE)	1.90 (0.71, 5.07)	0.2043	
	mild	35/ 53 (66.0)	0.7 (0.5, 4.2)	9/ 28 (32.1)	NE (0.7, NE)	2.10 (1.01, 4.38)	0.0444	
	moderate	21/ 39 (53.8)	3.0 (0.5, NE)	7/ 20 (35.0)	NE (0.5, NE)	1.49 (0.63, 3.51)	0.3581	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.2698
	normal	54/ 88 (61.4)	1.4 (0.6, 5.0)	14/ 47 (29.8)	NE (2.8, NE)	2.21 (1.23, 3.99)	0.0072	
	mild	22/ 36 (61.1)	1.0 (0.5, 4.2)	7/ 15 (46.7)	NE (0.3, NE)	1.20 (0.51, 2.81)	0.6907	
	moderate	1/ 1 (100.0)	1.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.1276
	yes	4/ 8 (50.0)	6.1 (0.5, NE)	3/ 5 (60.0)	1.4 (0.5, NE)	0.62 (0.14, 2.83)	0.5411	
	no	73/117 (62.4)	1.2 (0.6, 3.1)	18/ 57 (31.6)	NE (NE , NE)	2.09 (1.25, 3.50)	0.0046	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.2243
	yes	1/ 3 (33.3)	NE (6.1, NE)	2/ 4 (50.0)	NE (0.5, NE)	0.36 (0.03, 4.43)	0.4114	
	no	76/122 (62.3)	1.0 (0.6, 3.1)	19/ 58 (32.8)	NE (2.8, NE)	1.98 (1.20, 3.28)	0.0072	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Platelet count decreased	Region							0.1154
	Japan	44/ 99 (44.4)	9.8 (1.7, NE)	3/ 50 (6.0)	NE (NE , NE)	9.07 (2.81, 29.26)	<.0001	
	Korea	3/ 26 (11.5)	NE (NE , NE)	1/ 12 (8.3)	NE (NE , NE)	1.18 (0.12, 11.40)	0.8851	
	Lines of prior systemic therapy							0.9853
	2	22/ 66 (33.3)	NE (5.3, NE)	2/ 38 (5.3)	NE (NE , NE)	6.56 (1.54, 28.00)	0.0034	
	3	16/ 34 (47.1)	NE (0.3, NE)	2/ 18 (11.1)	NE (NE , NE)	5.70 (1.31, 24.83)	0.0096	
	>=4	9/ 25 (36.0)	NE (0.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Age							0.5463
	<65 years	20/ 55 (36.4)	NE (5.0, NE)	1/ 27 (3.7)	NE (NE , NE)	10.39 (1.39, 77.70)	0.0045	
	>=65 years	27/ 70 (38.6)	NE (5.3, NE)	3/ 35 (8.6)	NE (NE , NE)	5.36 (1.63, 17.70)	0.0021	
	Sex							0.9888
	female	7/ 30 (23.3)	NE (9.8, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	male	40/ 95 (42.1)	NE (1.9, NE)	4/ 47 (8.5)	NE (NE , NE)	5.88 (2.10, 16.44)	0.0001	
	ECOG PS							0.1870
	0	28/ 62 (45.2)	9.8 (1.6, NE)	1/ 30 (3.3)	NE (NE , NE)	16.30 (2.21, 120.00)	0.0002	
	1	19/ 63 (30.2)	NE (NE , NE)	3/ 32 (9.4)	NE (NE , NE)	3.52 (1.04, 11.90)	0.0332	
	HER2 Status in central laboratory							0.7264
	IHC 3+	34/ 96 (35.4)	NE (9.8, NE)	3/ 47 (6.4)	NE (NE , NE)	5.98 (1.83, 19.52)	0.0008	
	IHC 2+/ISH +	13/ 29 (44.8)	NE (0.3, NE)	1/ 15 (6.7)	NE (NE , NE)	8.94 (1.17, 68.48)	0.0108	
	Primary tumor location							0.9883
	Gastric	42/108 (38.9)	NE (5.3, NE)	4/ 55 (7.3)	NE (NE , NE)	6.29 (2.25, 17.56)	<.0001	
	GEJ	5/ 17 (29.4)	NE (1.7, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	Histological subtype							0.3862
	intestinal	38/ 89 (42.7)	9.8 (1.9, NE)	3/ 38 (7.9)	NE (NE , NE)	6.42 (1.98, 20.84)	0.0004	
	diffuse	8/ 28 (28.6)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
	others	1/ 8 (12.5)	NE (0.3, NE)	1/ 6 (16.7)	NE (0.4, NE)	0.80 (0.05, 12.84)	0.8757	
	Number of metastatic sites							0.9898
	<2	11/ 24 (45.8)	NE (0.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	>= 2	36/101 (35.6)	NE (9.8, NE)	4/ 52 (7.7)	NE (NE , NE)	5.33 (1.89, 15.01)	0.0004	
	Previous total gastrectomy							0.2018
	yes	4/ 22 (18.2)	NE (NE , NE)	1/ 9 (11.1)	NE (0.5, NE)	1.81 (0.20, 16.18)	0.5951	
	no	43/103 (41.7)	NE (5.0, NE)	3/ 53 (5.7)	NE (NE , NE)	8.59 (2.66, 27.73)	<.0001	
	Prior adjuvant/ neoadjuvant therapy							0.5610
	yes	10/ 30 (33.3)	NE (5.0, NE)	1/ 10 (10.0)	NE (0.5, NE)	3.86 (0.49, 30.24)	0.1670	
	no	37/ 95 (38.9)	NE (5.3, NE)	3/ 52 (5.8)	NE (NE , NE)	7.80 (2.40, 25.33)	<.0001	
	Prior ramucirumab contained treatment							0.9111
	yes	39/ 94 (41.5)	NE (1.9, NE)	3/ 41 (7.3)	NE (NE , NE)	6.69 (2.07, 21.68)	0.0002	
	no	8/ 31 (25.8)	NE (9.8, NE)	1/ 21 (4.8)	NE (NE , NE)	5.46 (0.68, 44.08)	0.0751	

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Daiichi Sankyo

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Protocol DS8201-A-J202
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Primary Cohort
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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Platelet count decreased	Prior nivolumab contained treatment							0.5233
	yes	18/ 33 (54.5)	1.7 (0.3, NE)	1/ 15 (6.7)	NE (NE , NE)	11.38 (1.52, 85.45)	0.0027	
	no	29/ 92 (31.5)	NE (9.8, NE)	3/ 47 (6.4)	NE (NE , NE)	5.22 (1.59, 17.19)	0.0025	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.6293
	yes	20/ 44 (45.5)	NE (0.3, NE)	1/ 17 (5.9)	NE (NE , NE)	10.06 (1.35, 75.02)	0.0052	
	no	27/ 81 (33.3)	NE (9.8, NE)	3/ 45 (6.7)	NE (NE , NE)	5.33 (1.61, 17.60)	0.0022	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9877
	yes	7/ 22 (31.8)	NE (0.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	40/103 (38.8)	NE (5.3, NE)	4/ 55 (7.3)	NE (NE , NE)	6.04 (2.16, 16.92)	0.0001	
	Presence of liver metastasis at baseline							0.9895
	yes	28/ 67 (41.8)	9.8 (1.7, NE)	4/ 34 (11.8)	NE (NE , NE)	4.22 (1.48, 12.07)	0.0036	
	no	19/ 58 (32.8)	NE (5.3, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
	Renal impairment at baseline							0.9999
	normal	13/ 33 (39.4)	NE (5.0, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
	mild	22/ 53 (41.5)	NE (0.5, NE)	4/ 28 (14.3)	NE (NE , NE)	3.62 (1.25, 10.53)	0.0125	
	moderate	12/ 39 (30.8)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.3676
	normal	32/ 88 (36.4)	NE (9.8, NE)	2/ 47 (4.3)	NE (NE , NE)	9.54 (2.28, 39.87)	0.0002	
	mild	15/ 36 (41.7)	NE (0.3, NE)	2/ 15 (13.3)	NE (NE , NE)	3.83 (0.87, 16.77)	0.0558	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9904
	yes	1/ 8 (12.5)	NE (0.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
	no	46/117 (39.3)	NE (5.3, NE)	4/ 57 (7.0)	NE (NE , NE)	6.44 (2.31, 17.92)	<.0001	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9991
	yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	47/122 (38.5)	NE (5.3, NE)	4/ 58 (6.9)	NE (NE , NE)	6.40 (2.30, 17.81)	<.0001	

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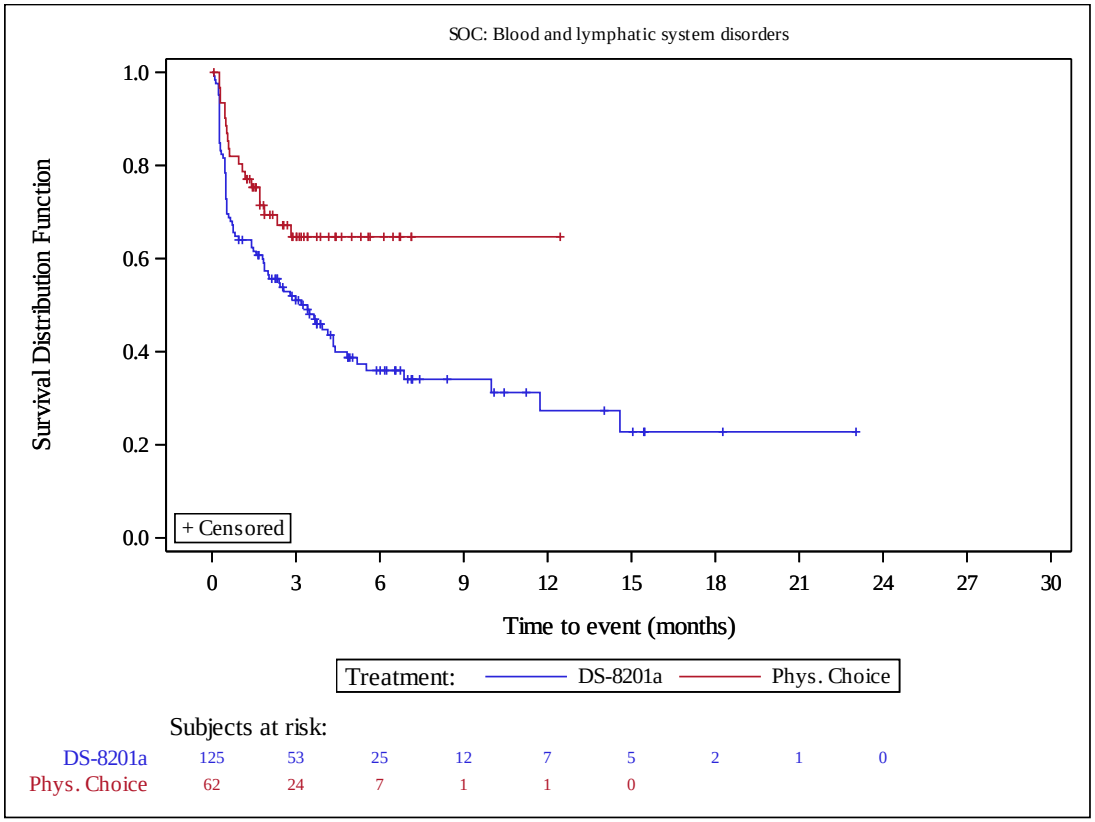
Primary Cohort
Kaplan Meier Plot of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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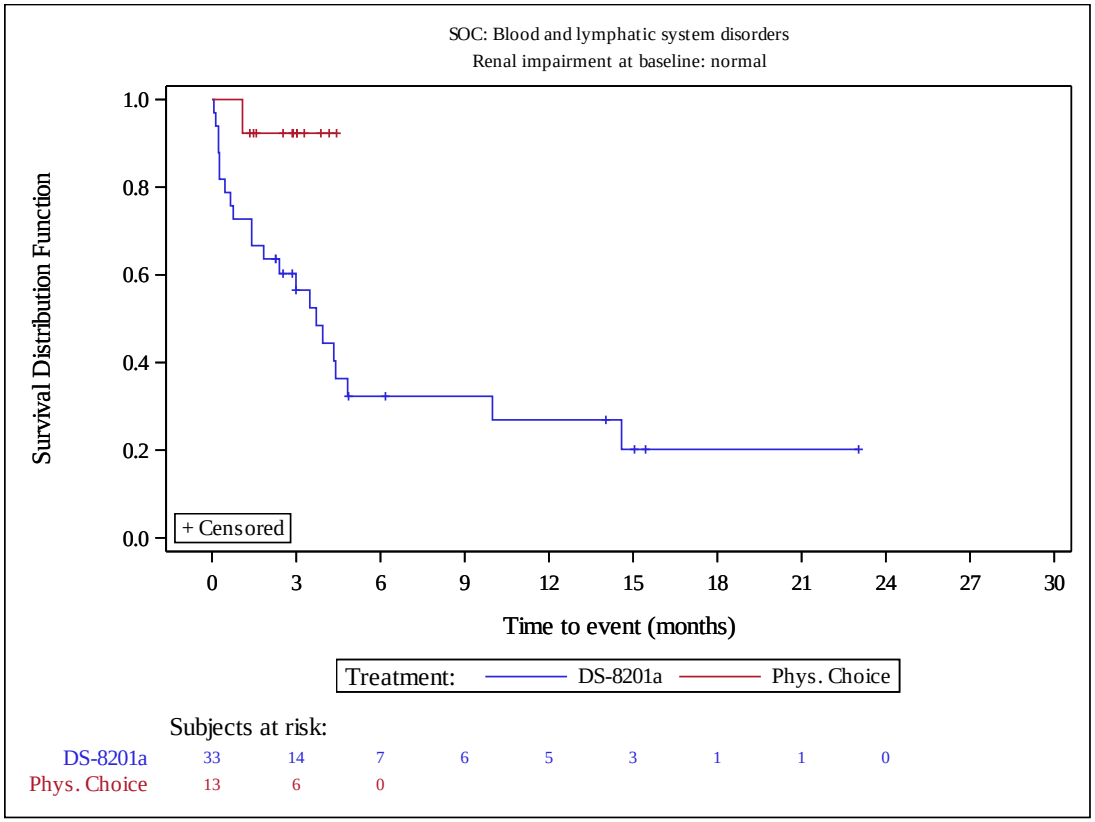

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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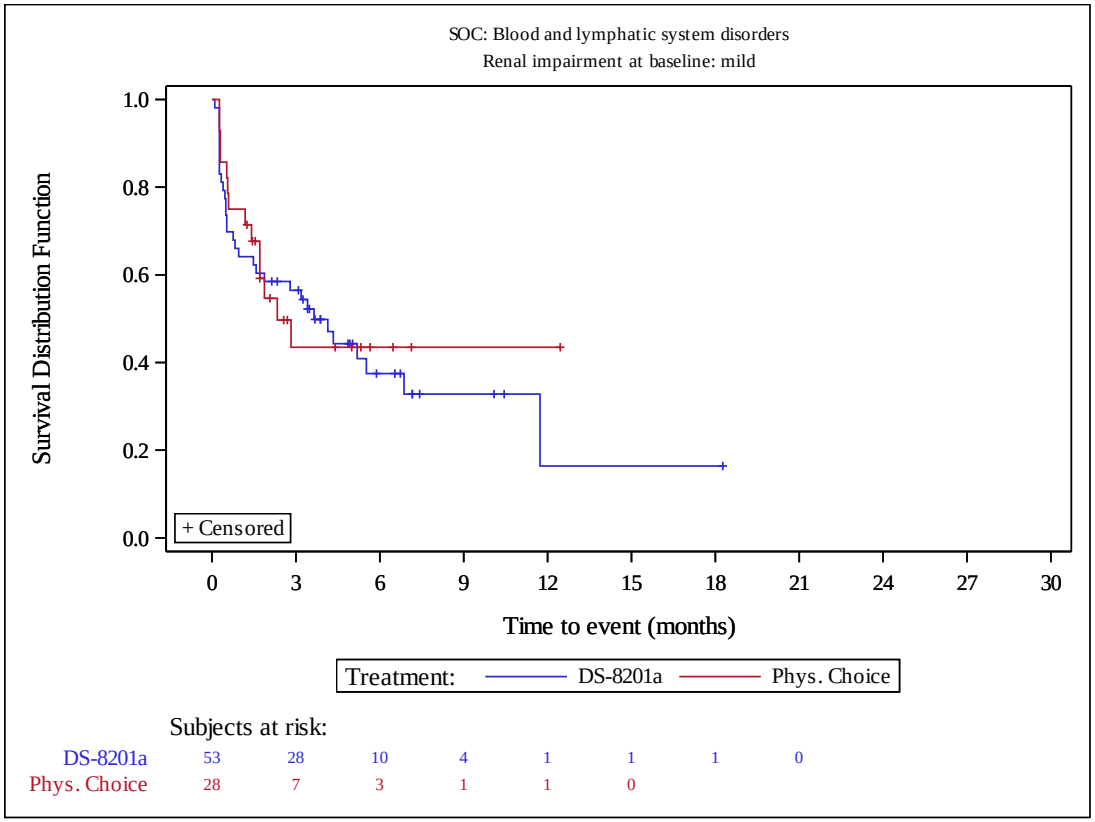

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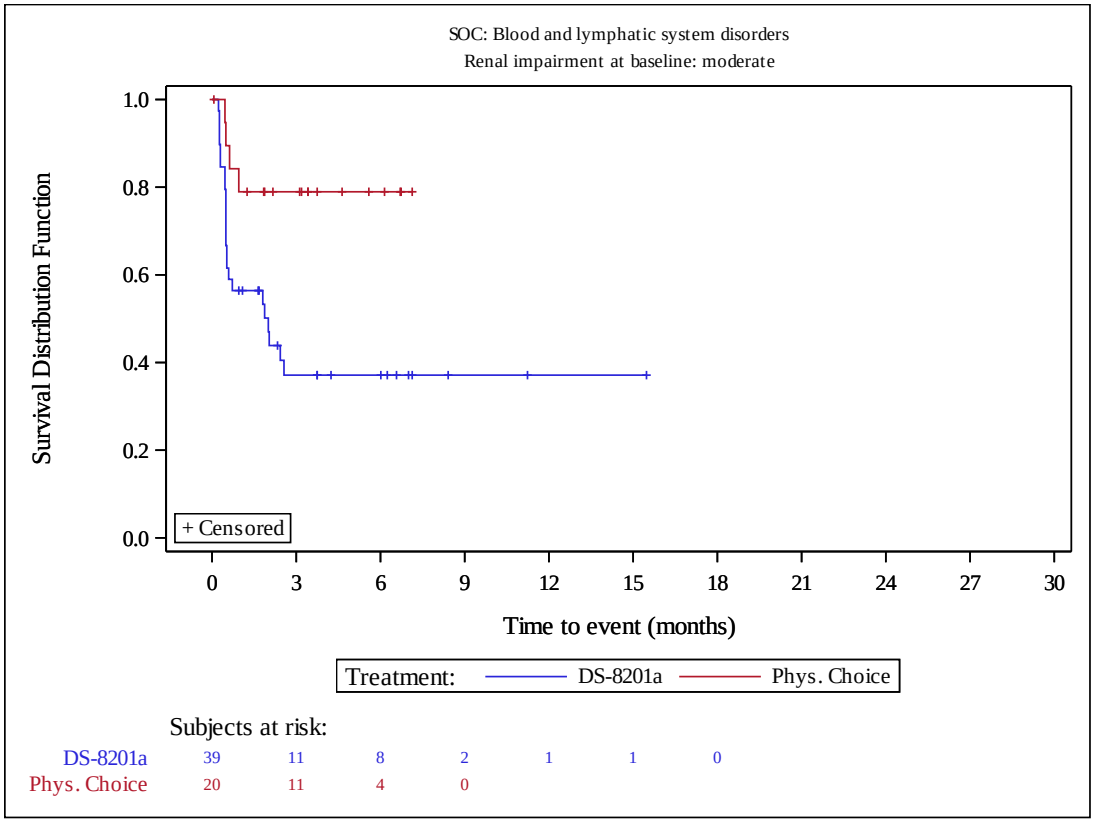

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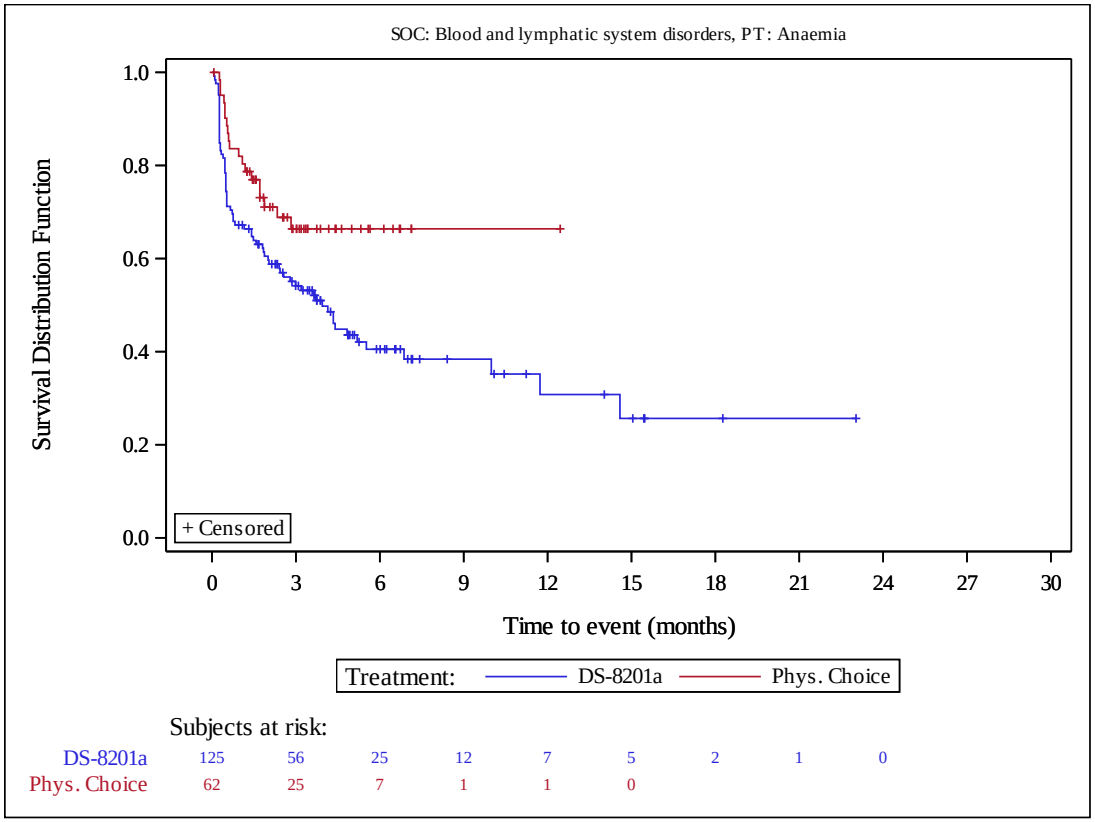

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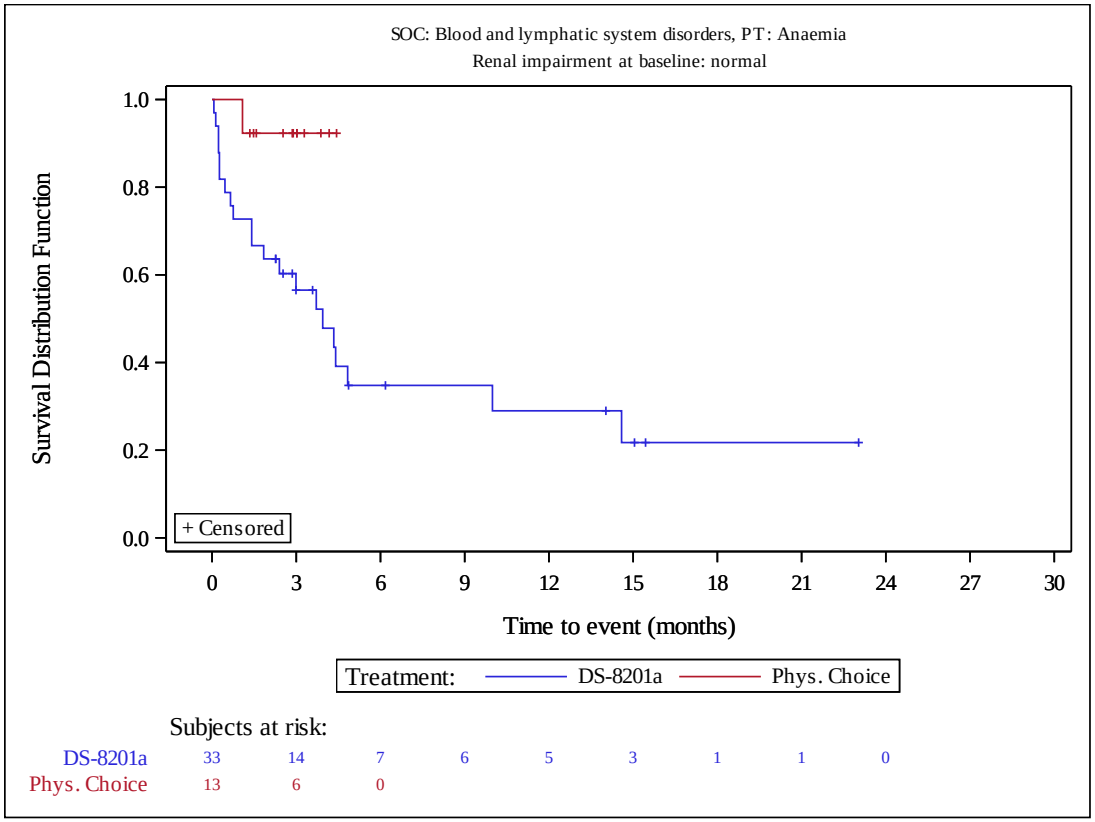

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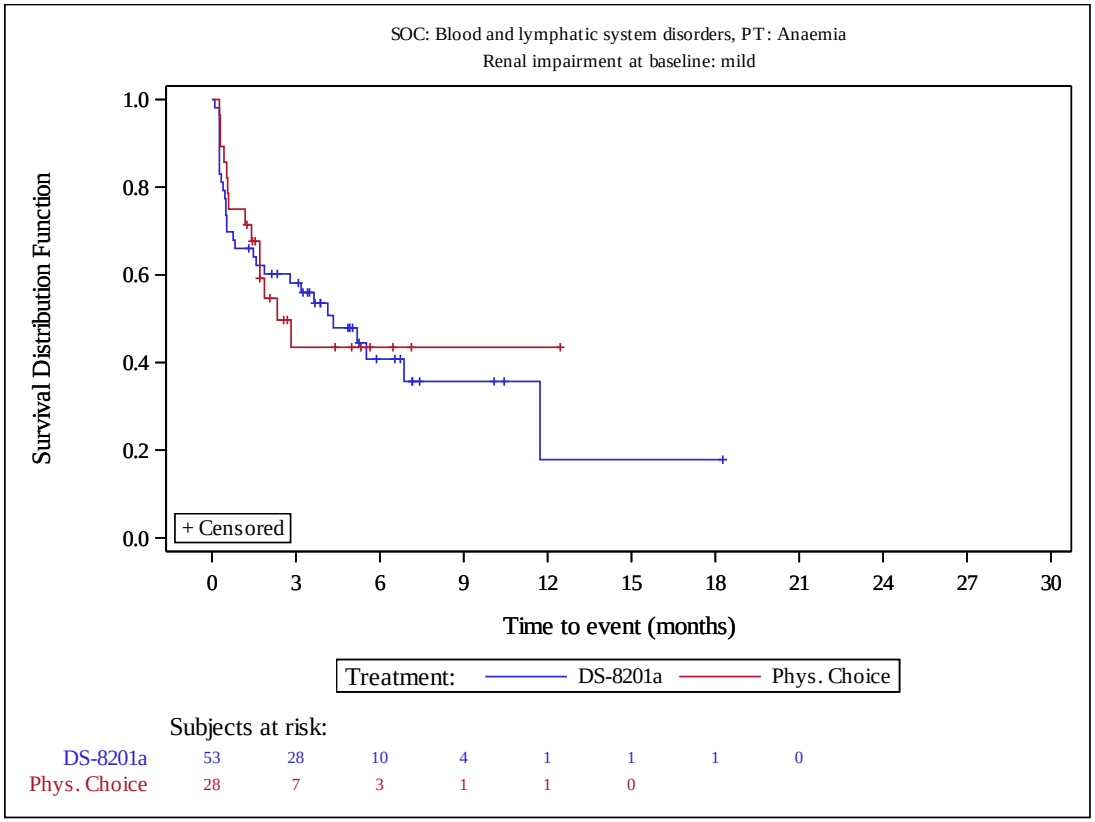

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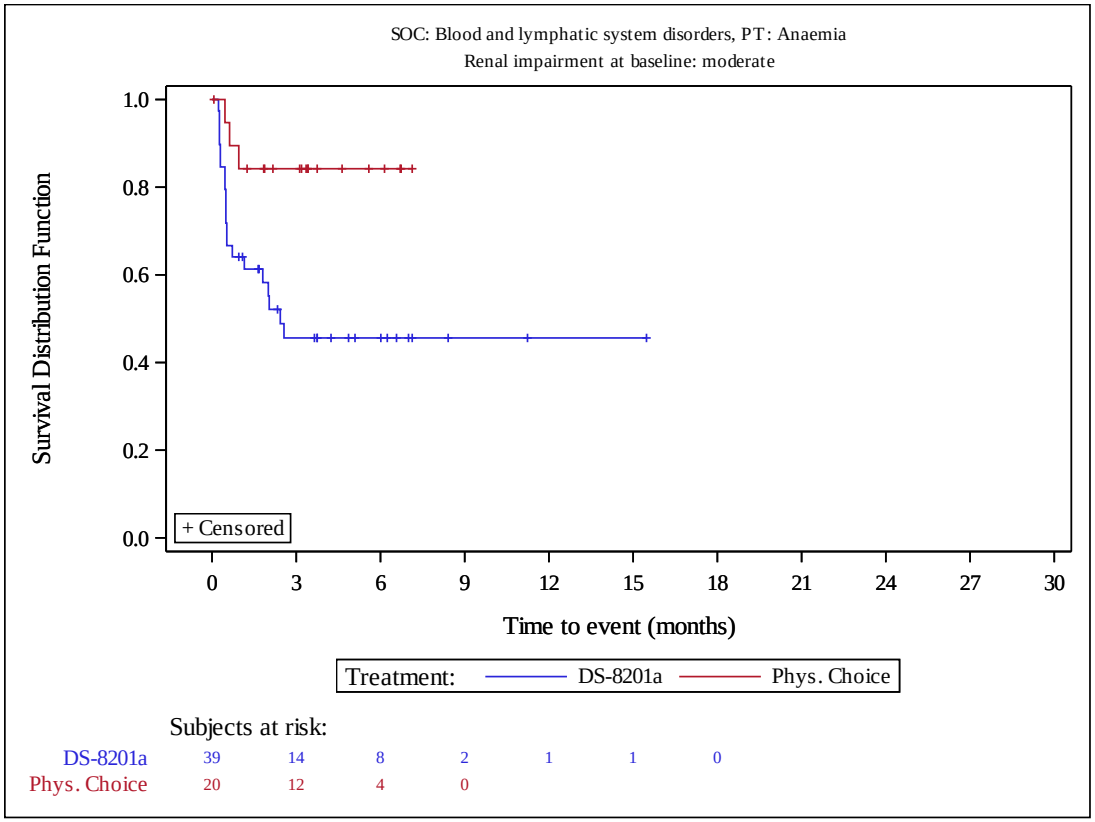

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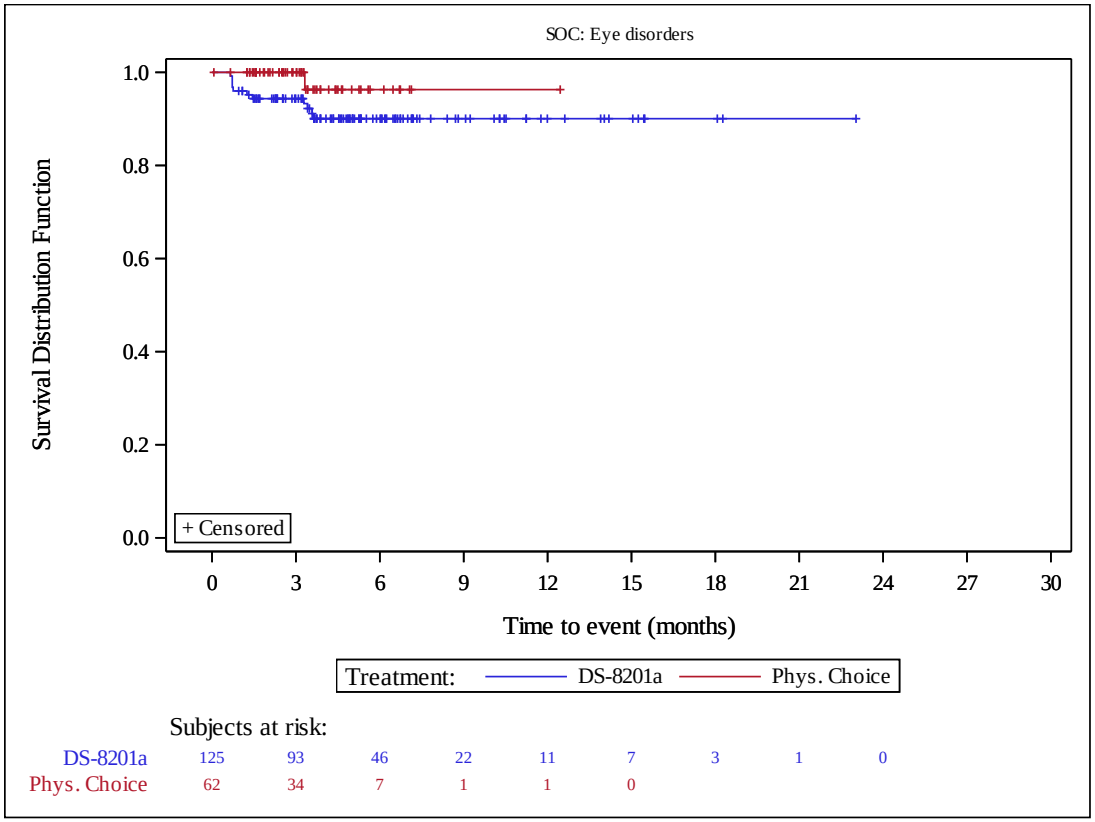

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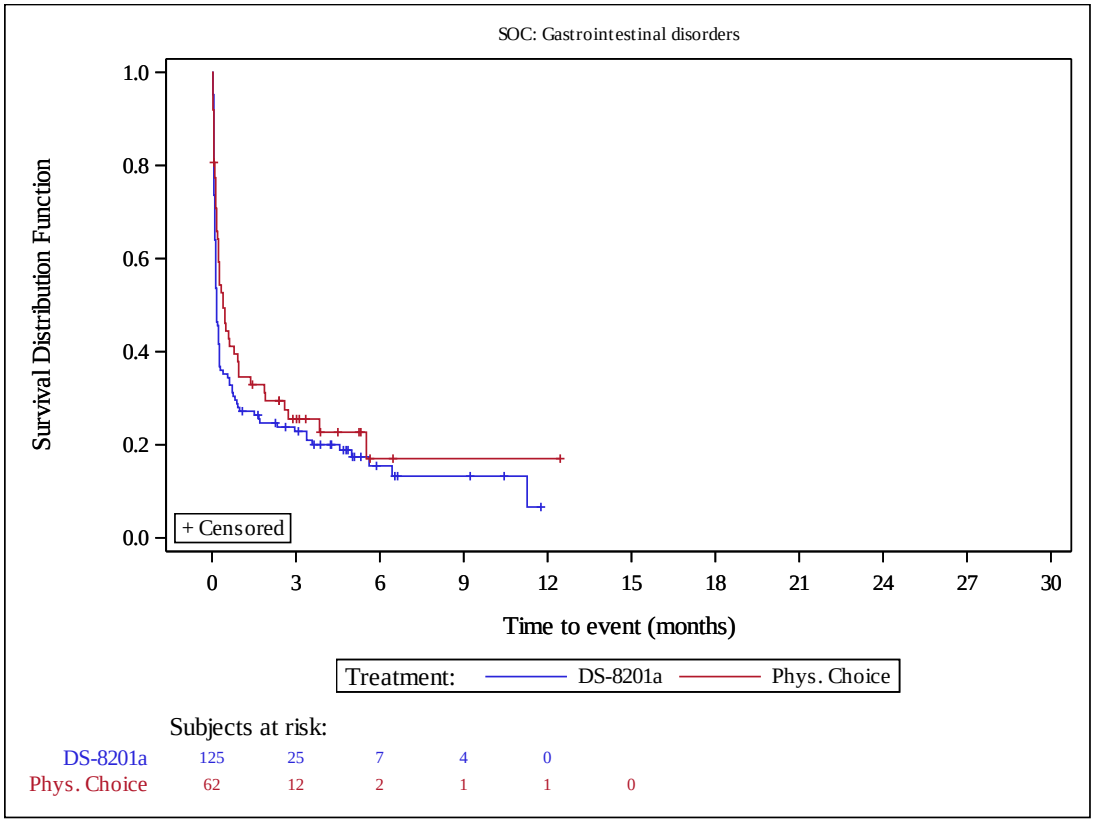

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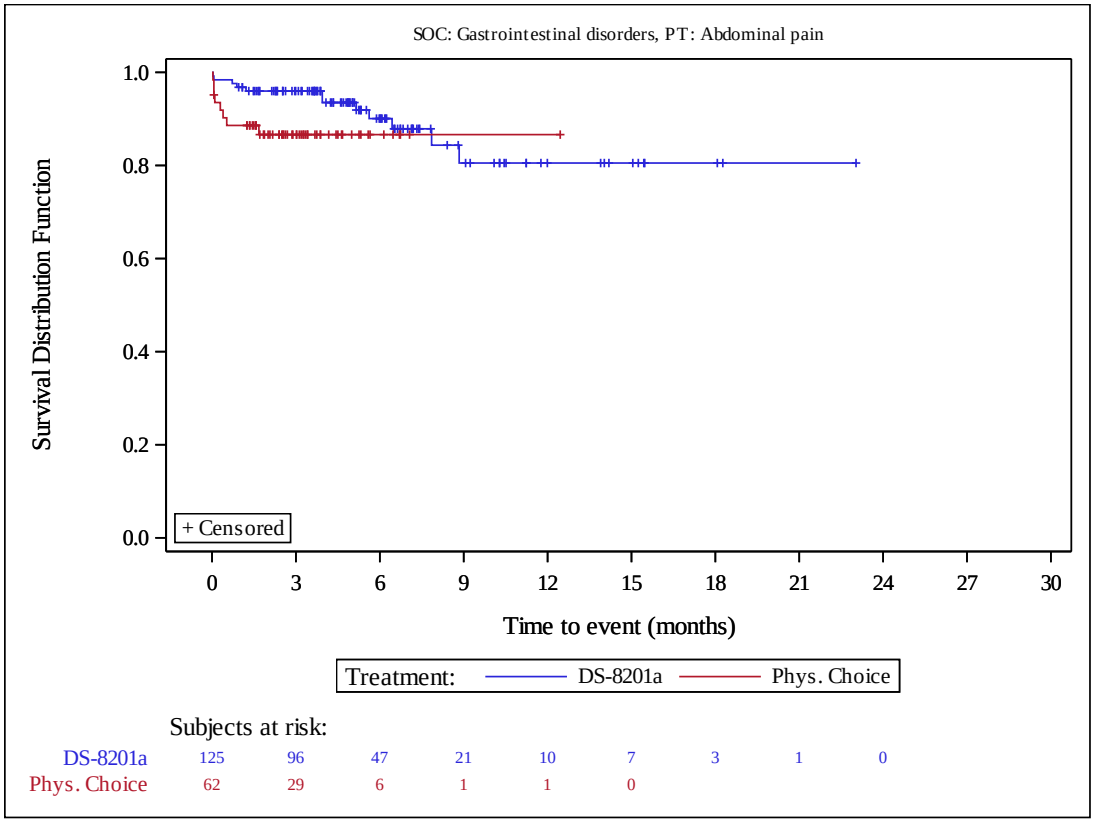

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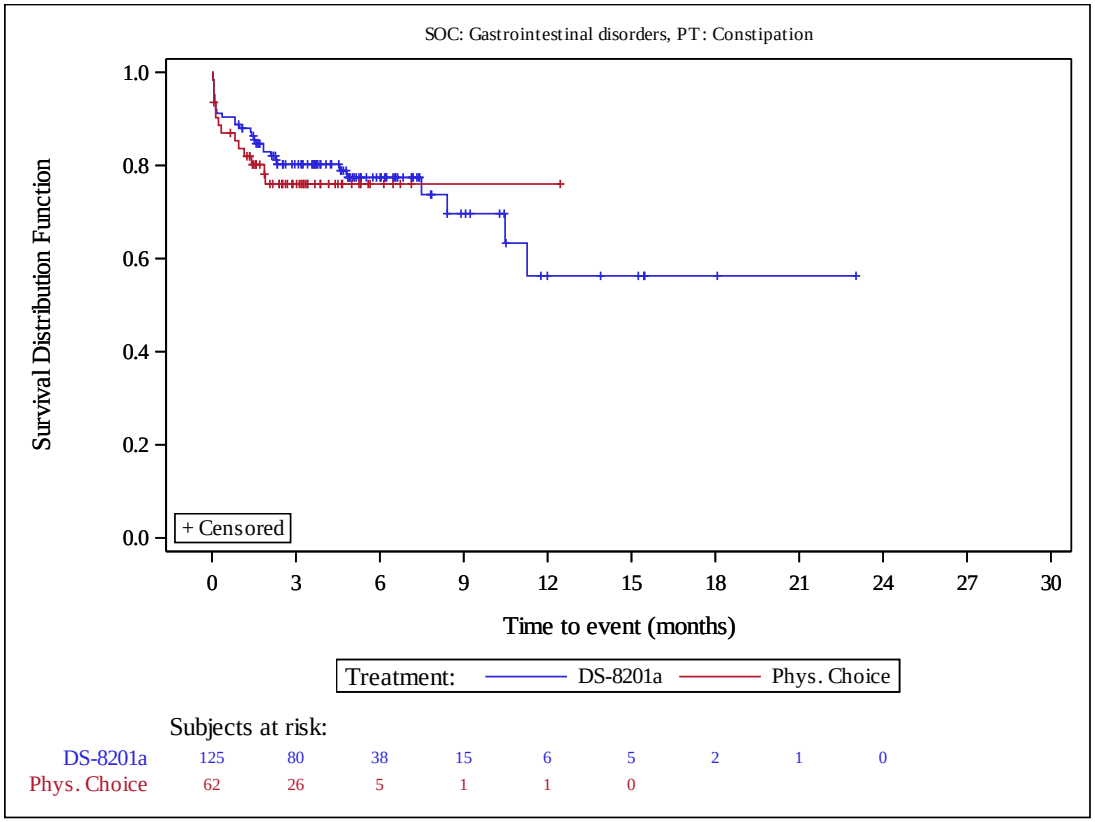

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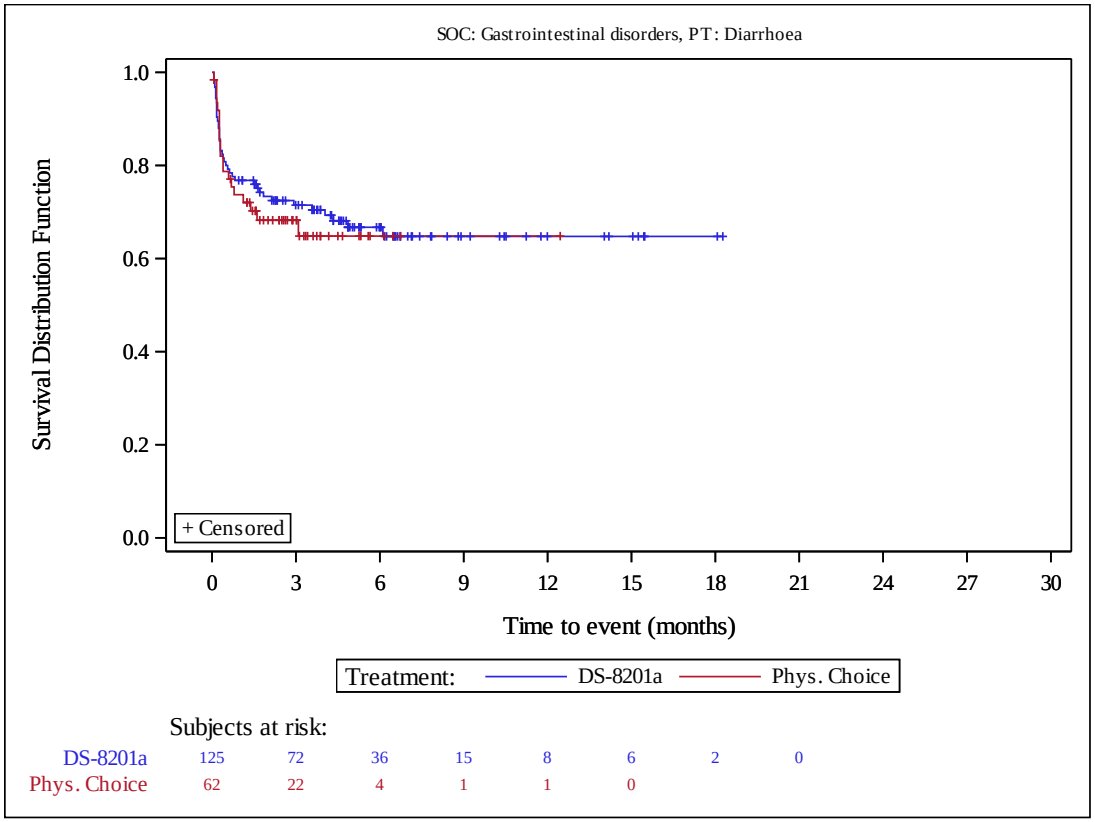

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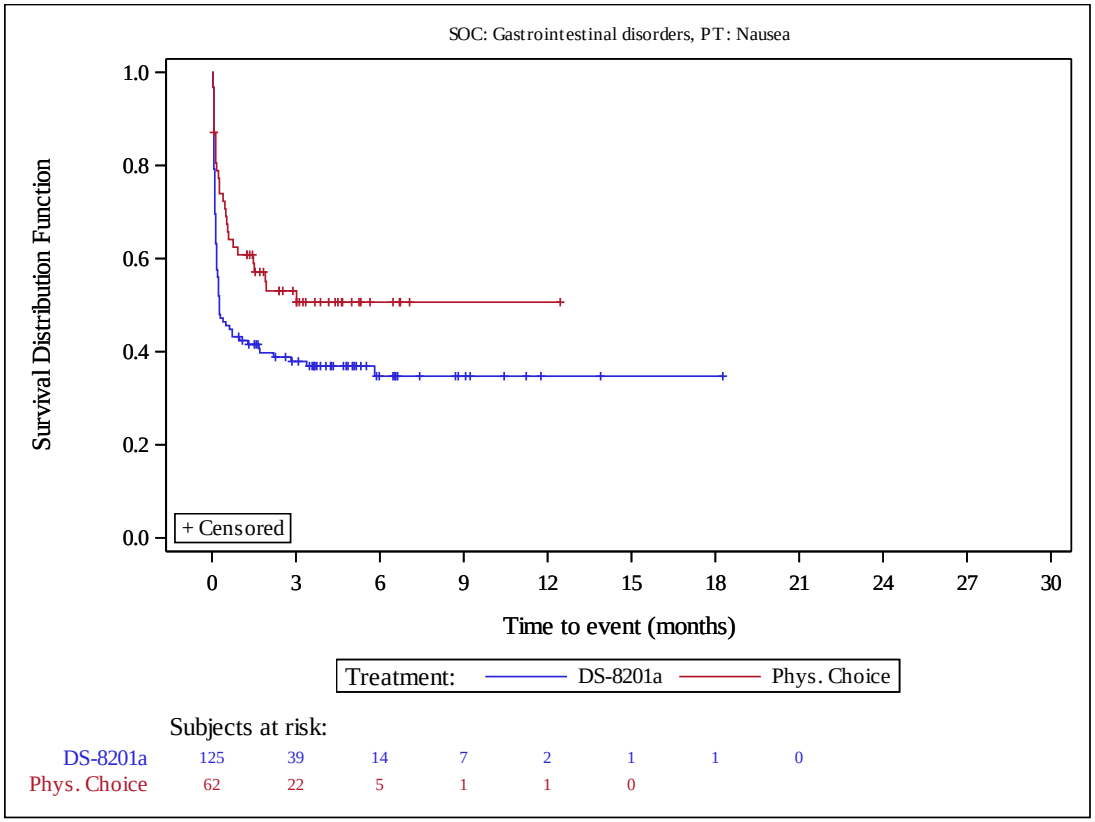

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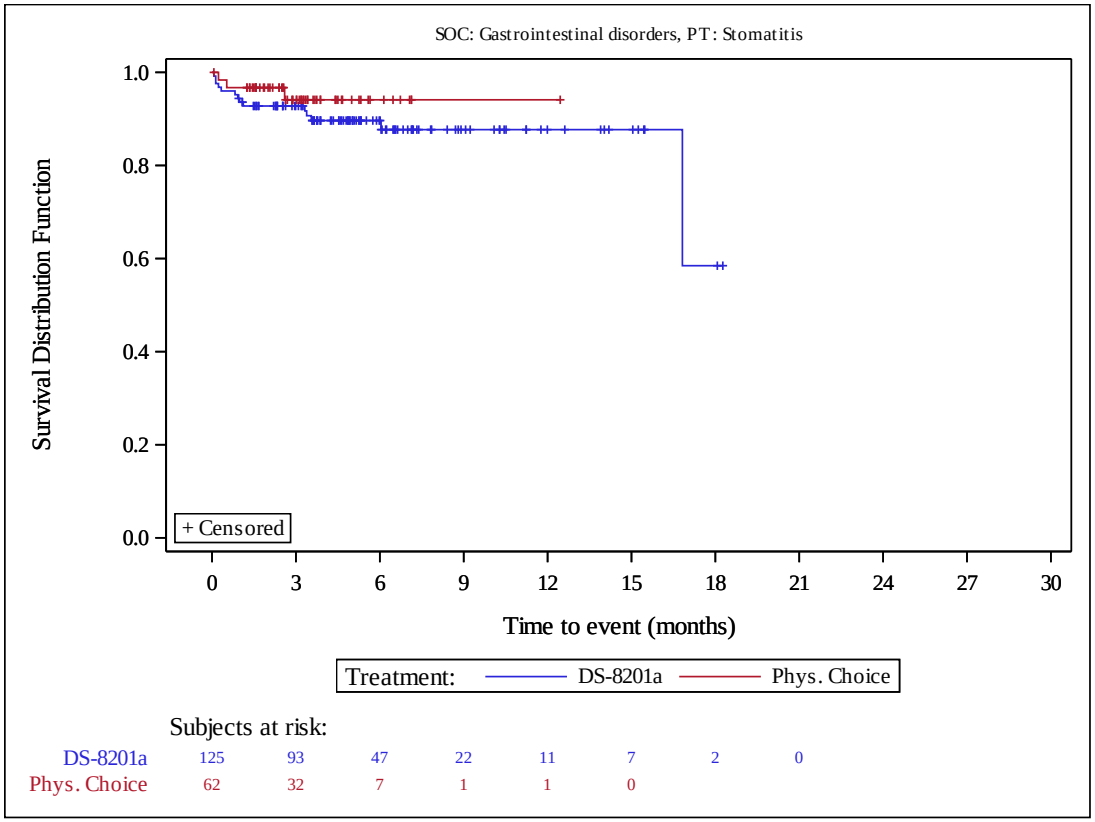

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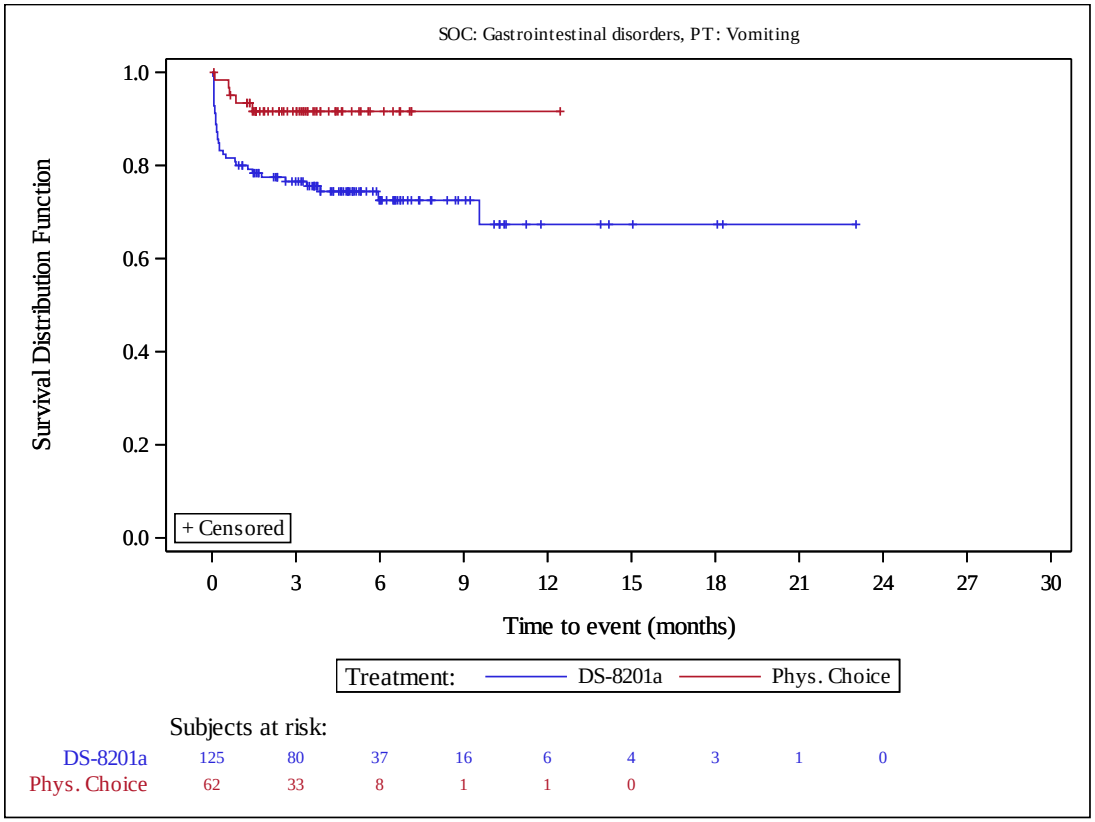

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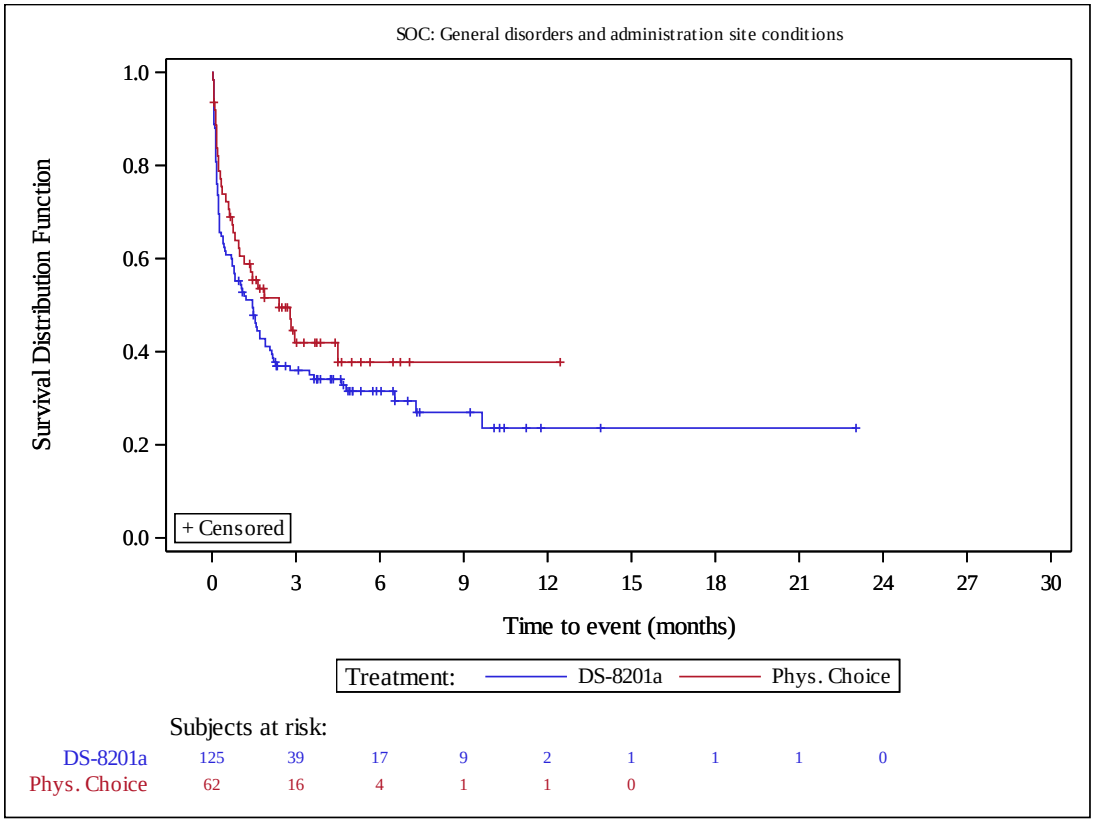

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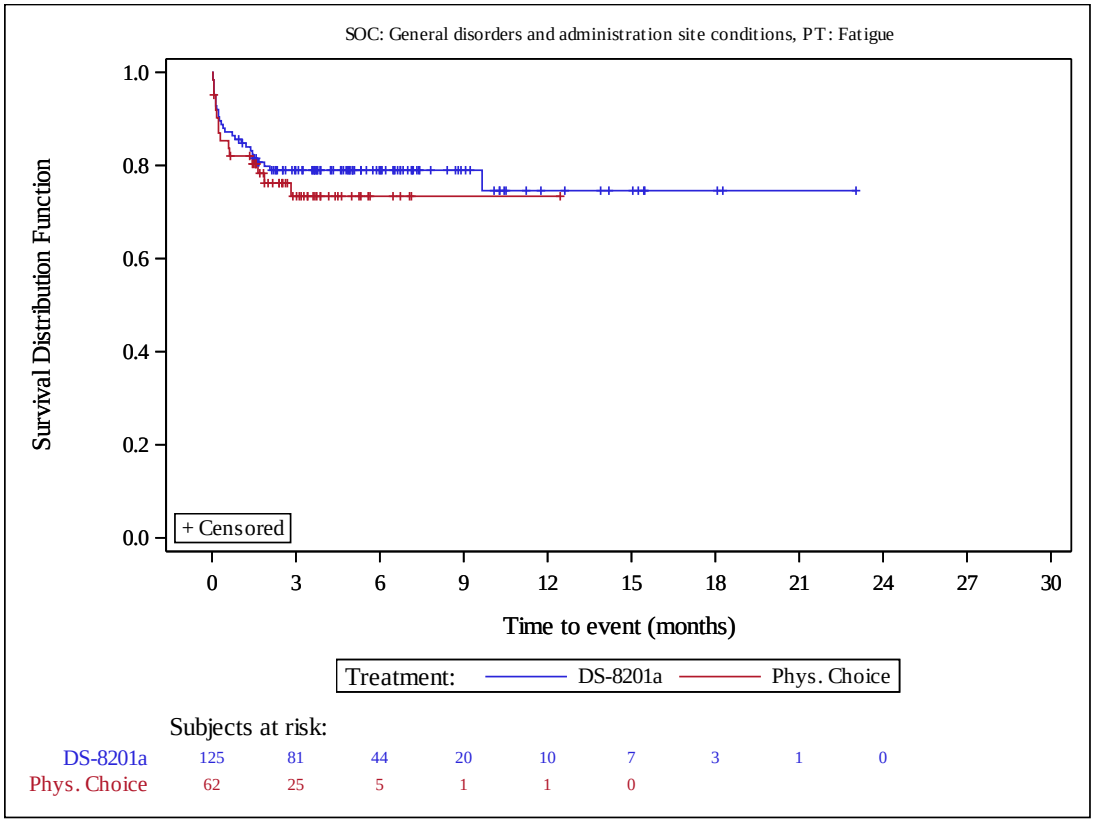

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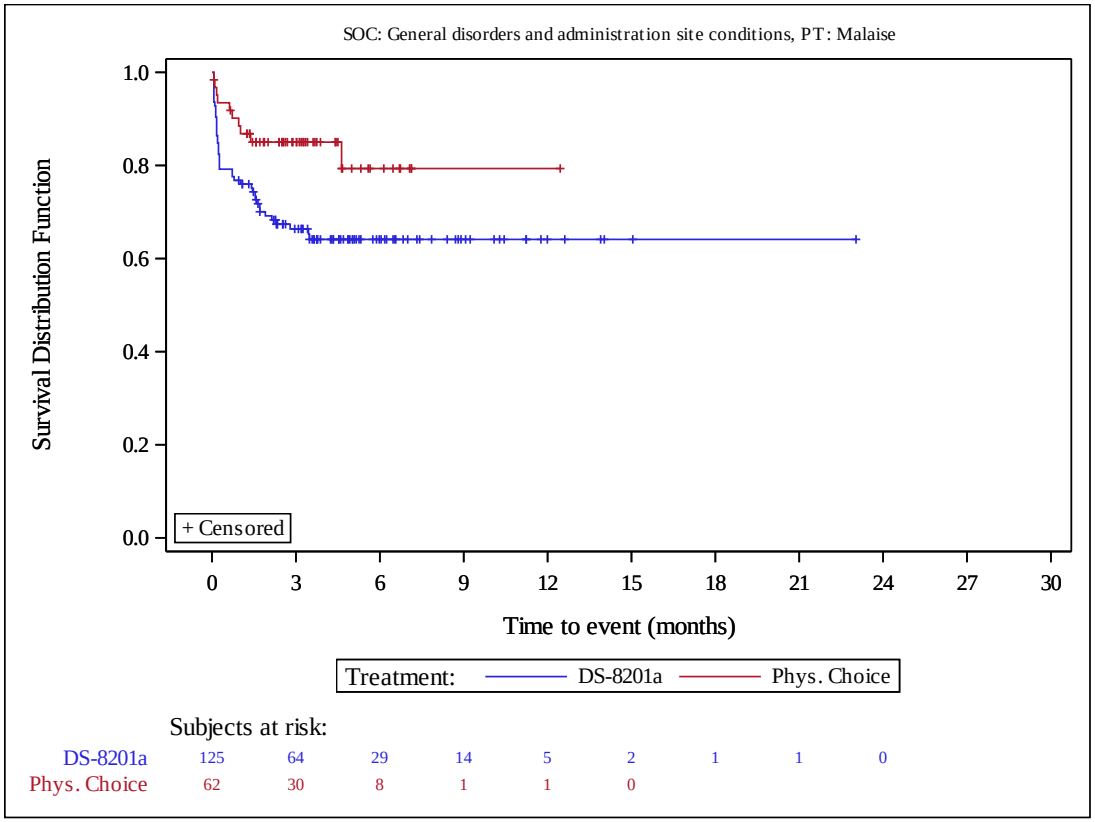

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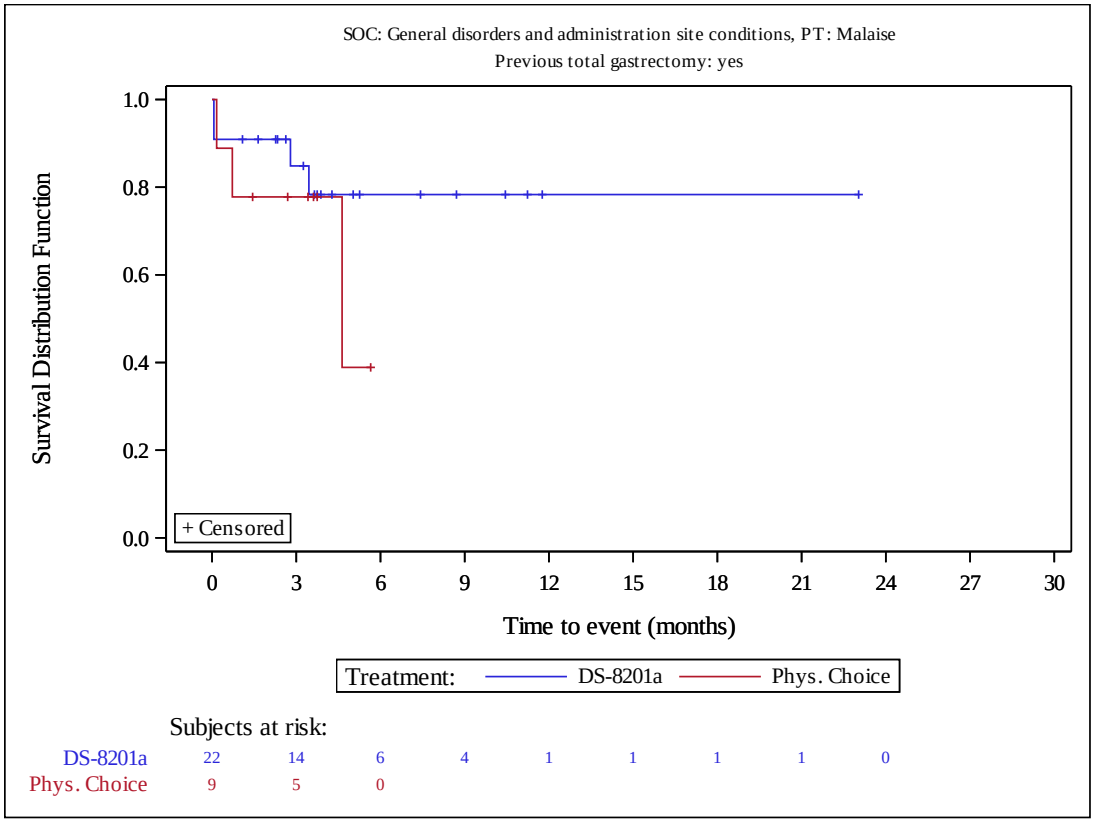

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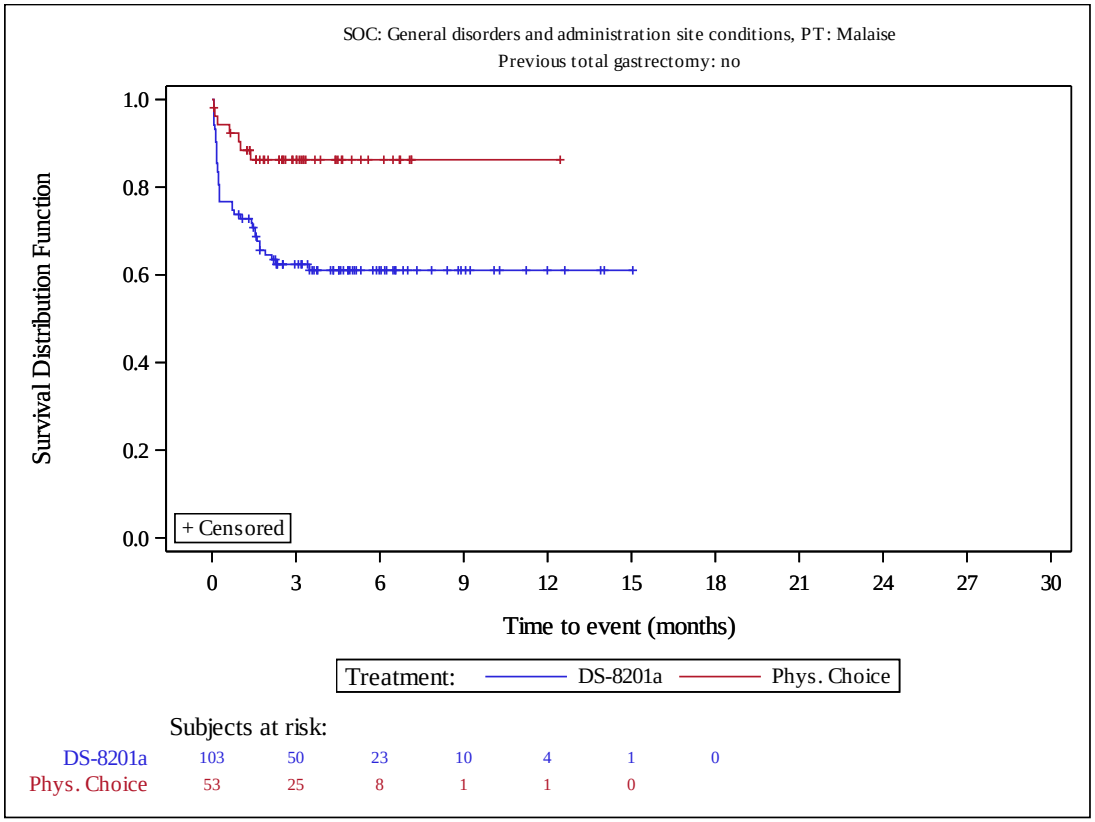

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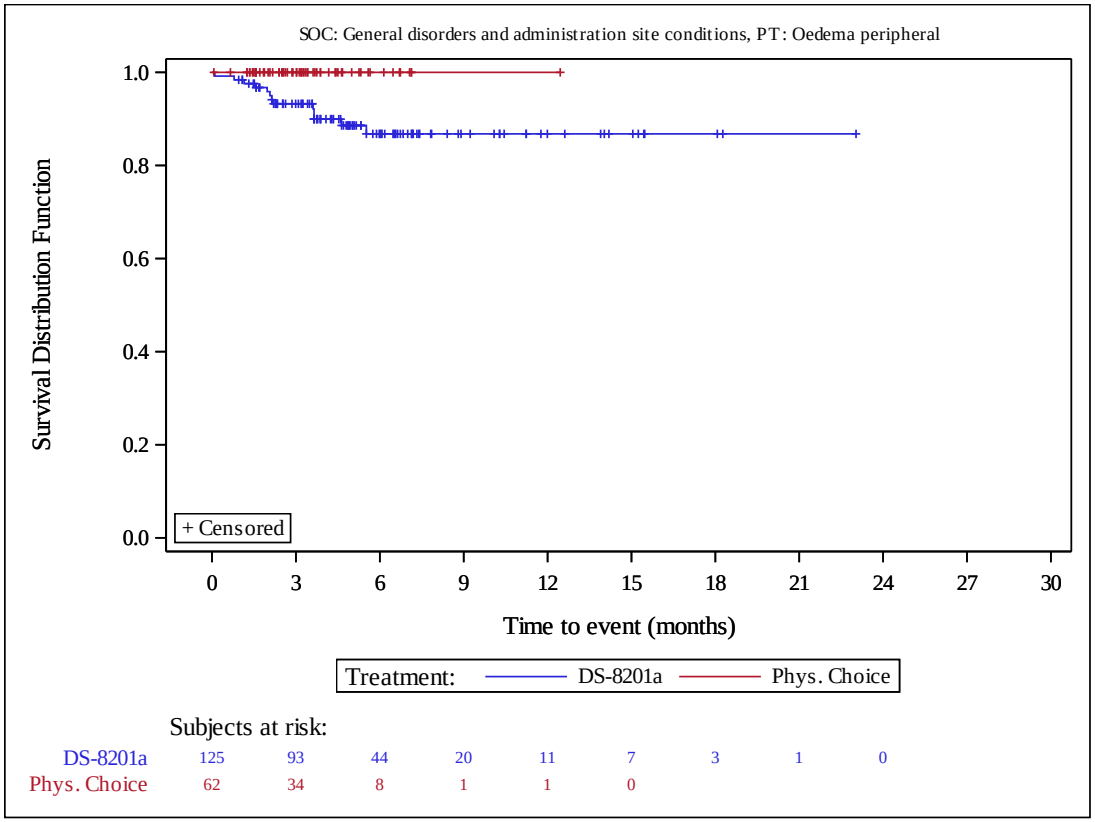

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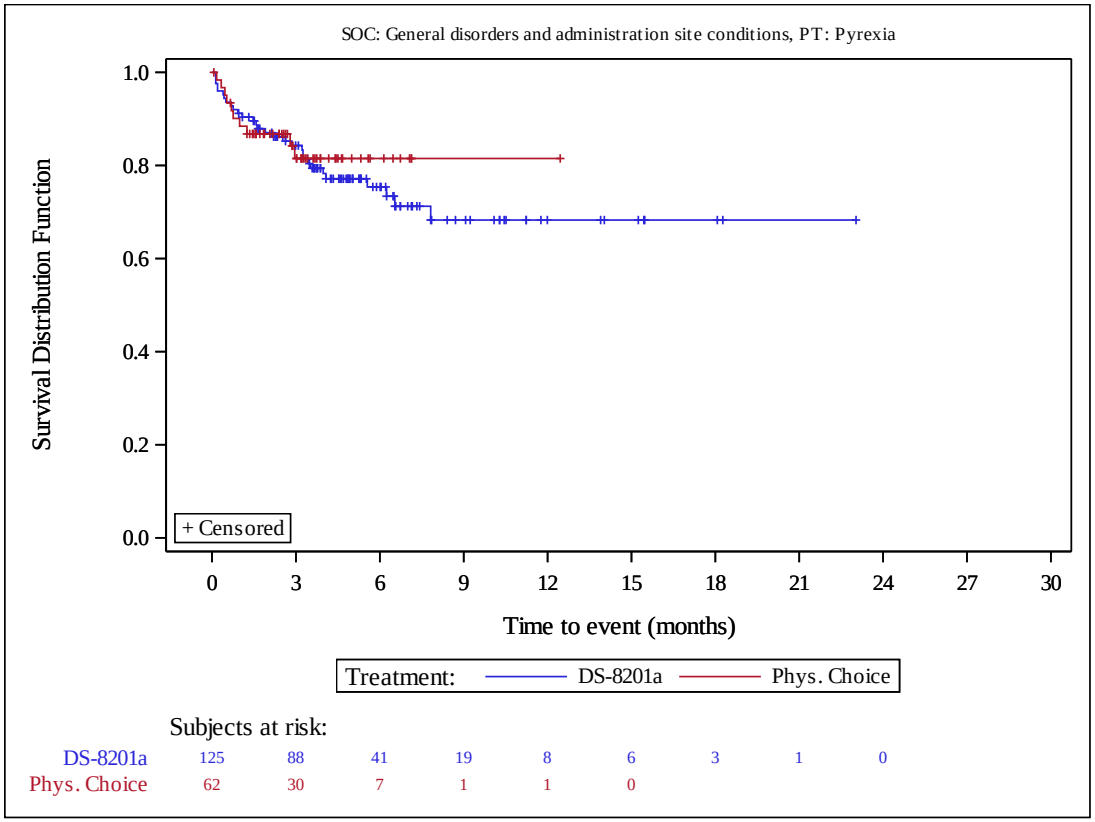

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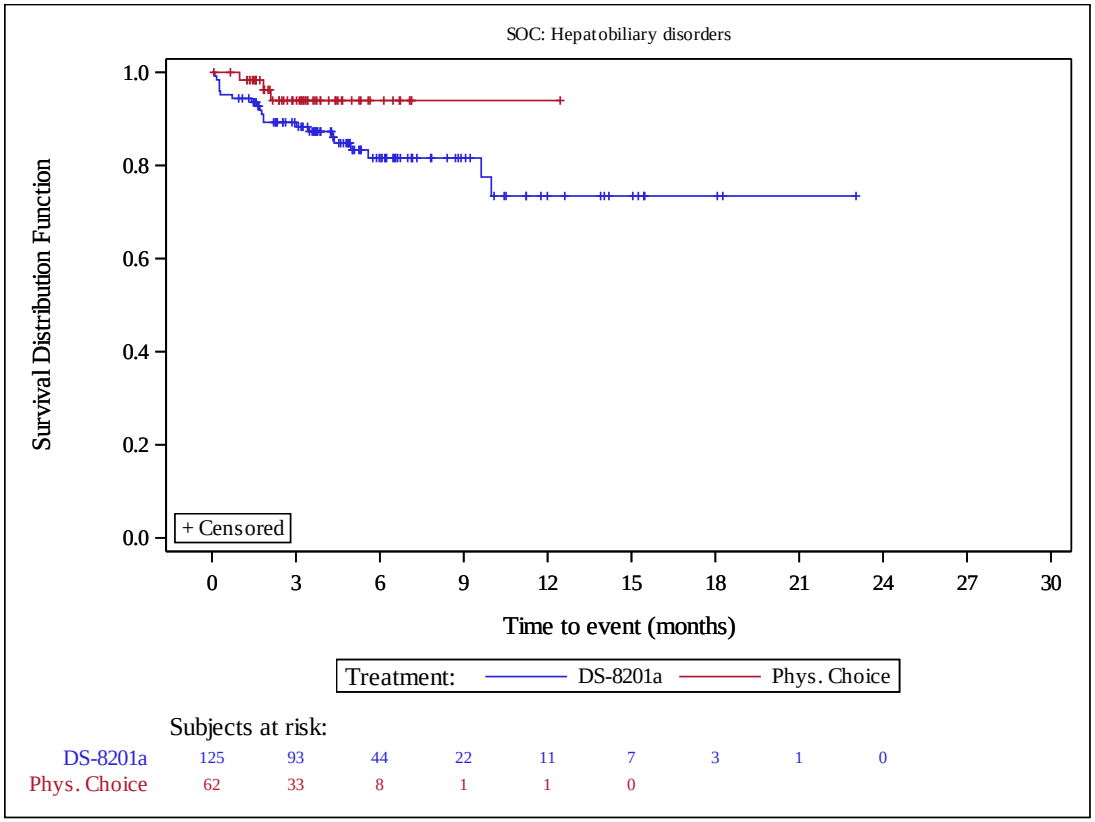

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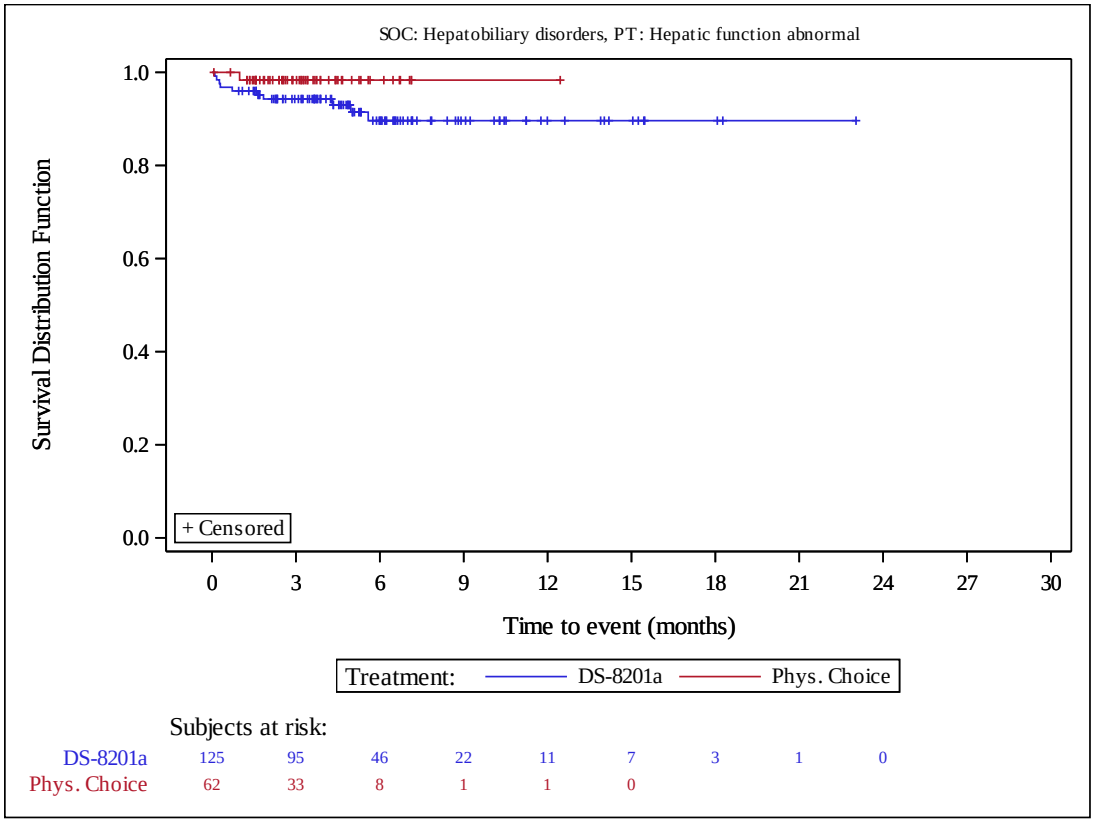

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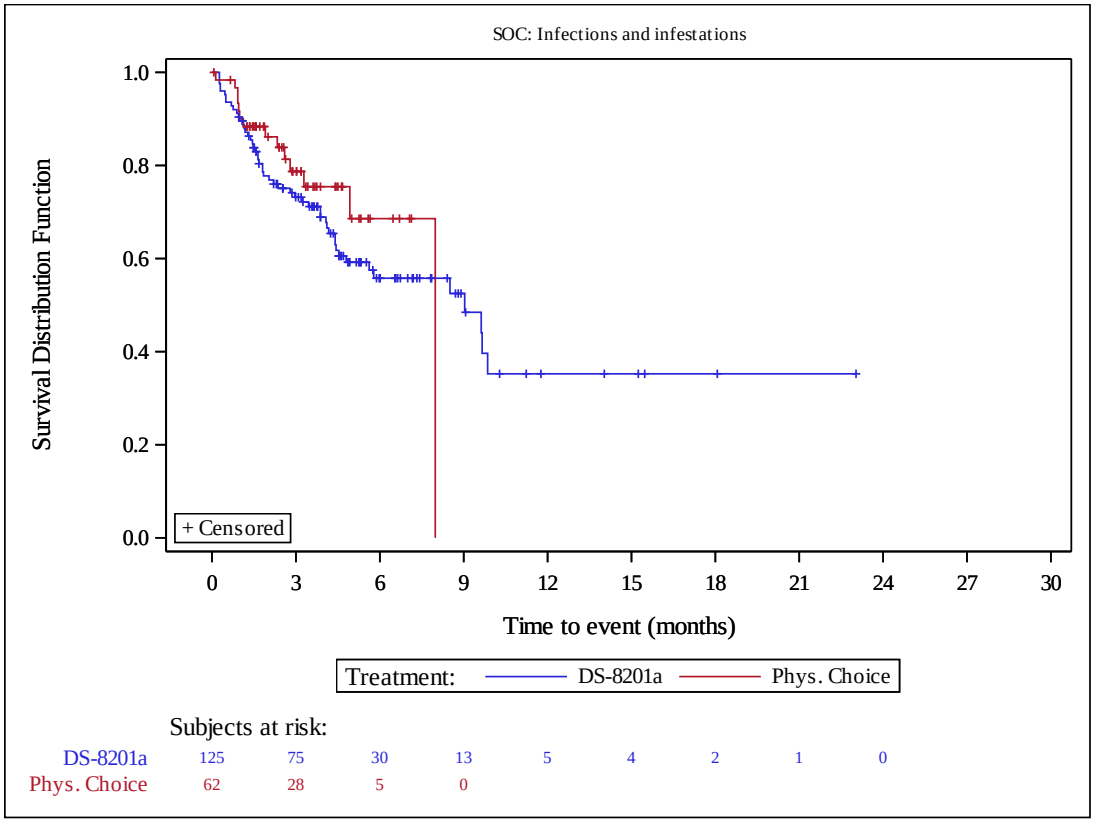

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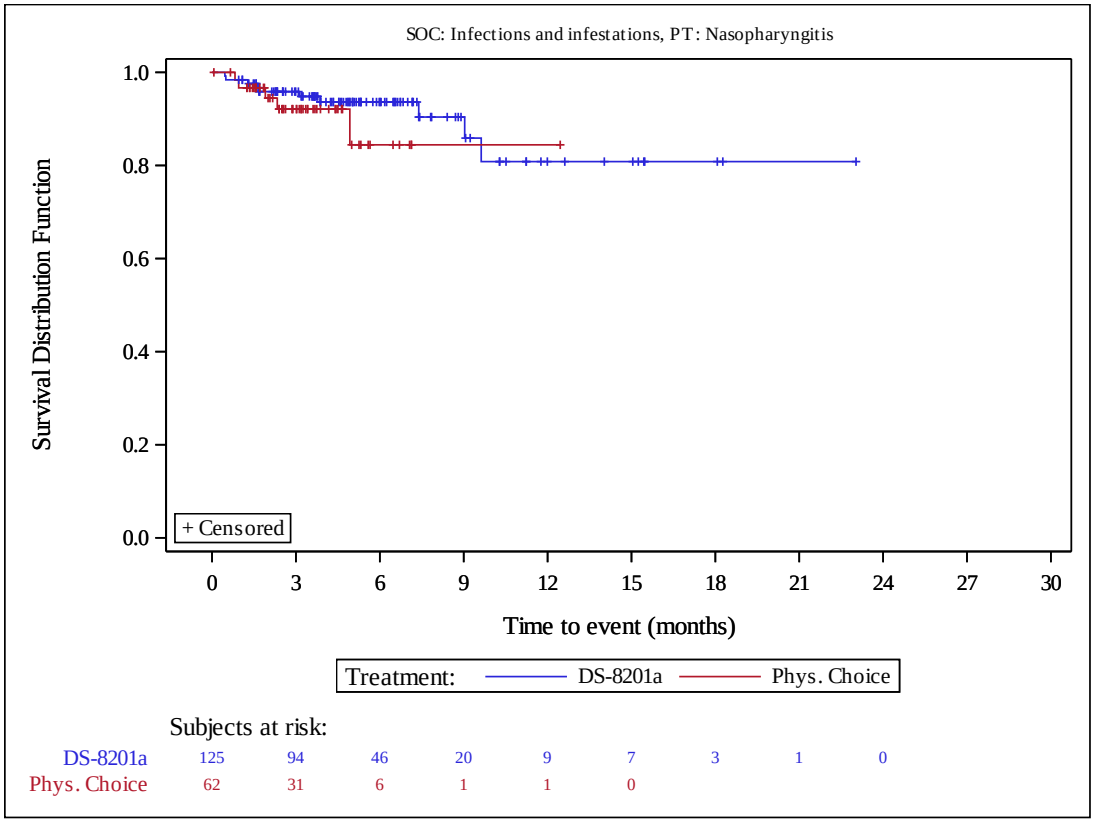

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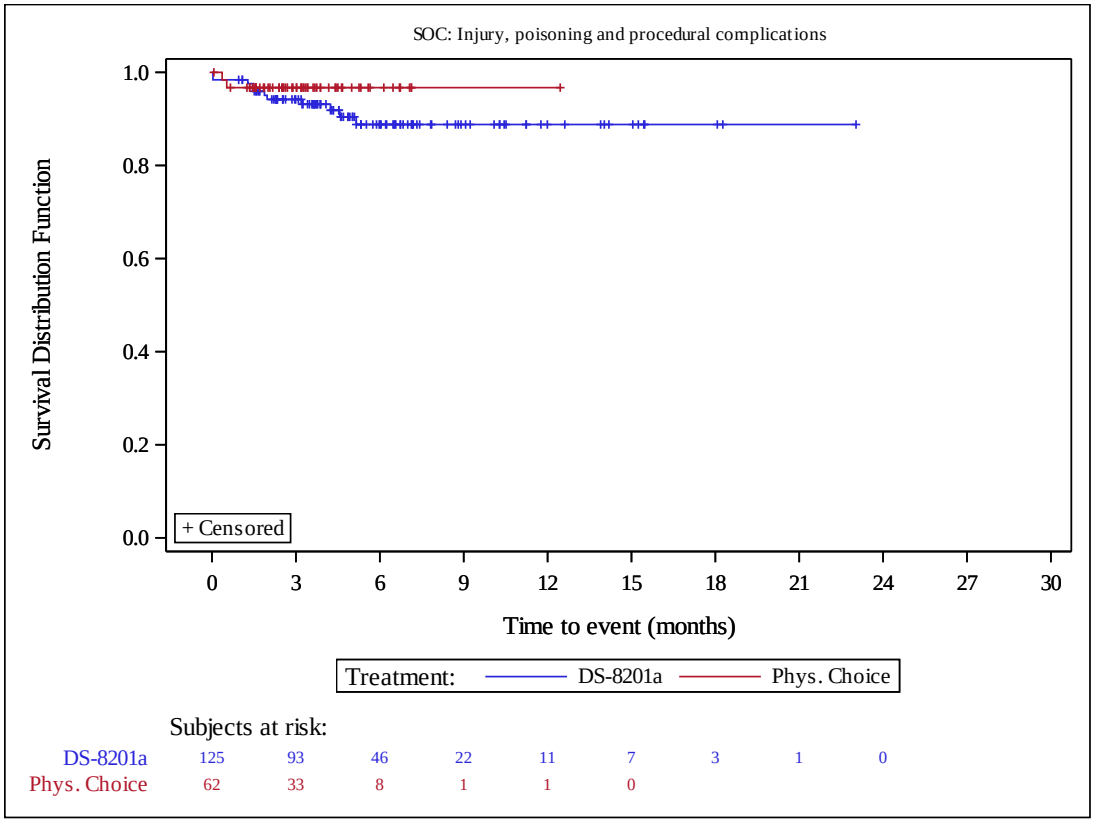

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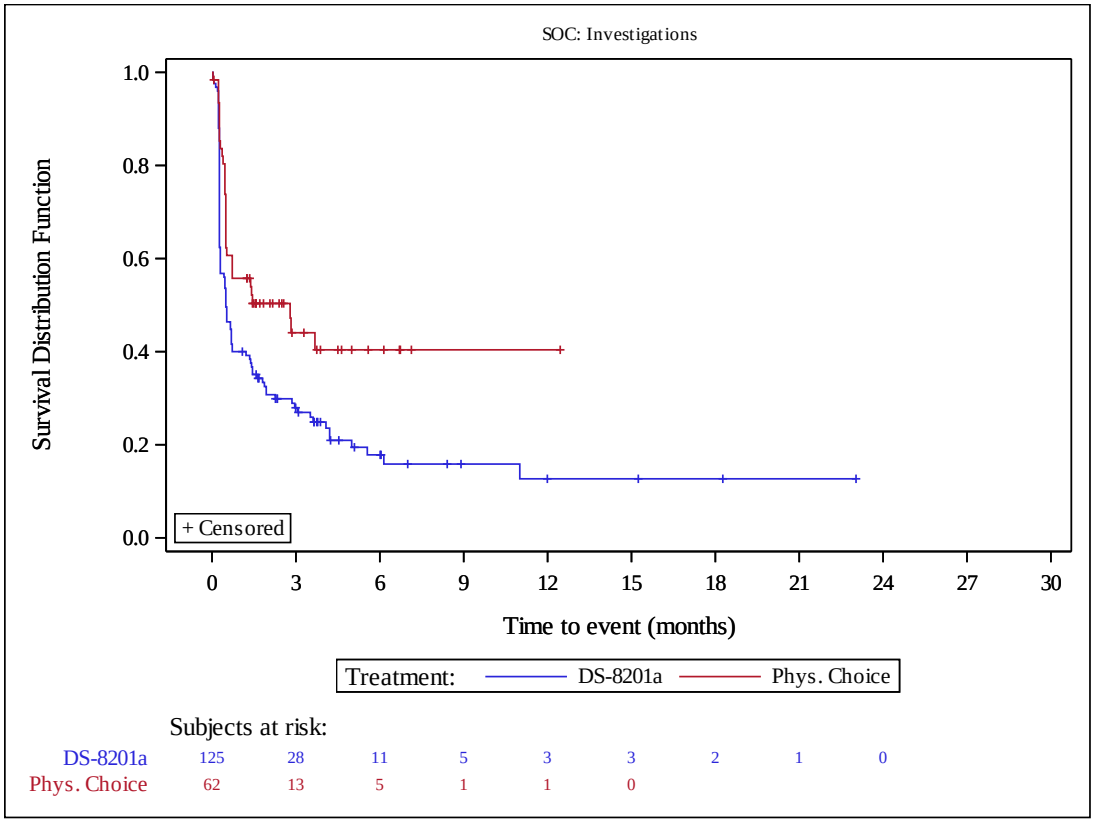

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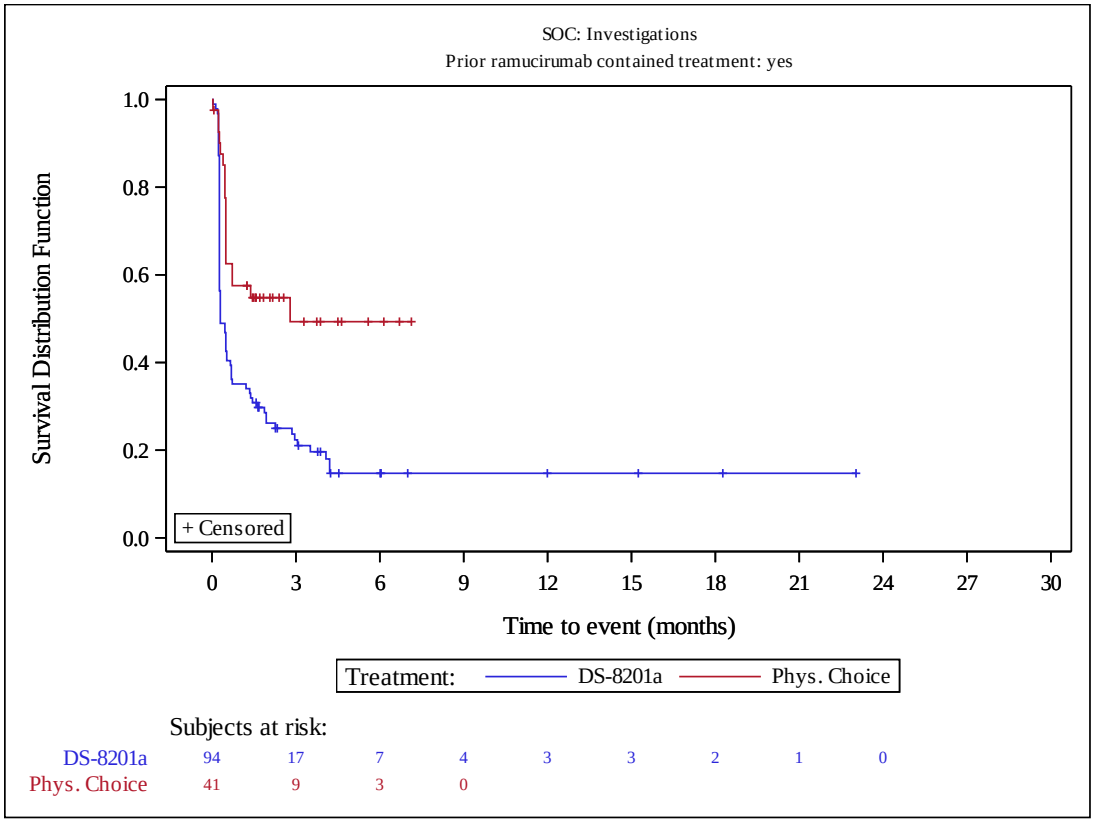
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



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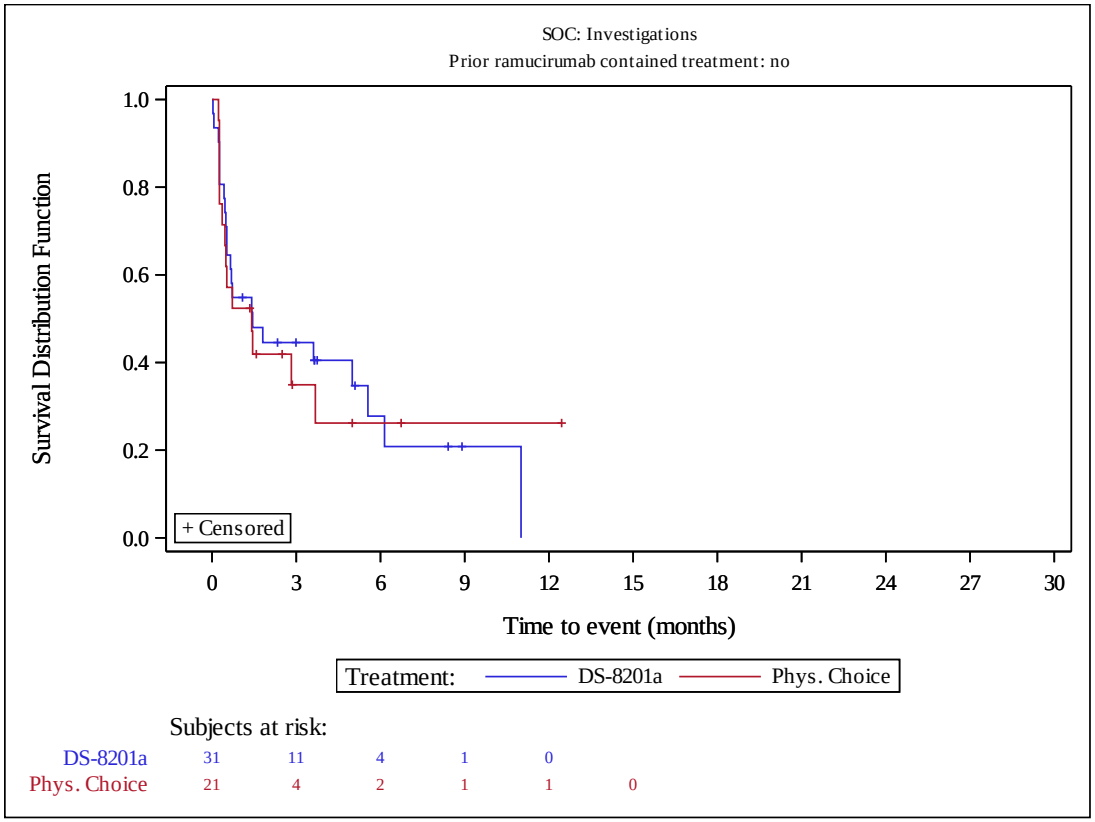

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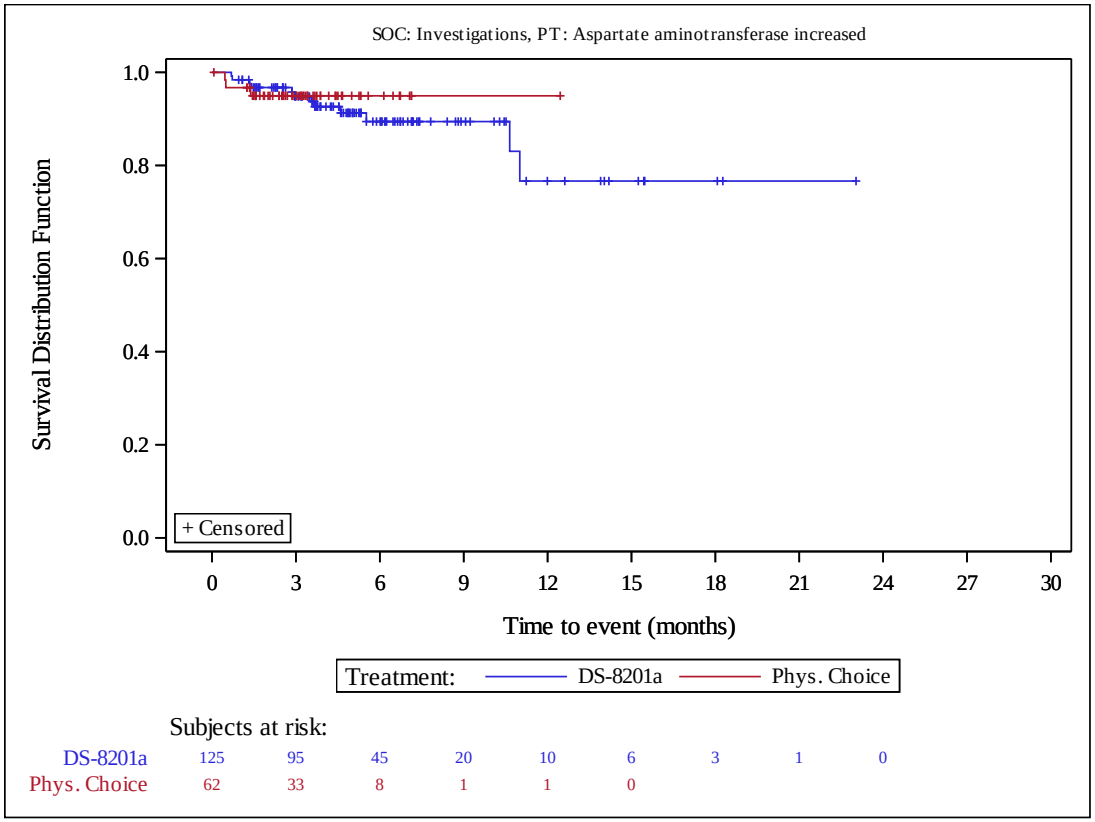

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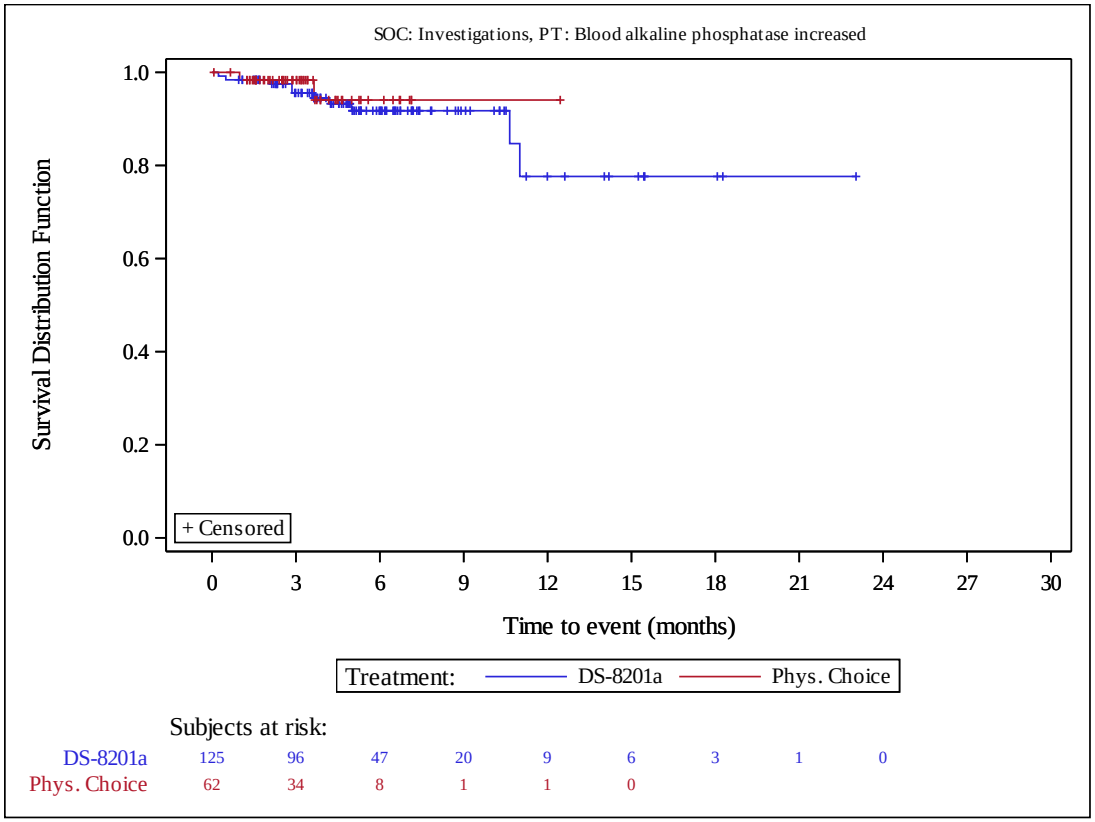

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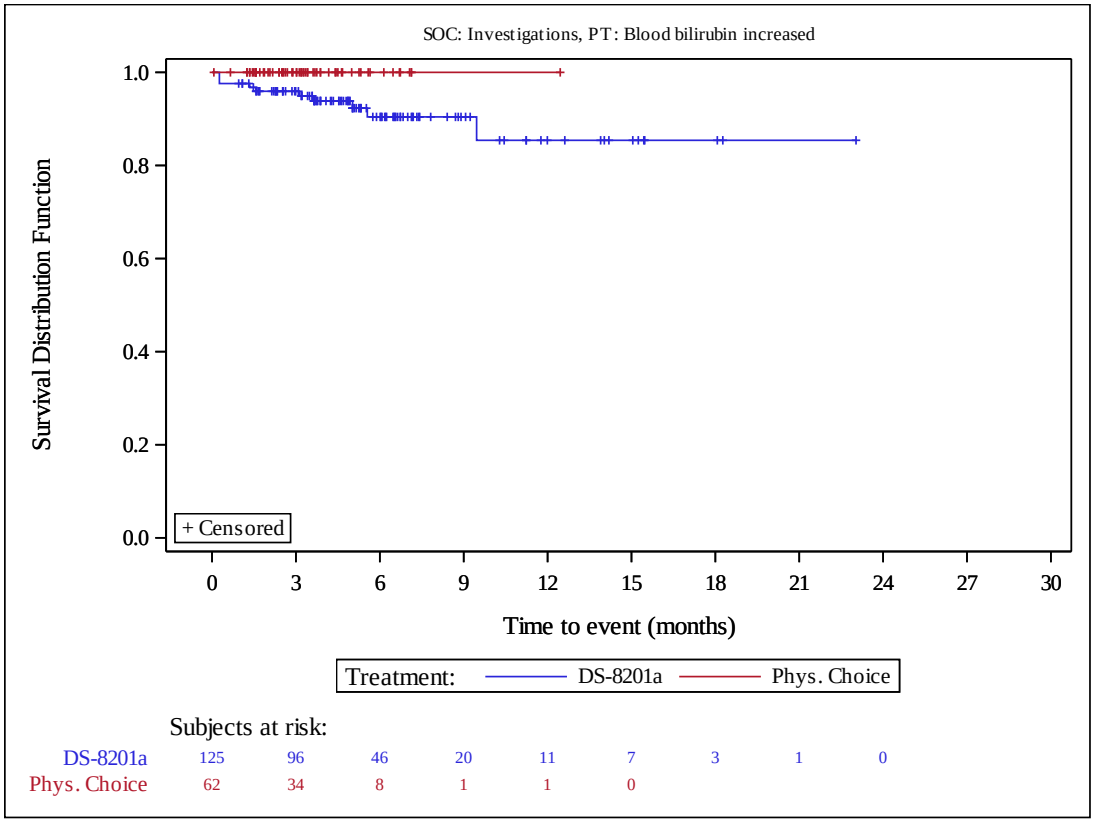

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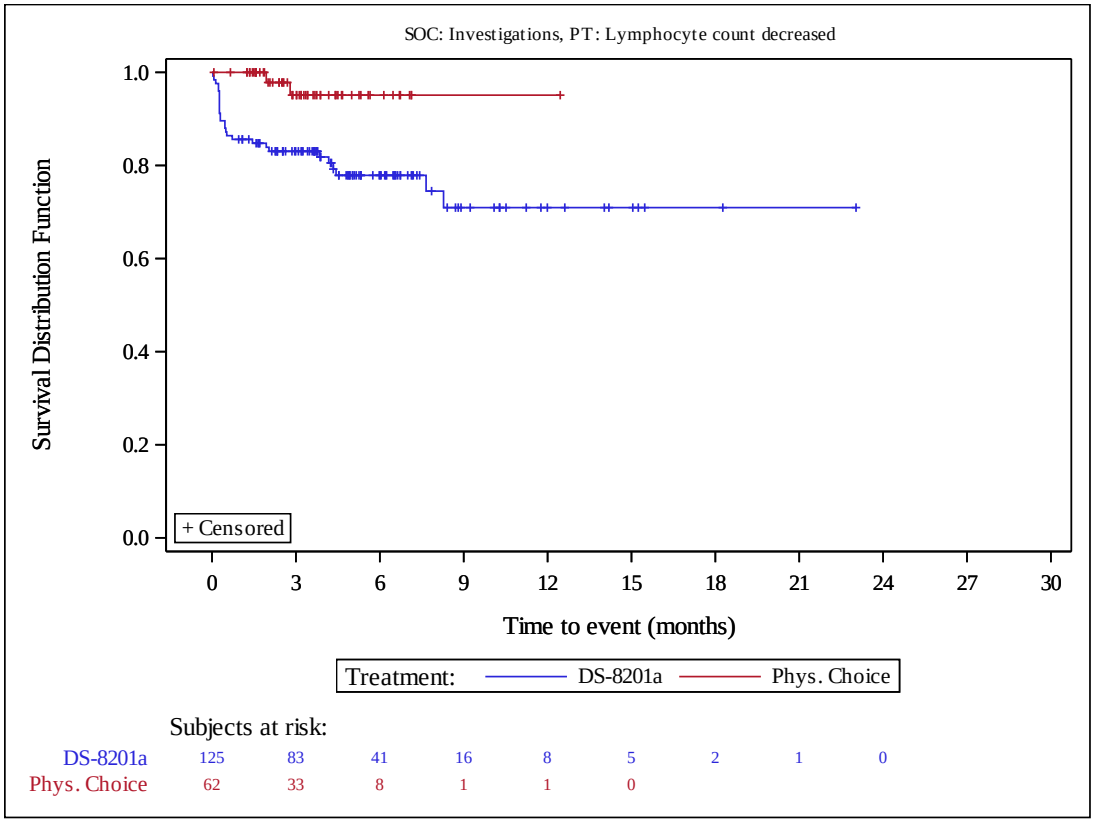

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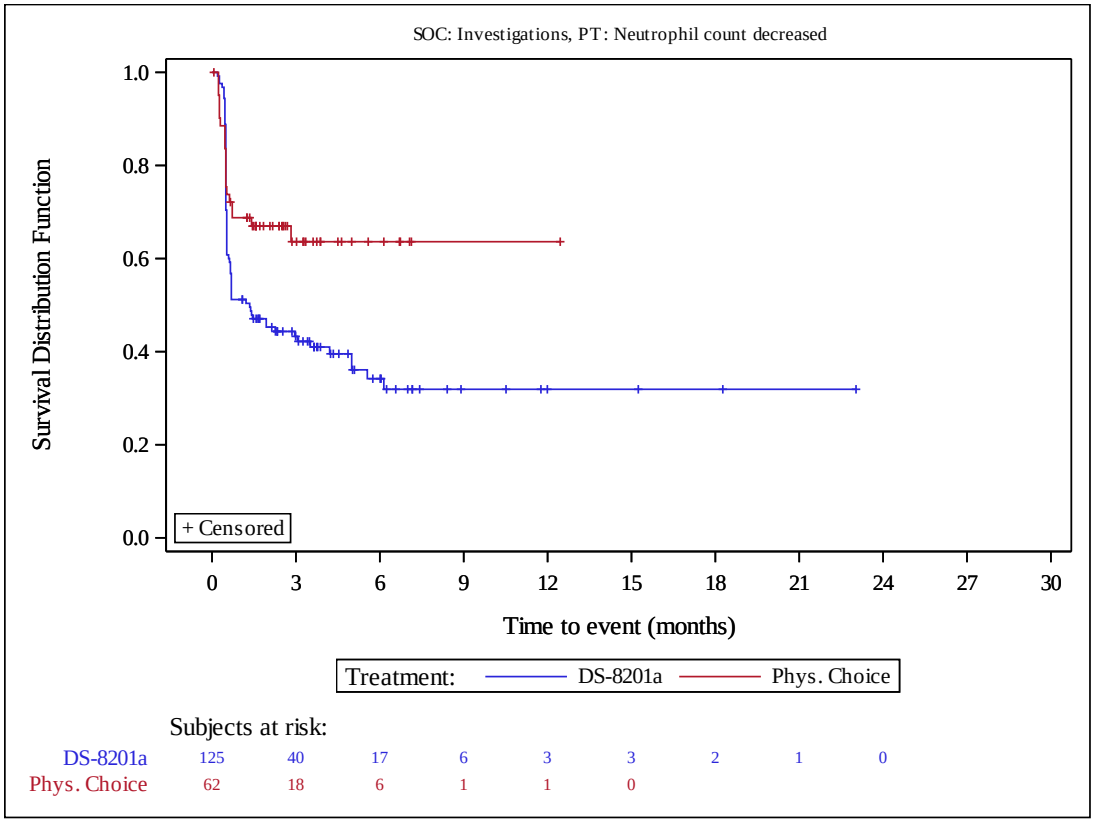

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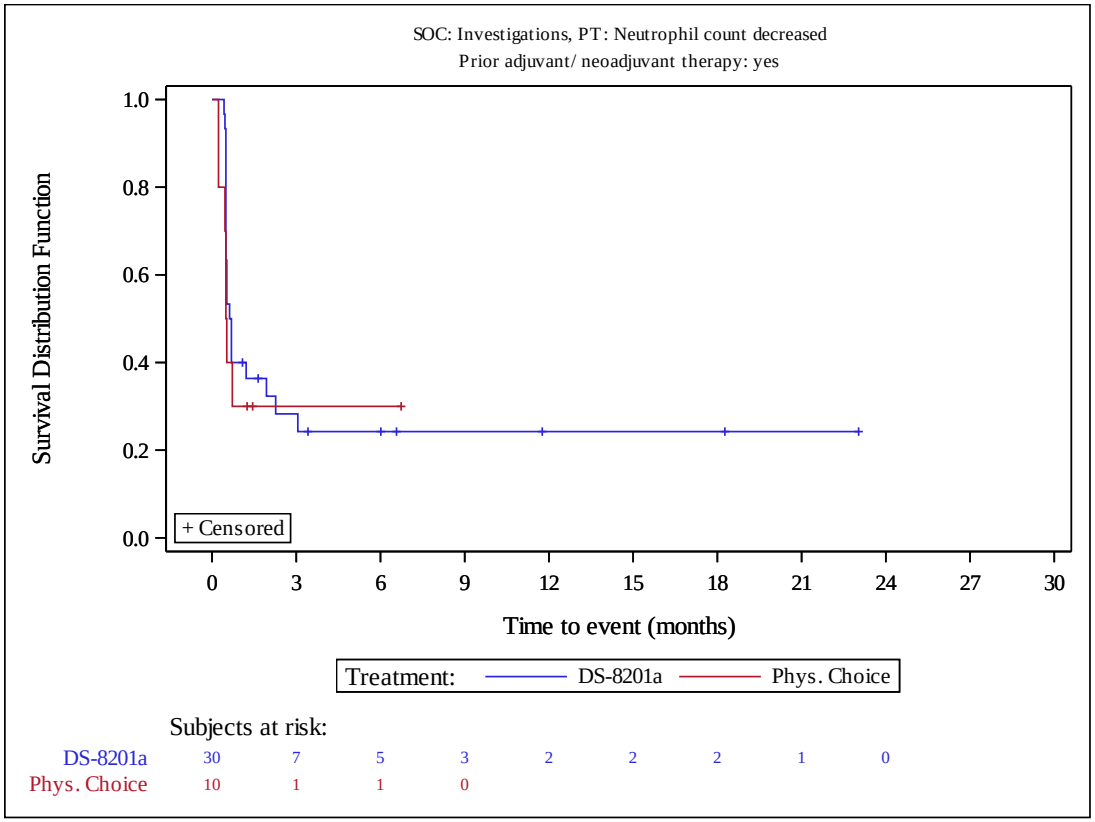

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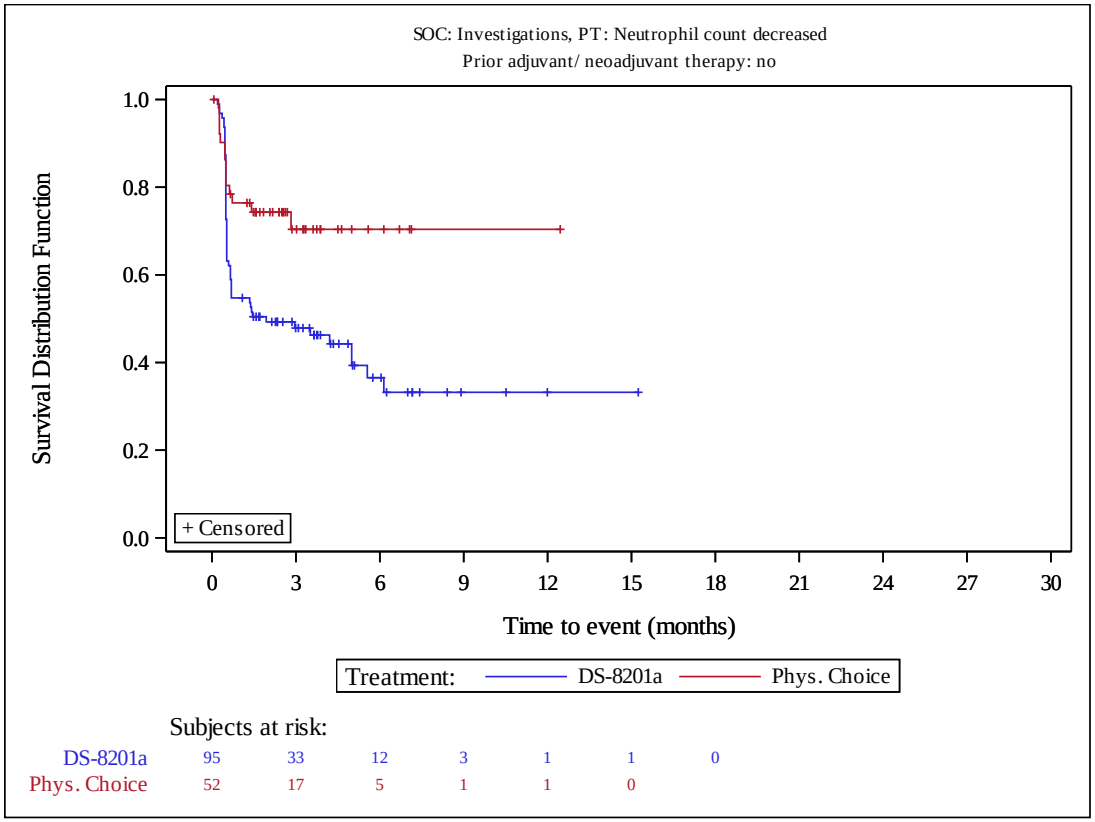

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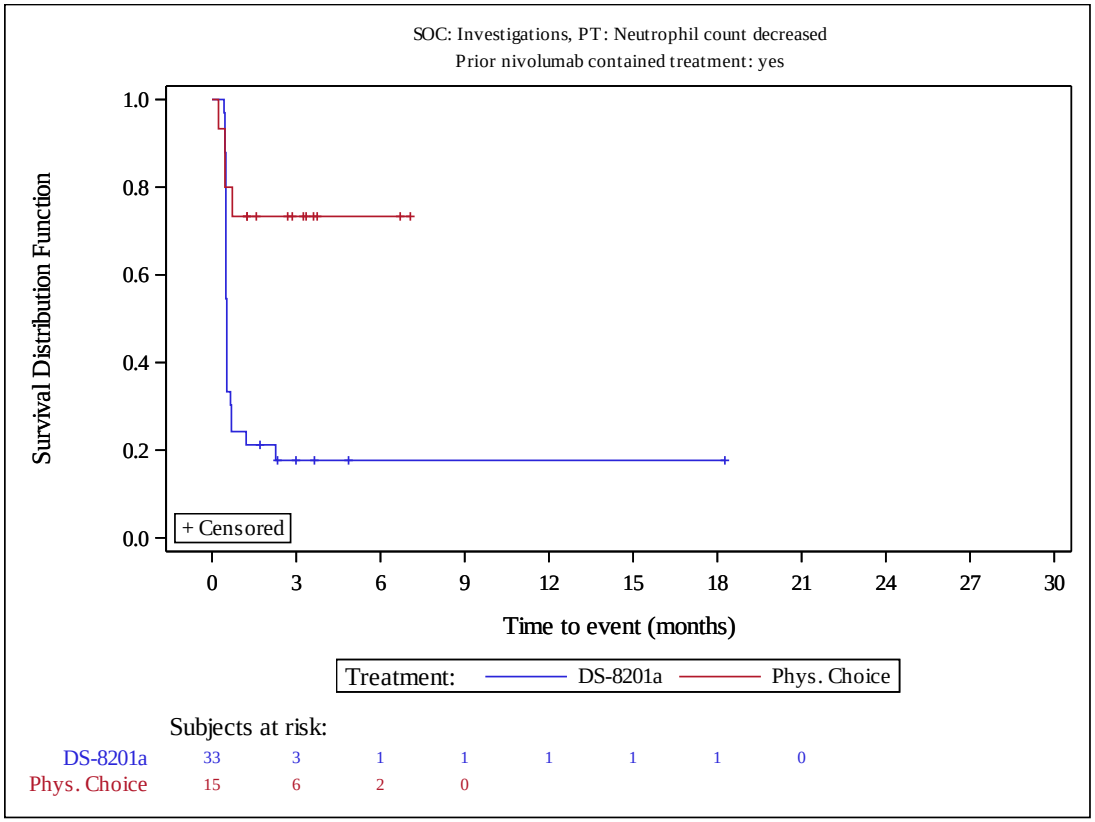

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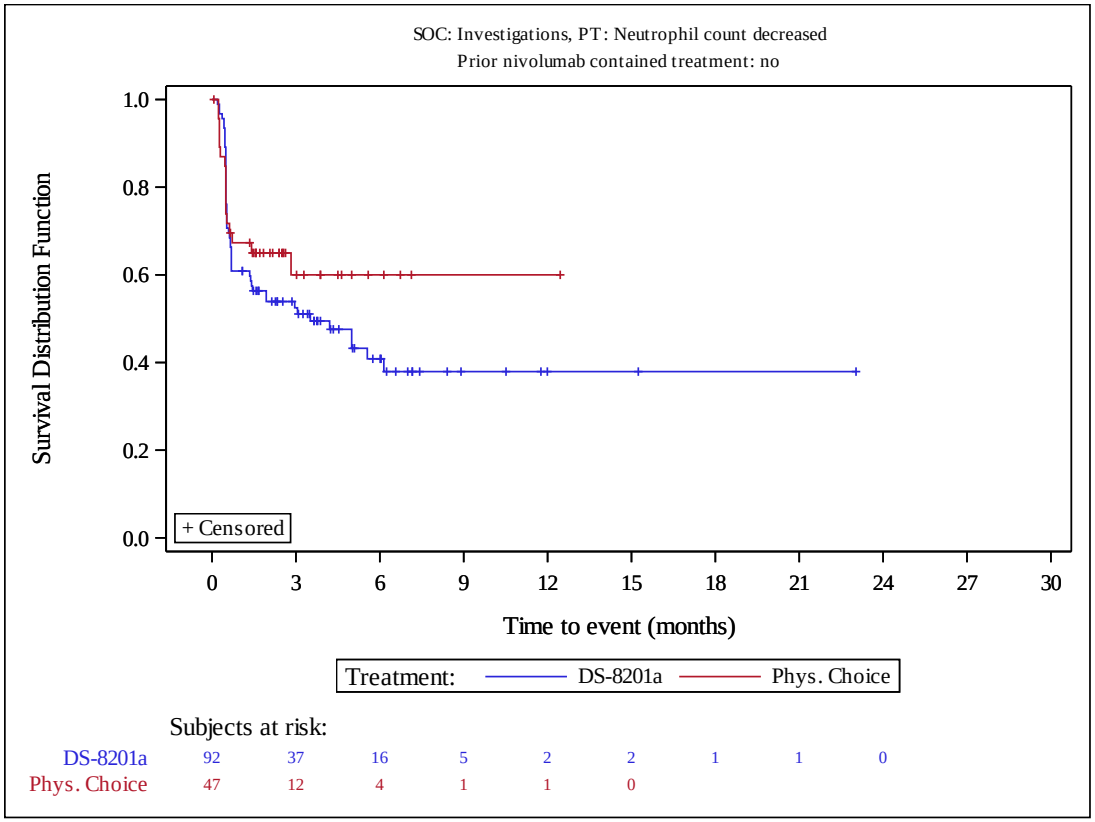

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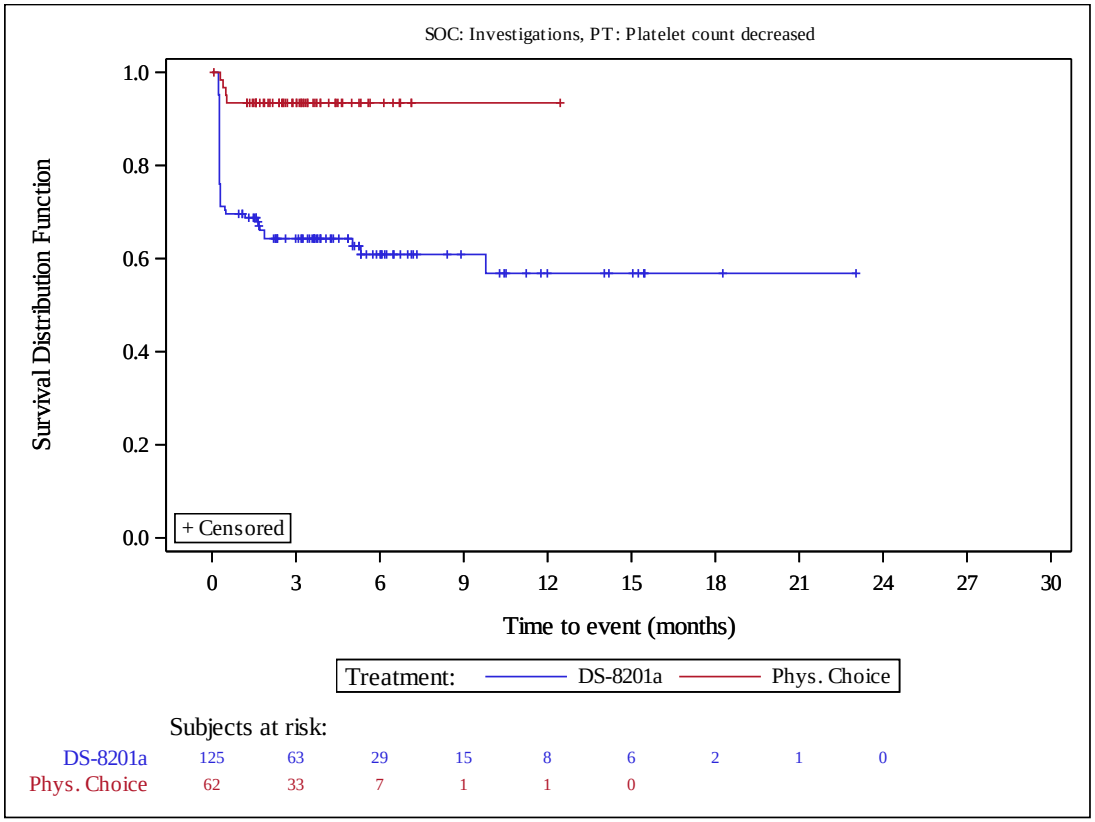

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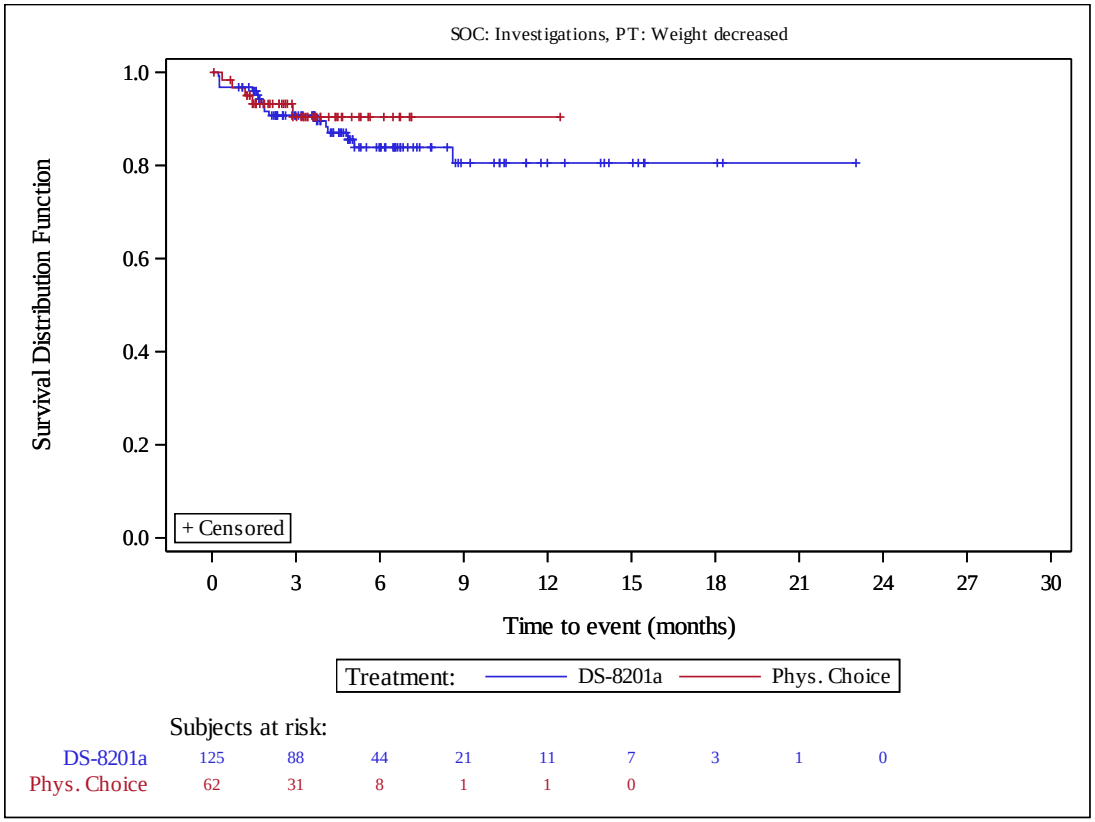

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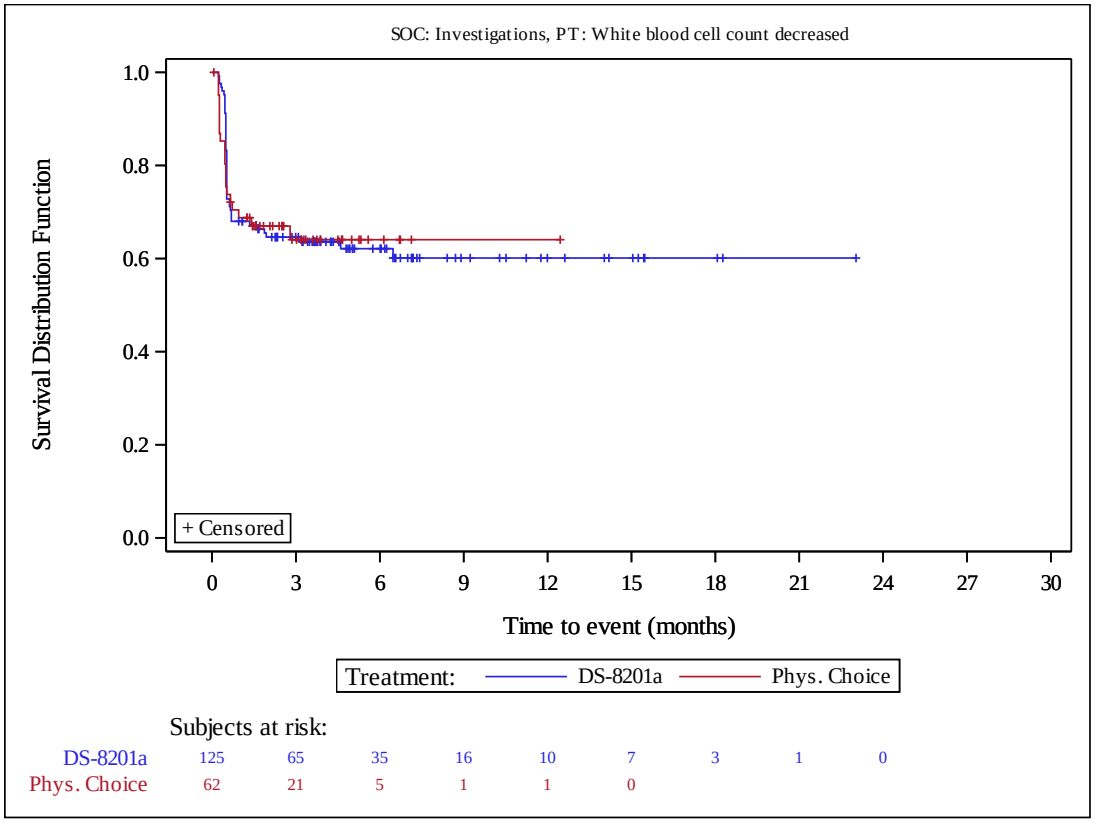

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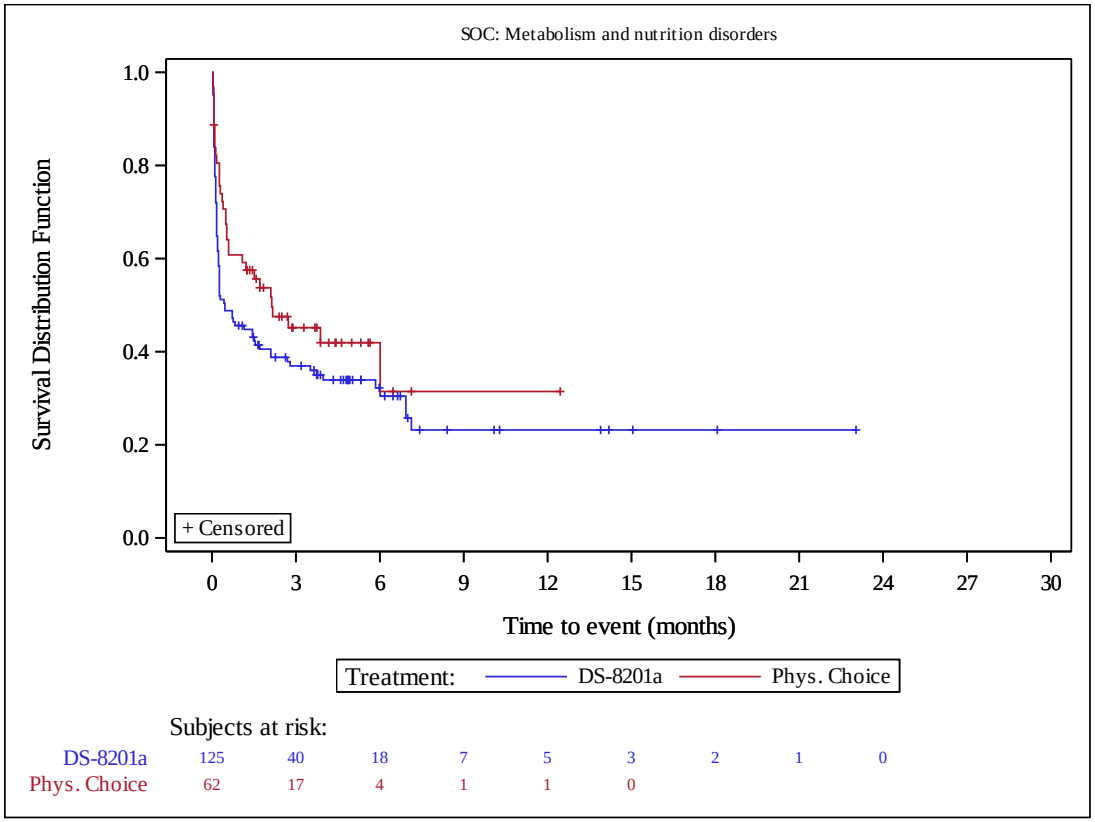

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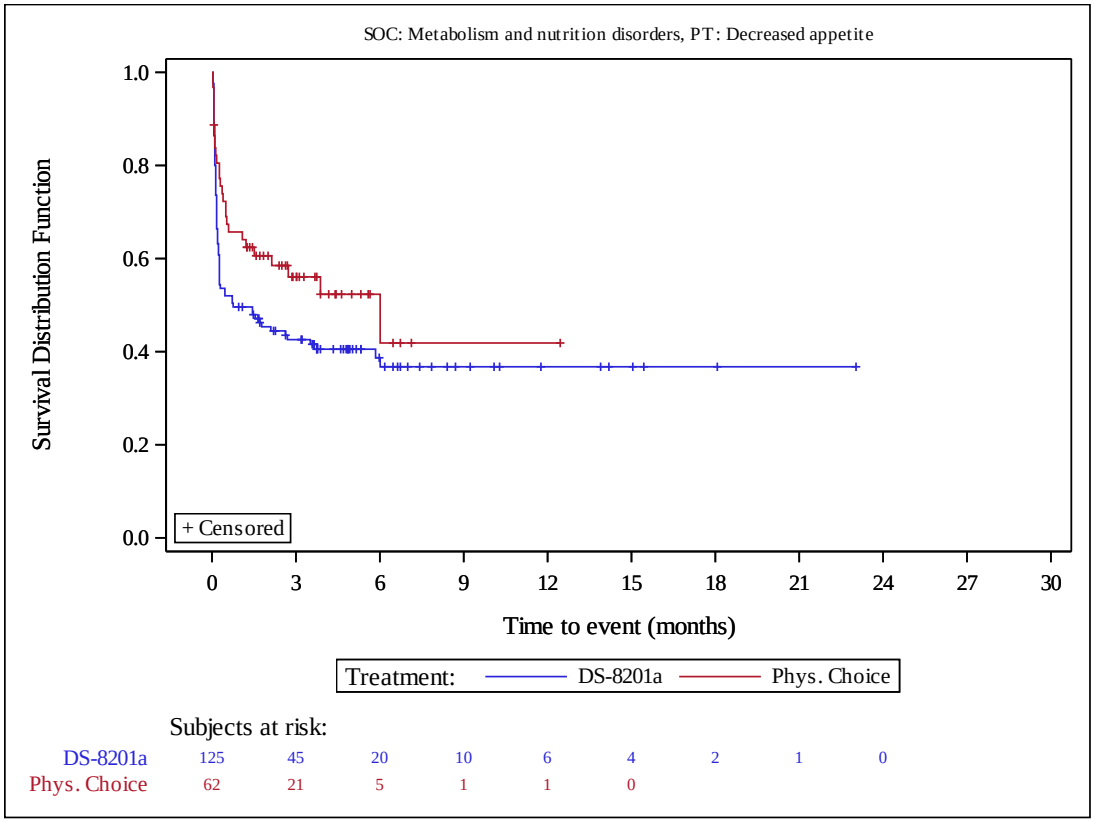

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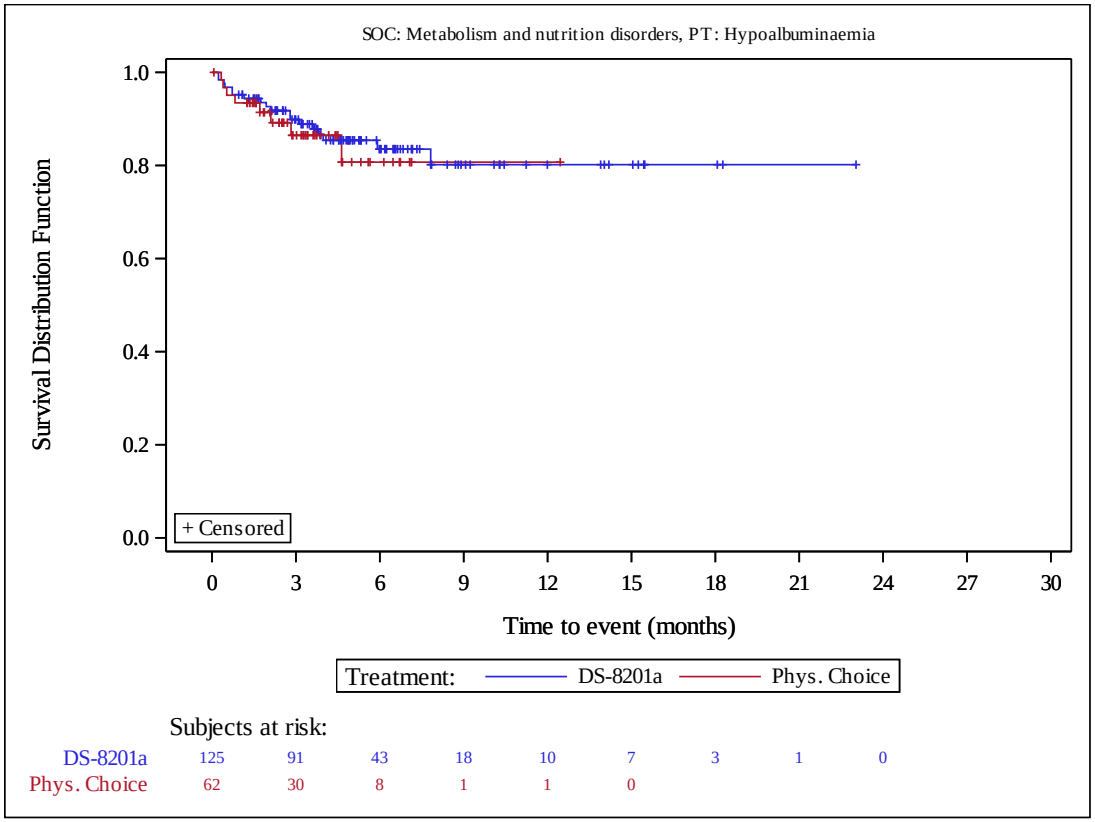

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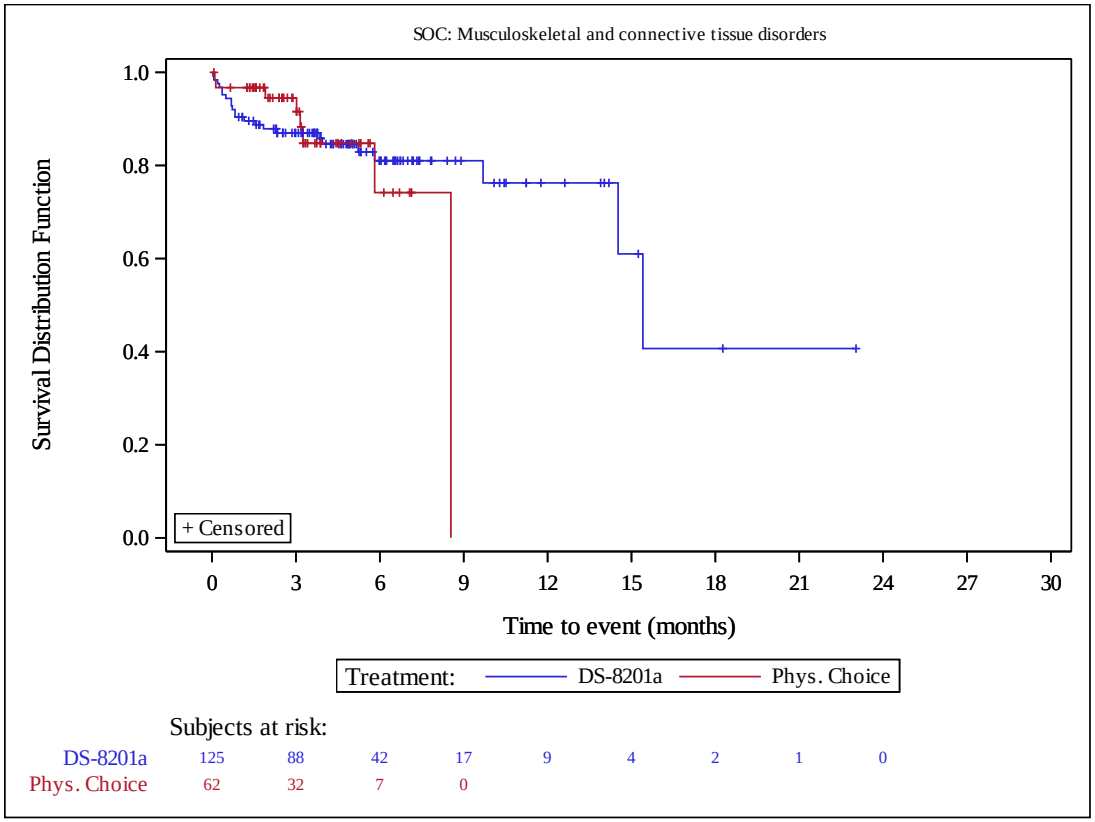

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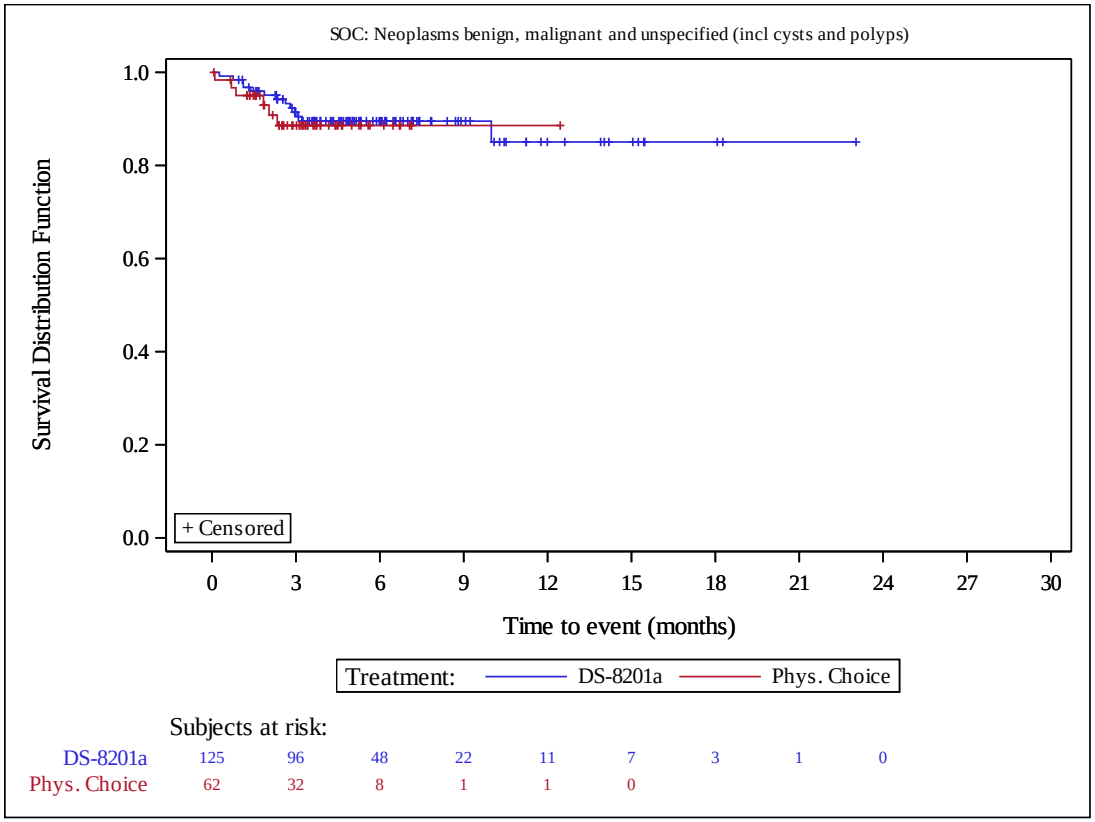

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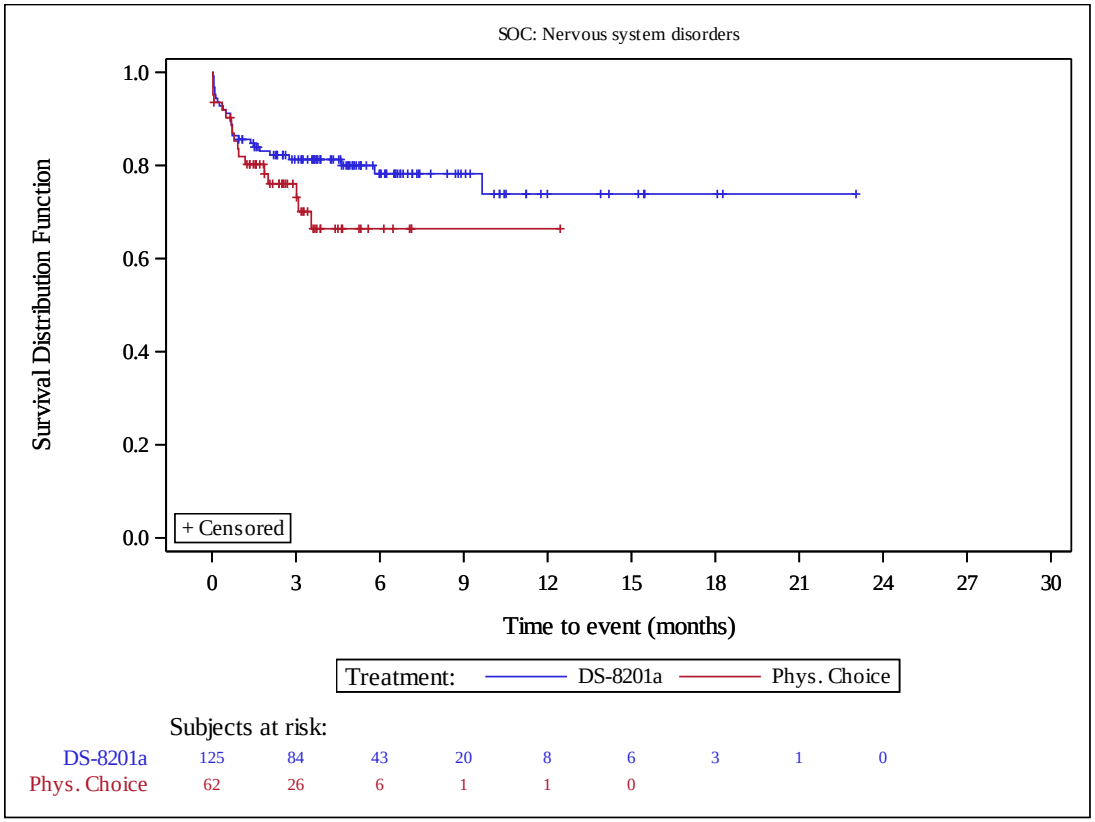

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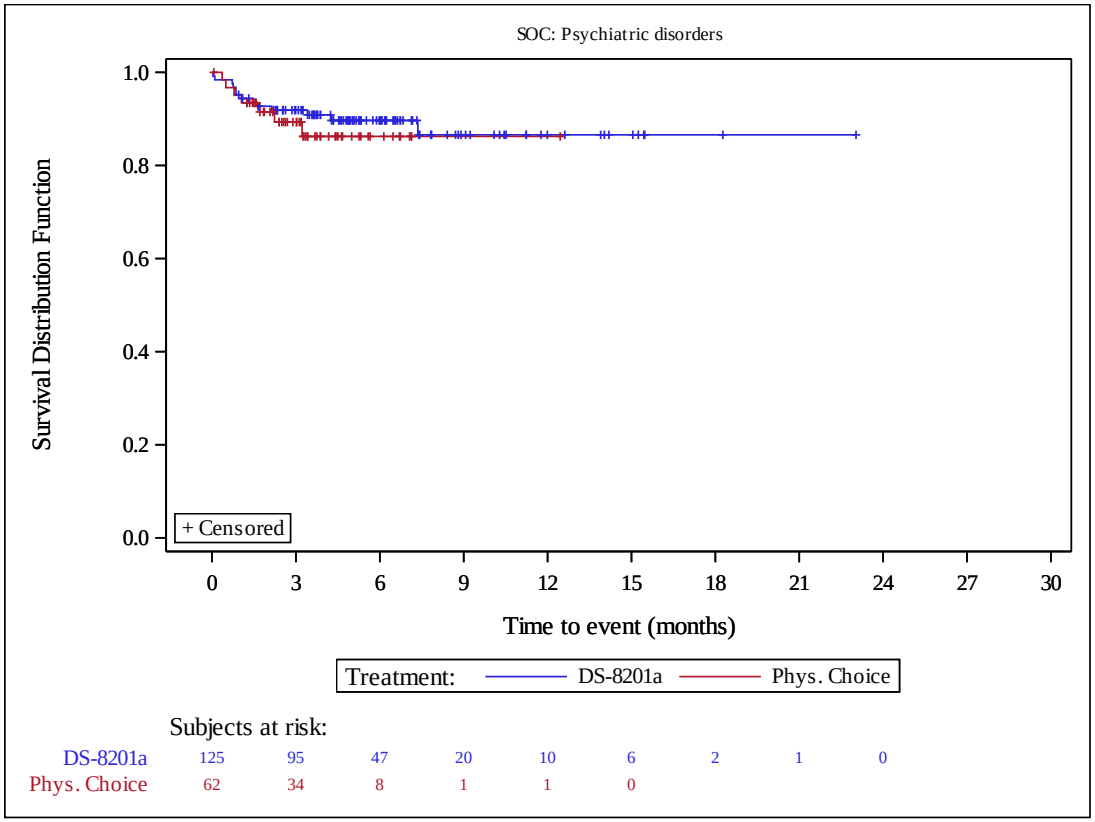

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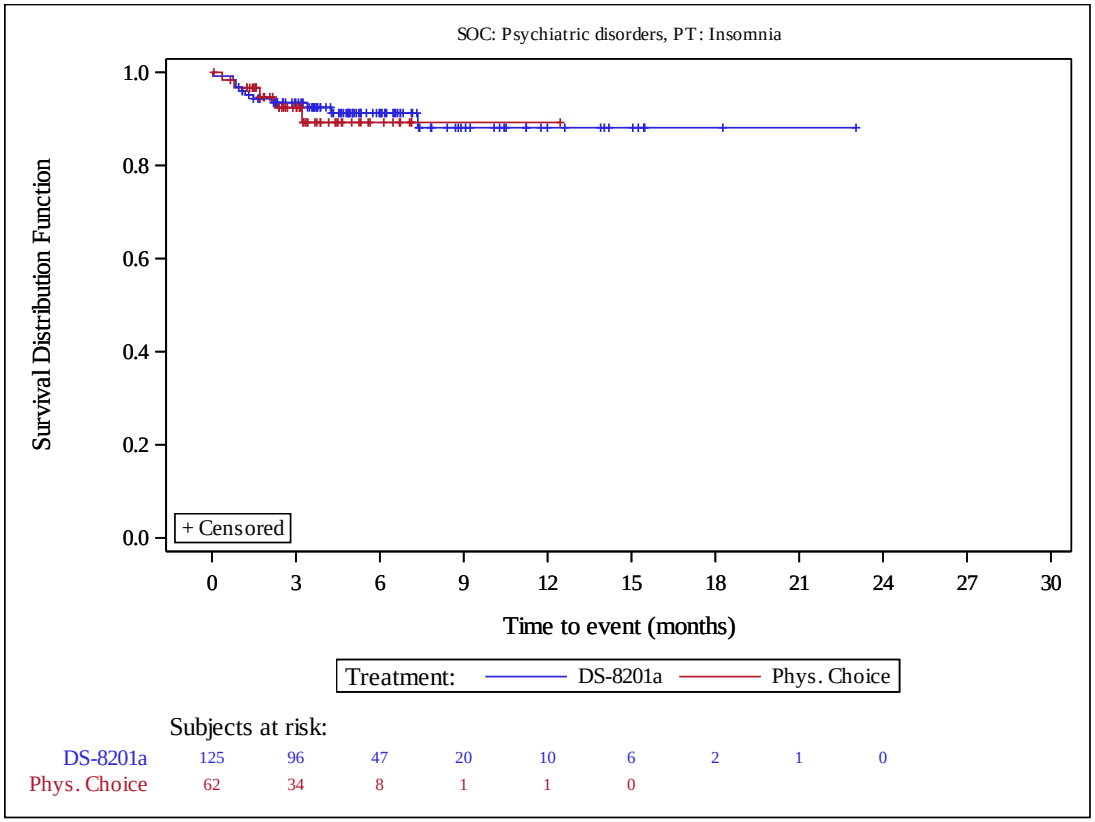

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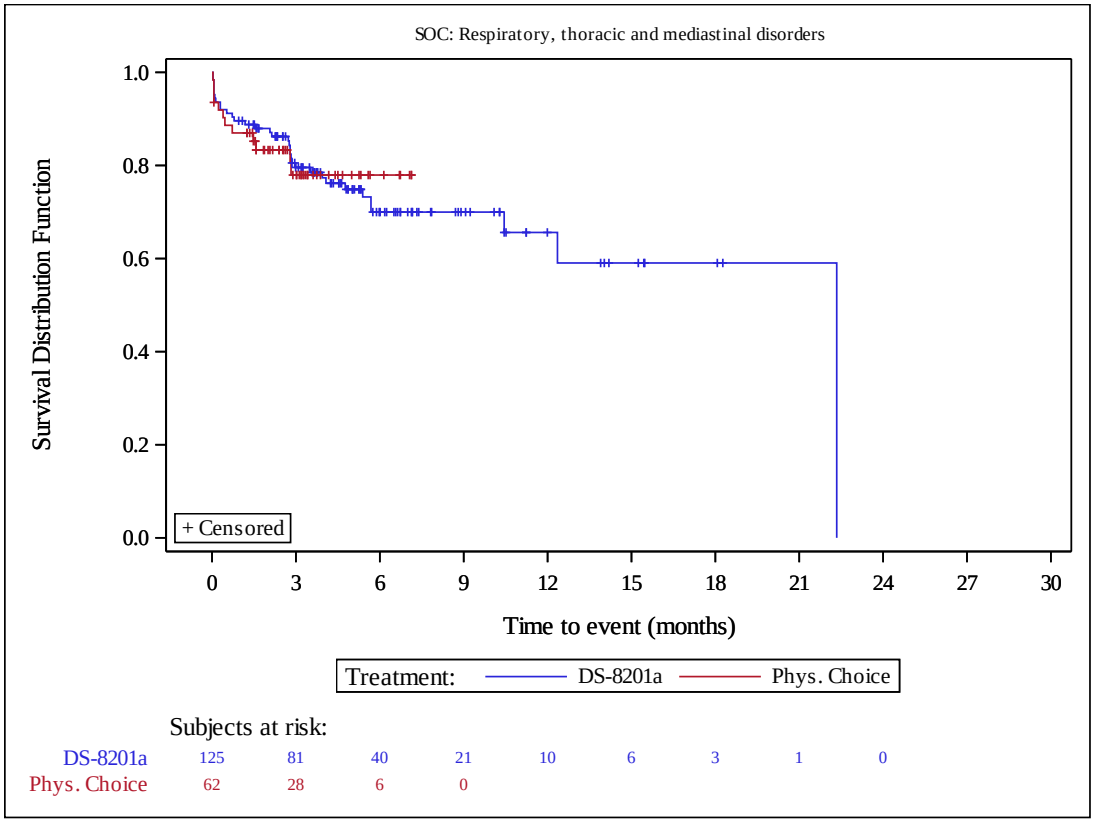

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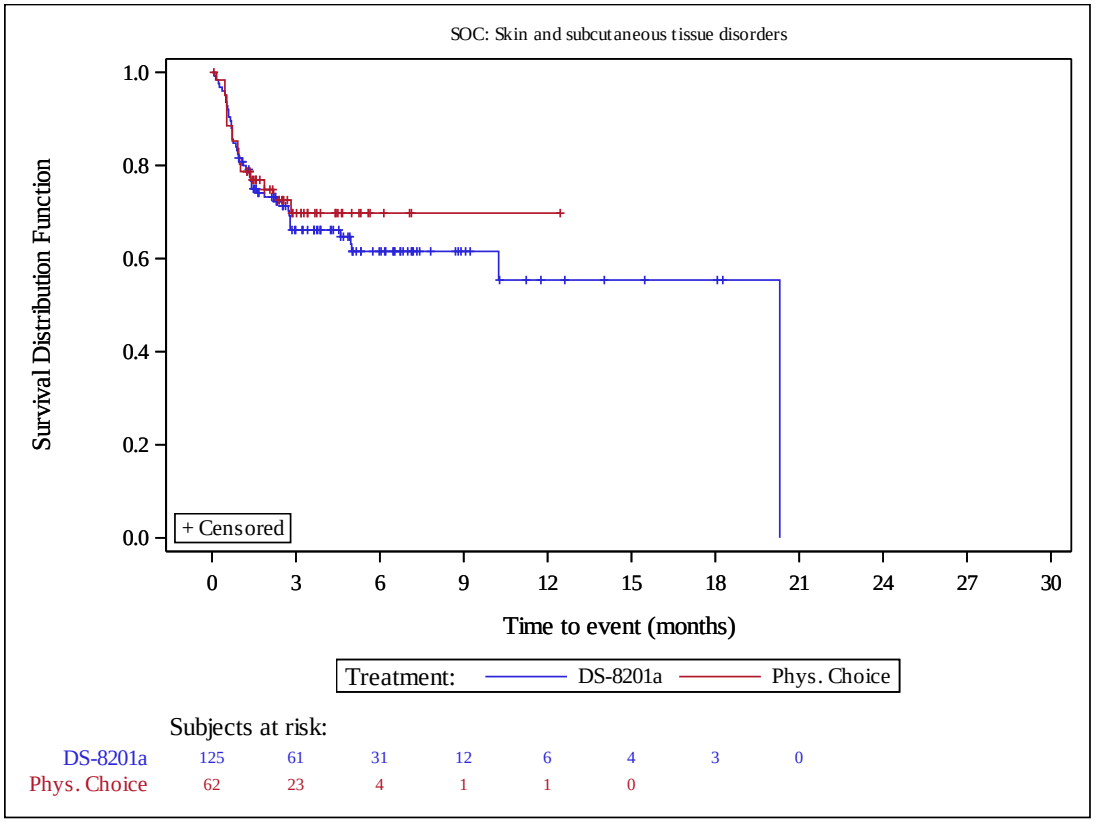

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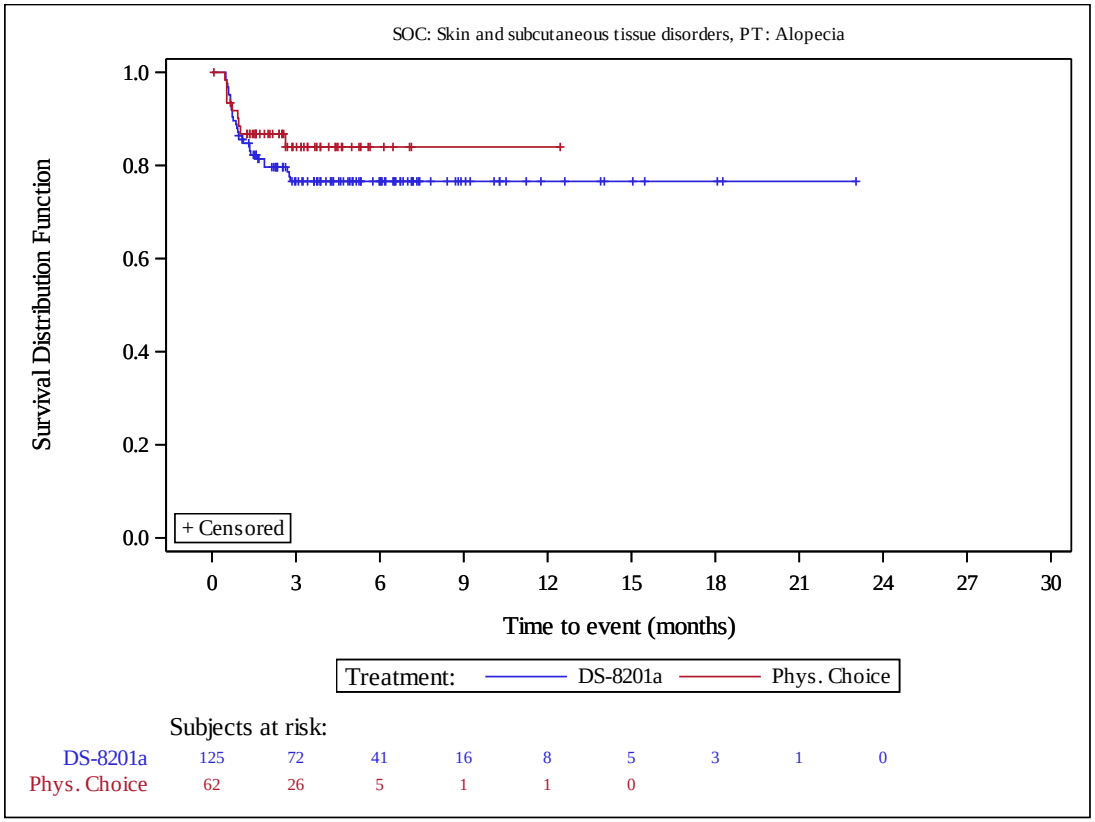

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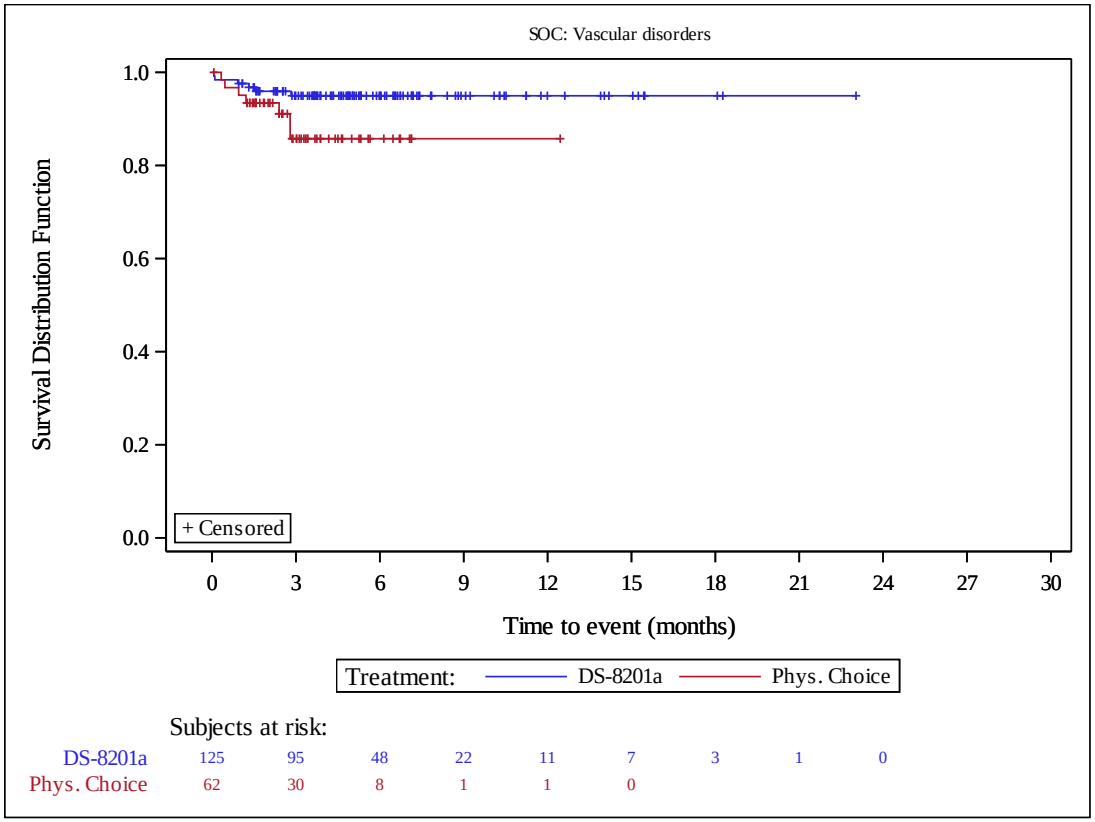

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	6 (4.8)	4 (6.5)
	Number of censored subjects, n (%)	119 (95.2)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.55 (0.15, 1.99)	
	p-value [c]	0.3578	
	Relative Risk (95% CI) [d]	0.74 (0.22, 2.54)	
	p-value	0.6369	
	Odds Ratio (95% CI) [d]	0.73 (0.20, 2.69)	
	p-value	0.6377	
	Risk Difference (95% CI) [e]	-1.65 (-10.03, 6.73)	
	p-value	0.6992	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	14 (11.2)	1 (1.6)
	Number of censored subjects, n (%)	111 (88.8)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (15.1, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	5.12 (0.66, 39.44)	
	p-value [c]	0.0810	
	Relative Risk (95% CI) [d]	6.94 (0.93, 51.61)	
	p-value	0.0583	
	Odds Ratio (95% CI) [d]	7.69 (0.99, 59.92)	
	p-value	0.0514	
	Risk Difference (95% CI) [e]	9.59 (2.02, 17.15)	
	p-value	0.0130	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
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Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	7 (5.6)	4 (6.5)
	Number of censored subjects, n (%)	118 (94.4)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.59 (0.17, 2.10)	
	p-value [c]	0.4140	
	Relative Risk (95% CI) [d]	0.87 (0.26, 2.85)	
	p-value	0.8157	
	Odds Ratio (95% CI) [d]	0.86 (0.24, 3.06)	
	p-value	0.8159	
	Risk Difference (95% CI) [e]	-0.85 (-9.38, 7.68)	
	p-value	0.8449	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders	Number of subjects with events, n (%)	8 (6.4)	3 (4.8)
	Number of censored subjects, n (%)	117 (93.6)	59 (95.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.89 (0.23, 3.44)	
	p-value [c]	0.8628	
	Relative Risk (95% CI) [d]	1.32 (0.36, 4.81)	
	p-value	0.6713	
	Odds Ratio (95% CI) [d]	1.34 (0.34, 5.26)	
	p-value	0.6702	
	Risk Difference (95% CI) [e]	1.56 (-6.50, 9.62)	
	p-value	0.7041	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations	Number of subjects with events, n (%)	12 (9.6)	1 (1.6)
	Number of censored subjects, n (%)	113 (90.4)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	3.92 (0.50, 30.51)	
	p-value [c]	0.1594	
	Relative Risk (95% CI) [d]	5.95 (0.79, 44.74)	
	p-value	0.0831	
	Odds Ratio (95% CI) [d]	6.48 (0.82, 51.01)	
	p-value	0.0760	
	Risk Difference (95% CI) [e]	7.99 (0.74, 15.24)	
	p-value	0.0308	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	18 (14.4)	1 (1.6)
	Number of censored subjects, n (%)	107 (85.6)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	7.18 (0.95, 54.16)	
	p-value [c]	0.0256	
	Relative Risk (95% CI) [d]	8.93 (1.22, 65.35)	
	p-value	0.0311	
	Odds Ratio (95% CI) [d]	10.26 (1.34, 78.77)	
	p-value	0.0251	
	Risk Difference (95% CI) [e]	12.79 (4.67, 20.90)	
	p-value	0.0020	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Number of subjects with events, n (%)	13 (10.4)	1 (1.6)
	Number of censored subjects, n (%)	112 (89.6)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	5.16 (0.67, 39.78)	
	p-value [c]	0.0793	
	Relative Risk (95% CI) [d]	6.45 (0.86, 48.17)	
	p-value	0.0693	
	Odds Ratio (95% CI) [d]	7.08 (0.90, 55.43)	
	p-value	0.0623	
	Risk Difference (95% CI) [e]	8.79 (1.38, 16.20)	
	p-value	0.0201	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Metabolism and nutrition disorders	Region							0.9932
	Japan	17/ 99 (17.2)	NE (NE , NE)	1/ 50 (2.0)	NE (NE , NE)	7.08 (0.94, 53.61)	0.0273	
	Korea	1/ 26 (3.8)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
	Lines of prior systemic therapy							0.9999
	2	7/ 66 (10.6)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	3.98 (0.49, 32.35)	0.1622	
	3	6/ 34 (17.6)	NE (7.8, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
	>=4	5/ 25 (20.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Age							0.9921
	<65 years	5/ 55 (9.1)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
	>=65 years	13/ 70 (18.6)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	5.48 (0.71, 42.22)	0.0664	
	Sex							0.9935
	female	5/ 30 (16.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	male	13/ 95 (13.7)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	4.96 (0.64, 38.47)	0.0896	
	ECOG PS							0.9911
	0	7/ 62 (11.3)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
	1	11/ 63 (17.5)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	4.79 (0.61, 37.45)	0.0992	
	HER2 Status in central laboratory							0.9903
	IHC 3+	11/ 96 (11.5)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	4.41 (0.56, 34.50)	0.1221	
	IHC 2+/ISH +	7/ 29 (24.1)	NE (6.4, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	Primary tumor location							0.9995
	Gastric	18/108 (16.7)	NE (NE , NE)	1/ 55 (1.8)	NE (NE , NE)	7.53 (1.00, 56.76)	0.0212	
	GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	Histological subtype							1.0000
	intestinal	13/ 89 (14.6)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	4.58 (0.59, 35.39)	0.1091	
	diffuse	5/ 28 (17.9)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
	others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Number of metastatic sites							0.9914
	<2	6/ 24 (25.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	>= 2	12/101 (11.9)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	4.50 (0.57, 35.18)	0.1170	
	Previous total gastrectomy							0.9931
	yes	2/ 22 (9.1)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
	no	16/103 (15.5)	NE (NE , NE)	1/ 53 (1.9)	NE (NE , NE)	6.47 (0.85, 49.20)	0.0381	
	Prior adjuvant/ neoadjuvant therapy							0.9922
	yes	3/ 30 (10.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	no	15/ 95 (15.8)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	6.19 (0.81, 47.36)	0.0453	
	Prior ramucirumab contained treatment							0.9922
	yes	14/ 94 (14.9)	NE (NE , NE)	1/ 41 (2.4)	NE (NE , NE)	4.75 (0.62, 36.57)	0.0987	
	no	4/ 31 (12.9)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	

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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Metabolism and nutrition disorders	Prior nivolumab contained treatment							0.9901
	yes	8/ 33 (24.2)	NE (7.8, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	no	10/ 92 (10.9)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	4.22 (0.54, 33.24)	0.1369	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9931
	yes	9/ 44 (20.5)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
	no	9/ 81 (11.1)	NE (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	4.37 (0.55, 34.71)	0.1273	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9933
	yes	5/ 22 (22.7)	NE (6.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	13/103 (12.6)	NE (NE , NE)	1/ 55 (1.8)	NE (NE , NE)	5.52 (0.71, 42.68)	0.0656	
	Presence of liver metastasis at baseline							0.9908
	yes	6/ 67 (9.0)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	2.49 (0.30, 20.86)	0.3857	
	no	12/ 58 (20.7)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
	Renal impairment at baseline							0.9999
	normal	1/ 33 (3.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
	mild	12/ 53 (22.6)	NE (7.8, NE)	1/ 28 (3.6)	NE (NE , NE)	5.22 (0.67, 40.55)	0.0779	
	moderate	5/ 39 (12.8)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.9932
	normal	10/ 88 (11.4)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
	mild	8/ 36 (22.2)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	3.45 (0.43, 27.59)	0.2132	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9908
	yes	3/ 8 (37.5)	NE (0.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
	no	15/117 (12.8)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	5.78 (0.76, 44.20)	0.0557	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9912
	yes	1/ 3 (33.3)	NE (6.4, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	17/122 (13.9)	NE (NE , NE)	1/ 58 (1.7)	NE (NE , NE)	6.63 (0.88, 50.24)	0.0345	

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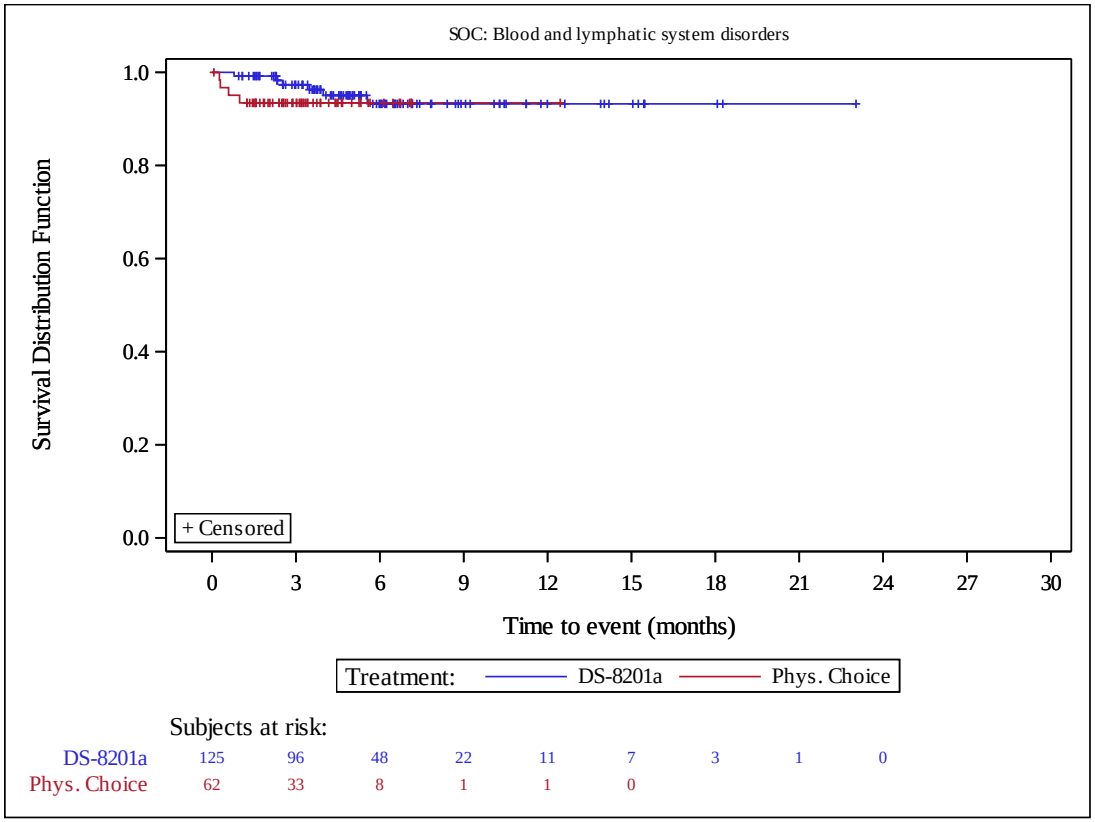
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Protocol DS8201-A-J202
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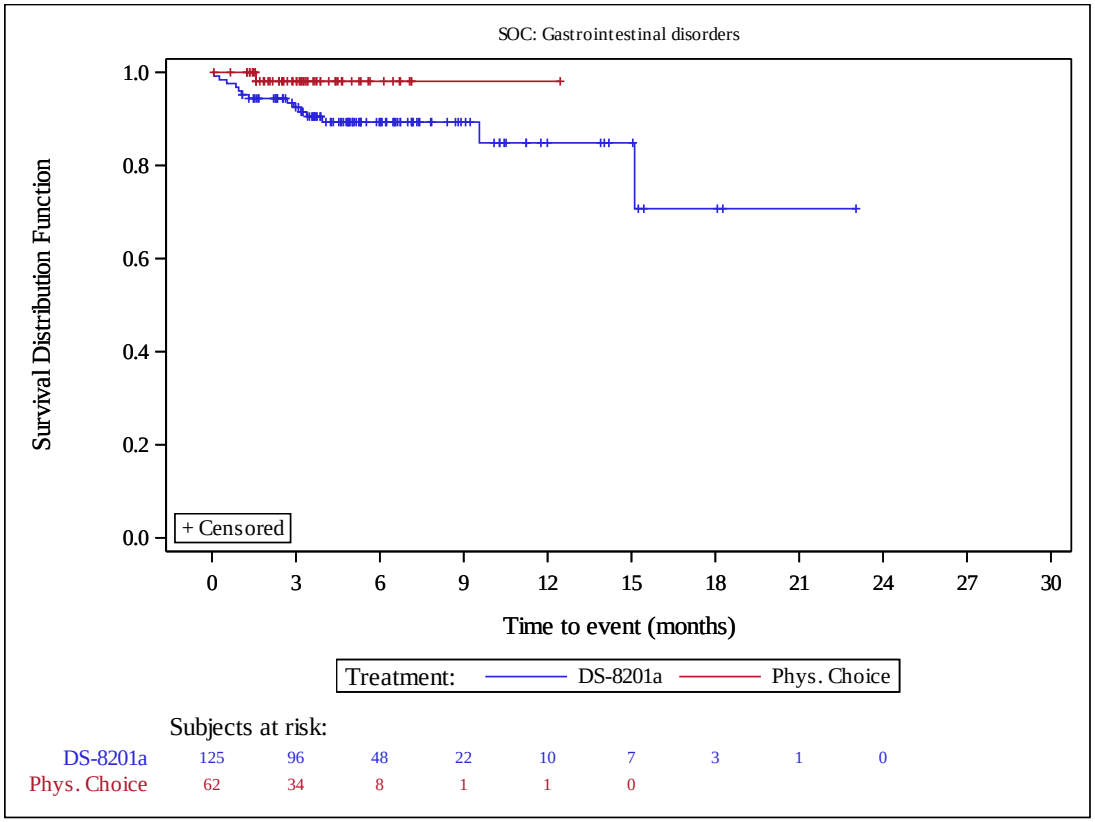
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
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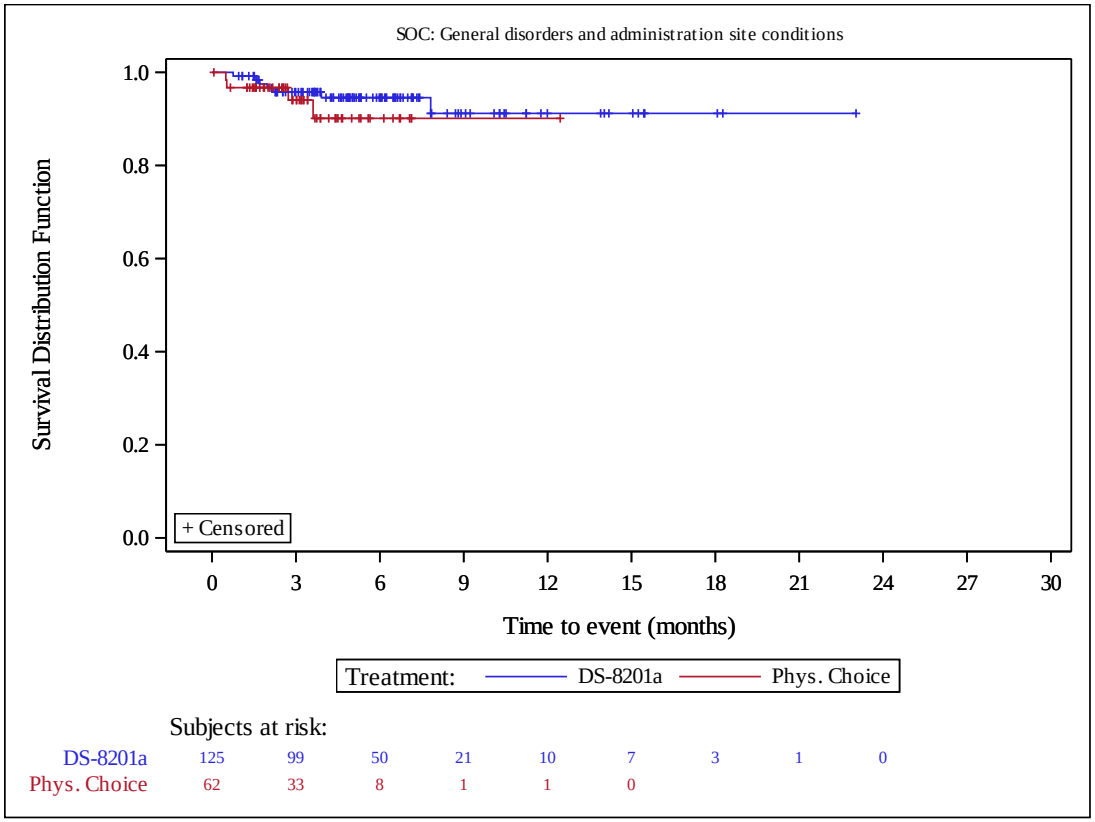
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



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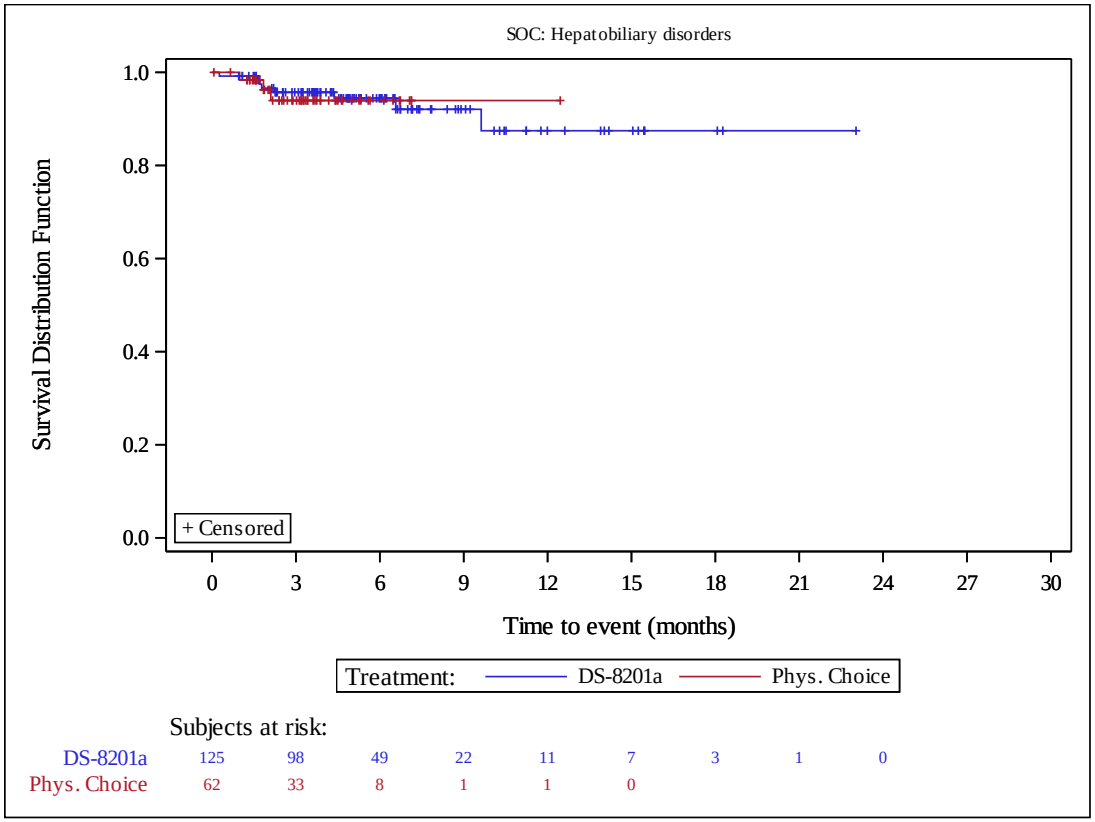
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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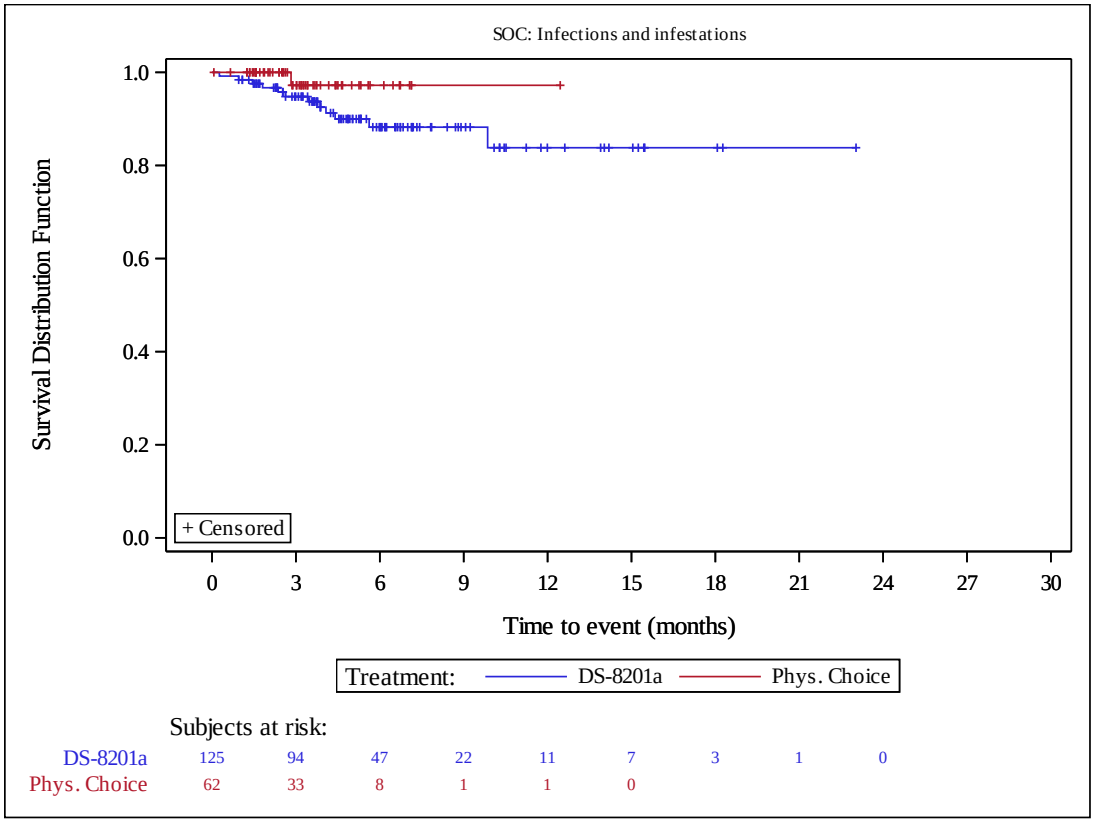
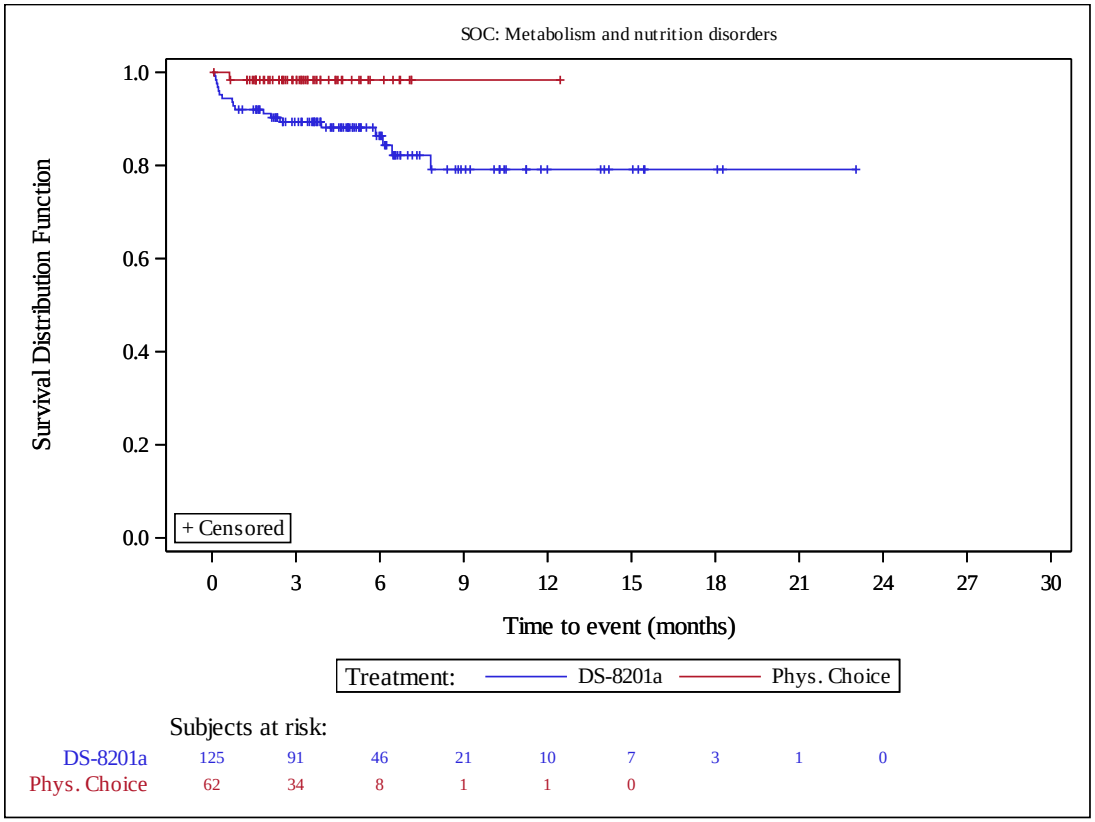
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

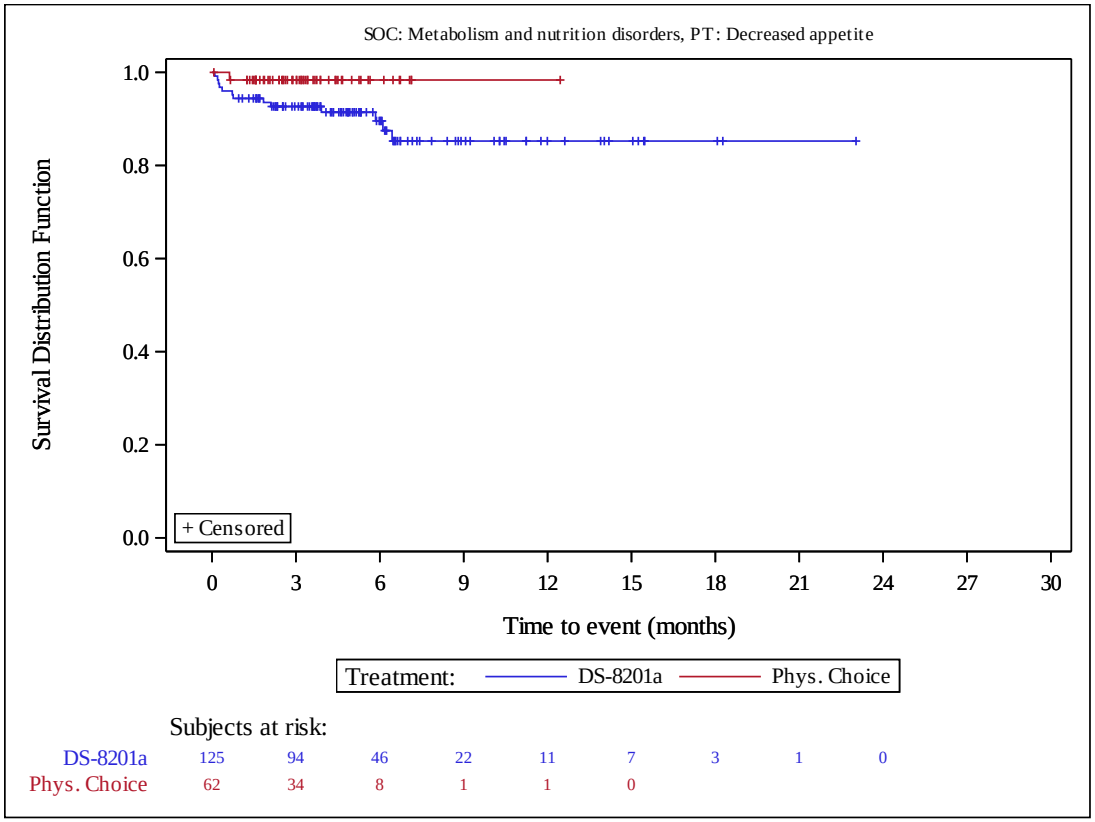
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	52 (41.6)	14 (22.6)
	Number of censored subjects, n (%)	73 (58.4)	48 (77.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	9.9 (5.6, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.60 (0.88, 2.89)	
	p-value [c]	0.1206	
	Relative Risk (95% CI) [d]	1.84 (1.11, 3.05)	
	p-value	0.0178	
	Odds Ratio (95% CI) [d]	2.44 (1.22, 4.89)	
	p-value	0.0116	
	Risk Difference (95% CI) [e]	19.02 (4.29, 33.75)	
	p-value	0.0114	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders, PT: Anaemia	Number of subjects with events, n (%)	47 (37.6)	14 (22.6)
	Number of censored subjects, n (%)	78 (62.4)	48 (77.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	10.0 (5.8, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.39 (0.76, 2.54)	
	p-value [c]	0.2861	
	Relative Risk (95% CI) [d]	1.67 (1.00, 2.78)	
	p-value	0.0515	
	Odds Ratio (95% CI) [d]	2.07 (1.03, 4.15)	
	p-value	0.0412	
	Risk Difference (95% CI) [e]	15.02 (0.38, 29.66)	
	p-value	0.0443	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	22 (17.6)	5 (8.1)
	Number of censored subjects, n (%)	103 (82.4)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (14.2, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.72 (0.64, 4.62)	
	p-value [c]	0.2732	
	Relative Risk (95% CI) [d]	2.18 (0.87, 5.49)	
	p-value	0.0971	
	Odds Ratio (95% CI) [d]	2.43 (0.87, 6.78)	
	p-value	0.0884	
	Risk Difference (95% CI) [e]	9.54 (-1.18, 20.26)	
	p-value	0.0813	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	14 (11.2)	5 (8.1)
	Number of censored subjects, n (%)	111 (88.8)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.23 (0.44, 3.44)	
	p-value [c]	0.6886	
	Relative Risk (95% CI) [d]	1.39 (0.52, 3.68)	
	p-value	0.5090	
	Odds Ratio (95% CI) [d]	1.44 (0.49, 4.19)	
	p-value	0.5059	
	Risk Difference (95% CI) [e]	3.14 (-6.82, 13.09)	
	p-value	0.5369	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	9 (7.2)	2 (3.2)
	Number of censored subjects, n (%)	116 (92.8)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.22 (0.48, 10.29)	
	p-value [c]	0.2943	
	Relative Risk (95% CI) [d]	2.23 (0.50, 10.02)	
	p-value	0.2947	
	Odds Ratio (95% CI) [d]	2.33 (0.49, 11.12)	
	p-value	0.2896	
	Risk Difference (95% CI) [e]	3.97 (-3.55, 11.50)	
	p-value	0.3004	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders	Number of subjects with events, n (%)	11 (8.8)	3 (4.8)
	Number of censored subjects, n (%)	114 (91.2)	59 (95.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.15 (0.31, 4.24)	
	p-value [c]	0.8392	
	Relative Risk (95% CI) [d]	1.82 (0.53, 6.28)	
	p-value	0.3444	
	Odds Ratio (95% CI) [d]	1.90 (0.51, 7.07)	
	p-value	0.3396	
	Risk Difference (95% CI) [e]	3.96 (-4.54, 12.46)	
	p-value	0.3610	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations	Number of subjects with events, n (%)	13 (10.4)	1 (1.6)
	Number of censored subjects, n (%)	112 (89.6)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	3.95 (0.51, 30.69)	
	p-value [c]	0.1564	
	Relative Risk (95% CI) [d]	6.45 (0.86, 48.17)	
	p-value	0.0693	
	Odds Ratio (95% CI) [d]	7.08 (0.90, 55.43)	
	p-value	0.0623	
	Risk Difference (95% CI) [e]	8.79 (1.38, 16.20)	
	p-value	0.0201	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations	Number of subjects with events, n (%)	79 (63.2)	18 (29.0)
	Number of censored subjects, n (%)	46 (36.8)	44 (71.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	2.7 (0.7, 3.7)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.26 (1.35, 3.77)	
	p-value [c]	0.0014	
	Relative Risk (95% CI) [d]	2.18 (1.44, 3.29)	
	p-value	0.0002	
	Odds Ratio (95% CI) [d]	4.20 (2.17, 8.11)	
	p-value	<.0001	
	Risk Difference (95% CI) [e]	34.17 (18.85, 49.49)	
	p-value	<.0001	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Lymphocyte count decreased	Number of subjects with events, n (%)	14 (11.2)	1 (1.6)
	Number of censored subjects, n (%)	111 (88.8)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	5.11 (0.66, 39.40)	
	p-value [c]	0.0814	
	Relative Risk (95% CI) [d]	6.94 (0.93, 51.61)	
	p-value	0.0583	
	Odds Ratio (95% CI) [d]	7.69 (0.99, 59.92)	
	p-value	0.0514	
	Risk Difference (95% CI) [e]	9.59 (2.02, 17.15)	
	p-value	0.0130	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Neutrophil count decreased	Number of subjects with events, n (%)	62 (49.6)	14 (22.6)
	Number of censored subjects, n (%)	63 (50.4)	48 (77.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	4.2 (1.9, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.18 (1.22, 3.89)	
	p-value [c]	0.0069	
	Relative Risk (95% CI) [d]	2.20 (1.34, 3.60)	
	p-value	0.0018	
	Odds Ratio (95% CI) [d]	3.37 (1.69, 6.73)	
	p-value	0.0006	
	Risk Difference (95% CI) [e]	27.02 (12.21, 41.83)	
	p-value	0.0004	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Platelet count decreased	Number of subjects with events, n (%)	14 (11.2)	2 (3.2)
	Number of censored subjects, n (%)	111 (88.8)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	3.08 (0.70, 13.62)	
	p-value [c]	0.1194	
	Relative Risk (95% CI) [d]	3.47 (0.81, 14.80)	
	p-value	0.0925	
	Odds Ratio (95% CI) [d]	3.78 (0.83, 17.21)	
	p-value	0.0850	
	Risk Difference (95% CI) [e]	7.97 (-0.30, 16.25)	
	p-value	0.0588	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: White blood cell count decreased	Number of subjects with events, n (%)	26 (20.8)	7 (11.3)
	Number of censored subjects, n (%)	99 (79.2)	55 (88.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.60 (0.69, 3.69)	
	p-value [c]	0.2725	
	Relative Risk (95% CI) [d]	1.84 (0.85, 4.01)	
	p-value	0.1233	
	Odds Ratio (95% CI) [d]	2.06 (0.84, 5.06)	
	p-value	0.1136	
	Risk Difference (95% CI) [e]	9.51 (-2.31, 21.33)	
	p-value	0.1149	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	28 (22.4)	12 (19.4)
	Number of censored subjects, n (%)	97 (77.6)	50 (80.6)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.97 (0.49, 1.92)	
	p-value [c]	0.9283	
	Relative Risk (95% CI) [d]	1.16 (0.63, 2.12)	
	p-value	0.6353	
	Odds Ratio (95% CI) [d]	1.20 (0.56, 2.57)	
	p-value	0.6329	
	Risk Difference (95% CI) [e]	3.05 (-10.41, 16.50)	
	p-value	0.6574	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Number of subjects with events, n (%)	21 (16.8)	8 (12.9)
	Number of censored subjects, n (%)	104 (83.2)	54 (87.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.14 (0.50, 2.60)	
	p-value [c]	0.7471	
	Relative Risk (95% CI) [d]	1.30 (0.61, 2.77)	
	p-value	0.4934	
	Odds Ratio (95% CI) [d]	1.36 (0.57, 3.28)	
	p-value	0.4895	
	Risk Difference (95% CI) [e]	3.90 (-7.92, 15.71)	
	p-value	0.5181	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Number of subjects with events, n (%)	5 (4.0)	4 (6.5)
	Number of censored subjects, n (%)	120 (96.0)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.47 (0.12, 1.77)	
	p-value [c]	0.2524	
	Relative Risk (95% CI) [d]	0.62 (0.17, 2.23)	
	p-value	0.4638	
	Odds Ratio (95% CI) [d]	0.60 (0.16, 2.33)	
	p-value	0.4650	
	Risk Difference (95% CI) [e]	-2.45 (-10.67, 5.77)	
	p-value	0.5589	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	7 (5.6)	2 (3.2)
	Number of censored subjects, n (%)	118 (94.4)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.28 (0.26, 6.29)	
	p-value [c]	0.7637	
	Relative Risk (95% CI) [d]	1.74 (0.37, 8.11)	
	p-value	0.4832	
	Odds Ratio (95% CI) [d]	1.78 (0.36, 8.83)	
	p-value	0.4806	
	Risk Difference (95% CI) [e]	2.37 (-4.80, 9.55)	
	p-value	0.5165	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations	Region							0.1753
	Japan	66/ 99 (66.7)	1.0 (0.7, 3.4)	14/ 50 (28.0)	NE (NE , NE)	2.69 (1.51, 4.80)	0.0005	
	Korea	13/ 26 (50.0)	3.9 (2.9, NE)	4/ 12 (33.3)	NE (0.5, NE)	0.96 (0.31, 3.00)	0.9468	
	Lines of prior systemic therapy							0.2678
	2	38/ 66 (57.6)	3.5 (1.9, 5.6)	12/ 38 (31.6)	NE (2.4, NE)	1.69 (0.88, 3.24)	0.1075	
	3	26/ 34 (76.5)	0.5 (0.5, 0.7)	4/ 18 (22.2)	NE (NE , NE)	4.43 (1.54, 12.76)	0.0028	
	>=4	15/ 25 (60.0)	3.2 (0.5, NE)	2/ 6 (33.3)	NE (0.5, NE)	1.62 (0.37, 7.14)	0.5180	
	Age							0.2117
	<65 years	37/ 55 (67.3)	3.4 (1.4, 4.3)	10/ 27 (37.0)	NE (0.7, NE)	1.38 (0.68, 2.82)	0.3653	
	>=65 years	42/ 70 (60.0)	1.1 (0.6, NE)	8/ 35 (22.9)	NE (NE , NE)	3.08 (1.44, 6.57)	0.0022	
	Sex							0.8219
	female	16/ 30 (53.3)	4.2 (0.5, NE)	4/ 15 (26.7)	NE (0.7, NE)	1.85 (0.61, 5.60)	0.2742	
	male	63/ 95 (66.3)	1.6 (0.7, 3.5)	14/ 47 (29.8)	NE (NE , NE)	2.37 (1.32, 4.23)	0.0026	
	ECOG PS							0.2668
	0	40/ 62 (64.5)	1.5 (0.7, 6.6)	7/ 30 (23.3)	NE (NE , NE)	3.17 (1.41, 7.09)	0.0029	
	1	39/ 63 (61.9)	3.0 (0.7, 4.2)	11/ 32 (34.4)	NE (2.4, NE)	1.72 (0.88, 3.36)	0.1099	
	HER2 Status in central laboratory							0.7002
	IHC 3+	61/ 96 (63.5)	2.7 (0.7, 3.9)	14/ 47 (29.8)	NE (2.8, NE)	2.12 (1.19, 3.80)	0.0094	
	IHC 2+/ISH +	18/ 29 (62.1)	1.4 (0.5, NE)	4/ 15 (26.7)	NE (0.5, NE)	2.68 (0.90, 7.94)	0.0628	
	Primary tumor location							0.4027
	Gastric	67/108 (62.0)	2.7 (0.7, 4.2)	17/ 55 (30.9)	NE (NE , NE)	2.07 (1.22, 3.54)	0.0061	
	GEJ	12/ 17 (70.6)	1.9 (0.5, 4.3)	1/ 7 (14.3)	NE (0.5, NE)	5.10 (0.66, 39.31)	0.0801	
	Histological subtype							0.4041
	intestinal	55/ 89 (61.8)	1.9 (0.7, 4.2)	10/ 38 (26.3)	NE (NE , NE)	2.54 (1.29, 4.98)	0.0050	
	diffuse	20/ 28 (71.4)	1.6 (0.5, 3.9)	5/ 18 (27.8)	NE (2.4, NE)	2.43 (0.90, 6.57)	0.0702	
	others	4/ 8 (50.0)	4.2 (0.3, NE)	3/ 6 (50.0)	2.4 (0.4, NE)	0.87 (0.19, 3.96)	0.8594	
	Number of metastatic sites							0.1795
	<2	16/ 24 (66.7)	1.7 (0.6, 7.7)	5/ 10 (50.0)	NE (0.2, NE)	1.19 (0.44, 3.26)	0.6843	
	>= 2	63/101 (62.4)	2.7 (0.7, 4.2)	13/ 52 (25.0)	NE (NE , NE)	2.65 (1.45, 4.82)	0.0009	
	Previous total gastrectomy							0.8704
	yes	13/ 22 (59.1)	3.4 (0.7, NE)	2/ 9 (22.2)	NE (0.5, NE)	2.59 (0.58, 11.58)	0.2001	
	no	66/103 (64.1)	1.6 (0.7, 3.9)	16/ 53 (30.2)	NE (2.8, NE)	2.26 (1.31, 3.90)	0.0027	
	Prior adjuvant/ neoadjuvant therapy							0.7158
	yes	22/ 30 (73.3)	0.7 (0.6, 3.2)	4/ 10 (40.0)	NE (0.2, NE)	1.93 (0.66, 5.63)	0.2253	
	no	57/ 95 (60.0)	3.0 (1.3, 4.2)	14/ 52 (26.9)	NE (NE , NE)	2.27 (1.26, 4.08)	0.0047	
	Prior ramucirumab contained treatment							0.8067
	yes	62/ 94 (66.0)	1.5 (0.7, 3.4)	12/ 41 (29.3)	NE (NE , NE)	2.29 (1.23, 4.25)	0.0068	
	no	17/ 31 (54.8)	4.3 (0.7, NE)	6/ 21 (28.6)	NE (2.4, NE)	1.89 (0.74, 4.83)	0.1776	

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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations	Prior nivolumab contained treatment							0.0712
	yes	26/ 33 (78.8)	0.5 (0.5, 0.6)	3/ 15 (20.0)	NE (0.5, NE)	5.27 (1.58, 17.56)	0.0026	
	no	53/ 92 (57.6)	3.7 (1.8, 5.6)	15/ 47 (31.9)	NE (2.8, NE)	1.69 (0.95, 3.00)	0.0692	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0518
	yes	33/ 44 (75.0)	0.5 (0.5, 1.4)	3/ 17 (17.6)	NE (NE , NE)	5.42 (1.66, 17.74)	0.0017	
	no	46/ 81 (56.8)	3.5 (1.8, 6.6)	15/ 45 (33.3)	NE (2.4, NE)	1.55 (0.86, 2.78)	0.1352	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.5162
	yes	14/ 22 (63.6)	1.4 (0.5, NE)	3/ 7 (42.9)	NE (0.3, NE)	1.51 (0.43, 5.29)	0.5013	
	no	65/103 (63.1)	2.8 (0.7, 3.9)	15/ 55 (27.3)	NE (NE , NE)	2.37 (1.35, 4.17)	0.0020	
	Presence of liver metastasis at baseline							0.0868
	yes	46/ 67 (68.7)	1.4 (0.5, 3.4)	8/ 34 (23.5)	NE (NE , NE)	3.46 (1.63, 7.35)	0.0006	
	no	33/ 58 (56.9)	3.7 (1.0, 8.3)	10/ 28 (35.7)	NE (0.7, NE)	1.45 (0.71, 2.94)	0.2973	
	Renal impairment at baseline							0.1982
	normal	22/ 33 (66.7)	1.6 (0.6, 5.6)	6/ 13 (46.2)	2.8 (0.5, NE)	1.30 (0.52, 3.28)	0.5657	
	mild	35/ 53 (66.0)	1.9 (0.7, 3.9)	9/ 28 (32.1)	NE (0.7, NE)	2.04 (0.98, 4.26)	0.0501	
	moderate	22/ 39 (56.4)	2.7 (0.5, NE)	2/ 20 (10.0)	NE (NE , NE)	6.72 (1.58, 28.67)	0.0029	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.7 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.3273
	normal	56/ 88 (63.6)	1.8 (0.7, 4.2)	12/ 47 (25.5)	NE (NE , NE)	2.70 (1.44, 5.05)	0.0012	
	mild	22/ 36 (61.1)	3.0 (0.5, 4.2)	6/ 15 (40.0)	NE (0.5, NE)	1.48 (0.60, 3.67)	0.3856	
	moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3848
	yes	5/ 8 (62.5)	6.6 (0.3, NE)	2/ 5 (40.0)	NE (0.5, NE)	1.06 (0.20, 5.64)	0.9452	
	no	74/117 (63.2)	1.9 (0.7, 3.5)	16/ 57 (28.1)	NE (NE , NE)	2.43 (1.42, 4.18)	0.0009	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.8682
	yes	2/ 3 (66.7)	6.6 (4.3, NE)	1/ 4 (25.0)	NE (0.5, NE)	1.28 (0.11, 15.48)	0.8483	
	no	77/122 (63.1)	1.9 (0.7, 3.7)	17/ 58 (29.3)	NE (NE , NE)	2.25 (1.33, 3.82)	0.0019	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Neutrophil count decreased	Region							0.7006
	Japan	53/ 99 (53.5)	3.4 (0.7, NE)	12/ 50 (24.0)	NE (NE , NE)	2.36 (1.26, 4.43)	0.0055	
	Korea	9/ 26 (34.6)	NE (3.5, NE)	2/ 12 (16.7)	NE (2.8, NE)	1.31 (0.28, 6.18)	0.7296	
	Lines of prior systemic therapy							0.2528
	2	28/ 66 (42.4)	NE (3.0, NE)	9/ 38 (23.7)	NE (NE , NE)	1.66 (0.78, 3.53)	0.1757	
	3	22/ 34 (64.7)	0.7 (0.5, 4.2)	3/ 18 (16.7)	NE (NE , NE)	4.62 (1.38, 15.49)	0.0065	
	>=4	12/ 25 (48.0)	5.0 (0.7, NE)	2/ 6 (33.3)	NE (0.5, NE)	1.09 (0.24, 4.90)	0.8996	
	Age							0.2701
	<65 years	25/ 55 (45.5)	5.6 (3.4, NE)	7/ 27 (25.9)	NE (2.8, NE)	1.34 (0.57, 3.15)	0.4908	
	>=65 years	37/ 70 (52.9)	1.9 (0.7, NE)	7/ 35 (20.0)	NE (NE , NE)	2.89 (1.29, 6.49)	0.0068	
	Sex							0.5864
	female	12/ 30 (40.0)	NE (0.6, NE)	2/ 15 (13.3)	NE (NE , NE)	2.89 (0.64, 12.99)	0.1472	
	male	50/ 95 (52.6)	3.5 (1.4, NE)	12/ 47 (25.5)	NE (NE , NE)	2.03 (1.08, 3.82)	0.0238	
	ECOG PS							0.3981
	0	32/ 62 (51.6)	5.0 (0.7, NE)	6/ 30 (20.0)	NE (NE , NE)	2.93 (1.22, 7.00)	0.0111	
	1	30/ 63 (47.6)	4.1 (2.0, NE)	8/ 32 (25.0)	NE (2.8, NE)	1.67 (0.77, 3.65)	0.1872	
	HER2 Status in central laboratory							0.6639
	IHC 3+	49/ 96 (51.0)	4.1 (1.4, NE)	10/ 47 (21.3)	NE (NE , NE)	2.31 (1.17, 4.57)	0.0131	
	IHC 2+/ISH +	13/ 29 (44.8)	NE (0.6, NE)	4/ 15 (26.7)	NE (0.5, NE)	1.77 (0.58, 5.44)	0.3070	
	Primary tumor location							0.5622
	Gastric	53/108 (49.1)	4.2 (1.9, NE)	13/ 55 (23.6)	NE (NE , NE)	2.04 (1.11, 3.75)	0.0181	
	GEJ	9/ 17 (52.9)	3.4 (0.5, NE)	1/ 7 (14.3)	NE (0.5, NE)	3.78 (0.48, 29.87)	0.1737	
	Histological subtype							0.6418
	intestinal	43/ 89 (48.3)	5.0 (1.4, NE)	10/ 38 (26.3)	NE (NE , NE)	1.82 (0.91, 3.63)	0.0853	
	diffuse	16/ 28 (57.1)	2.3 (0.5, NE)	3/ 18 (16.7)	NE (2.8, NE)	3.26 (0.94, 11.25)	0.0461	
	others	3/ 8 (37.5)	NE (0.3, NE)	1/ 6 (16.7)	NE (0.5, NE)	2.10 (0.22, 20.32)	0.5133	
	Number of metastatic sites							0.2296
	<2	13/ 24 (54.2)	2.4 (0.7, NE)	4/ 10 (40.0)	NE (0.2, NE)	1.20 (0.39, 3.68)	0.7108	
	>= 2	49/101 (48.5)	4.2 (1.9, NE)	10/ 52 (19.2)	NE (NE , NE)	2.54 (1.28, 5.02)	0.0056	
	Previous total gastrectomy							0.9159
	yes	10/ 22 (45.5)	3.7 (0.7, NE)	2/ 9 (22.2)	NE (0.5, NE)	2.07 (0.45, 9.49)	0.3421	
	no	52/103 (50.5)	4.2 (1.4, NE)	12/ 53 (22.6)	NE (NE , NE)	2.22 (1.18, 4.16)	0.0103	
	Prior adjuvant/ neoadjuvant therapy							0.4625
	yes	19/ 30 (63.3)	1.1 (0.7, NE)	4/ 10 (40.0)	NE (0.2, NE)	1.54 (0.52, 4.53)	0.4428	
	no	43/ 95 (45.3)	5.6 (3.0, NE)	10/ 52 (19.2)	NE (NE , NE)	2.29 (1.15, 4.56)	0.0151	
	Prior ramucirumab contained treatment							0.6134
	yes	50/ 94 (53.2)	3.4 (1.3, NE)	9/ 41 (22.0)	NE (NE , NE)	2.33 (1.15, 4.74)	0.0154	
	no	12/ 31 (38.7)	NE (2.3, NE)	5/ 21 (23.8)	NE (2.8, NE)	1.63 (0.57, 4.65)	0.3632	

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[c] Two-sided p-value derived from log-rank test.
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Primary Cohort
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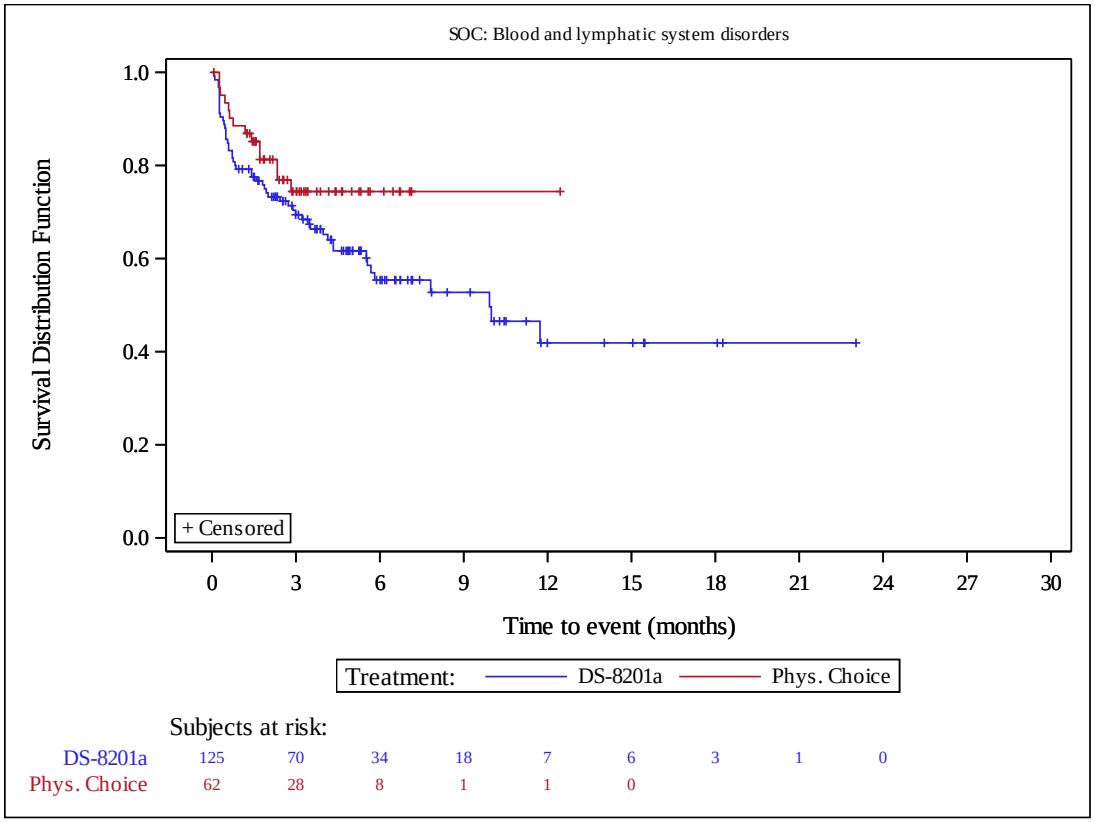
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Neutrophil count decreased	Prior nivolumab contained treatment							0.1986
	yes	22/ 33 (66.7)	0.5 (0.5, 1.8)	3/ 15 (20.0)	NE (0.5, NE)	4.06 (1.21, 13.61)	0.0145	
	no	40/ 92 (43.5)	NE (3.5, NE)	11/ 47 (23.4)	NE (NE , NE)	1.68 (0.86, 3.28)	0.1192	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.1601
	yes	28/ 44 (63.6)	1.1 (0.5, 5.0)	3/ 17 (17.6)	NE (NE , NE)	4.07 (1.23, 13.40)	0.0125	
	no	34/ 81 (42.0)	NE (3.4, NE)	11/ 45 (24.4)	NE (NE , NE)	1.58 (0.80, 3.12)	0.1803	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.1212
	yes	10/ 22 (45.5)	NE (0.7, NE)	3/ 7 (42.9)	NE (0.3, NE)	0.81 (0.22, 2.96)	0.7406	
	no	52/103 (50.5)	4.2 (1.8, NE)	11/ 55 (20.0)	NE (NE , NE)	2.55 (1.33, 4.89)	0.0035	
	Presence of liver metastasis at baseline							0.1903
	yes	38/ 67 (56.7)	2.3 (0.7, 5.6)	7/ 34 (20.6)	NE (NE , NE)	3.09 (1.38, 6.92)	0.0039	
	no	24/ 58 (41.4)	NE (2.0, NE)	7/ 28 (25.0)	NE (NE , NE)	1.48 (0.64, 3.44)	0.3470	
	Renal impairment at baseline							0.4928
	normal	17/ 33 (51.5)	5.6 (0.7, NE)	4/ 13 (30.8)	NE (0.5, NE)	1.61 (0.54, 4.81)	0.3943	
	mild	29/ 53 (54.7)	3.5 (0.7, NE)	8/ 28 (28.6)	NE (NE , NE)	1.80 (0.82, 3.94)	0.1339	
	moderate	16/ 39 (41.0)	NE (1.4, NE)	2/ 20 (10.0)	NE (NE , NE)	4.29 (0.98, 18.69)	0.0345	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.1036
	normal	43/ 88 (48.9)	5.6 (0.7, NE)	8/ 47 (17.0)	NE (NE , NE)	3.02 (1.42, 6.43)	0.0027	
	mild	18/ 36 (50.0)	3.7 (1.3, NE)	6/ 15 (40.0)	NE (0.5, NE)	1.12 (0.44, 2.82)	0.7805	
	moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.0897
	yes	2/ 8 (25.0)	NE (0.6, NE)	2/ 5 (40.0)	NE (0.5, NE)	0.47 (0.07, 3.39)	0.4463	
	no	60/117 (51.3)	4.1 (1.8, NE)	12/ 57 (21.1)	NE (NE , NE)	2.48 (1.33, 4.61)	0.0030	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9862
	yes	0/ 3 (0.0)	NE (NE , NE)	1/ 4 (25.0)	NE (0.5, NE)	NE	NE	
	no	62/122 (50.8)	4.1 (1.8, NE)	13/ 58 (22.4)	NE (NE , NE)	2.26 (1.24, 4.12)	0.0059	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
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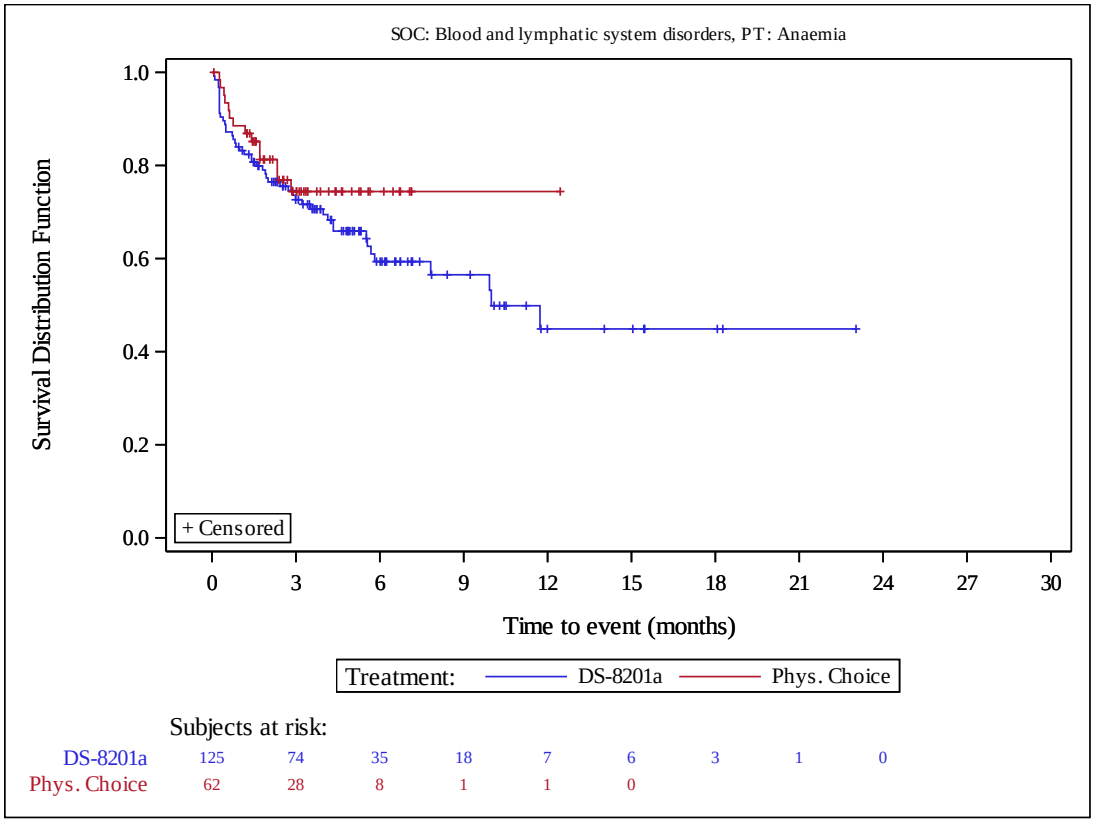
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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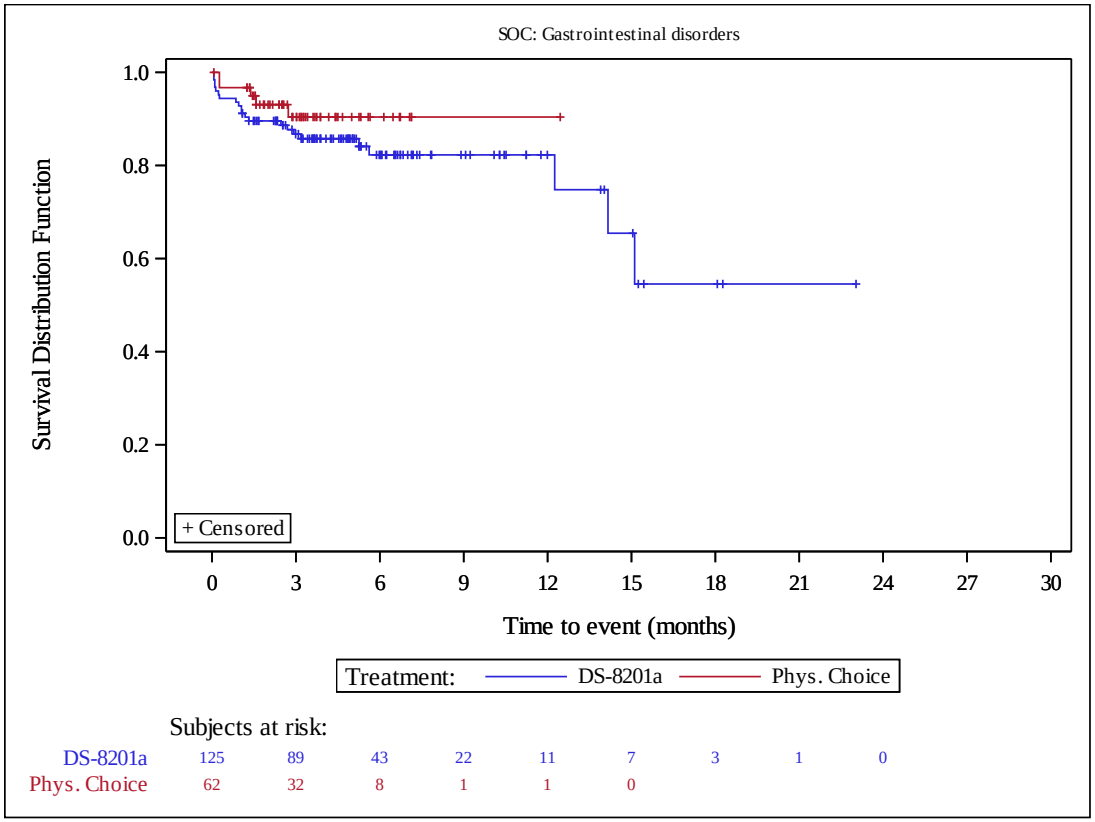
Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



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Source data: ADAM.ADSL and ADAM.ADAE
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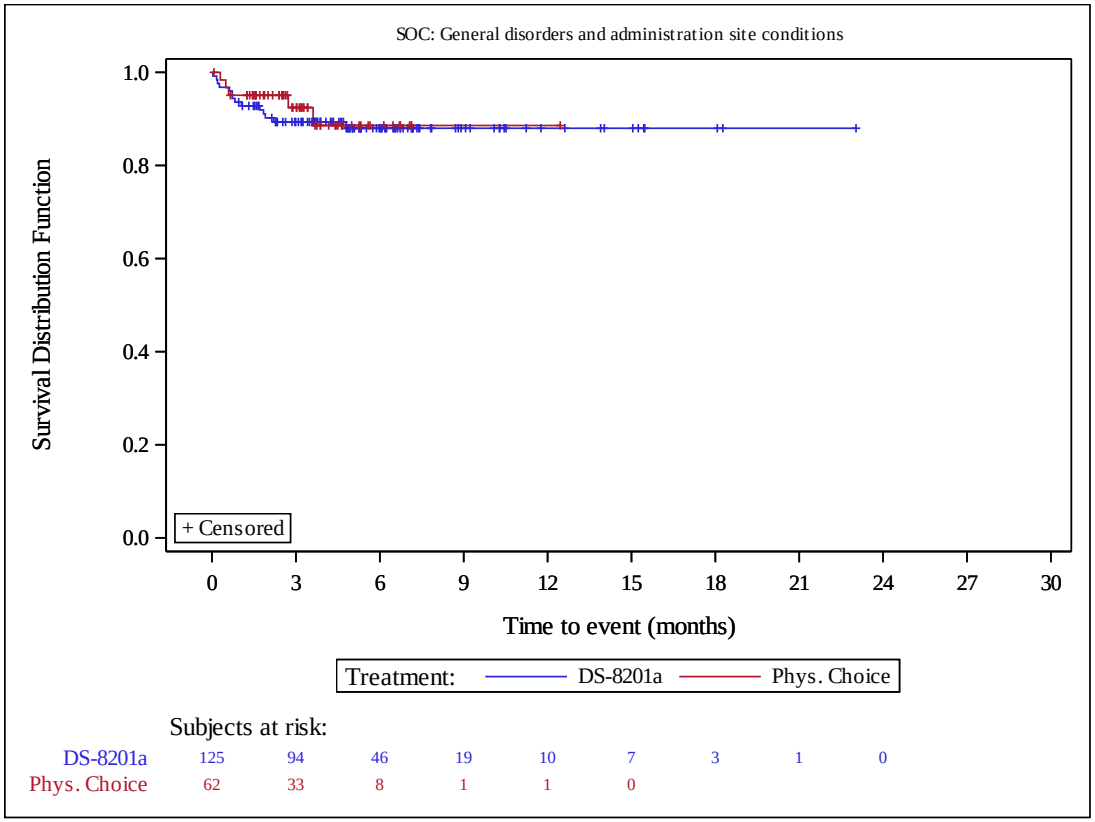

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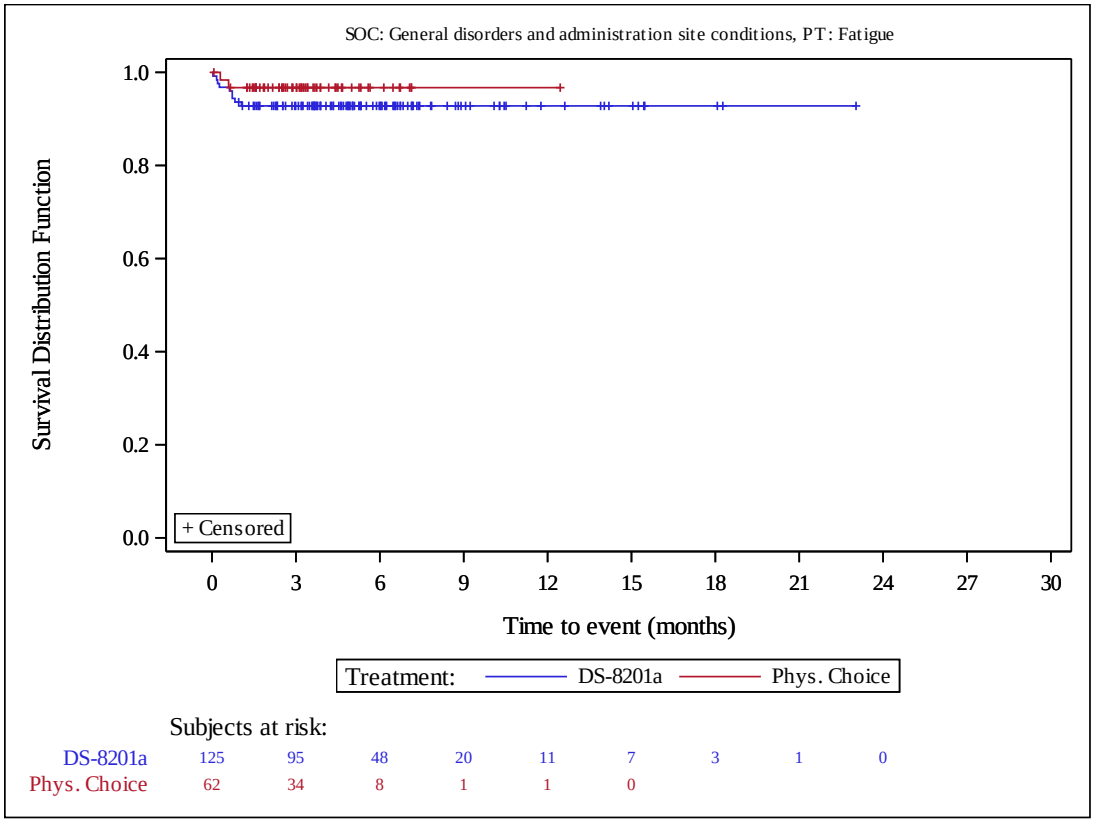

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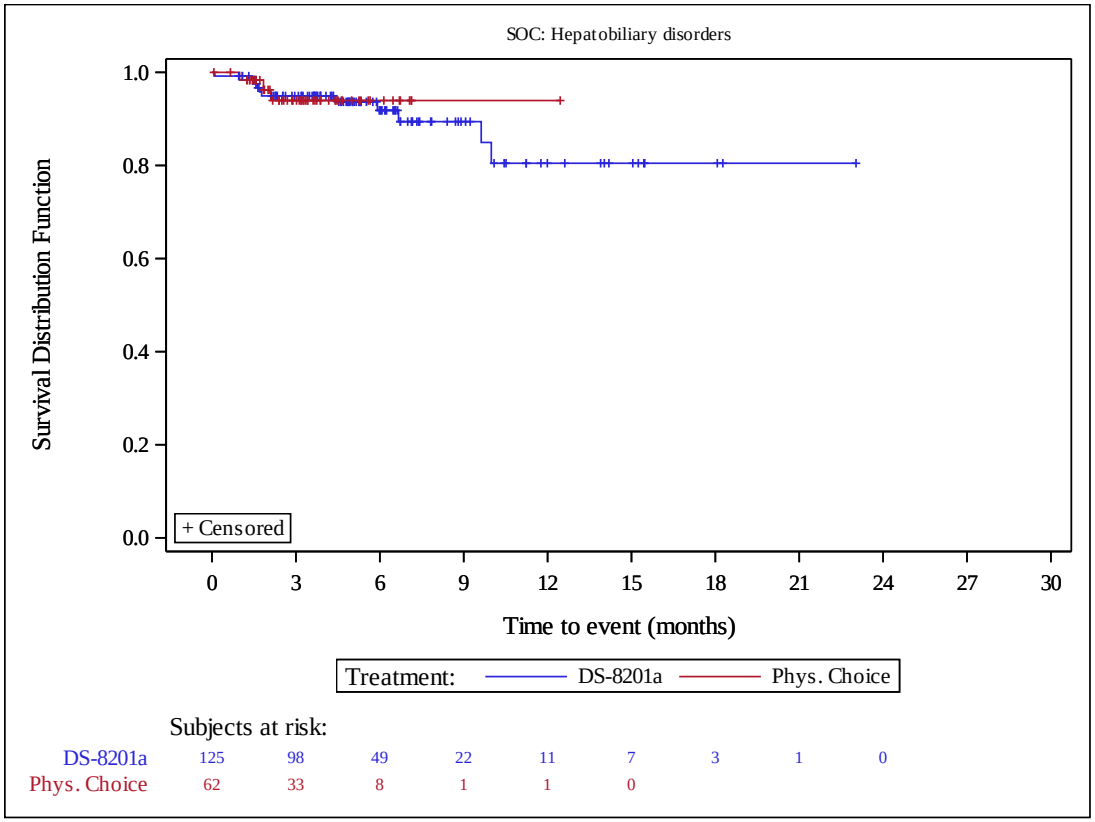

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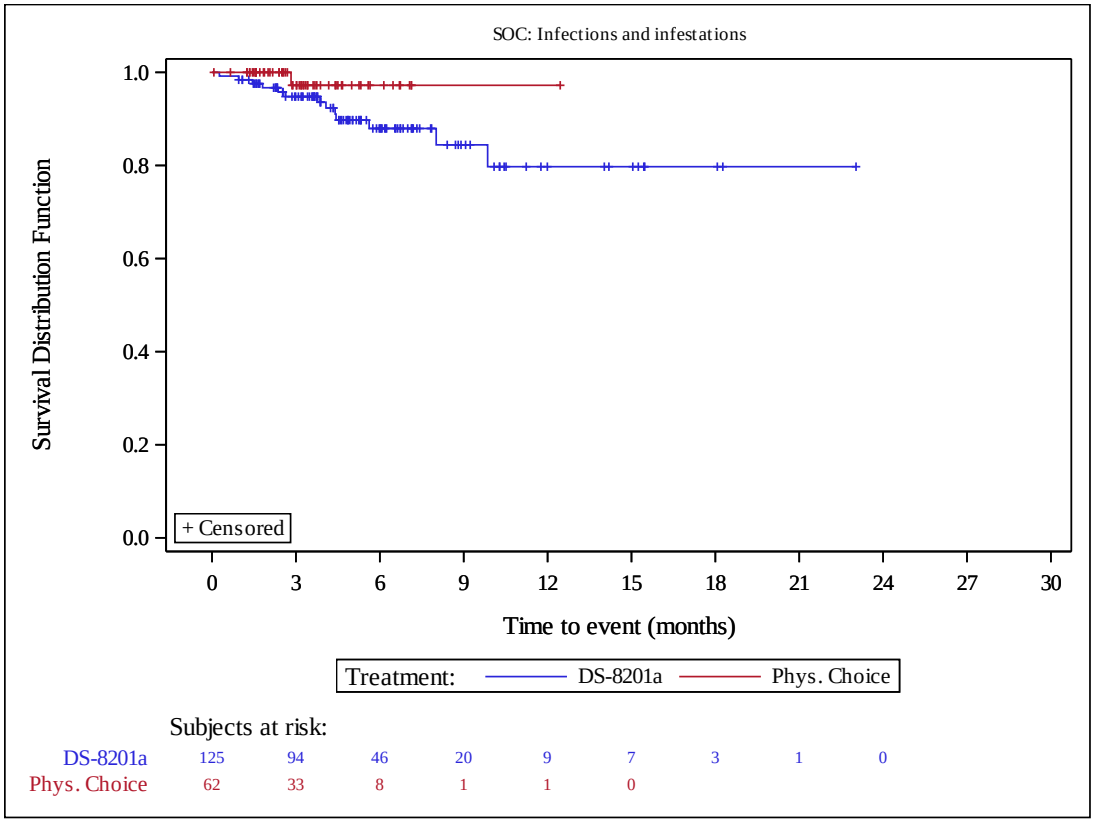

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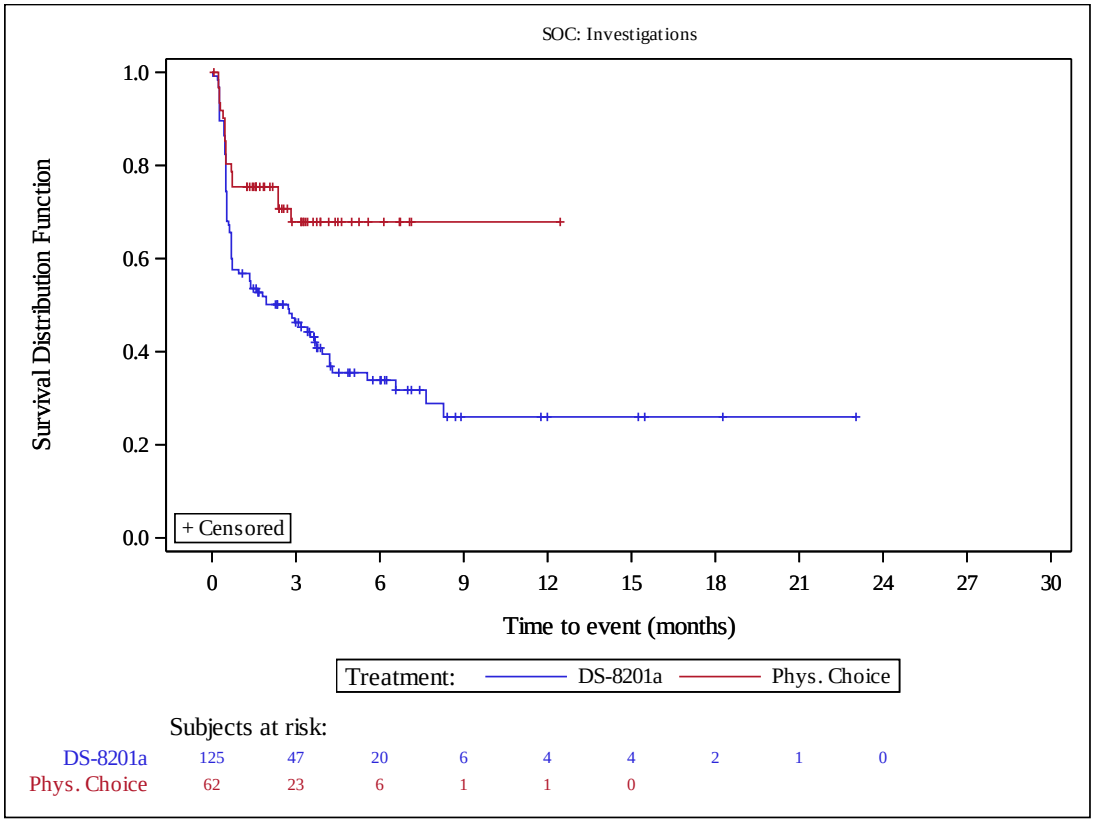

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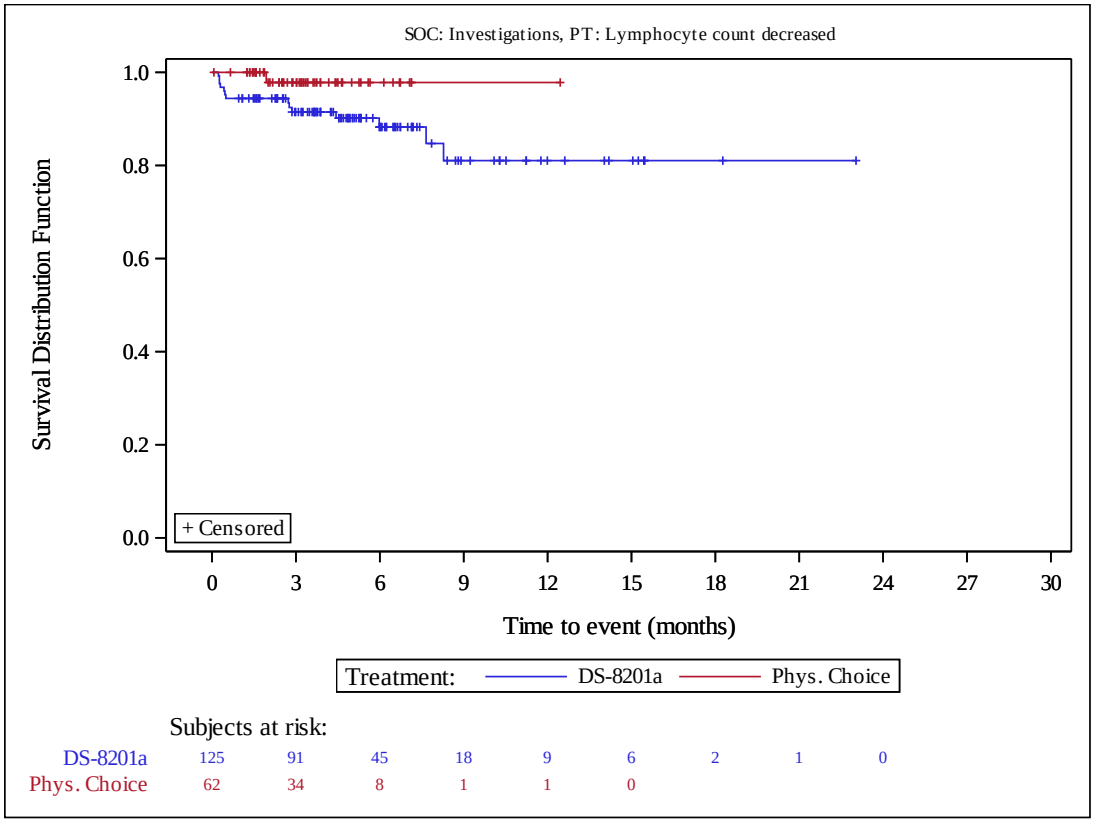

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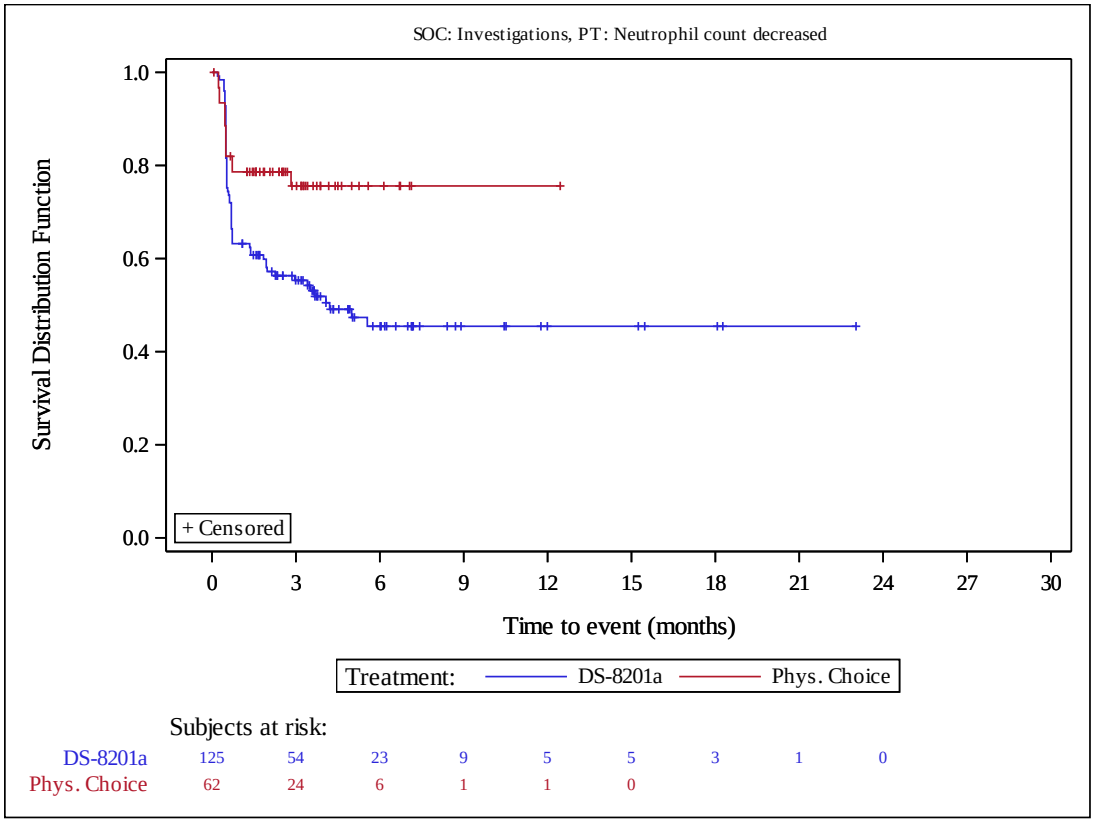

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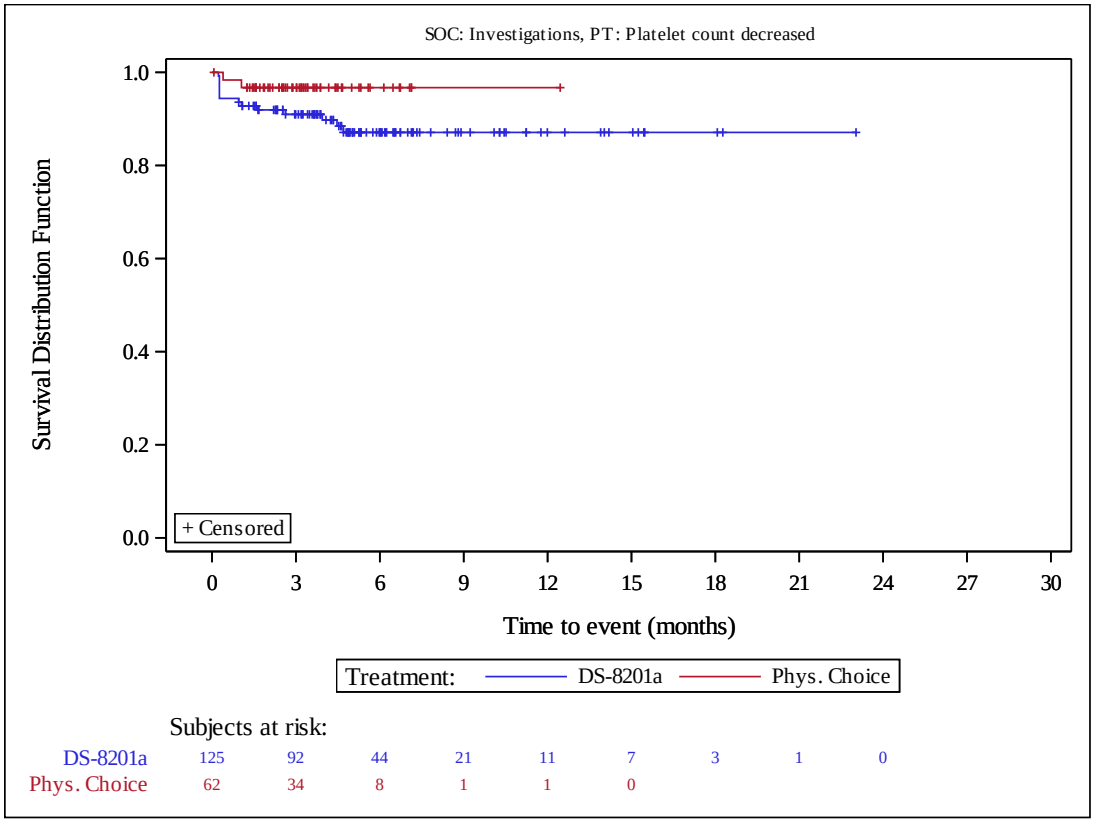
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



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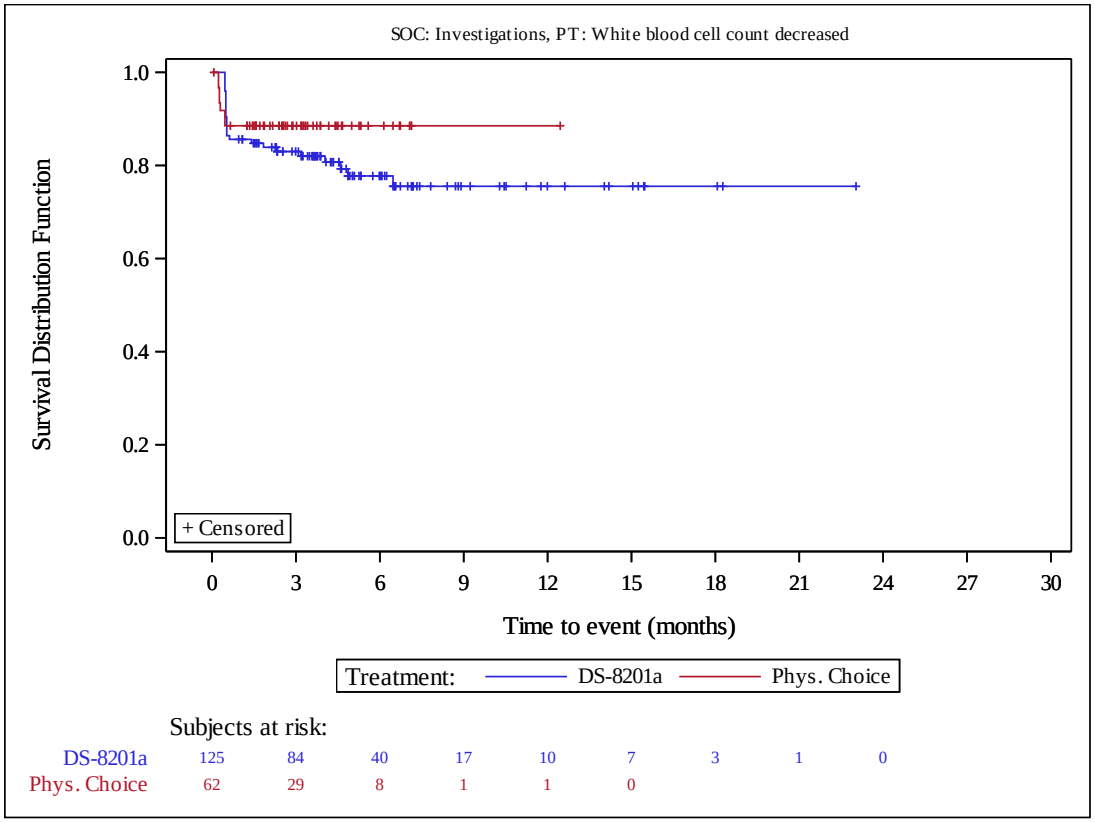

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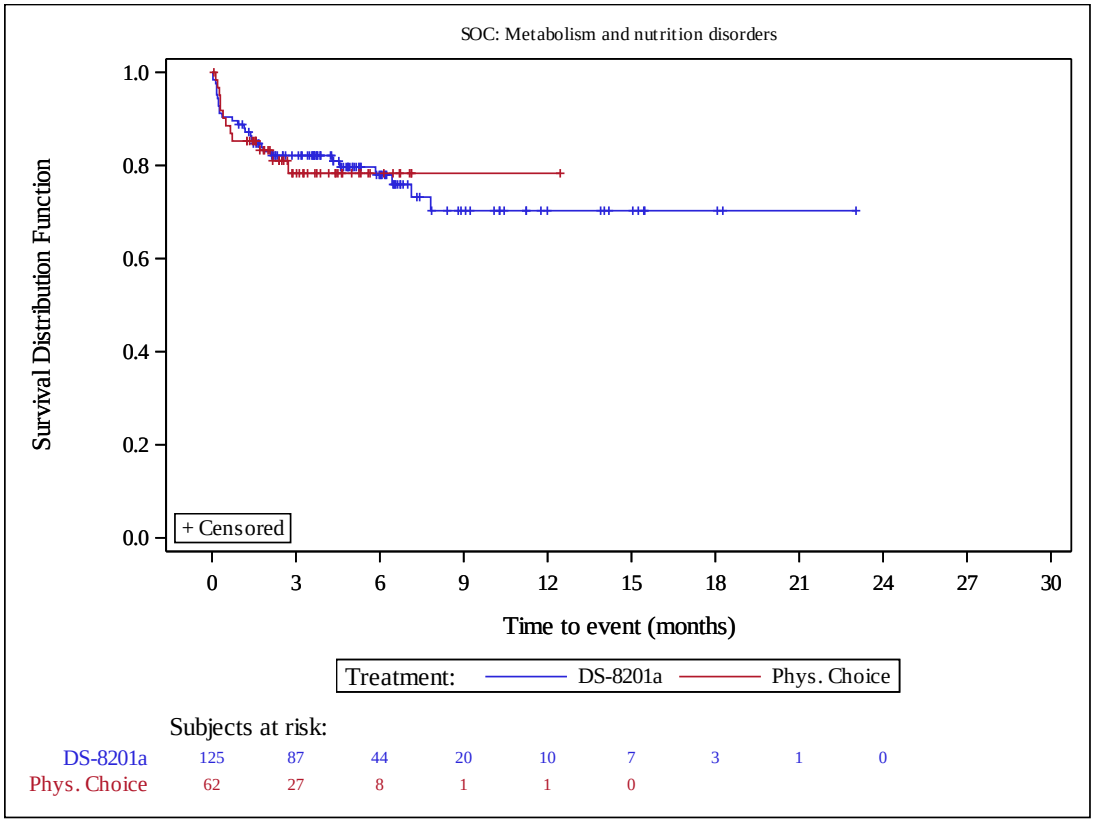
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



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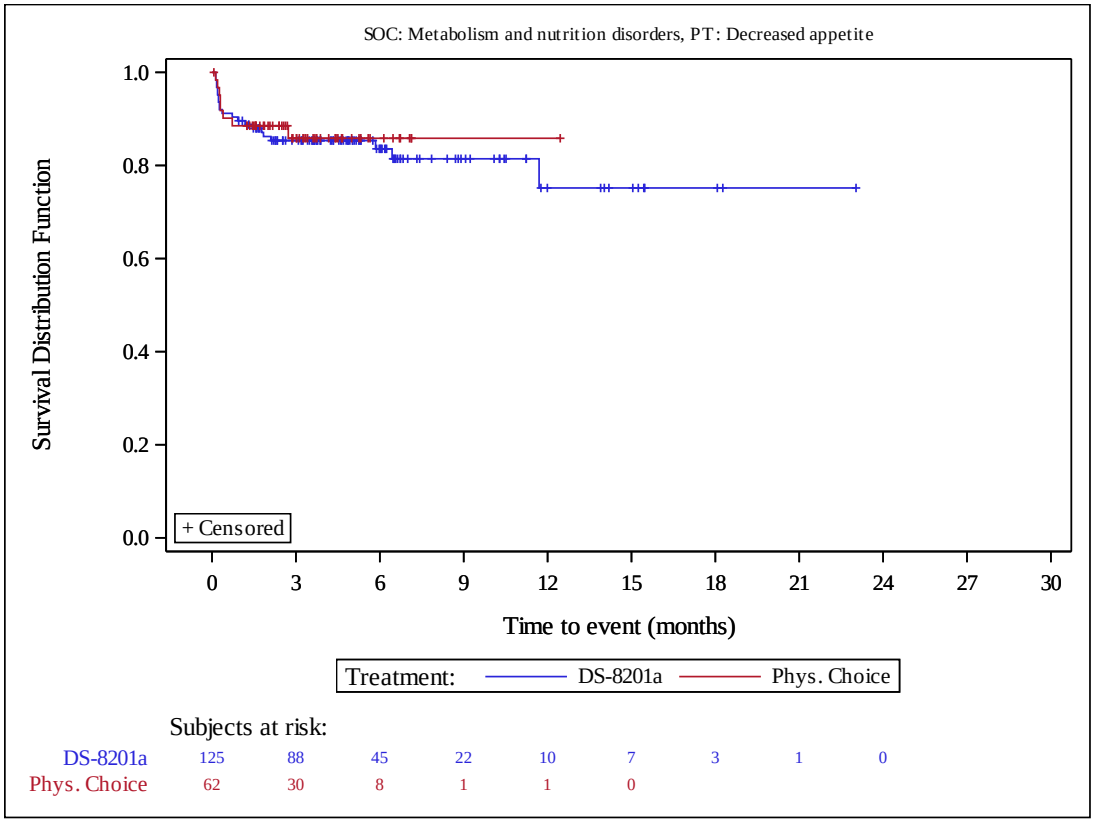
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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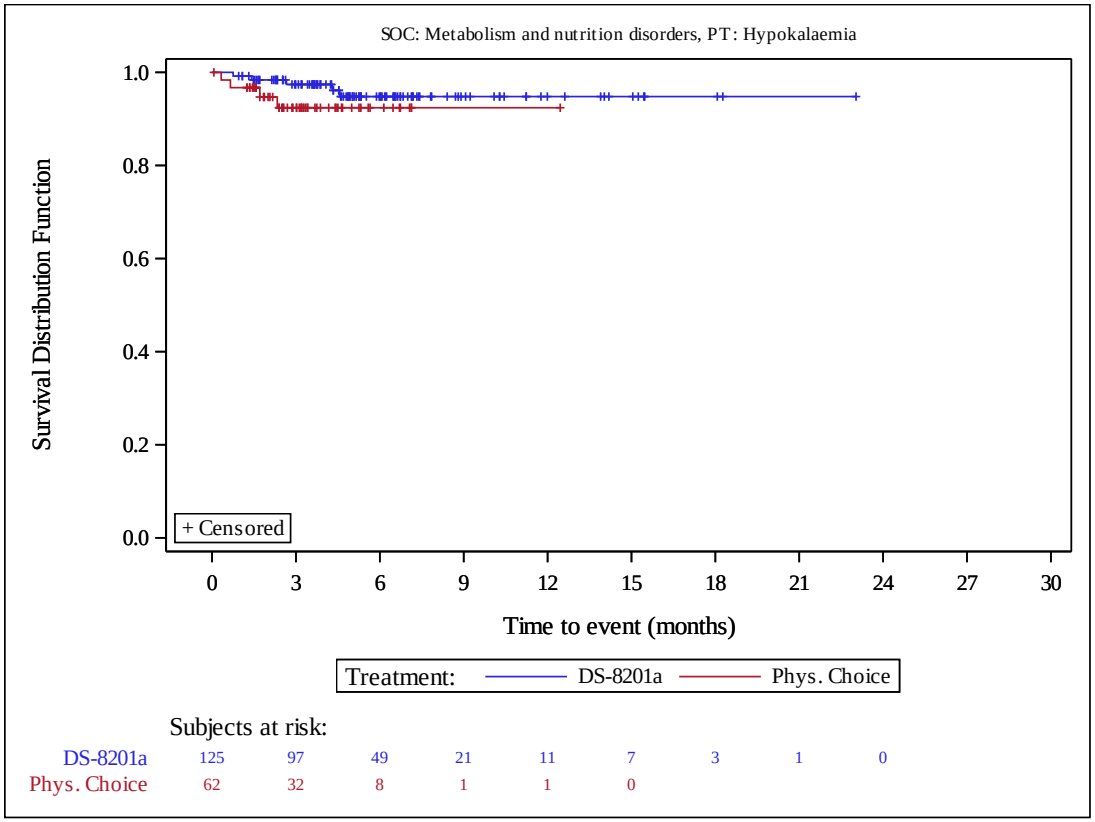
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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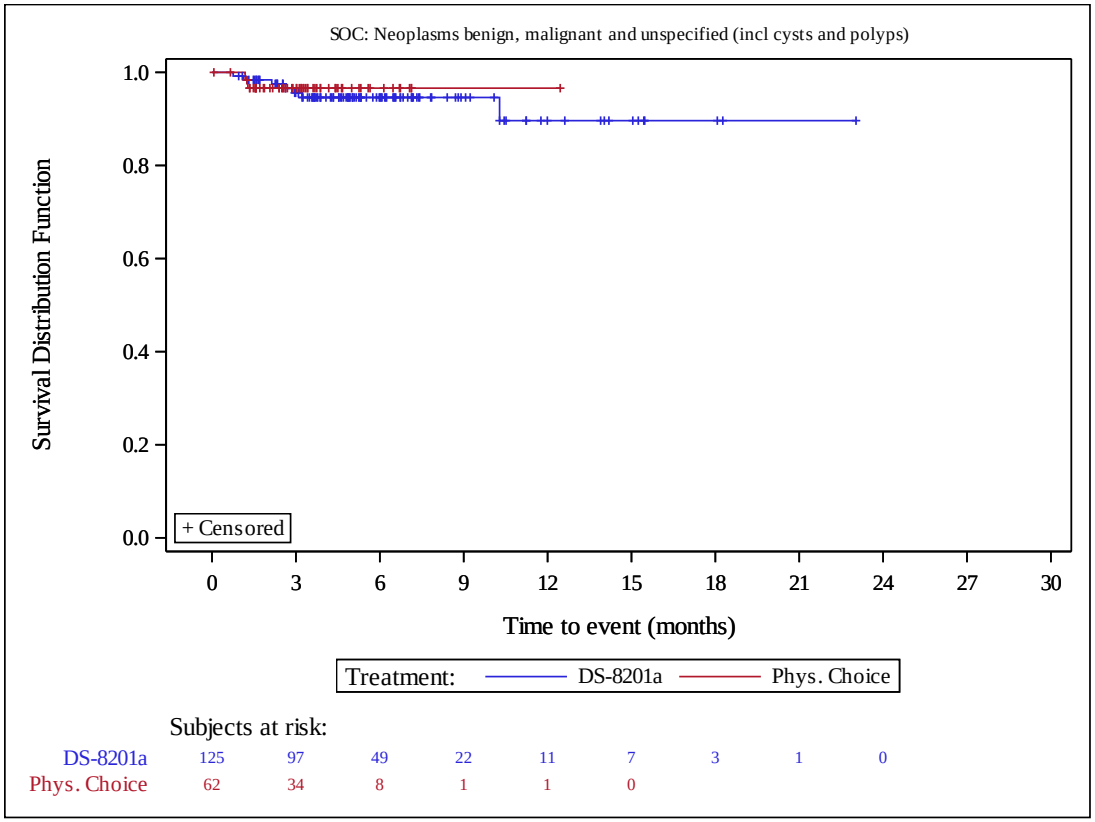
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders, PT: Anaemia	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Gastrointestinal obstruction	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Large intestine perforation	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	2 (1.6)	1 (1.6)
	Number of censored subjects, n (%)	123 (98.4)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.17 (0.01, 2.16)	
	p-value [c]	0.1264	
	Relative Risk (95% CI) [d]	0.99 (0.09, 10.73)	
	p-value	0.9947	
	Odds Ratio (95% CI) [d]	0.99 (0.09, 11.15)	
	p-value	0.9947	
	Risk Difference (95% CI) [e]	-0.01 (-5.05, 5.02)	
	p-value	0.9960	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Asthenia	Number of subjects with events, n (%)	1 (0.8)	1 (1.6)
	Number of censored subjects, n (%)	124 (99.2)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.09 (0.00, 1.85)	
	p-value [c]	0.0614	
	Relative Risk (95% CI) [d]	0.50 (0.03, 7.80)	
	p-value	0.6179	
	Odds Ratio (95% CI) [d]	0.49 (0.03, 8.00)	
	p-value	0.6181	
	Risk Difference (95% CI) [e]	-0.81 (-5.52, 3.90)	
	p-value	0.7351	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders, PT: Hepatic function abnormal	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations	Number of subjects with events, n (%)	4 (3.2)	0 (0.0)
	Number of censored subjects, n (%)	121 (96.8)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	4.50 (0.25, 82.28)	
	p-value	0.3104	
	Odds Ratio (95% CI) [d]	4.63 (0.25, 87.37)	
	p-value	0.3066	
	Risk Difference (95% CI) [e]	3.20 (-1.09, 7.49)	
	p-value	0.1439	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations, PT: Pneumonia bacterial	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations, PT: Sepsis	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations	Number of subjects with events, n (%)	0 (0.0)	2 (3.2)
	Number of censored subjects, n (%)	125 (100.0)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	0.10 (0.00, 2.05)	
	p-value	0.1352	
	Odds Ratio (95% CI) [d]	0.10 (0.00, 2.04)	
	p-value	0.1330	
	Risk Difference (95% CI) [e]	-3.23 (-8.83, 2.38)	
	p-value	0.2593	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Neutrophil count decreased	Number of subjects with events, n (%)	0 (0.0)	2 (3.2)
	Number of censored subjects, n (%)	125 (100.0)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	0.10 (0.00, 2.05)	
	p-value	0.1352	
	Odds Ratio (95% CI) [d]	0.10 (0.00, 2.04)	
	p-value	0.1330	
	Risk Difference (95% CI) [e]	-3.23 (-8.83, 2.38)	
	p-value	0.2593	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Hyponatraemia	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Nervous system disorders	Number of subjects with events, n (%)	1 (0.8)	1 (1.6)
	Number of censored subjects, n (%)	124 (99.2)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.20 (0.01, 3.26)	
	p-value [c]	0.2101	
	Relative Risk (95% CI) [d]	0.50 (0.03, 7.80)	
	p-value	0.6179	
	Odds Ratio (95% CI) [d]	0.49 (0.03, 8.00)	
	p-value	0.6181	
	Risk Difference (95% CI) [e]	-0.81 (-5.52, 3.90)	
	p-value	0.7351	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Nervous system disorders, PT: Cerebral infarction	Number of subjects with events, n (%)	0 (0.0)	1 (1.6)
	Number of censored subjects, n (%)	125 (100.0)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	0.17 (0.01, 4.03)	
	p-value	0.2704	
	Odds Ratio (95% CI) [d]	0.16 (0.01, 4.07)	
	p-value	0.2694	
	Risk Difference (95% CI) [e]	-1.61 (-5.95, 2.73)	
	p-value	0.4666	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Nervous system disorders, PT: Hemiplegia	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	7 (5.6)	0 (0.0)
	Number of censored subjects, n (%)	118 (94.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	7.50 (0.44, 129.23)	
	p-value	0.1654	
	Odds Ratio (95% CI) [d]	7.91 (0.44, 140.80)	
	p-value	0.1591	
	Risk Difference (95% CI) [e]	5.60 (0.36, 10.84)	
	p-value	0.0361	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Interstitial lung disease	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Pneumonitis	Number of subjects with events, n (%)	5 (4.0)	0 (0.0)
	Number of censored subjects, n (%)	120 (96.0)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	5.50 (0.31, 97.90)	
	p-value	0.2459	
	Odds Ratio (95% CI) [d]	5.71 (0.31, 104.85)	
	p-value	0.2410	
	Risk Difference (95% CI) [e]	4.00 (-0.64, 8.64)	
	p-value	0.0912	

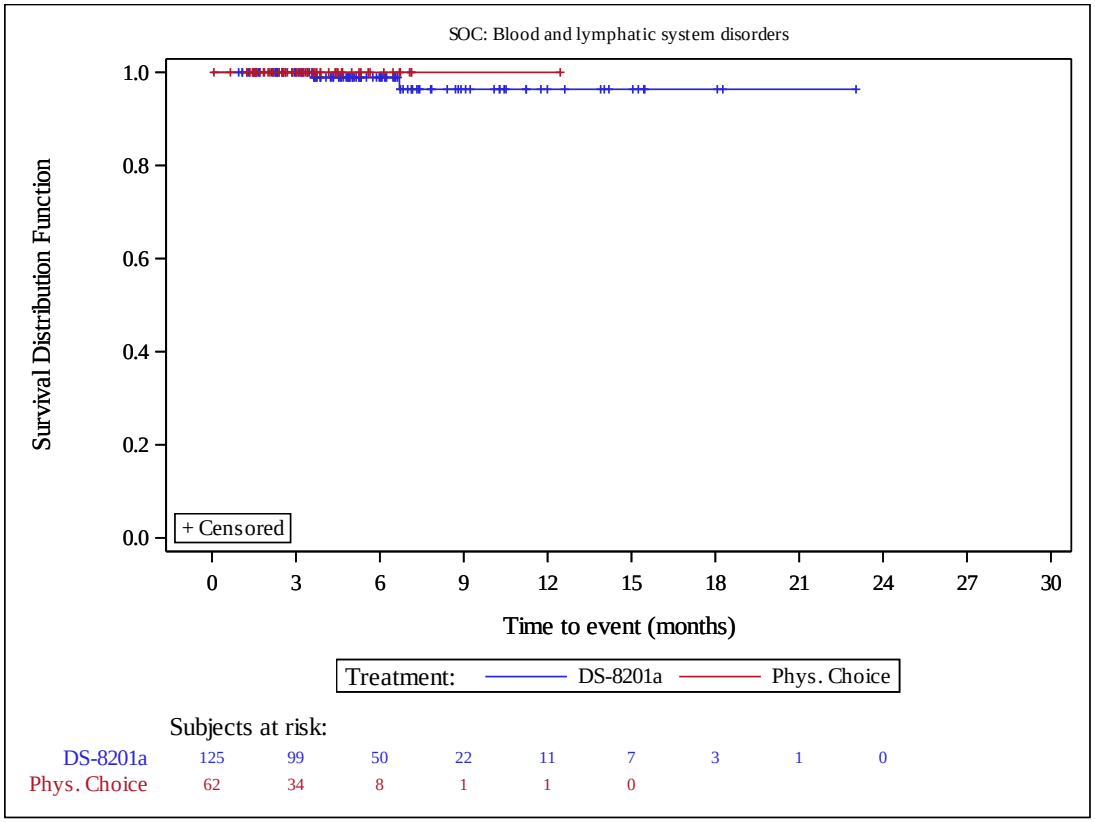
Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT - Subgroup analysis
Safety Analysis Set

No subgroups displayed.

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
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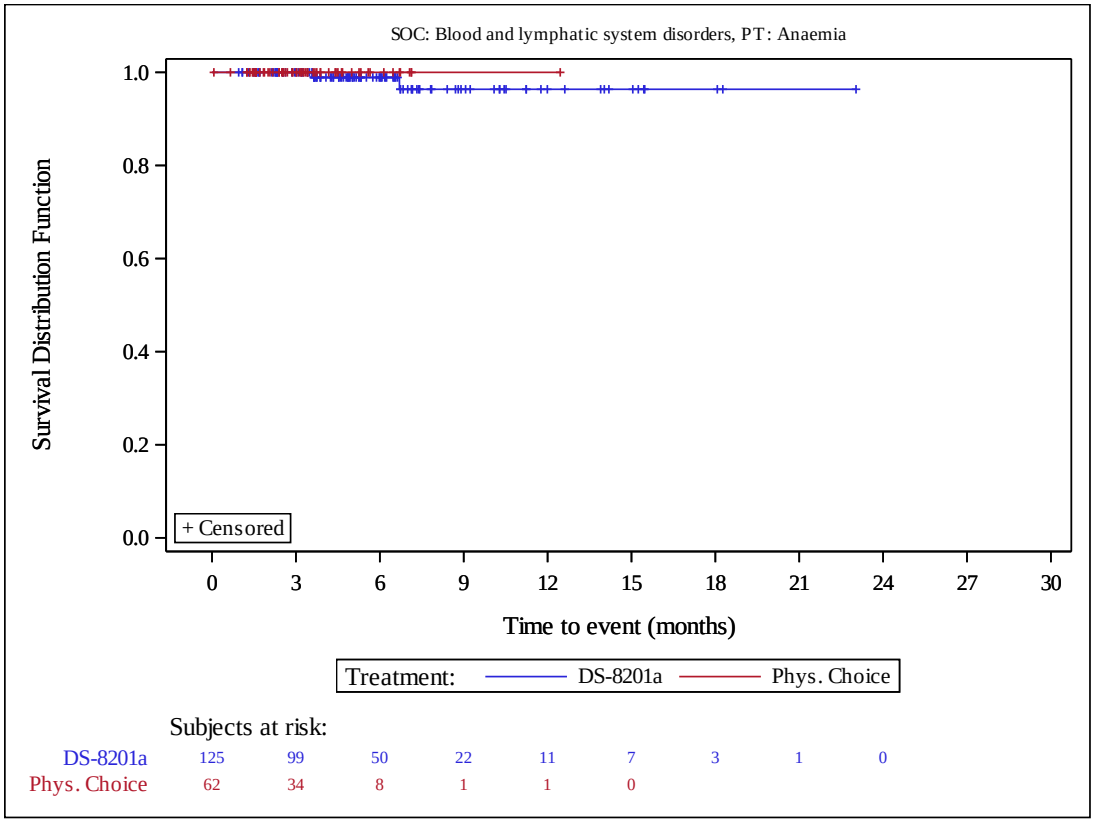
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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[c] Two-sided p-value derived from log-rank test.
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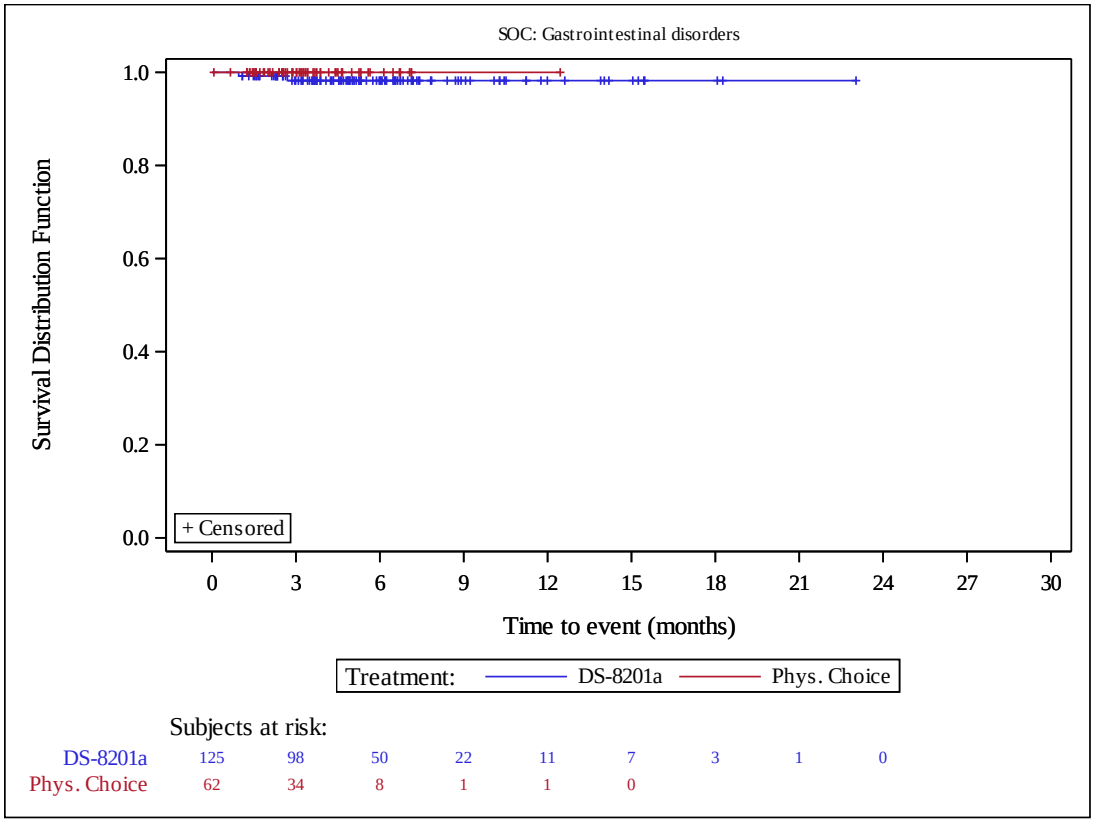
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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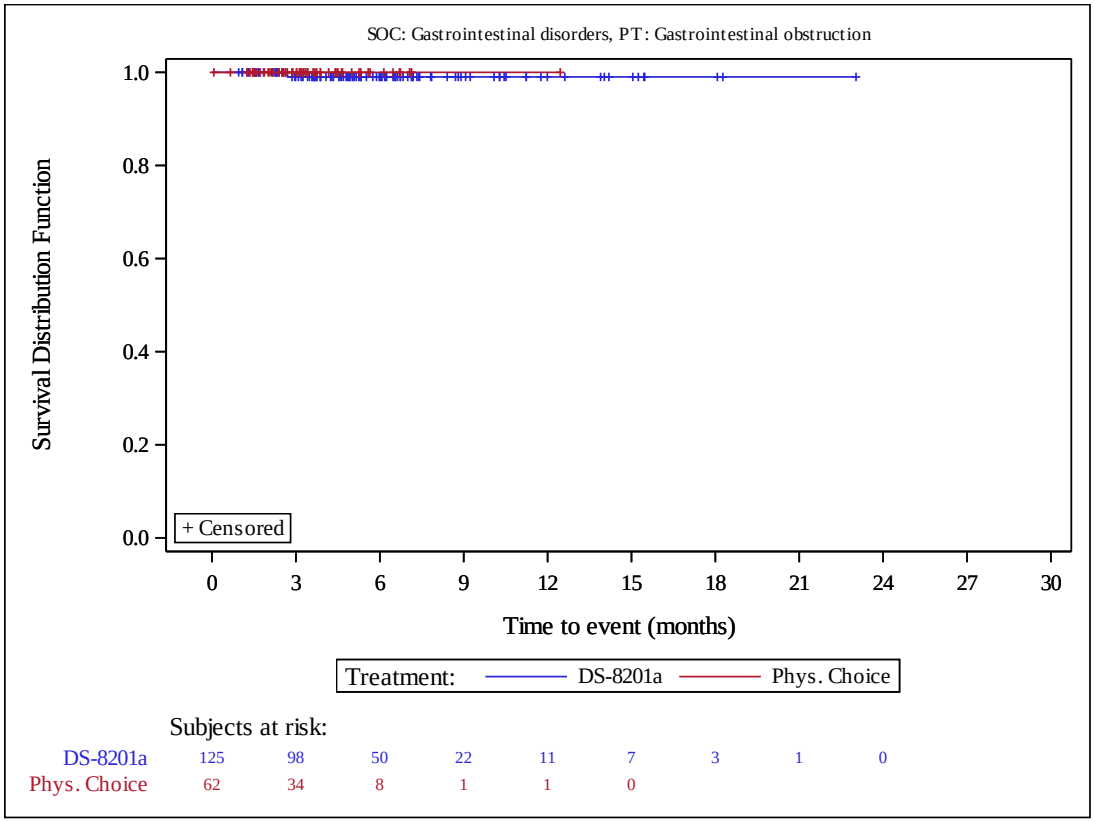
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
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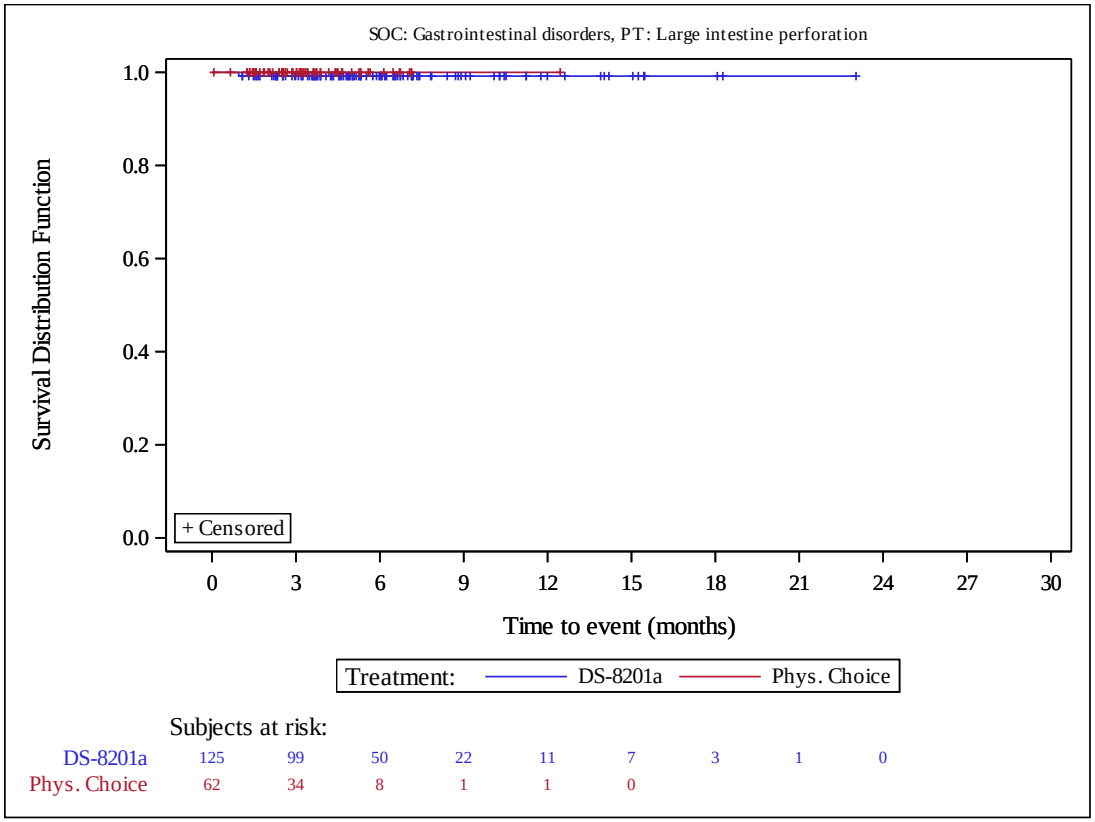
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
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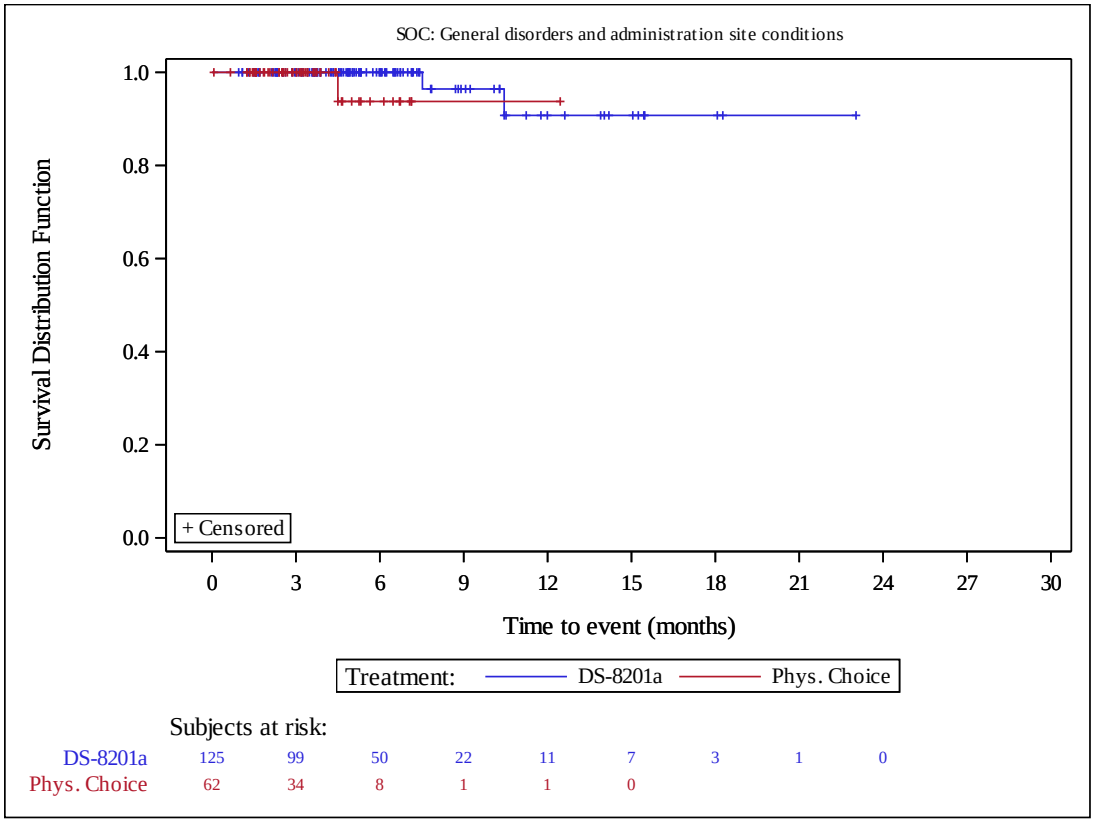
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
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[b] Derived from Cox proportional hazards model.
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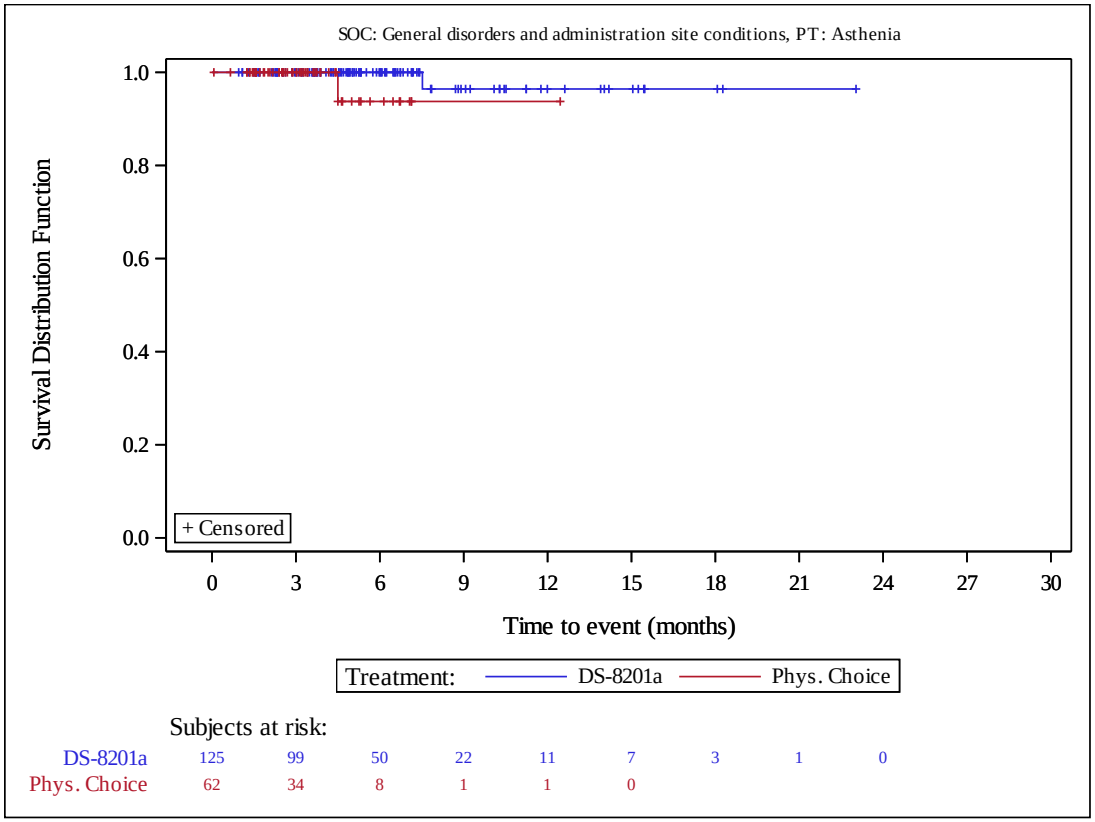
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
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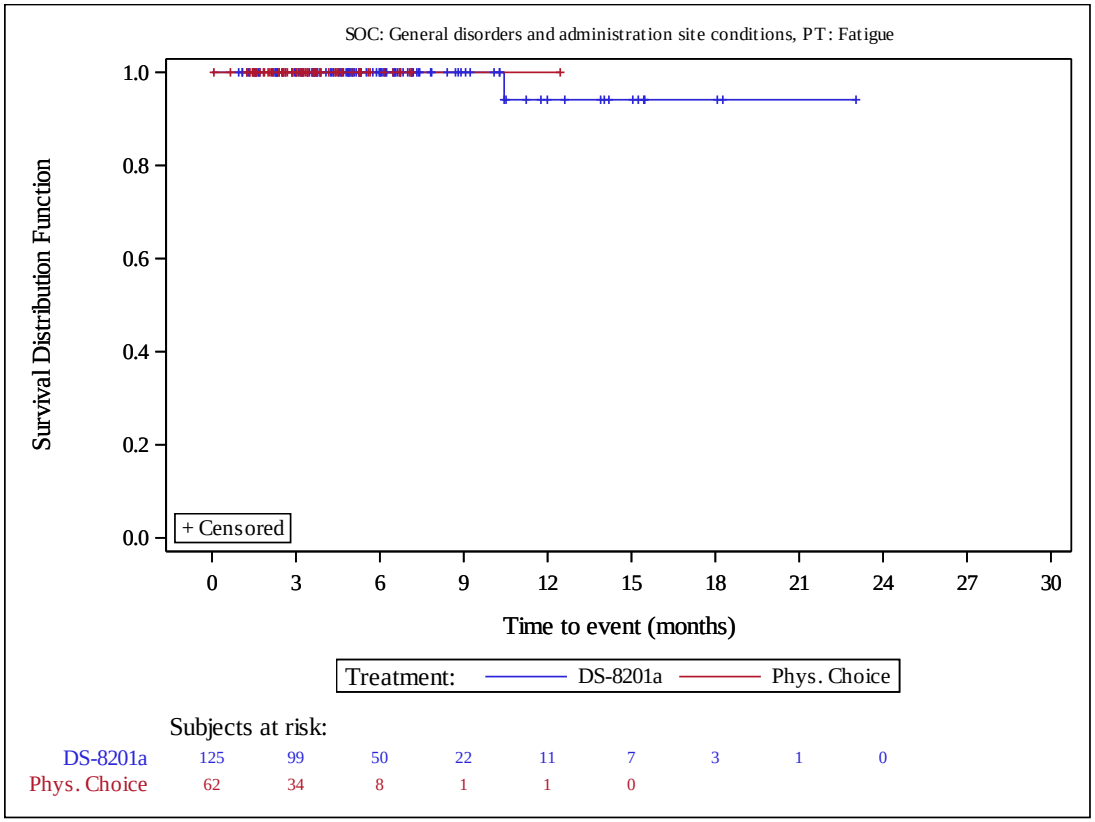
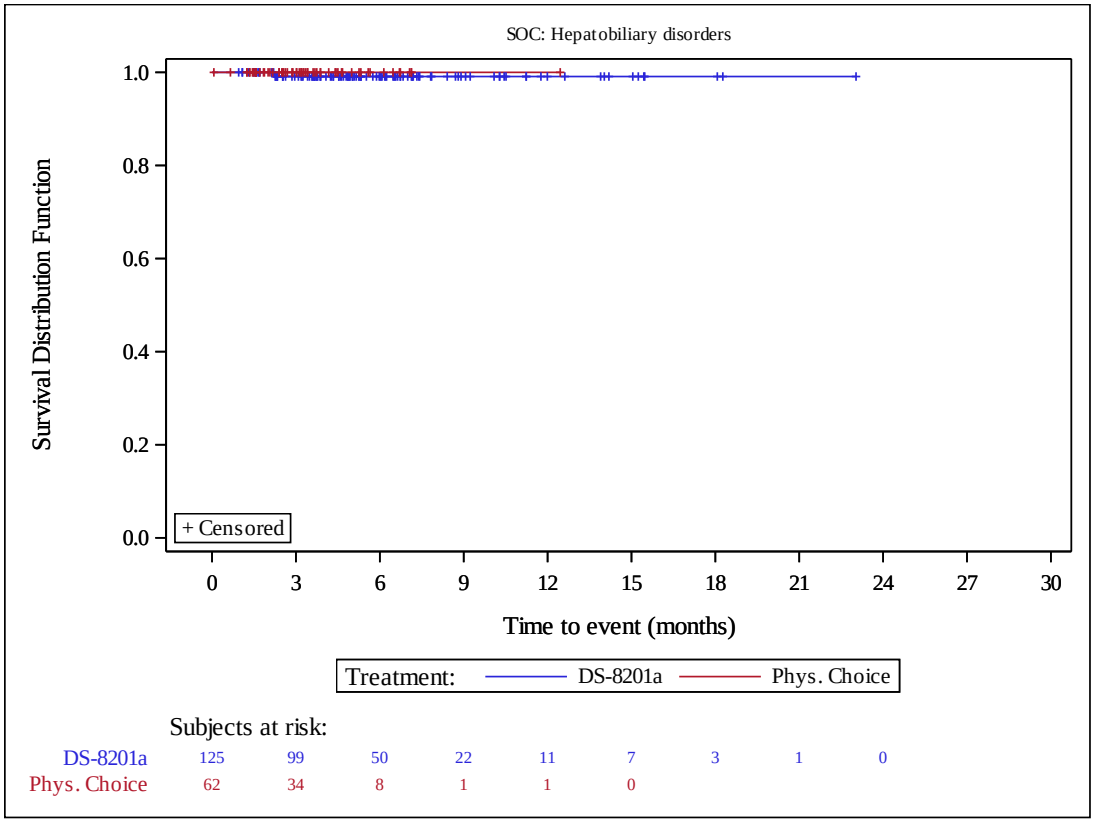
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
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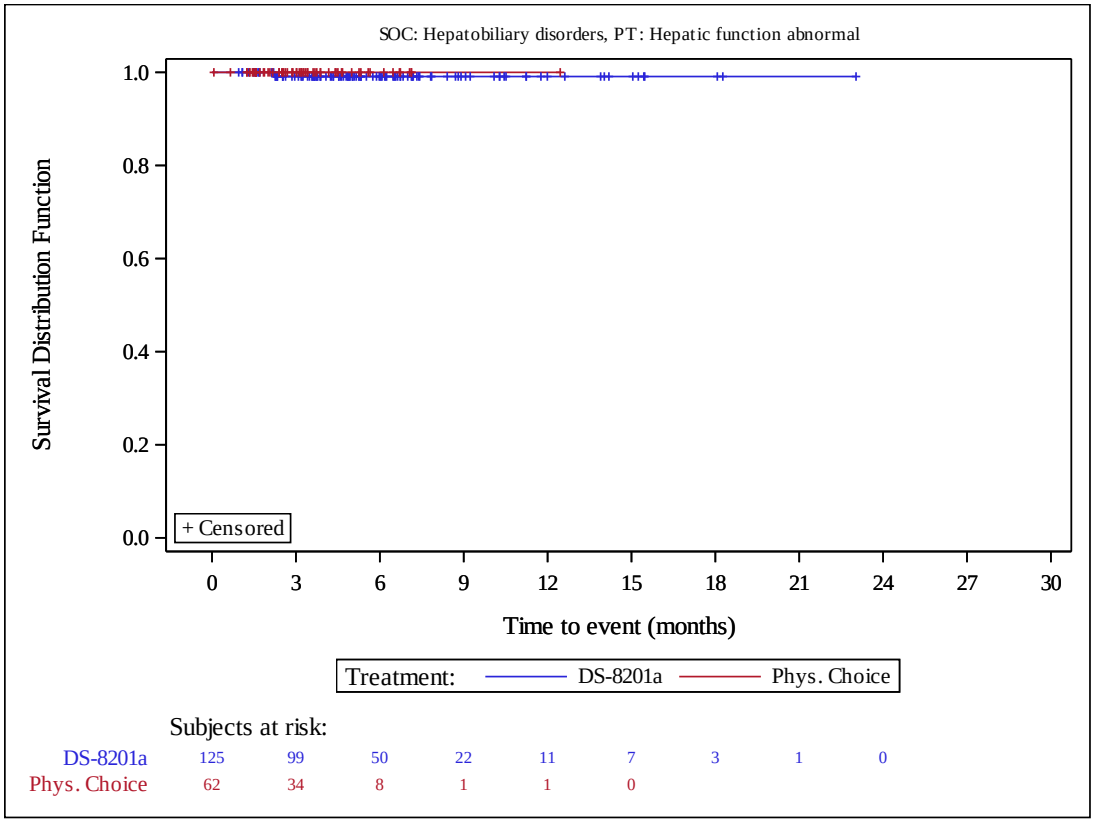
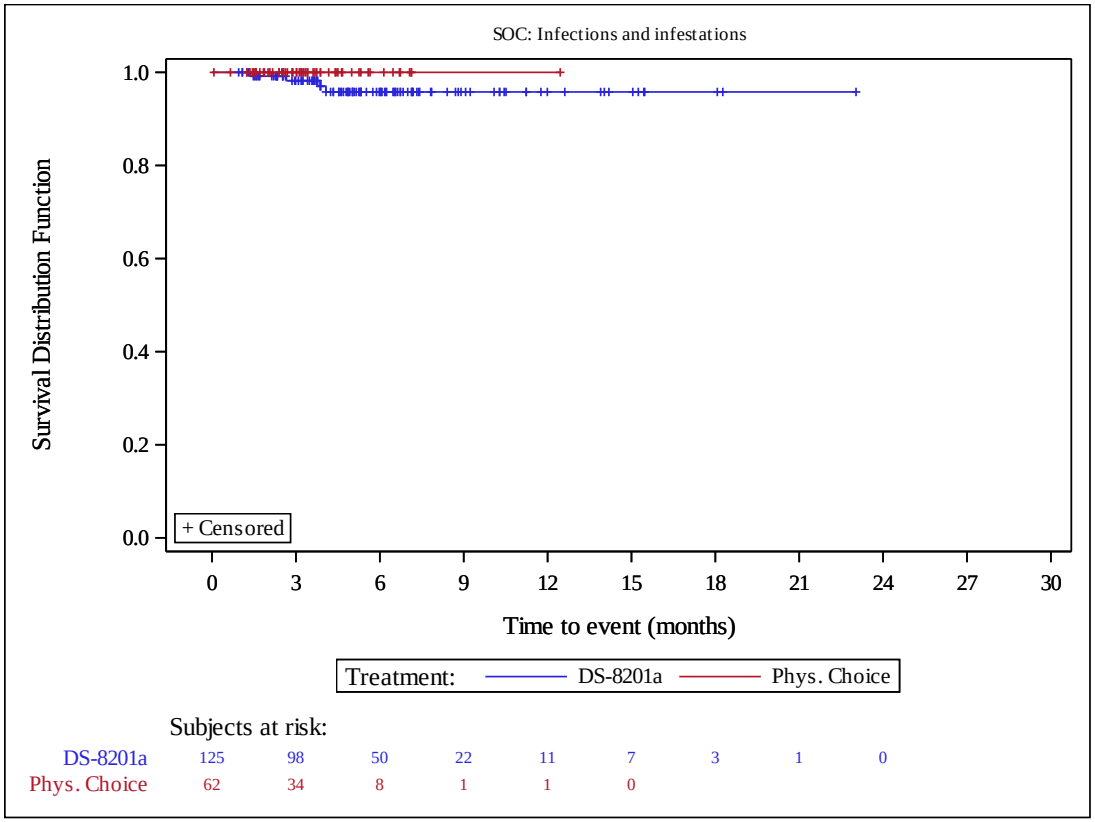
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



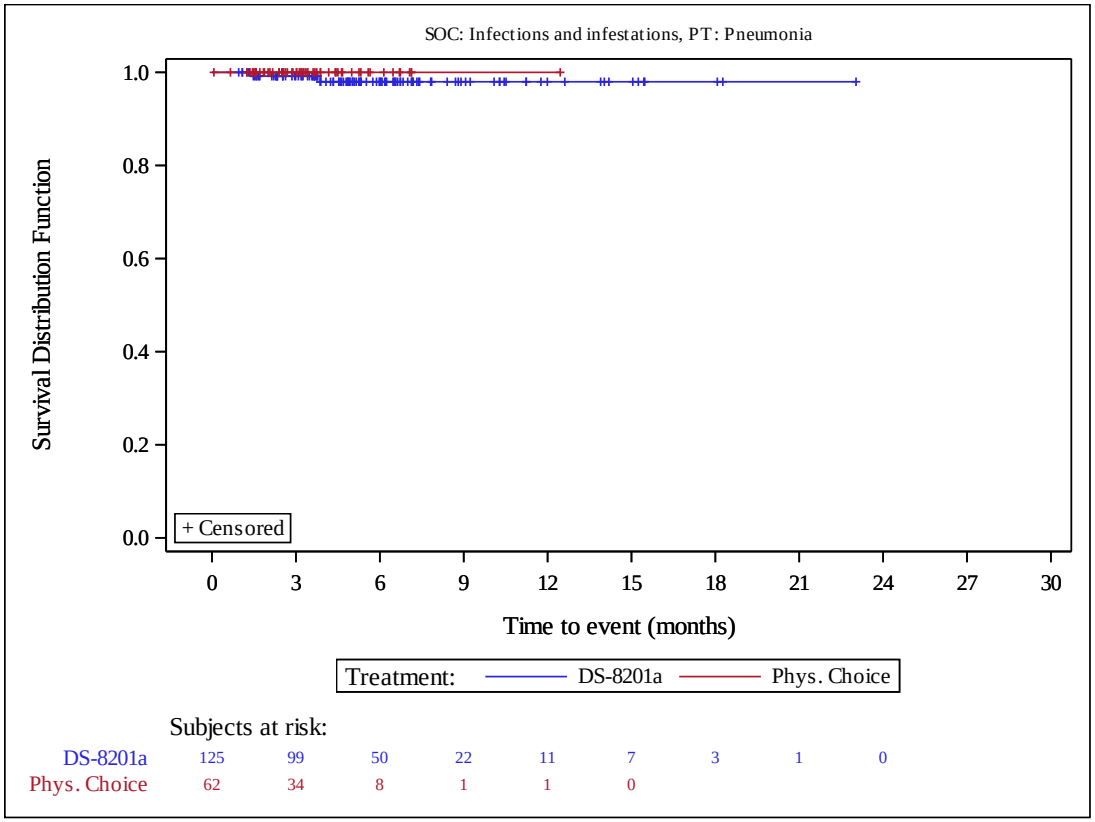
Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



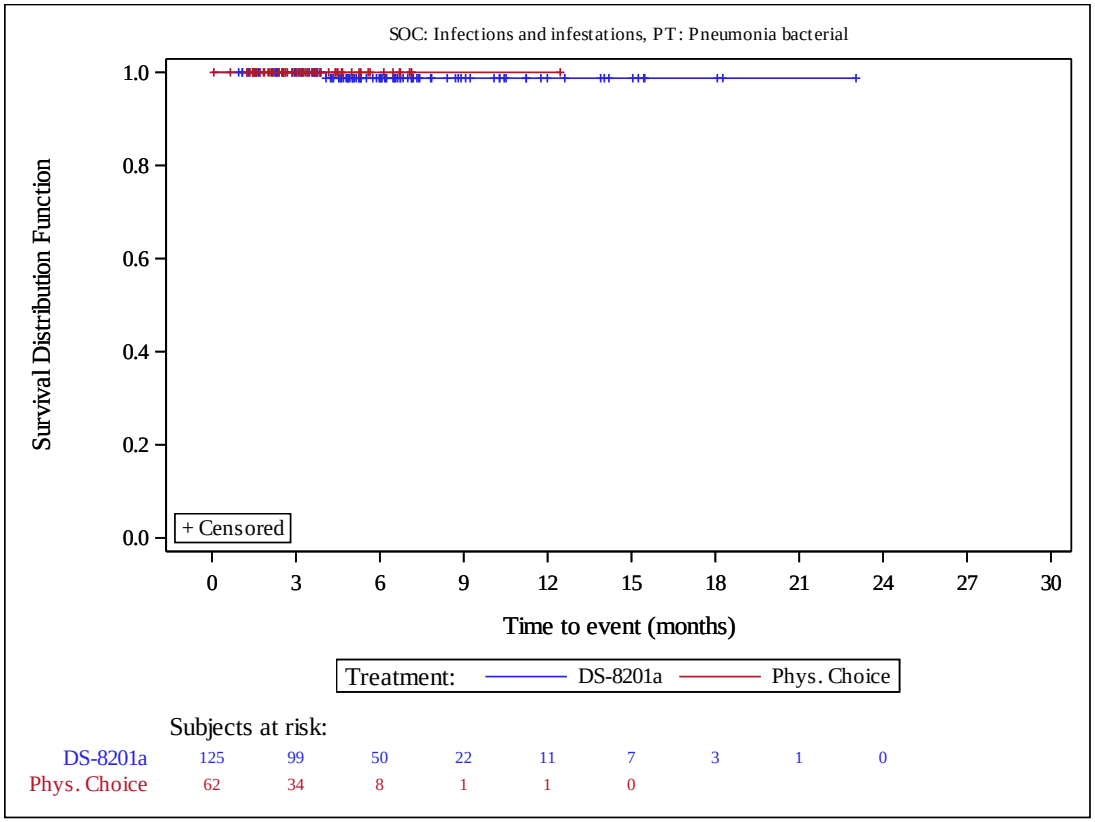
Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
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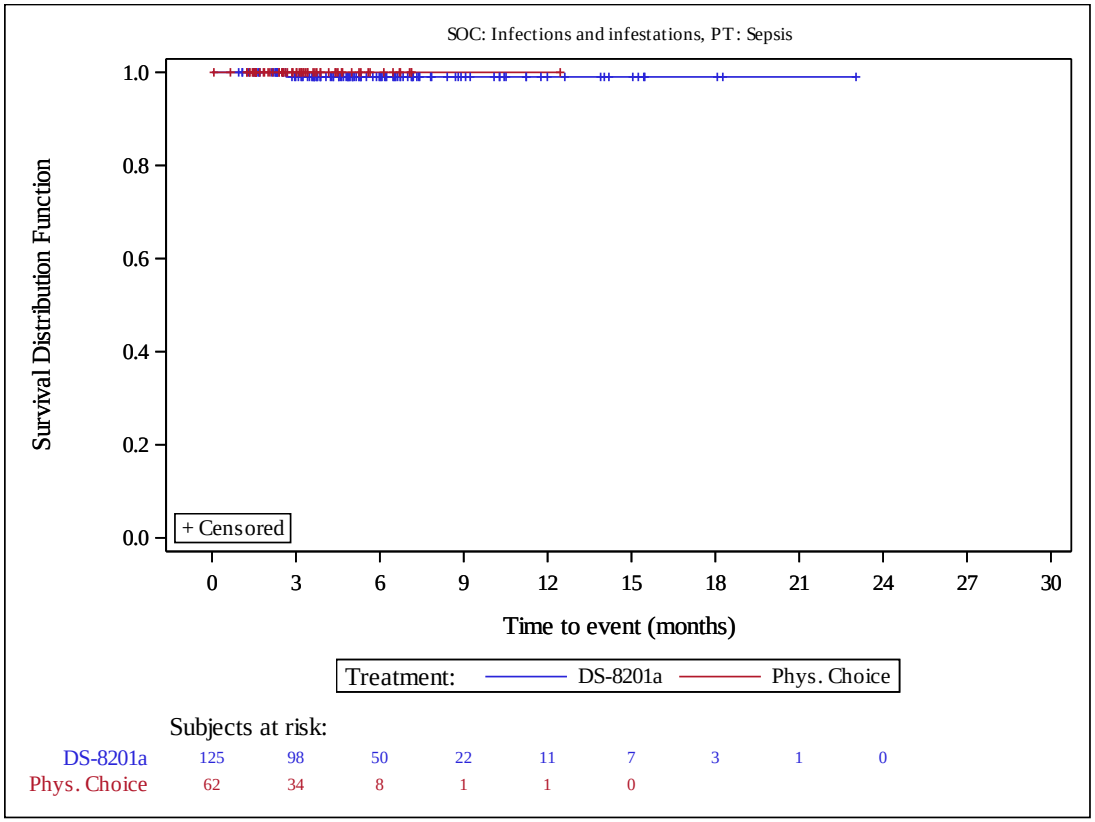
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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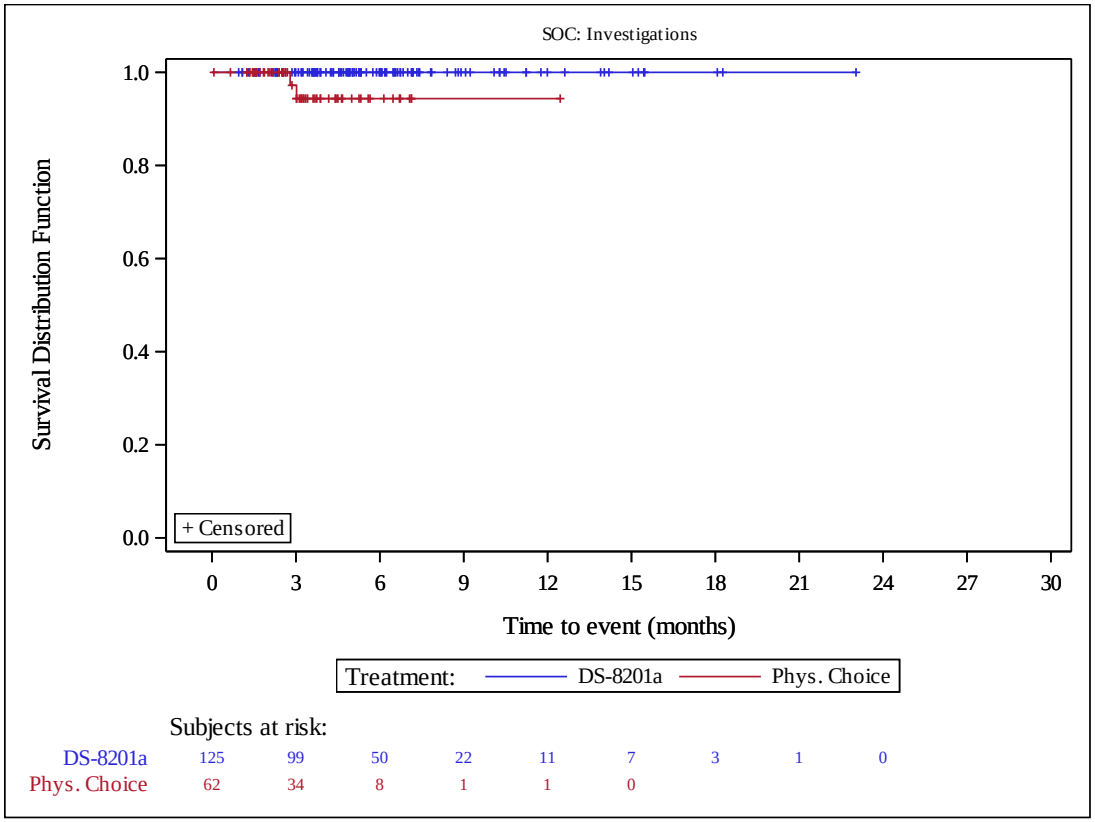
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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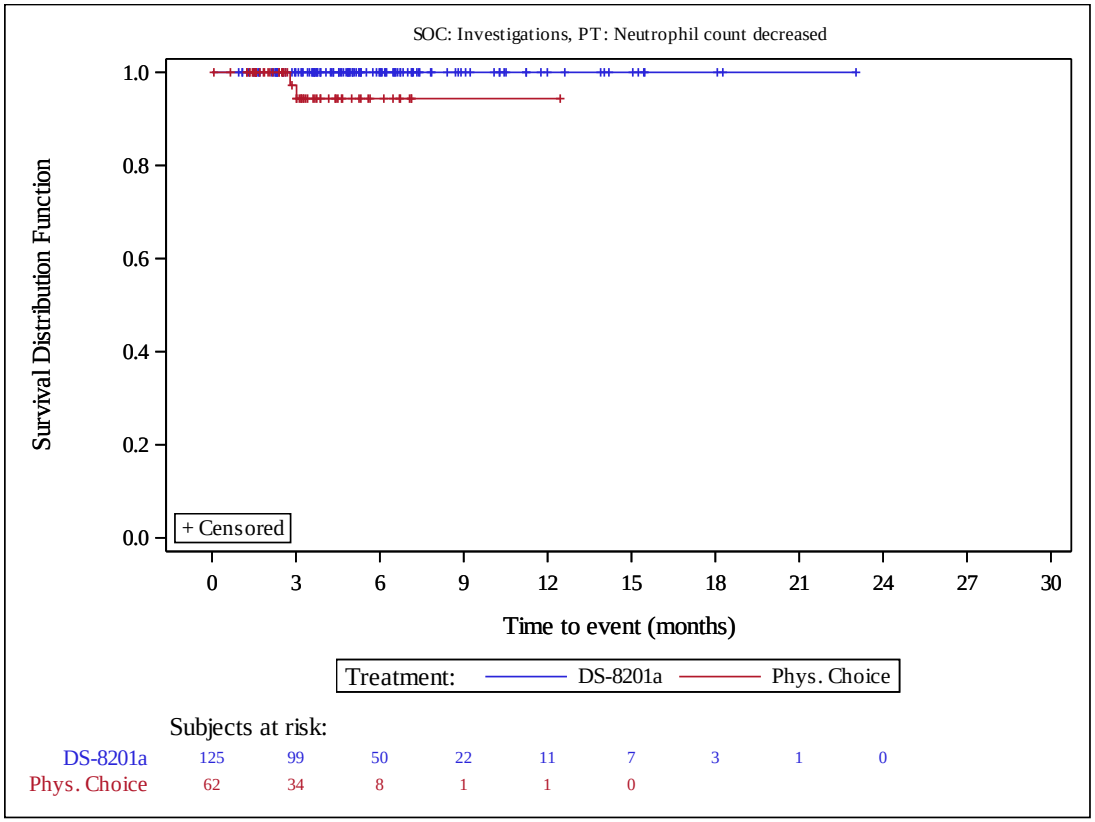
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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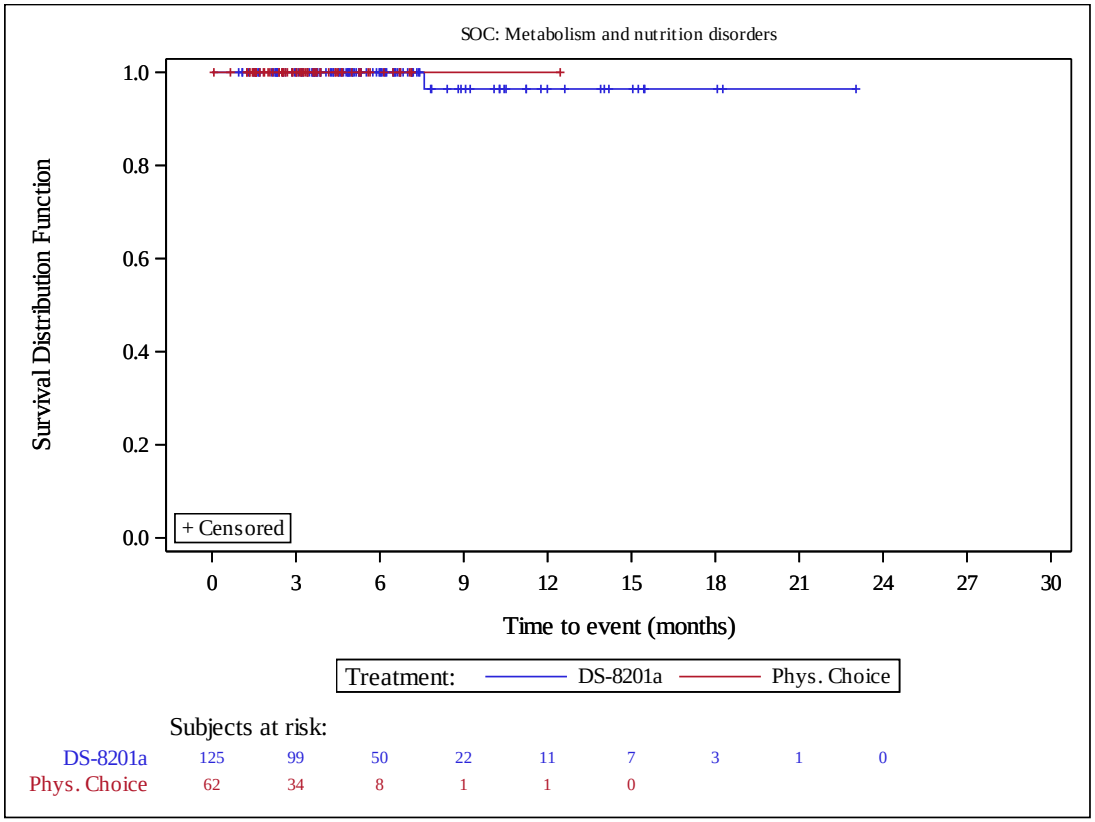
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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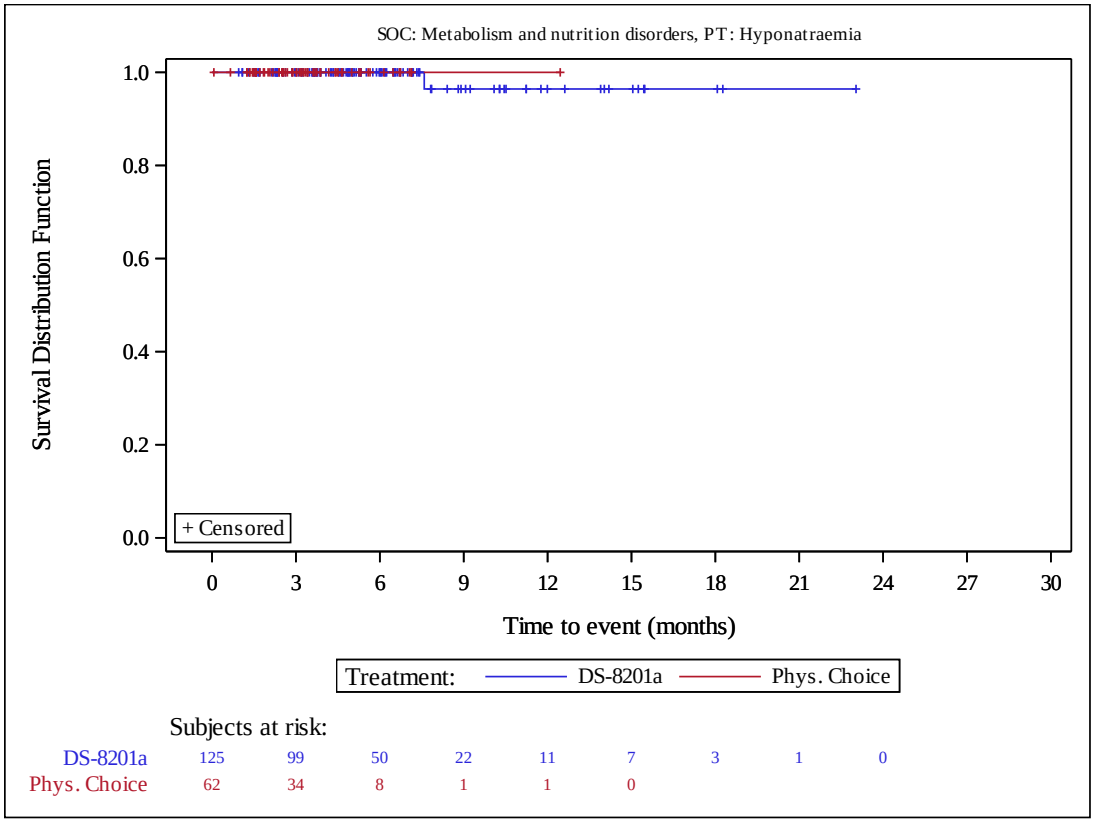
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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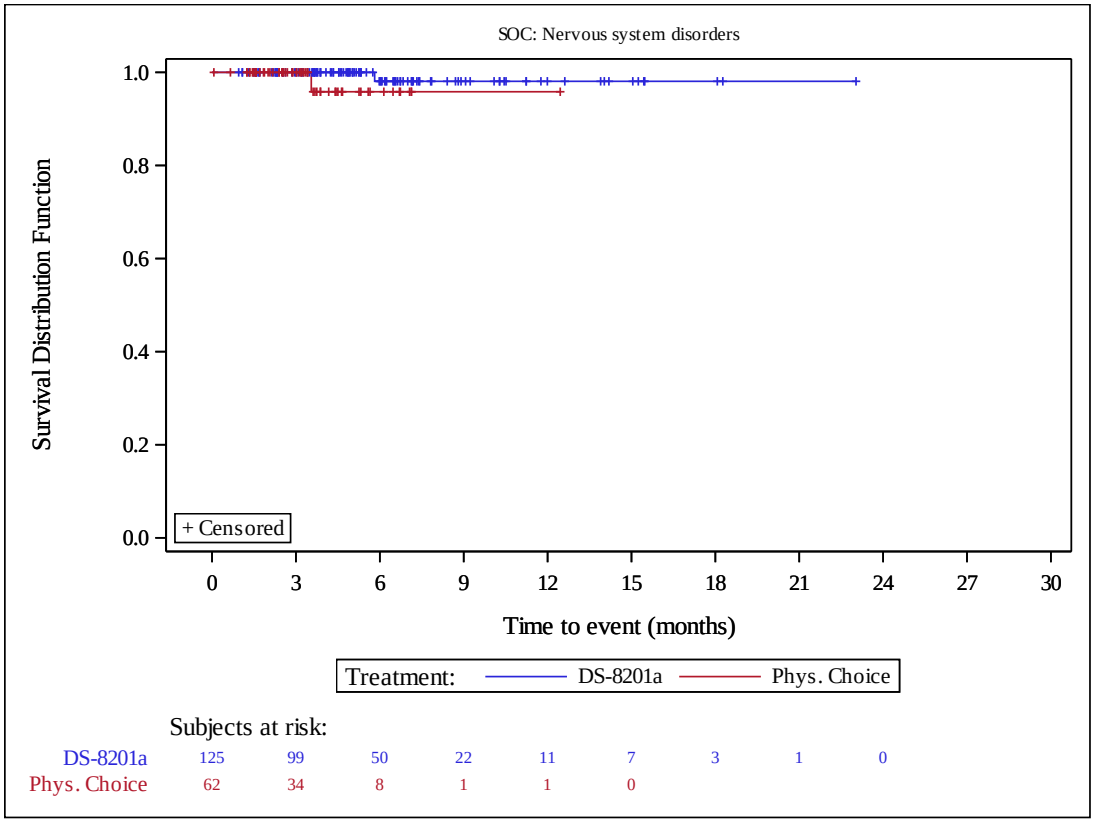
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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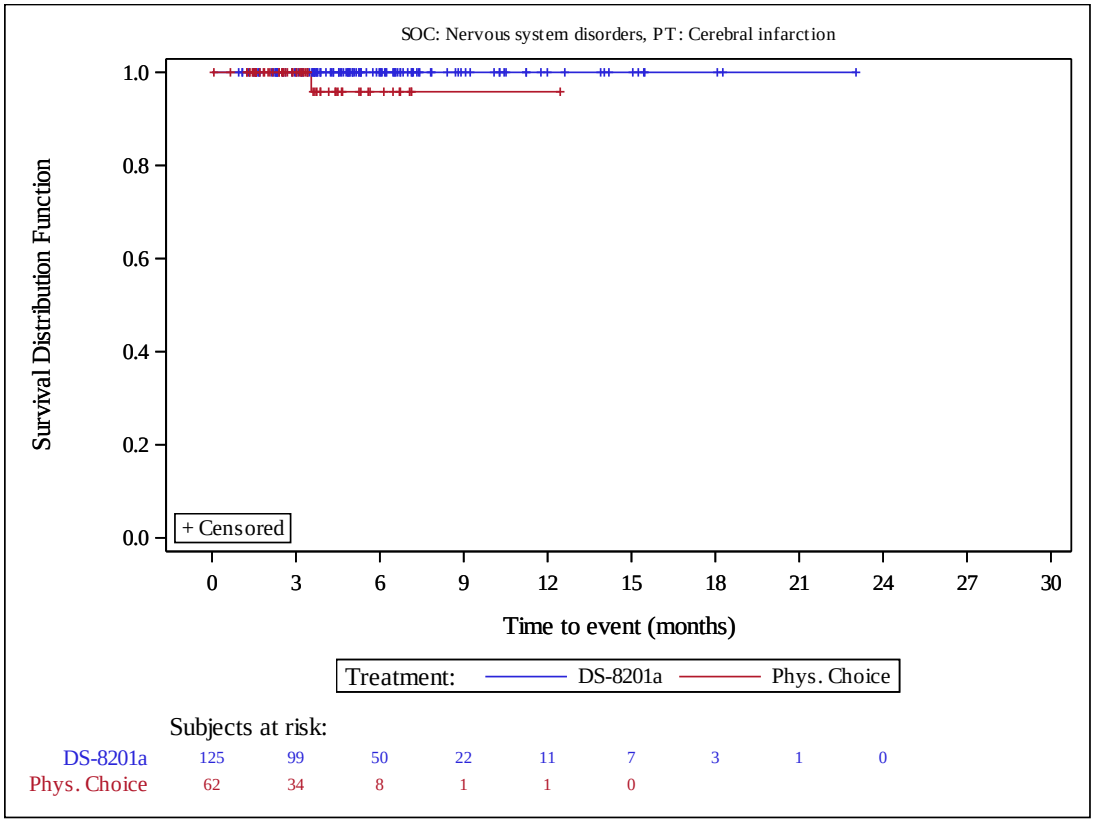
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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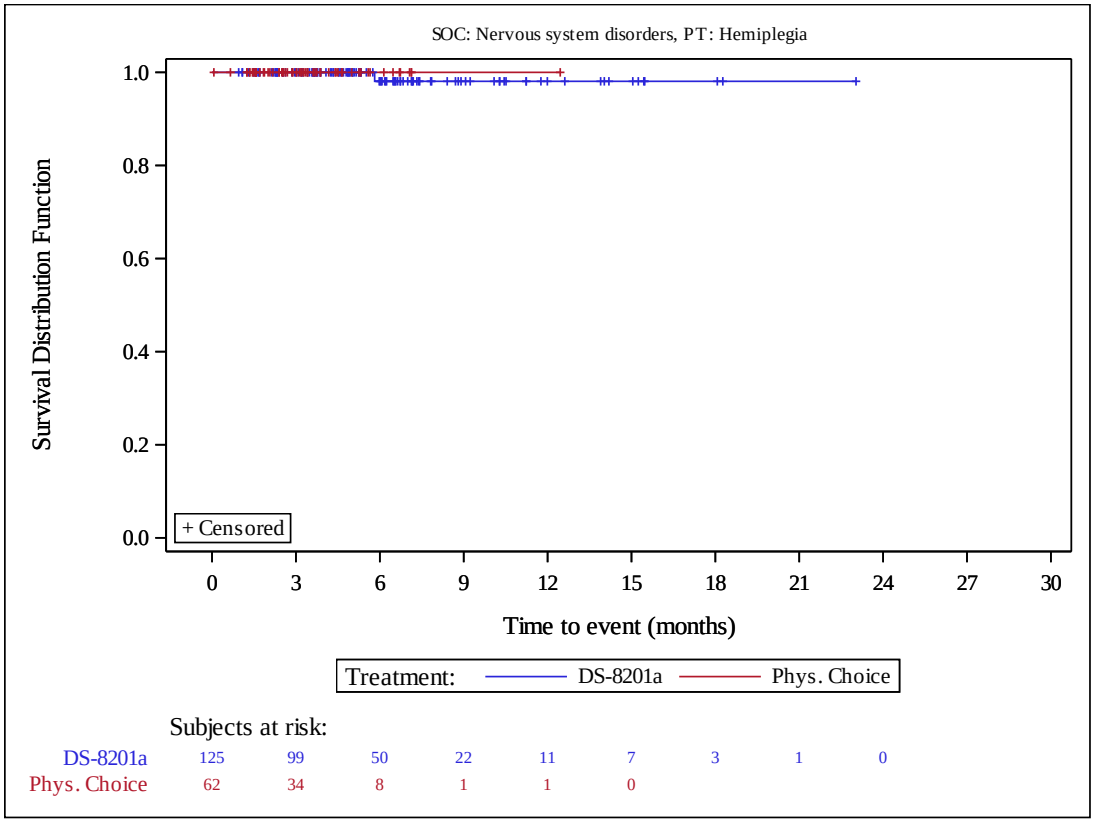
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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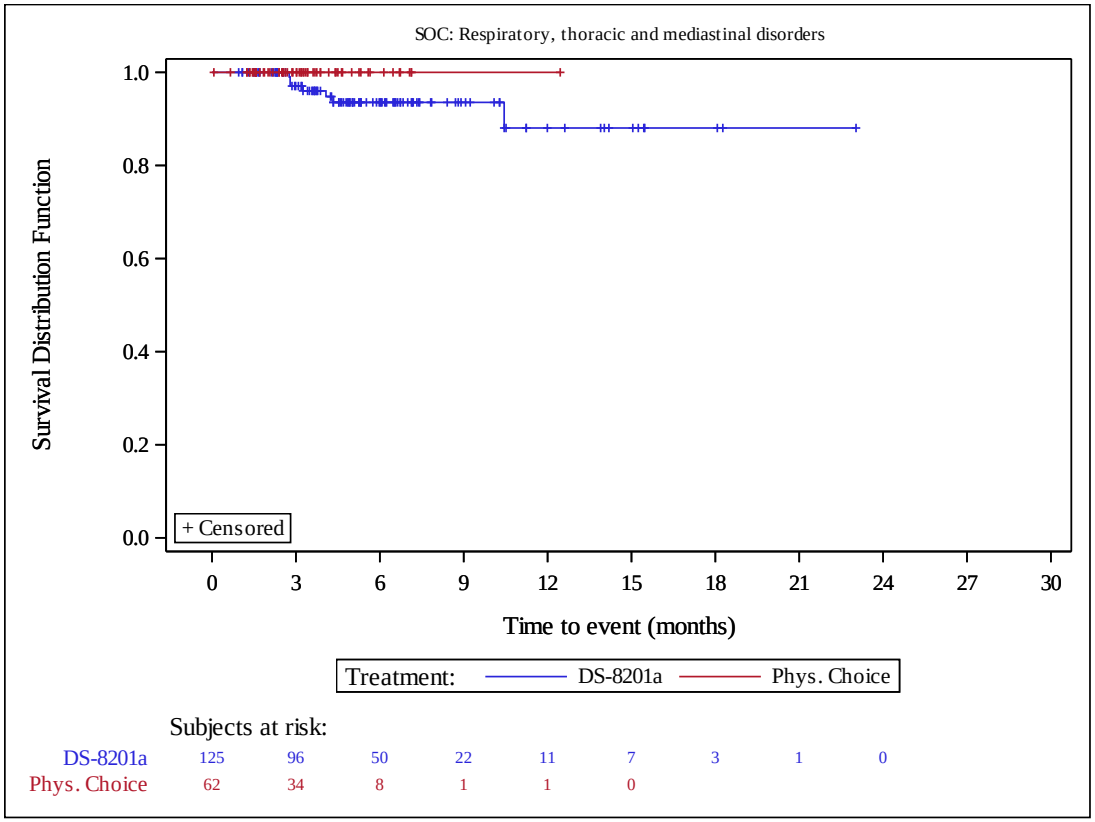
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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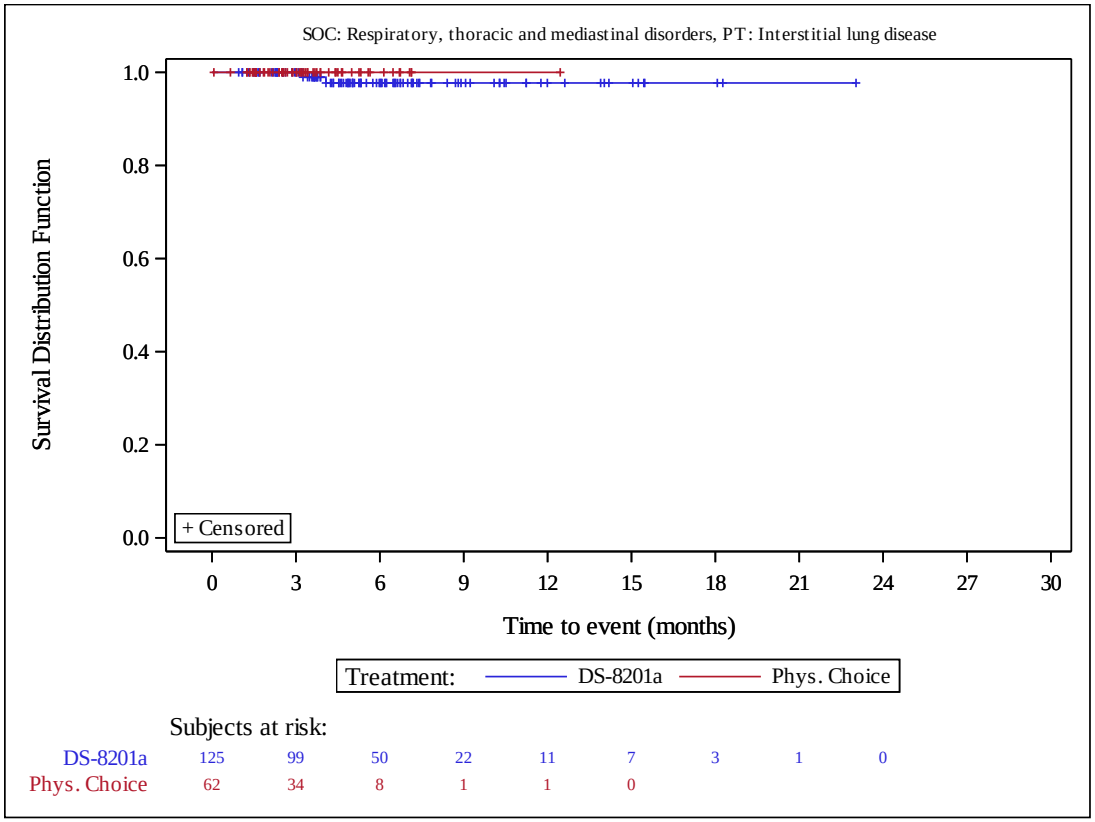
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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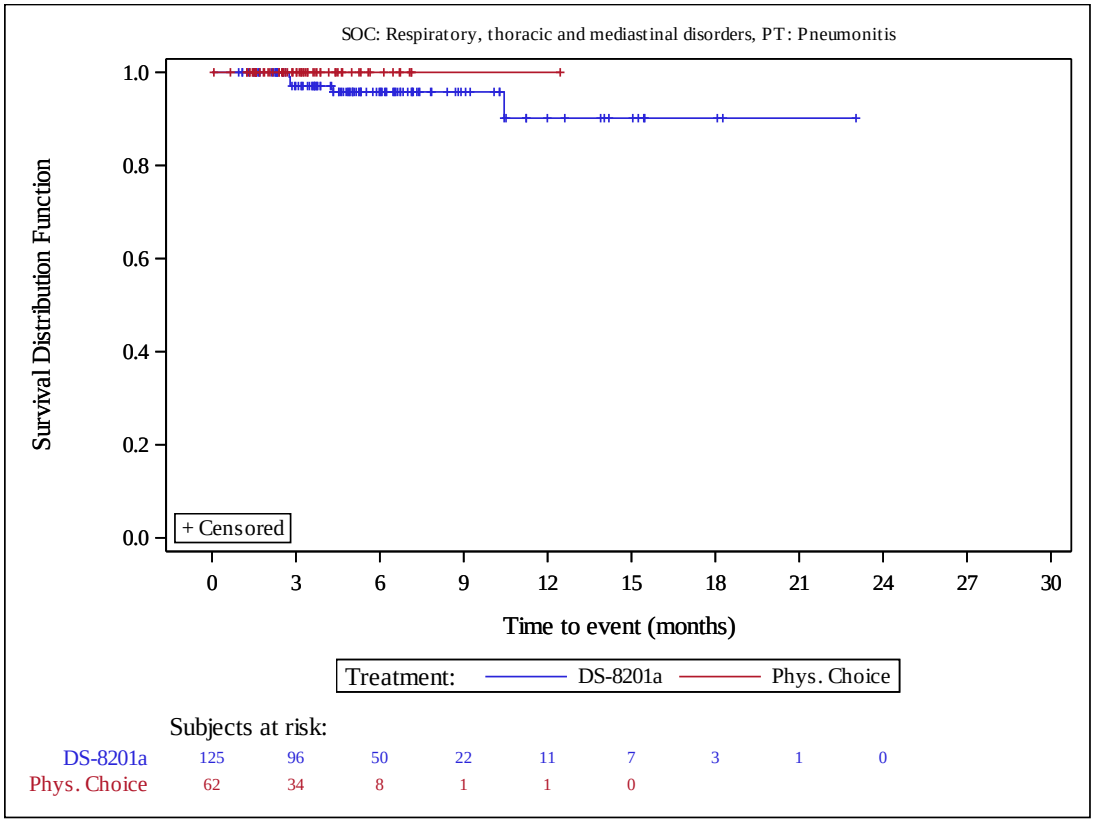
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2019)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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Anhang 4-G 1.2: Datenschnitt 03. Juni 2020

Anhang 4-G 1.2.1: Behandlungs- und Beobachtungsdauer

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Study duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Study duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	11.65 (6.204)	8.93 (5.566)
	Median	11.96	8.53
	Q1, Q3	6.47, 15.70	4.14, 12.16
	Min, Max	1.0, 29.7	0.3, 26.5

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to participation end date.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Treatment duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Treatment duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.71 (5.717)	3.18 (2.377)
	Median	4.60	2.76
	Q1, Q3	2.79, 8.71	1.51, 4.17
	Min, Max	0.7, 29.7	0.5, 13.1

Duration of follow-up (months) was derived applying descriptive statistics.
DS-8201a: Time from treatment start to last date of treatment + 21; Phys. Choice (Irinotecan): Time from treatment start to last date of treatment + 14; Phys. Choice (Paclitaxel): Time from treatment start to last date of treatment + 28, 21 or 14 for 1st, 2nd or 3rd dose in the last cycle, respectively.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Survival Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Overall Survival Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	11.65 (6.204)	8.93 (5.566)
	Median	11.96	8.53
	Q1, Q3	6.47, 15.70	4.14, 12.16
	Min, Max	1.0, 29.7	0.3, 26.5

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the date of death due to any cause or censoring of Overall Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Progression-free Survival Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Progression-free Survival Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.44 (5.598)	2.72 (1.908)
	Median	4.44	2.25
	Q1, Q3	2.79, 8.25	1.38, 4.11
	Min, Max	0.0, 29.5	0.0, 7.0

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the earliest date of the first objective documentation of disease progression, death due to any cause or censoring of Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Duration of Confirmed Response Follow-up duration (months) - for responders only
Full Analysis Set

		DS-8201a (N=50)	Phys. Choice (N=7)
Duration of Confirmed Response Follow-up duration (months)	n (missing)	50 (0)	7 (0)
	Mean (SD)	8.65 (6.390)	3.44 (1.166)
	Median	5.63	3.94
	Q1, Q3	3.91, 12.02	2.63, 4.21
	Min, Max	1.4, 28.1	1.4, 4.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression, death due to any cause or censoring of Duration of Confirmed Response.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Duration of Response Follow-up duration (months) - for responders only
Full Analysis Set

		DS-8201a (N=61)	Phys. Choice (N=8)
Duration of Response Follow-up duration (months)	n (missing)	61 (0)	8 (0)
	Mean (SD)	7.29 (6.495)	3.01 (1.616)
	Median	5.49	3.48
	Q1, Q3	2.76, 11.10	2.02, 4.07
	Min, Max	0.0, 28.1	0.0, 4.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression, death due to any cause or censoring of Duration of Response.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Time to Confirmed Response Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Time to Confirmed Response Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	3.00 (2.297)	2.34 (1.671)
	Median	2.66	1.68
	Q1, Q3	1.45, 3.65	1.38, 2.83
	Min, Max	0.0, 15.2	0.0, 7.0

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR or censoring the same way as for Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Time to Response Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Time to Response Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	2.90 (2.302)	2.34 (1.671)
	Median	2.40	1.68
	Q1, Q3	1.41, 3.35	1.38, 2.83
	Min, Max	0.0, 15.2	0.0, 7.0

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR or censoring the same way as for Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Measureable Tumors based on ICR Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Measureable Tumors based on ICR Follow-up duration (months)	n (missing)	119 (6)	56 (6)
	Mean (SD)	6.38 (5.712)	2.73 (1.807)
	Median	4.40	2.63
	Q1, Q3	2.76, 7.13	1.38, 4.09
	Min, Max	0.0, 29.5	0.0, 7.0

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing tumor assessment. Subjects with assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
EQ-5D VAS score Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
EQ-5D VAS score Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.46 (5.652)	2.97 (2.424)
	Median	4.34	2.76
	Q1, Q3	2.76, 8.44	1.41, 4.17
	Min, Max	0.0, 29.0	0.0, 12.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Fact-Ga Total Score Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Fact-Ga Total Score Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.45 (5.658)	3.00 (2.403)
	Median	4.34	2.76
	Q1, Q3	2.76, 8.44	1.41, 4.17
	Min, Max	0.0, 29.0	0.0, 12.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Physical Well-being Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Physical Well-being Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.46 (5.652)	3.00 (2.403)
	Median	4.34	2.76
	Q1, Q3	2.76, 8.44	1.41, 4.17
	Min, Max	0.0, 29.0	0.0, 12.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Social/Family Well-being Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Social/Family Well-being Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.45 (5.658)	3.00 (2.403)
	Median	4.34	2.76
	Q1, Q3	2.76, 8.44	1.41, 4.17
	Min, Max	0.0, 29.0	0.0, 12.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Emotional Well-being Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Emotional Well-being Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.45 (5.658)	3.00 (2.403)
	Median	4.34	2.76
	Q1, Q3	2.76, 8.44	1.41, 4.17
	Min, Max	0.0, 29.0	0.0, 12.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Functional Well-being Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Functional Well-being Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.45 (5.658)	3.00 (2.403)
	Median	4.34	2.76
	Q1, Q3	2.76, 8.44	1.41, 4.17
	Min, Max	0.0, 29.0	0.0, 12.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Gastric Cancer Symptom (GaCS) Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Gastric Cancer Symptom (GaCS) Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.45 (5.658)	3.00 (2.403)
	Median	4.34	2.76
	Q1, Q3	2.76, 8.44	1.41, 4.17
	Min, Max	0.0, 29.0	0.0, 12.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Fact-G Total Score Follow-up duration (months)
Full Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Fact-G Total Score Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	6.45 (5.658)	3.00 (2.403)
	Median	4.34	2.76
	Q1, Q3	2.76, 8.44	1.41, 4.17
	Min, Max	0.0, 29.0	0.0, 12.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Safety Follow-up duration (months)
Safety Analysis Set

		DS-8201a (N=125)	Phys. Choice (N=62)
Safety Follow-up duration (months)	n (missing)	125 (0)	62 (0)
	Mean (SD)	7.19 (5.553)	3.62 (2.411)
	Median	5.16	3.15
	Q1, Q3	3.48, 9.59	1.87, 4.50
	Min, Max	1.0, 29.7	0.1, 13.3

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to death date, last date of treatment (last dose of study drug) + 47 days, start of new anti-cancer therapy or last contact date, whichever occured earlier.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADEQ5D, ADAM.ADFACTG and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 07JUN2022

Anhang 4-G 1.2.2: Mortalität

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Overall Survival
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	84 (67.2)	49 (79.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	12.5 (10.3, 15.2)	8.9 (6.4, 10.4)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	92.7 (86.5, 96.2)	90.0 (79.1, 95.4)
6 Months (95% CI)	80.7 (72.5, 86.6)	65.0 (51.5, 75.6)
9 Months (95% CI)	63.7 (54.6, 71.5)	50.0 (36.8, 61.8)
12 Months (95% CI)	52.2 (43.1, 60.6)	29.7 (18.7, 41.5)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.60 (0.42, 0.86)	
p-value [c]	0.0051	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.60 (0.42, 0.86)	
p-value [c]	0.0049	

Overall Survival (OS) is defined as the time from the date of randomization to the date of death due to any cause. See SAP for the handling of censored cases.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Overall Survival - Subgroup analysis
Full Analysis Set

Subgroup	DS-8201a (N=125)		Phys. Choice (N=62)		Analysis DS-8201a vs. Phys. Choice			Interaction
Level	n/ N (%)	Median (95% CI) [a]	n/ N (%)	Median (95% CI) [a]	Hazard Ratio (95% CI) [b]		p-Value [c]	p-value [d]
Region								0.6851
Japan	65/ 99 (65.7)	12.5 (10.3, 15.6)	39/ 50 (78.0)	8.5 (5.7, 10.8)	0.62 (0.42,	0.93)	0.0198	
Korea	19/ 26 (73.1)	12.0 (5.9, 16.4)	10/ 12 (83.3)	9.2 (3.6, 10.4)	0.53 (0.24,	1.16)	0.1064	
Lines of prior systemic therapy								0.1160
2	47/ 66 (71.2)	10.8 (8.6, 12.8)	29/ 38 (76.3)	9.3 (5.8, 13.4)	0.85 (0.54,	1.36)	0.5013	
3	21/ 34 (61.8)	16.6 (8.2, 19.3)	15/ 18 (83.3)	8.1 (4.9, 9.5)	0.38 (0.19,	0.76)	0.0048	
>=4	16/ 25 (64.0)	15.4 (9.6, 18.2)	5/ 6 (83.3)	6.9 (1.6, NE)	0.49 (0.18,	1.36)	0.1628	
Age								0.2640
<65 years	38/ 55 (69.1)	12.1 (8.6, 17.0)	20/ 27 (74.1)	10.2 (7.0, 14.3)	0.76 (0.44,	1.31)	0.3281	
>=65 years	46/ 70 (65.7)	12.8 (9.1, 15.4)	29/ 35 (82.9)	7.2 (4.9, 9.2)	0.49 (0.31,	0.79)	0.0027	
Sex								0.5774
female	23/ 30 (76.7)	9.1 (5.9, 12.6)	14/ 15 (93.3)	9.1 (3.3, 10.7)	0.73 (0.37,	1.43)	0.3589	
male	61/ 95 (64.2)	13.8 (11.5, 16.4)	35/ 47 (74.5)	8.4 (5.8, 10.5)	0.58 (0.38,	0.88)	0.0101	
ECOG PS								0.8045
0	37/ 62 (59.7)	15.6 (10.8, 19.3)	23/ 30 (76.7)	9.5 (7.1, 11.7)	0.55 (0.33,	0.93)	0.0247	
1	47/ 63 (74.6)	11.5 (7.3, 13.9)	26/ 32 (81.3)	7.6 (4.2, 10.4)	0.63 (0.39,	1.02)	0.0591	
HER2 Status in central laboratory								0.0136
IHC 3+	60/ 96 (62.5)	12.8 (10.8, 16.4)	38/ 47 (80.9)	8.6 (5.8, 10.4)	0.47 (0.31,	0.71)	0.0003	
IHC 2+/ISH +	24/ 29 (82.8)	10.1 (5.4, 13.1)	11/ 15 (73.3)	9.2 (3.9, 20.0)	1.48 (0.70,	3.16)	0.3052	
Primary tumor location								0.8694
Gastric	73/108 (67.6)	12.0 (9.1, 14.4)	43/ 55 (78.2)	8.4 (5.8, 9.9)	0.60 (0.41,	0.88)	0.0088	
GEJ	11/ 17 (64.7)	15.2 (8.2, NE)	6/ 7 (85.7)	13.6 (3.4, 19.0)	0.64 (0.23,	1.76)	0.3825	
Histological subtype								0.2121
intestinal	59/ 89 (66.3)	12.8 (10.8, 15.6)	30/ 38 (78.9)	9.3 (6.4, 13.4)	0.66 (0.42,	1.02)	0.0597	
diffuse	19/ 28 (67.9)	12.6 (6.5, 17.0)	15/ 18 (83.3)	7.1 (3.4, 9.5)	0.43 (0.21,	0.88)	0.0178	
others	6/ 8 (75.0)	7.2 (1.0, NE)	4/ 6 (66.7)	9.9 (3.0, 17.1)	1.25 (0.35,	4.49)	0.7302	
Number of metastatic sites								0.8166
<2	12/ 23 (52.2)	17.6 (11.5, NE)	7/ 10 (70.0)	9.3 (3.0, NE)	0.56 (0.22,	1.43)	0.2189	
>= 2	72/102 (70.6)	11.9 (8.6, 14.3)	42/ 52 (80.8)	8.9 (5.7, 10.4)	0.62 (0.42,	0.91)	0.0130	
Previous total gastrectomy								0.0194
yes	13/ 22 (59.1)	15.6 (7.7, NE)	9/ 9 (100.0)	8.4 (1.6, 10.7)	0.17 (0.06,	0.50)	0.0003	
no	71/103 (68.9)	11.5 (9.1, 14.3)	40/ 53 (75.5)	9.2 (5.8, 10.8)	0.72 (0.49,	1.06)	0.0951	
Prior adjuvant/ neoadjuvant therapy								0.0390
yes	15/ 30 (50.0)	15.7 (12.5, NE)	9/ 10 (90.0)	7.9 (1.6, 11.7)	0.23 (0.10,	0.55)	0.0003	
no	69/ 95 (72.6)	10.6 (8.3, 13.0)	40/ 52 (76.9)	9.1 (6.4, 10.5)	0.74 (0.50,	1.10)	0.1381	
Prior ramucirumab contained treatment								0.7964
yes	62/ 94 (66.0)	12.0 (9.0, 15.4)	33/ 41 (80.5)	8.4 (5.7, 10.5)	0.58 (0.38,	0.89)	0.0116	
no	22/ 31 (71.0)	13.8 (9.1, 16.4)	16/ 21 (76.2)	9.3 (5.7, 14.3)	0.62 (0.32,	1.21)	0.1581	

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NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

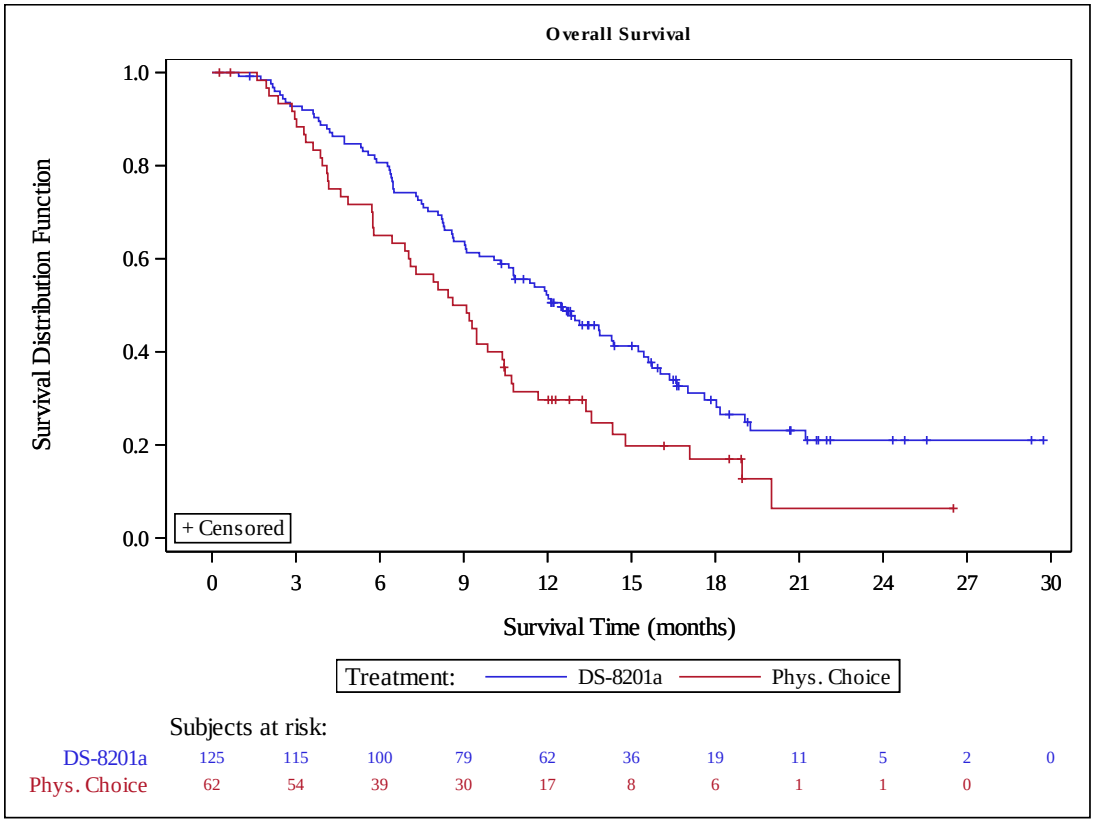
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Overall Survival - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.0143
yes	18/ 33 (54.5)	18.0 (12.5, 21.2)	14/ 15 (93.3)	8.6 (3.4, 10.4)	0.27 (0.13, 0.56)	0.0002	
no	66/ 92 (71.7)	10.8 (8.6, 13.0)	35/ 47 (74.5)	9.1 (6.9, 10.8)	0.79 (0.53, 1.20)	0.2693	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0234
yes	25/ 44 (56.8)	17.0 (12.5, 21.2)	15/ 17 (88.2)	8.6 (3.6, 10.7)	0.34 (0.17, 0.65)	0.0007	
no	59/ 81 (72.8)	10.6 (8.2, 13.0)	34/ 45 (75.6)	9.1 (6.9, 10.8)	0.82 (0.53, 1.25)	0.3476	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.4215
yes	15/ 22 (68.2)	10.8 (6.3, 19.1)	5/ 7 (71.4)	9.5 (6.9, NE)	0.86 (0.31, 2.41)	0.7732	
no	69/103 (67.0)	12.6 (10.1, 15.4)	44/ 55 (80.0)	8.6 (5.7, 10.5)	0.57 (0.39, 0.84)	0.0036	
Presence of liver metastasis at baseline							0.7532
yes	48/ 68 (70.6)	10.8 (8.3, 14.4)	29/ 34 (85.3)	7.1 (4.6, 10.4)	0.58 (0.36, 0.92)	0.0189	
no	36/ 57 (63.2)	13.9 (10.8, 16.4)	20/ 28 (71.4)	9.5 (5.8, 13.6)	0.65 (0.38, 1.13)	0.1265	
Renal impairment at baseline							0.5135
normal	24/ 33 (72.7)	12.0 (8.6, 18.2)	12/ 13 (92.3)	9.5 (3.4, 10.4)	0.45 (0.21, 0.94)	0.0293	
mild	39/ 53 (73.6)	11.5 (8.3, 15.6)	21/ 28 (75.0)	7.1 (4.1, 13.6)	0.77 (0.45, 1.32)	0.3403	
moderate	21/ 39 (53.8)	14.4 (7.3, NE)	15/ 20 (75.0)	8.4 (5.7, 11.7)	0.56 (0.29, 1.10)	0.0863	
severe	0	NE (NE , NE)	1/ 1 (100.0)	3.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7919
normal	57/ 88 (64.8)	13.8 (10.8, 16.0)	37/ 47 (78.7)	9.3 (7.1, 10.7)	0.56 (0.37, 0.85)	0.0056	
mild	26/ 36 (72.2)	8.6 (6.3, 15.4)	12/ 15 (80.0)	5.7 (2.0, 10.4)	0.64 (0.32, 1.29)	0.2101	
moderate	1/ 1 (100.0)	7.5 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.5709
yes	6/ 8 (75.0)	12.2 (5.8, NE)	3/ 5 (60.0)	14.3 (2.0, NE)	0.99 (0.25, 3.99)	0.9900	
no	78/117 (66.7)	12.6 (10.1, 15.4)	46/ 57 (80.7)	8.6 (6.4, 10.4)	0.59 (0.41, 0.85)	0.0040	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.1848
yes	3/ 3 (100.0)	12.0 (9.1, 15.2)	2/ 4 (50.0)	14.3 (3.4, NE)	1.99 (0.33, 12.10)	0.4456	
no	81/122 (66.4)	12.6 (10.3, 15.4)	47/ 58 (81.0)	8.5 (6.4, 9.9)	0.57 (0.40, 0.82)	0.0020	

Overall Survival (OS) is defined as the time from the date of randomization to the date of death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

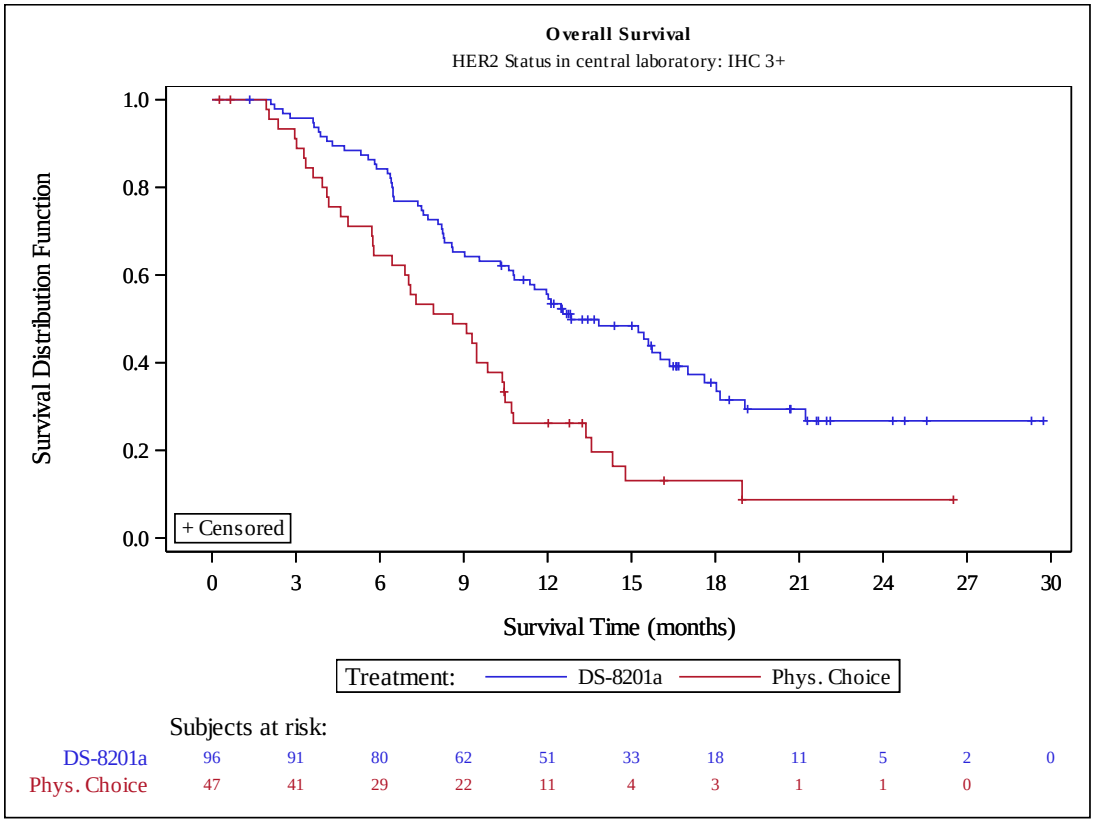
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



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Daiichi Sankyo

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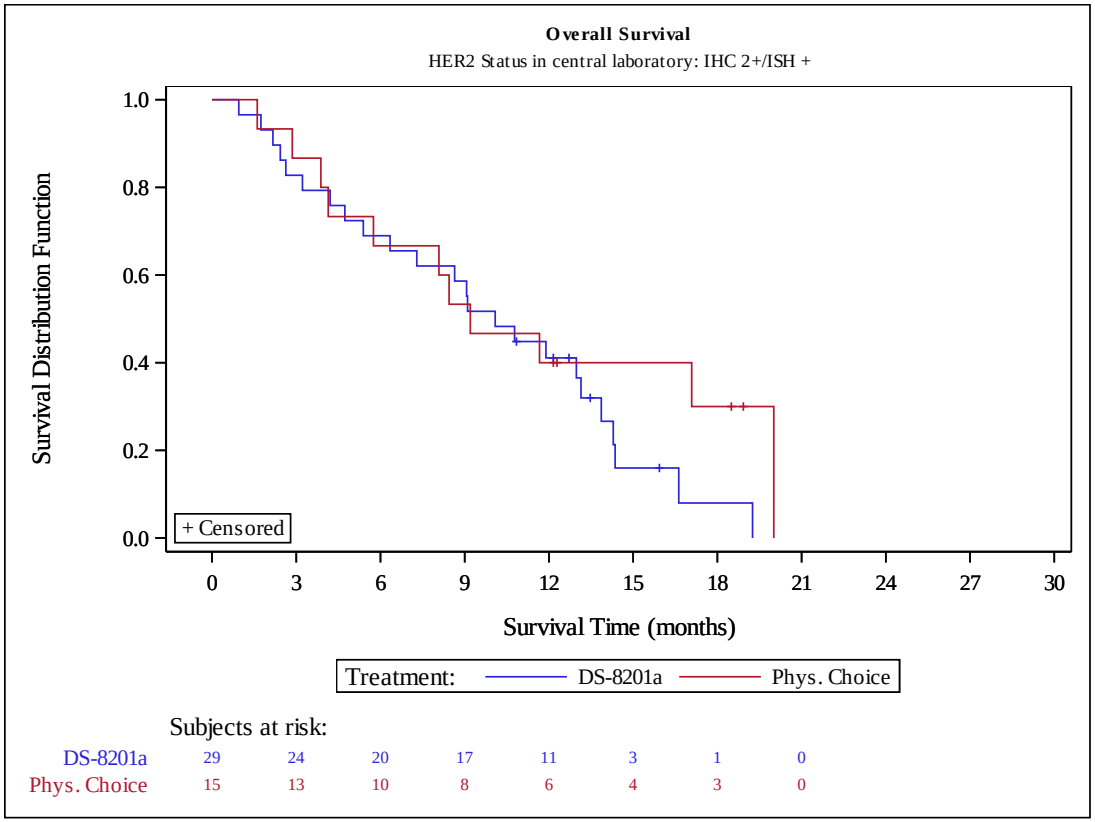
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

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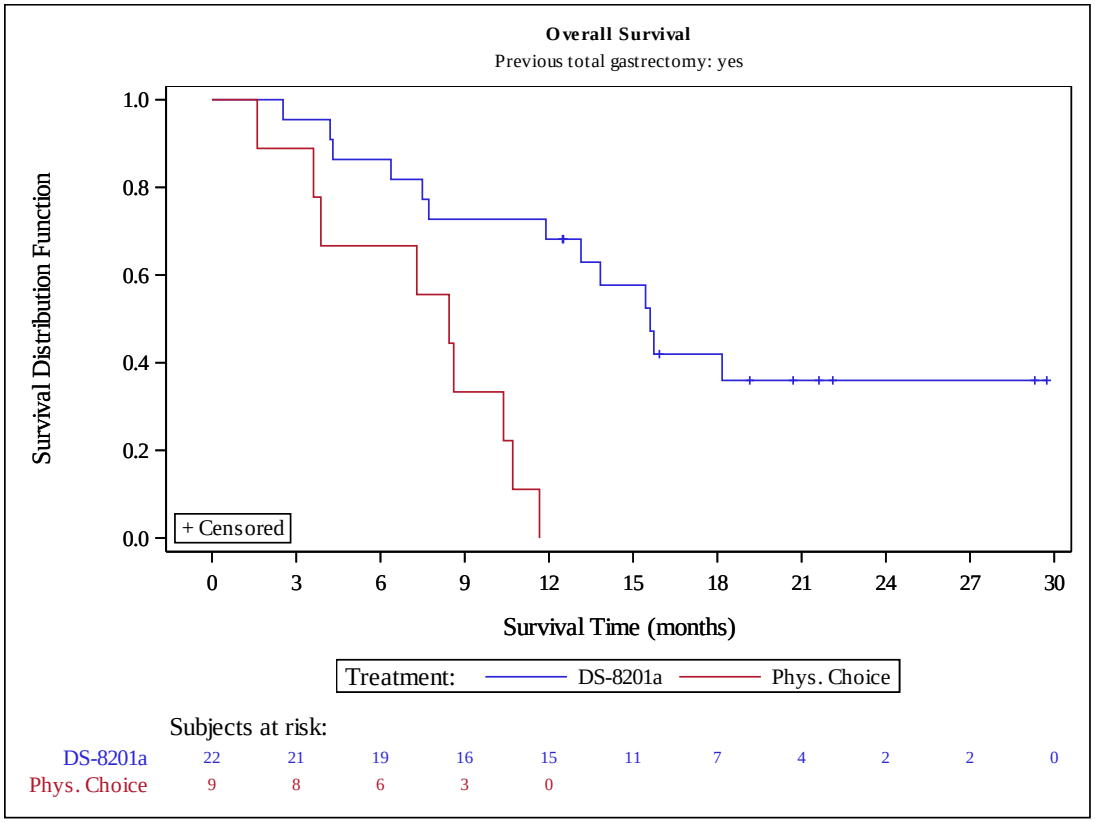
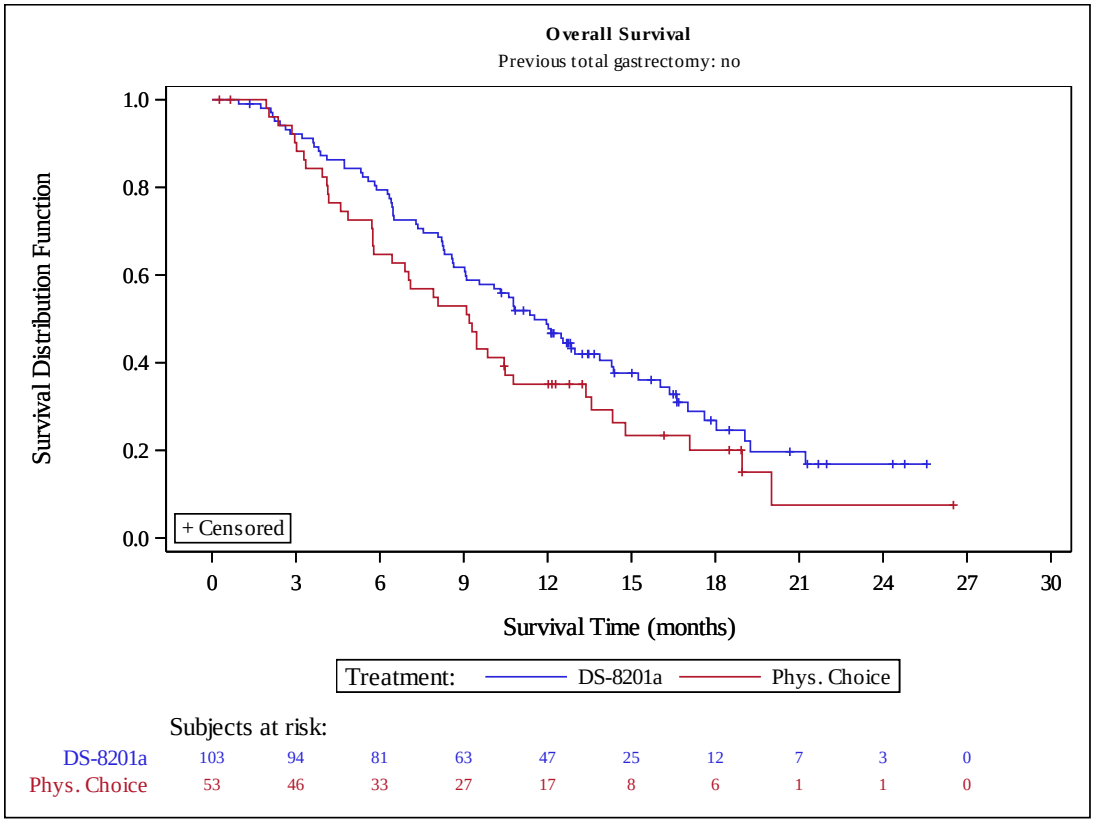
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



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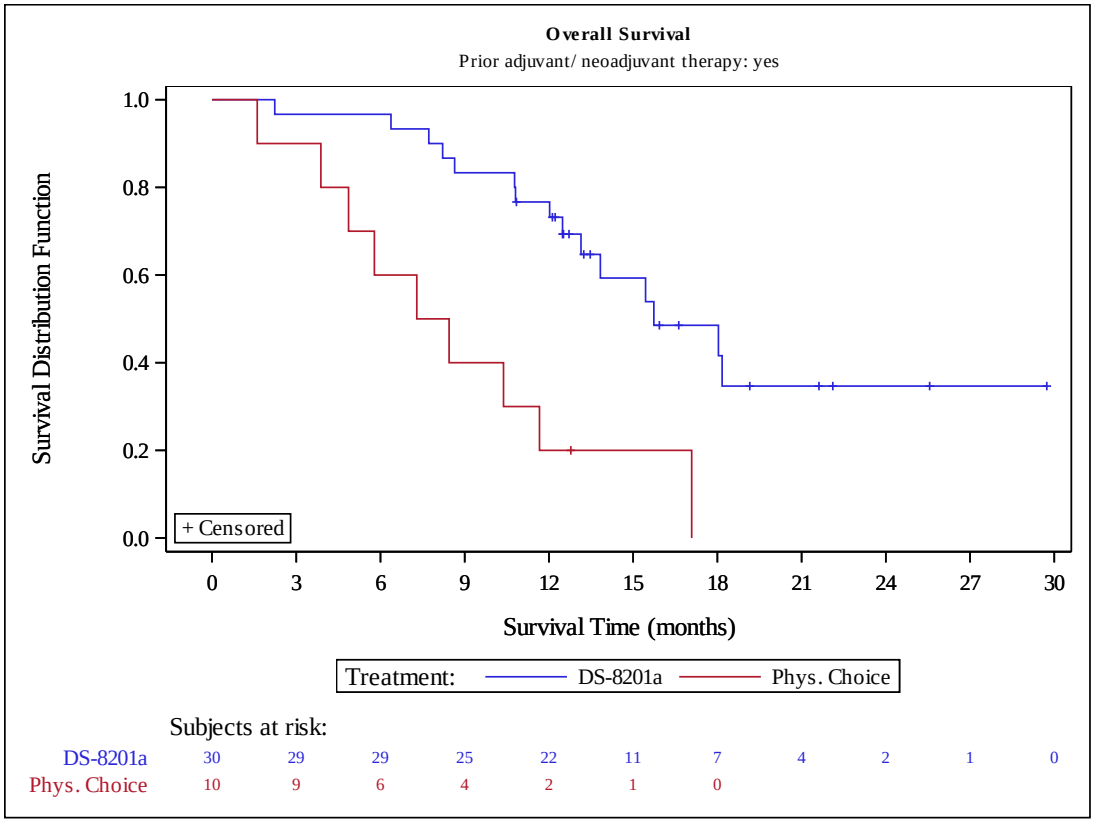
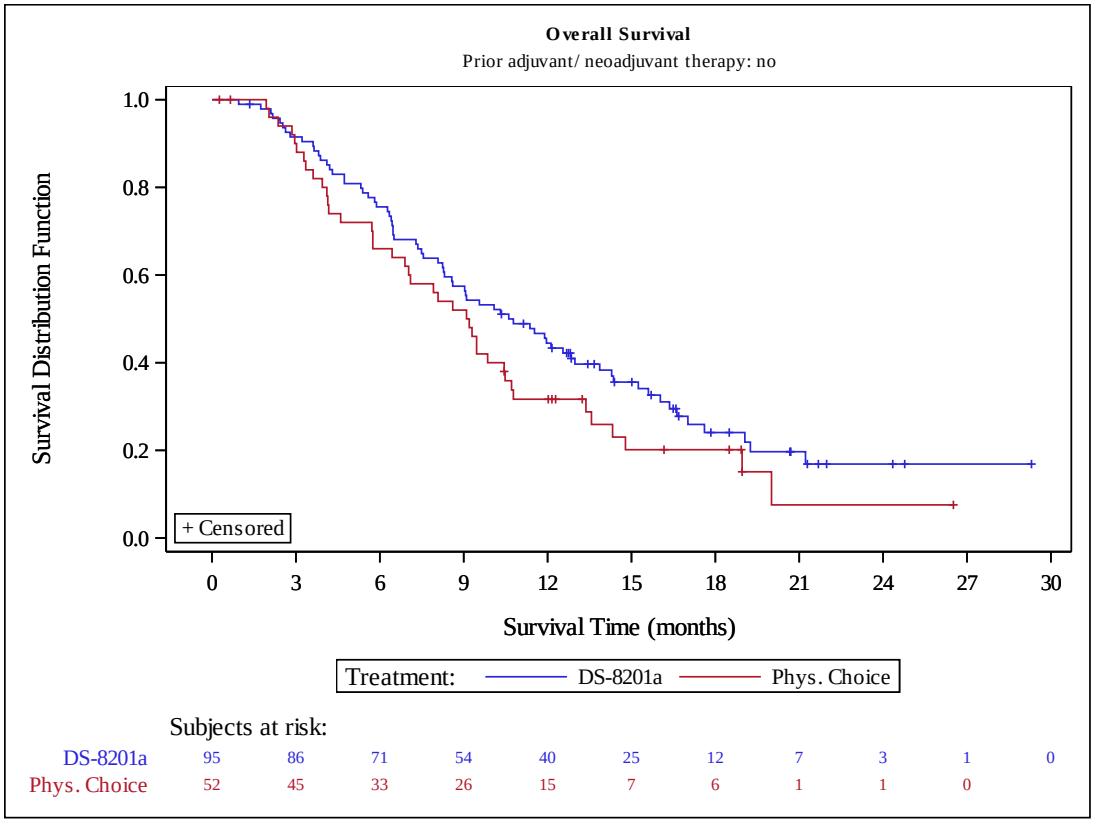
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Overall Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

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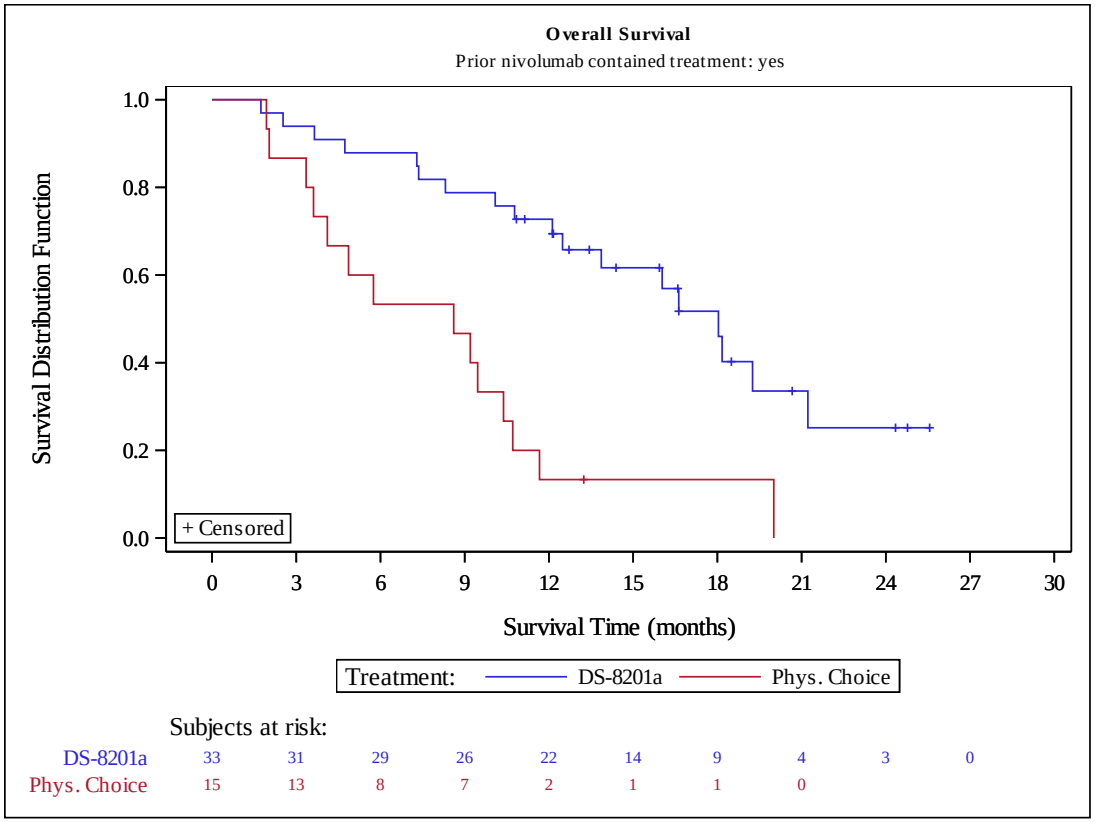

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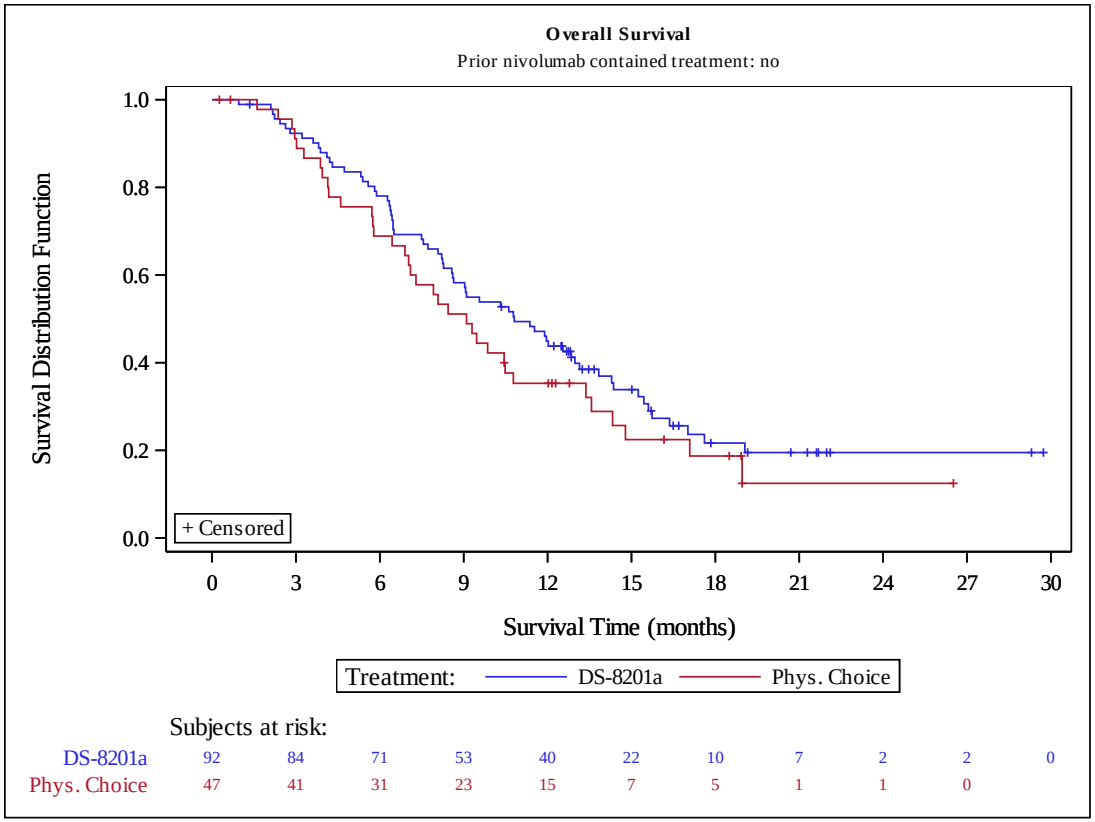

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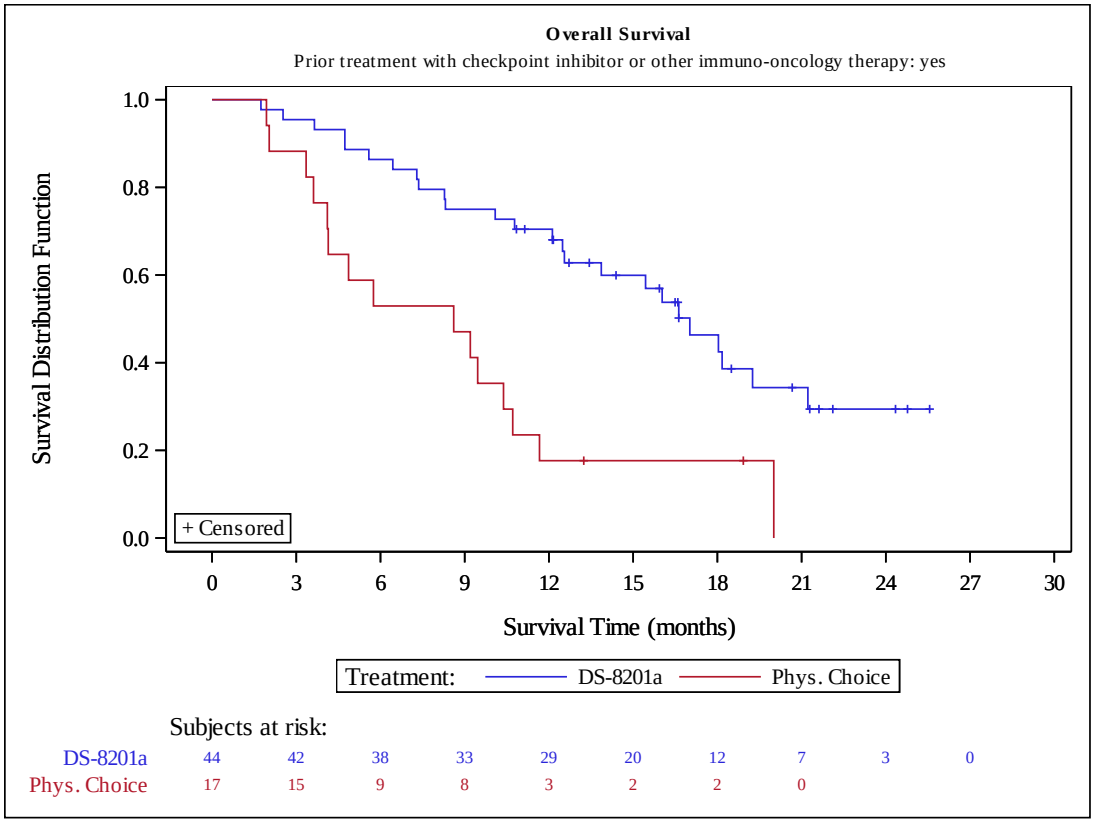

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
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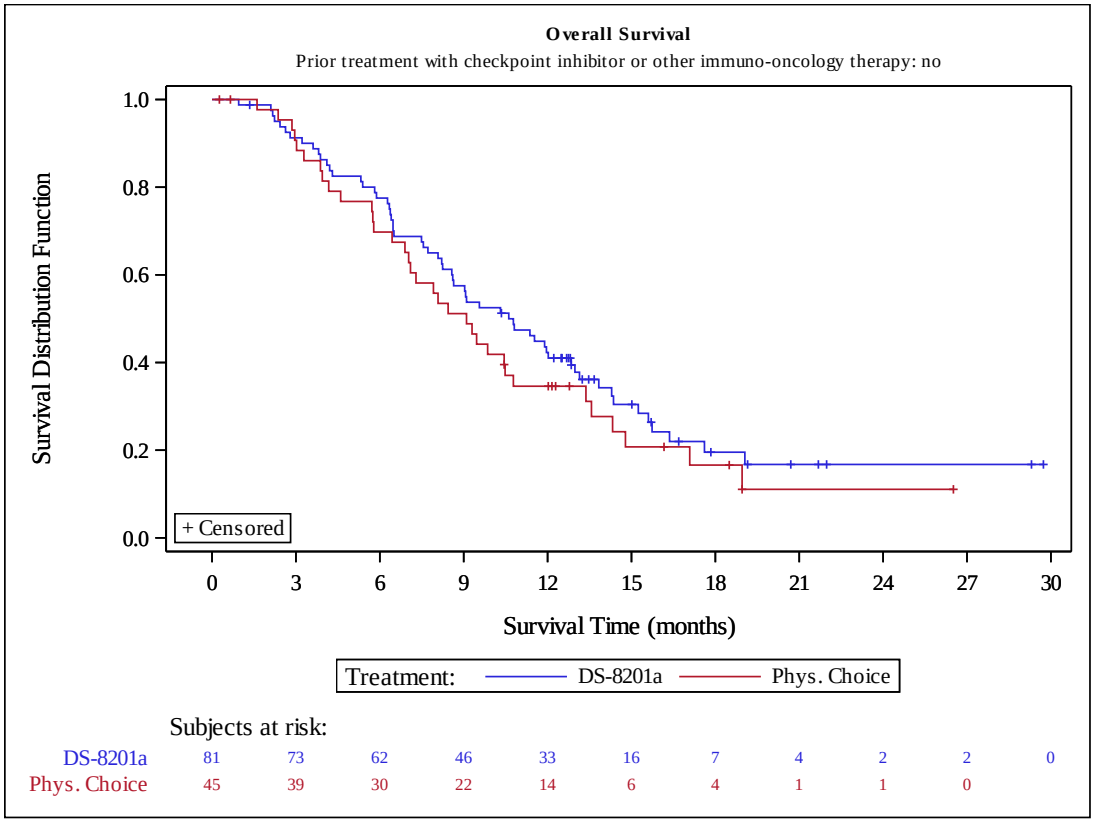

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Anhang 4-G 1.2.3: Morbidität

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Confirmed Objective Response Rate (ORR) based on ICR
Response Evaluable Set

	DS-8201a (N=119)	Phys. Choice (N=56)
Number of subjects with events, n (%)	50 (42.0)	7 (12.5)
95% CI [a]	33.0, 51.4	5.2, 24.1
Analysis DS-8201a vs. Phys. Choice (stratified)		
Relative Risk (95% CI) [b]	3.37 (1.63, 6.94)	
p-value	0.0010	
Odds Ratio (95% CI) [b]	5.13 (2.14, 12.29)	
p-value	0.0002	
Risk Difference (95% CI) [c]	29.56 (17.20, 41.93)	
p-value	<.0001	
CMH test [d]		
p-value	0.0001	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Relative Risk (95% CI) [e]	3.36 (1.63, 6.94)	
p-value	0.0010	
Odds Ratio (95% CI) [e]	5.07 (2.12, 12.13)	
p-value	0.0003	
Risk Difference (95% CI) [f]	29.52 (15.81, 43.23)	
p-value	<.0001	
CMH test [d]		
p-value	0.0001	

Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Mantel-Haenszel estimators for Common Odds Ratio and Relative Risks. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the common risk difference of two proportions.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[f] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Confirmed Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Region										0.9253
Japan	42/ 95 (44.2) [34.0, 54.8]	6/ 45 (13.3) [5.1, 26.8]	3.32 (1.52, 7.22)	0.0025	5.15 (1.99, 13.32)	0.0007	30.88 (15.16, 46.60)	0.0001	0.0003	
Korea	8/ 24 (33.3) [15.6, 55.3]	1/ 11 (9.1) [0.2, 41.3]	3.67 (0.52, 25.84)	0.1922	5.00 (0.54, 46.22)	0.1561	24.24 (-7.77, 56.25)	0.1377	0.1332	
Lines of prior systemic therapy										0.7969
2	20/ 60 (33.3) [21.7, 46.7]	4/ 33 (12.1) [3.4, 28.2]	2.75 (1.03, 7.37)	0.0443	3.63 (1.12, 11.74)	0.0317	21.21 (2.55, 39.88)	0.0259	0.0261	
3	17/ 34 (50.0) [32.4, 67.6]	3/ 17 (17.6) [3.8, 43.4]	2.83 (0.96, 8.35)	0.0589	4.67 (1.13, 19.24)	0.0331	32.35 (3.23, 61.48)	0.0295	0.0272	
>=4	13/ 25 (52.0) [31.3, 72.2]	0/ 6 (0.0) [0.0, 45.9]	7.27 (0.49, 107.78)	0.1493	14.04 (0.71, 275.74)	0.0820	52.00 (22.08, 81.92)	0.0007	0.0226	
Age										0.1742
<65 years	23/ 52 (44.2) [30.5, 58.7]	1/ 22 (4.5) [0.1, 22.8]	9.73 (1.40, 67.65)	0.0215	16.66 (2.08, 133.23)	0.0080	39.69 (20.39, 58.98)	<.0001	0.0009	
>=65 years	27/ 67 (40.3) [28.5, 53.0]	6/ 34 (17.6) [6.8, 34.5]	2.28 (1.04, 4.99)	0.0386	3.15 (1.15, 8.63)	0.0257	22.65 (3.05, 42.25)	0.0235	0.0225	
Sex										0.4064
female	10/ 30 (33.3) [17.3, 52.8]	2/ 12 (16.7) [2.1, 48.4]	2.00 (0.51, 7.81)	0.3188	2.50 (0.46, 13.65)	0.2900	16.67 (-16.17, 49.50)	0.3198	0.2859	
male	40/ 89 (44.9) [34.4, 55.9]	5/ 44 (11.4) [3.8, 24.6]	3.96 (1.68, 9.32)	0.0017	6.37 (2.30, 17.67)	0.0004	33.58 (17.93, 49.23)	<.0001	0.0001	
ECOG PS										0.4093
0	28/ 59 (47.5) [34.3, 60.9]	3/ 29 (10.3) [2.2, 27.4]	4.59 (1.52, 13.85)	0.0069	7.83 (2.13, 28.72)	0.0019	37.11 (17.65, 56.57)	0.0002	0.0007	
1	22/ 60 (36.7) [24.6, 50.1]	4/ 27 (14.8) [4.2, 33.7]	2.48 (0.94, 6.49)	0.0653	3.33 (1.02, 10.88)	0.0466	21.85 (1.05, 42.65)	0.0395	0.0406	
HER2 Status in central laboratory										0.0204
IHC 3+	44/ 91 (48.4) [37.7, 59.1]	4/ 44 (9.1) [2.5, 21.7]	5.32 (2.04, 13.87)	0.0006	9.36 (3.09, 28.32)	<.0001	39.26 (24.25, 54.27)	<.0001	<.0001	
IHC 2+/ISH +	6/ 28 (21.4) [8.3, 41.0]	3/ 12 (25.0) [5.5, 57.2]	0.86 (0.26, 2.87)	0.8028	0.82 (0.17, 4.00)	0.8044	-3.57 (-38.35, 31.21)	0.8405	0.8066	
Primary tumor location										0.9049
Gastric	42/104 (40.4) [30.9, 50.5]	6/ 49 (12.2) [4.6, 24.8]	3.30 (1.50, 7.23)	0.0029	4.85 (1.90, 12.42)	0.0010	28.14 (13.48, 42.80)	0.0002	0.0005	
GEJ	8/ 15 (53.3) [26.6, 78.7]	1/ 7 (14.3) [0.4, 57.9]	3.73 (0.57, 24.35)	0.1686	6.86 (0.66, 71.72)	0.1080	39.05 (-7.61, 85.71)	0.1010	0.0900	
Histological subtype										0.1579
intestinal	35/ 86 (40.7) [30.2, 51.8]	7/ 37 (18.9) [8.0, 35.2]	2.15 (1.05, 4.39)	0.0355	2.94 (1.16, 7.44)	0.0228	21.78 (3.50, 40.05)	0.0195	0.0200	
diffuse	15/ 27 (55.6) [35.3, 74.5]	0/ 14 (0.0) [0.0, 23.2]	16.61 (1.07, 258.60)	0.0449	35.96 (1.95, 664.08)	0.0160	55.56 (31.39, 79.72)	<.0001	0.0005	
others	0/ 6 (0.0) [0.0, 45.9]	0/ 5 (0.0) [0.0, 52.2]	NE	NE	NE	NE	NE	NE	NE	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Confirmed Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Number of metastatic sites										0.9535
<2	12/ 21 (57.1) [34.0, 78.2]	1/ 6 (16.7) [0.4, 64.1]	3.43 (0.55, 21.31)	0.1863	6.67 (0.66, 67.46)	0.1082	40.48 (-6.81, 87.76)	0.0934	0.0859	
>= 2	38/ 98 (38.8) [29.1, 49.2]	6/ 50 (12.0) [4.5, 24.3]	3.23 (1.47, 7.13)	0.0036	4.64 (1.81, 11.95)	0.0014	26.78 (12.07, 41.48)	0.0004	0.0008	
Previous total gastrectomy										0.3894
yes	11/ 21 (52.4) [29.8, 74.3]	0/ 8 (0.0) [0.0, 36.9]	9.41 (0.62, 143.28)	0.1067	18.62 (0.95, 363.77)	0.0538	52.38 (22.39, 82.37)	0.0006	0.0107	
no	39/ 98 (39.8) [30.0, 50.2]	7/ 48 (14.6) [6.1, 27.8]	2.73 (1.32, 5.64)	0.0068	3.87 (1.58, 9.50)	0.0031	25.21 (9.75, 40.68)	0.0014	0.0021	
Prior adjuvant/ neoadjuvant therapy										0.3186
yes	17/ 29 (58.6) [38.9, 76.5]	0/ 8 (0.0) [0.0, 36.9]	10.50 (0.70, 157.91)	0.0891	23.80 (1.25, 451.58)	0.0348	58.62 (32.72, 84.52)	<.0001	0.0037	
no	33/ 90 (36.7) [26.8, 47.5]	7/ 48 (14.6) [6.1, 27.8]	2.51 (1.20, 5.25)	0.0141	3.39 (1.37, 8.42)	0.0085	22.08 (6.39, 37.78)	0.0058	0.0067	
Prior ramucirumab contained treatment										0.7239
yes	37/ 89 (41.6) [31.2, 52.5]	5/ 37 (13.5) [4.5, 28.8]	3.08 (1.31, 7.21)	0.0097	4.55 (1.62, 12.79)	0.0040	28.06 (11.11, 45.01)	0.0012	0.0024	
no	13/ 30 (43.3) [25.5, 62.6]	2/ 19 (10.5) [1.3, 33.1]	4.12 (1.04, 16.25)	0.0434	6.50 (1.27, 33.29)	0.0247	32.81 (6.04, 59.57)	0.0163	0.0163	
Prior nivolumab contained treatment										0.7223
yes	20/ 33 (60.6) [42.1, 77.1]	3/ 14 (21.4) [4.7, 50.8]	2.83 (1.00, 8.00)	0.0501	5.64 (1.32, 24.17)	0.0198	39.18 (6.89, 71.47)	0.0174	0.0151	
no	30/ 86 (34.9) [24.9, 45.9]	4/ 42 (9.5) [2.7, 22.6]	3.66 (1.38, 9.72)	0.0091	5.09 (1.66, 15.62)	0.0045	25.36 (10.16, 40.56)	0.0011	0.0024	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy										0.8968
yes	25/ 44 (56.8) [41.0, 71.7]	3/ 16 (18.8) [4.0, 45.6]	3.03 (1.06, 8.68)	0.0389	5.70 (1.42, 22.89)	0.0141	38.07 (9.72, 66.41)	0.0085	0.0095	
no	25/ 75 (33.3) [22.9, 45.2]	4/ 40 (10.0) [2.8, 23.7]	3.33 (1.25, 8.91)	0.0164	4.50 (1.44, 14.06)	0.0097	23.33 (7.27, 39.40)	0.0044	0.0063	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug										0.7205
yes	8/ 22 (36.4) [17.2, 59.3]	0/ 6 (0.0) [0.0, 45.9]	5.17 (0.34, 78.84)	0.2369	7.62 (0.38, 152.83)	0.1843	36.36 (5.66, 67.07)	0.0203	0.0861	
no	42/ 97 (43.3) [33.3, 53.7]	7/ 50 (14.0) [5.8, 26.7]	3.09 (1.50, 6.38)	0.0022	4.69 (1.92, 11.47)	0.0007	29.30 (14.01, 44.59)	0.0002	0.0004	
Presence of liver metastasis at baseline										0.7736
yes	25/ 68 (36.8) [25.4, 49.3]	4/ 33 (12.1) [3.4, 28.2]	3.03 (1.15, 8.00)	0.0250	4.22 (1.33, 13.39)	0.0147	24.64 (6.41, 42.87)	0.0081	0.0106	
no	25/ 51 (49.0) [34.8, 63.4]	3/ 23 (13.0) [2.8, 33.6]	3.76 (1.26, 11.20)	0.0175	6.41 (1.69, 24.28)	0.0063	35.98 (13.39, 58.56)	0.0018	0.0034	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
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[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
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Protocol DS8201-A-J202
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Primary Cohort
Confirmed Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Renal impairment at baseline										0.4014
normal	16/ 32 (50.0) [31.9, 68.1]	0/ 12 (0.0) [0.0, 26.5]	13.00 (0.84, 201.19)	0.0665	25.00 (1.36, 457.96)	0.0300	50.00 (26.95, 73.05)	<.0001	0.0024	
mild	19/ 52 (36.5) [23.6, 51.0]	3/ 26 (11.5) [2.4, 30.2]	3.17 (1.03, 9.73)	0.0442	4.41 (1.17, 16.67)	0.0285	25.00 (4.17, 45.83)	0.0187	0.0216	
moderate	15/ 35 (42.9) [26.3, 60.6]	4/ 18 (22.2) [6.4, 47.6]	1.93 (0.75, 4.96)	0.1732	2.63 (0.72, 9.61)	0.1448	20.63 (-8.82, 50.09)	0.1698	0.1417	
Hepatic impairment at baseline										0.6506
normal	36/ 84 (42.9) [32.1, 54.1]	6/ 43 (14.0) [5.3, 27.9]	3.07 (1.40, 6.72)	0.0049	4.63 (1.76, 12.14)	0.0019	28.90 (12.34, 45.47)	0.0006	0.0011	
mild	13/ 34 (38.2) [22.2, 56.4]	1/ 13 (7.7) [0.2, 36.0]	4.97 (0.72, 34.28)	0.1036	7.43 (0.86, 64.03)	0.0681	30.54 (3.39, 57.69)	0.0275	0.0427	
moderate	1/ 1 (100.0) [2.5, 100.0]	0 [NE, NE]	NE	NE	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors										0.4733
yes	3/ 7 (42.9) [9.9, 81.6]	1/ 4 (25.0) [0.6, 80.6]	1.71 (0.26, 11.47)	0.5784	2.25 (0.15, 33.93)	0.5580	17.86 (-57.86, 93.58)	0.6439	0.5723	
no	47/112 (42.0) [32.7, 51.7]	6/ 52 (11.5) [4.4, 23.4]	3.64 (1.66, 7.96)	0.0012	5.54 (2.19, 14.05)	0.0003	30.43 (16.41, 44.44)	<.0001	0.0001	
Most recently treatment with irinotecan or other topoisomerase I inhibitors										0.4331
yes	1/ 2 (50.0) [1.3, 98.7]	1/ 3 (33.3) [0.8, 90.6]	1.50 (0.18, 12.46)	0.7074	2.00 (0.05, 78.25)	0.7110	16.67 (-100.00, 100.00)	0.7795	0.7389	
no	49/117 (41.9) [32.8, 51.4]	6/ 53 (11.3) [4.3, 23.0]	3.70 (1.69, 8.10)	0.0011	5.64 (2.24, 14.24)	0.0002	30.56 (16.83, 44.29)	<.0001	<.0001	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
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Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Objective Response Rate (ORR) based on ICR
Response Evaluable Set

	DS-8201a (N=119)	Phys. Choice (N=56)
Number of subjects with events, n (%)	61 (51.3)	8 (14.3)
95% CI [a]	41.9, 60.5	6.4, 26.2
Analysis DS-8201a vs. Phys. Choice (stratified)		
Relative Risk (95% CI) [b]	3.59 (1.84, 6.99)	
p-value	0.0002	
Odds Ratio (95% CI) [b]	6.28 (2.74, 14.41)	
p-value	<.0001	
Risk Difference (95% CI) [c]	36.97 (24.13, 49.82)	
p-value	<.0001	
CMH test [d]		
p-value	<.0001	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Relative Risk (95% CI) [e]	3.59 (1.85, 6.98)	
p-value	0.0002	
Odds Ratio (95% CI) [e]	6.31 (2.75, 14.48)	
p-value	<.0001	
Risk Difference (95% CI) [f]	36.97 (22.83, 51.12)	
p-value	<.0001	
CMH test [d]		
p-value	<.0001	

Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Mantel-Haenszel estimators for Common Odds Ratio and Relative Risks. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the common risk difference of two proportions.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[f] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Region										0.5585
Japan	48/ 95 (50.5) [40.1, 60.9]	7/ 45 (15.6) [6.5, 29.5]	3.25 (1.60, 6.60)	0.0011	5.54 (2.25, 13.65)	0.0002	34.97 (18.73, 51.21)	<.0001	<.0001	
Korea	13/ 24 (54.2) [32.8, 74.4]	1/ 11 (9.1) [0.2, 41.3]	5.96 (0.89, 40.02)	0.0663	11.82 (1.30, 107.40)	0.0283	45.08 (12.26, 77.90)	0.0071	0.0128	
Lines of prior systemic therapy										0.9266
2	29/ 60 (48.3) [35.2, 61.6]	4/ 33 (12.1) [3.4, 28.2]	3.99 (1.53, 10.36)	0.0045	6.78 (2.12, 21.67)	0.0012	36.21 (17.01, 55.41)	0.0002	0.0005	
3	18/ 34 (52.9) [35.1, 70.2]	3/ 17 (17.6) [3.8, 43.4]	3.00 (1.02, 8.79)	0.0451	5.25 (1.27, 21.66)	0.0218	35.29 (6.19, 64.40)	0.0175	0.0168	
>=4	14/ 25 (56.0) [34.9, 75.6]	1/ 6 (16.7) [0.4, 64.1]	3.36 (0.54, 20.79)	0.1925	6.36 (0.65, 62.69)	0.1128	39.33 (-6.61, 85.27)	0.0933	0.0885	
Age										0.0987
<65 years	30/ 52 (57.7) [43.2, 71.3]	1/ 22 (4.5) [0.1, 22.8]	12.69 (1.84, 87.36)	0.0098	28.64 (3.58, 229.25)	0.0016	53.15 (33.91, 72.38)	<.0001	<.0001	
>=65 years	31/ 67 (46.3) [34.0, 58.9]	7/ 34 (20.6) [8.7, 37.9]	2.25 (1.11, 4.57)	0.0251	3.32 (1.27, 8.67)	0.0143	25.68 (5.37, 45.99)	0.0132	0.0122	
Sex										0.6776
female	14/ 30 (46.7) [28.3, 65.7]	2/ 12 (16.7) [2.1, 48.4]	2.80 (0.75, 10.50)	0.1268	4.38 (0.82, 23.45)	0.0849	30.00 (-3.46, 63.46)	0.0789	0.0739	
male	47/ 89 (52.8) [41.9, 63.5]	6/ 44 (13.6) [5.2, 27.4]	3.87 (1.79, 8.36)	0.0006	7.09 (2.72, 18.44)	<.0001	39.17 (22.97, 55.38)	<.0001	<.0001	
ECOG PS										0.3685
0	31/ 59 (52.5) [39.1, 65.7]	3/ 29 (10.3) [2.2, 27.4]	5.08 (1.69, 15.24)	0.0037	9.60 (2.62, 35.20)	0.0006	42.20 (22.74, 61.66)	<.0001	0.0001	
1	30/ 60 (50.0) [36.8, 63.2]	5/ 27 (18.5) [6.3, 38.1]	2.70 (1.18, 6.20)	0.0191	4.40 (1.47, 13.15)	0.0080	31.48 (9.44, 53.52)	0.0051	0.0059	
HER2 Status in central laboratory										0.0382
IHC 3+	53/ 91 (58.2) [47.4, 68.5]	5/ 44 (11.4) [3.8, 24.6]	5.13 (2.21, 11.91)	0.0001	10.88 (3.92, 30.17)	<.0001	46.88 (31.39, 62.37)	<.0001	<.0001	
IHC 2+/ISH +	8/ 28 (28.6) [13.2, 48.7]	3/ 12 (25.0) [5.5, 57.2]	1.14 (0.36, 3.58)	0.8187	1.20 (0.26, 5.61)	0.8168	3.57 (-32.05, 39.19)	0.8442	0.8189	
Primary tumor location										0.8577
Gastric	52/104 (50.0) [40.0, 60.0]	7/ 49 (14.3) [5.9, 27.2]	3.50 (1.72, 7.14)	0.0006	6.00 (2.47, 14.58)	<.0001	35.71 (20.49, 50.94)	<.0001	<.0001	
GEJ	9/ 15 (60.0) [32.3, 83.7]	1/ 7 (14.3) [0.4, 57.9]	4.20 (0.65, 27.01)	0.1307	9.00 (0.85, 94.90)	0.0675	45.71 (-0.63, 92.06)	0.0532	0.0500	
Histological subtype										0.2902
intestinal	41/ 86 (47.7) [36.8, 58.7]	8/ 37 (21.6) [9.8, 38.2]	2.20 (1.15, 4.23)	0.0175	3.30 (1.36, 8.04)	0.0085	26.05 (7.17, 44.94)	0.0069	0.0070	
diffuse	18/ 27 (66.7) [46.0, 83.5]	0/ 14 (0.0) [0.0, 23.2]	19.82 (1.28, 306.40)	0.0325	56.47 (3.03,1053.10)	0.0069	66.67 (43.46, 89.87)	<.0001	<.0001	
others	2/ 6 (33.3) [4.3, 77.7]	0/ 5 (0.0) [0.0, 52.2]	4.29 (0.25, 72.90)	0.3142	6.11 (0.23, 162.73)	0.2797	33.33 (-22.72, 89.39)	0.2438	0.1736	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Number of metastatic sites										0.9522
<2	13/ 21 (61.9) [38.4, 81.9]	1/ 6 (16.7) [0.4, 64.1]	3.71 (0.60, 22.93)	0.1577	8.13 (0.80, 82.73)	0.0768	45.24 (-1.82, 92.29)	0.0595	0.0549	
>= 2	48/ 98 (49.0) [38.7, 59.3]	7/ 50 (14.0) [5.8, 26.7]	3.50 (1.71, 7.16)	0.0006	5.90 (2.42, 14.38)	<.0001	34.98 (19.67, 50.29)	<.0001	<.0001	
Previous total gastrectomy										0.7782
yes	12/ 21 (57.1) [34.0, 78.2]	1/ 8 (12.5) [0.3, 52.7]	4.57 (0.70, 29.67)	0.1113	9.33 (0.97, 90.03)	0.0534	44.64 (4.82, 84.47)	0.0280	0.0338	
no	49/ 98 (50.0) [39.7, 60.3]	7/ 48 (14.6) [6.1, 27.8]	3.43 (1.68, 6.99)	0.0007	5.86 (2.40, 14.32)	0.0001	35.42 (19.80, 51.03)	<.0001	<.0001	
Prior adjuvant/ neoadjuvant therapy										0.6820
yes	18/ 29 (62.1) [42.3, 79.3]	1/ 8 (12.5) [0.3, 52.7]	4.97 (0.78, 31.75)	0.0905	11.45 (1.24, 106.05)	0.0318	49.57 (12.66, 86.48)	0.0085	0.0143	
no	43/ 90 (47.8) [37.1, 58.6]	7/ 48 (14.6) [6.1, 27.8]	3.28 (1.60, 6.72)	0.0012	5.36 (2.17, 13.21)	0.0003	33.19 (17.24, 49.15)	<.0001	0.0001	
Prior ramucirumab contained treatment										0.3559
yes	42/ 89 (47.2) [36.5, 58.1]	6/ 37 (16.2) [6.2, 32.0]	2.91 (1.35, 6.25)	0.0062	4.62 (1.75, 12.16)	0.0020	30.97 (13.29, 48.66)	0.0006	0.0012	
no	19/ 30 (63.3) [43.9, 80.1]	2/ 19 (10.5) [1.3, 33.1]	6.02 (1.58, 22.95)	0.0086	14.68 (2.84, 75.88)	0.0013	52.81 (26.42, 79.19)	<.0001	0.0003	
Prior nivolumab contained treatment										0.2789
yes	22/ 33 (66.7) [48.2, 82.0]	4/ 14 (28.6) [8.4, 58.1]	2.33 (0.98, 5.53)	0.0542	5.00 (1.27, 19.62)	0.0210	38.10 (4.40, 71.79)	0.0267	0.0175	
no	39/ 86 (45.3) [34.6, 56.5]	4/ 42 (9.5) [2.7, 22.6]	4.76 (1.82, 12.44)	0.0015	7.88 (2.59, 24.02)	0.0003	35.83 (20.29, 51.36)	<.0001	<.0001	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy										0.4691
yes	29/ 44 (65.9) [50.1, 79.5]	4/ 16 (25.0) [7.3, 52.4]	2.64 (1.10, 6.32)	0.0299	5.80 (1.59, 21.11)	0.0077	40.91 (11.22, 70.59)	0.0069	0.0052	
no	32/ 75 (42.7) [31.3, 54.6]	4/ 40 (10.0) [2.8, 23.7]	4.27 (1.62, 11.21)	0.0032	6.70 (2.16, 20.73)	0.0010	32.67 (16.20, 49.13)	0.0001	0.0003	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug										0.6614
yes	9/ 22 (40.9) [20.7, 63.6]	1/ 6 (16.7) [0.4, 64.1]	2.45 (0.38, 15.74)	0.3436	3.46 (0.34, 34.84)	0.2919	24.24 (-22.58, 71.06)	0.3102	0.2807	
no	52/ 97 (53.6) [43.2, 63.8]	7/ 50 (14.0) [5.8, 26.7]	3.83 (1.88, 7.80)	0.0002	7.10 (2.91, 17.34)	<.0001	39.61 (24.27, 54.94)	<.0001	<.0001	
Presence of liver metastasis at baseline										0.5635
yes	31/ 68 (45.6) [33.5, 58.1]	5/ 33 (15.2) [5.1, 31.9]	3.01 (1.29, 7.03)	0.0109	4.69 (1.62, 13.60)	0.0044	30.44 (11.16, 49.71)	0.0020	0.0029	
no	30/ 51 (58.8) [44.2, 72.4]	3/ 23 (13.0) [2.8, 33.6]	4.51 (1.53, 13.28)	0.0063	9.52 (2.51, 36.21)	0.0009	45.78 (23.34, 68.22)	<.0001	0.0003	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Objective Response Rate (ORR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Renal impairment at baseline										0.4350
normal	19/ 32 (59.4) [40.6, 76.3]	0/ 12 (0.0) [0.0, 26.5]	15.36 (1.00, 236.22)	0.0501	36.11 (1.97, 663.30)	0.0157	59.38 (36.63, 82.12)	<.0001	0.0005	
mild	24/ 52 (46.2) [32.2, 60.5]	4/ 26 (15.4) [4.4, 34.9]	3.00 (1.16, 7.74)	0.0231	4.71 (1.42, 15.60)	0.0111	30.77 (8.50, 53.04)	0.0068	0.0080	
moderate	18/ 35 (51.4) [34.0, 68.6]	4/ 18 (22.2) [6.4, 47.6]	2.31 (0.92, 5.82)	0.0746	3.71 (1.02, 13.52)	0.0472	29.21 (-0.36, 58.77)	0.0528	0.0429	
Hepatic impairment at baseline										0.6264
normal	46/ 84 (54.8) [43.5, 65.7]	6/ 43 (14.0) [5.3, 27.9]	3.92 (1.82, 8.45)	0.0005	7.46 (2.85, 19.57)	<.0001	40.81 (24.20, 57.42)	<.0001	<.0001	
mild	14/ 34 (41.2) [24.6, 59.3]	2/ 13 (15.4) [1.9, 45.4]	2.68 (0.70, 10.19)	0.1489	3.85 (0.74, 20.13)	0.1102	25.79 (-5.18, 56.77)	0.1027	0.0987	
moderate	1/ 1 (100.0) [2.5, 100.0]	0 [NE, NE]	NE	NE	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors										0.4351
yes	3/ 7 (42.9) [9.9, 81.6]	1/ 4 (25.0) [0.6, 80.6]	1.71 (0.26, 11.47)	0.5784	2.25 (0.15, 33.93)	0.5580	17.86 (-57.86, 93.58)	0.6439	0.5723	
no	58/112 (51.8) [42.1, 61.3]	7/ 52 (13.5) [5.6, 25.8]	3.85 (1.89, 7.84)	0.0002	6.90 (2.87, 16.62)	<.0001	38.32 (23.81, 52.84)	<.0001	<.0001	
Most recently treatment with irinotecan or other topoisomerase I inhibitors										0.4040
yes	1/ 2 (50.0) [1.3, 98.7]	1/ 3 (33.3) [0.8, 90.6]	1.50 (0.18, 12.46)	0.7074	2.00 (0.05, 78.25)	0.7110	16.67 (-100.00, 100.00)	0.7795	0.7389	
no	60/117 (51.3) [41.9, 60.6]	7/ 53 (13.2) [5.5, 25.3]	3.88 (1.90, 7.92)	0.0002	6.92 (2.89, 16.58)	<.0001	38.07 (23.85, 52.29)	<.0001	<.0001	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Confirmed Disease Control Rate (DCR) based on ICR
Response Evaluable Set

	DS-8201a (N=119)	Phys. Choice (N=56)
Number of subjects with events, n (%)	102 (85.7)	35 (62.5)
95% CI [a]	78.1, 91.5	48.5, 75.1
Analysis DS-8201a vs. Phys. Choice (stratified)		
Relative Risk (95% CI) [b]	1.37 (1.11, 1.70)	
p-value	0.0040	
Odds Ratio (95% CI) [b]	3.62 (1.71, 7.64)	
p-value	0.0007	
Risk Difference (95% CI) [c]	23.24 (9.11, 37.38)	
p-value	0.0013	
CMH test [d]		
p-value	0.0005	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Relative Risk (95% CI) [e]	1.37 (1.11, 1.70)	
p-value	0.0041	
Odds Ratio (95% CI) [e]	3.60 (1.71, 7.59)	
p-value	0.0008	
Risk Difference (95% CI) [f]	23.21 (7.75, 38.68)	
p-value	0.0033	
CMH test [d]		
p-value	0.0005	

Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Mantel-Haenszel estimators for Common Odds Ratio and Relative Risks. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the common risk difference of two proportions.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[f] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Confirmed Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Region										0.6742
Japan	82/ 95 (86.3) [77.7, 92.5]	29/ 45 (64.4) [48.8, 78.1]	1.34 (1.06, 1.69)	0.0133	3.48 (1.49, 8.11)	0.0038	21.87 (4.63, 39.11)	0.0129	0.0030	
Korea	20/ 24 (83.3) [62.6, 95.3]	6/ 11 (54.5) [23.4, 83.3]	1.53 (0.87, 2.70)	0.1439	4.17 (0.84, 20.64)	0.0805	28.79 (-10.83, 68.40)	0.1544	0.0746	
Lines of prior systemic therapy										0.7867
2	49/ 60 (81.7) [69.6, 90.5]	20/ 33 (60.6) [42.1, 77.1]	1.35 (1.00, 1.82)	0.0514	2.90 (1.11, 7.54)	0.0294	21.06 (-0.62, 42.74)	0.0569	0.0272	
3	31/ 34 (91.2) [76.3, 98.1]	12/ 17 (70.6) [44.0, 89.7]	1.29 (0.93, 1.79)	0.1218	4.31 (0.89, 20.88)	0.0699	20.59 (-7.49, 48.67)	0.1507	0.0592	
>=4	22/ 25 (88.0) [68.8, 97.5]	3/ 6 (50.0) [11.8, 88.2]	1.76 (0.78, 3.97)	0.1730	7.33 (0.99, 54.40)	0.0513	38.00 (-14.32, 90.32)	0.1546	0.0374	
Age										0.4232
<65 years	44/ 52 (84.6) [71.9, 93.1]	12/ 22 (54.5) [32.2, 75.6]	1.55 (1.04, 2.31)	0.0309	4.58 (1.48, 14.16)	0.0081	30.07 (3.83, 56.31)	0.0247	0.0062	
>=65 years	58/ 67 (86.6) [76.0, 93.7]	23/ 34 (67.6) [49.5, 82.6]	1.28 (1.00, 1.64)	0.0540	3.08 (1.13, 8.42)	0.0281	18.92 (-1.02, 38.86)	0.0629	0.0249	
Sex										0.7862
female	26/ 30 (86.7) [69.3, 96.2]	8/ 12 (66.7) [34.9, 90.1]	1.30 (0.85, 1.99)	0.2252	3.25 (0.66, 16.04)	0.1479	20.00 (-15.15, 55.15)	0.2647	0.1407	
male	76/ 89 (85.4) [76.3, 92.0]	27/ 44 (61.4) [45.5, 75.6]	1.39 (1.08, 1.79)	0.0095	3.68 (1.58, 8.57)	0.0025	24.03 (6.18, 41.88)	0.0083	0.0019	
ECOG PS										0.9816
0	53/ 59 (89.8) [79.2, 96.2]	19/ 29 (65.5) [45.7, 82.1]	1.37 (1.04, 1.81)	0.0259	4.65 (1.49, 14.53)	0.0082	24.31 (2.80, 45.83)	0.0267	0.0057	
1	49/ 60 (81.7) [69.6, 90.5]	16/ 27 (59.3) [38.8, 77.6]	1.38 (0.99, 1.93)	0.0606	3.06 (1.12, 8.40)	0.0296	22.41 (-1.24, 46.05)	0.0633	0.0270	
HER2 Status in central laboratory										0.2925
IHC 3+	78/ 91 (85.7) [76.8, 92.2]	26/ 44 (59.1) [43.2, 73.7]	1.45 (1.12, 1.88)	0.0050	4.15 (1.79, 9.62)	0.0009	26.62 (8.73, 44.52)	0.0035	0.0006	
IHC 2+/ISH +	24/ 28 (85.7) [67.3, 96.0]	9/ 12 (75.0) [42.8, 94.5]	1.14 (0.80, 1.64)	0.4672	2.00 (0.37, 10.75)	0.4192	10.71 (-22.95, 44.38)	0.5328	0.4197	
Primary tumor location										0.5727
Gastric	88/104 (84.6) [76.2, 90.9]	31/ 49 (63.3) [48.3, 76.6]	1.34 (1.06, 1.68)	0.0126	3.19 (1.45, 7.02)	0.0039	21.35 (4.67, 38.03)	0.0121	0.0031	
GEJ	14/ 15 (93.3) [68.1, 99.8]	4/ 7 (57.1) [18.4, 90.1]	1.63 (0.85, 3.15)	0.1425	10.50 (0.84, 130.66)	0.0676	36.19 (-13.06, 85.44)	0.1498	0.0452	
Histological subtype										0.6249
intestinal	76/ 86 (88.4) [79.7, 94.3]	24/ 37 (64.9) [47.5, 79.8]	1.36 (1.06, 1.75)	0.0150	4.12 (1.60, 10.58)	0.0033	23.51 (4.77, 42.25)	0.0140	0.0023	
diffuse	23/ 27 (85.2) [66.3, 95.8]	8/ 14 (57.1) [28.9, 82.3]	1.49 (0.92, 2.41)	0.1031	4.31 (0.96, 19.31)	0.0561	28.04 (-6.56, 62.65)	0.1122	0.0502	
others	3/ 6 (50.0) [11.8, 88.2]	3/ 5 (60.0) [14.7, 94.7]	0.83 (0.28, 2.44)	0.7392	0.67 (0.06, 7.35)	0.7406	-10.00 (-87.02, 67.02)	0.7991	0.7518	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Confirmed Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Number of metastatic sites										0.8572
<2	20/ 21 (95.2) [76.2, 99.9]	4/ 6 (66.7) [22.3, 95.7]	1.43 (0.80, 2.54)	0.2231	10.00 (0.72, 138.68)	0.0861	28.57 (-20.95, 78.09)	0.2581	0.0539	
>= 2	82/ 98 (83.7) [74.8, 90.4]	31/ 50 (62.0) [47.2, 75.3]	1.35 (1.07, 1.71)	0.0120	3.14 (1.44, 6.87)	0.0042	21.67 (4.85, 38.50)	0.0116	0.0034	
Previous total gastrectomy										0.3962
yes	18/ 21 (85.7) [63.7, 97.0]	6/ 8 (75.0) [34.9, 96.8]	1.14 (0.74, 1.77)	0.5488	2.00 (0.27, 14.98)	0.4999	10.71 (-31.45, 52.88)	0.6184	0.5023	
no	84/ 98 (85.7) [77.2, 92.0]	29/ 48 (60.4) [45.3, 74.2]	1.42 (1.11, 1.81)	0.0048	3.93 (1.75, 8.83)	0.0009	25.30 (8.27, 42.32)	0.0036	0.0006	
Prior adjuvant/ neoadjuvant therapy										0.6673
yes	27/ 29 (93.1) [77.2, 99.2]	6/ 8 (75.0) [34.9, 96.8]	1.24 (0.82, 1.87)	0.3038	4.50 (0.52, 38.65)	0.1704	18.10 (-21.26, 57.47)	0.3674	0.1499	
no	75/ 90 (83.3) [74.0, 90.4]	29/ 48 (60.4) [45.3, 74.2]	1.38 (1.08, 1.77)	0.0107	3.28 (1.47, 7.30)	0.0037	22.92 (5.49, 40.35)	0.0100	0.0030	
Prior ramucirumab contained treatment										0.3584
yes	75/ 89 (84.3) [75.0, 91.1]	21/ 37 (56.8) [39.5, 72.9]	1.48 (1.11, 1.99)	0.0087	4.08 (1.72, 9.70)	0.0014	27.51 (7.94, 47.09)	0.0059	0.0010	
no	27/ 30 (90.0) [73.5, 97.9]	14/ 19 (73.7) [48.8, 90.9]	1.22 (0.91, 1.64)	0.1824	3.21 (0.67, 15.45)	0.1450	16.32 (-10.51, 43.14)	0.2332	0.1362	
Prior nivolumab contained treatment										0.3542
yes	31/ 33 (93.9) [79.8, 99.3]	11/ 14 (78.6) [49.2, 95.3]	1.20 (0.90, 1.59)	0.2224	4.23 (0.62, 28.74)	0.1405	15.37 (-12.70, 43.44)	0.2833	0.1221	
no	71/ 86 (82.6) [72.9, 89.9]	24/ 42 (57.1) [41.0, 72.3]	1.44 (1.09, 1.91)	0.0098	3.55 (1.55, 8.12)	0.0027	25.42 (6.66, 44.17)	0.0079	0.0021	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy										0.2015
yes	41/ 44 (93.2) [81.3, 98.6]	13/ 16 (81.3) [54.4, 96.0]	1.15 (0.89, 1.47)	0.2800	3.15 (0.57, 17.57)	0.1900	11.93 (-12.85, 36.72)	0.3454	0.1767	
no	61/ 75 (81.3) [70.7, 89.4]	22/ 40 (55.0) [38.5, 70.7]	1.48 (1.09, 2.00)	0.0107	3.56 (1.52, 8.35)	0.0034	26.33 (6.66, 46.01)	0.0087	0.0028	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug										0.6929
yes	18/ 22 (81.8) [59.7, 94.8]	4/ 6 (66.7) [22.3, 95.7]	1.23 (0.67, 2.23)	0.5029	2.25 (0.30, 16.85)	0.4299	15.15 (-36.47, 66.78)	0.5651	0.4311	
no	84/ 97 (86.6) [78.2, 92.7]	31/ 50 (62.0) [47.2, 75.3]	1.40 (1.11, 1.76)	0.0045	3.96 (1.75, 8.96)	0.0010	24.60 (8.02, 41.18)	0.0036	0.0006	
Presence of liver metastasis at baseline										0.0407
yes	56/ 68 (82.4) [71.2, 90.5]	16/ 33 (48.5) [30.8, 66.5]	1.70 (1.17, 2.46)	0.0048	4.96 (1.97, 12.50)	0.0007	33.87 (12.31, 55.43)	0.0021	0.0004	
no	46/ 51 (90.2) [78.6, 96.7]	19/ 23 (82.6) [61.2, 95.0]	1.09 (0.89, 1.34)	0.4081	1.94 (0.47, 8.01)	0.3613	7.59 (-13.08, 28.25)	0.4717	0.3586	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Confirmed Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Renal impairment at baseline										0.1039
normal	27/ 32 (84.4) [67.2, 94.7]	9/ 12 (75.0) [42.8, 94.5]	1.13 (0.79, 1.61)	0.5203	1.80 (0.36, 9.08)	0.4765	9.38 (-23.89, 42.64)	0.5807	0.4778	
mild	45/ 52 (86.5) [74.2, 94.4]	12/ 26 (46.2) [26.6, 66.6]	1.88 (1.22, 2.88)	0.0041	7.50 (2.48, 22.72)	0.0004	40.38 (16.21, 64.56)	0.0011	0.0002	
moderate	30/ 35 (85.7) [69.7, 95.2]	14/ 18 (77.8) [52.4, 93.6]	1.10 (0.83, 1.46)	0.4988	1.71 (0.40, 7.38)	0.4693	7.94 (-18.70, 34.58)	0.5593	0.4704	
Hepatic impairment at baseline										0.9063
normal	75/ 84 (89.3) [80.6, 95.0]	28/ 43 (65.1) [49.1, 79.0]	1.37 (1.09, 1.73)	0.0074	4.46 (1.76, 11.35)	0.0017	24.17 (6.71, 41.63)	0.0067	0.0010	
mild	26/ 34 (76.5) [58.8, 89.3]	7/ 13 (53.8) [25.1, 80.8]	1.42 (0.83, 2.43)	0.2002	2.79 (0.72, 10.72)	0.1363	22.62 (-13.31, 58.56)	0.2172	0.1334	
moderate	1/ 1 (100.0) [2.5, 100.0]	0 [NE, NE]	NE	NE	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors										0.6559
yes	6/ 7 (85.7) [42.1, 99.6]	2/ 4 (50.0) [6.8, 93.2]	1.71 (0.61, 4.78)	0.3030	6.00 (0.34, 107.42)	0.2235	35.71 (-39.36, 100.00)	0.3511	0.2225	
no	96/112 (85.7) [77.8, 91.6]	33/ 52 (63.5) [49.0, 76.4]	1.35 (1.08, 1.68)	0.0073	3.45 (1.59, 7.49)	0.0017	22.25 (6.24, 38.27)	0.0065	0.0013	
Most recently treatment with irinotecan or other topoisomerase I inhibitors										0.8342
yes	2/ 2 (100.0) [15.8, 100.0]	2/ 3 (66.7) [9.4, 99.2]	1.50 (0.67, 3.34)	0.3206	3.00 (0.08, 115.34)	0.5552	33.33 (-61.68, 100.00)	0.4917	0.4142	
no	100/117 (85.5) [77.8, 91.3]	33/ 53 (62.3) [47.9, 75.2]	1.37 (1.10, 1.71)	0.0053	3.57 (1.67, 7.60)	0.0010	23.21 (7.31, 39.11)	0.0042	0.0007	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Disease Control Rate (DCR) based on ICR
Response Evaluable Set

	DS-8201a (N=119)	Phys. Choice (N=56)
Number of subjects with events, n (%)	103 (86.6)	35 (62.5)
95% CI [a]	79.1, 92.1	48.5, 75.1
Analysis DS-8201a vs. Phys. Choice (stratified)		
Relative Risk (95% CI) [b]	1.39 (1.12, 1.72)	
p-value	0.0030	
Odds Ratio (95% CI) [b]	3.86 (1.81, 8.20)	
p-value	0.0005	
Risk Difference (95% CI) [c]	24.07 (9.98, 38.16)	
p-value	0.0008	
CMH test [d]		
p-value	0.0003	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Relative Risk (95% CI) [e]	1.38 (1.12, 1.72)	
p-value	0.0030	
Odds Ratio (95% CI) [e]	3.86 (1.82, 8.22)	
p-value	0.0005	
Risk Difference (95% CI) [f]	24.05 (8.66, 39.45)	
p-value	0.0022	
CMH test [d]		
p-value	0.0003	

Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Mantel-Haenszel estimators for Common Odds Ratio and Relative Risks. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the common risk difference of two proportions.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[f] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Region										0.5597
Japan	82/ 95 (86.3) [77.7, 92.5]	29/ 45 (64.4) [48.8, 78.1]	1.34 (1.06, 1.69)	0.0133	3.48 (1.49, 8.11)	0.0038	21.87 (4.63, 39.11)	0.0129	0.0030	
Korea	21/ 24 (87.5) [67.6, 97.3]	6/ 11 (54.5) [23.4, 83.3]	1.60 (0.92, 2.81)	0.0983	5.83 (1.07, 31.76)	0.0414	32.95 (-5.94, 71.85)	0.0968	0.0336	
Lines of prior systemic therapy										0.7833
2	50/ 60 (83.3) [71.5, 91.7]	20/ 33 (60.6) [42.1, 77.1]	1.38 (1.02, 1.85)	0.0359	3.25 (1.23, 8.61)	0.0177	22.73 (1.23, 44.23)	0.0383	0.0156	
3	31/ 34 (91.2) [76.3, 98.1]	12/ 17 (70.6) [44.0, 89.7]	1.29 (0.93, 1.79)	0.1218	4.31 (0.89, 20.88)	0.0699	20.59 (-7.49, 48.67)	0.1507	0.0592	
>=4	22/ 25 (88.0) [68.8, 97.5]	3/ 6 (50.0) [11.8, 88.2]	1.76 (0.78, 3.97)	0.1730	7.33 (0.99, 54.40)	0.0513	38.00 (-14.32, 90.32)	0.1546	0.0374	
Age										0.3690
<65 years	45/ 52 (86.5) [74.2, 94.4]	12/ 22 (54.5) [32.2, 75.6]	1.59 (1.07, 2.36)	0.0224	5.36 (1.68, 17.04)	0.0045	31.99 (5.98, 58.01)	0.0159	0.0030	
>=65 years	58/ 67 (86.6) [76.0, 93.7]	23/ 34 (67.6) [49.5, 82.6]	1.28 (1.00, 1.64)	0.0540	3.08 (1.13, 8.42)	0.0281	18.92 (-1.02, 38.86)	0.0629	0.0249	
Sex										0.9027
female	27/ 30 (90.0) [73.5, 97.9]	8/ 12 (66.7) [34.9, 90.1]	1.35 (0.89, 2.05)	0.1589	4.50 (0.83, 24.44)	0.0815	23.33 (-11.25, 57.92)	0.1861	0.0701	
male	76/ 89 (85.4) [76.3, 92.0]	27/ 44 (61.4) [45.5, 75.6]	1.39 (1.08, 1.79)	0.0095	3.68 (1.58, 8.57)	0.0025	24.03 (6.18, 41.88)	0.0083	0.0019	
ECOG PS										0.9088
0	53/ 59 (89.8) [79.2, 96.2]	19/ 29 (65.5) [45.7, 82.1]	1.37 (1.04, 1.81)	0.0259	4.65 (1.49, 14.53)	0.0082	24.31 (2.80, 45.83)	0.0267	0.0057	
1	50/ 60 (83.3) [71.5, 91.7]	16/ 27 (59.3) [38.8, 77.6]	1.41 (1.01, 1.96)	0.0445	3.44 (1.23, 9.58)	0.0182	24.07 (0.59, 47.55)	0.0445	0.0158	
HER2 Status in central laboratory										0.3751
IHC 3+	78/ 91 (85.7) [76.8, 92.2]	26/ 44 (59.1) [43.2, 73.7]	1.45 (1.12, 1.88)	0.0050	4.15 (1.79, 9.62)	0.0009	26.62 (8.73, 44.52)	0.0035	0.0006	
IHC 2+/ISH +	25/ 28 (89.3) [71.8, 97.7]	9/ 12 (75.0) [42.8, 94.5]	1.19 (0.84, 1.69)	0.3302	2.78 (0.47, 16.35)	0.2586	14.29 (-18.71, 47.28)	0.3962	0.2522	
Primary tumor location										0.5944
Gastric	89/104 (85.6) [77.3, 91.7]	31/ 49 (63.3) [48.3, 76.6]	1.35 (1.08, 1.70)	0.0092	3.45 (1.55, 7.65)	0.0024	22.31 (5.72, 38.91)	0.0084	0.0018	
GEJ	14/ 15 (93.3) [68.1, 99.8]	4/ 7 (57.1) [18.4, 90.1]	1.63 (0.85, 3.15)	0.1425	10.50 (0.84, 130.66)	0.0676	36.19 (-13.06, 85.44)	0.1498	0.0452	
Histological subtype										0.8508
intestinal	76/ 86 (88.4) [79.7, 94.3]	24/ 37 (64.9) [47.5, 79.8]	1.36 (1.06, 1.75)	0.0150	4.12 (1.60, 10.58)	0.0033	23.51 (4.77, 42.25)	0.0140	0.0023	
diffuse	23/ 27 (85.2) [66.3, 95.8]	8/ 14 (57.1) [28.9, 82.3]	1.49 (0.92, 2.41)	0.1031	4.31 (0.96, 19.31)	0.0561	28.04 (-6.56, 62.65)	0.1122	0.0502	
others	4/ 6 (66.7) [22.3, 95.7]	3/ 5 (60.0) [14.7, 94.7]	1.11 (0.45, 2.77)	0.8209	1.33 (0.11, 15.70)	0.8192	6.67 (-68.82, 82.15)	0.8626	0.8273	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice: Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Number of metastatic sites										0.8873
<2	20/ 21 (95.2) [76.2, 99.9]	4/ 6 (66.7) [22.3, 95.7]	1.43 (0.80, 2.54)	0.2231	10.00 (0.72, 138.68)	0.0861	28.57 (-20.95, 78.09)	0.2581	0.0539	
>= 2	83/ 98 (84.7) [76.0, 91.2]	31/ 50 (62.0) [47.2, 75.3]	1.37 (1.08, 1.72)	0.0086	3.39 (1.53, 7.49)	0.0025	22.69 (5.96, 39.43)	0.0079	0.0020	
Previous total gastrectomy										0.3704
yes	18/ 21 (85.7) [63.7, 97.0]	6/ 8 (75.0) [34.9, 96.8]	1.14 (0.74, 1.77)	0.5488	2.00 (0.27, 14.98)	0.4999	10.71 (-31.45, 52.88)	0.6184	0.5023	
no	85/ 98 (86.7) [78.4, 92.7]	29/ 48 (60.4) [45.3, 74.2]	1.44 (1.13, 1.83)	0.0034	4.28 (1.88, 9.74)	0.0005	26.32 (9.39, 43.25)	0.0023	0.0003	
Prior adjuvant/ neoadjuvant therapy										0.6280
yes	27/ 29 (93.1) [77.2, 99.2]	6/ 8 (75.0) [34.9, 96.8]	1.24 (0.82, 1.87)	0.3038	4.50 (0.52, 38.65)	0.1704	18.10 (-21.26, 57.47)	0.3674	0.1499	
no	76/ 90 (84.4) [75.3, 91.2]	29/ 48 (60.4) [45.3, 74.2]	1.40 (1.09, 1.79)	0.0075	3.56 (1.58, 8.01)	0.0022	24.03 (6.70, 41.36)	0.0066	0.0017	
Prior ramucirumab contained treatment										0.3258
yes	76/ 89 (85.4) [76.3, 92.0]	21/ 37 (56.8) [39.5, 72.9]	1.50 (1.12, 2.02)	0.0065	4.45 (1.85, 10.71)	0.0008	28.64 (9.15, 48.12)	0.0040	0.0005	
no	27/ 30 (90.0) [73.5, 97.9]	14/ 19 (73.7) [48.8, 90.9]	1.22 (0.91, 1.64)	0.1824	3.21 (0.67, 15.45)	0.1450	16.32 (-10.51, 43.14)	0.2332	0.1362	
Prior nivolumab contained treatment										0.3186
yes	31/ 33 (93.9) [79.8, 99.3]	11/ 14 (78.6) [49.2, 95.3]	1.20 (0.90, 1.59)	0.2224	4.23 (0.62, 28.74)	0.1405	15.37 (-12.70, 43.44)	0.2833	0.1221	
no	72/ 86 (83.7) [74.2, 90.8]	24/ 42 (57.1) [41.0, 72.3]	1.47 (1.11, 1.93)	0.0071	3.86 (1.67, 8.91)	0.0016	26.58 (7.93, 45.23)	0.0052	0.0012	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy										0.1727
yes	41/ 44 (93.2) [81.3, 98.6]	13/ 16 (81.3) [54.4, 96.0]	1.15 (0.89, 1.47)	0.2800	3.15 (0.57, 17.57)	0.1900	11.93 (-12.85, 36.72)	0.3454	0.1767	
no	62/ 75 (82.7) [72.2, 90.4]	22/ 40 (55.0) [38.5, 70.7]	1.50 (1.11, 2.03)	0.0075	3.90 (1.65, 9.25)	0.0020	27.67 (8.11, 47.22)	0.0056	0.0015	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug										0.6662
yes	18/ 22 (81.8) [59.7, 94.8]	4/ 6 (66.7) [22.3, 95.7]	1.23 (0.67, 2.23)	0.5029	2.25 (0.30, 16.85)	0.4299	15.15 (-36.47, 66.78)	0.5651	0.4311	
no	85/ 97 (87.6) [79.4, 93.4]	31/ 50 (62.0) [47.2, 75.3]	1.41 (1.12, 1.78)	0.0031	4.34 (1.89, 9.97)	0.0005	25.63 (9.15, 42.11)	0.0023	0.0003	
Presence of liver metastasis at baseline										0.0504
yes	56/ 68 (82.4) [71.2, 90.5]	16/ 33 (48.5) [30.8, 66.5]	1.70 (1.17, 2.46)	0.0048	4.96 (1.97, 12.50)	0.0007	33.87 (12.31, 55.43)	0.0021	0.0004	
no	47/ 51 (92.2) [81.1, 97.8]	19/ 23 (82.6) [61.2, 95.0]	1.12 (0.91, 1.37)	0.2931	2.47 (0.56, 10.92)	0.2319	9.55 (-10.76, 29.86)	0.3569	0.2240	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Disease Control Rate (DCR) based on ICR - Subgroup analysis
Response Evaluable Set

Subgroup Level	DS-8201a (N=119) n/ N (%) [95% CI] [a]	Phys. Choice (N=56) n/ N (%) [95% CI] [a]	Analysis DS-8201a vs. Phys. Choice Relative Risk [b] (95% CI)	p-value	Odds Ratio [b] (95% CI)	p-value	Risk Difference [c] (95% CI)	p-value	CMH [d] p-value	Interaction p-value [e]
Renal impairment at baseline										0.1221
normal	27/ 32 (84.4) [67.2, 94.7]	9/ 12 (75.0) [42.8, 94.5]	1.13 (0.79, 1.61)	0.5203	1.80 (0.36, 9.08)	0.4765	9.38 (-23.89, 42.64)	0.5807	0.4778	
mild	45/ 52 (86.5) [74.2, 94.4]	12/ 26 (46.2) [26.6, 66.6]	1.88 (1.22, 2.88)	0.0041	7.50 (2.48, 22.72)	0.0004	40.38 (16.21, 64.56)	0.0011	0.0002	
moderate	31/ 35 (88.6) [73.3, 96.8]	14/ 18 (77.8) [52.4, 93.6]	1.14 (0.87, 1.50)	0.3528	2.21 (0.48, 10.15)	0.3063	10.79 (-15.32, 36.91)	0.4179	0.3032	
Hepatic impairment at baseline										0.9415
normal	76/ 84 (90.5) [82.1, 95.8]	28/ 43 (65.1) [49.1, 79.0]	1.39 (1.10, 1.75)	0.0050	5.09 (1.95, 13.31)	0.0009	25.36 (8.03, 42.68)	0.0041	0.0005	
mild	26/ 34 (76.5) [58.8, 89.3]	7/ 13 (53.8) [25.1, 80.8]	1.42 (0.83, 2.43)	0.2002	2.79 (0.72, 10.72)	0.1363	22.62 (-13.31, 58.56)	0.2172	0.1334	
moderate	1/ 1 (100.0) [2.5, 100.0]	0 [NE, NE]	NE	NE	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors										0.6699
yes	6/ 7 (85.7) [42.1, 99.6]	2/ 4 (50.0) [6.8, 93.2]	1.71 (0.61, 4.78)	0.3030	6.00 (0.34, 107.42)	0.2235	35.71 (-39.36, 100.00)	0.3511	0.2225	
no	97/112 (86.6) [78.9, 92.3]	33/ 52 (63.5) [49.0, 76.4]	1.36 (1.10, 1.70)	0.0053	3.72 (1.70, 8.15)	0.0010	23.15 (7.21, 39.08)	0.0044	0.0007	
Most recently treatment with irinotecan or other topoisomerase I inhibitors										0.8526
yes	2/ 2 (100.0) [15.8, 100.0]	2/ 3 (66.7) [9.4, 99.2]	1.50 (0.67, 3.34)	0.3206	3.00 (0.08, 115.34)	0.5552	33.33 (-61.68, 100.00)	0.4917	0.4142	
no	101/117 (86.3) [78.7, 92.0]	33/ 53 (62.3) [47.9, 75.2]	1.39 (1.11, 1.73)	0.0039	3.83 (1.78, 8.23)	0.0006	24.06 (8.23, 39.89)	0.0029	0.0004	

NE: Not estimable.
[a] Based on Clopper-Pearson method.
[b] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[c] Derived from the risk difference of two proportions with continuity correction.
[d] Derived from Cochrane-Mantel-Haenszel (CMH) test.
[e] Derived from test for heterogeneity of the Relative Risks in the subgroups using Cochrane`s Q statistic.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Progression-free Survival
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	82 (65.6)	36 (58.1)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	5.6 (4.3, 6.9)	3.5 (2.0, 4.3)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	71.9 (63.0, 79.1)	50.3 (35.5, 63.5)
6 Months (95% CI)	43.0 (33.6, 52.0)	20.6 (8.9, 35.6)
9 Months (95% CI)	33.3 (24.4, 42.4)	NE (NE, NE)
12 Months (95% CI)	30.4 (21.5, 39.7)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.47 (0.31, 0.71)	
p-value [c]	0.0003	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.47 (0.31, 0.71)	
p-value [c]	0.0003	

Progression-free survival (PFS) is defined as the time from the date of randomization to the earliest date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Progression-free Survival - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.8944
Japan	65/ 99 (65.7)	5.6 (4.4, 6.9)	30/ 50 (60.0)	4.1 (2.0, 4.9)	0.46 (0.29, 0.73)	0.0008	
Korea	17/ 26 (65.4)	4.4 (2.9, 15.2)	6/ 12 (50.0)	2.8 (1.3, NE)	0.52 (0.19, 1.38)	0.1760	
Lines of prior systemic therapy							0.4591
2	45/ 66 (68.2)	4.3 (3.6, 8.2)	22/ 38 (57.9)	3.5 (1.7, 5.5)	0.60 (0.35, 1.03)	0.0601	
3	22/ 34 (64.7)	5.7 (4.5, 14.2)	11/ 18 (61.1)	4.1 (1.6, 5.6)	0.24 (0.10, 0.56)	0.0004	
>=4	15/ 25 (60.0)	5.6 (3.6, NE)	3/ 6 (50.0)	2.8 (0.7, NE)	0.43 (0.12, 1.53)	0.1785	
Age							0.5740
<65 years	39/ 55 (70.9)	5.4 (3.6, 7.0)	13/ 27 (48.1)	2.8 (1.4, NE)	0.57 (0.30, 1.11)	0.0940	
>=65 years	43/ 70 (61.4)	5.7 (4.4, 8.2)	23/ 35 (65.7)	4.1 (2.0, 5.5)	0.40 (0.23, 0.68)	0.0006	
Sex							0.5709
female	21/ 30 (70.0)	4.5 (2.8, 7.0)	8/ 15 (53.3)	3.5 (1.6, NE)	0.54 (0.23, 1.29)	0.1580	
male	61/ 95 (64.2)	5.7 (4.3, 7.1)	28/ 47 (59.6)	4.1 (2.0, 5.5)	0.45 (0.28, 0.72)	0.0007	
ECOG PS							0.3937
0	40/ 62 (64.5)	5.8 (4.7, 9.8)	18/ 30 (60.0)	4.3 (1.6, 5.6)	0.39 (0.21, 0.70)	0.0013	
1	42/ 63 (66.7)	4.5 (3.6, 6.9)	18/ 32 (56.3)	2.8 (1.8, 4.3)	0.56 (0.31, 0.99)	0.0441	
HER2 Status in central laboratory							0.0238
IHC 3+	59/ 96 (61.5)	5.8 (4.4, 9.8)	29/ 47 (61.7)	2.8 (1.8, 4.3)	0.37 (0.23, 0.59)	<.0001	
IHC 2+/ISH +	23/ 29 (79.3)	4.3 (2.7, 5.7)	7/ 15 (46.7)	4.3 (1.6, NE)	1.01 (0.42, 2.42)	0.9729	
Primary tumor location							0.8556
Gastric	72/108 (66.7)	5.4 (4.1, 6.7)	33/ 55 (60.0)	2.8 (2.0, 4.9)	0.50 (0.32, 0.77)	0.0014	
GEJ	10/ 17 (58.8)	6.9 (5.4, 14.2)	3/ 7 (42.9)	4.3 (1.4, 4.3)	0.21 (0.04, 1.06)	0.0383	
Histological subtype							0.2289
intestinal	57/ 89 (64.0)	5.6 (4.4, 7.0)	26/ 38 (68.4)	4.1 (2.0, 4.9)	0.45 (0.28, 0.73)	0.0011	
diffuse	18/ 28 (64.3)	5.8 (3.6, 20.7)	7/ 18 (38.9)	2.6 (1.4, NE)	0.33 (0.12, 0.88)	0.0215	
others	7/ 8 (87.5)	2.9 (1.0, 15.2)	3/ 6 (50.0)	5.6 (1.4, NE)	1.46 (0.36, 5.89)	0.5904	
Number of metastatic sites							0.7973
<2	14/ 23 (60.9)	12.0 (3.9, 20.7)	5/ 10 (50.0)	4.2 (1.3, NE)	0.44 (0.15, 1.29)	0.1226	
>= 2	68/102 (66.7)	5.6 (4.3, 5.8)	31/ 52 (59.6)	3.5 (2.0, 4.3)	0.49 (0.31, 0.76)	0.0014	
Previous total gastrectomy							0.1438
yes	10/ 22 (45.5)	8.3 (4.0, NE)	5/ 9 (55.6)	2.8 (0.7, 4.9)	0.21 (0.06, 0.74)	0.0087	
no	72/103 (69.9)	5.4 (4.2, 6.7)	31/ 53 (58.5)	3.5 (2.0, 5.5)	0.53 (0.34, 0.82)	0.0040	
Prior adjuvant/ neoadjuvant therapy							0.7571
yes	15/ 30 (50.0)	7.1 (5.6, NE)	5/ 10 (50.0)	2.8 (0.7, NE)	0.39 (0.13, 1.13)	0.0783	
no	67/ 95 (70.5)	4.6 (4.1, 5.8)	31/ 52 (59.6)	3.5 (2.0, 4.3)	0.51 (0.33, 0.80)	0.0028	
Prior ramucirumab contained treatment							0.5596
yes	62/ 94 (66.0)	5.5 (4.2, 6.9)	25/ 41 (61.0)	2.8 (1.8, 4.3)	0.45 (0.28, 0.73)	0.0010	
no	20/ 31 (64.5)	6.7 (3.6, 12.0)	11/ 21 (52.4)	4.3 (1.7, 6.4)	0.48 (0.22, 1.05)	0.0600	

Progression-free survival (PFS) is defined as the time from the date of randomization to the earliest date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

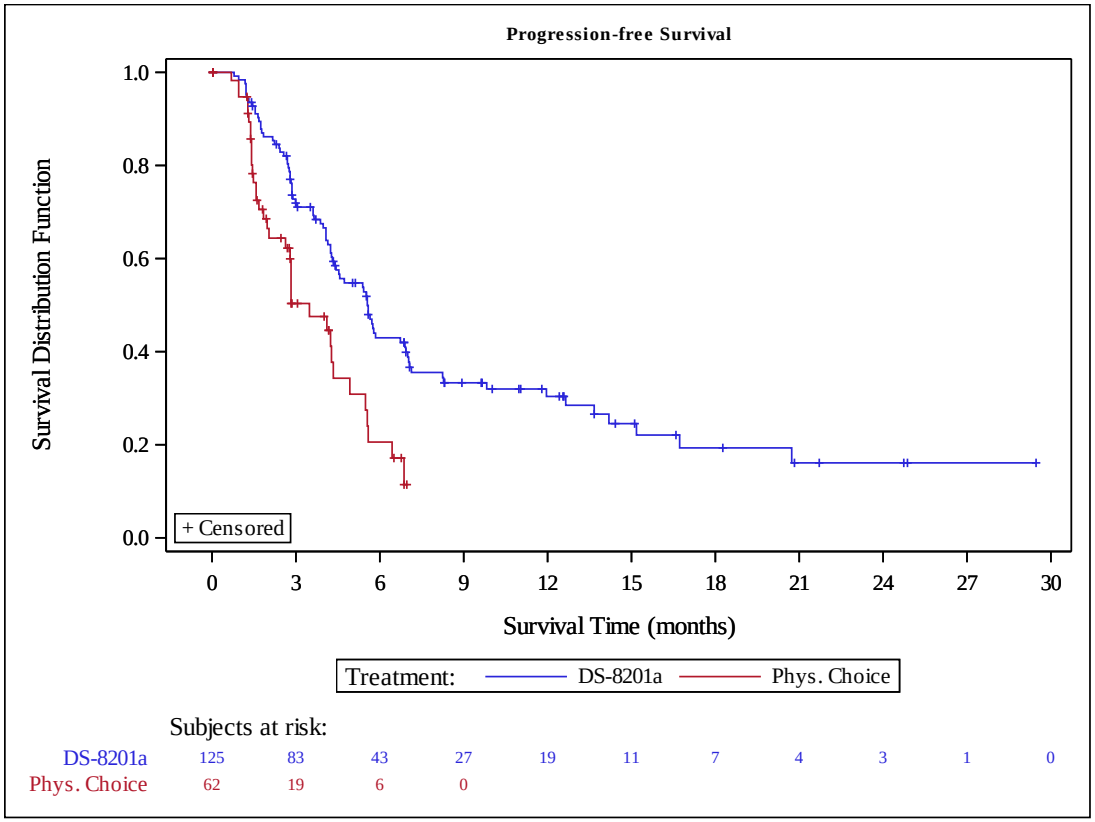
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Progression-free Survival - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.2596
yes	23/ 33 (69.7)	6.7 (5.5, 14.2)	9/ 15 (60.0)	2.8 (2.0, 4.3)	0.21 (0.08, 0.52)	0.0004	
no	59/ 92 (64.1)	4.5 (4.1, 6.9)	27/ 47 (57.4)	3.5 (1.7, 5.5)	0.57 (0.36, 0.92)	0.0199	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.3414
yes	29/ 44 (65.9)	5.8 (5.4, 14.2)	9/ 17 (52.9)	2.8 (2.6, 5.6)	0.26 (0.11, 0.60)	0.0010	
no	53/ 81 (65.4)	4.5 (4.0, 6.9)	27/ 45 (60.0)	3.5 (1.6, 5.5)	0.57 (0.35, 0.93)	0.0215	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.1890
yes	14/ 22 (63.6)	4.3 (2.8, 5.8)	2/ 7 (28.6)	NE (1.3, NE)	1.44 (0.33, 6.42)	0.6217	
no	68/103 (66.0)	5.7 (4.4, 7.0)	34/ 55 (61.8)	2.8 (2.0, 4.3)	0.40 (0.26, 0.63)	<.0001	
Presence of liver metastasis at baseline							0.0627
yes	44/ 68 (64.7)	4.7 (3.6, 6.9)	26/ 34 (76.5)	2.0 (1.4, 4.2)	0.37 (0.22, 0.61)	<.0001	
no	38/ 57 (66.7)	5.8 (4.4, 12.0)	10/ 28 (35.7)	4.9 (2.8, NE)	0.73 (0.35, 1.52)	0.3994	
Renal impairment at baseline							0.6907
normal	23/ 33 (69.7)	5.6 (3.9, 13.7)	5/ 13 (38.5)	3.5 (1.4, 4.3)	0.45 (0.15, 1.31)	0.1344	
mild	35/ 53 (66.0)	4.5 (3.6, 5.8)	19/ 28 (67.9)	2.0 (1.4, 5.5)	0.45 (0.26, 0.81)	0.0059	
moderate	24/ 39 (61.5)	6.9 (4.2, 12.0)	11/ 20 (55.0)	4.3 (2.8, 6.9)	0.50 (0.23, 1.08)	0.0752	
severe	0	NE (NE , NE)	1/ 1 (100.0)	2.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.4313
normal	58/ 88 (65.9)	5.6 (4.5, 7.0)	26/ 47 (55.3)	3.5 (2.0, 4.9)	0.39 (0.24, 0.65)	0.0001	
mild	24/ 36 (66.7)	3.6 (2.6, 7.1)	10/ 15 (66.7)	2.8 (1.4, NE)	0.71 (0.33, 1.52)	0.3792	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.5722
yes	5/ 8 (62.5)	6.9 (1.2, NE)	3/ 5 (60.0)	4.3 (2.0, 5.5)	0.17 (0.03, 1.08)	0.0356	
no	77/117 (65.8)	5.6 (4.2, 6.7)	33/ 57 (57.9)	2.8 (2.0, 4.9)	0.50 (0.32, 0.76)	0.0011	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.7695
yes	3/ 3 (100.0)	6.9 (5.6, 12.0)	2/ 4 (50.0)	4.9 (4.3, 5.5)	0.00 (0.00, NE)	0.0389	
no	79/122 (64.8)	5.6 (4.3, 6.9)	34/ 58 (58.6)	2.8 (2.0, 4.3)	0.48 (0.31, 0.73)	0.0005	

Progression-free survival (PFS) is defined as the time from the date of randomization to the earliest date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

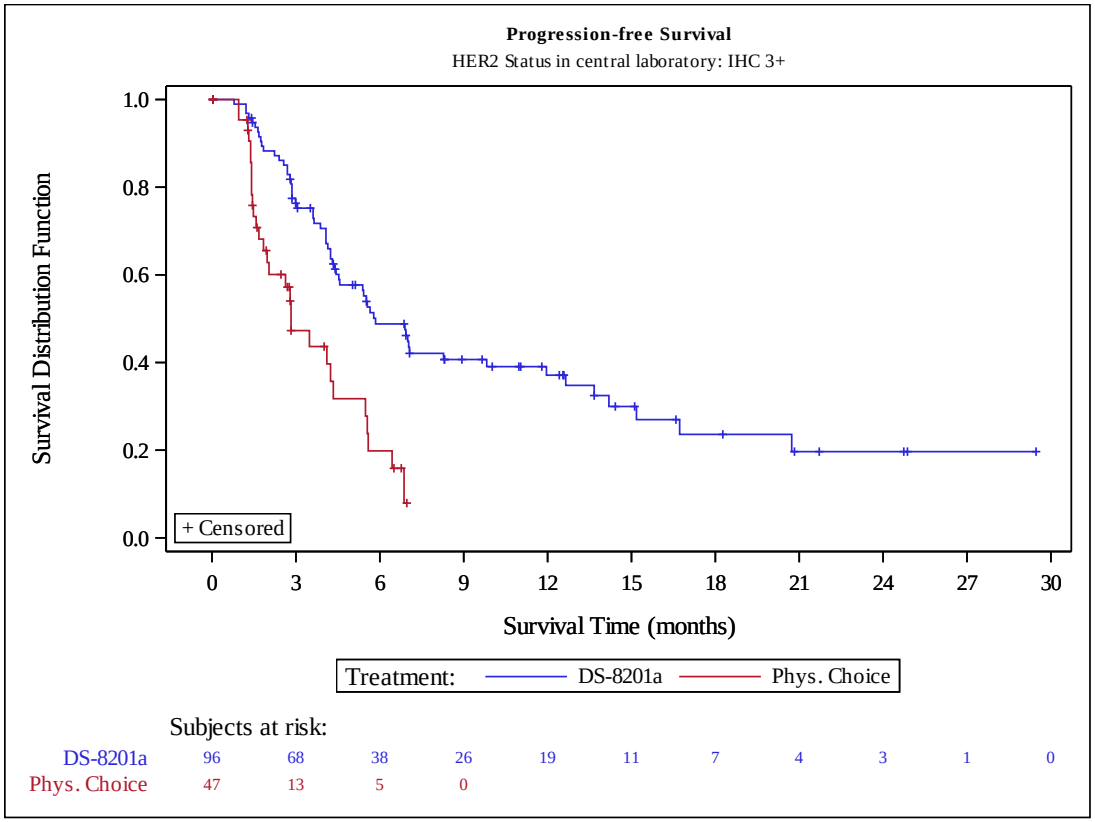
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Progression-free Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

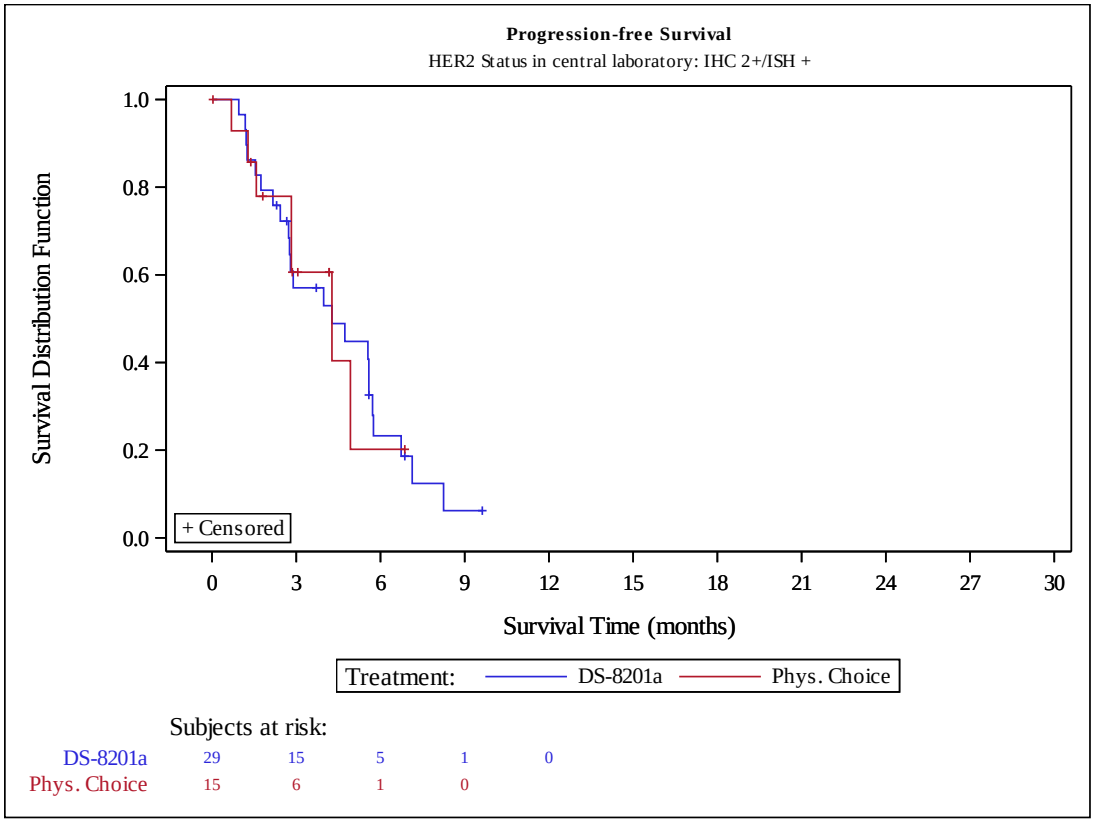
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Progression-free Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Progression-free Survival
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Duration of Confirmed Response
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with confirmed response (CR+PR), N*	50	7
Number of subjects with events, n (%)	23 (46.0)	5 (71.4)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	12.5 (5.6, NE)	3.9 (3.0, 4.9)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	87.3 (73.9, 94.1)	100.0 (100.0, 100.0)
6 Months (95% CI)	61.3 (45.1, 74.0)	NE (NE, NE)
9 Months (95% CI)	58.4 (42.0, 71.6)	NE (NE, NE)
12 Months (95% CI)	54.2 (37.1, 68.5)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.22 (0.07, 0.63)	
p-value [c]	0.0022	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.20 (0.07, 0.58)	
p-value [c]	0.0011	

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Duration of Confirmed Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N* (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N* (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.8823
Japan	19/ 42 (45.2)	12.5 (5.6, NE)	4/ 6 (66.7)	4.1 (3.0, 4.9)	0.19 (0.06, 0.63)	0.0024	
Korea	4/ 8 (50.0)	18.1 (3.0, 18.1)	1/ 1 (100.0)	3.9 (NE , NE)	0.34 (0.03, 3.74)	0.3530	
Lines of prior systemic therapy							0.7240
2	10/ 20 (50.0)	11.3 (5.5, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.24 (0.05, 1.10)	0.0550	
3	8/ 17 (47.1)	14.0 (4.1, NE)	2/ 3 (66.7)	3.6 (3.0, 4.2)	0.25 (0.05, 1.32)	0.0788	
>=4	5/ 13 (38.5)	NE (5.5, NE)	0	NE (NE , NE)	NE	NE	
Age							0.9921
<65 years	13/ 23 (56.5)	8.4 (4.1, 18.1)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	10/ 27 (37.0)	14.0 (5.6, NE)	5/ 6 (83.3)	3.9 (3.0, 4.9)	0.15 (0.04, 0.53)	0.0009	
Sex							0.5692
female	5/ 10 (50.0)	8.4 (2.5, NE)	1/ 2 (50.0)	3.0 (NE , NE)	0.11 (0.01, 1.69)	0.0515	
male	18/ 40 (45.0)	12.7 (5.6, NE)	4/ 5 (80.0)	4.1 (3.9, 4.9)	0.22 (0.07, 0.72)	0.0070	
ECOG PS							0.1482
0	12/ 28 (42.9)	14.0 (5.7, NE)	3/ 3 (100.0)	3.9 (3.0, 3.9)	0.05 (0.01, 0.32)	<.0001	
1	11/ 22 (50.0)	5.6 (3.0, 18.1)	2/ 4 (50.0)	4.6 (4.2, 4.9)	0.38 (0.08, 1.88)	0.2165	
HER2 Status in central laboratory							0.7929
IHC 3+	19/ 44 (43.2)	12.7 (5.7, NE)	4/ 4 (100.0)	4.1 (3.9, 4.9)	0.20 (0.06, 0.66)	0.0040	
IHC 2+/ISH +	4/ 6 (66.7)	5.6 (2.9, NE)	1/ 3 (33.3)	3.0 (NE , NE)	0.18 (0.01, 2.93)	0.1768	
Primary tumor location							0.9921
Gastric	18/ 42 (42.9)	14.0 (5.6, NE)	5/ 6 (83.3)	3.9 (3.0, 4.9)	0.20 (0.07, 0.60)	0.0017	
GEJ	5/ 8 (62.5)	8.4 (4.1, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	16/ 35 (45.7)	12.5 (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.20 (0.07, 0.63)	0.0025	
diffuse	7/ 15 (46.7)	18.1 (4.2, 18.1)	0	NE (NE , NE)	NE	NE	
others	0	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.5016
<2	4/ 12 (33.3)	12.7 (12.5, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.10 (0.01, 1.61)	0.0453	
>= 2	19/ 38 (50.0)	8.4 (5.5, NE)	4/ 6 (66.7)	4.1 (3.0, 4.9)	0.25 (0.08, 0.80)	0.0110	
Previous total gastrectomy							NE
yes	3/ 11 (27.3)	18.1 (4.1, NE)	0	NE (NE , NE)	NE	NE	
no	20/ 39 (51.3)	11.3 (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.21 (0.07, 0.65)	0.0031	
Prior adjuvant/ neoadjuvant therapy							NE
yes	6/ 17 (35.3)	18.1 (4.2, NE)	0	NE (NE , NE)	NE	NE	
no	17/ 33 (51.5)	11.3 (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.24 (0.08, 0.73)	0.0075	
Prior ramucirumab contained treatment							0.7043
yes	16/ 37 (43.2)	12.7 (5.6, NE)	3/ 5 (60.0)	3.9 (3.0, 4.2)	0.21 (0.06, 0.78)	0.0103	
no	7/ 13 (53.8)	11.3 (5.5, 18.1)	2/ 2 (100.0)	4.4 (3.9, 4.9)	0.15 (0.02, 1.09)	0.0305	

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

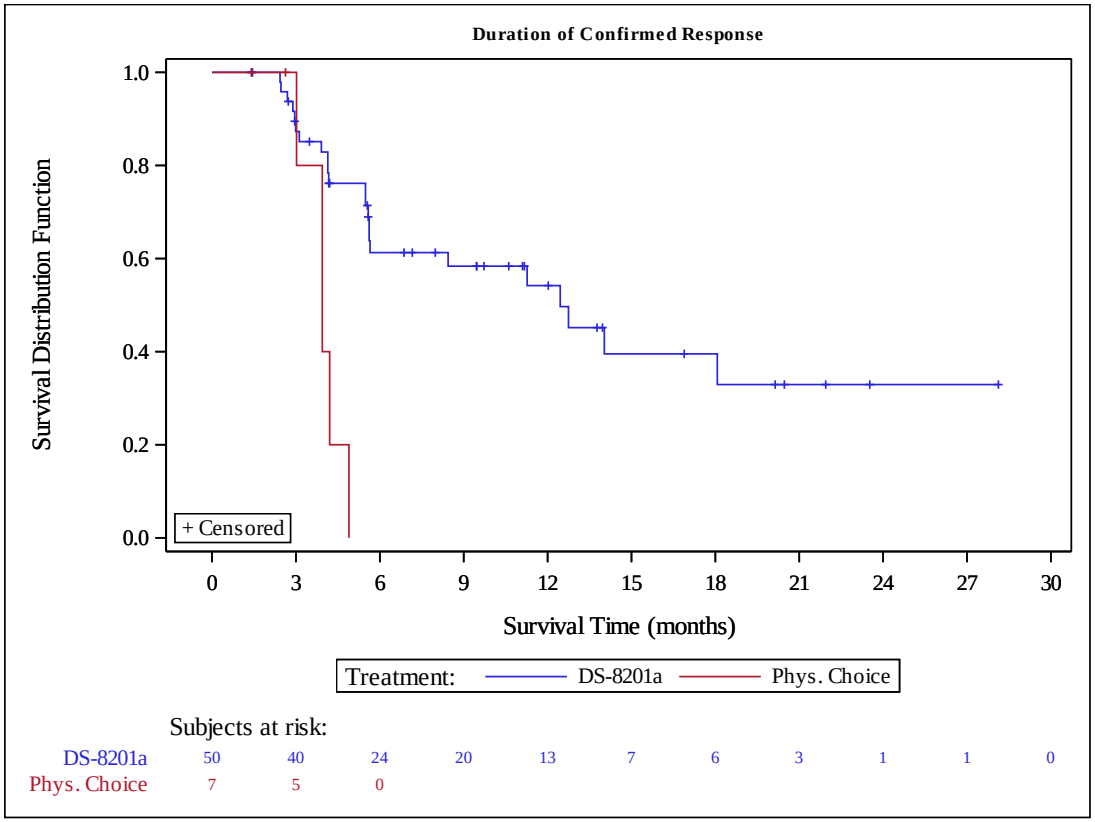
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Duration of Confirmed Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N* (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N* (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.9756
yes	11/ 20 (55.0)	12.7 (4.1, NE)	2/ 3 (66.7)	3.6 (3.0, 4.2)	0.18 (0.03, 0.91)	0.0181	
no	12/ 30 (40.0)	12.5 (5.6, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.22 (0.05, 0.89)	0.0245	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8123
yes	13/ 25 (52.0)	14.0 (5.5, NE)	2/ 3 (66.7)	3.6 (3.0, 4.2)	0.18 (0.04, 0.90)	0.0179	
no	10/ 25 (40.0)	11.3 (5.5, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.22 (0.05, 0.95)	0.0317	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	3/ 8 (37.5)	NE (2.4, NE)	0	NE (NE , NE)	NE	NE	
no	20/ 42 (47.6)	12.5 (5.6, 18.1)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.17 (0.05, 0.52)	0.0005	
Presence of liver metastasis at baseline							0.8829
yes	13/ 25 (52.0)	12.7 (4.1, NE)	4/ 4 (100.0)	4.1 (3.0, 4.9)	0.24 (0.07, 0.84)	0.0151	
no	10/ 25 (40.0)	12.5 (5.5, NE)	1/ 3 (33.3)	3.9 (NE , NE)	0.15 (0.02, 1.44)	0.0566	
Renal impairment at baseline							0.8212
normal	10/ 16 (62.5)	12.5 (4.1, NE)	0	NE (NE , NE)	NE	NE	
mild	6/ 19 (31.6)	NE (3.9, NE)	3/ 3 (100.0)	4.2 (3.9, 4.9)	0.31 (0.07, 1.29)	0.0887	
moderate	7/ 15 (46.7)	11.3 (5.6, NE)	2/ 4 (50.0)	3.5 (3.0, 3.9)	0.13 (0.02, 0.96)	0.0186	
severe	0	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7442
normal	17/ 36 (47.2)	12.7 (5.6, NE)	4/ 6 (66.7)	3.9 (3.0, 4.9)	0.17 (0.05, 0.58)	0.0017	
mild	6/ 13 (46.2)	12.5 (2.9, NE)	1/ 1 (100.0)	4.2 (NE , NE)	0.30 (0.03, 2.88)	0.2661	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.5300
yes	1/ 3 (33.3)	NE (5.5, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.00 (0.00, NE)	0.0833	
no	22/ 47 (46.8)	12.5 (5.6, NE)	4/ 6 (66.7)	4.1 (3.0, 4.9)	0.23 (0.07, 0.72)	0.0059	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.5598
yes	1/ 1 (100.0)	5.5 (NE , NE)	1/ 1 (100.0)	3.9 (NE , NE)	NE	NE	
no	22/ 49 (44.9)	12.7 (5.6, NE)	4/ 6 (66.7)	4.1 (3.0, 4.9)	0.22 (0.07, 0.68)	0.0041	

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Duration of Confirmed Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Duration of Response
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with response (CR+PR), N*	61	8
Number of subjects with events, n (%)	30 (49.2)	5 (62.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	11.3 (5.5, 18.1)	3.9 (3.0, 4.9)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	78.3 (65.0, 87.1)	100.0 (100.0, 100.0)
6 Months (95% CI)	53.5 (38.8, 66.2)	NE (NE, NE)
9 Months (95% CI)	51.0 (36.2, 63.9)	NE (NE, NE)
12 Months (95% CI)	47.3 (32.1, 61.1)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.36 (0.13, 0.98)	
p-value [c]	0.0358	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.34 (0.12, 0.93)	
p-value [c]	0.0286	

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Duration of Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N* (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N* (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.9098
Japan	23/ 48 (47.9)	11.3 (5.5, NE)	4/ 7 (57.1)	4.1 (3.0, 4.9)	0.29 (0.09, 0.89)	0.0215	
Korea	7/ 13 (53.8)	5.6 (1.3, 18.1)	1/ 1 (100.0)	3.9 (NE , NE)	0.67 (0.08, 5.78)	0.7104	
Lines of prior systemic therapy							0.7708
2	16/ 29 (55.2)	5.6 (3.0, 12.5)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.58 (0.16, 2.12)	0.4318	
3	8/ 18 (44.4)	14.0 (4.1, NE)	2/ 3 (66.7)	3.6 (3.0, 4.2)	0.25 (0.05, 1.32)	0.0788	
>=4	6/ 14 (42.9)	NE (4.2, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9919
<65 years	18/ 30 (60.0)	5.5 (3.9, 12.7)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	12/ 31 (38.7)	14.0 (5.6, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.22 (0.07, 0.72)	0.0072	
Sex							0.9533
female	8/ 14 (57.1)	5.6 (1.3, NE)	1/ 2 (50.0)	3.0 (NE , NE)	0.56 (0.06, 5.02)	0.5963	
male	22/ 47 (46.8)	12.5 (5.5, 18.1)	4/ 6 (66.7)	4.1 (3.9, 4.9)	0.31 (0.10, 0.95)	0.0324	
ECOG PS							0.1470
0	15/ 31 (48.4)	12.7 (5.6, NE)	3/ 3 (100.0)	3.9 (3.0, 3.9)	0.11 (0.02, 0.50)	0.0009	
1	15/ 30 (50.0)	5.6 (3.0, 18.1)	2/ 5 (40.0)	4.6 (4.2, 4.9)	0.66 (0.14, 3.04)	0.5948	
HER2 Status in central laboratory							0.5137
IHC 3+	25/ 53 (47.2)	12.5 (5.5, 18.1)	4/ 5 (80.0)	4.1 (3.9, 4.9)	0.31 (0.10, 0.95)	0.0337	
IHC 2+/ISH +	5/ 8 (62.5)	5.5 (0.0, NE)	1/ 3 (33.3)	3.0 (NE , NE)	0.47 (0.04, 5.40)	0.5378	
Primary tumor location							0.9921
Gastric	24/ 52 (46.2)	12.5 (5.5, NE)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.35 (0.13, 0.97)	0.0380	
GEJ	6/ 9 (66.7)	5.5 (4.1, 12.7)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	19/ 41 (46.3)	11.3 (5.5, NE)	5/ 8 (62.5)	3.9 (3.0, 4.9)	0.27 (0.09, 0.80)	0.0124	
diffuse	10/ 18 (55.6)	5.6 (2.8, 18.1)	0	NE (NE , NE)	NE	NE	
others	1/ 2 (50.0)	NE (0.0, NE)	0	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.4765
<2	5/ 13 (38.5)	12.7 (2.7, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.18 (0.02, 2.05)	0.1224	
>= 2	25/ 48 (52.1)	5.6 (4.2, 14.0)	4/ 7 (57.1)	4.1 (3.0, 4.9)	0.41 (0.14, 1.24)	0.1014	
Previous total gastrectomy							0.9941
yes	3/ 12 (25.0)	18.1 (4.1, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
no	27/ 49 (55.1)	5.7 (4.2, 12.7)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.39 (0.14, 1.08)	0.0635	
Prior adjuvant/ neoadjuvant therapy							0.9940
yes	6/ 18 (33.3)	18.1 (4.2, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
no	24/ 43 (55.8)	5.7 (3.9, 12.7)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.44 (0.16, 1.23)	0.1145	
Prior ramucirumab contained treatment							0.6253
yes	19/ 42 (45.2)	12.5 (4.2, NE)	3/ 6 (50.0)	3.9 (3.0, 4.2)	0.28 (0.08, 1.02)	0.0389	
no	11/ 19 (57.9)	8.4 (2.4, 18.1)	2/ 2 (100.0)	4.4 (3.9, 4.9)	0.42 (0.08, 2.11)	0.2790	

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N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Duration of Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N* (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N* (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.9353
yes	13/ 22 (59.1)	5.7 (4.1, NE)	2/ 4 (50.0)	3.6 (3.0, 4.2)	0.22 (0.04, 1.12)	0.0437	
no	17/ 39 (43.6)	11.3 (4.2, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.41 (0.11, 1.49)	0.1762	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8942
yes	17/ 29 (58.6)	12.7 (4.1, NE)	2/ 4 (50.0)	3.6 (3.0, 4.2)	0.30 (0.06, 1.42)	0.1052	
no	13/ 32 (40.6)	11.3 (4.2, NE)	3/ 4 (75.0)	3.9 (3.9, 4.9)	0.36 (0.10, 1.39)	0.1376	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9938
yes	3/ 9 (33.3)	NE (2.4, NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
no	27/ 52 (51.9)	8.4 (5.5, 14.0)	5/ 7 (71.4)	3.9 (3.0, 4.9)	0.33 (0.12, 0.92)	0.0275	
Presence of liver metastasis at baseline							0.7830
yes	16/ 31 (51.6)	8.4 (4.1, NE)	4/ 5 (80.0)	4.1 (3.0, 4.9)	0.32 (0.10, 1.04)	0.0455	
no	14/ 30 (46.7)	11.3 (4.2, NE)	1/ 3 (33.3)	3.9 (NE , NE)	0.54 (0.07, 4.50)	0.5661	
Renal impairment at baseline							0.9138
normal	13/ 19 (68.4)	8.4 (4.1, 18.1)	0	NE (NE , NE)	NE	NE	
mild	9/ 24 (37.5)	NE (3.1, NE)	3/ 4 (75.0)	4.2 (3.9, 4.9)	0.46 (0.12, 1.76)	0.2464	
moderate	8/ 18 (44.4)	11.3 (5.6, NE)	2/ 4 (50.0)	3.5 (3.0, 3.9)	0.22 (0.04, 1.36)	0.0752	
severe	0	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9497
normal	23/ 46 (50.0)	11.3 (4.2, 18.1)	4/ 6 (66.7)	3.9 (3.0, 4.9)	0.33 (0.11, 1.03)	0.0492	
mild	7/ 14 (50.0)	12.5 (2.9, NE)	1/ 2 (50.0)	4.2 (NE , NE)	0.37 (0.04, 3.37)	0.3611	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4265
yes	1/ 3 (33.3)	NE (5.5, NE)	1/ 1 (100.0)	3.9 (NE , NE)	0.00 (0.00, NE)	0.0833	
no	29/ 58 (50.0)	11.3 (4.2, 14.0)	4/ 7 (57.1)	4.1 (3.0, 4.9)	0.39 (0.13, 1.16)	0.0793	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.7575
yes	1/ 1 (100.0)	5.5 (NE , NE)	1/ 1 (100.0)	3.9 (NE , NE)	NE	NE	
no	29/ 60 (48.3)	11.3 (5.5, 18.1)	4/ 7 (57.1)	4.1 (3.0, 4.9)	0.37 (0.13, 1.11)	0.0645	

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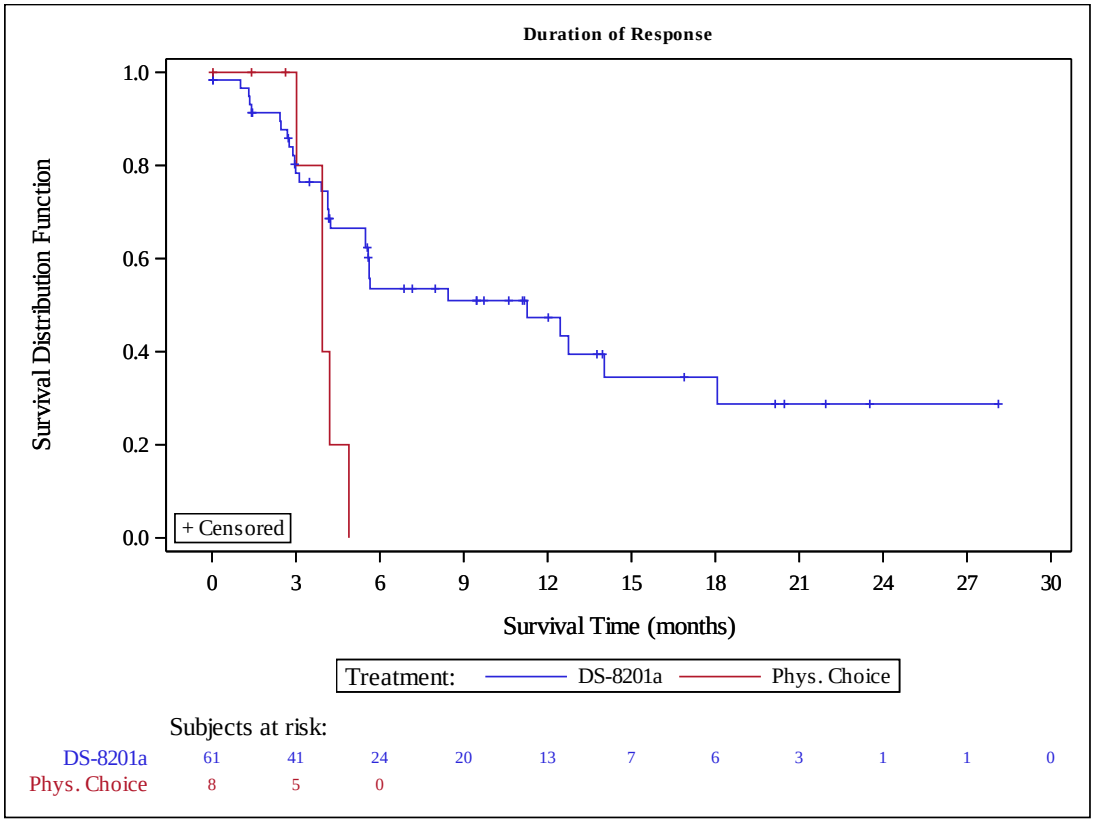
NE: Not estimable.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Duration of Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Confirmed Response
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	50 (40.0)	7 (11.3)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	5.5 (2.9, NE)	NE (NE, NE)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	55.4 (44.9, 64.8)	79.0 (57.5, 90.5)
6 Months (95% CI)	47.0 (34.9, 58.2)	79.0 (57.5, 90.5)
9 Months (95% CI)	47.0 (34.9, 58.2)	NE (NE, NE)
12 Months (95% CI)	47.0 (34.9, 58.2)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	2.97 (1.34, 6.55)	
p-value [c]	0.0046	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	2.92 (1.32, 6.43)	
p-value [c]	0.0053	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Confirmed Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.8516
Japan	42/ 99 (42.4)	3.4 (2.8, NE)	6/ 50 (12.0)	NE (NE , NE)	3.07 (1.31, 7.24)	0.0065	
Korea	8/ 26 (30.8)	NE (2.7, NE)	1/ 12 (8.3)	NE (3.0, NE)	2.35 (0.29, 18.88)	0.4083	
Lines of prior systemic therapy							0.9738
2	20/ 66 (30.3)	NE (2.9, NE)	4/ 38 (10.5)	NE (3.0, NE)	2.51 (0.86, 7.36)	0.0798	
3	17/ 34 (50.0)	2.9 (1.7, NE)	3/ 18 (16.7)	NE (1.7, NE)	2.12 (0.62, 7.27)	0.2159	
>=4	13/ 25 (52.0)	3.0 (1.5, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.1646
<65 years	23/ 55 (41.8)	3.0 (2.7, NE)	1/ 27 (3.7)	NE (NE , NE)	8.73 (1.18, 64.63)	0.0103	
>=65 years	27/ 70 (38.6)	NE (2.9, NE)	6/ 35 (17.1)	NE (3.0, NE)	1.90 (0.78, 4.63)	0.1477	
Sex							0.6241
female	10/ 30 (33.3)	NE (2.7, NE)	2/ 15 (13.3)	NE (1.7, NE)	2.08 (0.45, 9.49)	0.3340	
male	40/ 95 (42.1)	4.1 (2.8, NE)	5/ 47 (10.6)	NE (NE , NE)	3.25 (1.28, 8.25)	0.0083	
ECOG PS							0.5507
0	28/ 62 (45.2)	3.4 (2.7, NE)	3/ 30 (10.0)	NE (3.0, NE)	3.70 (1.12, 12.19)	0.0207	
1	22/ 63 (34.9)	5.5 (2.8, NE)	4/ 32 (12.5)	NE (NE , NE)	2.25 (0.77, 6.55)	0.1239	
HER2 Status in central laboratory							0.0542
IHC 3+	44/ 96 (45.8)	3.2 (2.8, NE)	4/ 47 (8.5)	NE (NE , NE)	4.48 (1.61, 12.49)	0.0016	
IHC 2+/ISH +	6/ 29 (20.7)	NE (2.9, NE)	3/ 15 (20.0)	NE (1.6, NE)	0.81 (0.20, 3.23)	0.7620	
Primary tumor location							0.8646
Gastric	42/108 (38.9)	5.5 (2.9, NE)	6/ 55 (10.9)	NE (NE , NE)	2.93 (1.24, 6.90)	0.0096	
GEJ	8/ 17 (47.1)	2.8 (1.4, NE)	1/ 7 (14.3)	NE (1.6, NE)	2.36 (0.29, 18.89)	0.3964	
Histological subtype							0.9999
intestinal	35/ 89 (39.3)	5.5 (2.9, NE)	7/ 38 (18.4)	NE (3.0, NE)	1.95 (0.87, 4.41)	0.0973	
diffuse	15/ 28 (53.6)	2.8 (1.7, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.6969
<2	12/ 23 (52.2)	3.4 (1.6, NE)	1/ 10 (10.0)	NE (1.6, NE)	4.21 (0.55, 32.41)	0.1334	
>= 2	38/102 (37.3)	NE (2.9, NE)	6/ 52 (11.5)	NE (NE , NE)	2.68 (1.13, 6.34)	0.0193	
Previous total gastrectomy							0.9857
yes	11/ 22 (50.0)	2.8 (1.6, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	39/103 (37.9)	5.5 (3.0, NE)	7/ 53 (13.2)	NE (NE , NE)	2.36 (1.06, 5.29)	0.0302	
Prior adjuvant/ neoadjuvant therapy							0.9888
yes	17/ 30 (56.7)	2.8 (1.6, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	33/ 95 (34.7)	NE (3.0, NE)	7/ 52 (13.5)	NE (3.0, NE)	2.00 (0.88, 4.54)	0.0868	
Prior ramucirumab contained treatment							0.5811
yes	37/ 94 (39.4)	5.5 (2.8, NE)	5/ 41 (12.2)	NE (3.0, NE)	2.51 (0.99, 6.39)	0.0449	
no	13/ 31 (41.9)	3.4 (1.7, NE)	2/ 21 (9.5)	NE (NE , NE)	4.13 (0.93, 18.31)	0.0425	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

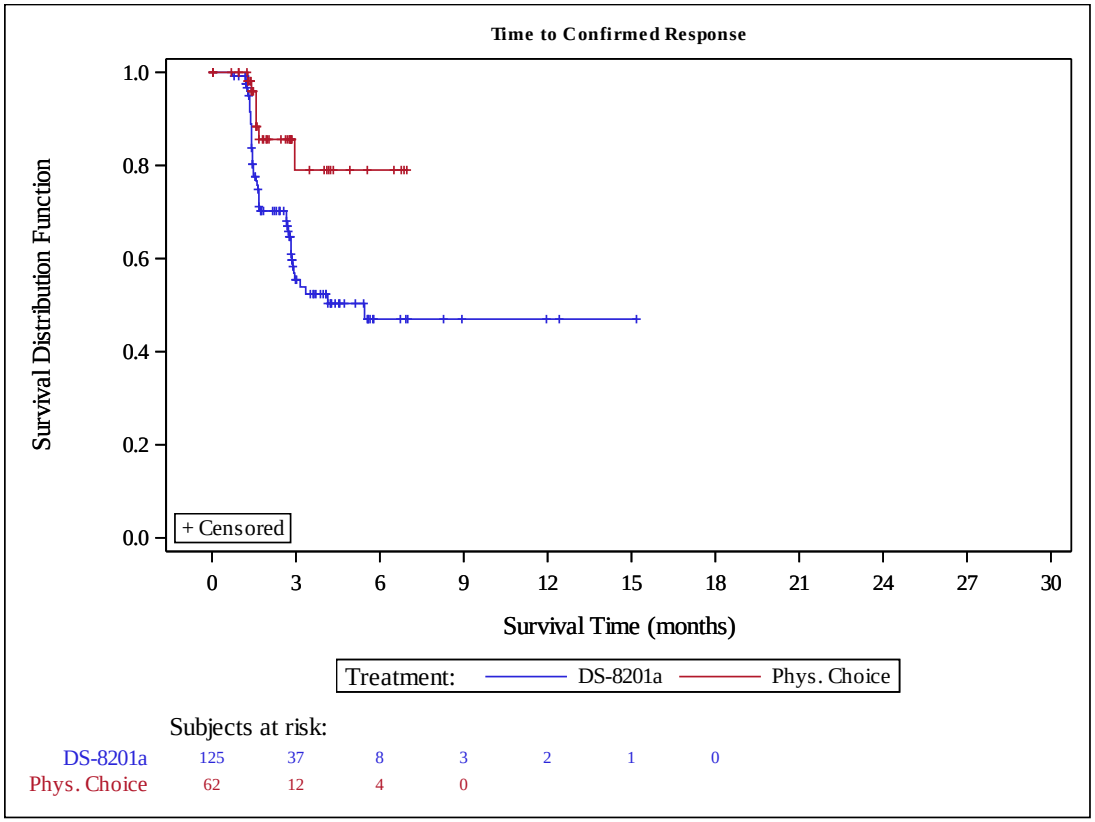
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Confirmed Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.5583
yes	20/ 33 (60.6)	2.8 (1.5, 4.1)	3/ 15 (20.0)	NE (1.4, NE)	1.95 (0.57, 6.63)	0.2747	
no	30/ 92 (32.6)	NE (2.9, NE)	4/ 47 (8.5)	NE (NE , NE)	3.29 (1.16, 9.35)	0.0171	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7945
yes	25/ 44 (56.8)	2.8 (1.6, 4.1)	3/ 17 (17.6)	NE (1.7, NE)	2.35 (0.71, 7.79)	0.1500	
no	25/ 81 (30.9)	NE (3.0, NE)	4/ 45 (8.9)	NE (NE , NE)	2.91 (1.01, 8.38)	0.0363	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9859
yes	8/ 22 (36.4)	3.2 (1.7, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	42/103 (40.8)	5.5 (2.8, NE)	7/ 55 (12.7)	NE (NE , NE)	2.50 (1.12, 5.58)	0.0196	
Presence of liver metastasis at baseline							0.5575
yes	25/ 68 (36.8)	NE (2.8, NE)	4/ 34 (11.8)	NE (3.0, NE)	2.32 (0.81, 6.68)	0.1065	
no	25/ 57 (43.9)	5.5 (2.7, NE)	3/ 28 (10.7)	NE (NE , NE)	3.81 (1.15, 12.65)	0.0181	
Renal impairment at baseline							0.9856
normal	16/ 33 (48.5)	2.8 (1.6, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	19/ 53 (35.8)	NE (2.9, NE)	3/ 28 (10.7)	NE (NE , NE)	2.19 (0.64, 7.43)	0.1933	
moderate	15/ 39 (38.5)	5.5 (2.8, NE)	4/ 20 (20.0)	NE (3.0, NE)	1.79 (0.59, 5.40)	0.2964	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.3529
normal	36/ 88 (40.9)	NE (2.8, NE)	6/ 47 (12.8)	NE (3.0, NE)	2.36 (0.99, 5.61)	0.0446	
mild	13/ 36 (36.1)	2.9 (2.8, NE)	1/ 15 (6.7)	NE (NE , NE)	7.29 (0.95, 56.20)	0.0264	
moderate	1/ 1 (100.0)	1.6 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3673
yes	3/ 8 (37.5)	NE (1.4, NE)	1/ 5 (20.0)	NE (1.6, NE)	1.26 (0.13, 12.43)	0.8454	
no	47/117 (40.2)	4.1 (2.8, NE)	6/ 57 (10.5)	NE (NE , NE)	3.23 (1.38, 7.55)	0.0041	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.2322
yes	1/ 3 (33.3)	NE (1.4, NE)	1/ 4 (25.0)	NE (1.6, NE)	0.82 (0.05, 13.24)	0.8864	
no	49/122 (40.2)	4.1 (2.9, NE)	6/ 58 (10.3)	NE (NE , NE)	3.28 (1.40, 7.66)	0.0035	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Time to Confirmed Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Response
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	61 (48.8)	8 (12.9)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	3.0 (2.7, 5.6)	NE (NE, NE)
Kaplan-Meier estimates on each time point		
3 Months (95% CI)	49.3 (39.0, 58.7)	76.6 (55.6, 88.6)
6 Months (95% CI)	36.3 (24.6, 48.1)	76.6 (55.6, 88.6)
9 Months (95% CI)	36.3 (24.6, 48.1)	NE (NE, NE)
12 Months (95% CI)	36.3 (24.6, 48.1)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	3.19 (1.52, 6.68)	
p-value [c]	0.0011	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	3.18 (1.52, 6.66)	
p-value [c]	0.0011	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.8096
Japan	48/ 99 (48.5)	3.0 (2.7, 5.6)	7/ 50 (14.0)	NE (NE , NE)	3.07 (1.39, 6.79)	0.0033	
Korea	13/ 26 (50.0)	2.8 (1.4, NE)	1/ 12 (8.3)	NE (3.0, NE)	4.00 (0.52, 30.83)	0.1506	
Lines of prior systemic therapy							0.8139
2	29/ 66 (43.9)	5.5 (2.7, NE)	4/ 38 (10.5)	NE (3.0, NE)	3.68 (1.29, 10.50)	0.0086	
3	18/ 34 (52.9)	2.9 (1.7, NE)	3/ 18 (16.7)	NE (1.7, NE)	2.17 (0.64, 7.43)	0.1994	
>=4	14/ 25 (56.0)	2.9 (1.4, 3.4)	1/ 6 (16.7)	NE (1.6, NE)	2.71 (0.36, 20.65)	0.3167	
Age							0.0840
<65 years	30/ 55 (54.5)	2.8 (1.7, 5.5)	1/ 27 (3.7)	NE (NE , NE)	12.09 (1.65, 88.80)	0.0017	
>=65 years	31/ 70 (44.3)	4.4 (2.8, NE)	7/ 35 (20.0)	NE (3.0, NE)	1.84 (0.81, 4.20)	0.1391	
Sex							0.9302
female	14/ 30 (46.7)	3.0 (1.6, NE)	2/ 15 (13.3)	NE (1.7, NE)	2.96 (0.67, 13.05)	0.1322	
male	47/ 95 (49.5)	2.9 (2.7, 5.6)	6/ 47 (12.8)	NE (3.0, NE)	3.26 (1.39, 7.64)	0.0039	
ECOG PS							0.4764
0	31/ 62 (50.0)	3.0 (1.7, NE)	3/ 30 (10.0)	NE (3.0, NE)	4.31 (1.32, 14.12)	0.0082	
1	30/ 63 (47.6)	4.1 (2.7, 5.6)	5/ 32 (15.6)	NE (NE , NE)	2.44 (0.94, 6.33)	0.0559	
HER2 Status in central laboratory							0.0869
IHC 3+	53/ 96 (55.2)	2.8 (1.7, 4.1)	5/ 47 (10.6)	NE (NE , NE)	4.48 (1.79, 11.21)	0.0004	
IHC 2+/ISH +	8/ 29 (27.6)	NE (2.9, NE)	3/ 15 (20.0)	NE (1.6, NE)	1.04 (0.28, 3.96)	0.9442	
Primary tumor location							0.9468
Gastric	52/108 (48.1)	3.2 (2.7, 5.6)	7/ 55 (12.7)	NE (NE , NE)	3.16 (1.43, 6.96)	0.0025	
GEJ	9/ 17 (52.9)	2.8 (1.4, NE)	1/ 7 (14.3)	NE (1.6, NE)	2.94 (0.37, 23.20)	0.2760	
Histological subtype							0.9998
intestinal	41/ 89 (46.1)	4.1 (2.8, NE)	8/ 38 (21.1)	NE (3.0, NE)	2.02 (0.95, 4.32)	0.0618	
diffuse	18/ 28 (64.3)	2.7 (1.5, 2.9)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	2/ 8 (25.0)	12.4 (1.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.6909
<2	13/ 23 (56.5)	2.8 (1.5, NE)	1/ 10 (10.0)	NE (1.6, NE)	4.68 (0.61, 35.81)	0.1015	
>= 2	48/102 (47.1)	3.0 (2.7, 12.4)	7/ 52 (13.5)	NE (NE , NE)	2.96 (1.34, 6.55)	0.0048	
Previous total gastrectomy							0.7767
yes	12/ 22 (54.5)	2.8 (1.6, 4.4)	1/ 9 (11.1)	NE (1.6, NE)	4.02 (0.52, 31.10)	0.1492	
no	49/103 (47.6)	3.4 (2.7, NE)	7/ 53 (13.2)	NE (NE , NE)	3.06 (1.38, 6.77)	0.0035	
Prior adjuvant/ neoadjuvant therapy							0.4267
yes	18/ 30 (60.0)	2.8 (1.6, 4.4)	1/ 10 (10.0)	NE (1.6, NE)	6.28 (0.84, 47.15)	0.0399	
no	43/ 95 (45.3)	4.1 (2.7, NE)	7/ 52 (13.5)	NE (3.0, NE)	2.69 (1.21, 6.00)	0.0112	
Prior ramucirumab contained treatment							0.2319
yes	42/ 94 (44.7)	4.1 (2.8, NE)	6/ 41 (14.6)	NE (3.0, NE)	2.36 (1.00, 5.56)	0.0427	
no	19/ 31 (61.3)	2.7 (1.4, 4.4)	2/ 21 (9.5)	NE (NE , NE)	6.71 (1.56, 28.84)	0.0030	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

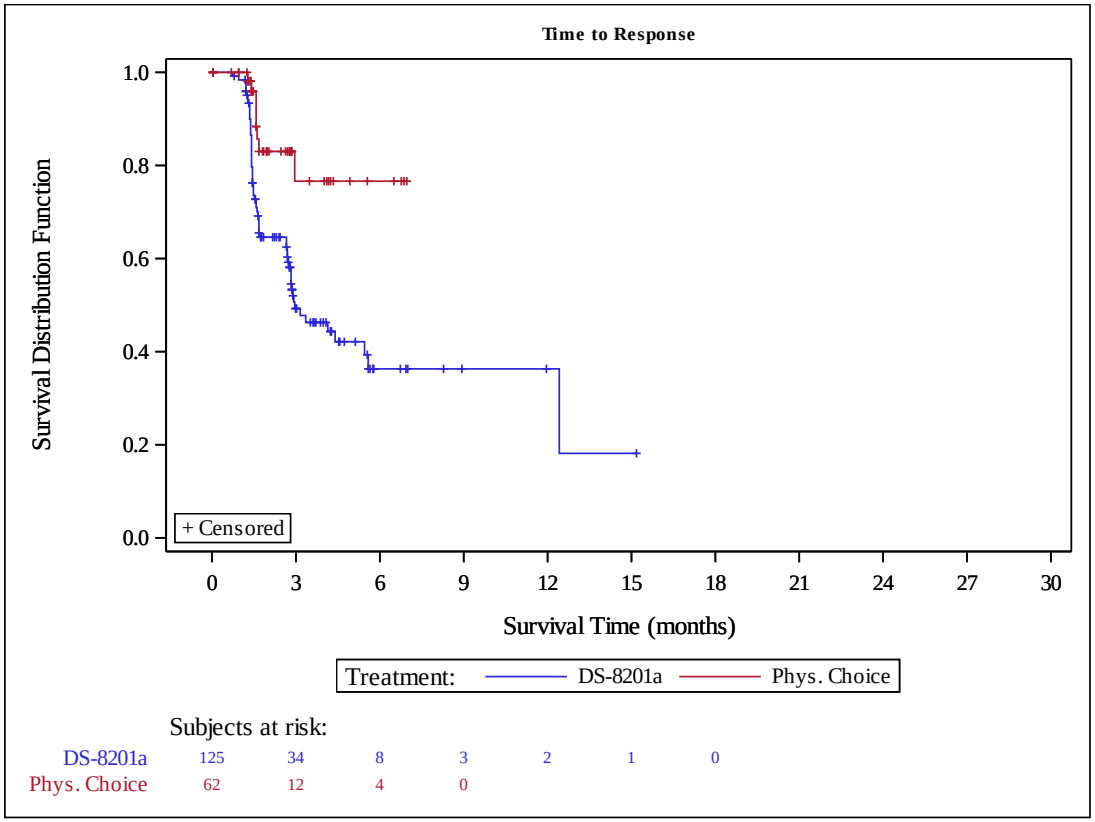
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Response - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior nivolumab contained treatment							0.2405
yes	22/ 33 (66.7)	2.7 (1.5, 3.4)	4/ 15 (26.7)	NE (1.4, NE)	1.76 (0.60, 5.17)	0.2953	
no	39/ 92 (42.4)	4.4 (2.8, NE)	4/ 47 (8.5)	NE (NE , NE)	4.32 (1.54, 12.12)	0.0023	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.5156
yes	29/ 44 (65.9)	2.7 (1.5, 3.2)	4/ 17 (23.5)	NE (1.6, NE)	2.29 (0.81, 6.54)	0.1090	
no	32/ 81 (39.5)	5.5 (2.9, NE)	4/ 45 (8.9)	NE (NE , NE)	3.65 (1.29, 10.34)	0.0087	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9821
yes	9/ 22 (40.9)	3.2 (1.7, NE)	1/ 7 (14.3)	NE (1.6, NE)	3.04 (0.38, 23.98)	0.2683	
no	52/103 (50.5)	2.9 (2.7, 5.6)	7/ 55 (12.7)	NE (NE , NE)	3.17 (1.44, 7.00)	0.0024	
Presence of liver metastasis at baseline							0.4146
yes	31/ 68 (45.6)	3.0 (2.7, 12.4)	5/ 34 (14.7)	NE (3.0, NE)	2.33 (0.90, 6.02)	0.0700	
no	30/ 57 (52.6)	2.9 (1.7, NE)	3/ 28 (10.7)	NE (NE , NE)	4.71 (1.44, 15.46)	0.0046	
Renal impairment at baseline							0.9962
normal	19/ 33 (57.6)	2.7 (1.5, 3.0)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	24/ 53 (45.3)	3.4 (2.7, 12.4)	4/ 28 (14.3)	NE (1.6, NE)	2.00 (0.69, 5.80)	0.1896	
moderate	18/ 39 (46.2)	4.1 (2.7, NE)	4/ 20 (20.0)	NE (3.0, NE)	2.13 (0.72, 6.30)	0.1641	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8492
normal	46/ 88 (52.3)	3.2 (2.7, NE)	6/ 47 (12.8)	NE (3.0, NE)	3.09 (1.31, 7.25)	0.0063	
mild	14/ 36 (38.9)	2.9 (2.7, 5.5)	2/ 15 (13.3)	NE (1.6, NE)	3.84 (0.87, 17.06)	0.0579	
moderate	1/ 1 (100.0)	1.6 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3058
yes	3/ 8 (37.5)	NE (1.4, NE)	1/ 5 (20.0)	NE (1.6, NE)	1.26 (0.13, 12.43)	0.8454	
no	58/117 (49.6)	3.0 (2.7, 5.5)	7/ 57 (12.3)	NE (NE , NE)	3.51 (1.60, 7.70)	0.0008	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.1875
yes	1/ 3 (33.3)	NE (1.4, NE)	1/ 4 (25.0)	NE (1.6, NE)	0.82 (0.05, 13.24)	0.8864	
no	60/122 (49.2)	3.0 (2.7, 5.5)	7/ 58 (12.1)	NE (NE , NE)	3.54 (1.62, 7.75)	0.0007	

Time to response is defined as the time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Time to Response
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADTTE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Results (mm)		
n	117	52
Mean (SD)	39.9 (37.26)	60.0 (54.40)
Median	30.0	42.5
Q1, Q3	14.0, 57.0	26.0, 72.5
Min, Max	0.0, 183.0	0.0, 302.0
Change from Baseline (mm)		
n	117	52
Mean (SD)	-19.9 (25.03)	-2.0 (19.34)
Median	-15.0	-3.0
Q1, Q3	-30.0, -3.0	-10.5, 3.0
Min, Max	-87.0, 29.0	-58.0, 74.0
Percent Change from Baseline (%)		
n	117	52
Mean (SD)	-35.8 (37.12)	-9.0 (29.63)
Median	-32.2	-5.3
Q1, Q3	-65.6, -6.5	-26.6, 6.8
Min, Max	-100.0, 34.0	-100.0, 65.0
LSMean (95% CI) [a]	-35.73 (-42.02, -29.45)	-9.23 (-18.66, 0.21)
Difference of LSMeans (95% CI)	-26.51 (-37.85, -15.17)	
p-value	<.0001	
Hegdes' g (95% CI)	-0.76 (-1.10, -0.43)	
p-value	<.0001	

[a] LSMean obtained from a linear model adjusting for treatment and baseline value.
Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N	Mean (SD)	LSMean (95% CI) [a]	Phys. Choice (N=62) N	Mean (SD)	LSMean (95% CI) [a]	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region											0.5933
Japan	94	-35.2 (37.79)	-35.09 (-42.13, -28.06)	43	-9.8 (27.97)	-10.09 (-20.49, 0.32)	-25.01 (-37.57, -12.44)	<.0001	-0.72 (-1.09, -0.35)	0.0001	
Korea	23	-38.2 (34.93)	-38.34 (-52.94, -23.74)	9	-5.5 (38.34)	-5.19 (-28.54, 18.15)	-33.15 (-60.68, -5.61)	0.0183	-0.93 (-1.73, -0.12)	0.0236	
Lines of prior systemic therapy											0.9552
2	59	-32.2 (37.33)	-31.73 (-40.65, -22.80)	32	-4.7 (32.29)	-5.52 (-17.65, 6.61)	-26.21 (-41.29, -11.13)	0.0007	-0.75 (-1.19, -0.31)	0.0009	
3	33	-37.0 (35.95)	-36.98 (-48.25, -25.72)	15	-14.1 (23.44)	-14.08 (-30.78, 2.63)	-22.91 (-43.06, -2.76)	0.0259	-0.69 (-1.32, -0.07)	0.0298	
>=4	25	-42.9 (38.45)	-43.12 (-57.80, -28.43)	5	-21.4 (27.38)	-20.57 (-53.49, 12.34)	-22.54 (-58.62, 13.53)	0.2207	-0.60 (-1.57, 0.37)	0.2252	
Age											0.0445
<65 years	52	-40.0 (37.01)	-40.23 (-49.46, -31.01)	19	0.0 (25.84)	0.63 (-14.65, 15.90)	-40.86 (-58.71, -23.01)	<.0001	-1.20 (-1.76, -0.64)	<.0001	
>=65 years	65	-32.5 (37.15)	-32.09 (-40.62, -23.57)	33	-14.2 (30.77)	-14.98 (-26.97, -3.00)	-17.11 (-31.86, -2.36)	0.0230	-0.49 (-0.91, -0.06)	0.0243	
Sex											0.8133
female	30	-31.2 (35.94)	-30.89 (-42.86, -18.93)	12	-5.7 (24.94)	-6.40 (-25.37, 12.56)	-24.49 (-46.96, -2.02)	0.0327	-0.73 (-1.42, -0.04)	0.0370	
male	87	-37.4 (37.58)	-37.43 (-44.87, -29.99)	40	-10.0 (31.11)	-10.02 (-21.00, 0.95)	-27.40 (-40.66, -14.14)	<.0001	-0.77 (-1.16, -0.39)	<.0001	
ECOG PS											0.3247
0	58	-38.1 (38.77)	-38.67 (-48.03, -29.31)	28	-7.5 (31.91)	-6.24 (-19.76, 7.28)	-32.43 (-48.94, -15.93)	0.0001	-0.89 (-1.36, -0.42)	0.0002	
1	59	-33.6 (35.61)	-33.10 (-41.65, -24.54)	24	-10.8 (27.29)	-12.11 (-25.61, 1.40)	-20.99 (-37.09, -4.89)	0.0106	-0.62 (-1.11, -0.14)	0.0114	
HER2 Status in central laboratory											0.0533
IHC 3+	89	-39.7 (37.93)	-39.32 (-46.62, -32.01)	40	-6.0 (29.32)	-6.82 (-17.73, 4.09)	-32.50 (-45.65, -19.35)	<.0001	-0.92 (-1.31, -0.53)	<.0001	
IHC 2+/ISH +	28	-23.6 (32.02)	-23.58 (-35.41, -11.74)	12	-19.0 (29.67)	-19.08 (-37.28, -0.88)	-4.50 (-26.36, 17.36)	0.6867	-0.14 (-0.82, 0.54)	0.6841	
Primary tumor location											0.5164
Gastric	102	-34.9 (37.02)	-34.69 (-41.44, -27.93)	46	-9.3 (30.55)	-9.70 (-19.76, 0.37)	-24.99 (-37.12, -12.86)	<.0001	-0.72 (-1.08, -0.36)	<.0001	
GEJ	15	-42.2 (38.43)	-42.58 (-60.68, -24.48)	6	-7.2 (23.45)	-6.33 (-35.02, 22.37)	-36.25 (-70.27, -2.24)	0.0367	-1.01 (-2.01, -0.02)	0.0460	
Histological subtype											0.1700
intestinal	85	-34.9 (37.61)	-34.69 (-42.26, -27.12)	36	-14.2 (32.57)	-14.59 (-26.23, -2.95)	-20.10 (-33.99, -6.21)	0.0046	-0.56 (-0.96, -0.17)	0.0052	
diffuse	26	-40.7 (32.77)	-40.73 (-51.89, -29.57)	12	4.7 (15.39)	4.73 (-11.72, 21.17)	-45.46 (-65.35, -25.56)	<.0001	-1.57 (-2.33, -0.80)	<.0001	
others	6	-28.1 (51.14)	-26.77 (-63.71, 10.18)	4	-4.0 (23.80)	-6.01 (-51.61, 39.59)	-20.75 (-80.53, 39.02)	0.4962	-0.45 (-1.73, 0.83)	0.4926	
Number of metastatic sites											0.4293
<2	21	-50.2 (42.30)	-50.95 (-67.40, -34.49)	6	-12.9 (25.23)	-10.30 (-41.22, 20.61)	-40.64 (-75.75, -5.54)	0.0233	-1.06 (-2.01, -0.11)	0.0294	
>= 2	96	-32.7 (35.35)	-32.66 (-39.42, -25.91)	46	-8.5 (30.36)	-8.55 (-18.31, 1.21)	-24.11 (-35.98, -12.24)	<.0001	-0.71 (-1.08, -0.35)	0.0001	
Previous total gastrectomy											0.4020
yes	20	-42.5 (36.36)	-41.51 (-56.22, -26.79)	8	-6.0 (32.00)	-8.54 (-31.89, 14.81)	-32.97 (-60.66, -5.28)	0.0196	-0.98 (-1.84, -0.12)	0.0252	
no	97	-34.4 (37.31)	-34.19 (-41.02, -27.37)	44	-9.6 (29.53)	-10.12 (-20.26, 0.01)	-24.07 (-36.29, -11.85)	0.0001	-0.70 (-1.07, -0.34)	0.0002	
Prior adjuvant/ neoadjuvant therapy											0.1154
yes	27	-51.3 (37.50)	-51.71 (-65.27, -38.15)	8	-6.8 (31.15)	-5.34 (-30.33, 19.64)	-46.37 (-74.85, -17.88)	0.0014	-1.29 (-2.13, -0.44)	0.0028	
no	90	-31.2 (35.92)	-31.10 (-38.10, -24.09)	44	-9.4 (29.70)	-9.62 (-19.64, 0.40)	-21.48 (-33.71, -9.25)	0.0006	-0.63 (-1.00, -0.27)	0.0008	
Prior ramucirumab contained treatment											0.4285
yes	88	-33.9 (39.06)	-33.82 (-41.60, -26.05)	33	-9.8 (31.90)	-10.01 (-22.71, 2.69)	-23.82 (-38.71, -8.92)	0.0017	-0.64 (-1.05, -0.23)	0.0021	
no	29	-41.7 (30.32)	-41.43 (-51.54, -31.32)	19	-7.7 (25.97)	-8.03 (-20.52, 4.46)	-33.39 (-49.47, -17.32)	<.0001	-1.20 (-1.83, -0.58)	0.0002	
Prior nivolumab contained treatment											0.7667
yes	33	-47.4 (34.80)	-47.46 (-58.41, -36.51)	13	-18.8 (23.18)	-18.62 (-36.08, -1.17)	-28.84 (-49.45, -8.23)	0.0061	-0.90 (-1.57, -0.23)	0.0083	
no	84	-31.3 (37.21)	-31.12 (-38.62, -23.61)	39	-5.8 (31.05)	-6.12 (-17.14, 4.90)	-25.00 (-38.34, -11.66)	0.0002	-0.71 (-1.10, -0.32)	0.0003	

[a] LSMean obtained from a linear model adjusting for treatment and baseline value.
[b] P-value obtained from the same linear model plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 07JUN2022

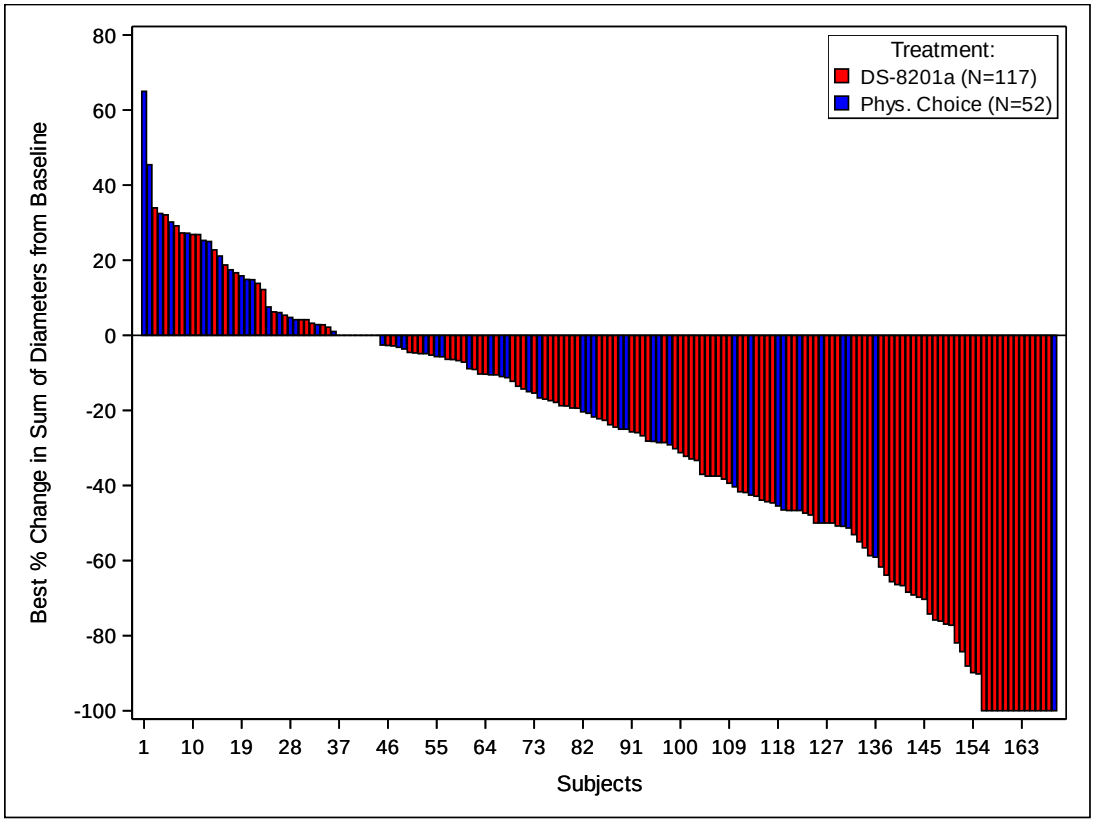
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N	Mean (SD)	LSMean (95% CI) [a]	Phys. Choice (N=62) N	Mean (SD)	LSMean (95% CI) [a]	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy											0.4764
yes	43	-48.2 (34.28)	-48.40 (-57.78, -39.02)	15	-17.9 (22.15)	-17.28 (-33.18, -1.38)	-31.11 (-49.59, -12.64)	0.0010	-0.99 (-1.61, -0.38)	0.0016	
no	74	-28.6 (37.02)	-28.37 (-36.37, -20.37)	37	-5.4 (31.72)	-5.98 (-17.31, 5.35)	-22.39 (-36.28, -8.50)	0.0016	-0.64 (-1.04, -0.23)	0.0020	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug											0.4392
yes	21	-28.0 (35.38)	-27.84 (-42.47, -13.20)	5	-14.4 (24.06)	-15.01 (-45.06, 15.04)	-12.83 (-46.29, 20.63)	0.4525	-0.37 (-1.36, 0.61)	0.4539	
no	96	-37.5 (37.44)	-37.40 (-44.35, -30.45)	47	-8.5 (30.32)	-8.74 (-18.67, 1.19)	-28.66 (-40.78, -16.53)	<.0001	-0.82 (-1.19, -0.46)	<.0001	
Presence of liver metastasis at baseline											0.9033
yes	66	-31.7 (35.62)	-31.59 (-40.10, -23.08)	30	-5.3 (34.29)	-5.57 (-18.20, 7.06)	-26.02 (-41.26, -10.78)	0.0008	-0.74 (-1.18, -0.29)	0.0011	
no	51	-41.1 (38.68)	-41.30 (-50.74, -31.86)	22	-14.2 (21.43)	-13.76 (-28.14, 0.63)	-27.54 (-44.76, -10.33)	0.0017	-0.80 (-1.32, -0.28)	0.0024	
Renal impairment at baseline											0.2064
normal	32	-40.1 (38.86)	-39.91 (-51.95, -27.86)	10	-1.9 (15.96)	-2.38 (-23.94, 19.18)	-37.53 (-62.23, -12.82)	0.0029	-1.08 (-1.83, -0.33)	0.0046	
mild	51	-34.8 (36.83)	-34.27 (-43.77, -24.78)	25	-2.3 (30.22)	-3.38 (-16.97, 10.21)	-30.89 (-47.53, -14.26)	0.0003	-0.89 (-1.39, -0.39)	0.0005	
moderate	34	-33.4 (36.65)	-33.07 (-45.00, -21.14)	17	-23.1 (31.15)	-23.73 (-40.71, -6.74)	-9.34 (-30.29, 11.61)	0.3822	-0.26 (-0.85, 0.32)	0.3786	
severe	0	-	NE	0	-	NE	NE	NE	NE	NE	
Hepatic impairment at baseline											0.5905
normal	82	-39.3 (35.99)	-39.30 (-46.73, -31.88)	39	-10.9 (30.88)	-10.86 (-21.62, -0.09)	-28.45 (-41.53, -15.37)	<.0001	-0.83 (-1.22, -0.43)	<.0001	
mild	34	-26.6 (38.89)	-25.95 (-37.91, -13.98)	13	-3.3 (25.77)	-4.92 (-24.36, 14.52)	-21.03 (-43.94, 1.88)	0.0721	-0.59 (-1.24, 0.06)	0.0754	
moderate	1	-68.4 (-)	-68.42 (-70.38, -66.46)	0	-	NE	NE	NE	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors											0.3644
yes	7	-35.6 (43.48)	-34.24 (-66.84, -1.64)	3	-26.3 (29.18)	-29.37 (-80.90, 22.16)	-4.87 (-67.98, 58.23)	0.8798	-0.11 (-1.46, 1.24)	0.8737	
no	110	-35.8 (36.91)	-35.82 (-42.27, -29.37)	49	-8.0 (29.62)	-8.02 (-17.68, 1.65)	-27.80 (-39.42, -16.18)	<.0001	-0.81 (-1.15, -0.46)	<.0001	
Most recently treatment with irinotecan or other topoisomerase I inhibitors											0.4477
yes	2	-45.2 (30.30)	-36.67 (-78.34, 5.00)	2	-37.9 (30.00)	-46.44 (-88.12, -4.77)	9.77 (-52.73, 72.28)	0.7593	0.33 (-1.65, 2.30)	0.7468	
no	115	-35.7 (37.31)	-35.63 (-41.99, -29.26)	50	-7.9 (29.32)	-7.95 (-17.60, 1.70)	-27.67 (-39.24, -16.11)	<.0001	-0.79 (-1.14, -0.45)	<.0001	

[a] LSMean obtained from a linear model adjusting for treatment and baseline value.
[b] P-value obtained from the same linear model plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

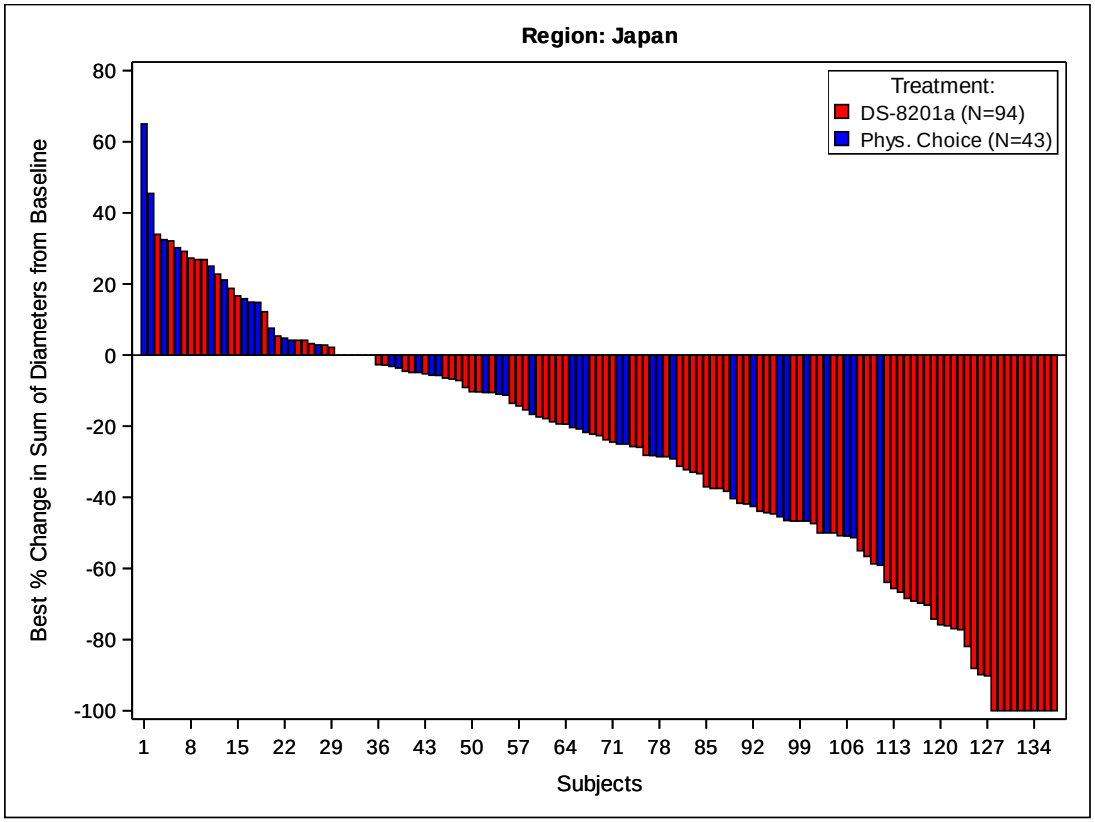
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



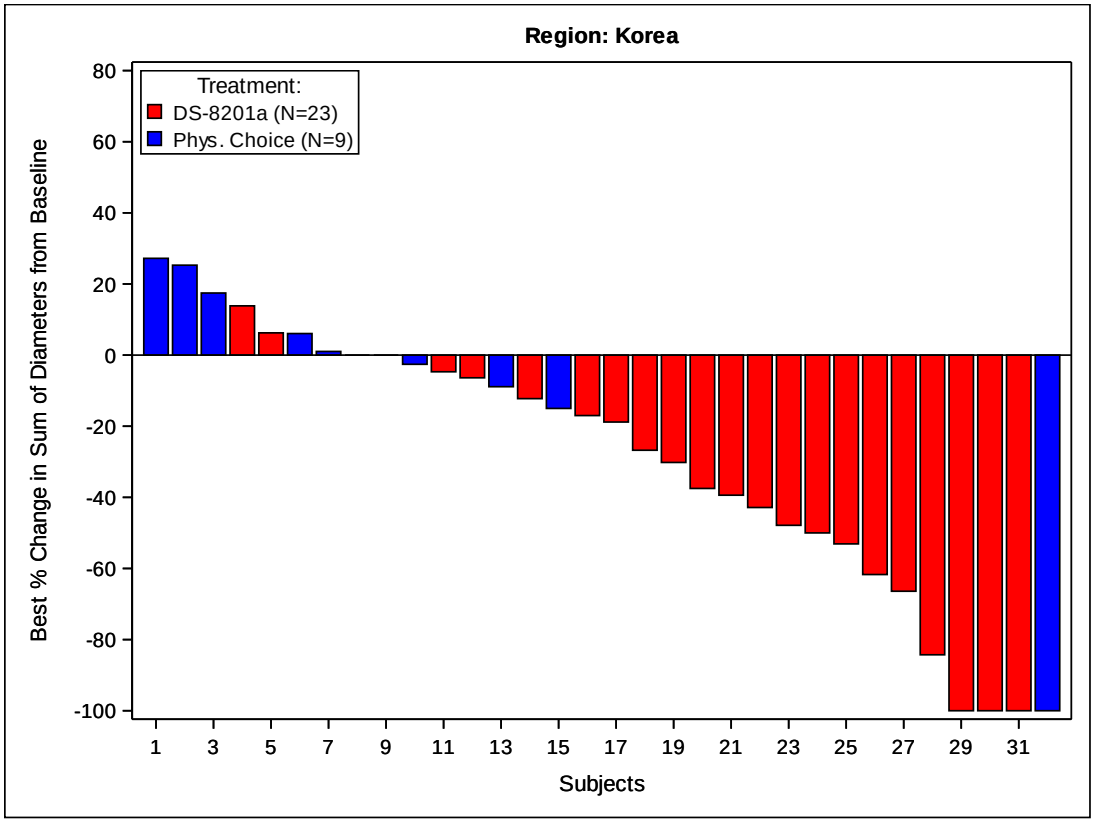
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



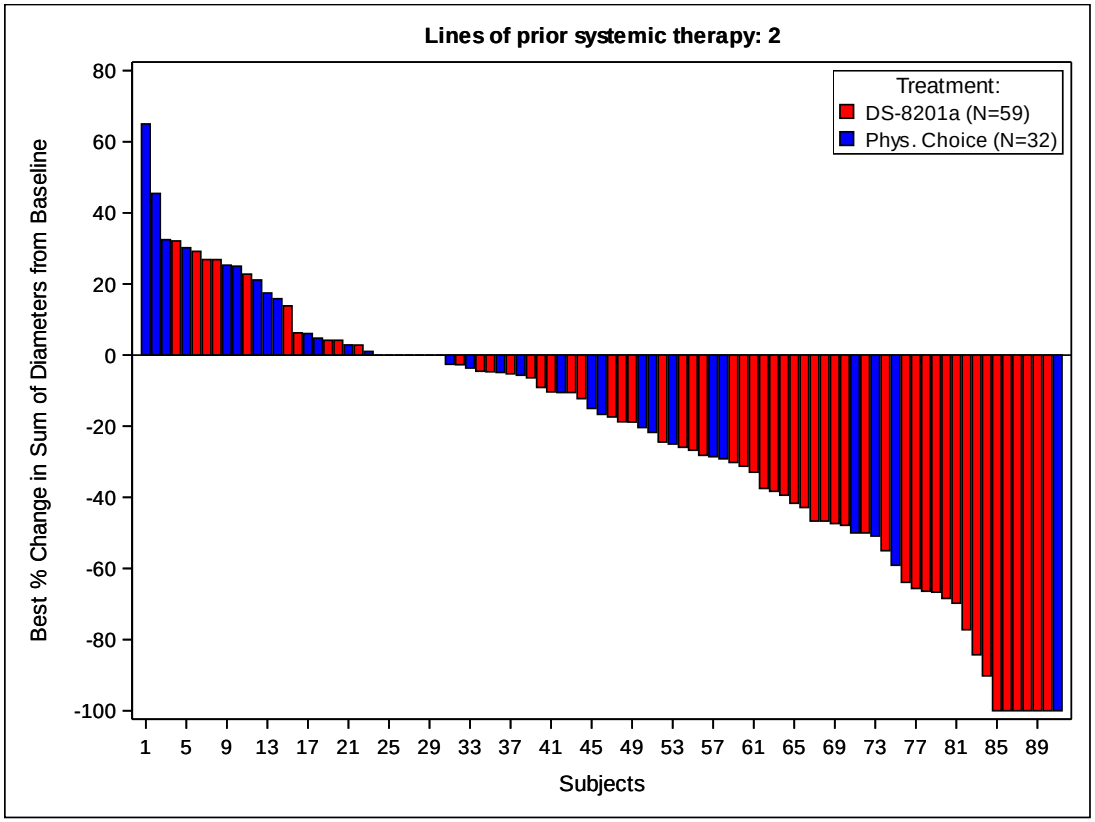
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



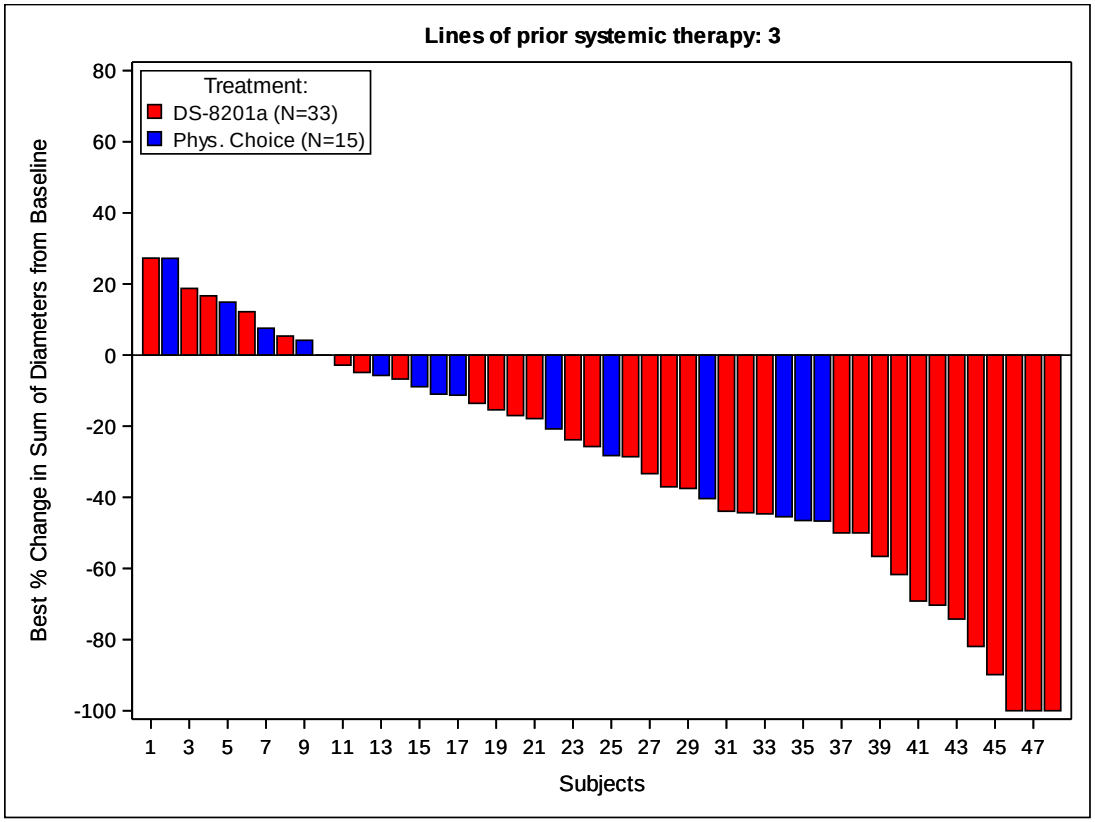
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



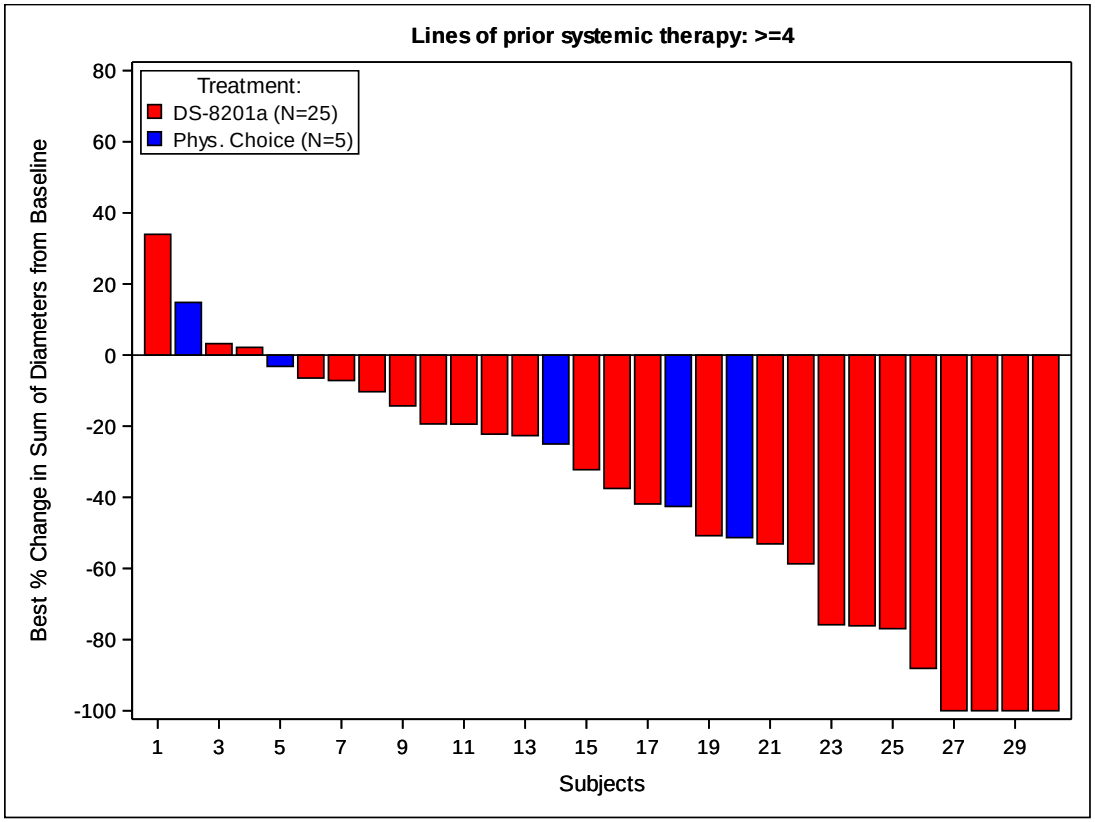
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



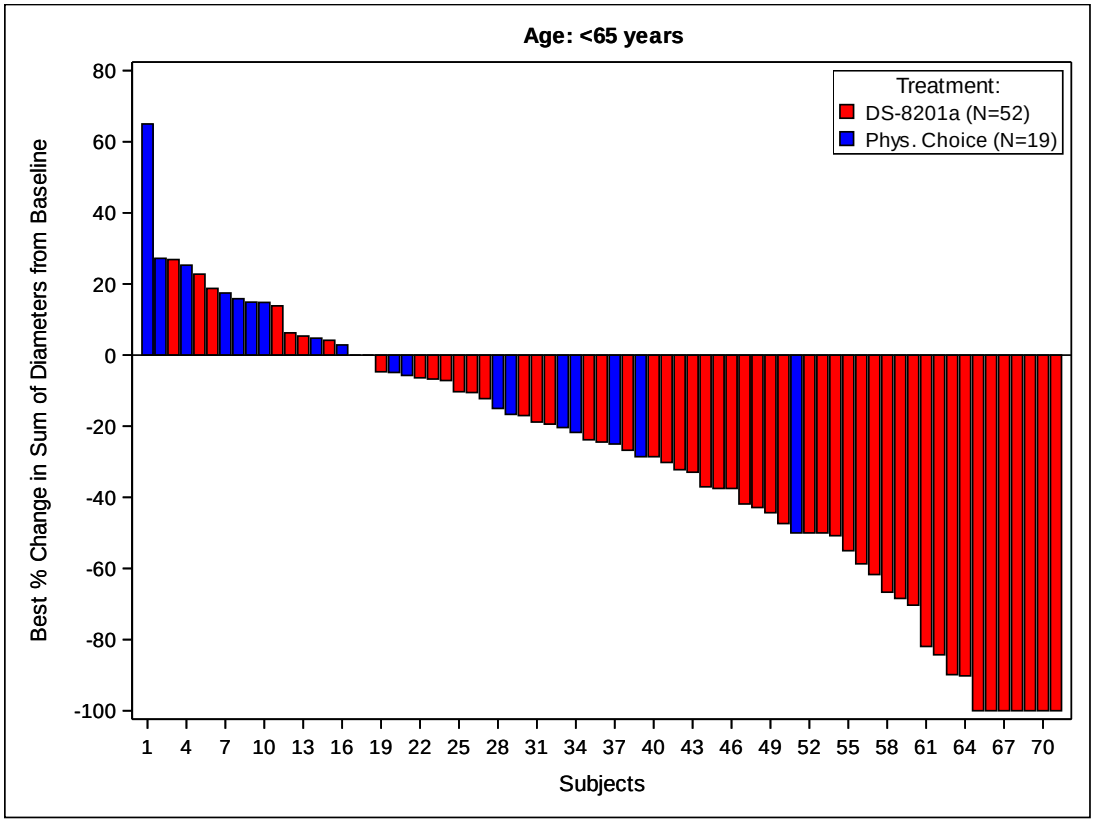
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
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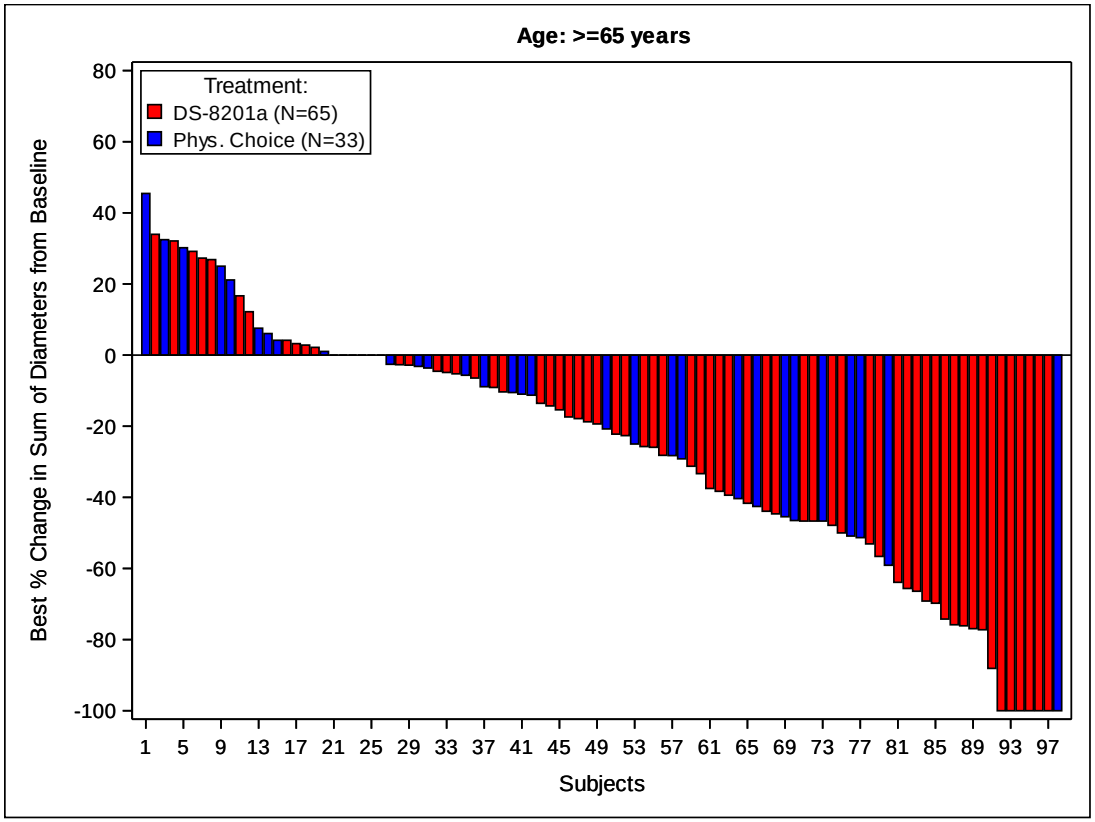

Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
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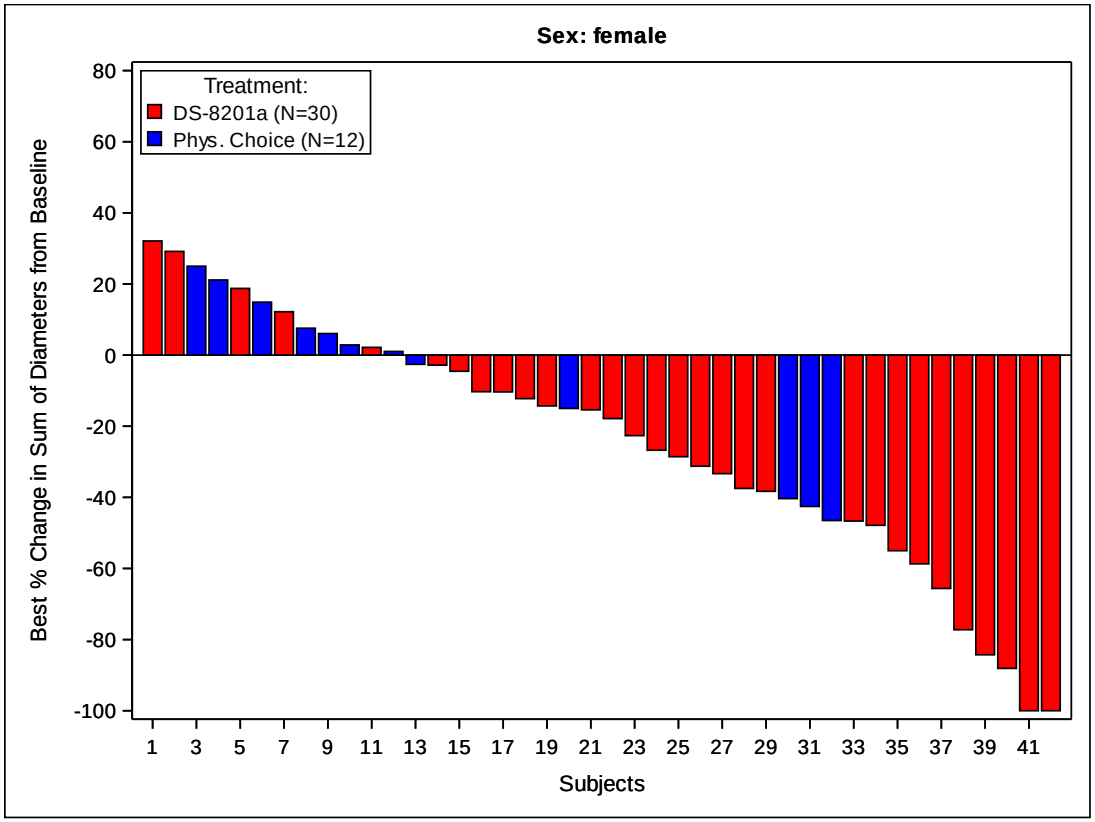

Source data: ADAM.ADSL and ADAM.ADTR

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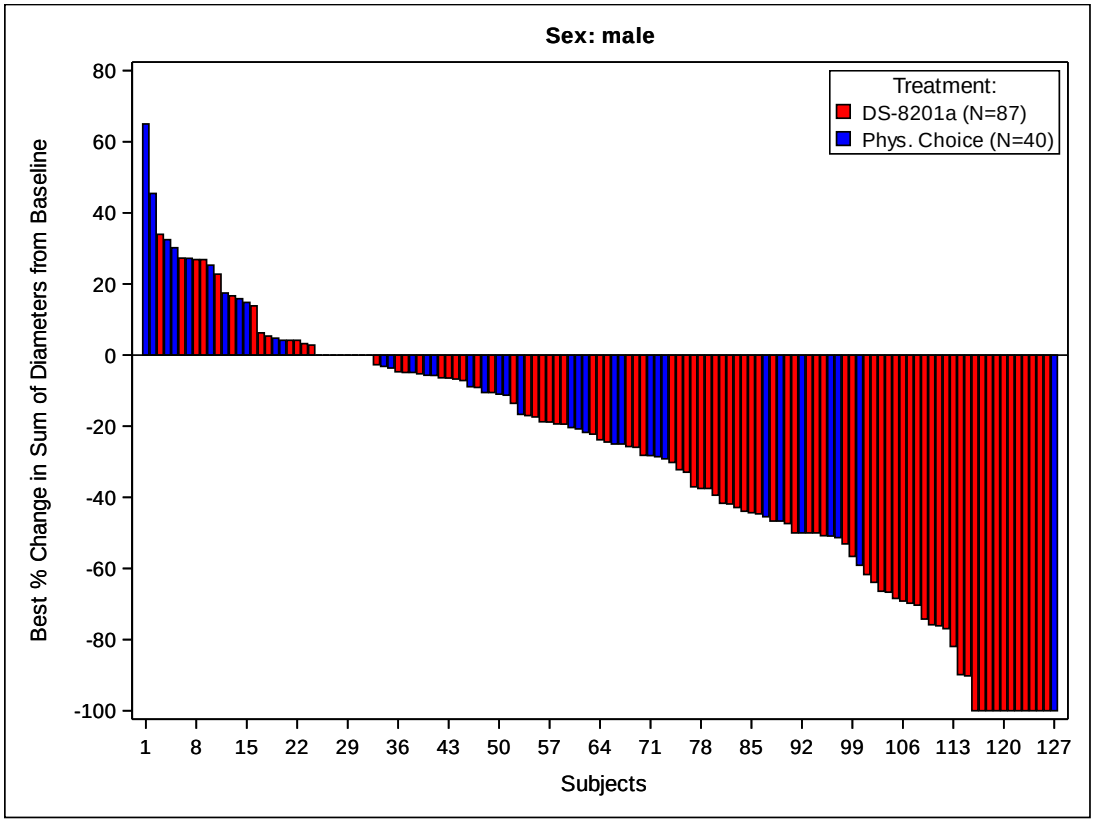

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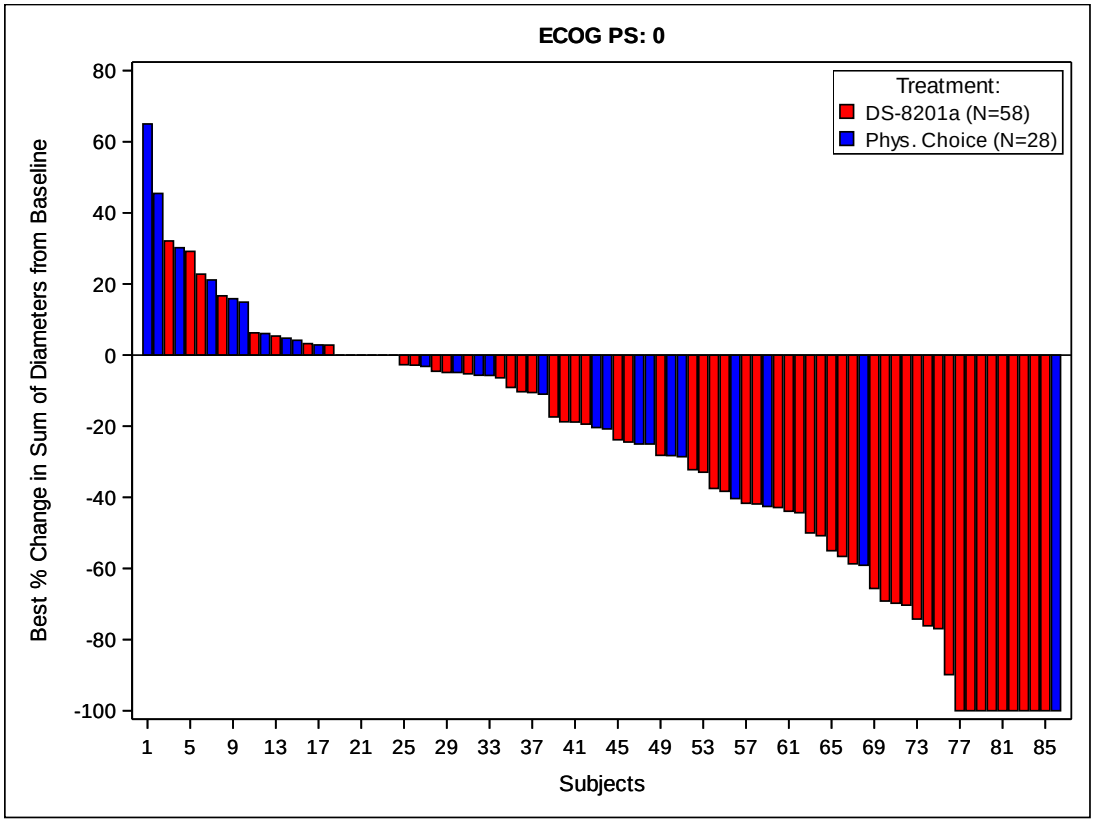

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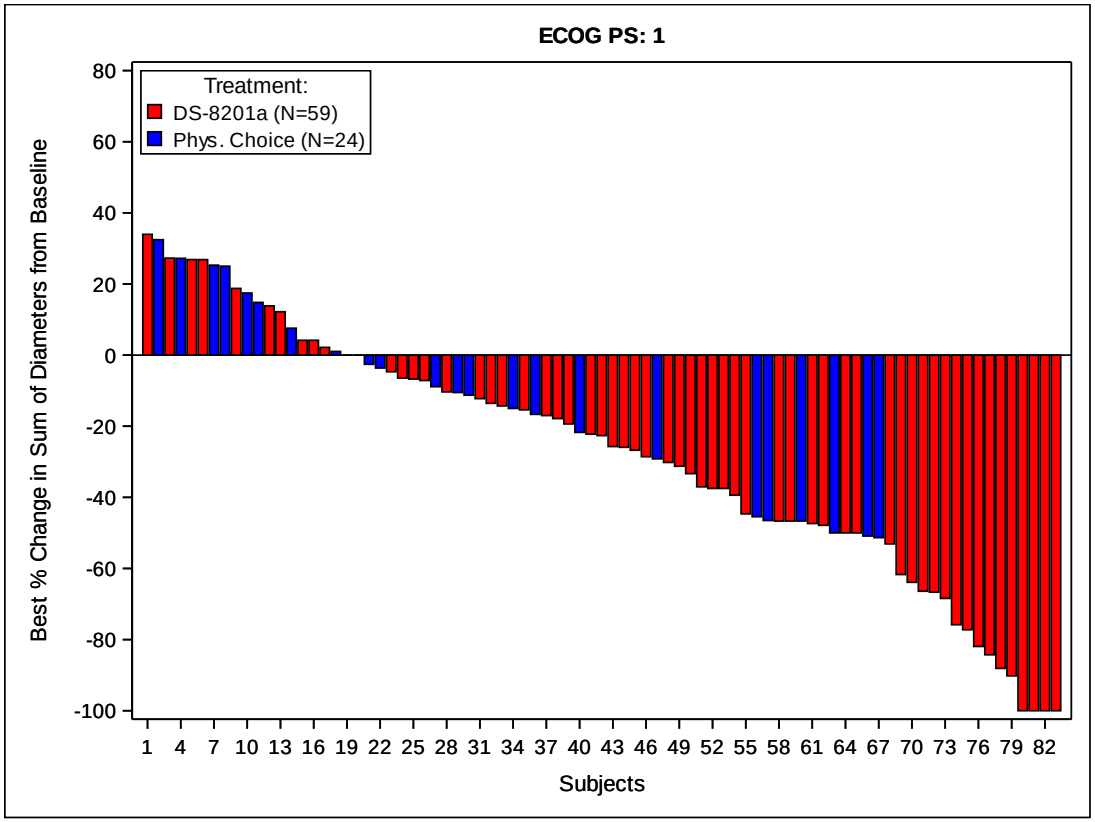

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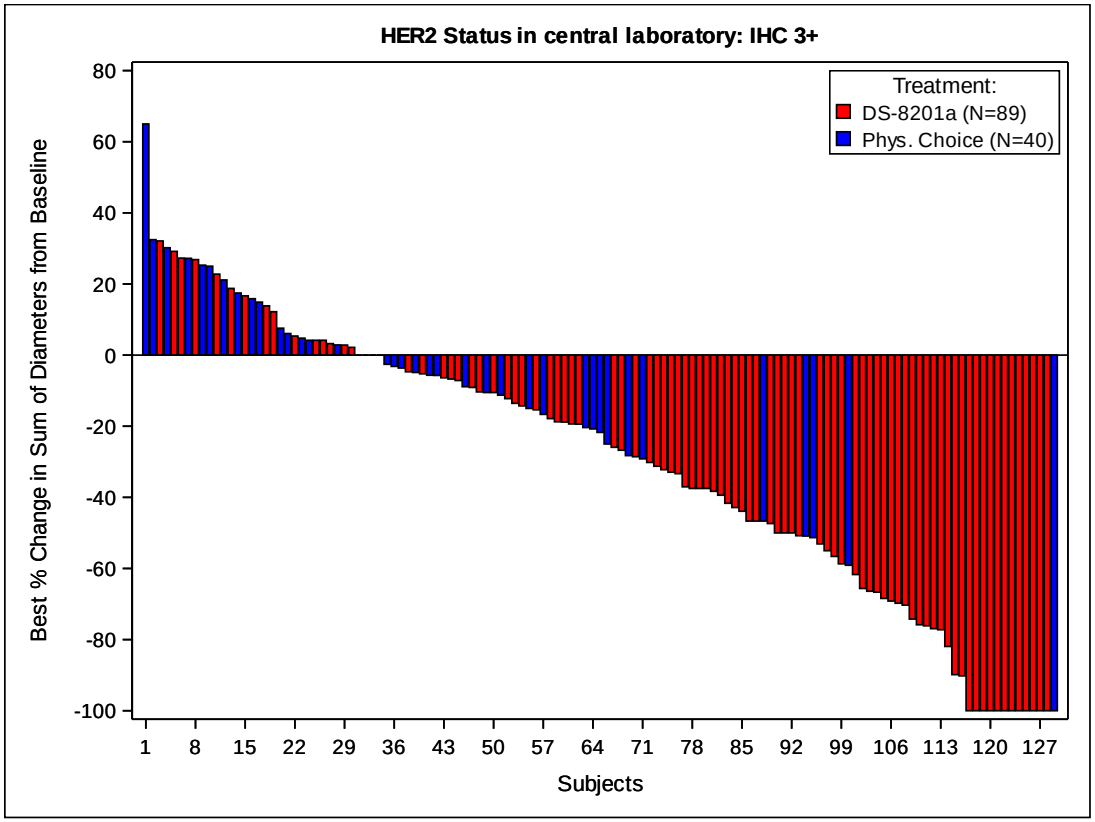

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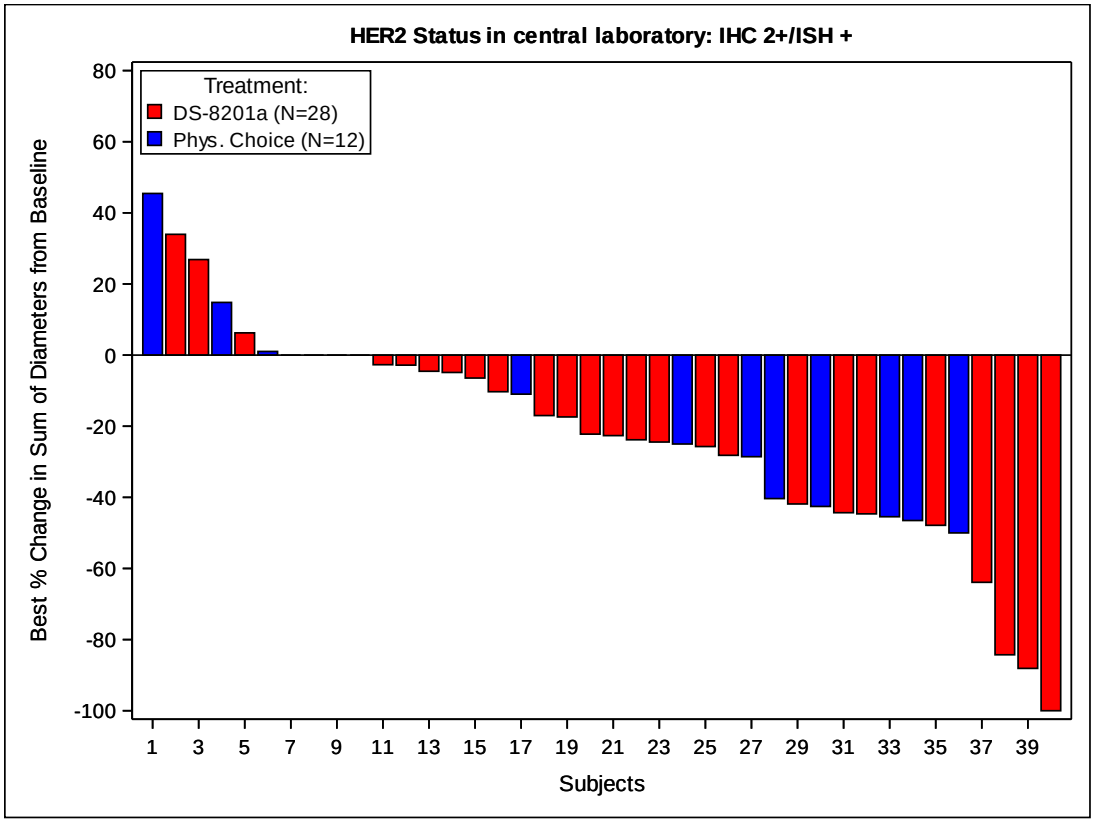

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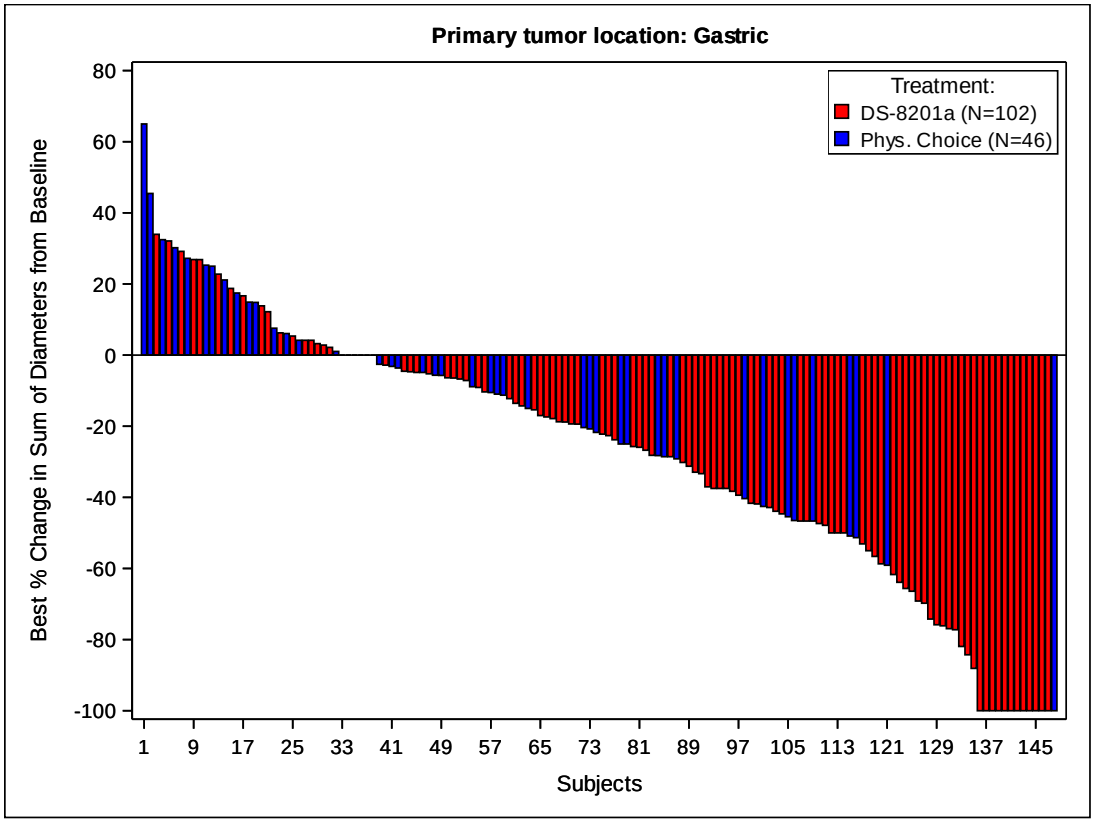

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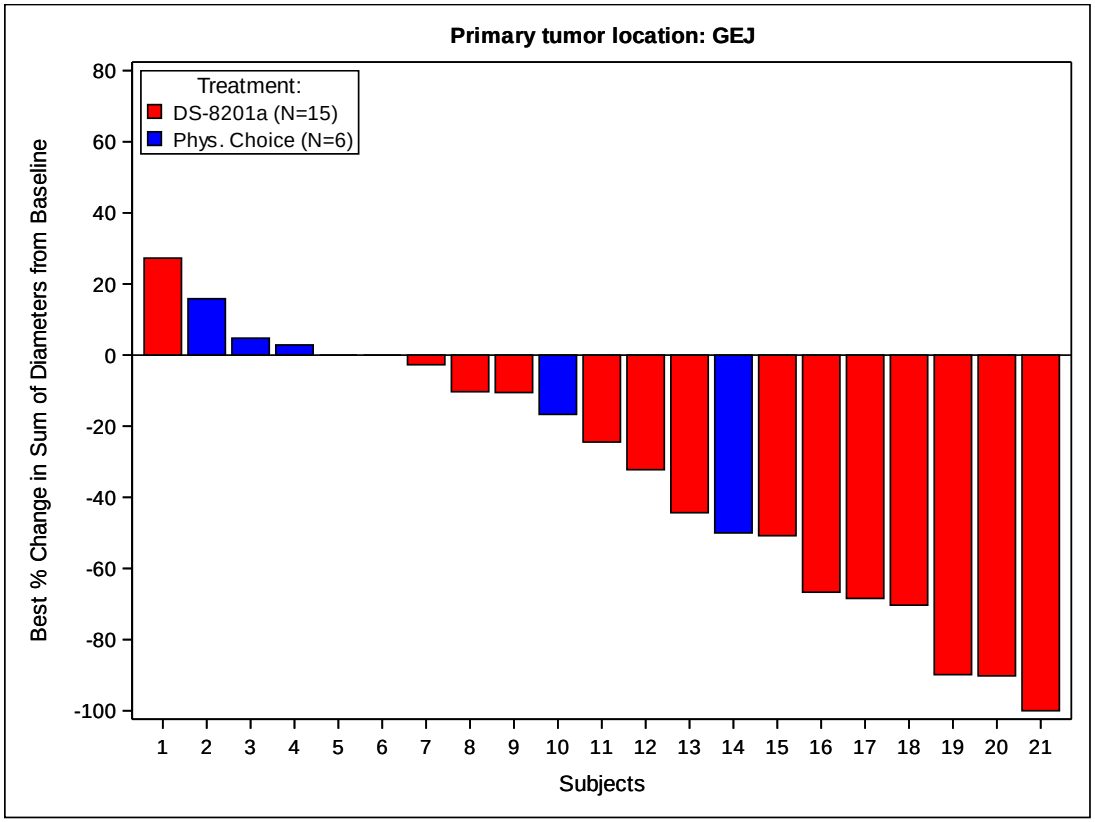

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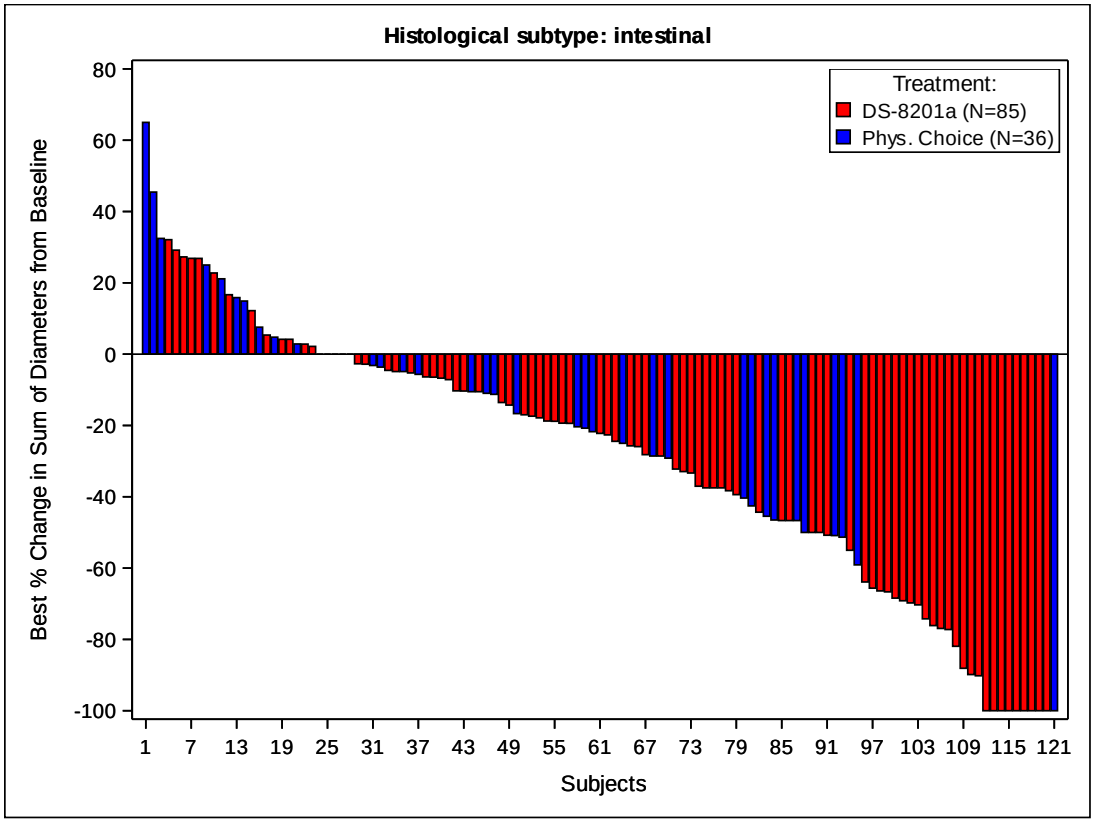

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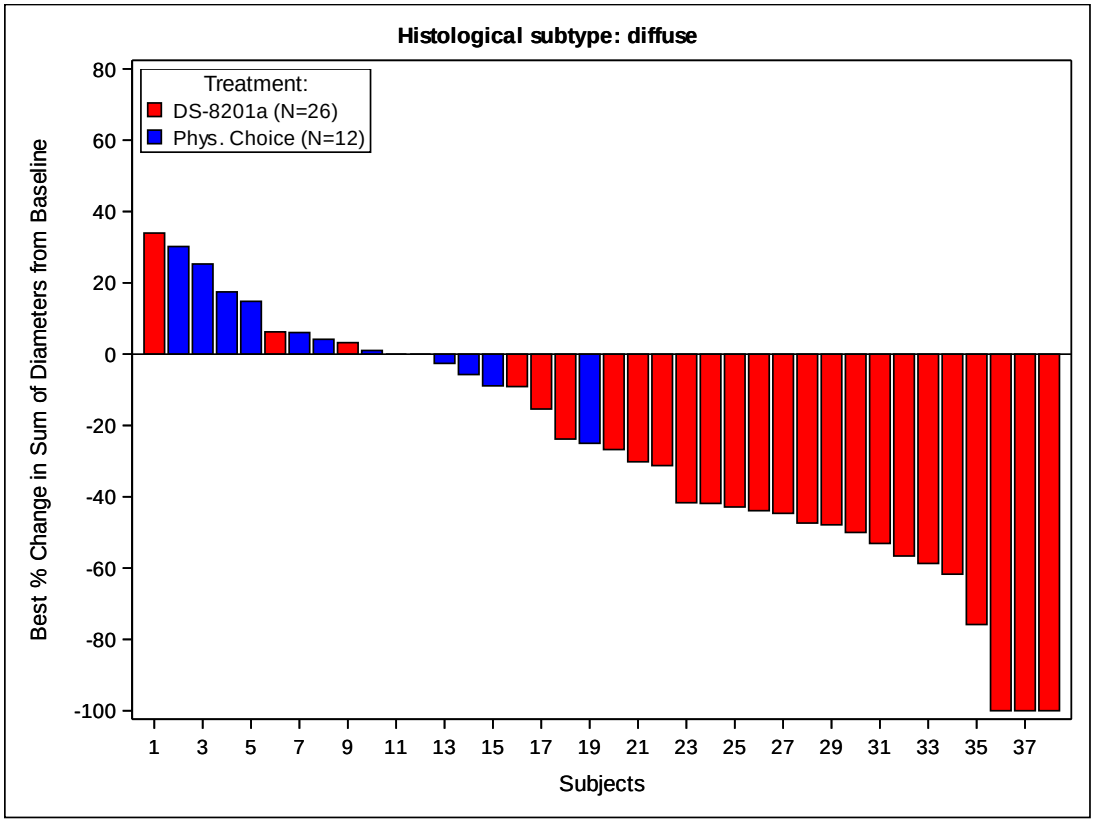

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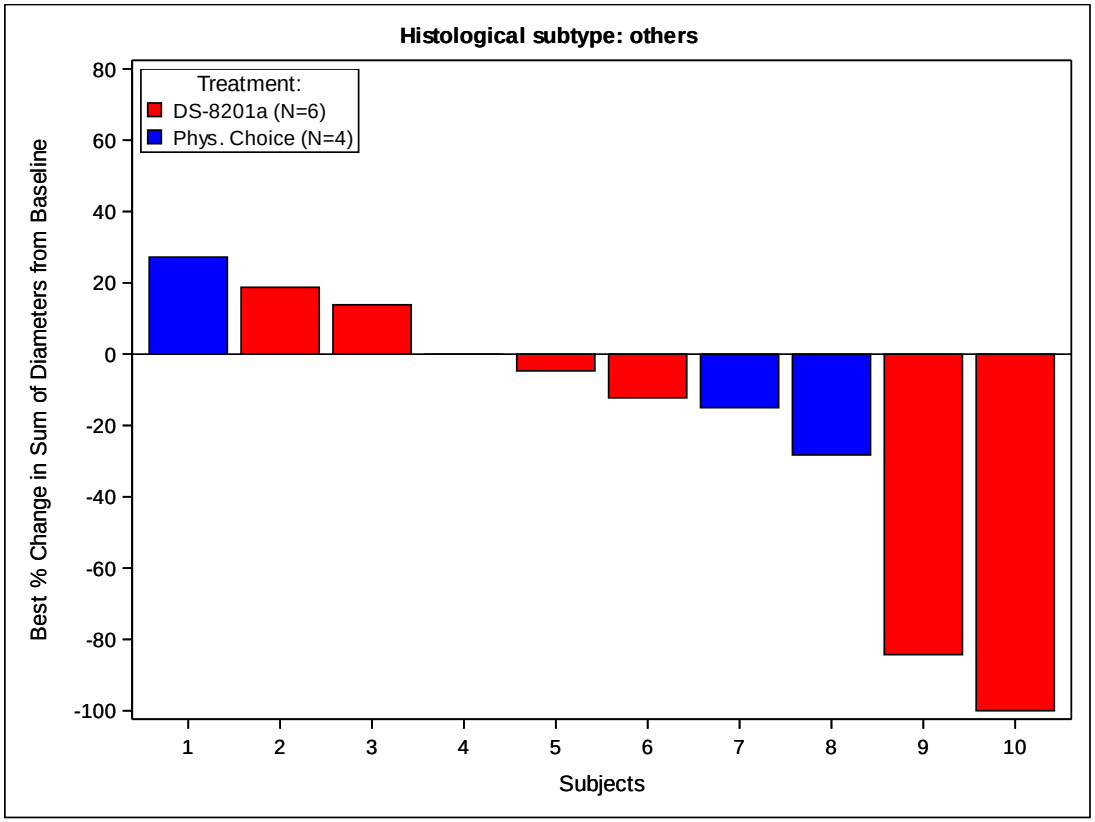

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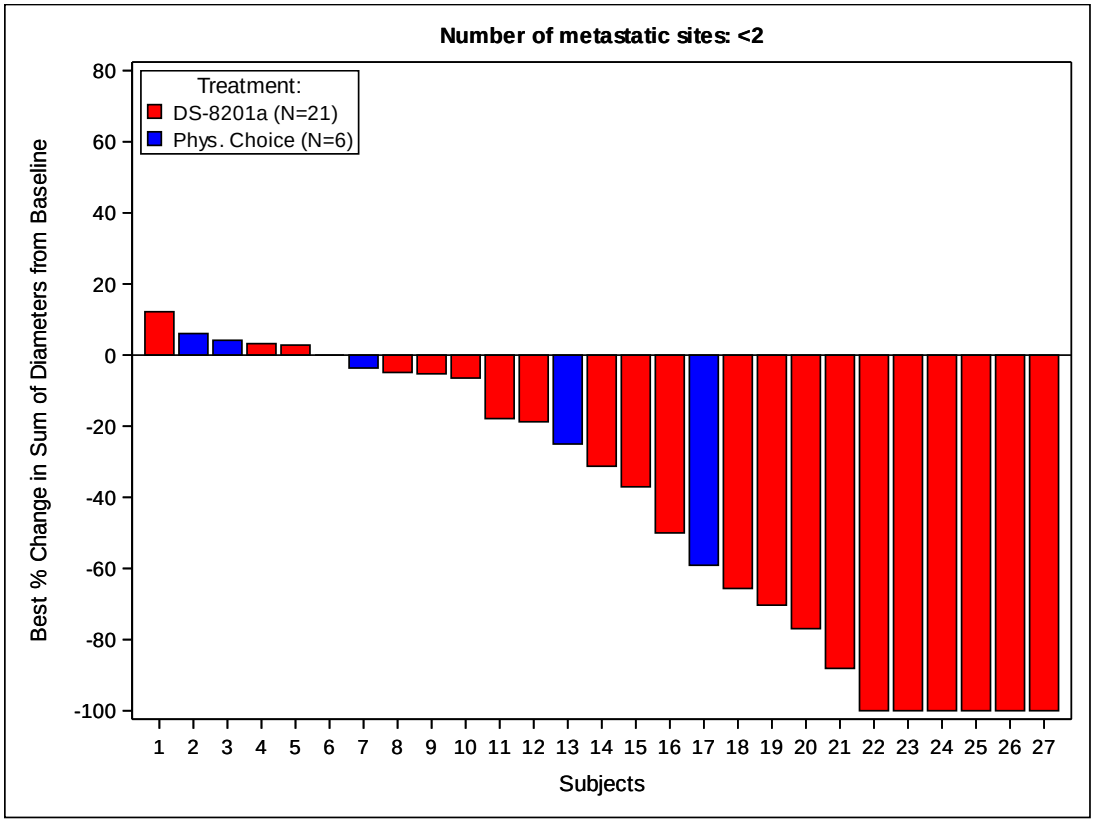

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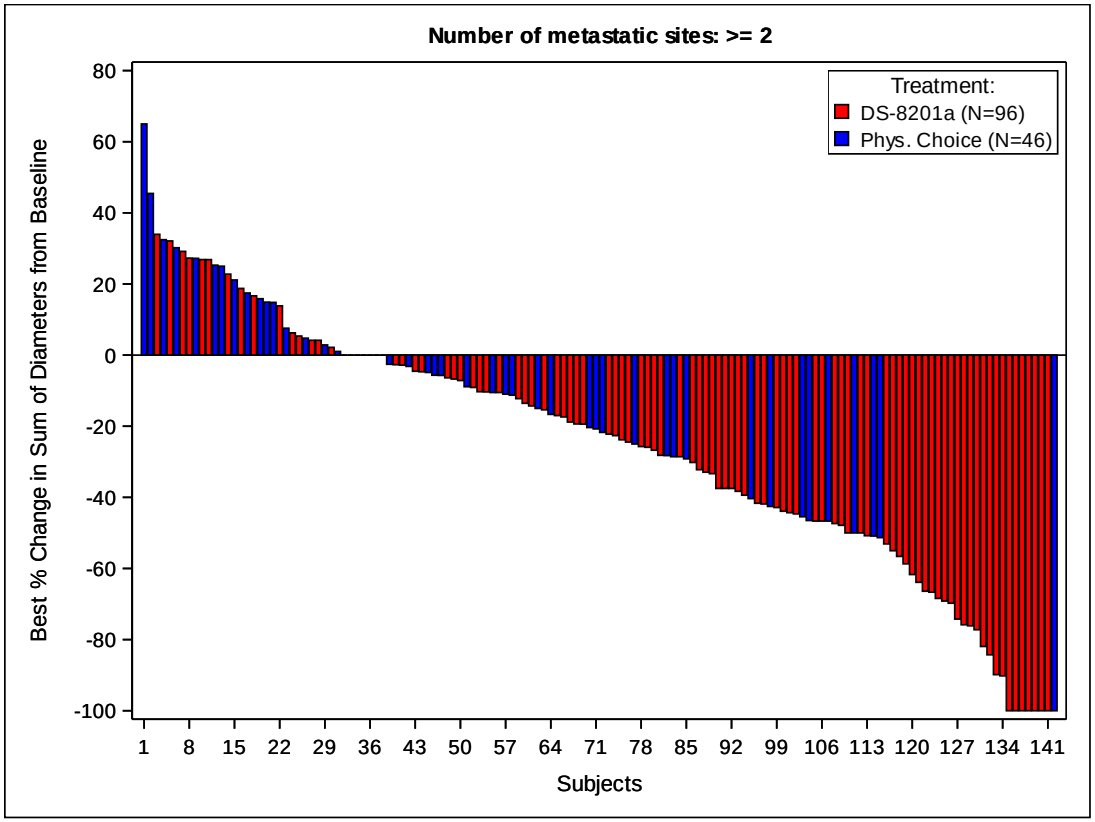

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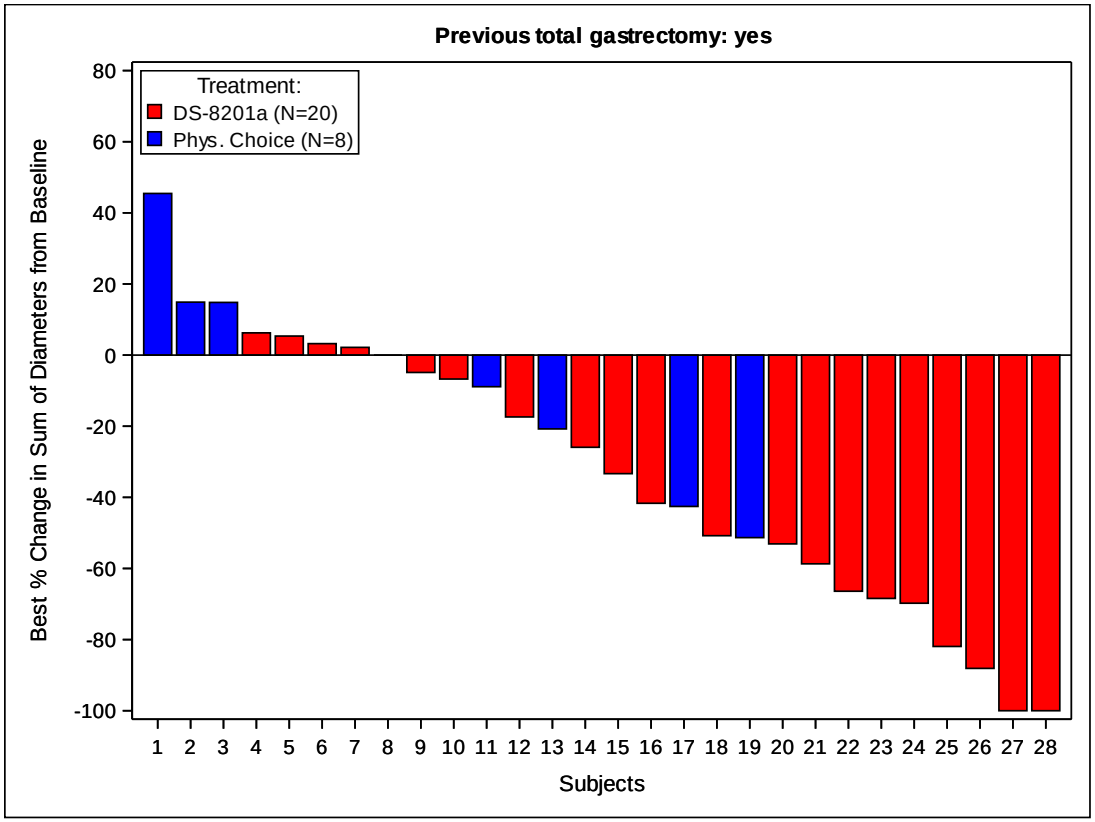

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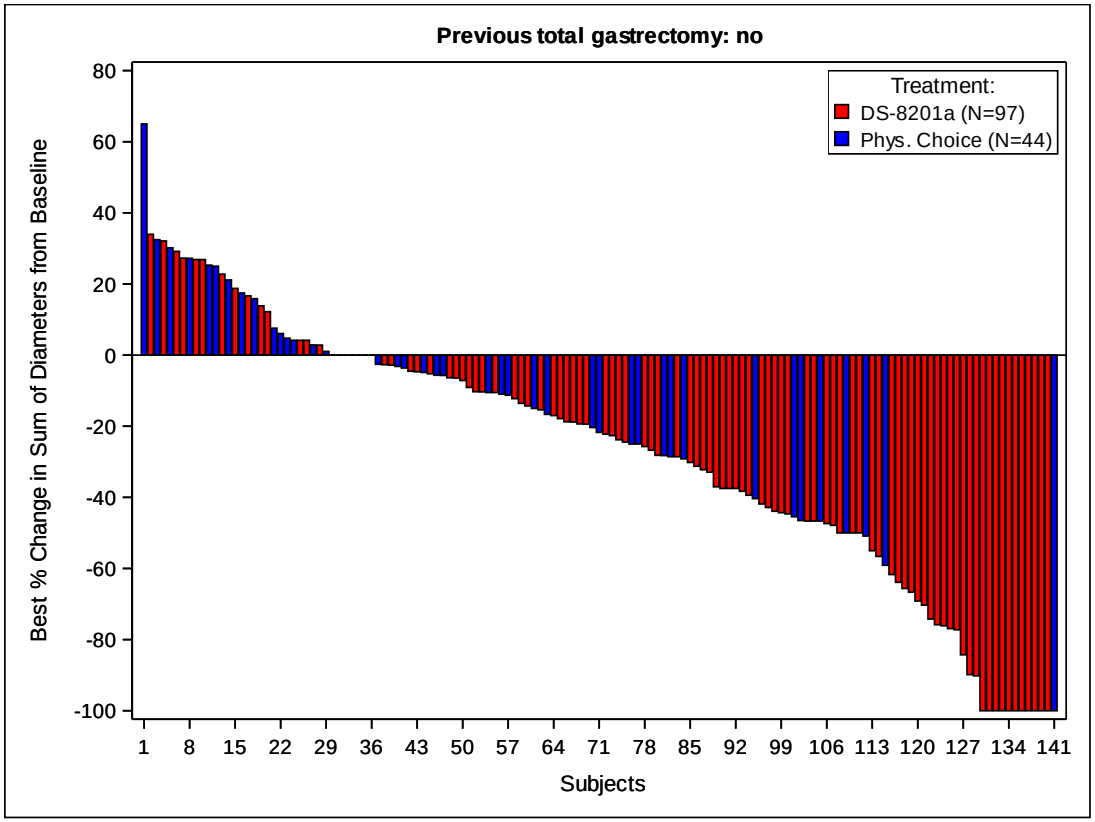

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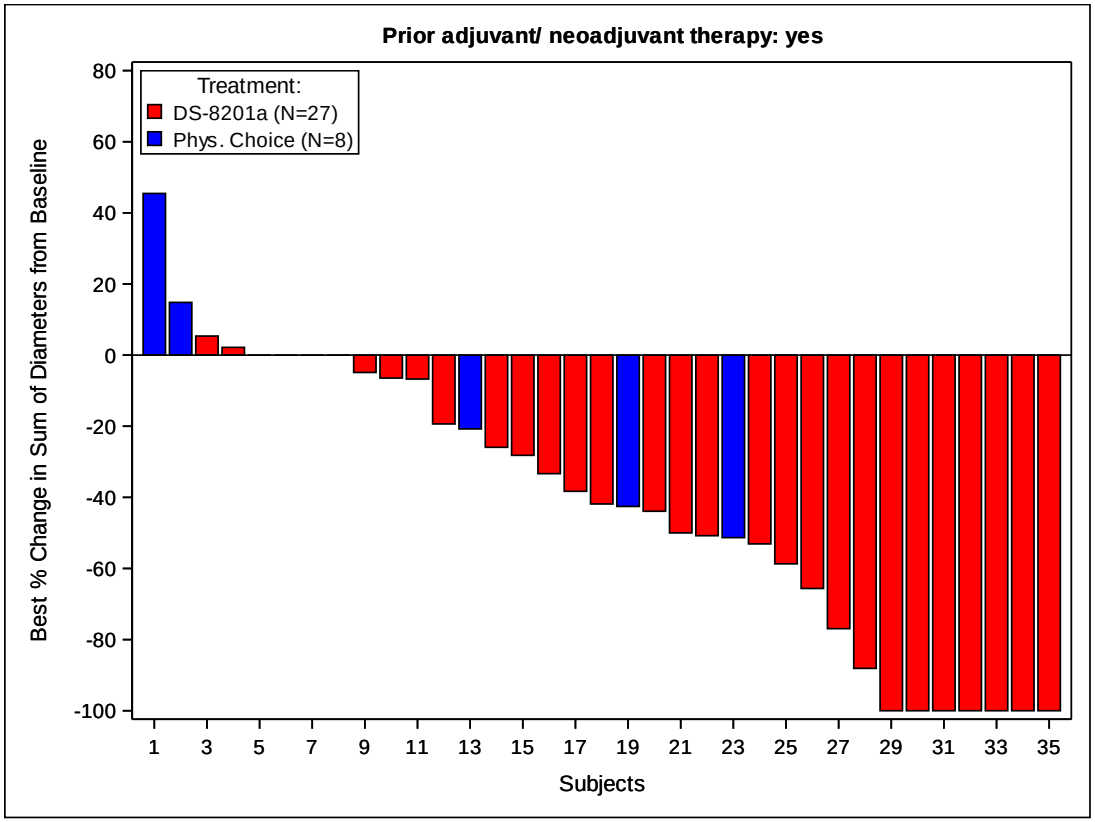

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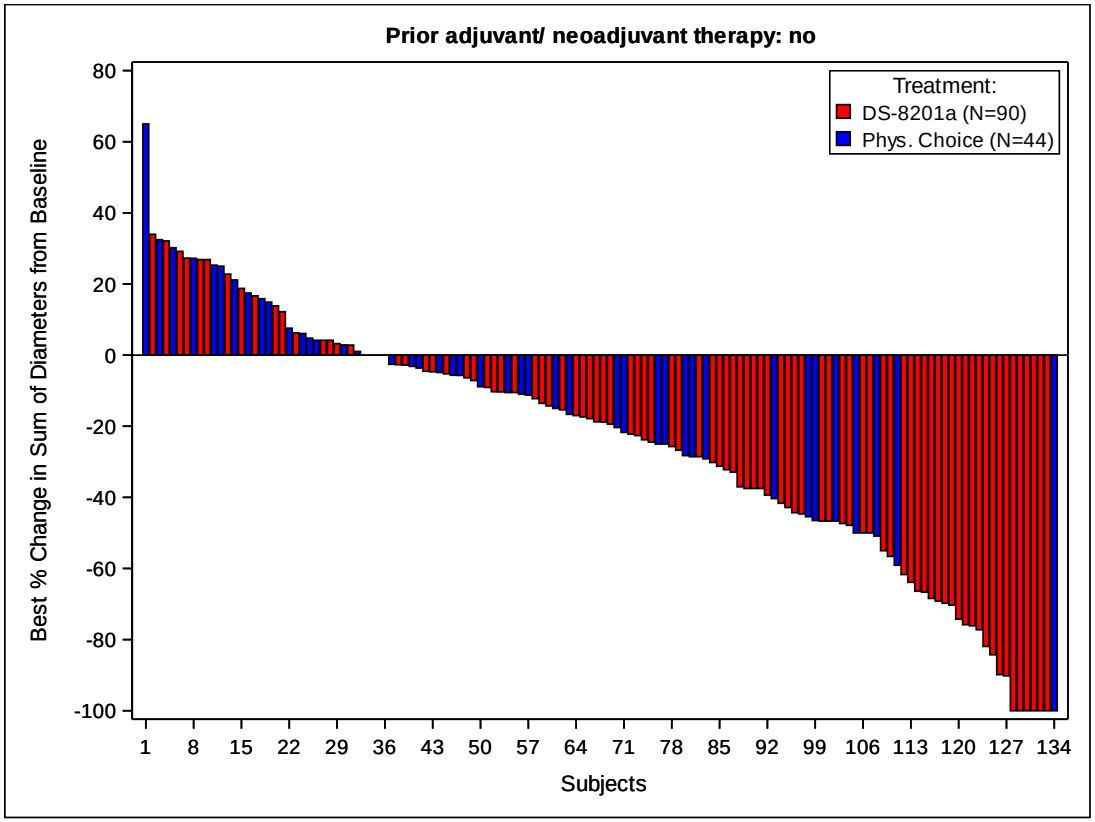

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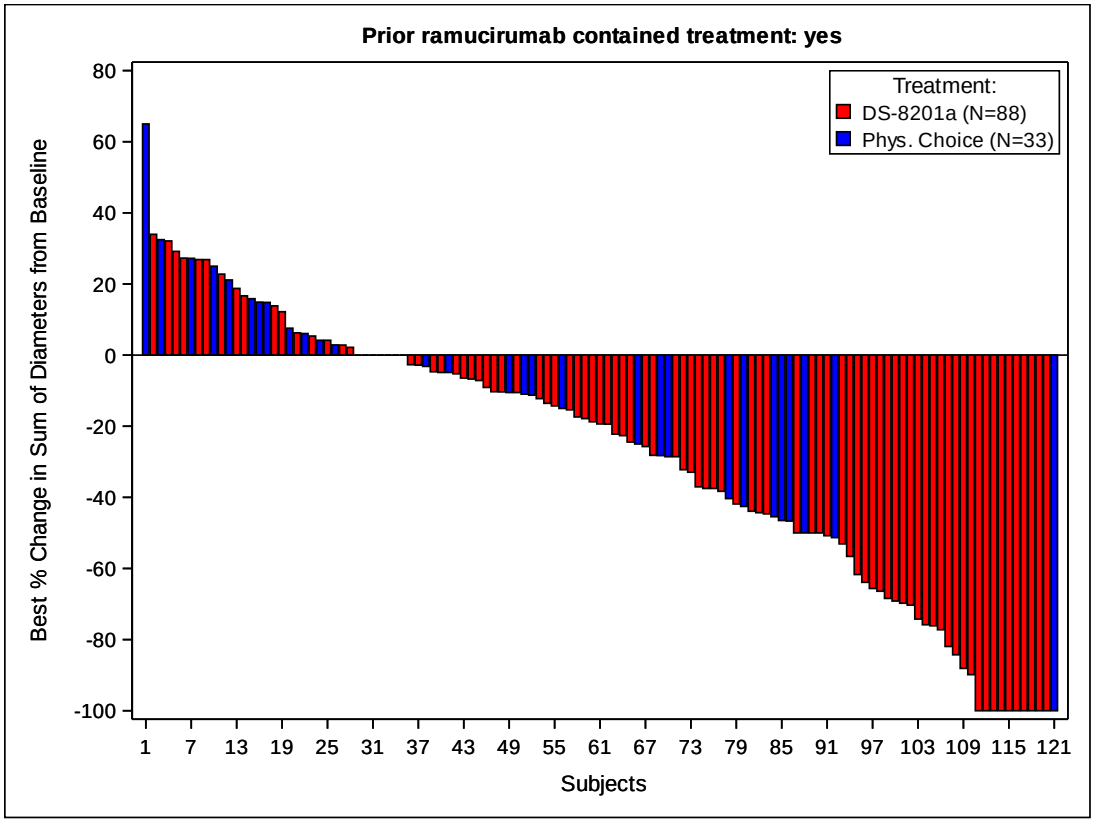

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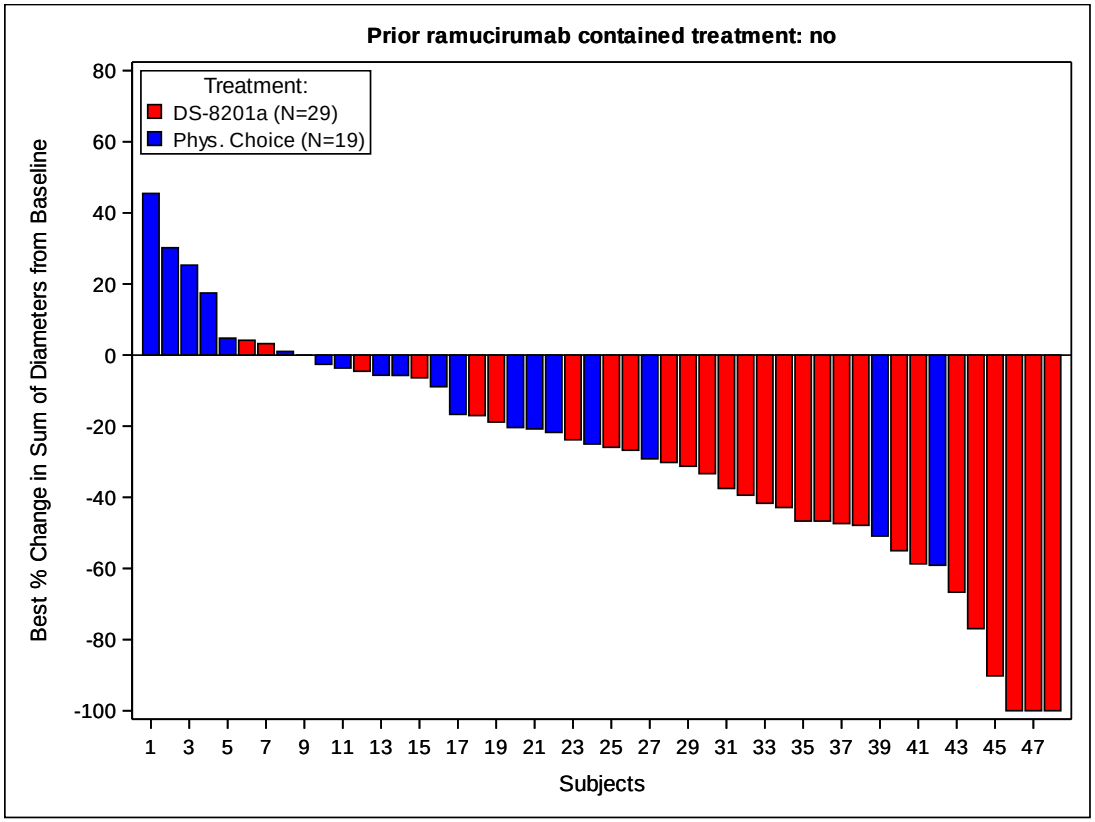

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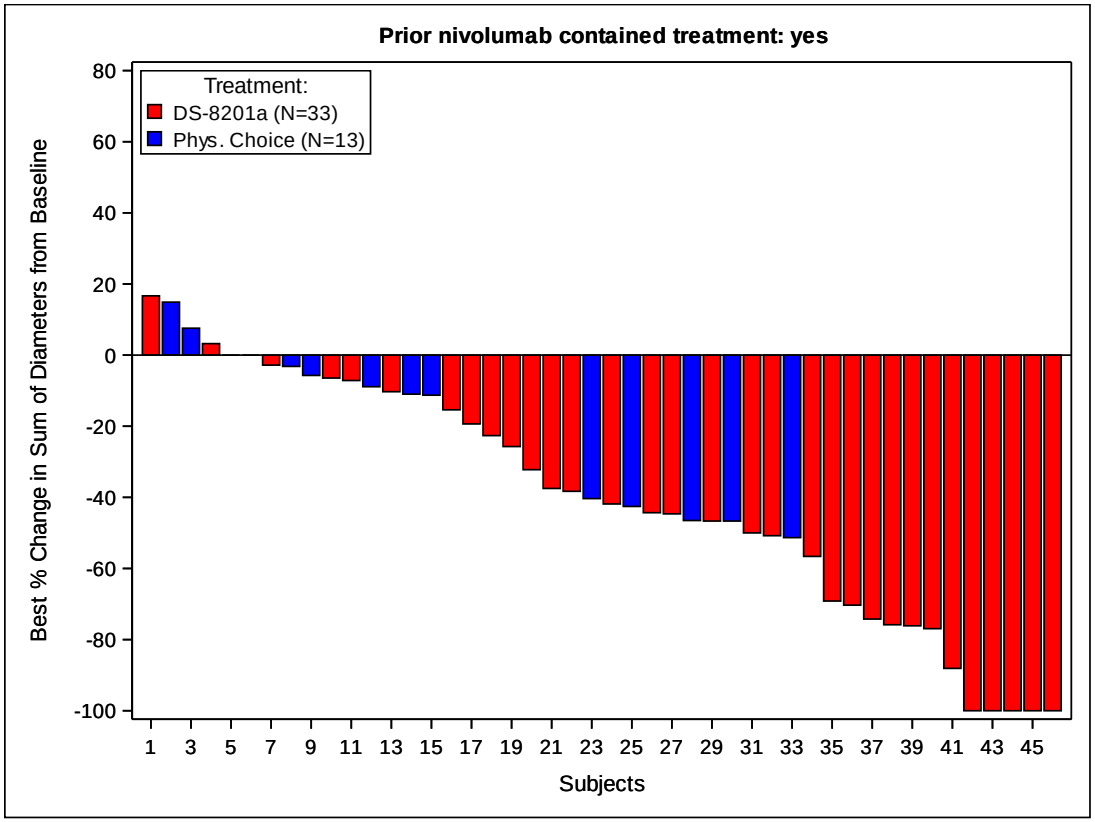

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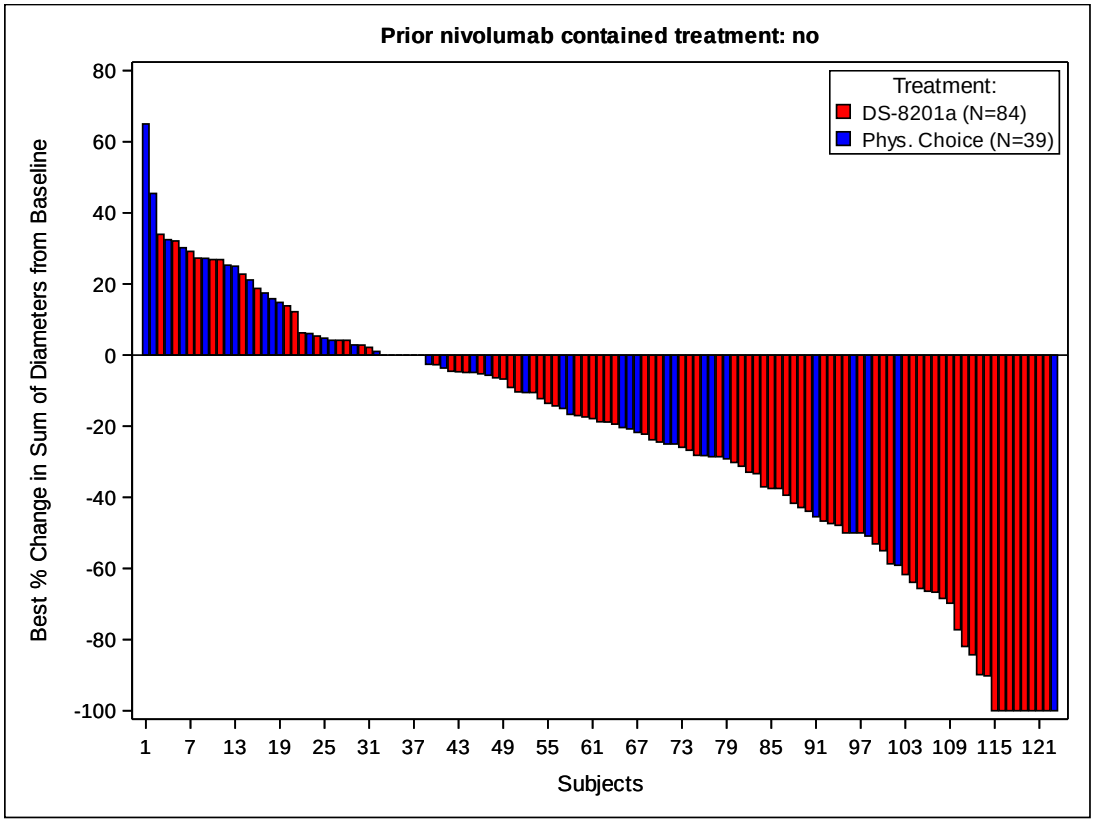

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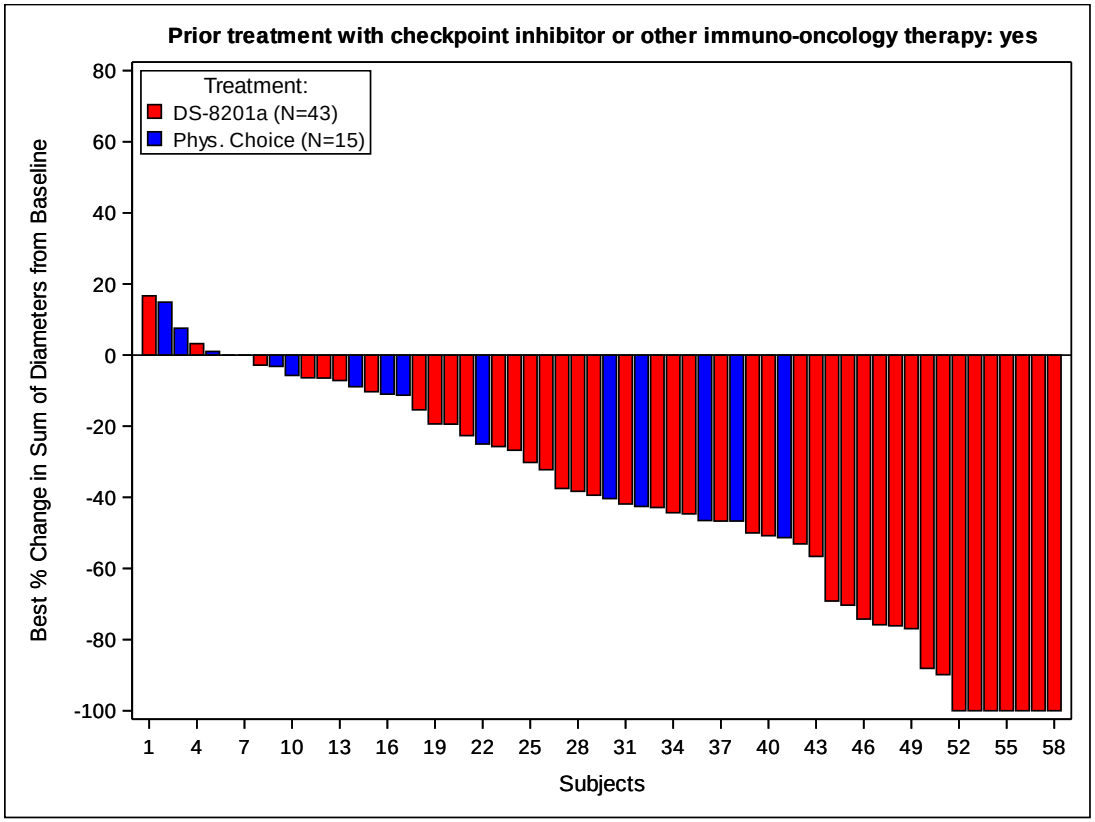

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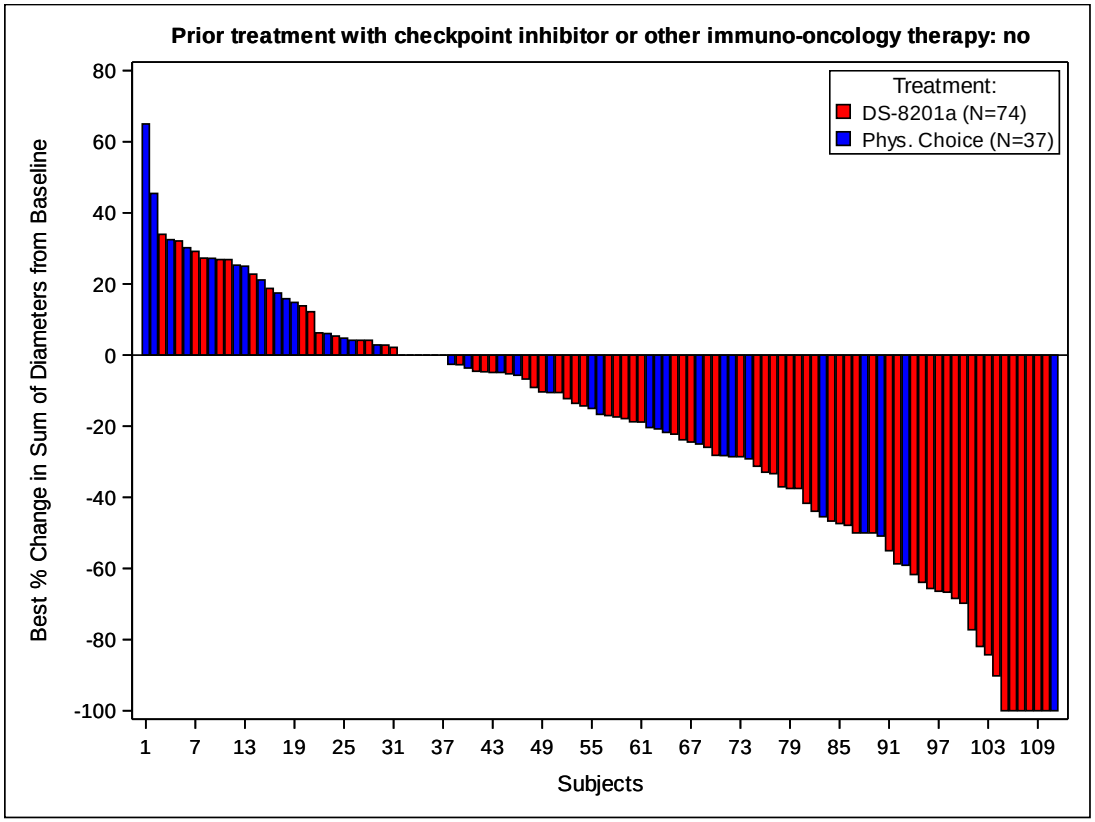

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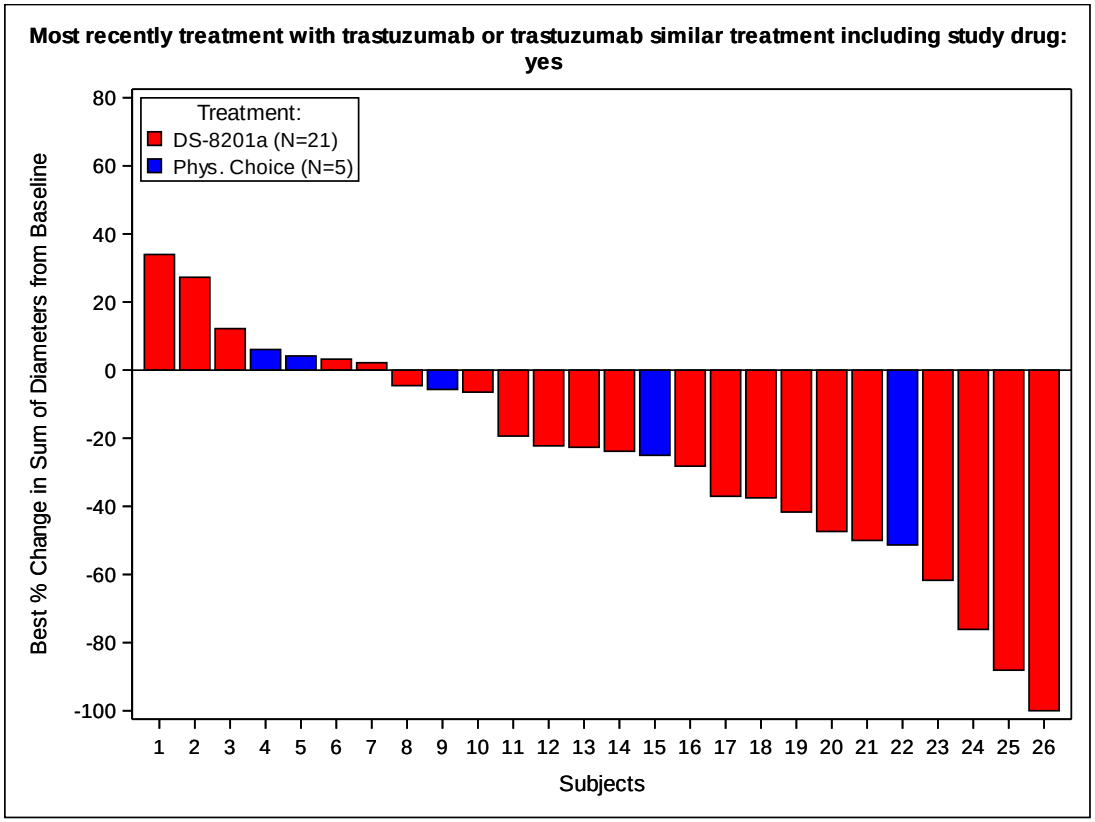

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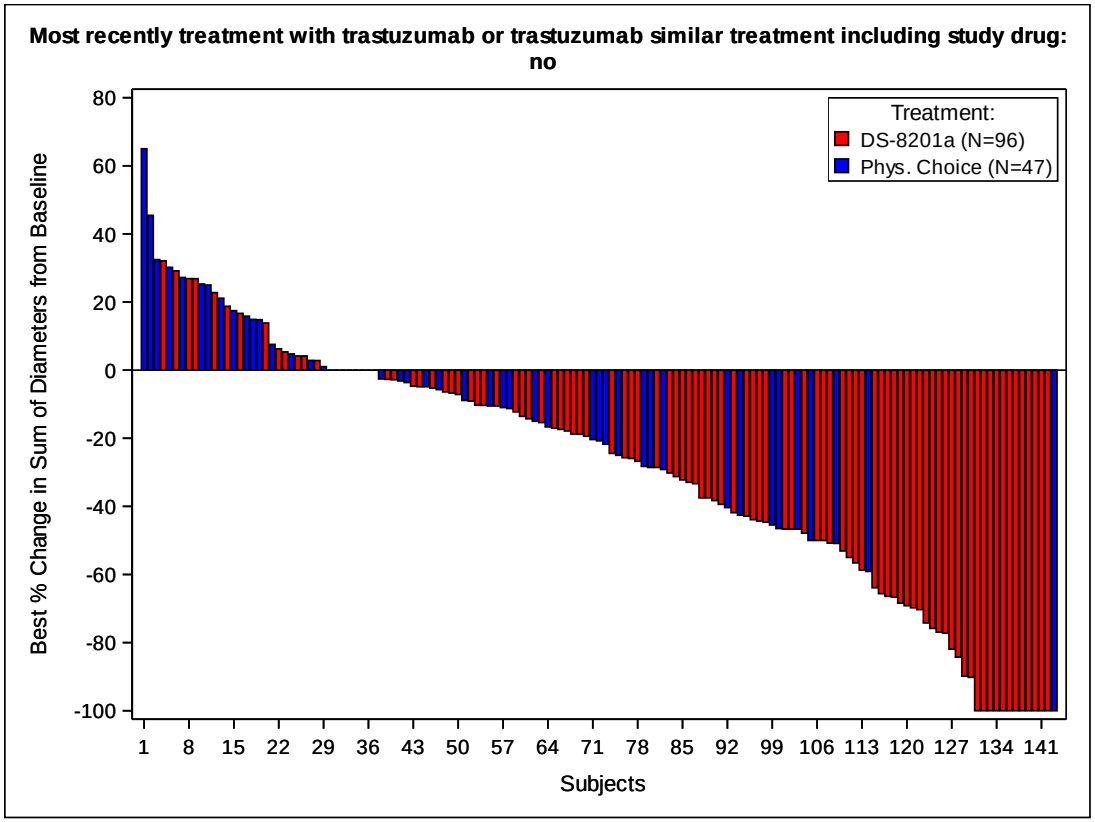

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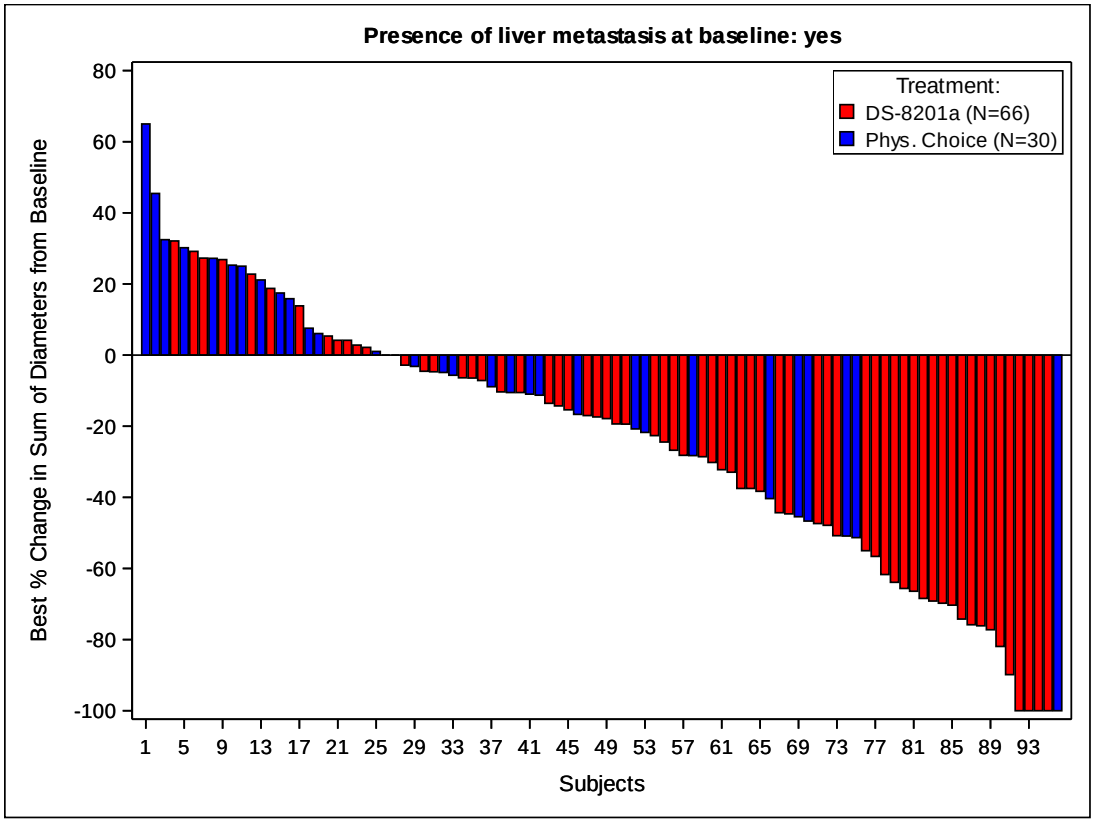

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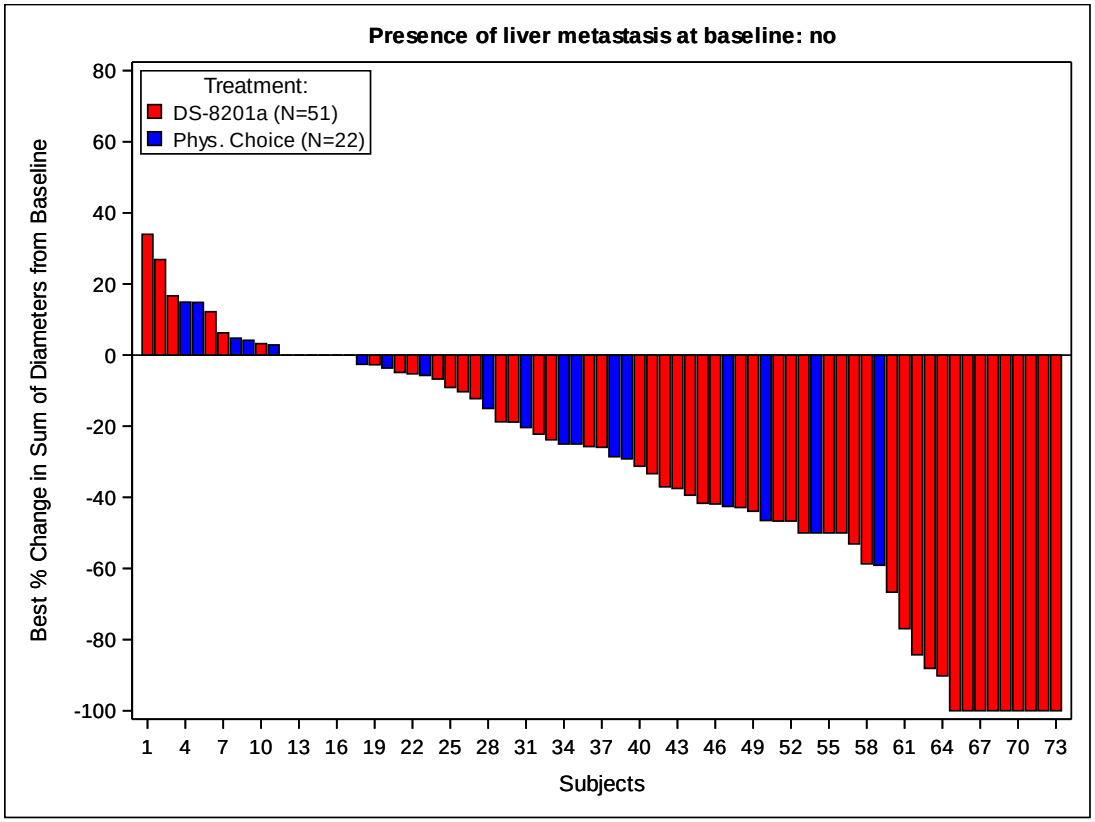

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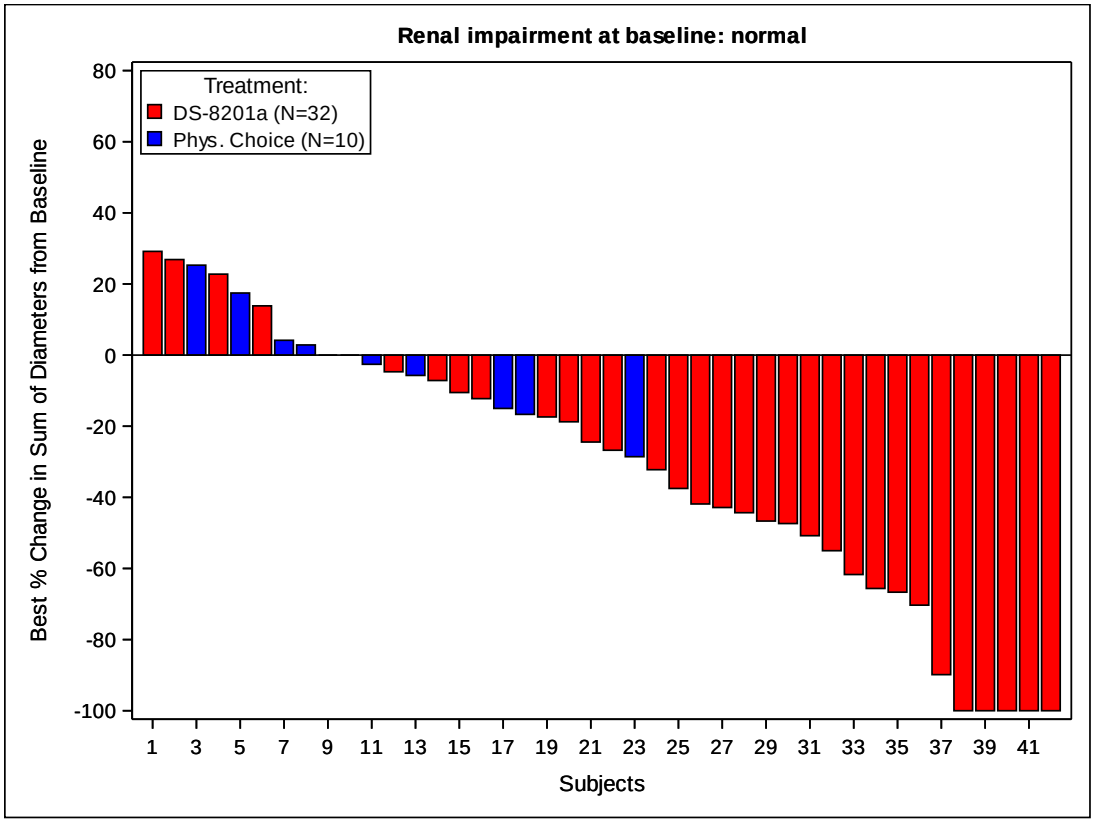

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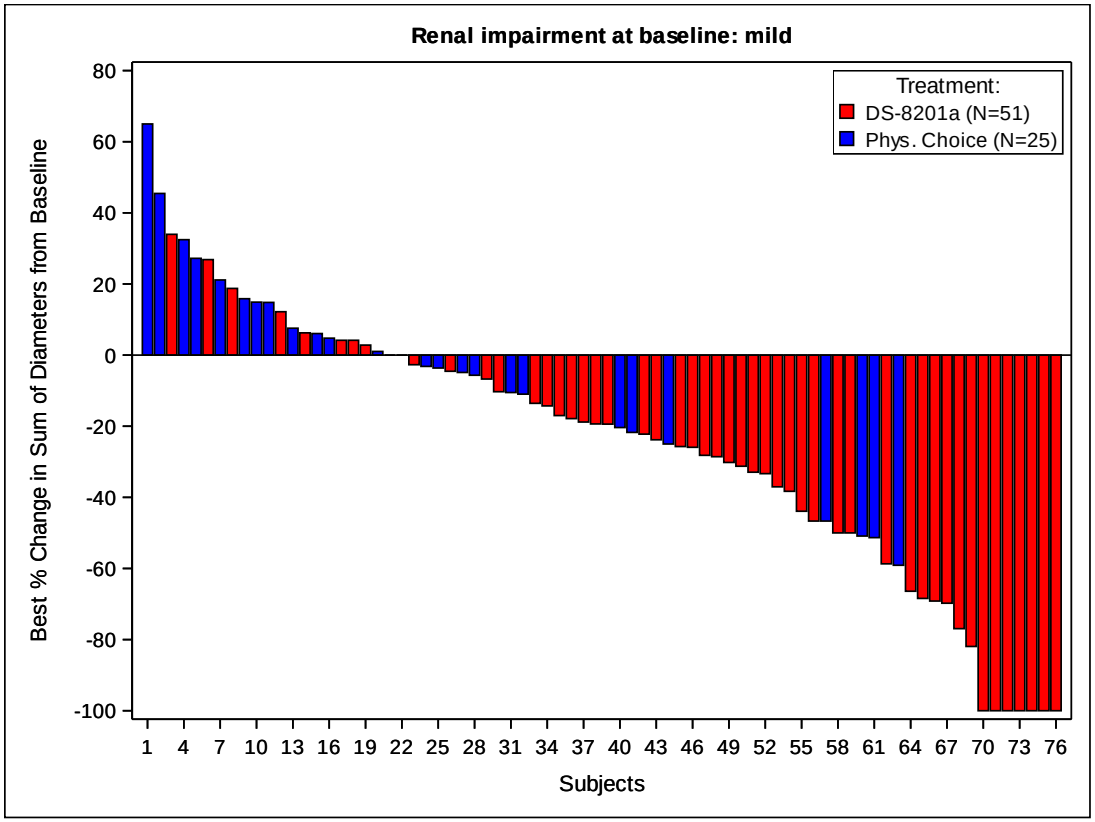

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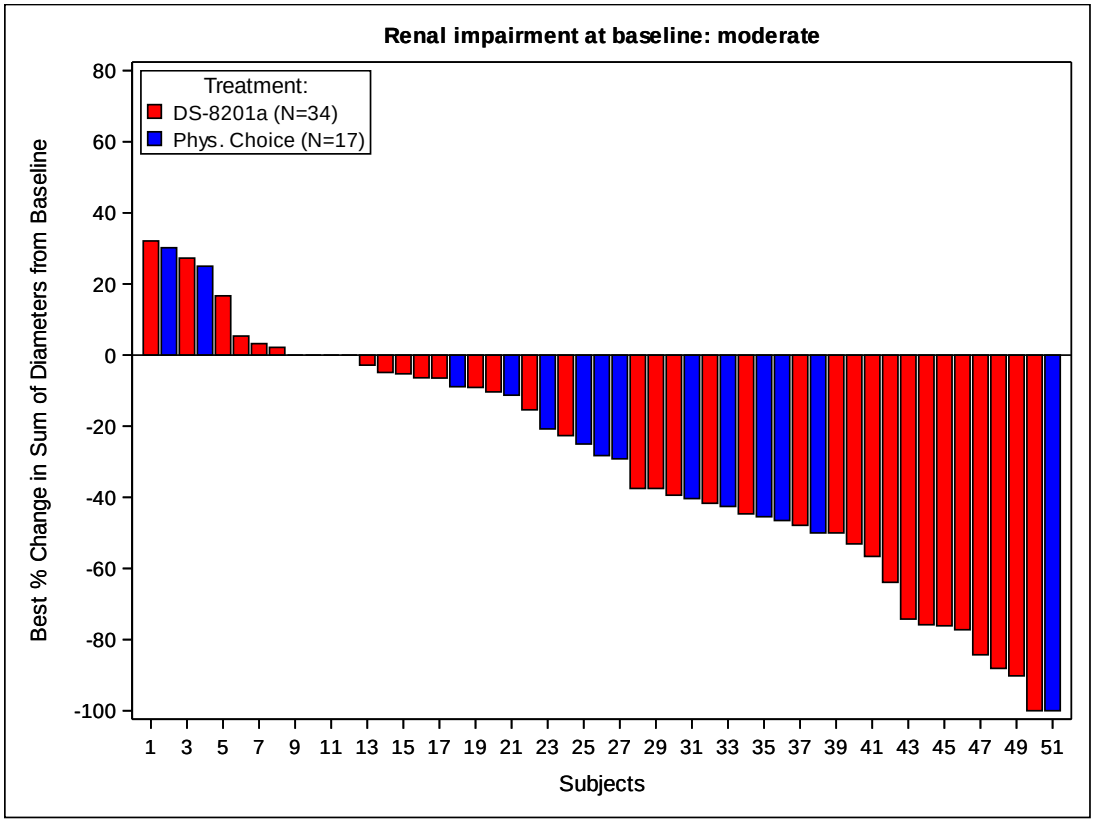

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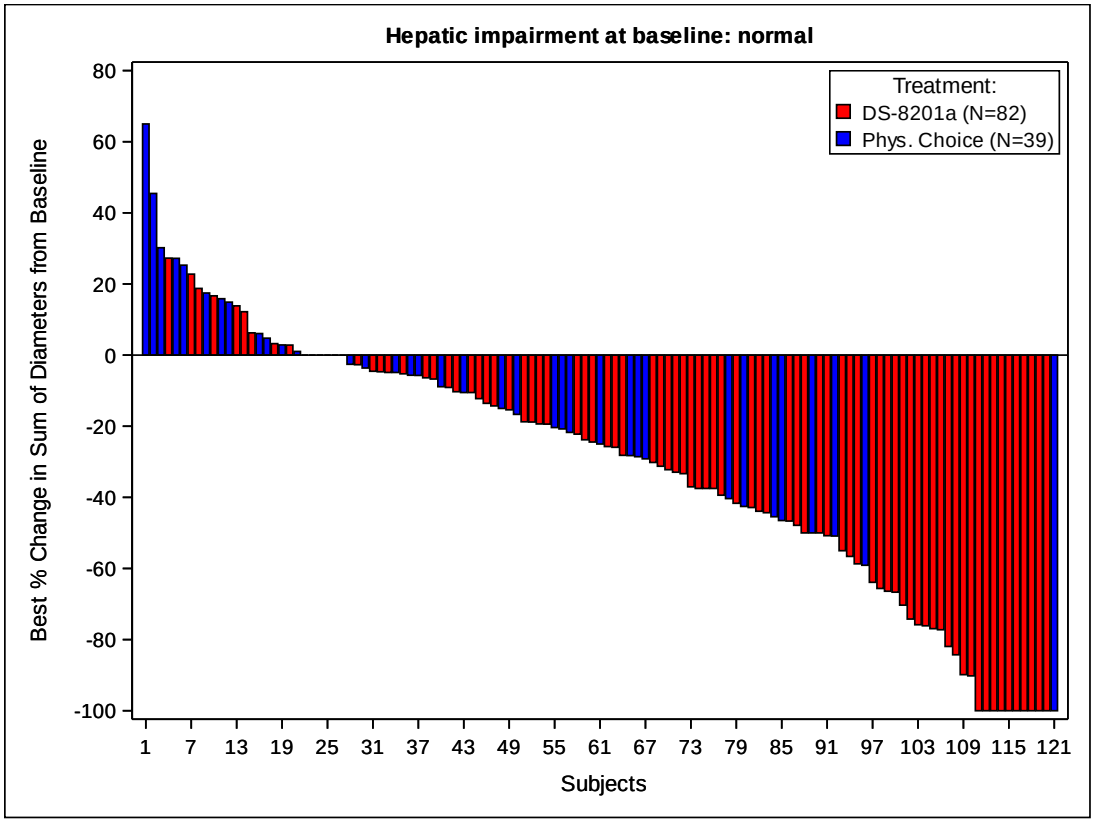

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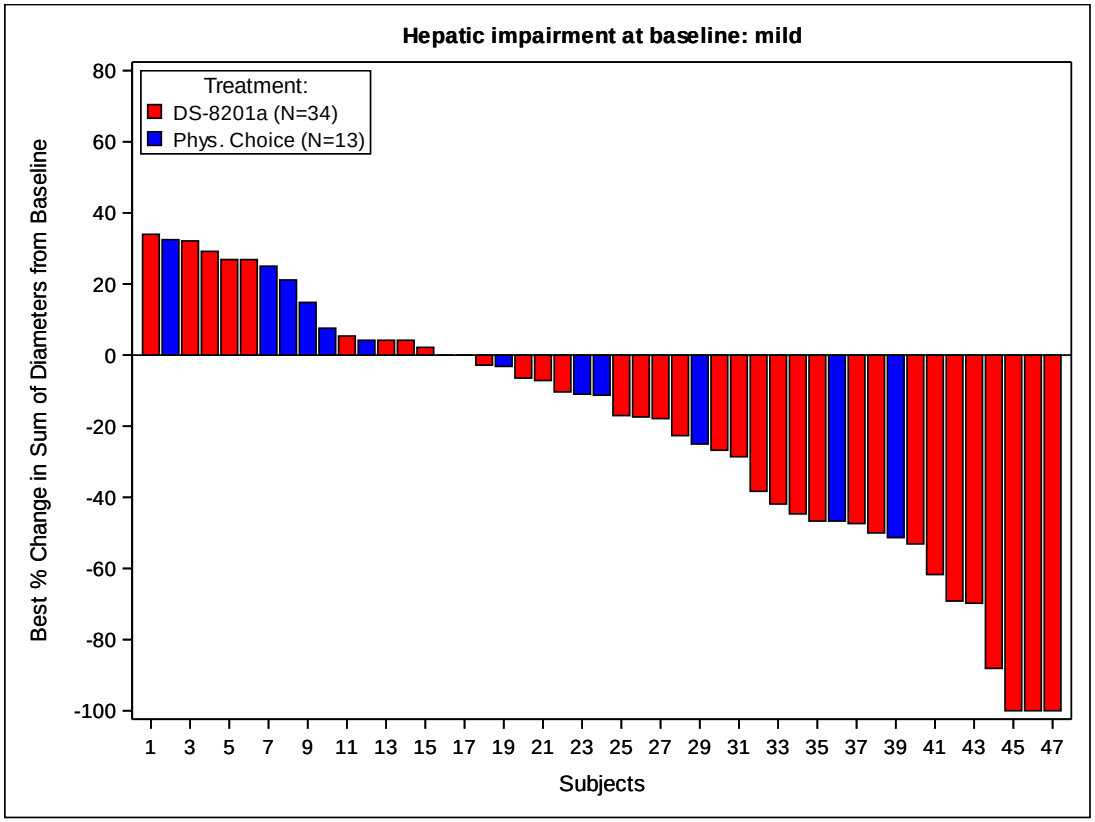
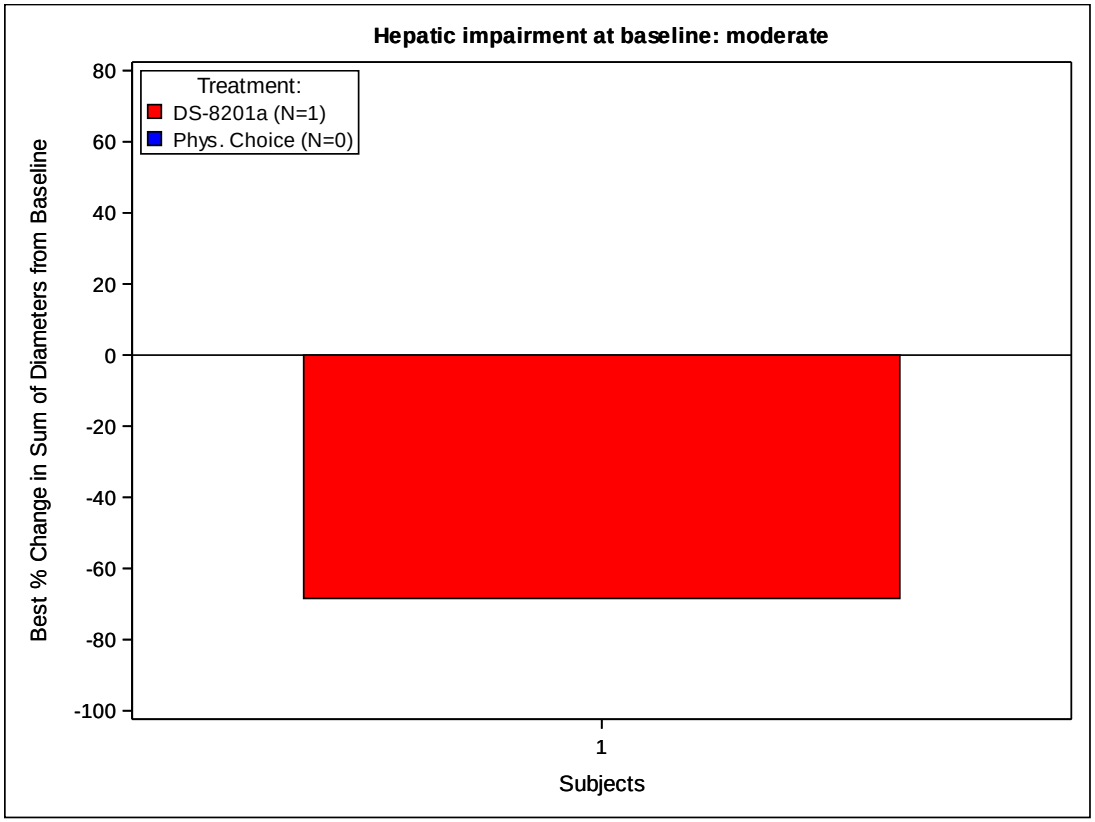
Full Analysis Set



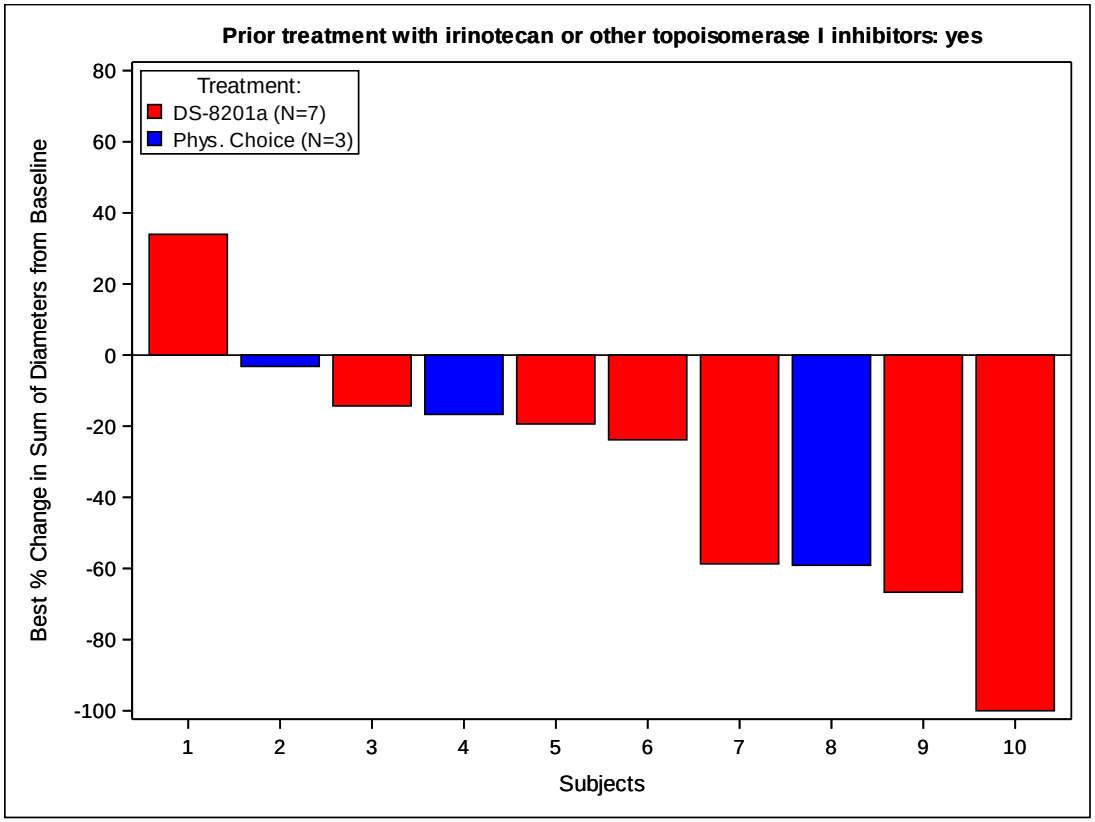
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



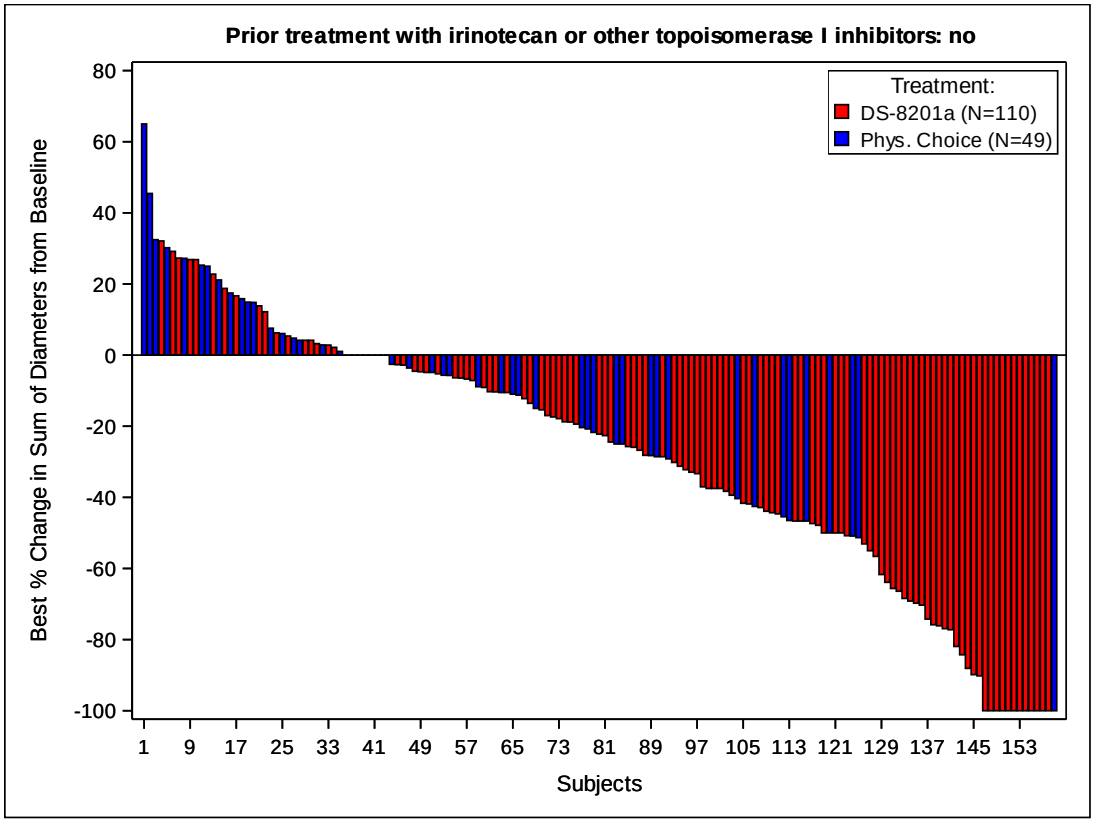
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



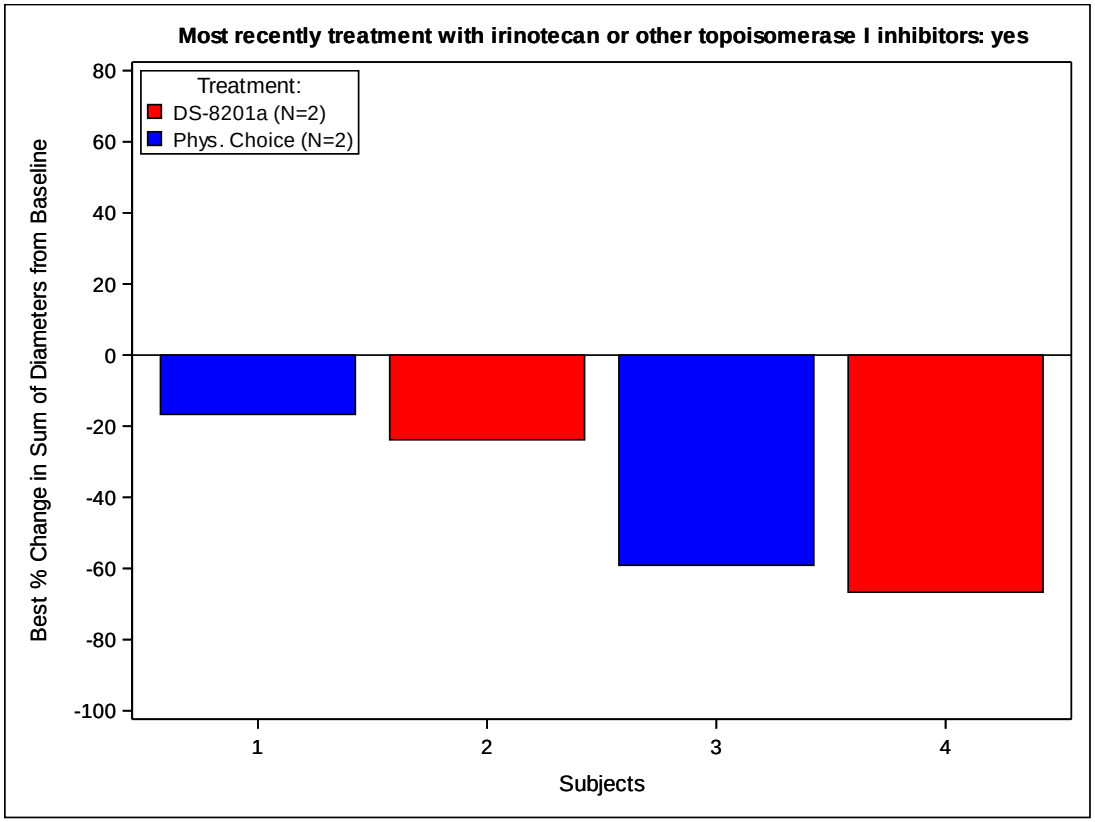
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



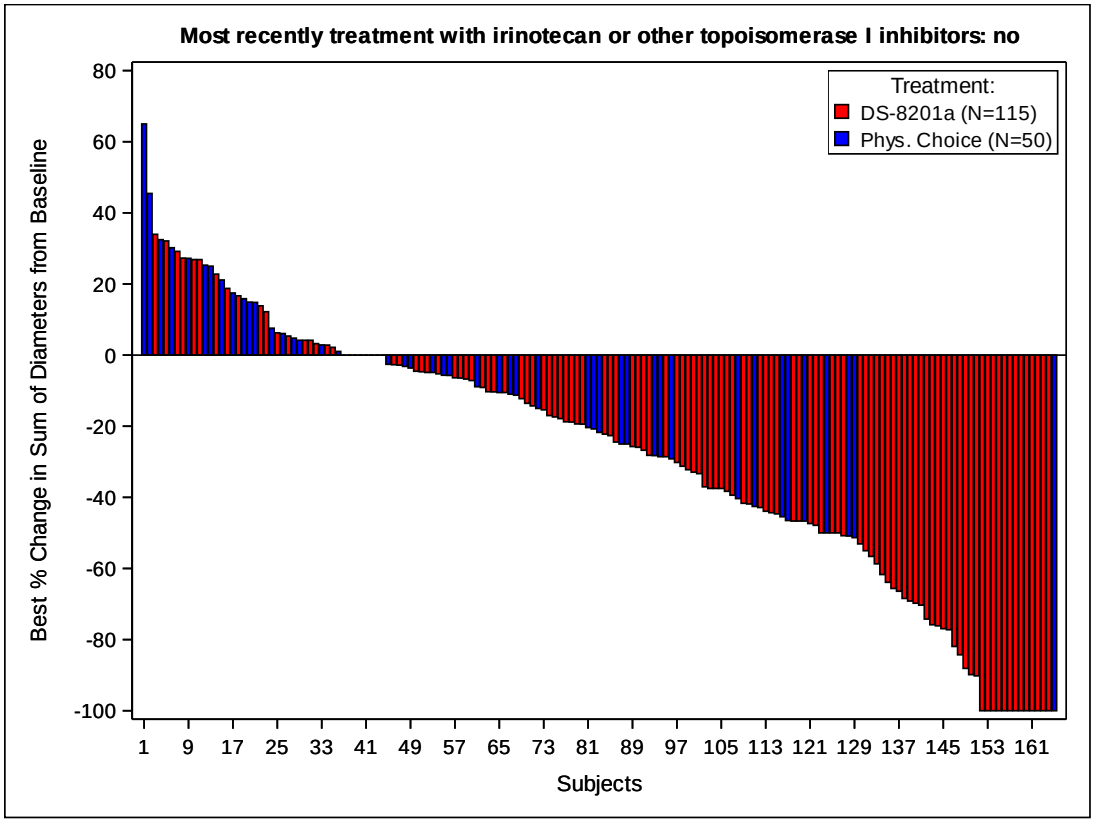
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of EQ-5D VAS score Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	125 (100.0)	62	60 (96.8)
Day 15	125	120 (96.0)	62	53 (85.5)
Day 43	124	118 (95.2)	62	52 (83.9)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	75 (67.6)	50	19 (38.0)
Day 169	105	57 (54.3)	45	11 (24.4)
Day 211	93	44 (47.3)	40	4 (10.0)
Day 253	84	37 (44.0)	34	2 (5.9)
Day 295	77	29 (37.7)	27	2 (7.4)
Day 337	70	27 (38.6)	21	2 (9.5)
Day 379	60	21 (35.0)	20	1 (5.0)
Day 421	50	16 (32.0)	15	0 (0.0)
Day 463	39	12 (30.8)	9	0 (0.0)
Day 505	30	8 (26.7)	9	0 (0.0)
Day 547	24	6 (25.0)	8	0 (0.0)
Day 589	17	5 (29.4)	5	0 (0.0)
Day 631	13	4 (30.8)	1	0 (0.0)
Day 673	9	2 (22.2)	1	0 (0.0)
Day 715	5	3 (60.0)	1	0 (0.0)
Day 757	5	3 (60.0)	1	0 (0.0)
Day 799	3	1 (33.3)	1	0 (0.0)
Day 841	2	1 (50.0)	0	0 (0.0)
Day 883	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of EQ-5D VAS score by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	125	69.5 (17.24)			60	74.8 (14.76)		
Day 15	120	66.0 (18.35)	120	-3.5 (18.36)	53	71.6 (20.49)	51	-3.5 (16.12)
Day 43	118	70.1 (18.16)	118	0.8 (17.35)	52	71.3 (18.31)	51	-4.3 (14.93)
Day 85	99	71.1 (16.60)	99	1.3 (16.60)	36	74.4 (21.71)	36	-3.6 (19.72)
Day 127	75	71.2 (16.96)	75	0.5 (18.58)	19	80.3 (11.24)	19	0.3 (12.85)
Day 169	57	74.1 (15.72)	57	5.5 (18.36)	11	82.4 (12.16)	11	-3.1 (7.45)
Day 211	44	74.6 (15.29)	44	5.1 (17.01)	4	91.0 (8.21)	4	-0.3 (7.09)
Day 253	37	74.1 (14.64)	37	6.3 (16.08)	2	87.5 (10.61)	2	5.0 (0.00)
Day 295	29	77.1 (13.26)	29	8.1 (16.06)	2	90.0 (7.07)	2	7.5 (3.54)
Day 337	27	75.2 (15.60)	27	6.7 (22.22)	2	87.5 (3.54)	2	5.0 (7.07)
Day 379	21	76.1 (13.51)	21	3.0 (22.41)	1	70.0 (-)	1	-5.0 (-)
Day 421	16	75.9 (12.81)	16	0.9 (22.44)	0	-	0	-
Day 463	12	73.3 (17.23)	12	-1.7 (11.93)	0	-	0	-
Day 505	8	76.9 (11.93)	8	-1.3 (13.30)	0	-	0	-
Day 547	6	81.7 (5.16)	6	4.2 (10.68)	0	-	0	-
Day 589	5	80.0 (6.12)	5	-1.0 (5.48)	0	-	0	-
Day 631	4	81.3 (4.79)	4	2.5 (2.89)	0	-	0	-
Day 673	2	80.0 (0.00)	2	0.0 (7.07)	0	-	0	-
Day 715	3	80.0 (0.00)	3	-3.3 (7.64)	0	-	0	-
Day 757	3	78.3 (2.89)	3	-5.0 (10.00)	0	-	0	-
Day 799	1	80.0 (-)	1	-5.0 (-)	0	-	0	-
Day 841	1	70.0 (-)	1	-15.0 (-)	0	-	0	-
Day 883	1	75.0 (-)	1	-10.0 (-)	0	-	0	-
End of Treatment	98	63.4 (20.29)	98	-7.1 (20.02)	55	63.4 (24.57)	53	-11.2 (21.92)

Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of EQ-5D VAS score by Visit
Full Analysis Set

Visit	DS-8201a (N=125)			Phys. Choice (N=62)			Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
	N [a]	N_MISS [b]	LSMean (95% CI)	N [a]	N_MISS [b]	LSMean (95% CI)				
Day 15			-2.39 (-5.11, 0.34)			-2.28 (-6.50, 1.94)	-0.11 (-4.74, 4.52)	0.9635		
Day 43			-2.10 (-4.68, 0.48)			-2.05 (-5.86, 1.75)	-0.05 (-4.21, 4.11)	0.9821		
Day 85			-1.67 (-4.09, 0.75)			-1.72 (-5.50, 2.07)	0.04 (-3.99, 4.07)	0.9831		
Day 127			-1.25 (-3.59, 1.10)			-1.38 (-5.83, 3.07)	0.13 (-4.49, 4.75)	0.9544		
Day 169			-0.82 (-3.18, 1.55)			-1.04 (-6.62, 4.53)	0.22 (-5.49, 5.94)	0.9383		
Day 211			-0.39 (-2.87, 2.09)			-0.71 (-7.64, 6.23)	0.32 (-6.76, 7.39)	0.9301		
Day 253			0.04 (-2.63, 2.70)			-0.37 (-8.79, 8.05)	0.41 (-8.18, 8.99)	0.9259		
Day 295			0.46 (-2.46, 3.39)			-0.03 (-10.00, 9.94)	0.50 (-9.67, 10.67)	0.9235		
Day 337			0.89 (-2.34, 4.12)			0.30 (-11.26, 11.87)	0.59 (-11.22, 12.40)	0.9221		
Day 379			1.32 (-2.25, 4.89)			0.64 (-12.54, 13.82)	0.68 (-12.80, 14.15)	0.9212		
Day 421			1.75 (-2.19, 5.68)			0.98 (-13.84, 15.79)	0.77 (-14.39, 15.93)	0.9206		
Day 463			2.17 (-2.15, 6.50)			1.31 (-15.15, 17.77)	0.86 (-16.00, 17.72)	0.9202		
OVERALL	124	1	-1.07 (-3.41, 1.28)	55	7	-1.24 (-6.12, 3.65)	0.17 (-4.86, 5.21)	0.9463	0.01 (-0.31, 0.33)	0.9434

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of EQ-5D VAS score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.1878
Japan	99	-1.85 (-4.02, 0.31)	47	-1.48 (-6.56, 3.60)	-0.37 (-5.92, 5.18)	0.8952	-0.03 (-0.37, 0.32)	0.8760	
Korea	25	1.21 (-2.65, 5.07)	8	-1.54 (-12.91, 9.82)	2.75 (-9.25, 14.76)	0.6484	0.24 (-0.55, 1.04)	0.5498	
Lines of prior systemic therapy									0.4063
2	65	0.54 (-2.02, 3.11)	34	-0.81 (-5.85, 4.24)	1.35 (-4.34, 7.04)	0.6396	0.11 (-0.30, 0.53)	0.5990	
3	34	-1.55 (-5.42, 2.31)	16	-0.50 (-9.38, 8.39)	-1.06 (-10.83, 8.71)	0.8298	-0.08 (-0.67, 0.52)	0.7981	
>=4	25	-5.37 (-10.26, -0.47)	5	-2.44 (-25.55, 20.68)	-2.93 (-26.59, 20.72)	0.8056	-0.20 (-1.16, 0.76)	0.6833	
Age									0.6238
<65 years	54	-0.39 (-3.38, 2.59)	24	0.35 (-7.88, 8.57)	-0.74 (-9.58, 8.10)	0.8690	-0.05 (-0.53, 0.43)	0.8354	
>=65 years	70	-1.98 (-4.51, 0.56)	31	-2.65 (-8.30, 3.01)	0.67 (-5.54, 6.88)	0.8310	0.05 (-0.37, 0.48)	0.8037	
Sex									0.8878
female	29	-2.39 (-7.08, 2.30)	14	-2.68 (-12.87, 7.51)	0.29 (-10.97, 11.55)	0.9593	0.02 (-0.62, 0.66)	0.9525	
male	95	-1.02 (-3.14, 1.10)	41	-1.30 (-6.51, 3.91)	0.28 (-5.37, 5.93)	0.9224	0.02 (-0.34, 0.39)	0.9065	
ECOG PS									0.2362
0	62	-0.48 (-2.43, 1.47)	28	1.00 (-4.84, 6.83)	-1.48 (-7.65, 4.69)	0.6358	-0.14 (-0.58, 0.31)	0.5468	
1	62	-2.09 (-5.62, 1.43)	27	-4.85 (-11.61, 1.91)	2.75 (-4.93, 10.43)	0.4788	0.18 (-0.27, 0.63)	0.4323	
HER2 Status in central laboratory									0.4496
IHC 3+	96	-0.38 (-2.45, 1.70)	41	-1.26 (-6.70, 4.18)	0.88 (-4.97, 6.74)	0.7661	0.07 (-0.30, 0.43)	0.7135	
IHC 2+/ISH +	28	-5.14 (-10.15, -0.14)	14	-2.92 (-11.08, 5.23)	-2.22 (-11.78, 7.35)	0.6426	-0.16 (-0.80, 0.48)	0.6233	
Primary tumor location									0.9475
Gastric	107	-2.26 (-4.31, -0.20)	50	-2.37 (-7.06, 2.31)	0.11 (-5.02, 5.25)	0.9654	0.01 (-0.33, 0.34)	0.9594	
GEJ	17	4.50 (-0.99, 9.99)	5	5.94 (-16.10, 27.97)	-1.44 (-24.21, 21.34)	0.9002	-0.10 (-1.09, 0.90)	0.8482	
Histological subtype									0.6057
intestinal	89	-1.79 (-4.01, 0.43)	37	-1.67 (-6.94, 3.61)	-0.13 (-5.86, 5.61)	0.9650	-0.01 (-0.39, 0.37)	0.9583	
diffuse	28	1.29 (-3.00, 5.58)	13	2.34 (-10.87, 15.55)	-1.05 (-15.02, 12.92)	0.8813	-0.06 (-0.72, 0.59)	0.8466	
others	7	-9.60 (-25.79, 6.60)	5	-5.73 (-25.64, 14.19)	-3.87 (-29.68, 21.94)	0.7445	-0.20 (-1.35, 0.95)	0.7306	
Number of metastatic sites									0.6859
<2	23	-0.93 (-5.29, 3.42)	10	-0.85 (-10.52, 8.81)	-0.08 (-10.73, 10.57)	0.9881	-0.01 (-0.75, 0.74)	0.9859	
>= 2	101	-1.46 (-3.64, 0.71)	45	-1.66 (-7.10, 3.79)	0.19 (-5.69, 6.08)	0.9483	0.01 (-0.34, 0.37)	0.9374	
Previous total gastrectomy									0.2083
yes	22	-2.87 (-7.22, 1.49)	9	7.70 (-9.56, 24.96)	-10.56 (-28.34, 7.21)	0.2406	-0.66 (-1.45, 0.13)	0.1039	
no	102	-0.98 (-3.13, 1.16)	46	-2.58 (-7.47, 2.31)	1.59 (-3.78, 6.97)	0.5596	0.12 (-0.23, 0.47)	0.4918	
Prior adjuvant/ neoadjuvant therapy									0.2389
yes	30	-1.28 (-4.22, 1.65)	9	10.37 (-1.29, 22.03)	-11.65 (-23.68, 0.37)	0.0574	-1.08 (-1.86, -0.30)	0.0068	
no	94	-1.10 (-3.44, 1.25)	46	-3.72 (-8.72, 1.27)	2.63 (-2.93, 8.19)	0.3523	0.19 (-0.16, 0.55)	0.2834	
Prior ramucirumab contained treatment									0.7603
yes	93	-2.42 (-4.49, -0.35)	37	-2.12 (-8.38, 4.15)	-0.31 (-6.92, 6.30)	0.9273	-0.02 (-0.40, 0.36)	0.9060	
no	31	2.09 (-2.48, 6.66)	18	2.64 (-4.78, 10.05)	-0.55 (-9.42, 8.32)	0.9014	-0.04 (-0.62, 0.54)	0.8930	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

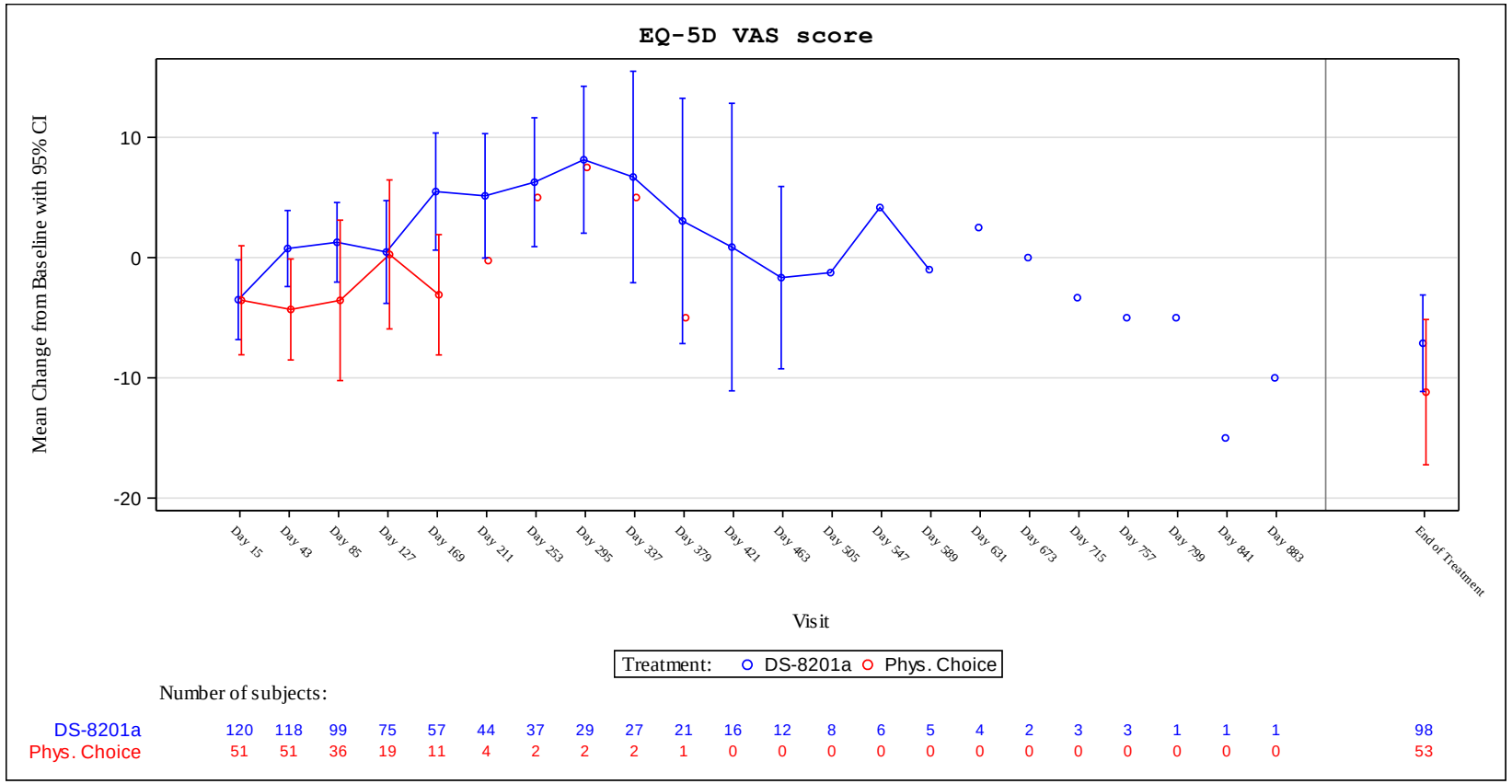
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of EQ-5D VAS score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.5685
yes	33	-4.62 (-8.46, -0.78)	13	-5.98 (-16.74, 4.78)	1.35 (-10.11, 12.82)	0.8146	0.10 (-0.54, 0.74)	0.7642	
no	91	0.23 (-2.03, 2.49)	42	-0.36 (-5.38, 4.66)	0.59 (-4.94, 6.12)	0.8338	0.05 (-0.32, 0.41)	0.8067	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.5521
yes	44	-3.53 (-6.74, -0.32)	14	-3.90 (-14.00, 6.20)	0.37 (-10.28, 11.01)	0.9454	0.03 (-0.57, 0.63)	0.9268	
no	80	0.14 (-2.32, 2.60)	41	-0.68 (-5.68, 4.32)	0.82 (-4.78, 6.43)	0.7726	0.06 (-0.31, 0.44)	0.7433	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.0929
yes	22	-1.94 (-7.49, 3.61)	6	6.29 (-6.64, 19.22)	-8.23 (-22.64, 6.18)	0.2538	-0.62 (-1.54, 0.30)	0.1852	
no	102	-1.19 (-3.23, 0.84)	49	-2.40 (-7.40, 2.59)	1.21 (-4.20, 6.62)	0.6598	0.09 (-0.25, 0.43)	0.5988	
Presence of liver metastasis at baseline									0.6502
yes	68	0.45 (-2.12, 3.02)	29	0.35 (-5.99, 6.69)	0.09 (-6.76, 6.95)	0.9784	0.01 (-0.43, 0.44)	0.9739	
no	56	-3.23 (-6.10, -0.36)	26	-3.12 (-9.89, 3.65)	-0.11 (-7.52, 7.30)	0.9769	-0.01 (-0.47, 0.46)	0.9724	
Renal impairment at baseline									0.6361
normal	33	2.61 (0.03, 5.18)	11	1.29 (-14.83, 17.40)	1.32 (-14.99, 17.63)	0.8735	0.09 (-0.59, 0.77)	0.7965	
mild	53	-2.58 (-6.07, 0.91)	25	-1.94 (-8.43, 4.55)	-0.64 (-8.10, 6.82)	0.8642	-0.05 (-0.52, 0.43)	0.8493	
moderate	38	-3.22 (-6.78, 0.33)	18	-3.20 (-11.19, 4.79)	-0.02 (-8.78, 8.73)	0.9959	-0.00 (-0.56, 0.56)	0.9952	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.3036
normal	87	-0.75 (-2.98, 1.48)	40	-1.77 (-7.13, 3.59)	1.02 (-4.80, 6.84)	0.7305	0.08 (-0.30, 0.45)	0.6813	
mild	36	-2.42 (-6.38, 1.54)	15	-2.10 (-11.65, 7.46)	-0.32 (-10.80, 10.16)	0.9511	-0.02 (-0.63, 0.58)	0.9403	
moderate	1	NE	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.9748
yes	8	1.15 (-7.11, 9.42)	4	0.23 (-15.44, 15.91)	0.92 (-17.23, 19.08)	0.9061	0.09 (-1.11, 1.29)	0.8860	
no	116	-1.52 (-3.53, 0.49)	51	-2.19 (-7.32, 2.93)	0.67 (-4.86, 6.20)	0.8111	0.05 (-0.28, 0.38)	0.7711	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.3338
yes	3	13.05 (2.49, 23.62)	3	-0.28 (-11.92, 11.36)	13.33 (-7.14, 33.80)	0.1479	1.88 (-0.04, 3.80)	0.0554	
no	121	-1.50 (-3.46, 0.47)	52	-2.42 (-7.79, 2.94)	0.93 (-4.81, 6.66)	0.7511	0.07 (-0.26, 0.39)	0.6926	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Graphical Summary of EQ-5D VAS score by Visit - Mean Change from Baseline
Full Analysis Set



Number of subjects:

DS-8201a	120	118	99	75	57	44	37	29	27	21	16	12	8	6	5	4	2	3	3	1	1	1	98
Phys. Choice	51	51	36	19	11	4	2	2	2	1	0	0	0	0	0	0	0	0	0	0	0	0	53

95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADEQ5D

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	54 (43.2)	27 (43.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	11.3 (4.4, 27.7)	3.8 (1.7, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.69 (0.43, 1.11)	
p-value [c]	0.1151	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.68 (0.42, 1.09)	
p-value [c]	0.1028	

Time to Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.0409
Japan	46/ 99 (46.5)	6.8 (4.0, 27.7)	21/ 50 (42.0)	4.3 (1.8, NE)	0.86 (0.51, 1.45)	0.5501	
Korea	8/ 26 (30.8)	11.3 (4.2, NE)	6/ 12 (50.0)	1.4 (0.5, NE)	0.20 (0.06, 0.64)	0.0029	
Lines of prior systemic therapy							0.3107
2	27/ 66 (40.9)	6.8 (3.6, NE)	15/ 38 (39.5)	4.3 (1.8, NE)	0.79 (0.42, 1.49)	0.4726	
3	13/ 34 (38.2)	12.6 (4.4, NE)	10/ 18 (55.6)	2.2 (1.3, NE)	0.39 (0.16, 0.94)	0.0267	
>=4	14/ 25 (56.0)	11.3 (1.1, 27.7)	2/ 6 (33.3)	NE (0.5, NE)	0.95 (0.21, 4.36)	0.9511	
Age							0.5312
<65 years	21/ 55 (38.2)	12.5 (4.6, NE)	12/ 27 (44.4)	3.8 (1.4, NE)	0.54 (0.26, 1.12)	0.0894	
>=65 years	33/ 70 (47.1)	5.9 (3.1, 27.7)	15/ 35 (42.9)	4.0 (1.4, NE)	0.79 (0.43, 1.47)	0.4499	
Sex							0.6930
female	16/ 30 (53.3)	4.5 (2.9, 6.8)	8/ 15 (53.3)	2.8 (0.5, NE)	0.72 (0.30, 1.71)	0.4507	
male	38/ 95 (40.0)	12.5 (5.5, 27.7)	19/ 47 (40.4)	4.0 (1.8, NE)	0.68 (0.39, 1.19)	0.1650	
ECOG PS							0.3864
0	28/ 62 (45.2)	12.5 (4.0, 27.7)	11/ 30 (36.7)	4.0 (1.9, NE)	0.86 (0.42, 1.74)	0.6614	
1	26/ 63 (41.3)	5.5 (4.2, NE)	16/ 32 (50.0)	1.8 (0.9, NE)	0.56 (0.30, 1.06)	0.0667	
HER2 Status in central laboratory							0.2208
IHC 3+	42/ 96 (43.8)	11.3 (4.5, 27.7)	22/ 47 (46.8)	3.8 (1.4, NE)	0.57 (0.34, 0.97)	0.0353	
IHC 2+/ISH +	12/ 29 (41.4)	12.5 (1.4, 12.5)	5/ 15 (33.3)	NE (0.7, NE)	1.17 (0.41, 3.39)	0.7771	
Primary tumor location							0.6827
Gastric	48/108 (44.4)	6.8 (4.3, 27.7)	25/ 55 (45.5)	3.8 (1.7, NE)	0.70 (0.43, 1.15)	0.1576	
GEJ	6/ 17 (35.3)	12.6 (1.5, NE)	2/ 7 (28.6)	NE (0.5, NE)	0.62 (0.12, 3.27)	0.5703	
Histological subtype							0.1271
intestinal	41/ 89 (46.1)	6.8 (4.0, 27.7)	15/ 38 (39.5)	4.3 (1.7, NE)	0.93 (0.51, 1.69)	0.8056	
diffuse	11/ 28 (39.3)	12.5 (3.1, NE)	8/ 18 (44.4)	2.6 (0.9, NE)	0.45 (0.17, 1.18)	0.0951	
others	2/ 8 (25.0)	NE (0.5, NE)	4/ 6 (66.7)	1.4 (0.5, NE)	0.17 (0.02, 1.53)	0.0754	
Number of metastatic sites							0.7404
<2	10/ 23 (43.5)	NE (2.8, NE)	6/ 10 (60.0)	3.1 (0.5, NE)	0.64 (0.23, 1.76)	0.3794	
>= 2	44/102 (43.1)	11.3 (4.4, 12.6)	21/ 52 (40.4)	4.3 (1.7, NE)	0.68 (0.39, 1.16)	0.1490	
Previous total gastrectomy							0.4503
yes	10/ 22 (45.5)	5.5 (3.1, 27.7)	3/ 9 (33.3)	NE (0.7, NE)	0.93 (0.24, 3.54)	0.9111	
no	44/103 (42.7)	12.4 (4.3, NE)	24/ 53 (45.3)	3.1 (1.4, NE)	0.65 (0.39, 1.07)	0.0837	
Prior adjuvant/ neoadjuvant therapy							0.4360
yes	15/ 30 (50.0)	11.3 (3.1, 27.7)	3/ 10 (30.0)	NE (0.5, NE)	1.02 (0.29, 3.64)	0.9784	
no	39/ 95 (41.1)	12.4 (4.3, NE)	24/ 52 (46.2)	3.8 (1.4, NE)	0.64 (0.38, 1.07)	0.0812	
Prior ramucirumab contained treatment							0.3056
yes	43/ 94 (45.7)	11.3 (4.5, 12.6)	21/ 41 (51.2)	1.9 (1.4, NE)	0.56 (0.33, 0.97)	0.0342	
no	11/ 31 (35.5)	NE (3.6, NE)	6/ 21 (28.6)	NE (2.6, NE)	0.97 (0.36, 2.62)	0.9551	
Prior nivolumab contained treatment							0.5703
yes	16/ 33 (48.5)	12.4 (1.5, NE)	8/ 15 (53.3)	2.6 (0.6, NE)	0.61 (0.25, 1.48)	0.2540	
no	38/ 92 (41.3)	11.3 (4.3, 27.7)	19/ 47 (40.4)	4.3 (1.8, NE)	0.71 (0.40, 1.24)	0.2229	

Time to Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

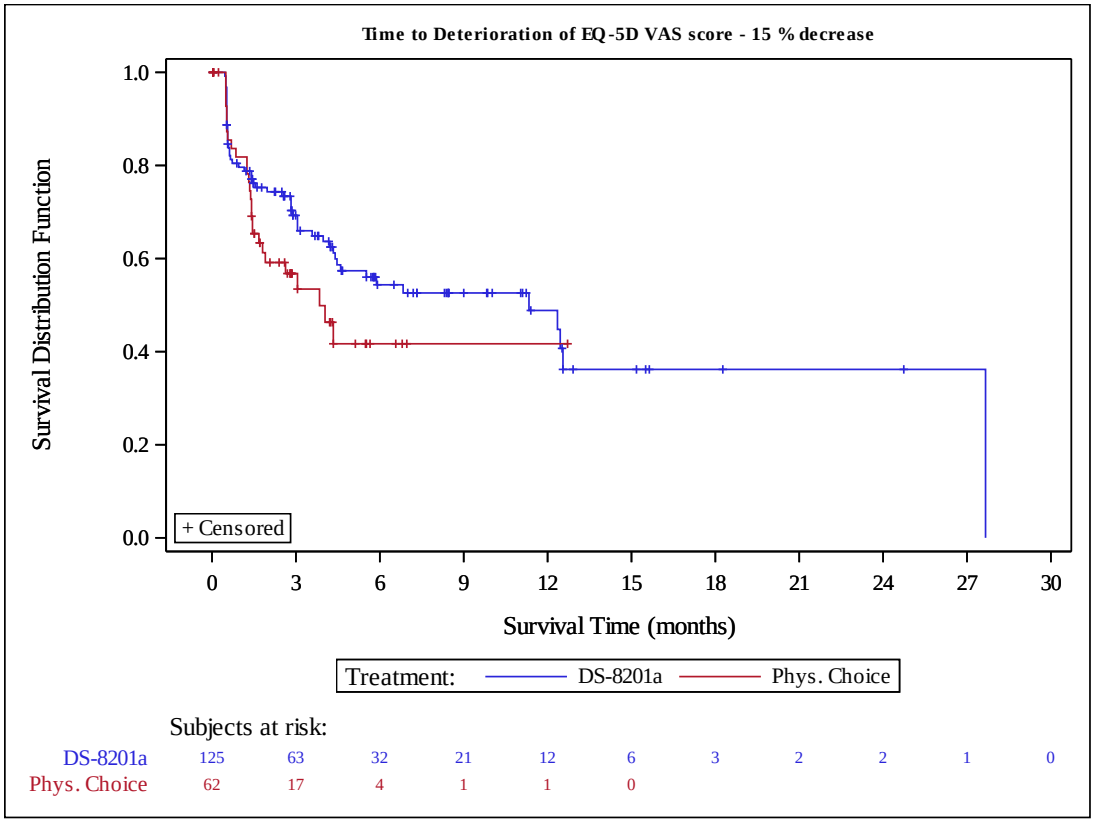
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8106
yes	22/ 44 (50.0)	11.3 (2.9, NE)	8/ 17 (47.1)	3.2 (0.6, NE)	0.61 (0.26, 1.42)	0.2367	
no	32/ 81 (39.5)	27.7 (4.3, 27.7)	19/ 45 (42.2)	4.0 (1.4, NE)	0.68 (0.38, 1.21)	0.1870	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.4212
yes	8/ 22 (36.4)	12.4 (0.6, NE)	2/ 7 (28.6)	NE (1.3, NE)	1.15 (0.24, 5.55)	0.8918	
no	46/103 (44.7)	11.3 (4.3, 27.7)	25/ 55 (45.5)	3.8 (1.7, NE)	0.63 (0.38, 1.03)	0.0629	
Presence of liver metastasis at baseline							0.8595
yes	28/ 68 (41.2)	6.8 (4.2, NE)	13/ 34 (38.2)	4.3 (1.4, NE)	0.69 (0.35, 1.36)	0.2764	
no	26/ 57 (45.6)	11.3 (4.0, 27.7)	14/ 28 (50.0)	3.1 (1.3, NE)	0.67 (0.35, 1.30)	0.2262	
Renal impairment at baseline							0.1667
normal	10/ 33 (30.3)	12.6 (12.5, 27.7)	6/ 13 (46.2)	2.6 (1.2, NE)	0.23 (0.07, 0.74)	0.0074	
mild	28/ 53 (52.8)	4.4 (3.1, NE)	11/ 28 (39.3)	4.3 (1.4, NE)	0.95 (0.47, 1.92)	0.8873	
moderate	16/ 39 (41.0)	11.3 (1.4, NE)	9/ 20 (45.0)	4.0 (1.4, NE)	0.81 (0.35, 1.87)	0.5906	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.9 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.3317
normal	39/ 88 (44.3)	12.4 (4.2, NE)	19/ 47 (40.4)	4.0 (1.8, NE)	0.76 (0.43, 1.32)	0.3167	
mild	14/ 36 (38.9)	11.3 (2.9, 27.7)	8/ 15 (53.3)	1.3 (0.5, NE)	0.43 (0.17, 1.07)	0.0619	
moderate	1/ 1 (100.0)	0.5 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7235
yes	3/ 8 (37.5)	27.7 (0.5, 27.7)	1/ 5 (20.0)	NE (0.5, NE)	0.91 (0.08, 10.10)	0.9397	
no	51/117 (43.6)	11.3 (4.3, 12.6)	26/ 57 (45.6)	3.8 (1.4, NE)	0.64 (0.39, 1.04)	0.0639	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9998
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	54/122 (44.3)	11.3 (4.3, 12.6)	27/ 58 (46.6)	3.8 (1.4, NE)	0.61 (0.38, 0.99)	0.0416	

Time to Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

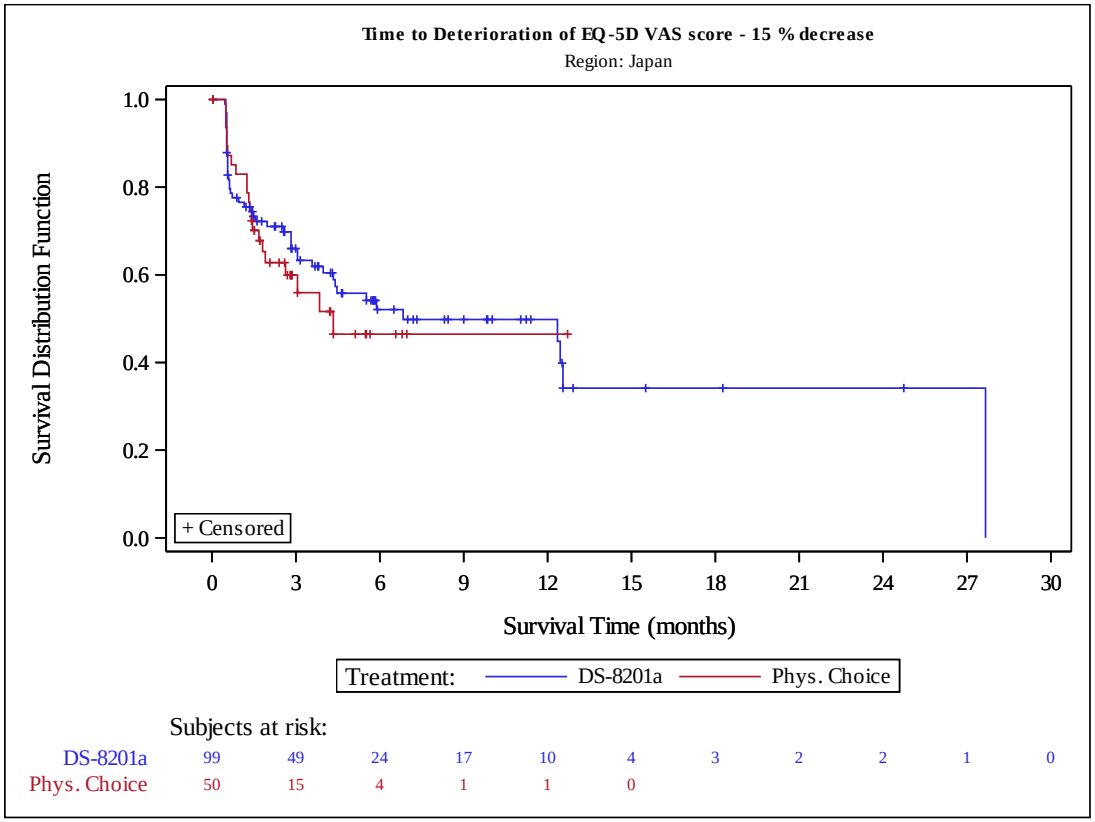
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

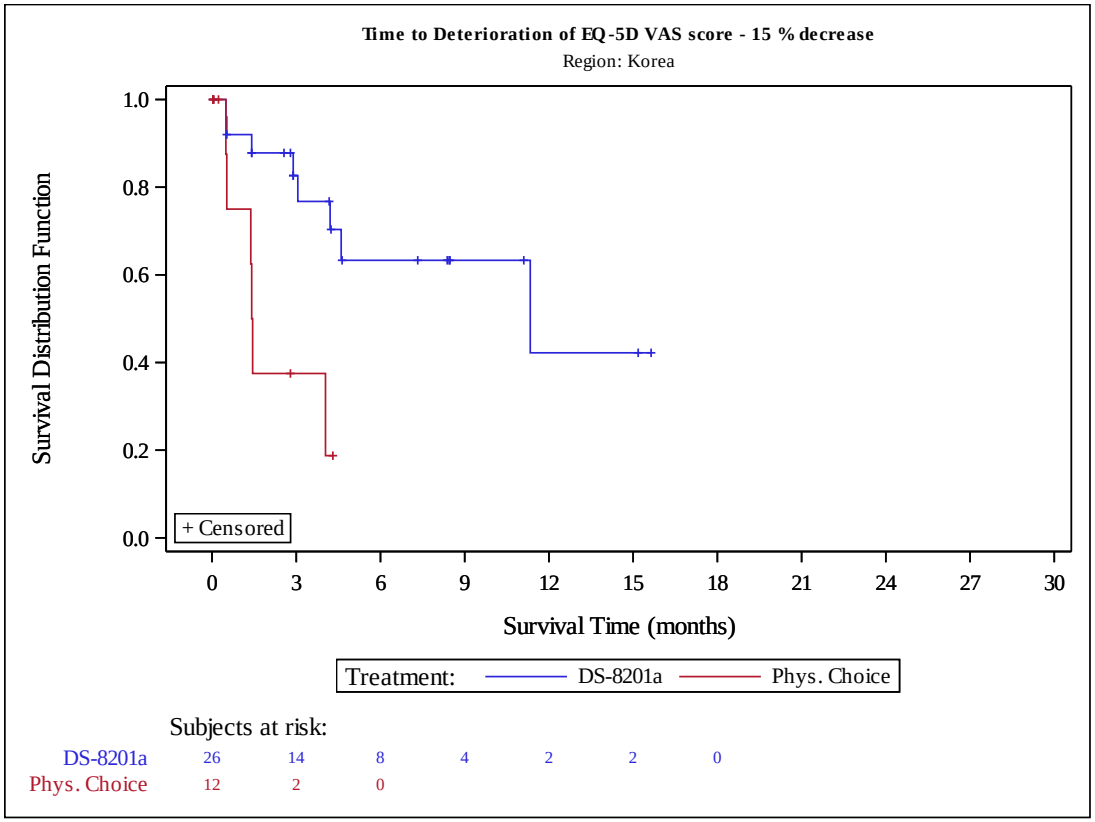
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	38 (30.4)	20 (32.3)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	16.6 (11.3, NE)	NE (3.8, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.63 (0.36, 1.10)	
p-value [c]	0.1025	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.64 (0.37, 1.11)	
p-value [c]	0.1062	

Time to Definitive Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.1590
Japan	31/ 99 (31.3)	NE (6.9, NE)	15/ 50 (30.0)	NE (3.8, NE)	0.79 (0.42, 1.48)	0.4640	
Korea	7/ 26 (26.9)	16.6 (4.6, 16.6)	5/ 12 (41.7)	3.2 (1.4, NE)	0.22 (0.06, 0.79)	0.0116	
Lines of prior systemic therapy							0.6829
2	20/ 66 (30.3)	NE (4.6, NE)	12/ 38 (31.6)	NE (3.1, NE)	0.76 (0.37, 1.56)	0.4506	
3	8/ 34 (23.5)	16.6 (16.6, NE)	6/ 18 (33.3)	NE (1.7, NE)	0.41 (0.13, 1.25)	0.1041	
>=4	10/ 25 (40.0)	12.5 (4.1, NE)	2/ 6 (33.3)	NE (0.5, NE)	0.60 (0.12, 2.90)	0.5272	
Age							0.2369
<65 years	13/ 55 (23.6)	16.6 (12.5, NE)	9/ 27 (33.3)	NE (1.9, NE)	0.40 (0.16, 0.97)	0.0365	
>=65 years	25/ 70 (35.7)	11.3 (4.4, NE)	11/ 35 (31.4)	NE (3.1, NE)	0.85 (0.41, 1.73)	0.6540	
Sex							0.8040
female	13/ 30 (43.3)	4.6 (2.9, NE)	8/ 15 (53.3)	2.4 (0.9, NE)	0.61 (0.25, 1.49)	0.2728	
male	25/ 95 (26.3)	16.6 (12.5, NE)	12/ 47 (25.5)	NE (4.0, NE)	0.68 (0.33, 1.37)	0.2734	
ECOG PS							0.9339
0	19/ 62 (30.6)	NE (12.5, NE)	9/ 30 (30.0)	NE (3.8, NE)	0.69 (0.31, 1.54)	0.3581	
1	19/ 63 (30.2)	16.6 (5.5, 16.6)	11/ 32 (34.4)	NE (1.8, NE)	0.61 (0.28, 1.29)	0.1927	
HER2 Status in central laboratory							0.0159
IHC 3+	26/ 96 (27.1)	NE (11.3, NE)	17/ 47 (36.2)	4.3 (2.6, NE)	0.42 (0.22, 0.79)	0.0056	
IHC 2+/ISH +	12/ 29 (41.4)	12.5 (1.5, 12.5)	3/ 15 (20.0)	NE (1.8, NE)	2.32 (0.65, 8.35)	0.1859	
Primary tumor location							0.6100
Gastric	36/108 (33.3)	16.6 (6.9, NE)	19/ 55 (34.5)	NE (3.1, NE)	0.68 (0.38, 1.19)	0.1755	
GEJ	2/ 17 (11.8)	NE (NE , NE)	1/ 7 (14.3)	NE (1.2, NE)	0.57 (0.05, 6.29)	0.6417	
Histological subtype							0.2694
intestinal	27/ 89 (30.3)	NE (6.9, NE)	10/ 38 (26.3)	NE (4.0, NE)	0.89 (0.43, 1.85)	0.7621	
diffuse	9/ 28 (32.1)	16.6 (11.3, NE)	8/ 18 (44.4)	2.6 (1.4, NE)	0.29 (0.10, 0.83)	0.0148	
others	2/ 8 (25.0)	NE (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	0.88 (0.12, 6.33)	0.8973	
Number of metastatic sites							0.9502
<2	7/ 23 (30.4)	NE (4.0, NE)	4/ 10 (40.0)	NE (0.9, NE)	0.69 (0.20, 2.36)	0.5485	
>= 2	31/102 (30.4)	16.6 (6.9, NE)	16/ 52 (30.8)	NE (4.0, NE)	0.62 (0.33, 1.15)	0.1273	
Previous total gastrectomy							0.8516
yes	7/ 22 (31.8)	11.3 (4.4, NE)	3/ 9 (33.3)	NE (0.7, NE)	0.61 (0.15, 2.51)	0.4906	
no	31/103 (30.1)	16.6 (12.5, NE)	17/ 53 (32.1)	NE (3.1, NE)	0.63 (0.34, 1.15)	0.1305	
Prior adjuvant/ neoadjuvant therapy							0.1274
yes	11/ 30 (36.7)	12.5 (5.9, NE)	1/ 10 (10.0)	NE (0.7, NE)	2.09 (0.26, 16.82)	0.4806	
no	27/ 95 (28.4)	NE (16.6, NE)	19/ 52 (36.5)	4.3 (2.6, NE)	0.55 (0.30, 0.99)	0.0437	
Prior ramucirumab contained treatment							0.6803
yes	29/ 94 (30.9)	16.6 (11.3, NE)	14/ 41 (34.1)	NE (1.9, NE)	0.59 (0.31, 1.14)	0.1120	
no	9/ 31 (29.0)	NE (4.3, NE)	6/ 21 (28.6)	NE (2.6, NE)	0.73 (0.26, 2.06)	0.5524	
Prior nivolumab contained treatment							0.8597
yes	13/ 33 (39.4)	12.5 (4.1, NE)	6/ 15 (40.0)	3.8 (1.4, NE)	0.59 (0.22, 1.61)	0.3004	
no	25/ 92 (27.2)	16.6 (11.3, NE)	14/ 47 (29.8)	NE (3.1, NE)	0.64 (0.33, 1.25)	0.1875	

Time to Definitive Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

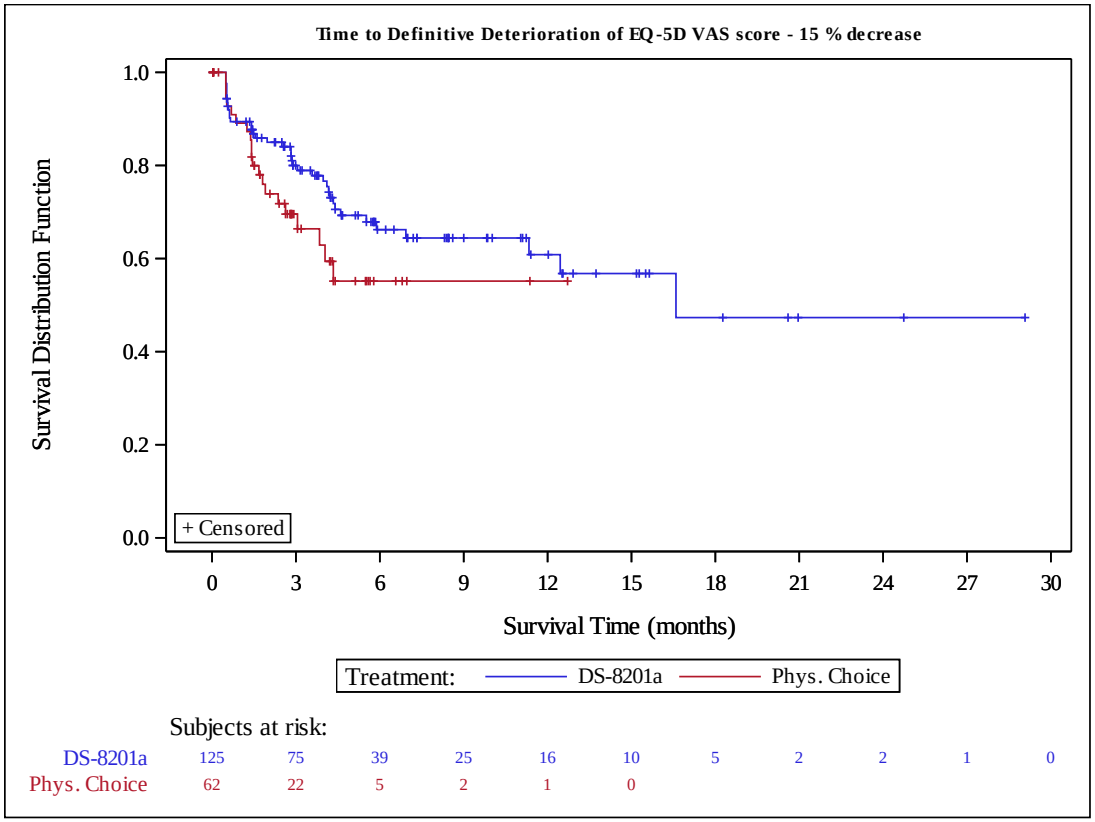
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8485
yes	16/ 44 (36.4)	12.5 (5.9, NE)	6/ 17 (35.3)	NE (1.4, NE)	0.56 (0.22, 1.48)	0.2410	
no	22/ 81 (27.2)	16.6 (16.6, NE)	14/ 45 (31.1)	NE (3.1, NE)	0.65 (0.33, 1.29)	0.2163	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.4899
yes	5/ 22 (22.7)	16.6 (NE , NE)	1/ 7 (14.3)	NE (1.4, NE)	1.16 (0.13, 10.43)	0.8934	
no	33/103 (32.0)	NE (6.9, NE)	19/ 55 (34.5)	NE (3.1, NE)	0.61 (0.34, 1.08)	0.0890	
Presence of liver metastasis at baseline							0.8727
yes	19/ 68 (27.9)	NE (5.9, NE)	9/ 34 (26.5)	NE (4.0, NE)	0.70 (0.31, 1.57)	0.3870	
no	19/ 57 (33.3)	12.5 (6.9, NE)	11/ 28 (39.3)	NE (2.4, NE)	0.61 (0.29, 1.30)	0.1957	
Renal impairment at baseline							0.1903
normal	7/ 33 (21.2)	NE (12.5, NE)	5/ 13 (38.5)	NE (1.8, NE)	0.18 (0.05, 0.70)	0.0056	
mild	19/ 53 (35.8)	NE (4.4, NE)	9/ 28 (32.1)	NE (1.4, NE)	0.78 (0.35, 1.73)	0.5407	
moderate	12/ 39 (30.8)	NE (4.2, NE)	5/ 20 (25.0)	NE (3.8, NE)	1.10 (0.38, 3.18)	0.8655	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.9 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.4324
normal	27/ 88 (30.7)	NE (NE , NE)	16/ 47 (34.0)	4.3 (3.1, NE)	0.59 (0.31, 1.10)	0.0934	
mild	11/ 36 (30.6)	12.5 (4.1, NE)	4/ 15 (26.7)	NE (0.5, NE)	0.80 (0.24, 2.61)	0.7087	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7628
yes	1/ 8 (12.5)	NE (3.1, NE)	1/ 5 (20.0)	NE (0.5, NE)	0.46 (0.03, 7.42)	0.5770	
no	37/117 (31.6)	16.6 (11.3, NE)	19/ 57 (33.3)	NE (3.1, NE)	0.63 (0.36, 1.11)	0.1060	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9997
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	38/122 (31.1)	16.6 (11.3, NE)	20/ 58 (34.5)	NE (3.1, NE)	0.59 (0.34, 1.02)	0.0578	

Time to Definitive Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

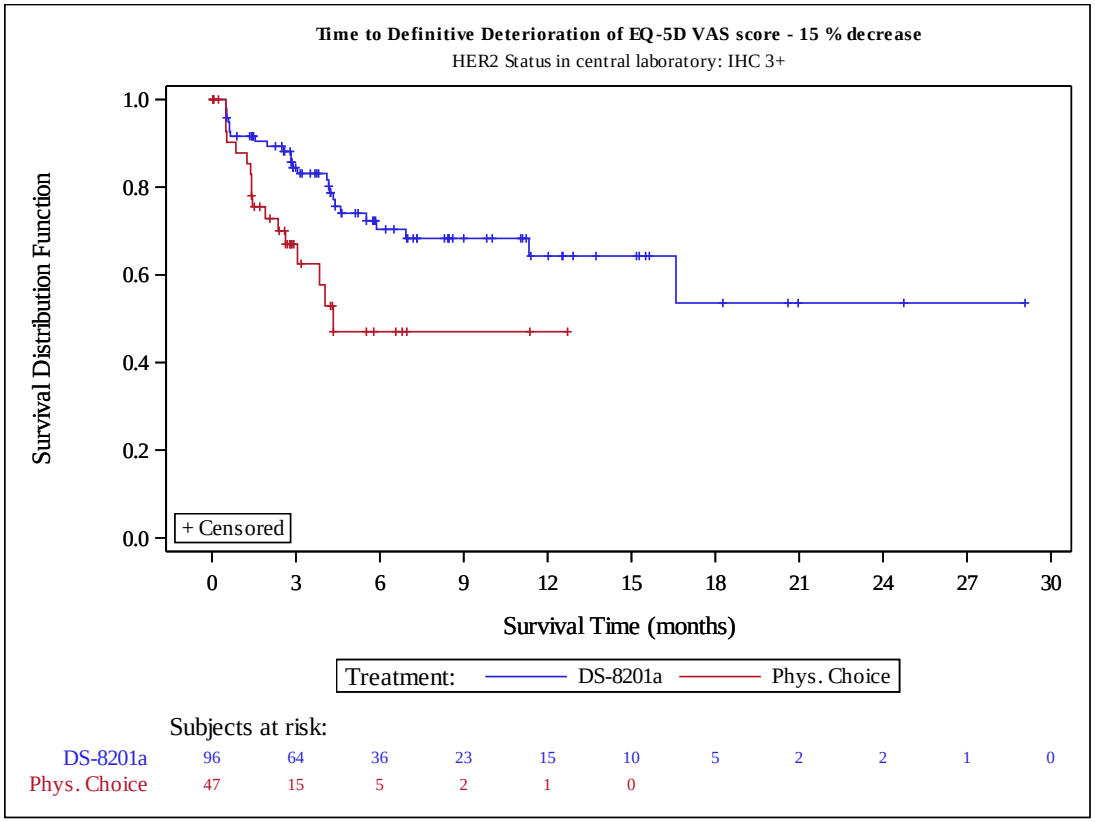
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

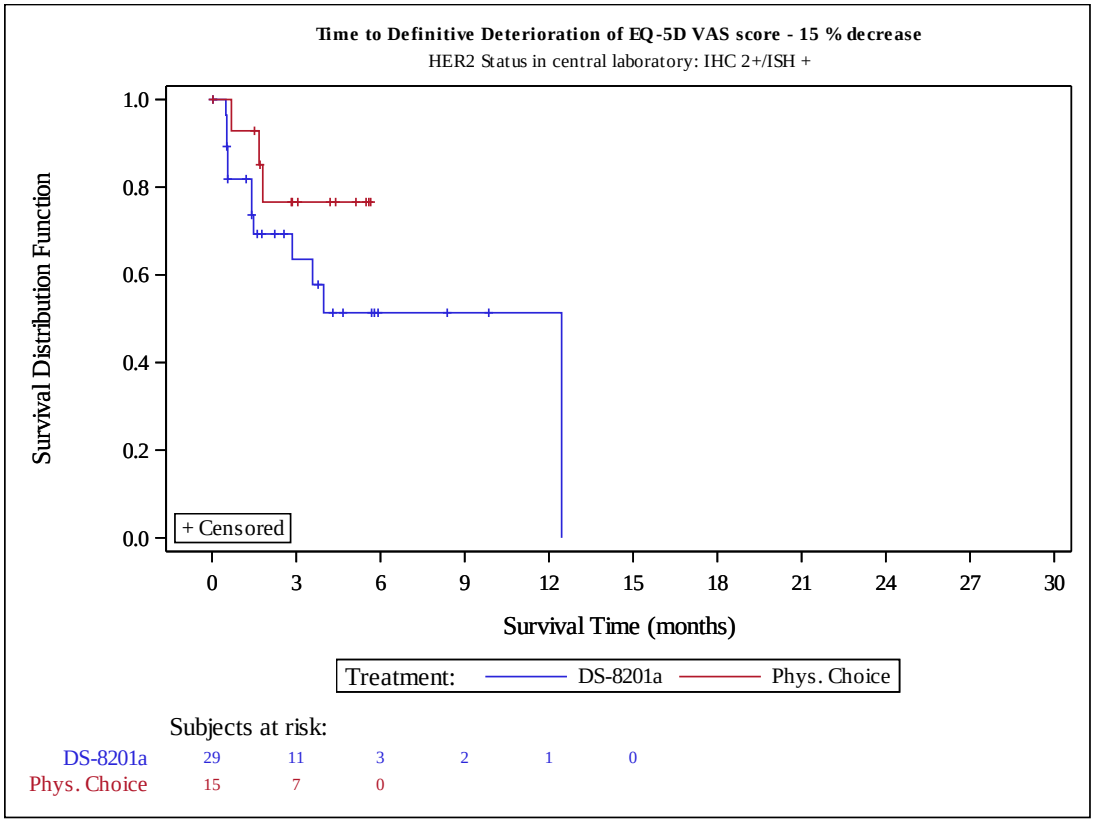
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	120	18 (15.0)	76 (63.3)	26 (21.7)	53	3 (5.7)	40 (75.5)	10 (18.9)
	Day 43	118	23 (19.5)	79 (66.9)	16 (13.6)	52	3 (5.8)	35 (67.3)	14 (26.9)
	Day 85	99	18 (18.2)	63 (63.6)	18 (18.2)	36	4 (11.1)	27 (75.0)	5 (13.9)
	Day 127	75	17 (22.7)	43 (57.3)	15 (20.0)	19	4 (21.1)	12 (63.2)	3 (15.8)
	Day 169	57	13 (22.8)	38 (66.7)	6 (10.5)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	44	8 (18.2)	33 (75.0)	3 (6.8)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	37	8 (21.6)	27 (73.0)	2 (5.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	29	7 (24.1)	22 (75.9)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	27	7 (25.9)	17 (63.0)	3 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	21	5 (23.8)	11 (52.4)	5 (23.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	2 (12.5)	11 (68.8)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	2 (25.0)	4 (50.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	98	12 (12.2)	57 (58.2)	29 (29.6)	55	4 (7.3)	32 (58.2)	19 (34.5)
Region									
Japan									
	Day 15	98	13 (13.3)	61 (62.2)	24 (24.5)	46	3 (6.5)	35 (76.1)	8 (17.4)
	Day 43	94	16 (17.0)	64 (68.1)	14 (14.9)	43	2 (4.7)	30 (69.8)	11 (25.6)
	Day 85	77	13 (16.9)	50 (64.9)	14 (18.2)	32	3 (9.4)	24 (75.0)	5 (15.6)
	Day 127	61	14 (23.0)	34 (55.7)	13 (21.3)	16	3 (18.8)	11 (68.8)	2 (12.5)
	Day 169	49	11 (22.4)	32 (65.3)	6 (12.2)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 211	36	5 (13.9)	28 (77.8)	3 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	29	6 (20.7)	21 (72.4)	2 (6.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	23	5 (21.7)	18 (78.3)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	21	5 (23.8)	14 (66.7)	2 (9.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	18	4 (22.2)	9 (50.0)	5 (27.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	10 (12.7)	46 (58.2)	23 (29.1)	48	3 (6.3)	31 (64.6)	14 (29.2)
Region									
Korea									
	Day 15	22	5 (22.7)	15 (68.2)	2 (9.1)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 43	24	7 (29.2)	15 (62.5)	2 (8.3)	9	1 (11.1)	5 (55.6)	3 (33.3)
	Day 85	22	5 (22.7)	13 (59.1)	4 (18.2)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 127	14	3 (21.4)	9 (64.3)	2 (14.3)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 169	8	2 (25.0)	6 (75.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	3 (37.5)	5 (62.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	6	2 (33.3)	3 (50.0)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	19	2 (10.5)	11 (57.9)	6 (31.6)	7	1 (14.3)	1 (14.3)	5 (71.4)
Lines of prior systemic therapy 2									
	Day 15	61	9 (14.8)	40 (65.6)	12 (19.7)	34	2 (5.9)	26 (76.5)	6 (17.6)
	Day 43	62	12 (19.4)	41 (66.1)	9 (14.5)	35	2 (5.7)	25 (71.4)	8 (22.9)
	Day 85	50	8 (16.0)	32 (64.0)	10 (20.0)	21	3 (14.3)	15 (71.4)	3 (14.3)
	Day 127	34	9 (26.5)	16 (47.1)	9 (26.5)	14	3 (21.4)	9 (64.3)	2 (14.3)
	Day 169	24	8 (33.3)	14 (58.3)	2 (8.3)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	21	5 (23.8)	15 (71.4)	1 (4.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	4 (22.2)	14 (77.8)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	5 (41.7)	7 (58.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	4 (36.4)	7 (63.6)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	2 (28.6)	5 (71.4)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	52	4 (7.7)	32 (61.5)	16 (30.8)	33	3 (9.1)	19 (57.6)	11 (33.3)
Lines of prior systemic therapy 3									
	Day 15	34	4 (11.8)	23 (67.6)	7 (20.6)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 43	33	5 (15.2)	24 (72.7)	4 (12.1)	14	1 (7.1)	7 (50.0)	6 (42.9)
	Day 85	28	6 (21.4)	20 (71.4)	2 (7.1)	12	1 (8.3)	9 (75.0)	2 (16.7)
	Day 127	23	4 (17.4)	14 (60.9)	5 (21.7)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 169	19	3 (15.8)	13 (68.4)	3 (15.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	13	2 (15.4)	10 (76.9)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	3 (27.3)	7 (63.6)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	9	1 (11.1)	8 (88.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	3 (37.5)	4 (50.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	3 (37.5)	4 (50.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	5 (19.2)	15 (57.7)	6 (23.1)	17	1 (5.9)	10 (58.8)	6 (35.3)
Lines of prior systemic therapy >=4									
	Day 15	25	5 (20.0)	13 (52.0)	7 (28.0)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 43	23	6 (26.1)	14 (60.9)	3 (13.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	4 (19.0)	11 (52.4)	6 (28.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	4 (22.2)	13 (72.2)	1 (5.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	14	2 (14.3)	11 (78.6)	1 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	2 (33.3)	4 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	3 (15.0)	10 (50.0)	7 (35.0)	5	0 (0.0)	3 (60.0)	2 (40.0)
Age									
<65 years									
	Day 15	52	9 (17.3)	33 (63.5)	10 (19.2)	22	0 (0.0)	18 (81.8)	4 (18.2)
	Day 43	52	15 (28.8)	33 (63.5)	4 (7.7)	23	1 (4.3)	16 (69.6)	6 (26.1)
	Day 85	47	8 (17.0)	34 (72.3)	5 (10.6)	16	2 (12.5)	12 (75.0)	2 (12.5)
	Day 127	34	9 (26.5)	21 (61.8)	4 (11.8)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 169	27	6 (22.2)	20 (74.1)	1 (3.7)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	18	3 (16.7)	13 (72.2)	2 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	16	2 (12.5)	14 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	3 (23.1)	10 (76.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	3 (27.3)	8 (72.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	2 (25.0)	4 (50.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	42	6 (14.3)	24 (57.1)	12 (28.6)	22	2 (9.1)	12 (54.5)	8 (36.4)
Age									
>=65 years									
	Day 15	68	9 (13.2)	43 (63.2)	16 (23.5)	31	3 (9.7)	22 (71.0)	6 (19.4)
	Day 43	66	8 (12.1)	46 (69.7)	12 (18.2)	29	2 (6.9)	19 (65.5)	8 (27.6)
	Day 85	52	10 (19.2)	29 (55.8)	13 (25.0)	20	2 (10.0)	15 (75.0)	3 (15.0)
	Day 127	41	8 (19.5)	22 (53.7)	11 (26.8)	11	3 (27.3)	5 (45.5)	3 (27.3)
	Day 169	30	7 (23.3)	18 (60.0)	5 (16.7)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	26	5 (19.2)	20 (76.9)	1 (3.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	6 (28.6)	13 (61.9)	2 (9.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	16	4 (25.0)	12 (75.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	4 (25.0)	9 (56.3)	3 (18.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	13	3 (23.1)	7 (53.8)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	1 (11.1)	5 (55.6)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	End of Treatment	56	6 (10.7)	33 (58.9)	17 (30.4)	33	2 (6.1)	20 (60.6)	11 (33.3)
Sex									
female									
	Day 15	28	5 (17.9)	15 (53.6)	8 (28.6)	14	1 (7.1)	9 (64.3)	4 (28.6)
	Day 43	28	5 (17.9)	17 (60.7)	6 (21.4)	13	0 (0.0)	8 (61.5)	5 (38.5)
	Day 85	20	4 (20.0)	10 (50.0)	6 (30.0)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	13	5 (38.5)	4 (30.8)	4 (30.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	10	3 (30.0)	6 (60.0)	1 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	2 (25.0)	5 (62.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	22	1 (4.5)	10 (45.5)	11 (50.0)	14	0 (0.0)	7 (50.0)	7 (50.0)
Sex									
male									
	Day 15	92	13 (14.1)	61 (66.3)	18 (19.6)	39	2 (5.1)	31 (79.5)	6 (15.4)
	Day 43	90	18 (20.0)	62 (68.9)	10 (11.1)	39	3 (7.7)	27 (69.2)	9 (23.1)
	Day 85	79	14 (17.7)	53 (67.1)	12 (15.2)	28	4 (14.3)	21 (75.0)	3 (10.7)
	Day 127	62	12 (19.4)	39 (62.9)	11 (17.7)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	47	10 (21.3)	32 (68.1)	5 (10.6)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	36	6 (16.7)	28 (77.8)	2 (5.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	30	7 (23.3)	21 (70.0)	2 (6.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	6 (24.0)	19 (76.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	6 (25.0)	15 (62.5)	3 (12.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	5 (26.3)	9 (47.4)	5 (26.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	15	2 (13.3)	10 (66.7)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	2 (28.6)	3 (42.9)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	2 (40.0)	3 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	76	11 (14.5)	47 (61.8)	18 (23.7)	41	4 (9.8)	25 (61.0)	12 (29.3)
ECOG PS									
0									
	Day 15	61	12 (19.7)	38 (62.3)	11 (18.0)	27	2 (7.4)	23 (85.2)	2 (7.4)
	Day 43	60	13 (21.7)	40 (66.7)	7 (11.7)	26	2 (7.7)	18 (69.2)	6 (23.1)
	Day 85	54	9 (16.7)	34 (63.0)	11 (20.4)	19	2 (10.5)	15 (78.9)	2 (10.5)
	Day 127	42	8 (19.0)	27 (64.3)	7 (16.7)	9	3 (33.3)	4 (44.4)	2 (22.2)
	Day 169	36	9 (25.0)	25 (69.4)	2 (5.6)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	27	5 (18.5)	20 (74.1)	2 (7.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	24	5 (20.8)	17 (70.8)	2 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	18	4 (22.2)	14 (77.8)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	4 (25.0)	11 (68.8)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	14	3 (21.4)	6 (42.9)	5 (35.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 505	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	48	6 (12.5)	27 (56.3)	15 (31.3)	29	2 (6.9)	19 (65.5)	8 (27.6)
ECOG PS									
1									
	Day 15	59	6 (10.2)	38 (64.4)	15 (25.4)	26	1 (3.8)	17 (65.4)	8 (30.8)
	Day 43	58	10 (17.2)	39 (67.2)	9 (15.5)	26	1 (3.8)	17 (65.4)	8 (30.8)
	Day 85	45	9 (20.0)	29 (64.4)	7 (15.6)	17	2 (11.8)	12 (70.6)	3 (17.6)
	Day 127	33	9 (27.3)	16 (48.5)	8 (24.2)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	21	4 (19.0)	13 (61.9)	4 (19.0)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	17	3 (17.6)	13 (76.5)	1 (5.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	13	3 (23.1)	10 (76.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	3 (27.3)	8 (72.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	3 (27.3)	6 (54.5)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	2 (28.6)	5 (71.4)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	6 (12.0)	30 (60.0)	14 (28.0)	26	2 (7.7)	13 (50.0)	11 (42.3)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	93	12 (12.9)	61 (65.6)	20 (21.5)	38	0 (0.0)	31 (81.6)	7 (18.4)
	Day 43	92	17 (18.5)	67 (72.8)	8 (8.7)	39	2 (5.1)	25 (64.1)	12 (30.8)
	Day 85	79	13 (16.5)	55 (69.6)	11 (13.9)	26	3 (11.5)	19 (73.1)	4 (15.4)
	Day 127	60	15 (25.0)	35 (58.3)	10 (16.7)	13	2 (15.4)	8 (61.5)	3 (23.1)
	Day 169	46	13 (28.3)	31 (67.4)	2 (4.3)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	38	8 (21.1)	27 (71.1)	3 (7.9)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	32	8 (25.0)	22 (68.8)	2 (6.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	7 (26.9)	19 (73.1)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	25	7 (28.0)	16 (64.0)	2 (8.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	5 (26.3)	10 (52.6)	4 (21.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	2 (12.5)	11 (68.8)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	2 (25.0)	4 (50.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	75	8 (10.7)	46 (61.3)	21 (28.0)	41	3 (7.3)	22 (53.7)	16 (39.0)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	6 (22.2)	15 (55.6)	6 (22.2)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 43	26	6 (23.1)	12 (46.2)	8 (30.8)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 85	20	5 (25.0)	8 (40.0)	7 (35.0)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 127	15	2 (13.3)	8 (53.3)	5 (33.3)	6	2 (33.3)	4 (66.7)	0 (0.0)
	Day 169	11	0 (0.0)	7 (63.6)	4 (36.4)	3	0 (0.0)	3 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	4 (17.4)	11 (47.8)	8 (34.8)	14	1 (7.1)	10 (71.4)	3 (21.4)
Primary tumor location									
Gastric									
	Day 15	103	17 (16.5)	63 (61.2)	23 (22.3)	47	3 (6.4)	35 (74.5)	9 (19.1)
	Day 43	101	19 (18.8)	68 (67.3)	14 (13.9)	47	3 (6.4)	31 (66.0)	13 (27.7)
	Day 85	84	15 (17.9)	53 (63.1)	16 (19.0)	33	4 (12.1)	25 (75.8)	4 (12.1)
	Day 127	64	12 (18.8)	37 (57.8)	15 (23.4)	16	4 (25.0)	9 (56.3)	3 (18.8)
	Day 169	47	9 (19.1)	32 (68.1)	6 (12.8)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	38	6 (15.8)	29 (76.3)	3 (7.9)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	31	6 (19.4)	23 (74.2)	2 (6.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	24	5 (20.8)	19 (79.2)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	22	4 (18.2)	15 (68.2)	3 (13.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	17	2 (11.8)	11 (64.7)	4 (23.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	1 (7.7)	9 (69.2)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	2 (28.6)	3 (42.9)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	2 (40.0)	3 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	8 (9.6)	48 (57.8)	27 (32.5)	49	4 (8.2)	26 (53.1)	19 (38.8)
Primary tumor location									
GEJ									
	Day 15	17	1 (5.9)	13 (76.5)	3 (17.6)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 43	17	4 (23.5)	11 (64.7)	2 (11.8)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 85	15	3 (20.0)	10 (66.7)	2 (13.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 127	11	5 (45.5)	6 (54.5)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	4 (40.0)	6 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	3 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	3 (60.0)	2 (40.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	4	3 (75.0)	0 (0.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	4 (26.7)	9 (60.0)	2 (13.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	88	11 (12.5)	57 (64.8)	20 (22.7)	36	3 (8.3)	27 (75.0)	6 (16.7)
	Day 43	86	17 (19.8)	57 (66.3)	12 (14.0)	34	2 (5.9)	24 (70.6)	8 (23.5)
	Day 85	73	12 (16.4)	46 (63.0)	15 (20.5)	27	3 (11.1)	20 (74.1)	4 (14.8)
	Day 127	56	13 (23.2)	30 (53.6)	13 (23.2)	14	3 (21.4)	9 (64.3)	2 (14.3)
	Day 169	44	10 (22.7)	28 (63.6)	6 (13.6)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	32	4 (12.5)	25 (78.1)	3 (9.4)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	25	4 (16.0)	19 (76.0)	2 (8.0)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	18	4 (22.2)	14 (77.8)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	3 (18.8)	11 (68.8)	2 (12.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	13	2 (15.4)	7 (53.8)	4 (30.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	73	8 (11.0)	45 (61.6)	20 (27.4)	37	3 (8.1)	25 (67.6)	9 (24.3)
Histological subtype									
diffuse									
	Day 15	26	6 (23.1)	15 (57.7)	5 (19.2)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 43	26	5 (19.2)	18 (69.2)	3 (11.5)	13	1 (7.7)	8 (61.5)	4 (30.8)
	Day 85	22	5 (22.7)	14 (63.6)	3 (13.6)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 127	15	4 (26.7)	9 (60.0)	2 (13.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	11	3 (27.3)	8 (72.7)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	4 (40.0)	6 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	3 (30.0)	7 (70.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	2 (22.2)	7 (77.8)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	9	3 (33.3)	5 (55.6)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	3 (42.9)	3 (42.9)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	4 (19.0)	10 (47.6)	7 (33.3)	15	1 (6.7)	6 (40.0)	8 (53.3)
Histological subtype									
others									
	Day 15	6	1 (16.7)	4 (66.7)	1 (16.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 43	6	1 (16.7)	4 (66.7)	1 (16.7)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 85	4	1 (25.0)	3 (75.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	4	0 (0.0)	4 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	2 (50.0)	2 (50.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites									
<2									
	Day 15	22	3 (13.6)	14 (63.6)	5 (22.7)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	22	4 (18.2)	15 (68.2)	3 (13.6)	10	0 (0.0)	7 (70.0)	3 (30.0)
	Day 85	21	3 (14.3)	13 (61.9)	5 (23.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 127	17	5 (29.4)	9 (52.9)	3 (17.6)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	16	5 (31.3)	8 (50.0)	3 (18.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	14	3 (21.4)	11 (78.6)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	3 (30.0)	7 (70.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	3 (37.5)	5 (62.5)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	3 (37.5)	4 (50.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	5	1 (20.0)	3 (60.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	13 (72.2)	4 (22.2)	9	0 (0.0)	5 (55.6)	4 (44.4)
Number of metastatic sites									
>= 2									
	Day 15	98	15 (15.3)	62 (63.3)	21 (21.4)	43	3 (7.0)	32 (74.4)	8 (18.6)
	Day 43	96	19 (19.8)	64 (66.7)	13 (13.5)	42	3 (7.1)	28 (66.7)	11 (26.2)
	Day 85	78	15 (19.2)	50 (64.1)	13 (16.7)	28	4 (14.3)	20 (71.4)	4 (14.3)
	Day 127	58	12 (20.7)	34 (58.6)	12 (20.7)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 169	41	8 (19.5)	30 (73.2)	3 (7.3)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	30	5 (16.7)	22 (73.3)	3 (10.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	5 (18.5)	20 (74.1)	2 (7.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	21	4 (19.0)	17 (81.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	19	4 (21.1)	13 (68.4)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	4 (25.0)	8 (50.0)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	12	2 (16.7)	8 (66.7)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	80	11 (13.8)	44 (55.0)	25 (31.3)	46	4 (8.7)	27 (58.7)	15 (32.6)
Previous total gastrectomy									
yes									
	Day 15	20	5 (25.0)	12 (60.0)	3 (15.0)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 43	20	2 (10.0)	16 (80.0)	2 (10.0)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 85	18	2 (11.1)	13 (72.2)	3 (16.7)	6	2 (33.3)	4 (66.7)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	8	3 (37.5)	4 (50.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	3 (16.7)	10 (55.6)	5 (27.8)	9	2 (22.2)	4 (44.4)	3 (33.3)
Previous total gastrectomy									
no									
	Day 15	100	13 (13.0)	64 (64.0)	23 (23.0)	45	1 (2.2)	35 (77.8)	9 (20.0)
	Day 43	98	21 (21.4)	63 (64.3)	14 (14.3)	44	1 (2.3)	30 (68.2)	13 (29.5)
	Day 85	81	16 (19.8)	50 (61.7)	15 (18.5)	30	2 (6.7)	23 (76.7)	5 (16.7)
	Day 127	64	16 (25.0)	35 (54.7)	13 (20.3)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 169	49	12 (24.5)	34 (69.4)	3 (6.1)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 211	36	5 (13.9)	29 (80.6)	2 (5.6)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	33	7 (21.2)	24 (72.7)	2 (6.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	6 (24.0)	19 (76.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	23	6 (26.1)	15 (65.2)	2 (8.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	4 (21.1)	10 (52.6)	5 (26.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	14	2 (14.3)	10 (71.4)	2 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	2 (28.6)	3 (42.9)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	2 (40.0)	3 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	80	9 (11.3)	47 (58.8)	24 (30.0)	46	2 (4.3)	28 (60.9)	16 (34.8)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	6 (20.7)	17 (58.6)	6 (20.7)	9	2 (22.2)	5 (55.6)	2 (22.2)
	Day 43	28	3 (10.7)	22 (78.6)	3 (10.7)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 85	27	5 (18.5)	16 (59.3)	6 (22.2)	7	2 (28.6)	5 (71.4)	0 (0.0)
	Day 127	22	4 (18.2)	14 (63.6)	4 (18.2)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	15	4 (26.7)	9 (60.0)	2 (13.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	12	4 (33.3)	7 (58.3)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	4 (40.0)	5 (50.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	10	3 (30.0)	7 (70.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	3 (30.0)	5 (50.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	2 (33.3)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	25	3 (12.0)	13 (52.0)	9 (36.0)	9	2 (22.2)	6 (66.7)	1 (11.1)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	91	12 (13.2)	59 (64.8)	20 (22.0)	44	1 (2.3)	35 (79.5)	8 (18.2)
	Day 43	90	20 (22.2)	57 (63.3)	13 (14.4)	44	1 (2.3)	30 (68.2)	13 (29.5)
	Day 85	72	13 (18.1)	47 (65.3)	12 (16.7)	29	2 (6.9)	22 (75.9)	5 (17.2)
	Day 127	53	13 (24.5)	29 (54.7)	11 (20.8)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 169	42	9 (21.4)	29 (69.0)	4 (9.5)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	32	4 (12.5)	26 (81.3)	2 (6.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	4 (14.8)	22 (81.5)	1 (3.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	19	4 (21.1)	15 (78.9)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	17	4 (23.5)	12 (70.6)	1 (5.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	15	4 (26.7)	9 (60.0)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	2 (16.7)	10 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	2 (33.3)	3 (50.0)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	2 (50.0)	2 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	73	9 (12.3)	44 (60.3)	20 (27.4)	46	2 (4.3)	26 (56.5)	18 (39.1)
Prior ramucirumab contained treatment									
yes									
	Day 15	91	14 (15.4)	55 (60.4)	22 (24.2)	35	2 (5.7)	25 (71.4)	8 (22.9)
	Day 43	90	14 (15.6)	62 (68.9)	14 (15.6)	33	0 (0.0)	21 (63.6)	12 (36.4)
	Day 85	73	11 (15.1)	48 (65.8)	14 (19.2)	23	1 (4.3)	20 (87.0)	2 (8.7)
	Day 127	59	9 (15.3)	39 (66.1)	11 (18.6)	11	2 (18.2)	7 (63.6)	2 (18.2)
	Day 169	45	8 (17.8)	31 (68.9)	6 (13.3)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	32	3 (9.4)	26 (81.3)	3 (9.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	25	5 (20.0)	18 (72.0)	2 (8.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	22	5 (22.7)	17 (77.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	4 (19.0)	15 (71.4)	2 (9.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	17	3 (17.6)	10 (58.8)	4 (23.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	13	0 (0.0)	11 (84.6)	2 (15.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	2 (25.0)	4 (50.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	9 (12.2)	43 (58.1)	22 (29.7)	36	0 (0.0)	23 (63.9)	13 (36.1)
Prior ramucirumab contained treatment									
no									
	Day 15	29	4 (13.8)	21 (72.4)	4 (13.8)	18	1 (5.6)	15 (83.3)	2 (11.1)
	Day 43	28	9 (32.1)	17 (60.7)	2 (7.1)	19	3 (15.8)	14 (73.7)	2 (10.5)
	Day 85	26	7 (26.9)	15 (57.7)	4 (15.4)	13	3 (23.1)	7 (53.8)	3 (23.1)
	Day 127	16	8 (50.0)	4 (25.0)	4 (25.0)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 169	12	5 (41.7)	7 (58.3)	0 (0.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	12	5 (41.7)	7 (58.3)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	3 (25.0)	9 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	2 (28.6)	5 (71.4)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	3 (50.0)	2 (33.3)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	2 (50.0)	1 (25.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	3	2 (66.7)	0 (0.0)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	3 (12.5)	14 (58.3)	7 (29.2)	19	4 (21.1)	9 (47.4)	6 (31.6)
Prior nivolumab contained treatment									
yes									
	Day 15	33	3 (9.1)	20 (60.6)	10 (30.3)	14	1 (7.1)	10 (71.4)	3 (21.4)
	Day 43	31	5 (16.1)	20 (64.5)	6 (19.4)	10	0 (0.0)	7 (70.0)	3 (30.0)
	Day 85	27	4 (14.8)	15 (55.6)	8 (29.6)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	26	2 (7.7)	20 (76.9)	4 (15.4)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	21	3 (14.3)	16 (76.2)	2 (9.5)	3	0 (0.0)	3 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	16	1 (6.3)	14 (87.5)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	14	2 (14.3)	10 (71.4)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	2 (16.7)	10 (83.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	8 (72.7)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	2 (20.0)	4 (40.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	2 (50.0)	1 (25.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	2 (66.7)	1 (33.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	3 (11.5)	15 (57.7)	8 (30.8)	14	0 (0.0)	8 (57.1)	6 (42.9)
Prior nivolumab contained treatment									
no									
	Day 15	87	15 (17.2)	56 (64.4)	16 (18.4)	39	2 (5.1)	30 (76.9)	7 (17.9)
	Day 43	87	18 (20.7)	59 (67.8)	10 (11.5)	42	3 (7.1)	28 (66.7)	11 (26.2)
	Day 85	72	14 (19.4)	48 (66.7)	10 (13.9)	26	4 (15.4)	19 (73.1)	3 (11.5)
	Day 127	49	15 (30.6)	23 (46.9)	11 (22.4)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	36	10 (27.8)	22 (61.1)	4 (11.1)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	28	7 (25.0)	19 (67.9)	2 (7.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	23	6 (26.1)	17 (73.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	5 (29.4)	12 (70.6)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	6 (37.5)	9 (56.3)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	3 (27.3)	7 (63.6)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	9 (12.5)	42 (58.3)	21 (29.2)	41	4 (9.8)	24 (58.5)	13 (31.7)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	43	4 (9.3)	28 (65.1)	11 (25.6)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 43	41	8 (19.5)	27 (65.9)	6 (14.6)	12	0 (0.0)	9 (75.0)	3 (25.0)
	Day 85	37	5 (13.5)	22 (59.5)	10 (27.0)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 127	31	3 (9.7)	23 (74.2)	5 (16.1)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	24	5 (20.8)	17 (70.8)	2 (8.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	20	3 (15.0)	16 (80.0)	1 (5.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	17	3 (17.6)	12 (70.6)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	3 (18.8)	13 (81.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	2 (13.3)	10 (66.7)	3 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	12	3 (25.0)	4 (33.3)	5 (41.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	2 (50.0)	2 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	35	4 (11.4)	20 (57.1)	11 (31.4)	16	0 (0.0)	10 (62.5)	6 (37.5)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	77	14 (18.2)	48 (62.3)	15 (19.5)	37	2 (5.4)	28 (75.7)	7 (18.9)
	Day 43	77	15 (19.5)	52 (67.5)	10 (13.0)	40	3 (7.5)	26 (65.0)	11 (27.5)
	Day 85	62	13 (21.0)	41 (66.1)	8 (12.9)	25	4 (16.0)	18 (72.0)	3 (12.0)
	Day 127	44	14 (31.8)	20 (45.5)	10 (22.7)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 169	33	8 (24.2)	21 (63.6)	4 (12.1)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	24	5 (20.8)	17 (70.8)	2 (8.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	5 (25.0)	15 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	4 (30.8)	9 (69.2)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	5 (41.7)	7 (58.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	9	2 (22.2)	7 (77.8)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	8 (12.7)	37 (58.7)	18 (28.6)	39	4 (10.3)	22 (56.4)	13 (33.3)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
yes									
	Day 15	22	2 (9.1)	14 (63.6)	6 (27.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	19	4 (21.1)	14 (73.7)	1 (5.3)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 85	16	4 (25.0)	11 (68.8)	1 (6.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 127	12	2 (16.7)	10 (83.3)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	9	1 (11.1)	7 (77.8)	1 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	2 (14.3)	10 (71.4)	2 (14.3)	6	0 (0.0)	5 (83.3)	1 (16.7)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
no									
	Day 15	98	16 (16.3)	62 (63.3)	20 (20.4)	47	3 (6.4)	34 (72.3)	10 (21.3)
	Day 43	99	19 (19.2)	65 (65.7)	15 (15.2)	46	3 (6.5)	31 (67.4)	12 (26.1)
	Day 85	83	14 (16.9)	52 (62.7)	17 (20.5)	31	4 (12.9)	22 (71.0)	5 (16.1)
	Day 127	63	15 (23.8)	33 (52.4)	15 (23.8)	16	4 (25.0)	9 (56.3)	3 (18.8)
	Day 169	48	12 (25.0)	31 (64.6)	5 (10.4)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	39	7 (17.9)	29 (74.4)	3 (7.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	7 (21.2)	24 (72.7)	2 (6.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	6 (23.1)	20 (76.9)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	6 (25.0)	15 (62.5)	3 (12.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	18	4 (22.2)	10 (55.6)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	1 (7.7)	9 (69.2)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	84	10 (11.9)	47 (56.0)	27 (32.1)	49	4 (8.2)	27 (55.1)	18 (36.7)
Presence of liver metastasis at baseline									
yes									
	Day 15	65	11 (16.9)	40 (61.5)	14 (21.5)	27	1 (3.7)	22 (81.5)	4 (14.8)
	Day 43	64	14 (21.9)	42 (65.6)	8 (12.5)	27	3 (11.1)	16 (59.3)	8 (29.6)
	Day 85	51	10 (19.6)	34 (66.7)	7 (13.7)	16	3 (18.8)	13 (81.3)	0 (0.0)
	Day 127	37	7 (18.9)	23 (62.2)	7 (18.9)	10	2 (20.0)	5 (50.0)	3 (30.0)
	Day 169	28	8 (28.6)	18 (64.3)	2 (7.1)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	20	3 (15.0)	15 (75.0)	2 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	4 (21.1)	14 (73.7)	1 (5.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	4 (28.6)	10 (71.4)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	13	4 (30.8)	9 (69.2)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	3 (27.3)	6 (54.5)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	1 (11.1)	8 (88.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	2 (33.3)	3 (50.0)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	2 (50.0)	2 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	7 (14.0)	28 (56.0)	15 (30.0)	30	4 (13.3)	17 (56.7)	9 (30.0)
Presence of liver metastasis at baseline									
no									
	Day 15	55	7 (12.7)	36 (65.5)	12 (21.8)	26	2 (7.7)	18 (69.2)	6 (23.1)
	Day 43	54	9 (16.7)	37 (68.5)	8 (14.8)	25	0 (0.0)	19 (76.0)	6 (24.0)
	Day 85	48	8 (16.7)	29 (60.4)	11 (22.9)	20	1 (5.0)	14 (70.0)	5 (25.0)
	Day 127	38	10 (26.3)	20 (52.6)	8 (21.1)	9	2 (22.2)	7 (77.8)	0 (0.0)
	Day 169	29	5 (17.2)	20 (69.0)	4 (13.8)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	24	5 (20.8)	18 (75.0)	1 (4.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	4 (22.2)	13 (72.2)	1 (5.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	3 (20.0)	12 (80.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	3 (21.4)	8 (57.1)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	2 (20.0)	5 (50.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	7	1 (14.3)	3 (42.9)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	48	5 (10.4)	29 (60.4)	14 (29.2)	25	0 (0.0)	15 (60.0)	10 (40.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Renal impairment at baseline									
normal									
	Day 15	32	6 (18.8)	24 (75.0)	2 (6.3)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 43	33	9 (27.3)	24 (72.7)	0 (0.0)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 85	26	3 (11.5)	20 (76.9)	3 (11.5)	8	1 (12.5)	5 (62.5)	2 (25.0)
	Day 127	19	6 (31.6)	12 (63.2)	1 (5.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	17	5 (29.4)	12 (70.6)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	12	2 (16.7)	10 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	13	1 (7.7)	12 (92.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	2 (16.7)	10 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	2 (18.2)	9 (81.8)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	4 (16.7)	15 (62.5)	5 (20.8)	10	1 (10.0)	5 (50.0)	4 (40.0)
Renal impairment at baseline									
mild									
	Day 15	51	9 (17.6)	29 (56.9)	13 (25.5)	25	1 (4.0)	18 (72.0)	6 (24.0)
	Day 43	51	9 (17.6)	33 (64.7)	9 (17.6)	23	1 (4.3)	18 (78.3)	4 (17.4)
	Day 85	45	11 (24.4)	25 (55.6)	9 (20.0)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 127	32	7 (21.9)	19 (59.4)	6 (18.8)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	23	4 (17.4)	17 (73.9)	2 (8.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	17	3 (17.6)	11 (64.7)	3 (17.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	13	5 (38.5)	7 (53.8)	1 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	9	3 (33.3)	6 (66.7)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	8	3 (37.5)	3 (37.5)	2 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	6	1 (16.7)	3 (50.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	46	7 (15.2)	23 (50.0)	16 (34.8)	25	2 (8.0)	14 (56.0)	9 (36.0)
Renal impairment at baseline									
moderate									
	Day 15	37	3 (8.1)	23 (62.2)	11 (29.7)	17	2 (11.8)	13 (76.5)	2 (11.8)
	Day 43	34	5 (14.7)	22 (64.7)	7 (20.6)	17	1 (5.9)	10 (58.8)	6 (35.3)
	Day 85	28	4 (14.3)	18 (64.3)	6 (21.4)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 127	24	4 (16.7)	12 (50.0)	8 (33.3)	7	2 (28.6)	3 (42.9)	2 (28.6)
	Day 169	17	4 (23.5)	9 (52.9)	4 (23.5)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	15	3 (20.0)	12 (80.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	2 (18.2)	8 (72.7)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	2 (25.0)	5 (62.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	3 (42.9)	3 (42.9)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup / Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	1 (3.6)	19 (67.9)	8 (28.6)	19	1 (5.3)	13 (68.4)	5 (26.3)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
Hepatic impairment at baseline									
normal									
	Day 15	84	11 (13.1)	55 (65.5)	18 (21.4)	38	3 (7.9)	31 (81.6)	4 (10.5)
	Day 43	84	16 (19.0)	56 (66.7)	12 (14.3)	40	3 (7.5)	26 (65.0)	11 (27.5)
	Day 85	76	16 (21.1)	46 (60.5)	14 (18.4)	27	4 (14.8)	18 (66.7)	5 (18.5)
	Day 127	59	16 (27.1)	31 (52.5)	12 (20.3)	14	4 (28.6)	7 (50.0)	3 (21.4)
	Day 169	45	11 (24.4)	29 (64.4)	5 (11.1)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	34	7 (20.6)	24 (70.6)	3 (8.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	30	7 (23.3)	21 (70.0)	2 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	23	6 (26.1)	17 (73.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	7 (33.3)	12 (57.1)	2 (9.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	5 (31.3)	7 (43.8)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	2 (18.2)	7 (63.6)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	68	8 (11.8)	39 (57.4)	21 (30.9)	41	4 (9.8)	22 (53.7)	15 (36.6)
Hepatic impairment at baseline									
mild									
	Day 15	35	7 (20.0)	21 (60.0)	7 (20.0)	15	0 (0.0)	9 (60.0)	6 (40.0)
	Day 43	33	7 (21.2)	22 (66.7)	4 (12.1)	12	0 (0.0)	9 (75.0)	3 (25.0)
	Day 85	22	2 (9.1)	16 (72.7)	4 (18.2)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 127	15	1 (6.7)	11 (73.3)	3 (20.0)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 169	12	2 (16.7)	9 (75.0)	1 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	9 (90.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	7	1 (14.3)	6 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	5 (83.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	0 (0.0)	5 (83.3)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	29	4 (13.8)	17 (58.6)	8 (27.6)	14	0 (0.0)	10 (71.4)	4 (28.6)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	1 (12.5)	6 (75.0)	1 (12.5)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	3 (37.5)	5 (62.5)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	4 (57.1)	2 (28.6)	1 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	3 (50.0)	3 (50.0)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	5	1 (20.0)	4 (80.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	2 (50.0)	2 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	4 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	6	2 (33.3)	3 (50.0)	1 (16.7)	4	0 (0.0)	3 (75.0)	1 (25.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	112	17 (15.2)	70 (62.5)	25 (22.3)	49	3 (6.1)	37 (75.5)	9 (18.4)
	Day 43	110	20 (18.2)	74 (67.3)	16 (14.5)	49	3 (6.1)	32 (65.3)	14 (28.6)
	Day 85	92	14 (15.2)	61 (66.3)	17 (18.5)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	69	14 (20.3)	40 (58.0)	15 (21.7)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	52	12 (23.1)	34 (65.4)	6 (11.5)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	40	6 (15.0)	31 (77.5)	3 (7.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	8 (24.2)	23 (69.7)	2 (6.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	27	7 (25.9)	20 (74.1)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	25	7 (28.0)	15 (60.0)	3 (12.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	20	5 (25.0)	10 (50.0)	5 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	15	2 (13.3)	10 (66.7)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	2 (28.6)	3 (42.9)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	2 (40.0)	3 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	92	10 (10.9)	54 (58.7)	28 (30.4)	51	4 (7.8)	29 (56.9)	18 (35.3)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	1 (33.3)	2 (66.7)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	2 (66.7)	1 (33.3)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	2 (66.7)	1 (33.3)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	3	1 (33.3)	2 (66.7)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	117	18 (15.4)	73 (62.4)	26 (22.2)	50	3 (6.0)	37 (74.0)	10 (20.0)
	Day 43	115	22 (19.1)	77 (67.0)	16 (13.9)	49	3 (6.1)	32 (65.3)	14 (28.6)
	Day 85	96	16 (16.7)	62 (64.6)	18 (18.8)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	72	15 (20.8)	42 (58.3)	15 (20.8)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	54	12 (22.2)	36 (66.7)	6 (11.1)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	42	7 (16.7)	32 (76.2)	3 (7.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	35	8 (22.9)	25 (71.4)	2 (5.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	28	7 (25.0)	21 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	26	7 (26.9)	16 (61.5)	3 (11.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	21	5 (23.8)	11 (52.4)	5 (23.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	16	2 (12.5)	11 (68.8)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	2 (25.0)	4 (50.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	2 (33.3)	4 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	96	12 (12.5)	55 (57.3)	29 (30.2)	52	4 (7.7)	29 (55.8)	19 (36.5)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADEQ5D
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Anhang 4-G 1.2.4: Gesundheitsbezogene Lebensqualität

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Fact-Ga Total Score Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	124 (99.2)	62	58 (93.5)
Day 15	125	117 (93.6)	62	52 (83.9)
Day 43	124	117 (94.4)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	57 (54.3)	45	11 (24.4)
Day 211	93	44 (47.3)	40	4 (10.0)
Day 253	84	37 (44.0)	34	2 (5.9)
Day 295	77	29 (37.7)	27	2 (7.4)
Day 337	70	27 (38.6)	21	2 (9.5)
Day 379	60	21 (35.0)	20	1 (5.0)
Day 421	50	16 (32.0)	15	0 (0.0)
Day 463	39	12 (30.8)	9	0 (0.0)
Day 505	30	8 (26.7)	9	0 (0.0)
Day 547	24	6 (25.0)	8	0 (0.0)
Day 589	17	5 (29.4)	5	0 (0.0)
Day 631	13	4 (30.8)	1	0 (0.0)
Day 673	9	2 (22.2)	1	0 (0.0)
Day 715	5	3 (60.0)	1	0 (0.0)
Day 757	5	3 (60.0)	1	0 (0.0)
Day 799	3	1 (33.3)	1	0 (0.0)
Day 841	2	1 (50.0)	0	0 (0.0)
Day 883	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Fact-Ga Total Score by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	124	125.3 (25.36)			58	128.0 (23.42)		
Day 15	117	117.8 (24.91)	116	-7.9 (20.85)	52	127.1 (27.13)	49	-4.4 (18.92)
Day 43	117	121.0 (27.78)	116	-5.6 (22.66)	53	126.3 (30.44)	50	-4.8 (19.13)
Day 85	99	121.5 (27.79)	98	-6.4 (22.82)	36	129.7 (30.60)	34	-5.6 (17.11)
Day 127	74	126.8 (22.99)	73	-4.0 (21.97)	19	135.5 (26.91)	18	-7.3 (21.04)
Day 169	57	126.4 (24.91)	56	-2.3 (20.99)	11	140.9 (28.11)	10	-5.7 (17.03)
Day 211	44	126.7 (24.27)	43	-2.2 (23.28)	4	164.6 (17.25)	3	1.2 (11.41)
Day 253	37	123.5 (24.50)	37	-3.2 (23.77)	2	161.1 (19.68)	2	8.3 (11.20)
Day 295	29	128.1 (23.63)	29	-1.1 (25.02)	2	172.0 (5.66)	2	19.2 (2.83)
Day 337	27	128.0 (25.36)	27	0.2 (29.16)	2	158.5 (24.75)	2	5.7 (16.26)
Day 379	21	126.5 (26.83)	21	-6.2 (29.13)	1	173.0 (-)	1	14.2 (-)
Day 421	16	122.0 (27.22)	16	-8.8 (24.39)	0	-	0	-
Day 463	12	125.2 (29.76)	12	-4.6 (21.49)	0	-	0	-
Day 505	8	122.5 (31.62)	8	-7.0 (24.31)	0	-	0	-
Day 547	6	129.4 (25.89)	6	-3.7 (17.92)	0	-	0	-
Day 589	5	129.5 (27.95)	5	-8.4 (17.57)	0	-	0	-
Day 631	4	120.6 (27.06)	4	-8.5 (22.75)	0	-	0	-
Day 673	2	104.8 (11.67)	2	-19.8 (20.86)	0	-	0	-
Day 715	3	127.0 (40.60)	3	-13.7 (28.45)	0	-	0	-
Day 757	3	126.1 (35.35)	3	-14.6 (23.54)	0	-	0	-
Day 799	1	90.0 (-)	1	-41.0 (-)	0	-	0	-
Day 841	1	79.3 (-)	1	-51.7 (-)	0	-	0	-
Day 883	1	73.5 (-)	1	-57.5 (-)	0	-	0	-
End of Treatment	96	111.6 (31.04)	95	-15.6 (26.78)	56	115.6 (32.98)	52	-15.5 (21.13)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Visit	DS-8201a (N=125) N [a]	N_MISS [b]	LSMean (95% CI)	Phys. Choice (N=62) N [a]	N_MISS [b]	LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
Day 15			-9.38 (-13.38, -5.39)			-6.90 (-12.85, -0.95)	-2.49 (-9.02, 4.05)	0.4544		
Day 43			-9.50 (-13.30, -5.71)			-7.67 (-13.12, -2.23)	-1.83 (-7.79, 4.13)	0.5454		
Day 85			-9.68 (-13.28, -6.09)			-8.84 (-14.30, -3.38)	-0.85 (-6.69, 5.00)	0.7752		
Day 127			-9.87 (-13.37, -6.36)			-10.00 (-16.36, -3.64)	0.13 (-6.52, 6.78)	0.9683		
Day 169			-10.05 (-13.59, -6.50)			-11.16 (-19.01, -3.32)	1.12 (-6.98, 9.22)	0.7865		
Day 211			-10.23 (-13.93, -6.52)			-12.33 (-21.98, -2.67)	2.10 (-7.82, 12.02)	0.6777		
Day 253			-10.41 (-14.39, -6.43)			-13.49 (-25.12, -1.86)	3.08 (-8.86, 15.02)	0.6123		
Day 295			-10.59 (-14.93, -6.25)			-14.65 (-28.36, -0.94)	4.06 (-10.01, 18.14)	0.5708		
Day 337			-10.77 (-15.54, -6.00)			-15.81 (-31.66, 0.03)	5.05 (-11.24, 21.33)	0.5429		
Day 379			-10.95 (-16.20, -5.70)			-16.98 (-35.00, 1.04)	6.03 (-12.50, 24.56)	0.5231		
Day 421			-11.13 (-16.89, -5.36)			-18.14 (-38.36, 2.08)	7.01 (-13.80, 27.83)	0.5084		
Day 463			-11.31 (-17.62, -5.00)			-19.30 (-41.75, 3.14)	7.99 (-15.12, 31.11)	0.4972		
OVERALL	123	2	-9.95 (-13.45, -6.44)	54	8	-10.53 (-17.50, -3.55)	0.58 (-6.67, 7.83)	0.8751	0.03 (-0.29, 0.35)	0.8709

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-Ga Total Score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0077
Japan	98	-8.34 (-11.20, -5.49)	45	-4.55 (-11.14, 2.03)	-3.79 (-10.98, 3.41)	0.3008	-0.22 (-0.57, 0.13)	0.2241	
Korea	25	-5.67 (-14.05, 2.70)	9	-30.56 (-52.41, -8.72)	24.89 (1.50, 48.28)	0.0374	1.03 (0.23, 1.83)	0.0119	
Lines of prior systemic therapy									0.4679
2	64	-5.36 (-9.26, -1.46)	34	-7.72 (-15.18, -0.27)	2.36 (-6.10, 10.83)	0.5817	0.13 (-0.29, 0.55)	0.5392	
3	34	-7.45 (-13.16, -1.74)	16	-10.15 (-22.46, 2.16)	2.70 (-10.87, 16.27)	0.6934	0.14 (-0.46, 0.73)	0.6482	
>=4	25	-14.82 (-21.17, -8.48)	4	4.88 (-28.05, 37.81)	-19.70 (-53.28, 13.87)	0.2462	-1.08 (-2.17, 0.01)	0.0528	
Age									0.5582
<65 years	54	-6.12 (-10.33, -1.91)	25	-10.19 (-21.34, 0.96)	4.07 (-7.94, 16.08)	0.5047	0.20 (-0.28, 0.67)	0.4101	
>=65 years	69	-9.58 (-13.54, -5.63)	29	-7.91 (-16.50, 0.68)	-1.67 (-11.13, 7.78)	0.7266	-0.09 (-0.52, 0.34)	0.6875	
Sex									0.8905
female	29	-4.75 (-10.58, 1.09)	12	-11.10 (-26.58, 4.39)	6.35 (-10.18, 22.88)	0.4473	0.33 (-0.35, 1.00)	0.3441	
male	94	-8.92 (-12.26, -5.58)	42	-8.33 (-15.87, -0.80)	-0.59 (-8.86, 7.68)	0.8888	-0.03 (-0.39, 0.33)	0.8700	
ECOG PS									0.1296
0	61	-9.31 (-12.82, -5.80)	27	-7.23 (-16.75, 2.29)	-2.08 (-12.26, 8.10)	0.6873	-0.12 (-0.57, 0.34)	0.6168	
1	62	-6.02 (-10.66, -1.39)	27	-9.54 (-18.41, -0.67)	3.52 (-6.51, 13.54)	0.4886	0.18 (-0.28, 0.63)	0.4457	
HER2 Status in central laboratory									0.1472
IHC 3+	95	-7.08 (-10.42, -3.74)	41	-8.80 (-17.01, -0.60)	1.72 (-7.16, 10.61)	0.7029	0.09 (-0.28, 0.45)	0.6461	
IHC 2+/ISH +	28	-11.48 (-17.21, -5.74)	13	-5.15 (-14.89, 4.60)	-6.33 (-17.62, 4.95)	0.2649	-0.40 (-1.06, 0.26)	0.2370	
Primary tumor location									0.7537
Gastric	106	-8.36 (-11.49, -5.22)	49	-8.47 (-15.39, -1.55)	0.11 (-7.51, 7.73)	0.9769	0.01 (-0.33, 0.34)	0.9732	
GEJ	17	-5.79 (-13.02, 1.45)	5	-7.91 (-33.15, 17.32)	2.13 (-24.08, 28.33)	0.8716	0.12 (-0.88, 1.12)	0.8154	
Histological subtype									0.3867
intestinal	88	-8.12 (-11.15, -5.09)	35	-5.51 (-12.62, 1.61)	-2.61 (-10.35, 5.13)	0.5068	-0.16 (-0.55, 0.23)	0.4321	
diffuse	28	-8.30 (-15.81, -0.79)	14	-14.89 (-34.70, 4.91)	6.59 (-14.69, 27.87)	0.5404	0.25 (-0.40, 0.89)	0.4532	
others	7	-3.82 (-24.05, 16.41)	5	-12.41 (-42.41, 17.58)	8.59 (-27.77, 44.95)	0.6134	0.33 (-0.83, 1.48)	0.5775	
Number of metastatic sites									0.1468
<2	22	-9.88 (-15.89, -3.86)	10	3.40 (-9.32, 16.13)	-13.28 (-27.37, 0.80)	0.0638	-0.83 (-1.61, -0.06)	0.0348	
>= 2	101	-7.55 (-10.82, -4.28)	44	-13.51 (-21.36, -5.65)	5.96 (-2.57, 14.49)	0.1703	0.30 (-0.06, 0.65)	0.1026	
Previous total gastrectomy									0.0261
yes	22	-11.47 (-19.77, -3.17)	8	-0.78 (-26.72, 25.16)	-10.68 (-37.93, 16.56)	0.4375	-0.43 (-1.25, 0.38)	0.2983	
no	101	-7.10 (-10.08, -4.12)	46	-9.44 (-16.10, -2.78)	2.34 (-4.97, 9.65)	0.5288	0.13 (-0.22, 0.48)	0.4633	
Prior adjuvant/ neoadjuvant therapy									0.4244
yes	30	-7.23 (-13.02, -1.44)	7	-6.53 (-29.38, 16.32)	-0.70 (-24.25, 22.85)	0.9530	-0.04 (-0.86, 0.79)	0.9299	
no	93	-7.98 (-11.23, -4.73)	47	-8.46 (-15.11, -1.81)	0.48 (-6.96, 7.91)	0.8994	0.03 (-0.33, 0.38)	0.8859	
Prior ramucirumab contained treatment									0.0499
yes	92	-9.90 (-12.80, -7.01)	36	-9.21 (-17.58, -0.84)	-0.69 (-9.56, 8.17)	0.8777	-0.04 (-0.42, 0.35)	0.8444	
no	31	-1.89 (-9.10, 5.32)	18	-6.57 (-17.91, 4.78)	4.68 (-8.90, 18.26)	0.4928	0.22 (-0.36, 0.80)	0.4640	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

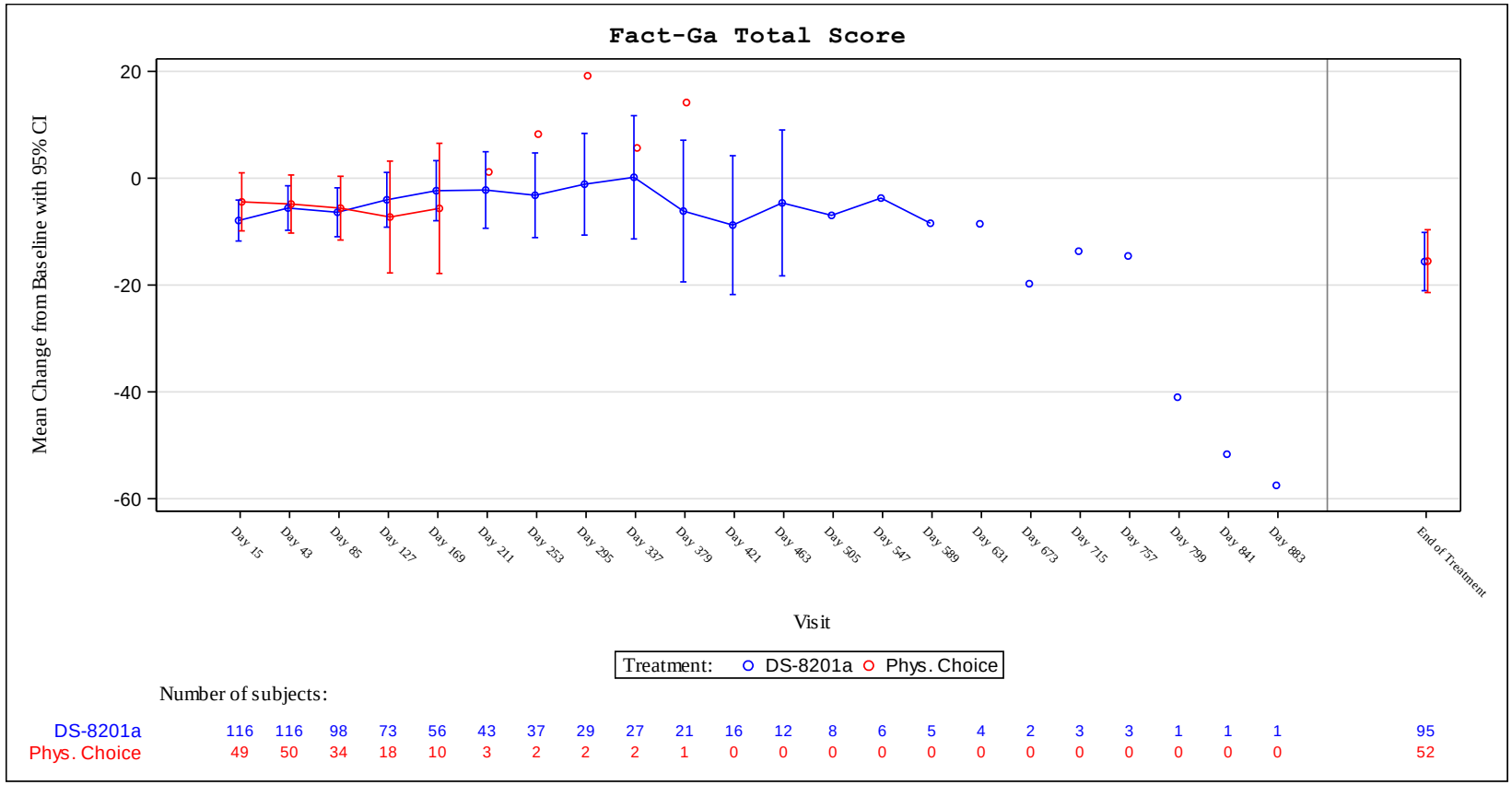
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-Ga Total Score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.1786
yes	33	-10.93 (-15.63, -6.23)	12	-6.04 (-20.01, 7.94)	-4.90 (-19.63, 9.84)	0.5100	-0.29 (-0.95, 0.37)	0.3908	
no	90	-6.60 (-10.20, -2.99)	42	-8.81 (-16.30, -1.31)	2.21 (-6.16, 10.58)	0.6034	0.11 (-0.26, 0.48)	0.5529	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.2037
yes	44	-10.12 (-14.92, -5.31)	13	-6.84 (-21.82, 8.14)	-3.27 (-19.01, 12.46)	0.6807	-0.17 (-0.79, 0.45)	0.5848	
no	79	-6.64 (-10.21, -3.06)	41	-8.78 (-15.73, -1.83)	2.14 (-5.72, 10.00)	0.5913	0.12 (-0.26, 0.49)	0.5478	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.4122
yes	22	-3.88 (-11.74, 3.98)	5	1.05 (-19.43, 21.53)	-4.93 (-26.97, 17.11)	0.6538	-0.26 (-1.24, 0.71)	0.5965	
no	101	-8.81 (-11.92, -5.70)	49	-9.42 (-16.53, -2.31)	0.61 (-7.16, 8.39)	0.8769	0.03 (-0.31, 0.37)	0.8562	
Presence of liver metastasis at baseline									0.2221
yes	68	-5.86 (-9.52, -2.21)	29	-12.92 (-22.25, -3.60)	7.06 (-2.98, 17.09)	0.1668	0.38 (-0.06, 0.81)	0.0927	
no	55	-10.18 (-14.73, -5.63)	25	-4.28 (-13.89, 5.33)	-5.91 (-16.56, 4.75)	0.2748	-0.30 (-0.78, 0.17)	0.2116	
Renal impairment at baseline									0.1966
normal	33	-8.62 (-13.58, -3.66)	12	-34.37 (-57.62, -11.12)	25.74 (1.97, 49.51)	0.0339	1.07 (0.38, 1.77)	0.0026	
mild	53	-7.06 (-11.91, -2.21)	25	-1.19 (-9.87, 7.48)	-5.87 (-15.86, 4.13)	0.2465	-0.31 (-0.79, 0.17)	0.2078	
moderate	37	-8.50 (-13.38, -3.63)	16	-13.57 (-24.79, -2.35)	5.07 (-7.16, 17.29)	0.4130	0.29 (-0.30, 0.88)	0.3342	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.4443
normal	86	-7.48 (-10.89, -4.07)	40	-10.41 (-17.99, -2.83)	2.93 (-5.39, 11.25)	0.4886	0.15 (-0.22, 0.53)	0.4213	
mild	36	-9.62 (-14.89, -4.36)	14	-2.19 (-15.80, 11.43)	-7.44 (-22.11, 7.24)	0.3159	-0.39 (-1.02, 0.23)	0.2149	
moderate	1	NE	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.2399
yes	8	-15.89 (-27.37, -4.42)	4	9.90 (-11.62, 31.42)	-25.79 (-51.13, -0.46)	0.0466	-1.62 (-2.98, -0.25)	0.0202	
no	115	-7.41 (-10.33, -4.50)	50	-11.55 (-18.71, -4.39)	4.14 (-3.60, 11.88)	0.2937	0.21 (-0.12, 0.55)	0.2081	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.4644
yes	3	-9.17 (-39.35, 21.01)	3	4.77 (-26.33, 35.87)	-13.94 (-59.64, 31.77)	0.4097	-0.83 (-2.50, 0.84)	0.3284	
no	120	-8.05 (-10.97, -5.13)	51	-12.33 (-19.91, -4.75)	4.28 (-3.86, 12.42)	0.3017	0.21 (-0.12, 0.54)	0.2069	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Graphical Summary of Fact-Ga Total Score by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	44 (35.2)	13 (21.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	11.2 (6.9, NE)	NE (5.4, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.15 (0.61, 2.16)	
p-value [c]	0.6782	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.14 (0.61, 2.15)	
p-value [c]	0.6835	

Time to Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.0237
Japan	36/ 99 (36.4)	11.2 (5.8, NE)	8/ 50 (16.0)	NE (NE , NE)	1.70 (0.78, 3.70)	0.1776	
Korea	8/ 26 (30.8)	NE (4.6, NE)	5/ 12 (41.7)	3.3 (0.5, NE)	0.34 (0.10, 1.12)	0.0619	
Lines of prior systemic therapy							0.5055
2	21/ 66 (31.8)	NE (5.9, NE)	7/ 38 (18.4)	NE (5.4, NE)	1.25 (0.52, 2.99)	0.6222	
3	12/ 34 (35.3)	16.7 (5.8, NE)	4/ 18 (22.2)	NE (2.6, NE)	1.04 (0.32, 3.36)	0.9545	
>=4	11/ 25 (44.0)	6.9 (2.0, NE)	2/ 6 (33.3)	NE (0.5, NE)	0.51 (0.11, 2.36)	0.3804	
Age							0.6032
<65 years	18/ 55 (32.7)	NE (5.7, NE)	6/ 27 (22.2)	NE (2.6, NE)	1.00 (0.39, 2.58)	0.9907	
>=65 years	26/ 70 (37.1)	11.0 (5.9, NE)	7/ 35 (20.0)	NE (3.3, NE)	1.28 (0.55, 2.99)	0.5675	
Sex							0.6911
female	10/ 30 (33.3)	8.3 (4.4, NE)	2/ 15 (13.3)	NE (1.6, NE)	1.04 (0.21, 5.17)	0.9579	
male	34/ 95 (35.8)	16.7 (6.9, NE)	11/ 47 (23.4)	NE (5.4, NE)	1.15 (0.57, 2.29)	0.7061	
ECOG PS							0.9144
0	25/ 62 (40.3)	11.0 (5.9, NE)	7/ 30 (23.3)	NE (5.4, NE)	1.03 (0.43, 2.44)	0.9504	
1	19/ 63 (30.2)	NE (5.8, NE)	6/ 32 (18.8)	NE (3.3, NE)	1.27 (0.50, 3.20)	0.6155	
HER2 Status in central laboratory							0.9871
IHC 3+	32/ 96 (33.3)	16.7 (8.3, NE)	13/ 47 (27.7)	NE (3.3, NE)	0.77 (0.40, 1.49)	0.4270	
IHC 2+/ISH +	12/ 29 (41.4)	5.9 (2.8, 11.2)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9884
Gastric	38/108 (35.2)	11.0 (5.9, NE)	13/ 55 (23.6)	NE (5.4, NE)	1.04 (0.55, 1.98)	0.9068	
GEJ	6/ 17 (35.3)	NE (2.8, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.5062
intestinal	30/ 89 (33.7)	11.0 (6.9, NE)	6/ 38 (15.8)	NE (5.4, NE)	1.48 (0.61, 3.59)	0.3906	
diffuse	11/ 28 (39.3)	NE (1.5, NE)	5/ 18 (27.8)	3.3 (0.6, NE)	0.95 (0.33, 2.80)	0.9318	
others	3/ 8 (37.5)	4.6 (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.36 (0.22, 8.23)	0.7372	
Number of metastatic sites							0.9885
<2	7/ 23 (30.4)	NE (8.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	37/102 (36.3)	11.2 (5.8, NE)	13/ 52 (25.0)	NE (3.3, NE)	0.95 (0.50, 1.82)	0.8804	
Previous total gastrectomy							0.5696
yes	6/ 22 (27.3)	NE (1.5, NE)	1/ 9 (11.1)	NE (3.3, NE)	2.46 (0.30, 20.41)	0.3913	
no	38/103 (36.9)	11.0 (5.9, NE)	12/ 53 (22.6)	NE (5.4, NE)	1.04 (0.54, 2.02)	0.9098	
Prior adjuvant/ neoadjuvant therapy							0.9860
yes	10/ 30 (33.3)	11.0 (5.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	34/ 95 (35.8)	11.2 (5.8, NE)	13/ 52 (25.0)	NE (3.3, NE)	1.05 (0.54, 2.01)	0.8980	
Prior ramucirumab contained treatment							0.4822
yes	35/ 94 (37.2)	11.2 (5.8, NE)	8/ 41 (19.5)	NE (5.4, NE)	1.32 (0.60, 2.88)	0.4982	
no	9/ 31 (29.0)	NE (5.7, NE)	5/ 21 (23.8)	NE (2.6, NE)	0.79 (0.26, 2.43)	0.6783	
Prior nivolumab contained treatment							0.8925
yes	15/ 33 (45.5)	11.2 (3.0, NE)	4/ 15 (26.7)	NE (2.6, NE)	1.10 (0.35, 3.39)	0.8709	
no	29/ 92 (31.5)	NE (5.9, NE)	9/ 47 (19.1)	NE (5.4, NE)	1.16 (0.54, 2.50)	0.7032	

Time to Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

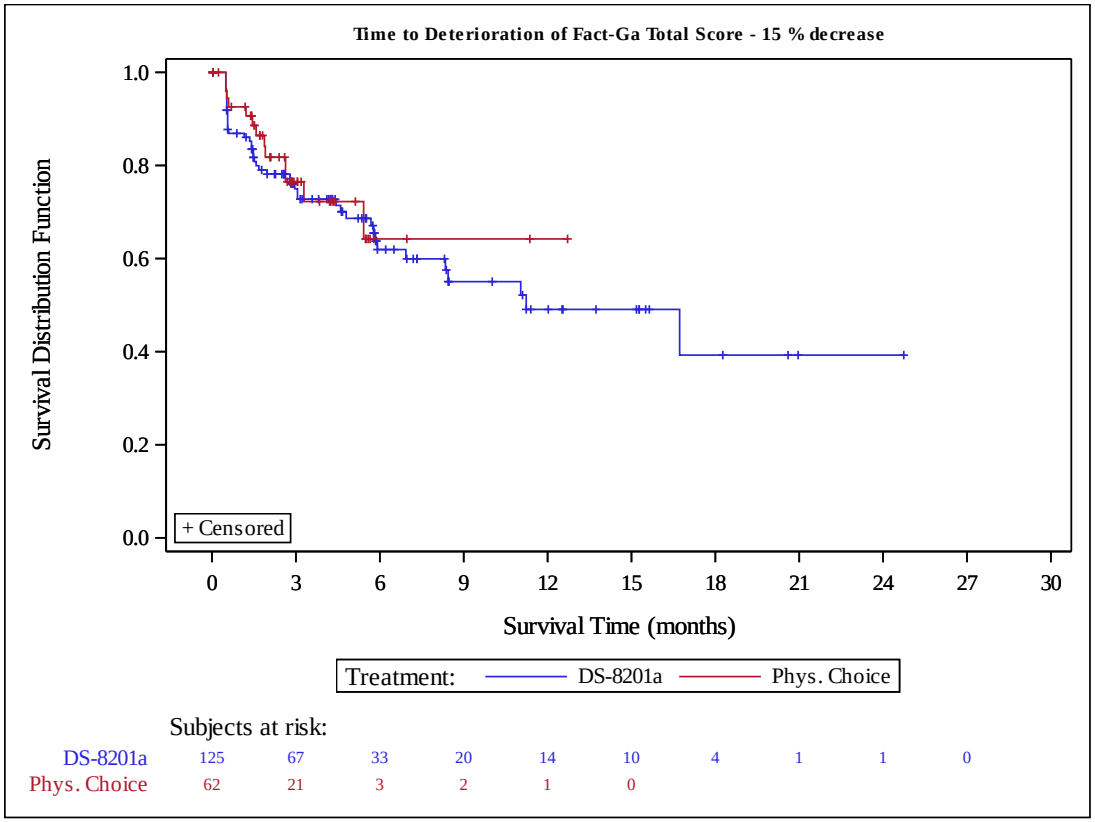
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7598
yes	17/ 44 (38.6)	16.7 (5.8, NE)	4/ 17 (23.5)	NE (2.6, NE)	1.06 (0.35, 3.21)	0.9230	
no	27/ 81 (33.3)	11.0 (5.8, NE)	9/ 45 (20.0)	NE (5.4, NE)	1.17 (0.54, 2.53)	0.6900	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9879
yes	7/ 22 (31.8)	NE (2.8, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	37/103 (35.9)	11.2 (6.9, NE)	13/ 55 (23.6)	NE (5.4, NE)	1.01 (0.53, 1.93)	0.9844	
Presence of liver metastasis at baseline							0.2423
yes	20/ 68 (29.4)	16.7 (8.3, NE)	8/ 34 (23.5)	NE (3.3, NE)	0.83 (0.36, 1.93)	0.6603	
no	24/ 57 (42.1)	8.4 (4.8, NE)	5/ 28 (17.9)	NE (NE , NE)	1.65 (0.62, 4.41)	0.3105	
Renal impairment at baseline							0.2127
normal	10/ 33 (30.3)	NE (8.3, NE)	4/ 13 (30.8)	NE (0.5, NE)	0.57 (0.17, 1.97)	0.3719	
mild	21/ 53 (39.6)	11.2 (5.7, NE)	4/ 28 (14.3)	NE (NE , NE)	2.19 (0.75, 6.42)	0.1424	
moderate	13/ 39 (33.3)	16.7 (4.8, NE)	5/ 20 (25.0)	5.4 (2.6, NE)	0.79 (0.26, 2.35)	0.6613	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7677
normal	36/ 88 (40.9)	11.0 (5.8, NE)	10/ 47 (21.3)	NE (5.4, NE)	1.17 (0.57, 2.40)	0.6818	
mild	8/ 36 (22.2)	NE (5.8, NE)	3/ 15 (20.0)	NE (1.6, NE)	1.00 (0.26, 3.81)	0.9913	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4525
yes	5/ 8 (62.5)	5.7 (0.5, NE)	1/ 5 (20.0)	NE (0.5, NE)	2.05 (0.24, 17.72)	0.5137	
no	39/117 (33.3)	16.7 (6.9, NE)	12/ 57 (21.1)	NE (5.4, NE)	1.07 (0.55, 2.07)	0.8513	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9880
yes	2/ 3 (66.7)	8.4 (5.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	42/122 (34.4)	16.7 (6.9, NE)	13/ 58 (22.4)	NE (5.4, NE)	1.05 (0.56, 1.98)	0.8878	

Time to Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

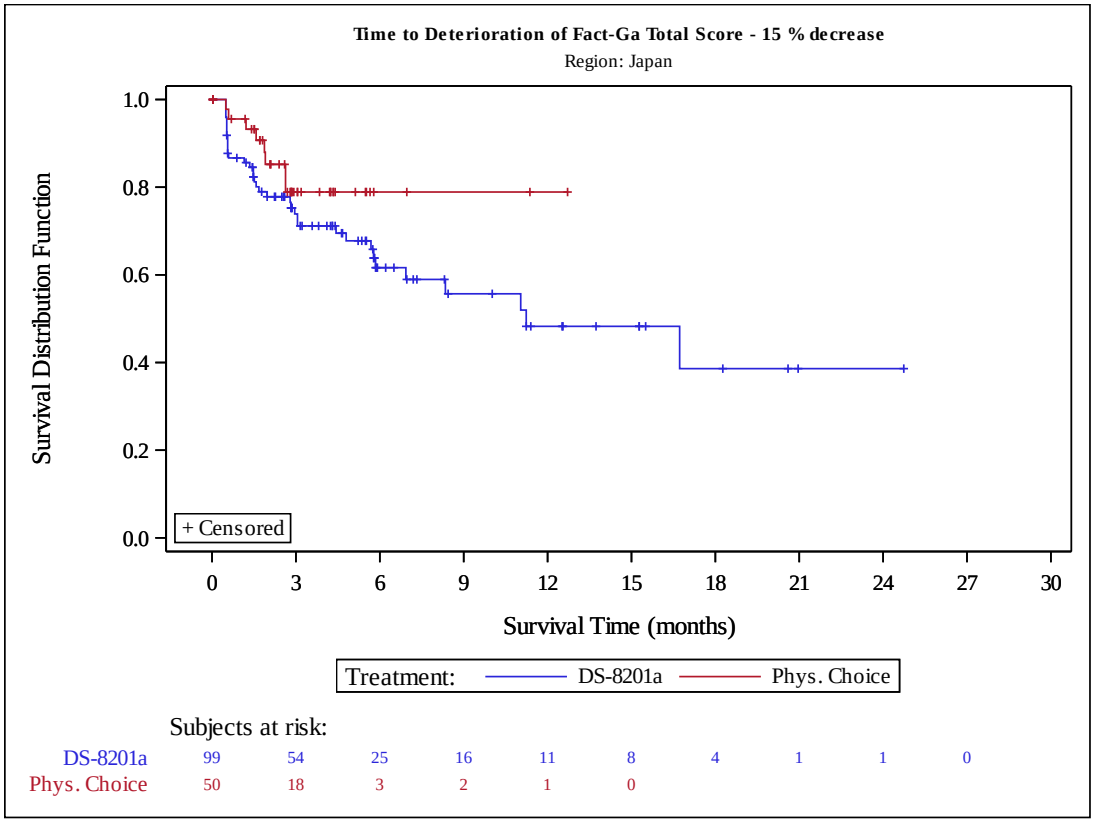
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

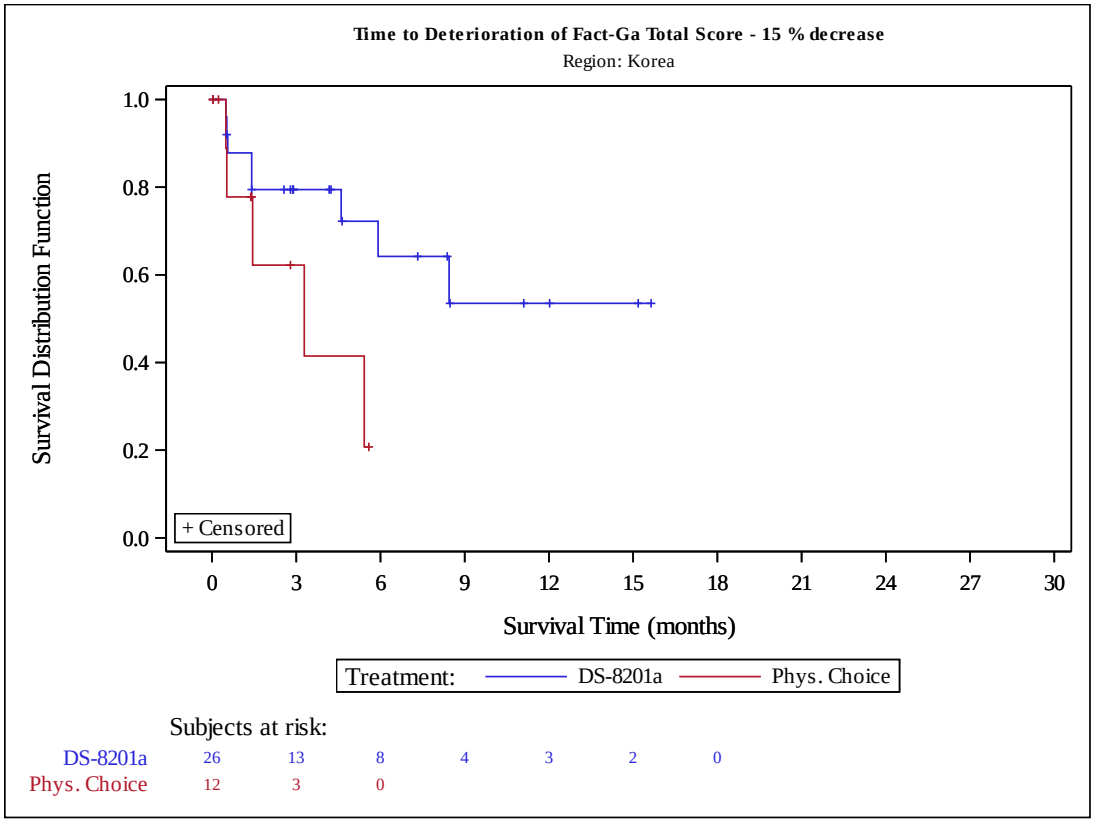
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	33 (26.4)	12 (19.4)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	16.7 (11.0, NE)	NE (5.4, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.77 (0.39, 1.53)	
p-value [c]	0.4522	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.79 (0.40, 1.57)	
p-value [c]	0.5007	

Time to Definitive Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.0654
Japan	25/ 99 (25.3)	NE (11.0, NE)	7/ 50 (14.0)	NE (NE , NE)	1.17 (0.50, 2.75)	0.7231	
Korea	8/ 26 (30.8)	14.1 (5.9, NE)	5/ 12 (41.7)	3.3 (0.5, NE)	0.27 (0.08, 0.93)	0.0253	
Lines of prior systemic therapy							0.9666
2	16/ 66 (24.2)	NE (8.3, NE)	7/ 38 (18.4)	NE (5.4, NE)	0.83 (0.33, 2.07)	0.6866	
3	9/ 34 (26.5)	16.7 (11.2, NE)	4/ 18 (22.2)	NE (2.6, NE)	0.58 (0.16, 2.07)	0.4034	
>=4	8/ 25 (32.0)	NE (4.4, NE)	1/ 6 (16.7)	NE (0.5, NE)	0.87 (0.11, 7.12)	0.9106	
Age							0.9220
<65 years	14/ 55 (25.5)	NE (8.3, NE)	5/ 27 (18.5)	NE (NE , NE)	0.81 (0.28, 2.36)	0.7026	
>=65 years	19/ 70 (27.1)	16.7 (8.4, NE)	7/ 35 (20.0)	NE (3.3, NE)	0.80 (0.33, 1.95)	0.6213	
Sex							0.6371
female	8/ 30 (26.7)	11.0 (4.4, NE)	2/ 15 (13.3)	NE (1.6, NE)	0.84 (0.16, 4.34)	0.8391	
male	25/ 95 (26.3)	16.7 (14.1, NE)	10/ 47 (21.3)	NE (5.4, NE)	0.76 (0.36, 1.63)	0.4824	
ECOG PS							0.8576
0	19/ 62 (30.6)	16.7 (8.3, NE)	6/ 30 (20.0)	NE (5.4, NE)	0.78 (0.30, 2.03)	0.6144	
1	14/ 63 (22.2)	14.1 (11.2, NE)	6/ 32 (18.8)	NE (3.3, NE)	0.80 (0.30, 2.13)	0.6531	
HER2 Status in central laboratory							0.9891
IHC 3+	25/ 96 (26.0)	16.7 (14.1, NE)	12/ 47 (25.5)	NE (3.3, NE)	0.56 (0.27, 1.14)	0.1026	
IHC 2+/ISH +	8/ 29 (27.6)	11.2 (5.7, 11.2)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9900
Gastric	28/108 (25.9)	16.7 (11.0, NE)	12/ 55 (21.8)	NE (5.4, NE)	0.70 (0.35, 1.42)	0.3209	
GEJ	5/ 17 (29.4)	NE (3.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.7525
intestinal	22/ 89 (24.7)	16.7 (8.4, NE)	6/ 38 (15.8)	NE (5.4, NE)	0.93 (0.37, 2.33)	0.8713	
diffuse	8/ 28 (28.6)	14.1 (5.7, NE)	4/ 18 (22.2)	NE (2.6, NE)	0.72 (0.21, 2.51)	0.5964	
others	3/ 8 (37.5)	4.6 (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.36 (0.22, 8.23)	0.7372	
Number of metastatic sites							0.9846
<2	6/ 23 (26.1)	NE (8.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	27/102 (26.5)	16.7 (11.2, NE)	12/ 52 (23.1)	NE (3.3, NE)	0.63 (0.31, 1.28)	0.2013	
Previous total gastrectomy							0.5313
yes	5/ 22 (22.7)	NE (7.2, NE)	1/ 9 (11.1)	NE (3.3, NE)	1.51 (0.17, 13.51)	0.7157	
no	28/103 (27.2)	16.7 (11.0, NE)	11/ 53 (20.8)	NE (5.4, NE)	0.73 (0.35, 1.49)	0.3823	
Prior adjuvant/ neoadjuvant therapy							0.9880
yes	8/ 30 (26.7)	NE (5.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	25/ 95 (26.3)	16.7 (11.2, NE)	12/ 52 (23.1)	NE (5.4, NE)	0.72 (0.35, 1.46)	0.3547	
Prior ramucirumab contained treatment							0.3289
yes	27/ 94 (28.7)	16.7 (11.0, NE)	7/ 41 (17.1)	NE (5.4, NE)	1.01 (0.43, 2.37)	0.9913	
no	6/ 31 (19.4)	NE (8.3, NE)	5/ 21 (23.8)	NE (2.6, NE)	0.45 (0.13, 1.55)	0.1892	
Prior nivolumab contained treatment							0.3397
yes	9/ 33 (27.3)	NE (11.2, NE)	4/ 15 (26.7)	NE (2.6, NE)	0.53 (0.16, 1.81)	0.3150	
no	24/ 92 (26.1)	14.1 (8.3, NE)	8/ 47 (17.0)	NE (5.4, NE)	0.94 (0.41, 2.14)	0.8694	

Time to Definitive Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.3445
yes	11/ 44 (25.0)	NE (11.2, NE)	4/ 17 (23.5)	NE (2.6, NE)	0.61 (0.19, 1.96)	0.4039	
no	22/ 81 (27.2)	14.1 (8.3, NE)	8/ 45 (17.8)	NE (5.4, NE)	0.91 (0.39, 2.10)	0.8155	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9897
yes	5/ 22 (22.7)	14.1 (5.7, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	28/103 (27.2)	16.7 (11.0, NE)	12/ 55 (21.8)	NE (5.4, NE)	0.74 (0.37, 1.49)	0.4037	
Presence of liver metastasis at baseline							0.1315
yes	15/ 68 (22.1)	16.7 (11.0, NE)	8/ 34 (23.5)	NE (3.3, NE)	0.52 (0.21, 1.28)	0.1442	
no	18/ 57 (31.6)	NE (5.9, NE)	4/ 28 (14.3)	NE (NE , NE)	1.38 (0.46, 4.15)	0.5699	
Renal impairment at baseline							0.2364
normal	8/ 33 (24.2)	NE (8.3, NE)	4/ 13 (30.8)	NE (0.5, NE)	0.20 (0.04, 0.92)	0.0226	
mild	15/ 53 (28.3)	NE (11.2, NE)	4/ 28 (14.3)	NE (NE , NE)	1.47 (0.49, 4.46)	0.4896	
moderate	10/ 39 (25.6)	16.7 (5.9, NE)	4/ 20 (20.0)	NE (3.3, NE)	0.71 (0.21, 2.41)	0.5740	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.6905
normal	27/ 88 (30.7)	16.7 (11.0, NE)	9/ 47 (19.1)	NE (5.4, NE)	0.86 (0.39, 1.87)	0.6919	
mild	6/ 36 (16.7)	NE (7.2, NE)	3/ 15 (20.0)	NE (1.6, NE)	0.57 (0.13, 2.43)	0.4372	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4940
yes	4/ 8 (50.0)	8.4 (3.1, NE)	1/ 5 (20.0)	NE (0.5, NE)	1.34 (0.15, 12.22)	0.7942	
no	29/117 (24.8)	16.7 (11.2, NE)	11/ 57 (19.3)	NE (5.4, NE)	0.78 (0.38, 1.59)	0.4830	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9891
yes	2/ 3 (66.7)	8.4 (5.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	31/122 (25.4)	16.7 (11.2, NE)	12/ 58 (20.7)	NE (5.4, NE)	0.71 (0.36, 1.42)	0.3315	

Time to Definitive Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

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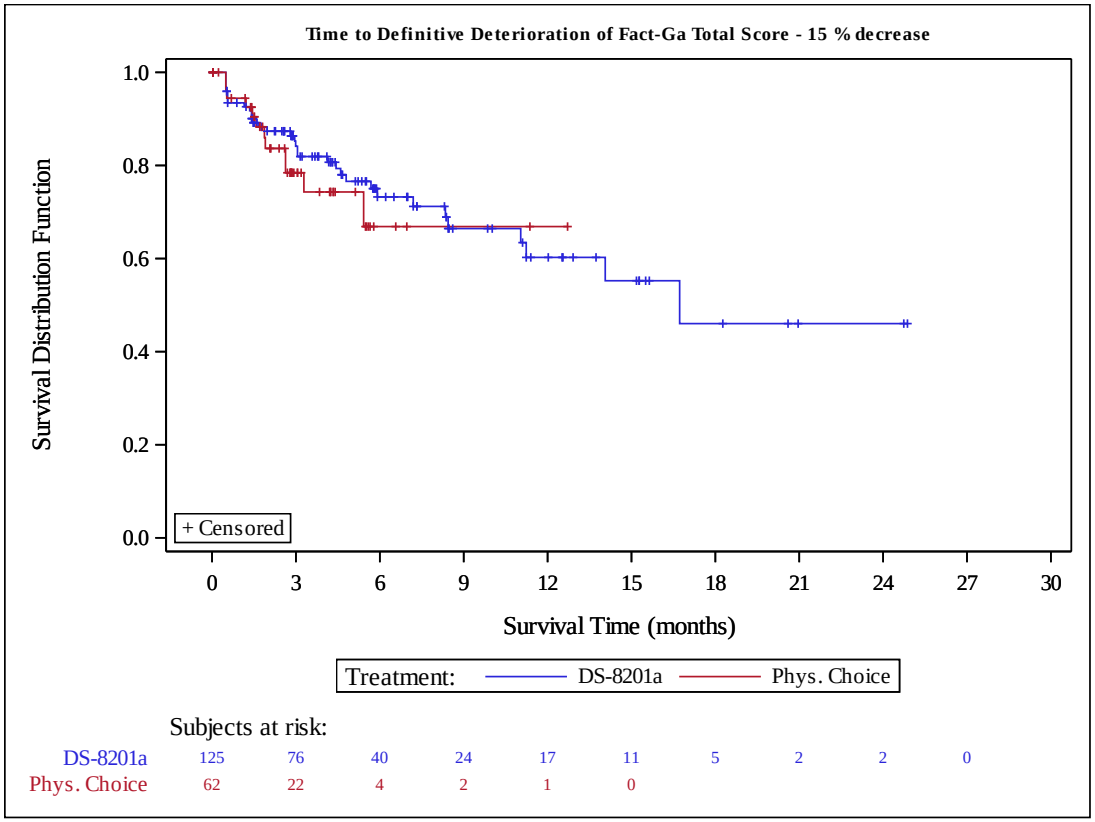
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	117	6 (5.1)	95 (81.2)	16 (13.7)	52	2 (3.8)	46 (88.5)	4 (7.7)
	Day 43	117	7 (6.0)	94 (80.3)	16 (13.7)	53	2 (3.8)	46 (86.8)	5 (9.4)
	Day 85	99	4 (4.0)	81 (81.8)	14 (14.1)	36	0 (0.0)	32 (88.9)	4 (11.1)
	Day 127	74	7 (9.5)	58 (78.4)	9 (12.2)	19	1 (5.3)	17 (89.5)	1 (5.3)
	Day 169	57	5 (8.8)	45 (78.9)	7 (12.3)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	44	4 (9.1)	35 (79.5)	5 (11.4)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	37	3 (8.1)	28 (75.7)	6 (16.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	29	5 (17.2)	20 (69.0)	4 (13.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	27	4 (14.8)	18 (66.7)	5 (18.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	21	2 (9.5)	15 (71.4)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	0 (0.0)	12 (75.0)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	96	3 (3.1)	70 (72.9)	23 (24.0)	56	0 (0.0)	44 (78.6)	12 (21.4)
Region									
Japan									
	Day 15	95	3 (3.2)	79 (83.2)	13 (13.7)	45	2 (4.4)	41 (91.1)	2 (4.4)
	Day 43	93	6 (6.5)	75 (80.6)	12 (12.9)	43	1 (2.3)	40 (93.0)	2 (4.7)
	Day 85	77	2 (2.6)	64 (83.1)	11 (14.3)	32	0 (0.0)	29 (90.6)	3 (9.4)
	Day 127	60	5 (8.3)	48 (80.0)	7 (11.7)	16	1 (6.3)	15 (93.8)	0 (0.0)
	Day 169	49	3 (6.1)	39 (79.6)	7 (14.3)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 211	36	2 (5.6)	29 (80.6)	5 (13.9)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	29	1 (3.4)	23 (79.3)	5 (17.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	23	2 (8.7)	18 (78.3)	3 (13.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	21	1 (4.8)	16 (76.2)	4 (19.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	18	1 (5.6)	13 (72.2)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	0 (0.0)	10 (83.3)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	77	1 (1.3)	60 (77.9)	16 (20.8)	48	0 (0.0)	41 (85.4)	7 (14.6)
Region									
Korea									
	Day 15	22	3 (13.6)	16 (72.7)	3 (13.6)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 43	24	1 (4.2)	19 (79.2)	4 (16.7)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 85	22	2 (9.1)	17 (77.3)	3 (13.6)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 127	14	2 (14.3)	10 (71.4)	2 (14.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	8	2 (25.0)	6 (75.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	2 (25.0)	5 (62.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	6	3 (50.0)	2 (33.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	6	3 (50.0)	2 (33.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	19	2 (10.5)	10 (52.6)	7 (36.8)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy									
2									
	Day 15	60	4 (6.7)	50 (83.3)	6 (10.0)	34	0 (0.0)	32 (94.1)	2 (5.9)
	Day 43	62	3 (4.8)	50 (80.6)	9 (14.5)	36	1 (2.8)	31 (86.1)	4 (11.1)
	Day 85	50	2 (4.0)	42 (84.0)	6 (12.0)	21	0 (0.0)	19 (90.5)	2 (9.5)
	Day 127	33	3 (9.1)	28 (84.8)	2 (6.1)	14	0 (0.0)	13 (92.9)	1 (7.1)
	Day 169	24	2 (8.3)	21 (87.5)	1 (4.2)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	21	2 (9.5)	19 (90.5)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	13 (72.2)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	3 (25.0)	8 (66.7)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	3 (27.3)	7 (63.6)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	1 (14.3)	6 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	2 (4.0)	38 (76.0)	10 (20.0)	34	0 (0.0)	27 (79.4)	7 (20.6)
Lines of prior systemic therapy									
3									
	Day 15	33	1 (3.0)	26 (78.8)	6 (18.2)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 43	33	2 (6.1)	28 (84.8)	3 (9.1)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 85	28	2 (7.1)	23 (82.1)	3 (10.7)	12	0 (0.0)	10 (83.3)	2 (16.7)
	Day 127	23	2 (8.7)	17 (73.9)	4 (17.4)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	19	2 (10.5)	12 (63.2)	5 (26.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	13	2 (15.4)	9 (69.2)	2 (15.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	1 (9.1)	10 (90.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	9	1 (11.1)	8 (88.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	1 (3.8)	18 (69.2)	7 (26.9)	17	0 (0.0)	13 (76.5)	4 (23.5)
Lines of prior systemic therapy									
>=4									
	Day 15	24	1 (4.2)	19 (79.2)	4 (16.7)	4	1 (25.0)	1 (25.0)	2 (50.0)
	Day 43	22	2 (9.1)	16 (72.7)	4 (18.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	0 (0.0)	16 (76.2)	5 (23.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	2 (11.1)	13 (72.2)	3 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	14	1 (7.1)	12 (85.7)	1 (7.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	0 (0.0)	14 (70.0)	6 (30.0)	5	0 (0.0)	4 (80.0)	1 (20.0)
Age									
<65 years									
	Day 15	51	3 (5.9)	42 (82.4)	6 (11.8)	22	0 (0.0)	20 (90.9)	2 (9.1)
	Day 43	52	4 (7.7)	41 (78.8)	7 (13.5)	24	1 (4.2)	21 (87.5)	2 (8.3)
	Day 85	47	1 (2.1)	38 (80.9)	8 (17.0)	16	0 (0.0)	14 (87.5)	2 (12.5)
	Day 127	34	4 (11.8)	26 (76.5)	4 (11.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	27	1 (3.7)	22 (81.5)	4 (14.8)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	18	2 (11.1)	13 (72.2)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	16	2 (12.5)	12 (75.0)	2 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	3 (23.1)	9 (69.2)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	3 (27.3)	8 (72.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	42	2 (4.8)	30 (71.4)	10 (23.8)	23	0 (0.0)	18 (78.3)	5 (21.7)
Age									
>=65 years									
	Day 15	66	3 (4.5)	53 (80.3)	10 (15.2)	30	2 (6.7)	26 (86.7)	2 (6.7)
	Day 43	65	3 (4.6)	53 (81.5)	9 (13.8)	29	1 (3.4)	25 (86.2)	3 (10.3)
	Day 85	52	3 (5.8)	43 (82.7)	6 (11.5)	20	0 (0.0)	18 (90.0)	2 (10.0)
	Day 127	40	3 (7.5)	32 (80.0)	5 (12.5)	11	1 (9.1)	10 (90.9)	0 (0.0)
	Day 169	30	4 (13.3)	23 (76.7)	3 (10.0)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	26	2 (7.7)	22 (84.6)	2 (7.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	1 (4.8)	16 (76.2)	4 (19.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	16	2 (12.5)	11 (68.8)	3 (18.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	10 (62.5)	5 (31.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	13	1 (7.7)	9 (69.2)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	End of Treatment	54	1 (1.9)	40 (74.1)	13 (24.1)	33	0 (0.0)	26 (78.8)	7 (21.2)
Sex									
female									
	Day 15	27	1 (3.7)	23 (85.2)	3 (11.1)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 43	28	3 (10.7)	23 (82.1)	2 (7.1)	13	0 (0.0)	11 (84.6)	2 (15.4)
	Day 85	20	1 (5.0)	17 (85.0)	2 (10.0)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 127	13	3 (23.1)	9 (69.2)	1 (7.7)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	10	1 (10.0)	8 (80.0)	1 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	0 (0.0)	8 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	22	0 (0.0)	17 (77.3)	5 (22.7)	14	0 (0.0)	12 (85.7)	2 (14.3)
Sex									
male									
	Day 15	90	5 (5.6)	72 (80.0)	13 (14.4)	39	1 (2.6)	35 (89.7)	3 (7.7)
	Day 43	89	4 (4.5)	71 (79.8)	14 (15.7)	40	2 (5.0)	35 (87.5)	3 (7.5)
	Day 85	79	3 (3.8)	64 (81.0)	12 (15.2)	28	0 (0.0)	24 (85.7)	4 (14.3)
	Day 127	61	4 (6.6)	49 (80.3)	8 (13.1)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 169	47	4 (8.5)	37 (78.7)	6 (12.8)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	36	4 (11.1)	27 (75.0)	5 (13.9)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	30	2 (6.7)	23 (76.7)	5 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	5 (20.0)	17 (68.0)	3 (12.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	4 (16.7)	16 (66.7)	4 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	2 (10.5)	13 (68.4)	4 (21.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	15	0 (0.0)	11 (73.3)	4 (26.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	3 (4.1)	53 (71.6)	18 (24.3)	42	0 (0.0)	32 (76.2)	10 (23.8)
ECOG PS									
0									
	Day 15	59	0 (0.0)	53 (89.8)	6 (10.2)	26	0 (0.0)	24 (92.3)	2 (7.7)
	Day 43	59	3 (5.1)	50 (84.7)	6 (10.2)	26	1 (3.8)	24 (92.3)	1 (3.8)
	Day 85	54	1 (1.9)	45 (83.3)	8 (14.8)	19	0 (0.0)	18 (94.7)	1 (5.3)
	Day 127	42	4 (9.5)	36 (85.7)	2 (4.8)	9	1 (11.1)	8 (88.9)	0 (0.0)
	Day 169	36	2 (5.6)	30 (83.3)	4 (11.1)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	27	1 (3.7)	23 (85.2)	3 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	24	1 (4.2)	17 (70.8)	6 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	18	1 (5.6)	14 (77.8)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	0 (0.0)	13 (81.3)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	14	0 (0.0)	11 (78.6)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	47	0 (0.0)	36 (76.6)	11 (23.4)	29	0 (0.0)	23 (79.3)	6 (20.7)
ECOG PS									
1									
	Day 15	58	6 (10.3)	42 (72.4)	10 (17.2)	26	2 (7.7)	22 (84.6)	2 (7.7)
	Day 43	58	4 (6.9)	44 (75.9)	10 (17.2)	27	1 (3.7)	22 (81.5)	4 (14.8)
	Day 85	45	3 (6.7)	36 (80.0)	6 (13.3)	17	0 (0.0)	14 (82.4)	3 (17.6)
	Day 127	32	3 (9.4)	22 (68.8)	7 (21.9)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 169	21	3 (14.3)	15 (71.4)	3 (14.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	17	3 (17.6)	12 (70.6)	2 (11.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	13	2 (15.4)	11 (84.6)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	4 (36.4)	6 (54.5)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	4 (36.4)	5 (45.5)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	49	3 (6.1)	34 (69.4)	12 (24.5)	27	0 (0.0)	21 (77.8)	6 (22.2)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	91	6 (6.6)	72 (79.1)	13 (14.3)	38	1 (2.6)	33 (86.8)	4 (10.5)
	Day 43	91	6 (6.6)	74 (81.3)	11 (12.1)	40	1 (2.5)	34 (85.0)	5 (12.5)
	Day 85	79	3 (3.8)	67 (84.8)	9 (11.4)	26	0 (0.0)	22 (84.6)	4 (15.4)
	Day 127	59	6 (10.2)	45 (76.3)	8 (13.6)	13	0 (0.0)	12 (92.3)	1 (7.7)
	Day 169	46	4 (8.7)	36 (78.3)	6 (13.0)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	38	4 (10.5)	30 (78.9)	4 (10.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	32	3 (9.4)	24 (75.0)	5 (15.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	5 (19.2)	17 (65.4)	4 (15.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	25	4 (16.0)	17 (68.0)	4 (16.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	2 (10.5)	15 (78.9)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	0 (0.0)	12 (75.0)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	73	3 (4.1)	54 (74.0)	16 (21.9)	42	0 (0.0)	30 (71.4)	12 (28.6)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	26	0 (0.0)	23 (88.5)	3 (11.5)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 43	26	1 (3.8)	20 (76.9)	5 (19.2)	13	1 (7.7)	12 (92.3)	0 (0.0)
	Day 85	20	1 (5.0)	14 (70.0)	5 (25.0)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 127	15	1 (6.7)	13 (86.7)	1 (6.7)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 169	11	1 (9.1)	9 (81.8)	1 (9.1)	3	0 (0.0)	3 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	0 (0.0)	16 (69.6)	7 (30.4)	14	0 (0.0)	14 (100.0)	0 (0.0)
Primary tumor location									
Gastric									
	Day 15	101	6 (5.9)	81 (80.2)	14 (13.9)	46	2 (4.3)	40 (87.0)	4 (8.7)
	Day 43	100	6 (6.0)	80 (80.0)	14 (14.0)	48	2 (4.2)	41 (85.4)	5 (10.4)
	Day 85	84	3 (3.6)	71 (84.5)	10 (11.9)	33	0 (0.0)	29 (87.9)	4 (12.1)
	Day 127	63	6 (9.5)	49 (77.8)	8 (12.7)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	47	4 (8.5)	37 (78.7)	6 (12.8)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	38	3 (7.9)	30 (78.9)	5 (13.2)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	31	3 (9.7)	23 (74.2)	5 (16.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	24	4 (16.7)	16 (66.7)	4 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	22	3 (13.6)	14 (63.6)	5 (22.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	17	1 (5.9)	12 (70.6)	4 (23.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	0 (0.0)	9 (69.2)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	81	2 (2.5)	59 (72.8)	20 (24.7)	50	0 (0.0)	38 (76.0)	12 (24.0)
Primary tumor location									
GEJ									
	Day 15	16	0 (0.0)	14 (87.5)	2 (12.5)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	17	1 (5.9)	14 (82.4)	2 (11.8)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 85	15	1 (6.7)	10 (66.7)	4 (26.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	9 (81.8)	1 (9.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	1 (6.7)	11 (73.3)	3 (20.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	85	4 (4.7)	72 (84.7)	9 (10.6)	35	2 (5.7)	32 (91.4)	1 (2.9)
	Day 43	85	6 (7.1)	72 (84.7)	7 (8.2)	34	0 (0.0)	32 (94.1)	2 (5.9)
	Day 85	73	2 (2.7)	62 (84.9)	9 (12.3)	27	0 (0.0)	25 (92.6)	2 (7.4)
	Day 127	55	5 (9.1)	45 (81.8)	5 (9.1)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 169	44	3 (6.8)	35 (79.5)	6 (13.6)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	32	2 (6.3)	26 (81.3)	4 (12.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	25	1 (4.0)	19 (76.0)	5 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	18	2 (11.1)	13 (72.2)	3 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	11 (68.8)	4 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	13	1 (7.7)	9 (69.2)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	1 (1.4)	55 (77.5)	15 (21.1)	37	0 (0.0)	31 (83.8)	6 (16.2)
Histological subtype diffuse									
	Day 15	26	1 (3.8)	19 (73.1)	6 (23.1)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 43	26	1 (3.8)	18 (69.2)	7 (26.9)	14	0 (0.0)	12 (85.7)	2 (14.3)
	Day 85	22	2 (9.1)	15 (68.2)	5 (22.7)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 127	15	2 (13.3)	9 (60.0)	4 (26.7)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	11	2 (18.2)	8 (72.7)	1 (9.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	2 (20.0)	7 (70.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	2 (20.0)	7 (70.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	14 (66.7)	5 (23.8)	16	0 (0.0)	12 (75.0)	4 (25.0)
Histological subtype others									
	Day 15	6	1 (16.7)	4 (66.7)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	0 (0.0)	4 (66.7)	2 (33.3)	5	2 (40.0)	2 (40.0)	1 (20.0)
	Day 85	4	0 (0.0)	4 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	4	0 (0.0)	4 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	1 (25.0)	3 (75.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	22	0 (0.0)	20 (90.9)	2 (9.1)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 43	21	0 (0.0)	20 (95.2)	1 (4.8)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 85	21	0 (0.0)	18 (85.7)	3 (14.3)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 127	17	0 (0.0)	16 (94.1)	1 (5.9)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	16	1 (6.3)	13 (81.3)	2 (12.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	14	1 (7.1)	12 (85.7)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	7 (70.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	2 (25.0)	5 (62.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	5 (62.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	13 (76.5)	3 (17.6)	9	0 (0.0)	9 (100.0)	0 (0.0)
Number of metastatic sites >= 2									
	Day 15	95	6 (6.3)	75 (78.9)	14 (14.7)	42	2 (4.8)	36 (85.7)	4 (9.5)
	Day 43	96	7 (7.3)	74 (77.1)	15 (15.6)	43	1 (2.3)	37 (86.0)	5 (11.6)
	Day 85	78	4 (5.1)	63 (80.8)	11 (14.1)	28	0 (0.0)	24 (85.7)	4 (14.3)
	Day 127	57	7 (12.3)	42 (73.7)	8 (14.0)	15	1 (6.7)	13 (86.7)	1 (6.7)
	Day 169	41	4 (9.8)	32 (78.0)	5 (12.2)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	30	3 (10.0)	23 (76.7)	4 (13.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	2 (7.4)	21 (77.8)	4 (14.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	21	3 (14.3)	15 (71.4)	3 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	19	3 (15.8)	13 (68.4)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	2 (12.5)	11 (68.8)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	2 (2.5)	57 (72.2)	20 (25.3)	47	0 (0.0)	35 (74.5)	12 (25.5)
Previous total gastrectomy yes									
	Day 15	20	2 (10.0)	14 (70.0)	4 (20.0)	7	1 (14.3)	6 (85.7)	0 (0.0)
	Day 43	20	1 (5.0)	15 (75.0)	4 (20.0)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 85	18	0 (0.0)	15 (83.3)	3 (16.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 127	11	0 (0.0)	9 (81.8)	2 (18.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	8	0 (0.0)	7 (87.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	14 (77.8)	3 (16.7)	9	0 (0.0)	8 (88.9)	1 (11.1)
Previous total gastrectomy									
no									
	Day 15	97	4 (4.1)	81 (83.5)	12 (12.4)	45	1 (2.2)	40 (88.9)	4 (8.9)
	Day 43	97	6 (6.2)	79 (81.4)	12 (12.4)	45	2 (4.4)	38 (84.4)	5 (11.1)
	Day 85	81	4 (4.9)	66 (81.5)	11 (13.6)	30	0 (0.0)	26 (86.7)	4 (13.3)
	Day 127	63	7 (11.1)	49 (77.8)	7 (11.1)	17	1 (5.9)	15 (88.2)	1 (5.9)
	Day 169	49	5 (10.2)	38 (77.6)	6 (12.2)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 211	36	3 (8.3)	30 (83.3)	3 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	33	2 (6.1)	26 (78.8)	5 (15.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	4 (16.0)	19 (76.0)	2 (8.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	23	3 (13.0)	17 (73.9)	3 (13.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	2 (10.5)	14 (73.7)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	14	0 (0.0)	12 (85.7)	2 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	2 (2.6)	56 (71.8)	20 (25.6)	47	0 (0.0)	36 (76.6)	11 (23.4)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	2 (6.9)	24 (82.8)	3 (10.3)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 43	27	1 (3.7)	23 (85.2)	3 (11.1)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 85	27	0 (0.0)	24 (88.9)	3 (11.1)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 127	22	0 (0.0)	20 (90.9)	2 (9.1)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	15	1 (6.7)	13 (86.7)	1 (6.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	12	1 (8.3)	8 (66.7)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	25	1 (4.0)	18 (72.0)	6 (24.0)	9	0 (0.0)	9 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	88	4 (4.5)	71 (80.7)	13 (14.8)	44	1 (2.3)	39 (88.6)	4 (9.1)
	Day 43	90	6 (6.7)	71 (78.9)	13 (14.4)	45	1 (2.2)	39 (86.7)	5 (11.1)
	Day 85	72	4 (5.6)	57 (79.2)	11 (15.3)	29	0 (0.0)	25 (86.2)	4 (13.8)
	Day 127	52	7 (13.5)	38 (73.1)	7 (13.5)	15	1 (6.7)	13 (86.7)	1 (6.7)
	Day 169	42	4 (9.5)	32 (76.2)	6 (14.3)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	32	3 (9.4)	27 (84.4)	2 (6.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	2 (7.4)	22 (81.5)	3 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	19	3 (15.8)	15 (78.9)	1 (5.3)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	17	3 (17.6)	13 (76.5)	1 (5.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	15	2 (13.3)	12 (80.0)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	0 (0.0)	11 (91.7)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	2 (2.8)	52 (73.2)	17 (23.9)	47	0 (0.0)	35 (74.5)	12 (25.5)
Prior ramucirumab contained treatment									
yes									
	Day 15	89	3 (3.4)	74 (83.1)	12 (13.5)	34	2 (5.9)	30 (88.2)	2 (5.9)
	Day 43	89	2 (2.2)	74 (83.1)	13 (14.6)	33	2 (6.1)	29 (87.9)	2 (6.1)
	Day 85	73	1 (1.4)	60 (82.2)	12 (16.4)	23	0 (0.0)	22 (95.7)	1 (4.3)
	Day 127	59	4 (6.8)	47 (79.7)	8 (13.6)	11	1 (9.1)	10 (90.9)	0 (0.0)
	Day 169	45	2 (4.4)	38 (84.4)	5 (11.1)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	32	1 (3.1)	26 (81.3)	5 (15.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	25	1 (4.0)	21 (84.0)	3 (12.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	22	2 (9.1)	18 (81.8)	2 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	1 (4.8)	16 (76.2)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	17	0 (0.0)	14 (82.4)	3 (17.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	13	0 (0.0)	10 (76.9)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	73	0 (0.0)	53 (72.6)	20 (27.4)	36	0 (0.0)	29 (80.6)	7 (19.4)
Prior ramucirumab contained treatment									
no									
	Day 15	28	3 (10.7)	21 (75.0)	4 (14.3)	18	0 (0.0)	16 (88.9)	2 (11.1)
	Day 43	28	5 (17.9)	20 (71.4)	3 (10.7)	20	0 (0.0)	17 (85.0)	3 (15.0)
	Day 85	26	3 (11.5)	21 (80.8)	2 (7.7)	13	0 (0.0)	10 (76.9)	3 (23.1)
	Day 127	15	3 (20.0)	11 (73.3)	1 (6.7)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	12	3 (25.0)	7 (58.3)	2 (16.7)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	12	3 (25.0)	9 (75.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	2 (16.7)	7 (58.3)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	3 (42.9)	2 (28.6)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	3 (50.0)	2 (33.3)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	2 (50.0)	1 (25.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	3 (13.0)	17 (73.9)	3 (13.0)	20	0 (0.0)	15 (75.0)	5 (25.0)
Prior nivolumab contained treatment									
yes									
	Day 15	31	0 (0.0)	25 (80.6)	6 (19.4)	13	2 (15.4)	10 (76.9)	1 (7.7)
	Day 43	30	2 (6.7)	24 (80.0)	4 (13.3)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 85	27	1 (3.7)	22 (81.5)	4 (14.8)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	26	1 (3.8)	21 (80.8)	4 (15.4)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	21	2 (9.5)	17 (81.0)	2 (9.5)	3	0 (0.0)	3 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	16	1 (6.3)	13 (81.3)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	14	0 (0.0)	12 (85.7)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	1 (8.3)	10 (83.3)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	0 (0.0)	9 (81.8)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	0 (0.0)	18 (69.2)	8 (30.8)	14	0 (0.0)	10 (71.4)	4 (28.6)
Prior nivolumab contained treatment									
no									
	Day 15	86	6 (7.0)	70 (81.4)	10 (11.6)	39	0 (0.0)	36 (92.3)	3 (7.7)
	Day 43	87	5 (5.7)	70 (80.5)	12 (13.8)	43	2 (4.7)	36 (83.7)	5 (11.6)
	Day 85	72	3 (4.2)	59 (81.9)	10 (13.9)	26	0 (0.0)	24 (92.3)	2 (7.7)
	Day 127	48	6 (12.5)	37 (77.1)	5 (10.4)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 169	36	3 (8.3)	28 (77.8)	5 (13.9)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	28	3 (10.7)	22 (78.6)	3 (10.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	23	3 (13.0)	16 (69.6)	4 (17.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	4 (23.5)	10 (58.8)	3 (17.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	4 (25.0)	9 (56.3)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	2 (18.2)	8 (72.7)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	70	3 (4.3)	52 (74.3)	15 (21.4)	42	0 (0.0)	34 (81.0)	8 (19.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	41	1 (2.4)	32 (78.0)	8 (19.5)	15	2 (13.3)	12 (80.0)	1 (6.7)
	Day 43	40	2 (5.0)	32 (80.0)	6 (15.0)	12	0 (0.0)	12 (100.0)	0 (0.0)
	Day 85	37	2 (5.4)	29 (78.4)	6 (16.2)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 127	31	3 (9.7)	22 (71.0)	6 (19.4)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	24	3 (12.5)	19 (79.2)	2 (8.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	20	3 (15.0)	15 (75.0)	2 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	17	2 (11.8)	13 (76.5)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	3 (18.8)	11 (68.8)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	2 (13.3)	10 (66.7)	3 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	12	1 (8.3)	8 (66.7)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	35	2 (5.7)	23 (65.7)	10 (28.6)	16	0 (0.0)	12 (75.0)	4 (25.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	76	5 (6.6)	63 (82.9)	8 (10.5)	37	0 (0.0)	34 (91.9)	3 (8.1)
	Day 43	77	5 (6.5)	62 (80.5)	10 (13.0)	41	2 (4.9)	34 (82.9)	5 (12.2)
	Day 85	62	2 (3.2)	52 (83.9)	8 (12.9)	25	0 (0.0)	23 (92.0)	2 (8.0)
	Day 127	43	4 (9.3)	36 (83.7)	3 (7.0)	15	0 (0.0)	14 (93.3)	1 (6.7)
	Day 169	33	2 (6.1)	26 (78.8)	5 (15.2)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	24	1 (4.2)	20 (83.3)	3 (12.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	1 (5.0)	15 (75.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	2 (15.4)	9 (69.2)	2 (15.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	9	1 (11.1)	7 (77.8)	1 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	61	1 (1.6)	47 (77.0)	13 (21.3)	40	0 (0.0)	32 (80.0)	8 (20.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
yes									
	Day 15	22	2 (9.1)	17 (77.3)	3 (13.6)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	19	0 (0.0)	18 (94.7)	1 (5.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 85	16	1 (6.3)	14 (87.5)	1 (6.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 127	12	1 (8.3)	10 (83.3)	1 (8.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	9	1 (11.1)	6 (66.7)	2 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	5	1 (20.0)	3 (60.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	1 (7.1)	11 (78.6)	2 (14.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
no									
	Day 15	95	4 (4.2)	78 (82.1)	13 (13.7)	46	1 (2.2)	41 (89.1)	4 (8.7)
	Day 43	98	7 (7.1)	76 (77.6)	15 (15.3)	47	2 (4.3)	40 (85.1)	5 (10.6)
	Day 85	83	3 (3.6)	67 (80.7)	13 (15.7)	31	0 (0.0)	27 (87.1)	4 (12.9)
	Day 127	62	6 (9.7)	48 (77.4)	8 (12.9)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	48	4 (8.3)	39 (81.3)	5 (10.4)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	39	3 (7.7)	32 (82.1)	4 (10.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	2 (6.1)	25 (75.8)	6 (18.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	4 (15.4)	18 (69.2)	4 (15.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	3 (12.5)	16 (66.7)	5 (20.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	18	1 (5.6)	13 (72.2)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	0 (0.0)	10 (76.9)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	2 (2.4)	59 (72.0)	21 (25.6)	50	0 (0.0)	38 (76.0)	12 (24.0)
Presence of liver metastasis at baseline									
yes									
	Day 15	63	6 (9.5)	48 (76.2)	9 (14.3)	27	1 (3.7)	24 (88.9)	2 (7.4)
	Day 43	64	3 (4.7)	53 (82.8)	8 (12.5)	28	1 (3.6)	24 (85.7)	3 (10.7)
	Day 85	51	3 (5.9)	41 (80.4)	7 (13.7)	16	0 (0.0)	14 (87.5)	2 (12.5)
	Day 127	37	6 (16.2)	27 (73.0)	4 (10.8)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	28	3 (10.7)	23 (82.1)	2 (7.1)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	20	2 (10.0)	17 (85.0)	1 (5.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	2 (10.5)	16 (84.2)	1 (5.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	2 (14.3)	11 (78.6)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	13	2 (15.4)	10 (76.9)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	1 (9.1)	10 (90.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	49	1 (2.0)	39 (79.6)	9 (18.4)	31	0 (0.0)	23 (74.2)	8 (25.8)
Presence of liver metastasis at baseline									
no									
	Day 15	54	0 (0.0)	47 (87.0)	7 (13.0)	25	1 (4.0)	22 (88.0)	2 (8.0)
	Day 43	53	4 (7.5)	41 (77.4)	8 (15.1)	25	1 (4.0)	22 (88.0)	2 (8.0)
	Day 85	48	1 (2.1)	40 (83.3)	7 (14.6)	20	0 (0.0)	18 (90.0)	2 (10.0)
	Day 127	37	1 (2.7)	31 (83.8)	5 (13.5)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 169	29	2 (6.9)	22 (75.9)	5 (17.2)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	24	2 (8.3)	18 (75.0)	4 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	1 (5.6)	12 (66.7)	5 (27.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	3 (20.0)	9 (60.0)	3 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	8 (57.1)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	5 (50.0)	4 (40.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	47	2 (4.3)	31 (66.0)	14 (29.8)	25	0 (0.0)	21 (84.0)	4 (16.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Renal impairment at baseline									
normal									
	Day 15	31	1 (3.2)	27 (87.1)	3 (9.7)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	33	2 (6.1)	28 (84.8)	3 (9.1)	12	0 (0.0)	10 (83.3)	2 (16.7)
	Day 85	26	0 (0.0)	23 (88.5)	3 (11.5)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	1 (5.3)	18 (94.7)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	17	0 (0.0)	17 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	13	1 (7.7)	9 (69.2)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	1 (4.2)	20 (83.3)	3 (12.5)	11	0 (0.0)	7 (63.6)	4 (36.4)
Renal impairment at baseline									
mild									
	Day 15	50	2 (4.0)	40 (80.0)	8 (16.0)	25	1 (4.0)	23 (92.0)	1 (4.0)
	Day 43	50	4 (8.0)	38 (76.0)	8 (16.0)	23	1 (4.3)	20 (87.0)	2 (8.7)
	Day 85	45	2 (4.4)	34 (75.6)	9 (20.0)	14	0 (0.0)	14 (100.0)	0 (0.0)
	Day 127	31	4 (12.9)	24 (77.4)	3 (9.7)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 169	23	3 (13.0)	15 (65.2)	5 (21.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	17	2 (11.8)	12 (70.6)	3 (17.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	13	2 (15.4)	10 (76.9)	1 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	9	3 (33.3)	5 (55.6)	1 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	4 (50.0)	2 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	6	1 (16.7)	3 (50.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	1 (2.3)	30 (68.2)	13 (29.5)	25	0 (0.0)	21 (84.0)	4 (16.0)
Renal impairment at baseline									
moderate									
	Day 15	36	3 (8.3)	28 (77.8)	5 (13.9)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 43	34	1 (2.9)	28 (82.4)	5 (14.7)	17	1 (5.9)	15 (88.2)	1 (5.9)
	Day 85	28	2 (7.1)	24 (85.7)	2 (7.1)	14	0 (0.0)	12 (85.7)	2 (14.3)
	Day 127	24	2 (8.3)	16 (66.7)	6 (25.0)	7	1 (14.3)	6 (85.7)	0 (0.0)
	Day 169	17	2 (11.8)	13 (76.5)	2 (11.8)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	15	1 (6.7)	14 (93.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	1 (3.6)	20 (71.4)	7 (25.0)	19	0 (0.0)	15 (78.9)	4 (21.1)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	82	3 (3.7)	67 (81.7)	12 (14.6)	37	1 (2.7)	33 (89.2)	3 (8.1)
	Day 43	83	4 (4.8)	68 (81.9)	11 (13.3)	41	1 (2.4)	36 (87.8)	4 (9.8)
	Day 85	76	3 (3.9)	62 (81.6)	11 (14.5)	27	0 (0.0)	24 (88.9)	3 (11.1)
	Day 127	58	6 (10.3)	45 (77.6)	7 (12.1)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 169	45	4 (8.9)	35 (77.8)	6 (13.3)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	34	3 (8.8)	28 (82.4)	3 (8.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	30	3 (10.0)	23 (76.7)	4 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	23	5 (21.7)	16 (69.6)	2 (8.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	4 (19.0)	14 (66.7)	3 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	2 (12.5)	12 (75.0)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	10 (90.9)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	66	3 (4.5)	44 (66.7)	19 (28.8)	42	0 (0.0)	33 (78.6)	9 (21.4)
Hepatic impairment at baseline									
mild									
	Day 15	34	3 (8.8)	27 (79.4)	4 (11.8)	15	1 (6.7)	13 (86.7)	1 (6.7)
	Day 43	33	3 (9.1)	25 (75.8)	5 (15.2)	12	1 (8.3)	10 (83.3)	1 (8.3)
	Day 85	22	1 (4.5)	18 (81.8)	3 (13.6)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 127	15	1 (6.7)	12 (80.0)	2 (13.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	7 (70.0)	2 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	7	0 (0.0)	5 (71.4)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	0 (0.0)	4 (66.7)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	0 (0.0)	4 (66.7)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	29	0 (0.0)	25 (86.2)	4 (13.8)	14	0 (0.0)	11 (78.6)	3 (21.4)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	0 (0.0)	6 (75.0)	2 (25.0)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	1 (12.5)	7 (87.5)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	0 (0.0)	6 (85.7)	1 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	0 (0.0)	6 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	0 (0.0)	4 (80.0)	1 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	6	0 (0.0)	4 (66.7)	2 (33.3)	4	0 (0.0)	3 (75.0)	1 (25.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	109	6 (5.5)	89 (81.7)	14 (12.8)	48	2 (4.2)	43 (89.6)	3 (6.3)
	Day 43	109	6 (5.5)	87 (79.8)	16 (14.7)	50	2 (4.0)	43 (86.0)	5 (10.0)
	Day 85	92	4 (4.3)	75 (81.5)	13 (14.1)	33	0 (0.0)	29 (87.9)	4 (12.1)
	Day 127	68	7 (10.3)	52 (76.5)	9 (13.2)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	52	5 (9.6)	41 (78.8)	6 (11.5)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	40	4 (10.0)	32 (80.0)	4 (10.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	3 (9.1)	26 (78.8)	4 (12.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	27	5 (18.5)	19 (70.4)	3 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	25	4 (16.0)	17 (68.0)	4 (16.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	20	2 (10.0)	15 (75.0)	3 (15.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	15	0 (0.0)	12 (80.0)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	90	3 (3.3)	66 (73.3)	21 (23.3)	52	0 (0.0)	41 (78.8)	11 (21.2)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	0 (0.0)	2 (66.7)	1 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	1 (50.0)	1 (50.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	114	6 (5.3)	92 (80.7)	16 (14.0)	49	2 (4.1)	43 (87.8)	4 (8.2)
	Day 43	114	7 (6.1)	91 (79.8)	16 (14.0)	50	2 (4.0)	43 (86.0)	5 (10.0)
	Day 85	96	4 (4.2)	78 (81.3)	14 (14.6)	33	0 (0.0)	29 (87.9)	4 (12.1)
	Day 127	71	7 (9.9)	55 (77.5)	9 (12.7)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	54	5 (9.3)	43 (79.6)	6 (11.1)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	42	4 (9.5)	33 (78.6)	5 (11.9)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	35	3 (8.6)	27 (77.1)	5 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	28	5 (17.9)	19 (67.9)	4 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	26	4 (15.4)	17 (65.4)	5 (19.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	21	2 (9.5)	15 (71.4)	4 (19.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	16	0 (0.0)	12 (75.0)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	94	3 (3.2)	69 (73.4)	22 (23.4)	53	0 (0.0)	41 (77.4)	12 (22.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Physical Well-being Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	125 (100.0)	62	59 (95.2)
Day 15	125	121 (96.8)	62	52 (83.9)
Day 43	124	118 (95.2)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	75 (67.6)	50	19 (38.0)
Day 169	105	57 (54.3)	45	11 (24.4)
Day 211	93	44 (47.3)	40	4 (10.0)
Day 253	84	37 (44.0)	34	2 (5.9)
Day 295	77	29 (37.7)	27	2 (7.4)
Day 337	70	27 (38.6)	21	2 (9.5)
Day 379	60	21 (35.0)	20	1 (5.0)
Day 421	50	16 (32.0)	15	0 (0.0)
Day 463	39	12 (30.8)	9	0 (0.0)
Day 505	30	8 (26.7)	9	0 (0.0)
Day 547	24	6 (25.0)	8	0 (0.0)
Day 589	17	5 (29.4)	5	0 (0.0)
Day 631	13	4 (30.8)	1	0 (0.0)
Day 673	9	2 (22.2)	1	0 (0.0)
Day 715	5	3 (60.0)	1	0 (0.0)
Day 757	5	3 (60.0)	1	0 (0.0)
Day 799	3	1 (33.3)	1	0 (0.0)
Day 841	2	1 (50.0)	0	0 (0.0)
Day 883	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Physical Well-being by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	125	20.4 (5.60)			59	21.4 (5.35)		
Day 15	121	19.2 (5.68)	121	-1.4 (5.82)	52	20.1 (5.84)	50	-1.6 (4.91)
Day 43	118	19.4 (6.11)	118	-1.2 (6.38)	53	20.3 (6.12)	51	-1.2 (5.92)
Day 85	99	19.8 (5.76)	99	-1.1 (5.52)	36	21.9 (5.08)	35	-0.8 (5.38)
Day 127	75	20.8 (4.80)	75	-0.7 (5.26)	19	21.5 (5.22)	19	-2.2 (4.08)
Day 169	57	21.1 (5.03)	57	-0.2 (4.09)	11	22.8 (5.29)	11	-2.4 (5.92)
Day 211	44	21.1 (4.38)	44	-0.6 (4.48)	4	26.0 (1.41)	4	-0.5 (1.00)
Day 253	37	20.7 (5.57)	37	-0.7 (5.24)	2	26.5 (2.12)	2	1.0 (2.83)
Day 295	29	21.8 (4.74)	29	-0.3 (5.46)	2	26.0 (1.41)	2	0.5 (2.12)
Day 337	27	21.1 (4.99)	27	-1.0 (6.24)	2	26.5 (0.71)	2	1.0 (0.00)
Day 379	21	21.1 (5.57)	21	-1.1 (5.74)	1	22.0 (-)	1	-4.0 (-)
Day 421	16	21.3 (5.99)	16	-1.2 (5.61)	0	-	0	-
Day 463	12	21.3 (4.99)	12	-0.7 (3.08)	0	-	0	-
Day 505	8	20.8 (5.82)	8	-1.6 (3.81)	0	-	0	-
Day 547	6	23.3 (2.42)	6	0.3 (2.94)	0	-	0	-
Day 589	5	20.6 (4.72)	5	-2.2 (3.49)	0	-	0	-
Day 631	4	20.0 (4.55)	4	-1.8 (4.86)	0	-	0	-
Day 673	2	19.0 (8.49)	2	-4.0 (8.49)	0	-	0	-
Day 715	3	21.7 (5.86)	3	-2.7 (4.73)	0	-	0	-
Day 757	3	20.3 (8.08)	3	-4.0 (7.21)	0	-	0	-
Day 799	1	15.0 (-)	1	-8.0 (-)	0	-	0	-
Day 841	1	13.0 (-)	1	-10.0 (-)	0	-	0	-
Day 883	1	14.0 (-)	1	-9.0 (-)	0	-	0	-
End of Treatment	98	17.4 (6.17)	98	-3.2 (6.42)	56	18.1 (6.96)	53	-3.4 (6.40)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Physical Well-being by Visit
Full Analysis Set

Visit	DS-8201a (N=125)			Phys. Choice (N=62)			Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
	N [a]	N_MISS [b]	LSMean (95% CI)	N [a]	N_MISS [b]	LSMean (95% CI)				
Day 15			-2.39 (-3.28, -1.51)			-2.13 (-3.48, -0.78)	-0.27 (-1.75, 1.22)	0.7229		
Day 43			-2.40 (-3.23, -1.56)			-2.18 (-3.40, -0.96)	-0.22 (-1.56, 1.12)	0.7464		
Day 85			-2.40 (-3.19, -1.62)			-2.26 (-3.47, -1.04)	-0.15 (-1.45, 1.15)	0.8226		
Day 127			-2.41 (-3.17, -1.65)			-2.33 (-3.76, -0.90)	-0.08 (-1.56, 1.41)	0.9199		
Day 169			-2.42 (-3.18, -1.65)			-2.41 (-4.20, -0.62)	-0.00 (-1.84, 1.83)	0.9965		
Day 211			-2.42 (-3.23, -1.62)			-2.49 (-4.71, -0.27)	0.07 (-2.20, 2.34)	0.9531		
Day 253			-2.43 (-3.30, -1.56)			-2.57 (-5.26, 0.13)	0.14 (-2.61, 2.89)	0.9204		
Day 295			-2.43 (-3.39, -1.48)			-2.64 (-5.83, 0.54)	0.21 (-3.04, 3.47)	0.8983		
Day 337			-2.44 (-3.49, -1.39)			-2.72 (-6.42, 0.97)	0.28 (-3.49, 4.06)	0.8827		
Day 379			-2.44 (-3.61, -1.28)			-2.80 (-7.01, 1.41)	0.36 (-3.95, 4.66)	0.8712		
Day 421			-2.45 (-3.73, -1.17)			-2.88 (-7.61, 1.85)	0.43 (-4.42, 5.27)	0.8624		
Day 463			-2.46 (-3.87, -1.05)			-2.96 (-8.21, 2.30)	0.50 (-4.89, 5.89)	0.8555		
OVERALL	124	1	-2.41 (-3.17, -1.65)	55	7	-2.37 (-3.94, -0.80)	-0.05 (-1.66, 1.57)	0.9558	-0.01 (-0.33, 0.31)	0.9537

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Physical Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0934
Japan	99	-1.47 (-2.15, -0.78)	46	-0.87 (-2.43, 0.68)	-0.59 (-2.30, 1.11)	0.4929	-0.14 (-0.49, 0.21)	0.4217	
Korea	25	-2.77 (-4.40, -1.13)	9	-6.47 (-11.39, -1.55)	3.70 (-1.48, 8.89)	0.1585	0.73 (-0.05, 1.51)	0.0675	
Lines of prior systemic therapy									0.8154
2	65	-1.76 (-2.57, -0.95)	35	-1.79 (-3.37, -0.22)	0.03 (-1.75, 1.81)	0.9728	0.01 (-0.40, 0.42)	0.9696	
3	34	-0.75 (-2.21, 0.72)	16	-1.55 (-4.58, 1.49)	0.80 (-2.58, 4.18)	0.6382	0.16 (-0.43, 0.76)	0.5897	
>=4	25	-3.00 (-4.56, -1.44)	4	1.72 (-6.38, 9.82)	-4.73 (-12.99, 3.53)	0.2579	-1.05 (-2.14, 0.04)	0.0582	
Age									0.4594
<65 years	54	-1.32 (-2.20, -0.43)	25	-1.44 (-4.02, 1.13)	0.12 (-2.61, 2.85)	0.9283	0.03 (-0.45, 0.50)	0.9097	
>=65 years	70	-2.05 (-2.99, -1.12)	30	-1.77 (-3.75, 0.22)	-0.29 (-2.49, 1.91)	0.7958	-0.06 (-0.49, 0.36)	0.7670	
Sex									0.8509
female	29	-1.90 (-3.42, -0.38)	13	-1.79 (-5.28, 1.70)	-0.11 (-3.93, 3.71)	0.9556	-0.02 (-0.68, 0.63)	0.9472	
male	95	-1.70 (-2.42, -0.97)	42	-1.57 (-3.26, 0.12)	-0.13 (-1.97, 1.71)	0.8911	-0.03 (-0.39, 0.33)	0.8712	
ECOG PS									0.9756
0	62	-1.31 (-2.10, -0.53)	27	-1.90 (-4.11, 0.31)	0.59 (-1.77, 2.94)	0.6240	0.14 (-0.31, 0.59)	0.5372	
1	62	-2.22 (-3.25, -1.19)	28	-1.44 (-3.40, 0.52)	-0.78 (-2.99, 1.43)	0.4860	-0.17 (-0.62, 0.27)	0.4432	
HER2 Status in central laboratory									0.1943
IHC 3+	96	-1.53 (-2.25, -0.80)	42	-1.66 (-3.50, 0.17)	0.14 (-1.84, 2.11)	0.8919	0.03 (-0.33, 0.39)	0.8687	
IHC 2+/ISH +	28	-2.58 (-4.05, -1.10)	13	-0.96 (-3.42, 1.50)	-1.61 (-4.48, 1.25)	0.2621	-0.40 (-1.06, 0.26)	0.2364	
Primary tumor location									0.6998
Gastric	107	-1.77 (-2.47, -1.06)	50	-1.54 (-3.12, 0.04)	-0.22 (-1.96, 1.51)	0.8002	-0.05 (-0.39, 0.29)	0.7679	
GEJ	17	-1.44 (-2.96, 0.08)	5	-2.10 (-7.93, 3.72)	0.66 (-5.35, 6.67)	0.8268	0.17 (-0.83, 1.16)	0.7436	
Histological subtype									0.6122
intestinal	89	-1.49 (-2.19, -0.78)	36	-1.13 (-2.78, 0.52)	-0.36 (-2.16, 1.44)	0.6940	-0.09 (-0.48, 0.30)	0.6414	
diffuse	28	-2.56 (-4.28, -0.84)	14	-2.32 (-6.77, 2.13)	-0.24 (-5.01, 4.53)	0.9207	-0.04 (-0.68, 0.60)	0.9035	
others	7	-1.90 (-5.07, 1.26)	5	-0.54 (-6.58, 5.49)	-1.36 (-8.22, 5.50)	0.6753	-0.28 (-1.43, 0.87)	0.6362	
Number of metastatic sites									0.3840
<2	23	-2.39 (-3.78, -1.00)	10	-0.56 (-3.60, 2.47)	-1.83 (-5.17, 1.52)	0.2767	-0.49 (-1.24, 0.27)	0.2057	
>= 2	101	-1.55 (-2.28, -0.81)	45	-2.08 (-3.86, -0.29)	0.53 (-1.41, 2.47)	0.5903	0.12 (-0.24, 0.47)	0.5191	
Previous total gastrectomy									0.0190
yes	22	-2.23 (-3.68, -0.78)	8	1.14 (-4.29, 6.57)	-3.37 (-8.98, 2.24)	0.2353	-0.70 (-1.53, 0.13)	0.0968	
no	102	-1.58 (-2.26, -0.90)	47	-2.02 (-3.56, -0.48)	0.44 (-1.25, 2.13)	0.6104	0.11 (-0.24, 0.45)	0.5517	
Prior adjuvant/ neoadjuvant therapy									0.1063
yes	30	-1.80 (-2.82, -0.79)	8	1.02 (-2.93, 4.97)	-2.82 (-6.90, 1.26)	0.1730	-0.80 (-1.60, -0.00)	0.0491	
no	94	-1.66 (-2.42, -0.91)	47	-2.04 (-3.62, -0.47)	0.38 (-1.38, 2.14)	0.6711	0.09 (-0.26, 0.44)	0.6274	
Prior ramucirumab contained treatment									0.9085
yes	93	-1.80 (-2.49, -1.11)	36	-1.59 (-3.66, 0.49)	-0.21 (-2.41, 1.98)	0.8473	-0.05 (-0.43, 0.34)	0.8036	
no	31	-1.63 (-3.22, -0.03)	19	-1.02 (-3.44, 1.40)	-0.61 (-3.54, 2.33)	0.6810	-0.13 (-0.70, 0.44)	0.6620	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

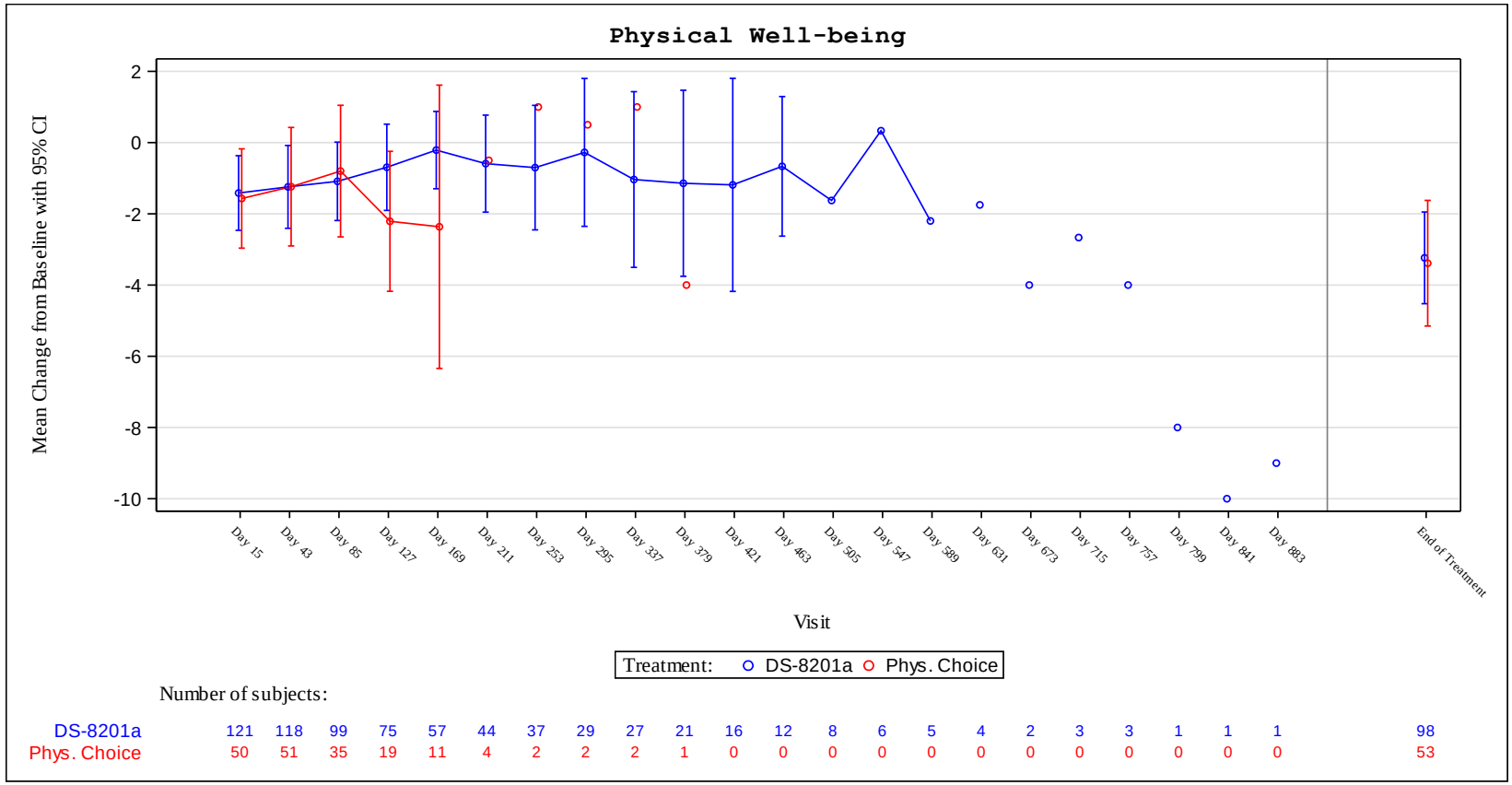
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Physical Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.8420
yes	33	-2.25 (-3.59, -0.91)	12	-2.13 (-5.79, 1.53)	-0.12 (-4.01, 3.77)	0.9515	-0.03 (-0.69, 0.63)	0.9386	
no	91	-1.58 (-2.33, -0.83)	43	-1.33 (-2.95, 0.29)	-0.25 (-2.05, 1.54)	0.7799	-0.06 (-0.42, 0.30)	0.7466	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.4852
yes	44	-2.44 (-3.60, -1.28)	13	-1.59 (-5.08, 1.91)	-0.85 (-4.54, 2.83)	0.6470	-0.19 (-0.81, 0.43)	0.5490	
no	80	-1.37 (-2.16, -0.59)	42	-1.35 (-2.91, 0.22)	-0.03 (-1.79, 1.74)	0.9762	-0.01 (-0.38, 0.37)	0.9731	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.0567
yes	22	-0.96 (-2.55, 0.63)	6	0.58 (-3.21, 4.36)	-1.54 (-5.74, 2.67)	0.4589	-0.41 (-1.32, 0.50)	0.3792	
no	102	-1.79 (-2.48, -1.11)	49	-2.05 (-3.69, -0.42)	0.26 (-1.51, 2.04)	0.7718	0.06 (-0.28, 0.40)	0.7311	
Presence of liver metastasis at baseline									0.3686
yes	68	-1.01 (-1.89, -0.14)	30	-2.12 (-4.24, 0.01)	1.10 (-1.21, 3.41)	0.3484	0.25 (-0.18, 0.68)	0.2607	
no	56	-2.48 (-3.42, -1.54)	25	-1.12 (-3.29, 1.04)	-1.35 (-3.72, 1.01)	0.2595	-0.32 (-0.79, 0.15)	0.1853	
Renal impairment at baseline									0.0995
normal	33	-1.99 (-3.04, -0.94)	12	-6.64 (-12.87, -0.41)	4.65 (-1.67, 10.97)	0.1484	0.76 (0.08, 1.44)	0.0283	
mild	53	-0.99 (-2.05, 0.08)	25	-0.14 (-2.08, 1.79)	-0.84 (-3.07, 1.39)	0.4541	-0.20 (-0.68, 0.28)	0.4115	
moderate	38	-2.51 (-3.72, -1.31)	17	-2.35 (-4.92, 0.22)	-0.17 (-3.01, 2.67)	0.9067	-0.04 (-0.61, 0.53)	0.8926	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.1906
normal	87	-1.60 (-2.35, -0.86)	40	-2.61 (-4.34, -0.88)	1.01 (-0.88, 2.90)	0.2951	0.24 (-0.14, 0.61)	0.2176	
mild	36	-2.14 (-3.44, -0.85)	15	1.06 (-2.07, 4.20)	-3.21 (-6.63, 0.21)	0.0657	-0.70 (-1.31, -0.08)	0.0272	
moderate	1	0.32 (NE, NE)	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.3965
yes	8	-2.79 (-4.37, -1.22)	4	-0.17 (-3.40, 3.06)	-2.62 (-6.35, 1.11)	0.1521	-1.12 (-2.40, 0.16)	0.0871	
no	116	-1.62 (-2.29, -0.95)	51	-1.75 (-3.41, -0.08)	0.12 (-1.67, 1.92)	0.8914	0.03 (-0.30, 0.36)	0.8694	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.5819
yes	3	-1.45 (-6.26, 3.36)	3	-1.33 (-6.25, 3.59)	-0.12 (-7.63, 7.39)	0.9553	-0.06 (-1.66, 1.54)	0.9449	
no	121	-1.71 (-2.37, -1.05)	52	-1.77 (-3.52, -0.03)	0.06 (-1.81, 1.93)	0.9517	0.01 (-0.31, 0.34)	0.9406	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Graphical Summary of Physical Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	66 (52.8)	23 (37.1)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	4.4 (2.8, 8.5)	5.4 (1.6, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.15 (0.71, 1.86)	
p-value [c]	0.5708	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.18 (0.73, 1.91)	
p-value [c]	0.5087	

Time to Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.7583
Japan	51/ 99 (51.5)	5.5 (2.8, 9.8)	18/ 50 (36.0)	NE (1.9, NE)	1.20 (0.70, 2.07)	0.5136	
Korea	15/ 26 (57.7)	1.6 (0.6, NE)	5/ 12 (41.7)	3.4 (0.5, NE)	0.99 (0.36, 2.77)	0.9664	
Lines of prior systemic therapy							0.1323
2	40/ 66 (60.6)	2.9 (1.4, 5.5)	14/ 38 (36.8)	5.4 (1.6, NE)	1.58 (0.86, 2.91)	0.1420	
3	13/ 34 (38.2)	NE (4.0, NE)	6/ 18 (33.3)	NE (1.4, NE)	0.88 (0.33, 2.37)	0.7888	
>=4	13/ 25 (52.0)	6.9 (0.8, NE)	3/ 6 (50.0)	0.6 (0.5, NE)	0.45 (0.12, 1.60)	0.1879	
Age							0.3502
<65 years	29/ 55 (52.7)	5.7 (1.4, NE)	12/ 27 (44.4)	1.9 (1.4, NE)	0.96 (0.48, 1.92)	0.8925	
>=65 years	37/ 70 (52.9)	4.3 (1.7, 6.9)	11/ 35 (31.4)	5.4 (2.6, NE)	1.44 (0.73, 2.83)	0.2835	
Sex							0.9099
female	16/ 30 (53.3)	4.4 (1.4, 9.8)	5/ 15 (33.3)	NE (0.9, NE)	1.16 (0.42, 3.26)	0.7858	
male	50/ 95 (52.6)	4.8 (1.7, 8.5)	18/ 47 (38.3)	5.4 (1.6, NE)	1.18 (0.69, 2.03)	0.5583	
ECOG PS							0.8397
0	32/ 62 (51.6)	5.7 (2.9, NE)	10/ 30 (33.3)	5.4 (1.6, NE)	1.20 (0.59, 2.46)	0.6235	
1	34/ 63 (54.0)	3.1 (1.4, 8.5)	13/ 32 (40.6)	4.3 (1.4, NE)	1.19 (0.63, 2.27)	0.6114	
HER2 Status in central laboratory							0.4061
IHC 3+	50/ 96 (52.1)	4.4 (1.8, 9.8)	19/ 47 (40.4)	4.3 (1.6, NE)	1.07 (0.63, 1.83)	0.8203	
IHC 2+/ISH +	16/ 29 (55.2)	4.0 (1.4, 5.7)	4/ 15 (26.7)	NE (0.6, NE)	1.70 (0.56, 5.13)	0.3351	
Primary tumor location							0.1622
Gastric	58/108 (53.7)	4.3 (1.7, 6.9)	20/ 55 (36.4)	5.4 (1.9, NE)	1.31 (0.78, 2.18)	0.3104	
GEJ	8/ 17 (47.1)	NE (0.6, NE)	3/ 7 (42.9)	1.6 (0.5, NE)	0.46 (0.11, 1.96)	0.2788	
Histological subtype							0.8571
intestinal	47/ 89 (52.8)	4.8 (2.8, 8.5)	14/ 38 (36.8)	5.4 (1.6, NE)	1.22 (0.67, 2.24)	0.5136	
diffuse	16/ 28 (57.1)	1.7 (1.2, NE)	7/ 18 (38.9)	1.5 (0.6, NE)	1.02 (0.41, 2.50)	0.9818	
others	3/ 8 (37.5)	NE (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.65 (0.27, 10.04)	0.5796	
Number of metastatic sites							0.0588
<2	15/ 23 (65.2)	1.8 (0.5, NE)	2/ 10 (20.0)	NE (0.6, NE)	4.30 (0.98, 18.81)	0.0357	
>= 2	51/102 (50.0)	5.5 (2.9, 9.8)	21/ 52 (40.4)	4.3 (1.5, NE)	0.90 (0.54, 1.51)	0.6766	
Previous total gastrectomy							0.7922
yes	8/ 22 (36.4)	NE (1.6, NE)	2/ 9 (22.2)	NE (0.7, NE)	1.45 (0.31, 6.85)	0.6298	
no	58/103 (56.3)	4.3 (1.7, 6.9)	21/ 53 (39.6)	4.3 (1.6, NE)	1.16 (0.70, 1.93)	0.5631	
Prior adjuvant/ neoadjuvant therapy							0.5184
yes	14/ 30 (46.7)	6.9 (1.7, NE)	2/ 10 (20.0)	NE (0.6, NE)	1.83 (0.41, 8.12)	0.4183	
no	52/ 95 (54.7)	4.3 (1.5, 8.5)	21/ 52 (40.4)	4.3 (1.6, NE)	1.15 (0.69, 1.91)	0.6184	
Prior ramucirumab contained treatment							0.6493
yes	50/ 94 (53.2)	4.0 (1.7, 6.9)	16/ 41 (39.0)	5.4 (1.4, NE)	1.09 (0.62, 1.93)	0.7805	
no	16/ 31 (51.6)	5.7 (1.4, NE)	7/ 21 (33.3)	NE (1.5, NE)	1.31 (0.53, 3.23)	0.5518	
Prior nivolumab contained treatment							0.6118
yes	19/ 33 (57.6)	4.4 (0.6, NE)	6/ 15 (40.0)	2.6 (0.6, NE)	1.08 (0.42, 2.73)	0.8764	
no	47/ 92 (51.1)	4.8 (2.8, 8.5)	17/ 47 (36.2)	5.4 (1.6, NE)	1.22 (0.70, 2.13)	0.4876	

Time to Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

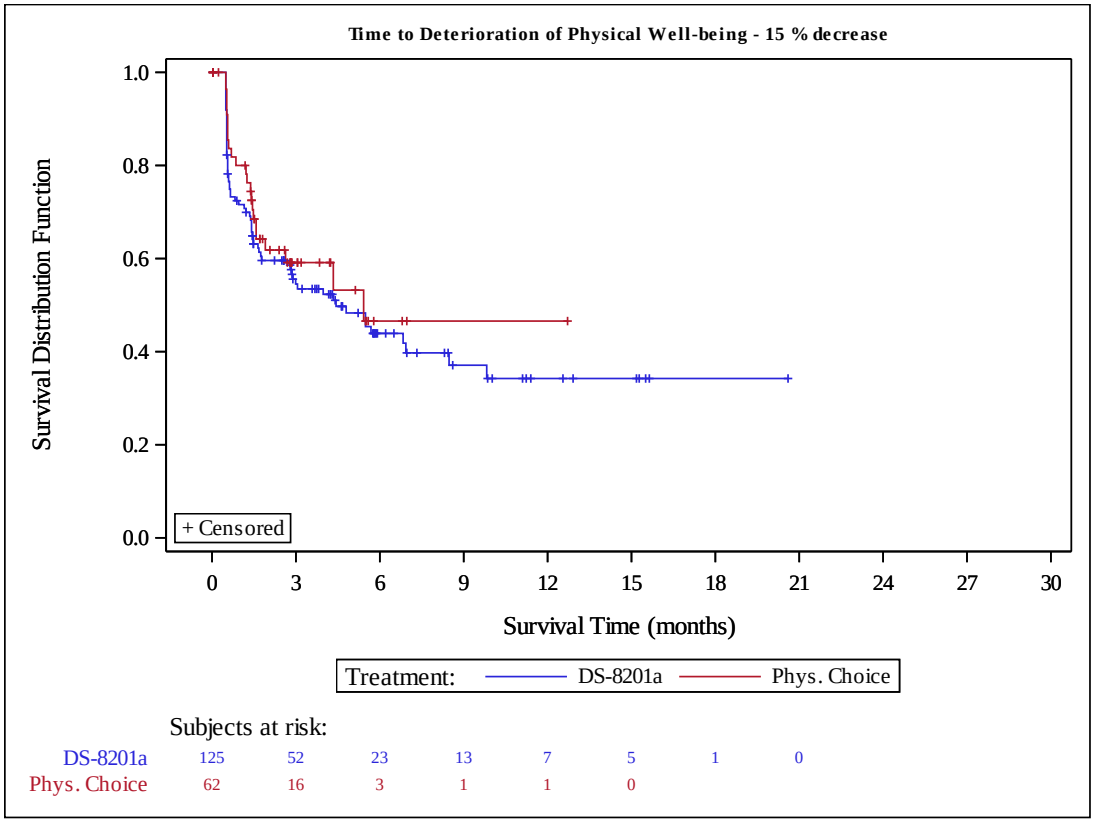
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7050
yes	24/ 44 (54.5)	4.4 (0.7, NE)	6/ 17 (35.3)	NE (0.6, NE)	1.14 (0.46, 2.81)	0.7814	
no	42/ 81 (51.9)	4.8 (2.8, 8.5)	17/ 45 (37.8)	5.4 (1.6, NE)	1.20 (0.68, 2.11)	0.5369	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9806
yes	11/ 22 (50.0)	5.7 (0.6, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	55/103 (53.4)	4.3 (1.7, 6.9)	23/ 55 (41.8)	4.3 (1.5, NE)	1.02 (0.62, 1.66)	0.9610	
Presence of liver metastasis at baseline							0.7517
yes	33/ 68 (48.5)	6.8 (1.7, NE)	12/ 34 (35.3)	4.3 (1.6, NE)	1.07 (0.54, 2.09)	0.8597	
no	33/ 57 (57.9)	4.3 (1.4, 6.9)	11/ 28 (39.3)	NE (1.2, NE)	1.31 (0.66, 2.60)	0.4408	
Renal impairment at baseline							0.4189
normal	19/ 33 (57.6)	2.8 (1.2, NE)	7/ 13 (53.8)	1.6 (0.5, NE)	0.81 (0.34, 1.96)	0.6395	
mild	24/ 53 (45.3)	6.8 (3.1, NE)	7/ 28 (25.0)	NE (4.3, NE)	1.47 (0.63, 3.43)	0.3738	
moderate	23/ 39 (59.0)	2.9 (0.6, 5.5)	8/ 20 (40.0)	5.4 (0.6, NE)	1.41 (0.63, 3.18)	0.4051	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.9 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.5228
normal	47/ 88 (53.4)	5.5 (2.9, 8.5)	17/ 47 (36.2)	5.4 (1.6, NE)	1.05 (0.60, 1.85)	0.8710	
mild	19/ 36 (52.8)	1.7 (0.6, NE)	6/ 15 (40.0)	NE (0.6, NE)	1.59 (0.64, 4.00)	0.3226	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8259
yes	5/ 8 (62.5)	3.1 (0.5, NE)	2/ 5 (40.0)	NE (0.5, NE)	1.22 (0.23, 6.38)	0.8159	
no	61/117 (52.1)	4.4 (1.8, 8.5)	21/ 57 (36.8)	5.4 (1.9, NE)	1.16 (0.70, 1.91)	0.5760	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.5410
yes	2/ 3 (66.7)	5.7 (0.5, NE)	1/ 4 (25.0)	NE (1.6, NE)	1.88 (0.16, 21.86)	0.6076	
no	64/122 (52.5)	4.4 (1.8, 8.5)	22/ 58 (37.9)	5.4 (1.6, NE)	1.13 (0.69, 1.84)	0.6498	

Time to Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	52 (41.6)	21 (33.9)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	8.4 (5.7, NE)	5.4 (4.2, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.72 (0.42, 1.21)	
p-value [c]	0.2166	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.76 (0.45, 1.28)	
p-value [c]	0.2978	

Time to Definitive Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.8847
Japan	37/ 99 (37.4)	16.7 (5.7, NE)	16/ 50 (32.0)	NE (4.2, NE)	0.75 (0.41, 1.37)	0.3553	
Korea	15/ 26 (57.7)	5.9 (1.4, 8.5)	5/ 12 (41.7)	3.4 (0.5, NE)	0.62 (0.21, 1.80)	0.3708	
Lines of prior systemic therapy							0.4779
2	30/ 66 (45.5)	7.2 (4.3, 9.8)	13/ 38 (34.2)	5.4 (4.2, NE)	0.92 (0.47, 1.78)	0.8057	
3	11/ 34 (32.4)	16.7 (5.5, NE)	6/ 18 (33.3)	NE (1.4, NE)	0.37 (0.12, 1.15)	0.0757	
>=4	11/ 25 (44.0)	7.0 (1.0, NE)	2/ 6 (33.3)	NE (0.5, NE)	0.68 (0.15, 3.11)	0.6133	
Age							0.8093
<65 years	23/ 55 (41.8)	8.5 (5.5, NE)	10/ 27 (37.0)	4.3 (1.9, NE)	0.72 (0.33, 1.56)	0.3867	
>=65 years	29/ 70 (41.4)	8.4 (4.8, NE)	11/ 35 (31.4)	5.4 (2.6, NE)	0.79 (0.39, 1.61)	0.5329	
Sex							0.6847
female	14/ 30 (46.7)	8.4 (2.9, NE)	5/ 15 (33.3)	4.2 (1.6, NE)	0.92 (0.32, 2.65)	0.8654	
male	38/ 95 (40.0)	8.5 (5.7, NE)	16/ 47 (34.0)	5.4 (2.6, NE)	0.72 (0.39, 1.31)	0.2789	
ECOG PS							0.6305
0	22/ 62 (35.5)	16.7 (7.0, NE)	9/ 30 (30.0)	5.4 (4.2, NE)	0.68 (0.30, 1.50)	0.3333	
1	30/ 63 (47.6)	5.5 (4.1, 8.5)	12/ 32 (37.5)	4.3 (1.4, NE)	0.85 (0.43, 1.70)	0.6592	
HER2 Status in central laboratory							0.1484
IHC 3+	38/ 96 (39.6)	16.7 (5.5, NE)	18/ 47 (38.3)	4.3 (2.1, NE)	0.65 (0.37, 1.16)	0.1448	
IHC 2+/ISH +	14/ 29 (48.3)	5.9 (4.1, 8.4)	3/ 15 (20.0)	NE (0.7, NE)	1.24 (0.33, 4.60)	0.7512	
Primary tumor location							0.8069
Gastric	46/108 (42.6)	8.4 (5.5, 16.7)	19/ 55 (34.5)	NE (2.6, NE)	0.77 (0.44, 1.33)	0.3485	
GEJ	6/ 17 (35.3)	NE (1.5, NE)	2/ 7 (28.6)	4.3 (4.2, NE)	0.72 (0.14, 3.76)	0.7004	
Histological subtype							0.9178
intestinal	36/ 89 (40.4)	8.5 (5.5, NE)	13/ 38 (34.2)	5.4 (4.2, NE)	0.71 (0.37, 1.36)	0.3097	
diffuse	13/ 28 (46.4)	7.0 (1.4, NE)	6/ 18 (33.3)	NE (0.7, NE)	0.80 (0.29, 2.20)	0.6584	
others	3/ 8 (37.5)	NE (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.65 (0.27, 10.04)	0.5796	
Number of metastatic sites							0.1945
<2	11/ 23 (47.8)	8.4 (3.0, NE)	2/ 10 (20.0)	NE (0.6, NE)	1.98 (0.43, 9.04)	0.3699	
>= 2	41/102 (40.2)	8.4 (5.5, NE)	19/ 52 (36.5)	4.3 (2.6, NE)	0.63 (0.36, 1.11)	0.1028	
Previous total gastrectomy							0.6442
yes	7/ 22 (31.8)	NE (4.0, NE)	2/ 9 (22.2)	NE (0.7, NE)	1.16 (0.24, 5.65)	0.8526	
no	45/103 (43.7)	8.4 (5.7, NE)	19/ 53 (35.8)	4.3 (2.6, NE)	0.71 (0.41, 1.24)	0.2344	
Prior adjuvant/ neoadjuvant therapy							0.5214
yes	11/ 30 (36.7)	7.0 (4.0, NE)	2/ 10 (20.0)	NE (0.6, NE)	1.21 (0.26, 5.55)	0.7999	
no	41/ 95 (43.2)	8.4 (5.5, NE)	19/ 52 (36.5)	4.3 (2.6, NE)	0.71 (0.40, 1.24)	0.2259	
Prior ramucirumab contained treatment							0.7477
yes	39/ 94 (41.5)	8.3 (4.8, NE)	14/ 41 (34.1)	5.4 (2.1, NE)	0.74 (0.40, 1.39)	0.3459	
no	13/ 31 (41.9)	8.5 (4.3, NE)	7/ 21 (33.3)	4.3 (1.5, NE)	0.79 (0.31, 2.03)	0.6393	
Prior nivolumab contained treatment							0.0851
yes	13/ 33 (39.4)	16.7 (4.4, NE)	6/ 15 (40.0)	2.6 (0.6, NE)	0.42 (0.15, 1.20)	0.0957	
no	39/ 92 (42.4)	8.4 (4.8, NE)	15/ 47 (31.9)	5.4 (4.2, NE)	0.94 (0.51, 1.72)	0.8459	

Time to Definitive Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

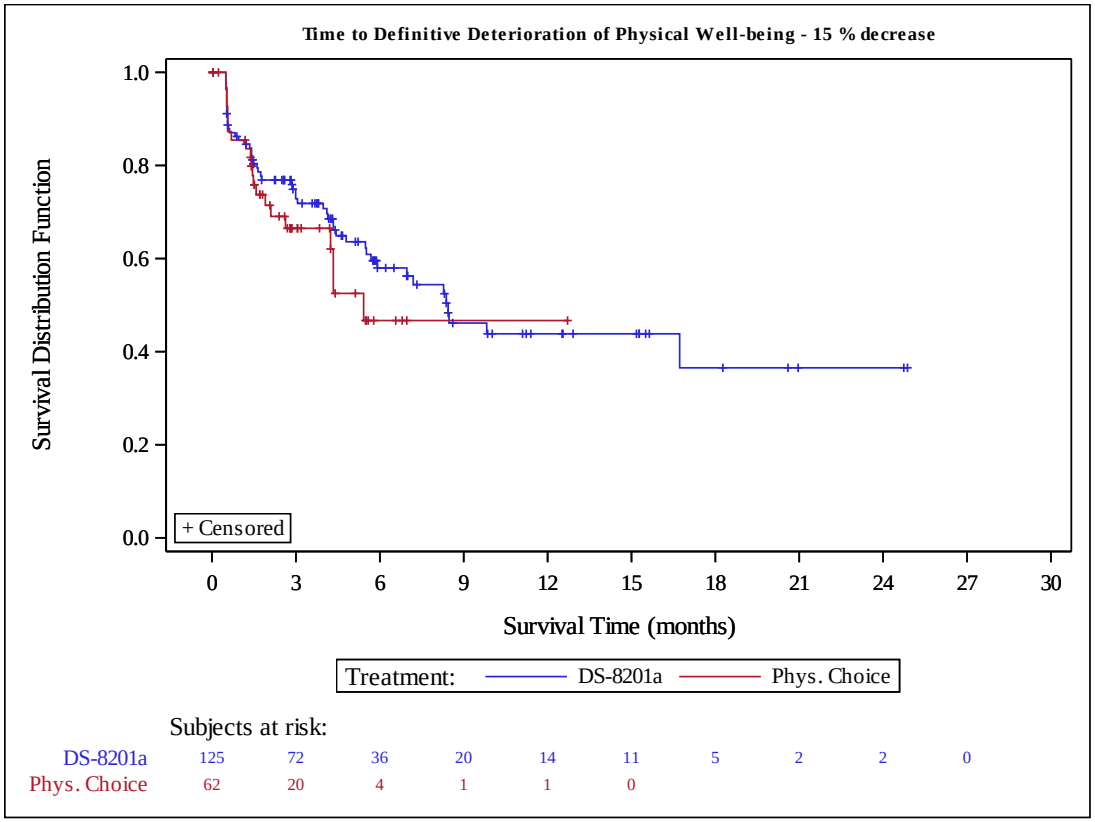
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.2103
yes	18/ 44 (40.9)	16.7 (4.4, NE)	6/ 17 (35.3)	NE (0.6, NE)	0.59 (0.22, 1.54)	0.2720	
no	34/ 81 (42.0)	7.2 (4.8, NE)	15/ 45 (33.3)	5.4 (4.2, NE)	0.87 (0.47, 1.61)	0.6577	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9841
yes	8/ 22 (36.4)	8.5 (1.8, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	44/103 (42.7)	8.4 (5.5, NE)	21/ 55 (38.2)	4.3 (2.1, NE)	0.65 (0.38, 1.11)	0.1096	
Presence of liver metastasis at baseline							0.2861
yes	25/ 68 (36.8)	9.8 (5.5, NE)	12/ 34 (35.3)	4.3 (2.6, NE)	0.57 (0.28, 1.17)	0.1215	
no	27/ 57 (47.4)	7.2 (4.3, NE)	9/ 28 (32.1)	NE (1.9, NE)	1.03 (0.48, 2.21)	0.9461	
Renal impairment at baseline							0.2234
normal	14/ 33 (42.4)	9.8 (3.0, NE)	7/ 13 (53.8)	4.2 (0.5, 4.3)	0.47 (0.18, 1.21)	0.1040	
mild	18/ 53 (34.0)	NE (5.7, NE)	7/ 28 (25.0)	NE (4.3, NE)	0.90 (0.37, 2.19)	0.8171	
moderate	20/ 39 (51.3)	5.5 (4.1, 8.5)	6/ 20 (30.0)	NE (1.4, NE)	1.02 (0.40, 2.63)	0.9549	
severe	0	NE (NE , NE)	1/ 1 (100.0)	2.1 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8432
normal	37/ 88 (42.0)	8.5 (5.7, NE)	15/ 47 (31.9)	5.4 (4.2, NE)	0.72 (0.39, 1.34)	0.2976	
mild	15/ 36 (41.7)	7.0 (2.9, NE)	6/ 15 (40.0)	NE (0.6, NE)	0.84 (0.32, 2.22)	0.7120	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8411
yes	4/ 8 (50.0)	8.4 (0.5, NE)	2/ 5 (40.0)	NE (0.5, NE)	0.83 (0.15, 4.60)	0.8314	
no	48/117 (41.0)	8.4 (5.5, NE)	19/ 57 (33.3)	5.4 (2.6, NE)	0.75 (0.43, 1.31)	0.3098	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.4976
yes	2/ 3 (66.7)	8.4 (5.7, NE)	1/ 4 (25.0)	NE (4.3, NE)	1.14 (0.10, 13.27)	0.9183	
no	50/122 (41.0)	8.4 (5.5, NE)	20/ 58 (34.5)	5.4 (2.6, NE)	0.73 (0.42, 1.24)	0.2390	

Time to Definitive Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	121	15 (12.4)	71 (58.7)	35 (28.9)	52	3 (5.8)	38 (73.1)	11 (21.2)
	Day 43	118	16 (13.6)	73 (61.9)	29 (24.6)	53	6 (11.3)	34 (64.2)	13 (24.5)
	Day 85	99	11 (11.1)	69 (69.7)	19 (19.2)	36	4 (11.1)	27 (75.0)	5 (13.9)
	Day 127	75	10 (13.3)	51 (68.0)	14 (18.7)	19	1 (5.3)	13 (68.4)	5 (26.3)
	Day 169	57	4 (7.0)	44 (77.2)	9 (15.8)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 211	44	5 (11.4)	30 (68.2)	9 (20.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	37	4 (10.8)	23 (62.2)	10 (27.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	29	3 (10.3)	20 (69.0)	6 (20.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	27	3 (11.1)	18 (66.7)	6 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	21	2 (9.5)	14 (66.7)	5 (23.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	1 (6.3)	11 (68.8)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	0 (0.0)	10 (83.3)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	98	8 (8.2)	53 (54.1)	37 (37.8)	56	3 (5.4)	35 (62.5)	18 (32.1)
Region									
Japan									
	Day 15	98	12 (12.2)	59 (60.2)	27 (27.6)	45	3 (6.7)	33 (73.3)	9 (20.0)
	Day 43	94	15 (16.0)	60 (63.8)	19 (20.2)	43	5 (11.6)	29 (67.4)	9 (20.9)
	Day 85	77	9 (11.7)	56 (72.7)	12 (15.6)	32	3 (9.4)	25 (78.1)	4 (12.5)
	Day 127	61	7 (11.5)	44 (72.1)	10 (16.4)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	49	4 (8.2)	37 (75.5)	8 (16.3)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	36	4 (11.1)	24 (66.7)	8 (22.2)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	29	4 (13.8)	20 (69.0)	5 (17.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	23	2 (8.7)	16 (69.6)	5 (21.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	21	2 (9.5)	15 (71.4)	4 (19.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	18	2 (11.1)	12 (66.7)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	0 (0.0)	9 (90.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	6 (7.6)	48 (60.8)	25 (31.6)	48	3 (6.3)	32 (66.7)	13 (27.1)
Region									
Korea									
	Day 15	23	3 (13.0)	12 (52.2)	8 (34.8)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 43	24	1 (4.2)	13 (54.2)	10 (41.7)	10	1 (10.0)	5 (50.0)	4 (40.0)
	Day 85	22	2 (9.1)	13 (59.1)	7 (31.8)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 127	14	3 (21.4)	7 (50.0)	4 (28.6)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	8	0 (0.0)	7 (87.5)	1 (12.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	0 (0.0)	3 (37.5)	5 (62.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	19	2 (10.5)	5 (26.3)	12 (63.2)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy 2									
	Day 15	62	4 (6.5)	39 (62.9)	19 (30.6)	34	2 (5.9)	26 (76.5)	6 (17.6)
	Day 43	62	7 (11.3)	39 (62.9)	16 (25.8)	36	3 (8.3)	24 (66.7)	9 (25.0)
	Day 85	50	4 (8.0)	32 (64.0)	14 (28.0)	21	2 (9.5)	17 (81.0)	2 (9.5)
	Day 127	34	4 (11.8)	21 (61.8)	9 (26.5)	14	0 (0.0)	10 (71.4)	4 (28.6)
	Day 169	24	2 (8.3)	18 (75.0)	4 (16.7)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	21	3 (14.3)	16 (76.2)	2 (9.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	11 (61.1)	5 (27.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	2 (18.2)	7 (63.6)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	1 (14.3)	6 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	52	3 (5.8)	27 (51.9)	22 (42.3)	34	1 (2.9)	22 (64.7)	11 (32.4)
Lines of prior systemic therapy 3									
	Day 15	34	7 (20.6)	20 (58.8)	7 (20.6)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 43	33	4 (12.1)	23 (69.7)	6 (18.2)	14	2 (14.3)	8 (57.1)	4 (28.6)
	Day 85	28	5 (17.9)	22 (78.6)	1 (3.6)	12	2 (16.7)	7 (58.3)	3 (25.0)
	Day 127	23	4 (17.4)	16 (69.6)	3 (13.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	19	1 (5.3)	13 (68.4)	5 (26.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	13	2 (15.4)	9 (69.2)	2 (15.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	2 (18.2)	7 (63.6)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	9	1 (11.1)	7 (77.8)	1 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	4 (15.4)	14 (53.8)	8 (30.8)	17	2 (11.8)	10 (58.8)	5 (29.4)
Lines of prior systemic therapy >=4									
	Day 15	25	4 (16.0)	12 (48.0)	9 (36.0)	4	0 (0.0)	1 (25.0)	3 (75.0)
	Day 43	23	5 (21.7)	11 (47.8)	7 (30.4)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	21	2 (9.5)	15 (71.4)	4 (19.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	2 (11.1)	14 (77.8)	2 (11.1)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 169	14	1 (7.1)	13 (92.9)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	0 (0.0)	5 (50.0)	5 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	12 (60.0)	7 (35.0)	5	0 (0.0)	3 (60.0)	2 (40.0)
Age									
<65 years									
	Day 15	52	8 (15.4)	29 (55.8)	15 (28.8)	22	0 (0.0)	16 (72.7)	6 (27.3)
	Day 43	52	8 (15.4)	29 (55.8)	15 (28.8)	24	2 (8.3)	15 (62.5)	7 (29.2)
	Day 85	47	6 (12.8)	32 (68.1)	9 (19.1)	16	1 (6.3)	13 (81.3)	2 (12.5)
	Day 127	34	7 (20.6)	21 (61.8)	6 (17.6)	8	0 (0.0)	4 (50.0)	4 (50.0)
	Day 169	27	2 (7.4)	20 (74.1)	5 (18.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	18	2 (11.1)	12 (66.7)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	16	1 (6.3)	11 (68.8)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	2 (15.4)	10 (76.9)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	2 (18.2)	8 (72.7)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	42	3 (7.1)	22 (52.4)	17 (40.5)	23	0 (0.0)	14 (60.9)	9 (39.1)
Age									
>=65 years									
	Day 15	69	7 (10.1)	42 (60.9)	20 (29.0)	30	3 (10.0)	22 (73.3)	5 (16.7)
	Day 43	66	8 (12.1)	44 (66.7)	14 (21.2)	29	4 (13.8)	19 (65.5)	6 (20.7)
	Day 85	52	5 (9.6)	37 (71.2)	10 (19.2)	20	3 (15.0)	14 (70.0)	3 (15.0)
	Day 127	41	3 (7.3)	30 (73.2)	8 (19.5)	11	1 (9.1)	9 (81.8)	1 (9.1)
	Day 169	30	2 (6.7)	24 (80.0)	4 (13.3)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	26	3 (11.5)	18 (69.2)	5 (19.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	3 (14.3)	12 (57.1)	6 (28.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	16	1 (6.3)	10 (62.5)	5 (31.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	10 (62.5)	5 (31.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	13	1 (7.7)	9 (69.2)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

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Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	End of Treatment	56	5 (8.9)	31 (55.4)	20 (35.7)	33	3 (9.1)	21 (63.6)	9 (27.3)
Sex									
female									
	Day 15	29	3 (10.3)	18 (62.1)	8 (27.6)	13	2 (15.4)	8 (61.5)	3 (23.1)
	Day 43	28	5 (17.9)	15 (53.6)	8 (28.6)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 85	20	2 (10.0)	10 (50.0)	8 (40.0)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 127	13	1 (7.7)	8 (61.5)	4 (30.8)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	10	1 (10.0)	9 (90.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	0 (0.0)	7 (87.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	22	1 (4.5)	12 (54.5)	9 (40.9)	14	1 (7.1)	8 (57.1)	5 (35.7)
Sex									
male									
	Day 15	92	12 (13.0)	53 (57.6)	27 (29.3)	39	1 (2.6)	30 (76.9)	8 (20.5)
	Day 43	90	11 (12.2)	58 (64.4)	21 (23.3)	40	5 (12.5)	25 (62.5)	10 (25.0)
	Day 85	79	9 (11.4)	59 (74.7)	11 (13.9)	28	3 (10.7)	21 (75.0)	4 (14.3)
	Day 127	62	9 (14.5)	43 (69.4)	10 (16.1)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	47	3 (6.4)	35 (74.5)	9 (19.1)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	36	5 (13.9)	23 (63.9)	8 (22.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	30	3 (10.0)	18 (60.0)	9 (30.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	3 (12.0)	18 (72.0)	4 (16.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	3 (12.5)	16 (66.7)	5 (20.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	2 (10.5)	12 (63.2)	5 (26.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	15	1 (6.7)	10 (66.7)	4 (26.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	76	7 (9.2)	41 (53.9)	28 (36.8)	42	2 (4.8)	27 (64.3)	13 (31.0)
ECOG PS									
0									
	Day 15	61	8 (13.1)	37 (60.7)	16 (26.2)	26	0 (0.0)	22 (84.6)	4 (15.4)
	Day 43	60	10 (16.7)	41 (68.3)	9 (15.0)	26	1 (3.8)	20 (76.9)	5 (19.2)
	Day 85	54	4 (7.4)	40 (74.1)	10 (18.5)	19	1 (5.3)	16 (84.2)	2 (10.5)
	Day 127	42	5 (11.9)	33 (78.6)	4 (9.5)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 169	36	3 (8.3)	30 (83.3)	3 (8.3)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	27	3 (11.1)	18 (66.7)	6 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	24	4 (16.7)	15 (62.5)	5 (20.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	18	1 (5.6)	13 (72.2)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	12 (75.0)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	14	1 (7.1)	10 (71.4)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	48	2 (4.2)	32 (66.7)	14 (29.2)	29	1 (3.4)	20 (69.0)	8 (27.6)
ECOG PS									
1									
	Day 15	60	7 (11.7)	34 (56.7)	19 (31.7)	26	3 (11.5)	16 (61.5)	7 (26.9)
	Day 43	58	6 (10.3)	32 (55.2)	20 (34.5)	27	5 (18.5)	14 (51.9)	8 (29.6)
	Day 85	45	7 (15.6)	29 (64.4)	9 (20.0)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 127	33	5 (15.2)	18 (54.5)	10 (30.3)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 169	21	1 (4.8)	14 (66.7)	6 (28.6)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	17	2 (11.8)	12 (70.6)	3 (17.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	13	0 (0.0)	8 (61.5)	5 (38.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	2 (18.2)	7 (63.6)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	2 (18.2)	6 (54.5)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	6 (12.0)	21 (42.0)	23 (46.0)	27	2 (7.4)	15 (55.6)	10 (37.0)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	93	11 (11.8)	53 (57.0)	29 (31.2)	38	2 (5.3)	29 (76.3)	7 (18.4)
	Day 43	92	13 (14.1)	57 (62.0)	22 (23.9)	40	3 (7.5)	25 (62.5)	12 (30.0)
	Day 85	79	10 (12.7)	53 (67.1)	16 (20.3)	26	2 (7.7)	20 (76.9)	4 (15.4)
	Day 127	60	10 (16.7)	38 (63.3)	12 (20.0)	13	1 (7.7)	7 (53.8)	5 (38.5)
	Day 169	46	4 (8.7)	37 (80.4)	5 (10.9)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	38	5 (13.2)	25 (65.8)	8 (21.1)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	32	4 (12.5)	21 (65.6)	7 (21.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	3 (11.5)	18 (69.2)	5 (19.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	25	3 (12.0)	17 (68.0)	5 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	2 (10.5)	14 (73.7)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	1 (6.3)	11 (68.8)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	0 (0.0)	10 (83.3)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	75	6 (8.0)	43 (57.3)	26 (34.7)	42	2 (4.8)	24 (57.1)	16 (38.1)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	28	4 (14.3)	18 (64.3)	6 (21.4)	14	1 (7.1)	9 (64.3)	4 (28.6)
	Day 43	26	3 (11.5)	16 (61.5)	7 (26.9)	13	3 (23.1)	9 (69.2)	1 (7.7)
	Day 85	20	1 (5.0)	16 (80.0)	3 (15.0)	10	2 (20.0)	7 (70.0)	1 (10.0)
	Day 127	15	0 (0.0)	13 (86.7)	2 (13.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 169	11	0 (0.0)	7 (63.6)	4 (36.4)	3	0 (0.0)	2 (66.7)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	2 (8.7)	10 (43.5)	11 (47.8)	14	1 (7.1)	11 (78.6)	2 (14.3)
Primary tumor location									
Gastric									
	Day 15	104	14 (13.5)	59 (56.7)	31 (29.8)	46	3 (6.5)	33 (71.7)	10 (21.7)
	Day 43	101	15 (14.9)	61 (60.4)	25 (24.8)	48	5 (10.4)	32 (66.7)	11 (22.9)
	Day 85	84	9 (10.7)	61 (72.6)	14 (16.7)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	64	9 (14.1)	43 (67.2)	12 (18.8)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	47	3 (6.4)	37 (78.7)	7 (14.9)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 211	38	4 (10.5)	25 (65.8)	9 (23.7)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	31	4 (12.9)	18 (58.1)	9 (29.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	24	2 (8.3)	16 (66.7)	6 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	22	2 (9.1)	14 (63.6)	6 (27.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	17	1 (5.9)	11 (64.7)	5 (29.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	0 (0.0)	9 (69.2)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	8 (9.6)	42 (50.6)	33 (39.8)	50	3 (6.0)	31 (62.0)	16 (32.0)
Primary tumor location									
GEJ									
	Day 15	17	1 (5.9)	12 (70.6)	4 (23.5)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 43	17	1 (5.9)	12 (70.6)	4 (23.5)	5	1 (20.0)	2 (40.0)	2 (40.0)
	Day 85	15	2 (13.3)	8 (53.3)	5 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	0 (0.0)	11 (73.3)	4 (26.7)	6	0 (0.0)	4 (66.7)	2 (33.3)
Histological subtype									
intestinal									
	Day 15	88	10 (11.4)	52 (59.1)	26 (29.5)	35	3 (8.6)	26 (74.3)	6 (17.1)
	Day 43	86	14 (16.3)	58 (67.4)	14 (16.3)	34	5 (14.7)	21 (61.8)	8 (23.5)
	Day 85	73	9 (12.3)	52 (71.2)	12 (16.4)	27	3 (11.1)	21 (77.8)	3 (11.1)
	Day 127	56	7 (12.5)	39 (69.6)	10 (17.9)	14	1 (7.1)	10 (71.4)	3 (21.4)
	Day 169	44	4 (9.1)	32 (72.7)	8 (18.2)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	32	3 (9.4)	22 (68.8)	7 (21.9)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	25	3 (12.0)	16 (64.0)	6 (24.0)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	18	1 (5.6)	12 (66.7)	5 (27.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	11 (68.8)	4 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	13	1 (7.7)	9 (69.2)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	73	7 (9.6)	41 (56.2)	25 (34.2)	37	3 (8.1)	24 (64.9)	10 (27.0)
Histological subtype diffuse									
	Day 15	27	5 (18.5)	14 (51.9)	8 (29.6)	15	0 (0.0)	10 (66.7)	5 (33.3)
	Day 43	26	2 (7.7)	12 (46.2)	12 (46.2)	14	0 (0.0)	10 (71.4)	4 (28.6)
	Day 85	22	1 (4.5)	15 (68.2)	6 (27.3)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 127	15	2 (13.3)	10 (66.7)	3 (20.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	11	0 (0.0)	10 (90.9)	1 (9.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	11 (52.4)	9 (42.9)	16	0 (0.0)	10 (62.5)	6 (37.5)
Histological subtype others									
	Day 15	6	0 (0.0)	5 (83.3)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	0 (0.0)	3 (50.0)	3 (50.0)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 85	4	1 (25.0)	2 (50.0)	1 (25.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	4	1 (25.0)	2 (50.0)	1 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	1 (25.0)	3 (75.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	22	1 (4.5)	11 (50.0)	10 (45.5)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	22	2 (9.1)	15 (68.2)	5 (22.7)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 85	21	3 (14.3)	13 (61.9)	5 (23.8)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	17	1 (5.9)	11 (64.7)	5 (29.4)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	16	1 (6.3)	11 (68.8)	4 (25.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	14	2 (14.3)	10 (71.4)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	2 (20.0)	5 (50.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	1 (12.5)	5 (62.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	5	1 (20.0)	3 (60.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	2 (11.1)	9 (50.0)	7 (38.9)	9	0 (0.0)	8 (88.9)	1 (11.1)
Number of metastatic sites									
>= 2									
	Day 15	99	14 (14.1)	60 (60.6)	25 (25.3)	42	3 (7.1)	30 (71.4)	9 (21.4)
	Day 43	96	14 (14.6)	58 (60.4)	24 (25.0)	43	5 (11.6)	26 (60.5)	12 (27.9)
	Day 85	78	8 (10.3)	56 (71.8)	14 (17.9)	28	3 (10.7)	20 (71.4)	5 (17.9)
	Day 127	58	9 (15.5)	40 (69.0)	9 (15.5)	15	1 (6.7)	9 (60.0)	5 (33.3)
	Day 169	41	3 (7.3)	33 (80.5)	5 (12.2)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	30	3 (10.0)	20 (66.7)	7 (23.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	2 (7.4)	18 (66.7)	7 (25.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	21	2 (9.5)	15 (71.4)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	19	2 (10.5)	14 (73.7)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	1 (6.3)	11 (68.8)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	12	1 (8.3)	8 (66.7)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	80	6 (7.5)	44 (55.0)	30 (37.5)	47	3 (6.4)	27 (57.4)	17 (36.2)
Previous total gastrectomy									
yes									
	Day 15	20	6 (30.0)	11 (55.0)	3 (15.0)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 43	20	4 (20.0)	11 (55.0)	5 (25.0)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 85	18	2 (11.1)	12 (66.7)	4 (22.2)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	0 (0.0)	6 (75.0)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	13 (72.2)	4 (22.2)	9	1 (11.1)	6 (66.7)	2 (22.2)
Previous total gastrectomy									
no									
	Day 15	101	9 (8.9)	60 (59.4)	32 (31.7)	45	3 (6.7)	32 (71.1)	10 (22.2)
	Day 43	98	12 (12.2)	62 (63.3)	24 (24.5)	45	4 (8.9)	29 (64.4)	12 (26.7)
	Day 85	81	9 (11.1)	57 (70.4)	15 (18.5)	30	3 (10.0)	22 (73.3)	5 (16.7)
	Day 127	64	9 (14.1)	43 (67.2)	12 (18.8)	17	0 (0.0)	12 (70.6)	5 (29.4)
	Day 169	49	4 (8.2)	38 (77.6)	7 (14.3)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 211	36	5 (13.9)	25 (69.4)	6 (16.7)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	33	4 (12.1)	21 (63.6)	8 (24.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	3 (12.0)	18 (72.0)	4 (16.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	23	3 (13.0)	17 (73.9)	3 (13.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	2 (10.5)	13 (68.4)	4 (21.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	14	1 (7.1)	11 (78.6)	2 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	80	7 (8.8)	40 (50.0)	33 (41.3)	47	2 (4.3)	29 (61.7)	16 (34.0)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	6 (20.7)	17 (58.6)	6 (20.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 43	28	4 (14.3)	18 (64.3)	6 (21.4)	8	3 (37.5)	4 (50.0)	1 (12.5)
	Day 85	27	3 (11.1)	19 (70.4)	5 (18.5)	7	2 (28.6)	5 (71.4)	0 (0.0)
	Day 127	22	1 (4.5)	16 (72.7)	5 (22.7)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	15	0 (0.0)	13 (86.7)	2 (13.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	12	1 (8.3)	6 (50.0)	5 (41.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	4 (40.0)	5 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	1 (16.7)	2 (33.3)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	25	1 (4.0)	16 (64.0)	8 (32.0)	9	1 (11.1)	7 (77.8)	1 (11.1)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	92	9 (9.8)	54 (58.7)	29 (31.5)	44	3 (6.8)	32 (72.7)	9 (20.5)
	Day 43	90	12 (13.3)	55 (61.1)	23 (25.6)	45	3 (6.7)	30 (66.7)	12 (26.7)
	Day 85	72	8 (11.1)	50 (69.4)	14 (19.4)	29	2 (6.9)	22 (75.9)	5 (17.2)
	Day 127	53	9 (17.0)	35 (66.0)	9 (17.0)	15	0 (0.0)	10 (66.7)	5 (33.3)
	Day 169	42	4 (9.5)	31 (73.8)	7 (16.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	32	4 (12.5)	24 (75.0)	4 (12.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	3 (11.1)	18 (66.7)	6 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	19	2 (10.5)	15 (78.9)	2 (10.5)	2	0 (0.0)	2 (100.0)	0 (0.0)

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Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
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Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	17	2 (11.8)	14 (82.4)	1 (5.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	15	1 (6.7)	12 (80.0)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	0 (0.0)	9 (90.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	73	7 (9.6)	37 (50.7)	29 (39.7)	47	2 (4.3)	28 (59.6)	17 (36.2)
Prior ramucirumab contained treatment									
yes									
	Day 15	91	8 (8.8)	56 (61.5)	27 (29.7)	34	3 (8.8)	22 (64.7)	9 (26.5)
	Day 43	90	10 (11.1)	58 (64.4)	22 (24.4)	33	5 (15.2)	21 (63.6)	7 (21.2)
	Day 85	73	8 (11.0)	51 (69.9)	14 (19.2)	23	3 (13.0)	18 (78.3)	2 (8.7)
	Day 127	59	7 (11.9)	40 (67.8)	12 (20.3)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 169	45	3 (6.7)	34 (75.6)	8 (17.8)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	32	3 (9.4)	21 (65.6)	8 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	25	3 (12.0)	17 (68.0)	5 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	22	1 (4.5)	17 (77.3)	4 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	1 (4.8)	16 (76.2)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	17	0 (0.0)	13 (76.5)	4 (23.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	13	0 (0.0)	10 (76.9)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	5 (6.8)	40 (54.1)	29 (39.2)	36	2 (5.6)	23 (63.9)	11 (30.6)
Prior ramucirumab contained treatment									
no									
	Day 15	30	7 (23.3)	15 (50.0)	8 (26.7)	18	0 (0.0)	16 (88.9)	2 (11.1)
	Day 43	28	6 (21.4)	15 (53.6)	7 (25.0)	20	1 (5.0)	13 (65.0)	6 (30.0)
	Day 85	26	3 (11.5)	18 (69.2)	5 (19.2)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 127	16	3 (18.8)	11 (68.8)	2 (12.5)	8	0 (0.0)	5 (62.5)	3 (37.5)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	12	2 (16.7)	9 (75.0)	1 (8.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	6 (50.0)	5 (41.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	2 (28.6)	3 (42.9)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	2 (33.3)	2 (33.3)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	2 (50.0)	1 (25.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	3 (12.5)	13 (54.2)	8 (33.3)	20	1 (5.0)	12 (60.0)	7 (35.0)
Prior nivolumab contained treatment									
yes									
	Day 15	33	2 (6.1)	17 (51.5)	14 (42.4)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 43	31	3 (9.7)	21 (67.7)	7 (22.6)	10	2 (20.0)	5 (50.0)	3 (30.0)
	Day 85	27	2 (7.4)	23 (85.2)	2 (7.4)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 127	26	2 (7.7)	21 (80.8)	3 (11.5)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	21	1 (4.8)	19 (90.5)	1 (4.8)	3	0 (0.0)	2 (66.7)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	16	1 (6.3)	11 (68.8)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	14	1 (7.1)	10 (71.4)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	0 (0.0)	10 (83.3)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	0 (0.0)	9 (81.8)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	1 (3.8)	15 (57.7)	10 (38.5)	14	1 (7.1)	8 (57.1)	5 (35.7)
Prior nivolumab contained treatment									
no									
	Day 15	88	13 (14.8)	54 (61.4)	21 (23.9)	39	2 (5.1)	29 (74.4)	8 (20.5)
	Day 43	87	13 (14.9)	52 (59.8)	22 (25.3)	43	4 (9.3)	29 (67.4)	10 (23.3)
	Day 85	72	9 (12.5)	46 (63.9)	17 (23.6)	26	3 (11.5)	21 (80.8)	2 (7.7)
	Day 127	49	8 (16.3)	30 (61.2)	11 (22.4)	16	0 (0.0)	11 (68.8)	5 (31.3)
	Day 169	36	3 (8.3)	25 (69.4)	8 (22.2)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	28	4 (14.3)	19 (67.9)	5 (17.9)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	23	3 (13.0)	13 (56.5)	7 (30.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	3 (17.6)	10 (58.8)	4 (23.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	3 (18.8)	9 (56.3)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	2 (18.2)	7 (63.6)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	1 (11.1)	5 (55.6)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	7 (9.7)	38 (52.8)	27 (37.5)	42	2 (4.8)	27 (64.3)	13 (31.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	43	4 (9.3)	22 (51.2)	17 (39.5)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 43	41	4 (9.8)	26 (63.4)	11 (26.8)	12	2 (16.7)	7 (58.3)	3 (25.0)
	Day 85	37	2 (5.4)	28 (75.7)	7 (18.9)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 127	31	3 (9.7)	23 (74.2)	5 (16.1)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	24	1 (4.2)	22 (91.7)	1 (4.2)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	20	1 (5.0)	14 (70.0)	5 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	17	1 (5.9)	12 (70.6)	4 (23.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	0 (0.0)	13 (81.3)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	0 (0.0)	11 (73.3)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	35	2 (5.7)	19 (54.3)	14 (40.0)	16	1 (6.3)	10 (62.5)	5 (31.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	78	11 (14.1)	49 (62.8)	18 (23.1)	37	2 (5.4)	27 (73.0)	8 (21.6)
	Day 43	77	12 (15.6)	47 (61.0)	18 (23.4)	41	4 (9.8)	27 (65.9)	10 (24.4)
	Day 85	62	9 (14.5)	41 (66.1)	12 (19.4)	25	3 (12.0)	20 (80.0)	2 (8.0)
	Day 127	44	7 (15.9)	28 (63.6)	9 (20.5)	15	0 (0.0)	10 (66.7)	5 (33.3)
	Day 169	33	3 (9.1)	22 (66.7)	8 (24.2)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	24	4 (16.7)	16 (66.7)	4 (16.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	3 (15.0)	11 (55.0)	6 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	3 (23.1)	7 (53.8)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	3 (25.0)	7 (58.3)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	9	2 (22.2)	5 (55.6)	2 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	63	6 (9.5)	34 (54.0)	23 (36.5)	40	2 (5.0)	25 (62.5)	13 (32.5)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
yes									
	Day 15	22	4 (18.2)	12 (54.5)	6 (27.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	19	3 (15.8)	12 (63.2)	4 (21.1)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 85	16	1 (6.3)	14 (87.5)	1 (6.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 127	12	2 (16.7)	10 (83.3)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	9	0 (0.0)	7 (77.8)	2 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	5	0 (0.0)	5 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	1 (7.1)	12 (85.7)	1 (7.1)	6	0 (0.0)	6 (100.0)	0 (0.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
no									
	Day 15	99	11 (11.1)	59 (59.6)	29 (29.3)	46	3 (6.5)	32 (69.6)	11 (23.9)
	Day 43	99	13 (13.1)	61 (61.6)	25 (25.3)	47	5 (10.6)	29 (61.7)	13 (27.7)
	Day 85	83	10 (12.0)	55 (66.3)	18 (21.7)	31	4 (12.9)	22 (71.0)	5 (16.1)
	Day 127	63	8 (12.7)	41 (65.1)	14 (22.2)	16	0 (0.0)	11 (68.8)	5 (31.3)
	Day 169	48	4 (8.3)	37 (77.1)	7 (14.6)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	39	5 (12.8)	25 (64.1)	9 (23.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	4 (12.1)	21 (63.6)	8 (24.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	3 (11.5)	17 (65.4)	6 (23.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	3 (12.5)	15 (62.5)	6 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	18	2 (11.1)	12 (66.7)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	1 (7.7)	9 (69.2)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	11	0 (0.0)	10 (90.9)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	84	7 (8.3)	41 (48.8)	36 (42.9)	50	3 (6.0)	29 (58.0)	18 (36.0)
Presence of liver metastasis at baseline									
yes									
	Day 15	66	10 (15.2)	39 (59.1)	17 (25.8)	27	2 (7.4)	21 (77.8)	4 (14.8)
	Day 43	64	10 (15.6)	39 (60.9)	15 (23.4)	28	3 (10.7)	18 (64.3)	7 (25.0)
	Day 85	51	7 (13.7)	35 (68.6)	9 (17.6)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 127	37	7 (18.9)	26 (70.3)	4 (10.8)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 169	28	2 (7.1)	24 (85.7)	2 (7.1)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	20	2 (10.0)	16 (80.0)	2 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	2 (10.5)	14 (73.7)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	1 (7.1)	11 (78.6)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	13	1 (7.7)	11 (84.6)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	0 (0.0)	10 (90.9)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	4 (8.0)	30 (60.0)	16 (32.0)	31	2 (6.5)	18 (58.1)	11 (35.5)
Presence of liver metastasis at baseline									
no									
	Day 15	55	5 (9.1)	32 (58.2)	18 (32.7)	25	1 (4.0)	17 (68.0)	7 (28.0)
	Day 43	54	6 (11.1)	34 (63.0)	14 (25.9)	25	3 (12.0)	16 (64.0)	6 (24.0)
	Day 85	48	4 (8.3)	34 (70.8)	10 (20.8)	20	2 (10.0)	16 (80.0)	2 (10.0)
	Day 127	38	3 (7.9)	25 (65.8)	10 (26.3)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 169	29	2 (6.9)	20 (69.0)	7 (24.1)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	24	3 (12.5)	14 (58.3)	7 (29.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	9 (50.0)	7 (38.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	2 (13.3)	9 (60.0)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	7 (50.0)	5 (35.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	2 (20.0)	4 (40.0)	4 (40.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	7	1 (14.3)	3 (42.9)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	48	4 (8.3)	23 (47.9)	21 (43.8)	25	1 (4.0)	17 (68.0)	7 (28.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Renal impairment at baseline									
normal									
	Day 15	32	2 (6.3)	20 (62.5)	10 (31.3)	10	0 (0.0)	7 (70.0)	3 (30.0)
	Day 43	33	4 (12.1)	18 (54.5)	11 (33.3)	12	0 (0.0)	6 (50.0)	6 (50.0)
	Day 85	26	2 (7.7)	17 (65.4)	7 (26.9)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	2 (10.5)	14 (73.7)	3 (15.8)	3	0 (0.0)	0 (0.0)	3 (100.0)
	Day 169	17	2 (11.8)	14 (82.4)	1 (5.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	13	1 (7.7)	8 (61.5)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	1 (4.2)	15 (62.5)	8 (33.3)	11	0 (0.0)	5 (45.5)	6 (54.5)
Renal impairment at baseline									
mild									
	Day 15	51	10 (19.6)	30 (58.8)	11 (21.6)	25	1 (4.0)	21 (84.0)	3 (12.0)
	Day 43	51	10 (19.6)	29 (56.9)	12 (23.5)	23	3 (13.0)	16 (69.6)	4 (17.4)
	Day 85	45	8 (17.8)	30 (66.7)	7 (15.6)	14	2 (14.3)	12 (85.7)	0 (0.0)
	Day 127	32	6 (18.8)	23 (71.9)	3 (9.4)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	23	1 (4.3)	18 (78.3)	4 (17.4)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	17	3 (17.6)	9 (52.9)	5 (29.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	13	3 (23.1)	8 (61.5)	2 (15.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	9	2 (22.2)	5 (55.6)	2 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	4 (50.0)	2 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	6	1 (16.7)	3 (50.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	46	6 (13.0)	24 (52.2)	16 (34.8)	25	1 (4.0)	18 (72.0)	6 (24.0)
Renal impairment at baseline									
moderate									
	Day 15	38	3 (7.9)	21 (55.3)	14 (36.8)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 43	34	2 (5.9)	26 (76.5)	6 (17.6)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 85	28	1 (3.6)	22 (78.6)	5 (17.9)	14	2 (14.3)	9 (64.3)	3 (21.4)
	Day 127	24	2 (8.3)	14 (58.3)	8 (33.3)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 169	17	1 (5.9)	12 (70.6)	4 (23.5)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 211	15	1 (6.7)	12 (80.0)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	1 (3.6)	14 (50.0)	13 (46.4)	19	2 (10.5)	12 (63.2)	5 (26.3)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
Hepatic impairment at baseline									
normal									
	Day 15	85	9 (10.6)	54 (63.5)	22 (25.9)	37	2 (5.4)	28 (75.7)	7 (18.9)
	Day 43	84	10 (11.9)	56 (66.7)	18 (21.4)	41	3 (7.3)	28 (68.3)	10 (24.4)
	Day 85	76	7 (9.2)	54 (71.1)	15 (19.7)	27	3 (11.1)	20 (74.1)	4 (14.8)
	Day 127	59	7 (11.9)	42 (71.2)	10 (16.9)	14	0 (0.0)	9 (64.3)	5 (35.7)
	Day 169	45	3 (6.7)	34 (75.6)	8 (17.8)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	34	4 (11.8)	25 (73.5)	5 (14.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	30	3 (10.0)	20 (66.7)	7 (23.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	23	3 (13.0)	16 (69.6)	4 (17.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	3 (14.3)	14 (66.7)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	2 (12.5)	12 (75.0)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	68	3 (4.4)	40 (58.8)	25 (36.8)	42	2 (4.8)	26 (61.9)	14 (33.3)
Hepatic impairment at baseline									
mild									
	Day 15	35	6 (17.1)	16 (45.7)	13 (37.1)	15	1 (6.7)	10 (66.7)	4 (26.7)
	Day 43	33	6 (18.2)	16 (48.5)	11 (33.3)	12	3 (25.0)	6 (50.0)	3 (25.0)
	Day 85	22	3 (13.6)	15 (68.2)	4 (18.2)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 127	15	3 (20.0)	8 (53.3)	4 (26.7)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	5 (50.0)	4 (40.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	7	1 (14.3)	3 (42.9)	3 (42.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	0 (0.0)	4 (66.7)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	0 (0.0)	4 (66.7)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	29	5 (17.2)	12 (41.4)	12 (41.4)	14	1 (7.1)	9 (64.3)	4 (28.6)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	3 (37.5)	2 (25.0)	3 (37.5)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	3 (37.5)	4 (50.0)	1 (12.5)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 85	7	1 (14.3)	5 (71.4)	1 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	0 (0.0)	6 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	5	0 (0.0)	4 (80.0)	1 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	6	1 (16.7)	3 (50.0)	2 (33.3)	4	0 (0.0)	2 (50.0)	2 (50.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	113	12 (10.6)	69 (61.1)	32 (28.3)	48	3 (6.3)	35 (72.9)	10 (20.8)
	Day 43	110	13 (11.8)	69 (62.7)	28 (25.5)	50	6 (12.0)	32 (64.0)	12 (24.0)
	Day 85	92	10 (10.9)	64 (69.6)	18 (19.6)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	69	10 (14.5)	45 (65.2)	14 (20.3)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	52	4 (7.7)	40 (76.9)	8 (15.4)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	40	5 (12.5)	27 (67.5)	8 (20.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	4 (12.1)	21 (63.6)	8 (24.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	27	3 (11.1)	19 (70.4)	5 (18.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	25	3 (12.0)	17 (68.0)	5 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	20	2 (10.0)	14 (70.0)	4 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	15	1 (6.7)	11 (73.3)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	92	7 (7.6)	50 (54.3)	35 (38.0)	52	3 (5.8)	33 (63.5)	16 (30.8)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	1 (33.3)	1 (33.3)	1 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	3	0 (0.0)	2 (66.7)	1 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	1 (50.0)	1 (50.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	118	14 (11.9)	70 (59.3)	34 (28.8)	49	3 (6.1)	35 (71.4)	11 (22.4)
	Day 43	115	16 (13.9)	70 (60.9)	29 (25.2)	50	6 (12.0)	32 (64.0)	12 (24.0)
	Day 85	96	11 (11.5)	66 (68.8)	19 (19.8)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	72	10 (13.9)	48 (66.7)	14 (19.4)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	54	4 (7.4)	42 (77.8)	8 (14.8)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	42	5 (11.9)	28 (66.7)	9 (21.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	35	4 (11.4)	22 (62.9)	9 (25.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	28	3 (10.7)	19 (67.9)	6 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	26	3 (11.5)	17 (65.4)	6 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	21	2 (9.5)	14 (66.7)	5 (23.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	16	1 (6.3)	11 (68.8)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	0 (0.0)	10 (83.3)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	96	8 (8.3)	52 (54.2)	36 (37.5)	53	3 (5.7)	33 (62.3)	17 (32.1)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Social/Family Well-being Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	125 (100.0)	62	59 (95.2)
Day 15	125	121 (96.8)	62	52 (83.9)
Day 43	124	118 (95.2)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	57 (54.3)	45	11 (24.4)
Day 211	93	44 (47.3)	40	4 (10.0)
Day 253	84	37 (44.0)	34	2 (5.9)
Day 295	77	29 (37.7)	27	2 (7.4)
Day 337	70	27 (38.6)	21	2 (9.5)
Day 379	60	21 (35.0)	20	1 (5.0)
Day 421	50	16 (32.0)	15	0 (0.0)
Day 463	39	12 (30.8)	9	0 (0.0)
Day 505	30	8 (26.7)	9	0 (0.0)
Day 547	24	6 (25.0)	8	0 (0.0)
Day 589	17	5 (29.4)	5	0 (0.0)
Day 631	13	4 (30.8)	1	0 (0.0)
Day 673	9	2 (22.2)	1	0 (0.0)
Day 715	5	3 (60.0)	1	0 (0.0)
Day 757	5	3 (60.0)	1	0 (0.0)
Day 799	3	1 (33.3)	1	0 (0.0)
Day 841	2	1 (50.0)	0	0 (0.0)
Day 883	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Social/Family Well-being by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	125	17.9 (5.67)			59	18.6 (5.74)		
Day 15	121	16.5 (6.76)	121	-1.3 (5.69)	52	18.8 (6.26)	50	0.2 (3.88)
Day 43	118	16.5 (6.33)	118	-1.4 (5.69)	53	18.0 (7.22)	51	-0.9 (5.80)
Day 85	99	16.7 (6.08)	99	-1.2 (4.30)	36	17.5 (7.55)	35	-0.8 (4.85)
Day 127	74	16.4 (6.80)	74	-1.5 (5.65)	19	17.2 (6.36)	19	-2.1 (5.29)
Day 169	57	16.8 (5.89)	57	-0.7 (4.15)	11	17.9 (5.90)	11	-2.0 (4.28)
Day 211	44	16.0 (6.72)	44	-1.0 (5.87)	4	22.3 (4.92)	4	-1.9 (1.59)
Day 253	37	15.1 (7.50)	37	-1.9 (6.05)	2	21.6 (9.07)	2	-1.7 (4.12)
Day 295	29	15.3 (7.95)	29	-2.4 (5.56)	2	24.5 (4.95)	2	1.2 (0.00)
Day 337	27	16.3 (8.34)	27	-0.9 (5.19)	2	17.5 (14.85)	2	-5.8 (9.90)
Day 379	21	16.9 (7.63)	21	-0.8 (3.25)	1	28.0 (-)	1	1.2 (-)
Day 421	16	15.0 (8.73)	16	-2.0 (4.31)	0	-	0	-
Day 463	12	15.9 (8.97)	12	-0.6 (4.11)	0	-	0	-
Day 505	8	14.1 (10.13)	8	-0.5 (3.56)	0	-	0	-
Day 547	6	13.4 (11.60)	6	-1.1 (2.59)	0	-	0	-
Day 589	5	15.7 (9.95)	5	-1.6 (2.14)	0	-	0	-
Day 631	4	13.6 (10.01)	4	-1.8 (1.69)	0	-	0	-
Day 673	2	8.8 (12.37)	2	-0.3 (0.35)	0	-	0	-
Day 715	3	13.3 (12.42)	3	-1.0 (3.61)	0	-	0	-
Day 757	3	13.8 (12.69)	3	-0.6 (0.96)	0	-	0	-
Day 799	1	14.0 (-)	1	-4.0 (-)	0	-	0	-
Day 841	1	16.3 (-)	1	-1.7 (-)	0	-	0	-
Day 883	1	10.5 (-)	1	-7.5 (-)	0	-	0	-
End of Treatment	97	17.6 (5.65)	97	-0.7 (4.56)	56	17.5 (7.09)	53	-1.2 (4.67)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Social/Family Well-being by Visit
Full Analysis Set

Visit	DS-8201a (N=125)			Phys. Choice (N=62)			Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
	N [a]	N_MISS [b]	LSMean (95% CI)	N [a]	N_MISS [b]	LSMean (95% CI)				
Day 15			-1.41 (-2.17, -0.65)			-0.24 (-1.49, 1.00)	-1.17 (-2.53, 0.19)	0.0906		
Day 43			-1.43 (-2.15, -0.72)			-0.48 (-1.57, 0.62)	-0.96 (-2.15, 0.23)	0.1150		
Day 85			-1.47 (-2.13, -0.80)			-0.83 (-1.90, 0.24)	-0.64 (-1.77, 0.50)	0.2710		
Day 127			-1.50 (-2.14, -0.85)			-1.19 (-2.47, 0.10)	-0.31 (-1.64, 1.01)	0.6416		
Day 169			-1.53 (-2.18, -0.88)			-1.54 (-3.19, 0.11)	0.01 (-1.67, 1.69)	0.9921		
Day 211			-1.56 (-2.24, -0.89)			-1.89 (-3.98, 0.20)	0.33 (-1.79, 2.45)	0.7594		
Day 253			-1.60 (-2.33, -0.87)			-2.25 (-4.81, 0.31)	0.65 (-1.95, 3.25)	0.6223		
Day 295			-1.63 (-2.43, -0.82)			-2.60 (-5.66, 0.45)	0.97 (-2.13, 4.08)	0.5377		
Day 337			-1.66 (-2.55, -0.77)			-2.96 (-6.51, 0.60)	1.30 (-2.32, 4.92)	0.4822		
Day 379			-1.69 (-2.68, -0.70)			-3.31 (-7.38, 0.76)	1.62 (-2.53, 5.76)	0.4436		
Day 421			-1.72 (-2.82, -0.63)			-3.66 (-8.25, 0.92)	1.94 (-2.74, 6.61)	0.4154		
Day 463			-1.76 (-2.96, -0.55)			-4.02 (-9.12, 1.09)	2.26 (-2.95, 7.47)	0.3941		
OVERALL	124	1	-1.51 (-2.15, -0.87)	55	7	-1.33 (-2.76, 0.09)	-0.18 (-1.64, 1.28)	0.8114	-0.04 (-0.36, 0.28)	0.7964

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Social/Family Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.3396
Japan	99	-1.27 (-1.84, -0.70)	46	-0.88 (-2.32, 0.55)	-0.39 (-1.94, 1.16)	0.6209	-0.11 (-0.46, 0.24)	0.5507	
Korea	25	-1.54 (-2.75, -0.32)	9	-3.92 (-7.91, 0.06)	2.39 (-1.78, 6.55)	0.2568	0.60 (-0.17, 1.38)	0.1285	
Lines of prior systemic therapy									0.7681
2	65	-0.99 (-1.67, -0.30)	35	-0.43 (-1.82, 0.97)	-0.56 (-2.12, 1.01)	0.4813	-0.17 (-0.58, 0.24)	0.4247	
3	34	-1.33 (-2.56, -0.10)	16	-1.32 (-4.34, 1.70)	-0.01 (-3.27, 3.25)	0.9953	-0.00 (-0.60, 0.59)	0.9943	
>=4	25	-2.18 (-3.25, -1.12)	4	-5.91 (-13.27, 1.45)	3.73 (-3.71, 11.17)	0.3214	1.06 (-0.03, 2.15)	0.0559	
Age									0.9943
<65 years	54	-1.63 (-2.42, -0.83)	25	-2.49 (-5.03, 0.05)	0.86 (-1.80, 3.53)	0.5226	0.20 (-0.28, 0.67)	0.4119	
>=65 years	70	-1.09 (-1.80, -0.38)	30	-0.60 (-2.27, 1.06)	-0.49 (-2.30, 1.32)	0.5948	-0.14 (-0.57, 0.29)	0.5283	
Sex									0.2545
female	29	-1.59 (-2.86, -0.31)	13	1.49 (-1.53, 4.51)	-3.08 (-6.35, 0.20)	0.0653	-0.74 (-1.42, -0.07)	0.0303	
male	95	-1.27 (-1.85, -0.69)	42	-1.68 (-3.20, -0.15)	0.40 (-1.23, 2.04)	0.6264	0.11 (-0.25, 0.47)	0.5501	
ECOG PS									0.1536
0	62	-1.28 (-1.96, -0.59)	27	0.36 (-1.73, 2.45)	-1.63 (-3.83, 0.56)	0.1441	-0.43 (-0.89, 0.02)	0.0629	
1	62	-1.49 (-2.28, -0.70)	28	-2.07 (-3.68, -0.47)	0.58 (-1.21, 2.38)	0.5225	0.16 (-0.28, 0.61)	0.4699	
HER2 Status in central laboratory									0.4092
IHC 3+	96	-1.28 (-1.85, -0.70)	42	-0.83 (-2.43, 0.78)	-0.45 (-2.16, 1.26)	0.6043	-0.12 (-0.48, 0.24)	0.5174	
IHC 2+/ISH +	28	-1.55 (-2.87, -0.24)	13	-1.99 (-4.34, 0.37)	0.43 (-2.27, 3.14)	0.7504	0.12 (-0.54, 0.77)	0.7299	
Primary tumor location									0.4242
Gastric	107	-1.46 (-2.05, -0.86)	50	-0.99 (-2.43, 0.45)	-0.46 (-2.03, 1.10)	0.5582	-0.12 (-0.46, 0.22)	0.4850	
GEJ	17	-0.65 (-1.65, 0.35)	5	-3.63 (-9.21, 1.94)	2.98 (-2.68, 8.64)	0.2986	0.89 (-0.14, 1.92)	0.0903	
Histological subtype									0.5008
intestinal	89	-0.97 (-1.56, -0.38)	36	-1.01 (-2.49, 0.48)	0.04 (-1.57, 1.64)	0.9651	0.01 (-0.38, 0.40)	0.9576	
diffuse	28	-2.01 (-3.28, -0.74)	14	-1.03 (-5.39, 3.34)	-0.99 (-5.55, 3.58)	0.6689	-0.18 (-0.82, 0.46)	0.5800	
others	7	-3.46 (-4.65, -2.27)	5	-4.69 (-7.34, -2.05)	1.23 (-1.73, 4.20)	0.3958	0.58 (-0.59, 1.75)	0.3350	
Number of metastatic sites									0.4065
<2	23	-1.30 (-2.65, 0.05)	10	0.07 (-3.03, 3.17)	-1.37 (-4.77, 2.04)	0.4227	-0.36 (-1.11, 0.38)	0.3396	
>= 2	101	-1.37 (-1.94, -0.79)	45	-1.71 (-3.31, -0.11)	0.34 (-1.36, 2.05)	0.6912	0.09 (-0.26, 0.44)	0.6220	
Previous total gastrectomy									0.4166
yes	22	-0.96 (-2.27, 0.35)	8	-2.81 (-9.31, 3.68)	1.86 (-4.80, 8.51)	0.5804	0.35 (-0.46, 1.16)	0.3992	
no	102	-1.41 (-1.99, -0.83)	47	-1.00 (-2.39, 0.39)	-0.41 (-1.92, 1.10)	0.5927	-0.11 (-0.46, 0.23)	0.5245	
Prior adjuvant/ neoadjuvant therapy									0.3972
yes	30	-1.30 (-2.45, -0.16)	8	-3.47 (-8.29, 1.34)	2.17 (-2.81, 7.15)	0.3891	0.53 (-0.26, 1.32)	0.1909	
no	94	-1.31 (-1.91, -0.71)	47	-0.74 (-2.09, 0.62)	-0.58 (-2.06, 0.91)	0.4455	-0.16 (-0.51, 0.19)	0.3756	
Prior ramucirumab contained treatment									0.2447
yes	93	-1.46 (-2.02, -0.91)	36	-2.10 (-3.97, -0.24)	0.64 (-1.31, 2.58)	0.5196	0.17 (-0.22, 0.55)	0.3893	
no	31	-0.91 (-2.19, 0.36)	19	-0.88 (-2.92, 1.17)	-0.03 (-2.48, 2.41)	0.9779	-0.01 (-0.58, 0.56)	0.9762	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

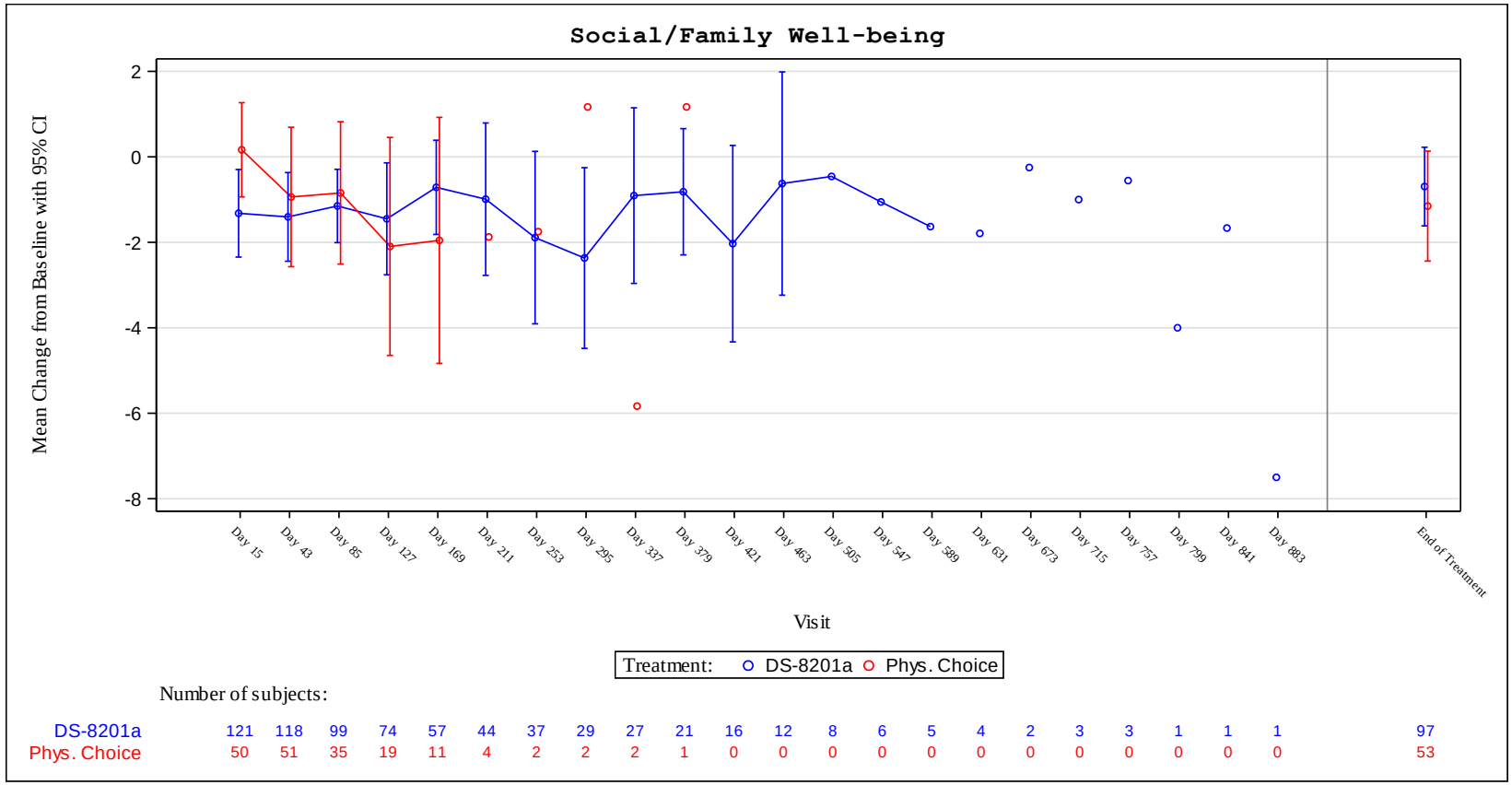
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Social/Family Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.5737
yes	33	-1.80 (-2.82, -0.79)	12	-2.67 (-6.03, 0.69)	0.86 (-2.65, 4.38)	0.6259	0.22 (-0.44, 0.88)	0.5103	
no	91	-1.12 (-1.73, -0.51)	43	-0.65 (-2.06, 0.76)	-0.47 (-2.01, 1.07)	0.5500	-0.13 (-0.49, 0.23)	0.4823	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.6098
yes	44	-1.44 (-2.36, -0.53)	13	-3.23 (-6.56, 0.10)	1.79 (-1.66, 5.24)	0.3069	0.46 (-0.17, 1.08)	0.1511	
no	80	-1.26 (-1.89, -0.63)	42	-0.36 (-1.69, 0.96)	-0.90 (-2.37, 0.58)	0.2319	-0.26 (-0.64, 0.11)	0.1724	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.8591
yes	22	-0.94 (-2.35, 0.48)	6	-0.81 (-4.29, 2.68)	-0.13 (-3.90, 3.64)	0.9451	-0.04 (-0.94, 0.87)	0.9352	
no	102	-1.40 (-1.97, -0.83)	49	-1.16 (-2.65, 0.34)	-0.24 (-1.84, 1.36)	0.7682	-0.06 (-0.40, 0.28)	0.7207	
Presence of liver metastasis at baseline									0.1360
yes	68	-1.81 (-2.53, -1.10)	30	-1.72 (-3.64, 0.20)	-0.09 (-2.14, 1.96)	0.9299	-0.02 (-0.45, 0.41)	0.9135	
no	56	-0.82 (-1.57, -0.06)	25	-0.52 (-2.43, 1.38)	-0.30 (-2.35, 1.76)	0.7770	-0.08 (-0.55, 0.39)	0.7306	
Renal impairment at baseline									0.9439
normal	33	-1.92 (-2.84, -1.01)	12	-1.48 (-7.70, 4.73)	-0.44 (-6.72, 5.84)	0.8902	-0.07 (-0.73, 0.59)	0.8270	
mild	53	-1.32 (-2.16, -0.47)	25	-1.40 (-3.01, 0.20)	0.09 (-1.73, 1.90)	0.9228	0.03 (-0.45, 0.50)	0.9146	
moderate	38	-0.70 (-1.71, 0.31)	17	0.31 (-2.16, 2.77)	-1.01 (-3.68, 1.66)	0.4554	-0.26 (-0.84, 0.31)	0.3696	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.9536
normal	87	-1.22 (-1.81, -0.63)	40	-0.20 (-1.75, 1.36)	-1.03 (-2.69, 0.64)	0.2272	-0.28 (-0.66, 0.09)	0.1411	
mild	36	-1.60 (-2.73, -0.47)	15	-3.43 (-6.28, -0.57)	1.82 (-1.25, 4.90)	0.2408	0.44 (-0.17, 1.05)	0.1537	
moderate	1	-1.37 (-3.54, 0.79)	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.8363
yes	8	-0.92 (-2.59, 0.74)	4	-1.26 (-4.96, 2.44)	0.34 (-3.96, 4.64)	0.8699	0.13 (-1.07, 1.33)	0.8342	
no	116	-1.33 (-1.88, -0.78)	51	-1.65 (-3.19, -0.11)	0.32 (-1.31, 1.96)	0.6965	0.08 (-0.25, 0.41)	0.6267	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.3331
yes	3	2.11 (-0.57, 4.78)	3	-1.74 (-4.50, 1.01)	3.85 (-0.58, 8.28)	0.0770	2.06 (0.08, 4.05)	0.0411	
no	121	-1.39 (-1.92, -0.86)	52	-1.78 (-3.39, -0.18)	0.39 (-1.30, 2.08)	0.6504	0.10 (-0.23, 0.42)	0.5625	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Graphical Summary of Social/Family Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	56 (44.8)	18 (29.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	8.3 (4.2, NE)	8.4 (4.1, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.36 (0.79, 2.32)	
p-value [c]	0.2809	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.36 (0.79, 2.33)	
p-value [c]	0.2764	

Time to Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.6008
Japan	44/ 99 (44.4)	8.3 (4.2, NE)	14/ 50 (28.0)	8.4 (4.1, NE)	1.45 (0.79, 2.66)	0.2358	
Korea	12/ 26 (46.2)	13.8 (1.4, NE)	4/ 12 (33.3)	4.4 (0.5, NE)	1.04 (0.33, 3.30)	0.9801	
Lines of prior systemic therapy							0.5661
2	28/ 66 (42.4)	8.3 (4.2, NE)	10/ 38 (26.3)	NE (3.0, NE)	1.47 (0.71, 3.06)	0.3051	
3	19/ 34 (55.9)	4.2 (1.4, NE)	6/ 18 (33.3)	8.4 (1.5, 8.4)	1.52 (0.60, 3.84)	0.3795	
>=4	9/ 25 (36.0)	NE (0.6, NE)	2/ 6 (33.3)	4.1 (0.7, NE)	0.81 (0.17, 3.76)	0.7714	
Age							0.7204
<65 years	25/ 55 (45.5)	4.2 (1.4, NE)	8/ 27 (29.6)	4.4 (2.6, NE)	1.62 (0.73, 3.61)	0.2458	
>=65 years	31/ 70 (44.3)	8.3 (4.2, NE)	10/ 35 (28.6)	8.4 (3.0, NE)	1.19 (0.58, 2.46)	0.6391	
Sex							0.4142
female	11/ 30 (36.7)	NE (1.6, NE)	2/ 15 (13.3)	NE (NE , NE)	2.56 (0.57, 11.59)	0.1933	
male	45/ 95 (47.4)	5.9 (3.2, NE)	16/ 47 (34.0)	4.4 (3.0, NE)	1.22 (0.68, 2.17)	0.5336	
ECOG PS							0.1000
0	27/ 62 (43.5)	13.9 (4.2, NE)	4/ 30 (13.3)	NE (NE , NE)	2.92 (1.01, 8.38)	0.0373	
1	29/ 63 (46.0)	4.6 (1.4, NE)	14/ 32 (43.8)	4.1 (1.5, 8.4)	0.92 (0.48, 1.76)	0.7600	
HER2 Status in central laboratory							0.2780
IHC 3+	43/ 96 (44.8)	13.8 (4.2, NE)	11/ 47 (23.4)	8.4 (4.1, NE)	1.68 (0.86, 3.29)	0.1303	
IHC 2+/ISH +	13/ 29 (44.8)	4.2 (1.4, NE)	7/ 15 (46.7)	4.4 (0.7, NE)	0.86 (0.34, 2.18)	0.7252	
Primary tumor location							0.4974
Gastric	47/108 (43.5)	13.8 (4.2, NE)	17/ 55 (30.9)	8.4 (4.1, NE)	1.30 (0.74, 2.28)	0.3784	
GEJ	9/ 17 (52.9)	4.2 (1.4, NE)	1/ 7 (14.3)	4.4 (NE , NE)	2.61 (0.32, 20.97)	0.3487	
Histological subtype							0.6017
intestinal	40/ 89 (44.9)	5.9 (4.2, NE)	11/ 38 (28.9)	8.4 (4.1, NE)	1.44 (0.74, 2.83)	0.2899	
diffuse	13/ 28 (46.4)	13.8 (0.6, NE)	6/ 18 (33.3)	NE (0.7, NE)	1.11 (0.41, 3.00)	0.8691	
others	3/ 8 (37.5)	1.4 (1.4, NE)	1/ 6 (16.7)	NE (4.4, NE)	4.00 (0.41, 39.49)	0.2063	
Number of metastatic sites							0.7127
<2	10/ 23 (43.5)	13.9 (2.8, NE)	3/ 10 (30.0)	4.4 (0.5, NE)	1.10 (0.29, 4.12)	0.8941	
>= 2	46/102 (45.1)	5.9 (1.8, NE)	15/ 52 (28.8)	8.4 (3.0, 8.4)	1.44 (0.80, 2.60)	0.2321	
Previous total gastrectomy							0.7273
yes	9/ 22 (40.9)	8.3 (0.6, NE)	3/ 9 (33.3)	4.1 (0.7, NE)	1.13 (0.30, 4.29)	0.8718	
no	47/103 (45.6)	5.9 (3.2, NE)	15/ 53 (28.3)	8.4 (4.4, NE)	1.41 (0.78, 2.54)	0.2577	
Prior adjuvant/ neoadjuvant therapy							0.3610
yes	13/ 30 (43.3)	8.3 (1.4, NE)	4/ 10 (40.0)	4.4 (0.7, NE)	0.88 (0.28, 2.73)	0.8077	
no	43/ 95 (45.3)	5.9 (3.2, NE)	14/ 52 (26.9)	8.4 (4.4, NE)	1.52 (0.83, 2.80)	0.1818	
Prior ramucirumab contained treatment							0.3872
yes	42/ 94 (44.7)	8.3 (2.8, NE)	10/ 41 (24.4)	8.4 (4.1, 8.4)	1.64 (0.82, 3.29)	0.1660	
no	14/ 31 (45.2)	13.8 (1.4, NE)	8/ 21 (38.1)	NE (1.4, NE)	1.02 (0.42, 2.48)	0.9793	
Prior nivolumab contained treatment							0.8409
yes	19/ 33 (57.6)	4.2 (1.4, NE)	5/ 15 (33.3)	4.1 (0.6, 8.4)	1.30 (0.48, 3.50)	0.6133	
no	37/ 92 (40.2)	13.8 (4.2, NE)	13/ 47 (27.7)	NE (4.4, NE)	1.34 (0.70, 2.54)	0.3896	

Time to Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

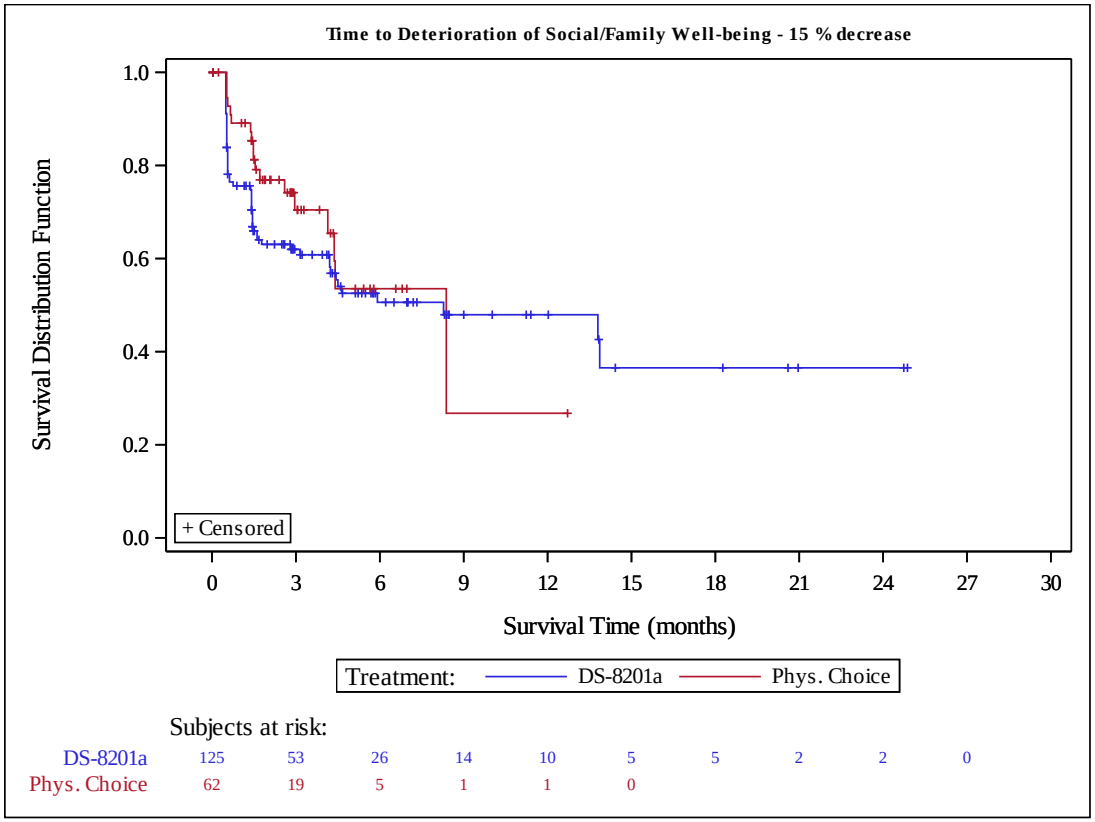
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.3298
yes	23/ 44 (52.3)	4.5 (1.4, NE)	6/ 17 (35.3)	4.1 (0.6, 8.4)	0.93 (0.37, 2.31)	0.8686	
no	33/ 81 (40.7)	8.3 (4.2, NE)	12/ 45 (26.7)	NE (4.4, NE)	1.54 (0.79, 3.01)	0.2099	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.7151
yes	8/ 22 (36.4)	13.8 (4.2, 13.8)	2/ 7 (28.6)	4.1 (0.5, NE)	0.86 (0.18, 4.19)	0.8550	
no	48/103 (46.6)	4.6 (2.8, NE)	16/ 55 (29.1)	8.4 (4.4, NE)	1.47 (0.83, 2.60)	0.1939	
Presence of liver metastasis at baseline							0.9077
yes	30/ 68 (44.1)	4.5 (1.6, NE)	10/ 34 (29.4)	8.4 (2.6, 8.4)	1.40 (0.68, 2.89)	0.3705	
no	26/ 57 (45.6)	8.3 (2.8, NE)	8/ 28 (28.6)	NE (4.4, NE)	1.30 (0.58, 2.90)	0.5309	
Renal impairment at baseline							0.8690
normal	17/ 33 (51.5)	3.2 (1.4, NE)	4/ 13 (30.8)	NE (1.4, NE)	1.66 (0.56, 4.98)	0.3644	
mild	23/ 53 (43.4)	5.9 (4.2, NE)	9/ 28 (32.1)	4.4 (2.6, NE)	1.08 (0.49, 2.36)	0.8811	
moderate	16/ 39 (41.0)	8.3 (1.8, NE)	5/ 20 (25.0)	NE (1.7, NE)	1.52 (0.55, 4.20)	0.4212	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.5917
normal	41/ 88 (46.6)	5.9 (3.2, NE)	12/ 47 (25.5)	NE (3.0, NE)	1.56 (0.81, 2.99)	0.1827	
mild	15/ 36 (41.7)	13.9 (1.4, NE)	6/ 15 (40.0)	4.4 (0.7, 8.4)	1.05 (0.40, 2.74)	0.9442	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3790
yes	1/ 8 (12.5)	NE (0.5, NE)	1/ 5 (20.0)	NE (0.7, NE)	0.53 (0.03, 8.56)	0.6528	
no	55/117 (47.0)	4.6 (3.2, 13.9)	17/ 57 (29.8)	8.4 (4.1, 8.4)	1.41 (0.81, 2.45)	0.2311	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9855
yes	0/ 3 (0.0)	NE (NE , NE)	1/ 4 (25.0)	NE (0.7, NE)	NE	NE	
no	56/122 (45.9)	5.9 (3.2, NE)	17/ 58 (29.3)	8.4 (4.1, 8.4)	1.39 (0.80, 2.41)	0.2505	

Time to Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	39 (31.2)	15 (24.2)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (7.0, NE)	11.4 (4.4, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.88 (0.48, 1.61)	
p-value [c]	0.6544	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.89 (0.49, 1.63)	
p-value [c]	0.6918	

Time to Definitive Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.4953
Japan	29/ 99 (29.3)	NE (7.0, NE)	11/ 50 (22.0)	11.4 (4.4, NE)	1.00 (0.49, 2.03)	0.9928	
Korea	10/ 26 (38.5)	9.9 (4.2, NE)	4/ 12 (33.3)	4.4 (0.5, NE)	0.56 (0.17, 1.90)	0.3326	
Lines of prior systemic therapy							0.4810
2	18/ 66 (27.3)	NE (5.6, NE)	9/ 38 (23.7)	5.5 (4.3, NE)	0.86 (0.38, 1.94)	0.7086	
3	14/ 34 (41.2)	9.9 (2.9, NE)	4/ 18 (22.2)	11.4 (NE , NE)	1.38 (0.45, 4.23)	0.5735	
>=4	7/ 25 (28.0)	NE (5.9, NE)	2/ 6 (33.3)	4.1 (0.7, NE)	0.51 (0.10, 2.53)	0.3849	
Age							0.9839
<65 years	18/ 55 (32.7)	NE (5.6, NE)	7/ 27 (25.9)	4.4 (4.3, NE)	0.85 (0.35, 2.10)	0.7182	
>=65 years	21/ 70 (30.0)	NE (5.9, NE)	8/ 35 (22.9)	11.4 (4.1, NE)	0.91 (0.40, 2.06)	0.8075	
Sex							0.4751
female	9/ 30 (30.0)	NE (2.9, NE)	2/ 15 (13.3)	NE (NE , NE)	1.55 (0.33, 7.36)	0.5687	
male	30/ 95 (31.6)	NE (7.0, NE)	13/ 47 (27.7)	5.5 (4.3, NE)	0.78 (0.40, 1.51)	0.4397	
ECOG PS							0.0526
0	18/ 62 (29.0)	NE (7.0, NE)	2/ 30 (6.7)	NE (NE , NE)	3.06 (0.70, 13.34)	0.1190	
1	21/ 63 (33.3)	9.9 (4.6, NE)	13/ 32 (40.6)	4.4 (4.1, 11.4)	0.57 (0.28, 1.15)	0.1098	
HER2 Status in central laboratory							0.3951
IHC 3+	29/ 96 (30.2)	NE (7.2, NE)	8/ 47 (17.0)	11.4 (4.3, NE)	1.16 (0.52, 2.58)	0.7175	
IHC 2+/ISH +	10/ 29 (34.5)	5.9 (1.8, NE)	7/ 15 (46.7)	4.4 (1.7, NE)	0.64 (0.24, 1.73)	0.3646	
Primary tumor location							0.9393
Gastric	35/108 (32.4)	NE (7.0, NE)	14/ 55 (25.5)	11.4 (4.3, NE)	0.91 (0.49, 1.72)	0.7652	
GEJ	4/ 17 (23.5)	NE (3.2, NE)	1/ 7 (14.3)	4.4 (NE , NE)	0.96 (0.11, 8.73)	0.9701	
Histological subtype							0.6069
intestinal	26/ 89 (29.2)	NE (7.2, NE)	9/ 38 (23.7)	11.4 (4.1, NE)	0.93 (0.43, 2.01)	0.8522	
diffuse	10/ 28 (35.7)	NE (2.9, NE)	5/ 18 (27.8)	5.5 (1.4, NE)	0.73 (0.24, 2.27)	0.5705	
others	3/ 8 (37.5)	5.6 (1.4, 5.6)	1/ 6 (16.7)	NE (4.4, NE)	2.73 (0.28, 26.42)	0.3657	
Number of metastatic sites							0.8595
<2	8/ 23 (34.8)	NE (3.2, NE)	3/ 10 (30.0)	5.5 (2.8, NE)	0.74 (0.19, 2.84)	0.6608	
>= 2	31/102 (30.4)	NE (7.0, NE)	12/ 52 (23.1)	11.4 (4.3, 11.4)	0.94 (0.48, 1.86)	0.8454	
Previous total gastrectomy							0.4197
yes	4/ 22 (18.2)	NE (7.2, NE)	2/ 9 (22.2)	4.1 (0.7, NE)	0.51 (0.08, 3.15)	0.4634	
no	35/103 (34.0)	NE (5.9, NE)	13/ 53 (24.5)	11.4 (4.4, NE)	0.99 (0.52, 1.88)	0.9512	
Prior adjuvant/ neoadjuvant therapy							0.3771
yes	8/ 30 (26.7)	NE (7.0, NE)	3/ 10 (30.0)	4.4 (0.7, NE)	0.52 (0.13, 2.07)	0.3376	
no	31/ 95 (32.6)	NE (5.6, NE)	12/ 52 (23.1)	11.4 (4.4, NE)	1.03 (0.52, 2.02)	0.9480	
Prior ramucirumab contained treatment							0.7639
yes	29/ 94 (30.9)	NE (7.2, NE)	10/ 41 (24.4)	11.4 (4.1, 11.4)	0.85 (0.41, 1.76)	0.6429	
no	10/ 31 (32.3)	NE (4.6, NE)	5/ 21 (23.8)	NE (4.3, NE)	0.96 (0.32, 2.88)	0.9218	
Prior nivolumab contained treatment							0.8851
yes	14/ 33 (42.4)	NE (1.8, NE)	4/ 15 (26.7)	11.4 (0.6, 11.4)	1.05 (0.34, 3.23)	0.9410	
no	25/ 92 (27.2)	NE (7.0, NE)	11/ 47 (23.4)	5.5 (4.4, NE)	0.78 (0.37, 1.61)	0.4876	

Time to Definitive Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

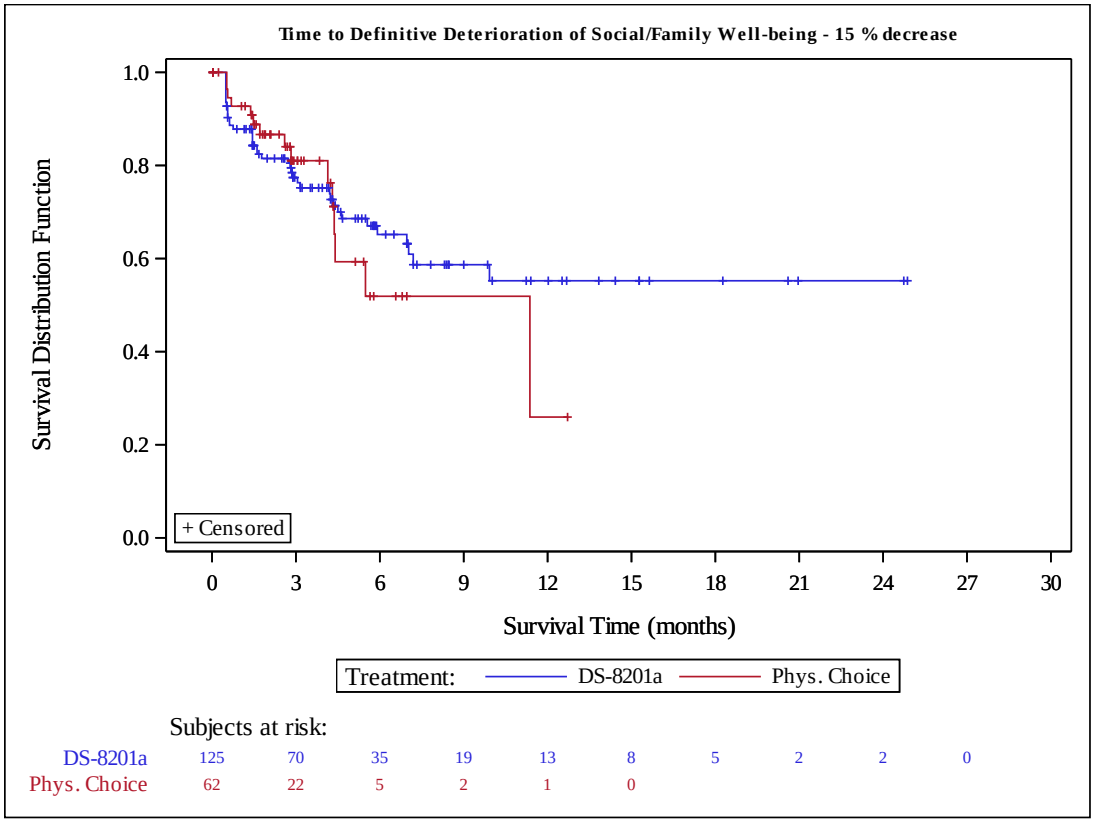
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.6320
yes	17/ 44 (38.6)	NE (4.2, NE)	5/ 17 (29.4)	4.1 (2.8, 11.4)	0.79 (0.29, 2.16)	0.6225	
no	22/ 81 (27.2)	NE (7.0, NE)	10/ 45 (22.2)	NE (4.4, NE)	0.85 (0.40, 1.84)	0.6768	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.5705
yes	5/ 22 (22.7)	9.9 (5.9, NE)	2/ 7 (28.6)	4.1 (2.8, NE)	0.53 (0.09, 2.92)	0.4548	
no	34/103 (33.0)	NE (7.0, NE)	13/ 55 (23.6)	11.4 (4.4, NE)	0.98 (0.51, 1.87)	0.9276	
Presence of liver metastasis at baseline							0.5502
yes	23/ 68 (33.8)	9.9 (4.2, NE)	8/ 34 (23.5)	11.4 (4.1, 11.4)	1.06 (0.47, 2.40)	0.8932	
no	16/ 57 (28.1)	NE (7.0, NE)	7/ 28 (25.0)	5.5 (4.4, NE)	0.70 (0.28, 1.75)	0.4377	
Renal impairment at baseline							0.5705
normal	14/ 33 (42.4)	7.2 (3.2, NE)	3/ 13 (23.1)	4.3 (1.4, NE)	1.01 (0.28, 3.72)	0.9979	
mild	13/ 53 (24.5)	NE (7.0, NE)	8/ 28 (28.6)	5.5 (2.8, NE)	0.57 (0.24, 1.40)	0.2106	
moderate	12/ 39 (30.8)	NE (4.5, NE)	4/ 20 (20.0)	NE (4.4, NE)	1.38 (0.44, 4.29)	0.5783	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7276
normal	26/ 88 (29.5)	NE (7.0, NE)	9/ 47 (19.1)	NE (4.4, NE)	1.02 (0.47, 2.22)	0.9631	
mild	13/ 36 (36.1)	7.2 (2.9, NE)	6/ 15 (40.0)	4.4 (2.8, 11.4)	0.80 (0.30, 2.12)	0.6481	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.6118
yes	1/ 8 (12.5)	NE (7.2, NE)	1/ 5 (20.0)	NE (5.5, NE)	0.32 (0.02, 5.15)	0.3940	
no	38/117 (32.5)	NE (7.0, NE)	14/ 57 (24.6)	11.4 (4.3, 11.4)	0.93 (0.50, 1.73)	0.7910	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9877
yes	0/ 3 (0.0)	NE (NE , NE)	1/ 4 (25.0)	NE (5.5, NE)	NE	NE	
no	39/122 (32.0)	NE (7.0, NE)	14/ 58 (24.1)	11.4 (4.3, 11.4)	0.89 (0.48, 1.67)	0.7052	

Time to Definitive Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	121	17 (14.0)	74 (61.2)	30 (24.8)	52	6 (11.5)	40 (76.9)	6 (11.5)
	Day 43	118	14 (11.9)	77 (65.3)	27 (22.9)	53	6 (11.3)	39 (73.6)	8 (15.1)
	Day 85	99	7 (7.1)	72 (72.7)	20 (20.2)	36	4 (11.1)	26 (72.2)	6 (16.7)
	Day 127	74	10 (13.5)	43 (58.1)	21 (28.4)	19	1 (5.3)	13 (68.4)	5 (26.3)
	Day 169	57	4 (7.0)	42 (73.7)	11 (19.3)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 211	44	8 (18.2)	25 (56.8)	11 (25.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	37	3 (8.1)	20 (54.1)	14 (37.8)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	29	2 (6.9)	15 (51.7)	12 (41.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	27	2 (7.4)	18 (66.7)	7 (25.9)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	21	2 (9.5)	16 (76.2)	3 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	0 (0.0)	11 (68.8)	5 (31.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	97	11 (11.3)	65 (67.0)	21 (21.6)	56	4 (7.1)	40 (71.4)	12 (21.4)
Region									
Japan									
	Day 15	98	14 (14.3)	60 (61.2)	24 (24.5)	45	6 (13.3)	34 (75.6)	5 (11.1)
	Day 43	94	13 (13.8)	61 (64.9)	20 (21.3)	43	5 (11.6)	33 (76.7)	5 (11.6)
	Day 85	77	6 (7.8)	56 (72.7)	15 (19.5)	32	3 (9.4)	23 (71.9)	6 (18.8)
	Day 127	60	7 (11.7)	37 (61.7)	16 (26.7)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	49	3 (6.1)	38 (77.6)	8 (16.3)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	36	4 (11.1)	23 (63.9)	9 (25.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	29	1 (3.4)	15 (51.7)	13 (44.8)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	23	1 (4.3)	13 (56.5)	9 (39.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	21	0 (0.0)	17 (81.0)	4 (19.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	18	1 (5.6)	14 (77.8)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	7 (9.0)	56 (71.8)	15 (19.2)	48	4 (8.3)	35 (72.9)	9 (18.8)
Region									
Korea									
	Day 15	23	3 (13.0)	14 (60.9)	6 (26.1)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 43	24	1 (4.2)	16 (66.7)	7 (29.2)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 85	22	1 (4.5)	16 (72.7)	5 (22.7)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 127	14	3 (21.4)	6 (42.9)	5 (35.7)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	8	1 (12.5)	4 (50.0)	3 (37.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	4 (50.0)	2 (25.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	2 (25.0)	5 (62.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	6	1 (16.7)	2 (33.3)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	6	2 (33.3)	1 (16.7)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	19	4 (21.1)	9 (47.4)	6 (31.6)	8	0 (0.0)	5 (62.5)	3 (37.5)
Lines of prior systemic therapy									
2									
	Day 15	62	10 (16.1)	39 (62.9)	13 (21.0)	34	3 (8.8)	28 (82.4)	3 (8.8)
	Day 43	62	8 (12.9)	42 (67.7)	12 (19.4)	36	4 (11.1)	28 (77.8)	4 (11.1)
	Day 85	50	2 (4.0)	38 (76.0)	10 (20.0)	21	2 (9.5)	14 (66.7)	5 (23.8)
	Day 127	33	3 (9.1)	20 (60.6)	10 (30.3)	14	0 (0.0)	10 (71.4)	4 (28.6)
	Day 169	24	0 (0.0)	19 (79.2)	5 (20.8)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	21	5 (23.8)	11 (52.4)	5 (23.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	11 (61.1)	5 (27.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	0 (0.0)	8 (66.7)	4 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	1 (14.3)	6 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	51	6 (11.8)	34 (66.7)	11 (21.6)	34	1 (2.9)	26 (76.5)	7 (20.6)
Lines of prior systemic therapy									
3									
	Day 15	34	4 (11.8)	20 (58.8)	10 (29.4)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 43	33	5 (15.2)	18 (54.5)	10 (30.3)	14	2 (14.3)	8 (57.1)	4 (28.6)
	Day 85	28	4 (14.3)	17 (60.7)	7 (25.0)	12	2 (16.7)	9 (75.0)	1 (8.3)
	Day 127	23	4 (17.4)	11 (47.8)	8 (34.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	19	3 (15.8)	13 (68.4)	3 (15.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 211	13	2 (15.4)	8 (61.5)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	0 (0.0)	5 (45.5)	6 (54.5)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	9	1 (11.1)	4 (44.4)	4 (44.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	4 (15.4)	15 (57.7)	7 (26.9)	17	3 (17.6)	11 (64.7)	3 (17.6)
Lines of prior systemic therapy									
>=4									
	Day 15	25	3 (12.0)	15 (60.0)	7 (28.0)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 43	23	1 (4.3)	17 (73.9)	5 (21.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	1 (4.8)	17 (81.0)	3 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	3 (16.7)	12 (66.7)	3 (16.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	14	1 (7.1)	10 (71.4)	3 (21.4)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	3 (37.5)	4 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	16 (80.0)	3 (15.0)	5	0 (0.0)	3 (60.0)	2 (40.0)
Age									
<65 years									
	Day 15	52	5 (9.6)	33 (63.5)	14 (26.9)	22	1 (4.5)	19 (86.4)	2 (9.1)
	Day 43	52	5 (9.6)	34 (65.4)	13 (25.0)	24	3 (12.5)	18 (75.0)	3 (12.5)
	Day 85	47	3 (6.4)	35 (74.5)	9 (19.1)	16	2 (12.5)	12 (75.0)	2 (12.5)
	Day 127	34	4 (11.8)	20 (58.8)	10 (29.4)	8	0 (0.0)	5 (62.5)	3 (37.5)
	Day 169	27	1 (3.7)	21 (77.8)	5 (18.5)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 211	18	2 (11.1)	10 (55.6)	6 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	16	1 (6.3)	10 (62.5)	5 (31.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	0 (0.0)	7 (53.8)	6 (46.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	5 (45.5)	5 (45.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	42	4 (9.5)	29 (69.0)	9 (21.4)	23	1 (4.3)	16 (69.6)	6 (26.1)
Age									
>=65 years									
	Day 15	69	12 (17.4)	41 (59.4)	16 (23.2)	30	5 (16.7)	21 (70.0)	4 (13.3)
	Day 43	66	9 (13.6)	43 (65.2)	14 (21.2)	29	3 (10.3)	21 (72.4)	5 (17.2)
	Day 85	52	4 (7.7)	37 (71.2)	11 (21.2)	20	2 (10.0)	14 (70.0)	4 (20.0)
	Day 127	40	6 (15.0)	23 (57.5)	11 (27.5)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 169	30	3 (10.0)	21 (70.0)	6 (20.0)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	26	6 (23.1)	15 (57.7)	5 (19.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	2 (9.5)	10 (47.6)	9 (42.9)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	16	2 (12.5)	8 (50.0)	6 (37.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	13 (81.3)	2 (12.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	13	1 (7.7)	11 (84.6)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

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Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	End of Treatment	55	7 (12.7)	36 (65.5)	12 (21.8)	33	3 (9.1)	24 (72.7)	6 (18.2)
Sex									
female									
	Day 15	29	5 (17.2)	16 (55.2)	8 (27.6)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 43	28	3 (10.7)	19 (67.9)	6 (21.4)	13	2 (15.4)	9 (69.2)	2 (15.4)
	Day 85	20	0 (0.0)	17 (85.0)	3 (15.0)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	13	3 (23.1)	7 (53.8)	3 (23.1)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	10	0 (0.0)	8 (80.0)	2 (20.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	22	0 (0.0)	17 (77.3)	5 (22.7)	14	2 (14.3)	11 (78.6)	1 (7.1)
Sex									
male									
	Day 15	92	12 (13.0)	58 (63.0)	22 (23.9)	39	5 (12.8)	30 (76.9)	4 (10.3)
	Day 43	90	11 (12.2)	58 (64.4)	21 (23.3)	40	4 (10.0)	30 (75.0)	6 (15.0)
	Day 85	79	7 (8.9)	55 (69.6)	17 (21.5)	28	3 (10.7)	19 (67.9)	6 (21.4)
	Day 127	61	7 (11.5)	36 (59.0)	18 (29.5)	16	0 (0.0)	11 (68.8)	5 (31.3)
	Day 169	47	4 (8.5)	34 (72.3)	9 (19.1)	9	0 (0.0)	6 (66.7)	3 (33.3)
	Day 211	36	7 (19.4)	21 (58.3)	8 (22.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	30	3 (10.0)	16 (53.3)	11 (36.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	25	2 (8.0)	13 (52.0)	10 (40.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	2 (8.3)	16 (66.7)	6 (25.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	19	2 (10.5)	14 (73.7)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	15	0 (0.0)	10 (66.7)	5 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	75	11 (14.7)	48 (64.0)	16 (21.3)	42	2 (4.8)	29 (69.0)	11 (26.2)
ECOG PS									
0									
	Day 15	61	10 (16.4)	37 (60.7)	14 (23.0)	26	4 (15.4)	21 (80.8)	1 (3.8)
	Day 43	60	5 (8.3)	42 (70.0)	13 (21.7)	26	2 (7.7)	22 (84.6)	2 (7.7)
	Day 85	54	4 (7.4)	40 (74.1)	10 (18.5)	19	2 (10.5)	15 (78.9)	2 (10.5)
	Day 127	42	7 (16.7)	25 (59.5)	10 (23.8)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	36	2 (5.6)	30 (83.3)	4 (11.1)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 211	27	4 (14.8)	16 (59.3)	7 (25.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	24	2 (8.3)	12 (50.0)	10 (41.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	18	1 (5.6)	9 (50.0)	8 (44.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	0 (0.0)	12 (75.0)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	14	0 (0.0)	11 (78.6)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup / Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	48	6 (12.5)	36 (75.0)	6 (12.5)	29	2 (6.9)	25 (86.2)	2 (6.9)
ECOG PS									
1									
	Day 15	60	7 (11.7)	37 (61.7)	16 (26.7)	26	2 (7.7)	19 (73.1)	5 (19.2)
	Day 43	58	9 (15.5)	35 (60.3)	14 (24.1)	27	4 (14.8)	17 (63.0)	6 (22.2)
	Day 85	45	3 (6.7)	32 (71.1)	10 (22.2)	17	2 (11.8)	11 (64.7)	4 (23.5)
	Day 127	32	3 (9.4)	18 (56.3)	11 (34.4)	10	0 (0.0)	6 (60.0)	4 (40.0)
	Day 169	21	2 (9.5)	12 (57.1)	7 (33.3)	5	0 (0.0)	2 (40.0)	3 (60.0)
	Day 211	17	4 (23.5)	9 (52.9)	4 (23.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	13	1 (7.7)	8 (61.5)	4 (30.8)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	11	1 (9.1)	6 (54.5)	4 (36.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	2 (18.2)	6 (54.5)	3 (27.3)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	7	2 (28.6)	5 (71.4)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	49	5 (10.2)	29 (59.2)	15 (30.6)	27	2 (7.4)	15 (55.6)	10 (37.0)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	93	13 (14.0)	56 (60.2)	24 (25.8)	38	3 (7.9)	33 (86.8)	2 (5.3)
	Day 43	92	14 (15.2)	58 (63.0)	20 (21.7)	40	5 (12.5)	28 (70.0)	7 (17.5)
	Day 85	79	7 (8.9)	59 (74.7)	13 (16.5)	26	4 (15.4)	18 (69.2)	4 (15.4)
	Day 127	59	8 (13.6)	35 (59.3)	16 (27.1)	13	0 (0.0)	11 (84.6)	2 (15.4)
	Day 169	46	3 (6.5)	36 (78.3)	7 (15.2)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	38	7 (18.4)	22 (57.9)	9 (23.7)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	32	3 (9.4)	18 (56.3)	11 (34.4)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	26	2 (7.7)	13 (50.0)	11 (42.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	25	2 (8.0)	17 (68.0)	6 (24.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	19	2 (10.5)	15 (78.9)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	0 (0.0)	11 (68.8)	5 (31.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	10 (13.5)	50 (67.6)	14 (18.9)	42	3 (7.1)	32 (76.2)	7 (16.7)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	28	4 (14.3)	18 (64.3)	6 (21.4)	14	3 (21.4)	7 (50.0)	4 (28.6)
	Day 43	26	0 (0.0)	19 (73.1)	7 (26.9)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 85	20	0 (0.0)	13 (65.0)	7 (35.0)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	15	2 (13.3)	8 (53.3)	5 (33.3)	6	1 (16.7)	2 (33.3)	3 (50.0)
	Day 169	11	1 (9.1)	6 (54.5)	4 (36.4)	3	1 (33.3)	0 (0.0)	2 (66.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	1 (4.3)	15 (65.2)	7 (30.4)	14	1 (7.1)	8 (57.1)	5 (35.7)
Primary tumor location									
Gastric									
	Day 15	104	15 (14.4)	62 (59.6)	27 (26.0)	46	6 (13.0)	34 (73.9)	6 (13.0)
	Day 43	101	12 (11.9)	65 (64.4)	24 (23.8)	48	5 (10.4)	35 (72.9)	8 (16.7)
	Day 85	84	6 (7.1)	62 (73.8)	16 (19.0)	33	4 (12.1)	23 (69.7)	6 (18.2)
	Day 127	63	9 (14.3)	36 (57.1)	18 (28.6)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	47	4 (8.5)	32 (68.1)	11 (23.4)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 211	38	6 (15.8)	22 (57.9)	10 (26.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	31	3 (9.7)	16 (51.6)	12 (38.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	24	2 (8.3)	11 (45.8)	11 (45.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	22	2 (9.1)	14 (63.6)	6 (27.3)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	17	1 (5.9)	14 (82.4)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	0 (0.0)	9 (69.2)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	9 (11.0)	53 (64.6)	20 (24.4)	50	4 (8.0)	35 (70.0)	11 (22.0)
Primary tumor location									
GEJ									
	Day 15	17	2 (11.8)	12 (70.6)	3 (17.6)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	17	2 (11.8)	12 (70.6)	3 (17.6)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 85	15	1 (6.7)	10 (66.7)	4 (26.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	7 (63.6)	3 (27.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	10	0 (0.0)	10 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	6	2 (33.3)	3 (50.0)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	2 (13.3)	12 (80.0)	1 (6.7)	6	0 (0.0)	5 (83.3)	1 (16.7)
Histological subtype									
intestinal									
	Day 15	88	12 (13.6)	55 (62.5)	21 (23.9)	35	5 (14.3)	27 (77.1)	3 (8.6)
	Day 43	86	11 (12.8)	58 (67.4)	17 (19.8)	34	3 (8.8)	27 (79.4)	4 (11.8)
	Day 85	73	5 (6.8)	54 (74.0)	14 (19.2)	27	1 (3.7)	21 (77.8)	5 (18.5)
	Day 127	55	8 (14.5)	33 (60.0)	14 (25.5)	14	1 (7.1)	10 (71.4)	3 (21.4)
	Day 169	44	3 (6.8)	34 (77.3)	7 (15.9)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	32	5 (15.6)	21 (65.6)	6 (18.8)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	25	2 (8.0)	14 (56.0)	9 (36.0)	2	0 (0.0)	1 (50.0)	1 (50.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	18	1 (5.6)	11 (61.1)	6 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	0 (0.0)	14 (87.5)	2 (12.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	13	1 (7.7)	11 (84.6)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	8 (11.1)	51 (70.8)	13 (18.1)	37	3 (8.1)	27 (73.0)	7 (18.9)
Histological subtype									
diffuse									
	Day 15	27	5 (18.5)	13 (48.1)	9 (33.3)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 43	26	2 (7.7)	17 (65.4)	7 (26.9)	14	1 (7.1)	9 (64.3)	4 (28.6)
	Day 85	22	2 (9.1)	15 (68.2)	5 (22.7)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 127	15	2 (13.3)	8 (53.3)	5 (33.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	11	1 (9.1)	8 (72.7)	2 (18.2)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	10	3 (30.0)	4 (40.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	1 (11.1)	4 (44.4)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	9	2 (22.2)	4 (44.4)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	2 (9.5)	12 (57.1)	7 (33.3)	16	1 (6.3)	10 (62.5)	5 (31.3)
Histological subtype									
others									
	Day 15	6	0 (0.0)	6 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	1 (16.7)	2 (33.3)	3 (50.0)	5	2 (40.0)	3 (60.0)	0 (0.0)
	Day 85	4	0 (0.0)	3 (75.0)	1 (25.0)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 127	4	0 (0.0)	2 (50.0)	2 (50.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	2	0 (0.0)	0 (0.0)	2 (100.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	1 (25.0)	2 (50.0)	1 (25.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
Number of metastatic sites									
<2									
	Day 15	22	4 (18.2)	14 (63.6)	4 (18.2)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	22	3 (13.6)	17 (77.3)	2 (9.1)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 85	21	1 (4.8)	15 (71.4)	5 (23.8)	8	1 (12.5)	5 (62.5)	2 (25.0)
	Day 127	17	3 (17.6)	8 (47.1)	6 (35.3)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 169	16	2 (12.5)	12 (75.0)	2 (12.5)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 211	14	3 (21.4)	8 (57.1)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	3 (30.0)	4 (40.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	5	0 (0.0)	3 (60.0)	2 (40.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	4 (22.2)	11 (61.1)	3 (16.7)	9	1 (11.1)	6 (66.7)	2 (22.2)
Number of metastatic sites									
>= 2									
	Day 15	99	13 (13.1)	60 (60.6)	26 (26.3)	42	6 (14.3)	32 (76.2)	4 (9.5)
	Day 43	96	11 (11.5)	60 (62.5)	25 (26.0)	43	5 (11.6)	30 (69.8)	8 (18.6)
	Day 85	78	6 (7.7)	57 (73.1)	15 (19.2)	28	3 (10.7)	21 (75.0)	4 (14.3)
	Day 127	57	7 (12.3)	35 (61.4)	15 (26.3)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	41	2 (4.9)	30 (73.2)	9 (22.0)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 211	30	5 (16.7)	17 (56.7)	8 (26.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	0 (0.0)	16 (59.3)	11 (40.7)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	21	1 (4.8)	11 (52.4)	9 (42.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	19	1 (5.3)	14 (73.7)	4 (21.1)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	16	2 (12.5)	13 (81.3)	1 (6.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	7 (8.9)	54 (68.4)	18 (22.8)	47	3 (6.4)	34 (72.3)	10 (21.3)
Previous total gastrectomy									
yes									
	Day 15	20	6 (30.0)	8 (40.0)	6 (30.0)	7	2 (28.6)	4 (57.1)	1 (14.3)
	Day 43	20	2 (10.0)	14 (70.0)	4 (20.0)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 85	18	1 (5.6)	17 (94.4)	0 (0.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	10 (90.9)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	8	1 (12.5)	7 (87.5)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 211	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

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Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	3 (16.7)	14 (77.8)	1 (5.6)	9	0 (0.0)	7 (77.8)	2 (22.2)
Previous total gastrectomy									
no									
	Day 15	101	11 (10.9)	66 (65.3)	24 (23.8)	45	4 (8.9)	36 (80.0)	5 (11.1)
	Day 43	98	12 (12.2)	63 (64.3)	23 (23.5)	45	6 (13.3)	32 (71.1)	7 (15.6)
	Day 85	81	6 (7.4)	55 (67.9)	20 (24.7)	30	4 (13.3)	20 (66.7)	6 (20.0)
	Day 127	63	9 (14.3)	33 (52.4)	21 (33.3)	17	1 (5.9)	12 (70.6)	4 (23.5)
	Day 169	49	3 (6.1)	35 (71.4)	11 (22.4)	10	1 (10.0)	7 (70.0)	2 (20.0)
	Day 211	36	7 (19.4)	19 (52.8)	10 (27.8)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	33	2 (6.1)	19 (57.6)	12 (36.4)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	25	2 (8.0)	12 (48.0)	11 (44.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	23	1 (4.3)	15 (65.2)	7 (30.4)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	19	2 (10.5)	14 (73.7)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	14	0 (0.0)	10 (71.4)	4 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	8 (10.1)	51 (64.6)	20 (25.3)	47	4 (8.5)	33 (70.2)	10 (21.3)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	8 (27.6)	14 (48.3)	7 (24.1)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 43	28	4 (14.3)	17 (60.7)	7 (25.0)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 85	27	2 (7.4)	20 (74.1)	5 (18.5)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 127	22	2 (9.1)	14 (63.6)	6 (27.3)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 169	15	2 (13.3)	11 (73.3)	2 (13.3)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 211	12	2 (16.7)	6 (50.0)	4 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	2 (20.0)	3 (30.0)	5 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	10	1 (10.0)	5 (50.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	25	4 (16.0)	20 (80.0)	1 (4.0)	9	0 (0.0)	7 (77.8)	2 (22.2)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	92	9 (9.8)	60 (65.2)	23 (25.0)	44	4 (9.1)	35 (79.5)	5 (11.4)
	Day 43	90	10 (11.1)	60 (66.7)	20 (22.2)	45	6 (13.3)	32 (71.1)	7 (15.6)
	Day 85	72	5 (6.9)	52 (72.2)	15 (20.8)	29	4 (13.8)	19 (65.5)	6 (20.7)
	Day 127	52	8 (15.4)	29 (55.8)	15 (28.8)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	42	2 (4.8)	31 (73.8)	9 (21.4)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 211	32	6 (18.8)	19 (59.4)	7 (21.9)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	1 (3.7)	17 (63.0)	9 (33.3)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	19	1 (5.3)	10 (52.6)	8 (42.1)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	17	1 (5.9)	12 (70.6)	4 (23.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	15	2 (13.3)	12 (80.0)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	0 (0.0)	8 (66.7)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	7 (9.7)	45 (62.5)	20 (27.8)	47	4 (8.5)	33 (70.2)	10 (21.3)
Prior ramucirumab contained treatment									
yes									
	Day 15	91	13 (14.3)	56 (61.5)	22 (24.2)	34	3 (8.8)	28 (82.4)	3 (8.8)
	Day 43	90	10 (11.1)	59 (65.6)	21 (23.3)	33	5 (15.2)	25 (75.8)	3 (9.1)
	Day 85	73	5 (6.8)	51 (69.9)	17 (23.3)	23	3 (13.0)	17 (73.9)	3 (13.0)
	Day 127	59	6 (10.2)	36 (61.0)	17 (28.8)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 169	45	3 (6.7)	32 (71.1)	10 (22.2)	7	1 (14.3)	4 (57.1)	2 (28.6)
	Day 211	32	3 (9.4)	21 (65.6)	8 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	25	1 (4.0)	13 (52.0)	11 (44.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	22	1 (4.5)	11 (50.0)	10 (45.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	0 (0.0)	15 (71.4)	6 (28.6)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	17	0 (0.0)	15 (88.2)	2 (11.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	13	0 (0.0)	9 (69.2)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	7 (9.5)	53 (71.6)	14 (18.9)	36	3 (8.3)	26 (72.2)	7 (19.4)
Prior ramucirumab contained treatment									
no									
	Day 15	30	4 (13.3)	18 (60.0)	8 (26.7)	18	3 (16.7)	12 (66.7)	3 (16.7)
	Day 43	28	4 (14.3)	18 (64.3)	6 (21.4)	20	1 (5.0)	14 (70.0)	5 (25.0)
	Day 85	26	2 (7.7)	21 (80.8)	3 (11.5)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 127	15	4 (26.7)	7 (46.7)	4 (26.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 211	12	5 (41.7)	4 (33.3)	3 (25.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	2 (16.7)	7 (58.3)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	1 (14.3)	4 (57.1)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	2 (33.3)	3 (50.0)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	2 (50.0)	1 (25.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	4 (17.4)	12 (52.2)	7 (30.4)	20	1 (5.0)	14 (70.0)	5 (25.0)
Prior nivolumab contained treatment									
yes									
	Day 15	33	4 (12.1)	19 (57.6)	10 (30.3)	13	3 (23.1)	8 (61.5)	2 (15.4)
	Day 43	31	2 (6.5)	18 (58.1)	11 (35.5)	10	0 (0.0)	7 (70.0)	3 (30.0)
	Day 85	27	3 (11.1)	17 (63.0)	7 (25.9)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 127	26	4 (15.4)	12 (46.2)	10 (38.5)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 169	21	2 (9.5)	14 (66.7)	5 (23.8)	3	1 (33.3)	1 (33.3)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	16	2 (12.5)	10 (62.5)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	14	1 (7.1)	6 (42.9)	7 (50.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	12	1 (8.3)	6 (50.0)	5 (41.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	0 (0.0)	9 (81.8)	2 (18.2)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	2 (7.7)	17 (65.4)	7 (26.9)	14	2 (14.3)	9 (64.3)	3 (21.4)
Prior nivolumab contained treatment									
no									
	Day 15	88	13 (14.8)	55 (62.5)	20 (22.7)	39	3 (7.7)	32 (82.1)	4 (10.3)
	Day 43	87	12 (13.8)	59 (67.8)	16 (18.4)	43	6 (14.0)	32 (74.4)	5 (11.6)
	Day 85	72	4 (5.6)	55 (76.4)	13 (18.1)	26	4 (15.4)	17 (65.4)	5 (19.2)
	Day 127	48	6 (12.5)	31 (64.6)	11 (22.9)	16	0 (0.0)	12 (75.0)	4 (25.0)
	Day 169	36	2 (5.6)	28 (77.8)	6 (16.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	28	6 (21.4)	15 (53.6)	7 (25.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	23	2 (8.7)	14 (60.9)	7 (30.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	1 (5.9)	9 (52.9)	7 (41.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	2 (12.5)	9 (56.3)	5 (31.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	2 (18.2)	8 (72.7)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	0 (0.0)	5 (55.6)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	9 (12.7)	48 (67.6)	14 (19.7)	42	2 (4.8)	31 (73.8)	9 (21.4)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	43	5 (11.6)	26 (60.5)	12 (27.9)	15	3 (20.0)	9 (60.0)	3 (20.0)
	Day 43	41	2 (4.9)	27 (65.9)	12 (29.3)	12	0 (0.0)	9 (75.0)	3 (25.0)
	Day 85	37	4 (10.8)	24 (64.9)	9 (24.3)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 127	31	5 (16.1)	15 (48.4)	11 (35.5)	4	1 (25.0)	1 (25.0)	2 (50.0)
	Day 169	24	3 (12.5)	16 (66.7)	5 (20.8)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 211	20	4 (20.0)	12 (60.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	17	2 (11.8)	8 (47.1)	7 (41.2)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	16	2 (12.5)	9 (56.3)	5 (31.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	2 (13.3)	11 (73.3)	2 (13.3)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	35	4 (11.4)	21 (60.0)	10 (28.6)	16	2 (12.5)	10 (62.5)	4 (25.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	78	12 (15.4)	48 (61.5)	18 (23.1)	37	3 (8.1)	31 (83.8)	3 (8.1)
	Day 43	77	12 (15.6)	50 (64.9)	15 (19.5)	41	6 (14.6)	30 (73.2)	5 (12.2)
	Day 85	62	3 (4.8)	48 (77.4)	11 (17.7)	25	4 (16.0)	17 (68.0)	4 (16.0)
	Day 127	43	5 (11.6)	28 (65.1)	10 (23.3)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 169	33	1 (3.0)	26 (78.8)	6 (18.2)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	24	4 (16.7)	13 (54.2)	7 (29.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	1 (5.0)	12 (60.0)	7 (35.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	0 (0.0)	6 (46.2)	7 (53.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	0 (0.0)	7 (58.3)	5 (41.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	9	1 (11.1)	7 (77.8)	1 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	7 (11.3)	44 (71.0)	11 (17.7)	40	2 (5.0)	30 (75.0)	8 (20.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
yes									
	Day 15	22	3 (13.6)	14 (63.6)	5 (22.7)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 43	19	2 (10.5)	15 (78.9)	2 (10.5)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 85	16	2 (12.5)	12 (75.0)	2 (12.5)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 127	12	1 (8.3)	9 (75.0)	2 (16.7)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	9	1 (11.1)	7 (77.8)	1 (11.1)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	0 (0.0)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	1 (7.1)	11 (78.6)	2 (14.3)	6	1 (16.7)	3 (50.0)	2 (33.3)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
no									
	Day 15	99	14 (14.1)	60 (60.6)	25 (25.3)	46	5 (10.9)	36 (78.3)	5 (10.9)
	Day 43	99	12 (12.1)	62 (62.6)	25 (25.3)	47	5 (10.6)	34 (72.3)	8 (17.0)
	Day 85	83	5 (6.0)	60 (72.3)	18 (21.7)	31	3 (9.7)	23 (74.2)	5 (16.1)
	Day 127	62	9 (14.5)	34 (54.8)	19 (30.6)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	48	3 (6.3)	35 (72.9)	10 (20.8)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	39	7 (17.9)	21 (53.8)	11 (28.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	3 (9.1)	16 (48.5)	14 (42.4)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	26	1 (3.8)	15 (57.7)	10 (38.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	1 (4.2)	17 (70.8)	6 (25.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	18	1 (5.6)	14 (77.8)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	0 (0.0)	9 (69.2)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	10 (12.0)	54 (65.1)	19 (22.9)	50	3 (6.0)	37 (74.0)	10 (20.0)
Presence of liver metastasis at baseline yes									
	Day 15	66	8 (12.1)	40 (60.6)	18 (27.3)	27	6 (22.2)	20 (74.1)	1 (3.7)
	Day 43	64	6 (9.4)	43 (67.2)	15 (23.4)	28	3 (10.7)	20 (71.4)	5 (17.9)
	Day 85	51	3 (5.9)	32 (62.7)	16 (31.4)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 127	37	5 (13.5)	19 (51.4)	13 (35.1)	10	1 (10.0)	7 (70.0)	2 (20.0)
	Day 169	28	1 (3.6)	21 (75.0)	6 (21.4)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 211	20	2 (10.0)	11 (55.0)	7 (35.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	0 (0.0)	10 (52.6)	9 (47.4)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	14	1 (7.1)	5 (35.7)	8 (57.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	13	1 (7.7)	8 (61.5)	4 (30.8)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	4 (8.0)	32 (64.0)	14 (28.0)	31	3 (9.7)	21 (67.7)	7 (22.6)
Presence of liver metastasis at baseline no									
	Day 15	55	9 (16.4)	34 (61.8)	12 (21.8)	25	0 (0.0)	20 (80.0)	5 (20.0)
	Day 43	54	8 (14.8)	34 (63.0)	12 (22.2)	25	3 (12.0)	19 (76.0)	3 (12.0)
	Day 85	48	4 (8.3)	40 (83.3)	4 (8.3)	20	2 (10.0)	16 (80.0)	2 (10.0)
	Day 127	37	5 (13.5)	24 (64.9)	8 (21.6)	9	0 (0.0)	6 (66.7)	3 (33.3)
	Day 169	29	3 (10.3)	21 (72.4)	5 (17.2)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 211	24	6 (25.0)	14 (58.3)	4 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	3 (16.7)	10 (55.6)	5 (27.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	1 (6.7)	10 (66.7)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	1 (7.1)	10 (71.4)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	7 (70.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	47	7 (14.9)	33 (70.2)	7 (14.9)	25	1 (4.0)	19 (76.0)	5 (20.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Renal impairment at baseline									
normal									
	Day 15	32	4 (12.5)	20 (62.5)	8 (25.0)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 43	33	2 (6.1)	23 (69.7)	8 (24.2)	12	2 (16.7)	6 (50.0)	4 (33.3)
	Day 85	26	1 (3.8)	18 (69.2)	7 (26.9)	8	2 (25.0)	6 (75.0)	0 (0.0)
	Day 127	19	3 (15.8)	11 (57.9)	5 (26.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	17	0 (0.0)	14 (82.4)	3 (17.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	12	1 (8.3)	5 (41.7)	6 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	13	1 (7.7)	7 (53.8)	5 (38.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	0 (0.0)	5 (41.7)	7 (58.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	5 (45.5)	5 (45.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	3 (42.9)	4 (57.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	2 (8.3)	16 (66.7)	6 (25.0)	11	1 (9.1)	7 (63.6)	3 (27.3)
Renal impairment at baseline									
mild									
	Day 15	51	5 (9.8)	34 (66.7)	12 (23.5)	25	4 (16.0)	18 (72.0)	3 (12.0)
	Day 43	51	8 (15.7)	32 (62.7)	11 (21.6)	23	1 (4.3)	21 (91.3)	1 (4.3)
	Day 85	45	3 (6.7)	33 (73.3)	9 (20.0)	14	1 (7.1)	8 (57.1)	5 (35.7)
	Day 127	31	3 (9.7)	19 (61.3)	9 (29.0)	9	0 (0.0)	6 (66.7)	3 (33.3)
	Day 169	23	3 (13.0)	15 (65.2)	5 (21.7)	6	0 (0.0)	3 (50.0)	3 (50.0)
	Day 211	17	2 (11.8)	11 (64.7)	4 (23.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	13	1 (7.7)	6 (46.2)	6 (46.2)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 295	9	2 (22.2)	5 (55.6)	2 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	5 (62.5)	2 (25.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	6	1 (16.7)	4 (66.7)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	3 (6.7)	33 (73.3)	9 (20.0)	25	2 (8.0)	17 (68.0)	6 (24.0)
Renal impairment at baseline									
moderate									
	Day 15	38	8 (21.1)	20 (52.6)	10 (26.3)	16	2 (12.5)	12 (75.0)	2 (12.5)
	Day 43	34	4 (11.8)	22 (64.7)	8 (23.5)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 85	28	3 (10.7)	21 (75.0)	4 (14.3)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 127	24	4 (16.7)	13 (54.2)	7 (29.2)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 169	17	1 (5.9)	13 (76.5)	3 (17.6)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 211	15	5 (33.3)	9 (60.0)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	0 (0.0)	8 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	6 (21.4)	16 (57.1)	6 (21.4)	19	1 (5.3)	15 (78.9)	3 (15.8)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	85	9 (10.6)	56 (65.9)	20 (23.5)	37	4 (10.8)	30 (81.1)	3 (8.1)
	Day 43	84	11 (13.1)	52 (61.9)	21 (25.0)	41	4 (9.8)	30 (73.2)	7 (17.1)
	Day 85	76	5 (6.6)	57 (75.0)	14 (18.4)	27	3 (11.1)	20 (74.1)	4 (14.8)
	Day 127	58	10 (17.2)	33 (56.9)	15 (25.9)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 169	45	4 (8.9)	33 (73.3)	8 (17.8)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	34	8 (23.5)	18 (52.9)	8 (23.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	30	3 (10.0)	17 (56.7)	10 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	23	2 (8.7)	12 (52.2)	9 (39.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	2 (9.5)	14 (66.7)	5 (23.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	2 (12.5)	12 (75.0)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	67	9 (13.4)	47 (70.1)	11 (16.4)	42	2 (4.8)	33 (78.6)	7 (16.7)
Hepatic impairment at baseline									
mild									
	Day 15	35	8 (22.9)	17 (48.6)	10 (28.6)	15	2 (13.3)	10 (66.7)	3 (20.0)
	Day 43	33	3 (9.1)	24 (72.7)	6 (18.2)	12	2 (16.7)	9 (75.0)	1 (8.3)
	Day 85	22	2 (9.1)	14 (63.6)	6 (27.3)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 127	15	0 (0.0)	9 (60.0)	6 (40.0)	5	0 (0.0)	2 (40.0)	3 (60.0)
	Day 169	12	0 (0.0)	9 (75.0)	3 (25.0)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 211	10	0 (0.0)	7 (70.0)	3 (30.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	7	0 (0.0)	3 (42.9)	4 (57.1)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	6	0 (0.0)	3 (50.0)	3 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	0 (0.0)	4 (66.7)	2 (33.3)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	29	2 (6.9)	17 (58.6)	10 (34.5)	14	2 (14.3)	7 (50.0)	5 (35.7)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	0 (0.0)	7 (87.5)	1 (12.5)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	0 (0.0)	8 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	0 (0.0)	7 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 127	6	1 (16.7)	5 (83.3)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	0 (0.0)	5 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	6	1 (16.7)	5 (83.3)	0 (0.0)	4	0 (0.0)	3 (75.0)	1 (25.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	113	17 (15.0)	67 (59.3)	29 (25.7)	48	6 (12.5)	37 (77.1)	5 (10.4)
	Day 43	110	14 (12.7)	69 (62.7)	27 (24.5)	50	6 (12.0)	36 (72.0)	8 (16.0)
	Day 85	92	7 (7.6)	65 (70.7)	20 (21.7)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	68	9 (13.2)	38 (55.9)	21 (30.9)	16	1 (6.3)	10 (62.5)	5 (31.3)
	Day 169	52	4 (7.7)	37 (71.2)	11 (21.2)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	40	7 (17.5)	23 (57.5)	10 (25.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	2 (6.1)	18 (54.5)	13 (39.4)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	27	2 (7.4)	14 (51.9)	11 (40.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	25	2 (8.0)	16 (64.0)	7 (28.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	20	2 (10.0)	15 (75.0)	3 (15.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	15	0 (0.0)	11 (73.3)	4 (26.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	91	10 (11.0)	60 (65.9)	21 (23.1)	52	4 (7.7)	37 (71.2)	11 (21.2)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 127	3	1 (33.3)	2 (66.7)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	0 (0.0)	3 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	1 (50.0)	1 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	1 (50.0)	1 (50.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	118	17 (14.4)	71 (60.2)	30 (25.4)	49	6 (12.2)	38 (77.6)	5 (10.2)
	Day 43	115	14 (12.2)	74 (64.3)	27 (23.5)	50	6 (12.0)	36 (72.0)	8 (16.0)
	Day 85	96	7 (7.3)	69 (71.9)	20 (20.8)	33	4 (12.1)	24 (72.7)	5 (15.2)
	Day 127	71	9 (12.7)	41 (57.7)	21 (29.6)	16	1 (6.3)	10 (62.5)	5 (31.3)
	Day 169	54	4 (7.4)	39 (72.2)	11 (20.4)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	42	7 (16.7)	24 (57.1)	11 (26.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	35	2 (5.7)	19 (54.3)	14 (40.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	28	2 (7.1)	14 (50.0)	12 (42.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	26	2 (7.7)	17 (65.4)	7 (26.9)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	21	2 (9.5)	16 (76.2)	3 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	16	0 (0.0)	11 (68.8)	5 (31.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	9 (75.0)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	95	10 (10.5)	64 (67.4)	21 (22.1)	53	4 (7.5)	38 (71.7)	11 (20.8)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Emotional Well-being Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	124 (99.2)	62	58 (93.5)
Day 15	125	118 (94.4)	62	52 (83.9)
Day 43	124	117 (94.4)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	57 (54.3)	45	11 (24.4)
Day 211	93	44 (47.3)	40	4 (10.0)
Day 253	84	37 (44.0)	34	2 (5.9)
Day 295	77	29 (37.7)	27	2 (7.4)
Day 337	70	27 (38.6)	21	2 (9.5)
Day 379	60	21 (35.0)	20	1 (5.0)
Day 421	50	16 (32.0)	15	0 (0.0)
Day 463	39	12 (30.8)	9	0 (0.0)
Day 505	30	8 (26.7)	9	0 (0.0)
Day 547	24	6 (25.0)	8	0 (0.0)
Day 589	17	5 (29.4)	5	0 (0.0)
Day 631	13	4 (30.8)	1	0 (0.0)
Day 673	9	2 (22.2)	1	0 (0.0)
Day 715	5	3 (60.0)	1	0 (0.0)
Day 757	5	3 (60.0)	1	0 (0.0)
Day 799	3	1 (33.3)	1	0 (0.0)
Day 841	2	1 (50.0)	0	0 (0.0)
Day 883	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Emotional Well-being by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	124	16.2 (4.27)			58	16.7 (5.07)		
Day 15	118	16.3 (4.30)	117	0.1 (3.35)	52	17.8 (4.73)	49	0.5 (4.10)
Day 43	117	16.4 (4.69)	116	0.1 (3.52)	53	17.4 (4.97)	50	0.3 (3.91)
Day 85	99	16.5 (4.49)	98	0.0 (3.79)	36	17.2 (5.75)	34	-0.6 (4.04)
Day 127	74	17.6 (3.93)	73	0.3 (3.67)	19	17.9 (4.86)	18	-0.9 (5.10)
Day 169	57	17.3 (4.16)	56	0.2 (3.24)	11	18.9 (4.37)	10	0.0 (4.64)
Day 211	44	17.7 (4.32)	43	0.5 (3.62)	4	21.3 (2.87)	3	-1.3 (3.06)
Day 253	37	17.2 (4.26)	37	0.5 (3.93)	2	23.0 (0.00)	2	0.5 (2.12)
Day 295	29	18.0 (3.82)	29	1.3 (3.51)	2	23.0 (0.00)	2	0.5 (2.12)
Day 337	27	17.7 (4.16)	27	1.3 (3.69)	2	22.5 (0.71)	2	0.0 (1.41)
Day 379	21	18.0 (3.99)	21	0.7 (3.78)	1	23.0 (-)	1	2.0 (-)
Day 421	16	17.3 (3.96)	16	0.8 (2.79)	0	-	0	-
Day 463	12	17.4 (3.63)	12	0.7 (2.64)	0	-	0	-
Day 505	8	16.1 (3.98)	8	0.0 (3.70)	0	-	0	-
Day 547	6	18.0 (2.19)	6	1.2 (2.04)	0	-	0	-
Day 589	5	17.2 (3.63)	5	0.4 (3.13)	0	-	0	-
Day 631	4	13.8 (3.50)	4	-2.3 (2.50)	0	-	0	-
Day 673	2	15.0 (1.41)	2	-1.0 (0.00)	0	-	0	-
Day 715	3	16.0 (6.00)	3	-1.3 (3.51)	0	-	0	-
Day 757	3	17.7 (4.51)	3	0.3 (2.08)	0	-	0	-
Day 799	1	15.0 (-)	1	0.0 (-)	0	-	0	-
Day 841	1	10.0 (-)	1	-5.0 (-)	0	-	0	-
Day 883	1	8.0 (-)	1	-7.0 (-)	0	-	0	-
End of Treatment	97	15.4 (5.23)	96	-1.2 (4.04)	56	15.3 (6.17)	52	-1.8 (4.82)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Emotional Well-being by Visit
Full Analysis Set

Visit	DS-8201a (N=125)			Phys. Choice (N=62)			Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
	N [a]	N_MISS [b]	LSMean (95% CI)	N [a]	N_MISS [b]	LSMean (95% CI)				
Day 15			-0.23 (-0.85, 0.39)			0.05 (-0.92, 1.01)	-0.28 (-1.33, 0.78)	0.6061		
Day 43			-0.24 (-0.83, 0.35)			-0.16 (-1.02, 0.70)	-0.08 (-1.03, 0.86)	0.8667		
Day 85			-0.26 (-0.81, 0.30)			-0.47 (-1.33, 0.39)	0.21 (-0.71, 1.13)	0.6484		
Day 127			-0.27 (-0.81, 0.26)			-0.78 (-1.80, 0.24)	0.51 (-0.56, 1.57)	0.3495		
Day 169			-0.29 (-0.83, 0.25)			-1.09 (-2.38, 0.20)	0.80 (-0.53, 2.13)	0.2357		
Day 211			-0.31 (-0.87, 0.26)			-1.40 (-3.01, 0.21)	1.09 (-0.55, 2.74)	0.1925		
Day 253			-0.32 (-0.93, 0.29)			-1.71 (-3.67, 0.25)	1.39 (-0.62, 3.39)	0.1739		
Day 295			-0.34 (-1.00, 0.33)			-2.02 (-4.34, 0.31)	1.68 (-0.69, 4.06)	0.1648		
Day 337			-0.35 (-1.09, 0.38)			-2.33 (-5.03, 0.37)	1.98 (-0.78, 4.73)	0.1601		
Day 379			-0.37 (-1.18, 0.45)			-2.64 (-5.71, 0.44)	2.27 (-0.88, 5.42)	0.1574		
Day 421			-0.38 (-1.28, 0.51)			-2.95 (-6.41, 0.51)	2.56 (-0.98, 6.11)	0.1559		
Day 463			-0.40 (-1.39, 0.59)			-3.26 (-7.10, 0.59)	2.86 (-1.08, 6.80)	0.1550		
OVERALL	123	2	-0.28 (-0.82, 0.26)	54	8	-0.92 (-2.05, 0.21)	0.64 (-0.53, 1.81)	0.2840	0.19 (-0.13, 0.51)	0.2547

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Emotional Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0045
Japan	98	-0.03 (-0.46, 0.39)	45	0.11 (-0.93, 1.16)	-0.15 (-1.28, 0.98)	0.8000	-0.05 (-0.41, 0.30)	0.7612	
Korea	25	0.26 (-1.17, 1.69)	9	-5.22 (-9.22, -1.22)	5.48 (1.22, 9.74)	0.0126	1.28 (0.46, 2.10)	0.0022	
Lines of prior systemic therapy									0.0888
2	64	0.24 (-0.35, 0.83)	34	-0.99 (-2.15, 0.17)	1.23 (-0.08, 2.53)	0.0651	0.44 (0.02, 0.86)	0.0389	
3	34	-0.02 (-0.98, 0.93)	16	-0.58 (-2.77, 1.61)	0.56 (-1.83, 2.95)	0.6416	0.17 (-0.43, 0.76)	0.5828	
>=4	25	-0.40 (-1.29, 0.49)	4	6.18 (0.80, 11.56)	-6.58 (-12.04, -1.12)	0.0187	-2.40 (-3.62, -1.18)	0.0001	
Age									0.8180
<65 years	54	0.23 (-0.41, 0.87)	25	-1.44 (-3.26, 0.38)	1.67 (-0.27, 3.61)	0.0916	0.52 (0.04, 1.00)	0.0350	
>=65 years	69	-0.16 (-0.77, 0.46)	29	-0.31 (-1.72, 1.09)	0.16 (-1.38, 1.70)	0.8385	0.05 (-0.38, 0.49)	0.8107	
Sex									0.7957
female	29	-0.18 (-1.20, 0.85)	12	-0.88 (-3.71, 1.95)	0.70 (-2.30, 3.71)	0.6431	0.20 (-0.47, 0.88)	0.5575	
male	94	0.08 (-0.40, 0.57)	42	-0.59 (-1.78, 0.60)	0.67 (-0.61, 1.96)	0.3032	0.23 (-0.13, 0.59)	0.2168	
ECOG PS									0.1993
0	61	-0.13 (-0.61, 0.34)	27	-0.37 (-1.79, 1.04)	0.24 (-1.26, 1.74)	0.7519	0.09 (-0.36, 0.55)	0.6866	
1	62	0.28 (-0.46, 1.03)	27	-0.58 (-2.07, 0.90)	0.87 (-0.80, 2.54)	0.3062	0.27 (-0.19, 0.72)	0.2512	
HER2 Status in central laboratory									0.1141
IHC 3+	95	0.17 (-0.31, 0.65)	41	-0.68 (-1.98, 0.62)	0.85 (-0.54, 2.24)	0.2301	0.28 (-0.09, 0.65)	0.1377	
IHC 2+/ISH +	28	-0.64 (-1.69, 0.42)	13	0.13 (-1.65, 1.91)	-0.76 (-2.84, 1.31)	0.4625	-0.26 (-0.92, 0.40)	0.4351	
Primary tumor location									0.4993
Gastric	106	0.01 (-0.47, 0.49)	49	-0.62 (-1.76, 0.52)	0.63 (-0.60, 1.87)	0.3140	0.21 (-0.13, 0.55)	0.2325	
GEJ	17	-0.01 (-1.17, 1.15)	5	0.70 (-3.17, 4.58)	-0.71 (-4.75, 3.32)	0.7254	-0.25 (-1.25, 0.75)	0.6210	
Histological subtype									0.1097
intestinal	88	-0.06 (-0.52, 0.40)	35	0.15 (-0.99, 1.29)	-0.21 (-1.44, 1.02)	0.7348	-0.08 (-0.47, 0.31)	0.6823	
diffuse	28	0.02 (-1.22, 1.26)	14	-5.25 (-8.75, -1.74)	5.26 (1.54, 8.99)	0.0060	1.14 (0.45, 1.83)	0.0011	
others	7	0.69 (-1.36, 2.75)	5	1.05 (-2.64, 4.74)	-0.36 (-4.62, 3.91)	0.8596	-0.12 (-1.26, 1.03)	0.8435	
Number of metastatic sites									0.8458
<2	22	0.39 (-0.37, 1.15)	10	0.33 (-1.39, 2.04)	0.06 (-1.81, 1.94)	0.9462	0.03 (-0.72, 0.78)	0.9364	
>= 2	101	-0.08 (-0.60, 0.44)	44	-1.08 (-2.42, 0.25)	1.00 (-0.44, 2.44)	0.1717	0.30 (-0.05, 0.66)	0.0961	
Previous total gastrectomy									0.0565
yes	22	-0.56 (-1.74, 0.62)	8	3.87 (-0.54, 8.29)	-4.43 (-8.99, 0.13)	0.0569	-1.13 (-1.99, -0.27)	0.0098	
no	101	0.16 (-0.30, 0.61)	46	-0.93 (-2.02, 0.15)	1.09 (-0.09, 2.27)	0.0711	0.38 (0.03, 0.73)	0.0329	
Prior adjuvant/ neoadjuvant therapy									0.3380
yes	30	-0.03 (-0.81, 0.75)	7	2.44 (-1.45, 6.32)	-2.47 (-6.43, 1.50)	0.2203	-0.85 (-1.70, -0.01)	0.0482	
no	93	0.04 (-0.49, 0.57)	47	-0.84 (-1.95, 0.27)	0.88 (-0.35, 2.12)	0.1609	0.29 (-0.06, 0.64)	0.1090	
Prior ramucirumab contained treatment									0.0540
yes	92	-0.09 (-0.53, 0.36)	36	0.10 (-1.29, 1.49)	-0.19 (-1.65, 1.27)	0.7996	-0.07 (-0.45, 0.32)	0.7398	
no	31	0.37 (-0.83, 1.58)	18	-1.54 (-3.47, 0.38)	1.92 (-0.37, 4.20)	0.0982	0.53 (-0.06, 1.12)	0.0782	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

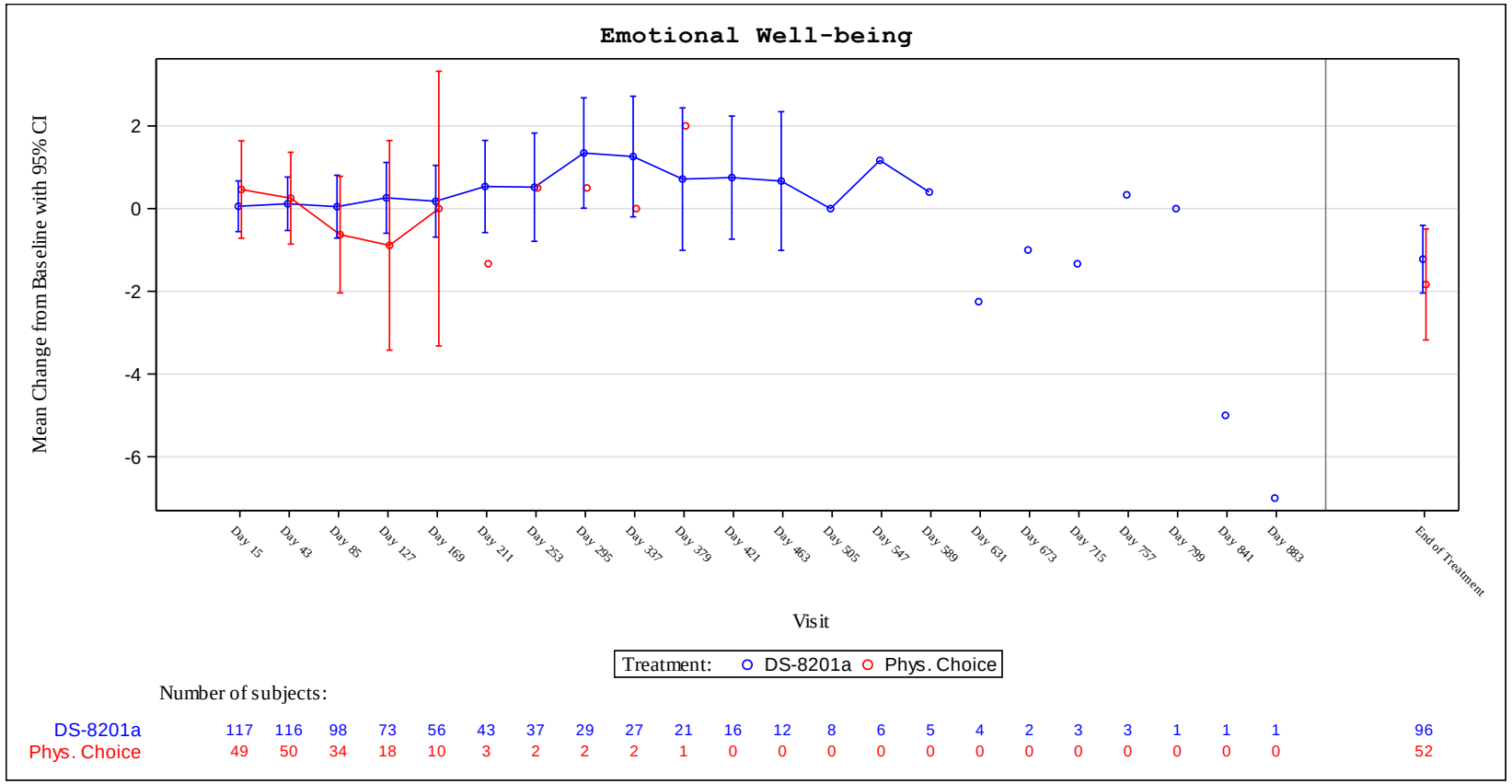
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Emotional Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.1446
yes	33	-0.22 (-1.03, 0.59)	12	0.61 (-1.85, 3.07)	-0.83 (-3.42, 1.76)	0.5266	-0.28 (-0.94, 0.38)	0.4058	
no	90	0.11 (-0.41, 0.63)	42	-0.82 (-1.99, 0.36)	0.93 (-0.36, 2.22)	0.1579	0.31 (-0.06, 0.68)	0.0988	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.0500
yes	44	-0.41 (-1.18, 0.35)	13	0.31 (-2.22, 2.83)	-0.72 (-3.35, 1.92)	0.5899	-0.23 (-0.85, 0.39)	0.4636	
no	79	0.29 (-0.24, 0.82)	41	-0.72 (-1.81, 0.38)	1.01 (-0.22, 2.23)	0.1058	0.36 (-0.02, 0.74)	0.0662	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.7291
yes	22	1.09 (-0.02, 2.20)	5	2.56 (-0.67, 5.79)	-1.48 (-4.90, 1.95)	0.3905	-0.54 (-1.52, 0.44)	0.2816	
no	101	-0.16 (-0.63, 0.32)	49	-0.96 (-2.12, 0.21)	0.80 (-0.46, 2.06)	0.2122	0.26 (-0.08, 0.60)	0.1379	
Presence of liver metastasis at baseline									0.9358
yes	68	0.29 (-0.24, 0.83)	29	-0.46 (-1.94, 1.01)	0.75 (-0.82, 2.33)	0.3453	0.26 (-0.17, 0.70)	0.2388	
no	55	-0.28 (-1.00, 0.45)	25	-0.80 (-2.42, 0.82)	0.53 (-1.25, 2.31)	0.5590	0.16 (-0.31, 0.64)	0.4946	
Renal impairment at baseline									0.1327
normal	33	0.18 (-0.62, 0.97)	12	-5.96 (-10.36, -1.57)	6.14 (1.68, 10.61)	0.0073	1.41 (0.69, 2.13)	0.0001	
mild	53	-0.02 (-0.63, 0.59)	25	0.69 (-0.46, 1.85)	-0.71 (-2.02, 0.60)	0.2844	-0.29 (-0.77, 0.19)	0.2376	
moderate	37	-0.12 (-1.09, 0.84)	16	-2.28 (-4.43, -0.14)	2.16 (-0.19, 4.51)	0.0710	0.64 (0.04, 1.24)	0.0373	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.2298
normal	86	0.03 (-0.49, 0.56)	40	-1.18 (-2.43, 0.06)	1.22 (-0.14, 2.57)	0.0779	0.40 (0.02, 0.78)	0.0376	
mild	36	-0.11 (-0.90, 0.68)	14	1.35 (-0.85, 3.55)	-1.46 (-3.81, 0.89)	0.2187	-0.50 (-1.12, 0.13)	0.1186	
moderate	1	0.55 (NE, NE)	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.0795
yes	8	-0.92 (-1.85, 0.01)	4	0.27 (-1.80, 2.33)	-1.19 (-3.56, 1.18)	0.3058	-0.80 (-2.04, 0.44)	0.2084	
no	115	0.14 (-0.32, 0.60)	50	-1.11 (-2.32, 0.10)	1.25 (-0.05, 2.54)	0.0598	0.39 (0.06, 0.73)	0.0216	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.3239
yes	3	-0.80 (-2.76, 1.16)	3	0.05 (-1.95, 2.05)	-0.85 (-3.70, 1.99)	0.4365	-0.73 (-2.38, 0.92)	0.3859	
no	120	0.06 (-0.39, 0.51)	51	-1.18 (-2.45, 0.10)	1.24 (-0.11, 2.60)	0.0726	0.38 (0.05, 0.71)	0.0246	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Graphical Summary of Emotional Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	44 (35.2)	18 (29.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	11.3 (7.0, NE)	7.0 (3.0, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.77 (0.44, 1.37)	
p-value [c]	0.3653	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.80 (0.46, 1.41)	
p-value [c]	0.4369	

Time to Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.8995
Japan	31/ 99 (31.3)	21.0 (7.0, NE)	14/ 50 (28.0)	7.0 (3.0, NE)	0.84 (0.44, 1.60)	0.5918	
Korea	13/ 26 (50.0)	8.4 (2.9, 11.3)	4/ 12 (33.3)	3.3 (0.5, NE)	0.56 (0.17, 1.89)	0.3279	
Lines of prior systemic therapy							0.7794
2	22/ 66 (33.3)	11.3 (5.9, NE)	12/ 38 (31.6)	5.5 (2.9, NE)	0.58 (0.28, 1.22)	0.1485	
3	12/ 34 (35.3)	NE (2.8, NE)	5/ 18 (27.8)	NE (2.6, NE)	1.16 (0.41, 3.31)	0.7872	
>=4	10/ 25 (40.0)	9.7 (2.9, NE)	1/ 6 (16.7)	NE (1.1, NE)	1.01 (0.12, 8.22)	0.9960	
Age							0.9685
<65 years	18/ 55 (32.7)	12.5 (7.0, NE)	7/ 27 (25.9)	7.0 (2.9, 7.0)	0.69 (0.27, 1.72)	0.4118	
>=65 years	26/ 70 (37.1)	8.4 (5.9, NE)	11/ 35 (31.4)	4.0 (2.9, NE)	0.85 (0.42, 1.74)	0.6464	
Sex							0.1627
female	14/ 30 (46.7)	5.9 (2.9, 21.0)	2/ 15 (13.3)	NE (1.2, NE)	1.80 (0.39, 8.27)	0.4461	
male	30/ 95 (31.6)	NE (8.4, NE)	16/ 47 (34.0)	5.5 (2.9, NE)	0.65 (0.35, 1.22)	0.1687	
ECOG PS							0.5403
0	23/ 62 (37.1)	12.5 (5.9, NE)	7/ 30 (23.3)	7.0 (4.0, NE)	0.93 (0.39, 2.22)	0.8691	
1	21/ 63 (33.3)	11.3 (4.6, NE)	11/ 32 (34.4)	5.5 (2.9, NE)	0.75 (0.36, 1.57)	0.4307	
HER2 Status in central laboratory							0.2342
IHC 3+	33/ 96 (34.4)	21.0 (7.0, NE)	15/ 47 (31.9)	7.0 (2.9, NE)	0.68 (0.36, 1.28)	0.2205	
IHC 2+/ISH +	11/ 29 (37.9)	8.4 (2.8, 12.5)	3/ 15 (20.0)	NE (2.8, NE)	1.45 (0.38, 5.50)	0.5801	
Primary tumor location							0.9875
Gastric	39/108 (36.1)	11.3 (6.9, NE)	18/ 55 (32.7)	5.5 (2.9, NE)	0.74 (0.42, 1.31)	0.2908	
GEJ	5/ 17 (29.4)	NE (2.7, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.7940
intestinal	29/ 89 (32.6)	21.0 (6.9, NE)	12/ 38 (31.6)	7.0 (2.9, NE)	0.78 (0.39, 1.55)	0.4787	
diffuse	12/ 28 (42.9)	9.7 (2.9, NE)	5/ 18 (27.8)	3.3 (2.6, NE)	0.73 (0.24, 2.20)	0.5495	
others	3/ 8 (37.5)	11.3 (0.5, 11.3)	1/ 6 (16.7)	NE (1.9, NE)	1.57 (0.14, 17.46)	0.7115	
Number of metastatic sites							0.8568
<2	7/ 23 (30.4)	NE (4.2, NE)	3/ 10 (30.0)	5.5 (2.8, NE)	0.74 (0.19, 2.93)	0.6718	
>= 2	37/102 (36.3)	9.7 (5.9, 21.0)	15/ 52 (28.8)	7.0 (2.9, NE)	0.81 (0.43, 1.50)	0.4783	
Previous total gastrectomy							0.2034
yes	8/ 22 (36.4)	9.7 (2.8, NE)	1/ 9 (11.1)	NE (3.3, NE)	2.91 (0.36, 23.66)	0.2956	
no	36/103 (35.0)	12.5 (7.0, NE)	17/ 53 (32.1)	5.5 (2.9, NE)	0.68 (0.38, 1.24)	0.1999	
Prior adjuvant/ neoadjuvant therapy							0.3294
yes	12/ 30 (40.0)	9.7 (5.9, NE)	1/ 10 (10.0)	NE (2.9, NE)	1.49 (0.18, 12.10)	0.7121	
no	32/ 95 (33.7)	21.0 (8.4, NE)	17/ 52 (32.7)	5.5 (2.9, NE)	0.76 (0.42, 1.39)	0.3627	
Prior ramucirumab contained treatment							0.3694
yes	31/ 94 (33.0)	12.5 (6.9, NE)	8/ 41 (19.5)	NE (4.0, NE)	1.16 (0.52, 2.57)	0.7263	
no	13/ 31 (41.9)	8.4 (2.9, NE)	10/ 21 (47.6)	3.0 (2.8, 7.0)	0.57 (0.25, 1.33)	0.1829	
Prior nivolumab contained treatment							0.6029
yes	12/ 33 (36.4)	12.5 (5.9, NE)	5/ 15 (33.3)	NE (1.2, NE)	0.71 (0.24, 2.09)	0.5218	
no	32/ 92 (34.8)	9.7 (7.0, 21.0)	13/ 47 (27.7)	5.5 (2.9, NE)	0.82 (0.42, 1.59)	0.5481	

Time to Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

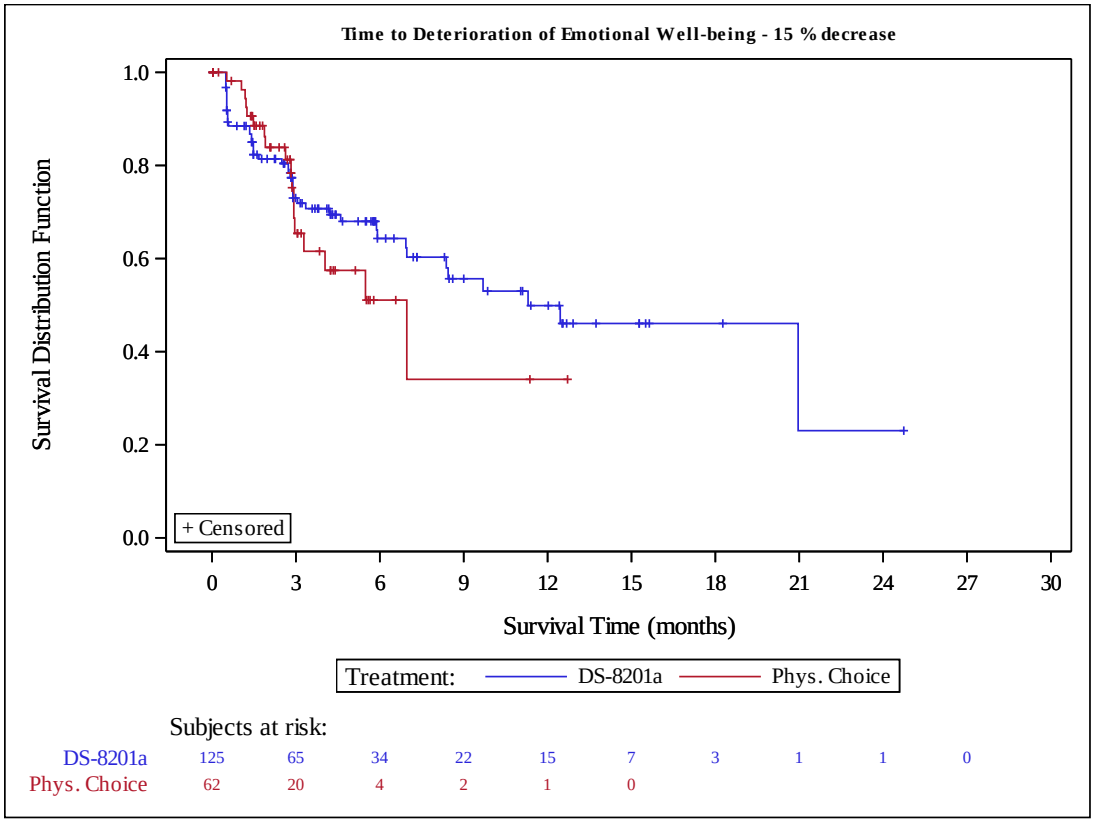
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.6421
yes	18/ 44 (40.9)	12.5 (3.4, NE)	6/ 17 (35.3)	3.3 (1.2, NE)	0.73 (0.28, 1.88)	0.4947	
no	26/ 81 (32.1)	11.3 (7.0, 21.0)	12/ 45 (26.7)	7.0 (2.9, NE)	0.79 (0.39, 1.61)	0.5242	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9874
yes	4/ 22 (18.2)	NE (4.2, NE)	1/ 7 (14.3)	NE (2.8, NE)	0.95 (0.10, 8.65)	0.9557	
no	40/103 (38.8)	11.3 (6.9, NE)	17/ 55 (30.9)	5.5 (3.0, NE)	0.82 (0.46, 1.47)	0.4950	
Presence of liver metastasis at baseline							0.4456
yes	21/ 68 (30.9)	21.0 (7.0, NE)	10/ 34 (29.4)	4.0 (2.9, NE)	0.71 (0.33, 1.53)	0.3624	
no	23/ 57 (40.4)	9.7 (4.6, NE)	8/ 28 (28.6)	7.0 (2.9, NE)	0.96 (0.42, 2.18)	0.9125	
Renal impairment at baseline							0.5593
normal	12/ 33 (36.4)	11.3 (4.6, NE)	4/ 13 (30.8)	NE (1.9, NE)	0.57 (0.17, 1.90)	0.3373	
mild	22/ 53 (41.5)	21.0 (3.4, 21.0)	8/ 28 (28.6)	7.0 (2.9, NE)	1.12 (0.50, 2.55)	0.7936	
moderate	10/ 39 (25.6)	NE (8.4, NE)	6/ 20 (30.0)	NE (2.9, NE)	0.49 (0.16, 1.48)	0.1924	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9177
normal	32/ 88 (36.4)	21.0 (6.9, 21.0)	13/ 47 (27.7)	5.5 (3.3, NE)	0.79 (0.41, 1.54)	0.4854	
mild	12/ 36 (33.3)	9.7 (2.9, NE)	5/ 15 (33.3)	2.9 (1.2, NE)	0.81 (0.28, 2.36)	0.6867	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.1195
yes	6/ 8 (75.0)	2.7 (0.5, 8.4)	2/ 5 (40.0)	5.5 (1.1, NE)	2.24 (0.45, 11.24)	0.3168	
no	38/117 (32.5)	12.5 (8.4, NE)	16/ 57 (28.1)	7.0 (2.9, NE)	0.71 (0.39, 1.30)	0.2615	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.3278
yes	2/ 3 (66.7)	8.4 (2.7, 8.4)	1/ 4 (25.0)	NE (5.5, NE)	2.00 (0.18, 22.05)	0.5637	
no	42/122 (34.4)	12.5 (7.0, NE)	17/ 58 (29.3)	7.0 (2.9, NE)	0.76 (0.42, 1.36)	0.3397	

Time to Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	35 (28.0)	15 (24.2)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	16.7 (11.3, 27.7)	7.0 (3.3, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.52 (0.27, 1.00)	
p-value [c]	0.0449	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.56 (0.29, 1.06)	
p-value [c]	0.0697	

Time to Definitive Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.9887
Japan	23/ 99 (23.2)	21.0 (14.4, 27.7)	11/ 50 (22.0)	7.0 (5.5, NE)	0.55 (0.26, 1.18)	0.1188	
Korea	12/ 26 (46.2)	8.4 (4.6, NE)	4/ 12 (33.3)	3.3 (0.5, NE)	0.45 (0.13, 1.58)	0.1890	
Lines of prior systemic therapy							0.8946
2	18/ 66 (27.3)	21.0 (8.4, NE)	11/ 38 (28.9)	5.5 (2.9, NE)	0.47 (0.21, 1.04)	0.0560	
3	8/ 34 (23.5)	16.7 (16.7, NE)	3/ 18 (16.7)	NE (3.3, NE)	0.91 (0.23, 3.60)	0.8972	
>=4	9/ 25 (36.0)	14.4 (5.6, 27.7)	1/ 6 (16.7)	NE (1.1, NE)	0.59 (0.07, 5.10)	0.6264	
Age							0.6620
<65 years	14/ 55 (25.5)	21.0 (11.3, NE)	7/ 27 (25.9)	7.0 (2.9, 7.0)	0.41 (0.15, 1.12)	0.0752	
>=65 years	21/ 70 (30.0)	16.7 (8.4, 27.7)	8/ 35 (22.9)	NE (3.3, NE)	0.67 (0.28, 1.56)	0.3433	
Sex							0.2164
female	11/ 30 (36.7)	7.0 (4.6, 21.0)	2/ 15 (13.3)	NE (1.2, NE)	0.93 (0.19, 4.64)	0.9328	
male	24/ 95 (25.3)	16.7 (12.5, 27.7)	13/ 47 (27.7)	7.0 (2.9, NE)	0.47 (0.23, 0.97)	0.0348	
ECOG PS							0.9193
0	19/ 62 (30.6)	16.7 (12.5, 27.7)	7/ 30 (23.3)	7.0 (4.0, NE)	0.55 (0.22, 1.40)	0.2066	
1	16/ 63 (25.4)	NE (8.4, NE)	8/ 32 (25.0)	5.5 (2.9, NE)	0.61 (0.25, 1.45)	0.2593	
HER2 Status in central laboratory							0.0639
IHC 3+	25/ 96 (26.0)	21.0 (11.3, 27.7)	13/ 47 (27.7)	7.0 (2.9, NE)	0.40 (0.19, 0.81)	0.0090	
IHC 2+/ISH +	10/ 29 (34.5)	8.4 (2.8, 12.5)	2/ 15 (13.3)	NE (2.8, NE)	1.82 (0.38, 8.79)	0.4516	
Primary tumor location							0.9855
Gastric	32/108 (29.6)	14.4 (8.4, 27.7)	15/ 55 (27.3)	7.0 (2.9, NE)	0.52 (0.27, 0.99)	0.0443	
GEJ	3/ 17 (17.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.8188
intestinal	23/ 89 (25.8)	21.0 (14.4, 27.7)	9/ 38 (23.7)	7.0 (4.0, NE)	0.59 (0.26, 1.33)	0.1966	
diffuse	10/ 28 (35.7)	12.5 (5.6, NE)	5/ 18 (27.8)	3.3 (2.6, NE)	0.45 (0.14, 1.47)	0.1699	
others	2/ 8 (25.0)	11.3 (4.6, 11.3)	1/ 6 (16.7)	NE (1.9, NE)	0.82 (0.05, 13.24)	0.8864	
Number of metastatic sites							0.6846
<2	5/ 23 (21.7)	NE (8.4, NE)	3/ 10 (30.0)	5.5 (2.8, NE)	0.39 (0.08, 1.80)	0.2099	
>= 2	30/102 (29.4)	16.7 (9.7, 27.7)	12/ 52 (23.1)	7.0 (3.3, NE)	0.59 (0.29, 1.21)	0.1459	
Previous total gastrectomy							0.3396
yes	7/ 22 (31.8)	27.7 (5.6, 27.7)	1/ 9 (11.1)	NE (3.3, NE)	1.47 (0.16, 13.19)	0.7277	
no	28/103 (27.2)	16.7 (11.3, NE)	14/ 53 (26.4)	7.0 (2.9, NE)	0.48 (0.24, 0.95)	0.0316	
Prior adjuvant/ neoadjuvant therapy							0.5279
yes	10/ 30 (33.3)	14.4 (5.9, 27.7)	1/ 10 (10.0)	NE (2.9, NE)	0.56 (0.06, 5.41)	0.6115	
no	25/ 95 (26.3)	16.7 (11.3, NE)	14/ 52 (26.9)	7.0 (3.3, NE)	0.58 (0.29, 1.14)	0.1085	
Prior ramucirumab contained treatment							0.2038
yes	26/ 94 (27.7)	21.0 (11.3, 27.7)	6/ 41 (14.6)	NE (4.0, NE)	1.00 (0.40, 2.51)	0.9937	
no	9/ 31 (29.0)	14.4 (7.0, NE)	9/ 21 (42.9)	3.3 (2.8, 7.0)	0.28 (0.10, 0.77)	0.0089	
Prior nivolumab contained treatment							0.6990
yes	10/ 33 (30.3)	16.7 (12.5, NE)	4/ 15 (26.7)	NE (1.2, NE)	0.53 (0.15, 1.88)	0.3213	
no	25/ 92 (27.2)	21.0 (8.4, 27.7)	11/ 47 (23.4)	7.0 (2.9, NE)	0.56 (0.27, 1.19)	0.1257	

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NE: Not estimable.
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[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

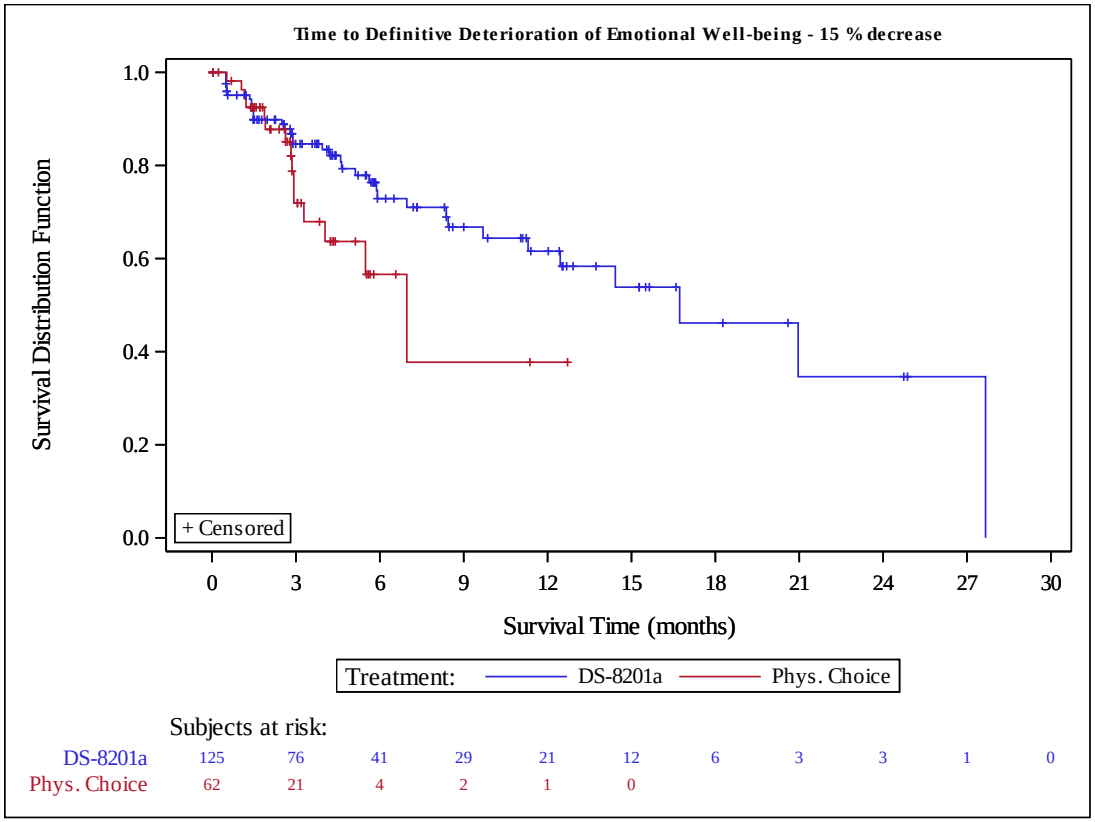
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.6912
yes	15/ 44 (34.1)	16.7 (9.7, NE)	5/ 17 (29.4)	NE (2.6, NE)	0.58 (0.20, 1.67)	0.3013	
no	20/ 81 (24.7)	21.0 (8.4, 27.7)	10/ 45 (22.2)	7.0 (4.0, NE)	0.52 (0.23, 1.17)	0.1091	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.8379
yes	3/ 22 (13.6)	NE (5.1, NE)	1/ 7 (14.3)	NE (2.8, NE)	0.54 (0.05, 5.39)	0.5907	
no	32/103 (31.1)	16.7 (9.7, 27.7)	14/ 55 (25.5)	7.0 (3.3, NE)	0.58 (0.30, 1.14)	0.1089	
Presence of liver metastasis at baseline							0.8518
yes	16/ 68 (23.5)	21.0 (8.4, NE)	7/ 34 (20.6)	NE (2.9, NE)	0.54 (0.21, 1.37)	0.1853	
no	19/ 57 (33.3)	12.5 (8.4, 27.7)	8/ 28 (28.6)	7.0 (2.9, NE)	0.59 (0.25, 1.41)	0.2321	
Renal impairment at baseline							0.3904
normal	9/ 33 (27.3)	27.7 (11.3, 27.7)	4/ 13 (30.8)	NE (1.9, NE)	0.25 (0.06, 1.01)	0.0341	
mild	16/ 53 (30.2)	14.4 (5.9, NE)	7/ 28 (25.0)	7.0 (2.9, NE)	0.71 (0.28, 1.79)	0.4636	
moderate	10/ 39 (25.6)	16.7 (8.4, NE)	4/ 20 (20.0)	NE (2.9, NE)	0.59 (0.16, 2.14)	0.4151	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8618
normal	24/ 88 (27.3)	16.7 (11.3, NE)	11/ 47 (23.4)	7.0 (4.0, NE)	0.48 (0.22, 1.03)	0.0538	
mild	11/ 36 (30.6)	12.5 (5.9, 27.7)	4/ 15 (26.7)	NE (2.8, NE)	0.75 (0.23, 2.47)	0.6315	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7647
yes	5/ 8 (62.5)	8.4 (3.9, 27.7)	2/ 5 (40.0)	5.5 (1.1, NE)	0.71 (0.13, 3.96)	0.6993	
no	30/117 (25.6)	16.7 (12.5, NE)	13/ 57 (22.8)	7.0 (3.3, NE)	0.55 (0.28, 1.11)	0.0919	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.7226
yes	1/ 3 (33.3)	NE (8.4, NE)	1/ 4 (25.0)	NE (5.5, NE)	0.58 (0.04, 9.30)	0.6949	
no	34/122 (27.9)	16.7 (11.3, 27.7)	14/ 58 (24.1)	7.0 (3.3, NE)	0.54 (0.28, 1.05)	0.0649	

Time to Definitive Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	118	16 (13.6)	88 (74.6)	14 (11.9)	52	8 (15.4)	43 (82.7)	1 (1.9)
	Day 43	117	17 (14.5)	86 (73.5)	14 (12.0)	53	5 (9.4)	44 (83.0)	4 (7.5)
	Day 85	99	16 (16.2)	65 (65.7)	18 (18.2)	36	4 (11.1)	25 (69.4)	7 (19.4)
	Day 127	74	11 (14.9)	55 (74.3)	8 (10.8)	19	2 (10.5)	14 (73.7)	3 (15.8)
	Day 169	57	6 (10.5)	45 (78.9)	6 (10.5)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 211	44	8 (18.2)	30 (68.2)	6 (13.6)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 253	37	8 (21.6)	24 (64.9)	5 (13.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	29	6 (20.7)	21 (72.4)	2 (6.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	27	6 (22.2)	19 (70.4)	2 (7.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	21	4 (19.0)	15 (71.4)	2 (9.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	1 (6.3)	13 (81.3)	2 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	97	8 (8.2)	63 (64.9)	26 (26.8)	56	3 (5.4)	38 (67.9)	15 (26.8)
Region									
Japan									
	Day 15	96	12 (12.5)	73 (76.0)	11 (11.5)	45	7 (15.6)	38 (84.4)	0 (0.0)
	Day 43	93	13 (14.0)	70 (75.3)	10 (10.8)	43	5 (11.6)	35 (81.4)	3 (7.0)
	Day 85	77	9 (11.7)	55 (71.4)	13 (16.9)	32	3 (9.4)	23 (71.9)	6 (18.8)
	Day 127	60	6 (10.0)	47 (78.3)	7 (11.7)	16	2 (12.5)	13 (81.3)	1 (6.3)
	Day 169	49	4 (8.2)	39 (79.6)	6 (12.2)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 211	36	4 (11.1)	26 (72.2)	6 (16.7)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 253	29	5 (17.2)	21 (72.4)	3 (10.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	23	2 (8.7)	20 (87.0)	1 (4.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	21	2 (9.5)	19 (90.5)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	18	3 (16.7)	14 (77.8)	1 (5.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	6 (7.7)	56 (71.8)	16 (20.5)	48	3 (6.3)	34 (70.8)	11 (22.9)
Region									
Korea									
	Day 15	22	4 (18.2)	15 (68.2)	3 (13.6)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 43	24	4 (16.7)	16 (66.7)	4 (16.7)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 85	22	7 (31.8)	10 (45.5)	5 (22.7)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 127	14	5 (35.7)	8 (57.1)	1 (7.1)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	8	2 (25.0)	6 (75.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	4 (50.0)	4 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	3 (37.5)	3 (37.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	6	4 (66.7)	1 (16.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	6	4 (66.7)	0 (0.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	19	2 (10.5)	7 (36.8)	10 (52.6)	8	0 (0.0)	4 (50.0)	4 (50.0)
Lines of prior systemic therapy									
2									
	Day 15	60	10 (16.7)	45 (75.0)	5 (8.3)	34	5 (14.7)	28 (82.4)	1 (2.9)
	Day 43	62	11 (17.7)	44 (71.0)	7 (11.3)	36	1 (2.8)	33 (91.7)	2 (5.6)
	Day 85	50	6 (12.0)	36 (72.0)	8 (16.0)	21	2 (9.5)	13 (61.9)	6 (28.6)
	Day 127	33	6 (18.2)	26 (78.8)	1 (3.0)	14	0 (0.0)	11 (78.6)	3 (21.4)
	Day 169	24	2 (8.3)	22 (91.7)	0 (0.0)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	21	5 (23.8)	15 (71.4)	1 (4.8)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	18	3 (16.7)	12 (66.7)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	3 (25.0)	8 (66.7)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	3 (27.3)	7 (63.6)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	2 (28.6)	4 (57.1)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	51	4 (7.8)	34 (66.7)	13 (25.5)	34	2 (5.9)	21 (61.8)	11 (32.4)
Lines of prior systemic therapy									
3									
	Day 15	34	4 (11.8)	24 (70.6)	6 (17.6)	14	3 (21.4)	11 (78.6)	0 (0.0)
	Day 43	33	5 (15.2)	24 (72.7)	4 (12.1)	14	3 (21.4)	9 (64.3)	2 (14.3)
	Day 85	28	6 (21.4)	16 (57.1)	6 (21.4)	12	1 (8.3)	10 (83.3)	1 (8.3)
	Day 127	23	2 (8.7)	15 (65.2)	6 (26.1)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	19	1 (5.3)	14 (73.7)	4 (21.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	13	3 (23.1)	8 (61.5)	2 (15.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	4 (36.4)	6 (54.5)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	9	2 (22.2)	7 (77.8)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	6 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	3 (11.5)	18 (69.2)	5 (19.2)	17	0 (0.0)	14 (82.4)	3 (17.6)
Lines of prior systemic therapy									
>=4									
	Day 15	24	2 (8.3)	19 (79.2)	3 (12.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 43	22	1 (4.5)	18 (81.8)	3 (13.6)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	21	4 (19.0)	13 (61.9)	4 (19.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	18	3 (16.7)	14 (77.8)	1 (5.6)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	14	3 (21.4)	9 (64.3)	2 (14.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	11 (55.0)	8 (40.0)	5	1 (20.0)	3 (60.0)	1 (20.0)
Age									
<65 years									
	Day 15	51	8 (15.7)	39 (76.5)	4 (7.8)	22	3 (13.6)	19 (86.4)	0 (0.0)
	Day 43	52	10 (19.2)	37 (71.2)	5 (9.6)	24	1 (4.2)	23 (95.8)	0 (0.0)
	Day 85	47	10 (21.3)	28 (59.6)	9 (19.1)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 127	34	7 (20.6)	24 (70.6)	3 (8.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	27	3 (11.1)	21 (77.8)	3 (11.1)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 211	18	4 (22.2)	11 (61.1)	3 (16.7)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 253	16	4 (25.0)	9 (56.3)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	4 (30.8)	8 (61.5)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	4 (36.4)	6 (54.5)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	42	5 (11.9)	27 (64.3)	10 (23.8)	23	1 (4.3)	15 (65.2)	7 (30.4)
Age									
>=65 years									
	Day 15	67	8 (11.9)	49 (73.1)	10 (14.9)	30	5 (16.7)	24 (80.0)	1 (3.3)
	Day 43	65	7 (10.8)	49 (75.4)	9 (13.8)	29	4 (13.8)	21 (72.4)	4 (13.8)
	Day 85	52	6 (11.5)	37 (71.2)	9 (17.3)	20	3 (15.0)	13 (65.0)	4 (20.0)
	Day 127	40	4 (10.0)	31 (77.5)	5 (12.5)	11	2 (18.2)	7 (63.6)	2 (18.2)
	Day 169	30	3 (10.0)	24 (80.0)	3 (10.0)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	26	4 (15.4)	19 (73.1)	3 (11.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	4 (19.0)	15 (71.4)	2 (9.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	16	2 (12.5)	13 (81.3)	1 (6.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	2 (12.5)	13 (81.3)	1 (6.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	13	3 (23.1)	10 (76.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	End of Treatment	55	3 (5.5)	36 (65.5)	16 (29.1)	33	2 (6.1)	23 (69.7)	8 (24.2)
Sex									
female									
	Day 15	28	5 (17.9)	20 (71.4)	3 (10.7)	13	2 (15.4)	10 (76.9)	1 (7.7)
	Day 43	28	1 (3.6)	23 (82.1)	4 (14.3)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 85	20	3 (15.0)	13 (65.0)	4 (20.0)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 127	13	3 (23.1)	9 (69.2)	1 (7.7)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	10	1 (10.0)	7 (70.0)	2 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	7	1 (14.3)	3 (42.9)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	22	1 (4.5)	12 (54.5)	9 (40.9)	14	0 (0.0)	12 (85.7)	2 (14.3)
Sex									
male									
	Day 15	90	11 (12.2)	68 (75.6)	11 (12.2)	39	6 (15.4)	33 (84.6)	0 (0.0)
	Day 43	89	16 (18.0)	63 (70.8)	10 (11.2)	40	4 (10.0)	33 (82.5)	3 (7.5)
	Day 85	79	13 (16.5)	52 (65.8)	14 (17.7)	28	4 (14.3)	17 (60.7)	7 (25.0)
	Day 127	61	8 (13.1)	46 (75.4)	7 (11.5)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	47	5 (10.6)	38 (80.9)	4 (8.5)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 211	36	7 (19.4)	26 (72.2)	3 (8.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	30	7 (23.3)	21 (70.0)	2 (6.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	6 (24.0)	18 (72.0)	1 (4.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	6 (25.0)	16 (66.7)	2 (8.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	3 (15.8)	14 (73.7)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	15	1 (6.7)	12 (80.0)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	75	7 (9.3)	51 (68.0)	17 (22.7)	42	3 (7.1)	26 (61.9)	13 (31.0)
ECOG PS									
0									
	Day 15	60	7 (11.7)	49 (81.7)	4 (6.7)	26	4 (15.4)	22 (84.6)	0 (0.0)
	Day 43	59	6 (10.2)	48 (81.4)	5 (8.5)	26	2 (7.7)	24 (92.3)	0 (0.0)
	Day 85	54	4 (7.4)	39 (72.2)	11 (20.4)	19	1 (5.3)	16 (84.2)	2 (10.5)
	Day 127	42	4 (9.5)	35 (83.3)	3 (7.1)	9	1 (11.1)	6 (66.7)	2 (22.2)
	Day 169	36	3 (8.3)	30 (83.3)	3 (8.3)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	27	2 (7.4)	21 (77.8)	4 (14.8)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	24	4 (16.7)	16 (66.7)	4 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	18	1 (5.6)	16 (88.9)	1 (5.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	15 (93.8)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	14	1 (7.1)	12 (85.7)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	10 (90.9)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	48	2 (4.2)	32 (66.7)	14 (29.2)	29	0 (0.0)	22 (75.9)	7 (24.1)
ECOG PS									
1									
	Day 15	58	9 (15.5)	39 (67.2)	10 (17.2)	26	4 (15.4)	21 (80.8)	1 (3.8)
	Day 43	58	11 (19.0)	38 (65.5)	9 (15.5)	27	3 (11.1)	20 (74.1)	4 (14.8)
	Day 85	45	12 (26.7)	26 (57.8)	7 (15.6)	17	3 (17.6)	9 (52.9)	5 (29.4)
	Day 127	32	7 (21.9)	20 (62.5)	5 (15.6)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	21	3 (14.3)	15 (71.4)	3 (14.3)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 211	17	6 (35.3)	9 (52.9)	2 (11.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	13	4 (30.8)	8 (61.5)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	5 (45.5)	5 (45.5)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	5 (45.5)	4 (36.4)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	3 (42.9)	3 (42.9)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	49	6 (12.2)	31 (63.3)	12 (24.5)	27	3 (11.1)	16 (59.3)	8 (29.6)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	91	12 (13.2)	67 (73.6)	12 (13.2)	38	6 (15.8)	31 (81.6)	1 (2.6)
	Day 43	91	14 (15.4)	69 (75.8)	8 (8.8)	40	3 (7.5)	34 (85.0)	3 (7.5)
	Day 85	79	14 (17.7)	52 (65.8)	13 (16.5)	26	3 (11.5)	17 (65.4)	6 (23.1)
	Day 127	59	10 (16.9)	44 (74.6)	5 (8.5)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 169	46	6 (13.0)	36 (78.3)	4 (8.7)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 211	38	7 (18.4)	26 (68.4)	5 (13.2)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 253	32	7 (21.9)	21 (65.6)	4 (12.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	6 (23.1)	18 (69.2)	2 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	25	6 (24.0)	17 (68.0)	2 (8.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	4 (21.1)	14 (73.7)	1 (5.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	1 (6.3)	13 (81.3)	2 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	7 (9.5)	50 (67.6)	17 (23.0)	42	2 (4.8)	27 (64.3)	13 (31.0)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	4 (14.8)	21 (77.8)	2 (7.4)	14	2 (14.3)	12 (85.7)	0 (0.0)
	Day 43	26	3 (11.5)	17 (65.4)	6 (23.1)	13	2 (15.4)	10 (76.9)	1 (7.7)
	Day 85	20	2 (10.0)	13 (65.0)	5 (25.0)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 127	15	1 (6.7)	11 (73.3)	3 (20.0)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 169	11	0 (0.0)	9 (81.8)	2 (18.2)	3	0 (0.0)	2 (66.7)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	1 (4.3)	13 (56.5)	9 (39.1)	14	1 (7.1)	11 (78.6)	2 (14.3)
Primary tumor location									
Gastric									
	Day 15	102	14 (13.7)	74 (72.5)	14 (13.7)	46	7 (15.2)	38 (82.6)	1 (2.2)
	Day 43	100	16 (16.0)	73 (73.0)	11 (11.0)	48	5 (10.4)	39 (81.3)	4 (8.3)
	Day 85	84	15 (17.9)	55 (65.5)	14 (16.7)	33	4 (12.1)	22 (66.7)	7 (21.2)
	Day 127	63	10 (15.9)	45 (71.4)	8 (12.7)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 169	47	5 (10.6)	36 (76.6)	6 (12.8)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 211	38	7 (18.4)	25 (65.8)	6 (15.8)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 253	31	7 (22.6)	20 (64.5)	4 (12.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	24	5 (20.8)	17 (70.8)	2 (8.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	22	5 (22.7)	15 (68.2)	2 (9.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	17	3 (17.6)	12 (70.6)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	0 (0.0)	11 (84.6)	2 (15.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	7 (8.5)	51 (62.2)	24 (29.3)	50	3 (6.0)	32 (64.0)	15 (30.0)
Primary tumor location									
GEJ									
	Day 15	16	2 (12.5)	14 (87.5)	0 (0.0)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	17	1 (5.9)	13 (76.5)	3 (17.6)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 85	15	1 (6.7)	10 (66.7)	4 (26.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	10 (90.9)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	1 (6.7)	12 (80.0)	2 (13.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	86	12 (14.0)	64 (74.4)	10 (11.6)	35	6 (17.1)	29 (82.9)	0 (0.0)
	Day 43	85	13 (15.3)	62 (72.9)	10 (11.8)	34	3 (8.8)	28 (82.4)	3 (8.8)
	Day 85	73	10 (13.7)	51 (69.9)	12 (16.4)	27	2 (7.4)	20 (74.1)	5 (18.5)
	Day 127	55	6 (10.9)	43 (78.2)	6 (10.9)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 169	44	4 (9.1)	35 (79.5)	5 (11.4)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	32	4 (12.5)	23 (71.9)	5 (15.6)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 253	25	4 (16.0)	18 (72.0)	3 (12.0)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	18	2 (11.1)	15 (83.3)	1 (5.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	2 (12.5)	14 (87.5)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	13	2 (15.4)	11 (84.6)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	5 (6.9)	51 (70.8)	16 (22.2)	37	2 (5.4)	26 (70.3)	9 (24.3)
Histological subtype diffuse									
	Day 15	26	3 (11.5)	20 (76.9)	3 (11.5)	15	2 (13.3)	12 (80.0)	1 (6.7)
	Day 43	26	3 (11.5)	19 (73.1)	4 (15.4)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 85	22	4 (18.2)	12 (54.5)	6 (27.3)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 127	15	3 (20.0)	10 (66.7)	2 (13.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	11	1 (9.1)	9 (81.8)	1 (9.1)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	10	3 (30.0)	6 (60.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	4 (40.0)	4 (40.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	3 (33.3)	5 (55.6)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	9	3 (33.3)	5 (55.6)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	3 (14.3)	9 (42.9)	9 (42.9)	16	1 (6.3)	10 (62.5)	5 (31.3)
Histological subtype others									
	Day 15	6	1 (16.7)	4 (66.7)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	1 (16.7)	5 (83.3)	0 (0.0)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 85	4	2 (50.0)	2 (50.0)	0 (0.0)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 127	4	2 (50.0)	2 (50.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	1 (50.0)	1 (50.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	3 (75.0)	1 (25.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Number of metastatic sites <2									
	Day 15	22	2 (9.1)	18 (81.8)	2 (9.1)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 43	21	3 (14.3)	17 (81.0)	1 (4.8)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 85	21	2 (9.5)	15 (71.4)	4 (19.0)	8	2 (25.0)	4 (50.0)	2 (25.0)
	Day 127	17	1 (5.9)	13 (76.5)	3 (17.6)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 169	16	0 (0.0)	13 (81.3)	3 (18.8)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	14	2 (14.3)	11 (78.6)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	4 (40.0)	5 (50.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	2 (25.0)	6 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	7 (87.5)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup / Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	5	0 (0.0)	5 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	2 (11.1)	12 (66.7)	4 (22.2)	9	1 (11.1)	5 (55.6)	3 (33.3)
Number of metastatic sites									
>= 2									
	Day 15	96	14 (14.6)	70 (72.9)	12 (12.5)	42	7 (16.7)	34 (81.0)	1 (2.4)
	Day 43	96	14 (14.6)	69 (71.9)	13 (13.5)	43	5 (11.6)	34 (79.1)	4 (9.3)
	Day 85	78	14 (17.9)	50 (64.1)	14 (17.9)	28	2 (7.1)	21 (75.0)	5 (17.9)
	Day 127	57	10 (17.5)	42 (73.7)	5 (8.8)	15	2 (13.3)	11 (73.3)	2 (13.3)
	Day 169	41	6 (14.6)	32 (78.0)	3 (7.3)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 211	30	6 (20.0)	19 (63.3)	5 (16.7)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	27	4 (14.8)	19 (70.4)	4 (14.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	21	4 (19.0)	15 (71.4)	2 (9.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	19	5 (26.3)	12 (63.2)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	4 (25.0)	10 (62.5)	2 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	6 (7.6)	51 (64.6)	22 (27.8)	47	2 (4.3)	33 (70.2)	12 (25.5)
Previous total gastrectomy									
yes									
	Day 15	20	5 (25.0)	12 (60.0)	3 (15.0)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 43	20	2 (10.0)	14 (70.0)	4 (20.0)	8	2 (25.0)	6 (75.0)	0 (0.0)
	Day 85	18	2 (11.1)	11 (61.1)	5 (27.8)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 127	11	0 (0.0)	8 (72.7)	3 (27.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	1 (12.5)	3 (37.5)	4 (50.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 211	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	3 (16.7)	9 (50.0)	6 (33.3)	9	1 (11.1)	7 (77.8)	1 (11.1)
Previous total gastrectomy									
no									
	Day 15	98	11 (11.2)	76 (77.6)	11 (11.2)	45	8 (17.8)	36 (80.0)	1 (2.2)
	Day 43	97	15 (15.5)	72 (74.2)	10 (10.3)	45	3 (6.7)	38 (84.4)	4 (8.9)
	Day 85	81	14 (17.3)	54 (66.7)	13 (16.0)	30	3 (10.0)	20 (66.7)	7 (23.3)
	Day 127	63	11 (17.5)	47 (74.6)	5 (7.9)	17	1 (5.9)	13 (76.5)	3 (17.6)
	Day 169	49	5 (10.2)	42 (85.7)	2 (4.1)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 211	36	7 (19.4)	26 (72.2)	3 (8.3)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 253	33	7 (21.2)	22 (66.7)	4 (12.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	5 (20.0)	19 (76.0)	1 (4.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	23	5 (21.7)	17 (73.9)	1 (4.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	19	4 (21.1)	13 (68.4)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	14	1 (7.1)	12 (85.7)	1 (7.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	10 (90.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	5 (6.3)	54 (68.4)	20 (25.3)	47	2 (4.3)	31 (66.0)	14 (29.8)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	4 (13.8)	22 (75.9)	3 (10.3)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 43	27	1 (3.7)	24 (88.9)	2 (7.4)	8	2 (25.0)	6 (75.0)	0 (0.0)
	Day 85	27	1 (3.7)	22 (81.5)	4 (14.8)	7	2 (28.6)	4 (57.1)	1 (14.3)
	Day 127	22	1 (4.5)	19 (86.4)	2 (9.1)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	15	1 (6.7)	11 (73.3)	3 (20.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 211	12	2 (16.7)	7 (58.3)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	4 (40.0)	5 (50.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	10	2 (20.0)	7 (70.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	25	2 (8.0)	14 (56.0)	9 (36.0)	9	1 (11.1)	7 (77.8)	1 (11.1)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	89	12 (13.5)	66 (74.2)	11 (12.4)	44	8 (18.2)	35 (79.5)	1 (2.3)
	Day 43	90	16 (17.8)	62 (68.9)	12 (13.3)	45	3 (6.7)	38 (84.4)	4 (8.9)
	Day 85	72	15 (20.8)	43 (59.7)	14 (19.4)	29	2 (6.9)	21 (72.4)	6 (20.7)
	Day 127	52	10 (19.2)	36 (69.2)	6 (11.5)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	42	5 (11.9)	34 (81.0)	3 (7.1)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	32	6 (18.8)	23 (71.9)	3 (9.4)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	27	4 (14.8)	19 (70.4)	4 (14.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	19	4 (21.1)	14 (73.7)	1 (5.3)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	17	5 (29.4)	11 (64.7)	1 (5.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	15	4 (26.7)	10 (66.7)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	1 (8.3)	11 (91.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	9 (90.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	6 (8.3)	49 (68.1)	17 (23.6)	47	2 (4.3)	31 (66.0)	14 (29.8)
Prior ramucirumab contained treatment									
yes									
	Day 15	90	10 (11.1)	70 (77.8)	10 (11.1)	34	4 (11.8)	30 (88.2)	0 (0.0)
	Day 43	89	11 (12.4)	67 (75.3)	11 (12.4)	33	4 (12.1)	27 (81.8)	2 (6.1)
	Day 85	73	11 (15.1)	51 (69.9)	11 (15.1)	23	3 (13.0)	19 (82.6)	1 (4.3)
	Day 127	59	7 (11.9)	45 (76.3)	7 (11.9)	11	2 (18.2)	8 (72.7)	1 (9.1)
	Day 169	45	4 (8.9)	36 (80.0)	5 (11.1)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 211	32	4 (12.5)	24 (75.0)	4 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	25	4 (16.0)	20 (80.0)	1 (4.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	22	3 (13.6)	18 (81.8)	1 (4.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	3 (14.3)	16 (76.2)	2 (9.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	17	2 (11.8)	13 (76.5)	2 (11.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	13	0 (0.0)	12 (92.3)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	10 (90.9)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	4 (5.4)	51 (68.9)	19 (25.7)	36	2 (5.6)	28 (77.8)	6 (16.7)
Prior ramucirumab contained treatment									
no									
	Day 15	28	6 (21.4)	18 (64.3)	4 (14.3)	18	4 (22.2)	13 (72.2)	1 (5.6)
	Day 43	28	6 (21.4)	19 (67.9)	3 (10.7)	20	1 (5.0)	17 (85.0)	2 (10.0)
	Day 85	26	5 (19.2)	14 (53.8)	7 (26.9)	13	1 (7.7)	6 (46.2)	6 (46.2)
	Day 127	15	4 (26.7)	10 (66.7)	1 (6.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 169	12	2 (16.7)	9 (75.0)	1 (8.3)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 211	12	4 (33.3)	6 (50.0)	2 (16.7)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	12	4 (33.3)	4 (33.3)	4 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	3 (42.9)	3 (42.9)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	3 (50.0)	3 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	2 (50.0)	2 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	4 (17.4)	12 (52.2)	7 (30.4)	20	1 (5.0)	10 (50.0)	9 (45.0)
Prior nivolumab contained treatment									
yes									
	Day 15	32	1 (3.1)	26 (81.3)	5 (15.6)	13	3 (23.1)	10 (76.9)	0 (0.0)
	Day 43	30	5 (16.7)	21 (70.0)	4 (13.3)	10	2 (20.0)	7 (70.0)	1 (10.0)
	Day 85	27	3 (11.1)	18 (66.7)	6 (22.2)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 127	26	1 (3.8)	21 (80.8)	4 (15.4)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 169	21	1 (4.8)	18 (85.7)	2 (9.5)	3	1 (33.3)	2 (66.7)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	16	2 (12.5)	11 (68.8)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	14	2 (14.3)	12 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	1 (8.3)	11 (91.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	10 (90.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	1 (3.8)	17 (65.4)	8 (30.8)	14	1 (7.1)	9 (64.3)	4 (28.6)
Prior nivolumab contained treatment									
no									
	Day 15	86	15 (17.4)	62 (72.1)	9 (10.5)	39	5 (12.8)	33 (84.6)	1 (2.6)
	Day 43	87	12 (13.8)	65 (74.7)	10 (11.5)	43	3 (7.0)	37 (86.0)	3 (7.0)
	Day 85	72	13 (18.1)	47 (65.3)	12 (16.7)	26	3 (11.5)	17 (65.4)	6 (23.1)
	Day 127	48	10 (20.8)	34 (70.8)	4 (8.3)	16	0 (0.0)	13 (81.3)	3 (18.8)
	Day 169	36	5 (13.9)	27 (75.0)	4 (11.1)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	28	6 (21.4)	19 (67.9)	3 (10.7)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	23	6 (26.1)	12 (52.2)	5 (21.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	5 (29.4)	10 (58.8)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	5 (31.3)	9 (56.3)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	3 (27.3)	7 (63.6)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	1 (11.1)	7 (77.8)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	7 (9.9)	46 (64.8)	18 (25.4)	42	2 (4.8)	29 (69.0)	11 (26.2)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	42	2 (4.8)	33 (78.6)	7 (16.7)	15	3 (20.0)	12 (80.0)	0 (0.0)
	Day 43	40	5 (12.5)	29 (72.5)	6 (15.0)	12	2 (16.7)	9 (75.0)	1 (8.3)
	Day 85	37	4 (10.8)	22 (59.5)	11 (29.7)	11	1 (9.1)	8 (72.7)	2 (18.2)
	Day 127	31	2 (6.5)	24 (77.4)	5 (16.1)	4	2 (50.0)	1 (25.0)	1 (25.0)
	Day 169	24	2 (8.3)	20 (83.3)	2 (8.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 211	20	4 (20.0)	13 (65.0)	3 (15.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	17	4 (23.5)	12 (70.6)	1 (5.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	3 (18.8)	12 (75.0)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	3 (20.0)	11 (73.3)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	12	2 (16.7)	9 (75.0)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	35	2 (5.7)	21 (60.0)	12 (34.3)	16	1 (6.3)	10 (62.5)	5 (31.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	76	14 (18.4)	55 (72.4)	7 (9.2)	37	5 (13.5)	31 (83.8)	1 (2.7)
	Day 43	77	12 (15.6)	57 (74.0)	8 (10.4)	41	3 (7.3)	35 (85.4)	3 (7.3)
	Day 85	62	12 (19.4)	43 (69.4)	7 (11.3)	25	3 (12.0)	17 (68.0)	5 (20.0)
	Day 127	43	9 (20.9)	31 (72.1)	3 (7.0)	15	0 (0.0)	13 (86.7)	2 (13.3)
	Day 169	33	4 (12.1)	25 (75.8)	4 (12.1)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	24	4 (16.7)	17 (70.8)	3 (12.5)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	20	4 (20.0)	12 (60.0)	4 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	3 (23.1)	9 (69.2)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	3 (25.0)	8 (66.7)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	9	2 (22.2)	6 (66.7)	1 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	6 (9.7)	42 (67.7)	14 (22.6)	40	2 (5.0)	28 (70.0)	10 (25.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
yes									
	Day 15	22	4 (18.2)	15 (68.2)	3 (13.6)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	19	2 (10.5)	16 (84.2)	1 (5.3)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 85	16	6 (37.5)	9 (56.3)	1 (6.3)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 127	12	4 (33.3)	6 (50.0)	2 (16.7)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 169	9	2 (22.2)	5 (55.6)	2 (22.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	5	2 (40.0)	2 (40.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	2 (50.0)	2 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	2 (66.7)	1 (33.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	3 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	1 (7.1)	11 (78.6)	2 (14.3)	6	1 (16.7)	4 (66.7)	1 (16.7)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
no									
	Day 15	96	12 (12.5)	73 (76.0)	11 (11.5)	46	8 (17.4)	37 (80.4)	1 (2.2)
	Day 43	98	15 (15.3)	70 (71.4)	13 (13.3)	47	4 (8.5)	39 (83.0)	4 (8.5)
	Day 85	83	10 (12.0)	56 (67.5)	17 (20.5)	31	3 (9.7)	22 (71.0)	6 (19.4)
	Day 127	62	7 (11.3)	49 (79.0)	6 (9.7)	16	1 (6.3)	13 (81.3)	2 (12.5)
	Day 169	48	4 (8.3)	40 (83.3)	4 (8.3)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	39	6 (15.4)	28 (71.8)	5 (12.8)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	33	6 (18.2)	22 (66.7)	5 (15.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	4 (15.4)	20 (76.9)	2 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	3 (12.5)	19 (79.2)	2 (8.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	18	3 (16.7)	13 (72.2)	2 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	1 (7.7)	10 (76.9)	2 (15.4)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	7 (8.4)	52 (62.7)	24 (28.9)	50	2 (4.0)	34 (68.0)	14 (28.0)
Presence of liver metastasis at baseline									
yes									
	Day 15	64	12 (18.8)	43 (67.2)	9 (14.1)	27	5 (18.5)	22 (81.5)	0 (0.0)
	Day 43	64	8 (12.5)	49 (76.6)	7 (10.9)	28	3 (10.7)	23 (82.1)	2 (7.1)
	Day 85	51	10 (19.6)	34 (66.7)	7 (13.7)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 127	37	6 (16.2)	27 (73.0)	4 (10.8)	10	2 (20.0)	6 (60.0)	2 (20.0)
	Day 169	28	4 (14.3)	23 (82.1)	1 (3.6)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 211	20	5 (25.0)	13 (65.0)	2 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	3 (15.8)	13 (68.4)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	3 (21.4)	10 (71.4)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	13	4 (30.8)	9 (69.2)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	3 (27.3)	8 (72.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	9 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	3 (6.0)	35 (70.0)	12 (24.0)	31	1 (3.2)	23 (74.2)	7 (22.6)
Presence of liver metastasis at baseline									
no									
	Day 15	54	4 (7.4)	45 (83.3)	5 (9.3)	25	3 (12.0)	21 (84.0)	1 (4.0)
	Day 43	53	9 (17.0)	37 (69.8)	7 (13.2)	25	2 (8.0)	21 (84.0)	2 (8.0)
	Day 85	48	6 (12.5)	31 (64.6)	11 (22.9)	20	2 (10.0)	14 (70.0)	4 (20.0)
	Day 127	37	5 (13.5)	28 (75.7)	4 (10.8)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 169	29	2 (6.9)	22 (75.9)	5 (17.2)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	24	3 (12.5)	17 (70.8)	4 (16.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	18	5 (27.8)	11 (61.1)	2 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	3 (20.0)	11 (73.3)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	10 (71.4)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	7 (70.0)	2 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	47	5 (10.6)	28 (59.6)	14 (29.8)	25	2 (8.0)	15 (60.0)	8 (32.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
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Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Renal impairment at baseline									
normal									
	Day 15	31	4 (12.9)	25 (80.6)	2 (6.5)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 43	33	2 (6.1)	30 (90.9)	1 (3.0)	12	1 (8.3)	10 (83.3)	1 (8.3)
	Day 85	26	5 (19.2)	17 (65.4)	4 (15.4)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	3 (15.8)	16 (84.2)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	17	2 (11.8)	15 (88.2)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	12	2 (16.7)	9 (75.0)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	13	3 (23.1)	8 (61.5)	2 (15.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	2 (16.7)	9 (75.0)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	2 (18.2)	8 (72.7)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	2 (8.3)	16 (66.7)	6 (25.0)	11	1 (9.1)	6 (54.5)	4 (36.4)
Renal impairment at baseline									
mild									
	Day 15	50	4 (8.0)	37 (74.0)	9 (18.0)	25	5 (20.0)	20 (80.0)	0 (0.0)
	Day 43	50	7 (14.0)	33 (66.0)	10 (20.0)	23	1 (4.3)	22 (95.7)	0 (0.0)
	Day 85	45	5 (11.1)	32 (71.1)	8 (17.8)	14	3 (21.4)	8 (57.1)	3 (21.4)
	Day 127	31	5 (16.1)	22 (71.0)	4 (12.9)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	23	2 (8.7)	18 (78.3)	3 (13.0)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 211	17	3 (17.6)	11 (64.7)	3 (17.6)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	13	4 (30.8)	8 (61.5)	1 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	9	3 (33.3)	6 (66.7)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	6 (75.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 379	6	1 (16.7)	5 (83.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	3 (6.7)	30 (66.7)	12 (26.7)	25	2 (8.0)	16 (64.0)	7 (28.0)
Renal impairment at baseline									
moderate									
	Day 15	37	8 (21.6)	26 (70.3)	3 (8.1)	16	2 (12.5)	14 (87.5)	0 (0.0)
	Day 43	34	8 (23.5)	23 (67.6)	3 (8.8)	17	3 (17.6)	11 (64.7)	3 (17.6)
	Day 85	28	6 (21.4)	16 (57.1)	6 (21.4)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 127	24	3 (12.5)	17 (70.8)	4 (16.7)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 169	17	2 (11.8)	12 (70.6)	3 (17.6)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	15	3 (20.0)	10 (66.7)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	2 (25.0)	5 (62.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	3 (42.9)	4 (57.1)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	3 (10.7)	17 (60.7)	8 (28.6)	19	0 (0.0)	15 (78.9)	4 (21.1)
Renal impairment at baseline severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline normal									
	Day 15	82	9 (11.0)	64 (78.0)	9 (11.0)	37	6 (16.2)	30 (81.1)	1 (2.7)
	Day 43	83	11 (13.3)	63 (75.9)	9 (10.8)	41	4 (9.8)	34 (82.9)	3 (7.3)
	Day 85	76	11 (14.5)	50 (65.8)	15 (19.7)	27	2 (7.4)	20 (74.1)	5 (18.5)
	Day 127	58	10 (17.2)	43 (74.1)	5 (8.6)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 169	45	5 (11.1)	35 (77.8)	5 (11.1)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	34	8 (23.5)	21 (61.8)	5 (14.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	30	7 (23.3)	18 (60.0)	5 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	23	5 (21.7)	17 (73.9)	1 (4.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	5 (23.8)	15 (71.4)	1 (4.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	4 (25.0)	11 (68.8)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	8	1 (12.5)	7 (87.5)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	67	5 (7.5)	44 (65.7)	18 (26.9)	42	2 (4.8)	29 (69.0)	11 (26.2)
Hepatic impairment at baseline mild									
	Day 15	35	7 (20.0)	23 (65.7)	5 (14.3)	15	2 (13.3)	13 (86.7)	0 (0.0)
	Day 43	33	6 (18.2)	22 (66.7)	5 (15.2)	12	1 (8.3)	10 (83.3)	1 (8.3)
	Day 85	22	5 (22.7)	14 (63.6)	3 (13.6)	9	2 (22.2)	5 (55.6)	2 (22.2)
	Day 127	15	1 (6.7)	11 (73.3)	3 (20.0)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 211	10	0 (0.0)	9 (90.0)	1 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	7	1 (14.3)	6 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	1 (16.7)	4 (66.7)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	1 (16.7)	4 (66.7)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	29	3 (10.3)	18 (62.1)	8 (27.6)	14	1 (7.1)	9 (64.3)	4 (28.6)
Hepatic impairment at baseline moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	0 (0.0)	6 (75.0)	2 (25.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 43	8	0 (0.0)	7 (87.5)	1 (12.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	0 (0.0)	5 (71.4)	2 (28.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	0 (0.0)	6 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	1 (20.0)	3 (60.0)	1 (20.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	6	0 (0.0)	2 (33.3)	4 (66.7)	4	0 (0.0)	2 (50.0)	2 (50.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	110	16 (14.5)	82 (74.5)	12 (10.9)	48	8 (16.7)	39 (81.3)	1 (2.1)
	Day 43	109	17 (15.6)	79 (72.5)	13 (11.9)	50	5 (10.0)	41 (82.0)	4 (8.0)
	Day 85	92	16 (17.4)	60 (65.2)	16 (17.4)	33	4 (12.1)	22 (66.7)	7 (21.2)
	Day 127	68	11 (16.2)	49 (72.1)	8 (11.8)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 169	52	5 (9.6)	42 (80.8)	5 (9.6)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 211	40	8 (20.0)	27 (67.5)	5 (12.5)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	33	8 (24.2)	22 (66.7)	3 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	27	6 (22.2)	19 (70.4)	2 (7.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	25	6 (24.0)	17 (68.0)	2 (8.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	20	4 (20.0)	14 (70.0)	2 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	15	1 (6.7)	12 (80.0)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	10 (90.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	91	8 (8.8)	61 (67.0)	22 (24.2)	52	3 (5.8)	36 (69.2)	13 (25.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	2 (66.7)	1 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	0 (0.0)	3 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	1 (50.0)	1 (50.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	115	16 (13.9)	85 (73.9)	14 (12.2)	49	8 (16.3)	40 (81.6)	1 (2.0)
	Day 43	114	17 (14.9)	83 (72.8)	14 (12.3)	50	5 (10.0)	41 (82.0)	4 (8.0)
	Day 85	96	16 (16.7)	63 (65.6)	17 (17.7)	33	4 (12.1)	22 (66.7)	7 (21.2)
	Day 127	71	11 (15.5)	52 (73.2)	8 (11.3)	16	2 (12.5)	11 (68.8)	3 (18.8)
	Day 169	54	6 (11.1)	42 (77.8)	6 (11.1)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 211	42	8 (19.0)	28 (66.7)	6 (14.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	35	8 (22.9)	23 (65.7)	4 (11.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	28	6 (21.4)	20 (71.4)	2 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	26	6 (23.1)	18 (69.2)	2 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	21	4 (19.0)	15 (71.4)	2 (9.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	16	1 (6.3)	13 (81.3)	2 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	95	8 (8.4)	62 (65.3)	25 (26.3)	53	3 (5.7)	36 (67.9)	14 (26.4)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Functional Well-being Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	124 (99.2)	62	58 (93.5)
Day 15	125	118 (94.4)	62	52 (83.9)
Day 43	124	117 (94.4)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	57 (54.3)	45	11 (24.4)
Day 211	93	44 (47.3)	40	4 (10.0)
Day 253	84	37 (44.0)	34	2 (5.9)
Day 295	77	29 (37.7)	27	2 (7.4)
Day 337	70	27 (38.6)	21	2 (9.5)
Day 379	60	21 (35.0)	20	1 (5.0)
Day 421	50	16 (32.0)	15	0 (0.0)
Day 463	39	12 (30.8)	9	0 (0.0)
Day 505	30	8 (26.7)	9	0 (0.0)
Day 547	24	6 (25.0)	8	0 (0.0)
Day 589	17	5 (29.4)	5	0 (0.0)
Day 631	13	4 (30.8)	1	0 (0.0)
Day 673	9	2 (22.2)	1	0 (0.0)
Day 715	5	3 (60.0)	1	0 (0.0)
Day 757	5	3 (60.0)	1	0 (0.0)
Day 799	3	1 (33.3)	1	0 (0.0)
Day 841	2	1 (50.0)	0	0 (0.0)
Day 883	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Functional Well-being by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	124	17.6 (5.93)			58	17.1 (5.33)		
Day 15	118	15.9 (6.15)	117	-1.8 (5.49)	52	17.1 (6.10)	49	-0.7 (4.54)
Day 43	117	16.6 (6.87)	116	-1.3 (5.67)	53	16.2 (7.29)	50	-1.7 (6.23)
Day 85	99	17.1 (6.32)	98	-1.2 (4.72)	36	16.8 (7.55)	34	-1.3 (4.71)
Day 127	74	17.4 (6.04)	73	-1.4 (5.51)	19	17.1 (7.01)	18	-0.5 (4.44)
Day 169	57	18.0 (5.98)	56	-0.5 (5.74)	11	17.3 (6.39)	10	-1.4 (6.02)
Day 211	44	17.5 (6.07)	43	-0.7 (5.36)	4	23.8 (5.68)	3	0.7 (6.51)
Day 253	37	16.6 (6.60)	37	-0.9 (5.37)	2	21.0 (9.90)	2	-0.5 (10.61)
Day 295	29	18.1 (6.50)	29	-0.3 (5.14)	2	27.0 (1.41)	2	5.5 (2.12)
Day 337	27	16.9 (6.78)	27	-1.1 (6.60)	2	22.0 (8.49)	2	0.5 (9.19)
Day 379	21	17.2 (6.16)	21	-2.2 (5.18)	1	28.0 (-)	1	7.0 (-)
Day 421	16	14.4 (7.54)	16	-4.3 (4.46)	0	-	0	-
Day 463	12	16.3 (7.56)	12	-2.6 (3.03)	0	-	0	-
Day 505	8	19.3 (6.84)	8	0.0 (8.14)	0	-	0	-
Day 547	6	17.0 (9.61)	6	-2.7 (4.76)	0	-	0	-
Day 589	5	21.0 (5.43)	5	-0.6 (0.89)	0	-	0	-
Day 631	4	18.8 (4.72)	4	-1.3 (3.50)	0	-	0	-
Day 673	2	14.0 (4.24)	2	-4.5 (2.12)	0	-	0	-
Day 715	3	21.0 (7.94)	3	-0.7 (4.51)	0	-	0	-
Day 757	3	21.0 (7.00)	3	-0.7 (2.08)	0	-	0	-
Day 799	1	13.0 (-)	1	-4.0 (-)	0	-	0	-
Day 841	1	12.0 (-)	1	-5.0 (-)	0	-	0	-
Day 883	1	12.0 (-)	1	-5.0 (-)	0	-	0	-
End of Treatment	97	14.6 (6.40)	96	-3.3 (6.30)	56	14.5 (7.08)	52	-3.3 (4.93)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Functional Well-being by Visit
Full Analysis Set

Visit	DS-8201a (N=125)			Phys. Choice (N=62)			Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
	N [a]	N_MISS [b]	LSMean (95% CI)	N [a]	N_MISS [b]	LSMean (95% CI)				
Day 15			-2.02 (-2.84, -1.20)			-2.20 (-3.52, -0.87)	0.18 (-1.26, 1.62)	0.8058		
Day 43			-2.03 (-2.80, -1.26)			-2.11 (-3.28, -0.94)	0.08 (-1.18, 1.35)	0.8980		
Day 85			-2.04 (-2.76, -1.33)			-1.98 (-3.13, -0.83)	-0.06 (-1.27, 1.15)	0.9175		
Day 127			-2.06 (-2.75, -1.37)			-1.85 (-3.23, -0.47)	-0.21 (-1.63, 1.21)	0.7709		
Day 169			-2.07 (-2.76, -1.38)			-1.72 (-3.49, 0.06)	-0.36 (-2.16, 1.44)	0.6971		
Day 211			-2.09 (-2.81, -1.36)			-1.58 (-3.82, 0.66)	-0.50 (-2.77, 1.77)	0.6633		
Day 253			-2.10 (-2.88, -1.32)			-1.45 (-4.20, 1.29)	-0.65 (-3.43, 2.13)	0.6467		
Day 295			-2.11 (-2.97, -1.26)			-1.32 (-4.59, 1.95)	-0.80 (-4.11, 2.52)	0.6378		
Day 337			-2.13 (-3.07, -1.18)			-1.19 (-5.00, 2.62)	-0.94 (-4.81, 2.93)	0.6326		
Day 379			-2.14 (-3.19, -1.10)			-1.06 (-5.41, 3.30)	-1.09 (-5.52, 3.34)	0.6294		
Day 421			-2.16 (-3.32, -1.00)			-0.92 (-5.83, 3.98)	-1.23 (-6.23, 3.76)	0.6273		
Day 463			-2.17 (-3.45, -0.90)			-0.79 (-6.25, 4.67)	-1.38 (-6.94, 4.18)	0.6259		
OVERALL	123	2	-2.06 (-2.75, -1.38)	54	8	-1.79 (-3.33, -0.25)	-0.28 (-1.85, 1.30)	0.7305	-0.06 (-0.38, 0.26)	0.7089

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Functional Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.2492
Japan	98	-1.39 (-1.98, -0.81)	45	-0.76 (-2.27, 0.75)	-0.64 (-2.25, 0.98)	0.4391	-0.17 (-0.52, 0.18)	0.3481	
Korea	25	-1.93 (-3.35, -0.51)	9	-4.72 (-9.16, -0.28)	2.79 (-1.88, 7.46)	0.2375	0.62 (-0.16, 1.39)	0.1191	
Lines of prior systemic therapy									0.9642
2	64	-0.88 (-1.66, -0.09)	34	-0.25 (-1.83, 1.33)	-0.63 (-2.39, 1.14)	0.4830	-0.17 (-0.58, 0.25)	0.4304	
3	34	-2.82 (-3.82, -1.82)	16	-3.05 (-5.67, -0.43)	0.23 (-2.58, 3.04)	0.8707	0.06 (-0.53, 0.65)	0.8423	
>=4	25	-1.35 (-2.74, 0.04)	4	-1.60 (-10.27, 7.06)	0.25 (-8.53, 9.03)	0.9552	0.06 (-1.00, 1.11)	0.9152	
Age									0.2774
<65 years	54	-1.86 (-2.65, -1.07)	25	-1.83 (-4.26, 0.61)	-0.03 (-2.59, 2.53)	0.9803	-0.01 (-0.48, 0.47)	0.9749	
>=65 years	69	-1.31 (-2.11, -0.50)	29	-1.07 (-3.00, 0.86)	-0.24 (-2.33, 1.86)	0.8241	-0.06 (-0.49, 0.38)	0.7909	
Sex									0.6932
female	29	-0.99 (-2.26, 0.29)	12	-2.08 (-5.99, 1.82)	1.10 (-3.01, 5.20)	0.5968	0.24 (-0.44, 0.91)	0.4906	
male	94	-1.68 (-2.31, -1.04)	42	-1.04 (-2.68, 0.60)	-0.64 (-2.40, 1.12)	0.4731	-0.16 (-0.53, 0.20)	0.3831	
ECOG PS									0.7492
0	61	-1.43 (-2.14, -0.72)	27	-0.31 (-2.51, 1.89)	-1.12 (-3.43, 1.19)	0.3412	-0.28 (-0.74, 0.17)	0.2226	
1	62	-1.62 (-2.50, -0.75)	27	-1.86 (-3.69, -0.02)	0.24 (-1.80, 2.27)	0.8194	0.06 (-0.39, 0.51)	0.7953	
HER2 Status in central laboratory									0.5617
IHC 3+	95	-1.53 (-2.16, -0.90)	41	-1.17 (-2.94, 0.60)	-0.36 (-2.24, 1.52)	0.7043	-0.09 (-0.46, 0.28)	0.6346	
IHC 2+/ISH +	28	-1.47 (-2.85, -0.09)	13	-1.27 (-3.78, 1.23)	-0.20 (-3.07, 2.67)	0.8914	-0.05 (-0.71, 0.61)	0.8813	
Primary tumor location									0.7805
Gastric	106	-1.58 (-2.23, -0.93)	49	-1.26 (-2.85, 0.33)	-0.31 (-2.03, 1.40)	0.7184	-0.07 (-0.41, 0.26)	0.6665	
GEJ	17	-1.13 (-2.01, -0.26)	5	-1.76 (-6.67, 3.16)	0.62 (-4.37, 5.62)	0.8040	0.21 (-0.79, 1.21)	0.6758	
Histological subtype									0.1540
intestinal	88	-1.29 (-1.93, -0.66)	35	-0.93 (-2.57, 0.70)	-0.36 (-2.11, 1.40)	0.6866	-0.10 (-0.49, 0.29)	0.6224	
diffuse	28	-1.97 (-3.33, -0.62)	14	-3.37 (-8.06, 1.31)	1.40 (-3.48, 6.28)	0.5709	0.24 (-0.40, 0.88)	0.4651	
others	7	-1.77 (-4.30, 0.76)	5	-1.71 (-7.01, 3.59)	-0.06 (-6.30, 6.19)	0.9846	-0.01 (-1.16, 1.13)	0.9815	
Number of metastatic sites									0.0704
<2	22	-1.14 (-2.43, 0.15)	10	2.25 (-0.67, 5.18)	-3.39 (-6.59, -0.20)	0.0381	-0.96 (-1.74, -0.18)	0.0164	
>= 2	101	-1.63 (-2.25, -1.01)	44	-2.76 (-4.51, -1.01)	1.13 (-0.73, 2.98)	0.2327	0.27 (-0.08, 0.63)	0.1354	
Previous total gastrectomy									0.1818
yes	22	-2.43 (-4.10, -0.76)	8	1.47 (-4.80, 7.74)	-3.91 (-10.39, 2.58)	0.2349	-0.70 (-1.53, 0.13)	0.0968	
no	101	-1.32 (-1.92, -0.73)	46	-1.32 (-2.81, 0.16)	-0.00 (-1.60, 1.60)	0.9981	-0.00 (-0.35, 0.35)	0.9977	
Prior adjuvant/ neoadjuvant therapy									0.6328
yes	30	-0.90 (-2.20, 0.39)	7	1.01 (-4.86, 6.89)	-1.92 (-7.94, 4.10)	0.5293	-0.42 (-1.25, 0.41)	0.3195	
no	93	-1.77 (-2.40, -1.14)	47	-1.27 (-2.69, 0.15)	-0.50 (-2.05, 1.05)	0.5272	-0.13 (-0.48, 0.22)	0.4632	
Prior ramucirumab contained treatment									0.0477
yes	92	-2.03 (-2.62, -1.43)	36	-2.49 (-4.53, -0.46)	0.47 (-1.65, 2.59)	0.6647	0.11 (-0.27, 0.50)	0.5616	
no	31	-0.11 (-1.47, 1.25)	18	-0.74 (-2.94, 1.47)	0.63 (-1.98, 3.23)	0.6330	0.15 (-0.43, 0.73)	0.6088	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

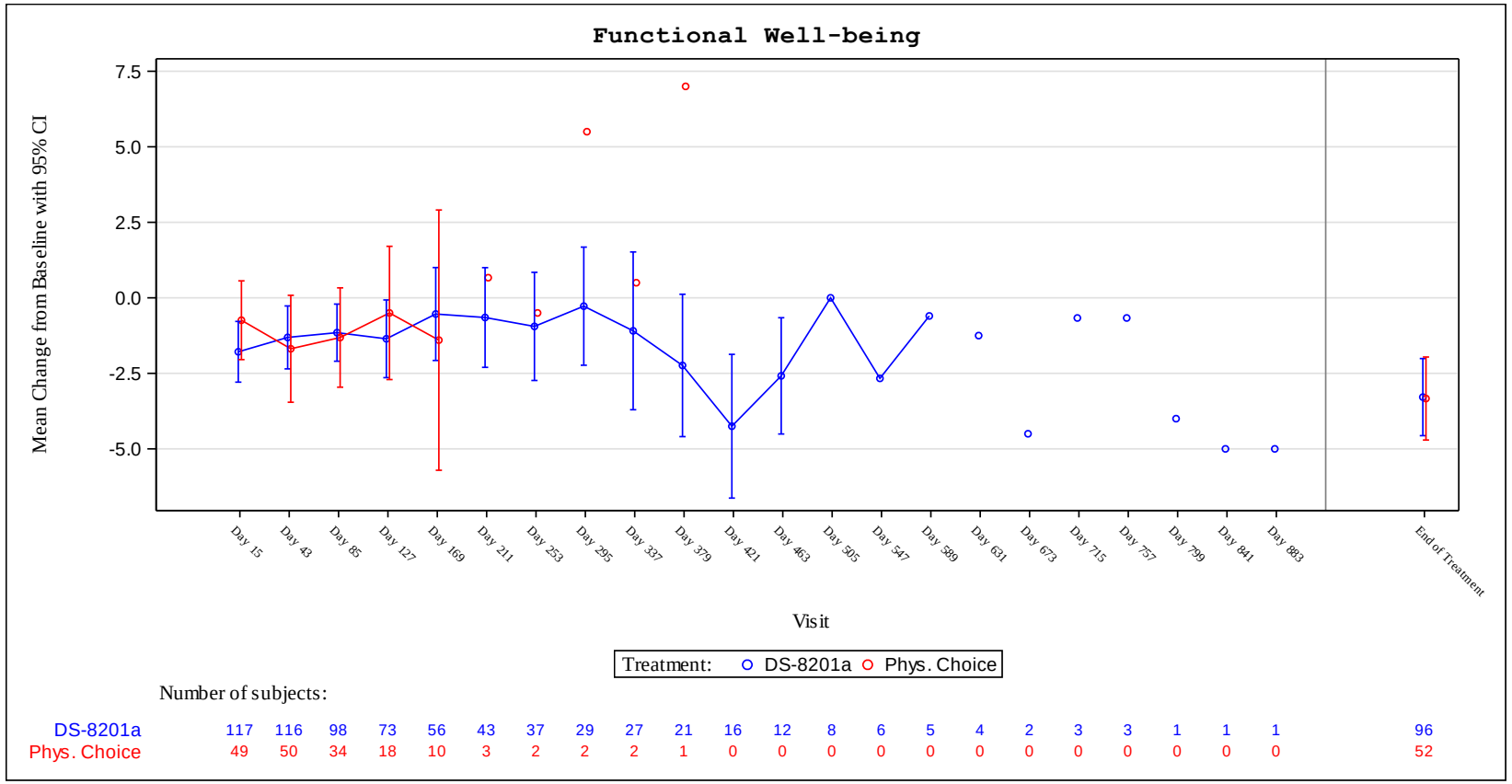
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Functional Well-being - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.4591
yes	33	-1.42 (-2.51, -0.32)	12	-2.76 (-6.43, 0.91)	1.34 (-2.49, 5.17)	0.4873	0.32 (-0.35, 0.98)	0.3477	
no	90	-1.60 (-2.27, -0.93)	42	-0.80 (-2.35, 0.75)	-0.80 (-2.49, 0.88)	0.3485	-0.21 (-0.57, 0.16)	0.2724	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.6212
yes	44	-1.45 (-2.45, -0.45)	13	-2.55 (-6.18, 1.09)	1.09 (-2.68, 4.86)	0.5667	0.26 (-0.36, 0.88)	0.4183	
no	79	-1.61 (-2.29, -0.93)	41	-0.74 (-2.18, 0.70)	-0.87 (-2.46, 0.72)	0.2835	-0.24 (-0.61, 0.14)	0.2221	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.3717
yes	22	-0.51 (-1.89, 0.86)	5	-0.95 (-5.05, 3.15)	0.44 (-3.89, 4.76)	0.8396	0.13 (-0.84, 1.10)	0.7952	
no	101	-1.72 (-2.33, -1.10)	49	-1.27 (-2.86, 0.33)	-0.45 (-2.16, 1.26)	0.6056	-0.11 (-0.45, 0.23)	0.5331	
Presence of liver metastasis at baseline									0.0220
yes	68	-1.64 (-2.42, -0.87)	29	-3.70 (-5.90, -1.50)	2.05 (-0.28, 4.39)	0.0839	0.49 (0.05, 0.93)	0.0307	
no	55	-1.39 (-2.21, -0.58)	25	1.03 (-0.96, 3.01)	-2.42 (-4.57, -0.28)	0.0272	-0.64 (-1.13, -0.16)	0.0090	
Renal impairment at baseline									0.6772
normal	33	-1.71 (-2.69, -0.73)	12	-3.95 (-9.99, 2.10)	2.24 (-3.88, 8.35)	0.4722	0.38 (-0.29, 1.05)	0.2631	
mild	53	-1.07 (-2.11, -0.04)	25	-0.91 (-2.83, 1.01)	-0.16 (-2.35, 2.02)	0.8836	-0.04 (-0.51, 0.44)	0.8725	
moderate	37	-2.04 (-2.95, -1.14)	16	-2.69 (-5.40, 0.03)	0.64 (-2.22, 3.50)	0.6573	0.17 (-0.42, 0.76)	0.5702	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.2932
normal	86	-1.32 (-1.99, -0.65)	40	-1.06 (-2.77, 0.66)	-0.27 (-2.11, 1.58)	0.7769	-0.07 (-0.44, 0.31)	0.7318	
mild	36	-2.12 (-3.19, -1.05)	14	-1.46 (-4.47, 1.54)	-0.66 (-3.85, 2.54)	0.6827	-0.16 (-0.78, 0.45)	0.6039	
moderate	1	NE	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.1309
yes	8	-1.72 (-3.93, 0.50)	4	3.47 (-0.84, 7.79)	-5.19 (-10.05, -0.33)	0.0386	-1.65 (-3.02, -0.28)	0.0181	
no	115	-1.53 (-2.11, -0.94)	50	-2.51 (-4.19, -0.83)	0.98 (-0.80, 2.76)	0.2795	0.23 (-0.10, 0.56)	0.1745	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.1344
yes	3	-2.27 (-9.45, 4.92)	3	2.03 (-5.34, 9.41)	-4.30 (-14.64, 6.04)	0.2886	-1.05 (-2.75, 0.66)	0.2288	
no	120	-1.54 (-2.11, -0.98)	51	-2.58 (-4.34, -0.82)	1.04 (-0.81, 2.89)	0.2712	0.24 (-0.09, 0.57)	0.1569	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Graphical Summary of Functional Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	71 (56.8)	26 (41.9)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	4.2 (2.8, 6.0)	3.2 (2.6, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.01 (0.64, 1.59)	
p-value [c]	0.9947	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.02 (0.65, 1.61)	
p-value [c]	0.9505	

Time to Deterioration of Functional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.2103
Japan	56/ 99 (56.6)	4.1 (2.8, 6.0)	20/ 50 (40.0)	4.3 (2.6, NE)	1.15 (0.69, 1.94)	0.6119	
Korea	15/ 26 (57.7)	4.2 (1.4, 13.8)	6/ 12 (50.0)	1.4 (0.5, NE)	0.58 (0.22, 1.54)	0.2596	
Lines of prior systemic therapy							0.2423
2	37/ 66 (56.1)	4.2 (2.6, 6.0)	13/ 38 (34.2)	NE (2.9, NE)	1.45 (0.76, 2.74)	0.2596	
3	22/ 34 (64.7)	2.8 (0.6, 13.8)	11/ 18 (61.1)	2.2 (0.6, 5.7)	0.80 (0.38, 1.69)	0.5266	
>=4	12/ 25 (48.0)	7.0 (2.8, NE)	2/ 6 (33.3)	NE (0.5, NE)	0.54 (0.12, 2.50)	0.4266	
Age							0.0022
<65 years	38/ 55 (69.1)	2.8 (1.4, 4.3)	6/ 27 (22.2)	NE (3.2, NE)	2.74 (1.15, 6.54)	0.0186	
>=65 years	33/ 70 (47.1)	5.7 (3.1, 13.8)	20/ 35 (57.1)	2.6 (0.7, 4.3)	0.54 (0.30, 0.95)	0.0286	
Sex							0.3655
female	13/ 30 (43.3)	5.5 (2.9, NE)	6/ 15 (40.0)	5.7 (0.5, 5.7)	0.61 (0.22, 1.67)	0.3198	
male	58/ 95 (61.1)	4.1 (1.5, 6.0)	20/ 47 (42.6)	3.2 (2.6, NE)	1.16 (0.69, 1.95)	0.5845	
ECOG PS							0.6653
0	38/ 62 (61.3)	4.3 (2.7, 7.0)	12/ 30 (40.0)	5.7 (1.7, NE)	1.16 (0.60, 2.25)	0.6737	
1	33/ 63 (52.4)	4.1 (2.8, 13.8)	14/ 32 (43.8)	3.1 (1.4, NE)	0.92 (0.49, 1.75)	0.8078	
HER2 Status in central laboratory							0.3291
IHC 3+	56/ 96 (58.3)	4.2 (2.8, 9.8)	21/ 47 (44.7)	3.1 (1.7, NE)	0.91 (0.54, 1.52)	0.7013	
IHC 2+/ISH +	15/ 29 (51.7)	3.8 (1.4, NE)	5/ 15 (33.3)	5.7 (1.7, 5.7)	1.51 (0.54, 4.22)	0.4313	
Primary tumor location							0.9818
Gastric	58/108 (53.7)	4.3 (2.8, 7.0)	26/ 55 (47.3)	3.1 (1.7, 5.7)	0.86 (0.54, 1.37)	0.5087	
GEJ	13/ 17 (76.5)	1.5 (0.5, 15.3)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.3595
intestinal	51/ 89 (57.3)	4.2 (2.8, 6.0)	18/ 38 (47.4)	3.2 (2.6, NE)	0.99 (0.57, 1.71)	0.9459	
diffuse	14/ 28 (50.0)	7.0 (1.4, 13.8)	6/ 18 (33.3)	NE (0.5, NE)	0.87 (0.32, 2.33)	0.7725	
others	6/ 8 (75.0)	2.8 (0.5, 11.3)	2/ 6 (33.3)	NE (1.4, NE)	2.73 (0.52, 14.23)	0.1904	
Number of metastatic sites							0.0869
<2	14/ 23 (60.9)	4.3 (0.5, 15.5)	2/ 10 (20.0)	NE (1.4, NE)	3.09 (0.69, 13.93)	0.1256	
>= 2	57/102 (55.9)	4.2 (2.8, 6.0)	24/ 52 (46.2)	3.0 (1.7, 5.7)	0.82 (0.51, 1.34)	0.4282	
Previous total gastrectomy							0.5028
yes	13/ 22 (59.1)	2.8 (0.5, NE)	3/ 9 (33.3)	NE (0.5, NE)	1.52 (0.43, 5.38)	0.5192	
no	58/103 (56.3)	4.3 (2.9, 7.0)	23/ 53 (43.4)	3.2 (2.6, NE)	0.93 (0.57, 1.52)	0.7511	
Prior adjuvant/ neoadjuvant therapy							0.8420
yes	14/ 30 (46.7)	7.0 (2.8, NE)	2/ 10 (20.0)	NE (0.6, NE)	1.25 (0.28, 5.66)	0.7855	
no	57/ 95 (60.0)	3.8 (2.6, 4.6)	24/ 52 (46.2)	3.1 (1.7, NE)	1.08 (0.66, 1.75)	0.7745	
Prior ramucirumab contained treatment							0.3794
yes	58/ 94 (61.7)	3.1 (1.5, 4.3)	18/ 41 (43.9)	3.0 (1.7, NE)	1.14 (0.67, 1.95)	0.6512	
no	13/ 31 (41.9)	12.8 (4.3, 15.3)	8/ 21 (38.1)	4.3 (1.4, NE)	0.60 (0.23, 1.54)	0.2694	
Prior nivolumab contained treatment							0.0548
yes	18/ 33 (54.5)	7.0 (0.7, 15.5)	8/ 15 (53.3)	2.2 (0.5, 5.7)	0.53 (0.22, 1.26)	0.1450	
no	53/ 92 (57.6)	4.2 (2.8, 5.6)	18/ 47 (38.3)	4.3 (2.6, NE)	1.27 (0.74, 2.18)	0.3976	

Time to Deterioration of Functional Well-being is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0812
yes	23/ 44 (52.3)	7.0 (1.4, 15.5)	8/ 17 (47.1)	2.6 (0.5, 5.7)	0.59 (0.26, 1.35)	0.2106	
no	48/ 81 (59.3)	3.8 (2.8, 5.5)	18/ 45 (40.0)	3.2 (2.6, NE)	1.28 (0.74, 2.21)	0.3830	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9058
yes	9/ 22 (40.9)	13.8 (2.6, 13.8)	2/ 7 (28.6)	NE (1.4, NE)	0.96 (0.20, 4.54)	0.9548	
no	62/103 (60.2)	4.1 (2.8, 5.6)	24/ 55 (43.6)	3.1 (1.7, NE)	1.08 (0.67, 1.74)	0.7731	
Presence of liver metastasis at baseline							0.0383
yes	43/ 68 (63.2)	3.1 (1.4, 4.6)	21/ 34 (61.8)	1.7 (0.7, 3.0)	0.71 (0.42, 1.21)	0.2007	
no	28/ 57 (49.1)	7.0 (2.8, 15.3)	5/ 28 (17.9)	NE (3.1, NE)	2.23 (0.85, 5.84)	0.0966	
Renal impairment at baseline							0.4183
normal	24/ 33 (72.7)	3.8 (1.4, 5.7)	4/ 13 (30.8)	3.2 (0.5, NE)	1.61 (0.54, 4.79)	0.3846	
mild	28/ 53 (52.8)	4.6 (2.7, 13.8)	12/ 28 (42.9)	3.1 (1.4, NE)	0.93 (0.47, 1.86)	0.8286	
moderate	19/ 39 (48.7)	4.2 (2.8, 15.3)	10/ 20 (50.0)	2.8 (1.4, NE)	0.78 (0.36, 1.72)	0.5157	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8103
normal	50/ 88 (56.8)	4.6 (2.8, 11.3)	19/ 47 (40.4)	3.2 (2.6, NE)	0.97 (0.56, 1.66)	0.8833	
mild	20/ 36 (55.6)	2.9 (1.3, 5.6)	7/ 15 (46.7)	2.6 (0.5, NE)	1.05 (0.44, 2.50)	0.9134	
moderate	1/ 1 (100.0)	0.5 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4241
yes	4/ 8 (50.0)	4.3 (0.5, NE)	1/ 5 (20.0)	NE (0.5, NE)	2.18 (0.24, 19.72)	0.4613	
no	67/117 (57.3)	4.2 (2.8, 6.0)	25/ 57 (43.9)	3.1 (1.7, NE)	0.95 (0.59, 1.52)	0.8133	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9830
yes	2/ 3 (66.7)	4.3 (0.5, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	69/122 (56.6)	4.2 (2.8, 6.0)	26/ 58 (44.8)	3.1 (1.7, NE)	0.90 (0.57, 1.44)	0.6523	

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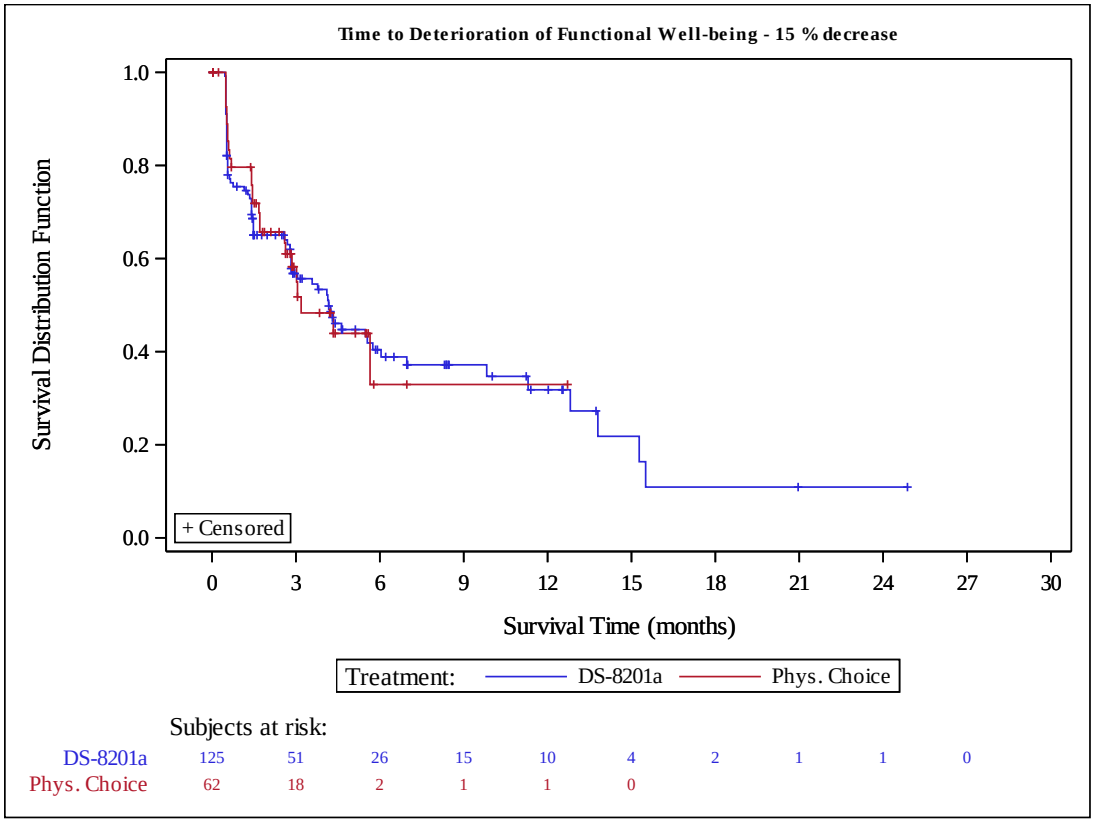
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

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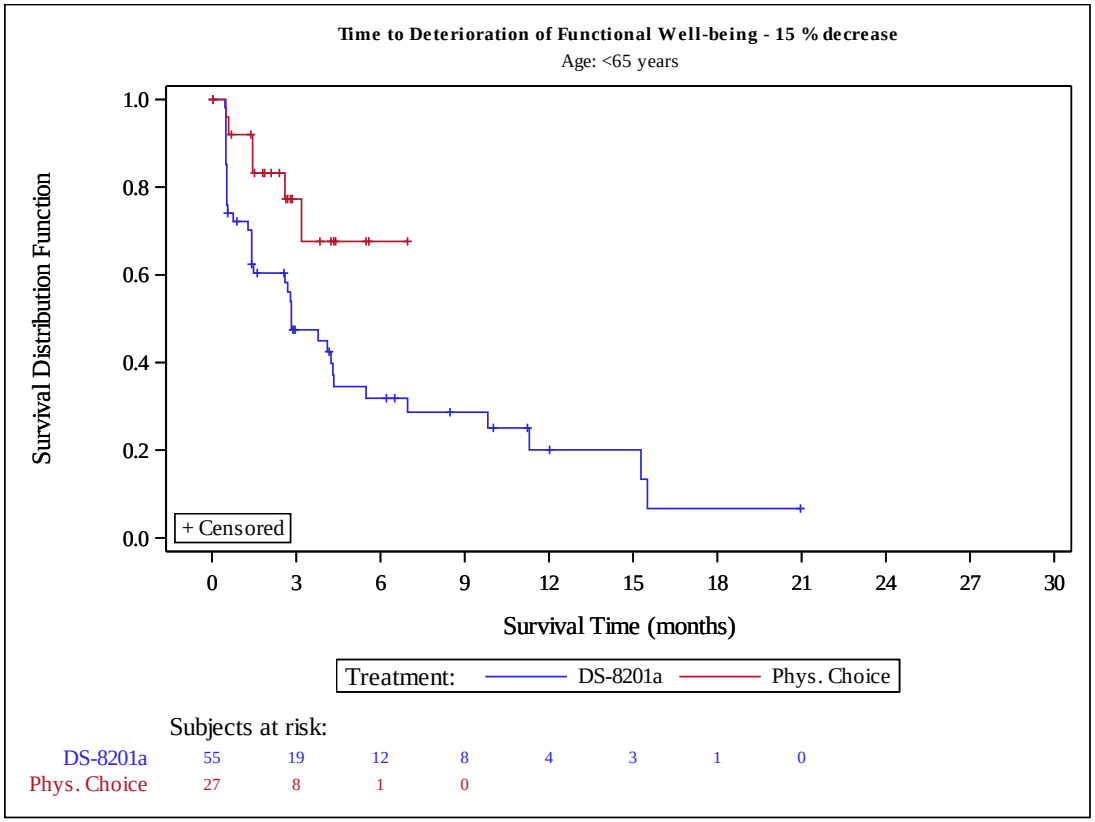
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



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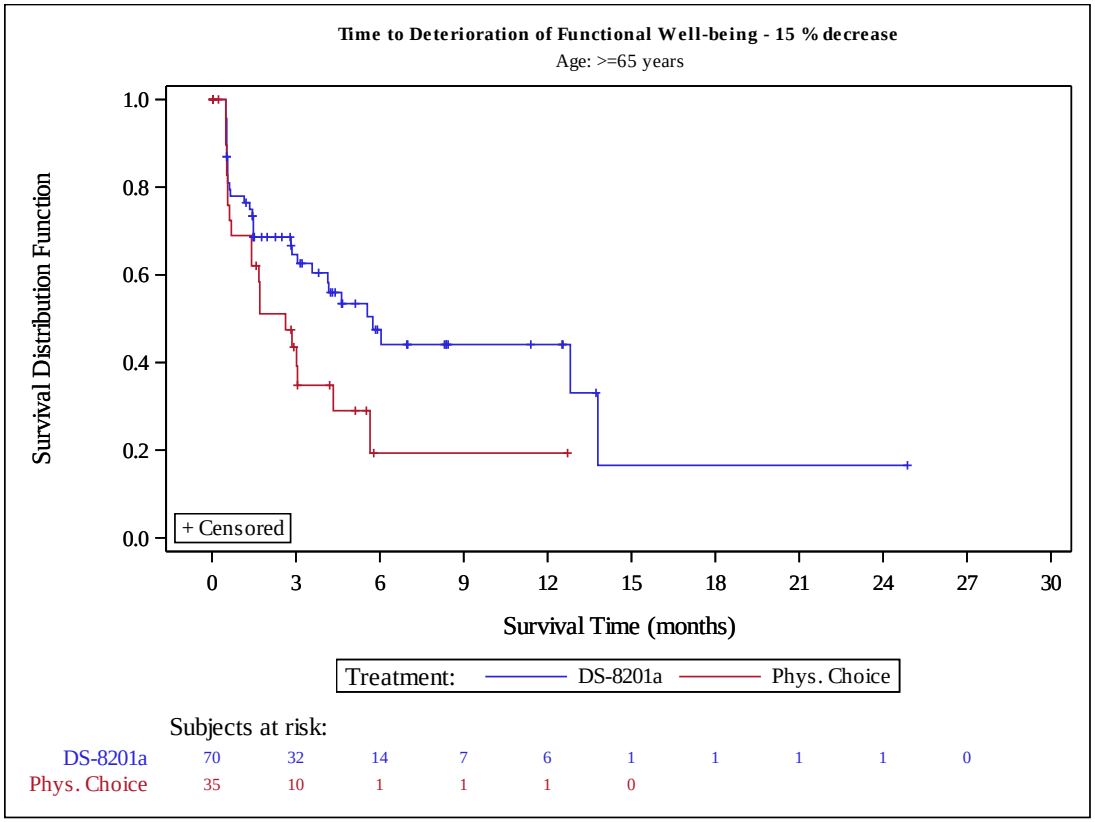
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
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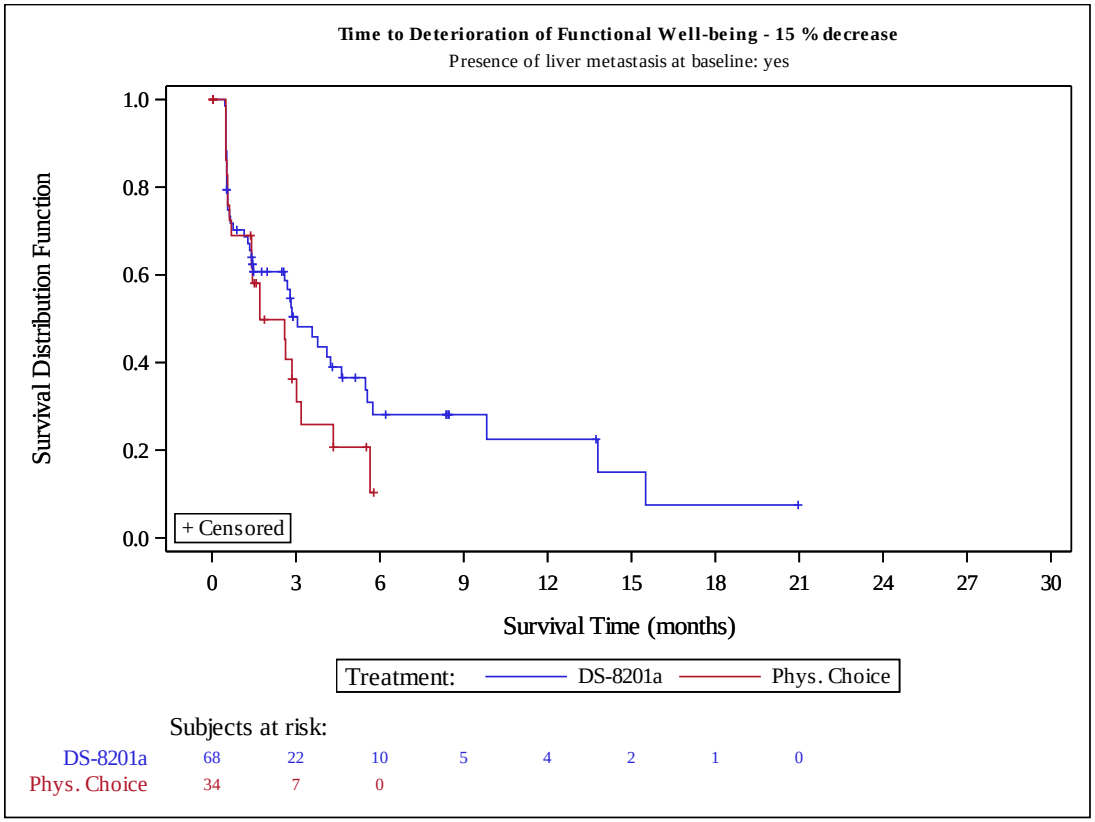
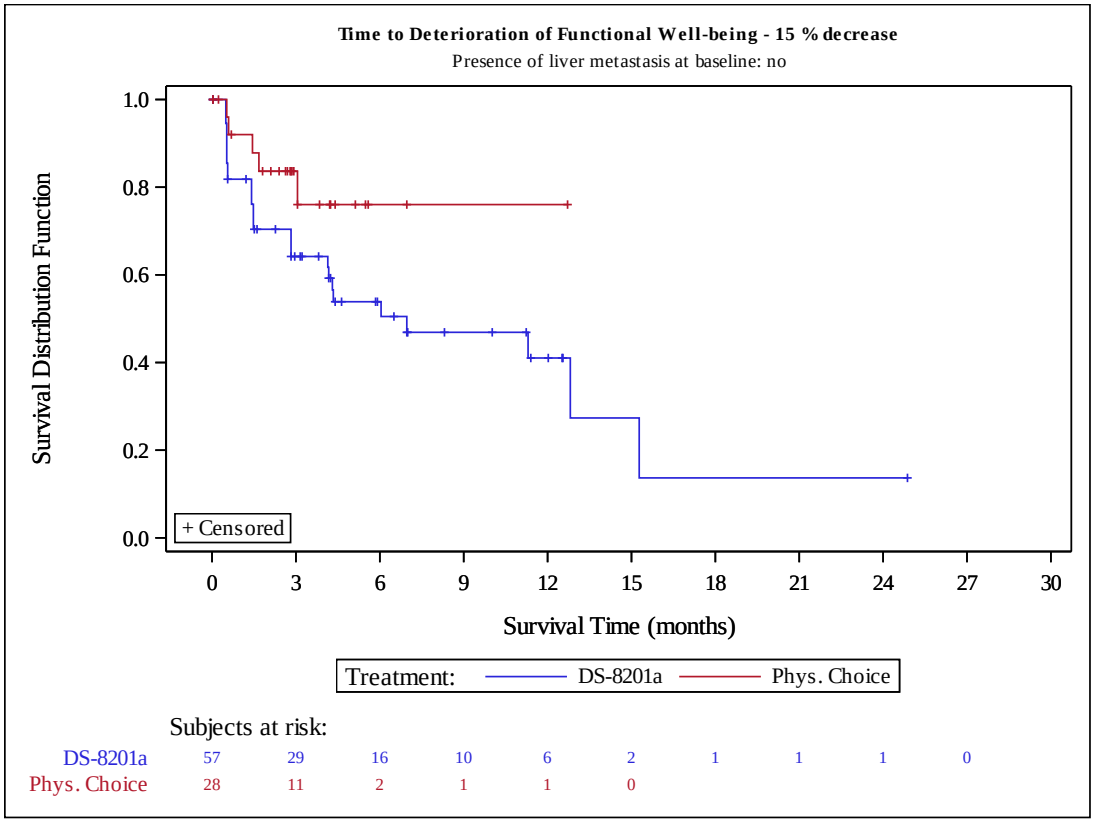
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	53 (42.4)	22 (35.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	8.4 (5.5, 15.3)	4.3 (3.0, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.60 (0.36, 1.01)	
p-value [c]	0.0530	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.63 (0.38, 1.06)	
p-value [c]	0.0814	

Time to Definitive Deterioration of Functional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.1302
Japan	41/ 99 (41.4)	9.0 (5.5, 15.3)	16/ 50 (32.0)	5.7 (3.2, NE)	0.71 (0.39, 1.29)	0.2541	
Korea	12/ 26 (46.2)	5.7 (2.8, NE)	6/ 12 (50.0)	1.4 (0.5, NE)	0.35 (0.12, 0.99)	0.0393	
Lines of prior systemic therapy							0.4250
2	27/ 66 (40.9)	8.4 (4.3, 15.3)	11/ 38 (28.9)	NE (3.0, NE)	0.84 (0.41, 1.74)	0.6450	
3	16/ 34 (47.1)	5.7 (3.1, NE)	9/ 18 (50.0)	3.2 (0.6, NE)	0.52 (0.22, 1.22)	0.1228	
>=4	10/ 25 (40.0)	11.3 (4.1, NE)	2/ 6 (33.3)	4.3 (0.5, NE)	0.43 (0.09, 2.11)	0.2939	
Age							0.0622
<65 years	27/ 55 (49.1)	9.8 (4.1, 15.5)	6/ 27 (22.2)	NE (3.2, NE)	1.21 (0.49, 3.02)	0.6750	
>=65 years	26/ 70 (37.1)	8.4 (5.7, NE)	16/ 35 (45.7)	3.1 (1.7, NE)	0.42 (0.22, 0.80)	0.0066	
Sex							0.6685
female	12/ 30 (40.0)	5.7 (3.1, NE)	4/ 15 (26.7)	5.7 (0.5, 5.7)	0.63 (0.19, 2.08)	0.4403	
male	41/ 95 (43.2)	9.0 (5.5, 15.5)	18/ 47 (38.3)	4.3 (2.9, NE)	0.63 (0.35, 1.12)	0.1157	
ECOG PS							0.6851
0	27/ 62 (43.5)	9.8 (5.9, 15.5)	11/ 30 (36.7)	4.3 (3.0, NE)	0.53 (0.25, 1.11)	0.0862	
1	26/ 63 (41.3)	5.5 (4.1, NE)	11/ 32 (34.4)	4.3 (2.6, NE)	0.77 (0.38, 1.58)	0.4865	
HER2 Status in central laboratory							0.2586
IHC 3+	42/ 96 (43.8)	8.4 (5.5, 15.5)	18/ 47 (38.3)	3.2 (2.9, NE)	0.54 (0.30, 0.97)	0.0367	
IHC 2+/ISH +	11/ 29 (37.9)	11.3 (3.8, 11.3)	4/ 15 (26.7)	5.7 (1.7, 5.7)	1.06 (0.33, 3.39)	0.9241	
Primary tumor location							0.9864
Gastric	45/108 (41.7)	7.3 (4.6, 12.8)	22/ 55 (40.0)	4.3 (2.9, NE)	0.60 (0.35, 1.01)	0.0538	
GEJ	8/ 17 (47.1)	15.3 (3.8, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.3246
intestinal	37/ 89 (41.6)	8.4 (5.5, 15.3)	14/ 38 (36.8)	4.3 (3.0, NE)	0.57 (0.30, 1.08)	0.0816	
diffuse	11/ 28 (39.3)	11.3 (2.7, NE)	6/ 18 (33.3)	4.3 (0.5, NE)	0.58 (0.20, 1.65)	0.3066	
others	5/ 8 (62.5)	2.8 (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	2.25 (0.43, 11.68)	0.2925	
Number of metastatic sites							0.4795
<2	8/ 23 (34.8)	12.8 (5.7, NE)	2/ 10 (20.0)	NE (1.4, NE)	0.68 (0.13, 3.53)	0.6415	
>= 2	45/102 (44.1)	7.2 (4.2, 11.3)	20/ 52 (38.5)	4.3 (2.6, NE)	0.60 (0.35, 1.04)	0.0676	
Previous total gastrectomy							0.4664
yes	9/ 22 (40.9)	7.2 (2.8, NE)	2/ 9 (22.2)	NE (0.5, NE)	1.10 (0.23, 5.36)	0.9005	
no	44/103 (42.7)	9.0 (5.5, 15.3)	20/ 53 (37.7)	4.3 (2.9, NE)	0.58 (0.34, 1.01)	0.0512	
Prior adjuvant/ neoadjuvant therapy							0.3034
yes	13/ 30 (43.3)	11.3 (5.5, NE)	1/ 10 (10.0)	NE (0.6, NE)	1.46 (0.18, 11.76)	0.7224	
no	40/ 95 (42.1)	8.4 (4.3, 15.5)	21/ 52 (40.4)	4.3 (2.9, NE)	0.63 (0.36, 1.08)	0.0924	
Prior ramucirumab contained treatment							0.6395
yes	43/ 94 (45.7)	5.9 (4.3, 11.3)	15/ 41 (36.6)	4.3 (2.6, NE)	0.66 (0.36, 1.21)	0.1735	
no	10/ 31 (32.3)	12.8 (8.4, NE)	7/ 21 (33.3)	NE (1.7, NE)	0.47 (0.16, 1.32)	0.1380	
Prior nivolumab contained treatment							0.0423
yes	13/ 33 (39.4)	12.8 (5.9, NE)	7/ 15 (46.7)	4.1 (0.5, 5.7)	0.28 (0.10, 0.78)	0.0102	
no	40/ 92 (43.5)	7.2 (4.3, 9.8)	15/ 47 (31.9)	4.3 (3.0, NE)	0.82 (0.45, 1.51)	0.5270	

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NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

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Protocol DS8201-A-J202
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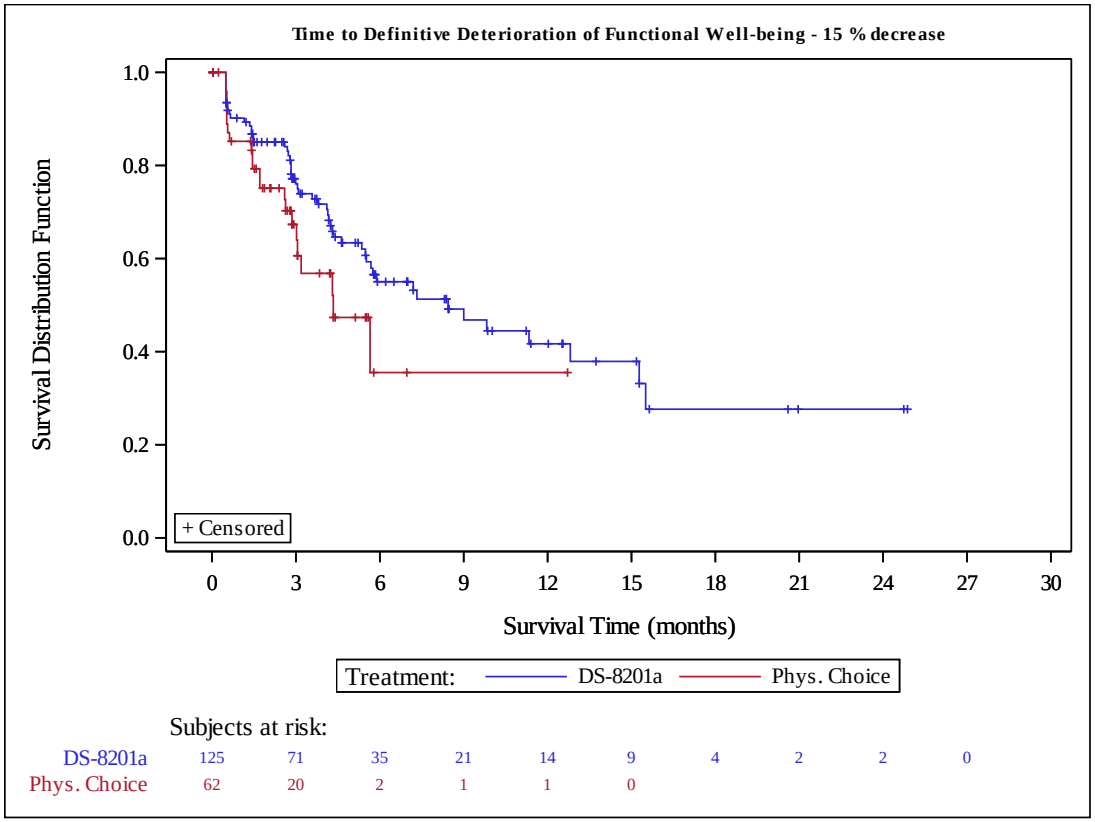
Primary Cohort
Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0275
yes	15/ 44 (34.1)	15.5 (11.3, NE)	7/ 17 (41.2)	5.7 (0.5, 5.7)	0.32 (0.12, 0.83)	0.0153	
no	38/ 81 (46.9)	5.7 (4.3, 9.0)	15/ 45 (33.3)	4.3 (3.0, NE)	0.84 (0.46, 1.56)	0.5863	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.7508
yes	6/ 22 (27.3)	NE (4.3, NE)	2/ 7 (28.6)	NE (1.4, NE)	0.50 (0.10, 2.63)	0.4048	
no	47/103 (45.6)	7.3 (5.4, 12.8)	20/ 55 (36.4)	4.3 (2.9, NE)	0.66 (0.38, 1.14)	0.1392	
Presence of liver metastasis at baseline							0.0325
yes	32/ 68 (47.1)	5.7 (3.6, 15.5)	18/ 34 (52.9)	2.6 (1.4, 4.3)	0.41 (0.23, 0.76)	0.0034	
no	21/ 57 (36.8)	11.3 (7.2, NE)	4/ 28 (14.3)	NE (4.3, NE)	1.39 (0.46, 4.17)	0.5579	
Renal impairment at baseline							0.6799
normal	15/ 33 (45.5)	9.8 (5.5, NE)	4/ 13 (30.8)	3.2 (0.5, NE)	0.34 (0.10, 1.20)	0.0791	
mild	21/ 53 (39.6)	12.8 (4.3, NE)	11/ 28 (39.3)	4.3 (1.4, NE)	0.63 (0.30, 1.32)	0.2121	
moderate	17/ 39 (43.6)	8.4 (2.9, 15.3)	7/ 20 (35.0)	5.7 (2.6, NE)	0.84 (0.34, 2.09)	0.7044	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8708
normal	38/ 88 (43.2)	9.8 (5.5, 15.5)	17/ 47 (36.2)	4.3 (3.0, NE)	0.64 (0.35, 1.17)	0.1427	
mild	15/ 36 (41.7)	5.9 (3.1, 11.3)	5/ 15 (33.3)	NE (0.5, NE)	0.58 (0.20, 1.70)	0.3217	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3355
yes	4/ 8 (50.0)	8.4 (3.1, NE)	1/ 5 (20.0)	NE (0.5, NE)	1.59 (0.18, 14.38)	0.6772	
no	49/117 (41.9)	9.0 (5.5, 15.3)	21/ 57 (36.8)	4.3 (2.9, NE)	0.59 (0.34, 1.01)	0.0501	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9854
yes	2/ 3 (66.7)	8.4 (4.3, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	51/122 (41.8)	9.0 (5.5, 15.3)	22/ 58 (37.9)	4.3 (2.9, NE)	0.55 (0.32, 0.93)	0.0244	

Time to Definitive Deterioration of Functional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

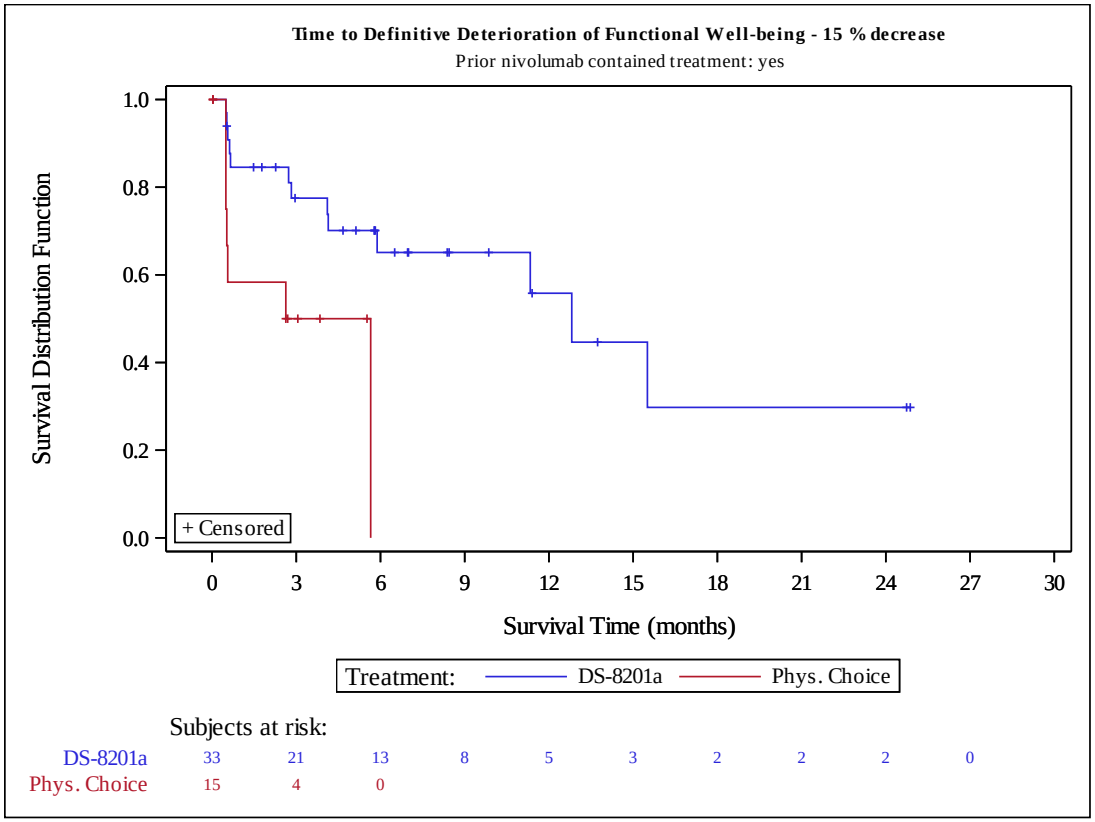
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

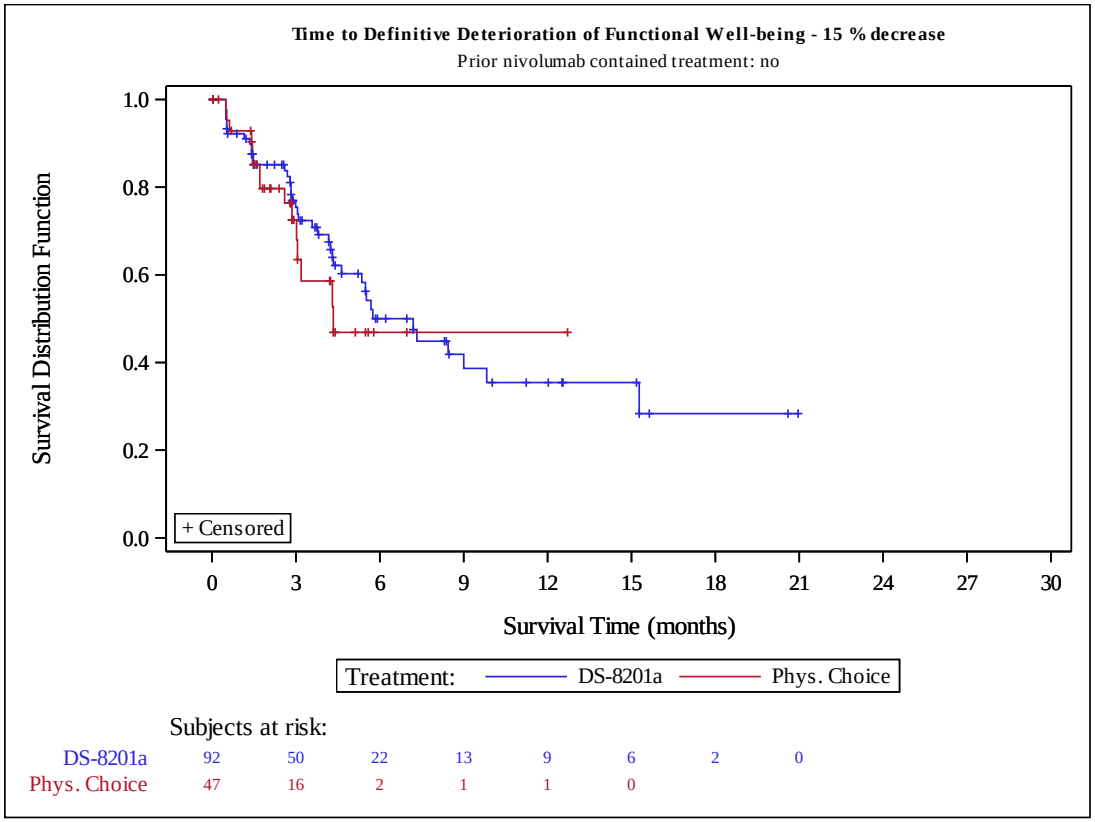
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

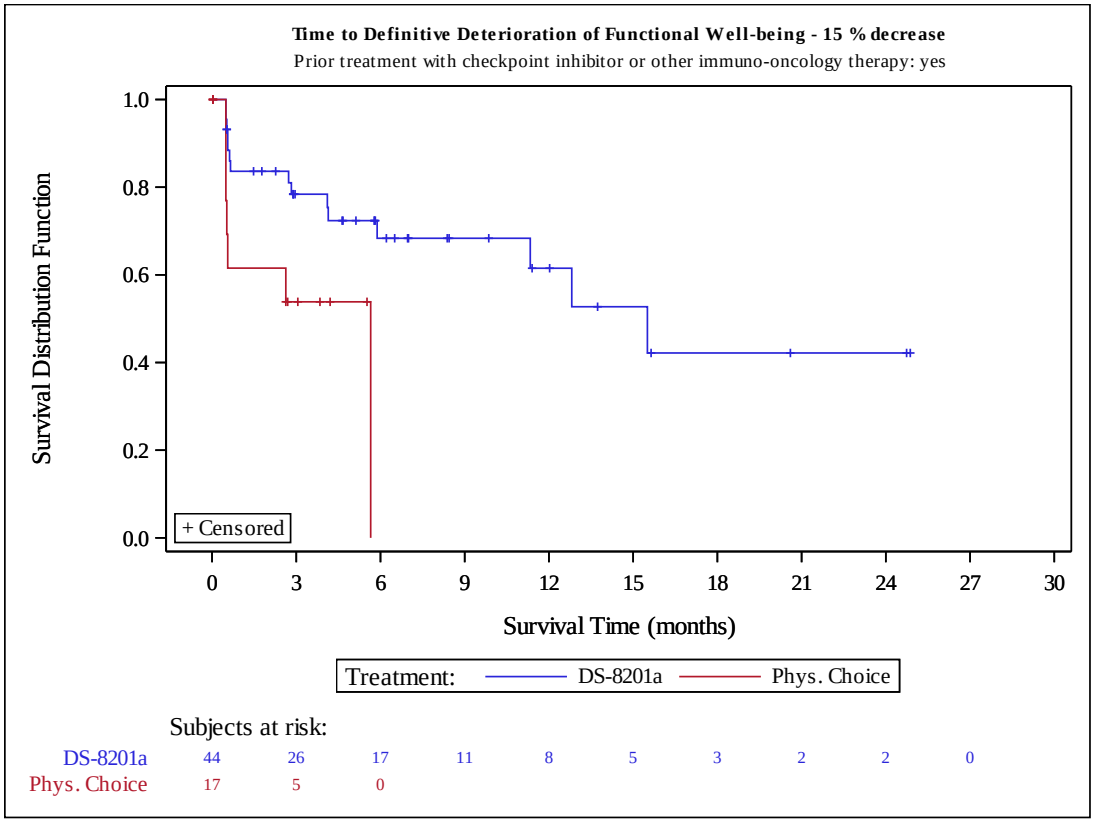
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

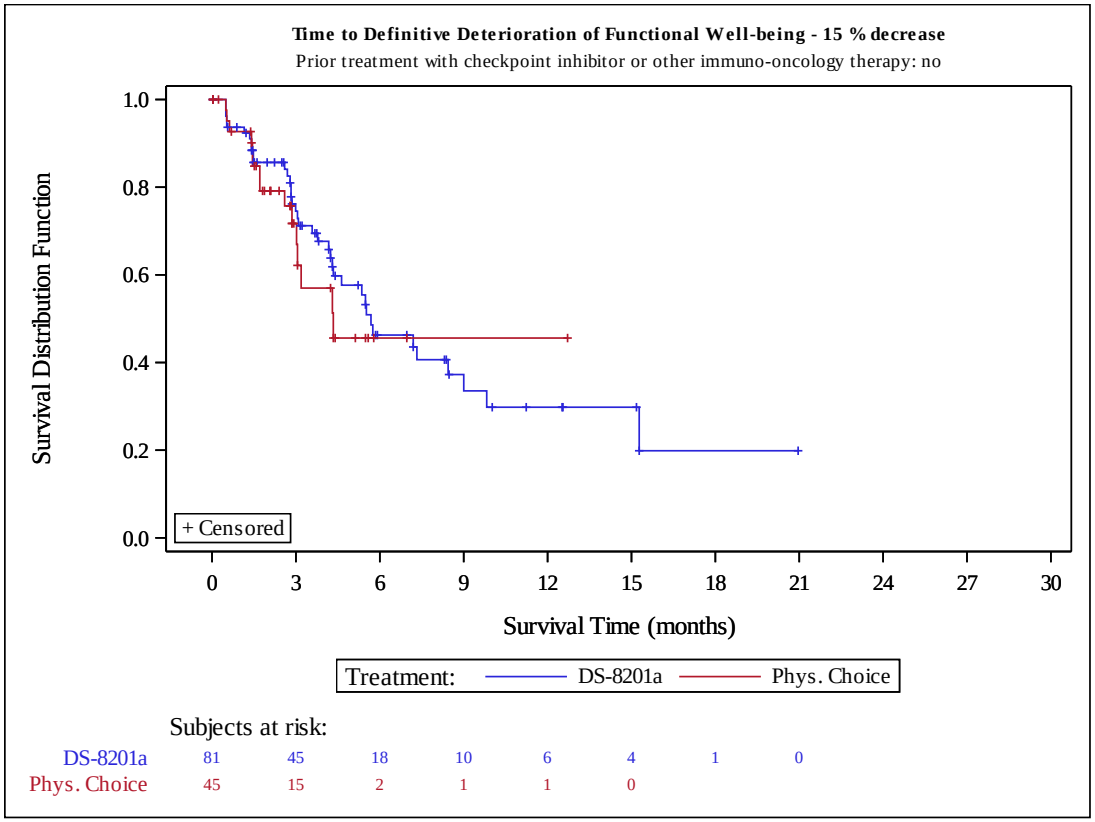
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

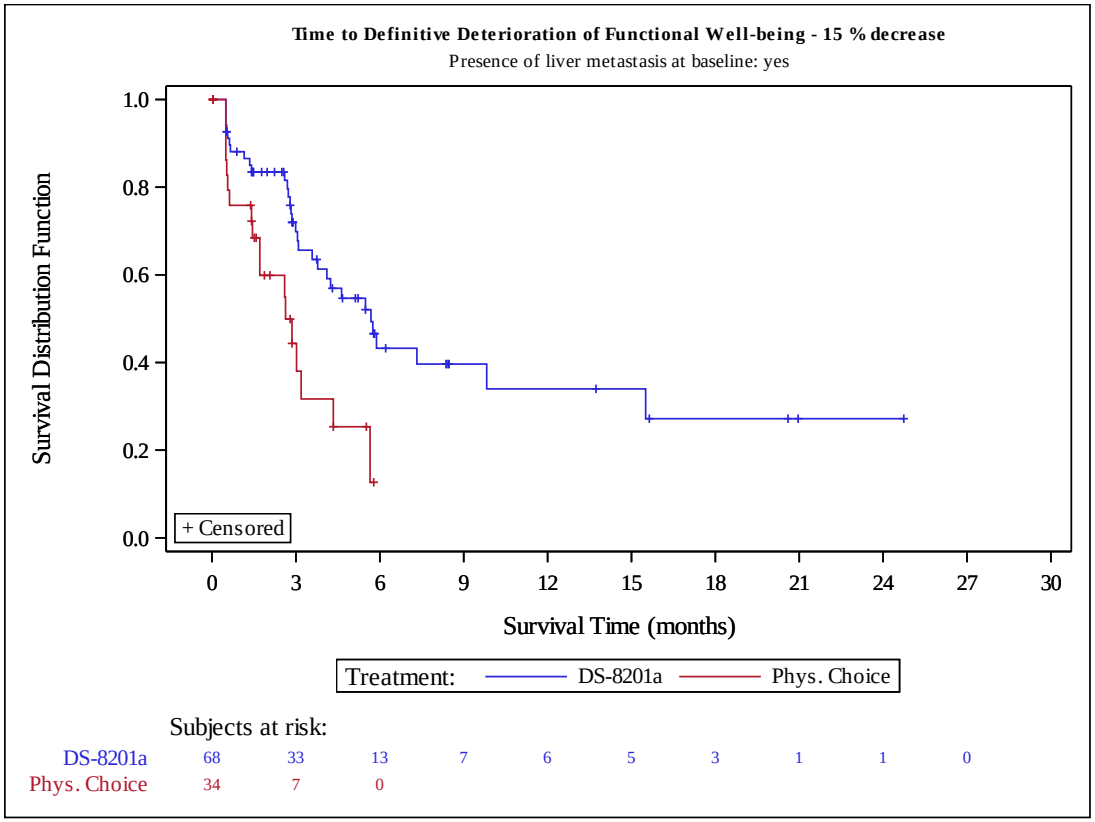
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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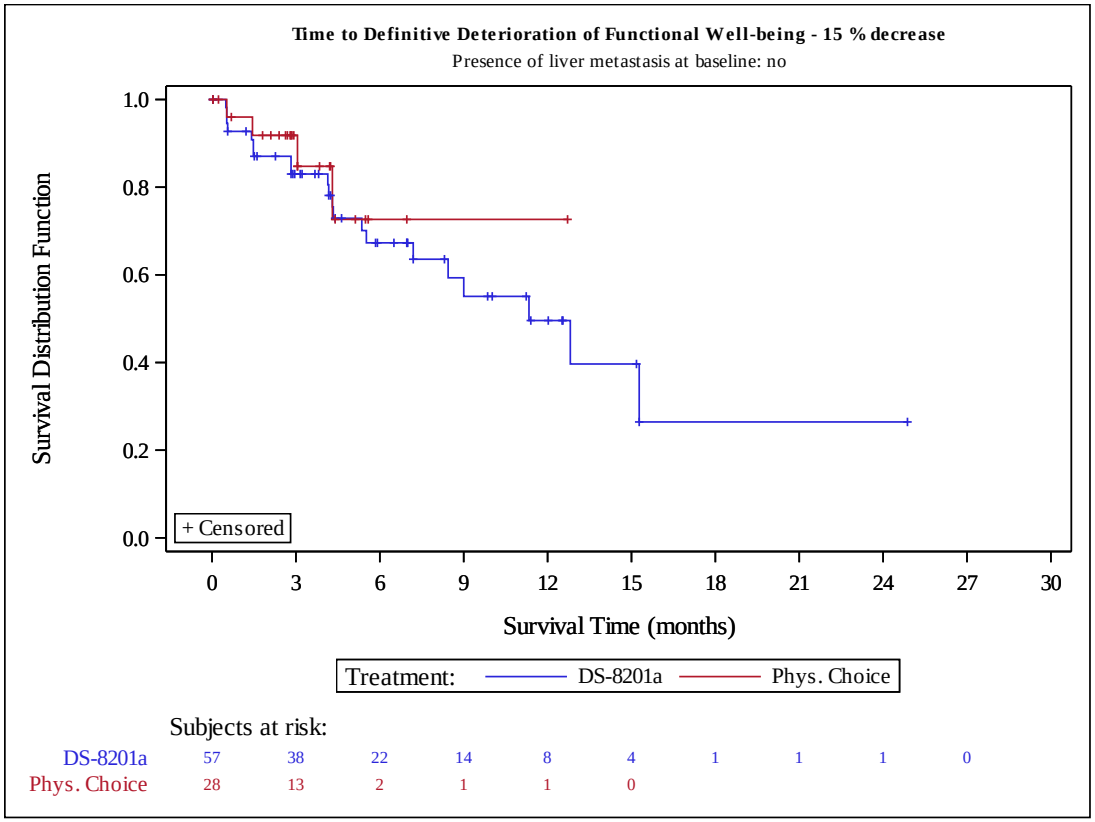
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	118	10 (8.5)	78 (66.1)	30 (25.4)	52	3 (5.8)	38 (73.1)	11 (21.2)
	Day 43	117	10 (8.5)	85 (72.6)	22 (18.8)	53	6 (11.3)	35 (66.0)	12 (22.6)
	Day 85	99	11 (11.1)	63 (63.6)	25 (25.3)	36	3 (8.3)	24 (66.7)	9 (25.0)
	Day 127	74	8 (10.8)	47 (63.5)	19 (25.7)	19	3 (15.8)	12 (63.2)	4 (21.1)
	Day 169	57	9 (15.8)	33 (57.9)	15 (26.3)	11	2 (18.2)	5 (45.5)	4 (36.4)
	Day 211	44	7 (15.9)	28 (63.6)	9 (20.5)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 253	37	5 (13.5)	23 (62.2)	9 (24.3)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	29	3 (10.3)	20 (69.0)	6 (20.7)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	27	4 (14.8)	15 (55.6)	8 (29.6)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	21	3 (14.3)	14 (66.7)	4 (19.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	16	0 (0.0)	10 (62.5)	6 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	0 (0.0)	8 (66.7)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	97	9 (9.3)	48 (49.5)	40 (41.2)	56	2 (3.6)	34 (60.7)	20 (35.7)
Region									
Japan									
	Day 15	96	7 (7.3)	65 (67.7)	24 (25.0)	45	2 (4.4)	35 (77.8)	8 (17.8)
	Day 43	93	6 (6.5)	71 (76.3)	16 (17.2)	43	5 (11.6)	31 (72.1)	7 (16.3)
	Day 85	77	10 (13.0)	48 (62.3)	19 (24.7)	32	3 (9.4)	22 (68.8)	7 (21.9)
	Day 127	60	6 (10.0)	42 (70.0)	12 (20.0)	16	3 (18.8)	10 (62.5)	3 (18.8)
	Day 169	49	8 (16.3)	29 (59.2)	12 (24.5)	9	1 (11.1)	5 (55.6)	3 (33.3)
	Day 211	36	4 (11.1)	24 (66.7)	8 (22.2)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 253	29	4 (13.8)	18 (62.1)	7 (24.1)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	23	1 (4.3)	18 (78.3)	4 (17.4)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	21	2 (9.5)	14 (66.7)	5 (23.8)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	18	2 (11.1)	12 (66.7)	4 (22.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	0 (0.0)	7 (70.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	7 (9.0)	41 (52.6)	30 (38.5)	48	2 (4.2)	31 (64.6)	15 (31.3)
Region									
Korea									
	Day 15	22	3 (13.6)	13 (59.1)	6 (27.3)	7	1 (14.3)	3 (42.9)	3 (42.9)
	Day 43	24	4 (16.7)	14 (58.3)	6 (25.0)	10	1 (10.0)	4 (40.0)	5 (50.0)
	Day 85	22	1 (4.5)	15 (68.2)	6 (27.3)	4	0 (0.0)	2 (50.0)	2 (50.0)
	Day 127	14	2 (14.3)	5 (35.7)	7 (50.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	8	1 (12.5)	4 (50.0)	3 (37.5)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 211	8	3 (37.5)	4 (50.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	6	2 (33.3)	2 (33.3)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	6	2 (33.3)	1 (16.7)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	19	2 (10.5)	7 (36.8)	10 (52.6)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy									
2									
	Day 15	60	8 (13.3)	40 (66.7)	12 (20.0)	34	2 (5.9)	27 (79.4)	5 (14.7)
	Day 43	62	7 (11.3)	44 (71.0)	11 (17.7)	36	4 (11.1)	26 (72.2)	6 (16.7)
	Day 85	50	5 (10.0)	35 (70.0)	10 (20.0)	21	1 (4.8)	15 (71.4)	5 (23.8)
	Day 127	33	4 (12.1)	21 (63.6)	8 (24.2)	14	1 (7.1)	10 (71.4)	3 (21.4)
	Day 169	24	5 (20.8)	12 (50.0)	7 (29.2)	6	2 (33.3)	3 (50.0)	1 (16.7)
	Day 211	21	4 (19.0)	15 (71.4)	2 (9.5)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 253	18	3 (16.7)	12 (66.7)	3 (16.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	12	1 (8.3)	9 (75.0)	2 (16.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	11	2 (18.2)	6 (54.5)	3 (27.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	7	2 (28.6)	5 (71.4)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	51	4 (7.8)	27 (52.9)	20 (39.2)	34	1 (2.9)	23 (67.6)	10 (29.4)
Lines of prior systemic therapy									
3									
	Day 15	34	1 (2.9)	20 (58.8)	13 (38.2)	14	0 (0.0)	10 (71.4)	4 (28.6)
	Day 43	33	2 (6.1)	23 (69.7)	8 (24.2)	14	1 (7.1)	7 (50.0)	6 (42.9)
	Day 85	28	2 (7.1)	15 (53.6)	11 (39.3)	12	2 (16.7)	6 (50.0)	4 (33.3)
	Day 127	23	2 (8.7)	13 (56.5)	8 (34.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	19	1 (5.3)	12 (63.2)	6 (31.6)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 211	13	2 (15.4)	6 (46.2)	5 (38.5)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 253	11	1 (9.1)	5 (45.5)	5 (45.5)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	9	1 (11.1)	5 (55.6)	3 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	3 (50.0)	3 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	3 (11.5)	10 (38.5)	13 (50.0)	17	1 (5.9)	7 (41.2)	9 (52.9)
Lines of prior systemic therapy									
>=4									
	Day 15	24	1 (4.2)	18 (75.0)	5 (20.8)	4	1 (25.0)	1 (25.0)	2 (50.0)
	Day 43	22	1 (4.5)	18 (81.8)	3 (13.6)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	21	4 (19.0)	13 (61.9)	4 (19.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	2 (11.1)	13 (72.2)	3 (16.7)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 169	14	3 (21.4)	9 (64.3)	2 (14.3)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	2 (10.0)	11 (55.0)	7 (35.0)	5	0 (0.0)	4 (80.0)	1 (20.0)
Age									
<65 years									
	Day 15	51	5 (9.8)	31 (60.8)	15 (29.4)	22	2 (9.1)	18 (81.8)	2 (9.1)
	Day 43	52	3 (5.8)	38 (73.1)	11 (21.2)	24	2 (8.3)	19 (79.2)	3 (12.5)
	Day 85	47	3 (6.4)	29 (61.7)	15 (31.9)	16	0 (0.0)	13 (81.3)	3 (18.8)
	Day 127	34	2 (5.9)	21 (61.8)	11 (32.4)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	27	4 (14.8)	15 (55.6)	8 (29.6)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 211	18	2 (11.1)	12 (66.7)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	16	3 (18.8)	11 (68.8)	2 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	1 (7.7)	9 (69.2)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	2 (18.2)	6 (54.5)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	2 (25.0)	5 (62.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	42	3 (7.1)	18 (42.9)	21 (50.0)	23	0 (0.0)	19 (82.6)	4 (17.4)
Age									
>=65 years									
	Day 15	67	5 (7.5)	47 (70.1)	15 (22.4)	30	1 (3.3)	20 (66.7)	9 (30.0)
	Day 43	65	7 (10.8)	47 (72.3)	11 (16.9)	29	4 (13.8)	16 (55.2)	9 (31.0)
	Day 85	52	8 (15.4)	34 (65.4)	10 (19.2)	20	3 (15.0)	11 (55.0)	6 (30.0)
	Day 127	40	6 (15.0)	26 (65.0)	8 (20.0)	11	3 (27.3)	5 (45.5)	3 (27.3)
	Day 169	30	5 (16.7)	18 (60.0)	7 (23.3)	7	1 (14.3)	3 (42.9)	3 (42.9)
	Day 211	26	5 (19.2)	16 (61.5)	5 (19.2)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	21	2 (9.5)	12 (57.1)	7 (33.3)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	16	2 (12.5)	11 (68.8)	3 (18.8)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	16	2 (12.5)	9 (56.3)	5 (31.3)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	13	1 (7.7)	9 (69.2)	3 (23.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	4 (44.4)	5 (55.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	End of Treatment	55	6 (10.9)	30 (54.5)	19 (34.5)	33	2 (6.1)	15 (45.5)	16 (48.5)
Sex									
female									
	Day 15	28	4 (14.3)	18 (64.3)	6 (21.4)	13	0 (0.0)	10 (76.9)	3 (23.1)
	Day 43	28	2 (7.1)	24 (85.7)	2 (7.1)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 85	20	2 (10.0)	13 (65.0)	5 (25.0)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	13	1 (7.7)	8 (61.5)	4 (30.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	10	1 (10.0)	6 (60.0)	3 (30.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	1 (12.5)	5 (62.5)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	22	2 (9.1)	11 (50.0)	9 (40.9)	14	1 (7.1)	9 (64.3)	4 (28.6)
Sex									
male									
	Day 15	90	6 (6.7)	60 (66.7)	24 (26.7)	39	3 (7.7)	28 (71.8)	8 (20.5)
	Day 43	89	8 (9.0)	61 (68.5)	20 (22.5)	40	5 (12.5)	26 (65.0)	9 (22.5)
	Day 85	79	9 (11.4)	50 (63.3)	20 (25.3)	28	2 (7.1)	17 (60.7)	9 (32.1)
	Day 127	61	7 (11.5)	39 (63.9)	15 (24.6)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 169	47	8 (17.0)	27 (57.4)	12 (25.5)	9	2 (22.2)	4 (44.4)	3 (33.3)
	Day 211	36	6 (16.7)	23 (63.9)	7 (19.4)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	30	4 (13.3)	19 (63.3)	7 (23.3)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	25	3 (12.0)	17 (68.0)	5 (20.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	24	4 (16.7)	13 (54.2)	7 (29.2)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	19	2 (10.5)	13 (68.4)	4 (21.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	15	0 (0.0)	9 (60.0)	6 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	3 (42.9)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	75	7 (9.3)	37 (49.3)	31 (41.3)	42	1 (2.4)	25 (59.5)	16 (38.1)
ECOG PS									
0									
	Day 15	60	2 (3.3)	45 (75.0)	13 (21.7)	26	0 (0.0)	22 (84.6)	4 (15.4)
	Day 43	59	4 (6.8)	45 (76.3)	10 (16.9)	26	3 (11.5)	17 (65.4)	6 (23.1)
	Day 85	54	5 (9.3)	38 (70.4)	11 (20.4)	19	2 (10.5)	13 (68.4)	4 (21.1)
	Day 127	42	5 (11.9)	31 (73.8)	6 (14.3)	9	2 (22.2)	5 (55.6)	2 (22.2)
	Day 169	36	4 (11.1)	25 (69.4)	7 (19.4)	6	1 (16.7)	2 (33.3)	3 (50.0)
	Day 211	27	3 (11.1)	19 (70.4)	5 (18.5)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 253	24	3 (12.5)	15 (62.5)	6 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	18	1 (5.6)	14 (77.8)	3 (16.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	16	1 (6.3)	11 (68.8)	4 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	14	1 (7.1)	10 (71.4)	3 (21.4)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	48	3 (6.3)	26 (54.2)	19 (39.6)	29	1 (3.4)	18 (62.1)	10 (34.5)
ECOG PS									
1									
	Day 15	58	8 (13.8)	33 (56.9)	17 (29.3)	26	3 (11.5)	16 (61.5)	7 (26.9)
	Day 43	58	6 (10.3)	40 (69.0)	12 (20.7)	27	3 (11.1)	18 (66.7)	6 (22.2)
	Day 85	45	6 (13.3)	25 (55.6)	14 (31.1)	17	1 (5.9)	11 (64.7)	5 (29.4)
	Day 127	32	3 (9.4)	16 (50.0)	13 (40.6)	10	1 (10.0)	7 (70.0)	2 (20.0)
	Day 169	21	5 (23.8)	8 (38.1)	8 (38.1)	5	1 (20.0)	3 (60.0)	1 (20.0)
	Day 211	17	4 (23.5)	9 (52.9)	4 (23.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	13	2 (15.4)	8 (61.5)	3 (23.1)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	11	2 (18.2)	6 (54.5)	3 (27.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	3 (27.3)	4 (36.4)	4 (36.4)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	49	6 (12.2)	22 (44.9)	21 (42.9)	27	1 (3.7)	16 (59.3)	10 (37.0)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	91	10 (11.0)	57 (62.6)	24 (26.4)	38	1 (2.6)	28 (73.7)	9 (23.7)
	Day 43	91	7 (7.7)	67 (73.6)	17 (18.7)	40	5 (12.5)	26 (65.0)	9 (22.5)
	Day 85	79	8 (10.1)	51 (64.6)	20 (25.3)	26	2 (7.7)	16 (61.5)	8 (30.8)
	Day 127	59	6 (10.2)	38 (64.4)	15 (25.4)	13	2 (15.4)	7 (53.8)	4 (30.8)
	Day 169	46	6 (13.0)	28 (60.9)	12 (26.1)	8	1 (12.5)	4 (50.0)	3 (37.5)
	Day 211	38	5 (13.2)	26 (68.4)	7 (18.4)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 253	32	5 (15.6)	19 (59.4)	8 (25.0)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	26	3 (11.5)	18 (69.2)	5 (19.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	25	4 (16.0)	15 (60.0)	6 (24.0)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	19	3 (15.8)	14 (73.7)	2 (10.5)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	16	0 (0.0)	10 (62.5)	6 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	0 (0.0)	8 (66.7)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	7 (9.5)	37 (50.0)	30 (40.5)	42	1 (2.4)	25 (59.5)	16 (38.1)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	0 (0.0)	21 (77.8)	6 (22.2)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 43	26	3 (11.5)	18 (69.2)	5 (19.2)	13	1 (7.7)	9 (69.2)	3 (23.1)
	Day 85	20	3 (15.0)	12 (60.0)	5 (25.0)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 127	15	2 (13.3)	9 (60.0)	4 (26.7)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 169	11	3 (27.3)	5 (45.5)	3 (27.3)	3	1 (33.3)	1 (33.3)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	6	2 (33.3)	2 (33.3)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	2 (8.7)	11 (47.8)	10 (43.5)	14	1 (7.1)	9 (64.3)	4 (28.6)
Primary tumor location									
Gastric									
	Day 15	102	9 (8.8)	67 (65.7)	26 (25.5)	46	2 (4.3)	33 (71.7)	11 (23.9)
	Day 43	100	10 (10.0)	73 (73.0)	17 (17.0)	48	5 (10.4)	31 (64.6)	12 (25.0)
	Day 85	84	10 (11.9)	52 (61.9)	22 (26.2)	33	3 (9.1)	21 (63.6)	9 (27.3)
	Day 127	63	6 (9.5)	39 (61.9)	18 (28.6)	16	3 (18.8)	9 (56.3)	4 (25.0)
	Day 169	47	7 (14.9)	27 (57.4)	13 (27.7)	11	2 (18.2)	5 (45.5)	4 (36.4)
	Day 211	38	6 (15.8)	23 (60.5)	9 (23.7)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 253	31	4 (12.9)	18 (58.1)	9 (29.0)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	24	3 (12.5)	15 (62.5)	6 (25.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	22	3 (13.6)	11 (50.0)	8 (36.4)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	17	2 (11.8)	11 (64.7)	4 (23.5)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	13	0 (0.0)	7 (53.8)	6 (46.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	3 (42.9)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	8 (9.8)	40 (48.8)	34 (41.5)	50	2 (4.0)	28 (56.0)	20 (40.0)
Primary tumor location									
GEJ									
	Day 15	16	1 (6.3)	11 (68.8)	4 (25.0)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	17	0 (0.0)	12 (70.6)	5 (29.4)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 85	15	1 (6.7)	11 (73.3)	3 (20.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	2 (18.2)	8 (72.7)	1 (9.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	1 (6.7)	8 (53.3)	6 (40.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	86	7 (8.1)	58 (67.4)	21 (24.4)	35	2 (5.7)	26 (74.3)	7 (20.0)
	Day 43	85	6 (7.1)	66 (77.6)	13 (15.3)	34	4 (11.8)	25 (73.5)	5 (14.7)
	Day 85	73	9 (12.3)	47 (64.4)	17 (23.3)	27	2 (7.4)	17 (63.0)	8 (29.6)
	Day 127	55	5 (9.1)	40 (72.7)	10 (18.2)	14	3 (21.4)	8 (57.1)	3 (21.4)
	Day 169	44	8 (18.2)	25 (56.8)	11 (25.0)	7	1 (14.3)	3 (42.9)	3 (42.9)
	Day 211	32	4 (12.5)	22 (68.8)	6 (18.8)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 253	25	4 (16.0)	14 (56.0)	7 (28.0)	2	1 (50.0)	0 (0.0)	1 (50.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	18	1 (5.6)	14 (77.8)	3 (16.7)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	16	2 (12.5)	10 (62.5)	4 (25.0)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	13	2 (15.4)	8 (61.5)	3 (23.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	6 (8.3)	35 (48.6)	31 (43.1)	37	2 (5.4)	21 (56.8)	14 (37.8)
Histological subtype									
diffuse									
	Day 15	26	2 (7.7)	17 (65.4)	7 (26.9)	15	0 (0.0)	11 (73.3)	4 (26.7)
	Day 43	26	3 (11.5)	16 (61.5)	7 (26.9)	14	0 (0.0)	9 (64.3)	5 (35.7)
	Day 85	22	2 (9.1)	14 (63.6)	6 (27.3)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 127	15	3 (20.0)	6 (40.0)	6 (40.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	11	1 (9.1)	7 (63.6)	3 (27.3)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	10	3 (30.0)	5 (50.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	2 (22.2)	4 (44.4)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	9	2 (22.2)	4 (44.4)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	0 (0.0)	4 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	3 (14.3)	13 (61.9)	5 (23.8)	16	0 (0.0)	12 (75.0)	4 (25.0)
Histological subtype									
others									
	Day 15	6	1 (16.7)	3 (50.0)	2 (33.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 43	6	1 (16.7)	3 (50.0)	2 (33.3)	5	2 (40.0)	1 (20.0)	2 (40.0)
	Day 85	4	0 (0.0)	2 (50.0)	2 (50.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	4	0 (0.0)	1 (25.0)	3 (75.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	1 (50.0)	1 (50.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	0 (0.0)	4 (100.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites									
<2									
	Day 15	22	1 (4.5)	14 (63.6)	7 (31.8)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 43	21	0 (0.0)	20 (95.2)	1 (4.8)	10	2 (20.0)	7 (70.0)	1 (10.0)
	Day 85	21	4 (19.0)	14 (66.7)	3 (14.3)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 127	17	1 (5.9)	15 (88.2)	1 (5.9)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	16	2 (12.5)	9 (56.3)	5 (31.3)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 211	14	2 (14.3)	11 (78.6)	1 (7.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 253	10	2 (20.0)	5 (50.0)	3 (30.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	8	2 (25.0)	5 (62.5)	1 (12.5)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	8	2 (25.0)	4 (50.0)	2 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	3 (16.7)	9 (50.0)	6 (33.3)	9	1 (11.1)	6 (66.7)	2 (22.2)
Number of metastatic sites									
>= 2									
	Day 15	96	9 (9.4)	64 (66.7)	23 (24.0)	42	2 (4.8)	29 (69.0)	11 (26.2)
	Day 43	96	10 (10.4)	65 (67.7)	21 (21.9)	43	4 (9.3)	28 (65.1)	11 (25.6)
	Day 85	78	7 (9.0)	49 (62.8)	22 (28.2)	28	2 (7.1)	18 (64.3)	8 (28.6)
	Day 127	57	7 (12.3)	32 (56.1)	18 (31.6)	15	2 (13.3)	9 (60.0)	4 (26.7)
	Day 169	41	7 (17.1)	24 (58.5)	10 (24.4)	8	0 (0.0)	4 (50.0)	4 (50.0)
	Day 211	30	5 (16.7)	17 (56.7)	8 (26.7)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	27	3 (11.1)	18 (66.7)	6 (22.2)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	21	1 (4.8)	15 (71.4)	5 (23.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	19	2 (10.5)	11 (57.9)	6 (31.6)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	16	3 (18.8)	10 (62.5)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	12	0 (0.0)	7 (58.3)	5 (41.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	3 (42.9)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	6 (7.6)	39 (49.4)	34 (43.0)	47	1 (2.1)	28 (59.6)	18 (38.3)
Previous total gastrectomy									
yes									
	Day 15	20	1 (5.0)	12 (60.0)	7 (35.0)	7	1 (14.3)	4 (57.1)	2 (28.6)
	Day 43	20	0 (0.0)	14 (70.0)	6 (30.0)	8	1 (12.5)	4 (50.0)	3 (37.5)
	Day 85	18	0 (0.0)	11 (61.1)	7 (38.9)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	0 (0.0)	5 (62.5)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	10 (55.6)	7 (38.9)	9	0 (0.0)	7 (77.8)	2 (22.2)
Previous total gastrectomy									
no									
	Day 15	98	9 (9.2)	66 (67.3)	23 (23.5)	45	2 (4.4)	34 (75.6)	9 (20.0)
	Day 43	97	10 (10.3)	71 (73.2)	16 (16.5)	45	5 (11.1)	31 (68.9)	9 (20.0)
	Day 85	81	11 (13.6)	52 (64.2)	18 (22.2)	30	3 (10.0)	18 (60.0)	9 (30.0)
	Day 127	63	7 (11.1)	39 (61.9)	17 (27.0)	17	2 (11.8)	11 (64.7)	4 (23.5)
	Day 169	49	9 (18.4)	28 (57.1)	12 (24.5)	10	2 (20.0)	4 (40.0)	4 (40.0)
	Day 211	36	6 (16.7)	23 (63.9)	7 (19.4)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 253	33	4 (12.1)	21 (63.6)	8 (24.2)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	25	2 (8.0)	18 (72.0)	5 (20.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	23	3 (13.0)	13 (56.5)	7 (30.4)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	19	3 (15.8)	12 (63.2)	4 (21.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	14	0 (0.0)	10 (71.4)	4 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	8 (10.1)	38 (48.1)	33 (41.8)	47	2 (4.3)	27 (57.4)	18 (38.3)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	3 (10.3)	21 (72.4)	5 (17.2)	8	2 (25.0)	5 (62.5)	1 (12.5)
	Day 43	27	3 (11.1)	21 (77.8)	3 (11.1)	8	2 (25.0)	4 (50.0)	2 (25.0)
	Day 85	27	3 (11.1)	18 (66.7)	6 (22.2)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 127	22	2 (9.1)	17 (77.3)	3 (13.6)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	15	1 (6.7)	11 (73.3)	3 (20.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 211	12	2 (16.7)	7 (58.3)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	10	2 (20.0)	7 (70.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	25	3 (12.0)	11 (44.0)	11 (44.0)	9	0 (0.0)	8 (88.9)	1 (11.1)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	89	7 (7.9)	57 (64.0)	25 (28.1)	44	1 (2.3)	33 (75.0)	10 (22.7)
	Day 43	90	7 (7.8)	64 (71.1)	19 (21.1)	45	4 (8.9)	31 (68.9)	10 (22.2)
	Day 85	72	8 (11.1)	45 (62.5)	19 (26.4)	29	3 (10.3)	17 (58.6)	9 (31.0)
	Day 127	52	6 (11.5)	30 (57.7)	16 (30.8)	15	2 (13.3)	9 (60.0)	4 (26.7)
	Day 169	42	8 (19.0)	22 (52.4)	12 (28.6)	8	1 (12.5)	3 (37.5)	4 (50.0)
	Day 211	32	5 (15.6)	21 (65.6)	6 (18.8)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	27	3 (11.1)	17 (63.0)	7 (25.9)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	19	1 (5.3)	13 (68.4)	5 (26.3)	2	1 (50.0)	1 (50.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
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Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	17	2 (11.8)	10 (58.8)	5 (29.4)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	15	3 (20.0)	10 (66.7)	2 (13.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	12	0 (0.0)	9 (75.0)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	0 (0.0)	6 (60.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	6 (8.3)	37 (51.4)	29 (40.3)	47	2 (4.3)	26 (55.3)	19 (40.4)
Prior ramucirumab contained treatment									
yes									
	Day 15	90	5 (5.6)	59 (65.6)	26 (28.9)	34	3 (8.8)	24 (70.6)	7 (20.6)
	Day 43	89	6 (6.7)	65 (73.0)	18 (20.2)	33	4 (12.1)	23 (69.7)	6 (18.2)
	Day 85	73	8 (11.0)	43 (58.9)	22 (30.1)	23	2 (8.7)	14 (60.9)	7 (30.4)
	Day 127	59	4 (6.8)	38 (64.4)	17 (28.8)	11	2 (18.2)	6 (54.5)	3 (27.3)
	Day 169	45	5 (11.1)	26 (57.8)	14 (31.1)	7	1 (14.3)	2 (28.6)	4 (57.1)
	Day 211	32	2 (6.3)	21 (65.6)	9 (28.1)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 253	25	3 (12.0)	14 (56.0)	8 (32.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	22	1 (4.5)	16 (72.7)	5 (22.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	1 (4.8)	12 (57.1)	8 (38.1)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	17	1 (5.9)	13 (76.5)	3 (17.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	13	0 (0.0)	9 (69.2)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	6 (8.1)	34 (45.9)	34 (45.9)	36	1 (2.8)	21 (58.3)	14 (38.9)
Prior ramucirumab contained treatment									
no									
	Day 15	28	5 (17.9)	19 (67.9)	4 (14.3)	18	0 (0.0)	14 (77.8)	4 (22.2)
	Day 43	28	4 (14.3)	20 (71.4)	4 (14.3)	20	2 (10.0)	12 (60.0)	6 (30.0)
	Day 85	26	3 (11.5)	20 (76.9)	3 (11.5)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 127	15	4 (26.7)	9 (60.0)	2 (13.3)	8	1 (12.5)	6 (75.0)	1 (12.5)
	Day 169	12	4 (33.3)	7 (58.3)	1 (8.3)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 211	12	5 (41.7)	7 (58.3)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 253	12	2 (16.7)	9 (75.0)	1 (8.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	7	2 (28.6)	4 (57.1)	1 (14.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	6	3 (50.0)	3 (50.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	4	2 (50.0)	1 (25.0)	1 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	3 (13.0)	14 (60.9)	6 (26.1)	20	1 (5.0)	13 (65.0)	6 (30.0)
Prior nivolumab contained treatment									
yes									
	Day 15	32	2 (6.3)	19 (59.4)	11 (34.4)	13	1 (7.7)	7 (53.8)	5 (38.5)
	Day 43	30	4 (13.3)	21 (70.0)	5 (16.7)	10	1 (10.0)	5 (50.0)	4 (40.0)
	Day 85	27	5 (18.5)	16 (59.3)	6 (22.2)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 127	26	3 (11.5)	17 (65.4)	6 (23.1)	3	2 (66.7)	1 (33.3)	0 (0.0)
	Day 169	21	3 (14.3)	16 (76.2)	2 (9.5)	3	0 (0.0)	1 (33.3)	2 (66.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	16	3 (18.8)	9 (56.3)	4 (25.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 253	14	2 (14.3)	9 (64.3)	3 (21.4)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	12	1 (8.3)	8 (66.7)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	7 (63.6)	3 (27.3)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	10	0 (0.0)	6 (60.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	3 (11.5)	13 (50.0)	10 (38.5)	14	1 (7.1)	6 (42.9)	7 (50.0)
Prior nivolumab contained treatment									
no									
	Day 15	86	8 (9.3)	59 (68.6)	19 (22.1)	39	2 (5.1)	31 (79.5)	6 (15.4)
	Day 43	87	6 (6.9)	64 (73.6)	17 (19.5)	43	5 (11.6)	30 (69.8)	8 (18.6)
	Day 85	72	6 (8.3)	47 (65.3)	19 (26.4)	26	2 (7.7)	18 (69.2)	6 (23.1)
	Day 127	48	5 (10.4)	30 (62.5)	13 (27.1)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 169	36	6 (16.7)	17 (47.2)	13 (36.1)	8	2 (25.0)	4 (50.0)	2 (25.0)
	Day 211	28	4 (14.3)	19 (67.9)	5 (17.9)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 253	23	3 (13.0)	14 (60.9)	6 (26.1)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	17	2 (11.8)	12 (70.6)	3 (17.6)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	16	3 (18.8)	8 (50.0)	5 (31.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	11	3 (27.3)	8 (72.7)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	5 (55.6)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	6 (8.5)	35 (49.3)	30 (42.3)	42	1 (2.4)	28 (66.7)	13 (31.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	42	4 (9.5)	25 (59.5)	13 (31.0)	15	1 (6.7)	9 (60.0)	5 (33.3)
	Day 43	40	5 (12.5)	26 (65.0)	9 (22.5)	12	1 (8.3)	7 (58.3)	4 (33.3)
	Day 85	37	5 (13.5)	24 (64.9)	8 (21.6)	11	1 (9.1)	7 (63.6)	3 (27.3)
	Day 127	31	5 (16.1)	17 (54.8)	9 (29.0)	4	2 (50.0)	2 (50.0)	0 (0.0)
	Day 169	24	4 (16.7)	18 (75.0)	2 (8.3)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 211	20	5 (25.0)	11 (55.0)	4 (20.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 253	17	3 (17.6)	11 (64.7)	3 (17.6)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	16	3 (18.8)	9 (56.3)	4 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	3 (20.0)	8 (53.3)	4 (26.7)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	12	1 (8.3)	7 (58.3)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	6 (60.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	35	4 (11.4)	19 (54.3)	12 (34.3)	16	1 (6.3)	8 (50.0)	7 (43.8)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	76	6 (7.9)	53 (69.7)	17 (22.4)	37	2 (5.4)	29 (78.4)	6 (16.2)
	Day 43	77	5 (6.5)	59 (76.6)	13 (16.9)	41	5 (12.2)	28 (68.3)	8 (19.5)
	Day 85	62	6 (9.7)	39 (62.9)	17 (27.4)	25	2 (8.0)	17 (68.0)	6 (24.0)
	Day 127	43	3 (7.0)	30 (69.8)	10 (23.3)	15	1 (6.7)	10 (66.7)	4 (26.7)
	Day 169	33	5 (15.2)	15 (45.5)	13 (39.4)	8	2 (25.0)	4 (50.0)	2 (25.0)
	Day 211	24	2 (8.3)	17 (70.8)	5 (20.8)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 253	20	2 (10.0)	12 (60.0)	6 (30.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	13	0 (0.0)	11 (84.6)	2 (15.4)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	12	1 (8.3)	7 (58.3)	4 (33.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	9	2 (22.2)	7 (77.8)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	5 (8.1)	29 (46.8)	28 (45.2)	40	1 (2.5)	26 (65.0)	13 (32.5)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
yes									
	Day 15	22	1 (4.5)	19 (86.4)	2 (9.1)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	19	1 (5.3)	17 (89.5)	1 (5.3)	6	1 (16.7)	4 (66.7)	1 (16.7)
	Day 85	16	2 (12.5)	12 (75.0)	2 (12.5)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 127	12	1 (8.3)	10 (83.3)	1 (8.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	9	1 (11.1)	6 (66.7)	2 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	1 (7.1)	11 (78.6)	2 (14.3)	6	0 (0.0)	4 (66.7)	2 (33.3)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
no									
	Day 15	96	9 (9.4)	59 (61.5)	28 (29.2)	46	2 (4.3)	33 (71.7)	11 (23.9)
	Day 43	98	9 (9.2)	68 (69.4)	21 (21.4)	47	5 (10.6)	31 (66.0)	11 (23.4)
	Day 85	83	9 (10.8)	51 (61.4)	23 (27.7)	31	3 (9.7)	20 (64.5)	8 (25.8)
	Day 127	62	7 (11.3)	37 (59.7)	18 (29.0)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 169	48	8 (16.7)	27 (56.3)	13 (27.1)	9	2 (22.2)	3 (33.3)	4 (44.4)
	Day 211	39	6 (15.4)	24 (61.5)	9 (23.1)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	33	5 (15.2)	20 (60.6)	8 (24.2)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	26	2 (7.7)	19 (73.1)	5 (19.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	24	3 (12.5)	14 (58.3)	7 (29.2)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	18	2 (11.1)	12 (66.7)	4 (22.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	13	0 (0.0)	9 (69.2)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	8 (9.6)	37 (44.6)	38 (45.8)	50	2 (4.0)	30 (60.0)	18 (36.0)
Presence of liver metastasis at baseline									
yes									
	Day 15	64	8 (12.5)	36 (56.3)	20 (31.3)	27	1 (3.7)	17 (63.0)	9 (33.3)
	Day 43	64	6 (9.4)	45 (70.3)	13 (20.3)	28	3 (10.7)	16 (57.1)	9 (32.1)
	Day 85	51	6 (11.8)	29 (56.9)	16 (31.4)	16	1 (6.3)	7 (43.8)	8 (50.0)
	Day 127	37	5 (13.5)	21 (56.8)	11 (29.7)	10	2 (20.0)	5 (50.0)	3 (30.0)
	Day 169	28	4 (14.3)	16 (57.1)	8 (28.6)	6	0 (0.0)	3 (50.0)	3 (50.0)
	Day 211	20	4 (20.0)	10 (50.0)	6 (30.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	19	2 (10.5)	12 (63.2)	5 (26.3)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	14	1 (7.1)	9 (64.3)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	13	1 (7.7)	9 (69.2)	3 (23.1)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	11	2 (18.2)	8 (72.7)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	3 (6.0)	24 (48.0)	23 (46.0)	31	0 (0.0)	14 (45.2)	17 (54.8)
Presence of liver metastasis at baseline									
no									
	Day 15	54	2 (3.7)	42 (77.8)	10 (18.5)	25	2 (8.0)	21 (84.0)	2 (8.0)
	Day 43	53	4 (7.5)	40 (75.5)	9 (17.0)	25	3 (12.0)	19 (76.0)	3 (12.0)
	Day 85	48	5 (10.4)	34 (70.8)	9 (18.8)	20	2 (10.0)	17 (85.0)	1 (5.0)
	Day 127	37	3 (8.1)	26 (70.3)	8 (21.6)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	29	5 (17.2)	17 (58.6)	7 (24.1)	5	2 (40.0)	2 (40.0)	1 (20.0)
	Day 211	24	3 (12.5)	18 (75.0)	3 (12.5)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 253	18	3 (16.7)	11 (61.1)	4 (22.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	15	2 (13.3)	11 (73.3)	2 (13.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	14	3 (21.4)	6 (42.9)	5 (35.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	47	6 (12.8)	24 (51.1)	17 (36.2)	25	2 (8.0)	20 (80.0)	3 (12.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Renal impairment at baseline									
normal									
	Day 15	31	5 (16.1)	18 (58.1)	8 (25.8)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	33	4 (12.1)	23 (69.7)	6 (18.2)	12	1 (8.3)	8 (66.7)	3 (25.0)
	Day 85	26	2 (7.7)	20 (76.9)	4 (15.4)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	0 (0.0)	16 (84.2)	3 (15.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	17	1 (5.9)	11 (64.7)	5 (29.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	12	2 (16.7)	7 (58.3)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	13	2 (15.4)	7 (53.8)	4 (30.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	1 (8.3)	8 (66.7)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	2 (18.2)	4 (36.4)	5 (45.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	4 (16.7)	11 (45.8)	9 (37.5)	11	0 (0.0)	8 (72.7)	3 (27.3)
Renal impairment at baseline									
mild									
	Day 15	50	4 (8.0)	33 (66.0)	13 (26.0)	25	2 (8.0)	17 (68.0)	6 (24.0)
	Day 43	50	5 (10.0)	35 (70.0)	10 (20.0)	23	4 (17.4)	14 (60.9)	5 (21.7)
	Day 85	45	8 (17.8)	24 (53.3)	13 (28.9)	14	1 (7.1)	8 (57.1)	5 (35.7)
	Day 127	31	5 (16.1)	19 (61.3)	7 (22.6)	9	2 (22.2)	5 (55.6)	2 (22.2)
	Day 169	23	6 (26.1)	11 (47.8)	6 (26.1)	6	2 (33.3)	3 (50.0)	1 (16.7)
	Day 211	17	4 (23.5)	9 (52.9)	4 (23.5)	3	1 (33.3)	1 (33.3)	1 (33.3)
	Day 253	13	3 (23.1)	8 (61.5)	2 (15.4)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 295	9	2 (22.2)	6 (66.7)	1 (11.1)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	8	2 (25.0)	5 (62.5)	1 (12.5)	2	1 (50.0)	0 (0.0)	1 (50.0)
	Day 379	6	2 (33.3)	2 (33.3)	2 (33.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	5 (11.1)	22 (48.9)	18 (40.0)	25	1 (4.0)	13 (52.0)	11 (44.0)
Renal impairment at baseline									
moderate									
	Day 15	37	1 (2.7)	27 (73.0)	9 (24.3)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 43	34	1 (2.9)	27 (79.4)	6 (17.6)	17	1 (5.9)	12 (70.6)	4 (23.5)
	Day 85	28	1 (3.6)	19 (67.9)	8 (28.6)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 127	24	3 (12.5)	12 (50.0)	9 (37.5)	7	1 (14.3)	4 (57.1)	2 (28.6)
	Day 169	17	2 (11.8)	11 (64.7)	4 (23.5)	5	0 (0.0)	2 (40.0)	3 (60.0)
	Day 211	15	1 (6.7)	12 (80.0)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	0 (0.0)	15 (53.6)	13 (46.4)	19	1 (5.3)	12 (63.2)	6 (31.6)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	82	6 (7.3)	58 (70.7)	18 (22.0)	37	1 (2.7)	31 (83.8)	5 (13.5)
	Day 43	83	6 (7.2)	59 (71.1)	18 (21.7)	41	4 (9.8)	27 (65.9)	10 (24.4)
	Day 85	76	8 (10.5)	50 (65.8)	18 (23.7)	27	3 (11.1)	18 (66.7)	6 (22.2)
	Day 127	58	7 (12.1)	36 (62.1)	15 (25.9)	14	2 (14.3)	8 (57.1)	4 (28.6)
	Day 169	45	7 (15.6)	28 (62.2)	10 (22.2)	7	1 (14.3)	3 (42.9)	3 (42.9)
	Day 211	34	6 (17.6)	22 (64.7)	6 (17.6)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 253	30	4 (13.3)	21 (70.0)	5 (16.7)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	23	3 (13.0)	17 (73.9)	3 (13.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	21	4 (19.0)	13 (61.9)	4 (19.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	16	3 (18.8)	10 (62.5)	3 (18.8)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	11	0 (0.0)	8 (72.7)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	67	5 (7.5)	34 (50.7)	28 (41.8)	42	2 (4.8)	25 (59.5)	15 (35.7)
Hepatic impairment at baseline									
mild									
	Day 15	35	4 (11.4)	20 (57.1)	11 (31.4)	15	2 (13.3)	7 (46.7)	6 (40.0)
	Day 43	33	4 (12.1)	25 (75.8)	4 (12.1)	12	2 (16.7)	8 (66.7)	2 (16.7)
	Day 85	22	3 (13.6)	12 (54.5)	7 (31.8)	9	0 (0.0)	6 (66.7)	3 (33.3)
	Day 127	15	1 (6.7)	10 (66.7)	4 (26.7)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 169	12	2 (16.7)	5 (41.7)	5 (41.7)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 211	10	1 (10.0)	6 (60.0)	3 (30.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 253	7	1 (14.3)	2 (28.6)	4 (57.1)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	6	0 (0.0)	3 (50.0)	3 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	0 (0.0)	2 (33.3)	4 (66.7)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	29	4 (13.8)	13 (44.8)	12 (41.4)	14	0 (0.0)	9 (64.3)	5 (35.7)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	2 (25.0)	4 (50.0)	2 (25.0)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	1 (12.5)	7 (87.5)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	7	1 (14.3)	5 (71.4)	1 (14.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	6	0 (0.0)	5 (83.3)	1 (16.7)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	5	1 (20.0)	3 (60.0)	1 (20.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	4	1 (25.0)	2 (50.0)	1 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	1 (25.0)	2 (50.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	2	1 (50.0)	1 (50.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	6	1 (16.7)	3 (50.0)	2 (33.3)	4	1 (25.0)	2 (50.0)	1 (25.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	110	8 (7.3)	74 (67.3)	28 (25.5)	48	3 (6.3)	35 (72.9)	10 (20.8)
	Day 43	109	9 (8.3)	78 (71.6)	22 (20.2)	50	5 (10.0)	33 (66.0)	12 (24.0)
	Day 85	92	10 (10.9)	58 (63.0)	24 (26.1)	33	2 (6.1)	22 (66.7)	9 (27.3)
	Day 127	68	8 (11.8)	42 (61.8)	18 (26.5)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 169	52	8 (15.4)	30 (57.7)	14 (26.9)	9	1 (11.1)	4 (44.4)	4 (44.4)
	Day 211	40	6 (15.0)	26 (65.0)	8 (20.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	33	4 (12.1)	22 (66.7)	7 (21.2)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	27	3 (11.1)	18 (66.7)	6 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	25	3 (12.0)	14 (56.0)	8 (32.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	20	3 (15.0)	13 (65.0)	4 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	15	0 (0.0)	10 (66.7)	5 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	91	8 (8.8)	45 (49.5)	38 (41.8)	52	1 (1.9)	32 (61.5)	19 (36.5)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	1 (33.3)	1 (33.3)	1 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	3	0 (0.0)	2 (66.7)	1 (33.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	3	1 (33.3)	1 (33.3)	1 (33.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 253	2	1 (50.0)	0 (0.0)	1 (50.0)	1	1 (100.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	1	1 (100.0)	0 (0.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	0	0 (0.0)	0 (0.0)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	2	1 (50.0)	0 (0.0)	1 (50.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	115	9 (7.8)	77 (67.0)	29 (25.2)	49	3 (6.1)	35 (71.4)	11 (22.4)
	Day 43	114	10 (8.8)	82 (71.9)	22 (19.3)	50	5 (10.0)	33 (66.0)	12 (24.0)
	Day 85	96	11 (11.5)	60 (62.5)	25 (26.0)	33	2 (6.1)	22 (66.7)	9 (27.3)
	Day 127	71	8 (11.3)	45 (63.4)	18 (25.4)	16	2 (12.5)	10 (62.5)	4 (25.0)
	Day 169	54	8 (14.8)	32 (59.3)	14 (25.9)	9	1 (11.1)	4 (44.4)	4 (44.4)
	Day 211	42	6 (14.3)	27 (64.3)	9 (21.4)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 253	35	4 (11.4)	23 (65.7)	8 (22.9)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 295	28	3 (10.7)	19 (67.9)	6 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	26	3 (11.5)	15 (57.7)	8 (30.8)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	21	3 (14.3)	14 (66.7)	4 (19.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	16	0 (0.0)	10 (62.5)	6 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	0 (0.0)	8 (66.7)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	95	8 (8.4)	48 (50.5)	39 (41.1)	53	1 (1.9)	32 (60.4)	20 (37.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Gastric Cancer Symptom (GaCS) Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	125 (100.0)	62	59 (95.2)
Day 15	125	120 (96.0)	62	52 (83.9)
Day 43	124	118 (95.2)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	57 (54.3)	45	11 (24.4)
Day 211	93	44 (47.3)	40	4 (10.0)
Day 253	84	37 (44.0)	34	2 (5.9)
Day 295	77	29 (37.7)	27	2 (7.4)
Day 337	70	27 (38.6)	21	2 (9.5)
Day 379	60	21 (35.0)	20	1 (5.0)
Day 421	50	16 (32.0)	15	0 (0.0)
Day 463	39	12 (30.8)	9	0 (0.0)
Day 505	30	8 (26.7)	9	0 (0.0)
Day 547	24	6 (25.0)	8	0 (0.0)
Day 589	17	5 (29.4)	5	0 (0.0)
Day 631	13	4 (30.8)	1	0 (0.0)
Day 673	9	2 (22.2)	1	0 (0.0)
Day 715	5	3 (60.0)	1	0 (0.0)
Day 757	5	3 (60.0)	1	0 (0.0)
Day 799	3	1 (33.3)	1	0 (0.0)
Day 841	2	1 (50.0)	0	0 (0.0)
Day 883	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	125	53.3 (13.15)			59	54.6 (13.02)		
Day 15	120	50.2 (12.22)	120	-3.6 (11.20)	52	53.2 (14.20)	50	-2.6 (9.99)
Day 43	118	52.0 (14.27)	118	-1.6 (13.48)	53	54.5 (14.85)	51	-1.1 (10.75)
Day 85	99	51.5 (14.24)	99	-3.0 (13.23)	36	56.3 (14.92)	35	-1.8 (8.64)
Day 127	74	54.4 (11.10)	74	-0.9 (12.07)	19	61.9 (11.44)	19	-1.0 (10.34)
Day 169	57	53.2 (12.52)	57	-1.2 (11.64)	11	64.0 (9.98)	11	0.8 (6.27)
Day 211	44	54.4 (11.79)	44	-0.5 (12.66)	4	71.3 (5.12)	4	5.3 (4.27)
Day 253	37	53.9 (11.33)	37	-0.2 (14.00)	2	69.0 (2.83)	2	9.0 (2.83)
Day 295	29	54.9 (10.64)	29	0.4 (13.78)	2	71.5 (0.71)	2	11.5 (4.95)
Day 337	27	56.0 (10.49)	27	1.9 (15.75)	2	70.0 (1.41)	2	10.0 (4.24)
Day 379	21	53.3 (13.04)	21	-2.7 (15.51)	1	72.0 (-)	1	8.0 (-)
Day 421	16	53.9 (14.53)	16	-2.1 (16.32)	0	-	0	-
Day 463	12	54.4 (15.19)	12	-1.4 (14.66)	0	-	0	-
Day 505	8	52.3 (16.29)	8	-4.9 (12.49)	0	-	0	-
Day 547	6	57.7 (9.58)	6	-1.5 (10.21)	0	-	0	-
Day 589	5	55.0 (14.61)	5	-4.4 (12.90)	0	-	0	-
Day 631	4	54.5 (14.71)	4	-1.5 (13.03)	0	-	0	-
Day 673	2	48.0 (9.90)	2	-10.0 (9.90)	0	-	0	-
Day 715	3	55.0 (16.52)	3	-8.0 (13.53)	0	-	0	-
Day 757	3	53.3 (14.15)	3	-9.7 (12.06)	0	-	0	-
Day 799	1	33.0 (-)	1	-25.0 (-)	0	-	0	-
Day 841	1	28.0 (-)	1	-30.0 (-)	0	-	0	-
Day 883	1	29.0 (-)	1	-29.0 (-)	0	-	0	-
End of Treatment	96	46.6 (16.35)	96	-7.1 (14.45)	56	50.2 (16.83)	53	-5.5 (9.84)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Visit	DS-8201a (N=125)			Phys. Choice (N=62)			Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
	N [a]	N_MISS [b]	LSMean (95% CI)	N [a]	N_MISS [b]	LSMean (95% CI)				
Day 15			-3.71 (-5.83, -1.59)			-2.80 (-5.96, 0.36)	-0.91 (-4.37, 2.55)	0.6048		
Day 43			-3.71 (-5.73, -1.70)			-2.49 (-5.37, 0.39)	-1.22 (-4.36, 1.92)	0.4441		
Day 85			-3.71 (-5.62, -1.81)			-2.02 (-4.89, 0.85)	-1.69 (-4.75, 1.37)	0.2780		
Day 127			-3.71 (-5.57, -1.86)			-1.55 (-4.89, 1.78)	-2.16 (-5.63, 1.32)	0.2226		
Day 169			-3.71 (-5.59, -1.84)			-1.09 (-5.20, 3.03)	-2.63 (-6.86, 1.61)	0.2239		
Day 211			-3.71 (-5.68, -1.75)			-0.62 (-5.69, 4.45)	-3.09 (-8.29, 2.11)	0.2429		
Day 253			-3.71 (-5.82, -1.61)			-0.15 (-6.26, 5.96)	-3.56 (-9.83, 2.71)	0.2648		
Day 295			-3.71 (-6.01, -1.42)			0.31 (-6.90, 7.53)	-4.03 (-11.43, 3.37)	0.2851		
Day 337			-3.72 (-6.24, -1.19)			0.78 (-7.56, 9.12)	-4.50 (-13.07, 4.07)	0.3028		
Day 379			-3.72 (-6.50, -0.93)			1.25 (-8.24, 10.74)	-4.97 (-14.72, 4.79)	0.3179		
Day 421			-3.72 (-6.78, -0.66)			1.72 (-8.94, 12.37)	-5.43 (-16.40, 5.53)	0.3308		
Day 463			-3.72 (-7.07, -0.37)			2.18 (-9.64, 14.01)	-5.90 (-18.09, 6.28)	0.3418		
OVERALL	124	1	-3.71 (-5.57, -1.86)	55	7	-1.35 (-4.99, 2.28)	-2.36 (-6.13, 1.41)	0.2192	-0.20 (-0.52, 0.11)	0.2092

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Gastric Cancer Symptom (GaCS) - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0065
Japan	99	-4.28 (-5.81, -2.76)	46	0.14 (-3.32, 3.60)	-4.42 (-8.21, -0.63)	0.0224	-0.48 (-0.83, -0.13)	0.0080	
Korea	25	1.09 (-2.93, 5.11)	9	-7.29 (-18.16, 3.58)	8.38 (-3.19, 19.96)	0.1530	0.71 (-0.07, 1.49)	0.0751	
Lines of prior systemic therapy									0.3449
2	65	-2.26 (-4.25, -0.27)	35	-1.40 (-5.10, 2.29)	-0.86 (-5.07, 3.35)	0.6871	-0.09 (-0.50, 0.32)	0.6569	
3	34	-2.36 (-5.45, 0.72)	16	-1.97 (-8.77, 4.84)	-0.39 (-7.87, 7.08)	0.9167	-0.04 (-0.63, 0.56)	0.9028	
>=4	25	-7.46 (-10.42, -4.51)	4	8.22 (-8.37, 24.82)	-15.69 (-32.56, 1.19)	0.0681	-1.79 (-2.94, -0.63)	0.0024	
Age									0.2521
<65 years	54	-1.29 (-3.44, 0.85)	25	-1.22 (-7.12, 4.69)	-0.08 (-6.43, 6.27)	0.9811	-0.01 (-0.48, 0.47)	0.9763	
>=65 years	70	-5.14 (-7.21, -3.06)	30	-1.01 (-5.43, 3.42)	-4.13 (-9.01, 0.75)	0.0964	-0.42 (-0.85, 0.02)	0.0585	
Sex									0.9539
female	29	0.01 (-2.57, 2.60)	13	-0.20 (-6.27, 5.87)	0.21 (-6.40, 6.83)	0.9486	0.03 (-0.63, 0.68)	0.9384	
male	95	-4.31 (-6.10, -2.52)	42	-1.20 (-5.26, 2.86)	-3.11 (-7.55, 1.34)	0.1697	-0.30 (-0.66, 0.07)	0.1085	
ECOG PS									0.1065
0	62	-5.12 (-7.03, -3.21)	27	-1.52 (-6.70, 3.66)	-3.60 (-9.14, 1.93)	0.2007	-0.37 (-0.82, 0.09)	0.1131	
1	62	-1.17 (-3.56, 1.21)	28	-0.87 (-5.31, 3.56)	-0.30 (-5.35, 4.75)	0.9058	-0.03 (-0.48, 0.42)	0.8970	
HER2 Status in central laboratory									0.1421
IHC 3+	96	-2.92 (-4.64, -1.20)	42	-0.76 (-4.92, 3.40)	-2.17 (-6.68, 2.34)	0.3445	-0.21 (-0.57, 0.15)	0.2588	
IHC 2+/ISH +	28	-5.31 (-8.44, -2.17)	13	-1.13 (-6.47, 4.22)	-4.18 (-10.40, 2.04)	0.1828	-0.48 (-1.15, 0.18)	0.1556	
Primary tumor location									0.4838
Gastric	107	-3.67 (-5.28, -2.06)	50	-1.06 (-4.57, 2.45)	-2.61 (-6.48, 1.26)	0.1849	-0.26 (-0.60, 0.07)	0.1263	
GEJ	17	-1.93 (-6.04, 2.19)	5	0.42 (-14.33, 15.17)	-2.34 (-17.66, 12.97)	0.7606	-0.23 (-1.23, 0.77)	0.6554	
Histological subtype									0.2747
intestinal	89	-4.39 (-6.01, -2.78)	36	-0.05 (-3.80, 3.69)	-4.34 (-8.42, -0.26)	0.0373	-0.49 (-0.88, -0.10)	0.0148	
diffuse	28	-1.50 (-5.20, 2.19)	14	-2.71 (-12.44, 7.01)	1.21 (-9.22, 11.64)	0.8188	0.09 (-0.55, 0.73)	0.7792	
others	7	2.39 (-11.09, 15.87)	5	-5.60 (-25.07, 13.86)	8.00 (-16.62, 32.62)	0.4896	0.46 (-0.70, 1.63)	0.4345	
Number of metastatic sites									0.3852
<2	23	-5.21 (-8.46, -1.95)	10	2.43 (-4.47, 9.33)	-7.63 (-15.26, -0.00)	0.0499	-0.88 (-1.65, -0.10)	0.0260	
>= 2	101	-3.01 (-4.71, -1.31)	45	-2.27 (-6.31, 1.78)	-0.74 (-5.15, 3.66)	0.7402	-0.07 (-0.42, 0.28)	0.6930	
Previous total gastrectomy									0.0091
yes	22	-5.85 (-9.62, -2.08)	8	-1.75 (-15.24, 11.74)	-4.09 (-18.10, 9.91)	0.5625	-0.34 (-1.15, 0.48)	0.4169	
no	102	-2.90 (-4.50, -1.31)	47	-1.48 (-4.96, 2.00)	-1.42 (-5.26, 2.42)	0.4668	-0.15 (-0.49, 0.20)	0.4004	
Prior adjuvant/ neoadjuvant therapy									0.1590
yes	30	-3.73 (-6.64, -0.81)	8	1.80 (-8.21, 11.81)	-5.53 (-15.95, 4.89)	0.2947	-0.58 (-1.38, 0.21)	0.1475	
no	94	-3.20 (-4.89, -1.51)	47	-1.54 (-5.04, 1.95)	-1.66 (-5.56, 2.24)	0.4015	-0.17 (-0.52, 0.18)	0.3404	
Prior ramucirumab contained treatment									0.2285
yes	93	-4.51 (-6.09, -2.93)	36	-1.73 (-6.30, 2.84)	-2.78 (-7.62, 2.06)	0.2586	-0.28 (-0.67, 0.10)	0.1505	
no	31	0.23 (-3.14, 3.61)	19	1.21 (-3.97, 6.40)	-0.98 (-7.22, 5.26)	0.7542	-0.10 (-0.67, 0.47)	0.7399	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

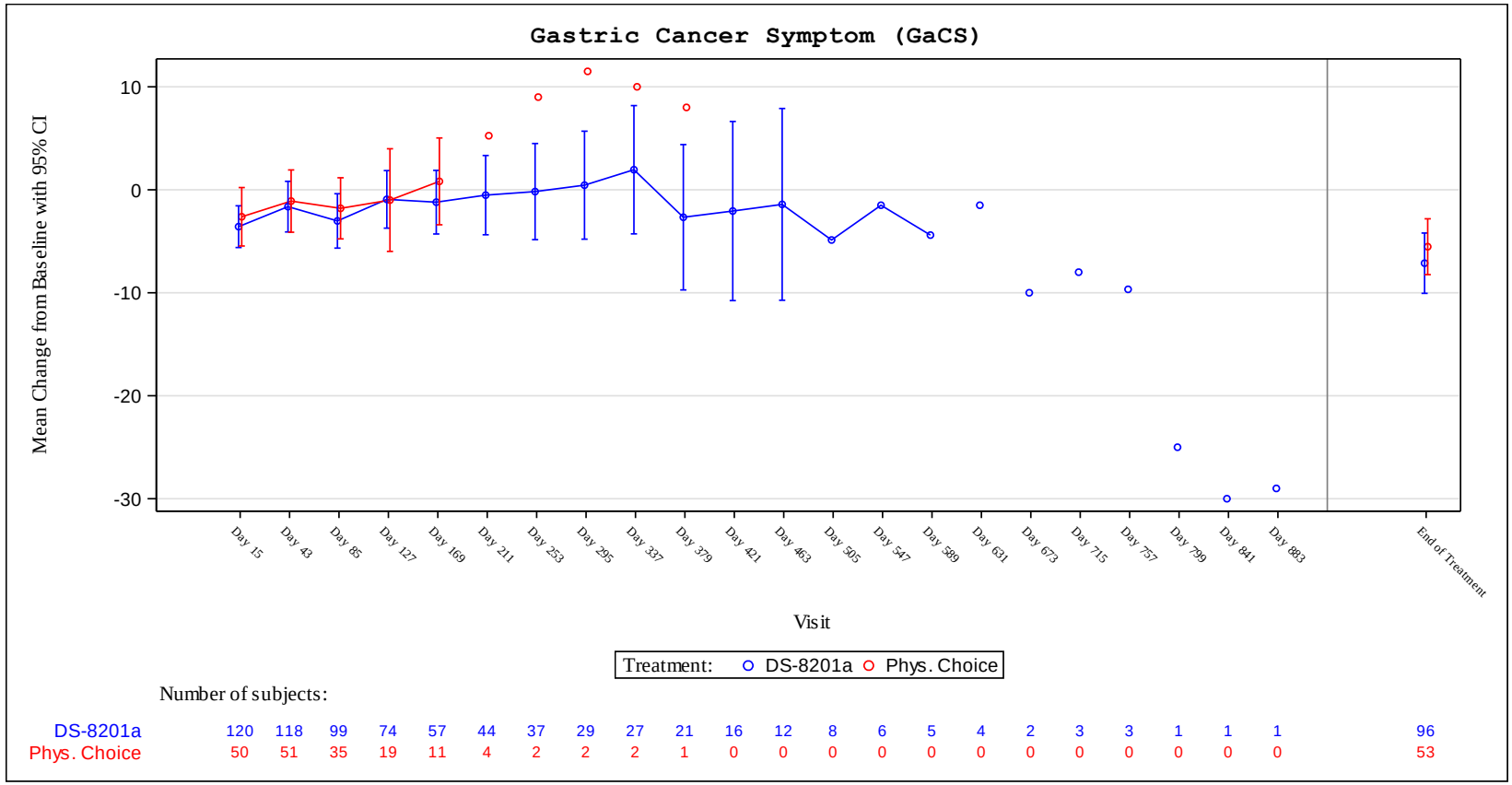
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Gastric Cancer Symptom (GaCS) - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.2103
yes	33	-5.25 (-7.87, -2.63)	12	0.91 (-6.72, 8.55)	-6.16 (-14.23, 1.91)	0.1325	-0.66 (-1.34, 0.01)	0.0543	
no	91	-2.63 (-4.48, -0.78)	43	-1.41 (-5.24, 2.43)	-1.22 (-5.51, 3.07)	0.5755	-0.12 (-0.48, 0.24)	0.5228	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.2775
yes	44	-4.07 (-6.62, -1.52)	13	1.02 (-6.81, 8.84)	-5.09 (-13.31, 3.14)	0.2231	-0.51 (-1.13, 0.12)	0.1112	
no	80	-3.07 (-4.91, -1.24)	42	-1.64 (-5.20, 1.93)	-1.44 (-5.47, 2.60)	0.4835	-0.15 (-0.52, 0.22)	0.4331	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.2064
yes	22	-2.45 (-6.68, 1.79)	6	5.29 (-4.26, 14.85)	-7.74 (-18.36, 2.88)	0.1479	-0.77 (-1.69, 0.16)	0.1033	
no	102	-3.64 (-5.25, -2.03)	49	-1.84 (-5.58, 1.90)	-1.79 (-5.87, 2.28)	0.3864	-0.18 (-0.52, 0.16)	0.3092	
Presence of liver metastasis at baseline									0.2451
yes	68	-1.86 (-3.85, 0.13)	30	-1.24 (-6.01, 3.54)	-0.63 (-5.82, 4.57)	0.8120	-0.06 (-0.49, 0.37)	0.7758	
no	56	-5.10 (-7.34, -2.87)	25	-0.56 (-5.51, 4.39)	-4.54 (-9.98, 0.89)	0.1008	-0.46 (-0.94, 0.02)	0.0580	
Renal impairment at baseline									0.1160
normal	33	-3.05 (-5.54, -0.56)	12	-14.43 (-26.67, -2.19)	11.38 (-1.12, 23.88)	0.0741	0.91 (0.22, 1.60)	0.0094	
mild	53	-3.85 (-6.49, -1.21)	25	2.49 (-2.23, 7.21)	-6.34 (-11.78, -0.90)	0.0229	-0.61 (-1.10, -0.13)	0.0137	
moderate	38	-3.38 (-5.88, -0.87)	17	-3.19 (-8.70, 2.31)	-0.18 (-6.23, 5.87)	0.9524	-0.02 (-0.59, 0.55)	0.9446	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.2582
normal	87	-3.08 (-4.84, -1.32)	40	-2.89 (-6.90, 1.12)	-0.19 (-4.57, 4.19)	0.9328	-0.02 (-0.39, 0.36)	0.9214	
mild	36	-4.01 (-6.72, -1.30)	15	3.70 (-2.72, 10.12)	-7.71 (-14.74, -0.69)	0.0318	-0.81 (-1.43, -0.18)	0.0111	
moderate	1	-13.69 (NE, NE)	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.2773
yes	8	-8.24 (-13.62, -2.87)	4	9.23 (-1.26, 19.71)	-17.47 (-29.61, -5.34)	0.0089	-2.27 (-3.78, -0.77)	0.0031	
no	116	-3.10 (-4.62, -1.58)	51	-2.04 (-5.70, 1.63)	-1.06 (-5.04, 2.91)	0.5981	-0.11 (-0.44, 0.22)	0.5292	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.5617
yes	3	-3.65 (-15.02, 7.71)	3	5.56 (-6.35, 17.46)	-9.21 (-26.54, 8.12)	0.1983	-1.40 (-3.18, 0.39)	0.1253	
no	121	-3.47 (-5.01, -1.93)	52	-2.17 (-6.09, 1.76)	-1.30 (-5.53, 2.92)	0.5447	-0.12 (-0.45, 0.20)	0.4613	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Graphical Summary of Gastric Cancer Symptom (GaCS) by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	58 (46.4)	19 (30.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	5.9 (4.1, NE)	NE (3.1, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.19 (0.70, 2.02)	
p-value [c]	0.5215	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.18 (0.70, 1.99)	
p-value [c]	0.5501	

Time to Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.1321
Japan	48/ 99 (48.5)	5.8 (3.0, 9.8)	14/ 50 (28.0)	NE (3.1, NE)	1.43 (0.78, 2.61)	0.2444	
Korea	10/ 26 (38.5)	NE (2.9, NE)	5/ 12 (41.7)	3.3 (0.5, NE)	0.57 (0.19, 1.73)	0.3099	
Lines of prior systemic therapy							0.9246
2	31/ 66 (47.0)	6.9 (2.9, NE)	13/ 38 (34.2)	NE (1.6, NE)	1.15 (0.60, 2.22)	0.6782	
3	14/ 34 (41.2)	9.8 (2.8, NE)	5/ 18 (27.8)	3.3 (2.7, NE)	1.13 (0.39, 3.24)	0.8509	
>=4	13/ 25 (52.0)	5.8 (2.8, NE)	1/ 6 (16.7)	NE (0.5, NE)	1.66 (0.22, 12.81)	0.6152	
Age							0.4849
<65 years	24/ 55 (43.6)	8.3 (3.0, NE)	9/ 27 (33.3)	NE (1.4, NE)	1.01 (0.46, 2.20)	0.9934	
>=65 years	34/ 70 (48.6)	5.9 (2.9, 9.8)	10/ 35 (28.6)	5.4 (3.1, NE)	1.34 (0.66, 2.74)	0.4140	
Sex							0.2753
female	10/ 30 (33.3)	6.9 (4.6, NE)	5/ 15 (33.3)	3.1 (1.2, NE)	0.45 (0.14, 1.43)	0.1678	
male	48/ 95 (50.5)	5.8 (2.8, NE)	14/ 47 (29.8)	NE (3.3, NE)	1.43 (0.79, 2.62)	0.2364	
ECOG PS							0.6001
0	32/ 62 (51.6)	6.9 (2.8, NE)	9/ 30 (30.0)	NE (2.7, NE)	1.35 (0.64, 2.87)	0.4327	
1	26/ 63 (41.3)	5.8 (3.0, NE)	10/ 32 (31.3)	NE (1.4, NE)	1.06 (0.51, 2.21)	0.8852	
HER2 Status in central laboratory							0.6610
IHC 3+	45/ 96 (46.9)	6.9 (4.1, NE)	15/ 47 (31.9)	NE (3.3, NE)	1.13 (0.63, 2.05)	0.6880	
IHC 2+/ISH +	13/ 29 (44.8)	5.7 (2.8, NE)	4/ 15 (26.7)	NE (1.4, NE)	1.35 (0.43, 4.25)	0.6024	
Primary tumor location							0.5420
Gastric	50/108 (46.3)	5.9 (3.1, 9.8)	17/ 55 (30.9)	NE (3.1, NE)	1.21 (0.69, 2.12)	0.5054	
GEJ	8/ 17 (47.1)	NE (0.8, NE)	2/ 7 (28.6)	NE (0.5, NE)	0.93 (0.19, 4.45)	0.9373	
Histological subtype							0.7634
intestinal	44/ 89 (49.4)	5.9 (3.0, 9.8)	12/ 38 (31.6)	NE (3.1, NE)	1.30 (0.68, 2.48)	0.4229	
diffuse	11/ 28 (39.3)	NE (1.5, NE)	5/ 18 (27.8)	NE (0.9, NE)	0.96 (0.33, 2.80)	0.9271	
others	3/ 8 (37.5)	4.6 (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.36 (0.22, 8.23)	0.7372	
Number of metastatic sites							0.2425
<2	12/ 23 (52.2)	6.9 (0.8, NE)	2/ 10 (20.0)	NE (0.6, NE)	2.94 (0.65, 13.19)	0.1433	
>= 2	46/102 (45.1)	5.9 (4.1, 9.8)	17/ 52 (32.7)	5.4 (2.7, NE)	0.96 (0.54, 1.69)	0.8715	
Previous total gastrectomy							0.3027
yes	9/ 22 (40.9)	7.1 (1.5, NE)	1/ 9 (11.1)	NE (3.3, NE)	3.15 (0.39, 25.29)	0.2551	
no	49/103 (47.6)	5.9 (3.0, NE)	18/ 53 (34.0)	NE (2.7, NE)	1.07 (0.62, 1.86)	0.8066	
Prior adjuvant/ neoadjuvant therapy							0.5778
yes	10/ 30 (33.3)	NE (5.9, NE)	1/ 10 (10.0)	NE (0.6, NE)	1.87 (0.23, 15.08)	0.5442	
no	48/ 95 (50.5)	4.6 (2.9, 9.8)	18/ 52 (34.6)	5.4 (2.7, NE)	1.22 (0.70, 2.11)	0.4958	
Prior ramucirumab contained treatment							0.8987
yes	47/ 94 (50.0)	5.8 (2.9, 9.8)	14/ 41 (34.1)	5.4 (1.9, NE)	1.07 (0.58, 1.98)	0.8403	
no	11/ 31 (35.5)	NE (3.0, NE)	5/ 21 (23.8)	NE (3.3, NE)	1.20 (0.41, 3.51)	0.7259	
Prior nivolumab contained treatment							0.6983
yes	17/ 33 (51.5)	6.9 (0.8, NE)	5/ 15 (33.3)	3.3 (0.6, NE)	0.94 (0.33, 2.63)	0.8822	
no	41/ 92 (44.6)	5.9 (3.1, NE)	14/ 47 (29.8)	NE (5.4, NE)	1.24 (0.67, 2.29)	0.4989	

Time to Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

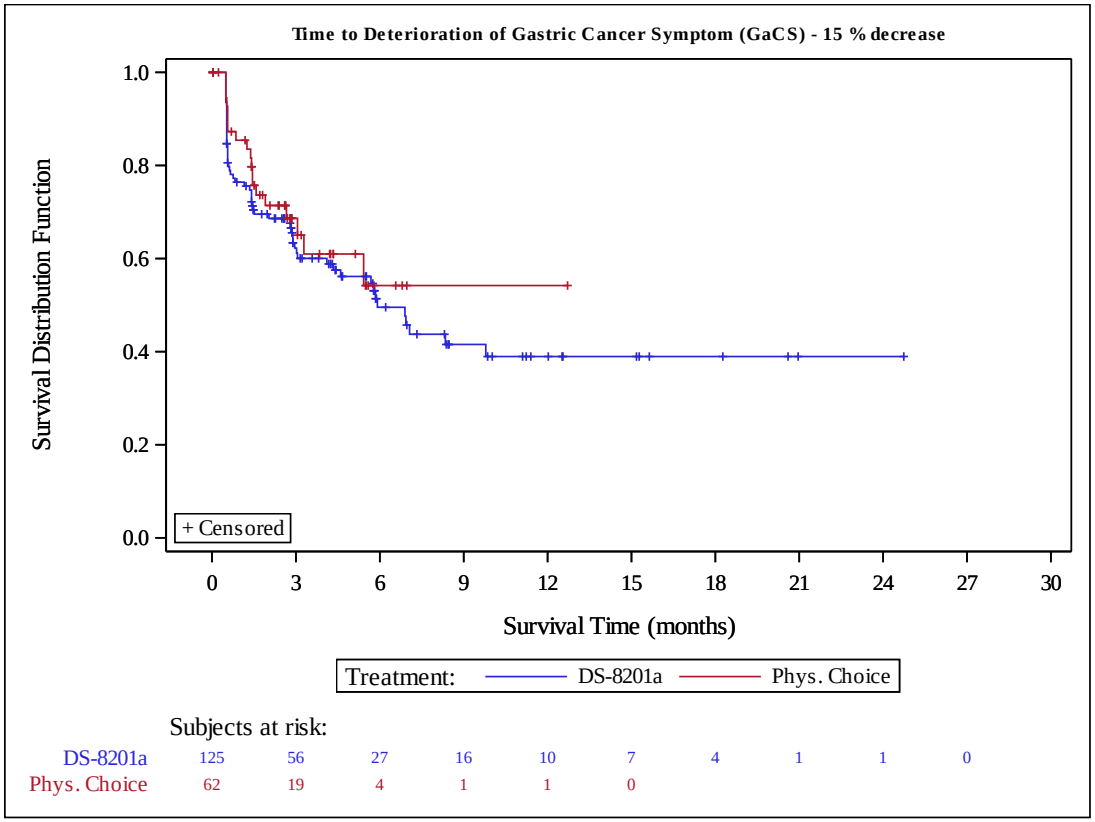
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.6987
yes	21/ 44 (47.7)	6.9 (2.9, NE)	5/ 17 (29.4)	3.3 (2.7, NE)	1.02 (0.38, 2.75)	0.9862	
no	37/ 81 (45.7)	5.9 (3.1, NE)	14/ 45 (31.1)	NE (5.4, NE)	1.25 (0.67, 2.32)	0.4950	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9827
yes	9/ 22 (40.9)	5.7 (1.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	49/103 (47.6)	5.9 (3.1, NE)	19/ 55 (34.5)	5.4 (2.7, NE)	1.01 (0.59, 1.74)	0.9736	
Presence of liver metastasis at baseline							0.4167
yes	29/ 68 (42.6)	7.1 (4.1, NE)	11/ 34 (32.4)	5.4 (2.7, NE)	0.88 (0.43, 1.81)	0.7249	
no	29/ 57 (50.9)	5.7 (2.0, NE)	8/ 28 (28.6)	NE (1.9, NE)	1.58 (0.72, 3.48)	0.2549	
Renal impairment at baseline							0.2292
normal	14/ 33 (42.4)	8.3 (2.8, NE)	5/ 13 (38.5)	NE (1.2, NE)	0.71 (0.24, 2.07)	0.5233	
mild	26/ 53 (49.1)	5.8 (2.9, NE)	5/ 28 (17.9)	NE (NE , NE)	2.34 (0.89, 6.13)	0.0765	
moderate	18/ 39 (46.2)	5.8 (2.8, NE)	8/ 20 (40.0)	5.4 (0.6, NE)	0.98 (0.42, 2.27)	0.9572	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.9 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9215
normal	44/ 88 (50.0)	5.9 (3.0, NE)	15/ 47 (31.9)	5.4 (3.1, NE)	1.19 (0.66, 2.16)	0.5813	
mild	13/ 36 (36.1)	5.8 (2.9, NE)	4/ 15 (26.7)	NE (0.6, NE)	1.18 (0.38, 3.68)	0.7724	
moderate	1/ 1 (100.0)	4.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3647
yes	5/ 8 (62.5)	3.1 (0.5, NE)	1/ 5 (20.0)	NE (0.5, NE)	2.46 (0.28, 21.31)	0.3901	
no	53/117 (45.3)	6.9 (4.1, NE)	18/ 57 (31.6)	NE (3.1, NE)	1.08 (0.63, 1.87)	0.7882	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9855
yes	2/ 3 (66.7)	5.7 (0.5, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	56/122 (45.9)	6.9 (3.1, NE)	19/ 58 (32.8)	5.4 (3.1, NE)	1.06 (0.62, 1.80)	0.8504	

Time to Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	45 (36.0)	11 (17.7)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	14.1 (7.0, NE)	NE (5.4, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	1.36 (0.69, 2.66)	
p-value [c]	0.3731	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	1.38 (0.70, 2.69)	
p-value [c]	0.3502	

Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%.
Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.0373
Japan	35/ 99 (35.4)	15.3 (6.9, NE)	6/ 50 (12.0)	NE (NE , NE)	2.20 (0.92, 5.27)	0.0701	
Korea	10/ 26 (38.5)	14.1 (3.0, NE)	5/ 12 (41.7)	3.3 (1.4, NE)	0.41 (0.13, 1.32)	0.1211	
Lines of prior systemic therapy							0.8658
2	25/ 66 (37.9)	8.4 (4.3, NE)	7/ 38 (18.4)	NE (5.4, NE)	1.64 (0.70, 3.83)	0.2508	
3	11/ 34 (32.4)	15.3 (5.7, NE)	3/ 18 (16.7)	NE (3.1, NE)	0.99 (0.26, 3.79)	0.9906	
>=4	9/ 25 (36.0)	NE (4.1, NE)	1/ 6 (16.7)	NE (0.5, NE)	1.03 (0.13, 8.29)	0.9635	
Age							0.5449
<65 years	18/ 55 (32.7)	NE (7.0, NE)	5/ 27 (18.5)	NE (2.9, NE)	1.09 (0.39, 3.04)	0.8705	
>=65 years	27/ 70 (38.6)	9.7 (5.4, NE)	6/ 35 (17.1)	NE (3.3, NE)	1.63 (0.67, 3.99)	0.2767	
Sex							0.9818
female	8/ 30 (26.7)	8.3 (4.6, NE)	2/ 15 (13.3)	NE (3.1, NE)	1.04 (0.21, 5.22)	0.9523	
male	37/ 95 (38.9)	14.1 (5.9, NE)	9/ 47 (19.1)	NE (5.4, NE)	1.43 (0.68, 3.01)	0.3373	
ECOG PS							0.7679
0	25/ 62 (40.3)	15.3 (5.9, NE)	5/ 30 (16.7)	NE (5.4, NE)	1.54 (0.58, 4.09)	0.3877	
1	20/ 63 (31.7)	14.1 (4.6, NE)	6/ 32 (18.8)	NE (3.1, NE)	1.26 (0.50, 3.17)	0.6250	
HER2 Status in central laboratory							0.1370
IHC 3+	33/ 96 (34.4)	15.3 (8.3, NE)	10/ 47 (21.3)	NE (5.4, NE)	1.08 (0.53, 2.23)	0.8297	
IHC 2+/ISH +	12/ 29 (41.4)	5.9 (3.0, NE)	1/ 15 (6.7)	NE (3.1, NE)	3.88 (0.48, 31.10)	0.1694	
Primary tumor location							0.9885
Gastric	38/108 (35.2)	14.1 (6.9, NE)	11/ 55 (20.0)	NE (5.4, NE)	1.20 (0.61, 2.39)	0.5983	
GEJ	7/ 17 (41.2)	NE (2.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.6941
intestinal	33/ 89 (37.1)	9.7 (5.9, NE)	6/ 38 (15.8)	NE (5.4, NE)	1.74 (0.72, 4.18)	0.2100	
diffuse	9/ 28 (32.1)	14.1 (5.7, NE)	3/ 18 (16.7)	NE (2.9, NE)	1.04 (0.26, 4.13)	0.9721	
others	3/ 8 (37.5)	4.6 (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	1.36 (0.22, 8.23)	0.7372	
Number of metastatic sites							0.9888
<2	8/ 23 (34.8)	NE (5.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	37/102 (36.3)	14.1 (5.7, NE)	11/ 52 (21.2)	NE (3.3, NE)	1.11 (0.56, 2.21)	0.7628	
Previous total gastrectomy							0.4798
yes	8/ 22 (36.4)	NE (1.5, NE)	1/ 9 (11.1)	NE (3.3, NE)	2.88 (0.36, 23.21)	0.3018	
no	37/103 (35.9)	14.1 (7.0, NE)	10/ 53 (18.9)	NE (5.4, NE)	1.22 (0.60, 2.48)	0.5886	
Prior adjuvant/ neoadjuvant therapy							0.9853
yes	9/ 30 (30.0)	NE (5.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	36/ 95 (37.9)	14.1 (4.6, NE)	11/ 52 (21.2)	NE (5.4, NE)	1.29 (0.65, 2.57)	0.4623	
Prior ramucirumab contained treatment							0.8911
yes	35/ 94 (37.2)	14.1 (5.9, NE)	7/ 41 (17.1)	NE (5.4, NE)	1.44 (0.63, 3.28)	0.3894	
no	10/ 31 (32.3)	NE (5.7, NE)	4/ 21 (19.0)	NE (2.9, NE)	1.21 (0.37, 3.96)	0.7491	
Prior nivolumab contained treatment							0.4694
yes	12/ 33 (36.4)	15.3 (5.1, NE)	3/ 15 (20.0)	NE (3.1, NE)	0.85 (0.23, 3.12)	0.8103	
no	33/ 92 (35.9)	14.1 (5.7, NE)	8/ 47 (17.0)	NE (5.4, NE)	1.62 (0.74, 3.54)	0.2271	

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NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.6013
yes	16/ 44 (36.4)	15.3 (5.1, NE)	3/ 17 (17.6)	NE (3.1, NE)	1.11 (0.32, 3.90)	0.8646	
no	29/ 81 (35.8)	8.4 (5.7, NE)	8/ 45 (17.8)	NE (5.4, NE)	1.54 (0.70, 3.43)	0.2831	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9868
yes	7/ 22 (31.8)	14.1 (5.1, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	38/103 (36.9)	15.3 (6.9, NE)	11/ 55 (20.0)	NE (5.4, NE)	1.24 (0.62, 2.45)	0.5420	
Presence of liver metastasis at baseline							0.1269
yes	22/ 68 (32.4)	15.3 (6.9, NE)	8/ 34 (23.5)	NE (3.3, NE)	0.88 (0.38, 2.01)	0.7507	
no	23/ 57 (40.4)	9.7 (5.4, NE)	3/ 28 (10.7)	NE (NE , NE)	2.73 (0.81, 9.20)	0.0913	
Renal impairment at baseline							0.7147
normal	12/ 33 (36.4)	14.1 (6.9, NE)	3/ 13 (23.1)	NE (1.9, NE)	0.69 (0.17, 2.73)	0.5897	
mild	18/ 53 (34.0)	NE (5.1, NE)	4/ 28 (14.3)	NE (NE , NE)	1.88 (0.63, 5.57)	0.2489	
moderate	15/ 39 (38.5)	8.4 (3.0, NE)	4/ 20 (20.0)	NE (3.1, NE)	1.45 (0.47, 4.48)	0.5147	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.6011
normal	34/ 88 (38.6)	15.3 (5.9, NE)	9/ 47 (19.1)	NE (5.4, NE)	1.23 (0.58, 2.61)	0.5945	
mild	10/ 36 (27.8)	14.1 (4.1, NE)	2/ 15 (13.3)	NE (NE , NE)	1.76 (0.38, 8.23)	0.4674	
moderate	1/ 1 (100.0)	4.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.6279
yes	5/ 8 (62.5)	5.7 (0.5, NE)	1/ 5 (20.0)	NE (0.5, NE)	1.95 (0.23, 16.81)	0.5367	
no	40/117 (34.2)	15.3 (7.0, NE)	10/ 57 (17.5)	NE (5.4, NE)	1.34 (0.66, 2.72)	0.4200	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9883
yes	2/ 3 (66.7)	8.4 (5.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	43/122 (35.2)	14.1 (7.0, NE)	11/ 58 (19.0)	NE (5.4, NE)	1.27 (0.64, 2.49)	0.4936	

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[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
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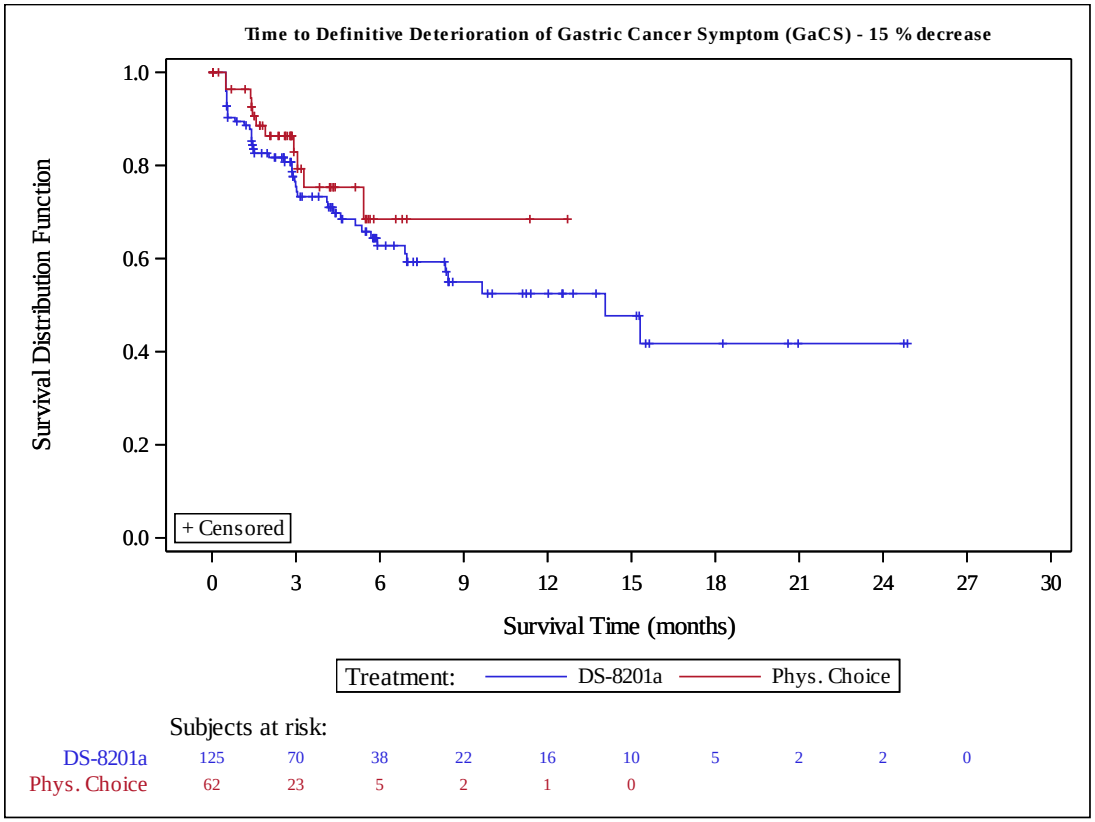
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

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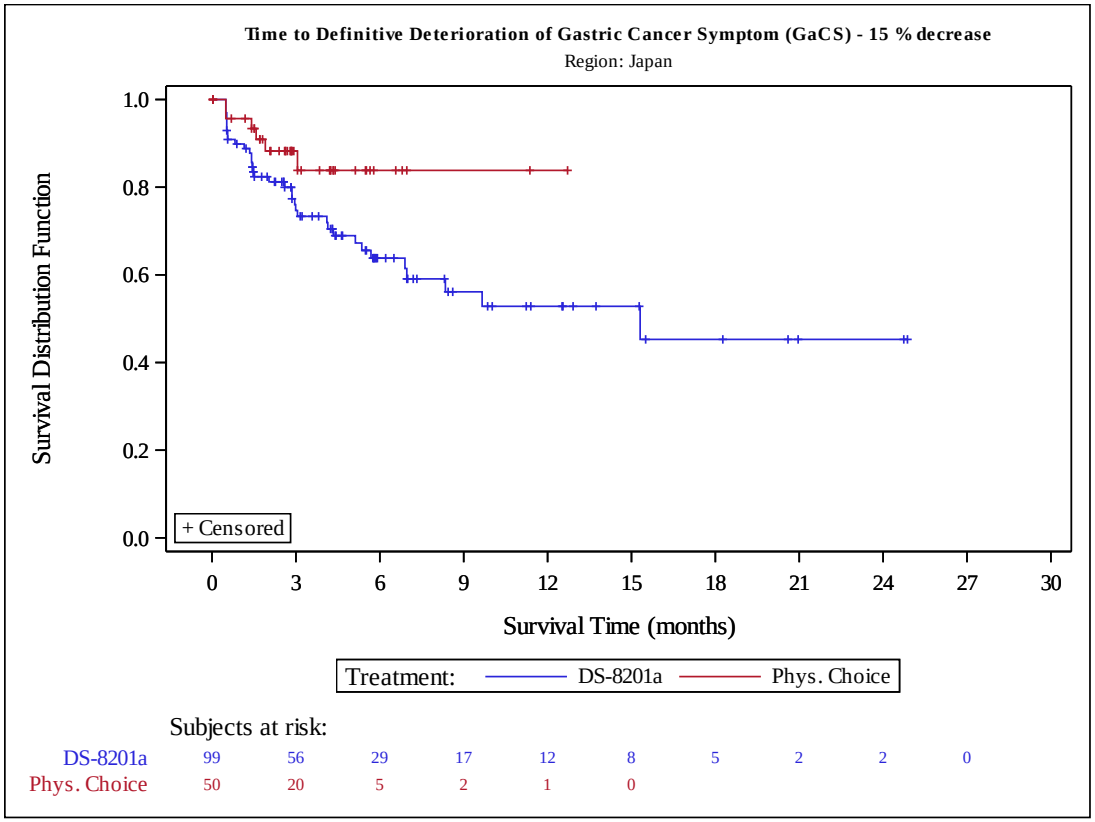
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
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Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
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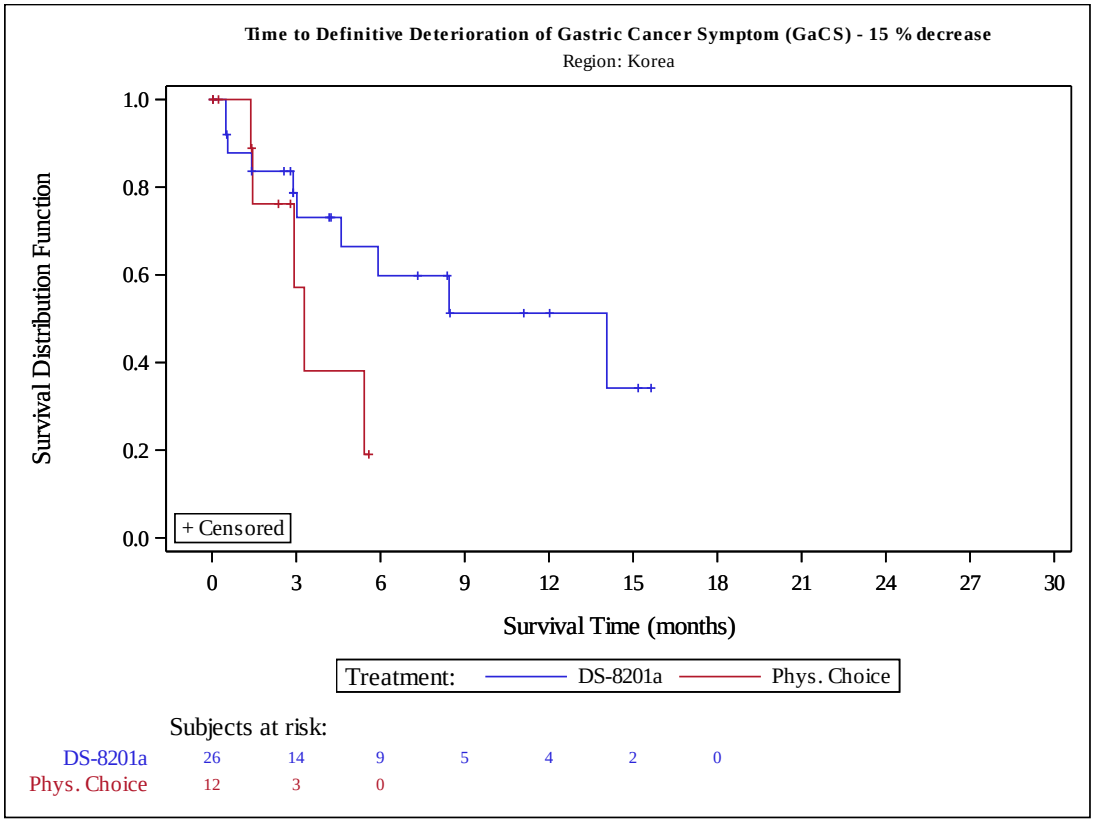

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	120	9 (7.5)	82 (68.3)	29 (24.2)	52	1 (1.9)	43 (82.7)	8 (15.4)
	Day 43	118	17 (14.4)	81 (68.6)	20 (16.9)	53	2 (3.8)	44 (83.0)	7 (13.2)
	Day 85	99	10 (10.1)	65 (65.7)	24 (24.2)	36	1 (2.8)	31 (86.1)	4 (11.1)
	Day 127	74	11 (14.9)	52 (70.3)	11 (14.9)	19	1 (5.3)	17 (89.5)	1 (5.3)
	Day 169	57	7 (12.3)	40 (70.2)	10 (17.5)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	44	8 (18.2)	24 (54.5)	12 (27.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	37	8 (21.6)	21 (56.8)	8 (21.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	29	5 (17.2)	18 (62.1)	6 (20.7)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	27	5 (18.5)	18 (66.7)	4 (14.8)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	21	2 (9.5)	14 (66.7)	5 (23.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	3 (18.8)	10 (62.5)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	7 (58.3)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	96	5 (5.2)	59 (61.5)	32 (33.3)	56	2 (3.6)	43 (76.8)	11 (19.6)
Region									
Japan									
	Day 15	97	4 (4.1)	69 (71.1)	24 (24.7)	45	1 (2.2)	37 (82.2)	7 (15.6)
	Day 43	94	11 (11.7)	67 (71.3)	16 (17.0)	43	2 (4.7)	36 (83.7)	5 (11.6)
	Day 85	77	6 (7.8)	52 (67.5)	19 (24.7)	32	1 (3.1)	28 (87.5)	3 (9.4)
	Day 127	60	7 (11.7)	44 (73.3)	9 (15.0)	16	1 (6.3)	15 (93.8)	0 (0.0)
	Day 169	49	5 (10.2)	34 (69.4)	10 (20.4)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 211	36	4 (11.1)	21 (58.3)	11 (30.6)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	29	5 (17.2)	18 (62.1)	6 (20.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	23	2 (8.7)	16 (69.6)	5 (21.7)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	21	2 (9.5)	16 (76.2)	3 (14.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	18	1 (5.6)	12 (66.7)	5 (27.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	2 (16.7)	8 (66.7)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	77	3 (3.9)	51 (66.2)	23 (29.9)	48	2 (4.2)	40 (83.3)	6 (12.5)
Region									
Korea									
	Day 15	23	5 (21.7)	13 (56.5)	5 (21.7)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 43	24	6 (25.0)	14 (58.3)	4 (16.7)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 85	22	4 (18.2)	13 (59.1)	5 (22.7)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 127	14	4 (28.6)	8 (57.1)	2 (14.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	8	2 (25.0)	6 (75.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	4 (50.0)	3 (37.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	3 (37.5)	3 (37.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	6	3 (50.0)	2 (33.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
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Daiichi Sankyo

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Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	6	3 (50.0)	2 (33.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	19	2 (10.5)	8 (42.1)	9 (47.4)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy 2									
	Day 15	62	4 (6.5)	44 (71.0)	14 (22.6)	34	0 (0.0)	28 (82.4)	6 (17.6)
	Day 43	62	7 (11.3)	42 (67.7)	13 (21.0)	36	0 (0.0)	30 (83.3)	6 (16.7)
	Day 85	50	5 (10.0)	33 (66.0)	12 (24.0)	21	1 (4.8)	18 (85.7)	2 (9.5)
	Day 127	33	6 (18.2)	23 (69.7)	4 (12.1)	14	0 (0.0)	13 (92.9)	1 (7.1)
	Day 169	24	4 (16.7)	19 (79.2)	1 (4.2)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	21	5 (23.8)	13 (61.9)	3 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	6 (33.3)	8 (44.4)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	4 (33.3)	7 (58.3)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	4 (36.4)	7 (63.6)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	1 (14.3)	6 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	5	2 (40.0)	3 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	3 (6.0)	30 (60.0)	17 (34.0)	34	1 (2.9)	26 (76.5)	7 (20.6)
Lines of prior systemic therapy 3									
	Day 15	33	4 (12.1)	20 (60.6)	9 (27.3)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 43	33	5 (15.2)	24 (72.7)	4 (12.1)	14	2 (14.3)	11 (78.6)	1 (7.1)
	Day 85	28	2 (7.1)	22 (78.6)	4 (14.3)	12	0 (0.0)	10 (83.3)	2 (16.7)
	Day 127	23	2 (8.7)	16 (69.6)	5 (21.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	19	2 (10.5)	11 (57.9)	6 (31.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	13	2 (15.4)	8 (61.5)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	1 (9.1)	9 (81.8)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	9	1 (11.1)	6 (66.7)	2 (22.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	1 (3.8)	17 (65.4)	8 (30.8)	17	1 (5.9)	13 (76.5)	3 (17.6)
Lines of prior systemic therapy >=4									
	Day 15	25	1 (4.0)	18 (72.0)	6 (24.0)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	23	5 (21.7)	15 (65.2)	3 (13.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	3 (14.3)	10 (47.6)	8 (38.1)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	18	3 (16.7)	13 (72.2)	2 (11.1)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	14	1 (7.1)	10 (71.4)	3 (21.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	3 (30.0)	6 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	1 (12.5)	4 (50.0)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	2 (33.3)	4 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	12 (60.0)	7 (35.0)	5	0 (0.0)	4 (80.0)	1 (20.0)
Age									
<65 years									
	Day 15	52	5 (9.6)	36 (69.2)	11 (21.2)	22	0 (0.0)	19 (86.4)	3 (13.6)
	Day 43	52	11 (21.2)	33 (63.5)	8 (15.4)	24	0 (0.0)	19 (79.2)	5 (20.8)
	Day 85	47	6 (12.8)	32 (68.1)	9 (19.1)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 127	34	7 (20.6)	23 (67.6)	4 (11.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	27	3 (11.1)	20 (74.1)	4 (14.8)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	18	5 (27.8)	10 (55.6)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	16	6 (37.5)	7 (43.8)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	4 (30.8)	8 (61.5)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	3 (27.3)	8 (72.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	42	2 (4.8)	26 (61.9)	14 (33.3)	23	0 (0.0)	18 (78.3)	5 (21.7)
Age									
>=65 years									
	Day 15	68	4 (5.9)	46 (67.6)	18 (26.5)	30	1 (3.3)	24 (80.0)	5 (16.7)
	Day 43	66	6 (9.1)	48 (72.7)	12 (18.2)	29	2 (6.9)	25 (86.2)	2 (6.9)
	Day 85	52	4 (7.7)	33 (63.5)	15 (28.8)	20	1 (5.0)	16 (80.0)	3 (15.0)
	Day 127	40	4 (10.0)	29 (72.5)	7 (17.5)	11	1 (9.1)	10 (90.9)	0 (0.0)
	Day 169	30	4 (13.3)	20 (66.7)	6 (20.0)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	26	3 (11.5)	14 (53.8)	9 (34.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	2 (9.5)	14 (66.7)	5 (23.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	16	1 (6.3)	10 (62.5)	5 (31.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	16	2 (12.5)	10 (62.5)	4 (25.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	13	1 (7.7)	8 (61.5)	4 (30.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	1 (11.1)	6 (66.7)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	End of Treatment	54	3 (5.6)	33 (61.1)	18 (33.3)	33	2 (6.1)	25 (75.8)	6 (18.2)
Sex									
female									
	Day 15	28	0 (0.0)	25 (89.3)	3 (10.7)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 43	28	5 (17.9)	21 (75.0)	2 (7.1)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 85	20	3 (15.0)	14 (70.0)	3 (15.0)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	13	5 (38.5)	8 (61.5)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	3 (30.0)	6 (60.0)	1 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	8	2 (25.0)	5 (62.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	7	2 (28.6)	3 (42.9)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	22	1 (4.5)	16 (72.7)	5 (22.7)	14	0 (0.0)	12 (85.7)	2 (14.3)
Sex									
male									
	Day 15	92	9 (9.8)	57 (62.0)	26 (28.3)	39	0 (0.0)	32 (82.1)	7 (17.9)
	Day 43	90	12 (13.3)	60 (66.7)	18 (20.0)	40	1 (2.5)	34 (85.0)	5 (12.5)
	Day 85	79	7 (8.9)	51 (64.6)	21 (26.6)	28	1 (3.6)	25 (89.3)	2 (7.1)
	Day 127	61	6 (9.8)	44 (72.1)	11 (18.0)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	47	4 (8.5)	34 (72.3)	9 (19.1)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	36	6 (16.7)	19 (52.8)	11 (30.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	30	6 (20.0)	18 (60.0)	6 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	5 (20.0)	15 (60.0)	5 (20.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	24	5 (20.8)	15 (62.5)	4 (16.7)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	19	2 (10.5)	12 (63.2)	5 (26.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	15	2 (13.3)	10 (66.7)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	6 (54.5)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	4 (5.4)	43 (58.1)	27 (36.5)	42	2 (4.8)	31 (73.8)	9 (21.4)
ECOG PS									
0									
	Day 15	60	1 (1.7)	43 (71.7)	16 (26.7)	26	0 (0.0)	24 (92.3)	2 (7.7)
	Day 43	60	6 (10.0)	44 (73.3)	10 (16.7)	26	1 (3.8)	21 (80.8)	4 (15.4)
	Day 85	54	5 (9.3)	33 (61.1)	16 (29.6)	19	0 (0.0)	18 (94.7)	1 (5.3)
	Day 127	42	6 (14.3)	32 (76.2)	4 (9.5)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 169	36	3 (8.3)	27 (75.0)	6 (16.7)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	27	2 (7.4)	16 (59.3)	9 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	24	3 (12.5)	14 (58.3)	7 (29.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	18	0 (0.0)	14 (77.8)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	13 (81.3)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	14	0 (0.0)	10 (71.4)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	47	1 (2.1)	31 (66.0)	15 (31.9)	29	0 (0.0)	24 (82.8)	5 (17.2)
ECOG PS									
1									
	Day 15	60	8 (13.3)	39 (65.0)	13 (21.7)	26	1 (3.8)	19 (73.1)	6 (23.1)
	Day 43	58	11 (19.0)	37 (63.8)	10 (17.2)	27	1 (3.7)	23 (85.2)	3 (11.1)
	Day 85	45	5 (11.1)	32 (71.1)	8 (17.8)	17	1 (5.9)	13 (76.5)	3 (17.6)
	Day 127	32	5 (15.6)	20 (62.5)	7 (21.9)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	21	4 (19.0)	13 (61.9)	4 (19.0)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	17	6 (35.3)	8 (47.1)	3 (17.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	13	5 (38.5)	7 (53.8)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	5 (45.5)	4 (36.4)	2 (18.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	11	4 (36.4)	5 (45.5)	2 (18.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	2 (40.0)	2 (40.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	49	4 (8.2)	28 (57.1)	17 (34.7)	27	2 (7.4)	19 (70.4)	6 (22.2)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	93	7 (7.5)	62 (66.7)	24 (25.8)	38	0 (0.0)	31 (81.6)	7 (18.4)
	Day 43	92	14 (15.2)	63 (68.5)	15 (16.3)	40	1 (2.5)	33 (82.5)	6 (15.0)
	Day 85	79	9 (11.4)	53 (67.1)	17 (21.5)	26	1 (3.8)	23 (88.5)	2 (7.7)
	Day 127	59	10 (16.9)	40 (67.8)	9 (15.3)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 169	46	6 (13.0)	32 (69.6)	8 (17.4)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	38	7 (18.4)	20 (52.6)	11 (28.9)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	32	8 (25.0)	17 (53.1)	7 (21.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	5 (19.2)	16 (61.5)	5 (19.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	25	5 (20.0)	17 (68.0)	3 (12.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	19	2 (10.5)	14 (73.7)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	3 (18.8)	10 (62.5)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	7 (58.3)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	73	4 (5.5)	46 (63.0)	23 (31.5)	42	2 (4.8)	30 (71.4)	10 (23.8)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	2 (7.4)	20 (74.1)	5 (18.5)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 43	26	3 (11.5)	18 (69.2)	5 (19.2)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 85	20	1 (5.0)	12 (60.0)	7 (35.0)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	15	1 (6.7)	12 (80.0)	2 (13.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 169	11	1 (9.1)	8 (72.7)	2 (18.2)	3	0 (0.0)	3 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	1 (4.3)	13 (56.5)	9 (39.1)	14	0 (0.0)	13 (92.9)	1 (7.1)
Primary tumor location									
Gastric									
	Day 15	103	8 (7.8)	70 (68.0)	25 (24.3)	46	1 (2.2)	38 (82.6)	7 (15.2)
	Day 43	101	14 (13.9)	71 (70.3)	16 (15.8)	48	2 (4.2)	40 (83.3)	6 (12.5)
	Day 85	84	8 (9.5)	57 (67.9)	19 (22.6)	33	1 (3.0)	28 (84.8)	4 (12.1)
	Day 127	63	10 (15.9)	44 (69.8)	9 (14.3)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	47	5 (10.6)	33 (70.2)	9 (19.1)	11	0 (0.0)	10 (90.9)	1 (9.1)
	Day 211	38	6 (15.8)	21 (55.3)	11 (28.9)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	31	5 (16.1)	19 (61.3)	7 (22.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	24	3 (12.5)	15 (62.5)	6 (25.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	22	3 (13.6)	15 (68.2)	4 (18.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	17	1 (5.9)	11 (64.7)	5 (29.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	2 (15.4)	8 (61.5)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	5 (55.6)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	81	4 (4.9)	51 (63.0)	26 (32.1)	50	2 (4.0)	37 (74.0)	11 (22.0)
Primary tumor location									
GEJ									
	Day 15	17	1 (5.9)	12 (70.6)	4 (23.5)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 43	17	3 (17.6)	10 (58.8)	4 (23.5)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 85	15	2 (13.3)	8 (53.3)	5 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	8 (72.7)	2 (18.2)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	2 (20.0)	7 (70.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	6	2 (33.3)	3 (50.0)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	3 (50.0)	2 (33.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	2 (40.0)	3 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	2 (40.0)	3 (60.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	1 (6.7)	8 (53.3)	6 (40.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	87	5 (5.7)	61 (70.1)	21 (24.1)	35	1 (2.9)	29 (82.9)	5 (14.3)
	Day 43	86	10 (11.6)	63 (73.3)	13 (15.1)	34	2 (5.9)	27 (79.4)	5 (14.7)
	Day 85	73	5 (6.8)	49 (67.1)	19 (26.0)	27	1 (3.7)	23 (85.2)	3 (11.1)
	Day 127	55	7 (12.7)	40 (72.7)	8 (14.5)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 169	44	4 (9.1)	32 (72.7)	8 (18.2)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	32	3 (9.4)	19 (59.4)	10 (31.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	25	3 (12.0)	16 (64.0)	6 (24.0)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	18	2 (11.1)	11 (61.1)	5 (27.8)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	16	1 (6.3)	12 (75.0)	3 (18.8)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	13	1 (7.7)	8 (61.5)	4 (30.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	2 (18.2)	7 (63.6)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	5 (55.6)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	2 (2.8)	44 (62.0)	25 (35.2)	37	2 (5.4)	29 (78.4)	6 (16.2)
Histological subtype diffuse									
	Day 15	27	3 (11.1)	17 (63.0)	7 (25.9)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 43	26	5 (19.2)	16 (61.5)	5 (19.2)	14	0 (0.0)	13 (92.9)	1 (7.1)
	Day 85	22	3 (13.6)	14 (63.6)	5 (22.7)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 127	15	3 (20.0)	9 (60.0)	3 (20.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	11	3 (27.3)	6 (54.5)	2 (18.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	4 (40.0)	4 (40.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	4 (40.0)	4 (40.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	9	3 (33.3)	5 (55.6)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	3 (14.3)	14 (66.7)	4 (19.0)	16	0 (0.0)	13 (81.3)	3 (18.8)
Histological subtype others									
	Day 15	6	1 (16.7)	4 (66.7)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	2 (33.3)	2 (33.3)	2 (33.3)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 85	4	2 (50.0)	2 (50.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	4	1 (25.0)	3 (75.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	1 (25.0)	3 (75.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	22	0 (0.0)	14 (63.6)	8 (36.4)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 43	22	1 (4.5)	17 (77.3)	4 (18.2)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 85	21	0 (0.0)	17 (81.0)	4 (19.0)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	17	0 (0.0)	15 (88.2)	2 (11.8)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	16	0 (0.0)	13 (81.3)	3 (18.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	14	1 (7.1)	10 (71.4)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	1 (10.0)	6 (60.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	12 (70.6)	4 (23.5)	9	1 (11.1)	8 (88.9)	0 (0.0)
Number of metastatic sites									
>= 2									
	Day 15	98	9 (9.2)	68 (69.4)	21 (21.4)	42	1 (2.4)	35 (83.3)	6 (14.3)
	Day 43	96	16 (16.7)	64 (66.7)	16 (16.7)	43	2 (4.7)	34 (79.1)	7 (16.3)
	Day 85	78	10 (12.8)	48 (61.5)	20 (25.6)	28	0 (0.0)	24 (85.7)	4 (14.3)
	Day 127	57	11 (19.3)	37 (64.9)	9 (15.8)	15	1 (6.7)	13 (86.7)	1 (6.7)
	Day 169	41	7 (17.1)	27 (65.9)	7 (17.1)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	30	7 (23.3)	14 (46.7)	9 (30.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	7 (25.9)	15 (55.6)	5 (18.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	21	4 (19.0)	12 (57.1)	5 (23.8)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	19	4 (21.1)	12 (63.2)	3 (15.8)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	16	2 (12.5)	10 (62.5)	4 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	12	3 (25.0)	7 (58.3)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	1 (11.1)	4 (44.4)	4 (44.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	4 (5.1)	47 (59.5)	28 (35.4)	47	1 (2.1)	35 (74.5)	11 (23.4)
Previous total gastrectomy									
yes									
	Day 15	20	1 (5.0)	14 (70.0)	5 (25.0)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 43	20	2 (10.0)	13 (65.0)	5 (25.0)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 85	18	1 (5.6)	11 (61.1)	6 (33.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 127	11	1 (9.1)	7 (63.6)	3 (27.3)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 169	8	1 (12.5)	4 (50.0)	3 (37.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	8	2 (25.0)	2 (25.0)	4 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	3 (75.0)	0 (0.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	1 (25.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	2 (50.0)	0 (0.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	12 (66.7)	5 (27.8)	9	0 (0.0)	8 (88.9)	1 (11.1)
Previous total gastrectomy									
no									
	Day 15	100	8 (8.0)	68 (68.0)	24 (24.0)	45	1 (2.2)	36 (80.0)	8 (17.8)
	Day 43	98	15 (15.3)	68 (69.4)	15 (15.3)	45	1 (2.2)	37 (82.2)	7 (15.6)
	Day 85	81	9 (11.1)	54 (66.7)	18 (22.2)	30	1 (3.3)	25 (83.3)	4 (13.3)
	Day 127	63	10 (15.9)	45 (71.4)	8 (12.7)	17	0 (0.0)	16 (94.1)	1 (5.9)
	Day 169	49	6 (12.2)	36 (73.5)	7 (14.3)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 211	36	6 (16.7)	22 (61.1)	8 (22.2)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	33	5 (15.2)	21 (63.6)	7 (21.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	4 (16.0)	17 (68.0)	4 (16.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	23	3 (13.0)	18 (78.3)	2 (8.7)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	19	2 (10.5)	13 (68.4)	4 (21.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	14	3 (21.4)	9 (64.3)	2 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	4 (5.1)	47 (60.3)	27 (34.6)	47	2 (4.3)	35 (74.5)	10 (21.3)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	1 (3.4)	24 (82.8)	4 (13.8)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 43	28	3 (10.7)	22 (78.6)	3 (10.7)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 85	27	2 (7.4)	20 (74.1)	5 (18.5)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 127	22	2 (9.1)	18 (81.8)	2 (9.1)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	15	2 (13.3)	10 (66.7)	3 (20.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	12	2 (16.7)	4 (33.3)	6 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	3 (30.0)	3 (30.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	10	1 (10.0)	6 (60.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	2 (20.0)	5 (50.0)	3 (30.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	2 (33.3)	4 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	25	2 (8.0)	16 (64.0)	7 (28.0)	9	0 (0.0)	9 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	91	8 (8.8)	58 (63.7)	25 (27.5)	44	1 (2.3)	36 (81.8)	7 (15.9)
	Day 43	90	14 (15.6)	59 (65.6)	17 (18.9)	45	1 (2.2)	37 (82.2)	7 (15.6)
	Day 85	72	8 (11.1)	45 (62.5)	19 (26.4)	29	1 (3.4)	24 (82.8)	4 (13.8)
	Day 127	52	9 (17.3)	34 (65.4)	9 (17.3)	15	0 (0.0)	14 (93.3)	1 (6.7)
	Day 169	42	5 (11.9)	30 (71.4)	7 (16.7)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	32	6 (18.8)	20 (62.5)	6 (18.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	5 (18.5)	18 (66.7)	4 (14.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	19	4 (21.1)	12 (63.2)	3 (15.8)	2	1 (50.0)	1 (50.0)	0 (0.0)

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Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
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Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	17	3 (17.6)	13 (76.5)	1 (5.9)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	15	2 (13.3)	12 (80.0)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	3 (25.0)	8 (66.7)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	3 (4.2)	43 (60.6)	25 (35.2)	47	2 (4.3)	34 (72.3)	11 (23.4)
Prior ramucirumab contained treatment									
yes									
	Day 15	90	3 (3.3)	64 (71.1)	23 (25.6)	34	1 (2.9)	28 (82.4)	5 (14.7)
	Day 43	90	11 (12.2)	62 (68.9)	17 (18.9)	33	1 (3.0)	27 (81.8)	5 (15.2)
	Day 85	73	6 (8.2)	49 (67.1)	18 (24.7)	23	0 (0.0)	21 (91.3)	2 (8.7)
	Day 127	59	6 (10.2)	45 (76.3)	8 (13.6)	11	1 (9.1)	10 (90.9)	0 (0.0)
	Day 169	45	2 (4.4)	35 (77.8)	8 (17.8)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	32	2 (6.3)	19 (59.4)	11 (34.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	25	3 (12.0)	17 (68.0)	5 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	22	1 (4.5)	17 (77.3)	4 (18.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	21	2 (9.5)	16 (76.2)	3 (14.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	17	0 (0.0)	13 (76.5)	4 (23.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	13	1 (7.7)	10 (76.9)	2 (15.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	7 (63.6)	4 (36.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	73	2 (2.7)	44 (60.3)	27 (37.0)	36	1 (2.8)	28 (77.8)	7 (19.4)
Prior ramucirumab contained treatment									
no									
	Day 15	30	6 (20.0)	18 (60.0)	6 (20.0)	18	0 (0.0)	15 (83.3)	3 (16.7)
	Day 43	28	6 (21.4)	19 (67.9)	3 (10.7)	20	1 (5.0)	17 (85.0)	2 (10.0)
	Day 85	26	4 (15.4)	16 (61.5)	6 (23.1)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 127	15	5 (33.3)	7 (46.7)	3 (20.0)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 169	12	5 (41.7)	5 (41.7)	2 (16.7)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	12	6 (50.0)	5 (41.7)	1 (8.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	5 (41.7)	4 (33.3)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	4 (57.1)	1 (14.3)	2 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	3 (50.0)	2 (33.3)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	2 (50.0)	1 (25.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	3	2 (66.7)	0 (0.0)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	1 (100.0)	0 (0.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	3 (13.0)	15 (65.2)	5 (21.7)	20	1 (5.0)	15 (75.0)	4 (20.0)
Prior nivolumab contained treatment									
yes									
	Day 15	32	1 (3.1)	20 (62.5)	11 (34.4)	13	1 (7.7)	10 (76.9)	2 (15.4)
	Day 43	31	3 (9.7)	26 (83.9)	2 (6.5)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 85	27	3 (11.1)	18 (66.7)	6 (22.2)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 127	26	2 (7.7)	19 (73.1)	5 (19.2)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	21	2 (9.5)	16 (76.2)	3 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	16	1 (6.3)	10 (62.5)	5 (31.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	14	0 (0.0)	12 (85.7)	2 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	0 (0.0)	9 (75.0)	3 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	11	0 (0.0)	9 (81.8)	2 (18.2)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	10	0 (0.0)	6 (60.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	1 (3.8)	16 (61.5)	9 (34.6)	14	1 (7.1)	10 (71.4)	3 (21.4)
Prior nivolumab contained treatment									
no									
	Day 15	88	8 (9.1)	62 (70.5)	18 (20.5)	39	0 (0.0)	33 (84.6)	6 (15.4)
	Day 43	87	14 (16.1)	55 (63.2)	18 (20.7)	43	1 (2.3)	35 (81.4)	7 (16.3)
	Day 85	72	7 (9.7)	47 (65.3)	18 (25.0)	26	1 (3.8)	23 (88.5)	2 (7.7)
	Day 127	48	9 (18.8)	33 (68.8)	6 (12.5)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 169	36	5 (13.9)	24 (66.7)	7 (19.4)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	28	7 (25.0)	14 (50.0)	7 (25.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	23	8 (34.8)	9 (39.1)	6 (26.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	5 (29.4)	9 (52.9)	3 (17.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	5 (31.3)	9 (56.3)	2 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	2 (18.2)	8 (72.7)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	3 (33.3)	4 (44.4)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	70	4 (5.7)	43 (61.4)	23 (32.9)	42	1 (2.4)	33 (78.6)	8 (19.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	42	3 (7.1)	26 (61.9)	13 (31.0)	15	1 (6.7)	12 (80.0)	2 (13.3)
	Day 43	41	6 (14.6)	31 (75.6)	4 (9.8)	12	1 (8.3)	11 (91.7)	0 (0.0)
	Day 85	37	5 (13.5)	22 (59.5)	10 (27.0)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 127	31	4 (12.9)	20 (64.5)	7 (22.6)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	24	3 (12.5)	18 (75.0)	3 (12.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	20	3 (15.0)	11 (55.0)	6 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	17	2 (11.8)	13 (76.5)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	2 (12.5)	10 (62.5)	4 (25.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	15	2 (13.3)	10 (66.7)	3 (20.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	12	1 (8.3)	7 (58.3)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	35	3 (8.6)	19 (54.3)	13 (37.1)	16	1 (6.3)	12 (75.0)	3 (18.8)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	78	6 (7.7)	56 (71.8)	16 (20.5)	37	0 (0.0)	31 (83.8)	6 (16.2)
	Day 43	77	11 (14.3)	50 (64.9)	16 (20.8)	41	1 (2.4)	33 (80.5)	7 (17.1)
	Day 85	62	5 (8.1)	43 (69.4)	14 (22.6)	25	1 (4.0)	22 (88.0)	2 (8.0)
	Day 127	43	7 (16.3)	32 (74.4)	4 (9.3)	15	0 (0.0)	14 (93.3)	1 (6.7)
	Day 169	33	4 (12.1)	22 (66.7)	7 (21.2)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	24	5 (20.8)	13 (54.2)	6 (25.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	6 (30.0)	8 (40.0)	6 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	3 (23.1)	8 (61.5)	2 (15.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	3 (25.0)	8 (66.7)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	9	1 (11.1)	7 (77.8)	1 (11.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	6	2 (33.3)	2 (33.3)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	1 (16.7)	3 (50.0)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	61	2 (3.3)	40 (65.6)	19 (31.1)	40	1 (2.5)	31 (77.5)	8 (20.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
yes									
	Day 15	22	3 (13.6)	15 (68.2)	4 (18.2)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	19	3 (15.8)	14 (73.7)	2 (10.5)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 85	16	1 (6.3)	11 (68.8)	4 (25.0)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 127	12	2 (16.7)	9 (75.0)	1 (8.3)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	9	1 (11.1)	6 (66.7)	2 (22.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	5	1 (20.0)	2 (40.0)	2 (40.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	2 (14.3)	9 (64.3)	3 (21.4)	6	0 (0.0)	6 (100.0)	0 (0.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
no									
	Day 15	98	6 (6.1)	67 (68.4)	25 (25.5)	46	1 (2.2)	37 (80.4)	8 (17.4)
	Day 43	99	14 (14.1)	67 (67.7)	18 (18.2)	47	2 (4.3)	38 (80.9)	7 (14.9)
	Day 85	83	9 (10.8)	54 (65.1)	20 (24.1)	31	1 (3.2)	26 (83.9)	4 (12.9)
	Day 127	62	9 (14.5)	43 (69.4)	10 (16.1)	16	0 (0.0)	15 (93.8)	1 (6.3)
	Day 169	48	6 (12.5)	34 (70.8)	8 (16.7)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	39	7 (17.9)	22 (56.4)	10 (25.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	7 (21.2)	19 (57.6)	7 (21.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	4 (15.4)	16 (61.5)	6 (23.1)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	24	4 (16.7)	16 (66.7)	4 (16.7)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	18	1 (5.6)	12 (66.7)	5 (27.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	2 (15.4)	9 (69.2)	2 (15.4)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	3 (3.7)	50 (61.0)	29 (35.4)	50	2 (4.0)	37 (74.0)	11 (22.0)
Presence of liver metastasis at baseline									
yes									
	Day 15	65	7 (10.8)	45 (69.2)	13 (20.0)	27	0 (0.0)	23 (85.2)	4 (14.8)
	Day 43	64	12 (18.8)	43 (67.2)	9 (14.1)	28	1 (3.6)	23 (82.1)	4 (14.3)
	Day 85	51	8 (15.7)	33 (64.7)	10 (19.6)	16	0 (0.0)	14 (87.5)	2 (12.5)
	Day 127	37	9 (24.3)	23 (62.2)	5 (13.5)	10	1 (10.0)	8 (80.0)	1 (10.0)
	Day 169	28	4 (14.3)	21 (75.0)	3 (10.7)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	20	4 (20.0)	12 (60.0)	4 (20.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	3 (15.8)	13 (68.4)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	2 (14.3)	10 (71.4)	2 (14.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	13	2 (15.4)	11 (84.6)	0 (0.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	11	1 (9.1)	10 (90.9)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	49	2 (4.1)	33 (67.3)	14 (28.6)	31	1 (3.2)	22 (71.0)	8 (25.8)
Presence of liver metastasis at baseline									
no									
	Day 15	55	2 (3.6)	37 (67.3)	16 (29.1)	25	1 (4.0)	20 (80.0)	4 (16.0)
	Day 43	54	5 (9.3)	38 (70.4)	11 (20.4)	25	1 (4.0)	21 (84.0)	3 (12.0)
	Day 85	48	2 (4.2)	32 (66.7)	14 (29.2)	20	1 (5.0)	17 (85.0)	2 (10.0)
	Day 127	37	2 (5.4)	29 (78.4)	6 (16.2)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 169	29	3 (10.3)	19 (65.5)	7 (24.1)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	24	4 (16.7)	12 (50.0)	8 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	5 (27.8)	8 (44.4)	5 (27.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	3 (20.0)	8 (53.3)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	3 (21.4)	7 (50.0)	4 (28.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	4 (40.0)	5 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	7	1 (14.3)	4 (57.1)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	1 (20.0)	2 (40.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	47	3 (6.4)	26 (55.3)	18 (38.3)	25	1 (4.0)	21 (84.0)	3 (12.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Renal impairment at baseline									
normal									
	Day 15	32	2 (6.3)	24 (75.0)	6 (18.8)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 43	33	4 (12.1)	24 (72.7)	5 (15.2)	12	0 (0.0)	9 (75.0)	3 (25.0)
	Day 85	26	2 (7.7)	20 (76.9)	4 (15.4)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 127	19	1 (5.3)	18 (94.7)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	17	1 (5.9)	15 (88.2)	1 (5.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	12	2 (16.7)	7 (58.3)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	13	2 (15.4)	6 (46.2)	5 (38.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	2 (16.7)	8 (66.7)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	0 (0.0)	6 (75.0)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	1 (4.2)	17 (70.8)	6 (25.0)	11	0 (0.0)	8 (72.7)	3 (27.3)
Renal impairment at baseline									
mild									
	Day 15	51	5 (9.8)	32 (62.7)	14 (27.5)	25	0 (0.0)	23 (92.0)	2 (8.0)
	Day 43	51	10 (19.6)	31 (60.8)	10 (19.6)	23	0 (0.0)	20 (87.0)	3 (13.0)
	Day 85	45	6 (13.3)	28 (62.2)	11 (24.4)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 127	31	7 (22.6)	18 (58.1)	6 (19.4)	9	1 (11.1)	8 (88.9)	0 (0.0)
	Day 169	23	4 (17.4)	14 (60.9)	5 (21.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	17	4 (23.5)	8 (47.1)	5 (29.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	13	4 (30.8)	8 (61.5)	1 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	9	2 (22.2)	5 (55.6)	2 (22.2)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 337	8	2 (25.0)	4 (50.0)	2 (25.0)	2	1 (50.0)	1 (50.0)	0 (0.0)
	Day 379	6	1 (16.7)	2 (33.3)	3 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	2 (50.0)	1 (25.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	44	3 (6.8)	26 (59.1)	15 (34.1)	25	2 (8.0)	19 (76.0)	4 (16.0)
Renal impairment at baseline									
moderate									
	Day 15	37	2 (5.4)	26 (70.3)	9 (24.3)	16	1 (6.3)	11 (68.8)	4 (25.0)
	Day 43	34	3 (8.8)	26 (76.5)	5 (14.7)	17	2 (11.8)	14 (82.4)	1 (5.9)
	Day 85	28	2 (7.1)	17 (60.7)	9 (32.1)	14	0 (0.0)	11 (78.6)	3 (21.4)
	Day 127	24	3 (12.5)	16 (66.7)	5 (20.8)	7	0 (0.0)	7 (100.0)	0 (0.0)
	Day 169	17	2 (11.8)	11 (64.7)	4 (23.5)	5	0 (0.0)	4 (80.0)	1 (20.0)
	Day 211	15	2 (13.3)	9 (60.0)	4 (26.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	2 (18.2)	7 (63.6)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	2 (25.0)	5 (62.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	6 (85.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	3	1 (33.3)	1 (33.3)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	1 (3.6)	16 (57.1)	11 (39.3)	19	0 (0.0)	15 (78.9)	4 (21.1)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	85	5 (5.9)	57 (67.1)	23 (27.1)	37	1 (2.7)	31 (83.8)	5 (13.5)
	Day 43	84	11 (13.1)	59 (70.2)	14 (16.7)	41	2 (4.9)	33 (80.5)	6 (14.6)
	Day 85	76	8 (10.5)	48 (63.2)	20 (26.3)	27	1 (3.7)	22 (81.5)	4 (14.8)
	Day 127	58	9 (15.5)	41 (70.7)	8 (13.8)	14	0 (0.0)	13 (92.9)	1 (7.1)
	Day 169	45	5 (11.1)	32 (71.1)	8 (17.8)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 211	34	7 (20.6)	19 (55.9)	8 (23.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	30	8 (26.7)	17 (56.7)	5 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	23	5 (21.7)	14 (60.9)	4 (17.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	5 (23.8)	14 (66.7)	2 (9.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	2 (12.5)	11 (68.8)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	3 (27.3)	7 (63.6)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	66	3 (4.5)	38 (57.6)	25 (37.9)	42	1 (2.4)	32 (76.2)	9 (21.4)
Hepatic impairment at baseline									
mild									
	Day 15	34	4 (11.8)	24 (70.6)	6 (17.6)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 43	33	6 (18.2)	21 (63.6)	6 (18.2)	12	0 (0.0)	11 (91.7)	1 (8.3)
	Day 85	22	2 (9.1)	16 (72.7)	4 (18.2)	9	0 (0.0)	9 (100.0)	0 (0.0)
	Day 127	15	2 (13.3)	11 (73.3)	2 (13.3)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 169	12	2 (16.7)	8 (66.7)	2 (16.7)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	5 (50.0)	4 (40.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	7	0 (0.0)	4 (57.1)	3 (42.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	0 (0.0)	4 (66.7)	2 (33.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	6	0 (0.0)	4 (66.7)	2 (33.3)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	2 (50.0)	2 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	1 (33.3)	2 (66.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	29	2 (6.9)	21 (72.4)	6 (20.7)	14	1 (7.1)	11 (78.6)	2 (14.3)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	2 (25.0)	3 (37.5)	3 (37.5)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 43	8	2 (25.0)	5 (62.5)	1 (12.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	1 (14.3)	4 (57.1)	2 (28.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	1 (16.7)	5 (83.3)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	2 (40.0)	1 (20.0)	2 (40.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	2 (50.0)	1 (25.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	2 (50.0)	0 (0.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	1 (50.0)	0 (0.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	0 (0.0)	1 (100.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	6	1 (16.7)	2 (33.3)	3 (50.0)	4	0 (0.0)	3 (75.0)	1 (25.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	112	7 (6.3)	79 (70.5)	26 (23.2)	48	1 (2.1)	40 (83.3)	7 (14.6)
	Day 43	110	15 (13.6)	76 (69.1)	19 (17.3)	50	2 (4.0)	41 (82.0)	7 (14.0)
	Day 85	92	9 (9.8)	61 (66.3)	22 (23.9)	33	1 (3.0)	28 (84.8)	4 (12.1)
	Day 127	68	10 (14.7)	47 (69.1)	11 (16.2)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	52	5 (9.6)	39 (75.0)	8 (15.4)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	40	6 (15.0)	23 (57.5)	11 (27.5)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	6 (18.2)	21 (63.6)	6 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	27	4 (14.8)	18 (66.7)	5 (18.5)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	25	5 (20.0)	17 (68.0)	3 (12.0)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	20	2 (10.0)	14 (70.0)	4 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	15	3 (20.0)	10 (66.7)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	1 (9.1)	7 (63.6)	3 (27.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	0 (0.0)	5 (71.4)	2 (28.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	90	4 (4.4)	57 (63.3)	29 (32.2)	52	2 (3.8)	40 (76.9)	10 (19.2)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	1 (33.3)	1 (33.3)	1 (33.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	1 (33.3)	1 (33.3)	1 (33.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	1 (50.0)	1 (50.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	1 (50.0)	0 (0.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	1	1 (100.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	1 (50.0)	1 (50.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	117	8 (6.8)	81 (69.2)	28 (23.9)	49	1 (2.0)	40 (81.6)	8 (16.3)
	Day 43	115	17 (14.8)	78 (67.8)	20 (17.4)	50	2 (4.0)	41 (82.0)	7 (14.0)
	Day 85	96	10 (10.4)	62 (64.6)	24 (25.0)	33	1 (3.0)	28 (84.8)	4 (12.1)
	Day 127	71	11 (15.5)	49 (69.0)	11 (15.5)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 169	54	6 (11.1)	39 (72.2)	9 (16.7)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	42	7 (16.7)	23 (54.8)	12 (28.6)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	35	7 (20.0)	21 (60.0)	7 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	28	4 (14.3)	18 (64.3)	6 (21.4)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 337	26	5 (19.2)	17 (65.4)	4 (15.4)	1	1 (100.0)	0 (0.0)	0 (0.0)
	Day 379	21	2 (9.5)	14 (66.7)	5 (23.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	16	3 (18.8)	10 (62.5)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	1 (8.3)	7 (58.3)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	0 (0.0)	5 (62.5)	3 (37.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	94	5 (5.3)	58 (61.7)	31 (33.0)	53	2 (3.8)	40 (75.5)	11 (20.8)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Fact-G Total Score Completion Rates by Visit
Full Analysis Set

	DS-8201a (N=125)		Phys. Choice (N=62)	
Visit	Number of subjects alive	Completed (%)	Number of subjects alive	Completed (%)
Baseline	125	124 (99.2)	62	58 (93.5)
Day 15	125	118 (94.4)	62	52 (83.9)
Day 43	124	117 (94.4)	62	53 (85.5)
Day 85	117	99 (84.6)	57	36 (63.2)
Day 127	111	74 (66.7)	50	19 (38.0)
Day 169	105	57 (54.3)	45	11 (24.4)
Day 211	93	44 (47.3)	40	4 (10.0)
Day 253	84	37 (44.0)	34	2 (5.9)
Day 295	77	29 (37.7)	27	2 (7.4)
Day 337	70	27 (38.6)	21	2 (9.5)
Day 379	60	21 (35.0)	20	1 (5.0)
Day 421	50	16 (32.0)	15	0 (0.0)
Day 463	39	12 (30.8)	9	0 (0.0)
Day 505	30	8 (26.7)	9	0 (0.0)
Day 547	24	6 (25.0)	8	0 (0.0)
Day 589	17	5 (29.4)	5	0 (0.0)
Day 631	13	4 (30.8)	1	0 (0.0)
Day 673	9	2 (22.2)	1	0 (0.0)
Day 715	5	3 (60.0)	1	0 (0.0)
Day 757	5	3 (60.0)	1	0 (0.0)
Day 799	3	1 (33.3)	1	0 (0.0)
Day 841	2	1 (50.0)	0	0 (0.0)
Day 883	2	1 (50.0)	0	0 (0.0)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Fact-G Total Score by Visit
Full Analysis Set

	DS-8201a (N=125)				Phys. Choice (N=62)			
	Value at Visit		Change from Baseline		Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)	N	Mean (SD)
Baseline	124	72.1 (14.96)			58	73.6 (14.07)		
Day 15	118	67.9 (16.04)	117	-4.4 (12.74)	52	73.9 (15.80)	49	-1.7 (12.41)
Day 43	117	69.0 (16.82)	116	-4.0 (13.24)	53	71.8 (18.69)	50	-3.6 (13.79)
Day 85	99	70.0 (15.98)	98	-3.3 (11.73)	36	73.4 (19.87)	34	-3.6 (12.55)
Day 127	74	72.3 (14.55)	73	-3.1 (12.71)	19	73.6 (17.11)	18	-5.9 (12.50)
Day 169	57	73.2 (14.86)	56	-1.2 (11.59)	11	76.9 (19.38)	10	-6.1 (11.88)
Day 211	44	72.3 (14.44)	43	-1.6 (12.66)	4	93.3 (12.85)	3	-3.8 (9.06)
Day 253	37	69.6 (15.51)	37	-3.0 (12.43)	2	92.1 (16.85)	2	-0.8 (14.02)
Day 295	29	73.2 (15.70)	29	-1.6 (12.82)	2	100.5 (4.95)	2	7.7 (2.12)
Day 337	27	72.0 (17.35)	27	-1.8 (15.33)	2	88.5 (23.33)	2	-4.3 (20.51)
Day 379	21	73.3 (16.17)	21	-3.5 (15.10)	1	101.0 (-)	1	6.2 (-)
Day 421	16	68.0 (16.22)	16	-6.7 (11.27)	0	-	0	-
Day 463	12	70.8 (18.32)	12	-3.2 (8.51)	0	-	0	-
Day 505	8	70.2 (16.96)	8	-2.1 (12.67)	0	-	0	-
Day 547	6	71.7 (20.02)	6	-2.2 (8.40)	0	-	0	-
Day 589	5	74.5 (16.56)	5	-4.0 (5.85)	0	-	0	-
Day 631	4	66.1 (13.83)	4	-7.0 (10.01)	0	-	0	-
Day 673	2	56.8 (1.77)	2	-9.8 (10.96)	0	-	0	-
Day 715	3	72.0 (26.26)	3	-5.7 (15.30)	0	-	0	-
Day 757	3	72.8 (24.07)	3	-4.9 (12.10)	0	-	0	-
Day 799	1	57.0 (-)	1	-16.0 (-)	0	-	0	-
Day 841	1	51.3 (-)	1	-21.7 (-)	0	-	0	-
Day 883	1	44.5 (-)	1	-28.5 (-)	0	-	0	-
End of Treatment	97	65.0 (16.28)	96	-8.4 (14.49)	56	65.5 (19.76)	52	-9.8 (15.39)

Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-G Total Score by Visit
Full Analysis Set

Visit	DS-8201a (N=125)			Phys. Choice (N=62)			Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value
	N [a]	N_MISS [b]	LSMean (95% CI)	N [a]	N_MISS [b]	LSMean (95% CI)				
Day 15			-5.77 (-7.87, -3.68)			-4.43 (-7.71, -1.14)	-1.35 (-4.94, 2.24)	0.4607		
Day 43			-5.83 (-7.82, -3.85)			-4.99 (-7.93, -2.06)	-0.84 (-4.04, 2.37)	0.6065		
Day 85			-5.92 (-7.78, -4.07)			-5.85 (-8.76, -2.94)	-0.08 (-3.18, 3.03)	0.9619		
Day 127			-6.01 (-7.81, -4.21)			-6.70 (-10.18, -3.22)	0.69 (-2.92, 4.30)	0.7076		
Day 169			-6.10 (-7.91, -4.29)			-7.55 (-11.97, -3.14)	1.45 (-3.07, 5.97)	0.5277		
Day 211			-6.19 (-8.08, -4.30)			-8.41 (-13.94, -2.87)	2.22 (-3.43, 7.86)	0.4403		
Day 253			-6.28 (-8.31, -4.24)			-9.26 (-16.00, -2.51)	2.98 (-3.89, 9.86)	0.3945		
Day 295			-6.37 (-8.60, -4.13)			-10.11 (-18.12, -2.10)	3.75 (-4.42, 11.91)	0.3679		
Day 337			-6.45 (-8.92, -3.99)			-10.96 (-20.27, -1.66)	4.51 (-4.99, 14.00)	0.3511		
Day 379			-6.54 (-9.27, -3.81)			-11.82 (-22.43, -1.20)	5.27 (-5.57, 16.12)	0.3398		
Day 421			-6.63 (-9.65, -3.62)			-12.67 (-24.61, -0.73)	6.04 (-6.17, 18.25)	0.3317		
Day 463			-6.72 (-10.03, -3.41)			-13.52 (-26.80, -0.24)	6.80 (-6.78, 20.39)	0.3257		
OVERALL	123	2	-6.05 (-7.84, -4.26)	54	8	-7.08 (-10.95, -3.22)	1.03 (-2.95, 5.02)	0.6105	0.09 (-0.23, 0.41)	0.5851

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, region as stratification factor, time of visit (days), and treatment by time of visit interaction.
OVERALL: Results over the following visits: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] N_MISS displays number of subjects not included in MMRM.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-G Total Score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Region									0.0246
Japan	98	-3.78 (-5.24, -2.33)	45	-2.81 (-6.46, 0.83)	-0.97 (-4.90, 2.97)	0.6286	-0.11 (-0.46, 0.25)	0.5595	
Korea	25	-6.48 (-11.04, -1.93)	9	-20.90 (-33.53, -8.27)	14.42 (1.00, 27.84)	0.0356	1.06 (0.26, 1.86)	0.0095	
Lines of prior systemic therapy									0.6581
2	64	-3.12 (-5.22, -1.02)	34	-4.48 (-8.67, -0.29)	1.36 (-3.36, 6.08)	0.5697	0.14 (-0.28, 0.55)	0.5213	
3	34	-4.52 (-7.32, -1.72)	16	-6.10 (-12.87, 0.68)	1.58 (-5.76, 8.92)	0.6702	0.15 (-0.44, 0.75)	0.6099	
>=4	25	-6.99 (-10.51, -3.47)	4	-0.00 (-20.49, 20.49)	-6.99 (-27.79, 13.81)	0.5055	-0.66 (-1.73, 0.41)	0.2279	
Age									0.9586
<65 years	54	-4.66 (-6.94, -2.37)	25	-7.77 (-14.18, -1.36)	3.11 (-3.71, 9.94)	0.3693	0.27 (-0.20, 0.75)	0.2635	
>=65 years	69	-4.15 (-6.12, -2.17)	29	-3.95 (-8.60, 0.70)	-0.20 (-5.25, 4.86)	0.9389	-0.02 (-0.45, 0.41)	0.9275	
Sex									0.8745
female	29	-4.71 (-8.44, -0.99)	12	-5.53 (-15.59, 4.52)	0.82 (-9.89, 11.53)	0.8797	0.07 (-0.61, 0.74)	0.8491	
male	94	-4.26 (-5.92, -2.61)	42	-5.28 (-9.39, -1.17)	1.02 (-3.43, 5.47)	0.6529	0.10 (-0.26, 0.46)	0.5874	
ECOG PS									0.3292
0	61	-3.80 (-5.51, -2.08)	27	-3.26 (-8.44, 1.91)	-0.53 (-6.00, 4.93)	0.8475	-0.06 (-0.51, 0.40)	0.8057	
1	62	-4.83 (-7.30, -2.37)	27	-6.72 (-11.68, -1.77)	1.89 (-3.65, 7.43)	0.5006	0.17 (-0.28, 0.63)	0.4501	
HER2 Status in central laboratory									0.2516
IHC 3+	95	-3.97 (-5.72, -2.22)	41	-5.62 (-10.29, -0.96)	1.65 (-3.35, 6.65)	0.5157	0.15 (-0.22, 0.52)	0.4217	
IHC 2+/ISH +	28	-5.77 (-8.72, -2.83)	13	-3.28 (-8.58, 2.01)	-2.49 (-8.55, 3.57)	0.4136	-0.30 (-0.96, 0.36)	0.3758	
Primary tumor location									0.9559
Gastric	106	-4.48 (-6.13, -2.83)	49	-5.19 (-9.14, -1.25)	0.71 (-3.58, 5.00)	0.7439	0.07 (-0.27, 0.41)	0.6976	
GEJ	17	-3.38 (-6.66, -0.10)	5	-7.11 (-20.56, 6.35)	3.73 (-10.12, 17.57)	0.5932	0.42 (-0.59, 1.42)	0.4153	
Histological subtype									0.2157
intestinal	88	-3.38 (-4.90, -1.85)	35	-3.47 (-7.32, 0.37)	0.10 (-4.05, 4.24)	0.9639	0.01 (-0.38, 0.40)	0.9561	
diffuse	28	-6.59 (-10.77, -2.40)	14	-11.64 (-23.98, 0.69)	5.06 (-8.02, 18.14)	0.4450	0.32 (-0.33, 0.96)	0.3381	
others	7	-6.71 (-13.89, 0.47)	5	-4.92 (-18.49, 8.64)	-1.79 (-17.56, 13.99)	0.8105	-0.16 (-1.31, 0.99)	0.7814	
Number of metastatic sites									0.1486
<2	22	-4.08 (-7.04, -1.13)	10	1.84 (-4.89, 8.57)	-5.92 (-13.30, 1.46)	0.1130	-0.73 (-1.50, 0.04)	0.0634	
>= 2	101	-4.37 (-6.08, -2.65)	44	-8.57 (-13.08, -4.06)	4.20 (-0.63, 9.03)	0.0880	0.38 (0.02, 0.74)	0.0371	
Previous total gastrectomy									0.0750
yes	22	-5.79 (-10.09, -1.48)	8	4.54 (-11.24, 20.32)	-10.33 (-26.69, 6.04)	0.2131	-0.73 (-1.56, 0.10)	0.0833	
no	101	-3.96 (-5.51, -2.40)	46	-5.90 (-9.62, -2.18)	1.94 (-2.10, 5.99)	0.3442	0.20 (-0.15, 0.55)	0.2608	
Prior adjuvant/ neoadjuvant therapy									0.4956
yes	30	-3.81 (-6.96, -0.65)	7	-2.44 (-16.21, 11.32)	-1.37 (-15.48, 12.75)	0.8484	-0.13 (-0.95, 0.70)	0.7649	
no	93	-4.40 (-6.08, -2.72)	47	-5.19 (-8.86, -1.51)	0.79 (-3.27, 4.85)	0.7014	0.08 (-0.27, 0.43)	0.6576	
Prior ramucirumab contained treatment									0.0245
yes	92	-5.21 (-6.70, -3.72)	36	-6.13 (-10.92, -1.33)	0.92 (-4.10, 5.94)	0.7191	0.09 (-0.29, 0.48)	0.6355	
no	31	-1.85 (-5.98, 2.28)	18	-5.82 (-12.43, 0.80)	3.97 (-3.95, 11.88)	0.3192	0.32 (-0.26, 0.90)	0.2834	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

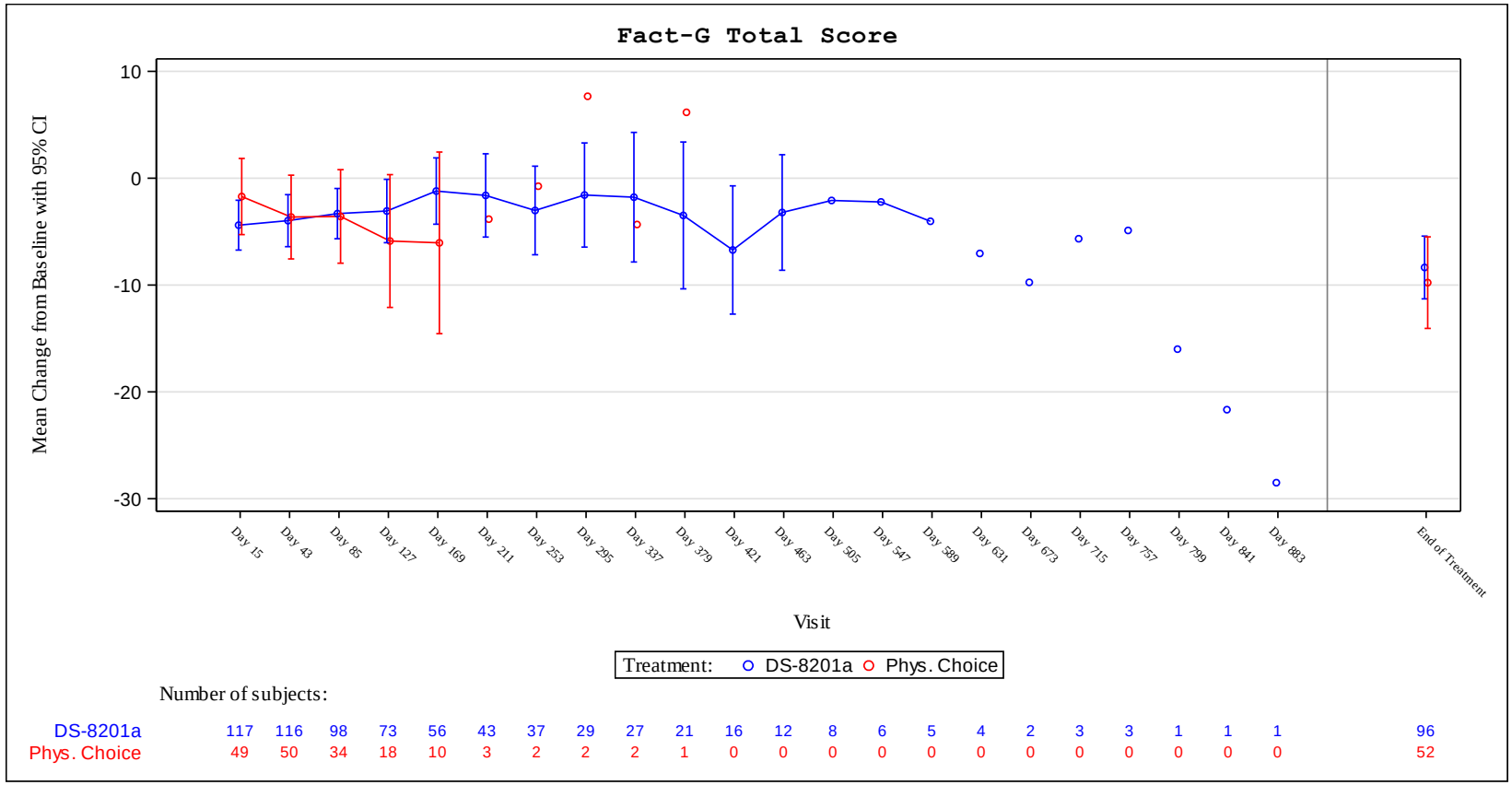
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Mixed Model Analysis of Change from Baseline of Fact-G Total Score - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) N [a]	DS-8201a (N=125) LSMean (95% CI)	Phys. Choice (N=62) N [a]	Phys. Choice (N=62) LSMean (95% CI)	Difference of LSMeans (95% CI)	p-Value	Hedges' g (95% CI)	p-Value	Interaction p-Value [b]
Prior nivolumab contained treatment									0.4166
yes	33	-5.09 (-7.46, -2.72)	12	-5.44 (-13.22, 2.34)	0.35 (-7.78, 8.49)	0.9312	0.04 (-0.62, 0.70)	0.9073	
no	90	-3.93 (-5.83, -2.03)	42	-5.16 (-9.34, -0.97)	1.23 (-3.39, 5.85)	0.6014	0.11 (-0.25, 0.48)	0.5436	
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									0.3910
yes	44	-5.36 (-7.78, -2.94)	13	-6.26 (-14.71, 2.18)	0.90 (-7.89, 9.69)	0.8390	0.09 (-0.53, 0.71)	0.7771	
no	79	-3.59 (-5.49, -1.69)	41	-4.84 (-8.73, -0.96)	1.26 (-3.09, 5.60)	0.5685	0.12 (-0.25, 0.50)	0.5178	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug									0.4026
yes	22	-1.29 (-5.12, 2.55)	5	0.03 (-11.05, 11.12)	-1.32 (-13.08, 10.43)	0.8217	-0.14 (-1.11, 0.83)	0.7760	
no	101	-4.89 (-6.51, -3.27)	49	-5.82 (-9.83, -1.81)	0.93 (-3.41, 5.27)	0.6729	0.09 (-0.25, 0.43)	0.6138	
Presence of liver metastasis at baseline									0.3893
yes	68	-3.84 (-5.66, -2.02)	29	-8.75 (-13.82, -3.68)	4.91 (-0.48, 10.30)	0.0740	0.50 (0.06, 0.94)	0.0263	
no	55	-4.84 (-7.32, -2.36)	25	-2.21 (-7.82, 3.40)	-2.63 (-8.78, 3.52)	0.3987	-0.24 (-0.71, 0.23)	0.3222	
Renal impairment at baseline									0.3136
normal	33	-5.65 (-8.74, -2.56)	12	-19.19 (-33.93, -4.44)	13.54 (-1.52, 28.59)	0.0777	0.89 (0.21, 1.58)	0.0106	
mild	53	-2.98 (-5.35, -0.61)	25	-2.01 (-6.44, 2.41)	-0.97 (-6.01, 4.08)	0.7048	-0.10 (-0.58, 0.37)	0.6764	
moderate	37	-4.73 (-7.14, -2.32)	16	-7.25 (-13.73, -0.77)	2.52 (-4.39, 9.44)	0.4709	0.27 (-0.32, 0.86)	0.3711	
severe	0	NE	1	NE	NE		NE		
Hepatic impairment at baseline									0.3428
normal	86	-3.90 (-5.62, -2.18)	40	-5.30 (-9.52, -1.08)	1.40 (-3.17, 5.97)	0.5466	0.14 (-0.24, 0.51)	0.4704	
mild	36	-5.58 (-8.52, -2.65)	14	-4.55 (-12.44, 3.33)	-1.03 (-9.48, 7.43)	0.8093	-0.10 (-0.71, 0.52)	0.7613	
moderate	1	NE	0	NE	NE		NE		
Prior treatment with irinotecan or other topoisomerase I inhibitors									0.1815
yes	8	-6.92 (-11.92, -1.92)	4	2.26 (-7.73, 12.25)	-9.18 (-20.82, 2.45)	0.1113	-1.27 (-2.57, 0.04)	0.0568	
no	115	-4.08 (-5.62, -2.55)	50	-7.53 (-11.68, -3.38)	3.45 (-0.98, 7.88)	0.1268	0.32 (-0.01, 0.65)	0.0597	
Most recently treatment with irinotecan or other topoisomerase I inhibitors									0.4987
yes	3	-4.12 (-22.72, 14.48)	3	-1.36 (-20.25, 17.54)	-2.76 (-30.68, 25.15)	0.7711	-0.28 (-1.89, 1.33)	0.7328	
no	120	-4.35 (-5.86, -2.84)	51	-7.96 (-12.34, -3.59)	3.61 (-1.02, 8.24)	0.1263	0.32 (-0.01, 0.65)	0.0538	

Results based on a linear MMRM to assess the treatment effect over time including terms for treatment, baseline value, time of visit (days), and treatment by time of visit interaction.
Only OVERALL results over the following visits are presented: Day 15, Day 43, Day 85, Day 127, Day 169, Day 211, Day 253, Day 295, Day 337, Day 379, Day 421, Day 463, Day 505, Day 547, Day 589, Day 631, Day 673, Day 715, Day 757, Day 799, Day 841 and Day 883
An AR(1) covariance structure is used to model the correlation within patients.
Table displays overall treatment estimates.
NE: Not estimable.
[a] N displays number of subjects included in MMRM.
[b] P-value obtained from the same linear MMRM plus a treatment subgroup interaction term.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Graphical Summary of Fact-G Total Score by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADFACTG

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	43 (34.4)	15 (24.2)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	11.3 (7.0, NE)	5.7 (4.3, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.95 (0.52, 1.74)	
p-value [c]	0.8645	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.99 (0.54, 1.79)	
p-value [c]	0.9540	

Time to Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.1984
Japan	32/ 99 (32.3)	NE (7.0, NE)	10/ 50 (20.0)	11.4 (4.3, NE)	1.24 (0.61, 2.56)	0.5580	
Korea	11/ 26 (42.3)	8.4 (4.3, NE)	5/ 12 (41.7)	3.3 (0.5, NE)	0.42 (0.13, 1.32)	0.1263	
Lines of prior systemic therapy							0.4878
2	21/ 66 (31.8)	11.3 (7.0, NE)	7/ 38 (18.4)	NE (4.3, NE)	1.15 (0.48, 2.78)	0.7558	
3	11/ 34 (32.4)	NE (4.1, NE)	6/ 18 (33.3)	5.7 (2.6, 11.4)	0.65 (0.23, 1.81)	0.3925	
>=4	11/ 25 (44.0)	NE (1.6, NE)	2/ 6 (33.3)	1.1 (0.6, NE)	0.54 (0.12, 2.50)	0.4241	
Age							0.9559
<65 years	18/ 55 (32.7)	NE (5.8, NE)	6/ 27 (22.2)	NE (2.6, NE)	1.06 (0.41, 2.75)	0.9128	
>=65 years	25/ 70 (35.7)	11.0 (5.9, NE)	9/ 35 (25.7)	5.7 (3.3, NE)	0.99 (0.46, 2.13)	0.9752	
Sex							0.2670
female	13/ 30 (43.3)	7.0 (3.1, 11.0)	2/ 15 (13.3)	5.7 (NE , NE)	1.48 (0.31, 6.96)	0.6165	
male	30/ 95 (31.6)	NE (8.4, NE)	13/ 47 (27.7)	11.4 (3.3, NE)	0.87 (0.45, 1.68)	0.6716	
ECOG PS							0.7164
0	20/ 62 (32.3)	NE (7.0, NE)	7/ 30 (23.3)	5.7 (5.4, NE)	0.96 (0.40, 2.31)	0.9171	
1	23/ 63 (36.5)	8.4 (4.3, NE)	8/ 32 (25.0)	11.4 (3.3, 11.4)	1.08 (0.48, 2.44)	0.8467	
HER2 Status in central laboratory							0.1178
IHC 3+	34/ 96 (35.4)	NE (7.0, NE)	14/ 47 (29.8)	5.4 (3.3, NE)	0.79 (0.42, 1.49)	0.4503	
IHC 2+/ISH +	9/ 29 (31.0)	8.4 (4.0, NE)	1/ 15 (6.7)	5.7 (NE , NE)	3.38 (0.41, 27.74)	0.2296	
Primary tumor location							0.9880
Gastric	37/108 (34.3)	11.0 (5.9, NE)	15/ 55 (27.3)	5.7 (4.3, NE)	0.89 (0.48, 1.64)	0.6978	
GEJ	6/ 17 (35.3)	NE (1.5, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.7036
intestinal	29/ 89 (32.6)	11.0 (5.9, NE)	8/ 38 (21.1)	5.7 (4.3, NE)	1.10 (0.50, 2.44)	0.8154	
diffuse	11/ 28 (39.3)	NE (1.6, NE)	5/ 18 (27.8)	3.3 (1.5, NE)	0.94 (0.32, 2.78)	0.9101	
others	3/ 8 (37.5)	11.3 (0.5, 11.3)	2/ 6 (33.3)	NE (1.4, NE)	1.12 (0.15, 8.11)	0.9176	
Number of metastatic sites							0.9880
<2	9/ 23 (39.1)	11.0 (4.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	34/102 (33.3)	11.3 (5.9, NE)	15/ 52 (28.8)	5.4 (3.3, 11.4)	0.78 (0.42, 1.45)	0.4295	
Previous total gastrectomy							0.5127
yes	6/ 22 (27.3)	NE (1.4, NE)	1/ 9 (11.1)	NE (3.3, NE)	2.43 (0.29, 20.21)	0.3969	
no	37/103 (35.9)	11.0 (5.9, NE)	14/ 53 (26.4)	5.7 (4.3, NE)	0.89 (0.48, 1.67)	0.7154	
Prior adjuvant/ neoadjuvant therapy							0.9858
yes	10/ 30 (33.3)	NE (5.5, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	33/ 95 (34.7)	11.3 (5.8, NE)	15/ 52 (28.8)	5.7 (3.3, NE)	0.92 (0.49, 1.71)	0.7829	
Prior ramucirumab contained treatment							0.4032
yes	34/ 94 (36.2)	11.3 (5.5, NE)	9/ 41 (22.0)	5.7 (5.4, 11.4)	1.19 (0.56, 2.51)	0.6590	
no	9/ 31 (29.0)	NE (7.0, NE)	6/ 21 (28.6)	4.3 (3.1, NE)	0.61 (0.21, 1.77)	0.3523	
Prior nivolumab contained treatment							0.2744
yes	13/ 33 (39.4)	NE (3.4, NE)	6/ 15 (40.0)	5.7 (1.2, 11.4)	0.63 (0.24, 1.68)	0.3494	
no	30/ 92 (32.6)	11.0 (7.0, NE)	9/ 47 (19.1)	NE (4.3, NE)	1.18 (0.55, 2.54)	0.6705	

Time to Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

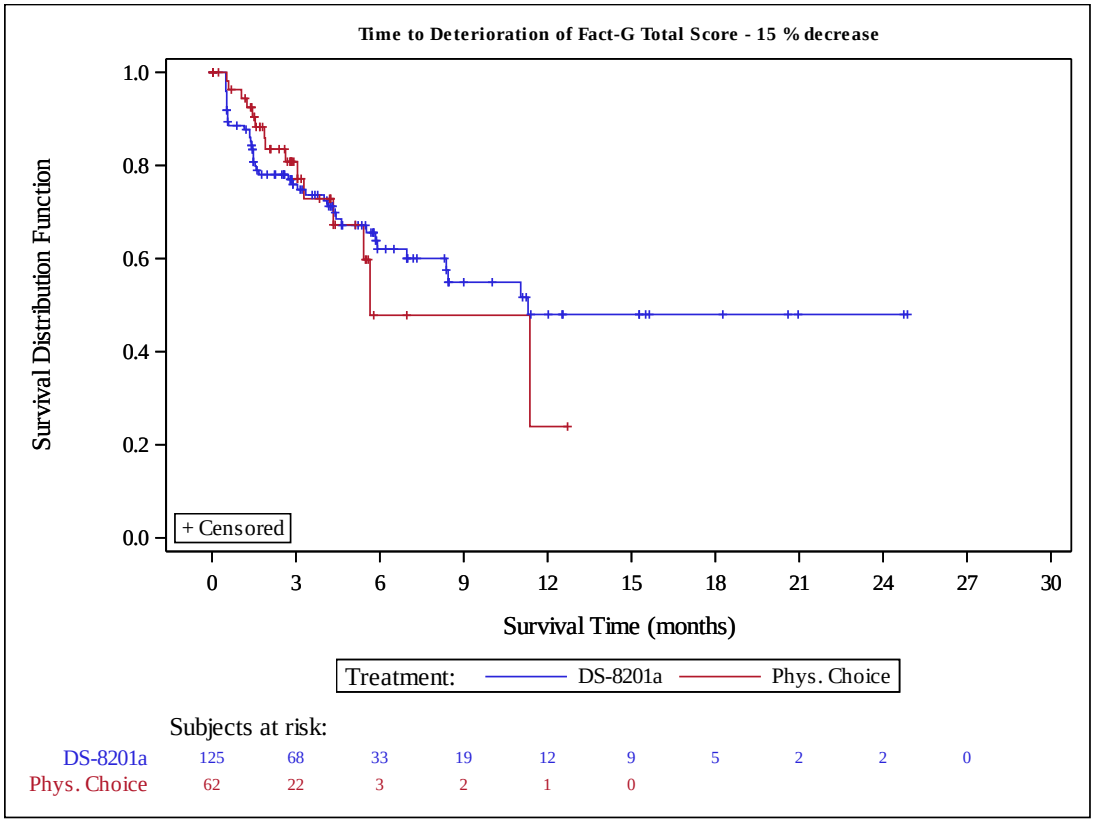
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.2638
yes	16/ 44 (36.4)	NE (4.0, NE)	6/ 17 (35.3)	5.7 (1.2, 11.4)	0.68 (0.26, 1.75)	0.4160	
no	27/ 81 (33.3)	11.0 (5.9, NE)	9/ 45 (20.0)	NE (4.3, NE)	1.16 (0.53, 2.52)	0.7133	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9885
yes	4/ 22 (18.2)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	39/103 (37.9)	11.0 (5.8, NE)	15/ 55 (27.3)	5.7 (4.3, NE)	0.95 (0.51, 1.74)	0.8485	
Presence of liver metastasis at baseline							0.3192
yes	22/ 68 (32.4)	11.0 (5.8, NE)	10/ 34 (29.4)	5.4 (3.3, 11.4)	0.72 (0.34, 1.56)	0.3965	
no	21/ 57 (36.8)	11.3 (5.5, NE)	5/ 28 (17.9)	NE (NE , NE)	1.50 (0.56, 4.05)	0.4159	
Renal impairment at baseline							0.4387
normal	11/ 33 (33.3)	11.3 (5.5, NE)	4/ 13 (30.8)	NE (1.5, NE)	0.60 (0.17, 2.06)	0.4086	
mild	19/ 53 (35.8)	NE (4.6, NE)	5/ 28 (17.9)	11.4 (4.3, NE)	1.67 (0.62, 4.51)	0.3058	
moderate	13/ 39 (33.3)	8.4 (4.3, NE)	6/ 20 (30.0)	5.4 (3.1, NE)	0.67 (0.24, 1.87)	0.4372	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.6709
normal	33/ 88 (37.5)	11.3 (7.0, NE)	12/ 47 (25.5)	5.7 (3.3, NE)	0.92 (0.46, 1.81)	0.7981	
mild	10/ 36 (27.8)	NE (4.3, NE)	3/ 15 (20.0)	11.4 (1.2, 11.4)	1.27 (0.35, 4.66)	0.7233	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.6629
yes	3/ 8 (37.5)	8.4 (0.5, NE)	1/ 5 (20.0)	NE (1.1, NE)	1.42 (0.15, 13.72)	0.7629	
no	40/117 (34.2)	11.3 (5.9, NE)	14/ 57 (24.6)	5.7 (4.3, 11.4)	0.93 (0.50, 1.75)	0.8239	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9878
yes	1/ 3 (33.3)	NE (8.4, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	42/122 (34.4)	11.3 (5.9, NE)	15/ 58 (25.9)	5.7 (4.3, 11.4)	0.90 (0.49, 1.65)	0.7228	

Time to Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of the earliest deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	32 (25.6)	14 (22.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	16.7 (11.0, NE)	11.4 (4.3, NE)
Analysis DS-8201a vs. Phys. Choice (stratified)		
Hazard Ratio (95% CI) [b]	0.52 (0.27, 1.01)	
p-value [c]	0.0502	
Analysis DS-8201a vs. Phys. Choice (unstratified)		
Hazard Ratio (95% CI) [b]	0.55 (0.29, 1.07)	
p-value [c]	0.0751	

Time to Definitive Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
Stratification variable: Region (Japan vs. Korea). NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Region							0.2159
Japan	23/ 99 (23.2)	16.7 (11.2, NE)	9/ 50 (18.0)	11.4 (5.7, NE)	0.68 (0.30, 1.52)	0.3349	
Korea	9/ 26 (34.6)	8.4 (5.9, NE)	5/ 12 (41.7)	3.3 (0.5, NE)	0.26 (0.07, 0.91)	0.0242	
Lines of prior systemic therapy							0.3777
2	17/ 66 (25.8)	NE (7.3, NE)	7/ 38 (18.4)	NE (4.3, NE)	0.78 (0.31, 1.95)	0.5877	
3	7/ 34 (20.6)	16.7 (11.2, NE)	6/ 18 (33.3)	5.7 (2.6, 11.4)	0.27 (0.08, 0.87)	0.0208	
>=4	8/ 25 (32.0)	12.8 (7.0, NE)	1/ 6 (16.7)	NE (1.1, NE)	0.65 (0.08, 5.62)	0.6949	
Age							0.7112
<65 years	14/ 55 (25.5)	NE (7.0, NE)	5/ 27 (18.5)	NE (NE , NE)	0.75 (0.26, 2.20)	0.6005	
>=65 years	18/ 70 (25.7)	12.8 (8.4, NE)	9/ 35 (25.7)	5.7 (3.3, NE)	0.48 (0.21, 1.10)	0.0761	
Sex							0.1729
female	11/ 30 (36.7)	7.0 (4.2, NE)	2/ 15 (13.3)	5.7 (NE , NE)	0.94 (0.19, 4.68)	0.9433	
male	21/ 95 (22.1)	NE (12.8, NE)	12/ 47 (25.5)	11.4 (4.3, NE)	0.45 (0.21, 0.95)	0.0312	
ECOG PS							0.9999
0	16/ 62 (25.8)	16.7 (11.0, NE)	6/ 30 (20.0)	NE (5.4, NE)	0.55 (0.20, 1.51)	0.2410	
1	16/ 63 (25.4)	NE (7.3, NE)	8/ 32 (25.0)	11.4 (3.3, 11.4)	0.60 (0.25, 1.43)	0.2381	
HER2 Status in central laboratory							0.0824
IHC 3+	24/ 96 (25.0)	NE (11.0, NE)	13/ 47 (27.7)	11.4 (3.3, NE)	0.43 (0.21, 0.87)	0.0162	
IHC 2+/ISH +	8/ 29 (27.6)	8.4 (5.9, 11.2)	1/ 15 (6.7)	5.7 (NE , NE)	1.68 (0.18, 15.58)	0.6454	
Primary tumor location							0.9858
Gastric	27/108 (25.0)	16.7 (8.4, NE)	14/ 55 (25.5)	5.7 (4.3, NE)	0.48 (0.24, 0.94)	0.0291	
GEJ	5/ 17 (29.4)	NE (3.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.8552
intestinal	22/ 89 (24.7)	16.7 (8.4, NE)	8/ 38 (21.1)	5.7 (4.3, NE)	0.55 (0.23, 1.27)	0.1550	
diffuse	8/ 28 (28.6)	NE (7.0, NE)	4/ 18 (22.2)	NE (1.5, NE)	0.66 (0.19, 2.38)	0.5158	
others	2/ 8 (25.0)	NE (0.5, NE)	2/ 6 (33.3)	NE (1.4, NE)	0.82 (0.11, 5.98)	0.8429	
Number of metastatic sites							0.9856
<2	6/ 23 (26.1)	12.8 (8.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	26/102 (25.5)	16.7 (8.4, NE)	14/ 52 (26.9)	5.7 (3.3, 11.4)	0.48 (0.24, 0.95)	0.0311	
Previous total gastrectomy							0.4381
yes	5/ 22 (22.7)	NE (7.2, NE)	1/ 9 (11.1)	NE (3.3, NE)	1.51 (0.17, 13.51)	0.7157	
no	27/103 (26.2)	16.7 (11.0, NE)	13/ 53 (24.5)	11.4 (4.3, NE)	0.49 (0.24, 0.98)	0.0398	
Prior adjuvant/ neoadjuvant therapy							0.9889
yes	9/ 30 (30.0)	12.8 (5.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	23/ 95 (24.2)	16.7 (8.4, NE)	14/ 52 (26.9)	5.7 (4.3, NE)	0.52 (0.26, 1.05)	0.0624	
Prior ramucirumab contained treatment							0.4898
yes	25/ 94 (26.6)	16.7 (11.0, NE)	8/ 41 (19.5)	11.4 (5.4, 11.4)	0.69 (0.30, 1.58)	0.3714	
no	7/ 31 (22.6)	12.8 (8.4, NE)	6/ 21 (28.6)	4.3 (3.1, NE)	0.35 (0.11, 1.15)	0.0699	
Prior nivolumab contained treatment							0.0471
yes	8/ 33 (24.2)	16.7 (11.2, NE)	6/ 15 (40.0)	5.7 (1.2, 11.4)	0.20 (0.06, 0.65)	0.0034	
no	24/ 92 (26.1)	NE (7.3, NE)	8/ 47 (17.0)	NE (4.3, NE)	0.87 (0.38, 1.99)	0.7374	

Time to Definitive Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

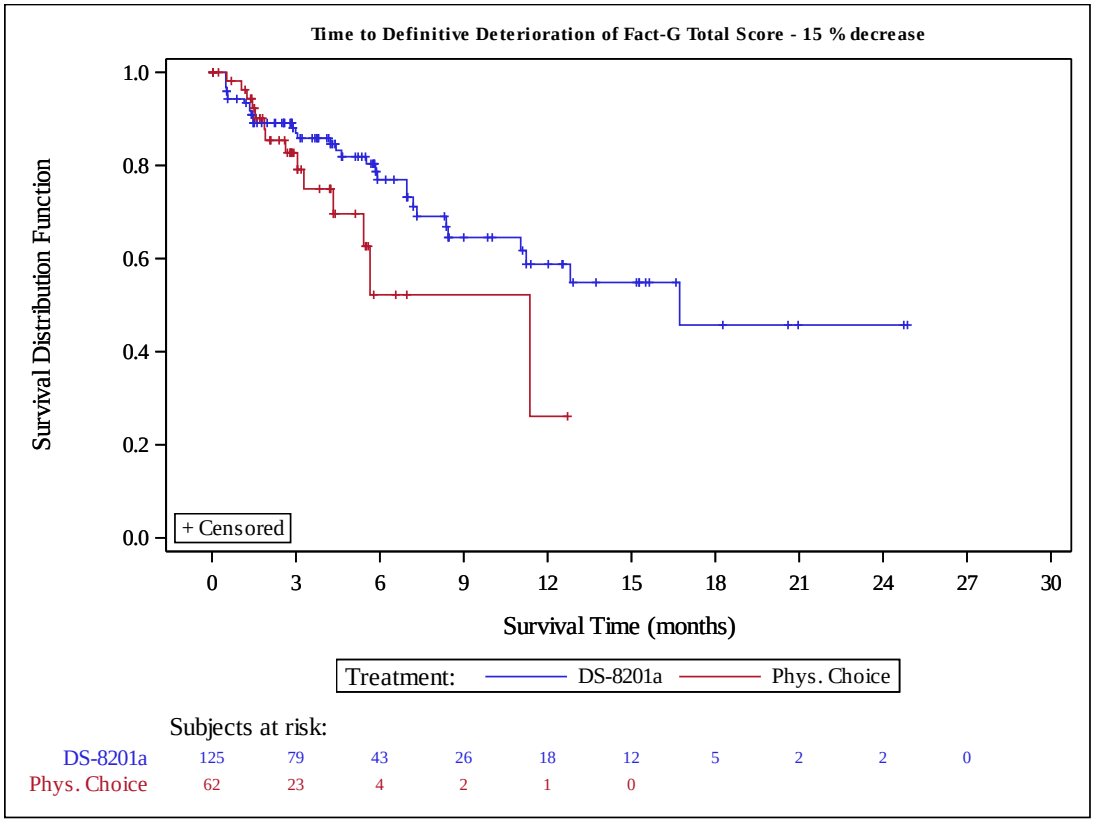
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease - Subgroup analysis
Full Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0754
yes	11/ 44 (25.0)	NE (12.8, NE)	6/ 17 (35.3)	5.7 (1.2, 11.4)	0.29 (0.10, 0.85)	0.0158	
no	21/ 81 (25.9)	11.0 (7.2, NE)	8/ 45 (17.8)	NE (4.3, NE)	0.79 (0.34, 1.86)	0.5920	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9869
yes	2/ 22 (9.1)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	30/103 (29.1)	12.8 (8.4, NE)	14/ 55 (25.5)	5.7 (4.3, NE)	0.55 (0.28, 1.07)	0.0737	
Presence of liver metastasis at baseline							0.1411
yes	16/ 68 (23.5)	16.7 (8.4, NE)	10/ 34 (29.4)	5.4 (3.3, 11.4)	0.38 (0.16, 0.88)	0.0187	
no	16/ 57 (28.1)	12.8 (7.3, NE)	4/ 28 (14.3)	NE (NE , NE)	0.99 (0.32, 3.12)	0.9872	
Renal impairment at baseline							0.3242
normal	8/ 33 (24.2)	NE (7.0, NE)	4/ 13 (30.8)	NE (1.5, NE)	0.15 (0.03, 0.70)	0.0060	
mild	14/ 53 (26.4)	12.8 (11.2, NE)	5/ 28 (17.9)	11.4 (4.3, NE)	1.01 (0.36, 2.85)	0.9976	
moderate	10/ 39 (25.6)	16.7 (7.3, NE)	5/ 20 (25.0)	5.7 (3.1, NE)	0.40 (0.12, 1.37)	0.1296	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.6624
normal	24/ 88 (27.3)	16.7 (11.0, NE)	11/ 47 (23.4)	5.7 (4.3, NE)	0.54 (0.25, 1.15)	0.1040	
mild	8/ 36 (22.2)	NE (7.0, NE)	3/ 15 (20.0)	11.4 (1.2, 11.4)	0.70 (0.18, 2.73)	0.5995	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4503
yes	3/ 8 (37.5)	8.4 (3.1, NE)	1/ 5 (20.0)	NE (1.1, NE)	1.12 (0.11, 10.88)	0.9248	
no	29/117 (24.8)	16.7 (11.2, NE)	13/ 57 (22.8)	5.7 (4.3, 11.4)	0.51 (0.26, 1.04)	0.0568	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9894
yes	1/ 3 (33.3)	NE (8.4, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	31/122 (25.4)	16.7 (11.0, NE)	14/ 58 (24.1)	5.7 (4.3, 11.4)	0.49 (0.25, 0.96)	0.0331	

Time to Definitive Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from unstratified Cox proportional hazards model with treatment as the only covariate.
[c] Two-sided p-value derived from unstratified log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

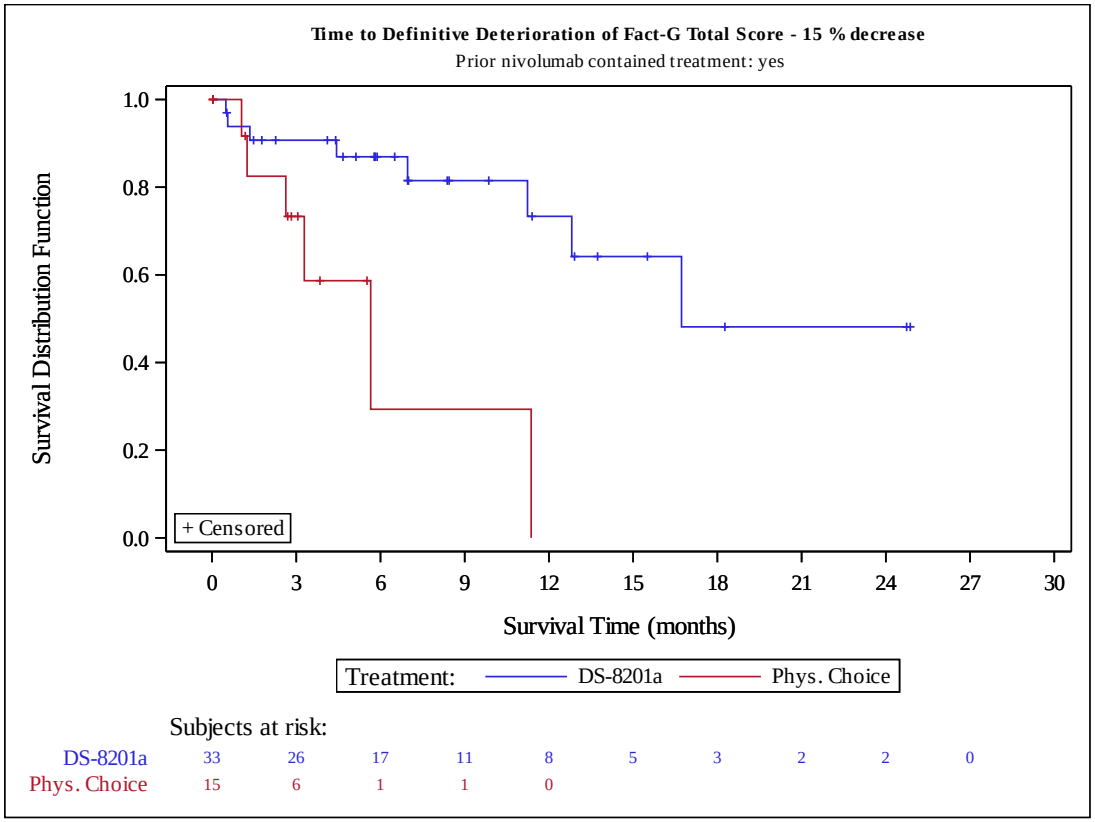
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
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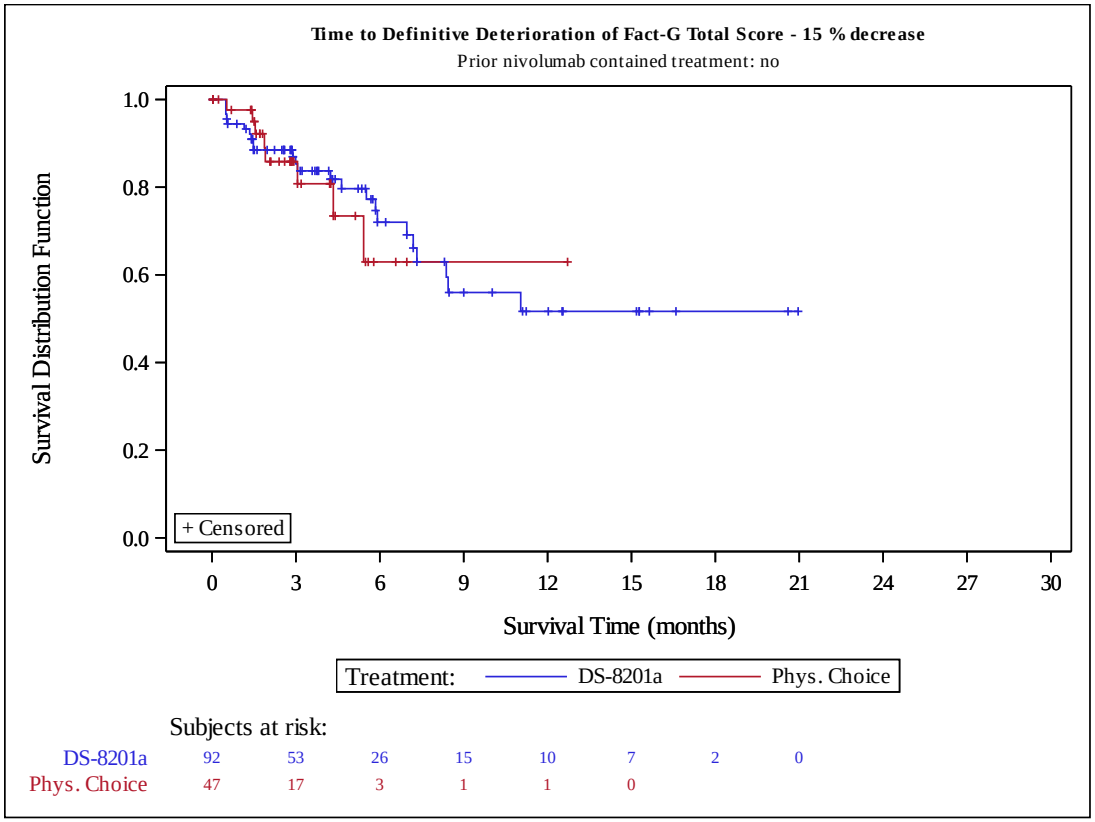
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall									
	Day 15	118	6 (5.1)	98 (83.1)	14 (11.9)	52	2 (3.8)	48 (92.3)	2 (3.8)
	Day 43	117	6 (5.1)	94 (80.3)	17 (14.5)	53	3 (5.7)	46 (86.8)	4 (7.5)
	Day 85	99	3 (3.0)	83 (83.8)	13 (13.1)	36	3 (8.3)	29 (80.6)	4 (11.1)
	Day 127	74	4 (5.4)	60 (81.1)	10 (13.5)	19	1 (5.3)	15 (78.9)	3 (15.8)
	Day 169	57	3 (5.3)	51 (89.5)	3 (5.3)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 211	44	5 (11.4)	34 (77.3)	5 (11.4)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	37	2 (5.4)	29 (78.4)	6 (16.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	29	4 (13.8)	23 (79.3)	2 (6.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	27	3 (11.1)	20 (74.1)	4 (14.8)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	21	2 (9.5)	15 (71.4)	4 (19.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	0 (0.0)	13 (81.3)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	0 (0.0)	11 (91.7)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	97	2 (2.1)	70 (72.2)	25 (25.8)	56	1 (1.8)	41 (73.2)	14 (25.0)
Region									
Japan									
	Day 15	96	4 (4.2)	81 (84.4)	11 (11.5)	45	2 (4.4)	42 (93.3)	1 (2.2)
	Day 43	93	6 (6.5)	74 (79.6)	13 (14.0)	43	2 (4.7)	40 (93.0)	1 (2.3)
	Day 85	77	2 (2.6)	66 (85.7)	9 (11.7)	32	3 (9.4)	26 (81.3)	3 (9.4)
	Day 127	60	2 (3.3)	52 (86.7)	6 (10.0)	16	1 (6.3)	13 (81.3)	2 (12.5)
	Day 169	49	3 (6.1)	43 (87.8)	3 (6.1)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	36	3 (8.3)	28 (77.8)	5 (13.9)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	29	1 (3.4)	24 (82.8)	4 (13.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	23	2 (8.7)	20 (87.0)	1 (4.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	21	1 (4.8)	18 (85.7)	2 (9.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	18	1 (5.6)	13 (72.2)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	0 (0.0)	10 (83.3)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	0 (0.0)	9 (90.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	78	1 (1.3)	61 (78.2)	16 (20.5)	48	1 (2.1)	38 (79.2)	9 (18.8)
Region									
Korea									
	Day 15	22	2 (9.1)	17 (77.3)	3 (13.6)	7	0 (0.0)	6 (85.7)	1 (14.3)
	Day 43	24	0 (0.0)	20 (83.3)	4 (16.7)	10	1 (10.0)	6 (60.0)	3 (30.0)
	Day 85	22	1 (4.5)	17 (77.3)	4 (18.2)	4	0 (0.0)	3 (75.0)	1 (25.0)
	Day 127	14	2 (14.3)	8 (57.1)	4 (28.6)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	8	0 (0.0)	8 (100.0)	0 (0.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	2 (25.0)	6 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	6	2 (33.3)	3 (50.0)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	6	2 (33.3)	2 (33.3)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	19	1 (5.3)	9 (47.4)	9 (47.4)	8	0 (0.0)	3 (37.5)	5 (62.5)
Lines of prior systemic therapy 2									
	Day 15	60	3 (5.0)	52 (86.7)	5 (8.3)	34	0 (0.0)	33 (97.1)	1 (2.9)
	Day 43	62	4 (6.5)	50 (80.6)	8 (12.9)	36	1 (2.8)	33 (91.7)	2 (5.6)
	Day 85	50	2 (4.0)	42 (84.0)	6 (12.0)	21	0 (0.0)	19 (90.5)	2 (9.5)
	Day 127	33	1 (3.0)	28 (84.8)	4 (12.1)	14	0 (0.0)	12 (85.7)	2 (14.3)
	Day 169	24	1 (4.2)	22 (91.7)	1 (4.2)	6	0 (0.0)	5 (83.3)	1 (16.7)
	Day 211	21	2 (9.5)	18 (85.7)	1 (4.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	18	1 (5.6)	14 (77.8)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	2 (16.7)	9 (75.0)	1 (8.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	8 (72.7)	2 (18.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	7	1 (14.3)	6 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	51	1 (2.0)	38 (74.5)	12 (23.5)	34	0 (0.0)	27 (79.4)	7 (20.6)
Lines of prior systemic therapy 3									
	Day 15	34	2 (5.9)	26 (76.5)	6 (17.6)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 43	33	1 (3.0)	29 (87.9)	3 (9.1)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 85	28	1 (3.6)	24 (85.7)	3 (10.7)	12	2 (16.7)	8 (66.7)	2 (16.7)
	Day 127	23	2 (8.7)	18 (78.3)	3 (13.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	19	1 (5.3)	16 (84.2)	2 (10.5)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	13	2 (15.4)	9 (69.2)	2 (15.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	0 (0.0)	10 (90.9)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	9	1 (11.1)	8 (88.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	0 (0.0)	19 (73.1)	7 (26.9)	17	1 (5.9)	10 (58.8)	6 (35.3)
Lines of prior systemic therapy >=4									
	Day 15	24	1 (4.2)	20 (83.3)	3 (12.5)	4	1 (25.0)	2 (50.0)	1 (25.0)
	Day 43	22	1 (4.5)	15 (68.2)	6 (27.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	21	0 (0.0)	17 (81.0)	4 (19.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	18	1 (5.6)	14 (77.8)	3 (16.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 169	14	1 (7.1)	13 (92.9)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 421	5	0 (0.0)	2 (40.0)	3 (60.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	20	1 (5.0)	13 (65.0)	6 (30.0)	5	0 (0.0)	4 (80.0)	1 (20.0)
Age									
<65 years									
	Day 15	51	3 (5.9)	42 (82.4)	6 (11.8)	22	0 (0.0)	21 (95.5)	1 (4.5)
	Day 43	52	3 (5.8)	41 (78.8)	8 (15.4)	24	1 (4.2)	21 (87.5)	2 (8.3)
	Day 85	47	1 (2.1)	40 (85.1)	6 (12.8)	16	0 (0.0)	14 (87.5)	2 (12.5)
	Day 127	34	2 (5.9)	28 (82.4)	4 (11.8)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 169	27	1 (3.7)	23 (85.2)	3 (11.1)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	18	2 (11.1)	12 (66.7)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	16	1 (6.3)	12 (75.0)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	13	2 (15.4)	10 (76.9)	1 (7.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	42	1 (2.4)	29 (69.0)	12 (28.6)	23	0 (0.0)	18 (78.3)	5 (21.7)
Age									
>=65 years									
	Day 15	67	3 (4.5)	56 (83.6)	8 (11.9)	30	2 (6.7)	27 (90.0)	1 (3.3)
	Day 43	65	3 (4.6)	53 (81.5)	9 (13.8)	29	2 (6.9)	25 (86.2)	2 (6.9)
	Day 85	52	2 (3.8)	43 (82.7)	7 (13.5)	20	3 (15.0)	15 (75.0)	2 (10.0)
	Day 127	40	2 (5.0)	32 (80.0)	6 (15.0)	11	1 (9.1)	9 (81.8)	1 (9.1)
	Day 169	30	2 (6.7)	28 (93.3)	0 (0.0)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	26	3 (11.5)	22 (84.6)	1 (3.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	21	1 (4.8)	17 (81.0)	3 (14.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	16	2 (12.5)	13 (81.3)	1 (6.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	2 (12.5)	11 (68.8)	3 (18.8)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	13	1 (7.7)	9 (69.2)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	0 (0.0)	6 (66.7)	3 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	End of Treatment	55	1 (1.8)	41 (74.5)	13 (23.6)	33	1 (3.0)	23 (69.7)	9 (27.3)
Sex									
female									
	Day 15	28	1 (3.6)	23 (82.1)	4 (14.3)	13	1 (7.7)	11 (84.6)	1 (7.7)
	Day 43	28	2 (7.1)	22 (78.6)	4 (14.3)	13	0 (0.0)	12 (92.3)	1 (7.7)
	Day 85	20	0 (0.0)	17 (85.0)	3 (15.0)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 127	13	2 (15.4)	8 (61.5)	3 (23.1)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	10	0 (0.0)	9 (90.0)	1 (10.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 211	8	0 (0.0)	6 (75.0)	2 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	22	0 (0.0)	14 (63.6)	8 (36.4)	14	1 (7.1)	11 (78.6)	2 (14.3)
Sex									
male									
	Day 15	90	5 (5.6)	75 (83.3)	10 (11.1)	39	1 (2.6)	37 (94.9)	1 (2.6)
	Day 43	89	4 (4.5)	72 (80.9)	13 (14.6)	40	3 (7.5)	34 (85.0)	3 (7.5)
	Day 85	79	3 (3.8)	66 (83.5)	10 (12.7)	28	2 (7.1)	22 (78.6)	4 (14.3)
	Day 127	61	2 (3.3)	52 (85.2)	7 (11.5)	16	0 (0.0)	13 (81.3)	3 (18.8)
	Day 169	47	3 (6.4)	42 (89.4)	2 (4.3)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 211	36	5 (13.9)	28 (77.8)	3 (8.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	30	2 (6.7)	25 (83.3)	3 (10.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	4 (16.0)	20 (80.0)	1 (4.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	3 (12.5)	18 (75.0)	3 (12.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	19	2 (10.5)	13 (68.4)	4 (21.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	15	0 (0.0)	12 (80.0)	3 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	10 (90.9)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	75	2 (2.7)	56 (74.7)	17 (22.7)	42	0 (0.0)	30 (71.4)	12 (28.6)
ECOG PS									
0									
	Day 15	60	2 (3.3)	53 (88.3)	5 (8.3)	26	0 (0.0)	25 (96.2)	1 (3.8)
	Day 43	59	3 (5.1)	49 (83.1)	7 (11.9)	26	2 (7.7)	24 (92.3)	0 (0.0)
	Day 85	54	0 (0.0)	47 (87.0)	7 (13.0)	19	1 (5.3)	17 (89.5)	1 (5.3)
	Day 127	42	1 (2.4)	40 (95.2)	1 (2.4)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 169	36	2 (5.6)	34 (94.4)	0 (0.0)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	27	2 (7.4)	22 (81.5)	3 (11.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	24	1 (4.2)	19 (79.2)	4 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	18	1 (5.6)	16 (88.9)	1 (5.6)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	14 (87.5)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	14	0 (0.0)	11 (78.6)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	48	1 (2.1)	37 (77.1)	10 (20.8)	29	0 (0.0)	23 (79.3)	6 (20.7)
ECOG PS									
1									
	Day 15	58	4 (6.9)	45 (77.6)	9 (15.5)	26	2 (7.7)	23 (88.5)	1 (3.8)
	Day 43	58	3 (5.2)	45 (77.6)	10 (17.2)	27	1 (3.7)	22 (81.5)	4 (14.8)
	Day 85	45	3 (6.7)	36 (80.0)	6 (13.3)	17	2 (11.8)	12 (70.6)	3 (17.6)
	Day 127	32	3 (9.4)	20 (62.5)	9 (28.1)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 169	21	1 (4.8)	17 (81.0)	3 (14.3)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	17	3 (17.6)	12 (70.6)	2 (11.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	13	1 (7.7)	10 (76.9)	2 (15.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	11	3 (27.3)	7 (63.6)	1 (9.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	2 (18.2)	6 (54.5)	3 (27.3)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	7	2 (28.6)	4 (57.1)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	49	1 (2.0)	33 (67.3)	15 (30.6)	27	1 (3.7)	18 (66.7)	8 (29.6)
HER2 Status in central laboratory									
IHC 3+									
	Day 15	91	6 (6.6)	73 (80.2)	12 (13.2)	38	1 (2.6)	35 (92.1)	2 (5.3)
	Day 43	91	6 (6.6)	73 (80.2)	12 (13.2)	40	2 (5.0)	34 (85.0)	4 (10.0)
	Day 85	79	3 (3.8)	66 (83.5)	10 (12.7)	26	2 (7.7)	20 (76.9)	4 (15.4)
	Day 127	59	3 (5.1)	48 (81.4)	8 (13.6)	13	0 (0.0)	10 (76.9)	3 (23.1)
	Day 169	46	3 (6.5)	40 (87.0)	3 (6.5)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	38	5 (13.2)	29 (76.3)	4 (10.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	32	2 (6.3)	26 (81.3)	4 (12.5)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	4 (15.4)	20 (76.9)	2 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	25	3 (12.0)	19 (76.0)	3 (12.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	19	2 (10.5)	15 (78.9)	2 (10.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	16	0 (0.0)	13 (81.3)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	0 (0.0)	11 (91.7)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	2 (2.7)	55 (74.3)	17 (23.0)	42	0 (0.0)	29 (69.0)	13 (31.0)
HER2 Status in central laboratory									
IHC 2+/ISH +									
	Day 15	27	0 (0.0)	25 (92.6)	2 (7.4)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 43	26	0 (0.0)	21 (80.8)	5 (19.2)	13	1 (7.7)	12 (92.3)	0 (0.0)
	Day 85	20	0 (0.0)	17 (85.0)	3 (15.0)	10	1 (10.0)	9 (90.0)	0 (0.0)
	Day 127	15	1 (6.7)	12 (80.0)	2 (13.3)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 169	11	0 (0.0)	11 (100.0)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	0 (0.0)	15 (65.2)	8 (34.8)	14	1 (7.1)	12 (85.7)	1 (7.1)
Primary tumor location									
Gastric									
	Day 15	102	6 (5.9)	83 (81.4)	13 (12.7)	46	2 (4.3)	42 (91.3)	2 (4.3)
	Day 43	100	5 (5.0)	82 (82.0)	13 (13.0)	48	3 (6.3)	41 (85.4)	4 (8.3)
	Day 85	84	2 (2.4)	72 (85.7)	10 (11.9)	33	3 (9.1)	26 (78.8)	4 (12.1)
	Day 127	63	4 (6.3)	49 (77.8)	10 (15.9)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	47	2 (4.3)	43 (91.5)	2 (4.3)	11	0 (0.0)	9 (81.8)	2 (18.2)
	Day 211	38	4 (10.5)	29 (76.3)	5 (13.2)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	31	2 (6.5)	23 (74.2)	6 (19.4)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	24	3 (12.5)	19 (79.2)	2 (8.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	22	3 (13.6)	15 (68.2)	4 (18.2)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	17	1 (5.9)	12 (70.6)	4 (23.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	0 (0.0)	10 (76.9)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	82	2 (2.4)	58 (70.7)	22 (26.8)	50	1 (2.0)	35 (70.0)	14 (28.0)
Primary tumor location									
GEJ									
	Day 15	16	0 (0.0)	15 (93.8)	1 (6.3)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 43	17	1 (5.9)	12 (70.6)	4 (23.5)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 85	15	1 (6.7)	11 (73.3)	3 (20.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	11	0 (0.0)	11 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	10	1 (10.0)	8 (80.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	6	1 (16.7)	5 (83.3)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	5	1 (20.0)	4 (80.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	4	1 (25.0)	3 (75.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	15	0 (0.0)	12 (80.0)	3 (20.0)	6	0 (0.0)	6 (100.0)	0 (0.0)
Histological subtype									
intestinal									
	Day 15	86	4 (4.7)	75 (87.2)	7 (8.1)	35	2 (5.7)	33 (94.3)	0 (0.0)
	Day 43	85	6 (7.1)	70 (82.4)	9 (10.6)	34	0 (0.0)	33 (97.1)	1 (2.9)
	Day 85	73	2 (2.7)	63 (86.3)	8 (11.0)	27	2 (7.4)	23 (85.2)	2 (7.4)
	Day 127	55	2 (3.6)	48 (87.3)	5 (9.1)	14	1 (7.1)	12 (85.7)	1 (7.1)
	Day 169	44	3 (6.8)	38 (86.4)	3 (6.8)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	32	3 (9.4)	25 (78.1)	4 (12.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	25	1 (4.0)	20 (80.0)	4 (16.0)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	18	2 (11.1)	15 (83.3)	1 (5.6)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	16	1 (6.3)	13 (81.3)	2 (12.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	13	1 (7.7)	9 (69.2)	3 (23.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	1 (1.4)	55 (76.4)	16 (22.2)	37	1 (2.7)	28 (75.7)	8 (21.6)
Histological subtype diffuse									
	Day 15	26	2 (7.7)	18 (69.2)	6 (23.1)	15	0 (0.0)	13 (86.7)	2 (13.3)
	Day 43	26	0 (0.0)	20 (76.9)	6 (23.1)	14	1 (7.1)	11 (78.6)	2 (14.3)
	Day 85	22	1 (4.5)	16 (72.7)	5 (22.7)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 127	15	2 (13.3)	9 (60.0)	4 (26.7)	3	0 (0.0)	1 (33.3)	2 (66.7)
	Day 169	11	0 (0.0)	11 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	10	2 (20.0)	7 (70.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	10	1 (10.0)	7 (70.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	9	2 (22.2)	6 (66.7)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	1 (50.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	21	1 (4.8)	13 (61.9)	7 (33.3)	16	0 (0.0)	12 (75.0)	4 (25.0)
Histological subtype others									
	Day 15	6	0 (0.0)	5 (83.3)	1 (16.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 43	6	0 (0.0)	4 (66.7)	2 (33.3)	5	2 (40.0)	2 (40.0)	1 (20.0)
	Day 85	4	0 (0.0)	4 (100.0)	0 (0.0)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 127	4	0 (0.0)	3 (75.0)	1 (25.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	2	0 (0.0)	2 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	2 (50.0)	2 (50.0)	3	0 (0.0)	1 (33.3)	2 (66.7)
Number of metastatic sites <2									
	Day 15	22	0 (0.0)	18 (81.8)	4 (18.2)	10	0 (0.0)	10 (100.0)	0 (0.0)
	Day 43	21	1 (4.8)	20 (95.2)	0 (0.0)	10	2 (20.0)	8 (80.0)	0 (0.0)
	Day 85	21	0 (0.0)	19 (90.5)	2 (9.5)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 127	17	0 (0.0)	16 (94.1)	1 (5.9)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	16	1 (6.3)	14 (87.5)	1 (6.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	14	2 (14.3)	12 (85.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	2 (20.0)	7 (70.0)	1 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	8	2 (25.0)	6 (75.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	5 (62.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup / Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	2 (11.1)	12 (66.7)	4 (22.2)	9	0 (0.0)	9 (100.0)	0 (0.0)
Number of metastatic sites									
>= 2									
	Day 15	96	6 (6.3)	80 (83.3)	10 (10.4)	42	2 (4.8)	38 (90.5)	2 (4.8)
	Day 43	96	5 (5.2)	74 (77.1)	17 (17.7)	43	1 (2.3)	38 (88.4)	4 (9.3)
	Day 85	78	3 (3.8)	64 (82.1)	11 (14.1)	28	3 (10.7)	21 (75.0)	4 (14.3)
	Day 127	57	4 (7.0)	44 (77.2)	9 (15.8)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	41	2 (4.9)	37 (90.2)	2 (4.9)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	30	3 (10.0)	22 (73.3)	5 (16.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	0 (0.0)	22 (81.5)	5 (18.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	21	2 (9.5)	17 (81.0)	2 (9.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	19	1 (5.3)	15 (78.9)	3 (15.8)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	16	2 (12.5)	11 (68.8)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	12	0 (0.0)	10 (83.3)	2 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	9	0 (0.0)	8 (88.9)	1 (11.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	0 (0.0)	58 (73.4)	21 (26.6)	47	1 (2.1)	32 (68.1)	14 (29.8)
Previous total gastrectomy									
yes									
	Day 15	20	3 (15.0)	13 (65.0)	4 (20.0)	7	1 (14.3)	6 (85.7)	0 (0.0)
	Day 43	20	1 (5.0)	15 (75.0)	4 (20.0)	8	0 (0.0)	8 (100.0)	0 (0.0)
	Day 85	18	0 (0.0)	15 (83.3)	3 (16.7)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 127	11	0 (0.0)	10 (90.9)	1 (9.1)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 169	8	0 (0.0)	7 (87.5)	1 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 211	8	1 (12.5)	5 (62.5)	2 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	2	0 (0.0)	0 (0.0)	2 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	18	1 (5.6)	14 (77.8)	3 (16.7)	9	0 (0.0)	8 (88.9)	1 (11.1)
Previous total gastrectomy									
no									
	Day 15	98	3 (3.1)	85 (86.7)	10 (10.2)	45	1 (2.2)	42 (93.3)	2 (4.4)
	Day 43	97	5 (5.2)	79 (81.4)	13 (13.4)	45	3 (6.7)	38 (84.4)	4 (8.9)
	Day 85	81	3 (3.7)	68 (84.0)	10 (12.3)	30	2 (6.7)	24 (80.0)	4 (13.3)
	Day 127	63	4 (6.3)	50 (79.4)	9 (14.3)	17	1 (5.9)	13 (76.5)	3 (17.6)
	Day 169	49	3 (6.1)	44 (89.8)	2 (4.1)	10	0 (0.0)	8 (80.0)	2 (20.0)
	Day 211	36	4 (11.1)	29 (80.6)	3 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 253	33	1 (3.0)	27 (81.8)	5 (15.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	25	3 (12.0)	21 (84.0)	1 (4.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	23	2 (8.7)	18 (78.3)	3 (13.0)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	19	2 (10.5)	13 (68.4)	4 (21.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	14	0 (0.0)	13 (92.9)	1 (7.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	11 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	79	1 (1.3)	56 (70.9)	22 (27.8)	47	1 (2.1)	33 (70.2)	13 (27.7)
Prior adjuvant/ neoadjuvant therapy									
yes									
	Day 15	29	3 (10.3)	24 (82.8)	2 (6.9)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 43	27	1 (3.7)	23 (85.2)	3 (11.1)	8	1 (12.5)	7 (87.5)	0 (0.0)
	Day 85	27	0 (0.0)	25 (92.6)	2 (7.4)	7	1 (14.3)	6 (85.7)	0 (0.0)
	Day 127	22	0 (0.0)	20 (90.9)	2 (9.1)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 169	15	1 (6.7)	13 (86.7)	1 (6.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 211	12	2 (16.7)	8 (66.7)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	10	2 (20.0)	7 (70.0)	1 (10.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	10	2 (20.0)	6 (60.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	6	0 (0.0)	4 (66.7)	2 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	4	0 (0.0)	1 (25.0)	3 (75.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	25	2 (8.0)	16 (64.0)	7 (28.0)	9	0 (0.0)	9 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy									
no									
	Day 15	89	3 (3.4)	74 (83.1)	12 (13.5)	44	1 (2.3)	41 (93.2)	2 (4.5)
	Day 43	90	5 (5.6)	71 (78.9)	14 (15.6)	45	2 (4.4)	39 (86.7)	4 (8.9)
	Day 85	72	3 (4.2)	58 (80.6)	11 (15.3)	29	2 (6.9)	23 (79.3)	4 (13.8)
	Day 127	52	4 (7.7)	40 (76.9)	8 (15.4)	15	1 (6.7)	11 (73.3)	3 (20.0)
	Day 169	42	2 (4.8)	38 (90.5)	2 (4.8)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 211	32	3 (9.4)	26 (81.3)	3 (9.4)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	27	0 (0.0)	23 (85.2)	4 (14.8)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	19	2 (10.5)	16 (84.2)	1 (5.3)	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 337	17	1 (5.9)	14 (82.4)	2 (11.8)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	15	2 (13.3)	11 (73.3)	2 (13.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	12	0 (0.0)	12 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	10	0 (0.0)	10 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	72	0 (0.0)	54 (75.0)	18 (25.0)	47	1 (2.1)	32 (68.1)	14 (29.8)
Prior ramucirumab contained treatment									
yes									
	Day 15	90	3 (3.3)	76 (84.4)	11 (12.2)	34	2 (5.9)	31 (91.2)	1 (2.9)
	Day 43	89	3 (3.4)	71 (79.8)	15 (16.9)	33	3 (9.1)	28 (84.8)	2 (6.1)
	Day 85	73	0 (0.0)	63 (86.3)	10 (13.7)	23	3 (13.0)	19 (82.6)	1 (4.3)
	Day 127	59	2 (3.4)	48 (81.4)	9 (15.3)	11	1 (9.1)	9 (81.8)	1 (9.1)
	Day 169	45	2 (4.4)	40 (88.9)	3 (6.7)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	32	2 (6.3)	26 (81.3)	4 (12.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	25	1 (4.0)	21 (84.0)	3 (12.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	22	1 (4.5)	20 (90.9)	1 (4.5)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	1 (4.8)	16 (76.2)	4 (19.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	17	0 (0.0)	14 (82.4)	3 (17.6)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	13	0 (0.0)	11 (84.6)	2 (15.4)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	10 (90.9)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	74	1 (1.4)	53 (71.6)	20 (27.0)	36	1 (2.8)	27 (75.0)	8 (22.2)
Prior ramucirumab contained treatment									
no									
	Day 15	28	3 (10.7)	22 (78.6)	3 (10.7)	18	0 (0.0)	17 (94.4)	1 (5.6)
	Day 43	28	3 (10.7)	23 (82.1)	2 (7.1)	20	0 (0.0)	18 (90.0)	2 (10.0)
	Day 85	26	3 (11.5)	20 (76.9)	3 (11.5)	13	0 (0.0)	10 (76.9)	3 (23.1)
	Day 127	15	2 (13.3)	12 (80.0)	1 (6.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 169	12	1 (8.3)	11 (91.7)	0 (0.0)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	12	3 (25.0)	8 (66.7)	1 (8.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	12	1 (8.3)	8 (66.7)	3 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	7	3 (42.9)	3 (42.9)	1 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	2 (33.3)	4 (66.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	4	2 (50.0)	1 (25.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	23	1 (4.3)	17 (73.9)	5 (21.7)	20	0 (0.0)	14 (70.0)	6 (30.0)
Prior nivolumab contained treatment									
yes									
	Day 15	32	0 (0.0)	29 (90.6)	3 (9.4)	13	2 (15.4)	11 (84.6)	0 (0.0)
	Day 43	30	1 (3.3)	23 (76.7)	6 (20.0)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 85	27	0 (0.0)	23 (85.2)	4 (14.8)	10	2 (20.0)	6 (60.0)	2 (20.0)
	Day 127	26	1 (3.8)	20 (76.9)	5 (19.2)	3	1 (33.3)	2 (66.7)	0 (0.0)
	Day 169	21	2 (9.5)	19 (90.5)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 211	16	2 (12.5)	13 (81.3)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	14	1 (7.1)	12 (85.7)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	12	1 (8.3)	11 (91.7)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	11	1 (9.1)	9 (81.8)	1 (9.1)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	10	0 (0.0)	6 (60.0)	4 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	1 (25.0)	2 (50.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	26	1 (3.8)	18 (69.2)	7 (26.9)	14	1 (7.1)	7 (50.0)	6 (42.9)
Prior nivolumab contained treatment									
no									
	Day 15	86	6 (7.0)	69 (80.2)	11 (12.8)	39	0 (0.0)	37 (94.9)	2 (5.1)
	Day 43	87	5 (5.7)	71 (81.6)	11 (12.6)	43	3 (7.0)	37 (86.0)	3 (7.0)
	Day 85	72	3 (4.2)	60 (83.3)	9 (12.5)	26	1 (3.8)	23 (88.5)	2 (7.7)
	Day 127	48	3 (6.3)	40 (83.3)	5 (10.4)	16	0 (0.0)	13 (81.3)	3 (18.8)
	Day 169	36	1 (2.8)	32 (88.9)	3 (8.3)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	28	3 (10.7)	21 (75.0)	4 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	23	1 (4.3)	17 (73.9)	5 (21.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	17	3 (17.6)	12 (70.6)	2 (11.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	16	2 (12.5)	11 (68.8)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	11	2 (18.2)	9 (81.8)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	9	0 (0.0)	7 (77.8)	2 (22.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	71	1 (1.4)	52 (73.2)	18 (25.4)	42	0 (0.0)	34 (81.0)	8 (19.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
yes									
	Day 15	42	2 (4.8)	35 (83.3)	5 (11.9)	15	2 (13.3)	13 (86.7)	0 (0.0)
	Day 43	40	1 (2.5)	31 (77.5)	8 (20.0)	12	0 (0.0)	11 (91.7)	1 (8.3)
	Day 85	37	1 (2.7)	29 (78.4)	7 (18.9)	11	2 (18.2)	7 (63.6)	2 (18.2)
	Day 127	31	2 (6.5)	22 (71.0)	7 (22.6)	4	1 (25.0)	3 (75.0)	0 (0.0)
	Day 169	24	2 (8.3)	22 (91.7)	0 (0.0)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 211	20	4 (20.0)	15 (75.0)	1 (5.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	17	2 (11.8)	14 (82.4)	1 (5.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	16	3 (18.8)	12 (75.0)	1 (6.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	15	3 (20.0)	10 (66.7)	2 (13.3)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	12	1 (8.3)	7 (58.3)	4 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	10	0 (0.0)	8 (80.0)	2 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	35	2 (5.7)	23 (65.7)	10 (28.6)	16	1 (6.3)	9 (56.3)	6 (37.5)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy									
no									
	Day 15	76	4 (5.3)	63 (82.9)	9 (11.8)	37	0 (0.0)	35 (94.6)	2 (5.4)
	Day 43	77	5 (6.5)	63 (81.8)	9 (11.7)	41	3 (7.3)	35 (85.4)	3 (7.3)
	Day 85	62	2 (3.2)	54 (87.1)	6 (9.7)	25	1 (4.0)	22 (88.0)	2 (8.0)
	Day 127	43	2 (4.7)	38 (88.4)	3 (7.0)	15	0 (0.0)	12 (80.0)	3 (20.0)
	Day 169	33	1 (3.0)	29 (87.9)	3 (9.1)	8	0 (0.0)	7 (87.5)	1 (12.5)
	Day 211	24	1 (4.2)	19 (79.2)	4 (16.7)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	20	0 (0.0)	15 (75.0)	5 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	13	1 (7.7)	11 (84.6)	1 (7.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	12	0 (0.0)	10 (83.3)	2 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	9	1 (11.1)	8 (88.9)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	6	0 (0.0)	5 (83.3)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	62	0 (0.0)	47 (75.8)	15 (24.2)	40	0 (0.0)	32 (80.0)	8 (20.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
yes									
	Day 15	22	1 (4.5)	19 (86.4)	2 (9.1)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 43	19	0 (0.0)	18 (94.7)	1 (5.3)	6	1 (16.7)	5 (83.3)	0 (0.0)
	Day 85	16	1 (6.3)	15 (93.8)	0 (0.0)	5	1 (20.0)	4 (80.0)	0 (0.0)
	Day 127	12	1 (8.3)	11 (91.7)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	9	0 (0.0)	9 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	5	1 (20.0)	4 (80.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	3	1 (33.3)	2 (66.7)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	14	0 (0.0)	13 (92.9)	1 (7.1)	6	0 (0.0)	6 (100.0)	0 (0.0)
Most recently treatment with trastuzumab or trastuzumab similar treatment includ ing study drug									
no									
	Day 15	96	5 (5.2)	79 (82.3)	12 (12.5)	46	1 (2.2)	43 (93.5)	2 (4.3)
	Day 43	98	6 (6.1)	76 (77.6)	16 (16.3)	47	2 (4.3)	41 (87.2)	4 (8.5)
	Day 85	83	2 (2.4)	68 (81.9)	13 (15.7)	31	2 (6.5)	25 (80.6)	4 (12.9)
	Day 127	62	3 (4.8)	49 (79.0)	10 (16.1)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	48	3 (6.3)	42 (87.5)	3 (6.3)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	39	4 (10.3)	30 (76.9)	5 (12.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	2 (6.1)	25 (75.8)	6 (18.2)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	26	3 (11.5)	21 (80.8)	2 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	24	2 (8.3)	18 (75.0)	4 (16.7)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	18	1 (5.6)	13 (72.2)	4 (22.2)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	13	0 (0.0)	10 (76.9)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	11	0 (0.0)	10 (90.9)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	83	2 (2.4)	57 (68.7)	24 (28.9)	50	1 (2.0)	35 (70.0)	14 (28.0)
Presence of liver metastasis at baseline									
yes									
	Day 15	64	5 (7.8)	50 (78.1)	9 (14.1)	27	1 (3.7)	26 (96.3)	0 (0.0)
	Day 43	64	3 (4.7)	52 (81.3)	9 (14.1)	28	1 (3.6)	24 (85.7)	3 (10.7)
	Day 85	51	1 (2.0)	42 (82.4)	8 (15.7)	16	2 (12.5)	12 (75.0)	2 (12.5)
	Day 127	37	3 (8.1)	30 (81.1)	4 (10.8)	10	1 (10.0)	7 (70.0)	2 (20.0)
	Day 169	28	1 (3.6)	25 (89.3)	2 (7.1)	6	0 (0.0)	4 (66.7)	2 (33.3)
	Day 211	20	2 (10.0)	15 (75.0)	3 (15.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	19	0 (0.0)	16 (84.2)	3 (15.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	14	1 (7.1)	12 (85.7)	1 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	13	1 (7.7)	11 (84.6)	1 (7.7)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	11	1 (9.1)	9 (81.8)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	9	0 (0.0)	9 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	7 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	6	1 (16.7)	4 (66.7)	1 (16.7)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	50	0 (0.0)	38 (76.0)	12 (24.0)	31	0 (0.0)	21 (67.7)	10 (32.3)
Presence of liver metastasis at baseline									
no									
	Day 15	54	1 (1.9)	48 (88.9)	5 (9.3)	25	1 (4.0)	22 (88.0)	2 (8.0)
	Day 43	53	3 (5.7)	42 (79.2)	8 (15.1)	25	2 (8.0)	22 (88.0)	1 (4.0)
	Day 85	48	2 (4.2)	41 (85.4)	5 (10.4)	20	1 (5.0)	17 (85.0)	2 (10.0)
	Day 127	37	1 (2.7)	30 (81.1)	6 (16.2)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 169	29	2 (6.9)	26 (89.7)	1 (3.4)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 211	24	3 (12.5)	19 (79.2)	2 (8.3)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	18	2 (11.1)	13 (72.2)	3 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	15	3 (20.0)	11 (73.3)	1 (6.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	14	2 (14.3)	9 (64.3)	3 (21.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	10	1 (10.0)	6 (60.0)	3 (30.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	7	0 (0.0)	4 (57.1)	3 (42.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	47	2 (4.3)	32 (68.1)	13 (27.7)	25	1 (4.0)	20 (80.0)	4 (16.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Renal impairment at baseline									
normal									
	Day 15	31	1 (3.2)	27 (87.1)	3 (9.7)	10	0 (0.0)	9 (90.0)	1 (10.0)
	Day 43	33	2 (6.1)	28 (84.8)	3 (9.1)	12	1 (8.3)	9 (75.0)	2 (16.7)
	Day 85	26	0 (0.0)	24 (92.3)	2 (7.7)	8	0 (0.0)	6 (75.0)	2 (25.0)
	Day 127	19	1 (5.3)	17 (89.5)	1 (5.3)	3	0 (0.0)	2 (66.7)	1 (33.3)
	Day 169	17	0 (0.0)	16 (94.1)	1 (5.9)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 211	12	1 (8.3)	8 (66.7)	3 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 253	13	1 (7.7)	9 (69.2)	3 (23.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	12	1 (8.3)	10 (83.3)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	11	1 (9.1)	8 (72.7)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	7	0 (0.0)	6 (85.7)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	24	1 (4.2)	19 (79.2)	4 (16.7)	11	0 (0.0)	7 (63.6)	4 (36.4)
Renal impairment at baseline									
mild									
	Day 15	50	2 (4.0)	41 (82.0)	7 (14.0)	25	1 (4.0)	24 (96.0)	0 (0.0)
	Day 43	50	2 (4.0)	39 (78.0)	9 (18.0)	23	1 (4.3)	21 (91.3)	1 (4.3)
	Day 85	45	2 (4.4)	35 (77.8)	8 (17.8)	14	1 (7.1)	13 (92.9)	0 (0.0)
	Day 127	31	2 (6.5)	27 (87.1)	2 (6.5)	9	0 (0.0)	8 (88.9)	1 (11.1)
	Day 169	23	2 (8.7)	19 (82.6)	2 (8.7)	6	0 (0.0)	6 (100.0)	0 (0.0)
	Day 211	17	3 (17.6)	12 (70.6)	2 (11.8)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	13	1 (7.7)	11 (84.6)	1 (7.7)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 295	9	2 (22.2)	7 (77.8)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 337	8	2 (25.0)	5 (62.5)	1 (12.5)	2	0 (0.0)	1 (50.0)	1 (50.0)
	Day 379	6	1 (16.7)	3 (50.0)	2 (33.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	45	1 (2.2)	31 (68.9)	13 (28.9)	25	0 (0.0)	20 (80.0)	5 (20.0)
Renal impairment at baseline									
moderate									
	Day 15	37	3 (8.1)	30 (81.1)	4 (10.8)	16	1 (6.3)	14 (87.5)	1 (6.3)
	Day 43	34	2 (5.9)	27 (79.4)	5 (14.7)	17	1 (5.9)	15 (88.2)	1 (5.9)
	Day 85	28	1 (3.6)	24 (85.7)	3 (10.7)	14	2 (14.3)	10 (71.4)	2 (14.3)
	Day 127	24	1 (4.2)	16 (66.7)	7 (29.2)	7	1 (14.3)	5 (71.4)	1 (14.3)
	Day 169	17	1 (5.9)	16 (94.1)	0 (0.0)	5	0 (0.0)	3 (60.0)	2 (40.0)
	Day 211	15	1 (6.7)	14 (93.3)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	11	0 (0.0)	9 (81.8)	2 (18.2)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 295	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 337	8	0 (0.0)	7 (87.5)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 379	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 463	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	2	1 (50.0)	0 (0.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	28	0 (0.0)	20 (71.4)	8 (28.6)	19	1 (5.3)	13 (68.4)	5 (26.3)
Renal impairment at baseline									
severe									
	Day 15	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 43	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline									
normal									
	Day 15	82	2 (2.4)	71 (86.6)	9 (11.0)	37	1 (2.7)	34 (91.9)	2 (5.4)
	Day 43	83	4 (4.8)	66 (79.5)	13 (15.7)	41	1 (2.4)	37 (90.2)	3 (7.3)
	Day 85	76	3 (3.9)	63 (82.9)	10 (13.2)	27	2 (7.4)	22 (81.5)	3 (11.1)
	Day 127	58	4 (6.9)	47 (81.0)	7 (12.1)	14	1 (7.1)	10 (71.4)	3 (21.4)
	Day 169	45	2 (4.4)	41 (91.1)	2 (4.4)	7	0 (0.0)	5 (71.4)	2 (28.6)
	Day 211	34	4 (11.8)	28 (82.4)	2 (5.9)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	30	2 (6.7)	25 (83.3)	3 (10.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	23	4 (17.4)	18 (78.3)	1 (4.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	21	3 (14.3)	15 (71.4)	3 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	16	2 (12.5)	11 (68.8)	3 (18.8)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	11	0 (0.0)	10 (90.9)	1 (9.1)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	8	0 (0.0)	8 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	5	1 (20.0)	3 (60.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	67	2 (3.0)	47 (70.1)	18 (26.9)	42	1 (2.4)	30 (71.4)	11 (26.2)
Hepatic impairment at baseline									
mild									
	Day 15	35	4 (11.4)	26 (74.3)	5 (14.3)	15	1 (6.7)	14 (93.3)	0 (0.0)
	Day 43	33	2 (6.1)	27 (81.8)	4 (12.1)	12	2 (16.7)	9 (75.0)	1 (8.3)
	Day 85	22	0 (0.0)	19 (86.4)	3 (13.6)	9	1 (11.1)	7 (77.8)	1 (11.1)
	Day 127	15	0 (0.0)	12 (80.0)	3 (20.0)	5	0 (0.0)	5 (100.0)	0 (0.0)
	Day 169	12	1 (8.3)	10 (83.3)	1 (8.3)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 211	10	1 (10.0)	6 (60.0)	3 (30.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 253	7	0 (0.0)	4 (57.1)	3 (42.9)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	6	0 (0.0)	5 (83.3)	1 (16.7)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	6	0 (0.0)	5 (83.3)	1 (16.7)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	5	0 (0.0)	4 (80.0)	1 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	5	0 (0.0)	3 (60.0)	2 (40.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	29	0 (0.0)	22 (75.9)	7 (24.1)	14	0 (0.0)	11 (78.6)	3 (21.4)
Hepatic impairment at baseline									
moderate									
	Day 15	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 43	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 85	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 127	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	8	0 (0.0)	7 (87.5)	1 (12.5)	4	0 (0.0)	4 (100.0)	0 (0.0)
	Day 43	8	0 (0.0)	8 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	7	0 (0.0)	6 (85.7)	1 (14.3)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	6	0 (0.0)	6 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	5	0 (0.0)	5 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	4	0 (0.0)	3 (75.0)	1 (25.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	4	0 (0.0)	2 (50.0)	2 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 421	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	6	0 (0.0)	4 (66.7)	2 (33.3)	4	0 (0.0)	3 (75.0)	1 (25.0)
Prior treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	110	6 (5.5)	91 (82.7)	13 (11.8)	48	2 (4.2)	44 (91.7)	2 (4.2)
	Day 43	109	6 (5.5)	86 (78.9)	17 (15.6)	50	3 (6.0)	43 (86.0)	4 (8.0)
	Day 85	92	3 (3.3)	77 (83.7)	12 (13.0)	33	3 (9.1)	26 (78.8)	4 (12.1)
	Day 127	68	4 (5.9)	54 (79.4)	10 (14.7)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	52	3 (5.8)	46 (88.5)	3 (5.8)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	40	5 (12.5)	31 (77.5)	4 (10.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	33	2 (6.1)	27 (81.8)	4 (12.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	27	4 (14.8)	21 (77.8)	2 (7.4)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	25	3 (12.0)	18 (72.0)	4 (16.0)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	20	2 (10.0)	14 (70.0)	4 (20.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	15	0 (0.0)	13 (86.7)	2 (13.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	11	0 (0.0)	11 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	7	1 (14.3)	5 (71.4)	1 (14.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	4	0 (0.0)	4 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	3	0 (0.0)	3 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	2	0 (0.0)	2 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	91	2 (2.2)	66 (72.5)	23 (25.3)	52	1 (1.9)	38 (73.1)	13 (25.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
yes									
	Day 15	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 43	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 85	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 127	3	0 (0.0)	3 (100.0)	0 (0.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 169	3	0 (0.0)	3 (100.0)	0 (0.0)	2	0 (0.0)	2 (100.0)	0 (0.0)
	Day 211	2	0 (0.0)	2 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 253	2	0 (0.0)	1 (50.0)	1 (50.0)	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	DS-8201a (N=125) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)	Phys. Choice (N=62) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Day 295	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	1	0 (0.0)	1 (100.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 379	0	0 (0.0)	0 (0.0)	0 (0.0)	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	1 (50.0)	1 (50.0)	3	0 (0.0)	3 (100.0)	0 (0.0)
Most recently treatment with irinotecan or other topoisomerase I inhibitors									
no									
	Day 15	115	6 (5.2)	95 (82.6)	14 (12.2)	49	2 (4.1)	45 (91.8)	2 (4.1)
	Day 43	114	6 (5.3)	91 (79.8)	17 (14.9)	50	3 (6.0)	43 (86.0)	4 (8.0)
	Day 85	96	3 (3.1)	80 (83.3)	13 (13.5)	33	3 (9.1)	26 (78.8)	4 (12.1)
	Day 127	71	4 (5.6)	57 (80.3)	10 (14.1)	16	1 (6.3)	12 (75.0)	3 (18.8)
	Day 169	54	3 (5.6)	48 (88.9)	3 (5.6)	9	0 (0.0)	7 (77.8)	2 (22.2)
	Day 211	42	5 (11.9)	32 (76.2)	5 (11.9)	3	0 (0.0)	3 (100.0)	0 (0.0)
	Day 253	35	2 (5.7)	28 (80.0)	5 (14.3)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 295	28	4 (14.3)	22 (78.6)	2 (7.1)	1	0 (0.0)	1 (100.0)	0 (0.0)
	Day 337	26	3 (11.5)	19 (73.1)	4 (15.4)	1	0 (0.0)	0 (0.0)	1 (100.0)
	Day 379	21	2 (9.5)	15 (71.4)	4 (19.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 421	16	0 (0.0)	13 (81.3)	3 (18.8)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 463	12	0 (0.0)	11 (91.7)	1 (8.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 505	8	1 (12.5)	6 (75.0)	1 (12.5)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 547	6	0 (0.0)	6 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 589	5	0 (0.0)	5 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 631	4	0 (0.0)	3 (75.0)	1 (25.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 673	2	0 (0.0)	1 (50.0)	1 (50.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 715	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 757	3	0 (0.0)	2 (66.7)	1 (33.3)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 799	1	0 (0.0)	1 (100.0)	0 (0.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 841	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	Day 883	1	0 (0.0)	0 (0.0)	1 (100.0)	0	0 (0.0)	0 (0.0)	0 (0.0)
	End of Treatment	95	2 (2.1)	69 (72.6)	24 (25.3)	53	1 (1.9)	38 (71.7)	14 (26.4)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADFACTG
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Summary of Questionnaires with patients having Baseline and at least one Post-Baseline Visit

	DS-8201a (N=125)		Phys. Choice (N=62)	
	n	(%)	n	(%)
EQ-5D VAS score	124	(99.2)	55	(88.7)
Fact-Ga Total Score	123	(98.4)	54	(87.1)
Physical Well-being	124	(99.2)	55	(88.7)
Social/Family Well-being	124	(99.2)	55	(88.7)
Emotional Well-being	123	(98.4)	54	(87.1)
Functional Well-being	123	(98.4)	54	(87.1)
Gastric Cancer Symptom (GaCS)	124	(99.2)	55	(88.7)
Fact-G Total Score	123	(98.4)	54	(87.1)

Daiichi Sankyo Date of Table Generation: 07JUN2022

Anhang 4-G 1.2.5: Sicherheit

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Subjects with events	125 (100.0)	61 (98.4)
Gastrointestinal disorders	104 (83.2)	49 (79.0)
Nausea	79 (63.2)	29 (46.8)
Diarrhoea	41 (32.8)	20 (32.3)
Constipation	31 (24.8)	15 (24.2)
Vomiting	33 (26.4)	5 (8.1)
Abdominal pain	14 (11.2)	8 (12.9)
Stomatitis	14 (11.2)	3 (4.8)
Ascites	8 (6.4)	2 (3.2)
Dyspepsia	4 (3.2)	3 (4.8)
Abdominal distension	4 (3.2)	2 (3.2)
Abdominal pain upper	5 (4.0)	1 (1.6)
Haemorrhoids	4 (3.2)	0
Oesophageal stenosis	2 (1.6)	2 (3.2)
Upper gastrointestinal haemorrhage	4 (3.2)	0
Gastric stenosis	3 (2.4)	0
Gastrooesophageal reflux disease	2 (1.6)	1 (1.6)
Periodontal disease	2 (1.6)	1 (1.6)
Gastric haemorrhage	2 (1.6)	0
Gastrointestinal obstruction	1 (0.8)	1 (1.6)
Inguinal hernia	2 (1.6)	0
Abdominal discomfort	0	1 (1.6)
Anal haemorrhage	1 (0.8)	0
Anal incontinence	1 (0.8)	0
Anal stenosis	1 (0.8)	0
Colitis	1 (0.8)	0
Gastritis	1 (0.8)	0
Glossitis	1 (0.8)	0
Haemorrhoidal haemorrhage	1 (0.8)	0
Large intestine perforation	1 (0.8)	0
Lip dry	1 (0.8)	0
Melaena	1 (0.8)	0
Pancreatitis	1 (0.8)	0
Proctalgia	1 (0.8)	0
Salivary hypersecretion	1 (0.8)	0
Tooth loss	1 (0.8)	0
Investigations	102 (81.6)	33 (53.2)
Neutrophil count decreased	79 (63.2)	21 (33.9)
White blood cell count decreased	48 (38.4)	21 (33.9)
Platelet count decreased	48 (38.4)	4 (6.5)
Lymphocyte count decreased	29 (23.2)	2 (3.2)
Weight decreased	19 (15.2)	5 (8.1)
Aspartate aminotransferase increased	12 (9.6)	3 (4.8)
Blood alkaline phosphatase increased	11 (8.8)	2 (3.2)
Alanine aminotransferase increased	9 (7.2)	3 (4.8)
Blood bilirubin increased	10 (8.0)	0
Blood creatinine increased	1 (0.8)	6 (9.7)
Gamma-glutamyltransferase increased	4 (3.2)	0
C-reactive protein increased	2 (1.6)	0
Electrocardiogram QT prolonged	1 (0.8)	1 (1.6)
Troponin T increased	2 (1.6)	0
Amylase increased	1 (0.8)	0
Blood pressure decreased	1 (0.8)	0
Central venous pressure increased	1 (0.8)	0
Haemoglobin decreased	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Lipase increased	1 (0.8)	0
Liver function test abnormal	1 (0.8)	0
Troponin I increased	1 (0.8)	0
Vascular resistance systemic increased	1 (0.8)	0
Weight increased	0	1 (1.6)
General disorders and administration site conditions	87 (69.6)	34 (54.8)
Malaise	43 (34.4)	10 (16.1)
Fatigue	27 (21.6)	15 (24.2)
Pyrexia	31 (24.8)	10 (16.1)
Oedema peripheral	14 (11.2)	0
Oedema	6 (4.8)	1 (1.6)
Disease progression	3 (2.4)	2 (3.2)
Asthenia	1 (0.8)	3 (4.8)
Mucosal inflammation	1 (0.8)	1 (1.6)
Pain	2 (1.6)	0
Catheter site pain	1 (0.8)	0
Chest pain	1 (0.8)	0
Condition aggravated	1 (0.8)	0
Face oedema	0	1 (1.6)
General physical health deterioration	1 (0.8)	0
Influenza like illness	0	1 (1.6)
Infusion site erythema	1 (0.8)	0
Swelling	1 (0.8)	0
Metabolism and nutrition disorders	87 (69.6)	34 (54.8)
Decreased appetite	76 (60.8)	28 (45.2)
Hypoalbuminaemia	18 (14.4)	8 (12.9)
Hypokalaemia	10 (8.0)	4 (6.5)
Dehydration	8 (6.4)	2 (3.2)
Hyponatraemia	3 (2.4)	3 (4.8)
Hyperkalaemia	1 (0.8)	4 (6.5)
Hypocalcaemia	1 (0.8)	3 (4.8)
Hyperglycaemia	3 (2.4)	0
Hypophosphataemia	1 (0.8)	2 (3.2)
Hyperuricaemia	2 (1.6)	0
Hypoglycaemia	2 (1.6)	0
Hypomagnesaemia	0	2 (3.2)
Diabetes mellitus	1 (0.8)	0
Hypercalcaemia	1 (0.8)	0
Hypophagia	1 (0.8)	0
Hypovolaemia	1 (0.8)	0
Hypozincaemia	1 (0.8)	0
Blood and lymphatic system disorders	77 (61.6)	20 (32.3)
Anaemia	71 (56.8)	19 (30.6)
Febrile neutropenia	6 (4.8)	2 (3.2)
Neutropenia	3 (2.4)	1 (1.6)
Disseminated intravascular coagulation	2 (1.6)	0
Leukopenia	1 (0.8)	1 (1.6)
Thrombocytopenia	2 (1.6)	0
Anaemia vitamin B12 deficiency	1 (0.8)	0
Iron deficiency anaemia	1 (0.8)	0
Skin and subcutaneous tissue disorders	51 (40.8)	17 (27.4)
Alopecia	28 (22.4)	9 (14.5)
Pruritus	10 (8.0)	2 (3.2)
Dry skin	8 (6.4)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Rash	6 (4.8)	1 (1.6)
Decubitus ulcer	2 (1.6)	1 (1.6)
Rash maculo-papular	1 (0.8)	2 (3.2)
Dermatitis acneiform	2 (1.6)	0
Erythema	1 (0.8)	1 (1.6)
Skin ulcer	1 (0.8)	1 (1.6)
Dermal cyst	1 (0.8)	0
Dermatitis	0	1 (1.6)
Eczema	1 (0.8)	0
Erythema multiforme	1 (0.8)	0
Haemorrhage subcutaneous	1 (0.8)	0
Ingrowing nail	0	1 (1.6)
Lichen planus	1 (0.8)	0
Nail disorder	0	1 (1.6)
Nail ridging	1 (0.8)	0
Onychomadesis	1 (0.8)	0
Palmoplantar keratoderma	1 (0.8)	0
Seborrhoeic dermatitis	0	1 (1.6)
Skin hyperpigmentation	1 (0.8)	0
Urticaria	1 (0.8)	0
Infections and infestations	53 (42.4)	14 (22.6)
Nasopharyngitis	11 (8.8)	5 (8.1)
Pneumonia	7 (5.6)	1 (1.6)
Upper respiratory tract infection	6 (4.8)	2 (3.2)
Lung infection	6 (4.8)	0
Influenza	4 (3.2)	0
Herpes zoster	2 (1.6)	1 (1.6)
Pharyngitis	3 (2.4)	0
Pneumonia bacterial	3 (2.4)	0
Tinea pedis	3 (2.4)	0
Urinary tract infection	3 (2.4)	0
Device related infection	1 (0.8)	1 (1.6)
Folliculitis	1 (0.8)	1 (1.6)
Gingivitis	2 (1.6)	0
Sepsis	2 (1.6)	0
Bacteraemia	1 (0.8)	0
Biliary sepsis	1 (0.8)	0
Biliary tract infection	1 (0.8)	0
Cholangitis infective	1 (0.8)	0
Conjunctivitis	1 (0.8)	0
Cystitis	1 (0.8)	0
Dermatophytosis of nail	1 (0.8)	0
Enterocolitis infectious	1 (0.8)	0
Furuncle	1 (0.8)	0
Infection	1 (0.8)	0
Infectious pleural effusion	0	1 (1.6)
Liver abscess	1 (0.8)	0
Nail infection	1 (0.8)	0
Oesophageal candidiasis	1 (0.8)	0
Oral candidiasis	1 (0.8)	0
Otitis media	0	1 (1.6)
Paronychia	1 (0.8)	0
Pericoronitis	0	1 (1.6)
Peritonitis bacterial	1 (0.8)	0
Pneumonia staphylococcal	0	1 (1.6)
Prostatic abscess	0	1 (1.6)
Pulmonary tuberculosis	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Rhinitis	1 (0.8)	0
Tinea capitis	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders	39 (31.2)	13 (21.0)
Hiccups	6 (4.8)	6 (9.7)
Pneumonitis	11 (8.8)	0
Cough	6 (4.8)	2 (3.2)
Interstitial lung disease	7 (5.6)	0
Epistaxis	4 (3.2)	0
Oropharyngeal pain	3 (2.4)	1 (1.6)
Productive cough	2 (1.6)	1 (1.6)
Dyspnoea	1 (0.8)	1 (1.6)
Pneumonia aspiration	1 (0.8)	1 (1.6)
Rhinitis allergic	2 (1.6)	0
Upper respiratory tract inflammation	1 (0.8)	1 (1.6)
Dry throat	0	1 (1.6)
Dysphonia	1 (0.8)	0
Emphysema	1 (0.8)	0
Pharyngeal inflammation	1 (0.8)	0
Pleural effusion	1 (0.8)	0
Pulmonary hypertension	1 (0.8)	0
Nervous system disorders	26 (20.8)	18 (29.0)
Dysgeusia	9 (7.2)	4 (6.5)
Dizziness	5 (4.0)	3 (4.8)
Headache	4 (3.2)	4 (6.5)
Peripheral sensory neuropathy	4 (3.2)	2 (3.2)
Cholinergic syndrome	0	3 (4.8)
Brain oedema	0	1 (1.6)
Cerebral infarction	0	1 (1.6)
Cognitive disorder	1 (0.8)	0
Diplegia	0	1 (1.6)
Facial spasm	0	1 (1.6)
Head discomfort	1 (0.8)	0
Hemiplegia	1 (0.8)	0
Hypoaesthesia	0	1 (1.6)
Loss of consciousness	1 (0.8)	0
Neuropathy peripheral	0	1 (1.6)
Presyncope	1 (0.8)	0
Somnolence	1 (0.8)	0
Syncope	0	1 (1.6)
Vagus nerve disorder	0	1 (1.6)
Musculoskeletal and connective tissue disorders	25 (20.0)	8 (12.9)
Back pain	10 (8.0)	3 (4.8)
Myalgia	3 (2.4)	2 (3.2)
Pain in extremity	3 (2.4)	1 (1.6)
Muscle spasms	3 (2.4)	0
Arthralgia	2 (1.6)	0
Muscular weakness	1 (0.8)	1 (1.6)
Musculoskeletal pain	1 (0.8)	1 (1.6)
Neck pain	2 (1.6)	0
Flank pain	1 (0.8)	0
Limb discomfort	1 (0.8)	0
Musculoskeletal chest pain	1 (0.8)	0
Musculoskeletal stiffness	1 (0.8)	0
Pain in jaw	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Hepatobiliary disorders	22 (17.6)	4 (6.5)
Hepatic function abnormal	10 (8.0)	1 (1.6)
Jaundice cholestatic	5 (4.0)	1 (1.6)
Cholangitis	3 (2.4)	1 (1.6)
Liver disorder	3 (2.4)	1 (1.6)
Bile duct obstruction	1 (0.8)	0
Bile duct stone	1 (0.8)	0
Cholangitis acute	1 (0.8)	0
Cholelithiasis	1 (0.8)	0
Liver injury	1 (0.8)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	14 (11.2)	6 (9.7)
Cancer pain	6 (4.8)	3 (4.8)
Tumour pain	2 (1.6)	3 (4.8)
Neoplasm progression	2 (1.6)	1 (1.6)
Tumour haemorrhage	3 (2.4)	0
Tumour associated fever	2 (1.6)	0
Lymphangiosis carcinomatosa	1 (0.8)	0
Pericarditis malignant	1 (0.8)	0
Psychiatric disorders	13 (10.4)	7 (11.3)
Insomnia	11 (8.8)	5 (8.1)
Delirium	4 (3.2)	1 (1.6)
Agitation	0	1 (1.6)
Injury, poisoning and procedural complications	11 (8.8)	3 (4.8)
Fall	3 (2.4)	1 (1.6)
Infusion related reaction	2 (1.6)	0
Procedural pain	1 (0.8)	1 (1.6)
Animal bite	0	1 (1.6)
Arthropod bite	1 (0.8)	0
Arthropod sting	1 (0.8)	0
Facial bones fracture	1 (0.8)	0
Foot fracture	1 (0.8)	0
Spinal compression fracture	1 (0.8)	0
Vascular access site pain	1 (0.8)	0
Eye disorders	11 (8.8)	2 (3.2)
Cataract	2 (1.6)	1 (1.6)
Dry eye	1 (0.8)	1 (1.6)
Retinal exudates	2 (1.6)	0
Retinal haemorrhage	2 (1.6)	0
Blepharitis	1 (0.8)	0
Eye haemorrhage	1 (0.8)	0
Keratitis	1 (0.8)	0
Macular fibrosis	1 (0.8)	0
Macular oedema	1 (0.8)	0
Retinal detachment	1 (0.8)	0
Retinopathy	1 (0.8)	0
Vascular disorders	6 (4.8)	7 (11.3)
Hypotension	3 (2.4)	1 (1.6)
Embolism	1 (0.8)	1 (1.6)
Hypertension	0	2 (3.2)
Deep vein thrombosis	0	1 (1.6)
Hot flush	1 (0.8)	0
Internal haemorrhage	0	1 (1.6)
Jugular vein thrombosis	0	1 (1.6)

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Venous thrombosis	1 (0.8)	0
Cardiac disorders	9 (7.2)	1 (1.6)
Acute coronary syndrome	1 (0.8)	0
Atrial fibrillation	1 (0.8)	0
Bundle branch block right	1 (0.8)	0
Cardiomyopathy	1 (0.8)	0
Pericardial effusion	1 (0.8)	0
Stress cardiomyopathy	1 (0.8)	0
Supraventricular extrasystoles	1 (0.8)	0
Supraventricular tachycardia	0	1 (1.6)
Tachycardia	1 (0.8)	0
Ventricular extrasystoles	1 (0.8)	0
Renal and urinary disorders	7 (5.6)	3 (4.8)
Acute kidney injury	1 (0.8)	1 (1.6)
Hydronephrosis	1 (0.8)	1 (1.6)
Proteinuria	2 (1.6)	0
Bladder spasm	1 (0.8)	0
Dysuria	1 (0.8)	0
Haematuria	1 (0.8)	0
Pollakiuria	1 (0.8)	0
Renal impairment	1 (0.8)	0
Urethral pain	0	1 (1.6)
Urinary retention	1 (0.8)	0
Ear and labyrinth disorders	4 (3.2)	0
Tinnitus	2 (1.6)	0
Deafness	1 (0.8)	0
Hypoacusis	1 (0.8)	0
Immune system disorders	2 (1.6)	1 (1.6)
Contrast media allergy	1 (0.8)	1 (1.6)
Anaphylactic reaction	1 (0.8)	0
Hypersensitivity	1 (0.8)	0
Congenital, familial and genetic disorders	1 (0.8)	0
Pyloric stenosis	1 (0.8)	0
Endocrine disorders	1 (0.8)	0
Adrenal insufficiency	1 (0.8)	0
Reproductive system and breast disorders	1 (0.8)	0
Perineal erythema	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious TEAE by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Subjects with events	56 (44.8)	16 (25.8)
Metabolism and nutrition disorders	18 (14.4)	1 (1.6)
Decreased appetite	13 (10.4)	1 (1.6)
Dehydration	4 (3.2)	0
Hypophagia	1 (0.8)	0
Gastrointestinal disorders	14 (11.2)	1 (1.6)
Diarrhoea	2 (1.6)	0
Gastric stenosis	2 (1.6)	0
Gastrointestinal obstruction	1 (0.8)	1 (1.6)
Abdominal distension	1 (0.8)	0
Abdominal pain	1 (0.8)	0
Anal stenosis	1 (0.8)	0
Gastric haemorrhage	1 (0.8)	0
Inguinal hernia	1 (0.8)	0
Large intestine perforation	1 (0.8)	0
Nausea	1 (0.8)	0
Oesophageal stenosis	1 (0.8)	0
Pancreatitis	1 (0.8)	0
Stomatitis	1 (0.8)	0
Upper gastrointestinal haemorrhage	1 (0.8)	0
Vomiting	1 (0.8)	0
Hepatobiliary disorders	9 (7.2)	4 (6.5)
Cholangitis	3 (2.4)	1 (1.6)
Jaundice cholestatic	3 (2.4)	1 (1.6)
Hepatic function abnormal	1 (0.8)	1 (1.6)
Bile duct obstruction	1 (0.8)	0
Bile duct stone	1 (0.8)	0
Cholangitis acute	1 (0.8)	0
Liver disorder	0	1 (1.6)
Liver injury	1 (0.8)	0
Infections and infestations	12 (9.6)	1 (1.6)
Pneumonia	3 (2.4)	0
Lung infection	2 (1.6)	0
Sepsis	2 (1.6)	0
Bacteraemia	1 (0.8)	0
Biliary sepsis	1 (0.8)	0
Biliary tract infection	1 (0.8)	0
Cholangitis infective	1 (0.8)	0
Device related infection	1 (0.8)	0
Infectious pleural effusion	0	1 (1.6)
Pneumonia bacterial	1 (0.8)	0
General disorders and administration site conditions	7 (5.6)	4 (6.5)
Disease progression	3 (2.4)	2 (3.2)
Pyrexia	3 (2.4)	1 (1.6)
Fatigue	1 (0.8)	1 (1.6)
Asthenia	0	1 (1.6)
Condition aggravated	1 (0.8)	0
General physical health deterioration	1 (0.8)	0
Blood and lymphatic system disorders	6 (4.8)	4 (6.5)
Anaemia	4 (3.2)	2 (3.2)
Febrile neutropenia	1 (0.8)	1 (1.6)

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious TEAE by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Disseminated intravascular coagulation	1 (0.8)	0
Neutropenia	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders	8 (6.4)	1 (1.6)
Pneumonitis	5 (4.0)	0
Interstitial lung disease	2 (1.6)	0
Pneumonia aspiration	1 (0.8)	1 (1.6)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	6 (4.8)	2 (3.2)
Neoplasm progression	2 (1.6)	1 (1.6)
Tumour haemorrhage	3 (2.4)	0
Cancer pain	0	1 (1.6)
Pericarditis malignant	1 (0.8)	0
Investigations	1 (0.8)	3 (4.8)
Blood creatinine increased	0	2 (3.2)
Neutrophil count decreased	0	1 (1.6)
Platelet count decreased	1 (0.8)	0
White blood cell count decreased	0	1 (1.6)
Nervous system disorders	2 (1.6)	2 (3.2)
Cerebral infarction	0	1 (1.6)
Dizziness	0	1 (1.6)
Hemiplegia	1 (0.8)	0
Presyncope	1 (0.8)	0
Renal and urinary disorders	2 (1.6)	2 (3.2)
Acute kidney injury	1 (0.8)	1 (1.6)
Hydronephrosis	1 (0.8)	1 (1.6)
Cardiac disorders	3 (2.4)	0
Acute coronary syndrome	1 (0.8)	0
Pericardial effusion	1 (0.8)	0
Stress cardiomyopathy	1 (0.8)	0
Vascular disorders	2 (1.6)	0
Hypotension	2 (1.6)	0
Congenital, familial and genetic disorders	1 (0.8)	0
Pyloric stenosis	1 (0.8)	0
Musculoskeletal and connective tissue disorders	1 (0.8)	0
Neck pain	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Subjects with events	107 (85.6)	35 (56.5)
Investigations	79 (63.2)	18 (29.0)
Neutrophil count decreased	62 (49.6)	14 (22.6)
White blood cell count decreased	26 (20.8)	7 (11.3)
Lymphocyte count decreased	15 (12.0)	1 (1.6)
Platelet count decreased	14 (11.2)	2 (3.2)
Blood alkaline phosphatase increased	4 (3.2)	0
Aspartate aminotransferase increased	3 (2.4)	0
Alanine aminotransferase increased	2 (1.6)	0
Electrocardiogram QT prolonged	1 (0.8)	1 (1.6)
Weight decreased	1 (0.8)	1 (1.6)
Amylase increased	1 (0.8)	0
Blood bilirubin increased	1 (0.8)	0
Blood creatinine increased	0	1 (1.6)
Lipase increased	1 (0.8)	0
Liver function test abnormal	1 (0.8)	0
Troponin T increased	1 (0.8)	0
Blood and lymphatic system disorders	53 (42.4)	14 (22.6)
Anaemia	48 (38.4)	14 (22.6)
Febrile neutropenia	6 (4.8)	2 (3.2)
Neutropenia	2 (1.6)	1 (1.6)
Disseminated intravascular coagulation	2 (1.6)	0
Leukopenia	1 (0.8)	0
Metabolism and nutrition disorders	28 (22.4)	12 (19.4)
Decreased appetite	21 (16.8)	8 (12.9)
Hypokalaemia	5 (4.0)	4 (6.5)
Hypoalbuminaemia	4 (3.2)	3 (4.8)
Hyponatraemia	3 (2.4)	3 (4.8)
Dehydration	3 (2.4)	1 (1.6)
Hyperglycaemia	2 (1.6)	0
Hyperkalaemia	0	1 (1.6)
Hyperuricaemia	1 (0.8)	0
Hypophosphataemia	0	1 (1.6)
Gastrointestinal disorders	23 (18.4)	5 (8.1)
Nausea	7 (5.6)	1 (1.6)
Ascites	3 (2.4)	1 (1.6)
Diarrhoea	3 (2.4)	1 (1.6)
Abdominal pain	1 (0.8)	2 (3.2)
Abdominal distension	1 (0.8)	1 (1.6)
Gastrointestinal obstruction	1 (0.8)	1 (1.6)
Oesophageal stenosis	1 (0.8)	1 (1.6)
Stomatitis	2 (1.6)	0
Anal stenosis	1 (0.8)	0
Colitis	1 (0.8)	0
Gastric haemorrhage	1 (0.8)	0
Gastric stenosis	1 (0.8)	0
Large intestine perforation	1 (0.8)	0
Pancreatitis	1 (0.8)	0
Upper gastrointestinal haemorrhage	1 (0.8)	0
General disorders and administration site conditions	14 (11.2)	5 (8.1)
Fatigue	9 (7.2)	2 (3.2)
Disease progression	3 (2.4)	2 (3.2)

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Asthenia	1 (0.8)	1 (1.6)
Condition aggravated	1 (0.8)	0
General physical health deterioration	1 (0.8)	0
Malaise	1 (0.8)	0
Hepatobiliary disorders	12 (9.6)	4 (6.5)
Hepatic function abnormal	4 (3.2)	1 (1.6)
Jaundice cholestatic	4 (3.2)	1 (1.6)
Cholangitis	1 (0.8)	1 (1.6)
Bile duct obstruction	1 (0.8)	0
Bile duct stone	1 (0.8)	0
Cholangitis acute	1 (0.8)	0
Liver disorder	0	1 (1.6)
Liver injury	1 (0.8)	0
Infections and infestations	13 (10.4)	1 (1.6)
Device related infection	1 (0.8)	1 (1.6)
Lung infection	2 (1.6)	0
Pneumonia	2 (1.6)	0
Sepsis	2 (1.6)	0
Bacteraemia	1 (0.8)	0
Biliary sepsis	1 (0.8)	0
Biliary tract infection	1 (0.8)	0
Cholangitis infective	1 (0.8)	0
Infectious pleural effusion	0	1 (1.6)
Influenza	1 (0.8)	0
Pneumonia bacterial	1 (0.8)	0
Urinary tract infection	1 (0.8)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (5.6)	2 (3.2)
Neoplasm progression	2 (1.6)	1 (1.6)
Tumour haemorrhage	3 (2.4)	0
Cancer pain	1 (0.8)	0
Pericarditis malignant	1 (0.8)	0
Tumour pain	0	1 (1.6)
Vascular disorders	3 (2.4)	3 (4.8)
Hypotension	2 (1.6)	1 (1.6)
Hypertension	0	2 (3.2)
Embolism	1 (0.8)	0
Nervous system disorders	2 (1.6)	3 (4.8)
Cerebral infarction	0	1 (1.6)
Dizziness	0	1 (1.6)
Hemiplegia	1 (0.8)	0
Presyncope	1 (0.8)	0
Syncope	0	1 (1.6)
Cardiac disorders	3 (2.4)	1 (1.6)
Acute coronary syndrome	1 (0.8)	0
Pericardial effusion	1 (0.8)	0
Stress cardiomyopathy	1 (0.8)	0
Supraventricular tachycardia	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders	3 (2.4)	1 (1.6)
Pneumonia aspiration	1 (0.8)	1 (1.6)
Interstitial lung disease	1 (0.8)	0
Pneumonitis	1 (0.8)	0

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	DS-8201a (N=125) n (%)	Phys. Choice (N=62) n (%)
Renal and urinary disorders	2 (1.6)	1 (1.6)
Hydronephrosis	1 (0.8)	1 (1.6)
Acute kidney injury	1 (0.8)	0
Immune system disorders	1 (0.8)	0
Anaphylactic reaction	1 (0.8)	0
Musculoskeletal and connective tissue disorders	0	1 (1.6)
Myalgia	0	1 (1.6)
Skin and subcutaneous tissue disorders	0	1 (1.6)
Skin ulcer	0	1 (1.6)

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	125 (100.0)	61 (98.4)
Number of censored subjects, n (%)	0 (0.0)	1 (1.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	0.1 (0.1, 0.1)	0.1 (0.1, 0.2)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.40 (1.03, 1.92)	
p-value [c]	0.0492	
Relative Risk (95% CI) [d]	1.02 (0.98, 1.05)	
p-value	0.3173	
Odds Ratio (95% CI) [d]	6.12 (0.25, 152.47)	
p-value	0.2694	
Risk Difference (95% CI) [e]	1.61 (-2.73, 5.95)	
p-value	0.4666	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.7684
Japan	99/ 99 (100.0)	0.1 (0.1, 0.1)	50/ 50 (100.0)	0.1 (0.1, 0.2)	1.52 (1.06, 2.17)	0.0332	
Korea	26/ 26 (100.0)	0.1 (0.0, 0.2)	11/ 12 (91.7)	0.1 (0.0, 0.4)	1.26 (0.61, 2.59)	0.6321	
Lines of prior systemic therapy							0.8081
2	66/ 66 (100.0)	0.1 (0.1, 0.1)	37/ 38 (97.4)	0.2 (0.1, 0.3)	1.42 (0.94, 2.13)	0.1212	
3	34/ 34 (100.0)	0.1 (0.1, 0.1)	18/ 18 (100.0)	0.1 (0.1, 0.2)	1.20 (0.66, 2.18)	0.5971	
>=4	25/ 25 (100.0)	0.1 (0.1, 0.3)	6/ 6 (100.0)	0.2 (0.0, 0.5)	2.11 (0.76, 5.85)	0.1686	
Age							0.5792
<65 years	55/ 55 (100.0)	0.1 (0.1, 0.1)	27/ 27 (100.0)	0.1 (0.1, 0.2)	1.16 (0.72, 1.85)	0.5930	
>=65 years	70/ 70 (100.0)	0.1 (0.1, 0.1)	34/ 35 (97.1)	0.2 (0.1, 0.3)	1.58 (1.04, 2.41)	0.0497	
Sex							0.4381
female	30/ 30 (100.0)	0.1 (0.1, 0.1)	15/ 15 (100.0)	0.1 (0.0, 0.2)	1.11 (0.58, 2.12)	0.8266	
male	95/ 95 (100.0)	0.1 (0.1, 0.1)	46/ 47 (97.9)	0.2 (0.1, 0.3)	1.48 (1.03, 2.12)	0.0400	
ECOG PS							0.9970
0	62/ 62 (100.0)	0.1 (0.1, 0.1)	30/ 30 (100.0)	0.1 (0.1, 0.3)	1.38 (0.88, 2.16)	0.1807	
1	63/ 63 (100.0)	0.1 (0.1, 0.1)	31/ 32 (96.9)	0.1 (0.1, 0.3)	1.40 (0.90, 2.18)	0.1626	
HER2 Status in central laboratory							0.8946
IHC 3+	96/ 96 (100.0)	0.1 (0.1, 0.1)	46/ 47 (97.9)	0.1 (0.1, 0.2)	1.36 (0.95, 1.94)	0.1193	
IHC 2+/ISH +	29/ 29 (100.0)	0.1 (0.1, 0.2)	15/ 15 (100.0)	0.2 (0.0, 0.3)	1.98 (0.95, 4.10)	0.0810	
Primary tumor location							0.8768
Gastric	108/108 (100.0)	0.1 (0.1, 0.1)	54/ 55 (98.2)	0.2 (0.1, 0.3)	1.39 (1.00, 1.94)	0.0716	
GEJ	17/ 17 (100.0)	0.1 (0.0, 0.1)	7/ 7 (100.0)	0.1 (0.0, 0.2)	1.28 (0.50, 3.27)	0.5960	
Histological subtype							0.0493
intestinal	89/ 89 (100.0)	0.1 (0.1, 0.1)	38/ 38 (100.0)	0.2 (0.1, 0.2)	1.73 (1.15, 2.60)	0.0128	
diffuse	28/ 28 (100.0)	0.1 (0.1, 0.1)	17/ 18 (94.4)	0.1 (0.1, 0.5)	1.40 (0.75, 2.62)	0.3118	
others	8/ 8 (100.0)	0.1 (0.0, 0.3)	6/ 6 (100.0)	0.1 (0.0, 0.1)	0.36 (0.10, 1.34)	0.1114	
Number of metastatic sites							0.4863
<2	23/ 23 (100.0)	0.1 (0.1, 0.2)	10/ 10 (100.0)	0.2 (0.0, 0.5)	2.00 (0.90, 4.47)	0.0830	
>= 2	102/102 (100.0)	0.1 (0.1, 0.1)	51/ 52 (98.1)	0.1 (0.1, 0.2)	1.34 (0.95, 1.89)	0.1309	
Previous total gastrectomy							0.0467
yes	22/ 22 (100.0)	0.2 (0.1, 0.3)	9/ 9 (100.0)	0.1 (0.0, 0.5)	0.69 (0.31, 1.56)	0.3369	
no	103/103 (100.0)	0.1 (0.1, 0.1)	52/ 53 (98.1)	0.2 (0.1, 0.2)	1.62 (1.15, 2.27)	0.0088	
Prior adjuvant/ neoadjuvant therapy							0.1649
yes	30/ 30 (100.0)	0.1 (0.1, 0.3)	10/ 10 (100.0)	0.2 (0.0, 0.3)	0.86 (0.41, 1.81)	0.6739	
no	95/ 95 (100.0)	0.1 (0.1, 0.1)	51/ 52 (98.1)	0.1 (0.1, 0.2)	1.56 (1.10, 2.21)	0.0187	
Prior ramucirumab contained treatment							0.9330
yes	94/ 94 (100.0)	0.1 (0.1, 0.1)	40/ 41 (97.6)	0.1 (0.1, 0.2)	1.44 (0.98, 2.11)	0.0872	
no	31/ 31 (100.0)	0.1 (0.1, 0.2)	21/ 21 (100.0)	0.2 (0.1, 0.3)	1.42 (0.80, 2.51)	0.2692	
Prior nivolumab contained treatment							0.7752
yes	33/ 33 (100.0)	0.1 (0.1, 0.1)	15/ 15 (100.0)	0.1 (0.0, 0.2)	1.40 (0.73, 2.70)	0.2781	
no	92/ 92 (100.0)	0.1 (0.1, 0.2)	46/ 47 (97.9)	0.2 (0.1, 0.3)	1.42 (0.99, 2.04)	0.0760	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

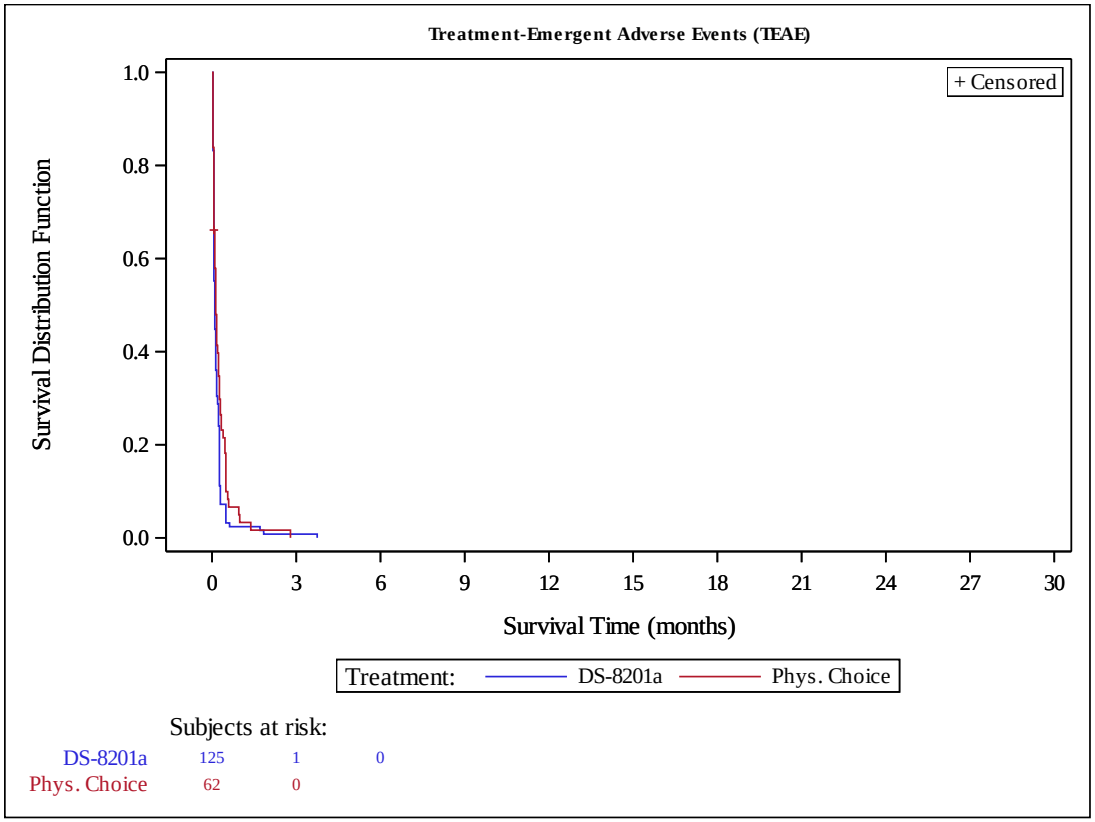
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Treatment-Emergent Adverse Events (TEAE) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.4991
yes	44/ 44 (100.0)	0.1 (0.1, 0.1)	17/ 17 (100.0)	0.1 (0.0, 0.2)	1.17 (0.66, 2.08)	0.6218	
no	81/ 81 (100.0)	0.1 (0.1, 0.2)	44/ 45 (97.8)	0.2 (0.1, 0.3)	1.46 (1.00, 2.12)	0.0675	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.3343
yes	22/ 22 (100.0)	0.1 (0.1, 0.2)	7/ 7 (100.0)	0.3 (0.1, 0.5)	2.59 (1.02, 6.59)	0.0417	
no	103/103 (100.0)	0.1 (0.1, 0.1)	54/ 55 (98.2)	0.1 (0.1, 0.2)	1.28 (0.92, 1.79)	0.2145	
Presence of liver metastasis at baseline							0.1480
yes	68/ 68 (100.0)	0.1 (0.1, 0.1)	34/ 34 (100.0)	0.2 (0.1, 0.3)	1.82 (1.18, 2.78)	0.0078	
no	57/ 57 (100.0)	0.1 (0.1, 0.2)	27/ 28 (96.4)	0.1 (0.1, 0.2)	1.03 (0.65, 1.64)	0.9967	
Renal impairment at baseline							0.0682
normal	33/ 33 (100.0)	0.1 (0.1, 0.1)	13/ 13 (100.0)	0.1 (0.0, 0.5)	1.68 (0.85, 3.29)	0.1429	
mild	53/ 53 (100.0)	0.1 (0.1, 0.2)	28/ 28 (100.0)	0.2 (0.1, 0.4)	1.81 (1.12, 2.92)	0.0188	
moderate	39/ 39 (100.0)	0.1 (0.1, 0.2)	19/ 20 (95.0)	0.1 (0.1, 0.2)	0.83 (0.47, 1.46)	0.4899	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9063
normal	88/ 88 (100.0)	0.1 (0.1, 0.1)	46/ 47 (97.9)	0.1 (0.1, 0.2)	1.35 (0.94, 1.95)	0.1229	
mild	36/ 36 (100.0)	0.1 (0.1, 0.2)	15/ 15 (100.0)	0.2 (0.1, 0.3)	1.72 (0.89, 3.34)	0.1429	
moderate	1/ 1 (100.0)	0.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.6151
yes	8/ 8 (100.0)	0.2 (0.1, 0.3)	5/ 5 (100.0)	0.3 (0.1, 2.8)	2.44 (0.63, 9.38)	0.2205	
no	117/117 (100.0)	0.1 (0.1, 0.1)	56/ 57 (98.2)	0.1 (0.1, 0.2)	1.33 (0.96, 1.84)	0.1143	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.2575
yes	3/ 3 (100.0)	0.1 (0.1, 0.2)	4/ 4 (100.0)	0.3 (0.1, 2.8)	3.20 (0.52, 19.89)	0.1886	
no	122/122 (100.0)	0.1 (0.1, 0.1)	57/ 58 (98.3)	0.1 (0.1, 0.2)	1.32 (0.96, 1.82)	0.1281	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

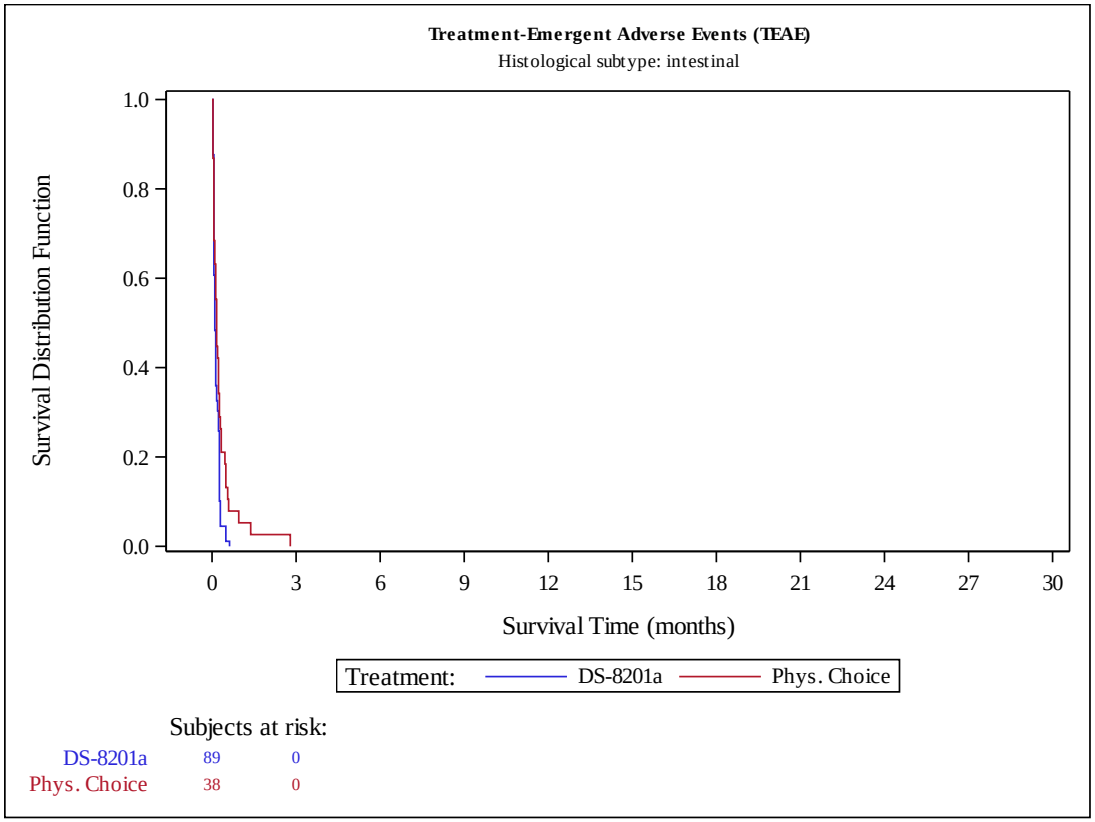
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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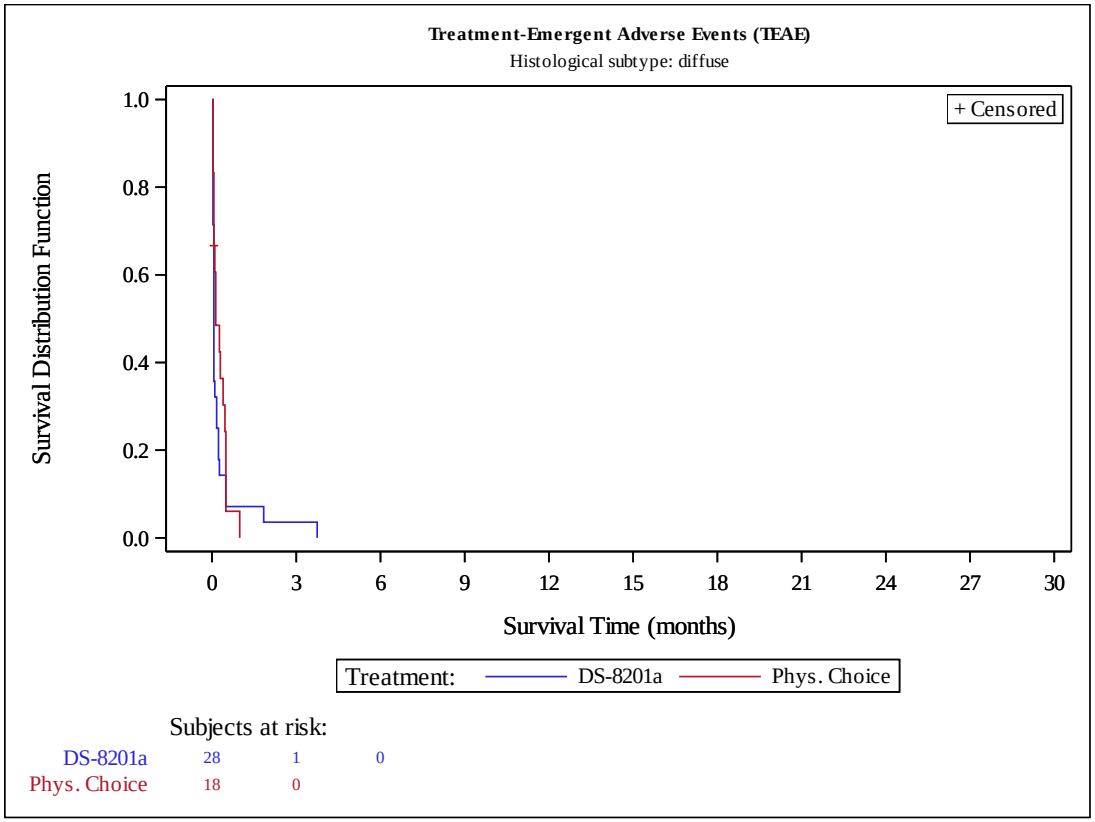
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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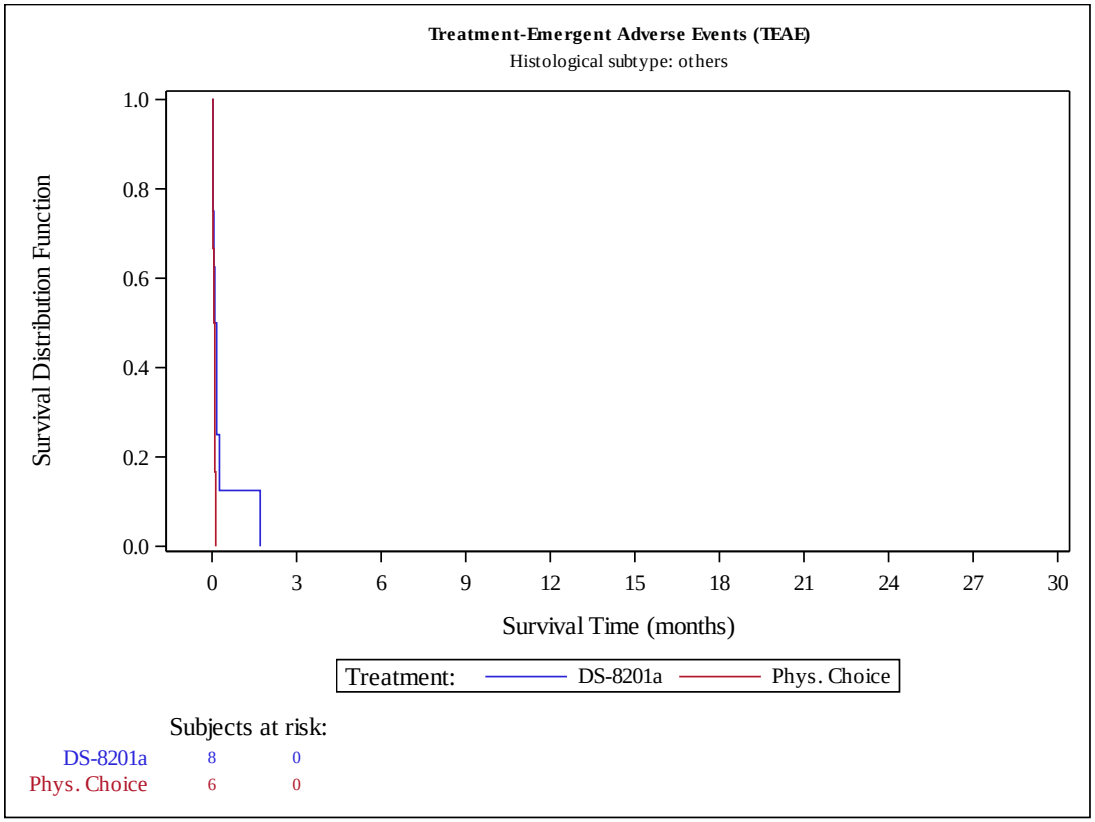
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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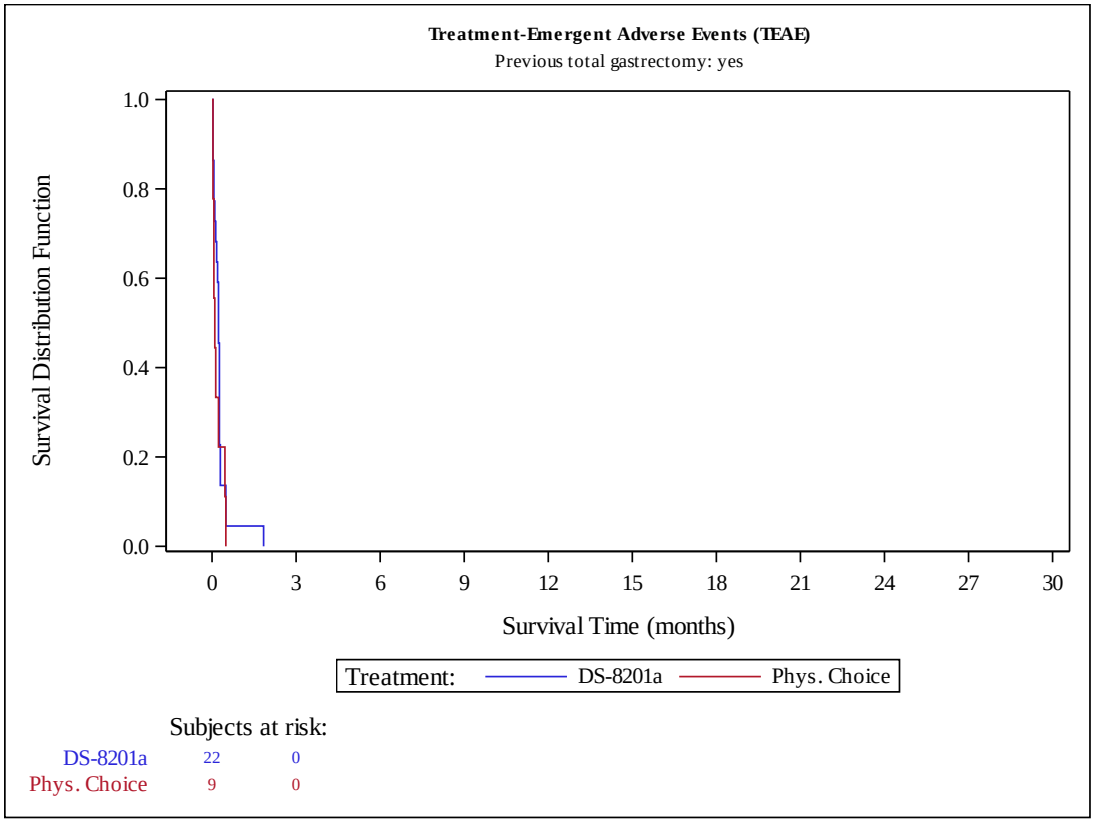
Date of Table Generation: 07JUN2022

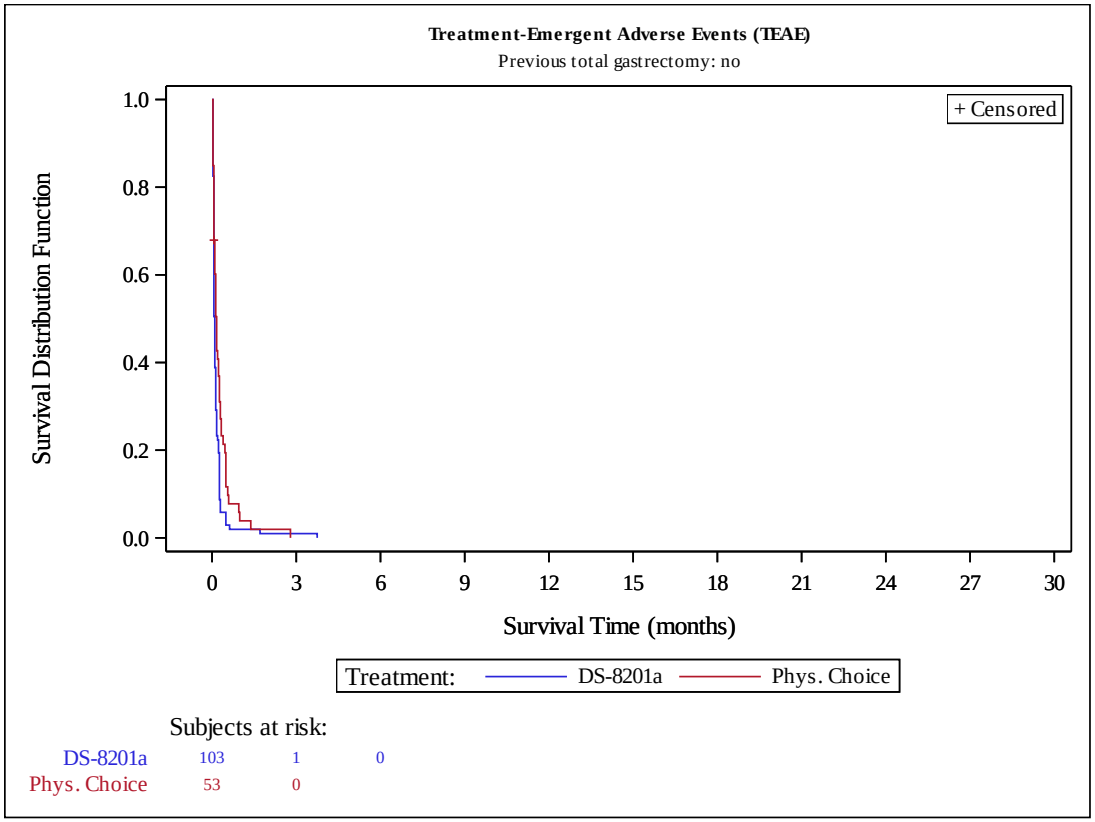
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious TEAE
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	56 (44.8)	16 (25.8)
Number of censored subjects, n (%)	69 (55.2)	46 (74.2)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	9.9 (5.6, NE)	NE (6.9, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.33 (0.76, 2.35)	
p-value [c]	0.3152	
Relative Risk (95% CI) [d]	1.74 (1.09, 2.76)	
p-value	0.0200	
Odds Ratio (95% CI) [d]	2.33 (1.19, 4.56)	
p-value	0.0131	
Risk Difference (95% CI) [e]	18.99 (3.84, 34.15)	
p-value	0.0140	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious TEAE - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.7479
Japan	42/ 99 (42.4)	15.1 (5.6, NE)	12/ 50 (24.0)	NE (6.9, NE)	1.41 (0.73, 2.70)	0.3016	
Korea	14/ 26 (53.8)	9.6 (2.6, 10.4)	4/ 12 (33.3)	NE (0.5, NE)	1.05 (0.33, 3.34)	0.9323	
Lines of prior systemic therapy							0.8387
2	32/ 66 (48.5)	7.3 (3.5, NE)	10/ 38 (26.3)	6.9 (6.9, NE)	1.47 (0.72, 3.03)	0.2921	
3	11/ 34 (32.4)	NE (5.8, NE)	4/ 18 (22.2)	NE (3.0, NE)	0.94 (0.29, 3.05)	0.9176	
>=4	13/ 25 (52.0)	5.4 (1.8, NE)	2/ 6 (33.3)	NE (0.5, NE)	1.34 (0.30, 5.99)	0.7066	
Age							0.7335
<65 years	24/ 55 (43.6)	10.4 (3.5, NE)	7/ 27 (25.9)	NE (6.9, NE)	1.20 (0.51, 2.83)	0.6835	
>=65 years	32/ 70 (45.7)	7.8 (4.0, NE)	9/ 35 (25.7)	NE (3.5, NE)	1.46 (0.69, 3.08)	0.3182	
Sex							0.1238
female	17/ 30 (56.7)	3.9 (2.3, NE)	2/ 15 (13.3)	NE (NE , NE)	3.82 (0.88, 16.66)	0.0551	
male	39/ 95 (41.1)	10.4 (7.3, NE)	14/ 47 (29.8)	NE (3.5, NE)	1.01 (0.54, 1.89)	0.9709	
ECOG PS							0.5430
0	20/ 62 (32.3)	NE (10.3, NE)	4/ 30 (13.3)	NE (6.9, NE)	1.88 (0.63, 5.56)	0.2480	
1	36/ 63 (57.1)	5.4 (2.7, 9.9)	12/ 32 (37.5)	NE (2.7, NE)	1.17 (0.60, 2.28)	0.6361	
HER2 Status in central laboratory							0.0352
IHC 3+	39/ 96 (40.6)	15.1 (5.8, NE)	15/ 47 (31.9)	6.9 (3.0, NE)	0.91 (0.50, 1.68)	0.7688	
IHC 2+/ISH +	17/ 29 (58.6)	5.4 (1.7, NE)	1/ 15 (6.7)	NE (NE , NE)	7.80 (1.03, 59.19)	0.0187	
Primary tumor location							0.9852
Gastric	49/108 (45.4)	9.9 (5.6, NE)	16/ 55 (29.1)	NE (6.9, NE)	1.22 (0.69, 2.16)	0.4942	
GEJ	7/ 17 (41.2)	15.1 (2.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.9596
intestinal	35/ 89 (39.3)	15.1 (5.8, NE)	9/ 38 (23.7)	6.9 (6.9, NE)	1.29 (0.62, 2.72)	0.4970	
diffuse	15/ 28 (53.6)	9.6 (1.8, NE)	4/ 18 (22.2)	NE (3.0, NE)	1.54 (0.49, 4.81)	0.4565	
others	6/ 8 (75.0)	1.9 (0.1, NE)	3/ 6 (50.0)	NE (0.3, NE)	1.71 (0.43, 6.88)	0.4364	
Number of metastatic sites							0.9454
<2	8/ 23 (34.8)	NE (3.9, NE)	2/ 10 (20.0)	NE (0.0, NE)	1.54 (0.32, 7.34)	0.5833	
>= 2	48/102 (47.1)	7.8 (5.4, NE)	14/ 52 (26.9)	6.9 (6.9, NE)	1.28 (0.70, 2.36)	0.4201	
Previous total gastrectomy							0.9899
yes	8/ 22 (36.4)	10.4 (3.9, NE)	2/ 9 (22.2)	NE (0.5, NE)	1.15 (0.23, 5.77)	0.8629	
no	48/103 (46.6)	9.6 (5.4, NE)	14/ 53 (26.4)	NE (6.9, NE)	1.37 (0.75, 2.50)	0.3095	
Prior adjuvant/ neoadjuvant therapy							0.7145
yes	8/ 30 (26.7)	NE (9.9, NE)	1/ 10 (10.0)	NE (0.5, NE)	1.84 (0.22, 15.40)	0.5688	
no	48/ 95 (50.5)	7.3 (3.5, NE)	15/ 52 (28.8)	6.9 (3.5, NE)	1.36 (0.76, 2.46)	0.2994	
Prior ramucirumab contained treatment							0.5381
yes	39/ 94 (41.5)	9.9 (5.6, NE)	8/ 41 (19.5)	NE (NE , NE)	1.70 (0.79, 3.66)	0.1710	
no	17/ 31 (54.8)	9.6 (2.6, 15.1)	8/ 21 (38.1)	6.9 (2.8, NE)	1.00 (0.42, 2.39)	0.9996	
Prior nivolumab contained treatment							0.6614
yes	15/ 33 (45.5)	NE (2.4, NE)	3/ 15 (20.0)	NE (2.7, NE)	1.92 (0.55, 6.73)	0.2997	
no	41/ 92 (44.6)	9.9 (5.4, NE)	13/ 47 (27.7)	NE (6.9, NE)	1.21 (0.64, 2.28)	0.5605	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

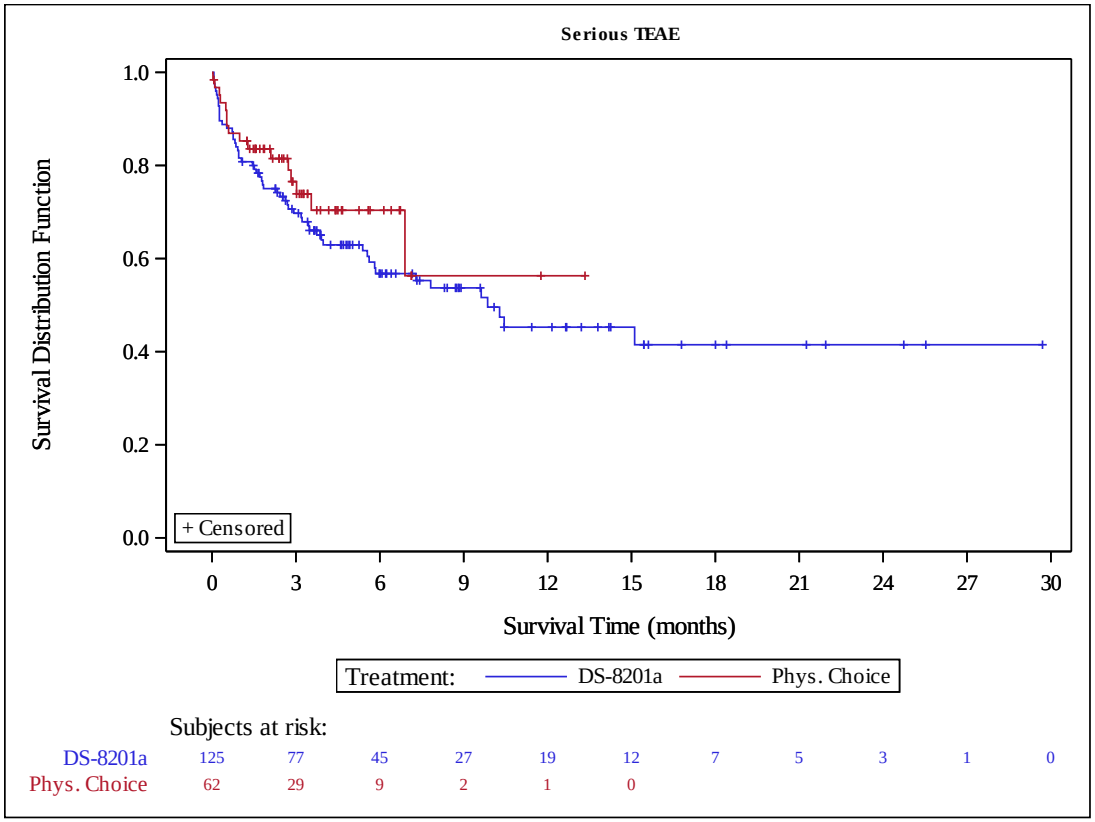
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious TEAE - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.2610
yes	23/ 44 (52.3)	9.6 (2.4, NE)	3/ 17 (17.6)	NE (3.0, NE)	2.53 (0.75, 8.55)	0.1221	
no	33/ 81 (40.7)	10.3 (5.4, NE)	13/ 45 (28.9)	NE (6.9, NE)	1.07 (0.56, 2.05)	0.8437	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.2998
yes	12/ 22 (54.5)	5.4 (1.5, NE)	1/ 7 (14.3)	NE (0.6, NE)	3.45 (0.44, 26.75)	0.2072	
no	44/103 (42.7)	10.4 (5.8, NE)	15/ 55 (27.3)	NE (6.9, NE)	1.17 (0.65, 2.13)	0.5984	
Presence of liver metastasis at baseline							0.5117
yes	27/ 68 (39.7)	10.3 (5.6, NE)	9/ 34 (26.5)	NE (3.0, NE)	1.10 (0.51, 2.37)	0.8071	
no	29/ 57 (50.9)	9.9 (3.9, NE)	7/ 28 (25.0)	NE (6.9, NE)	1.61 (0.69, 3.72)	0.2626	
Renal impairment at baseline							0.3626
normal	11/ 33 (33.3)	NE (3.5, NE)	2/ 13 (15.4)	NE (2.1, NE)	1.36 (0.29, 6.36)	0.6937	
mild	25/ 53 (47.2)	7.8 (4.0, NE)	10/ 28 (35.7)	6.9 (2.8, NE)	1.10 (0.52, 2.30)	0.8025	
moderate	20/ 39 (51.3)	7.3 (1.8, NE)	3/ 20 (15.0)	NE (NE , NE)	3.26 (0.95, 11.16)	0.0459	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.6708
normal	39/ 88 (44.3)	10.3 (5.6, NE)	12/ 47 (25.5)	6.9 (6.9, NE)	1.18 (0.61, 2.29)	0.6338	
mild	17/ 36 (47.2)	9.9 (1.8, NE)	4/ 15 (26.7)	NE (1.3, NE)	1.74 (0.58, 5.20)	0.3063	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.6315
yes	4/ 8 (50.0)	NE (0.3, NE)	1/ 5 (20.0)	NE (1.3, NE)	2.43 (0.27, 21.96)	0.4154	
no	52/117 (44.4)	9.9 (5.8, NE)	15/ 57 (26.3)	NE (6.9, NE)	1.25 (0.69, 2.24)	0.4590	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9869
yes	1/ 3 (33.3)	NE (5.6, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	55/122 (45.1)	9.9 (5.6, NE)	16/ 58 (27.6)	NE (6.9, NE)	1.23 (0.70, 2.16)	0.4801	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

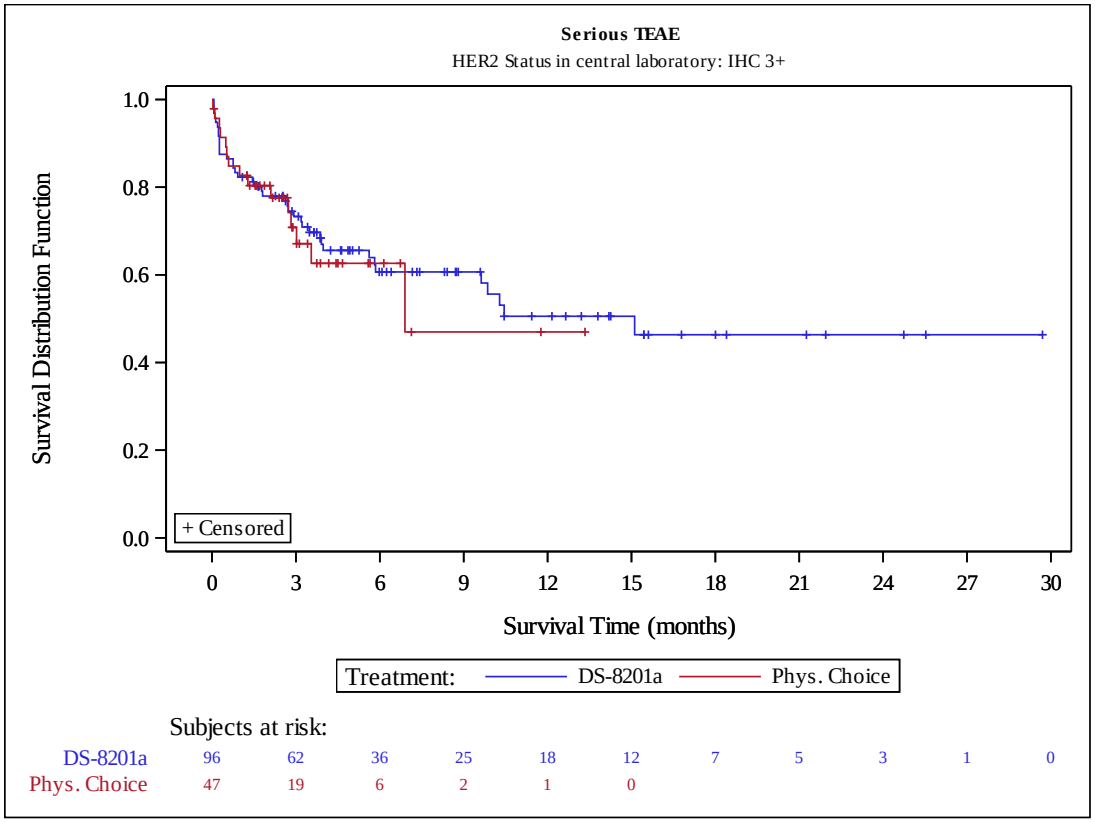
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Serious TEAE
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Serious TEAE
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Serious TEAE
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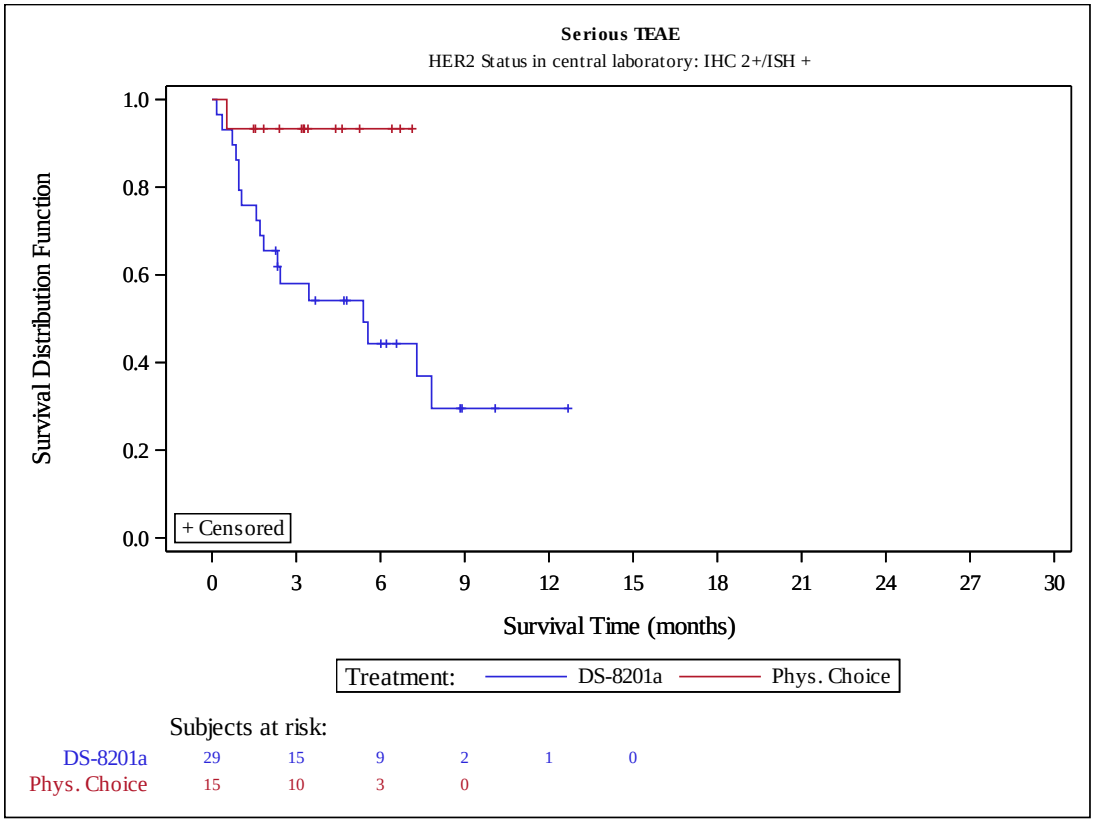


Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	107 (85.6)	35 (56.5)
Number of censored subjects, n (%)	18 (14.4)	27 (43.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	0.7 (0.5, 0.7)	1.2 (0.6, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.72 (1.18, 2.53)	
p-value [c]	0.0045	
Relative Risk (95% CI) [d]	1.52 (1.20, 1.91)	
p-value	0.0004	
Odds Ratio (95% CI) [d]	4.59 (2.26, 9.31)	
p-value	<.0001	
Risk Difference (95% CI) [e]	29.15 (14.15, 44.15)	
p-value	0.0001	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.8138
Japan	84/ 99 (84.8)	0.7 (0.5, 0.7)	29/ 50 (58.0)	1.3 (0.5, NE)	1.67 (1.09, 2.55)	0.0160	
Korea	23/ 26 (88.5)	0.7 (0.3, 1.4)	6/ 12 (50.0)	1.0 (0.5, NE)	1.92 (0.78, 4.71)	0.1475	
Lines of prior systemic therapy							0.7141
2	56/ 66 (84.8)	0.7 (0.5, 1.4)	21/ 38 (55.3)	1.2 (0.7, NE)	1.63 (0.99, 2.70)	0.0531	
3	29/ 34 (85.3)	0.5 (0.5, 0.7)	10/ 18 (55.6)	1.4 (0.5, NE)	1.96 (0.95, 4.03)	0.0602	
>=4	22/ 25 (88.0)	0.5 (0.3, 1.4)	4/ 6 (66.7)	0.5 (0.2, NE)	1.27 (0.44, 3.71)	0.6914	
Age							0.7240
<65 years	52/ 55 (94.5)	0.7 (0.5, 1.4)	16/ 27 (59.3)	0.7 (0.5, NE)	1.48 (0.84, 2.62)	0.1590	
>=65 years	55/ 70 (78.6)	0.6 (0.5, 0.7)	19/ 35 (54.3)	1.4 (0.5, NE)	1.80 (1.07, 3.03)	0.0258	
Sex							0.2133
female	26/ 30 (86.7)	0.6 (0.3, 2.7)	6/ 15 (40.0)	NE (0.5, NE)	2.52 (1.03, 6.15)	0.0388	
male	81/ 95 (85.3)	0.7 (0.5, 0.8)	29/ 47 (61.7)	0.7 (0.5, 3.5)	1.51 (0.99, 2.31)	0.0523	
ECOG PS							0.5370
0	50/ 62 (80.6)	0.7 (0.5, 1.4)	15/ 30 (50.0)	2.7 (0.7, NE)	1.98 (1.11, 3.53)	0.0182	
1	57/ 63 (90.5)	0.5 (0.4, 0.7)	20/ 32 (62.5)	0.5 (0.5, NE)	1.52 (0.91, 2.53)	0.1034	
HER2 Status in central laboratory							0.7615
IHC 3+	82/ 96 (85.4)	0.7 (0.5, 0.8)	26/ 47 (55.3)	1.8 (0.5, NE)	1.77 (1.14, 2.76)	0.0099	
IHC 2+/ISH +	25/ 29 (86.2)	0.5 (0.4, 1.4)	9/ 15 (60.0)	1.2 (0.3, NE)	1.52 (0.70, 3.30)	0.2777	
Primary tumor location							0.7756
Gastric	92/108 (85.2)	0.7 (0.5, 0.7)	31/ 55 (56.4)	1.2 (0.5, NE)	1.78 (1.18, 2.67)	0.0048	
GEJ	15/ 17 (88.2)	1.0 (0.5, 2.8)	4/ 7 (57.1)	2.3 (0.3, NE)	1.27 (0.41, 3.92)	0.6870	
Histological subtype							0.2647
intestinal	74/ 89 (83.1)	0.7 (0.5, 1.3)	24/ 38 (63.2)	1.2 (0.5, 3.5)	1.41 (0.89, 2.23)	0.1454	
diffuse	25/ 28 (89.3)	0.5 (0.3, 0.8)	7/ 18 (38.9)	NE (0.5, NE)	3.06 (1.32, 7.13)	0.0059	
others	8/ 8 (100.0)	0.4 (0.0, 1.4)	4/ 6 (66.7)	0.6 (0.3, NE)	2.21 (0.65, 7.45)	0.1626	
Number of metastatic sites							0.7686
<2	19/ 23 (82.6)	0.7 (0.4, 0.9)	6/ 10 (60.0)	0.5 (0.2, NE)	1.41 (0.56, 3.55)	0.4293	
>= 2	88/102 (86.3)	0.7 (0.5, 0.8)	29/ 52 (55.8)	1.4 (0.7, NE)	1.76 (1.16, 2.68)	0.0076	
Previous total gastrectomy							0.1750
yes	17/ 22 (77.3)	1.5 (0.5, 3.4)	6/ 9 (66.7)	0.7 (0.2, NE)	1.02 (0.40, 2.62)	0.9516	
no	90/103 (87.4)	0.5 (0.5, 0.7)	29/ 53 (54.7)	1.3 (0.6, NE)	1.94 (1.28, 2.96)	0.0015	
Prior adjuvant/ neoadjuvant therapy							0.1385
yes	23/ 30 (76.7)	0.7 (0.5, 1.4)	7/ 10 (70.0)	0.6 (0.2, NE)	1.01 (0.43, 2.38)	0.9953	
no	84/ 95 (88.4)	0.5 (0.5, 0.9)	28/ 52 (53.8)	1.4 (0.6, NE)	1.96 (1.28, 3.01)	0.0016	
Prior ramucirumab contained treatment							0.9500
yes	79/ 94 (84.0)	0.7 (0.5, 0.8)	22/ 41 (53.7)	1.2 (0.5, NE)	1.73 (1.08, 2.77)	0.0206	
no	28/ 31 (90.3)	0.5 (0.3, 1.7)	13/ 21 (61.9)	2.3 (0.5, NE)	1.68 (0.86, 3.26)	0.1267	
Prior nivolumab contained treatment							0.1232
yes	31/ 33 (93.9)	0.5 (0.3, 0.5)	8/ 15 (53.3)	1.4 (0.5, NE)	2.96 (1.34, 6.54)	0.0050	
no	76/ 92 (82.6)	0.8 (0.7, 1.5)	27/ 47 (57.4)	1.1 (0.5, NE)	1.47 (0.94, 2.28)	0.0839	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

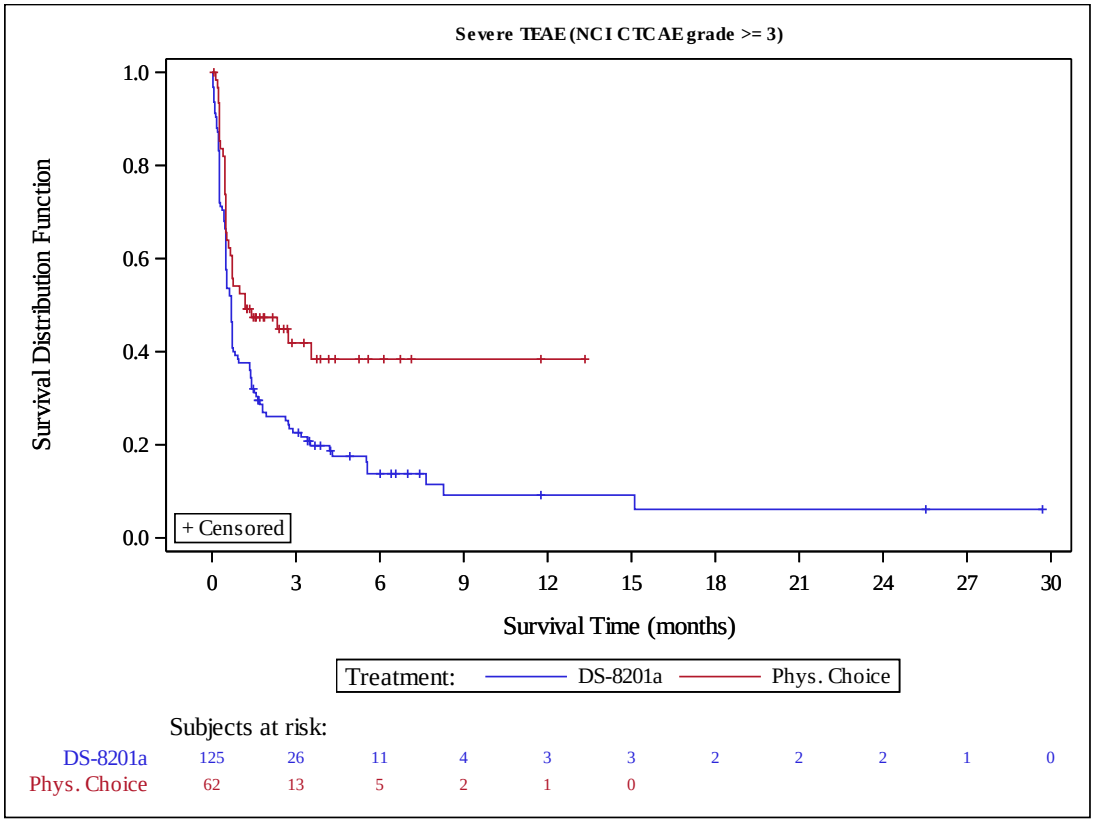
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0314
yes	41/ 44 (93.2)	0.5 (0.3, 0.5)	8/ 17 (47.1)	NE (0.5, NE)	3.37 (1.57, 7.27)	0.0010	
no	66/ 81 (81.5)	1.0 (0.7, 1.6)	27/ 45 (60.0)	0.9 (0.5, 3.5)	1.29 (0.82, 2.02)	0.2591	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9603
yes	19/ 22 (86.4)	0.7 (0.3, 1.5)	4/ 7 (57.1)	0.5 (0.1, NE)	1.67 (0.56, 4.97)	0.3407	
no	88/103 (85.4)	0.7 (0.5, 0.8)	31/ 55 (56.4)	1.3 (0.7, NE)	1.72 (1.14, 2.59)	0.0085	
Presence of liver metastasis at baseline							0.3799
yes	60/ 68 (88.2)	0.6 (0.5, 1.3)	19/ 34 (55.9)	1.4 (0.6, NE)	1.98 (1.18, 3.33)	0.0078	
no	47/ 57 (82.5)	0.7 (0.5, 0.9)	16/ 28 (57.1)	0.7 (0.5, NE)	1.45 (0.82, 2.56)	0.1956	
Renal impairment at baseline							0.2284
normal	31/ 33 (93.9)	0.6 (0.5, 0.8)	6/ 13 (46.2)	NE (0.5, NE)	2.52 (1.04, 6.11)	0.0323	
mild	44/ 53 (83.0)	0.7 (0.5, 1.4)	19/ 28 (67.9)	0.7 (0.5, 3.5)	1.24 (0.72, 2.13)	0.4284	
moderate	32/ 39 (82.1)	0.5 (0.3, 1.4)	9/ 20 (45.0)	2.7 (0.4, NE)	2.26 (1.07, 4.78)	0.0278	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.5 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9638
normal	75/ 88 (85.2)	0.7 (0.5, 1.0)	26/ 47 (55.3)	1.8 (0.7, NE)	1.73 (1.10, 2.70)	0.0151	
mild	31/ 36 (86.1)	0.6 (0.4, 0.8)	9/ 15 (60.0)	0.5 (0.5, NE)	1.69 (0.81, 3.56)	0.1491	
moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8179
yes	7/ 8 (87.5)	2.9 (0.1, 8.3)	2/ 5 (40.0)	NE (0.5, NE)	2.13 (0.43, 10.47)	0.3402	
no	100/117 (85.5)	0.7 (0.5, 0.7)	33/ 57 (57.9)	1.2 (0.6, NE)	1.70 (1.14, 2.52)	0.0075	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.3728
yes	3/ 3 (100.0)	4.3 (0.1, 5.6)	1/ 4 (25.0)	NE (0.5, NE)	3.44 (0.34, 34.64)	0.2690	
no	104/122 (85.2)	0.7 (0.5, 0.7)	34/ 58 (58.6)	1.2 (0.5, 3.5)	1.62 (1.10, 2.39)	0.0130	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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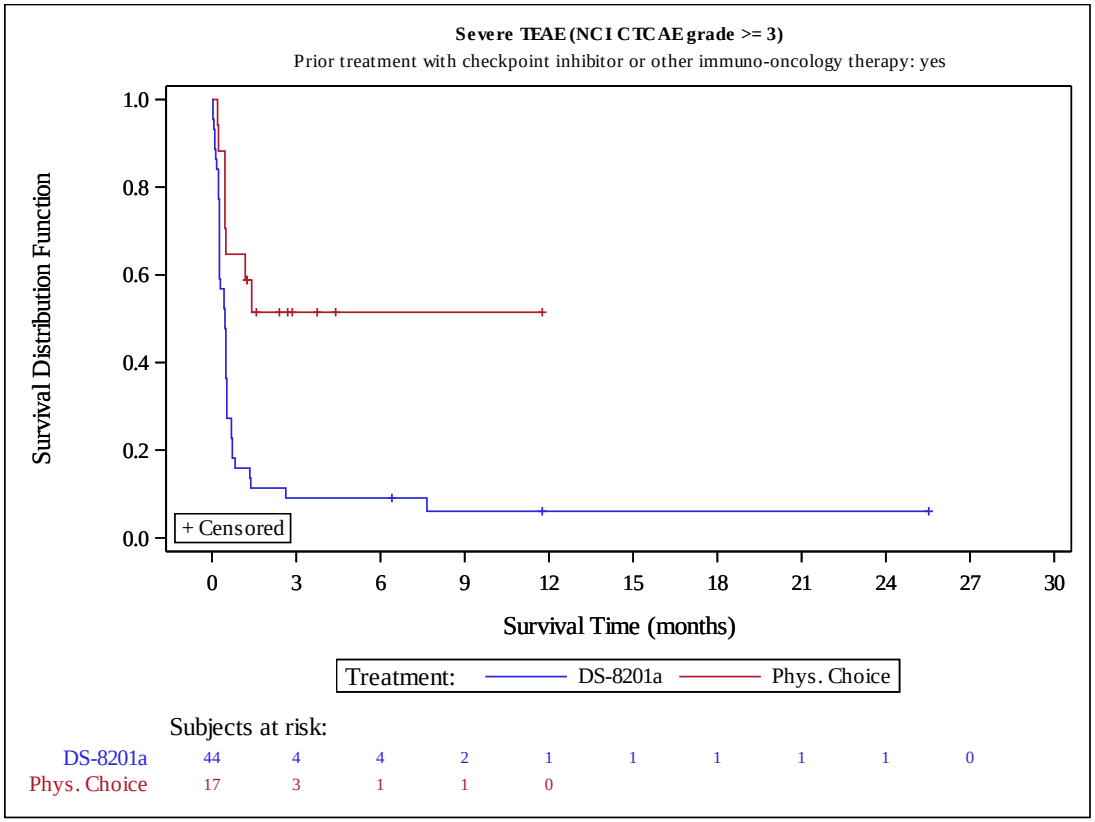

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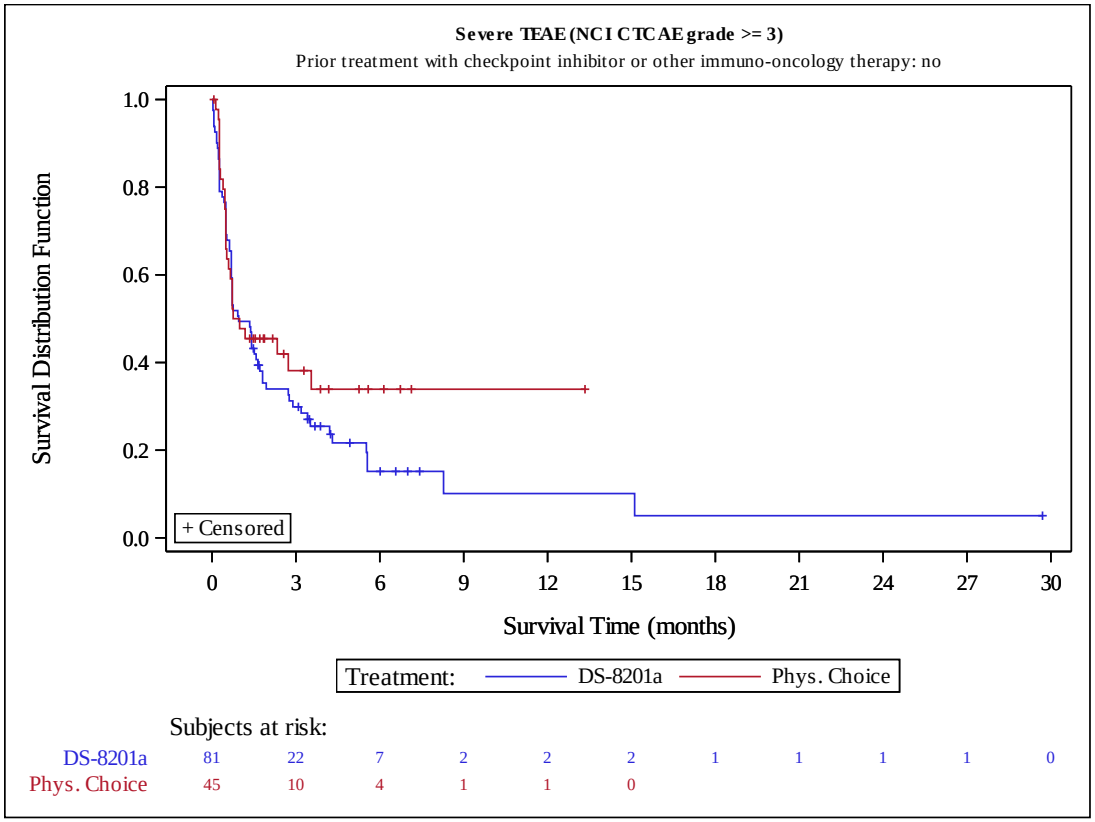

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	124 (99.2)	61 (98.4)
Number of censored subjects, n (%)	1 (0.8)	1 (1.6)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	0.1 (0.1, 0.1)	0.1 (0.1, 0.2)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.32 (0.97, 1.80)	
p-value [c]	0.1073	
Relative Risk (95% CI) [d]	1.01 (0.97, 1.04)	
p-value	0.6500	
Odds Ratio (95% CI) [d]	2.03 (0.13, 33.05)	
p-value	0.6181	
Risk Difference (95% CI) [e]	0.81 (-3.90, 5.52)	
p-value	0.7351	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.3233
Japan	99/ 99 (100.0)	0.1 (0.1, 0.1)	50/ 50 (100.0)	0.1 (0.1, 0.2)	1.53 (1.07, 2.19)	0.0299	
Korea	25/ 26 (96.2)	0.1 (0.0, 0.3)	11/ 12 (91.7)	0.1 (0.0, 0.4)	0.98 (0.47, 2.03)	0.8801	
Lines of prior systemic therapy							0.7547
2	66/ 66 (100.0)	0.1 (0.1, 0.1)	37/ 38 (97.4)	0.2 (0.1, 0.3)	1.35 (0.90, 2.03)	0.1821	
3	33/ 34 (97.1)	0.1 (0.1, 0.2)	18/ 18 (100.0)	0.1 (0.1, 0.2)	1.06 (0.59, 1.90)	0.9110	
>=4	25/ 25 (100.0)	0.1 (0.1, 0.3)	6/ 6 (100.0)	0.2 (0.0, 0.5)	2.11 (0.76, 5.85)	0.1686	
Age							0.9744
<65 years	55/ 55 (100.0)	0.1 (0.1, 0.1)	27/ 27 (100.0)	0.1 (0.1, 0.2)	1.21 (0.75, 1.94)	0.4613	
>=65 years	69/ 70 (98.6)	0.1 (0.1, 0.2)	34/ 35 (97.1)	0.2 (0.1, 0.3)	1.37 (0.90, 2.08)	0.1824	
Sex							0.4443
female	30/ 30 (100.0)	0.1 (0.1, 0.2)	15/ 15 (100.0)	0.1 (0.0, 0.2)	1.07 (0.56, 2.03)	0.9566	
male	94/ 95 (98.9)	0.1 (0.1, 0.2)	46/ 47 (97.9)	0.2 (0.1, 0.3)	1.39 (0.97, 1.99)	0.0842	
ECOG PS							0.7410
0	62/ 62 (100.0)	0.1 (0.1, 0.1)	30/ 30 (100.0)	0.1 (0.1, 0.3)	1.39 (0.89, 2.17)	0.1725	
1	62/ 63 (98.4)	0.1 (0.1, 0.2)	31/ 32 (96.9)	0.1 (0.1, 0.3)	1.25 (0.80, 1.94)	0.3696	
HER2 Status in central laboratory							0.8450
IHC 3+	95/ 96 (99.0)	0.1 (0.1, 0.2)	46/ 47 (97.9)	0.1 (0.1, 0.3)	1.28 (0.90, 1.83)	0.2138	
IHC 2+/ISH +	29/ 29 (100.0)	0.1 (0.1, 0.2)	15/ 15 (100.0)	0.2 (0.0, 0.3)	1.58 (0.81, 3.07)	0.1964	
Primary tumor location							0.8903
Gastric	107/108 (99.1)	0.1 (0.1, 0.2)	54/ 55 (98.2)	0.2 (0.1, 0.3)	1.31 (0.94, 1.82)	0.1463	
GEJ	17/ 17 (100.0)	0.1 (0.0, 0.1)	7/ 7 (100.0)	0.1 (0.0, 0.2)	1.23 (0.48, 3.16)	0.6535	
Histological subtype							0.0378
intestinal	89/ 89 (100.0)	0.1 (0.1, 0.1)	38/ 38 (100.0)	0.2 (0.1, 0.3)	1.78 (1.18, 2.69)	0.0083	
diffuse	27/ 28 (96.4)	0.1 (0.1, 0.2)	17/ 18 (94.4)	0.1 (0.1, 0.5)	1.13 (0.61, 2.10)	0.7822	
others	8/ 8 (100.0)	0.1 (0.0, 0.3)	6/ 6 (100.0)	0.1 (0.0, 0.1)	0.36 (0.10, 1.34)	0.1114	
Number of metastatic sites							0.2963
<2	23/ 23 (100.0)	0.1 (0.1, 0.2)	10/ 10 (100.0)	0.3 (0.0, 0.5)	2.18 (0.96, 4.94)	0.0659	
>= 2	101/102 (99.0)	0.1 (0.1, 0.1)	51/ 52 (98.1)	0.1 (0.1, 0.2)	1.22 (0.87, 1.72)	0.3020	
Previous total gastrectomy							0.0132
yes	21/ 22 (95.5)	0.3 (0.1, 0.3)	9/ 9 (100.0)	0.1 (0.0, 0.5)	0.52 (0.23, 1.18)	0.0993	
no	103/103 (100.0)	0.1 (0.1, 0.1)	52/ 53 (98.1)	0.2 (0.1, 0.3)	1.60 (1.14, 2.26)	0.0095	
Prior adjuvant/ neoadjuvant therapy							0.1633
yes	29/ 30 (96.7)	0.1 (0.1, 0.3)	10/ 10 (100.0)	0.2 (0.0, 0.4)	0.84 (0.40, 1.76)	0.6074	
no	95/ 95 (100.0)	0.1 (0.1, 0.1)	51/ 52 (98.1)	0.1 (0.1, 0.2)	1.48 (1.04, 2.10)	0.0340	
Prior ramucirumab contained treatment							0.7016
yes	94/ 94 (100.0)	0.1 (0.1, 0.1)	40/ 41 (97.6)	0.1 (0.1, 0.3)	1.43 (0.97, 2.10)	0.0943	
no	30/ 31 (96.8)	0.1 (0.1, 0.2)	21/ 21 (100.0)	0.2 (0.1, 0.3)	1.21 (0.68, 2.14)	0.5668	
Prior nivolumab contained treatment							0.8080
yes	33/ 33 (100.0)	0.1 (0.1, 0.1)	15/ 15 (100.0)	0.1 (0.0, 0.2)	1.35 (0.70, 2.59)	0.3387	
no	91/ 92 (98.9)	0.1 (0.1, 0.2)	46/ 47 (97.9)	0.2 (0.1, 0.3)	1.34 (0.93, 1.92)	0.1455	

NE: Not estimable.
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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.1660
yes	43/ 44 (97.7)	0.1 (0.1, 0.1)	17/ 17 (100.0)	0.1 (0.0, 0.2)	0.93 (0.53, 1.65)	0.8122	
no	81/ 81 (100.0)	0.1 (0.1, 0.2)	44/ 45 (97.8)	0.2 (0.1, 0.3)	1.49 (1.02, 2.17)	0.0558	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.1327
yes	22/ 22 (100.0)	0.1 (0.1, 0.2)	7/ 7 (100.0)	0.4 (0.1, 0.5)	3.54 (1.30, 9.68)	0.0110	
no	102/103 (99.0)	0.1 (0.1, 0.1)	54/ 55 (98.2)	0.1 (0.1, 0.2)	1.17 (0.84, 1.63)	0.4622	
Presence of liver metastasis at baseline							0.3461
yes	67/ 68 (98.5)	0.1 (0.1, 0.1)	34/ 34 (100.0)	0.2 (0.1, 0.3)	1.54 (1.01, 2.35)	0.0514	
no	57/ 57 (100.0)	0.1 (0.1, 0.2)	27/ 28 (96.4)	0.1 (0.1, 0.2)	1.07 (0.67, 1.70)	0.9111	
Renal impairment at baseline							0.0218
normal	33/ 33 (100.0)	0.1 (0.1, 0.1)	13/ 13 (100.0)	0.1 (0.0, 0.5)	1.60 (0.82, 3.11)	0.1743	
mild	53/ 53 (100.0)	0.1 (0.1, 0.2)	28/ 28 (100.0)	0.2 (0.1, 0.4)	1.80 (1.11, 2.90)	0.0203	
moderate	38/ 39 (97.4)	0.1 (0.1, 0.2)	19/ 20 (95.0)	0.1 (0.1, 0.2)	0.71 (0.40, 1.25)	0.2113	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.0 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9295
normal	87/ 88 (98.9)	0.1 (0.1, 0.1)	46/ 47 (97.9)	0.1 (0.1, 0.2)	1.25 (0.87, 1.79)	0.2658	
mild	36/ 36 (100.0)	0.1 (0.1, 0.3)	15/ 15 (100.0)	0.2 (0.1, 0.3)	1.51 (0.80, 2.82)	0.2261	
moderate	1/ 1 (100.0)	0.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4352
yes	8/ 8 (100.0)	0.2 (0.1, 0.3)	5/ 5 (100.0)	0.3 (0.1, 2.8)	2.76 (0.70, 10.84)	0.1473	
no	116/117 (99.1)	0.1 (0.1, 0.1)	56/ 57 (98.2)	0.1 (0.1, 0.2)	1.24 (0.89, 1.71)	0.2462	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.1764
yes	3/ 3 (100.0)	0.1 (0.1, 0.2)	4/ 4 (100.0)	0.4 (0.1, 2.8)	3.20 (0.52, 19.89)	0.1886	
no	121/122 (99.2)	0.1 (0.1, 0.1)	57/ 58 (98.3)	0.1 (0.1, 0.2)	1.23 (0.90, 1.70)	0.2578	

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Daiichi Sankyo

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Protocol DS8201-A-J202
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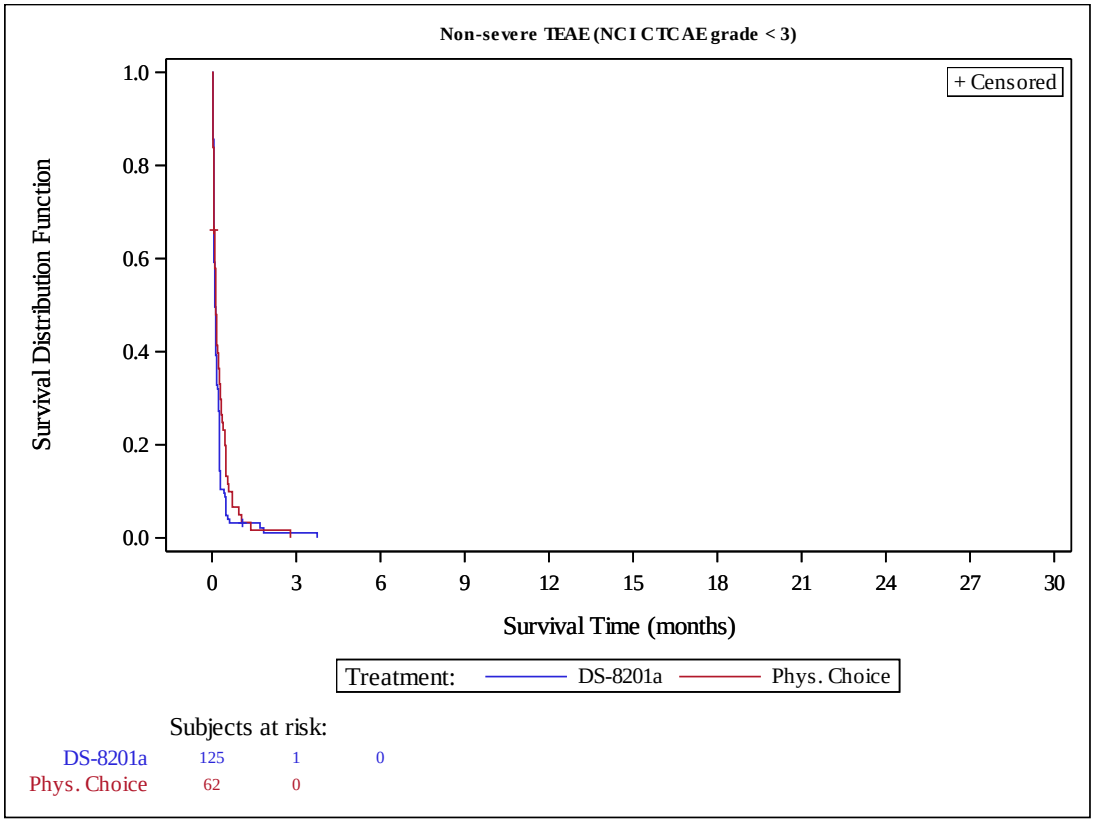
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



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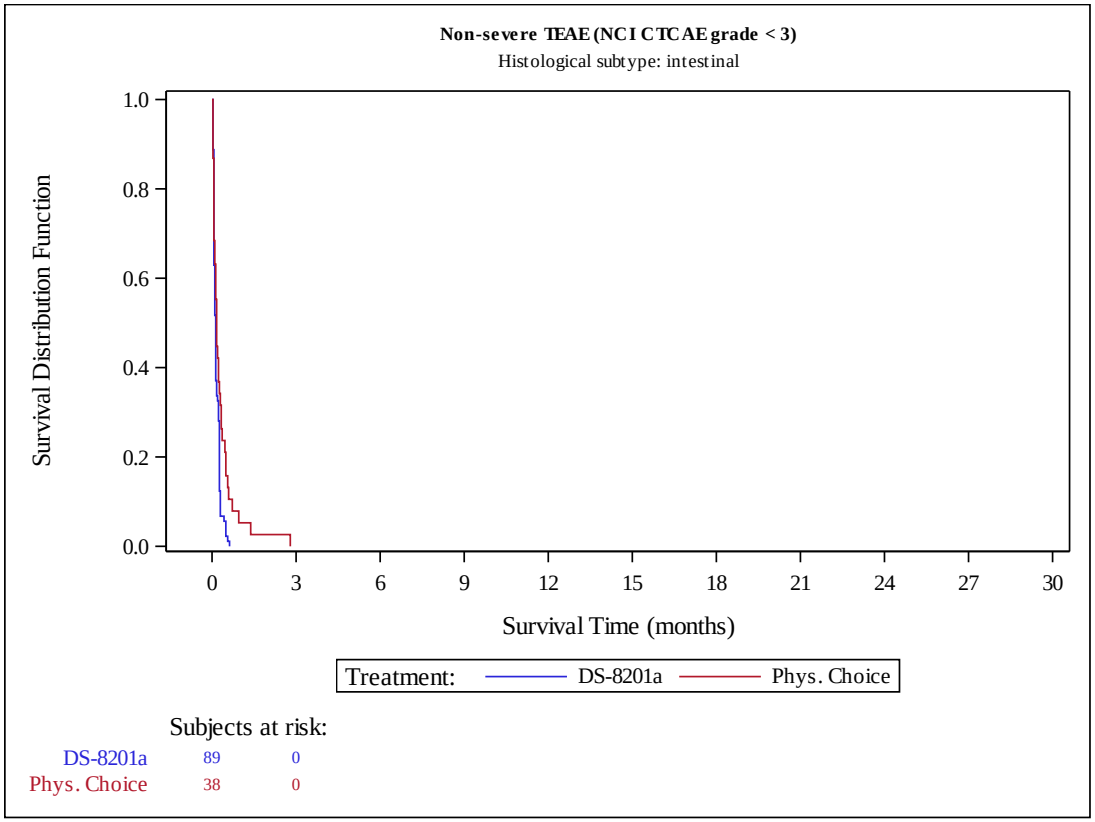

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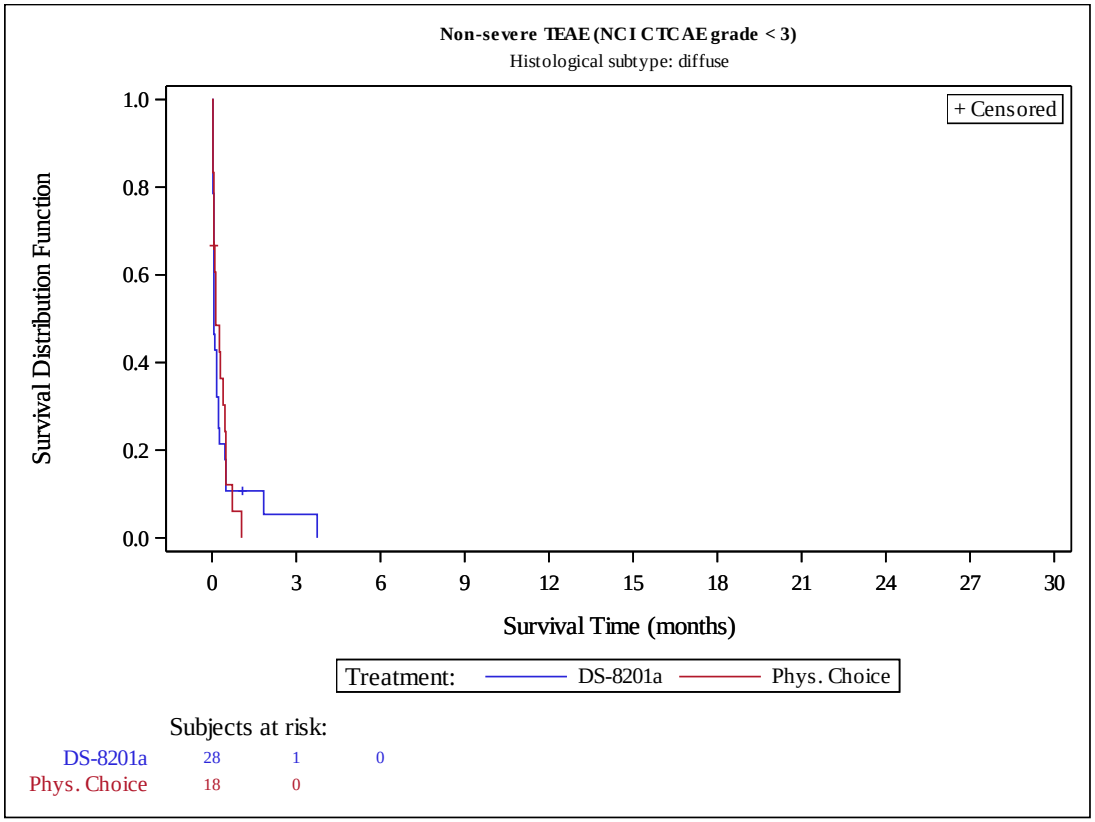

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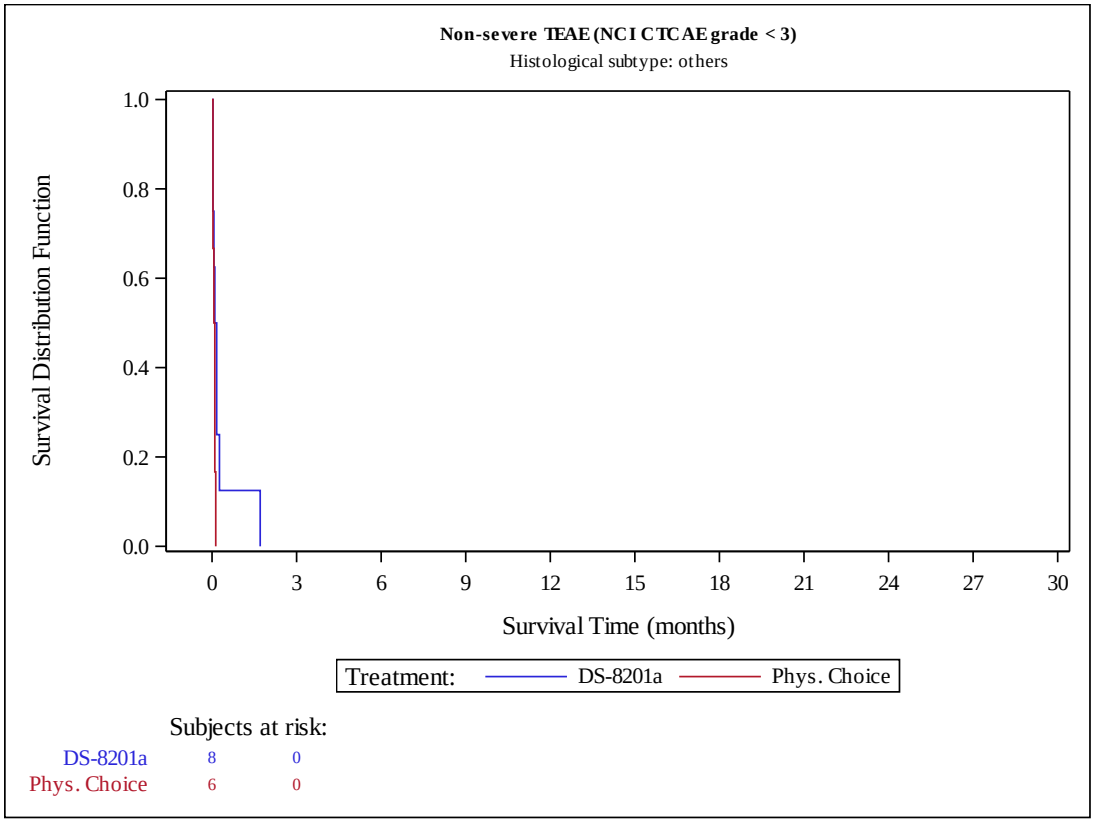

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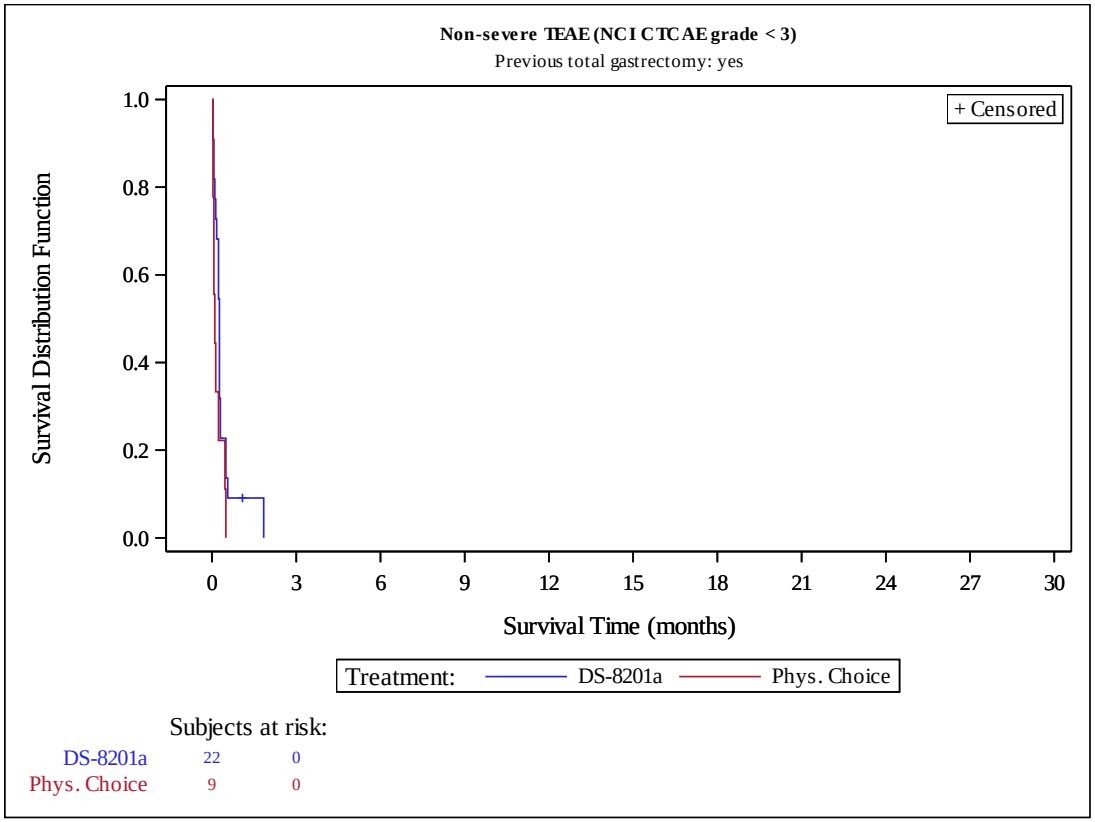

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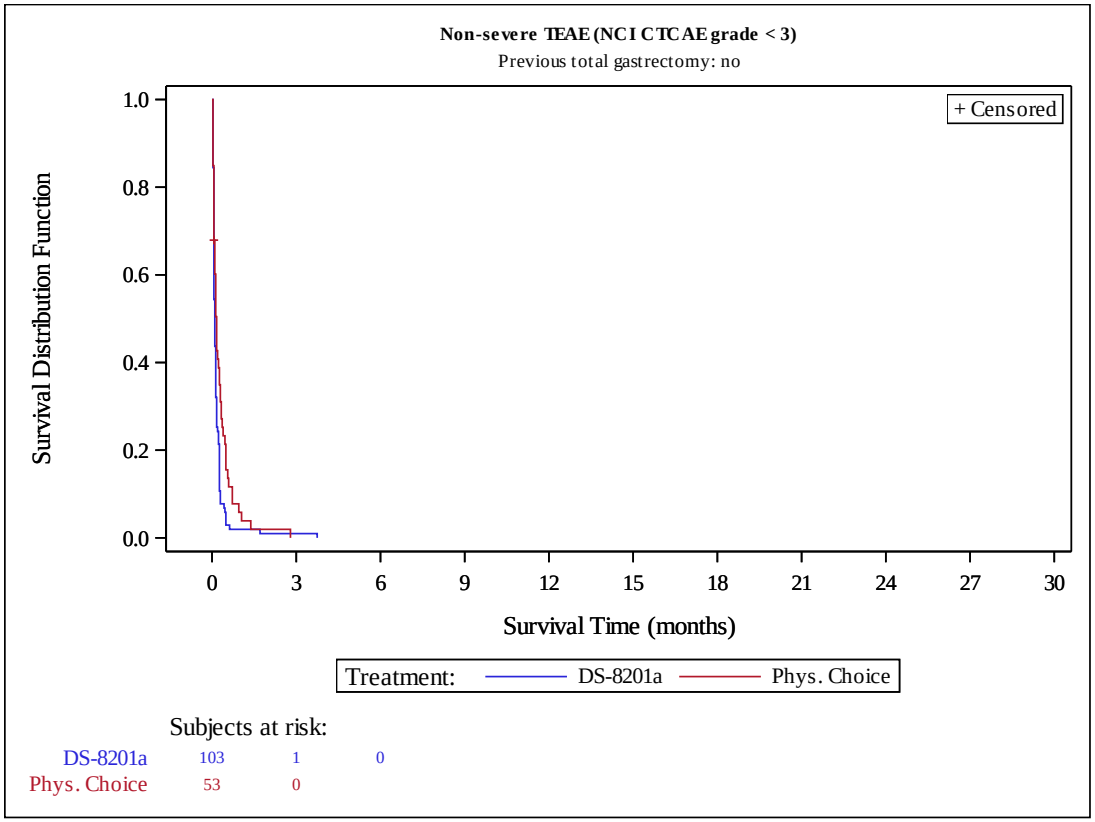

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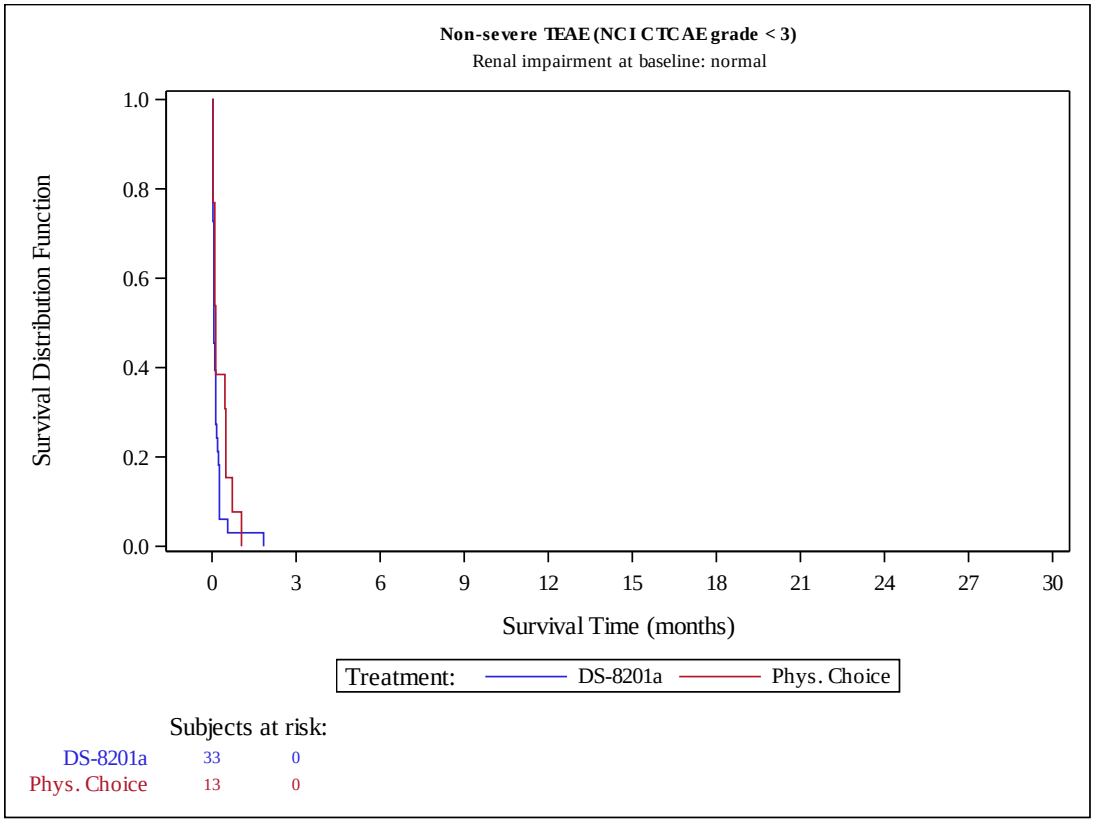

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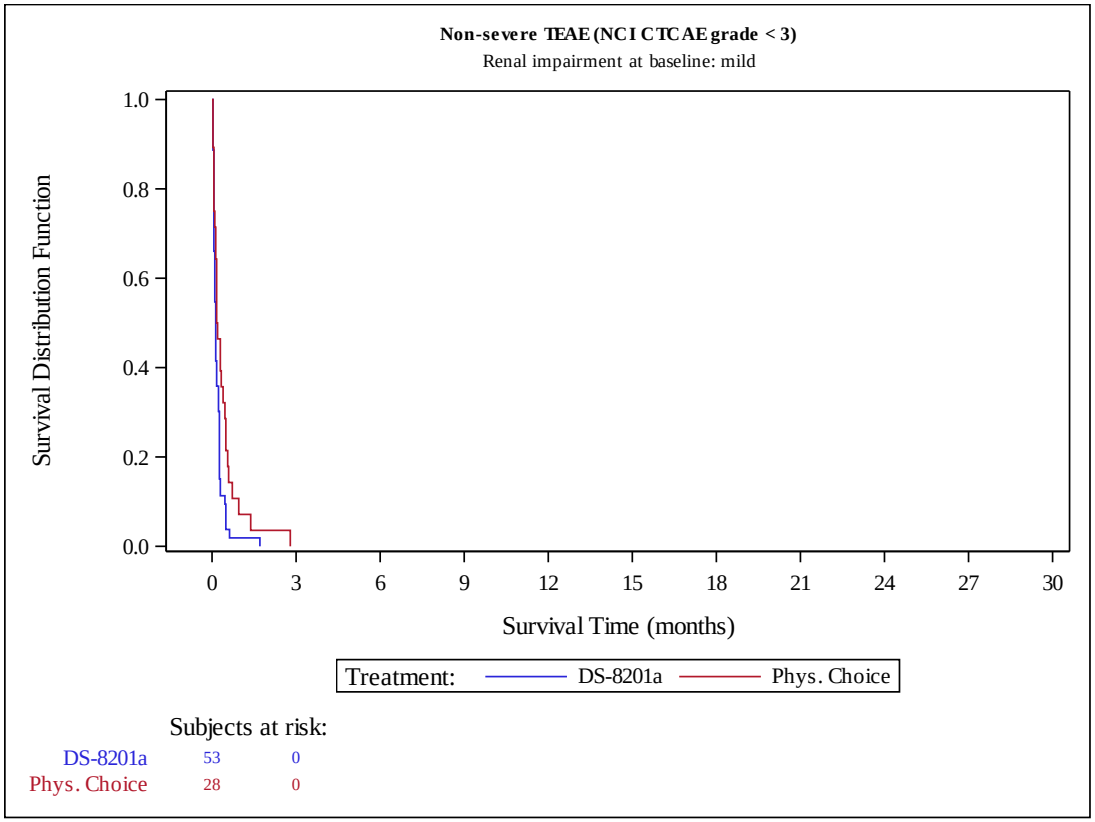
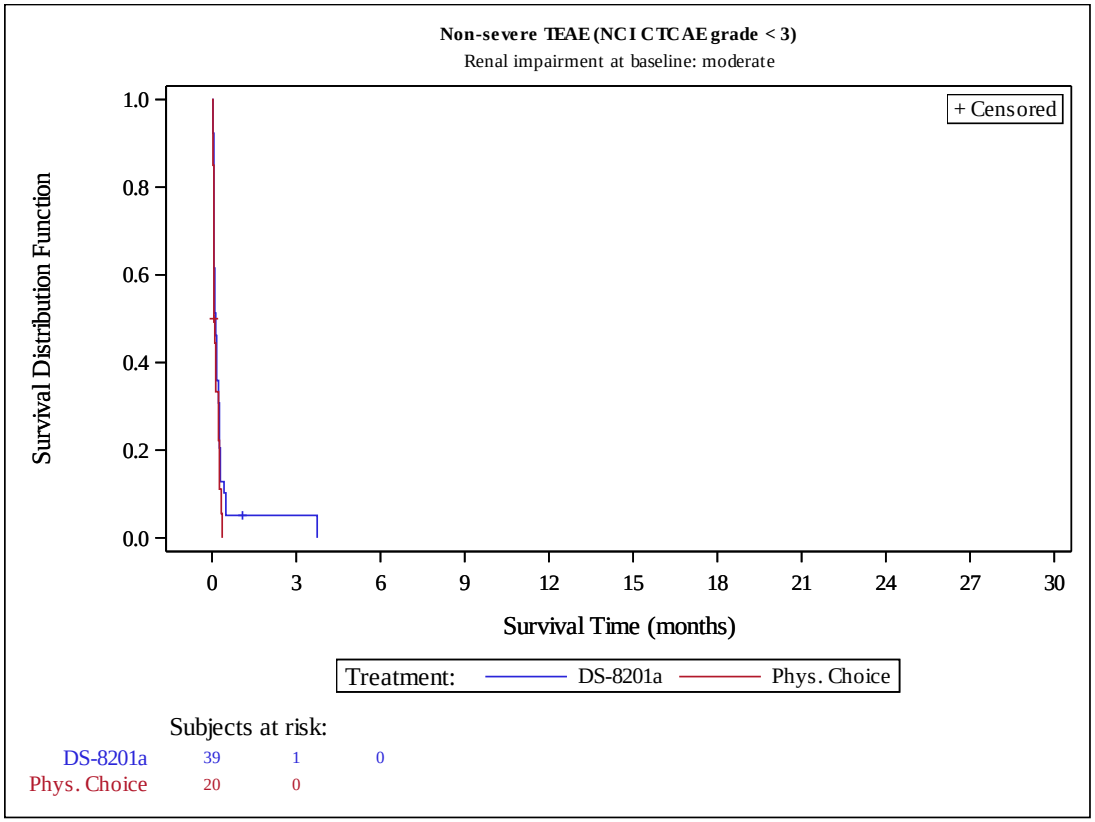
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set

For <<Renal impairment at baseline: severe>> there is only one subject, hence no Kaplan Meier Plot is produced.

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	22 (17.6)	4 (6.5)
Number of censored subjects, n (%)	103 (82.4)	58 (93.5)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.32 (0.45, 3.91)	
p-value [c]	0.6154	
Relative Risk (95% CI) [d]	2.73 (0.98, 7.57)	
p-value	0.0540	
Odds Ratio (95% CI) [d]	3.10 (1.02, 9.42)	
p-value	0.0465	
Risk Difference (95% CI) [e]	11.15 (0.89, 21.41)	
p-value	0.0332	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.8455
Japan	16/ 99 (16.2)	NE (NE , NE)	3/ 50 (6.0)	NE (NE , NE)	1.53 (0.44, 5.34)	0.4970	
Korea	6/ 26 (23.1)	11.8 (7.5, NE)	1/ 12 (8.3)	NE (4.5, NE)	0.53 (0.05, 5.99)	0.6034	
Lines of prior systemic therapy							0.6402
2	13/ 66 (19.7)	NE (10.4, NE)	2/ 38 (5.3)	NE (4.5, NE)	2.00 (0.44, 9.09)	0.3605	
3	6/ 34 (17.6)	NE (7.6, NE)	2/ 18 (11.1)	NE (3.0, NE)	0.76 (0.14, 3.97)	0.7424	
>=4	3/ 25 (12.0)	NE (10.4, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9913
<65 years	7/ 55 (12.7)	NE (11.8, NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	15/ 70 (21.4)	NE (10.4, NE)	4/ 35 (11.4)	NE (4.5, NE)	1.12 (0.36, 3.42)	0.8475	
Sex							0.8619
female	6/ 30 (20.0)	NE (5.8, NE)	1/ 15 (6.7)	NE (3.0, NE)	2.21 (0.26, 18.59)	0.4536	
male	16/ 95 (16.8)	NE (NE , NE)	3/ 47 (6.4)	NE (NE , NE)	1.12 (0.32, 3.95)	0.8569	
ECOG PS							0.5109
0	9/ 62 (14.5)	NE (NE , NE)	2/ 30 (6.7)	NE (4.5, NE)	0.95 (0.20, 4.53)	0.9464	
1	13/ 63 (20.6)	NE (10.4, NE)	2/ 32 (6.3)	NE (NE , NE)	1.85 (0.41, 8.38)	0.4206	
HER2 Status in central laboratory							0.7489
IHC 3+	17/ 96 (17.7)	NE (NE , NE)	3/ 47 (6.4)	NE (NE , NE)	1.10 (0.32, 3.85)	0.8754	
IHC 2+/ISH +	5/ 29 (17.2)	NE (6.7, NE)	1/ 15 (6.7)	NE (3.0, NE)	2.23 (0.26, 19.28)	0.4536	
Primary tumor location							0.9910
Gastric	21/108 (19.4)	NE (11.8, NE)	4/ 55 (7.3)	NE (NE , NE)	1.40 (0.47, 4.15)	0.5402	
GEJ	1/ 17 (5.9)	NE (8.5, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.9859
intestinal	15/ 89 (16.9)	NE (NE , NE)	3/ 38 (7.9)	NE (4.5, NE)	1.21 (0.34, 4.26)	0.7641	
diffuse	5/ 28 (17.9)	NE (10.4, NE)	1/ 18 (5.6)	NE (2.8, NE)	0.69 (0.07, 7.06)	0.7611	
others	2/ 8 (25.0)	11.8 (1.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.5615
<2	3/ 23 (13.0)	NE (10.4, NE)	1/ 10 (10.0)	NE (2.8, NE)	0.63 (0.06, 6.48)	0.6967	
>= 2	19/102 (18.6)	NE (11.8, NE)	3/ 52 (5.8)	NE (NE , NE)	1.56 (0.45, 5.40)	0.4781	
Previous total gastrectomy							0.9917
yes	7/ 22 (31.8)	10.4 (7.6, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	15/103 (14.6)	NE (NE , NE)	4/ 53 (7.5)	NE (NE , NE)	0.94 (0.31, 2.90)	0.9188	
Prior adjuvant/ neoadjuvant therapy							0.9906
yes	5/ 30 (16.7)	NE (10.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	17/ 95 (17.9)	NE (NE , NE)	4/ 52 (7.7)	NE (NE , NE)	1.21 (0.40, 3.68)	0.7321	
Prior ramucirumab contained treatment							0.3732
yes	15/ 94 (16.0)	NE (NE , NE)	3/ 41 (7.3)	NE (NE , NE)	0.95 (0.27, 3.39)	0.9390	
no	7/ 31 (22.6)	NE (7.5, NE)	1/ 21 (4.8)	NE (NE , NE)	2.76 (0.33, 23.02)	0.3316	
Prior nivolumab contained treatment							0.9838
yes	7/ 33 (21.2)	NE (NE , NE)	1/ 15 (6.7)	NE (3.0, NE)	1.62 (0.19, 13.58)	0.6531	
no	15/ 92 (16.3)	NE (10.4, NE)	3/ 47 (6.4)	NE (NE , NE)	1.16 (0.32, 4.16)	0.8168	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

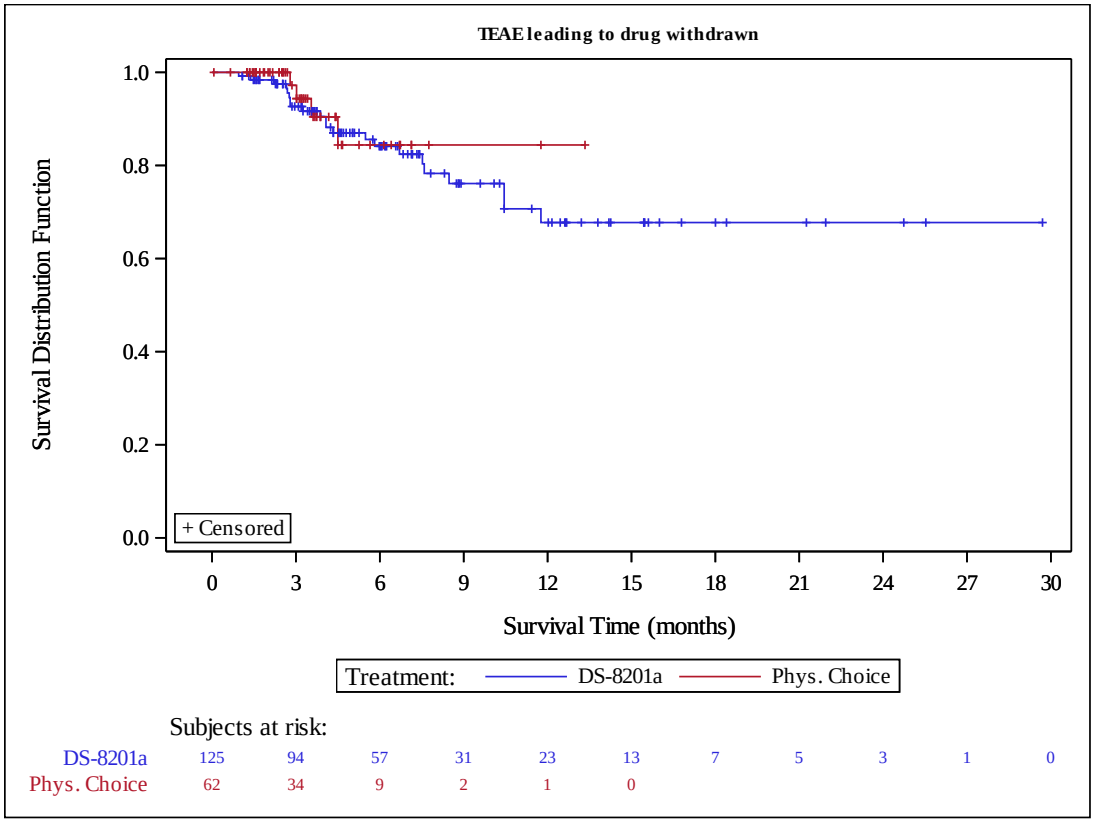
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9064
yes	9/ 44 (20.5)	NE (10.4, NE)	1/ 17 (5.9)	NE (3.0, NE)	1.54 (0.19, 12.57)	0.6840	
no	13/ 81 (16.0)	NE (11.8, NE)	3/ 45 (6.7)	NE (NE , NE)	1.24 (0.34, 4.49)	0.7369	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.3018
yes	2/ 22 (9.1)	NE (6.7, NE)	1/ 7 (14.3)	NE (2.8, NE)	0.48 (0.04, 5.47)	0.5539	
no	20/103 (19.4)	NE (NE , NE)	3/ 55 (5.5)	NE (NE , NE)	1.64 (0.48, 5.65)	0.4274	
Presence of liver metastasis at baseline							0.6488
yes	9/ 68 (13.2)	NE (NE , NE)	2/ 34 (5.9)	NE (4.5, NE)	1.02 (0.21, 4.87)	0.9766	
no	13/ 57 (22.8)	NE (10.4, NE)	2/ 28 (7.1)	NE (NE , NE)	1.69 (0.37, 7.72)	0.4948	
Renal impairment at baseline							0.4775
normal	3/ 33 (9.1)	NE (NE , NE)	1/ 13 (7.7)	NE (2.8, NE)	0.67 (0.06, 7.42)	0.7441	
mild	10/ 53 (18.9)	NE (7.6, NE)	1/ 28 (3.6)	NE (NE , NE)	2.60 (0.33, 20.35)	0.3441	
moderate	9/ 39 (23.1)	NE (8.5, NE)	2/ 20 (10.0)	NE (4.5, NE)	1.31 (0.26, 6.54)	0.7422	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7405
normal	16/ 88 (18.2)	NE (NE , NE)	3/ 47 (6.4)	NE (NE , NE)	1.11 (0.31, 3.94)	0.8758	
mild	6/ 36 (16.7)	NE (10.4, NE)	1/ 15 (6.7)	NE (2.8, NE)	1.93 (0.23, 16.17)	0.5388	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9915
yes	3/ 8 (37.5)	NE (2.7, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	19/117 (16.2)	NE (NE , NE)	4/ 57 (7.0)	NE (NE , NE)	1.08 (0.36, 3.26)	0.8954	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9915
yes	2/ 3 (66.7)	7.5 (6.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	20/122 (16.4)	NE (NE , NE)	4/ 58 (6.9)	NE (NE , NE)	1.12 (0.37, 3.38)	0.8364	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of TEAE leading to drug withdrawn
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to death
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	8 (6.4)	2 (3.2)
Number of censored subjects, n (%)	117 (93.6)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.28 (0.27, 6.16)	
p-value [c]	0.7537	
Relative Risk (95% CI) [d]	1.98 (0.43, 9.06)	
p-value	0.3768	
Odds Ratio (95% CI) [d]	2.05 (0.42, 9.96)	
p-value	0.3729	
Risk Difference (95% CI) [e]	3.17 (-4.18, 10.52)	
p-value	0.3974	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to death - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.4008
Japan	6/ 99 (6.1)	NE (NE , NE)	1/ 50 (2.0)	NE (NE , NE)	2.05 (0.24, 17.39)	0.4999	
Korea	2/ 26 (7.7)	NE (NE , NE)	1/ 12 (8.3)	NE (3.6, NE)	0.58 (0.05, 6.47)	0.6537	
Lines of prior systemic therapy							1.0000
2	7/ 66 (10.6)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (3.6, NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	1/ 6 (16.7)	NE (2.0, NE)	0.18 (0.01, 2.84)	0.1680	
Age							0.9932
<65 years	4/ 55 (7.3)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	4/ 70 (5.7)	NE (NE , NE)	2/ 35 (5.7)	NE (NE , NE)	0.70 (0.13, 3.86)	0.6818	
Sex							0.9923
female	3/ 30 (10.0)	NE (10.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	5/ 95 (5.3)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.79 (0.15, 4.08)	0.7760	
ECOG PS							0.6392
0	3/ 62 (4.8)	NE (NE , NE)	1/ 30 (3.3)	NE (NE , NE)	0.82 (0.08, 8.51)	0.8696	
1	5/ 63 (7.9)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	1.92 (0.22, 16.47)	0.5459	
HER2 Status in central laboratory							0.9930
IHC 3+	4/ 96 (4.2)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.48 (0.08, 2.74)	0.3998	
IHC 2+/ISH +	4/ 29 (13.8)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9949
Gastric	7/108 (6.5)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	1.14 (0.23, 5.60)	0.8738	
GEJ	1/ 17 (5.9)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.6096
intestinal	6/ 89 (6.7)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	1.85 (0.22, 15.59)	0.5644	
diffuse	1/ 28 (3.6)	NE (NE , NE)	1/ 18 (5.6)	NE (3.6, NE)	0.27 (0.02, 4.32)	0.3211	
others	1/ 8 (12.5)	NE (1.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	8/102 (7.8)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.26 (0.26, 6.06)	0.7726	
Previous total gastrectomy							0.2301
yes	1/ 22 (4.5)	NE (NE , NE)	1/ 9 (11.1)	NE (3.6, NE)	0.19 (0.01, 3.10)	0.1934	
no	7/103 (6.8)	NE (NE , NE)	1/ 53 (1.9)	NE (NE , NE)	2.46 (0.30, 20.27)	0.3886	
Prior adjuvant/ neoadjuvant therapy							0.9943
yes	1/ 30 (3.3)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 95 (7.4)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.25 (0.26, 6.14)	0.7814	
Prior ramucirumab contained treatment							0.7869
yes	6/ 94 (6.4)	NE (NE , NE)	1/ 41 (2.4)	NE (NE , NE)	1.91 (0.23, 15.97)	0.5426	
no	2/ 31 (6.5)	NE (10.3, NE)	1/ 21 (4.8)	NE (NE , NE)	0.65 (0.05, 7.78)	0.7310	
Prior nivolumab contained treatment							0.9921
yes	1/ 33 (3.0)	NE (NE , NE)	2/ 15 (13.3)	NE (3.6, NE)	0.15 (0.01, 1.66)	0.0744	
no	7/ 92 (7.6)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

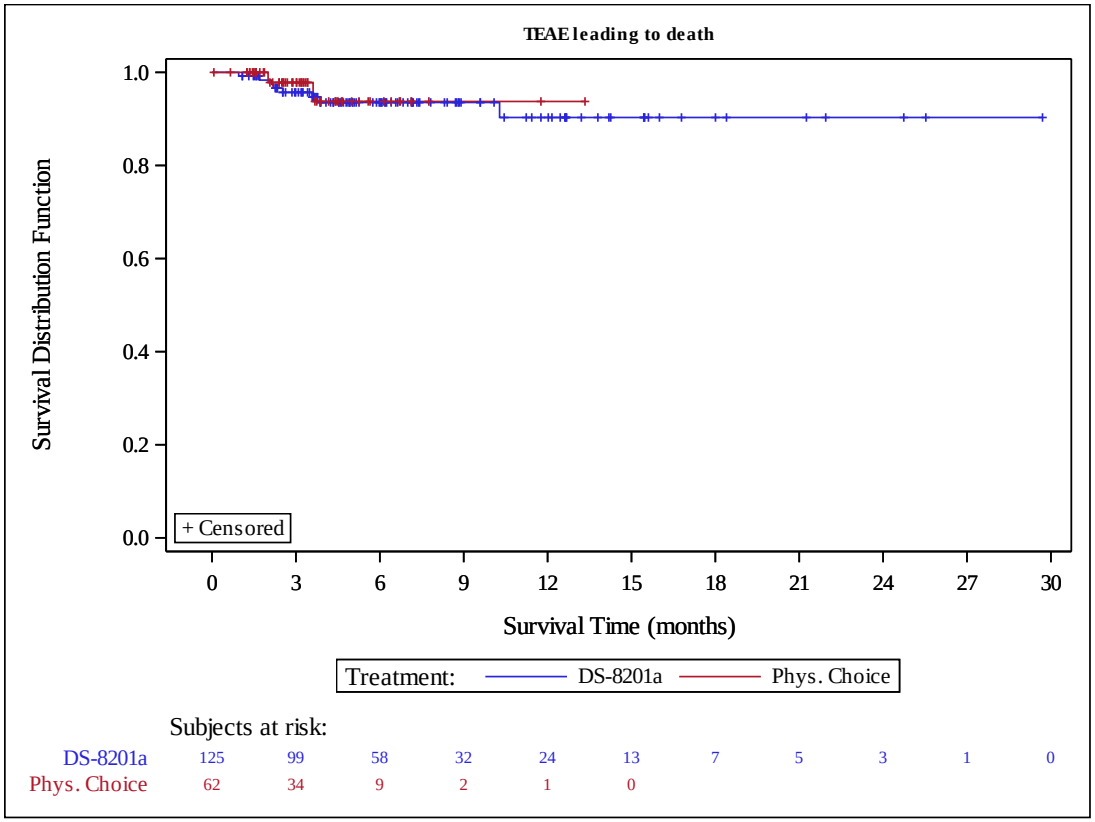
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to death - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9917
yes	1/ 44 (2.3)	NE (NE , NE)	2/ 17 (11.8)	NE (3.6, NE)	0.13 (0.01, 1.48)	0.0545	
no	7/ 81 (8.6)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9948
yes	3/ 22 (13.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	5/103 (4.9)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	0.79 (0.15, 4.25)	0.7878	
Presence of liver metastasis at baseline							0.9930
yes	5/ 68 (7.4)	NE (NE , NE)	2/ 34 (5.9)	NE (NE , NE)	0.65 (0.12, 3.46)	0.6122	
no	3/ 57 (5.3)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							0.9871
normal	3/ 33 (9.1)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 53 (5.7)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	1.01 (0.10, 9.69)	0.9963	
moderate	2/ 39 (5.1)	NE (NE , NE)	1/ 20 (5.0)	NE (3.6, NE)	0.89 (0.08, 9.97)	0.9242	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7435
normal	5/ 88 (5.7)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	1.49 (0.17, 13.34)	0.7181	
mild	3/ 36 (8.3)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	1.00 (0.10, 9.67)	0.9996	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9927
yes	0/ 8 (0.0)	NE (NE , NE)	1/ 5 (20.0)	NE (2.0, NE)	NE	NE	
no	8/117 (6.8)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	2.43 (0.30, 19.80)	0.3915	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							1.0000
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	8/122 (6.6)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	1.19 (0.25, 5.75)	0.8267	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of TEAE leading to death
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	2 (1.6)	10 (16.1)
Number of censored subjects, n (%)	123 (98.4)	52 (83.9)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	0.08 (0.02, 0.39)	
p-value [c]	<.0001	
Relative Risk (95% CI) [d]	0.10 (0.02, 0.44)	
p-value	0.0023	
Odds Ratio (95% CI) [d]	0.08 (0.02, 0.40)	
p-value	0.0018	
Risk Difference (95% CI) [e]	-14.53 (-25.15, -3.91)	
p-value	0.0073	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9935
Japan	2/ 99 (2.0)	NE (NE , NE)	7/ 50 (14.0)	NE (NE , NE)	0.12 (0.03, 0.60)	0.0021	
Korea	0/ 26 (0.0)	NE (NE , NE)	3/ 12 (25.0)	NE (0.4, NE)	NE	NE	
Lines of prior systemic therapy							0.9496
2	1/ 66 (1.5)	NE (NE , NE)	6/ 38 (15.8)	NE (NE , NE)	0.08 (0.01, 0.69)	0.0032	
3	1/ 34 (2.9)	NE (NE , NE)	3/ 18 (16.7)	NE (NE , NE)	0.17 (0.02, 1.59)	0.0753	
>=4	0/ 25 (0.0)	NE (NE , NE)	1/ 6 (16.7)	NE (0.1, NE)	NE	NE	
Age							0.9933
<65 years	0/ 55 (0.0)	NE (NE , NE)	6/ 27 (22.2)	NE (NE , NE)	NE	NE	
>=65 years	2/ 70 (2.9)	NE (NE , NE)	4/ 35 (11.4)	NE (NE , NE)	0.21 (0.04, 1.14)	0.0465	
Sex							0.8370
female	1/ 30 (3.3)	NE (NE , NE)	4/ 15 (26.7)	NE (0.1, NE)	0.11 (0.01, 0.99)	0.0170	
male	1/ 95 (1.1)	NE (NE , NE)	6/ 47 (12.8)	NE (NE , NE)	0.07 (0.01, 0.56)	0.0010	
ECOG PS							0.5250
0	1/ 62 (1.6)	NE (NE , NE)	7/ 30 (23.3)	NE (NE , NE)	0.05 (0.01, 0.43)	0.0002	
1	1/ 63 (1.6)	NE (NE , NE)	3/ 32 (9.4)	NE (NE , NE)	0.16 (0.02, 1.55)	0.0705	
HER2 Status in central laboratory							0.9942
IHC 3+	2/ 96 (2.1)	NE (NE , NE)	8/ 47 (17.0)	NE (NE , NE)	0.10 (0.02, 0.47)	0.0004	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9994
Gastric	2/108 (1.9)	NE (NE , NE)	10/ 55 (18.2)	NE (NE , NE)	0.08 (0.02, 0.39)	<.0001	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.9873
intestinal	1/ 89 (1.1)	NE (NE , NE)	4/ 38 (10.5)	NE (NE , NE)	0.10 (0.01, 0.93)	0.0127	
diffuse	1/ 28 (3.6)	NE (NE , NE)	4/ 18 (22.2)	NE (0.5, NE)	0.09 (0.01, 0.93)	0.0161	
others	0/ 8 (0.0)	NE (NE , NE)	2/ 6 (33.3)	NE (0.0, NE)	NE	NE	
Number of metastatic sites							0.4421
<2	1/ 23 (4.3)	NE (NE , NE)	2/ 10 (20.0)	NE (0.1, NE)	0.21 (0.02, 2.27)	0.1527	
>= 2	1/102 (1.0)	NE (NE , NE)	8/ 52 (15.4)	NE (NE , NE)	0.05 (0.01, 0.42)	0.0001	
Previous total gastrectomy							0.9949
yes	0/ 22 (0.0)	NE (NE , NE)	1/ 9 (11.1)	NE (0.1, NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	9/ 53 (17.0)	NE (NE , NE)	0.10 (0.02, 0.45)	0.0002	
Prior adjuvant/ neoadjuvant therapy							0.9996
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 95 (2.1)	NE (NE , NE)	10/ 52 (19.2)	NE (NE , NE)	0.09 (0.02, 0.42)	0.0001	
Prior ramucirumab contained treatment							0.9945
yes	2/ 94 (2.1)	NE (NE , NE)	9/ 41 (22.0)	NE (NE , NE)	0.08 (0.02, 0.36)	<.0001	
no	0/ 31 (0.0)	NE (NE , NE)	1/ 21 (4.8)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9948
yes	0/ 33 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
no	2/ 92 (2.2)	NE (NE , NE)	9/ 47 (19.1)	NE (NE , NE)	0.10 (0.02, 0.44)	0.0002	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

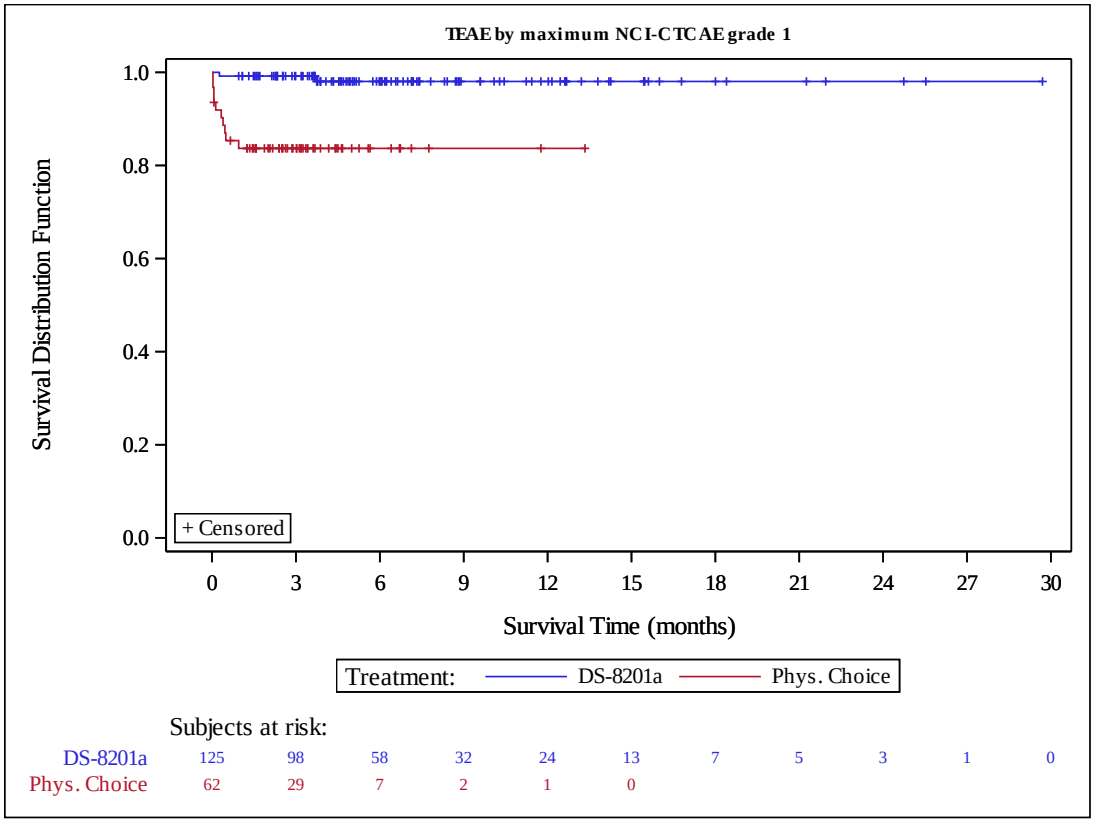
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9944
yes	0/ 44 (0.0)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	NE	NE	
no	2/ 81 (2.5)	NE (NE , NE)	9/ 45 (20.0)	NE (NE , NE)	0.10 (0.02, 0.48)	0.0004	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9948
yes	0/ 22 (0.0)	NE (NE , NE)	1/ 7 (14.3)	NE (0.4, NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	9/ 55 (16.4)	NE (NE , NE)	0.10 (0.02, 0.46)	0.0003	
Presence of liver metastasis at baseline							0.8274
yes	1/ 68 (1.5)	NE (NE , NE)	6/ 34 (17.6)	NE (NE , NE)	0.08 (0.01, 0.64)	0.0022	
no	1/ 57 (1.8)	NE (NE , NE)	4/ 28 (14.3)	NE (NE , NE)	0.10 (0.01, 0.88)	0.0108	
Renal impairment at baseline							0.9598
normal	0/ 33 (0.0)	NE (NE , NE)	3/ 13 (23.1)	NE (0.5, NE)	NE	NE	
mild	1/ 53 (1.9)	NE (NE , NE)	3/ 28 (10.7)	NE (NE , NE)	0.17 (0.02, 1.63)	0.0809	
moderate	1/ 39 (2.6)	NE (NE , NE)	4/ 20 (20.0)	NE (NE , NE)	0.09 (0.01, 0.85)	0.0098	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.2367
normal	1/ 88 (1.1)	NE (NE , NE)	9/ 47 (19.1)	NE (NE , NE)	0.05 (0.01, 0.37)	<.0001	
mild	1/ 36 (2.8)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.40 (0.03, 6.44)	0.5056	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9995
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	2/117 (1.7)	NE (NE , NE)	10/ 57 (17.5)	NE (NE , NE)	0.08 (0.02, 0.37)	<.0001	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9993
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	2/122 (1.6)	NE (NE , NE)	10/ 58 (17.2)	NE (NE , NE)	0.08 (0.02, 0.36)	<.0001	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	16 (12.8)	16 (25.8)
Number of censored subjects, n (%)	109 (87.2)	46 (74.2)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	8.0 (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	0.37 (0.18, 0.75)	
p-value [c]	0.0044	
Relative Risk (95% CI) [d]	0.50 (0.27, 0.92)	
p-value	0.0273	
Odds Ratio (95% CI) [d]	0.42 (0.19, 0.92)	
p-value	0.0289	
Risk Difference (95% CI) [e]	-13.01 (-26.58, 0.57)	
p-value	0.0604	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	p-Value [c]	Interaction p-Value [d]
Region							0.7394
Japan	13/ 99 (13.1)	NE (NE , NE)	14/ 50 (28.0)	8.0 (NE , NE)	0.34 (0.16, 0.75)	0.0050	
Korea	3/ 26 (11.5)	NE (NE , NE)	2/ 12 (16.7)	NE (0.3, NE)	0.54 (0.09, 3.26)	0.4917	
Lines of prior systemic therapy							0.8460
2	9/ 66 (13.6)	NE (NE , NE)	10/ 38 (26.3)	8.0 (NE , NE)	0.41 (0.16, 1.02)	0.0488	
3	4/ 34 (11.8)	NE (NE , NE)	5/ 18 (27.8)	NE (1.1, NE)	0.34 (0.09, 1.28)	0.0953	
>=4	3/ 25 (12.0)	NE (6.9, NE)	1/ 6 (16.7)	NE (0.1, NE)	0.49 (0.05, 4.80)	0.5302	
Age							0.4403
<65 years	3/ 55 (5.5)	NE (NE , NE)	5/ 27 (18.5)	NE (NE , NE)	0.26 (0.06, 1.09)	0.0467	
>=65 years	13/ 70 (18.6)	NE (NE , NE)	11/ 35 (31.4)	8.0 (NE , NE)	0.41 (0.18, 0.95)	0.0314	
Sex							0.4299
female	3/ 30 (10.0)	NE (NE , NE)	5/ 15 (33.3)	NE (0.3, NE)	0.27 (0.07, 1.15)	0.0555	
male	13/ 95 (13.7)	NE (NE , NE)	11/ 47 (23.4)	8.0 (NE , NE)	0.42 (0.18, 0.95)	0.0329	
ECOG PS							0.3261
0	11/ 62 (17.7)	NE (NE , NE)	8/ 30 (26.7)	8.0 (NE , NE)	0.46 (0.18, 1.18)	0.1007	
1	5/ 63 (7.9)	NE (NE , NE)	8/ 32 (25.0)	NE (NE , NE)	0.27 (0.09, 0.83)	0.0147	
HER2 Status in central laboratory							0.7567
IHC 3+	12/ 96 (12.5)	NE (NE , NE)	12/ 47 (25.5)	8.0 (NE , NE)	0.34 (0.15, 0.78)	0.0079	
IHC 2+/ISH +	4/ 29 (13.8)	NE (NE , NE)	4/ 15 (26.7)	NE (0.5, NE)	0.46 (0.11, 1.86)	0.2642	
Primary tumor location							0.3654
Gastric	14/108 (13.0)	NE (NE , NE)	13/ 55 (23.6)	8.0 (NE , NE)	0.40 (0.18, 0.87)	0.0178	
GEJ	2/ 17 (11.8)	NE (NE , NE)	3/ 7 (42.9)	NE (0.0, NE)	0.25 (0.04, 1.49)	0.0994	
Histological subtype							0.4163
intestinal	14/ 89 (15.7)	NE (NE , NE)	10/ 38 (26.3)	8.0 (NE , NE)	0.44 (0.19, 1.01)	0.0477	
diffuse	2/ 28 (7.1)	NE (NE , NE)	6/ 18 (33.3)	NE (0.3, NE)	0.17 (0.03, 0.84)	0.0139	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.6817
<2	3/ 23 (13.0)	NE (NE , NE)	2/ 10 (20.0)	8.0 (0.3, 8.0)	0.46 (0.07, 2.88)	0.3940	
>= 2	13/102 (12.7)	NE (NE , NE)	14/ 52 (26.9)	NE (NE , NE)	0.37 (0.17, 0.79)	0.0081	
Previous total gastrectomy							0.2631
yes	5/ 22 (22.7)	NE (4.9, NE)	2/ 9 (22.2)	NE (0.5, NE)	0.64 (0.12, 3.44)	0.6157	
no	11/103 (10.7)	NE (NE , NE)	14/ 53 (26.4)	8.0 (NE , NE)	0.32 (0.14, 0.72)	0.0037	
Prior adjuvant/ neoadjuvant therapy							0.3941
yes	7/ 30 (23.3)	NE (6.9, NE)	3/ 10 (30.0)	NE (0.0, NE)	0.51 (0.13, 2.05)	0.3341	
no	9/ 95 (9.5)	NE (NE , NE)	13/ 52 (25.0)	8.0 (NE , NE)	0.29 (0.12, 0.70)	0.0037	
Prior ramucirumab contained treatment							0.3544
yes	13/ 94 (13.8)	NE (NE , NE)	9/ 41 (22.0)	NE (NE , NE)	0.47 (0.20, 1.13)	0.0864	
no	3/ 31 (9.7)	NE (NE , NE)	7/ 21 (33.3)	8.0 (1.4, 8.0)	0.20 (0.05, 0.82)	0.0146	
Prior nivolumab contained treatment							0.0385
yes	2/ 33 (6.1)	NE (NE , NE)	6/ 15 (40.0)	NE (0.1, NE)	0.06 (0.01, 0.51)	0.0005	
no	14/ 92 (15.2)	NE (NE , NE)	10/ 47 (21.3)	8.0 (NE , NE)	0.57 (0.25, 1.31)	0.1795	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

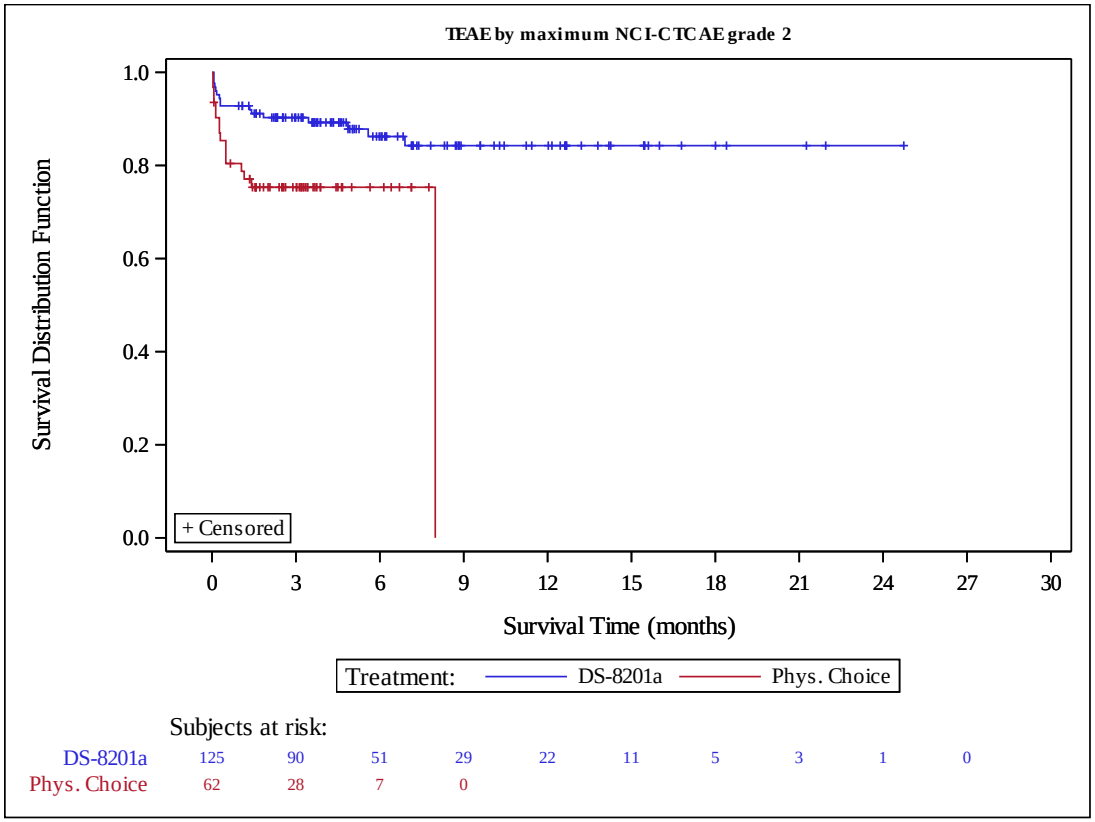
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0065
yes	3/ 44 (6.8)	NE (NE , NE)	8/ 17 (47.1)	NE (0.1, NE)	0.07 (0.02, 0.35)	<.0001	
no	13/ 81 (16.0)	NE (NE , NE)	8/ 45 (17.8)	8.0 (NE , NE)	0.74 (0.30, 1.81)	0.5006	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9905
yes	3/ 22 (13.6)	NE (NE , NE)	2/ 7 (28.6)	NE (0.3, NE)	0.46 (0.08, 2.78)	0.4049	
no	13/103 (12.6)	NE (NE , NE)	14/ 55 (25.5)	8.0 (NE , NE)	0.35 (0.16, 0.77)	0.0063	
Presence of liver metastasis at baseline							0.4593
yes	7/ 68 (10.3)	NE (NE , NE)	9/ 34 (26.5)	NE (NE , NE)	0.32 (0.12, 0.88)	0.0201	
no	9/ 57 (15.8)	NE (NE , NE)	7/ 28 (25.0)	8.0 (NE , NE)	0.45 (0.16, 1.24)	0.1134	
Renal impairment at baseline							0.3298
normal	2/ 33 (6.1)	NE (NE , NE)	4/ 13 (30.8)	NE (1.1, NE)	0.08 (0.01, 0.70)	0.0035	
mild	8/ 53 (15.1)	NE (NE , NE)	6/ 28 (21.4)	8.0 (NE , NE)	0.55 (0.19, 1.64)	0.2786	
moderate	6/ 39 (15.4)	NE (NE , NE)	6/ 20 (30.0)	NE (0.5, NE)	0.42 (0.13, 1.30)	0.1191	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.4434
normal	12/ 88 (13.6)	NE (NE , NE)	11/ 47 (23.4)	8.0 (NE , NE)	0.45 (0.20, 1.06)	0.0606	
mild	4/ 36 (11.1)	NE (NE , NE)	5/ 15 (33.3)	NE (0.3, NE)	0.23 (0.06, 0.88)	0.0204	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4301
yes	1/ 8 (12.5)	NE (4.9, NE)	3/ 5 (60.0)	8.0 (0.1, 8.0)	0.14 (0.01, 1.38)	0.0510	
no	15/117 (12.8)	NE (NE , NE)	13/ 57 (22.8)	NE (NE , NE)	0.45 (0.21, 0.97)	0.0360	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9879
yes	0/ 3 (0.0)	NE (NE , NE)	3/ 4 (75.0)	4.7 (0.1, 8.0)	NE	NE	
no	16/122 (13.1)	NE (NE , NE)	13/ 58 (22.4)	NE (NE , NE)	0.46 (0.22, 0.96)	0.0355	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

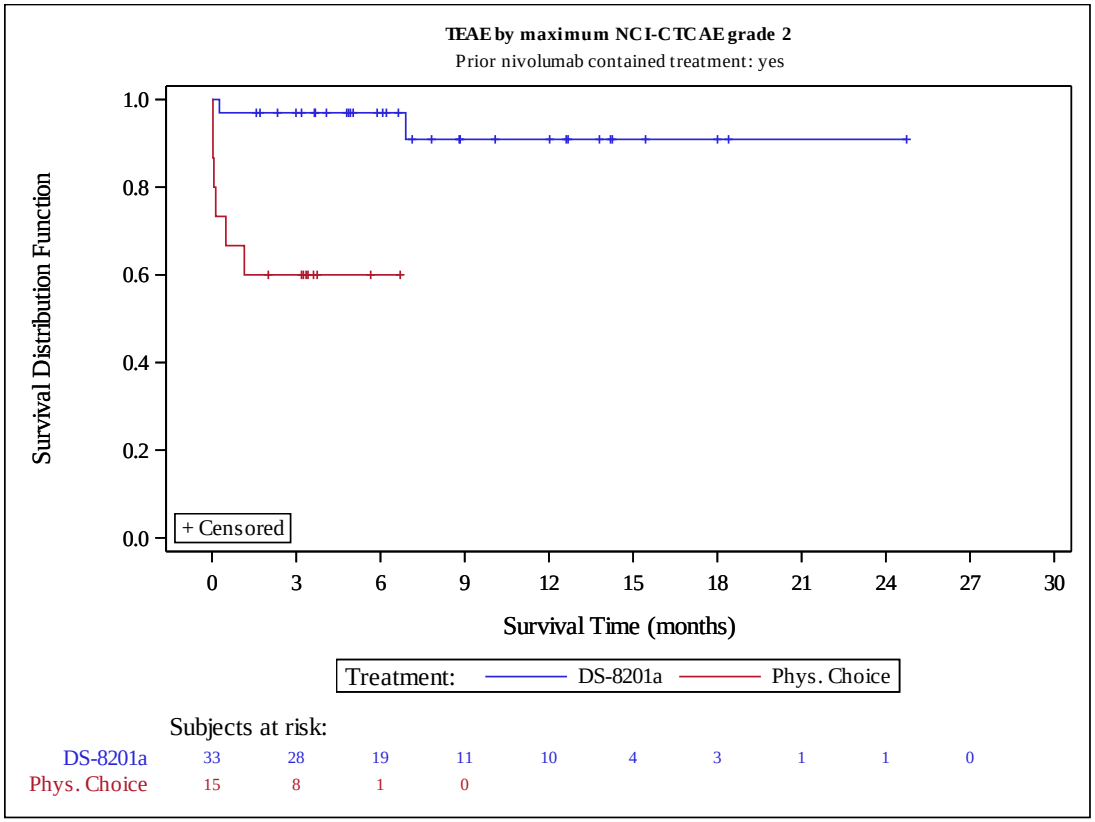
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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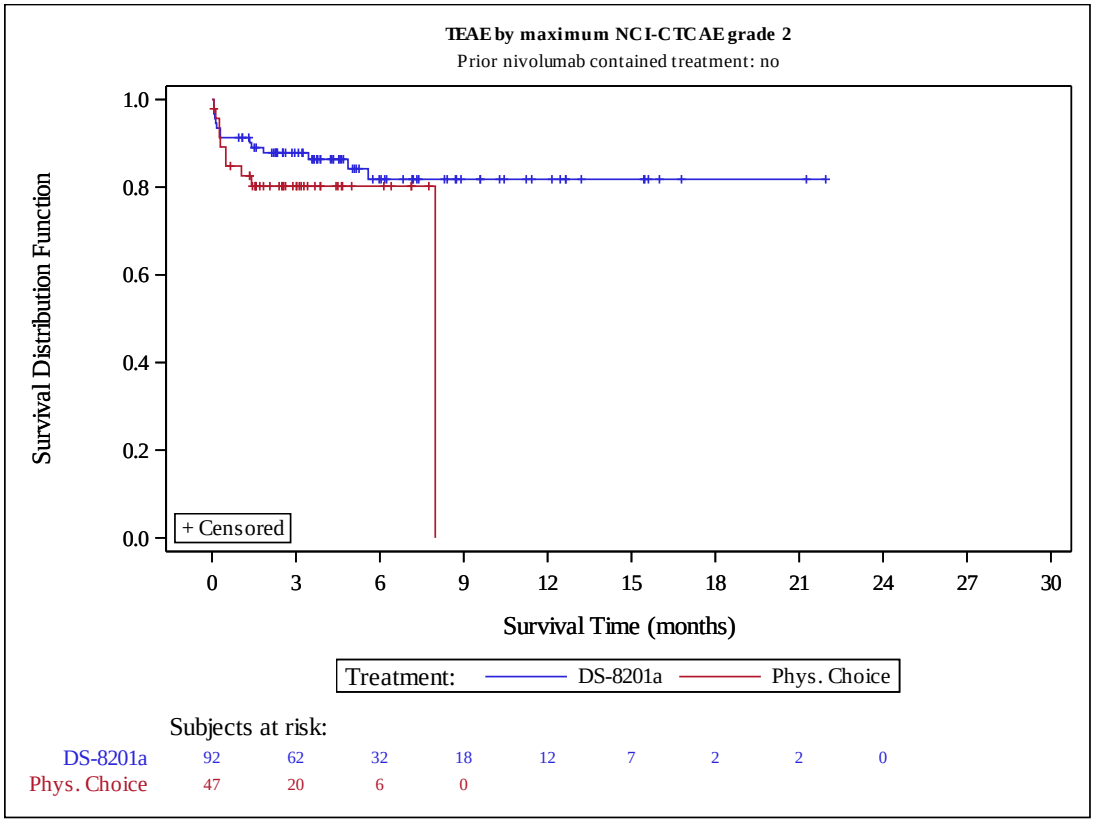

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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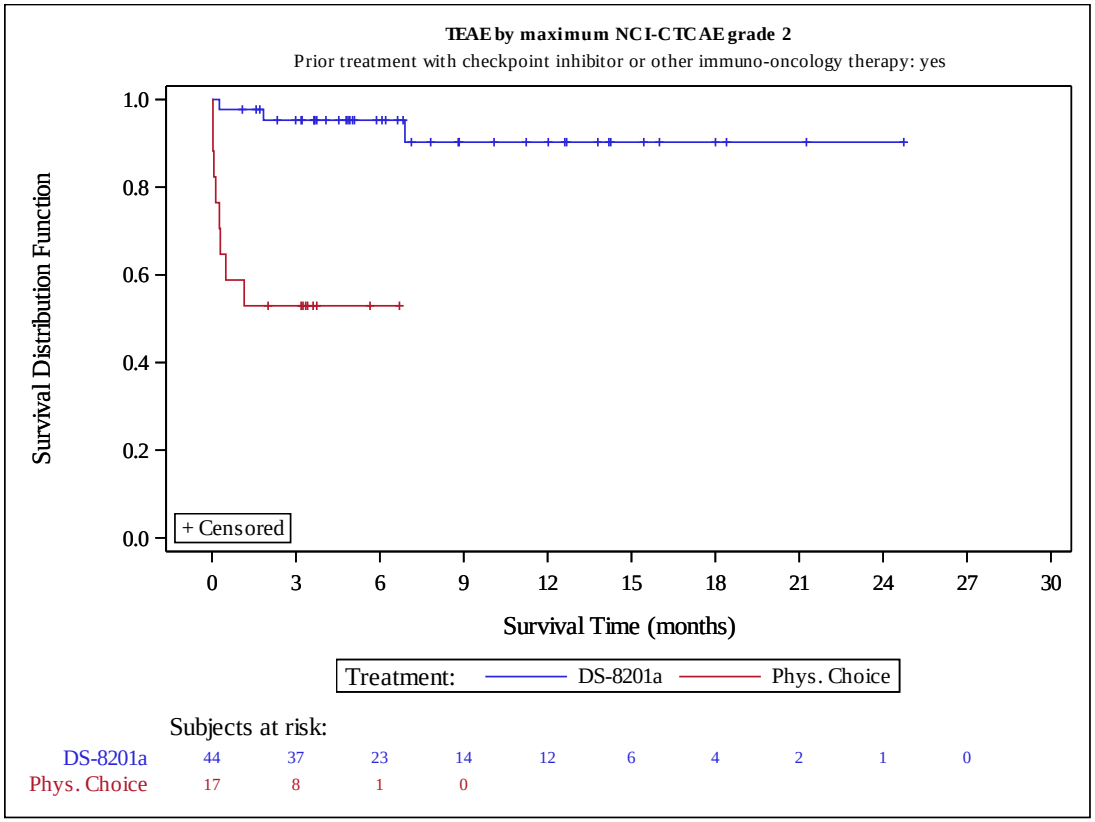
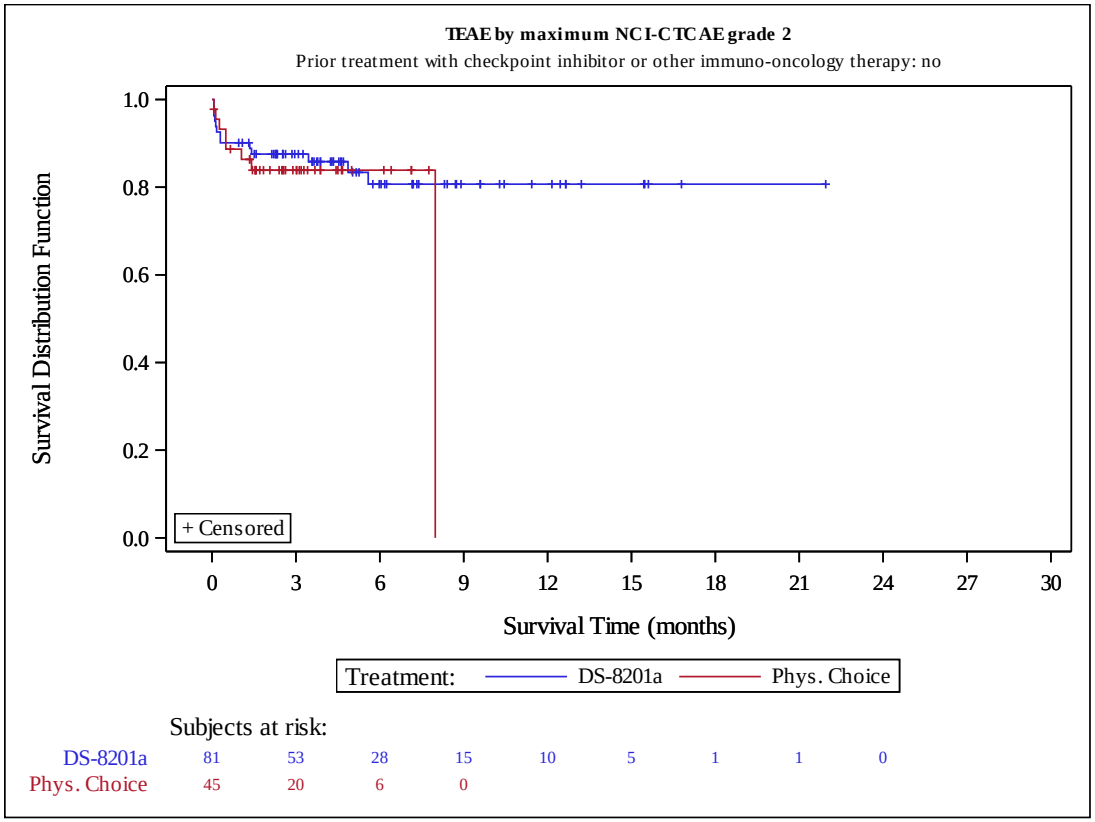


Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	76 (60.8)	26 (41.9)
Number of censored subjects, n (%)	49 (39.2)	36 (58.1)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	1.8 (1.3, 4.3)	NE (1.4, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.39 (0.89, 2.17)	
p-value [c]	0.1474	
Relative Risk (95% CI) [d]	1.45 (1.05, 2.01)	
p-value	0.0251	
Odds Ratio (95% CI) [d]	2.15 (1.16, 3.99)	
p-value	0.0155	
Risk Difference (95% CI) [e]	18.86 (2.69, 35.04)	
p-value	0.0223	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.5861
Japan	59/ 99 (59.6)	2.8 (0.9, 5.6)	22/ 50 (44.0)	NE (1.2, NE)	1.29 (0.79, 2.11)	0.3115	
Korea	17/ 26 (65.4)	1.4 (0.7, NE)	4/ 12 (33.3)	NE (0.5, NE)	1.83 (0.61, 5.44)	0.2716	
Lines of prior systemic therapy							0.8902
2	40/ 66 (60.6)	2.7 (1.4, 7.7)	15/ 38 (39.5)	NE (1.2, NE)	1.43 (0.79, 2.60)	0.2341	
3	20/ 34 (58.8)	1.6 (0.5, NE)	8/ 18 (44.4)	2.7 (0.5, NE)	1.30 (0.57, 2.97)	0.5186	
>=4	16/ 25 (64.0)	1.4 (0.5, NE)	3/ 6 (50.0)	NE (0.2, NE)	1.17 (0.34, 4.03)	0.8143	
Age							0.4478
<65 years	37/ 55 (67.3)	2.8 (1.4, 4.3)	10/ 27 (37.0)	NE (0.7, NE)	1.59 (0.79, 3.22)	0.1873	
>=65 years	39/ 70 (55.7)	1.5 (0.7, NE)	16/ 35 (45.7)	3.5 (1.0, NE)	1.24 (0.69, 2.22)	0.4684	
Sex							0.4052
female	16/ 30 (53.3)	3.2 (0.7, NE)	4/ 15 (26.7)	NE (1.0, NE)	2.00 (0.67, 6.01)	0.2102	
male	60/ 95 (63.2)	1.6 (0.8, 4.3)	22/ 47 (46.8)	3.5 (0.7, NE)	1.26 (0.77, 2.06)	0.3482	
ECOG PS							0.7113
0	34/ 62 (54.8)	2.9 (1.3, NE)	11/ 30 (36.7)	NE (2.3, NE)	1.54 (0.78, 3.05)	0.2084	
1	42/ 63 (66.7)	1.4 (0.7, 3.5)	15/ 32 (46.9)	3.5 (0.5, NE)	1.25 (0.69, 2.27)	0.4453	
HER2 Status in central laboratory							0.1212
IHC 3+	59/ 96 (61.5)	1.8 (0.8, 4.2)	17/ 47 (36.2)	NE (2.3, NE)	1.70 (0.99, 2.92)	0.0520	
IHC 2+/ISH +	17/ 29 (58.6)	2.8 (0.7, NE)	9/ 15 (60.0)	1.2 (0.3, NE)	0.74 (0.32, 1.70)	0.4886	
Primary tumor location							0.9936
Gastric	65/108 (60.2)	1.6 (0.8, 5.5)	23/ 55 (41.8)	NE (1.2, NE)	1.41 (0.88, 2.27)	0.1513	
GEJ	11/ 17 (64.7)	3.4 (0.5, 15.1)	3/ 7 (42.9)	2.3 (0.3, NE)	1.22 (0.33, 4.45)	0.7682	
Histological subtype							0.1707
intestinal	51/ 89 (57.3)	2.9 (1.4, 7.7)	19/ 38 (50.0)	2.7 (0.8, NE)	1.03 (0.61, 1.75)	0.9162	
diffuse	19/ 28 (67.9)	1.1 (0.4, 5.6)	5/ 18 (27.8)	NE (0.7, NE)	2.85 (1.06, 7.66)	0.0289	
others	6/ 8 (75.0)	1.1 (0.0, 3.5)	2/ 6 (33.3)	NE (0.5, NE)	2.92 (0.58, 14.78)	0.1514	
Number of metastatic sites							0.6050
<2	18/ 23 (78.3)	0.7 (0.5, 1.3)	5/ 10 (50.0)	NE (0.2, NE)	1.68 (0.62, 4.53)	0.2778	
>= 2	58/102 (56.9)	2.9 (1.5, 5.6)	21/ 52 (40.4)	NE (1.4, NE)	1.29 (0.78, 2.13)	0.3193	
Previous total gastrectomy							0.6177
yes	14/ 22 (63.6)	1.5 (0.7, NE)	5/ 9 (55.6)	2.7 (0.2, NE)	1.17 (0.42, 3.26)	0.7606	
no	62/103 (60.2)	2.7 (1.3, 5.5)	21/ 53 (39.6)	NE (1.4, NE)	1.45 (0.88, 2.38)	0.1381	
Prior adjuvant/ neoadjuvant therapy							0.0871
yes	18/ 30 (60.0)	0.8 (0.7, NE)	7/ 10 (70.0)	0.6 (0.2, NE)	0.70 (0.29, 1.69)	0.3991	
no	58/ 95 (61.1)	2.7 (1.4, 5.5)	19/ 52 (36.5)	NE (2.3, NE)	1.61 (0.96, 2.71)	0.0688	
Prior ramucirumab contained treatment							0.8969
yes	56/ 94 (59.6)	1.8 (0.9, 5.5)	16/ 41 (39.0)	NE (1.2, NE)	1.39 (0.80, 2.43)	0.2359	
no	20/ 31 (64.5)	1.8 (0.5, 15.1)	10/ 21 (47.6)	3.5 (0.7, NE)	1.39 (0.64, 2.99)	0.4068	
Prior nivolumab contained treatment							0.9594
yes	19/ 33 (57.6)	0.7 (0.5, NE)	6/ 15 (40.0)	NE (0.5, NE)	1.59 (0.63, 4.00)	0.3241	
no	57/ 92 (62.0)	2.6 (1.4, 4.2)	20/ 47 (42.6)	NE (1.0, NE)	1.36 (0.81, 2.26)	0.2373	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

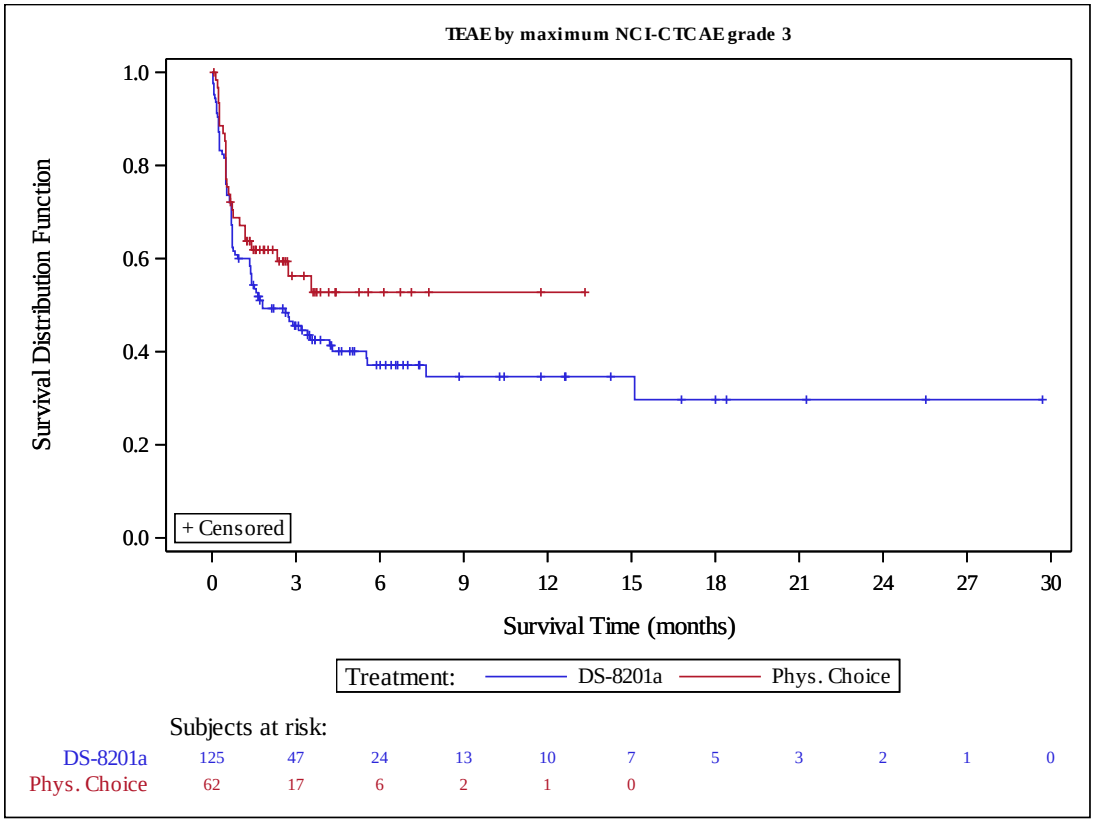
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8501
yes	24/ 44 (54.5)	2.0 (0.5, NE)	6/ 17 (35.3)	NE (0.5, NE)	1.67 (0.68, 4.10)	0.2583	
no	52/ 81 (64.2)	1.8 (1.4, 4.2)	20/ 45 (44.4)	3.5 (0.8, NE)	1.34 (0.80, 2.25)	0.2600	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.2800
yes	13/ 22 (59.1)	1.8 (0.7, NE)	4/ 7 (57.1)	0.5 (0.1, NE)	0.80 (0.26, 2.47)	0.6912	
no	63/103 (61.2)	1.8 (0.8, 4.2)	22/ 55 (40.0)	NE (1.4, NE)	1.51 (0.93, 2.46)	0.0938	
Presence of liver metastasis at baseline							0.6557
yes	38/ 68 (55.9)	3.2 (1.6, NE)	14/ 34 (41.2)	3.5 (1.2, NE)	1.21 (0.65, 2.24)	0.5469	
no	38/ 57 (66.7)	0.9 (0.7, 5.5)	12/ 28 (42.9)	NE (0.5, NE)	1.51 (0.79, 2.91)	0.2082	
Renal impairment at baseline							0.5042
normal	22/ 33 (66.7)	1.4 (0.7, 7.7)	4/ 13 (30.8)	NE (0.7, NE)	2.24 (0.77, 6.54)	0.1290	
mild	31/ 53 (58.5)	3.4 (0.7, 5.6)	14/ 28 (50.0)	3.5 (0.7, NE)	1.05 (0.56, 1.99)	0.8672	
moderate	23/ 39 (59.0)	1.8 (0.7, NE)	8/ 20 (40.0)	NE (0.4, NE)	1.45 (0.64, 3.25)	0.3689	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.8831
normal	52/ 88 (59.1)	2.6 (1.4, 5.6)	19/ 47 (40.4)	NE (1.2, NE)	1.40 (0.83, 2.38)	0.2103	
mild	23/ 36 (63.9)	1.4 (0.7, 7.7)	7/ 15 (46.7)	NE (0.5, NE)	1.32 (0.57, 3.09)	0.4909	
moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.4633
yes	5/ 8 (62.5)	4.9 (0.1, NE)	1/ 5 (20.0)	NE (0.5, NE)	2.73 (0.31, 24.03)	0.3458	
no	71/117 (60.7)	1.8 (0.9, 4.2)	25/ 57 (43.9)	NE (1.2, NE)	1.32 (0.84, 2.09)	0.2307	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.3050
yes	3/ 3 (100.0)	4.3 (0.1, 5.6)	1/ 4 (25.0)	NE (0.5, NE)	3.44 (0.34, 34.64)	0.2690	
no	73/122 (59.8)	1.8 (1.3, 4.2)	25/ 58 (43.1)	NE (1.2, NE)	1.32 (0.84, 2.08)	0.2302	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	23 (18.4)	7 (11.3)
Number of censored subjects, n (%)	102 (81.6)	55 (88.7)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.46 (0.62, 3.42)	
p-value [c]	0.3791	
Relative Risk (95% CI) [d]	1.63 (0.74, 3.59)	
p-value	0.2253	
Odds Ratio (95% CI) [d]	1.77 (0.72, 4.39)	
p-value	0.2167	
Risk Difference (95% CI) [e]	7.11 (-4.50, 18.72)	
p-value	0.2300	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9826
Japan	19/ 99 (19.2)	NE (NE , NE)	6/ 50 (12.0)	NE (NE , NE)	1.48 (0.59, 3.73)	0.4031	
Korea	4/ 26 (15.4)	NE (NE , NE)	1/ 12 (8.3)	NE (NE , NE)	1.44 (0.16, 13.04)	0.7428	
Lines of prior systemic therapy							0.3218
2	9/ 66 (13.6)	NE (NE , NE)	6/ 38 (15.8)	NE (NE , NE)	0.78 (0.28, 2.19)	0.6337	
3	9/ 34 (26.5)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	4.63 (0.58, 36.80)	0.1110	
>=4	5/ 25 (20.0)	NE (8.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.0820
<65 years	11/ 55 (20.0)	NE (NE , NE)	6/ 27 (22.2)	NE (2.7, NE)	0.74 (0.27, 2.05)	0.5623	
>=65 years	12/ 70 (17.1)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	5.68 (0.74, 43.77)	0.0592	
Sex							0.8457
female	7/ 30 (23.3)	NE (8.3, NE)	2/ 15 (13.3)	NE (2.4, NE)	1.59 (0.32, 7.89)	0.5648	
male	16/ 95 (16.8)	NE (NE , NE)	5/ 47 (10.6)	NE (NE , NE)	1.44 (0.52, 3.93)	0.4788	
ECOG PS							0.5345
0	13/ 62 (21.0)	NE (NE , NE)	3/ 30 (10.0)	NE (NE , NE)	1.92 (0.54, 6.83)	0.3016	
1	10/ 63 (15.9)	NE (NE , NE)	4/ 32 (12.5)	NE (NE , NE)	1.13 (0.35, 3.60)	0.8380	
HER2 Status in central laboratory							0.9901
IHC 3+	19/ 96 (19.8)	NE (NE , NE)	7/ 47 (14.9)	NE (NE , NE)	1.12 (0.47, 2.68)	0.8039	
IHC 2+/ISH +	4/ 29 (13.8)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.7413
Gastric	20/108 (18.5)	NE (NE , NE)	6/ 55 (10.9)	NE (NE , NE)	1.51 (0.60, 3.78)	0.3748	
GEJ	3/ 17 (17.6)	NE (NE , NE)	1/ 7 (14.3)	NE (0.5, NE)	1.19 (0.12, 11.41)	0.8739	
Histological subtype							0.3836
intestinal	17/ 89 (19.1)	NE (NE , NE)	4/ 38 (10.5)	NE (NE , NE)	1.75 (0.59, 5.22)	0.3063	
diffuse	5/ 28 (17.9)	NE (8.3, NE)	1/ 18 (5.6)	NE (2.4, NE)	2.06 (0.23, 18.82)	0.5129	
others	1/ 8 (12.5)	NE (0.6, NE)	2/ 6 (33.3)	NE (0.3, NE)	0.39 (0.03, 4.30)	0.4220	
Number of metastatic sites							0.3091
<2	1/ 23 (4.3)	NE (NE , NE)	1/ 10 (10.0)	NE (2.4, NE)	0.42 (0.03, 6.72)	0.5267	
>= 2	22/102 (21.6)	NE (NE , NE)	6/ 52 (11.5)	NE (NE , NE)	1.68 (0.68, 4.18)	0.2547	
Previous total gastrectomy							0.9890
yes	2/ 22 (9.1)	NE (8.3, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	21/103 (20.4)	NE (NE , NE)	7/ 53 (13.2)	NE (NE , NE)	1.43 (0.61, 3.38)	0.4069	
Prior adjuvant/ neoadjuvant therapy							0.9879
yes	4/ 30 (13.3)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	19/ 95 (20.0)	NE (NE , NE)	7/ 52 (13.5)	NE (NE , NE)	1.40 (0.59, 3.35)	0.4433	
Prior ramucirumab contained treatment							0.7510
yes	17/ 94 (18.1)	NE (NE , NE)	5/ 41 (12.2)	NE (NE , NE)	1.38 (0.51, 3.76)	0.5243	
no	6/ 31 (19.4)	NE (8.3, NE)	2/ 21 (9.5)	NE (NE , NE)	1.62 (0.32, 8.27)	0.5553	
Prior nivolumab contained treatment							0.9901
yes	11/ 33 (33.3)	NE (4.4, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	12/ 92 (13.0)	NE (NE , NE)	7/ 47 (14.9)	NE (NE , NE)	0.74 (0.29, 1.90)	0.5294	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

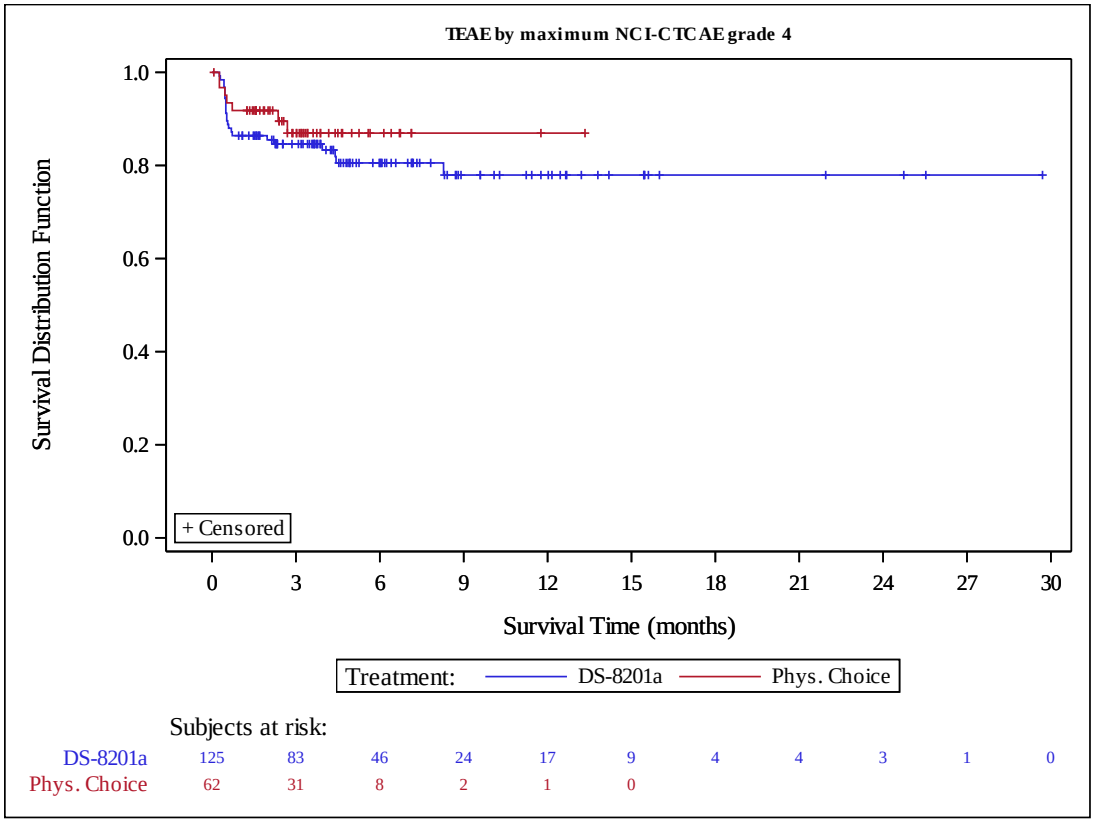
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9899
yes	16/ 44 (36.4)	NE (4.4, NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 81 (8.6)	NE (NE , NE)	7/ 45 (15.6)	NE (NE , NE)	0.44 (0.15, 1.29)	0.1247	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9897
yes	3/ 22 (13.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	20/103 (19.4)	NE (NE , NE)	7/ 55 (12.7)	NE (NE , NE)	1.36 (0.57, 3.24)	0.4814	
Presence of liver metastasis at baseline							0.0963
yes	17/ 68 (25.0)	NE (NE , NE)	3/ 34 (8.8)	NE (NE , NE)	2.81 (0.82, 9.60)	0.0841	
no	6/ 57 (10.5)	NE (NE , NE)	4/ 28 (14.3)	NE (NE , NE)	0.60 (0.16, 2.19)	0.4329	
Renal impairment at baseline							0.9944
normal	6/ 33 (18.2)	NE (NE , NE)	2/ 13 (15.4)	NE (2.7, NE)	1.17 (0.24, 5.81)	0.8463	
mild	10/ 53 (18.9)	NE (NE , NE)	4/ 28 (14.3)	NE (NE , NE)	1.13 (0.35, 3.63)	0.8332	
moderate	7/ 39 (17.9)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	1/ 1 (100.0)	2.4 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7168
normal	18/ 88 (20.5)	NE (NE , NE)	6/ 47 (12.8)	NE (NE , NE)	1.35 (0.53, 3.43)	0.5293	
mild	5/ 36 (13.9)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	2.14 (0.25, 18.33)	0.4788	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9907
yes	2/ 8 (25.0)	NE (4.4, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	21/117 (17.9)	NE (NE , NE)	7/ 57 (12.3)	NE (NE , NE)	1.38 (0.59, 3.25)	0.4599	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9999
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	23/122 (18.9)	NE (NE , NE)	7/ 58 (12.1)	NE (NE , NE)	1.39 (0.59, 3.25)	0.4505	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	8 (6.4)	2 (3.2)
Number of censored subjects, n (%)	117 (93.6)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.28 (0.27, 6.16)	
p-value [c]	0.7537	
Relative Risk (95% CI) [d]	1.98 (0.43, 9.06)	
p-value	0.3768	
Odds Ratio (95% CI) [d]	2.05 (0.42, 9.96)	
p-value	0.3729	
Risk Difference (95% CI) [e]	3.17 (-4.18, 10.52)	
p-value	0.3974	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.4008
Japan	6/ 99 (6.1)	NE (NE , NE)	1/ 50 (2.0)	NE (NE , NE)	2.05 (0.24, 17.39)	0.4999	
Korea	2/ 26 (7.7)	NE (NE , NE)	1/ 12 (8.3)	NE (3.6, NE)	0.58 (0.05, 6.47)	0.6537	
Lines of prior systemic therapy							1.0000
2	7/ 66 (10.6)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (3.6, NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	1/ 6 (16.7)	NE (2.0, NE)	0.18 (0.01, 2.84)	0.1680	
Age							0.9932
<65 years	4/ 55 (7.3)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	4/ 70 (5.7)	NE (NE , NE)	2/ 35 (5.7)	NE (NE , NE)	0.70 (0.13, 3.86)	0.6818	
Sex							0.9923
female	3/ 30 (10.0)	NE (10.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	5/ 95 (5.3)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.79 (0.15, 4.08)	0.7760	
ECOG PS							0.6392
0	3/ 62 (4.8)	NE (NE , NE)	1/ 30 (3.3)	NE (NE , NE)	0.82 (0.08, 8.51)	0.8696	
1	5/ 63 (7.9)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	1.92 (0.22, 16.47)	0.5459	
HER2 Status in central laboratory							0.9930
IHC 3+	4/ 96 (4.2)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.48 (0.08, 2.74)	0.3998	
IHC 2+/ISH +	4/ 29 (13.8)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9949
Gastric	7/108 (6.5)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	1.14 (0.23, 5.60)	0.8738	
GEJ	1/ 17 (5.9)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							0.6096
intestinal	6/ 89 (6.7)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	1.85 (0.22, 15.59)	0.5644	
diffuse	1/ 28 (3.6)	NE (NE , NE)	1/ 18 (5.6)	NE (3.6, NE)	0.27 (0.02, 4.32)	0.3211	
others	1/ 8 (12.5)	NE (1.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	8/102 (7.8)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.26 (0.26, 6.06)	0.7726	
Previous total gastrectomy							0.2301
yes	1/ 22 (4.5)	NE (NE , NE)	1/ 9 (11.1)	NE (3.6, NE)	0.19 (0.01, 3.10)	0.1934	
no	7/103 (6.8)	NE (NE , NE)	1/ 53 (1.9)	NE (NE , NE)	2.46 (0.30, 20.27)	0.3886	
Prior adjuvant/ neoadjuvant therapy							0.9943
yes	1/ 30 (3.3)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 95 (7.4)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.25 (0.26, 6.14)	0.7814	
Prior ramucirumab contained treatment							0.7869
yes	6/ 94 (6.4)	NE (NE , NE)	1/ 41 (2.4)	NE (NE , NE)	1.91 (0.23, 15.97)	0.5426	
no	2/ 31 (6.5)	NE (10.3, NE)	1/ 21 (4.8)	NE (NE , NE)	0.65 (0.05, 7.78)	0.7310	
Prior nivolumab contained treatment							0.9921
yes	1/ 33 (3.0)	NE (NE , NE)	2/ 15 (13.3)	NE (3.6, NE)	0.15 (0.01, 1.66)	0.0744	
no	7/ 92 (7.6)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

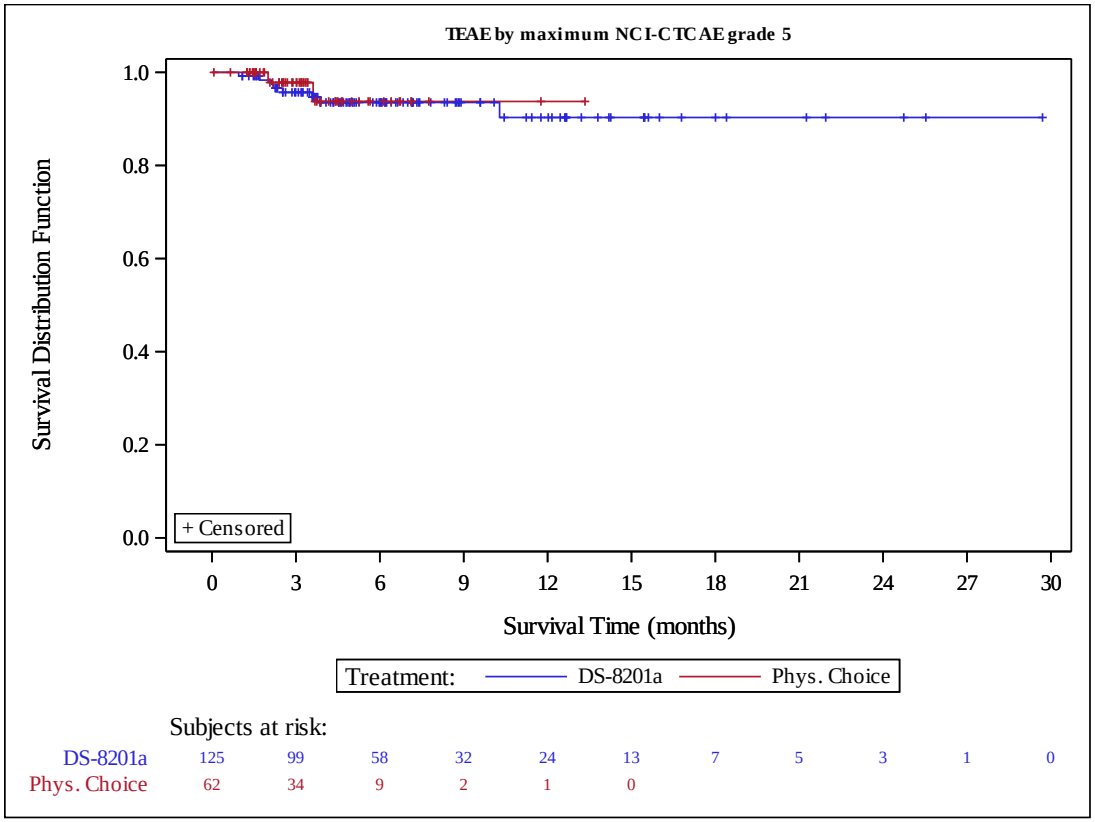
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5 - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9917
yes	1/ 44 (2.3)	NE (NE , NE)	2/ 17 (11.8)	NE (3.6, NE)	0.13 (0.01, 1.48)	0.0545	
no	7/ 81 (8.6)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9948
yes	3/ 22 (13.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	5/103 (4.9)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	0.79 (0.15, 4.25)	0.7878	
Presence of liver metastasis at baseline							0.9930
yes	5/ 68 (7.4)	NE (NE , NE)	2/ 34 (5.9)	NE (NE , NE)	0.65 (0.12, 3.46)	0.6122	
no	3/ 57 (5.3)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							0.9871
normal	3/ 33 (9.1)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 53 (5.7)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	1.01 (0.10, 9.69)	0.9963	
moderate	2/ 39 (5.1)	NE (NE , NE)	1/ 20 (5.0)	NE (3.6, NE)	0.89 (0.08, 9.97)	0.9242	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.7435
normal	5/ 88 (5.7)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	1.49 (0.17, 13.34)	0.7181	
mild	3/ 36 (8.3)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	1.00 (0.10, 9.67)	0.9996	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9927
yes	0/ 8 (0.0)	NE (NE , NE)	1/ 5 (20.0)	NE (2.0, NE)	NE	NE	
no	8/117 (6.8)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	2.43 (0.30, 19.80)	0.3915	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							1.0000
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	8/122 (6.6)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	1.19 (0.25, 5.75)	0.8267	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Investigator)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	18 (14.4)	0 (0.0)
Number of censored subjects, n (%)	107 (85.6)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	22.3 (22.3, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	18.50 (1.13, 302.01)	
p-value	0.0406	
Odds Ratio (95% CI) [d]	21.51 (1.27, 363.16)	
p-value	0.0333	
Risk Difference (95% CI) [e]	14.40 (7.04, 21.76)	
p-value	0.0001	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9999
Japan	16/ 99 (16.2)	22.3 (22.3, NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	2/ 26 (7.7)	NE (10.4, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	11/ 66 (16.7)	NE (10.4, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	3/ 34 (8.8)	NE (12.5, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	4/ 25 (16.0)	22.3 (22.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9999
<65 years	5/ 55 (9.1)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	13/ 70 (18.6)	22.3 (12.5, NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	4/ 30 (13.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	14/ 95 (14.7)	22.3 (22.3, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9998
0	7/ 62 (11.3)	NE (22.3, NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	11/ 63 (17.5)	NE (10.4, NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	14/ 96 (14.6)	NE (22.3, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	4/ 29 (13.8)	NE (7.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9999
Gastric	17/108 (15.7)	22.3 (22.3, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (8.5, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	15/ 89 (16.9)	NE (22.3, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	3/ 28 (10.7)	NE (12.5, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9999
<2	3/ 23 (13.0)	NE (10.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	15/102 (14.7)	22.3 (22.3, NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	22.3 (10.4, 22.3)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	14/103 (13.6)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	5/ 30 (16.7)	22.3 (12.5, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	13/ 95 (13.7)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9997
yes	10/ 94 (10.6)	NE (22.3, NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 31 (25.8)	12.5 (10.4, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	4/ 33 (12.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	14/ 92 (15.2)	22.3 (12.5, 22.3)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

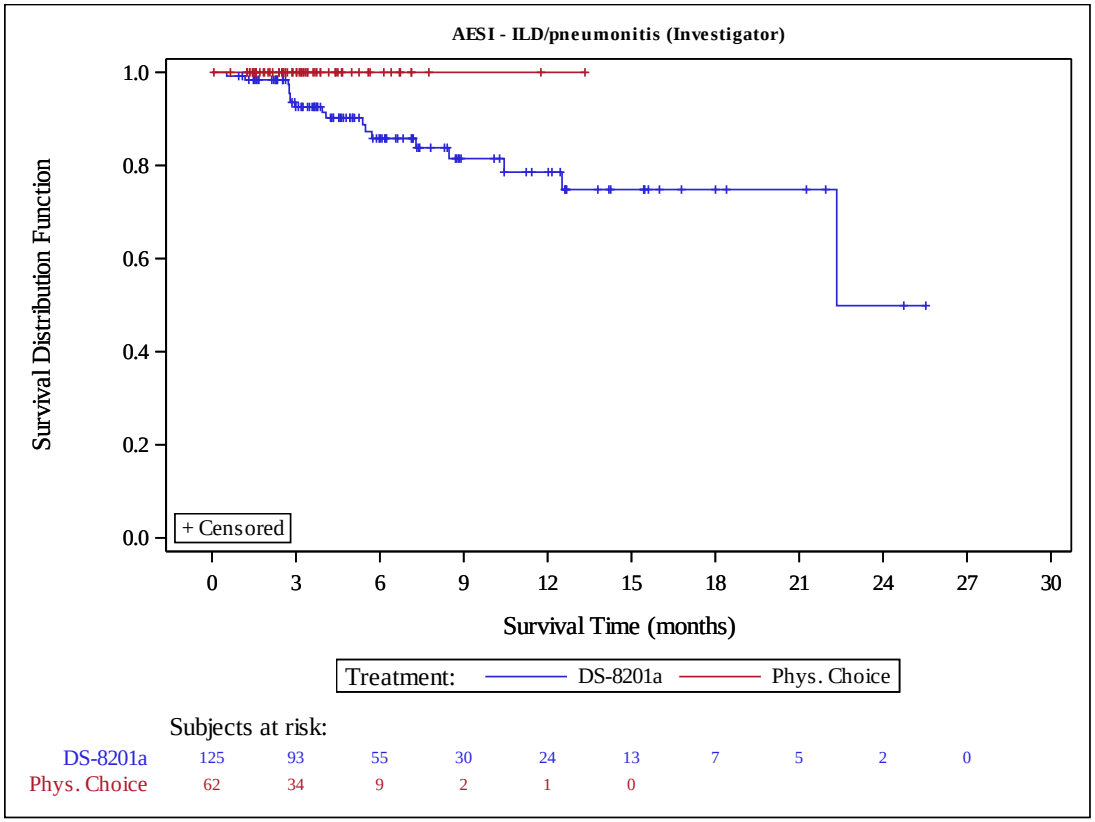
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9999
yes	5/ 44 (11.4)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	13/ 81 (16.0)	22.3 (12.5, 22.3)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	5/ 22 (22.7)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	13/103 (12.6)	NE (22.3, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	7/ 68 (10.3)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	11/ 57 (19.3)	22.3 (12.5, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	22.3 (22.3, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	8/ 53 (15.1)	NE (12.5, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	8/ 39 (20.5)	NE (8.5, NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							1.0000
normal	14/ 88 (15.9)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	4/ 36 (11.1)	22.3 (22.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9999
yes	1/ 8 (12.5)	22.3 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	17/117 (14.5)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9981
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	18/122 (14.8)	22.3 (22.3, NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of AESI - ILD/pneumonitis (Investigator)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Investigator)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	7 (5.6)	0 (0.0)
Number of censored subjects, n (%)	118 (94.4)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	7.50 (0.44, 129.23)	
p-value	0.1654	
Odds Ratio (95% CI) [d]	7.91 (0.44, 140.80)	
p-value	0.1591	
Risk Difference (95% CI) [e]	5.60 (0.36, 10.84)	
p-value	0.0361	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							1.0000
Japan	6/ 99 (6.1)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (10.4, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	5/ 66 (7.6)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	2/ 25 (8.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9997
<65 years	1/ 55 (1.8)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	6/ 70 (8.6)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	5/ 95 (5.3)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9996
0	1/ 62 (1.6)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	6/ 63 (9.5)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9998
IHC 3+	4/ 96 (4.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	3/ 29 (10.3)	NE (7.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							1.0000
Gastric	6/108 (5.6)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (8.5, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	6/ 89 (6.7)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	1/ 28 (3.6)	NE (10.4, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9999
<2	1/ 23 (4.3)	NE (10.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	6/102 (5.9)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							1.0000
yes	1/ 22 (4.5)	NE (10.4, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	6/103 (5.8)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9999
yes	1/ 30 (3.3)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 95 (6.3)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							1.0000
yes	5/ 94 (5.3)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 31 (6.5)	NE (10.4, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9998
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 92 (6.5)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

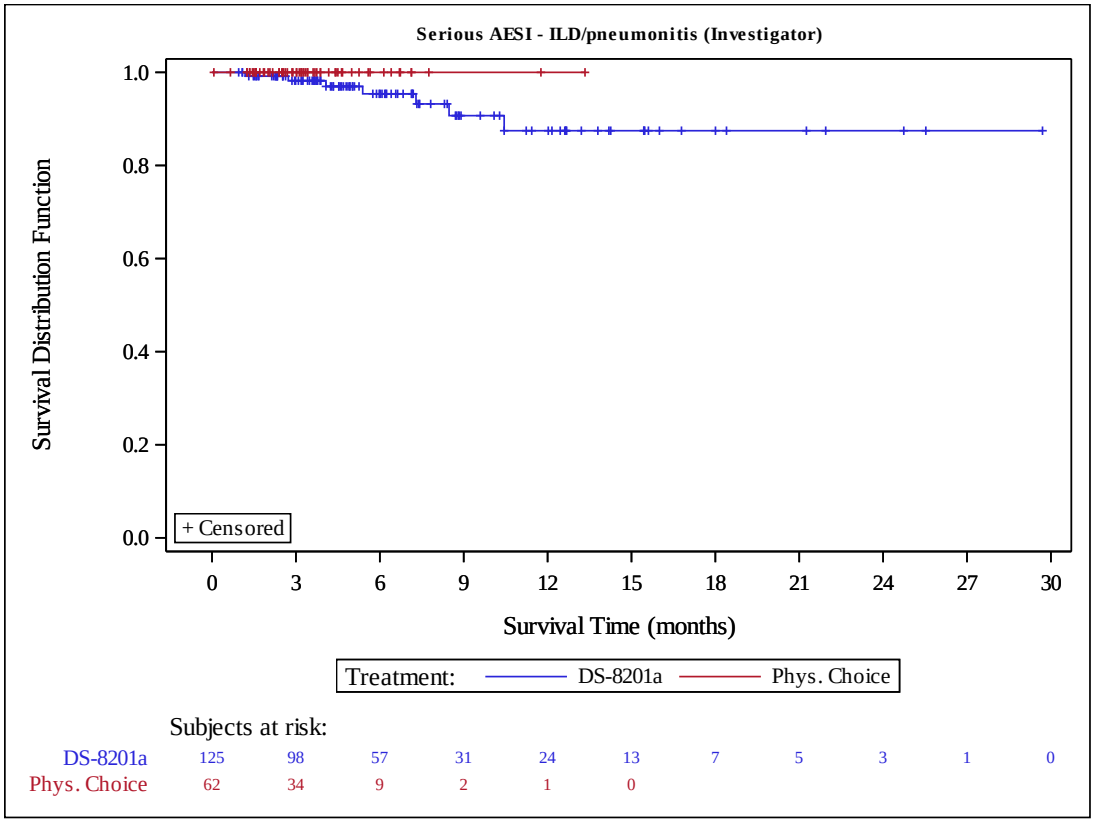
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9999
yes	2/ 44 (4.5)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	5/ 81 (6.2)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	2/ 22 (9.1)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	5/103 (4.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							1.0000
yes	3/ 68 (4.4)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 57 (7.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	4/ 39 (10.3)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							1.0000
normal	5/ 88 (5.7)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9986
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	7/117 (6.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9988
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	7/122 (5.7)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Investigator)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Investigator)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
p-value	0.5522	
Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
p-value	0.5510	
Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
p-value	0.3572	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9991
Japan	2/ 99 (2.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	1/ 66 (1.5)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9989
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	2/ 70 (2.9)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	1/ 30 (3.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9990
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	2/ 63 (3.2)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	1/ 96 (1.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9992
Gastric	2/108 (1.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	2/ 89 (2.2)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9991
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	2/102 (2.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9992
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9991
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 95 (2.1)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9999
yes	1/ 94 (1.1)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 92 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

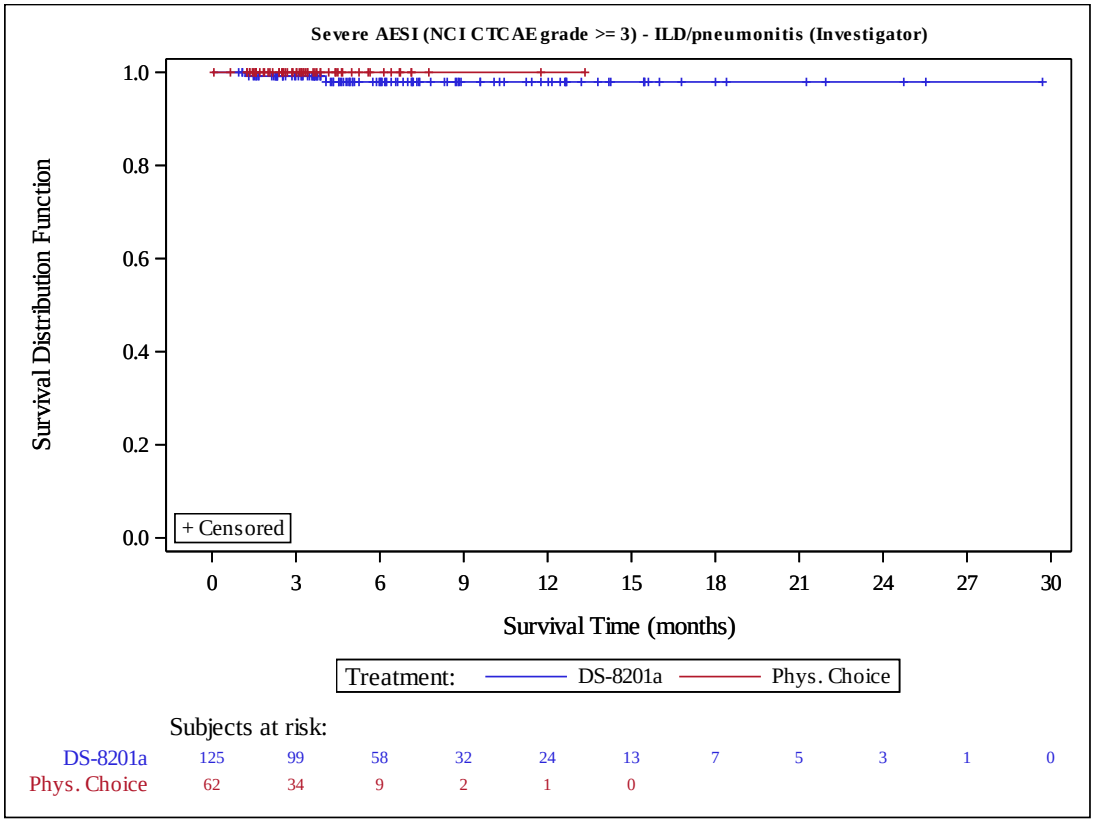
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	1/ 44 (2.3)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 81 (1.2)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	1/ 22 (4.5)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							1.0000
yes	1/ 68 (1.5)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 57 (1.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 53 (1.9)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	1/ 39 (2.6)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	1/ 88 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 36 (2.8)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9993
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	2/117 (1.7)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9994
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	2/122 (1.6)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Investigator)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Investigator)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	16 (12.8)	0 (0.0)
Number of censored subjects, n (%)	109 (87.2)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (22.3, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	16.50 (1.01, 270.58)	
p-value	0.0495	
Odds Ratio (95% CI) [d]	18.84 (1.11, 319.37)	
p-value	0.0421	
Risk Difference (95% CI) [e]	12.80 (5.74, 19.86)	
p-value	0.0004	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9999
Japan	14/ 99 (14.1)	NE (22.3, NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	2/ 26 (7.7)	NE (10.4, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	10/ 66 (15.2)	NE (10.4, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	3/ 34 (8.8)	NE (12.5, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	3/ 25 (12.0)	22.3 (22.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9999
<65 years	5/ 55 (9.1)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	11/ 70 (15.7)	22.3 (22.3, NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							1.0000
female	3/ 30 (10.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	13/ 95 (13.7)	NE (22.3, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9999
0	7/ 62 (11.3)	NE (22.3, NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	9/ 63 (14.3)	NE (10.4, NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							1.0000
IHC 3+	13/ 96 (13.5)	NE (22.3, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	3/ 29 (10.3)	NE (7.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9999
Gastric	15/108 (13.9)	NE (22.3, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (8.5, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	13/ 89 (14.6)	NE (22.3, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	3/ 28 (10.7)	NE (12.5, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9999
<2	3/ 23 (13.0)	NE (10.4, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	13/102 (12.7)	22.3 (22.3, NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	22.3 (10.4, 22.3)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	12/103 (11.7)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	5/ 30 (16.7)	22.3 (12.5, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	11/ 95 (11.6)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9997
yes	9/ 94 (9.6)	NE (22.3, NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 31 (22.6)	NE (10.4, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9998
yes	3/ 33 (9.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	13/ 92 (14.1)	22.3 (12.5, 22.3)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

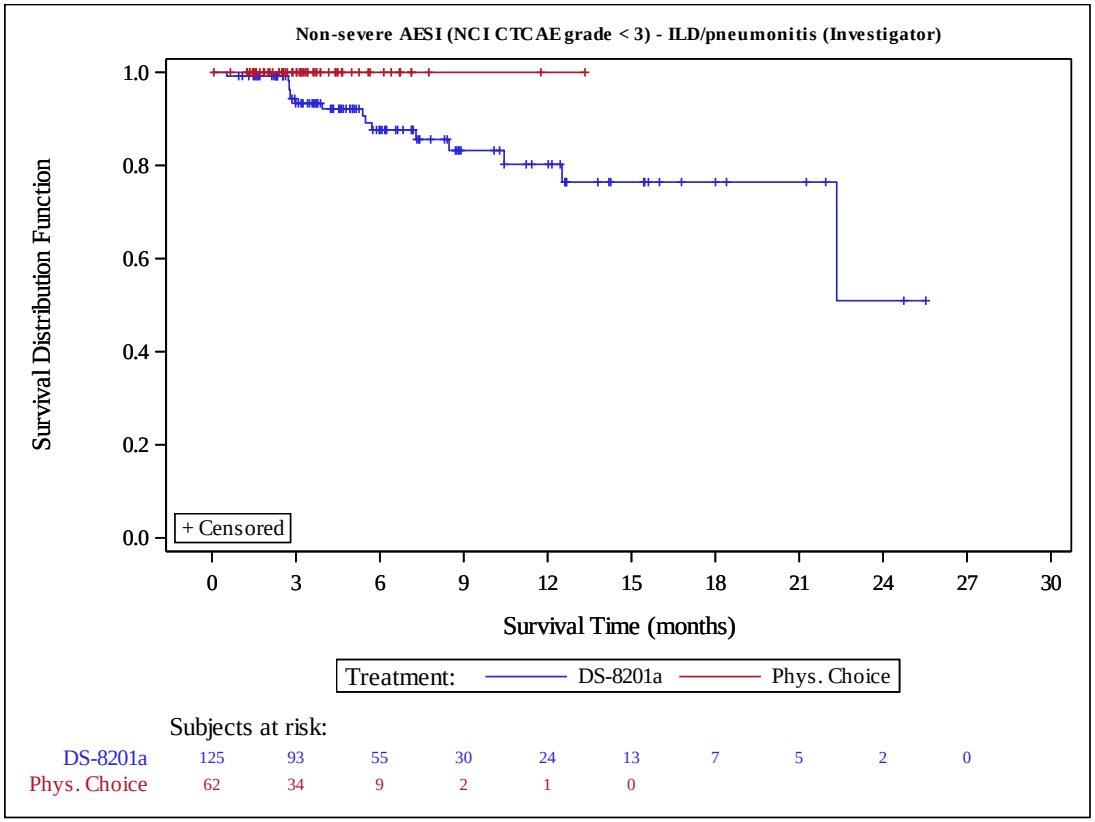
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Investigator) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9998
yes	4/ 44 (9.1)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	12/ 81 (14.8)	22.3 (12.5, 22.3)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	4/ 22 (18.2)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	12/103 (11.7)	NE (22.3, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	6/ 68 (8.8)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	10/ 57 (17.5)	22.3 (12.5, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	22.3 (22.3, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	7/ 53 (13.2)	NE (12.5, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	7/ 39 (17.9)	NE (8.5, NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	13/ 88 (14.8)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 36 (8.3)	22.3 (22.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9999
yes	1/ 8 (12.5)	22.3 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	15/117 (12.8)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9982
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	16/122 (13.1)	NE (22.3, NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Investigator)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	16 (12.8)	0 (0.0)
Number of censored subjects, n (%)	109 (87.2)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (21.0, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	16.50 (1.01, 270.58)	
p-value	0.0495	
Odds Ratio (95% CI) [d]	18.84 (1.11, 319.37)	
p-value	0.0421	
Risk Difference (95% CI) [e]	12.80 (5.74, 19.86)	
p-value	0.0004	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9999
Japan	14/ 99 (14.1)	NE (21.0, NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	2/ 26 (7.7)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	10/ 66 (15.2)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	2/ 34 (5.9)	NE (10.9, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	4/ 25 (16.0)	21.0 (21.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9997
<65 years	3/ 55 (5.5)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	13/ 70 (18.6)	21.0 (21.0, NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	4/ 30 (13.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	12/ 95 (12.6)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9999
0	7/ 62 (11.3)	NE (21.0, NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	9/ 63 (14.3)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	12/ 96 (12.5)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	4/ 29 (13.8)	NE (5.4, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9999
Gastric	15/108 (13.9)	NE (21.0, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (7.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	13/ 89 (14.6)	NE (21.0, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	3/ 28 (10.7)	NE (10.9, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9999
<2	3/ 23 (13.0)	NE (10.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	13/102 (12.7)	NE (21.0, NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	21.0 (8.1, 21.0)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	12/103 (11.7)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	5/ 30 (16.7)	21.0 (10.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	11/ 95 (11.6)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9997
yes	9/ 94 (9.6)	NE (21.0, NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 31 (22.6)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	3/ 33 (9.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	13/ 92 (14.1)	21.0 (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

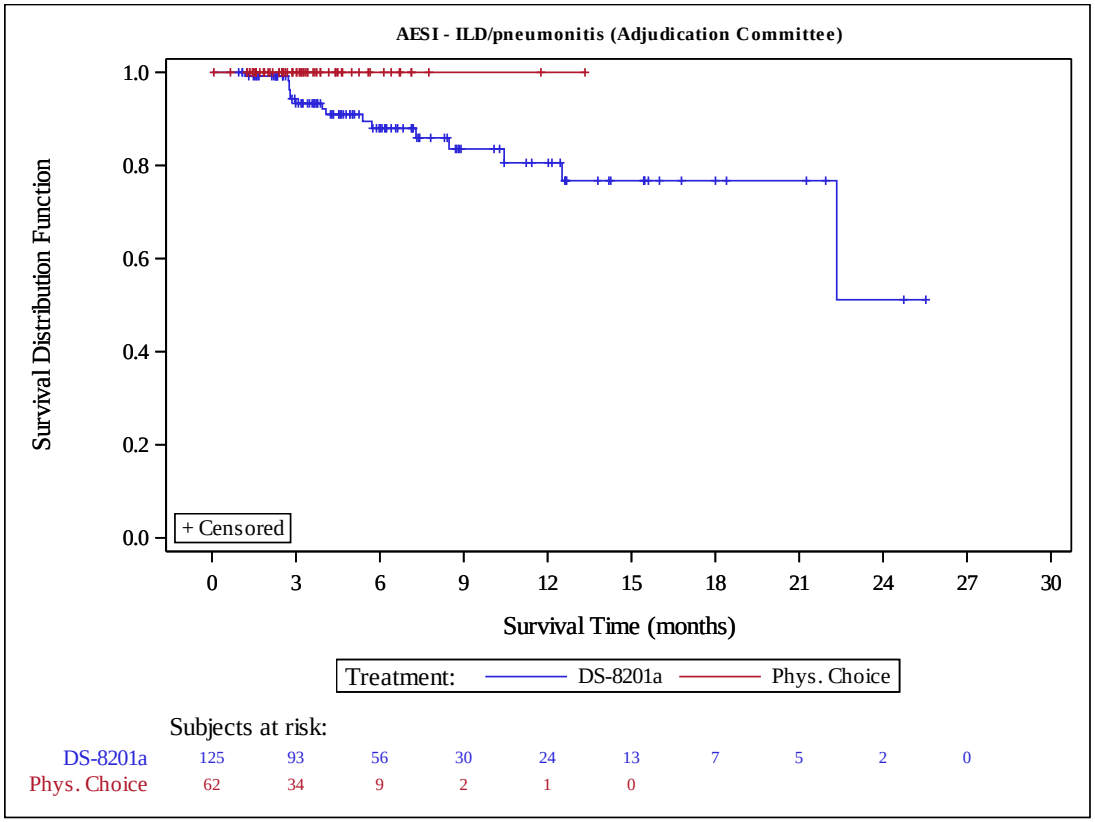
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9998
yes	4/ 44 (9.1)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	12/ 81 (14.8)	21.0 (21.0, NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	5/ 22 (22.7)	NE (4.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	11/103 (10.7)	NE (21.0, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	6/ 68 (8.8)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	10/ 57 (17.5)	21.0 (21.0, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	NE (21.0, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	6/ 53 (11.3)	NE (10.9, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	8/ 39 (20.5)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	13/ 88 (14.8)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 36 (8.3)	21.0 (21.0, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9999
yes	1/ 8 (12.5)	21.0 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	15/117 (12.8)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9983
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	16/122 (13.1)	NE (21.0, NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	7 (5.6)	0 (0.0)
Number of censored subjects, n (%)	118 (94.4)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	7.50 (0.44, 129.23)	
p-value	0.1654	
Odds Ratio (95% CI) [d]	7.91 (0.44, 140.80)	
p-value	0.1591	
Risk Difference (95% CI) [e]	5.60 (0.36, 10.84)	
p-value	0.0361	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							1.0000
Japan	6/ 99 (6.1)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	5/ 66 (7.6)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	2/ 25 (8.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9997
<65 years	1/ 55 (1.8)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	6/ 70 (8.6)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	5/ 95 (5.3)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9996
0	1/ 62 (1.6)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	6/ 63 (9.5)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9998
IHC 3+	4/ 96 (4.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	3/ 29 (10.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							1.0000
Gastric	6/108 (5.6)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (7.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	6/ 89 (6.7)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	1/ 28 (3.6)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9999
<2	1/ 23 (4.3)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	6/102 (5.9)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							1.0000
yes	1/ 22 (4.5)	NE (8.1, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	6/103 (5.8)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9999
yes	1/ 30 (3.3)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 95 (6.3)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							1.0000
yes	5/ 94 (5.3)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 31 (6.5)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 92 (6.5)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

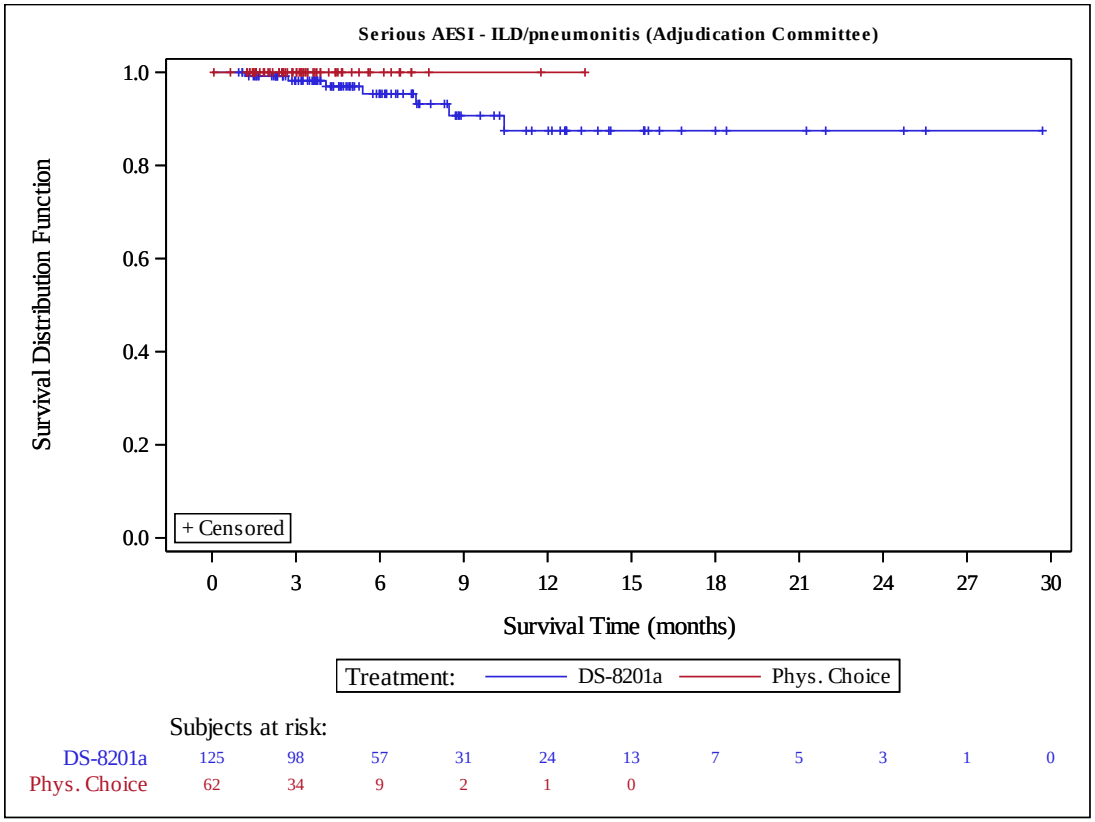
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9999
yes	2/ 44 (4.5)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	5/ 81 (6.2)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	2/ 22 (9.1)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	5/103 (4.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							1.0000
yes	3/ 68 (4.4)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 57 (7.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	4/ 39 (10.3)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							1.0000
normal	5/ 88 (5.7)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9987
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	7/117 (6.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9988
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	7/122 (5.7)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	3 (2.4)	0 (0.0)
Number of censored subjects, n (%)	122 (97.6)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	3.50 (0.18, 66.72)	
p-value	0.4049	
Odds Ratio (95% CI) [d]	3.57 (0.18, 70.23)	
p-value	0.4023	
Risk Difference (95% CI) [e]	2.40 (-1.49, 6.29)	
p-value	0.2265	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9989
Japan	3/ 99 (3.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	2/ 66 (3.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9987
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	3/ 70 (4.3)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9998
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9988
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	3/ 63 (4.8)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	2/ 96 (2.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9990
Gastric	3/108 (2.8)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	3/ 89 (3.4)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9988
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	3/102 (2.9)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9989
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	3/103 (2.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9988
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 95 (3.2)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							1.0000
yes	2/ 94 (2.1)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							1.0000
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 92 (2.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

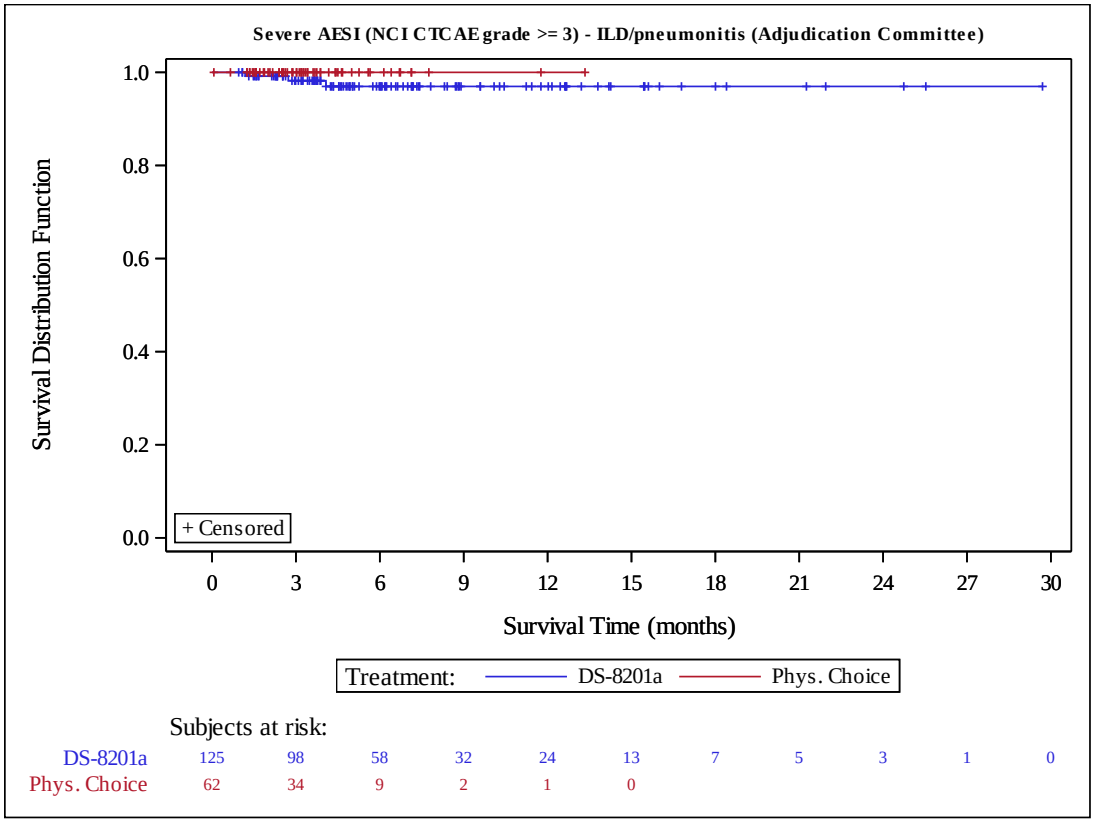
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	1/ 44 (2.3)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 81 (2.5)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	1/ 22 (4.5)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	2/ 68 (2.9)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 57 (1.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 53 (1.9)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	2/ 39 (5.1)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	1/ 88 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9992
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	3/117 (2.6)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9993
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	3/122 (2.5)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	13 (10.4)	0 (0.0)
Number of censored subjects, n (%)	112 (89.6)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (21.0, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	13.50 (0.82, 223.43)	
p-value	0.0691	
Odds Ratio (95% CI) [d]	15.00 (0.88, 256.62)	
p-value	0.0616	
Risk Difference (95% CI) [e]	10.40 (3.84, 16.96)	
p-value	0.0019	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							1.0000
Japan	11/ 99 (11.1)	NE (21.0, NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	2/ 26 (7.7)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	8/ 66 (12.1)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	2/ 34 (5.9)	NE (10.9, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	3/ 25 (12.0)	21.0 (21.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9998
<65 years	3/ 55 (5.5)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	10/ 70 (14.3)	21.0 (21.0, NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							1.0000
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	11/ 95 (11.6)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							1.0000
0	7/ 62 (11.3)	NE (21.0, NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	6/ 63 (9.5)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	10/ 96 (10.4)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	3/ 29 (10.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9999
Gastric	12/108 (11.1)	NE (21.0, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (7.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	10/ 89 (11.2)	NE (21.0, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	3/ 28 (10.7)	NE (10.9, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	3/ 23 (13.0)	NE (10.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	10/102 (9.8)	NE (21.0, NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	21.0 (8.1, 21.0)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	9/103 (8.7)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9999
yes	5/ 30 (16.7)	21.0 (10.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 95 (8.4)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9997
yes	7/ 94 (7.4)	NE (21.0, NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 31 (19.4)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9998
yes	2/ 33 (6.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	11/ 92 (12.0)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

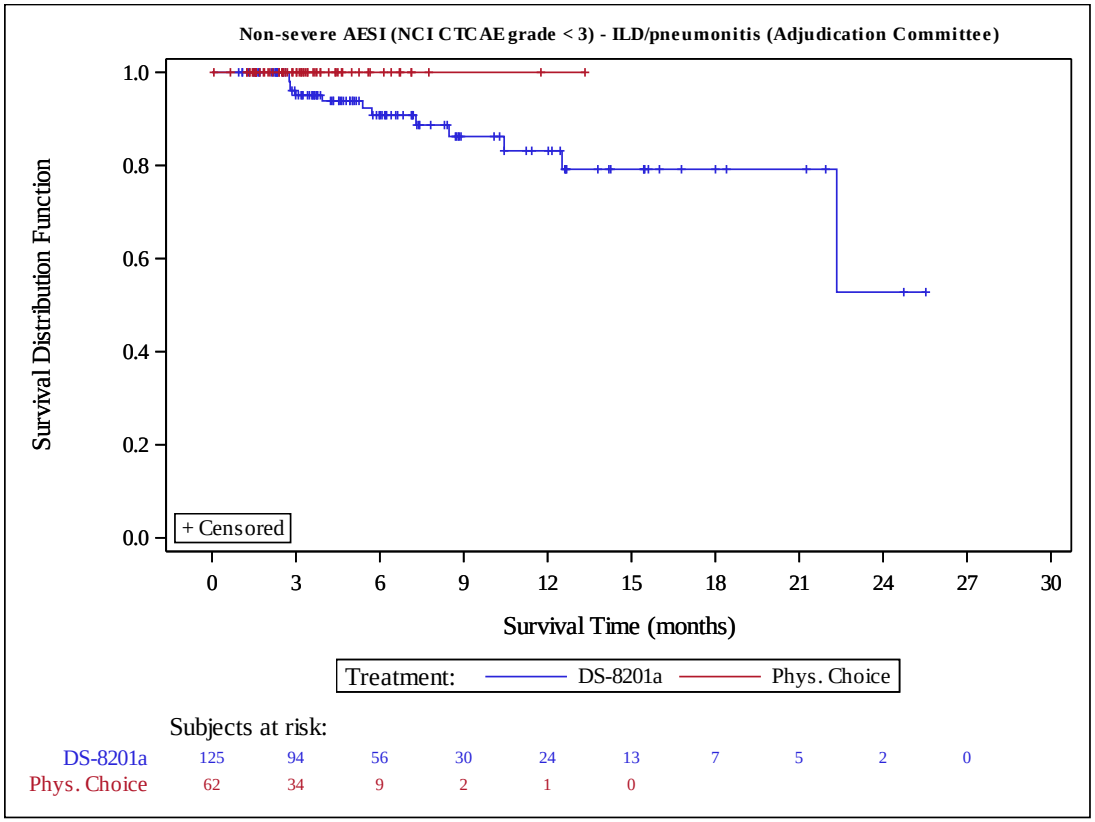
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9998
yes	3/ 44 (6.8)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	10/ 81 (12.3)	21.0 (21.0, NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	4/ 22 (18.2)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	9/103 (8.7)	NE (21.0, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9998
yes	4/ 68 (5.9)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	9/ 57 (15.8)	21.0 (21.0, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	NE (21.0, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	5/ 53 (9.4)	NE (10.9, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	6/ 39 (15.4)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9998
normal	12/ 88 (13.6)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 36 (2.8)	NE (21.0, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							1.0000
yes	1/ 8 (12.5)	21.0 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	12/117 (10.3)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9984
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	13/122 (10.7)	NE (21.0, NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	16 (12.8)	0 (0.0)
Number of censored subjects, n (%)	109 (87.2)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (21.0, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	16.50 (1.01, 270.58)	
p-value	0.0495	
Odds Ratio (95% CI) [d]	18.84 (1.11, 319.37)	
p-value	0.0421	
Risk Difference (95% CI) [e]	12.80 (5.74, 19.86)	
p-value	0.0004	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9999
Japan	14/ 99 (14.1)	NE (21.0, NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	2/ 26 (7.7)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	10/ 66 (15.2)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	2/ 34 (5.9)	NE (10.9, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	4/ 25 (16.0)	21.0 (21.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9997
<65 years	3/ 55 (5.5)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	13/ 70 (18.6)	21.0 (21.0, NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	4/ 30 (13.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	12/ 95 (12.6)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9999
0	7/ 62 (11.3)	NE (21.0, NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	9/ 63 (14.3)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	12/ 96 (12.5)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	4/ 29 (13.8)	NE (5.4, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9999
Gastric	15/108 (13.9)	NE (21.0, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (7.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	13/ 89 (14.6)	NE (21.0, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	3/ 28 (10.7)	NE (10.9, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9999
<2	3/ 23 (13.0)	NE (10.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	13/102 (12.7)	NE (21.0, NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	21.0 (8.1, 21.0)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	12/103 (11.7)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							1.0000
yes	5/ 30 (16.7)	21.0 (10.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	11/ 95 (11.6)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9997
yes	9/ 94 (9.6)	NE (21.0, NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	7/ 31 (22.6)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	3/ 33 (9.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	13/ 92 (14.1)	21.0 (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

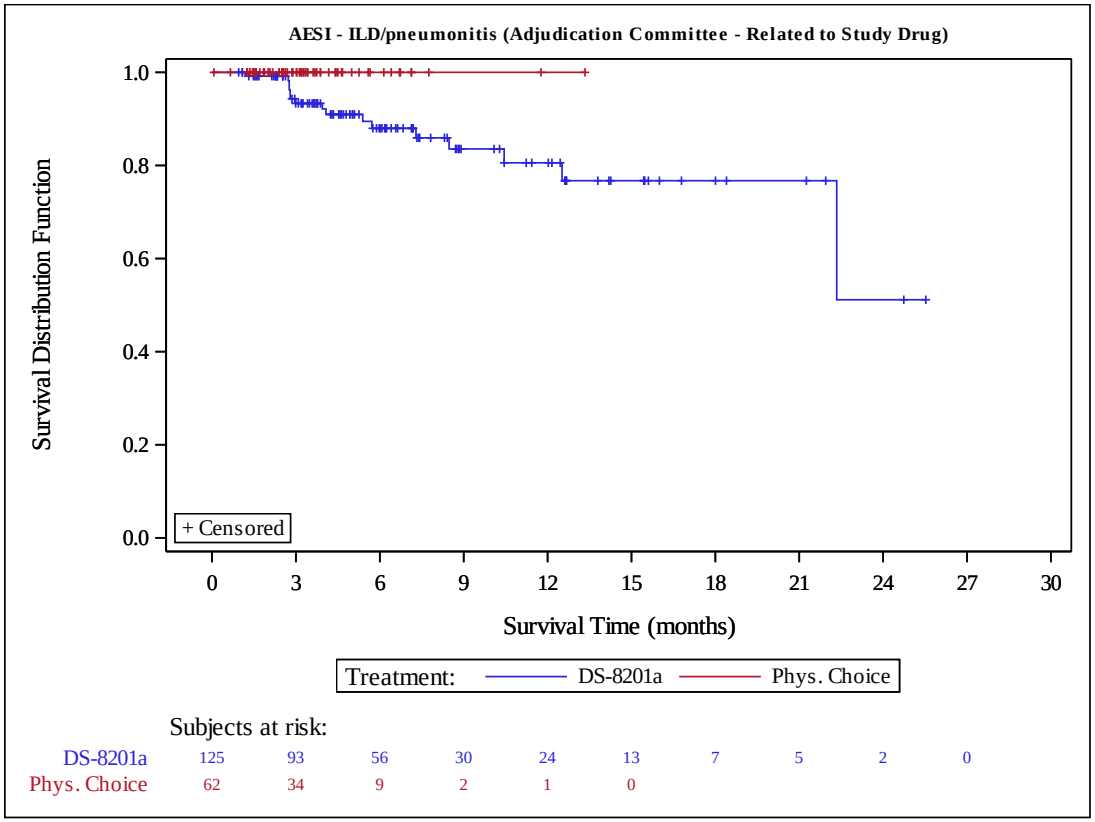
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9998
yes	4/ 44 (9.1)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	12/ 81 (14.8)	21.0 (21.0, NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	5/ 22 (22.7)	NE (4.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	11/103 (10.7)	NE (21.0, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	6/ 68 (8.8)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	10/ 57 (17.5)	21.0 (21.0, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	NE (21.0, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	6/ 53 (11.3)	NE (10.9, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	8/ 39 (20.5)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	13/ 88 (14.8)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	3/ 36 (8.3)	21.0 (21.0, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9999
yes	1/ 8 (12.5)	21.0 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	15/117 (12.8)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9983
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	16/122 (13.1)	NE (21.0, NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	7 (5.6)	0 (0.0)
Number of censored subjects, n (%)	118 (94.4)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	7.50 (0.44, 129.23)	
p-value	0.1654	
Odds Ratio (95% CI) [d]	7.91 (0.44, 140.80)	
p-value	0.1591	
Risk Difference (95% CI) [e]	5.60 (0.36, 10.84)	
p-value	0.0361	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							1.0000
Japan	6/ 99 (6.1)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	1/ 26 (3.8)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	5/ 66 (7.6)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	2/ 25 (8.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9997
<65 years	1/ 55 (1.8)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	6/ 70 (8.6)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9999
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	5/ 95 (5.3)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9996
0	1/ 62 (1.6)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	6/ 63 (9.5)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9998
IHC 3+	4/ 96 (4.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	3/ 29 (10.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							1.0000
Gastric	6/108 (5.6)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (7.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	6/ 89 (6.7)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	1/ 28 (3.6)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9999
<2	1/ 23 (4.3)	NE (8.1, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	6/102 (5.9)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							1.0000
yes	1/ 22 (4.5)	NE (8.1, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	6/103 (5.8)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9999
yes	1/ 30 (3.3)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 95 (6.3)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							1.0000
yes	5/ 94 (5.3)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 31 (6.5)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9999
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 92 (6.5)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

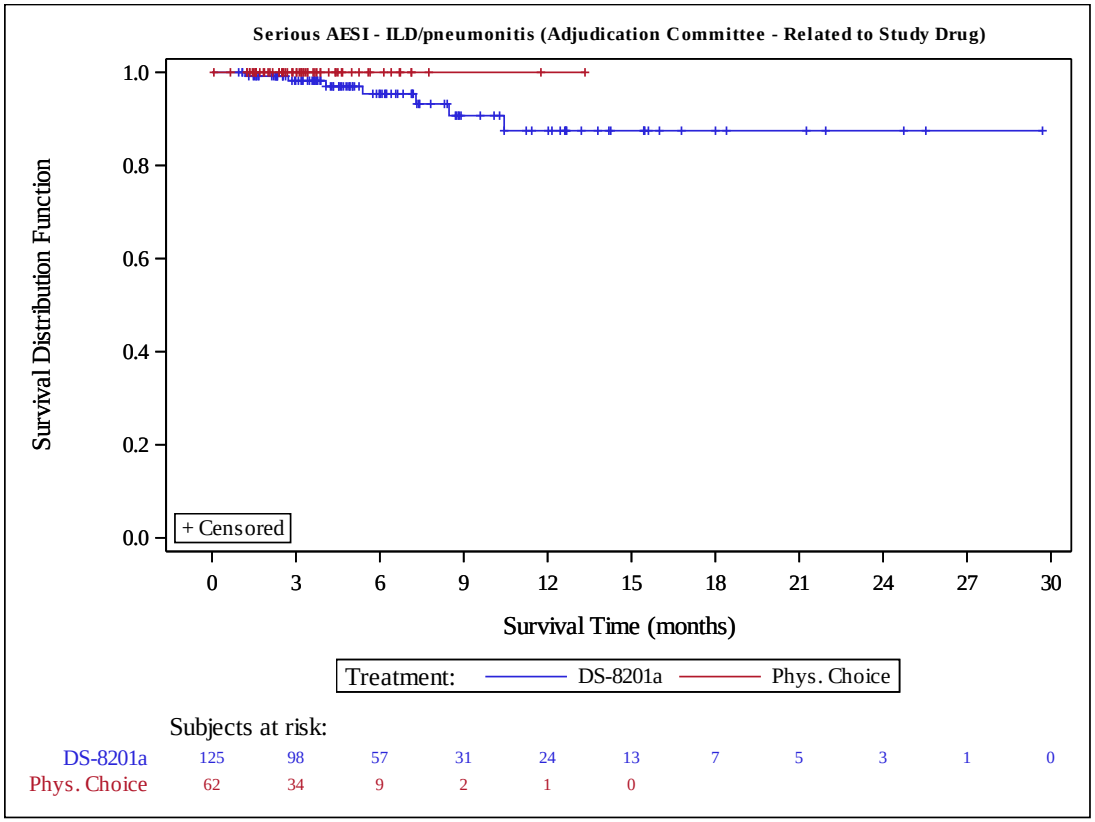
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9999
yes	2/ 44 (4.5)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	5/ 81 (6.2)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	2/ 22 (9.1)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	5/103 (4.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							1.0000
yes	3/ 68 (4.4)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	4/ 57 (7.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	4/ 39 (10.3)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							1.0000
normal	5/ 88 (5.7)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9987
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	7/117 (6.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9988
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	7/122 (5.7)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	3 (2.4)	0 (0.0)
Number of censored subjects, n (%)	122 (97.6)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	3.50 (0.18, 66.72)	
p-value	0.4049	
Odds Ratio (95% CI) [d]	3.57 (0.18, 70.23)	
p-value	0.4023	
Risk Difference (95% CI) [e]	2.40 (-1.49, 6.29)	
p-value	0.2265	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9989
Japan	3/ 99 (3.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	2/ 66 (3.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	1/ 25 (4.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9987
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	3/ 70 (4.3)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							0.9998
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9988
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	3/ 63 (4.8)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	2/ 96 (2.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9990
Gastric	3/108 (2.8)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	3/ 89 (3.4)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9988
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	3/102 (2.9)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9989
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	3/103 (2.9)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9988
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	3/ 95 (3.2)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							1.0000
yes	2/ 94 (2.1)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							1.0000
yes	1/ 33 (3.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 92 (2.2)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

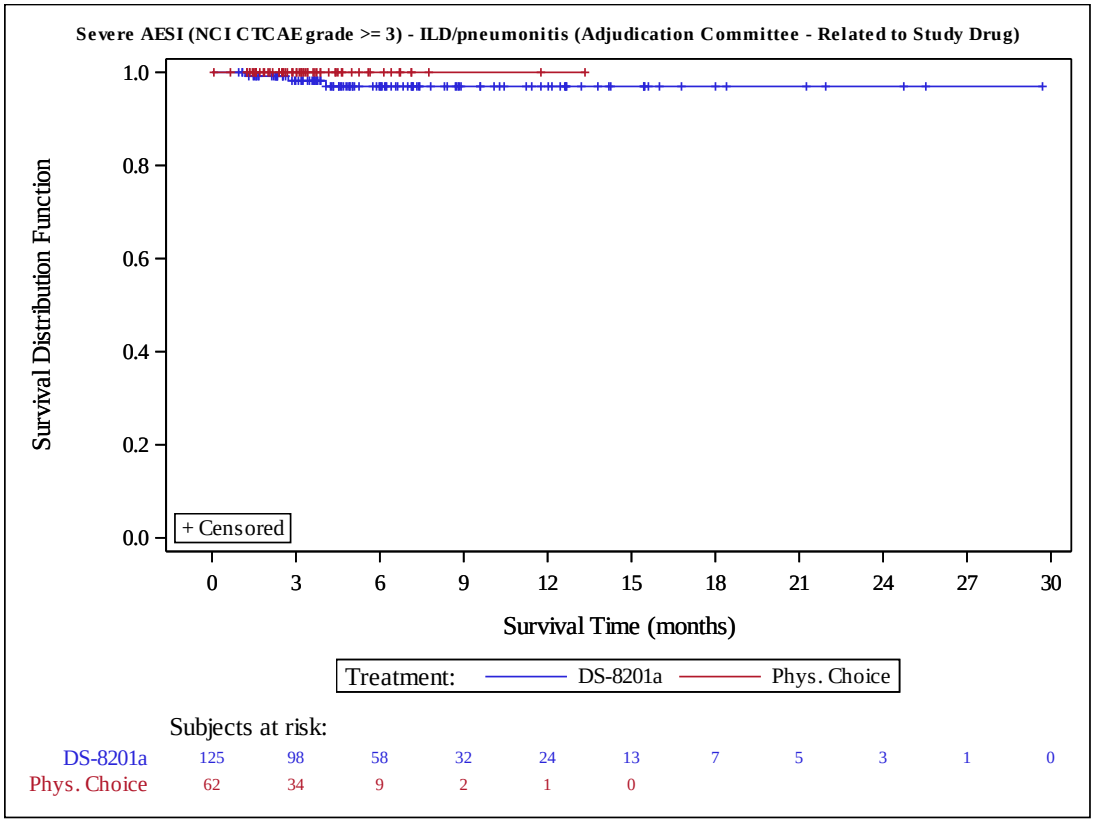
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							1.0000
yes	1/ 44 (2.3)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	2/ 81 (2.5)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9999
yes	1/ 22 (4.5)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	2/103 (1.9)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9999
yes	2/ 68 (2.9)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 57 (1.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 53 (1.9)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	2/ 39 (5.1)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9999
normal	1/ 88 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	2/ 36 (5.6)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9992
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	3/117 (2.6)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9993
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	3/122 (2.5)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	13 (10.4)	0 (0.0)
Number of censored subjects, n (%)	112 (89.6)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (21.0, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	13.50 (0.82, 223.43)	
p-value	0.0691	
Odds Ratio (95% CI) [d]	15.00 (0.88, 256.62)	
p-value	0.0616	
Risk Difference (95% CI) [e]	10.40 (3.84, 16.96)	
p-value	0.0019	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							1.0000
Japan	11/ 99 (11.1)	NE (21.0, NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	2/ 26 (7.7)	NE (8.1, NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	8/ 66 (12.1)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	2/ 34 (5.9)	NE (10.9, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	3/ 25 (12.0)	21.0 (21.0, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9998
<65 years	3/ 55 (5.5)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	10/ 70 (14.3)	21.0 (21.0, NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							1.0000
female	2/ 30 (6.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	11/ 95 (11.6)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							1.0000
0	7/ 62 (11.3)	NE (21.0, NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	6/ 63 (9.5)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.9999
IHC 3+	10/ 96 (10.4)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	3/ 29 (10.3)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9999
Gastric	12/108 (11.1)	NE (21.0, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (7.0, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	10/ 89 (11.2)	NE (21.0, NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	3/ 28 (10.7)	NE (10.9, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							1.0000
<2	3/ 23 (13.0)	NE (10.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	10/102 (9.8)	NE (21.0, NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							0.9999
yes	4/ 22 (18.2)	21.0 (8.1, 21.0)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	9/103 (8.7)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							0.9999
yes	5/ 30 (16.7)	21.0 (10.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	8/ 95 (8.4)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							0.9997
yes	7/ 94 (7.4)	NE (21.0, NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 31 (19.4)	NE (8.1, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9998
yes	2/ 33 (6.1)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	11/ 92 (12.0)	NE (21.0, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

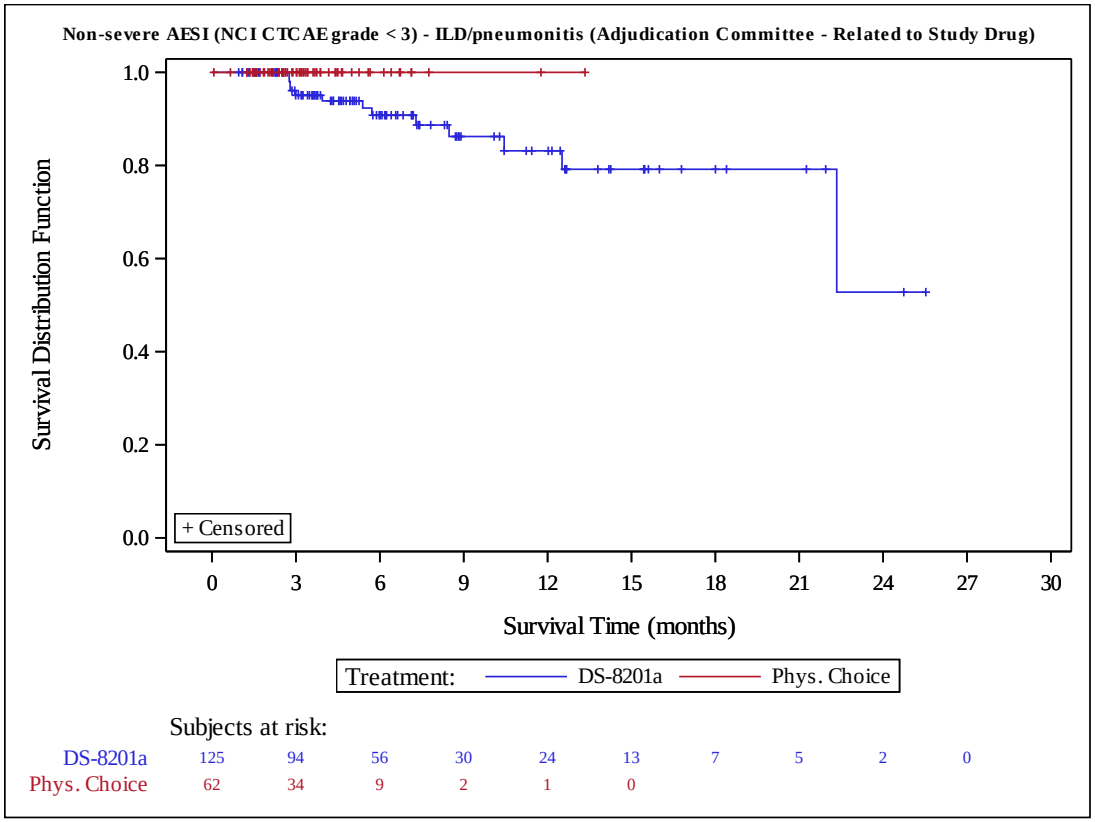
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug) - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9998
yes	3/ 44 (6.8)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	10/ 81 (12.3)	21.0 (21.0, NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	4/ 22 (18.2)	NE (5.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	9/103 (8.7)	NE (21.0, NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							0.9998
yes	4/ 68 (5.9)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	9/ 57 (15.8)	21.0 (21.0, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							1.0000
normal	2/ 33 (6.1)	NE (21.0, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	5/ 53 (9.4)	NE (10.9, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	6/ 39 (15.4)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9998
normal	12/ 88 (13.6)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	1/ 36 (2.8)	NE (21.0, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							1.0000
yes	1/ 8 (12.5)	21.0 (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	12/117 (10.3)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9984
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	13/122 (10.7)	NE (21.0, NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - LVEF decrease
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/102 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

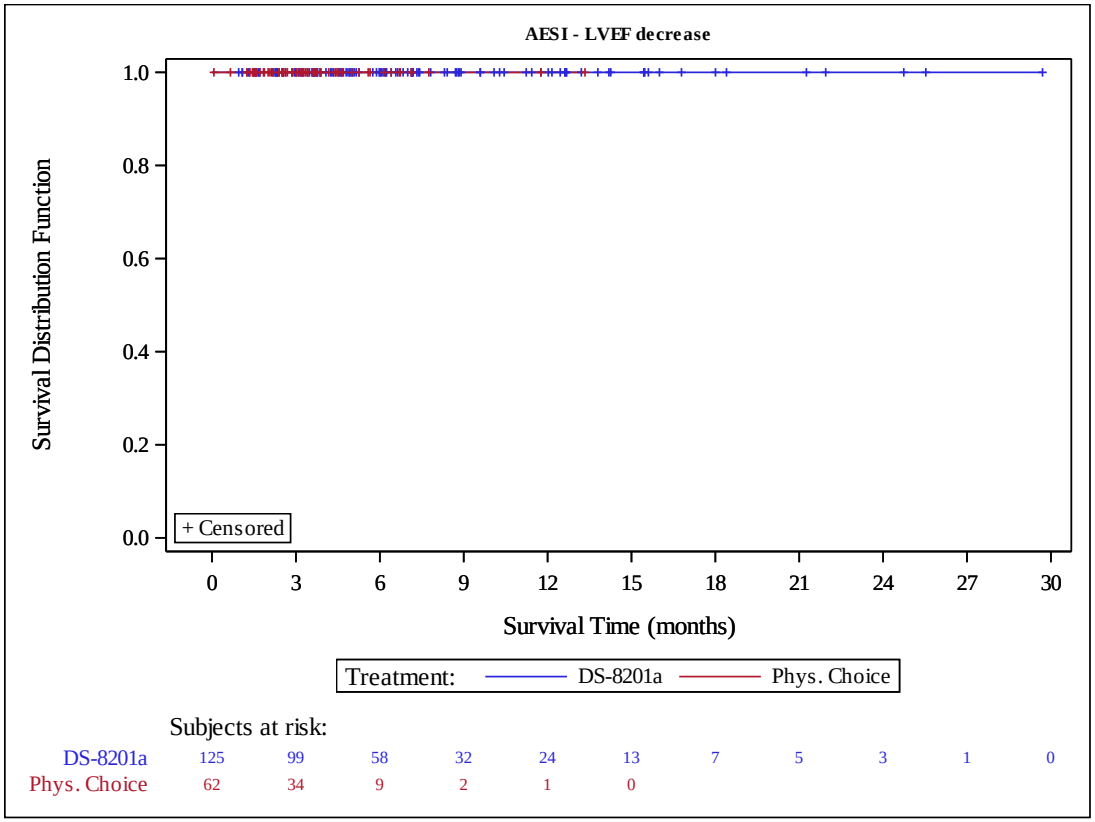
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 68 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 57 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of AESI - LVEF decrease
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - LVEF decrease
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/102 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

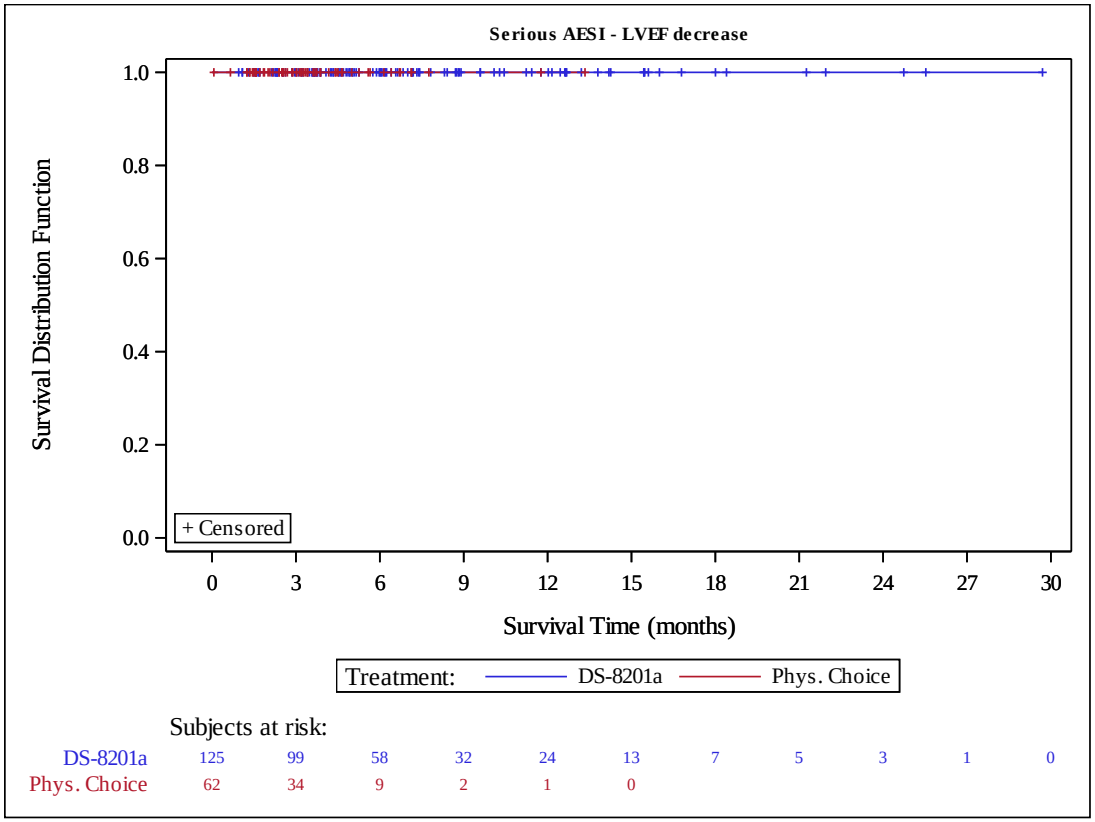
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 68 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 57 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Serious AESI - LVEF decrease
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/102 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

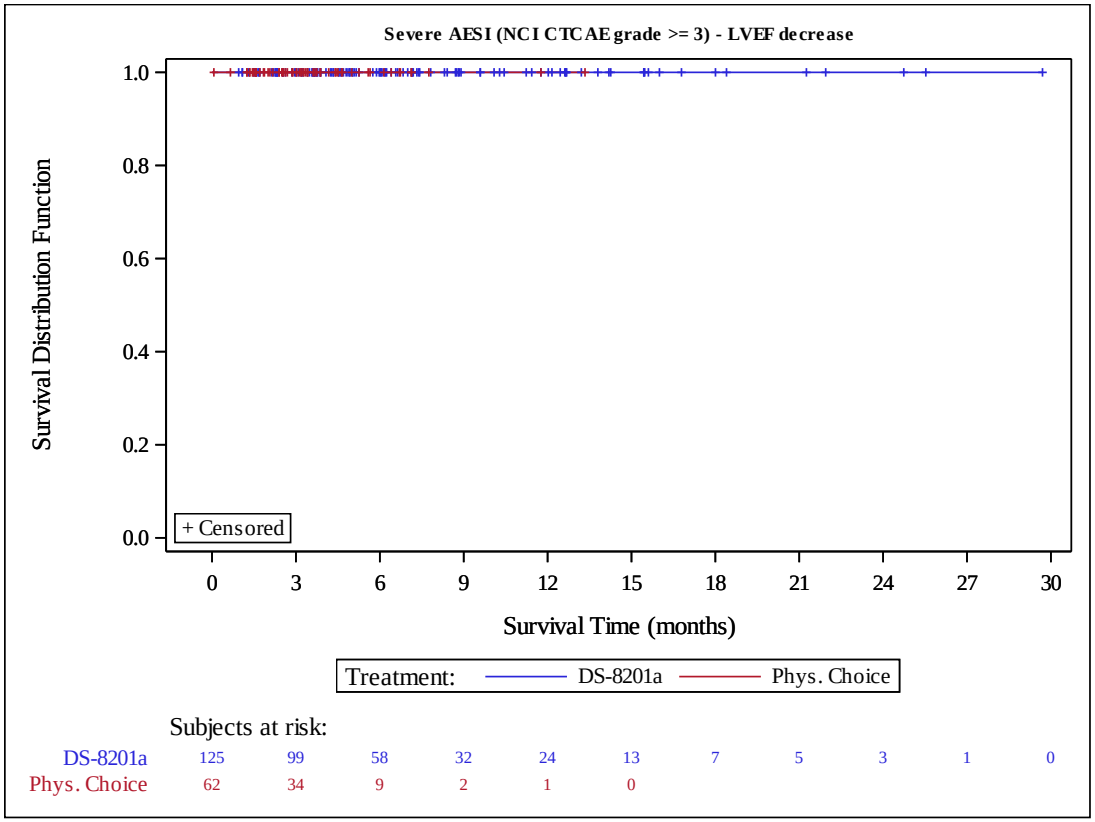
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 68 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 57 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/102 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

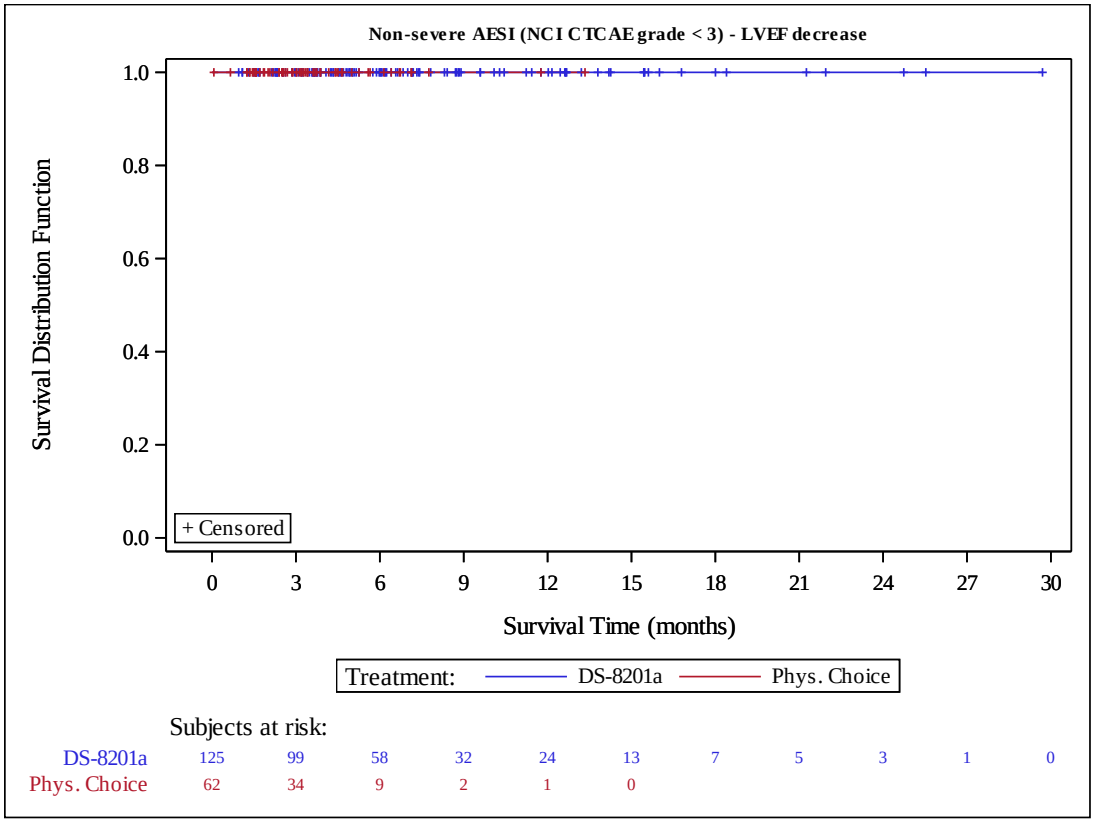
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 68 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 57 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - QT prolongation
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	1 (0.8)	2 (3.2)
Number of censored subjects, n (%)	124 (99.2)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	0.18 (0.02, 2.09)	
p-value [c]	0.1271	
Relative Risk (95% CI) [d]	0.25 (0.02, 2.68)	
p-value	0.2511	
Odds Ratio (95% CI) [d]	0.24 (0.02, 2.72)	
p-value	0.2505	
Risk Difference (95% CI) [e]	-2.43 (-8.30, 3.45)	
p-value	0.4182	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9998
Japan	1/ 99 (1.0)	NE (NE , NE)	2/ 50 (4.0)	NE (NE , NE)	0.19 (0.02, 2.17)	0.1386	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	1/ 66 (1.5)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	0.45 (0.03, 7.32)	0.5647	
3	0/ 34 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9965
<65 years	1/ 55 (1.8)	NE (NE , NE)	1/ 27 (3.7)	NE (NE , NE)	0.30 (0.02, 5.19)	0.3858	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	NE	NE	
Sex							0.9973
female	0/ 30 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9965
0	0/ 62 (0.0)	NE (NE , NE)	1/ 30 (3.3)	NE (NE , NE)	NE	NE	
1	1/ 63 (1.6)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	0.35 (0.02, 5.78)	0.4438	
HER2 Status in central laboratory							0.9970
IHC 3+	1/ 96 (1.0)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	0.30 (0.02, 5.18)	0.3858	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9982
Gastric	0/108 (0.0)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	1/ 89 (1.1)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	0.30 (0.02, 5.01)	0.3749	
diffuse	0/ 28 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9963
<2	0/ 23 (0.0)	NE (NE , NE)	1/ 10 (10.0)	NE (0.7, NE)	NE	NE	
>= 2	1/102 (1.0)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	0.34 (0.02, 5.70)	0.4303	
Previous total gastrectomy							0.9998
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	0.19 (0.02, 2.15)	0.1360	
Prior adjuvant/ neoadjuvant therapy							0.9998
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 95 (1.1)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	0.20 (0.02, 2.28)	0.1524	
Prior ramucirumab contained treatment							0.9977
yes	0/ 94 (0.0)	NE (NE , NE)	2/ 41 (4.9)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9966
yes	0/ 33 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
no	1/ 92 (1.1)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	0.38 (0.02, 6.15)	0.4759	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

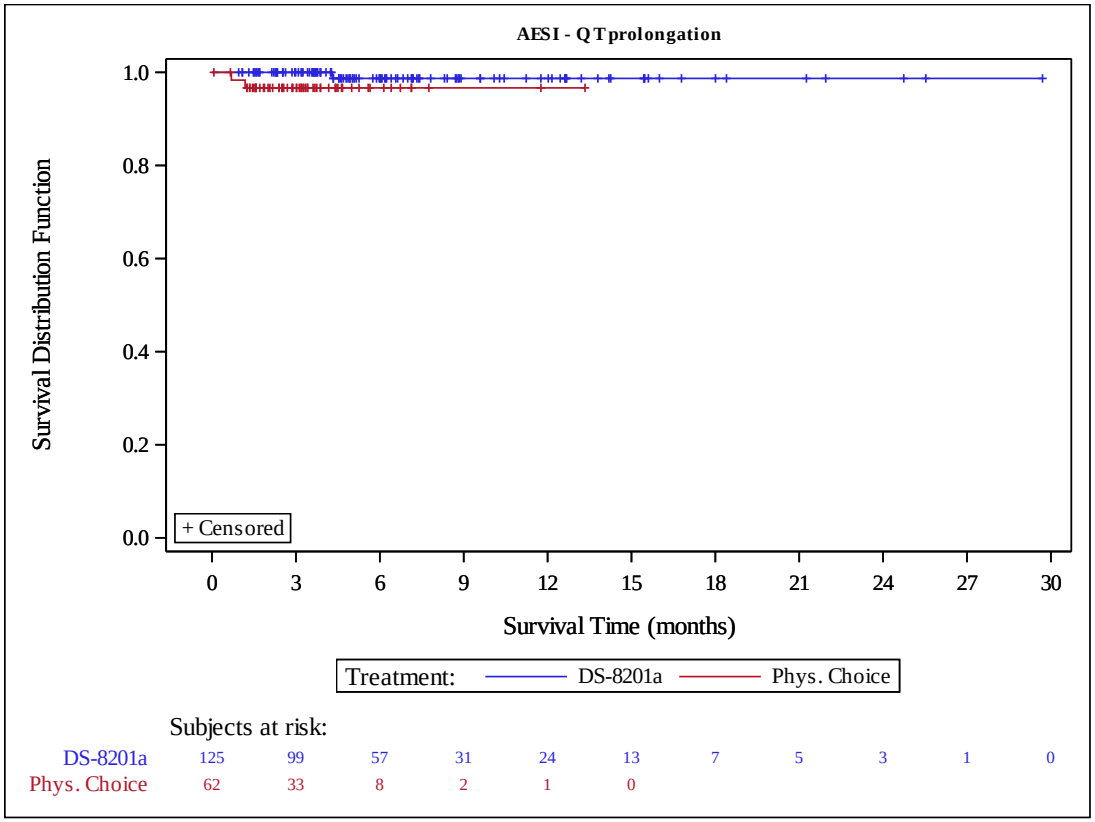
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9958
yes	0/ 44 (0.0)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	NE	NE	
no	1/ 81 (1.2)	NE (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	0.41 (0.02, 6.66)	0.5147	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	0.19 (0.02, 2.19)	0.1404	
Presence of liver metastasis at baseline							0.9965
yes	0/ 68 (0.0)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	NE	NE	
no	1/ 57 (1.8)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	0.33 (0.02, 5.53)	0.4198	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.7 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9998
normal	1/ 88 (1.1)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.18 (0.02, 2.11)	0.1298	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9985
yes	1/ 8 (12.5)	NE (4.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9971
yes	1/ 3 (33.3)	NE (4.3, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of AESI - QT prolongation
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - QT prolongation
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/102 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

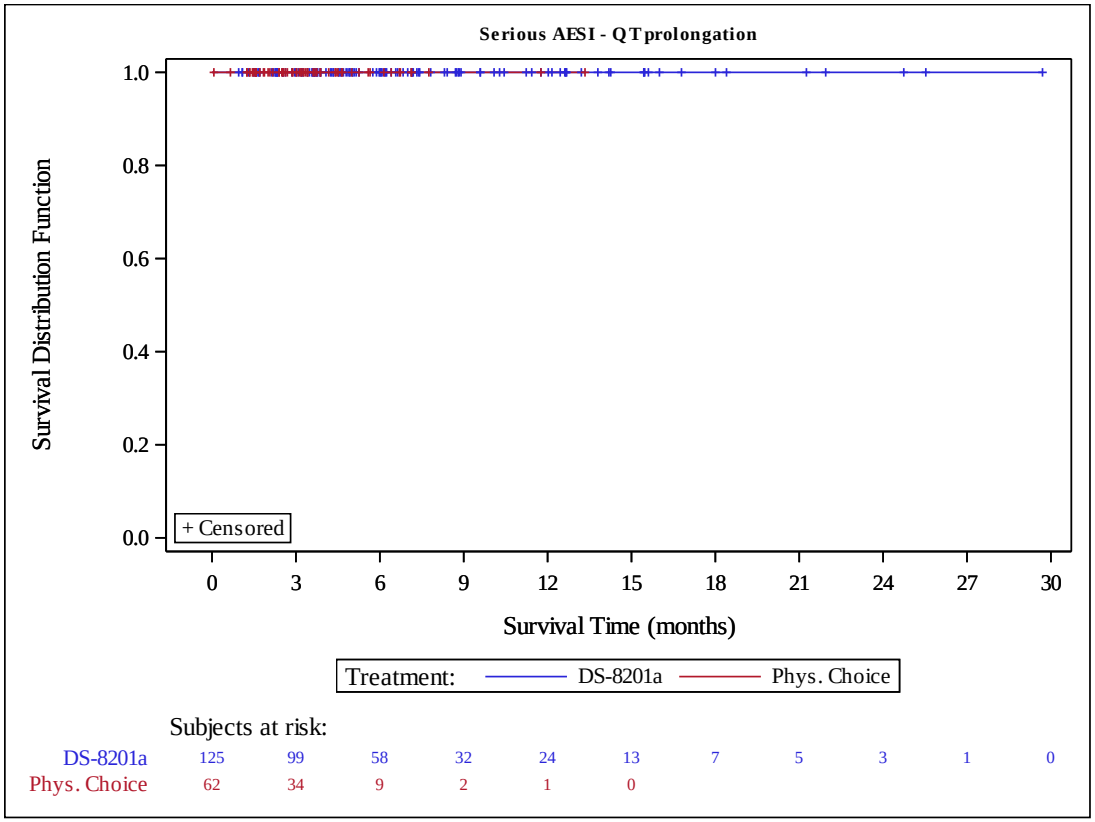
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 68 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 57 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Serious AESI - QT prolongation
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - QT prolongation
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	1 (0.8)	2 (3.2)
Number of censored subjects, n (%)	124 (99.2)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	0.18 (0.02, 2.09)	
p-value [c]	0.1271	
Relative Risk (95% CI) [d]	0.25 (0.02, 2.68)	
p-value	0.2511	
Odds Ratio (95% CI) [d]	0.24 (0.02, 2.72)	
p-value	0.2505	
Risk Difference (95% CI) [e]	-2.43 (-8.30, 3.45)	
p-value	0.4182	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9998
Japan	1/ 99 (1.0)	NE (NE , NE)	2/ 50 (4.0)	NE (NE , NE)	0.19 (0.02, 2.17)	0.1386	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							1.0000
2	1/ 66 (1.5)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	0.45 (0.03, 7.32)	0.5647	
3	0/ 34 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.9965
<65 years	1/ 55 (1.8)	NE (NE , NE)	1/ 27 (3.7)	NE (NE , NE)	0.30 (0.02, 5.19)	0.3858	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	NE	NE	
Sex							0.9973
female	0/ 30 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
male	1/ 95 (1.1)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9965
0	0/ 62 (0.0)	NE (NE , NE)	1/ 30 (3.3)	NE (NE , NE)	NE	NE	
1	1/ 63 (1.6)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	0.35 (0.02, 5.78)	0.4438	
HER2 Status in central laboratory							0.9970
IHC 3+	1/ 96 (1.0)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	0.30 (0.02, 5.18)	0.3858	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
Primary tumor location							0.9982
Gastric	0/108 (0.0)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	NE	NE	
GEJ	1/ 17 (5.9)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							1.0000
intestinal	1/ 89 (1.1)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	0.30 (0.02, 5.01)	0.3749	
diffuse	0/ 28 (0.0)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9963
<2	0/ 23 (0.0)	NE (NE , NE)	1/ 10 (10.0)	NE (0.7, NE)	NE	NE	
>= 2	1/102 (1.0)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	0.34 (0.02, 5.70)	0.4303	
Previous total gastrectomy							0.9998
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	0.19 (0.02, 2.15)	0.1360	
Prior adjuvant/ neoadjuvant therapy							0.9998
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	1/ 95 (1.1)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	0.20 (0.02, 2.28)	0.1524	
Prior ramucirumab contained treatment							0.9977
yes	0/ 94 (0.0)	NE (NE , NE)	2/ 41 (4.9)	NE (NE , NE)	NE	NE	
no	1/ 31 (3.2)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.9966
yes	0/ 33 (0.0)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	NE	NE	
no	1/ 92 (1.1)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	0.38 (0.02, 6.15)	0.4759	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

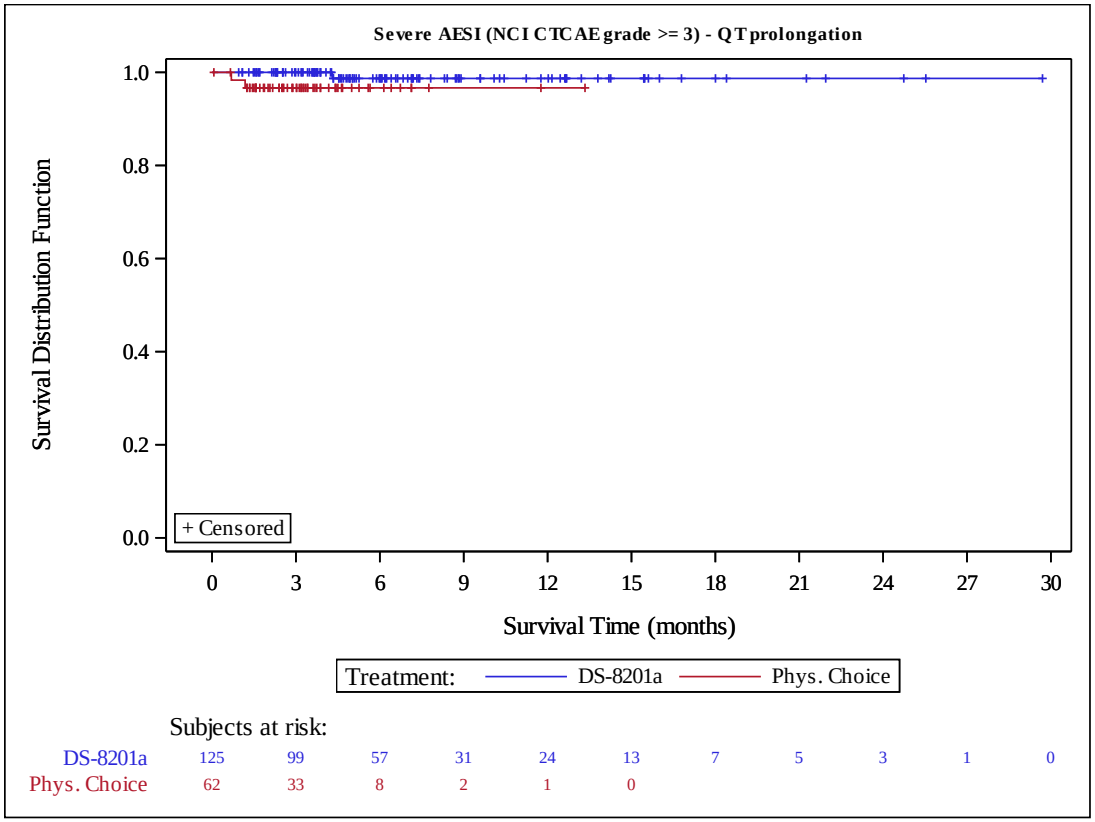
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9958
yes	0/ 44 (0.0)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	NE	NE	
no	1/ 81 (1.2)	NE (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	0.41 (0.02, 6.66)	0.5147	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9998
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	1/103 (1.0)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	0.19 (0.02, 2.19)	0.1404	
Presence of liver metastasis at baseline							0.9965
yes	0/ 68 (0.0)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	NE	NE	
no	1/ 57 (1.8)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	0.33 (0.02, 5.53)	0.4198	
Renal impairment at baseline							1.0000
normal	1/ 33 (3.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	1/ 1 (100.0)	0.7 (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9998
normal	1/ 88 (1.1)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	0.18 (0.02, 2.11)	0.1298	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9985
yes	1/ 8 (12.5)	NE (4.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9971
yes	1/ 3 (33.3)	NE (4.3, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - QT prolongation
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - QT prolongation
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/102 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

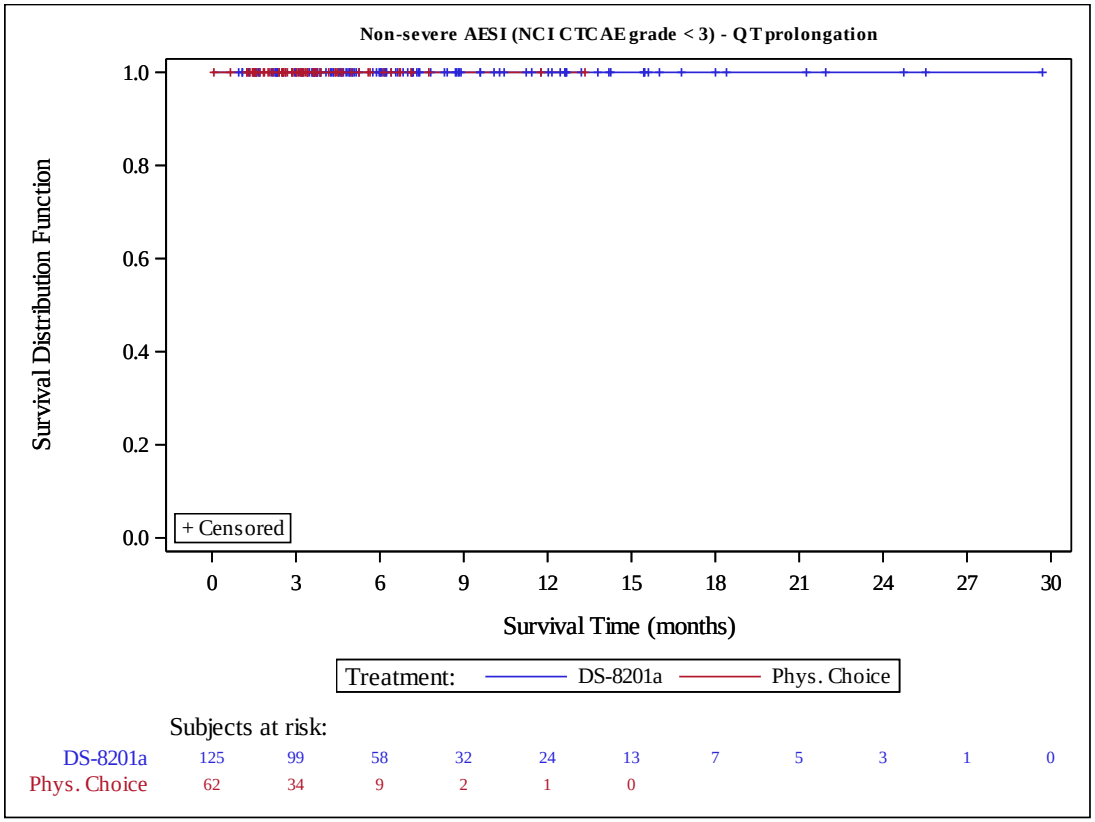
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - QT prolongation - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 68 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 57 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - QT prolongation
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - IRR
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	8 (6.4)	2 (3.2)
Number of censored subjects, n (%)	117 (93.6)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (20.3, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.34 (0.27, 6.51)	
p-value [c]	0.7191	
Relative Risk (95% CI) [d]	1.98 (0.43, 9.06)	
p-value	0.3768	
Odds Ratio (95% CI) [d]	2.05 (0.42, 9.96)	
p-value	0.3729	
Risk Difference (95% CI) [e]	3.17 (-4.18, 10.52)	
p-value	0.3974	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9932
Japan	6/ 99 (6.1)	NE (20.3, NE)	2/ 50 (4.0)	NE (NE , NE)	0.96 (0.18, 5.04)	0.9609	
Korea	2/ 26 (7.7)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							0.6899
2	4/ 66 (6.1)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	1.97 (0.22, 17.73)	0.5364	
3	1/ 34 (2.9)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	0.40 (0.02, 6.38)	0.5010	
>=4	3/ 25 (12.0)	20.3 (20.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.6638
<65 years	3/ 55 (5.5)	NE (NE , NE)	1/ 27 (3.7)	NE (NE , NE)	1.28 (0.13, 12.46)	0.8266	
>=65 years	5/ 70 (7.1)	20.3 (20.3, NE)	1/ 35 (2.9)	NE (NE , NE)	1.37 (0.15, 12.57)	0.7811	
Sex							0.9940
female	0/ 30 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
male	8/ 95 (8.4)	NE (20.3, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9939
0	7/ 62 (11.3)	NE (20.3, NE)	2/ 30 (6.7)	NE (NE , NE)	1.07 (0.21, 5.43)	0.9329	
1	1/ 63 (1.6)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.3801
IHC 3+	7/ 96 (7.3)	NE (20.3, NE)	1/ 47 (2.1)	NE (NE , NE)	2.23 (0.26, 18.82)	0.4482	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.45 (0.03, 7.26)	0.5668	
Primary tumor location							0.1493
Gastric	7/108 (6.5)	NE (20.3, NE)	1/ 55 (1.8)	NE (NE , NE)	2.28 (0.27, 19.09)	0.4363	
GEJ	1/ 17 (5.9)	NE (NE , NE)	1/ 7 (14.3)	NE (0.0, NE)	0.40 (0.03, 6.45)	0.5075	
Histological subtype							1.0000
intestinal	8/ 89 (9.0)	NE (20.3, NE)	2/ 38 (5.3)	NE (NE , NE)	1.20 (0.25, 5.85)	0.8217	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9933
<2	4/ 23 (17.4)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	4/102 (3.9)	NE (20.3, NE)	2/ 52 (3.8)	NE (NE , NE)	0.55 (0.09, 3.51)	0.5263	
Previous total gastrectomy							0.9937
yes	2/ 22 (9.1)	20.3 (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	6/103 (5.8)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	1.19 (0.24, 5.99)	0.8283	
Prior adjuvant/ neoadjuvant therapy							0.9933
yes	2/ 30 (6.7)	20.3 (20.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 95 (6.3)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.26 (0.25, 6.36)	0.7766	
Prior ramucirumab contained treatment							0.9935
yes	6/ 94 (6.4)	NE (20.3, NE)	2/ 41 (4.9)	NE (NE , NE)	0.74 (0.14, 3.92)	0.7181	
no	2/ 31 (6.5)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.4012
yes	2/ 33 (6.1)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.50 (0.04, 6.51)	0.5933	
no	6/ 92 (6.5)	NE (20.3, NE)	1/ 47 (2.1)	NE (NE , NE)	2.11 (0.25, 18.16)	0.4854	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

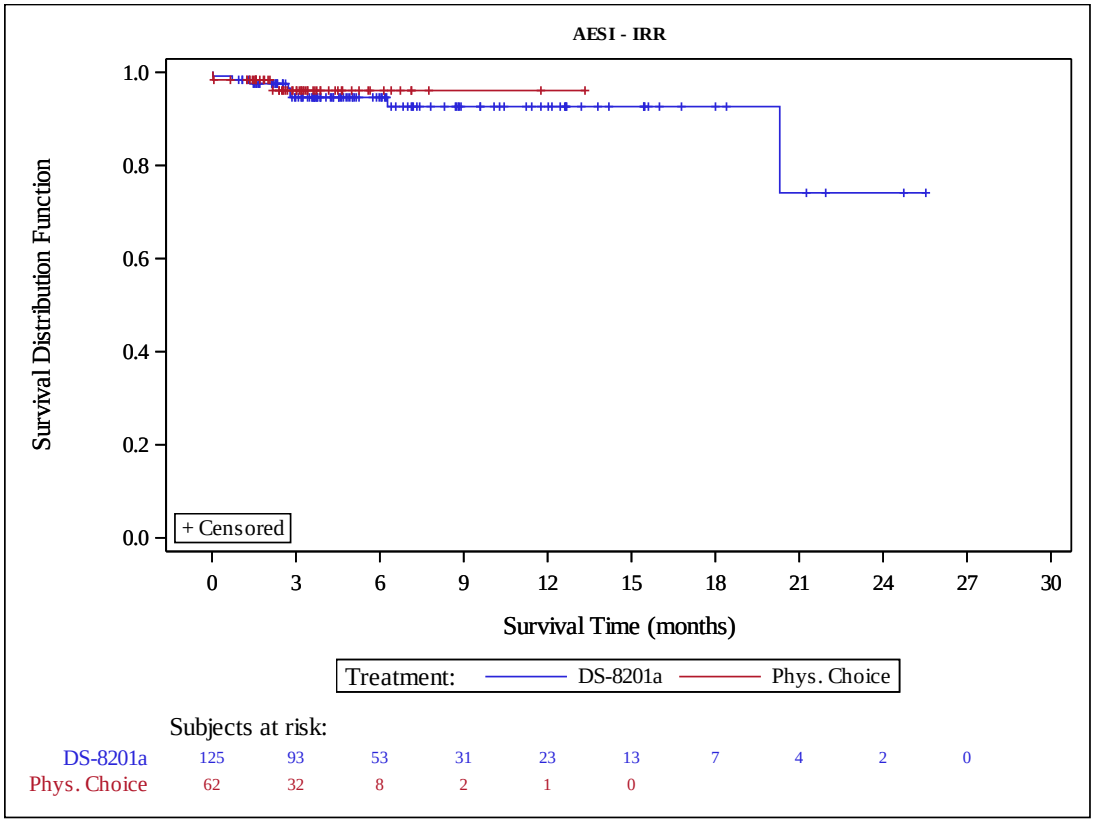
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of AESI - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.3000
yes	2/ 44 (4.5)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	0.43 (0.03, 5.62)	0.5084	
no	6/ 81 (7.4)	20.3 (20.3, NE)	1/ 45 (2.2)	NE (NE , NE)	2.33 (0.27, 19.97)	0.4283	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9944
yes	1/ 22 (4.5)	NE (6.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	7/103 (6.8)	NE (20.3, NE)	2/ 55 (3.6)	NE (NE , NE)	1.32 (0.26, 6.55)	0.7374	
Presence of liver metastasis at baseline							0.4380
yes	2/ 68 (2.9)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	0.54 (0.04, 6.77)	0.6320	
no	6/ 57 (10.5)	20.3 (20.3, NE)	1/ 28 (3.6)	NE (NE , NE)	2.18 (0.26, 18.71)	0.4656	
Renal impairment at baseline							0.6661
normal	2/ 33 (6.1)	NE (20.3, NE)	1/ 13 (7.7)	NE (NE , NE)	0.39 (0.02, 6.23)	0.4899	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	4/ 39 (10.3)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	1.65 (0.18, 15.23)	0.6542	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9949
normal	6/ 88 (6.8)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	1.18 (0.23, 6.00)	0.8369	
mild	2/ 36 (5.6)	20.3 (20.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9929
yes	2/ 8 (25.0)	20.3 (2.7, 20.3)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	6/117 (5.1)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	1.12 (0.22, 5.64)	0.8941	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9928
yes	1/ 3 (33.3)	NE (2.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	7/122 (5.7)	NE (20.3, NE)	2/ 58 (3.4)	NE (NE , NE)	1.08 (0.21, 5.46)	0.9245	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of AESI - IRR
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - IRR
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/102 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

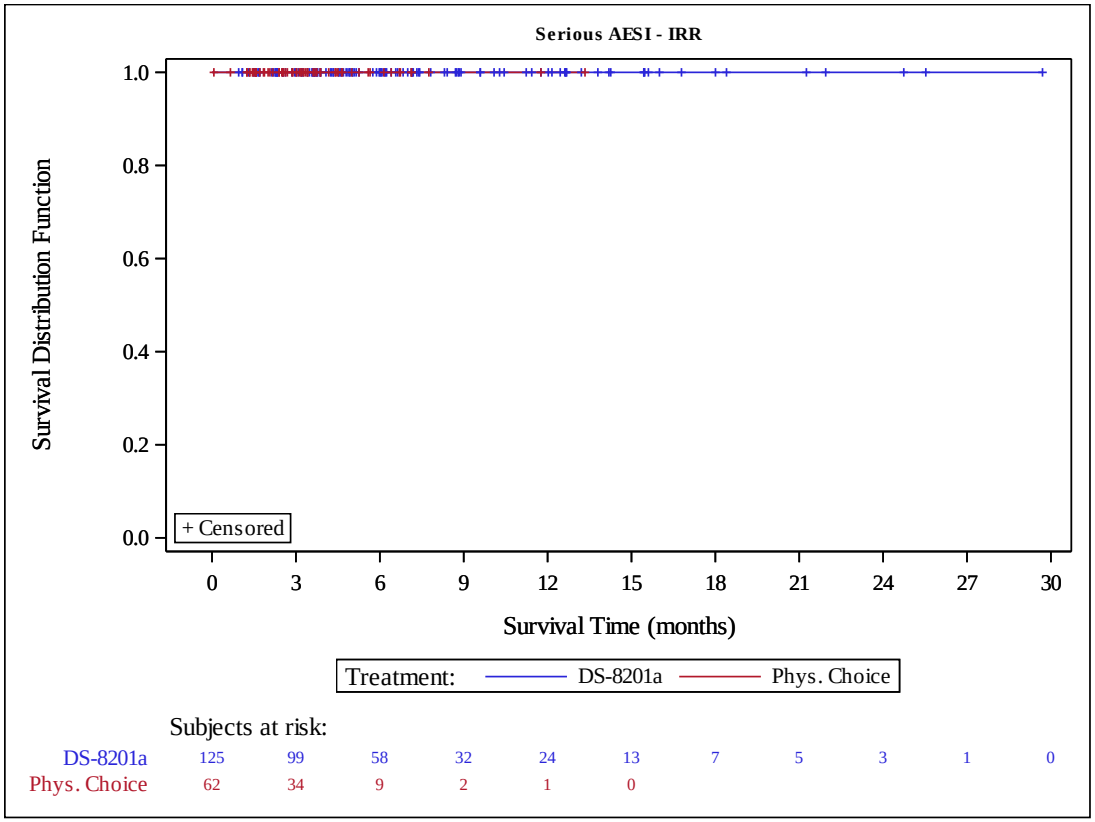
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Serious AESI - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 68 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 57 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Serious AESI - IRR
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - IRR
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	0 (0.0)	0 (0.0)
Number of censored subjects, n (%)	125 (100.0)	62 (100.0)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (NE, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	NE	
p-value [c]		
Relative Risk (95% CI) [d]	NE	
p-value		
Odds Ratio (95% CI) [d]	NE	
p-value		
Risk Difference (95% CI) [e]	NE	
p-value		

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							NE
Japan	0/ 99 (0.0)	NE (NE , NE)	0/ 50 (0.0)	NE (NE , NE)	NE	NE	
Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							NE
2	0/ 66 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
3	0/ 34 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
>=4	0/ 25 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							NE
<65 years	0/ 55 (0.0)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
>=65 years	0/ 70 (0.0)	NE (NE , NE)	0/ 35 (0.0)	NE (NE , NE)	NE	NE	
Sex							NE
female	0/ 30 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
male	0/ 95 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							NE
0	0/ 62 (0.0)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
1	0/ 63 (0.0)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							NE
IHC 3+	0/ 96 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
IHC 2+/ISH +	0/ 29 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
Primary tumor location							NE
Gastric	0/108 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
Histological subtype							NE
intestinal	0/ 89 (0.0)	NE (NE , NE)	0/ 38 (0.0)	NE (NE , NE)	NE	NE	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							NE
<2	0/ 23 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	0/102 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Previous total gastrectomy							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 53 (0.0)	NE (NE , NE)	NE	NE	
Prior adjuvant/ neoadjuvant therapy							NE
yes	0/ 30 (0.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 95 (0.0)	NE (NE , NE)	0/ 52 (0.0)	NE (NE , NE)	NE	NE	
Prior ramucirumab contained treatment							NE
yes	0/ 94 (0.0)	NE (NE , NE)	0/ 41 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 31 (0.0)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							NE
yes	0/ 33 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 92 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

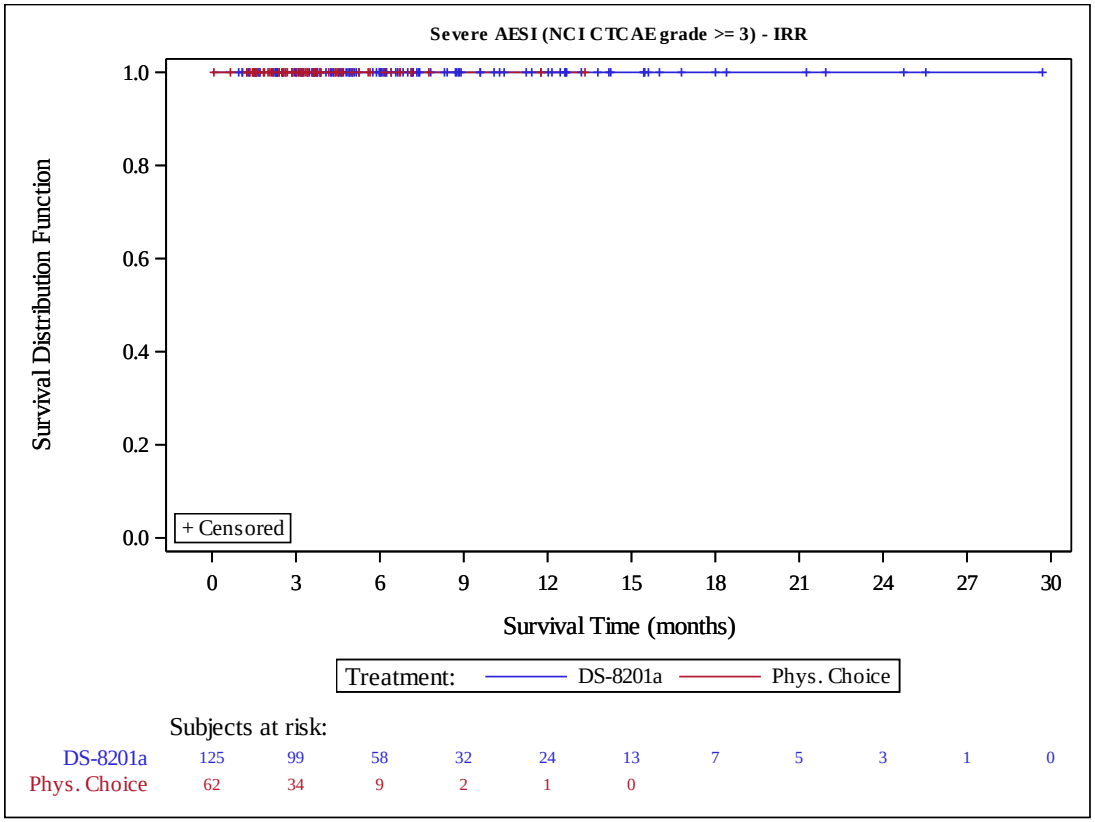
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							NE
yes	0/ 44 (0.0)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 81 (0.0)	NE (NE , NE)	0/ 45 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							NE
yes	0/ 22 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	0/103 (0.0)	NE (NE , NE)	0/ 55 (0.0)	NE (NE , NE)	NE	NE	
Presence of liver metastasis at baseline							NE
yes	0/ 68 (0.0)	NE (NE , NE)	0/ 34 (0.0)	NE (NE , NE)	NE	NE	
no	0/ 57 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
Renal impairment at baseline							NE
normal	0/ 33 (0.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 53 (0.0)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 39 (0.0)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							NE
normal	0/ 88 (0.0)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
mild	0/ 36 (0.0)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 8 (0.0)	NE (NE , NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	0/117 (0.0)	NE (NE , NE)	0/ 57 (0.0)	NE (NE , NE)	NE	NE	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							NE
yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	0/122 (0.0)	NE (NE , NE)	0/ 58 (0.0)	NE (NE , NE)	NE	NE	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - IRR
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - IRR
Safety Analysis Set

	DS-8201a (N=125)	Phys. Choice (N=62)
Number of subjects with events, n (%)	8 (6.4)	2 (3.2)
Number of censored subjects, n (%)	117 (93.6)	60 (96.8)
Kaplan-Meier estimates of Time to Event (months) [a]		
Median (95% CI)	NE (20.3, NE)	NE (NE, NE)
Analysis DS-8201a vs. Phys. Choice		
Hazard Ratio (95% CI) [b]	1.34 (0.27, 6.51)	
p-value [c]	0.7191	
Relative Risk (95% CI) [d]	1.98 (0.43, 9.06)	
p-value	0.3768	
Odds Ratio (95% CI) [d]	2.05 (0.42, 9.96)	
p-value	0.3729	
Risk Difference (95% CI) [e]	3.17 (-4.18, 10.52)	
p-value	0.3974	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Region							0.9932
Japan	6/ 99 (6.1)	NE (20.3, NE)	2/ 50 (4.0)	NE (NE , NE)	0.96 (0.18, 5.04)	0.9609	
Korea	2/ 26 (7.7)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
Lines of prior systemic therapy							0.6899
2	4/ 66 (6.1)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	1.97 (0.22, 17.73)	0.5364	
3	1/ 34 (2.9)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	0.40 (0.02, 6.38)	0.5010	
>=4	3/ 25 (12.0)	20.3 (20.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Age							0.6638
<65 years	3/ 55 (5.5)	NE (NE , NE)	1/ 27 (3.7)	NE (NE , NE)	1.28 (0.13, 12.46)	0.8266	
>=65 years	5/ 70 (7.1)	20.3 (20.3, NE)	1/ 35 (2.9)	NE (NE , NE)	1.37 (0.15, 12.57)	0.7811	
Sex							0.9940
female	0/ 30 (0.0)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	NE	NE	
male	8/ 95 (8.4)	NE (20.3, NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
ECOG PS							0.9939
0	7/ 62 (11.3)	NE (20.3, NE)	2/ 30 (6.7)	NE (NE , NE)	1.07 (0.21, 5.43)	0.9329	
1	1/ 63 (1.6)	NE (NE , NE)	0/ 32 (0.0)	NE (NE , NE)	NE	NE	
HER2 Status in central laboratory							0.3801
IHC 3+	7/ 96 (7.3)	NE (20.3, NE)	1/ 47 (2.1)	NE (NE , NE)	2.23 (0.26, 18.82)	0.4482	
IHC 2+/ISH +	1/ 29 (3.4)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.45 (0.03, 7.26)	0.5668	
Primary tumor location							0.1493
Gastric	7/108 (6.5)	NE (20.3, NE)	1/ 55 (1.8)	NE (NE , NE)	2.28 (0.27, 19.09)	0.4363	
GEJ	1/ 17 (5.9)	NE (NE , NE)	1/ 7 (14.3)	NE (0.0, NE)	0.40 (0.03, 6.45)	0.5075	
Histological subtype							1.0000
intestinal	8/ 89 (9.0)	NE (20.3, NE)	2/ 38 (5.3)	NE (NE , NE)	1.20 (0.25, 5.85)	0.8217	
diffuse	0/ 28 (0.0)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
Number of metastatic sites							0.9933
<2	4/ 23 (17.4)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
>= 2	4/102 (3.9)	NE (20.3, NE)	2/ 52 (3.8)	NE (NE , NE)	0.55 (0.09, 3.51)	0.5263	
Previous total gastrectomy							0.9937
yes	2/ 22 (9.1)	20.3 (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
no	6/103 (5.8)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	1.19 (0.24, 5.99)	0.8283	
Prior adjuvant/ neoadjuvant therapy							0.9933
yes	2/ 30 (6.7)	20.3 (20.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
no	6/ 95 (6.3)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	1.26 (0.25, 6.36)	0.7766	
Prior ramucirumab contained treatment							0.9935
yes	6/ 94 (6.4)	NE (20.3, NE)	2/ 41 (4.9)	NE (NE , NE)	0.74 (0.14, 3.92)	0.7181	
no	2/ 31 (6.5)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	
Prior nivolumab contained treatment							0.4012
yes	2/ 33 (6.1)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	0.50 (0.04, 6.51)	0.5933	
no	6/ 92 (6.5)	NE (20.3, NE)	1/ 47 (2.1)	NE (NE , NE)	2.11 (0.25, 18.16)	0.4854	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

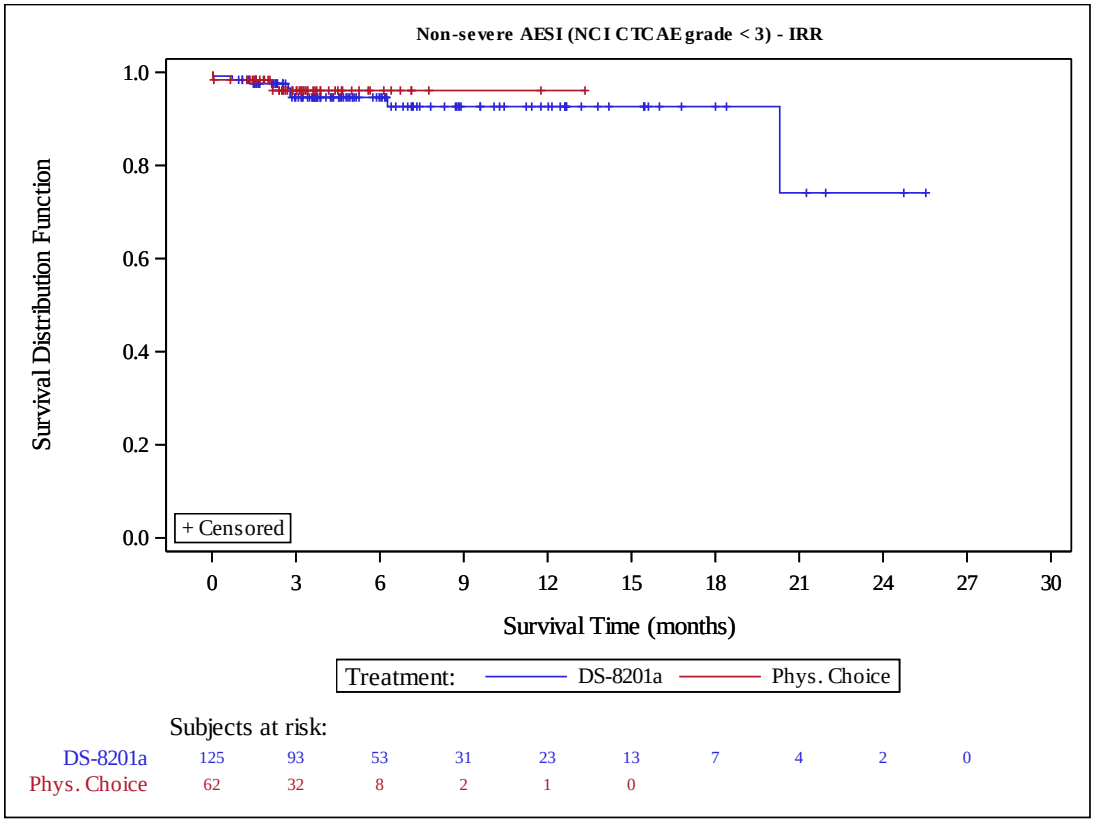
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - IRR - Subgroup analysis
Safety Analysis Set

Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.3000
yes	2/ 44 (4.5)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	0.43 (0.03, 5.62)	0.5084	
no	6/ 81 (7.4)	20.3 (20.3, NE)	1/ 45 (2.2)	NE (NE , NE)	2.33 (0.27, 19.97)	0.4283	
Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9944
yes	1/ 22 (4.5)	NE (6.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
no	7/103 (6.8)	NE (20.3, NE)	2/ 55 (3.6)	NE (NE , NE)	1.32 (0.26, 6.55)	0.7374	
Presence of liver metastasis at baseline							0.4380
yes	2/ 68 (2.9)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	0.54 (0.04, 6.77)	0.6320	
no	6/ 57 (10.5)	20.3 (20.3, NE)	1/ 28 (3.6)	NE (NE , NE)	2.18 (0.26, 18.71)	0.4656	
Renal impairment at baseline							0.6661
normal	2/ 33 (6.1)	NE (20.3, NE)	1/ 13 (7.7)	NE (NE , NE)	0.39 (0.02, 6.23)	0.4899	
mild	2/ 53 (3.8)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
moderate	4/ 39 (10.3)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	1.65 (0.18, 15.23)	0.6542	
severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
Hepatic impairment at baseline							0.9949
normal	6/ 88 (6.8)	NE (NE , NE)	2/ 47 (4.3)	NE (NE , NE)	1.18 (0.23, 6.00)	0.8369	
mild	2/ 36 (5.6)	20.3 (20.3, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9929
yes	2/ 8 (25.0)	20.3 (2.7, 20.3)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
no	6/117 (5.1)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	1.12 (0.22, 5.64)	0.8941	
Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9928
yes	1/ 3 (33.3)	NE (2.7, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
no	7/122 (5.7)	NE (20.3, NE)	2/ 58 (3.4)	NE (NE , NE)	1.08 (0.21, 5.46)	0.9245	

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - IRR
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	77 (61.6)	20 (32.3)
	Number of censored subjects, n (%)	48 (38.4)	42 (67.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	3.4 (1.8, 4.4)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.92 (1.17, 3.15)	
	p-value [c]	0.0085	
	Relative Risk (95% CI) [d]	1.91 (1.30, 2.81)	
	p-value	0.0010	
	Odds Ratio (95% CI) [d]	3.37 (1.77, 6.41)	
	p-value	0.0002	
	Risk Difference (95% CI) [e]	29.34 (13.71, 44.97)	
	p-value	0.0002	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders, PT: Anaemia	Number of subjects with events, n (%)	71 (56.8)	19 (30.6)
	Number of censored subjects, n (%)	54 (43.2)	43 (69.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	3.9 (2.0, 6.9)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.85 (1.11, 3.08)	
	p-value [c]	0.0167	
	Relative Risk (95% CI) [d]	1.85 (1.24, 2.78)	
	p-value	0.0028	
	Odds Ratio (95% CI) [d]	2.98 (1.56, 5.67)	
	p-value	0.0009	
	Risk Difference (95% CI) [e]	26.15 (10.56, 41.75)	
	p-value	0.0010	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Eye disorders	Number of subjects with events, n (%)	11 (8.8)	2 (3.2)
	Number of censored subjects, n (%)	114 (91.2)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	11.6 (11.6, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.07 (0.45, 9.46)	
	p-value [c]	0.3381	
	Relative Risk (95% CI) [d]	2.73 (0.62, 11.93)	
	p-value	0.1825	
	Odds Ratio (95% CI) [d]	2.89 (0.62, 13.49)	
	p-value	0.1758	
	Risk Difference (95% CI) [e]	5.57 (-2.27, 13.41)	
	p-value	0.1635	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	104 (83.2)	49 (79.0)
	Number of censored subjects, n (%)	21 (16.8)	13 (21.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.2 (0.1, 0.3)	0.4 (0.2, 0.9)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.21 (0.86, 1.70)	
	p-value [c]	0.3181	
	Relative Risk (95% CI) [d]	1.05 (0.91, 1.22)	
	p-value	0.5033	
	Odds Ratio (95% CI) [d]	1.31 (0.61, 2.84)	
	p-value	0.4874	
	Risk Difference (95% CI) [e]	4.17 (-9.11, 17.44)	
	p-value	0.5383	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Abdominal pain	Number of subjects with events, n (%)	14 (11.2)	8 (12.9)
	Number of censored subjects, n (%)	111 (88.8)	54 (87.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.49 (0.20, 1.24)	
	p-value [c]	0.1249	
	Relative Risk (95% CI) [d]	0.87 (0.38, 1.96)	
	p-value	0.7331	
	Odds Ratio (95% CI) [d]	0.85 (0.34, 2.15)	
	p-value	0.7338	
	Risk Difference (95% CI) [e]	-1.70 (-12.92, 9.51)	
	p-value	0.7660	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Constipation	Number of subjects with events, n (%)	31 (24.8)	15 (24.2)
	Number of censored subjects, n (%)	94 (75.2)	47 (75.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	25.5 (11.3, 25.5)	13.0 (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.76 (0.40, 1.44)	
	p-value [c]	0.3985	
	Relative Risk (95% CI) [d]	1.03 (0.60, 1.75)	
	p-value	0.9279	
	Odds Ratio (95% CI) [d]	1.03 (0.51, 2.10)	
	p-value	0.9278	
	Risk Difference (95% CI) [e]	0.61 (-13.67, 14.89)	
	p-value	0.9337	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Diarrhoea	Number of subjects with events, n (%)	41 (32.8)	20 (32.3)
	Number of censored subjects, n (%)	84 (67.2)	42 (67.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (13.0, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.88 (0.51, 1.51)	
	p-value [c]	0.6552	
	Relative Risk (95% CI) [d]	1.02 (0.66, 1.58)	
	p-value	0.9408	
	Odds Ratio (95% CI) [d]	1.03 (0.53, 1.96)	
	p-value	0.9407	
	Risk Difference (95% CI) [e]	0.54 (-14.92, 16.00)	
	p-value	0.9452	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	79 (63.2)	29 (46.8)
	Number of censored subjects, n (%)	46 (36.8)	33 (53.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.3 (0.2, 1.7)	NE (0.8, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.64 (1.07, 2.51)	
	p-value [c]	0.0238	
	Relative Risk (95% CI) [d]	1.35 (1.00, 1.82)	
	p-value	0.0473	
	Odds Ratio (95% CI) [d]	1.95 (1.05, 3.62)	
	p-value	0.0334	
	Risk Difference (95% CI) [e]	16.43 (0.20, 32.66)	
	p-value	0.0473	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Stomatitis	Number of subjects with events, n (%)	14 (11.2)	3 (4.8)
	Number of censored subjects, n (%)	111 (88.8)	59 (95.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (16.8, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.82 (0.51, 6.44)	
	p-value [c]	0.3456	
	Relative Risk (95% CI) [d]	2.31 (0.69, 7.76)	
	p-value	0.1737	
	Odds Ratio (95% CI) [d]	2.48 (0.69, 8.98)	
	p-value	0.1663	
	Risk Difference (95% CI) [e]	6.36 (-2.53, 15.26)	
	p-value	0.1610	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Vomiting	Number of subjects with events, n (%)	33 (26.4)	5 (8.1)
	Number of censored subjects, n (%)	92 (73.6)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	3.31 (1.29, 8.49)	
	p-value [c]	0.0085	
	Relative Risk (95% CI) [d]	3.27 (1.34, 7.97)	
	p-value	0.0090	
	Odds Ratio (95% CI) [d]	4.09 (1.51, 11.08)	
	p-value	0.0056	
	Risk Difference (95% CI) [e]	18.34 (6.85, 29.82)	
	p-value	0.0018	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	87 (69.6)	34 (54.8)
	Number of censored subjects, n (%)	38 (30.4)	28 (45.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	1.4 (0.7, 1.9)	2.4 (1.0, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.31 (0.88, 1.95)	
	p-value [c]	0.1855	
	Relative Risk (95% CI) [d]	1.27 (0.98, 1.64)	
	p-value	0.0657	
	Odds Ratio (95% CI) [d]	1.89 (1.01, 3.54)	
	p-value	0.0481	
	Risk Difference (95% CI) [e]	14.76 (-1.23, 30.75)	
	p-value	0.0703	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	27 (21.6)	15 (24.2)
	Number of censored subjects, n (%)	98 (78.4)	47 (75.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.81 (0.43, 1.53)	
	p-value [c]	0.5161	
	Relative Risk (95% CI) [d]	0.89 (0.51, 1.55)	
	p-value	0.6877	
	Odds Ratio (95% CI) [d]	0.86 (0.42, 1.77)	
	p-value	0.6892	
	Risk Difference (95% CI) [e]	-2.59 (-16.67, 11.48)	
	p-value	0.7180	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Malaise	Number of subjects with events, n (%)	43 (34.4)	10 (16.1)
	Number of censored subjects, n (%)	82 (65.6)	52 (83.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.23 (1.12, 4.44)	
	p-value [c]	0.0192	
	Relative Risk (95% CI) [d]	2.13 (1.15, 3.95)	
	p-value	0.0161	
	Odds Ratio (95% CI) [d]	2.73 (1.26, 5.89)	
	p-value	0.0108	
	Risk Difference (95% CI) [e]	18.27 (4.69, 31.85)	
	p-value	0.0084	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Oedema peripheral	Number of subjects with events, n (%)	14 (11.2)	0 (0.0)
	Number of censored subjects, n (%)	111 (88.8)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	14.50 (0.88, 239.15)	
	p-value	0.0615	
	Odds Ratio (95% CI) [d]	16.26 (0.95, 277.16)	
	p-value	0.0540	
	Risk Difference (95% CI) [e]	11.20 (4.47, 17.93)	
	p-value	0.0011	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Pyrexia	Number of subjects with events, n (%)	31 (24.8)	10 (16.1)
	Number of censored subjects, n (%)	94 (75.2)	52 (83.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.16 (0.57, 2.40)	
	p-value [c]	0.6813	
	Relative Risk (95% CI) [d]	1.54 (0.81, 2.93)	
	p-value	0.1908	
	Odds Ratio (95% CI) [d]	1.71 (0.78, 3.78)	
	p-value	0.1804	
	Risk Difference (95% CI) [e]	8.67 (-4.42, 21.76)	
	p-value	0.1941	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders	Number of subjects with events, n (%)	22 (17.6)	4 (6.5)
	Number of censored subjects, n (%)	103 (82.4)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (6.9, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.95 (0.66, 5.73)	
	p-value [c]	0.2187	
	Relative Risk (95% CI) [d]	2.73 (0.98, 7.57)	
	p-value	0.0540	
	Odds Ratio (95% CI) [d]	3.10 (1.02, 9.42)	
	p-value	0.0465	
	Risk Difference (95% CI) [e]	11.15 (0.89, 21.41)	
	p-value	0.0332	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders, PT: Hepatic function abnormal	Number of subjects with events, n (%)	10 (8.0)	1 (1.6)
	Number of censored subjects, n (%)	115 (92.0)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	4.04 (0.51, 31.79)	
	p-value [c]	0.1517	
	Relative Risk (95% CI) [d]	4.96 (0.65, 37.88)	
	p-value	0.1226	
	Odds Ratio (95% CI) [d]	5.30 (0.66, 42.41)	
	p-value	0.1157	
	Risk Difference (95% CI) [e]	6.39 (-0.52, 13.29)	
	p-value	0.0698	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations	Number of subjects with events, n (%)	53 (42.4)	14 (22.6)
	Number of censored subjects, n (%)	72 (57.6)	48 (77.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	9.6 (4.8, 13.7)	8.0 (4.9, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.36 (0.75, 2.47)	
	p-value [c]	0.3145	
	Relative Risk (95% CI) [d]	1.88 (1.13, 3.11)	
	p-value	0.0143	
	Odds Ratio (95% CI) [d]	2.52 (1.26, 5.05)	
	p-value	0.0088	
	Risk Difference (95% CI) [e]	19.82 (5.07, 34.57)	
	p-value	0.0084	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations, PT: Nasopharyngitis	Number of subjects with events, n (%)	11 (8.8)	5 (8.1)
	Number of censored subjects, n (%)	114 (91.2)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.61 (0.20, 1.85)	
	p-value [c]	0.3743	
	Relative Risk (95% CI) [d]	1.09 (0.40, 3.00)	
	p-value	0.8658	
	Odds Ratio (95% CI) [d]	1.10 (0.36, 3.32)	
	p-value	0.8656	
	Risk Difference (95% CI) [e]	0.74 (-8.87, 10.34)	
	p-value	0.8807	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
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Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Injury, poisoning and procedural complications	Number of subjects with events, n (%)	11 (8.8)	3 (4.8)
	Number of censored subjects, n (%)	114 (91.2)	59 (95.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (5.9, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.38 (0.38, 5.00)	
	p-value [c]	0.6234	
	Relative Risk (95% CI) [d]	1.82 (0.53, 6.28)	
	p-value	0.3444	
	Odds Ratio (95% CI) [d]	1.90 (0.51, 7.07)	
	p-value	0.3396	
	Risk Difference (95% CI) [e]	3.96 (-4.54, 12.46)	
	p-value	0.3610	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations	Number of subjects with events, n (%)	102 (81.6)	33 (53.2)
	Number of censored subjects, n (%)	23 (18.4)	29 (46.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.5 (0.3, 0.7)	2.8 (0.5, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.78 (1.20, 2.64)	
	p-value [c]	0.0043	
	Relative Risk (95% CI) [d]	1.53 (1.20, 1.96)	
	p-value	0.0007	
	Odds Ratio (95% CI) [d]	3.90 (1.99, 7.64)	
	p-value	<.0001	
	Risk Difference (95% CI) [e]	28.37 (13.01, 43.74)	
	p-value	0.0003	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Aspartate aminotransferase increased	Number of subjects with events, n (%)	12 (9.6)	3 (4.8)
	Number of censored subjects, n (%)	113 (90.4)	59 (95.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.30 (0.36, 4.72)	
	p-value [c]	0.6867	
	Relative Risk (95% CI) [d]	1.98 (0.58, 6.77)	
	p-value	0.2742	
	Odds Ratio (95% CI) [d]	2.09 (0.57, 7.69)	
	p-value	0.2682	
	Risk Difference (95% CI) [e]	4.76 (-3.87, 13.40)	
	p-value	0.2799	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Blood alkaline phosphatase increased	Number of subjects with events, n (%)	11 (8.8)	2 (3.2)
	Number of censored subjects, n (%)	114 (91.2)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.50 (0.32, 7.00)	
	p-value [c]	0.5996	
	Relative Risk (95% CI) [d]	2.73 (0.62, 11.93)	
	p-value	0.1825	
	Odds Ratio (95% CI) [d]	2.89 (0.62, 13.49)	
	p-value	0.1758	
	Risk Difference (95% CI) [e]	5.57 (-2.27, 13.41)	
	p-value	0.1635	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Blood bilirubin increased	Number of subjects with events, n (%)	10 (8.0)	0 (0.0)
	Number of censored subjects, n (%)	115 (92.0)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	10.50 (0.63, 176.31)	
	p-value	0.1023	
	Odds Ratio (95% CI) [d]	11.36 (0.65, 197.18)	
	p-value	0.0951	
	Risk Difference (95% CI) [e]	8.00 (2.04, 13.96)	
	p-value	0.0085	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Lymphocyte count decreased	Number of subjects with events, n (%)	29 (23.2)	2 (3.2)
	Number of censored subjects, n (%)	96 (76.8)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	6.18 (1.46, 26.04)	
	p-value [c]	0.0046	
	Relative Risk (95% CI) [d]	7.19 (1.77, 29.17)	
	p-value	0.0057	
	Odds Ratio (95% CI) [d]	9.06 (2.09, 39.37)	
	p-value	0.0033	
	Risk Difference (95% CI) [e]	19.97 (10.16, 29.79)	
	p-value	<.0001	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Neutrophil count decreased	Number of subjects with events, n (%)	79 (63.2)	21 (33.9)
	Number of censored subjects, n (%)	46 (36.8)	41 (66.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	1.3 (0.7, 3.5)	NE (2.8, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.87 (1.15, 3.04)	
	p-value [c]	0.0105	
	Relative Risk (95% CI) [d]	1.87 (1.29, 2.71)	
	p-value	0.0010	
	Odds Ratio (95% CI) [d]	3.35 (1.77, 6.35)	
	p-value	0.0002	
	Risk Difference (95% CI) [e]	29.33 (13.62, 45.04)	
	p-value	0.0003	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Platelet count decreased	Number of subjects with events, n (%)	48 (38.4)	4 (6.5)
	Number of censored subjects, n (%)	77 (61.6)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (7.8, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	6.68 (2.40, 18.56)	
	p-value [c]	<.0001	
	Relative Risk (95% CI) [d]	5.95 (2.25, 15.76)	
	p-value	0.0003	
	Odds Ratio (95% CI) [d]	9.04 (3.08, 26.50)	
	p-value	<.0001	
	Risk Difference (95% CI) [e]	31.95 (20.25, 43.65)	
	p-value	<.0001	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Weight decreased	Number of subjects with events, n (%)	19 (15.2)	5 (8.1)
	Number of censored subjects, n (%)	106 (84.8)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.33 (0.49, 3.61)	
	p-value [c]	0.5790	
	Relative Risk (95% CI) [d]	1.88 (0.74, 4.81)	
	p-value	0.1849	
	Odds Ratio (95% CI) [d]	2.04 (0.72, 5.76)	
	p-value	0.1766	
	Risk Difference (95% CI) [e]	7.14 (-3.32, 17.59)	
	p-value	0.1810	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: White blood cell count decreased	Number of subjects with events, n (%)	48 (38.4)	21 (33.9)
	Number of censored subjects, n (%)	77 (61.6)	41 (66.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (8.1, NE)	NE (2.8, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.99 (0.59, 1.65)	
	p-value [c]	0.9317	
	Relative Risk (95% CI) [d]	1.13 (0.75, 1.71)	
	p-value	0.5511	
	Odds Ratio (95% CI) [d]	1.22 (0.64, 2.30)	
	p-value	0.5459	
	Risk Difference (95% CI) [e]	4.53 (-11.22, 20.28)	
	p-value	0.5730	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	87 (69.6)	34 (54.8)
	Number of censored subjects, n (%)	38 (30.4)	28 (45.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.5 (0.2, 1.5)	2.1 (0.6, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.39 (0.93, 2.07)	
	p-value [c]	0.1107	
	Relative Risk (95% CI) [d]	1.27 (0.98, 1.64)	
	p-value	0.0657	
	Odds Ratio (95% CI) [d]	1.89 (1.01, 3.54)	
	p-value	0.0481	
	Risk Difference (95% CI) [e]	14.76 (-1.23, 30.75)	
	p-value	0.0703	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Number of subjects with events, n (%)	76 (60.8)	28 (45.2)
	Number of censored subjects, n (%)	49 (39.2)	34 (54.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	0.8 (0.3, 3.7)	6.0 (1.2, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.47 (0.95, 2.27)	
	p-value [c]	0.0858	
	Relative Risk (95% CI) [d]	1.35 (0.99, 1.83)	
	p-value	0.0587	
	Odds Ratio (95% CI) [d]	1.88 (1.02, 3.49)	
	p-value	0.0439	
	Risk Difference (95% CI) [e]	15.64 (-0.62, 31.90)	
	p-value	0.0595	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Hypoalbuminaemia	Number of subjects with events, n (%)	18 (14.4)	8 (12.9)
	Number of censored subjects, n (%)	107 (85.6)	54 (87.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.84 (0.36, 1.94)	
	p-value [c]	0.6749	
	Relative Risk (95% CI) [d]	1.12 (0.51, 2.42)	
	p-value	0.7814	
	Odds Ratio (95% CI) [d]	1.14 (0.46, 2.78)	
	p-value	0.7807	
	Risk Difference (95% CI) [e]	1.50 (-10.08, 13.07)	
	p-value	0.7999	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Number of subjects with events, n (%)	10 (8.0)	4 (6.5)
	Number of censored subjects, n (%)	115 (92.0)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.86 (0.26, 2.80)	
	p-value [c]	0.7964	
	Relative Risk (95% CI) [d]	1.24 (0.41, 3.80)	
	p-value	0.7063	
	Odds Ratio (95% CI) [d]	1.26 (0.38, 4.19)	
	p-value	0.7054	
	Risk Difference (95% CI) [e]	1.55 (-7.40, 10.50)	
	p-value	0.7346	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Musculoskeletal and connective tissue disorders	Number of subjects with events, n (%)	25 (20.0)	8 (12.9)
	Number of censored subjects, n (%)	100 (80.0)	54 (87.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (14.5, NE)	8.5 (5.8, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.00 (0.44, 2.29)	
	p-value [c]	0.9980	
	Relative Risk (95% CI) [d]	1.55 (0.74, 3.23)	
	p-value	0.2429	
	Odds Ratio (95% CI) [d]	1.69 (0.71, 4.00)	
	p-value	0.2343	
	Risk Difference (95% CI) [e]	7.10 (-5.01, 19.20)	
	p-value	0.2506	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Musculoskeletal and connective tissue disorders, PT: Back pain	Number of subjects with events, n (%)	10 (8.0)	3 (4.8)
	Number of censored subjects, n (%)	115 (92.0)	59 (95.2)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (15.4, NE)	NE (5.8, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.84 (0.21, 3.30)	
	p-value [c]	0.7989	
	Relative Risk (95% CI) [d]	1.65 (0.47, 5.79)	
	p-value	0.4319	
	Odds Ratio (95% CI) [d]	1.71 (0.45, 6.45)	
	p-value	0.4283	
	Risk Difference (95% CI) [e]	3.16 (-5.20, 11.52)	
	p-value	0.4585	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	14 (11.2)	6 (9.7)
	Number of censored subjects, n (%)	111 (88.8)	56 (90.3)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.85 (0.32, 2.23)	
	p-value [c]	0.7351	
	Relative Risk (95% CI) [d]	1.16 (0.47, 2.87)	
	p-value	0.7521	
	Odds Ratio (95% CI) [d]	1.18 (0.43, 3.23)	
	p-value	0.7513	
	Risk Difference (95% CI) [e]	1.52 (-8.89, 11.93)	
	p-value	0.7744	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Nervous system disorders	Number of subjects with events, n (%)	26 (20.8)	18 (29.0)
	Number of censored subjects, n (%)	99 (79.2)	44 (71.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	12.9 (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.58 (0.32, 1.07)	
	p-value [c]	0.0772	
	Relative Risk (95% CI) [d]	0.72 (0.43, 1.20)	
	p-value	0.2072	
	Odds Ratio (95% CI) [d]	0.64 (0.32, 1.29)	
	p-value	0.2133	
	Risk Difference (95% CI) [e]	-8.23 (-22.79, 6.33)	
	p-value	0.2677	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Psychiatric disorders	Number of subjects with events, n (%)	13 (10.4)	7 (11.3)
	Number of censored subjects, n (%)	112 (89.6)	55 (88.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.75 (0.30, 1.91)	
	p-value [c]	0.5516	
	Relative Risk (95% CI) [d]	0.92 (0.39, 2.19)	
	p-value	0.8527	
	Odds Ratio (95% CI) [d]	0.91 (0.34, 2.42)	
	p-value	0.8529	
	Risk Difference (95% CI) [e]	-0.89 (-11.62, 9.84)	
	p-value	0.8708	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Psychiatric disorders, PT: Insomnia	Number of subjects with events, n (%)	11 (8.8)	5 (8.1)
	Number of censored subjects, n (%)	114 (91.2)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.86 (0.29, 2.50)	
	p-value [c]	0.7780	
	Relative Risk (95% CI) [d]	1.09 (0.40, 3.00)	
	p-value	0.8658	
	Odds Ratio (95% CI) [d]	1.10 (0.36, 3.32)	
	p-value	0.8656	
	Risk Difference (95% CI) [e]	0.74 (-8.87, 10.34)	
	p-value	0.8807	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	39 (31.2)	13 (21.0)
	Number of censored subjects, n (%)	86 (68.8)	49 (79.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	22.3 (10.4, NE)	9.0 (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.94 (0.49, 1.80)	
	p-value [c]	0.8538	
	Relative Risk (95% CI) [d]	1.49 (0.86, 2.58)	
	p-value	0.1559	
	Odds Ratio (95% CI) [d]	1.71 (0.83, 3.51)	
	p-value	0.1440	
	Risk Difference (95% CI) [e]	10.23 (-3.96, 24.42)	
	p-value	0.1576	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Pneumonitis	Number of subjects with events, n (%)	11 (8.8)	0 (0.0)
	Number of censored subjects, n (%)	114 (91.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	11.50 (0.69, 192.01)	
	p-value	0.0891	
	Odds Ratio (95% CI) [d]	12.55 (0.73, 216.64)	
	p-value	0.0817	
	Risk Difference (95% CI) [e]	8.80 (2.63, 14.97)	
	p-value	0.0052	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Skin and subcutaneous tissue disorders	Number of subjects with events, n (%)	51 (40.8)	17 (27.4)
	Number of censored subjects, n (%)	74 (59.2)	45 (72.6)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	10.9 (7.0, 20.4)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.20 (0.68, 2.09)	
	p-value [c]	0.5224	
	Relative Risk (95% CI) [d]	1.49 (0.94, 2.35)	
	p-value	0.0881	
	Odds Ratio (95% CI) [d]	1.82 (0.94, 3.54)	
	p-value	0.0752	
	Risk Difference (95% CI) [e]	13.38 (-1.88, 28.64)	
	p-value	0.0857	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Skin and subcutaneous tissue disorders, PT: Alopecia	Number of subjects with events, n (%)	28 (22.4)	9 (14.5)
	Number of censored subjects, n (%)	97 (77.6)	53 (85.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.46 (0.69, 3.09)	
	p-value [c]	0.3197	
	Relative Risk (95% CI) [d]	1.54 (0.78, 3.07)	
	p-value	0.2156	
	Odds Ratio (95% CI) [d]	1.70 (0.75, 3.87)	
	p-value	0.2060	
	Risk Difference (95% CI) [e]	7.88 (-4.74, 20.51)	
	p-value	0.2209	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Skin and subcutaneous tissue disorders, PT: Pruritus	Number of subjects with events, n (%)	10 (8.0)	2 (3.2)
	Number of censored subjects, n (%)	115 (92.0)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (16.8, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.44 (0.30, 6.80)	
	p-value [c]	0.6471	
	Relative Risk (95% CI) [d]	2.48 (0.56, 10.97)	
	p-value	0.2314	
	Odds Ratio (95% CI) [d]	2.61 (0.55, 12.29)	
	p-value	0.2253	
	Risk Difference (95% CI) [e]	4.77 (-2.91, 12.46)	
	p-value	0.2233	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Vascular disorders	Number of subjects with events, n (%)	6 (4.8)	7 (11.3)
	Number of censored subjects, n (%)	119 (95.2)	55 (88.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.37 (0.12, 1.11)	
	p-value [c]	0.0649	
	Relative Risk (95% CI) [d]	0.43 (0.15, 1.21)	
	p-value	0.1094	
	Odds Ratio (95% CI) [d]	0.40 (0.13, 1.23)	
	p-value	0.1102	
	Risk Difference (95% CI) [e]	-6.49 (-16.42, 3.44)	
	p-value	0.2002	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Blood and lymphatic system disorders	Region							0.4955
	Japan	61/ 99 (61.6)	3.6 (1.9, 4.8)	15/ 50 (30.0)	NE (NE , NE)	2.08 (1.18, 3.67)	0.0104	
	Korea	16/ 26 (61.5)	1.8 (0.7, NE)	5/ 12 (41.7)	NE (0.3, NE)	1.43 (0.52, 3.90)	0.4849	
	Lines of prior systemic therapy							0.4865
	2	42/ 66 (63.6)	2.0 (1.0, 4.4)	13/ 38 (34.2)	NE (2.3, NE)	1.96 (1.05, 3.65)	0.0320	
	3	18/ 34 (52.9)	4.1 (2.0, NE)	6/ 18 (33.3)	NE (1.4, NE)	1.30 (0.51, 3.33)	0.5835	
	>=4	17/ 25 (68.0)	2.6 (0.5, 11.7)	1/ 6 (16.7)	NE (1.7, NE)	4.63 (0.61, 34.95)	0.1030	
	Age							0.4280
	<65 years	35/ 55 (63.6)	3.4 (1.4, 5.2)	7/ 27 (25.9)	NE (2.3, NE)	2.38 (1.05, 5.40)	0.0310	
	>=65 years	42/ 70 (60.0)	3.2 (1.0, 5.5)	13/ 35 (37.1)	NE (1.7, NE)	1.65 (0.88, 3.08)	0.1171	
	Sex							0.0594
	female	20/ 30 (66.7)	1.4 (0.5, 10.0)	2/ 15 (13.3)	NE (NE , NE)	6.00 (1.40, 25.80)	0.0060	
	male	57/ 95 (60.0)	3.5 (1.9, 5.2)	18/ 47 (38.3)	NE (1.9, NE)	1.47 (0.86, 2.50)	0.1591	
	ECOG PS							0.5117
	0	33/ 62 (53.2)	4.8 (1.9, NE)	7/ 30 (23.3)	NE (NE , NE)	2.40 (1.05, 5.47)	0.0328	
	1	44/ 63 (69.8)	2.0 (1.0, 3.6)	13/ 32 (40.6)	NE (1.2, NE)	1.66 (0.89, 3.09)	0.1029	
	HER2 Status in central laboratory							0.6303
	IHC 3+	60/ 96 (62.5)	3.4 (1.6, 4.4)	16/ 47 (34.0)	NE (2.3, NE)	1.80 (1.03, 3.13)	0.0362	
	IHC 2+/ISH +	17/ 29 (58.6)	2.8 (0.8, 6.9)	4/ 15 (26.7)	NE (1.0, NE)	2.43 (0.81, 7.24)	0.1015	
	Primary tumor location							0.9163
	Gastric	67/108 (62.0)	2.8 (1.5, 4.3)	18/ 55 (32.7)	NE (2.8, NE)	1.96 (1.16, 3.31)	0.0103	
	GEJ	10/ 17 (58.8)	4.3 (1.4, NE)	2/ 7 (28.6)	NE (0.6, NE)	1.65 (0.36, 7.67)	0.5185	
	Histological subtype							0.4695
	intestinal	52/ 89 (58.4)	4.1 (1.9, 10.0)	14/ 38 (36.8)	NE (2.3, NE)	1.58 (0.87, 2.86)	0.1345	
	diffuse	19/ 28 (67.9)	2.0 (0.5, 3.9)	4/ 18 (22.2)	NE (1.1, NE)	2.81 (0.95, 8.31)	0.0506	
	others	6/ 8 (75.0)	1.0 (0.1, 5.2)	2/ 6 (33.3)	NE (0.3, NE)	3.65 (0.71, 18.70)	0.0996	
	Number of metastatic sites							0.6789
	<2	12/ 23 (52.2)	11.7 (1.8, NE)	2/ 10 (20.0)	NE (0.5, NE)	2.34 (0.52, 10.60)	0.2528	
	>= 2	65/102 (63.7)	2.6 (1.4, 3.9)	18/ 52 (34.6)	NE (1.9, NE)	1.90 (1.12, 3.21)	0.0152	
	Previous total gastrectomy							0.4045
	yes	10/ 22 (45.5)	4.8 (1.9, NE)	3/ 9 (33.3)	NE (0.5, NE)	1.13 (0.31, 4.14)	0.8487	
	no	67/103 (65.0)	2.8 (1.0, 4.3)	17/ 53 (32.1)	NE (2.8, NE)	2.12 (1.24, 3.63)	0.0048	
	Prior adjuvant/ neoadjuvant therapy							0.6986
	yes	16/ 30 (53.3)	4.3 (1.8, NE)	2/ 10 (20.0)	NE (0.5, NE)	2.52 (0.57, 11.07)	0.2055	
	no	61/ 95 (64.2)	2.4 (1.4, 4.3)	18/ 52 (34.6)	NE (2.3, NE)	1.91 (1.13, 3.24)	0.0145	
	Prior ramucirumab contained treatment							0.3201
	yes	58/ 94 (61.7)	3.0 (1.4, 4.8)	11/ 41 (26.8)	NE (NE , NE)	2.40 (1.25, 4.58)	0.0065	
	no	19/ 31 (61.3)	3.5 (1.8, 11.7)	9/ 21 (42.9)	NE (0.6, NE)	1.33 (0.60, 2.95)	0.4829	

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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Blood and lymphatic system disorders	Prior nivolumab contained treatment							0.8670
	yes	23/ 33 (69.7)	2.4 (0.5, 11.7)	5/ 15 (33.3)	NE (1.4, NE)	2.02 (0.75, 5.41)	0.1606	
	no	54/ 92 (58.7)	3.5 (1.8, 4.4)	15/ 47 (31.9)	NE (2.8, NE)	1.88 (1.06, 3.34)	0.0280	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7968
	yes	31/ 44 (70.5)	2.0 (0.5, 4.8)	6/ 17 (35.3)	NE (1.4, NE)	2.05 (0.85, 4.97)	0.1075	
	no	46/ 81 (56.8)	3.7 (1.9, 5.5)	14/ 45 (31.1)	NE (2.8, NE)	1.81 (0.99, 3.30)	0.0493	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.2876
	yes	14/ 22 (63.6)	3.2 (0.5, 5.5)	1/ 7 (14.3)	NE (0.6, NE)	5.67 (0.74, 43.18)	0.0583	
	no	63/103 (61.2)	3.4 (1.5, 4.8)	19/ 55 (34.5)	NE (2.3, NE)	1.75 (1.04, 2.93)	0.0327	
	Presence of liver metastasis at baseline							0.2454
	yes	46/ 68 (67.6)	2.0 (0.5, 3.5)	15/ 34 (44.1)	NE (1.2, NE)	1.59 (0.88, 2.86)	0.1218	
	no	31/ 57 (54.4)	4.3 (2.6, NE)	5/ 28 (17.9)	NE (NE , NE)	3.01 (1.17, 7.77)	0.0167	
	Renal impairment at baseline							0.0485
	normal	22/ 33 (66.7)	3.7 (1.4, 4.8)	1/ 13 (7.7)	NE (NE , NE)	7.18 (0.95, 53.95)	0.0254	
	mild	32/ 53 (60.4)	3.6 (1.0, 6.9)	14/ 28 (50.0)	2.3 (1.4, NE)	1.12 (0.59, 2.10)	0.7436	
	moderate	23/ 39 (59.0)	2.0 (0.5, NE)	4/ 20 (20.0)	NE (NE , NE)	3.73 (1.29, 10.80)	0.0090	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.5 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.9572
	normal	54/ 88 (61.4)	3.6 (1.6, 5.2)	15/ 47 (31.9)	NE (2.8, NE)	1.94 (1.09, 3.44)	0.0222	
	mild	22/ 36 (61.1)	2.6 (0.8, 14.6)	5/ 15 (33.3)	NE (1.4, NE)	1.84 (0.69, 4.89)	0.2149	
	moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7836
	yes	4/ 8 (50.0)	NE (0.3, NE)	1/ 5 (20.0)	NE (1.7, NE)	2.31 (0.26, 20.78)	0.4435	
	no	73/117 (62.4)	3.2 (1.8, 4.3)	19/ 57 (33.3)	NE (2.8, NE)	1.86 (1.12, 3.09)	0.0156	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9835
	yes	2/ 3 (66.7)	4.4 (2.8, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	75/122 (61.5)	3.2 (1.8, 4.3)	20/ 58 (34.5)	NE (2.8, NE)	1.76 (1.07, 2.90)	0.0240	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Region							0.4380
	Japan	56/ 99 (56.6)	4.3 (2.4, 10.0)	14/ 50 (28.0)	NE (NE , NE)	2.03 (1.13, 3.66)	0.0171	
	Korea	15/ 26 (57.7)	2.6 (0.7, NE)	5/ 12 (41.7)	NE (0.4, NE)	1.31 (0.47, 3.61)	0.6070	
	Lines of prior systemic therapy							0.6778
	2	37/ 66 (56.1)	3.7 (1.4, 14.6)	13/ 38 (34.2)	NE (2.3, NE)	1.68 (0.89, 3.18)	0.1043	
	3	18/ 34 (52.9)	4.1 (2.0, NE)	5/ 18 (27.8)	NE (1.7, NE)	1.64 (0.60, 4.48)	0.3321	
	>=4	16/ 25 (64.0)	3.9 (0.5, 11.7)	1/ 6 (16.7)	NE (1.7, NE)	4.14 (0.55, 31.37)	0.1376	
	Age							0.5792
	<65 years	32/ 55 (58.2)	4.3 (1.6, 14.6)	7/ 27 (25.9)	NE (2.3, NE)	2.15 (0.94, 4.90)	0.0627	
	>=65 years	39/ 70 (55.7)	3.7 (1.9, 11.7)	12/ 35 (34.3)	NE (1.9, NE)	1.65 (0.86, 3.16)	0.1342	
	Sex							0.0755
	female	19/ 30 (63.3)	2.0 (0.5, 10.0)	2/ 15 (13.3)	NE (NE , NE)	5.52 (1.28, 23.84)	0.0098	
	male	52/ 95 (54.7)	4.3 (2.4, 11.7)	17/ 47 (36.2)	NE (1.9, NE)	1.43 (0.82, 2.48)	0.2093	
	ECOG PS							0.6111
	0	31/ 62 (50.0)	10.0 (2.4, NE)	7/ 30 (23.3)	NE (NE , NE)	2.20 (0.96, 5.03)	0.0588	
	1	40/ 63 (63.5)	2.6 (1.5, 4.3)	12/ 32 (37.5)	NE (1.7, NE)	1.64 (0.86, 3.13)	0.1297	
	HER2 Status in central laboratory							0.5929
	IHC 3+	54/ 96 (56.3)	4.3 (1.9, 11.7)	15/ 47 (31.9)	NE (2.8, NE)	1.71 (0.96, 3.05)	0.0663	
	IHC 2+/ISH +	17/ 29 (58.6)	2.8 (0.8, 6.9)	4/ 15 (26.7)	NE (1.0, NE)	2.40 (0.81, 7.17)	0.1045	
	Primary tumor location							0.8162
	Gastric	62/108 (57.4)	3.7 (1.8, 6.9)	17/ 55 (30.9)	NE (NE , NE)	1.90 (1.11, 3.27)	0.0179	
	GEJ	9/ 17 (52.9)	4.4 (1.4, NE)	2/ 7 (28.6)	NE (0.6, NE)	1.44 (0.30, 6.84)	0.6423	
	Histological subtype							0.5180
	intestinal	48/ 89 (53.9)	4.4 (2.4, 11.7)	13/ 38 (34.2)	NE (2.3, NE)	1.54 (0.83, 2.85)	0.1768	
	diffuse	17/ 28 (60.7)	2.6 (0.5, NE)	4/ 18 (22.2)	NE (1.1, NE)	2.54 (0.85, 7.60)	0.0834	
	others	6/ 8 (75.0)	1.0 (0.1, 5.2)	2/ 6 (33.3)	NE (0.4, NE)	3.78 (0.74, 19.28)	0.0883	
	Number of metastatic sites							0.6332
	<2	12/ 23 (52.2)	11.7 (1.8, NE)	2/ 10 (20.0)	NE (0.5, NE)	2.34 (0.52, 10.60)	0.2528	
	>= 2	59/102 (57.8)	3.2 (1.8, 5.2)	17/ 52 (32.7)	NE (2.3, NE)	1.81 (1.05, 3.11)	0.0310	
	Previous total gastrectomy							0.2558
	yes	8/ 22 (36.4)	NE (2.6, NE)	3/ 9 (33.3)	NE (0.5, NE)	0.89 (0.23, 3.38)	0.8622	
	no	63/103 (61.2)	3.2 (1.4, 5.2)	16/ 53 (30.2)	NE (NE , NE)	2.10 (1.21, 3.65)	0.0072	
	Prior adjuvant/ neoadjuvant therapy							0.7587
	yes	15/ 30 (50.0)	4.8 (1.8, NE)	2/ 10 (20.0)	NE (0.5, NE)	2.24 (0.51, 9.92)	0.2740	
	no	56/ 95 (58.9)	3.2 (1.5, 5.5)	17/ 52 (32.7)	NE (2.8, NE)	1.86 (1.08, 3.21)	0.0243	
	Prior ramucirumab contained treatment							0.1533
	yes	55/ 94 (58.5)	3.7 (1.4, 5.5)	10/ 41 (24.4)	NE (NE , NE)	2.51 (1.27, 4.94)	0.0062	
	no	16/ 31 (51.6)	4.4 (1.9, NE)	9/ 21 (42.9)	NE (0.6, NE)	1.07 (0.47, 2.44)	0.8672	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Prior nivolumab contained treatment							0.5255
	yes	22/ 33 (66.7)	2.4 (0.5, 11.7)	4/ 15 (26.7)	NE (1.7, NE)	2.41 (0.81, 7.12)	0.1057	
	no	49/ 92 (53.3)	4.1 (2.0, 10.0)	15/ 47 (31.9)	NE (2.8, NE)	1.69 (0.95, 3.02)	0.0739	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.5587
	yes	29/ 44 (65.9)	2.4 (0.5, 6.9)	5/ 17 (29.4)	NE (1.7, NE)	2.27 (0.87, 5.92)	0.0896	
	no	42/ 81 (51.9)	4.3 (2.0, NE)	14/ 45 (31.1)	NE (2.8, NE)	1.66 (0.90, 3.04)	0.0998	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.3684
	yes	12/ 22 (54.5)	4.1 (0.5, NE)	1/ 7 (14.3)	NE (0.6, NE)	4.72 (0.61, 36.36)	0.1005	
	no	59/103 (57.3)	3.9 (1.9, 10.0)	18/ 55 (32.7)	NE (2.8, NE)	1.71 (1.00, 2.91)	0.0473	
	Presence of liver metastasis at baseline							0.3807
	yes	43/ 68 (63.2)	2.0 (0.5, 4.8)	14/ 34 (41.2)	NE (1.4, NE)	1.64 (0.89, 3.01)	0.1139	
	no	28/ 57 (49.1)	5.5 (3.6, NE)	5/ 28 (17.9)	NE (NE , NE)	2.58 (0.99, 6.70)	0.0441	
	Renal impairment at baseline							0.0428
	normal	21/ 33 (63.6)	3.9 (1.4, 10.0)	1/ 13 (7.7)	NE (NE , NE)	6.96 (0.92, 52.43)	0.0287	
	mild	30/ 53 (56.6)	4.3 (1.5, 11.7)	14/ 28 (50.0)	2.3 (1.4, NE)	1.06 (0.56, 2.00)	0.8873	
	moderate	20/ 39 (51.3)	2.4 (0.5, NE)	3/ 20 (15.0)	NE (NE , NE)	4.16 (1.24, 14.03)	0.0124	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.5 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.7324
	normal	51/ 88 (58.0)	4.3 (1.8, 6.9)	15/ 47 (31.9)	NE (2.8, NE)	1.79 (1.00, 3.19)	0.0487	
	mild	20/ 36 (55.6)	3.7 (1.1, NE)	4/ 15 (26.7)	NE (1.7, NE)	2.19 (0.74, 6.43)	0.1468	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.7582
	yes	4/ 8 (50.0)	NE (0.3, NE)	1/ 5 (20.0)	NE (1.7, NE)	2.31 (0.26, 20.78)	0.4435	
	no	67/117 (57.3)	3.9 (1.9, 5.5)	18/ 57 (31.6)	NE (NE , NE)	1.78 (1.06, 3.01)	0.0294	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9841
	yes	2/ 3 (66.7)	4.4 (2.8, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	69/122 (56.6)	3.9 (2.0, 6.9)	19/ 58 (32.8)	NE (2.8, NE)	1.70 (1.02, 2.83)	0.0426	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Gastrointestinal disorders, PT: Nausea	Region							0.1909
	Japan	65/ 99 (65.7)	0.3 (0.2, 1.0)	22/ 50 (44.0)	NE (0.9, NE)	1.90 (1.17, 3.09)	0.0085	
	Korea	14/ 26 (53.8)	1.2 (0.1, NE)	7/ 12 (58.3)	0.6 (0.0, NE)	0.93 (0.38, 2.32)	0.8326	
	Lines of prior systemic therapy							0.5240
	2	40/ 66 (60.6)	0.3 (0.1, NE)	16/ 38 (42.1)	NE (0.6, NE)	1.77 (0.99, 3.16)	0.0560	
	3	23/ 34 (67.6)	0.2 (0.1, 5.8)	9/ 18 (50.0)	3.0 (0.3, NE)	1.81 (0.83, 3.92)	0.1324	
	>=4	16/ 25 (64.0)	1.0 (0.1, NE)	4/ 6 (66.7)	1.1 (0.1, NE)	0.87 (0.29, 2.61)	0.8264	
	Age							0.8683
	<65 years	41/ 55 (74.5)	0.2 (0.1, 0.3)	17/ 27 (63.0)	0.8 (0.4, NE)	1.65 (0.93, 2.91)	0.0951	
	>=65 years	38/ 70 (54.3)	1.7 (0.2, NE)	12/ 35 (34.3)	NE (1.9, NE)	1.74 (0.91, 3.33)	0.0867	
	Sex							0.2956
	female	20/ 30 (66.7)	0.3 (0.1, 2.2)	9/ 15 (60.0)	0.8 (0.1, NE)	1.11 (0.51, 2.45)	0.7722	
	male	59/ 95 (62.1)	0.3 (0.2, 2.8)	20/ 47 (42.6)	NE (0.9, NE)	1.87 (1.13, 3.11)	0.0159	
	ECOG PS							0.4334
	0	42/ 62 (67.7)	0.2 (0.2, 0.6)	17/ 30 (56.7)	1.5 (0.3, NE)	1.41 (0.80, 2.48)	0.2318	
	1	37/ 63 (58.7)	0.7 (0.1, NE)	12/ 32 (37.5)	NE (0.6, NE)	1.92 (1.00, 3.68)	0.0507	
	HER2 Status in central laboratory							0.1068
	IHC 3+	57/ 96 (59.4)	0.3 (0.2, 5.8)	24/ 47 (51.1)	1.9 (0.6, NE)	1.33 (0.83, 2.15)	0.2508	
	IHC 2+/ISH +	22/ 29 (75.9)	0.2 (0.1, 1.3)	5/ 15 (33.3)	NE (0.2, NE)	3.32 (1.25, 8.82)	0.0106	
	Primary tumor location							0.2949
	Gastric	65/108 (60.2)	0.4 (0.2, 3.4)	26/ 55 (47.3)	NE (0.6, NE)	1.47 (0.93, 2.32)	0.1004	
	GEJ	14/ 17 (82.4)	0.2 (0.1, 0.3)	3/ 7 (42.9)	NE (0.2, NE)	3.49 (0.99, 12.30)	0.0392	
	Histological subtype							0.2315
	intestinal	57/ 89 (64.0)	0.3 (0.2, 2.2)	15/ 38 (39.5)	NE (1.5, NE)	2.02 (1.14, 3.58)	0.0131	
	diffuse	17/ 28 (60.7)	0.2 (0.1, NE)	9/ 18 (50.0)	1.9 (0.4, NE)	1.63 (0.72, 3.67)	0.2559	
	others	5/ 8 (62.5)	0.4 (0.0, NE)	5/ 6 (83.3)	0.2 (0.0, NE)	0.62 (0.18, 2.18)	0.4462	
	Number of metastatic sites							0.2618
	<2	16/ 23 (69.6)	0.2 (0.1, 1.7)	3/ 10 (30.0)	NE (0.0, NE)	3.05 (0.88, 10.55)	0.0662	
	>= 2	63/102 (61.8)	0.3 (0.2, 2.8)	26/ 52 (50.0)	1.9 (0.6, NE)	1.46 (0.92, 2.31)	0.1124	
	Previous total gastrectomy							0.1162
	yes	10/ 22 (45.5)	NE (0.2, NE)	5/ 9 (55.6)	3.0 (0.1, NE)	0.74 (0.25, 2.18)	0.5759	
	no	69/103 (67.0)	0.2 (0.1, 0.7)	24/ 53 (45.3)	NE (0.6, NE)	1.90 (1.19, 3.03)	0.0068	
	Prior adjuvant/ neoadjuvant therapy							0.9082
	yes	14/ 30 (46.7)	NE (0.2, NE)	3/ 10 (30.0)	NE (0.0, NE)	1.58 (0.45, 5.49)	0.4795	
	no	65/ 95 (68.4)	0.2 (0.1, 0.6)	26/ 52 (50.0)	1.9 (0.6, NE)	1.77 (1.12, 2.79)	0.0142	
	Prior ramucirumab contained treatment							0.3732
	yes	60/ 94 (63.8)	0.3 (0.2, 1.7)	21/ 41 (51.2)	1.9 (0.5, NE)	1.41 (0.85, 2.32)	0.1865	
	no	19/ 31 (61.3)	0.6 (0.1, NE)	8/ 21 (38.1)	NE (0.9, NE)	2.18 (0.95, 4.99)	0.0648	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Gastrointestinal disorders, PT: Nausea	Prior nivolumab contained treatment							0.8228
	yes	23/ 33 (69.7)	0.3 (0.2, 2.8)	8/ 15 (53.3)	1.9 (0.1, NE)	1.51 (0.67, 3.38)	0.3154	
	no	56/ 92 (60.9)	0.3 (0.2, 1.7)	21/ 47 (44.7)	NE (0.6, NE)	1.67 (1.01, 2.76)	0.0477	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.8761
	yes	28/ 44 (63.6)	0.6 (0.2, 5.8)	8/ 17 (47.1)	NE (0.2, NE)	1.54 (0.70, 3.38)	0.2816	
	no	51/ 81 (63.0)	0.2 (0.1, 1.0)	21/ 45 (46.7)	NE (0.6, NE)	1.69 (1.02, 2.82)	0.0450	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.1171
	yes	15/ 22 (68.2)	0.2 (0.1, 2.8)	1/ 7 (14.3)	NE (0.1, NE)	7.32 (0.96, 55.74)	0.0235	
	no	64/103 (62.1)	0.3 (0.2, 1.7)	28/ 55 (50.9)	1.9 (0.6, NE)	1.42 (0.91, 2.22)	0.1268	
	Presence of liver metastasis at baseline							0.4100
	yes	43/ 68 (63.2)	0.3 (0.2, 2.8)	15/ 34 (44.1)	NE (0.6, NE)	1.93 (1.07, 3.48)	0.0288	
	no	36/ 57 (63.2)	0.3 (0.1, 5.8)	14/ 28 (50.0)	1.9 (0.2, NE)	1.34 (0.72, 2.49)	0.3603	
	Renal impairment at baseline							0.2725
	normal	23/ 33 (69.7)	0.2 (0.1, 0.3)	7/ 13 (53.8)	0.9 (0.5, NE)	2.03 (0.86, 4.77)	0.1103	
	mild	33/ 53 (62.3)	0.6 (0.1, 3.4)	10/ 28 (35.7)	NE (1.5, NE)	2.21 (1.09, 4.48)	0.0256	
	moderate	23/ 39 (59.0)	0.5 (0.2, NE)	11/ 20 (55.0)	1.5 (0.1, NE)	0.99 (0.48, 2.04)	0.9962	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	1.9 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.1800
	normal	55/ 88 (62.5)	0.2 (0.2, 2.8)	25/ 47 (53.2)	1.5 (0.5, NE)	1.41 (0.88, 2.26)	0.1686	
	mild	23/ 36 (63.9)	0.4 (0.1, NE)	4/ 15 (26.7)	NE (0.1, NE)	2.98 (1.03, 8.66)	0.0320	
	moderate	1/ 1 (100.0)	0.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.5319
	yes	6/ 8 (75.0)	0.6 (0.1, NE)	2/ 5 (40.0)	NE (0.4, NE)	3.23 (0.64, 16.33)	0.1354	
	no	73/117 (62.4)	0.3 (0.2, 1.7)	27/ 57 (47.4)	3.0 (0.6, NE)	1.56 (1.00, 2.43)	0.0496	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.0781
	yes [e]	3/ 3 (100.0)	0.1 (0.1, 0.2)	1/ 4 (25.0)	NE (0.4, NE)	2.72E8 (0.00, NE)	0.0101	
	no	76/122 (62.3)	0.3 (0.2, 1.7)	28/ 58 (48.3)	3.0 (0.6, NE)	1.51 (0.98, 2.34)	0.0636	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Gastrointestinal disorders, PT: Vomiting	Region							0.9909
	Japan	27/ 99 (27.3)	NE (NE , NE)	5/ 50 (10.0)	NE (NE , NE)	2.73 (1.05, 7.10)	0.0327	
	Korea	6/ 26 (23.1)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
	Lines of prior systemic therapy							0.7446
	2	18/ 66 (27.3)	NE (NE , NE)	4/ 38 (10.5)	NE (NE , NE)	2.70 (0.91, 7.97)	0.0625	
	3	12/ 34 (35.3)	NE (5.9, NE)	1/ 18 (5.6)	NE (NE , NE)	6.34 (0.82, 49.07)	0.0421	
	>=4	3/ 25 (12.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Age							0.3121
	<65 years	18/ 55 (32.7)	NE (5.9, NE)	4/ 27 (14.8)	NE (NE , NE)	2.28 (0.77, 6.75)	0.1282	
	>=65 years	15/ 70 (21.4)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	7.59 (1.00, 57.58)	0.0208	
	Sex							0.4252
	female	11/ 30 (36.7)	NE (0.5, NE)	1/ 15 (6.7)	NE (NE , NE)	6.78 (0.87, 52.60)	0.0338	
	male	22/ 95 (23.2)	NE (NE , NE)	4/ 47 (8.5)	NE (NE , NE)	2.52 (0.86, 7.34)	0.0803	
	ECOG PS							0.2360
	0	12/ 62 (19.4)	NE (NE , NE)	3/ 30 (10.0)	NE (NE , NE)	1.85 (0.52, 6.59)	0.3373	
	1	21/ 63 (33.3)	NE (9.6, NE)	2/ 32 (6.3)	NE (NE , NE)	5.65 (1.32, 24.15)	0.0084	
	HER2 Status in central laboratory							0.9890
	IHC 3+	23/ 96 (24.0)	NE (NE , NE)	5/ 47 (10.6)	NE (NE , NE)	2.30 (0.87, 6.07)	0.0834	
	IHC 2+/ISH +	10/ 29 (34.5)	9.6 (5.9, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	Primary tumor location							0.9889
	Gastric	28/108 (25.9)	NE (NE , NE)	5/ 55 (9.1)	NE (NE , NE)	2.89 (1.11, 7.50)	0.0231	
	GEJ	5/ 17 (29.4)	NE (1.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	Histological subtype							0.8339
	intestinal	21/ 89 (23.6)	NE (NE , NE)	2/ 38 (5.3)	NE (NE , NE)	4.64 (1.08, 19.82)	0.0229	
	diffuse	8/ 28 (28.6)	NE (5.9, NE)	2/ 18 (11.1)	NE (NE , NE)	2.26 (0.48, 10.78)	0.2961	
	others	4/ 8 (50.0)	NE (0.0, NE)	1/ 6 (16.7)	NE (0.1, NE)	3.54 (0.40, 31.77)	0.2275	
	Number of metastatic sites							0.8597
	<2	8/ 23 (34.8)	NE (0.4, NE)	1/ 10 (10.0)	NE (0.6, NE)	4.01 (0.50, 32.10)	0.1581	
	>= 2	25/102 (24.5)	NE (NE , NE)	4/ 52 (7.7)	NE (NE , NE)	3.09 (1.07, 8.93)	0.0278	
	Previous total gastrectomy							0.9997
	yes	0/ 22 (0.0)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
	no	33/103 (32.0)	NE (NE , NE)	5/ 53 (9.4)	NE (NE , NE)	3.52 (1.37, 9.04)	0.0053	
	Prior adjuvant/ neoadjuvant therapy							0.9889
	yes	2/ 30 (6.7)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	no	31/ 95 (32.6)	NE (9.6, NE)	5/ 52 (9.6)	NE (NE , NE)	3.52 (1.36, 9.07)	0.0056	
	Prior ramucirumab contained treatment							0.5236
	yes	27/ 94 (28.7)	NE (NE , NE)	3/ 41 (7.3)	NE (NE , NE)	3.98 (1.20, 13.16)	0.0144	
	no	6/ 31 (19.4)	NE (NE , NE)	2/ 21 (9.5)	NE (NE , NE)	1.96 (0.39, 9.79)	0.4023	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Gastrointestinal disorders, PT: Vomiting	Prior nivolumab contained treatment							0.8380
	yes	9/ 33 (27.3)	NE (9.6, NE)	1/ 15 (6.7)	NE (NE , NE)	3.99 (0.50, 31.72)	0.1558	
	no	24/ 92 (26.1)	NE (NE , NE)	4/ 47 (8.5)	NE (NE , NE)	3.15 (1.09, 9.09)	0.0255	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9323
	yes	10/ 44 (22.7)	NE (NE , NE)	1/ 17 (5.9)	NE (NE , NE)	3.79 (0.48, 29.79)	0.1722	
	no	23/ 81 (28.4)	NE (NE , NE)	4/ 45 (8.9)	NE (NE , NE)	3.33 (1.15, 9.66)	0.0188	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9887
	yes	6/ 22 (27.3)	NE (5.9, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	27/103 (26.2)	NE (NE , NE)	5/ 55 (9.1)	NE (NE , NE)	2.94 (1.13, 7.66)	0.0206	
	Presence of liver metastasis at baseline							0.1227
	yes	19/ 68 (27.9)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	10.27 (1.38, 76.76)	0.0048	
	no	14/ 57 (24.6)	NE (NE , NE)	4/ 28 (14.3)	NE (NE , NE)	1.56 (0.51, 4.79)	0.4342	
	Renal impairment at baseline							0.7361
	normal	12/ 33 (36.4)	NE (2.6, NE)	2/ 13 (15.4)	NE (1.4, NE)	2.54 (0.57, 11.35)	0.2074	
	mild	12/ 53 (22.6)	NE (9.6, NE)	1/ 28 (3.6)	NE (NE , NE)	5.98 (0.77, 46.20)	0.0514	
	moderate	9/ 39 (23.1)	NE (NE , NE)	1/ 20 (5.0)	NE (NE , NE)	5.06 (0.64, 39.96)	0.0872	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.6 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.9892
	normal	20/ 88 (22.7)	NE (NE , NE)	5/ 47 (10.6)	NE (NE , NE)	2.06 (0.77, 5.53)	0.1436	
	mild	13/ 36 (36.1)	NE (2.6, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9910
	yes	1/ 8 (12.5)	NE (5.9, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
	no	32/117 (27.4)	NE (NE , NE)	5/ 57 (8.8)	NE (NE , NE)	3.21 (1.25, 8.27)	0.0106	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9910
	yes	1/ 3 (33.3)	NE (5.9, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	32/122 (26.2)	NE (NE , NE)	5/ 58 (8.6)	NE (NE , NE)	3.11 (1.21, 8.01)	0.0131	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
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Daiichi Sankyo

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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: General disorders and administration site conditions, PT: Malaise	Region							0.9997
	Japan	43/ 99 (43.4)	NE (2.1, NE)	10/ 50 (20.0)	NE (NE , NE)	2.42 (1.22, 4.82)	0.0094	
	Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
	Lines of prior systemic therapy							0.3289
	2	19/ 66 (28.8)	NE (NE , NE)	8/ 38 (21.1)	NE (4.6, NE)	1.39 (0.61, 3.17)	0.4432	
	3	12/ 34 (35.3)	NE (2.3, NE)	1/ 18 (5.6)	NE (NE , NE)	6.68 (0.87, 51.44)	0.0351	
	>=4	12/ 25 (48.0)	NE (0.3, NE)	1/ 6 (16.7)	NE (0.2, NE)	2.99 (0.39, 23.04)	0.2696	
	Age							0.3949
	<65 years	19/ 55 (34.5)	NE (2.8, NE)	3/ 27 (11.1)	NE (NE , NE)	3.36 (1.00, 11.37)	0.0385	
	>=65 years	24/ 70 (34.3)	NE (NE , NE)	7/ 35 (20.0)	NE (4.6, NE)	1.73 (0.75, 4.02)	0.1964	
	Sex							0.3435
	female	11/ 30 (36.7)	NE (1.6, NE)	4/ 15 (26.7)	NE (0.6, NE)	1.40 (0.44, 4.39)	0.5643	
	male	32/ 95 (33.7)	NE (NE , NE)	6/ 47 (12.8)	NE (NE , NE)	2.77 (1.16, 6.63)	0.0172	
	ECOG PS							0.4841
	0	26/ 62 (41.9)	NE (2.3, NE)	5/ 30 (16.7)	NE (4.6, NE)	2.73 (1.05, 7.12)	0.0326	
	1	17/ 63 (27.0)	NE (NE , NE)	5/ 32 (15.6)	NE (NE , NE)	1.75 (0.64, 4.74)	0.2681	
	HER2 Status in central laboratory							0.1786
	IHC 3+	32/ 96 (33.3)	NE (NE , NE)	5/ 47 (10.6)	NE (NE , NE)	3.29 (1.28, 8.43)	0.0088	
	IHC 2+/ISH +	11/ 29 (37.9)	NE (1.4, NE)	5/ 15 (33.3)	NE (0.7, NE)	1.22 (0.42, 3.52)	0.7157	
	Primary tumor location							0.3402
	Gastric	33/108 (30.6)	NE (NE , NE)	9/ 55 (16.4)	NE (NE , NE)	1.88 (0.90, 3.94)	0.0875	
	GEJ	10/ 17 (58.8)	1.5 (0.1, NE)	1/ 7 (14.3)	NE (1.4, NE)	5.20 (0.66, 40.80)	0.0804	
	Histological subtype							0.8713
	intestinal	37/ 89 (41.6)	NE (2.8, NE)	9/ 38 (23.7)	NE (4.6, NE)	1.94 (0.93, 4.01)	0.0714	
	diffuse	6/ 28 (21.4)	NE (NE , NE)	1/ 18 (5.6)	NE (NE , NE)	3.66 (0.44, 30.42)	0.1978	
	others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Number of metastatic sites							0.2525
	<2	12/ 23 (52.2)	3.5 (0.3, NE)	1/ 10 (10.0)	NE (0.2, NE)	6.24 (0.81, 48.03)	0.0439	
	>= 2	31/102 (30.4)	NE (NE , NE)	9/ 52 (17.3)	NE (NE , NE)	1.80 (0.86, 3.78)	0.1168	
	Previous total gastrectomy							0.0388
	yes	4/ 22 (18.2)	NE (NE , NE)	3/ 9 (33.3)	4.6 (0.2, NE)	0.48 (0.11, 2.18)	0.3263	
	no	39/103 (37.9)	NE (NE , NE)	7/ 53 (13.2)	NE (NE , NE)	3.12 (1.39, 6.97)	0.0035	
	Prior adjuvant/ neoadjuvant therapy							0.3334
	yes	11/ 30 (36.7)	NE (1.9, NE)	3/ 10 (30.0)	NE (0.2, NE)	1.22 (0.34, 4.38)	0.7686	
	no	32/ 95 (33.7)	NE (NE , NE)	7/ 52 (13.5)	NE (NE , NE)	2.68 (1.18, 6.08)	0.0141	
	Prior ramucirumab contained treatment							0.9824
	yes	34/ 94 (36.2)	NE (NE , NE)	7/ 41 (17.1)	NE (4.6, NE)	2.17 (0.96, 4.90)	0.0564	
	no	9/ 31 (29.0)	NE (NE , NE)	3/ 21 (14.3)	NE (NE , NE)	2.17 (0.59, 8.02)	0.2333	

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[c] Two-sided p-value derived from log-rank test.
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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: General disorders and administration site conditions, PT: Malaise	Prior nivolumab contained treatment							0.0752
	yes	21/ 33 (63.6)	1.4 (0.2, NE)	2/ 15 (13.3)	NE (NE , NE)	6.38 (1.49, 27.24)	0.0040	
	no	22/ 92 (23.9)	NE (NE , NE)	8/ 47 (17.0)	NE (NE , NE)	1.36 (0.60, 3.06)	0.4636	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.1809
	yes	21/ 44 (47.7)	NE (0.7, NE)	2/ 17 (11.8)	NE (NE , NE)	4.84 (1.13, 20.65)	0.0184	
	no	22/ 81 (27.2)	NE (NE , NE)	8/ 45 (17.8)	NE (NE , NE)	1.50 (0.67, 3.37)	0.3292	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9852
	yes	10/ 22 (45.5)	NE (0.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	33/103 (32.0)	NE (NE , NE)	10/ 55 (18.2)	NE (NE , NE)	1.77 (0.87, 3.59)	0.1110	
	Presence of liver metastasis at baseline							0.5387
	yes	25/ 68 (36.8)	NE (2.8, NE)	5/ 34 (14.7)	NE (NE , NE)	2.77 (1.06, 7.24)	0.0300	
	no	18/ 57 (31.6)	NE (NE , NE)	5/ 28 (17.9)	NE (4.6, NE)	1.73 (0.64, 4.65)	0.2806	
	Renal impairment at baseline							0.9610
	normal	13/ 33 (39.4)	NE (1.5, NE)	2/ 13 (15.4)	NE (1.4, NE)	2.71 (0.61, 12.03)	0.1722	
	mild	15/ 53 (28.3)	NE (NE , NE)	4/ 28 (14.3)	NE (NE , NE)	2.15 (0.71, 6.48)	0.1694	
	moderate	15/ 39 (38.5)	NE (2.3, NE)	4/ 20 (20.0)	NE (4.6, NE)	2.01 (0.67, 6.06)	0.2043	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.9164
	normal	32/ 88 (36.4)	NE (NE , NE)	8/ 47 (17.0)	NE (NE , NE)	2.19 (1.01, 4.77)	0.0423	
	mild	11/ 36 (30.6)	NE (NE , NE)	2/ 15 (13.3)	NE (NE , NE)	2.42 (0.54, 10.94)	0.2335	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.8459
	yes	4/ 8 (50.0)	NE (0.1, NE)	1/ 5 (20.0)	NE (1.4, NE)	2.74 (0.31, 24.61)	0.3471	
	no	39/117 (33.3)	NE (NE , NE)	9/ 57 (15.8)	NE (NE , NE)	2.19 (1.06, 4.53)	0.0298	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.8894
	yes	2/ 3 (66.7)	1.7 (1.5, NE)	1/ 4 (25.0)	NE (1.4, NE)	2.21 (0.20, 24.47)	0.5079	
	no	41/122 (33.6)	NE (NE , NE)	9/ 58 (15.5)	NE (NE , NE)	2.26 (1.10, 4.65)	0.0231	

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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations	Region							0.0979
	Japan	84/ 99 (84.8)	0.3 (0.3, 0.5)	26/ 50 (52.0)	2.8 (0.5, NE)	2.14 (1.37, 3.33)	0.0006	
	Korea	18/ 26 (69.2)	2.9 (0.7, 4.2)	7/ 12 (58.3)	1.4 (0.5, NE)	0.77 (0.32, 1.88)	0.5699	
	Lines of prior systemic therapy							0.7334
	2	52/ 66 (78.8)	1.3 (0.5, 1.9)	19/ 38 (50.0)	2.8 (0.5, NE)	1.60 (0.94, 2.71)	0.0790	
	3	30/ 34 (88.2)	0.3 (0.3, 0.5)	11/ 18 (61.1)	0.9 (0.5, NE)	2.29 (1.14, 4.62)	0.0184	
	>=4	20/ 25 (80.0)	0.5 (0.3, 1.9)	3/ 6 (50.0)	NE (0.5, NE)	1.89 (0.56, 6.42)	0.3125	
	Age							0.4915
	<65 years	48/ 55 (87.3)	0.7 (0.3, 1.8)	13/ 27 (48.1)	2.8 (0.5, NE)	1.95 (1.05, 3.62)	0.0331	
	>=65 years	54/ 70 (77.1)	0.5 (0.3, 0.7)	20/ 35 (57.1)	1.1 (0.5, NE)	1.59 (0.95, 2.66)	0.0829	
	Sex							0.7715
	female	24/ 30 (80.0)	0.5 (0.3, 2.3)	7/ 15 (46.7)	NE (0.5, NE)	1.96 (0.84, 4.57)	0.1240	
	male	78/ 95 (82.1)	0.5 (0.3, 0.7)	26/ 47 (55.3)	1.4 (0.5, NE)	1.73 (1.11, 2.70)	0.0161	
	ECOG PS							0.1520
	0	53/ 62 (85.5)	0.4 (0.3, 0.7)	14/ 30 (46.7)	NE (0.5, NE)	2.42 (1.34, 4.39)	0.0023	
	1	49/ 63 (77.8)	0.7 (0.4, 1.9)	19/ 32 (59.4)	1.4 (0.5, NE)	1.33 (0.78, 2.27)	0.3144	
	HER2 Status in central laboratory							0.9859
	IHC 3+	78/ 96 (81.3)	0.5 (0.4, 1.4)	24/ 47 (51.1)	2.8 (0.5, NE)	1.79 (1.13, 2.83)	0.0130	
	IHC 2+/ISH +	24/ 29 (82.8)	0.3 (0.3, 1.2)	9/ 15 (60.0)	0.7 (0.3, NE)	1.78 (0.82, 3.84)	0.1527	
	Primary tumor location							0.1746
	Gastric	86/108 (79.6)	0.5 (0.3, 0.7)	31/ 55 (56.4)	1.4 (0.5, NE)	1.60 (1.06, 2.42)	0.0264	
	GEJ	16/ 17 (94.1)	0.7 (0.3, 1.9)	2/ 7 (28.6)	NE (0.5, NE)	4.30 (0.97, 19.04)	0.0369	
	Histological subtype							0.5681
	intestinal	75/ 89 (84.3)	0.5 (0.3, 0.7)	21/ 38 (55.3)	1.4 (0.5, NE)	1.85 (1.14, 3.01)	0.0125	
	diffuse	22/ 28 (78.6)	0.5 (0.3, 2.9)	8/ 18 (44.4)	2.8 (0.5, NE)	1.83 (0.80, 4.15)	0.1440	
	others	5/ 8 (62.5)	3.5 (0.3, NE)	4/ 6 (66.7)	1.1 (0.4, NE)	0.81 (0.22, 3.08)	0.7426	
	Number of metastatic sites							0.2450
	<2	17/ 23 (73.9)	0.7 (0.3, 3.0)	7/ 10 (70.0)	0.5 (0.0, NE)	1.13 (0.46, 2.73)	0.7909	
	>= 2	85/102 (83.3)	0.5 (0.3, 0.7)	26/ 52 (50.0)	2.8 (0.5, NE)	1.98 (1.28, 3.09)	0.0022	
	Previous total gastrectomy							0.0371
	yes	17/ 22 (77.3)	1.3 (0.3, 2.9)	7/ 9 (77.8)	0.5 (0.2, NE)	0.72 (0.29, 1.79)	0.4956	
	no	85/103 (82.5)	0.5 (0.3, 0.7)	26/ 53 (49.1)	2.8 (0.7, NE)	2.09 (1.34, 3.24)	0.0010	
	Prior adjuvant/ neoadjuvant therapy							0.3659
	yes	27/ 30 (90.0)	0.3 (0.3, 0.7)	7/ 10 (70.0)	0.5 (0.2, NE)	1.27 (0.55, 2.94)	0.5836	
	no	75/ 95 (78.9)	0.5 (0.3, 1.4)	26/ 52 (50.0)	2.8 (0.7, NE)	1.86 (1.19, 2.91)	0.0067	
	Prior ramucirumab contained treatment							0.0354
	yes	80/ 94 (85.1)	0.3 (0.3, 0.7)	19/ 41 (46.3)	2.8 (0.5, NE)	2.36 (1.43, 3.91)	0.0007	
	no	22/ 31 (71.0)	1.4 (0.5, 5.6)	14/ 21 (66.7)	1.4 (0.4, 3.7)	0.96 (0.49, 1.88)	0.9285	

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SOC: Investigations	Prior nivolumab contained treatment							0.2879
	yes	31/ 33 (93.9)	0.3 (0.3, 0.3)	9/ 15 (60.0)	0.7 (0.5, NE)	2.73 (1.28, 5.80)	0.0077	
	no	71/ 92 (77.2)	0.7 (0.5, 1.8)	24/ 47 (51.1)	2.8 (0.5, NE)	1.58 (0.99, 2.51)	0.0525	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9082
	yes	39/ 44 (88.6)	0.3 (0.3, 0.5)	11/ 17 (64.7)	0.5 (0.5, NE)	1.87 (0.95, 3.69)	0.0711	
	no	63/ 81 (77.8)	0.7 (0.5, 1.8)	22/ 45 (48.9)	2.8 (0.5, NE)	1.71 (1.05, 2.79)	0.0299	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.5417
	yes	16/ 22 (72.7)	0.6 (0.3, 6.1)	4/ 7 (57.1)	0.5 (0.3, NE)	1.36 (0.45, 4.14)	0.5541	
	no	86/103 (83.5)	0.5 (0.3, 0.7)	29/ 55 (52.7)	2.8 (0.5, NE)	1.85 (1.21, 2.83)	0.0043	
	Presence of liver metastasis at baseline							0.1563
	yes	58/ 68 (85.3)	0.5 (0.3, 0.7)	17/ 34 (50.0)	2.8 (0.5, NE)	2.36 (1.37, 4.07)	0.0014	
	no	44/ 57 (77.2)	0.7 (0.3, 2.9)	16/ 28 (57.1)	0.7 (0.5, NE)	1.33 (0.75, 2.37)	0.3783	
	Renal impairment at baseline							0.9110
	normal	27/ 33 (81.8)	0.7 (0.3, 1.6)	7/ 13 (53.8)	2.8 (0.5, NE)	1.74 (0.75, 4.05)	0.2039	
	mild	47/ 53 (88.7)	0.3 (0.3, 0.7)	16/ 28 (57.1)	1.4 (0.5, NE)	2.03 (1.15, 3.61)	0.0151	
	moderate	28/ 39 (71.8)	1.2 (0.3, 3.1)	9/ 20 (45.0)	NE (0.4, NE)	1.60 (0.75, 3.41)	0.2180	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.0 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.4169
	normal	72/ 88 (81.8)	0.5 (0.3, 1.4)	23/ 47 (48.9)	3.7 (0.7, NE)	1.89 (1.18, 3.04)	0.0078	
	mild	29/ 36 (80.6)	0.4 (0.3, 0.7)	10/ 15 (66.7)	0.5 (0.3, NE)	1.41 (0.68, 2.91)	0.3505	
	moderate	1/ 1 (100.0)	1.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.2808
	yes	5/ 8 (62.5)	4.9 (0.3, NE)	3/ 5 (60.0)	1.4 (0.5, NE)	0.88 (0.21, 3.80)	0.8474	
	no	97/117 (82.9)	0.5 (0.3, 0.7)	30/ 57 (52.6)	2.8 (0.5, NE)	1.85 (1.23, 2.80)	0.0031	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.5387
	yes	2/ 3 (66.7)	6.1 (3.6, NE)	2/ 4 (50.0)	NE (0.5, NE)	0.69 (0.09, 5.25)	0.7166	
	no	100/122 (82.0)	0.5 (0.3, 0.7)	31/ 58 (53.4)	2.8 (0.5, NE)	1.78 (1.19, 2.68)	0.0051	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Lymphocyte count decreased	Region							0.9995
	Japan	29/ 99 (29.3)	NE (8.3, NE)	2/ 50 (4.0)	NE (NE , NE)	6.68 (1.58, 28.12)	0.0028	
	Korea	0/ 26 (0.0)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
	Lines of prior systemic therapy							0.9571
	2	13/ 66 (19.7)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	6.83 (0.89, 52.62)	0.0324	
	3	10/ 34 (29.4)	NE (4.4, NE)	1/ 18 (5.6)	NE (NE , NE)	3.50 (0.44, 28.01)	0.2092	
	>=4	6/ 25 (24.0)	NE (8.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Age							0.5390
	<65 years	9/ 55 (16.4)	NE (NE , NE)	1/ 27 (3.7)	NE (NE , NE)	3.39 (0.42, 27.52)	0.2258	
	>=65 years	20/ 70 (28.6)	NE (8.8, NE)	1/ 35 (2.9)	NE (NE , NE)	9.12 (1.22, 68.15)	0.0089	
	Sex							0.5648
	female	8/ 30 (26.7)	NE (8.3, NE)	1/ 15 (6.7)	NE (NE , NE)	3.83 (0.47, 31.12)	0.1761	
	male	21/ 95 (22.1)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	8.60 (1.15, 64.32)	0.0117	
	ECOG PS							0.7656
	0	18/ 62 (29.0)	NE (8.3, NE)	1/ 30 (3.3)	NE (NE , NE)	7.00 (0.92, 53.03)	0.0286	
	1	11/ 63 (17.5)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	5.21 (0.67, 40.46)	0.0780	
	HER2 Status in central laboratory							0.2558
	IHC 3+	25/ 96 (26.0)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	10.58 (1.43, 78.48)	0.0040	
	IHC 2+/ISH +	4/ 29 (13.8)	NE (7.7, NE)	1/ 15 (6.7)	NE (2.8, NE)	1.64 (0.17, 15.75)	0.6658	
	Primary tumor location							0.9916
	Gastric	26/108 (24.1)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	5.55 (1.31, 23.56)	0.0089	
	GEJ	3/ 17 (17.6)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	Histological subtype							0.7912
	intestinal	22/ 89 (24.7)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	9.01 (1.21, 66.98)	0.0092	
	diffuse	7/ 28 (25.0)	NE (8.3, NE)	1/ 18 (5.6)	NE (1.9, NE)	2.65 (0.30, 23.11)	0.3592	
	others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Number of metastatic sites							0.3977
	<2	7/ 23 (30.4)	NE (7.7, NE)	1/ 10 (10.0)	NE (1.9, NE)	2.50 (0.30, 20.71)	0.3792	
	>= 2	22/102 (21.6)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	9.93 (1.33, 73.93)	0.0057	
	Previous total gastrectomy							0.9913
	yes	2/ 22 (9.1)	NE (8.3, NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
	no	27/103 (26.2)	NE (NE , NE)	2/ 53 (3.8)	NE (NE , NE)	6.20 (1.47, 26.21)	0.0046	
	Prior adjuvant/ neoadjuvant therapy							0.9894
	yes	8/ 30 (26.7)	NE (8.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	no	21/ 95 (22.1)	NE (NE , NE)	2/ 52 (3.8)	NE (NE , NE)	4.99 (1.16, 21.40)	0.0163	
	Prior ramucirumab contained treatment							0.9904
	yes	25/ 94 (26.6)	NE (NE , NE)	2/ 41 (4.9)	NE (NE , NE)	5.08 (1.20, 21.53)	0.0141	
	no	4/ 31 (12.9)	NE (8.3, NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	

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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Lymphocyte count decreased	Prior nivolumab contained treatment							0.8505
	yes	13/ 33 (39.4)	NE (3.8, NE)	1/ 15 (6.7)	NE (2.8, NE)	5.13 (0.66, 39.75)	0.0821	
	no	16/ 92 (17.4)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	7.02 (0.92, 53.37)	0.0283	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.7698
	yes	14/ 44 (31.8)	NE (7.7, NE)	1/ 17 (5.9)	NE (NE , NE)	4.67 (0.61, 35.95)	0.1038	
	no	15/ 81 (18.5)	NE (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	7.06 (0.92, 53.90)	0.0282	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9912
	yes	5/ 22 (22.7)	NE (4.2, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	24/103 (23.3)	NE (NE , NE)	2/ 55 (3.6)	NE (NE , NE)	5.31 (1.24, 22.67)	0.0117	
	Presence of liver metastasis at baseline							0.5065
	yes	20/ 68 (29.4)	NE (7.7, NE)	1/ 34 (2.9)	NE (NE , NE)	9.23 (1.23, 69.08)	0.0084	
	no	9/ 57 (15.8)	NE (NE , NE)	1/ 28 (3.6)	NE (NE , NE)	3.33 (0.41, 26.89)	0.2307	
	Renal impairment at baseline							0.9999
	normal	5/ 33 (15.2)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
	mild	14/ 53 (26.4)	NE (8.3, NE)	1/ 28 (3.6)	NE (NE , NE)	6.19 (0.81, 47.47)	0.0455	
	moderate	10/ 39 (25.6)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	1.9 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.2462
	normal	24/ 88 (27.3)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	10.98 (1.48, 81.64)	0.0033	
	mild	5/ 36 (13.9)	NE (7.7, NE)	1/ 15 (6.7)	NE (2.8, NE)	1.80 (0.21, 15.67)	0.5893	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9916
	yes	3/ 8 (37.5)	NE (0.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
	no	26/117 (22.2)	NE (NE , NE)	2/ 57 (3.5)	NE (NE , NE)	5.43 (1.28, 23.03)	0.0100	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9993
	yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	29/122 (23.8)	NE (NE , NE)	2/ 58 (3.4)	NE (NE , NE)	5.84 (1.38, 24.65)	0.0065	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Neutrophil count decreased	Region							0.9465
	Japan	69/ 99 (69.7)	0.7 (0.5, 1.4)	19/ 50 (38.0)	NE (0.7, NE)	1.94 (1.16, 3.24)	0.0109	
	Korea	10/ 26 (38.5)	NE (3.0, NE)	2/ 12 (16.7)	NE (2.8, NE)	1.86 (0.40, 8.53)	0.4160	
	Lines of prior systemic therapy							0.1912
	2	36/ 66 (54.5)	3.5 (0.7, 18.3)	14/ 38 (36.8)	NE (1.4, NE)	1.36 (0.73, 2.54)	0.3308	
	3	25/ 34 (73.5)	0.6 (0.5, 0.7)	4/ 18 (22.2)	NE (NE , NE)	4.03 (1.40, 11.65)	0.0057	
	>=4	18/ 25 (72.0)	0.7 (0.5, 5.0)	3/ 6 (50.0)	NE (0.5, NE)	1.24 (0.36, 4.26)	0.7553	
	Age							0.5681
	<65 years	36/ 55 (65.5)	2.3 (0.7, 5.0)	8/ 27 (29.6)	NE (2.8, NE)	2.02 (0.93, 4.40)	0.0718	
	>=65 years	43/ 70 (61.4)	0.7 (0.5, NE)	13/ 35 (37.1)	NE (0.5, NE)	1.65 (0.88, 3.07)	0.1224	
	Sex							0.1057
	female	21/ 30 (70.0)	0.9 (0.5, 5.6)	3/ 15 (20.0)	NE (0.7, NE)	4.07 (1.20, 13.73)	0.0146	
	male	58/ 95 (61.1)	1.4 (0.7, 5.0)	18/ 47 (38.3)	NE (0.7, NE)	1.51 (0.88, 2.56)	0.1376	
	ECOG PS							0.7540
	0	44/ 62 (71.0)	0.7 (0.5, 2.3)	11/ 30 (36.7)	NE (0.7, NE)	2.06 (1.06, 4.00)	0.0300	
	1	35/ 63 (55.6)	3.0 (0.7, NE)	10/ 32 (31.3)	NE (2.8, NE)	1.72 (0.85, 3.48)	0.1329	
	HER2 Status in central laboratory							0.3840
	IHC 3+	61/ 96 (63.5)	1.4 (0.7, 4.2)	14/ 47 (29.8)	NE (2.8, NE)	2.13 (1.19, 3.82)	0.0105	
	IHC 2+/ISH +	18/ 29 (62.1)	0.6 (0.5, NE)	7/ 15 (46.7)	NE (0.5, NE)	1.34 (0.56, 3.23)	0.5001	
	Primary tumor location							0.5986
	Gastric	67/108 (62.0)	1.2 (0.6, 5.0)	19/ 55 (34.5)	NE (2.8, NE)	1.76 (1.06, 2.94)	0.0288	
	GEJ	12/ 17 (70.6)	1.3 (0.5, 5.0)	2/ 7 (28.6)	NE (0.5, NE)	2.74 (0.60, 12.40)	0.1761	
	Histological subtype							0.3657
	intestinal	58/ 89 (65.2)	1.2 (0.6, 4.2)	16/ 38 (42.1)	NE (0.6, NE)	1.47 (0.84, 2.57)	0.1975	
	diffuse	18/ 28 (64.3)	0.6 (0.5, 6.1)	4/ 18 (22.2)	NE (2.8, NE)	3.19 (1.08, 9.47)	0.0252	
	others	3/ 8 (37.5)	NE (0.3, NE)	1/ 6 (16.7)	NE (0.5, NE)	2.30 (0.24, 22.37)	0.4616	
	Number of metastatic sites							0.2302
	<2	14/ 23 (60.9)	0.7 (0.5, NE)	5/ 10 (50.0)	NE (0.2, NE)	1.08 (0.39, 3.01)	0.8418	
	>= 2	65/102 (63.7)	1.4 (0.5, 4.2)	16/ 52 (30.8)	NE (2.8, NE)	2.13 (1.23, 3.69)	0.0067	
	Previous total gastrectomy							0.0821
	yes	13/ 22 (59.1)	1.9 (0.5, NE)	5/ 9 (55.6)	0.7 (0.2, NE)	0.88 (0.31, 2.47)	0.7904	
	no	66/103 (64.1)	0.7 (0.5, 4.2)	16/ 53 (30.2)	NE (NE , NE)	2.19 (1.26, 3.79)	0.0045	
	Prior adjuvant/ neoadjuvant therapy							0.0364
	yes	23/ 30 (76.7)	0.7 (0.5, 1.9)	7/ 10 (70.0)	0.5 (0.2, NE)	0.79 (0.34, 1.86)	0.5480	
	no	56/ 95 (58.9)	1.9 (0.7, 5.6)	14/ 52 (26.9)	NE (NE , NE)	2.25 (1.25, 4.06)	0.0056	
	Prior ramucirumab contained treatment							0.1070
	yes	62/ 94 (66.0)	0.7 (0.5, 3.0)	11/ 41 (26.8)	NE (NE , NE)	2.52 (1.32, 4.80)	0.0036	
	no	17/ 31 (54.8)	5.0 (0.5, NE)	10/ 21 (47.6)	2.8 (0.5, NE)	1.06 (0.48, 2.32)	0.8971	

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[c] Two-sided p-value derived from log-rank test.
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SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Neutrophil count decreased	Prior nivolumab contained treatment							0.0481
	yes	28/ 33 (84.8)	0.5 (0.5, 0.5)	4/ 15 (26.7)	NE (0.5, NE)	4.69 (1.62, 13.58)	0.0019	
	no	51/ 92 (55.4)	3.5 (1.3, 6.1)	17/ 47 (36.2)	NE (1.4, NE)	1.36 (0.78, 2.37)	0.2678	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.1537
	yes	34/ 44 (77.3)	0.5 (0.5, 0.7)	5/ 17 (29.4)	NE (0.5, NE)	3.24 (1.26, 8.34)	0.0109	
	no	45/ 81 (55.6)	3.5 (0.7, NE)	16/ 45 (35.6)	NE (1.4, NE)	1.42 (0.80, 2.53)	0.2231	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.0803
	yes	13/ 22 (59.1)	1.3 (0.5, NE)	4/ 7 (57.1)	0.5 (0.3, NE)	0.72 (0.23, 2.24)	0.5417	
	no	66/103 (64.1)	1.3 (0.6, 3.5)	17/ 55 (30.9)	NE (NE , NE)	2.16 (1.26, 3.69)	0.0041	
	Presence of liver metastasis at baseline							0.0871
	yes	47/ 68 (69.1)	0.7 (0.5, 1.9)	10/ 34 (29.4)	NE (2.8, NE)	2.76 (1.39, 5.47)	0.0028	
	no	32/ 57 (56.1)	3.1 (0.7, NE)	11/ 28 (39.3)	NE (0.5, NE)	1.22 (0.61, 2.44)	0.5571	
	Renal impairment at baseline							0.8125
	normal	21/ 33 (63.6)	0.7 (0.5, NE)	5/ 13 (38.5)	NE (0.5, NE)	1.90 (0.71, 5.07)	0.2043	
	mild	37/ 53 (69.8)	0.7 (0.5, 4.2)	9/ 28 (32.1)	NE (0.7, NE)	2.09 (1.00, 4.36)	0.0459	
	moderate	21/ 39 (53.8)	3.0 (0.5, NE)	7/ 20 (35.0)	NE (0.5, NE)	1.49 (0.63, 3.51)	0.3581	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.2268
	normal	56/ 88 (63.6)	1.4 (0.6, 5.0)	14/ 47 (29.8)	NE (2.8, NE)	2.21 (1.22, 3.98)	0.0075	
	mild	22/ 36 (61.1)	1.0 (0.5, 4.2)	7/ 15 (46.7)	NE (0.3, NE)	1.20 (0.51, 2.81)	0.6907	
	moderate	1/ 1 (100.0)	1.3 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.0895
	yes	4/ 8 (50.0)	6.1 (0.5, NE)	3/ 5 (60.0)	1.4 (0.5, NE)	0.62 (0.14, 2.83)	0.5411	
	no	75/117 (64.1)	1.2 (0.6, 3.1)	18/ 57 (31.6)	NE (NE , NE)	2.08 (1.24, 3.50)	0.0047	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.2276
	yes	1/ 3 (33.3)	NE (6.1, NE)	2/ 4 (50.0)	NE (0.5, NE)	0.36 (0.03, 4.43)	0.4114	
	no	78/122 (63.9)	1.0 (0.6, 3.1)	19/ 58 (32.8)	NE (2.8, NE)	1.98 (1.20, 3.27)	0.0074	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
[e] 2.72E8 represents the number 271641304.29
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Platelet count decreased	Region							0.1090
	Japan	45/ 99 (45.5)	9.8 (1.7, NE)	3/ 50 (6.0)	NE (NE , NE)	9.08 (2.81, 29.27)	<.0001	
	Korea	3/ 26 (11.5)	NE (NE , NE)	1/ 12 (8.3)	NE (NE , NE)	1.18 (0.12, 11.40)	0.8851	
	Lines of prior systemic therapy							0.9787
	2	23/ 66 (34.8)	NE (5.3, NE)	2/ 38 (5.3)	NE (NE , NE)	6.56 (1.54, 27.96)	0.0034	
	3	16/ 34 (47.1)	NE (0.3, NE)	2/ 18 (11.1)	NE (NE , NE)	5.70 (1.31, 24.83)	0.0096	
	>=4	9/ 25 (36.0)	NE (0.3, NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Age							0.5690
	<65 years	20/ 55 (36.4)	NE (5.0, NE)	1/ 27 (3.7)	NE (NE , NE)	10.38 (1.39, 77.63)	0.0045	
	>=65 years	28/ 70 (40.0)	NE (5.3, NE)	3/ 35 (8.6)	NE (NE , NE)	5.39 (1.63, 17.77)	0.0020	
	Sex							0.9887
	female	8/ 30 (26.7)	NE (7.8, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	male	40/ 95 (42.1)	NE (1.9, NE)	4/ 47 (8.5)	NE (NE , NE)	5.87 (2.10, 16.41)	0.0001	
	ECOG PS							0.2017
	0	28/ 62 (45.2)	9.8 (1.6, NE)	1/ 30 (3.3)	NE (NE , NE)	16.26 (2.21, 119.71)	0.0002	
	1	20/ 63 (31.7)	NE (7.8, NE)	3/ 32 (9.4)	NE (NE , NE)	3.51 (1.04, 11.89)	0.0334	
	HER2 Status in central laboratory							0.7338
	IHC 3+	35/ 96 (36.5)	NE (7.8, NE)	3/ 47 (6.4)	NE (NE , NE)	5.98 (1.83, 19.52)	0.0008	
	IHC 2+/ISH +	13/ 29 (44.8)	NE (0.3, NE)	1/ 15 (6.7)	NE (NE , NE)	8.94 (1.17, 68.48)	0.0108	
	Primary tumor location							0.9883
	Gastric	43/108 (39.8)	NE (5.3, NE)	4/ 55 (7.3)	NE (NE , NE)	6.29 (2.25, 17.56)	<.0001	
	GEJ	5/ 17 (29.4)	NE (1.7, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	Histological subtype							0.3706
	intestinal	39/ 89 (43.8)	9.8 (1.9, NE)	3/ 38 (7.9)	NE (NE , NE)	6.43 (1.98, 20.85)	0.0004	
	diffuse	8/ 28 (28.6)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
	others	1/ 8 (12.5)	NE (0.3, NE)	1/ 6 (16.7)	NE (0.4, NE)	0.80 (0.05, 12.84)	0.8757	
	Number of metastatic sites							0.9898
	<2	11/ 23 (47.8)	5.3 (0.3, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	>= 2	37/102 (36.3)	NE (7.8, NE)	4/ 52 (7.7)	NE (NE , NE)	5.27 (1.87, 14.82)	0.0005	
	Previous total gastrectomy							0.1954
	yes	4/ 22 (18.2)	NE (NE , NE)	1/ 9 (11.1)	NE (0.5, NE)	1.81 (0.20, 16.18)	0.5951	
	no	44/103 (42.7)	9.8 (5.0, NE)	3/ 53 (5.7)	NE (NE , NE)	8.59 (2.66, 27.72)	<.0001	
	Prior adjuvant/ neoadjuvant therapy							0.5377
	yes	10/ 30 (33.3)	NE (5.0, NE)	1/ 10 (10.0)	NE (0.5, NE)	3.86 (0.49, 30.24)	0.1670	
	no	38/ 95 (40.0)	NE (5.3, NE)	3/ 52 (5.8)	NE (NE , NE)	7.81 (2.40, 25.35)	<.0001	
	Prior ramucirumab contained treatment							0.8911
	yes	40/ 94 (42.6)	NE (1.9, NE)	3/ 41 (7.3)	NE (NE , NE)	6.68 (2.06, 21.65)	0.0002	
	no	8/ 31 (25.8)	NE (9.8, NE)	1/ 21 (4.8)	NE (NE , NE)	5.46 (0.68, 44.08)	0.0751	

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[e] 2.72E8 represents the number 271641304.29
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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Platelet count decreased	Prior nivolumab contained treatment							0.5384
	yes	18/ 33 (54.5)	1.7 (0.3, NE)	1/ 15 (6.7)	NE (NE , NE)	11.38 (1.52, 85.45)	0.0027	
	no	30/ 92 (32.6)	NE (9.8, NE)	3/ 47 (6.4)	NE (NE , NE)	5.23 (1.59, 17.21)	0.0024	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.6485
	yes	20/ 44 (45.5)	NE (0.3, NE)	1/ 17 (5.9)	NE (NE , NE)	10.06 (1.35, 75.02)	0.0052	
	no	28/ 81 (34.6)	NE (7.8, NE)	3/ 45 (6.7)	NE (NE , NE)	5.33 (1.61, 17.61)	0.0022	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9877
	yes	7/ 22 (31.8)	NE (0.3, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	41/103 (39.8)	NE (5.3, NE)	4/ 55 (7.3)	NE (NE , NE)	6.04 (2.16, 16.93)	0.0001	
	Presence of liver metastasis at baseline							0.9895
	yes	29/ 68 (42.6)	9.8 (1.7, NE)	4/ 34 (11.8)	NE (NE , NE)	4.14 (1.45, 11.83)	0.0042	
	no	19/ 57 (33.3)	NE (5.3, NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
	Renal impairment at baseline							0.9999
	normal	13/ 33 (39.4)	NE (5.0, NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
	mild	22/ 53 (41.5)	NE (0.5, NE)	4/ 28 (14.3)	NE (NE , NE)	3.62 (1.25, 10.53)	0.0125	
	moderate	13/ 39 (33.3)	NE (7.8, NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.3602
	normal	33/ 88 (37.5)	NE (7.8, NE)	2/ 47 (4.3)	NE (NE , NE)	9.55 (2.29, 39.92)	0.0002	
	mild	15/ 36 (41.7)	NE (0.3, NE)	2/ 15 (13.3)	NE (NE , NE)	3.83 (0.87, 16.77)	0.0558	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9904
	yes	1/ 8 (12.5)	NE (0.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
	no	47/117 (40.2)	NE (5.3, NE)	4/ 57 (7.0)	NE (NE , NE)	6.43 (2.31, 17.90)	<.0001	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9994
	yes	0/ 3 (0.0)	NE (NE , NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	48/122 (39.3)	NE (5.3, NE)	4/ 58 (6.9)	NE (NE , NE)	6.40 (2.30, 17.79)	<.0001	

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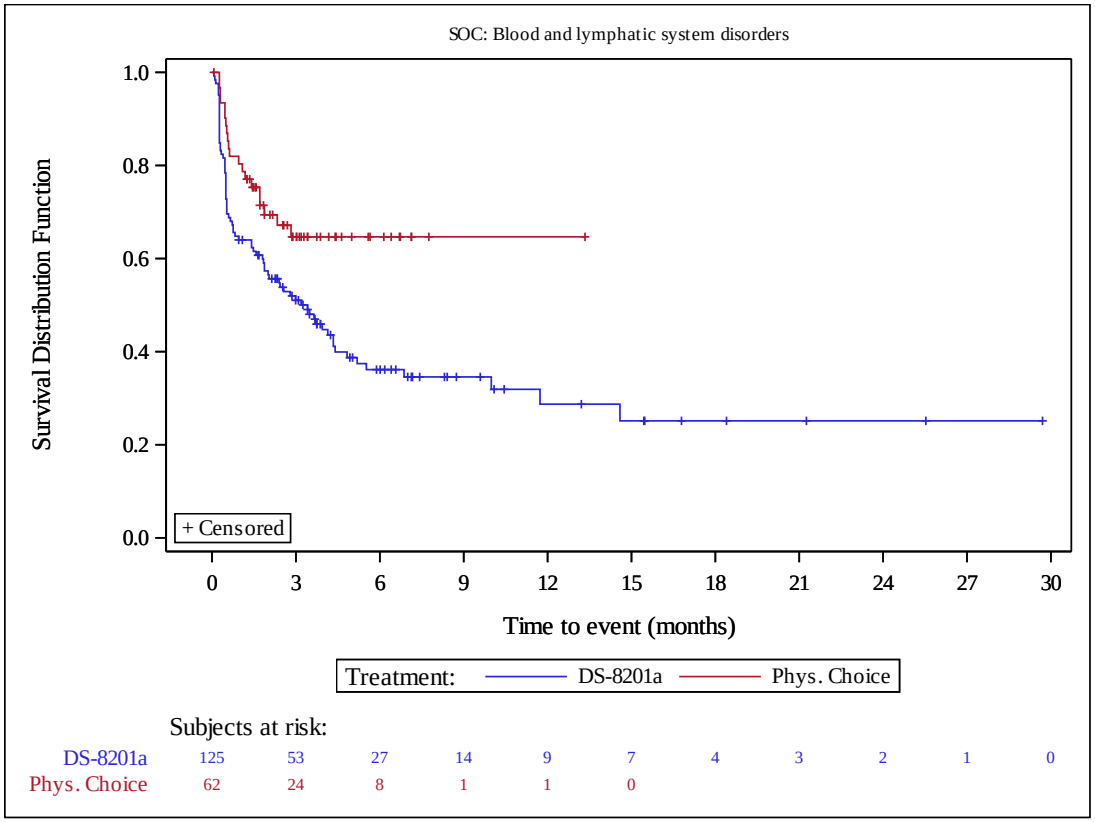
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
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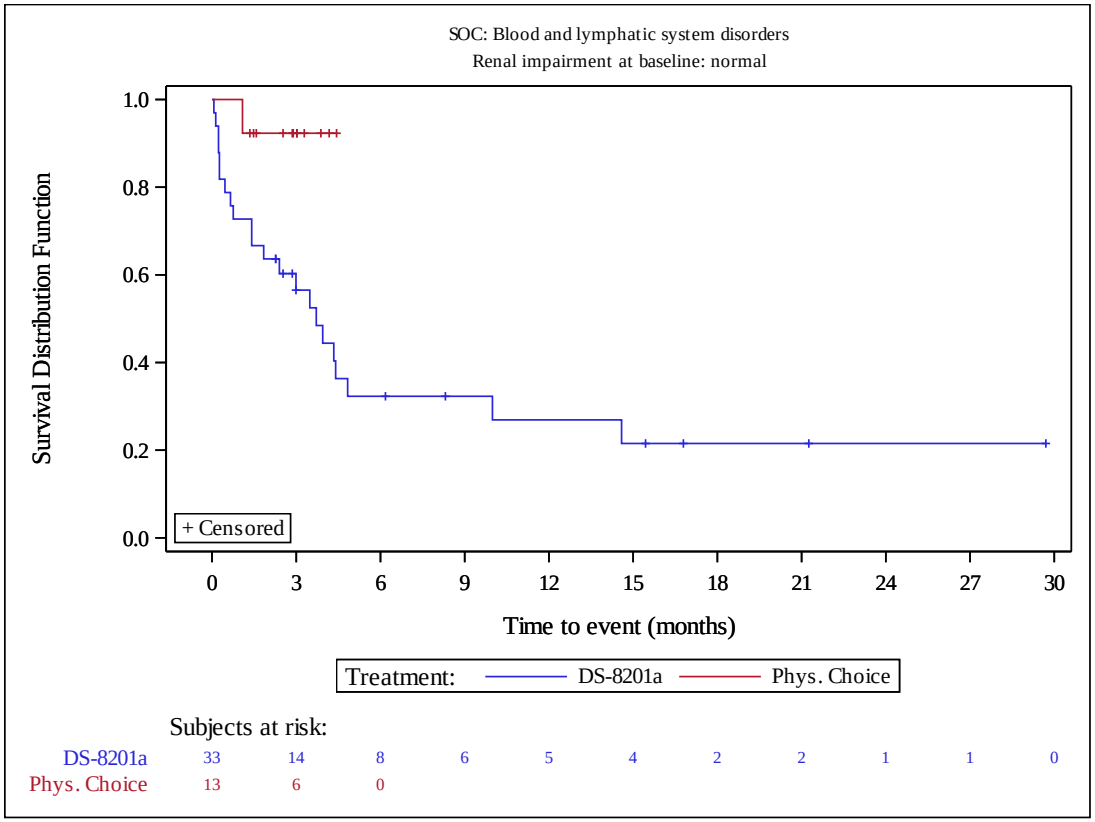

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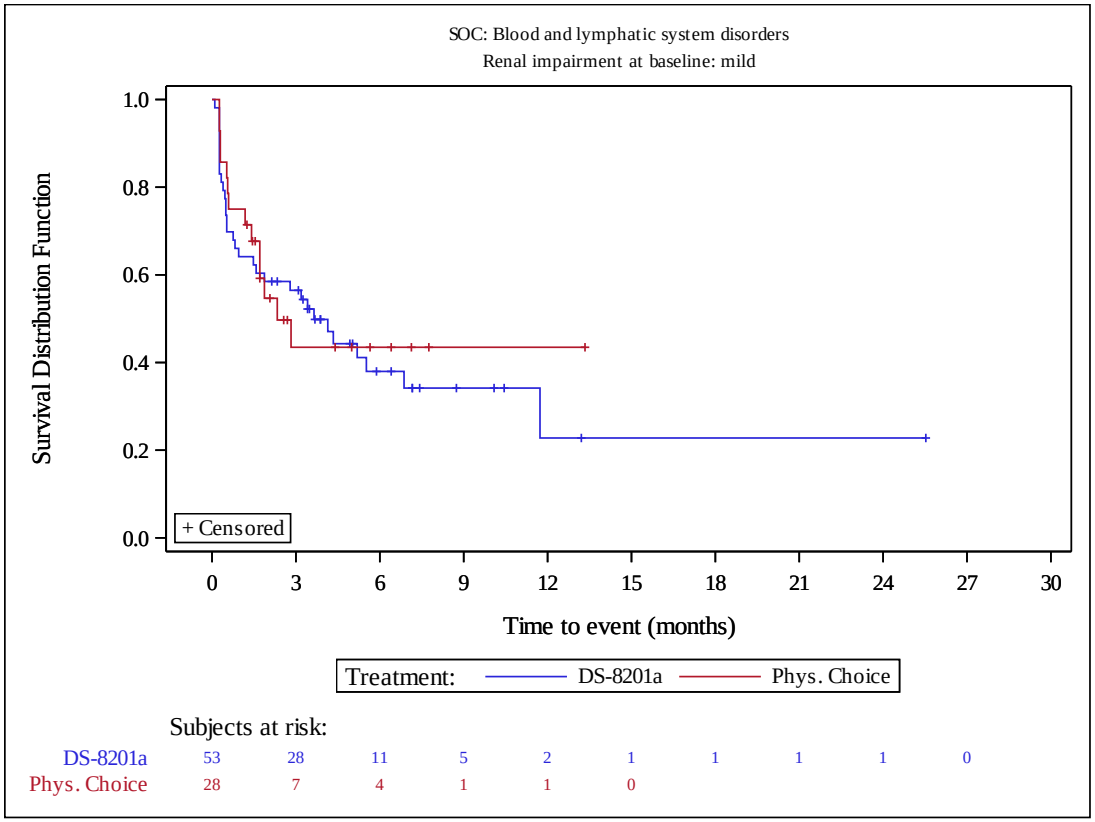

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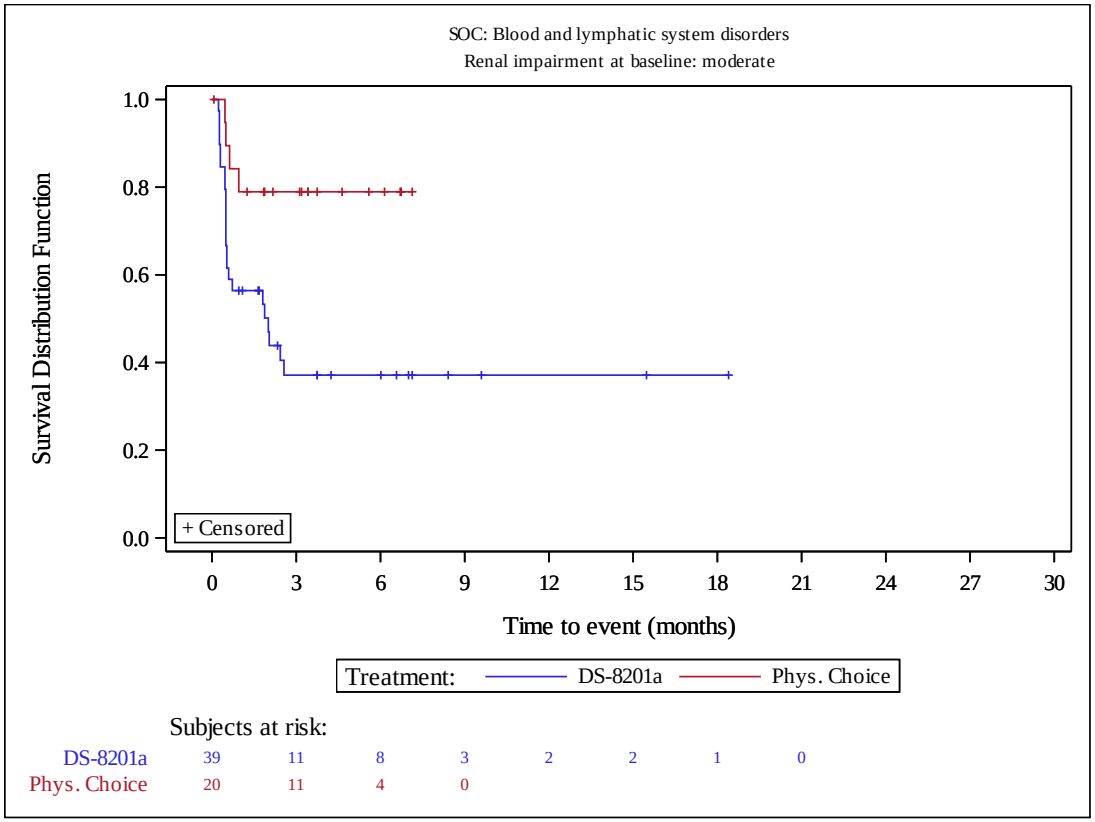

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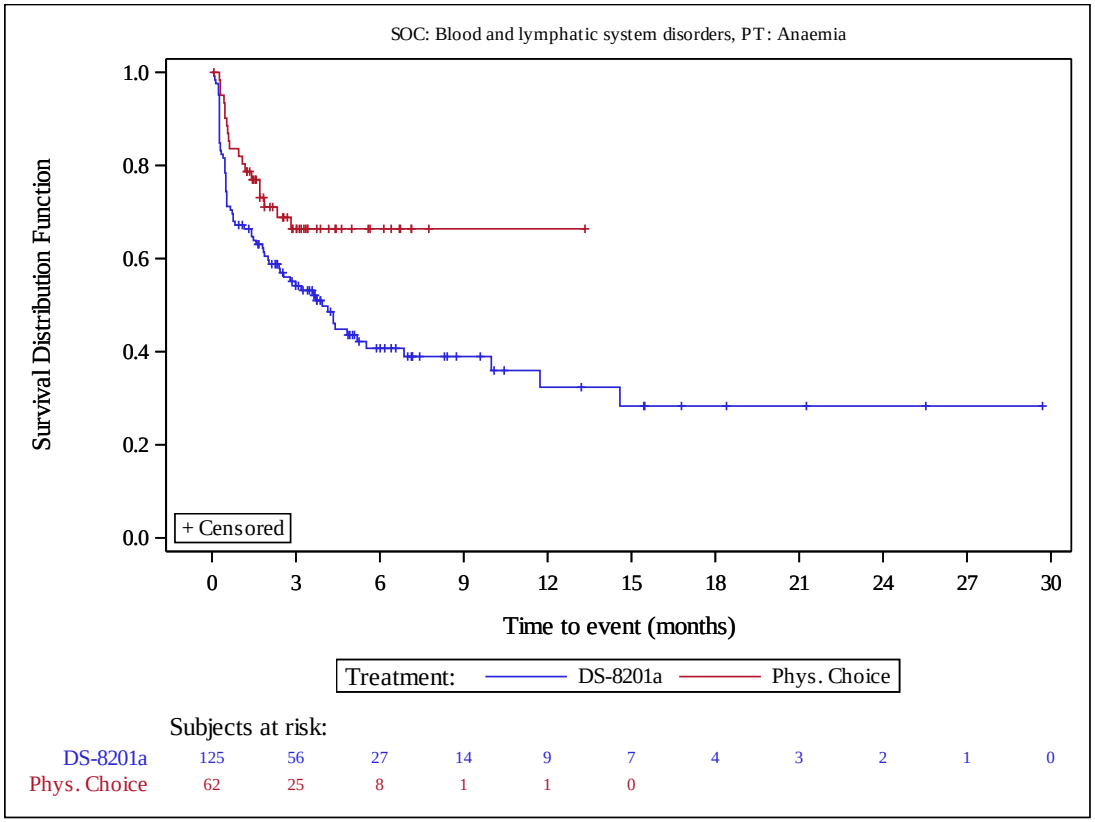

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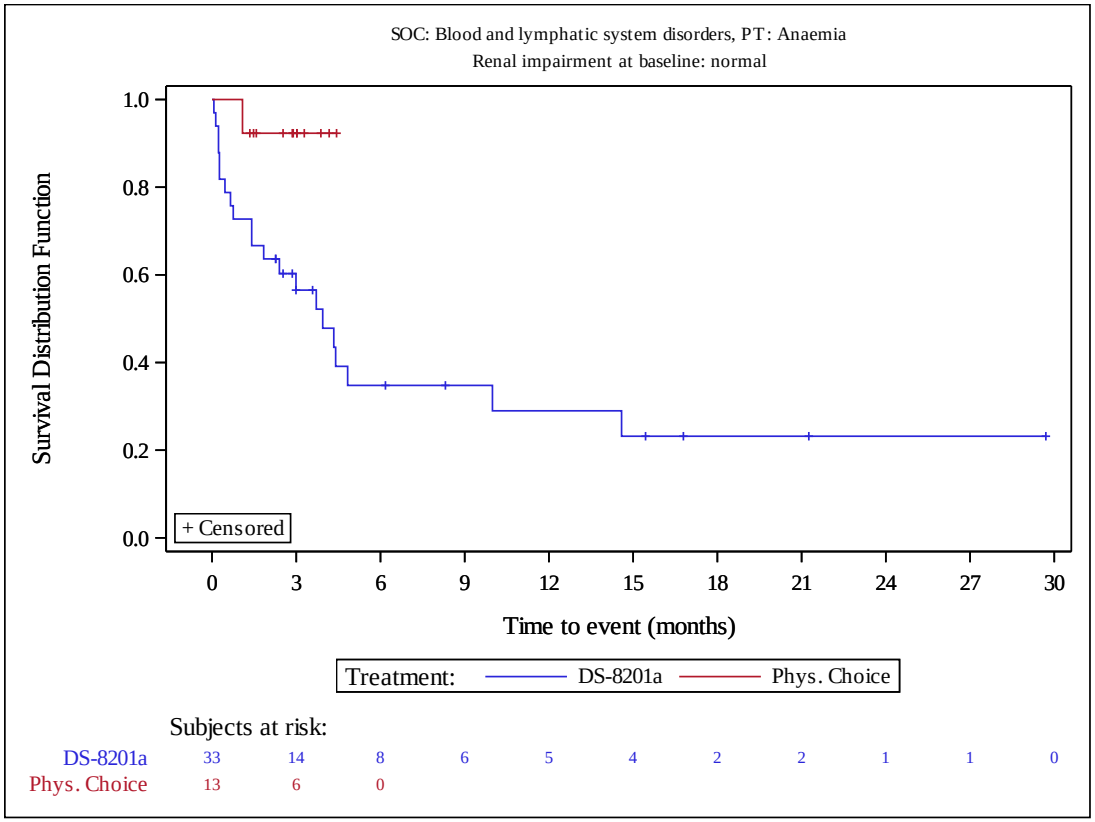

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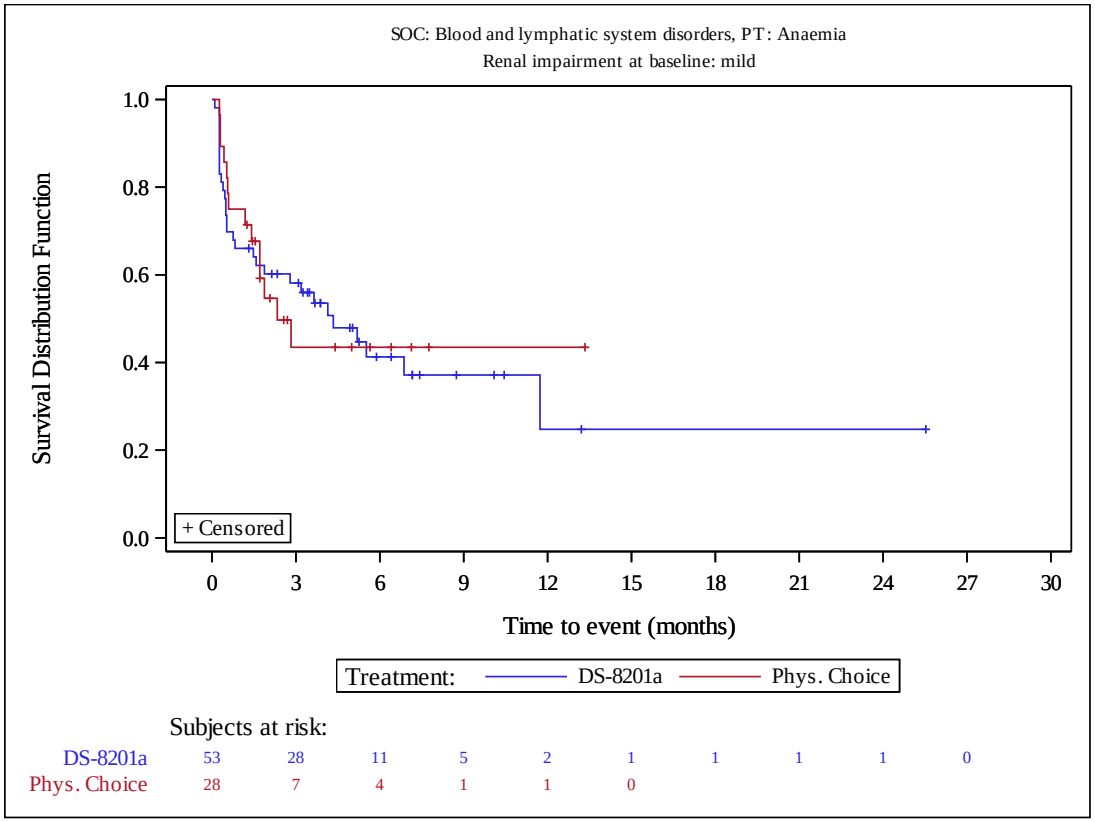

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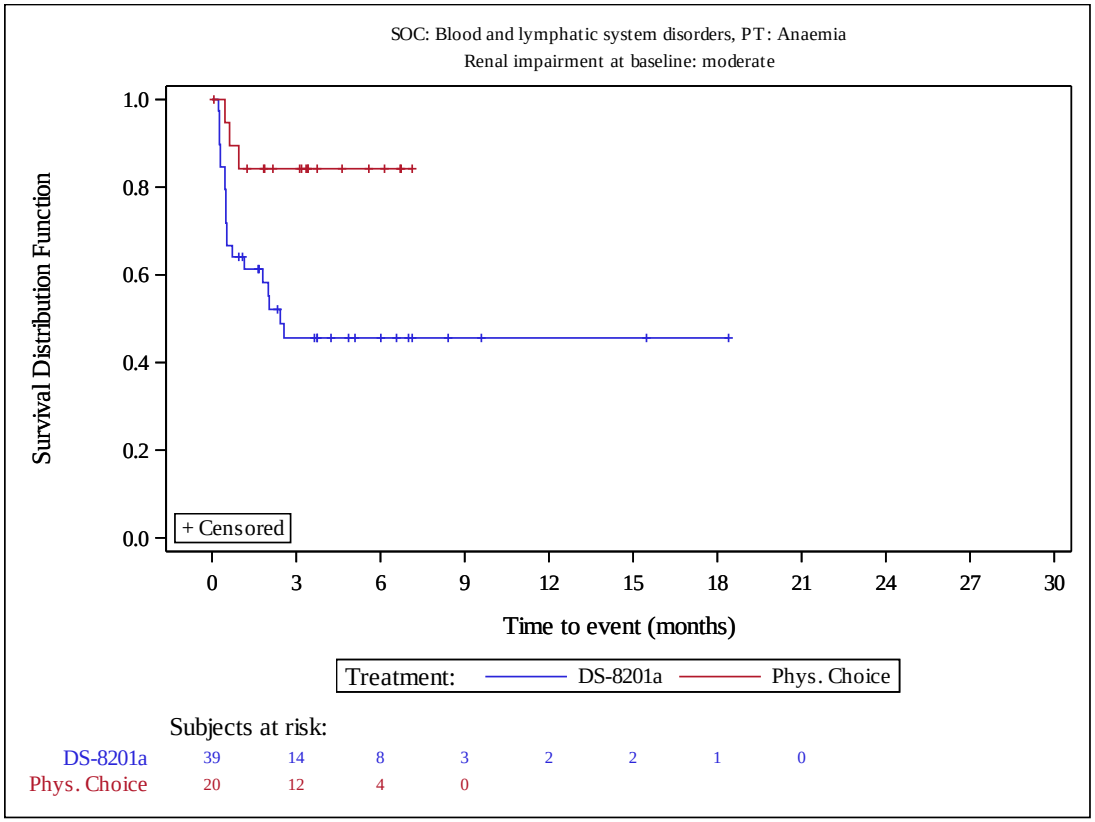

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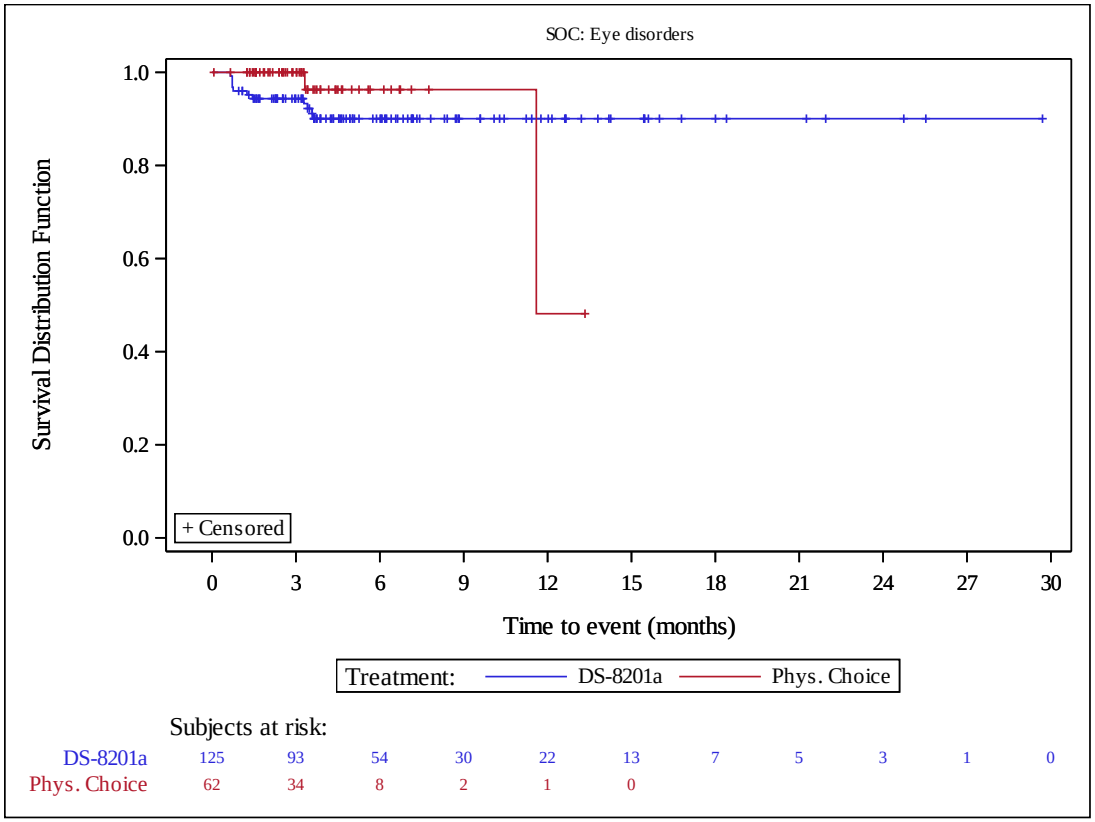

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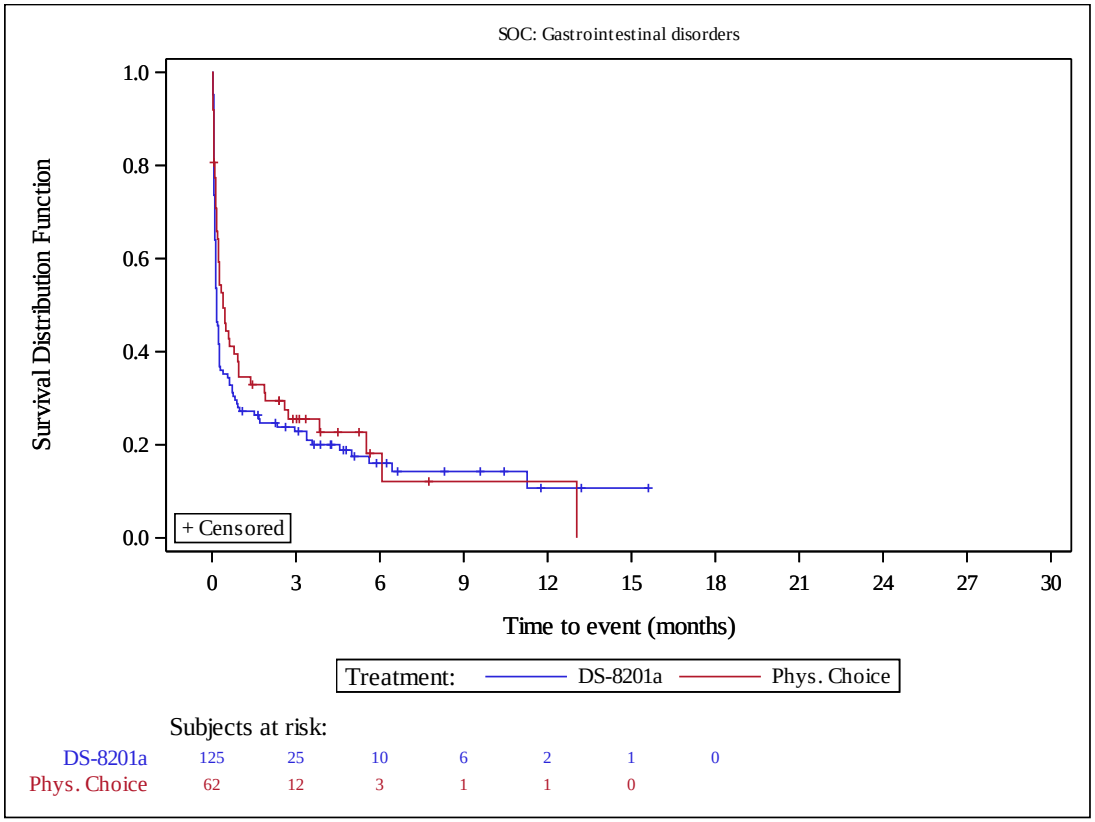

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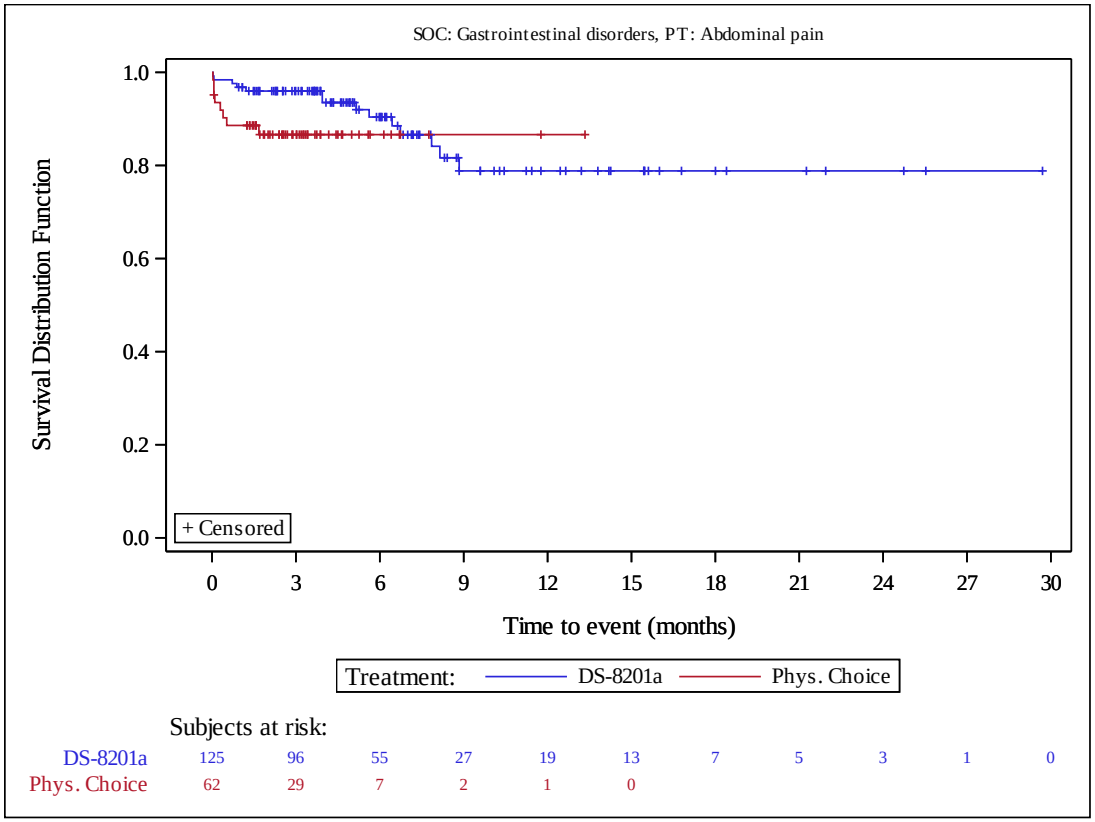

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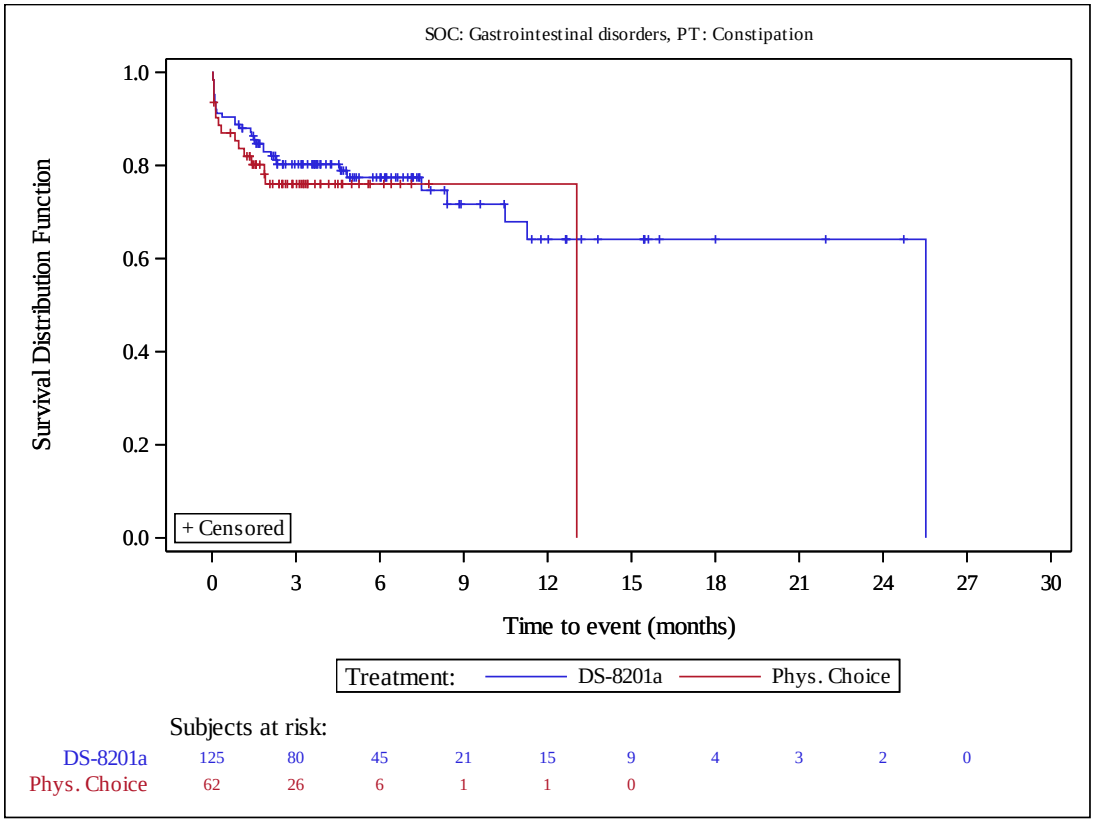

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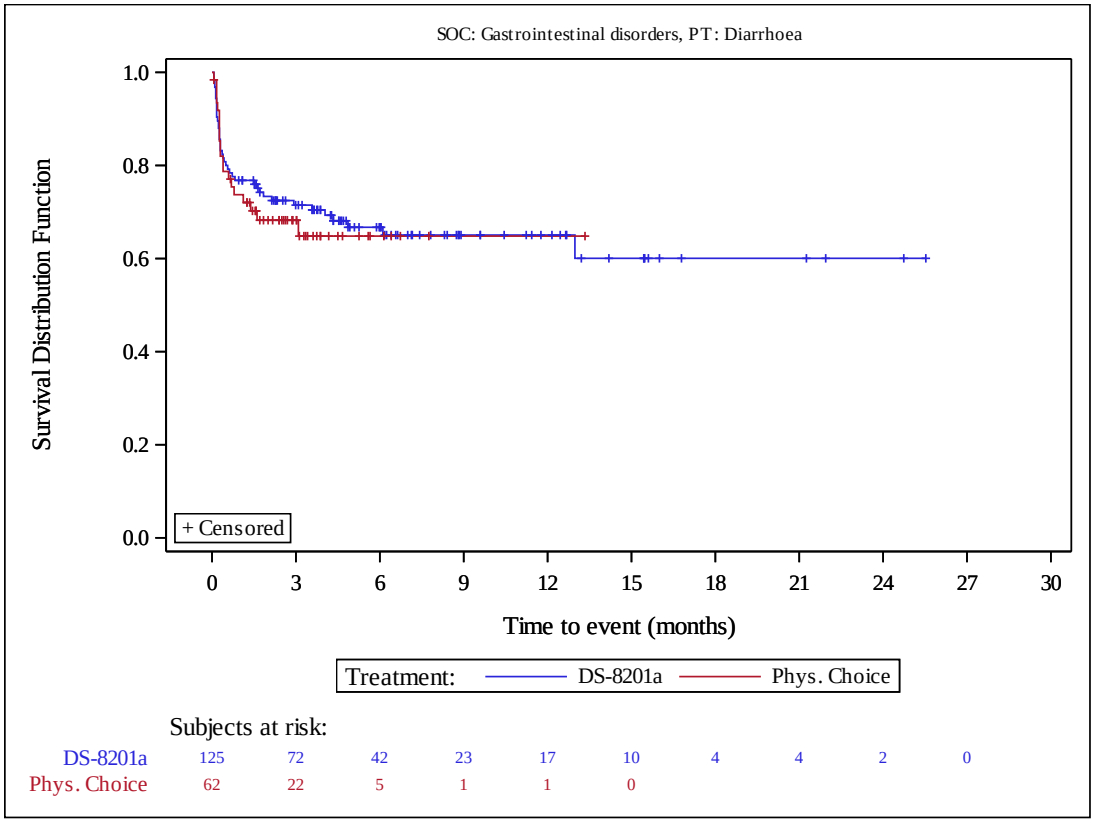

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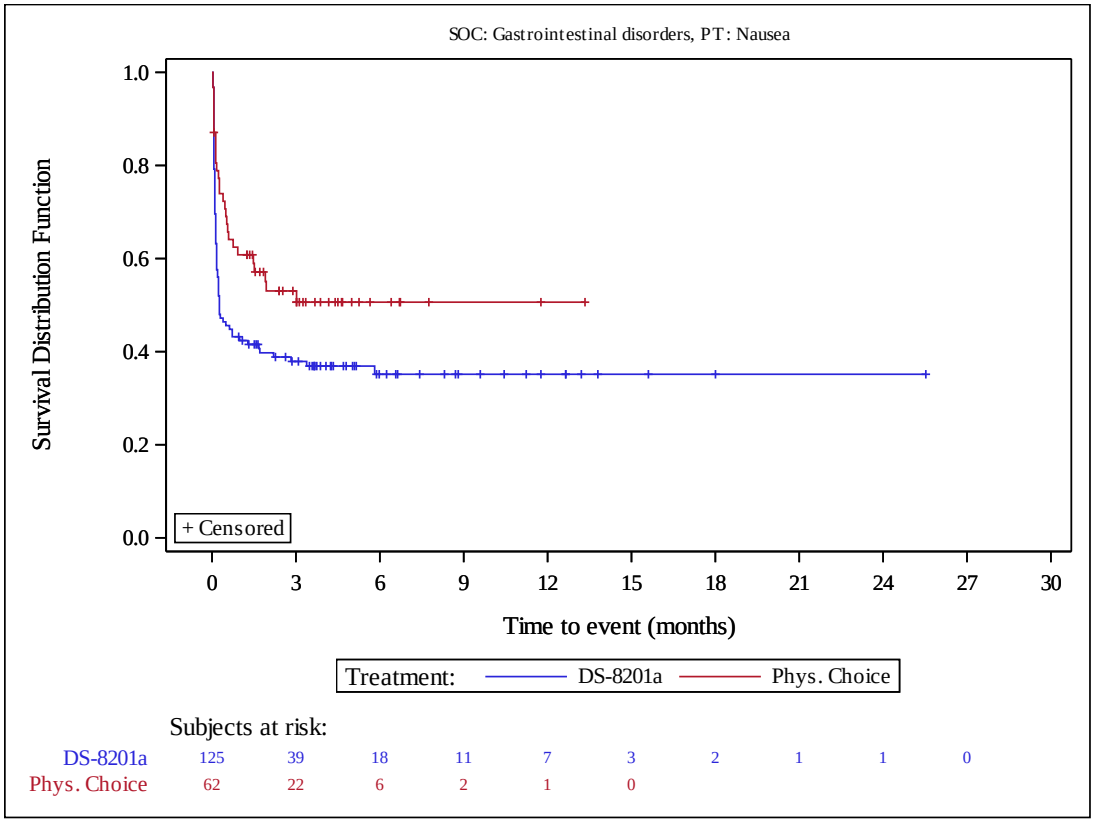

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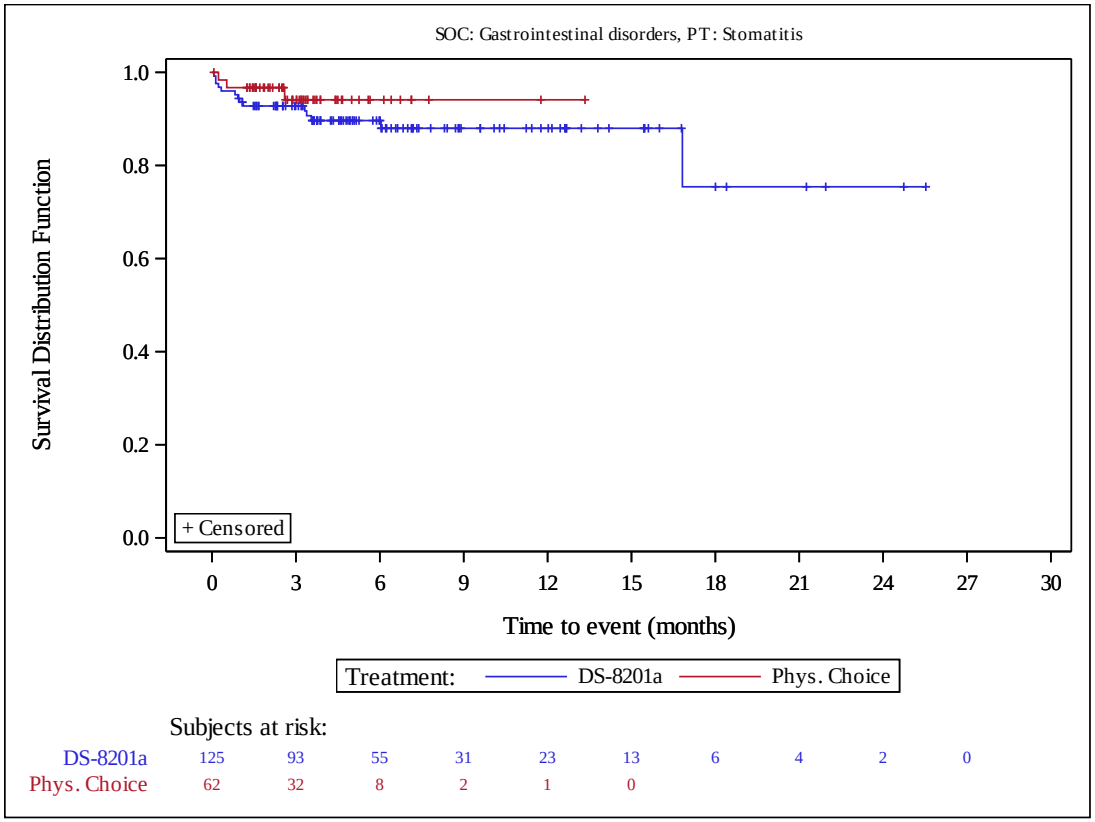

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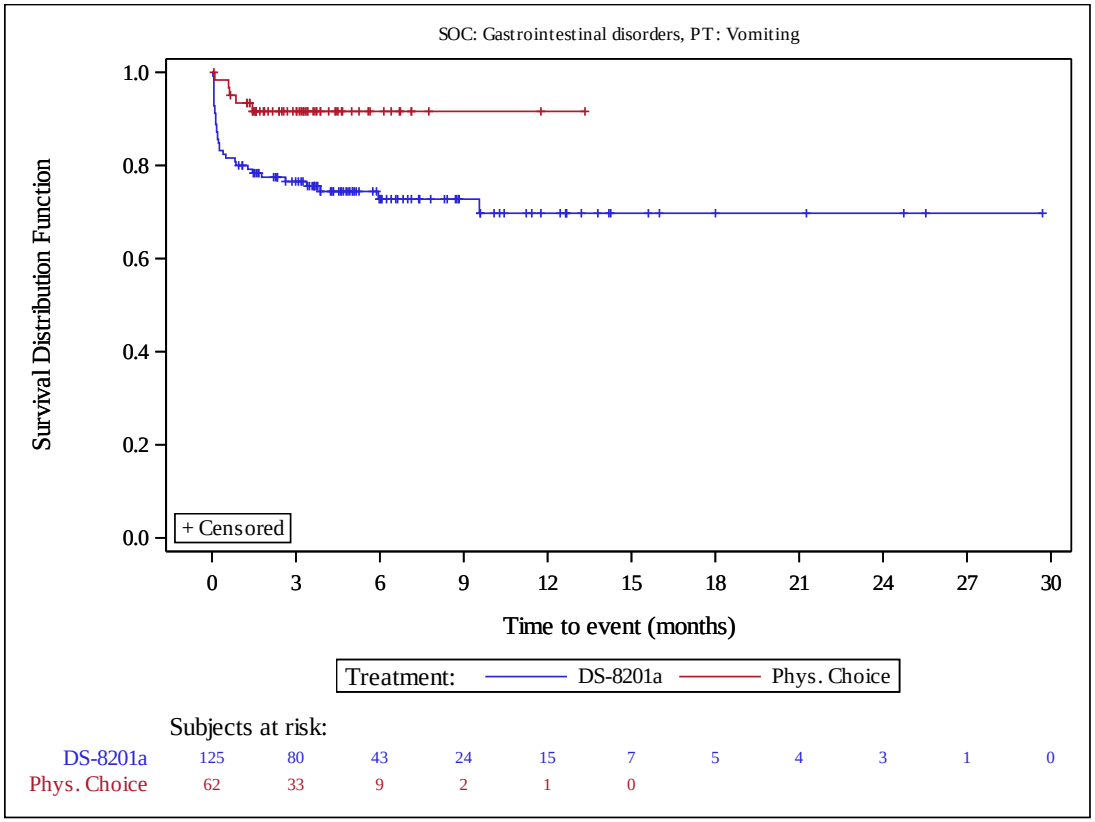

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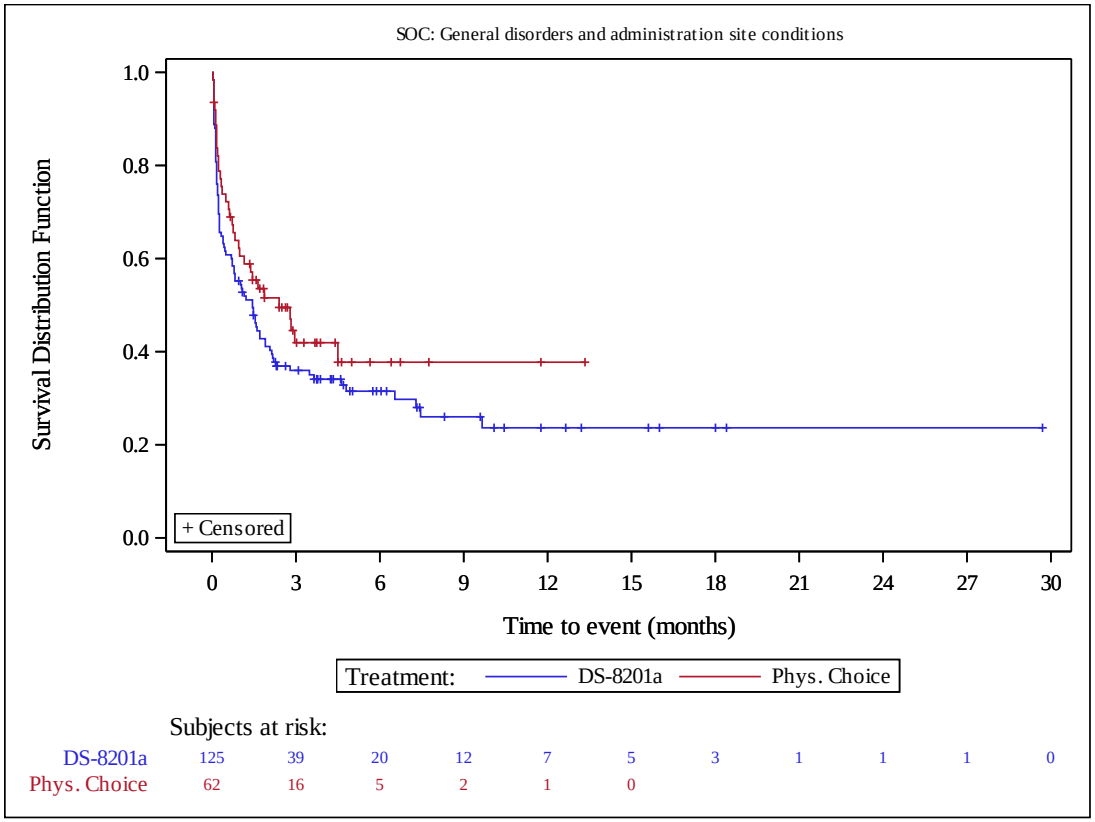

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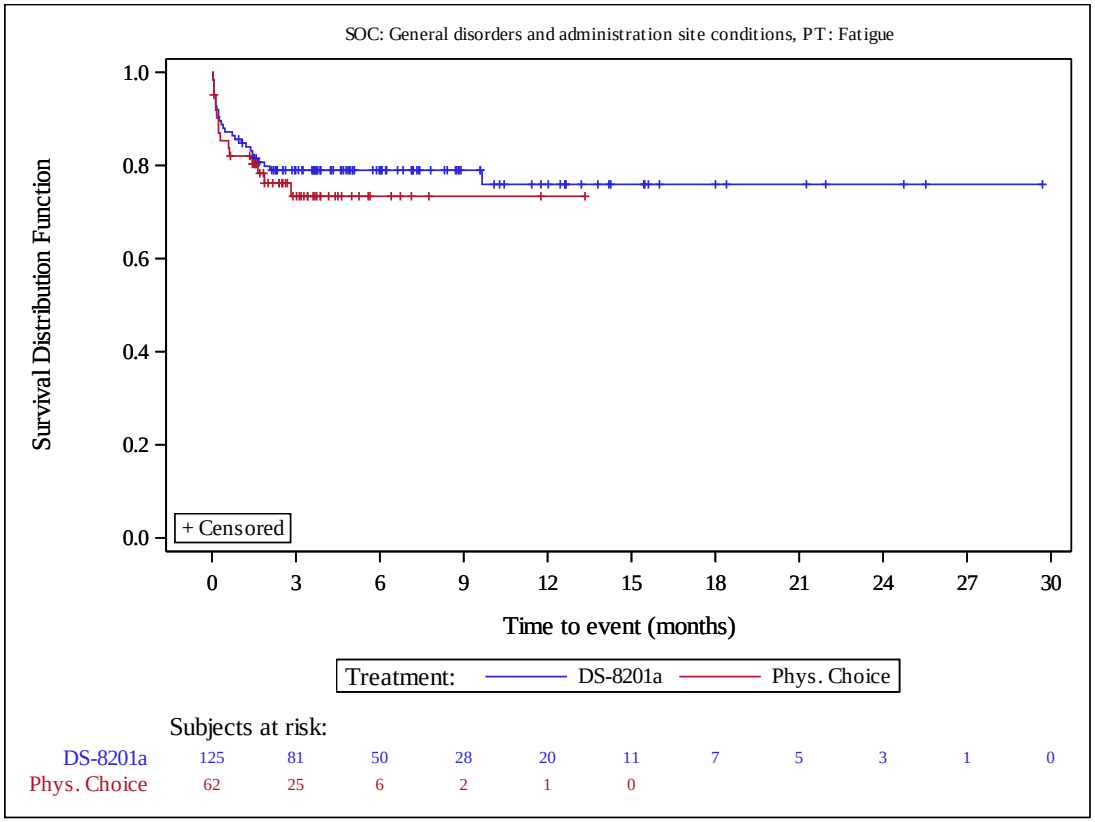

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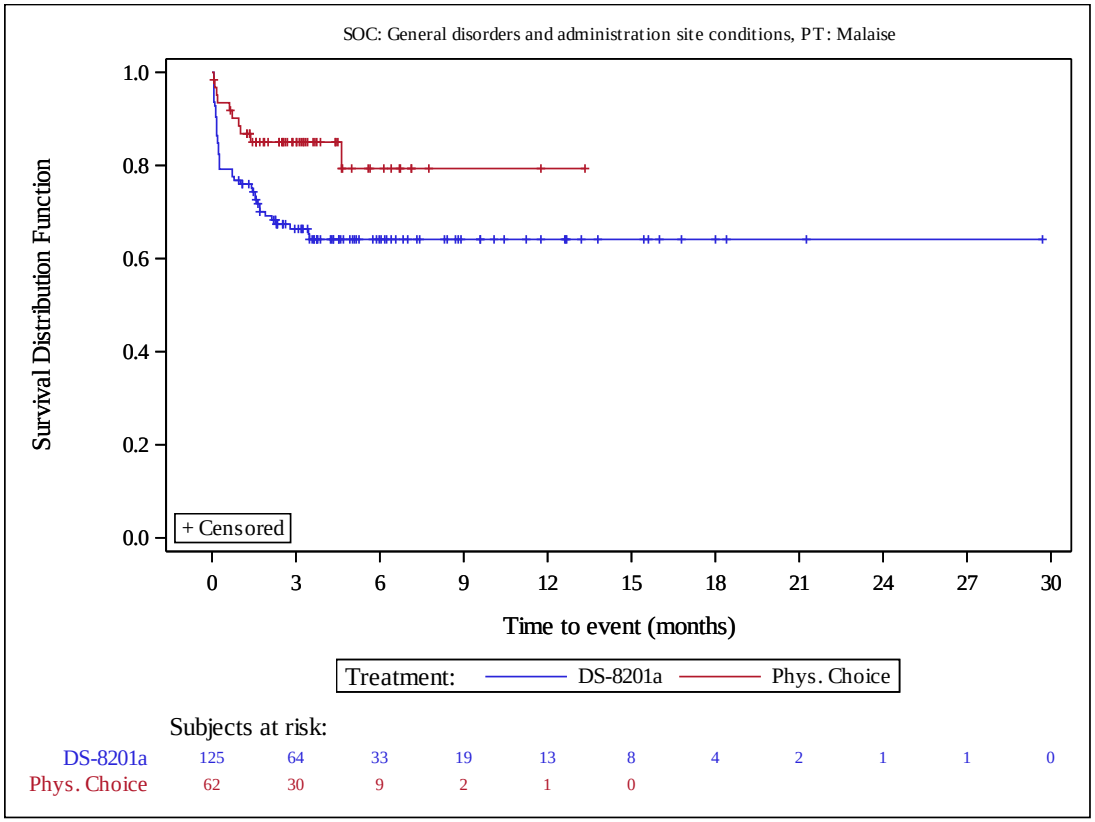

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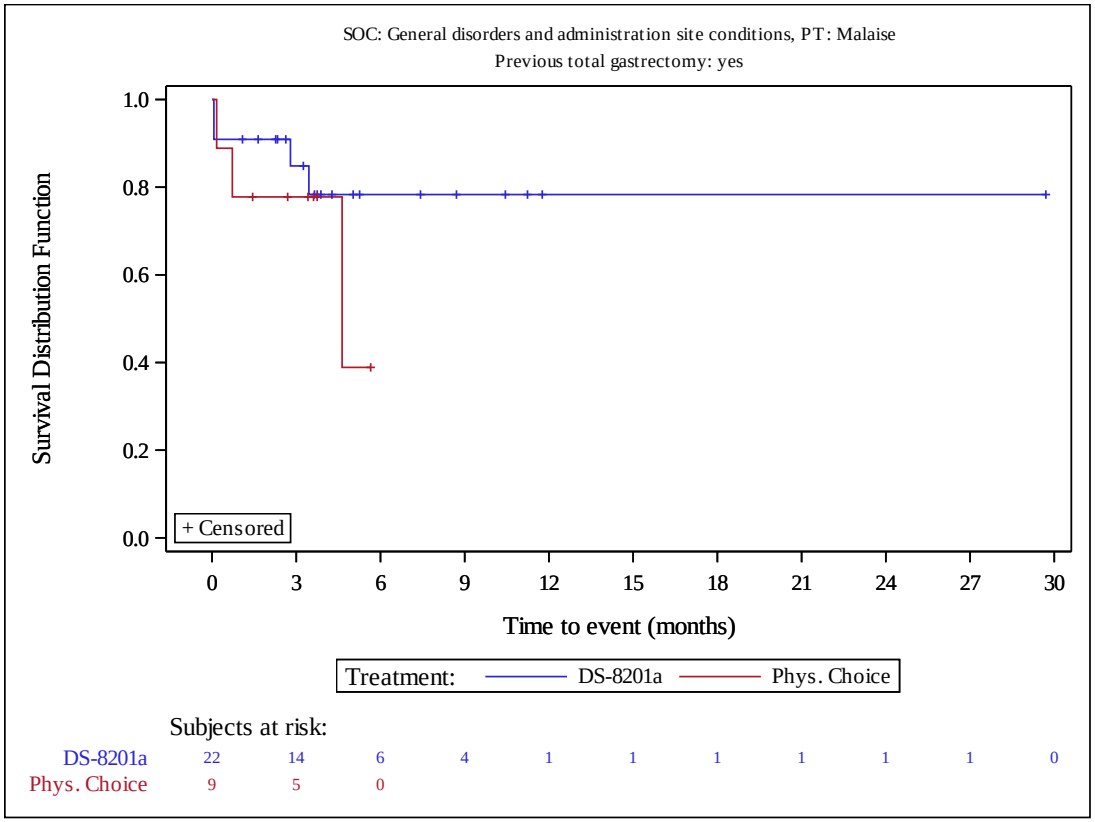

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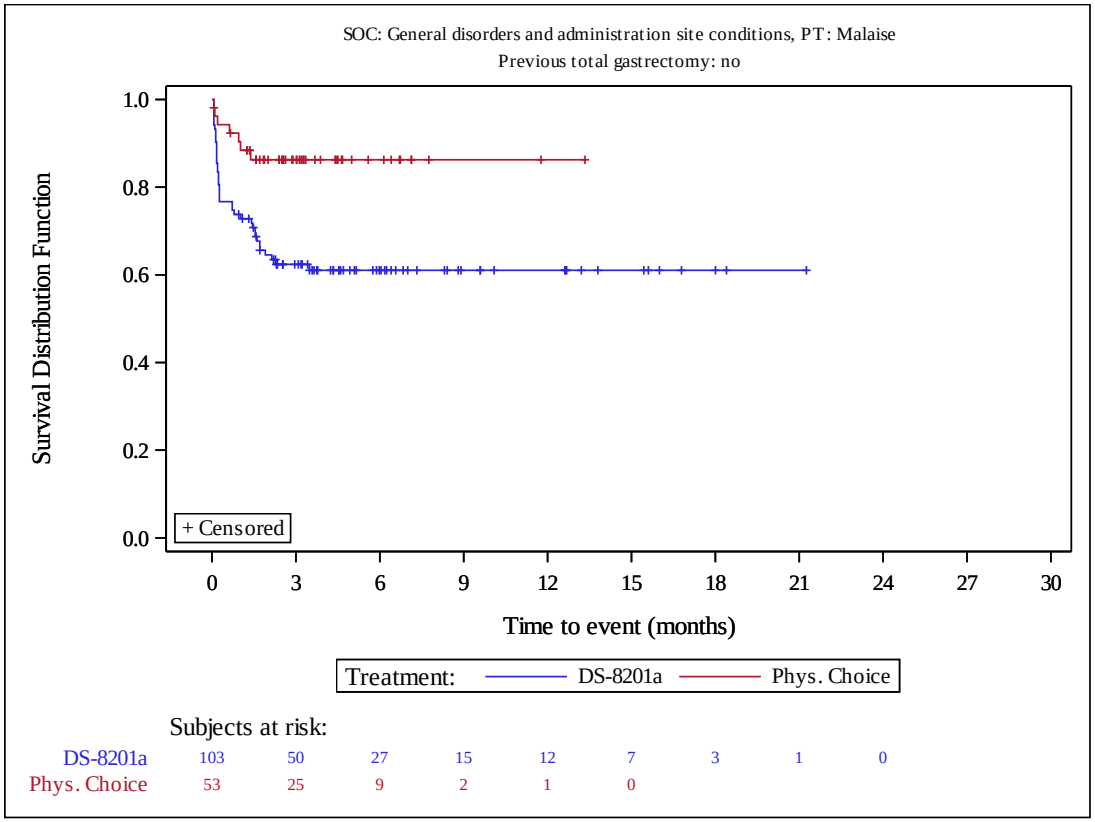

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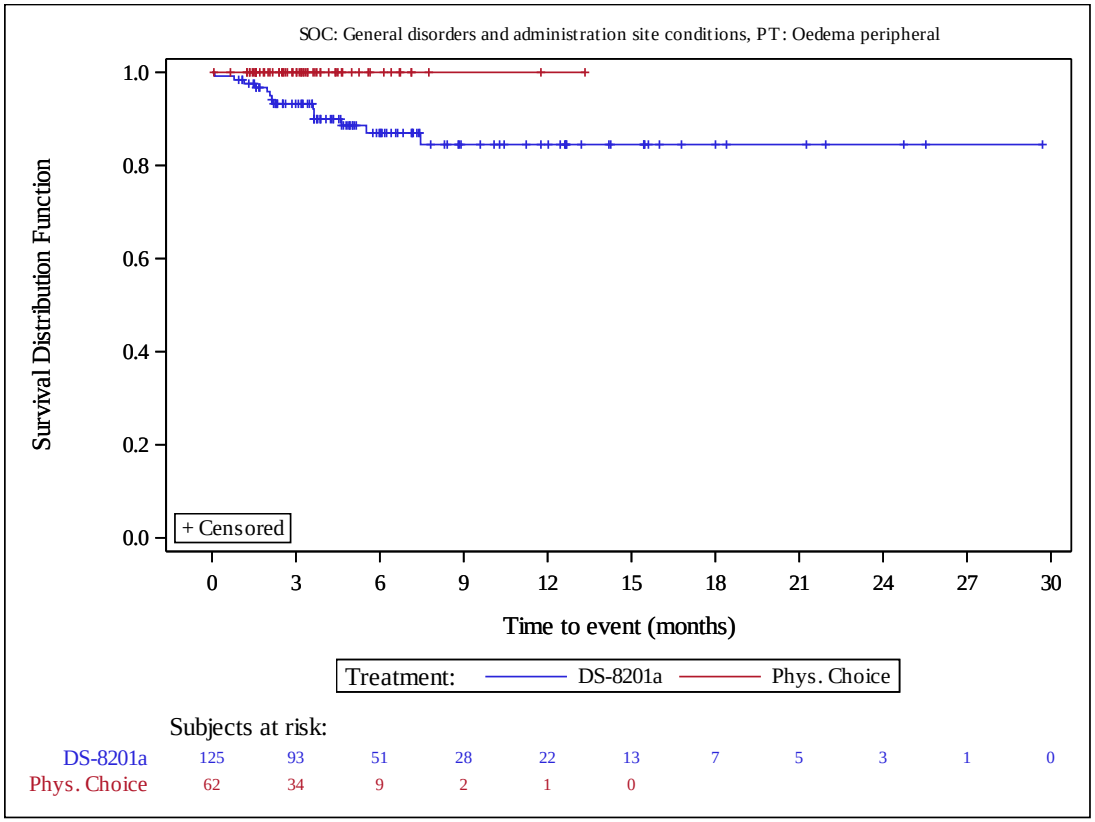

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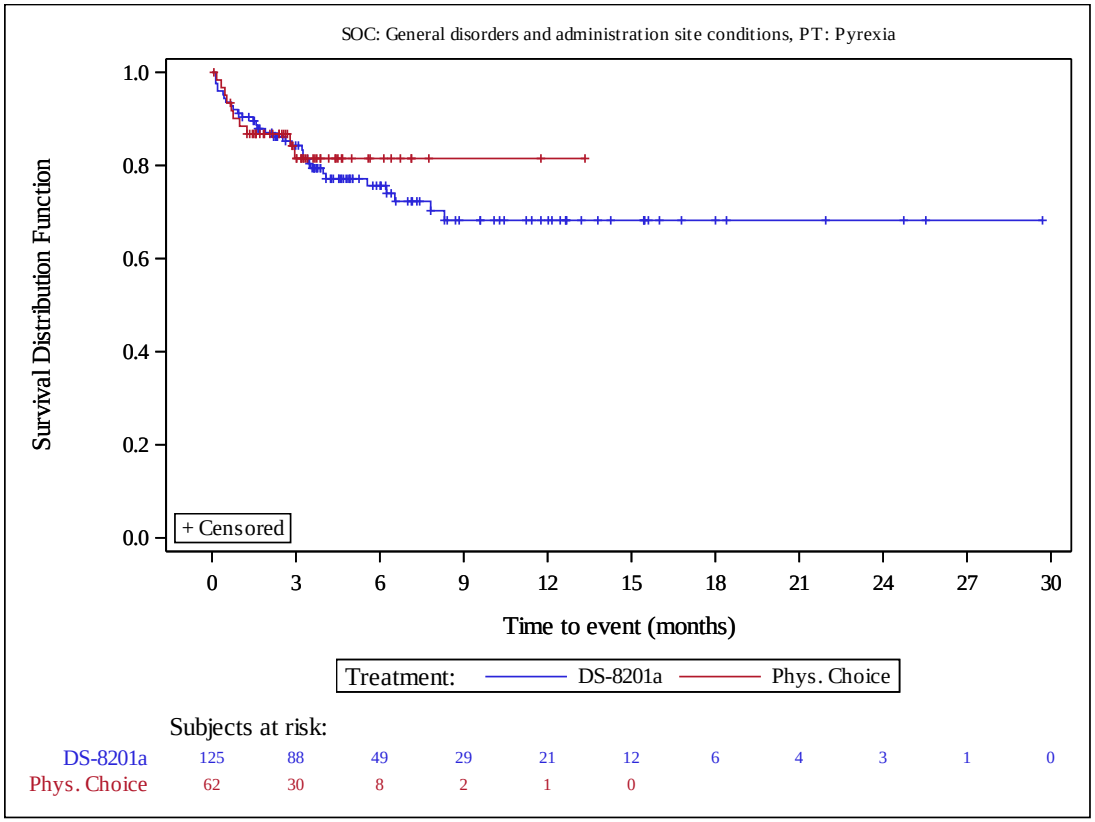

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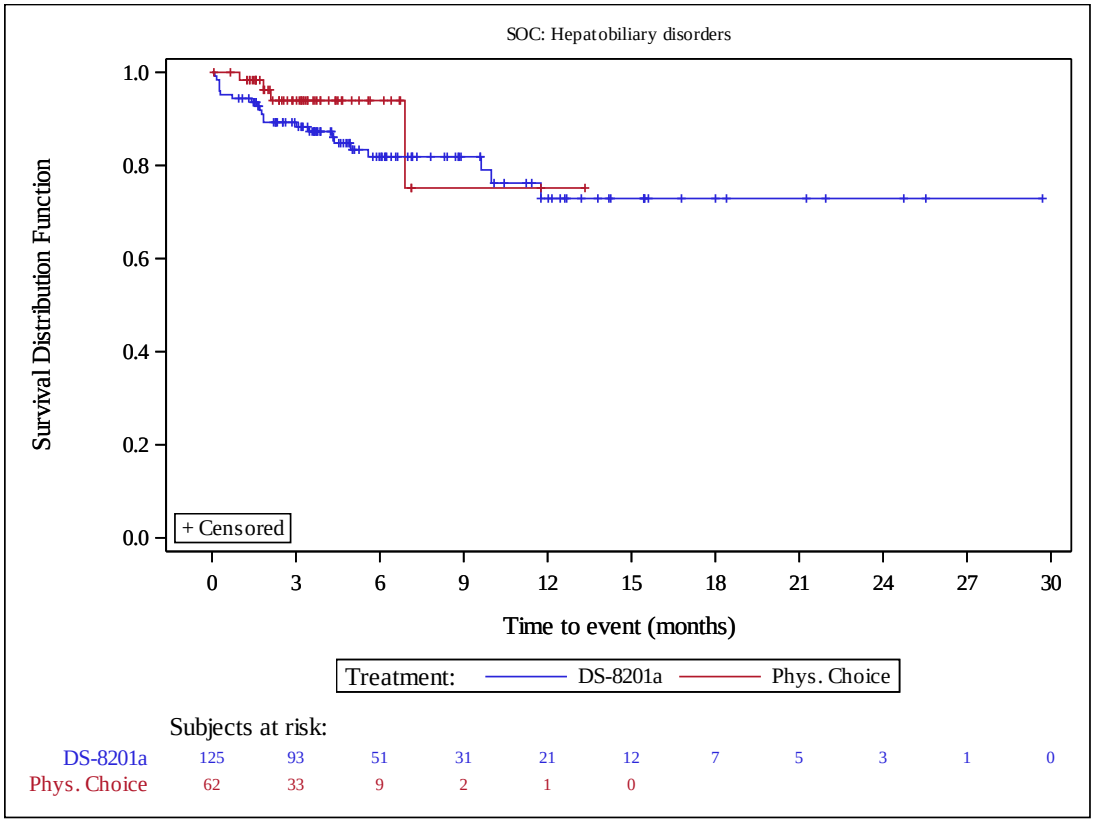

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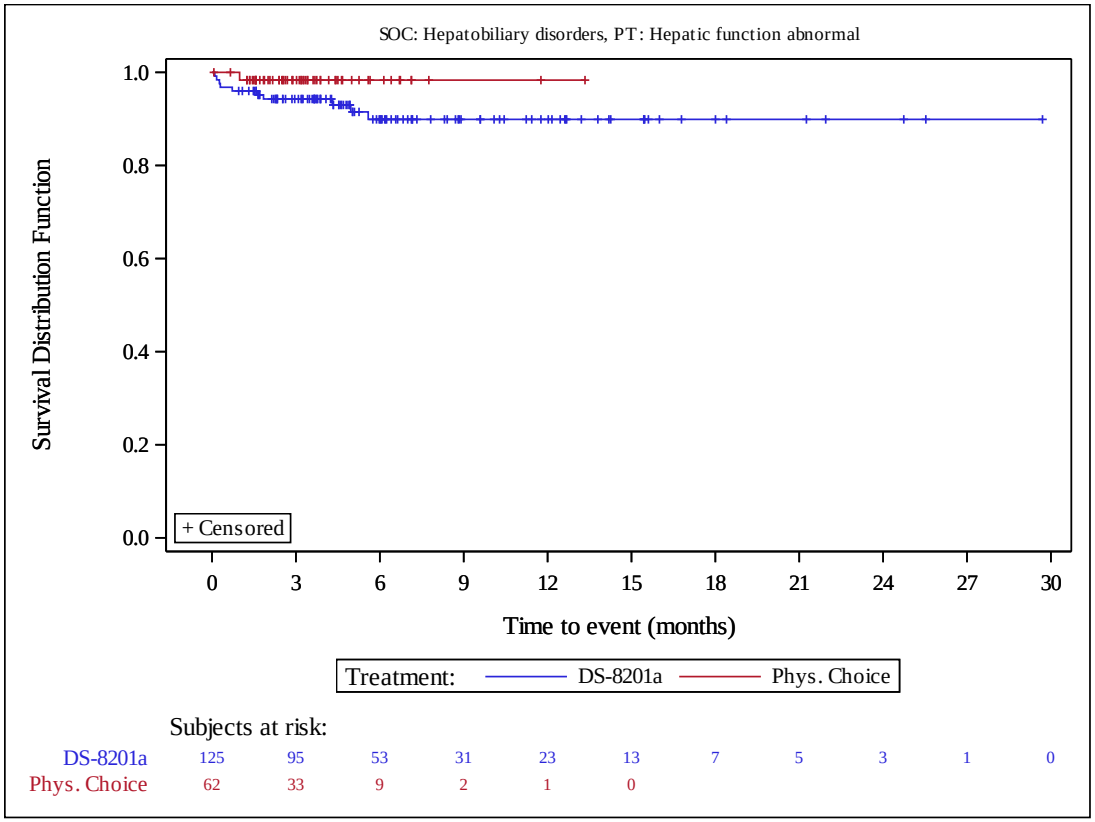

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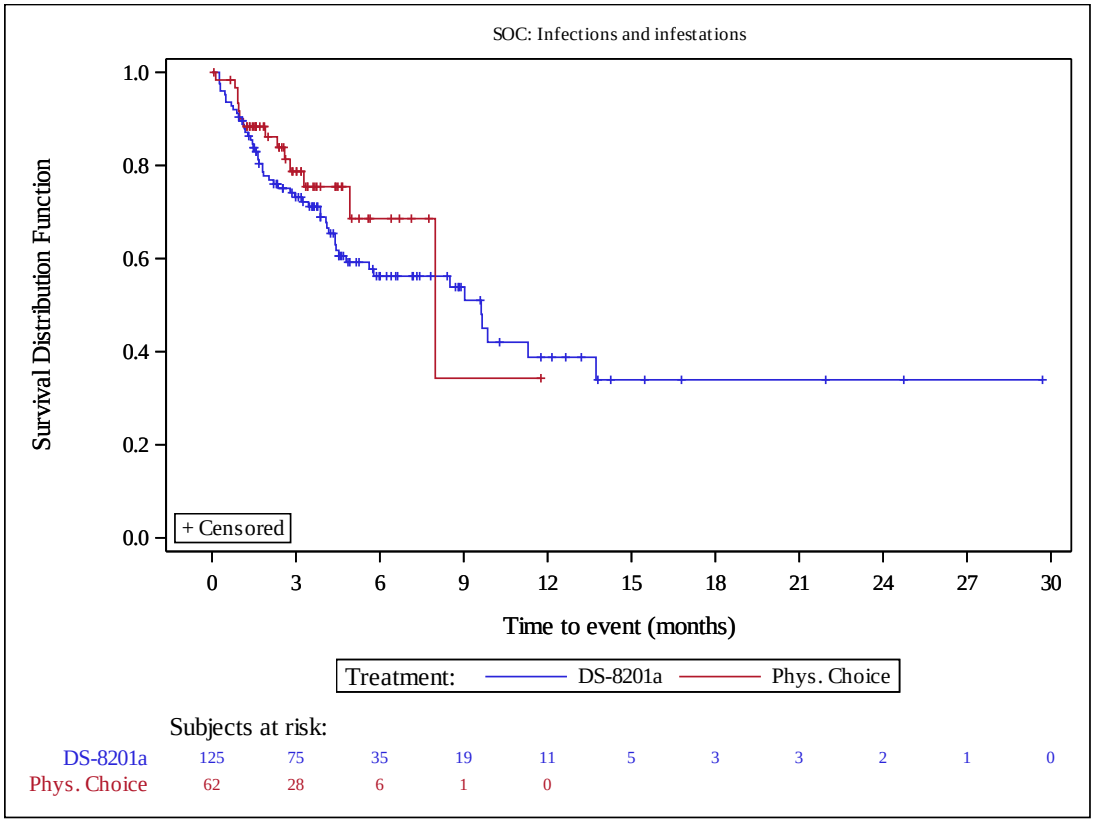

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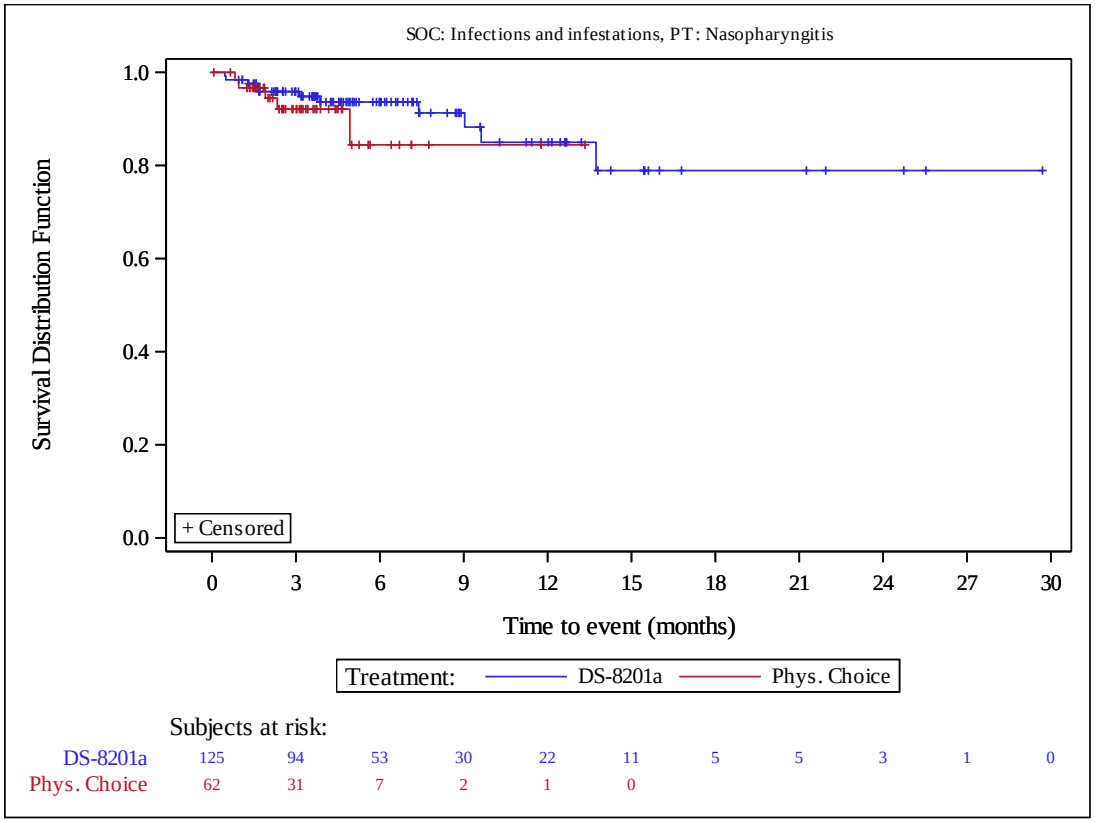

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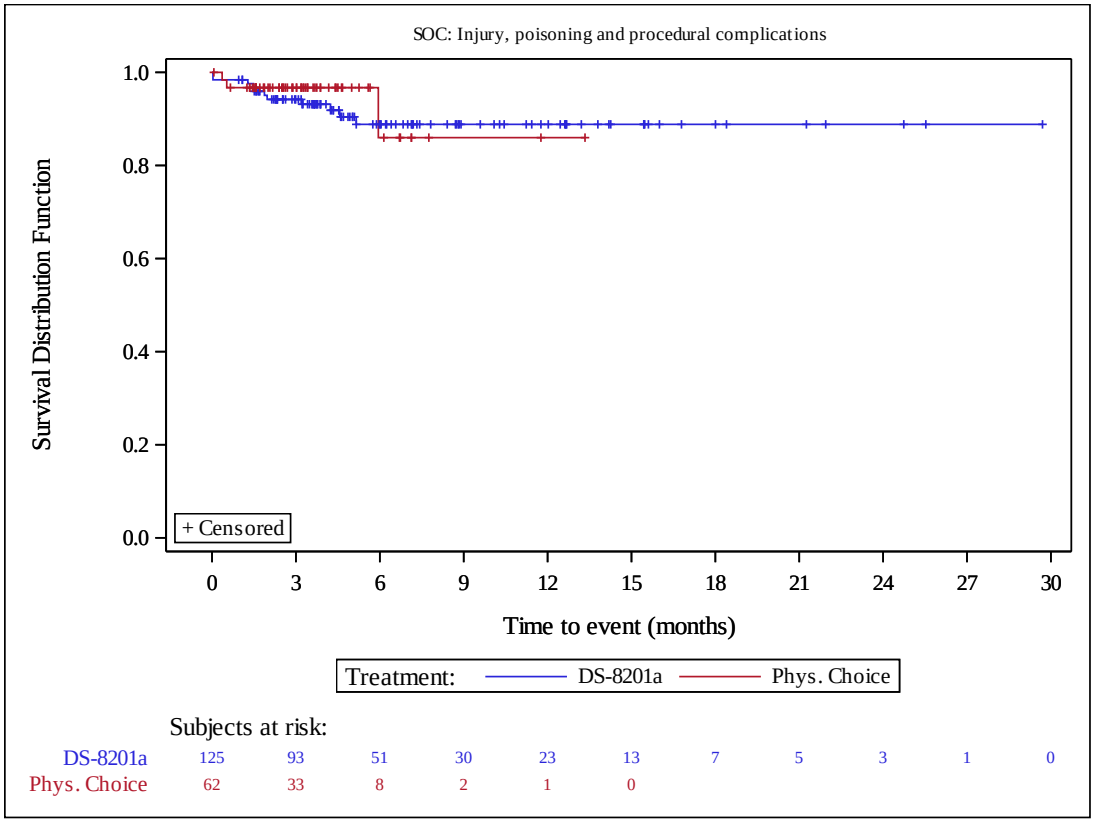

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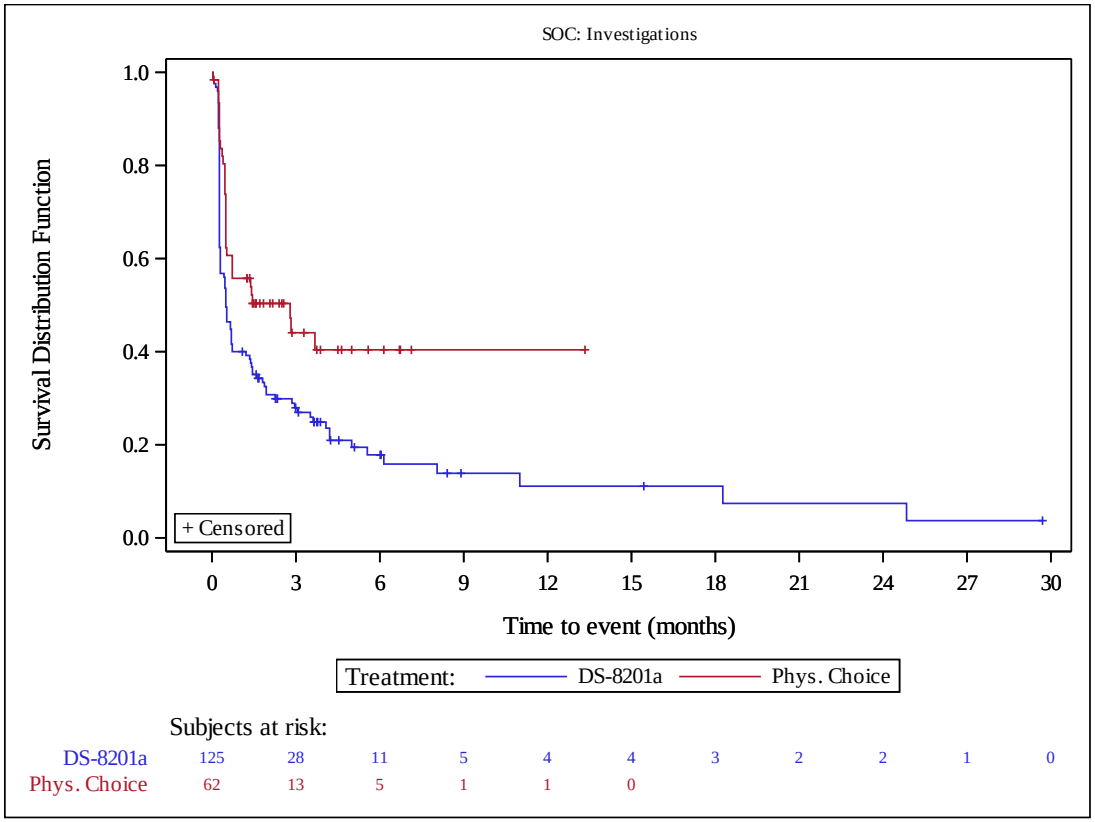

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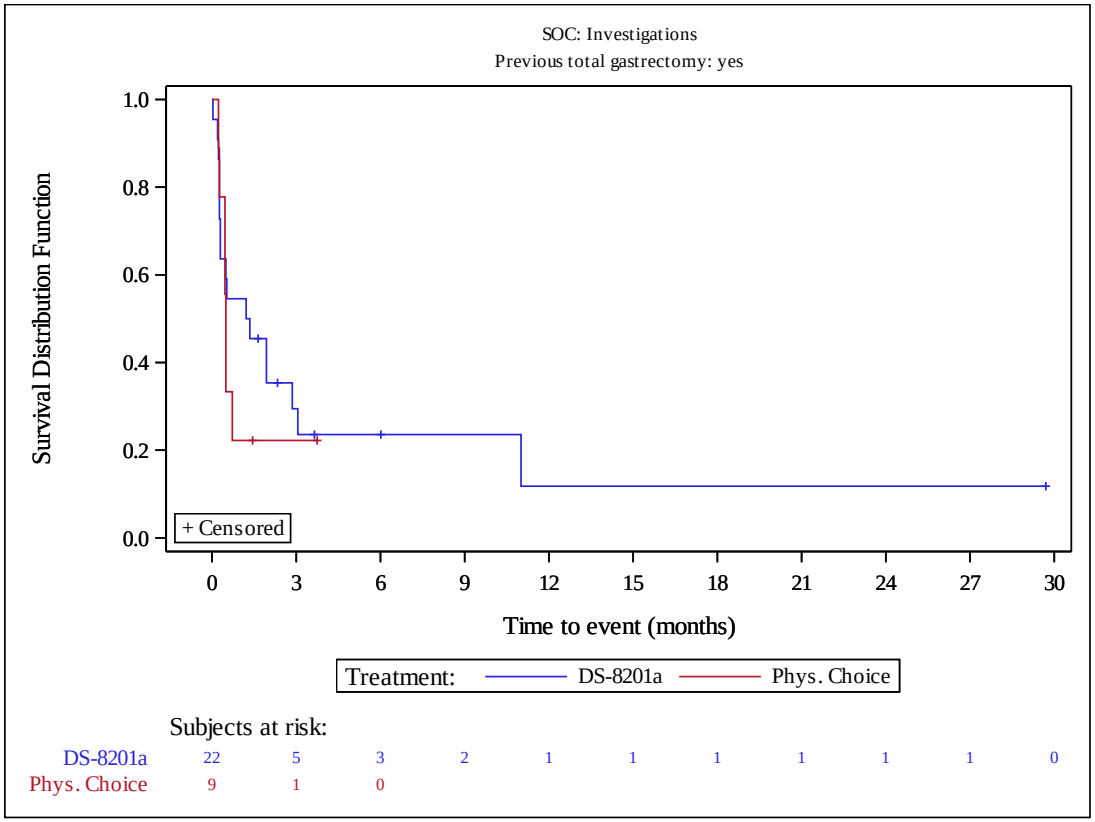

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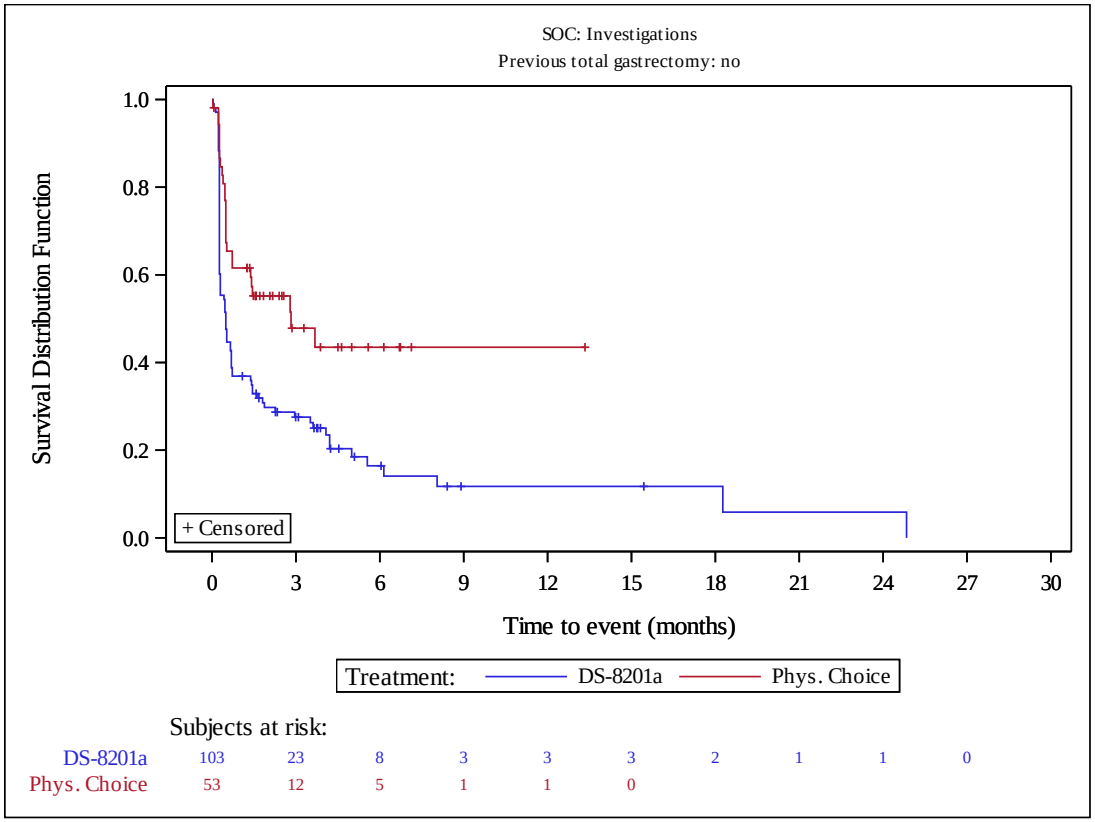

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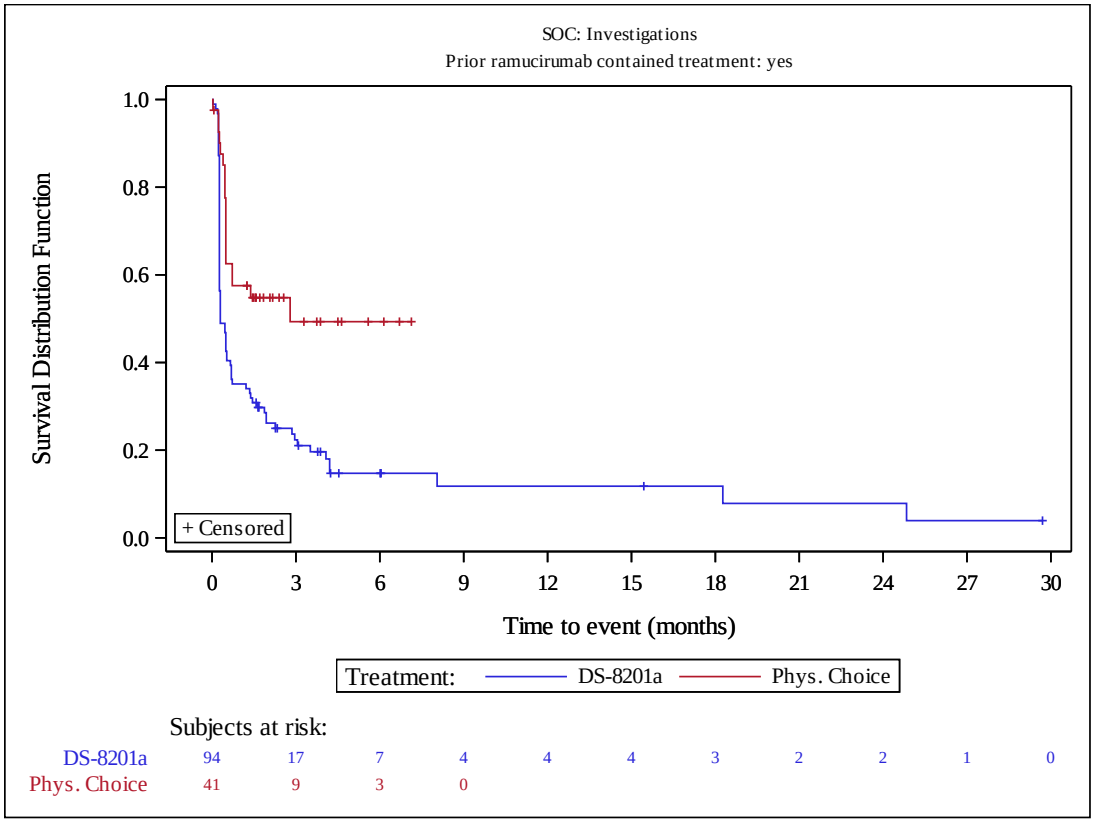

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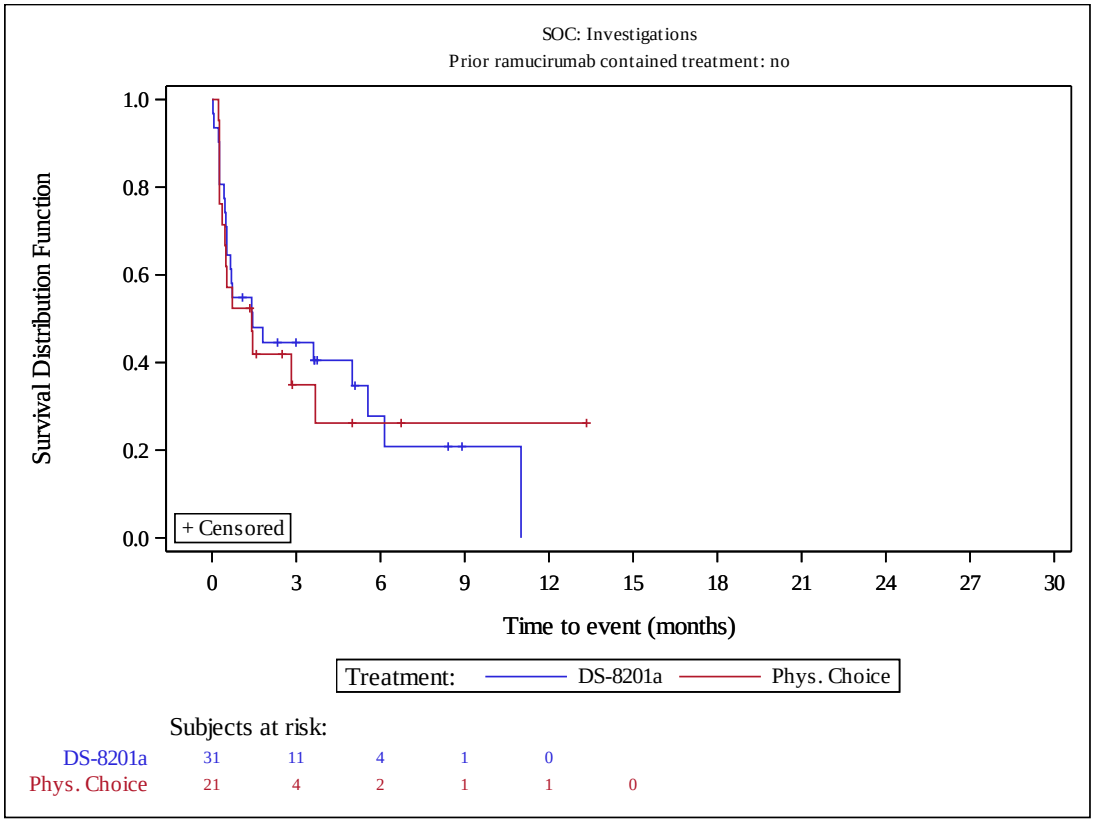

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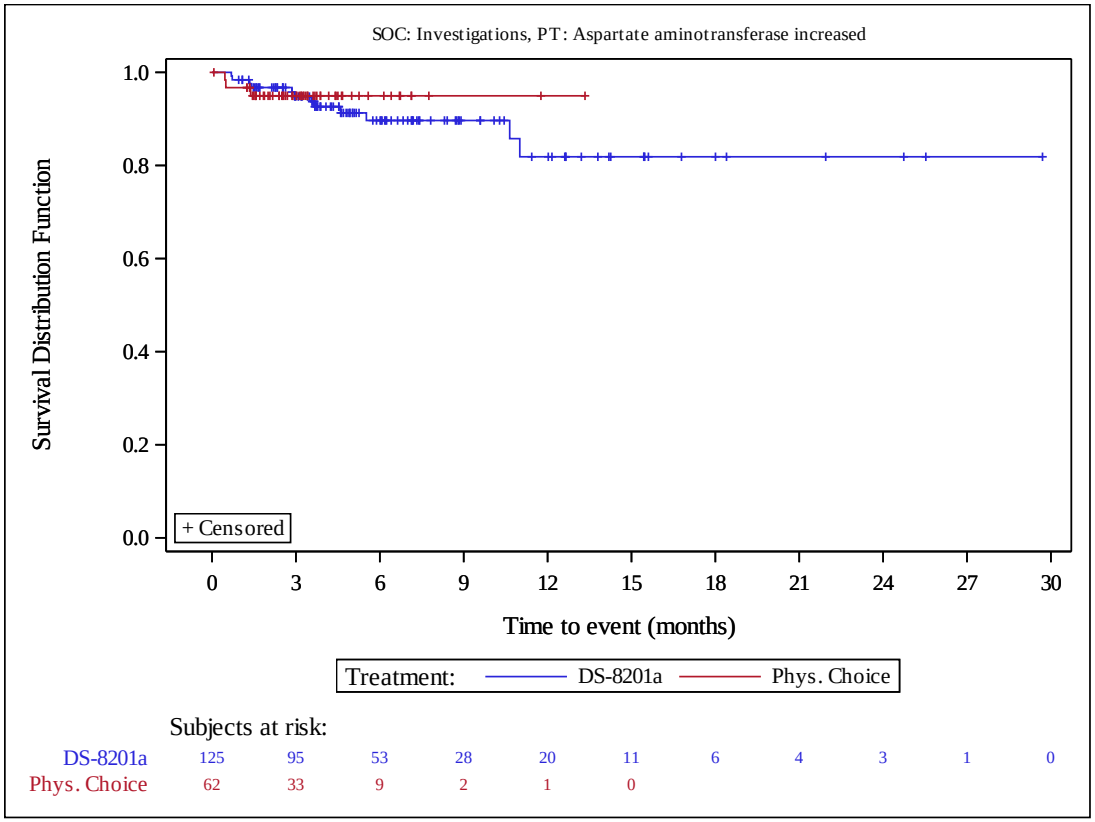

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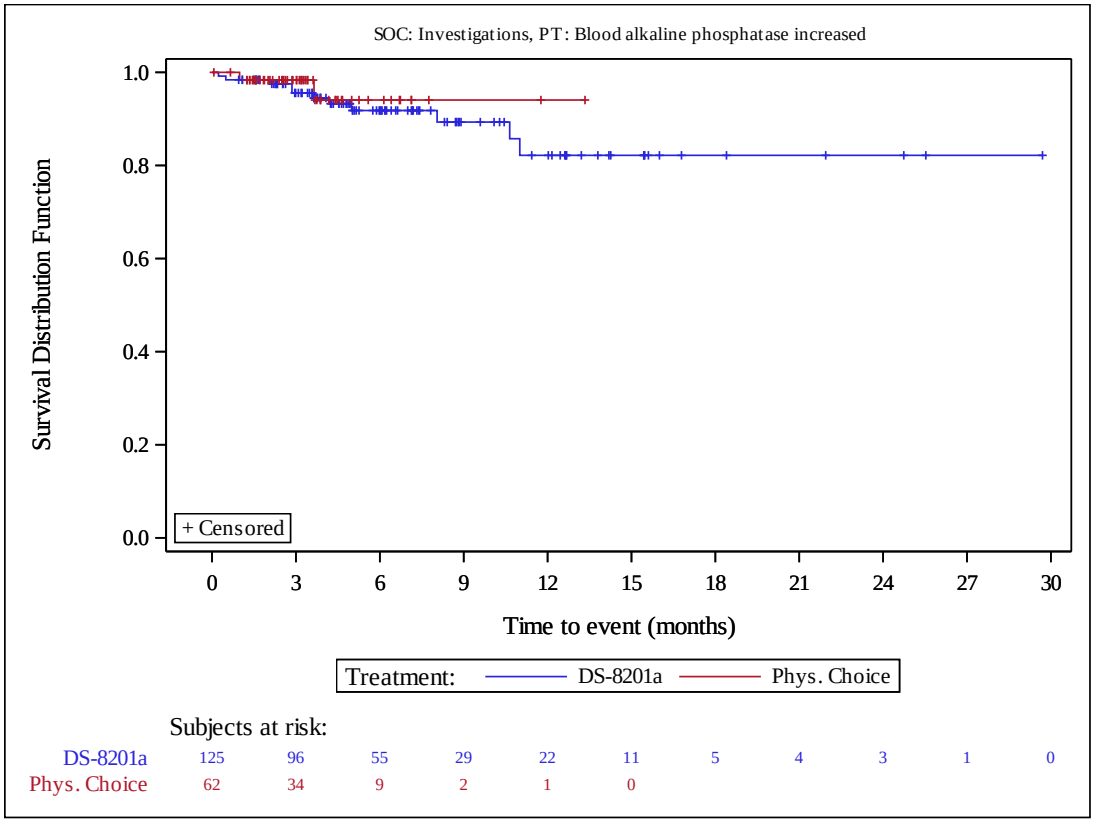

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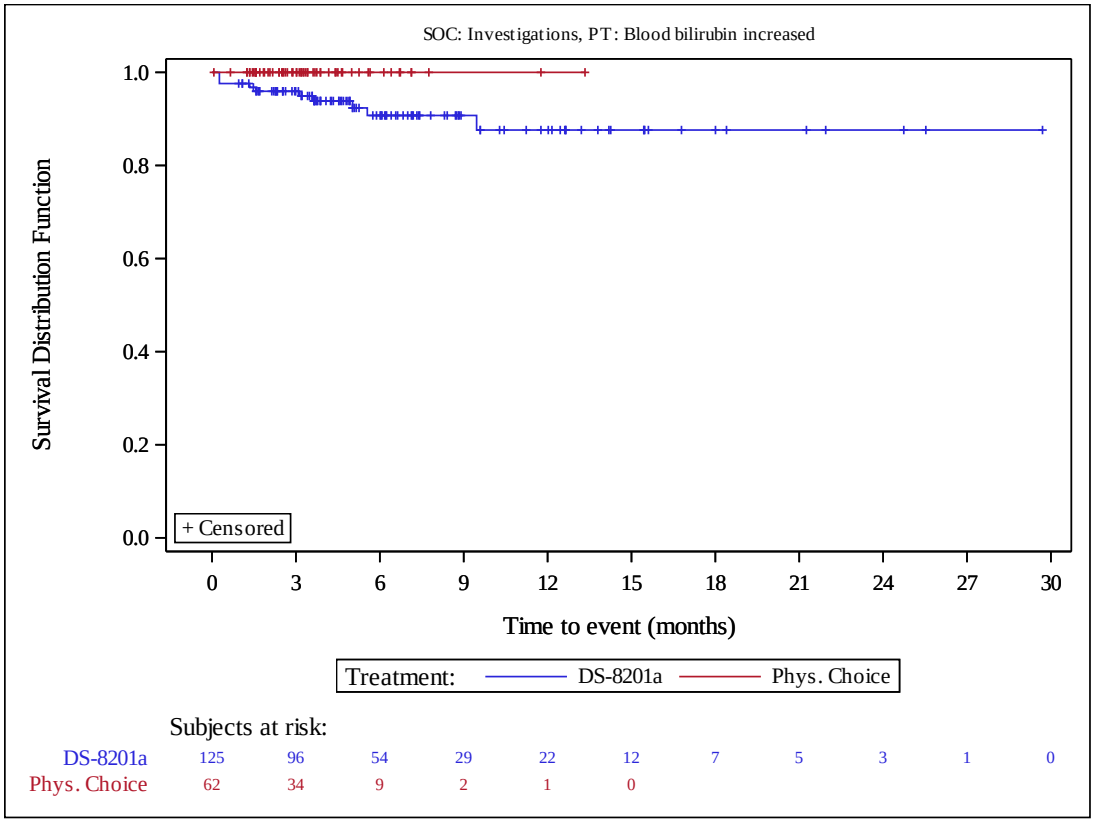

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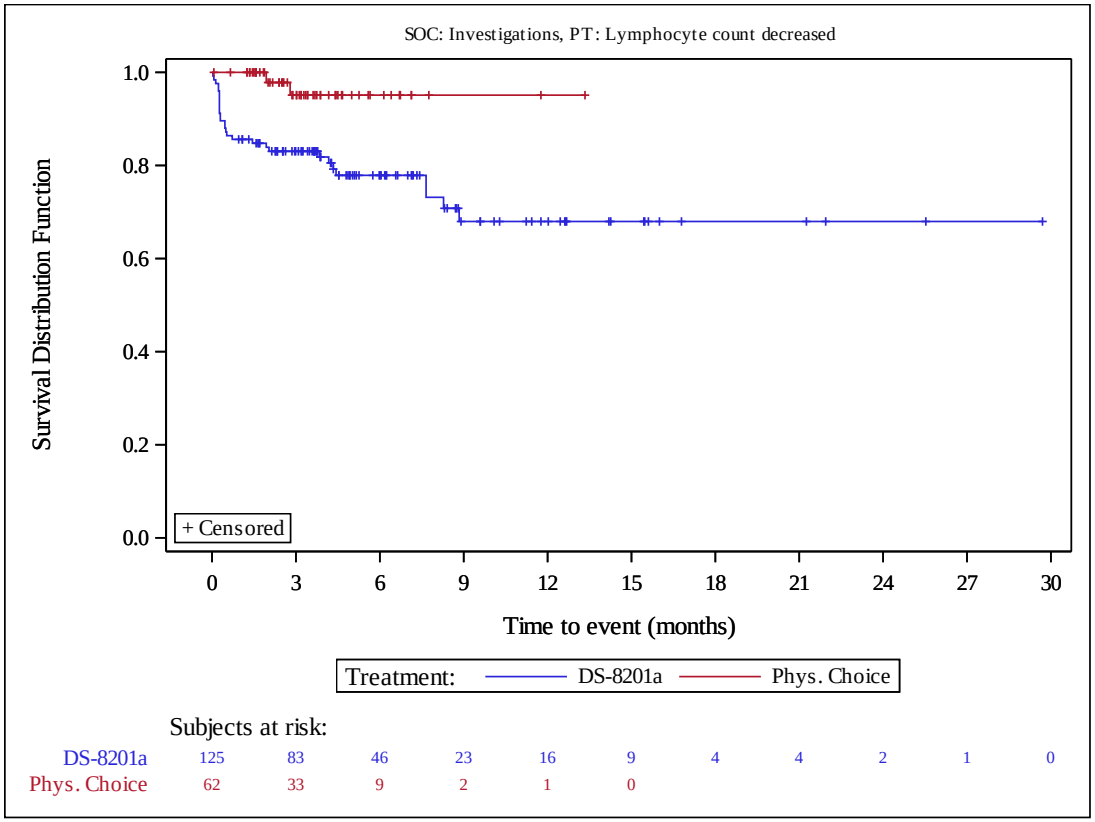

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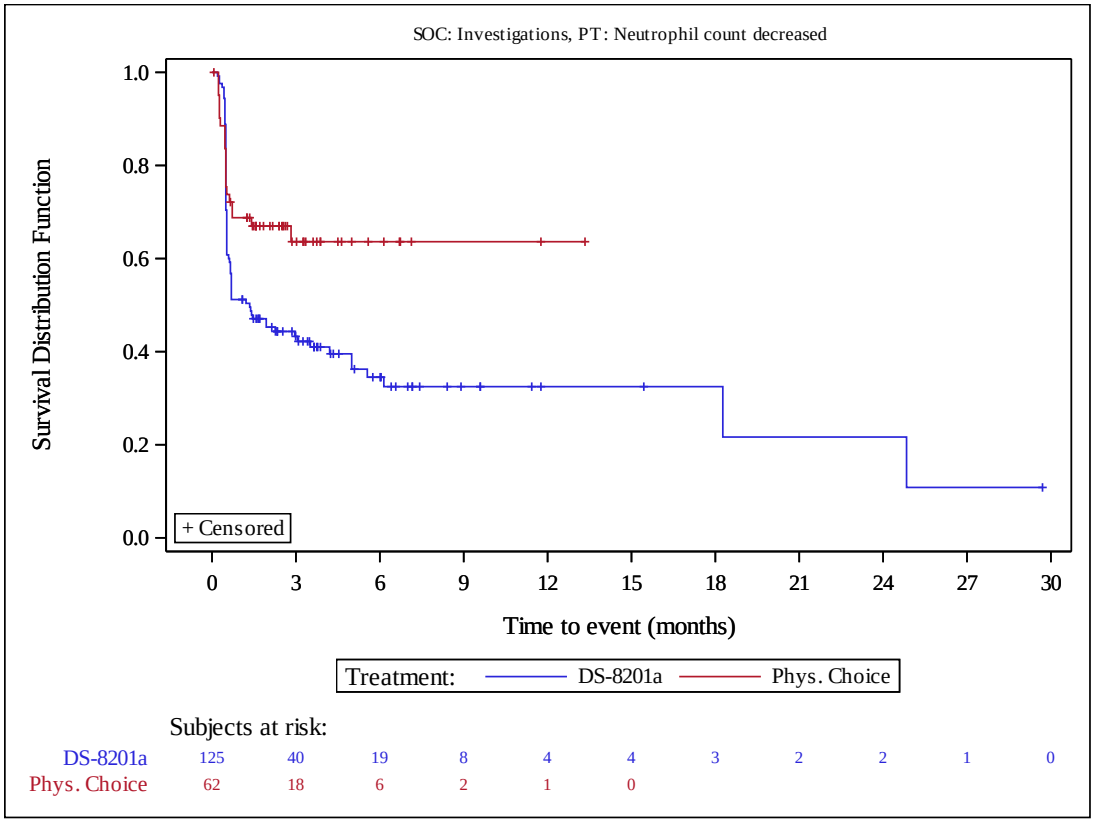

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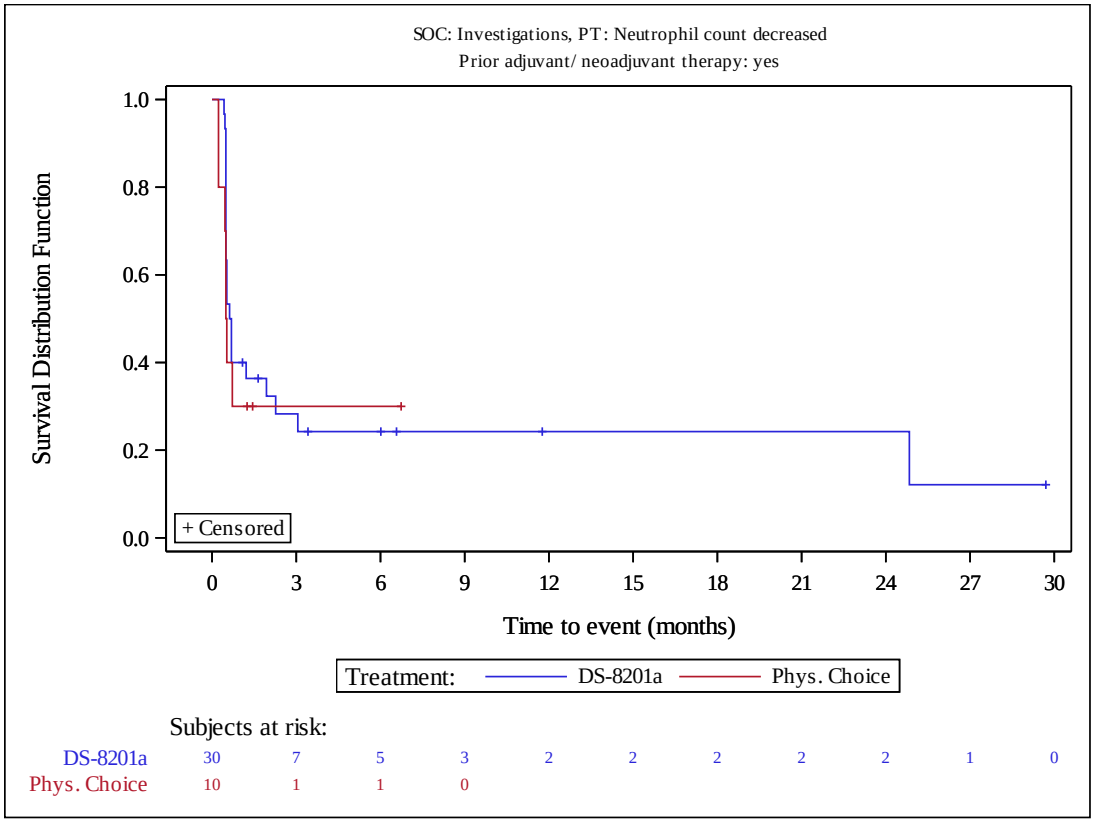

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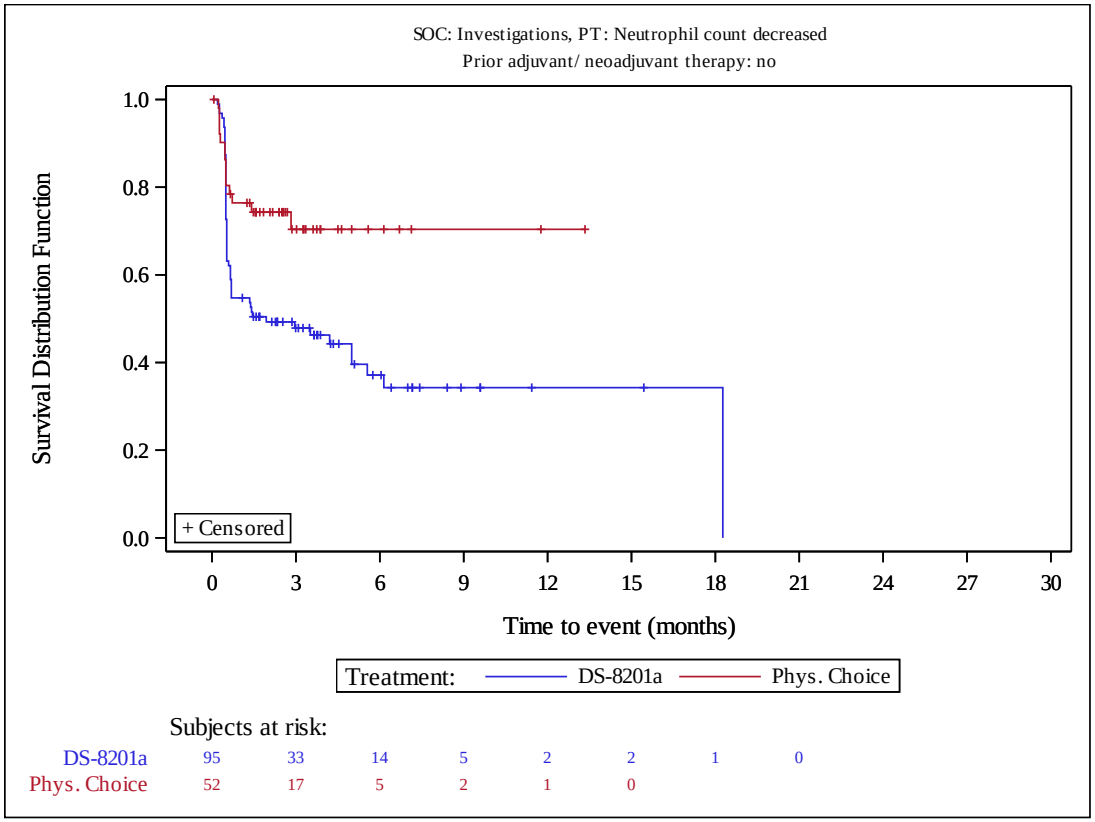

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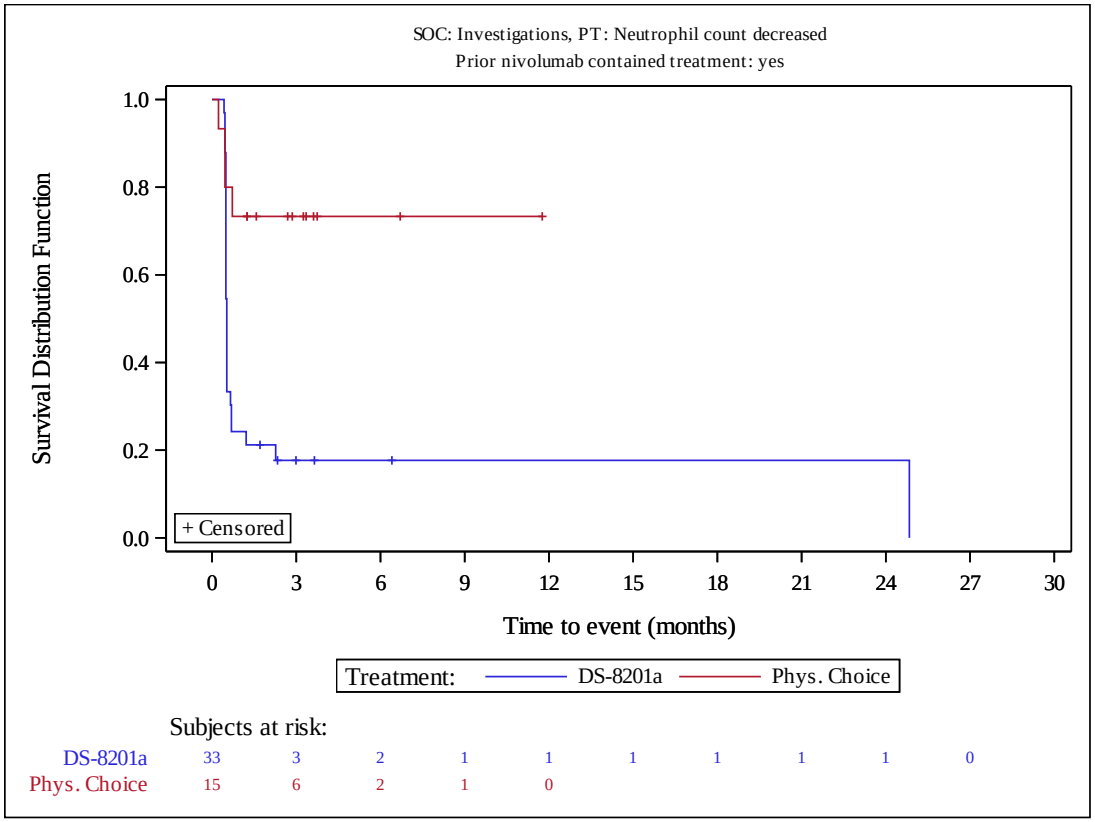
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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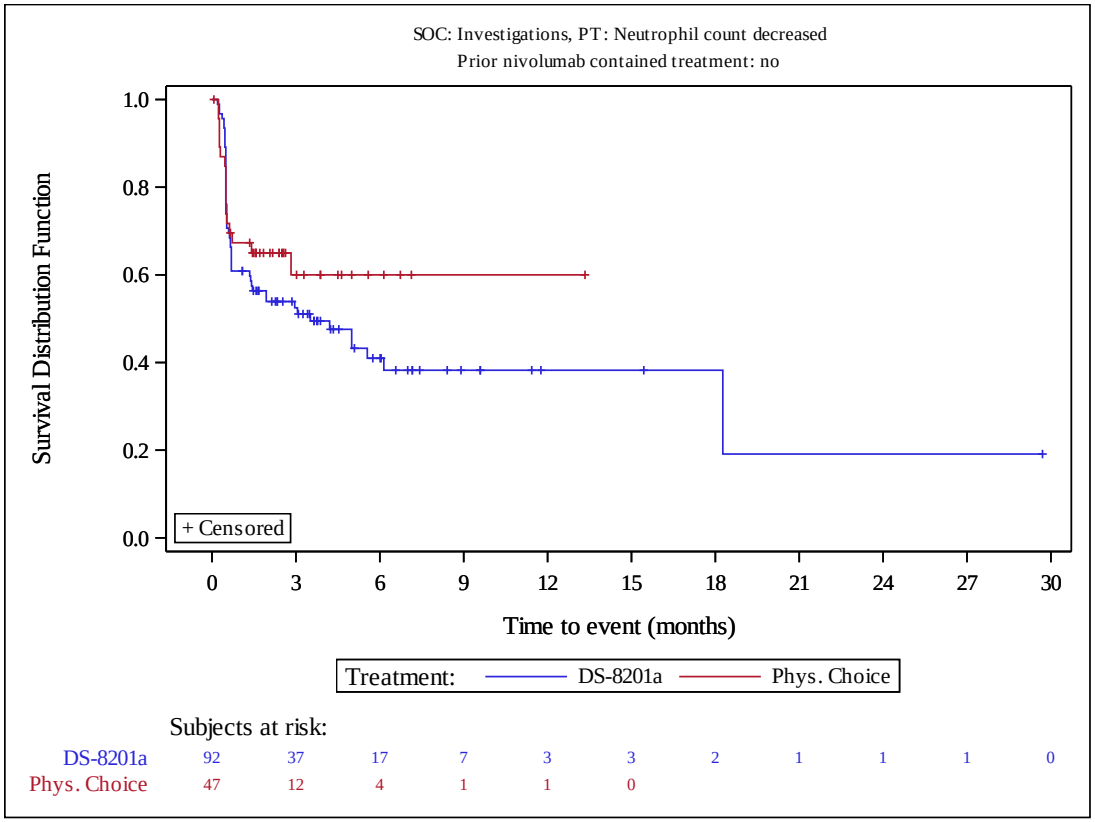

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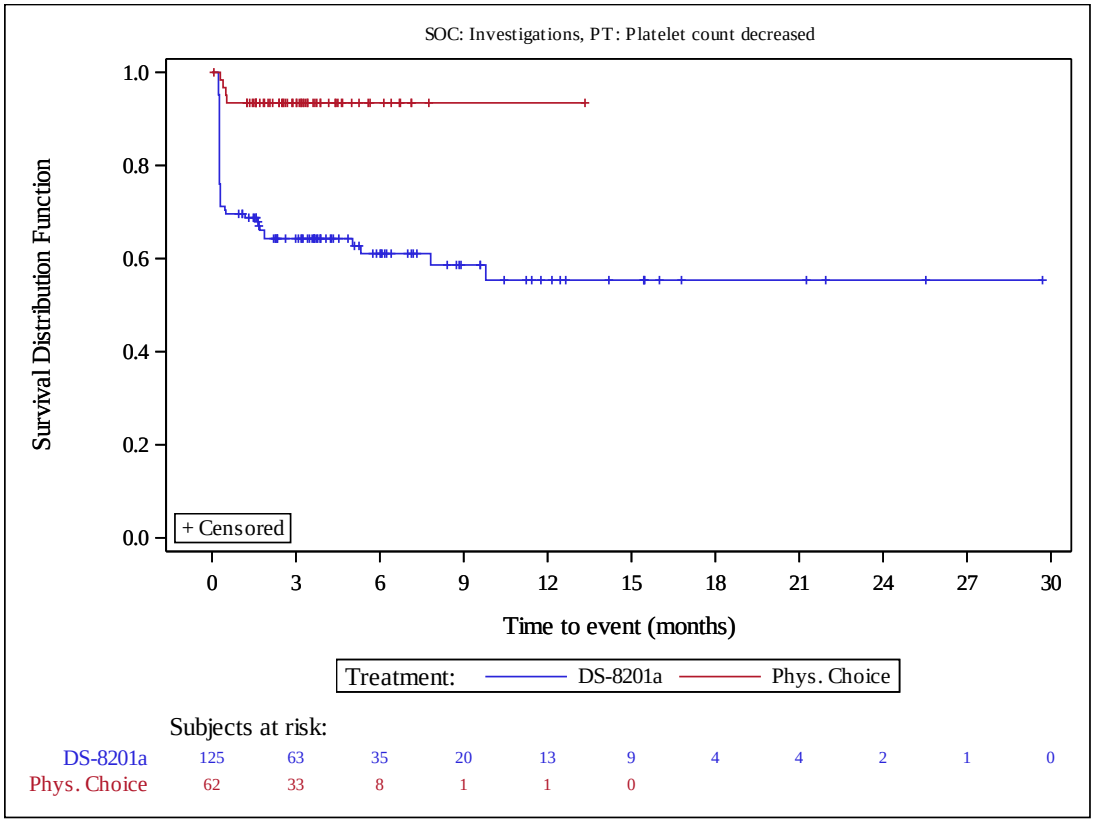

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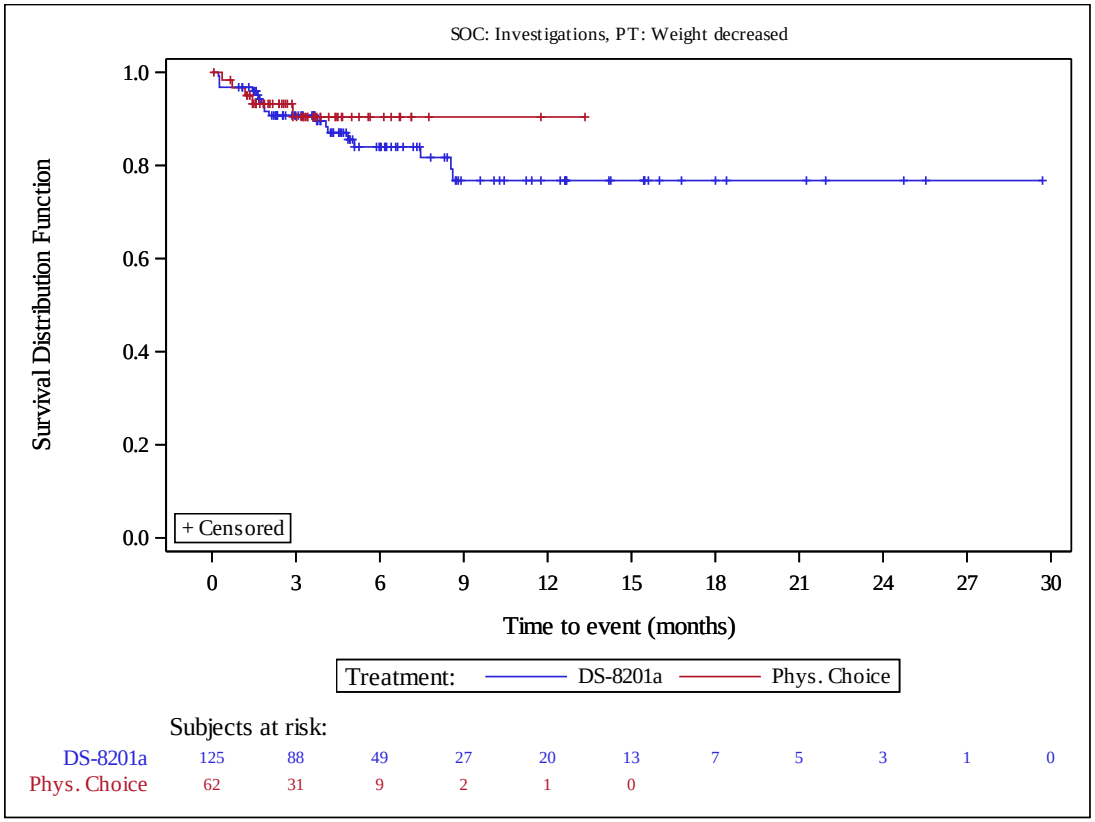

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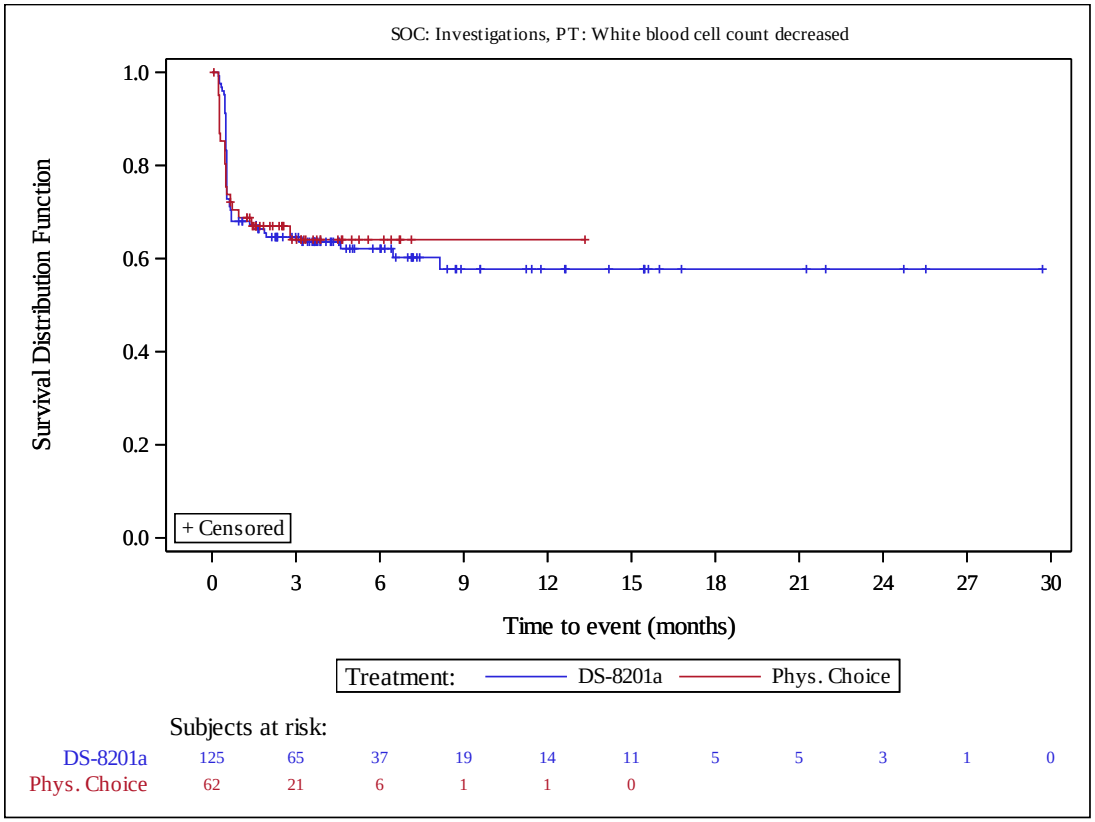

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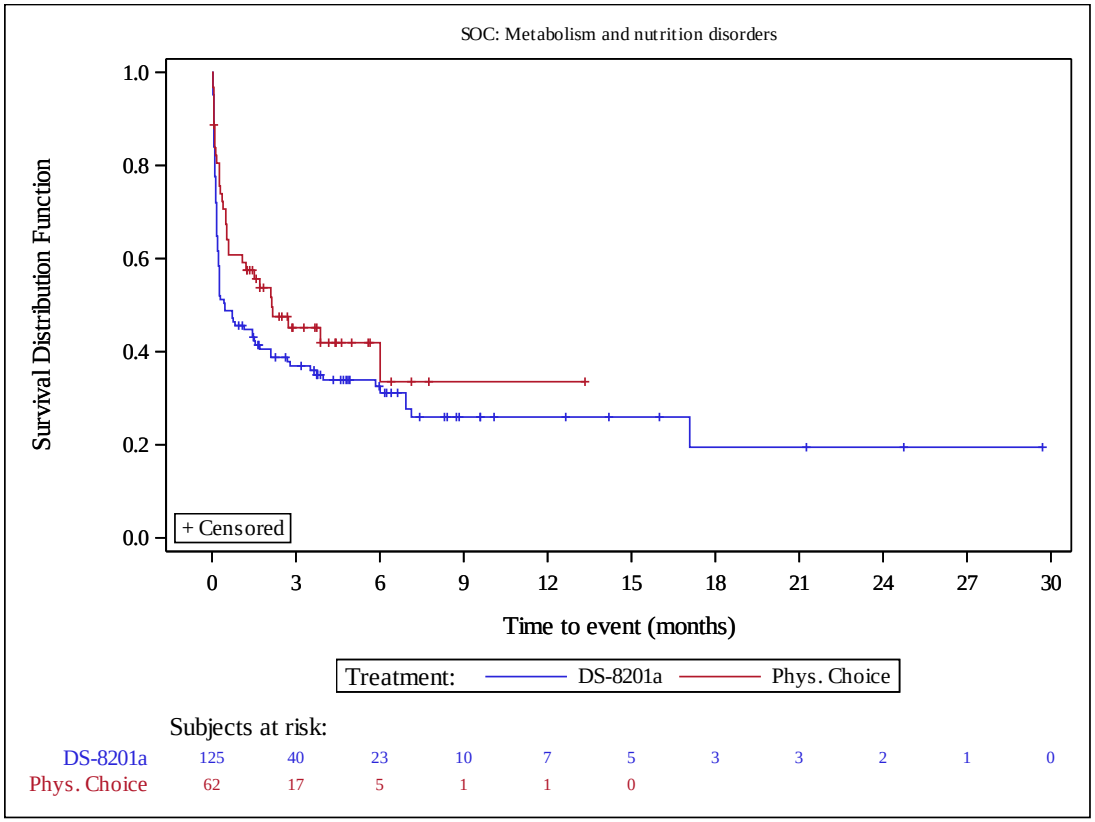

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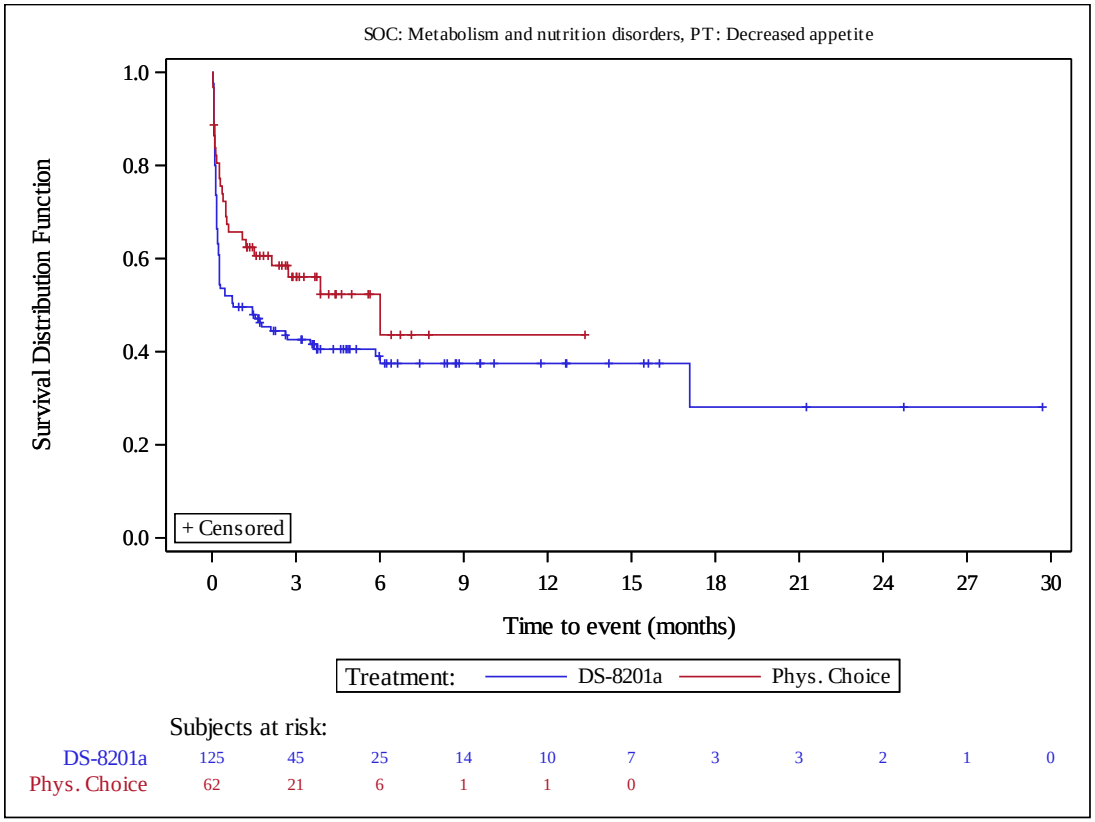

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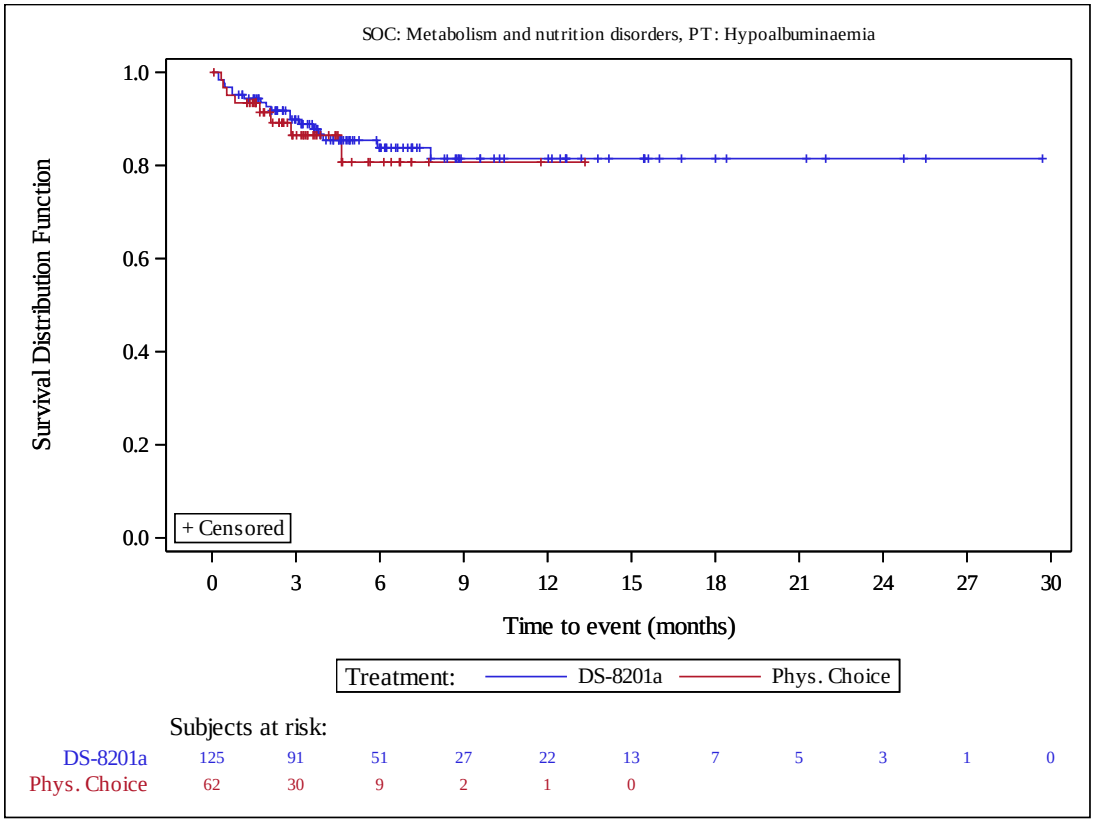

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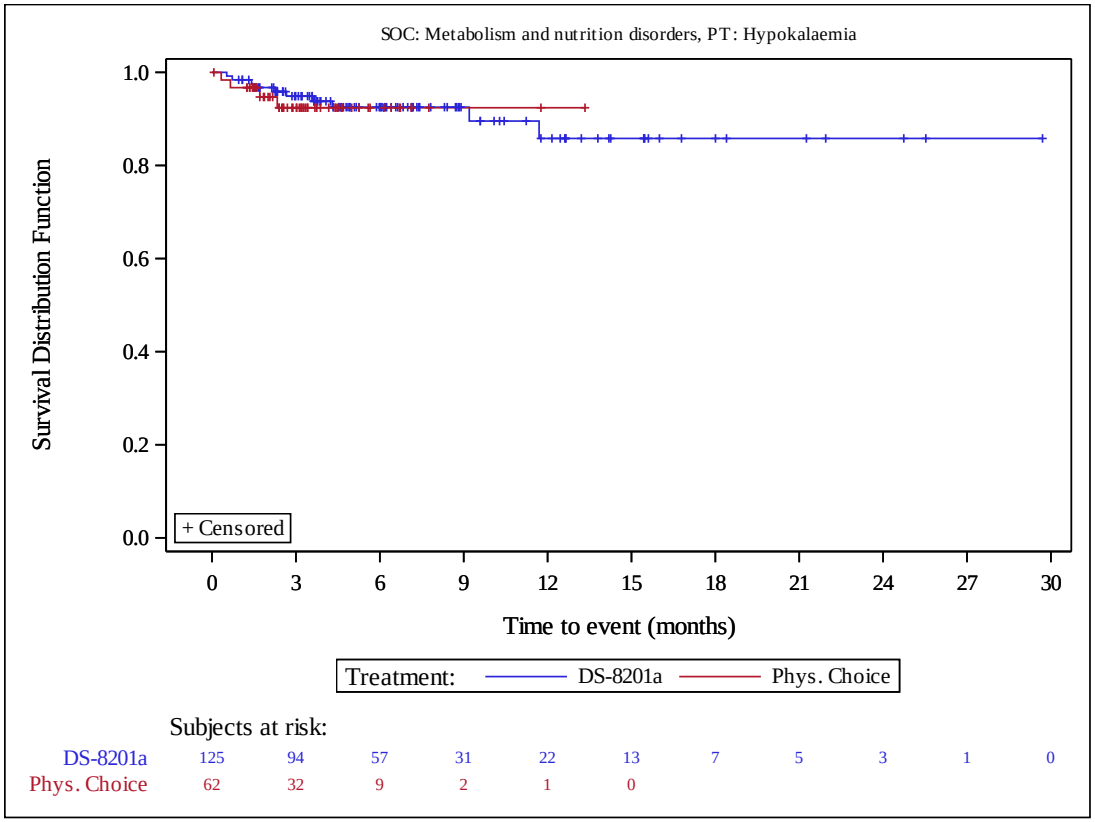

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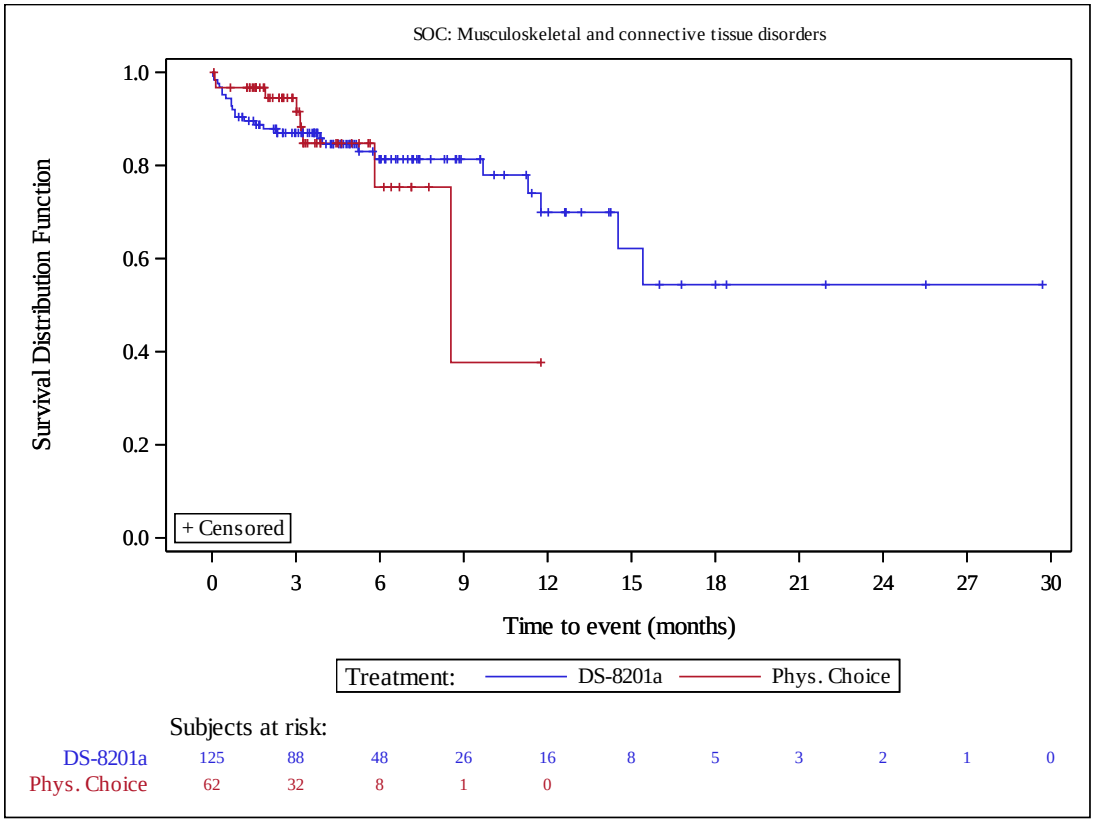

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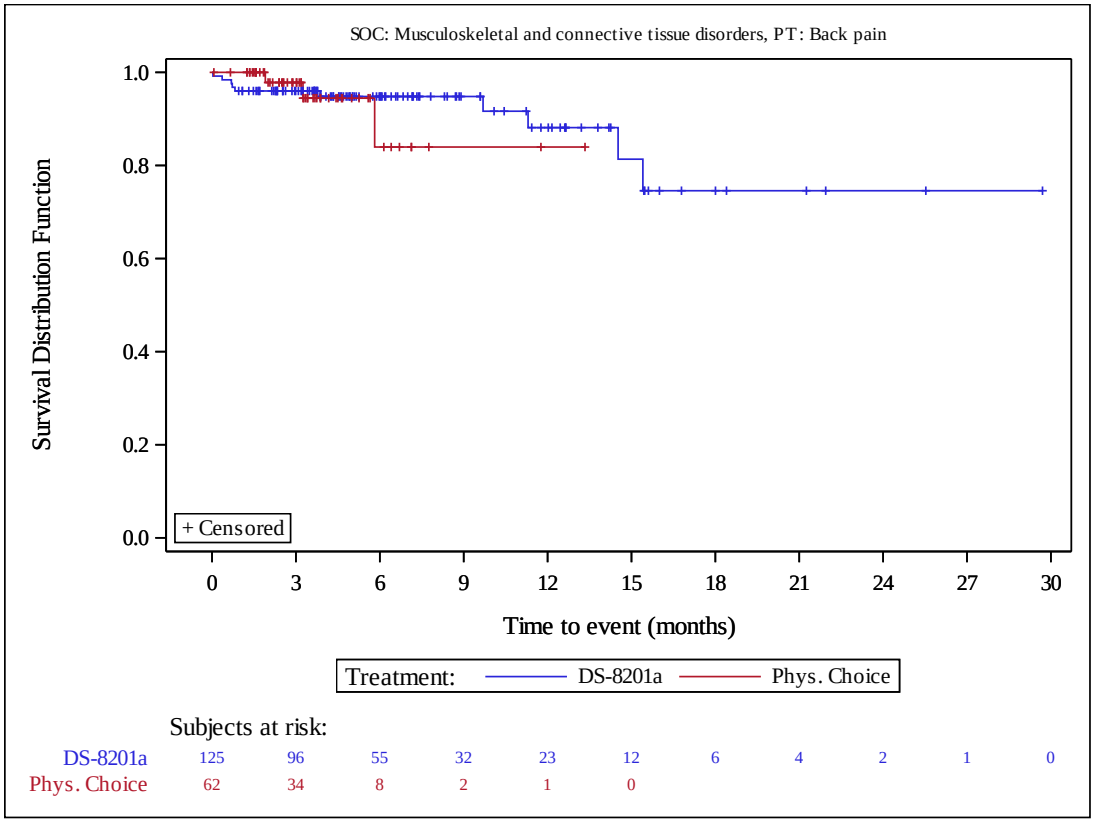

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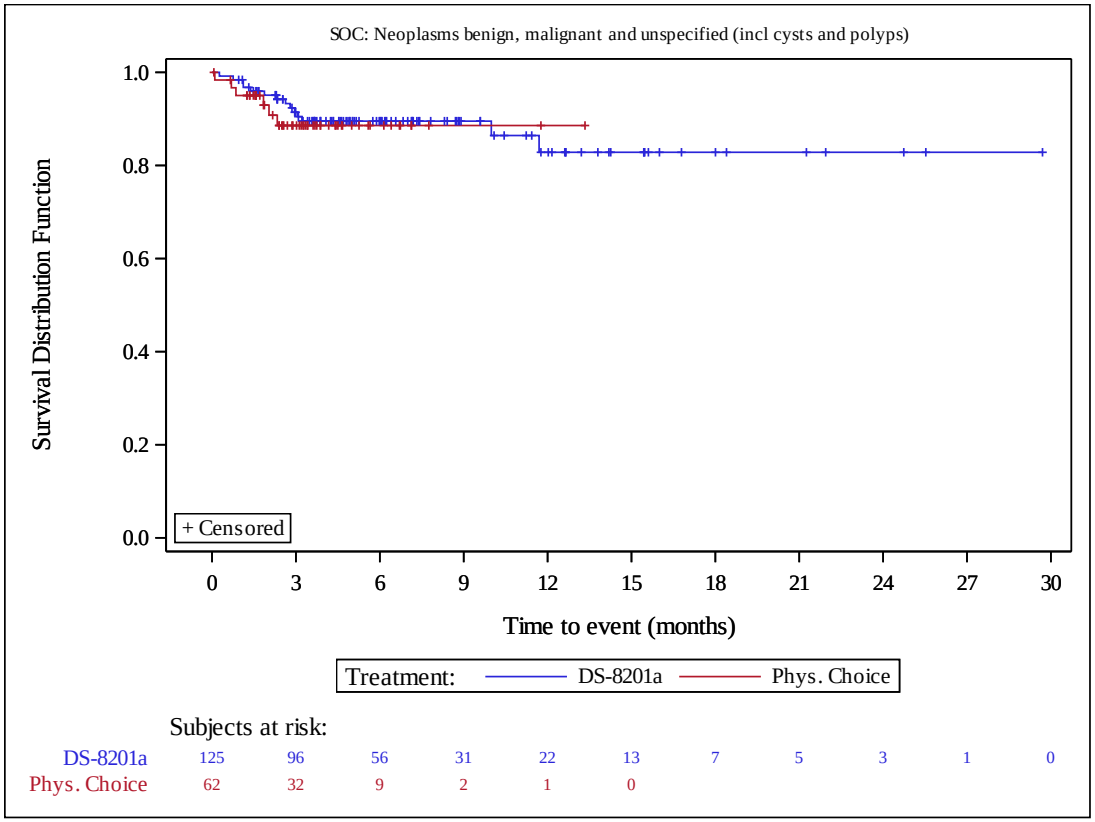

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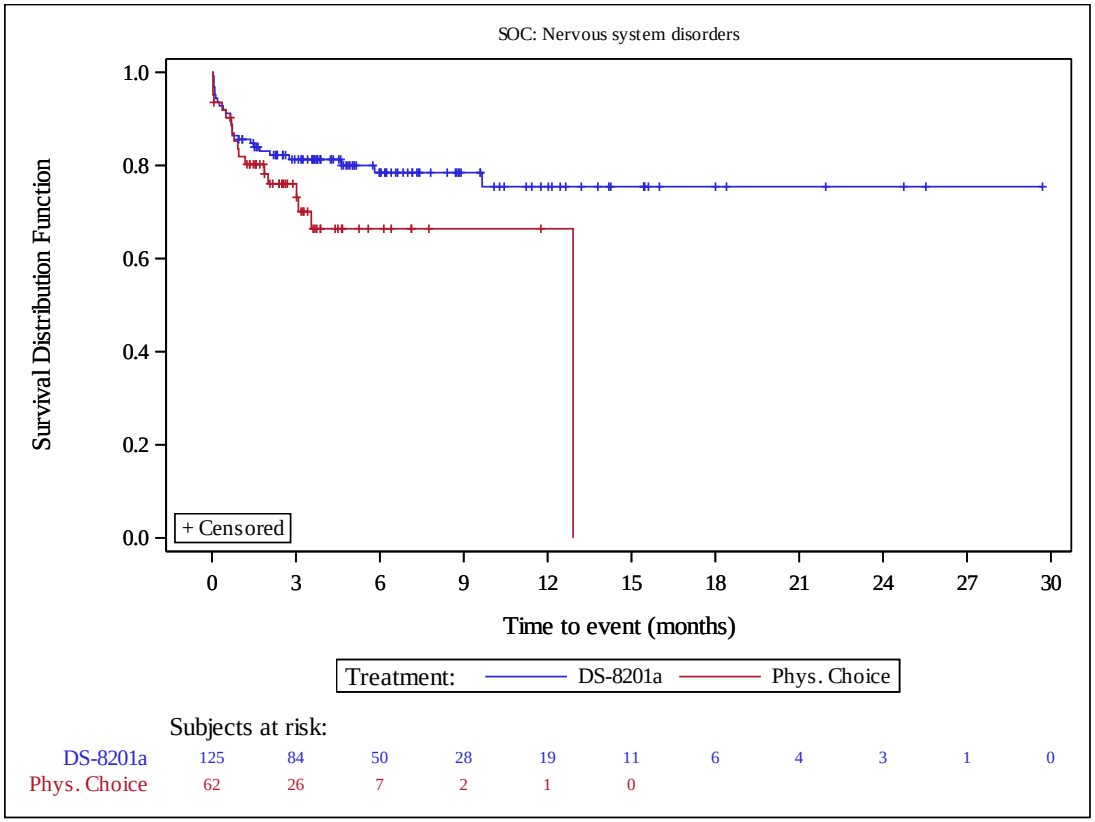

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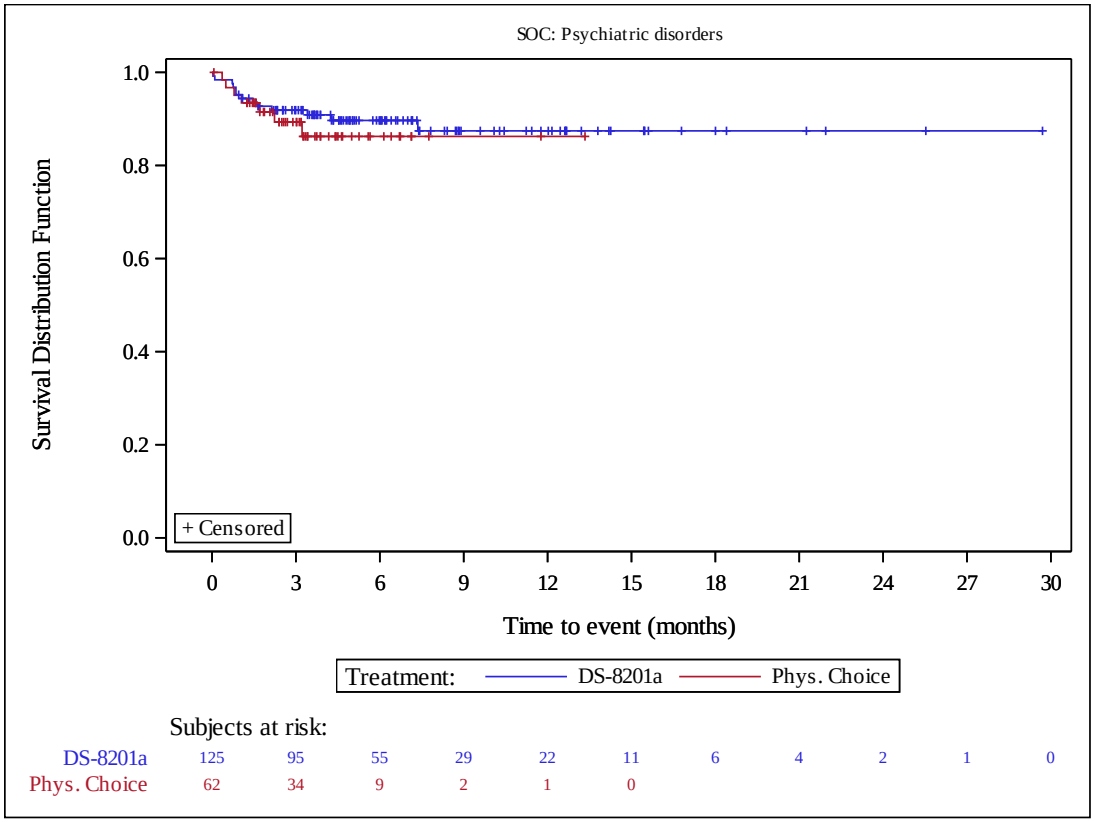

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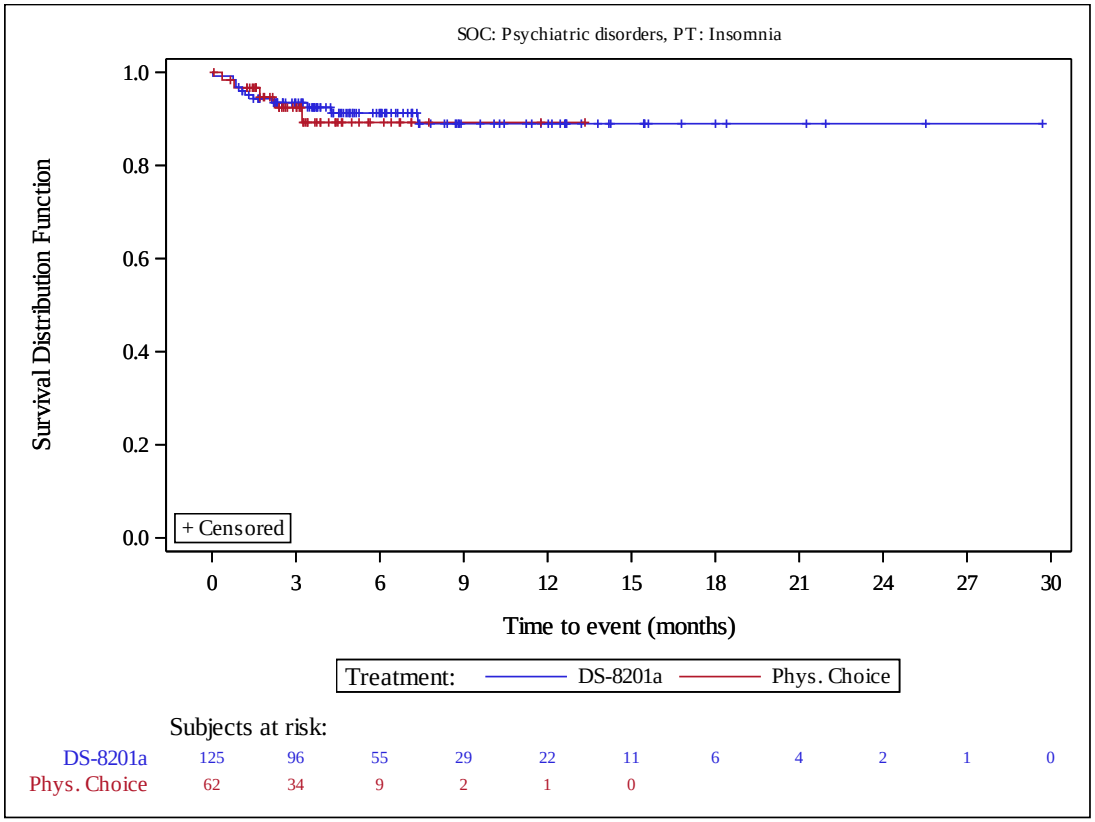

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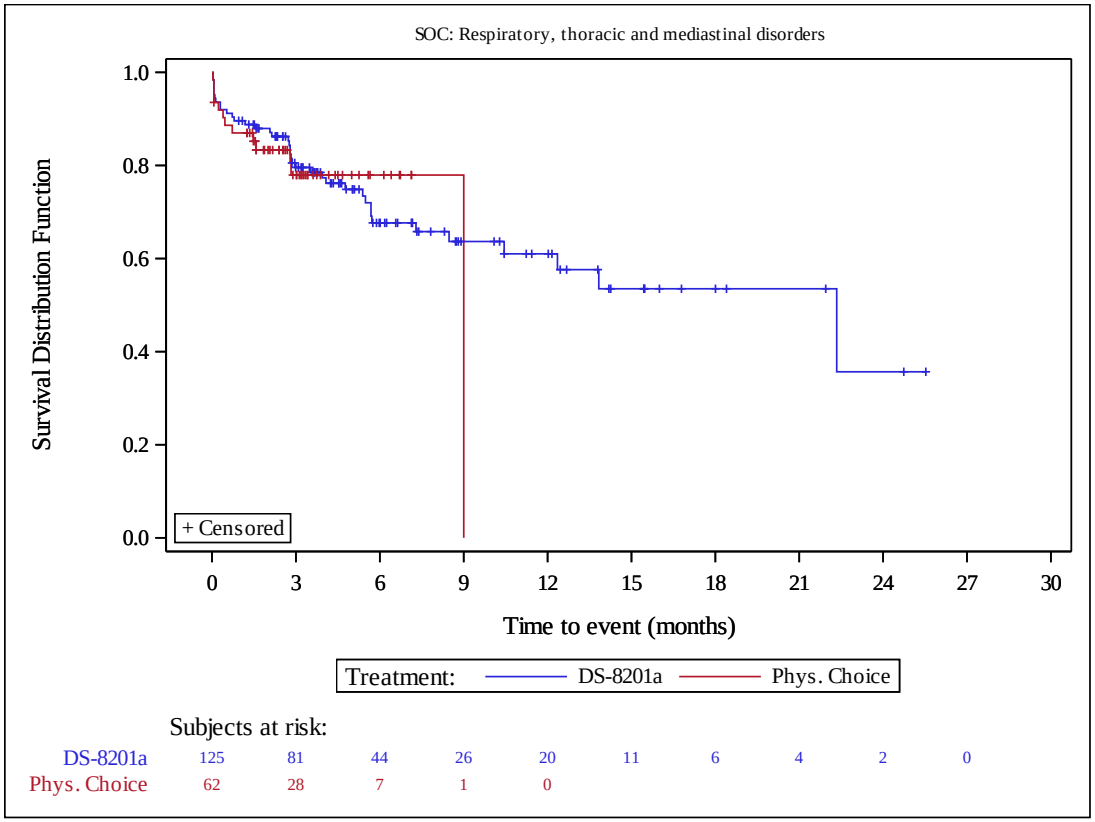

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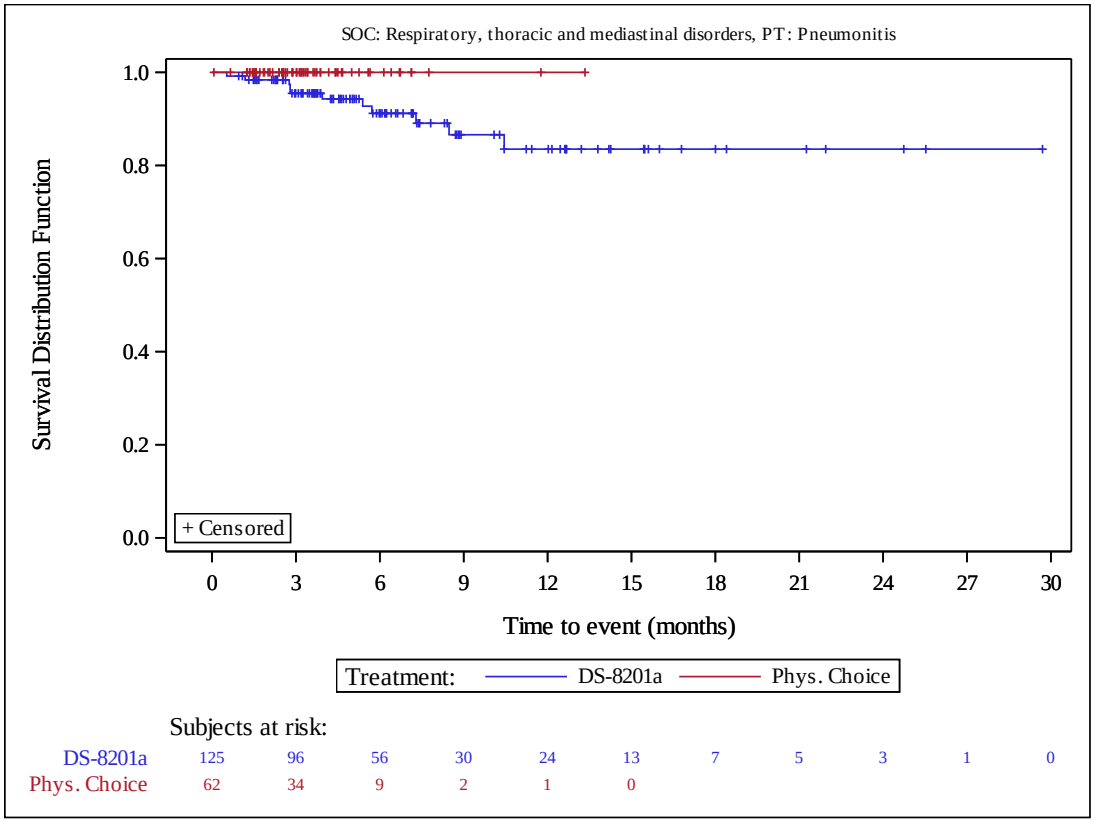

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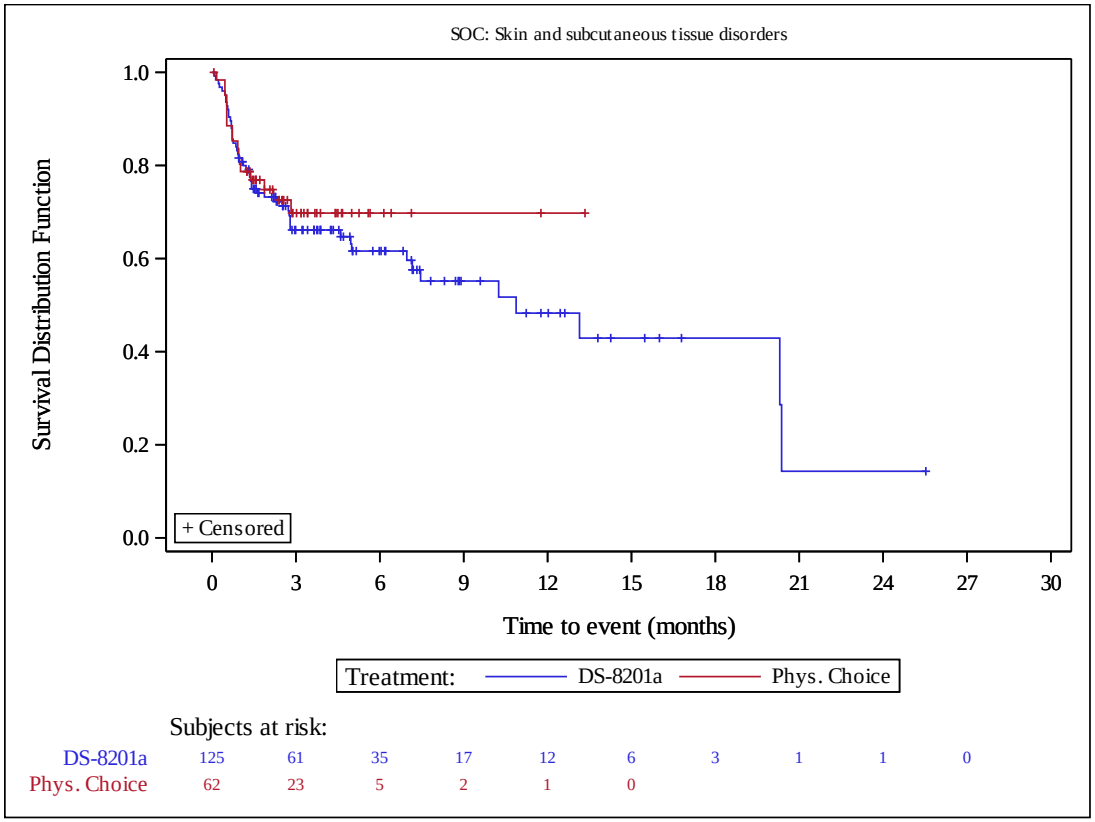

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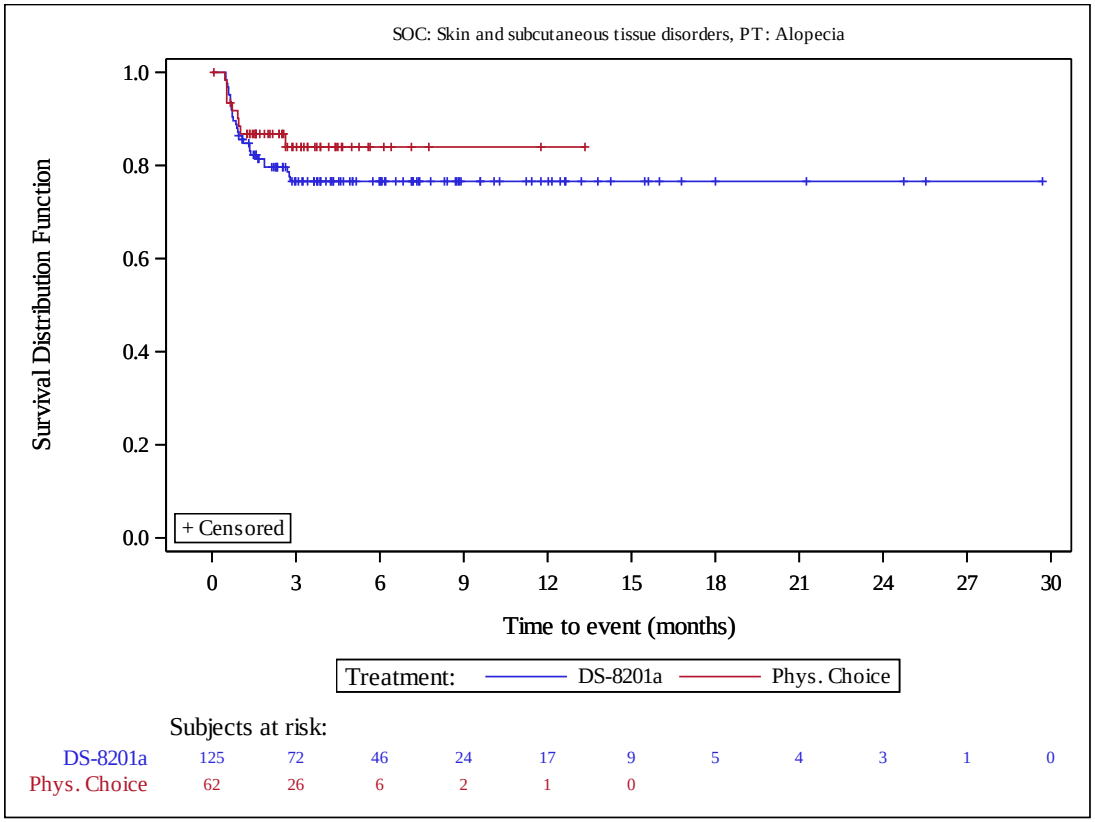

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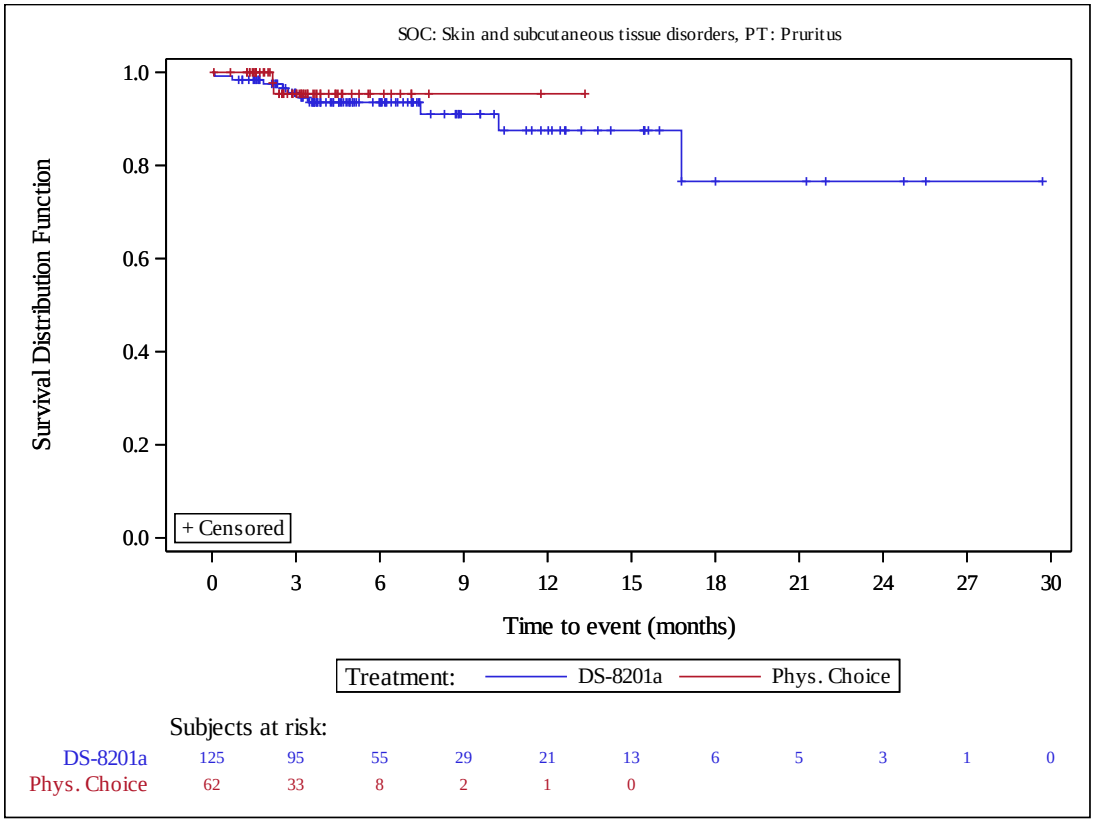

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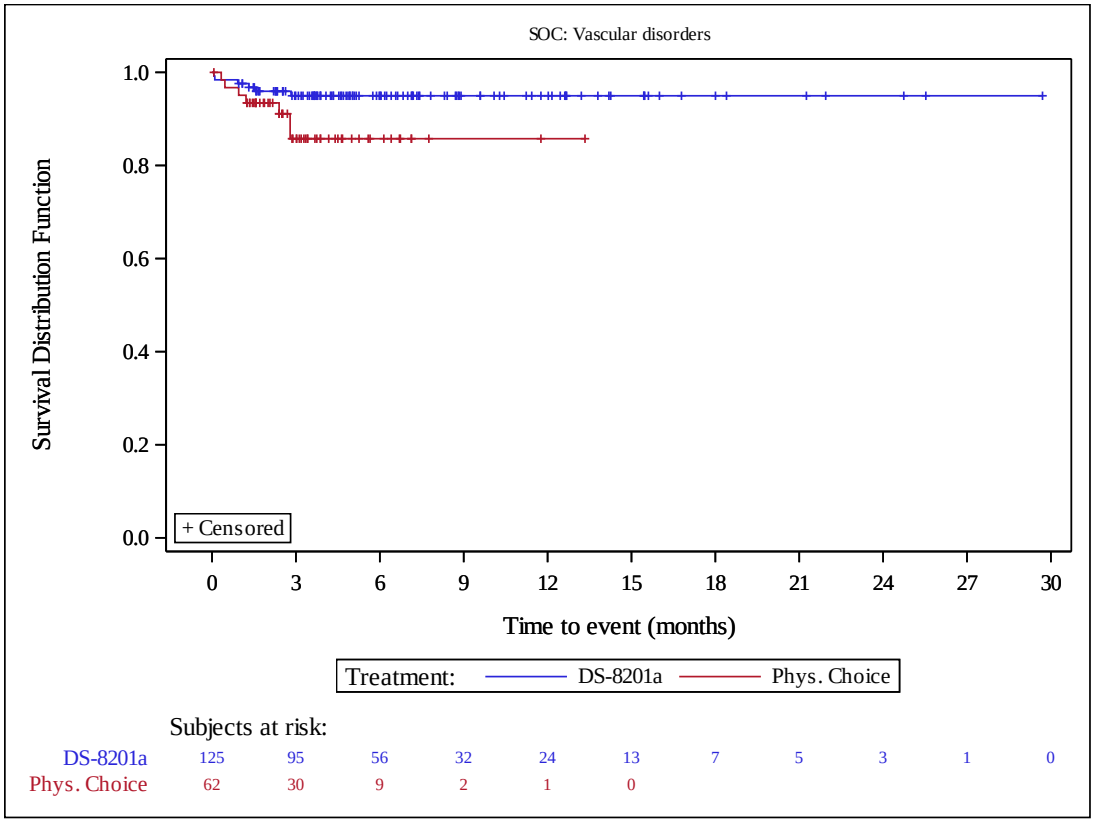

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Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	6 (4.8)	4 (6.5)
	Number of censored subjects, n (%)	119 (95.2)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.55 (0.15, 1.98)	
	p-value [c]	0.3549	
	Relative Risk (95% CI) [d]	0.74 (0.22, 2.54)	
	p-value	0.6369	
	Odds Ratio (95% CI) [d]	0.73 (0.20, 2.69)	
	p-value	0.6377	
	Risk Difference (95% CI) [e]	-1.65 (-10.03, 6.73)	
	p-value	0.6992	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	14 (11.2)	1 (1.6)
	Number of censored subjects, n (%)	111 (88.8)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	5.13 (0.67, 39.52)	
	p-value [c]	0.0803	
	Relative Risk (95% CI) [d]	6.94 (0.93, 51.61)	
	p-value	0.0583	
	Odds Ratio (95% CI) [d]	7.69 (0.99, 59.92)	
	p-value	0.0514	
	Risk Difference (95% CI) [e]	9.59 (2.02, 17.15)	
	p-value	0.0130	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
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Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	7 (5.6)	4 (6.5)
	Number of censored subjects, n (%)	118 (94.4)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.60 (0.17, 2.11)	
	p-value [c]	0.4207	
	Relative Risk (95% CI) [d]	0.87 (0.26, 2.85)	
	p-value	0.8157	
	Odds Ratio (95% CI) [d]	0.86 (0.24, 3.06)	
	p-value	0.8159	
	Risk Difference (95% CI) [e]	-0.85 (-9.38, 7.68)	
	p-value	0.8449	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
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Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders	Number of subjects with events, n (%)	9 (7.2)	4 (6.5)
	Number of censored subjects, n (%)	116 (92.8)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (6.9, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.64 (0.19, 2.17)	
	p-value [c]	0.4685	
	Relative Risk (95% CI) [d]	1.12 (0.36, 3.48)	
	p-value	0.8500	
	Odds Ratio (95% CI) [d]	1.13 (0.33, 3.81)	
	p-value	0.8498	
	Risk Difference (95% CI) [e]	0.75 (-8.07, 9.57)	
	p-value	0.8679	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations	Number of subjects with events, n (%)	12 (9.6)	1 (1.6)
	Number of censored subjects, n (%)	113 (90.4)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	3.94 (0.51, 30.61)	
	p-value [c]	0.1579	
	Relative Risk (95% CI) [d]	5.95 (0.79, 44.74)	
	p-value	0.0831	
	Odds Ratio (95% CI) [d]	6.48 (0.82, 51.01)	
	p-value	0.0760	
	Risk Difference (95% CI) [e]	7.99 (0.74, 15.24)	
	p-value	0.0308	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	18 (14.4)	1 (1.6)
	Number of censored subjects, n (%)	107 (85.6)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	7.16 (0.95, 54.04)	
	p-value [c]	0.0259	
	Relative Risk (95% CI) [d]	8.93 (1.22, 65.35)	
	p-value	0.0311	
	Odds Ratio (95% CI) [d]	10.26 (1.34, 78.77)	
	p-value	0.0251	
	Risk Difference (95% CI) [e]	12.79 (4.67, 20.90)	
	p-value	0.0020	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Number of subjects with events, n (%)	13 (10.4)	1 (1.6)
	Number of censored subjects, n (%)	112 (89.6)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	5.12 (0.66, 39.48)	
	p-value [c]	0.0813	
	Relative Risk (95% CI) [d]	6.45 (0.86, 48.17)	
	p-value	0.0693	
	Odds Ratio (95% CI) [d]	7.08 (0.90, 55.43)	
	p-value	0.0623	
	Risk Difference (95% CI) [e]	8.79 (1.38, 16.20)	
	p-value	0.0201	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	8 (6.4)	1 (1.6)
	Number of censored subjects, n (%)	117 (93.6)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.92 (0.23, 16.11)	
	p-value [c]	0.5394	
	Relative Risk (95% CI) [d]	3.97 (0.51, 31.02)	
	p-value	0.1890	
	Odds Ratio (95% CI) [d]	4.17 (0.51, 34.12)	
	p-value	0.1829	
	Risk Difference (95% CI) [e]	4.79 (-1.73, 11.31)	
	p-value	0.1502	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Metabolism and nutrition disorders	Region							0.9932
	Japan	17/ 99 (17.2)	NE (NE , NE)	1/ 50 (2.0)	NE (NE , NE)	7.06 (0.93, 53.47)	0.0276	
	Korea	1/ 26 (3.8)	NE (NE , NE)	0/ 12 (0.0)	NE (NE , NE)	NE	NE	
	Lines of prior systemic therapy							0.9999
	2	7/ 66 (10.6)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	3.98 (0.49, 32.35)	0.1622	
	3	6/ 34 (17.6)	NE (7.8, NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
	>=4	5/ 25 (20.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Age							0.9921
	<65 years	5/ 55 (9.1)	NE (NE , NE)	0/ 27 (0.0)	NE (NE , NE)	NE	NE	
	>=65 years	13/ 70 (18.6)	NE (NE , NE)	1/ 35 (2.9)	NE (NE , NE)	5.47 (0.71, 42.09)	0.0670	
	Sex							0.9935
	female	5/ 30 (16.7)	NE (NE , NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	male	13/ 95 (13.7)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	4.98 (0.64, 38.58)	0.0887	
	ECOG PS							0.9912
	0	7/ 62 (11.3)	NE (NE , NE)	0/ 30 (0.0)	NE (NE , NE)	NE	NE	
	1	11/ 63 (17.5)	NE (NE , NE)	1/ 32 (3.1)	NE (NE , NE)	4.86 (0.62, 37.91)	0.0952	
	HER2 Status in central laboratory							0.9903
	IHC 3+	11/ 96 (11.5)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	4.37 (0.56, 34.18)	0.1255	
	IHC 2+/ISH +	7/ 29 (24.1)	NE (6.4, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	Primary tumor location							0.9995
	Gastric	18/108 (16.7)	NE (NE , NE)	1/ 55 (1.8)	NE (NE , NE)	7.49 (0.99, 56.48)	0.0217	
	GEJ	0/ 17 (0.0)	NE (NE , NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	Histological subtype							1.0000
	intestinal	13/ 89 (14.6)	NE (NE , NE)	1/ 38 (2.6)	NE (NE , NE)	4.55 (0.59, 35.18)	0.1110	
	diffuse	5/ 28 (17.9)	NE (NE , NE)	0/ 18 (0.0)	NE (NE , NE)	NE	NE	
	others	0/ 8 (0.0)	NE (NE , NE)	0/ 6 (0.0)	NE (NE , NE)	NE	NE	
	Number of metastatic sites							0.9914
	<2	6/ 23 (26.1)	NE (3.9, NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	>= 2	12/102 (11.8)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	4.41 (0.56, 34.56)	0.1225	
	Previous total gastrectomy							0.9931
	yes	2/ 22 (9.1)	NE (NE , NE)	0/ 9 (0.0)	NE (NE , NE)	NE	NE	
	no	16/103 (15.5)	NE (NE , NE)	1/ 53 (1.9)	NE (NE , NE)	6.43 (0.85, 48.92)	0.0389	
	Prior adjuvant/ neoadjuvant therapy							0.9922
	yes	3/ 30 (10.0)	NE (NE , NE)	0/ 10 (0.0)	NE (NE , NE)	NE	NE	
	no	15/ 95 (15.8)	NE (NE , NE)	1/ 52 (1.9)	NE (NE , NE)	6.19 (0.81, 47.37)	0.0452	
	Prior ramucirumab contained treatment							0.9922
	yes	14/ 94 (14.9)	NE (NE , NE)	1/ 41 (2.4)	NE (NE , NE)	4.76 (0.62, 36.59)	0.0985	
	no	4/ 31 (12.9)	NE (NE , NE)	0/ 21 (0.0)	NE (NE , NE)	NE	NE	

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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Metabolism and nutrition disorders	Prior nivolumab contained treatment							0.9901
	yes	8/ 33 (24.2)	NE (7.8, NE)	0/ 15 (0.0)	NE (NE , NE)	NE	NE	
	no	10/ 92 (10.9)	NE (NE , NE)	1/ 47 (2.1)	NE (NE , NE)	4.19 (0.53, 33.01)	0.1396	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.9930
	yes	9/ 44 (20.5)	NE (NE , NE)	0/ 17 (0.0)	NE (NE , NE)	NE	NE	
	no	9/ 81 (11.1)	NE (NE , NE)	1/ 45 (2.2)	NE (NE , NE)	4.33 (0.55, 34.41)	0.1306	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.9933
	yes	5/ 22 (22.7)	NE (6.4, NE)	0/ 7 (0.0)	NE (NE , NE)	NE	NE	
	no	13/103 (12.6)	NE (NE , NE)	1/ 55 (1.8)	NE (NE , NE)	5.55 (0.72, 42.85)	0.0647	
	Presence of liver metastasis at baseline							0.9909
	yes	6/ 68 (8.8)	NE (NE , NE)	1/ 34 (2.9)	NE (NE , NE)	2.41 (0.29, 20.29)	0.4033	
	no	12/ 57 (21.1)	NE (NE , NE)	0/ 28 (0.0)	NE (NE , NE)	NE	NE	
	Renal impairment at baseline							0.9999
	normal	1/ 33 (3.0)	NE (NE , NE)	0/ 13 (0.0)	NE (NE , NE)	NE	NE	
	mild	12/ 53 (22.6)	NE (7.8, NE)	1/ 28 (3.6)	NE (NE , NE)	5.26 (0.68, 40.82)	0.0761	
	moderate	5/ 39 (12.8)	NE (NE , NE)	0/ 20 (0.0)	NE (NE , NE)	NE	NE	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.9897
	normal	10/ 88 (11.4)	NE (NE , NE)	0/ 47 (0.0)	NE (NE , NE)	NE	NE	
	mild	8/ 36 (22.2)	NE (NE , NE)	1/ 15 (6.7)	NE (NE , NE)	3.45 (0.43, 27.59)	0.2132	
	moderate	0/ 1 (0.0)	NE (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.9909
	yes	3/ 8 (37.5)	NE (0.3, NE)	0/ 5 (0.0)	NE (NE , NE)	NE	NE	
	no	15/117 (12.8)	NE (NE , NE)	1/ 57 (1.8)	NE (NE , NE)	5.76 (0.75, 44.05)	0.0564	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9910
	yes	1/ 3 (33.3)	NE (6.4, NE)	0/ 4 (0.0)	NE (NE , NE)	NE	NE	
	no	17/122 (13.9)	NE (NE , NE)	1/ 58 (1.7)	NE (NE , NE)	6.62 (0.87, 50.10)	0.0348	

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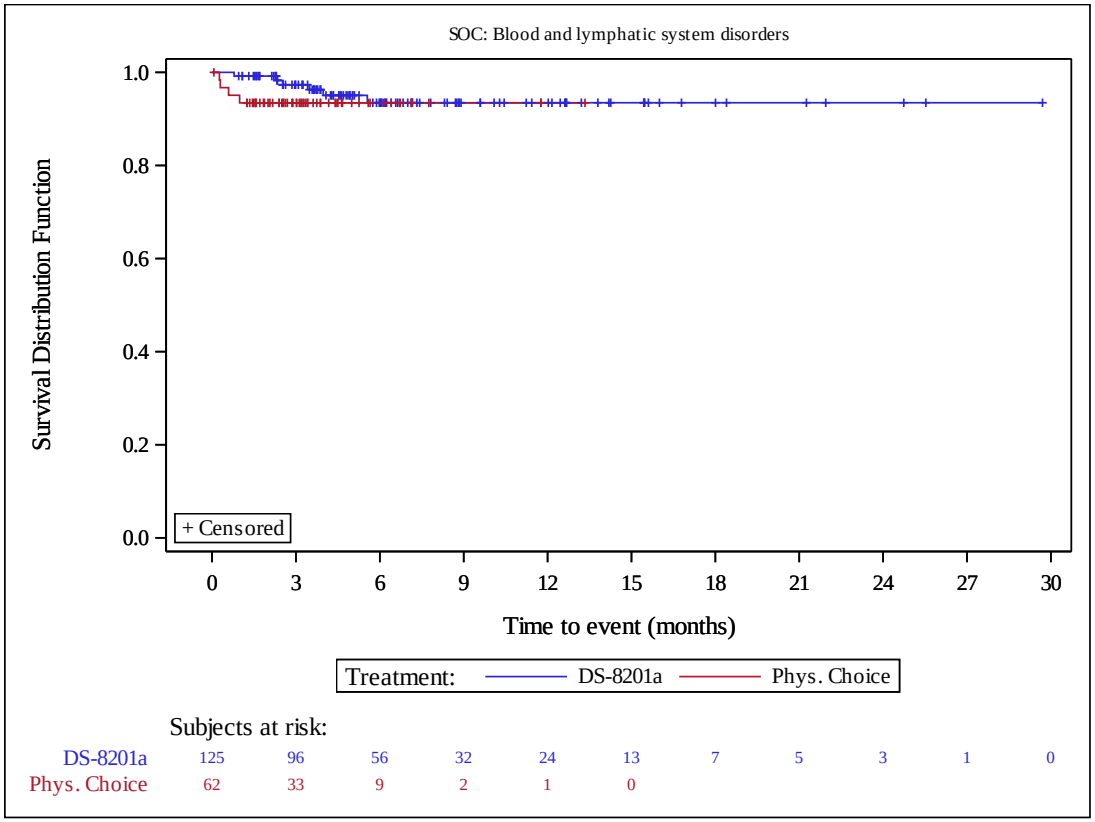
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

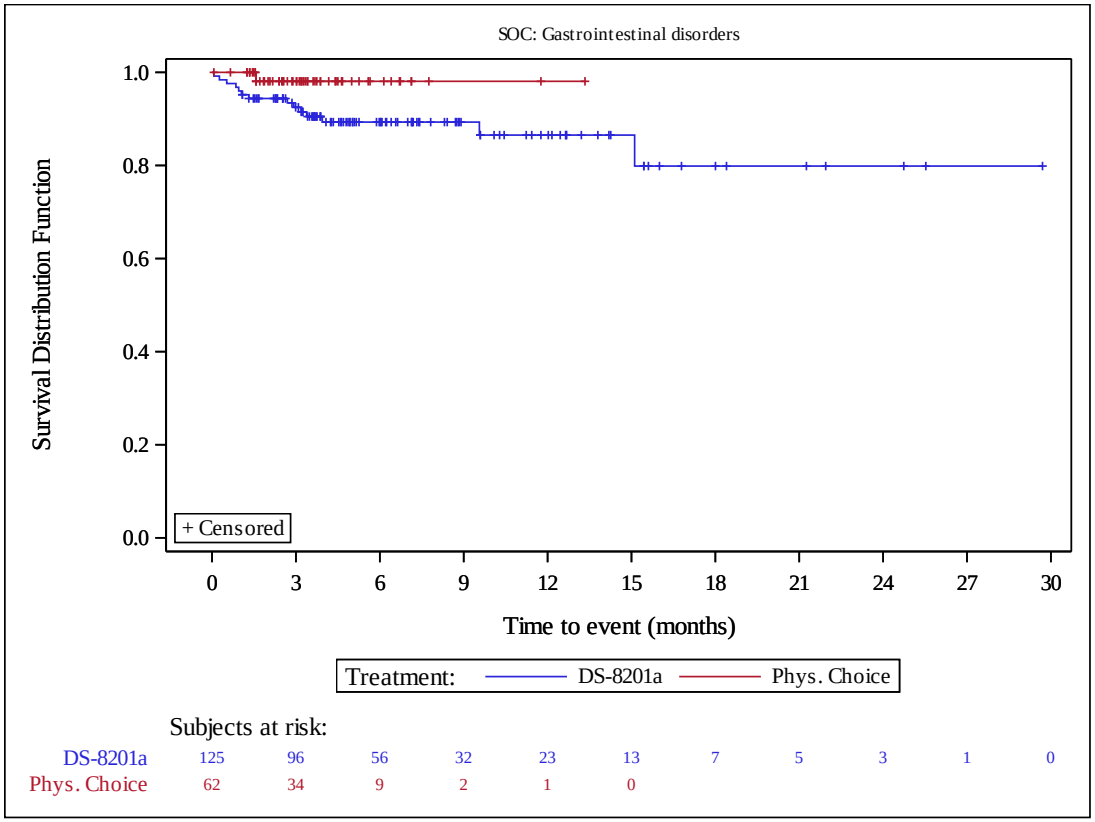
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



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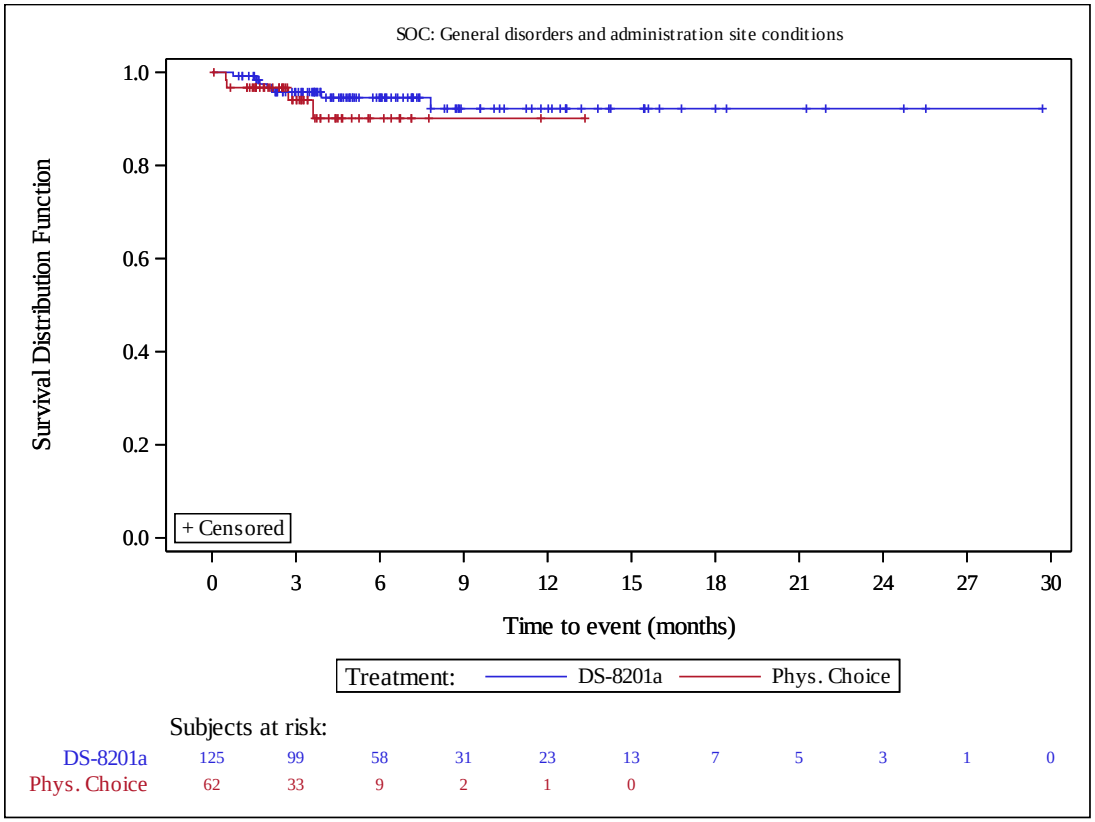
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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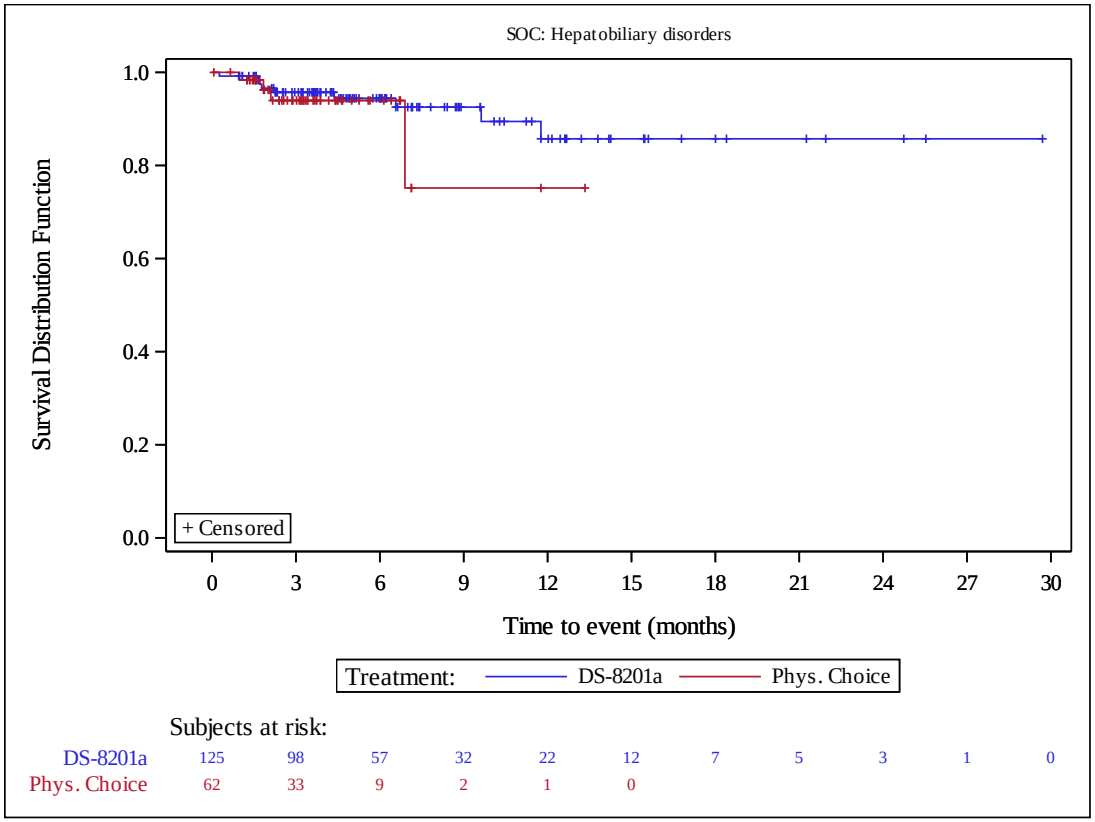
Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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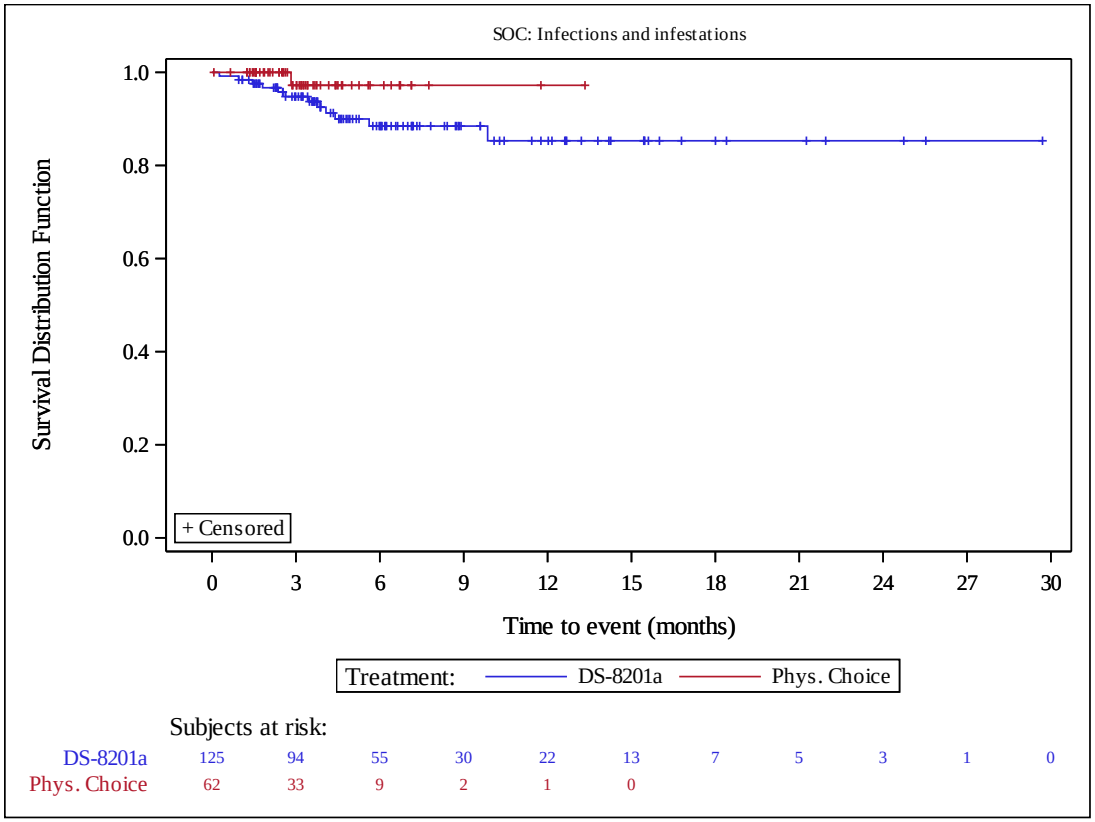
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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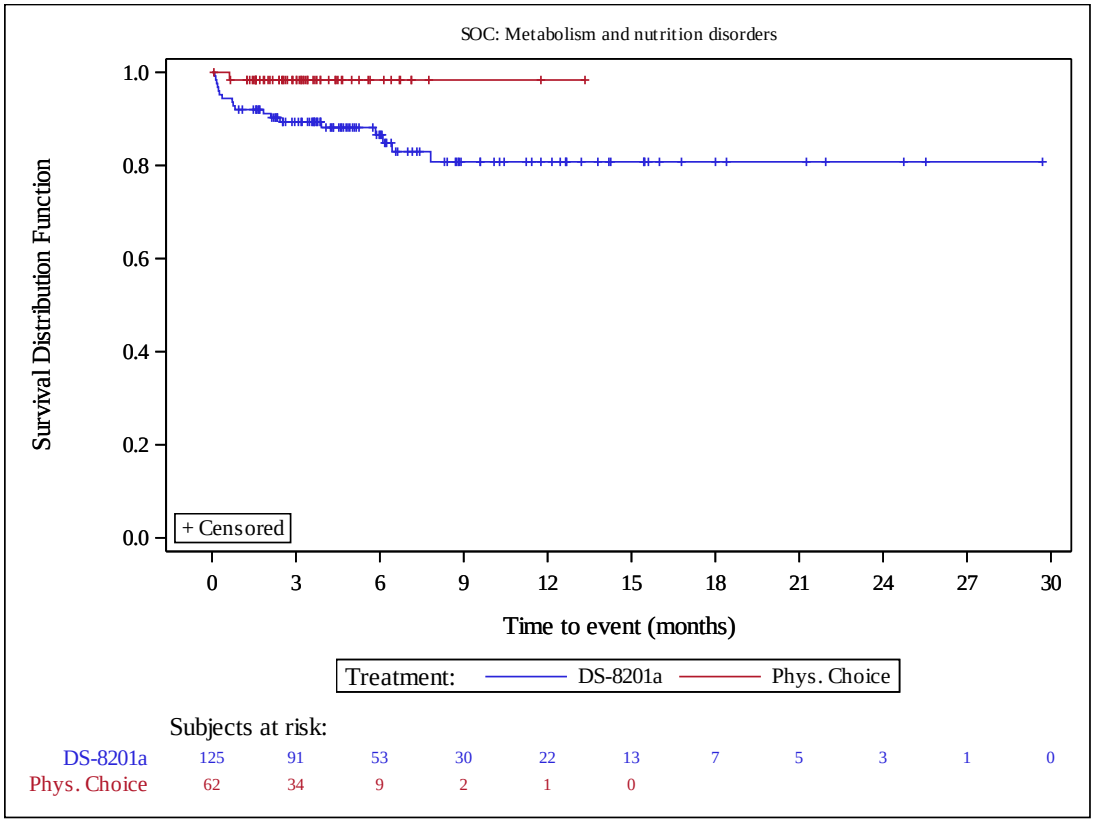
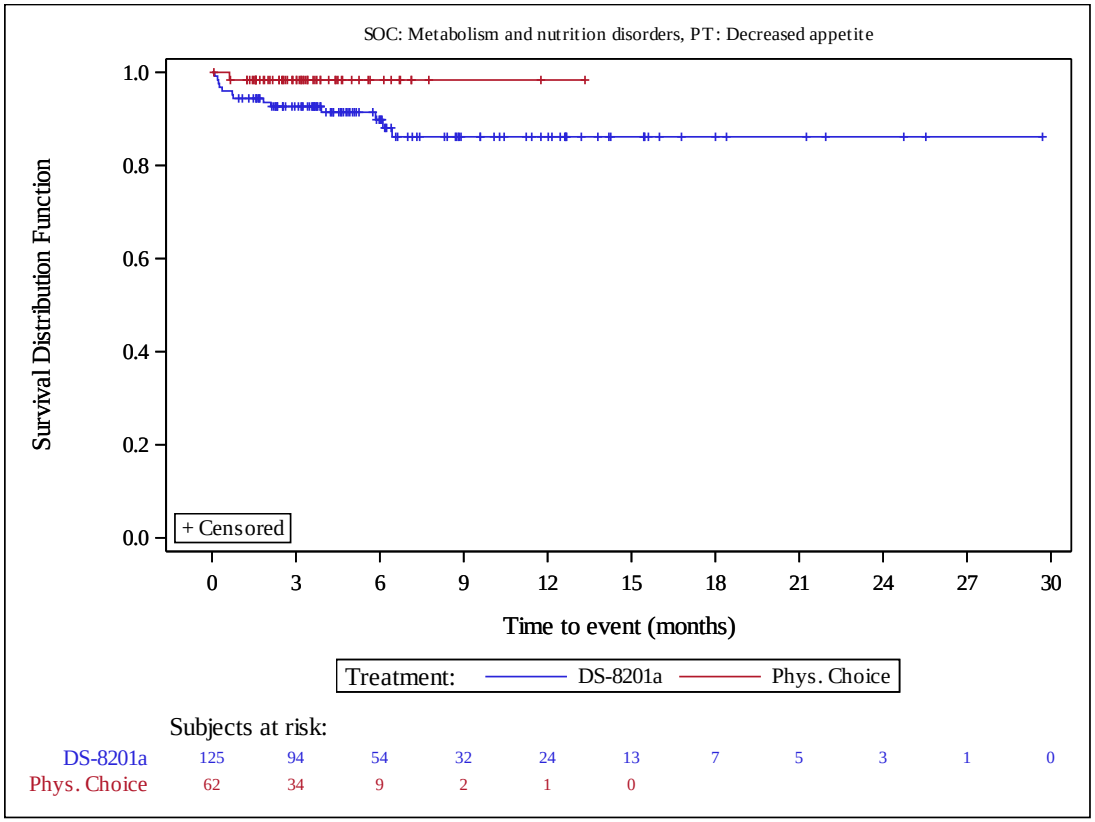
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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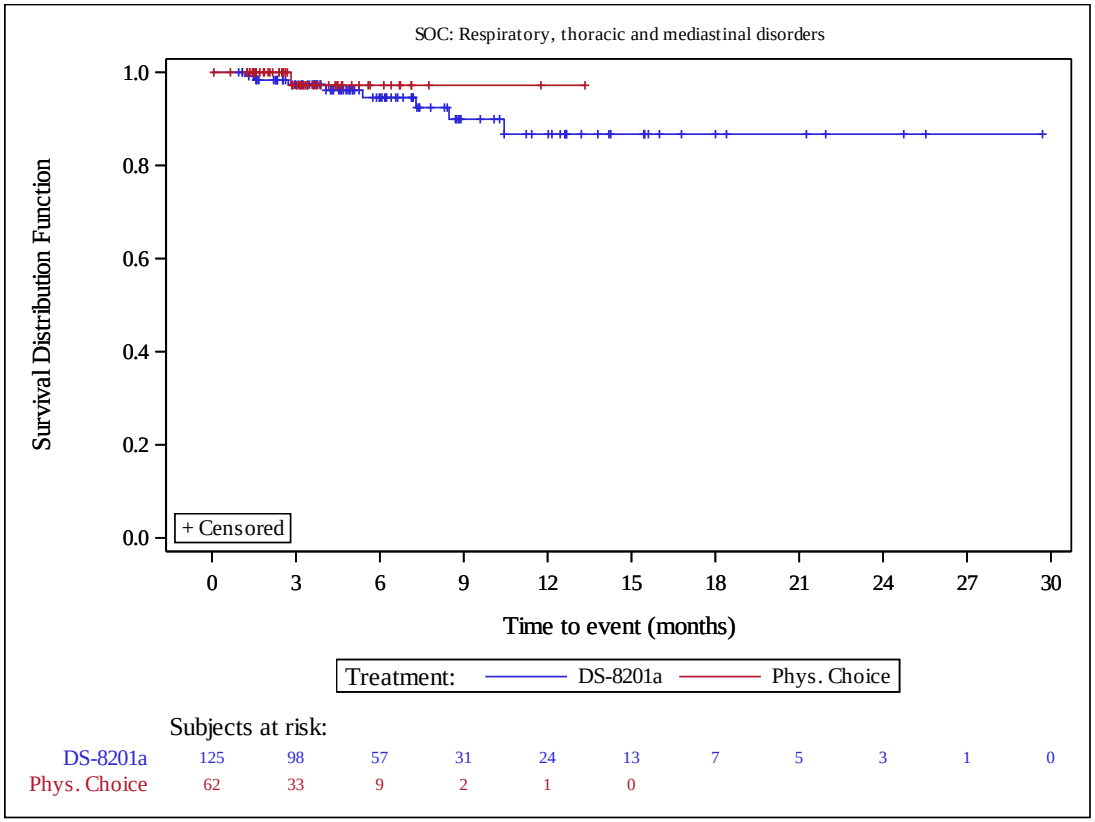
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	53 (42.4)	14 (22.6)
	Number of censored subjects, n (%)	72 (57.6)	48 (77.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	9.9 (5.6, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.61 (0.89, 2.91)	
	p-value [c]	0.1137	
	Relative Risk (95% CI) [d]	1.88 (1.13, 3.11)	
	p-value	0.0143	
	Odds Ratio (95% CI) [d]	2.52 (1.26, 5.05)	
	p-value	0.0088	
	Risk Difference (95% CI) [e]	19.82 (5.07, 34.57)	
	p-value	0.0084	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders, PT: Anaemia	Number of subjects with events, n (%)	48 (38.4)	14 (22.6)
	Number of censored subjects, n (%)	77 (61.6)	48 (77.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	11.7 (5.8, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.40 (0.77, 2.56)	
	p-value [c]	0.2710	
	Relative Risk (95% CI) [d]	1.70 (1.02, 2.84)	
	p-value	0.0419	
	Odds Ratio (95% CI) [d]	2.14 (1.07, 4.29)	
	p-value	0.0324	
	Risk Difference (95% CI) [e]	15.82 (1.16, 30.48)	
	p-value	0.0344	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	23 (18.4)	5 (8.1)
	Number of censored subjects, n (%)	102 (81.6)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (14.8, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.71 (0.64, 4.59)	
	p-value [c]	0.2812	
	Relative Risk (95% CI) [d]	2.28 (0.91, 5.71)	
	p-value	0.0782	
	Odds Ratio (95% CI) [d]	2.57 (0.93, 7.13)	
	p-value	0.0696	
	Risk Difference (95% CI) [e]	10.34 (-0.47, 21.14)	
	p-value	0.0608	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Nausea	Number of subjects with events, n (%)	7 (5.6)	1 (1.6)
	Number of censored subjects, n (%)	118 (94.4)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.99 (0.36, 24.87)	
	p-value [c]	0.2852	
	Relative Risk (95% CI) [d]	3.47 (0.44, 27.60)	
	p-value	0.2393	
	Odds Ratio (95% CI) [d]	3.62 (0.44, 30.09)	
	p-value	0.2340	
	Risk Difference (95% CI) [e]	3.99 (-2.33, 10.30)	
	p-value	0.2158	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	14 (11.2)	5 (8.1)
	Number of censored subjects, n (%)	111 (88.8)	57 (91.9)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.23 (0.44, 3.44)	
	p-value [c]	0.6886	
	Relative Risk (95% CI) [d]	1.39 (0.52, 3.68)	
	p-value	0.5090	
	Odds Ratio (95% CI) [d]	1.44 (0.49, 4.19)	
	p-value	0.5059	
	Risk Difference (95% CI) [e]	3.14 (-6.82, 13.09)	
	p-value	0.5369	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	9 (7.2)	2 (3.2)
	Number of censored subjects, n (%)	116 (92.8)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.22 (0.48, 10.29)	
	p-value [c]	0.2943	
	Relative Risk (95% CI) [d]	2.23 (0.50, 10.02)	
	p-value	0.2947	
	Odds Ratio (95% CI) [d]	2.33 (0.49, 11.12)	
	p-value	0.2896	
	Risk Difference (95% CI) [e]	3.97 (-3.55, 11.50)	
	p-value	0.3004	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders	Number of subjects with events, n (%)	12 (9.6)	4 (6.5)
	Number of censored subjects, n (%)	113 (90.4)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (6.9, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.83 (0.26, 2.69)	
	p-value [c]	0.7568	
	Relative Risk (95% CI) [d]	1.49 (0.50, 4.43)	
	p-value	0.4748	
	Odds Ratio (95% CI) [d]	1.54 (0.48, 4.99)	
	p-value	0.4715	
	Risk Difference (95% CI) [e]	3.15 (-6.06, 12.36)	
	p-value	0.5029	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations	Number of subjects with events, n (%)	13 (10.4)	1 (1.6)
	Number of censored subjects, n (%)	112 (89.6)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	3.98 (0.51, 30.90)	
	p-value [c]	0.1534	
	Relative Risk (95% CI) [d]	6.45 (0.86, 48.17)	
	p-value	0.0693	
	Odds Ratio (95% CI) [d]	7.08 (0.90, 55.43)	
	p-value	0.0623	
	Risk Difference (95% CI) [e]	8.79 (1.38, 16.20)	
	p-value	0.0201	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations	Number of subjects with events, n (%)	79 (63.2)	18 (29.0)
	Number of censored subjects, n (%)	46 (36.8)	44 (71.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	2.7 (0.7, 3.7)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.27 (1.36, 3.79)	
	p-value [c]	0.0013	
	Relative Risk (95% CI) [d]	2.18 (1.44, 3.29)	
	p-value	0.0002	
	Odds Ratio (95% CI) [d]	4.20 (2.17, 8.11)	
	p-value	<.0001	
	Risk Difference (95% CI) [e]	34.17 (18.85, 49.49)	
	p-value	<.0001	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Lymphocyte count decreased	Number of subjects with events, n (%)	15 (12.0)	1 (1.6)
	Number of censored subjects, n (%)	110 (88.0)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	5.23 (0.68, 40.20)	
	p-value [c]	0.0760	
	Relative Risk (95% CI) [d]	7.44 (1.01, 55.04)	
	p-value	0.0494	
	Odds Ratio (95% CI) [d]	8.32 (1.07, 64.50)	
	p-value	0.0427	
	Risk Difference (95% CI) [e]	10.39 (2.68, 18.10)	
	p-value	0.0083	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Neutrophil count decreased	Number of subjects with events, n (%)	62 (49.6)	14 (22.6)
	Number of censored subjects, n (%)	63 (50.4)	48 (77.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	4.2 (1.9, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	2.18 (1.22, 3.89)	
	p-value [c]	0.0070	
	Relative Risk (95% CI) [d]	2.20 (1.34, 3.60)	
	p-value	0.0018	
	Odds Ratio (95% CI) [d]	3.37 (1.69, 6.73)	
	p-value	0.0006	
	Risk Difference (95% CI) [e]	27.02 (12.21, 41.83)	
	p-value	0.0004	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Platelet count decreased	Number of subjects with events, n (%)	14 (11.2)	2 (3.2)
	Number of censored subjects, n (%)	111 (88.8)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	3.08 (0.70, 13.62)	
	p-value [c]	0.1194	
	Relative Risk (95% CI) [d]	3.47 (0.81, 14.80)	
	p-value	0.0925	
	Odds Ratio (95% CI) [d]	3.78 (0.83, 17.21)	
	p-value	0.0850	
	Risk Difference (95% CI) [e]	7.97 (-0.30, 16.25)	
	p-value	0.0588	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: White blood cell count decreased	Number of subjects with events, n (%)	26 (20.8)	7 (11.3)
	Number of censored subjects, n (%)	99 (79.2)	55 (88.7)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.59 (0.69, 3.68)	
	p-value [c]	0.2746	
	Relative Risk (95% CI) [d]	1.84 (0.85, 4.01)	
	p-value	0.1233	
	Odds Ratio (95% CI) [d]	2.06 (0.84, 5.06)	
	p-value	0.1136	
	Risk Difference (95% CI) [e]	9.51 (-2.31, 21.33)	
	p-value	0.1149	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	28 (22.4)	12 (19.4)
	Number of censored subjects, n (%)	97 (77.6)	50 (80.6)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.97 (0.49, 1.93)	
	p-value [c]	0.9338	
	Relative Risk (95% CI) [d]	1.16 (0.63, 2.12)	
	p-value	0.6353	
	Odds Ratio (95% CI) [d]	1.20 (0.56, 2.57)	
	p-value	0.6329	
	Risk Difference (95% CI) [e]	3.05 (-10.41, 16.50)	
	p-value	0.6574	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Number of subjects with events, n (%)	21 (16.8)	8 (12.9)
	Number of censored subjects, n (%)	104 (83.2)	54 (87.1)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.14 (0.50, 2.60)	
	p-value [c]	0.7490	
	Relative Risk (95% CI) [d]	1.30 (0.61, 2.77)	
	p-value	0.4934	
	Odds Ratio (95% CI) [d]	1.36 (0.57, 3.28)	
	p-value	0.4895	
	Risk Difference (95% CI) [e]	3.90 (-7.92, 15.71)	
	p-value	0.5181	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Number of subjects with events, n (%)	5 (4.0)	4 (6.5)
	Number of censored subjects, n (%)	120 (96.0)	58 (93.5)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.47 (0.12, 1.77)	
	p-value [c]	0.2524	
	Relative Risk (95% CI) [d]	0.62 (0.17, 2.23)	
	p-value	0.4638	
	Odds Ratio (95% CI) [d]	0.60 (0.16, 2.33)	
	p-value	0.4650	
	Risk Difference (95% CI) [e]	-2.45 (-10.67, 5.77)	
	p-value	0.5589	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Number of subjects with events, n (%)	7 (5.6)	2 (3.2)
	Number of censored subjects, n (%)	118 (94.4)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	1.29 (0.26, 6.32)	
	p-value [c]	0.7561	
	Relative Risk (95% CI) [d]	1.74 (0.37, 8.11)	
	p-value	0.4832	
	Odds Ratio (95% CI) [d]	1.78 (0.36, 8.83)	
	p-value	0.4806	
	Risk Difference (95% CI) [e]	2.37 (-4.80, 9.55)	
	p-value	0.5165	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations	Region							0.1768
	Japan	66/ 99 (66.7)	1.0 (0.7, 3.4)	14/ 50 (28.0)	NE (NE , NE)	2.71 (1.52, 4.82)	0.0004	
	Korea	13/ 26 (50.0)	3.9 (2.9, NE)	4/ 12 (33.3)	NE (0.5, NE)	0.96 (0.31, 3.00)	0.9468	
	Lines of prior systemic therapy							0.2580
	2	38/ 66 (57.6)	3.5 (1.9, 5.6)	12/ 38 (31.6)	NE (2.4, NE)	1.69 (0.88, 3.24)	0.1082	
	3	26/ 34 (76.5)	0.5 (0.5, 0.7)	4/ 18 (22.2)	NE (NE , NE)	4.43 (1.54, 12.76)	0.0028	
	>=4	15/ 25 (60.0)	3.2 (0.5, NE)	2/ 6 (33.3)	NE (0.5, NE)	1.62 (0.37, 7.14)	0.5180	
	Age							0.2121
	<65 years	37/ 55 (67.3)	3.4 (1.4, 4.3)	10/ 27 (37.0)	NE (0.7, NE)	1.38 (0.68, 2.82)	0.3663	
	>=65 years	42/ 70 (60.0)	1.1 (0.6, NE)	8/ 35 (22.9)	NE (NE , NE)	3.08 (1.44, 6.57)	0.0022	
	Sex							0.8221
	female	16/ 30 (53.3)	4.2 (0.5, NE)	4/ 15 (26.7)	NE (0.7, NE)	1.85 (0.61, 5.60)	0.2742	
	male	63/ 95 (66.3)	1.6 (0.7, 3.5)	14/ 47 (29.8)	NE (NE , NE)	2.37 (1.33, 4.24)	0.0025	
	ECOG PS							0.2757
	0	40/ 62 (64.5)	1.5 (0.7, 6.6)	7/ 30 (23.3)	NE (NE , NE)	3.16 (1.41, 7.07)	0.0030	
	1	39/ 63 (61.9)	3.0 (0.7, 4.2)	11/ 32 (34.4)	NE (2.4, NE)	1.72 (0.88, 3.36)	0.1099	
	HER2 Status in central laboratory							0.7071
	IHC 3+	61/ 96 (63.5)	2.7 (0.7, 3.9)	14/ 47 (29.8)	NE (2.8, NE)	2.14 (1.19, 3.82)	0.0088	
	IHC 2+/ISH +	18/ 29 (62.1)	1.4 (0.5, NE)	4/ 15 (26.7)	NE (0.5, NE)	2.67 (0.90, 7.90)	0.0644	
	Primary tumor location							0.4121
	Gastric	67/108 (62.0)	2.7 (0.7, 4.2)	17/ 55 (30.9)	NE (NE , NE)	2.09 (1.22, 3.56)	0.0057	
	GEJ	12/ 17 (70.6)	1.9 (0.5, 4.3)	1/ 7 (14.3)	NE (0.5, NE)	5.10 (0.66, 39.31)	0.0801	
	Histological subtype							0.4044
	intestinal	55/ 89 (61.8)	1.9 (0.7, 4.2)	10/ 38 (26.3)	NE (NE , NE)	2.55 (1.30, 5.00)	0.0048	
	diffuse	20/ 28 (71.4)	1.6 (0.5, 3.9)	5/ 18 (27.8)	NE (2.4, NE)	2.43 (0.90, 6.57)	0.0702	
	others	4/ 8 (50.0)	4.2 (0.3, NE)	3/ 6 (50.0)	2.4 (0.4, NE)	0.87 (0.19, 3.96)	0.8594	
	Number of metastatic sites							0.1657
	<2	15/ 23 (65.2)	1.4 (0.6, NE)	5/ 10 (50.0)	NE (0.2, NE)	1.18 (0.43, 3.25)	0.7032	
	>= 2	64/102 (62.7)	2.7 (0.7, 3.9)	13/ 52 (25.0)	NE (NE , NE)	2.67 (1.47, 4.86)	0.0008	
	Previous total gastrectomy							0.8652
	yes	13/ 22 (59.1)	3.4 (0.7, NE)	2/ 9 (22.2)	NE (0.5, NE)	2.59 (0.58, 11.58)	0.2001	
	no	66/103 (64.1)	1.6 (0.7, 3.9)	16/ 53 (30.2)	NE (2.8, NE)	2.26 (1.31, 3.90)	0.0026	
	Prior adjuvant/ neoadjuvant therapy							0.7191
	yes	22/ 30 (73.3)	0.7 (0.6, 3.2)	4/ 10 (40.0)	NE (0.2, NE)	1.93 (0.66, 5.63)	0.2253	
	no	57/ 95 (60.0)	3.0 (1.3, 4.2)	14/ 52 (26.9)	NE (NE , NE)	2.28 (1.27, 4.09)	0.0046	
	Prior ramucirumab contained treatment							0.8069
	yes	62/ 94 (66.0)	1.5 (0.7, 3.4)	12/ 41 (29.3)	NE (NE , NE)	2.30 (1.24, 4.27)	0.0064	
	no	17/ 31 (54.8)	4.3 (0.7, NE)	6/ 21 (28.6)	NE (2.4, NE)	1.89 (0.74, 4.83)	0.1776	

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[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients) - Subgroup analysis
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations	Prior nivolumab contained treatment							0.0673
	yes	26/ 33 (78.8)	0.5 (0.5, 0.6)	3/ 15 (20.0)	NE (0.5, NE)	5.45 (1.64, 18.09)	0.0020	
	no	53/ 92 (57.6)	3.7 (1.8, 5.6)	15/ 47 (31.9)	NE (2.8, NE)	1.69 (0.95, 3.00)	0.0698	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.0490
	yes	33/ 44 (75.0)	0.5 (0.5, 1.4)	3/ 17 (17.6)	NE (NE , NE)	5.54 (1.69, 18.09)	0.0014	
	no	46/ 81 (56.8)	3.5 (1.8, 6.6)	15/ 45 (33.3)	NE (2.4, NE)	1.55 (0.86, 2.78)	0.1366	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.5123
	yes	14/ 22 (63.6)	1.4 (0.5, NE)	3/ 7 (42.9)	NE (0.3, NE)	1.51 (0.43, 5.29)	0.5013	
	no	65/103 (63.1)	2.8 (0.7, 3.9)	15/ 55 (27.3)	NE (NE , NE)	2.38 (1.36, 4.19)	0.0018	
	Presence of liver metastasis at baseline							0.0804
	yes	47/ 68 (69.1)	1.4 (0.5, 3.4)	8/ 34 (23.5)	NE (NE , NE)	3.49 (1.65, 7.39)	0.0005	
	no	32/ 57 (56.1)	3.7 (0.7, NE)	10/ 28 (35.7)	NE (0.7, NE)	1.44 (0.71, 2.94)	0.3047	
	Renal impairment at baseline							0.2029
	normal	22/ 33 (66.7)	1.6 (0.6, 5.6)	6/ 13 (46.2)	2.8 (0.5, NE)	1.30 (0.52, 3.28)	0.5657	
	mild	35/ 53 (66.0)	1.9 (0.7, 3.9)	9/ 28 (32.1)	NE (0.7, NE)	2.07 (0.99, 4.31)	0.0459	
	moderate	22/ 39 (56.4)	2.7 (0.5, NE)	2/ 20 (10.0)	NE (NE , NE)	6.72 (1.58, 28.67)	0.0029	
	severe	0	NE (NE , NE)	1/ 1 (100.0)	0.7 (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.3468
	normal	56/ 88 (63.6)	1.8 (0.7, 4.2)	12/ 47 (25.5)	NE (NE , NE)	2.69 (1.44, 5.04)	0.0012	
	mild	22/ 36 (61.1)	3.0 (0.5, 4.2)	6/ 15 (40.0)	NE (0.5, NE)	1.56 (0.63, 3.85)	0.3219	
	moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.3848
	yes	5/ 8 (62.5)	6.6 (0.3, NE)	2/ 5 (40.0)	NE (0.5, NE)	1.06 (0.20, 5.64)	0.9452	
	no	74/117 (63.2)	1.9 (0.7, 3.5)	16/ 57 (28.1)	NE (NE , NE)	2.44 (1.42, 4.20)	0.0008	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.8660
	yes	2/ 3 (66.7)	6.6 (4.3, NE)	1/ 4 (25.0)	NE (0.5, NE)	1.28 (0.11, 15.48)	0.8483	
	no	77/122 (63.1)	1.9 (0.7, 3.7)	17/ 58 (29.3)	NE (NE , NE)	2.27 (1.34, 3.84)	0.0017	

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[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Neutrophil count decreased	Region							0.7003
	Japan	53/ 99 (53.5)	3.4 (0.7, NE)	12/ 50 (24.0)	NE (NE , NE)	2.36 (1.26, 4.43)	0.0056	
	Korea	9/ 26 (34.6)	NE (3.5, NE)	2/ 12 (16.7)	NE (2.8, NE)	1.31 (0.28, 6.18)	0.7296	
	Lines of prior systemic therapy							0.2558
	2	28/ 66 (42.4)	NE (3.0, NE)	9/ 38 (23.7)	NE (NE , NE)	1.66 (0.78, 3.53)	0.1765	
	3	22/ 34 (64.7)	0.7 (0.5, 4.2)	3/ 18 (16.7)	NE (NE , NE)	4.62 (1.38, 15.49)	0.0065	
	>=4	12/ 25 (48.0)	5.0 (0.7, NE)	2/ 6 (33.3)	NE (0.5, NE)	1.09 (0.24, 4.90)	0.8996	
	Age							0.2686
	<65 years	25/ 55 (45.5)	5.6 (3.4, NE)	7/ 27 (25.9)	NE (2.8, NE)	1.34 (0.57, 3.15)	0.4933	
	>=65 years	37/ 70 (52.9)	1.9 (0.7, NE)	7/ 35 (20.0)	NE (NE , NE)	2.89 (1.29, 6.49)	0.0068	
	Sex							0.5846
	female	12/ 30 (40.0)	NE (0.6, NE)	2/ 15 (13.3)	NE (NE , NE)	2.89 (0.64, 12.99)	0.1472	
	male	50/ 95 (52.6)	3.5 (1.4, NE)	12/ 47 (25.5)	NE (NE , NE)	2.03 (1.08, 3.82)	0.0239	
	ECOG PS							0.3956
	0	32/ 62 (51.6)	5.0 (0.7, NE)	6/ 30 (20.0)	NE (NE , NE)	2.93 (1.22, 7.00)	0.0111	
	1	30/ 63 (47.6)	4.1 (2.0, NE)	8/ 32 (25.0)	NE (2.8, NE)	1.67 (0.77, 3.65)	0.1872	
	HER2 Status in central laboratory							0.6668
	IHC 3+	49/ 96 (51.0)	4.1 (1.4, NE)	10/ 47 (21.3)	NE (NE , NE)	2.31 (1.17, 4.56)	0.0133	
	IHC 2+/ISH +	13/ 29 (44.8)	NE (0.6, NE)	4/ 15 (26.7)	NE (0.5, NE)	1.77 (0.58, 5.44)	0.3070	
	Primary tumor location							0.5607
	Gastric	53/108 (49.1)	4.2 (1.9, NE)	13/ 55 (23.6)	NE (NE , NE)	2.04 (1.11, 3.75)	0.0183	
	GEJ	9/ 17 (52.9)	3.4 (0.5, NE)	1/ 7 (14.3)	NE (0.5, NE)	3.78 (0.48, 29.87)	0.1737	
	Histological subtype							0.6398
	intestinal	43/ 89 (48.3)	5.0 (1.4, NE)	10/ 38 (26.3)	NE (NE , NE)	1.82 (0.91, 3.62)	0.0864	
	diffuse	16/ 28 (57.1)	2.3 (0.5, NE)	3/ 18 (16.7)	NE (2.8, NE)	3.26 (0.94, 11.25)	0.0461	
	others	3/ 8 (37.5)	NE (0.3, NE)	1/ 6 (16.7)	NE (0.5, NE)	2.10 (0.22, 20.32)	0.5133	
	Number of metastatic sites							0.2087
	<2	12/ 23 (52.2)	3.0 (0.7, NE)	4/ 10 (40.0)	NE (0.2, NE)	1.16 (0.37, 3.60)	0.7559	
	>= 2	50/102 (49.0)	4.2 (1.9, NE)	10/ 52 (19.2)	NE (NE , NE)	2.56 (1.30, 5.05)	0.0051	
	Previous total gastrectomy							0.9192
	yes	10/ 22 (45.5)	3.7 (0.7, NE)	2/ 9 (22.2)	NE (0.5, NE)	2.07 (0.45, 9.49)	0.3421	
	no	52/103 (50.5)	4.2 (1.4, NE)	12/ 53 (22.6)	NE (NE , NE)	2.22 (1.18, 4.15)	0.0105	
	Prior adjuvant/ neoadjuvant therapy							0.4644
	yes	19/ 30 (63.3)	1.1 (0.7, NE)	4/ 10 (40.0)	NE (0.2, NE)	1.54 (0.52, 4.53)	0.4428	
	no	43/ 95 (45.3)	5.6 (3.0, NE)	10/ 52 (19.2)	NE (NE , NE)	2.28 (1.15, 4.55)	0.0154	
	Prior ramucirumab contained treatment							0.6135
	yes	50/ 94 (53.2)	3.4 (1.3, NE)	9/ 41 (22.0)	NE (NE , NE)	2.33 (1.14, 4.74)	0.0155	
	no	12/ 31 (38.7)	NE (2.3, NE)	5/ 21 (23.8)	NE (2.8, NE)	1.62 (0.57, 4.64)	0.3674	

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[c] Two-sided p-value derived from log-rank test.
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Daiichi Sankyo

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Primary Cohort
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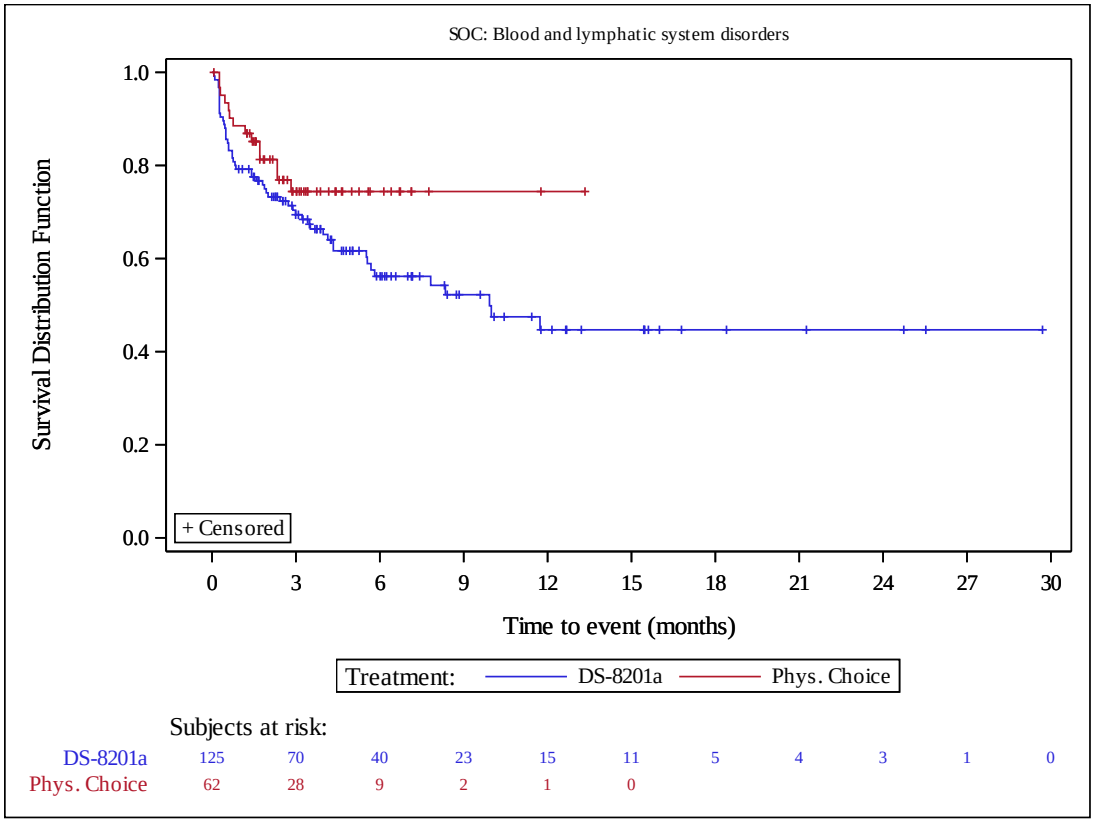
Safety Analysis Set

SOC/PT	Subgroup Level	DS-8201a (N=125) n/ N (%)	DS-8201a (N=125) Median (95% CI) [a]	Phys. Choice (N=62) n/ N (%)	Phys. Choice (N=62) Median (95% CI) [a]	Analysis DS-8201a vs. Phys. Choice Hazard Ratio (95% CI) [b]	Analysis DS-8201a vs. Phys. Choice p-Value [c]	Interaction p-Value [d]
SOC: Investigations, PT: Neutrophil count decreased	Prior nivolumab contained treatment							0.2015
	yes	22/ 33 (66.7)	0.5 (0.5, 1.8)	3/ 15 (20.0)	NE (0.5, NE)	4.06 (1.21, 13.61)	0.0145	
	no	40/ 92 (43.5)	NE (3.5, NE)	11/ 47 (23.4)	NE (NE , NE)	1.68 (0.86, 3.28)	0.1196	
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							0.1617
	yes	28/ 44 (63.6)	1.1 (0.5, 5.0)	3/ 17 (17.6)	NE (NE , NE)	4.05 (1.23, 13.35)	0.0128	
	no	34/ 81 (42.0)	NE (3.4, NE)	11/ 45 (24.4)	NE (NE , NE)	1.58 (0.80, 3.12)	0.1810	
	Most recently treatment with trastuzumab or trastuzumab similar treatment including study drug							0.1205
	yes	10/ 22 (45.5)	NE (0.7, NE)	3/ 7 (42.9)	NE (0.3, NE)	0.81 (0.22, 2.96)	0.7406	
	no	52/103 (50.5)	4.2 (1.8, NE)	11/ 55 (20.0)	NE (NE , NE)	2.55 (1.33, 4.89)	0.0035	
	Presence of liver metastasis at baseline							0.1753
	yes	39/ 68 (57.4)	3.4 (0.7, 5.0)	7/ 34 (20.6)	NE (NE , NE)	3.09 (1.38, 6.90)	0.0039	
	no	23/ 57 (40.4)	NE (2.0, NE)	7/ 28 (25.0)	NE (NE , NE)	1.47 (0.63, 3.42)	0.3613	
	Renal impairment at baseline							0.4942
	normal	17/ 33 (51.5)	5.6 (0.7, NE)	4/ 13 (30.8)	NE (0.5, NE)	1.61 (0.54, 4.81)	0.3943	
	mild	29/ 53 (54.7)	3.5 (0.7, NE)	8/ 28 (28.6)	NE (NE , NE)	1.79 (0.82, 3.93)	0.1352	
	moderate	16/ 39 (41.0)	NE (1.4, NE)	2/ 20 (10.0)	NE (NE , NE)	4.29 (0.98, 18.69)	0.0345	
	severe	0	NE (NE , NE)	0/ 1 (0.0)	NE (NE , NE)	NE	NE	
	Hepatic impairment at baseline							0.1041
	normal	43/ 88 (48.9)	5.6 (0.7, NE)	8/ 47 (17.0)	NE (NE , NE)	3.01 (1.41, 6.42)	0.0027	
	mild	18/ 36 (50.0)	3.7 (1.3, NE)	6/ 15 (40.0)	NE (0.5, NE)	1.12 (0.44, 2.82)	0.7805	
	moderate	1/ 1 (100.0)	3.4 (NE , NE)	0	NE (NE , NE)	NE	NE	
	Prior treatment with irinotecan or other topoisomerase I inhibitors							0.0903
	yes	2/ 8 (25.0)	NE (0.6, NE)	2/ 5 (40.0)	NE (0.5, NE)	0.47 (0.07, 3.39)	0.4463	
	no	60/117 (51.3)	4.1 (1.8, NE)	12/ 57 (21.1)	NE (NE , NE)	2.48 (1.33, 4.61)	0.0030	
	Most recently treatment with irinotecan or other topoisomerase I inhibitors							0.9862
	yes	0/ 3 (0.0)	NE (NE , NE)	1/ 4 (25.0)	NE (0.5, NE)	NE	NE	
	no	62/122 (50.8)	4.1 (1.8, NE)	13/ 58 (22.4)	NE (NE , NE)	2.26 (1.24, 4.12)	0.0059	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
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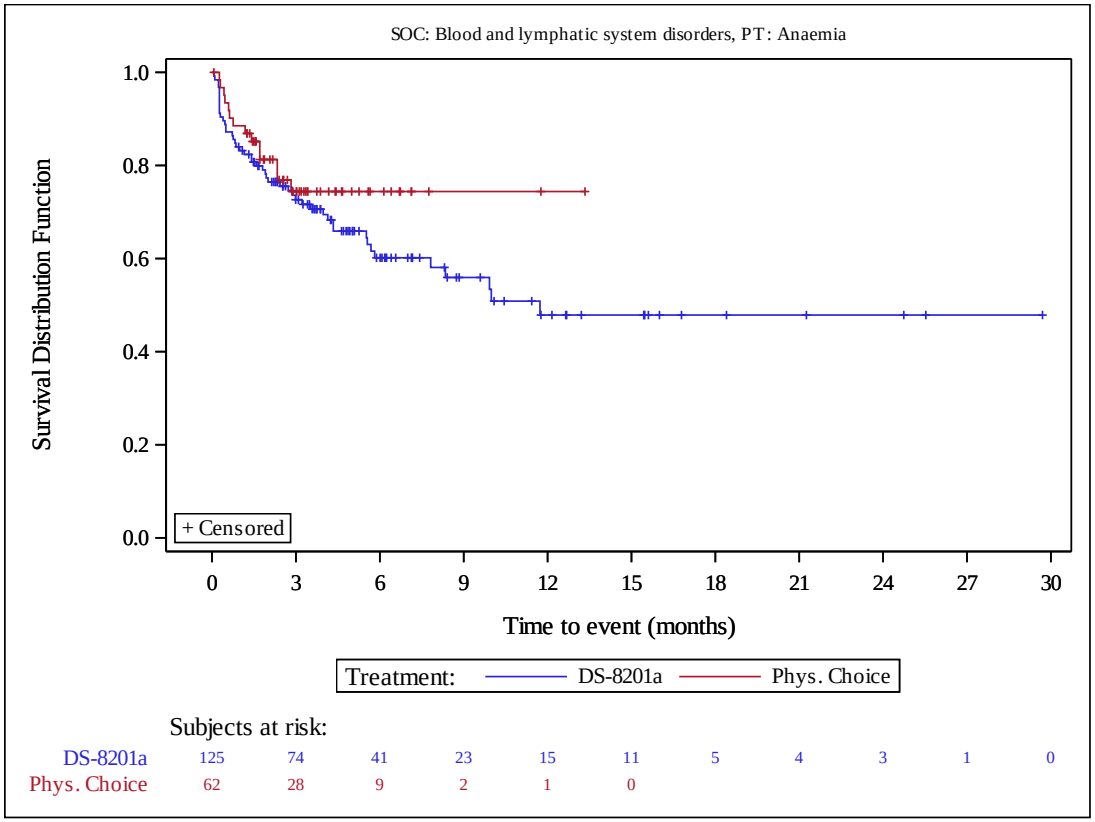
Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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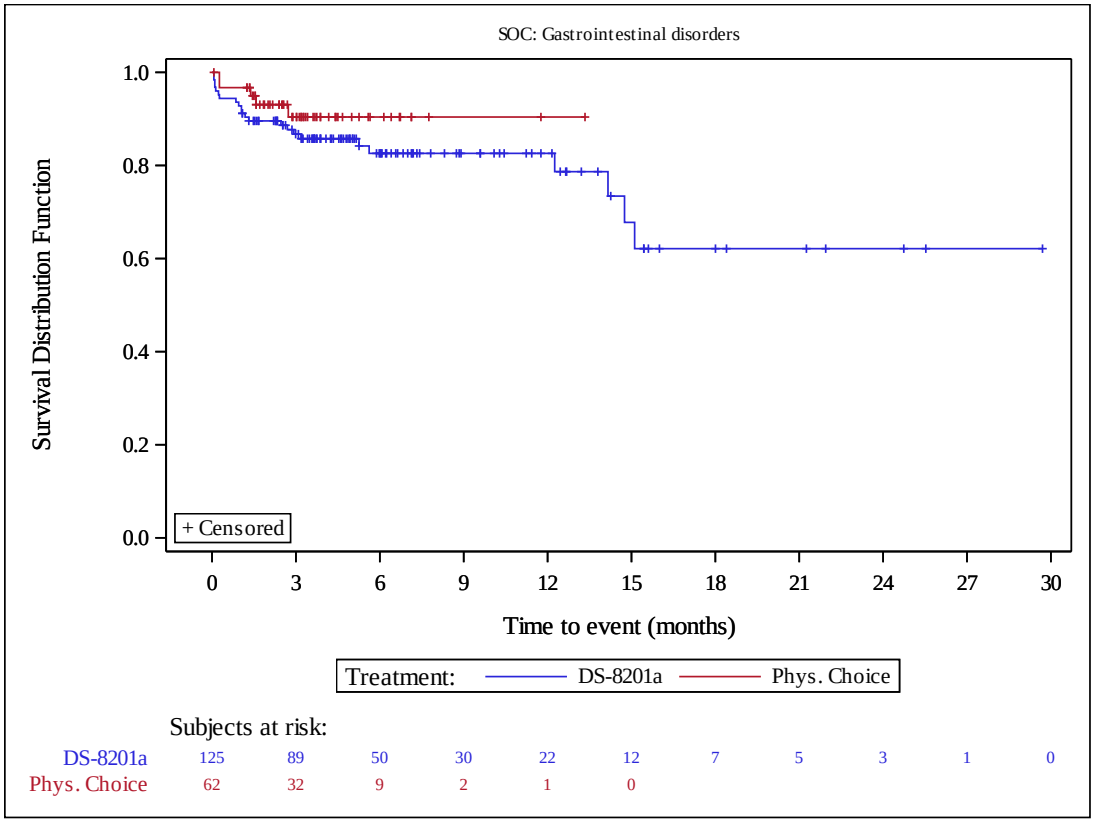
Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-J202
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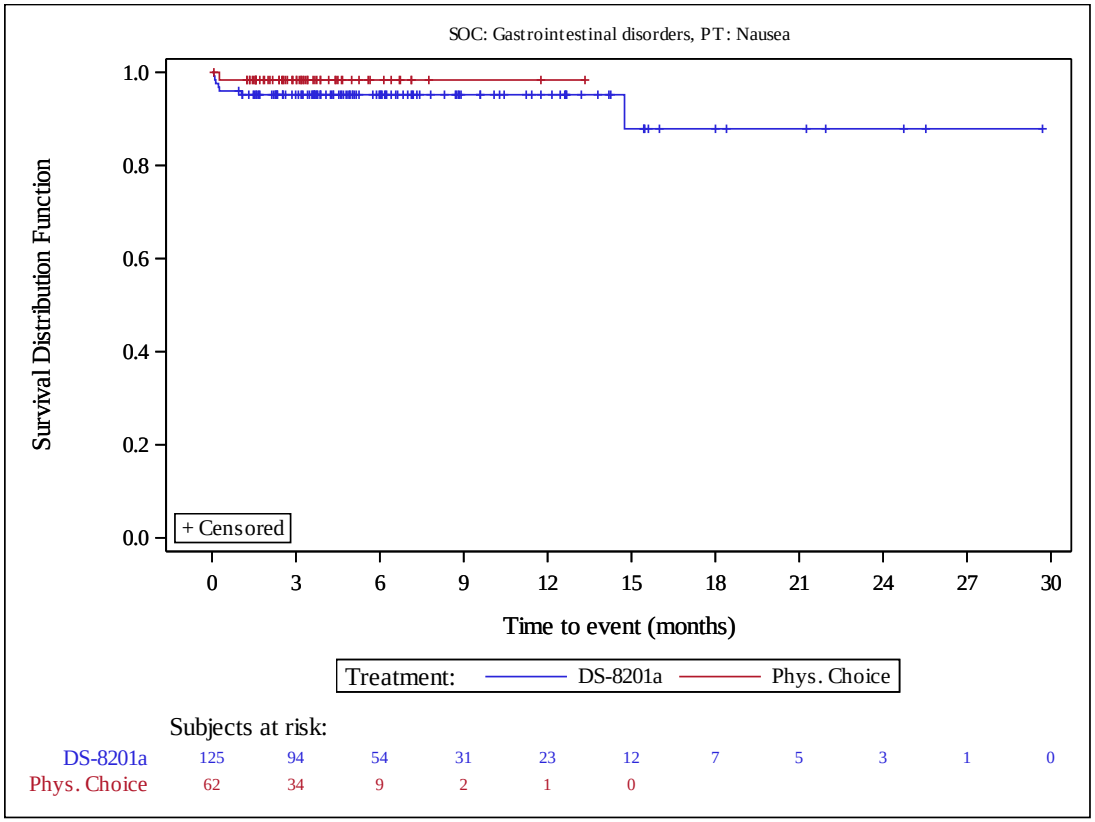
Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
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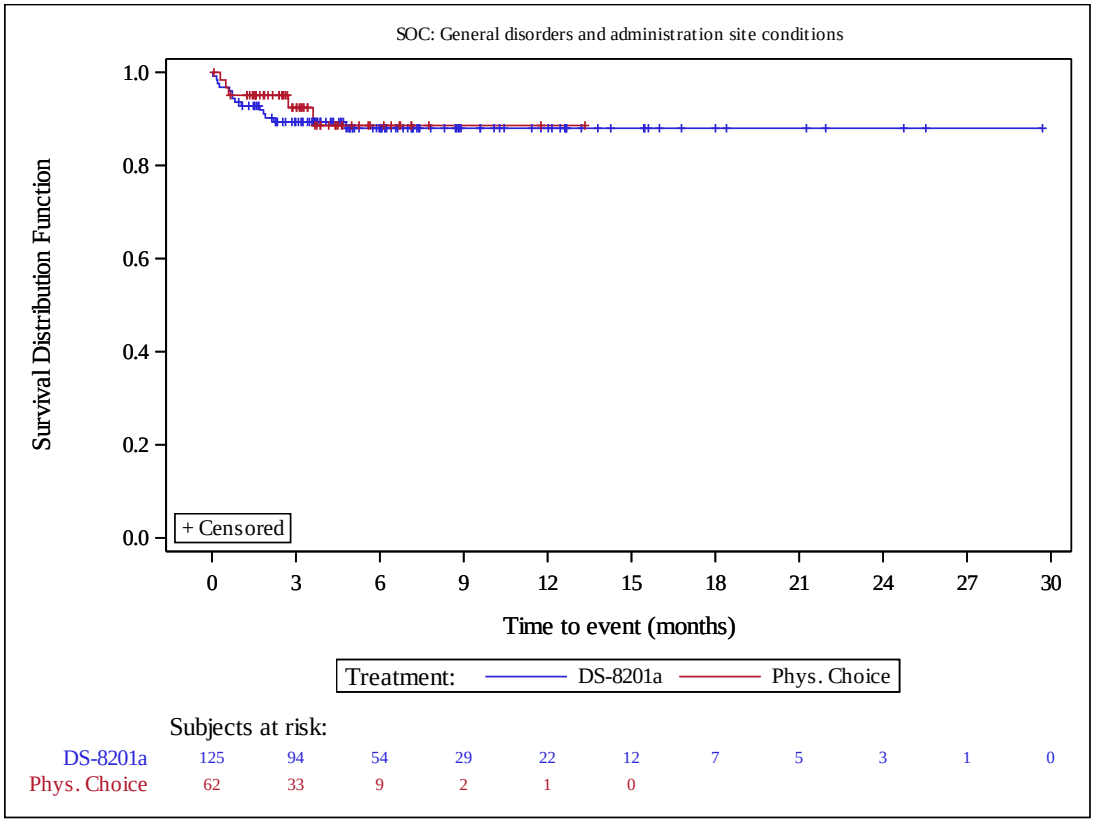
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



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Source data: ADAM.ADSL and ADAM.ADAE
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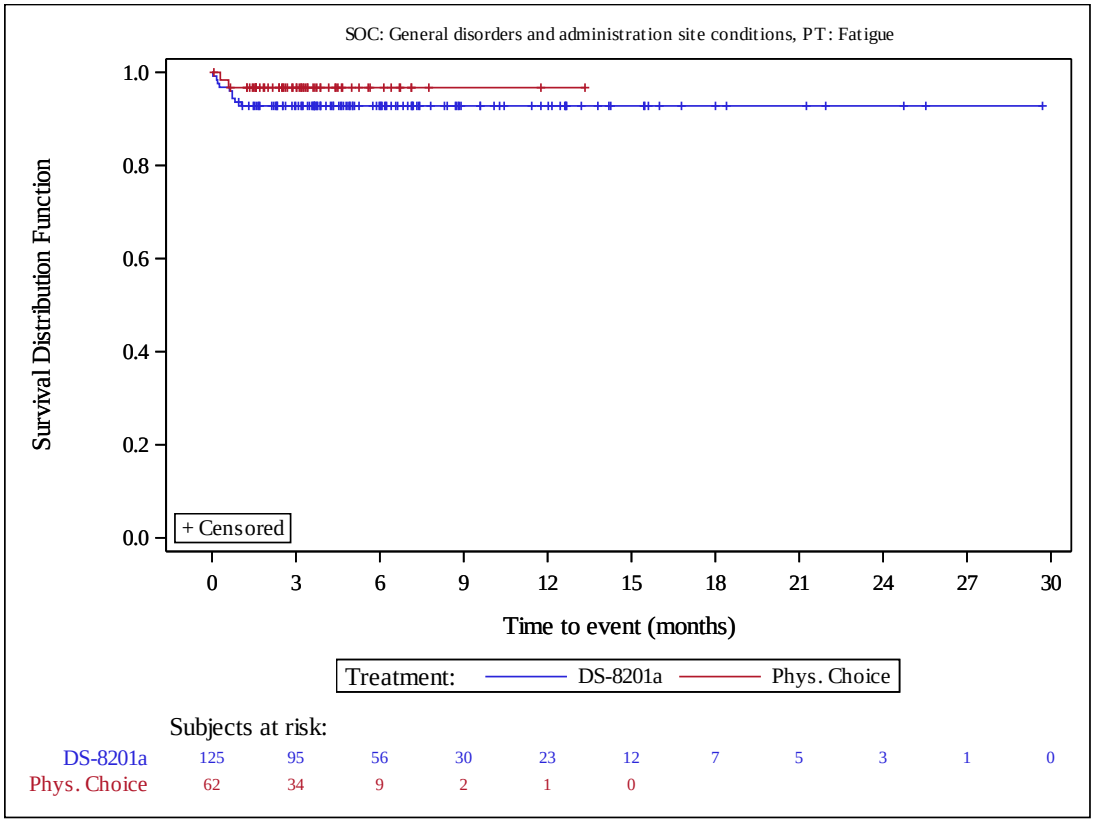

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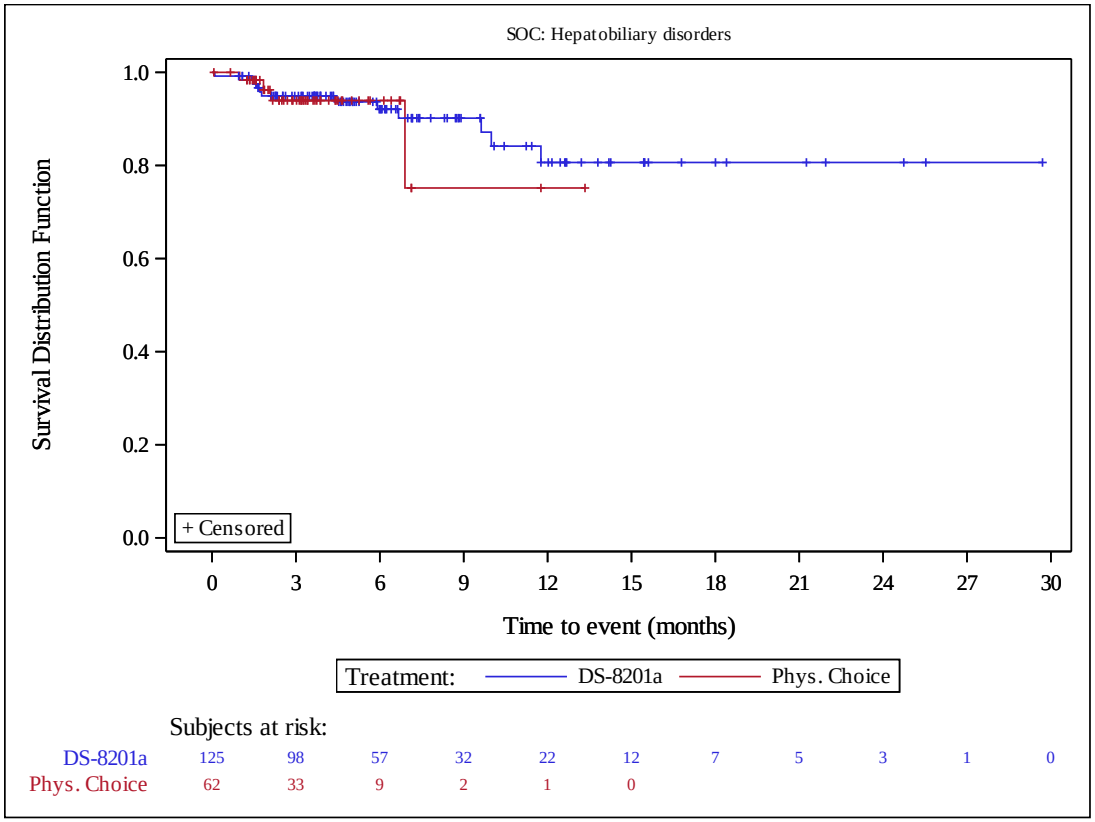

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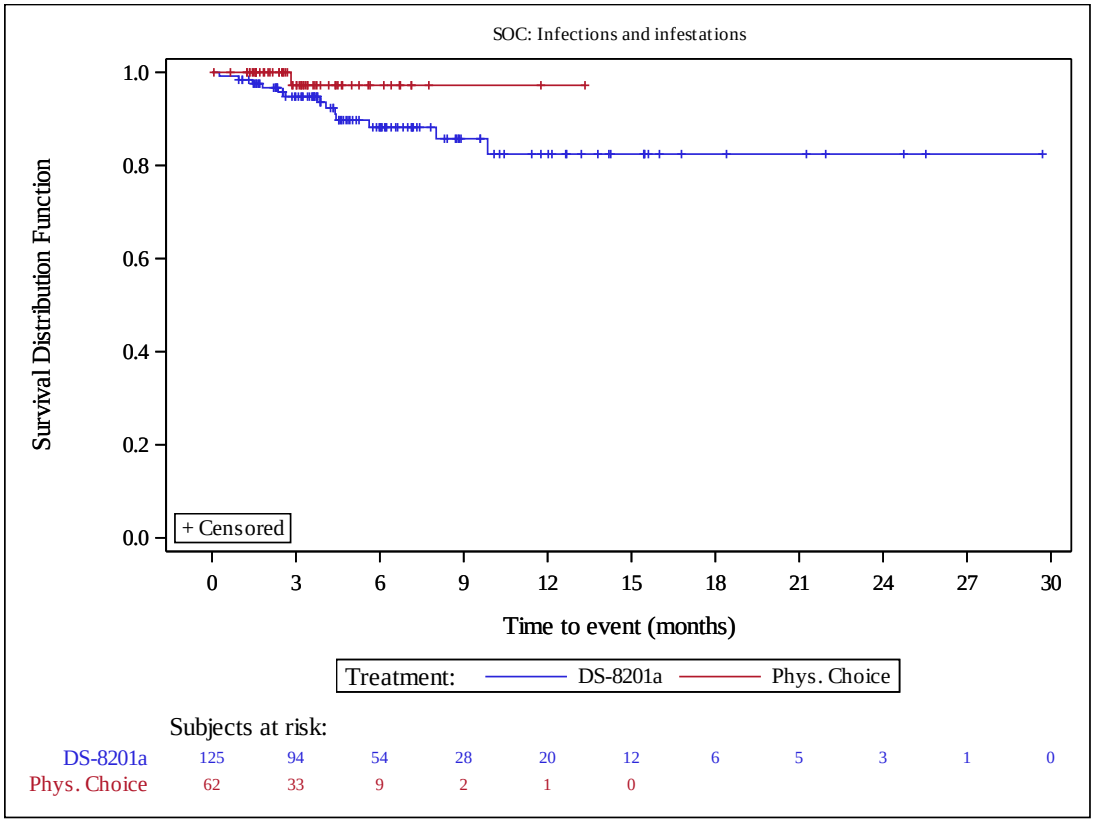

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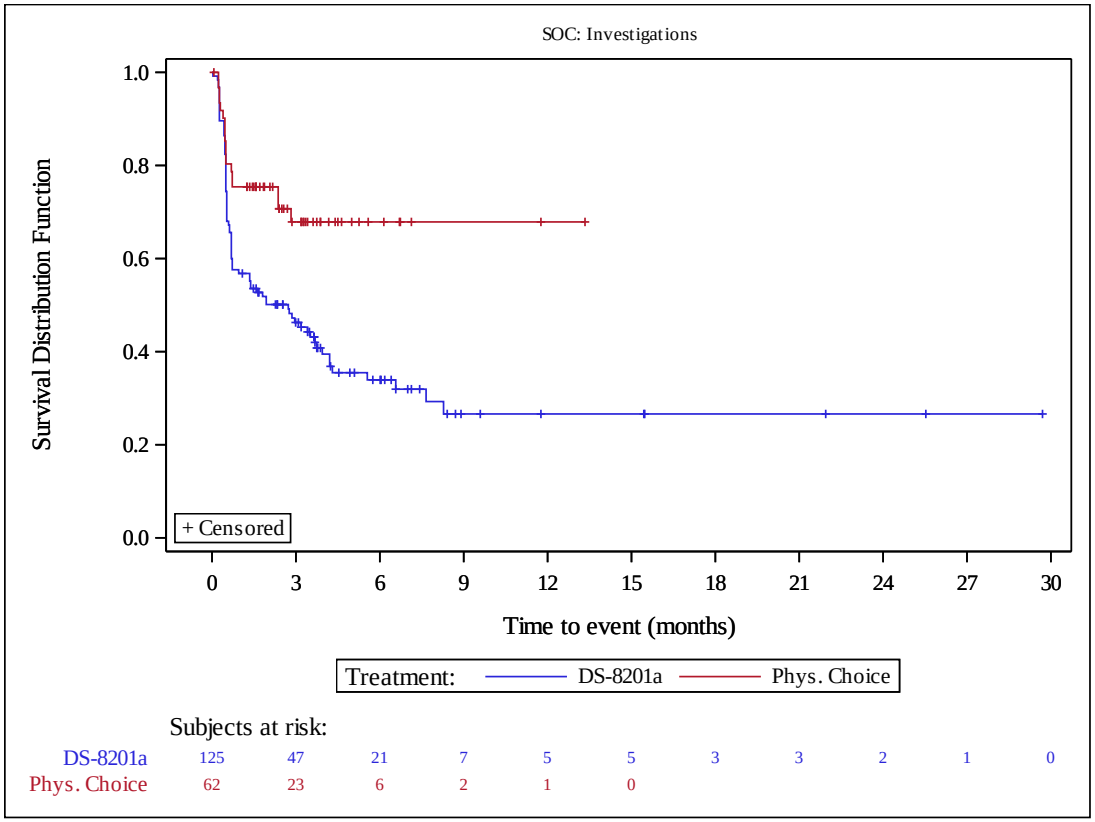

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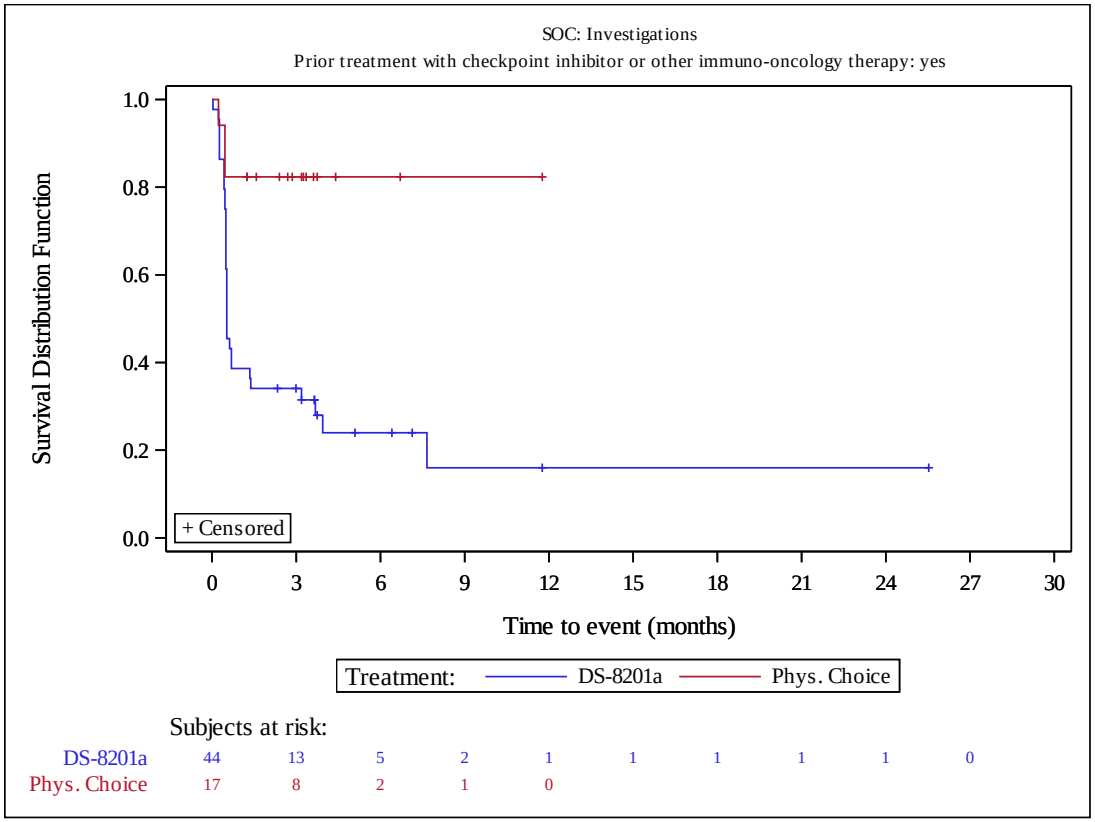

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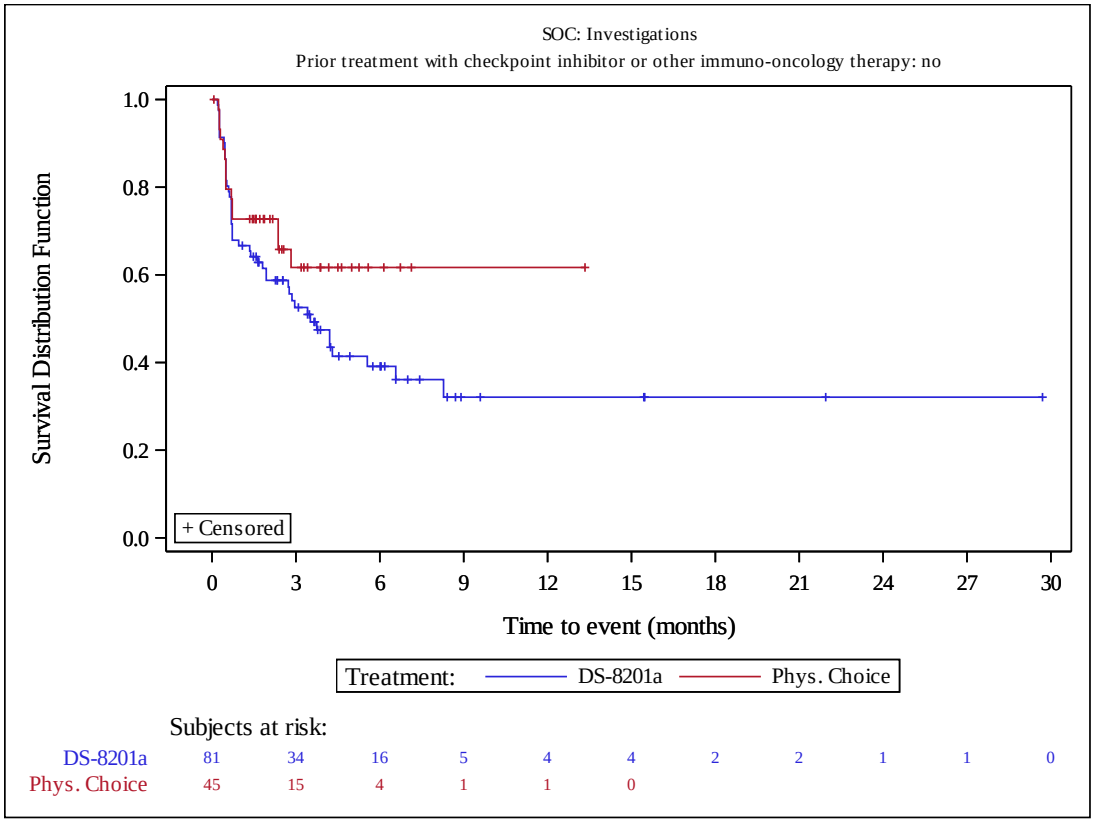

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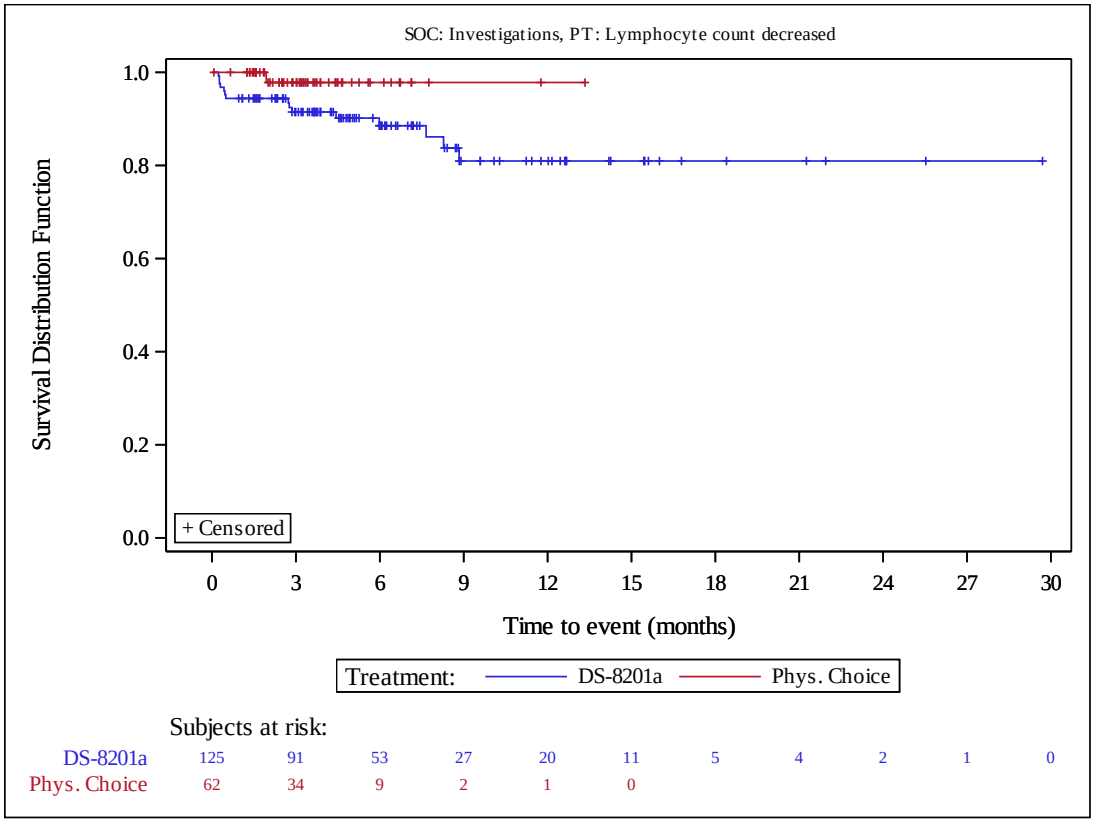

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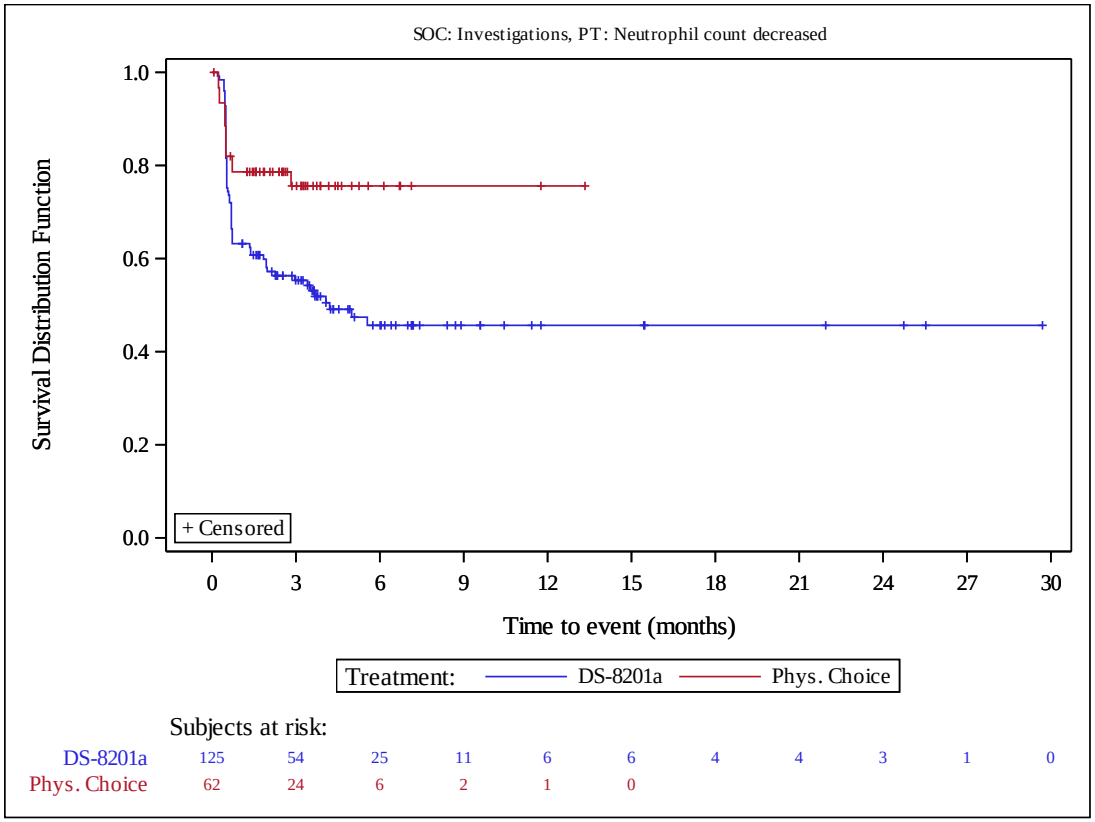

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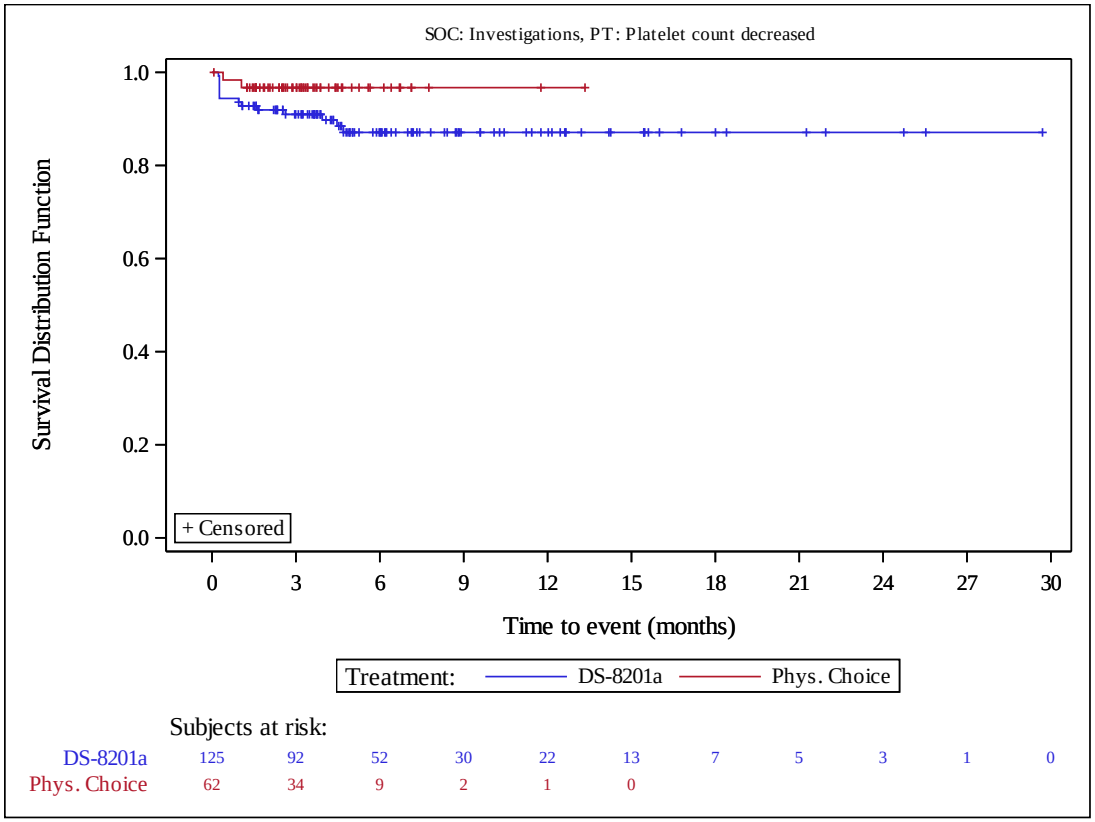

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Primary Cohort
Kaplan Meier Plot of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
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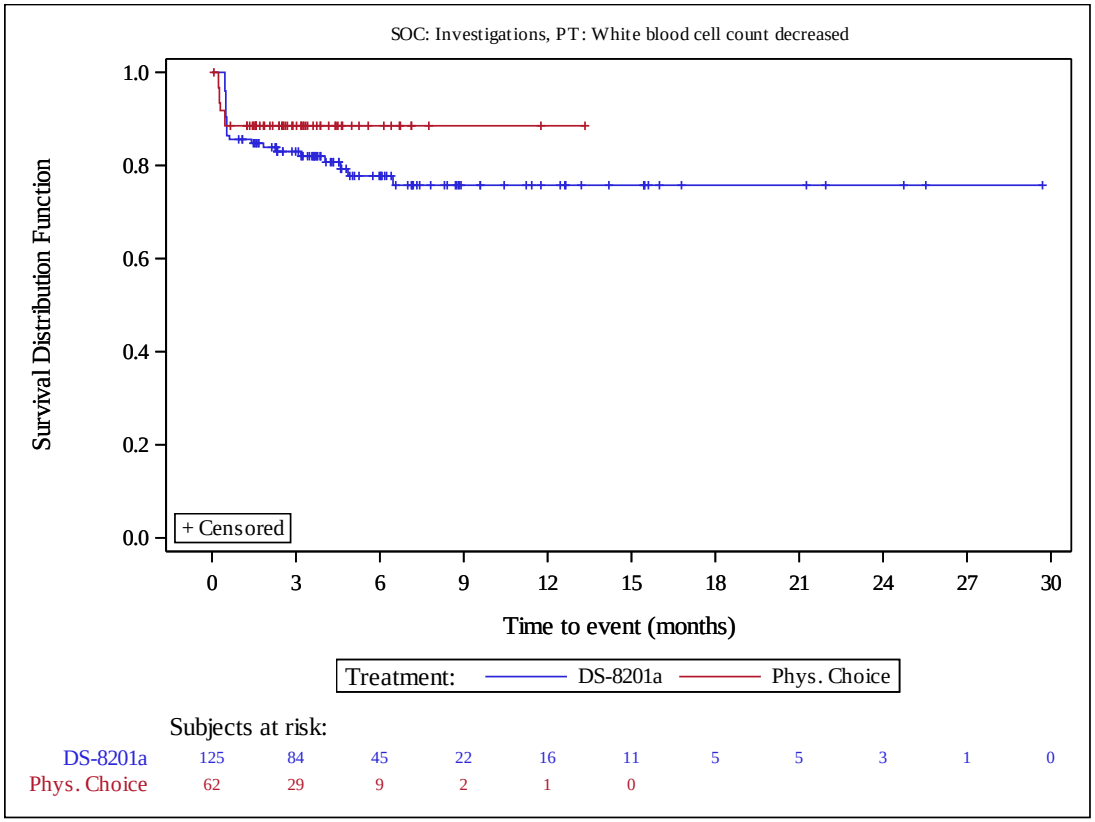

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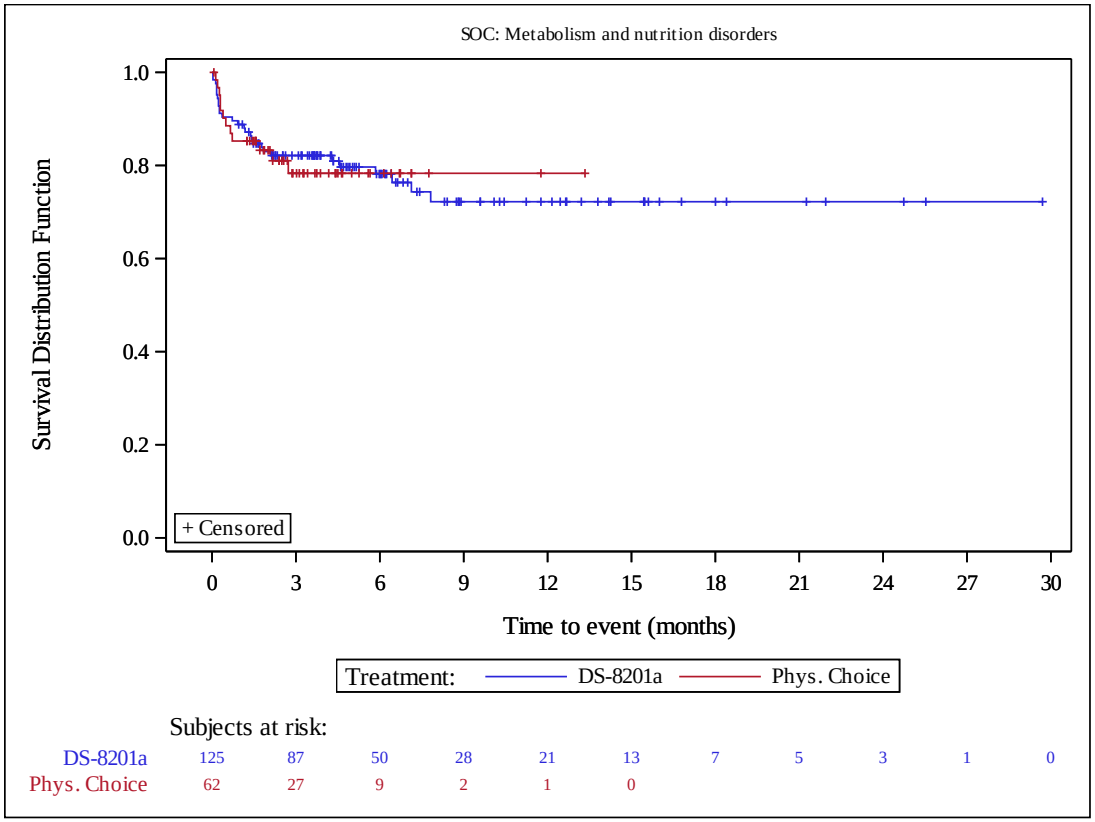
Safety Analysis Set



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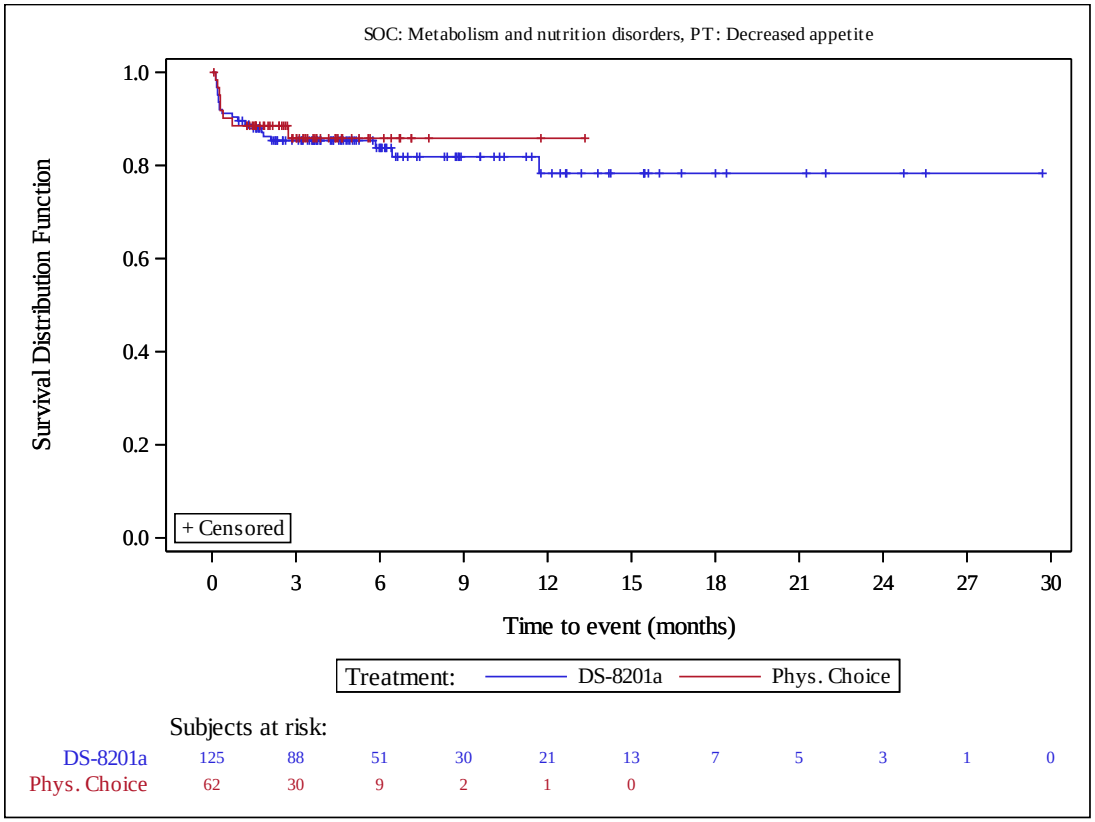

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Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
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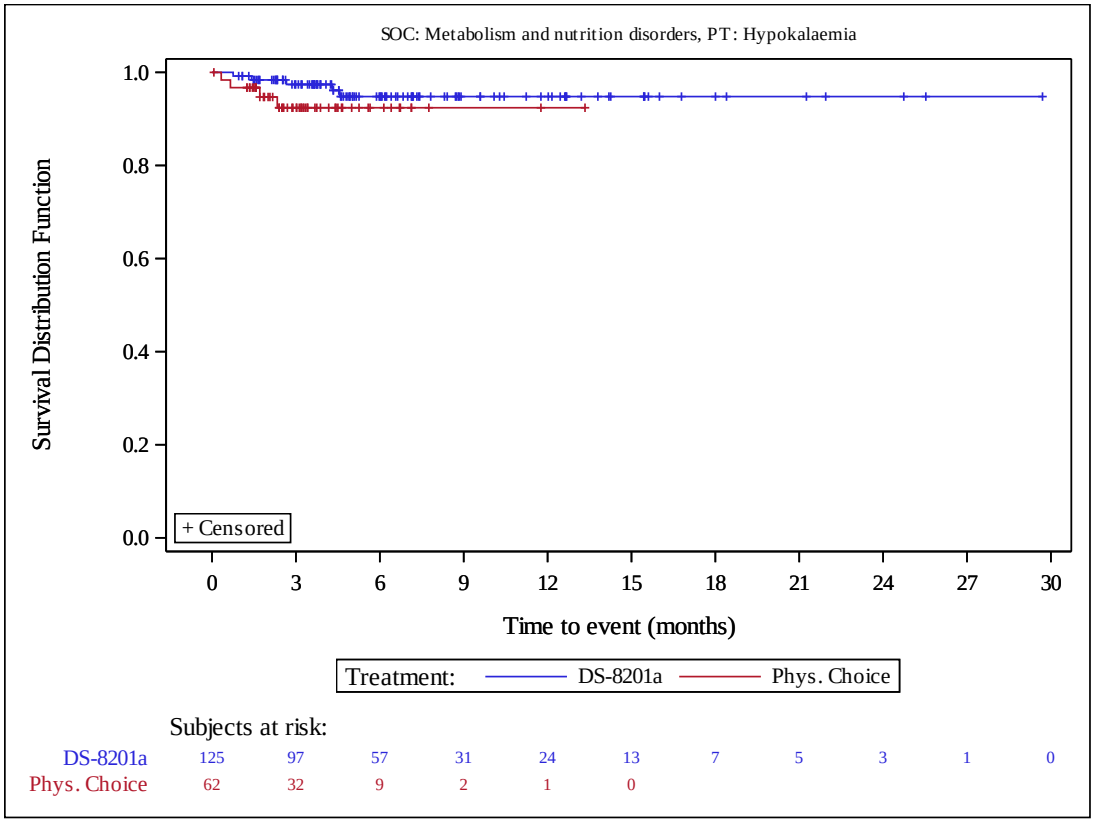
Safety Analysis Set



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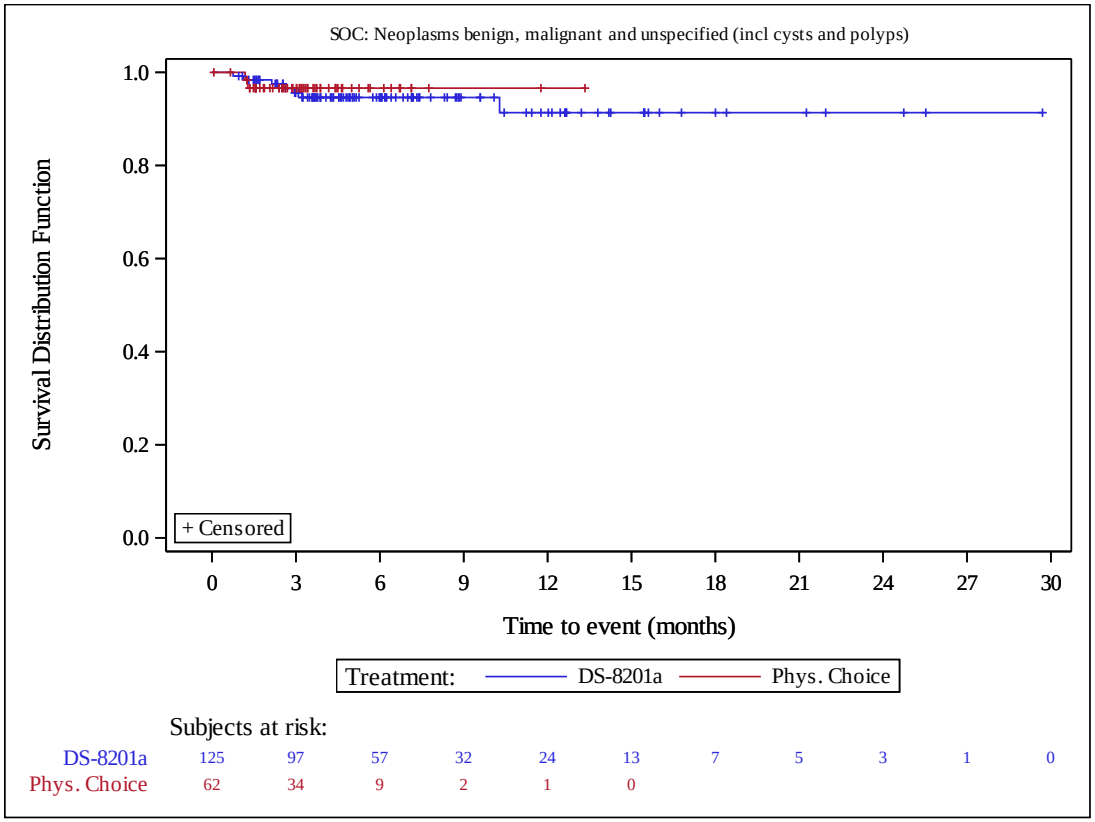

Kaplan-Meier Plots for subgroups only created if p-value for interaction <= 0.05.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Blood and lymphatic system disorders, PT: Anaemia	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
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[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
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[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Gastrointestinal obstruction	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Gastrointestinal disorders, PT: Large intestine perforation	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions	Number of subjects with events, n (%)	2 (1.6)	1 (1.6)
	Number of censored subjects, n (%)	123 (98.4)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.22 (0.02, 2.58)	
	p-value [c]	0.1873	
	Relative Risk (95% CI) [d]	0.99 (0.09, 10.73)	
	p-value	0.9947	
	Odds Ratio (95% CI) [d]	0.99 (0.09, 11.15)	
	p-value	0.9947	
	Risk Difference (95% CI) [e]	-0.01 (-5.05, 5.02)	
	p-value	0.9960	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Asthenia	Number of subjects with events, n (%)	1 (0.8)	1 (1.6)
	Number of censored subjects, n (%)	124 (99.2)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.13 (0.01, 2.22)	
	p-value [c]	0.0996	
	Relative Risk (95% CI) [d]	0.50 (0.03, 7.80)	
	p-value	0.6179	
	Odds Ratio (95% CI) [d]	0.49 (0.03, 8.00)	
	p-value	0.6181	
	Risk Difference (95% CI) [e]	-0.81 (-5.52, 3.90)	
	p-value	0.7351	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: General disorders and administration site conditions, PT: Fatigue	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders, PT: Cholangitis	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Hepatobiliary disorders, PT: Hepatic function abnormal	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations	Number of subjects with events, n (%)	4 (3.2)	0 (0.0)
	Number of censored subjects, n (%)	121 (96.8)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	4.50 (0.25, 82.28)	
	p-value	0.3104	
	Odds Ratio (95% CI) [d]	4.63 (0.25, 87.37)	
	p-value	0.3066	
	Risk Difference (95% CI) [e]	3.20 (-1.09, 7.49)	
	p-value	0.1439	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations, PT: Pneumonia	Number of subjects with events, n (%)	2 (1.6)	0 (0.0)
	Number of censored subjects, n (%)	123 (98.4)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	2.50 (0.12, 51.29)	
	p-value	0.5522	
	Odds Ratio (95% CI) [d]	2.53 (0.12, 53.51)	
	p-value	0.5510	
	Risk Difference (95% CI) [e]	1.60 (-1.81, 5.01)	
	p-value	0.3572	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations, PT: Pneumonia bacterial	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Infections and infestations, PT: Sepsis	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations	Number of subjects with events, n (%)	0 (0.0)	2 (3.2)
	Number of censored subjects, n (%)	125 (100.0)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	0.10 (0.00, 2.05)	
	p-value	0.1352	
	Odds Ratio (95% CI) [d]	0.10 (0.00, 2.04)	
	p-value	0.1330	
	Risk Difference (95% CI) [e]	-3.23 (-8.83, 2.38)	
	p-value	0.2593	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Investigations, PT: Neutrophil count decreased	Number of subjects with events, n (%)	0 (0.0)	2 (3.2)
	Number of censored subjects, n (%)	125 (100.0)	60 (96.8)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	0.10 (0.00, 2.05)	
	p-value	0.1352	
	Odds Ratio (95% CI) [d]	0.10 (0.00, 2.04)	
	p-value	0.1330	
	Risk Difference (95% CI) [e]	-3.23 (-8.83, 2.38)	
	p-value	0.2593	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Metabolism and nutrition disorders, PT: Hyponatraemia	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Nervous system disorders	Number of subjects with events, n (%)	1 (0.8)	1 (1.6)
	Number of censored subjects, n (%)	124 (99.2)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	0.20 (0.01, 3.23)	
	p-value [c]	0.2064	
	Relative Risk (95% CI) [d]	0.50 (0.03, 7.80)	
	p-value	0.6179	
	Odds Ratio (95% CI) [d]	0.49 (0.03, 8.00)	
	p-value	0.6181	
	Risk Difference (95% CI) [e]	-0.81 (-5.52, 3.90)	
	p-value	0.7351	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Nervous system disorders, PT: Cerebral infarction	Number of subjects with events, n (%)	0 (0.0)	1 (1.6)
	Number of censored subjects, n (%)	125 (100.0)	61 (98.4)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	0.17 (0.01, 4.03)	
	p-value	0.2704	
	Odds Ratio (95% CI) [d]	0.16 (0.01, 4.07)	
	p-value	0.2694	
	Risk Difference (95% CI) [e]	-1.61 (-5.95, 2.73)	
	p-value	0.4666	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Nervous system disorders, PT: Hemiplegia	Number of subjects with events, n (%)	1 (0.8)	0 (0.0)
	Number of censored subjects, n (%)	124 (99.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	1.50 (0.06, 36.30)	
	p-value	0.8030	
	Odds Ratio (95% CI) [d]	1.51 (0.06, 37.50)	
	p-value	0.8029	
	Risk Difference (95% CI) [e]	0.80 (-1.97, 3.57)	
	p-value	0.5711	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders	Number of subjects with events, n (%)	9 (7.2)	0 (0.0)
	Number of censored subjects, n (%)	116 (92.8)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	9.50 (0.56, 160.61)	
	p-value	0.1187	
	Odds Ratio (95% CI) [d]	10.19 (0.58, 178.05)	
	p-value	0.1116	
	Risk Difference (95% CI) [e]	7.20 (1.46, 12.94)	
	p-value	0.0139	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Interstitial lung disease	Number of subjects with events, n (%)	3 (2.4)	0 (0.0)
	Number of censored subjects, n (%)	122 (97.6)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	3.50 (0.18, 66.72)	
	p-value	0.4049	
	Odds Ratio (95% CI) [d]	3.57 (0.18, 70.23)	
	p-value	0.4023	
	Risk Difference (95% CI) [e]	2.40 (-1.49, 6.29)	
	p-value	0.2265	

Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set

SOC/PT		DS-8201a (N=125)	Phys. Choice (N=62)
SOC: Respiratory, thoracic and mediastinal disorders, PT: Pneumonitis	Number of subjects with events, n (%)	6 (4.8)	0 (0.0)
	Number of censored subjects, n (%)	119 (95.2)	62 (100.0)
	Kaplan-Meier estimates of Time to Event (months) [a]		
	Median (95% CI)	NE (NE, NE)	NE (NE, NE)
	Analysis DS-8201a vs. Phys. Choice		
	Hazard Ratio (95% CI) [b]	NE	
	p-value [c]		
	Relative Risk (95% CI) [d]	6.50 (0.37, 113.56)	
	p-value	0.1997	
	Odds Ratio (95% CI) [d]	6.80 (0.38, 122.67)	
	p-value	0.1940	
	Risk Difference (95% CI) [e]	4.80 (-0.15, 9.75)	
	p-value	0.0576	

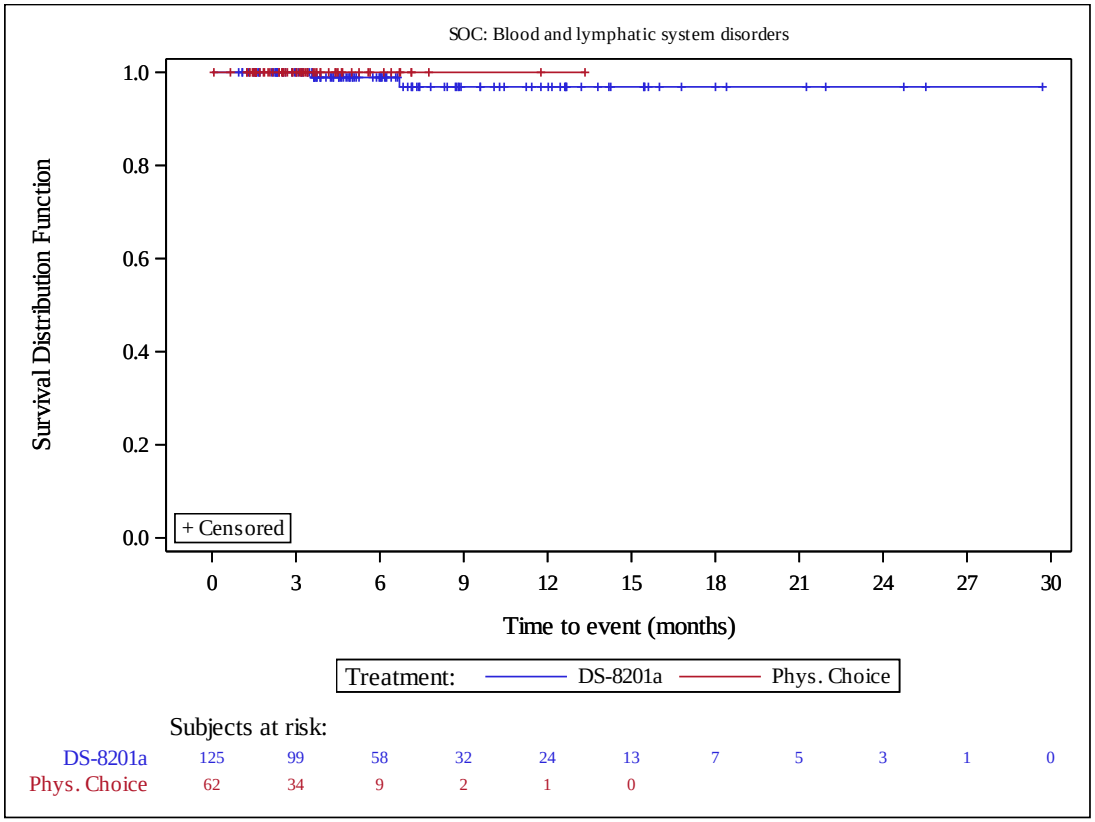
Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT - Subgroup analysis
Safety Analysis Set

No subgroups displayed.

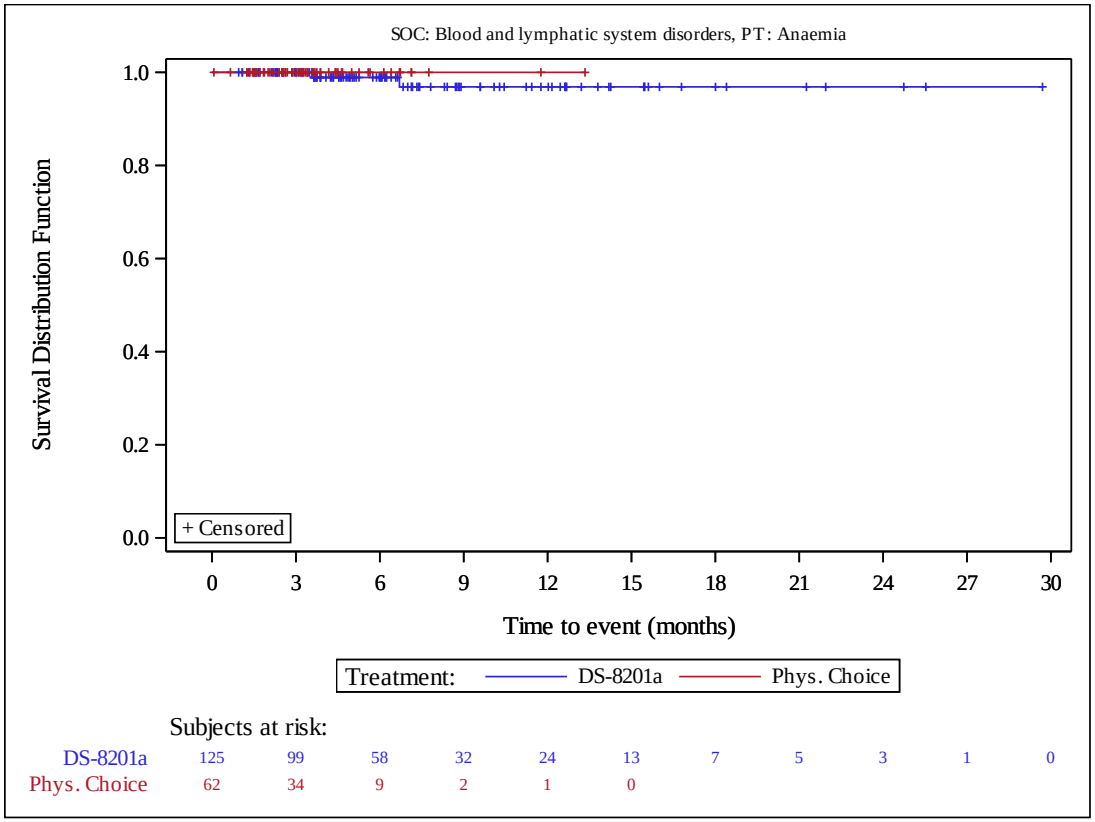
Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from unstratified Cox proportional hazards model with treatment, subgroup, and treatment by subgroup interaction.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 07JUN2022

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



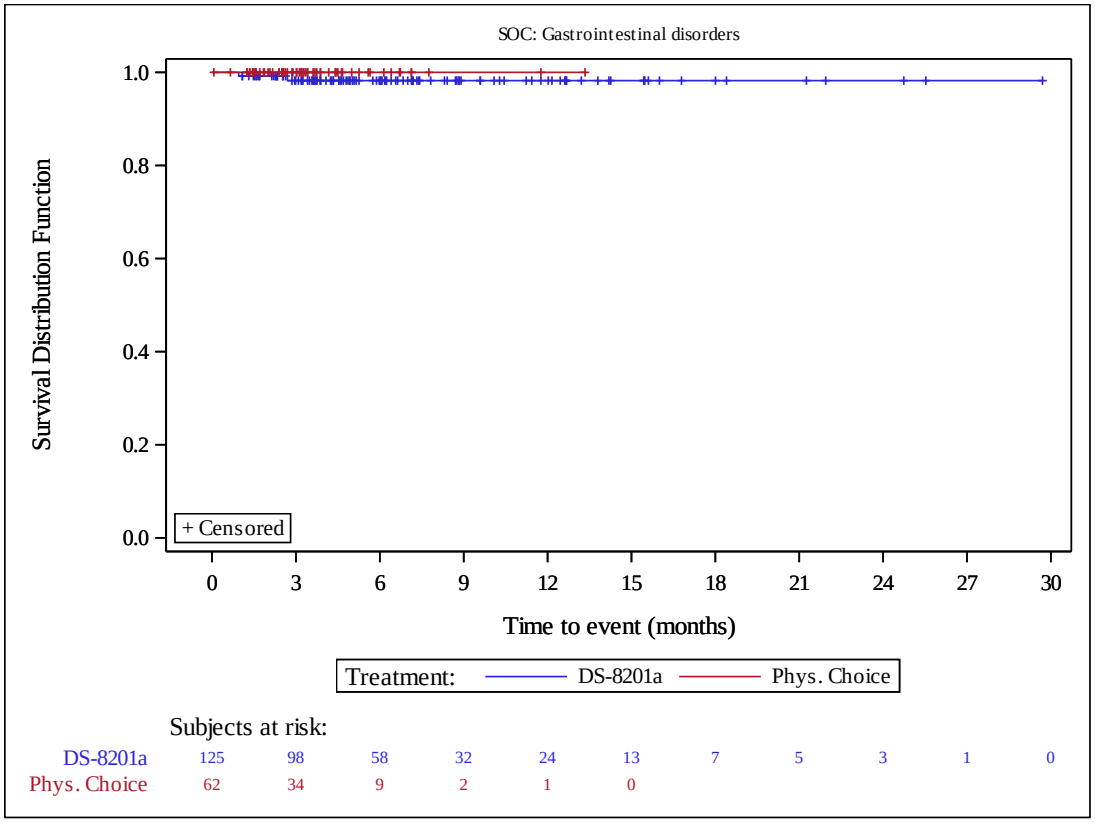
Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
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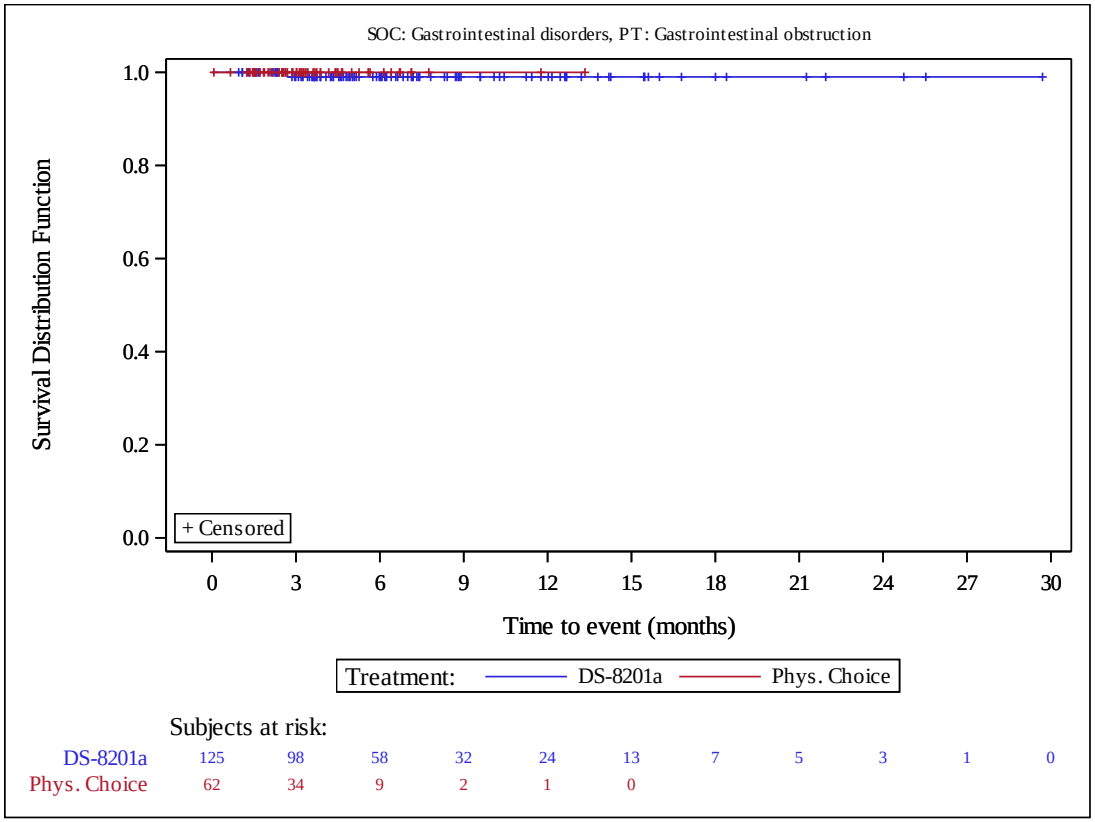
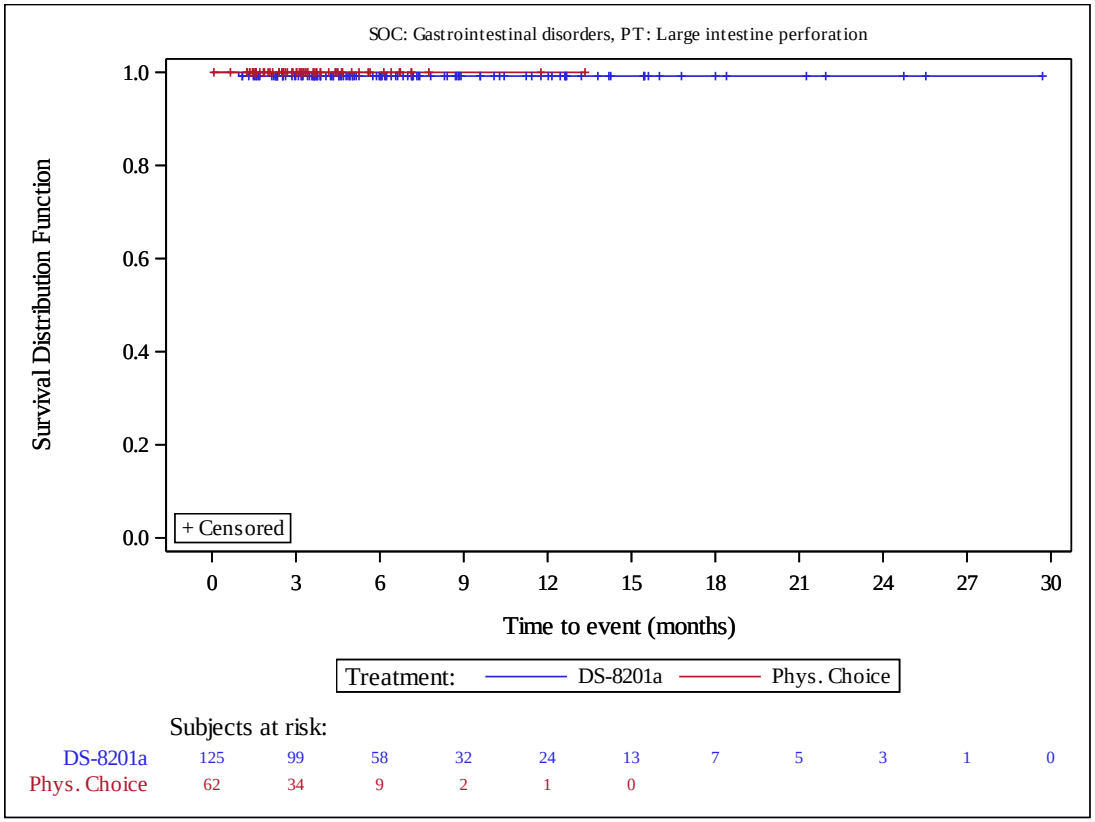
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



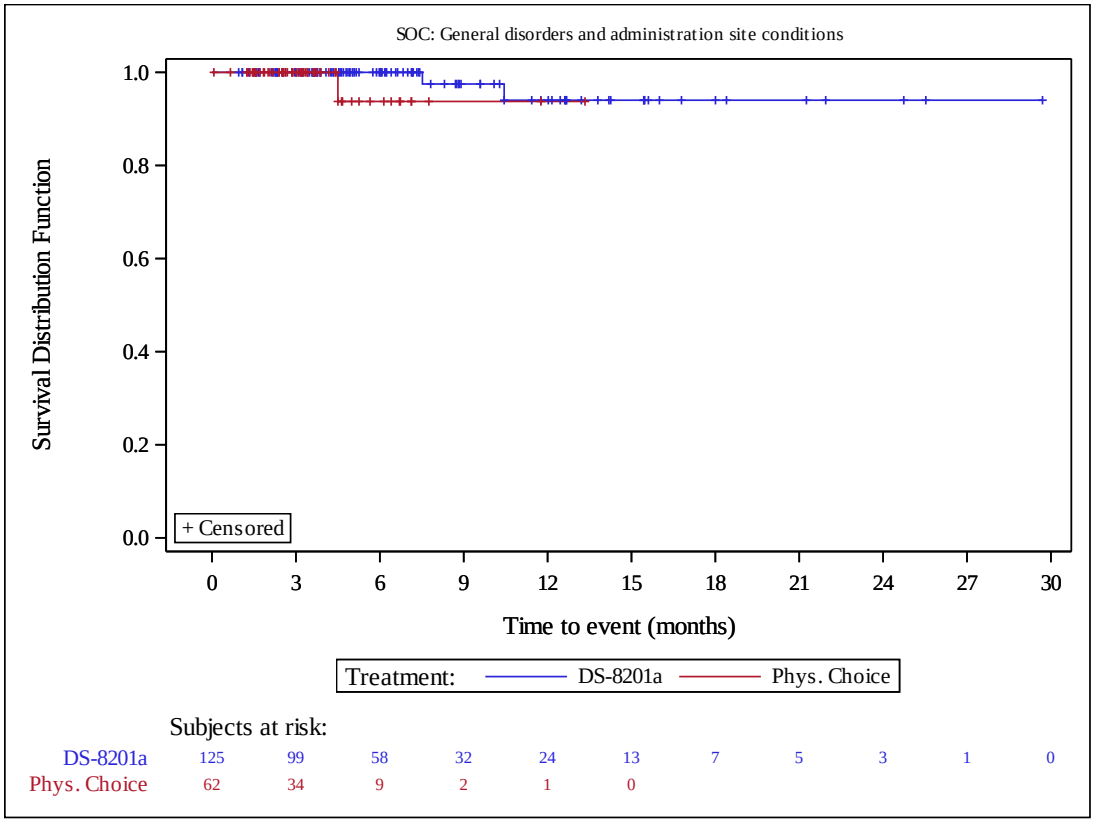
Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



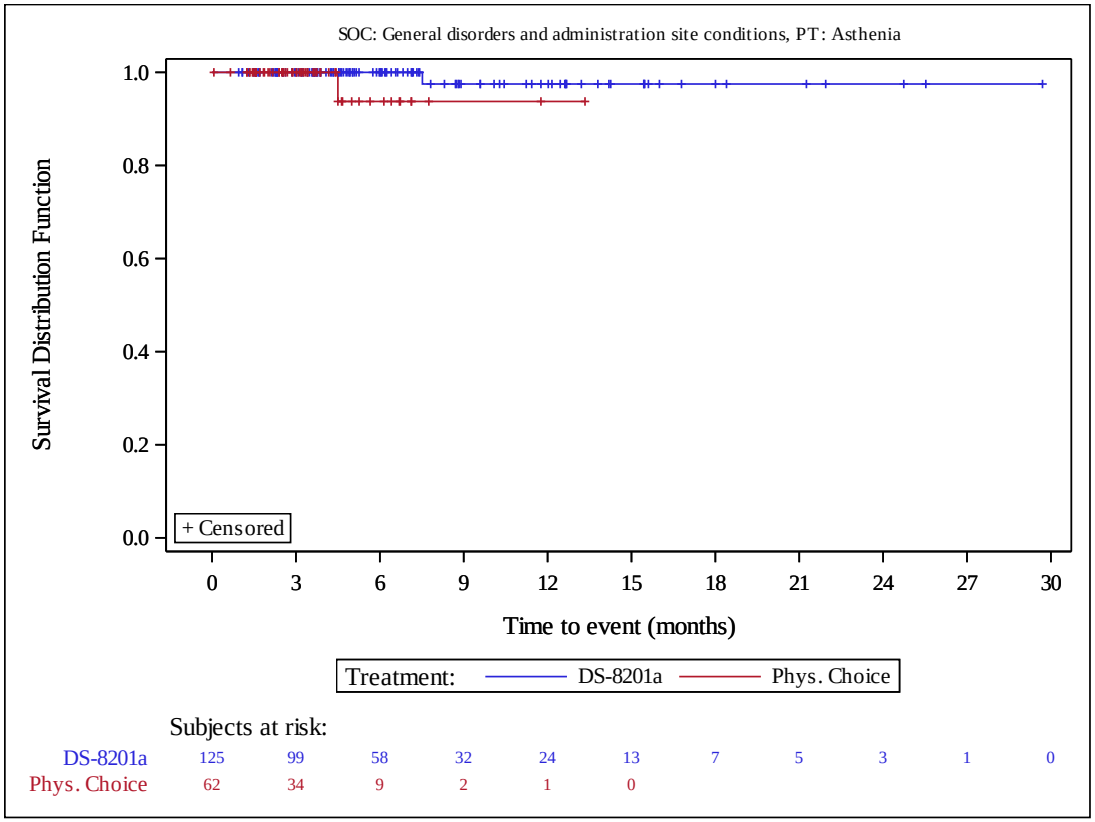
Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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[c] Two-sided p-value derived from log-rank test.
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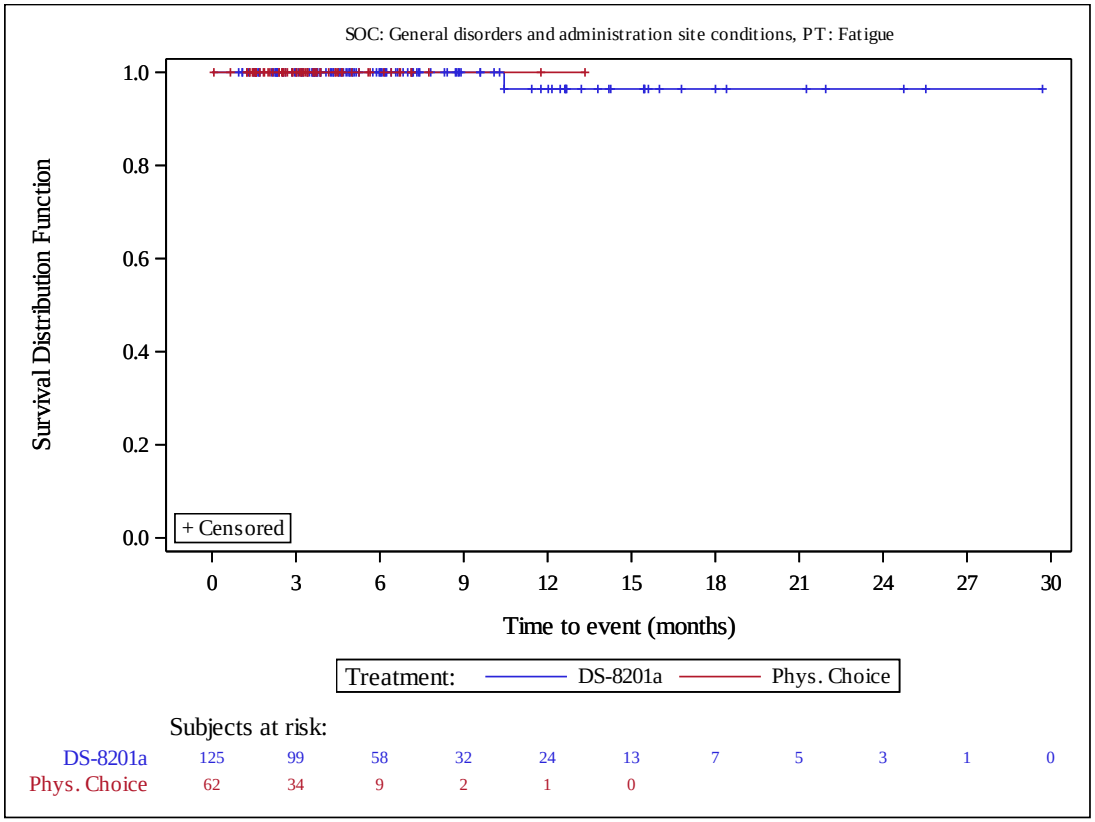
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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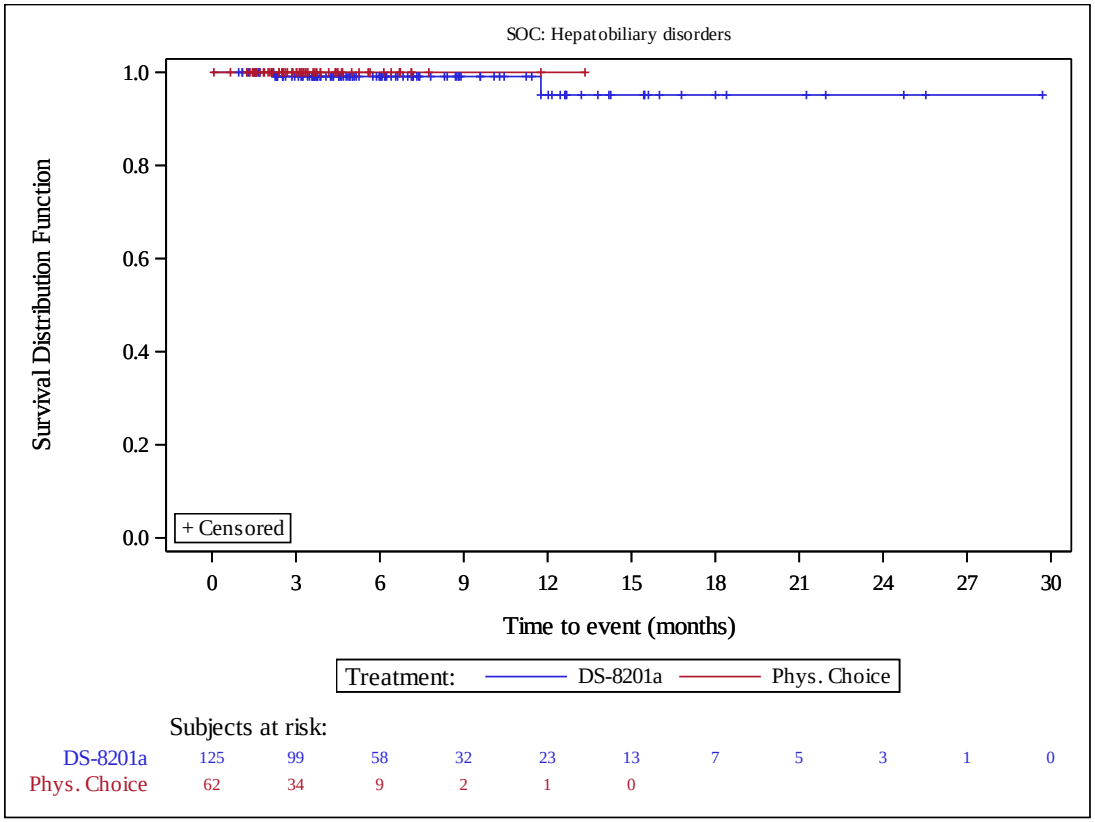
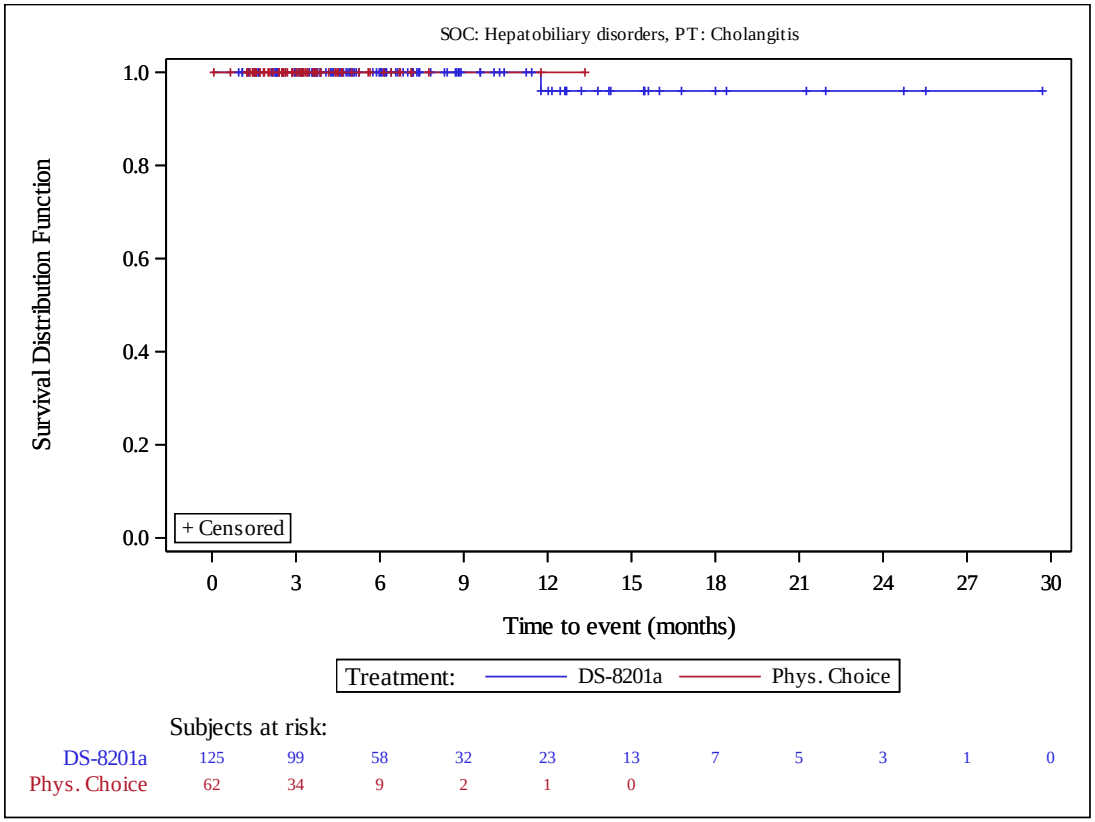
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 20.1 and graded according to NCI CTCAE v4.03. NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
[d] Derived from Logit estimators for Common Odds Ratio and Relative Risks. In the event of zero cells the correction value of 0.5 is added to each cell. Confidence limits and p-value calculated using normal approximation (Wald).
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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[a] CI for median is computed using the Brookmeyer-Crowley method.
[b] Derived from Cox proportional hazards model.
[c] Two-sided p-value derived from log-rank test.
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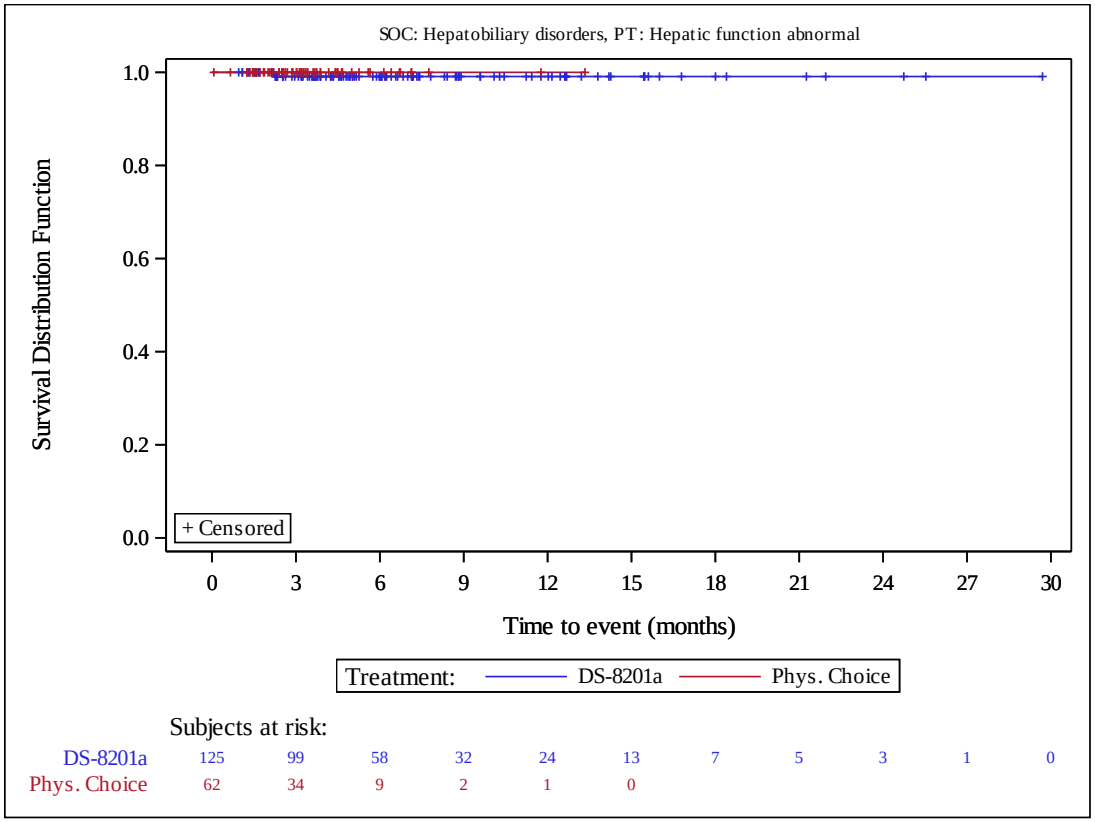
[e] Derived from the risk difference of two proportions with continuity correction.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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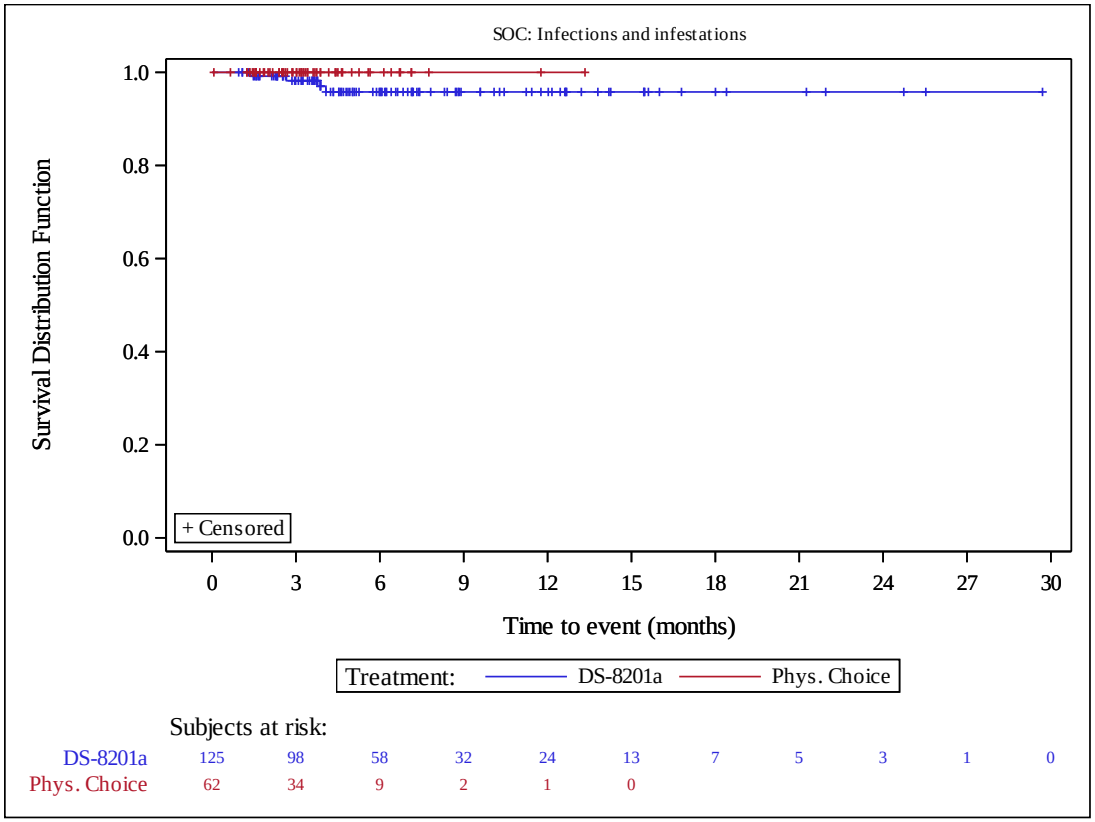
Protocol DS8201-A-J202
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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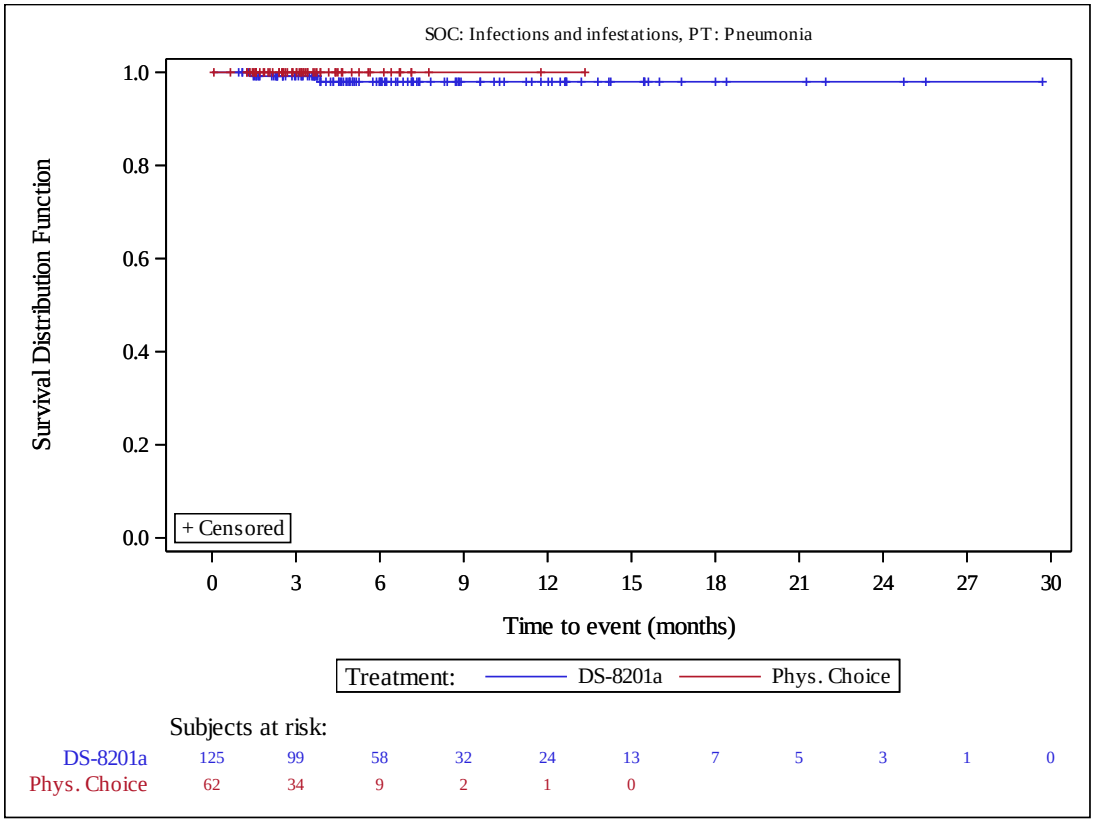

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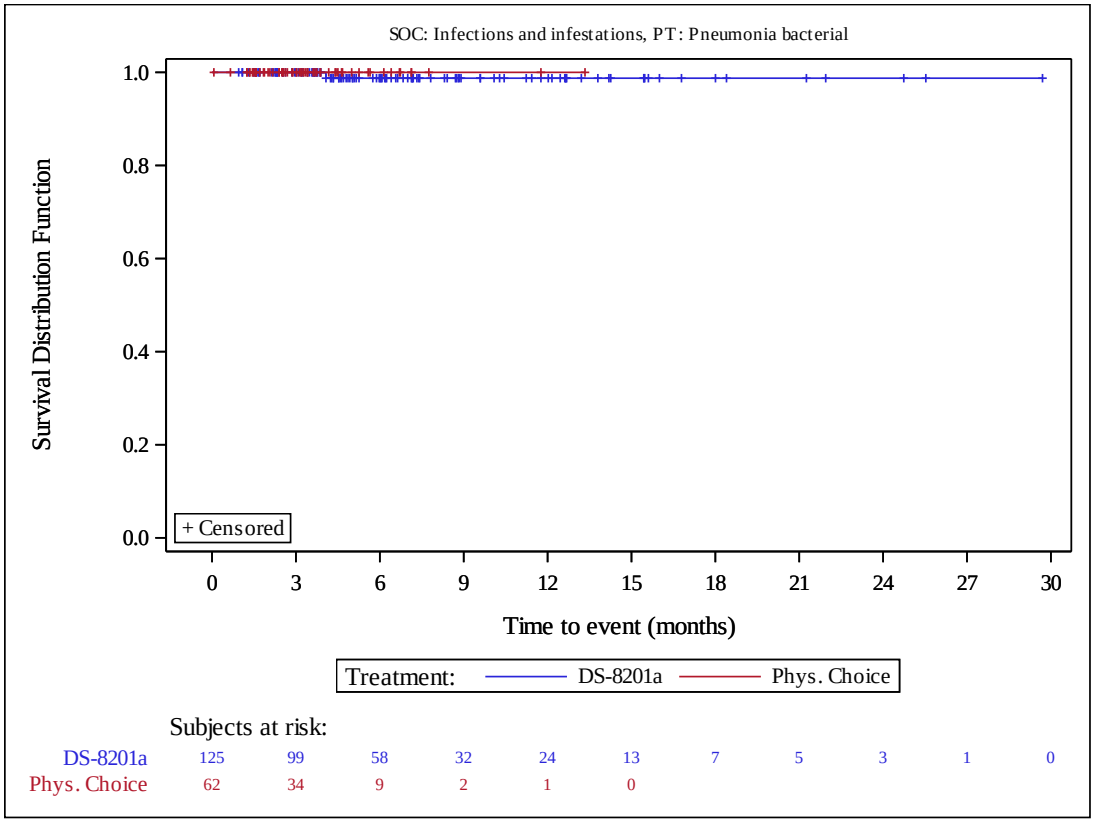
Trastuzumab deruxtecan - (Cutoff Date: 03JUN2020)
Primary Cohort
Overall Summary of TEAE leading to drug withdrawn by SOC, PT
Safety Analysis Set



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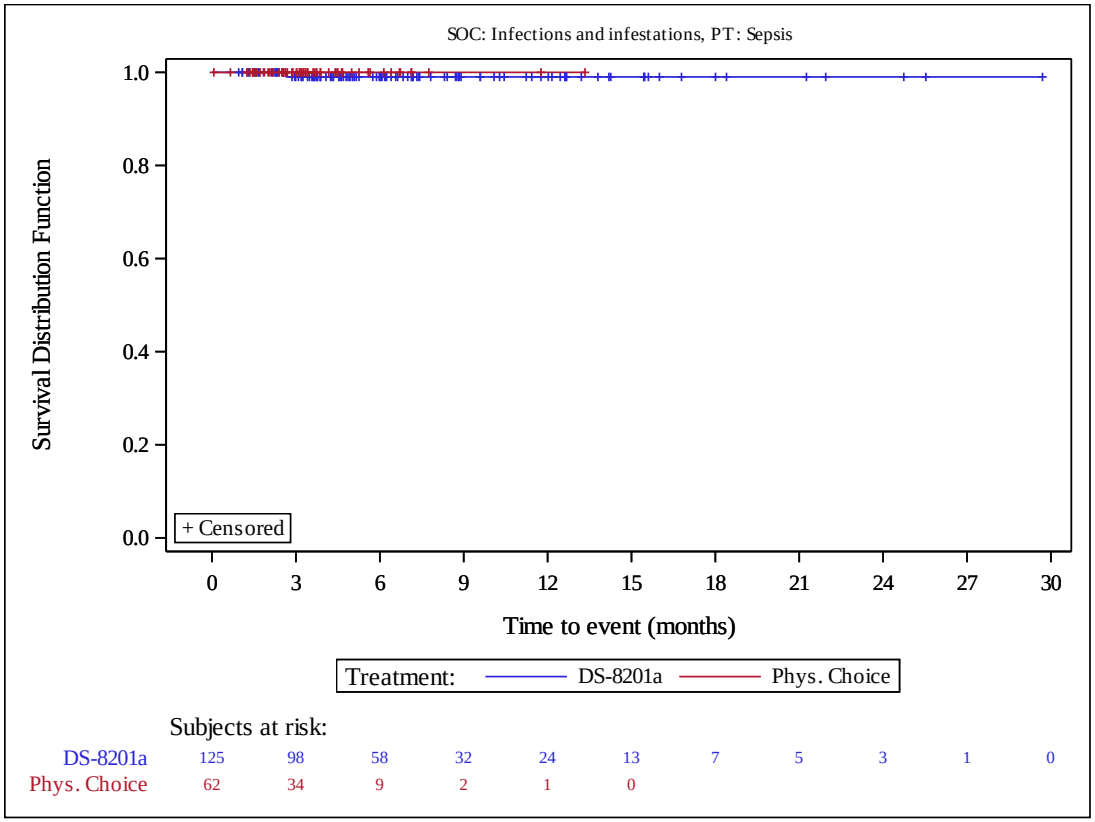
Safety Analysis Set



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Primary Cohort
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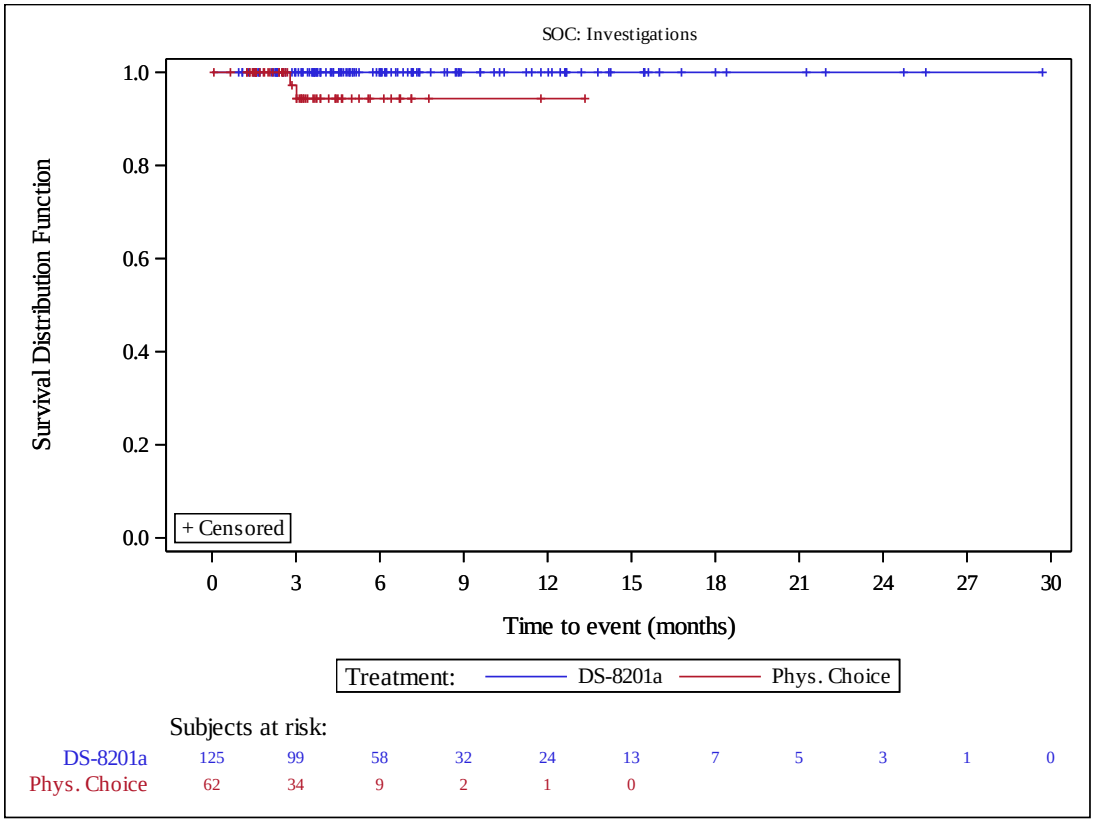
Safety Analysis Set



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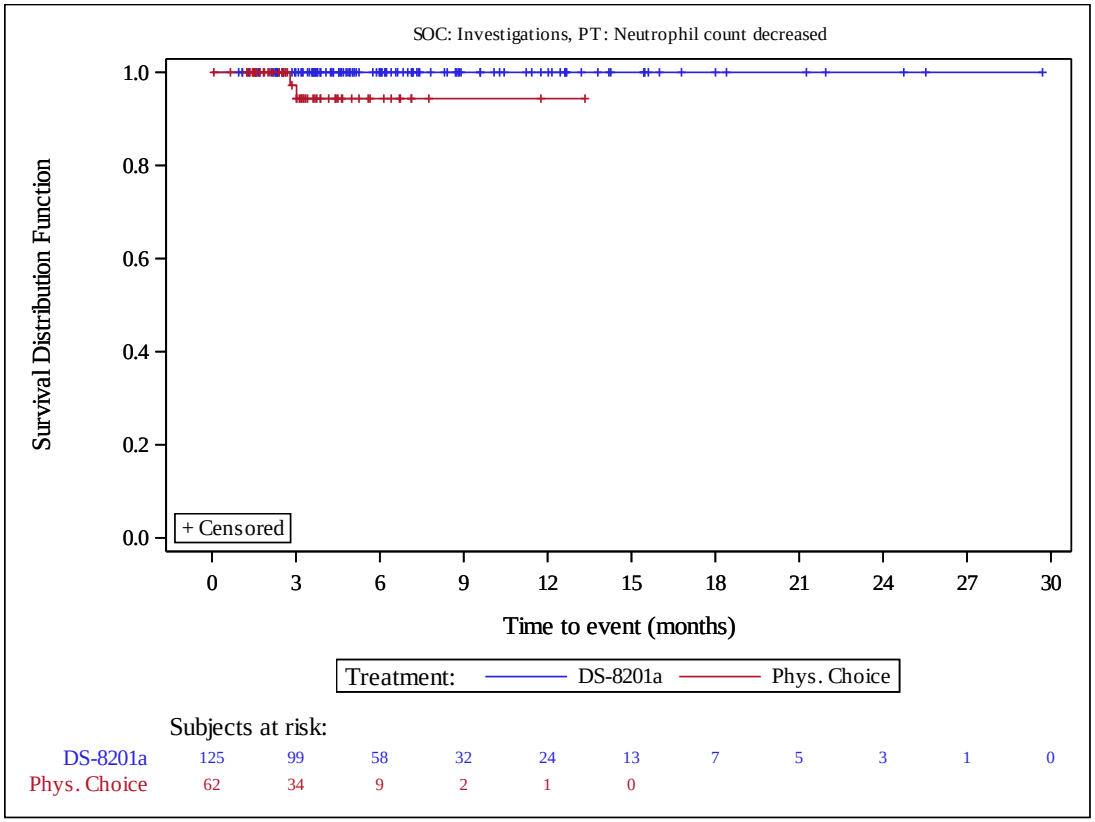

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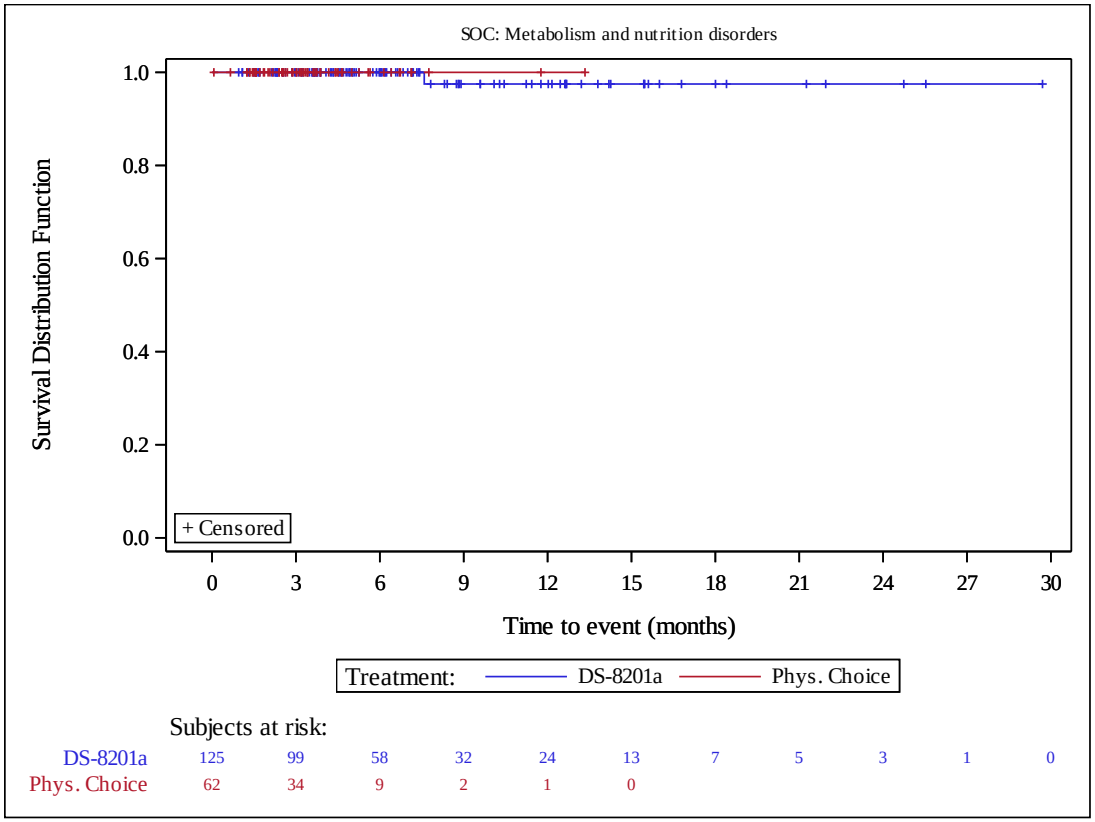

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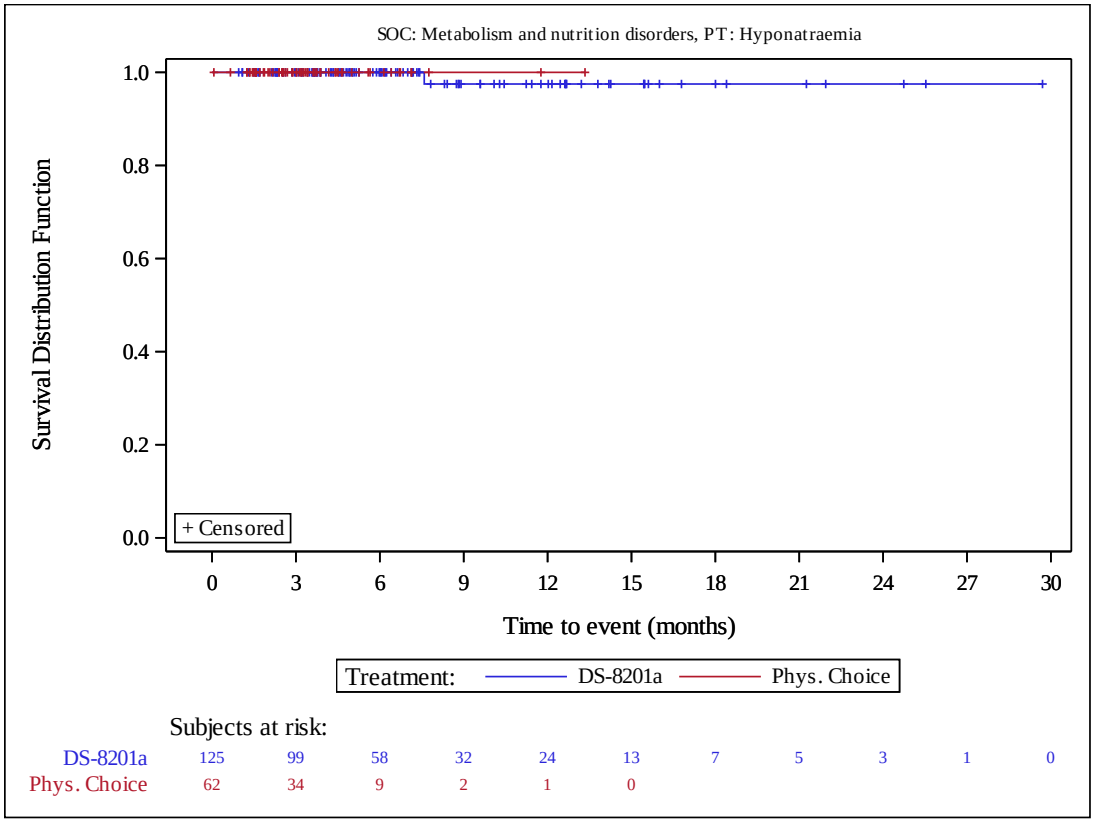

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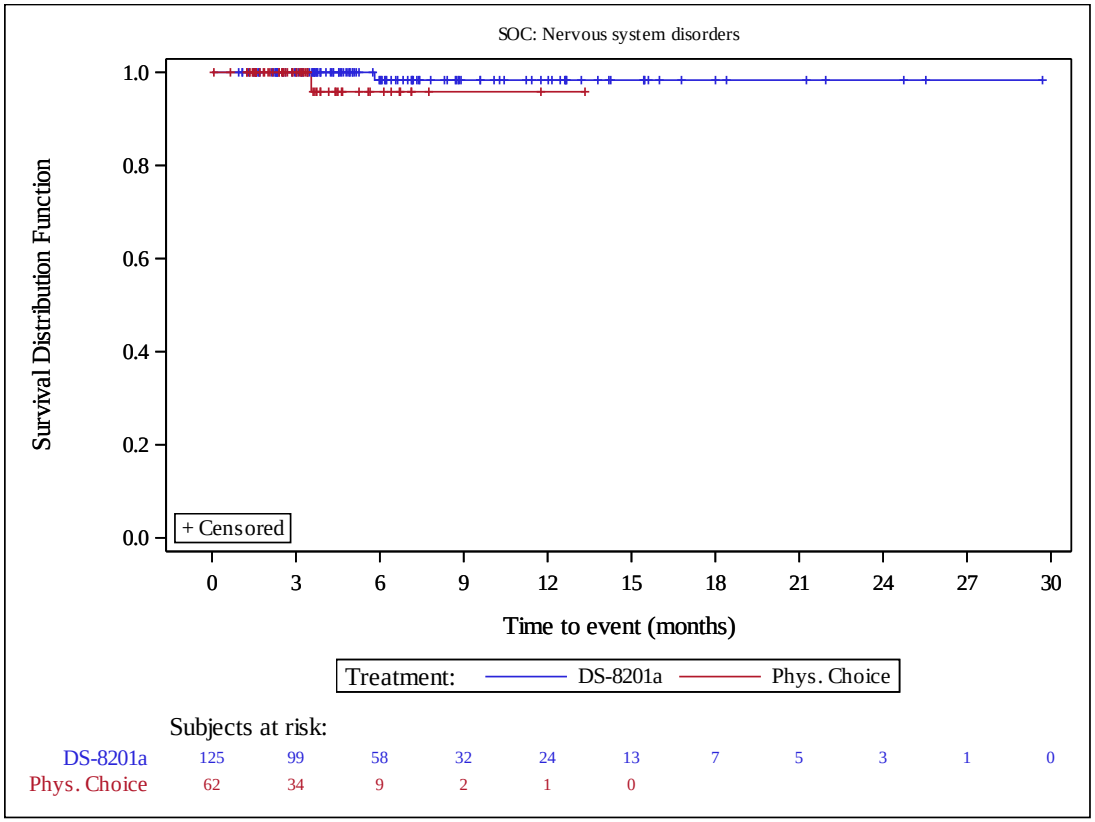

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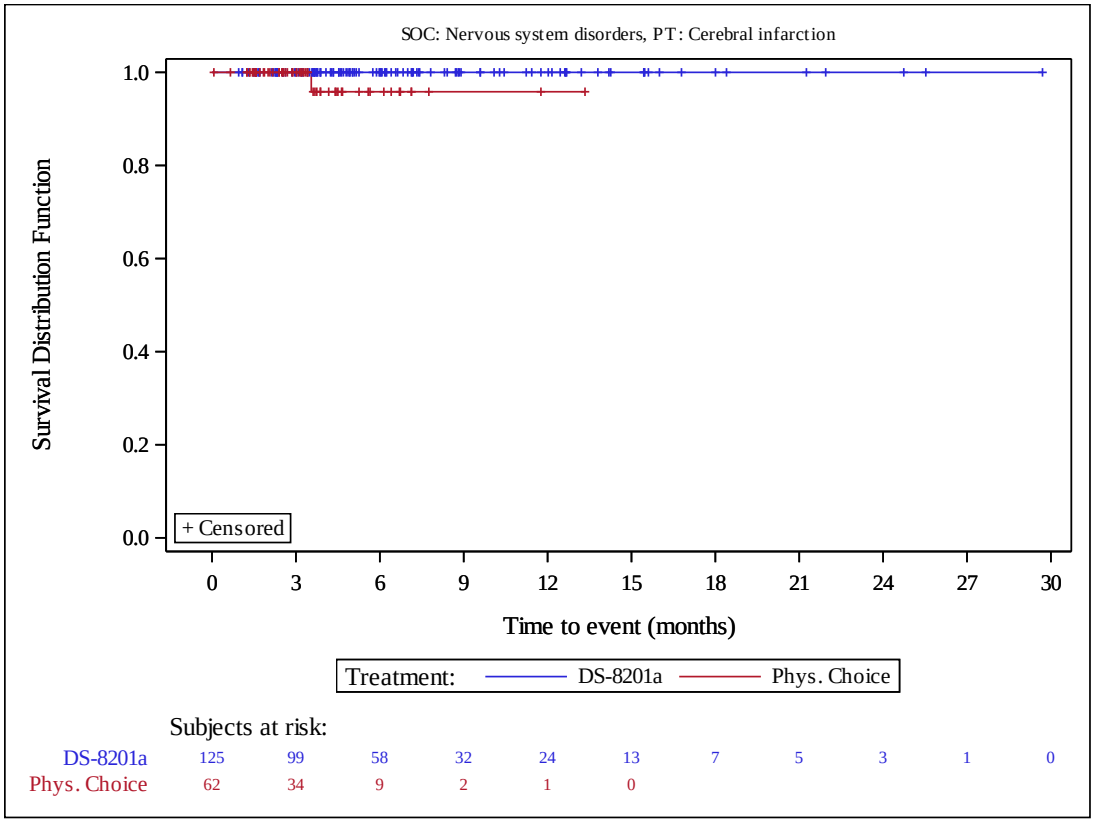

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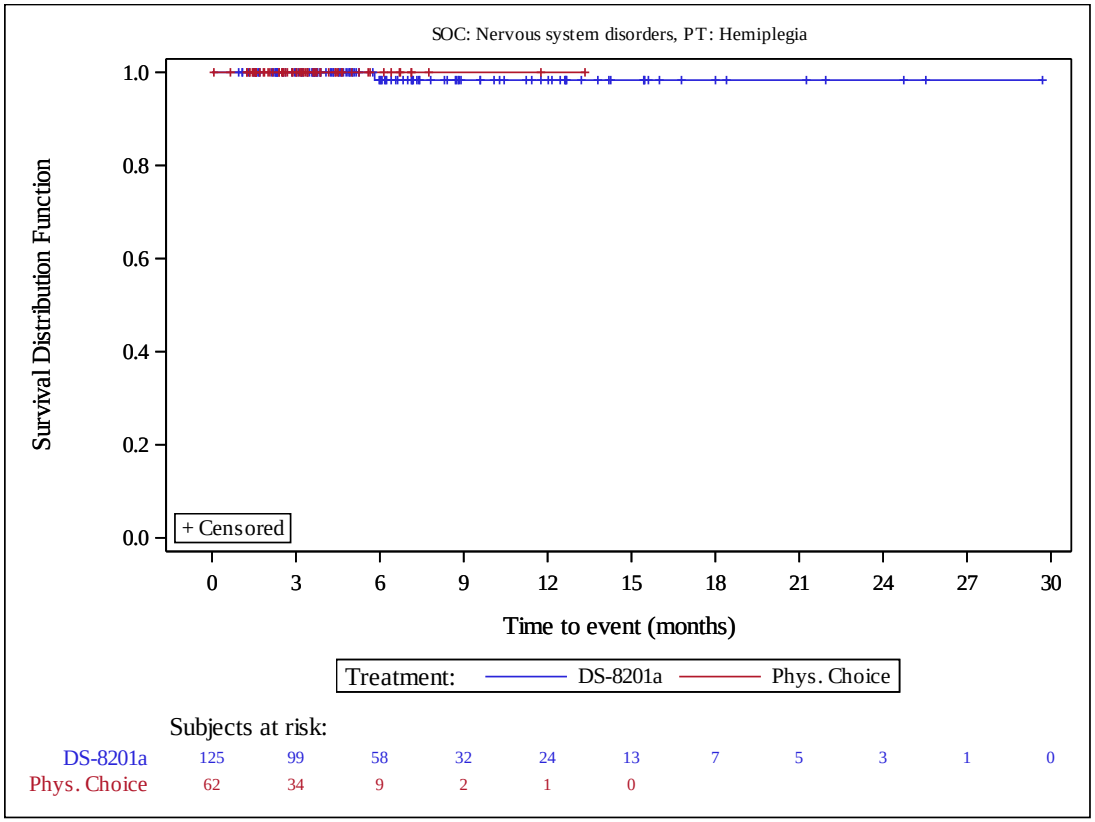

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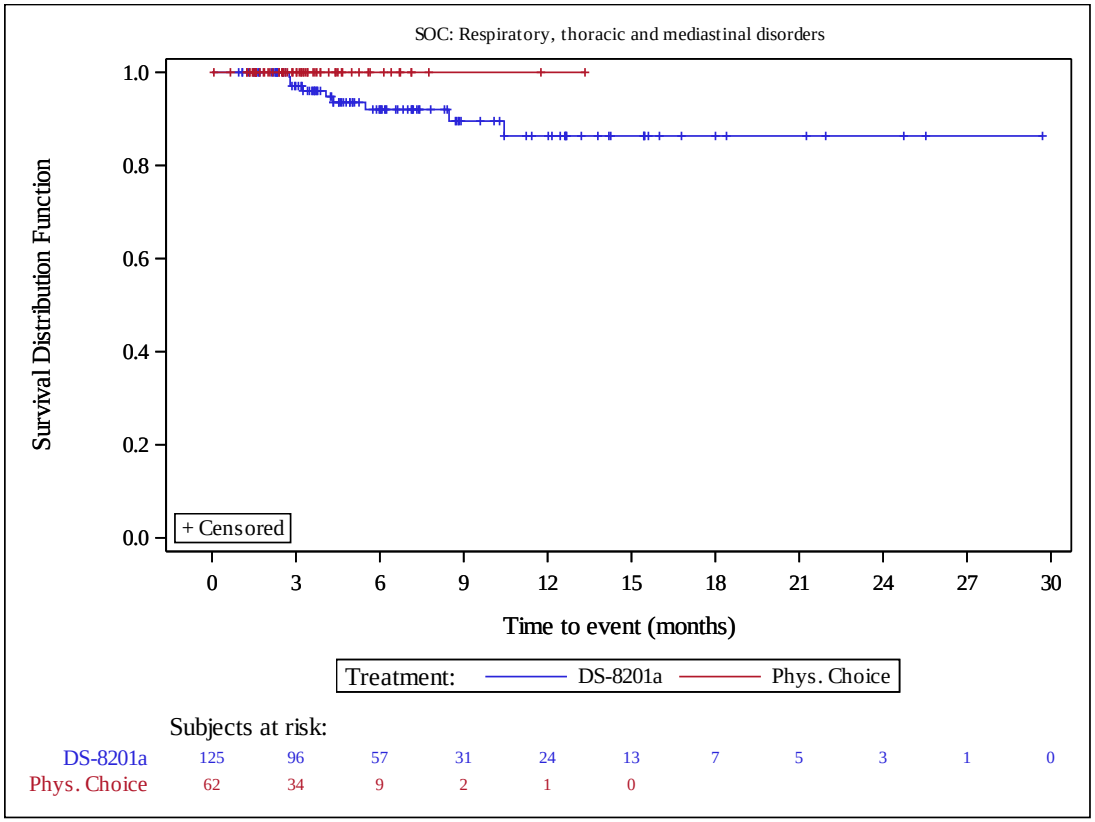

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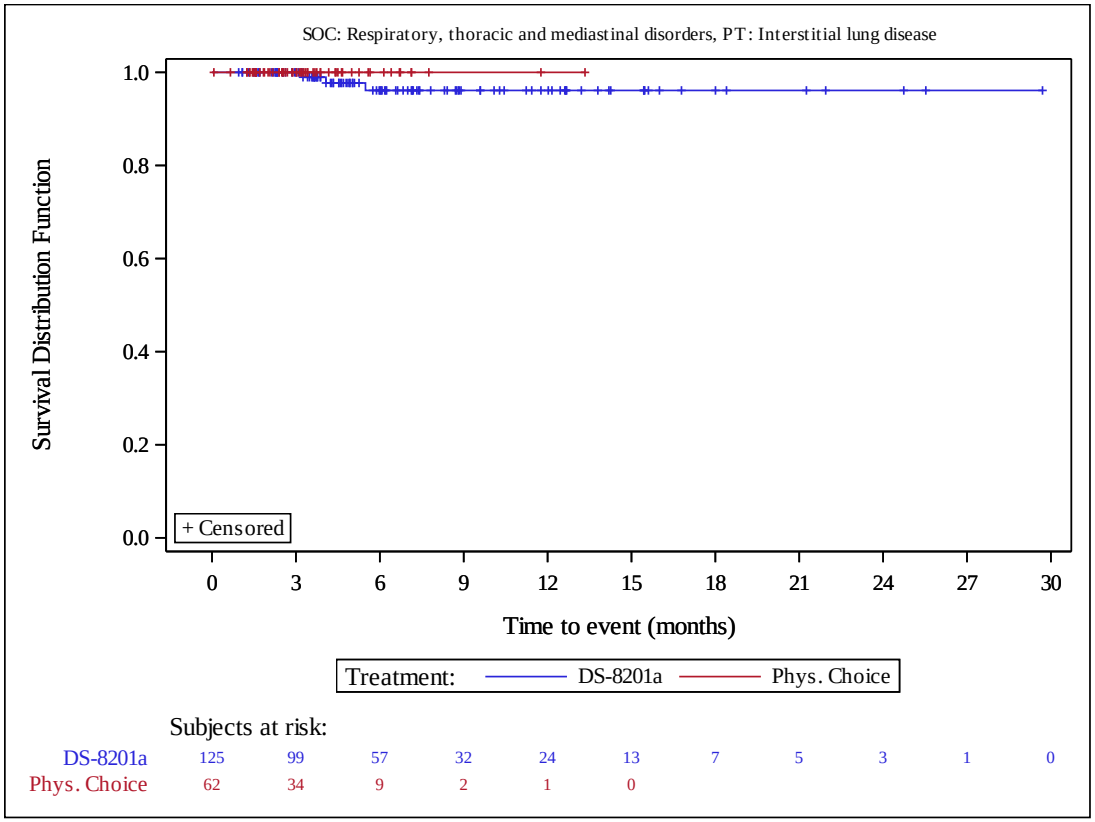

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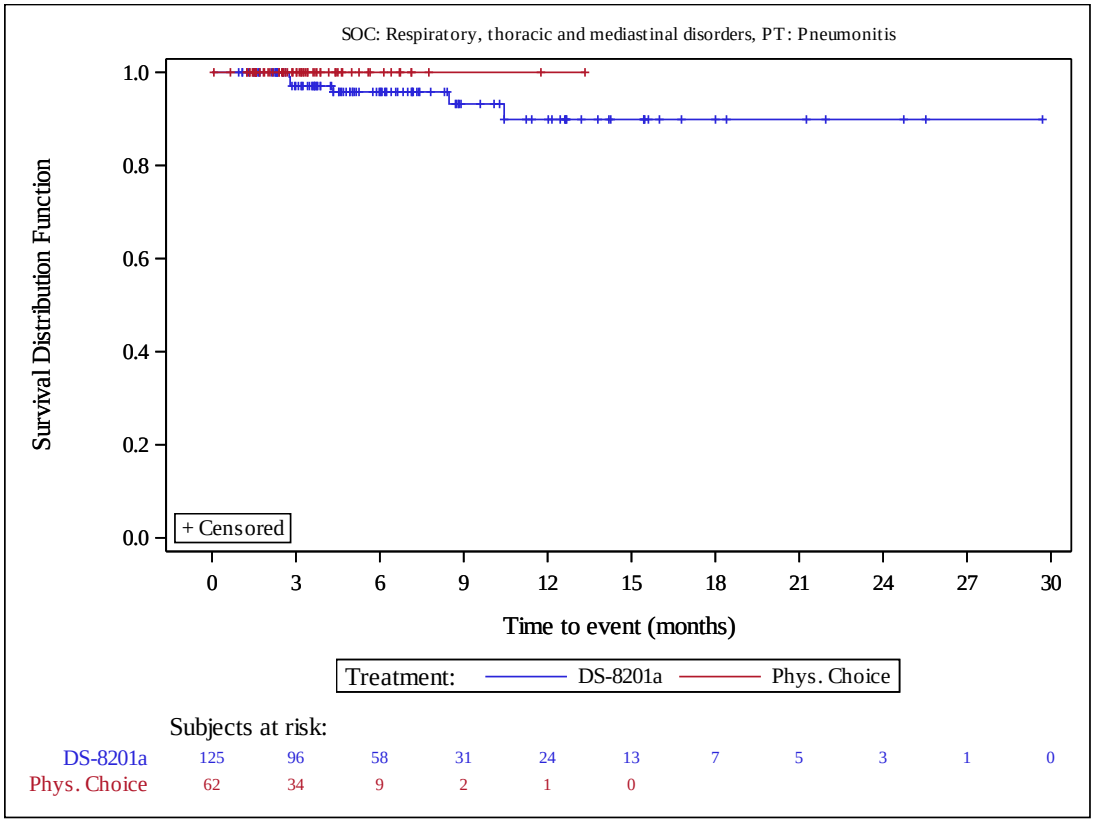

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Anhang 4-G 2: Ergänzende Analysen DESTINY-Gastric02

Anhang 4-G 2.1: Datenschnitt 09. April 2021

Anhang 4-G 2.1.1: Behandlungs- und Beobachtungsdauer

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Study duration (months)
Full Analysis Set

		T-DXd (N=79)
Study duration (months)	n (missing)	79 (0)
	Mean (SD)	6.72 (3.428)
	Median	5.88
	Q1, Q3	4.57, 8.57
	Min, Max	0.7, 15.4

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start date to participation end date, cutoff date or death date, whichever occured earlier.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Treatment duration (months)
Full Analysis Set

		T-DXd (N=79)
Treatment duration (months)	n (missing)	79 (0)
	Mean (SD)	5.06 (3.536)
	Median	4.34
	Q1, Q3	2.73, 6.87
	Min, Max	0.7, 15.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start date to last date of treatment + 21
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Survival Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Overall Survival Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	6.72 (3.428)
	Median	5.88
	Q1, Q3	4.57, 8.57
	Min, Max	0.7, 15.4

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start date to the date of death due to any cause or censoring of Overall Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Progression-free Survival Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Progression-free Survival Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	4.49 (3.010)
	Median	4.11
	Q1, Q3	2.10, 5.59
	Min, Max	0.6, 13.8

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start date to the date of documented radiographic disease progression per RECIST V1.1 or death due to any cause or censoring of Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Duration of Confirmed Response Follow-up duration (months) - for responders only
Full Analysis Set

		T-DXd (N=30)
Duration of Confirmed Response Follow-up duration (months)	n (missing)	30 (0)
	Mean (SD)	4.36 (2.728)
	Median	4.12
	Q1, Q3	2.30, 5.65
	Min, Max	1.2, 12.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression, death due to any cause or censoring of Duration of Confirmed Response.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Time to Confirmed Response Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Time to Confirmed Response Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	2.85 (2.015)
	Median	2.10
	Q1, Q3	1.38, 4.07
	Min, Max	0.6, 11.0

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR or censoring the same way as for Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Time to Hospitalization Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Time to Hospitalization Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	5.61 (4.071)
	Median	5.16
	Q1, Q3	1.94, 7.29
	Min, Max	0.1, 15.4

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of treatment start to the date of the first hospitalization.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Measureable Tumors based on ICR Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Measureable Tumors based on ICR Follow-up duration (months)	n (missing)	78 (1)
	Mean (SD)	4.34 (3.077)
	Median	3.94
	Q1, Q3	1.84, 5.55
	Min, Max	0.0, 13.8

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing tumor assessment. Subjects with assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
EQ-5D VAS score Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
EQ-5D VAS score Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	4.32 (3.487)
	Median	4.11
	Q1, Q3	1.61, 6.21
	Min, Max	0.0, 14.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Fact-Ga Total Score Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Fact-Ga Total Score Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	4.26 (3.495)
	Median	3.68
	Q1, Q3	1.61, 5.78
	Min, Max	0.0, 14.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Physical Well-being Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Physical Well-being Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	4.32 (3.487)
	Median	4.11
	Q1, Q3	1.61, 6.21
	Min, Max	0.0, 14.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Social/Family Well-being Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Social/Family Well-being Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	4.32 (3.487)
	Median	4.11
	Q1, Q3	1.61, 6.21
	Min, Max	0.0, 14.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Emotional Well-being Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Emotional Well-being Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	4.27 (3.484)
	Median	3.68
	Q1, Q3	1.61, 5.78
	Min, Max	0.0, 14.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Functional Well-being Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Functional Well-being Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	4.30 (3.498)
	Median	4.11
	Q1, Q3	1.61, 6.21
	Min, Max	0.0, 14.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Gastric Cancer Symptom (GaCS) Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Gastric Cancer Symptom (GaCS) Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	4.30 (3.498)
	Median	4.11
	Q1, Q3	1.61, 6.21
	Min, Max	0.0, 14.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Fact-G Total Score Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Fact-G Total Score Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	4.26 (3.495)
	Median	3.68
	Q1, Q3	1.61, 5.78
	Min, Max	0.0, 14.6

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing assessment. Subjects with no assessments or assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Safety Follow-up duration (months)
Safety Analysis Set

		T-DXd (N=79)
Safety Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	5.27 (3.234)
	Median	4.63
	Q1, Q3	3.15, 6.87
	Min, Max	0.7, 15.4

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to death date, last date of treatment (last dose of study drug) + 47 days, start of new anti-cancer therapy or last contact date, whichever occured earlier.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Anhang 4-G 2.1.2: Mortalität

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Overall Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	26 (32.9)	53 (67.1)	12.1 (8.6, NE)	94.9 (86.9, 98.0)	75.9 (63.9, 84.4)	60.9 (45.6, 73.1)	52.3 (35.0, 67.0)
Region							
North America	13 (38.2)	21 (61.8)	11.5 (6.4, NE)	94.0 (78.2, 98.5)	71.0 (51.4, 83.9)	57.0 (35.6, 73.6)	48.8 (25.8, 68.4)
EU	13 (28.9)	32 (71.1)	12.1 (8.6, NE)	95.5 (83.0, 98.8)	80.0 (63.6, 89.6)	63.9 (40.4, 80.2)	54.8 (28.8, 74.8)
Age (Category 1)							
<65 years	16 (34.8)	30 (65.2)	NE (6.4, NE)	93.4 (80.9, 97.8)	73.9 (57.5, 84.8)	50.9 (29.6, 68.8)	50.9 (29.6, 68.8)
>=65 years	10 (30.3)	23 (69.7)	12.1 (9.2, NE)	96.9 (79.8, 99.6)	79.3 (59.3, 90.2)	74.0 (52.2, 87.0)	56.4 (28.7, 76.8)
Age (Category 2)							
<75 years	25 (33.3)	50 (66.7)	11.5 (8.6, NE)	94.6 (86.2, 97.9)	76.0 (63.6, 84.7)	59.8 (43.7, 72.6)	49.9 (31.6, 65.8)
>=75 years	1 (25.0)	3 (75.0)	NE (4.7, NE)	100.0 (100.0, 100.0)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Sex							
female	6 (27.3)	16 (72.7)	12.1 (6.2, NE)	100.0 (100.0, 100.0)	82.8 (55.0, 94.2)	73.6 (42.2, 89.7)	55.2 (17.0, 81.9)
male	20 (35.1)	37 (64.9)	NE (6.7, NE)	92.9 (82.2, 97.3)	73.3 (58.8, 83.3)	56.4 (38.6, 70.9)	50.2 (30.7, 66.9)
ECOG PS							
0	9 (31.0)	20 (69.0)	12.1 (8.7, NE)	96.6 (77.9, 99.5)	85.5 (65.6, 94.3)	70.6 (47.0, 85.1)	64.2 (39.5, 80.9)
1	17 (34.0)	33 (66.0)	11.5 (6.2, NE)	93.9 (82.2, 98.0)	69.6 (53.0, 81.4)	53.2 (30.5, 71.5)	42.5 (18.1, 65.2)
HER2 Status in central laboratory							
IHC 3+	19 (27.9)	49 (72.1)	NE (9.2, NE)	95.5 (86.8, 98.5)	78.7 (65.9, 87.1)	67.1 (51.0, 78.9)	62.6 (45.1, 76.0)
IHC 2+/ISH +	6 (60.0)	4 (40.0)	8.7 (2.3, 11.5)	88.9 (43.3, 98.4)	66.7 (28.2, 87.8)	27.8 (1.6, 67.3)	NE (NE, NE)
Primary tumor location							
Gastric	7 (25.9)	20 (74.1)	12.1 (8.6, NE)	100.0 (100.0, 100.0)	75.5 (50.3, 89.2)	62.9 (30.4, 83.5)	62.9 (30.4, 83.5)
GEJ	19 (36.5)	33 (63.5)	11.5 (6.7, NE)	92.3 (80.8, 97.0)	76.0 (61.5, 85.7)	59.9 (42.1, 73.8)	48.8 (28.9, 66.0)

Overall Survival (OS) is defined as the time from the date of treatment start to the date of death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Overall Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	0	1	NE	100.0	100.0	100.0	100.0
	(0.0)	(100.0)	(NE, NE)	(100.0, 100.0)	(100.0, 100.0)	(100.0, 100.0)	(100.0, 100.0)
intestinal	8	11	6.4	100.0	67.9	33.0	33.0
	(42.1)	(57.9)	(5.6, NE)	(100.0, 100.0)	(38.9, 85.3)	(6.9, 63.2)	(6.9, 63.2)
other	18	41	12.1	93.2	78.7	68.5	56.2
	(30.5)	(69.5)	(9.2, NE)	(82.8, 97.4)	(65.5, 87.3)	(51.5, 80.6)	(34.7, 73.1)
Number of metastatic sites							
<2	0	5	NE	100.0	100.0	NE	NE
	(0.0)	(100.0)	(NE, NE)	(100.0, 100.0)	(100.0, 100.0)	(NE, NE)	(NE, NE)
>=2	26	48	12.1	94.5	74.3	58.9	50.7
	(35.1)	(64.9)	(8.6, NE)	(86.0, 97.9)	(61.8, 83.3)	(43.5, 71.5)	(33.6, 65.4)
Previous total gastrectomy							
no	26	53	12.1	94.9	75.9	60.9	52.3
	(32.9)	(67.1)	(8.6, NE)	(86.9, 98.0)	(63.9, 84.4)	(45.6, 73.1)	(35.0, 67.0)
Prior adjuvant/ neoadjuvant therapy							
yes	2	7	NE	88.9	88.9	88.9	59.3
	(22.2)	(77.8)	(1.2, NE)	(43.3, 98.4)	(43.3, 98.4)	(43.3, 98.4)	(7.7, 89.9)
no	24	46	12.1	95.6	74.3	57.3	51.5
	(34.3)	(65.7)	(8.6, NE)	(87.1, 98.6)	(61.3, 83.5)	(40.8, 70.7)	(33.3, 67.0)
Prior nivolumab or pembrolizumab treatment							
yes	2	4	NE	100.0	83.3	55.6	55.6
	(33.3)	(66.7)	(3.4, NE)	(100.0, 100.0)	(27.3, 97.5)	(7.3, 87.6)	(7.3, 87.6)
no	24	49	12.1	94.4	75.1	61.7	52.1
	(32.9)	(67.1)	(8.6, NE)	(85.8, 97.9)	(62.3, 84.1)	(46.0, 74.1)	(33.9, 67.5)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	3	4	8.7	100.0	71.4	47.6	47.6
	(42.9)	(57.1)	(3.4, NE)	(100.0, 100.0)	(25.8, 92.0)	(7.5, 80.8)	(7.5, 80.8)
no	23	49	12.1	94.3	76.2	62.6	52.9
	(31.9)	(68.1)	(8.6, NE)	(85.6, 97.8)	(63.3, 85.0)	(46.7, 75.0)	(34.4, 68.3)
Presence of liver metastasis at baseline							
yes	22	28	8.7	94.0	69.2	49.1	44.2
	(44.0)	(56.0)	(6.4, NE)	(82.5, 98.0)	(53.2, 80.7)	(31.5, 64.6)	(26.3, 60.7)
no	4	25	NE	96.6	88.7	88.7	66.5
	(13.8)	(86.2)	(9.2, NE)	(77.9, 99.5)	(68.7, 96.2)	(68.7, 96.2)	(18.3, 90.7)
Renal impairment at baseline							
normal	14	18	8.6	90.4	67.1	47.0	47.0
	(43.8)	(56.3)	(5.6, NE)	(73.1, 96.8)	(47.3, 80.8)	(25.7, 65.6)	(25.7, 65.6)
mild	7	18	12.1	96.0	85.7	69.6	59.7
	(28.0)	(72.0)	(8.7, NE)	(74.8, 99.4)	(61.4, 95.2)	(38.8, 87.1)	(28.3, 81.0)
moderate	3	5	9.2	100.0	72.9	72.9	36.5
	(37.5)	(62.5)	(4.3, NE)	(100.0, 100.0)	(27.6, 92.5)	(27.6, 92.5)	(1.4, 78.8)

Overall Survival (OS) is defined as the time from the date of treatment start to the date of death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

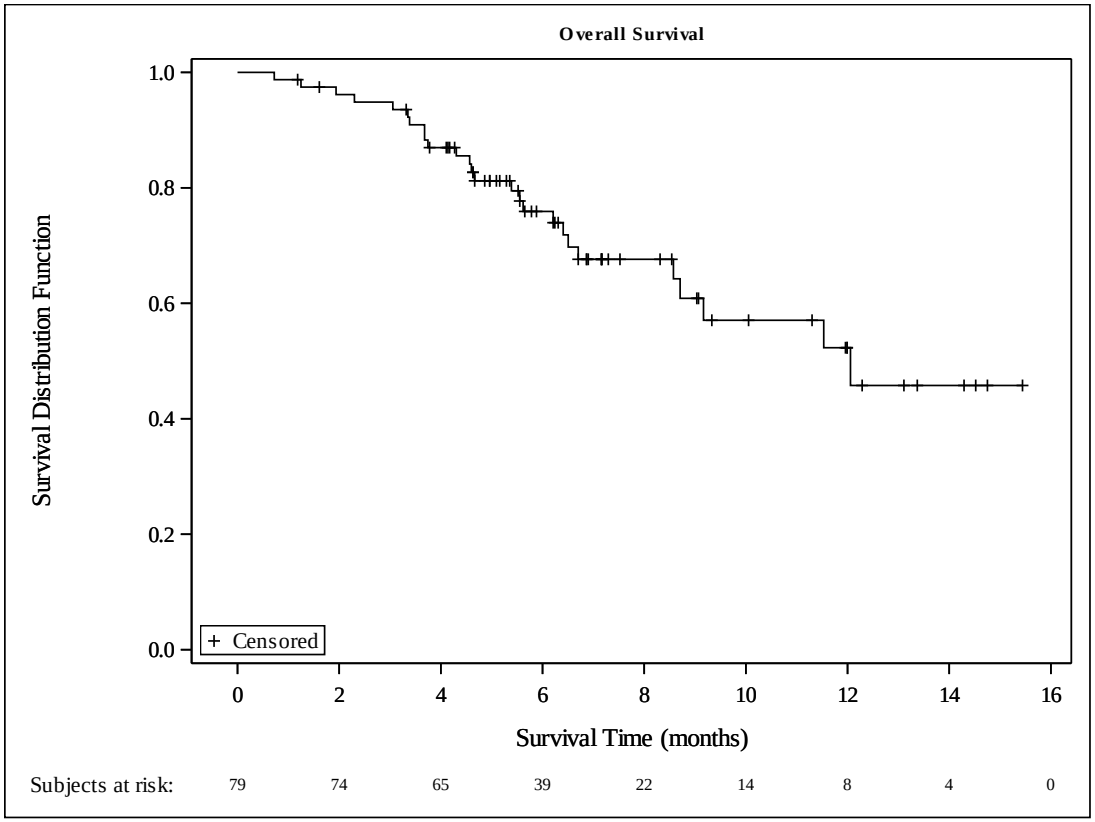
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Overall Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	16 (25.0)	48 (75.0)	NE (9.2, NE)	95.3 (86.0, 98.4)	82.5 (69.6, 90.3)	71.7 (56.1, 82.6)	58.8 (36.9, 75.4)
mild	10 (71.4)	4 (28.6)	5.6 (3.4, 12.1)	92.9 (59.1, 99.0)	49.0 (21.6, 71.7)	29.4 (7.8, 55.6)	29.4 (7.8, 55.6)
Race							
White	22 (31.9)	47 (68.1)	12.1 (8.7, NE)	94.1 (85.1, 97.8)	77.6 (65.0, 86.2)	64.6 (48.9, 76.6)	54.8 (36.2, 70.1)
Black or African American	1 (100.0)	0 (0.0)	4.7 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	8.6 (3.4, NE)	100.0 (100.0, 100.0)	85.7 (33.4, 97.9)	42.9 (1.1, 85.3)	NE (NE, NE)
Ethnicity							
Hispanic/Latino	2 (40.0)	3 (60.0)	NE (3.7, NE)	100.0 (100.0, 100.0)	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Non-Hispanic/Non-Latino	23 (32.9)	47 (67.1)	12.1 (8.6, NE)	94.2 (85.2, 97.8)	77.4 (64.6, 86.1)	60.6 (44.1, 73.7)	50.7 (31.9, 66.7)
Unknown	1 (25.0)	3 (75.0)	NE (4.6, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Overall Survival (OS) is defined as the time from the date of treatment start to the date of death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Overall Survival
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Anhang 4-G 2.1.3: Morbidität

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Confirmed Objective Response Rate (ORR) based on ICR
Full Analysis Set

	T-DXd (N=79)	
	n/ N (%)	95% CI [a]
Overall	30/ 79 (38.0)	(27.3, 49.6)
Region		
North America	10/ 34 (29.4)	(15.1, 47.5)
EU	20/ 45 (44.4)	(29.6, 60.0)
Age (Category 1)		
<65 years	16/ 46 (34.8)	(21.4, 50.2)
>=65 years	14/ 33 (42.4)	(25.5, 60.8)
Age (Category 2)		
<75 years	26/ 75 (34.7)	(24.0, 46.5)
>=75 years	4/ 4 (100.0)	(39.8, 100.0)
Sex		
female	11/ 22 (50.0)	(28.2, 71.8)
male	19/ 57 (33.3)	(21.4, 47.1)
ECOG PS		
0	7/ 29 (24.1)	(10.3, 43.5)
1	23/ 50 (46.0)	(31.8, 60.7)
HER2 Status in central laboratory		
IHC 3+	29/ 68 (42.6)	(30.7, 55.2)
IHC 2+/ISH +	1/ 10 (10.0)	(0.3, 44.5)
Primary tumor location		
Gastric	14/ 27 (51.9)	(31.9, 71.3)
GEJ	16/ 52 (30.8)	(18.7, 45.1)
Histological subtype		
diffuse	1/ 1 (100.0)	(2.5, 100.0)
intestinal	6/ 19 (31.6)	(12.6, 56.6)
other	23/ 59 (39.0)	(26.5, 52.6)
Number of metastatic sites		
<2	2/ 5 (40.0)	(5.3, 85.3)
>=2	28/ 74 (37.8)	(26.8, 49.9)
Previous total gastrectomy		
no	30/ 79 (38.0)	(27.3, 49.6)
Prior adjuvant/ neoadjuvant therapy		
yes	2/ 9 (22.2)	(2.8, 60.0)
no	28/ 70 (40.0)	(28.5, 52.4)
Prior nivolumab or pembrolizumab treatment		
yes	2/ 6 (33.3)	(4.3, 77.7)
no	28/ 73 (38.4)	(27.2, 50.5)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	(3.7, 71.0)
no	28/ 72 (38.9)	(27.6, 51.1)
Presence of liver metastasis at baseline		
yes	18/ 50 (36.0)	(22.9, 50.8)
no	12/ 29 (41.4)	(23.5, 61.1)

NE: Not estimable.
[a] Based on Clopper-Pearson method.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Confirmed Objective Response Rate (ORR) based on ICR
Full Analysis Set

	T-DXd (N=79)		
	n/ N	(%)	95% CI [a]
Renal impairment at baseline			
normal	8/ 32	(25.0)	(11.5, 43.4)
mild	12/ 25	(48.0)	(27.8, 68.7)
moderate	5/ 8	(62.5)	(24.5, 91.5)
Hepatic impairment at baseline			
normal	23/ 64	(35.9)	(24.3, 48.9)
mild	7/ 14	(50.0)	(23.0, 77.0)
Race			
White	27/ 69	(39.1)	(27.6, 51.6)
Black or African American	1/ 1	(100.0)	(2.5, 100.0)
Other	2/ 8	(25.0)	(3.2, 65.1)
Ethnicity			
Hispanic/Latino	2/ 5	(40.0)	(5.3, 85.3)
Non-Hispanic/Non-Latino	27/ 70	(38.6)	(27.2, 51.0)
Unknown	1/ 4	(25.0)	(0.6, 80.6)

NE: Not estimable.
[a] Based on Clopper-Pearson method.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Confirmed Disease Control Rate (DCR) based on ICR
Full Analysis Set

	T-DXd (N=79)		
	n/ N	(%)	95% CI [a]
Overall	64/ 79	(81.0)	(70.6, 89.0)
Region			
North America	26/ 34	(76.5)	(58.8, 89.3)
EU	38/ 45	(84.4)	(70.5, 93.5)
Age (Category 1)			
<65 years	40/ 46	(87.0)	(73.7, 95.1)
>=65 years	24/ 33	(72.7)	(54.5, 86.7)
Age (Category 2)			
<75 years	60/ 75	(80.0)	(69.2, 88.4)
>=75 years	4/ 4	(100.0)	(39.8, 100.0)
Sex			
female	19/ 22	(86.4)	(65.1, 97.1)
male	45/ 57	(78.9)	(66.1, 88.6)
ECOG PS			
0	22/ 29	(75.9)	(56.5, 89.7)
1	42/ 50	(84.0)	(70.9, 92.8)
HER2 Status in central laboratory			
IHC 3+	59/ 68	(86.8)	(76.4, 93.8)
IHC 2+/ISH +	5/ 10	(50.0)	(18.7, 81.3)
Primary tumor location			
Gastric	21/ 27	(77.8)	(57.7, 91.4)
GEJ	43/ 52	(82.7)	(69.7, 91.8)
Histological subtype			
diffuse	1/ 1	(100.0)	(2.5, 100.0)
intestinal	15/ 19	(78.9)	(54.4, 93.9)
other	48/ 59	(81.4)	(69.1, 90.3)
Number of metastatic sites			
<2	5/ 5	(100.0)	(47.8, 100.0)
>=2	59/ 74	(79.7)	(68.8, 88.2)
Previous total gastrectomy			
no	64/ 79	(81.0)	(70.6, 89.0)
Prior adjuvant/ neoadjuvant therapy			
yes	8/ 9	(88.9)	(51.8, 99.7)
no	56/ 70	(80.0)	(68.7, 88.6)
Prior nivolumab or pembrolizumab treatment			
yes	5/ 6	(83.3)	(35.9, 99.6)
no	59/ 73	(80.8)	(69.9, 89.1)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	6/ 7	(85.7)	(42.1, 99.6)
no	58/ 72	(80.6)	(69.5, 88.9)
Presence of liver metastasis at baseline			
yes	40/ 50	(80.0)	(66.3, 90.0)
no	24/ 29	(82.8)	(64.2, 94.2)

NE: Not estimable.
[a] Based on Clopper-Pearson method.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Confirmed Disease Control Rate (DCR) based on ICR
Full Analysis Set

	T-DXd (N=79)		
	n/ N	(%)	95% CI [a]
Renal impairment at baseline			
normal	26/ 32	(81.3)	(63.6, 92.8)
mild	18/ 25	(72.0)	(50.6, 87.9)
moderate	7/ 8	(87.5)	(47.3, 99.7)
Hepatic impairment at baseline			
normal	52/ 64	(81.3)	(69.5, 89.9)
mild	12/ 14	(85.7)	(57.2, 98.2)
Race			
White	55/ 69	(79.7)	(68.3, 88.4)
Black or African American	1/ 1	(100.0)	(2.5, 100.0)
Other	7/ 8	(87.5)	(47.3, 99.7)
Ethnicity			
Hispanic/Latino	5/ 5	(100.0)	(47.8, 100.0)
Non-Hispanic/Non-Latino	55/ 70	(78.6)	(67.1, 87.5)
Unknown	4/ 4	(100.0)	(39.8, 100.0)

NE: Not estimable.
[a] Based on Clopper-Pearson method.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Progression-free Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	44 (55.7)	35 (44.3)	5.5 (4.2, 7.2)	70.4 (58.5, 79.4)	45.7 (32.8, 57.6)	26.5 (13.8, 41.0)	16.6 (5.6, 32.7)
Region							
North America	25 (73.5)	9 (26.5)	4.7 (2.8, 7.2)	67.2 (48.5, 80.3)	41.7 (23.9, 58.7)	18.6 (6.2, 36.1)	9.3 (1.7, 25.2)
EU	19 (42.2)	26 (57.8)	5.5 (4.2, NE)	72.9 (56.2, 84.0)	49.0 (30.7, 64.9)	42.0 (22.5, 60.3)	42.0 (22.5, 60.3)
Age (Category 1)							
<65 years	28 (60.9)	18 (39.1)	4.8 (3.4, 7.1)	67.9 (51.8, 79.6)	41.8 (25.7, 57.2)	25.8 (10.5, 44.3)	NE (NE, NE)
>=65 years	16 (48.5)	17 (51.5)	6.7 (4.1, NE)	74.2 (55.0, 86.2)	51.5 (30.4, 69.0)	29.4 (10.5, 51.5)	29.4 (10.5, 51.5)
Age (Category 2)							
<75 years	43 (57.3)	32 (42.7)	5.5 (4.1, 7.1)	68.6 (56.3, 78.2)	43.7 (30.5, 56.2)	22.2 (9.9, 37.5)	11.8 (2.7, 28.3)
>=75 years	1 (25.0)	3 (75.0)	NE (4.7, NE)	100.0 (100.0, 100.0)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Sex							
female	10 (45.5)	12 (54.5)	6.7 (4.2, NE)	85.4 (61.3, 95.1)	53.3 (27.2, 73.7)	40.0 (13.2, 66.0)	20.0 (1.4, 54.4)
male	34 (59.6)	23 (40.4)	4.8 (2.8, 7.2)	64.4 (49.9, 75.7)	42.8 (28.1, 56.6)	22.2 (9.3, 38.5)	14.8 (3.6, 33.3)
ECOG PS							
0	20 (69.0)	9 (31.0)	5.1 (2.6, 7.3)	65.0 (44.7, 79.4)	44.0 (24.7, 61.8)	19.8 (5.6, 40.2)	NE (NE, NE)
1	24 (48.0)	26 (52.0)	5.6 (4.2, 11.5)	73.5 (57.9, 84.1)	46.5 (29.5, 61.9)	33.9 (16.0, 52.8)	25.5 (8.5, 46.7)
HER2 Status in central laboratory							
IHC 3+	34 (50.0)	34 (50.0)	6.4 (4.3, 8.3)	74.8 (62.1, 83.8)	52.1 (37.8, 64.6)	32.7 (17.5, 48.9)	20.5 (6.8, 39.1)
IHC 2+/ISH +	9 (90.0)	1 (10.0)	1.6 (1.2, 5.6)	44.4 (13.6, 71.9)	11.1 (0.6, 38.8)	NE (NE, NE)	NE (NE, NE)
Primary tumor location							
Gastric	11 (40.7)	16 (59.3)	6.7 (4.2, NE)	76.5 (55.0, 88.7)	60.4 (36.9, 77.5)	36.3 (10.9, 62.9)	36.3 (10.9, 62.9)
GEJ	33 (63.5)	19 (36.5)	5.1 (3.4, 6.4)	67.2 (52.1, 78.5)	38.2 (23.3, 52.9)	22.0 (9.3, 38.2)	8.3 (0.8, 27.6)

Progression-free survival (PFS) is defined as the time from the date of treatment start to the date of documented radiographic disease progression per RECIST V1.1 or death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Progression-free Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	1 (100.0)	0 (0.0)	11.0 (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	NE (NE, NE)
intestinal	9 (47.4)	10 (52.6)	6.4 (2.6, 7.1)	70.5 (42.8, 86.6)	61.7 (32.6, 81.2)	16.5 (1.0, 49.6)	NE (NE, NE)
other	34 (57.6)	25 (42.4)	5.1 (3.7, 7.3)	69.7 (55.8, 80.0)	39.5 (25.2, 53.4)	25.6 (11.7, 42.1)	19.2 (6.4, 37.1)
Number of metastatic sites							
<2	2 (40.0)	3 (60.0)	6.4 (5.6, 7.2)	100.0 (100.0, 100.0)	50.0 (0.6, 91.0)	NE (NE, NE)	NE (NE, NE)
>=2	42 (56.8)	32 (43.2)	5.1 (4.1, 7.1)	68.4 (56.0, 78.0)	44.6 (31.6, 56.8)	28.0 (15.0, 42.7)	17.5 (5.9, 34.1)
Previous total gastrectomy							
no	44 (55.7)	35 (44.3)	5.5 (4.2, 7.2)	70.4 (58.5, 79.4)	45.7 (32.8, 57.6)	26.5 (13.8, 41.0)	16.6 (5.6, 32.7)
Prior adjuvant/ neoadjuvant therapy							
yes	4 (44.4)	5 (55.6)	5.6 (1.2, NE)	88.9 (43.3, 98.4)	39.5 (6.4, 73.0)	39.5 (6.4, 73.0)	NE (NE, NE)
no	40 (57.1)	30 (42.9)	4.8 (3.7, 7.2)	67.9 (55.1, 77.8)	46.6 (33.2, 59.1)	23.7 (10.6, 39.7)	14.2 (4.1, 30.3)
Prior nivolumab or pembrolizumab treatment							
yes	3 (50.0)	3 (50.0)	5.6 (1.3, NE)	66.7 (19.5, 90.4)	33.3 (1.4, 75.5)	33.3 (1.4, 75.5)	33.3 (1.4, 75.5)
no	41 (56.2)	32 (43.8)	5.5 (4.2, 7.2)	70.7 (58.2, 80.0)	46.4 (33.1, 58.7)	25.4 (12.4, 40.7)	13.5 (3.2, 31.2)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	4 (57.1)	3 (42.9)	5.6 (1.3, NE)	57.1 (17.2, 83.7)	28.6 (1.4, 69.1)	28.6 (1.4, 69.1)	28.6 (1.4, 69.1)
no	40 (55.6)	32 (44.4)	5.5 (4.2, 7.2)	71.9 (59.4, 81.1)	47.2 (33.7, 59.5)	25.8 (12.6, 41.3)	13.8 (3.3, 31.6)
Presence of liver metastasis at baseline							
yes	31 (62.0)	19 (38.0)	4.8 (2.8, 7.2)	64.4 (49.0, 76.2)	47.1 (31.8, 61.0)	24.7 (10.5, 41.9)	13.2 (2.9, 31.3)
no	13 (44.8)	16 (55.2)	5.5 (4.1, NE)	81.4 (60.7, 91.9)	39.4 (16.9, 61.5)	26.3 (5.9, 53.2)	26.3 (5.9, 53.2)
Renal impairment at baseline							
normal	22 (68.8)	10 (31.3)	3.7 (2.8, 6.4)	61.3 (40.8, 76.5)	36.5 (18.6, 54.7)	7.6 (0.6, 27.9)	NE (NE, NE)
mild	11 (44.0)	14 (56.0)	11.0 (4.1, NE)	72.0 (50.1, 85.5)	53.2 (29.0, 72.4)	53.2 (29.0, 72.4)	39.9 (13.7, 65.3)
moderate	3 (37.5)	5 (62.5)	NE (1.3, NE)	75.0 (31.5, 93.1)	60.0 (19.5, 85.2)	60.0 (19.5, 85.2)	60.0 (19.5, 85.2)

Progression-free survival (PFS) is defined as the time from the date of treatment start to the date of documented radiographic disease progression per RECIST V1.1 or death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

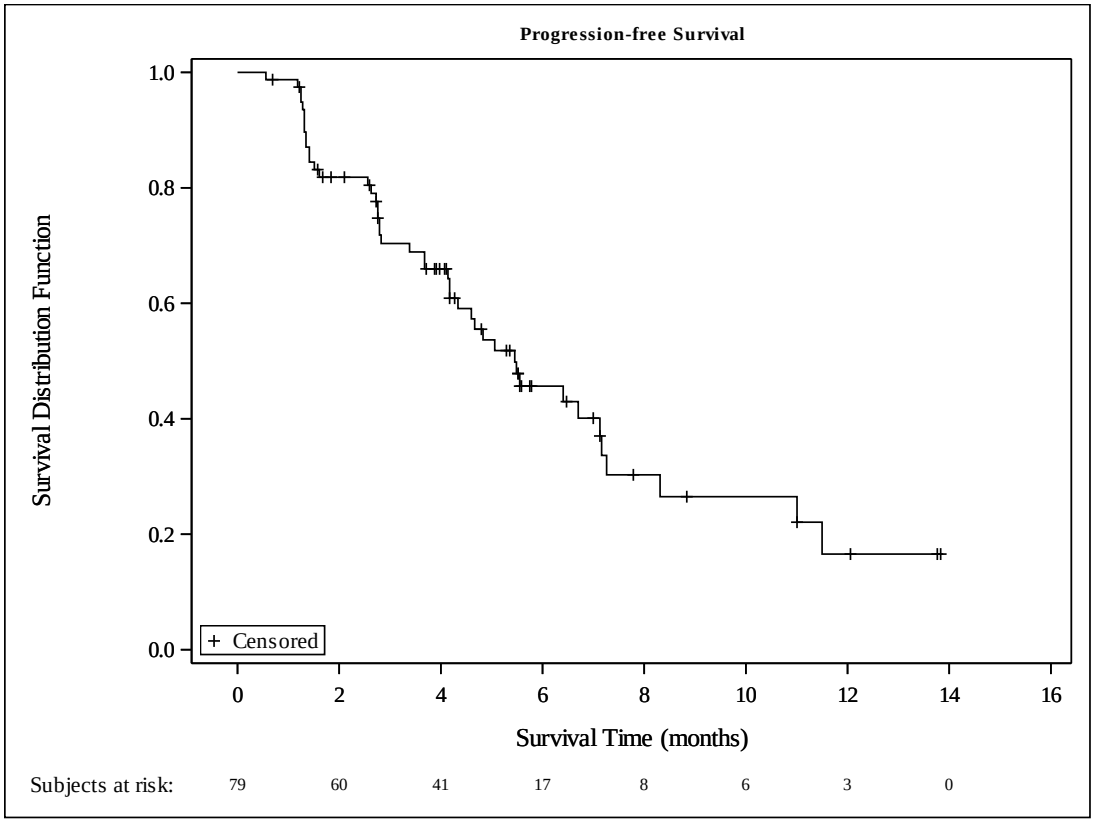
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Progression-free Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	33 (51.6)	31 (48.4)	6.4 (4.2, 7.3)	70.3 (56.9, 80.2)	52.1 (37.4, 65.0)	28.5 (13.8, 45.1)	21.4 (7.4, 40.0)
mild	11 (78.6)	3 (21.4)	4.7 (2.8, 11.0)	71.4 (40.6, 88.2)	25.7 (6.7, 50.6)	25.7 (6.7, 50.6)	NE (NE, NE)
Race							
White	37 (53.6)	32 (46.4)	5.5 (4.2, 8.3)	69.1 (56.2, 78.9)	46.5 (32.6, 59.3)	31.9 (17.5, 47.2)	19.9 (6.8, 38.0)
Black or African American	1 (100.0)	0 (0.0)	4.7 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	5 (62.5)	3 (37.5)	7.2 (1.6, 7.3)	72.9 (27.6, 92.5)	54.7 (13.7, 83.2)	NE (NE, NE)	NE (NE, NE)
Ethnicity							
Hispanic/Latino	4 (80.0)	1 (20.0)	4.3 (2.8, NE)	60.0 (12.6, 88.2)	40.0 (5.2, 75.3)	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Non-Hispanic/Non-Latino	38 (54.3)	32 (45.7)	5.6 (4.2, 7.3)	69.7 (56.9, 79.3)	47.6 (33.8, 60.2)	28.1 (14.0, 44.1)	15.0 (3.6, 33.9)
Unknown	2 (50.0)	2 (50.0)	4.4 (4.1, 4.6)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Progression-free survival (PFS) is defined as the time from the date of treatment start to the date of documented radiographic disease progression per RECIST V1.1 or death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Progression-free Survival
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Duration of Confirmed Response
Full Analysis Set

Subjects with confirmed response (CR+PR), N*=30	T-DXd (N=79) Events (%)	Censored (%)	Median (95% CI) [a]	Kaplan-Meier estimates on each time point 3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	10 (33.3)	20 (66.7)	8.1 (4.1, NE)	82.5 (59.7, 93.1)	51.9 (25.7, 72.9)	39.0 (12.7, 65.1)	39.0 (12.7, 65.1)
Region							
North America	5 (50.0)	5 (50.0)	5.9 (2.0, NE)	88.9 (43.3, 98.4)	47.6 (12.3, 76.9)	31.7 (4.9, 64.7)	31.7 (4.9, 64.7)
EU	5 (25.0)	15 (75.0)	NE (2.9, NE)	79.0 (47.9, 92.7)	56.9 (22.2, 80.9)	56.9 (22.2, 80.9)	NE (NE, NE)
Age (Category 1)							
<65 years	8 (50.0)	8 (50.0)	5.9 (2.9, 8.1)	76.9 (44.2, 91.9)	34.6 (7.2, 65.2)	NE (NE, NE)	NE (NE, NE)
>=65 years	2 (14.3)	12 (85.7)	NE (5.5, NE)	90.9 (50.8, 98.7)	72.7 (24.1, 93.1)	72.7 (24.1, 93.1)	72.7 (24.1, 93.1)
Age (Category 2)							
<75 years	9 (34.6)	17 (65.4)	5.9 (4.1, NE)	83.8 (57.7, 94.5)	45.4 (17.3, 70.0)	30.3 (6.1, 60.0)	30.3 (6.1, 60.0)
>=75 years	1 (25.0)	3 (75.0)	NE (2.0, NE)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	NE (NE, NE)
Sex							
female	5 (45.5)	6 (54.5)	8.1 (2.0, NE)	78.8 (38.1, 94.3)	50.6 (14.0, 79.0)	25.3 (1.4, 64.4)	25.3 (1.4, 64.4)
male	5 (26.3)	14 (73.7)	NE (3.5, NE)	85.1 (52.3, 96.1)	51.6 (15.9, 78.8)	51.6 (15.9, 78.8)	NE (NE, NE)
ECOG PS							
0	2 (28.6)	5 (71.4)	8.1 (2.9, 8.1)	80.0 (20.4, 96.9)	80.0 (20.4, 96.9)	NE (NE, NE)	NE (NE, NE)
1	8 (34.8)	15 (65.2)	5.9 (3.5, NE)	83.0 (55.9, 94.2)	44.0 (16.6, 68.8)	44.0 (16.6, 68.8)	44.0 (16.6, 68.8)
HER2 Status in central laboratory							
IHC 3+	9 (31.0)	20 (69.0)	8.1 (4.1, NE)	81.7 (58.2, 92.7)	58.3 (32.1, 77.4)	43.7 (14.7, 70.0)	43.7 (14.7, 70.0)
IHC 2+/ISH +	1 (100.0)	0 (0.0)	5.9 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Primary tumor location							
Gastric	4 (28.6)	10 (71.4)	5.9 (2.8, NE)	80.8 (42.3, 94.9)	48.5 (12.1, 78.0)	48.5 (12.1, 78.0)	48.5 (12.1, 78.0)
GEJ	6 (37.5)	10 (62.5)	8.1 (2.9, NE)	83.9 (49.4, 95.7)	58.7 (27.4, 80.4)	NE (NE, NE)	NE (NE, NE)

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) and the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Duration of Confirmed Response
Full Analysis Set

Subjects with confirmed response (CR+PR), N*=30	T-DXd (N=79) Events (%)	Censored (%)	Median (95% CI) [a]	Kaplan-Meier estimates on each time point 3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	1 (100.0)	0 (0.0)	8.1 (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)
intestinal	2 (33.3)	4 (66.7)	5.5 (3.5, 5.5)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
other	7 (30.4)	16 (69.6)	NE (4.1, NE)	77.5 (50.5, 91.0)	53.8 (24.7, 76.1)	53.8 (24.7, 76.1)	53.8 (24.7, 76.1)
Number of metastatic sites							
<2	1 (50.0)	1 (50.0)	5.9 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
>=2	9 (32.1)	19 (67.9)	8.1 (4.1, NE)	81.3 (57.6, 92.6)	58.1 (31.9, 77.2)	43.5 (14.7, 69.7)	43.5 (14.7, 69.7)
Previous total gastrectomy							
no	10 (33.3)	20 (66.7)	8.1 (4.1, NE)	82.5 (59.7, 93.1)	51.9 (25.7, 72.9)	39.0 (12.7, 65.1)	39.0 (12.7, 65.1)
Prior adjuvant/ neoadjuvant therapy							
yes	1 (50.0)	1 (50.0)	NE (4.1, NE)	100.0 (100.0, 100.0)	50.0 (0.6, 91.0)	NE (NE, NE)	NE (NE, NE)
no	9 (32.1)	19 (67.9)	8.1 (4.1, NE)	80.8 (56.5, 92.4)	51.3 (23.0, 73.9)	38.5 (11.7, 65.4)	38.5 (11.7, 65.4)
Prior nivolumab or pembrolizumab treatment							
yes	0 (0.0)	2 (100.0)	NE (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)
no	10 (35.7)	18 (64.3)	5.9 (4.1, NE)	81.3 (57.6, 92.6)	48.4 (21.7, 70.8)	32.3 (7.0, 61.7)	NE (NE, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	0 (0.0)	2 (100.0)	NE (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)
no	10 (35.7)	18 (64.3)	5.9 (4.1, NE)	81.3 (57.6, 92.6)	48.4 (21.7, 70.8)	32.3 (7.0, 61.7)	NE (NE, NE)
Presence of liver metastasis at baseline							
yes	6 (33.3)	12 (66.7)	5.9 (4.1, NE)	92.9 (59.1, 99.0)	46.4 (12.2, 75.6)	31.0 (4.8, 63.5)	NE (NE, NE)
no	4 (33.3)	8 (66.7)	NE (2.3, NE)	67.5 (29.1, 88.2)	54.0 (18.1, 80.1)	54.0 (18.1, 80.1)	54.0 (18.1, 80.1)
Renal impairment at baseline							
normal	4 (50.0)	4 (50.0)	5.9 (2.3, 5.9)	85.7 (33.4, 97.9)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
mild	2 (16.7)	10 (83.3)	NE (4.1, NE)	100.0 (100.0, 100.0)	83.3 (27.3, 97.5)	55.6 (7.3, 87.6)	55.6 (7.3, 87.6)
moderate	0 (0.0)	5 (100.0)	NE (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) and the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

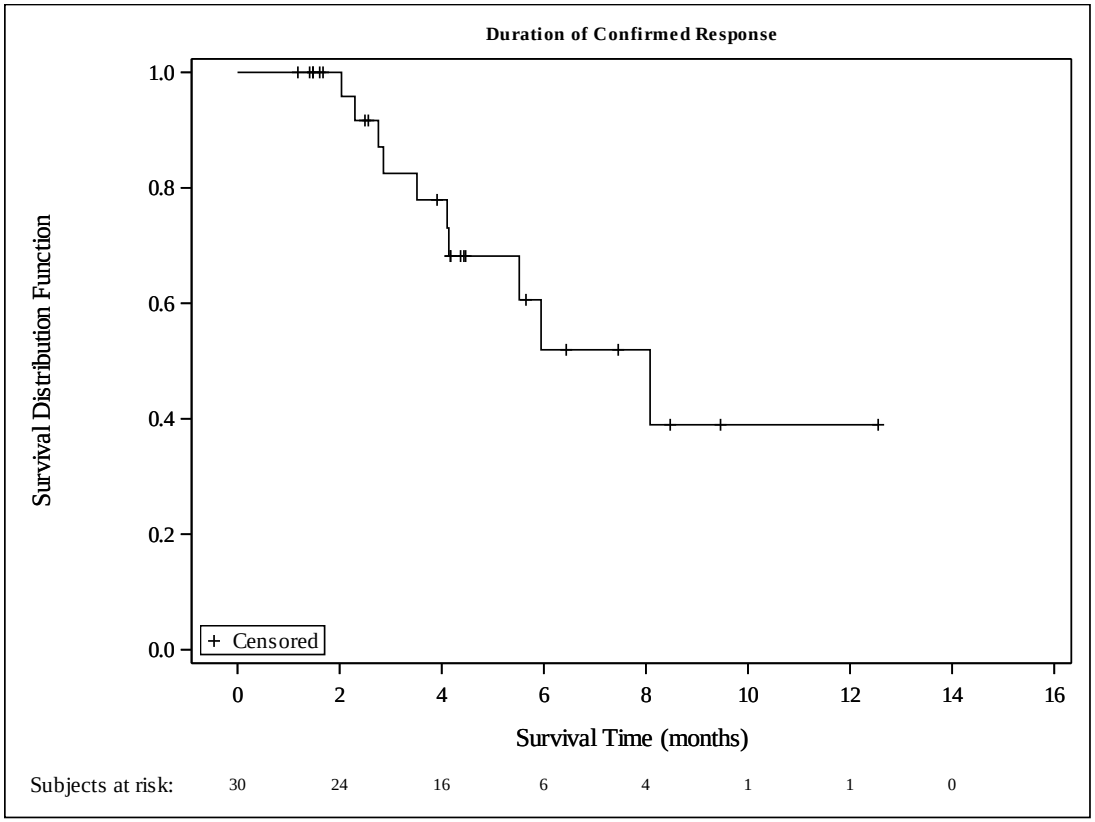
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Duration of Confirmed Response
Full Analysis Set

Subjects with confirmed response (CR+PR), N*=30	T-DXd (N=79) Events (%)	Censored (%)	Median (95% CI) [a]	Kaplan-Meier estimates on each time point 3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	6 (26.1)	17 (73.9)	NE (4.1, NE)	82.9 (55.7, 94.2)	55.8 (24.3, 78.6)	55.8 (24.3, 78.6)	55.8 (24.3, 78.6)
mild	4 (57.1)	3 (42.9)	4.1 (2.0, 8.1)	80.0 (20.4, 96.9)	40.0 (5.2, 75.3)	NE (NE, NE)	NE (NE, NE)
Race							
White	8 (29.6)	19 (70.4)	8.1 (4.1, NE)	84.7 (59.5, 94.8)	59.5 (32.0, 78.9)	44.6 (14.7, 71.2)	44.6 (14.7, 71.2)
Black or African American	1 (100.0)	0 (0.0)	2.0 (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	1 (50.0)	1 (50.0)	5.9 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Ethnicity							
Hispanic/Latino	1 (50.0)	1 (50.0)	NE (2.9, NE)	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)	NE (NE, NE)
Non-Hispanic/Non-Latino	9 (33.3)	18 (66.7)	8.1 (4.1, NE)	85.9 (62.2, 95.2)	51.1 (22.8, 73.7)	34.0 (7.2, 64.3)	34.0 (7.2, 64.3)
Unknown	0 (0.0)	1 (100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) and the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Duration of Confirmed Response
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Confirmed Response
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	30 (38.0)	49 (62.0)	4.8 (3.0, NE)	62.2 (48.6, 73.2)	44.5 (27.8, 59.9)	29.7 (8.1, 55.6)	NE (NE, NE)
Region							
North America	10 (29.4)	24 (70.6)	7.4 (3.0, NE)	70.0 (48.0, 84.1)	61.2 (35.4, 79.3)	NE (NE, NE)	NE (NE, NE)
EU	20 (44.4)	25 (55.6)	3.9 (1.5, NE)	57.3 (39.3, 71.7)	29.2 (9.8, 52.1)	29.2 (9.8, 52.1)	NE (NE, NE)
Age (Category 1)							
<65 years	16 (34.8)	30 (65.2)	7.4 (3.0, NE)	66.3 (48.2, 79.3)	52.7 (29.7, 71.4)	26.4 (1.9, 63.7)	NE (NE, NE)
>=65 years	14 (42.4)	19 (57.6)	3.1 (1.4, NE)	55.2 (32.7, 72.8)	31.9 (10.6, 55.9)	NE (NE, NE)	NE (NE, NE)
Age (Category 2)							
<75 years	26 (34.7)	49 (65.3)	5.4 (3.9, NE)	67.0 (53.2, 77.6)	47.9 (30.0, 63.8)	32.0 (8.5, 59.0)	NE (NE, NE)
>=75 years	4 (100.0)	0 (0.0)	2.0 (1.3, 2.7)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Sex							
female	11 (50.0)	11 (50.0)	3.0 (1.4, NE)	46.7 (23.0, 67.5)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
male	19 (33.3)	38 (66.7)	5.4 (3.1, NE)	69.0 (52.9, 80.6)	49.1 (28.5, 66.8)	32.7 (8.3, 60.6)	NE (NE, NE)
ECOG PS							
0	7 (24.1)	22 (75.9)	NE (3.0, NE)	71.6 (46.7, 86.4)	65.1 (39.4, 82.1)	65.1 (39.4, 82.1)	NE (NE, NE)
1	23 (46.0)	27 (54.0)	3.9 (1.4, 7.4)	57.4 (40.8, 70.8)	28.8 (9.3, 52.0)	NE (NE, NE)	NE (NE, NE)
HER2 Status in central laboratory							
IHC 3+	29 (42.6)	39 (57.4)	4.8 (2.8, NE)	60.3 (46.1, 71.9)	41.5 (24.6, 57.7)	27.7 (7.5, 52.9)	NE (NE, NE)
IHC 2+/ISH +	1 (10.0)	9 (90.0)	NE (1.2, NE)	88.9 (43.3, 98.4)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Primary tumor location							
Gastric	14 (51.9)	13 (48.1)	2.7 (1.4, 4.8)	49.6 (26.7, 69.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
GEJ	16 (30.8)	36 (69.2)	7.4 (3.9, NE)	68.5 (51.4, 80.6)	57.3 (36.1, 73.7)	38.2 (9.3, 67.7)	NE (NE, NE)

Time to response is defined as the time from the date of treatment start to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Confirmed Response
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	1 (100.0)	0 (0.0)	3.0 (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
intestinal	6 (31.6)	13 (68.4)	4.8 (1.4, NE)	76.6 (48.8, 90.5)	49.2 (15.2, 76.6)	49.2 (15.2, 76.6)	NE (NE, NE)
other	23 (39.0)	36 (61.0)	5.4 (2.7, NE)	60.6 (45.0, 73.0)	45.1 (25.5, 62.9)	NE (NE, NE)	NE (NE, NE)
Number of metastatic sites							
<2	2 (40.0)	3 (60.0)	NE (1.2, NE)	60.0 (12.6, 88.2)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
>=2	28 (37.8)	46 (62.2)	4.8 (3.0, NE)	62.4 (48.1, 73.7)	41.9 (23.9, 58.9)	27.9 (7.4, 53.5)	NE (NE, NE)
Previous total gastrectomy							
no	30 (38.0)	49 (62.0)	4.8 (3.0, NE)	62.2 (48.6, 73.2)	44.5 (27.8, 59.9)	29.7 (8.1, 55.6)	NE (NE, NE)
Prior adjuvant/ neoadjuvant therapy							
yes	2 (22.2)	7 (77.8)	NE (1.4, NE)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	NE (NE, NE)
no	28 (40.0)	42 (60.0)	4.8 (2.8, NE)	60.2 (45.4, 72.2)	37.6 (19.4, 55.8)	NE (NE, NE)	NE (NE, NE)
Prior nivolumab or pembrolizumab treatment							
yes	2 (33.3)	4 (66.7)	NE (1.2, NE)	62.5 (14.2, 89.3)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
no	28 (38.4)	45 (61.6)	4.8 (3.0, NE)	62.2 (48.0, 73.6)	42.9 (25.5, 59.2)	28.6 (7.7, 54.3)	NE (NE, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	2 (28.6)	5 (71.4)	NE (1.2, NE)	68.6 (21.3, 91.2)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
no	28 (38.9)	44 (61.1)	4.8 (3.0, NE)	61.6 (47.2, 73.2)	42.5 (25.2, 58.8)	28.3 (7.7, 53.9)	NE (NE, NE)
Presence of liver metastasis at baseline							
yes	18 (36.0)	32 (64.0)	4.8 (3.0, NE)	65.8 (47.7, 78.9)	42.5 (21.2, 62.4)	21.3 (1.8, 55.1)	NE (NE, NE)
no	12 (41.4)	17 (58.6)	NE (1.4, NE)	57.4 (36.3, 73.8)	51.0 (29.2, 69.2)	NE (NE, NE)	NE (NE, NE)
Renal impairment at baseline							
normal	8 (25.0)	24 (75.0)	7.4 (NE, NE)	73.4 (52.1, 86.3)	73.4 (52.1, 86.3)	NE (NE, NE)	NE (NE, NE)
mild	12 (48.0)	13 (52.0)	3.0 (1.4, NE)	50.0 (24.5, 71.0)	23.8 (5.1, 50.1)	23.8 (5.1, 50.1)	NE (NE, NE)
moderate	5 (62.5)	3 (37.5)	3.1 (1.3, 5.4)	58.3 (18.0, 84.4)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Time to response is defined as the time from the date of treatment start to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

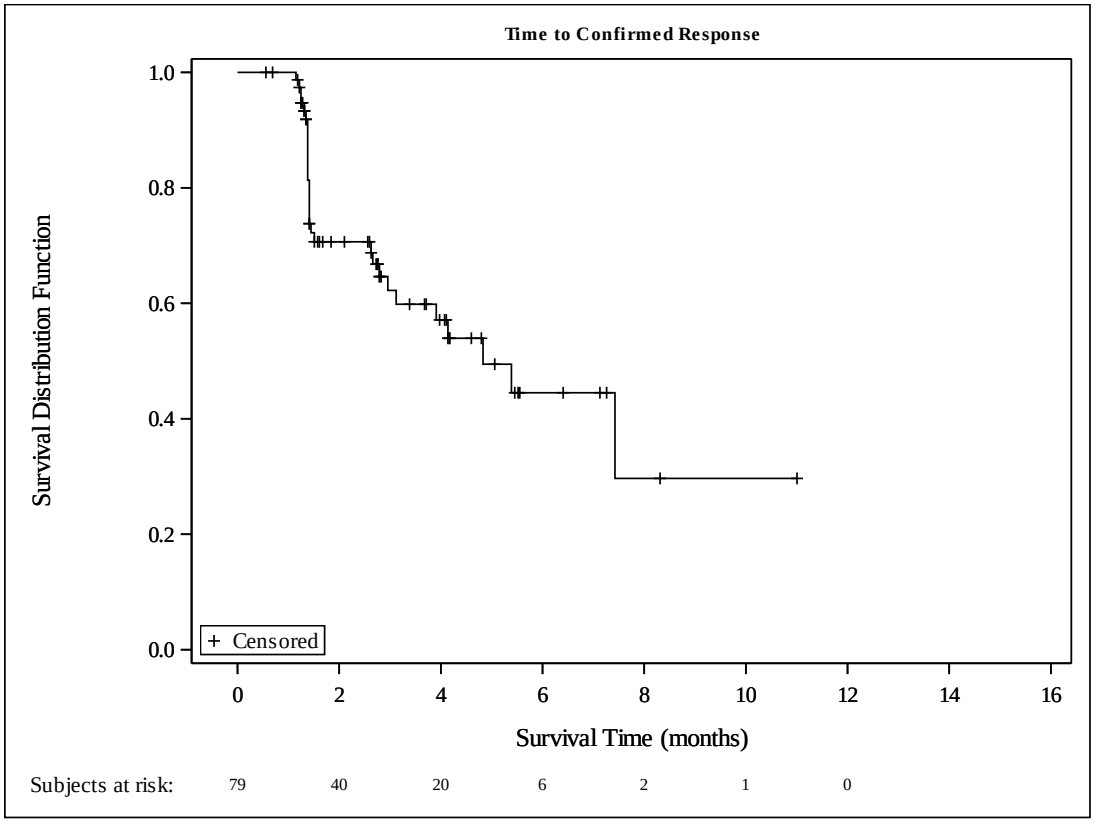
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Confirmed Response
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	23 (35.9)	41 (64.1)	5.4 (2.8, NE)	64.2 (49.3, 75.8)	49.4 (30.1, 66.1)	32.9 (8.5, 60.6)	NE (NE, NE)
mild	7 (50.0)	7 (50.0)	3.9 (1.4, NE)	55.9 (23.4, 79.3)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Race							
White	27 (39.1)	42 (60.9)	4.8 (2.8, NE)	61.4 (46.7, 73.2)	41.8 (24.4, 58.2)	27.8 (7.5, 53.2)	NE (NE, NE)
Black or African American	1 (100.0)	0 (0.0)	2.7 (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	NE (1.2, NE)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	NE (NE, NE)	NE (NE, NE)
Ethnicity							
Hispanic/Latino	2 (40.0)	3 (60.0)	NE (1.5, NE)	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)	NE (NE, NE)	NE (NE, NE)
Non-Hispanic/Non-Latino	27 (38.6)	43 (61.4)	4.8 (3.0, NE)	61.7 (46.9, 73.5)	42.0 (24.5, 58.5)	28.0 (7.5, 53.4)	NE (NE, NE)
Unknown	1 (25.0)	3 (75.0)	NE (1.1, NE)	75.0 (12.8, 96.1)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Time to response is defined as the time from the date of treatment start to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Time to Confirmed Response
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Hospitalization
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	27 (34.2)	52 (65.8)	NE (8.7, NE)	74.7 (63.5, 82.8)	66.2 (54.3, 75.6)	61.7 (47.4, 73.2)	61.7 (47.4, 73.2)
Region							
North America	11 (32.4)	23 (67.6)	NE (4.1, NE)	76.5 (58.4, 87.5)	67.3 (48.7, 80.4)	67.3 (48.7, 80.4)	67.3 (48.7, 80.4)
EU	16 (35.6)	29 (64.4)	NE (5.2, NE)	73.3 (57.8, 83.9)	65.2 (48.6, 77.5)	54.3 (29.6, 73.6)	54.3 (29.6, 73.6)
Age (Category 1)							
<65 years	17 (37.0)	29 (63.0)	NE (5.2, NE)	73.9 (58.7, 84.3)	63.8 (47.6, 76.2)	55.8 (34.8, 72.4)	55.8 (34.8, 72.4)
>=65 years	10 (30.3)	23 (69.7)	NE (NE, NE)	75.8 (57.3, 87.1)	69.4 (50.6, 82.3)	69.4 (50.6, 82.3)	69.4 (50.6, 82.3)
Age (Category 2)							
<75 years	25 (33.3)	50 (66.7)	NE (8.7, NE)	74.6 (63.2, 83.0)	67.1 (54.9, 76.7)	62.3 (47.2, 74.2)	62.3 (47.2, 74.2)
>=75 years	2 (50.0)	2 (50.0)	NE (1.2, NE)	75.0 (12.8, 96.1)	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)
Sex							
female	8 (36.4)	14 (63.6)	8.7 (4.1, NE)	81.8 (58.5, 92.8)	64.4 (38.5, 81.7)	48.3 (16.5, 74.6)	48.3 (16.5, 74.6)
male	19 (33.3)	38 (66.7)	NE (NE, NE)	71.9 (58.3, 81.7)	66.4 (52.5, 77.1)	66.4 (52.5, 77.1)	66.4 (52.5, 77.1)
ECOG PS							
0	3 (10.3)	26 (89.7)	NE (NE, NE)	96.4 (77.2, 99.5)	88.9 (69.3, 96.3)	88.9 (69.3, 96.3)	88.9 (69.3, 96.3)
1	24 (48.0)	26 (52.0)	8.7 (1.4, NE)	62.0 (47.1, 73.8)	52.8 (37.7, 65.8)	42.2 (20.9, 62.2)	42.2 (20.9, 62.2)
HER2 Status in central laboratory							
IHC 3+	21 (30.9)	47 (69.1)	NE (8.7, NE)	77.9 (66.1, 86.0)	69.5 (56.7, 79.2)	64.5 (48.7, 76.6)	64.5 (48.7, 76.6)
IHC 2+/ISH +	5 (50.0)	5 (50.0)	NE (0.4, NE)	60.0 (25.3, 82.7)	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)	NE (NE, NE)
Primary tumor location							
Gastric	10 (37.0)	17 (63.0)	8.7 (4.1, NE)	77.8 (57.1, 89.3)	66.1 (44.9, 80.7)	49.6 (17.9, 75.1)	49.6 (17.9, 75.1)
GEJ	17 (32.7)	35 (67.3)	NE (NE, NE)	73.0 (58.7, 83.0)	66.3 (51.3, 77.6)	66.3 (51.3, 77.6)	66.3 (51.3, 77.6)

Time to hospitalization is defined as the time from the date of treatment start to the date of the first hospitalization. Patients without hospitalization are censored at last known alive date.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Hospitalization
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	0	1	NE	100.0	100.0	100.0	100.0
	(0.0)	(100.0)	(NE, NE)	(100.0, 100.0)	(100.0, 100.0)	(100.0, 100.0)	(100.0, 100.0)
intestinal	5	14	NE	84.2	71.1	71.1	71.1
	(26.3)	(73.7)	(5.2, NE)	(58.7, 94.6)	(43.3, 87.0)	(43.3, 87.0)	(43.3, 87.0)
other	22	37	NE	71.1	64.0	58.7	58.7
	(37.3)	(62.7)	(8.7, NE)	(57.8, 81.0)	(50.3, 74.9)	(42.1, 72.0)	(42.1, 72.0)
Number of metastatic sites							
<2	0	5	NE	100.0	100.0	NE	NE
	(0.0)	(100.0)	(NE, NE)	(100.0, 100.0)	(100.0, 100.0)	(NE, NE)	(NE, NE)
>=2	27	47	NE	72.9	63.8	59.5	59.5
	(36.5)	(63.5)	(8.7, NE)	(61.3, 81.6)	(51.4, 73.8)	(45.1, 71.3)	(45.1, 71.3)
Previous total gastrectomy							
no	27	52	NE	74.7	66.2	61.7	61.7
	(34.2)	(65.8)	(8.7, NE)	(63.5, 82.8)	(54.3, 75.6)	(47.4, 73.2)	(47.4, 73.2)
Prior adjuvant/ neoadjuvant therapy							
yes	3	6	NE	77.8	66.7	66.7	66.7
	(33.3)	(66.7)	(0.1, NE)	(36.5, 93.9)	(28.2, 87.8)	(28.2, 87.8)	(28.2, 87.8)
no	24	46	NE	74.3	66.1	61.0	61.0
	(34.3)	(65.7)	(8.7, NE)	(62.3, 82.9)	(53.4, 76.1)	(45.3, 73.5)	(45.3, 73.5)
Prior nivolumab or pembrolizumab treatment							
yes	0	6	NE	100.0	100.0	100.0	100.0
	(0.0)	(100.0)	(NE, NE)	(100.0, 100.0)	(100.0, 100.0)	(100.0, 100.0)	(100.0, 100.0)
no	27	46	NE	72.6	63.4	58.5	58.5
	(37.0)	(63.0)	(8.7, NE)	(60.8, 81.4)	(51.0, 73.5)	(43.4, 70.9)	(43.4, 70.9)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	1	6	NE	100.0	83.3	83.3	83.3
	(14.3)	(85.7)	(3.6, NE)	(100.0, 100.0)	(27.3, 97.5)	(27.3, 97.5)	(27.3, 97.5)
no	26	46	NE	72.2	64.3	59.4	59.4
	(36.1)	(63.9)	(8.7, NE)	(60.3, 81.1)	(51.8, 74.4)	(44.1, 71.8)	(44.1, 71.8)
Presence of liver metastasis at baseline							
yes	16	34	NE	76.0	66.7	66.7	66.7
	(32.0)	(68.0)	(NE, NE)	(61.6, 85.6)	(51.4, 78.2)	(51.4, 78.2)	(51.4, 78.2)
no	11	18	8.7	72.4	65.2	48.9	48.9
	(37.9)	(62.1)	(3.6, NE)	(52.3, 85.1)	(44.9, 79.5)	(18.0, 74.2)	(18.0, 74.2)
Renal impairment at baseline							
normal	11	21	NE	68.8	65.3	65.3	65.3
	(34.4)	(65.6)	(1.7, NE)	(49.7, 81.8)	(46.1, 79.1)	(46.1, 79.1)	(46.1, 79.1)
mild	6	19	NE	80.0	74.7	74.7	74.7
	(24.0)	(76.0)	(NE, NE)	(58.4, 91.1)	(51.7, 87.9)	(51.7, 87.9)	(51.7, 87.9)
moderate	4	4	8.7	87.5	62.5	31.3	31.3
	(50.0)	(50.0)	(1.4, NE)	(38.7, 98.1)	(22.9, 86.1)	(1.5, 72.3)	(1.5, 72.3)

Time to hospitalization is defined as the time from the date of treatment start to the date of the first hospitalization. Patients without hospitalization are censored at last known alive date.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

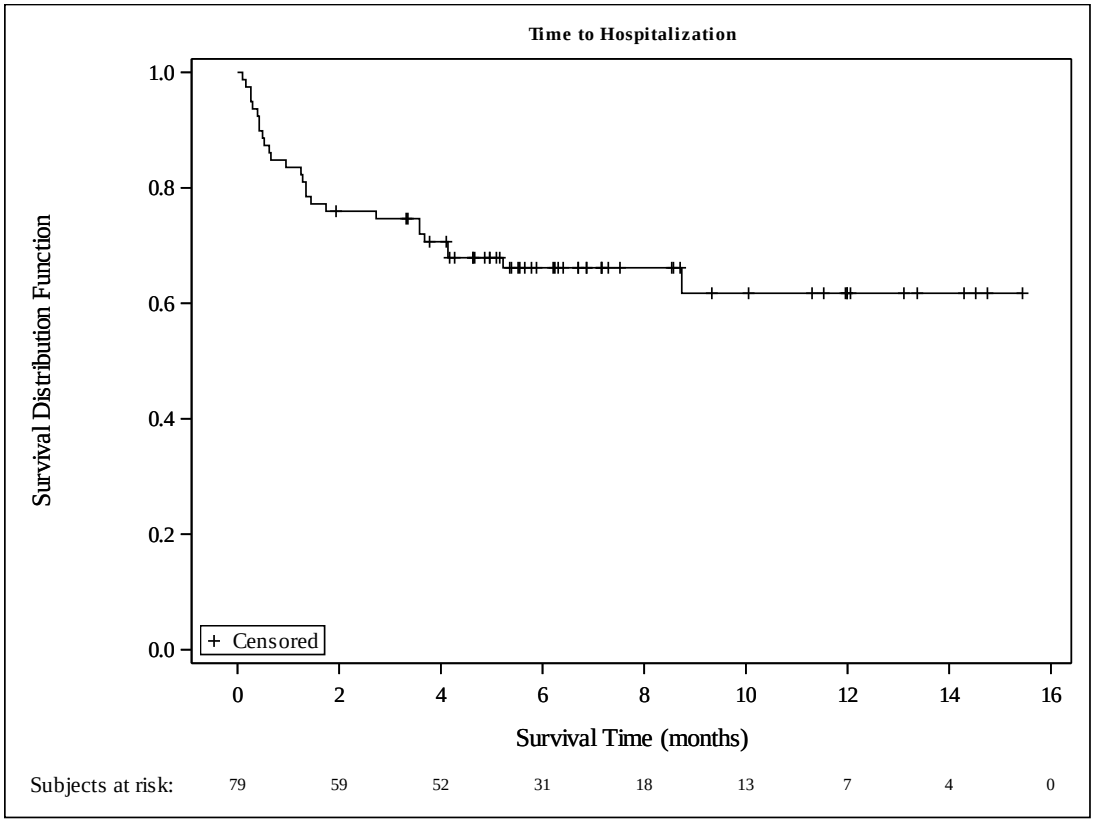
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Hospitalization
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	18 (28.1)	46 (71.9)	NE (8.7, NE)	78.1 (65.8, 86.4)	72.5 (59.4, 82.0)	66.5 (48.7, 79.3)	66.5 (48.7, 79.3)
mild	8 (57.1)	6 (42.9)	4.1 (0.5, NE)	64.3 (34.3, 83.3)	42.9 (17.7, 66.0)	42.9 (17.7, 66.0)	42.9 (17.7, 66.0)
Race							
White	23 (33.3)	46 (66.7)	NE (8.7, NE)	73.9 (61.8, 82.7)	67.4 (54.8, 77.3)	62.6 (47.2, 74.7)	62.6 (47.2, 74.7)
Black or African American	1 (100.0)	0 (0.0)	4.1 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	NE (0.4, NE)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	NE (NE, NE)
Ethnicity							
Hispanic/Latino	3 (60.0)	2 (40.0)	3.6 (1.2, NE)	80.0 (20.4, 96.9)	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Non-Hispanic/Non-Latino	23 (32.9)	47 (67.1)	NE (8.7, NE)	72.8 (60.8, 81.7)	67.8 (55.2, 77.5)	62.9 (47.5, 75.0)	62.9 (47.5, 75.0)
Unknown	1 (25.0)	3 (75.0)	NE (4.1, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Time to hospitalization is defined as the time from the date of treatment start to the date of the first hospitalization. Patients without hospitalization are censored at last known alive date.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Time to Hospitalization
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set

	T-DXd (N=79)
Results (mm)	
n	76
Mean (SD)	51.6 (48.27)
Median	32.5
Q1, Q3	20.0, 65.0
Min, Max	0.0, 232.0
Change from Baseline (mm)	
n	76
Mean (SD)	-24.4 (31.66)
Median	-17.0
Q1, Q3	-37.0, -7.0
Min, Max	-180.0, 31.0
Percent Change from Baseline (%)	
n	76
Mean (SD)	-35.2 (33.03)
Median	-37.5
Q1, Q3	-57.5, -12.5
Min, Max	-100.0, 59.0

Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR - Subgroup analysis
Full Analysis Set

Subgroup Level	T-DXd (N=79) N	Mean (SD)	Median	Q1,	Q3	Min,	Max
Region							
North America	32	-31.7 (36.30)	-32.0	-48.5,	-8.5	-100.0,	51.0
EU	44	-37.8 (30.60)	-40.5	-59.0,	-20.0	-100.0,	59.0
Age (Category 1)							
<65 years	44	-39.3 (27.89)	-40.5	-58.0,	-20.0	-100.0,	6.0
>=65 years	32	-29.7 (38.79)	-36.5	-56.5,	-8.5	-100.0,	59.0
Age (Category 2)							
<75 years	72	-33.8 (33.32)	-36.5	-56.5,	-11.0	-100.0,	59.0
>=75 years	4	-60.5 (9.61)	-60.5	-67.5,	-53.5	-72.0,	-49.0
Sex							
female	21	-47.1 (24.19)	-49.0	-63.0,	-30.0	-89.0,	0.0
male	55	-30.7 (34.96)	-34.0	-54.0,	-8.0	-100.0,	59.0
ECOG PS							
0	29	-26.3 (36.07)	-34.0	-42.0,	-8.0	-100.0,	59.0
1	47	-40.7 (30.08)	-43.0	-63.0,	-14.0	-100.0,	21.0
HER2 Status in central laboratory							
IHC 3+	65	-40.0 (30.57)	-41.0	-59.0,	-24.0	-100.0,	59.0
IHC 2+/ISH +	10	-8.0 (36.33)	-8.0	-13.0,	6.0	-92.0,	51.0
Primary tumor location							
Gastric	26	-38.7 (35.18)	-44.0	-63.0,	-24.0	-92.0,	59.0
GEJ	50	-33.4 (32.07)	-32.0	-56.0,	-12.0	-100.0,	51.0
Histological subtype							
diffuse	1	-59.0 (-)	-59.0	-59.0,	-59.0	-59.0,	-59.0
intestinal	19	-30.9 (31.04)	-38.0	-48.0,	-14.0	-75.0,	59.0
other	56	-36.3 (33.97)	-37.0	-58.5,	-10.5	-100.0,	51.0
Number of metastatic sites							
<2	4	-40.0 (36.23)	-28.0	-64.5,	-15.5	-92.0,	-12.0
>=2	72	-35.0 (33.10)	-38.0	-57.5,	-11.5	-100.0,	59.0
Previous total gastrectomy							
no	76	-35.2 (33.03)	-37.5	-57.5,	-12.5	-100.0,	59.0
Prior adjuvant/ neoadjuvant therapy							
yes	7	-32.7 (29.67)	-24.0	-72.0,	-12.0	-73.0,	5.0
no	69	-35.5 (33.54)	-38.0	-57.0,	-13.0	-100.0,	59.0
Prior nivolumab or pembrolizumab treatment							
yes	6	-42.2 (29.45)	-39.0	-61.0,	-13.0	-89.0,	-12.0
no	70	-34.6 (33.44)	-37.5	-57.0,	-10.0	-100.0,	59.0
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	7	-37.4 (29.66)	-37.0	-61.0,	-12.0	-89.0,	-9.0
no	69	-35.0 (33.54)	-38.0	-57.0,	-14.0	-100.0,	59.0
Presence of liver metastasis at baseline							
yes	49	-34.6 (36.15)	-38.0	-58.0,	-9.0	-100.0,	59.0
no	27	-36.4 (27.04)	-36.0	-57.0,	-19.0	-89.0,	34.0

Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 16AUG2022

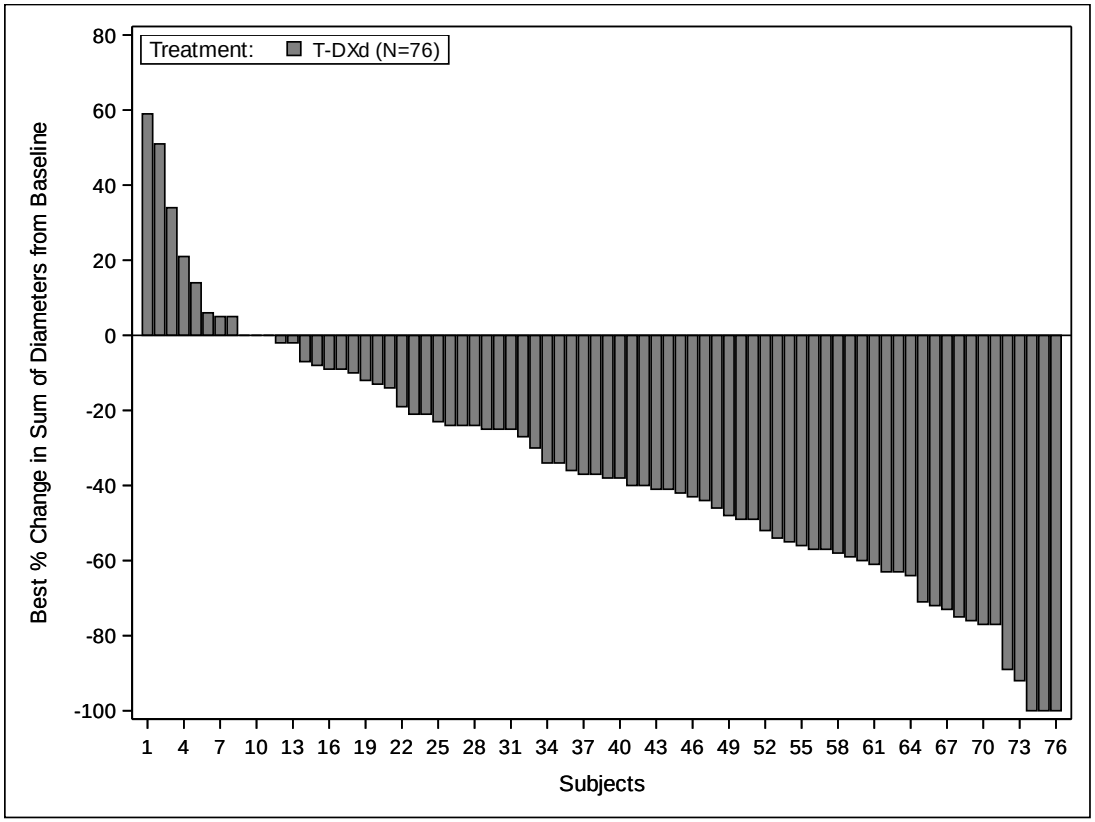
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR - Subgroup analysis
Full Analysis Set

Subgroup Level	T-DXd (N=79) N	Mean (SD)	Median	Q1,	Q3	Min,	Max
Renal impairment at baseline							
normal	31	-32.6 (34.19)	-38.0	-57.0,	-9.0	-100.0,	51.0
mild	24	-31.2 (36.92)	-33.5	-57.0,	-9.5	-100.0,	59.0
moderate	8	-47.8 (32.67)	-47.0	-70.0,	-24.0	-100.0,	0.0
Hepatic impairment at baseline							
normal	62	-34.9 (34.82)	-36.5	-58.0,	-14.0	-100.0,	59.0
mild	13	-38.9 (24.20)	-48.0	-54.0,	-13.0	-73.0,	-2.0
Race							
White	66	-34.5 (34.07)	-37.0	-58.0,	-12.0	-100.0,	59.0
Black or African American	1	-49.0 (-)	-49.0	-49.0,	-49.0	-49.0,	-49.0
Other	8	-44.0 (25.12)	-39.5	-55.0,	-32.0	-92.0,	-7.0
Ethnicity							
Hispanic/Latino	5	-33.6 (19.88)	-34.0	-38.0,	-24.0	-63.0,	-9.0
Non-Hispanic/Non-Latino	67	-35.8 (34.60)	-40.0	-59.0,	-12.0	-100.0,	59.0
Unknown	4	-27.3 (17.69)	-32.0	-38.5,	-16.0	-43.0,	-2.0

Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

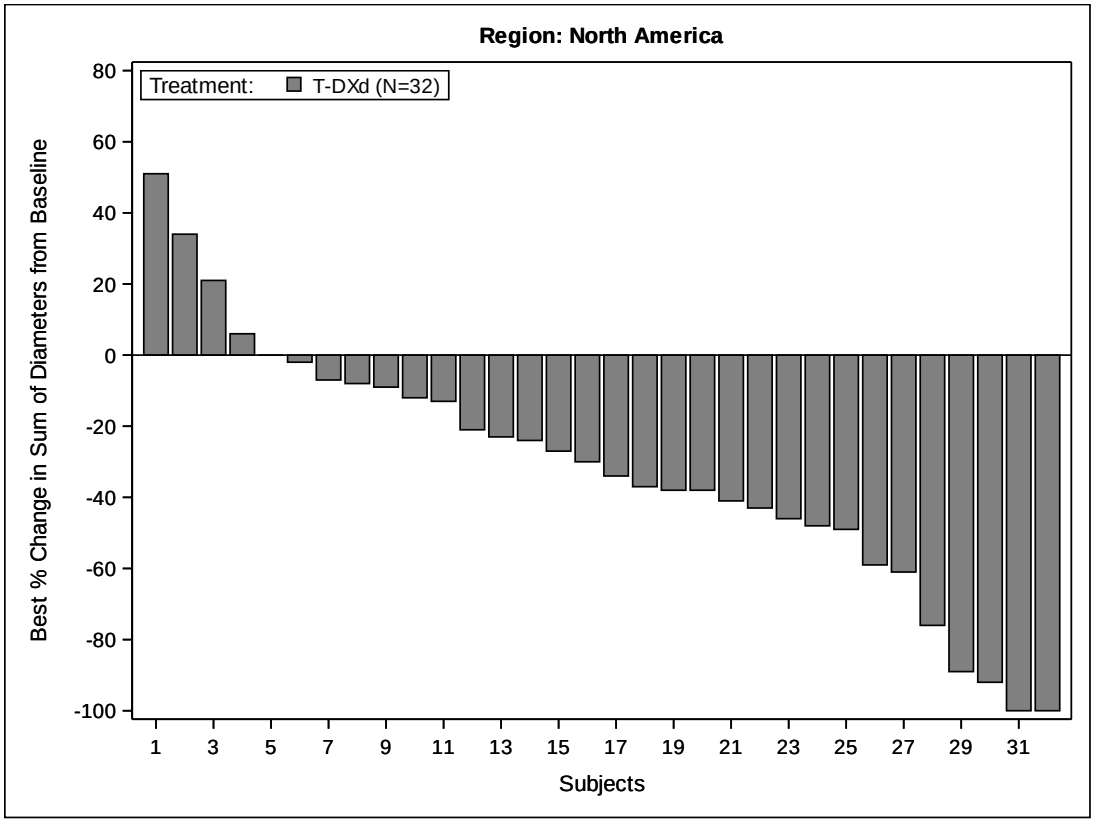
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



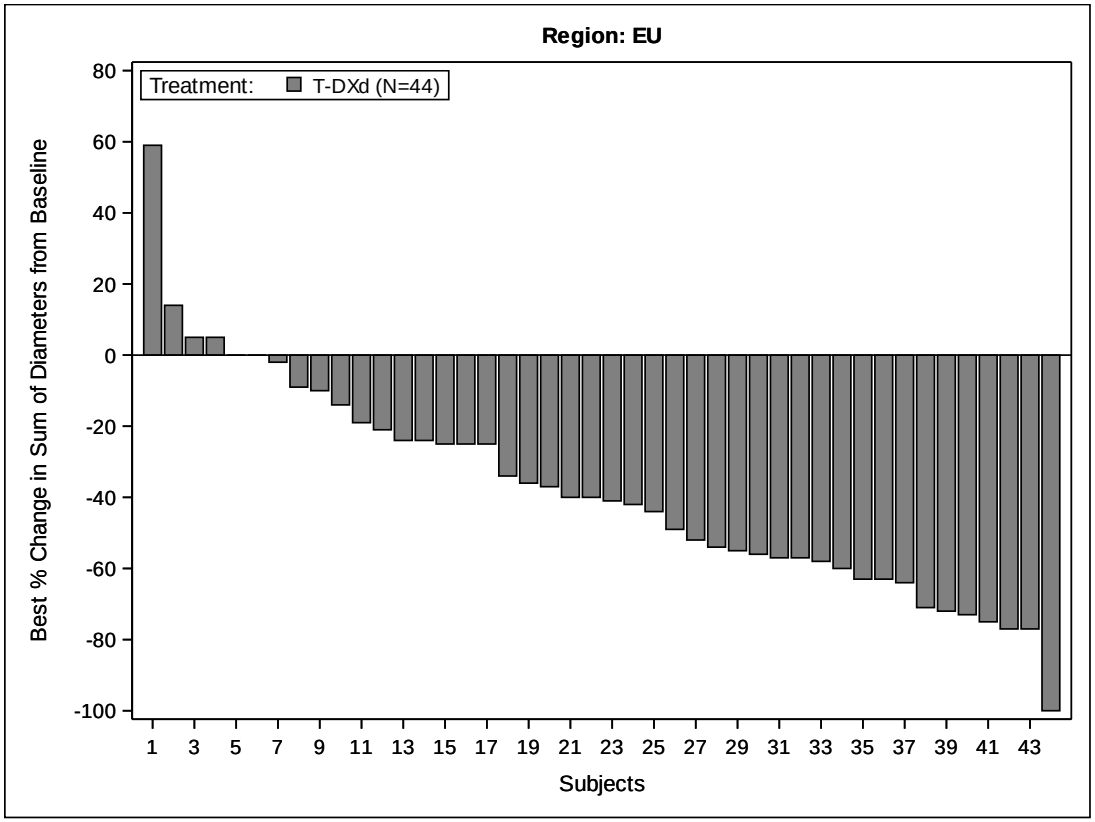
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



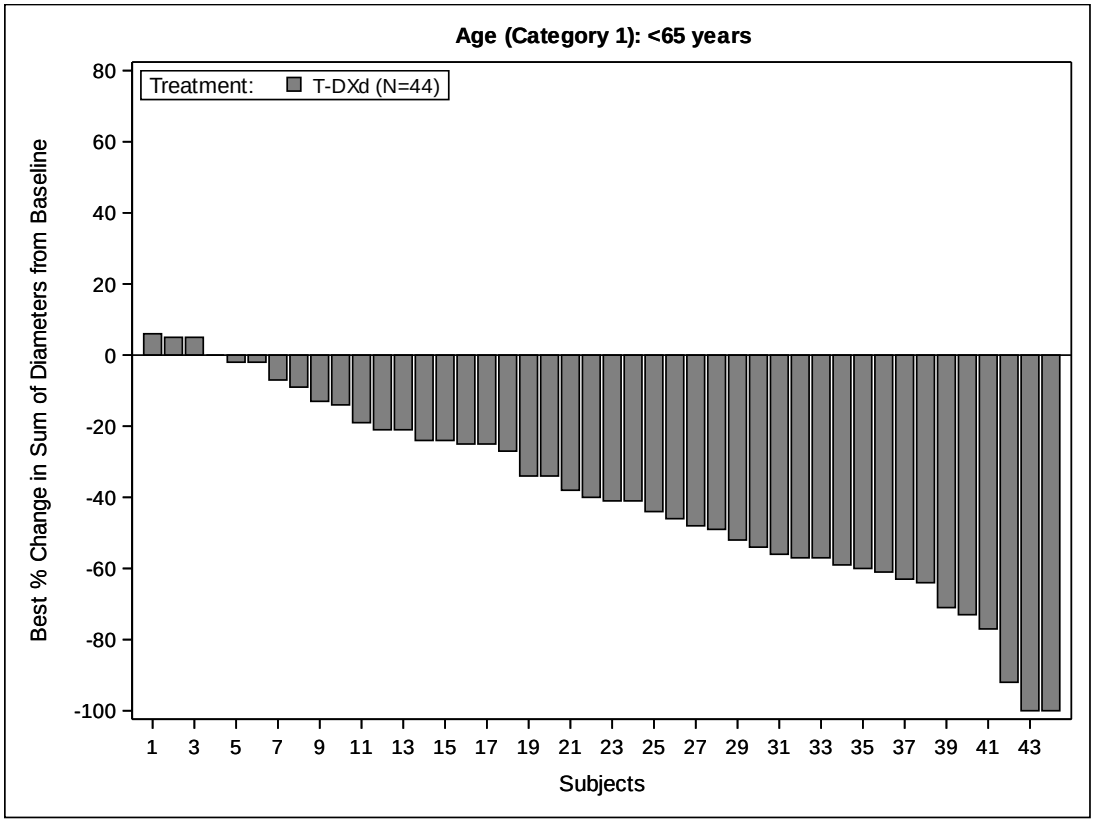
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



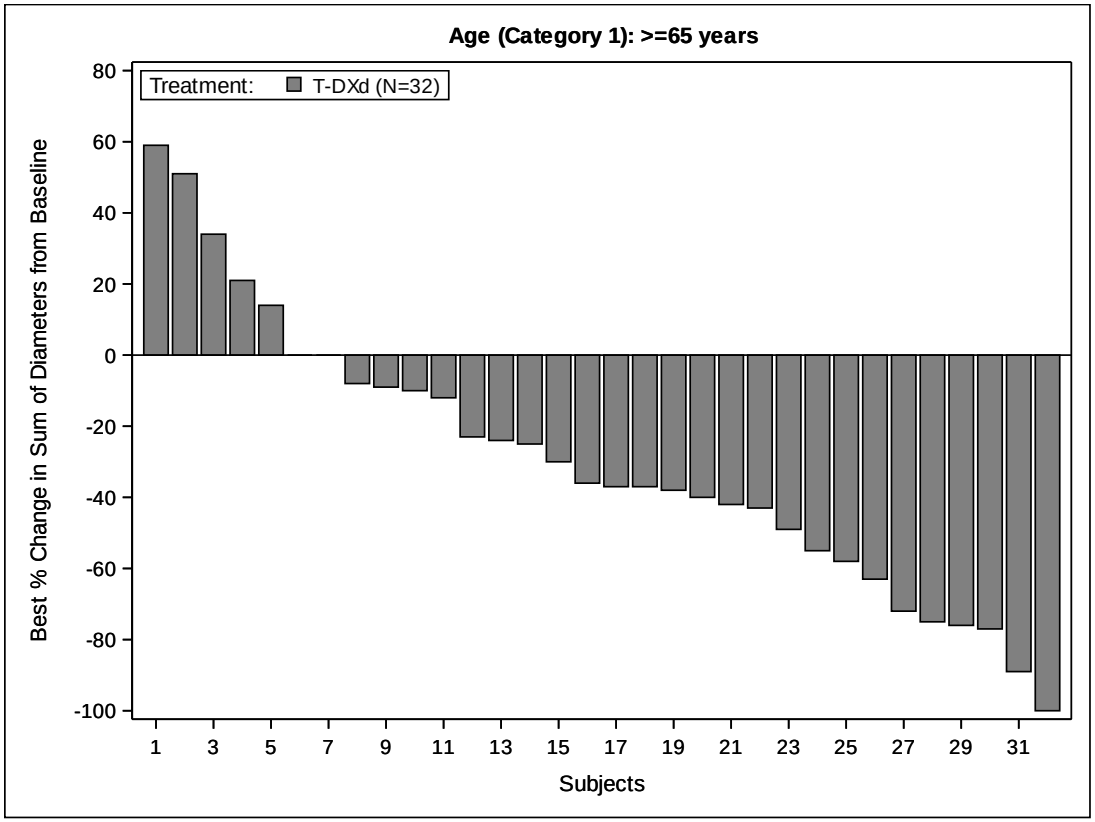
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



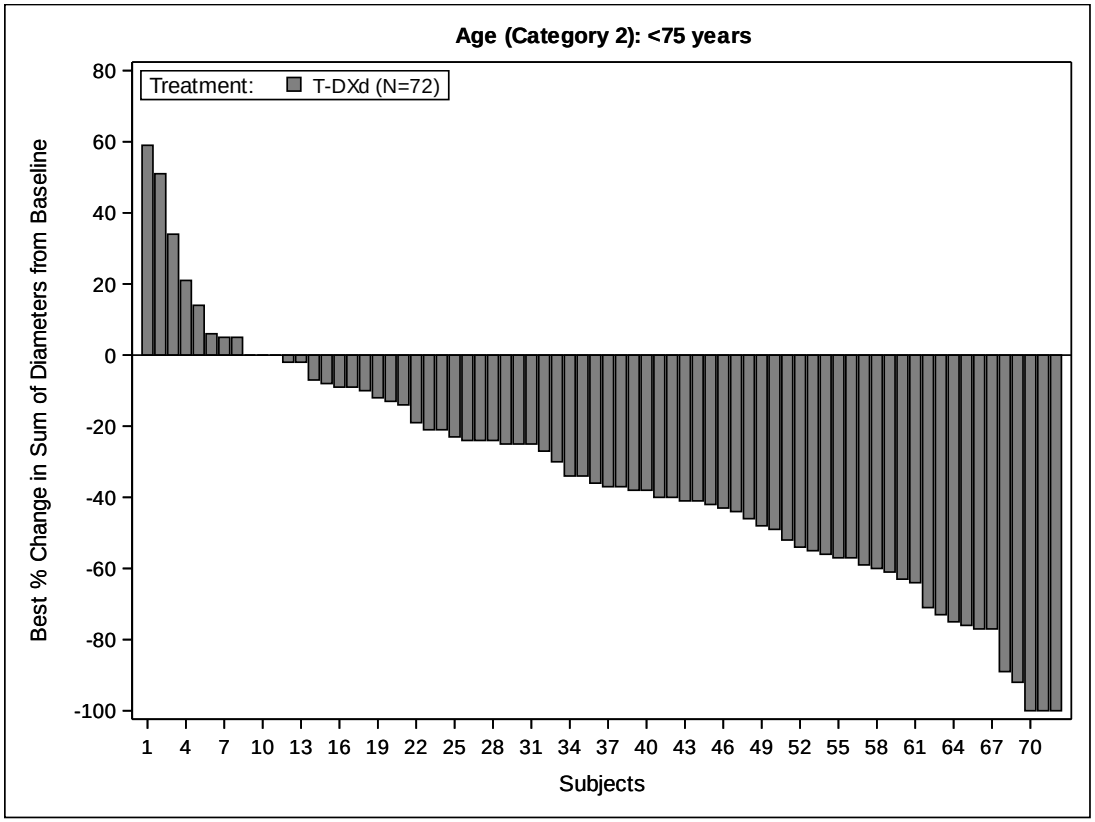
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



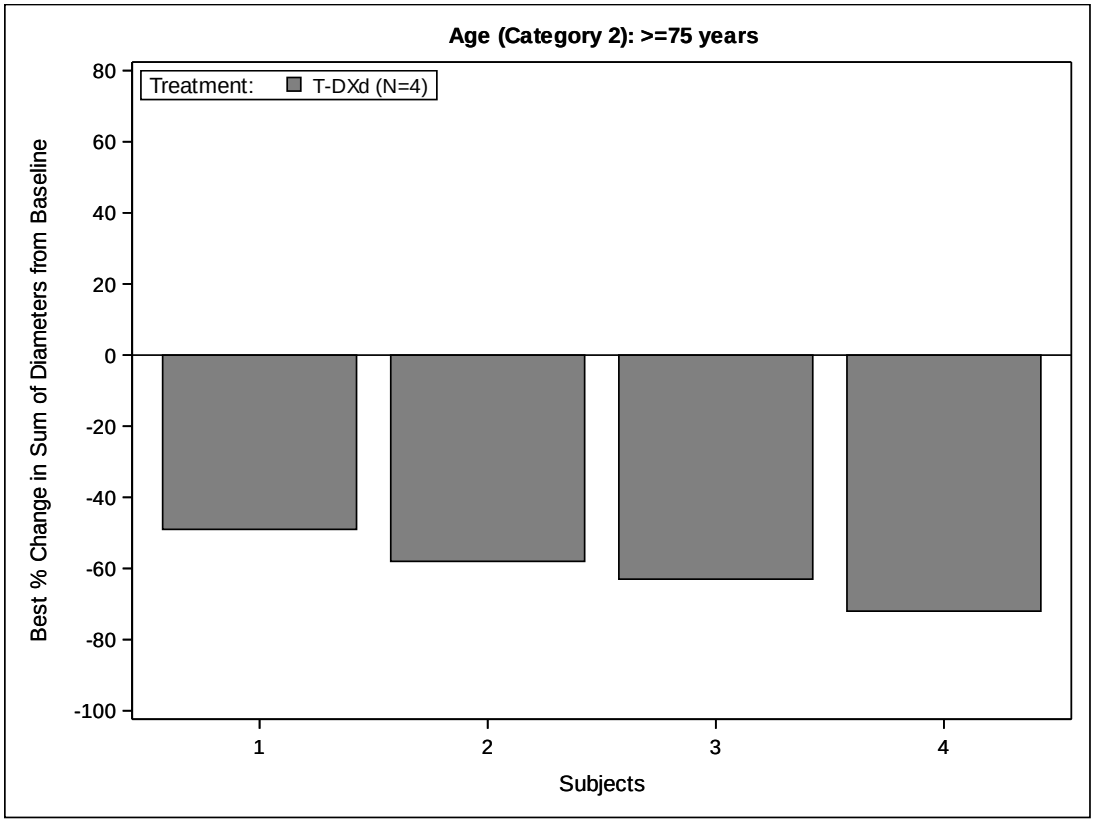
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



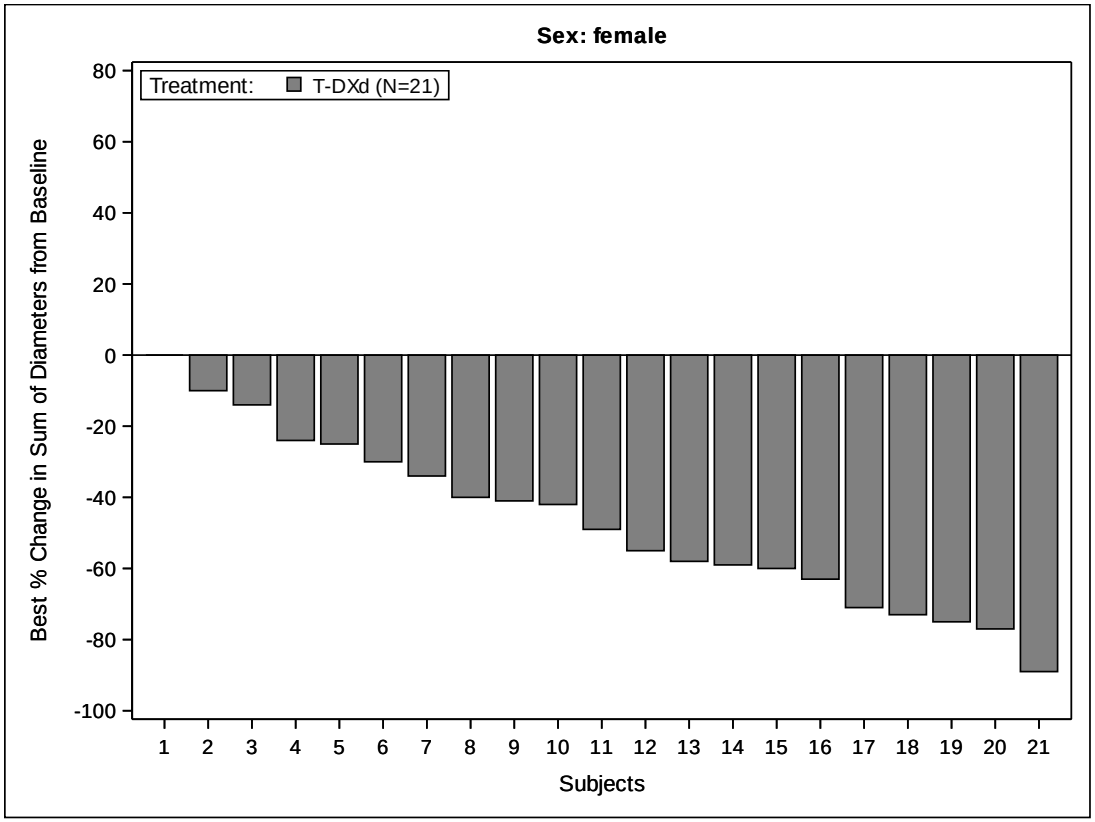
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



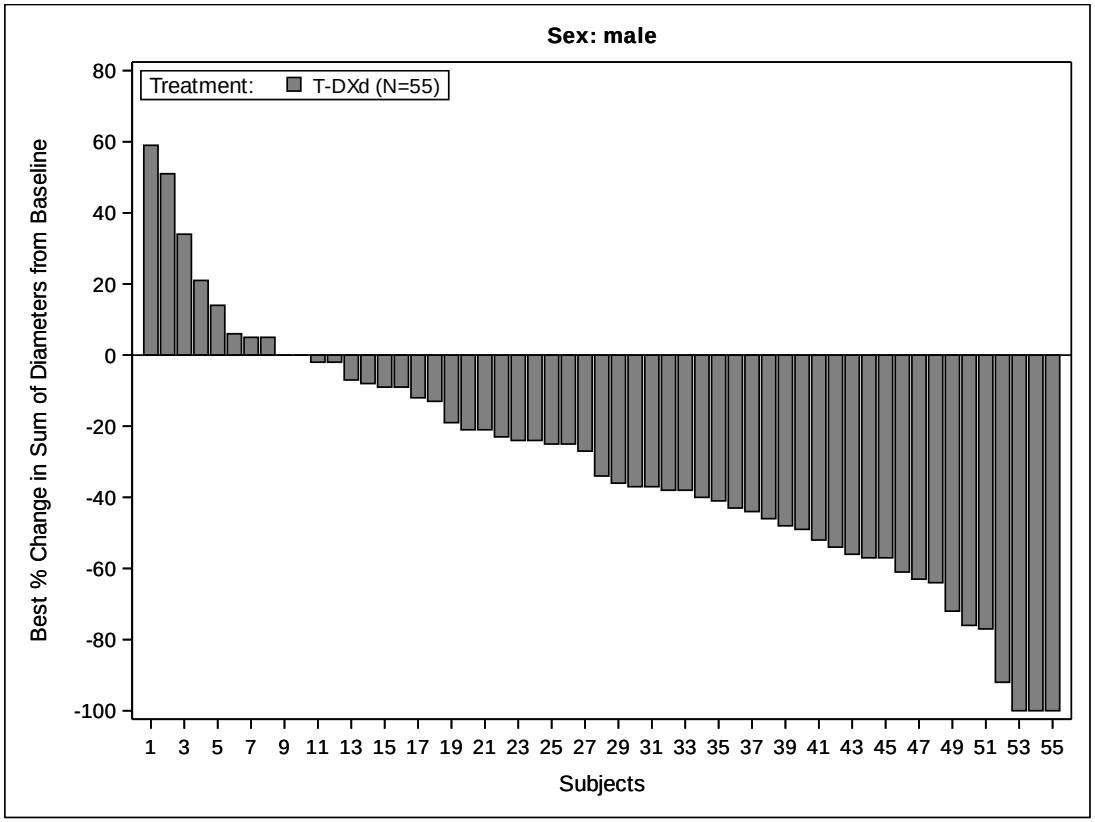
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



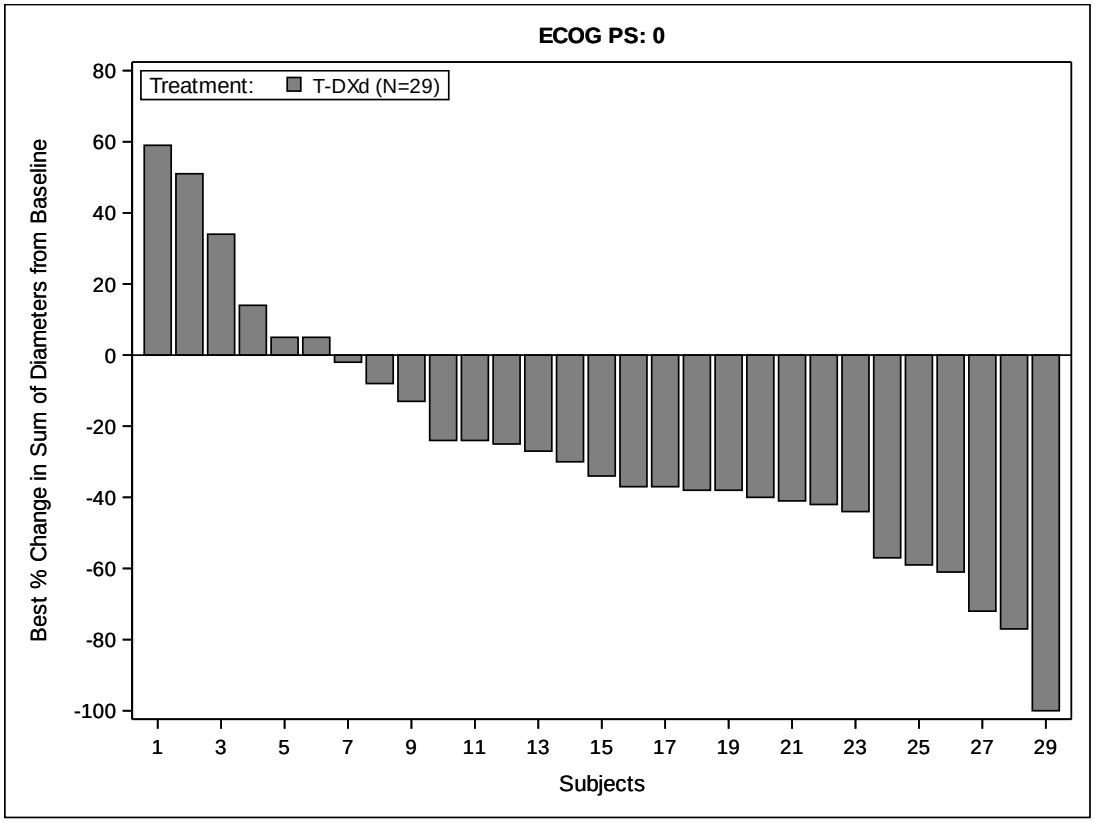
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



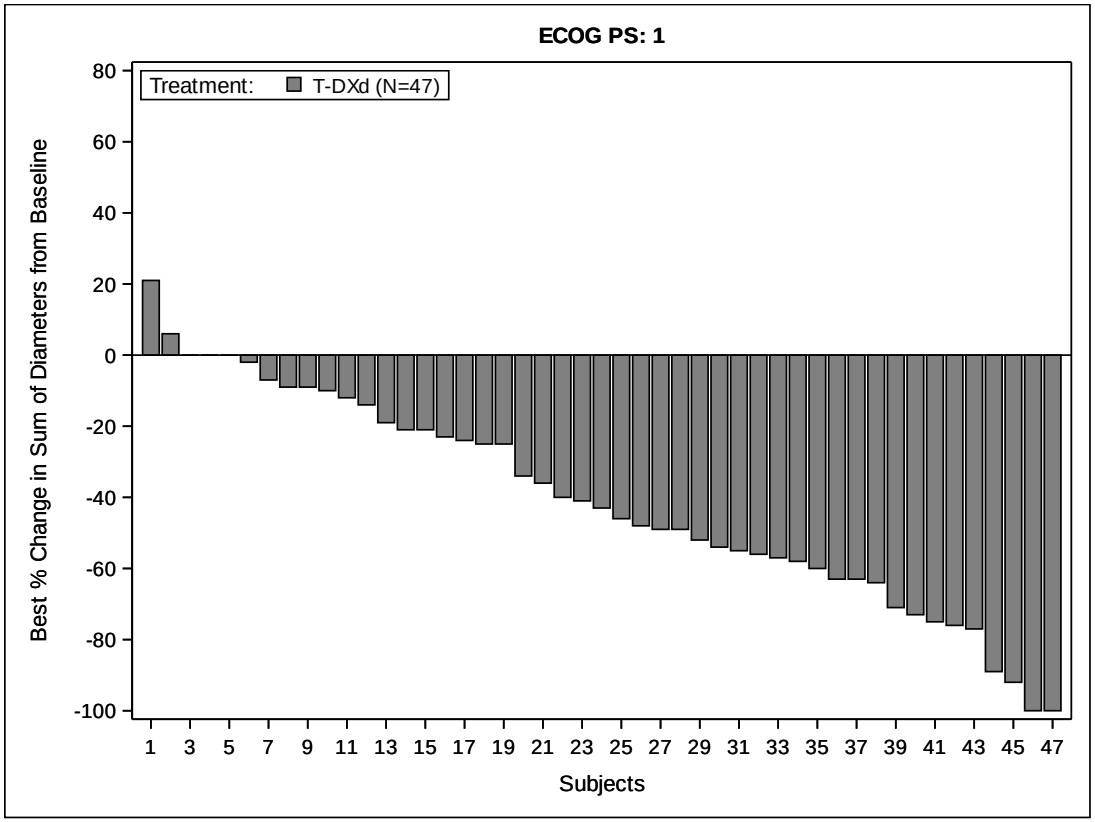
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



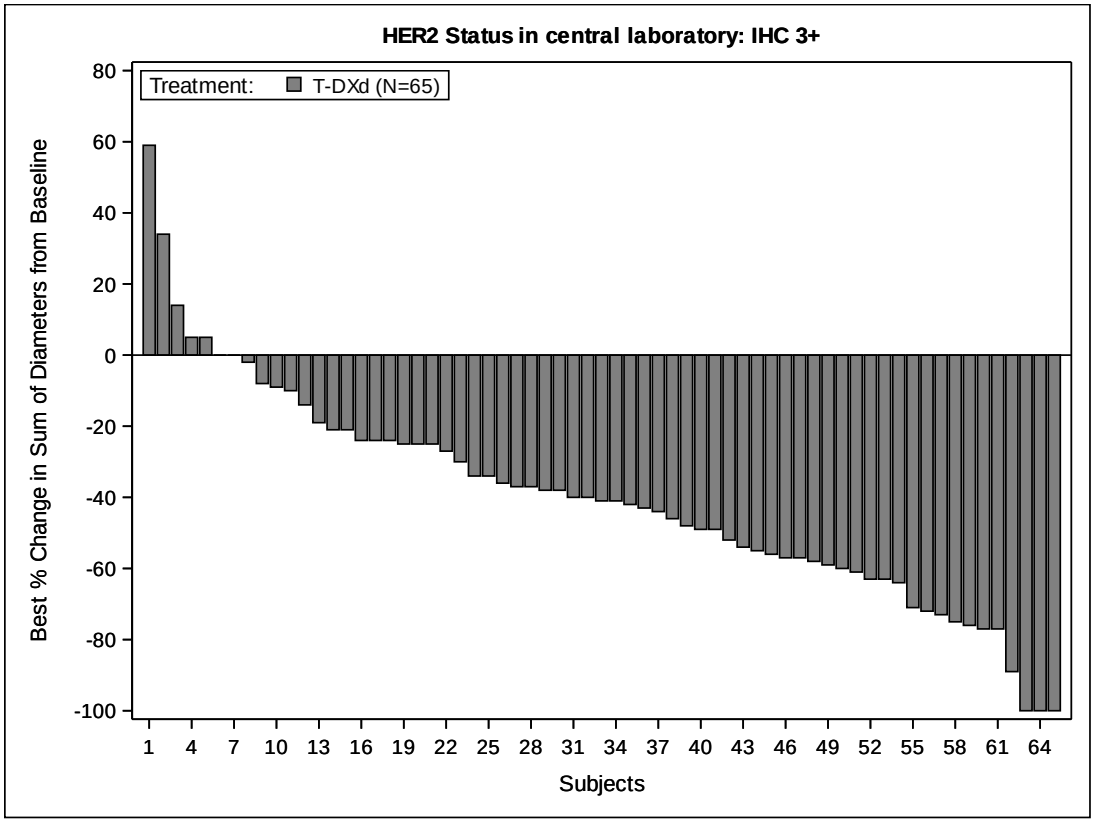
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



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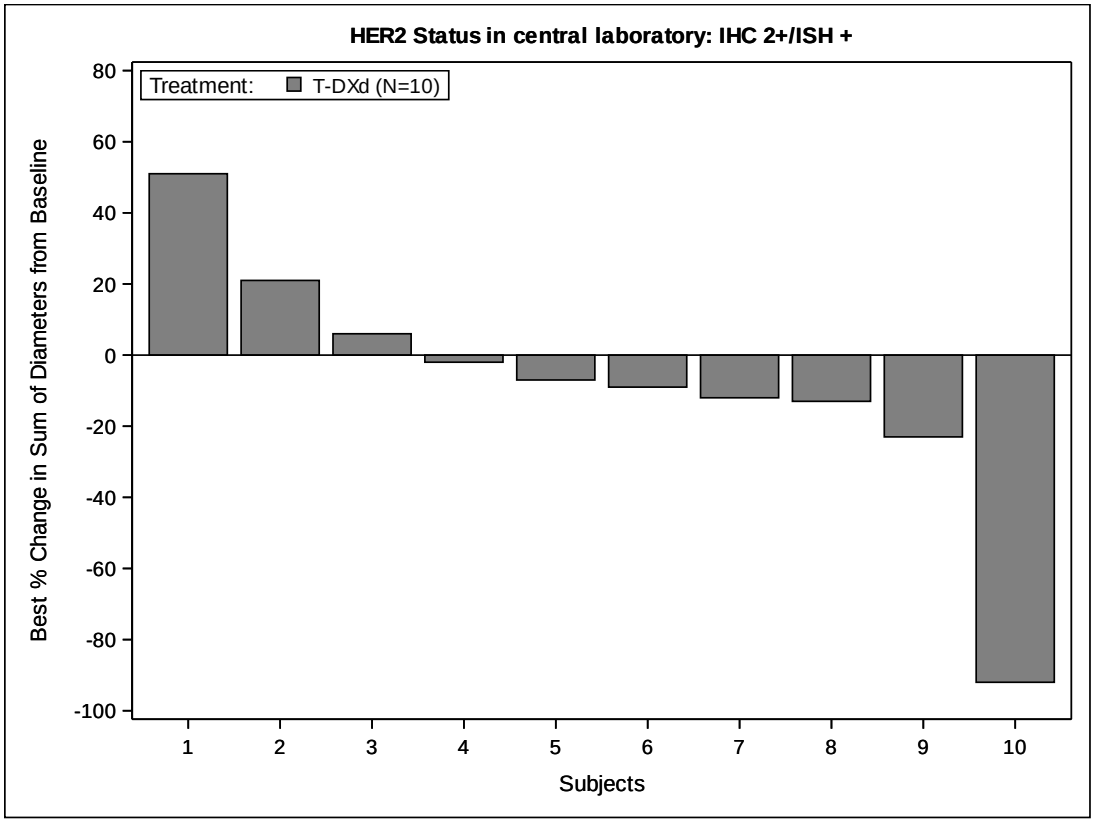
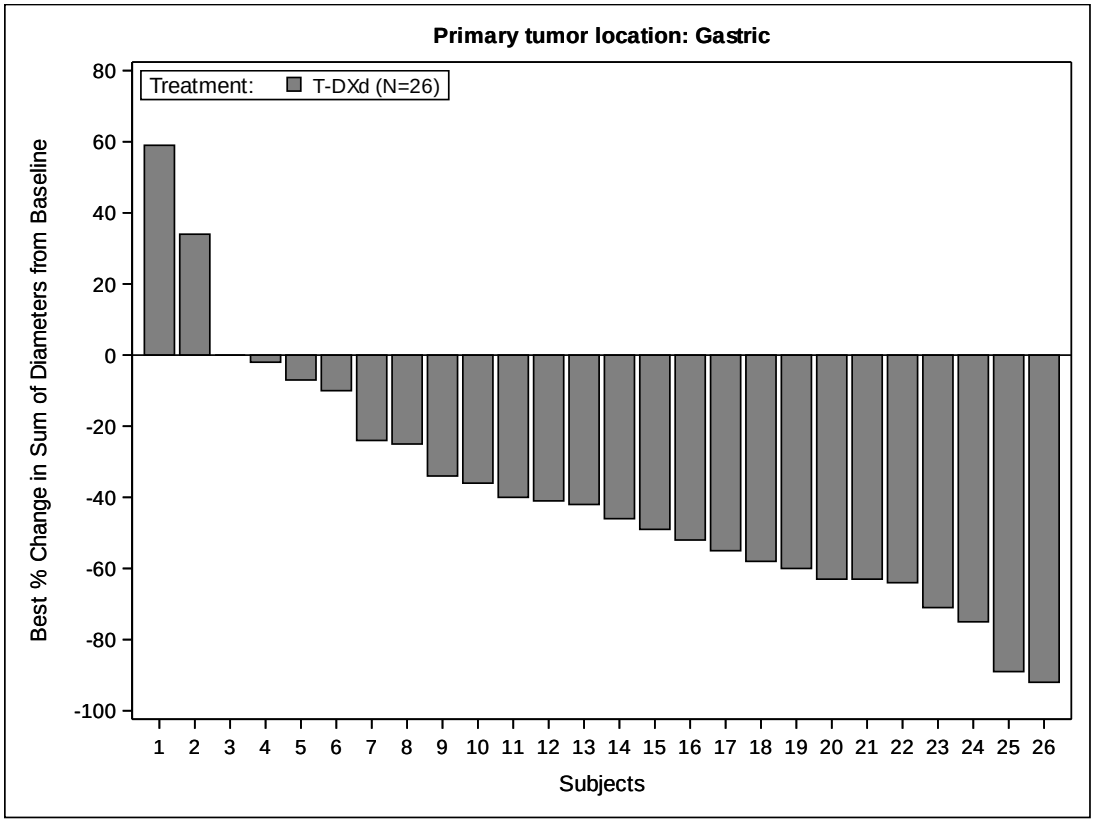
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



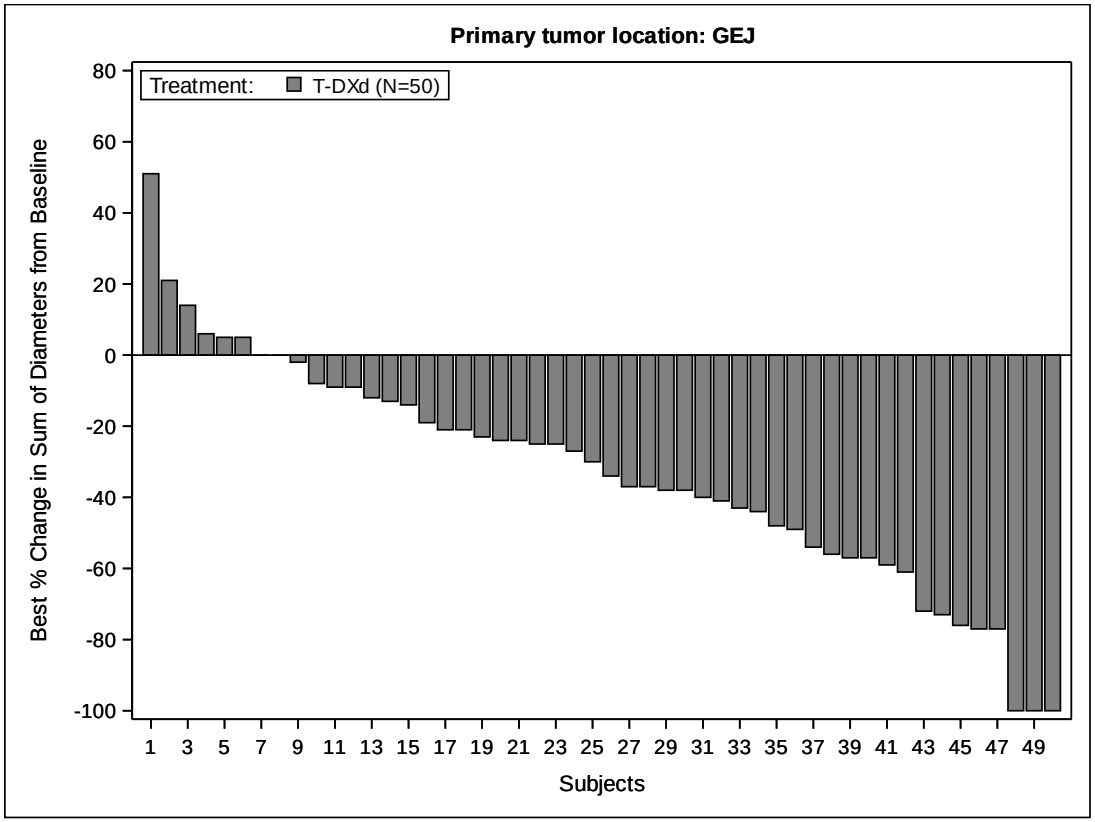
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



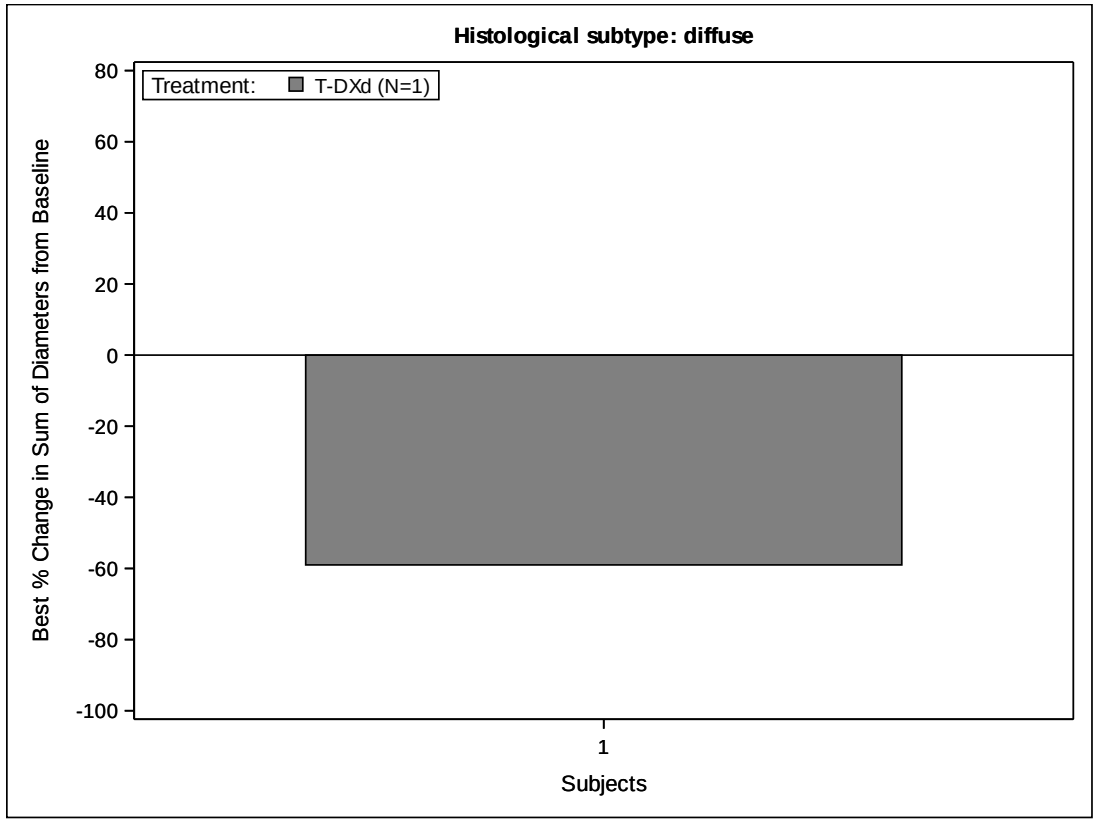
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



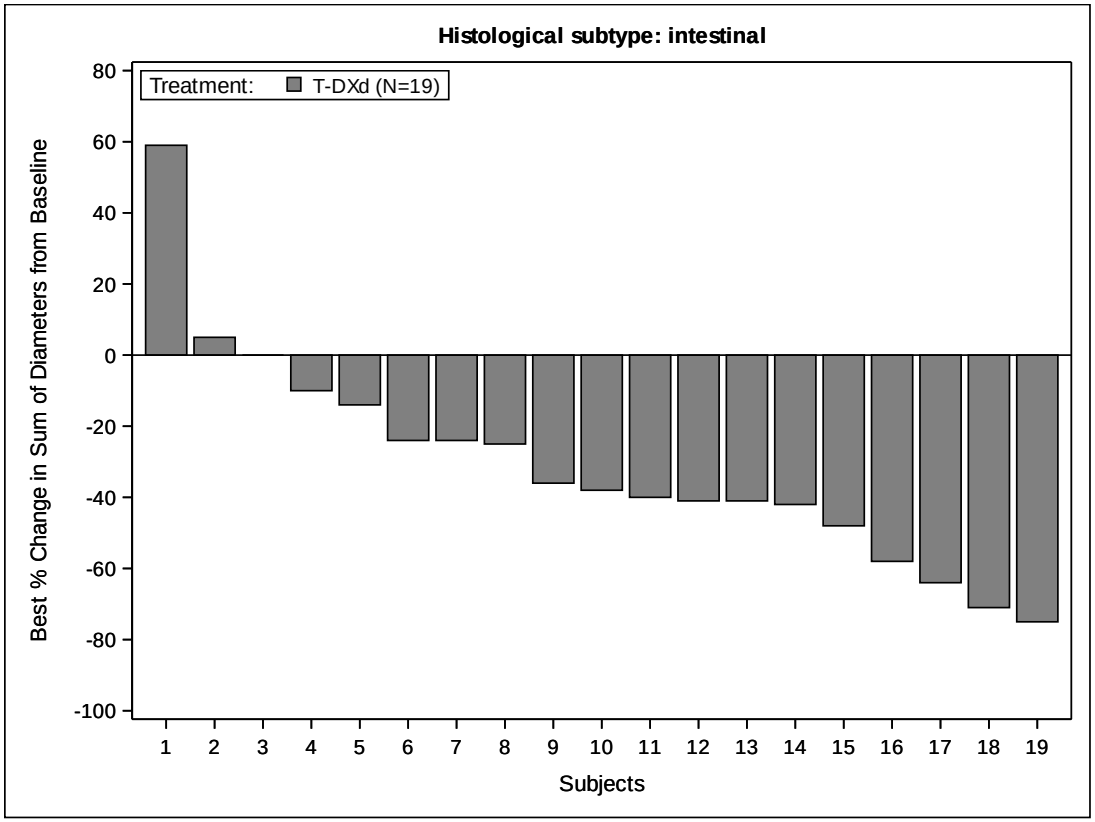
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



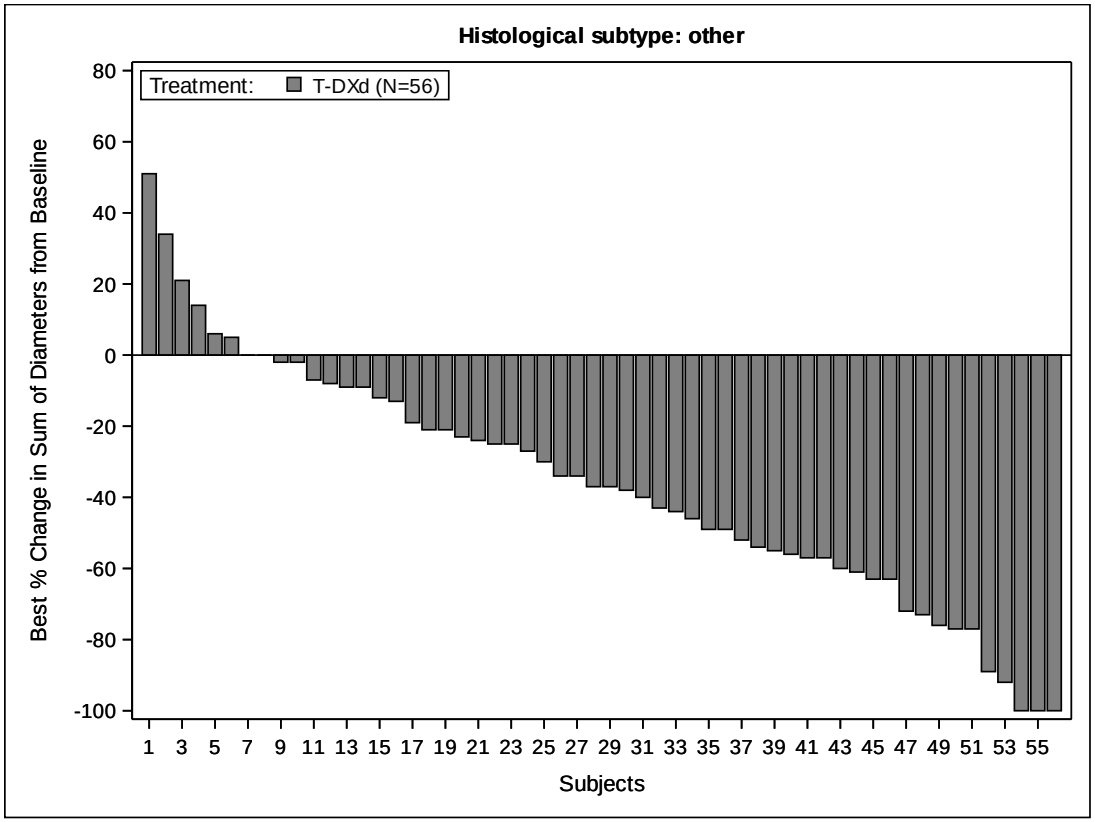
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



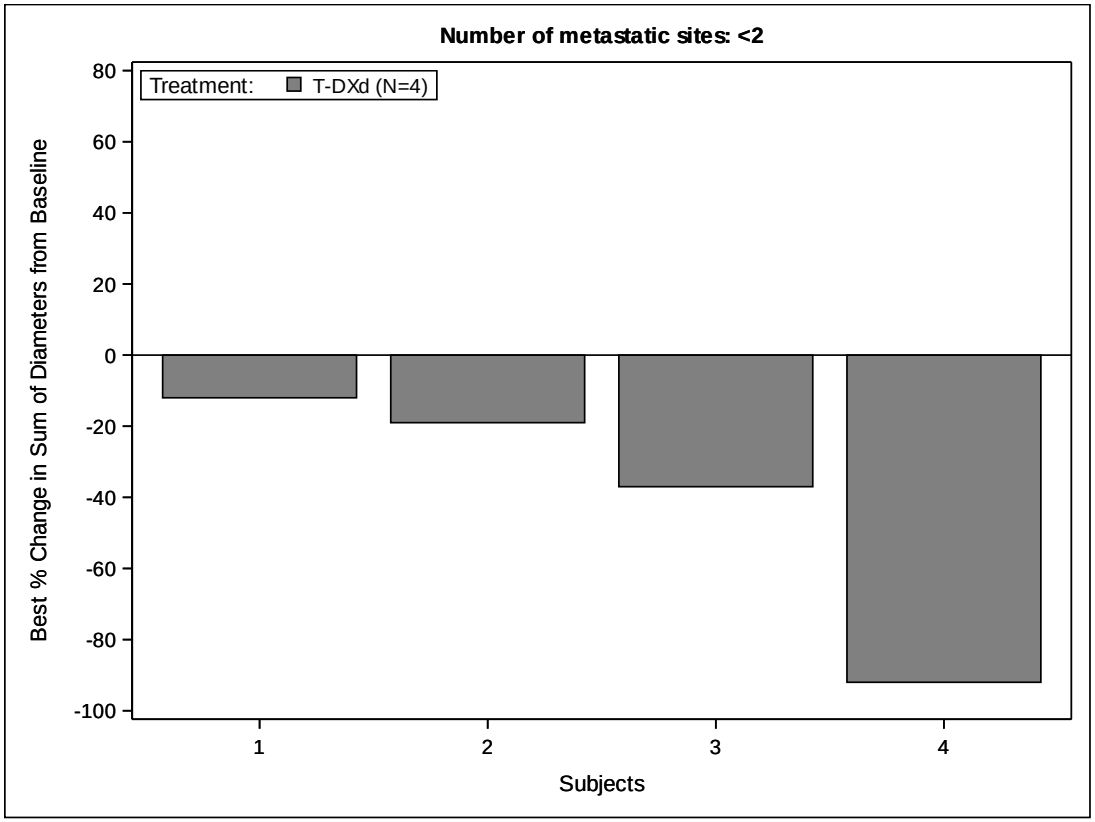
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



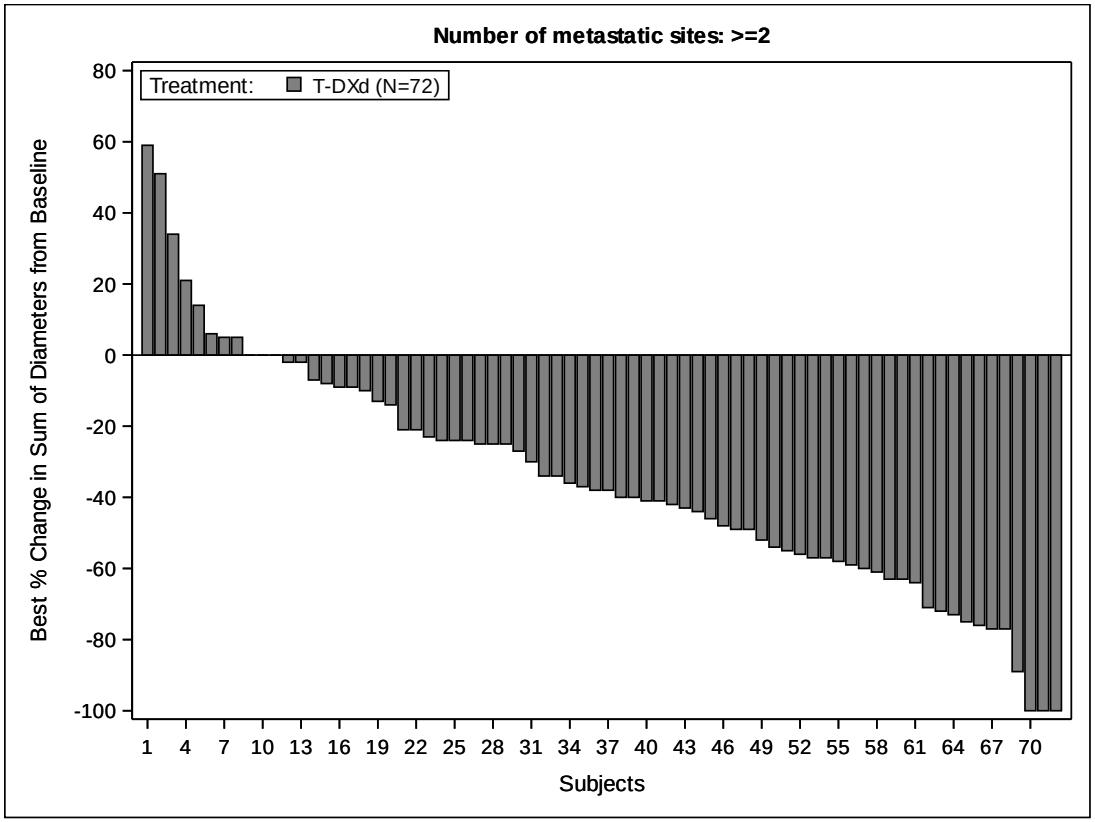
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



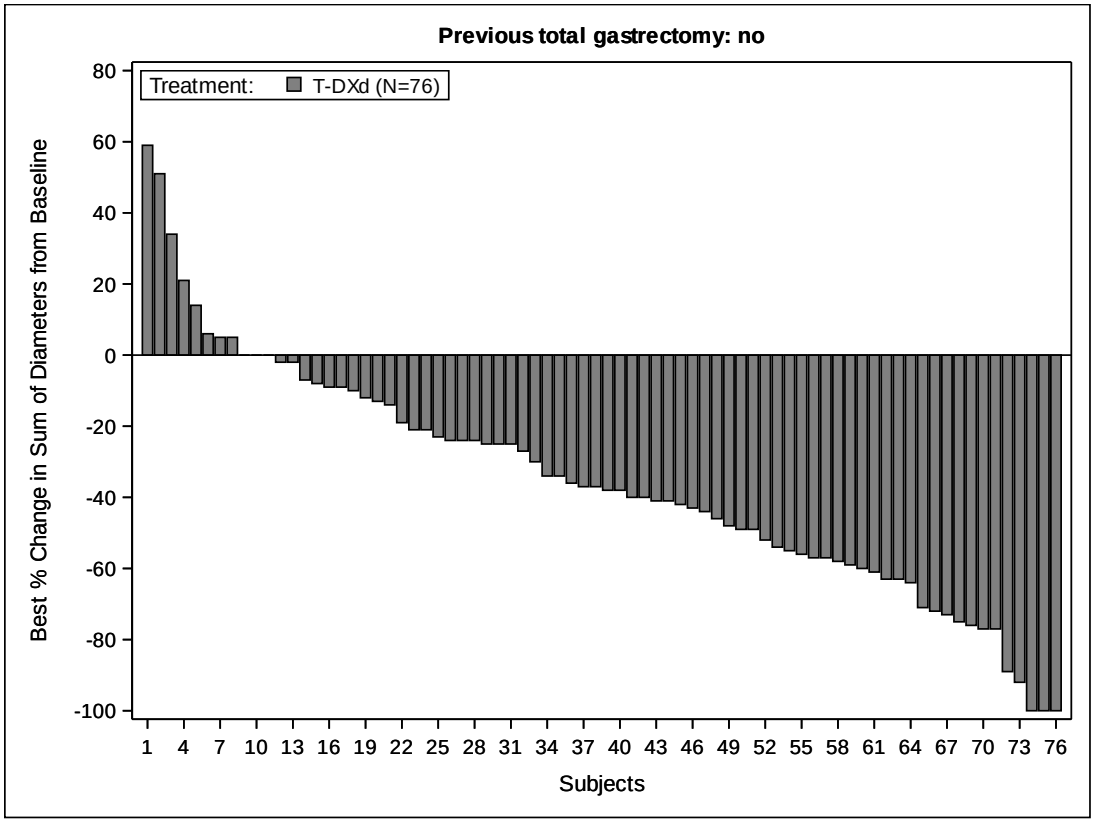
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



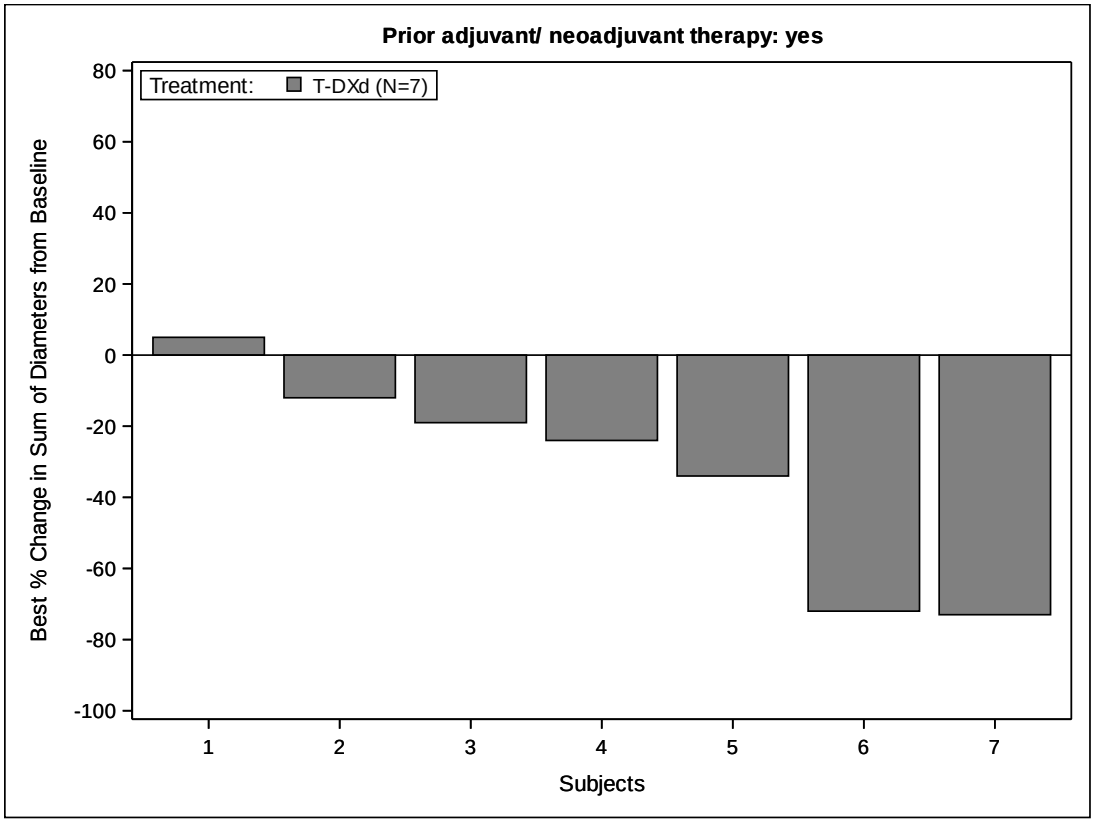
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



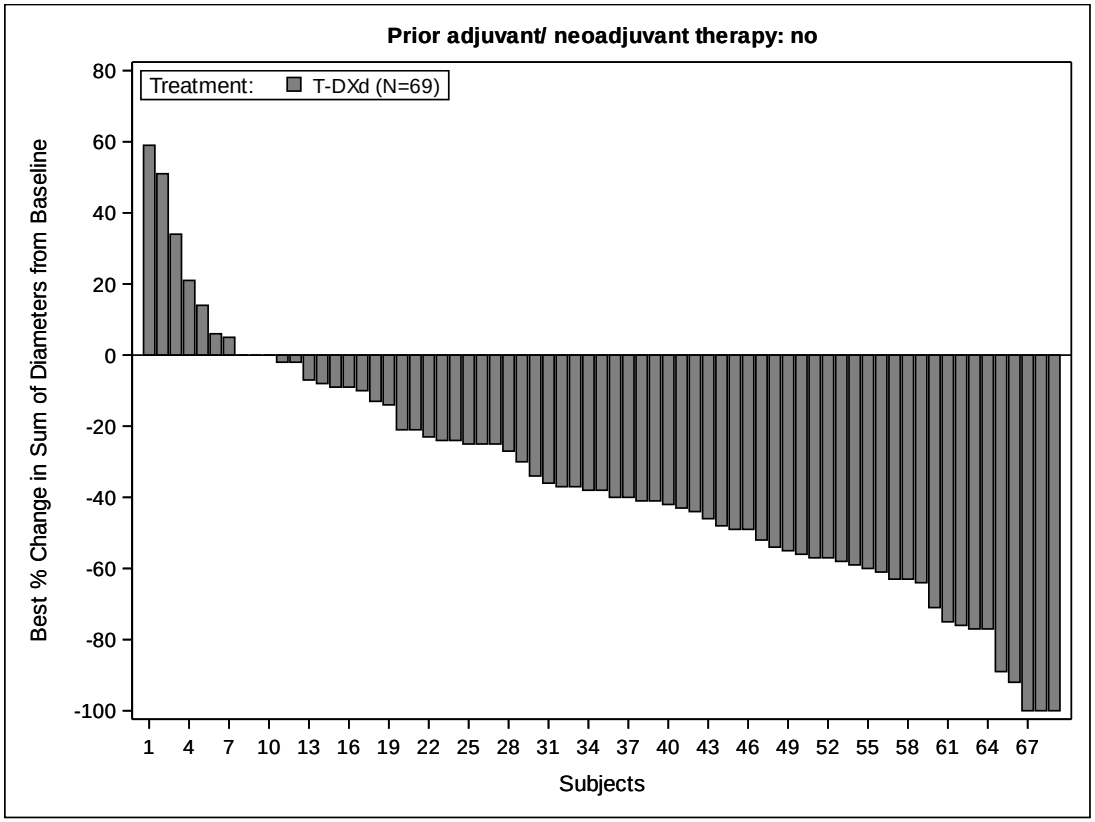
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



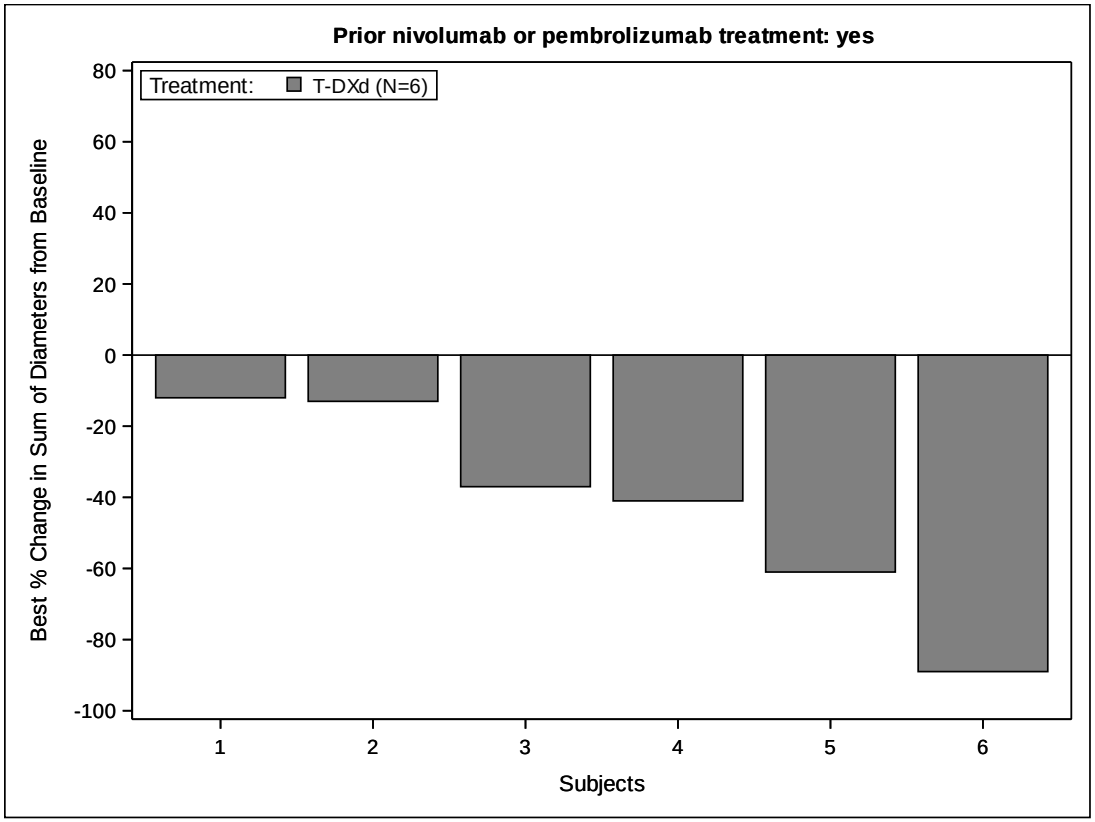
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



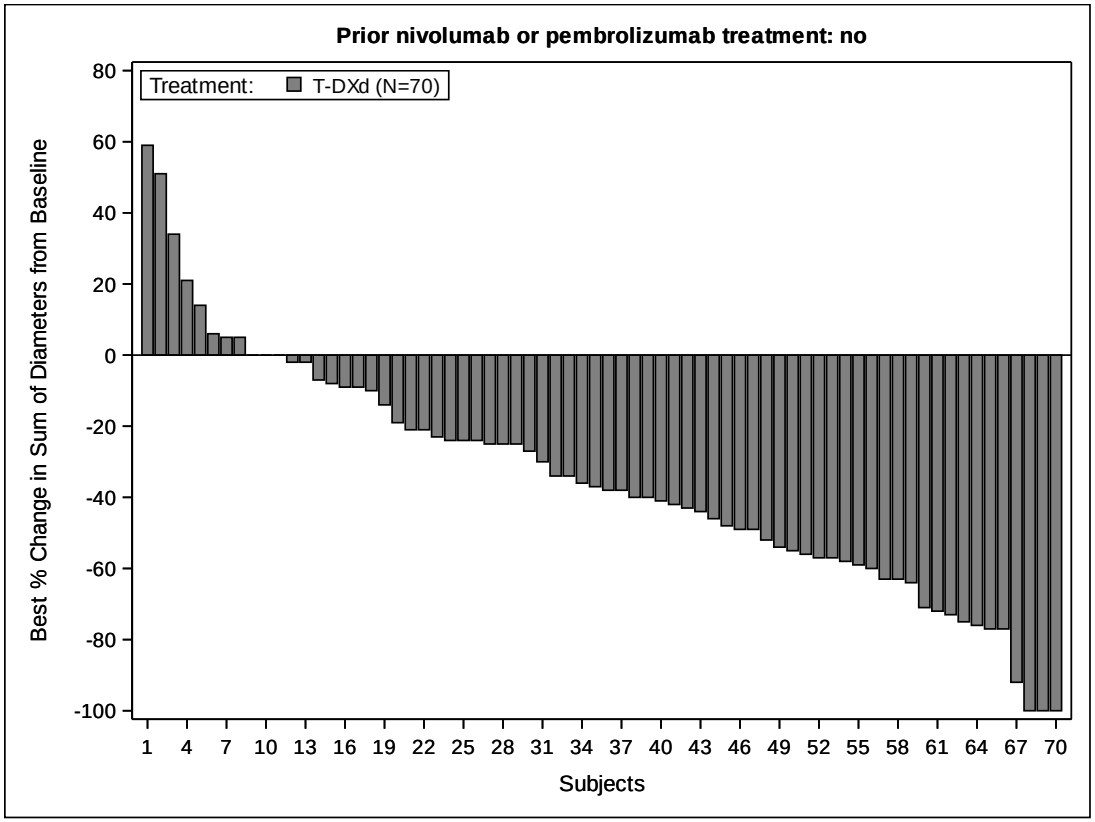
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



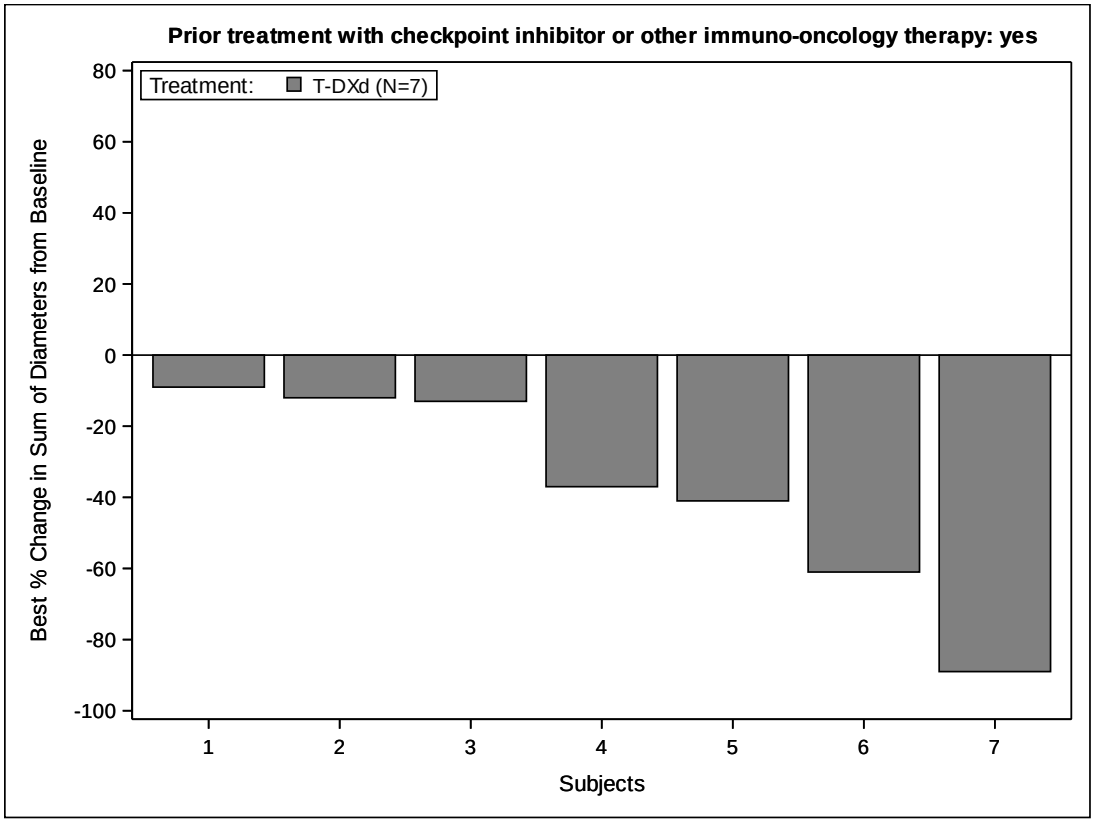
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



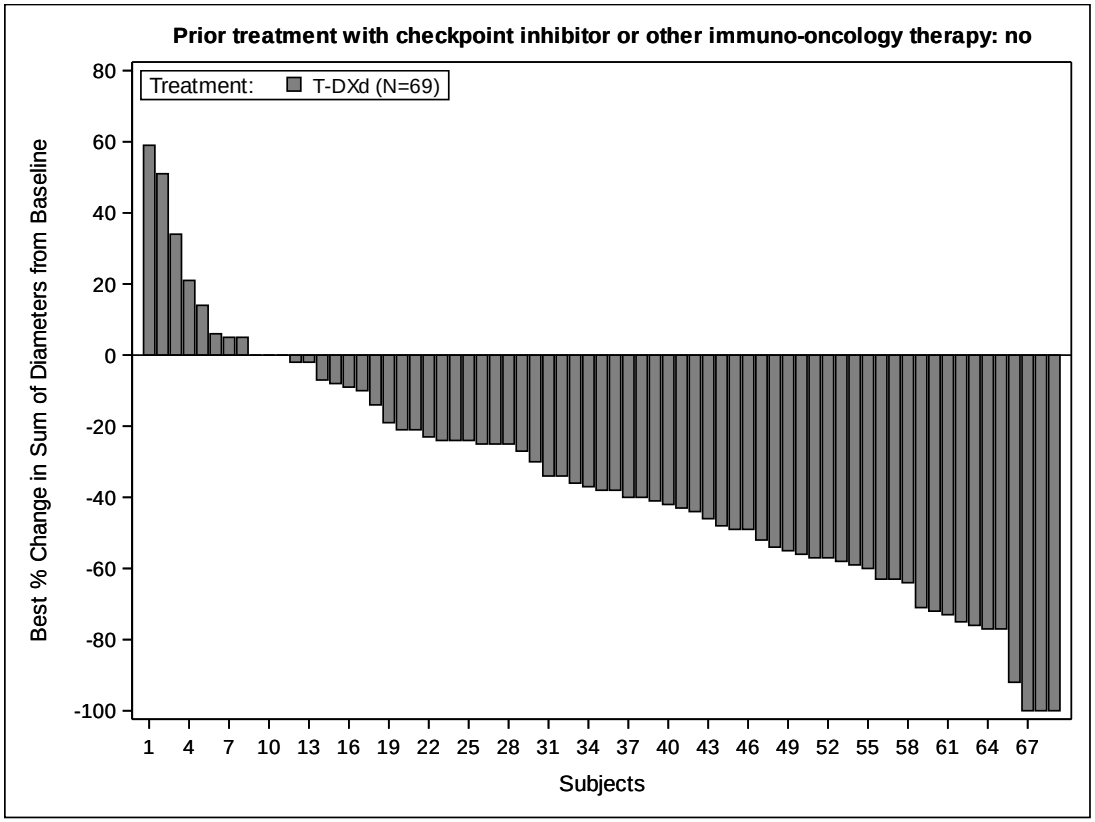
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



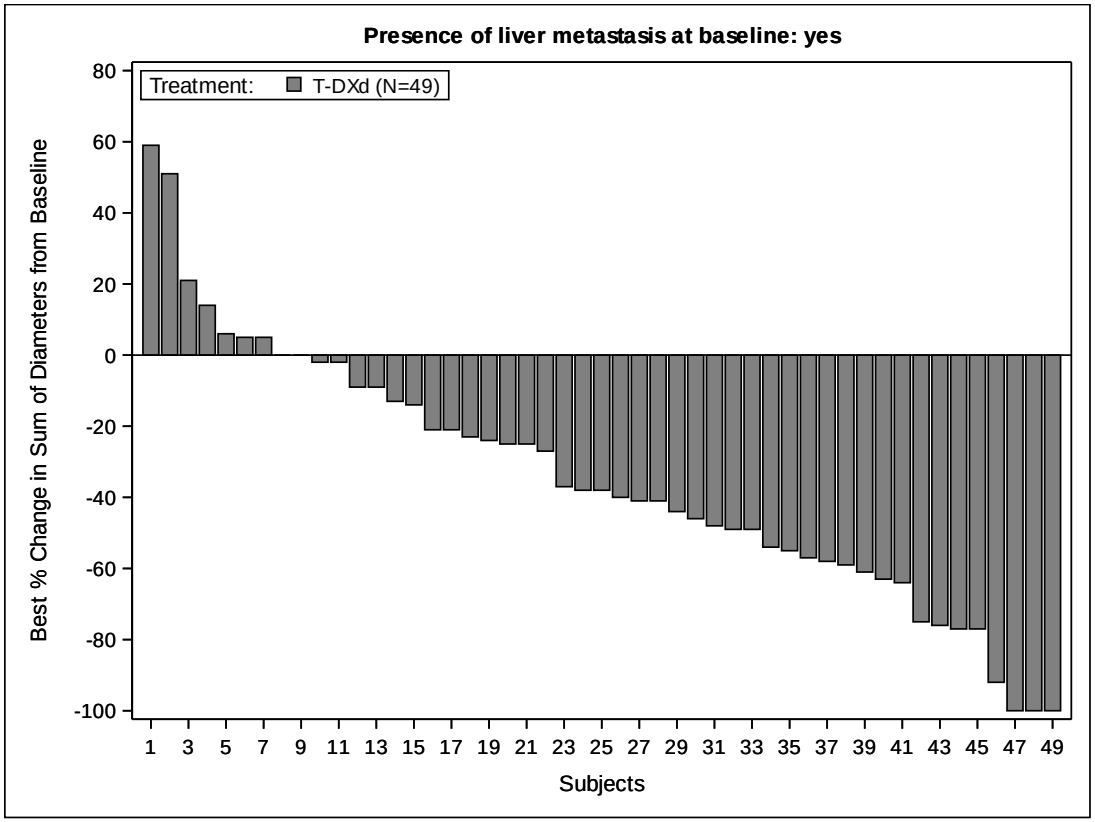
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



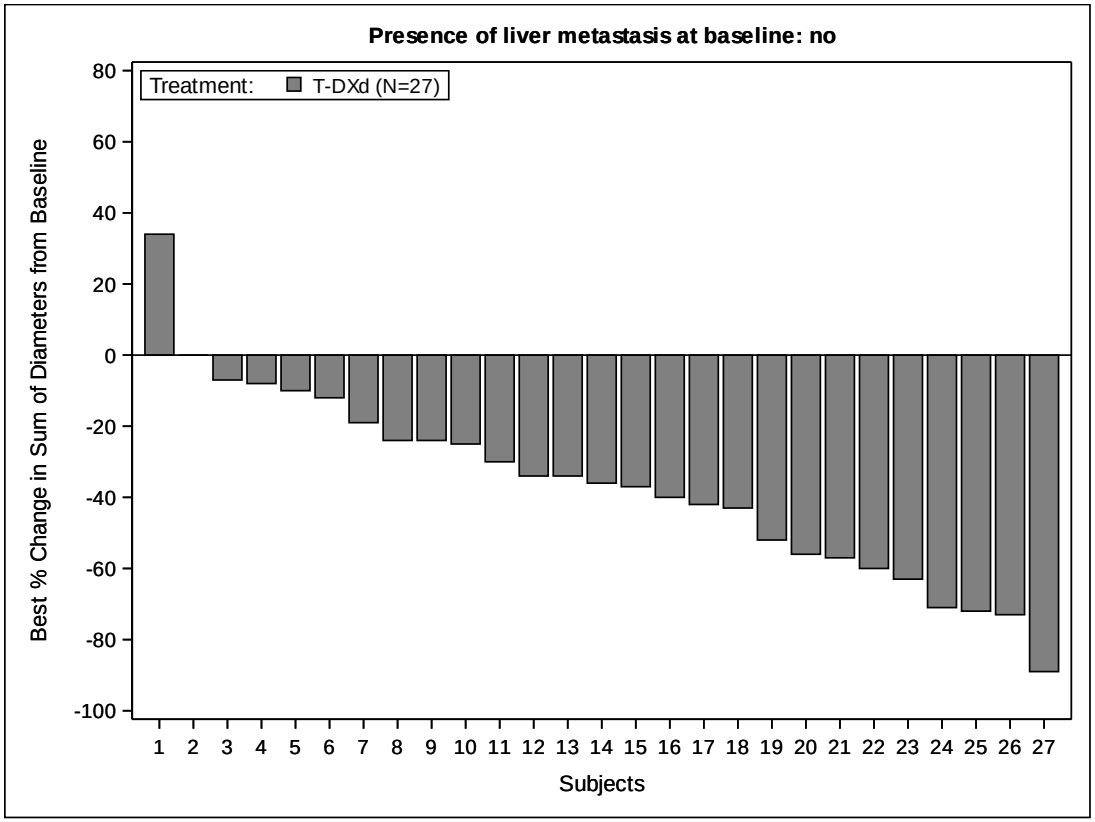
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



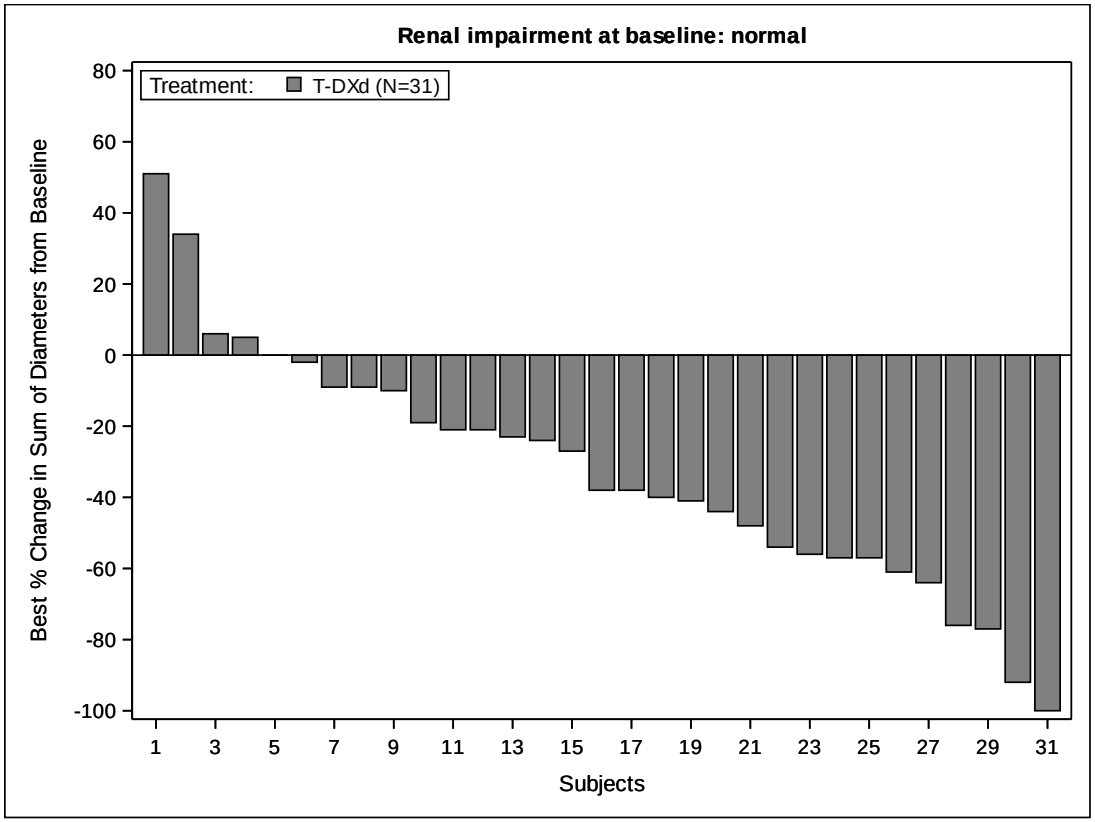
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



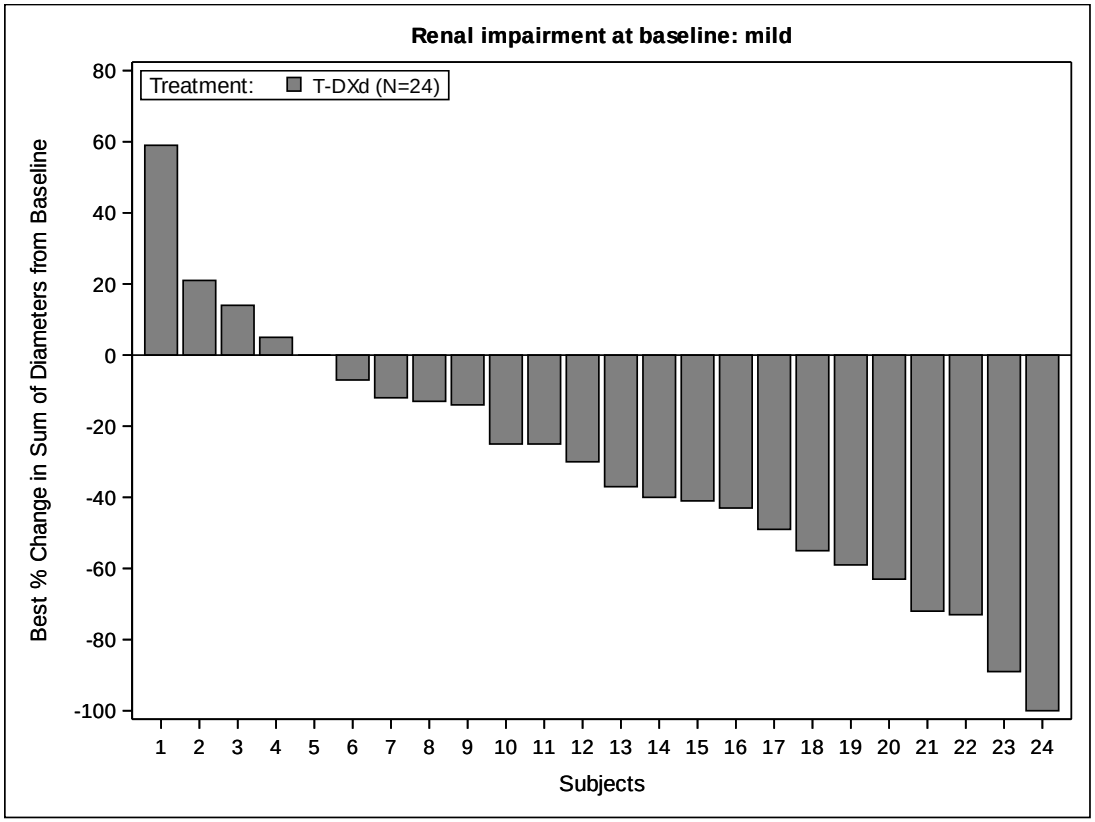
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



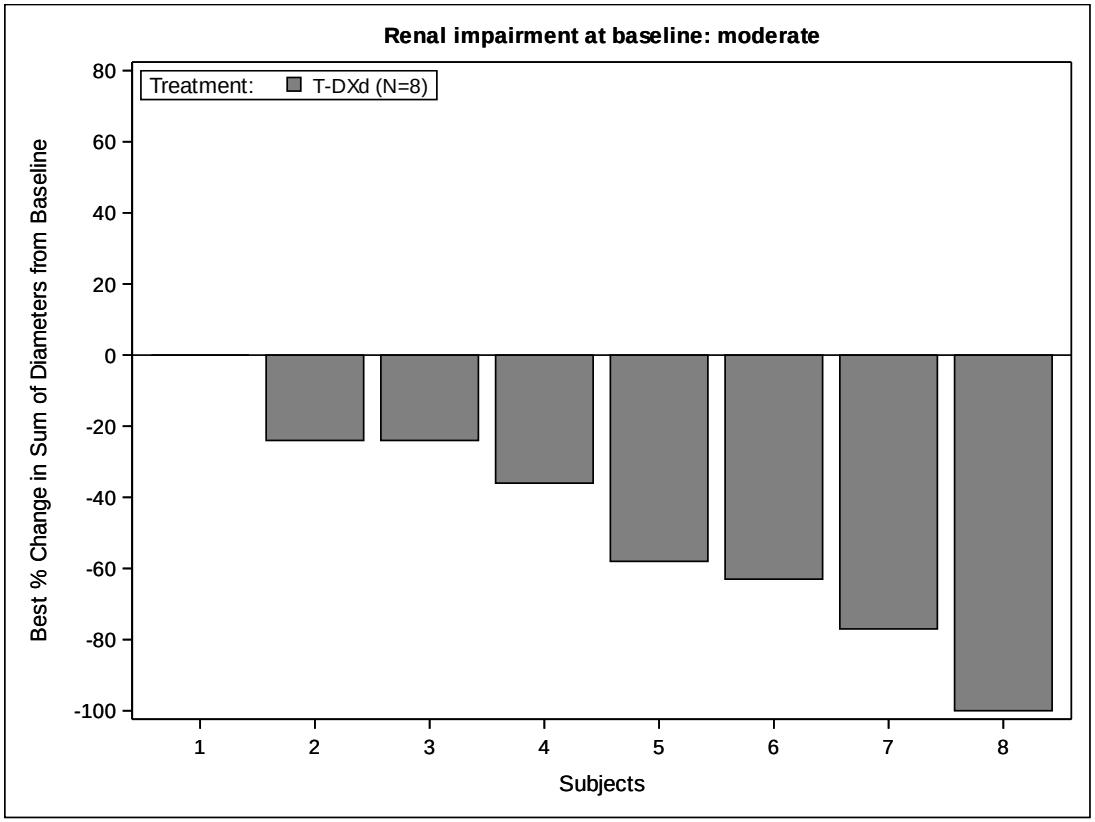
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



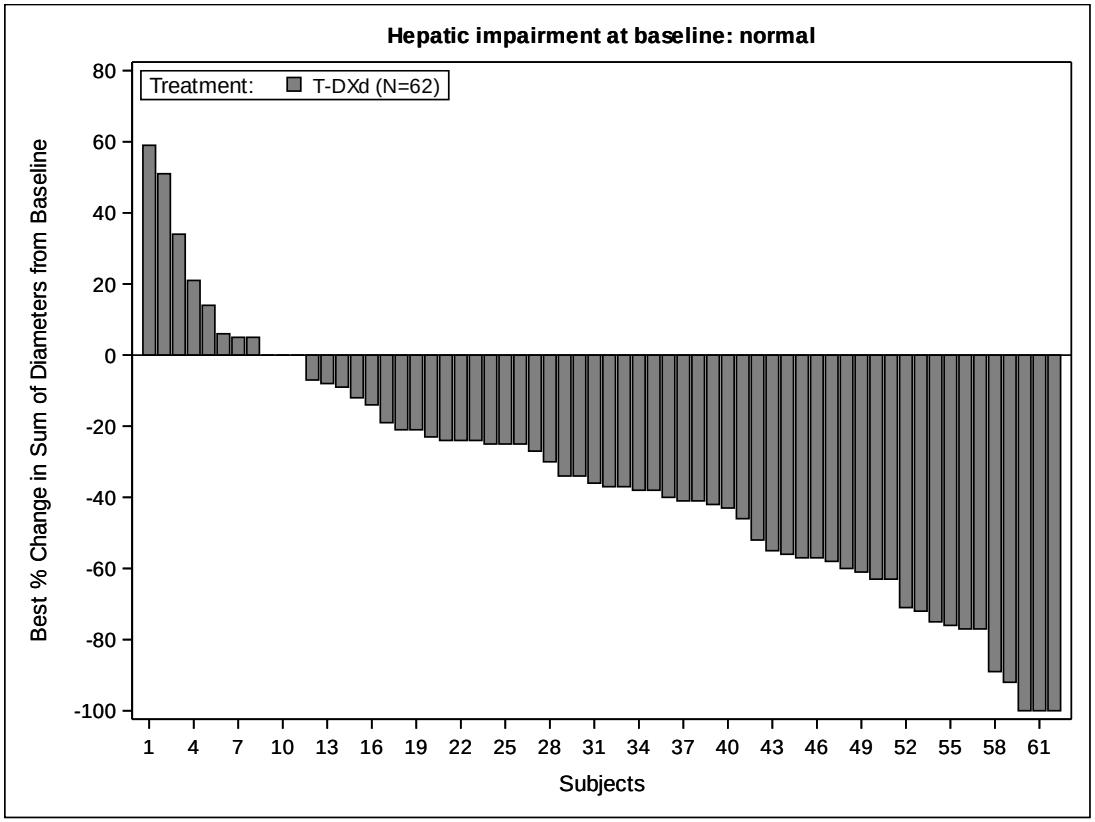
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



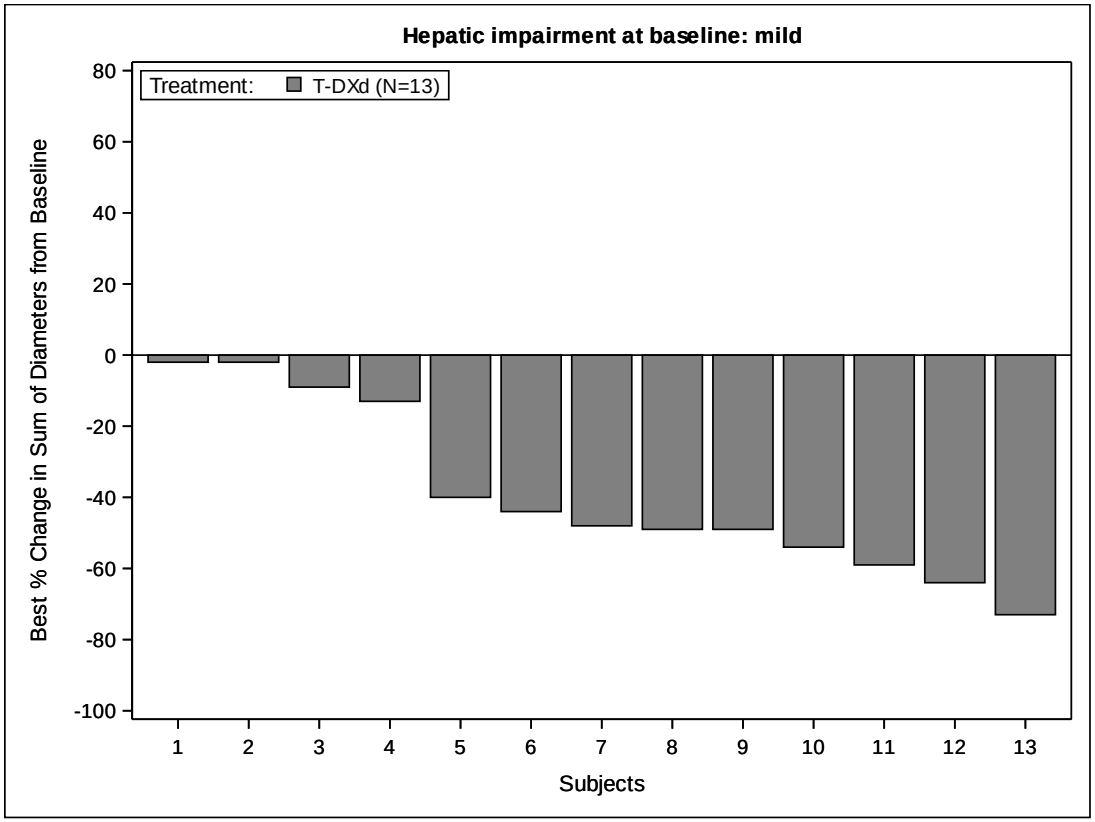
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



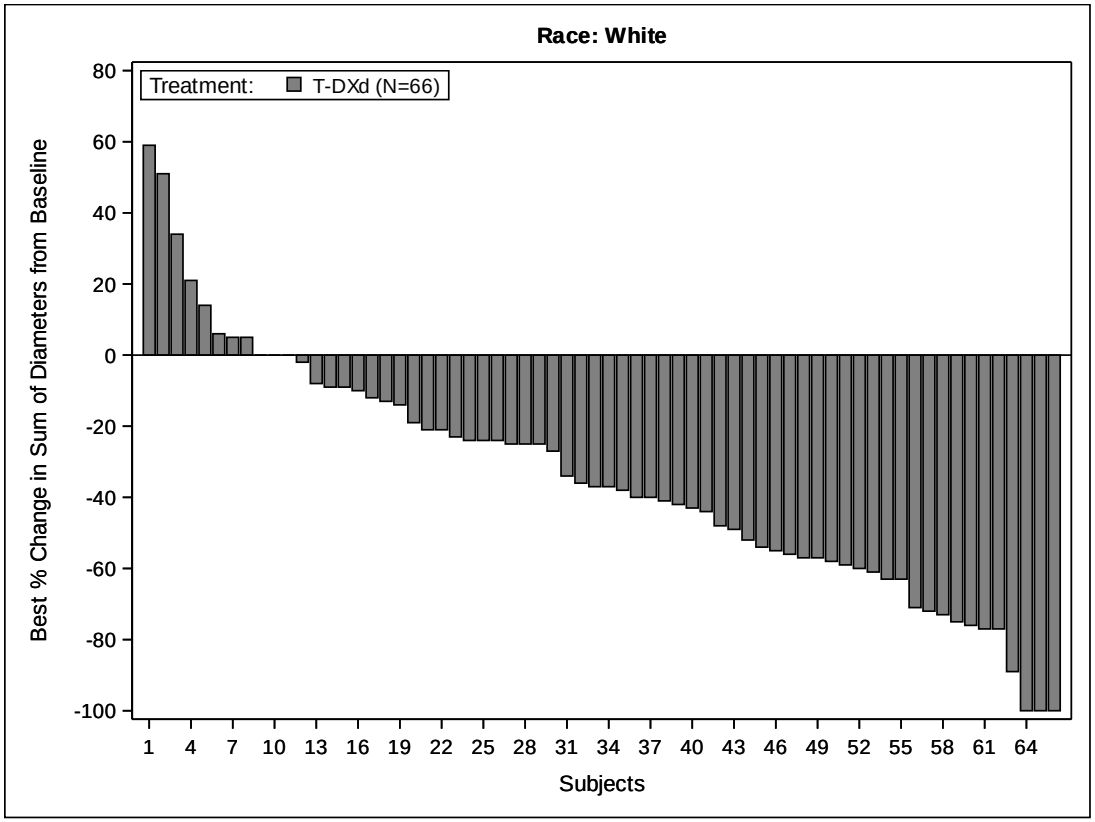
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



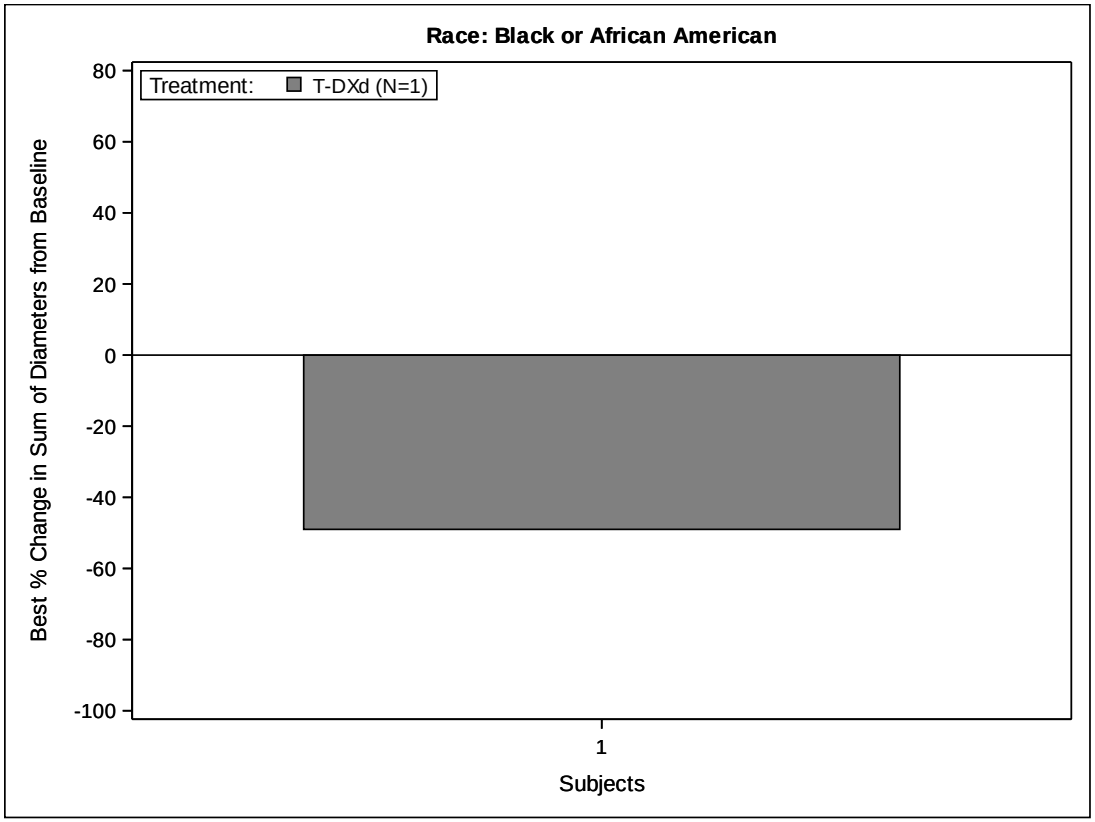
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



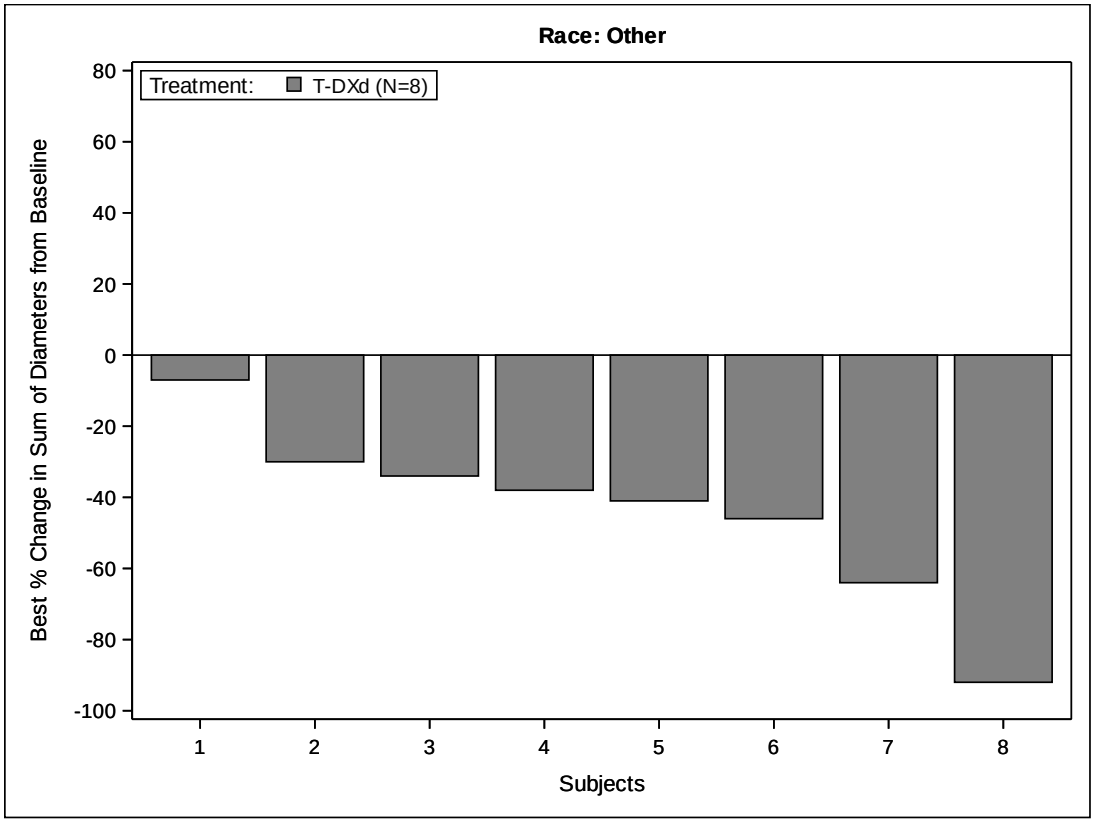
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



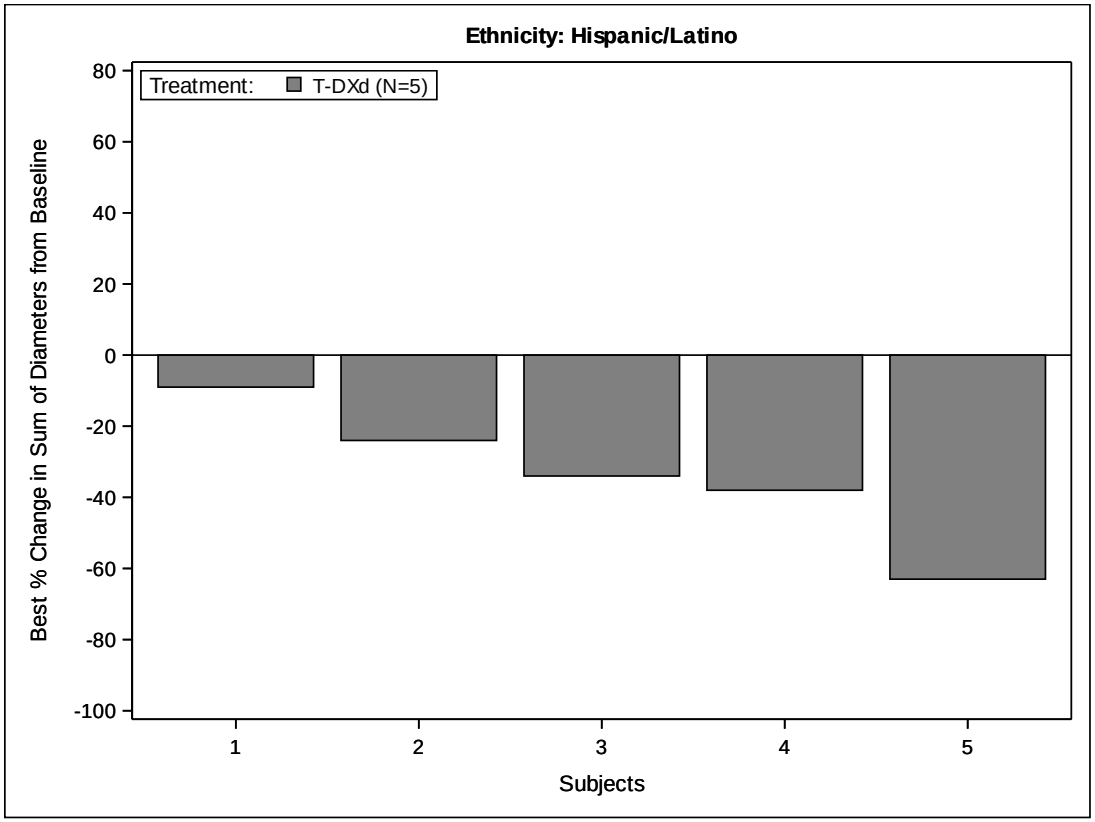
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



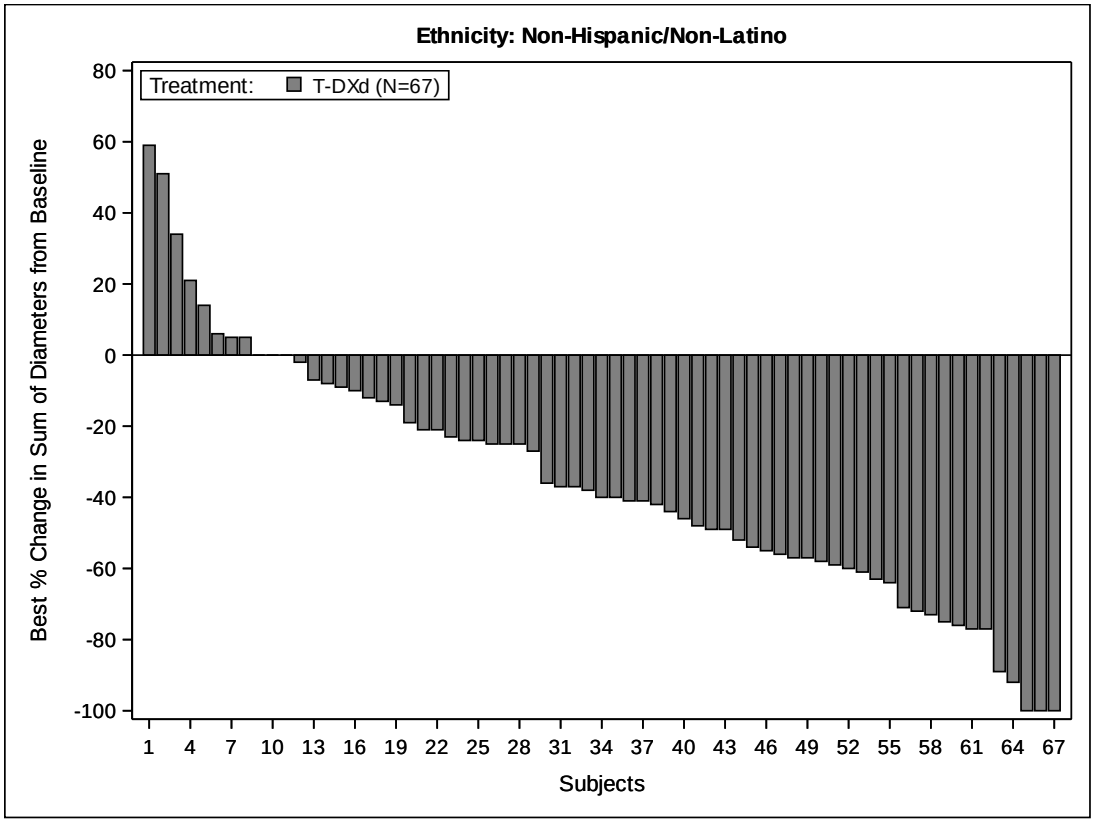
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



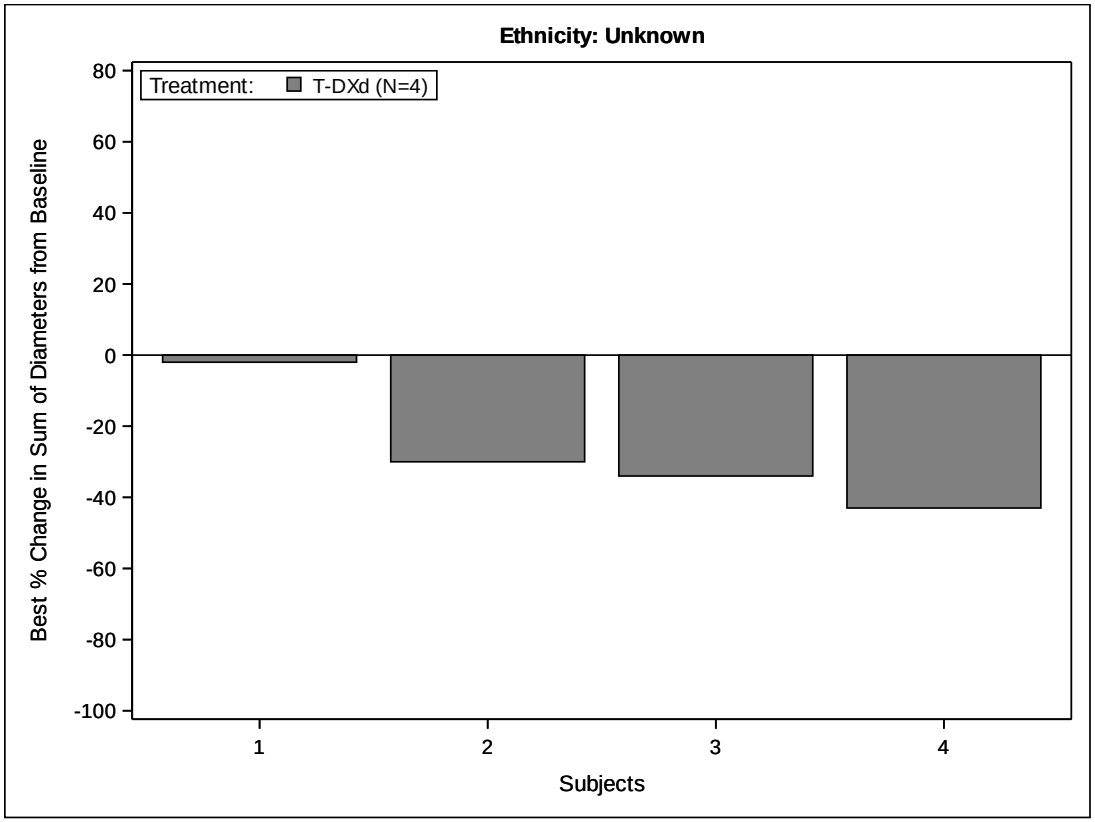
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of EQ-5D VAS score Completion Rates by Visit
Full Analysis Set

	T-DXd (N=79)	
Visit	Number of subjects alive	Completed (%)
Baseline	79	73 (92.4)
Cycle 3 Day 1	78	59 (75.6)
Cycle 5 Day 1	76	41 (53.9)
Cycle 7 Day 1	72	31 (43.1)
Cycle 9 Day 1	60	19 (31.7)
Cycle 11 Day 1	44	13 (29.5)
Cycle 13 Day 1	32	6 (18.8)
Cycle 15 Day 1	21	8 (38.1)
Cycle 17 Day 1	18	4 (22.2)
Cycle 19 Day 1	16	3 (18.8)
Cycle 21 Day 1	11	3 (27.3)
Cycle 23 Day 1	7	1 (14.3)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

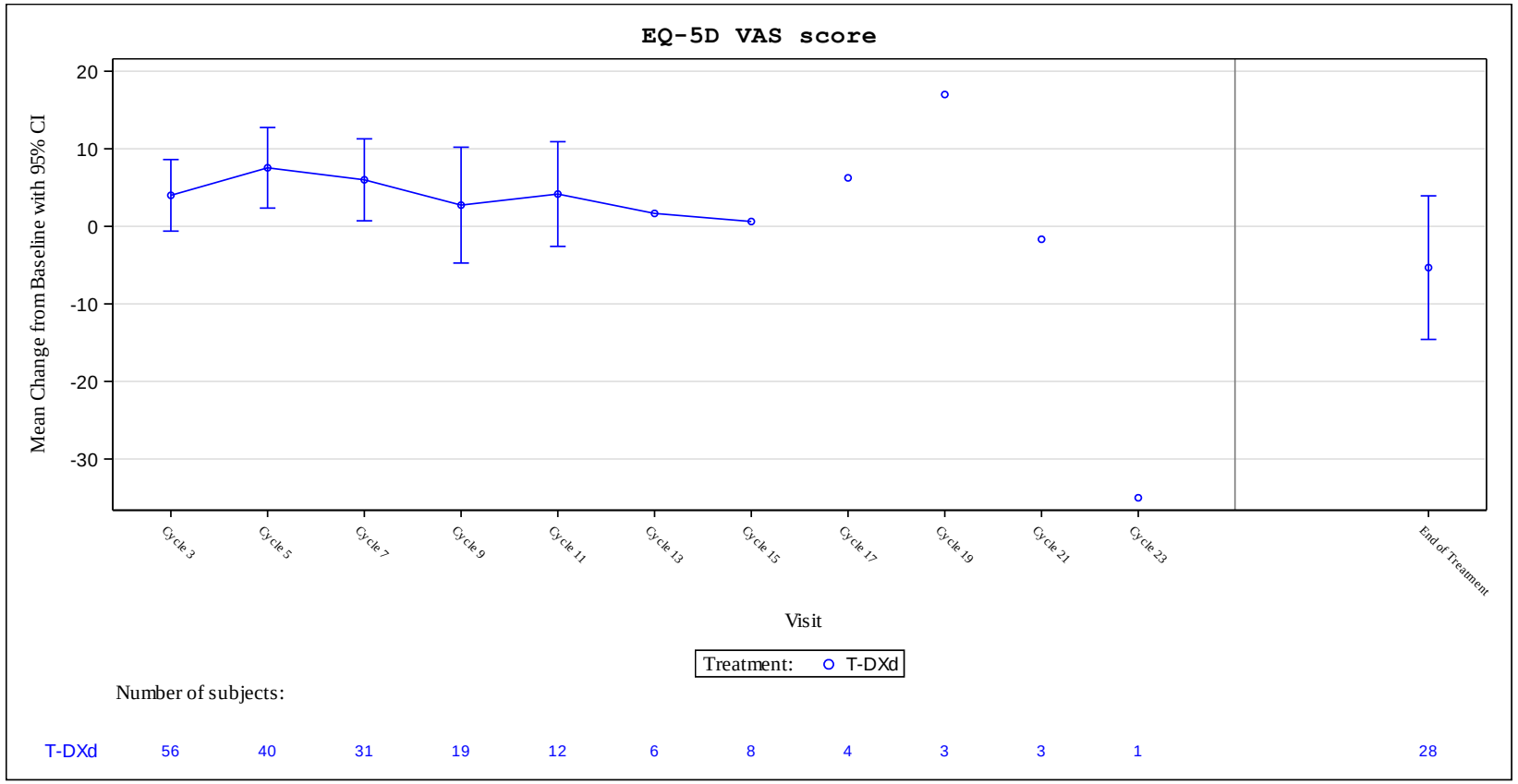
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of EQ-5D VAS score by Visit
Full Analysis Set

	T-DXd (N=79)			
	Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)
Baseline	73	72.0 (19.11)		
Cycle 3 Day 1	59	74.8 (15.64)	56	4.0 (17.23)
Cycle 5 Day 1	41	79.7 (12.68)	40	7.6 (16.24)
Cycle 7 Day 1	31	75.6 (14.63)	31	6.0 (14.41)
Cycle 9 Day 1	19	74.1 (15.56)	19	2.7 (15.49)
Cycle 11 Day 1	13	77.7 (14.81)	12	4.2 (10.62)
Cycle 13 Day 1	6	81.7 (6.83)	6	1.7 (15.06)
Cycle 15 Day 1	8	81.9 (8.84)	8	0.6 (12.94)
Cycle 17 Day 1	4	77.5 (2.89)	4	6.3 (14.36)
Cycle 19 Day 1	3	83.7 (2.31)	3	17.0 (13.11)
Cycle 21 Day 1	3	78.3 (5.77)	3	-1.7 (15.28)
Cycle 23 Day 1	1	55.0 (-)	1	-35.0 (-)
End of Treatment	31	69.0 (24.75)	28	-5.3 (23.87)

Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Graphical Summary of EQ-5D VAS score by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADQS

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	13 (16.5)	66 (83.5)	NE (NE, NE)
Region			
North America	5 (14.7)	29 (85.3)	NE (5.5, NE)
EU	8 (17.8)	37 (82.2)	NE (NE, NE)
Age (Category 1)			
<65 years	6 (13.0)	40 (87.0)	NE (NE, NE)
>=65 years	7 (21.2)	26 (78.8)	NE (4.3, NE)
Age (Category 2)			
<75 years	11 (14.7)	64 (85.3)	NE (NE, NE)
>=75 years	2 (50.0)	2 (50.0)	NE (1.4, NE)
Sex			
female	2 (9.1)	20 (90.9)	NE (NE, NE)
male	11 (19.3)	46 (80.7)	NE (5.5, NE)
ECOG PS			
0	6 (20.7)	23 (79.3)	NE (2.8, NE)
1	7 (14.0)	43 (86.0)	NE (NE, NE)
HER2 Status in central laboratory			
IHC 3+	11 (16.2)	57 (83.8)	NE (NE, NE)
IHC 2+/ISH +	2 (20.0)	8 (80.0)	NE (1.6, NE)
Primary tumor location			
Gastric	4 (14.8)	23 (85.2)	NE (NE, NE)
GEJ	9 (17.3)	43 (82.7)	NE (5.5, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	3 (15.8)	16 (84.2)	NE (4.3, NE)
other	10 (16.9)	49 (83.1)	NE (NE, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	13 (17.6)	61 (82.4)	NE (NE, NE)
Previous total gastrectomy			
no	13 (16.5)	66 (83.5)	NE (NE, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	2 (22.2)	7 (77.8)	NE (1.4, NE)
no	11 (15.7)	59 (84.3)	NE (NE, NE)
Prior nivolumab or pembrolizumab treatment			
yes	0 (0.0)	6 (100.0)	NE (NE, NE)
no	13 (17.8)	60 (82.2)	NE (NE, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	0 (0.0)	7 (100.0)	NE (NE, NE)
no	13 (18.1)	59 (81.9)	NE (NE, NE)

Time to Deterioration of EQ-5D VAS score is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

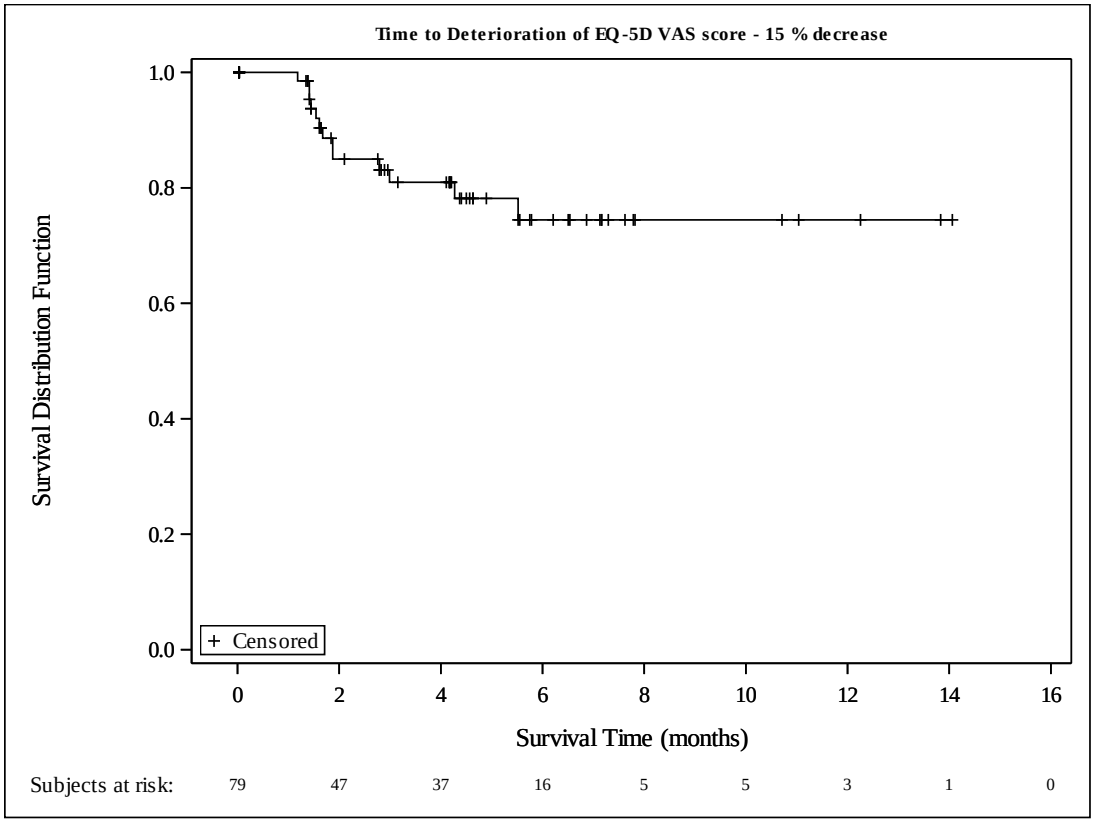
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	8 (16.0)	42 (84.0)	NE (NE, NE)
no	5 (17.2)	24 (82.8)	NE (NE, NE)
Renal impairment at baseline			
normal	4 (12.5)	28 (87.5)	NE (NE, NE)
mild	5 (20.0)	20 (80.0)	NE (2.8, NE)
moderate	2 (25.0)	6 (75.0)	NE (4.3, NE)
Hepatic impairment at baseline			
normal	11 (17.2)	53 (82.8)	NE (NE, NE)
mild	1 (7.1)	13 (92.9)	NE (NE, NE)
Race			
White	11 (15.9)	58 (84.1)	NE (NE, NE)
Black or African American	1 (100.0)	0 (0.0)	1.4 (NE, NE)
Other	1 (12.5)	7 (87.5)	NE (1.6, NE)
Ethnicity			
Hispanic/Latino	0 (0.0)	5 (100.0)	NE (NE, NE)
Non-Hispanic/Non-Latino	13 (18.6)	57 (81.4)	NE (NE, NE)
Unknown	0 (0.0)	4 (100.0)	NE (NE, NE)

Time to Deterioration of EQ-5D VAS score is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	11 (13.9)	68 (86.1)	NE (13.2, NE)
Region			
North America	4 (11.8)	30 (88.2)	NE (13.2, NE)
EU	7 (15.6)	38 (84.4)	NE (NE, NE)
Age (Category 1)			
<65 years	5 (10.9)	41 (89.1)	NE (NE, NE)
>=65 years	6 (18.2)	27 (81.8)	13.2 (4.3, NE)
Age (Category 2)			
<75 years	10 (13.3)	65 (86.7)	NE (13.2, NE)
>=75 years	1 (25.0)	3 (75.0)	NE (1.4, NE)
Sex			
female	1 (4.5)	21 (95.5)	NE (NE, NE)
male	10 (17.5)	47 (82.5)	13.2 (13.2, NE)
ECOG PS			
0	5 (17.2)	24 (82.8)	NE (NE, NE)
1	6 (12.0)	44 (88.0)	NE (13.2, NE)
HER2 Status in central laboratory			
IHC 3+	9 (13.2)	59 (86.8)	NE (13.2, NE)
IHC 2+/ISH +	2 (20.0)	8 (80.0)	NE (1.6, NE)
Primary tumor location			
Gastric	3 (11.1)	24 (88.9)	NE (NE, NE)
GEJ	8 (15.4)	44 (84.6)	13.2 (13.2, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	2 (10.5)	17 (89.5)	NE (4.3, NE)
other	9 (15.3)	50 (84.7)	NE (13.2, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	11 (14.9)	63 (85.1)	NE (13.2, NE)
Previous total gastrectomy			
no	11 (13.9)	68 (86.1)	NE (13.2, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	1 (11.1)	8 (88.9)	NE (1.4, NE)
no	10 (14.3)	60 (85.7)	NE (13.2, NE)
Prior nivolumab or pembrolizumab treatment			
yes	0 (0.0)	6 (100.0)	NE (NE, NE)
no	11 (15.1)	62 (84.9)	13.2 (13.2, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	0 (0.0)	7 (100.0)	NE (NE, NE)
no	11 (15.3)	61 (84.7)	13.2 (13.2, NE)

Time to Definitive Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

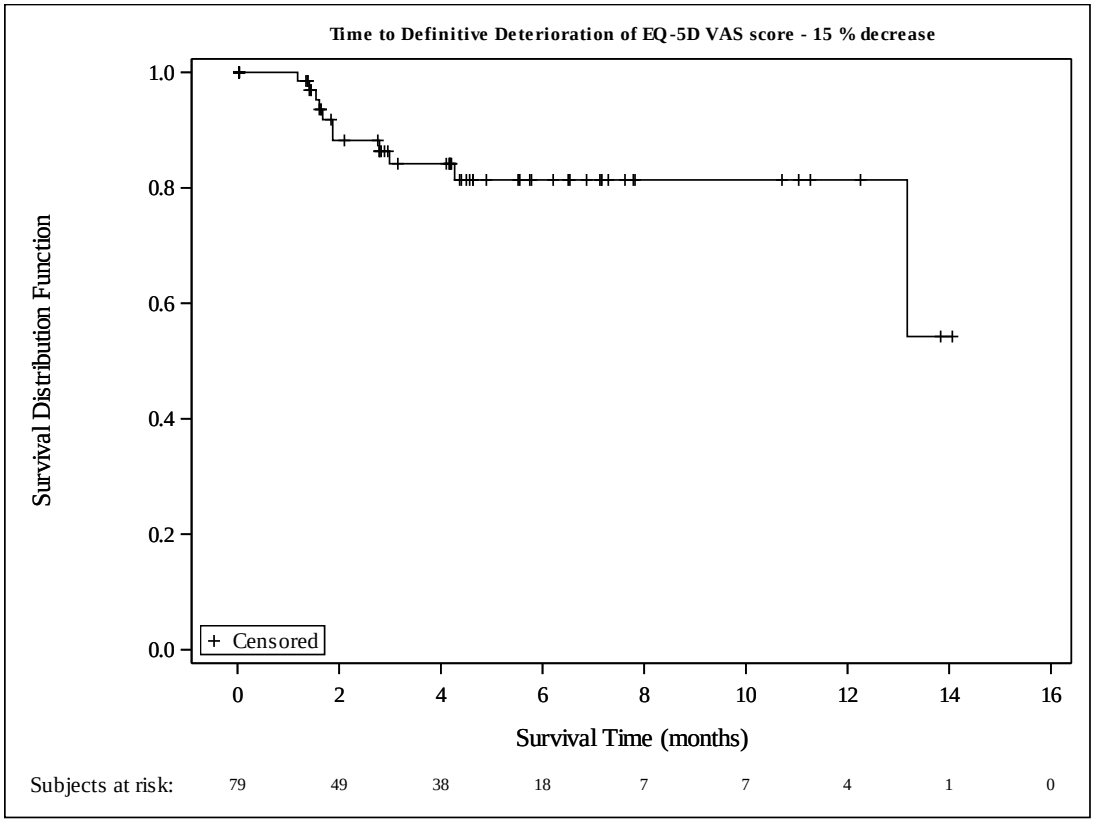
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	6 (12.0)	44 (88.0)	13.2 (13.2, NE)
no	5 (17.2)	24 (82.8)	NE (NE, NE)
Renal impairment at baseline			
normal	4 (12.5)	28 (87.5)	NE (NE, NE)
mild	4 (16.0)	21 (84.0)	NE (NE, NE)
moderate	2 (25.0)	6 (75.0)	13.2 (4.3, 13.2)
Hepatic impairment at baseline			
normal	10 (15.6)	54 (84.4)	NE (13.2, NE)
mild	0 (0.0)	14 (100.0)	NE (NE, NE)
Race			
White	10 (14.5)	59 (85.5)	NE (13.2, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	1 (12.5)	7 (87.5)	NE (1.6, NE)
Ethnicity			
Hispanic/Latino	0 (0.0)	5 (100.0)	NE (NE, NE)
Non-Hispanic/Non-Latino	11 (15.7)	59 (84.3)	NE (13.2, NE)
Unknown	0 (0.0)	4 (100.0)	NE (NE, NE)

Time to Definitive Deterioration of EQ-5D VAS score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of EQ-5D VAS score (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall					
	Cycle 3 Day 1	59	12 (20.3)	43 (72.9)	4 (6.8)
	Cycle 5 Day 1	41	13 (31.7)	27 (65.9)	1 (2.4)
	Cycle 7 Day 1	31	8 (25.8)	21 (67.7)	2 (6.5)
	Cycle 9 Day 1	19	4 (21.1)	14 (73.7)	1 (5.3)
	Cycle 11 Day 1	13	3 (23.1)	10 (76.9)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 19 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	4 (12.9)	20 (64.5)	7 (22.6)
Region					
North America					
	Cycle 3 Day 1	22	3 (13.6)	17 (77.3)	2 (9.1)
	Cycle 5 Day 1	14	2 (14.3)	12 (85.7)	0 (0.0)
	Cycle 7 Day 1	10	3 (30.0)	6 (60.0)	1 (10.0)
	Cycle 9 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	14	1 (7.1)	11 (78.6)	2 (14.3)
Region					
EU					
	Cycle 3 Day 1	37	9 (24.3)	26 (70.3)	2 (5.4)
	Cycle 5 Day 1	27	11 (40.7)	15 (55.6)	1 (3.7)
	Cycle 7 Day 1	21	5 (23.8)	15 (71.4)	1 (4.8)
	Cycle 9 Day 1	12	3 (25.0)	9 (75.0)	0 (0.0)
	Cycle 11 Day 1	7	3 (42.9)	4 (57.1)	0 (0.0)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 17 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 19 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	17	3 (17.6)	9 (52.9)	5 (29.4)
Age (Category 1)					
<65 years					
	Cycle 3 Day 1	38	10 (26.3)	27 (71.1)	1 (2.6)
	Cycle 5 Day 1	26	11 (42.3)	15 (57.7)	0 (0.0)
	Cycle 7 Day 1	17	6 (35.3)	11 (64.7)	0 (0.0)
	Cycle 9 Day 1	12	3 (25.0)	9 (75.0)	0 (0.0)
	Cycle 11 Day 1	9	2 (22.2)	7 (77.8)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	18	3 (16.7)	10 (55.6)	5 (27.8)
Age (Category 1)					
>=65 years					
	Cycle 3 Day 1	21	2 (9.5)	16 (76.2)	3 (14.3)
	Cycle 5 Day 1	15	2 (13.3)	12 (80.0)	1 (6.7)
	Cycle 7 Day 1	14	2 (14.3)	10 (71.4)	2 (14.3)
	Cycle 9 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 11 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 13 Day 1	2	1 (50.0)	0 (0.0)	1 (50.0)
	Cycle 15 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 17 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 19 Day 1	2	2 (100.0)	0 (0.0)	0 (0.0)
	Cycle 21 Day 1	2	1 (50.0)	0 (0.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	13	1 (7.7)	10 (76.9)	2 (15.4)
Age (Category 2)					
<75 years					
	Cycle 3 Day 1	55	11 (20.0)	42 (76.4)	2 (3.6)
	Cycle 5 Day 1	38	13 (34.2)	25 (65.8)	0 (0.0)
	Cycle 7 Day 1	29	8 (27.6)	19 (65.5)	2 (6.9)
	Cycle 9 Day 1	17	3 (17.6)	13 (76.5)	1 (5.9)
	Cycle 11 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 13 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	4 (12.9)	20 (64.5)	7 (22.6)
Age (Category 2)					
>=75 years					
	Cycle 3 Day 1	4	1 (25.0)	1 (25.0)	2 (50.0)
	Cycle 5 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 9 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 13 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 15 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 17 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 19 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
Sex					
female					
	Cycle 3 Day 1	18	4 (22.2)	13 (72.2)	1 (5.6)
	Cycle 5 Day 1	16	6 (37.5)	10 (62.5)	0 (0.0)
	Cycle 7 Day 1	13	4 (30.8)	9 (69.2)	0 (0.0)
	Cycle 9 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 11 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	7	1 (14.3)	5 (71.4)	1 (14.3)
Sex					
male					
	Cycle 3 Day 1	41	8 (19.5)	30 (73.2)	3 (7.3)
	Cycle 5 Day 1	25	7 (28.0)	17 (68.0)	1 (4.0)
	Cycle 7 Day 1	18	4 (22.2)	12 (66.7)	2 (11.1)
	Cycle 9 Day 1	13	3 (23.1)	9 (69.2)	1 (7.7)
	Cycle 11 Day 1	9	2 (22.2)	7 (77.8)	0 (0.0)
	Cycle 13 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 15 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 17 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 19 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	24	3 (12.5)	15 (62.5)	6 (25.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS					
0					
	Cycle 3 Day 1	21	0 (0.0)	18 (85.7)	3 (14.3)
	Cycle 5 Day 1	16	2 (12.5)	13 (81.3)	1 (6.3)
	Cycle 7 Day 1	11	1 (9.1)	9 (81.8)	1 (9.1)
	Cycle 9 Day 1	9	0 (0.0)	9 (100.0)	0 (0.0)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 15 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	15	0 (0.0)	12 (80.0)	3 (20.0)
ECOG PS					
1					
	Cycle 3 Day 1	38	12 (31.6)	25 (65.8)	1 (2.6)
	Cycle 5 Day 1	25	11 (44.0)	14 (56.0)	0 (0.0)
	Cycle 7 Day 1	20	7 (35.0)	12 (60.0)	1 (5.0)
	Cycle 9 Day 1	10	4 (40.0)	5 (50.0)	1 (10.0)
	Cycle 11 Day 1	7	3 (42.9)	4 (57.1)	0 (0.0)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 17 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 19 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	16	4 (25.0)	8 (50.0)	4 (25.0)
HER2 Status in central laboratory					
IHC 3+					
	Cycle 3 Day 1	56	11 (19.6)	41 (73.2)	4 (7.1)
	Cycle 5 Day 1	39	12 (30.8)	26 (66.7)	1 (2.6)
	Cycle 7 Day 1	29	7 (24.1)	20 (69.0)	2 (6.9)
	Cycle 9 Day 1	18	3 (16.7)	14 (77.8)	1 (5.6)
	Cycle 11 Day 1	13	3 (23.1)	10 (76.9)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 19 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	25	3 (12.0)	17 (68.0)	5 (20.0)
HER2 Status in central laboratory					
IHC 2+/ISH +					
	Cycle 3 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 5 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 7 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 9 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	6	1 (16.7)	3 (50.0)	2 (33.3)
Primary tumor location					
Gastric					
	Cycle 3 Day 1	21	8 (38.1)	12 (57.1)	1 (4.8)
	Cycle 5 Day 1	17	6 (35.3)	11 (64.7)	0 (0.0)
	Cycle 7 Day 1	15	6 (40.0)	8 (53.3)	1 (6.7)
	Cycle 9 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 11 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 13 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 15 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 17 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 19 Day 1	2	2 (100.0)	0 (0.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	10	2 (20.0)	6 (60.0)	2 (20.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Primary tumor location					
GEJ					
	Cycle 3 Day 1	38	4 (10.5)	31 (81.6)	3 (7.9)
	Cycle 5 Day 1	24	7 (29.2)	16 (66.7)	1 (4.2)
	Cycle 7 Day 1	16	2 (12.5)	13 (81.3)	1 (6.3)
	Cycle 9 Day 1	13	2 (15.4)	10 (76.9)	1 (7.7)
	Cycle 11 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	21	2 (9.5)	14 (66.7)	5 (23.8)
Histological subtype					
diffuse					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Histological subtype					
intestinal					
	Cycle 3 Day 1	14	4 (28.6)	9 (64.3)	1 (7.1)
	Cycle 5 Day 1	11	4 (36.4)	7 (63.6)	0 (0.0)
	Cycle 7 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 9 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 11 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	8	1 (12.5)	6 (75.0)	1 (12.5)
Histological subtype					
other					
	Cycle 3 Day 1	44	8 (18.2)	33 (75.0)	3 (6.8)
	Cycle 5 Day 1	29	9 (31.0)	19 (65.5)	1 (3.4)
	Cycle 7 Day 1	22	7 (31.8)	14 (63.6)	1 (4.5)
	Cycle 9 Day 1	13	4 (30.8)	8 (61.5)	1 (7.7)
	Cycle 11 Day 1	9	3 (33.3)	6 (66.7)	0 (0.0)
	Cycle 13 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 15 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 17 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 19 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	22	3 (13.6)	13 (59.1)	6 (27.3)
Number of metastatic sites					
<2					
	Cycle 3 Day 1	3	3 (100.0)	0 (0.0)	0 (0.0)
	Cycle 5 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 7 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 9 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	2	1 (50.0)	1 (50.0)	0 (0.0)
Number of metastatic sites					
>=2					
	Cycle 3 Day 1	56	9 (16.1)	43 (76.8)	4 (7.1)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 5 Day 1	38	11 (28.9)	26 (68.4)	1 (2.6)
	Cycle 7 Day 1	27	7 (25.9)	18 (66.7)	2 (7.4)
	Cycle 9 Day 1	18	3 (16.7)	14 (77.8)	1 (5.6)
	Cycle 11 Day 1	13	3 (23.1)	10 (76.9)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 19 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	29	3 (10.3)	19 (65.5)	7 (24.1)
Previous total gastrectomy					
no					
	Cycle 3 Day 1	59	12 (20.3)	43 (72.9)	4 (6.8)
	Cycle 5 Day 1	41	13 (31.7)	27 (65.9)	1 (2.4)
	Cycle 7 Day 1	31	8 (25.8)	21 (67.7)	2 (6.5)
	Cycle 9 Day 1	19	4 (21.1)	14 (73.7)	1 (5.3)
	Cycle 11 Day 1	13	3 (23.1)	10 (76.9)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 19 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	4 (12.9)	20 (64.5)	7 (22.6)
Prior adjuvant/ neoadjuvant therapy					
yes					
	Cycle 3 Day 1	7	2 (28.6)	3 (42.9)	2 (28.6)
	Cycle 5 Day 1	6	3 (50.0)	2 (33.3)	1 (16.7)
	Cycle 7 Day 1	7	2 (28.6)	5 (71.4)	0 (0.0)
	Cycle 9 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy					
no					
	Cycle 3 Day 1	52	10 (19.2)	40 (76.9)	2 (3.8)
	Cycle 5 Day 1	35	10 (28.6)	25 (71.4)	0 (0.0)
	Cycle 7 Day 1	24	6 (25.0)	16 (66.7)	2 (8.3)
	Cycle 9 Day 1	17	3 (17.6)	13 (76.5)	1 (5.9)
	Cycle 11 Day 1	12	3 (25.0)	9 (75.0)	0 (0.0)
	Cycle 13 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 19 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	4 (13.3)	19 (63.3)	7 (23.3)
Prior nivolumab or pembrolizumab treatment					
yes					
	Cycle 3 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior nivolumab or pembrolizumab treatment					
no					
	Cycle 3 Day 1	57	12 (21.1)	41 (71.9)	4 (7.0)
	Cycle 5 Day 1	40	13 (32.5)	26 (65.0)	1 (2.5)
	Cycle 7 Day 1	29	7 (24.1)	20 (69.0)	2 (6.9)
	Cycle 9 Day 1	19	4 (21.1)	14 (73.7)	1 (5.3)
	Cycle 11 Day 1	12	3 (25.0)	9 (75.0)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 19 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	4 (13.3)	19 (63.3)	7 (23.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
yes					
	Cycle 3 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
no					
	Cycle 3 Day 1	56	11 (19.6)	41 (73.2)	4 (7.1)
	Cycle 5 Day 1	39	13 (33.3)	25 (64.1)	1 (2.6)
	Cycle 7 Day 1	29	7 (24.1)	20 (69.0)	2 (6.9)
	Cycle 9 Day 1	19	4 (21.1)	14 (73.7)	1 (5.3)
	Cycle 11 Day 1	12	3 (25.0)	9 (75.0)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 19 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	4 (13.3)	19 (63.3)	7 (23.3)
Presence of liver metastasis at baseline					
yes					
	Cycle 3 Day 1	36	7 (19.4)	27 (75.0)	2 (5.6)
	Cycle 5 Day 1	25	6 (24.0)	19 (76.0)	0 (0.0)
	Cycle 7 Day 1	17	2 (11.8)	15 (88.2)	0 (0.0)
	Cycle 9 Day 1	14	2 (14.3)	11 (78.6)	1 (7.1)
	Cycle 11 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 13 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 15 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 17 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 19 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	18	3 (16.7)	10 (55.6)	5 (27.8)
Presence of liver metastasis at baseline					
no					
	Cycle 3 Day 1	23	5 (21.7)	16 (69.6)	2 (8.7)
	Cycle 5 Day 1	16	7 (43.8)	8 (50.0)	1 (6.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 7 Day 1	14	6 (42.9)	6 (42.9)	2 (14.3)
	Cycle 9 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 11 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 13 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	13	1 (7.7)	10 (76.9)	2 (15.4)
Renal impairment at baseline					
normal					
	Cycle 3 Day 1	24	4 (16.7)	20 (83.3)	0 (0.0)
	Cycle 5 Day 1	13	6 (46.2)	7 (53.8)	0 (0.0)
	Cycle 7 Day 1	7	3 (42.9)	4 (57.1)	0 (0.0)
	Cycle 9 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 11 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	1 (7.7)	8 (61.5)	4 (30.8)
Renal impairment at baseline					
mild					
	Cycle 3 Day 1	15	4 (26.7)	9 (60.0)	2 (13.3)
	Cycle 5 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 7 Day 1	11	1 (9.1)	10 (90.9)	0 (0.0)
	Cycle 9 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 11 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 17 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 19 Day 1	2	2 (100.0)	0 (0.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	2 (16.7)	7 (58.3)	3 (25.0)
Renal impairment at baseline					
moderate					
	Cycle 3 Day 1	7	0 (0.0)	7 (100.0)	0 (0.0)
	Cycle 5 Day 1	7	2 (28.6)	5 (71.4)	0 (0.0)
	Cycle 7 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 9 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline					
normal					
	Cycle 3 Day 1	47	10 (21.3)	34 (72.3)	3 (6.4)
	Cycle 5 Day 1	32	11 (34.4)	20 (62.5)	1 (3.1)
	Cycle 7 Day 1	26	7 (26.9)	17 (65.4)	2 (7.7)
	Cycle 9 Day 1	16	3 (18.8)	12 (75.0)	1 (6.3)
	Cycle 11 Day 1	12	3 (25.0)	9 (75.0)	0 (0.0)
	Cycle 13 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 19 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	28	4 (14.3)	18 (64.3)	6 (21.4)
Hepatic impairment at baseline					
mild					
	Cycle 3 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 5 Day 1	9	2 (22.2)	7 (77.8)	0 (0.0)
	Cycle 7 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 9 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Race					
White					
	Cycle 3 Day 1	52	10 (19.2)	39 (75.0)	3 (5.8)
	Cycle 5 Day 1	35	11 (31.4)	23 (65.7)	1 (2.9)
	Cycle 7 Day 1	27	5 (18.5)	20 (74.1)	2 (7.4)
	Cycle 9 Day 1	17	3 (17.6)	13 (76.5)	1 (5.9)
	Cycle 11 Day 1	12	3 (25.0)	9 (75.0)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 19 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	27	3 (11.1)	18 (66.7)	6 (22.2)
Race					
Black or African American					
	Cycle 3 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Race					
Other					
	Cycle 3 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 5 Day 1	4	2 (50.0)	2 (50.0)	0 (0.0)
	Cycle 7 Day 1	4	3 (75.0)	1 (25.0)	0 (0.0)
	Cycle 9 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	4	1 (25.0)	2 (50.0)	1 (25.0)
Ethnicity					
Hispanic/Latino					
	Cycle 3 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 5 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 7 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 9 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 11 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 13 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 15 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 17 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 19 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	3	0 (0.0)	3 (100.0)	0 (0.0)
Ethnicity					
Non-Hispanic/Non-Latino					
	Cycle 3 Day 1	50	10 (20.0)	36 (72.0)	4 (8.0)
	Cycle 5 Day 1	35	13 (37.1)	21 (60.0)	1 (2.9)
	Cycle 7 Day 1	27	7 (25.9)	18 (66.7)	2 (7.4)
	Cycle 9 Day 1	16	3 (18.8)	12 (75.0)	1 (6.3)
	Cycle 11 Day 1	11	2 (18.2)	9 (81.8)	0 (0.0)
	Cycle 13 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of EQ-5D VAS score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	26	4 (15.4)	15 (57.7)	7 (26.9)
Ethnicity					
Unknown					
	Cycle 3 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Anhang 4-G 2.1.4: Gesundheitsbezogene Lebensqualität

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Fact-Ga Total Score Completion Rates by Visit
Full Analysis Set

	T-DXd (N=79)	
Visit	Number of subjects alive	Completed (%)
Baseline	79	71 (89.9)
Cycle 3 Day 1	78	57 (73.1)
Cycle 5 Day 1	76	40 (52.6)
Cycle 7 Day 1	72	30 (41.7)
Cycle 9 Day 1	60	18 (30.0)
Cycle 11 Day 1	44	13 (29.5)
Cycle 13 Day 1	32	6 (18.8)
Cycle 15 Day 1	21	8 (38.1)
Cycle 17 Day 1	18	4 (22.2)
Cycle 19 Day 1	16	3 (18.8)
Cycle 21 Day 1	11	3 (27.3)
Cycle 23 Day 1	7	1 (14.3)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

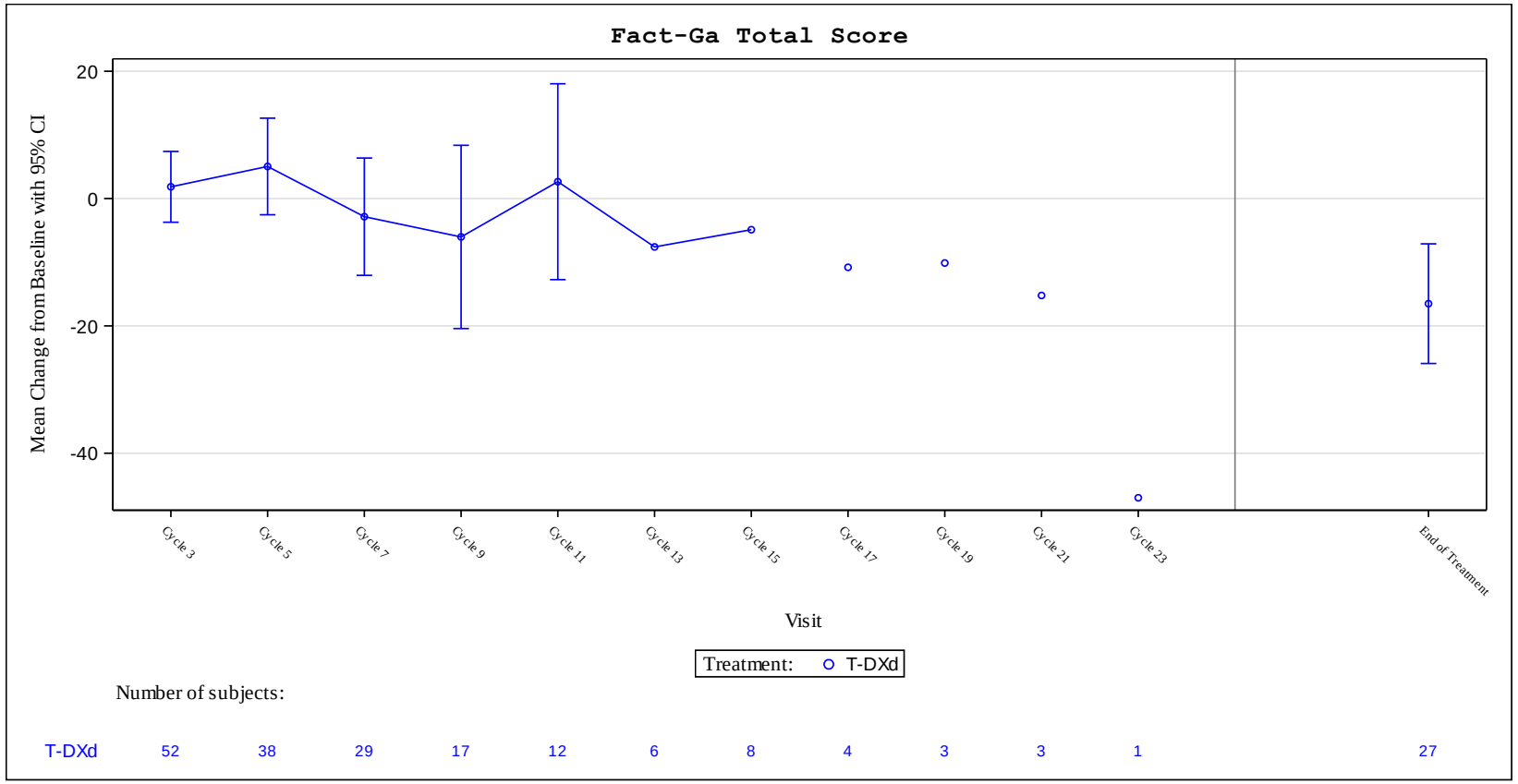
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Fact-Ga Total Score by Visit
Full Analysis Set

	T-DXd (N=79)			
	Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)
Baseline	71	130.1 (30.90)		
Cycle 3 Day 1	57	131.1 (25.85)	52	1.8 (19.97)
Cycle 5 Day 1	40	136.3 (28.96)	38	5.0 (23.07)
Cycle 7 Day 1	30	127.1 (30.36)	29	-2.8 (24.22)
Cycle 9 Day 1	18	130.3 (32.94)	17	-6.0 (27.99)
Cycle 11 Day 1	13	139.4 (27.22)	12	2.7 (24.21)
Cycle 13 Day 1	6	130.3 (28.15)	6	-7.6 (11.75)
Cycle 15 Day 1	8	142.6 (22.24)	8	-4.9 (14.02)
Cycle 17 Day 1	4	129.0 (15.34)	4	-10.8 (13.46)
Cycle 19 Day 1	3	130.3 (17.86)	3	-10.1 (13.70)
Cycle 21 Day 1	3	130.8 (17.77)	3	-15.2 (25.00)
Cycle 23 Day 1	1	120.0 (-)	1	-47.0 (-)
End of Treatment	31	120.5 (41.97)	27	-16.5 (23.75)

Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Graphical Summary of Fact-Ga Total Score by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADQS

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	16 (20.3)	63 (79.7)	NE (9.3, NE)
Region			
North America	7 (20.6)	27 (79.4)	9.3 (4.1, NE)
EU	9 (20.0)	36 (80.0)	NE (4.4, NE)
Age (Category 1)			
<65 years	11 (23.9)	35 (76.1)	9.3 (4.4, NE)
>=65 years	5 (15.2)	28 (84.8)	NE (4.2, NE)
Age (Category 2)			
<75 years	14 (18.7)	61 (81.3)	NE (9.3, NE)
>=75 years	2 (50.0)	2 (50.0)	3.7 (1.4, NE)
Sex			
female	4 (18.2)	18 (81.8)	NE (4.2, NE)
male	12 (21.1)	45 (78.9)	9.3 (4.1, NE)
ECOG PS			
0	6 (20.7)	23 (79.3)	9.3 (4.2, NE)
1	10 (20.0)	40 (80.0)	NE (4.1, NE)
HER2 Status in central laboratory			
IHC 3+	14 (20.6)	54 (79.4)	NE (9.3, NE)
IHC 2+/ISH +	2 (20.0)	8 (80.0)	NE (1.6, NE)
Primary tumor location			
Gastric	6 (22.2)	21 (77.8)	NE (3.7, NE)
GEJ	10 (19.2)	42 (80.8)	NE (4.2, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	3 (15.8)	16 (84.2)	9.3 (3.0, NE)
other	13 (22.0)	46 (78.0)	NE (4.2, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	16 (21.6)	58 (78.4)	NE (4.4, NE)
Previous total gastrectomy			
no	16 (20.3)	63 (79.7)	NE (9.3, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	2 (22.2)	7 (77.8)	NE (1.4, NE)
no	14 (20.0)	56 (80.0)	9.3 (4.4, NE)
Prior nivolumab or pembrolizumab treatment			
yes	0 (0.0)	6 (100.0)	NE (NE, NE)
no	16 (21.9)	57 (78.1)	9.3 (4.4, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	0 (0.0)	7 (100.0)	NE (NE, NE)
no	16 (22.2)	56 (77.8)	9.3 (4.4, NE)

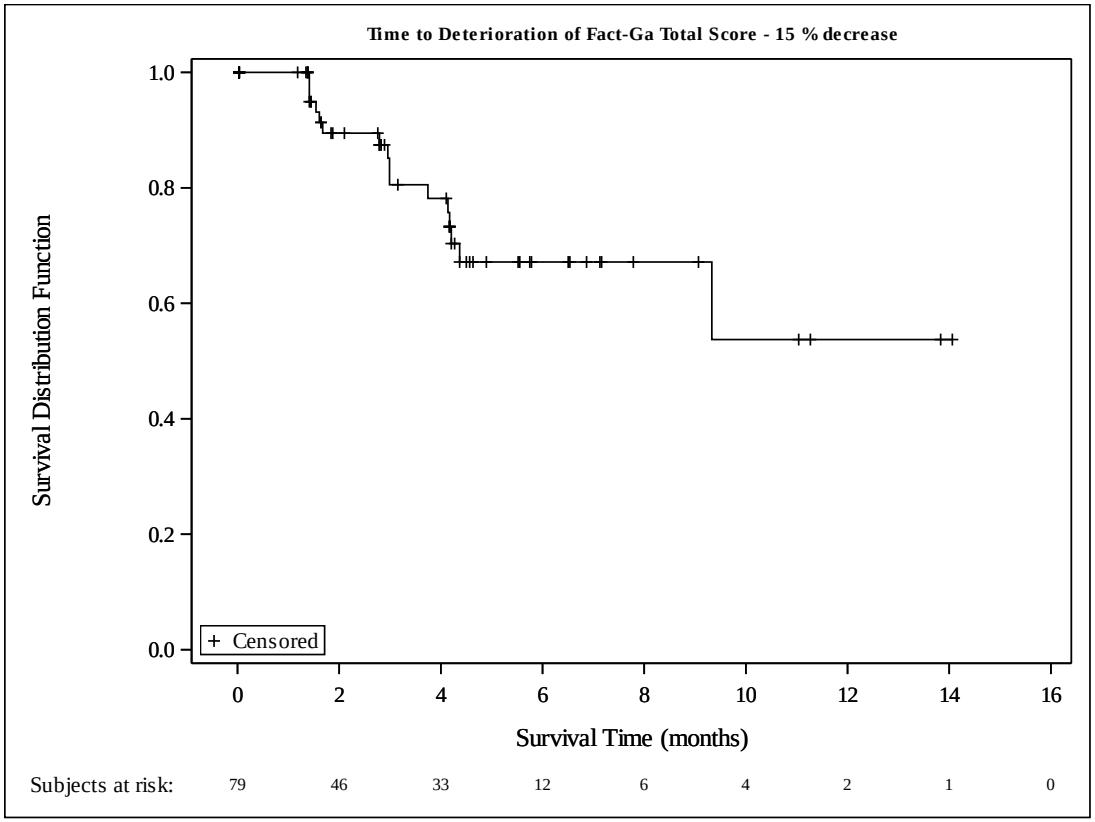
Time to Deterioration of Fact-Ga Total Score is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	10 (20.0)	40 (80.0)	NE (4.2, NE)
no	6 (20.7)	23 (79.3)	NE (4.2, NE)
Renal impairment at baseline			
normal	5 (15.6)	27 (84.4)	9.3 (3.0, NE)
mild	6 (24.0)	19 (76.0)	NE (3.7, NE)
moderate	1 (12.5)	7 (87.5)	NE (4.1, NE)
Hepatic impairment at baseline			
normal	16 (25.0)	48 (75.0)	9.3 (4.2, NE)
mild	0 (0.0)	14 (100.0)	NE (NE, NE)
Race			
White	12 (17.4)	57 (82.6)	NE (9.3, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	4 (50.0)	4 (50.0)	4.2 (1.4, NE)
Ethnicity			
Hispanic/Latino	2 (40.0)	3 (60.0)	9.3 (3.7, 9.3)
Non-Hispanic/Non-Latino	12 (17.1)	58 (82.9)	NE (NE, NE)
Unknown	2 (50.0)	2 (50.0)	4.2 (1.4, 4.2)

Time to Deterioration of Fact-Ga Total Score is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	12 (15.2)	67 (84.8)	NE (9.3, NE)
Region			
North America	5 (14.7)	29 (85.3)	NE (4.2, NE)
EU	7 (15.6)	38 (84.4)	NE (NE, NE)
Age (Category 1)			
<65 years	9 (19.6)	37 (80.4)	NE (9.3, NE)
>=65 years	3 (9.1)	30 (90.9)	NE (NE, NE)
Age (Category 2)			
<75 years	11 (14.7)	64 (85.3)	NE (9.3, NE)
>=75 years	1 (25.0)	3 (75.0)	NE (3.7, NE)
Sex			
female	2 (9.1)	20 (90.9)	NE (NE, NE)
male	10 (17.5)	47 (82.5)	9.3 (9.3, NE)
ECOG PS			
0	4 (13.8)	25 (86.2)	NE (9.3, NE)
1	8 (16.0)	42 (84.0)	NE (4.4, NE)
HER2 Status in central laboratory			
IHC 3+	10 (14.7)	58 (85.3)	NE (9.3, NE)
IHC 2+/ISH +	2 (20.0)	8 (80.0)	NE (1.6, NE)
Primary tumor location			
Gastric	4 (14.8)	23 (85.2)	NE (4.4, NE)
GEJ	8 (15.4)	44 (84.6)	NE (9.3, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	2 (10.5)	17 (89.5)	9.3 (9.3, NE)
other	10 (16.9)	49 (83.1)	NE (4.4, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	12 (16.2)	62 (83.8)	NE (9.3, NE)
Previous total gastrectomy			
no	12 (15.2)	67 (84.8)	NE (9.3, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	0 (0.0)	9 (100.0)	NE (NE, NE)
no	12 (17.1)	58 (82.9)	NE (9.3, NE)
Prior nivolumab or pembrolizumab treatment			
yes	0 (0.0)	6 (100.0)	NE (NE, NE)
no	12 (16.4)	61 (83.6)	NE (9.3, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	0 (0.0)	7 (100.0)	NE (NE, NE)
no	12 (16.7)	60 (83.3)	NE (9.3, NE)

Time to Definitive Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

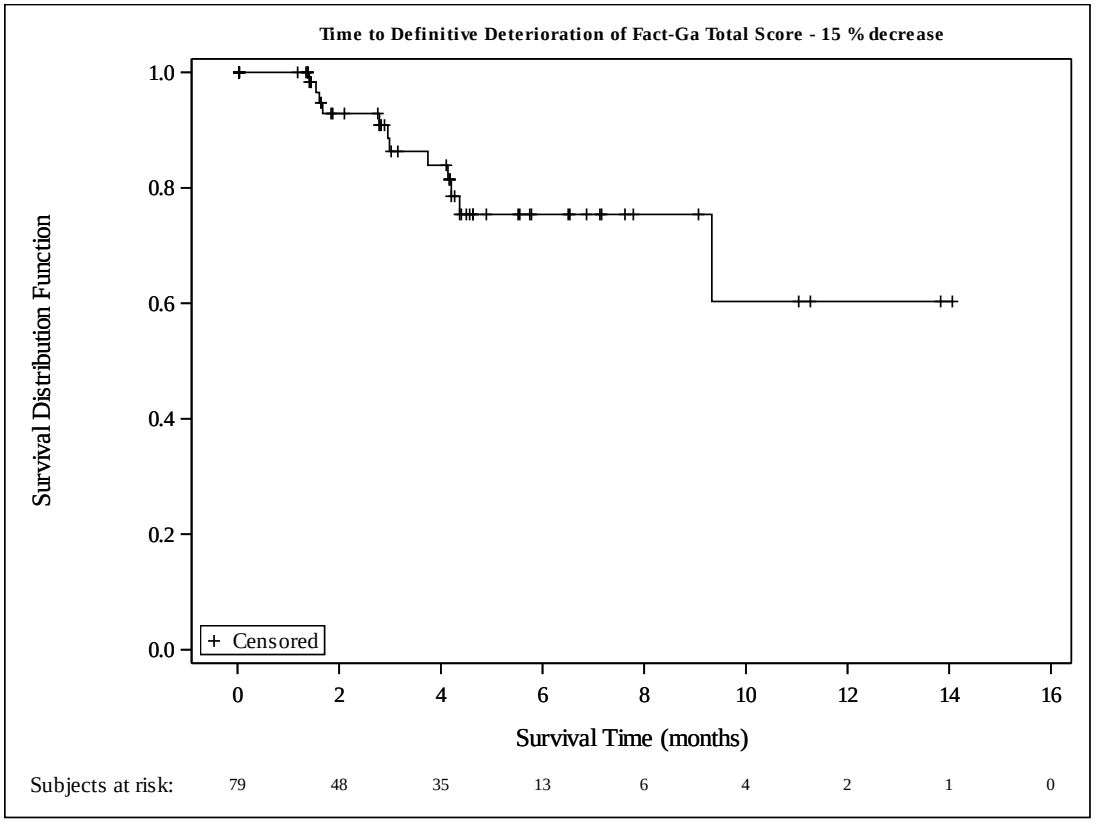
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	9 (18.0)	41 (82.0)	NE (9.3, NE)
no	3 (10.3)	26 (89.7)	NE (4.4, NE)
Renal impairment at baseline			
normal	4 (12.5)	28 (87.5)	9.3 (3.0, NE)
mild	5 (20.0)	20 (80.0)	NE (3.7, NE)
moderate	1 (12.5)	7 (87.5)	NE (4.1, NE)
Hepatic impairment at baseline			
normal	12 (18.8)	52 (81.3)	NE (9.3, NE)
mild	0 (0.0)	14 (100.0)	NE (NE, NE)
Race			
White	10 (14.5)	59 (85.5)	NE (9.3, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	NE (1.6, NE)
Ethnicity			
Hispanic/Latino	2 (40.0)	3 (60.0)	9.3 (3.7, 9.3)
Non-Hispanic/Non-Latino	9 (12.9)	61 (87.1)	NE (NE, NE)
Unknown	1 (25.0)	3 (75.0)	NE (4.2, NE)

Time to Definitive Deterioration of Fact-Ga Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Fact-Ga Total Score (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall					
	Cycle 3 Day 1	57	7 (12.3)	47 (82.5)	3 (5.3)
	Cycle 5 Day 1	40	6 (15.0)	32 (80.0)	2 (5.0)
	Cycle 7 Day 1	30	4 (13.3)	21 (70.0)	5 (16.7)
	Cycle 9 Day 1	18	2 (11.1)	12 (66.7)	4 (22.2)
	Cycle 11 Day 1	13	2 (15.4)	11 (84.6)	0 (0.0)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	22 (71.0)	9 (29.0)
Region					
North America					
	Cycle 3 Day 1	22	2 (9.1)	19 (86.4)	1 (4.5)
	Cycle 5 Day 1	14	1 (7.1)	13 (92.9)	0 (0.0)
	Cycle 7 Day 1	11	1 (9.1)	8 (72.7)	2 (18.2)
	Cycle 9 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	14	0 (0.0)	10 (71.4)	4 (28.6)
Region					
EU					
	Cycle 3 Day 1	35	5 (14.3)	28 (80.0)	2 (5.7)
	Cycle 5 Day 1	26	5 (19.2)	19 (73.1)	2 (7.7)
	Cycle 7 Day 1	19	3 (15.8)	13 (68.4)	3 (15.8)
	Cycle 9 Day 1	11	2 (18.2)	6 (54.5)	3 (27.3)
	Cycle 11 Day 1	7	2 (28.6)	5 (71.4)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	17	0 (0.0)	12 (70.6)	5 (29.4)
Age (Category 1)					
<65 years					
	Cycle 3 Day 1	36	5 (13.9)	29 (80.6)	2 (5.6)
	Cycle 5 Day 1	25	5 (20.0)	18 (72.0)	2 (8.0)
	Cycle 7 Day 1	16	3 (18.8)	11 (68.8)	2 (12.5)
	Cycle 9 Day 1	11	1 (9.1)	8 (72.7)	2 (18.2)
	Cycle 11 Day 1	9	2 (22.2)	7 (77.8)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	18	0 (0.0)	10 (55.6)	8 (44.4)
Age (Category 1)					
>=65 years					
	Cycle 3 Day 1	21	2 (9.5)	18 (85.7)	1 (4.8)
	Cycle 5 Day 1	15	1 (6.7)	14 (93.3)	0 (0.0)
	Cycle 7 Day 1	14	1 (7.1)	10 (71.4)	3 (21.4)
	Cycle 9 Day 1	7	1 (14.3)	4 (57.1)	2 (28.6)
	Cycle 11 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	13	0 (0.0)	12 (92.3)	1 (7.7)
Age (Category 2)					
<75 years					
	Cycle 3 Day 1	53	6 (11.3)	45 (84.9)	2 (3.8)
	Cycle 5 Day 1	37	6 (16.2)	29 (78.4)	2 (5.4)
	Cycle 7 Day 1	28	4 (14.3)	20 (71.4)	4 (14.3)
	Cycle 9 Day 1	16	1 (6.3)	12 (75.0)	3 (18.8)
	Cycle 11 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 13 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	22 (71.0)	9 (29.0)
Age (Category 2)					
>=75 years					
	Cycle 3 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 5 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 9 Day 1	2	1 (50.0)	0 (0.0)	1 (50.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Sex					
female					
	Cycle 3 Day 1	17	3 (17.6)	13 (76.5)	1 (5.9)
	Cycle 5 Day 1	16	2 (12.5)	13 (81.3)	1 (6.3)
	Cycle 7 Day 1	11	1 (9.1)	9 (81.8)	1 (9.1)
	Cycle 9 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 11 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	7	0 (0.0)	5 (71.4)	2 (28.6)
Sex					
male					
	Cycle 3 Day 1	40	4 (10.0)	34 (85.0)	2 (5.0)
	Cycle 5 Day 1	24	4 (16.7)	19 (79.2)	1 (4.2)
	Cycle 7 Day 1	19	3 (15.8)	12 (63.2)	4 (21.1)
	Cycle 9 Day 1	13	1 (7.7)	9 (69.2)	3 (23.1)
	Cycle 11 Day 1	9	1 (11.1)	8 (88.9)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	24	0 (0.0)	17 (70.8)	7 (29.2)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS					
0					
	Cycle 3 Day 1	21	0 (0.0)	20 (95.2)	1 (4.8)
	Cycle 5 Day 1	16	0 (0.0)	16 (100.0)	0 (0.0)
	Cycle 7 Day 1	10	0 (0.0)	9 (90.0)	1 (10.0)
	Cycle 9 Day 1	9	0 (0.0)	9 (100.0)	0 (0.0)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	15	0 (0.0)	11 (73.3)	4 (26.7)
ECOG PS					
1					
	Cycle 3 Day 1	36	7 (19.4)	27 (75.0)	2 (5.6)
	Cycle 5 Day 1	24	6 (25.0)	16 (66.7)	2 (8.3)
	Cycle 7 Day 1	20	4 (20.0)	12 (60.0)	4 (20.0)
	Cycle 9 Day 1	9	2 (22.2)	3 (33.3)	4 (44.4)
	Cycle 11 Day 1	7	2 (28.6)	5 (71.4)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	16	0 (0.0)	11 (68.8)	5 (31.3)
HER2 Status in central laboratory					
IHC 3+					
	Cycle 3 Day 1	54	7 (13.0)	44 (81.5)	3 (5.6)
	Cycle 5 Day 1	38	6 (15.8)	30 (78.9)	2 (5.3)
	Cycle 7 Day 1	28	4 (14.3)	19 (67.9)	5 (17.9)
	Cycle 9 Day 1	17	2 (11.8)	11 (64.7)	4 (23.5)
	Cycle 11 Day 1	13	2 (15.4)	11 (84.6)	0 (0.0)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	25	0 (0.0)	18 (72.0)	7 (28.0)
HER2 Status in central laboratory					
IHC 2+/ISH +					
	Cycle 3 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	6	0 (0.0)	4 (66.7)	2 (33.3)
Primary tumor location					
Gastric					
	Cycle 3 Day 1	21	5 (23.8)	14 (66.7)	2 (9.5)
	Cycle 5 Day 1	17	4 (23.5)	11 (64.7)	2 (11.8)
	Cycle 7 Day 1	14	3 (21.4)	8 (57.1)	3 (21.4)
	Cycle 9 Day 1	6	1 (16.7)	2 (33.3)	3 (50.0)
	Cycle 11 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	10	0 (0.0)	8 (80.0)	2 (20.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Primary tumor location					
GEJ					
	Cycle 3 Day 1	36	2 (5.6)	33 (91.7)	1 (2.8)
	Cycle 5 Day 1	23	2 (8.7)	21 (91.3)	0 (0.0)
	Cycle 7 Day 1	16	1 (6.3)	13 (81.3)	2 (12.5)
	Cycle 9 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 11 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	21	0 (0.0)	14 (66.7)	7 (33.3)
Histological subtype					
diffuse					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Histological subtype					
intestinal					
	Cycle 3 Day 1	14	3 (21.4)	10 (71.4)	1 (7.1)
	Cycle 5 Day 1	11	3 (27.3)	6 (54.5)	2 (18.2)
	Cycle 7 Day 1	8	2 (25.0)	5 (62.5)	1 (12.5)
	Cycle 9 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 11 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	8	0 (0.0)	7 (87.5)	1 (12.5)
Histological subtype					
other					
	Cycle 3 Day 1	42	4 (9.5)	36 (85.7)	2 (4.8)
	Cycle 5 Day 1	28	3 (10.7)	25 (89.3)	0 (0.0)
	Cycle 7 Day 1	21	2 (9.5)	15 (71.4)	4 (19.0)
	Cycle 9 Day 1	12	1 (8.3)	8 (66.7)	3 (25.0)
	Cycle 11 Day 1	9	2 (22.2)	7 (77.8)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	22	0 (0.0)	14 (63.6)	8 (36.4)
Number of metastatic sites					
<2					
	Cycle 3 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 5 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 7 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Number of metastatic sites					
>=2					
	Cycle 3 Day 1	54	5 (9.3)	46 (85.2)	3 (5.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 5 Day 1	37	5 (13.5)	30 (81.1)	2 (5.4)
	Cycle 7 Day 1	26	3 (11.5)	18 (69.2)	5 (19.2)
	Cycle 9 Day 1	17	2 (11.8)	11 (64.7)	4 (23.5)
	Cycle 11 Day 1	13	2 (15.4)	11 (84.6)	0 (0.0)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	29	0 (0.0)	20 (69.0)	9 (31.0)
Previous total gastrectomy					
no					
	Cycle 3 Day 1	57	7 (12.3)	47 (82.5)	3 (5.3)
	Cycle 5 Day 1	40	6 (15.0)	32 (80.0)	2 (5.0)
	Cycle 7 Day 1	30	4 (13.3)	21 (70.0)	5 (16.7)
	Cycle 9 Day 1	18	2 (11.1)	12 (66.7)	4 (22.2)
	Cycle 11 Day 1	13	2 (15.4)	11 (84.6)	0 (0.0)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	22 (71.0)	9 (29.0)
Prior adjuvant/ neoadjuvant therapy					
yes					
	Cycle 3 Day 1	6	2 (33.3)	2 (33.3)	2 (33.3)
	Cycle 5 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 7 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy					
no					
	Cycle 3 Day 1	51	5 (9.8)	45 (88.2)	1 (2.0)
	Cycle 5 Day 1	34	5 (14.7)	27 (79.4)	2 (5.9)
	Cycle 7 Day 1	24	3 (12.5)	16 (66.7)	5 (20.8)
	Cycle 9 Day 1	17	2 (11.8)	11 (64.7)	4 (23.5)
	Cycle 11 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 13 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	21 (70.0)	9 (30.0)
Prior nivolumab or pembrolizumab treatment					
yes					
	Cycle 3 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior nivolumab or pembrolizumab treatment					
no					
	Cycle 3 Day 1	55	7 (12.7)	45 (81.8)	3 (5.5)
	Cycle 5 Day 1	39	6 (15.4)	31 (79.5)	2 (5.1)
	Cycle 7 Day 1	28	4 (14.3)	19 (67.9)	5 (17.9)
	Cycle 9 Day 1	18	2 (11.1)	12 (66.7)	4 (22.2)
	Cycle 11 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	21 (70.0)	9 (30.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
yes					
	Cycle 3 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
no					
	Cycle 3 Day 1	54	7 (13.0)	44 (81.5)	3 (5.6)
	Cycle 5 Day 1	38	6 (15.8)	30 (78.9)	2 (5.3)
	Cycle 7 Day 1	28	4 (14.3)	19 (67.9)	5 (17.9)
	Cycle 9 Day 1	18	2 (11.1)	12 (66.7)	4 (22.2)
	Cycle 11 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	21 (70.0)	9 (30.0)
Presence of liver metastasis at baseline					
yes					
	Cycle 3 Day 1	36	3 (8.3)	32 (88.9)	1 (2.8)
	Cycle 5 Day 1	24	2 (8.3)	21 (87.5)	1 (4.2)
	Cycle 7 Day 1	17	1 (5.9)	12 (70.6)	4 (23.5)
	Cycle 9 Day 1	14	1 (7.1)	10 (71.4)	3 (21.4)
	Cycle 11 Day 1	8	0 (0.0)	8 (100.0)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	18	0 (0.0)	12 (66.7)	6 (33.3)
Presence of liver metastasis at baseline					
no					
	Cycle 3 Day 1	21	4 (19.0)	15 (71.4)	2 (9.5)
	Cycle 5 Day 1	16	4 (25.0)	11 (68.8)	1 (6.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 7 Day 1	13	3 (23.1)	9 (69.2)	1 (7.7)
	Cycle 9 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 11 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	10 (76.9)	3 (23.1)
Renal impairment at baseline					
normal					
	Cycle 3 Day 1	23	2 (8.7)	21 (91.3)	0 (0.0)
	Cycle 5 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 7 Day 1	7	2 (28.6)	4 (57.1)	1 (14.3)
	Cycle 9 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 11 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	9 (69.2)	4 (30.8)
Renal impairment at baseline					
mild					
	Cycle 3 Day 1	14	1 (7.1)	11 (78.6)	2 (14.3)
	Cycle 5 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 7 Day 1	9	0 (0.0)	7 (77.8)	2 (22.2)
	Cycle 9 Day 1	5	0 (0.0)	3 (60.0)	2 (40.0)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	9 (75.0)	3 (25.0)
Renal impairment at baseline					
moderate					
	Cycle 3 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 5 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 7 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 9 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline					
normal					
	Cycle 3 Day 1	46	5 (10.9)	38 (82.6)	3 (6.5)
	Cycle 5 Day 1	31	5 (16.1)	24 (77.4)	2 (6.5)
	Cycle 7 Day 1	27	3 (11.1)	19 (70.4)	5 (18.5)
	Cycle 9 Day 1	16	2 (12.5)	10 (62.5)	4 (25.0)
	Cycle 11 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 13 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	28	0 (0.0)	19 (67.9)	9 (32.1)
Hepatic impairment at baseline					
mild					
	Cycle 3 Day 1	11	2 (18.2)	9 (81.8)	0 (0.0)
	Cycle 5 Day 1	9	1 (11.1)	8 (88.9)	0 (0.0)
	Cycle 7 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Race					
White					
	Cycle 3 Day 1	50	5 (10.0)	43 (86.0)	2 (4.0)
	Cycle 5 Day 1	34	5 (14.7)	27 (79.4)	2 (5.9)
	Cycle 7 Day 1	26	3 (11.5)	19 (73.1)	4 (15.4)
	Cycle 9 Day 1	16	2 (12.5)	10 (62.5)	4 (25.0)
	Cycle 11 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	27	0 (0.0)	20 (74.1)	7 (25.9)
Race					
Black or African American					
	Cycle 3 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Race					
Other					
	Cycle 3 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 5 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 7 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	2 (50.0)	2 (50.0)
Ethnicity					
Hispanic/Latino					
	Cycle 3 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 5 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 7 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 9 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 11 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	3	0 (0.0)	2 (66.7)	1 (33.3)
Ethnicity					
Non-Hispanic/Non-Latino					
	Cycle 3 Day 1	48	7 (14.6)	39 (81.3)	2 (4.2)
	Cycle 5 Day 1	34	6 (17.6)	26 (76.5)	2 (5.9)
	Cycle 7 Day 1	26	4 (15.4)	18 (69.2)	4 (15.4)
	Cycle 9 Day 1	15	2 (13.3)	10 (66.7)	3 (20.0)
	Cycle 11 Day 1	11	2 (18.2)	9 (81.8)	0 (0.0)
	Cycle 13 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-Ga Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	26	0 (0.0)	19 (73.1)	7 (26.9)
Ethnicity					
Unknown					
	Cycle 3 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	1 (50.0)	1 (50.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Physical Well-being Completion Rates by Visit
Full Analysis Set

	T-DXd (N=79)	
Visit	Number of subjects alive	Completed (%)
Baseline	79	71 (89.9)
Cycle 3 Day 1	78	59 (75.6)
Cycle 5 Day 1	76	41 (53.9)
Cycle 7 Day 1	72	31 (43.1)
Cycle 9 Day 1	60	19 (31.7)
Cycle 11 Day 1	44	13 (29.5)
Cycle 13 Day 1	32	6 (18.8)
Cycle 15 Day 1	21	8 (38.1)
Cycle 17 Day 1	18	4 (22.2)
Cycle 19 Day 1	16	3 (18.8)
Cycle 21 Day 1	11	3 (27.3)
Cycle 23 Day 1	7	1 (14.3)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

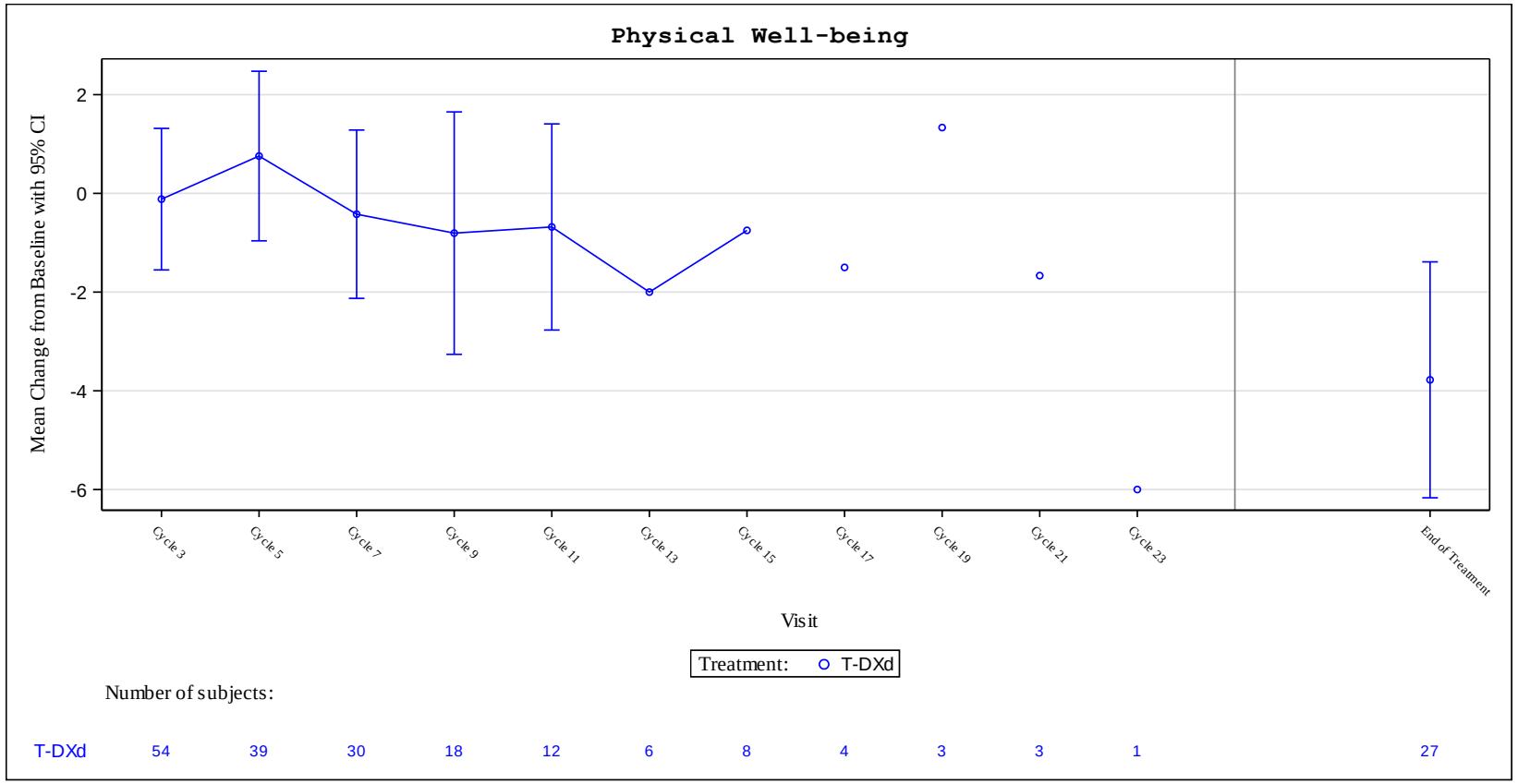
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Physical Well-being by Visit
Full Analysis Set

	T-DXd (N=79)			
	Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)
Baseline	71	21.0 (5.93)		
Cycle 3 Day 1	59	20.6 (4.66)	54	-0.1 (5.25)
Cycle 5 Day 1	41	21.9 (5.17)	39	0.8 (5.30)
Cycle 7 Day 1	31	20.7 (5.17)	30	-0.4 (4.57)
Cycle 9 Day 1	19	20.5 (5.98)	18	-0.8 (4.94)
Cycle 11 Day 1	13	21.4 (4.26)	12	-0.7 (3.29)
Cycle 13 Day 1	6	19.7 (5.24)	6	-2.0 (4.43)
Cycle 15 Day 1	8	23.3 (4.13)	8	-0.8 (4.13)
Cycle 17 Day 1	4	21.0 (3.83)	4	-1.5 (1.00)
Cycle 19 Day 1	3	22.3 (3.06)	3	1.3 (1.15)
Cycle 21 Day 1	3	21.7 (3.51)	3	-1.7 (3.79)
Cycle 23 Day 1	1	22.0 (-)	1	-6.0 (-)
End of Treatment	31	18.3 (7.68)	27	-3.8 (6.04)

Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Graphical Summary of Physical Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADQS

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	23 (29.1)	56 (70.9)	NE (4.2, NE)
Region			
North America	11 (32.4)	23 (67.6)	4.6 (1.7, NE)
EU	12 (26.7)	33 (73.3)	NE (4.2, NE)
Age (Category 1)			
<65 years	13 (28.3)	33 (71.7)	NE (4.2, NE)
>=65 years	10 (30.3)	23 (69.7)	4.6 (3.7, NE)
Age (Category 2)			
<75 years	21 (28.0)	54 (72.0)	NE (4.2, NE)
>=75 years	2 (50.0)	2 (50.0)	3.7 (1.4, NE)
Sex			
female	7 (31.8)	15 (68.2)	NE (4.2, NE)
male	16 (28.1)	41 (71.9)	5.5 (3.7, NE)
ECOG PS			
0	13 (44.8)	16 (55.2)	4.2 (1.5, NE)
1	10 (20.0)	40 (80.0)	NE (4.6, NE)
HER2 Status in central laboratory			
IHC 3+	19 (27.9)	49 (72.1)	NE (4.2, NE)
IHC 2+/ISH +	4 (40.0)	6 (60.0)	1.6 (1.4, 4.6)
Primary tumor location			
Gastric	7 (25.9)	20 (74.1)	NE (3.7, NE)
GEJ	16 (30.8)	36 (69.2)	5.5 (4.2, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	4 (21.1)	15 (78.9)	NE (2.9, NE)
other	19 (32.2)	40 (67.8)	4.6 (4.2, NE)
Number of metastatic sites			
<2	1 (20.0)	4 (80.0)	4.6 (NE, NE)
>=2	22 (29.7)	52 (70.3)	NE (4.2, NE)
Previous total gastrectomy			
no	23 (29.1)	56 (70.9)	NE (4.2, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	5 (55.6)	4 (44.4)	3.7 (1.4, NE)
no	18 (25.7)	52 (74.3)	NE (4.2, NE)
Prior nivolumab or pembrolizumab treatment			
yes	2 (33.3)	4 (66.7)	4.6 (1.3, NE)
no	21 (28.8)	52 (71.2)	NE (4.2, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	2 (28.6)	5 (71.4)	4.6 (1.3, NE)
no	21 (29.2)	51 (70.8)	NE (4.2, NE)

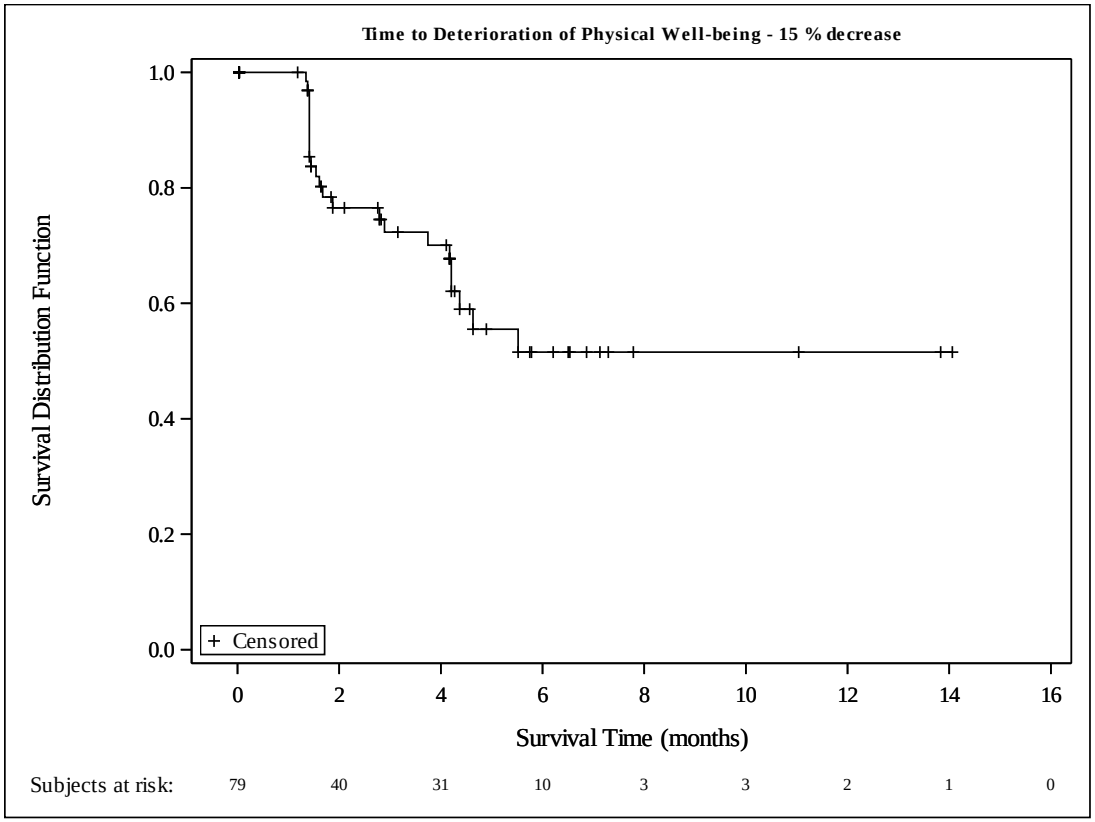
Time to Deterioration of Physical Well-being is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	13 (26.0)	37 (74.0)	NE (4.2, NE)
no	10 (34.5)	19 (65.5)	4.6 (2.8, NE)
Renal impairment at baseline			
normal	6 (18.8)	26 (81.3)	NE (4.2, NE)
mild	7 (28.0)	18 (72.0)	NE (3.7, NE)
moderate	3 (37.5)	5 (62.5)	5.5 (2.8, NE)
Hepatic impairment at baseline			
normal	22 (34.4)	42 (65.6)	4.6 (4.2, NE)
mild	1 (7.1)	13 (92.9)	NE (NE, NE)
Race			
White	18 (26.1)	51 (73.9)	NE (4.4, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	4 (50.0)	4 (50.0)	1.6 (1.4, NE)
Ethnicity			
Hispanic/Latino	2 (40.0)	3 (60.0)	4.2 (3.7, NE)
Non-Hispanic/Non-Latino	18 (25.7)	52 (74.3)	NE (4.4, NE)
Unknown	3 (75.0)	1 (25.0)	1.4 (1.4, 4.2)

Time to Deterioration of Physical Well-being is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	15 (19.0)	64 (81.0)	13.2 (8.5, NE)
Region			
North America	7 (20.6)	27 (79.4)	13.2 (4.2, NE)
EU	8 (17.8)	37 (82.2)	8.5 (8.5, NE)
Age (Category 1)			
<65 years	11 (23.9)	35 (76.1)	8.5 (8.5, NE)
>=65 years	4 (12.1)	29 (87.9)	13.2 (13.2, NE)
Age (Category 2)			
<75 years	15 (20.0)	60 (80.0)	13.2 (8.5, NE)
>=75 years	0 (0.0)	4 (100.0)	NE (NE, NE)
Sex			
female	4 (18.2)	18 (81.8)	NE (4.4, NE)
male	11 (19.3)	46 (80.7)	13.2 (8.5, NE)
ECOG PS			
0	8 (27.6)	21 (72.4)	8.5 (4.2, NE)
1	7 (14.0)	43 (86.0)	NE (13.2, NE)
HER2 Status in central laboratory			
IHC 3+	13 (19.1)	55 (80.9)	13.2 (8.5, NE)
IHC 2+/ISH +	2 (20.0)	8 (80.0)	NE (1.6, NE)
Primary tumor location			
Gastric	4 (14.8)	23 (85.2)	NE (4.4, NE)
GEJ	11 (21.2)	41 (78.8)	13.2 (8.5, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	4 (21.1)	15 (78.9)	8.5 (4.2, 8.5)
other	11 (18.6)	48 (81.4)	13.2 (13.2, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	15 (20.3)	59 (79.7)	13.2 (8.5, NE)
Previous total gastrectomy			
no	15 (19.0)	64 (81.0)	13.2 (8.5, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	1 (11.1)	8 (88.9)	8.5 (NE, NE)
no	14 (20.0)	56 (80.0)	13.2 (13.2, NE)
Prior nivolumab or pembrolizumab treatment			
yes	1 (16.7)	5 (83.3)	NE (1.3, NE)
no	14 (19.2)	59 (80.8)	13.2 (8.5, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	1 (14.3)	6 (85.7)	NE (1.3, NE)
no	14 (19.4)	58 (80.6)	13.2 (8.5, NE)

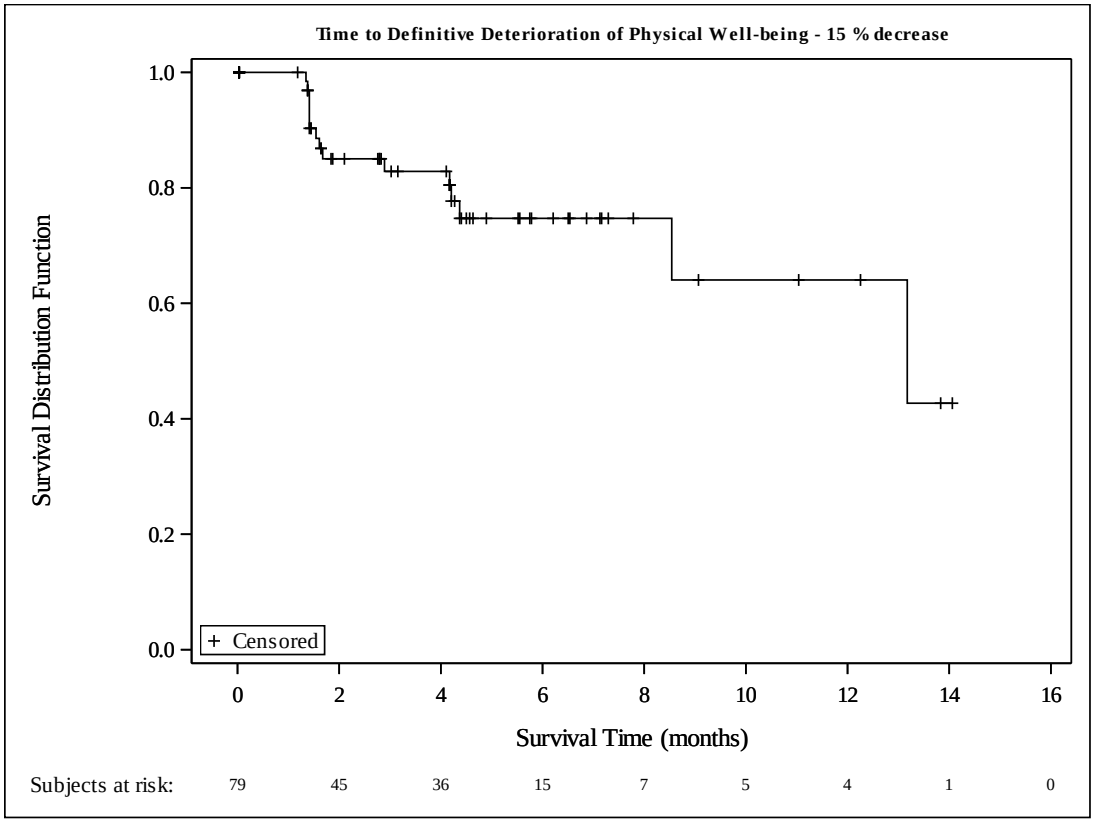
Time to Definitive Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	10 (20.0)	40 (80.0)	13.2 (8.5, NE)
no	5 (17.2)	24 (82.8)	NE (4.4, NE)
Renal impairment at baseline			
normal	6 (18.8)	26 (81.3)	NE (4.2, NE)
mild	4 (16.0)	21 (84.0)	NE (8.5, NE)
moderate	1 (12.5)	7 (87.5)	13.2 (NE, NE)
Hepatic impairment at baseline			
normal	15 (23.4)	49 (76.6)	13.2 (8.5, NE)
mild	0 (0.0)	14 (100.0)	NE (NE, NE)
Race			
White	12 (17.4)	57 (82.6)	13.2 (8.5, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	3 (37.5)	5 (62.5)	4.2 (1.4, NE)
Ethnicity			
Hispanic/Latino	1 (20.0)	4 (80.0)	NE (4.2, NE)
Non-Hispanic/Non-Latino	13 (18.6)	57 (81.4)	13.2 (8.5, NE)
Unknown	1 (25.0)	3 (75.0)	NE (4.2, NE)

Time to Definitive Deterioration of Physical Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Physical Well-being (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall					
	Cycle 3 Day 1	59	10 (16.9)	38 (64.4)	11 (18.6)
	Cycle 5 Day 1	41	10 (24.4)	28 (68.3)	3 (7.3)
	Cycle 7 Day 1	31	5 (16.1)	20 (64.5)	6 (19.4)
	Cycle 9 Day 1	19	2 (10.5)	13 (68.4)	4 (21.1)
	Cycle 11 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 13 Day 1	6	0 (0.0)	4 (66.7)	2 (33.3)
	Cycle 15 Day 1	8	1 (12.5)	5 (62.5)	2 (25.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	2 (6.5)	18 (58.1)	11 (35.5)
Region					
North America					
	Cycle 3 Day 1	22	1 (4.5)	16 (72.7)	5 (22.7)
	Cycle 5 Day 1	14	1 (7.1)	12 (85.7)	1 (7.1)
	Cycle 7 Day 1	11	0 (0.0)	8 (72.7)	3 (27.3)
	Cycle 9 Day 1	7	0 (0.0)	4 (57.1)	3 (42.9)
	Cycle 11 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 13 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 15 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	14	1 (7.1)	8 (57.1)	5 (35.7)
Region					
EU					
	Cycle 3 Day 1	37	9 (24.3)	22 (59.5)	6 (16.2)
	Cycle 5 Day 1	27	9 (33.3)	16 (59.3)	2 (7.4)
	Cycle 7 Day 1	20	5 (25.0)	12 (60.0)	3 (15.0)
	Cycle 9 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 11 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 13 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	17	1 (5.9)	10 (58.8)	6 (35.3)
Age (Category 1)					
<65 years					
	Cycle 3 Day 1	38	9 (23.7)	21 (55.3)	8 (21.1)
	Cycle 5 Day 1	26	9 (34.6)	16 (61.5)	1 (3.8)
	Cycle 7 Day 1	17	3 (17.6)	12 (70.6)	2 (11.8)
	Cycle 9 Day 1	12	2 (16.7)	8 (66.7)	2 (16.7)
	Cycle 11 Day 1	9	1 (11.1)	7 (77.8)	1 (11.1)
	Cycle 13 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 15 Day 1	4	1 (25.0)	1 (25.0)	2 (50.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	18	2 (11.1)	8 (44.4)	8 (44.4)
Age (Category 1)					
>=65 years					
	Cycle 3 Day 1	21	1 (4.8)	17 (81.0)	3 (14.3)
	Cycle 5 Day 1	15	1 (6.7)	12 (80.0)	2 (13.3)
	Cycle 7 Day 1	14	2 (14.3)	8 (57.1)	4 (28.6)
	Cycle 9 Day 1	7	0 (0.0)	5 (71.4)	2 (28.6)
	Cycle 11 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 13 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	13	0 (0.0)	10 (76.9)	3 (23.1)
Age (Category 2)					
<75 years					
	Cycle 3 Day 1	55	10 (18.2)	35 (63.6)	10 (18.2)
	Cycle 5 Day 1	38	10 (26.3)	25 (65.8)	3 (7.9)
	Cycle 7 Day 1	29	5 (17.2)	19 (65.5)	5 (17.2)
	Cycle 9 Day 1	17	2 (11.8)	11 (64.7)	4 (23.5)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	5	0 (0.0)	3 (60.0)	2 (40.0)
	Cycle 15 Day 1	7	1 (14.3)	4 (57.1)	2 (28.6)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	2 (6.5)	18 (58.1)	11 (35.5)
Age (Category 2)					
>=75 years					
	Cycle 3 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 5 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Sex					
female					
	Cycle 3 Day 1	18	2 (11.1)	14 (77.8)	2 (11.1)
	Cycle 5 Day 1	16	3 (18.8)	11 (68.8)	2 (12.5)
	Cycle 7 Day 1	12	2 (16.7)	8 (66.7)	2 (16.7)
	Cycle 9 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 11 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	7	0 (0.0)	4 (57.1)	3 (42.9)
Sex					
male					
	Cycle 3 Day 1	41	8 (19.5)	24 (58.5)	9 (22.0)
	Cycle 5 Day 1	25	7 (28.0)	17 (68.0)	1 (4.0)
	Cycle 7 Day 1	19	3 (15.8)	12 (63.2)	4 (21.1)
	Cycle 9 Day 1	13	1 (7.7)	9 (69.2)	3 (23.1)
	Cycle 11 Day 1	9	0 (0.0)	8 (88.9)	1 (11.1)
	Cycle 13 Day 1	4	0 (0.0)	2 (50.0)	2 (50.0)
	Cycle 15 Day 1	6	1 (16.7)	3 (50.0)	2 (33.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	24	2 (8.3)	14 (58.3)	8 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS					
0					
	Cycle 3 Day 1	21	1 (4.8)	13 (61.9)	7 (33.3)
	Cycle 5 Day 1	16	1 (6.3)	13 (81.3)	2 (12.5)
	Cycle 7 Day 1	10	0 (0.0)	7 (70.0)	3 (30.0)
	Cycle 9 Day 1	9	0 (0.0)	7 (77.8)	2 (22.2)
	Cycle 11 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 13 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 15 Day 1	4	0 (0.0)	2 (50.0)	2 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	15	1 (6.7)	8 (53.3)	6 (40.0)
ECOG PS					
1					
	Cycle 3 Day 1	38	9 (23.7)	25 (65.8)	4 (10.5)
	Cycle 5 Day 1	25	9 (36.0)	15 (60.0)	1 (4.0)
	Cycle 7 Day 1	21	5 (23.8)	13 (61.9)	3 (14.3)
	Cycle 9 Day 1	10	2 (20.0)	6 (60.0)	2 (20.0)
	Cycle 11 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	16	1 (6.3)	10 (62.5)	5 (31.3)
HER2 Status in central laboratory					
IHC 3+					
	Cycle 3 Day 1	56	10 (17.9)	36 (64.3)	10 (17.9)
	Cycle 5 Day 1	39	10 (25.6)	26 (66.7)	3 (7.7)
	Cycle 7 Day 1	29	5 (17.2)	19 (65.5)	5 (17.2)
	Cycle 9 Day 1	18	2 (11.1)	12 (66.7)	4 (22.2)
	Cycle 11 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 13 Day 1	6	0 (0.0)	4 (66.7)	2 (33.3)
	Cycle 15 Day 1	8	1 (12.5)	5 (62.5)	2 (25.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	25	2 (8.0)	14 (56.0)	9 (36.0)
HER2 Status in central laboratory					
IHC 2+/ISH +					
	Cycle 3 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	6	0 (0.0)	4 (66.7)	2 (33.3)
Primary tumor location					
Gastric					
	Cycle 3 Day 1	21	3 (14.3)	15 (71.4)	3 (14.3)
	Cycle 5 Day 1	17	4 (23.5)	12 (70.6)	1 (5.9)
	Cycle 7 Day 1	14	3 (21.4)	9 (64.3)	2 (14.3)
	Cycle 9 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 11 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	10	1 (10.0)	6 (60.0)	3 (30.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Primary tumor location					
GEJ					
	Cycle 3 Day 1	38	7 (18.4)	23 (60.5)	8 (21.1)
	Cycle 5 Day 1	24	6 (25.0)	16 (66.7)	2 (8.3)
	Cycle 7 Day 1	17	2 (11.8)	11 (64.7)	4 (23.5)
	Cycle 9 Day 1	13	2 (15.4)	8 (61.5)	3 (23.1)
	Cycle 11 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 13 Day 1	4	0 (0.0)	2 (50.0)	2 (50.0)
	Cycle 15 Day 1	6	1 (16.7)	3 (50.0)	2 (33.3)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	21	1 (4.8)	12 (57.1)	8 (38.1)
Histological subtype					
diffuse					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Histological subtype					
intestinal					
	Cycle 3 Day 1	14	4 (28.6)	8 (57.1)	2 (14.3)
	Cycle 5 Day 1	11	4 (36.4)	6 (54.5)	1 (9.1)
	Cycle 7 Day 1	8	3 (37.5)	4 (50.0)	1 (12.5)
	Cycle 9 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 11 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 15 Day 1	2	0 (0.0)	0 (0.0)	2 (100.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	8	1 (12.5)	5 (62.5)	2 (25.0)
Histological subtype					
other					
	Cycle 3 Day 1	44	6 (13.6)	29 (65.9)	9 (20.5)
	Cycle 5 Day 1	29	6 (20.7)	21 (72.4)	2 (6.9)
	Cycle 7 Day 1	22	2 (9.1)	15 (68.2)	5 (22.7)
	Cycle 9 Day 1	13	2 (15.4)	8 (61.5)	3 (23.1)
	Cycle 11 Day 1	9	1 (11.1)	6 (66.7)	2 (22.2)
	Cycle 13 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 15 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	22	1 (4.5)	12 (54.5)	9 (40.9)
Number of metastatic sites					
<2					
	Cycle 3 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 5 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 7 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Number of metastatic sites					
>=2					
	Cycle 3 Day 1	56	9 (16.1)	36 (64.3)	11 (19.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 5 Day 1	38	9 (23.7)	26 (68.4)	3 (7.9)
	Cycle 7 Day 1	27	5 (18.5)	17 (63.0)	5 (18.5)
	Cycle 9 Day 1	18	2 (11.1)	12 (66.7)	4 (22.2)
	Cycle 11 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 13 Day 1	6	0 (0.0)	4 (66.7)	2 (33.3)
	Cycle 15 Day 1	8	1 (12.5)	5 (62.5)	2 (25.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	29	2 (6.9)	16 (55.2)	11 (37.9)
Previous total gastrectomy					
no					
	Cycle 3 Day 1	59	10 (16.9)	38 (64.4)	11 (18.6)
	Cycle 5 Day 1	41	10 (24.4)	28 (68.3)	3 (7.3)
	Cycle 7 Day 1	31	5 (16.1)	20 (64.5)	6 (19.4)
	Cycle 9 Day 1	19	2 (10.5)	13 (68.4)	4 (21.1)
	Cycle 11 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 13 Day 1	6	0 (0.0)	4 (66.7)	2 (33.3)
	Cycle 15 Day 1	8	1 (12.5)	5 (62.5)	2 (25.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	2 (6.5)	18 (58.1)	11 (35.5)
Prior adjuvant/ neoadjuvant therapy					
yes					
	Cycle 3 Day 1	7	2 (28.6)	2 (28.6)	3 (42.9)
	Cycle 5 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 7 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 9 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 15 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy					
no					
	Cycle 3 Day 1	52	8 (15.4)	36 (69.2)	8 (15.4)
	Cycle 5 Day 1	35	8 (22.9)	25 (71.4)	2 (5.7)
	Cycle 7 Day 1	24	4 (16.7)	15 (62.5)	5 (20.8)
	Cycle 9 Day 1	17	1 (5.9)	12 (70.6)	4 (23.5)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	2 (6.7)	17 (56.7)	11 (36.7)
Prior nivolumab or pembrolizumab treatment					
yes					
	Cycle 3 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior nivolumab or pembrolizumab treatment					
no					
	Cycle 3 Day 1	57	10 (17.5)	37 (64.9)	10 (17.5)
	Cycle 5 Day 1	40	10 (25.0)	27 (67.5)	3 (7.5)
	Cycle 7 Day 1	29	5 (17.2)	19 (65.5)	5 (17.2)
	Cycle 9 Day 1	19	2 (10.5)	13 (68.4)	4 (21.1)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	6	0 (0.0)	4 (66.7)	2 (33.3)
	Cycle 15 Day 1	7	1 (14.3)	4 (57.1)	2 (28.6)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	2 (6.7)	17 (56.7)	11 (36.7)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
yes					
	Cycle 3 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
no					
	Cycle 3 Day 1	56	10 (17.9)	36 (64.3)	10 (17.9)
	Cycle 5 Day 1	39	10 (25.6)	26 (66.7)	3 (7.7)
	Cycle 7 Day 1	29	5 (17.2)	19 (65.5)	5 (17.2)
	Cycle 9 Day 1	19	2 (10.5)	13 (68.4)	4 (21.1)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	6	0 (0.0)	4 (66.7)	2 (33.3)
	Cycle 15 Day 1	7	1 (14.3)	4 (57.1)	2 (28.6)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	2 (6.7)	17 (56.7)	11 (36.7)
Presence of liver metastasis at baseline					
yes					
	Cycle 3 Day 1	36	4 (11.1)	25 (69.4)	7 (19.4)
	Cycle 5 Day 1	25	4 (16.0)	20 (80.0)	1 (4.0)
	Cycle 7 Day 1	17	2 (11.8)	11 (64.7)	4 (23.5)
	Cycle 9 Day 1	14	0 (0.0)	11 (78.6)	3 (21.4)
	Cycle 11 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 13 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 15 Day 1	6	1 (16.7)	3 (50.0)	2 (33.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	18	1 (5.6)	10 (55.6)	7 (38.9)
Presence of liver metastasis at baseline					
no					
	Cycle 3 Day 1	23	6 (26.1)	13 (56.5)	4 (17.4)
	Cycle 5 Day 1	16	6 (37.5)	8 (50.0)	2 (12.5)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 7 Day 1	14	3 (21.4)	9 (64.3)	2 (14.3)
	Cycle 9 Day 1	5	2 (40.0)	2 (40.0)	1 (20.0)
	Cycle 11 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 13 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	1 (7.7)	8 (61.5)	4 (30.8)
Renal impairment at baseline					
normal					
	Cycle 3 Day 1	24	6 (25.0)	15 (62.5)	3 (12.5)
	Cycle 5 Day 1	13	5 (38.5)	7 (53.8)	1 (7.7)
	Cycle 7 Day 1	7	2 (28.6)	3 (42.9)	2 (28.6)
	Cycle 9 Day 1	6	1 (16.7)	3 (50.0)	2 (33.3)
	Cycle 11 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	1 (50.0)	0 (0.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	1 (7.7)	7 (53.8)	5 (38.5)
Renal impairment at baseline					
mild					
	Cycle 3 Day 1	15	2 (13.3)	10 (66.7)	3 (20.0)
	Cycle 5 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 7 Day 1	10	1 (10.0)	7 (70.0)	2 (20.0)
	Cycle 9 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 15 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	9 (75.0)	3 (25.0)
Renal impairment at baseline					
moderate					
	Cycle 3 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 5 Day 1	7	2 (28.6)	4 (57.1)	1 (14.3)
	Cycle 7 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 9 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline					
normal					
	Cycle 3 Day 1	47	7 (14.9)	30 (63.8)	10 (21.3)
	Cycle 5 Day 1	32	8 (25.0)	21 (65.6)	3 (9.4)
	Cycle 7 Day 1	27	3 (11.1)	18 (66.7)	6 (22.2)
	Cycle 9 Day 1	16	1 (6.3)	11 (68.8)	4 (25.0)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	5	0 (0.0)	3 (60.0)	2 (40.0)
	Cycle 15 Day 1	7	1 (14.3)	4 (57.1)	2 (28.6)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	28	2 (7.1)	15 (53.6)	11 (39.3)
Hepatic impairment at baseline					
mild					
	Cycle 3 Day 1	12	3 (25.0)	8 (66.7)	1 (8.3)
	Cycle 5 Day 1	9	2 (22.2)	7 (77.8)	0 (0.0)
	Cycle 7 Day 1	4	2 (50.0)	2 (50.0)	0 (0.0)
	Cycle 9 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Race					
White					
	Cycle 3 Day 1	52	9 (17.3)	35 (67.3)	8 (15.4)
	Cycle 5 Day 1	35	9 (25.7)	24 (68.6)	2 (5.7)
	Cycle 7 Day 1	27	4 (14.8)	18 (66.7)	5 (18.5)
	Cycle 9 Day 1	17	2 (11.8)	12 (70.6)	3 (17.6)
	Cycle 11 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 13 Day 1	6	0 (0.0)	4 (66.7)	2 (33.3)
	Cycle 15 Day 1	8	1 (12.5)	5 (62.5)	2 (25.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	27	2 (7.4)	17 (63.0)	8 (29.6)
Race					
Black or African American					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Race					
Other					
	Cycle 3 Day 1	5	1 (20.0)	2 (40.0)	2 (40.0)
	Cycle 5 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 7 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 9 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 11 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	4	0 (0.0)	1 (25.0)	3 (75.0)
Ethnicity					
Hispanic/Latino					
	Cycle 3 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 5 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 7 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 9 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 11 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	3	0 (0.0)	2 (66.7)	1 (33.3)
Ethnicity					
Non-Hispanic/Non-Latino					
	Cycle 3 Day 1	50	10 (20.0)	31 (62.0)	9 (18.0)
	Cycle 5 Day 1	35	10 (28.6)	22 (62.9)	3 (8.6)
	Cycle 7 Day 1	27	5 (18.5)	18 (66.7)	4 (14.8)
	Cycle 9 Day 1	16	2 (12.5)	11 (68.8)	3 (18.8)
	Cycle 11 Day 1	11	1 (9.1)	8 (72.7)	2 (18.2)
	Cycle 13 Day 1	5	0 (0.0)	3 (60.0)	2 (40.0)
	Cycle 15 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Physical Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	26	2 (7.7)	15 (57.7)	9 (34.6)
Ethnicity					
Unknown					
	Cycle 3 Day 1	4	0 (0.0)	2 (50.0)	2 (50.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	1 (50.0)	1 (50.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Social/Family Well-being Completion Rates by Visit
Full Analysis Set

	T-DXd (N=79)	
Visit	Number of subjects alive	Completed (%)
Baseline	79	71 (89.9)
Cycle 3 Day 1	78	59 (75.6)
Cycle 5 Day 1	76	41 (53.9)
Cycle 7 Day 1	72	32 (44.4)
Cycle 9 Day 1	60	19 (31.7)
Cycle 11 Day 1	44	13 (29.5)
Cycle 13 Day 1	32	6 (18.8)
Cycle 15 Day 1	21	8 (38.1)
Cycle 17 Day 1	18	4 (22.2)
Cycle 19 Day 1	16	3 (18.8)
Cycle 21 Day 1	11	3 (27.3)
Cycle 23 Day 1	7	1 (14.3)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

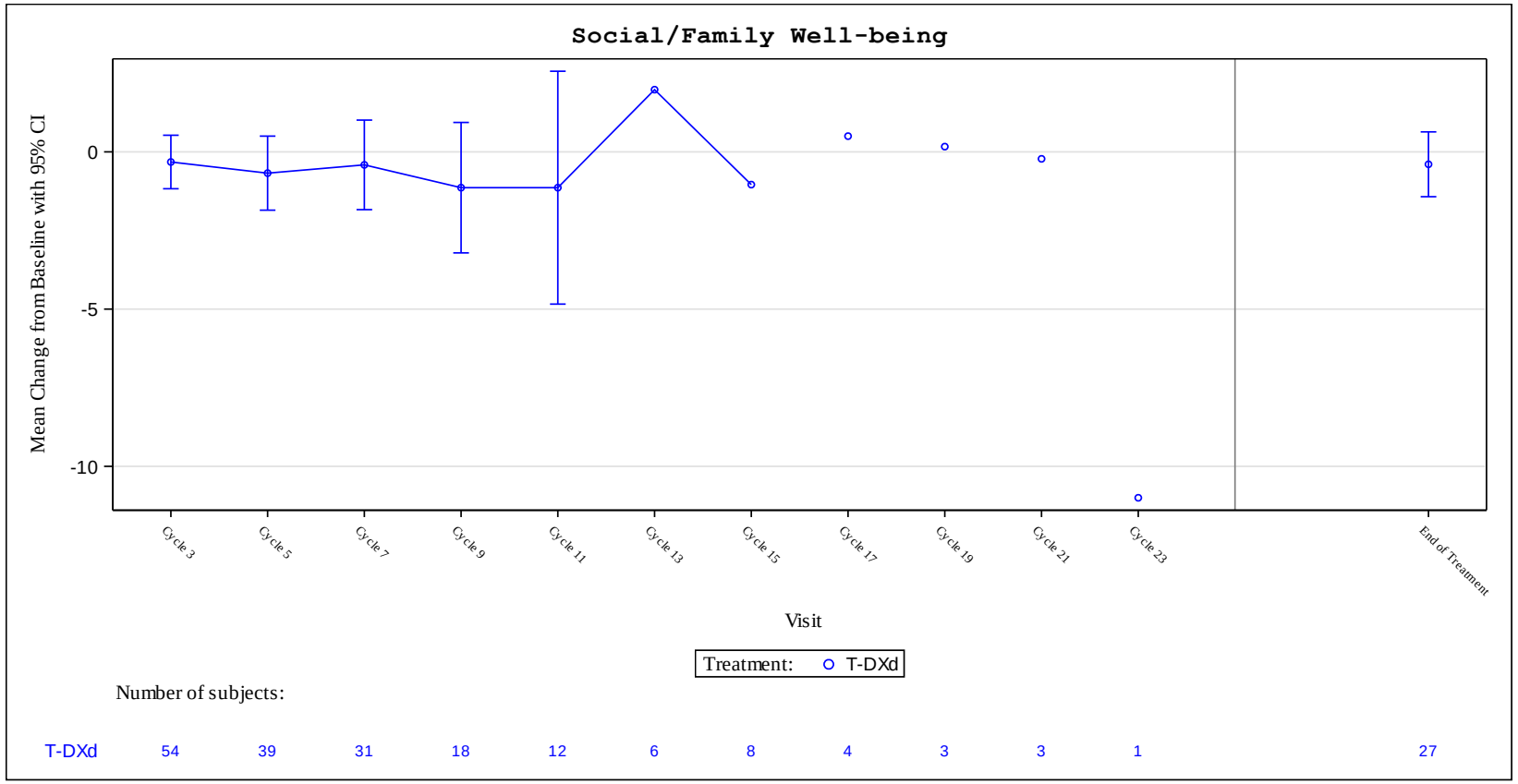
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Social/Family Well-being by Visit
Full Analysis Set

	T-DXd (N=79)			
	Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)
Baseline	71	22.9 (4.83)		
Cycle 3 Day 1	59	22.3 (5.14)	54	-0.3 (3.12)
Cycle 5 Day 1	41	21.7 (5.74)	39	-0.7 (3.63)
Cycle 7 Day 1	32	21.8 (5.50)	31	-0.4 (3.88)
Cycle 9 Day 1	19	22.7 (5.12)	18	-1.1 (4.17)
Cycle 11 Day 1	13	22.4 (7.12)	12	-1.1 (5.83)
Cycle 13 Day 1	6	24.4 (3.02)	6	2.0 (3.13)
Cycle 15 Day 1	8	23.8 (4.77)	8	-1.0 (5.28)
Cycle 17 Day 1	4	25.0 (3.56)	4	0.5 (1.00)
Cycle 19 Day 1	3	26.2 (0.60)	3	0.2 (2.17)
Cycle 21 Day 1	3	25.8 (1.18)	3	-0.2 (1.49)
Cycle 23 Day 1	1	17.0 (-)	1	-11.0 (-)
End of Treatment	31	23.3 (5.12)	27	-0.4 (2.60)

Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Graphical Summary of Social/Family Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADQS

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	11 (13.9)	68 (86.1)	NE (NE, NE)
Region			
North America	4 (11.8)	30 (88.2)	NE (4.2, NE)
EU	7 (15.6)	38 (84.4)	NE (NE, NE)
Age (Category 1)			
<65 years	6 (13.0)	40 (87.0)	NE (NE, NE)
>=65 years	5 (15.2)	28 (84.8)	NE (4.1, NE)
Age (Category 2)			
<75 years	9 (12.0)	66 (88.0)	NE (NE, NE)
>=75 years	2 (50.0)	2 (50.0)	NE (1.3, NE)
Sex			
female	5 (22.7)	17 (77.3)	NE (4.6, NE)
male	6 (10.5)	51 (89.5)	NE (NE, NE)
ECOG PS			
0	1 (3.4)	28 (96.6)	NE (NE, NE)
1	10 (20.0)	40 (80.0)	NE (4.6, NE)
HER2 Status in central laboratory			
IHC 3+	11 (16.2)	57 (83.8)	NE (NE, NE)
IHC 2+/ISH +	0 (0.0)	10 (100.0)	NE (NE, NE)
Primary tumor location			
Gastric	6 (22.2)	21 (77.8)	NE (2.8, NE)
GEJ	5 (9.6)	47 (90.4)	NE (NE, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	4 (21.1)	15 (78.9)	NE (4.2, NE)
other	7 (11.9)	52 (88.1)	NE (NE, NE)
Number of metastatic sites			
<2	1 (20.0)	4 (80.0)	NE (2.8, NE)
>=2	10 (13.5)	64 (86.5)	NE (NE, NE)
Previous total gastrectomy			
no	11 (13.9)	68 (86.1)	NE (NE, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	1 (11.1)	8 (88.9)	NE (2.8, NE)
no	10 (14.3)	60 (85.7)	NE (NE, NE)
Prior nivolumab or pembrolizumab treatment			
yes	1 (16.7)	5 (83.3)	NE (2.8, NE)
no	10 (13.7)	63 (86.3)	NE (NE, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	1 (14.3)	6 (85.7)	NE (2.8, NE)
no	10 (13.9)	62 (86.1)	NE (NE, NE)

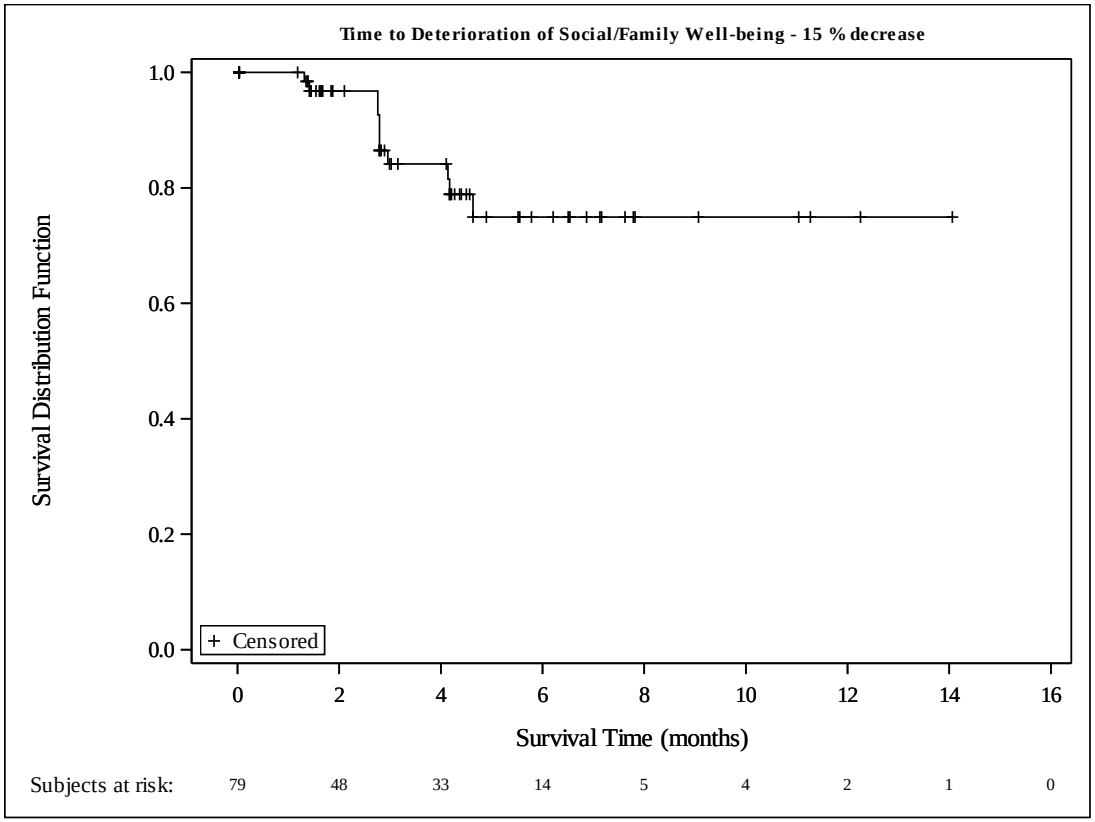
Time to Deterioration of Social/Family Well-being is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	8 (16.0)	42 (84.0)	NE (4.2, NE)
no	3 (10.3)	26 (89.7)	NE (4.6, NE)
Renal impairment at baseline			
normal	3 (9.4)	29 (90.6)	NE (4.2, NE)
mild	3 (12.0)	22 (88.0)	NE (NE, NE)
moderate	2 (25.0)	6 (75.0)	NE (1.3, NE)
Hepatic impairment at baseline			
normal	10 (15.6)	54 (84.4)	NE (NE, NE)
mild	1 (7.1)	13 (92.9)	NE (2.8, NE)
Race			
White	10 (14.5)	59 (85.5)	NE (NE, NE)
Black or African American	1 (100.0)	0 (0.0)	2.8 (NE, NE)
Other	0 (0.0)	8 (100.0)	NE (NE, NE)
Ethnicity			
Hispanic/Latino	1 (20.0)	4 (80.0)	NE (4.2, NE)
Non-Hispanic/Non-Latino	10 (14.3)	60 (85.7)	NE (NE, NE)
Unknown	0 (0.0)	4 (100.0)	NE (NE, NE)

Time to Deterioration of Social/Family Well-being is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	7 (8.9)	72 (91.1)	NE (NE, NE)
Region			
North America	3 (8.8)	31 (91.2)	NE (4.2, NE)
EU	4 (8.9)	41 (91.1)	NE (NE, NE)
Age (Category 1)			
<65 years	5 (10.9)	41 (89.1)	NE (NE, NE)
>=65 years	2 (6.1)	31 (93.9)	NE (NE, NE)
Age (Category 2)			
<75 years	6 (8.0)	69 (92.0)	NE (NE, NE)
>=75 years	1 (25.0)	3 (75.0)	NE (2.8, NE)
Sex			
female	2 (9.1)	20 (90.9)	NE (NE, NE)
male	5 (8.8)	52 (91.2)	NE (NE, NE)
ECOG PS			
0	1 (3.4)	28 (96.6)	NE (NE, NE)
1	6 (12.0)	44 (88.0)	NE (NE, NE)
HER2 Status in central laboratory			
IHC 3+	7 (10.3)	61 (89.7)	NE (NE, NE)
IHC 2+/ISH +	0 (0.0)	10 (100.0)	NE (NE, NE)
Primary tumor location			
Gastric	3 (11.1)	24 (88.9)	NE (4.6, NE)
GEJ	4 (7.7)	48 (92.3)	NE (NE, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	3 (15.8)	16 (84.2)	NE (4.2, NE)
other	4 (6.8)	55 (93.2)	NE (NE, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	7 (9.5)	67 (90.5)	NE (NE, NE)
Previous total gastrectomy			
no	7 (8.9)	72 (91.1)	NE (NE, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	0 (0.0)	9 (100.0)	NE (NE, NE)
no	7 (10.0)	63 (90.0)	NE (NE, NE)
Prior nivolumab or pembrolizumab treatment			
yes	0 (0.0)	6 (100.0)	NE (NE, NE)
no	7 (9.6)	66 (90.4)	NE (NE, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	0 (0.0)	7 (100.0)	NE (NE, NE)
no	7 (9.7)	65 (90.3)	NE (NE, NE)

Time to Definitive Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

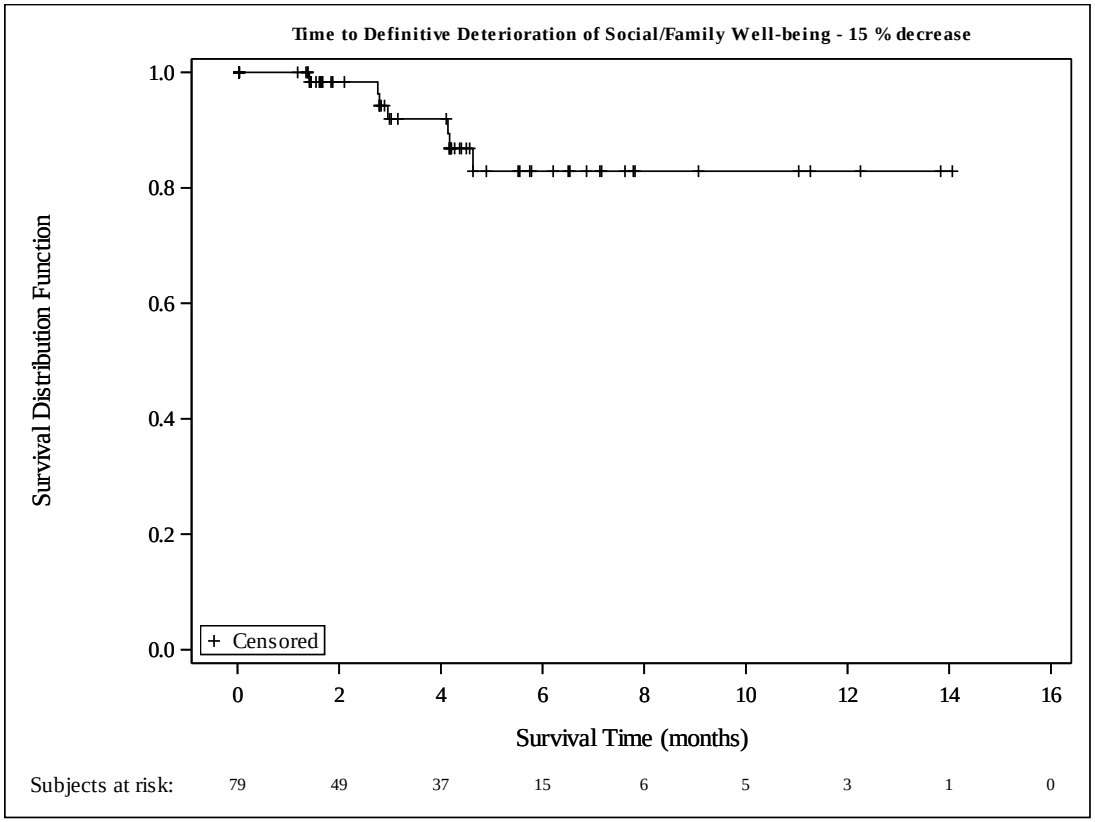
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	6 (12.0)	44 (88.0)	NE (NE, NE)
no	1 (3.4)	28 (96.6)	NE (4.6, NE)
Renal impairment at baseline			
normal	2 (6.3)	30 (93.8)	NE (4.2, NE)
mild	1 (4.0)	24 (96.0)	NE (NE, NE)
moderate	1 (12.5)	7 (87.5)	NE (4.1, NE)
Hepatic impairment at baseline			
normal	6 (9.4)	58 (90.6)	NE (NE, NE)
mild	1 (7.1)	13 (92.9)	NE (2.8, NE)
Race			
White	6 (8.7)	63 (91.3)	NE (NE, NE)
Black or African American	1 (100.0)	0 (0.0)	2.8 (NE, NE)
Other	0 (0.0)	8 (100.0)	NE (NE, NE)
Ethnicity			
Hispanic/Latino	1 (20.0)	4 (80.0)	NE (4.2, NE)
Non-Hispanic/Non-Latino	6 (8.6)	64 (91.4)	NE (NE, NE)
Unknown	0 (0.0)	4 (100.0)	NE (NE, NE)

Time to Definitive Deterioration of Social/Family Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Social/Family Well-being (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall					
	Cycle 3 Day 1	59	4 (6.8)	53 (89.8)	2 (3.4)
	Cycle 5 Day 1	41	3 (7.3)	32 (78.0)	6 (14.6)
	Cycle 7 Day 1	32	2 (6.3)	26 (81.3)	4 (12.5)
	Cycle 9 Day 1	19	1 (5.3)	15 (78.9)	3 (15.8)
	Cycle 11 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 13 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	29 (93.5)	2 (6.5)
Region					
North America					
	Cycle 3 Day 1	22	2 (9.1)	20 (90.9)	0 (0.0)
	Cycle 5 Day 1	14	1 (7.1)	11 (78.6)	2 (14.3)
	Cycle 7 Day 1	11	1 (9.1)	8 (72.7)	2 (18.2)
	Cycle 9 Day 1	7	1 (14.3)	4 (57.1)	2 (28.6)
	Cycle 11 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	14	0 (0.0)	13 (92.9)	1 (7.1)
Region					
EU					
	Cycle 3 Day 1	37	2 (5.4)	33 (89.2)	2 (5.4)
	Cycle 5 Day 1	27	2 (7.4)	21 (77.8)	4 (14.8)
	Cycle 7 Day 1	21	1 (4.8)	18 (85.7)	2 (9.5)
	Cycle 9 Day 1	12	0 (0.0)	11 (91.7)	1 (8.3)
	Cycle 11 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	17	0 (0.0)	16 (94.1)	1 (5.9)
Age (Category 1)					
<65 years					
	Cycle 3 Day 1	38	2 (5.3)	35 (92.1)	1 (2.6)
	Cycle 5 Day 1	26	1 (3.8)	22 (84.6)	3 (11.5)
	Cycle 7 Day 1	17	1 (5.9)	13 (76.5)	3 (17.6)
	Cycle 9 Day 1	12	0 (0.0)	10 (83.3)	2 (16.7)
	Cycle 11 Day 1	9	1 (11.1)	6 (66.7)	2 (22.2)
	Cycle 13 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	18	0 (0.0)	16 (88.9)	2 (11.1)
Age (Category 1)					
>=65 years					
	Cycle 3 Day 1	21	2 (9.5)	18 (85.7)	1 (4.8)
	Cycle 5 Day 1	15	2 (13.3)	10 (66.7)	3 (20.0)
	Cycle 7 Day 1	15	1 (6.7)	13 (86.7)	1 (6.7)
	Cycle 9 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 11 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 13 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 15 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	13	0 (0.0)	13 (100.0)	0 (0.0)
Age (Category 2)					
<75 years					
	Cycle 3 Day 1	55	4 (7.3)	50 (90.9)	1 (1.8)
	Cycle 5 Day 1	38	3 (7.9)	30 (78.9)	5 (13.2)
	Cycle 7 Day 1	30	2 (6.7)	24 (80.0)	4 (13.3)
	Cycle 9 Day 1	17	1 (5.9)	13 (76.5)	3 (17.6)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	29 (93.5)	2 (6.5)
Age (Category 2)					
>=75 years					
	Cycle 3 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 5 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Sex					
female					
	Cycle 3 Day 1	18	2 (11.1)	15 (83.3)	1 (5.6)
	Cycle 5 Day 1	16	2 (12.5)	11 (68.8)	3 (18.8)
	Cycle 7 Day 1	13	1 (7.7)	11 (84.6)	1 (7.7)
	Cycle 9 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 11 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 13 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	7	0 (0.0)	7 (100.0)	0 (0.0)
Sex					
male					
	Cycle 3 Day 1	41	2 (4.9)	38 (92.7)	1 (2.4)
	Cycle 5 Day 1	25	1 (4.0)	21 (84.0)	3 (12.0)
	Cycle 7 Day 1	19	1 (5.3)	15 (78.9)	3 (15.8)
	Cycle 9 Day 1	13	1 (7.7)	9 (69.2)	3 (23.1)
	Cycle 11 Day 1	9	0 (0.0)	7 (77.8)	2 (22.2)
	Cycle 13 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 15 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	24	0 (0.0)	22 (91.7)	2 (8.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS					
0					
	Cycle 3 Day 1	21	2 (9.5)	19 (90.5)	0 (0.0)
	Cycle 5 Day 1	16	1 (6.3)	15 (93.8)	0 (0.0)
	Cycle 7 Day 1	11	0 (0.0)	10 (90.9)	1 (9.1)
	Cycle 9 Day 1	9	1 (11.1)	7 (77.8)	1 (11.1)
	Cycle 11 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	15	0 (0.0)	14 (93.3)	1 (6.7)
ECOG PS					
1					
	Cycle 3 Day 1	38	2 (5.3)	34 (89.5)	2 (5.3)
	Cycle 5 Day 1	25	2 (8.0)	17 (68.0)	6 (24.0)
	Cycle 7 Day 1	21	2 (9.5)	16 (76.2)	3 (14.3)
	Cycle 9 Day 1	10	0 (0.0)	8 (80.0)	2 (20.0)
	Cycle 11 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	16	0 (0.0)	15 (93.8)	1 (6.3)
HER2 Status in central laboratory					
IHC 3+					
	Cycle 3 Day 1	56	4 (7.1)	50 (89.3)	2 (3.6)
	Cycle 5 Day 1	39	3 (7.7)	30 (76.9)	6 (15.4)
	Cycle 7 Day 1	30	2 (6.7)	24 (80.0)	4 (13.3)
	Cycle 9 Day 1	18	1 (5.6)	14 (77.8)	3 (16.7)
	Cycle 11 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 13 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	25	0 (0.0)	23 (92.0)	2 (8.0)
HER2 Status in central laboratory					
IHC 2+/ISH +					
	Cycle 3 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	6	0 (0.0)	6 (100.0)	0 (0.0)
Primary tumor location					
Gastric					
	Cycle 3 Day 1	21	2 (9.5)	17 (81.0)	2 (9.5)
	Cycle 5 Day 1	17	2 (11.8)	11 (64.7)	4 (23.5)
	Cycle 7 Day 1	15	2 (13.3)	11 (73.3)	2 (13.3)
	Cycle 9 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 11 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 13 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	10	0 (0.0)	10 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Primary tumor location					
GEJ					
	Cycle 3 Day 1	38	2 (5.3)	36 (94.7)	0 (0.0)
	Cycle 5 Day 1	24	1 (4.2)	21 (87.5)	2 (8.3)
	Cycle 7 Day 1	17	0 (0.0)	15 (88.2)	2 (11.8)
	Cycle 9 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 11 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 13 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 15 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	21	0 (0.0)	19 (90.5)	2 (9.5)
Histological subtype					
diffuse					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Histological subtype					
intestinal					
	Cycle 3 Day 1	14	0 (0.0)	12 (85.7)	2 (14.3)
	Cycle 5 Day 1	11	1 (9.1)	9 (81.8)	1 (9.1)
	Cycle 7 Day 1	8	1 (12.5)	4 (50.0)	3 (37.5)
	Cycle 9 Day 1	5	0 (0.0)	3 (60.0)	2 (40.0)
	Cycle 11 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	8	0 (0.0)	7 (87.5)	1 (12.5)
Histological subtype					
other					
	Cycle 3 Day 1	44	4 (9.1)	40 (90.9)	0 (0.0)
	Cycle 5 Day 1	29	2 (6.9)	22 (75.9)	5 (17.2)
	Cycle 7 Day 1	23	1 (4.3)	21 (91.3)	1 (4.3)
	Cycle 9 Day 1	13	1 (7.7)	11 (84.6)	1 (7.7)
	Cycle 11 Day 1	9	1 (11.1)	8 (88.9)	0 (0.0)
	Cycle 13 Day 1	4	2 (50.0)	2 (50.0)	0 (0.0)
	Cycle 15 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	22	0 (0.0)	21 (95.5)	1 (4.5)
Number of metastatic sites					
<2					
	Cycle 3 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 5 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 7 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Number of metastatic sites					
>=2					
	Cycle 3 Day 1	56	3 (5.4)	51 (91.1)	2 (3.6)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 5 Day 1	38	2 (5.3)	31 (81.6)	5 (13.2)
	Cycle 7 Day 1	28	1 (3.6)	23 (82.1)	4 (14.3)
	Cycle 9 Day 1	18	1 (5.6)	14 (77.8)	3 (16.7)
	Cycle 11 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 13 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	29	0 (0.0)	27 (93.1)	2 (6.9)
Previous total gastrectomy					
no					
	Cycle 3 Day 1	59	4 (6.8)	53 (89.8)	2 (3.4)
	Cycle 5 Day 1	41	3 (7.3)	32 (78.0)	6 (14.6)
	Cycle 7 Day 1	32	2 (6.3)	26 (81.3)	4 (12.5)
	Cycle 9 Day 1	19	1 (5.3)	15 (78.9)	3 (15.8)
	Cycle 11 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 13 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	29 (93.5)	2 (6.5)
Prior adjuvant/ neoadjuvant therapy					
yes					
	Cycle 3 Day 1	7	2 (28.6)	5 (71.4)	0 (0.0)
	Cycle 5 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 7 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy					
no					
	Cycle 3 Day 1	52	2 (3.8)	48 (92.3)	2 (3.8)
	Cycle 5 Day 1	35	1 (2.9)	29 (82.9)	5 (14.3)
	Cycle 7 Day 1	25	1 (4.0)	20 (80.0)	4 (16.0)
	Cycle 9 Day 1	17	1 (5.9)	13 (76.5)	3 (17.6)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	28 (93.3)	2 (6.7)
Prior nivolumab or pembrolizumab treatment					
yes					
	Cycle 3 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior nivolumab or pembrolizumab treatment					
no					
	Cycle 3 Day 1	57	4 (7.0)	51 (89.5)	2 (3.5)
	Cycle 5 Day 1	40	3 (7.5)	32 (80.0)	5 (12.5)
	Cycle 7 Day 1	30	2 (6.7)	24 (80.0)	4 (13.3)
	Cycle 9 Day 1	19	1 (5.3)	15 (78.9)	3 (15.8)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	28 (93.3)	2 (6.7)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
yes					
	Cycle 3 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
no					
	Cycle 3 Day 1	56	4 (7.1)	50 (89.3)	2 (3.6)
	Cycle 5 Day 1	39	3 (7.7)	31 (79.5)	5 (12.8)
	Cycle 7 Day 1	30	2 (6.7)	24 (80.0)	4 (13.3)
	Cycle 9 Day 1	19	1 (5.3)	15 (78.9)	3 (15.8)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	28 (93.3)	2 (6.7)
Presence of liver metastasis at baseline					
yes					
	Cycle 3 Day 1	36	0 (0.0)	34 (94.4)	2 (5.6)
	Cycle 5 Day 1	25	0 (0.0)	21 (84.0)	4 (16.0)
	Cycle 7 Day 1	18	0 (0.0)	15 (83.3)	3 (16.7)
	Cycle 9 Day 1	14	0 (0.0)	11 (78.6)	3 (21.4)
	Cycle 11 Day 1	8	0 (0.0)	6 (75.0)	2 (25.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	18	0 (0.0)	16 (88.9)	2 (11.1)
Presence of liver metastasis at baseline					
no					
	Cycle 3 Day 1	23	4 (17.4)	19 (82.6)	0 (0.0)
	Cycle 5 Day 1	16	3 (18.8)	11 (68.8)	2 (12.5)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 7 Day 1	14	2 (14.3)	11 (78.6)	1 (7.1)
	Cycle 9 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 11 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 13 Day 1	2	2 (100.0)	0 (0.0)	0 (0.0)
	Cycle 15 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	13 (100.0)	0 (0.0)
Renal impairment at baseline					
normal					
	Cycle 3 Day 1	24	0 (0.0)	24 (100.0)	0 (0.0)
	Cycle 5 Day 1	13	0 (0.0)	11 (84.6)	2 (15.4)
	Cycle 7 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 9 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 11 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	12 (92.3)	1 (7.7)
Renal impairment at baseline					
mild					
	Cycle 3 Day 1	15	0 (0.0)	14 (93.3)	1 (6.7)
	Cycle 5 Day 1	12	0 (0.0)	9 (75.0)	3 (25.0)
	Cycle 7 Day 1	11	0 (0.0)	10 (90.9)	1 (9.1)
	Cycle 9 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 11 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	12 (100.0)	0 (0.0)
Renal impairment at baseline					
moderate					
	Cycle 3 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 5 Day 1	7	2 (28.6)	5 (71.4)	0 (0.0)
	Cycle 7 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 9 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 13 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline					
normal					
	Cycle 3 Day 1	47	4 (8.5)	41 (87.2)	2 (4.3)
	Cycle 5 Day 1	32	3 (9.4)	24 (75.0)	5 (15.6)
	Cycle 7 Day 1	27	2 (7.4)	21 (77.8)	4 (14.8)
	Cycle 9 Day 1	16	1 (6.3)	12 (75.0)	3 (18.8)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 15 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)

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Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
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Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	28	0 (0.0)	26 (92.9)	2 (7.1)
Hepatic impairment at baseline					
mild					
	Cycle 3 Day 1	12	0 (0.0)	12 (100.0)	0 (0.0)
	Cycle 5 Day 1	9	0 (0.0)	8 (88.9)	1 (11.1)
	Cycle 7 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 9 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Race					
White					
	Cycle 3 Day 1	52	4 (7.7)	46 (88.5)	2 (3.8)
	Cycle 5 Day 1	35	3 (8.6)	27 (77.1)	5 (14.3)
	Cycle 7 Day 1	28	2 (7.1)	22 (78.6)	4 (14.3)
	Cycle 9 Day 1	17	1 (5.9)	13 (76.5)	3 (17.6)
	Cycle 11 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 13 Day 1	6	2 (33.3)	4 (66.7)	0 (0.0)
	Cycle 15 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	27	0 (0.0)	25 (92.6)	2 (7.4)
Race					
Black or African American					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
Race					
Other					
	Cycle 3 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 5 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 7 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	4 (100.0)	0 (0.0)
Ethnicity					
Hispanic/Latino					
	Cycle 3 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 5 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 7 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 9 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 11 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	3	0 (0.0)	2 (66.7)	1 (33.3)
Ethnicity					
Non-Hispanic/Non-Latino					
	Cycle 3 Day 1	50	4 (8.0)	44 (88.0)	2 (4.0)
	Cycle 5 Day 1	35	3 (8.6)	26 (74.3)	6 (17.1)
	Cycle 7 Day 1	28	2 (7.1)	23 (82.1)	3 (10.7)
	Cycle 9 Day 1	16	1 (6.3)	13 (81.3)	2 (12.5)
	Cycle 11 Day 1	11	1 (9.1)	9 (81.8)	1 (9.1)
	Cycle 13 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 15 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Social/Family Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	26	0 (0.0)	25 (96.2)	1 (3.8)
Ethnicity					
Unknown					
	Cycle 3 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Emotional Well-being Completion Rates by Visit
Full Analysis Set

	T-DXd (N=79)	
Visit	Number of subjects alive	Completed (%)
Baseline	79	71 (89.9)
Cycle 3 Day 1	78	58 (74.4)
Cycle 5 Day 1	76	41 (53.9)
Cycle 7 Day 1	72	31 (43.1)
Cycle 9 Day 1	60	18 (30.0)
Cycle 11 Day 1	44	13 (29.5)
Cycle 13 Day 1	32	6 (18.8)
Cycle 15 Day 1	21	8 (38.1)
Cycle 17 Day 1	18	4 (22.2)
Cycle 19 Day 1	16	3 (18.8)
Cycle 21 Day 1	11	3 (27.3)
Cycle 23 Day 1	7	1 (14.3)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

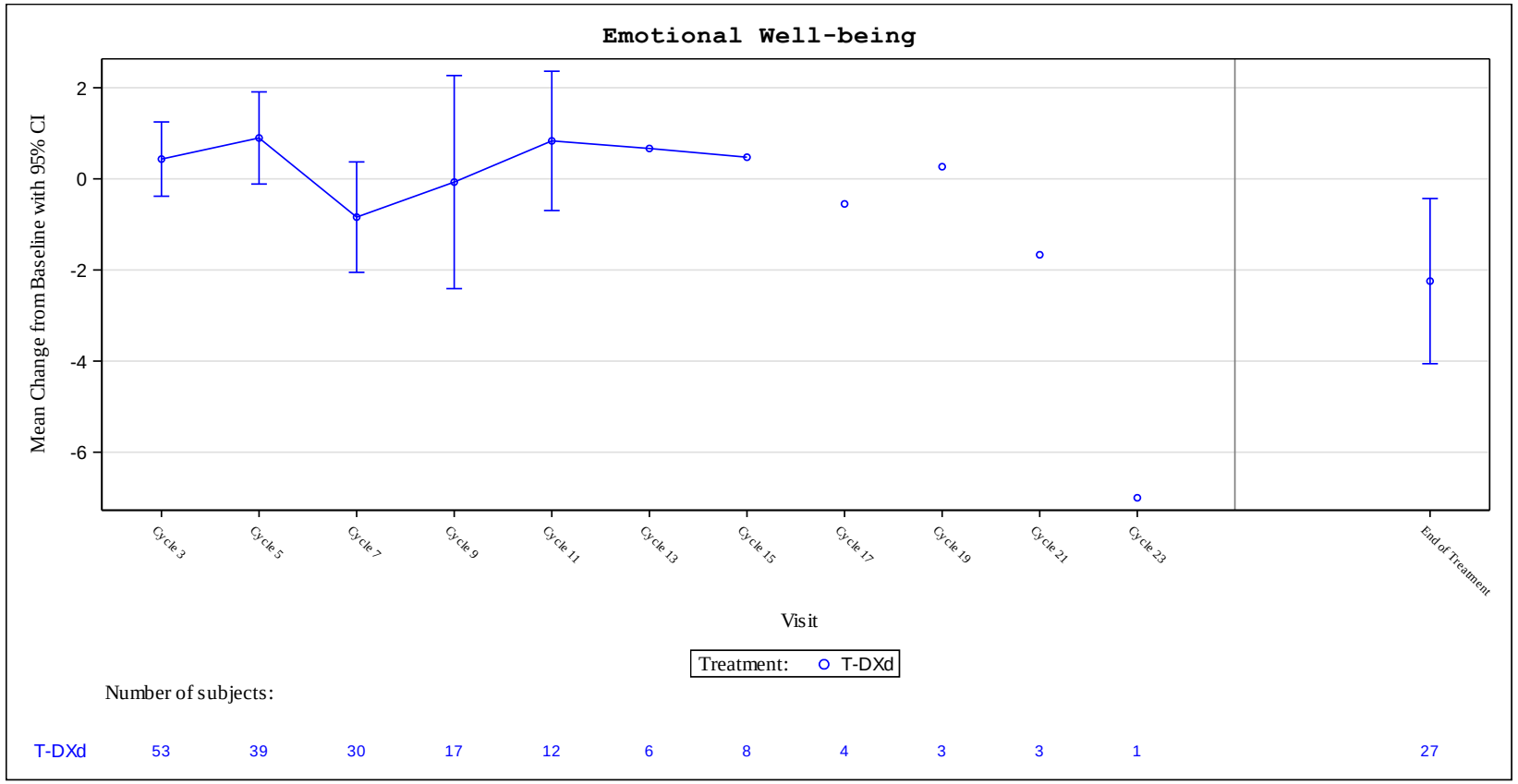
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Emotional Well-being by Visit
Full Analysis Set

	T-DXd (N=79)			
	Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)
Baseline	71	16.6 (4.68)		
Cycle 3 Day 1	58	16.8 (3.97)	53	0.4 (2.96)
Cycle 5 Day 1	41	17.2 (4.36)	39	0.9 (3.12)
Cycle 7 Day 1	31	15.8 (4.74)	30	-0.8 (3.25)
Cycle 9 Day 1	18	17.0 (4.12)	17	-0.1 (4.55)
Cycle 11 Day 1	13	17.8 (3.59)	12	0.8 (2.41)
Cycle 13 Day 1	6	18.7 (4.06)	6	0.7 (3.56)
Cycle 15 Day 1	8	18.3 (3.62)	8	0.5 (2.09)
Cycle 17 Day 1	4	15.5 (0.58)	4	-0.5 (2.16)
Cycle 19 Day 1	3	16.3 (1.53)	3	0.3 (1.62)
Cycle 21 Day 1	3	15.7 (1.15)	3	-1.7 (3.79)
Cycle 23 Day 1	1	16.0 (-)	1	-7.0 (-)
End of Treatment	31	15.3 (6.29)	27	-2.2 (4.58)

Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Graphical Summary of Emotional Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADQS

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	19 (24.1)	60 (75.9)	NE (5.5, NE)
Region			
North America	6 (17.6)	28 (82.4)	NE (4.2, NE)
EU	13 (28.9)	32 (71.1)	7.8 (3.7, NE)
Age (Category 1)			
<65 years	14 (30.4)	32 (69.6)	7.8 (3.0, NE)
>=65 years	5 (15.2)	28 (84.8)	NE (5.5, NE)
Age (Category 2)			
<75 years	17 (22.7)	58 (77.3)	NE (5.5, NE)
>=75 years	2 (50.0)	2 (50.0)	3.7 (1.4, NE)
Sex			
female	5 (22.7)	17 (77.3)	7.8 (4.6, NE)
male	14 (24.6)	43 (75.4)	NE (3.7, NE)
ECOG PS			
0	5 (17.2)	24 (82.8)	NE (4.2, NE)
1	14 (28.0)	36 (72.0)	7.8 (3.7, NE)
HER2 Status in central laboratory			
IHC 3+	17 (25.0)	51 (75.0)	NE (5.5, NE)
IHC 2+/ISH +	2 (20.0)	8 (80.0)	NE (1.6, NE)
Primary tumor location			
Gastric	7 (25.9)	20 (74.1)	7.8 (3.7, NE)
GEJ	12 (23.1)	40 (76.9)	NE (4.6, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	5 (26.3)	14 (73.7)	NE (2.1, NE)
other	14 (23.7)	45 (76.3)	7.8 (4.2, NE)
Number of metastatic sites			
<2	1 (20.0)	4 (80.0)	NE (4.2, NE)
>=2	18 (24.3)	56 (75.7)	NE (4.6, NE)
Previous total gastrectomy			
no	19 (24.1)	60 (75.9)	NE (5.5, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	3 (33.3)	6 (66.7)	NE (1.4, NE)
no	16 (22.9)	54 (77.1)	NE (4.6, NE)
Prior nivolumab or pembrolizumab treatment			
yes	0 (0.0)	6 (100.0)	NE (NE, NE)
no	19 (26.0)	54 (74.0)	NE (4.6, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	1 (14.3)	6 (85.7)	NE (2.8, NE)
no	18 (25.0)	54 (75.0)	NE (4.6, NE)

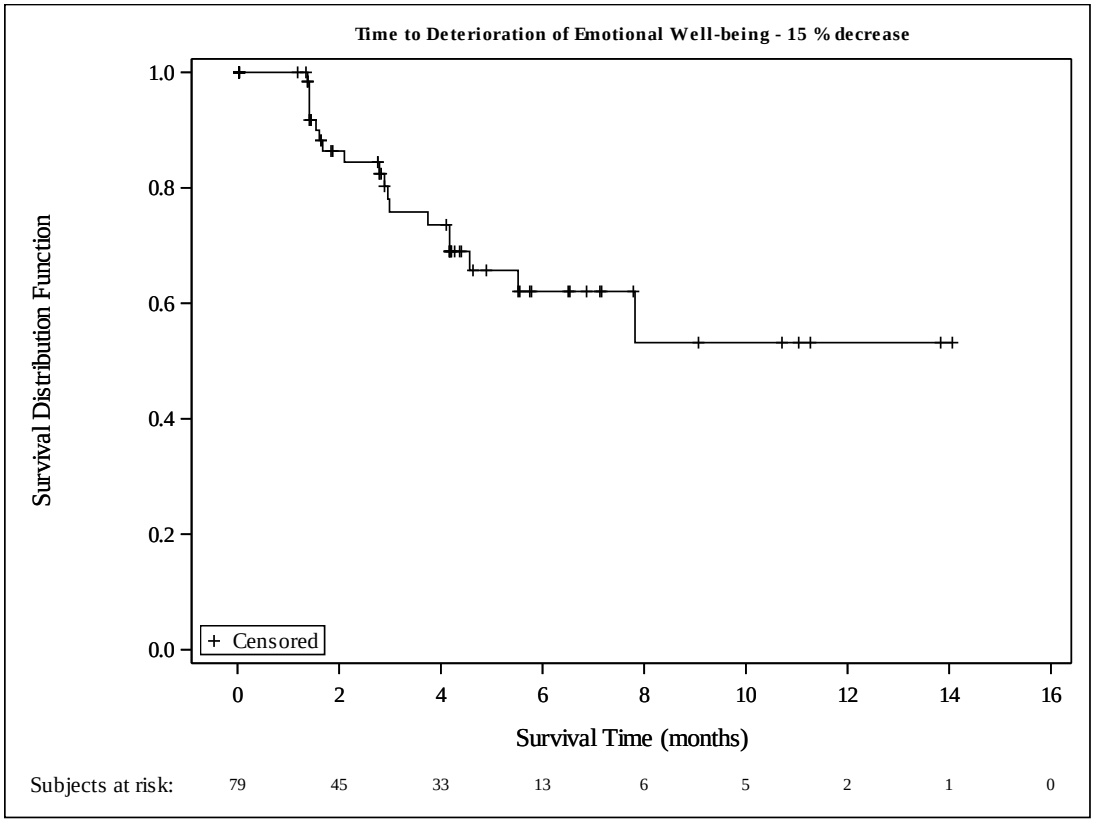
Time to Deterioration of Emotional Well-being is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	11 (22.0)	39 (78.0)	NE (4.2, NE)
no	8 (27.6)	21 (72.4)	7.8 (4.2, NE)
Renal impairment at baseline			
normal	6 (18.8)	26 (81.3)	NE (2.8, NE)
mild	6 (24.0)	19 (76.0)	NE (2.9, NE)
moderate	3 (37.5)	5 (62.5)	NE (1.4, NE)
Hepatic impairment at baseline			
normal	18 (28.1)	46 (71.9)	7.8 (4.2, NE)
mild	1 (7.1)	13 (92.9)	NE (2.8, NE)
Race			
White	17 (24.6)	52 (75.4)	NE (4.6, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	NE (1.6, NE)
Ethnicity			
Hispanic/Latino	3 (60.0)	2 (40.0)	3.7 (1.4, NE)
Non-Hispanic/Non-Latino	16 (22.9)	54 (77.1)	NE (4.6, NE)
Unknown	0 (0.0)	4 (100.0)	NE (NE, NE)

Time to Deterioration of Emotional Well-being is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)			
	Events (%)	Censored (%)	Median 95% CI [a]	
Overall	17 (21.5)	62 (78.5)	13.2 (7.8,	NE)
Region				
North America	6 (17.6)	28 (82.4)	13.2 (4.2,	NE)
EU	11 (24.4)	34 (75.6)	7.8 (4.6,	NE)
Age (Category 1)				
<65 years	14 (30.4)	32 (69.6)	7.8 (3.2,	NE)
>=65 years	3 (9.1)	30 (90.9)	13.2 (13.2,	NE)
Age (Category 2)				
<75 years	16 (21.3)	59 (78.7)	13.2 (7.8,	NE)
>=75 years	1 (25.0)	3 (75.0)	NE (3.7,	NE)
Sex				
female	4 (18.2)	18 (81.8)	7.8 (4.6,	NE)
male	13 (22.8)	44 (77.2)	13.2 (3.7,	NE)
ECOG PS				
0	3 (10.3)	26 (89.7)	NE (NE,	NE)
1	14 (28.0)	36 (72.0)	7.8 (4.2,	NE)
HER2 Status in central laboratory				
IHC 3+	15 (22.1)	53 (77.9)	13.2 (7.8,	NE)
IHC 2+/ISH +	2 (20.0)	8 (80.0)	NE (1.6,	NE)
Primary tumor location				
Gastric	7 (25.9)	20 (74.1)	7.8 (4.2,	NE)
GEJ	10 (19.2)	42 (80.8)	13.2 (4.6,	NE)
Histological subtype				
diffuse	0 (0.0)	1 (100.0)	NE (NE,	NE)
intestinal	5 (26.3)	14 (73.7)	NE (3.2,	NE)
other	12 (20.3)	47 (79.7)	13.2 (7.8,	NE)
Number of metastatic sites				
<2	1 (20.0)	4 (80.0)	NE (4.2,	NE)
>=2	16 (21.6)	58 (78.4)	13.2 (7.8,	NE)
Previous total gastrectomy				
no	17 (21.5)	62 (78.5)	13.2 (7.8,	NE)
Prior adjuvant/ neoadjuvant therapy				
yes	1 (11.1)	8 (88.9)	NE (4.2,	NE)
no	16 (22.9)	54 (77.1)	13.2 (4.6,	NE)
Prior nivolumab or pembrolizumab treatment				
yes	0 (0.0)	6 (100.0)	NE (NE,	NE)
no	17 (23.3)	56 (76.7)	13.2 (4.6,	NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy				
yes	1 (14.3)	6 (85.7)	NE (2.8,	NE)
no	16 (22.2)	56 (77.8)	13.2 (4.6,	NE)

Time to Definitive Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

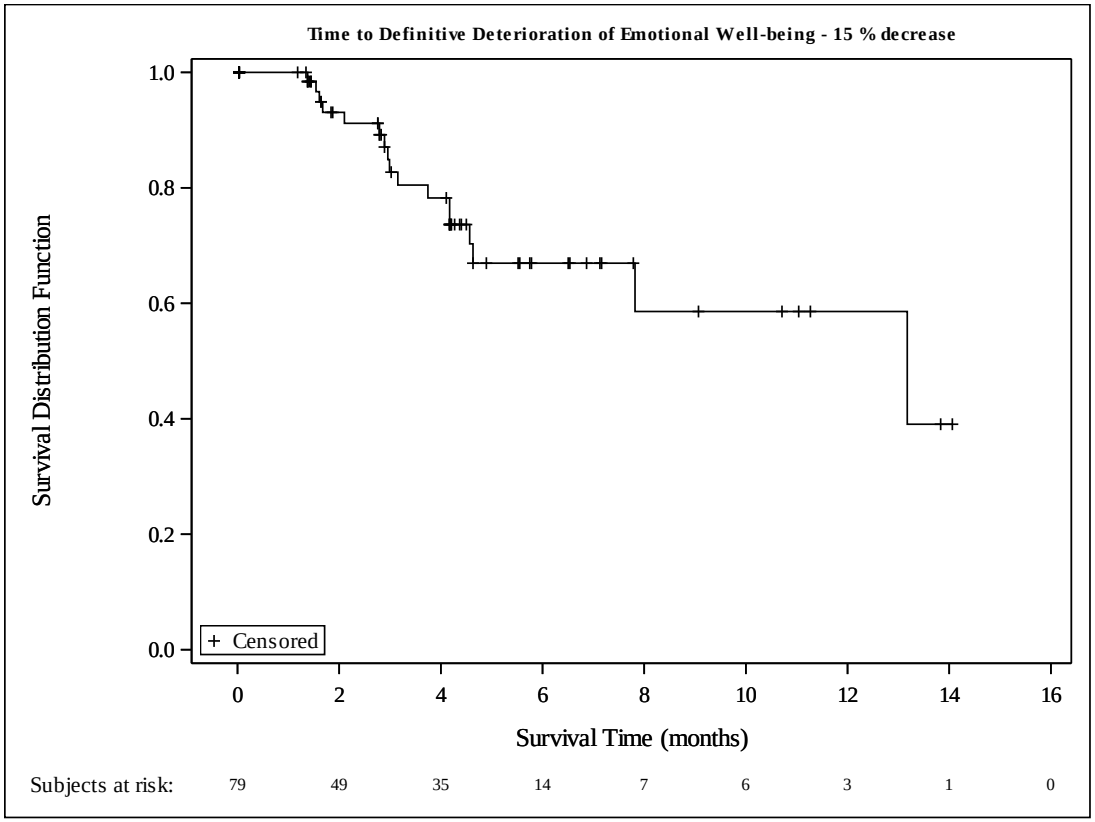
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	11 (22.0)	39 (78.0)	13.2 (4.2, NE)
no	6 (20.7)	23 (79.3)	7.8 (4.6, NE)
Renal impairment at baseline			
normal	6 (18.8)	26 (81.3)	NE (2.8, NE)
mild	5 (20.0)	20 (80.0)	NE (3.7, NE)
moderate	2 (25.0)	6 (75.0)	13.2 (3.2, 13.2)
Hepatic impairment at baseline			
normal	16 (25.0)	48 (75.0)	13.2 (4.6, NE)
mild	1 (7.1)	13 (92.9)	NE (2.8, NE)
Race			
White	15 (21.7)	54 (78.3)	13.2 (7.8, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	NE (1.6, NE)
Ethnicity			
Hispanic/Latino	3 (60.0)	2 (40.0)	3.7 (2.8, NE)
Non-Hispanic/Non-Latino	14 (20.0)	56 (80.0)	13.2 (7.8, NE)
Unknown	0 (0.0)	4 (100.0)	NE (NE, NE)

Time to Definitive Deterioration of Emotional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Emotional Well-being (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall					
	Cycle 3 Day 1	58	7 (12.1)	46 (79.3)	5 (8.6)
	Cycle 5 Day 1	41	9 (22.0)	30 (73.2)	2 (4.9)
	Cycle 7 Day 1	31	1 (3.2)	25 (80.6)	5 (16.1)
	Cycle 9 Day 1	18	2 (11.1)	13 (72.2)	3 (16.7)
	Cycle 11 Day 1	13	2 (15.4)	10 (76.9)	1 (7.7)
	Cycle 13 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	1 (3.2)	19 (61.3)	11 (35.5)
Region					
North America					
	Cycle 3 Day 1	22	1 (4.5)	21 (95.5)	0 (0.0)
	Cycle 5 Day 1	14	1 (7.1)	12 (85.7)	1 (7.1)
	Cycle 7 Day 1	11	1 (9.1)	8 (72.7)	2 (18.2)
	Cycle 9 Day 1	7	1 (14.3)	4 (57.1)	2 (28.6)
	Cycle 11 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	14	1 (7.1)	10 (71.4)	3 (21.4)
Region					
EU					
	Cycle 3 Day 1	36	6 (16.7)	25 (69.4)	5 (13.9)
	Cycle 5 Day 1	27	8 (29.6)	18 (66.7)	1 (3.7)
	Cycle 7 Day 1	20	0 (0.0)	17 (85.0)	3 (15.0)
	Cycle 9 Day 1	11	1 (9.1)	9 (81.8)	1 (9.1)
	Cycle 11 Day 1	7	2 (28.6)	5 (71.4)	0 (0.0)
	Cycle 13 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	17	0 (0.0)	9 (52.9)	8 (47.1)
Age (Category 1)					
<65 years					
	Cycle 3 Day 1	37	6 (16.2)	28 (75.7)	3 (8.1)
	Cycle 5 Day 1	26	7 (26.9)	17 (65.4)	2 (7.7)
	Cycle 7 Day 1	16	0 (0.0)	13 (81.3)	3 (18.8)
	Cycle 9 Day 1	11	1 (9.1)	10 (90.9)	0 (0.0)
	Cycle 11 Day 1	9	2 (22.2)	7 (77.8)	0 (0.0)
	Cycle 13 Day 1	4	2 (50.0)	2 (50.0)	0 (0.0)
	Cycle 15 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	18	0 (0.0)	8 (44.4)	10 (55.6)
Age (Category 1)					
>=65 years					
	Cycle 3 Day 1	21	1 (4.8)	18 (85.7)	2 (9.5)
	Cycle 5 Day 1	15	2 (13.3)	13 (86.7)	0 (0.0)
	Cycle 7 Day 1	15	1 (6.7)	12 (80.0)	2 (13.3)
	Cycle 9 Day 1	7	1 (14.3)	3 (42.9)	3 (42.9)
	Cycle 11 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 13 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	13	1 (7.7)	11 (84.6)	1 (7.7)
Age (Category 2)					
<75 years					
	Cycle 3 Day 1	54	7 (13.0)	43 (79.6)	4 (7.4)
	Cycle 5 Day 1	38	9 (23.7)	27 (71.1)	2 (5.3)
	Cycle 7 Day 1	29	1 (3.4)	24 (82.8)	4 (13.8)
	Cycle 9 Day 1	16	1 (6.3)	13 (81.3)	2 (12.5)
	Cycle 11 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 13 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 15 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	1 (3.2)	19 (61.3)	11 (35.5)
Age (Category 2)					
>=75 years					
	Cycle 3 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 5 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 9 Day 1	2	1 (50.0)	0 (0.0)	1 (50.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Sex					
female					
	Cycle 3 Day 1	17	3 (17.6)	12 (70.6)	2 (11.8)
	Cycle 5 Day 1	16	5 (31.3)	11 (68.8)	0 (0.0)
	Cycle 7 Day 1	12	0 (0.0)	10 (83.3)	2 (16.7)
	Cycle 9 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 11 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 13 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	7	0 (0.0)	5 (71.4)	2 (28.6)
Sex					
male					
	Cycle 3 Day 1	41	4 (9.8)	34 (82.9)	3 (7.3)
	Cycle 5 Day 1	25	4 (16.0)	19 (76.0)	2 (8.0)
	Cycle 7 Day 1	19	1 (5.3)	15 (78.9)	3 (15.8)
	Cycle 9 Day 1	13	1 (7.7)	9 (69.2)	3 (23.1)
	Cycle 11 Day 1	9	1 (11.1)	7 (77.8)	1 (11.1)
	Cycle 13 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 15 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	24	1 (4.2)	14 (58.3)	9 (37.5)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS					
0					
	Cycle 3 Day 1	21	0 (0.0)	18 (85.7)	3 (14.3)
	Cycle 5 Day 1	16	2 (12.5)	14 (87.5)	0 (0.0)
	Cycle 7 Day 1	11	0 (0.0)	10 (90.9)	1 (9.1)
	Cycle 9 Day 1	9	0 (0.0)	8 (88.9)	1 (11.1)
	Cycle 11 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	15	0 (0.0)	12 (80.0)	3 (20.0)
ECOG PS					
1					
	Cycle 3 Day 1	37	7 (18.9)	28 (75.7)	2 (5.4)
	Cycle 5 Day 1	25	7 (28.0)	16 (64.0)	2 (8.0)
	Cycle 7 Day 1	20	1 (5.0)	15 (75.0)	4 (20.0)
	Cycle 9 Day 1	9	2 (22.2)	5 (55.6)	2 (22.2)
	Cycle 11 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 13 Day 1	3	2 (66.7)	0 (0.0)	1 (33.3)
	Cycle 15 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	16	1 (6.3)	7 (43.8)	8 (50.0)
HER2 Status in central laboratory					
IHC 3+					
	Cycle 3 Day 1	55	7 (12.7)	43 (78.2)	5 (9.1)
	Cycle 5 Day 1	39	9 (23.1)	28 (71.8)	2 (5.1)
	Cycle 7 Day 1	29	0 (0.0)	24 (82.8)	5 (17.2)
	Cycle 9 Day 1	17	2 (11.8)	12 (70.6)	3 (17.6)
	Cycle 11 Day 1	13	2 (15.4)	10 (76.9)	1 (7.7)
	Cycle 13 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	25	0 (0.0)	16 (64.0)	9 (36.0)
HER2 Status in central laboratory					
IHC 2+/ISH +					
	Cycle 3 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	6	1 (16.7)	3 (50.0)	2 (33.3)
Primary tumor location					
Gastric					
	Cycle 3 Day 1	21	5 (23.8)	14 (66.7)	2 (9.5)
	Cycle 5 Day 1	17	4 (23.5)	12 (70.6)	1 (5.9)
	Cycle 7 Day 1	15	0 (0.0)	11 (73.3)	4 (26.7)
	Cycle 9 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 11 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 13 Day 1	2	1 (50.0)	0 (0.0)	1 (50.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	10	0 (0.0)	7 (70.0)	3 (30.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Primary tumor location					
GEJ					
	Cycle 3 Day 1	37	2 (5.4)	32 (86.5)	3 (8.1)
	Cycle 5 Day 1	24	5 (20.8)	18 (75.0)	1 (4.2)
	Cycle 7 Day 1	16	1 (6.3)	14 (87.5)	1 (6.3)
	Cycle 9 Day 1	12	1 (8.3)	9 (75.0)	2 (16.7)
	Cycle 11 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 13 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 15 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	21	1 (4.8)	12 (57.1)	8 (38.1)
Histological subtype					
diffuse					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Histological subtype					
intestinal					
	Cycle 3 Day 1	14	1 (7.1)	11 (78.6)	2 (14.3)
	Cycle 5 Day 1	11	3 (27.3)	7 (63.6)	1 (9.1)
	Cycle 7 Day 1	8	0 (0.0)	6 (75.0)	2 (25.0)
	Cycle 9 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 11 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	8	0 (0.0)	5 (62.5)	3 (37.5)
Histological subtype					
other					
	Cycle 3 Day 1	43	6 (14.0)	34 (79.1)	3 (7.0)
	Cycle 5 Day 1	29	6 (20.7)	22 (75.9)	1 (3.4)
	Cycle 7 Day 1	22	1 (4.5)	18 (81.8)	3 (13.6)
	Cycle 9 Day 1	12	1 (8.3)	8 (66.7)	3 (25.0)
	Cycle 11 Day 1	9	2 (22.2)	6 (66.7)	1 (11.1)
	Cycle 13 Day 1	4	2 (50.0)	1 (25.0)	1 (25.0)
	Cycle 15 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	22	1 (4.5)	13 (59.1)	8 (36.4)
Number of metastatic sites					
<2					
	Cycle 3 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 5 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 7 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	1 (50.0)	1 (50.0)	0 (0.0)
Number of metastatic sites					
>=2					
	Cycle 3 Day 1	55	5 (9.1)	45 (81.8)	5 (9.1)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
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Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 5 Day 1	38	7 (18.4)	29 (76.3)	2 (5.3)
	Cycle 7 Day 1	27	0 (0.0)	23 (85.2)	4 (14.8)
	Cycle 9 Day 1	17	2 (11.8)	12 (70.6)	3 (17.6)
	Cycle 11 Day 1	13	2 (15.4)	10 (76.9)	1 (7.7)
	Cycle 13 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	29	0 (0.0)	18 (62.1)	11 (37.9)
Previous total gastrectomy					
no					
	Cycle 3 Day 1	58	7 (12.1)	46 (79.3)	5 (8.6)
	Cycle 5 Day 1	41	9 (22.0)	30 (73.2)	2 (4.9)
	Cycle 7 Day 1	31	1 (3.2)	25 (80.6)	5 (16.1)
	Cycle 9 Day 1	18	2 (11.1)	13 (72.2)	3 (16.7)
	Cycle 11 Day 1	13	2 (15.4)	10 (76.9)	1 (7.7)
	Cycle 13 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	1 (3.2)	19 (61.3)	11 (35.5)
Prior adjuvant/ neoadjuvant therapy					
yes					
	Cycle 3 Day 1	6	2 (33.3)	2 (33.3)	2 (33.3)
	Cycle 5 Day 1	6	3 (50.0)	3 (50.0)	0 (0.0)
	Cycle 7 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	1 (100.0)	0 (0.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy					
no					
	Cycle 3 Day 1	52	5 (9.6)	44 (84.6)	3 (5.8)
	Cycle 5 Day 1	35	6 (17.1)	27 (77.1)	2 (5.7)
	Cycle 7 Day 1	25	0 (0.0)	21 (84.0)	4 (16.0)
	Cycle 9 Day 1	17	2 (11.8)	12 (70.6)	3 (17.6)
	Cycle 11 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 13 Day 1	5	2 (40.0)	2 (40.0)	1 (20.0)
	Cycle 15 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	19 (63.3)	11 (36.7)
Prior nivolumab or pembrolizumab treatment					
yes					
	Cycle 3 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)

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Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	1 (100.0)	0 (0.0)	0 (0.0)
Prior nivolumab or pembrolizumab treatment					
no					
	Cycle 3 Day 1	56	7 (12.5)	44 (78.6)	5 (8.9)
	Cycle 5 Day 1	40	9 (22.5)	29 (72.5)	2 (5.0)
	Cycle 7 Day 1	29	0 (0.0)	24 (82.8)	5 (17.2)
	Cycle 9 Day 1	18	2 (11.1)	13 (72.2)	3 (16.7)
	Cycle 11 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 13 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 15 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	19 (63.3)	11 (36.7)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
yes					
	Cycle 3 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 7 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	1 (100.0)	0 (0.0)	0 (0.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
no					
	Cycle 3 Day 1	55	7 (12.7)	43 (78.2)	5 (9.1)
	Cycle 5 Day 1	39	9 (23.1)	29 (74.4)	1 (2.6)
	Cycle 7 Day 1	29	0 (0.0)	24 (82.8)	5 (17.2)
	Cycle 9 Day 1	18	2 (11.1)	13 (72.2)	3 (16.7)
	Cycle 11 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 13 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 15 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	19 (63.3)	11 (36.7)
Presence of liver metastasis at baseline					
yes					
	Cycle 3 Day 1	36	2 (5.6)	33 (91.7)	1 (2.8)
	Cycle 5 Day 1	25	4 (16.0)	19 (76.0)	2 (8.0)
	Cycle 7 Day 1	18	0 (0.0)	15 (83.3)	3 (16.7)
	Cycle 9 Day 1	14	2 (14.3)	9 (64.3)	3 (21.4)
	Cycle 11 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 13 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 15 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	18	0 (0.0)	11 (61.1)	7 (38.9)
Presence of liver metastasis at baseline					
no					
	Cycle 3 Day 1	22	5 (22.7)	13 (59.1)	4 (18.2)
	Cycle 5 Day 1	16	5 (31.3)	11 (68.8)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 7 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 9 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 11 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 13 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	1 (7.7)	8 (61.5)	4 (30.8)
Renal impairment at baseline					
normal					
	Cycle 3 Day 1	24	2 (8.3)	22 (91.7)	0 (0.0)
	Cycle 5 Day 1	13	3 (23.1)	9 (69.2)	1 (7.7)
	Cycle 7 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 9 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 11 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 13 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 15 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	8 (61.5)	5 (38.5)
Renal impairment at baseline					
mild					
	Cycle 3 Day 1	14	1 (7.1)	11 (78.6)	2 (14.3)
	Cycle 5 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 7 Day 1	10	1 (10.0)	7 (70.0)	2 (20.0)
	Cycle 9 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 11 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	12	1 (8.3)	8 (66.7)	3 (25.0)
Renal impairment at baseline					
moderate					
	Cycle 3 Day 1	7	1 (14.3)	4 (57.1)	2 (28.6)
	Cycle 5 Day 1	7	3 (42.9)	4 (57.1)	0 (0.0)
	Cycle 7 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 9 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 13 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	1	0 (0.0)	0 (0.0)	1 (100.0)
Hepatic impairment at baseline					
normal					
	Cycle 3 Day 1	47	6 (12.8)	36 (76.6)	5 (10.6)
	Cycle 5 Day 1	32	6 (18.8)	25 (78.1)	1 (3.1)
	Cycle 7 Day 1	27	1 (3.7)	21 (77.8)	5 (18.5)
	Cycle 9 Day 1	16	2 (12.5)	11 (68.8)	3 (18.8)
	Cycle 11 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 13 Day 1	5	2 (40.0)	2 (40.0)	1 (20.0)
	Cycle 15 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	28	1 (3.6)	16 (57.1)	11 (39.3)
Hepatic impairment at baseline					
mild					
	Cycle 3 Day 1	11	1 (9.1)	10 (90.9)	0 (0.0)
	Cycle 5 Day 1	9	3 (33.3)	5 (55.6)	1 (11.1)
	Cycle 7 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Race					
White					
	Cycle 3 Day 1	51	6 (11.8)	40 (78.4)	5 (9.8)
	Cycle 5 Day 1	35	8 (22.9)	25 (71.4)	2 (5.7)
	Cycle 7 Day 1	27	1 (3.7)	22 (81.5)	4 (14.8)
	Cycle 9 Day 1	16	2 (12.5)	12 (75.0)	2 (12.5)
	Cycle 11 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 13 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	27	1 (3.7)	17 (63.0)	9 (33.3)
Race					
Black or African American					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Race					
Other					
	Cycle 3 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 5 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 7 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 9 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 11 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	4	0 (0.0)	2 (50.0)	2 (50.0)
Ethnicity					
Hispanic/Latino					
	Cycle 3 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 5 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 7 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 9 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 11 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	3	0 (0.0)	2 (66.7)	1 (33.3)
Ethnicity					
Non-Hispanic/Non-Latino					
	Cycle 3 Day 1	49	7 (14.3)	38 (77.6)	4 (8.2)
	Cycle 5 Day 1	35	9 (25.7)	25 (71.4)	1 (2.9)
	Cycle 7 Day 1	27	1 (3.7)	22 (81.5)	4 (14.8)
	Cycle 9 Day 1	15	2 (13.3)	11 (73.3)	2 (13.3)
	Cycle 11 Day 1	11	2 (18.2)	8 (72.7)	1 (9.1)
	Cycle 13 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 15 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Emotional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	26	1 (3.8)	15 (57.7)	10 (38.5)
Ethnicity					
Unknown					
	Cycle 3 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Functional Well-being Completion Rates by Visit
Full Analysis Set

	T-DXd (N=79)	
Visit	Number of subjects alive	Completed (%)
Baseline	79	71 (89.9)
Cycle 3 Day 1	78	58 (74.4)
Cycle 5 Day 1	76	40 (52.6)
Cycle 7 Day 1	72	32 (44.4)
Cycle 9 Day 1	60	19 (31.7)
Cycle 11 Day 1	44	13 (29.5)
Cycle 13 Day 1	32	6 (18.8)
Cycle 15 Day 1	21	8 (38.1)
Cycle 17 Day 1	18	4 (22.2)
Cycle 19 Day 1	16	3 (18.8)
Cycle 21 Day 1	11	3 (27.3)
Cycle 23 Day 1	7	1 (14.3)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

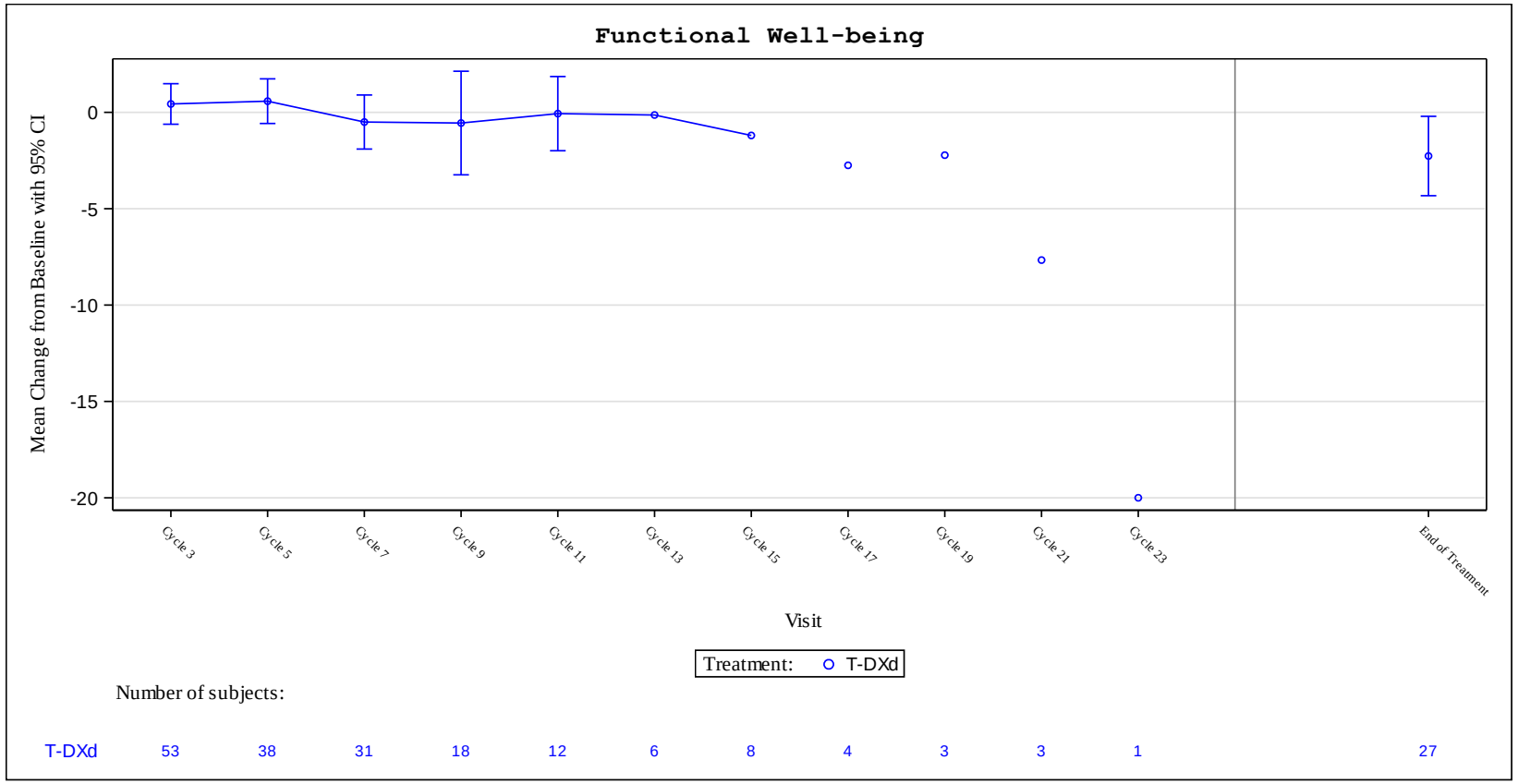
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Functional Well-being by Visit
Full Analysis Set

	T-DXd (N=79)			
	Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)
Baseline	71	16.9 (7.39)		
Cycle 3 Day 1	58	16.9 (6.71)	53	0.4 (3.82)
Cycle 5 Day 1	40	17.2 (7.75)	38	0.6 (3.52)
Cycle 7 Day 1	32	16.5 (7.84)	31	-0.5 (3.82)
Cycle 9 Day 1	19	17.3 (7.91)	18	-0.6 (5.40)
Cycle 11 Day 1	13	18.6 (7.83)	12	-0.1 (3.03)
Cycle 13 Day 1	6	19.4 (5.66)	6	-0.1 (3.16)
Cycle 15 Day 1	8	20.4 (5.90)	8	-1.2 (2.63)
Cycle 17 Day 1	4	16.8 (5.68)	4	-2.8 (2.50)
Cycle 19 Day 1	3	19.4 (4.19)	3	-2.2 (2.55)
Cycle 21 Day 1	3	15.0 (6.00)	3	-7.7 (10.26)
Cycle 23 Day 1	1	8.0 (-)	1	-20.0 (-)
End of Treatment	31	15.7 (8.52)	27	-2.3 (5.20)

Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Graphical Summary of Functional Well-being by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADQS

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	16 (20.3)	63 (79.7)	NE (9.3, NE)
Region			
North America	10 (29.4)	24 (70.6)	9.3 (1.7, NE)
EU	6 (13.3)	39 (86.7)	NE (5.9, NE)
Age (Category 1)			
<65 years	10 (21.7)	36 (78.3)	9.3 (5.9, NE)
>=65 years	6 (18.2)	27 (81.8)	NE (4.2, NE)
Age (Category 2)			
<75 years	14 (18.7)	61 (81.3)	NE (9.3, NE)
>=75 years	2 (50.0)	2 (50.0)	3.7 (1.4, NE)
Sex			
female	4 (18.2)	18 (81.8)	NE (4.2, NE)
male	12 (21.1)	45 (78.9)	9.3 (5.9, NE)
ECOG PS			
0	4 (13.8)	25 (86.2)	NE (9.3, NE)
1	12 (24.0)	38 (76.0)	NE (4.1, NE)
HER2 Status in central laboratory			
IHC 3+	13 (19.1)	55 (80.9)	NE (9.3, NE)
IHC 2+/ISH +	3 (30.0)	7 (70.0)	1.7 (1.4, NE)
Primary tumor location			
Gastric	6 (22.2)	21 (77.8)	NE (3.7, NE)
GEJ	10 (19.2)	42 (80.8)	9.3 (9.3, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	4 (21.1)	15 (78.9)	9.3 (5.9, NE)
other	12 (20.3)	47 (79.7)	NE (NE, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	16 (21.6)	58 (78.4)	NE (5.9, NE)
Previous total gastrectomy			
no	16 (20.3)	63 (79.7)	NE (9.3, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	2 (22.2)	7 (77.8)	NE (1.4, NE)
no	14 (20.0)	56 (80.0)	9.3 (5.9, NE)
Prior nivolumab or pembrolizumab treatment			
yes	1 (16.7)	5 (83.3)	NE (1.3, NE)
no	15 (20.5)	58 (79.5)	9.3 (5.9, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	2 (28.6)	5 (71.4)	NE (1.3, NE)
no	14 (19.4)	58 (80.6)	9.3 (9.3, NE)

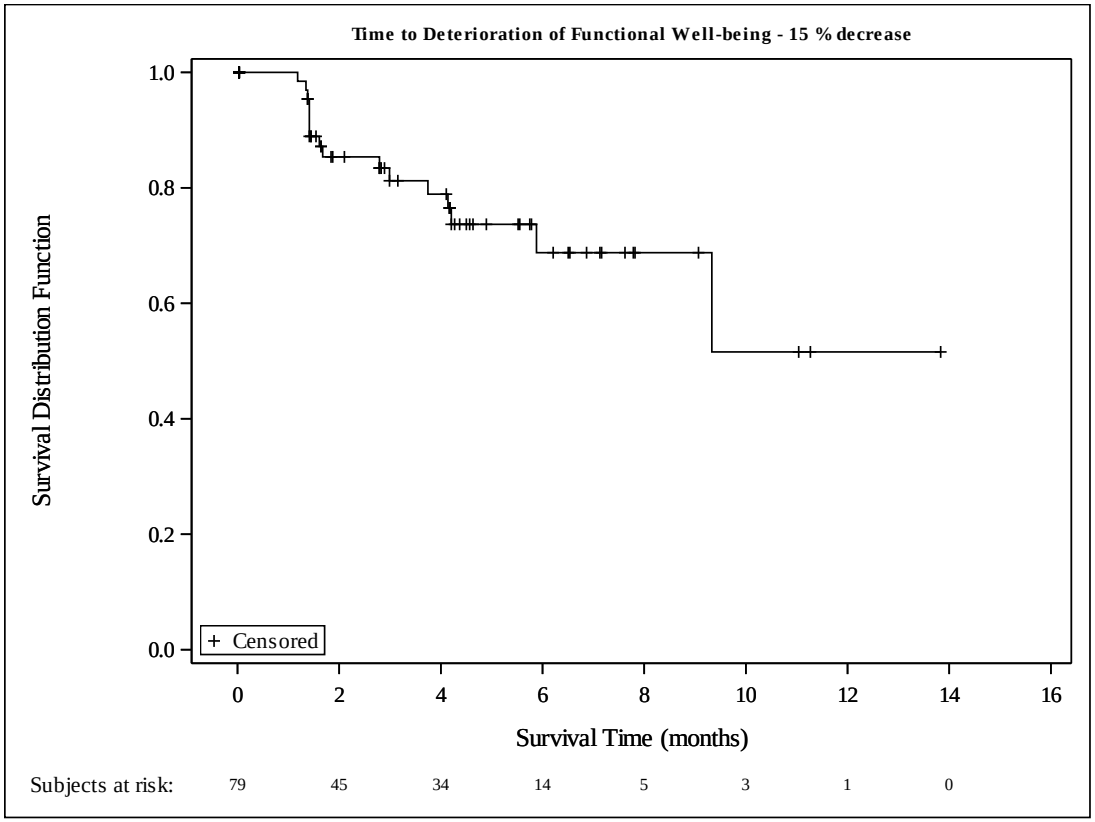
Time to Deterioration of Functional Well-being is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	10 (20.0)	40 (80.0)	9.3 (5.9, NE)
no	6 (20.7)	23 (79.3)	NE (4.2, NE)
Renal impairment at baseline			
normal	6 (18.8)	26 (81.3)	9.3 (2.8, 9.3)
mild	6 (24.0)	19 (76.0)	NE (4.2, NE)
moderate	1 (12.5)	7 (87.5)	NE (4.1, NE)
Hepatic impairment at baseline			
normal	14 (21.9)	50 (78.1)	9.3 (5.9, NE)
mild	1 (7.1)	13 (92.9)	NE (2.8, NE)
Race			
White	13 (18.8)	56 (81.2)	NE (9.3, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	3 (37.5)	5 (62.5)	4.2 (1.4, NE)
Ethnicity			
Hispanic/Latino	3 (60.0)	2 (40.0)	9.3 (2.8, 9.3)
Non-Hispanic/Non-Latino	11 (15.7)	59 (84.3)	NE (NE, NE)
Unknown	2 (50.0)	2 (50.0)	4.2 (1.4, 4.2)

Time to Deterioration of Functional Well-being is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	12 (15.2)	67 (84.8)	12.5 (9.3, NE)
Region			
North America	9 (26.5)	25 (73.5)	9.3 (4.1, NE)
EU	3 (6.7)	42 (93.3)	NE (NE, NE)
Age (Category 1)			
<65 years	8 (17.4)	38 (82.6)	12.5 (9.3, 12.5)
>=65 years	4 (12.1)	29 (87.9)	NE (NE, NE)
Age (Category 2)			
<75 years	12 (16.0)	63 (84.0)	12.5 (9.3, NE)
>=75 years	0 (0.0)	4 (100.0)	NE (NE, NE)
Sex			
female	3 (13.6)	19 (86.4)	NE (NE, NE)
male	9 (15.8)	48 (84.2)	12.5 (9.3, 12.5)
ECOG PS			
0	3 (10.3)	26 (89.7)	NE (9.3, NE)
1	9 (18.0)	41 (82.0)	12.5 (12.5, NE)
HER2 Status in central laboratory			
IHC 3+	9 (13.2)	59 (86.8)	12.5 (9.3, NE)
IHC 2+/ISH +	3 (30.0)	7 (70.0)	1.7 (1.4, NE)
Primary tumor location			
Gastric	3 (11.1)	24 (88.9)	NE (NE, NE)
GEJ	9 (17.3)	43 (82.7)	12.5 (9.3, 12.5)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	3 (15.8)	16 (84.2)	9.3 (9.3, NE)
other	9 (15.3)	50 (84.7)	12.5 (12.5, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	12 (16.2)	62 (83.8)	12.5 (9.3, NE)
Previous total gastrectomy			
no	12 (15.2)	67 (84.8)	12.5 (9.3, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	0 (0.0)	9 (100.0)	NE (NE, NE)
no	12 (17.1)	58 (82.9)	12.5 (9.3, NE)
Prior nivolumab or pembrolizumab treatment			
yes	1 (16.7)	5 (83.3)	NE (1.3, NE)
no	11 (15.1)	62 (84.9)	12.5 (9.3, 12.5)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	2 (28.6)	5 (71.4)	NE (1.3, NE)
no	10 (13.9)	62 (86.1)	12.5 (9.3, 12.5)

Time to Definitive Deterioration of Functional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

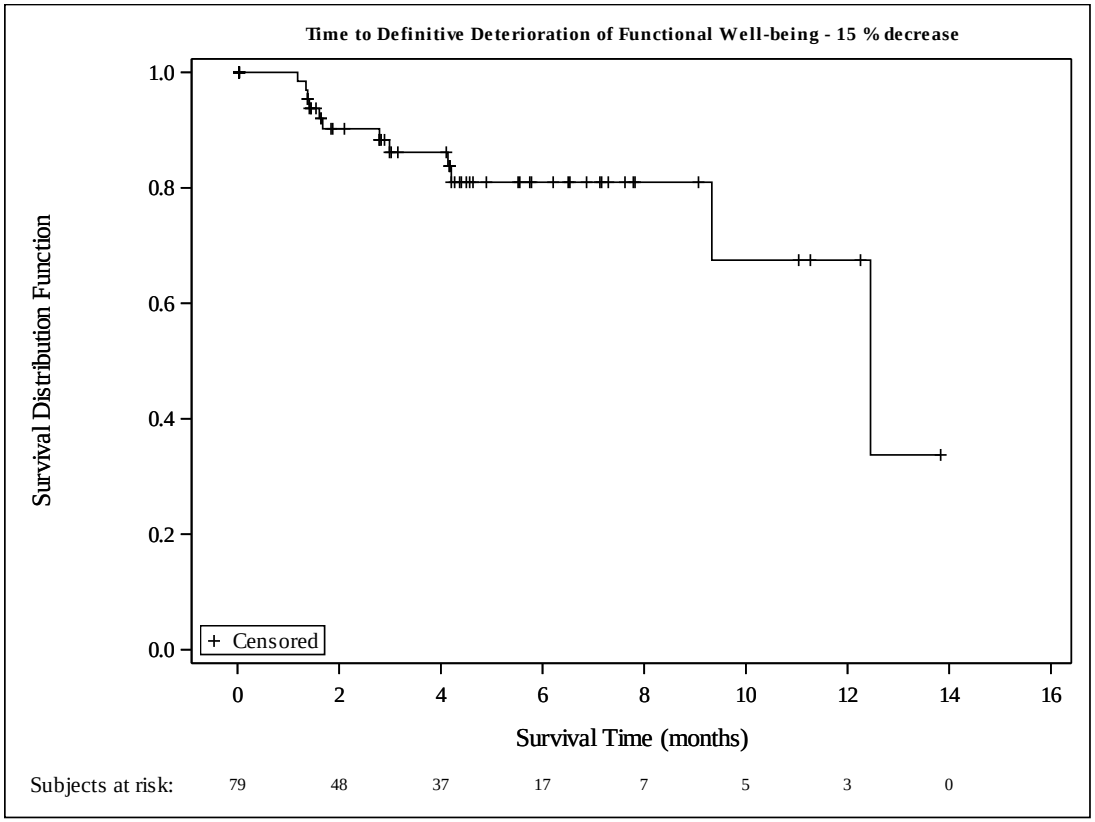
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	8 (16.0)	42 (84.0)	12.5 (9.3, 12.5)
no	4 (13.8)	25 (86.2)	NE (NE, NE)
Renal impairment at baseline			
normal	6 (18.8)	26 (81.3)	9.3 (9.3, 12.5)
mild	3 (12.0)	22 (88.0)	NE (NE, NE)
moderate	1 (12.5)	7 (87.5)	NE (4.1, NE)
Hepatic impairment at baseline			
normal	10 (15.6)	54 (84.4)	12.5 (9.3, NE)
mild	1 (7.1)	13 (92.9)	NE (2.8, NE)
Race			
White	10 (14.5)	59 (85.5)	12.5 (9.3, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	NE (1.6, NE)
Ethnicity			
Hispanic/Latino	2 (40.0)	3 (60.0)	9.3 (2.8, NE)
Non-Hispanic/Non-Latino	9 (12.9)	61 (87.1)	12.5 (12.5, NE)
Unknown	1 (25.0)	3 (75.0)	NE (4.2, NE)

Time to Definitive Deterioration of Functional Well-being is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Functional Well-being (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall					
	Cycle 3 Day 1	58	7 (12.1)	46 (79.3)	5 (8.6)
	Cycle 5 Day 1	40	5 (12.5)	33 (82.5)	2 (5.0)
	Cycle 7 Day 1	32	2 (6.3)	27 (84.4)	3 (9.4)
	Cycle 9 Day 1	19	3 (15.8)	14 (73.7)	2 (10.5)
	Cycle 11 Day 1	13	1 (7.7)	12 (92.3)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	24 (77.4)	7 (22.6)
Region					
North America					
	Cycle 3 Day 1	22	3 (13.6)	16 (72.7)	3 (13.6)
	Cycle 5 Day 1	14	0 (0.0)	13 (92.9)	1 (7.1)
	Cycle 7 Day 1	11	0 (0.0)	10 (90.9)	1 (9.1)
	Cycle 9 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	14	0 (0.0)	9 (64.3)	5 (35.7)
Region					
EU					
	Cycle 3 Day 1	36	4 (11.1)	30 (83.3)	2 (5.6)
	Cycle 5 Day 1	26	5 (19.2)	20 (76.9)	1 (3.8)
	Cycle 7 Day 1	21	2 (9.5)	17 (81.0)	2 (9.5)
	Cycle 9 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 11 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	17	0 (0.0)	15 (88.2)	2 (11.8)
Age (Category 1)					
<65 years					
	Cycle 3 Day 1	37	5 (13.5)	28 (75.7)	4 (10.8)
	Cycle 5 Day 1	25	4 (16.0)	19 (76.0)	2 (8.0)
	Cycle 7 Day 1	17	1 (5.9)	15 (88.2)	1 (5.9)
	Cycle 9 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 11 Day 1	9	1 (11.1)	8 (88.9)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	18	0 (0.0)	14 (77.8)	4 (22.2)
Age (Category 1)					
>=65 years					
	Cycle 3 Day 1	21	2 (9.5)	18 (85.7)	1 (4.8)
	Cycle 5 Day 1	15	1 (6.7)	14 (93.3)	0 (0.0)
	Cycle 7 Day 1	15	1 (6.7)	12 (80.0)	2 (13.3)
	Cycle 9 Day 1	7	2 (28.6)	4 (57.1)	1 (14.3)
	Cycle 11 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 13 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	13	0 (0.0)	10 (76.9)	3 (23.1)
Age (Category 2)					
<75 years					
	Cycle 3 Day 1	54	6 (11.1)	44 (81.5)	4 (7.4)
	Cycle 5 Day 1	37	5 (13.5)	30 (81.1)	2 (5.4)
	Cycle 7 Day 1	30	1 (3.3)	27 (90.0)	2 (6.7)
	Cycle 9 Day 1	17	2 (11.8)	13 (76.5)	2 (11.8)
	Cycle 11 Day 1	12	1 (8.3)	11 (91.7)	0 (0.0)
	Cycle 13 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	24 (77.4)	7 (22.6)
Age (Category 2)					
>=75 years					
	Cycle 3 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 5 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	1 (50.0)	0 (0.0)	1 (50.0)
	Cycle 9 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Sex					
female					
	Cycle 3 Day 1	18	3 (16.7)	14 (77.8)	1 (5.6)
	Cycle 5 Day 1	16	2 (12.5)	13 (81.3)	1 (6.3)
	Cycle 7 Day 1	13	1 (7.7)	11 (84.6)	1 (7.7)
	Cycle 9 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 11 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	7	0 (0.0)	5 (71.4)	2 (28.6)
Sex					
male					
	Cycle 3 Day 1	40	4 (10.0)	32 (80.0)	4 (10.0)
	Cycle 5 Day 1	24	3 (12.5)	20 (83.3)	1 (4.2)
	Cycle 7 Day 1	19	1 (5.3)	16 (84.2)	2 (10.5)
	Cycle 9 Day 1	13	2 (15.4)	9 (69.2)	2 (15.4)
	Cycle 11 Day 1	9	1 (11.1)	8 (88.9)	0 (0.0)
	Cycle 13 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	2	0 (0.0)	0 (0.0)	2 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	24	0 (0.0)	19 (79.2)	5 (20.8)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS					
0					
	Cycle 3 Day 1	21	1 (4.8)	18 (85.7)	2 (9.5)
	Cycle 5 Day 1	16	0 (0.0)	16 (100.0)	0 (0.0)
	Cycle 7 Day 1	11	0 (0.0)	11 (100.0)	0 (0.0)
	Cycle 9 Day 1	9	1 (11.1)	8 (88.9)	0 (0.0)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	15	0 (0.0)	13 (86.7)	2 (13.3)
ECOG PS					
1					
	Cycle 3 Day 1	37	6 (16.2)	28 (75.7)	3 (8.1)
	Cycle 5 Day 1	24	5 (20.8)	17 (70.8)	2 (8.3)
	Cycle 7 Day 1	21	2 (9.5)	16 (76.2)	3 (14.3)
	Cycle 9 Day 1	10	2 (20.0)	6 (60.0)	2 (20.0)
	Cycle 11 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	16	0 (0.0)	11 (68.8)	5 (31.3)
HER2 Status in central laboratory					
IHC 3+					
	Cycle 3 Day 1	55	7 (12.7)	43 (78.2)	5 (9.1)
	Cycle 5 Day 1	38	5 (13.2)	31 (81.6)	2 (5.3)
	Cycle 7 Day 1	30	2 (6.7)	25 (83.3)	3 (10.0)
	Cycle 9 Day 1	18	3 (16.7)	13 (72.2)	2 (11.1)
	Cycle 11 Day 1	13	1 (7.7)	12 (92.3)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	25	0 (0.0)	21 (84.0)	4 (16.0)
HER2 Status in central laboratory					
IHC 2+/ISH +					
	Cycle 3 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	6	0 (0.0)	3 (50.0)	3 (50.0)
Primary tumor location					
Gastric					
	Cycle 3 Day 1	21	4 (19.0)	16 (76.2)	1 (4.8)
	Cycle 5 Day 1	17	3 (17.6)	13 (76.5)	1 (5.9)
	Cycle 7 Day 1	15	1 (6.7)	12 (80.0)	2 (13.3)
	Cycle 9 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	10	0 (0.0)	8 (80.0)	2 (20.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Primary tumor location					
GEJ					
	Cycle 3 Day 1	37	3 (8.1)	30 (81.1)	4 (10.8)
	Cycle 5 Day 1	23	2 (8.7)	20 (87.0)	1 (4.3)
	Cycle 7 Day 1	17	1 (5.9)	15 (88.2)	1 (5.9)
	Cycle 9 Day 1	13	2 (15.4)	10 (76.9)	1 (7.7)
	Cycle 11 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 13 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 21 Day 1	2	0 (0.0)	0 (0.0)	2 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	21	0 (0.0)	16 (76.2)	5 (23.8)
Histological subtype					
diffuse					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Histological subtype					
intestinal					
	Cycle 3 Day 1	14	3 (21.4)	11 (78.6)	0 (0.0)
	Cycle 5 Day 1	11	3 (27.3)	7 (63.6)	1 (9.1)
	Cycle 7 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 9 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 11 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	8	0 (0.0)	6 (75.0)	2 (25.0)
Histological subtype					
other					
	Cycle 3 Day 1	43	4 (9.3)	34 (79.1)	5 (11.6)
	Cycle 5 Day 1	28	2 (7.1)	25 (89.3)	1 (3.6)
	Cycle 7 Day 1	23	1 (4.3)	20 (87.0)	2 (8.7)
	Cycle 9 Day 1	13	2 (15.4)	10 (76.9)	1 (7.7)
	Cycle 11 Day 1	9	1 (11.1)	8 (88.9)	0 (0.0)
	Cycle 13 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 15 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	22	0 (0.0)	17 (77.3)	5 (22.7)
Number of metastatic sites					
<2					
	Cycle 3 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 5 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 7 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Number of metastatic sites					
>=2					
	Cycle 3 Day 1	55	6 (10.9)	44 (80.0)	5 (9.1)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 5 Day 1	37	5 (13.5)	30 (81.1)	2 (5.4)
	Cycle 7 Day 1	28	2 (7.1)	23 (82.1)	3 (10.7)
	Cycle 9 Day 1	18	3 (16.7)	13 (72.2)	2 (11.1)
	Cycle 11 Day 1	13	1 (7.7)	12 (92.3)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	29	0 (0.0)	22 (75.9)	7 (24.1)
Previous total gastrectomy					
no					
	Cycle 3 Day 1	58	7 (12.1)	46 (79.3)	5 (8.6)
	Cycle 5 Day 1	40	5 (12.5)	33 (82.5)	2 (5.0)
	Cycle 7 Day 1	32	2 (6.3)	27 (84.4)	3 (9.4)
	Cycle 9 Day 1	19	3 (15.8)	14 (73.7)	2 (10.5)
	Cycle 11 Day 1	13	1 (7.7)	12 (92.3)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	24 (77.4)	7 (22.6)
Prior adjuvant/ neoadjuvant therapy					
yes					
	Cycle 3 Day 1	7	1 (14.3)	4 (57.1)	2 (28.6)
	Cycle 5 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 7 Day 1	7	0 (0.0)	7 (100.0)	0 (0.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy					
no					
	Cycle 3 Day 1	51	6 (11.8)	42 (82.4)	3 (5.9)
	Cycle 5 Day 1	34	5 (14.7)	27 (79.4)	2 (5.9)
	Cycle 7 Day 1	25	2 (8.0)	20 (80.0)	3 (12.0)
	Cycle 9 Day 1	17	3 (17.6)	12 (70.6)	2 (11.8)
	Cycle 11 Day 1	12	1 (8.3)	11 (91.7)	0 (0.0)
	Cycle 13 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	23 (76.7)	7 (23.3)
Prior nivolumab or pembrolizumab treatment					
yes					
	Cycle 3 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior nivolumab or pembrolizumab treatment					
no					
	Cycle 3 Day 1	56	7 (12.5)	45 (80.4)	4 (7.1)
	Cycle 5 Day 1	39	5 (12.8)	32 (82.1)	2 (5.1)
	Cycle 7 Day 1	30	2 (6.7)	25 (83.3)	3 (10.0)
	Cycle 9 Day 1	19	3 (15.8)	14 (73.7)	2 (10.5)
	Cycle 11 Day 1	12	1 (8.3)	11 (91.7)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	2	0 (0.0)	0 (0.0)	2 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	23 (76.7)	7 (23.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
yes					
	Cycle 3 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 5 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
no					
	Cycle 3 Day 1	55	7 (12.7)	44 (80.0)	4 (7.3)
	Cycle 5 Day 1	38	5 (13.2)	32 (84.2)	1 (2.6)
	Cycle 7 Day 1	30	2 (6.7)	25 (83.3)	3 (10.0)
	Cycle 9 Day 1	19	3 (15.8)	14 (73.7)	2 (10.5)
	Cycle 11 Day 1	12	1 (8.3)	11 (91.7)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	2	0 (0.0)	0 (0.0)	2 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	23 (76.7)	7 (23.3)
Presence of liver metastasis at baseline					
yes					
	Cycle 3 Day 1	36	3 (8.3)	30 (83.3)	3 (8.3)
	Cycle 5 Day 1	24	2 (8.3)	21 (87.5)	1 (4.2)
	Cycle 7 Day 1	18	1 (5.6)	15 (83.3)	2 (11.1)
	Cycle 9 Day 1	14	1 (7.1)	11 (78.6)	2 (14.3)
	Cycle 11 Day 1	8	0 (0.0)	8 (100.0)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	2	0 (0.0)	0 (0.0)	2 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	18	0 (0.0)	14 (77.8)	4 (22.2)
Presence of liver metastasis at baseline					
no					
	Cycle 3 Day 1	22	4 (18.2)	16 (72.7)	2 (9.1)
	Cycle 5 Day 1	16	3 (18.8)	12 (75.0)	1 (6.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 7 Day 1	14	1 (7.1)	12 (85.7)	1 (7.1)
	Cycle 9 Day 1	5	2 (40.0)	3 (60.0)	0 (0.0)
	Cycle 11 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 13 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	10 (76.9)	3 (23.1)
Renal impairment at baseline					
normal					
	Cycle 3 Day 1	23	2 (8.7)	19 (82.6)	2 (8.7)
	Cycle 5 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 7 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 9 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 11 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	13	0 (0.0)	10 (76.9)	3 (23.1)
Renal impairment at baseline					
mild					
	Cycle 3 Day 1	15	1 (6.7)	13 (86.7)	1 (6.7)
	Cycle 5 Day 1	12	1 (8.3)	11 (91.7)	0 (0.0)
	Cycle 7 Day 1	11	0 (0.0)	10 (90.9)	1 (9.1)
	Cycle 9 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	9 (75.0)	3 (25.0)
Renal impairment at baseline					
moderate					
	Cycle 3 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 5 Day 1	7	2 (28.6)	5 (71.4)	0 (0.0)
	Cycle 7 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 9 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline					
normal					
	Cycle 3 Day 1	46	5 (10.9)	36 (78.3)	5 (10.9)
	Cycle 5 Day 1	31	4 (12.9)	26 (83.9)	1 (3.2)
	Cycle 7 Day 1	27	2 (7.4)	22 (81.5)	3 (11.1)
	Cycle 9 Day 1	16	3 (18.8)	11 (68.8)	2 (12.5)
	Cycle 11 Day 1	12	1 (8.3)	11 (91.7)	0 (0.0)
	Cycle 13 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)

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Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	28	0 (0.0)	22 (78.6)	6 (21.4)
Hepatic impairment at baseline					
mild					
	Cycle 3 Day 1	12	2 (16.7)	10 (83.3)	0 (0.0)
	Cycle 5 Day 1	9	1 (11.1)	7 (77.8)	1 (11.1)
	Cycle 7 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 9 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Race					
White					
	Cycle 3 Day 1	51	5 (9.8)	42 (82.4)	4 (7.8)
	Cycle 5 Day 1	34	4 (11.8)	28 (82.4)	2 (5.9)
	Cycle 7 Day 1	28	2 (7.1)	23 (82.1)	3 (10.7)
	Cycle 9 Day 1	17	3 (17.6)	12 (70.6)	2 (11.8)
	Cycle 11 Day 1	12	1 (8.3)	11 (91.7)	0 (0.0)
	Cycle 13 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	27	0 (0.0)	22 (81.5)	5 (18.5)
Race					
Black or African American					
	Cycle 3 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Race					
Other					
	Cycle 3 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 5 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 7 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	2 (50.0)	2 (50.0)
Ethnicity					
Hispanic/Latino					
	Cycle 3 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 5 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 7 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 9 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 11 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	3	0 (0.0)	2 (66.7)	1 (33.3)
Ethnicity					
Non-Hispanic/Non-Latino					
	Cycle 3 Day 1	49	6 (12.2)	39 (79.6)	4 (8.2)
	Cycle 5 Day 1	34	5 (14.7)	28 (82.4)	1 (2.9)
	Cycle 7 Day 1	28	2 (7.1)	24 (85.7)	2 (7.1)
	Cycle 9 Day 1	16	3 (18.8)	11 (68.8)	2 (12.5)
	Cycle 11 Day 1	11	1 (9.1)	10 (90.9)	0 (0.0)
	Cycle 13 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)

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Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Functional Well-being by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	3	0 (0.0)	1 (33.3)	2 (66.7)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	26	0 (0.0)	21 (80.8)	5 (19.2)
Ethnicity					
Unknown					
	Cycle 3 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	1 (50.0)	1 (50.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Gastric Cancer Symptom (GaCS) Completion Rates by Visit
Full Analysis Set

	T-DXd (N=79)	
Visit	Number of subjects alive	Completed (%)
Baseline	79	71 (89.9)
Cycle 3 Day 1	78	58 (74.4)
Cycle 5 Day 1	76	40 (52.6)
Cycle 7 Day 1	72	32 (44.4)
Cycle 9 Day 1	60	19 (31.7)
Cycle 11 Day 1	44	13 (29.5)
Cycle 13 Day 1	32	6 (18.8)
Cycle 15 Day 1	21	8 (38.1)
Cycle 17 Day 1	18	4 (22.2)
Cycle 19 Day 1	16	3 (18.8)
Cycle 21 Day 1	11	3 (27.3)
Cycle 23 Day 1	7	1 (14.3)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

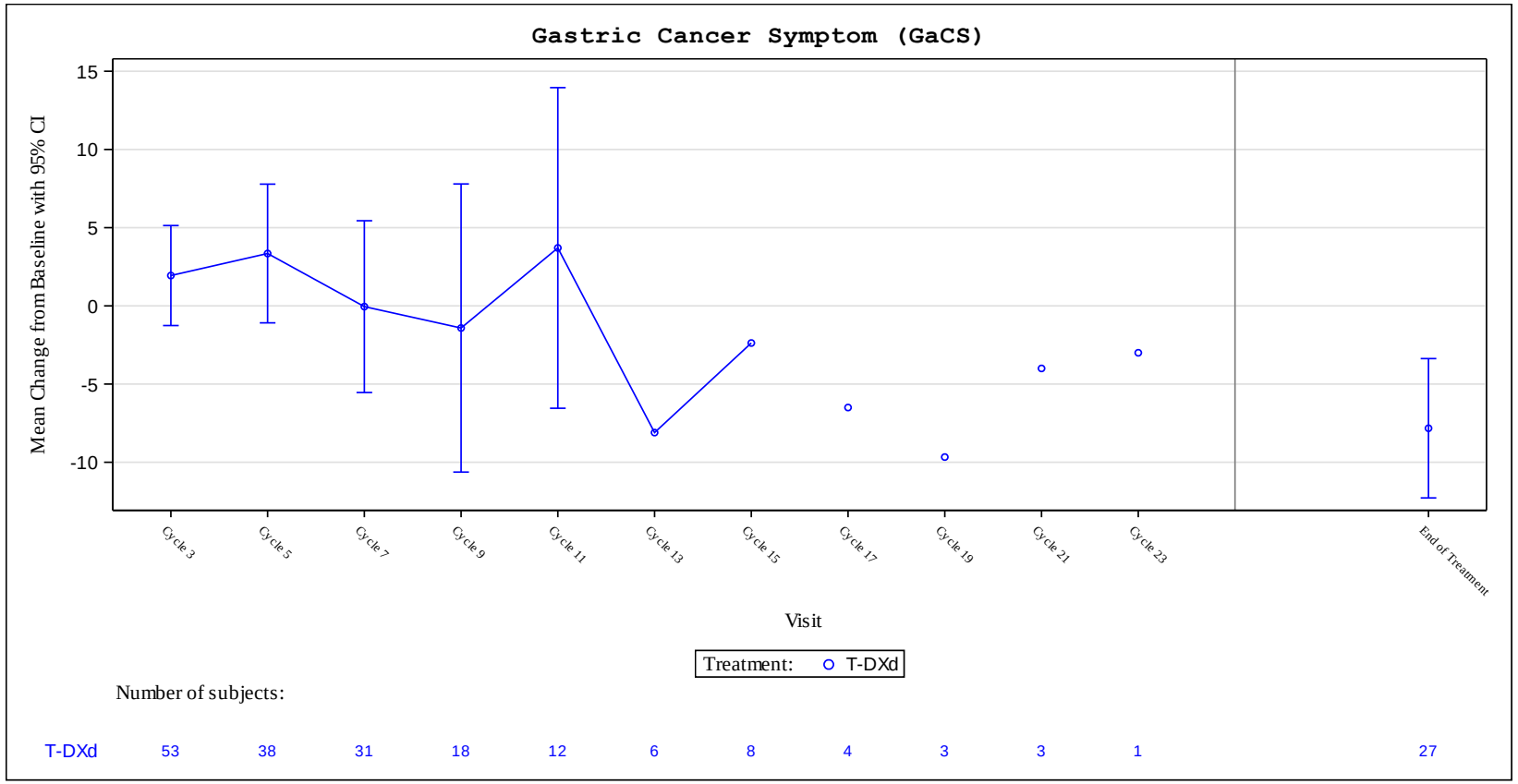
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

	T-DXd (N=79)			
	Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)
Baseline	71	52.7 (14.85)		
Cycle 3 Day 1	58	54.9 (12.32)	53	1.9 (11.60)
Cycle 5 Day 1	40	57.9 (11.26)	38	3.3 (13.49)
Cycle 7 Day 1	32	54.2 (12.36)	31	-0.0 (14.97)
Cycle 9 Day 1	19	54.3 (16.36)	18	-1.4 (18.52)
Cycle 11 Day 1	13	59.3 (9.25)	12	3.7 (16.13)
Cycle 13 Day 1	6	48.2 (17.07)	6	-8.1 (8.37)
Cycle 15 Day 1	8	56.9 (8.69)	8	-2.4 (7.29)
Cycle 17 Day 1	4	50.8 (9.50)	4	-6.5 (12.71)
Cycle 19 Day 1	3	46.0 (10.58)	3	-9.7 (15.18)
Cycle 21 Day 1	3	52.7 (10.69)	3	-4.0 (15.52)
Cycle 23 Day 1	1	57.0 (-)	1	-3.0 (-)
End of Treatment	31	48.1 (20.23)	27	-7.8 (11.26)

Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Graphical Summary of Gastric Cancer Symptom (GaCS) by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADQS

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	21 (26.6)	58 (73.4)	10.7 (5.6, NE)
Region			
North America	10 (29.4)	24 (70.6)	5.6 (1.7, NE)
EU	11 (24.4)	34 (75.6)	NE (NE, NE)
Age (Category 1)			
<65 years	12 (26.1)	34 (73.9)	10.7 (5.6, NE)
>=65 years	9 (27.3)	24 (72.7)	NE (2.8, NE)
Age (Category 2)			
<75 years	19 (25.3)	56 (74.7)	10.7 (5.6, NE)
>=75 years	2 (50.0)	2 (50.0)	3.7 (1.4, NE)
Sex			
female	6 (27.3)	16 (72.7)	NE (3.0, NE)
male	15 (26.3)	42 (73.7)	10.7 (3.7, NE)
ECOG PS			
0	10 (34.5)	19 (65.5)	10.7 (1.5, NE)
1	11 (22.0)	39 (78.0)	NE (5.6, NE)
HER2 Status in central laboratory			
IHC 3+	17 (25.0)	51 (75.0)	NE (5.6, NE)
IHC 2+/ISH +	4 (40.0)	6 (60.0)	1.5 (1.4, NE)
Primary tumor location			
Gastric	7 (25.9)	20 (74.1)	NE (3.0, NE)
GEJ	14 (26.9)	38 (73.1)	10.7 (4.2, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	4 (21.1)	15 (78.9)	10.7 (10.7, NE)
other	17 (28.8)	42 (71.2)	NE (3.0, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	21 (28.4)	53 (71.6)	10.7 (4.2, NE)
Previous total gastrectomy			
no	21 (26.6)	58 (73.4)	10.7 (5.6, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	3 (33.3)	6 (66.7)	NE (1.4, NE)
no	18 (25.7)	52 (74.3)	10.7 (4.2, NE)
Prior nivolumab or pembrolizumab treatment			
yes	0 (0.0)	6 (100.0)	NE (NE, NE)
no	21 (28.8)	52 (71.2)	10.7 (4.2, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	0 (0.0)	7 (100.0)	NE (NE, NE)
no	21 (29.2)	51 (70.8)	10.7 (4.2, NE)

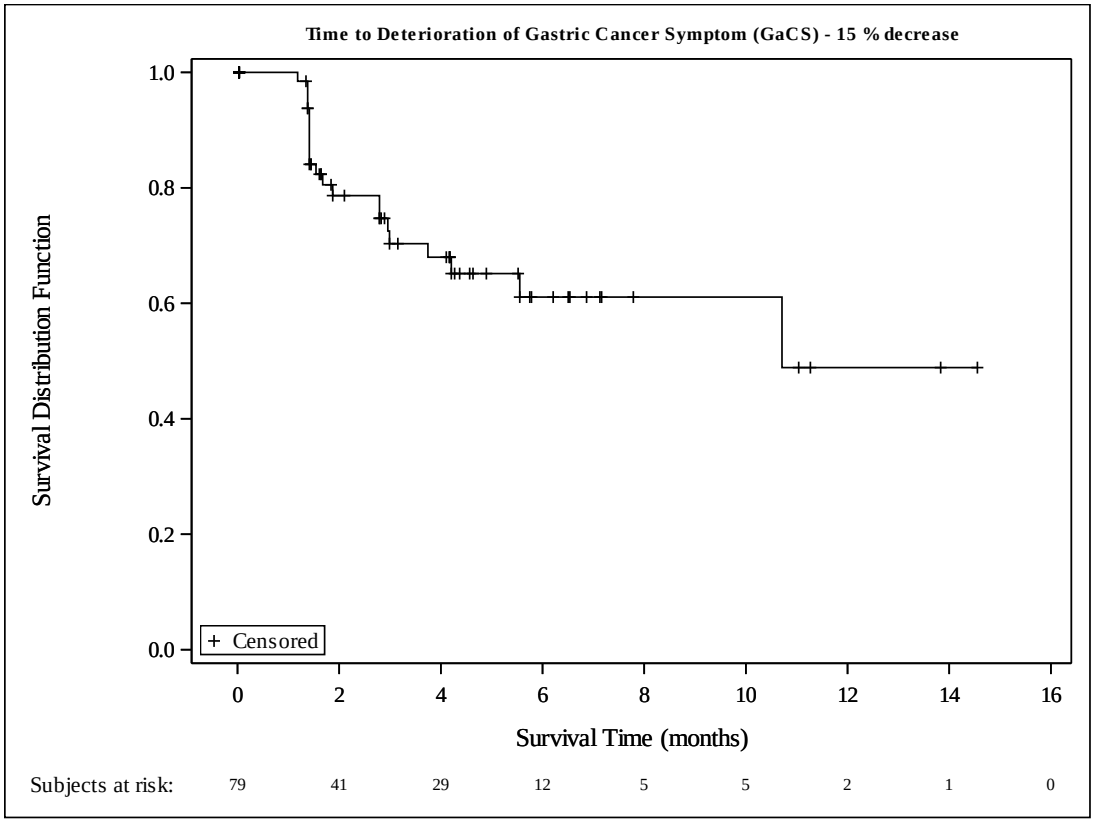
Time to Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	13 (26.0)	37 (74.0)	10.7 (3.7, NE)
no	8 (27.6)	21 (72.4)	NE (3.0, NE)
Renal impairment at baseline			
normal	7 (21.9)	25 (78.1)	10.7 (5.6, 10.7)
mild	7 (28.0)	18 (72.0)	NE (2.8, NE)
moderate	1 (12.5)	7 (87.5)	NE (2.8, NE)
Hepatic impairment at baseline			
normal	18 (28.1)	46 (71.9)	10.7 (4.2, NE)
mild	2 (14.3)	12 (85.7)	NE (2.8, NE)
Race			
White	17 (24.6)	52 (75.4)	NE (5.6, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	3 (37.5)	5 (62.5)	4.2 (1.4, NE)
Ethnicity			
Hispanic/Latino	2 (40.0)	3 (60.0)	10.7 (3.7, 10.7)
Non-Hispanic/Non-Latino	16 (22.9)	54 (77.1)	NE (5.6, NE)
Unknown	3 (75.0)	1 (25.0)	1.4 (1.4, 4.2)

Time to Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)			
	Events (%)	Censored (%)	Median 95% CI [a]	
Overall	18 (22.8)	61 (77.2)	11.1 (10.7,	NE)
Region				
North America	9 (26.5)	25 (73.5)	11.1 (1.9,	NE)
EU	9 (20.0)	36 (80.0)	NE (NE,	NE)
Age (Category 1)				
<65 years	11 (23.9)	35 (76.1)	11.1 (10.7,	NE)
>=65 years	7 (21.2)	26 (78.8)	NE (4.2,	NE)
Age (Category 2)				
<75 years	17 (22.7)	58 (77.3)	11.1 (10.7,	NE)
>=75 years	1 (25.0)	3 (75.0)	NE (3.7,	NE)
Sex				
female	5 (22.7)	17 (77.3)	NE (4.2,	NE)
male	13 (22.8)	44 (77.2)	11.1 (10.7,	NE)
ECOG PS				
0	7 (24.1)	22 (75.9)	10.7 (4.2,	NE)
1	11 (22.0)	39 (78.0)	11.1 (11.1,	NE)
HER2 Status in central laboratory				
IHC 3+	15 (22.1)	53 (77.9)	11.1 (10.7,	NE)
IHC 2+/ISH +	3 (30.0)	7 (70.0)	1.7 (1.4,	NE)
Primary tumor location				
Gastric	6 (22.2)	21 (77.8)	NE (3.7,	NE)
GEJ	12 (23.1)	40 (76.9)	11.1 (10.7,	NE)
Histological subtype				
diffuse	0 (0.0)	1 (100.0)	NE (NE,	NE)
intestinal	4 (21.1)	15 (78.9)	10.7 (10.7,	NE)
other	14 (23.7)	45 (76.3)	11.1 (4.2,	NE)
Number of metastatic sites				
<2	0 (0.0)	5 (100.0)	NE (NE,	NE)
>=2	18 (24.3)	56 (75.7)	11.1 (10.7,	NE)
Previous total gastrectomy				
no	18 (22.8)	61 (77.2)	11.1 (10.7,	NE)
Prior adjuvant/ neoadjuvant therapy				
yes	1 (11.1)	8 (88.9)	NE (1.4,	NE)
no	17 (24.3)	53 (75.7)	11.1 (10.7,	NE)
Prior nivolumab or pembrolizumab treatment				
yes	0 (0.0)	6 (100.0)	NE (NE,	NE)
no	18 (24.7)	55 (75.3)	11.1 (10.7,	NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy				
yes	0 (0.0)	7 (100.0)	NE (NE,	NE)
no	18 (25.0)	54 (75.0)	11.1 (10.7,	NE)

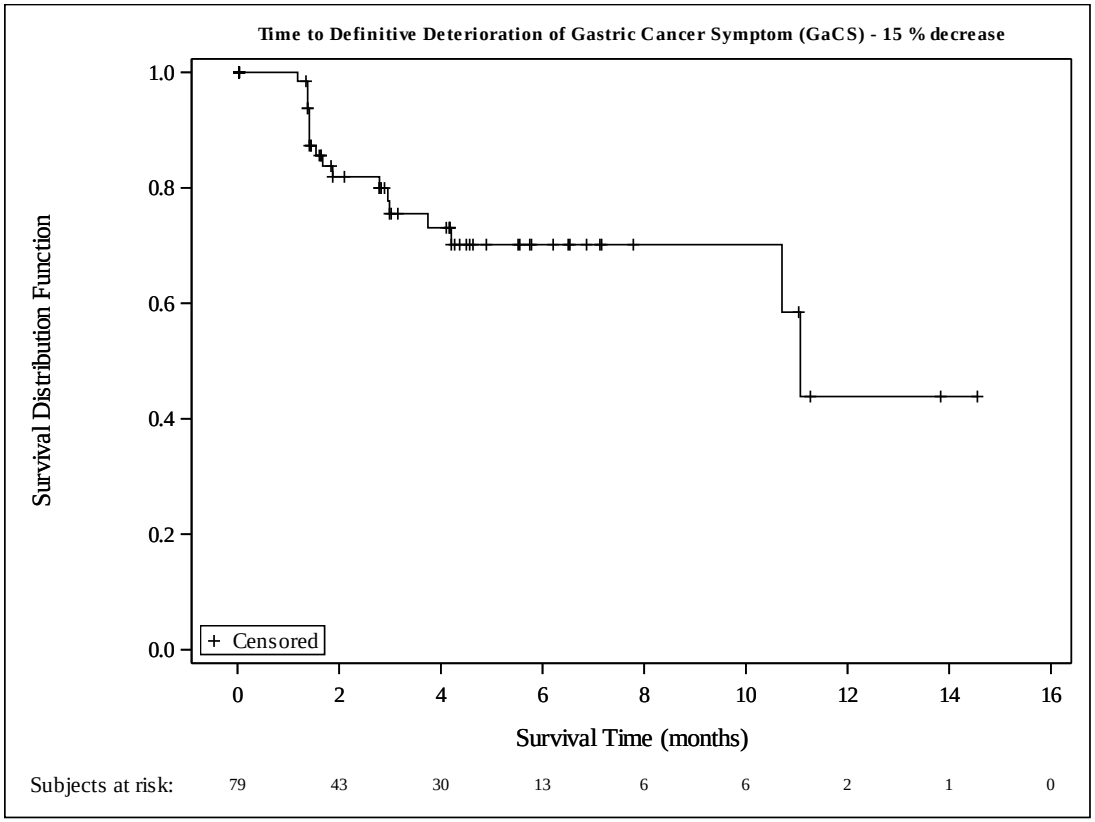
Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%.
Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	12 (24.0)	38 (76.0)	11.1 (10.7, NE)
no	6 (20.7)	23 (79.3)	NE (4.2, NE)
Renal impairment at baseline			
normal	7 (21.9)	25 (78.1)	10.7 (10.7, 11.1)
mild	6 (24.0)	19 (76.0)	NE (3.7, NE)
moderate	0 (0.0)	8 (100.0)	NE (NE, NE)
Hepatic impairment at baseline			
normal	16 (25.0)	48 (75.0)	11.1 (10.7, NE)
mild	1 (7.1)	13 (92.9)	NE (2.8, NE)
Race			
White	15 (21.7)	54 (78.3)	11.1 (10.7, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	3 (37.5)	5 (62.5)	4.2 (1.4, NE)
Ethnicity			
Hispanic/Latino	2 (40.0)	3 (60.0)	10.7 (3.7, 10.7)
Non-Hispanic/Non-Latino	14 (20.0)	56 (80.0)	NE (11.1, NE)
Unknown	2 (50.0)	2 (50.0)	4.2 (1.4, 4.2)

Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%.
Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Gastric Cancer Symptom (GaCS) (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall					
	Cycle 3 Day 1	58	14 (24.1)	36 (62.1)	8 (13.8)
	Cycle 5 Day 1	40	8 (20.0)	26 (65.0)	6 (15.0)
	Cycle 7 Day 1	32	5 (15.6)	20 (62.5)	7 (21.9)
	Cycle 9 Day 1	19	4 (21.1)	10 (52.6)	5 (26.3)
	Cycle 11 Day 1	13	3 (23.1)	9 (69.2)	1 (7.7)
	Cycle 13 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	31	0 (0.0)	21 (67.7)	10 (32.3)
Region					
North America					
	Cycle 3 Day 1	22	4 (18.2)	14 (63.6)	4 (18.2)
	Cycle 5 Day 1	14	1 (7.1)	12 (85.7)	1 (7.1)
	Cycle 7 Day 1	11	2 (18.2)	6 (54.5)	3 (27.3)
	Cycle 9 Day 1	7	0 (0.0)	5 (71.4)	2 (28.6)
	Cycle 11 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 15 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	14	0 (0.0)	9 (64.3)	5 (35.7)
Region					
EU					
	Cycle 3 Day 1	36	10 (27.8)	22 (61.1)	4 (11.1)
	Cycle 5 Day 1	26	7 (26.9)	14 (53.8)	5 (19.2)
	Cycle 7 Day 1	21	3 (14.3)	14 (66.7)	4 (19.0)
	Cycle 9 Day 1	12	4 (33.3)	5 (41.7)	3 (25.0)
	Cycle 11 Day 1	7	2 (28.6)	4 (57.1)	1 (14.3)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	17	0 (0.0)	12 (70.6)	5 (29.4)
Age (Category 1)					
<65 years					
	Cycle 3 Day 1	37	7 (18.9)	25 (67.6)	5 (13.5)
	Cycle 5 Day 1	25	5 (20.0)	16 (64.0)	4 (16.0)
	Cycle 7 Day 1	17	3 (17.6)	10 (58.8)	4 (23.5)
	Cycle 9 Day 1	12	2 (16.7)	7 (58.3)	3 (25.0)
	Cycle 11 Day 1	9	2 (22.2)	6 (66.7)	1 (11.1)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 19 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	18	0 (0.0)	12 (66.7)	6 (33.3)
Age (Category 1)					
>=65 years					
	Cycle 3 Day 1	21	7 (33.3)	11 (52.4)	3 (14.3)
	Cycle 5 Day 1	15	3 (20.0)	10 (66.7)	2 (13.3)
	Cycle 7 Day 1	15	2 (13.3)	10 (66.7)	3 (20.0)
	Cycle 9 Day 1	7	2 (28.6)	3 (42.9)	2 (28.6)
	Cycle 11 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 13 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 15 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	9 (69.2)	4 (30.8)
Age (Category 2)					
<75 years					
	Cycle 3 Day 1	54	13 (24.1)	34 (63.0)	7 (13.0)
	Cycle 5 Day 1	37	8 (21.6)	23 (62.2)	6 (16.2)
	Cycle 7 Day 1	30	5 (16.7)	19 (63.3)	6 (20.0)
	Cycle 9 Day 1	17	3 (17.6)	10 (58.8)	4 (23.5)
	Cycle 11 Day 1	12	3 (25.0)	8 (66.7)	1 (8.3)
	Cycle 13 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 15 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	31	0 (0.0)	21 (67.7)	10 (32.3)
Age (Category 2)					
>=75 years					
	Cycle 3 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 5 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 9 Day 1	2	1 (50.0)	0 (0.0)	1 (50.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Sex					
female					
	Cycle 3 Day 1	18	6 (33.3)	10 (55.6)	2 (11.1)
	Cycle 5 Day 1	16	4 (25.0)	9 (56.3)	3 (18.8)
	Cycle 7 Day 1	13	3 (23.1)	8 (61.5)	2 (15.4)
	Cycle 9 Day 1	6	3 (50.0)	2 (33.3)	1 (16.7)
	Cycle 11 Day 1	4	2 (50.0)	1 (25.0)	1 (25.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	7	0 (0.0)	4 (57.1)	3 (42.9)
Sex					
male					
	Cycle 3 Day 1	40	8 (20.0)	26 (65.0)	6 (15.0)
	Cycle 5 Day 1	24	4 (16.7)	17 (70.8)	3 (12.5)
	Cycle 7 Day 1	19	2 (10.5)	12 (63.2)	5 (26.3)
	Cycle 9 Day 1	13	1 (7.7)	8 (61.5)	4 (30.8)
	Cycle 11 Day 1	9	1 (11.1)	8 (88.9)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 15 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	24	0 (0.0)	17 (70.8)	7 (29.2)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS					
0					
	Cycle 3 Day 1	21	1 (4.8)	15 (71.4)	5 (23.8)
	Cycle 5 Day 1	16	1 (6.3)	13 (81.3)	2 (12.5)
	Cycle 7 Day 1	11	1 (9.1)	8 (72.7)	2 (18.2)
	Cycle 9 Day 1	9	1 (11.1)	7 (77.8)	1 (11.1)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	15	0 (0.0)	10 (66.7)	5 (33.3)
ECOG PS					
1					
	Cycle 3 Day 1	37	13 (35.1)	21 (56.8)	3 (8.1)
	Cycle 5 Day 1	24	7 (29.2)	13 (54.2)	4 (16.7)
	Cycle 7 Day 1	21	4 (19.0)	12 (57.1)	5 (23.8)
	Cycle 9 Day 1	10	3 (30.0)	3 (30.0)	4 (40.0)
	Cycle 11 Day 1	7	3 (42.9)	3 (42.9)	1 (14.3)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	16	0 (0.0)	11 (68.8)	5 (31.3)
HER2 Status in central laboratory					
IHC 3+					
	Cycle 3 Day 1	55	14 (25.5)	34 (61.8)	7 (12.7)
	Cycle 5 Day 1	38	8 (21.1)	24 (63.2)	6 (15.8)
	Cycle 7 Day 1	30	5 (16.7)	18 (60.0)	7 (23.3)
	Cycle 9 Day 1	18	4 (22.2)	9 (50.0)	5 (27.8)
	Cycle 11 Day 1	13	3 (23.1)	9 (69.2)	1 (7.7)
	Cycle 13 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	25	0 (0.0)	18 (72.0)	7 (28.0)
HER2 Status in central laboratory					
IHC 2+/ISH +					
	Cycle 3 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	6	0 (0.0)	3 (50.0)	3 (50.0)
Primary tumor location					
Gastric					
	Cycle 3 Day 1	21	7 (33.3)	10 (47.6)	4 (19.0)
	Cycle 5 Day 1	17	5 (29.4)	9 (52.9)	3 (17.6)
	Cycle 7 Day 1	15	3 (20.0)	8 (53.3)	4 (26.7)
	Cycle 9 Day 1	6	1 (16.7)	2 (33.3)	3 (50.0)
	Cycle 11 Day 1	6	2 (33.3)	3 (50.0)	1 (16.7)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	10	0 (0.0)	8 (80.0)	2 (20.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Primary tumor location					
GEJ					
	Cycle 3 Day 1	37	7 (18.9)	26 (70.3)	4 (10.8)
	Cycle 5 Day 1	23	3 (13.0)	17 (73.9)	3 (13.0)
	Cycle 7 Day 1	17	2 (11.8)	12 (70.6)	3 (17.6)
	Cycle 9 Day 1	13	3 (23.1)	8 (61.5)	2 (15.4)
	Cycle 11 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 15 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 19 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	21	0 (0.0)	13 (61.9)	8 (38.1)
Histological subtype					
diffuse					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Histological subtype					
intestinal					
	Cycle 3 Day 1	14	3 (21.4)	9 (64.3)	2 (14.3)
	Cycle 5 Day 1	11	3 (27.3)	6 (54.5)	2 (18.2)
	Cycle 7 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 9 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 11 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	8	0 (0.0)	6 (75.0)	2 (25.0)
Histological subtype					
other					
	Cycle 3 Day 1	43	11 (25.6)	26 (60.5)	6 (14.0)
	Cycle 5 Day 1	28	5 (17.9)	19 (67.9)	4 (14.3)
	Cycle 7 Day 1	23	4 (17.4)	13 (56.5)	6 (26.1)
	Cycle 9 Day 1	13	3 (23.1)	6 (46.2)	4 (30.8)
	Cycle 11 Day 1	9	3 (33.3)	5 (55.6)	1 (11.1)
	Cycle 13 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 15 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	22	0 (0.0)	14 (63.6)	8 (36.4)
Number of metastatic sites					
<2					
	Cycle 3 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 5 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 7 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Number of metastatic sites					
>=2					
	Cycle 3 Day 1	55	12 (21.8)	35 (63.6)	8 (14.5)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 5 Day 1	37	7 (18.9)	24 (64.9)	6 (16.2)
	Cycle 7 Day 1	28	4 (14.3)	17 (60.7)	7 (25.0)
	Cycle 9 Day 1	18	4 (22.2)	9 (50.0)	5 (27.8)
	Cycle 11 Day 1	13	3 (23.1)	9 (69.2)	1 (7.7)
	Cycle 13 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	29	0 (0.0)	19 (65.5)	10 (34.5)
Previous total gastrectomy					
no					
	Cycle 3 Day 1	58	14 (24.1)	36 (62.1)	8 (13.8)
	Cycle 5 Day 1	40	8 (20.0)	26 (65.0)	6 (15.0)
	Cycle 7 Day 1	32	5 (15.6)	20 (62.5)	7 (21.9)
	Cycle 9 Day 1	19	4 (21.1)	10 (52.6)	5 (26.3)
	Cycle 11 Day 1	13	3 (23.1)	9 (69.2)	1 (7.7)
	Cycle 13 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	31	0 (0.0)	21 (67.7)	10 (32.3)
Prior adjuvant/ neoadjuvant therapy					
yes					
	Cycle 3 Day 1	7	2 (28.6)	3 (42.9)	2 (28.6)
	Cycle 5 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 7 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 9 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy					
no					
	Cycle 3 Day 1	51	12 (23.5)	33 (64.7)	6 (11.8)
	Cycle 5 Day 1	34	7 (20.6)	22 (64.7)	5 (14.7)
	Cycle 7 Day 1	25	4 (16.0)	15 (60.0)	6 (24.0)
	Cycle 9 Day 1	17	3 (17.6)	9 (52.9)	5 (29.4)
	Cycle 11 Day 1	12	3 (25.0)	8 (66.7)	1 (8.3)
	Cycle 13 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 15 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	30	0 (0.0)	20 (66.7)	10 (33.3)
Prior nivolumab or pembrolizumab treatment					
yes					
	Cycle 3 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 15 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior nivolumab or pembrolizumab treatment					
no					
	Cycle 3 Day 1	56	13 (23.2)	35 (62.5)	8 (14.3)
	Cycle 5 Day 1	39	8 (20.5)	25 (64.1)	6 (15.4)
	Cycle 7 Day 1	30	4 (13.3)	19 (63.3)	7 (23.3)
	Cycle 9 Day 1	19	4 (21.1)	10 (52.6)	5 (26.3)
	Cycle 11 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 13 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 15 Day 1	7	0 (0.0)	7 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	30	0 (0.0)	20 (66.7)	10 (33.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
yes					
	Cycle 3 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 15 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
no					
	Cycle 3 Day 1	55	13 (23.6)	34 (61.8)	8 (14.5)
	Cycle 5 Day 1	38	8 (21.1)	24 (63.2)	6 (15.8)
	Cycle 7 Day 1	30	4 (13.3)	19 (63.3)	7 (23.3)
	Cycle 9 Day 1	19	4 (21.1)	10 (52.6)	5 (26.3)
	Cycle 11 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 13 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 15 Day 1	7	0 (0.0)	7 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	30	0 (0.0)	20 (66.7)	10 (33.3)
Presence of liver metastasis at baseline					
yes					
	Cycle 3 Day 1	36	9 (25.0)	23 (63.9)	4 (11.1)
	Cycle 5 Day 1	24	4 (16.7)	17 (70.8)	3 (12.5)
	Cycle 7 Day 1	18	2 (11.1)	12 (66.7)	4 (22.2)
	Cycle 9 Day 1	14	2 (14.3)	9 (64.3)	3 (21.4)
	Cycle 11 Day 1	8	0 (0.0)	8 (100.0)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	18	0 (0.0)	11 (61.1)	7 (38.9)
Presence of liver metastasis at baseline					
no					
	Cycle 3 Day 1	22	5 (22.7)	13 (59.1)	4 (18.2)
	Cycle 5 Day 1	16	4 (25.0)	9 (56.3)	3 (18.8)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
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Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 7 Day 1	14	3 (21.4)	8 (57.1)	3 (21.4)
	Cycle 9 Day 1	5	2 (40.0)	1 (20.0)	2 (40.0)
	Cycle 11 Day 1	5	3 (60.0)	1 (20.0)	1 (20.0)
	Cycle 13 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 15 Day 1	2	1 (50.0)	1 (50.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	10 (76.9)	3 (23.1)
Renal impairment at baseline					
normal					
	Cycle 3 Day 1	23	4 (17.4)	18 (78.3)	1 (4.3)
	Cycle 5 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 7 Day 1	7	2 (28.6)	4 (57.1)	1 (14.3)
	Cycle 9 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 11 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 19 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	13	0 (0.0)	8 (61.5)	5 (38.5)
Renal impairment at baseline					
mild					
	Cycle 3 Day 1	15	4 (26.7)	8 (53.3)	3 (20.0)
	Cycle 5 Day 1	12	2 (16.7)	8 (66.7)	2 (16.7)
	Cycle 7 Day 1	11	1 (9.1)	7 (63.6)	3 (27.3)
	Cycle 9 Day 1	6	1 (16.7)	3 (50.0)	2 (33.3)
	Cycle 11 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	9 (75.0)	3 (25.0)
Renal impairment at baseline					
moderate					
	Cycle 3 Day 1	7	3 (42.9)	4 (57.1)	0 (0.0)
	Cycle 5 Day 1	7	2 (28.6)	4 (57.1)	1 (14.3)
	Cycle 7 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 9 Day 1	3	2 (66.7)	1 (33.3)	0 (0.0)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline					
normal					
	Cycle 3 Day 1	46	11 (23.9)	28 (60.9)	7 (15.2)
	Cycle 5 Day 1	31	7 (22.6)	19 (61.3)	5 (16.1)
	Cycle 7 Day 1	27	4 (14.8)	17 (63.0)	6 (22.2)
	Cycle 9 Day 1	16	3 (18.8)	8 (50.0)	5 (31.3)
	Cycle 11 Day 1	12	3 (25.0)	8 (66.7)	1 (8.3)
	Cycle 13 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 15 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	28	0 (0.0)	19 (67.9)	9 (32.1)
Hepatic impairment at baseline					
mild					
	Cycle 3 Day 1	12	3 (25.0)	8 (66.7)	1 (8.3)
	Cycle 5 Day 1	9	1 (11.1)	7 (77.8)	1 (11.1)
	Cycle 7 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 9 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Race					
White					
	Cycle 3 Day 1	51	12 (23.5)	34 (66.7)	5 (9.8)
	Cycle 5 Day 1	34	7 (20.6)	22 (64.7)	5 (14.7)
	Cycle 7 Day 1	28	4 (14.3)	19 (67.9)	5 (17.9)
	Cycle 9 Day 1	17	4 (23.5)	8 (47.1)	5 (29.4)
	Cycle 11 Day 1	12	3 (25.0)	8 (66.7)	1 (8.3)
	Cycle 13 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 15 Day 1	8	1 (12.5)	7 (87.5)	0 (0.0)
	Cycle 17 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 19 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	27	0 (0.0)	18 (66.7)	9 (33.3)
Race					
Black or African American					
	Cycle 3 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Race					
Other					
	Cycle 3 Day 1	5	1 (20.0)	2 (40.0)	2 (40.0)
	Cycle 5 Day 1	4	1 (25.0)	2 (50.0)	1 (25.0)
	Cycle 7 Day 1	4	1 (25.0)	1 (25.0)	2 (50.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	3 (75.0)	1 (25.0)
Ethnicity					
Hispanic/Latino					
	Cycle 3 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 5 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 7 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 9 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 11 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	3	0 (0.0)	2 (66.7)	1 (33.3)
Ethnicity					
Non-Hispanic/Non-Latino					
	Cycle 3 Day 1	49	14 (28.6)	29 (59.2)	6 (12.2)
	Cycle 5 Day 1	34	8 (23.5)	20 (58.8)	6 (17.6)
	Cycle 7 Day 1	28	5 (17.9)	18 (64.3)	5 (17.9)
	Cycle 9 Day 1	16	4 (25.0)	8 (50.0)	4 (25.0)
	Cycle 11 Day 1	11	3 (27.3)	7 (63.6)	1 (9.1)
	Cycle 13 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 15 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Gastric Cancer Symptom (GaCS) by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 17 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 19 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 21 Day 1	3	1 (33.3)	1 (33.3)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	26	0 (0.0)	18 (69.2)	8 (30.8)
Ethnicity					
Unknown					
	Cycle 3 Day 1	4	0 (0.0)	2 (50.0)	2 (50.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	2	0 (0.0)	1 (50.0)	1 (50.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Fact-G Total Score Completion Rates by Visit
Full Analysis Set

	T-DXd (N=79)	
Visit	Number of subjects alive	Completed (%)
Baseline	79	71 (89.9)
Cycle 3 Day 1	78	57 (73.1)
Cycle 5 Day 1	76	40 (52.6)
Cycle 7 Day 1	72	30 (41.7)
Cycle 9 Day 1	60	18 (30.0)
Cycle 11 Day 1	44	13 (29.5)
Cycle 13 Day 1	32	6 (18.8)
Cycle 15 Day 1	21	8 (38.1)
Cycle 17 Day 1	18	4 (22.2)
Cycle 19 Day 1	16	3 (18.8)
Cycle 21 Day 1	11	3 (27.3)
Cycle 23 Day 1	7	1 (14.3)

Subjects defined as alive at the respective timepoint if minimum(death date, cutoff date) - treatment start + 1 >= start date of respective visit window.
Completed defined as non-missing value at the respective timepoint.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

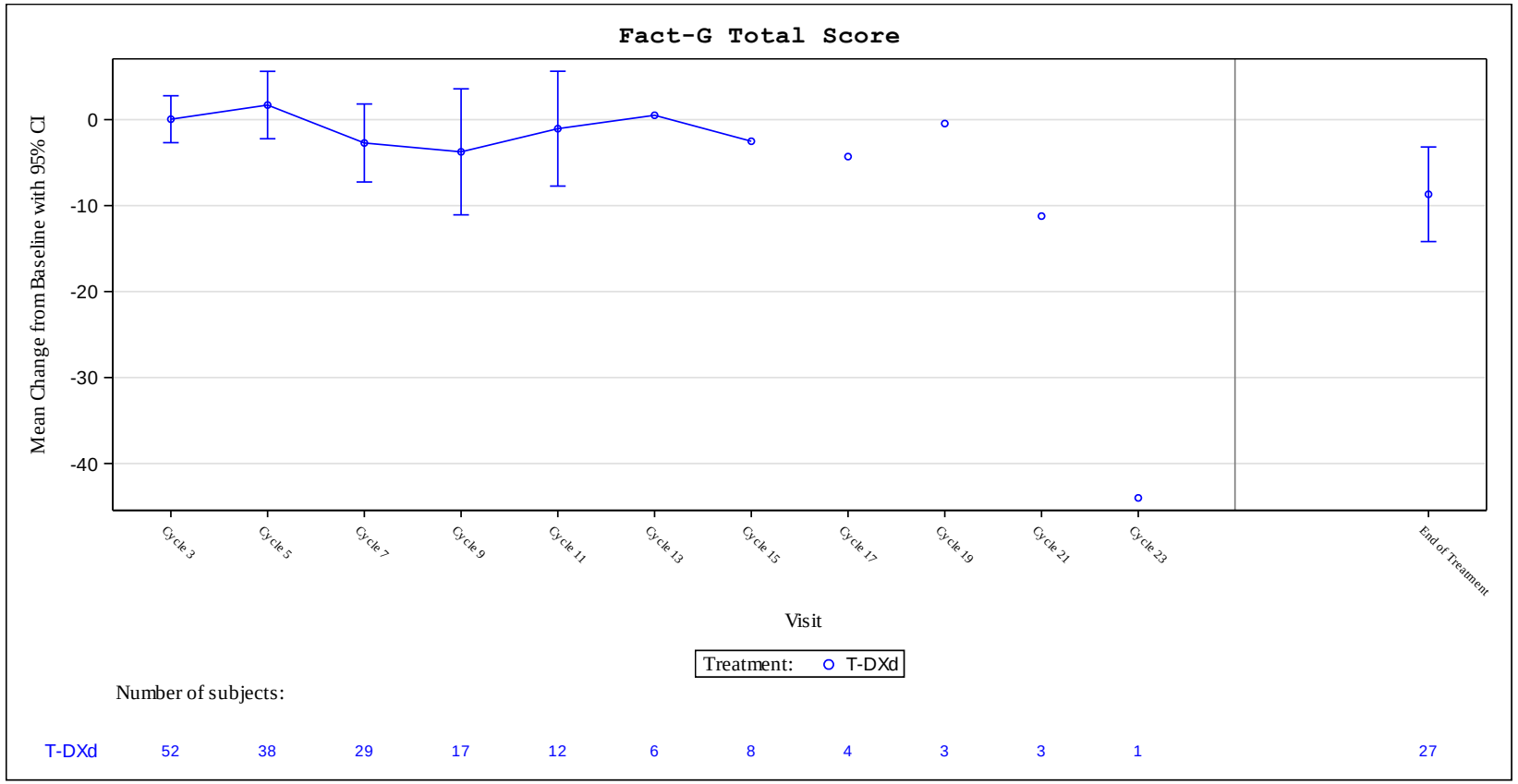
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Fact-G Total Score by Visit
Full Analysis Set

	T-DXd (N=79)			
	Value at Visit		Change from Baseline	
Visit	N	Mean (SD)	N	Mean (SD)
Baseline	71	77.4 (19.13)		
Cycle 3 Day 1	57	76.3 (16.19)	52	0.0 (9.80)
Cycle 5 Day 1	40	78.4 (19.45)	38	1.7 (11.93)
Cycle 7 Day 1	30	73.6 (19.50)	29	-2.7 (11.92)
Cycle 9 Day 1	18	76.6 (19.82)	17	-3.7 (14.25)
Cycle 11 Day 1	13	80.1 (20.62)	12	-1.1 (10.51)
Cycle 13 Day 1	6	82.1 (13.99)	6	0.5 (8.34)
Cycle 15 Day 1	8	85.7 (15.54)	8	-2.5 (10.52)
Cycle 17 Day 1	4	78.3 (9.22)	4	-4.3 (4.41)
Cycle 19 Day 1	3	84.3 (7.89)	3	-0.5 (1.91)
Cycle 21 Day 1	3	78.1 (7.79)	3	-11.2 (18.15)
Cycle 23 Day 1	1	63.0 (-)	1	-44.0 (-)
End of Treatment	31	72.5 (23.03)	27	-8.7 (13.91)

Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Graphical Summary of Fact-G Total Score by Visit - Mean Change from Baseline
Full Analysis Set



95% CIs are not drawn for visits with Number of subjects<10. Lines are not drawn for visits with Number of subjects<5.
Source data: ADAM.ADSL and ADAM.ADQS

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	12 (15.2)	67 (84.8)	NE (9.3, NE)
Region			
North America	5 (14.7)	29 (85.3)	NE (4.2, NE)
EU	7 (15.6)	38 (84.4)	NE (NE, NE)
Age (Category 1)			
<65 years	8 (17.4)	38 (82.6)	NE (9.3, NE)
>=65 years	4 (12.1)	29 (87.9)	NE (NE, NE)
Age (Category 2)			
<75 years	10 (13.3)	65 (86.7)	NE (9.3, NE)
>=75 years	2 (50.0)	2 (50.0)	3.7 (1.4, NE)
Sex			
female	1 (4.5)	21 (95.5)	NE (NE, NE)
male	11 (19.3)	46 (80.7)	9.3 (4.2, NE)
ECOG PS			
0	4 (13.8)	25 (86.2)	NE (9.3, NE)
1	8 (16.0)	42 (84.0)	NE (NE, NE)
HER2 Status in central laboratory			
IHC 3+	10 (14.7)	58 (85.3)	NE (9.3, NE)
IHC 2+/ISH +	2 (20.0)	8 (80.0)	NE (1.6, NE)
Primary tumor location			
Gastric	4 (14.8)	23 (85.2)	NE (3.7, NE)
GEJ	8 (15.4)	44 (84.6)	NE (9.3, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	3 (15.8)	16 (84.2)	9.3 (3.0, NE)
other	9 (15.3)	50 (84.7)	NE (NE, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	12 (16.2)	62 (83.8)	NE (9.3, NE)
Previous total gastrectomy			
no	12 (15.2)	67 (84.8)	NE (9.3, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	1 (11.1)	8 (88.9)	NE (1.4, NE)
no	11 (15.7)	59 (84.3)	NE (9.3, NE)
Prior nivolumab or pembrolizumab treatment			
yes	0 (0.0)	6 (100.0)	NE (NE, NE)
no	12 (16.4)	61 (83.6)	NE (9.3, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	0 (0.0)	7 (100.0)	NE (NE, NE)
no	12 (16.7)	60 (83.3)	NE (9.3, NE)

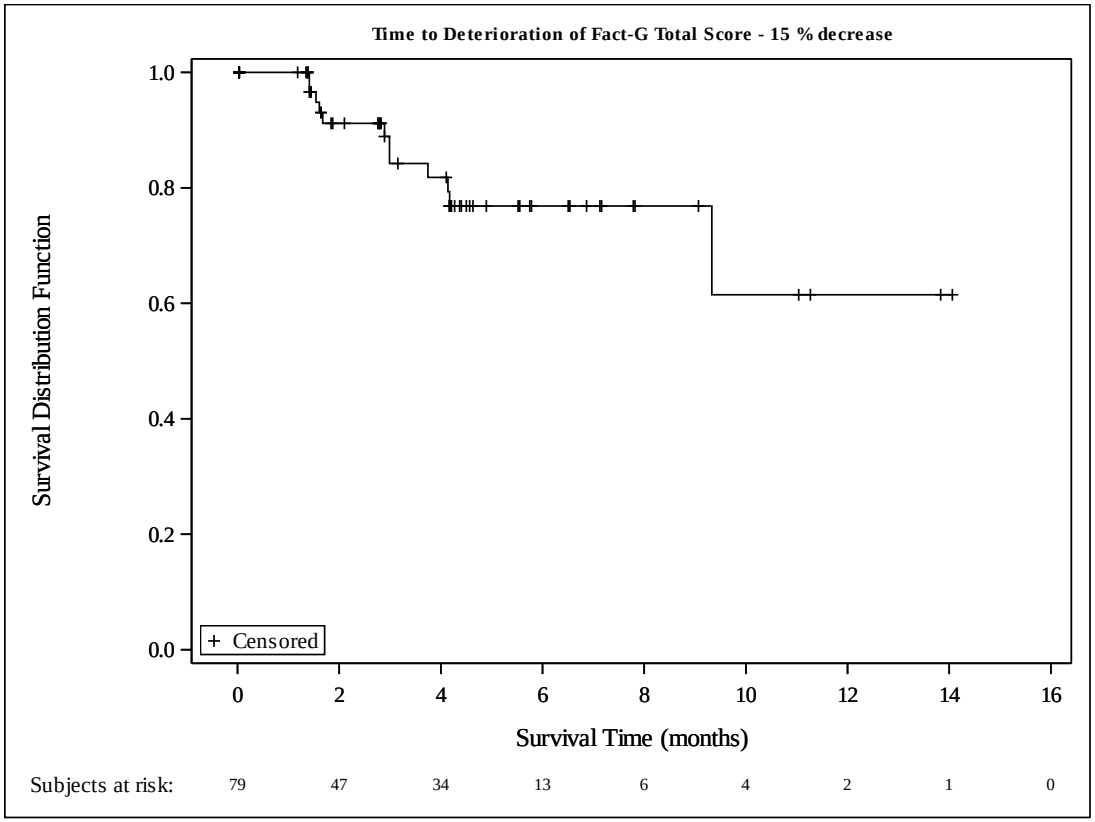
Time to Deterioration of Fact-G Total Score is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	9 (18.0)	41 (82.0)	NE (4.2, NE)
no	3 (10.3)	26 (89.7)	NE (NE, NE)
Renal impairment at baseline			
normal	5 (15.6)	27 (84.4)	9.3 (3.0, NE)
mild	4 (16.0)	21 (84.0)	NE (3.7, NE)
moderate	1 (12.5)	7 (87.5)	NE (4.1, NE)
Hepatic impairment at baseline			
normal	12 (18.8)	52 (81.3)	NE (9.3, NE)
mild	0 (0.0)	14 (100.0)	NE (NE, NE)
Race			
White	10 (14.5)	59 (85.5)	NE (9.3, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	NE (1.6, NE)
Ethnicity			
Hispanic/Latino	2 (40.0)	3 (60.0)	9.3 (3.7, 9.3)
Non-Hispanic/Non-Latino	10 (14.3)	60 (85.7)	NE (NE, NE)
Unknown	0 (0.0)	4 (100.0)	NE (NE, NE)

Time to Deterioration of Fact-G Total Score is defined as the time from the date of treatment start to the date of the earliest deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Overall	8 (10.1)	71 (89.9)	NE (9.3, NE)
Region			
North America	4 (11.8)	30 (88.2)	NE (9.3, NE)
EU	4 (8.9)	41 (91.1)	NE (NE, NE)
Age (Category 1)			
<65 years	7 (15.2)	39 (84.8)	NE (9.3, NE)
>=65 years	1 (3.0)	32 (97.0)	NE (NE, NE)
Age (Category 2)			
<75 years	8 (10.7)	67 (89.3)	NE (9.3, NE)
>=75 years	0 (0.0)	4 (100.0)	NE (NE, NE)
Sex			
female	0 (0.0)	22 (100.0)	NE (NE, NE)
male	8 (14.0)	49 (86.0)	NE (9.3, NE)
ECOG PS			
0	2 (6.9)	27 (93.1)	NE (9.3, NE)
1	6 (12.0)	44 (88.0)	NE (NE, NE)
HER2 Status in central laboratory			
IHC 3+	6 (8.8)	62 (91.2)	NE (9.3, NE)
IHC 2+/ISH +	2 (20.0)	8 (80.0)	NE (1.6, NE)
Primary tumor location			
Gastric	2 (7.4)	25 (92.6)	NE (NE, NE)
GEJ	6 (11.5)	46 (88.5)	NE (9.3, NE)
Histological subtype			
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)
intestinal	2 (10.5)	17 (89.5)	9.3 (9.3, NE)
other	6 (10.2)	53 (89.8)	NE (NE, NE)
Number of metastatic sites			
<2	0 (0.0)	5 (100.0)	NE (NE, NE)
>=2	8 (10.8)	66 (89.2)	NE (9.3, NE)
Previous total gastrectomy			
no	8 (10.1)	71 (89.9)	NE (9.3, NE)
Prior adjuvant/ neoadjuvant therapy			
yes	0 (0.0)	9 (100.0)	NE (NE, NE)
no	8 (11.4)	62 (88.6)	NE (9.3, NE)
Prior nivolumab or pembrolizumab treatment			
yes	0 (0.0)	6 (100.0)	NE (NE, NE)
no	8 (11.0)	65 (89.0)	NE (9.3, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	0 (0.0)	7 (100.0)	NE (NE, NE)
no	8 (11.1)	64 (88.9)	NE (9.3, NE)

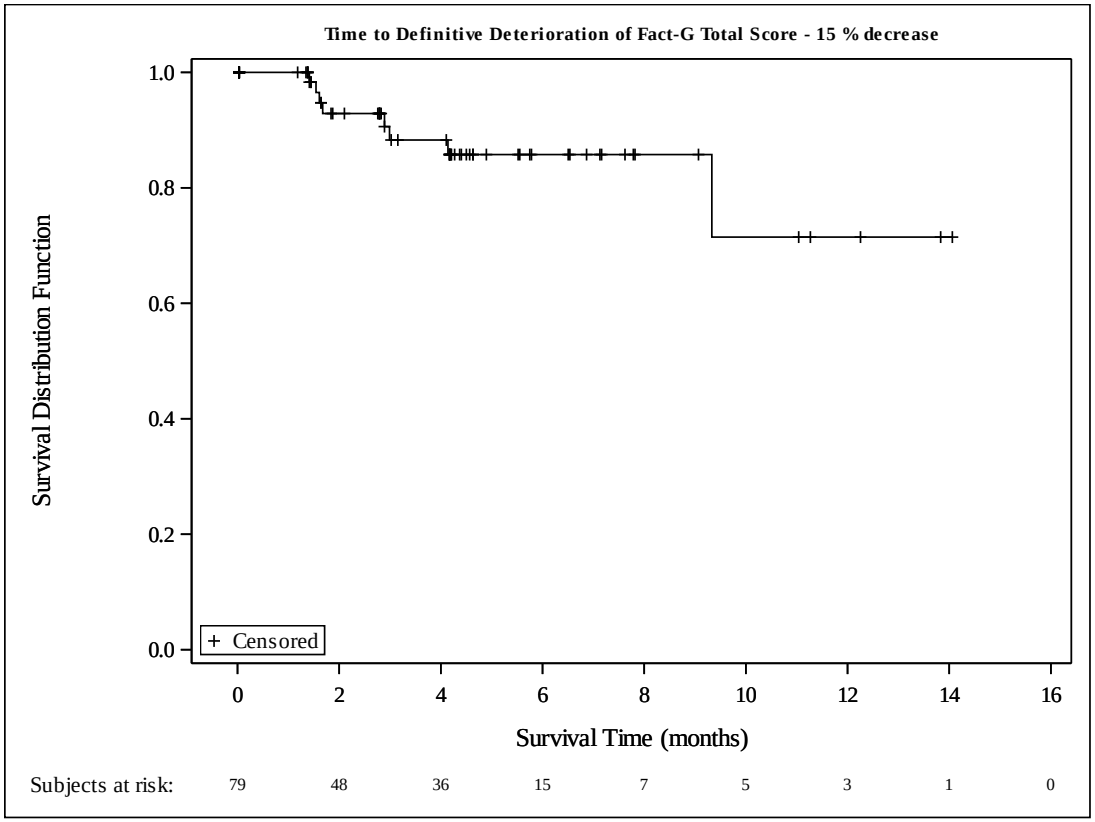
Time to Definitive Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set

	T-DXd (N=79)		
	Events (%)	Censored (%)	Median 95% CI [a]
Presence of liver metastasis at baseline			
yes	7 (14.0)	43 (86.0)	NE (9.3, NE)
no	1 (3.4)	28 (96.6)	NE (NE, NE)
Renal impairment at baseline			
normal	4 (12.5)	28 (87.5)	9.3 (3.0, NE)
mild	2 (8.0)	23 (92.0)	NE (NE, NE)
moderate	1 (12.5)	7 (87.5)	NE (4.1, NE)
Hepatic impairment at baseline			
normal	8 (12.5)	56 (87.5)	NE (9.3, NE)
mild	0 (0.0)	14 (100.0)	NE (NE, NE)
Race			
White	7 (10.1)	62 (89.9)	NE (9.3, NE)
Black or African American	0 (0.0)	1 (100.0)	NE (NE, NE)
Other	1 (12.5)	7 (87.5)	NE (1.6, NE)
Ethnicity			
Hispanic/Latino	1 (20.0)	4 (80.0)	NE (9.3, NE)
Non-Hispanic/Non-Latino	7 (10.0)	63 (90.0)	NE (NE, NE)
Unknown	0 (0.0)	4 (100.0)	NE (NE, NE)

Time to Definitive Deterioration of Fact-G Total Score is defined as the time from the date of randomization to the date of two consecutive visits or last assessment visit with deterioration >= 15%. Death is not considered as event.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Summary of Time to Definitive Deterioration of Fact-G Total Score (Months) - 15% decrease
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Overall					
	Cycle 3 Day 1	57	5 (8.8)	50 (87.7)	2 (3.5)
	Cycle 5 Day 1	40	5 (12.5)	33 (82.5)	2 (5.0)
	Cycle 7 Day 1	30	2 (6.7)	24 (80.0)	4 (13.3)
	Cycle 9 Day 1	18	1 (5.6)	15 (83.3)	2 (11.1)
	Cycle 11 Day 1	13	1 (7.7)	11 (84.6)	1 (7.7)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	25 (80.6)	6 (19.4)
Region					
North America					
	Cycle 3 Day 1	22	0 (0.0)	22 (100.0)	0 (0.0)
	Cycle 5 Day 1	14	0 (0.0)	14 (100.0)	0 (0.0)
	Cycle 7 Day 1	11	0 (0.0)	9 (81.8)	2 (18.2)
	Cycle 9 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	14	0 (0.0)	11 (78.6)	3 (21.4)
Region					
EU					
	Cycle 3 Day 1	35	5 (14.3)	28 (80.0)	2 (5.7)
	Cycle 5 Day 1	26	5 (19.2)	19 (73.1)	2 (7.7)
	Cycle 7 Day 1	19	2 (10.5)	15 (78.9)	2 (10.5)
	Cycle 9 Day 1	11	1 (9.1)	9 (81.8)	1 (9.1)
	Cycle 11 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	17	0 (0.0)	14 (82.4)	3 (17.6)
Age (Category 1)					
<65 years					
	Cycle 3 Day 1	36	4 (11.1)	31 (86.1)	1 (2.8)
	Cycle 5 Day 1	25	4 (16.0)	19 (76.0)	2 (8.0)
	Cycle 7 Day 1	16	1 (6.3)	14 (87.5)	1 (6.3)
	Cycle 9 Day 1	11	1 (9.1)	9 (81.8)	1 (9.1)
	Cycle 11 Day 1	9	1 (11.1)	7 (77.8)	1 (11.1)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	18	0 (0.0)	12 (66.7)	6 (33.3)
Age (Category 1)					
>=65 years					
	Cycle 3 Day 1	21	1 (4.8)	19 (90.5)	1 (4.8)
	Cycle 5 Day 1	15	1 (6.7)	14 (93.3)	0 (0.0)
	Cycle 7 Day 1	14	1 (7.1)	10 (71.4)	3 (21.4)
	Cycle 9 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 11 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	13	0 (0.0)	13 (100.0)	0 (0.0)
Age (Category 2)					
<75 years					
	Cycle 3 Day 1	53	5 (9.4)	47 (88.7)	1 (1.9)
	Cycle 5 Day 1	37	5 (13.5)	30 (81.1)	2 (5.4)
	Cycle 7 Day 1	28	2 (7.1)	23 (82.1)	3 (10.7)
	Cycle 9 Day 1	16	1 (6.3)	13 (81.3)	2 (12.5)
	Cycle 11 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 13 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	25 (80.6)	6 (19.4)
Age (Category 2)					
>=75 years					
	Cycle 3 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 5 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Sex					
female					
	Cycle 3 Day 1	17	1 (5.9)	16 (94.1)	0 (0.0)
	Cycle 5 Day 1	16	3 (18.8)	12 (75.0)	1 (6.3)
	Cycle 7 Day 1	11	0 (0.0)	11 (100.0)	0 (0.0)
	Cycle 9 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 11 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	7	0 (0.0)	7 (100.0)	0 (0.0)
Sex					
male					
	Cycle 3 Day 1	40	4 (10.0)	34 (85.0)	2 (5.0)
	Cycle 5 Day 1	24	2 (8.3)	21 (87.5)	1 (4.2)
	Cycle 7 Day 1	19	2 (10.5)	13 (68.4)	4 (21.1)
	Cycle 9 Day 1	13	1 (7.7)	10 (76.9)	2 (15.4)
	Cycle 11 Day 1	9	0 (0.0)	8 (88.9)	1 (11.1)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	24	0 (0.0)	18 (75.0)	6 (25.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
ECOG PS					
0					
	Cycle 3 Day 1	21	0 (0.0)	20 (95.2)	1 (4.8)
	Cycle 5 Day 1	16	0 (0.0)	16 (100.0)	0 (0.0)
	Cycle 7 Day 1	10	0 (0.0)	9 (90.0)	1 (10.0)
	Cycle 9 Day 1	9	0 (0.0)	9 (100.0)	0 (0.0)
	Cycle 11 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	15	0 (0.0)	13 (86.7)	2 (13.3)
ECOG PS					
1					
	Cycle 3 Day 1	36	5 (13.9)	30 (83.3)	1 (2.8)
	Cycle 5 Day 1	24	5 (20.8)	17 (70.8)	2 (8.3)
	Cycle 7 Day 1	20	2 (10.0)	15 (75.0)	3 (15.0)
	Cycle 9 Day 1	9	1 (11.1)	6 (66.7)	2 (22.2)
	Cycle 11 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	16	0 (0.0)	12 (75.0)	4 (25.0)
HER2 Status in central laboratory					
IHC 3+					
	Cycle 3 Day 1	54	5 (9.3)	47 (87.0)	2 (3.7)
	Cycle 5 Day 1	38	5 (13.2)	31 (81.6)	2 (5.3)
	Cycle 7 Day 1	28	2 (7.1)	22 (78.6)	4 (14.3)
	Cycle 9 Day 1	17	1 (5.9)	14 (82.4)	2 (11.8)
	Cycle 11 Day 1	13	1 (7.7)	11 (84.6)	1 (7.7)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	25	0 (0.0)	21 (84.0)	4 (16.0)
HER2 Status in central laboratory					
IHC 2+/ISH +					
	Cycle 3 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	6	0 (0.0)	4 (66.7)	2 (33.3)
Primary tumor location					
Gastric					
	Cycle 3 Day 1	21	3 (14.3)	18 (85.7)	0 (0.0)
	Cycle 5 Day 1	17	3 (17.6)	12 (70.6)	2 (11.8)
	Cycle 7 Day 1	14	1 (7.1)	11 (78.6)	2 (14.3)
	Cycle 9 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 11 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	10	0 (0.0)	9 (90.0)	1 (10.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
Primary tumor location					
GEJ					
	Cycle 3 Day 1	36	2 (5.6)	32 (88.9)	2 (5.6)
	Cycle 5 Day 1	23	2 (8.7)	21 (91.3)	0 (0.0)
	Cycle 7 Day 1	16	1 (6.3)	13 (81.3)	2 (12.5)
	Cycle 9 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 11 Day 1	7	0 (0.0)	7 (100.0)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	21	0 (0.0)	16 (76.2)	5 (23.8)
Histological subtype					
diffuse					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Histological subtype					
intestinal					
	Cycle 3 Day 1	14	3 (21.4)	11 (78.6)	0 (0.0)
	Cycle 5 Day 1	11	3 (27.3)	6 (54.5)	2 (18.2)
	Cycle 7 Day 1	8	1 (12.5)	6 (75.0)	1 (12.5)
	Cycle 9 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 11 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	8	0 (0.0)	7 (87.5)	1 (12.5)
Histological subtype					
other					
	Cycle 3 Day 1	42	2 (4.8)	38 (90.5)	2 (4.8)
	Cycle 5 Day 1	28	2 (7.1)	26 (92.9)	0 (0.0)
	Cycle 7 Day 1	21	1 (4.8)	17 (81.0)	3 (14.3)
	Cycle 9 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 11 Day 1	9	1 (11.1)	8 (88.9)	0 (0.0)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	22	0 (0.0)	17 (77.3)	5 (22.7)
Number of metastatic sites					
<2					
	Cycle 3 Day 1	3	1 (33.3)	2 (66.7)	0 (0.0)
	Cycle 5 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 7 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Number of metastatic sites					
>=2					
	Cycle 3 Day 1	54	4 (7.4)	48 (88.9)	2 (3.7)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 5 Day 1	37	5 (13.5)	30 (81.1)	2 (5.4)
	Cycle 7 Day 1	26	2 (7.7)	20 (76.9)	4 (15.4)
	Cycle 9 Day 1	17	1 (5.9)	14 (82.4)	2 (11.8)
	Cycle 11 Day 1	13	1 (7.7)	11 (84.6)	1 (7.7)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	29	0 (0.0)	23 (79.3)	6 (20.7)
Previous total gastrectomy					
no					
	Cycle 3 Day 1	57	5 (8.8)	50 (87.7)	2 (3.5)
	Cycle 5 Day 1	40	5 (12.5)	33 (82.5)	2 (5.0)
	Cycle 7 Day 1	30	2 (6.7)	24 (80.0)	4 (13.3)
	Cycle 9 Day 1	18	1 (5.6)	15 (83.3)	2 (11.1)
	Cycle 11 Day 1	13	1 (7.7)	11 (84.6)	1 (7.7)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	31	0 (0.0)	25 (80.6)	6 (19.4)
Prior adjuvant/ neoadjuvant therapy					
yes					
	Cycle 3 Day 1	6	1 (16.7)	4 (66.7)	1 (16.7)
	Cycle 5 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 7 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 9 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior adjuvant/ neoadjuvant therapy					
no					
	Cycle 3 Day 1	51	4 (7.8)	46 (90.2)	1 (2.0)
	Cycle 5 Day 1	34	4 (11.8)	28 (82.4)	2 (5.9)
	Cycle 7 Day 1	24	2 (8.3)	18 (75.0)	4 (16.7)
	Cycle 9 Day 1	17	1 (5.9)	14 (82.4)	2 (11.8)
	Cycle 11 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 13 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	24 (80.0)	6 (20.0)
Prior nivolumab or pembrolizumab treatment					
yes					
	Cycle 3 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior nivolumab or pembrolizumab treatment					
no					
	Cycle 3 Day 1	55	5 (9.1)	48 (87.3)	2 (3.6)
	Cycle 5 Day 1	39	5 (12.8)	32 (82.1)	2 (5.1)
	Cycle 7 Day 1	28	2 (7.1)	22 (78.6)	4 (14.3)
	Cycle 9 Day 1	18	1 (5.6)	15 (83.3)	2 (11.1)
	Cycle 11 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	24 (80.0)	6 (20.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
yes					
	Cycle 3 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy					
no					
	Cycle 3 Day 1	54	5 (9.3)	47 (87.0)	2 (3.7)
	Cycle 5 Day 1	38	5 (13.2)	31 (81.6)	2 (5.3)
	Cycle 7 Day 1	28	2 (7.1)	22 (78.6)	4 (14.3)
	Cycle 9 Day 1	18	1 (5.6)	15 (83.3)	2 (11.1)
	Cycle 11 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	30	0 (0.0)	24 (80.0)	6 (20.0)
Presence of liver metastasis at baseline					
yes					
	Cycle 3 Day 1	36	2 (5.6)	33 (91.7)	1 (2.8)
	Cycle 5 Day 1	24	2 (8.3)	21 (87.5)	1 (4.2)
	Cycle 7 Day 1	17	0 (0.0)	13 (76.5)	4 (23.5)
	Cycle 9 Day 1	14	0 (0.0)	12 (85.7)	2 (14.3)
	Cycle 11 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 13 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	18	0 (0.0)	13 (72.2)	5 (27.8)
Presence of liver metastasis at baseline					
no					
	Cycle 3 Day 1	21	3 (14.3)	17 (81.0)	1 (4.8)
	Cycle 5 Day 1	16	3 (18.8)	12 (75.0)	1 (6.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 7 Day 1	13	2 (15.4)	11 (84.6)	0 (0.0)
	Cycle 9 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 11 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 13 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	12 (92.3)	1 (7.7)
Renal impairment at baseline					
normal					
	Cycle 3 Day 1	23	2 (8.7)	21 (91.3)	0 (0.0)
	Cycle 5 Day 1	12	1 (8.3)	11 (91.7)	0 (0.0)
	Cycle 7 Day 1	7	1 (14.3)	5 (71.4)	1 (14.3)
	Cycle 9 Day 1	6	1 (16.7)	5 (83.3)	0 (0.0)
	Cycle 11 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	13	0 (0.0)	9 (69.2)	4 (30.8)
Renal impairment at baseline					
mild					
	Cycle 3 Day 1	14	1 (7.1)	12 (85.7)	1 (7.1)
	Cycle 5 Day 1	12	2 (16.7)	9 (75.0)	1 (8.3)
	Cycle 7 Day 1	9	0 (0.0)	7 (77.8)	2 (22.2)
	Cycle 9 Day 1	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 11 Day 1	6	0 (0.0)	5 (83.3)	1 (16.7)
	Cycle 13 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 15 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	12	0 (0.0)	11 (91.7)	1 (8.3)
Renal impairment at baseline					
moderate					
	Cycle 3 Day 1	7	1 (14.3)	6 (85.7)	0 (0.0)
	Cycle 5 Day 1	7	2 (28.6)	5 (71.4)	0 (0.0)
	Cycle 7 Day 1	5	1 (20.0)	3 (60.0)	1 (20.0)
	Cycle 9 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 11 Day 1	1	1 (100.0)	0 (0.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 21 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	1	0 (0.0)	1 (100.0)	0 (0.0)
Hepatic impairment at baseline					
normal					
	Cycle 3 Day 1	46	4 (8.7)	40 (87.0)	2 (4.3)
	Cycle 5 Day 1	31	3 (9.7)	26 (83.9)	2 (6.5)
	Cycle 7 Day 1	27	2 (7.4)	21 (77.8)	4 (14.8)
	Cycle 9 Day 1	16	1 (6.3)	13 (81.3)	2 (12.5)
	Cycle 11 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 13 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 15 Day 1	7	0 (0.0)	6 (85.7)	1 (14.3)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	28	0 (0.0)	22 (78.6)	6 (21.4)
Hepatic impairment at baseline					
mild					
	Cycle 3 Day 1	11	1 (9.1)	10 (90.9)	0 (0.0)
	Cycle 5 Day 1	9	2 (22.2)	7 (77.8)	0 (0.0)
	Cycle 7 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)
Race					
White					
	Cycle 3 Day 1	50	4 (8.0)	44 (88.0)	2 (4.0)
	Cycle 5 Day 1	34	4 (11.8)	28 (82.4)	2 (5.9)
	Cycle 7 Day 1	26	2 (7.7)	21 (80.8)	3 (11.5)
	Cycle 9 Day 1	16	1 (6.3)	13 (81.3)	2 (12.5)
	Cycle 11 Day 1	12	1 (8.3)	10 (83.3)	1 (8.3)
	Cycle 13 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)
	Cycle 15 Day 1	8	0 (0.0)	7 (87.5)	1 (12.5)
	Cycle 17 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 19 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	27	0 (0.0)	22 (81.5)	5 (18.5)
Race					
Black or African American					
	Cycle 3 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 5 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
Race					
Other					
	Cycle 3 Day 1	5	1 (20.0)	4 (80.0)	0 (0.0)
	Cycle 5 Day 1	4	1 (25.0)	3 (75.0)	0 (0.0)
	Cycle 7 Day 1	4	0 (0.0)	3 (75.0)	1 (25.0)
	Cycle 9 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 11 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	4	0 (0.0)	3 (75.0)	1 (25.0)
Ethnicity					
Hispanic/Latino					
	Cycle 3 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 5 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 7 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 9 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 11 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 13 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 15 Day 1	2	0 (0.0)	1 (50.0)	1 (50.0)
	Cycle 17 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	Cycle 19 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	3	0 (0.0)	2 (66.7)	1 (33.3)
Ethnicity					
Non-Hispanic/Non-Latino					
	Cycle 3 Day 1	48	5 (10.4)	41 (85.4)	2 (4.2)
	Cycle 5 Day 1	34	5 (14.7)	27 (79.4)	2 (5.9)
	Cycle 7 Day 1	26	2 (7.7)	21 (80.8)	3 (11.5)
	Cycle 9 Day 1	15	1 (6.7)	12 (80.0)	2 (13.3)
	Cycle 11 Day 1	11	1 (9.1)	9 (81.8)	1 (9.1)
	Cycle 13 Day 1	5	0 (0.0)	5 (100.0)	0 (0.0)
	Cycle 15 Day 1	6	0 (0.0)	6 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Improvement/No change/Deterioration of change from baseline of Fact-G Total Score by Visit
Full Analysis Set

Subgroup Level	Visit	T-DXd (N=79) N*	Improvement n (%)	No Change n (%)	Deterioration n (%)
	Cycle 17 Day 1	3	0 (0.0)	3 (100.0)	0 (0.0)
	Cycle 19 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 21 Day 1	3	0 (0.0)	2 (66.7)	1 (33.3)
	Cycle 23 Day 1	1	0 (0.0)	0 (0.0)	1 (100.0)
	End of Treatment	26	0 (0.0)	21 (80.8)	5 (19.2)
Ethnicity					
Unknown					
	Cycle 3 Day 1	4	0 (0.0)	4 (100.0)	0 (0.0)
	Cycle 5 Day 1	2	0 (0.0)	2 (100.0)	0 (0.0)
	Cycle 7 Day 1	1	0 (0.0)	1 (100.0)	0 (0.0)
	End of Treatment	2	0 (0.0)	2 (100.0)	0 (0.0)

Percentages are based on the number of patients that replied to the questions of each scale/subscale at a specific visit (N*).
Source data: ADAM.ADSL and ADAM.ADQS
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Summary of Questionnaires with patients having Baseline and at least one Post-Baseline Visit

	T-DXd (N=79)	
	n	(%)
EQ-5D VAS score	67	(84.8)
Fact-Ga Total Score	65	(82.3)
Physical Well-being	65	(82.3)
Social/Family Well-being	65	(82.3)
Emotional Well-being	65	(82.3)
Functional Well-being	65	(82.3)
Gastric Cancer Symptom (GaCS)	65	(82.3)
Fact-G Total Score	65	(82.3)

Anhang 4-G 2.1.5: Sicherheit

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Subjects with events	79 (100.0)
Gastrointestinal disorders	73 (92.4)
Nausea	52 (65.8)
Vomiting	33 (41.8)
Diarrhoea	28 (35.4)
Constipation	21 (26.6)
Abdominal pain	13 (16.5)
Gastrooesophageal reflux disease	8 (10.1)
Dysphagia	6 (7.6)
Ascites	5 (6.3)
Abdominal distension	3 (3.8)
Abdominal pain upper	3 (3.8)
Dyspepsia	3 (3.8)
Flatulence	3 (3.8)
Salivary hypersecretion	2 (2.5)
Abdominal discomfort	1 (1.3)
Abdominal pain lower	1 (1.3)
Anal fissure	1 (1.3)
Anal fistula	1 (1.3)
Colitis	1 (1.3)
Dry mouth	1 (1.3)
Duodenitis	1 (1.3)
Enteritis	1 (1.3)
Eructation	1 (1.3)
Gastritis	1 (1.3)
Haematemesis	1 (1.3)
Intestinal obstruction	1 (1.3)
Lip blister	1 (1.3)
Lip dry	1 (1.3)
Melaena	1 (1.3)
Obstruction gastric	1 (1.3)
Oesophageal obstruction	1 (1.3)
Oesophagitis	1 (1.3)
Proctalgia	1 (1.3)
Regurgitation	1 (1.3)
Retching	1 (1.3)
Stomatitis	1 (1.3)
General disorders and administration site conditions	55 (69.6)
Fatigue	32 (40.5)
Asthenia	12 (15.2)
Pyrexia	8 (10.1)
Oedema peripheral	4 (5.1)
Pain	3 (3.8)
Chills	2 (2.5)
Disease progression	2 (2.5)
Mucosal inflammation	2 (2.5)
Non-cardiac chest pain	2 (2.5)
Catheter site haematoma	1 (1.3)
Catheter site thrombosis	1 (1.3)
Chest discomfort	1 (1.3)
Chest pain	1 (1.3)
Early satiety	1 (1.3)
Gait disturbance	1 (1.3)
Hyperpyrexia	1 (1.3)
Influenza like illness	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Oedema	1 (1.3)
Peripheral swelling	1 (1.3)
Swelling	1 (1.3)
Investigations	50 (63.3)
Weight decreased	27 (34.2)
Platelet count decreased	14 (17.7)
Neutrophil count decreased	12 (15.2)
Aspartate aminotransferase increased	10 (12.7)
White blood cell count decreased	8 (10.1)
Alanine aminotransferase increased	6 (7.6)
Blood alkaline phosphatase increased	6 (7.6)
Blood bilirubin increased	4 (5.1)
Blood creatinine increased	3 (3.8)
Blood lactate dehydrogenase increased	3 (3.8)
Lymphocyte count decreased	3 (3.8)
Weight increased	3 (3.8)
Electrocardiogram QT prolonged	2 (2.5)
Blood folate decreased	1 (1.3)
C-reactive protein increased	1 (1.3)
Gamma-glutamyltransferase increased	1 (1.3)
Ophthalmological examination abnormal	1 (1.3)
SARS-CoV-2 test positive	1 (1.3)
Troponin T increased	1 (1.3)
Metabolism and nutrition disorders	43 (54.4)
Decreased appetite	26 (32.9)
Hypokalaemia	12 (15.2)
Hypoalbuminaemia	6 (7.6)
Hyponatraemia	6 (7.6)
Hypophosphataemia	4 (5.1)
Hypocalcaemia	3 (3.8)
Dehydration	2 (2.5)
Hyperkalaemia	2 (2.5)
Hypoglycaemia	2 (2.5)
Hypomagnesaemia	2 (2.5)
Electrolyte imbalance	1 (1.3)
Gout	1 (1.3)
Hypercreatininaemia	1 (1.3)
Hyperglycaemia	1 (1.3)
Vitamin D deficiency	1 (1.3)
Blood and lymphatic system disorders	34 (43.0)
Anaemia	27 (34.2)
Neutropenia	8 (10.1)
Thrombocytopenia	3 (3.8)
Febrile neutropenia	2 (2.5)
Lymph node pain	1 (1.3)
Lymphopenia	1 (1.3)
Respiratory, thoracic and mediastinal disorders	33 (41.8)
Cough	8 (10.1)
Dyspnoea	7 (8.9)
Epistaxis	6 (7.6)
Interstitial lung disease	4 (5.1)
Pneumonitis	4 (5.1)
Hiccups	3 (3.8)
Oropharyngeal pain	2 (2.5)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Pleural effusion	2 (2.5)
Pulmonary embolism	2 (2.5)
Rhinorrhoea	2 (2.5)
Dysphonia	1 (1.3)
Dyspnoea exertional	1 (1.3)
Nasal congestion	1 (1.3)
Nasal dryness	1 (1.3)
Pharyngeal ulceration	1 (1.3)
Throat clearing	1 (1.3)
Nervous system disorders	26 (32.9)
Headache	7 (8.9)
Dizziness	5 (6.3)
Dysgeusia	3 (3.8)
Paraesthesia	3 (3.8)
Lethargy	2 (2.5)
Neuropathy peripheral	2 (2.5)
Somnolence	2 (2.5)
Tremor	2 (2.5)
Basal ganglia infarction	1 (1.3)
Cerebrovascular accident	1 (1.3)
Dysaesthesia	1 (1.3)
Generalised tonic-clonic seizure	1 (1.3)
Peripheral sensory neuropathy	1 (1.3)
Skin and subcutaneous tissue disorders	25 (31.6)
Alopecia	19 (24.1)
Dry skin	3 (3.8)
Pruritus	2 (2.5)
Dermatitis	1 (1.3)
Dermatitis acneiform	1 (1.3)
Nail disorder	1 (1.3)
Onychoclasis	1 (1.3)
Rash maculo-papular	1 (1.3)
Rash pruritic	1 (1.3)
Skin hyperpigmentation	1 (1.3)
Infections and infestations	19 (24.1)
COVID-19	4 (5.1)
Device related infection	4 (5.1)
Urinary tract infection	3 (3.8)
Pneumonia	2 (2.5)
Scrotal infection	2 (2.5)
Asymptomatic COVID-19	1 (1.3)
Bacteraemia	1 (1.3)
Bacterial sepsis	1 (1.3)
COVID-19 pneumonia	1 (1.3)
Cellulitis	1 (1.3)
Conjunctivitis	1 (1.3)
Oral fungal infection	1 (1.3)
Oral herpes	1 (1.3)
Staphylococcal infection	1 (1.3)
Wound infection	1 (1.3)
Musculoskeletal and connective tissue disorders	16 (20.3)
Back pain	7 (8.9)
Arthralgia	2 (2.5)
Myalgia	2 (2.5)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Flank pain	1 (1.3)
Muscle spasms	1 (1.3)
Muscular weakness	1 (1.3)
Musculoskeletal chest pain	1 (1.3)
Musculoskeletal pain	1 (1.3)
Neck pain	1 (1.3)
Renal and urinary disorders	16 (20.3)
Urinary retention	5 (6.3)
Acute kidney injury	4 (5.1)
Dysuria	2 (2.5)
Hydronephrosis	1 (1.3)
Micturition urgency	1 (1.3)
Nephrolithiasis	1 (1.3)
Nocturia	1 (1.3)
Pollakiuria	1 (1.3)
Urinary tract obstruction	1 (1.3)
Psychiatric disorders	12 (15.2)
Insomnia	5 (6.3)
Depression	4 (5.1)
Anxiety	3 (3.8)
Confusional state	2 (2.5)
Hallucination	1 (1.3)
Vascular disorders	11 (13.9)
Hypotension	4 (5.1)
Deep vein thrombosis	3 (3.8)
Hypertension	3 (3.8)
Embolism	2 (2.5)
Hot flush	1 (1.3)
Thrombophlebitis superficial	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (8.9)
Cancer pain	2 (2.5)
Malignant neoplasm progression	2 (2.5)
Benign breast neoplasm	1 (1.3)
Lymphangiosis carcinomatosa	1 (1.3)
Tumour haemorrhage	1 (1.3)
Tumour pain	1 (1.3)
Hepatobiliary disorders	6 (7.6)
Hepatotoxicity	2 (2.5)
Hyperbilirubinaemia	2 (2.5)
Bile duct stenosis	1 (1.3)
Hypertransaminasaemia	1 (1.3)
Portal vein thrombosis	1 (1.3)
Eye disorders	5 (6.3)
Dry eye	2 (2.5)
Diplopia	1 (1.3)
Eye pain	1 (1.3)
Eye pruritus	1 (1.3)
Visual impairment	1 (1.3)
Cardiac disorders	4 (5.1)
Sinus bradycardia	2 (2.5)
Atrial fibrillation	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Cardiac flutter	1 (1.3)
Injury, poisoning and procedural complications	4 (5.1)
Animal bite	1 (1.3)
Exposure to communicable disease	1 (1.3)
Fall	1 (1.3)
Subdural haemorrhage	1 (1.3)
Tooth fracture	1 (1.3)
Reproductive system and breast disorders	3 (3.8)
Gynaecomastia	1 (1.3)
Pelvic pain	1 (1.3)
Testicular oedema	1 (1.3)
Ear and labyrinth disorders	1 (1.3)
Hypoacusis	1 (1.3)
Product issues	1 (1.3)
Device occlusion	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Serious TEAE by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Subjects with events	29 (36.7)
Gastrointestinal disorders	12 (15.2)
Nausea	4 (5.1)
Vomiting	3 (3.8)
Abdominal pain	2 (2.5)
Colitis	1 (1.3)
Diarrhoea	1 (1.3)
Dysphagia	1 (1.3)
Enteritis	1 (1.3)
Haematemesis	1 (1.3)
Intestinal obstruction	1 (1.3)
Infections and infestations	9 (11.4)
COVID-19	2 (2.5)
Pneumonia	2 (2.5)
Bacterial sepsis	1 (1.3)
COVID-19 pneumonia	1 (1.3)
Device related infection	1 (1.3)
Staphylococcal infection	1 (1.3)
Urinary tract infection	1 (1.3)
Wound infection	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (5.1)
Malignant neoplasm progression	2 (2.5)
Lymphangiosis carcinomatosa	1 (1.3)
Tumour haemorrhage	1 (1.3)
Renal and urinary disorders	4 (5.1)
Acute kidney injury	2 (2.5)
Hydronephrosis	1 (1.3)
Urinary tract obstruction	1 (1.3)
Respiratory, thoracic and mediastinal disorders	4 (5.1)
Interstitial lung disease	2 (2.5)
Pneumonitis	1 (1.3)
Pulmonary embolism	1 (1.3)
General disorders and administration site conditions	3 (3.8)
Disease progression	2 (2.5)
Hyperpyrexia	1 (1.3)
Nervous system disorders	3 (3.8)
Basal ganglia infarction	1 (1.3)
Cerebrovascular accident	1 (1.3)
Generalised tonic-clonic seizure	1 (1.3)
Hepatobiliary disorders	2 (2.5)
Bile duct stenosis	1 (1.3)
Hepatotoxicity	1 (1.3)
Injury, poisoning and procedural complications	1 (1.3)
Animal bite	1 (1.3)
Exposure to communicable disease	1 (1.3)
Product issues	1 (1.3)
Device occlusion	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Subjects with events	42 (53.2)
Blood and lymphatic system disorders	18 (22.8)
Anaemia	11 (13.9)
Neutropenia	4 (5.1)
Febrile neutropenia	2 (2.5)
Lymphopenia	1 (1.3)
Thrombocytopenia	1 (1.3)
Gastrointestinal disorders	18 (22.8)
Nausea	6 (7.6)
Dysphagia	3 (3.8)
Abdominal pain	2 (2.5)
Ascites	2 (2.5)
Vomiting	2 (2.5)
Anal fissure	1 (1.3)
Anal fistula	1 (1.3)
Colitis	1 (1.3)
Diarrhoea	1 (1.3)
Enteritis	1 (1.3)
Haematemesis	1 (1.3)
Intestinal obstruction	1 (1.3)
Obstruction gastric	1 (1.3)
Oesophageal obstruction	1 (1.3)
Investigations	11 (13.9)
Neutrophil count decreased	6 (7.6)
White blood cell count decreased	4 (5.1)
Weight decreased	3 (3.8)
Lymphocyte count decreased	2 (2.5)
Platelet count decreased	2 (2.5)
Alanine aminotransferase increased	1 (1.3)
Aspartate aminotransferase increased	1 (1.3)
Blood alkaline phosphatase increased	1 (1.3)
Blood bilirubin increased	1 (1.3)
Infections and infestations	10 (12.7)
COVID-19	3 (3.8)
Pneumonia	2 (2.5)
Bacterial sepsis	1 (1.3)
COVID-19 pneumonia	1 (1.3)
Device related infection	1 (1.3)
Staphylococcal infection	1 (1.3)
Urinary tract infection	1 (1.3)
Wound infection	1 (1.3)
Metabolism and nutrition disorders	8 (10.1)
Decreased appetite	4 (5.1)
Hypophosphataemia	2 (2.5)
Electrolyte imbalance	1 (1.3)
Hyperglycaemia	1 (1.3)
Hypokalaemia	1 (1.3)
General disorders and administration site conditions	6 (7.6)
Fatigue	3 (3.8)
Disease progression	2 (2.5)
Asthenia	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Oedema	1 (1.3)
Respiratory, thoracic and mediastinal disorders	6 (7.6)
Interstitial lung disease	2 (2.5)
Pulmonary embolism	2 (2.5)
Cough	1 (1.3)
Dyspnoea	1 (1.3)
Pleural effusion	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (5.1)
Malignant neoplasm progression	2 (2.5)
Cancer pain	1 (1.3)
Lymphangiosis carcinomatosa	1 (1.3)
Tumour haemorrhage	1 (1.3)
Nervous system disorders	4 (5.1)
Basal ganglia infarction	1 (1.3)
Cerebrovascular accident	1 (1.3)
Generalised tonic-clonic seizure	1 (1.3)
Somnolence	1 (1.3)
Renal and urinary disorders	4 (5.1)
Acute kidney injury	2 (2.5)
Hydronephrosis	1 (1.3)
Urinary tract obstruction	1 (1.3)
Vascular disorders	4 (5.1)
Embolism	2 (2.5)
Hypertension	1 (1.3)
Hypotension	1 (1.3)
Hepatobiliary disorders	2 (2.5)
Bile duct stenosis	1 (1.3)
Hepatotoxicity	1 (1.3)
Injury, poisoning and procedural complications	1 (1.3)
Animal bite	1 (1.3)
Exposure to communicable disease	1 (1.3)
Product issues	1 (1.3)
Device occlusion	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	79/ 79 (100.0)	0.1 (0.1, 0.1)
Region		
North America	34/ 34 (100.0)	0.1 (0.0, 0.1)
EU	45/ 45 (100.0)	0.1 (0.1, 0.2)
Age (Category 1)		
<65 years	46/ 46 (100.0)	0.1 (0.1, 0.1)
>=65 years	33/ 33 (100.0)	0.1 (0.1, 0.1)
Age (Category 2)		
<75 years	75/ 75 (100.0)	0.1 (0.1, 0.1)
>=75 years	4/ 4 (100.0)	0.2 (0.0, 1.9)
Sex		
female	22/ 22 (100.0)	0.1 (0.0, 0.3)
male	57/ 57 (100.0)	0.1 (0.1, 0.1)
ECOG PS		
0	29/ 29 (100.0)	0.1 (0.1, 0.2)
1	50/ 50 (100.0)	0.1 (0.1, 0.1)
HER2 Status in central laboratory		
IHC 3+	68/ 68 (100.0)	0.1 (0.1, 0.1)
IHC 2+/ISH +	10/ 10 (100.0)	0.1 (0.0, 0.2)
Primary tumor location		
Gastric	27/ 27 (100.0)	0.1 (0.1, 0.2)
GEJ	52/ 52 (100.0)	0.1 (0.1, 0.1)
Histological subtype		
diffuse	1/ 1 (100.0)	0.5 (NE , NE)
intestinal	19/ 19 (100.0)	0.1 (0.0, 0.3)
other	59/ 59 (100.0)	0.1 (0.1, 0.1)
Number of metastatic sites		
<2	5/ 5 (100.0)	0.1 (0.0, 0.5)
>=2	74/ 74 (100.0)	0.1 (0.1, 0.1)
Previous total gastrectomy		
no	79/ 79 (100.0)	0.1 (0.1, 0.1)
Prior adjuvant/ neoadjuvant therapy		
yes	9/ 9 (100.0)	0.1 (0.0, 0.3)
no	70/ 70 (100.0)	0.1 (0.1, 0.1)
Prior nivolumab or pembrolizumab treatment		
yes	6/ 6 (100.0)	0.1 (0.0, 0.5)
no	73/ 73 (100.0)	0.1 (0.1, 0.1)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	7/ 7 (100.0)	0.1 (0.0, 0.1)
no	72/ 72 (100.0)	0.1 (0.1, 0.1)
Presence of liver metastasis at baseline		
yes	50/ 50 (100.0)	0.1 (0.1, 0.2)
no	29/ 29 (100.0)	0.1 (0.1, 0.1)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

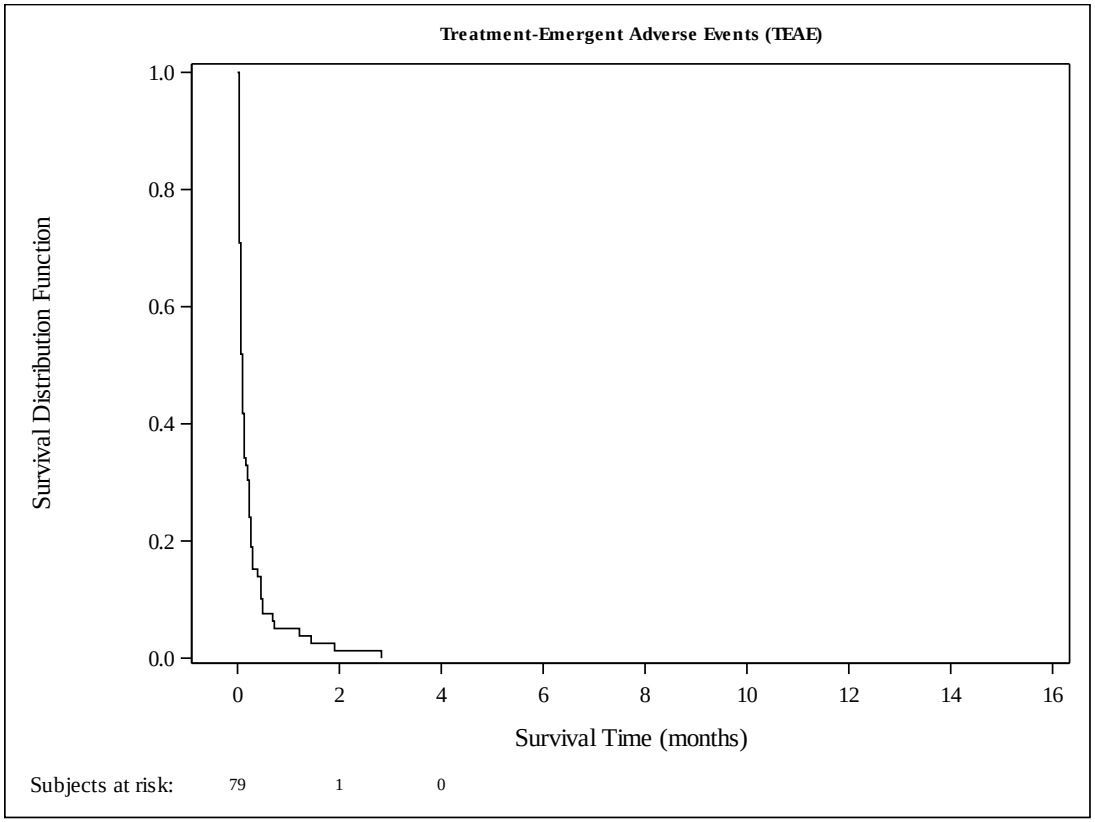
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	32/ 32 (100.0)	0.1 (0.0, 0.1)
mild	25/ 25 (100.0)	0.1 (0.0, 0.2)
moderate	8/ 8 (100.0)	0.1 (0.1, 1.9)
Hepatic impairment at baseline		
normal	64/ 64 (100.0)	0.1 (0.1, 0.1)
mild	14/ 14 (100.0)	0.0 (0.0, 0.1)
Race		
White	69/ 69 (100.0)	0.1 (0.1, 0.1)
Black or African American	1/ 1 (100.0)	0.1 (NE , NE)
Other	8/ 8 (100.0)	0.1 (0.0, 0.3)
Ethnicity		
Hispanic/Latino	5/ 5 (100.0)	0.2 (0.0, 2.8)
Non-Hispanic/Non-Latino	70/ 70 (100.0)	0.1 (0.1, 0.1)
Unknown	4/ 4 (100.0)	0.1 (0.0, 0.2)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Serious TEAE
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	29/ 79 (36.7)	NE (5.2, NE)
Region		
North America	13/ 34 (38.2)	NE (3.5, NE)
EU	16/ 45 (35.6)	8.5 (5.2, NE)
Age (Category 1)		
<65 years	18/ 46 (39.1)	8.5 (3.6, NE)
>=65 years	11/ 33 (33.3)	NE (4.0, NE)
Age (Category 2)		
<75 years	27/ 75 (36.0)	NE (6.0, NE)
>=75 years	2/ 4 (50.0)	NE (1.2, NE)
Sex		
female	9/ 22 (40.9)	8.5 (3.6, NE)
male	20/ 57 (35.1)	NE (6.0, NE)
ECOG PS		
0	4/ 29 (13.8)	NE (NE , NE)
1	25/ 50 (50.0)	6.0 (1.3, NE)
HER2 Status in central laboratory		
IHC 3+	23/ 68 (33.8)	NE (6.0, NE)
IHC 2+/ISH +	5/ 10 (50.0)	3.5 (0.4, NE)
Primary tumor location		
Gastric	10/ 27 (37.0)	8.5 (3.5, NE)
GEJ	19/ 52 (36.5)	NE (3.6, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	6/ 19 (31.6)	NE (3.5, NE)
other	23/ 59 (39.0)	8.5 (4.0, NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	29/ 74 (39.2)	NE (4.0, NE)
Previous total gastrectomy		
no	29/ 79 (36.7)	NE (5.2, NE)
Prior adjuvant/ neoadjuvant therapy		
yes	3/ 9 (33.3)	NE (0.1, NE)
no	26/ 70 (37.1)	NE (5.2, NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (3.4, NE)
no	28/ 73 (38.4)	NE (5.2, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (3.4, NE)
no	27/ 72 (37.5)	NE (5.2, NE)
Presence of liver metastasis at baseline		
yes	18/ 50 (36.0)	NE (4.0, NE)
no	11/ 29 (37.9)	8.5 (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

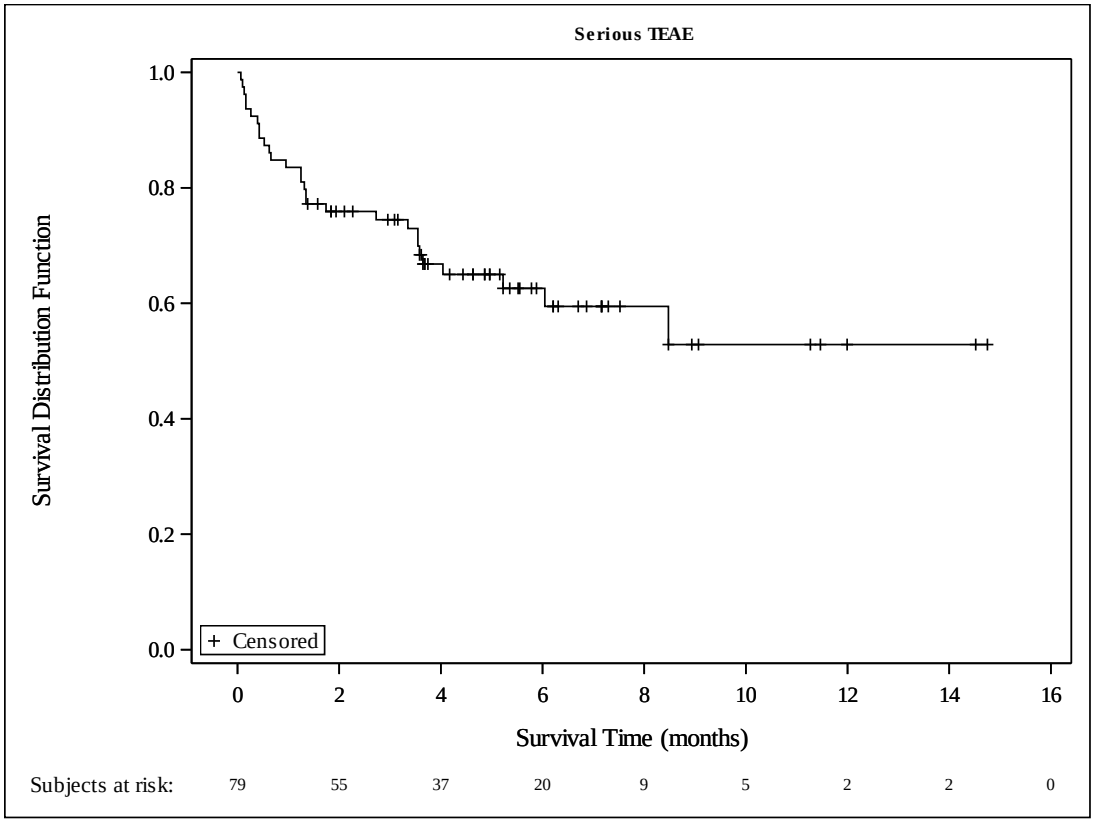
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Serious TEAE
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	12/ 32 (37.5)	NE (1.7, NE)
mild	6/ 25 (24.0)	NE (5.2, NE)
moderate	5/ 8 (62.5)	6.0 (1.3, 8.5)
Hepatic impairment at baseline		
normal	20/ 64 (31.3)	NE (6.0, NE)
mild	8/ 14 (57.1)	3.6 (0.3, NE)
Race		
White	24/ 69 (34.8)	NE (6.0, NE)
Black or African American	1/ 1 (100.0)	4.0 (NE , NE)
Other	3/ 8 (37.5)	NE (0.4, NE)
Ethnicity		
Hispanic/Latino	3/ 5 (60.0)	3.6 (1.2, NE)
Non-Hispanic/Non-Latino	25/ 70 (35.7)	NE (6.0, NE)
Unknown	1/ 4 (25.0)	NE (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Serious TEAE
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	42/ 79 (53.2)	4.1 (2.6, 11.3)
Region		
North America	17/ 34 (50.0)	6.0 (1.4, NE)
EU	25/ 45 (55.6)	3.5 (0.7, 11.3)
Age (Category 1)		
<65 years	29/ 46 (63.0)	3.0 (1.0, 9.8)
>=65 years	13/ 33 (39.4)	NE (2.6, NE)
Age (Category 2)		
<75 years	39/ 75 (52.0)	4.2 (2.7, 11.3)
>=75 years	3/ 4 (75.0)	0.5 (0.3, NE)
Sex		
female	12/ 22 (54.5)	3.6 (0.5, NE)
male	30/ 57 (52.6)	4.1 (1.4, 11.3)
ECOG PS		
0	9/ 29 (31.0)	9.8 (3.6, NE)
1	33/ 50 (66.0)	1.4 (0.5, 4.1)
HER2 Status in central laboratory		
IHC 3+	36/ 68 (52.9)	4.2 (2.6, 11.3)
IHC 2+/ISH +	5/ 10 (50.0)	3.5 (0.2, NE)
Primary tumor location		
Gastric	16/ 27 (59.3)	3.5 (0.5, NE)
GEJ	26/ 52 (50.0)	6.0 (2.6, 11.3)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	11/ 19 (57.9)	3.5 (1.0, 11.3)
other	31/ 59 (52.5)	4.1 (1.4, NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (0.5, NE)
>=2	41/ 74 (55.4)	3.6 (1.6, 11.3)
Previous total gastrectomy		
no	42/ 79 (53.2)	4.1 (2.6, 11.3)
Prior adjuvant/ neoadjuvant therapy		
yes	7/ 9 (77.8)	3.6 (0.0, 11.3)
no	35/ 70 (50.0)	4.1 (2.6, NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (0.5, NE)
no	41/ 73 (56.2)	3.6 (1.4, 11.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (0.5, NE)
no	40/ 72 (55.6)	3.6 (1.6, 11.3)
Presence of liver metastasis at baseline		
yes	25/ 50 (50.0)	6.0 (1.6, NE)
no	17/ 29 (58.6)	3.5 (0.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

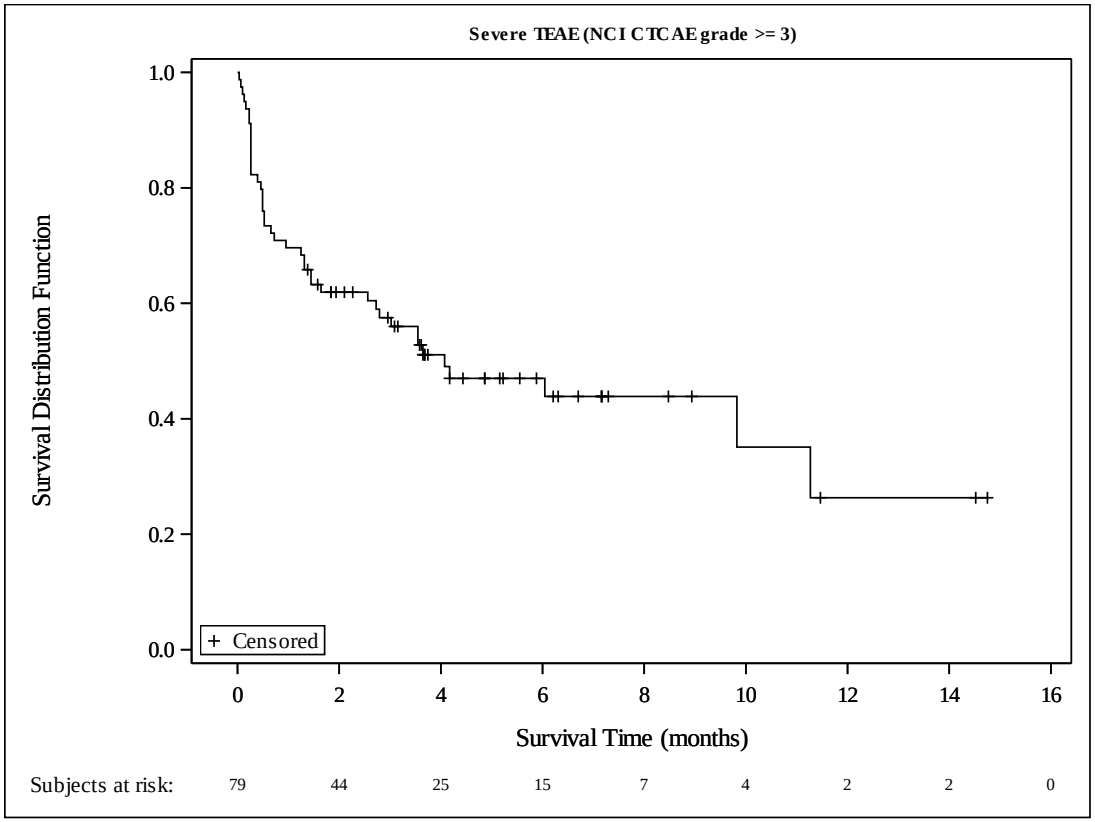
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	16/ 32 (50.0)	9.8 (0.7, NE)
mild	10/ 25 (40.0)	11.3 (2.8, NE)
moderate	6/ 8 (75.0)	3.6 (0.3, 6.0)
Hepatic impairment at baseline		
normal	30/ 64 (46.9)	9.8 (2.8, NE)
mild	11/ 14 (78.6)	0.7 (0.2, 4.1)
Race		
White	35/ 69 (50.7)	6.0 (2.6, 11.3)
Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
Other	5/ 8 (62.5)	2.3 (0.2, NE)
Ethnicity		
Hispanic/Latino	4/ 5 (80.0)	3.5 (0.3, 9.8)
Non-Hispanic/Non-Latino	36/ 70 (51.4)	4.1 (1.4, NE)
Unknown	2/ 4 (50.0)	4.2 (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Overall	79/ 79 (100.0)	0.1 (0.1, 0.1)
Region		
North America	34/ 34 (100.0)	0.1 (0.0, 0.1)
EU	45/ 45 (100.0)	0.1 (0.1, 0.2)
Age (Category 1)		
<65 years	46/ 46 (100.0)	0.1 (0.1, 0.2)
>=65 years	33/ 33 (100.0)	0.1 (0.1, 0.1)
Age (Category 2)		
<75 years	75/ 75 (100.0)	0.1 (0.1, 0.1)
>=75 years	4/ 4 (100.0)	0.2 (0.0, 1.9)
Sex		
female	22/ 22 (100.0)	0.1 (0.0, 0.3)
male	57/ 57 (100.0)	0.1 (0.1, 0.1)
ECOG PS		
0	29/ 29 (100.0)	0.1 (0.1, 0.2)
1	50/ 50 (100.0)	0.1 (0.1, 0.1)
HER2 Status in central laboratory		
IHC 3+	68/ 68 (100.0)	0.1 (0.1, 0.1)
IHC 2+/ISH +	10/ 10 (100.0)	0.1 (0.0, 0.2)
Primary tumor location		
Gastric	27/ 27 (100.0)	0.1 (0.1, 0.2)
GEJ	52/ 52 (100.0)	0.1 (0.1, 0.1)
Histological subtype		
diffuse	1/ 1 (100.0)	0.5 (NE , NE)
intestinal	19/ 19 (100.0)	0.1 (0.0, 0.3)
other	59/ 59 (100.0)	0.1 (0.1, 0.1)
Number of metastatic sites		
<2	5/ 5 (100.0)	0.1 (0.0, 2.8)
>=2	74/ 74 (100.0)	0.1 (0.1, 0.1)
Previous total gastrectomy		
no	79/ 79 (100.0)	0.1 (0.1, 0.1)
Prior adjuvant/ neoadjuvant therapy		
yes	9/ 9 (100.0)	0.1 (0.0, 0.3)
no	70/ 70 (100.0)	0.1 (0.1, 0.1)
Prior nivolumab or pembrolizumab treatment		
yes	6/ 6 (100.0)	0.1 (0.0, 0.7)
no	73/ 73 (100.0)	0.1 (0.1, 0.1)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	7/ 7 (100.0)	0.1 (0.0, 0.1)
no	72/ 72 (100.0)	0.1 (0.1, 0.1)
Presence of liver metastasis at baseline		
yes	50/ 50 (100.0)	0.1 (0.1, 0.2)
no	29/ 29 (100.0)	0.1 (0.1, 0.1)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

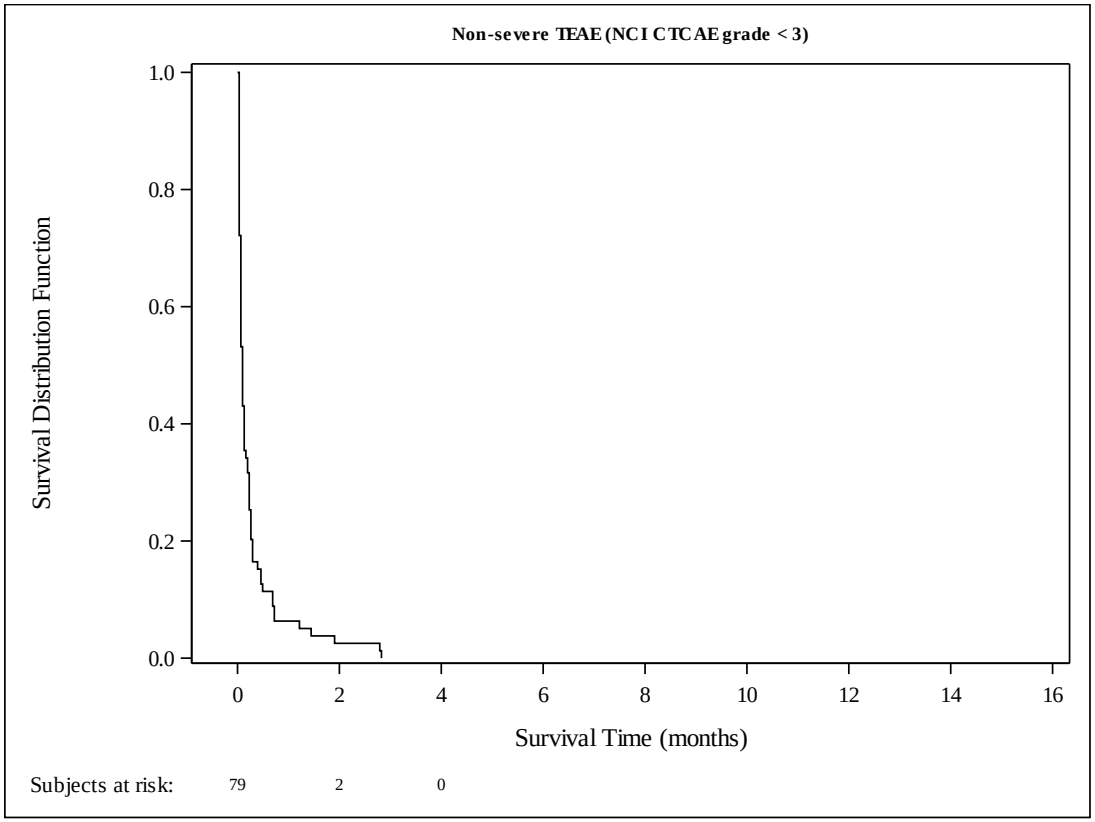
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	32/ 32 (100.0)	0.1 (0.0, 0.1)
mild	25/ 25 (100.0)	0.1 (0.0, 0.2)
moderate	8/ 8 (100.0)	0.1 (0.1, 1.9)
Hepatic impairment at baseline		
normal	64/ 64 (100.0)	0.1 (0.1, 0.2)
mild	14/ 14 (100.0)	0.0 (0.0, 0.1)
Race		
White	69/ 69 (100.0)	0.1 (0.1, 0.1)
Black or African American	1/ 1 (100.0)	0.1 (NE , NE)
Other	8/ 8 (100.0)	0.1 (0.0, 0.3)
Ethnicity		
Hispanic/Latino	5/ 5 (100.0)	0.2 (0.0, 2.8)
Non-Hispanic/Non-Latino	70/ 70 (100.0)	0.1 (0.1, 0.1)
Unknown	4/ 4 (100.0)	0.1 (0.0, 0.2)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE leading to drug withdrawn
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	12/ 79 (15.2)	NE (NE , NE)
Region		
North America	7/ 34 (20.6)	NE (NE , NE)
EU	5/ 45 (11.1)	NE (9.0, NE)
Age (Category 1)		
<65 years	7/ 46 (15.2)	NE (9.0, NE)
>=65 years	5/ 33 (15.2)	NE (NE , NE)
Age (Category 2)		
<75 years	11/ 75 (14.7)	NE (9.0, NE)
>=75 years	1/ 4 (25.0)	NE (3.5, NE)
Sex		
female	2/ 22 (9.1)	NE (9.0, NE)
male	10/ 57 (17.5)	NE (NE , NE)
ECOG PS		
0	3/ 29 (10.3)	NE (NE , NE)
1	9/ 50 (18.0)	NE (9.0, NE)
HER2 Status in central laboratory		
IHC 3+	9/ 68 (13.2)	NE (NE , NE)
IHC 2+/ISH +	3/ 10 (30.0)	NE (1.3, NE)
Primary tumor location		
Gastric	4/ 27 (14.8)	NE (9.0, NE)
GEJ	8/ 52 (15.4)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	11/ 59 (18.6)	NE (9.0, NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	11/ 74 (14.9)	NE (NE , NE)
Previous total gastrectomy		
no	12/ 79 (15.2)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	1/ 9 (11.1)	NE (0.2, NE)
no	11/ 70 (15.7)	NE (9.0, NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	11/ 73 (15.1)	NE (9.0, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (2.5, NE)
no	10/ 72 (13.9)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	10/ 50 (20.0)	NE (NE , NE)
no	2/ 29 (6.9)	NE (9.0, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

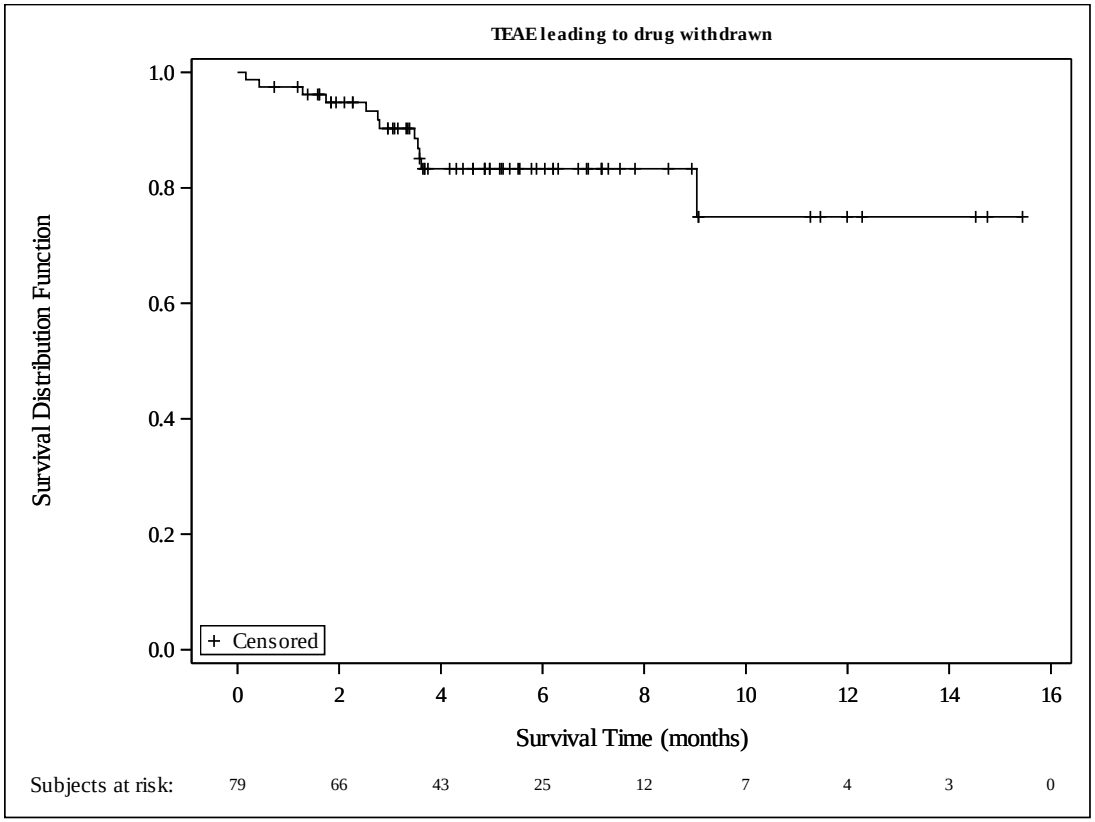
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE leading to drug withdrawn
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	6/ 32 (18.8)	NE (NE , NE)
mild	2/ 25 (8.0)	NE (NE , NE)
moderate	1/ 8 (12.5)	NE (9.0, NE)
Hepatic impairment at baseline		
normal	7/ 64 (10.9)	NE (NE , NE)
mild	5/ 14 (35.7)	NE (3.5, NE)
Race		
White	9/ 69 (13.0)	NE (NE , NE)
Black or African American	1/ 1 (100.0)	3.5 (NE , NE)
Other	1/ 8 (12.5)	NE (0.4, NE)
Ethnicity		
Hispanic/Latino	1/ 5 (20.0)	NE (3.6, NE)
Non-Hispanic/Non-Latino	10/ 70 (14.3)	NE (9.0, NE)
Unknown	1/ 4 (25.0)	NE (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of TEAE leading to drug withdrawn
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE leading to death
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	10/ 79 (12.7)	NE (NE , NE)
Region		
North America	5/ 34 (14.7)	NE (NE , NE)
EU	5/ 45 (11.1)	NE (NE , NE)
Age (Category 1)		
<65 years	9/ 46 (19.6)	NE (NE , NE)
>=65 years	1/ 33 (3.0)	NE (NE , NE)
Age (Category 2)		
<75 years	10/ 75 (13.3)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	1/ 22 (4.5)	NE (NE , NE)
male	9/ 57 (15.8)	NE (NE , NE)
ECOG PS		
0	2/ 29 (6.9)	NE (NE , NE)
1	8/ 50 (16.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	9/ 68 (13.2)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (3.5, NE)
Primary tumor location		
Gastric	2/ 27 (7.4)	NE (NE , NE)
GEJ	8/ 52 (15.4)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	3/ 19 (15.8)	NE (4.3, NE)
other	7/ 59 (11.9)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	10/ 74 (13.5)	NE (NE , NE)
Previous total gastrectomy		
no	10/ 79 (12.7)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	1/ 9 (11.1)	NE (0.9, NE)
no	9/ 70 (12.9)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (3.4, NE)
no	9/ 73 (12.3)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (3.4, NE)
no	8/ 72 (11.1)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	7/ 50 (14.0)	NE (NE , NE)
no	3/ 29 (10.3)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

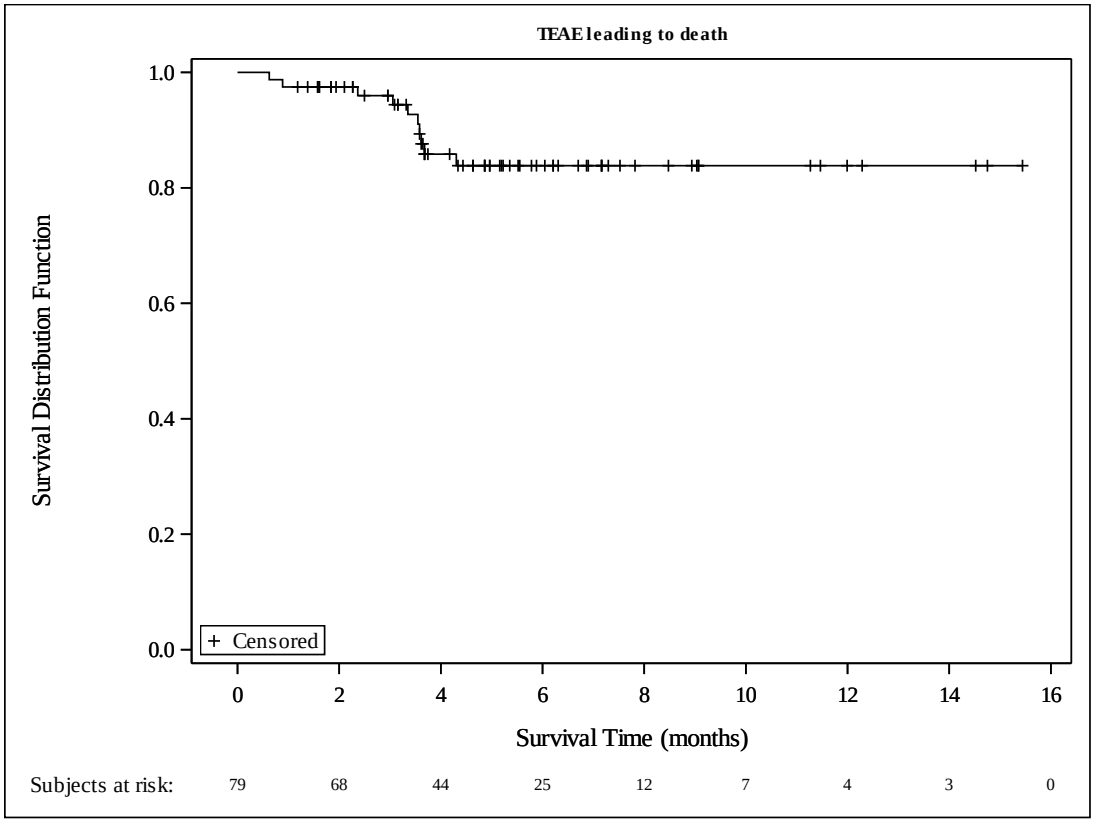
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE leading to death
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Renal impairment at baseline		
normal	7/ 32 (21.9)	NE (3.7, NE)
mild	1/ 25 (4.0)	NE (NE , NE)
moderate	1/ 8 (12.5)	NE (4.3, NE)
Hepatic impairment at baseline		
normal	4/ 64 (6.3)	NE (NE , NE)
mild	6/ 14 (42.9)	NE (3.1, NE)
Race		
White	8/ 69 (11.6)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	1/ 8 (12.5)	NE (3.4, NE)
Ethnicity		
Hispanic/Latino	2/ 5 (40.0)	NE (3.6, NE)
Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
Unknown	1/ 4 (25.0)	NE (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of TEAE leading to death
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Overall	6/ 79 (7.6)	NE (NE , NE)
Region		
North America	2/ 34 (5.9)	NE (NE , NE)
EU	4/ 45 (8.9)	NE (NE , NE)
Age (Category 1)		
<65 years	3/ 46 (6.5)	NE (NE , NE)
>=65 years	3/ 33 (9.1)	NE (NE , NE)
Age (Category 2)		
<75 years	6/ 75 (8.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	2/ 22 (9.1)	NE (NE , NE)
male	4/ 57 (7.0)	NE (NE , NE)
ECOG PS		
0	6/ 29 (20.7)	NE (NE , NE)
1	0/ 50 (0.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	5/ 68 (7.4)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (0.7, NE)
Primary tumor location		
Gastric	1/ 27 (3.7)	NE (NE , NE)
GEJ	5/ 52 (9.6)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	5/ 59 (8.5)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	6/ 74 (8.1)	NE (NE , NE)
Previous total gastrectomy		
no	6/ 79 (7.6)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	6/ 70 (8.6)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	6/ 73 (8.2)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	6/ 72 (8.3)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	3/ 50 (6.0)	NE (NE , NE)
no	3/ 29 (10.3)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

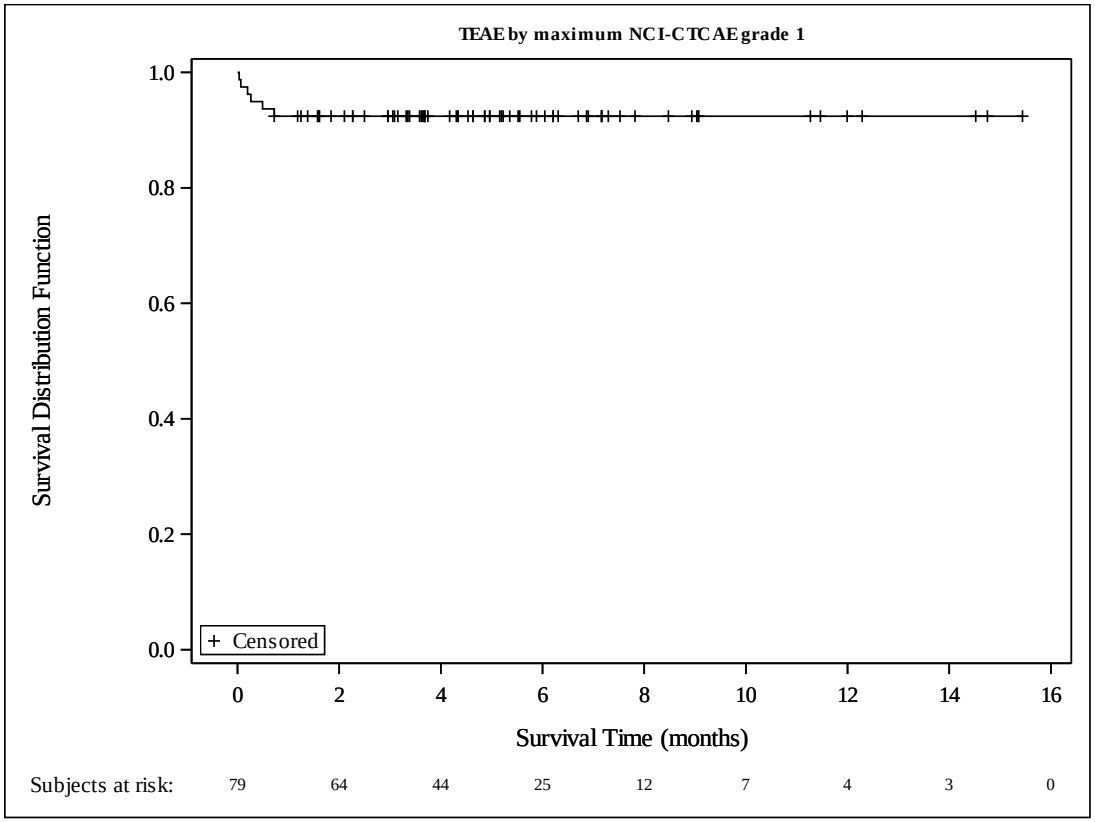
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	2/ 32 (6.3)	NE (NE , NE)
mild	2/ 25 (8.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	6/ 64 (9.4)	NE (NE , NE)
mild	0/ 14 (0.0)	NE (NE , NE)
Race		
White	5/ 69 (7.2)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	1/ 8 (12.5)	NE (0.0, NE)
Ethnicity		
Hispanic/Latino	1/ 5 (20.0)	NE (0.2, NE)
Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
Unknown	1/ 4 (25.0)	NE (0.0, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Overall	31/ 79 (39.2)	NE (3.7, NE)
Region		
North America	15/ 34 (44.1)	6.9 (0.5, NE)
EU	16/ 45 (35.6)	NE (2.8, NE)
Age (Category 1)		
<65 years	14/ 46 (30.4)	NE (NE , NE)
>=65 years	17/ 33 (51.5)	3.7 (0.7, NE)
Age (Category 2)		
<75 years	30/ 75 (40.0)	NE (2.1, NE)
>=75 years	1/ 4 (25.0)	NE (3.7, NE)
Sex		
female	8/ 22 (36.4)	NE (2.1, NE)
male	23/ 57 (40.4)	NE (1.4, NE)
ECOG PS		
0	14/ 29 (48.3)	6.9 (0.5, NE)
1	17/ 50 (34.0)	NE (3.7, NE)
HER2 Status in central laboratory		
IHC 3+	27/ 68 (39.7)	NE (2.8, NE)
IHC 2+/ISH +	4/ 10 (40.0)	NE (0.0, NE)
Primary tumor location		
Gastric	10/ 27 (37.0)	NE (0.7, NE)
GEJ	21/ 52 (40.4)	NE (2.0, NE)
Histological subtype		
diffuse	1/ 1 (100.0)	0.5 (NE , NE)
intestinal	7/ 19 (36.8)	NE (0.1, NE)
other	23/ 59 (39.0)	NE (2.1, NE)
Number of metastatic sites		
<2	4/ 5 (80.0)	1.4 (0.0, NE)
>=2	27/ 74 (36.5)	NE (6.9, NE)
Previous total gastrectomy		
no	31/ 79 (39.2)	NE (3.7, NE)
Prior adjuvant/ neoadjuvant therapy		
yes	2/ 9 (22.2)	NE (0.1, NE)
no	29/ 70 (41.4)	NE (2.1, NE)
Prior nivolumab or pembrolizumab treatment		
yes	5/ 6 (83.3)	0.3 (0.1, NE)
no	26/ 73 (35.6)	NE (6.9, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	5/ 7 (71.4)	0.4 (0.1, NE)
no	26/ 72 (36.1)	NE (6.9, NE)
Presence of liver metastasis at baseline		
yes	22/ 50 (44.0)	6.9 (1.4, NE)
no	9/ 29 (31.0)	NE (2.0, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

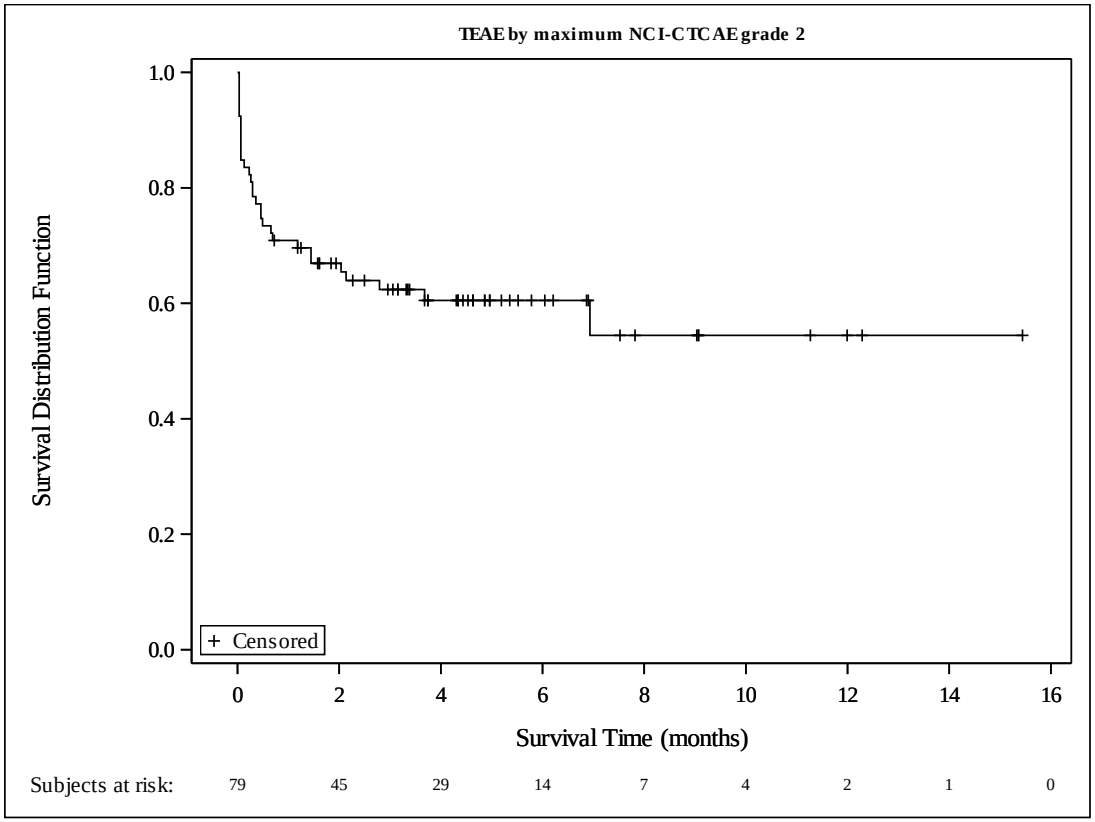
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Renal impairment at baseline		
normal	14/ 32 (43.8)	6.9 (0.5, NE)
mild	13/ 25 (52.0)	2.8 (0.3, NE)
moderate	2/ 8 (25.0)	NE (2.1, NE)
Hepatic impairment at baseline		
normal	28/ 64 (43.8)	NE (2.0, NE)
mild	3/ 14 (21.4)	NE (0.7, NE)
Race		
White	29/ 69 (42.0)	NE (2.0, NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	2/ 8 (25.0)	6.9 (0.0, 6.9)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	30/ 70 (42.9)	6.9 (2.0, NE)
Unknown	1/ 4 (25.0)	NE (0.1, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Overall	27/ 79 (34.2)	9.8 (6.0, NE)
Region		
North America	11/ 34 (32.4)	9.8 (6.0, NE)
EU	16/ 45 (35.6)	11.3 (3.6, 11.3)
Age (Category 1)		
<65 years	18/ 46 (39.1)	9.8 (4.1, NE)
>=65 years	9/ 33 (27.3)	NE (6.0, NE)
Age (Category 2)		
<75 years	25/ 75 (33.3)	11.3 (6.0, NE)
>=75 years	2/ 4 (50.0)	NE (0.3, NE)
Sex		
female	9/ 22 (40.9)	NE (2.7, NE)
male	18/ 57 (31.6)	9.8 (6.0, NE)
ECOG PS		
0	7/ 29 (24.1)	11.3 (9.8, NE)
1	20/ 50 (40.0)	NE (3.0, NE)
HER2 Status in central laboratory		
IHC 3+	23/ 68 (33.8)	11.3 (6.0, NE)
IHC 2+/ISH +	3/ 10 (30.0)	NE (0.2, NE)
Primary tumor location		
Gastric	10/ 27 (37.0)	NE (1.4, NE)
GEJ	17/ 52 (32.7)	9.8 (6.0, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	6/ 19 (31.6)	9.8 (9.8, 11.3)
other	21/ 59 (35.6)	NE (4.1, NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (0.5, NE)
>=2	26/ 74 (35.1)	9.8 (6.0, NE)
Previous total gastrectomy		
no	27/ 79 (34.2)	9.8 (6.0, NE)
Prior adjuvant/ neoadjuvant therapy		
yes	6/ 9 (66.7)	4.2 (0.1, 11.3)
no	21/ 70 (30.0)	9.8 (6.0, NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	27/ 73 (37.0)	9.8 (6.0, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	27/ 72 (37.5)	9.8 (4.2, NE)
Presence of liver metastasis at baseline		
yes	15/ 50 (30.0)	11.3 (6.0, NE)
no	12/ 29 (41.4)	NE (2.6, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

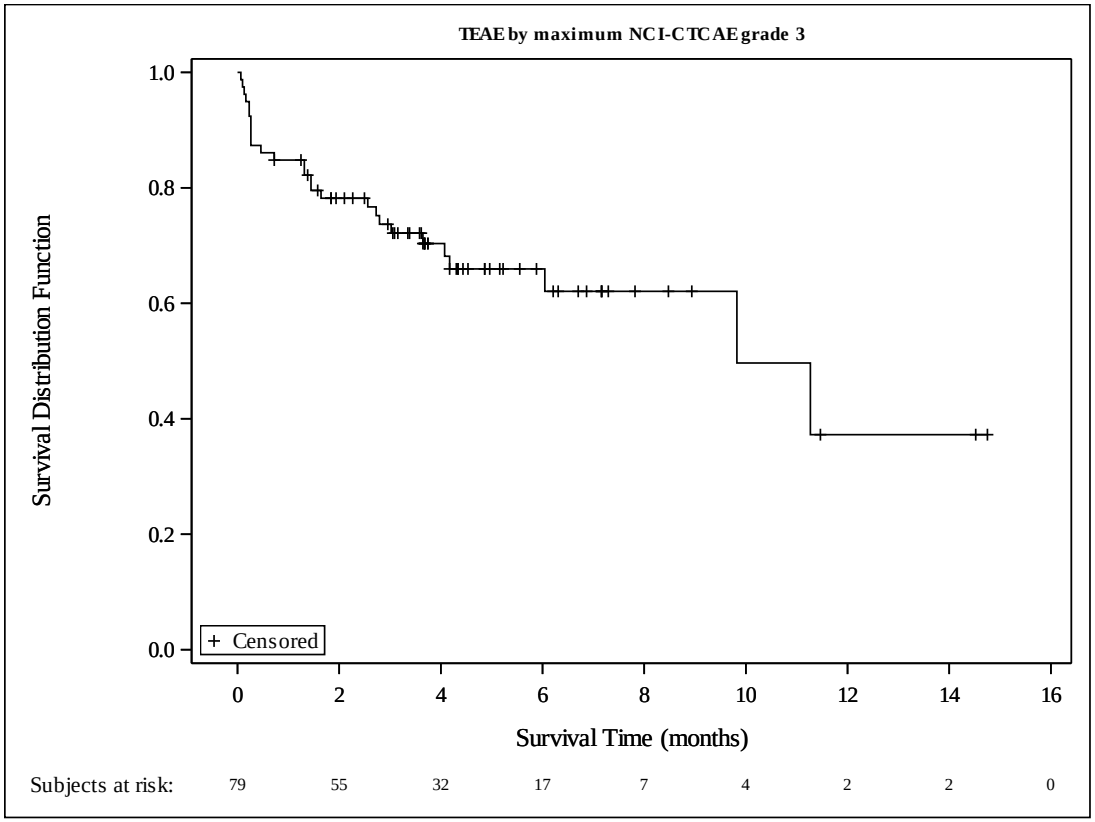
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	7/ 32 (21.9)	9.8 (9.8, NE)
mild	9/ 25 (36.0)	11.3 (3.0, NE)
moderate	4/ 8 (50.0)	6.0 (1.3, 6.0)
Hepatic impairment at baseline		
normal	23/ 64 (35.9)	9.8 (6.0, NE)
mild	3/ 14 (21.4)	NE (4.1, NE)
Race		
White	24/ 69 (34.8)	9.8 (6.0, NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	3/ 8 (37.5)	NE (0.2, NE)
Ethnicity		
Hispanic/Latino	2/ 5 (40.0)	9.8 (0.3, 9.8)
Non-Hispanic/Non-Latino	24/ 70 (34.3)	11.3 (6.0, NE)
Unknown	1/ 4 (25.0)	NE (4.2, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Overall	5/ 79 (6.3)	NE (NE , NE)
Region		
North America	1/ 34 (2.9)	NE (NE , NE)
EU	4/ 45 (8.9)	NE (NE , NE)
Age (Category 1)		
<65 years	2/ 46 (4.3)	NE (NE , NE)
>=65 years	3/ 33 (9.1)	NE (NE , NE)
Age (Category 2)		
<75 years	4/ 75 (5.3)	NE (NE , NE)
>=75 years	1/ 4 (25.0)	NE (0.5, NE)
Sex		
female	2/ 22 (9.1)	NE (NE , NE)
male	3/ 57 (5.3)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	5/ 50 (10.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	4/ 68 (5.9)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
Primary tumor location		
Gastric	4/ 27 (14.8)	NE (NE , NE)
GEJ	1/ 52 (1.9)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	2/ 19 (10.5)	NE (NE , NE)
other	3/ 59 (5.1)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	5/ 74 (6.8)	NE (NE , NE)
Previous total gastrectomy		
no	5/ 79 (6.3)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	5/ 70 (7.1)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	5/ 73 (6.8)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	5/ 72 (6.9)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	3/ 50 (6.0)	NE (NE , NE)
no	2/ 29 (6.9)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

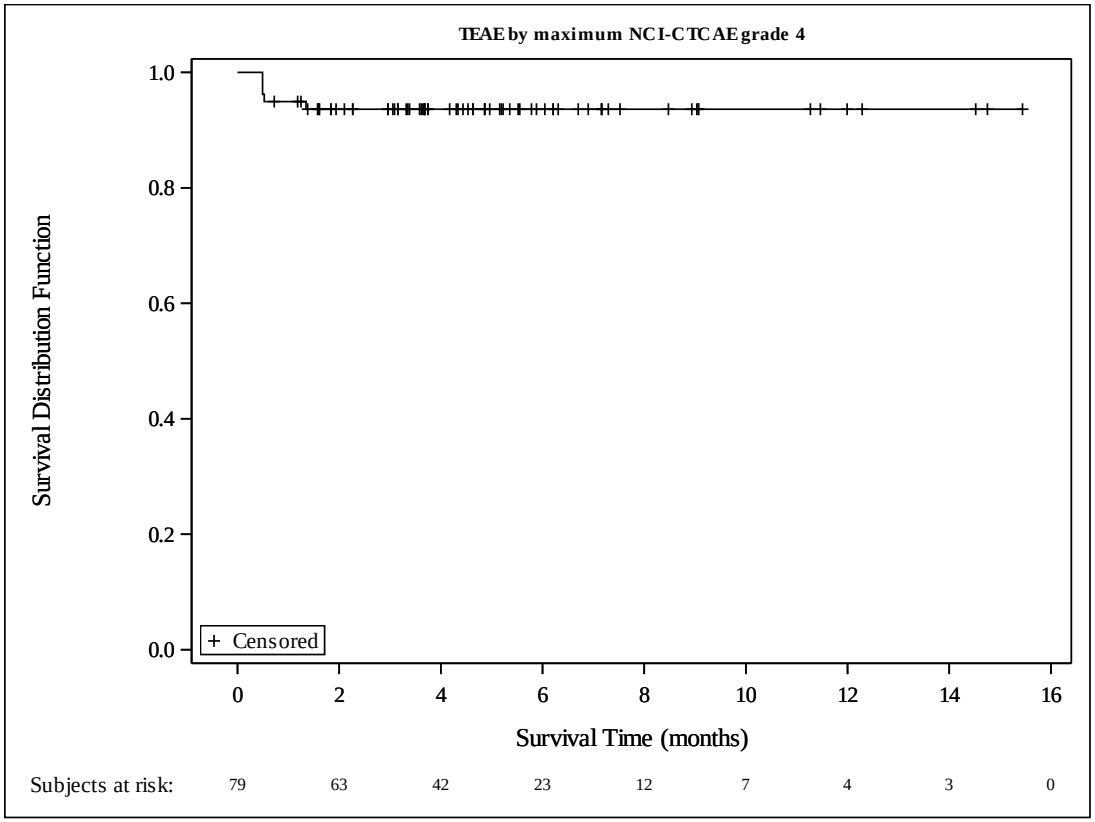
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	2/ 32 (6.3)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	1/ 8 (12.5)	NE (0.5, NE)
Hepatic impairment at baseline		
normal	3/ 64 (4.7)	NE (NE , NE)
mild	2/ 14 (14.3)	NE (NE , NE)
Race		
White	3/ 69 (4.3)	NE (NE , NE)
Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
Other	1/ 8 (12.5)	NE (0.5, NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	5/ 70 (7.1)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	10/ 79 (12.7)	NE (NE , NE)
Region		
North America	5/ 34 (14.7)	NE (NE , NE)
EU	5/ 45 (11.1)	NE (NE , NE)
Age (Category 1)		
<65 years	9/ 46 (19.6)	NE (NE , NE)
>=65 years	1/ 33 (3.0)	NE (NE , NE)
Age (Category 2)		
<75 years	10/ 75 (13.3)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	1/ 22 (4.5)	NE (NE , NE)
male	9/ 57 (15.8)	NE (NE , NE)
ECOG PS		
0	2/ 29 (6.9)	NE (NE , NE)
1	8/ 50 (16.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	9/ 68 (13.2)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (3.5, NE)
Primary tumor location		
Gastric	2/ 27 (7.4)	NE (NE , NE)
GEJ	8/ 52 (15.4)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	3/ 19 (15.8)	NE (4.3, NE)
other	7/ 59 (11.9)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	10/ 74 (13.5)	NE (NE , NE)
Previous total gastrectomy		
no	10/ 79 (12.7)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	1/ 9 (11.1)	NE (0.9, NE)
no	9/ 70 (12.9)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (3.4, NE)
no	9/ 73 (12.3)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (3.4, NE)
no	8/ 72 (11.1)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	7/ 50 (14.0)	NE (NE , NE)
no	3/ 29 (10.3)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

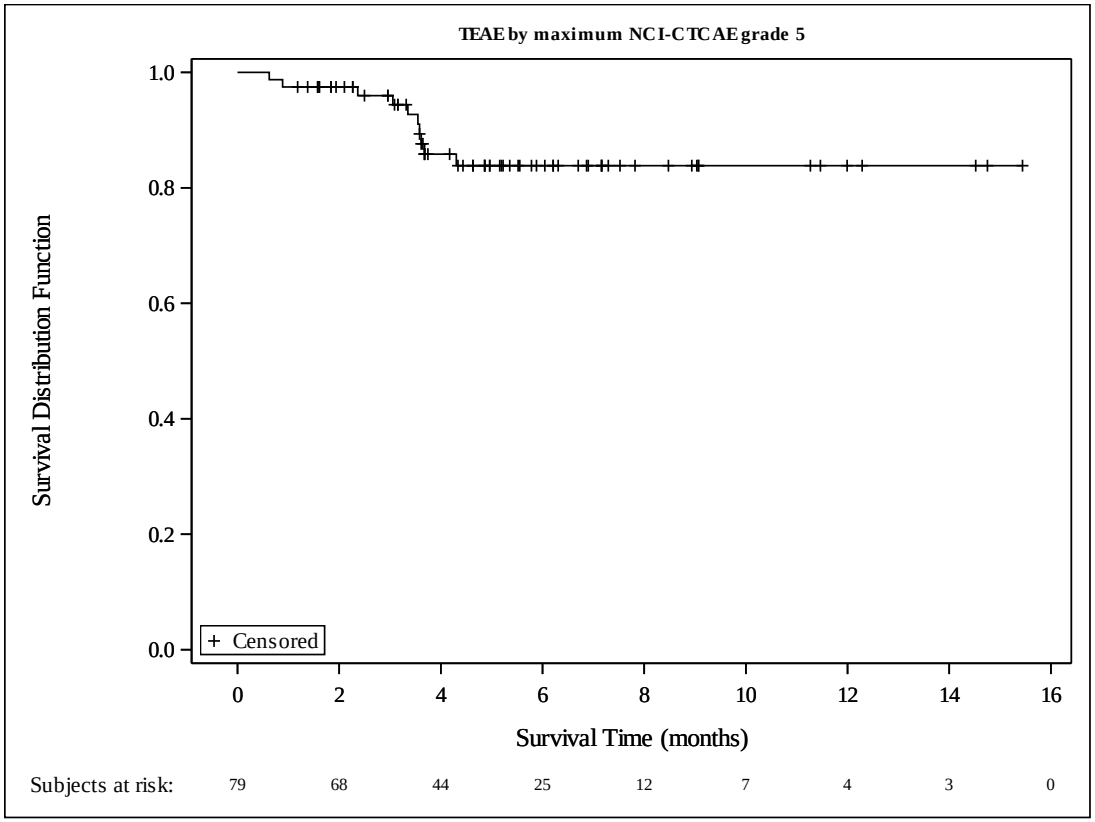
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	7/ 32 (21.9)	NE (3.7, NE)
mild	1/ 25 (4.0)	NE (NE , NE)
moderate	1/ 8 (12.5)	NE (4.3, NE)
Hepatic impairment at baseline		
normal	4/ 64 (6.3)	NE (NE , NE)
mild	6/ 14 (42.9)	NE (3.1, NE)
Race		
White	8/ 69 (11.6)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	1/ 8 (12.5)	NE (3.4, NE)
Ethnicity		
Hispanic/Latino	2/ 5 (40.0)	NE (3.6, NE)
Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
Unknown	1/ 4 (25.0)	NE (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Overall	7/ 79 (8.9)	NE (NE , NE)
Region		
North America	3/ 34 (8.8)	NE (NE , NE)
EU	4/ 45 (8.9)	NE (NE , NE)
Age (Category 1)		
<65 years	5/ 46 (10.9)	NE (NE , NE)
>=65 years	2/ 33 (6.1)	NE (NE , NE)
Age (Category 2)		
<75 years	7/ 75 (9.3)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	7/ 57 (12.3)	NE (NE , NE)
ECOG PS		
0	3/ 29 (10.3)	NE (NE , NE)
1	4/ 50 (8.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	6/ 68 (8.8)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	7/ 52 (13.5)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	6/ 59 (10.2)	NE (NE , NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	6/ 74 (8.1)	NE (NE , NE)
Previous total gastrectomy		
no	7/ 79 (8.9)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	7/ 70 (10.0)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	6/ 73 (8.2)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	1/ 7 (14.3)	NE (2.5, NE)
no	6/ 72 (8.3)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	6/ 50 (12.0)	NE (NE , NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

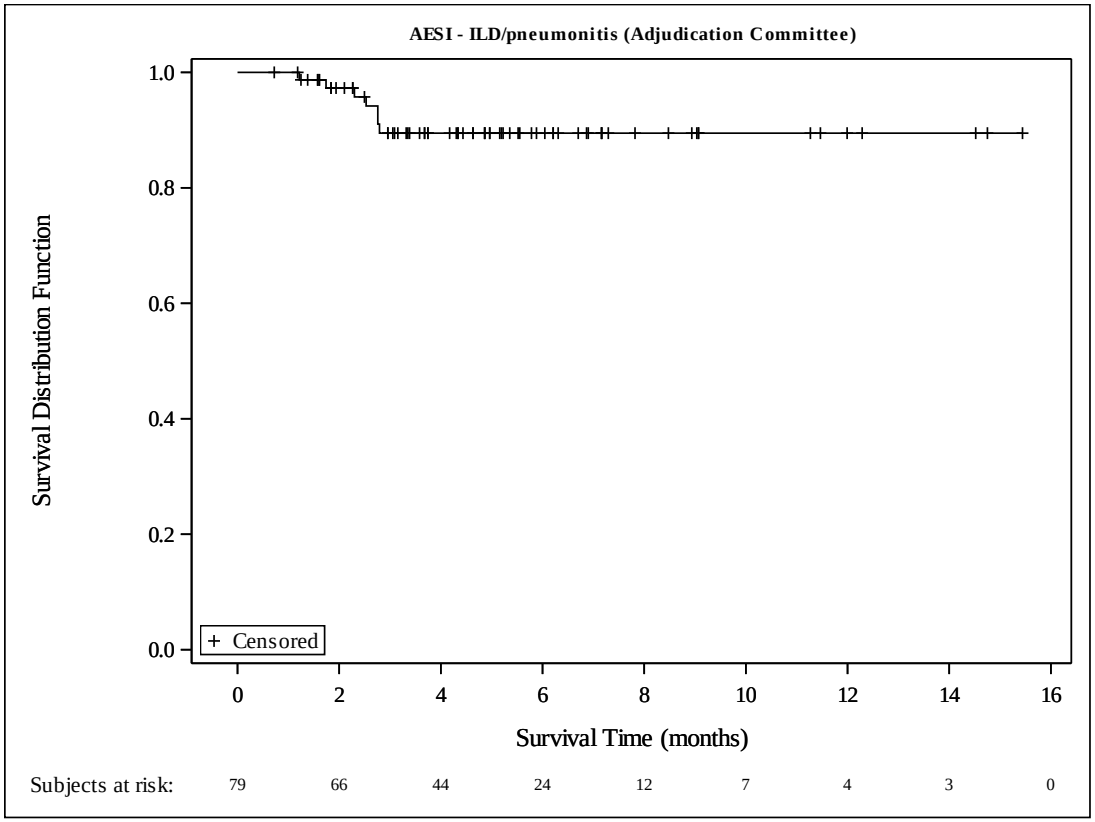
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	5/ 32 (15.6)	NE (NE , NE)
mild	2/ 25 (8.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	6/ 64 (9.4)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	7/ 69 (10.1)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	2/ 79 (2.5)	NE (NE , NE)
Region		
North America	2/ 34 (5.9)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (NE , NE)
>=65 years	1/ 33 (3.0)	NE (NE , NE)
Age (Category 2)		
<75 years	2/ 75 (2.7)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	2/ 57 (3.5)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	2/ 50 (4.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	1/ 68 (1.5)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	2/ 52 (3.8)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	1/ 59 (1.7)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	2/ 74 (2.7)	NE (NE , NE)
Previous total gastrectomy		
no	2/ 79 (2.5)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	2/ 70 (2.9)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	2/ 73 (2.7)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	2/ 72 (2.8)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	2/ 50 (4.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

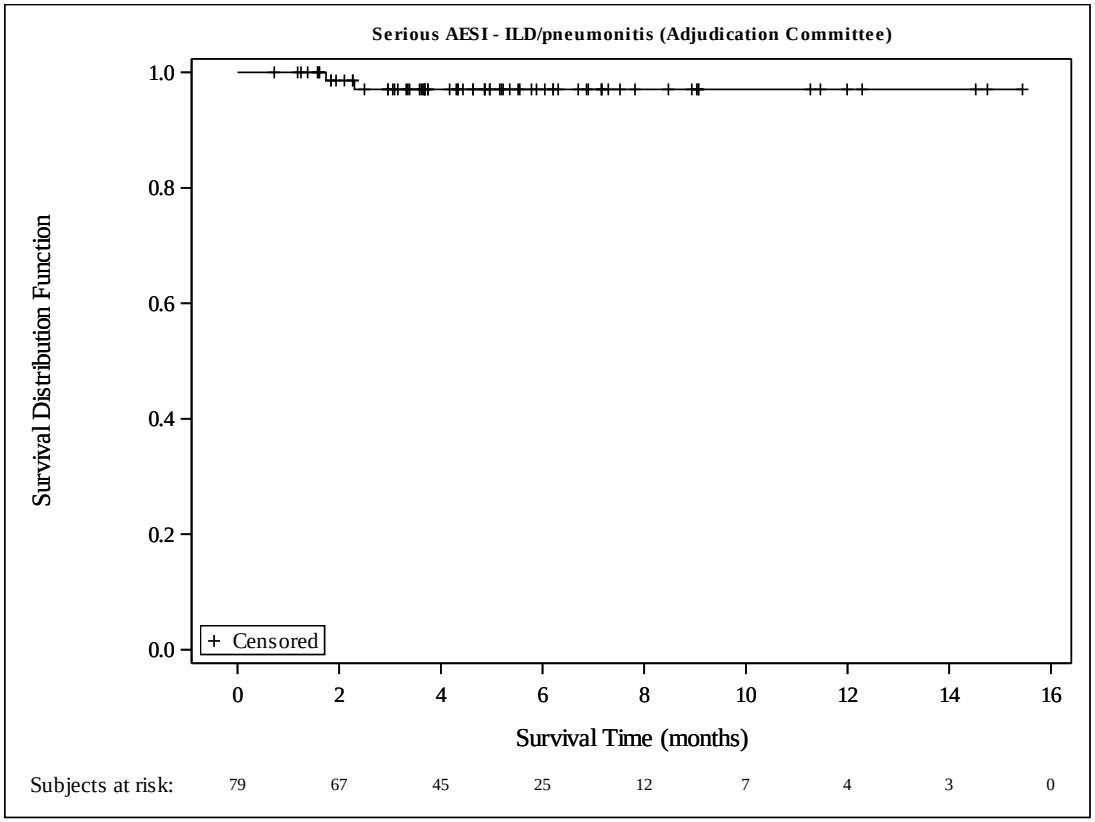
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	2/ 32 (6.3)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	1/ 64 (1.6)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	2/ 69 (2.9)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	2/ 70 (2.9)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	1/ 79 (1.3)	NE (NE , NE)
Region		
North America	1/ 34 (2.9)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (NE , NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	1/ 75 (1.3)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	1/ 57 (1.8)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	1/ 50 (2.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	1/ 68 (1.5)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	1/ 52 (1.9)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	0/ 59 (0.0)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	1/ 74 (1.4)	NE (NE , NE)
Previous total gastrectomy		
no	1/ 79 (1.3)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	1/ 70 (1.4)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	1/ 73 (1.4)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	1/ 72 (1.4)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	1/ 50 (2.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

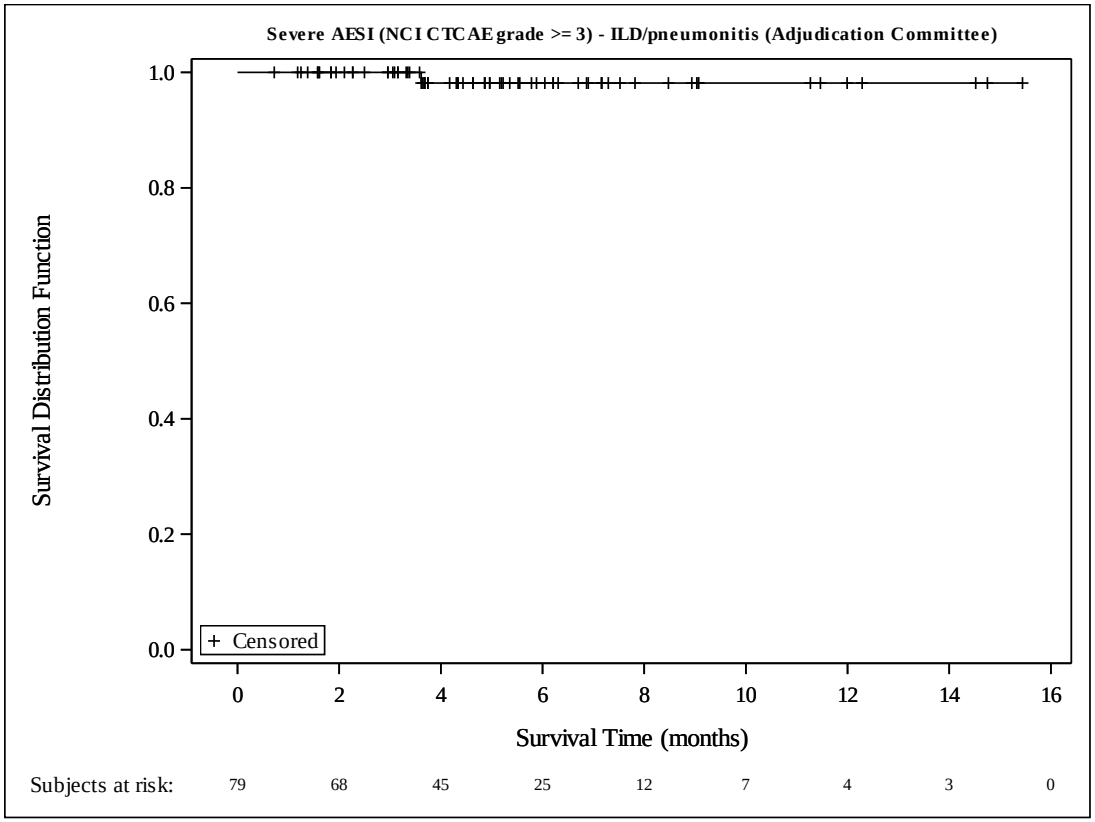
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	1/ 32 (3.1)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	1/ 69 (1.4)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	1/ 70 (1.4)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	7/ 79 (8.9)	NE (NE , NE)
Region		
North America	3/ 34 (8.8)	NE (NE , NE)
EU	4/ 45 (8.9)	NE (NE , NE)
Age (Category 1)		
<65 years	5/ 46 (10.9)	NE (NE , NE)
>=65 years	2/ 33 (6.1)	NE (NE , NE)
Age (Category 2)		
<75 years	7/ 75 (9.3)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	7/ 57 (12.3)	NE (NE , NE)
ECOG PS		
0	3/ 29 (10.3)	NE (NE , NE)
1	4/ 50 (8.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	6/ 68 (8.8)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	7/ 52 (13.5)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	6/ 59 (10.2)	NE (NE , NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	6/ 74 (8.1)	NE (NE , NE)
Previous total gastrectomy		
no	7/ 79 (8.9)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	7/ 70 (10.0)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	6/ 73 (8.2)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	1/ 7 (14.3)	NE (2.5, NE)
no	6/ 72 (8.3)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	6/ 50 (12.0)	NE (NE , NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

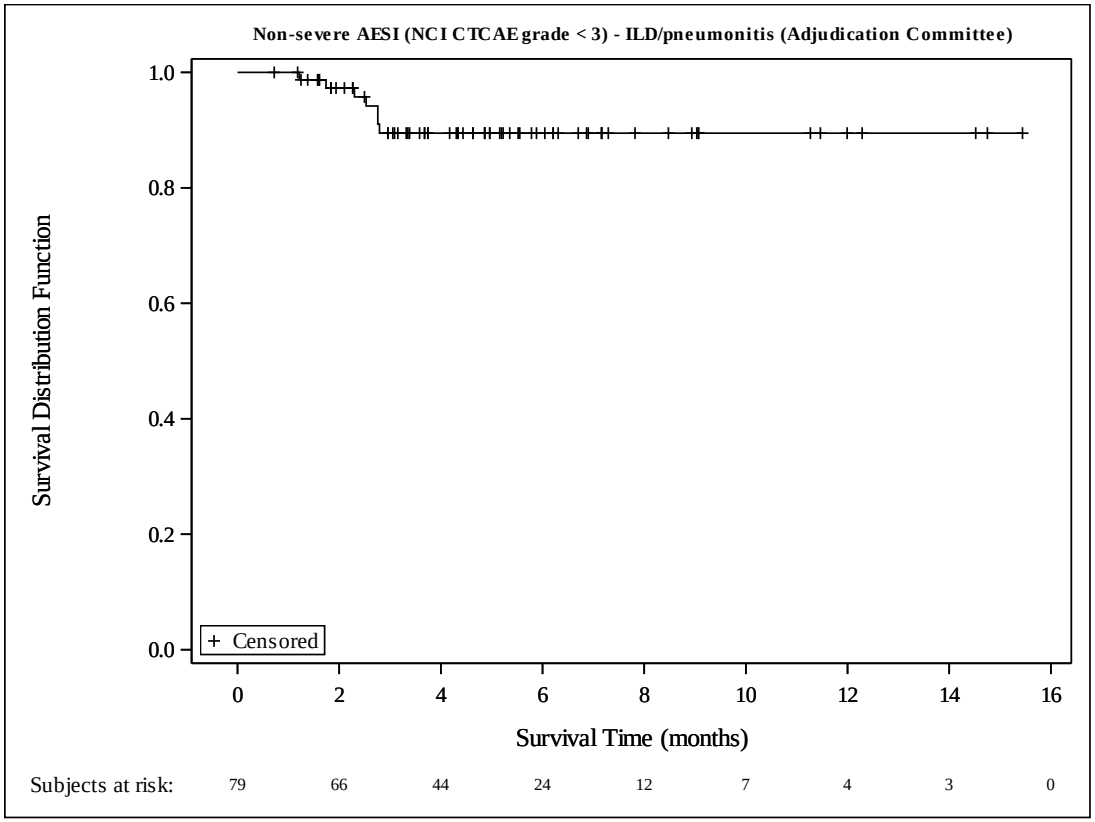
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	5/ 32 (15.6)	NE (NE , NE)
mild	2/ 25 (8.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	6/ 64 (9.4)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	7/ 69 (10.1)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	6/ 79 (7.6)	NE (NE , NE)
Region		
North America	3/ 34 (8.8)	NE (NE , NE)
EU	3/ 45 (6.7)	NE (NE , NE)
Age (Category 1)		
<65 years	4/ 46 (8.7)	NE (NE , NE)
>=65 years	2/ 33 (6.1)	NE (NE , NE)
Age (Category 2)		
<75 years	6/ 75 (8.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	6/ 57 (10.5)	NE (NE , NE)
ECOG PS		
0	2/ 29 (6.9)	NE (NE , NE)
1	4/ 50 (8.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	5/ 68 (7.4)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	6/ 52 (11.5)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	5/ 59 (8.5)	NE (NE , NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	5/ 74 (6.8)	NE (NE , NE)
Previous total gastrectomy		
no	6/ 79 (7.6)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	6/ 70 (8.6)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	5/ 73 (6.8)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	1/ 7 (14.3)	NE (2.5, NE)
no	5/ 72 (6.9)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	5/ 50 (10.0)	NE (NE , NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

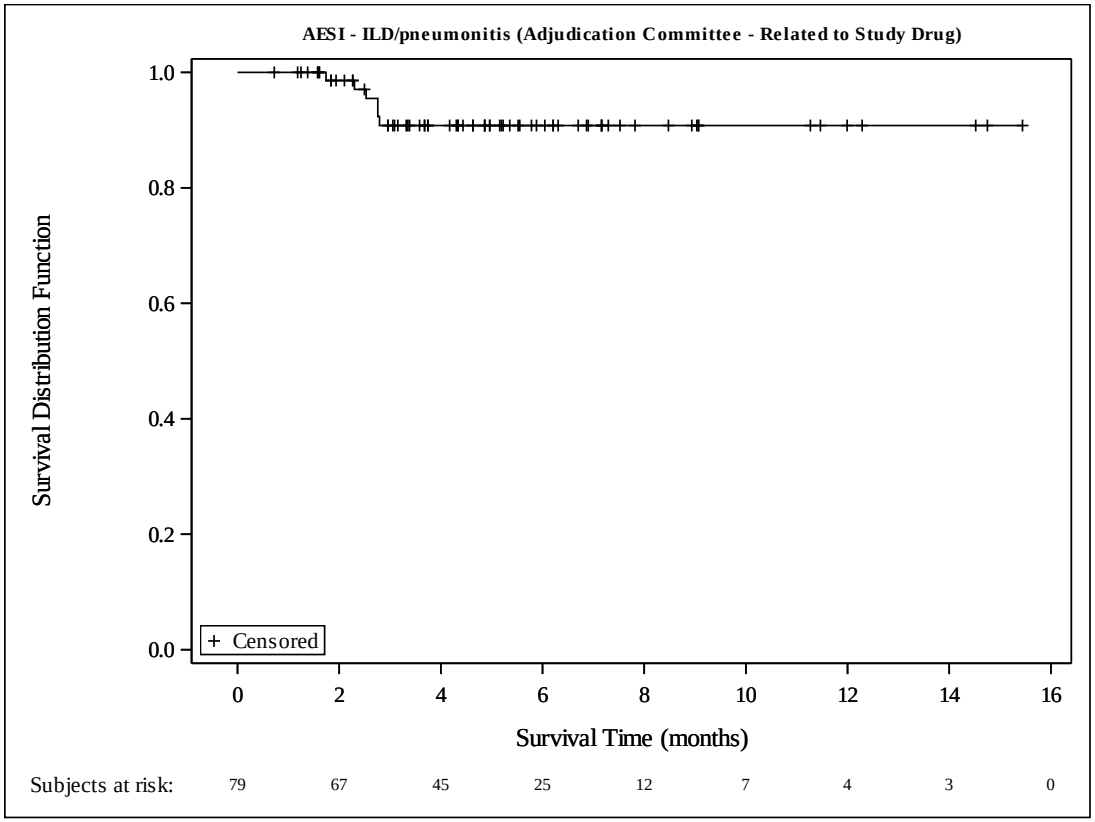
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	5/ 32 (15.6)	NE (NE , NE)
mild	1/ 25 (4.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	5/ 64 (7.8)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	6/ 69 (8.7)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	6/ 70 (8.6)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	2/ 79 (2.5)	NE (NE , NE)
Region		
North America	2/ 34 (5.9)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (NE , NE)
>=65 years	1/ 33 (3.0)	NE (NE , NE)
Age (Category 2)		
<75 years	2/ 75 (2.7)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	2/ 57 (3.5)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	2/ 50 (4.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	1/ 68 (1.5)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	2/ 52 (3.8)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	1/ 59 (1.7)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	2/ 74 (2.7)	NE (NE , NE)
Previous total gastrectomy		
no	2/ 79 (2.5)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	2/ 70 (2.9)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	2/ 73 (2.7)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	2/ 72 (2.8)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	2/ 50 (4.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

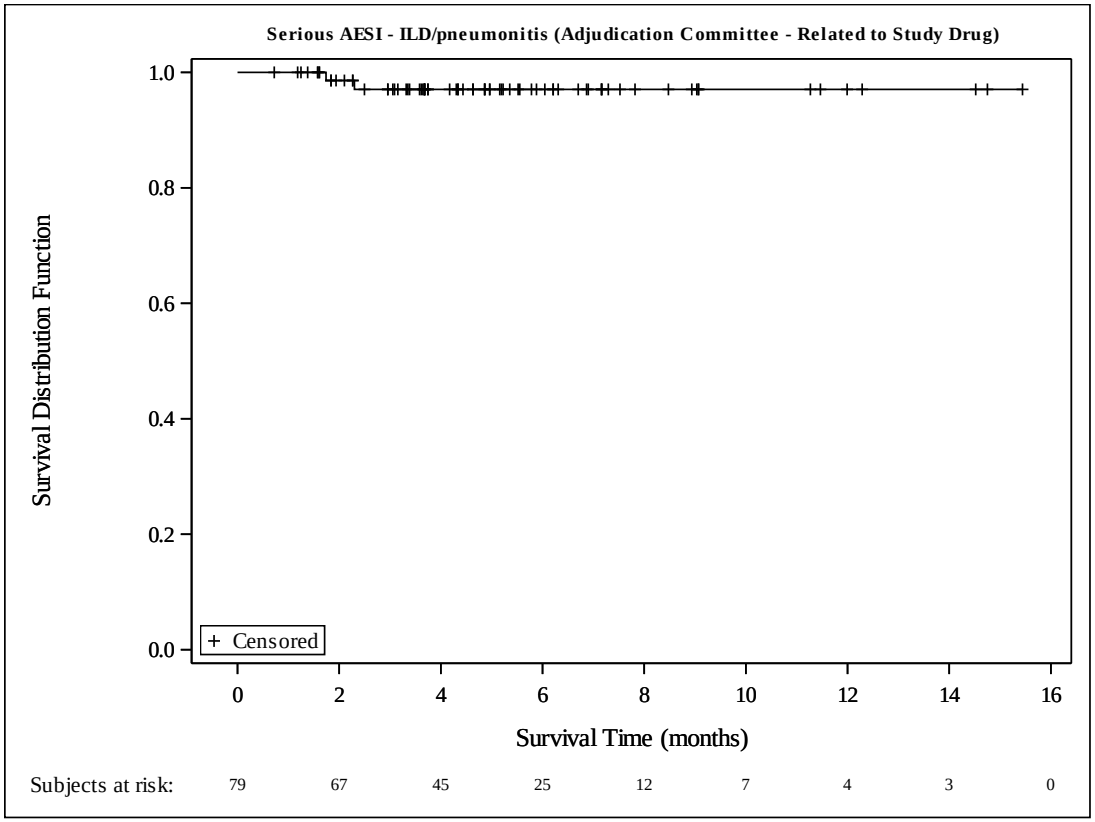
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	2/ 32 (6.3)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	1/ 64 (1.6)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	2/ 69 (2.9)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	2/ 70 (2.9)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	1/ 79 (1.3)	NE (NE , NE)
Region		
North America	1/ 34 (2.9)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (NE , NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	1/ 75 (1.3)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	1/ 57 (1.8)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	1/ 50 (2.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	1/ 68 (1.5)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	1/ 52 (1.9)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	0/ 59 (0.0)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	1/ 74 (1.4)	NE (NE , NE)
Previous total gastrectomy		
no	1/ 79 (1.3)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	1/ 70 (1.4)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	1/ 73 (1.4)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	1/ 72 (1.4)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	1/ 50 (2.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

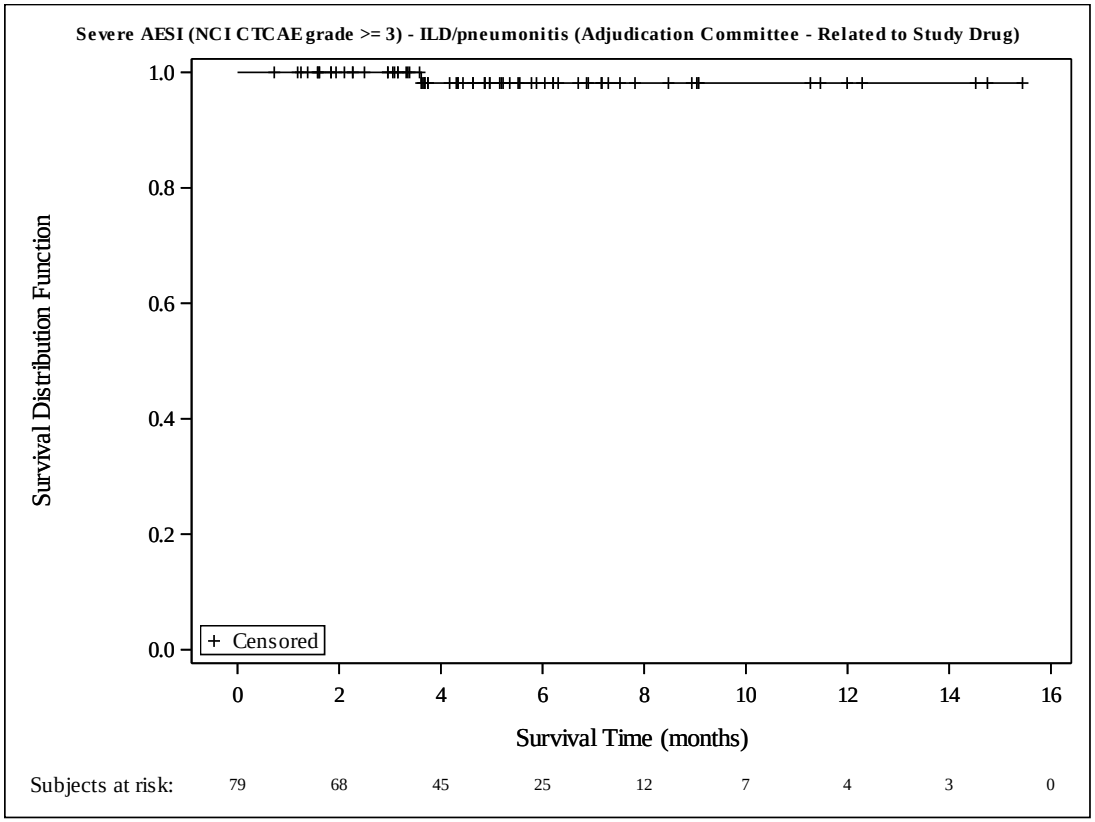
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	1/ 32 (3.1)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	1/ 69 (1.4)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	1/ 70 (1.4)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	6/ 79 (7.6)	NE (NE , NE)
Region		
North America	3/ 34 (8.8)	NE (NE , NE)
EU	3/ 45 (6.7)	NE (NE , NE)
Age (Category 1)		
<65 years	4/ 46 (8.7)	NE (NE , NE)
>=65 years	2/ 33 (6.1)	NE (NE , NE)
Age (Category 2)		
<75 years	6/ 75 (8.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	6/ 57 (10.5)	NE (NE , NE)
ECOG PS		
0	2/ 29 (6.9)	NE (NE , NE)
1	4/ 50 (8.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	5/ 68 (7.4)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	6/ 52 (11.5)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	5/ 59 (8.5)	NE (NE , NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	5/ 74 (6.8)	NE (NE , NE)
Previous total gastrectomy		
no	6/ 79 (7.6)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	6/ 70 (8.6)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	5/ 73 (6.8)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	1/ 7 (14.3)	NE (2.5, NE)
no	5/ 72 (6.9)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	5/ 50 (10.0)	NE (NE , NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

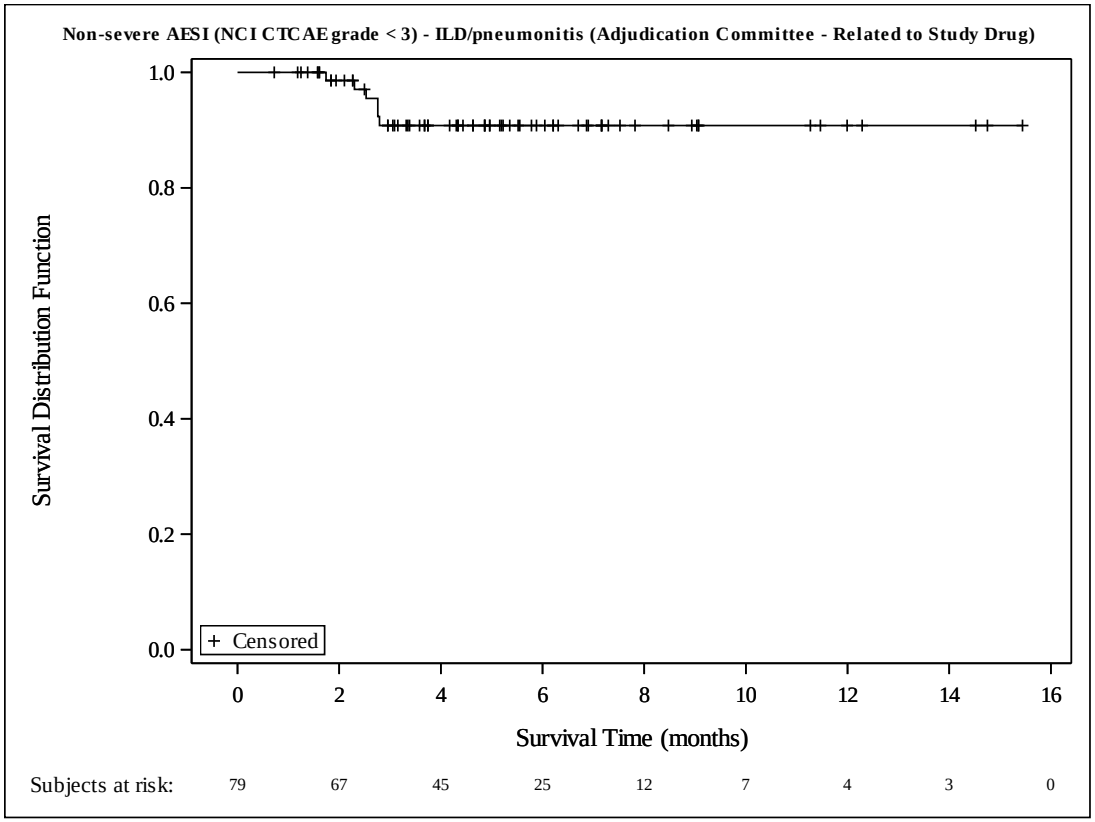
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	5/ 32 (15.6)	NE (NE , NE)
mild	1/ 25 (4.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	5/ 64 (7.8)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	6/ 69 (8.7)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	6/ 70 (8.6)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Overall	0/ 79 (0.0)	NE (NE , NE)
Region		
North America	0/ 34 (0.0)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	0/ 46 (0.0)	NE (NE , NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	0/ 75 (0.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	0/ 57 (0.0)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	0/ 50 (0.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	0/ 68 (0.0)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	0/ 52 (0.0)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	0/ 19 (0.0)	NE (NE , NE)
other	0/ 59 (0.0)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	0/ 74 (0.0)	NE (NE , NE)
Previous total gastrectomy		
no	0/ 79 (0.0)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	0/ 70 (0.0)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	0/ 73 (0.0)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	0/ 72 (0.0)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	0/ 50 (0.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

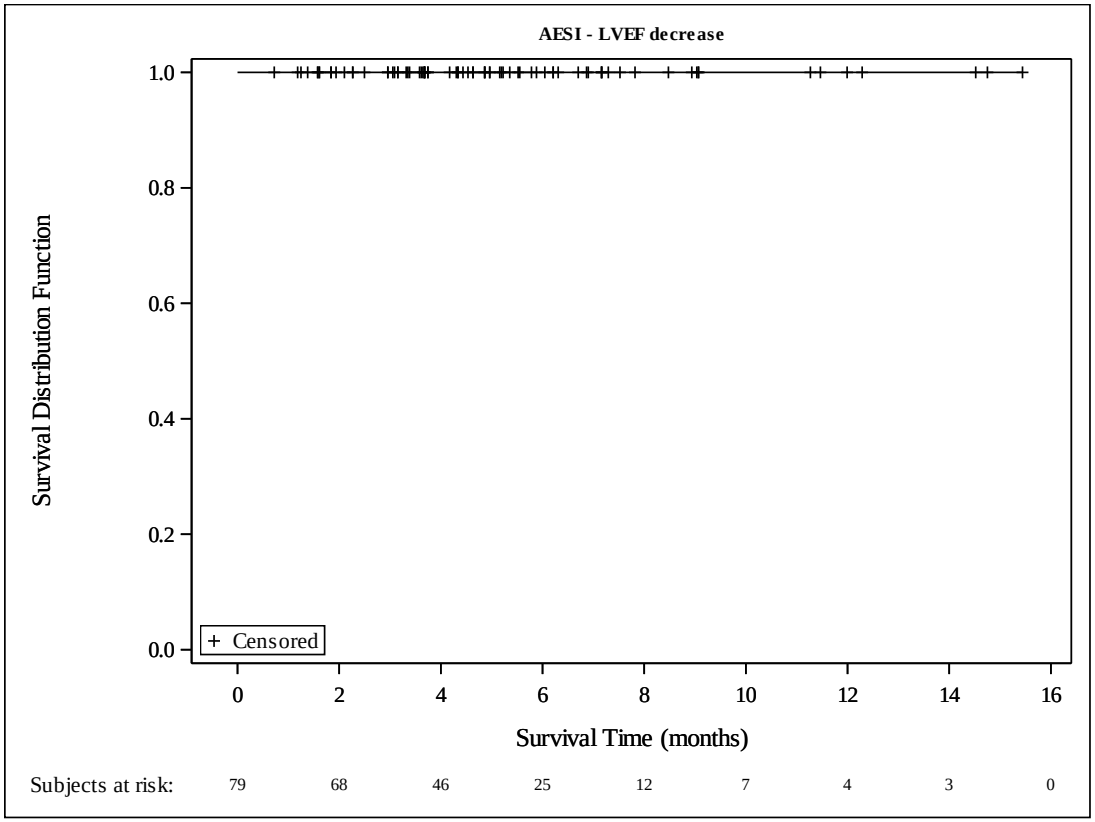
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	0/ 32 (0.0)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	0/ 14 (0.0)	NE (NE , NE)
Race		
White	0/ 69 (0.0)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	0/ 70 (0.0)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Serious AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	0/ 79 (0.0)	NE (NE , NE)
Region		
North America	0/ 34 (0.0)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	0/ 46 (0.0)	NE (NE , NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	0/ 75 (0.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	0/ 57 (0.0)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	0/ 50 (0.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	0/ 68 (0.0)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	0/ 52 (0.0)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	0/ 19 (0.0)	NE (NE , NE)
other	0/ 59 (0.0)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	0/ 74 (0.0)	NE (NE , NE)
Previous total gastrectomy		
no	0/ 79 (0.0)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	0/ 70 (0.0)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	0/ 73 (0.0)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	0/ 72 (0.0)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	0/ 50 (0.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

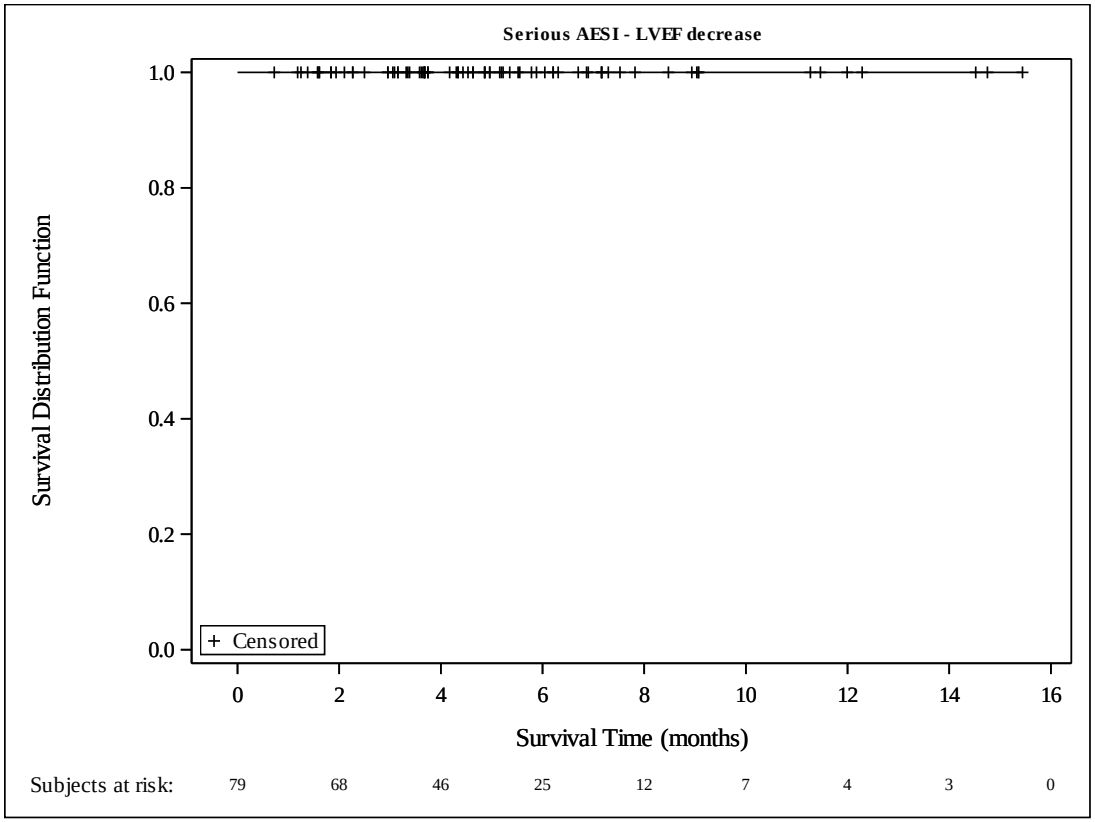
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Serious AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	0/ 32 (0.0)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	0/ 14 (0.0)	NE (NE , NE)
Race		
White	0/ 69 (0.0)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	0/ 70 (0.0)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Serious AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	0/ 79 (0.0)	NE (NE , NE)
Region		
North America	0/ 34 (0.0)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	0/ 46 (0.0)	NE (NE , NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	0/ 75 (0.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	0/ 57 (0.0)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	0/ 50 (0.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	0/ 68 (0.0)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	0/ 52 (0.0)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	0/ 19 (0.0)	NE (NE , NE)
other	0/ 59 (0.0)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	0/ 74 (0.0)	NE (NE , NE)
Previous total gastrectomy		
no	0/ 79 (0.0)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	0/ 70 (0.0)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	0/ 73 (0.0)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	0/ 72 (0.0)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	0/ 50 (0.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

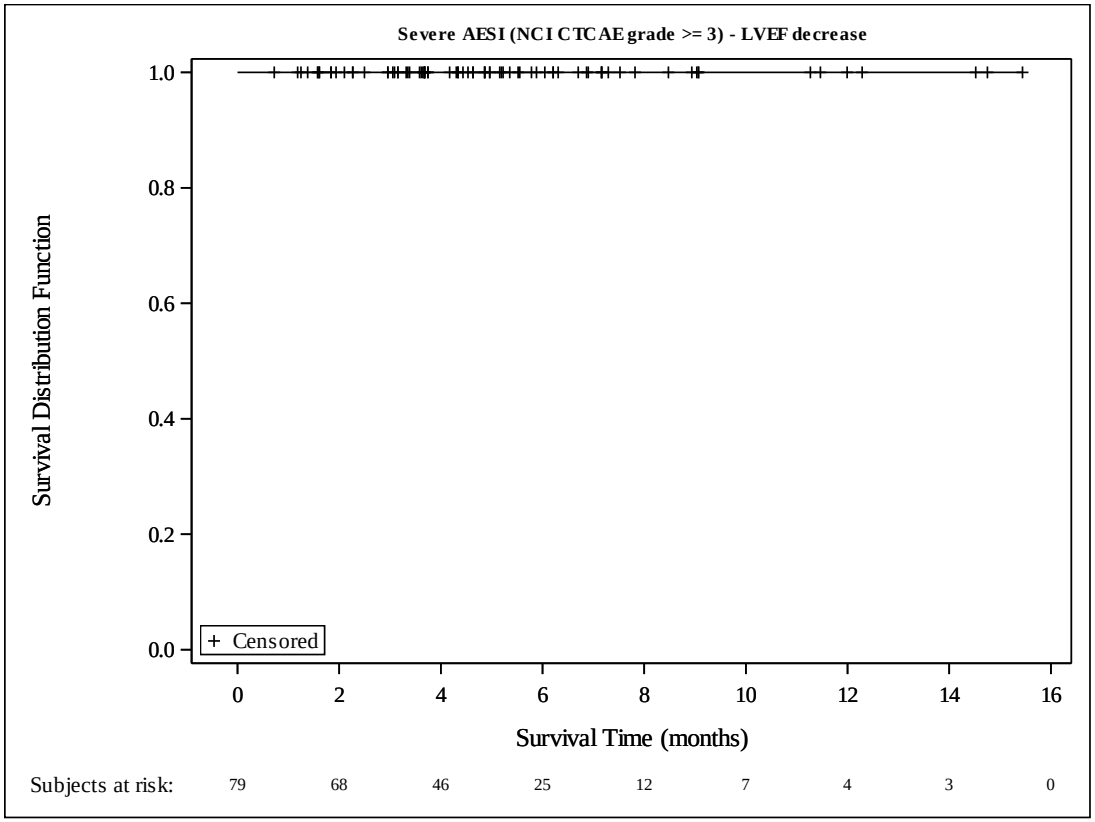
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	0/ 32 (0.0)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	0/ 14 (0.0)	NE (NE , NE)
Race		
White	0/ 69 (0.0)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	0/ 70 (0.0)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	0/ 79 (0.0)	NE (NE , NE)
Region		
North America	0/ 34 (0.0)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	0/ 46 (0.0)	NE (NE , NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	0/ 75 (0.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	0/ 57 (0.0)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	0/ 50 (0.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	0/ 68 (0.0)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	0/ 52 (0.0)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	0/ 19 (0.0)	NE (NE , NE)
other	0/ 59 (0.0)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	0/ 74 (0.0)	NE (NE , NE)
Previous total gastrectomy		
no	0/ 79 (0.0)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	0/ 70 (0.0)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	0/ 73 (0.0)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	0/ 72 (0.0)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	0/ 50 (0.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

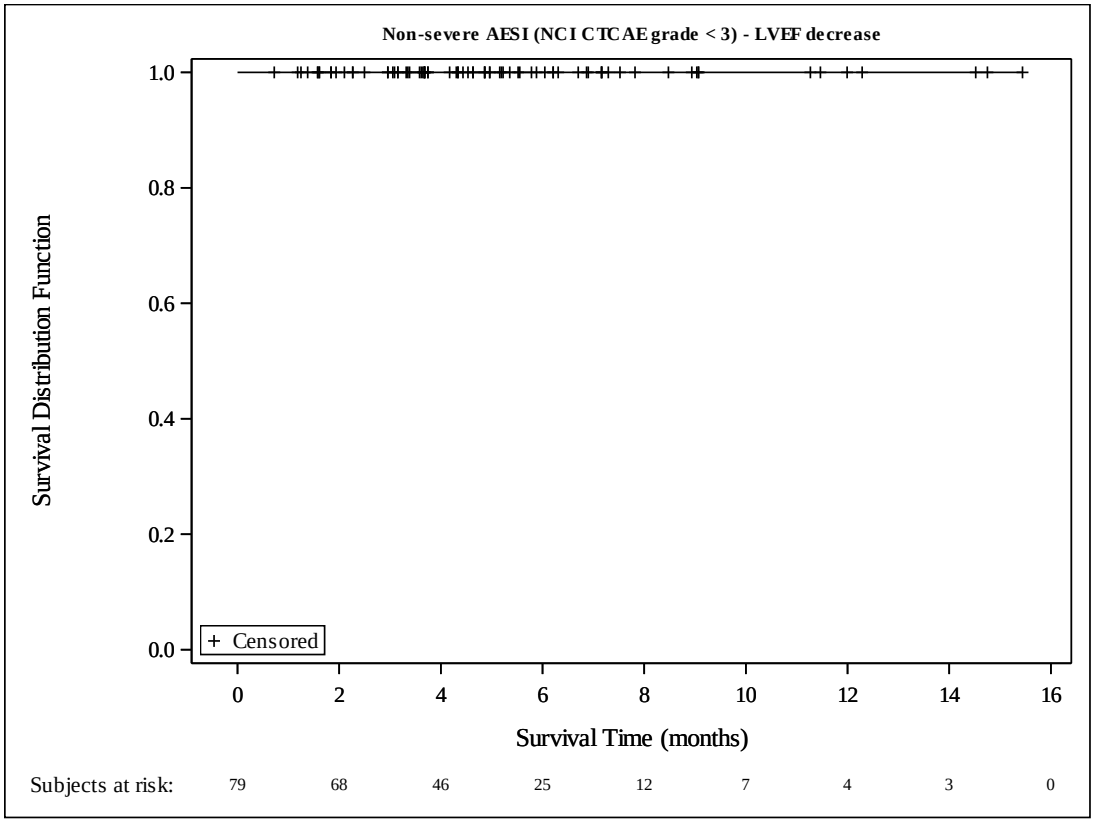
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	0/ 32 (0.0)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	0/ 14 (0.0)	NE (NE , NE)
Race		
White	0/ 69 (0.0)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	0/ 70 (0.0)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Blood and lymphatic system disorders	Overall	34/ 79 (43.0)	6.9 (5.1, NE)
	Region		
	North America	13/ 34 (38.2)	9.8 (6.9, NE)
	EU	21/ 45 (46.7)	5.1 (2.1, NE)
	Age (Category 1)		
	<65 years	20/ 46 (43.5)	6.9 (2.7, NE)
	>=65 years	14/ 33 (42.4)	6.9 (0.8, NE)
	Age (Category 2)		
	<75 years	32/ 75 (42.7)	6.9 (5.1, NE)
	>=75 years	2/ 4 (50.0)	NE (0.3, NE)
	Sex		
	female	15/ 22 (68.2)	1.4 (0.3, 6.9)
	male	19/ 57 (33.3)	9.8 (5.1, NE)
	ECOG PS		
	0	11/ 29 (37.9)	6.9 (6.0, 9.8)
	1	23/ 50 (46.0)	5.1 (1.4, NE)
	HER2 Status in central laboratory		
	IHC 3+	30/ 68 (44.1)	6.9 (5.1, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	17/ 27 (63.0)	2.2 (0.3, NE)
	GEJ	17/ 52 (32.7)	9.8 (6.0, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	6.9 (NE , NE)
	intestinal	10/ 19 (52.6)	5.1 (0.5, 9.8)
	other	23/ 59 (39.0)	6.9 (3.7, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.5, NE)
	>=2	33/ 74 (44.6)	6.9 (3.7, NE)
	Previous total gastrectomy		
	no	34/ 79 (43.0)	6.9 (5.1, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	3.7 (0.0, NE)
	no	29/ 70 (41.4)	6.9 (5.1, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (0.1, NE)
	no	32/ 73 (43.8)	6.9 (5.1, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.1, NE)
	no	32/ 72 (44.4)	6.9 (3.7, NE)
	Presence of liver metastasis at baseline		
	yes	22/ 50 (44.0)	6.9 (5.1, NE)
	no	12/ 29 (41.4)	NE (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders	Renal impairment at baseline		
	normal	11/ 32 (34.4)	9.8 (5.1, NE)
	mild	11/ 25 (44.0)	6.9 (1.4, NE)
	moderate	4/ 8 (50.0)	NE (0.4, NE)
	Hepatic impairment at baseline		
	normal	25/ 64 (39.1)	9.8 (5.1, NE)
	mild	8/ 14 (57.1)	5.1 (0.4, 6.9)
	Race		
	White	27/ 69 (39.1)	9.8 (5.1, NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	6/ 8 (75.0)	3.6 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	7.5 (5.1, 9.8)
	Non-Hispanic/Non-Latino	31/ 70 (44.3)	6.9 (2.7, NE)
	Unknown	1/ 4 (25.0)	NE (2.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Overall	27/ 79 (34.2)	9.8 (6.0, NE)
	Region		
	North America	10/ 34 (29.4)	9.8 (6.9, NE)
	EU	17/ 45 (37.8)	6.0 (5.1, NE)
	Age (Category 1)		
	<65 years	14/ 46 (30.4)	9.8 (6.0, NE)
	>=65 years	13/ 33 (39.4)	6.9 (3.7, NE)
	Age (Category 2)		
	<75 years	25/ 75 (33.3)	9.8 (6.0, NE)
	>=75 years	2/ 4 (50.0)	NE (0.3, NE)
	Sex		
	female	13/ 22 (59.1)	3.2 (0.3, NE)
	male	14/ 57 (24.6)	9.8 (6.0, NE)
	ECOG PS		
	0	9/ 29 (31.0)	9.8 (6.0, 9.8)
	1	18/ 50 (36.0)	NE (5.1, NE)
	HER2 Status in central laboratory		
	IHC 3+	23/ 68 (33.8)	9.8 (6.0, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	13/ 27 (48.1)	5.1 (0.5, NE)
	GEJ	14/ 52 (26.9)	9.8 (6.9, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	6.9 (NE , NE)
	intestinal	8/ 19 (42.1)	9.8 (0.7, 9.8)
	other	18/ 59 (30.5)	NE (6.0, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	27/ 74 (36.5)	6.9 (5.1, NE)
	Previous total gastrectomy		
	no	27/ 79 (34.2)	9.8 (6.0, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	NE (0.0, NE)
	no	23/ 70 (32.9)	9.8 (6.0, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.1, NE)
	no	26/ 73 (35.6)	9.8 (6.0, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.1, NE)
	no	26/ 72 (36.1)	9.8 (6.0, NE)
	Presence of liver metastasis at baseline		
	yes	18/ 50 (36.0)	6.9 (5.1, NE)
	no	9/ 29 (31.0)	NE (3.7, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Renal impairment at baseline		
	normal	9/ 32 (28.1)	9.8 (5.1, NE)
	mild	10/ 25 (40.0)	6.9 (1.4, NE)
	moderate	3/ 8 (37.5)	NE (0.7, NE)
	Hepatic impairment at baseline		
	normal	19/ 64 (29.7)	9.8 (6.9, NE)
	mild	7/ 14 (50.0)	6.0 (0.5, NE)
	Race		
	White	22/ 69 (31.9)	9.8 (6.0, NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	4/ 8 (50.0)	5.1 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	7.5 (5.1, 9.8)
	Non-Hispanic/Non-Latino	24/ 70 (34.3)	NE (6.0, NE)
	Unknown	1/ 4 (25.0)	NE (2.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	3/ 34 (8.8)	NE (NE , NE)
	EU	5/ 45 (11.1)	NE (NE , NE)
	Age (Category 1)		
	<65 years	6/ 46 (13.0)	NE (NE , NE)
	>=65 years	2/ 33 (6.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	5/ 22 (22.7)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	6/ 50 (12.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	8/ 68 (11.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.5, NE)
	>=2	7/ 74 (9.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.5, NE)
	no	6/ 70 (8.6)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (0.5, NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.5, NE)
	no	6/ 72 (8.3)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (NE , NE)
	no	4/ 29 (13.8)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders	Overall	73/ 79 (92.4)	0.2 (0.1, 0.2)
	Region		
	North America	32/ 34 (94.1)	0.2 (0.1, 0.3)
	EU	41/ 45 (91.1)	0.1 (0.1, 0.2)
	Age (Category 1)		
	<65 years	43/ 46 (93.5)	0.1 (0.1, 0.3)
	>=65 years	30/ 33 (90.9)	0.2 (0.1, 0.2)
	Age (Category 2)		
	<75 years	69/ 75 (92.0)	0.1 (0.1, 0.2)
	>=75 years	4/ 4 (100.0)	0.8 (0.1, 1.9)
	Sex		
	female	20/ 22 (90.9)	0.1 (0.1, 1.9)
	male	53/ 57 (93.0)	0.2 (0.1, 0.2)
	ECOG PS		
	0	24/ 29 (82.8)	0.2 (0.1, 0.7)
	1	49/ 50 (98.0)	0.1 (0.1, 0.2)
	HER2 Status in central laboratory		
	IHC 3+	62/ 68 (91.2)	0.1 (0.1, 0.3)
	IHC 2+/ISH +	10/ 10 (100.0)	0.2 (0.0, 0.2)
	Primary tumor location		
	Gastric	26/ 27 (96.3)	0.1 (0.1, 0.2)
	GEJ	47/ 52 (90.4)	0.2 (0.1, 0.3)
	Histological subtype		
	diffuse	1/ 1 (100.0)	0.5 (NE , NE)
	intestinal	18/ 19 (94.7)	0.2 (0.1, 0.7)
	other	54/ 59 (91.5)	0.1 (0.1, 0.2)
	Number of metastatic sites		
	<2	5/ 5 (100.0)	0.2 (0.1, 2.8)
	>=2	68/ 74 (91.9)	0.1 (0.1, 0.2)
	Previous total gastrectomy		
	no	73/ 79 (92.4)	0.2 (0.1, 0.2)
	Prior adjuvant/ neoadjuvant therapy		
	yes	9/ 9 (100.0)	0.2 (0.1, 1.4)
	no	64/ 70 (91.4)	0.1 (0.1, 0.2)
	Prior nivolumab or pembrolizumab treatment		
	yes	6/ 6 (100.0)	0.1 (0.0, 2.8)
	no	67/ 73 (91.8)	0.2 (0.1, 0.2)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	7/ 7 (100.0)	0.1 (0.0, 0.3)
	no	66/ 72 (91.7)	0.2 (0.1, 0.2)
	Presence of liver metastasis at baseline		
	yes	47/ 50 (94.0)	0.2 (0.1, 0.3)
	no	26/ 29 (89.7)	0.1 (0.1, 0.5)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Renal impairment at baseline		
	normal	30/ 32 (93.8)	0.1 (0.1, 0.4)
	mild	22/ 25 (88.0)	0.2 (0.1, 0.2)
	moderate	8/ 8 (100.0)	0.2 (0.1, 2.8)
	Hepatic impairment at baseline		
	normal	58/ 64 (90.6)	0.2 (0.1, 0.3)
	mild	14/ 14 (100.0)	0.1 (0.0, 0.2)
	Race		
	White	64/ 69 (92.8)	0.2 (0.1, 0.2)
	Black or African American	1/ 1 (100.0)	0.1 (NE , NE)
	Other	7/ 8 (87.5)	0.2 (0.0, 2.8)
	Ethnicity		
	Hispanic/Latino	5/ 5 (100.0)	0.2 (0.1, 2.8)
	Non-Hispanic/Non-Latino	66/ 70 (94.3)	0.1 (0.1, 0.2)
	Unknown	2/ 4 (50.0)	NE (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Abdominal pain	Overall	13/ 79 (16.5)	NE (NE , NE)
	Region		
	North America	6/ 34 (17.6)	NE (NE , NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	8/ 46 (17.4)	NE (NE , NE)
	>=65 years	5/ 33 (15.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	13/ 75 (17.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	5/ 22 (22.7)	NE (4.8, NE)
	male	8/ 57 (14.0)	NE (NE , NE)
	ECOG PS		
	0	5/ 29 (17.2)	NE (NE , NE)
	1	8/ 50 (16.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	11/ 68 (16.2)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.7, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	10/ 52 (19.2)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	4/ 19 (21.1)	NE (4.8, NE)
	other	9/ 59 (15.3)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	13/ 74 (17.6)	NE (NE , NE)
	Previous total gastrectomy		
	no	13/ 79 (16.5)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (2.8, NE)
	no	12/ 70 (17.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.8, NE)
	no	12/ 73 (16.4)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.8, NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	7/ 50 (14.0)	NE (NE , NE)
	no	6/ 29 (20.7)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Abdominal pain	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (2.8, NE)
	Hepatic impairment at baseline		
	normal	12/ 64 (18.8)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	11/ 69 (15.9)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (0.7, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.2, NE)
	Non-Hispanic/Non-Latino	12/ 70 (17.1)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Constipation	Overall	21/ 79 (26.6)	9.4 (9.4, NE)
	Region		
	North America	13/ 34 (38.2)	NE (1.4, NE)
	EU	8/ 45 (17.8)	9.4 (NE , NE)
	Age (Category 1)		
	<65 years	11/ 46 (23.9)	9.4 (9.4, NE)
	>=65 years	10/ 33 (30.3)	NE (3.5, NE)
	Age (Category 2)		
	<75 years	20/ 75 (26.7)	9.4 (9.4, NE)
	>=75 years	1/ 4 (25.0)	NE (1.7, NE)
	Sex		
	female	5/ 22 (22.7)	NE (NE , NE)
	male	16/ 57 (28.1)	9.4 (9.4, NE)
	ECOG PS		
	0	9/ 29 (31.0)	9.4 (9.4, NE)
	1	12/ 50 (24.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	17/ 68 (25.0)	9.4 (9.4, NE)
	IHC 2+/ISH +	4/ 10 (40.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	7/ 27 (25.9)	NE (2.8, NE)
	GEJ	14/ 52 (26.9)	9.4 (9.4, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	4/ 19 (21.1)	9.4 (NE , NE)
	other	17/ 59 (28.8)	NE (NE , NE)
	Number of metastatic sites		
	<2	3/ 5 (60.0)	2.8 (0.2, NE)
	>=2	18/ 74 (24.3)	9.4 (9.4, NE)
	Previous total gastrectomy		
	no	21/ 79 (26.6)	9.4 (9.4, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	9.4 (0.2, 9.4)
	no	17/ 70 (24.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	4/ 6 (66.7)	0.3 (0.1, NE)
	no	17/ 73 (23.3)	NE (9.4, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	5/ 7 (71.4)	0.3 (0.1, NE)
	no	16/ 72 (22.2)	NE (9.4, NE)
	Presence of liver metastasis at baseline		
	yes	14/ 50 (28.0)	9.4 (9.4, NE)
	no	7/ 29 (24.1)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Constipation	Renal impairment at baseline		
	normal	11/ 32 (34.4)	NE (1.6, NE)
	mild	8/ 25 (32.0)	9.4 (2.3, NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	15/ 64 (23.4)	9.4 (9.4, NE)
	mild	5/ 14 (35.7)	NE (0.6, NE)
	Race		
	White	21/ 69 (30.4)	9.4 (9.4, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	3/ 5 (60.0)	1.7 (0.1, NE)
	Non-Hispanic/Non-Latino	18/ 70 (25.7)	9.4 (9.4, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Diarrhoea	Overall	28/ 79 (35.4)	11.9 (6.6, NE)
	Region		
	North America	8/ 34 (23.5)	11.9 (6.6, NE)
	EU	20/ 45 (44.4)	NE (0.8, NE)
	Age (Category 1)		
	<65 years	16/ 46 (34.8)	NE (6.6, NE)
	>=65 years	12/ 33 (36.4)	11.9 (1.9, 11.9)
	Age (Category 2)		
	<75 years	24/ 75 (32.0)	11.9 (8.4, NE)
	>=75 years	4/ 4 (100.0)	1.3 (0.3, 1.9)
	Sex		
	female	11/ 22 (50.0)	6.6 (0.2, 11.9)
	male	17/ 57 (29.8)	NE (8.4, NE)
	ECOG PS		
	0	10/ 29 (34.5)	8.4 (6.6, NE)
	1	18/ 50 (36.0)	11.9 (1.9, NE)
	HER2 Status in central laboratory		
	IHC 3+	27/ 68 (39.7)	8.4 (6.6, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (0.1, NE)
	Primary tumor location		
	Gastric	12/ 27 (44.4)	11.9 (0.3, 11.9)
	GEJ	16/ 52 (30.8)	8.4 (6.6, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	6.6 (NE , NE)
	intestinal	9/ 19 (47.4)	NE (0.3, NE)
	other	18/ 59 (30.5)	11.9 (8.4, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	28/ 74 (37.8)	11.9 (6.6, NE)
	Previous total gastrectomy		
	no	28/ 79 (35.4)	11.9 (6.6, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	3/ 9 (33.3)	NE (0.1, NE)
	no	25/ 70 (35.7)	11.9 (6.6, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	11.9 (NE , NE)
	no	27/ 73 (37.0)	8.4 (6.6, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	11.9 (NE , NE)
	no	27/ 72 (37.5)	8.4 (6.6, NE)
	Presence of liver metastasis at baseline		
	yes	18/ 50 (36.0)	NE (6.6, NE)
	no	10/ 29 (34.5)	11.9 (8.4, 11.9)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Diarrhoea	Renal impairment at baseline		
	normal	8/ 32 (25.0)	NE (NE , NE)
	mild	10/ 25 (40.0)	11.9 (1.4, 11.9)
	moderate	2/ 8 (25.0)	NE (0.1, NE)
	Hepatic impairment at baseline		
	normal	23/ 64 (35.9)	11.9 (8.4, NE)
	mild	5/ 14 (35.7)	6.6 (0.3, NE)
	Race		
	White	25/ 69 (36.2)	8.4 (6.6, NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.1, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.6, NE)
	Non-Hispanic/Non-Latino	25/ 70 (35.7)	11.9 (6.6, NE)
	Unknown	1/ 4 (25.0)	NE (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	7/ 57 (12.3)	NE (NE , NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	5/ 50 (10.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	8/ 68 (11.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (NE , NE)
	GEJ	7/ 52 (13.5)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.8, NE)
	>=2	7/ 74 (9.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.8, NE)
	no	7/ 73 (9.6)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.8, NE)
	no	7/ 72 (9.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	5/ 50 (10.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (2.9, NE)
	Hepatic impairment at baseline		
	normal	6/ 64 (9.4)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (4.3, NE)
	Race		
	White	8/ 69 (11.6)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Overall	52/ 79 (65.8)	0.4 (0.2, 1.4)
	Region		
	North America	22/ 34 (64.7)	0.3 (0.1, 5.7)
	EU	30/ 45 (66.7)	0.5 (0.1, 3.5)
	Age (Category 1)		
	<65 years	37/ 46 (80.4)	0.2 (0.1, 0.5)
	>=65 years	15/ 33 (45.5)	NE (0.2, NE)
	Age (Category 2)		
	<75 years	52/ 75 (69.3)	0.3 (0.2, 0.8)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	13/ 22 (59.1)	2.0 (0.1, NE)
	male	39/ 57 (68.4)	0.3 (0.2, 0.9)
	ECOG PS		
	0	19/ 29 (65.5)	0.9 (0.1, 5.7)
	1	33/ 50 (66.0)	0.3 (0.1, 0.8)
	HER2 Status in central laboratory		
	IHC 3+	44/ 68 (64.7)	0.5 (0.1, 3.5)
	IHC 2+/ISH +	7/ 10 (70.0)	0.2 (0.0, NE)
	Primary tumor location		
	Gastric	18/ 27 (66.7)	0.2 (0.1, NE)
	GEJ	34/ 52 (65.4)	0.7 (0.2, 4.5)
	Histological subtype		
	diffuse	1/ 1 (100.0)	5.7 (NE , NE)
	intestinal	12/ 19 (63.2)	0.3 (0.1, NE)
	other	39/ 59 (66.1)	0.4 (0.2, 1.4)
	Number of metastatic sites		
	<2	4/ 5 (80.0)	0.2 (0.1, NE)
	>=2	48/ 74 (64.9)	0.4 (0.2, 1.6)
	Previous total gastrectomy		
	no	52/ 79 (65.8)	0.4 (0.2, 1.4)
	Prior adjuvant/ neoadjuvant therapy		
	yes	7/ 9 (77.8)	0.2 (0.1, NE)
	no	45/ 70 (64.3)	0.4 (0.2, 1.6)
	Prior nivolumab or pembrolizumab treatment		
	yes	5/ 6 (83.3)	0.1 (0.0, NE)
	no	47/ 73 (64.4)	0.5 (0.2, 3.5)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	6/ 7 (85.7)	0.2 (0.0, 0.5)
	no	46/ 72 (63.9)	0.5 (0.2, 3.5)
	Presence of liver metastasis at baseline		
	yes	34/ 50 (68.0)	0.5 (0.2, 3.5)
	no	18/ 29 (62.1)	0.3 (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Renal impairment at baseline		
	normal	22/ 32 (68.8)	0.4 (0.1, 1.6)
	mild	17/ 25 (68.0)	0.3 (0.1, 5.7)
	moderate	5/ 8 (62.5)	1.9 (0.1, NE)
	Hepatic impairment at baseline		
	normal	40/ 64 (62.5)	0.6 (0.2, 3.5)
	mild	12/ 14 (85.7)	0.1 (0.1, 0.5)
	Race		
	White	45/ 69 (65.2)	0.5 (0.2, 1.6)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	6/ 8 (75.0)	0.2 (0.0, NE)
	Ethnicity		
	Hispanic/Latino	3/ 5 (60.0)	0.5 (0.1, NE)
	Non-Hispanic/Non-Latino	47/ 70 (67.1)	0.4 (0.2, 1.4)
	Unknown	2/ 4 (50.0)	NE (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Vomiting	Overall	33/ 79 (41.8)	NE (2.8, NE)
	Region		
	North America	12/ 34 (35.3)	NE (1.9, NE)
	EU	21/ 45 (46.7)	NE (1.6, NE)
	Age (Category 1)		
	<65 years	21/ 46 (45.7)	5.0 (0.8, NE)
	>=65 years	12/ 33 (36.4)	NE (1.9, NE)
	Age (Category 2)		
	<75 years	32/ 75 (42.7)	NE (2.1, NE)
	>=75 years	1/ 4 (25.0)	NE (0.2, NE)
	Sex		
	female	9/ 22 (40.9)	NE (0.5, NE)
	male	24/ 57 (42.1)	NE (1.9, NE)
	ECOG PS		
	0	10/ 29 (34.5)	NE (2.1, NE)
	1	23/ 50 (46.0)	5.0 (1.4, NE)
	HER2 Status in central laboratory		
	IHC 3+	29/ 68 (42.6)	NE (2.1, NE)
	IHC 2+/ISH +	4/ 10 (40.0)	NE (0.0, NE)
	Primary tumor location		
	Gastric	13/ 27 (48.1)	5.0 (0.3, NE)
	GEJ	20/ 52 (38.5)	NE (1.9, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	9/ 19 (47.4)	NE (0.5, NE)
	other	24/ 59 (40.7)	NE (1.9, NE)
	Number of metastatic sites		
	<2	3/ 5 (60.0)	1.9 (0.1, NE)
	>=2	30/ 74 (40.5)	NE (2.8, NE)
	Previous total gastrectomy		
	no	33/ 79 (41.8)	NE (2.8, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	3/ 9 (33.3)	NE (0.1, NE)
	no	30/ 70 (42.9)	NE (1.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	3/ 6 (50.0)	1.9 (0.1, NE)
	no	30/ 73 (41.1)	NE (2.8, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	NE (0.1, NE)
	no	30/ 72 (41.7)	NE (2.8, NE)
	Presence of liver metastasis at baseline		
	yes	16/ 50 (32.0)	NE (NE , NE)
	no	17/ 29 (58.6)	3.1 (0.3, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Vomiting	Renal impairment at baseline		
	normal	13/ 32 (40.6)	NE (0.8, NE)
	mild	8/ 25 (32.0)	NE (1.4, NE)
	moderate	4/ 8 (50.0)	3.6 (0.3, NE)
	Hepatic impairment at baseline		
	normal	30/ 64 (46.9)	5.0 (1.6, NE)
	mild	2/ 14 (14.3)	NE (NE , NE)
	Race		
	White	29/ 69 (42.0)	NE (2.8, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.1, NE)
	Ethnicity		
	Hispanic/Latino	4/ 5 (80.0)	0.8 (0.2, NE)
	Non-Hispanic/Non-Latino	27/ 70 (38.6)	NE (3.1, NE)
	Unknown	2/ 4 (50.0)	NE (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: General disorders and administration site conditions	Overall	55/ 79 (69.6)	0.7 (0.3, 1.9)
	Region		
	North America	23/ 34 (67.6)	0.7 (0.1, 5.0)
	EU	32/ 45 (71.1)	0.5 (0.3, 1.9)
	Age (Category 1)		
	<65 years	30/ 46 (65.2)	1.7 (0.5, 4.3)
	>=65 years	25/ 33 (75.8)	0.3 (0.1, 0.7)
	Age (Category 2)		
	<75 years	51/ 75 (68.0)	0.7 (0.3, 1.9)
	>=75 years	4/ 4 (100.0)	0.2 (0.2, 3.7)
	Sex		
	female	20/ 22 (90.9)	0.3 (0.1, 1.4)
	male	35/ 57 (61.4)	0.8 (0.3, 4.3)
	ECOG PS		
	0	20/ 29 (69.0)	0.7 (0.1, 3.1)
	1	35/ 50 (70.0)	0.7 (0.3, 3.7)
	HER2 Status in central laboratory		
	IHC 3+	48/ 68 (70.6)	0.7 (0.3, 1.9)
	IHC 2+/ISH +	6/ 10 (60.0)	0.7 (0.0, NE)
	Primary tumor location		
	Gastric	23/ 27 (85.2)	0.4 (0.1, 0.8)
	GEJ	32/ 52 (61.5)	1.4 (0.3, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	18/ 19 (94.7)	0.5 (0.1, 1.5)
	other	37/ 59 (62.7)	0.7 (0.3, 5.0)
	Number of metastatic sites		
	<2	4/ 5 (80.0)	0.8 (0.0, NE)
	>=2	51/ 74 (68.9)	0.7 (0.3, 1.9)
	Previous total gastrectomy		
	no	55/ 79 (69.6)	0.7 (0.3, 1.9)
	Prior adjuvant/ neoadjuvant therapy		
	yes	9/ 9 (100.0)	0.2 (0.0, 4.1)
	no	46/ 70 (65.7)	0.7 (0.3, 1.9)
	Prior nivolumab or pembrolizumab treatment		
	yes	6/ 6 (100.0)	0.1 (0.0, 1.5)
	no	49/ 73 (67.1)	0.7 (0.3, 3.5)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	6/ 7 (85.7)	0.1 (0.0, 1.5)
	no	49/ 72 (68.1)	0.7 (0.3, 3.1)
	Presence of liver metastasis at baseline		
	yes	31/ 50 (62.0)	1.5 (0.3, 3.7)
	no	24/ 29 (82.8)	0.5 (0.1, 0.8)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions	Renal impairment at baseline		
	normal	21/ 32 (65.6)	1.1 (0.3, NE)
	mild	19/ 25 (76.0)	0.3 (0.1, 0.7)
	moderate	7/ 8 (87.5)	1.0 (0.1, 4.3)
	Hepatic impairment at baseline		
	normal	44/ 64 (68.8)	0.7 (0.3, 3.1)
	mild	10/ 14 (71.4)	1.7 (0.1, NE)
	Race		
	White	49/ 69 (71.0)	0.6 (0.3, 1.9)
	Black or African American	1/ 1 (100.0)	0.2 (NE , NE)
	Other	5/ 8 (62.5)	3.2 (0.0, NE)
	Ethnicity		
	Hispanic/Latino	3/ 5 (60.0)	4.3 (0.1, NE)
	Non-Hispanic/Non-Latino	49/ 70 (70.0)	0.7 (0.3, 1.5)
	Unknown	3/ 4 (75.0)	2.5 (0.0, 5.0)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Asthenia	Overall	12/ 79 (15.2)	NE (NE , NE)
	Region		
	North America	0/ 34 (0.0)	NE (NE , NE)
	EU	12/ 45 (26.7)	NE (5.7, NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	7/ 33 (21.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	11/ 75 (14.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (3.7, NE)
	Sex		
	female	6/ 22 (27.3)	NE (5.7, NE)
	male	6/ 57 (10.5)	NE (NE , NE)
	ECOG PS		
	0	5/ 29 (17.2)	NE (NE , NE)
	1	7/ 50 (14.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	12/ 68 (17.6)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (5.7, NE)
	GEJ	7/ 52 (13.5)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	5/ 19 (26.3)	NE (3.7, NE)
	other	7/ 59 (11.9)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	12/ 74 (16.2)	NE (NE , NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.1, NE)
	no	10/ 70 (14.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	12/ 73 (16.4)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	8/ 50 (16.0)	NE (NE , NE)
	no	4/ 29 (13.8)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Asthenia	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	3/ 8 (37.5)	NE (0.1, NE)
	Hepatic impairment at baseline		
	normal	10/ 64 (15.6)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	12/ 69 (17.4)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	12/ 70 (17.1)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Fatigue	Overall	32/ 79 (40.5)	NE (1.9, NE)
	Region		
	North America	17/ 34 (50.0)	4.1 (0.1, NE)
	EU	15/ 45 (33.3)	NE (NE , NE)
	Age (Category 1)		
	<65 years	17/ 46 (37.0)	NE (1.9, NE)
	>=65 years	15/ 33 (45.5)	NE (0.2, NE)
	Age (Category 2)		
	<75 years	30/ 75 (40.0)	NE (1.9, NE)
	>=75 years	2/ 4 (50.0)	NE (0.2, NE)
	Sex		
	female	11/ 22 (50.0)	4.1 (0.1, NE)
	male	21/ 57 (36.8)	NE (1.9, NE)
	ECOG PS		
	0	13/ 29 (44.8)	NE (0.2, NE)
	1	19/ 50 (38.0)	NE (1.9, NE)
	HER2 Status in central laboratory		
	IHC 3+	27/ 68 (39.7)	NE (1.9, NE)
	IHC 2+/ISH +	4/ 10 (40.0)	NE (0.0, NE)
	Primary tumor location		
	Gastric	12/ 27 (44.4)	NE (0.3, NE)
	GEJ	20/ 52 (38.5)	NE (1.5, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	9/ 19 (47.4)	NE (0.1, NE)
	other	23/ 59 (39.0)	NE (1.9, NE)
	Number of metastatic sites		
	<2	4/ 5 (80.0)	0.8 (0.0, NE)
	>=2	28/ 74 (37.8)	NE (1.9, NE)
	Previous total gastrectomy		
	no	32/ 79 (40.5)	NE (1.9, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	6/ 9 (66.7)	0.8 (0.0, NE)
	no	26/ 70 (37.1)	NE (1.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	6/ 6 (100.0)	0.1 (0.0, 1.5)
	no	26/ 73 (35.6)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	6/ 7 (85.7)	0.1 (0.0, 1.5)
	no	26/ 72 (36.1)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	17/ 50 (34.0)	NE (NE , NE)
	no	15/ 29 (51.7)	4.1 (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Fatigue	Renal impairment at baseline		
	normal	12/ 32 (37.5)	NE (0.8, NE)
	mild	13/ 25 (52.0)	0.3 (0.1, NE)
	moderate	3/ 8 (37.5)	NE (0.1, NE)
	Hepatic impairment at baseline		
	normal	27/ 64 (42.2)	NE (0.8, NE)
	mild	5/ 14 (35.7)	NE (0.1, NE)
	Race		
	White	30/ 69 (43.5)	NE (0.8, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (0.0, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.1, NE)
	Non-Hispanic/Non-Latino	28/ 70 (40.0)	NE (1.9, NE)
	Unknown	2/ 4 (50.0)	NE (0.0, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Pyrexia	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	6/ 45 (13.3)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	4/ 22 (18.2)	NE (5.8, NE)
	male	4/ 57 (7.0)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	8/ 50 (16.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	6/ 68 (8.8)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.5, NE)
	Primary tumor location		
	Gastric	7/ 27 (25.9)	NE (5.8, NE)
	GEJ	1/ 52 (1.9)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	5/ 19 (26.3)	NE (4.7, NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	8/ 74 (10.8)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	8/ 73 (11.0)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	8/ 72 (11.1)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	3/ 50 (6.0)	NE (NE , NE)
	no	5/ 29 (17.2)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Pyrexia	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (4.7, NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	6/ 69 (8.7)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (0.0, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Infections and infestations	Overall	19/ 79 (24.1)	NE (7.3, NE)
	Region		
	North America	8/ 34 (23.5)	NE (6.0, NE)
	EU	11/ 45 (24.4)	NE (6.6, NE)
	Age (Category 1)		
	<65 years	8/ 46 (17.4)	NE (7.3, NE)
	>=65 years	11/ 33 (33.3)	NE (4.2, NE)
	Age (Category 2)		
	<75 years	17/ 75 (22.7)	NE (7.3, NE)
	>=75 years	2/ 4 (50.0)	NE (2.1, NE)
	Sex		
	female	5/ 22 (22.7)	NE (7.3, NE)
	male	14/ 57 (24.6)	NE (6.6, NE)
	ECOG PS		
	0	6/ 29 (20.7)	NE (7.3, NE)
	1	13/ 50 (26.0)	NE (6.0, NE)
	HER2 Status in central laboratory		
	IHC 3+	17/ 68 (25.0)	NE (7.3, NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	8/ 27 (29.6)	NE (4.2, NE)
	GEJ	11/ 52 (21.2)	NE (7.3, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	7.3 (NE , NE)
	intestinal	3/ 19 (15.8)	NE (6.6, NE)
	other	15/ 59 (25.4)	NE (6.0, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	19/ 74 (25.7)	NE (6.6, NE)
	Previous total gastrectomy		
	no	19/ 79 (24.1)	NE (7.3, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.9, NE)
	no	18/ 70 (25.7)	NE (6.6, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.1, NE)
	no	18/ 73 (24.7)	NE (7.3, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.1, NE)
	no	18/ 72 (25.0)	NE (7.3, NE)
	Presence of liver metastasis at baseline		
	yes	15/ 50 (30.0)	7.3 (6.0, NE)
	no	4/ 29 (13.8)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Infections and infestations	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	8/ 25 (32.0)	7.3 (6.6, NE)
	moderate	1/ 8 (12.5)	NE (6.0, NE)
	Hepatic impairment at baseline		
	normal	11/ 64 (17.2)	NE (NE , NE)
	mild	8/ 14 (57.1)	4.2 (1.2, 7.3)
	Race		
	White	16/ 69 (23.2)	NE (7.3, NE)
	Black or African American	1/ 1 (100.0)	4.2 (NE , NE)
	Other	1/ 8 (12.5)	NE (0.4, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (2.1, NE)
	Non-Hispanic/Non-Latino	17/ 70 (24.3)	NE (7.3, NE)
	Unknown	1/ 4 (25.0)	NE (3.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Investigations	Overall	50/ 79 (63.3)	2.9 (2.1, 4.5)
	Region		
	North America	20/ 34 (58.8)	2.8 (0.8, 13.9)
	EU	30/ 45 (66.7)	3.2 (2.1, 5.1)
	Age (Category 1)		
	<65 years	27/ 46 (58.7)	3.2 (1.6, 5.5)
	>=65 years	23/ 33 (69.7)	2.6 (1.4, 5.5)
	Age (Category 2)		
	<75 years	46/ 75 (61.3)	2.9 (2.1, 4.5)
	>=75 years	4/ 4 (100.0)	2.5 (0.3, 8.5)
	Sex		
	female	16/ 22 (72.7)	3.5 (1.6, 5.1)
	male	34/ 57 (59.6)	2.9 (1.4, 8.5)
	ECOG PS		
	0	15/ 29 (51.7)	4.5 (2.1, NE)
	1	35/ 50 (70.0)	2.8 (0.8, 3.5)
	HER2 Status in central laboratory		
	IHC 3+	44/ 68 (64.7)	3.0 (2.1, 4.5)
	IHC 2+/ISH +	5/ 10 (50.0)	2.6 (0.3, NE)
	Primary tumor location		
	Gastric	19/ 27 (70.4)	3.2 (0.8, 5.1)
	GEJ	31/ 52 (59.6)	2.9 (2.0, 8.5)
	Histological subtype		
	diffuse	1/ 1 (100.0)	1.6 (NE , NE)
	intestinal	13/ 19 (68.4)	3.0 (0.3, 5.5)
	other	36/ 59 (61.0)	2.9 (2.1, 5.1)
	Number of metastatic sites		
	<2	3/ 5 (60.0)	2.6 (0.3, NE)
	>=2	47/ 74 (63.5)	3.0 (2.0, 4.5)
	Previous total gastrectomy		
	no	50/ 79 (63.3)	2.9 (2.1, 4.5)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	8.5 (0.3, NE)
	no	45/ 70 (64.3)	2.8 (1.6, 3.7)
	Prior nivolumab or pembrolizumab treatment		
	yes	4/ 6 (66.7)	2.6 (0.5, NE)
	no	46/ 73 (63.0)	3.0 (2.0, 5.1)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	5/ 7 (71.4)	2.6 (0.3, NE)
	no	45/ 72 (62.5)	3.2 (2.0, 5.1)
	Presence of liver metastasis at baseline		
	yes	29/ 50 (58.0)	2.9 (1.4, 13.9)
	no	21/ 29 (72.4)	3.2 (2.2, 5.1)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations	Renal impairment at baseline		
	normal	17/ 32 (53.1)	2.3 (0.5, NE)
	mild	16/ 25 (64.0)	2.8 (0.8, 8.5)
	moderate	7/ 8 (87.5)	4.0 (0.3, 13.9)
	Hepatic impairment at baseline		
	normal	40/ 64 (62.5)	3.2 (2.3, 5.1)
	mild	9/ 14 (64.3)	0.7 (0.3, NE)
	Race		
	White	44/ 69 (63.8)	2.9 (2.1, 4.5)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	5/ 8 (62.5)	2.2 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	4/ 5 (80.0)	3.2 (0.3, NE)
	Non-Hispanic/Non-Latino	44/ 70 (62.9)	2.9 (2.0, 4.5)
	Unknown	2/ 4 (50.0)	NE (0.3, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Investigations, PT: Aspartate aminotransferase increased	Overall	10/ 79 (12.7)	13.9 (11.1, NE)
	Region		
	North America	5/ 34 (14.7)	13.9 (11.1, NE)
	EU	5/ 45 (11.1)	NE (NE , NE)
	Age (Category 1)		
	<65 years	6/ 46 (13.0)	NE (6.9, NE)
	>=65 years	4/ 33 (12.1)	13.9 (13.9, NE)
	Age (Category 2)		
	<75 years	10/ 75 (13.3)	13.9 (11.1, NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	3/ 22 (13.6)	NE (6.9, NE)
	male	7/ 57 (12.3)	13.9 (11.1, 13.9)
	ECOG PS		
	0	5/ 29 (17.2)	NE (6.9, NE)
	1	5/ 50 (10.0)	13.9 (11.1, NE)
	HER2 Status in central laboratory		
	IHC 3+	8/ 68 (11.8)	13.9 (11.1, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.6, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	7/ 52 (13.5)	13.9 (11.1, 13.9)
	Histological subtype		
	diffuse	1/ 1 (100.0)	6.9 (NE , NE)
	intestinal	2/ 19 (10.5)	NE (5.5, NE)
	other	7/ 59 (11.9)	13.9 (11.1, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	10/ 74 (13.5)	13.9 (11.1, NE)
	Previous total gastrectomy		
	no	10/ 79 (12.7)	13.9 (11.1, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	10/ 70 (14.3)	13.9 (11.1, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	10/ 73 (13.7)	13.9 (11.1, 13.9)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	10/ 72 (13.9)	13.9 (11.1, 13.9)
	Presence of liver metastasis at baseline		
	yes	9/ 50 (18.0)	13.9 (6.9, 13.9)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Aspartate aminotransferase increased	Renal impairment at baseline		
	normal	3/ 32 (9.4)	11.1 (6.0, NE)
	mild	3/ 25 (12.0)	NE (6.9, NE)
	moderate	2/ 8 (25.0)	13.9 (1.4, 13.9)
	Hepatic impairment at baseline		
	normal	8/ 64 (12.5)	13.9 (11.1, NE)
	mild	2/ 14 (14.3)	6.9 (6.0, NE)
	Race		
	White	9/ 69 (13.0)	13.9 (11.1, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (1.6, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	10/ 70 (14.3)	13.9 (11.1, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Investigations, PT: Neutrophil count decreased	Overall	12/ 79 (15.2)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (NE , NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (NE , NE)
	>=65 years	8/ 33 (24.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	11/ 75 (14.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (0.3, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	9/ 57 (15.8)	NE (NE , NE)
	ECOG PS		
	0	4/ 29 (13.8)	NE (NE , NE)
	1	8/ 50 (16.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	11/ 68 (16.2)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (0.7, NE)
	Primary tumor location		
	Gastric	6/ 27 (22.2)	NE (NE , NE)
	GEJ	6/ 52 (11.5)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	9/ 59 (15.3)	NE (NE , NE)
	Number of metastatic sites		
	<2	2/ 5 (40.0)	NE (0.7, NE)
	>=2	10/ 74 (13.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.5, NE)
	no	11/ 70 (15.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.1, NE)
	no	11/ 73 (15.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.5, NE)
	no	10/ 72 (13.9)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	8/ 50 (16.0)	NE (NE , NE)
	no	4/ 29 (13.8)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Neutrophil count decreased	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (4.7, NE)
	mild	4/ 25 (16.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (0.5, NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	6/ 14 (42.9)	4.7 (0.5, NE)
	Race		
	White	9/ 69 (13.0)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	10/ 70 (14.3)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Platelet count decreased	Overall	14/ 79 (17.7)	NE (NE , NE)
	Region		
	North America	7/ 34 (20.6)	NE (7.6, NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	7/ 46 (15.2)	NE (NE , NE)
	>=65 years	7/ 33 (21.2)	NE (7.6, NE)
	Age (Category 2)		
	<75 years	13/ 75 (17.3)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (0.3, NE)
	Sex		
	female	3/ 22 (13.6)	NE (7.6, NE)
	male	11/ 57 (19.3)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	12/ 50 (24.0)	NE (7.6, NE)
	HER2 Status in central laboratory		
	IHC 3+	13/ 68 (19.1)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (2.1, NE)
	Primary tumor location		
	Gastric	6/ 27 (22.2)	NE (7.6, NE)
	GEJ	8/ 52 (15.4)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	11/ 59 (18.6)	NE (7.6, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.1, NE)
	>=2	13/ 74 (17.6)	NE (NE , NE)
	Previous total gastrectomy		
	no	14/ 79 (17.7)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.3, NE)
	no	13/ 70 (18.6)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	7.6 (NE , NE)
	no	13/ 73 (17.8)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	7.6 (0.3, 7.6)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	NE (NE , NE)
	no	4/ 29 (13.8)	NE (7.6, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Platelet count decreased	Renal impairment at baseline		
	normal	7/ 32 (21.9)	NE (NE , NE)
	mild	4/ 25 (16.0)	NE (7.6, NE)
	moderate	1/ 8 (12.5)	NE (3.2, NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (NE , NE)
	mild	6/ 14 (42.9)	NE (0.3, NE)
	Race		
	White	11/ 69 (15.9)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.3, NE)
	Non-Hispanic/Non-Latino	11/ 70 (15.7)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (0.3, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Investigations, PT: Weight decreased	Overall	27/ 79 (34.2)	10.4 (4.9, NE)
	Region		
	North America	11/ 34 (32.4)	10.4 (3.0, NE)
	EU	16/ 45 (35.6)	NE (4.1, NE)
	Age (Category 1)		
	<65 years	17/ 46 (37.0)	10.4 (4.3, NE)
	>=65 years	10/ 33 (30.3)	NE (3.7, NE)
	Age (Category 2)		
	<75 years	24/ 75 (32.0)	10.4 (5.1, NE)
	>=75 years	3/ 4 (75.0)	2.9 (1.7, NE)
	Sex		
	female	10/ 22 (45.5)	5.1 (3.0, NE)
	male	17/ 57 (29.8)	10.4 (5.5, NE)
	ECOG PS		
	0	7/ 29 (24.1)	NE (4.9, NE)
	1	20/ 50 (40.0)	10.4 (3.5, NE)
	HER2 Status in central laboratory		
	IHC 3+	24/ 68 (35.3)	10.4 (4.9, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.7, NE)
	Primary tumor location		
	Gastric	9/ 27 (33.3)	NE (3.7, NE)
	GEJ	18/ 52 (34.6)	10.4 (4.9, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	3.0 (NE , NE)
	intestinal	5/ 19 (26.3)	NE (3.0, NE)
	other	21/ 59 (35.6)	10.4 (4.3, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.6, NE)
	>=2	26/ 74 (35.1)	10.4 (4.3, NE)
	Previous total gastrectomy		
	no	27/ 79 (34.2)	10.4 (4.9, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (2.6, NE)
	no	25/ 70 (35.7)	10.4 (4.3, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (2.1, NE)
	no	25/ 73 (34.2)	10.4 (4.9, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (2.1, NE)
	no	25/ 72 (34.7)	10.4 (4.9, NE)
	Presence of liver metastasis at baseline		
	yes	17/ 50 (34.0)	10.4 (4.1, NE)
	no	10/ 29 (34.5)	NE (4.3, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Weight decreased	Renal impairment at baseline		
	normal	8/ 32 (25.0)	10.4 (4.9, NE)
	mild	10/ 25 (40.0)	4.1 (3.0, NE)
	moderate	2/ 8 (25.0)	NE (3.7, NE)
	Hepatic impairment at baseline		
	normal	21/ 64 (32.8)	10.4 (5.1, NE)
	mild	6/ 14 (42.9)	4.9 (3.0, NE)
	Race		
	White	24/ 69 (34.8)	10.4 (4.3, NE)
	Black or African American	1/ 1 (100.0)	2.1 (NE , NE)
	Other	2/ 8 (25.0)	NE (2.1, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	5.5 (1.7, NE)
	Non-Hispanic/Non-Latino	23/ 70 (32.9)	10.4 (4.3, NE)
	Unknown	2/ 4 (50.0)	NE (1.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: White blood cell count decreased	Overall	8/ 79 (10.1)	NE (11.1, NE)
	Region		
	North America	6/ 34 (17.6)	NE (11.1, NE)
	EU	2/ 45 (4.4)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (11.1, NE)
	Age (Category 2)		
	<75 years	7/ 75 (9.3)	NE (11.1, NE)
	>=75 years	1/ 4 (25.0)	NE (0.5, NE)
	Sex		
	female	3/ 22 (13.6)	11.1 (11.1, NE)
	male	5/ 57 (8.8)	NE (NE , NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	5/ 50 (10.0)	NE (11.1, NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	NE (11.1, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (2.1, NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	11.1 (11.1, NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	6/ 59 (10.2)	NE (11.1, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.1, NE)
	>=2	7/ 74 (9.5)	NE (11.1, NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (11.1, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (11.1, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	11.1 (0.5, 11.1)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	11.1 (0.5, 11.1)
	no	5/ 72 (6.9)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	7/ 50 (14.0)	NE (NE , NE)
	no	1/ 29 (3.4)	11.1 (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: White blood cell count decreased	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (11.1, NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (11.1, NE)
	mild	3/ 14 (21.4)	NE (3.0, NE)
	Race		
	White	4/ 69 (5.8)	NE (11.1, NE)
	Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
	Other	3/ 8 (37.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (11.1, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders	Overall	43/ 79 (54.4)	3.4 (1.4, 6.9)
	Region		
	North America	21/ 34 (61.8)	2.7 (0.7, 6.9)
	EU	22/ 45 (48.9)	5.9 (1.1, NE)
	Age (Category 1)		
	<65 years	26/ 46 (56.5)	2.8 (0.5, NE)
	>=65 years	17/ 33 (51.5)	3.4 (2.2, NE)
	Age (Category 2)		
	<75 years	40/ 75 (53.3)	2.9 (1.4, NE)
	>=75 years	3/ 4 (75.0)	2.4 (0.7, NE)
	Sex		
	female	11/ 22 (50.0)	4.8 (0.7, NE)
	male	32/ 57 (56.1)	2.7 (1.1, 6.9)
	ECOG PS		
	0	12/ 29 (41.4)	NE (2.5, NE)
	1	31/ 50 (62.0)	2.2 (0.7, 5.9)
	HER2 Status in central laboratory		
	IHC 3+	37/ 68 (54.4)	3.4 (1.4, NE)
	IHC 2+/ISH +	6/ 10 (60.0)	1.6 (0.3, NE)
	Primary tumor location		
	Gastric	15/ 27 (55.6)	3.4 (0.7, NE)
	GEJ	28/ 52 (53.8)	2.9 (1.1, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	10/ 19 (52.6)	4.8 (0.6, NE)
	other	33/ 59 (55.9)	2.7 (1.4, NE)
	Number of metastatic sites		
	<2	2/ 5 (40.0)	NE (0.3, NE)
	>=2	41/ 74 (55.4)	2.9 (1.4, 6.9)
	Previous total gastrectomy		
	no	43/ 79 (54.4)	3.4 (1.4, 6.9)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	2.2 (0.1, NE)
	no	38/ 70 (54.3)	3.4 (1.4, 6.9)
	Prior nivolumab or pembrolizumab treatment		
	yes	4/ 6 (66.7)	2.2 (0.3, NE)
	no	39/ 73 (53.4)	3.4 (1.4, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	5/ 7 (71.4)	2.2 (0.0, NE)
	no	38/ 72 (52.8)	3.4 (1.4, NE)
	Presence of liver metastasis at baseline		
	yes	27/ 50 (54.0)	3.4 (1.4, NE)
	no	16/ 29 (55.2)	2.7 (0.6, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders	Renal impairment at baseline		
	normal	20/ 32 (62.5)	2.2 (0.3, NE)
	mild	14/ 25 (56.0)	2.2 (0.8, NE)
	moderate	2/ 8 (25.0)	6.9 (0.4, 6.9)
	Hepatic impairment at baseline		
	normal	33/ 64 (51.6)	4.8 (1.6, NE)
	mild	9/ 14 (64.3)	2.1 (0.1, NE)
	Race		
	White	36/ 69 (52.2)	4.8 (1.4, NE)
	Black or African American	1/ 1 (100.0)	3.4 (NE , NE)
	Other	6/ 8 (75.0)	1.6 (0.1, NE)
	Ethnicity		
	Hispanic/Latino	3/ 5 (60.0)	1.4 (0.0, NE)
	Non-Hispanic/Non-Latino	37/ 70 (52.9)	3.4 (1.6, NE)
	Unknown	3/ 4 (75.0)	1.3 (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Overall	26/ 79 (32.9)	10.2 (10.2, NE)
	Region		
	North America	14/ 34 (41.2)	10.2 (2.2, NE)
	EU	12/ 45 (26.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	12/ 46 (26.1)	NE (NE , NE)
	>=65 years	14/ 33 (42.4)	10.2 (2.2, NE)
	Age (Category 2)		
	<75 years	25/ 75 (33.3)	10.2 (10.2, NE)
	>=75 years	1/ 4 (25.0)	NE (0.7, NE)
	Sex		
	female	6/ 22 (27.3)	NE (4.8, NE)
	male	20/ 57 (35.1)	10.2 (3.4, NE)
	ECOG PS		
	0	9/ 29 (31.0)	NE (3.1, NE)
	1	17/ 50 (34.0)	10.2 (4.8, NE)
	HER2 Status in central laboratory		
	IHC 3+	22/ 68 (32.4)	10.2 (10.2, NE)
	IHC 2+/ISH +	4/ 10 (40.0)	2.2 (1.3, NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (NE , NE)
	GEJ	21/ 52 (40.4)	10.2 (2.8, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	6/ 19 (31.6)	NE (1.1, NE)
	other	20/ 59 (33.9)	10.2 (10.2, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.2, NE)
	>=2	25/ 74 (33.8)	10.2 (10.2, NE)
	Previous total gastrectomy		
	no	26/ 79 (32.9)	10.2 (10.2, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	2.2 (0.1, NE)
	no	21/ 70 (30.0)	10.2 (10.2, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	3/ 6 (50.0)	2.2 (0.3, NE)
	no	23/ 73 (31.5)	10.2 (10.2, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	NE (0.3, NE)
	no	23/ 72 (31.9)	10.2 (10.2, NE)
	Presence of liver metastasis at baseline		
	yes	17/ 50 (34.0)	10.2 (4.8, NE)
	no	9/ 29 (31.0)	NE (3.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Renal impairment at baseline		
	normal	12/ 32 (37.5)	NE (1.6, NE)
	mild	9/ 25 (36.0)	NE (1.4, NE)
	moderate	1/ 8 (12.5)	10.2 (NE , NE)
	Hepatic impairment at baseline		
	normal	20/ 64 (31.3)	10.2 (10.2, NE)
	mild	5/ 14 (35.7)	NE (0.1, NE)
	Race		
	White	24/ 69 (34.8)	10.2 (10.2, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (0.1, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.1, NE)
	Non-Hispanic/Non-Latino	22/ 70 (31.4)	10.2 (10.2, NE)
	Unknown	3/ 4 (75.0)	1.3 (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Overall	12/ 79 (15.2)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (NE , NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	10/ 46 (21.7)	NE (NE , NE)
	>=65 years	2/ 33 (6.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	11/ 75 (14.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.4, NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	10/ 57 (17.5)	NE (NE , NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	9/ 50 (18.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	10/ 68 (14.7)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.3, NE)
	Primary tumor location		
	Gastric	6/ 27 (22.2)	NE (NE , NE)
	GEJ	6/ 52 (11.5)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	11/ 59 (18.6)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.3, NE)
	>=2	11/ 74 (14.9)	NE (NE , NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.5, NE)
	no	11/ 70 (15.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	12/ 73 (16.4)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	7/ 50 (14.0)	NE (NE , NE)
	no	5/ 29 (17.2)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Renal impairment at baseline		
	normal	6/ 32 (18.8)	NE (4.9, NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	9/ 64 (14.1)	NE (NE , NE)
	mild	3/ 14 (21.4)	NE (4.9, NE)
	Race		
	White	9/ 69 (13.0)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.3, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.4, NE)
	Non-Hispanic/Non-Latino	10/ 70 (14.3)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Musculoskeletal and connective tissue disorders	Overall	16/ 79 (20.3)	NE (8.5, NE)
	Region		
	North America	8/ 34 (23.5)	NE (4.9, NE)
	EU	8/ 45 (17.8)	NE (7.5, NE)
	Age (Category 1)		
	<65 years	11/ 46 (23.9)	NE (7.5, NE)
	>=65 years	5/ 33 (15.2)	NE (8.5, NE)
	Age (Category 2)		
	<75 years	15/ 75 (20.0)	NE (7.5, NE)
	>=75 years	1/ 4 (25.0)	NE (8.5, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	13/ 57 (22.8)	NE (7.5, NE)
	ECOG PS		
	0	6/ 29 (20.7)	NE (7.5, NE)
	1	10/ 50 (20.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	13/ 68 (19.1)	NE (8.5, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	4.9 (0.9, NE)
	Primary tumor location		
	Gastric	7/ 27 (25.9)	NE (4.4, NE)
	GEJ	9/ 52 (17.3)	NE (7.5, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	13/ 59 (22.0)	NE (7.5, NE)
	Number of metastatic sites		
	<2	3/ 5 (60.0)	4.9 (2.0, NE)
	>=2	13/ 74 (17.6)	NE (8.5, NE)
	Previous total gastrectomy		
	no	16/ 79 (20.3)	NE (8.5, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	8.5 (4.4, NE)
	no	14/ 70 (20.0)	NE (7.5, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.0, NE)
	no	15/ 73 (20.5)	NE (8.5, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.0, NE)
	no	15/ 72 (20.8)	NE (8.5, NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	NE (7.5, NE)
	no	6/ 29 (20.7)	NE (8.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Musculoskeletal and connective tissue disorders	Renal impairment at baseline		
	normal	6/ 32 (18.8)	NE (4.9, NE)
	mild	6/ 25 (24.0)	NE (7.5, NE)
	moderate	1/ 8 (12.5)	NE (3.2, NE)
	Hepatic impairment at baseline		
	normal	13/ 64 (20.3)	NE (8.5, NE)
	mild	3/ 14 (21.4)	NE (2.7, NE)
	Race		
	White	15/ 69 (21.7)	NE (8.5, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (4.9, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.2, NE)
	Non-Hispanic/Non-Latino	15/ 70 (21.4)	NE (7.5, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Nervous system disorders	Overall	26/ 79 (32.9)	9.9 (5.0, NE)
	Region		
	North America	11/ 34 (32.4)	NE (4.9, NE)
	EU	15/ 45 (33.3)	9.9 (4.8, NE)
	Age (Category 1)		
	<65 years	16/ 46 (34.8)	9.9 (4.9, NE)
	>=65 years	10/ 33 (30.3)	NE (4.7, NE)
	Age (Category 2)		
	<75 years	24/ 75 (32.0)	9.9 (5.0, NE)
	>=75 years	2/ 4 (50.0)	4.7 (1.9, NE)
	Sex		
	female	6/ 22 (27.3)	NE (4.8, NE)
	male	20/ 57 (35.1)	9.9 (4.7, NE)
	ECOG PS		
	0	7/ 29 (24.1)	9.9 (9.9, NE)
	1	19/ 50 (38.0)	NE (3.6, NE)
	HER2 Status in central laboratory		
	IHC 3+	23/ 68 (33.8)	9.9 (5.0, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	4.9 (1.3, 4.9)
	Primary tumor location		
	Gastric	9/ 27 (33.3)	NE (4.8, NE)
	GEJ	17/ 52 (32.7)	9.9 (4.7, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	9/ 19 (47.4)	9.9 (0.9, 9.9)
	other	17/ 59 (28.8)	NE (4.9, NE)
	Number of metastatic sites		
	<2	2/ 5 (40.0)	4.9 (1.4, NE)
	>=2	24/ 74 (32.4)	9.9 (5.0, NE)
	Previous total gastrectomy		
	no	26/ 79 (32.9)	9.9 (5.0, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	9.9 (0.1, 9.9)
	no	21/ 70 (30.0)	NE (4.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (1.4, NE)
	no	25/ 73 (34.2)	9.9 (4.9, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (1.4, NE)
	no	24/ 72 (33.3)	9.9 (5.0, NE)
	Presence of liver metastasis at baseline		
	yes	17/ 50 (34.0)	9.9 (4.9, NE)
	no	9/ 29 (31.0)	NE (4.8, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Nervous system disorders	Renal impairment at baseline		
	normal	14/ 32 (43.8)	4.9 (1.3, NE)
	mild	8/ 25 (32.0)	NE (4.7, NE)
	moderate	3/ 8 (37.5)	NE (0.7, NE)
	Hepatic impairment at baseline		
	normal	20/ 64 (31.3)	9.9 (5.0, NE)
	mild	5/ 14 (35.7)	NE (1.0, NE)
	Race		
	White	23/ 69 (33.3)	9.9 (4.8, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	5.0 (1.1, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.9, NE)
	Non-Hispanic/Non-Latino	22/ 70 (31.4)	9.9 (4.9, NE)
	Unknown	2/ 4 (50.0)	5.0 (0.5, 5.0)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Psychiatric disorders	Overall	12/ 79 (15.2)	NE (NE , NE)
	Region		
	North America	4/ 34 (11.8)	NE (NE , NE)
	EU	8/ 45 (17.8)	NE (NE , NE)
	Age (Category 1)		
	<65 years	9/ 46 (19.6)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	12/ 75 (16.0)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	11/ 57 (19.3)	NE (NE , NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	9/ 50 (18.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	9/ 68 (13.2)	NE (NE , NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.3, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	9/ 52 (17.3)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	11/ 59 (18.6)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (3.5, NE)
	>=2	11/ 74 (14.9)	NE (NE , NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	12/ 70 (17.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	12/ 73 (16.4)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	9/ 50 (18.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Psychiatric disorders	Renal impairment at baseline		
	normal	7/ 32 (21.9)	NE (4.2, NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (4.8, NE)
	Hepatic impairment at baseline		
	normal	11/ 64 (17.2)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (4.2, NE)
	Race		
	White	11/ 69 (15.9)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (3.5, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	12/ 70 (17.1)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Renal and urinary disorders	Overall	16/ 79 (20.3)	NE (NE , NE)
	Region		
	North America	10/ 34 (29.4)	NE (2.9, NE)
	EU	6/ 45 (13.3)	NE (NE , NE)
	Age (Category 1)		
	<65 years	10/ 46 (21.7)	NE (NE , NE)
	>=65 years	6/ 33 (18.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	15/ 75 (20.0)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.2, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	13/ 57 (22.8)	NE (NE , NE)
	ECOG PS		
	0	6/ 29 (20.7)	NE (NE , NE)
	1	10/ 50 (20.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	13/ 68 (19.1)	NE (NE , NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.0, NE)
	Primary tumor location		
	Gastric	6/ 27 (22.2)	NE (NE , NE)
	GEJ	10/ 52 (19.2)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	13/ 59 (22.0)	NE (NE , NE)
	Number of metastatic sites		
	<2	2/ 5 (40.0)	NE (0.0, NE)
	>=2	14/ 74 (18.9)	NE (NE , NE)
	Previous total gastrectomy		
	no	16/ 79 (20.3)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (1.3, NE)
	no	15/ 70 (21.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	3/ 6 (50.0)	2.9 (0.7, NE)
	no	13/ 73 (17.8)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	4/ 7 (57.1)	2.9 (0.5, NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	8/ 50 (16.0)	NE (NE , NE)
	no	8/ 29 (27.6)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Renal and urinary disorders	Renal impairment at baseline		
	normal	10/ 32 (31.3)	NE (2.9, NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	14/ 64 (21.9)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	13/ 69 (18.8)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.0, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	14/ 70 (20.0)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Overall	33/ 79 (41.8)	6.3 (4.1, NE)
	Region		
	North America	15/ 34 (44.1)	6.1 (2.7, NE)
	EU	18/ 45 (40.0)	8.8 (2.8, NE)
	Age (Category 1)		
	<65 years	23/ 46 (50.0)	4.3 (2.8, NE)
	>=65 years	10/ 33 (30.3)	NE (4.3, NE)
	Age (Category 2)		
	<75 years	31/ 75 (41.3)	6.3 (4.1, NE)
	>=75 years	2/ 4 (50.0)	NE (0.0, NE)
	Sex		
	female	7/ 22 (31.8)	NE (4.0, NE)
	male	26/ 57 (45.6)	6.1 (2.8, NE)
	ECOG PS		
	0	12/ 29 (41.4)	8.8 (2.7, NE)
	1	21/ 50 (42.0)	6.3 (4.0, NE)
	HER2 Status in central laboratory		
	IHC 3+	30/ 68 (44.1)	6.3 (4.1, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.1, NE)
	Primary tumor location		
	Gastric	7/ 27 (25.9)	NE (4.1, NE)
	GEJ	26/ 52 (50.0)	4.3 (2.8, 8.8)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	6/ 19 (31.6)	8.8 (2.7, 8.8)
	other	27/ 59 (45.8)	5.2 (2.8, NE)
	Number of metastatic sites		
	<2	3/ 5 (60.0)	4.1 (0.7, NE)
	>=2	30/ 74 (40.5)	6.3 (4.3, NE)
	Previous total gastrectomy		
	no	33/ 79 (41.8)	6.3 (4.1, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	8.8 (0.0, 8.8)
	no	29/ 70 (41.4)	6.1 (3.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	3/ 6 (50.0)	2.7 (0.7, NE)
	no	30/ 73 (41.1)	6.3 (4.1, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	NE (0.7, NE)
	no	30/ 72 (41.7)	6.3 (4.1, NE)
	Presence of liver metastasis at baseline		
	yes	21/ 50 (42.0)	6.3 (2.8, NE)
	no	12/ 29 (41.4)	6.1 (3.9, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Renal impairment at baseline		
	normal	16/ 32 (50.0)	4.3 (2.7, NE)
	mild	8/ 25 (32.0)	NE (5.2, NE)
	moderate	2/ 8 (25.0)	NE (0.3, NE)
	Hepatic impairment at baseline		
	normal	28/ 64 (43.8)	6.1 (3.9, NE)
	mild	5/ 14 (35.7)	NE (0.3, NE)
	Race		
	White	30/ 69 (43.5)	6.1 (3.9, NE)
	Black or African American	1/ 1 (100.0)	4.0 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.7, NE)
	Ethnicity		
	Hispanic/Latino	3/ 5 (60.0)	3.9 (0.7, NE)
	Non-Hispanic/Non-Latino	29/ 70 (41.4)	6.3 (4.1, NE)
	Unknown	1/ 4 (25.0)	NE (1.0, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	6/ 34 (17.6)	NE (6.1, NE)
	EU	2/ 45 (4.4)	NE (NE , NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (6.1, NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	0/ 22 (0.0)	NE (NE , NE)
	male	8/ 57 (14.0)	NE (NE , NE)
	ECOG PS		
	0	5/ 29 (17.2)	NE (6.1, NE)
	1	3/ 50 (6.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	8/ 68 (11.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	0/ 27 (0.0)	NE (NE , NE)
	GEJ	8/ 52 (15.4)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	6/ 59 (10.2)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.0, NE)
	>=2	7/ 74 (9.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (2.0, NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (2.0, NE)
	no	6/ 72 (8.3)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	6/ 50 (12.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (6.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	6/ 64 (9.4)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (2.4, NE)
	Race		
	White	8/ 69 (11.6)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.9, NE)
	Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Skin and subcutaneous tissue disorders	Overall	25/ 79 (31.6)	NE (NE , NE)
	Region		
	North America	10/ 34 (29.4)	NE (4.6, NE)
	EU	15/ 45 (33.3)	NE (4.1, NE)
	Age (Category 1)		
	<65 years	15/ 46 (32.6)	NE (4.6, NE)
	>=65 years	10/ 33 (30.3)	NE (4.1, NE)
	Age (Category 2)		
	<75 years	23/ 75 (30.7)	NE (NE , NE)
	>=75 years	2/ 4 (50.0)	NE (0.4, NE)
	Sex		
	female	11/ 22 (50.0)	2.1 (1.0, NE)
	male	14/ 57 (24.6)	NE (NE , NE)
	ECOG PS		
	0	10/ 29 (34.5)	NE (2.1, NE)
	1	15/ 50 (30.0)	NE (4.6, NE)
	HER2 Status in central laboratory		
	IHC 3+	23/ 68 (33.8)	NE (4.6, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (0.5, NE)
	Primary tumor location		
	Gastric	13/ 27 (48.1)	2.1 (0.9, NE)
	GEJ	12/ 52 (23.1)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	6/ 19 (31.6)	NE (1.4, NE)
	other	19/ 59 (32.2)	NE (4.6, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.3, NE)
	>=2	24/ 74 (32.4)	NE (4.6, NE)
	Previous total gastrectomy		
	no	25/ 79 (31.6)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	NE (0.0, NE)
	no	21/ 70 (30.0)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	3/ 6 (50.0)	2.1 (0.7, NE)
	no	22/ 73 (30.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	NE (0.7, NE)
	no	22/ 72 (30.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	15/ 50 (30.0)	NE (4.6, NE)
	no	10/ 29 (34.5)	NE (0.9, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Skin and subcutaneous tissue disorders	Renal impairment at baseline		
	normal	10/ 32 (31.3)	NE (4.6, NE)
	mild	6/ 25 (24.0)	NE (NE , NE)
	moderate	3/ 8 (37.5)	NE (0.8, NE)
	Hepatic impairment at baseline		
	normal	21/ 64 (32.8)	NE (4.6, NE)
	mild	4/ 14 (28.6)	NE (0.5, NE)
	Race		
	White	21/ 69 (30.4)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.2, NE)
	Non-Hispanic/Non-Latino	22/ 70 (31.4)	NE (NE , NE)
	Unknown	2/ 4 (50.0)	NE (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Skin and subcutaneous tissue disorders, PT: Alopecia	Overall	19/ 79 (24.1)	NE (NE , NE)
	Region		
	North America	6/ 34 (17.6)	NE (NE , NE)
	EU	13/ 45 (28.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	11/ 46 (23.9)	NE (NE , NE)
	>=65 years	8/ 33 (24.2)	NE (3.7, NE)
	Age (Category 2)		
	<75 years	17/ 75 (22.7)	NE (NE , NE)
	>=75 years	2/ 4 (50.0)	NE (0.4, NE)
	Sex		
	female	9/ 22 (40.9)	NE (1.4, NE)
	male	10/ 57 (17.5)	NE (NE , NE)
	ECOG PS		
	0	8/ 29 (27.6)	NE (NE , NE)
	1	11/ 50 (22.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	18/ 68 (26.5)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (0.5, NE)
	Primary tumor location		
	Gastric	11/ 27 (40.7)	NE (1.0, NE)
	GEJ	8/ 52 (15.4)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	5/ 19 (26.3)	NE (1.5, NE)
	other	14/ 59 (23.7)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.3, NE)
	>=2	18/ 74 (24.3)	NE (NE , NE)
	Previous total gastrectomy		
	no	19/ 79 (24.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	NE (0.0, NE)
	no	15/ 70 (21.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (1.5, NE)
	no	17/ 73 (23.3)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (1.5, NE)
	no	17/ 72 (23.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	NE (NE , NE)
	no	9/ 29 (31.0)	NE (2.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Skin and subcutaneous tissue disorders, PT: Alopecia	Renal impairment at baseline		
	normal	7/ 32 (21.9)	NE (NE , NE)
	mild	6/ 25 (24.0)	NE (3.7, NE)
	moderate	1/ 8 (12.5)	NE (2.1, NE)
	Hepatic impairment at baseline		
	normal	15/ 64 (23.4)	NE (NE , NE)
	mild	4/ 14 (28.6)	NE (0.5, NE)
	Race		
	White	15/ 69 (21.7)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.7, NE)
	Non-Hispanic/Non-Latino	16/ 70 (22.9)	NE (NE , NE)
	Unknown	2/ 4 (50.0)	NE (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Vascular disorders	Overall	11/ 79 (13.9)	NE (NE , NE)
	Region		
	North America	6/ 34 (17.6)	NE (NE , NE)
	EU	5/ 45 (11.1)	NE (NE , NE)
	Age (Category 1)		
	<65 years	6/ 46 (13.0)	NE (NE , NE)
	>=65 years	5/ 33 (15.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	9/ 75 (12.0)	NE (NE , NE)
	>=75 years	2/ 4 (50.0)	NE (1.2, NE)
	Sex		
	female	4/ 22 (18.2)	NE (NE , NE)
	male	7/ 57 (12.3)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	9/ 50 (18.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	9/ 68 (13.2)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (1.4, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	8/ 52 (15.4)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	9/ 59 (15.3)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (3.0, NE)
	>=2	10/ 74 (13.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	11/ 79 (13.9)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (3.0, NE)
	no	10/ 70 (14.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (2.8, NE)
	no	9/ 73 (12.3)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	NE (0.0, NE)
	no	8/ 72 (11.1)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	9/ 50 (18.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

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NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

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SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Vascular disorders	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	5/ 25 (20.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	9/ 64 (14.1)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (4.2, NE)
	Race		
	White	9/ 69 (13.0)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	4.2 (NE , NE)
	Other	1/ 8 (12.5)	NE (2.8, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.0, NE)
	Non-Hispanic/Non-Latino	9/ 70 (12.9)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

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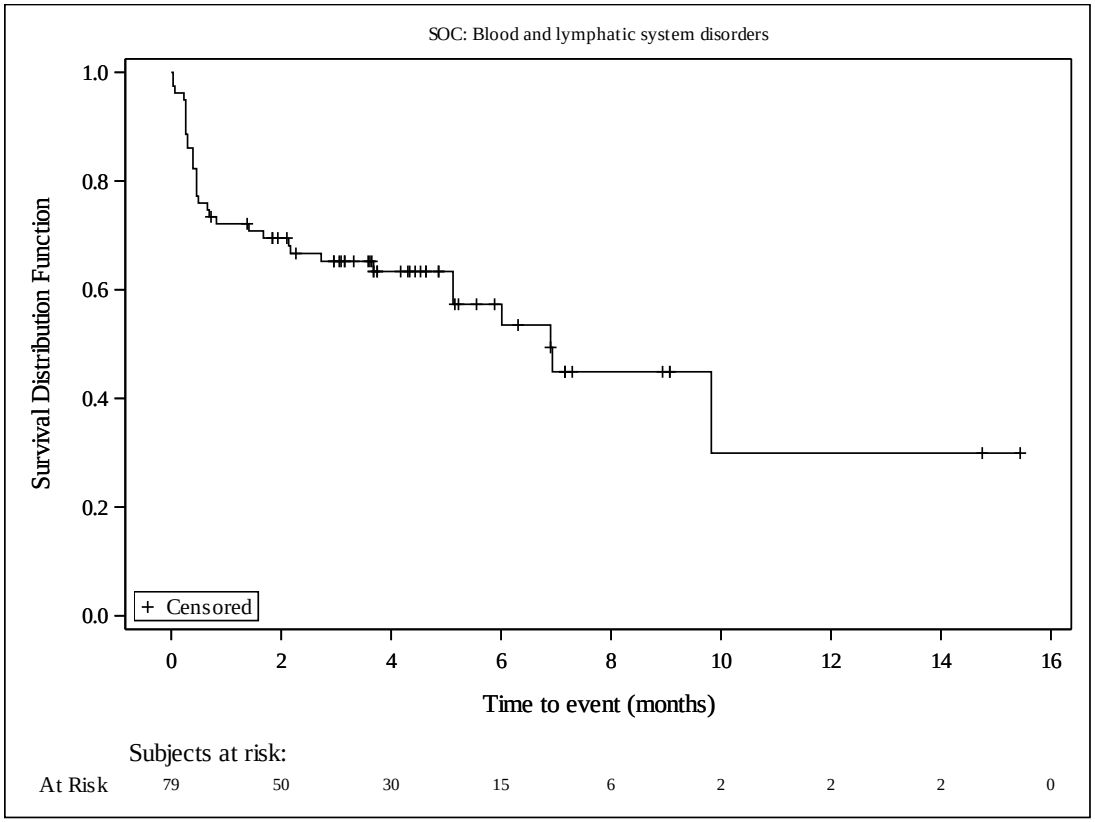

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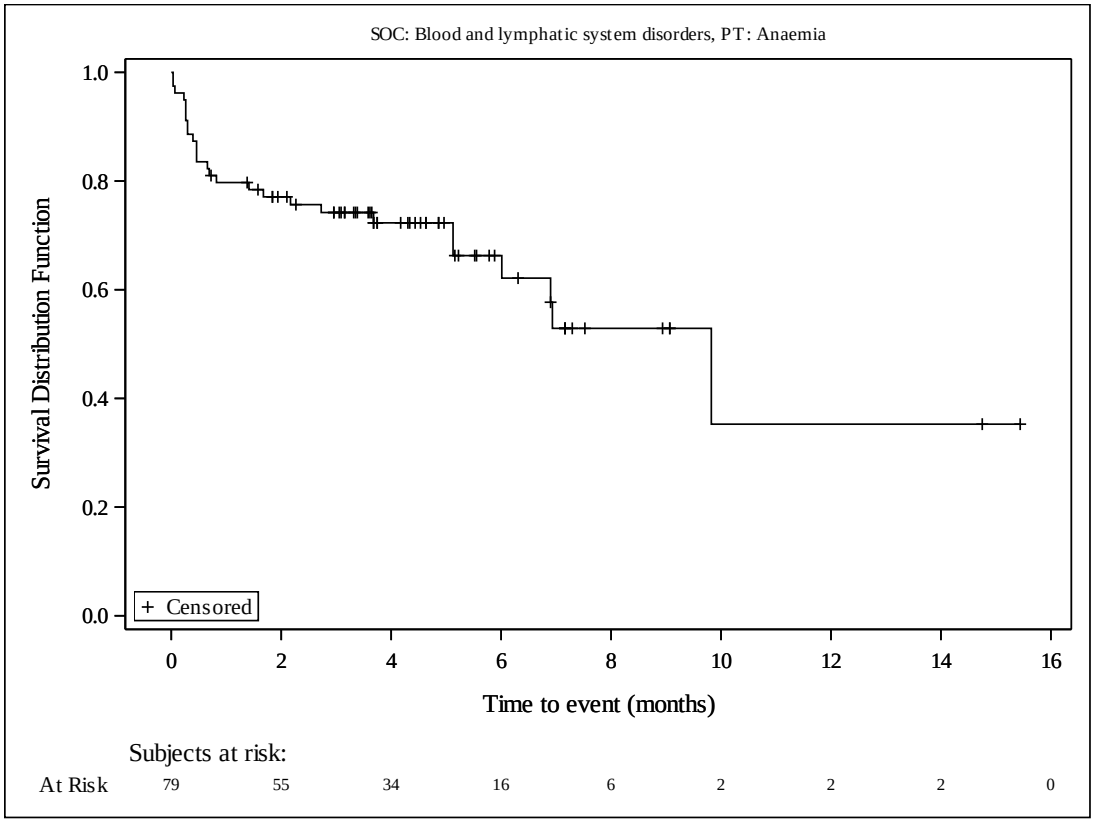

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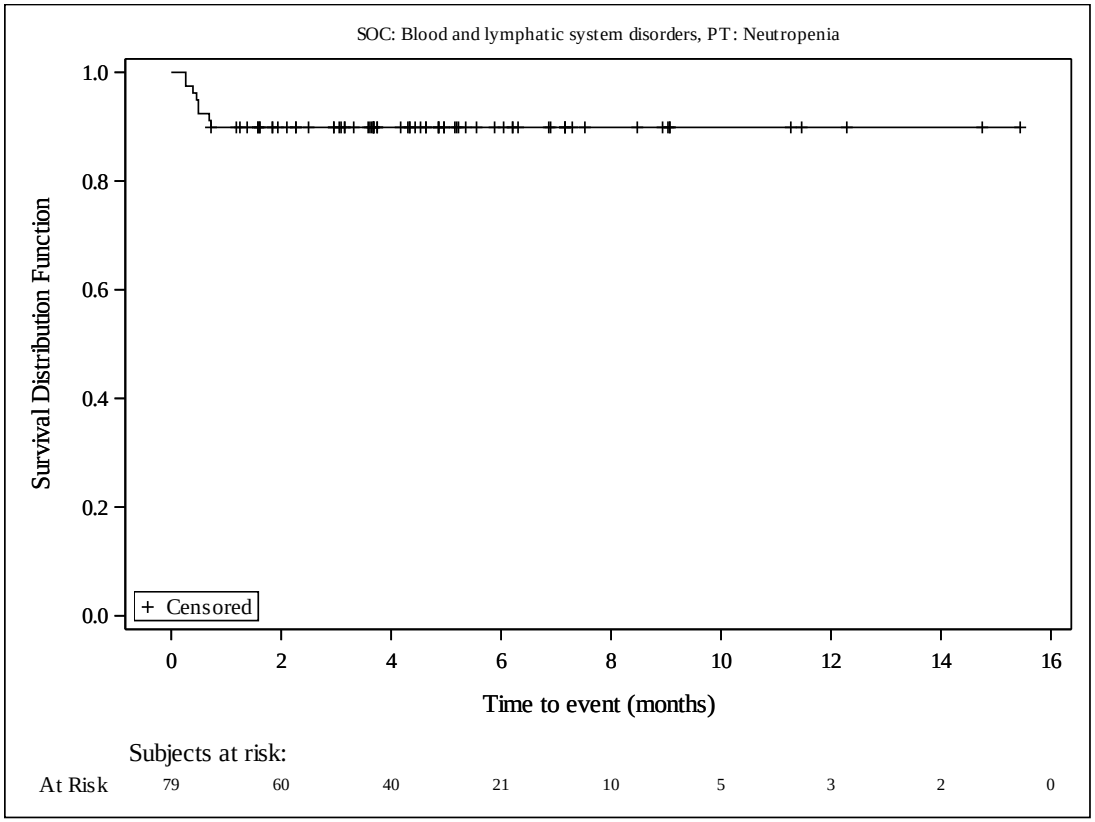

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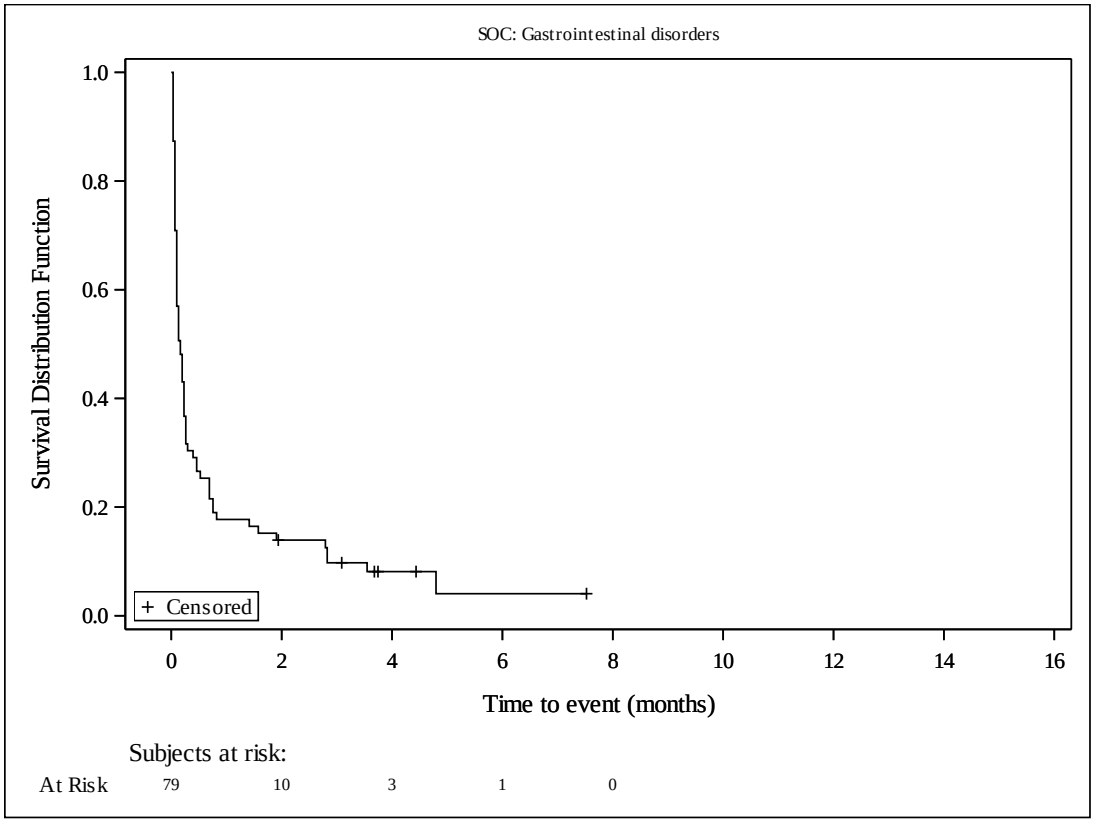

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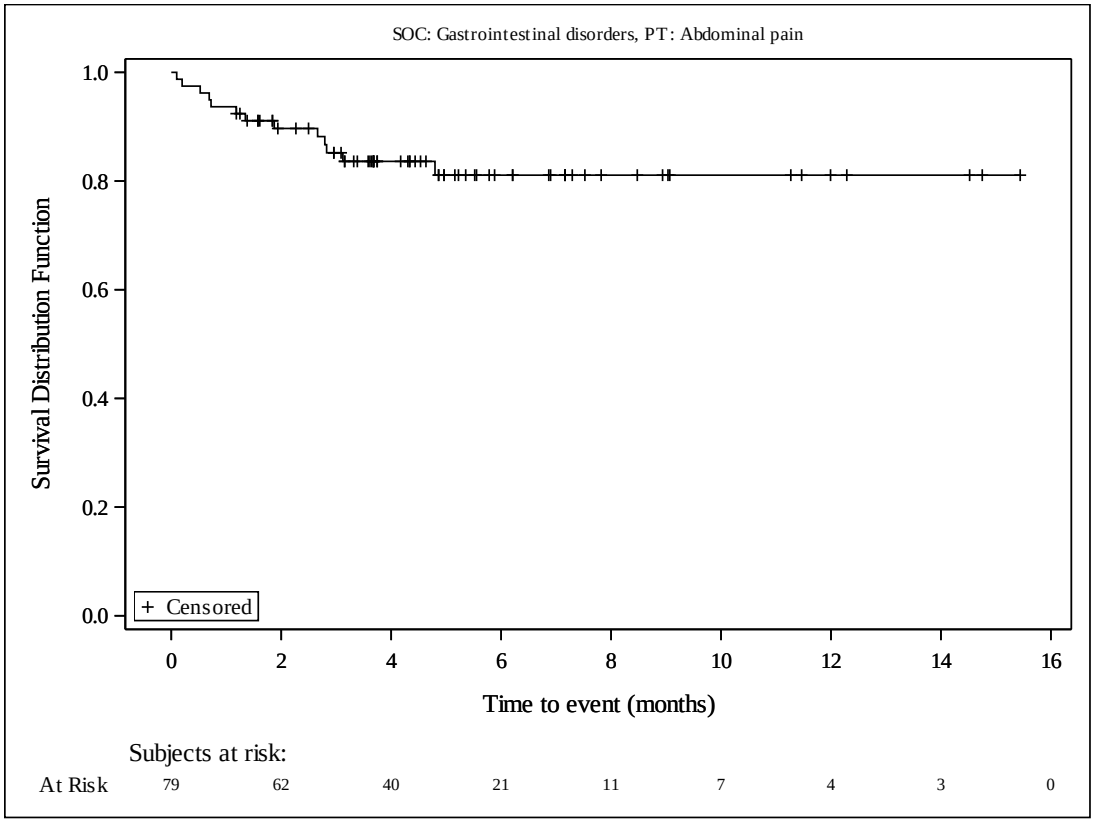

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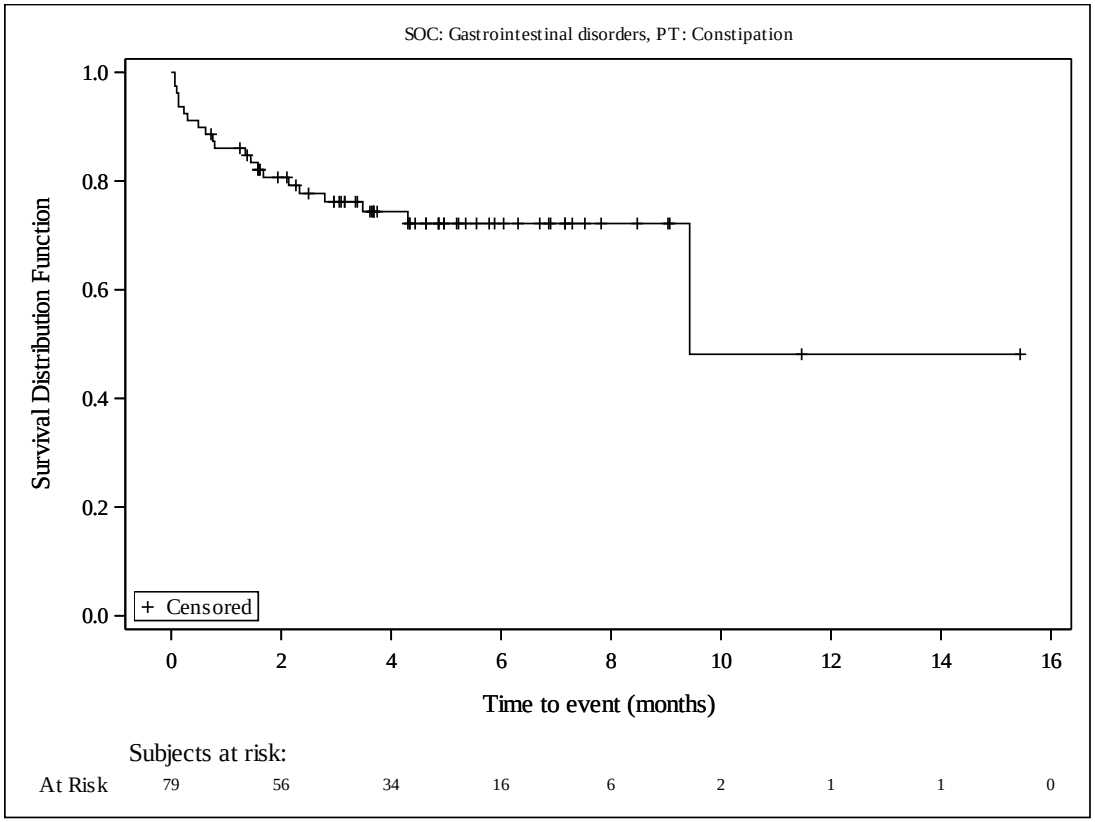

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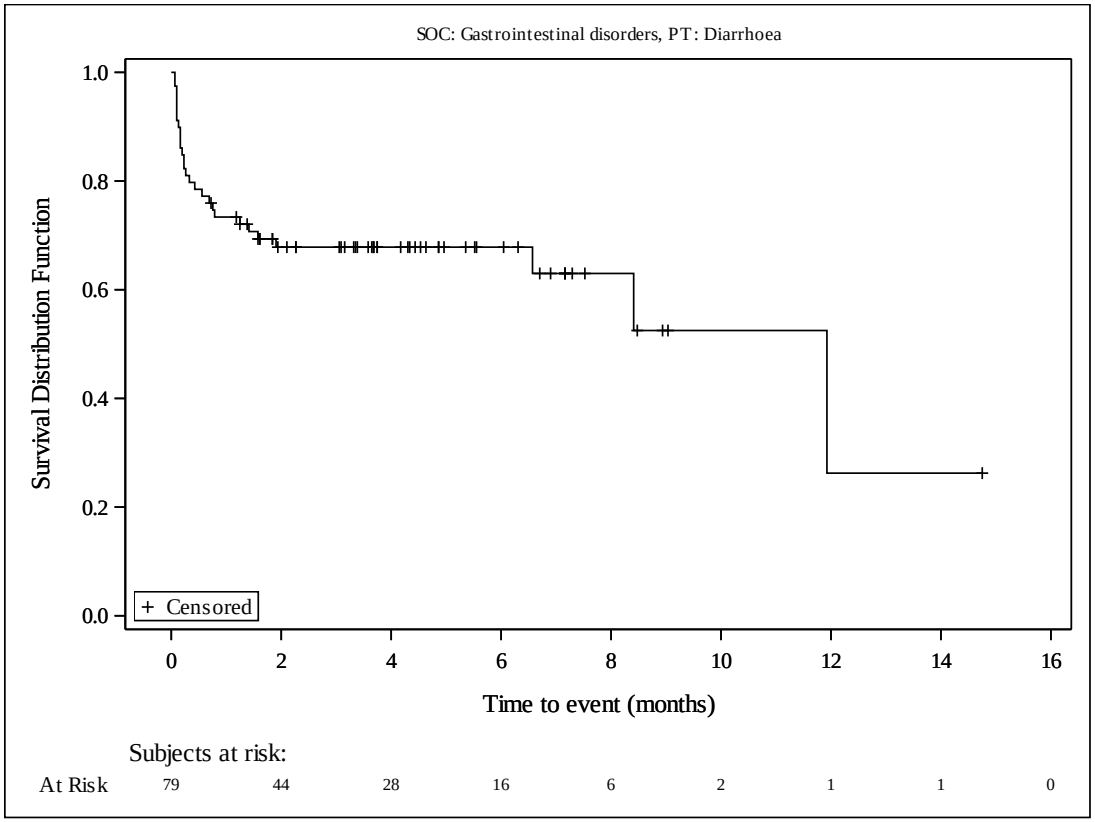

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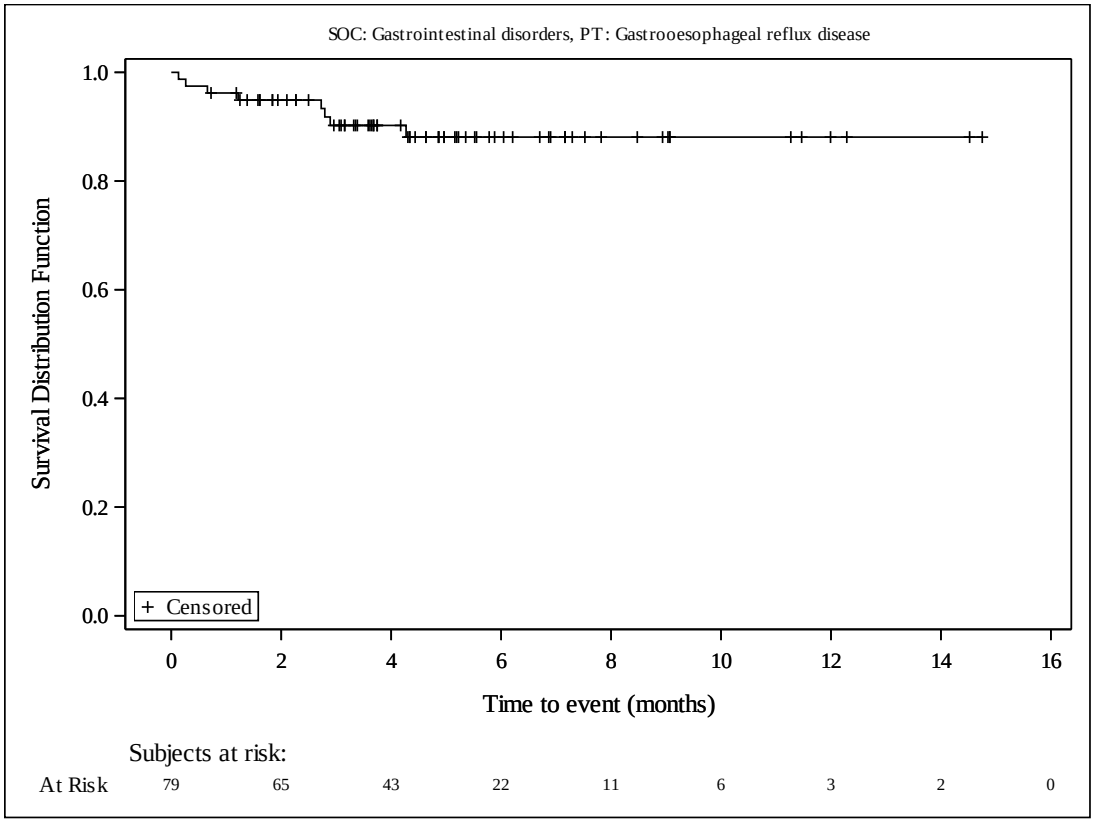

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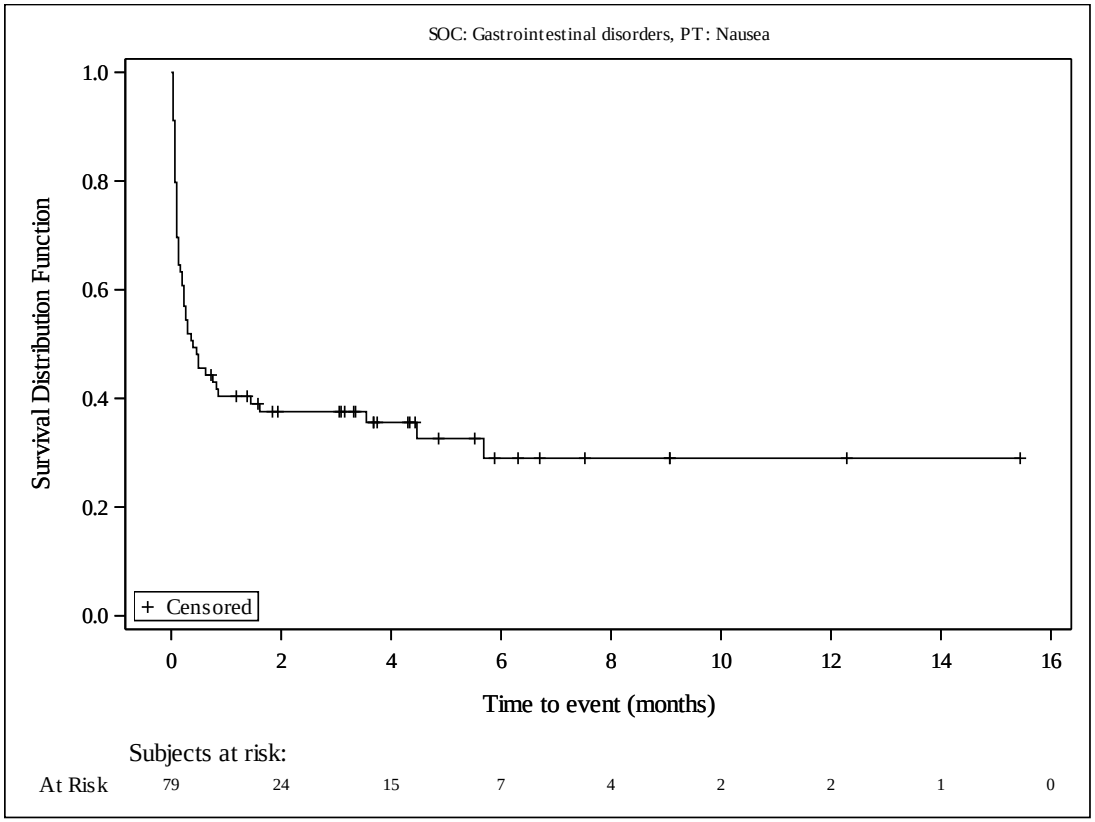

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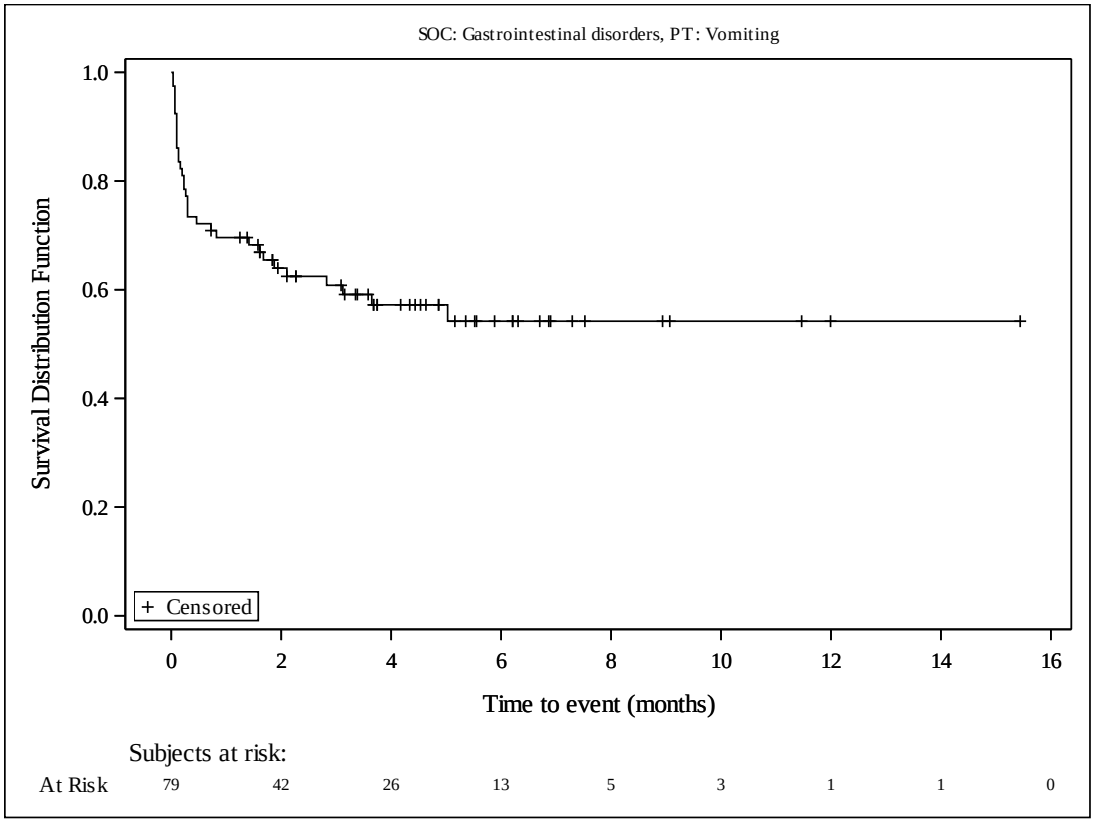

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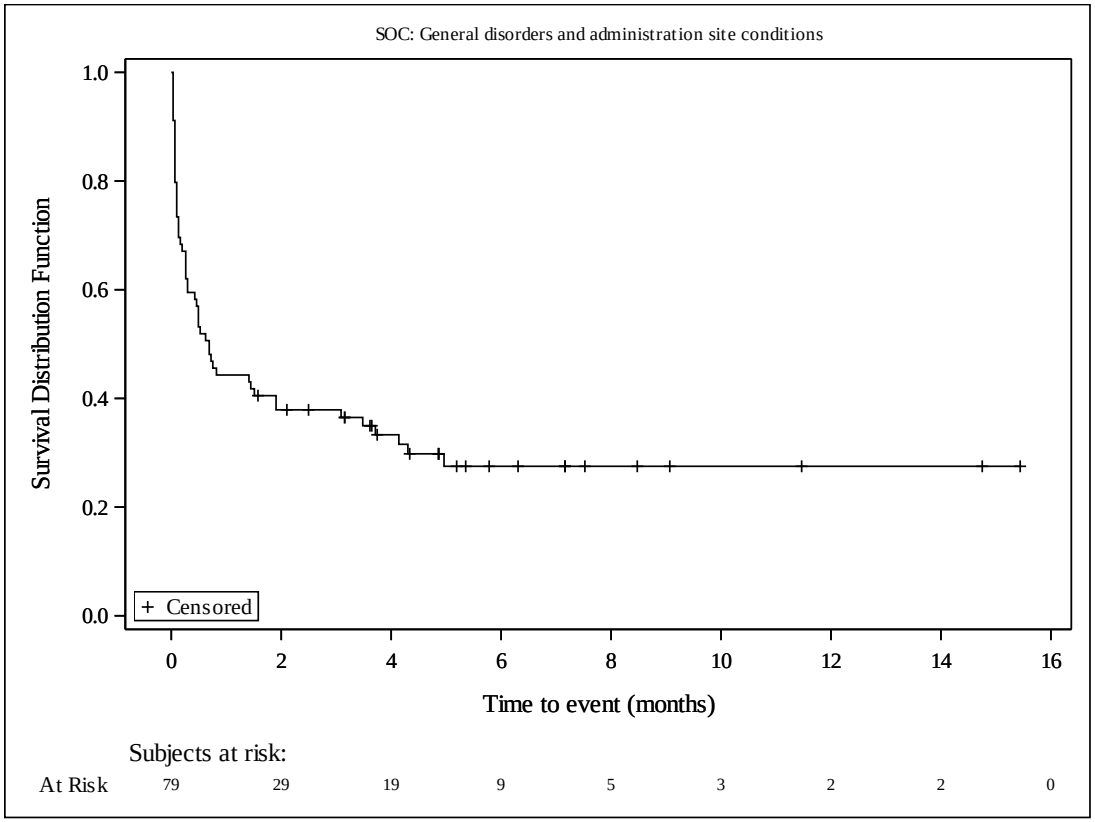

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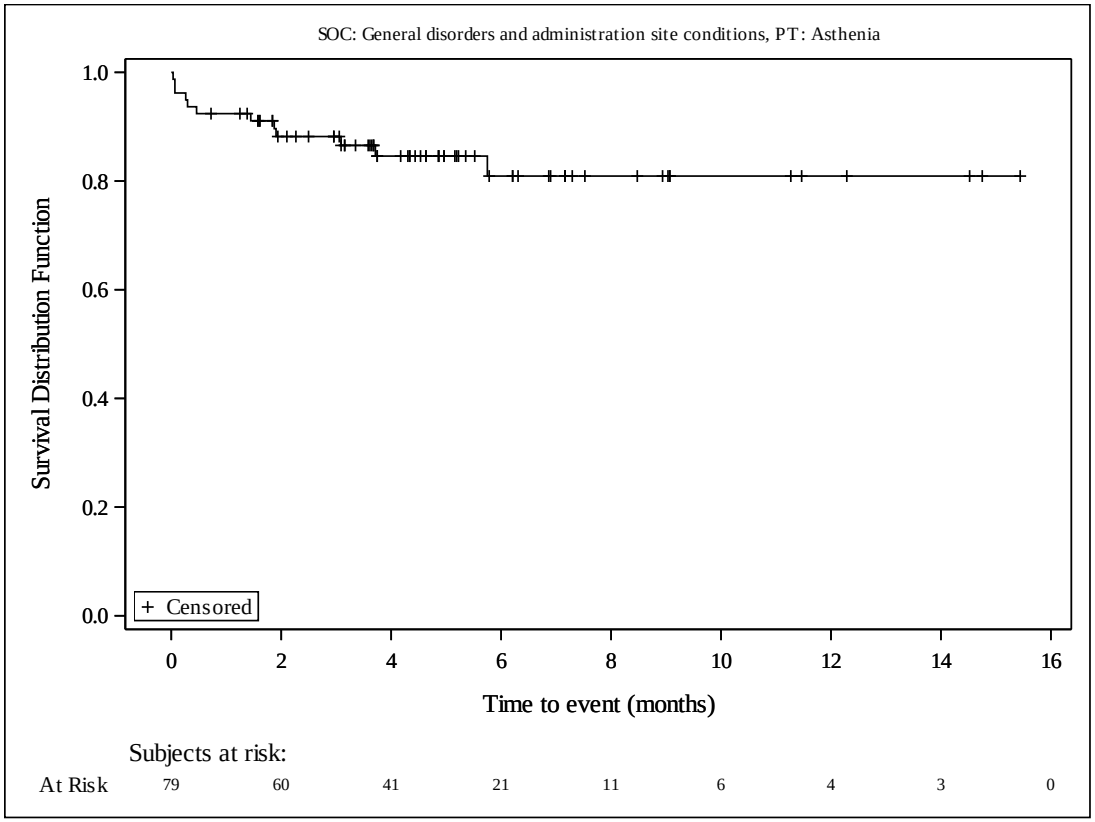

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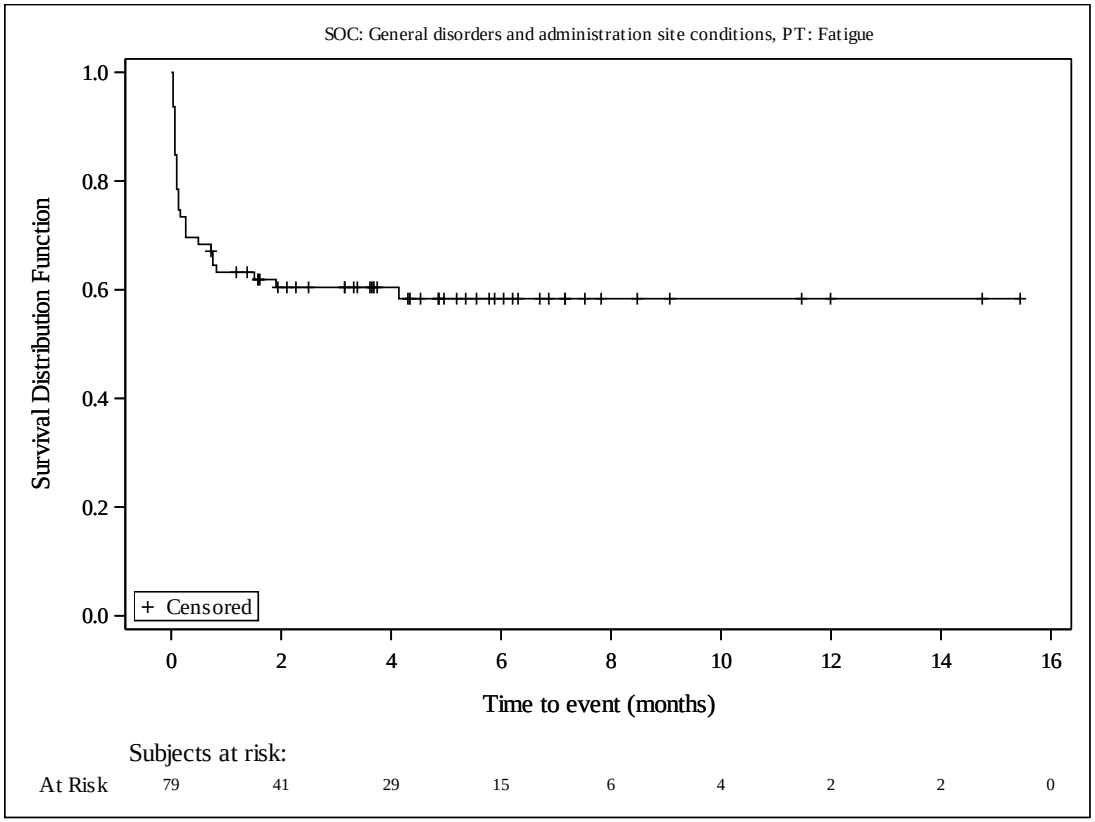

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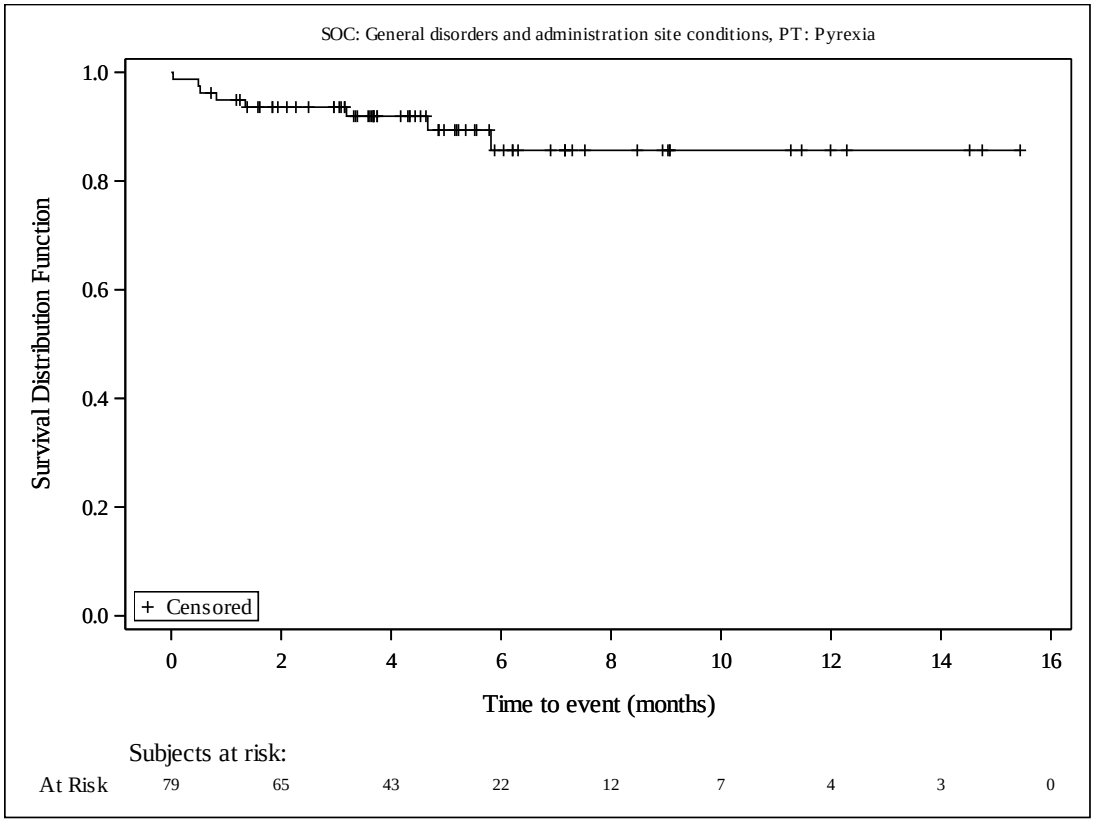

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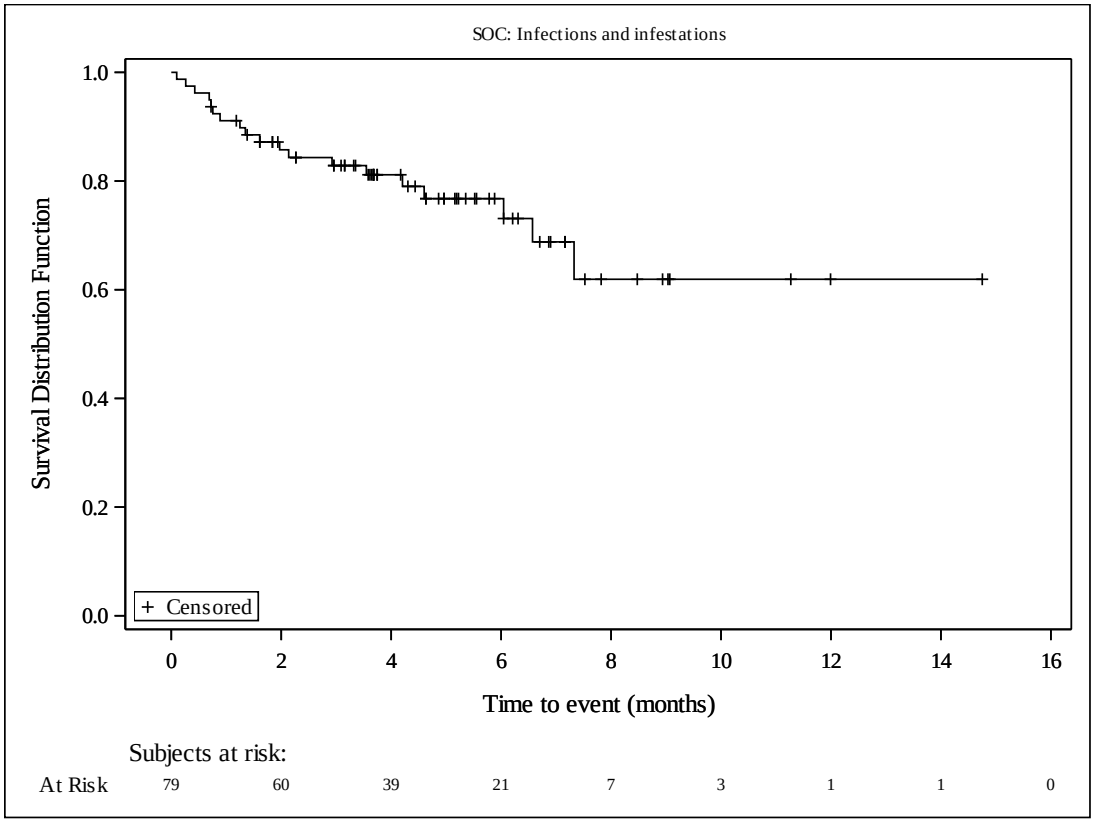

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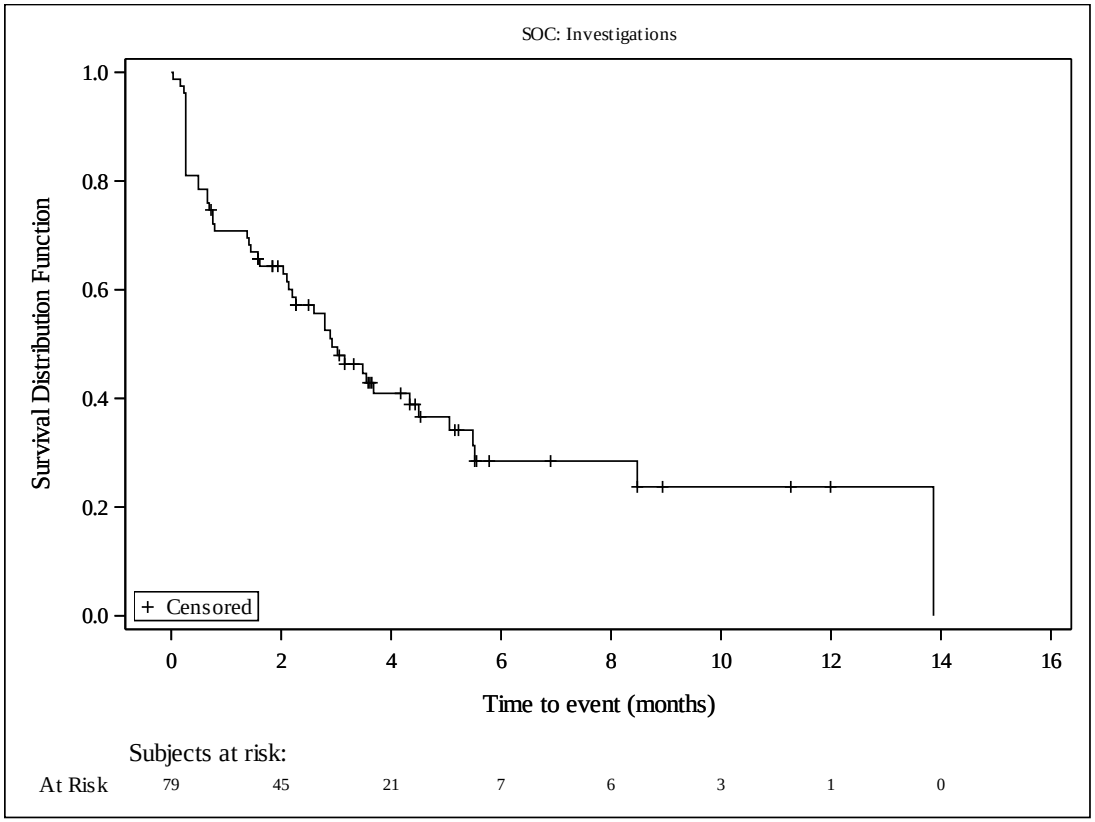

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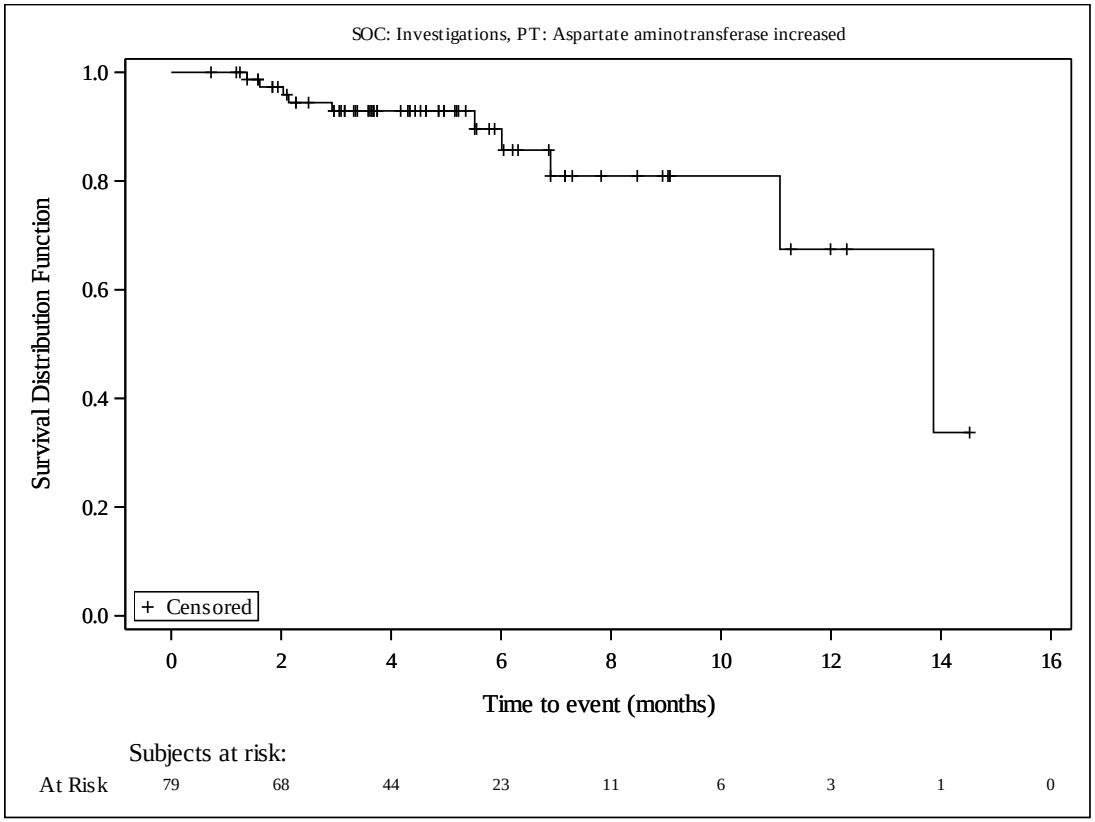

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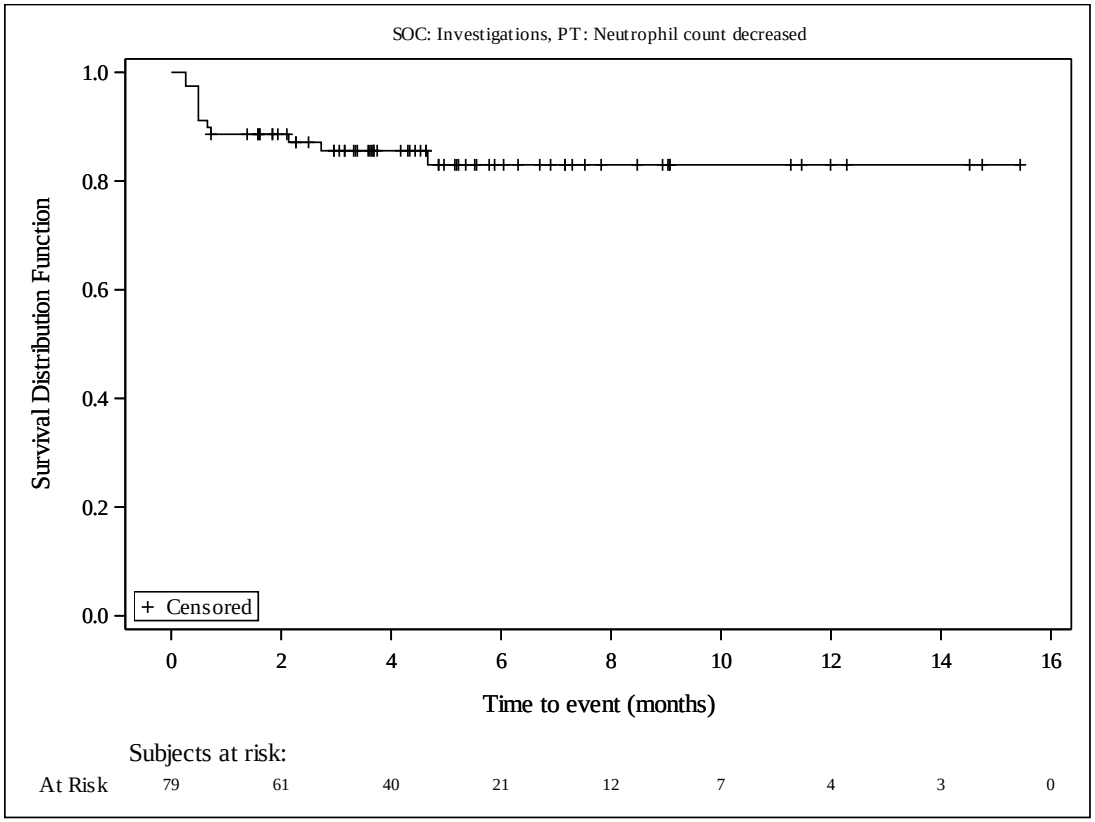

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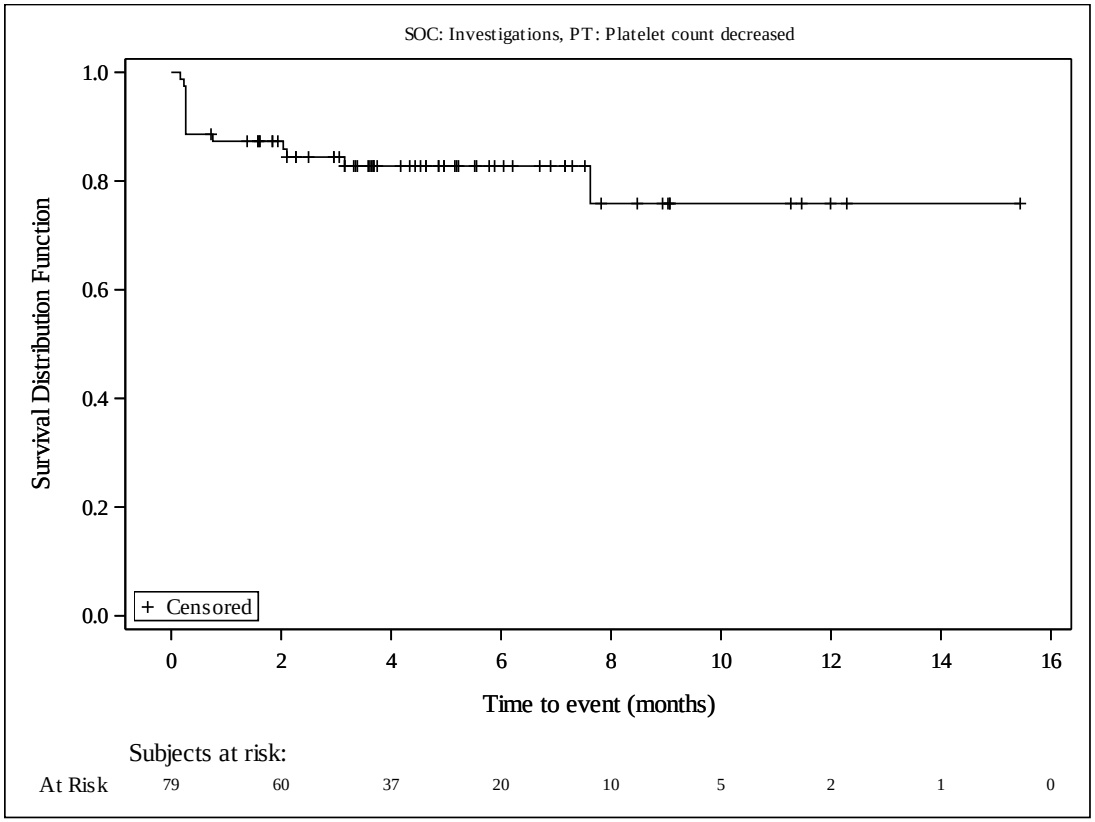

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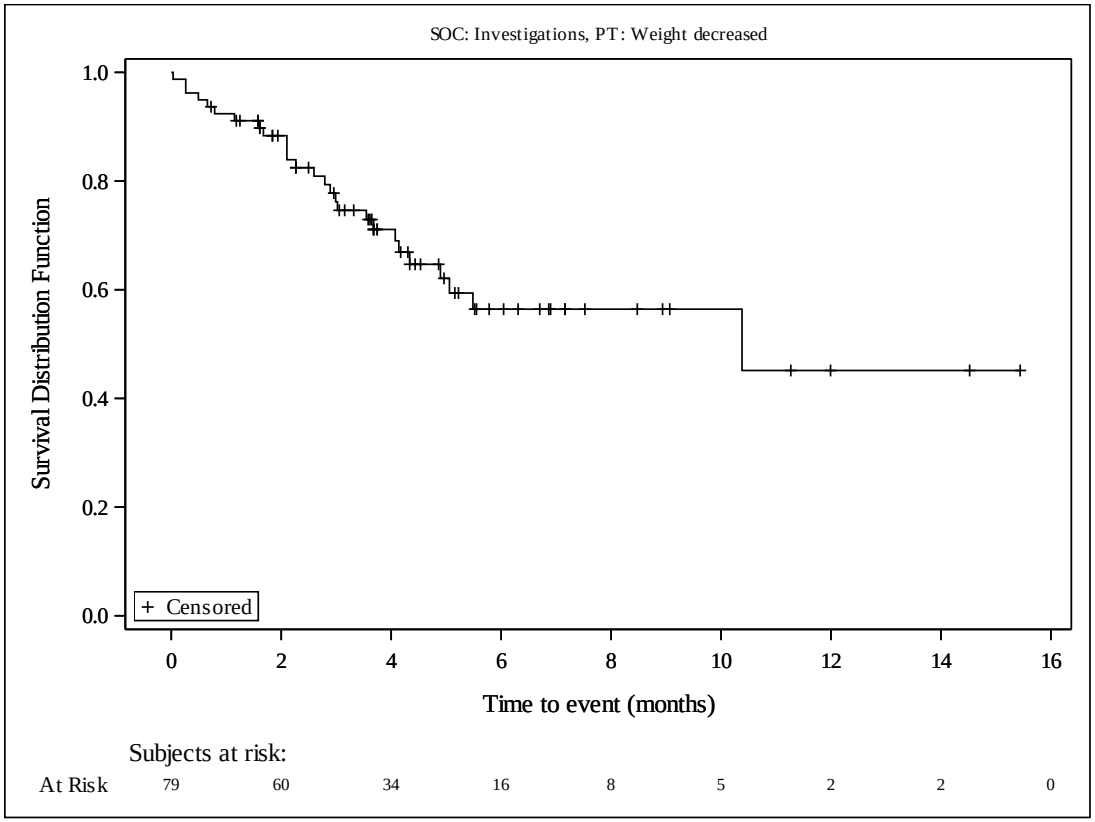

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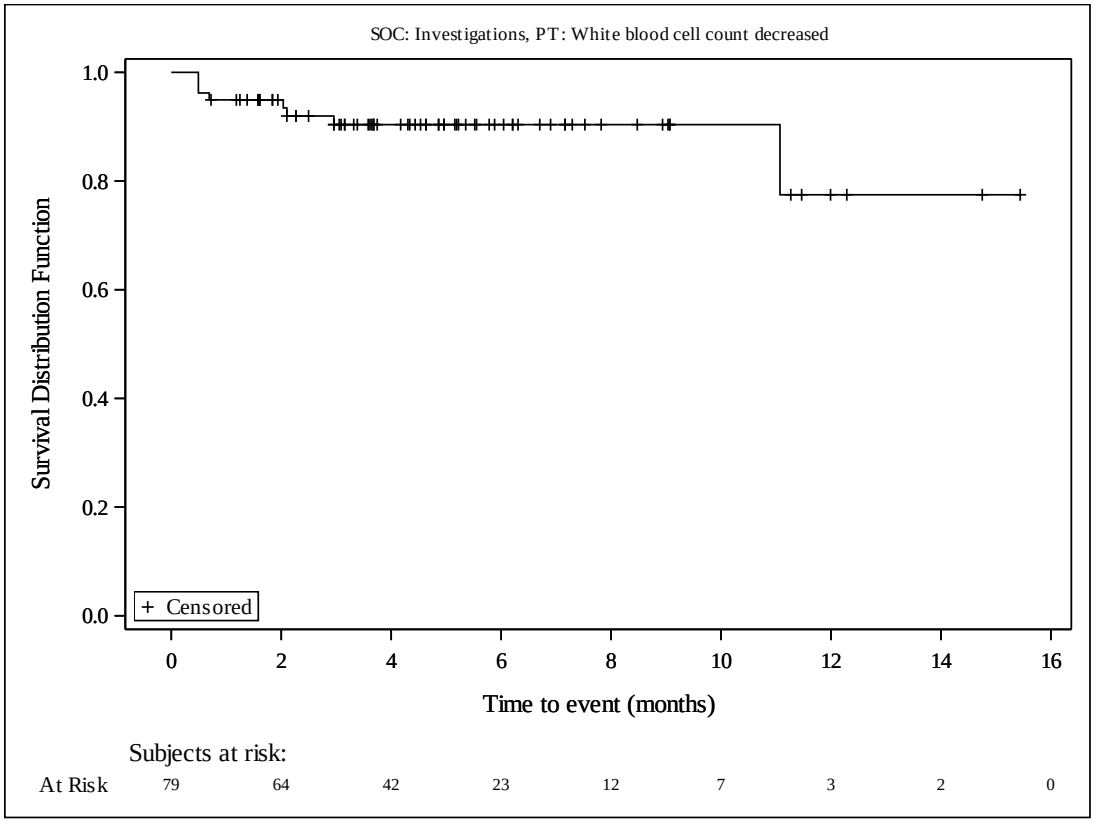

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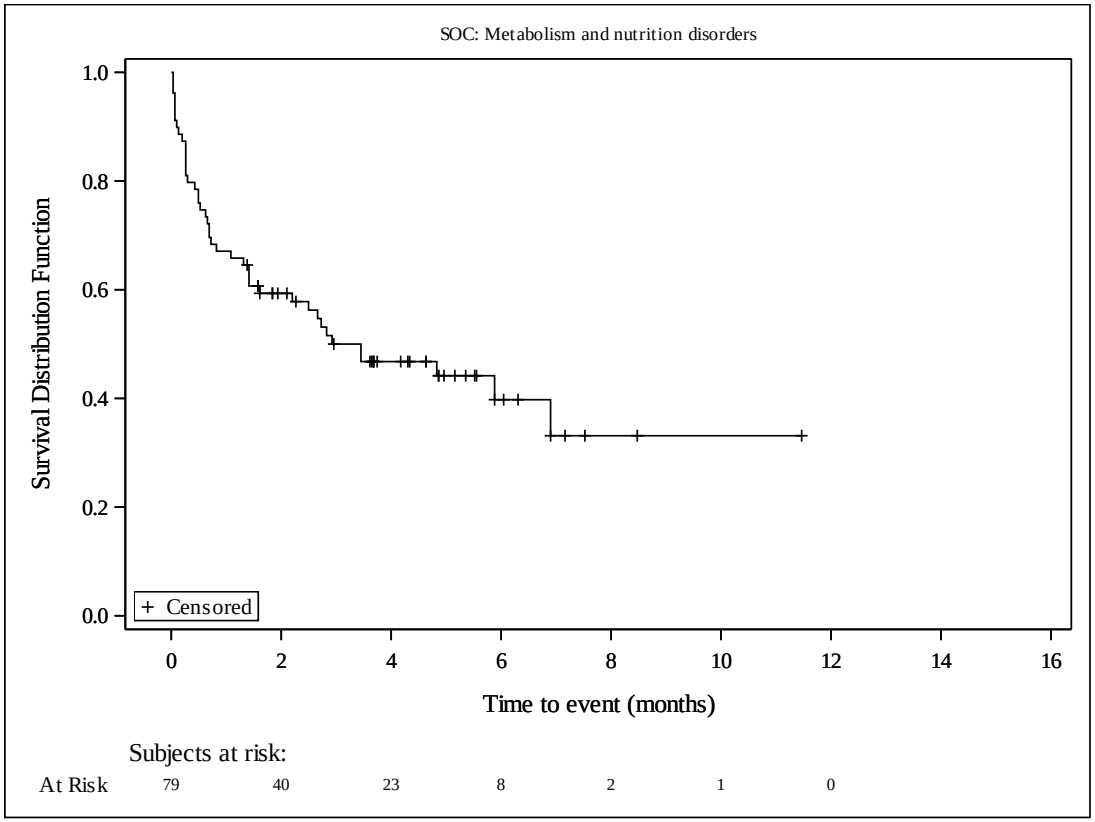

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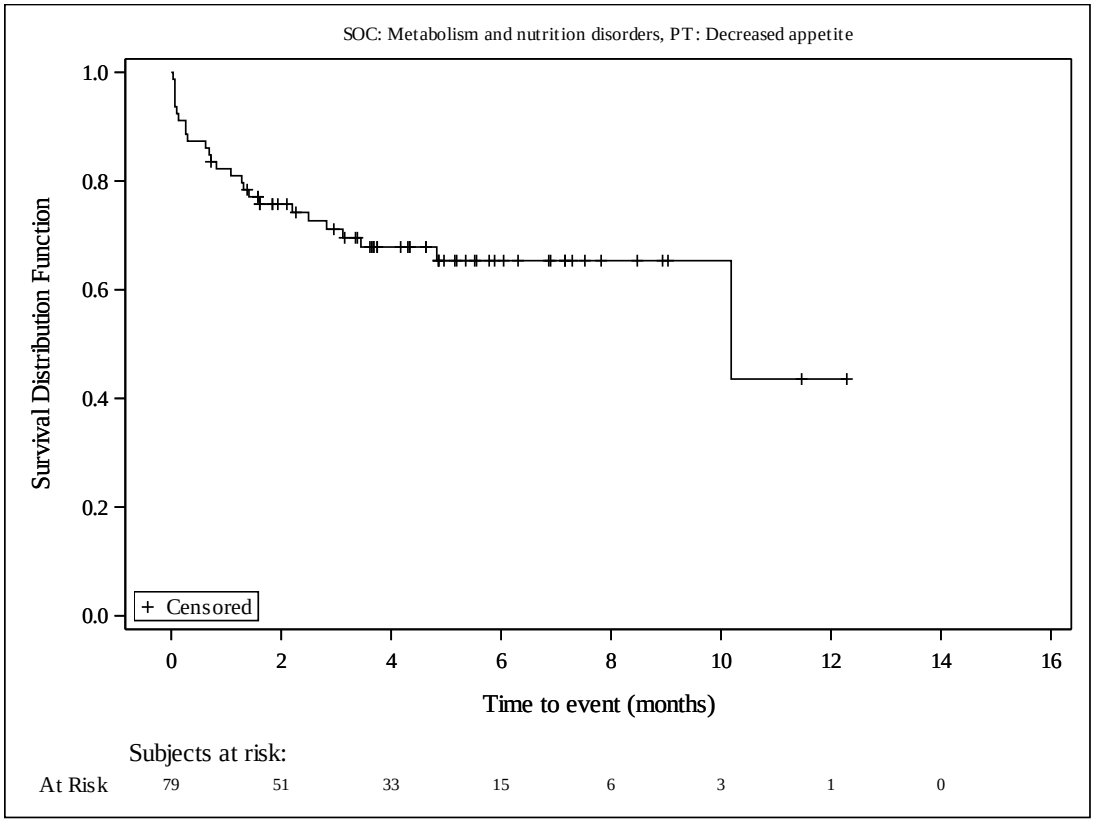
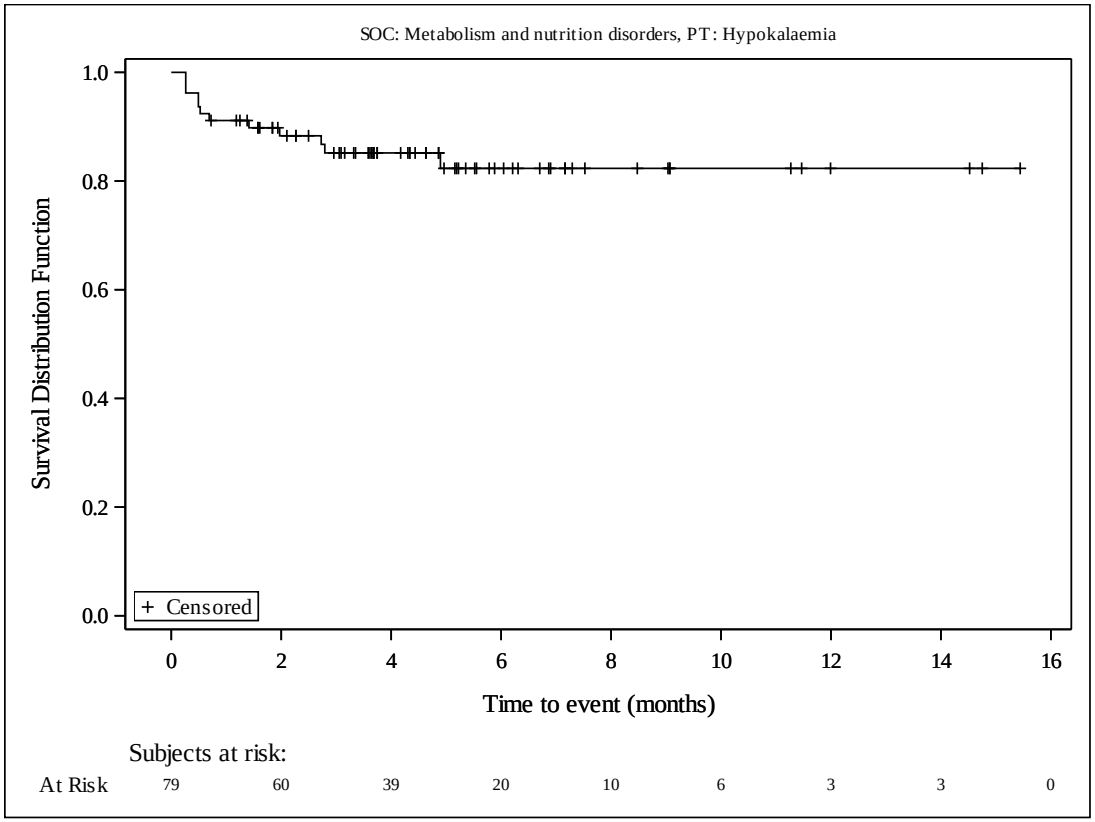


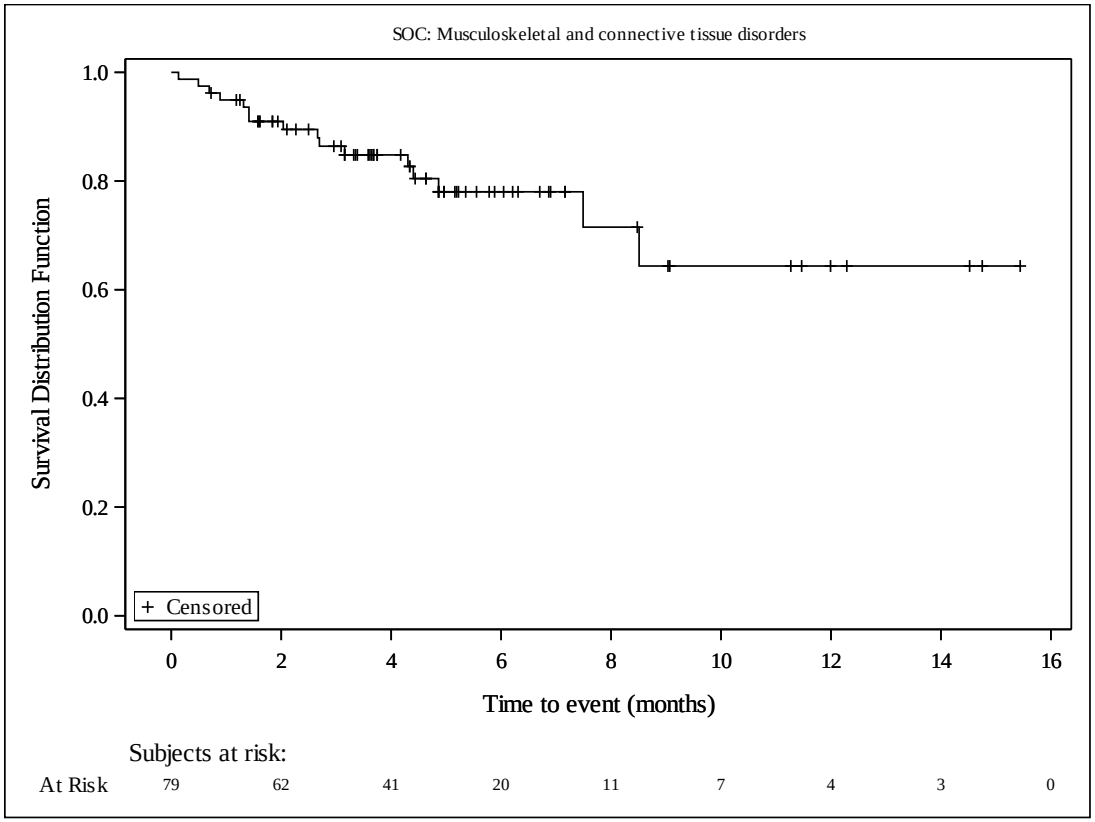
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



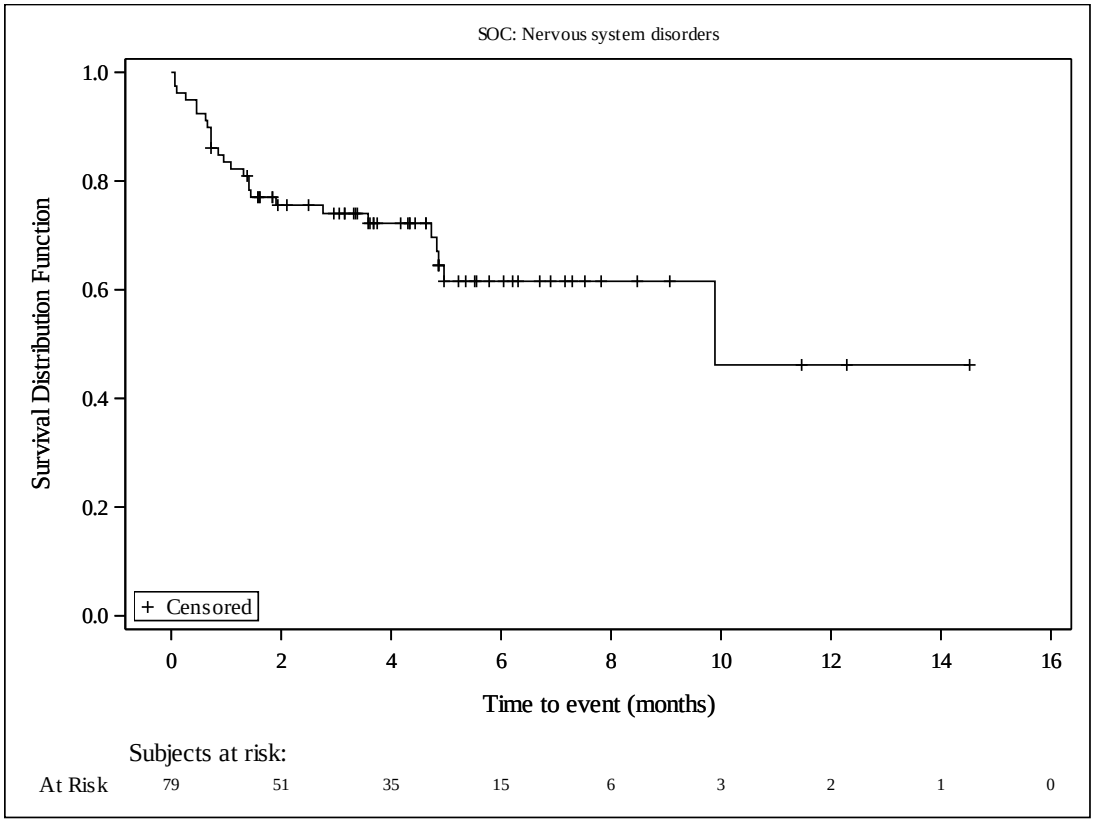
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



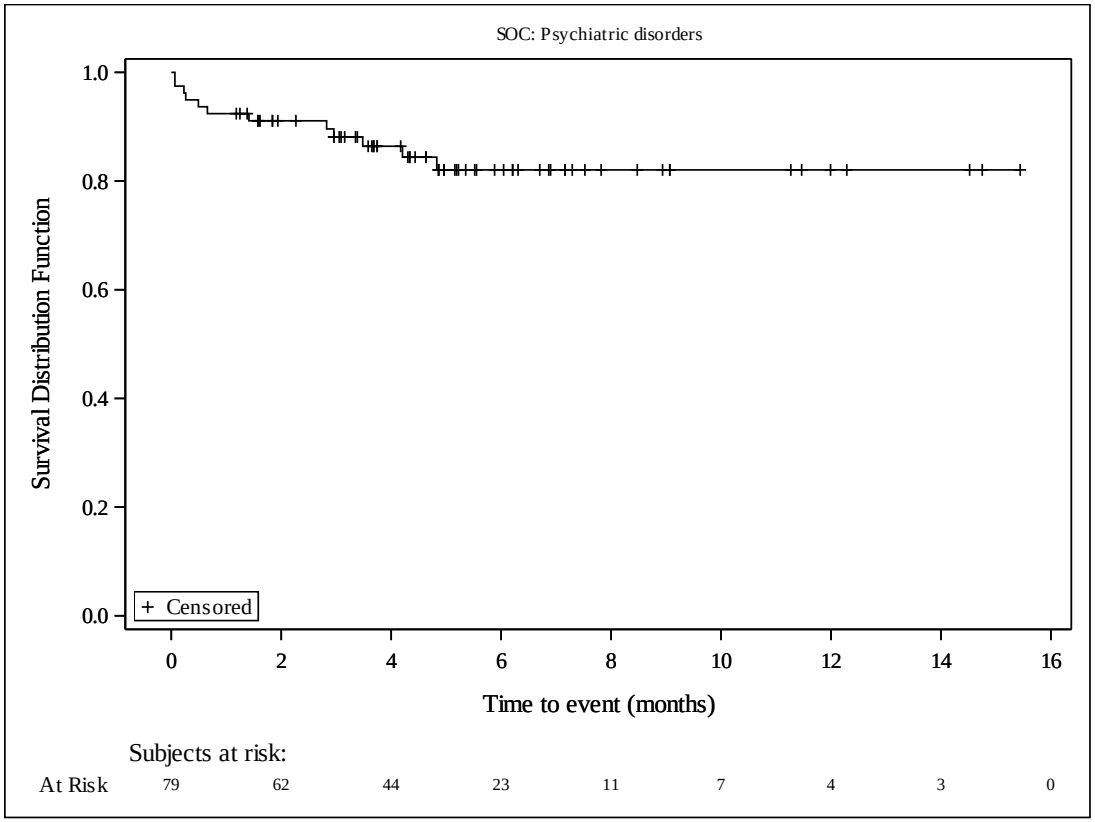
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



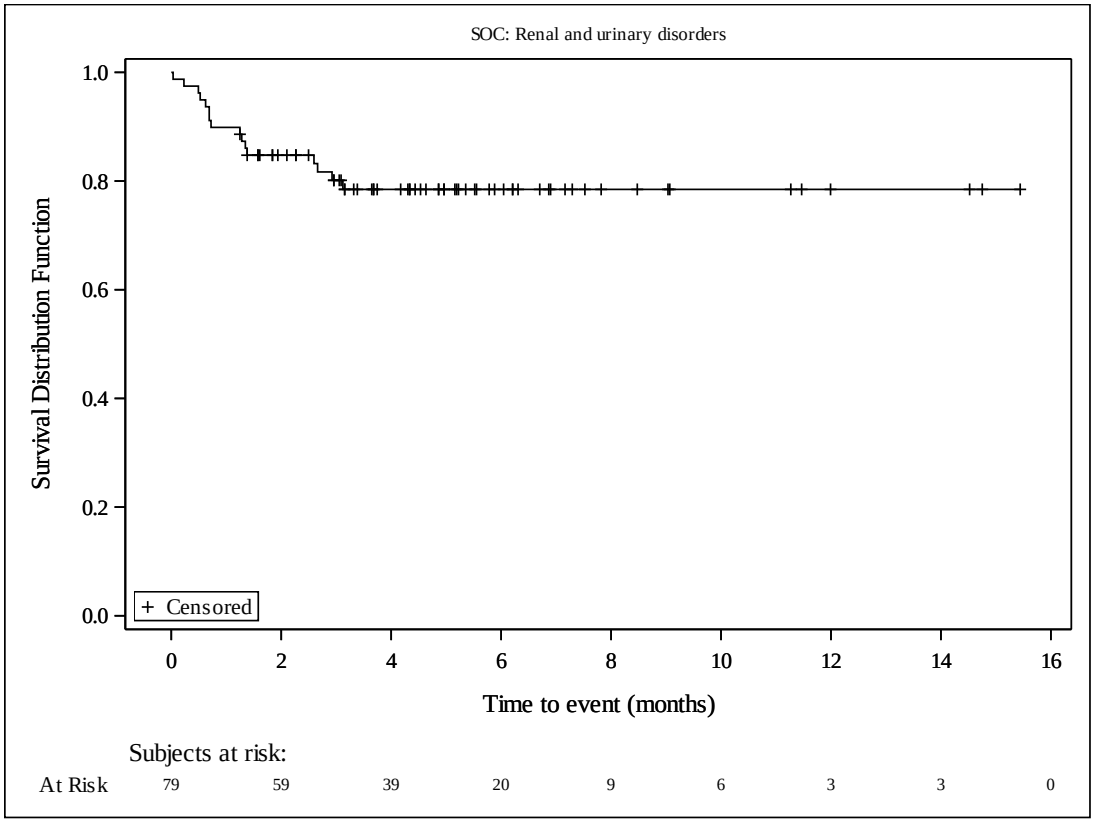
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



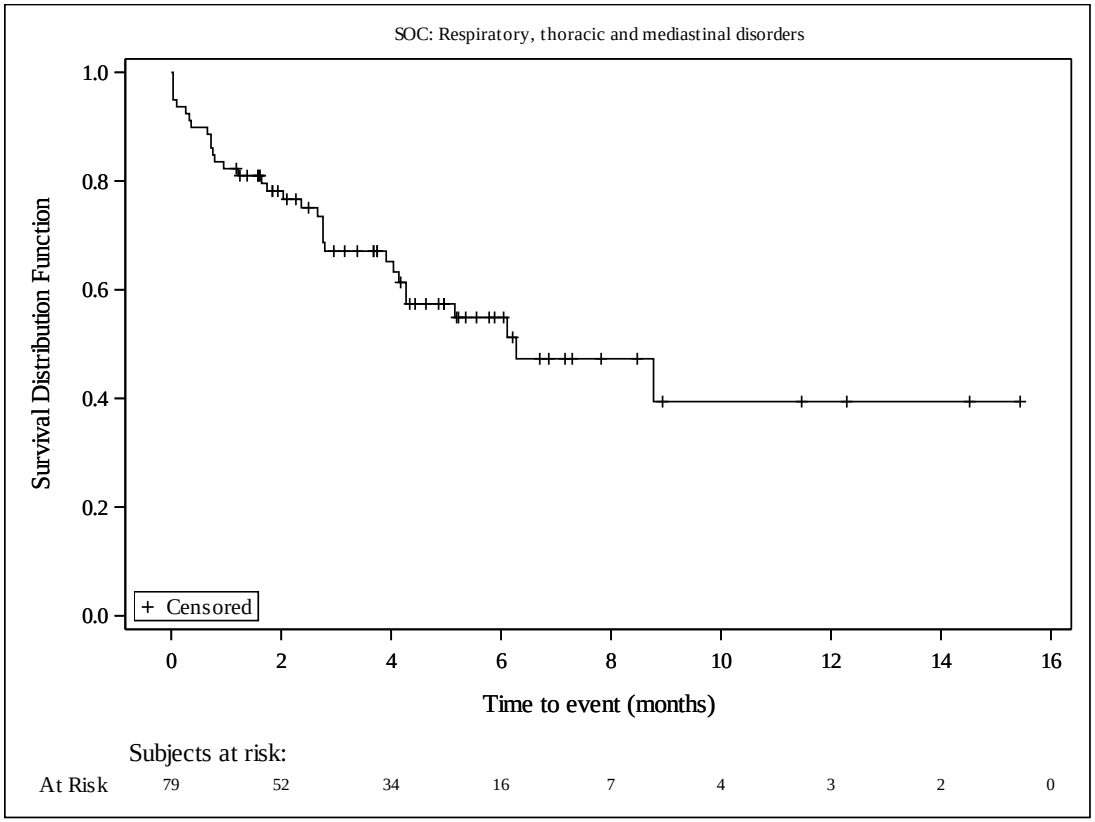
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



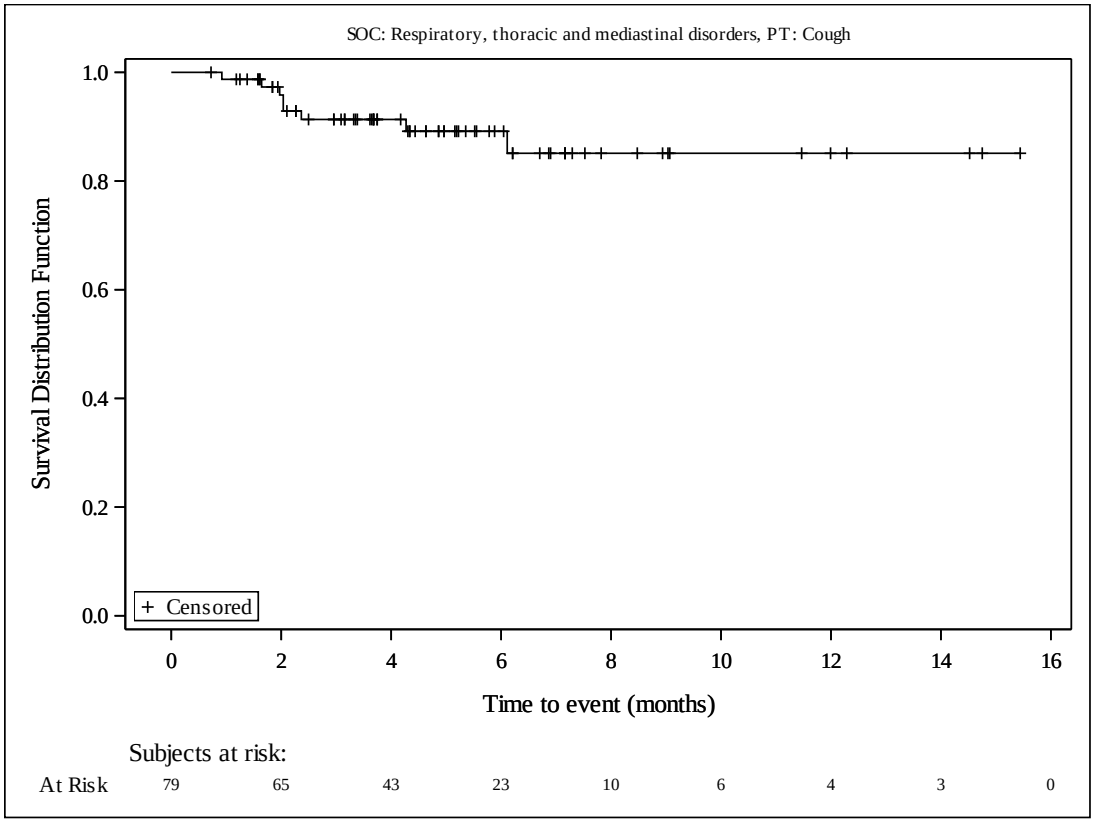
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



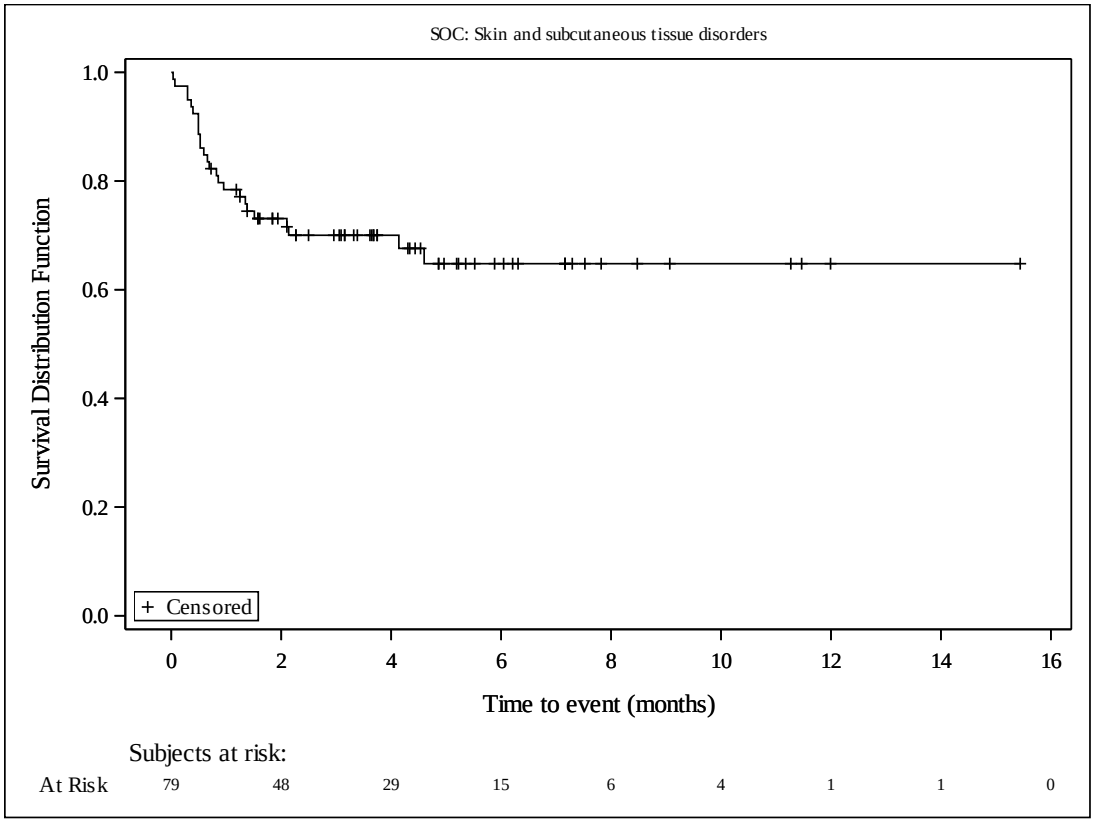
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



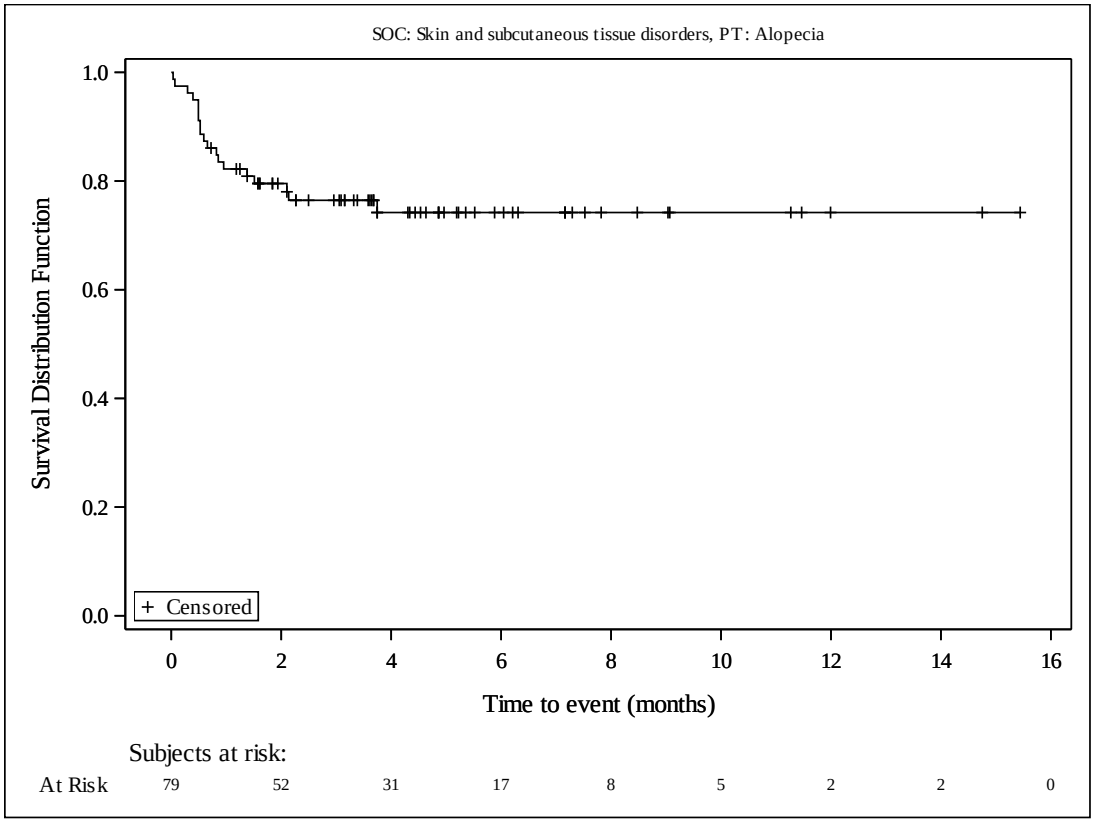
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



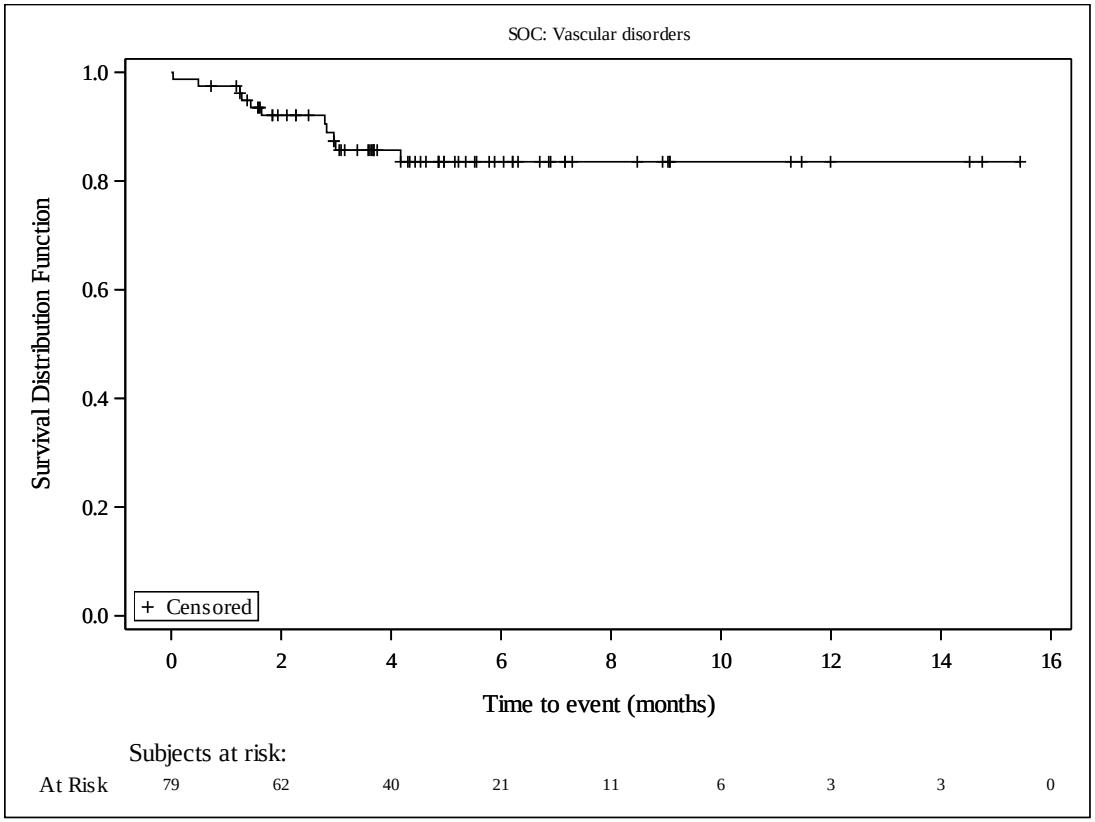
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Overall	12/ 79 (15.2)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	10/ 45 (22.2)	NE (NE , NE)
	Age (Category 1)		
	<65 years	8/ 46 (17.4)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	11/ 75 (14.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.2, NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	10/ 57 (17.5)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	12/ 50 (24.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	10/ 68 (14.7)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.4, NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	10/ 52 (19.2)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (5.2, NE)
	other	10/ 59 (16.9)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	12/ 74 (16.2)	NE (NE , NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.1, NE)
	no	10/ 70 (14.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	12/ 73 (16.4)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	7/ 50 (14.0)	NE (NE , NE)
	no	5/ 29 (17.2)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	5/ 25 (20.0)	NE (5.2, NE)
	moderate	1/ 8 (12.5)	NE (3.5, NE)
	Hepatic impairment at baseline		
	normal	10/ 64 (15.6)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (NE , NE)
	Race		
	White	12/ 69 (17.4)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (1.2, NE)
	Non-Hispanic/Non-Latino	10/ 70 (14.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	0/ 34 (0.0)	NE (NE , NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	4/ 50 (8.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	0/ 27 (0.0)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	0/ 19 (0.0)	NE (NE , NE)
	other	4/ 59 (6.8)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.1, NE)
	no	3/ 70 (4.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	4/ 73 (5.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	4/ 72 (5.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	3/ 64 (4.7)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	4/ 69 (5.8)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Infections and infestations	Overall	9/ 79 (11.4)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (6.0, NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	9/ 75 (12.0)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	0/ 22 (0.0)	NE (NE , NE)
	male	9/ 57 (15.8)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	7/ 50 (14.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	7/ 52 (13.5)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	8/ 59 (13.6)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	9/ 74 (12.2)	NE (NE , NE)
	Previous total gastrectomy		
	no	9/ 79 (11.4)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.9, NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	9/ 73 (12.3)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	9/ 72 (12.5)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	8/ 50 (16.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Infections and infestations	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (6.0, NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (NE , NE)
	mild	5/ 14 (35.7)	NE (1.2, NE)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (0.4, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (3.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	2/ 57 (3.5)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	2/ 50 (4.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	0/ 27 (0.0)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (3.6, NE)
	no	3/ 70 (4.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (3.4, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (3.4, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	3/ 50 (6.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (3.6, NE)
	Hepatic impairment at baseline		
	normal	2/ 64 (3.1)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (3.1, NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (3.4, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Renal and urinary disorders	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	2/ 46 (4.3)	NE (NE , NE)
	>=65 years	2/ 33 (6.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	3/ 75 (4.0)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.2, NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	4/ 50 (8.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	1/ 52 (1.9)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	4/ 73 (5.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	4/ 72 (5.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	1/ 50 (2.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Renal and urinary disorders	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	3/ 64 (4.7)	NE (NE , NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (1.3, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.2, NE)
	Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	3/ 34 (8.8)	NE (NE , NE)
	EU	1/ 45 (2.2)	NE (NE , NE)
	Age (Category 1)		
	<65 years	2/ 46 (4.3)	NE (NE , NE)
	>=65 years	2/ 33 (6.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	3/ 75 (4.0)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (4.0, NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	4/ 50 (8.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	2/ 52 (3.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (3.9, NE)
	other	2/ 59 (3.4)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	4/ 73 (5.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	4/ 72 (5.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	3/ 50 (6.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

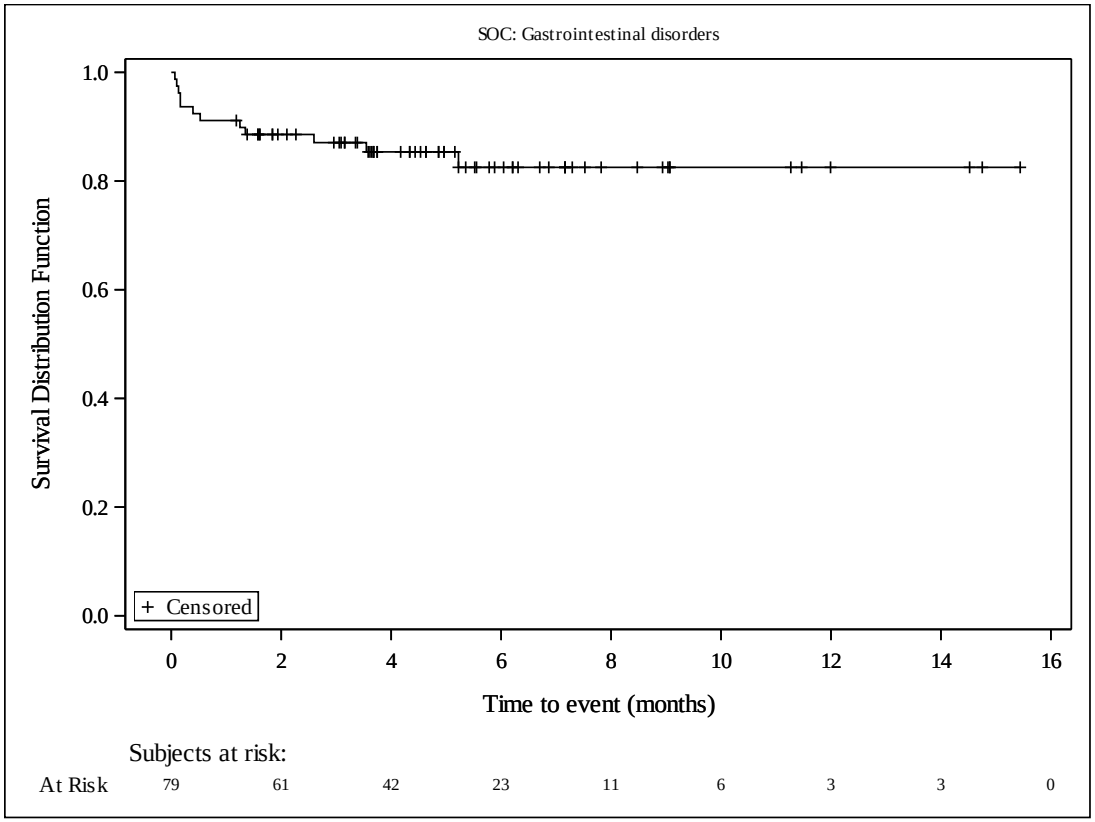
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (3.9, NE)
	Hepatic impairment at baseline		
	normal	2/ 64 (3.1)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (3.6, NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	4.0 (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.9, NE)
	Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

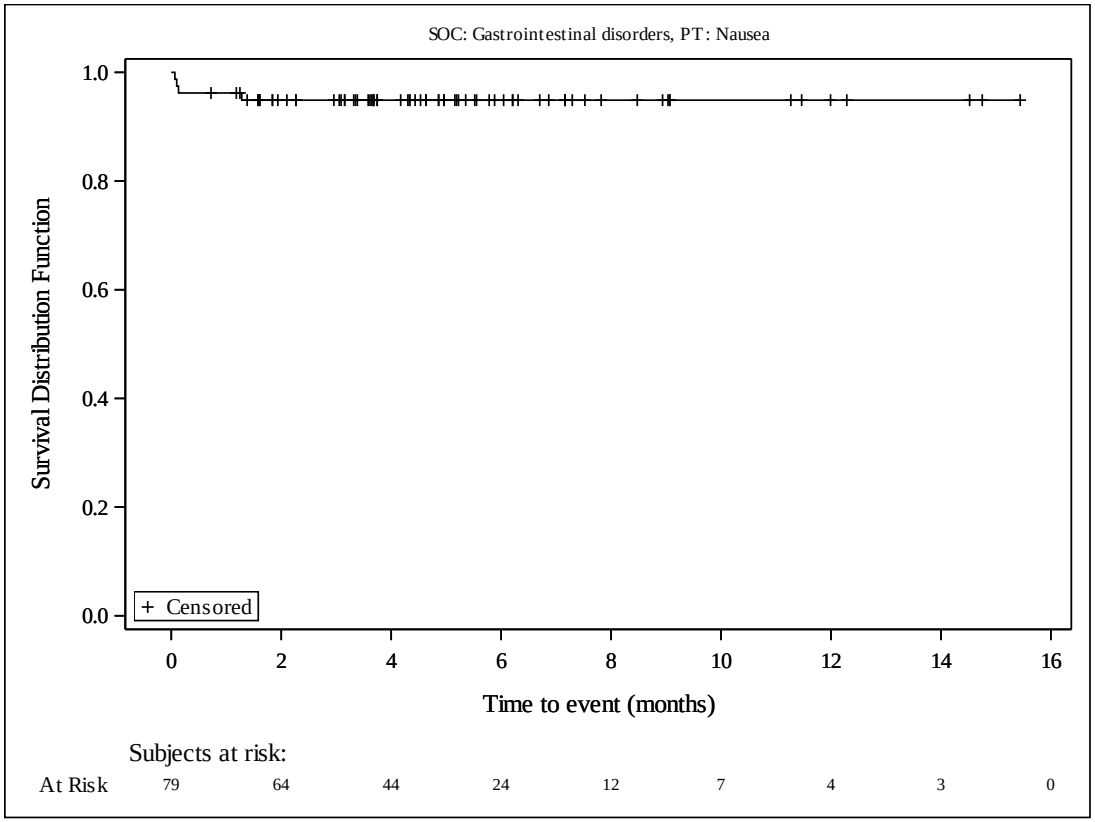
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



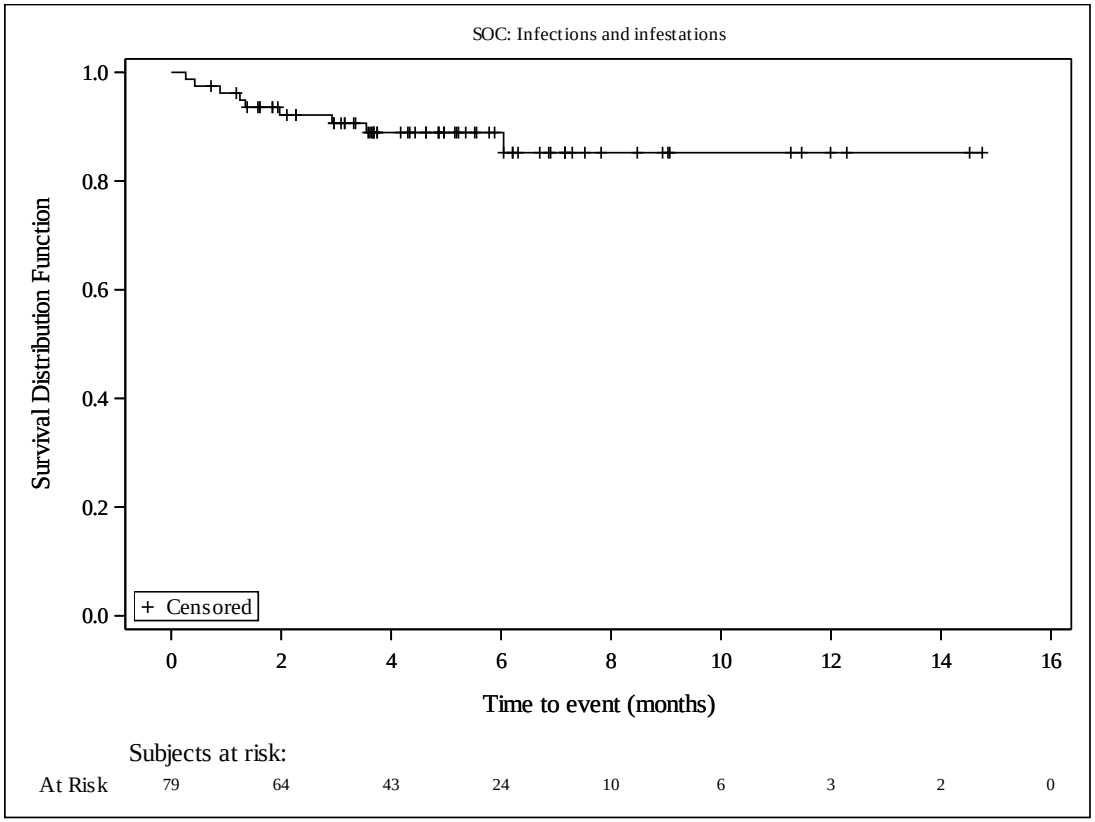
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



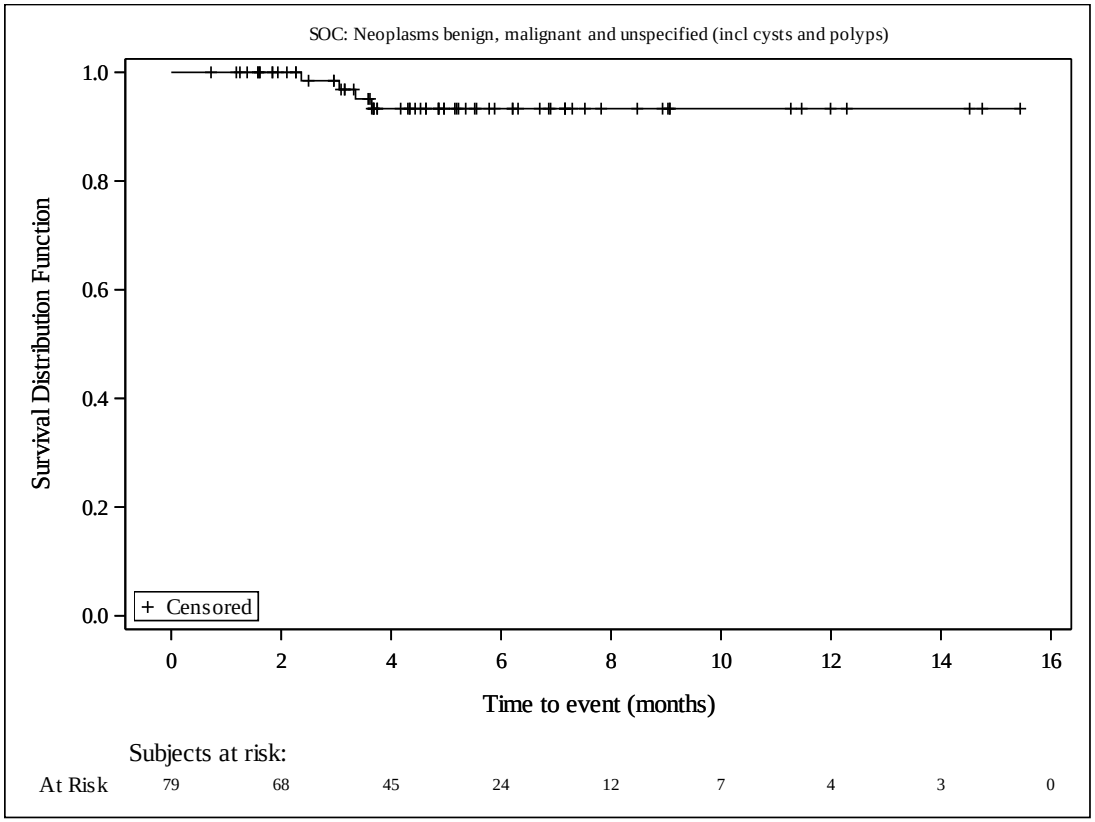
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



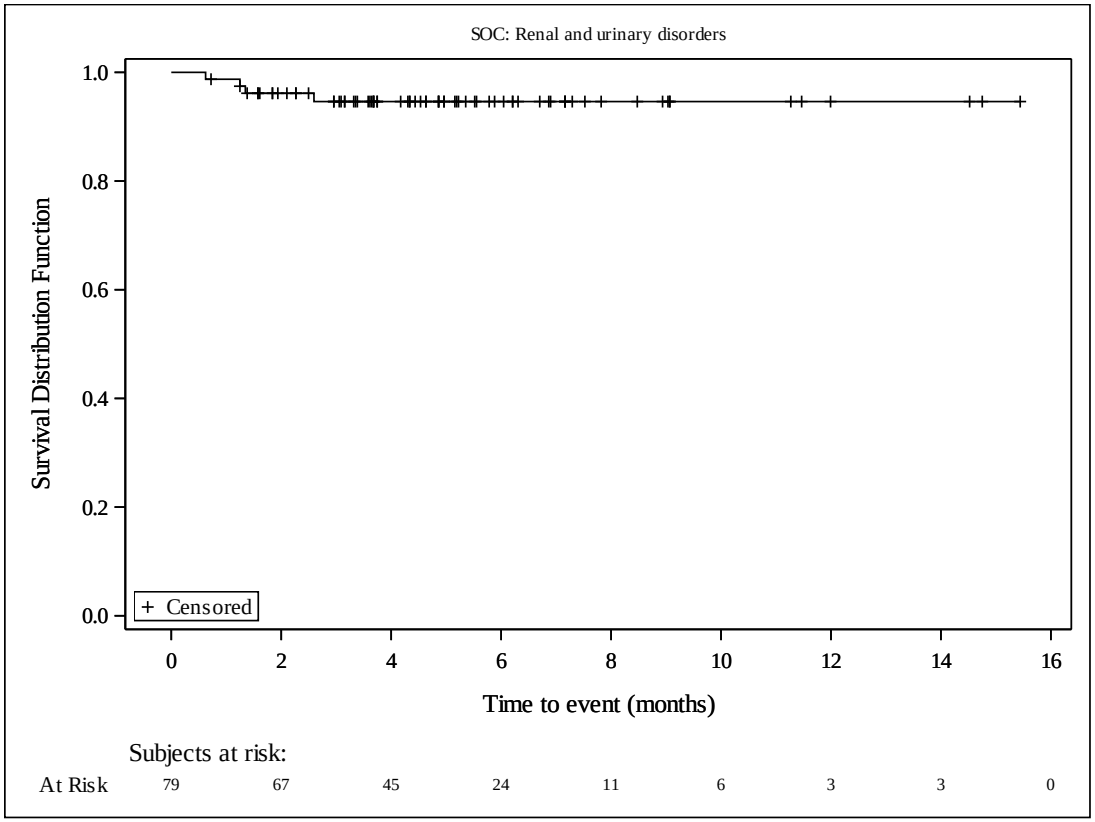
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



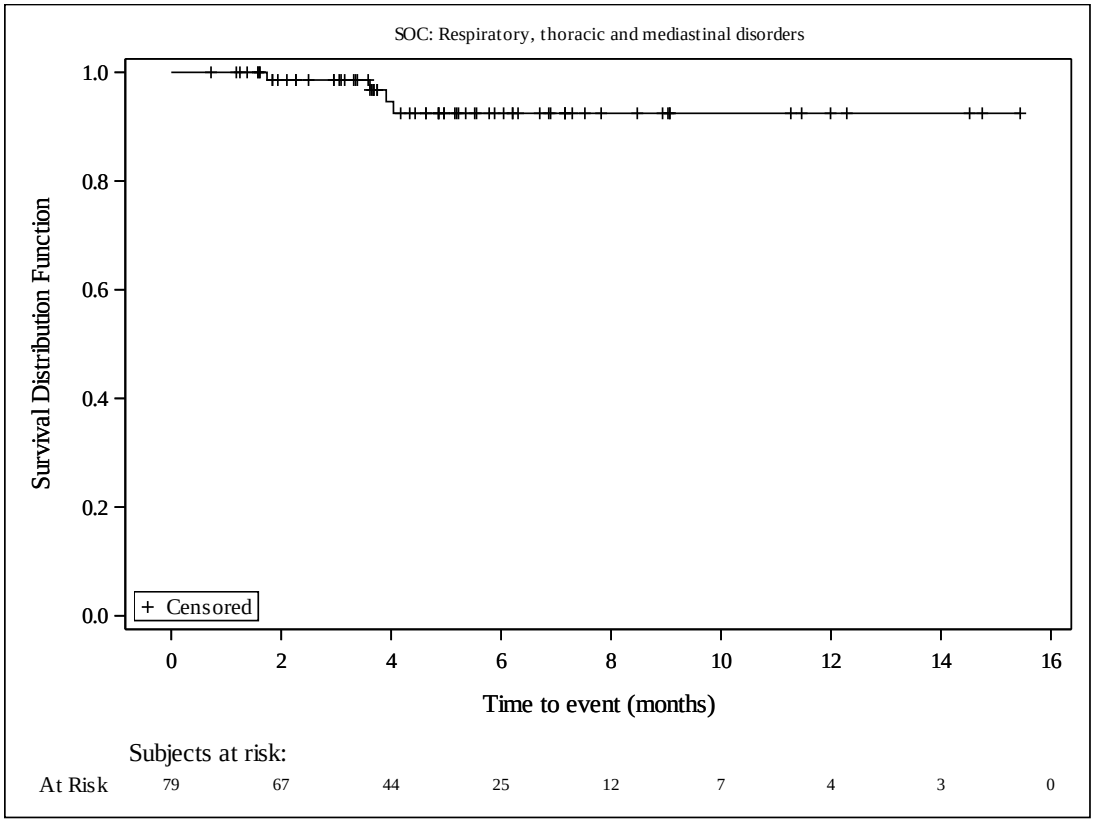
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders	Overall	18/ 79 (22.8)	NE (9.8, NE)
	Region		
	North America	7/ 34 (20.6)	NE (9.8, NE)
	EU	11/ 45 (24.4)	11.3 (NE , NE)
	Age (Category 1)		
	<65 years	11/ 46 (23.9)	11.3 (9.8, NE)
	>=65 years	7/ 33 (21.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	16/ 75 (21.3)	NE (9.8, NE)
	>=75 years	2/ 4 (50.0)	NE (0.3, NE)
	Sex		
	female	7/ 22 (31.8)	NE (3.7, NE)
	male	11/ 57 (19.3)	11.3 (9.8, NE)
	ECOG PS		
	0	4/ 29 (13.8)	11.3 (9.8, NE)
	1	14/ 50 (28.0)	NE (5.1, NE)
	HER2 Status in central laboratory		
	IHC 3+	16/ 68 (23.5)	11.3 (9.8, NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	11/ 27 (40.7)	NE (2.7, NE)
	GEJ	7/ 52 (13.5)	NE (9.8, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	6/ 19 (31.6)	9.8 (5.1, 11.3)
	other	12/ 59 (20.3)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.5, NE)
	>=2	17/ 74 (23.0)	11.3 (9.8, NE)
	Previous total gastrectomy		
	no	18/ 79 (22.8)	NE (9.8, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	11.3 (0.0, 11.3)
	no	13/ 70 (18.6)	NE (9.8, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.5, NE)
	no	17/ 73 (23.3)	11.3 (9.8, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.5, NE)
	no	17/ 72 (23.6)	11.3 (9.8, NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	11.3 (9.8, NE)
	no	8/ 29 (27.6)	NE (4.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders	Renal impairment at baseline		
	normal	6/ 32 (18.8)	9.8 (9.8, NE)
	mild	4/ 25 (16.0)	NE (11.3, NE)
	moderate	3/ 8 (37.5)	NE (0.4, NE)
	Hepatic impairment at baseline		
	normal	13/ 64 (20.3)	11.3 (9.8, NE)
	mild	4/ 14 (28.6)	NE (1.3, NE)
	Race		
	White	12/ 69 (17.4)	NE (9.8, NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	5/ 8 (62.5)	4.6 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	7.5 (5.1, 9.8)
	Non-Hispanic/Non-Latino	15/ 70 (21.4)	NE (11.3, NE)
	Unknown	1/ 4 (25.0)	NE (4.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Overall	11/ 79 (13.9)	NE (9.8, NE)
	Region		
	North America	4/ 34 (11.8)	NE (9.8, NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (9.8, NE)
	>=65 years	6/ 33 (18.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	9/ 75 (12.0)	NE (9.8, NE)
	>=75 years	2/ 4 (50.0)	NE (0.3, NE)
	Sex		
	female	5/ 22 (22.7)	NE (4.2, NE)
	male	6/ 57 (10.5)	NE (9.8, NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (9.8, NE)
	1	9/ 50 (18.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	9/ 68 (13.2)	NE (9.8, NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	7/ 27 (25.9)	NE (5.1, NE)
	GEJ	4/ 52 (7.7)	NE (9.8, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	9.8 (5.1, NE)
	other	8/ 59 (13.6)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	11/ 74 (14.9)	NE (9.8, NE)
	Previous total gastrectomy		
	no	11/ 79 (13.9)	NE (9.8, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	3/ 9 (33.3)	NE (0.0, NE)
	no	8/ 70 (11.4)	NE (9.8, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	11/ 73 (15.1)	NE (9.8, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	11/ 72 (15.3)	NE (9.8, NE)
	Presence of liver metastasis at baseline		
	yes	6/ 50 (12.0)	NE (9.8, NE)
	no	5/ 29 (17.2)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Renal impairment at baseline		
	normal	4/ 32 (12.5)	9.8 (9.8, NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	2/ 8 (25.0)	NE (2.7, NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (9.8, NE)
	mild	3/ 14 (21.4)	NE (5.1, NE)
	Race		
	White	7/ 69 (10.1)	NE (9.8, NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	3/ 8 (37.5)	5.1 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	7.5 (5.1, 9.8)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (4.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Overall	4/ 79 (5.1)	NE (11.3, NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	2/ 45 (4.4)	11.3 (11.3, NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (11.3, NE)
	>=65 years	0/ 33 (0.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (11.3, NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	2/ 57 (3.5)	NE (11.3, NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (11.3, NE)
	1	2/ 50 (4.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (11.3, NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	2/ 52 (3.8)	NE (11.3, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	11.3 (11.3, NE)
	other	2/ 59 (3.4)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.5, NE)
	>=2	3/ 74 (4.1)	NE (11.3, NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (11.3, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	11.3 (0.5, 11.3)
	no	2/ 70 (2.9)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.5, NE)
	no	3/ 73 (4.1)	NE (11.3, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.5, NE)
	no	3/ 72 (4.2)	NE (11.3, NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (11.3, NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Renal impairment at baseline		
	normal	1/ 32 (3.1)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (11.3, NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (11.3, NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	3/ 69 (4.3)	NE (11.3, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (11.3, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Overall	18/ 79 (22.8)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (NE , NE)
	EU	13/ 45 (28.9)	NE (5.2, NE)
	Age (Category 1)		
	<65 years	13/ 46 (28.3)	NE (5.2, NE)
	>=65 years	5/ 33 (15.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	18/ 75 (24.0)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	6/ 22 (27.3)	NE (5.2, NE)
	male	12/ 57 (21.1)	NE (NE , NE)
	ECOG PS		
	0	4/ 29 (13.8)	NE (NE , NE)
	1	14/ 50 (28.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	15/ 68 (22.1)	NE (NE , NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.4, NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (NE , NE)
	GEJ	13/ 52 (25.0)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	5/ 19 (26.3)	NE (3.5, NE)
	other	13/ 59 (22.0)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	18/ 74 (24.3)	NE (NE , NE)
	Previous total gastrectomy		
	no	18/ 79 (22.8)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.1, NE)
	no	16/ 70 (22.9)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.8, NE)
	no	17/ 73 (23.3)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.8, NE)
	no	17/ 72 (23.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	9/ 50 (18.0)	NE (NE , NE)
	no	9/ 29 (31.0)	NE (3.7, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Renal impairment at baseline		
	normal	8/ 32 (25.0)	NE (NE , NE)
	mild	4/ 25 (16.0)	NE (NE , NE)
	moderate	2/ 8 (25.0)	NE (3.5, NE)
	Hepatic impairment at baseline		
	normal	13/ 64 (20.3)	NE (NE , NE)
	mild	4/ 14 (28.6)	NE (0.8, NE)
	Race		
	White	16/ 69 (23.2)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (2.8, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.5, NE)
	Non-Hispanic/Non-Latino	16/ 70 (22.9)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (4.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Overall	6/ 79 (7.6)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	5/ 45 (11.1)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	6/ 75 (8.0)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	4/ 57 (7.0)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	6/ 50 (12.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.6, NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (NE , NE)
	GEJ	5/ 52 (9.6)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	6/ 74 (8.1)	NE (NE , NE)
	Previous total gastrectomy		
	no	6/ 79 (7.6)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.1, NE)
	no	5/ 70 (7.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	6/ 72 (8.3)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	3/ 50 (6.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	6/ 69 (8.7)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	6/ 70 (8.6)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: General disorders and administration site conditions	Overall	6/ 79 (7.6)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	2/ 4 (50.0)	NE (0.3, NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	4/ 57 (7.0)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	5/ 50 (10.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	6/ 68 (8.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	NE (NE , NE)
	GEJ	2/ 52 (3.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	4/ 59 (6.8)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (4.1, NE)
	>=2	5/ 74 (6.8)	NE (NE , NE)
	Previous total gastrectomy		
	no	6/ 79 (7.6)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.7, NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	6/ 72 (8.3)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	1/ 50 (2.0)	NE (NE , NE)
	no	5/ 29 (17.2)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (4.3, NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	6/ 69 (8.7)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.3, NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Infections and infestations	Overall	10/ 79 (12.7)	NE (NE , NE)
	Region		
	North America	6/ 34 (17.6)	NE (6.0, NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	5/ 33 (15.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	9/ 75 (12.0)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (4.2, NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	9/ 57 (15.8)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	8/ 50 (16.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	8/ 68 (11.8)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	7/ 52 (13.5)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	9/ 59 (15.3)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	10/ 74 (13.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	10/ 79 (12.7)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.9, NE)
	no	9/ 70 (12.9)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	10/ 73 (13.7)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	10/ 72 (13.9)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	9/ 50 (18.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Infections and infestations	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (6.0, NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (NE , NE)
	mild	6/ 14 (42.9)	NE (1.2, NE)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	4.2 (NE , NE)
	Other	1/ 8 (12.5)	NE (0.4, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	9/ 70 (12.9)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (3.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Investigations	Overall	11/ 79 (13.9)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (NE , NE)
	EU	6/ 45 (13.3)	NE (NE , NE)
	Age (Category 1)		
	<65 years	7/ 46 (15.2)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	10/ 75 (13.3)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (0.5, NE)
	Sex		
	female	4/ 22 (18.2)	NE (NE , NE)
	male	7/ 57 (12.3)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	9/ 50 (18.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	9/ 68 (13.2)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.6, NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (NE , NE)
	GEJ	6/ 52 (11.5)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	5/ 19 (26.3)	NE (3.0, NE)
	other	6/ 59 (10.2)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	11/ 74 (14.9)	NE (NE , NE)
	Previous total gastrectomy		
	no	11/ 79 (13.9)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.5, NE)
	no	10/ 70 (14.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.5, NE)
	no	10/ 73 (13.7)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.5, NE)
	no	9/ 72 (12.5)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	9/ 50 (18.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	4/ 25 (16.0)	NE (NE , NE)
	moderate	2/ 8 (25.0)	NE (0.3, NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	6/ 14 (42.9)	NE (0.5, NE)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
	Other	3/ 8 (37.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	10/ 70 (14.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Investigations, PT: Neutrophil count decreased	Overall	6/ 79 (7.6)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	5/ 75 (6.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (0.5, NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	5/ 57 (8.8)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	5/ 50 (10.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	6/ 68 (8.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	4/ 59 (6.8)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	6/ 74 (8.1)	NE (NE , NE)
	Previous total gastrectomy		
	no	6/ 79 (7.6)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.5, NE)
	no	5/ 70 (7.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.5, NE)
	no	5/ 72 (6.9)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	5/ 50 (10.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Neutrophil count decreased	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (0.5, NE)
	Hepatic impairment at baseline		
	normal	1/ 64 (1.6)	NE (NE , NE)
	mild	5/ 14 (35.7)	NE (0.5, NE)
	Race		
	White	4/ 69 (5.8)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
	Other	1/ 8 (12.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	5/ 70 (7.1)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: White blood cell count decreased	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	3/ 34 (8.8)	NE (NE , NE)
	EU	1/ 45 (2.2)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	3/ 75 (4.0)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (0.5, NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	2/ 57 (3.5)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	3/ 50 (6.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	2/ 52 (3.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	2/ 59 (3.4)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.5, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.5, NE)
	no	2/ 72 (2.8)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (NE , NE)
	no	0/ 29 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: White blood cell count decreased	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	1/ 64 (1.6)	NE (NE , NE)
	mild	3/ 14 (21.4)	NE (3.0, NE)
	Race		
	White	1/ 69 (1.4)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Metabolism and nutrition disorders	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	3/ 34 (8.8)	NE (NE , NE)
	EU	5/ 45 (11.1)	NE (NE , NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	7/ 75 (9.3)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.4, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	5/ 57 (8.8)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	6/ 50 (12.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	5/ 52 (9.6)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	8/ 74 (10.8)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.9, NE)
	no	7/ 73 (9.6)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.9, NE)
	no	7/ 72 (9.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	5/ 50 (10.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (3.4, NE)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (2.9, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.4, NE)
	Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	1/ 46 (2.2)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	3/ 50 (6.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	4/ 73 (5.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	4/ 72 (5.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	2/ 64 (3.1)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	4/ 69 (5.8)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	2/ 57 (3.5)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	2/ 50 (4.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	0/ 27 (0.0)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (3.6, NE)
	no	3/ 70 (4.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (3.0, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (3.0, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	3/ 50 (6.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (3.6, NE)
	Hepatic impairment at baseline		
	normal	2/ 64 (3.1)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (3.1, NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (3.0, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Nervous system disorders	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	2/ 45 (4.4)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	4/ 50 (8.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	2/ 59 (3.4)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	4/ 73 (5.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (3.6, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Nervous system disorders	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	1/ 64 (1.6)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (3.6, NE)
	Race		
	White	4/ 69 (5.8)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.6, NE)
	Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Renal and urinary disorders	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	2/ 45 (4.4)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	3/ 75 (4.0)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.2, NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	3/ 50 (6.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	2/ 52 (3.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.9, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.9, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Renal and urinary disorders	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (NE , NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	2/ 69 (2.9)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (1.3, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.2, NE)
	Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Overall	6/ 79 (7.6)	NE (NE , NE)
	Region		
	North America	4/ 34 (11.8)	NE (NE , NE)
	EU	2/ 45 (4.4)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	5/ 75 (6.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (4.0, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	5/ 50 (10.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	6/ 68 (8.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (3.9, NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (4.1, NE)
	>=2	5/ 74 (6.8)	NE (NE , NE)
	Previous total gastrectomy		
	no	6/ 79 (7.6)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (4.1, NE)
	no	5/ 70 (7.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.7, NE)
	no	5/ 73 (6.8)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.7, NE)
	no	5/ 72 (6.9)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (3.9, NE)
	Hepatic impairment at baseline		
	normal	3/ 64 (4.7)	NE (NE , NE)
	mild	3/ 14 (21.4)	NE (3.4, NE)
	Race		
	White	4/ 69 (5.8)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	4.0 (NE , NE)
	Other	1/ 8 (12.5)	NE (2.7, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.9, NE)
	Non-Hispanic/Non-Latino	5/ 70 (7.1)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Vascular disorders	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	3/ 34 (8.8)	NE (NE , NE)
	EU	1/ 45 (2.2)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	2/ 50 (4.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.4, NE)
	Primary tumor location		
	Gastric	0/ 27 (0.0)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.8, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.8, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (NE , NE)
	no	0/ 29 (0.0)	NE (NE , NE)

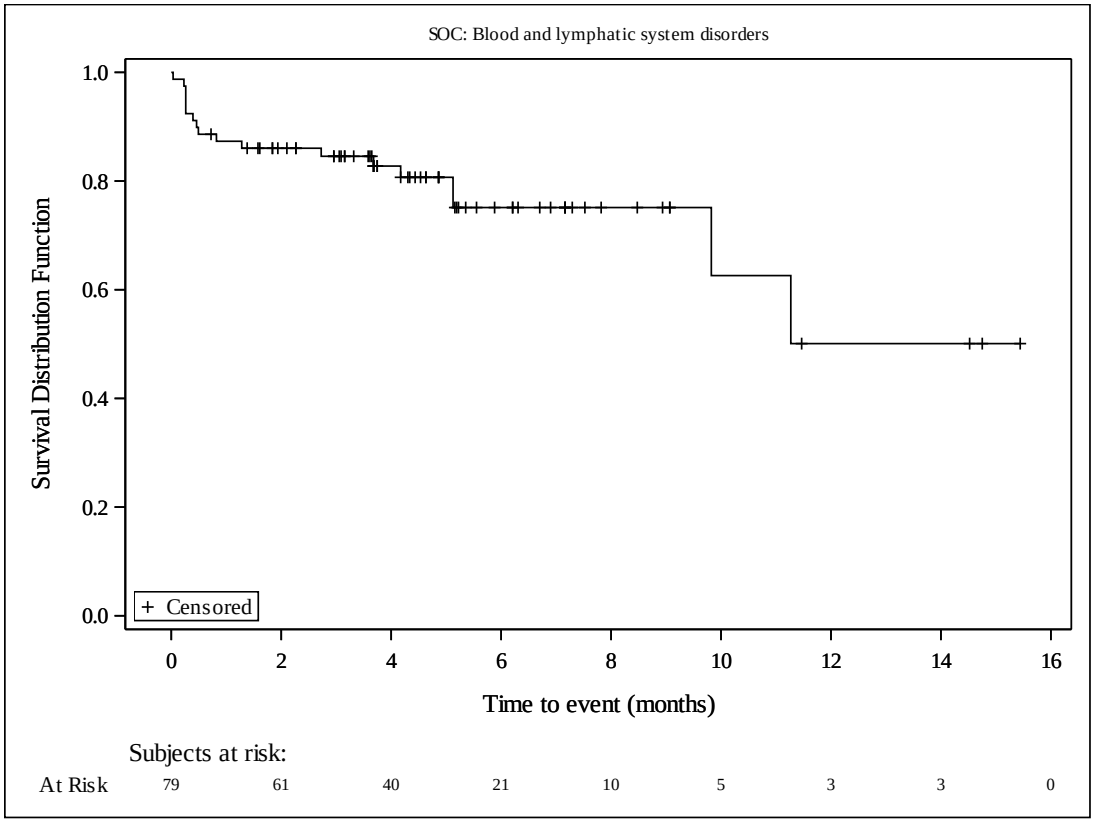
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Vascular disorders	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (NE , NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (2.8, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

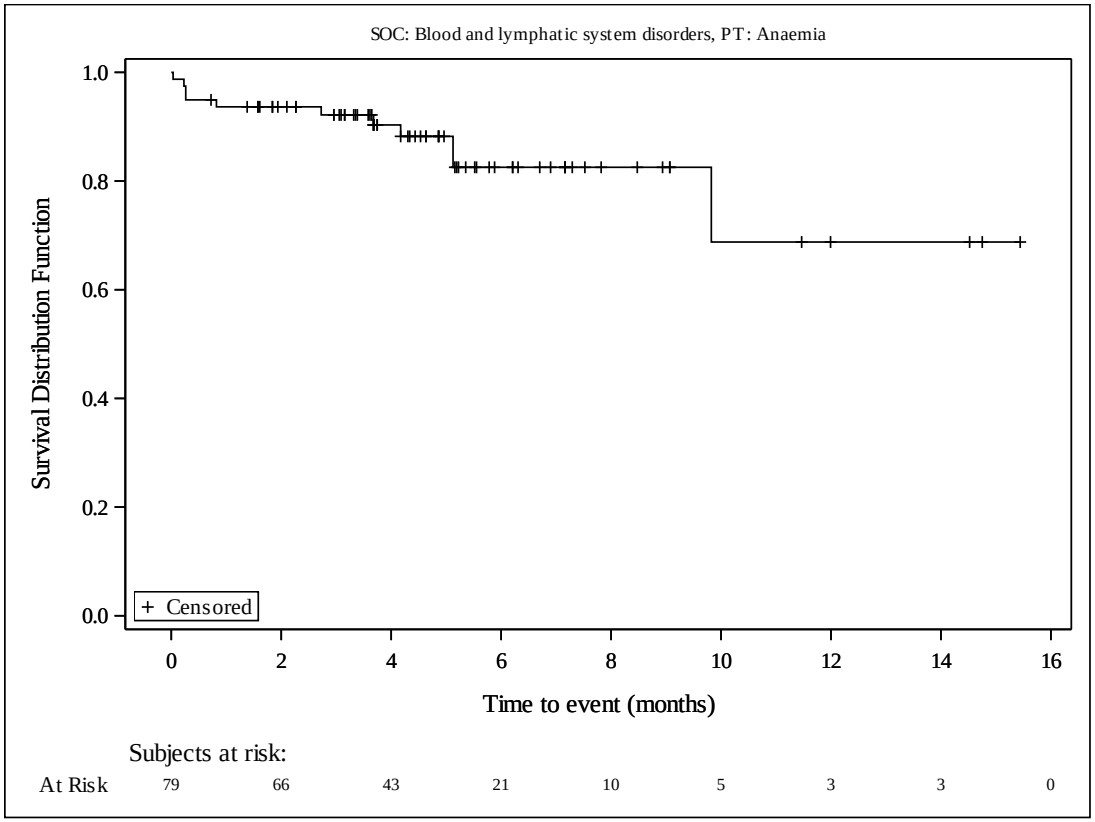
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



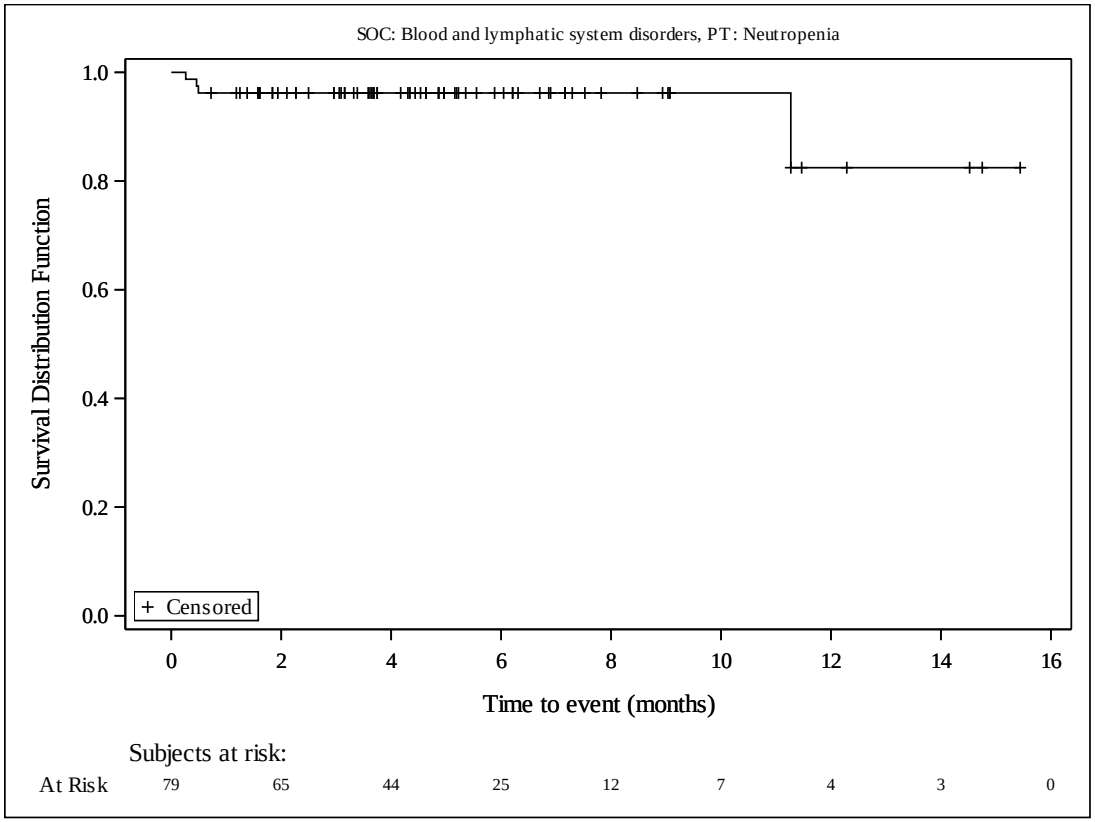
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



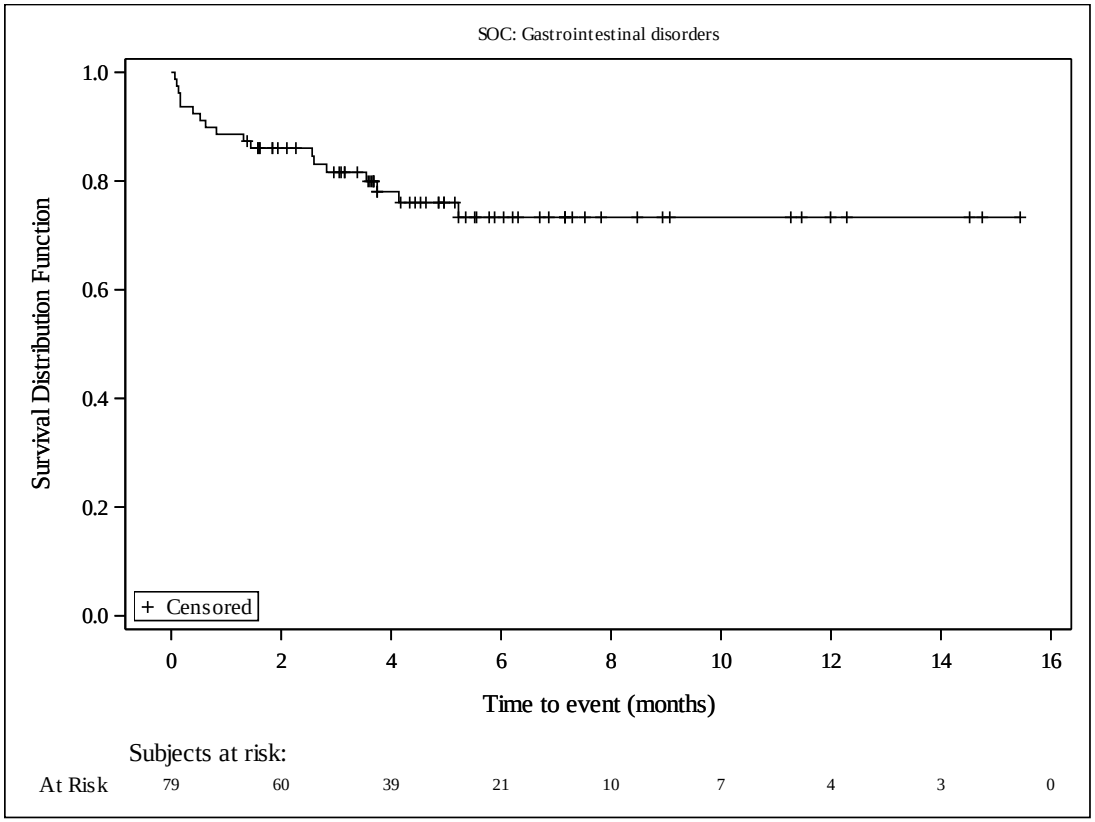
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



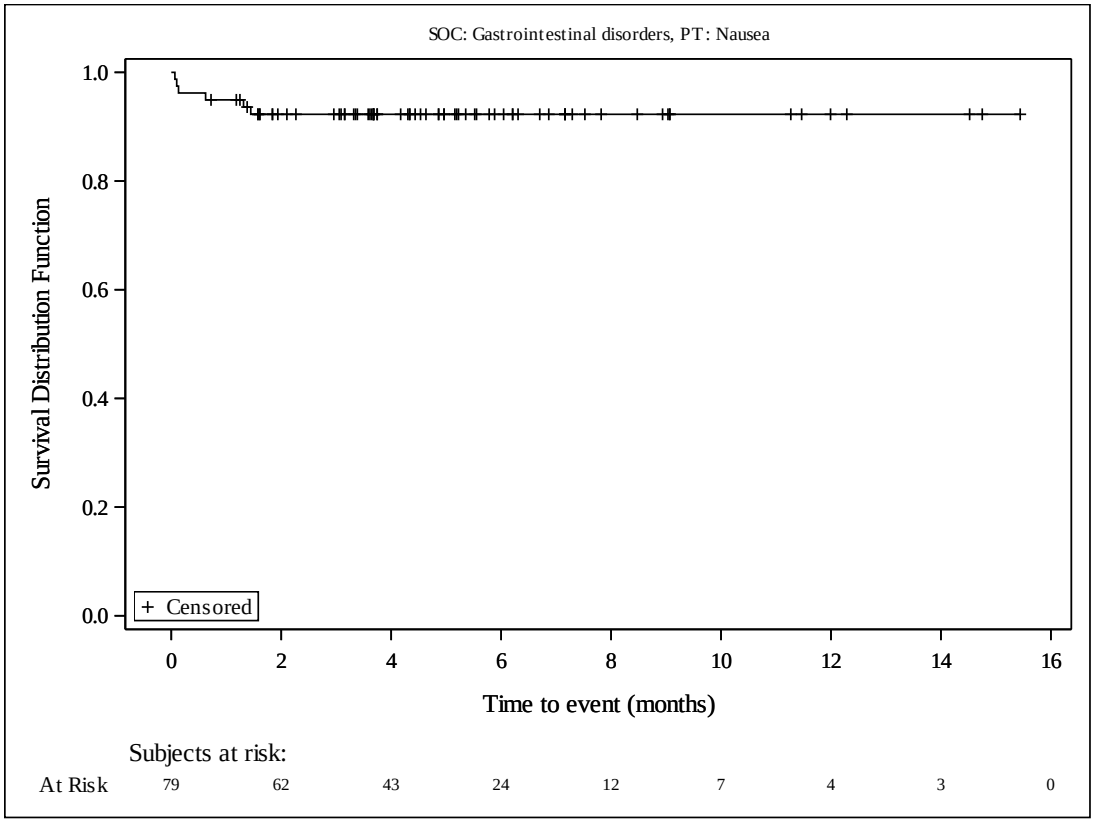
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



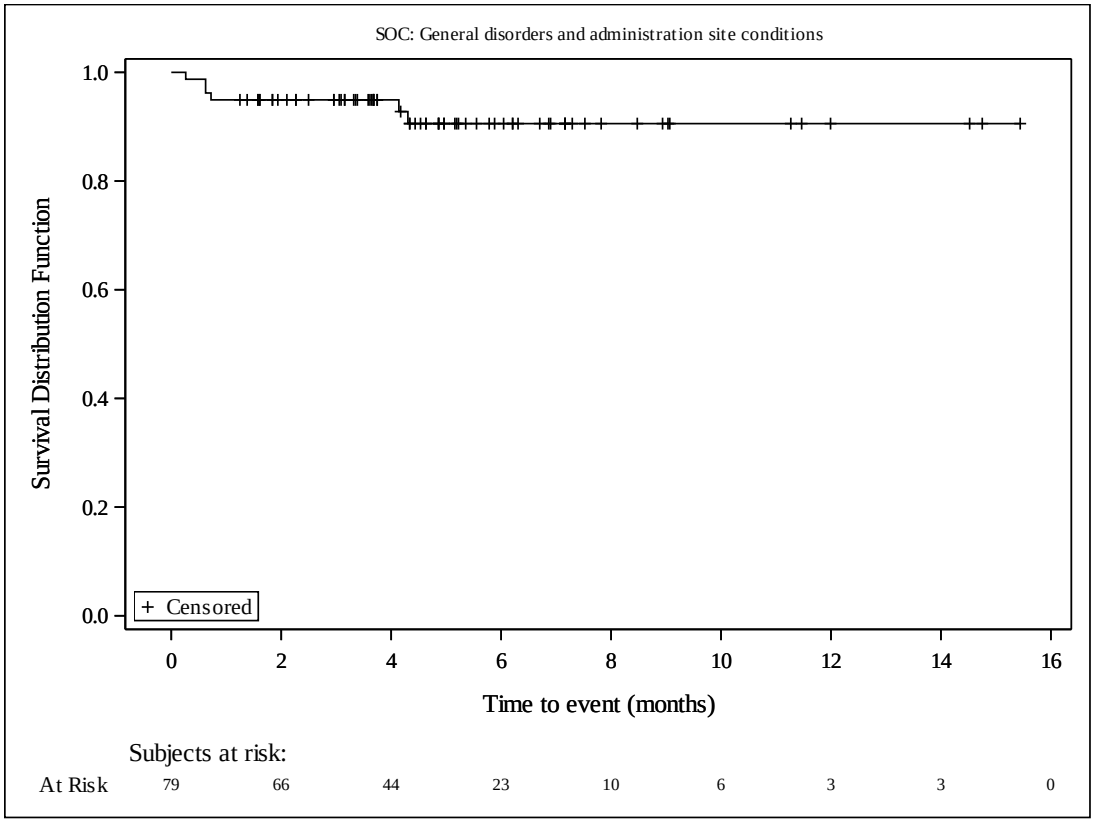
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



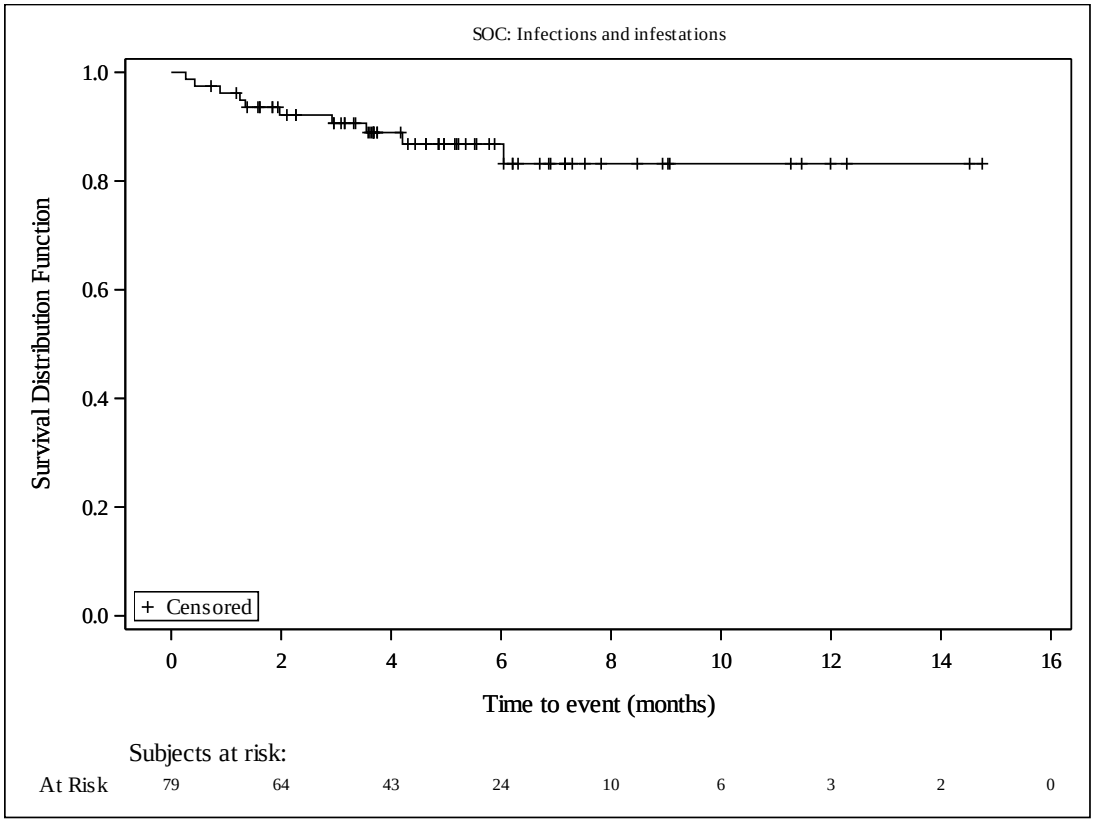
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



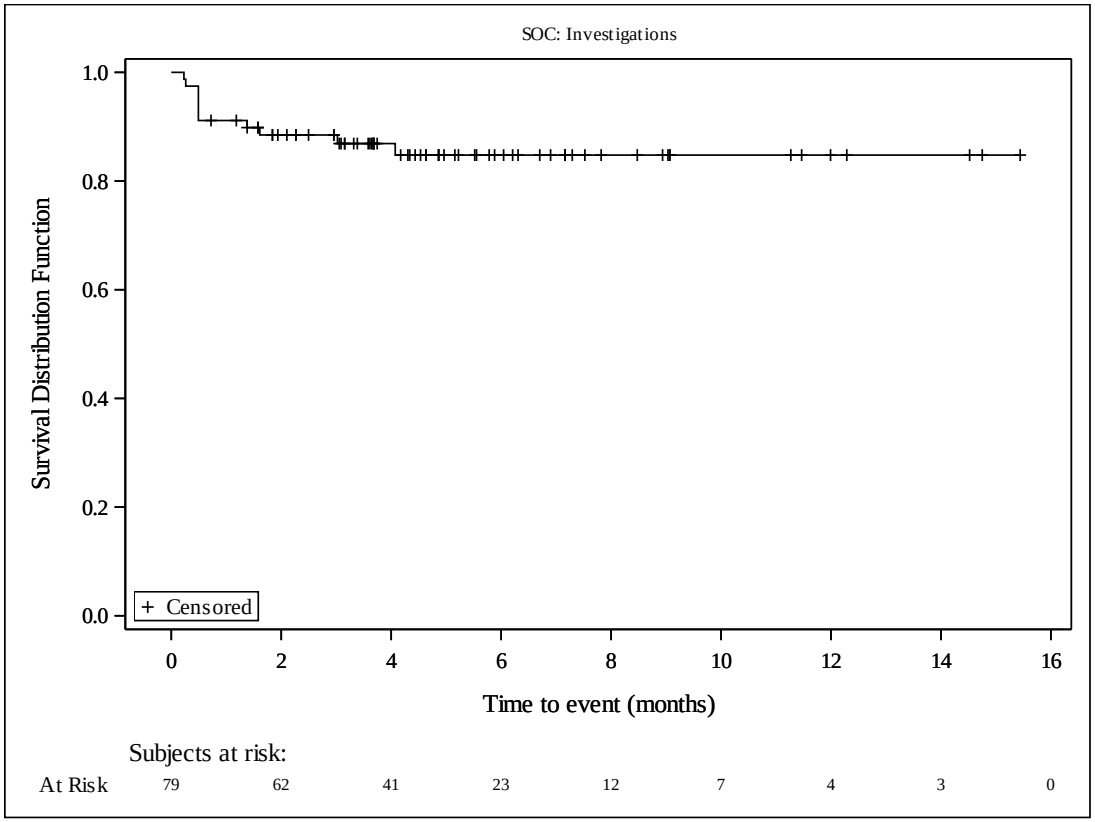
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



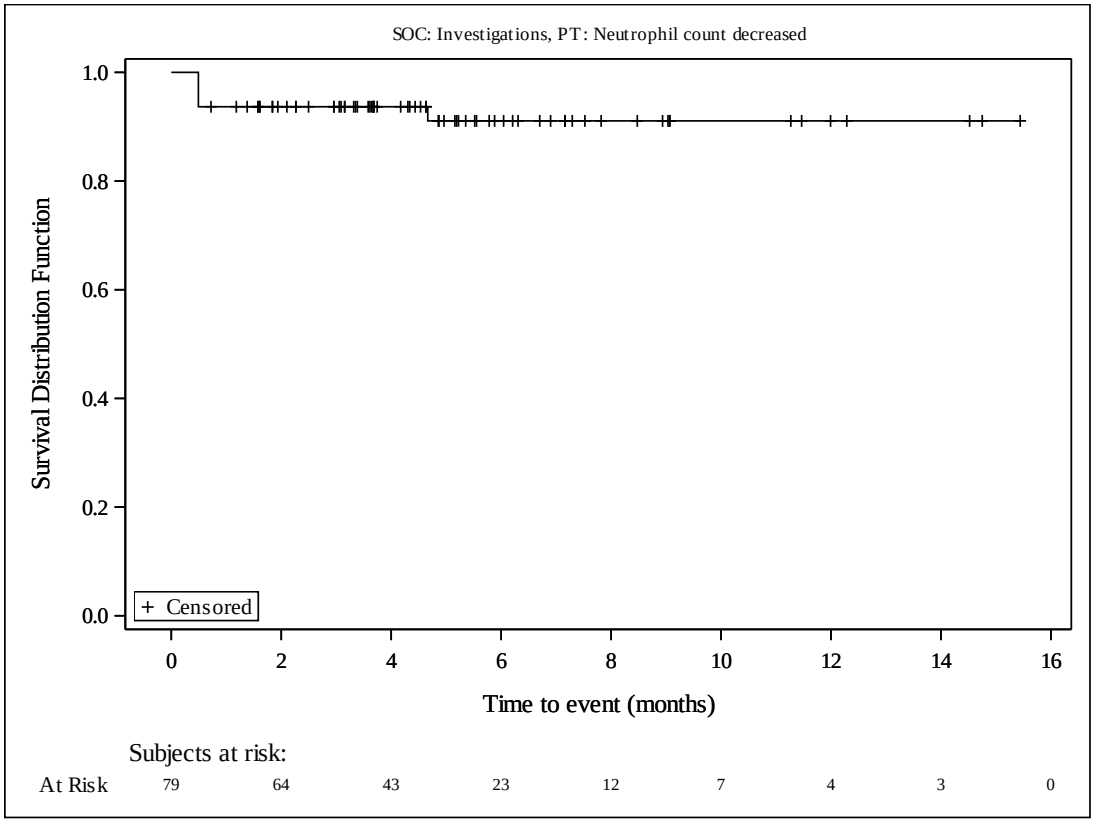
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



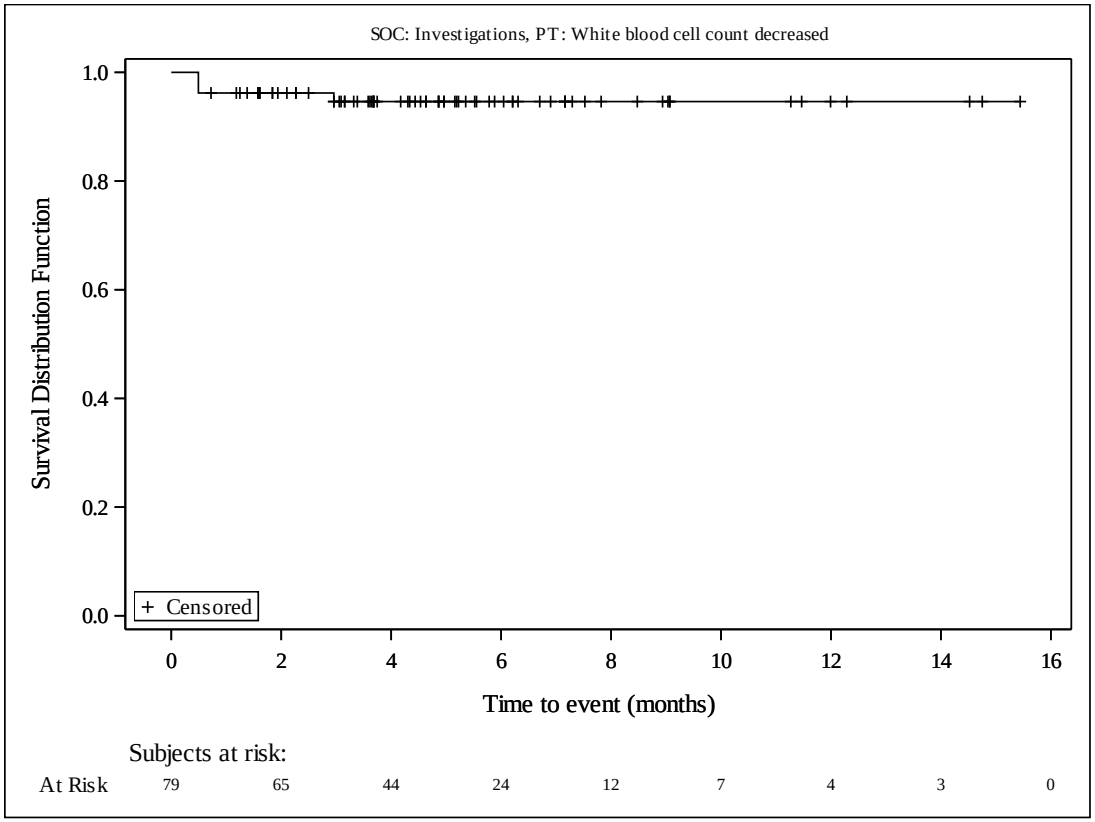
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



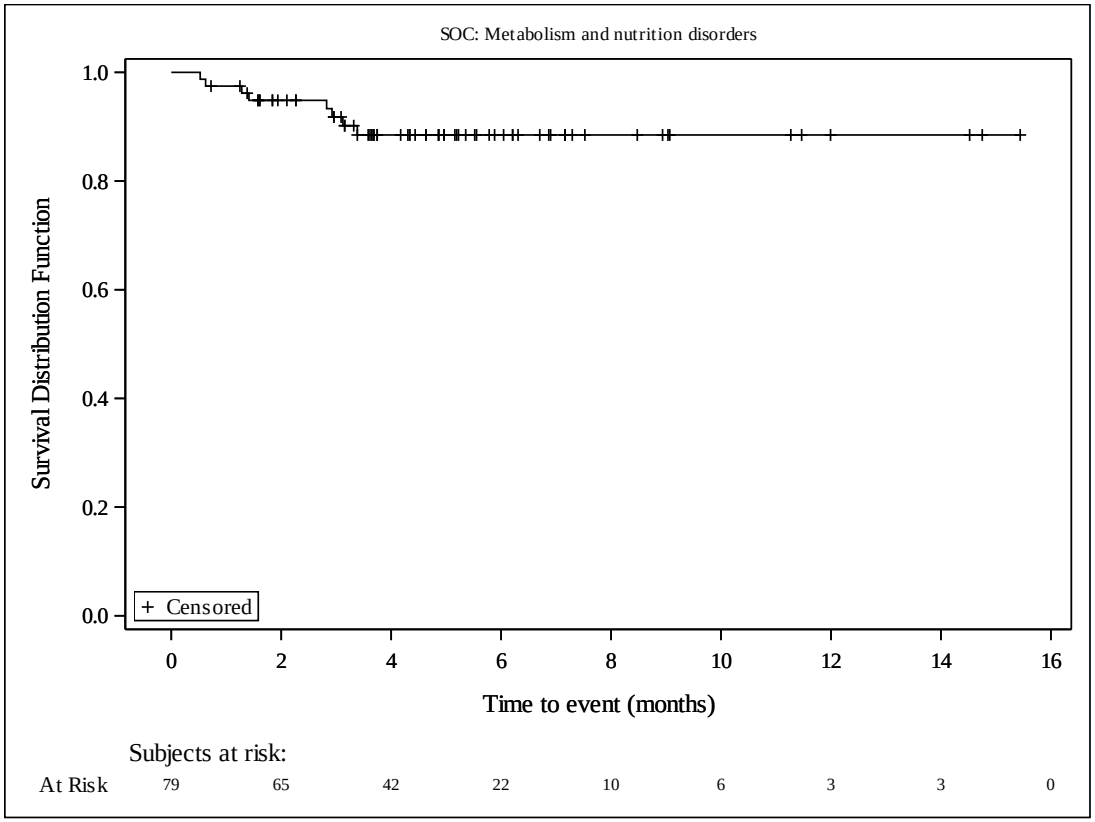
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



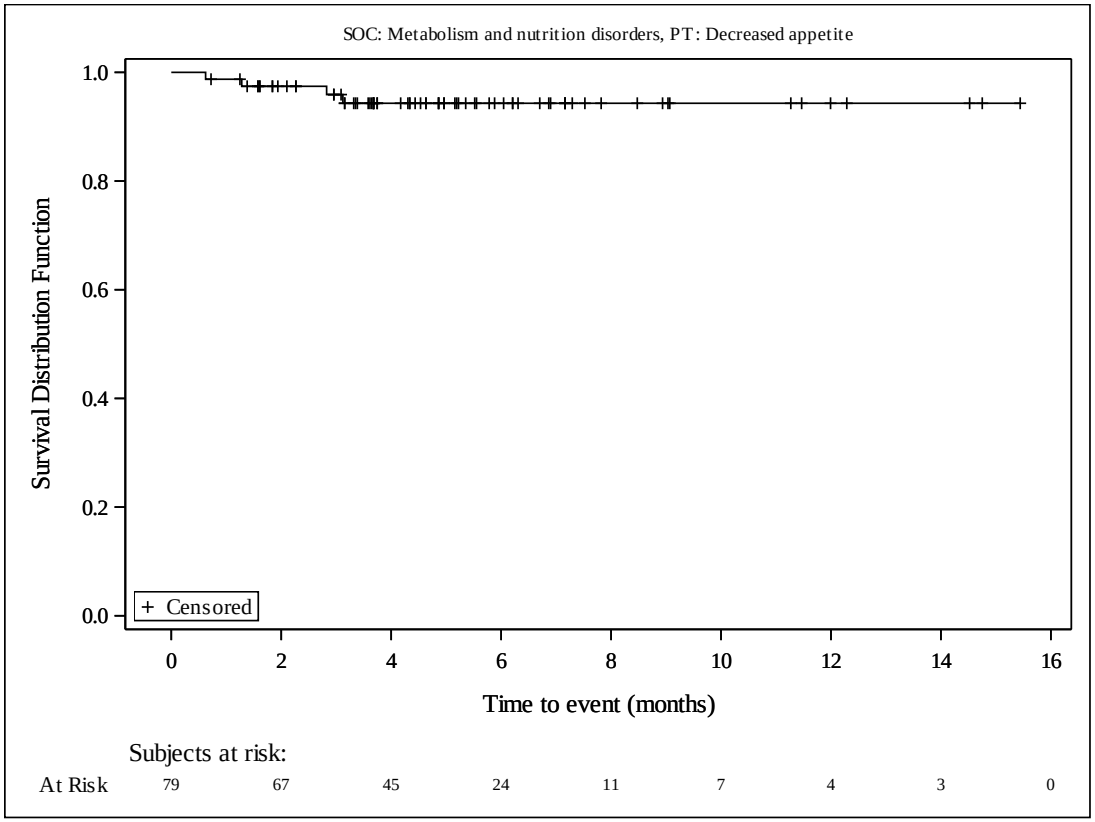
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



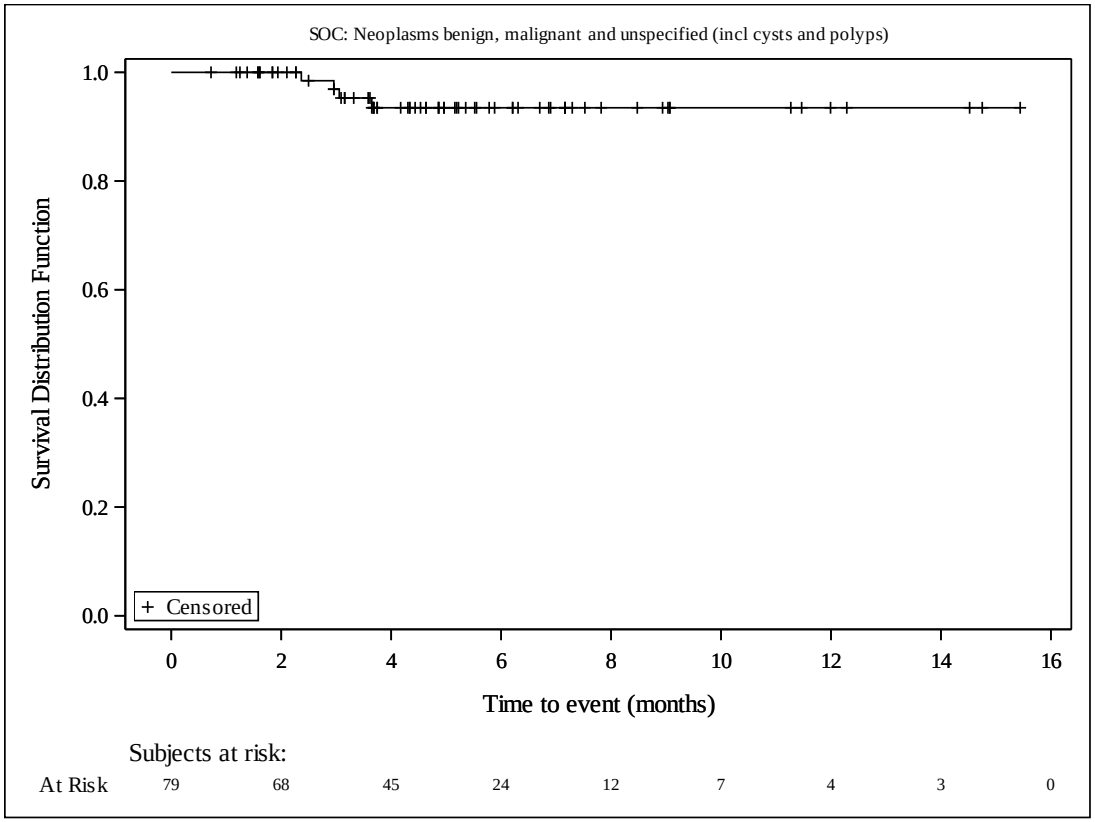
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



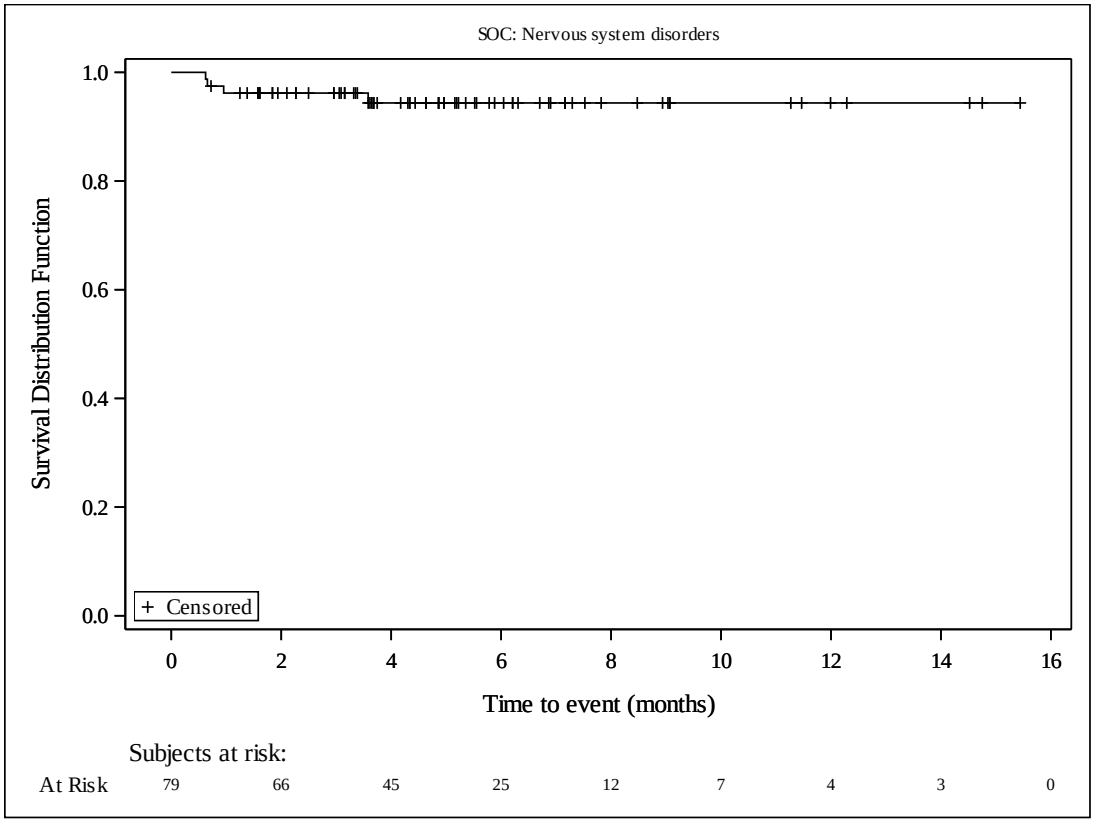
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



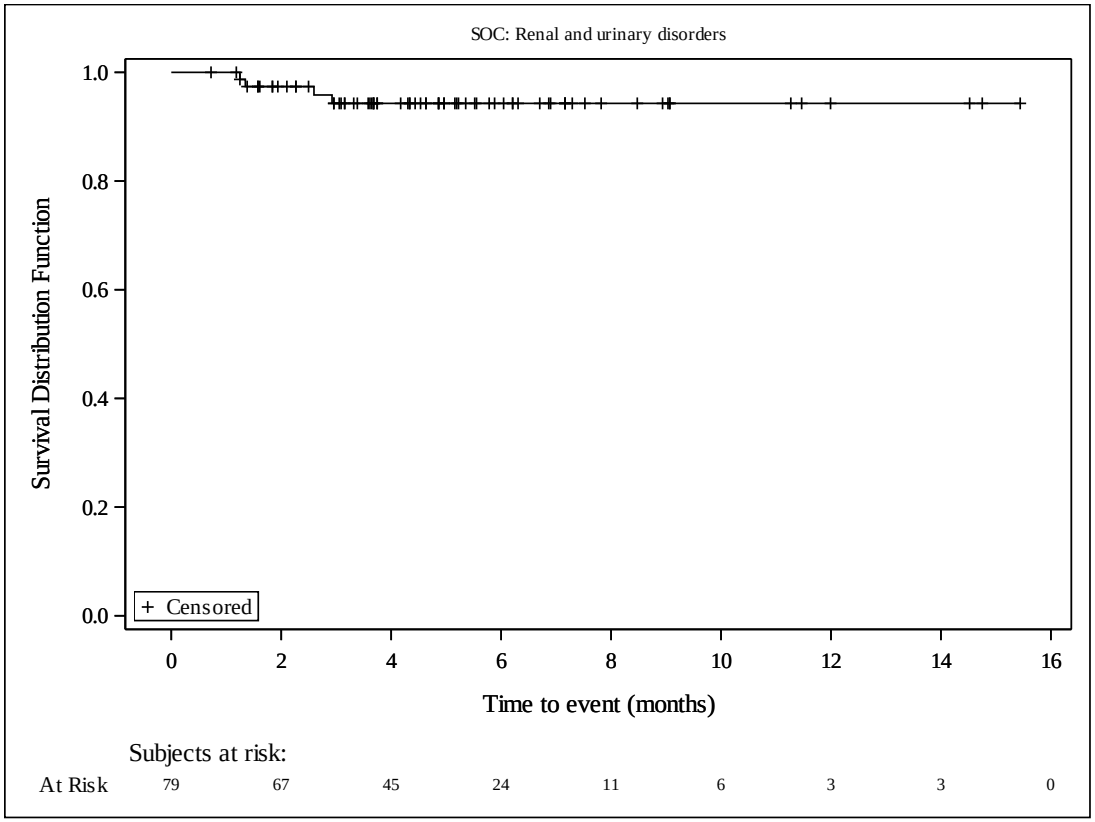
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



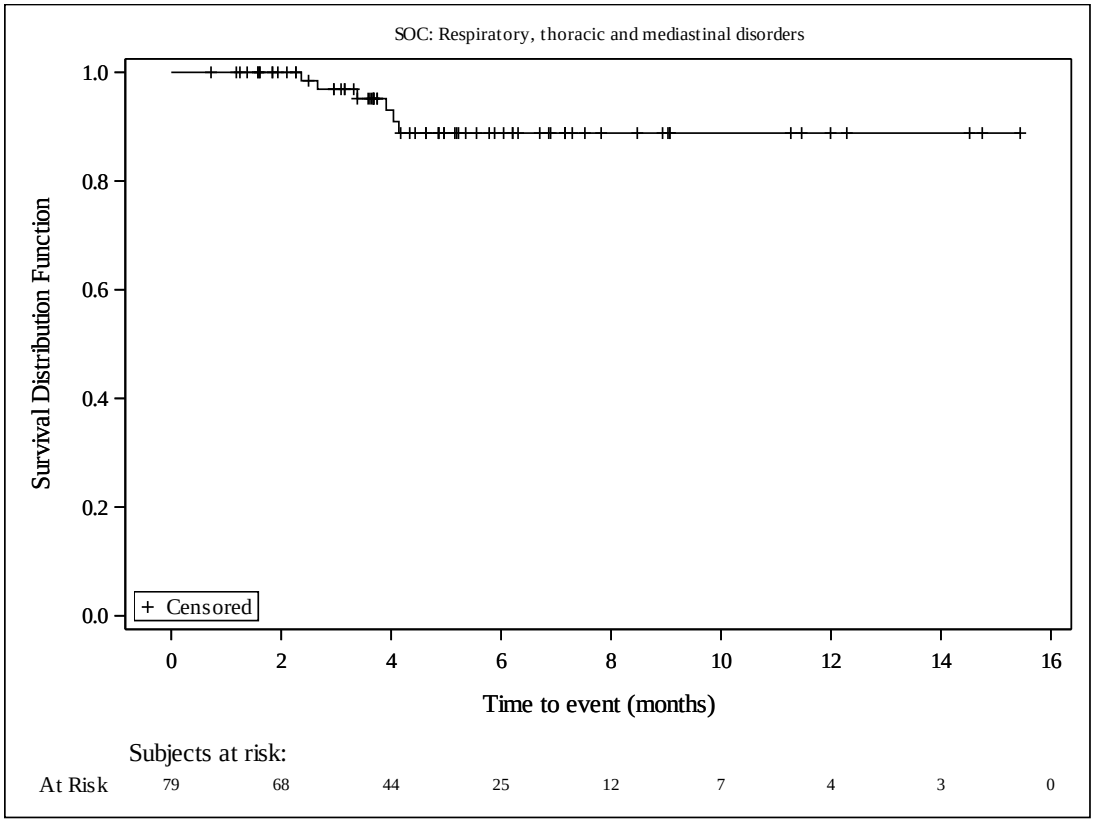
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



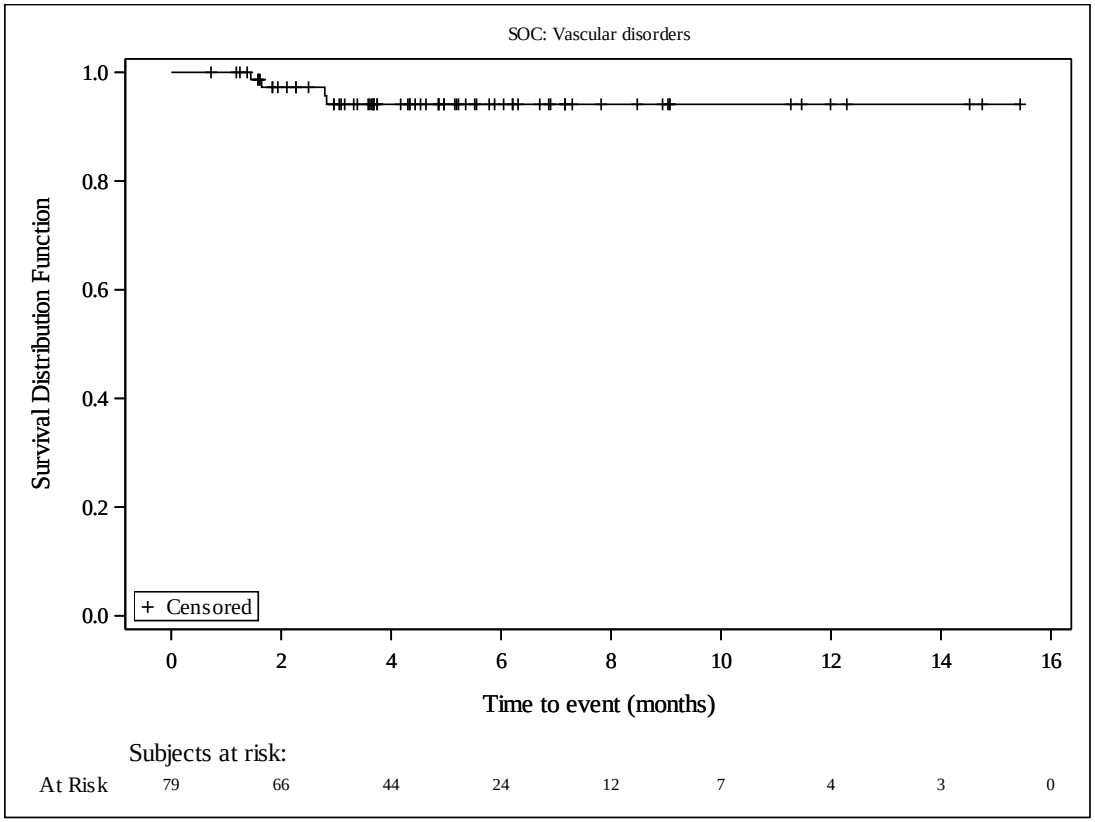
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 09APR2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Anhang 4-G 2.2: Datenschnitt 08. November 2021

Anhang 4-G 2.2.1: Behandlungs- und Beobachtungsdauer

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Study duration (months)
Full Analysis Set

		T-DXd (N=79)
Study duration (months)	n (missing)	79 (0)
	Mean (SD)	10.05 (5.354)
	Median	10.22
	Q1, Q3	5.62, 12.91
	Min, Max	0.7, 22.1

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start date to participation end date, cutoff date or death date, whichever occured earlier.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Treatment duration (months)
Full Analysis Set

		T-DXd (N=79)
Treatment duration (months)	n (missing)	79 (0)
	Mean (SD)	6.36 (5.217)
	Median	4.34
	Q1, Q3	2.73, 10.12
	Min, Max	0.7, 22.1

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start date to last date of treatment + 21
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Survival Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Overall Survival Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	10.05 (5.354)
	Median	10.22
	Q1, Q3	5.62, 12.91
	Min, Max	0.7, 22.1

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start date to the date of death due to any cause or censoring of Overall Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Progression-free Survival Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Progression-free Survival Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	5.67 (4.519)
	Median	4.34
	Q1, Q3	2.10, 8.84
	Min, Max	0.6, 21.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start date to the date of documented radiographic disease progression per RECIST V1.1 or death due to any cause or censoring of Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Duration of Confirmed Response Follow-up duration (months) - for responders only
Full Analysis Set

		T-DXd (N=33)
Duration of Confirmed Response Follow-up duration (months)	n (missing)	33 (0)
	Mean (SD)	6.43 (4.263)
	Median	5.95
	Q1, Q3	3.52, 8.08
	Min, Max	1.4, 18.1

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of the first documentation of objective response (CR or PR) to the date of the first objective documentation of disease progression, death due to any cause or censoring of Duration of Confirmed Response.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Time to Confirmed Response Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Time to Confirmed Response Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	3.00 (2.322)
	Median	2.10
	Q1, Q3	1.38, 4.14
	Min, Max	0.6, 13.7

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of randomization to the date of the first documentation of objective response (CR or PR) assessed by ICR or censoring the same way as for Progression-free Survival.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Time to Hospitalization Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Time to Hospitalization Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	8.45 (6.260)
	Median	8.74
	Q1, Q3	1.94, 12.52
	Min, Max	0.1, 22.1

Duration of follow-up (months) was derived applying descriptive statistics.
Time from the date of treatment start to the date of the first hospitalization.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Measureable Tumors based on ICR Follow-up duration (months)
Full Analysis Set

		T-DXd (N=79)
Measureable Tumors based on ICR Follow-up duration (months)	n (missing)	78 (1)
	Mean (SD)	5.49 (4.579)
	Median	4.16
	Q1, Q3	1.84, 8.31
	Min, Max	0.0, 21.9

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to last non-missing tumor assessment. Subjects with assessments only before treatment start were assigned a value of 1 day.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Safety Follow-up duration (months)
Safety Analysis Set

		T-DXd (N=79)
Safety Follow-up duration (months)	n (missing)	79 (0)
	Mean (SD)	6.76 (4.976)
	Median	4.86
	Q1, Q3	3.15, 10.38
	Min, Max	0.7, 22.1

Duration of follow-up (months) was derived applying descriptive statistics.
Time from treatment start to death date, last date of treatment (last dose of study drug) + 47 days, start of new anti-cancer therapy or last contact date, whichever occured earlier.
Source data: ADAM.ADSL, ADAM.ADEX, ADAM.ADTTE, ADAM.ADHO, ADAM.ADQS and ADAM.ADTR
Daiichi Sankyo Date of Table Generation: 16AUG2022

Anhang 4-G 2.2.2: Mortalität

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Overall Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	46 (58.2)	33 (41.8)	12.1 (9.4, 15.4)	94.9 (86.9, 98.0)	77.8 (66.8, 85.6)	65.6 (53.7, 75.2)	50.6 (38.4, 61.5)
Region							
North America	20 (58.8)	14 (41.2)	11.5 (6.7, 20.5)	94.0 (78.2, 98.5)	72.8 (54.2, 84.8)	63.4 (44.6, 77.3)	43.8 (25.3, 60.9)
EU	26 (57.8)	19 (42.2)	12.5 (9.2, 18.1)	95.5 (83.0, 98.8)	81.6 (66.6, 90.4)	67.4 (51.1, 79.2)	55.3 (39.2, 68.8)
Age (Category 1)							
<65 years	29 (63.0)	17 (37.0)	11.0 (8.6, 15.4)	93.4 (80.9, 97.8)	75.4 (60.0, 85.6)	58.8 (42.7, 71.7)	48.3 (32.6, 62.5)
>=65 years	17 (51.5)	16 (48.5)	15.4 (9.6, NE)	96.9 (79.8, 99.6)	81.3 (62.9, 91.1)	75.0 (56.2, 86.6)	54.2 (35.0, 70.0)
Age (Category 2)							
<75 years	44 (58.7)	31 (41.3)	11.6 (9.3, 15.4)	94.6 (86.2, 97.9)	78.0 (66.6, 85.9)	65.1 (52.8, 74.9)	49.2 (36.7, 60.5)
>=75 years	2 (50.0)	2 (50.0)	20.7 (4.7, 20.7)	100.0 (100.0, 100.0)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Sex							
female	12 (54.5)	10 (45.5)	12.8 (9.6, 20.5)	100.0 (100.0, 100.0)	85.7 (62.0, 95.2)	81.0 (56.9, 92.4)	60.7 (36.5, 78.1)
male	34 (59.6)	23 (40.4)	11.5 (8.6, 18.1)	92.9 (82.2, 97.3)	74.9 (61.2, 84.3)	59.8 (45.6, 71.5)	47.0 (32.8, 59.9)
ECOG PS							
0	20 (69.0)	9 (31.0)	15.4 (9.2, 19.4)	96.6 (77.9, 99.5)	86.2 (67.3, 94.6)	72.4 (52.3, 85.1)	54.4 (34.6, 70.5)
1	26 (52.0)	24 (48.0)	11.5 (8.6, NE)	93.9 (82.2, 98.0)	72.7 (57.7, 83.2)	61.4 (45.8, 73.7)	48.3 (32.5, 62.3)
HER2 Status in central laboratory							
IHC 3+	38 (55.9)	30 (44.1)	12.8 (9.7, 18.1)	95.5 (86.8, 98.5)	80.5 (68.8, 88.2)	69.7 (57.1, 79.3)	56.6 (43.5, 67.7)
IHC 2+/ISH +	7 (70.0)	3 (30.0)	8.7 (2.3, 11.5)	88.9 (43.3, 98.4)	66.7 (28.2, 87.8)	37.0 (6.8, 69.3)	NE (NE, NE)
Primary tumor location							
Gastric	12 (44.4)	15 (55.6)	12.8 (9.7, NE)	100.0 (100.0, 100.0)	80.0 (58.4, 91.1)	75.8 (53.8, 88.3)	62.9 (40.6, 78.7)
GEJ	34 (65.4)	18 (34.6)	10.1 (8.7, 15.4)	92.3 (80.8, 97.0)	76.8 (62.8, 86.1)	60.6 (45.8, 72.6)	45.0 (30.5, 58.4)

Overall Survival (OS) is defined as the time from the date of treatment start to the date of death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Overall Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	1 (100.0)	0 (0.0)	20.5 (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)
intestinal	11 (57.9)	8 (42.1)	11.4 (5.6, NE)	100.0 (100.0, 100.0)	72.2 (45.6, 87.4)	55.6 (30.5, 74.8)	50.0 (25.9, 70.1)
other	34 (57.6)	25 (42.4)	11.6 (9.4, 18.1)	93.2 (82.8, 97.4)	79.3 (66.4, 87.6)	68.2 (54.4, 78.7)	49.8 (35.6, 62.5)
Number of metastatic sites							
<2	2 (40.0)	3 (60.0)	13.2 (11.0, 15.4)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	50.0 (0.6, 91.0)
>=2	44 (59.5)	30 (40.5)	11.6 (9.2, 15.4)	94.5 (86.0, 97.9)	76.3 (64.6, 84.5)	63.4 (51.1, 73.4)	49.5 (37.1, 60.7)
Previous total gastrectomy							
no	46 (58.2)	33 (41.8)	12.1 (9.4, 15.4)	94.9 (86.9, 98.0)	77.8 (66.8, 85.6)	65.6 (53.7, 75.2)	50.6 (38.4, 61.5)
Prior adjuvant/ neoadjuvant therapy							
yes	4 (44.4)	5 (55.6)	20.7 (1.2, 20.7)	88.9 (43.3, 98.4)	88.9 (43.3, 98.4)	88.9 (43.3, 98.4)	55.6 (14.1, 83.8)
no	42 (60.0)	28 (40.0)	11.6 (9.0, 15.4)	95.6 (87.1, 98.6)	76.3 (64.3, 84.8)	62.7 (50.0, 73.1)	49.5 (36.8, 61.1)
Prior nivolumab or pembrolizumab treatment							
yes	3 (50.0)	3 (50.0)	15.4 (3.4, NE)	100.0 (100.0, 100.0)	83.3 (27.3, 97.5)	62.5 (14.2, 89.3)	62.5 (14.2, 89.3)
no	43 (58.9)	30 (41.1)	11.6 (9.4, 15.4)	94.4 (85.8, 97.9)	77.3 (65.7, 85.5)	65.7 (53.3, 75.5)	49.8 (37.2, 61.2)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	4 (57.1)	3 (42.9)	15.4 (3.4, NE)	100.0 (100.0, 100.0)	71.4 (25.8, 92.0)	53.6 (13.2, 82.5)	53.6 (13.2, 82.5)
no	42 (58.3)	30 (41.7)	12.1 (9.4, 18.1)	94.3 (85.6, 97.8)	78.5 (66.8, 86.4)	66.6 (54.1, 76.4)	50.5 (37.8, 61.9)
Presence of liver metastasis at baseline							
yes	31 (62.0)	19 (38.0)	10.1 (6.7, 18.1)	94.0 (82.5, 98.0)	71.7 (56.9, 82.2)	55.1 (40.2, 67.7)	45.9 (31.3, 59.3)
no	15 (51.7)	14 (48.3)	12.8 (10.2, 20.7)	96.6 (77.9, 99.5)	89.1 (69.9, 96.4)	85.1 (64.9, 94.1)	59.2 (36.9, 75.9)
Renal impairment at baseline							
normal	21 (65.6)	11 (34.4)	9.4 (5.6, 18.1)	90.4 (73.1, 96.8)	67.7 (48.2, 81.1)	50.3 (31.5, 66.5)	42.6 (24.5, 59.5)
mild	14 (56.0)	11 (44.0)	15.4 (9.3, 20.7)	96.0 (74.8, 99.4)	87.7 (66.4, 95.8)	74.4 (51.6, 87.7)	55.8 (33.3, 73.4)
moderate	4 (50.0)	4 (50.0)	12.8 (4.3, NE)	100.0 (100.0, 100.0)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	62.5 (22.9, 86.1)

Overall Survival (OS) is defined as the time from the date of treatment start to the date of death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

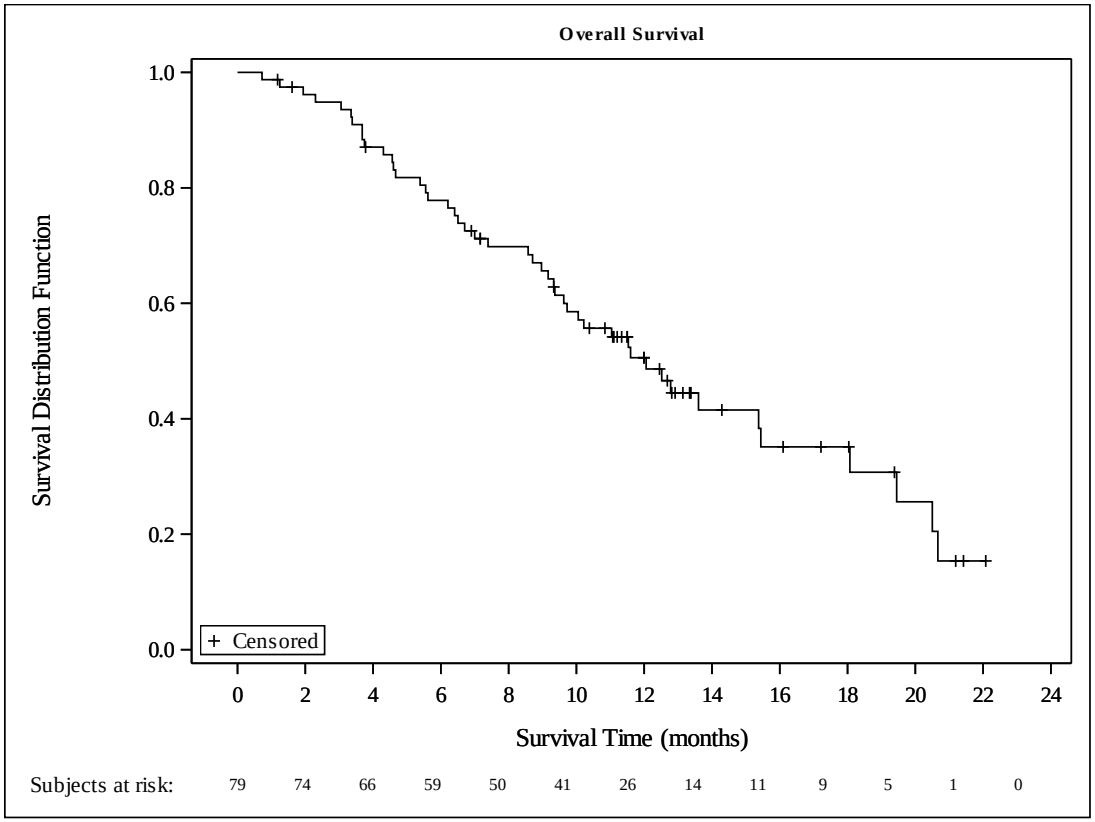
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Overall Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	34 (53.1)	30 (46.9)	12.8 (10.1, 19.4)	95.3 (86.0, 98.4)	84.0 (72.4, 91.1)	72.6 (59.6, 82.0)	54.2 (40.4, 66.1)
mild	12 (85.7)	2 (14.3)	7.1 (3.4, 12.1)	92.9 (59.1, 99.0)	50.0 (22.9, 72.2)	33.3 (10.9, 58.0)	33.3 (10.9, 58.0)
Race							
White	41 (59.4)	28 (40.6)	12.5 (9.4, 15.4)	94.1 (85.1, 97.8)	79.3 (67.6, 87.2)	67.1 (54.4, 77.0)	52.1 (39.1, 63.6)
Black or African American	1 (100.0)	0 (0.0)	4.7 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	3 (37.5)	5 (62.5)	NE (3.4, NE)	100.0 (100.0, 100.0)	85.7 (33.4, 97.9)	68.6 (21.3, 91.2)	51.4 (11.8, 81.3)
Ethnicity							
Hispanic/Latino	3 (60.0)	2 (40.0)	15.4 (3.7, NE)	100.0 (100.0, 100.0)	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
Non-Hispanic/Non-Latino	41 (58.6)	29 (41.4)	11.6 (9.3, 15.4)	94.2 (85.2, 97.8)	79.3 (67.6, 87.2)	65.4 (52.7, 75.5)	49.8 (36.8, 61.5)
Unknown	2 (50.0)	2 (50.0)	NE (4.6, NE)	100.0 (100.0, 100.0)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	50.0 (5.8, 84.5)

Overall Survival (OS) is defined as the time from the date of treatment start to the date of death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Overall Survival
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Anhang 4-G 2.2.3: Morbidität

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Confirmed Objective Response Rate (ORR) based on ICR
Full Analysis Set

	T-DXd (N=79)		
	n/ N	(%)	95% CI [a]
Overall	33/ 79	(41.8)	(30.8, 53.4)
Region			
North America	10/ 34	(29.4)	(15.1, 47.5)
EU	23/ 45	(51.1)	(35.8, 66.3)
Age (Category 1)			
<65 years	18/ 46	(39.1)	(25.1, 54.6)
>=65 years	15/ 33	(45.5)	(28.1, 63.6)
Age (Category 2)			
<75 years	29/ 75	(38.7)	(27.6, 50.6)
>=75 years	4/ 4	(100.0)	(39.8, 100.0)
Sex			
female	12/ 22	(54.5)	(32.2, 75.6)
male	21/ 57	(36.8)	(24.4, 50.7)
ECOG PS			
0	8/ 29	(27.6)	(12.7, 47.2)
1	25/ 50	(50.0)	(35.5, 64.5)
HER2 Status in central laboratory			
IHC 3+	32/ 68	(47.1)	(34.8, 59.6)
IHC 2+/ISH +	1/ 10	(10.0)	(0.3, 44.5)
Primary tumor location			
Gastric	15/ 27	(55.6)	(35.3, 74.5)
GEJ	18/ 52	(34.6)	(22.0, 49.1)
Histological subtype			
diffuse	1/ 1	(100.0)	(2.5, 100.0)
intestinal	7/ 19	(36.8)	(16.3, 61.6)
other	25/ 59	(42.4)	(29.6, 55.9)
Number of metastatic sites			
<2	3/ 5	(60.0)	(14.7, 94.7)
>=2	30/ 74	(40.5)	(29.3, 52.6)
Previous total gastrectomy			
no	33/ 79	(41.8)	(30.8, 53.4)
Prior adjuvant/ neoadjuvant therapy			
yes	3/ 9	(33.3)	(7.5, 70.1)
no	30/ 70	(42.9)	(31.1, 55.3)
Prior nivolumab or pembrolizumab treatment			
yes	2/ 6	(33.3)	(4.3, 77.7)
no	31/ 73	(42.5)	(31.0, 54.6)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy			
yes	2/ 7	(28.6)	(3.7, 71.0)
no	31/ 72	(43.1)	(31.4, 55.3)
Presence of liver metastasis at baseline			
yes	19/ 50	(38.0)	(24.7, 52.8)
no	14/ 29	(48.3)	(29.4, 67.5)

NE: Not estimable.
[a] Based on Clopper-Pearson method.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Confirmed Objective Response Rate (ORR) based on ICR
Full Analysis Set

	T-DXd (N=79)		
	n/ N	(%)	95% CI [a]
Renal impairment at baseline			
normal	9/ 32	(28.1)	(13.7, 46.7)
mild	12/ 25	(48.0)	(27.8, 68.7)
moderate	5/ 8	(62.5)	(24.5, 91.5)
Hepatic impairment at baseline			
normal	26/ 64	(40.6)	(28.5, 53.6)
mild	7/ 14	(50.0)	(23.0, 77.0)
Race			
White	30/ 69	(43.5)	(31.6, 56.0)
Black or African American	1/ 1	(100.0)	(2.5, 100.0)
Other	2/ 8	(25.0)	(3.2, 65.1)
Ethnicity			
Hispanic/Latino	2/ 5	(40.0)	(5.3, 85.3)
Non-Hispanic/Non-Latino	30/ 70	(42.9)	(31.1, 55.3)
Unknown	1/ 4	(25.0)	(0.6, 80.6)

NE: Not estimable.
[a] Based on Clopper-Pearson method.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Confirmed Disease Control Rate (DCR) based on ICR
Full Analysis Set

	T-DXd (N=79)	
	n/ N (%)	95% CI [a]
Overall	64/ 79 (81.0)	(70.6, 89.0)
Region		
North America	26/ 34 (76.5)	(58.8, 89.3)
EU	38/ 45 (84.4)	(70.5, 93.5)
Age (Category 1)		
<65 years	40/ 46 (87.0)	(73.7, 95.1)
>=65 years	24/ 33 (72.7)	(54.5, 86.7)
Age (Category 2)		
<75 years	60/ 75 (80.0)	(69.2, 88.4)
>=75 years	4/ 4 (100.0)	(39.8, 100.0)
Sex		
female	19/ 22 (86.4)	(65.1, 97.1)
male	45/ 57 (78.9)	(66.1, 88.6)
ECOG PS		
0	22/ 29 (75.9)	(56.5, 89.7)
1	42/ 50 (84.0)	(70.9, 92.8)
HER2 Status in central laboratory		
IHC 3+	59/ 68 (86.8)	(76.4, 93.8)
IHC 2+/ISH +	5/ 10 (50.0)	(18.7, 81.3)
Primary tumor location		
Gastric	21/ 27 (77.8)	(57.7, 91.4)
GEJ	43/ 52 (82.7)	(69.7, 91.8)
Histological subtype		
diffuse	1/ 1 (100.0)	(2.5, 100.0)
intestinal	15/ 19 (78.9)	(54.4, 93.9)
other	48/ 59 (81.4)	(69.1, 90.3)
Number of metastatic sites		
<2	5/ 5 (100.0)	(47.8, 100.0)
>=2	59/ 74 (79.7)	(68.8, 88.2)
Previous total gastrectomy		
no	64/ 79 (81.0)	(70.6, 89.0)
Prior adjuvant/ neoadjuvant therapy		
yes	8/ 9 (88.9)	(51.8, 99.7)
no	56/ 70 (80.0)	(68.7, 88.6)
Prior nivolumab or pembrolizumab treatment		
yes	5/ 6 (83.3)	(35.9, 99.6)
no	59/ 73 (80.8)	(69.9, 89.1)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	6/ 7 (85.7)	(42.1, 99.6)
no	58/ 72 (80.6)	(69.5, 88.9)
Presence of liver metastasis at baseline		
yes	40/ 50 (80.0)	(66.3, 90.0)
no	24/ 29 (82.8)	(64.2, 94.2)

NE: Not estimable.
[a] Based on Clopper-Pearson method.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Confirmed Disease Control Rate (DCR) based on ICR
Full Analysis Set

	T-DXd (N=79)	
	n/ N (%)	95% CI [a]
Renal impairment at baseline		
normal	26/ 32 (81.3)	(63.6, 92.8)
mild	18/ 25 (72.0)	(50.6, 87.9)
moderate	7/ 8 (87.5)	(47.3, 99.7)
Hepatic impairment at baseline		
normal	52/ 64 (81.3)	(69.5, 89.9)
mild	12/ 14 (85.7)	(57.2, 98.2)
Race		
White	55/ 69 (79.7)	(68.3, 88.4)
Black or African American	1/ 1 (100.0)	(2.5, 100.0)
Other	7/ 8 (87.5)	(47.3, 99.7)
Ethnicity		
Hispanic/Latino	5/ 5 (100.0)	(47.8, 100.0)
Non-Hispanic/Non-Latino	55/ 70 (78.6)	(67.1, 87.5)
Unknown	4/ 4 (100.0)	(39.8, 100.0)

NE: Not estimable.
[a] Based on Clopper-Pearson method.
Source data: ADAM.ADSL and ADAM.ADRS
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Progression-free Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	51 (64.6)	28 (35.4)	5.6 (4.2, 8.3)	70.5 (58.7, 79.5)	48.9 (36.6, 60.2)	36.3 (24.5, 48.1)	20.0 (9.4, 33.3)
Region							
North America	28 (82.4)	6 (17.6)	4.8 (2.8, 7.2)	67.2 (48.5, 80.3)	43.0 (25.3, 59.5)	23.4 (9.9, 40.3)	7.8 (1.4, 21.9)
EU	23 (51.1)	22 (48.9)	8.3 (4.2, 13.7)	73.3 (56.8, 84.3)	53.7 (36.6, 68.0)	47.0 (30.1, 62.2)	35.9 (17.9, 54.2)
Age (Category 1)							
<65 years	32 (69.6)	14 (30.4)	5.5 (3.7, 9.4)	68.4 (52.5, 79.9)	45.3 (29.7, 59.7)	35.6 (20.7, 50.8)	12.8 (2.9, 30.2)
>=65 years	19 (57.6)	14 (42.4)	7.3 (4.1, 21.9)	74.2 (55.0, 86.2)	54.8 (34.8, 71.0)	38.0 (19.9, 55.9)	32.5 (15.2, 51.2)
Age (Category 2)							
<75 years	50 (66.7)	25 (33.3)	5.5 (4.2, 7.3)	68.8 (56.6, 78.3)	47.4 (34.8, 59.0)	33.6 (21.8, 45.8)	16.8 (7.0, 30.2)
>=75 years	1 (25.0)	3 (75.0)	NE (4.7, NE)	100.0 (100.0, 100.0)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Sex							
female	14 (63.6)	8 (36.4)	8.3 (4.7, 10.6)	85.4 (61.3, 95.1)	59.2 (34.6, 77.2)	46.1 (22.5, 66.9)	11.0 (0.8, 36.6)
male	37 (64.9)	20 (35.1)	4.8 (3.4, 7.3)	64.7 (50.3, 75.9)	45.1 (30.9, 58.4)	32.6 (19.5, 46.4)	23.5 (10.5, 39.4)
ECOG PS							
0	22 (75.9)	7 (24.1)	5.1 (2.6, 8.3)	65.0 (44.7, 79.4)	45.3 (26.1, 62.7)	22.7 (8.6, 40.8)	17.0 (4.9, 35.2)
1	29 (58.0)	21 (42.0)	6.7 (4.2, 10.6)	73.8 (58.4, 84.2)	51.1 (35.0, 65.0)	45.0 (29.2, 59.7)	21.8 (7.5, 40.8)
HER2 Status in central laboratory							
IHC 3+	41 (60.3)	27 (39.7)	7.1 (4.7, 9.7)	75.0 (62.4, 83.9)	55.3 (41.7, 67.0)	42.6 (29.2, 55.3)	23.4 (11.0, 38.5)
IHC 2+/ISH +	9 (90.0)	1 (10.0)	1.6 (1.2, 5.6)	44.4 (13.6, 71.9)	11.1 (0.6, 38.8)	NE (NE, NE)	NE (NE, NE)
Primary tumor location							
Gastric	14 (51.9)	13 (48.1)	9.4 (4.6, NE)	76.5 (55.0, 88.7)	63.8 (41.7, 79.3)	52.2 (29.6, 70.7)	25.4 (5.8, 51.6)
GEJ	37 (71.2)	15 (28.8)	5.1 (3.7, 7.3)	67.6 (52.5, 78.8)	41.1 (26.4, 55.1)	28.2 (15.6, 42.3)	16.3 (5.7, 31.8)

Progression-free survival (PFS) is defined as the time from the date of treatment start to the date of documented radiographic disease progression per RECIST V1.1 or death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Progression-free Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	1 (100.0)	0 (0.0)	11.0 (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	NE (NE, NE)
intestinal	11 (57.9)	8 (42.1)	6.7 (2.6, 13.7)	70.5 (42.8, 86.6)	63.5 (35.6, 81.9)	39.7 (15.3, 63.4)	19.8 (1.5, 53.4)
other	39 (66.1)	20 (33.9)	5.5 (4.1, 8.3)	70.0 (56.1, 80.2)	43.5 (29.7, 56.5)	33.8 (20.9, 47.3)	20.8 (9.1, 35.8)
Number of metastatic sites							
<2	2 (40.0)	3 (60.0)	7.2 (5.6, NE)	100.0 (100.0, 100.0)	66.7 (5.4, 94.5)	33.3 (0.9, 77.4)	NE (NE, NE)
>=2	49 (66.2)	25 (33.8)	5.5 (4.1, 8.3)	68.4 (56.0, 78.0)	47.2 (34.6, 58.8)	35.8 (23.9, 47.9)	19.5 (9.1, 32.8)
Previous total gastrectomy							
no	51 (64.6)	28 (35.4)	5.6 (4.2, 8.3)	70.5 (58.7, 79.5)	48.9 (36.6, 60.2)	36.3 (24.5, 48.1)	20.0 (9.4, 33.3)
Prior adjuvant/ neoadjuvant therapy							
yes	6 (66.7)	3 (33.3)	9.7 (1.2, 13.7)	88.9 (43.3, 98.4)	53.3 (17.7, 79.6)	53.3 (17.7, 79.6)	35.6 (6.2, 68.1)
no	45 (64.3)	25 (35.7)	5.5 (3.7, 8.3)	67.9 (55.1, 77.8)	48.5 (35.4, 60.4)	33.7 (21.5, 46.4)	18.1 (7.5, 32.3)
Prior nivolumab or pembrolizumab treatment							
yes	3 (50.0)	3 (50.0)	5.6 (1.3, NE)	66.7 (19.5, 90.4)	33.3 (1.4, 75.5)	33.3 (1.4, 75.5)	33.3 (1.4, 75.5)
no	48 (65.8)	25 (34.2)	5.5 (4.2, 8.3)	70.9 (58.5, 80.2)	49.6 (36.8, 61.1)	36.2 (24.2, 48.4)	18.4 (7.8, 32.5)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	4 (57.1)	3 (42.9)	5.6 (1.3, NE)	57.1 (17.2, 83.7)	28.6 (1.4, 69.1)	28.6 (1.4, 69.1)	28.6 (1.4, 69.1)
no	47 (65.3)	25 (34.7)	6.4 (4.2, 8.3)	72.0 (59.7, 81.2)	50.4 (37.5, 62.0)	36.8 (24.6, 49.1)	18.7 (7.9, 33.0)
Presence of liver metastasis at baseline							
yes	35 (70.0)	15 (30.0)	5.5 (2.8, 7.3)	64.4 (49.0, 76.2)	48.3 (33.2, 61.8)	32.2 (18.7, 46.5)	20.5 (8.5, 36.1)
no	16 (55.2)	13 (44.8)	5.6 (4.2, 10.6)	81.6 (61.2, 91.9)	48.9 (27.2, 67.5)	43.5 (22.4, 62.8)	14.5 (1.3, 42.5)
Renal impairment at baseline							
normal	23 (71.9)	9 (28.1)	4.2 (2.8, 7.1)	62.1 (42.0, 77.0)	38.6 (20.6, 56.4)	19.3 (6.4, 37.4)	NE (NE, NE)
mild	12 (48.0)	13 (52.0)	11.0 (4.1, NE)	72.0 (50.1, 85.5)	55.7 (32.6, 73.7)	55.7 (32.6, 73.7)	46.4 (22.0, 67.8)
moderate	6 (75.0)	2 (25.0)	8.9 (1.3, 21.9)	75.0 (31.5, 93.1)	62.5 (22.9, 86.1)	50.0 (15.2, 77.5)	33.3 (5.6, 65.8)

Progression-free survival (PFS) is defined as the time from the date of treatment start to the date of documented radiographic disease progression per RECIST V1.1 or death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

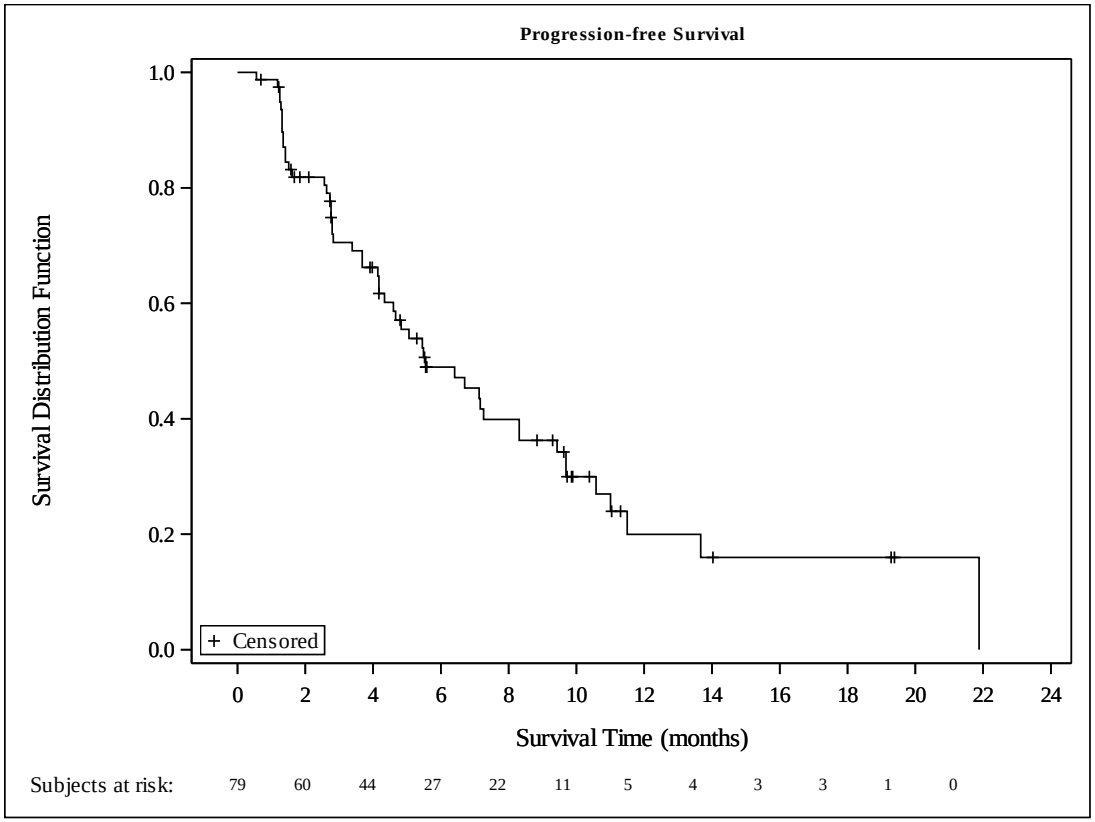
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Progression-free Survival
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	40 (62.5)	24 (37.5)	7.1 (4.2, 9.7)	70.5 (57.2, 80.3)	54.9 (40.9, 66.9)	39.5 (26.2, 52.6)	23.2 (10.8, 38.2)
mild	11 (78.6)	3 (21.4)	4.7 (2.8, 11.0)	71.4 (40.6, 88.2)	28.6 (8.8, 52.4)	28.6 (8.8, 52.4)	NE (NE, NE)
Race							
White	43 (62.3)	26 (37.7)	5.6 (4.2, 9.4)	69.3 (56.5, 79.0)	49.6 (36.3, 61.5)	39.3 (26.4, 51.8)	23.0 (10.9, 37.7)
Black or African American	1 (100.0)	0 (0.0)	4.7 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	6 (75.0)	2 (25.0)	7.2 (1.6, 9.7)	72.9 (27.6, 92.5)	58.3 (18.0, 84.4)	19.4 (0.9, 56.3)	NE (NE, NE)
Ethnicity							
Hispanic/Latino	4 (80.0)	1 (20.0)	4.3 (2.8, NE)	60.0 (12.6, 88.2)	40.0 (5.2, 75.3)	20.0 (0.8, 58.2)	20.0 (0.8, 58.2)
Non-Hispanic/Non-Latino	44 (62.9)	26 (37.1)	6.4 (4.2, 9.4)	69.8 (57.2, 79.4)	50.5 (37.3, 62.3)	37.9 (25.2, 50.5)	20.5 (8.7, 35.7)
Unknown	3 (75.0)	1 (25.0)	4.6 (4.1, 9.7)	100.0 (100.0, 100.0)	33.3 (0.9, 77.4)	33.3 (0.9, 77.4)	NE (NE, NE)

Progression-free survival (PFS) is defined as the time from the date of treatment start to the date of documented radiographic disease progression per RECIST V1.1 or death due to any cause. See SAP for the handling of censored cases.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Progression-free Survival
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Duration of Confirmed Response
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
Subjects with confirmed response (CR+PR), N*=33	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	15 (45.5)	18 (54.5)	8.1 (5.9, NE)	86.4 (67.7, 94.7)	67.3 (46.3, 81.6)	40.8 (20.1, 60.7)	40.8 (20.1, 60.7)
Region							
North America	7 (70.0)	3 (30.0)	8.1 (2.0, 16.5)	88.9 (43.3, 98.4)	50.8 (15.7, 78.1)	25.4 (3.8, 56.4)	25.4 (3.8, 56.4)
EU	8 (34.8)	15 (65.2)	NE (5.5, NE)	85.7 (62.0, 95.2)	74.5 (48.7, 88.6)	50.8 (23.0, 73.1)	50.8 (23.0, 73.1)
Age (Category 1)							
<65 years	10 (55.6)	8 (44.4)	6.9 (3.5, NE)	82.4 (54.7, 93.9)	54.6 (26.6, 75.9)	22.8 (4.0, 50.5)	NE (NE, NE)
>=65 years	5 (33.3)	10 (66.7)	16.5 (5.5, NE)	92.3 (56.6, 98.9)	83.9 (49.4, 95.7)	62.2 (26.3, 84.4)	62.2 (26.3, 84.4)
Age (Category 2)							
<75 years	14 (48.3)	15 (51.7)	8.1 (5.5, 16.5)	88.1 (67.6, 96.0)	65.6 (42.4, 81.3)	34.2 (13.6, 56.1)	34.2 (13.6, 56.1)
>=75 years	1 (25.0)	3 (75.0)	NE (2.0, NE)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)
Sex							
female	8 (66.7)	4 (33.3)	7.0 (2.8, NE)	81.8 (44.7, 95.1)	63.6 (29.7, 84.5)	27.3 (6.5, 53.9)	27.3 (6.5, 53.9)
male	7 (33.3)	14 (66.7)	16.5 (5.9, NE)	89.2 (63.1, 97.2)	69.9 (41.2, 86.5)	55.9 (22.6, 79.6)	55.9 (22.6, 79.6)
ECOG PS							
0	3 (37.5)	5 (62.5)	8.1 (2.9, NE)	83.3 (27.3, 97.5)	83.3 (27.3, 97.5)	33.3 (1.4, 75.5)	NE (NE, NE)
1	12 (48.0)	13 (52.0)	8.1 (5.5, NE)	87.0 (64.8, 95.6)	62.1 (37.8, 79.2)	41.9 (19.0, 63.5)	41.9 (19.0, 63.5)
HER2 Status in central laboratory							
IHC 3+	14 (43.8)	18 (56.3)	8.1 (5.5, NE)	85.9 (66.7, 94.5)	70.5 (49.3, 84.1)	42.8 (21.1, 62.9)	42.8 (21.1, 62.9)
IHC 2+/ISH +	1 (100.0)	0 (0.0)	5.9 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Primary tumor location							
Gastric	6 (40.0)	9 (60.0)	8.1 (5.5, NE)	85.7 (53.9, 96.2)	66.7 (32.9, 86.3)	44.4 (14.7, 71.0)	44.4 (14.7, 71.0)
GEJ	9 (50.0)	9 (50.0)	8.1 (4.1, 16.5)	87.1 (57.3, 96.6)	67.0 (37.9, 84.7)	35.7 (9.9, 63.2)	35.7 (9.9, 63.2)

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) and the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Duration of Confirmed Response
Full Analysis Set

Subjects with confirmed response (CR+PR), N*=33	T-DXd (N=79) Events (%)	Censored (%)	Median (95% CI) [a]	Kaplan-Meier estimates on each time point 3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	1 (100.0)	0 (0.0)	8.1 (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)
intestinal	3 (42.9)	4 (57.1)	6.9 (3.5, NE)	100.0 (100.0, 100.0)	64.3 (15.1, 90.2)	NE (NE, NE)	NE (NE, NE)
other	11 (44.0)	14 (56.0)	8.3 (4.1, NE)	81.3 (57.6, 92.6)	65.7 (41.0, 82.1)	45.2 (20.9, 66.8)	45.2 (20.9, 66.8)
Number of metastatic sites							
<2	1 (33.3)	2 (66.7)	5.9 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
>=2	14 (46.7)	16 (53.3)	8.1 (5.5, NE)	85.2 (65.2, 94.2)	69.4 (47.9, 83.4)	42.1 (20.7, 62.2)	42.1 (20.7, 62.2)
Previous total gastrectomy							
no	15 (45.5)	18 (54.5)	8.1 (5.9, NE)	86.4 (67.7, 94.7)	67.3 (46.3, 81.6)	40.8 (20.1, 60.7)	40.8 (20.1, 60.7)
Prior adjuvant/ neoadjuvant therapy							
yes	1 (33.3)	2 (66.7)	NE (4.1, NE)	100.0 (100.0, 100.0)	66.7 (5.4, 94.5)	NE (NE, NE)	NE (NE, NE)
no	14 (46.7)	16 (53.3)	8.1 (5.9, NE)	84.9 (64.5, 94.0)	67.9 (45.7, 82.6)	40.7 (19.7, 60.9)	40.7 (19.7, 60.9)
Prior nivolumab or pembrolizumab treatment							
yes	0 (0.0)	2 (100.0)	NE (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)
no	15 (48.4)	16 (51.6)	8.1 (5.5, NE)	85.7 (66.3, 94.4)	65.9 (44.4, 80.7)	37.7 (17.0, 58.3)	37.7 (17.0, 58.3)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	0 (0.0)	2 (100.0)	NE (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)
no	15 (48.4)	16 (51.6)	8.1 (5.5, NE)	85.7 (66.3, 94.4)	65.9 (44.4, 80.7)	37.7 (17.0, 58.3)	37.7 (17.0, 58.3)
Presence of liver metastasis at baseline							
yes	9 (47.4)	10 (52.6)	8.3 (5.5, NE)	94.1 (65.0, 99.1)	68.6 (40.0, 85.7)	44.1 (17.7, 67.9)	44.1 (17.7, 67.9)
no	6 (42.9)	8 (57.1)	8.1 (2.8, NE)	75.5 (41.6, 91.4)	66.1 (32.5, 85.8)	35.2 (6.6, 67.1)	35.2 (6.6, 67.1)
Renal impairment at baseline							
normal	5 (55.6)	4 (44.4)	5.9 (2.3, NE)	87.5 (38.7, 98.1)	41.7 (7.2, 74.7)	NE (NE, NE)	NE (NE, NE)
mild	2 (16.7)	10 (83.3)	NE (4.1, NE)	100.0 (100.0, 100.0)	88.9 (43.3, 98.4)	71.1 (23.3, 92.3)	71.1 (23.3, 92.3)
moderate	3 (60.0)	2 (40.0)	12.3 (7.0, 16.5)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	50.0 (5.8, 84.5)	50.0 (5.8, 84.5)

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) and the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

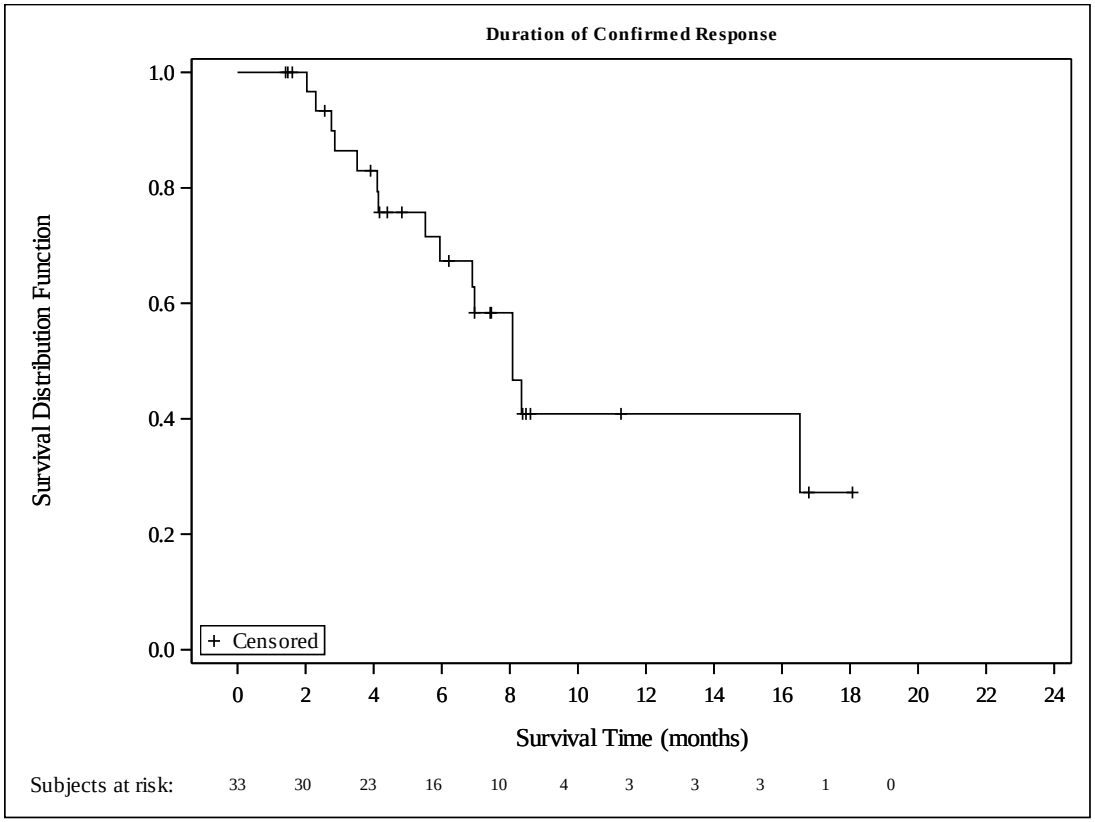
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Duration of Confirmed Response
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
Subjects with confirmed response (CR+PR), N*=33	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	11 (42.3)	15 (57.7)	8.3 (5.9, NE)	87.1 (65.2, 95.7)	72.2 (48.0, 86.6)	47.5 (23.5, 68.2)	47.5 (23.5, 68.2)
mild	4 (57.1)	3 (42.9)	6.1 (2.0, 8.1)	83.3 (27.3, 97.5)	50.0 (11.1, 80.4)	NE (NE, NE)	NE (NE, NE)
Race							
White	13 (43.3)	17 (56.7)	8.3 (6.9, NE)	88.6 (68.7, 96.2)	72.2 (50.1, 85.7)	43.8 (21.5, 64.2)	43.8 (21.5, 64.2)
Black or African American	1 (100.0)	0 (0.0)	2.0 (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	1 (50.0)	1 (50.0)	5.9 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Ethnicity							
Hispanic/Latino	1 (50.0)	1 (50.0)	NE (2.9, NE)	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)	50.0 (0.6, 91.0)
Non-Hispanic/Non-Latino	14 (46.7)	16 (53.3)	8.1 (5.9, NE)	89.1 (70.0, 96.4)	68.5 (46.4, 83.0)	39.2 (17.7, 60.2)	39.2 (17.7, 60.2)
Unknown	0 (0.0)	1 (100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Duration of response (DoR) is defined as the time from the date of the first documentation of objective response (CR or PR) and the date of the first objective documentation of disease progression or death due to any cause. See SAP for the handling of censored cases.
N*: Responding subjects (PR or CR).
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Duration of Confirmed Response
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Time to Confirmed Response
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	33 (41.8)	46 (58.2)	4.1 (3.0, 7.4)	62.5 (49.0, 73.3)	42.5 (27.2, 56.9)	27.9 (10.6, 48.3)	27.9 (10.6, 48.3)
Region							
North America	10 (29.4)	24 (70.6)	7.4 (3.0, NE)	70.0 (48.0, 84.1)	62.2 (37.4, 79.5)	41.5 (9.4, 72.1)	NE (NE, NE)
EU	23 (51.1)	22 (48.9)	3.7 (1.5, 4.8)	57.7 (40.0, 71.9)	26.1 (9.9, 45.9)	13.1 (1.2, 39.0)	13.1 (1.2, 39.0)
Age (Category 1)							
<65 years	18 (39.1)	28 (60.9)	6.0 (3.0, NE)	66.7 (48.9, 79.5)	51.8 (31.3, 69.0)	28.8 (6.9, 56.1)	28.8 (6.9, 56.1)
>=65 years	15 (45.5)	18 (54.5)	3.1 (1.4, NE)	55.2 (32.7, 72.8)	27.9 (8.9, 51.0)	NE (NE, NE)	NE (NE, NE)
Age (Category 2)							
<75 years	29 (38.7)	46 (61.3)	4.8 (3.7, NE)	67.2 (53.4, 77.7)	45.7 (29.4, 60.5)	30.0 (11.3, 51.4)	30.0 (11.3, 51.4)
>=75 years	4 (100.0)	0 (0.0)	2.0 (1.3, 2.7)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Sex							
female	12 (54.5)	10 (45.5)	3.0 (1.4, NE)	46.7 (23.0, 67.5)	33.4 (12.9, 55.6)	33.4 (12.9, 55.6)	NE (NE, NE)
male	21 (36.8)	36 (63.2)	5.4 (3.1, NE)	69.3 (53.3, 80.7)	47.3 (27.9, 64.4)	27.0 (6.8, 52.9)	27.0 (6.8, 52.9)
ECOG PS							
0	8 (27.6)	21 (72.4)	NE (3.0, NE)	71.6 (46.7, 86.4)	59.7 (34.5, 77.9)	59.7 (34.5, 77.9)	59.7 (34.5, 77.9)
1	25 (50.0)	25 (50.0)	3.7 (1.4, 6.0)	57.6 (41.2, 71.0)	32.0 (14.3, 51.3)	10.7 (0.8, 35.3)	NE (NE, NE)
HER2 Status in central laboratory							
IHC 3+	32 (47.1)	36 (52.9)	4.1 (2.8, 7.4)	60.6 (46.5, 72.1)	39.7 (24.4, 54.6)	26.0 (9.8, 45.9)	26.0 (9.8, 45.9)
IHC 2+/ISH +	1 (10.0)	9 (90.0)	NE (1.2, NE)	88.9 (43.3, 98.4)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Primary tumor location							
Gastric	15 (55.6)	12 (44.4)	2.7 (1.4, 4.8)	49.6 (26.7, 69.0)	18.9 (3.8, 42.7)	18.9 (3.8, 42.7)	NE (NE, NE)
GEJ	18 (34.6)	34 (65.4)	6.0 (3.9, NE)	68.8 (51.9, 80.8)	54.8 (34.7, 71.0)	31.3 (7.7, 59.1)	31.3 (7.7, 59.1)

Time to response is defined as the time from the date of treatment start to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Time to Confirmed Response
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	1 (100.0)	0 (0.0)	3.0 (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
intestinal	7 (36.8)	12 (63.2)	4.8 (1.4, NE)	76.6 (48.8, 90.5)	41.0 (11.8, 69.0)	41.0 (11.8, 69.0)	41.0 (11.8, 69.0)
other	25 (42.4)	34 (57.6)	5.4 (2.7, 7.4)	60.9 (45.4, 73.2)	44.7 (27.0, 61.0)	23.8 (5.7, 48.8)	NE (NE, NE)
Number of metastatic sites							
<2	3 (60.0)	2 (40.0)	6.0 (1.2, 6.0)	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)	NE (NE, NE)	NE (NE, NE)
>=2	30 (40.5)	44 (59.5)	4.1 (3.0, 7.4)	62.4 (48.1, 73.7)	38.8 (22.6, 54.8)	29.1 (11.2, 50.0)	29.1 (11.2, 50.0)
Previous total gastrectomy							
no	33 (41.8)	46 (58.2)	4.1 (3.0, 7.4)	62.5 (49.0, 73.3)	42.5 (27.2, 56.9)	27.9 (10.6, 48.3)	27.9 (10.6, 48.3)
Prior adjuvant/ neoadjuvant therapy							
yes	3 (33.3)	6 (66.7)	NE (1.4, NE)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	50.0 (8.0, 82.6)	50.0 (8.0, 82.6)
no	30 (42.9)	40 (57.1)	4.1 (2.8, 7.4)	60.2 (45.4, 72.2)	33.1 (16.7, 50.6)	NE (NE, NE)	NE (NE, NE)
Prior nivolumab or pembrolizumab treatment							
yes	2 (33.3)	4 (66.7)	NE (1.2, NE)	62.5 (14.2, 89.3)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
no	31 (42.5)	42 (57.5)	4.1 (3.0, 7.4)	62.5 (48.4, 73.8)	41.0 (25.3, 56.0)	26.9 (10.1, 47.2)	26.9 (10.1, 47.2)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	2 (28.6)	5 (71.4)	NE (1.2, NE)	68.6 (21.3, 91.2)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
no	31 (43.1)	41 (56.9)	4.1 (3.0, 7.4)	61.9 (47.7, 73.3)	40.6 (25.0, 55.6)	26.6 (10.0, 46.8)	26.6 (10.0, 46.8)
Presence of liver metastasis at baseline							
yes	19 (38.0)	31 (62.0)	4.8 (3.0, NE)	65.8 (47.7, 78.9)	39.5 (19.3, 59.1)	19.7 (1.7, 52.2)	19.7 (1.7, 52.2)
no	14 (48.3)	15 (51.7)	3.7 (1.4, NE)	57.4 (36.3, 73.8)	45.9 (24.7, 64.8)	30.6 (7.6, 58.0)	NE (NE, NE)
Renal impairment at baseline							
normal	9 (28.1)	23 (71.9)	7.4 (6.0, 7.4)	73.4 (52.1, 86.3)	73.4 (52.1, 86.3)	NE (NE, NE)	NE (NE, NE)
mild	12 (48.0)	13 (52.0)	3.0 (1.4, NE)	50.0 (24.5, 71.0)	23.8 (5.1, 50.1)	23.8 (5.1, 50.1)	23.8 (5.1, 50.1)
moderate	5 (62.5)	3 (37.5)	3.1 (1.3, 5.4)	58.3 (18.0, 84.4)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)

Time to response is defined as the time from the date of treatment start to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

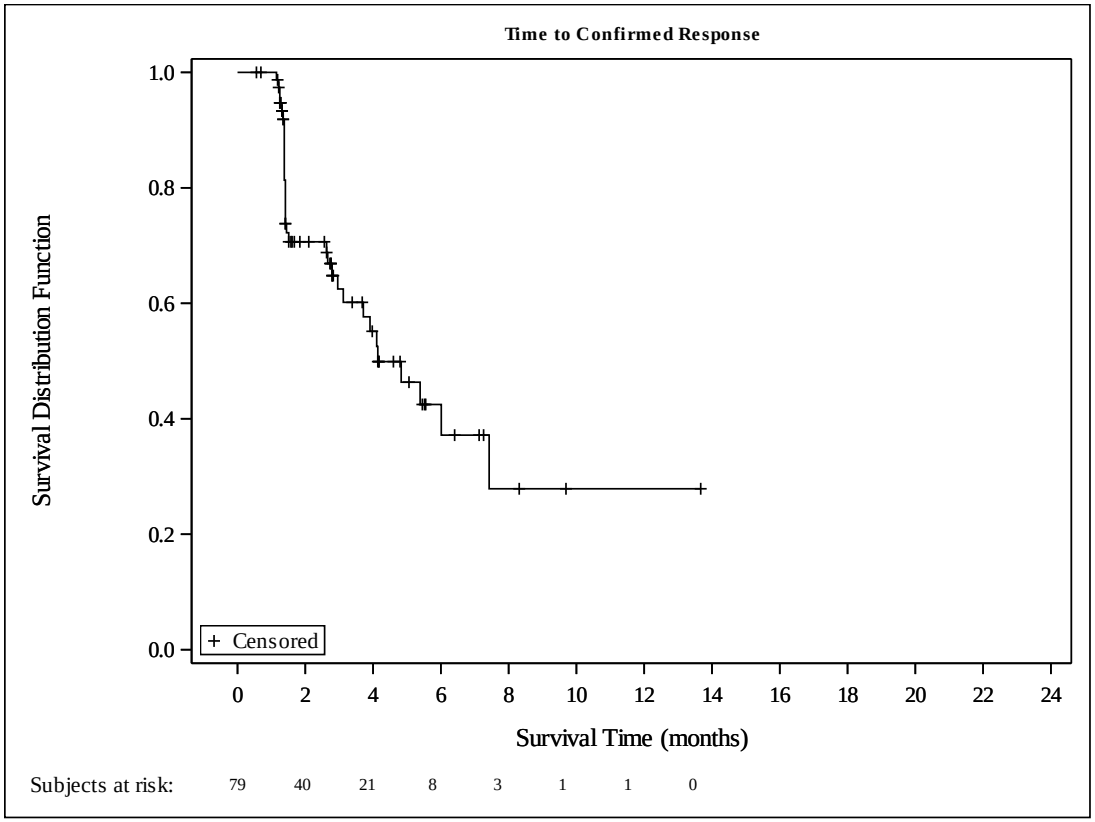
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Time to Confirmed Response
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	26 (40.6)	38 (59.4)	5.4 (2.8, NE)	64.4 (49.6, 75.9)	46.3 (29.0, 61.9)	30.4 (11.3, 52.2)	30.4 (11.3, 52.2)
mild	7 (50.0)	7 (50.0)	3.9 (1.4, NE)	55.9 (23.4, 79.3)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Race							
White	30 (43.5)	39 (56.5)	4.1 (3.0, 6.0)	61.7 (47.1, 73.4)	38.7 (22.8, 54.3)	21.5 (5.5, 44.2)	21.5 (5.5, 44.2)
Black or African American	1 (100.0)	0 (0.0)	2.7 (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	NE (1.2, NE)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	NE (NE, NE)
Ethnicity							
Hispanic/Latino	2 (40.0)	3 (60.0)	NE (1.5, NE)	60.0 (12.6, 88.2)	60.0 (12.6, 88.2)	NE (NE, NE)	NE (NE, NE)
Non-Hispanic/Non-Latino	30 (42.9)	40 (57.1)	4.1 (3.0, 7.4)	62.0 (47.3, 73.7)	38.9 (22.9, 54.5)	21.6 (5.6, 44.3)	21.6 (5.6, 44.3)
Unknown	1 (25.0)	3 (75.0)	NE (1.1, NE)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	NE (NE, NE)

Time to response is defined as the time from the date of treatment start to the date of the first documentation of objective response (CR or PR) assessed by ICR. Censored cases are handled the same way as PFS.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Time to Confirmed Response
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Time to Hospitalization
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Overall	31 (39.2)	48 (60.8)	NE (11.7, NE)	74.7 (63.5, 82.8)	66.7 (55.1, 76.0)	62.1 (50.1, 72.0)	59.6 (47.1, 70.1)
Region							
North America	11 (32.4)	23 (67.6)	NE (4.1, NE)	76.5 (58.4, 87.5)	67.3 (48.7, 80.4)	67.3 (48.7, 80.4)	67.3 (48.7, 80.4)
EU	20 (44.4)	25 (55.6)	NE (7.2, NE)	73.3 (57.8, 83.9)	66.4 (50.5, 78.2)	58.6 (42.5, 71.7)	54.7 (37.9, 68.7)
Age (Category 1)							
<65 years	18 (39.1)	28 (60.9)	NE (5.2, NE)	73.9 (58.7, 84.3)	64.5 (48.7, 76.6)	61.6 (45.5, 74.2)	56.5 (38.6, 70.9)
>=65 years	13 (39.4)	20 (60.6)	NE (7.2, NE)	75.8 (57.3, 87.1)	69.7 (51.0, 82.4)	62.7 (43.7, 76.9)	62.7 (43.7, 76.9)
Age (Category 2)							
<75 years	28 (37.3)	47 (62.7)	NE (11.7, NE)	74.6 (63.2, 83.0)	67.7 (55.7, 77.0)	64.4 (52.1, 74.2)	61.7 (48.8, 72.2)
>=75 years	3 (75.0)	1 (25.0)	5.7 (1.2, NE)	75.0 (12.8, 96.1)	50.0 (5.8, 84.5)	25.0 (0.9, 66.5)	25.0 (0.9, 66.5)
Sex							
female	10 (45.5)	12 (54.5)	12.1 (4.1, NE)	81.8 (58.5, 92.8)	67.4 (43.4, 83.0)	57.8 (34.4, 75.4)	57.8 (34.4, 75.4)
male	21 (36.8)	36 (63.2)	NE (11.7, NE)	71.9 (58.3, 81.7)	66.4 (52.6, 77.1)	64.2 (50.1, 75.3)	60.7 (45.5, 72.8)
ECOG PS							
0	3 (10.3)	26 (89.7)	NE (NE, NE)	96.4 (77.2, 99.5)	89.0 (69.7, 96.3)	89.0 (69.7, 96.3)	89.0 (69.7, 96.3)
1	28 (56.0)	22 (44.0)	7.7 (1.4, NE)	62.0 (47.1, 73.8)	53.9 (39.1, 66.5)	47.0 (32.5, 60.2)	42.7 (27.6, 57.1)
HER2 Status in central laboratory							
IHC 3+	25 (36.8)	43 (63.2)	NE (11.7, NE)	77.9 (66.1, 86.0)	70.2 (57.7, 79.7)	65.0 (52.1, 75.3)	62.4 (49.0, 73.3)
IHC 2+/ISH +	5 (50.0)	5 (50.0)	NE (0.4, NE)	60.0 (25.3, 82.7)	50.0 (18.4, 75.3)	50.0 (18.4, 75.3)	NE (NE, NE)
Primary tumor location							
Gastric	13 (48.1)	14 (51.9)	12.1 (4.1, NE)	77.8 (57.1, 89.3)	66.7 (45.7, 81.1)	53.8 (33.0, 70.8)	53.8 (33.0, 70.8)
GEJ	18 (34.6)	34 (65.4)	NE (11.7, NE)	73.0 (58.7, 83.0)	66.9 (52.2, 78.0)	66.9 (52.2, 78.0)	63.2 (47.4, 75.4)

Time to hospitalization is defined as the time from the date of treatment start to the date of the first hospitalization. Patients without hospitalization are censored at last known alive date.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Time to Hospitalization
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Histological subtype							
diffuse	0 (0.0)	1 (100.0)	NE (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)
intestinal	8 (42.1)	11 (57.9)	12.1 (5.2, NE)	84.2 (58.7, 94.6)	73.0 (46.7, 87.8)	59.7 (33.1, 78.6)	59.7 (33.1, 78.6)
other	23 (39.0)	36 (61.0)	NE (8.7, NE)	71.1 (57.8, 81.0)	64.1 (50.4, 74.9)	62.0 (48.2, 73.2)	58.6 (43.9, 70.7)
Number of metastatic sites							
<2	0 (0.0)	5 (100.0)	NE (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)
>=2	31 (41.9)	43 (58.1)	NE (7.7, NE)	72.9 (61.3, 81.6)	64.4 (52.3, 74.2)	59.6 (47.3, 70.0)	57.2 (44.3, 68.1)
Previous total gastrectomy							
no	31 (39.2)	48 (60.8)	NE (11.7, NE)	74.7 (63.5, 82.8)	66.7 (55.1, 76.0)	62.1 (50.1, 72.0)	59.6 (47.1, 70.1)
Prior adjuvant/ neoadjuvant therapy							
yes	3 (33.3)	6 (66.7)	NE (0.1, NE)	77.8 (36.5, 93.9)	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)	66.7 (28.2, 87.8)
no	28 (40.0)	42 (60.0)	NE (8.7, NE)	74.3 (62.3, 82.9)	66.7 (54.3, 76.5)	61.5 (48.7, 72.0)	58.8 (45.5, 70.0)
Prior nivolumab or pembrolizumab treatment							
yes	0 (0.0)	6 (100.0)	NE (NE, NE)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)	100.0 (100.0, 100.0)
no	31 (42.5)	42 (57.5)	NE (7.7, NE)	72.6 (60.8, 81.4)	64.1 (51.9, 74.0)	59.3 (46.8, 69.7)	56.7 (43.8, 67.7)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	1 (14.3)	6 (85.7)	NE (3.6, NE)	100.0 (100.0, 100.0)	83.3 (27.3, 97.5)	83.3 (27.3, 97.5)	83.3 (27.3, 97.5)
no	30 (41.7)	42 (58.3)	NE (7.7, NE)	72.2 (60.3, 81.1)	65.0 (52.8, 74.8)	60.1 (47.6, 70.5)	57.5 (44.5, 68.5)
Presence of liver metastasis at baseline							
yes	19 (38.0)	31 (62.0)	NE (7.2, NE)	76.0 (61.6, 85.6)	67.4 (52.3, 78.6)	64.8 (49.4, 76.5)	60.7 (44.2, 73.7)
no	12 (41.4)	17 (58.6)	NE (3.6, NE)	72.4 (52.3, 85.1)	65.5 (45.4, 79.7)	58.2 (38.3, 73.8)	58.2 (38.3, 73.8)
Renal impairment at baseline							
normal	11 (34.4)	21 (65.6)	NE (1.7, NE)	68.8 (49.7, 81.8)	65.3 (46.1, 79.1)	65.3 (46.1, 79.1)	65.3 (46.1, 79.1)
mild	7 (28.0)	18 (72.0)	NE (11.7, NE)	80.0 (58.4, 91.1)	76.0 (54.2, 88.4)	76.0 (54.2, 88.4)	69.1 (44.6, 84.4)
moderate	6 (75.0)	2 (25.0)	7.4 (1.4, NE)	87.5 (38.7, 98.1)	62.5 (22.9, 86.1)	25.0 (3.7, 55.8)	25.0 (3.7, 55.8)

Time to hospitalization is defined as the time from the date of treatment start to the date of the first hospitalization. Patients without hospitalization are censored at last known alive date.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

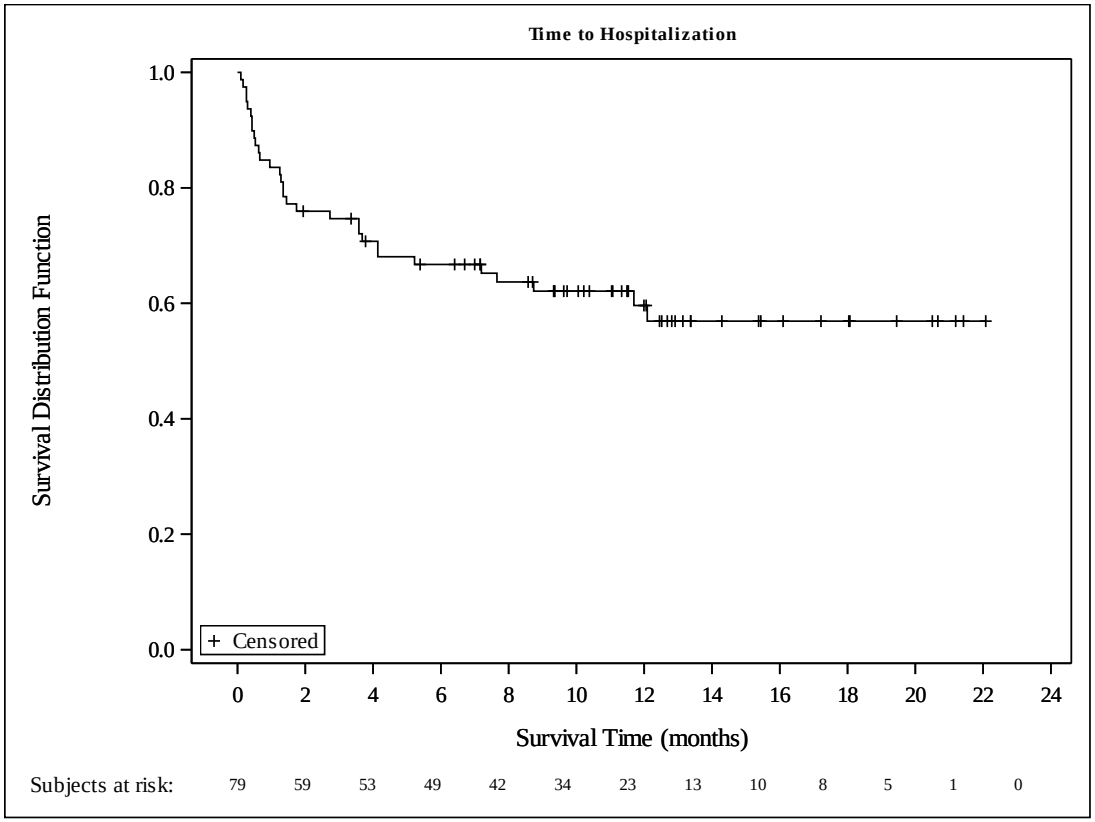
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Summary of Time to Hospitalization
Full Analysis Set

	T-DXd (N=79)						
				Kaplan-Meier estimates on each time point			
	Events (%)	Censored (%)	Median (95% CI) [a]	3 Months (95% CI)	6 Months (95% CI)	9 Months (95% CI)	12 Months (95% CI)
Hepatic impairment at baseline							
normal	21 (32.8)	43 (67.2)	NE (12.1, NE)	78.1 (65.8, 86.4)	73.2 (60.4, 82.4)	67.4 (54.0, 77.7)	67.4 (54.0, 77.7)
mild	9 (64.3)	5 (35.7)	4.1 (0.5, NE)	64.3 (34.3, 83.3)	42.9 (17.7, 66.0)	42.9 (17.7, 66.0)	32.1 (9.5, 57.9)
Race							
White	27 (39.1)	42 (60.9)	NE (11.7, NE)	73.9 (61.8, 82.7)	67.9 (55.5, 77.6)	62.8 (50.0, 73.2)	60.2 (46.9, 71.2)
Black or African American	1 (100.0)	0 (0.0)	4.1 (NE, NE)	100.0 (100.0, 100.0)	NE (NE, NE)	NE (NE, NE)	NE (NE, NE)
Other	2 (25.0)	6 (75.0)	NE (0.4, NE)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)	75.0 (31.5, 93.1)
Ethnicity							
Hispanic/Latino	3 (60.0)	2 (40.0)	3.6 (1.2, NE)	80.0 (20.4, 96.9)	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Non-Hispanic/Non-Latino	27 (38.6)	43 (61.4)	NE (11.7, NE)	72.8 (60.8, 81.7)	68.3 (55.9, 77.9)	63.0 (50.1, 73.3)	60.1 (46.6, 71.2)
Unknown	1 (25.0)	3 (75.0)	NE (4.1, NE)	100.0 (100.0, 100.0)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)	75.0 (12.8, 96.1)

Time to hospitalization is defined as the time from the date of treatment start to the date of the first hospitalization. Patients without hospitalization are censored at last known alive date.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Time to Hospitalization
Full Analysis Set



Source data: ADAM.ADSL, ADAM.ADTTE and ADAM.ADHO
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set

	T-DXd (N=79)
Results (mm)	
n	76
Mean (SD)	50.8 (48.74)
Median	32.5
Q1, Q3	17.5, 65.0
Min, Max	0.0, 232.0
Change from Baseline (mm)	
n	76
Mean (SD)	-25.3 (31.89)
Median	-19.0
Q1, Q3	-37.5, -7.0
Min, Max	-180.0, 31.0
Percent Change from Baseline (%)	
n	76
Mean (SD)	-37.1 (33.93)
Median	-40.0
Q1, Q3	-62.0, -12.5
Min, Max	-100.0, 59.0

Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR - Subgroup analysis
Full Analysis Set

Subgroup Level	T-DXd (N=79) N	Mean (SD)	Median	Q1,	Q3	Min,	Max
Region							
North America	32	-31.7 (36.30)	-32.0	-48.5,	-8.5	-100.0,	51.0
EU	44	-41.0 (31.94)	-48.0	-64.5,	-22.5	-100.0,	59.0
Age (Category 1)							
<65 years	44	-40.5 (28.07)	-41.0	-59.5,	-21.0	-100.0,	6.0
>=65 years	32	-32.5 (40.67)	-37.5	-68.5,	-8.5	-100.0,	59.0
Age (Category 2)							
<75 years	72	-35.7 (34.26)	-38.0	-59.5,	-11.0	-100.0,	59.0
>=75 years	4	-62.5 (9.68)	-64.5	-68.5,	-56.5	-72.0,	-49.0
Sex							
female	21	-48.3 (25.00)	-49.0	-71.0,	-30.0	-89.0,	0.0
male	55	-32.9 (36.06)	-37.0	-57.0,	-8.0	-100.0,	59.0
ECOG PS							
0	29	-27.7 (37.29)	-34.0	-44.0,	-8.0	-100.0,	59.0
1	47	-42.9 (30.66)	-48.0	-65.0,	-14.0	-100.0,	21.0
HER2 Status in central laboratory							
IHC 3+	65	-42.2 (31.36)	-43.0	-64.0,	-24.0	-100.0,	59.0
IHC 2+/ISH +	10	-8.0 (36.33)	-8.0	-13.0,	6.0	-92.0,	51.0
Primary tumor location							
Gastric	26	-40.5 (36.09)	-47.5	-64.0,	-24.0	-92.0,	59.0
GEJ	50	-35.3 (32.99)	-35.5	-57.0,	-12.0	-100.0,	51.0
Histological subtype							
diffuse	1	-59.0 (-)	-59.0	-59.0,	-59.0	-59.0,	-59.0
intestinal	19	-32.4 (31.94)	-40.0	-58.0,	-14.0	-75.0,	59.0
other	56	-38.3 (34.90)	-39.0	-64.0,	-10.5	-100.0,	51.0
Number of metastatic sites							
<2	4	-49.3 (33.72)	-46.5	-74.0,	-24.5	-92.0,	-12.0
>=2	72	-36.4 (34.05)	-40.0	-62.0,	-11.5	-100.0,	59.0
Previous total gastrectomy							
no	76	-37.1 (33.93)	-40.0	-62.0,	-12.5	-100.0,	59.0
Prior adjuvant/ neoadjuvant therapy							
yes	7	-38.0 (30.12)	-34.0	-72.0,	-12.0	-73.0,	5.0
no	69	-37.0 (34.49)	-40.0	-61.0,	-13.0	-100.0,	59.0
Prior nivolumab or pembrolizumab treatment							
yes	6	-42.2 (29.45)	-39.0	-61.0,	-13.0	-89.0,	-12.0
no	70	-36.7 (34.44)	-40.0	-63.0,	-10.0	-100.0,	59.0
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy							
yes	7	-37.4 (29.66)	-37.0	-61.0,	-12.0	-89.0,	-9.0
no	69	-37.1 (34.53)	-40.0	-63.0,	-14.0	-100.0,	59.0
Presence of liver metastasis at baseline							
yes	49	-36.3 (37.31)	-40.0	-64.0,	-9.0	-100.0,	59.0
no	27	-38.6 (27.33)	-40.0	-58.0,	-24.0	-89.0,	34.0

Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

Date of Table Generation: 16AUG2022

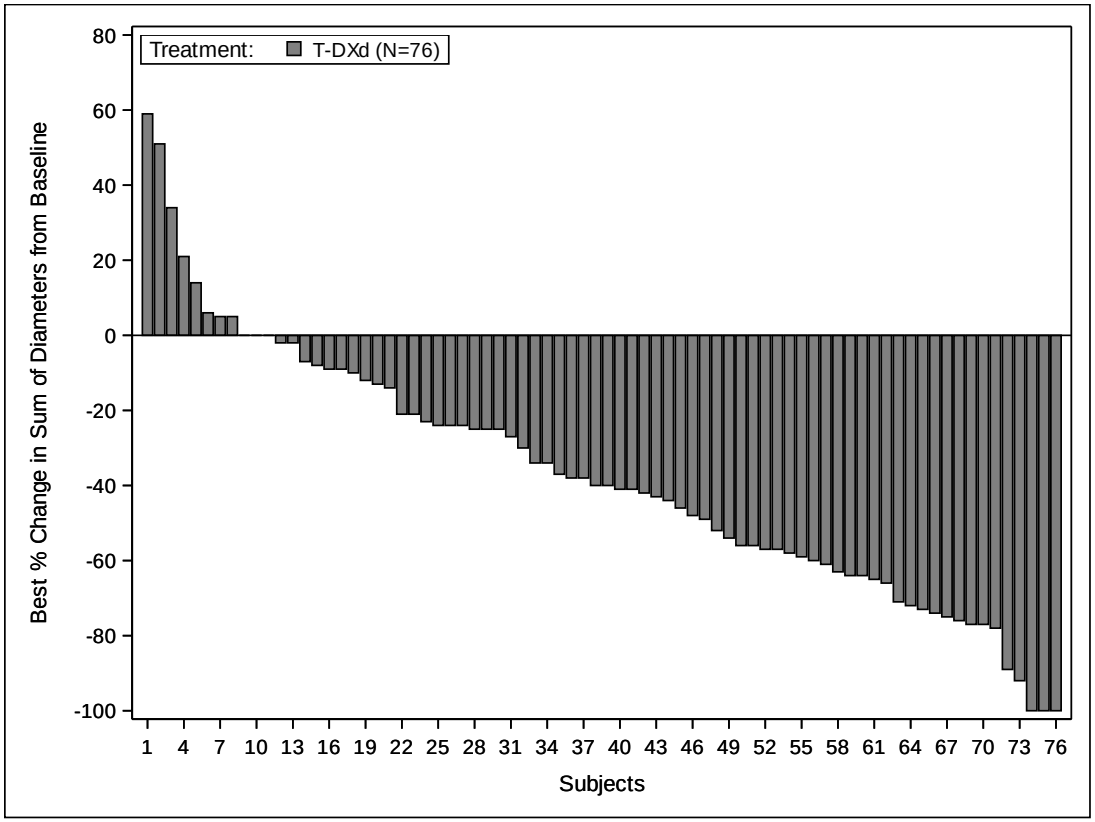
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR - Subgroup analysis
Full Analysis Set

Subgroup Level	T-DXd (N=79) N	Mean (SD)	Median	Q1,	Q3	Min,	Max
Renal impairment at baseline							
normal	31	-33.8 (34.34)	-38.0	-57.0,	-9.0	-100.0,	51.0
mild	24	-32.8 (38.21)	-33.5	-65.5,	-9.5	-100.0,	59.0
moderate	8	-51.3 (32.73)	-60.5	-70.5,	-24.0	-100.0,	0.0
Hepatic impairment at baseline							
normal	62	-36.9 (35.72)	-38.0	-63.0,	-14.0	-100.0,	59.0
mild	13	-40.2 (25.23)	-48.0	-59.0,	-13.0	-73.0,	-2.0
Race							
White	66	-36.6 (35.12)	-40.0	-63.0,	-12.0	-100.0,	59.0
Black or African American	1	-49.0 (-)	-49.0	-49.0,	-49.0	-49.0,	-49.0
Other	8	-44.0 (25.12)	-39.5	-55.0,	-32.0	-92.0,	-7.0
Ethnicity							
Hispanic/Latino	5	-34.0 (20.63)	-34.0	-38.0,	-24.0	-65.0,	-9.0
Non-Hispanic/Non-Latino	67	-37.9 (35.51)	-41.0	-64.0,	-12.0	-100.0,	59.0
Unknown	4	-27.3 (17.69)	-32.0	-38.5,	-16.0	-43.0,	-2.0

Source data: ADAM.ADSL and ADAM.ADTR
Daiichi Sankyo

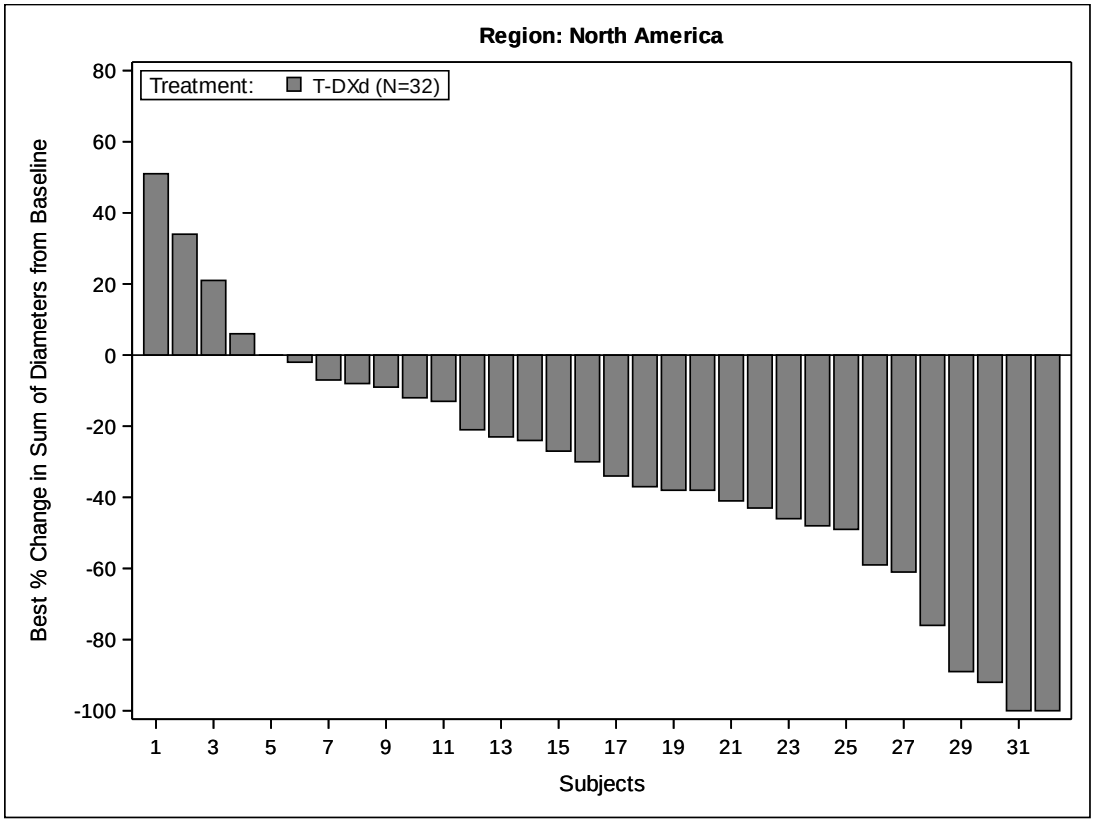
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



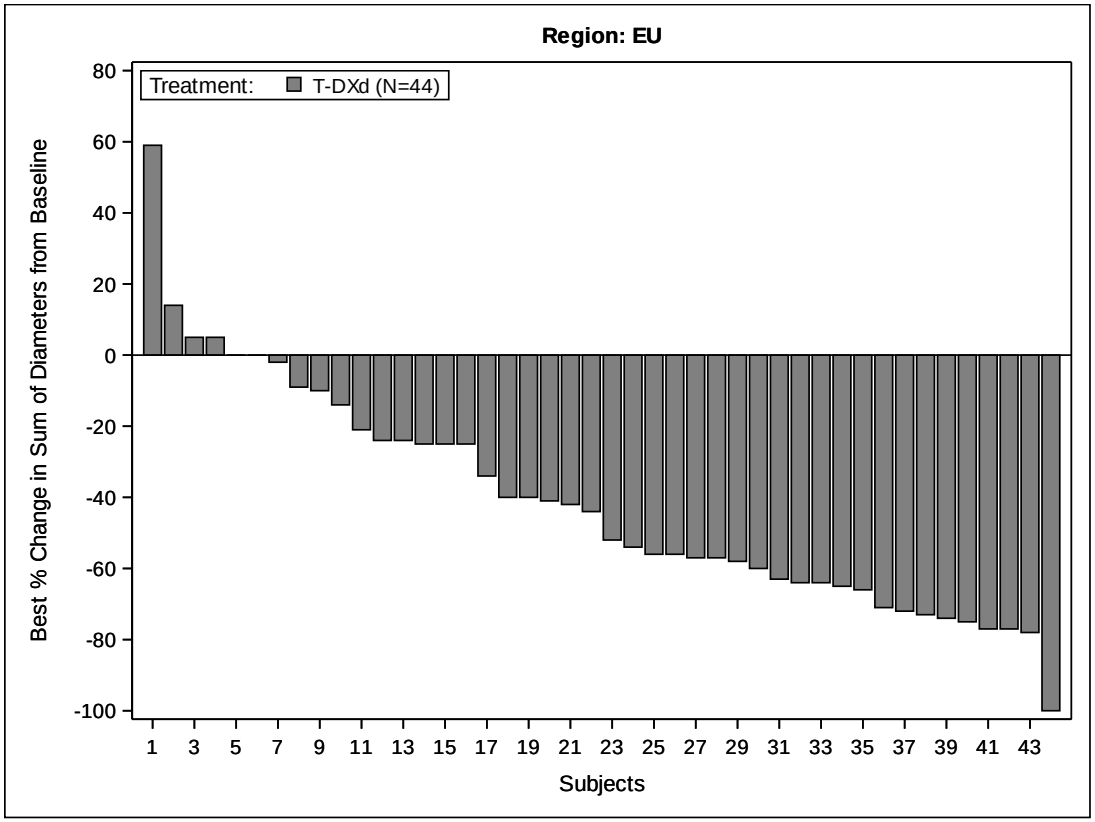
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



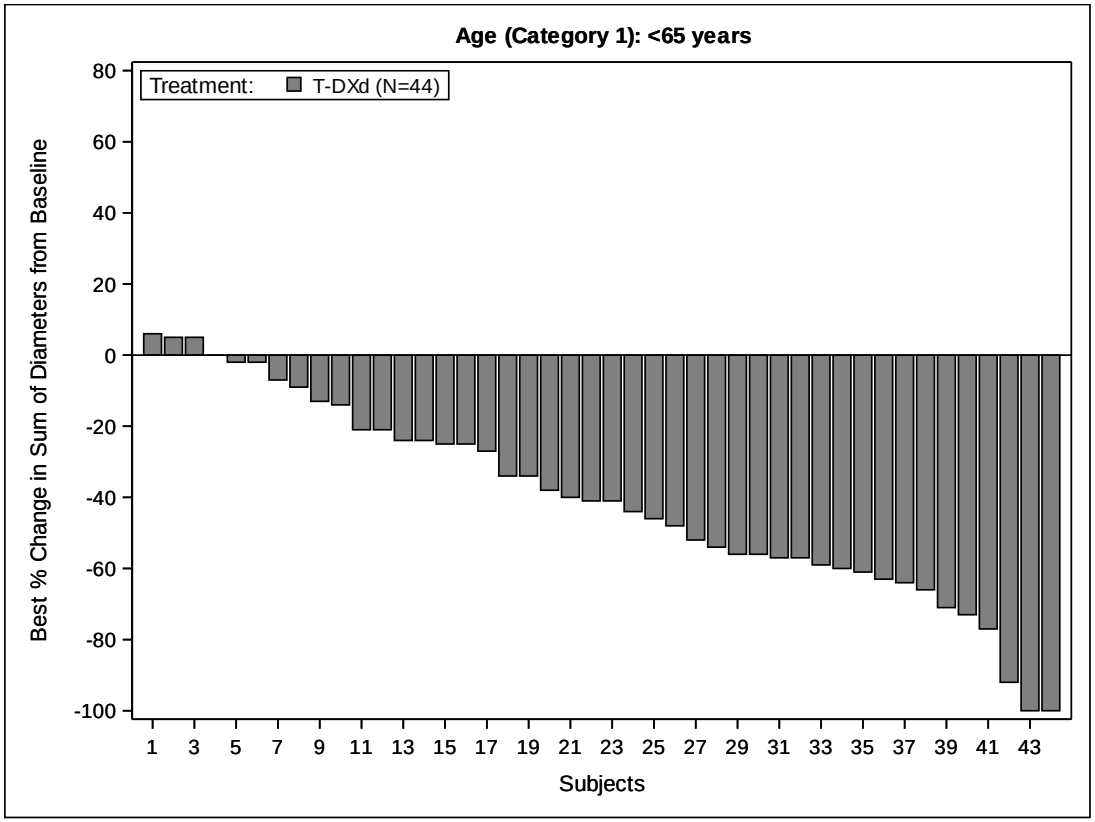
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



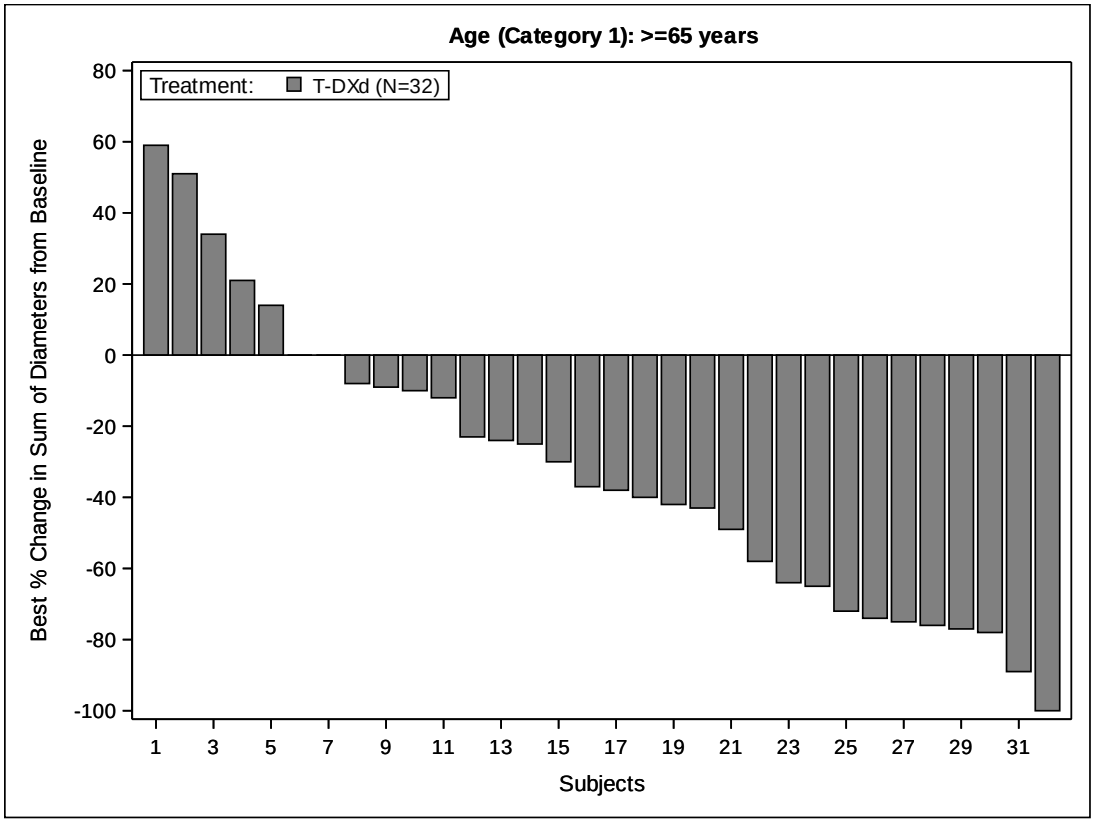
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



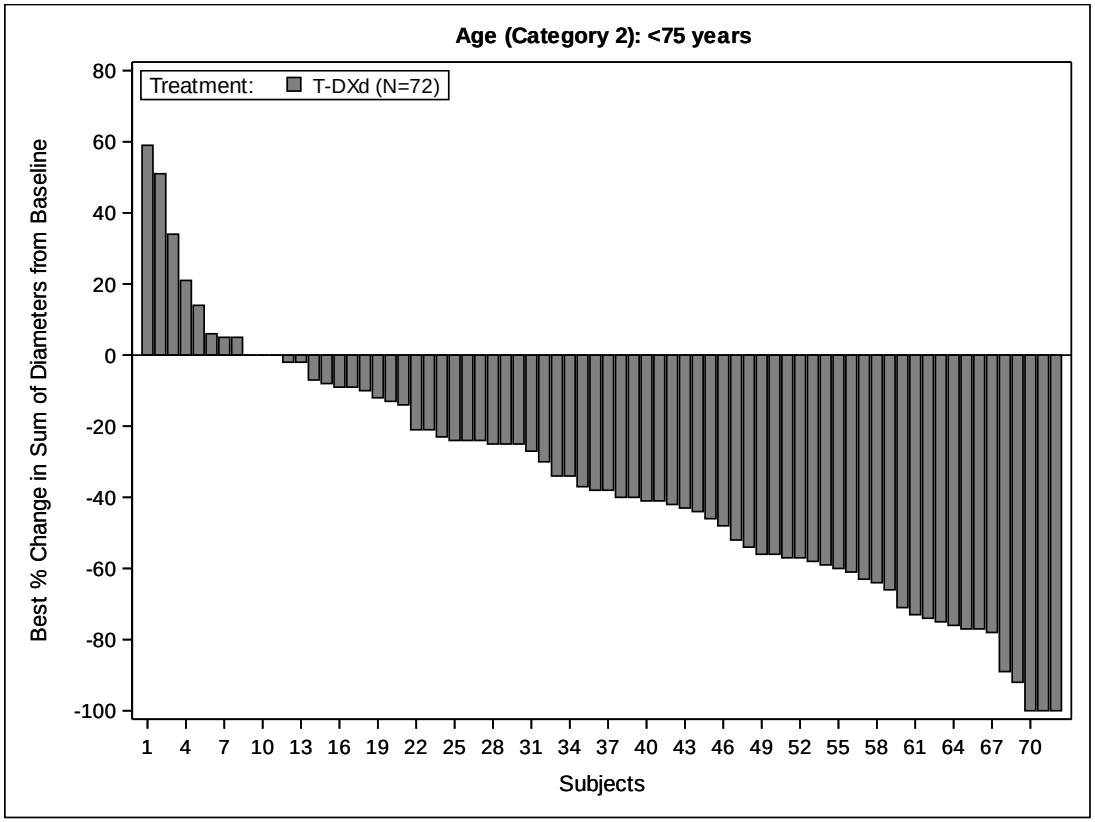
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



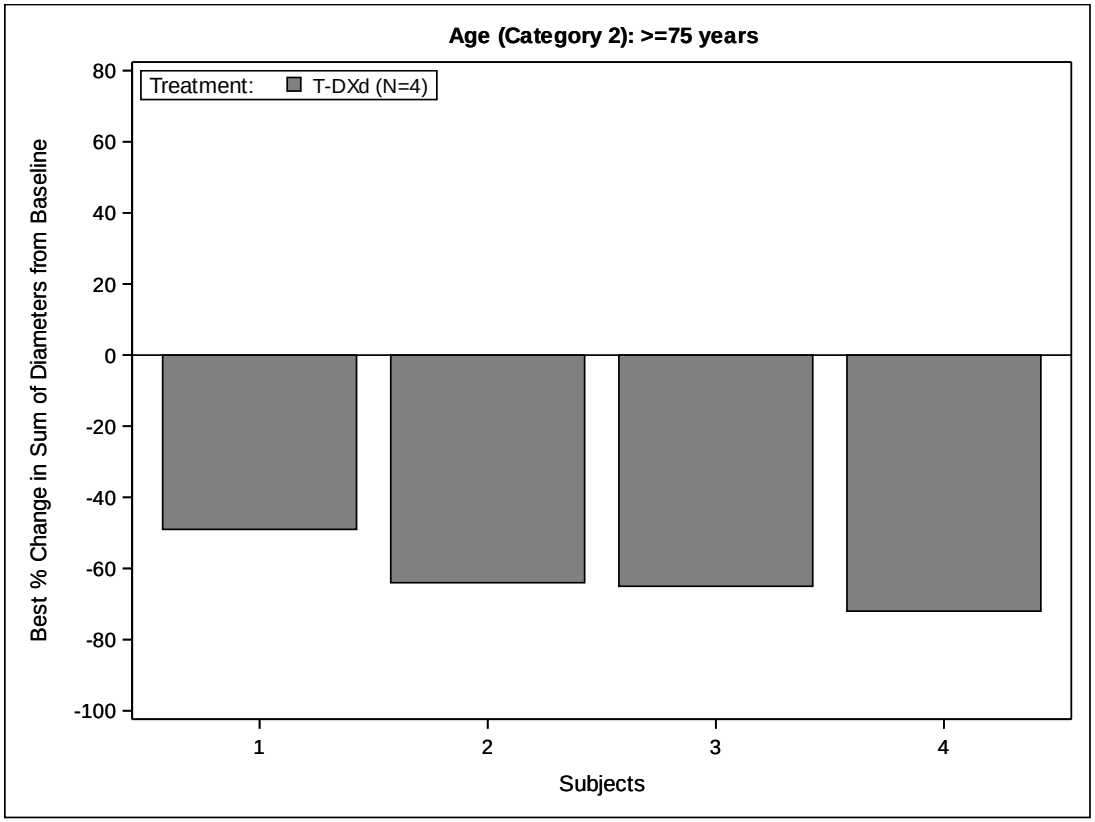
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



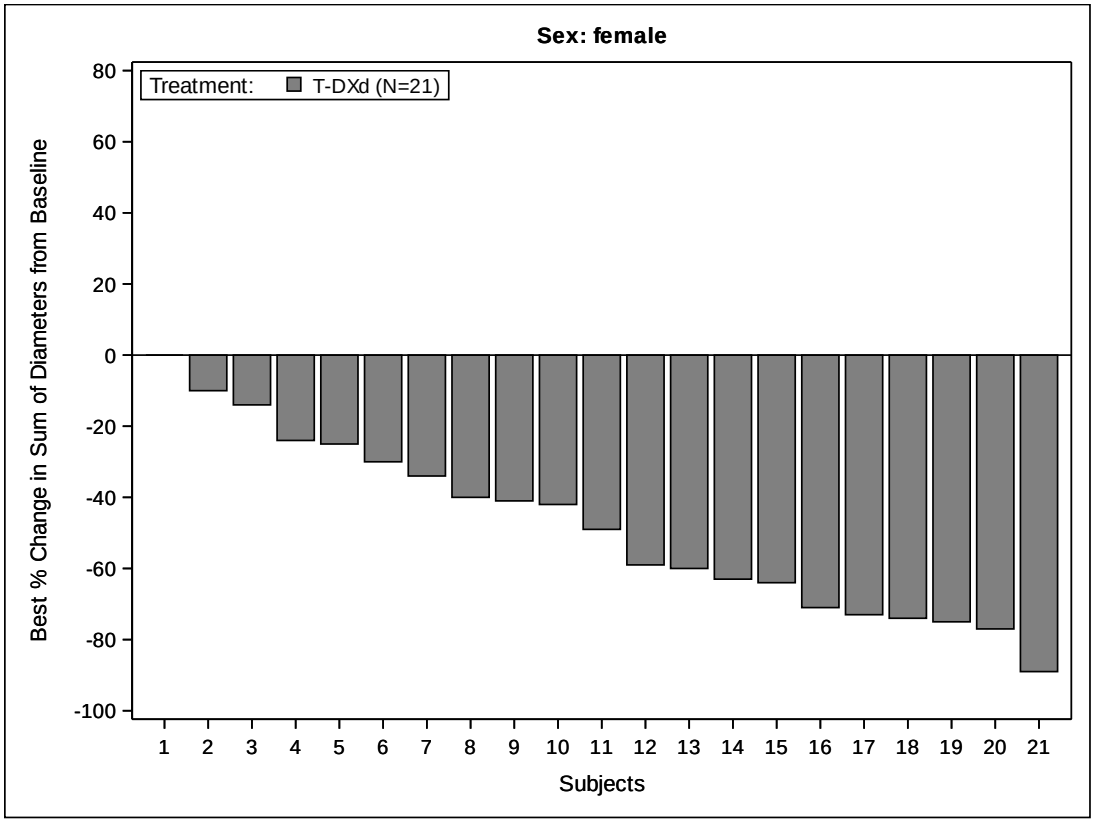
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



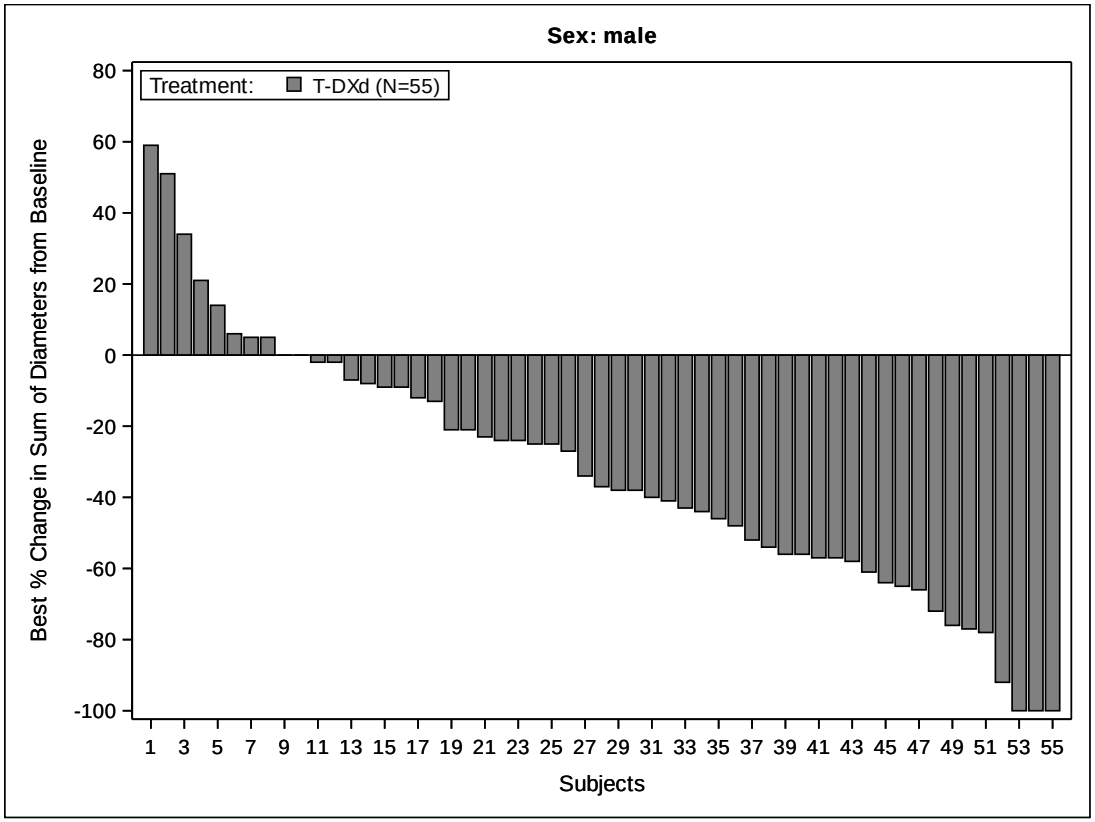
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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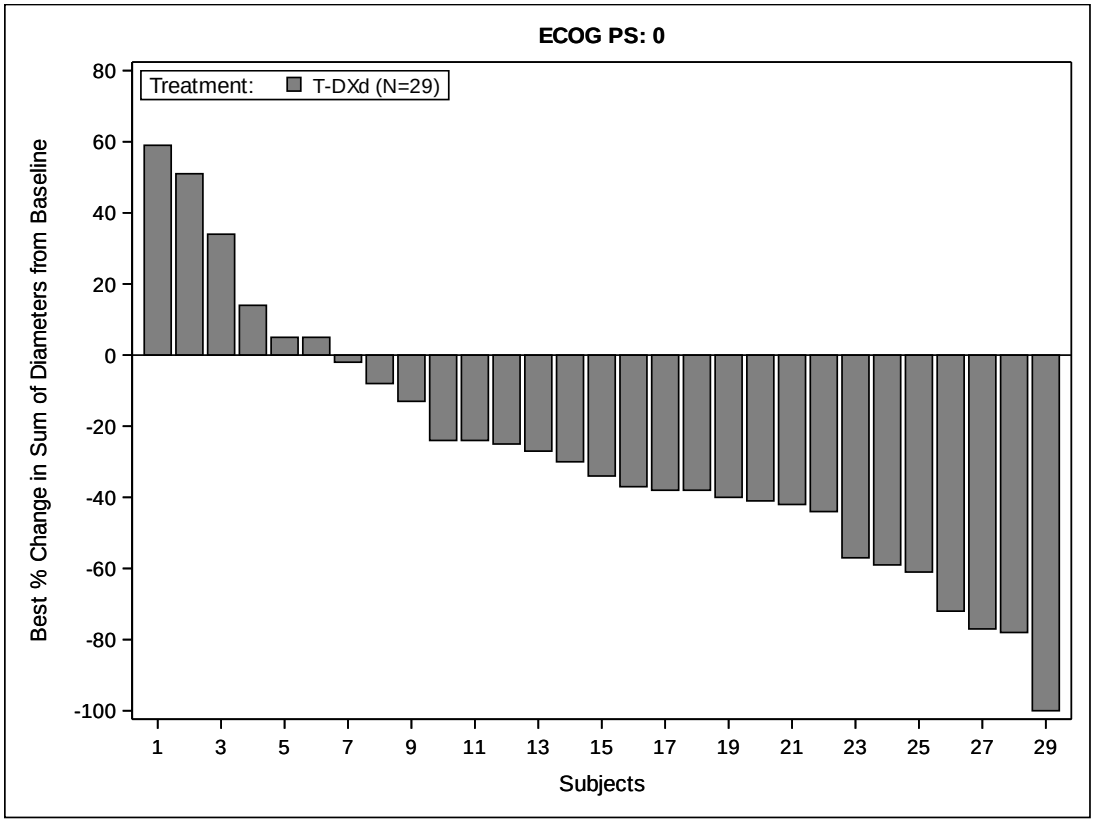

Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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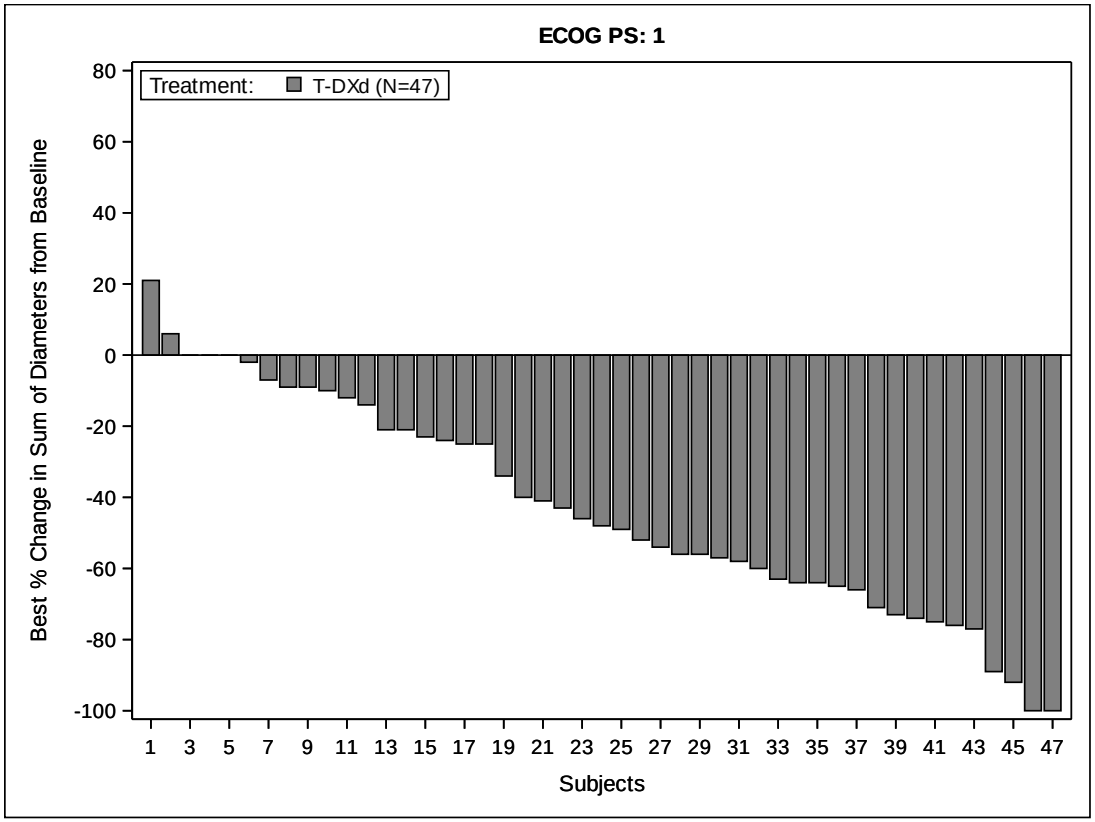

Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
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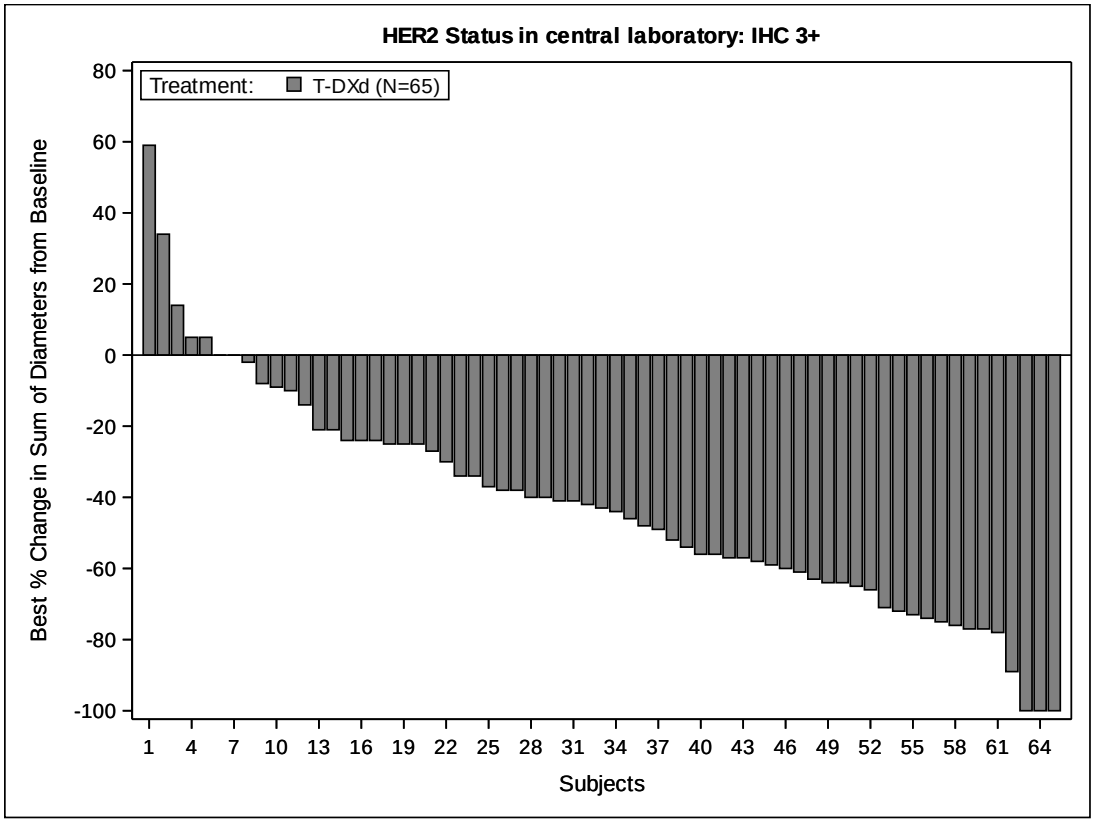

Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
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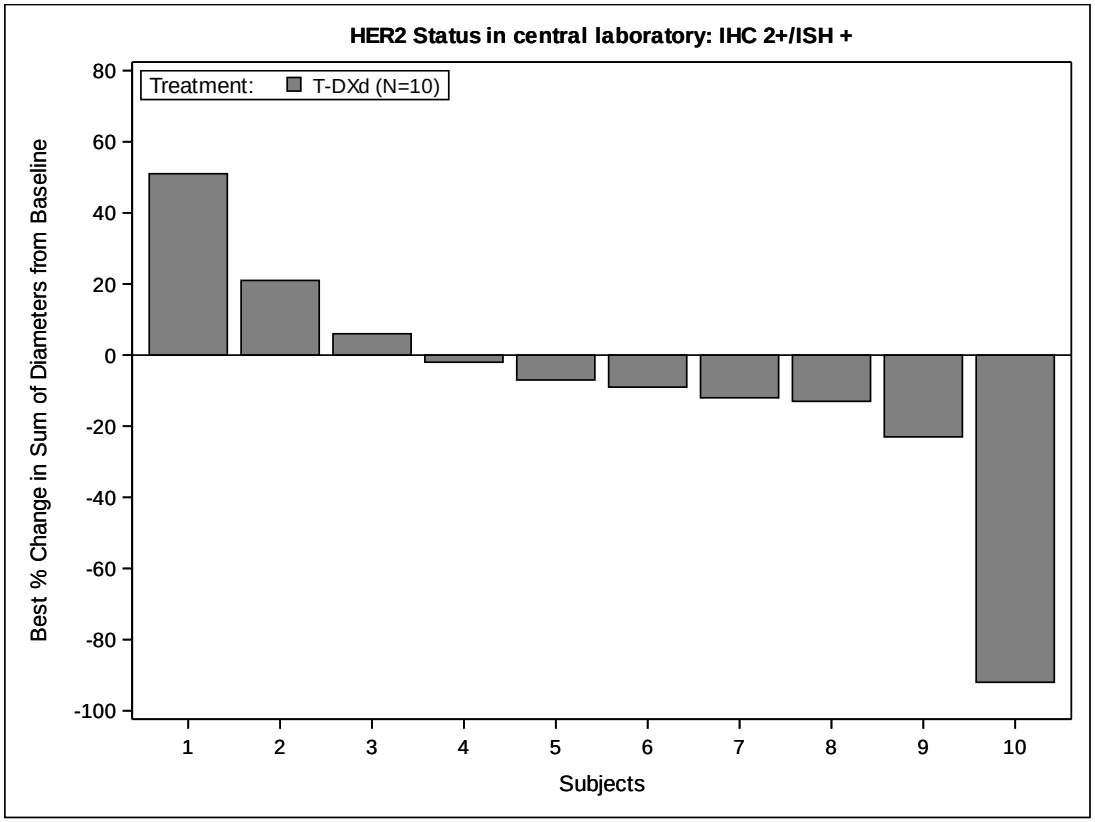

Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
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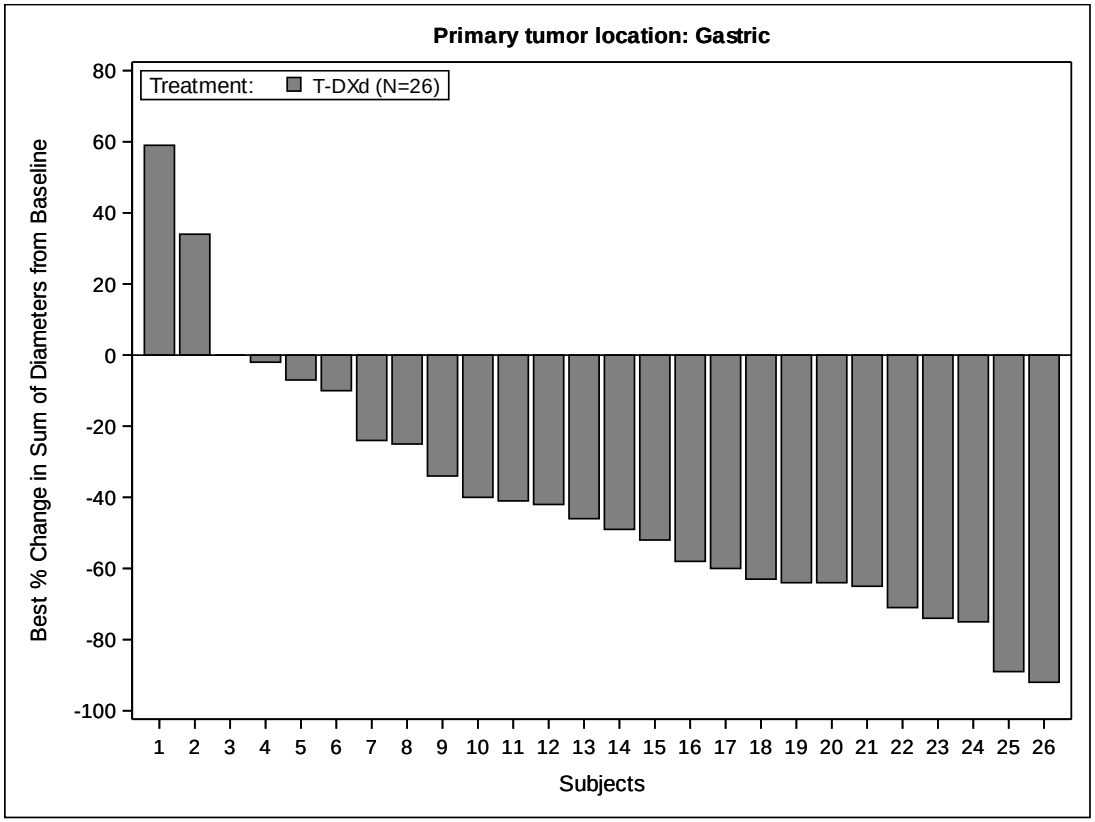

Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
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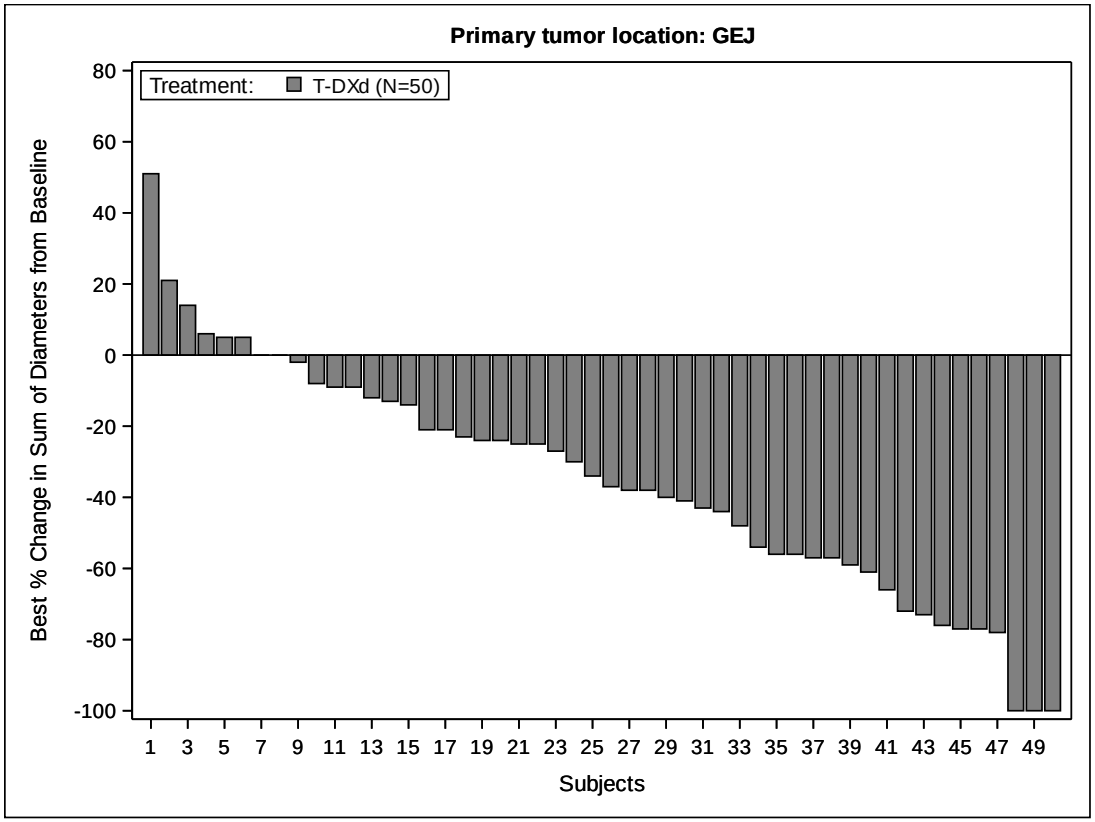

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Protocol DS8201-A-U205
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Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
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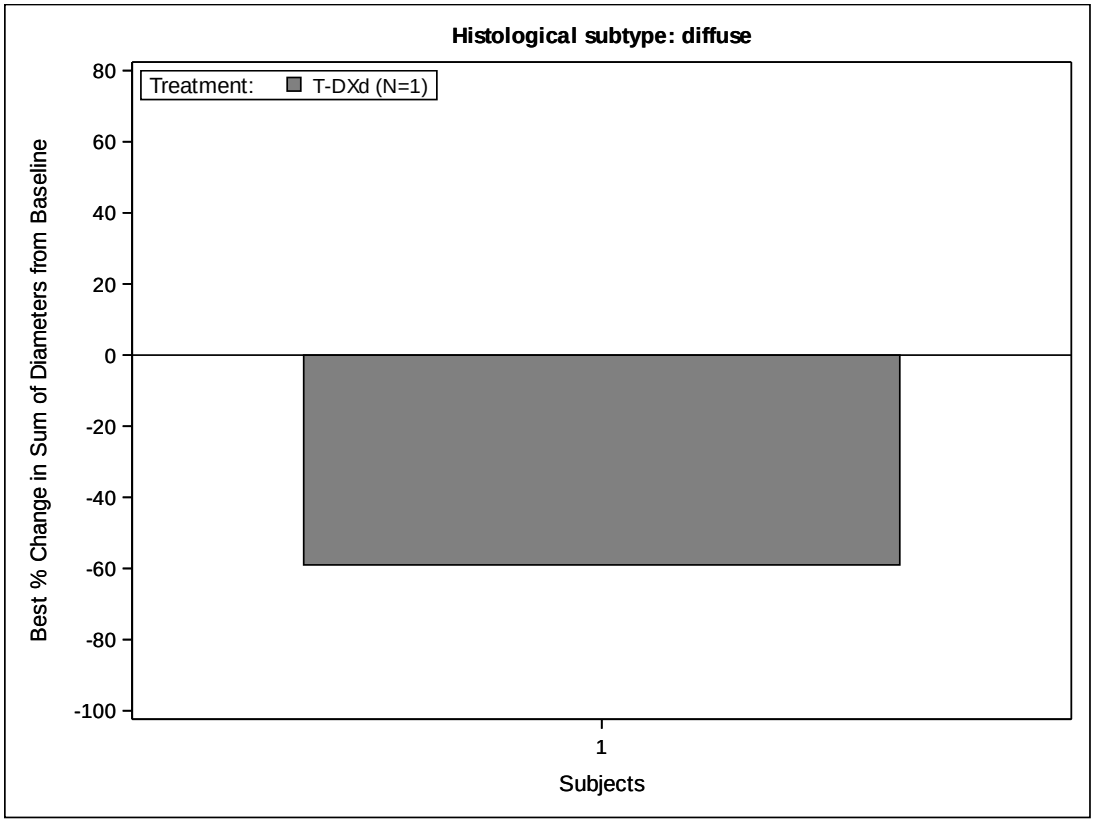

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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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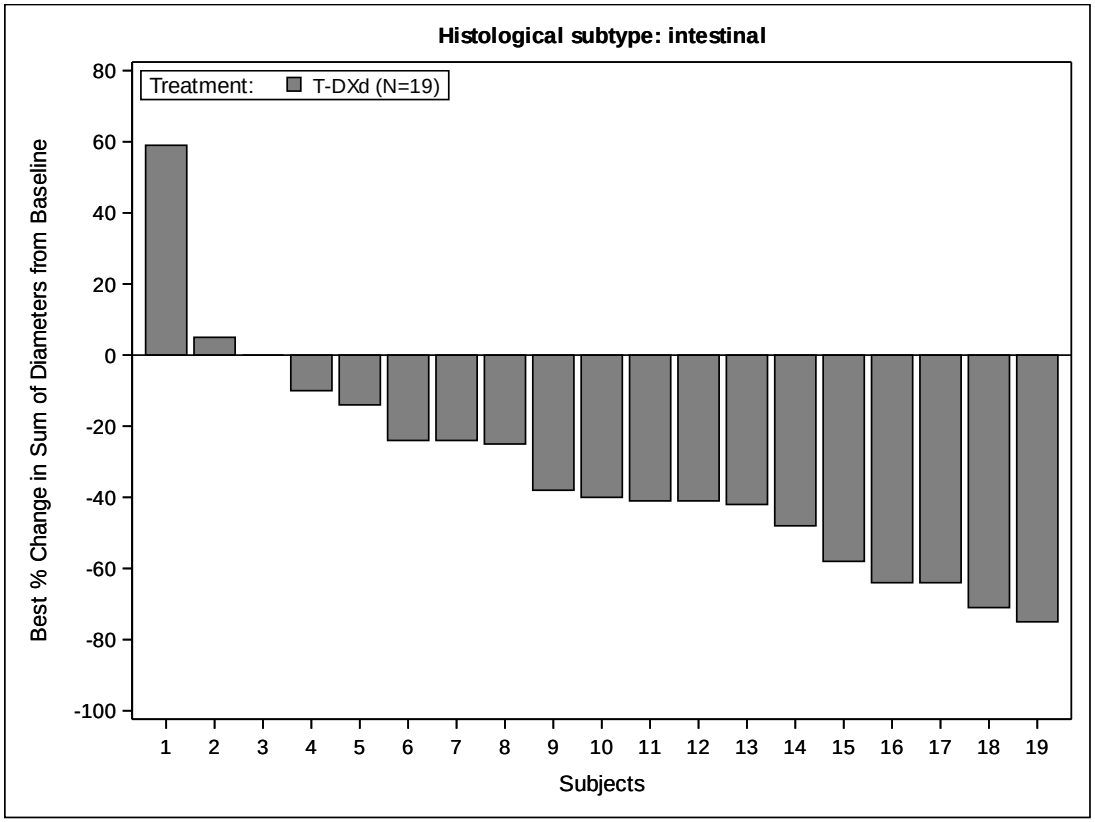

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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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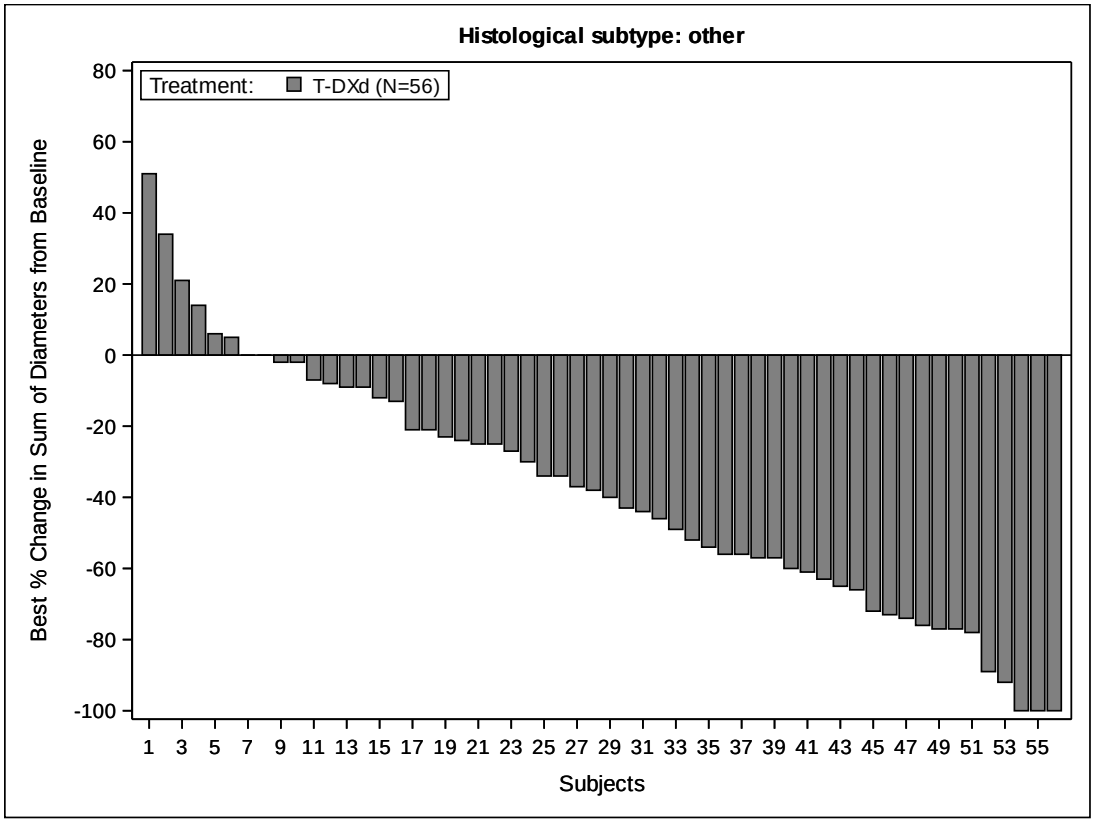

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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
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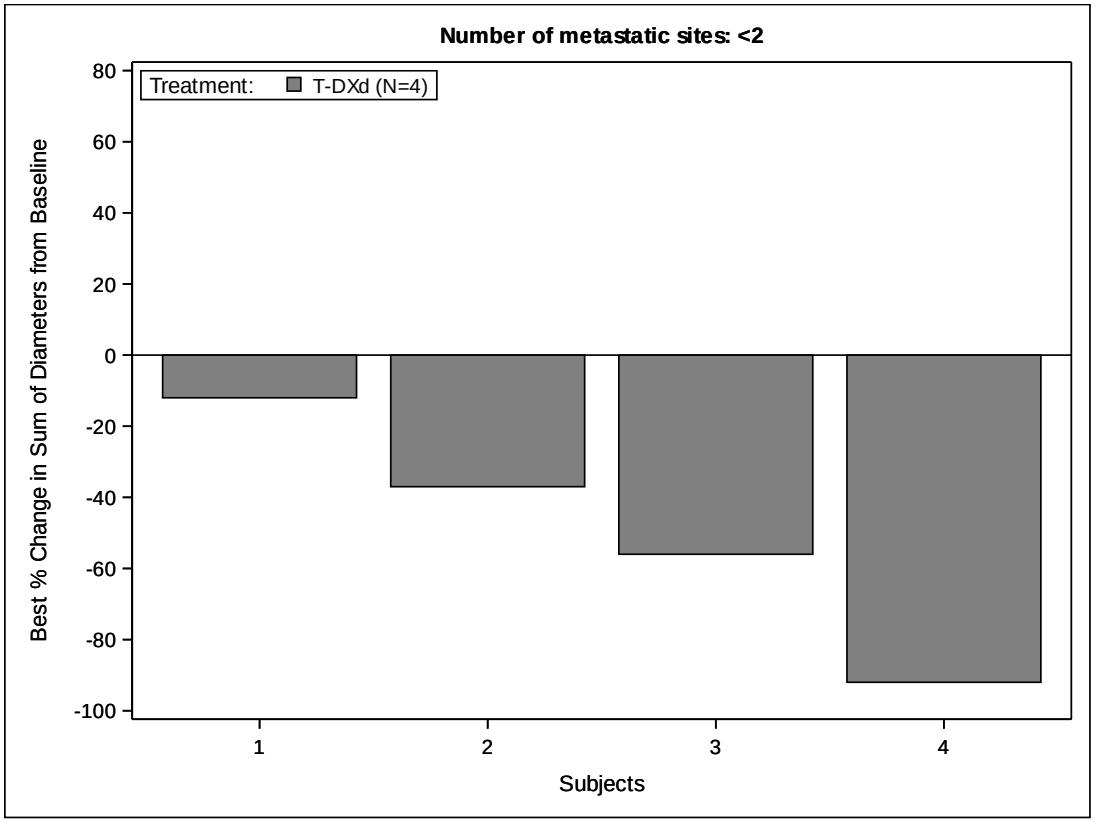

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Protocol DS8201-A-U205
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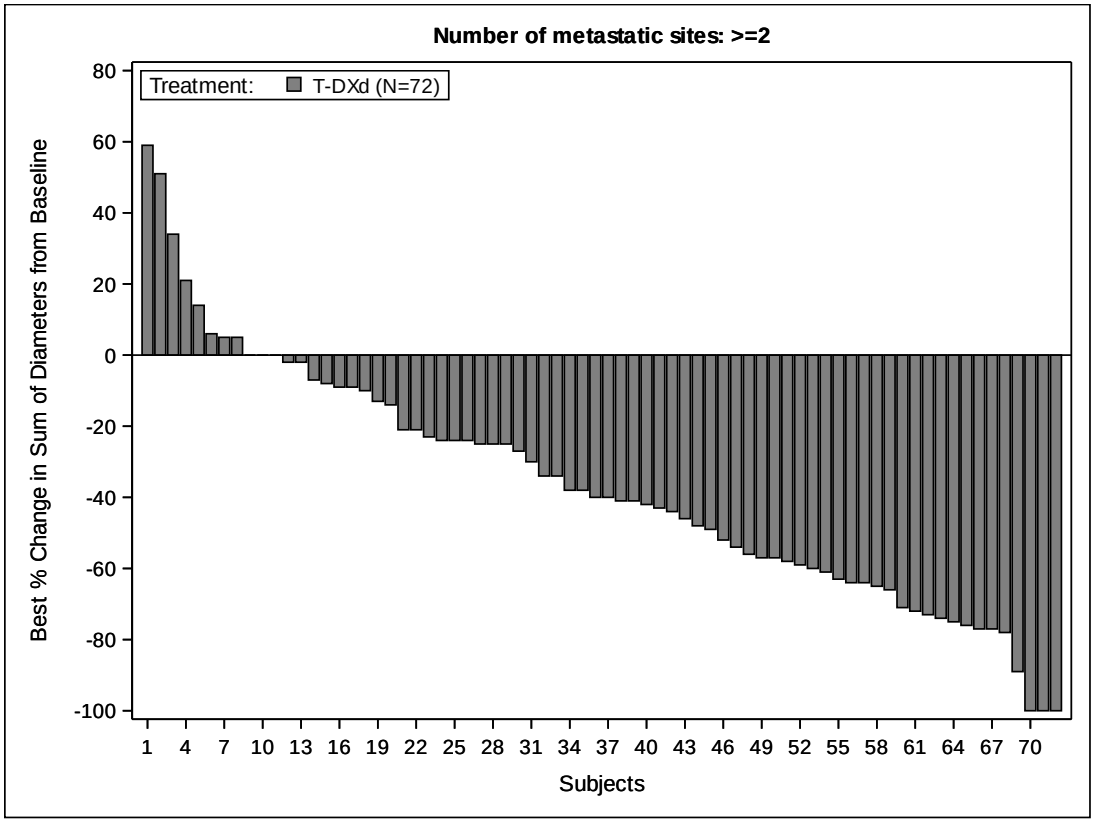

Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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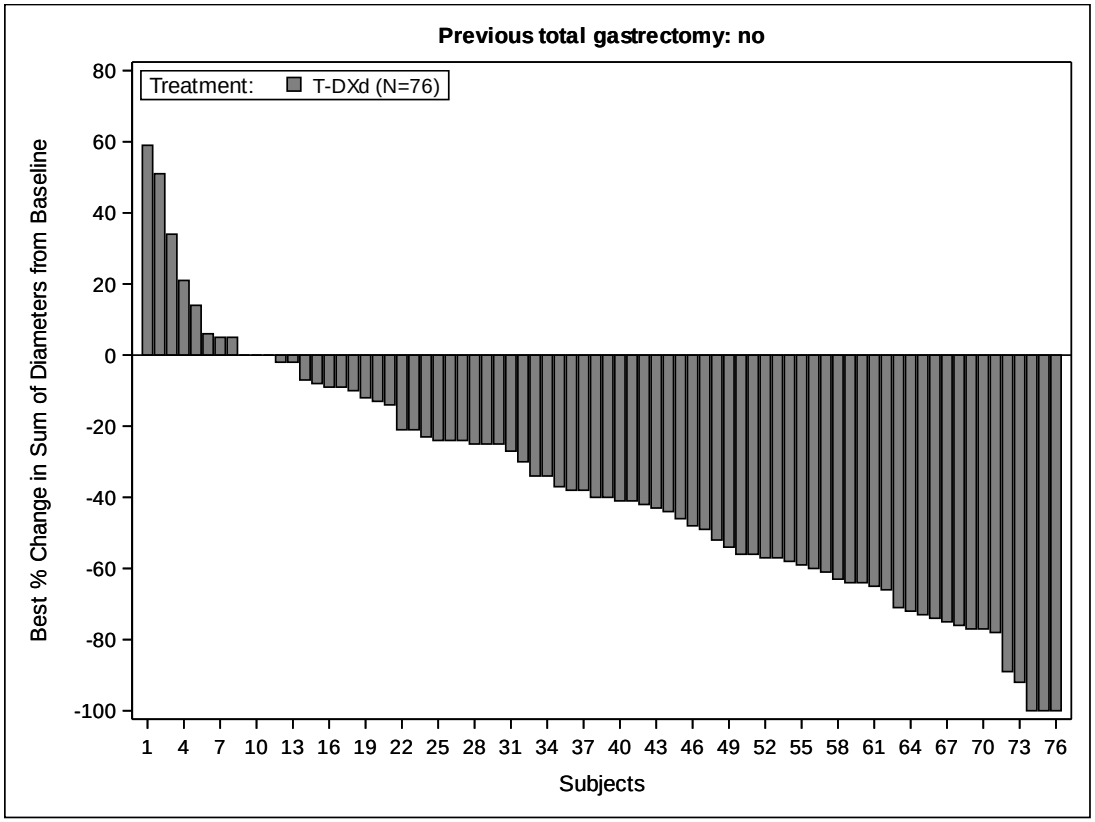

Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
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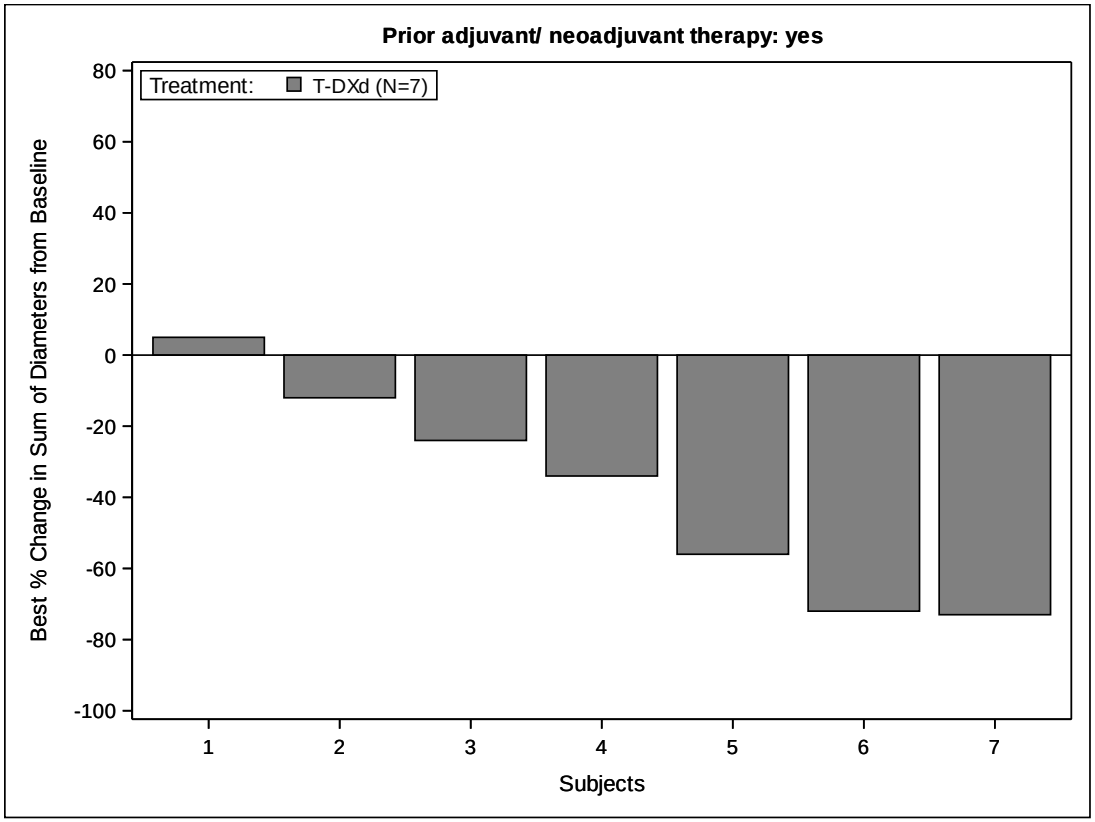

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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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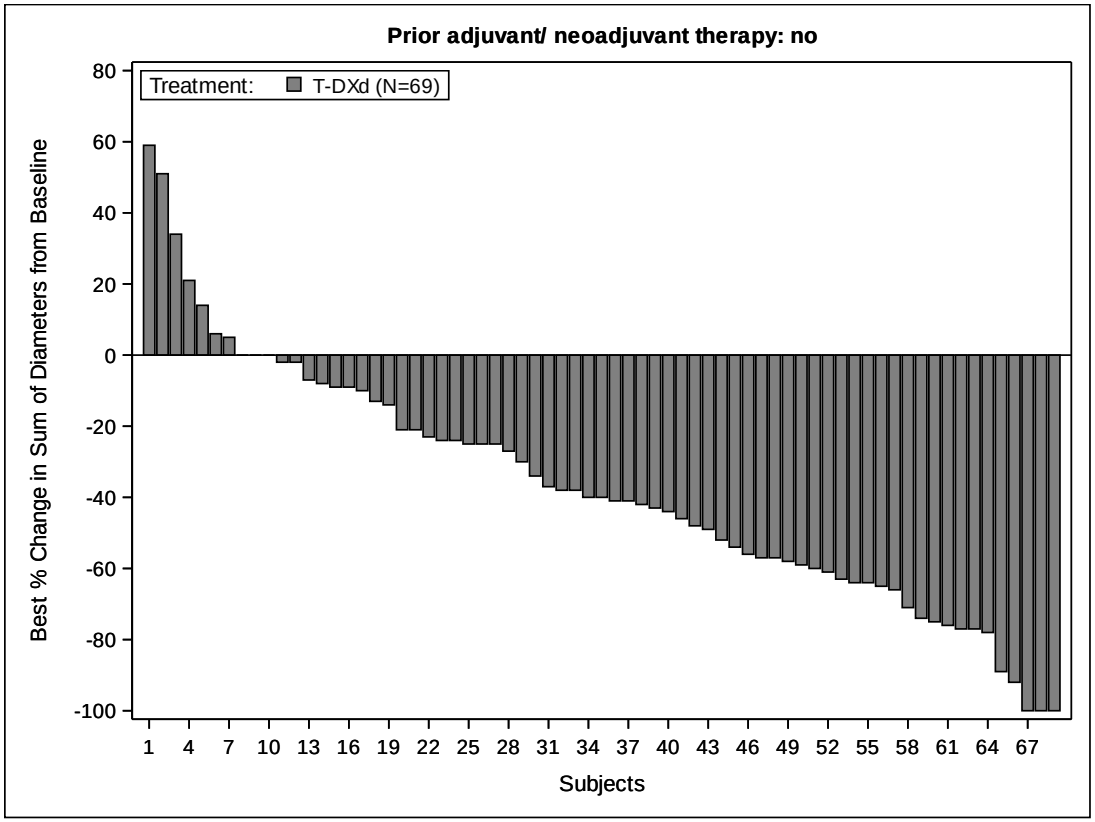

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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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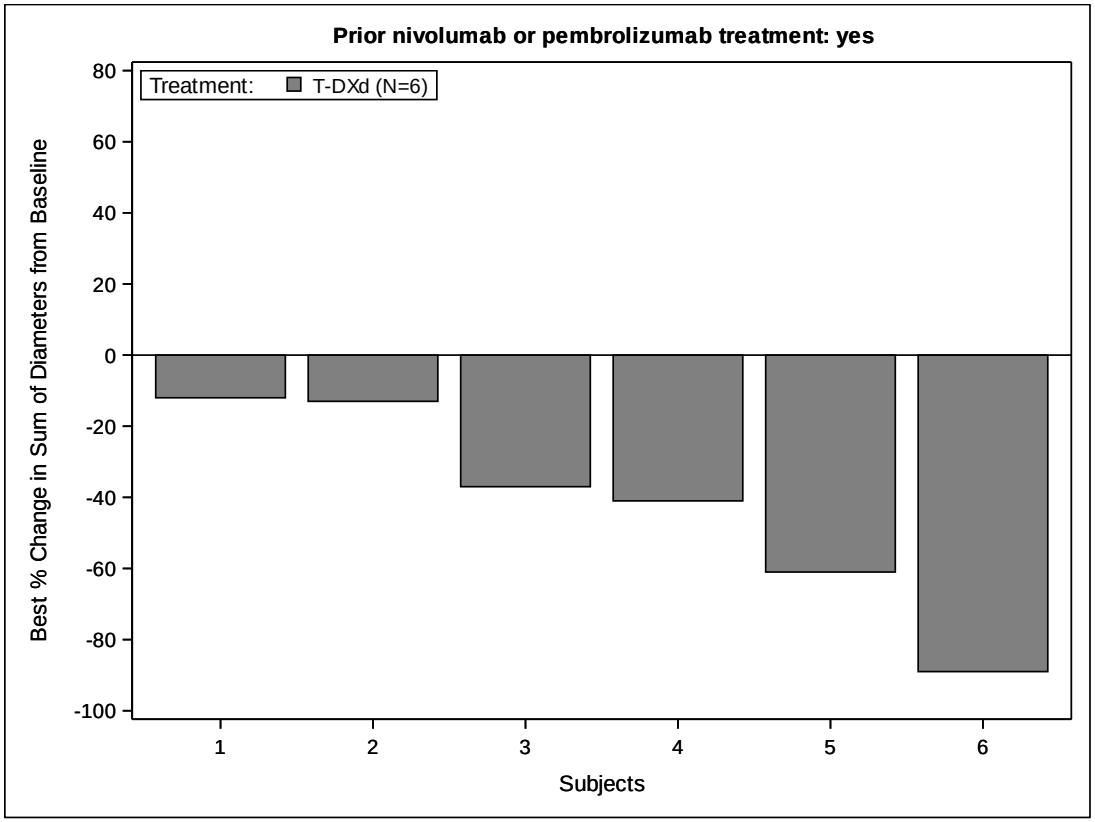

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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
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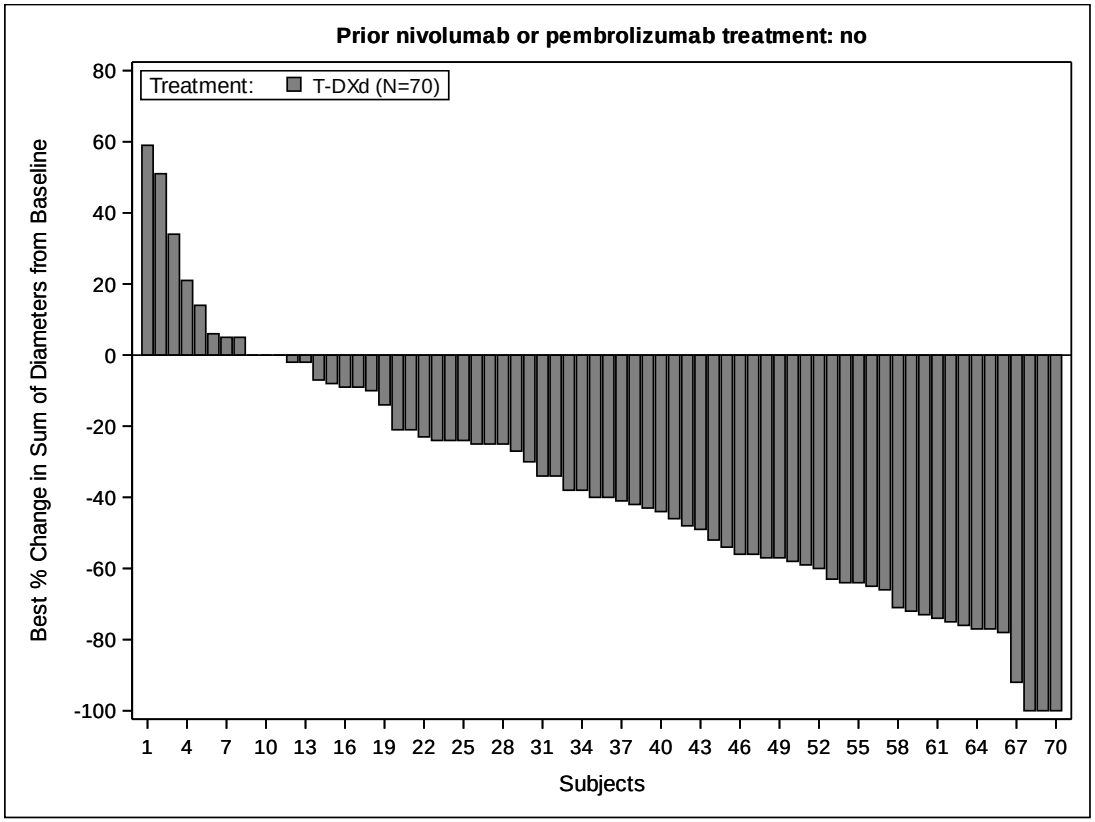

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Protocol DS8201-A-U205
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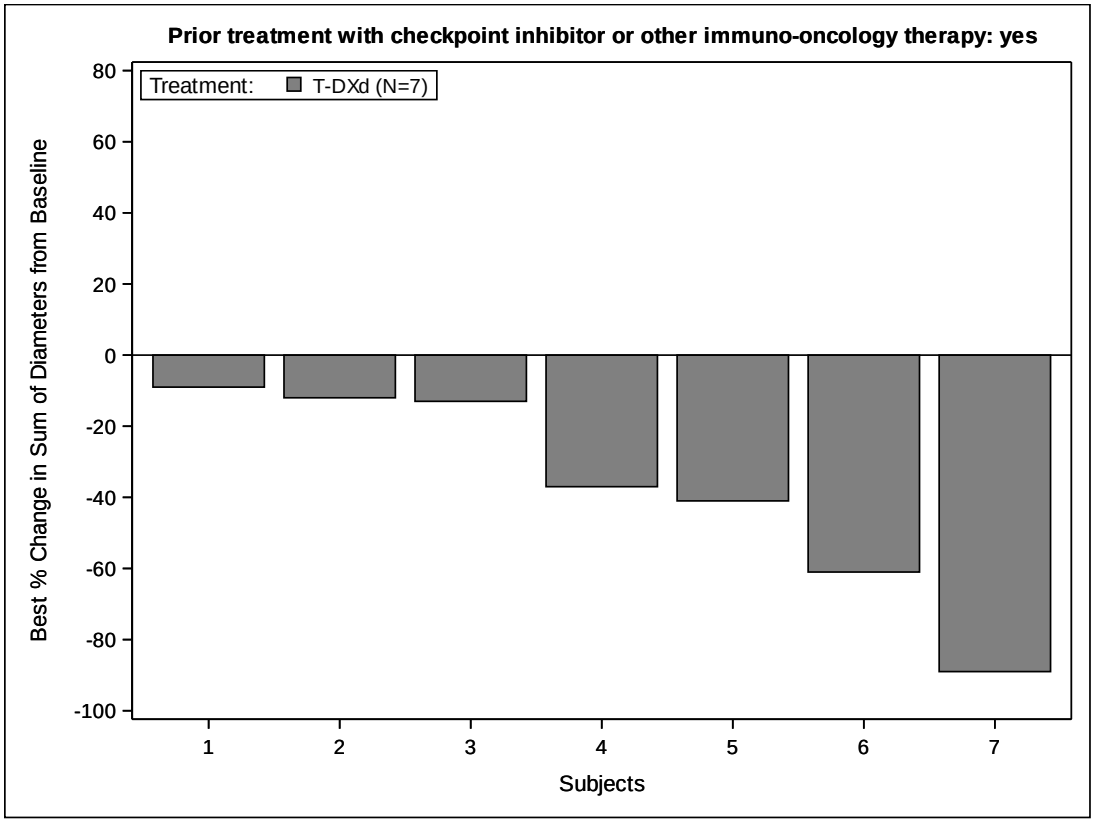

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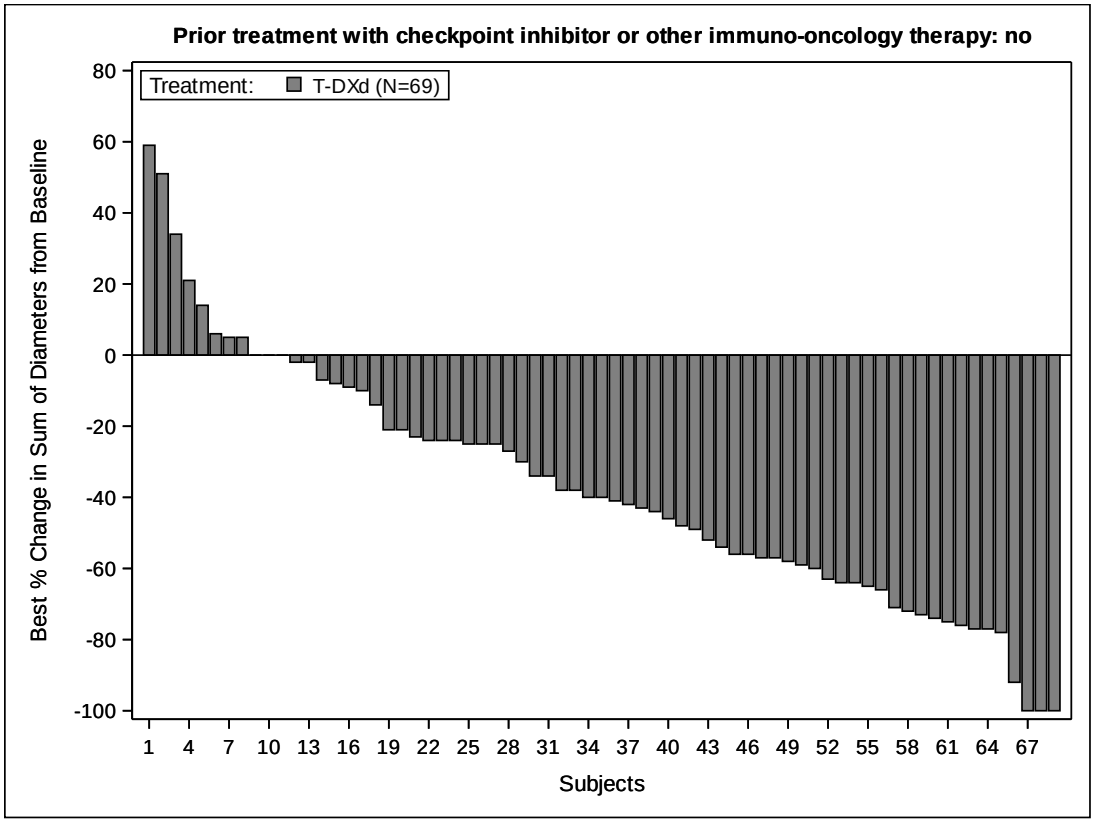

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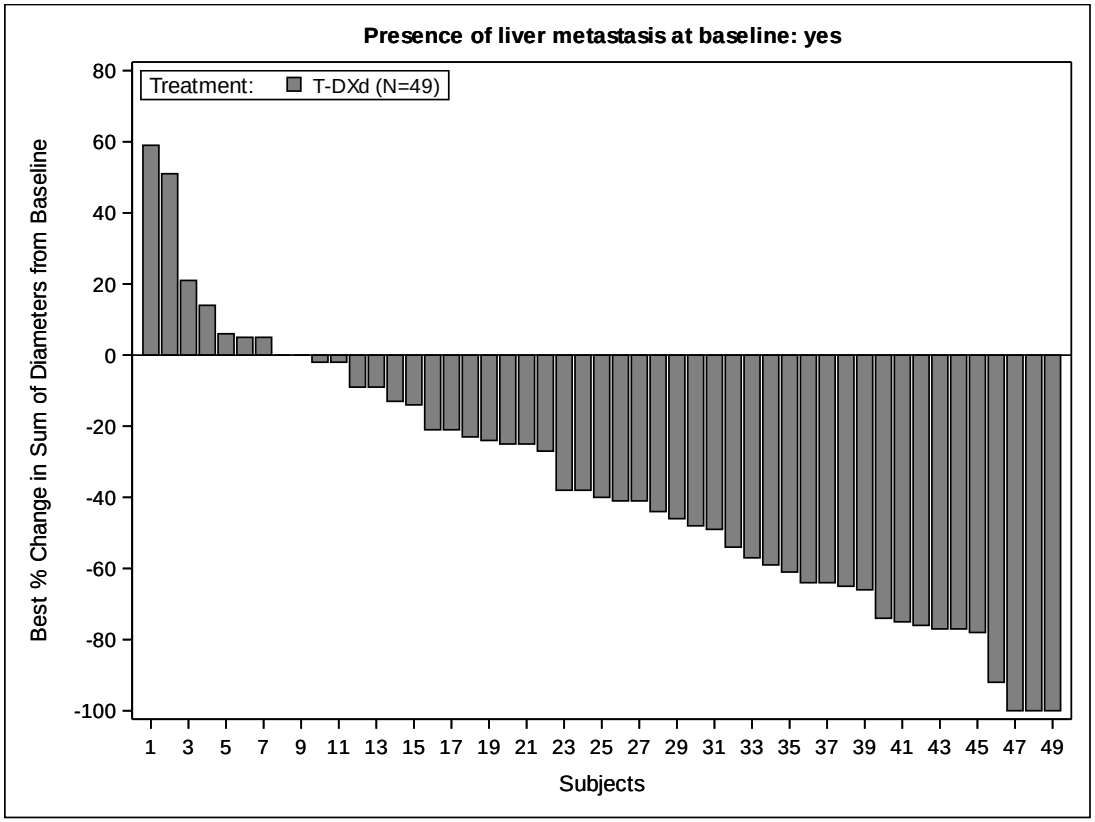

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Protocol DS8201-A-U205
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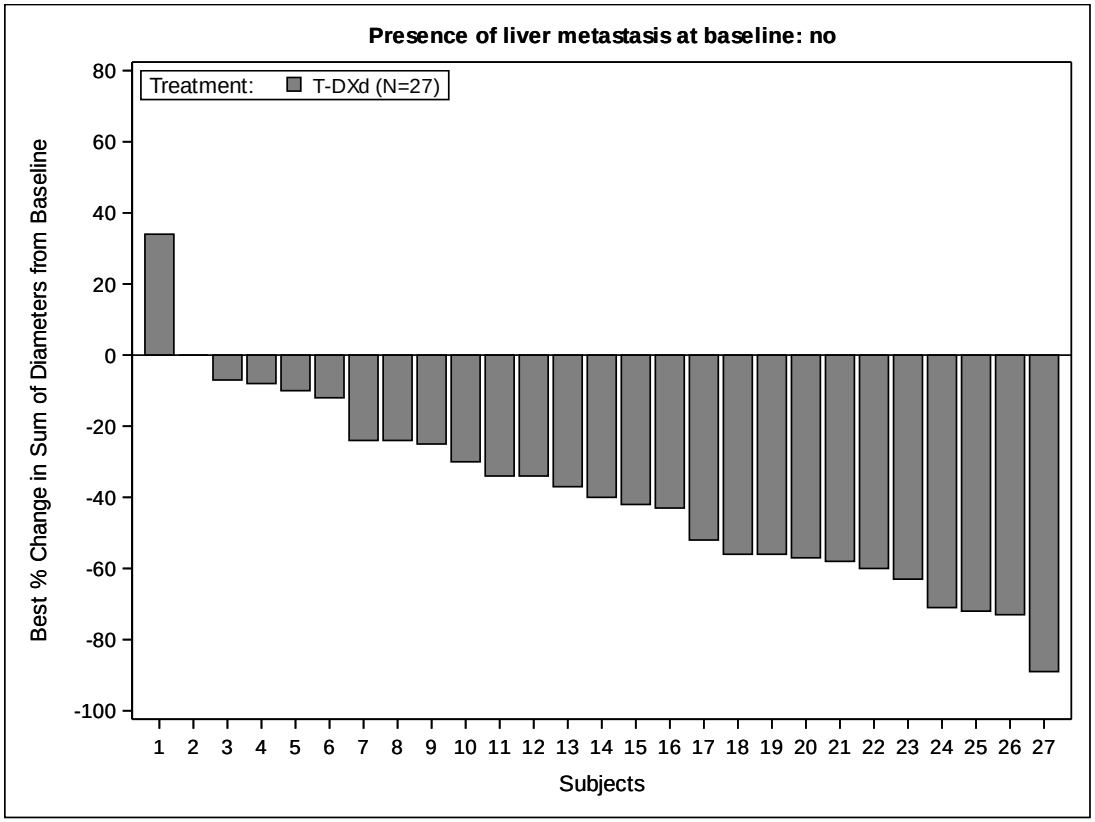

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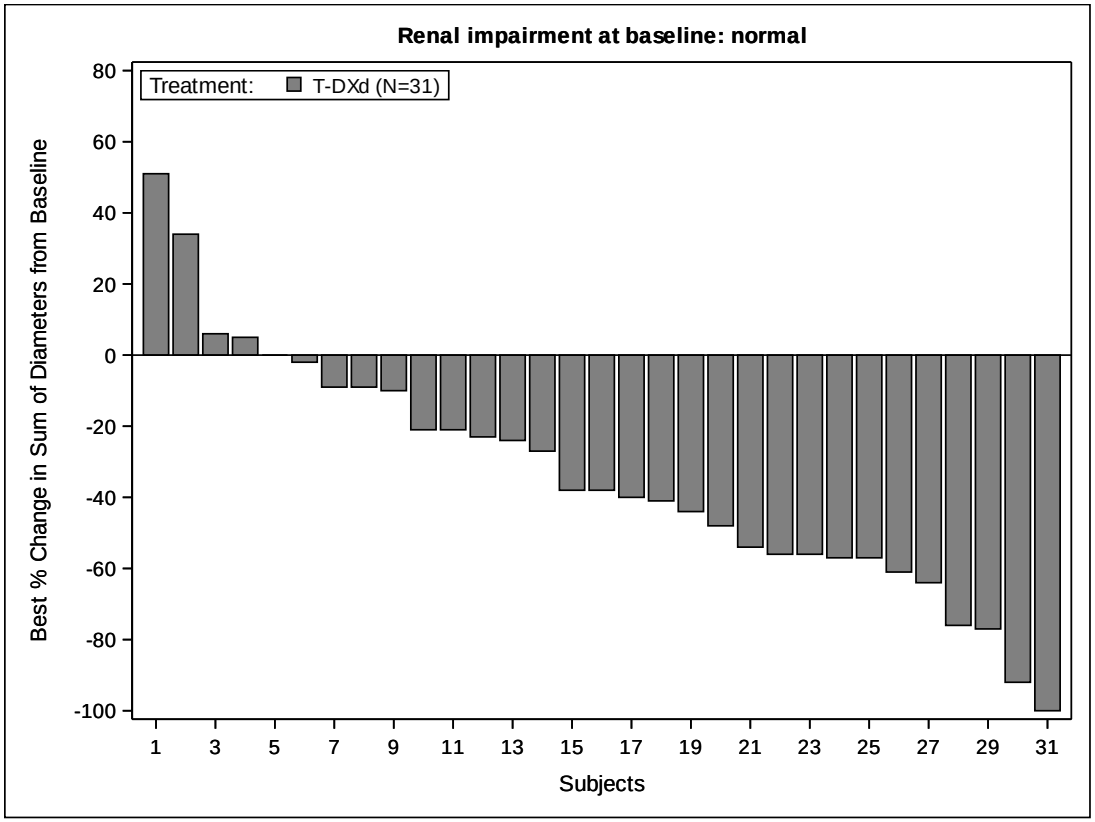

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Protocol DS8201-A-U205
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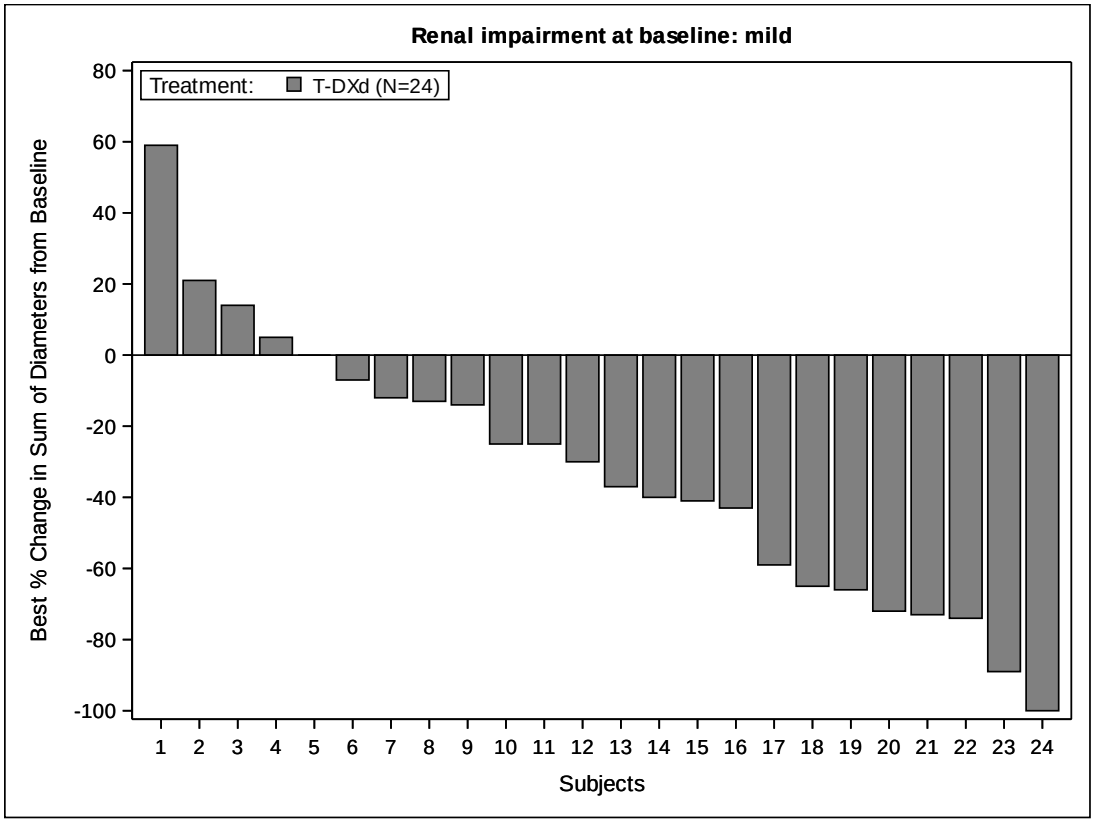

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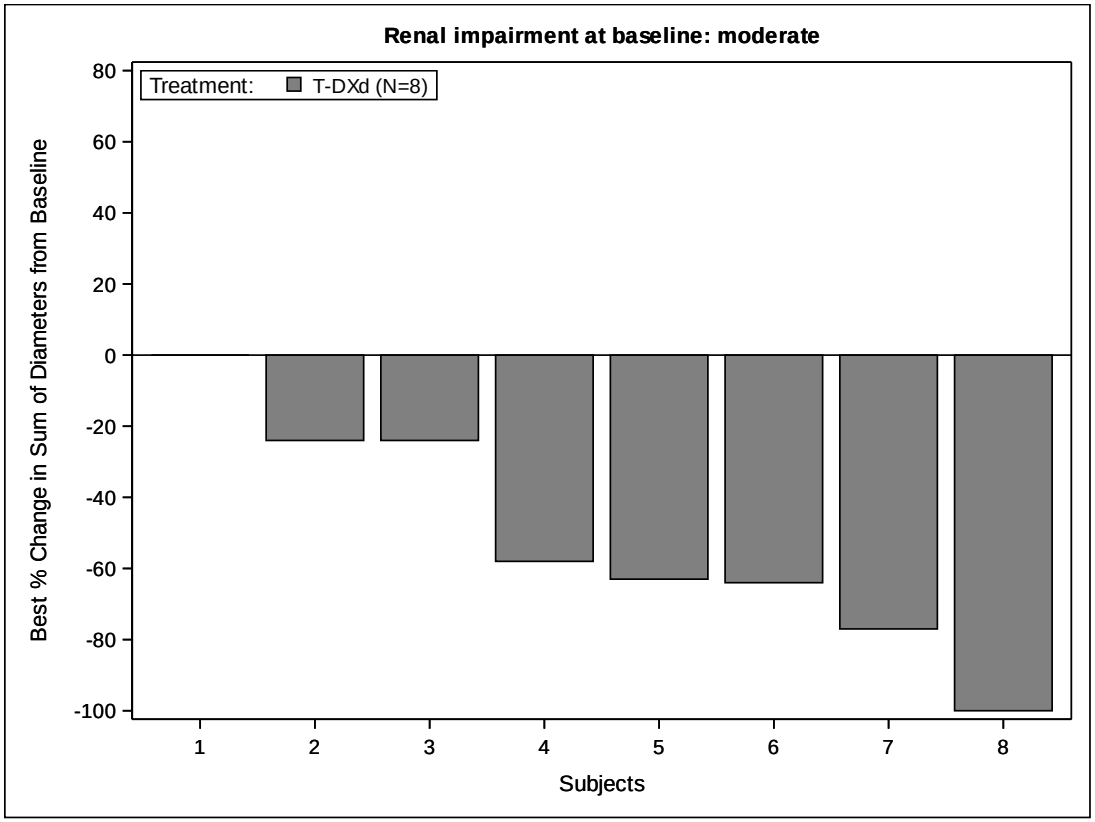

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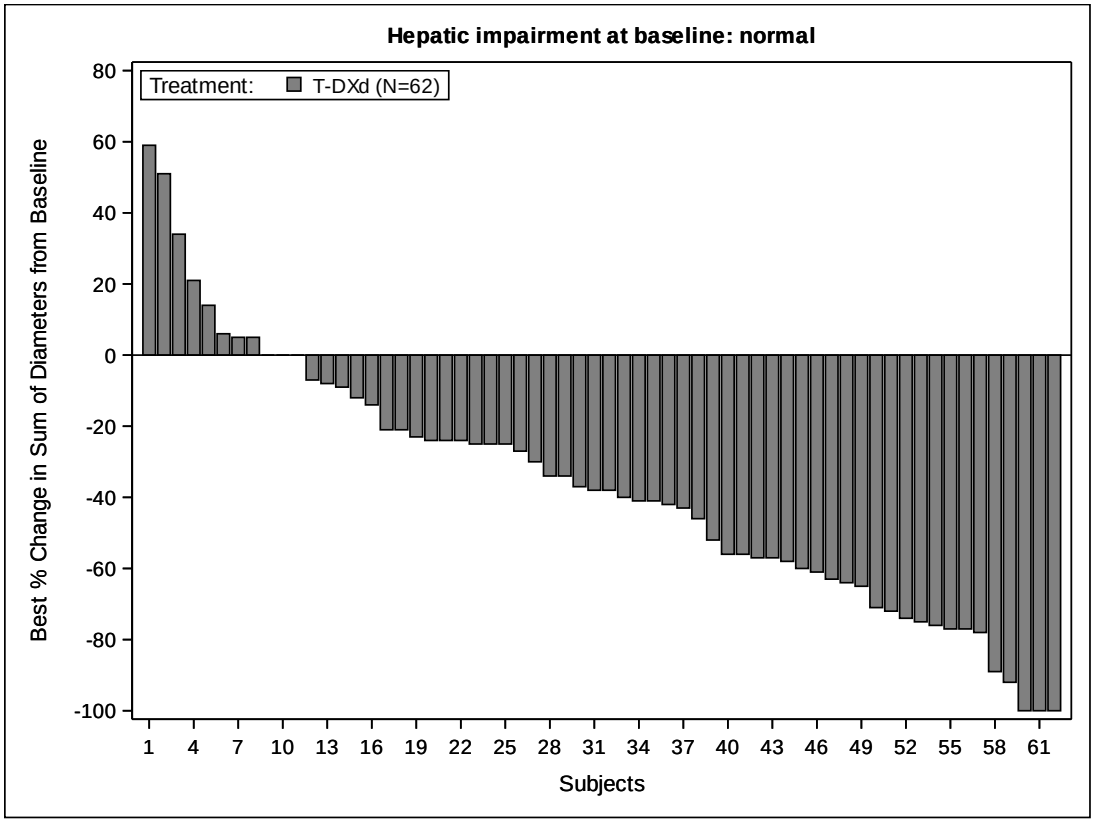

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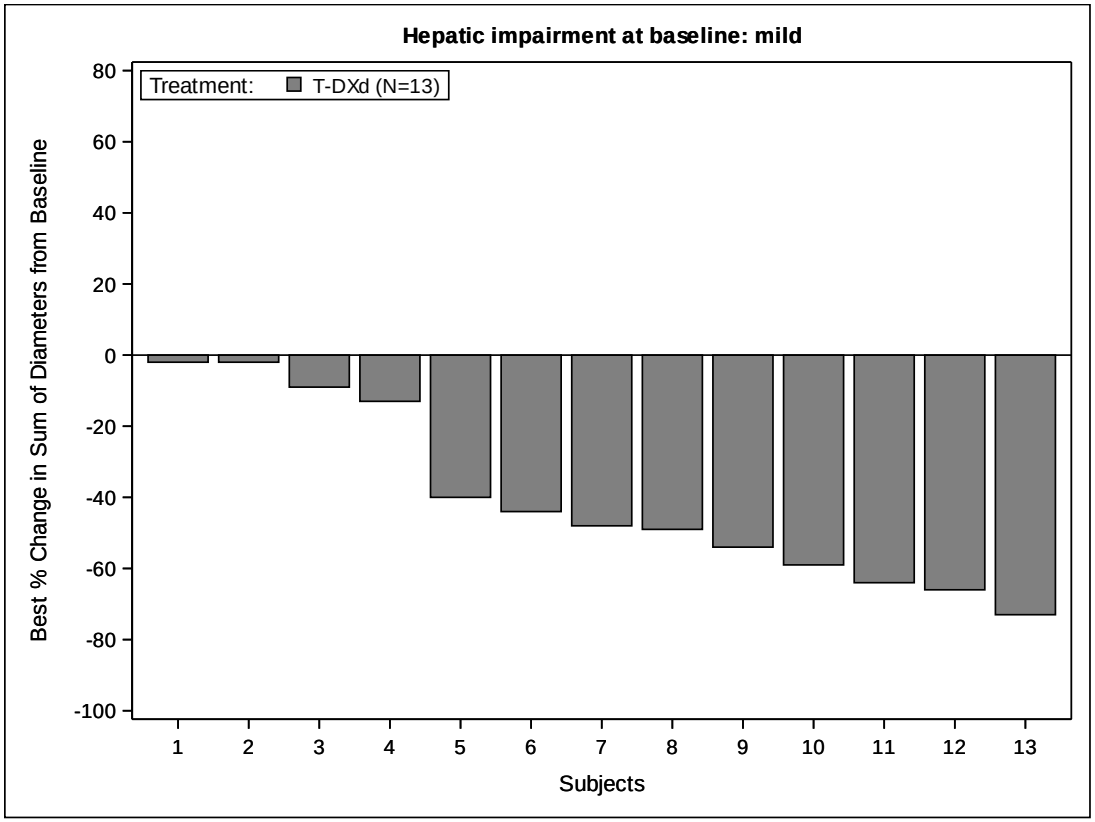
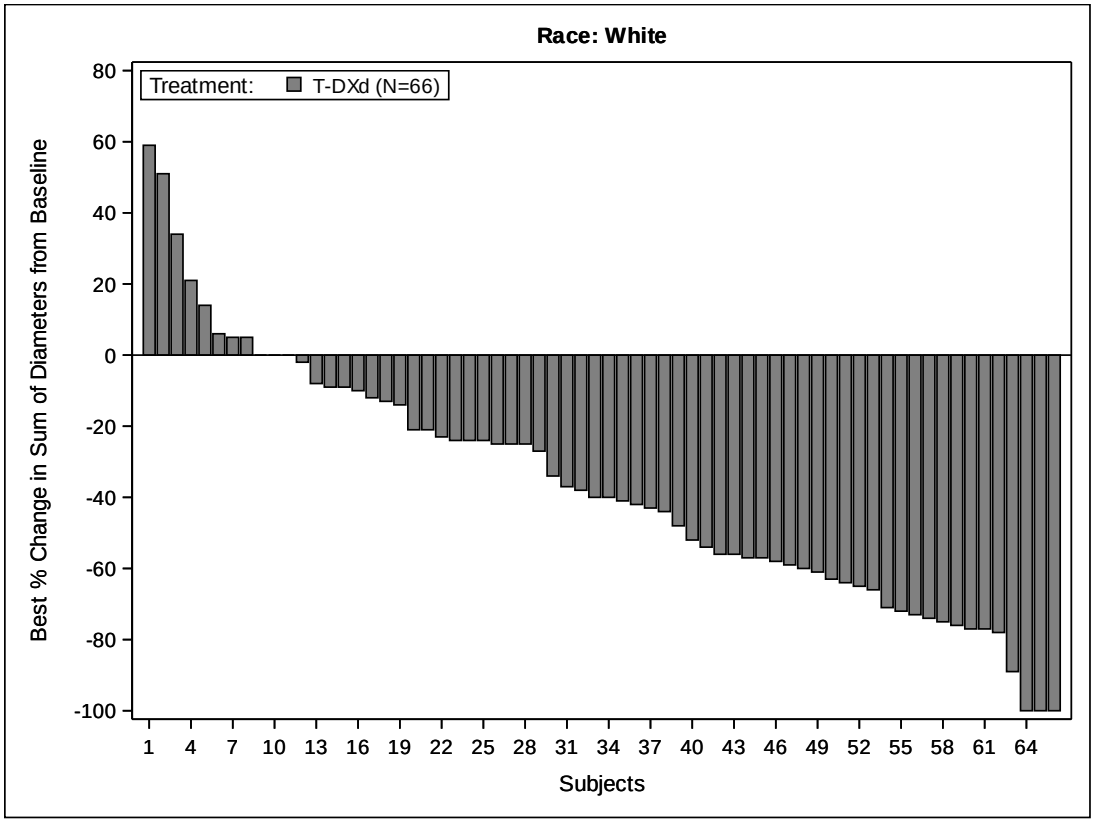
Full Analysis Set



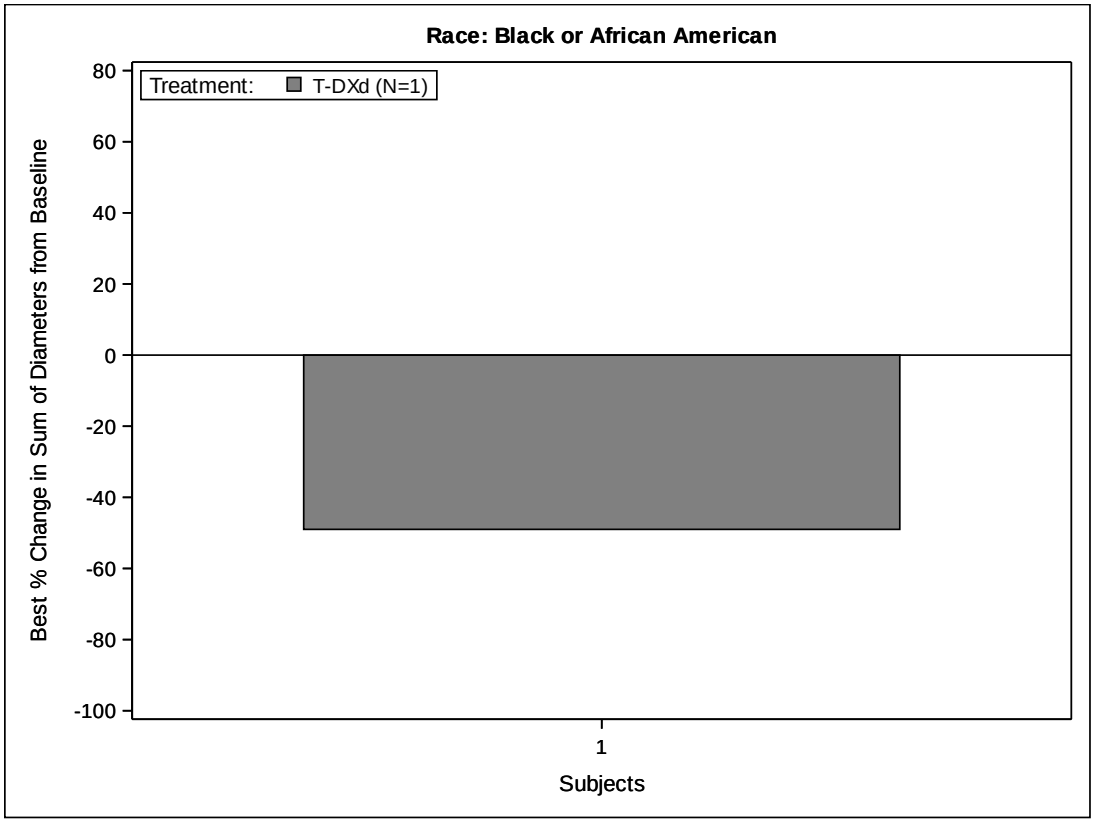
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



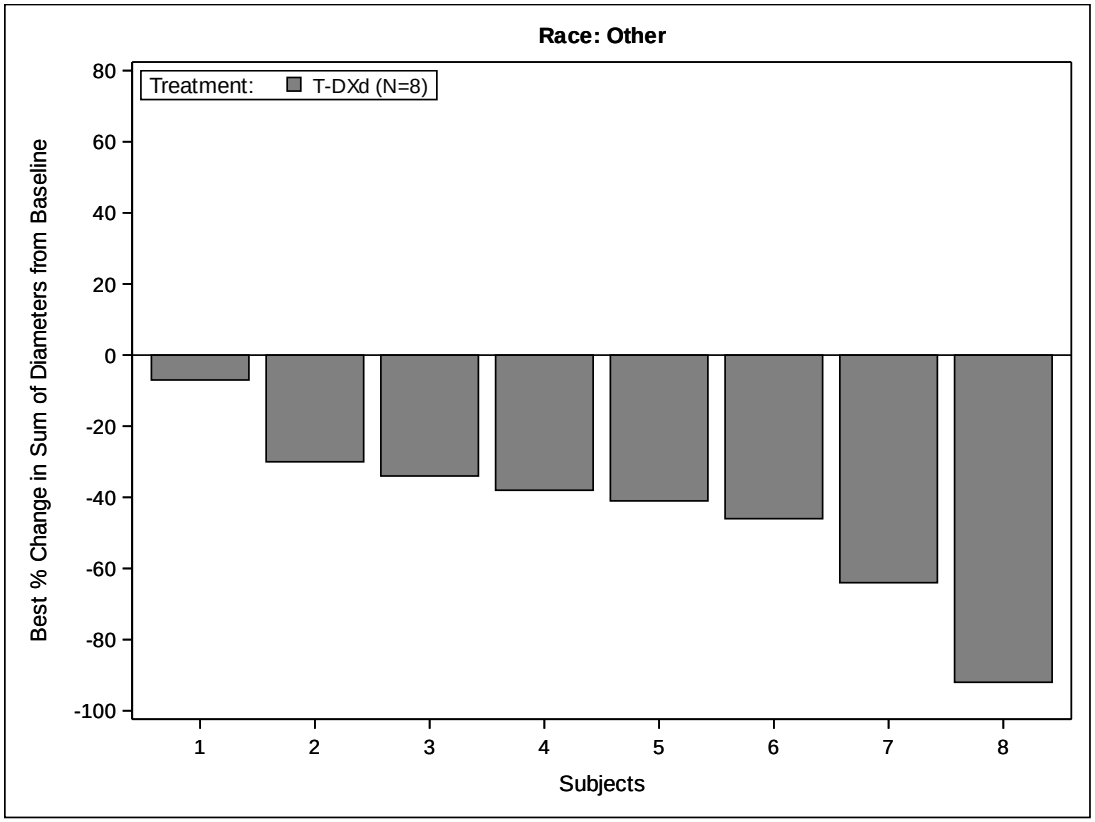
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



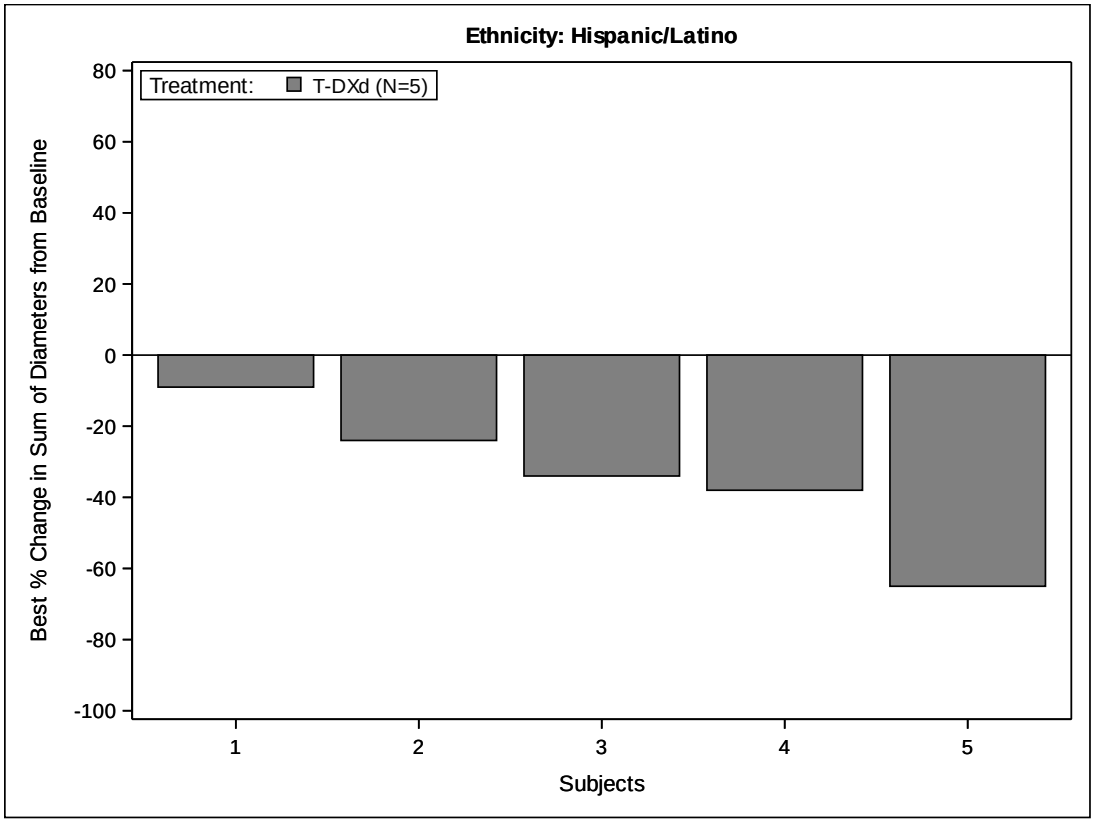
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



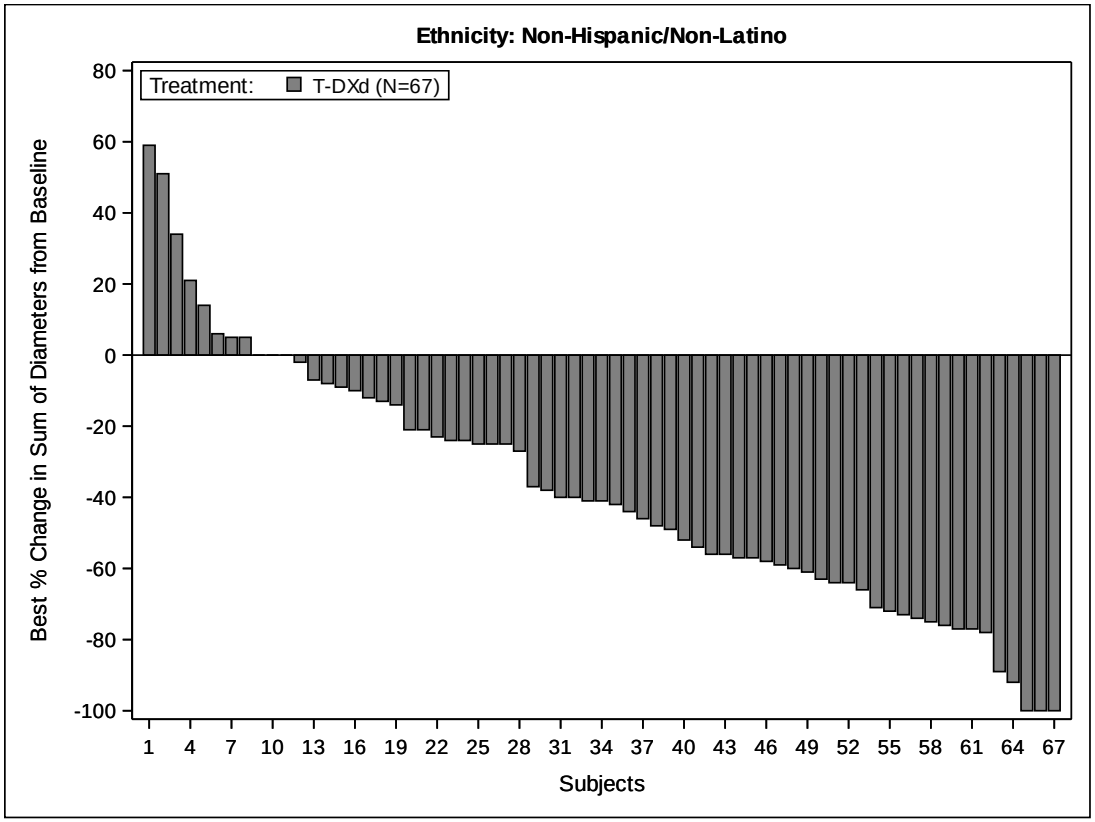
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



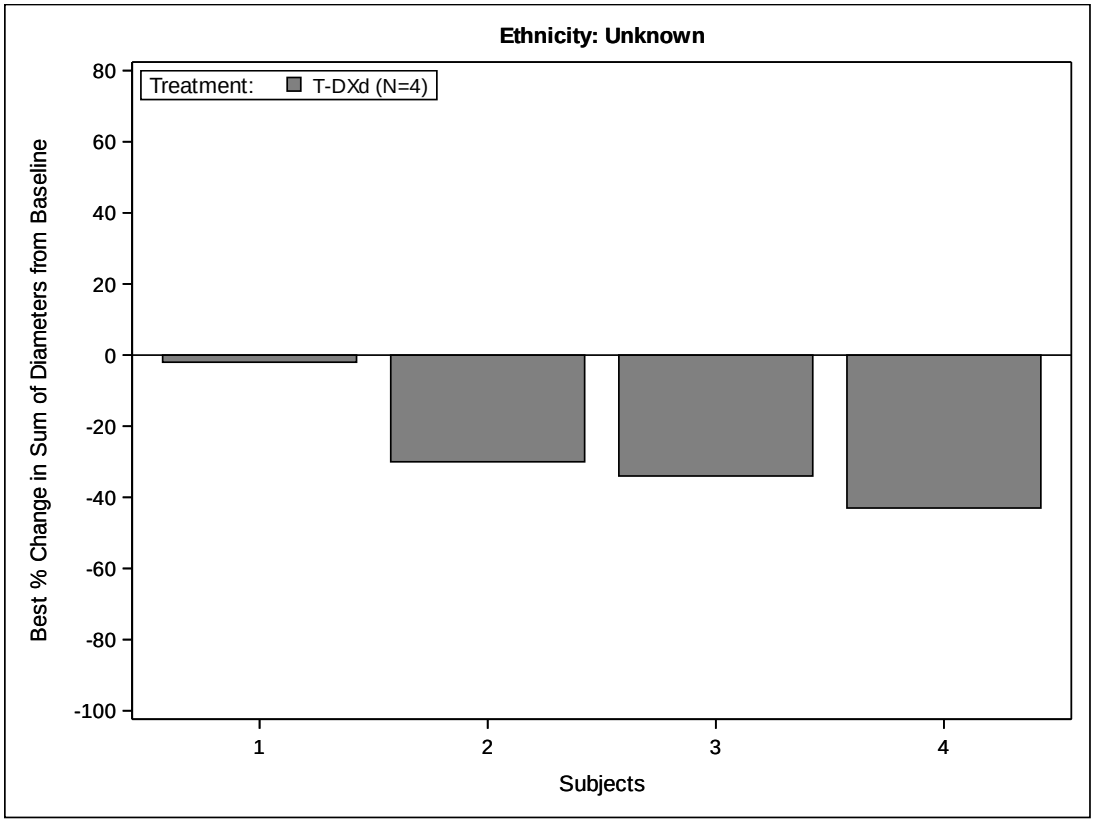
Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Waterfall plot for Best (Minimum) Percent Change in Sum of Diameters from Baseline for Measureable Tumors based on ICR
Full Analysis Set



Source data: ADAM.ADSL and ADAM.ADTR

Anhang 4-G 2.2.4: Sicherheit

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Subjects with events	79 (100.0)
Gastrointestinal disorders	73 (92.4)
Nausea	53 (67.1)
Vomiting	35 (44.3)
Diarrhoea	29 (36.7)
Constipation	23 (29.1)
Abdominal pain	13 (16.5)
Gastrooesophageal reflux disease	8 (10.1)
Dysphagia	6 (7.6)
Abdominal pain upper	5 (6.3)
Ascites	5 (6.3)
Flatulence	4 (5.1)
Abdominal distension	3 (3.8)
Dyspepsia	3 (3.8)
Salivary hypersecretion	2 (2.5)
Abdominal discomfort	1 (1.3)
Abdominal pain lower	1 (1.3)
Anal fissure	1 (1.3)
Anal fistula	1 (1.3)
Angular cheilitis	1 (1.3)
Colitis	1 (1.3)
Dry mouth	1 (1.3)
Duodenitis	1 (1.3)
Enteritis	1 (1.3)
Eructation	1 (1.3)
Gastritis	1 (1.3)
Haematemesis	1 (1.3)
Intestinal obstruction	1 (1.3)
Lip blister	1 (1.3)
Lip dry	1 (1.3)
Melaena	1 (1.3)
Obstruction gastric	1 (1.3)
Oesophageal obstruction	1 (1.3)
Oesophagitis	1 (1.3)
Pancreatic failure	1 (1.3)
Proctalgia	1 (1.3)
Regurgitation	1 (1.3)
Retching	1 (1.3)
Stomatitis	1 (1.3)
General disorders and administration site conditions	57 (72.2)
Fatigue	33 (41.8)
Asthenia	12 (15.2)
Pyrexia	9 (11.4)
Mucosal inflammation	4 (5.1)
Oedema peripheral	4 (5.1)
Pain	3 (3.8)
Chills	2 (2.5)
Disease progression	2 (2.5)
Early satiety	2 (2.5)
Hyperpyrexia	2 (2.5)
Non-cardiac chest pain	2 (2.5)
Catheter site haematoma	1 (1.3)
Catheter site pain	1 (1.3)
Catheter site thrombosis	1 (1.3)
Chest discomfort	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Chest pain	1 (1.3)
Gait disturbance	1 (1.3)
Influenza like illness	1 (1.3)
Oedema	1 (1.3)
Peripheral swelling	1 (1.3)
Swelling	1 (1.3)
Investigations	51 (64.6)
Weight decreased	28 (35.4)
Platelet count decreased	14 (17.7)
Aspartate aminotransferase increased	13 (16.5)
Neutrophil count decreased	13 (16.5)
Blood alkaline phosphatase increased	9 (11.4)
White blood cell count decreased	9 (11.4)
Alanine aminotransferase increased	8 (10.1)
Blood bilirubin increased	5 (6.3)
Weight increased	5 (6.3)
Blood creatinine increased	4 (5.1)
Blood lactate dehydrogenase increased	3 (3.8)
Lymphocyte count decreased	3 (3.8)
C-reactive protein increased	2 (2.5)
Electrocardiogram QT prolonged	2 (2.5)
Alanine aminotransferase	1 (1.3)
Blood folate decreased	1 (1.3)
Blood iron decreased	1 (1.3)
Ejection fraction decreased	1 (1.3)
Gamma-glutamyltransferase increased	1 (1.3)
Ophthalmological examination abnormal	1 (1.3)
SARS-CoV-2 test positive	1 (1.3)
Troponin T increased	1 (1.3)
Metabolism and nutrition disorders	44 (55.7)
Decreased appetite	26 (32.9)
Hypokalaemia	13 (16.5)
Hypoalbuminaemia	8 (10.1)
Hyponatraemia	6 (7.6)
Hypophosphataemia	4 (5.1)
Hypocalcaemia	3 (3.8)
Dehydration	2 (2.5)
Hyperglycaemia	2 (2.5)
Hyperkalaemia	2 (2.5)
Hypoglycaemia	2 (2.5)
Hypomagnesaemia	2 (2.5)
Electrolyte imbalance	1 (1.3)
Gout	1 (1.3)
Hyperchloraemia	1 (1.3)
Hypercreatininaemia	1 (1.3)
Hypoproteinaemia	1 (1.3)
Vitamin D deficiency	1 (1.3)
Blood and lymphatic system disorders	38 (48.1)
Anaemia	30 (38.0)
Neutropenia	8 (10.1)
Thrombocytopenia	5 (6.3)
Febrile neutropenia	2 (2.5)
Leukopenia	2 (2.5)
Iron deficiency anaemia	1 (1.3)
Lymph node pain	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Lymphopenia	1 (1.3)
Respiratory, thoracic and mediastinal disorders	37 (46.8)
Cough	9 (11.4)
Epistaxis	8 (10.1)
Pneumonitis	8 (10.1)
Dyspnoea	7 (8.9)
Interstitial lung disease	4 (5.1)
Hiccups	3 (3.8)
Rhinorrhoea	3 (3.8)
Dyspnoea exertional	2 (2.5)
Oropharyngeal pain	2 (2.5)
Pleural effusion	2 (2.5)
Pulmonary embolism	2 (2.5)
Dysphonia	1 (1.3)
Nasal congestion	1 (1.3)
Nasal dryness	1 (1.3)
Pharyngeal ulceration	1 (1.3)
Throat clearing	1 (1.3)
Nervous system disorders	28 (35.4)
Headache	7 (8.9)
Dizziness	6 (7.6)
Dysgeusia	3 (3.8)
Paraesthesia	3 (3.8)
Lethargy	2 (2.5)
Neuropathy peripheral	2 (2.5)
Somnolence	2 (2.5)
Tremor	2 (2.5)
Basal ganglia infarction	1 (1.3)
Cerebrovascular accident	1 (1.3)
Dysaesthesia	1 (1.3)
Generalised tonic-clonic seizure	1 (1.3)
Hypoaesthesia	1 (1.3)
Memory impairment	1 (1.3)
Peripheral sensory neuropathy	1 (1.3)
Skin and subcutaneous tissue disorders	26 (32.9)
Alopecia	19 (24.1)
Dry skin	3 (3.8)
Pruritus	3 (3.8)
Dermatitis	1 (1.3)
Dermatitis acneiform	1 (1.3)
Nail disorder	1 (1.3)
Onychoclasis	1 (1.3)
Palmar-plantar erythrodysaesthesia syndrome	1 (1.3)
Rash maculo-papular	1 (1.3)
Rash pruritic	1 (1.3)
Skin hyperpigmentation	1 (1.3)
Infections and infestations	21 (26.6)
COVID-19	5 (6.3)
Device related infection	4 (5.1)
Urinary tract infection	4 (5.1)
Pneumonia	2 (2.5)
Scrotal infection	2 (2.5)
Asymptomatic COVID-19	1 (1.3)
Bacteraemia	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Bacterial sepsis	1 (1.3)
COVID-19 pneumonia	1 (1.3)
Catheter site infection	1 (1.3)
Cellulitis	1 (1.3)
Conjunctivitis	1 (1.3)
Oral fungal infection	1 (1.3)
Oral herpes	1 (1.3)
Staphylococcal infection	1 (1.3)
Wound infection	1 (1.3)
Musculoskeletal and connective tissue disorders	18 (22.8)
Back pain	7 (8.9)
Arthralgia	3 (3.8)
Musculoskeletal chest pain	2 (2.5)
Myalgia	2 (2.5)
Flank pain	1 (1.3)
Muscle spasms	1 (1.3)
Muscular weakness	1 (1.3)
Musculoskeletal pain	1 (1.3)
Neck pain	1 (1.3)
Renal and urinary disorders	18 (22.8)
Urinary retention	5 (6.3)
Acute kidney injury	4 (5.1)
Dysuria	3 (3.8)
Chromaturia	1 (1.3)
Hydronephrosis	1 (1.3)
Micturition urgency	1 (1.3)
Nephrolithiasis	1 (1.3)
Nocturia	1 (1.3)
Pollakiuria	1 (1.3)
Urinary tract obstruction	1 (1.3)
Vascular disorders	13 (16.5)
Hypotension	6 (7.6)
Deep vein thrombosis	3 (3.8)
Hypertension	3 (3.8)
Embolism	2 (2.5)
Hot flush	1 (1.3)
Thrombophlebitis superficial	1 (1.3)
Psychiatric disorders	12 (15.2)
Insomnia	5 (6.3)
Depression	4 (5.1)
Anxiety	3 (3.8)
Confusional state	2 (2.5)
Hallucination	1 (1.3)
Hepatobiliary disorders	8 (10.1)
Hepatotoxicity	2 (2.5)
Hyperbilirubinaemia	2 (2.5)
Bile duct stenosis	1 (1.3)
Cholangitis	1 (1.3)
Gallbladder obstruction	1 (1.3)
Hypertransaminasaemia	1 (1.3)
Portal vein thrombosis	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (8.9)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Cancer pain	2 (2.5)
Malignant neoplasm progression	2 (2.5)
Benign breast neoplasm	1 (1.3)
Lymphangiosis carcinomatosa	1 (1.3)
Tumour haemorrhage	1 (1.3)
Tumour pain	1 (1.3)
Eye disorders	6 (7.6)
Dry eye	2 (2.5)
Diplopia	1 (1.3)
Eye pain	1 (1.3)
Eye pruritus	1 (1.3)
Macular fibrosis	1 (1.3)
Visual impairment	1 (1.3)
Cardiac disorders	4 (5.1)
Sinus bradycardia	2 (2.5)
Atrial fibrillation	1 (1.3)
Cardiac flutter	1 (1.3)
Injury, poisoning and procedural complications	4 (5.1)
Animal bite	1 (1.3)
Exposure to communicable disease	1 (1.3)
Fall	1 (1.3)
Subdural haemorrhage	1 (1.3)
Tooth fracture	1 (1.3)
Reproductive system and breast disorders	3 (3.8)
Gynaecomastia	1 (1.3)
Pelvic pain	1 (1.3)
Testicular oedema	1 (1.3)
Ear and labyrinth disorders	1 (1.3)
Hypoacusis	1 (1.3)
Product issues	1 (1.3)
Device occlusion	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious TEAE by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Subjects with events	33 (41.8)
Gastrointestinal disorders	12 (15.2)
Nausea	4 (5.1)
Vomiting	3 (3.8)
Abdominal pain	2 (2.5)
Colitis	1 (1.3)
Diarrhoea	1 (1.3)
Dysphagia	1 (1.3)
Enteritis	1 (1.3)
Haematemesis	1 (1.3)
Intestinal obstruction	1 (1.3)
Infections and infestations	11 (13.9)
COVID-19	2 (2.5)
Pneumonia	2 (2.5)
Urinary tract infection	2 (2.5)
Bacterial sepsis	1 (1.3)
COVID-19 pneumonia	1 (1.3)
Catheter site infection	1 (1.3)
Device related infection	1 (1.3)
Staphylococcal infection	1 (1.3)
Wound infection	1 (1.3)
Respiratory, thoracic and mediastinal disorders	6 (7.6)
Pneumonitis	3 (3.8)
Interstitial lung disease	2 (2.5)
Pulmonary embolism	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (5.1)
Malignant neoplasm progression	2 (2.5)
Lymphangiosis carcinomatosa	1 (1.3)
Tumour haemorrhage	1 (1.3)
Renal and urinary disorders	4 (5.1)
Acute kidney injury	2 (2.5)
Hydronephrosis	1 (1.3)
Urinary tract obstruction	1 (1.3)
General disorders and administration site conditions	3 (3.8)
Disease progression	2 (2.5)
Hyperpyrexia	1 (1.3)
Hepatobiliary disorders	3 (3.8)
Bile duct stenosis	1 (1.3)
Cholangitis	1 (1.3)
Hepatotoxicity	1 (1.3)
Nervous system disorders	3 (3.8)
Basal ganglia infarction	1 (1.3)
Cerebrovascular accident	1 (1.3)
Generalised tonic-clonic seizure	1 (1.3)
Injury, poisoning and procedural complications	1 (1.3)
Animal bite	1 (1.3)
Exposure to communicable disease	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious TEAE by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Product issues	1 (1.3)
Device occlusion	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Subjects with events	44 (55.7)
Blood and lymphatic system disorders	18 (22.8)
Anaemia	11 (13.9)
Neutropenia	4 (5.1)
Febrile neutropenia	2 (2.5)
Lymphopenia	1 (1.3)
Thrombocytopenia	1 (1.3)
Gastrointestinal disorders	18 (22.8)
Nausea	6 (7.6)
Dysphagia	3 (3.8)
Abdominal pain	2 (2.5)
Ascites	2 (2.5)
Vomiting	2 (2.5)
Anal fissure	1 (1.3)
Anal fistula	1 (1.3)
Colitis	1 (1.3)
Diarrhoea	1 (1.3)
Enteritis	1 (1.3)
Haematemesis	1 (1.3)
Intestinal obstruction	1 (1.3)
Obstruction gastric	1 (1.3)
Oesophageal obstruction	1 (1.3)
Infections and infestations	12 (15.2)
COVID-19	3 (3.8)
Pneumonia	2 (2.5)
Urinary tract infection	2 (2.5)
Bacterial sepsis	1 (1.3)
COVID-19 pneumonia	1 (1.3)
Catheter site infection	1 (1.3)
Device related infection	1 (1.3)
Staphylococcal infection	1 (1.3)
Wound infection	1 (1.3)
Investigations	12 (15.2)
Neutrophil count decreased	6 (7.6)
White blood cell count decreased	5 (6.3)
Weight decreased	3 (3.8)
Blood bilirubin increased	2 (2.5)
Lymphocyte count decreased	2 (2.5)
Platelet count decreased	2 (2.5)
Alanine aminotransferase increased	1 (1.3)
Aspartate aminotransferase increased	1 (1.3)
Blood alkaline phosphatase increased	1 (1.3)
Metabolism and nutrition disorders	8 (10.1)
Decreased appetite	4 (5.1)
Hypophosphataemia	2 (2.5)
Electrolyte imbalance	1 (1.3)
Hyperglycaemia	1 (1.3)
Hypokalaemia	1 (1.3)
Respiratory, thoracic and mediastinal disorders	7 (8.9)
Interstitial lung disease	2 (2.5)
Pulmonary embolism	2 (2.5)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT
Safety Analysis Set

System Organ Class (SOC) Preferred Term (PT)	T-DXd (N=79) n (%)
Cough	1 (1.3)
Dyspnoea	1 (1.3)
Pleural effusion	1 (1.3)
Pneumonitis	1 (1.3)
General disorders and administration site conditions	6 (7.6)
Fatigue	3 (3.8)
Disease progression	2 (2.5)
Asthenia	1 (1.3)
Oedema	1 (1.3)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (5.1)
Malignant neoplasm progression	2 (2.5)
Cancer pain	1 (1.3)
Lymphangiosis carcinomatosa	1 (1.3)
Tumour haemorrhage	1 (1.3)
Nervous system disorders	4 (5.1)
Basal ganglia infarction	1 (1.3)
Cerebrovascular accident	1 (1.3)
Generalised tonic-clonic seizure	1 (1.3)
Somnolence	1 (1.3)
Renal and urinary disorders	4 (5.1)
Acute kidney injury	2 (2.5)
Hydronephrosis	1 (1.3)
Urinary tract obstruction	1 (1.3)
Vascular disorders	4 (5.1)
Embolism	2 (2.5)
Hypertension	1 (1.3)
Hypotension	1 (1.3)
Hepatobiliary disorders	3 (3.8)
Bile duct stenosis	1 (1.3)
Gallbladder obstruction	1 (1.3)
Hepatotoxicity	1 (1.3)
Injury, poisoning and procedural complications	1 (1.3)
Animal bite	1 (1.3)
Exposure to communicable disease	1 (1.3)
Product issues	1 (1.3)
Device occlusion	1 (1.3)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	79/ 79 (100.0)	0.1 (0.1, 0.1)
Region		
North America	34/ 34 (100.0)	0.1 (0.0, 0.1)
EU	45/ 45 (100.0)	0.1 (0.1, 0.2)
Age (Category 1)		
<65 years	46/ 46 (100.0)	0.1 (0.1, 0.1)
>=65 years	33/ 33 (100.0)	0.1 (0.1, 0.1)
Age (Category 2)		
<75 years	75/ 75 (100.0)	0.1 (0.1, 0.1)
>=75 years	4/ 4 (100.0)	0.2 (0.0, 1.9)
Sex		
female	22/ 22 (100.0)	0.1 (0.0, 0.3)
male	57/ 57 (100.0)	0.1 (0.1, 0.1)
ECOG PS		
0	29/ 29 (100.0)	0.1 (0.1, 0.2)
1	50/ 50 (100.0)	0.1 (0.1, 0.1)
HER2 Status in central laboratory		
IHC 3+	68/ 68 (100.0)	0.1 (0.1, 0.1)
IHC 2+/ISH +	10/ 10 (100.0)	0.1 (0.0, 0.2)
Primary tumor location		
Gastric	27/ 27 (100.0)	0.1 (0.1, 0.2)
GEJ	52/ 52 (100.0)	0.1 (0.1, 0.1)
Histological subtype		
diffuse	1/ 1 (100.0)	0.5 (NE , NE)
intestinal	19/ 19 (100.0)	0.1 (0.0, 0.3)
other	59/ 59 (100.0)	0.1 (0.1, 0.1)
Number of metastatic sites		
<2	5/ 5 (100.0)	0.1 (0.0, 0.5)
>=2	74/ 74 (100.0)	0.1 (0.1, 0.1)
Previous total gastrectomy		
no	79/ 79 (100.0)	0.1 (0.1, 0.1)
Prior adjuvant/ neoadjuvant therapy		
yes	9/ 9 (100.0)	0.1 (0.0, 0.3)
no	70/ 70 (100.0)	0.1 (0.1, 0.1)
Prior nivolumab or pembrolizumab treatment		
yes	6/ 6 (100.0)	0.1 (0.0, 0.5)
no	73/ 73 (100.0)	0.1 (0.1, 0.1)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	7/ 7 (100.0)	0.1 (0.0, 0.1)
no	72/ 72 (100.0)	0.1 (0.1, 0.1)
Presence of liver metastasis at baseline		
yes	50/ 50 (100.0)	0.1 (0.1, 0.2)
no	29/ 29 (100.0)	0.1 (0.1, 0.1)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

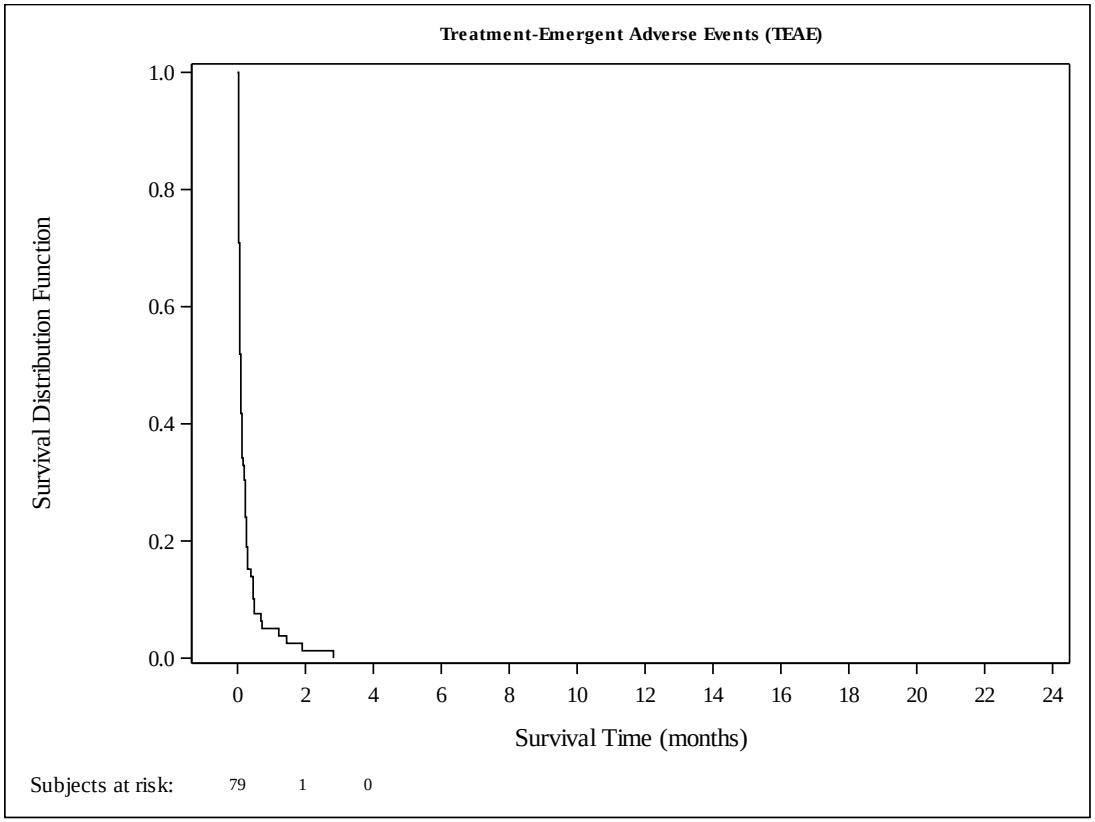
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	32/ 32 (100.0)	0.1 (0.0, 0.1)
mild	25/ 25 (100.0)	0.1 (0.0, 0.2)
moderate	8/ 8 (100.0)	0.1 (0.1, 1.9)
Hepatic impairment at baseline		
normal	64/ 64 (100.0)	0.1 (0.1, 0.1)
mild	14/ 14 (100.0)	0.0 (0.0, 0.1)
Race		
White	69/ 69 (100.0)	0.1 (0.1, 0.1)
Black or African American	1/ 1 (100.0)	0.1 (NE , NE)
Other	8/ 8 (100.0)	0.1 (0.0, 0.3)
Ethnicity		
Hispanic/Latino	5/ 5 (100.0)	0.2 (0.0, 2.8)
Non-Hispanic/Non-Latino	70/ 70 (100.0)	0.1 (0.1, 0.1)
Unknown	4/ 4 (100.0)	0.1 (0.0, 0.2)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Treatment-Emergent Adverse Events (TEAE)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious TEAE
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	33/ 79 (41.8)	11.7 (6.0, NE)
Region		
North America	13/ 34 (38.2)	NE (3.5, NE)
EU	20/ 45 (44.4)	11.7 (5.2, NE)
Age (Category 1)		
<65 years	19/ 46 (41.3)	11.7 (3.6, NE)
>=65 years	14/ 33 (42.4)	12.1 (4.0, NE)
Age (Category 2)		
<75 years	30/ 75 (40.0)	11.7 (6.0, NE)
>=75 years	3/ 4 (75.0)	5.6 (1.2, NE)
Sex		
female	11/ 22 (50.0)	8.5 (3.6, NE)
male	22/ 57 (38.6)	11.7 (6.0, NE)
ECOG PS		
0	4/ 29 (13.8)	NE (NE , NE)
1	29/ 50 (58.0)	6.0 (1.3, 12.1)
HER2 Status in central laboratory		
IHC 3+	27/ 68 (39.7)	11.7 (7.2, NE)
IHC 2+/ISH +	5/ 10 (50.0)	3.5 (0.4, NE)
Primary tumor location		
Gastric	13/ 27 (48.1)	8.5 (3.5, NE)
GEJ	20/ 52 (38.5)	11.7 (3.6, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	9/ 19 (47.4)	7.6 (3.5, NE)
other	24/ 59 (40.7)	11.7 (4.0, NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	33/ 74 (44.6)	11.7 (4.0, NE)
Previous total gastrectomy		
no	33/ 79 (41.8)	11.7 (6.0, NE)
Prior adjuvant/ neoadjuvant therapy		
yes	3/ 9 (33.3)	NE (0.1, NE)
no	30/ 70 (42.9)	11.7 (5.2, NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (3.4, NE)
no	32/ 73 (43.8)	11.7 (5.2, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (3.4, NE)
no	31/ 72 (43.1)	11.7 (6.0, NE)
Presence of liver metastasis at baseline		
yes	21/ 50 (42.0)	11.7 (4.0, NE)
no	12/ 29 (41.4)	8.5 (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

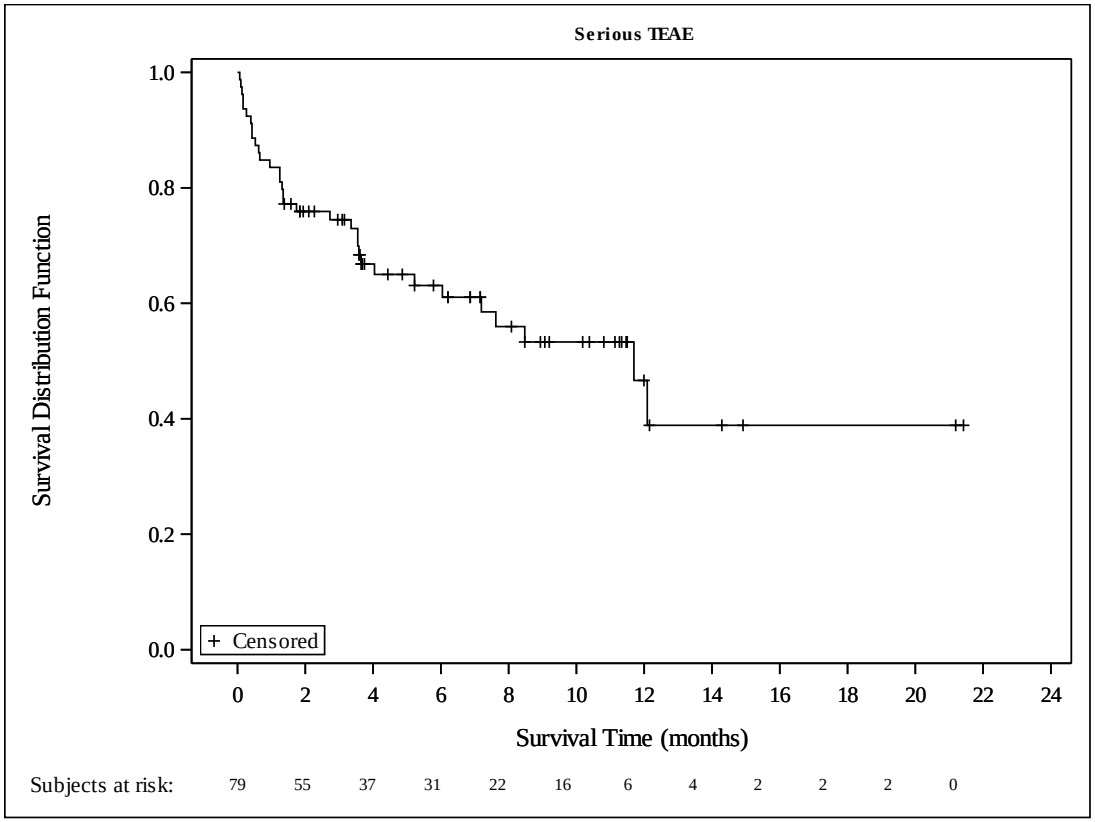
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious TEAE
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	12/ 32 (37.5)	NE (1.7, NE)
mild	7/ 25 (28.0)	NE (5.2, NE)
moderate	7/ 8 (87.5)	6.6 (1.3, 8.5)
Hepatic impairment at baseline		
normal	23/ 64 (35.9)	12.1 (7.2, NE)
mild	9/ 14 (64.3)	3.6 (0.3, 11.7)
Race		
White	28/ 69 (40.6)	11.7 (6.0, NE)
Black or African American	1/ 1 (100.0)	4.0 (NE , NE)
Other	3/ 8 (37.5)	NE (0.4, NE)
Ethnicity		
Hispanic/Latino	3/ 5 (60.0)	3.6 (1.2, NE)
Non-Hispanic/Non-Latino	29/ 70 (41.4)	11.7 (6.0, NE)
Unknown	1/ 4 (25.0)	NE (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Serious TEAE
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	44/ 79 (55.7)	4.1 (2.6, 11.3)
Region		
North America	18/ 34 (52.9)	6.0 (1.4, NE)
EU	26/ 45 (57.8)	3.5 (0.7, 11.3)
Age (Category 1)		
<65 years	30/ 46 (65.2)	3.0 (1.0, 9.8)
>=65 years	14/ 33 (42.4)	NE (2.6, NE)
Age (Category 2)		
<75 years	40/ 75 (53.3)	4.2 (2.7, 18.9)
>=75 years	4/ 4 (100.0)	0.5 (0.3, 7.2)
Sex		
female	13/ 22 (59.1)	3.6 (0.5, NE)
male	31/ 57 (54.4)	4.1 (1.4, 18.9)
ECOG PS		
0	9/ 29 (31.0)	11.3 (3.6, NE)
1	35/ 50 (70.0)	1.4 (0.5, 4.1)
HER2 Status in central laboratory		
IHC 3+	38/ 68 (55.9)	4.2 (2.6, 11.3)
IHC 2+/ISH +	5/ 10 (50.0)	3.5 (0.2, NE)
Primary tumor location		
Gastric	17/ 27 (63.0)	3.5 (0.5, NE)
GEJ	27/ 52 (51.9)	6.0 (2.6, 18.9)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	12/ 19 (63.2)	3.5 (1.0, 11.3)
other	32/ 59 (54.2)	4.1 (1.4, NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (0.5, NE)
>=2	43/ 74 (58.1)	3.6 (1.6, 9.8)
Previous total gastrectomy		
no	44/ 79 (55.7)	4.1 (2.6, 11.3)
Prior adjuvant/ neoadjuvant therapy		
yes	7/ 9 (77.8)	3.6 (0.0, 11.3)
no	37/ 70 (52.9)	4.1 (2.6, NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (0.5, NE)
no	43/ 73 (58.9)	3.6 (1.4, 9.8)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (0.5, NE)
no	42/ 72 (58.3)	3.6 (1.6, 9.8)
Presence of liver metastasis at baseline		
yes	27/ 50 (54.0)	6.0 (1.6, 18.9)
no	17/ 29 (58.6)	3.5 (0.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

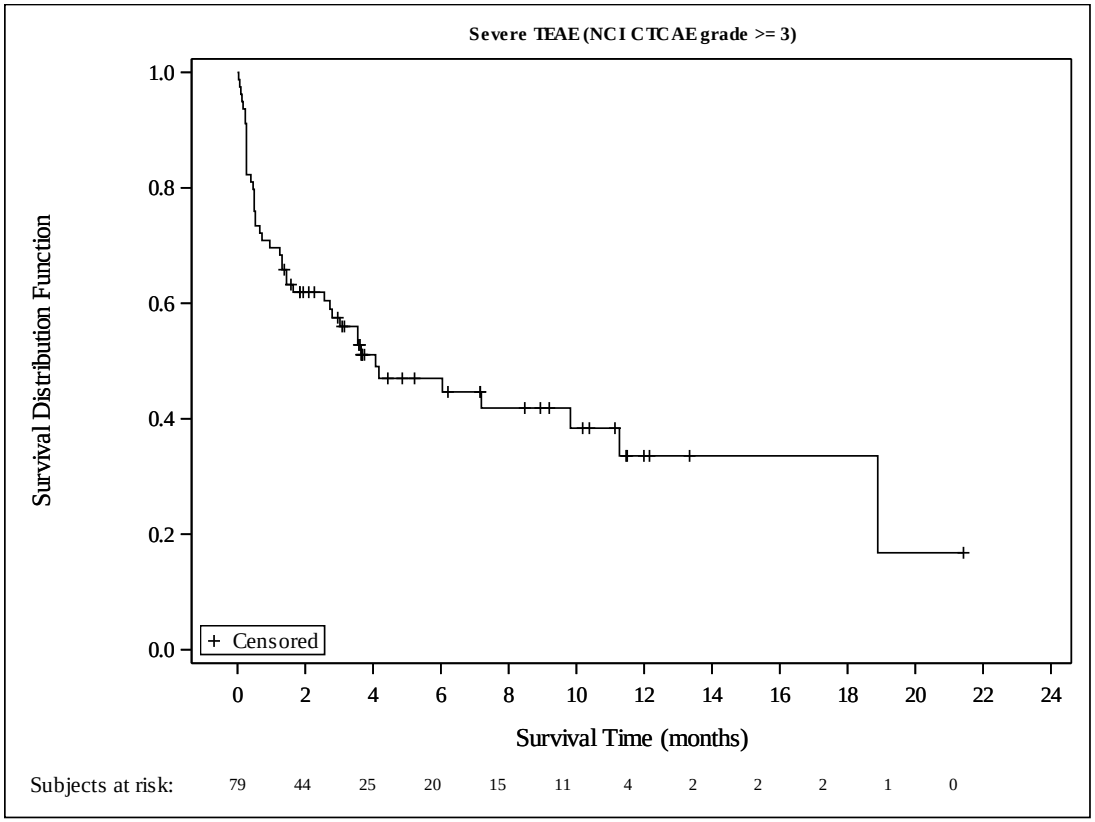
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	17/ 32 (53.1)	9.8 (0.7, 18.9)
mild	10/ 25 (40.0)	11.3 (2.8, NE)
moderate	7/ 8 (87.5)	3.6 (0.3, 7.2)
Hepatic impairment at baseline		
normal	32/ 64 (50.0)	7.2 (2.8, 18.9)
mild	11/ 14 (78.6)	0.7 (0.2, 4.1)
Race		
White	37/ 69 (53.6)	6.0 (2.6, 18.9)
Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
Other	5/ 8 (62.5)	2.3 (0.2, NE)
Ethnicity		
Hispanic/Latino	4/ 5 (80.0)	3.5 (0.3, 9.8)
Non-Hispanic/Non-Latino	38/ 70 (54.3)	4.1 (1.4, 18.9)
Unknown	2/ 4 (50.0)	4.2 (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Severe TEAE (NCI CTCAE grade >= 3)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	79/ 79 (100.0)	0.1 (0.1, 0.1)
Region		
North America	34/ 34 (100.0)	0.1 (0.0, 0.1)
EU	45/ 45 (100.0)	0.1 (0.1, 0.2)
Age (Category 1)		
<65 years	46/ 46 (100.0)	0.1 (0.1, 0.2)
>=65 years	33/ 33 (100.0)	0.1 (0.1, 0.1)
Age (Category 2)		
<75 years	75/ 75 (100.0)	0.1 (0.1, 0.1)
>=75 years	4/ 4 (100.0)	0.2 (0.0, 1.9)
Sex		
female	22/ 22 (100.0)	0.1 (0.0, 0.3)
male	57/ 57 (100.0)	0.1 (0.1, 0.1)
ECOG PS		
0	29/ 29 (100.0)	0.1 (0.1, 0.2)
1	50/ 50 (100.0)	0.1 (0.1, 0.1)
HER2 Status in central laboratory		
IHC 3+	68/ 68 (100.0)	0.1 (0.1, 0.1)
IHC 2+/ISH +	10/ 10 (100.0)	0.1 (0.0, 0.2)
Primary tumor location		
Gastric	27/ 27 (100.0)	0.1 (0.1, 0.2)
GEJ	52/ 52 (100.0)	0.1 (0.1, 0.1)
Histological subtype		
diffuse	1/ 1 (100.0)	0.5 (NE , NE)
intestinal	19/ 19 (100.0)	0.1 (0.0, 0.3)
other	59/ 59 (100.0)	0.1 (0.1, 0.1)
Number of metastatic sites		
<2	5/ 5 (100.0)	0.1 (0.0, 2.8)
>=2	74/ 74 (100.0)	0.1 (0.1, 0.1)
Previous total gastrectomy		
no	79/ 79 (100.0)	0.1 (0.1, 0.1)
Prior adjuvant/ neoadjuvant therapy		
yes	9/ 9 (100.0)	0.1 (0.0, 0.3)
no	70/ 70 (100.0)	0.1 (0.1, 0.1)
Prior nivolumab or pembrolizumab treatment		
yes	6/ 6 (100.0)	0.1 (0.0, 0.7)
no	73/ 73 (100.0)	0.1 (0.1, 0.1)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	7/ 7 (100.0)	0.1 (0.0, 0.1)
no	72/ 72 (100.0)	0.1 (0.1, 0.1)
Presence of liver metastasis at baseline		
yes	50/ 50 (100.0)	0.1 (0.1, 0.2)
no	29/ 29 (100.0)	0.1 (0.1, 0.1)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

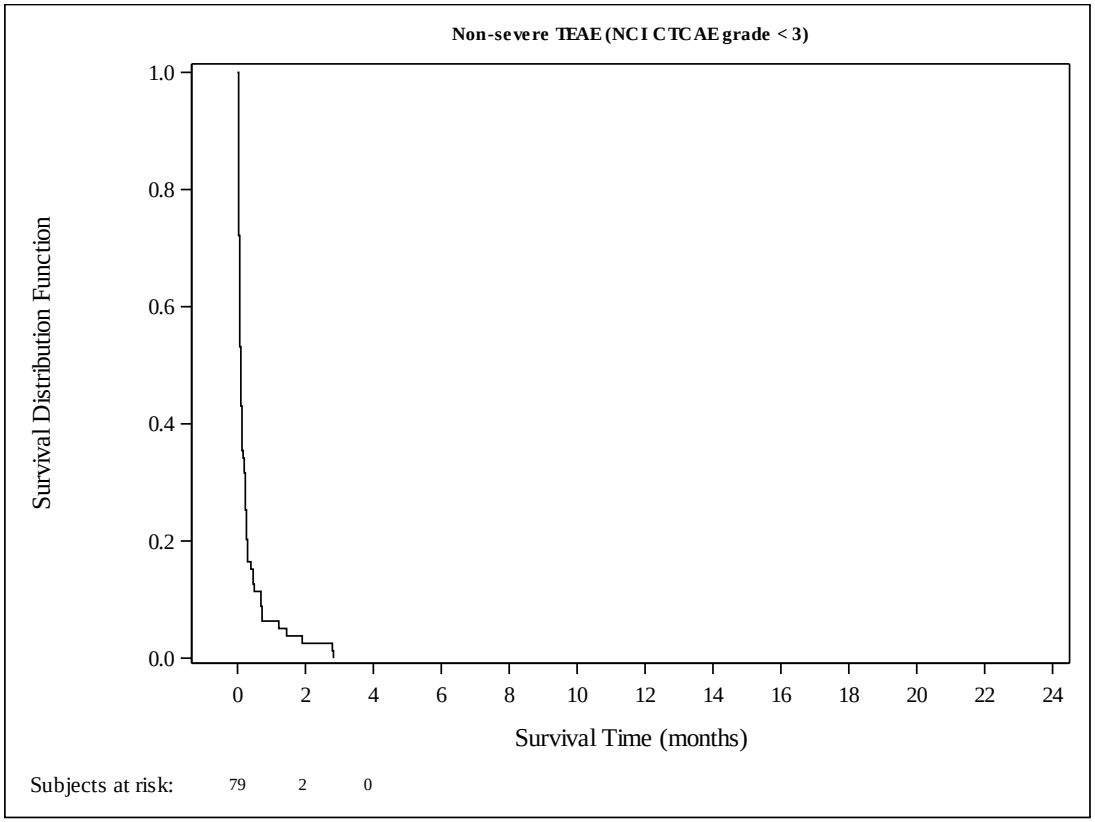
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	32/ 32 (100.0)	0.1 (0.0, 0.1)
mild	25/ 25 (100.0)	0.1 (0.0, 0.2)
moderate	8/ 8 (100.0)	0.1 (0.1, 1.9)
Hepatic impairment at baseline		
normal	64/ 64 (100.0)	0.1 (0.1, 0.2)
mild	14/ 14 (100.0)	0.0 (0.0, 0.1)
Race		
White	69/ 69 (100.0)	0.1 (0.1, 0.1)
Black or African American	1/ 1 (100.0)	0.1 (NE , NE)
Other	8/ 8 (100.0)	0.1 (0.0, 0.3)
Ethnicity		
Hispanic/Latino	5/ 5 (100.0)	0.2 (0.0, 2.8)
Non-Hispanic/Non-Latino	70/ 70 (100.0)	0.1 (0.1, 0.1)
Unknown	4/ 4 (100.0)	0.1 (0.0, 0.2)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Non-severe TEAE (NCI CTCAE grade < 3)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE leading to drug withdrawn
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	15/ 79 (19.0)	NE (11.5, NE)
Region		
North America	8/ 34 (23.5)	NE (10.4, NE)
EU	7/ 45 (15.6)	NE (11.5, NE)
Age (Category 1)		
<65 years	8/ 46 (17.4)	NE (11.5, NE)
>=65 years	7/ 33 (21.2)	NE (10.4, NE)
Age (Category 2)		
<75 years	14/ 75 (18.7)	NE (11.5, NE)
>=75 years	1/ 4 (25.0)	NE (3.5, NE)
Sex		
female	2/ 22 (9.1)	NE (9.0, NE)
male	13/ 57 (22.8)	NE (11.0, NE)
ECOG PS		
0	5/ 29 (17.2)	NE (10.4, NE)
1	10/ 50 (20.0)	NE (11.5, NE)
HER2 Status in central laboratory		
IHC 3+	12/ 68 (17.6)	NE (11.5, NE)
IHC 2+/ISH +	3/ 10 (30.0)	NE (1.3, NE)
Primary tumor location		
Gastric	4/ 27 (14.8)	NE (9.0, NE)
GEJ	11/ 52 (21.2)	NE (10.4, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	14/ 59 (23.7)	NE (10.4, NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	14/ 74 (18.9)	NE (11.5, NE)
Previous total gastrectomy		
no	15/ 79 (19.0)	NE (11.5, NE)
Prior adjuvant/ neoadjuvant therapy		
yes	1/ 9 (11.1)	NE (0.2, NE)
no	14/ 70 (20.0)	NE (11.0, NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	14/ 73 (19.2)	NE (11.5, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (2.5, NE)
no	13/ 72 (18.1)	NE (11.5, NE)
Presence of liver metastasis at baseline		
yes	12/ 50 (24.0)	NE (11.0, NE)
no	3/ 29 (10.3)	NE (9.0, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

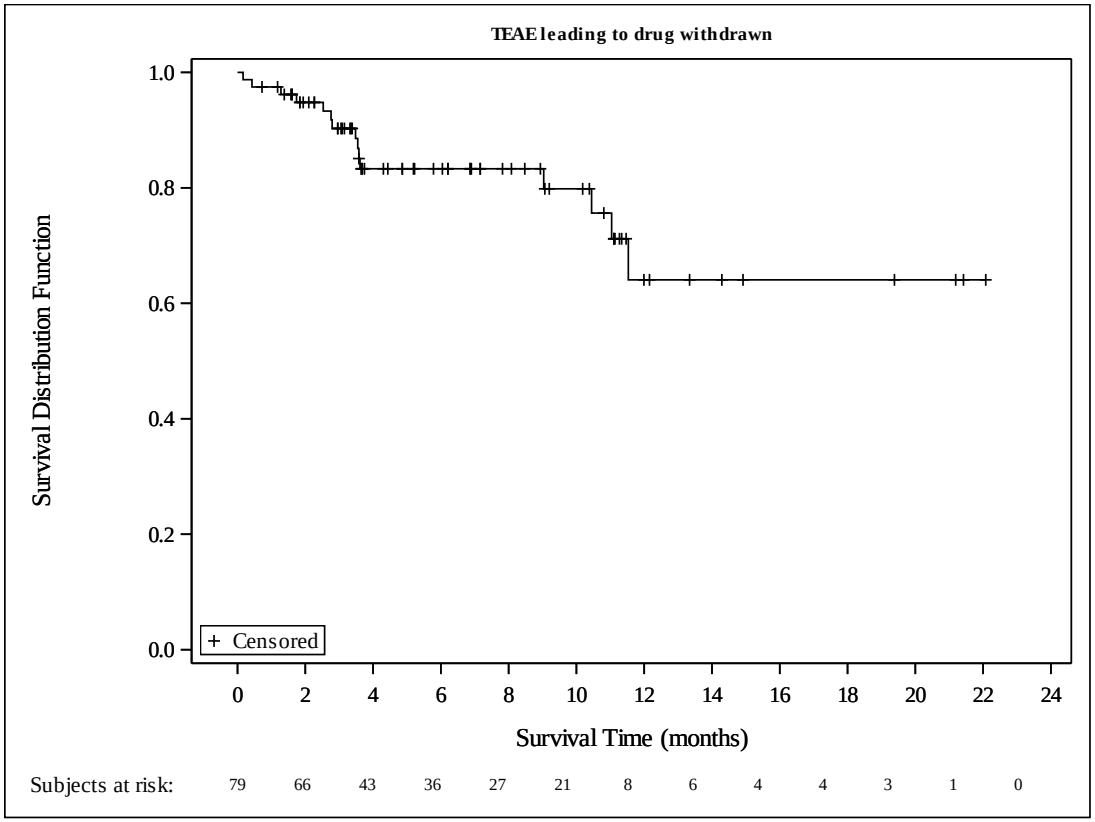
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE leading to drug withdrawn
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	6/ 32 (18.8)	NE (NE , NE)
mild	3/ 25 (12.0)	NE (11.5, NE)
moderate	1/ 8 (12.5)	NE (9.0, NE)
Hepatic impairment at baseline		
normal	9/ 64 (14.1)	NE (NE , NE)
mild	6/ 14 (42.9)	11.5 (3.5, 11.5)
Race		
White	12/ 69 (17.4)	NE (11.5, NE)
Black or African American	1/ 1 (100.0)	3.5 (NE , NE)
Other	1/ 8 (12.5)	NE (0.4, NE)
Ethnicity		
Hispanic/Latino	1/ 5 (20.0)	NE (3.6, NE)
Non-Hispanic/Non-Latino	13/ 70 (18.6)	NE (11.5, NE)
Unknown	1/ 4 (25.0)	NE (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of TEAE leading to drug withdrawn
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE leading to death
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	11/ 79 (13.9)	NE (NE , NE)
Region		
North America	6/ 34 (17.6)	NE (10.4, NE)
EU	5/ 45 (11.1)	NE (NE , NE)
Age (Category 1)		
<65 years	9/ 46 (19.6)	NE (NE , NE)
>=65 years	2/ 33 (6.1)	NE (10.4, NE)
Age (Category 2)		
<75 years	11/ 75 (14.7)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	1/ 22 (4.5)	NE (NE , NE)
male	10/ 57 (17.5)	NE (NE , NE)
ECOG PS		
0	3/ 29 (10.3)	NE (10.4, NE)
1	8/ 50 (16.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	10/ 68 (14.7)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (3.5, NE)
Primary tumor location		
Gastric	2/ 27 (7.4)	NE (NE , NE)
GEJ	9/ 52 (17.3)	NE (10.4, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	3/ 19 (15.8)	NE (4.3, NE)
other	8/ 59 (13.6)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	11/ 74 (14.9)	NE (NE , NE)
Previous total gastrectomy		
no	11/ 79 (13.9)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	1/ 9 (11.1)	NE (0.9, NE)
no	10/ 70 (14.3)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (3.4, NE)
no	10/ 73 (13.7)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (3.4, NE)
no	9/ 72 (12.5)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	7/ 50 (14.0)	NE (NE , NE)
no	4/ 29 (13.8)	NE (10.4, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

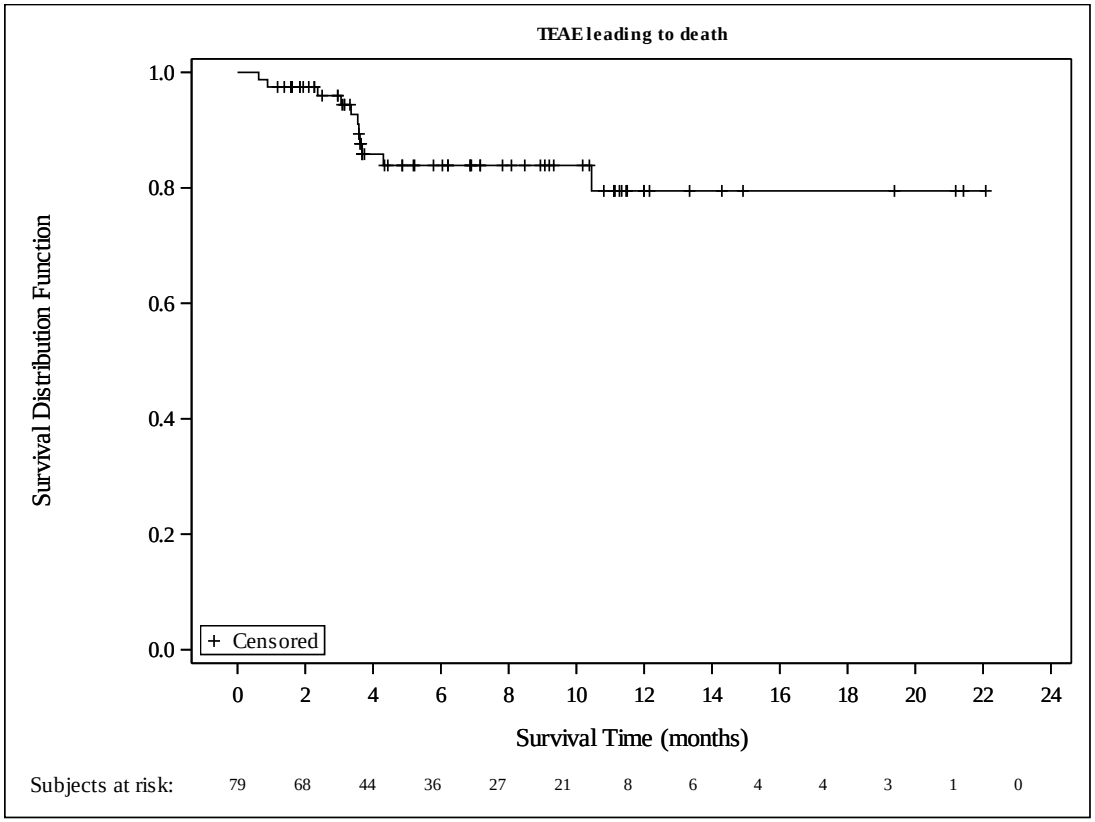
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE leading to death
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	7/ 32 (21.9)	NE (3.7, NE)
mild	1/ 25 (4.0)	NE (NE , NE)
moderate	1/ 8 (12.5)	NE (4.3, NE)
Hepatic impairment at baseline		
normal	5/ 64 (7.8)	NE (NE , NE)
mild	6/ 14 (42.9)	NE (3.1, NE)
Race		
White	9/ 69 (13.0)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	1/ 8 (12.5)	NE (3.4, NE)
Ethnicity		
Hispanic/Latino	2/ 5 (40.0)	NE (3.6, NE)
Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
Unknown	1/ 4 (25.0)	NE (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of TEAE leading to death
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	6/ 79 (7.6)	NE (NE , NE)
Region		
North America	2/ 34 (5.9)	NE (NE , NE)
EU	4/ 45 (8.9)	NE (NE , NE)
Age (Category 1)		
<65 years	3/ 46 (6.5)	NE (NE , NE)
>=65 years	3/ 33 (9.1)	NE (NE , NE)
Age (Category 2)		
<75 years	6/ 75 (8.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	2/ 22 (9.1)	NE (NE , NE)
male	4/ 57 (7.0)	NE (NE , NE)
ECOG PS		
0	6/ 29 (20.7)	NE (NE , NE)
1	0/ 50 (0.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	5/ 68 (7.4)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (0.7, NE)
Primary tumor location		
Gastric	1/ 27 (3.7)	NE (NE , NE)
GEJ	5/ 52 (9.6)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	5/ 59 (8.5)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	6/ 74 (8.1)	NE (NE , NE)
Previous total gastrectomy		
no	6/ 79 (7.6)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	6/ 70 (8.6)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	6/ 73 (8.2)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	6/ 72 (8.3)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	3/ 50 (6.0)	NE (NE , NE)
no	3/ 29 (10.3)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

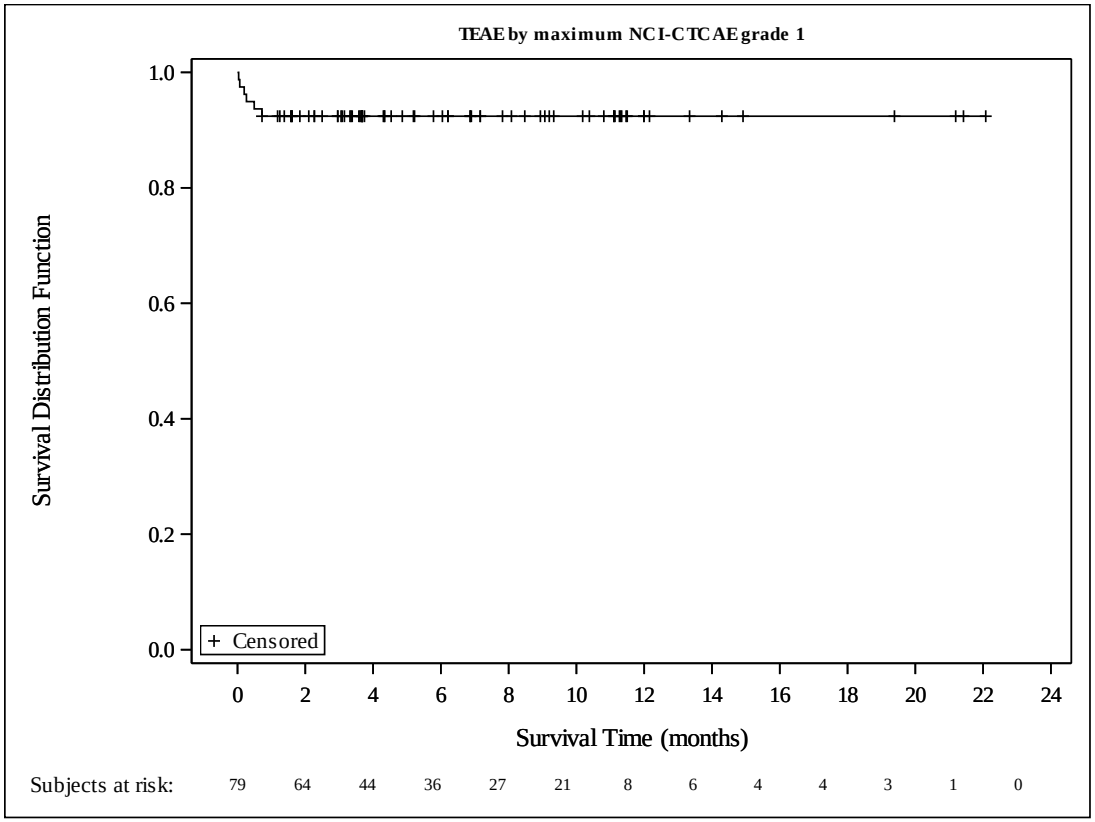
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	2/ 32 (6.3)	NE (NE , NE)
mild	2/ 25 (8.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	6/ 64 (9.4)	NE (NE , NE)
mild	0/ 14 (0.0)	NE (NE , NE)
Race		
White	5/ 69 (7.2)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	1/ 8 (12.5)	NE (0.0, NE)
Ethnicity		
Hispanic/Latino	1/ 5 (20.0)	NE (0.2, NE)
Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
Unknown	1/ 4 (25.0)	NE (0.0, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 1
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Overall	29/ 79 (36.7)	NE (6.9, NE)
Region		
North America	14/ 34 (41.2)	NE (0.7, NE)
EU	15/ 45 (33.3)	NE (2.8, NE)
Age (Category 1)		
<65 years	13/ 46 (28.3)	NE (NE , NE)
>=65 years	16/ 33 (48.5)	6.9 (0.7, NE)
Age (Category 2)		
<75 years	29/ 75 (38.7)	NE (2.8, NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	7/ 22 (31.8)	NE (2.1, NE)
male	22/ 57 (38.6)	NE (2.0, NE)
ECOG PS		
0	14/ 29 (48.3)	6.9 (0.5, NE)
1	15/ 50 (30.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	25/ 68 (36.8)	NE (6.9, NE)
IHC 2+/ISH +	4/ 10 (40.0)	NE (0.0, NE)
Primary tumor location		
Gastric	9/ 27 (33.3)	NE (0.7, NE)
GEJ	20/ 52 (38.5)	NE (2.1, NE)
Histological subtype		
diffuse	1/ 1 (100.0)	0.5 (NE , NE)
intestinal	6/ 19 (31.6)	NE (0.1, NE)
other	22/ 59 (37.3)	NE (2.8, NE)
Number of metastatic sites		
<2	4/ 5 (80.0)	1.4 (0.0, NE)
>=2	25/ 74 (33.8)	NE (6.9, NE)
Previous total gastrectomy		
no	29/ 79 (36.7)	NE (6.9, NE)
Prior adjuvant/ neoadjuvant therapy		
yes	2/ 9 (22.2)	NE (0.1, NE)
no	27/ 70 (38.6)	NE (2.8, NE)
Prior nivolumab or pembrolizumab treatment		
yes	5/ 6 (83.3)	0.3 (0.1, NE)
no	24/ 73 (32.9)	NE (6.9, NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	5/ 7 (71.4)	0.4 (0.1, NE)
no	24/ 72 (33.3)	NE (6.9, NE)
Presence of liver metastasis at baseline		
yes	20/ 50 (40.0)	NE (2.1, NE)
no	9/ 29 (31.0)	NE (2.0, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

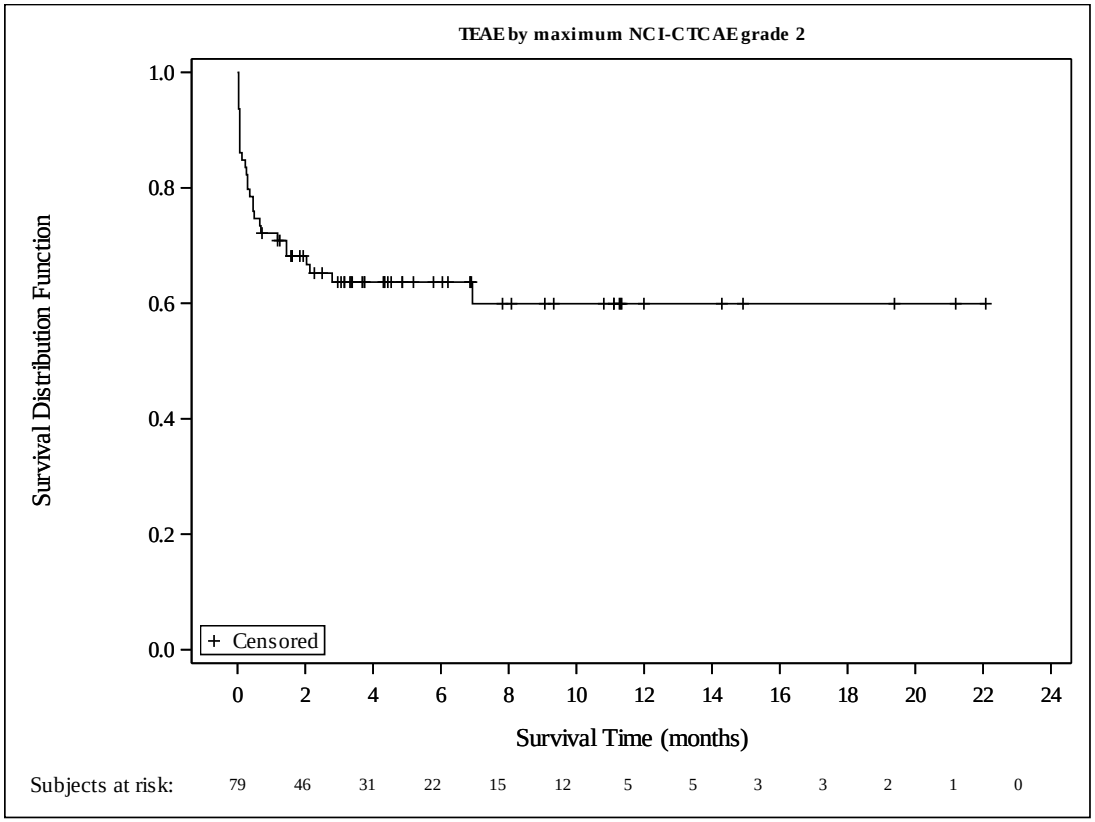
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	13/ 32 (40.6)	6.9 (1.2, NE)
mild	13/ 25 (52.0)	2.8 (0.3, NE)
moderate	1/ 8 (12.5)	NE (2.1, NE)
Hepatic impairment at baseline		
normal	26/ 64 (40.6)	NE (2.1, NE)
mild	3/ 14 (21.4)	NE (0.7, NE)
Race		
White	27/ 69 (39.1)	NE (2.1, NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	2/ 8 (25.0)	6.9 (0.0, NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	28/ 70 (40.0)	NE (2.1, NE)
Unknown	1/ 4 (25.0)	NE (0.1, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 2
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	28/ 79 (35.4)	18.9 (7.2, NE)
Region		
North America	11/ 34 (32.4)	18.9 (6.0, NE)
EU	17/ 45 (37.8)	11.3 (3.6, NE)
Age (Category 1)		
<65 years	19/ 46 (41.3)	11.3 (4.1, 18.9)
>=65 years	9/ 33 (27.3)	NE (7.2, NE)
Age (Category 2)		
<75 years	25/ 75 (33.3)	18.9 (9.8, NE)
>=75 years	3/ 4 (75.0)	4.0 (0.3, 7.2)
Sex		
female	10/ 22 (45.5)	7.2 (2.7, NE)
male	18/ 57 (31.6)	11.3 (9.8, 18.9)
ECOG PS		
0	6/ 29 (20.7)	NE (9.8, NE)
1	22/ 50 (44.0)	7.2 (3.0, NE)
HER2 Status in central laboratory		
IHC 3+	24/ 68 (35.3)	18.9 (7.2, NE)
IHC 2+/ISH +	3/ 10 (30.0)	NE (0.2, NE)
Primary tumor location		
Gastric	11/ 27 (40.7)	NE (1.4, NE)
GEJ	17/ 52 (32.7)	11.3 (6.0, 18.9)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	7/ 19 (36.8)	11.3 (7.2, NE)
other	21/ 59 (35.6)	18.9 (4.2, NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (0.5, NE)
>=2	27/ 74 (36.5)	11.3 (6.0, NE)
Previous total gastrectomy		
no	28/ 79 (35.4)	18.9 (7.2, NE)
Prior adjuvant/ neoadjuvant therapy		
yes	6/ 9 (66.7)	4.2 (0.1, 11.3)
no	22/ 70 (31.4)	18.9 (7.2, NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	28/ 73 (38.4)	11.3 (6.0, 18.9)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	28/ 72 (38.9)	11.3 (6.0, 18.9)
Presence of liver metastasis at baseline		
yes	17/ 50 (34.0)	11.3 (7.2, 18.9)
no	11/ 29 (37.9)	NE (2.7, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

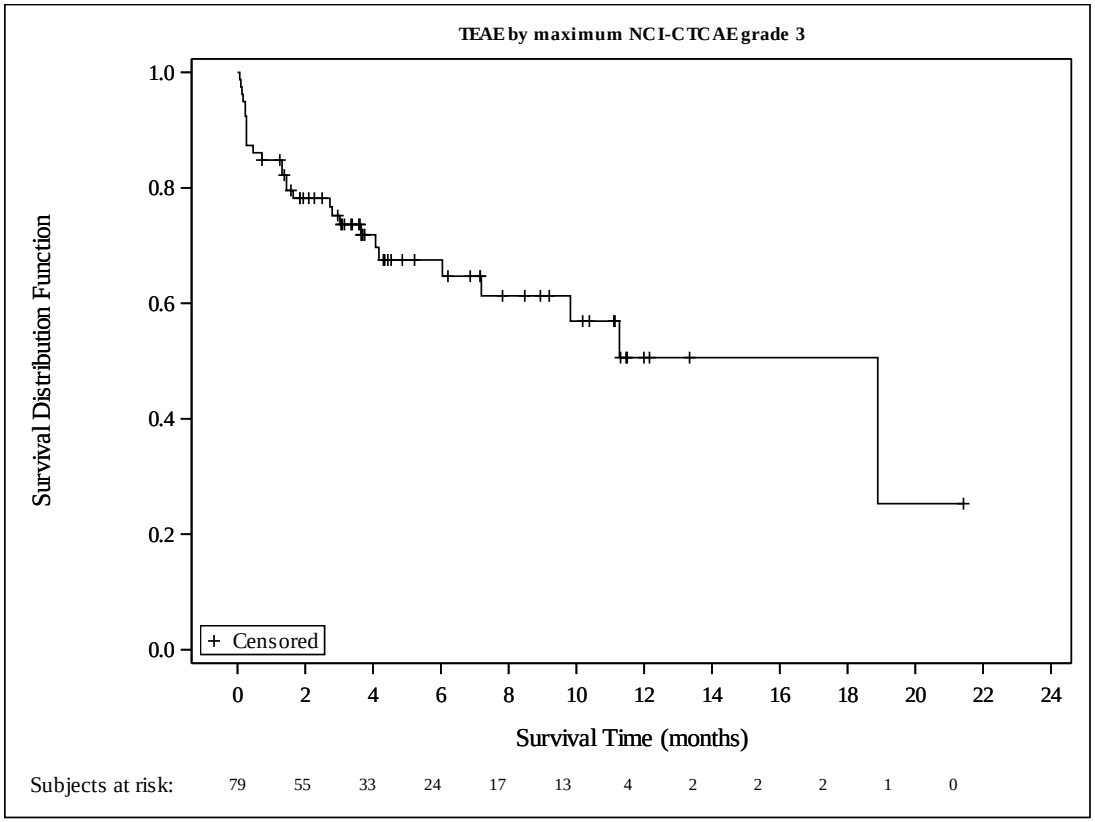
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	8/ 32 (25.0)	18.9 (9.8, 18.9)
mild	9/ 25 (36.0)	11.3 (3.0, NE)
moderate	5/ 8 (62.5)	6.0 (1.3, NE)
Hepatic impairment at baseline		
normal	24/ 64 (37.5)	11.3 (6.0, NE)
mild	3/ 14 (21.4)	NE (4.1, NE)
Race		
White	25/ 69 (36.2)	18.9 (6.0, NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	3/ 8 (37.5)	NE (0.2, NE)
Ethnicity		
Hispanic/Latino	2/ 5 (40.0)	9.8 (0.3, 9.8)
Non-Hispanic/Non-Latino	25/ 70 (35.7)	18.9 (6.0, NE)
Unknown	1/ 4 (25.0)	NE (4.2, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 3
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	5/ 79 (6.3)	NE (NE , NE)
Region		
North America	1/ 34 (2.9)	NE (NE , NE)
EU	4/ 45 (8.9)	NE (NE , NE)
Age (Category 1)		
<65 years	2/ 46 (4.3)	NE (NE , NE)
>=65 years	3/ 33 (9.1)	NE (NE , NE)
Age (Category 2)		
<75 years	4/ 75 (5.3)	NE (NE , NE)
>=75 years	1/ 4 (25.0)	NE (0.5, NE)
Sex		
female	2/ 22 (9.1)	NE (NE , NE)
male	3/ 57 (5.3)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	5/ 50 (10.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	4/ 68 (5.9)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
Primary tumor location		
Gastric	4/ 27 (14.8)	NE (NE , NE)
GEJ	1/ 52 (1.9)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	2/ 19 (10.5)	NE (NE , NE)
other	3/ 59 (5.1)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	5/ 74 (6.8)	NE (NE , NE)
Previous total gastrectomy		
no	5/ 79 (6.3)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	5/ 70 (7.1)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	5/ 73 (6.8)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	5/ 72 (6.9)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	3/ 50 (6.0)	NE (NE , NE)
no	2/ 29 (6.9)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

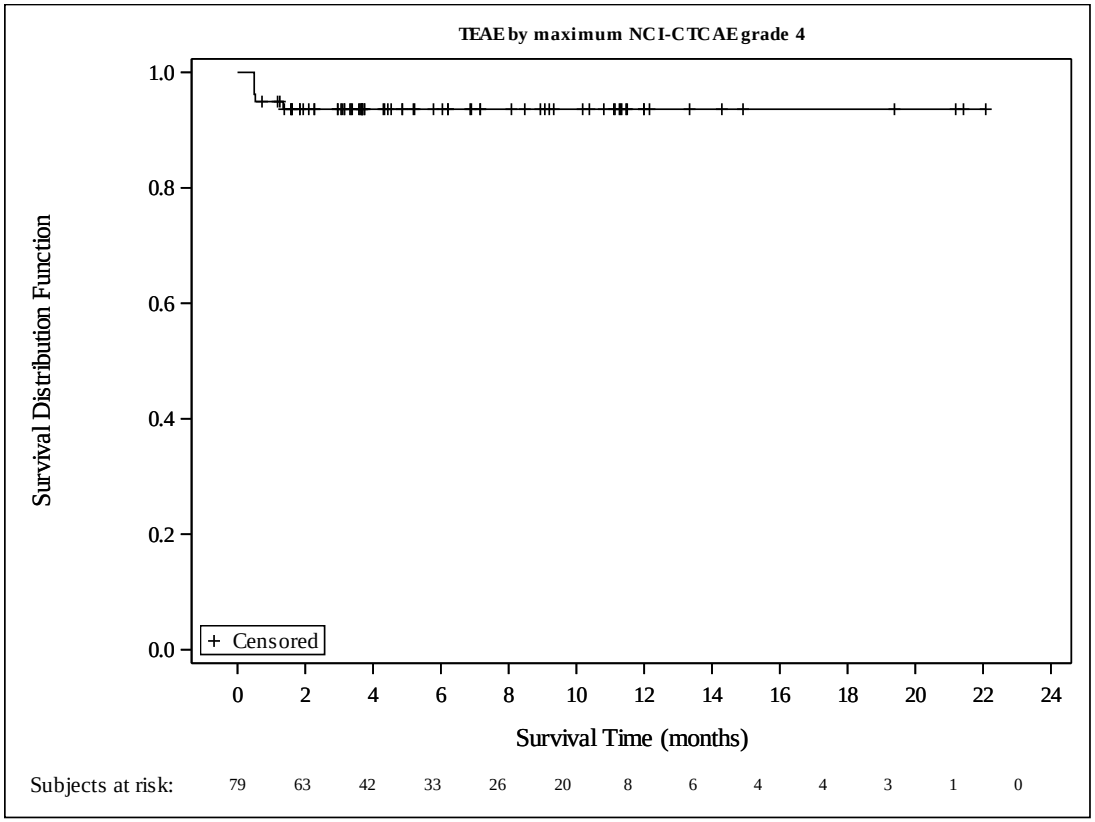
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	2/ 32 (6.3)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	1/ 8 (12.5)	NE (0.5, NE)
Hepatic impairment at baseline		
normal	3/ 64 (4.7)	NE (NE , NE)
mild	2/ 14 (14.3)	NE (NE , NE)
Race		
White	3/ 69 (4.3)	NE (NE , NE)
Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
Other	1/ 8 (12.5)	NE (0.5, NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	5/ 70 (7.1)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 4
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	11/ 79 (13.9)	NE (NE , NE)
Region		
North America	6/ 34 (17.6)	NE (10.4, NE)
EU	5/ 45 (11.1)	NE (NE , NE)
Age (Category 1)		
<65 years	9/ 46 (19.6)	NE (NE , NE)
>=65 years	2/ 33 (6.1)	NE (10.4, NE)
Age (Category 2)		
<75 years	11/ 75 (14.7)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	1/ 22 (4.5)	NE (NE , NE)
male	10/ 57 (17.5)	NE (NE , NE)
ECOG PS		
0	3/ 29 (10.3)	NE (10.4, NE)
1	8/ 50 (16.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	10/ 68 (14.7)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (3.5, NE)
Primary tumor location		
Gastric	2/ 27 (7.4)	NE (NE , NE)
GEJ	9/ 52 (17.3)	NE (10.4, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	3/ 19 (15.8)	NE (4.3, NE)
other	8/ 59 (13.6)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	11/ 74 (14.9)	NE (NE , NE)
Previous total gastrectomy		
no	11/ 79 (13.9)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	1/ 9 (11.1)	NE (0.9, NE)
no	10/ 70 (14.3)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (3.4, NE)
no	10/ 73 (13.7)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	2/ 7 (28.6)	NE (3.4, NE)
no	9/ 72 (12.5)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	7/ 50 (14.0)	NE (NE , NE)
no	4/ 29 (13.8)	NE (10.4, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

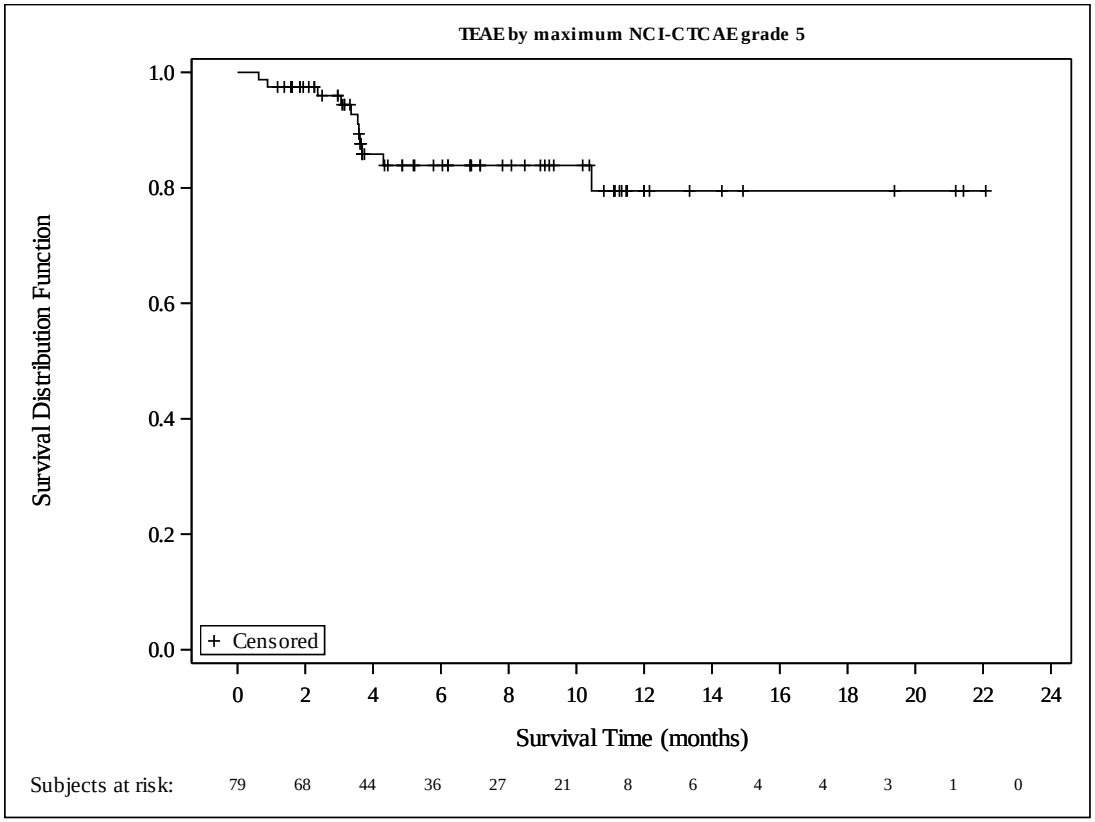
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	7/ 32 (21.9)	NE (3.7, NE)
mild	1/ 25 (4.0)	NE (NE , NE)
moderate	1/ 8 (12.5)	NE (4.3, NE)
Hepatic impairment at baseline		
normal	5/ 64 (7.8)	NE (NE , NE)
mild	6/ 14 (42.9)	NE (3.1, NE)
Race		
White	9/ 69 (13.0)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	1/ 8 (12.5)	NE (3.4, NE)
Ethnicity		
Hispanic/Latino	2/ 5 (40.0)	NE (3.6, NE)
Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
Unknown	1/ 4 (25.0)	NE (3.5, NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of TEAE with Worst NCI-CTCAE Grade 5
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	9/ 79 (11.4)	NE (NE , NE)
Region		
North America	4/ 34 (11.8)	NE (NE , NE)
EU	5/ 45 (11.1)	NE (11.3, NE)
Age (Category 1)		
<65 years	6/ 46 (13.0)	NE (11.3, NE)
>=65 years	3/ 33 (9.1)	NE (NE , NE)
Age (Category 2)		
<75 years	9/ 75 (12.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	9/ 57 (15.8)	NE (11.3, NE)
ECOG PS		
0	4/ 29 (13.8)	NE (6.9, NE)
1	5/ 50 (10.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	8/ 68 (11.8)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	9/ 52 (17.3)	NE (11.3, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	8/ 59 (13.6)	NE (11.3, NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	8/ 74 (10.8)	NE (NE , NE)
Previous total gastrectomy		
no	9/ 79 (11.4)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	9/ 70 (12.9)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	8/ 73 (11.0)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	1/ 7 (14.3)	NE (2.5, NE)
no	8/ 72 (11.1)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	7/ 50 (14.0)	NE (11.3, NE)
no	2/ 29 (6.9)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

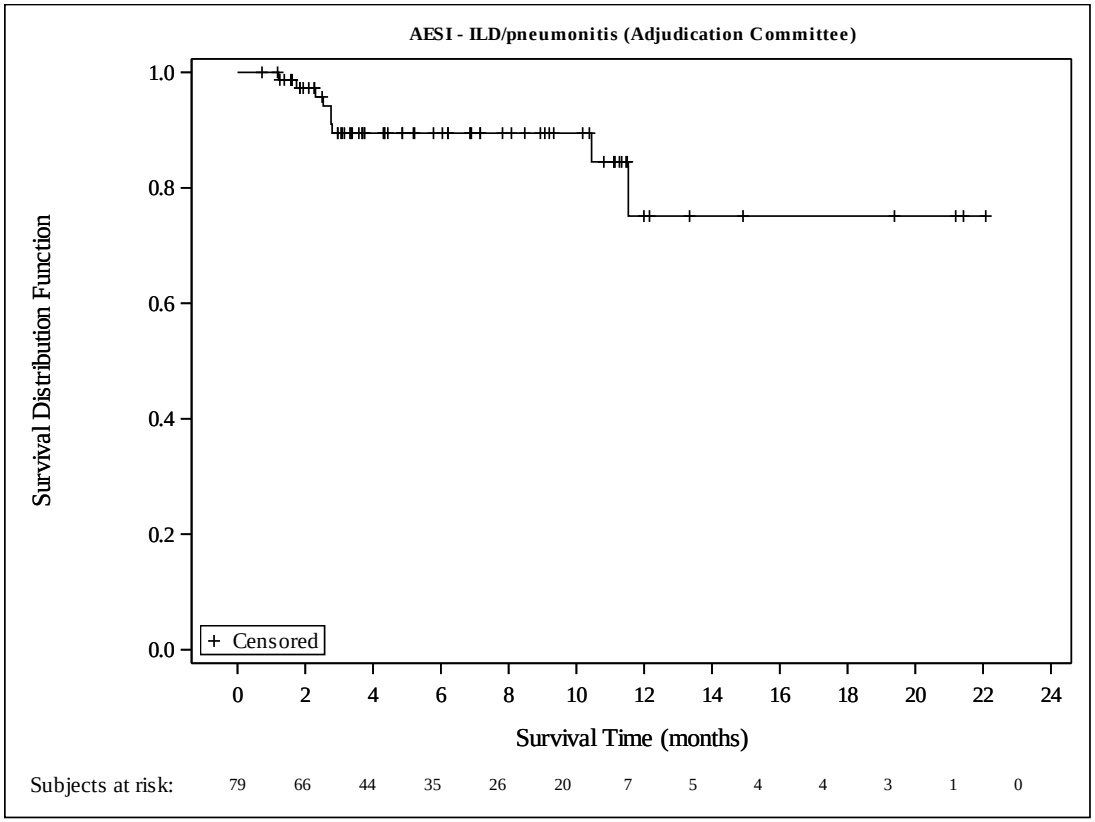
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	5/ 32 (15.6)	NE (NE , NE)
mild	3/ 25 (12.0)	NE (11.3, NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	7/ 64 (10.9)	NE (NE , NE)
mild	2/ 14 (14.3)	11.3 (11.3, NE)
Race		
White	9/ 69 (13.0)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	9/ 70 (12.9)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	3/ 79 (3.8)	NE (NE , NE)
Region		
North America	3/ 34 (8.8)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (NE , NE)
>=65 years	2/ 33 (6.1)	NE (NE , NE)
Age (Category 2)		
<75 years	3/ 75 (4.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	3/ 57 (5.3)	NE (NE , NE)
ECOG PS		
0	1/ 29 (3.4)	NE (6.9, NE)
1	2/ 50 (4.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	2/ 68 (2.9)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	3/ 52 (5.8)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	2/ 59 (3.4)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	3/ 74 (4.1)	NE (NE , NE)
Previous total gastrectomy		
no	3/ 79 (3.8)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	3/ 70 (4.3)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	3/ 73 (4.1)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	3/ 72 (4.2)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	2/ 50 (4.0)	NE (NE , NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

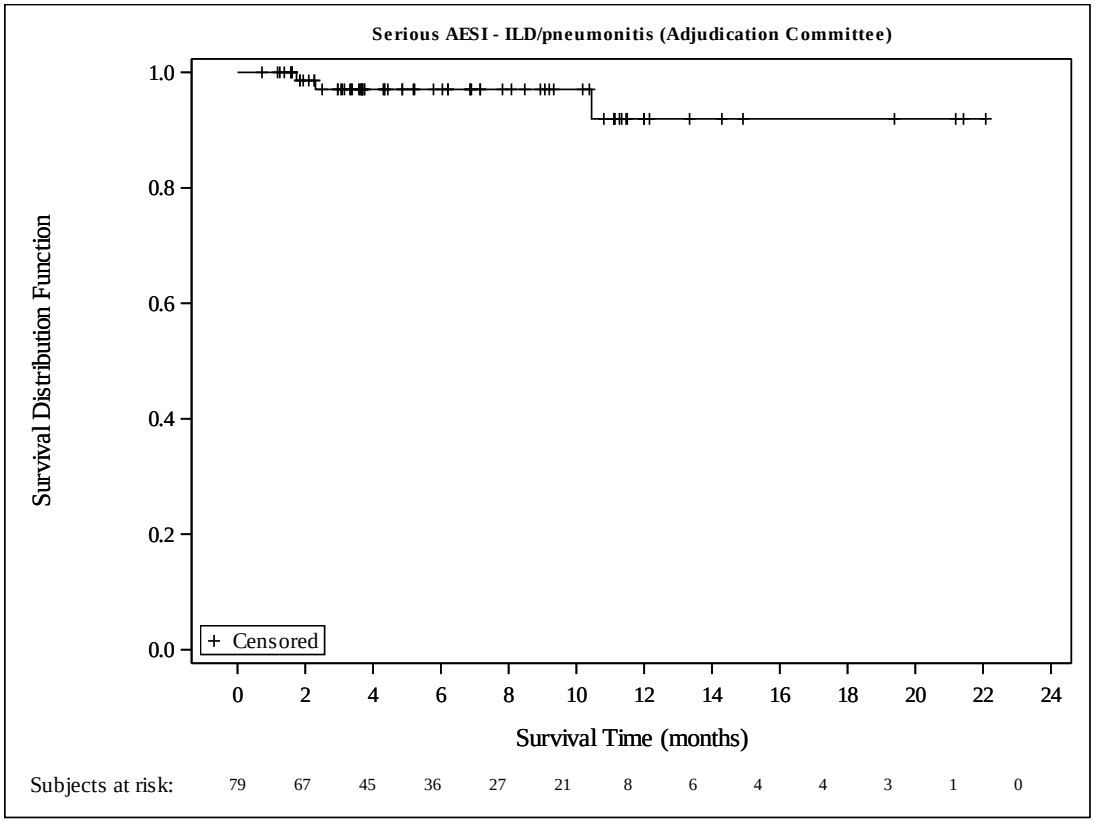
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	2/ 32 (6.3)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	2/ 64 (3.1)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	3/ 69 (4.3)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	2/ 79 (2.5)	NE (NE , NE)
Region		
North America	2/ 34 (5.9)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (NE , NE)
>=65 years	1/ 33 (3.0)	NE (NE , NE)
Age (Category 2)		
<75 years	2/ 75 (2.7)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	2/ 57 (3.5)	NE (NE , NE)
ECOG PS		
0	1/ 29 (3.4)	NE (6.9, NE)
1	1/ 50 (2.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	2/ 68 (2.9)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	2/ 52 (3.8)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	1/ 59 (1.7)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	2/ 74 (2.7)	NE (NE , NE)
Previous total gastrectomy		
no	2/ 79 (2.5)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	2/ 70 (2.9)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	2/ 73 (2.7)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	2/ 72 (2.8)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	1/ 50 (2.0)	NE (NE , NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

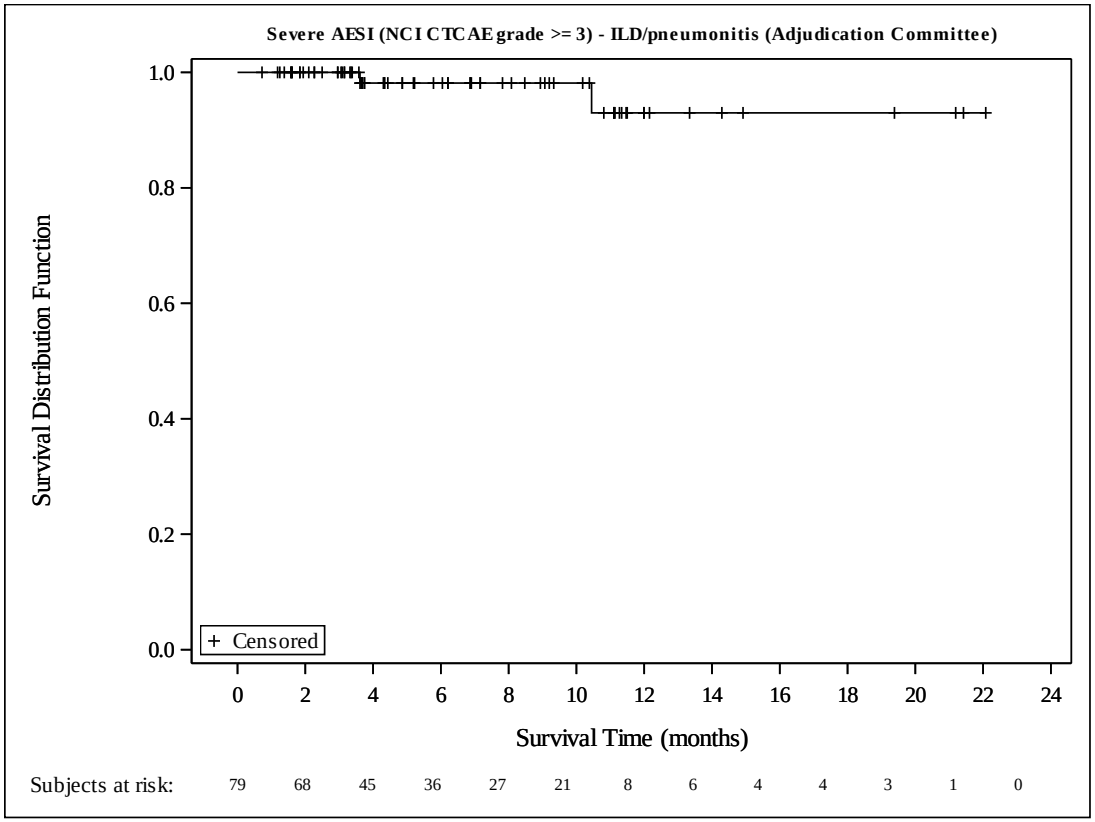
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	1/ 32 (3.1)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	1/ 64 (1.6)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	2/ 69 (2.9)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	2/ 70 (2.9)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	8/ 79 (10.1)	NE (NE , NE)
Region		
North America	3/ 34 (8.8)	NE (NE , NE)
EU	5/ 45 (11.1)	NE (11.3, NE)
Age (Category 1)		
<65 years	6/ 46 (13.0)	NE (11.3, NE)
>=65 years	2/ 33 (6.1)	NE (NE , NE)
Age (Category 2)		
<75 years	8/ 75 (10.7)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	8/ 57 (14.0)	NE (11.3, NE)
ECOG PS		
0	3/ 29 (10.3)	NE (NE , NE)
1	5/ 50 (10.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	7/ 68 (10.3)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	8/ 52 (15.4)	NE (11.3, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	7/ 59 (11.9)	NE (NE , NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	7/ 74 (9.5)	NE (NE , NE)
Previous total gastrectomy		
no	8/ 79 (10.1)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	8/ 70 (11.4)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	7/ 73 (9.6)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	1/ 7 (14.3)	NE (2.5, NE)
no	7/ 72 (9.7)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	7/ 50 (14.0)	NE (11.3, NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

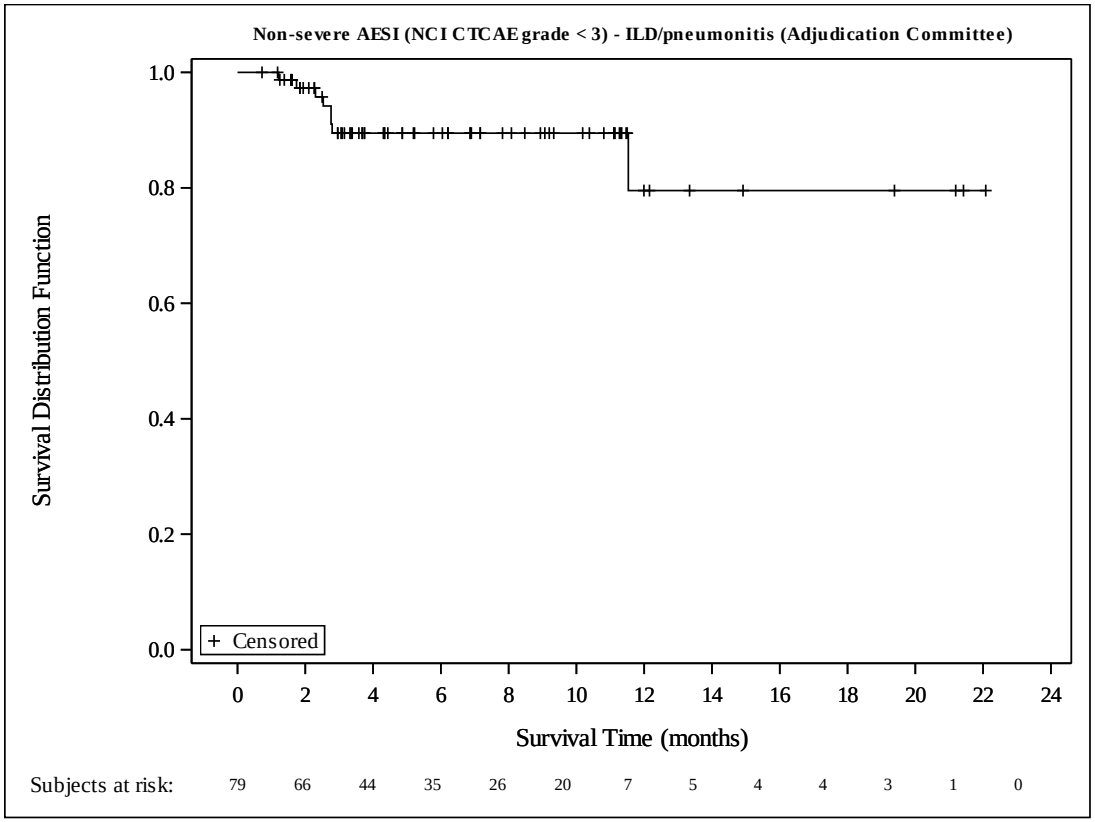
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	5/ 32 (15.6)	NE (NE , NE)
mild	3/ 25 (12.0)	NE (11.3, NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	6/ 64 (9.4)	NE (NE , NE)
mild	2/ 14 (14.3)	11.3 (11.3, NE)
Race		
White	8/ 69 (11.6)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	8/ 79 (10.1)	NE (NE , NE)
Region		
North America	4/ 34 (11.8)	NE (NE , NE)
EU	4/ 45 (8.9)	NE (11.3, NE)
Age (Category 1)		
<65 years	5/ 46 (10.9)	NE (11.3, NE)
>=65 years	3/ 33 (9.1)	NE (NE , NE)
Age (Category 2)		
<75 years	8/ 75 (10.7)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	8/ 57 (14.0)	NE (11.3, NE)
ECOG PS		
0	3/ 29 (10.3)	NE (NE , NE)
1	5/ 50 (10.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	7/ 68 (10.3)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	8/ 52 (15.4)	NE (11.3, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	7/ 59 (11.9)	NE (11.3, NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	7/ 74 (9.5)	NE (NE , NE)
Previous total gastrectomy		
no	8/ 79 (10.1)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	8/ 70 (11.4)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	7/ 73 (9.6)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	1/ 7 (14.3)	NE (2.5, NE)
no	7/ 72 (9.7)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	6/ 50 (12.0)	NE (NE , NE)
no	2/ 29 (6.9)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

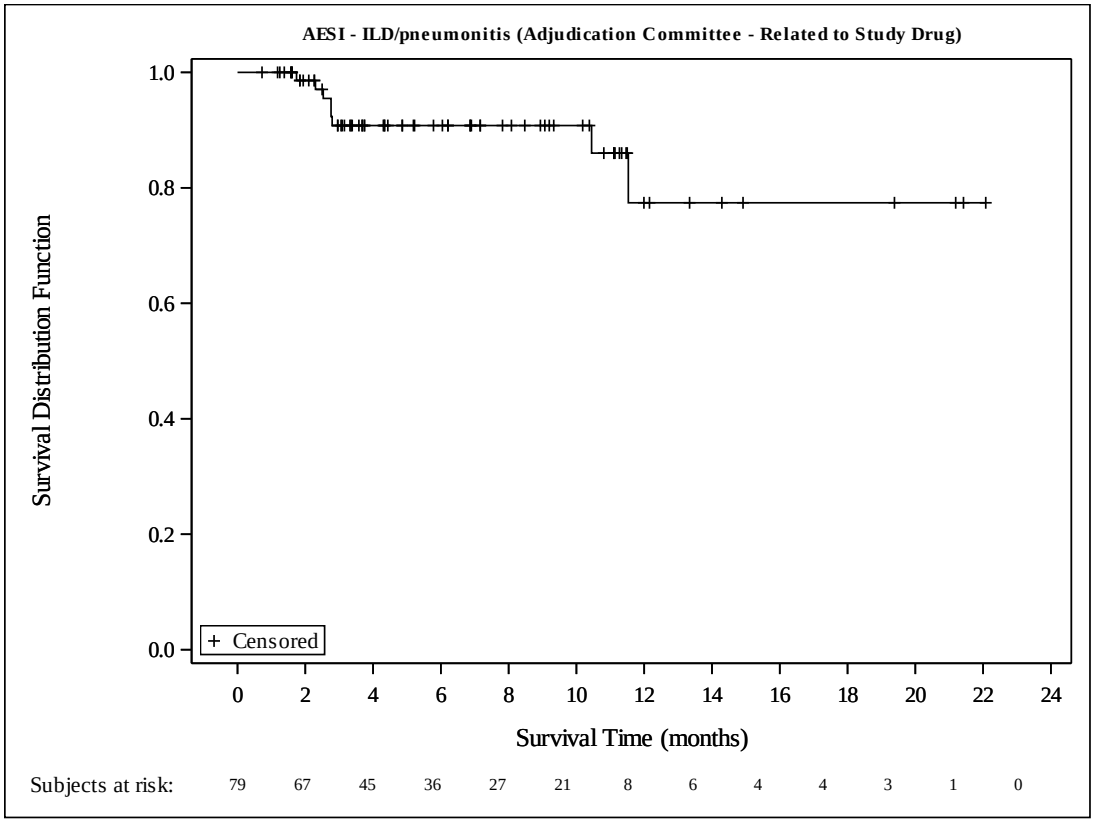
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	5/ 32 (15.6)	NE (NE , NE)
mild	2/ 25 (8.0)	NE (11.3, NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	6/ 64 (9.4)	NE (NE , NE)
mild	2/ 14 (14.3)	11.3 (11.3, NE)
Race		
White	8/ 69 (11.6)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	3/ 79 (3.8)	NE (NE , NE)
Region		
North America	3/ 34 (8.8)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (NE , NE)
>=65 years	2/ 33 (6.1)	NE (NE , NE)
Age (Category 2)		
<75 years	3/ 75 (4.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	3/ 57 (5.3)	NE (NE , NE)
ECOG PS		
0	1/ 29 (3.4)	NE (6.9, NE)
1	2/ 50 (4.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	2/ 68 (2.9)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	3/ 52 (5.8)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	2/ 59 (3.4)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	3/ 74 (4.1)	NE (NE , NE)
Previous total gastrectomy		
no	3/ 79 (3.8)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	3/ 70 (4.3)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	3/ 73 (4.1)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	3/ 72 (4.2)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	2/ 50 (4.0)	NE (NE , NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

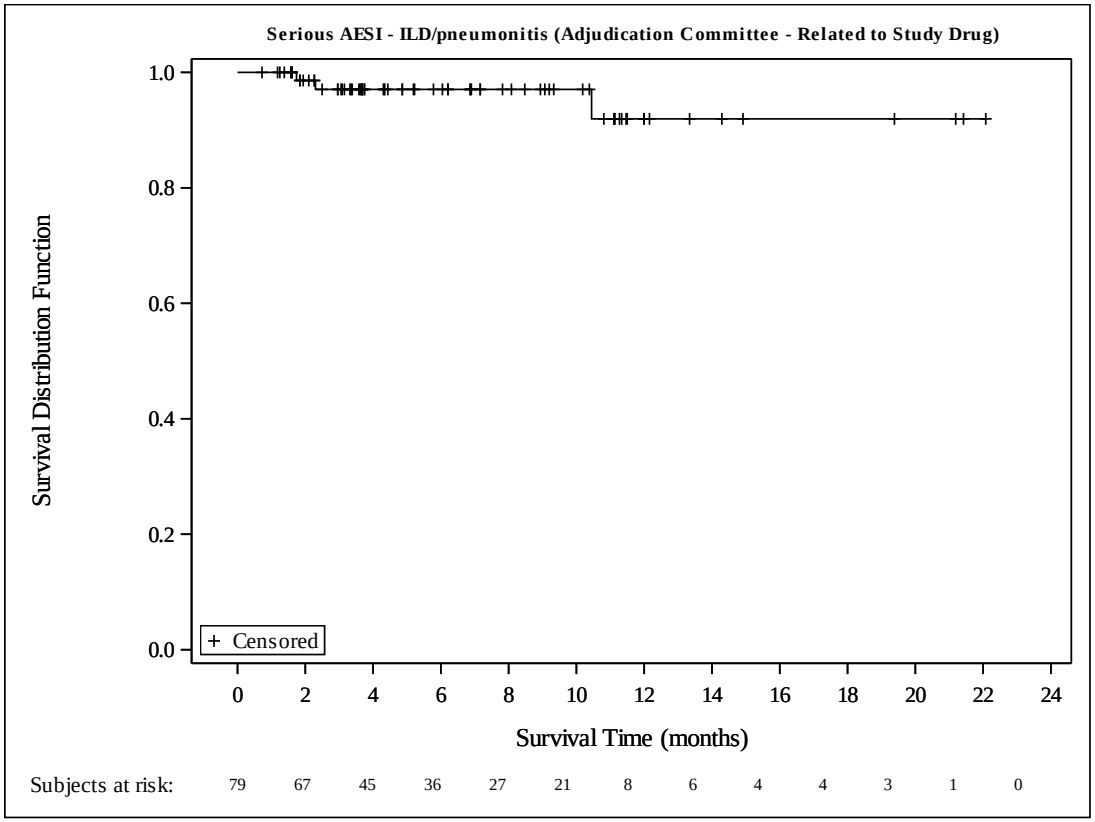
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	2/ 32 (6.3)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	2/ 64 (3.1)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	3/ 69 (4.3)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Serious AESI - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	2/ 79 (2.5)	NE (NE , NE)
Region		
North America	2/ 34 (5.9)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (NE , NE)
>=65 years	1/ 33 (3.0)	NE (NE , NE)
Age (Category 2)		
<75 years	2/ 75 (2.7)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	2/ 57 (3.5)	NE (NE , NE)
ECOG PS		
0	1/ 29 (3.4)	NE (6.9, NE)
1	1/ 50 (2.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	2/ 68 (2.9)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	2/ 52 (3.8)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	1/ 59 (1.7)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	2/ 74 (2.7)	NE (NE , NE)
Previous total gastrectomy		
no	2/ 79 (2.5)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	2/ 70 (2.9)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	2/ 73 (2.7)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	2/ 72 (2.8)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	1/ 50 (2.0)	NE (NE , NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

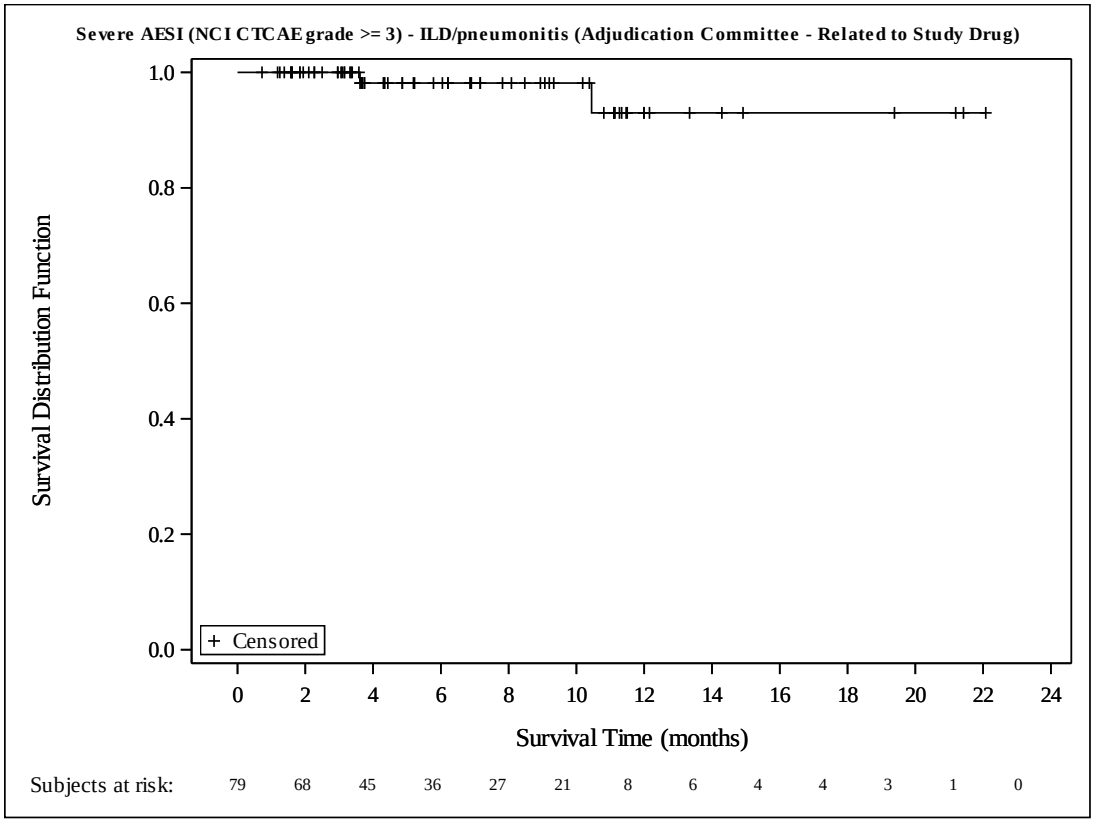
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	1/ 32 (3.1)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	1/ 64 (1.6)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (NE , NE)
Race		
White	2/ 69 (2.9)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	2/ 70 (2.9)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
Overall	7/ 79 (8.9)	NE (NE , NE)
Region		
North America	3/ 34 (8.8)	NE (NE , NE)
EU	4/ 45 (8.9)	NE (11.3, NE)
Age (Category 1)		
<65 years	5/ 46 (10.9)	NE (11.3, NE)
>=65 years	2/ 33 (6.1)	NE (NE , NE)
Age (Category 2)		
<75 years	7/ 75 (9.3)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	7/ 57 (12.3)	NE (NE , NE)
ECOG PS		
0	2/ 29 (6.9)	NE (NE , NE)
1	5/ 50 (10.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	6/ 68 (8.8)	NE (NE , NE)
IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	7/ 52 (13.5)	NE (11.3, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	1/ 19 (5.3)	NE (NE , NE)
other	6/ 59 (10.2)	NE (NE , NE)
Number of metastatic sites		
<2	1/ 5 (20.0)	NE (2.5, NE)
>=2	6/ 74 (8.1)	NE (NE , NE)
Previous total gastrectomy		
no	7/ 79 (8.9)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	7/ 70 (10.0)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	1/ 6 (16.7)	NE (2.5, NE)
no	6/ 73 (8.2)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	1/ 7 (14.3)	NE (2.5, NE)
no	6/ 72 (8.3)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	6/ 50 (12.0)	NE (NE , NE)
no	1/ 29 (3.4)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

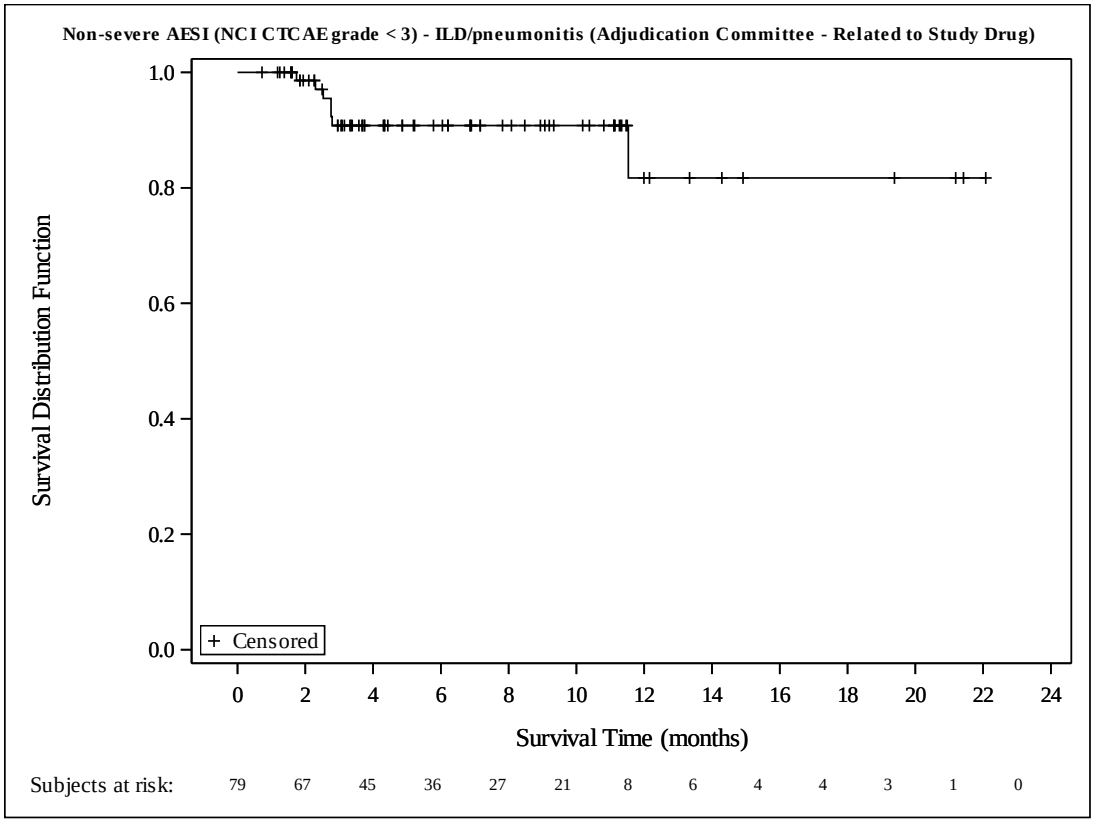
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	5/ 32 (15.6)	NE (NE , NE)
mild	2/ 25 (8.0)	NE (11.3, NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	5/ 64 (7.8)	NE (NE , NE)
mild	2/ 14 (14.3)	11.3 (11.3, NE)
Race		
White	7/ 69 (10.1)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - ILD/pneumonitis (Adjudication Committee - Related to Study Drug)
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	1/ 79 (1.3)	NE (NE , NE)
Region		
North America	0/ 34 (0.0)	NE (NE , NE)
EU	1/ 45 (2.2)	NE (11.3, NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (11.3, NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	1/ 75 (1.3)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	1/ 57 (1.8)	NE (11.3, NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	1/ 50 (2.0)	NE (11.3, NE)
HER2 Status in central laboratory		
IHC 3+	1/ 68 (1.5)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	1/ 52 (1.9)	NE (11.3, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	0/ 19 (0.0)	NE (NE , NE)
other	1/ 59 (1.7)	NE (11.3, NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	1/ 74 (1.4)	NE (NE , NE)
Previous total gastrectomy		
no	1/ 79 (1.3)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	1/ 70 (1.4)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	1/ 73 (1.4)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	1/ 72 (1.4)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	1/ 50 (2.0)	NE (11.3, NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

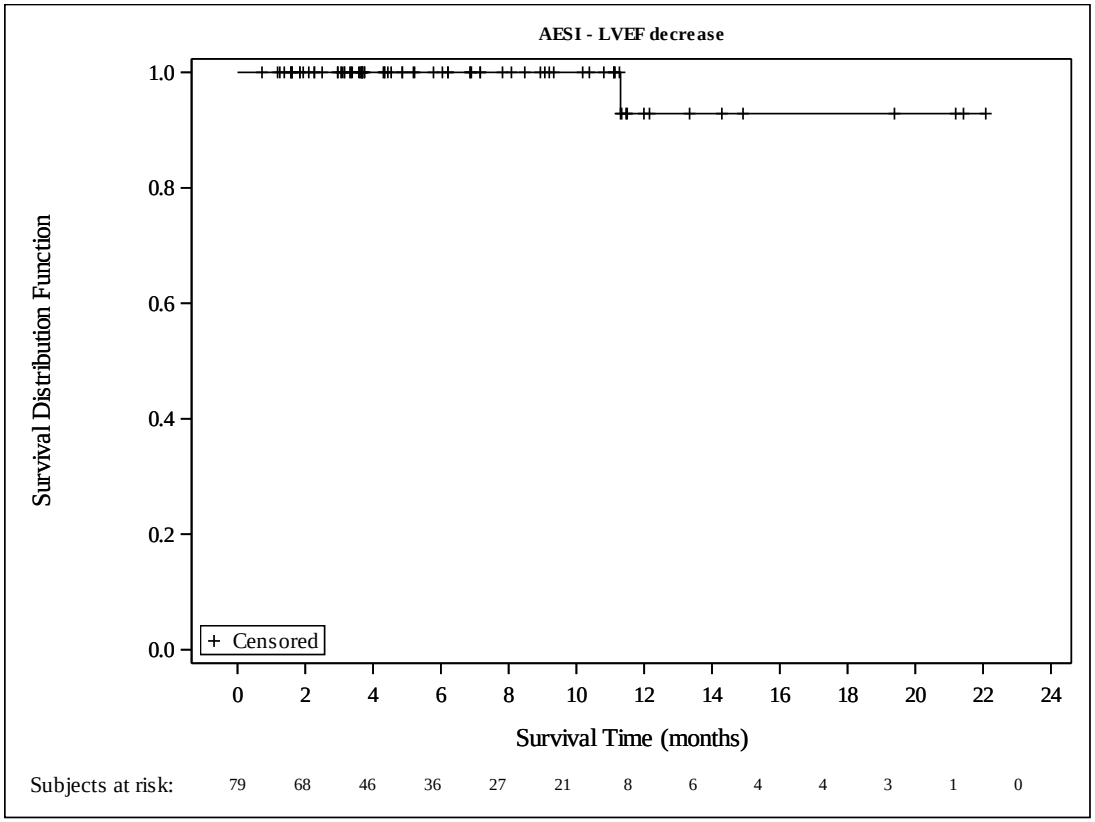
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	0/ 32 (0.0)	NE (NE , NE)
mild	1/ 25 (4.0)	NE (11.3, NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (11.3, NE)
Race		
White	1/ 69 (1.4)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	1/ 70 (1.4)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	0/ 79 (0.0)	NE (NE , NE)
Region		
North America	0/ 34 (0.0)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	0/ 46 (0.0)	NE (NE , NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	0/ 75 (0.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	0/ 57 (0.0)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	0/ 50 (0.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	0/ 68 (0.0)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	0/ 52 (0.0)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	0/ 19 (0.0)	NE (NE , NE)
other	0/ 59 (0.0)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	0/ 74 (0.0)	NE (NE , NE)
Previous total gastrectomy		
no	0/ 79 (0.0)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	0/ 70 (0.0)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	0/ 73 (0.0)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	0/ 72 (0.0)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	0/ 50 (0.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

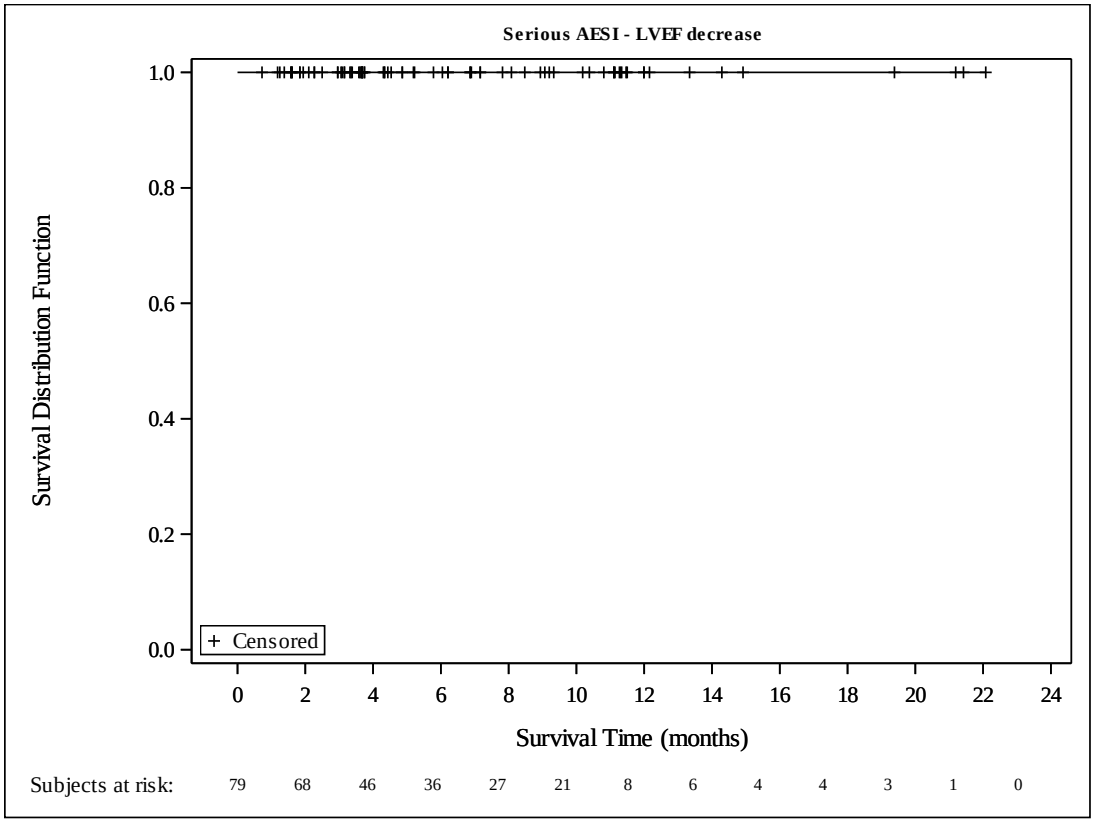
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Serious AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	0/ 32 (0.0)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	0/ 14 (0.0)	NE (NE , NE)
Race		
White	0/ 69 (0.0)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	0/ 70 (0.0)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Serious AESI - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	0/ 79 (0.0)	NE (NE , NE)
Region		
North America	0/ 34 (0.0)	NE (NE , NE)
EU	0/ 45 (0.0)	NE (NE , NE)
Age (Category 1)		
<65 years	0/ 46 (0.0)	NE (NE , NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	0/ 75 (0.0)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	0/ 57 (0.0)	NE (NE , NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	0/ 50 (0.0)	NE (NE , NE)
HER2 Status in central laboratory		
IHC 3+	0/ 68 (0.0)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	0/ 52 (0.0)	NE (NE , NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	0/ 19 (0.0)	NE (NE , NE)
other	0/ 59 (0.0)	NE (NE , NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	0/ 74 (0.0)	NE (NE , NE)
Previous total gastrectomy		
no	0/ 79 (0.0)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	0/ 70 (0.0)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	0/ 73 (0.0)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	0/ 72 (0.0)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	0/ 50 (0.0)	NE (NE , NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

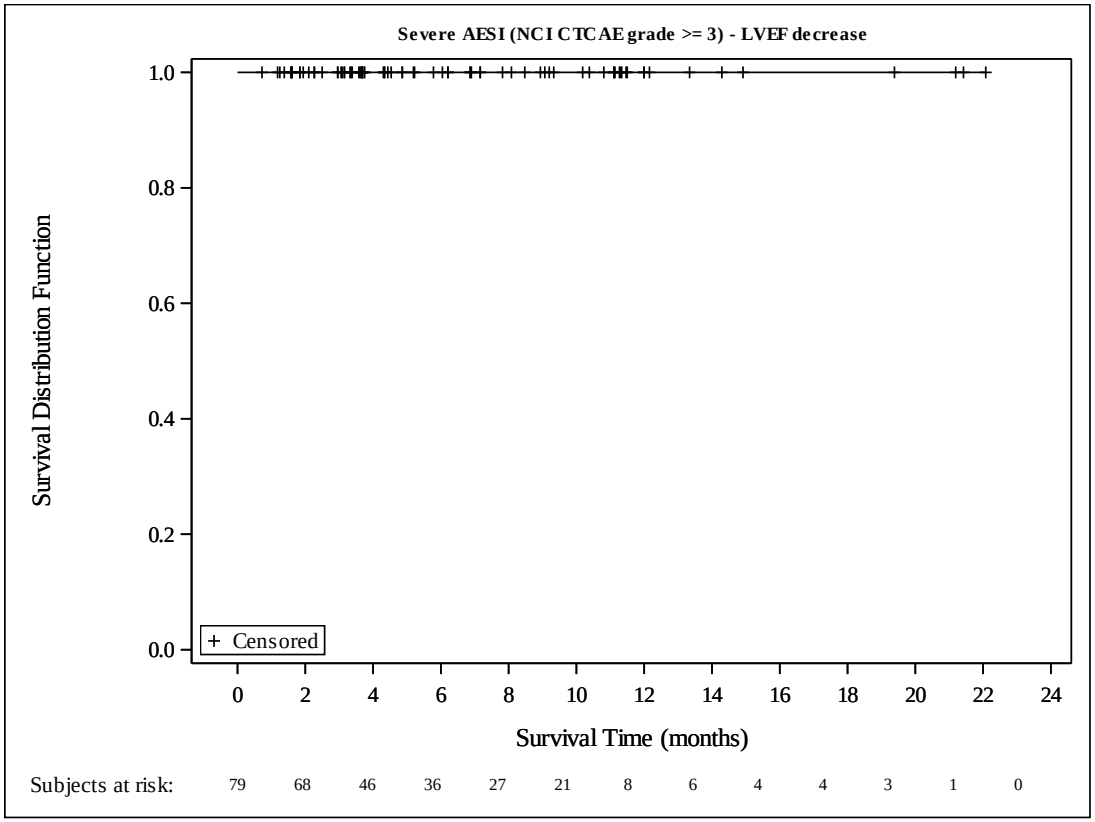
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	0/ 32 (0.0)	NE (NE , NE)
mild	0/ 25 (0.0)	NE (NE , NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	0/ 14 (0.0)	NE (NE , NE)
Race		
White	0/ 69 (0.0)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	0/ 70 (0.0)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Severe AESI (NCI CTCAE grade >= 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Overall	1/ 79 (1.3)	NE (NE , NE)
Region		
North America	0/ 34 (0.0)	NE (NE , NE)
EU	1/ 45 (2.2)	NE (11.3, NE)
Age (Category 1)		
<65 years	1/ 46 (2.2)	NE (11.3, NE)
>=65 years	0/ 33 (0.0)	NE (NE , NE)
Age (Category 2)		
<75 years	1/ 75 (1.3)	NE (NE , NE)
>=75 years	0/ 4 (0.0)	NE (NE , NE)
Sex		
female	0/ 22 (0.0)	NE (NE , NE)
male	1/ 57 (1.8)	NE (11.3, NE)
ECOG PS		
0	0/ 29 (0.0)	NE (NE , NE)
1	1/ 50 (2.0)	NE (11.3, NE)
HER2 Status in central laboratory		
IHC 3+	1/ 68 (1.5)	NE (NE , NE)
IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
Primary tumor location		
Gastric	0/ 27 (0.0)	NE (NE , NE)
GEJ	1/ 52 (1.9)	NE (11.3, NE)
Histological subtype		
diffuse	0/ 1 (0.0)	NE (NE , NE)
intestinal	0/ 19 (0.0)	NE (NE , NE)
other	1/ 59 (1.7)	NE (11.3, NE)
Number of metastatic sites		
<2	0/ 5 (0.0)	NE (NE , NE)
>=2	1/ 74 (1.4)	NE (NE , NE)
Previous total gastrectomy		
no	1/ 79 (1.3)	NE (NE , NE)
Prior adjuvant/ neoadjuvant therapy		
yes	0/ 9 (0.0)	NE (NE , NE)
no	1/ 70 (1.4)	NE (NE , NE)
Prior nivolumab or pembrolizumab treatment		
yes	0/ 6 (0.0)	NE (NE , NE)
no	1/ 73 (1.4)	NE (NE , NE)
Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
yes	0/ 7 (0.0)	NE (NE , NE)
no	1/ 72 (1.4)	NE (NE , NE)
Presence of liver metastasis at baseline		
yes	1/ 50 (2.0)	NE (11.3, NE)
no	0/ 29 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

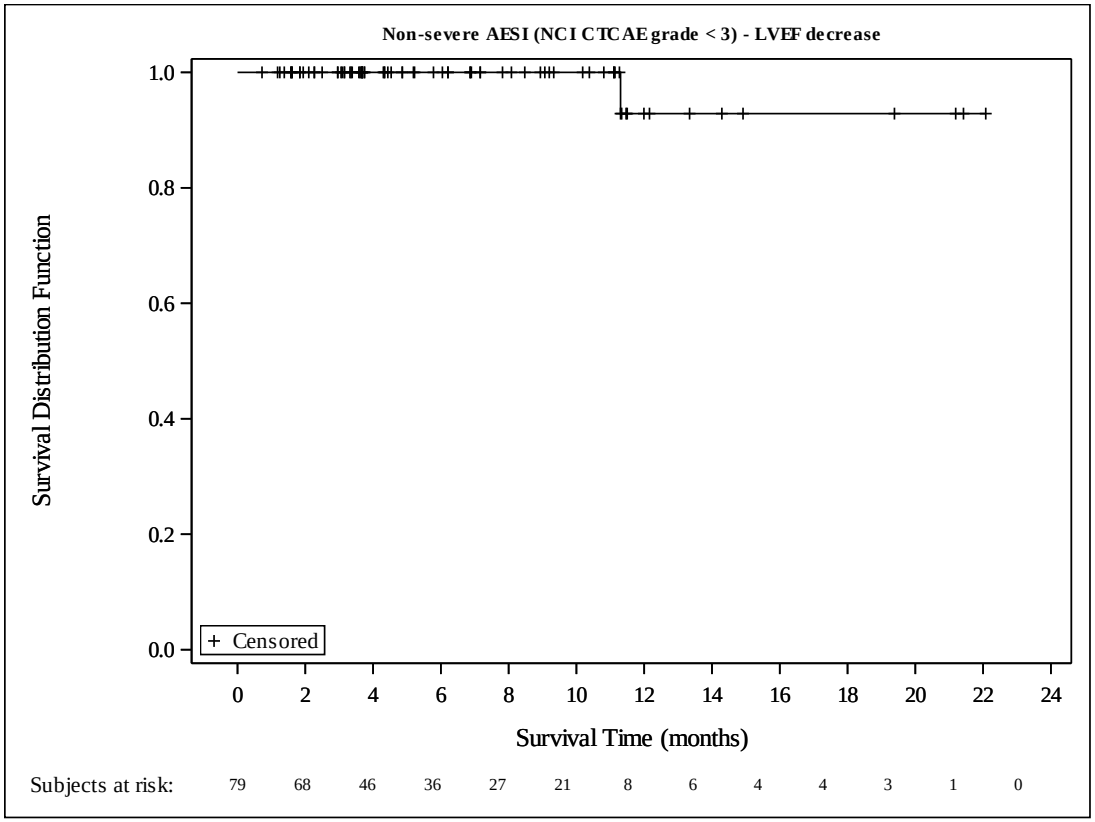
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set

Subgroup Level	T-DXd (N=79) n/ N (%)	 Median (95% CI) [a]
Renal impairment at baseline		
normal	0/ 32 (0.0)	NE (NE , NE)
mild	1/ 25 (4.0)	NE (11.3, NE)
moderate	0/ 8 (0.0)	NE (NE , NE)
Hepatic impairment at baseline		
normal	0/ 64 (0.0)	NE (NE , NE)
mild	1/ 14 (7.1)	NE (11.3, NE)
Race		
White	1/ 69 (1.4)	NE (NE , NE)
Black or African American	0/ 1 (0.0)	NE (NE , NE)
Other	0/ 8 (0.0)	NE (NE , NE)
Ethnicity		
Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
Non-Hispanic/Non-Latino	1/ 70 (1.4)	NE (NE , NE)
Unknown	0/ 4 (0.0)	NE (NE , NE)

NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Kaplan Meier Plot of Non-severe AESI (NCI CTCAE grade < 3) - LVEF decrease / left ventricular (LV) dysfunction
Safety Analysis Set



Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders	Overall	38/ 79 (48.1)	6.9 (5.1, 10.0)
	Region		
	North America	14/ 34 (41.2)	9.8 (6.9, NE)
	EU	24/ 45 (53.3)	5.1 (2.1, 8.9)
	Age (Category 1)		
	<65 years	22/ 46 (47.8)	6.9 (2.7, 9.8)
	>=65 years	16/ 33 (48.5)	7.2 (0.8, NE)
	Age (Category 2)		
	<75 years	35/ 75 (46.7)	8.1 (5.1, 10.0)
	>=75 years	3/ 4 (75.0)	6.2 (0.3, NE)
	Sex		
	female	17/ 22 (77.3)	1.4 (0.3, 7.2)
	male	21/ 57 (36.8)	9.8 (5.1, NE)
	ECOG PS		
	0	12/ 29 (41.4)	6.9 (6.0, 10.0)
	1	26/ 50 (52.0)	5.1 (1.4, NE)
	HER2 Status in central laboratory		
	IHC 3+	34/ 68 (50.0)	6.9 (5.1, 9.8)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	20/ 27 (74.1)	2.2 (0.3, 7.2)
	GEJ	18/ 52 (34.6)	9.8 (6.9, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	6.9 (NE , NE)
	intestinal	13/ 19 (68.4)	5.1 (0.5, 8.9)
	other	24/ 59 (40.7)	10.0 (3.7, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.5, NE)
	>=2	37/ 74 (50.0)	6.9 (3.7, 9.8)
	Previous total gastrectomy		
	no	38/ 79 (48.1)	6.9 (5.1, 10.0)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	3.7 (0.0, NE)
	no	33/ 70 (47.1)	6.9 (5.1, 9.8)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (0.1, NE)
	no	36/ 73 (49.3)	6.9 (5.1, 9.8)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.1, NE)
	no	36/ 72 (50.0)	6.9 (3.7, 9.8)
	Presence of liver metastasis at baseline		
	yes	24/ 50 (48.0)	6.9 (5.1, 9.8)
	no	14/ 29 (48.3)	8.1 (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders	Renal impairment at baseline		
	normal	11/ 32 (34.4)	9.8 (5.1, NE)
	mild	12/ 25 (48.0)	6.9 (1.4, NE)
	moderate	5/ 8 (62.5)	5.4 (0.4, NE)
	Hepatic impairment at baseline		
	normal	29/ 64 (45.3)	8.1 (5.1, NE)
	mild	8/ 14 (57.1)	5.1 (0.4, 6.9)
	Race		
	White	31/ 69 (44.9)	8.1 (5.1, NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	6/ 8 (75.0)	3.6 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	7.5 (5.1, 9.8)
	Non-Hispanic/Non-Latino	35/ 70 (50.0)	6.9 (2.7, 10.0)
	Unknown	1/ 4 (25.0)	NE (2.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Overall	30/ 79 (38.0)	8.9 (6.9, NE)
	Region		
	North America	10/ 34 (29.4)	NE (6.9, NE)
	EU	20/ 45 (44.4)	7.2 (5.1, NE)
	Age (Category 1)		
	<65 years	16/ 46 (34.8)	8.9 (6.0, NE)
	>=65 years	14/ 33 (42.4)	7.2 (3.7, NE)
	Age (Category 2)		
	<75 years	27/ 75 (36.0)	9.8 (6.9, NE)
	>=75 years	3/ 4 (75.0)	6.2 (0.3, NE)
	Sex		
	female	15/ 22 (68.2)	3.2 (0.3, 8.1)
	male	15/ 57 (26.3)	NE (6.9, NE)
	ECOG PS		
	0	9/ 29 (31.0)	9.8 (6.0, NE)
	1	21/ 50 (42.0)	8.1 (5.1, NE)
	HER2 Status in central laboratory		
	IHC 3+	26/ 68 (38.2)	8.9 (6.9, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	16/ 27 (59.3)	5.1 (0.5, 8.9)
	GEJ	14/ 52 (26.9)	NE (6.9, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	6.9 (NE , NE)
	intestinal	11/ 19 (57.9)	7.2 (0.7, 9.8)
	other	18/ 59 (30.5)	NE (6.0, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	30/ 74 (40.5)	8.1 (6.0, NE)
	Previous total gastrectomy		
	no	30/ 79 (38.0)	8.9 (6.9, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	NE (0.0, NE)
	no	26/ 70 (37.1)	8.1 (6.0, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.1, NE)
	no	29/ 73 (39.7)	8.9 (6.0, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.1, NE)
	no	29/ 72 (40.3)	8.1 (6.0, NE)
	Presence of liver metastasis at baseline		
	yes	20/ 50 (40.0)	7.2 (5.1, NE)
	no	10/ 29 (34.5)	NE (3.7, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Renal impairment at baseline		
	normal	9/ 32 (28.1)	9.8 (6.0, NE)
	mild	11/ 25 (44.0)	8.9 (1.4, NE)
	moderate	4/ 8 (50.0)	7.2 (0.7, NE)
	Hepatic impairment at baseline		
	normal	22/ 64 (34.4)	9.8 (7.2, NE)
	mild	7/ 14 (50.0)	6.0 (0.5, NE)
	Race		
	White	25/ 69 (36.2)	9.8 (6.9, NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	4/ 8 (50.0)	5.1 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	7.5 (5.1, 9.8)
	Non-Hispanic/Non-Latino	27/ 70 (38.6)	8.9 (6.9, NE)
	Unknown	1/ 4 (25.0)	NE (2.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	3/ 34 (8.8)	NE (NE , NE)
	EU	5/ 45 (11.1)	NE (NE , NE)
	Age (Category 1)		
	<65 years	6/ 46 (13.0)	NE (NE , NE)
	>=65 years	2/ 33 (6.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	5/ 22 (22.7)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	6/ 50 (12.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	8/ 68 (11.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.5, NE)
	>=2	7/ 74 (9.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.5, NE)
	no	6/ 70 (8.6)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (0.5, NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.5, NE)
	no	6/ 72 (8.3)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (NE , NE)
	no	4/ 29 (13.8)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Overall	73/ 79 (92.4)	0.2 (0.1, 0.2)
	Region		
	North America	32/ 34 (94.1)	0.2 (0.1, 0.3)
	EU	41/ 45 (91.1)	0.1 (0.1, 0.2)
	Age (Category 1)		
	<65 years	43/ 46 (93.5)	0.1 (0.1, 0.3)
	>=65 years	30/ 33 (90.9)	0.2 (0.1, 0.2)
	Age (Category 2)		
	<75 years	69/ 75 (92.0)	0.1 (0.1, 0.2)
	>=75 years	4/ 4 (100.0)	0.8 (0.1, 1.9)
	Sex		
	female	20/ 22 (90.9)	0.1 (0.1, 1.9)
	male	53/ 57 (93.0)	0.2 (0.1, 0.2)
	ECOG PS		
	0	24/ 29 (82.8)	0.2 (0.1, 0.7)
	1	49/ 50 (98.0)	0.1 (0.1, 0.2)
	HER2 Status in central laboratory		
	IHC 3+	62/ 68 (91.2)	0.1 (0.1, 0.3)
	IHC 2+/ISH +	10/ 10 (100.0)	0.2 (0.0, 0.2)
	Primary tumor location		
	Gastric	26/ 27 (96.3)	0.1 (0.1, 0.2)
	GEJ	47/ 52 (90.4)	0.2 (0.1, 0.3)
	Histological subtype		
	diffuse	1/ 1 (100.0)	0.5 (NE , NE)
	intestinal	18/ 19 (94.7)	0.2 (0.1, 0.7)
	other	54/ 59 (91.5)	0.1 (0.1, 0.2)
	Number of metastatic sites		
	<2	5/ 5 (100.0)	0.2 (0.1, 2.8)
	>=2	68/ 74 (91.9)	0.1 (0.1, 0.2)
	Previous total gastrectomy		
	no	73/ 79 (92.4)	0.2 (0.1, 0.2)
	Prior adjuvant/ neoadjuvant therapy		
	yes	9/ 9 (100.0)	0.2 (0.1, 1.4)
	no	64/ 70 (91.4)	0.1 (0.1, 0.2)
	Prior nivolumab or pembrolizumab treatment		
	yes	6/ 6 (100.0)	0.1 (0.0, 2.8)
	no	67/ 73 (91.8)	0.2 (0.1, 0.2)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	7/ 7 (100.0)	0.1 (0.0, 0.3)
	no	66/ 72 (91.7)	0.2 (0.1, 0.2)
	Presence of liver metastasis at baseline		
	yes	47/ 50 (94.0)	0.2 (0.1, 0.3)
	no	26/ 29 (89.7)	0.1 (0.1, 0.5)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Renal impairment at baseline		
	normal	30/ 32 (93.8)	0.1 (0.1, 0.4)
	mild	22/ 25 (88.0)	0.2 (0.1, 0.2)
	moderate	8/ 8 (100.0)	0.2 (0.1, 2.8)
	Hepatic impairment at baseline		
	normal	58/ 64 (90.6)	0.2 (0.1, 0.3)
	mild	14/ 14 (100.0)	0.1 (0.0, 0.2)
	Race		
	White	64/ 69 (92.8)	0.2 (0.1, 0.2)
	Black or African American	1/ 1 (100.0)	0.1 (NE , NE)
	Other	7/ 8 (87.5)	0.2 (0.0, 2.8)
	Ethnicity		
	Hispanic/Latino	5/ 5 (100.0)	0.2 (0.1, 2.8)
	Non-Hispanic/Non-Latino	66/ 70 (94.3)	0.1 (0.1, 0.2)
	Unknown	2/ 4 (50.0)	NE (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Abdominal pain	Overall	13/ 79 (16.5)	NE (NE , NE)
	Region		
	North America	6/ 34 (17.6)	NE (NE , NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	8/ 46 (17.4)	NE (NE , NE)
	>=65 years	5/ 33 (15.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	13/ 75 (17.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	5/ 22 (22.7)	NE (4.8, NE)
	male	8/ 57 (14.0)	NE (NE , NE)
	ECOG PS		
	0	5/ 29 (17.2)	NE (NE , NE)
	1	8/ 50 (16.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	11/ 68 (16.2)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.7, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	10/ 52 (19.2)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	4/ 19 (21.1)	NE (4.8, NE)
	other	9/ 59 (15.3)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	13/ 74 (17.6)	NE (NE , NE)
	Previous total gastrectomy		
	no	13/ 79 (16.5)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (2.8, NE)
	no	12/ 70 (17.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.8, NE)
	no	12/ 73 (16.4)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.8, NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	7/ 50 (14.0)	NE (NE , NE)
	no	6/ 29 (20.7)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Abdominal pain	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (2.8, NE)
	Hepatic impairment at baseline		
	normal	12/ 64 (18.8)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	11/ 69 (15.9)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (0.7, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.2, NE)
	Non-Hispanic/Non-Latino	12/ 70 (17.1)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Constipation	Overall	23/ 79 (29.1)	15.9 (9.4, 15.9)
	Region		
	North America	15/ 34 (44.1)	6.0 (1.4, 15.9)
	EU	8/ 45 (17.8)	NE (NE , NE)
	Age (Category 1)		
	<65 years	12/ 46 (26.1)	NE (9.4, NE)
	>=65 years	11/ 33 (33.3)	15.9 (3.5, 15.9)
	Age (Category 2)		
	<75 years	22/ 75 (29.3)	15.9 (9.4, 15.9)
	>=75 years	1/ 4 (25.0)	NE (1.7, NE)
	Sex		
	female	6/ 22 (27.3)	NE (6.0, NE)
	male	17/ 57 (29.8)	15.9 (9.4, 15.9)
	ECOG PS		
	0	9/ 29 (31.0)	NE (9.4, NE)
	1	14/ 50 (28.0)	15.9 (6.0, 15.9)
	HER2 Status in central laboratory		
	IHC 3+	19/ 68 (27.9)	15.9 (9.4, 15.9)
	IHC 2+/ISH +	4/ 10 (40.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	8/ 27 (29.6)	NE (2.8, NE)
	GEJ	15/ 52 (28.8)	15.9 (9.4, 15.9)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	4/ 19 (21.1)	NE (9.4, NE)
	other	19/ 59 (32.2)	15.9 (6.0, 15.9)
	Number of metastatic sites		
	<2	3/ 5 (60.0)	2.8 (0.2, NE)
	>=2	20/ 74 (27.0)	15.9 (9.4, 15.9)
	Previous total gastrectomy		
	no	23/ 79 (29.1)	15.9 (9.4, 15.9)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	9.4 (0.2, 9.4)
	no	18/ 70 (25.7)	15.9 (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	4/ 6 (66.7)	0.3 (0.1, NE)
	no	19/ 73 (26.0)	15.9 (9.4, 15.9)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	5/ 7 (71.4)	0.3 (0.1, NE)
	no	18/ 72 (25.0)	15.9 (9.4, 15.9)
	Presence of liver metastasis at baseline		
	yes	15/ 50 (30.0)	15.9 (9.4, 15.9)
	no	8/ 29 (27.6)	NE (6.0, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Constipation	Renal impairment at baseline		
	normal	11/ 32 (34.4)	NE (1.6, NE)
	mild	8/ 25 (32.0)	NE (2.3, NE)
	moderate	1/ 8 (12.5)	15.9 (NE , NE)
	Hepatic impairment at baseline		
	normal	17/ 64 (26.6)	15.9 (9.4, 15.9)
	mild	5/ 14 (35.7)	NE (0.6, NE)
	Race		
	White	22/ 69 (31.9)	15.9 (9.4, 15.9)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (6.0, NE)
	Ethnicity		
	Hispanic/Latino	3/ 5 (60.0)	1.7 (0.1, NE)
	Non-Hispanic/Non-Latino	19/ 70 (27.1)	15.9 (9.4, 15.9)
	Unknown	1/ 4 (25.0)	6.0 (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Diarrhoea	Overall	29/ 79 (36.7)	11.9 (6.6, NE)
	Region		
	North America	9/ 34 (26.5)	11.9 (6.6, NE)
	EU	20/ 45 (44.4)	NE (0.8, NE)
	Age (Category 1)		
	<65 years	17/ 46 (37.0)	NE (5.2, NE)
	>=65 years	12/ 33 (36.4)	11.9 (1.9, NE)
	Age (Category 2)		
	<75 years	25/ 75 (33.3)	NE (8.4, NE)
	>=75 years	4/ 4 (100.0)	1.3 (0.3, 1.9)
	Sex		
	female	11/ 22 (50.0)	9.2 (0.2, NE)
	male	18/ 57 (31.6)	NE (5.2, NE)
	ECOG PS		
	0	10/ 29 (34.5)	8.4 (6.6, NE)
	1	19/ 50 (38.0)	11.9 (1.9, NE)
	HER2 Status in central laboratory		
	IHC 3+	28/ 68 (41.2)	11.9 (5.2, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (0.1, NE)
	Primary tumor location		
	Gastric	12/ 27 (44.4)	11.9 (0.3, NE)
	GEJ	17/ 52 (32.7)	NE (6.6, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	6.6 (NE , NE)
	intestinal	9/ 19 (47.4)	NE (0.3, NE)
	other	19/ 59 (32.2)	NE (8.4, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	29/ 74 (39.2)	11.9 (5.2, NE)
	Previous total gastrectomy		
	no	29/ 79 (36.7)	11.9 (6.6, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	3/ 9 (33.3)	NE (0.1, NE)
	no	26/ 70 (37.1)	11.9 (5.2, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	11.9 (NE , NE)
	no	28/ 73 (38.4)	NE (5.2, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	11.9 (NE , NE)
	no	28/ 72 (38.9)	NE (5.2, NE)
	Presence of liver metastasis at baseline		
	yes	19/ 50 (38.0)	NE (5.2, NE)
	no	10/ 29 (34.5)	11.9 (8.4, NE)

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NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Diarrhoea	Renal impairment at baseline		
	normal	9/ 32 (28.1)	NE (5.2, NE)
	mild	10/ 25 (40.0)	11.9 (1.4, NE)
	moderate	2/ 8 (25.0)	NE (0.1, NE)
	Hepatic impairment at baseline		
	normal	24/ 64 (37.5)	11.9 (5.2, NE)
	mild	5/ 14 (35.7)	6.6 (0.3, NE)
	Race		
	White	26/ 69 (37.7)	11.9 (6.6, NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.1, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.6, NE)
	Non-Hispanic/Non-Latino	26/ 70 (37.1)	11.9 (6.6, NE)
	Unknown	1/ 4 (25.0)	NE (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	7/ 57 (12.3)	NE (NE , NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	5/ 50 (10.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	8/ 68 (11.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (NE , NE)
	GEJ	7/ 52 (13.5)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.8, NE)
	>=2	7/ 74 (9.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.8, NE)
	no	7/ 73 (9.6)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.8, NE)
	no	7/ 72 (9.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	5/ 50 (10.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Gastrooesophageal reflux disease	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (2.9, NE)
	Hepatic impairment at baseline		
	normal	6/ 64 (9.4)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (4.3, NE)
	Race		
	White	8/ 69 (11.6)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
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Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Overall	53/ 79 (67.1)	0.4 (0.2, 1.4)
	Region		
	North America	22/ 34 (64.7)	0.3 (0.1, 5.7)
	EU	31/ 45 (68.9)	0.5 (0.1, 3.5)
	Age (Category 1)		
	<65 years	37/ 46 (80.4)	0.2 (0.1, 0.5)
	>=65 years	16/ 33 (48.5)	7.2 (0.2, NE)
	Age (Category 2)		
	<75 years	52/ 75 (69.3)	0.3 (0.2, 0.8)
	>=75 years	1/ 4 (25.0)	NE (7.2, NE)
	Sex		
	female	14/ 22 (63.6)	2.0 (0.1, 7.2)
	male	39/ 57 (68.4)	0.3 (0.2, 0.9)
	ECOG PS		
	0	19/ 29 (65.5)	0.9 (0.1, 5.7)
	1	34/ 50 (68.0)	0.3 (0.1, 0.8)
	HER2 Status in central laboratory		
	IHC 3+	45/ 68 (66.2)	0.5 (0.1, 3.5)
	IHC 2+/ISH +	7/ 10 (70.0)	0.2 (0.0, NE)
	Primary tumor location		
	Gastric	19/ 27 (70.4)	0.2 (0.1, 7.2)
	GEJ	34/ 52 (65.4)	0.7 (0.2, 4.5)
	Histological subtype		
	diffuse	1/ 1 (100.0)	5.7 (NE , NE)
	intestinal	13/ 19 (68.4)	0.3 (0.1, 7.2)
	other	39/ 59 (66.1)	0.4 (0.2, 1.4)
	Number of metastatic sites		
	<2	4/ 5 (80.0)	0.2 (0.1, NE)
	>=2	49/ 74 (66.2)	0.4 (0.2, 1.6)
	Previous total gastrectomy		
	no	53/ 79 (67.1)	0.4 (0.2, 1.4)
	Prior adjuvant/ neoadjuvant therapy		
	yes	7/ 9 (77.8)	0.2 (0.1, NE)
	no	46/ 70 (65.7)	0.4 (0.2, 1.6)
	Prior nivolumab or pembrolizumab treatment		
	yes	5/ 6 (83.3)	0.1 (0.0, NE)
	no	48/ 73 (65.8)	0.5 (0.2, 3.5)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	6/ 7 (85.7)	0.2 (0.0, 0.5)
	no	47/ 72 (65.3)	0.5 (0.2, 3.5)
	Presence of liver metastasis at baseline		
	yes	35/ 50 (70.0)	0.5 (0.2, 3.5)
	no	18/ 29 (62.1)	0.3 (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Renal impairment at baseline		
	normal	22/ 32 (68.8)	0.4 (0.1, 1.6)
	mild	17/ 25 (68.0)	0.3 (0.1, 5.7)
	moderate	6/ 8 (75.0)	1.9 (0.1, NE)
	Hepatic impairment at baseline		
	normal	41/ 64 (64.1)	0.6 (0.2, 3.5)
	mild	12/ 14 (85.7)	0.1 (0.1, 0.5)
	Race		
	White	46/ 69 (66.7)	0.5 (0.2, 1.6)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	6/ 8 (75.0)	0.2 (0.0, NE)
	Ethnicity		
	Hispanic/Latino	3/ 5 (60.0)	0.5 (0.1, NE)
	Non-Hispanic/Non-Latino	48/ 70 (68.6)	0.4 (0.2, 1.4)
	Unknown	2/ 4 (50.0)	NE (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Vomiting	Overall	35/ 79 (44.3)	10.4 (2.8, NE)
	Region		
	North America	12/ 34 (35.3)	NE (1.9, NE)
	EU	23/ 45 (51.1)	10.4 (1.6, NE)
	Age (Category 1)		
	<65 years	22/ 46 (47.8)	10.4 (0.8, NE)
	>=65 years	13/ 33 (39.4)	11.3 (1.9, NE)
	Age (Category 2)		
	<75 years	34/ 75 (45.3)	10.4 (2.1, NE)
	>=75 years	1/ 4 (25.0)	NE (0.2, NE)
	Sex		
	female	10/ 22 (45.5)	11.3 (0.5, NE)
	male	25/ 57 (43.9)	10.4 (1.9, NE)
	ECOG PS		
	0	10/ 29 (34.5)	NE (2.1, NE)
	1	25/ 50 (50.0)	5.0 (1.4, NE)
	HER2 Status in central laboratory		
	IHC 3+	31/ 68 (45.6)	10.4 (2.1, NE)
	IHC 2+/ISH +	4/ 10 (40.0)	NE (0.0, NE)
	Primary tumor location		
	Gastric	14/ 27 (51.9)	5.0 (0.3, NE)
	GEJ	21/ 52 (40.4)	NE (1.9, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	9/ 19 (47.4)	NE (0.5, NE)
	other	26/ 59 (44.1)	10.4 (1.9, NE)
	Number of metastatic sites		
	<2	4/ 5 (80.0)	1.9 (0.1, 10.4)
	>=2	31/ 74 (41.9)	11.3 (2.8, NE)
	Previous total gastrectomy		
	no	35/ 79 (44.3)	10.4 (2.8, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	10.4 (0.1, NE)
	no	31/ 70 (44.3)	11.3 (1.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	3/ 6 (50.0)	1.9 (0.1, NE)
	no	32/ 73 (43.8)	11.3 (2.8, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	NE (0.1, NE)
	no	32/ 72 (44.4)	10.4 (2.8, NE)
	Presence of liver metastasis at baseline		
	yes	17/ 50 (34.0)	NE (11.3, NE)
	no	18/ 29 (62.1)	3.1 (0.3, 10.4)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Vomiting	Renal impairment at baseline		
	normal	14/ 32 (43.8)	10.4 (0.8, 10.4)
	mild	9/ 25 (36.0)	NE (1.4, NE)
	moderate	4/ 8 (50.0)	3.6 (0.3, NE)
	Hepatic impairment at baseline		
	normal	32/ 64 (50.0)	5.0 (1.6, NE)
	mild	2/ 14 (14.3)	NE (NE , NE)
	Race		
	White	31/ 69 (44.9)	10.4 (2.8, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.1, NE)
	Ethnicity		
	Hispanic/Latino	4/ 5 (80.0)	0.8 (0.2, NE)
	Non-Hispanic/Non-Latino	29/ 70 (41.4)	11.3 (3.1, NE)
	Unknown	2/ 4 (50.0)	NE (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions	Overall	57/ 79 (72.2)	0.7 (0.3, 1.9)
	Region		
	North America	23/ 34 (67.6)	0.7 (0.1, 5.0)
	EU	34/ 45 (75.6)	0.5 (0.3, 1.9)
	Age (Category 1)		
	<65 years	32/ 46 (69.6)	1.7 (0.5, 4.3)
	>=65 years	25/ 33 (75.8)	0.3 (0.1, 0.7)
	Age (Category 2)		
	<75 years	53/ 75 (70.7)	0.7 (0.3, 1.9)
	>=75 years	4/ 4 (100.0)	0.2 (0.2, 3.7)
	Sex		
	female	20/ 22 (90.9)	0.3 (0.1, 1.4)
	male	37/ 57 (64.9)	0.8 (0.3, 4.3)
	ECOG PS		
	0	21/ 29 (72.4)	0.7 (0.1, 3.1)
	1	36/ 50 (72.0)	0.7 (0.3, 3.7)
	HER2 Status in central laboratory		
	IHC 3+	50/ 68 (73.5)	0.7 (0.3, 1.9)
	IHC 2+/ISH +	6/ 10 (60.0)	0.7 (0.0, NE)
	Primary tumor location		
	Gastric	23/ 27 (85.2)	0.4 (0.1, 0.8)
	GEJ	34/ 52 (65.4)	1.4 (0.3, 6.9)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	18/ 19 (94.7)	0.5 (0.1, 1.5)
	other	39/ 59 (66.1)	0.7 (0.3, 5.0)
	Number of metastatic sites		
	<2	4/ 5 (80.0)	0.8 (0.0, NE)
	>=2	53/ 74 (71.6)	0.7 (0.3, 1.9)
	Previous total gastrectomy		
	no	57/ 79 (72.2)	0.7 (0.3, 1.9)
	Prior adjuvant/ neoadjuvant therapy		
	yes	9/ 9 (100.0)	0.2 (0.0, 4.1)
	no	48/ 70 (68.6)	0.7 (0.3, 1.9)
	Prior nivolumab or pembrolizumab treatment		
	yes	6/ 6 (100.0)	0.1 (0.0, 1.5)
	no	51/ 73 (69.9)	0.7 (0.3, 3.5)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	6/ 7 (85.7)	0.1 (0.0, 1.5)
	no	51/ 72 (70.8)	0.7 (0.3, 3.1)
	Presence of liver metastasis at baseline		
	yes	33/ 50 (66.0)	1.5 (0.3, 3.7)
	no	24/ 29 (82.8)	0.5 (0.1, 0.8)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions	Renal impairment at baseline		
	normal	21/ 32 (65.6)	1.1 (0.3, NE)
	mild	21/ 25 (84.0)	0.3 (0.1, 0.7)
	moderate	7/ 8 (87.5)	1.0 (0.1, 4.3)
	Hepatic impairment at baseline		
	normal	45/ 64 (70.3)	0.7 (0.3, 3.1)
	mild	11/ 14 (78.6)	1.7 (0.1, 6.9)
	Race		
	White	51/ 69 (73.9)	0.6 (0.3, 1.9)
	Black or African American	1/ 1 (100.0)	0.2 (NE , NE)
	Other	5/ 8 (62.5)	3.2 (0.0, NE)
	Ethnicity		
	Hispanic/Latino	3/ 5 (60.0)	4.3 (0.1, NE)
	Non-Hispanic/Non-Latino	51/ 70 (72.9)	0.7 (0.3, 1.5)
	Unknown	3/ 4 (75.0)	2.5 (0.0, 5.0)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Asthenia	Overall	12/ 79 (15.2)	NE (NE , NE)
	Region		
	North America	0/ 34 (0.0)	NE (NE , NE)
	EU	12/ 45 (26.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	7/ 33 (21.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	11/ 75 (14.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (3.7, NE)
	Sex		
	female	6/ 22 (27.3)	NE (5.7, NE)
	male	6/ 57 (10.5)	NE (NE , NE)
	ECOG PS		
	0	5/ 29 (17.2)	NE (NE , NE)
	1	7/ 50 (14.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	12/ 68 (17.6)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (NE , NE)
	GEJ	7/ 52 (13.5)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	5/ 19 (26.3)	NE (3.7, NE)
	other	7/ 59 (11.9)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	12/ 74 (16.2)	NE (NE , NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.1, NE)
	no	10/ 70 (14.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	12/ 73 (16.4)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	8/ 50 (16.0)	NE (NE , NE)
	no	4/ 29 (13.8)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Asthenia	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	3/ 8 (37.5)	NE (0.1, NE)
	Hepatic impairment at baseline		
	normal	10/ 64 (15.6)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	12/ 69 (17.4)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	12/ 70 (17.1)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Fatigue	Overall	33/ 79 (41.8)	NE (1.9, NE)
	Region		
	North America	18/ 34 (52.9)	4.1 (0.1, NE)
	EU	15/ 45 (33.3)	NE (NE , NE)
	Age (Category 1)		
	<65 years	18/ 46 (39.1)	NE (1.9, NE)
	>=65 years	15/ 33 (45.5)	NE (0.2, NE)
	Age (Category 2)		
	<75 years	31/ 75 (41.3)	NE (1.9, NE)
	>=75 years	2/ 4 (50.0)	NE (0.2, NE)
	Sex		
	female	12/ 22 (54.5)	4.1 (0.1, NE)
	male	21/ 57 (36.8)	NE (1.9, NE)
	ECOG PS		
	0	13/ 29 (44.8)	NE (0.2, NE)
	1	20/ 50 (40.0)	NE (1.9, NE)
	HER2 Status in central laboratory		
	IHC 3+	28/ 68 (41.2)	NE (1.9, NE)
	IHC 2+/ISH +	4/ 10 (40.0)	NE (0.0, NE)
	Primary tumor location		
	Gastric	13/ 27 (48.1)	5.5 (0.3, NE)
	GEJ	20/ 52 (38.5)	NE (1.5, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	9/ 19 (47.4)	NE (0.1, NE)
	other	24/ 59 (40.7)	NE (1.9, NE)
	Number of metastatic sites		
	<2	4/ 5 (80.0)	0.8 (0.0, NE)
	>=2	29/ 74 (39.2)	NE (1.9, NE)
	Previous total gastrectomy		
	no	33/ 79 (41.8)	NE (1.9, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	7/ 9 (77.8)	0.8 (0.0, NE)
	no	26/ 70 (37.1)	NE (1.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	6/ 6 (100.0)	0.1 (0.0, 1.5)
	no	27/ 73 (37.0)	NE (5.5, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	6/ 7 (85.7)	0.1 (0.0, 1.5)
	no	27/ 72 (37.5)	NE (5.5, NE)
	Presence of liver metastasis at baseline		
	yes	17/ 50 (34.0)	NE (NE , NE)
	no	16/ 29 (55.2)	4.1 (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Fatigue	Renal impairment at baseline		
	normal	12/ 32 (37.5)	NE (0.8, NE)
	mild	13/ 25 (52.0)	0.3 (0.1, NE)
	moderate	3/ 8 (37.5)	NE (0.1, NE)
	Hepatic impairment at baseline		
	normal	28/ 64 (43.8)	NE (0.8, NE)
	mild	5/ 14 (35.7)	NE (0.1, NE)
	Race		
	White	30/ 69 (43.5)	NE (0.8, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.0, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.1, NE)
	Non-Hispanic/Non-Latino	28/ 70 (40.0)	NE (1.9, NE)
	Unknown	3/ 4 (75.0)	2.8 (0.0, 5.5)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Pyrexia	Overall	9/ 79 (11.4)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (7.2, NE)
	Sex		
	female	5/ 22 (22.7)	NE (7.2, NE)
	male	4/ 57 (7.0)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	9/ 50 (18.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.5, NE)
	Primary tumor location		
	Gastric	8/ 27 (29.6)	NE (5.8, NE)
	GEJ	1/ 52 (1.9)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	6/ 19 (31.6)	7.2 (4.7, NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	9/ 74 (12.2)	NE (NE , NE)
	Previous total gastrectomy		
	no	9/ 79 (11.4)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	9/ 70 (12.9)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	9/ 73 (12.3)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	9/ 72 (12.5)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (NE , NE)
	no	5/ 29 (17.2)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions, PT: Pyrexia	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	2/ 8 (25.0)	NE (4.7, NE)
	Hepatic impairment at baseline		
	normal	8/ 64 (12.5)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (0.0, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	9/ 70 (12.9)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Hepatobiliary disorders	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	7/ 45 (15.6)	NE (9.6, NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (9.6, NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	7/ 75 (9.3)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.2, NE)
	Sex		
	female	3/ 22 (13.6)	NE (8.5, NE)
	male	5/ 57 (8.8)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	6/ 50 (12.0)	NE (9.6, NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	6/ 27 (22.2)	NE (8.5, NE)
	GEJ	2/ 52 (3.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	4/ 19 (21.1)	NE (7.6, NE)
	other	4/ 59 (6.8)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	8/ 74 (10.8)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.2, NE)
	no	7/ 70 (10.0)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	8/ 73 (11.0)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	8/ 72 (11.1)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (NE , NE)
	no	4/ 29 (13.8)	NE (8.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Hepatobiliary disorders	Renal impairment at baseline		
	normal	0/ 32 (0.0)	NE (NE , NE)
	mild	3/ 25 (12.0)	NE (9.6, NE)
	moderate	3/ 8 (37.5)	NE (1.3, NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (9.6, NE)
	Race		
	White	8/ 69 (11.6)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.2, NE)
	Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Infections and infestations	Overall	21/ 79 (26.6)	NE (7.3, NE)
	Region		
	North America	8/ 34 (23.5)	NE (6.0, NE)
	EU	13/ 45 (28.9)	NE (7.2, NE)
	Age (Category 1)		
	<65 years	9/ 46 (19.6)	NE (11.7, NE)
	>=65 years	12/ 33 (36.4)	NE (4.2, NE)
	Age (Category 2)		
	<75 years	18/ 75 (24.0)	NE (11.7, NE)
	>=75 years	3/ 4 (75.0)	5.7 (2.1, NE)
	Sex		
	female	6/ 22 (27.3)	NE (7.2, NE)
	male	15/ 57 (26.3)	NE (6.6, NE)
	ECOG PS		
	0	6/ 29 (20.7)	NE (7.3, NE)
	1	15/ 50 (30.0)	NE (7.2, NE)
	HER2 Status in central laboratory		
	IHC 3+	19/ 68 (27.9)	NE (7.3, NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	9/ 27 (33.3)	NE (4.2, NE)
	GEJ	12/ 52 (23.1)	NE (7.3, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	7.3 (NE , NE)
	intestinal	4/ 19 (21.1)	NE (6.6, NE)
	other	16/ 59 (27.1)	NE (11.7, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	21/ 74 (28.4)	NE (7.3, NE)
	Previous total gastrectomy		
	no	21/ 79 (26.6)	NE (7.3, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.9, NE)
	no	20/ 70 (28.6)	NE (7.2, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.1, NE)
	no	20/ 73 (27.4)	NE (7.3, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.1, NE)
	no	20/ 72 (27.8)	NE (7.3, NE)
	Presence of liver metastasis at baseline		
	yes	17/ 50 (34.0)	11.7 (6.0, NE)
	no	4/ 29 (13.8)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Infections and infestations	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	9/ 25 (36.0)	11.7 (6.6, NE)
	moderate	2/ 8 (25.0)	NE (6.0, NE)
	Hepatic impairment at baseline		
	normal	12/ 64 (18.8)	NE (NE , NE)
	mild	9/ 14 (64.3)	4.2 (1.2, 11.7)
	Race		
	White	18/ 69 (26.1)	NE (7.3, NE)
	Black or African American	1/ 1 (100.0)	4.2 (NE , NE)
	Other	1/ 8 (12.5)	NE (0.4, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (2.1, NE)
	Non-Hispanic/Non-Latino	19/ 70 (27.1)	NE (7.3, NE)
	Unknown	1/ 4 (25.0)	NE (3.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations	Overall	51/ 79 (64.6)	2.9 (2.1, 4.5)
	Region		
	North America	20/ 34 (58.8)	2.8 (0.8, 13.9)
	EU	31/ 45 (68.9)	3.2 (2.1, 5.1)
	Age (Category 1)		
	<65 years	28/ 46 (60.9)	3.2 (1.6, 5.5)
	>=65 years	23/ 33 (69.7)	2.6 (1.4, 5.5)
	Age (Category 2)		
	<75 years	47/ 75 (62.7)	2.9 (2.1, 4.5)
	>=75 years	4/ 4 (100.0)	2.5 (0.3, 8.5)
	Sex		
	female	16/ 22 (72.7)	3.5 (1.6, 5.1)
	male	35/ 57 (61.4)	2.9 (1.4, 6.2)
	ECOG PS		
	0	15/ 29 (51.7)	4.5 (2.1, NE)
	1	36/ 50 (72.0)	2.8 (0.8, 3.5)
	HER2 Status in central laboratory		
	IHC 3+	45/ 68 (66.2)	3.0 (2.1, 5.1)
	IHC 2+/ISH +	5/ 10 (50.0)	2.6 (0.3, NE)
	Primary tumor location		
	Gastric	19/ 27 (70.4)	3.2 (0.8, 5.1)
	GEJ	32/ 52 (61.5)	2.9 (2.0, 6.2)
	Histological subtype		
	diffuse	1/ 1 (100.0)	1.6 (NE , NE)
	intestinal	13/ 19 (68.4)	3.0 (0.3, 5.5)
	other	37/ 59 (62.7)	2.9 (2.1, 5.1)
	Number of metastatic sites		
	<2	4/ 5 (80.0)	2.6 (0.3, NE)
	>=2	47/ 74 (63.5)	3.0 (2.0, 4.5)
	Previous total gastrectomy		
	no	51/ 79 (64.6)	2.9 (2.1, 4.5)
	Prior adjuvant/ neoadjuvant therapy		
	yes	6/ 9 (66.7)	6.2 (0.3, NE)
	no	45/ 70 (64.3)	2.8 (1.6, 3.7)
	Prior nivolumab or pembrolizumab treatment		
	yes	4/ 6 (66.7)	2.6 (0.5, NE)
	no	47/ 73 (64.4)	3.0 (2.0, 5.1)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	5/ 7 (71.4)	2.6 (0.3, NE)
	no	46/ 72 (63.9)	3.2 (2.0, 5.1)
	Presence of liver metastasis at baseline		
	yes	29/ 50 (58.0)	2.9 (1.4, 13.9)
	no	22/ 29 (75.9)	3.2 (2.2, 5.1)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations	Renal impairment at baseline		
	normal	18/ 32 (56.3)	2.3 (0.5, NE)
	mild	16/ 25 (64.0)	2.8 (0.8, 8.5)
	moderate	7/ 8 (87.5)	4.0 (0.3, 13.9)
	Hepatic impairment at baseline		
	normal	41/ 64 (64.1)	3.2 (2.3, 5.1)
	mild	9/ 14 (64.3)	0.7 (0.3, NE)
	Race		
	White	45/ 69 (65.2)	2.9 (2.1, 4.5)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	5/ 8 (62.5)	2.2 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	4/ 5 (80.0)	3.2 (0.3, NE)
	Non-Hispanic/Non-Latino	45/ 70 (64.3)	2.9 (2.0, 4.5)
	Unknown	2/ 4 (50.0)	NE (0.3, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Investigations, PT: Alanine aminotransferase increased	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	4/ 34 (11.8)	NE (NE , NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	6/ 46 (13.0)	NE (NE , NE)
	>=65 years	2/ 33 (6.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	6/ 57 (10.5)	NE (NE , NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	5/ 50 (10.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	5/ 68 (7.4)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.3, NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	1.6 (NE , NE)
	intestinal	2/ 19 (10.5)	NE (6.3, NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.3, NE)
	>=2	7/ 74 (9.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	8/ 73 (11.0)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	8/ 72 (11.1)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	6/ 50 (12.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Alanine aminotransferase increased	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	4/ 25 (16.0)	NE (9.6, NE)
	moderate	2/ 8 (25.0)	NE (1.4, NE)
	Hepatic impairment at baseline		
	normal	6/ 64 (9.4)	NE (NE , NE)
	mild	2/ 14 (14.3)	9.6 (NE , NE)
	Race		
	White	6/ 69 (8.7)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (0.3, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Aspartate aminotransferase increased	Overall	13/ 79 (16.5)	NE (11.1, NE)
	Region		
	North America	5/ 34 (14.7)	13.9 (11.1, NE)
	EU	8/ 45 (17.8)	NE (9.6, NE)
	Age (Category 1)		
	<65 years	8/ 46 (17.4)	NE (9.6, NE)
	>=65 years	5/ 33 (15.2)	NE (13.9, NE)
	Age (Category 2)		
	<75 years	13/ 75 (17.3)	13.9 (11.1, NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	3/ 22 (13.6)	NE (6.9, NE)
	male	10/ 57 (17.5)	13.9 (9.6, NE)
	ECOG PS		
	0	5/ 29 (17.2)	NE (6.9, NE)
	1	8/ 50 (16.0)	13.9 (11.1, NE)
	HER2 Status in central laboratory		
	IHC 3+	11/ 68 (16.2)	NE (11.1, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.6, NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	NE (NE , NE)
	GEJ	9/ 52 (17.3)	13.9 (9.6, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	6.9 (NE , NE)
	intestinal	3/ 19 (15.8)	NE (5.5, NE)
	other	9/ 59 (15.3)	13.9 (11.1, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (6.2, NE)
	>=2	12/ 74 (16.2)	NE (11.1, NE)
	Previous total gastrectomy		
	no	13/ 79 (16.5)	NE (11.1, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (6.2, NE)
	no	12/ 70 (17.1)	13.9 (11.1, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	13/ 73 (17.8)	13.9 (11.1, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	13/ 72 (18.1)	13.9 (11.1, NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	13.9 (9.6, NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Aspartate aminotransferase increased	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (6.2, NE)
	mild	4/ 25 (16.0)	NE (6.9, NE)
	moderate	3/ 8 (37.5)	13.9 (1.4, 13.9)
	Hepatic impairment at baseline		
	normal	10/ 64 (15.6)	NE (13.9, NE)
	mild	3/ 14 (21.4)	9.6 (6.0, 9.6)
	Race		
	White	12/ 69 (17.4)	13.9 (11.1, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (1.6, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	13/ 70 (18.6)	13.9 (9.6, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Investigations, PT: Blood alkaline phosphatase increased	Overall	9/ 79 (11.4)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (7.8, NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (9.6, NE)
	>=65 years	4/ 33 (12.1)	NE (10.3, NE)
	Age (Category 2)		
	<75 years	9/ 75 (12.0)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	4/ 22 (18.2)	NE (10.3, NE)
	male	5/ 57 (8.8)	NE (NE , NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	6/ 50 (12.0)	NE (10.3, NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.3, NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	NE (10.3, NE)
	GEJ	5/ 52 (9.6)	NE (9.6, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	4.4 (NE , NE)
	intestinal	2/ 19 (10.5)	NE (10.3, NE)
	other	6/ 59 (10.2)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.3, NE)
	>=2	8/ 74 (10.8)	NE (NE , NE)
	Previous total gastrectomy		
	no	9/ 79 (11.4)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (4.5, NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	9/ 73 (12.3)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	9/ 72 (12.5)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	6/ 50 (12.0)	NE (9.6, NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Blood alkaline phosphatase increased	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (7.8, NE)
	mild	3/ 25 (12.0)	NE (9.6, NE)
	moderate	1/ 8 (12.5)	NE (4.5, NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (NE , NE)
	mild	2/ 14 (14.3)	9.6 (4.4, 9.6)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (0.3, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	9/ 70 (12.9)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Neutrophil count decreased	Overall	13/ 79 (16.5)	NE (18.9, NE)
	Region		
	North America	6/ 34 (17.6)	NE (18.9, NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	18.9 (NE , NE)
	>=65 years	8/ 33 (24.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	12/ 75 (16.0)	NE (18.9, NE)
	>=75 years	1/ 4 (25.0)	NE (0.3, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	10/ 57 (17.5)	NE (18.9, NE)
	ECOG PS		
	0	4/ 29 (13.8)	NE (NE , NE)
	1	9/ 50 (18.0)	NE (18.9, NE)
	HER2 Status in central laboratory		
	IHC 3+	12/ 68 (17.6)	NE (18.9, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (0.7, NE)
	Primary tumor location		
	Gastric	6/ 27 (22.2)	NE (NE , NE)
	GEJ	7/ 52 (13.5)	18.9 (18.9, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	10/ 59 (16.9)	NE (18.9, NE)
	Number of metastatic sites		
	<2	2/ 5 (40.0)	NE (0.7, NE)
	>=2	11/ 74 (14.9)	NE (18.9, NE)
	Previous total gastrectomy		
	no	13/ 79 (16.5)	NE (18.9, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.5, NE)
	no	12/ 70 (17.1)	NE (18.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.1, NE)
	no	12/ 73 (16.4)	NE (18.9, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.5, NE)
	no	11/ 72 (15.3)	NE (18.9, NE)
	Presence of liver metastasis at baseline		
	yes	9/ 50 (18.0)	NE (18.9, NE)
	no	4/ 29 (13.8)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Neutrophil count decreased	Renal impairment at baseline		
	normal	6/ 32 (18.8)	18.9 (NE , NE)
	mild	4/ 25 (16.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (0.5, NE)
	Hepatic impairment at baseline		
	normal	6/ 64 (9.4)	NE (18.9, NE)
	mild	6/ 14 (42.9)	4.7 (0.5, NE)
	Race		
	White	10/ 69 (14.5)	NE (18.9, NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	11/ 70 (15.7)	NE (18.9, NE)
	Unknown	1/ 4 (25.0)	NE (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Platelet count decreased	Overall	14/ 79 (17.7)	NE (NE , NE)
	Region		
	North America	7/ 34 (20.6)	NE (7.6, NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	7/ 46 (15.2)	NE (NE , NE)
	>=65 years	7/ 33 (21.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	13/ 75 (17.3)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (0.3, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	11/ 57 (19.3)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	12/ 50 (24.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	13/ 68 (19.1)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (2.1, NE)
	Primary tumor location		
	Gastric	6/ 27 (22.2)	NE (7.6, NE)
	GEJ	8/ 52 (15.4)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	11/ 59 (18.6)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.1, NE)
	>=2	13/ 74 (17.6)	NE (NE , NE)
	Previous total gastrectomy		
	no	14/ 79 (17.7)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.3, NE)
	no	13/ 70 (18.6)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	7.6 (NE , NE)
	no	13/ 73 (17.8)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	7.6 (0.3, 7.6)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	NE (NE , NE)
	no	4/ 29 (13.8)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Platelet count decreased	Renal impairment at baseline		
	normal	7/ 32 (21.9)	NE (NE , NE)
	mild	4/ 25 (16.0)	NE (7.6, NE)
	moderate	1/ 8 (12.5)	NE (3.2, NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (NE , NE)
	mild	6/ 14 (42.9)	NE (0.3, NE)
	Race		
	White	11/ 69 (15.9)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.3, NE)
	Non-Hispanic/Non-Latino	11/ 70 (15.7)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (0.3, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Weight decreased	Overall	28/ 79 (35.4)	10.4 (4.9, NE)
	Region		
	North America	11/ 34 (32.4)	10.4 (3.0, NE)
	EU	17/ 45 (37.8)	8.2 (4.1, NE)
	Age (Category 1)		
	<65 years	17/ 46 (37.0)	10.4 (4.3, NE)
	>=65 years	11/ 33 (33.3)	NE (3.7, NE)
	Age (Category 2)		
	<75 years	25/ 75 (33.3)	NE (5.1, NE)
	>=75 years	3/ 4 (75.0)	2.9 (1.7, NE)
	Sex		
	female	10/ 22 (45.5)	5.1 (3.0, NE)
	male	18/ 57 (31.6)	NE (5.5, NE)
	ECOG PS		
	0	7/ 29 (24.1)	NE (4.9, NE)
	1	21/ 50 (42.0)	8.2 (3.5, NE)
	HER2 Status in central laboratory		
	IHC 3+	25/ 68 (36.8)	10.4 (4.9, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.7, NE)
	Primary tumor location		
	Gastric	10/ 27 (37.0)	8.2 (3.7, NE)
	GEJ	18/ 52 (34.6)	NE (4.9, NE)
	Histological subtype		
	diffuse	1/ 1 (100.0)	3.0 (NE , NE)
	intestinal	6/ 19 (31.6)	NE (3.0, NE)
	other	21/ 59 (35.6)	10.4 (4.3, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.6, NE)
	>=2	27/ 74 (36.5)	10.4 (4.3, NE)
	Previous total gastrectomy		
	no	28/ 79 (35.4)	10.4 (4.9, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (2.6, NE)
	no	26/ 70 (37.1)	10.4 (4.3, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (2.1, NE)
	no	26/ 73 (35.6)	10.4 (4.9, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (2.1, NE)
	no	26/ 72 (36.1)	10.4 (4.9, NE)
	Presence of liver metastasis at baseline		
	yes	17/ 50 (34.0)	NE (4.1, NE)
	no	11/ 29 (37.9)	8.2 (4.3, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Weight decreased	Renal impairment at baseline		
	normal	8/ 32 (25.0)	NE (4.9, NE)
	mild	10/ 25 (40.0)	4.1 (3.0, NE)
	moderate	3/ 8 (37.5)	8.2 (3.7, NE)
	Hepatic impairment at baseline		
	normal	22/ 64 (34.4)	NE (5.1, NE)
	mild	6/ 14 (42.9)	4.9 (3.0, NE)
	Race		
	White	25/ 69 (36.2)	10.4 (4.9, NE)
	Black or African American	1/ 1 (100.0)	2.1 (NE , NE)
	Other	2/ 8 (25.0)	NE (2.1, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	5.5 (1.7, NE)
	Non-Hispanic/Non-Latino	24/ 70 (34.3)	10.4 (4.3, NE)
	Unknown	2/ 4 (50.0)	NE (1.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: White blood cell count decreased	Overall	9/ 79 (11.4)	NE (18.9, NE)
	Region		
	North America	7/ 34 (20.6)	18.9 (11.1, NE)
	EU	2/ 45 (4.4)	NE (NE , NE)
	Age (Category 1)		
	<65 years	6/ 46 (13.0)	18.9 (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (11.1, NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	18.9 (18.9, NE)
	>=75 years	1/ 4 (25.0)	NE (0.5, NE)
	Sex		
	female	3/ 22 (13.6)	NE (11.1, NE)
	male	6/ 57 (10.5)	NE (18.9, NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	6/ 50 (12.0)	NE (18.9, NE)
	HER2 Status in central laboratory		
	IHC 3+	8/ 68 (11.8)	NE (18.9, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (2.1, NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	NE (11.1, NE)
	GEJ	5/ 52 (9.6)	18.9 (18.9, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	7/ 59 (11.9)	NE (18.9, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.1, NE)
	>=2	8/ 74 (10.8)	NE (18.9, NE)
	Previous total gastrectomy		
	no	9/ 79 (11.4)	NE (18.9, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	9/ 70 (12.9)	NE (18.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	11.1 (0.5, 11.1)
	no	7/ 73 (9.6)	NE (18.9, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	11.1 (0.5, 11.1)
	no	6/ 72 (8.3)	NE (18.9, NE)
	Presence of liver metastasis at baseline		
	yes	8/ 50 (16.0)	NE (18.9, NE)
	no	1/ 29 (3.4)	NE (11.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: White blood cell count decreased	Renal impairment at baseline		
	normal	6/ 32 (18.8)	18.9 (NE , NE)
	mild	1/ 25 (4.0)	NE (11.1, NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	6/ 64 (9.4)	NE (18.9, NE)
	mild	3/ 14 (21.4)	NE (3.0, NE)
	Race		
	White	5/ 69 (7.2)	NE (18.9, NE)
	Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
	Other	3/ 8 (37.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	18.9 (18.9, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders	Overall	44/ 79 (55.7)	3.4 (1.4, 9.6)
	Region		
	North America	21/ 34 (61.8)	2.7 (0.7, 6.9)
	EU	23/ 45 (51.1)	5.9 (1.1, NE)
	Age (Category 1)		
	<65 years	27/ 46 (58.7)	2.8 (0.5, NE)
	>=65 years	17/ 33 (51.5)	3.4 (2.2, NE)
	Age (Category 2)		
	<75 years	41/ 75 (54.7)	2.9 (1.4, 9.6)
	>=75 years	3/ 4 (75.0)	2.4 (0.7, NE)
	Sex		
	female	11/ 22 (50.0)	4.8 (0.7, NE)
	male	33/ 57 (57.9)	2.7 (1.1, 9.6)
	ECOG PS		
	0	12/ 29 (41.4)	NE (2.5, NE)
	1	32/ 50 (64.0)	2.2 (0.7, 6.9)
	HER2 Status in central laboratory		
	IHC 3+	38/ 68 (55.9)	3.4 (1.4, NE)
	IHC 2+/ISH +	6/ 10 (60.0)	1.6 (0.3, NE)
	Primary tumor location		
	Gastric	15/ 27 (55.6)	3.4 (0.7, NE)
	GEJ	29/ 52 (55.8)	2.9 (1.1, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	10/ 19 (52.6)	4.8 (0.6, NE)
	other	34/ 59 (57.6)	2.7 (1.4, 9.6)
	Number of metastatic sites		
	<2	2/ 5 (40.0)	NE (0.3, NE)
	>=2	42/ 74 (56.8)	2.9 (1.4, 9.6)
	Previous total gastrectomy		
	no	44/ 79 (55.7)	3.4 (1.4, 9.6)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	2.2 (0.1, NE)
	no	39/ 70 (55.7)	3.4 (1.4, 9.6)
	Prior nivolumab or pembrolizumab treatment		
	yes	4/ 6 (66.7)	2.2 (0.3, NE)
	no	40/ 73 (54.8)	3.4 (1.4, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	5/ 7 (71.4)	2.2 (0.0, NE)
	no	39/ 72 (54.2)	3.4 (1.4, NE)
	Presence of liver metastasis at baseline		
	yes	28/ 50 (56.0)	3.4 (1.4, 9.6)
	no	16/ 29 (55.2)	2.7 (0.6, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders	Renal impairment at baseline		
	normal	20/ 32 (62.5)	2.2 (0.3, NE)
	mild	15/ 25 (60.0)	2.2 (0.8, NE)
	moderate	2/ 8 (25.0)	NE (0.4, NE)
	Hepatic impairment at baseline		
	normal	33/ 64 (51.6)	4.8 (1.6, NE)
	mild	10/ 14 (71.4)	2.1 (0.1, 9.6)
	Race		
	White	37/ 69 (53.6)	4.8 (1.4, NE)
	Black or African American	1/ 1 (100.0)	3.4 (NE , NE)
	Other	6/ 8 (75.0)	1.6 (0.1, NE)
	Ethnicity		
	Hispanic/Latino	3/ 5 (60.0)	1.4 (0.0, NE)
	Non-Hispanic/Non-Latino	38/ 70 (54.3)	3.4 (1.6, NE)
	Unknown	3/ 4 (75.0)	1.3 (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Overall	26/ 79 (32.9)	NE (10.2, NE)
	Region		
	North America	14/ 34 (41.2)	10.2 (2.2, NE)
	EU	12/ 45 (26.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	12/ 46 (26.1)	NE (NE , NE)
	>=65 years	14/ 33 (42.4)	10.2 (2.2, NE)
	Age (Category 2)		
	<75 years	25/ 75 (33.3)	NE (10.2, NE)
	>=75 years	1/ 4 (25.0)	NE (0.7, NE)
	Sex		
	female	6/ 22 (27.3)	NE (4.8, NE)
	male	20/ 57 (35.1)	NE (3.4, NE)
	ECOG PS		
	0	9/ 29 (31.0)	NE (3.1, NE)
	1	17/ 50 (34.0)	NE (4.8, NE)
	HER2 Status in central laboratory		
	IHC 3+	22/ 68 (32.4)	NE (10.2, NE)
	IHC 2+/ISH +	4/ 10 (40.0)	2.2 (1.3, NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (NE , NE)
	GEJ	21/ 52 (40.4)	NE (2.8, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	6/ 19 (31.6)	NE (1.1, NE)
	other	20/ 59 (33.9)	NE (10.2, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.2, NE)
	>=2	25/ 74 (33.8)	NE (10.2, NE)
	Previous total gastrectomy		
	no	26/ 79 (32.9)	NE (10.2, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	2.2 (0.1, NE)
	no	21/ 70 (30.0)	NE (10.2, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	3/ 6 (50.0)	2.2 (0.3, NE)
	no	23/ 73 (31.5)	NE (10.2, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	NE (0.3, NE)
	no	23/ 72 (31.9)	NE (10.2, NE)
	Presence of liver metastasis at baseline		
	yes	17/ 50 (34.0)	NE (4.8, NE)
	no	9/ 29 (31.0)	NE (3.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Renal impairment at baseline		
	normal	12/ 32 (37.5)	NE (1.6, NE)
	mild	9/ 25 (36.0)	NE (1.4, NE)
	moderate	1/ 8 (12.5)	NE (10.2, NE)
	Hepatic impairment at baseline		
	normal	20/ 64 (31.3)	NE (10.2, NE)
	mild	5/ 14 (35.7)	NE (0.1, NE)
	Race		
	White	24/ 69 (34.8)	NE (10.2, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (0.1, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.1, NE)
	Non-Hispanic/Non-Latino	22/ 70 (31.4)	NE (10.2, NE)
	Unknown	3/ 4 (75.0)	1.3 (0.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Hypoalbuminaemia	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	3/ 34 (8.8)	NE (NE , NE)
	EU	5/ 45 (11.1)	NE (NE , NE)
	Age (Category 1)		
	<65 years	7/ 46 (15.2)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (9.7, NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (9.7, NE)
	male	6/ 57 (10.5)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	7/ 50 (14.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	6/ 68 (8.8)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (1.4, NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	NE (9.7, NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (9.7, NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (1.4, NE)
	>=2	7/ 74 (9.5)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	8/ 73 (11.0)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.1, NE)
	no	7/ 72 (9.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	7/ 50 (14.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Hypoalbuminaemia	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	3/ 25 (12.0)	NE (9.6, NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (NE , NE)
	mild	4/ 14 (28.6)	9.6 (2.1, NE)
	Race		
	White	5/ 69 (7.2)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.2, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (2.1, NE)
	Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Overall	13/ 79 (16.5)	NE (20.7, NE)
	Region		
	North America	6/ 34 (17.6)	NE (20.7, NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	10/ 46 (21.7)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	20.7 (20.7, NE)
	Age (Category 2)		
	<75 years	12/ 75 (16.0)	NE (20.7, NE)
	>=75 years	1/ 4 (25.0)	NE (1.4, NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	11/ 57 (19.3)	20.7 (20.7, NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	10/ 50 (20.0)	NE (20.7, NE)
	HER2 Status in central laboratory		
	IHC 3+	11/ 68 (16.2)	NE (20.7, NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.3, NE)
	Primary tumor location		
	Gastric	6/ 27 (22.2)	NE (NE , NE)
	GEJ	7/ 52 (13.5)	20.7 (20.7, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	12/ 59 (20.3)	NE (20.7, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.3, NE)
	>=2	12/ 74 (16.2)	NE (20.7, NE)
	Previous total gastrectomy		
	no	13/ 79 (16.5)	NE (20.7, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.5, NE)
	no	12/ 70 (17.1)	NE (20.7, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	13/ 73 (17.8)	20.7 (20.7, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	13/ 72 (18.1)	20.7 (20.7, NE)
	Presence of liver metastasis at baseline		
	yes	8/ 50 (16.0)	20.7 (20.7, NE)
	no	5/ 29 (17.2)	NE (NE , NE)

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NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Hypokalaemia	Renal impairment at baseline		
	normal	6/ 32 (18.8)	NE (4.9, NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	20.7 (NE , NE)
	Hepatic impairment at baseline		
	normal	10/ 64 (15.6)	NE (20.7, NE)
	mild	3/ 14 (21.4)	NE (4.9, NE)
	Race		
	White	10/ 69 (14.5)	NE (20.7, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.3, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.4, NE)
	Non-Hispanic/Non-Latino	11/ 70 (15.7)	NE (20.7, NE)
	Unknown	1/ 4 (25.0)	NE (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Musculoskeletal and connective tissue disorders	Overall	18/ 79 (22.8)	19.2 (13.8, NE)
	Region		
	North America	9/ 34 (26.5)	19.2 (4.9, NE)
	EU	9/ 45 (20.0)	13.8 (13.8, NE)
	Age (Category 1)		
	<65 years	13/ 46 (28.3)	13.8 (7.5, 19.2)
	>=65 years	5/ 33 (15.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	17/ 75 (22.7)	19.2 (13.8, NE)
	>=75 years	1/ 4 (25.0)	NE (8.5, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	15/ 57 (26.3)	19.2 (8.5, NE)
	ECOG PS		
	0	7/ 29 (24.1)	13.8 (7.5, 13.8)
	1	11/ 50 (22.0)	NE (19.2, NE)
	HER2 Status in central laboratory		
	IHC 3+	15/ 68 (22.1)	19.2 (13.8, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	4.9 (0.9, NE)
	Primary tumor location		
	Gastric	7/ 27 (25.9)	NE (4.4, NE)
	GEJ	11/ 52 (21.2)	13.8 (13.8, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	4/ 19 (21.1)	13.8 (NE , NE)
	other	14/ 59 (23.7)	NE (8.5, NE)
	Number of metastatic sites		
	<2	3/ 5 (60.0)	4.9 (2.0, NE)
	>=2	15/ 74 (20.3)	19.2 (13.8, NE)
	Previous total gastrectomy		
	no	18/ 79 (22.8)	19.2 (13.8, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	3/ 9 (33.3)	13.8 (4.4, 13.8)
	no	15/ 70 (21.4)	NE (19.2, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.0, NE)
	no	17/ 73 (23.3)	19.2 (13.8, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.0, NE)
	no	17/ 72 (23.6)	19.2 (13.8, NE)
	Presence of liver metastasis at baseline		
	yes	12/ 50 (24.0)	19.2 (13.8, NE)
	no	6/ 29 (20.7)	NE (8.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Musculoskeletal and connective tissue disorders	Renal impairment at baseline		
	normal	7/ 32 (21.9)	19.2 (NE , NE)
	mild	7/ 25 (28.0)	13.8 (7.5, NE)
	moderate	1/ 8 (12.5)	NE (3.2, NE)
	Hepatic impairment at baseline		
	normal	15/ 64 (23.4)	19.2 (13.8, NE)
	mild	3/ 14 (21.4)	NE (2.7, NE)
	Race		
	White	17/ 69 (24.6)	19.2 (13.8, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (4.9, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.2, NE)
	Non-Hispanic/Non-Latino	17/ 70 (24.3)	19.2 (13.8, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Nervous system disorders	Overall	28/ 79 (35.4)	12.4 (5.0, NE)
	Region		
	North America	12/ 34 (35.3)	6.6 (4.9, NE)
	EU	16/ 45 (35.6)	12.4 (4.8, NE)
	Age (Category 1)		
	<65 years	17/ 46 (37.0)	9.9 (4.9, NE)
	>=65 years	11/ 33 (33.3)	12.4 (4.7, NE)
	Age (Category 2)		
	<75 years	26/ 75 (34.7)	12.4 (6.6, NE)
	>=75 years	2/ 4 (50.0)	4.7 (1.9, NE)
	Sex		
	female	7/ 22 (31.8)	12.4 (4.8, NE)
	male	21/ 57 (36.8)	NE (4.7, NE)
	ECOG PS		
	0	7/ 29 (24.1)	NE (9.9, NE)
	1	21/ 50 (42.0)	12.4 (3.6, NE)
	HER2 Status in central laboratory		
	IHC 3+	25/ 68 (36.8)	12.4 (5.0, NE)
	IHC 2+/ISH +	3/ 10 (30.0)	4.9 (1.3, 4.9)
	Primary tumor location		
	Gastric	10/ 27 (37.0)	12.4 (4.8, NE)
	GEJ	18/ 52 (34.6)	NE (4.7, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	10/ 19 (52.6)	9.9 (0.9, 12.4)
	other	18/ 59 (30.5)	NE (5.0, NE)
	Number of metastatic sites		
	<2	2/ 5 (40.0)	NE (1.4, NE)
	>=2	26/ 74 (35.1)	12.4 (5.0, NE)
	Previous total gastrectomy		
	no	28/ 79 (35.4)	12.4 (5.0, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	9.9 (0.1, NE)
	no	23/ 70 (32.9)	12.4 (6.6, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (1.4, NE)
	no	27/ 73 (37.0)	12.4 (5.0, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (1.4, NE)
	no	26/ 72 (36.1)	12.4 (5.0, NE)
	Presence of liver metastasis at baseline		
	yes	19/ 50 (38.0)	12.4 (4.9, NE)
	no	9/ 29 (31.0)	NE (4.8, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Nervous system disorders	Renal impairment at baseline		
	normal	15/ 32 (46.9)	4.9 (1.3, NE)
	mild	8/ 25 (32.0)	NE (4.7, NE)
	moderate	3/ 8 (37.5)	NE (0.7, NE)
	Hepatic impairment at baseline		
	normal	22/ 64 (34.4)	12.4 (5.0, NE)
	mild	5/ 14 (35.7)	NE (1.0, NE)
	Race		
	White	25/ 69 (36.2)	12.4 (6.6, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	5.0 (1.1, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.9, NE)
	Non-Hispanic/Non-Latino	24/ 70 (34.3)	12.4 (6.6, NE)
	Unknown	2/ 4 (50.0)	5.0 (0.5, 5.0)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Psychiatric disorders	Overall	12/ 79 (15.2)	NE (NE , NE)
	Region		
	North America	4/ 34 (11.8)	NE (NE , NE)
	EU	8/ 45 (17.8)	NE (NE , NE)
	Age (Category 1)		
	<65 years	9/ 46 (19.6)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	12/ 75 (16.0)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	11/ 57 (19.3)	NE (NE , NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (NE , NE)
	1	9/ 50 (18.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	9/ 68 (13.2)	NE (NE , NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.3, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	9/ 52 (17.3)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	11/ 59 (18.6)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (3.5, NE)
	>=2	11/ 74 (14.9)	NE (NE , NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	12/ 70 (17.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	12/ 73 (16.4)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	9/ 50 (18.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Psychiatric disorders	Renal impairment at baseline		
	normal	7/ 32 (21.9)	NE (NE , NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (4.8, NE)
	Hepatic impairment at baseline		
	normal	11/ 64 (17.2)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (4.2, NE)
	Race		
	White	11/ 69 (15.9)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (3.5, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	12/ 70 (17.1)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Renal and urinary disorders	Overall	18/ 79 (22.8)	NE (NE , NE)
	Region		
	North America	10/ 34 (29.4)	NE (2.9, NE)
	EU	8/ 45 (17.8)	NE (9.5, NE)
	Age (Category 1)		
	<65 years	11/ 46 (23.9)	NE (9.5, NE)
	>=65 years	7/ 33 (21.2)	NE (8.2, NE)
	Age (Category 2)		
	<75 years	17/ 75 (22.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.2, NE)
	Sex		
	female	4/ 22 (18.2)	NE (8.2, NE)
	male	14/ 57 (24.6)	NE (9.5, NE)
	ECOG PS		
	0	7/ 29 (24.1)	NE (8.2, NE)
	1	11/ 50 (22.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	15/ 68 (22.1)	NE (NE , NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.0, NE)
	Primary tumor location		
	Gastric	6/ 27 (22.2)	NE (NE , NE)
	GEJ	12/ 52 (23.1)	NE (9.5, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	15/ 59 (25.4)	NE (9.5, NE)
	Number of metastatic sites		
	<2	2/ 5 (40.0)	NE (0.0, NE)
	>=2	16/ 74 (21.6)	NE (NE , NE)
	Previous total gastrectomy		
	no	18/ 79 (22.8)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (1.3, NE)
	no	17/ 70 (24.3)	NE (9.5, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	3/ 6 (50.0)	2.9 (0.7, NE)
	no	15/ 73 (20.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	4/ 7 (57.1)	2.9 (0.5, NE)
	no	14/ 72 (19.4)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	NE (9.5, NE)
	no	8/ 29 (27.6)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Renal and urinary disorders	Renal impairment at baseline		
	normal	10/ 32 (31.3)	NE (2.9, NE)
	mild	4/ 25 (16.0)	NE (9.5, NE)
	moderate	1/ 8 (12.5)	NE (8.2, NE)
	Hepatic impairment at baseline		
	normal	15/ 64 (23.4)	NE (NE , NE)
	mild	2/ 14 (14.3)	9.5 (9.5, NE)
	Race		
	White	15/ 69 (21.7)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.0, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	16/ 70 (22.9)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Overall	37/ 79 (46.8)	8.8 (4.1, 18.3)
	Region		
	North America	16/ 34 (47.1)	6.1 (2.7, NE)
	EU	21/ 45 (46.7)	8.8 (2.8, 18.3)
	Age (Category 1)		
	<65 years	24/ 46 (52.2)	4.3 (2.8, 11.5)
	>=65 years	13/ 33 (39.4)	9.7 (4.3, 18.7)
	Age (Category 2)		
	<75 years	34/ 75 (45.3)	8.8 (4.1, 18.7)
	>=75 years	3/ 4 (75.0)	11.2 (0.0, 18.3)
	Sex		
	female	9/ 22 (40.9)	18.7 (4.0, 18.7)
	male	28/ 57 (49.1)	6.1 (2.8, 18.3)
	ECOG PS		
	0	12/ 29 (41.4)	8.8 (2.7, NE)
	1	25/ 50 (50.0)	6.3 (4.0, 18.3)
	HER2 Status in central laboratory		
	IHC 3+	34/ 68 (50.0)	6.3 (4.1, 18.3)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.1, NE)
	Primary tumor location		
	Gastric	10/ 27 (37.0)	18.3 (4.1, 18.7)
	GEJ	27/ 52 (51.9)	6.1 (2.8, 11.5)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	7/ 19 (36.8)	9.7 (2.7, NE)
	other	30/ 59 (50.8)	6.1 (2.8, 18.3)
	Number of metastatic sites		
	<2	3/ 5 (60.0)	4.1 (0.7, NE)
	>=2	34/ 74 (45.9)	8.8 (4.3, 18.3)
	Previous total gastrectomy		
	no	37/ 79 (46.8)	8.8 (4.1, 18.3)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	8.8 (0.0, NE)
	no	33/ 70 (47.1)	6.3 (3.9, 18.3)
	Prior nivolumab or pembrolizumab treatment		
	yes	4/ 6 (66.7)	2.7 (0.7, 18.7)
	no	33/ 73 (45.2)	8.8 (4.1, 18.3)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	4/ 7 (57.1)	18.7 (0.7, 18.7)
	no	33/ 72 (45.8)	8.8 (4.1, 18.3)
	Presence of liver metastasis at baseline		
	yes	24/ 50 (48.0)	8.8 (2.8, 18.3)
	no	13/ 29 (44.8)	6.1 (3.9, 18.7)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Renal impairment at baseline		
	normal	16/ 32 (50.0)	4.3 (2.7, NE)
	mild	11/ 25 (44.0)	11.5 (5.2, 18.7)
	moderate	2/ 8 (25.0)	NE (0.3, NE)
	Hepatic impairment at baseline		
	normal	31/ 64 (48.4)	6.3 (3.9, 18.7)
	mild	6/ 14 (42.9)	11.5 (0.3, 11.5)
	Race		
	White	34/ 69 (49.3)	6.3 (3.9, 18.3)
	Black or African American	1/ 1 (100.0)	4.0 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.7, NE)
	Ethnicity		
	Hispanic/Latino	4/ 5 (80.0)	3.9 (0.7, 18.3)
	Non-Hispanic/Non-Latino	32/ 70 (45.7)	8.8 (4.1, 18.7)
	Unknown	1/ 4 (25.0)	NE (1.0, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Overall	9/ 79 (11.4)	NE (NE , NE)
	Region		
	North America	6/ 34 (17.6)	NE (6.1, NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (NE , NE)
	>=65 years	5/ 33 (15.2)	NE (9.7, NE)
	Age (Category 2)		
	<75 years	9/ 75 (12.0)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (9.7, NE)
	male	8/ 57 (14.0)	NE (NE , NE)
	ECOG PS		
	0	5/ 29 (17.2)	NE (6.1, NE)
	1	4/ 50 (8.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	9/ 68 (13.2)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (9.7, NE)
	GEJ	8/ 52 (15.4)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (9.7, NE)
	other	6/ 59 (10.2)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.0, NE)
	>=2	8/ 74 (10.8)	NE (NE , NE)
	Previous total gastrectomy		
	no	9/ 79 (11.4)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	9/ 70 (12.9)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (2.0, NE)
	no	7/ 73 (9.6)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (2.0, NE)
	no	7/ 72 (9.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	7/ 50 (14.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Cough	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (2.4, NE)
	Race		
	White	9/ 69 (13.0)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.9, NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Epistaxis	Overall	8/ 79 (10.1)	18.7 (18.3, NE)
	Region		
	North America	4/ 34 (11.8)	18.7 (7.5, NE)
	EU	4/ 45 (8.9)	18.3 (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	5/ 33 (15.2)	18.7 (18.3, NE)
	Age (Category 2)		
	<75 years	7/ 75 (9.3)	18.7 (18.7, NE)
	>=75 years	1/ 4 (25.0)	18.3 (NE , NE)
	Sex		
	female	2/ 22 (9.1)	18.7 (NE , NE)
	male	6/ 57 (10.5)	18.3 (18.3, NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	6/ 50 (12.0)	18.7 (18.3, NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	18.7 (18.3, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (0.7, NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	18.3 (18.3, 18.7)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	0/ 19 (0.0)	NE (NE , NE)
	other	8/ 59 (13.6)	18.7 (18.3, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.7, NE)
	>=2	7/ 74 (9.5)	18.7 (18.3, NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	18.7 (18.3, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	18.7 (18.3, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	18.7 (NE , NE)
	no	7/ 73 (9.6)	18.3 (18.3, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	18.7 (NE , NE)
	no	7/ 72 (9.7)	18.3 (18.3, NE)
	Presence of liver metastasis at baseline		
	yes	5/ 50 (10.0)	18.3 (18.3, NE)
	no	3/ 29 (10.3)	18.7 (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Epistaxis	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (6.3, NE)
	mild	4/ 25 (16.0)	18.3 (18.3, 18.7)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	8/ 64 (12.5)	18.7 (18.3, NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	7/ 69 (10.1)	18.7 (18.3, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (0.7, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	18.3 (2.8, 18.3)
	Non-Hispanic/Non-Latino	6/ 70 (8.6)	18.7 (18.7, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Pneumonitis	Overall	8/ 79 (10.1)	NE (11.5, NE)
	Region		
	North America	3/ 34 (8.8)	NE (10.4, NE)
	EU	5/ 45 (11.1)	NE (11.5, NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (11.5, NE)
	>=65 years	5/ 33 (15.2)	NE (10.4, NE)
	Age (Category 2)		
	<75 years	8/ 75 (10.7)	NE (11.5, NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (12.1, NE)
	male	7/ 57 (12.3)	NE (11.0, NE)
	ECOG PS		
	0	3/ 29 (10.3)	NE (10.4, NE)
	1	5/ 50 (10.0)	NE (11.5, NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	NE (11.5, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (12.1, NE)
	GEJ	7/ 52 (13.5)	NE (11.0, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (12.1, NE)
	other	7/ 59 (11.9)	NE (11.0, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (2.5, NE)
	>=2	7/ 74 (9.5)	NE (11.5, NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (11.5, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (11.5, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.5, NE)
	no	7/ 73 (9.6)	NE (11.5, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.5, NE)
	no	7/ 72 (9.7)	NE (11.5, NE)
	Presence of liver metastasis at baseline		
	yes	6/ 50 (12.0)	NE (11.5, NE)
	no	2/ 29 (6.9)	NE (10.4, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders, PT: Pneumonitis	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (11.5, NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (12.1, NE)
	mild	1/ 14 (7.1)	11.5 (NE , NE)
	Race		
	White	8/ 69 (11.6)	NE (11.5, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (11.5, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Skin and subcutaneous tissue disorders	Overall	26/ 79 (32.9)	NE (9.5, NE)
	Region		
	North America	10/ 34 (29.4)	NE (4.6, NE)
	EU	16/ 45 (35.6)	NE (4.1, NE)
	Age (Category 1)		
	<65 years	16/ 46 (34.8)	NE (4.6, NE)
	>=65 years	10/ 33 (30.3)	NE (4.1, NE)
	Age (Category 2)		
	<75 years	24/ 75 (32.0)	NE (9.5, NE)
	>=75 years	2/ 4 (50.0)	NE (0.4, NE)
	Sex		
	female	11/ 22 (50.0)	2.1 (1.0, NE)
	male	15/ 57 (26.3)	NE (9.5, NE)
	ECOG PS		
	0	10/ 29 (34.5)	NE (2.1, NE)
	1	16/ 50 (32.0)	NE (4.6, NE)
	HER2 Status in central laboratory		
	IHC 3+	24/ 68 (35.3)	NE (4.6, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (0.5, NE)
	Primary tumor location		
	Gastric	13/ 27 (48.1)	2.1 (0.9, NE)
	GEJ	13/ 52 (25.0)	NE (9.5, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	6/ 19 (31.6)	NE (1.4, NE)
	other	20/ 59 (33.9)	NE (4.6, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.3, NE)
	>=2	25/ 74 (33.8)	NE (4.6, NE)
	Previous total gastrectomy		
	no	26/ 79 (32.9)	NE (9.5, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	NE (0.0, NE)
	no	22/ 70 (31.4)	NE (9.5, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	3/ 6 (50.0)	2.1 (0.7, NE)
	no	23/ 73 (31.5)	NE (9.5, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	NE (0.7, NE)
	no	23/ 72 (31.9)	NE (9.5, NE)
	Presence of liver metastasis at baseline		
	yes	16/ 50 (32.0)	NE (4.6, NE)
	no	10/ 29 (34.5)	NE (0.9, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Skin and subcutaneous tissue disorders	Renal impairment at baseline		
	normal	10/ 32 (31.3)	NE (4.6, NE)
	mild	7/ 25 (28.0)	NE (9.5, NE)
	moderate	3/ 8 (37.5)	NE (0.8, NE)
	Hepatic impairment at baseline		
	normal	21/ 64 (32.8)	NE (4.6, NE)
	mild	5/ 14 (35.7)	9.5 (0.5, NE)
	Race		
	White	22/ 69 (31.9)	NE (9.5, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.2, NE)
	Non-Hispanic/Non-Latino	23/ 70 (32.9)	NE (9.5, NE)
	Unknown	2/ 4 (50.0)	NE (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Skin and subcutaneous tissue disorders, PT: Alopecia	Overall	19/ 79 (24.1)	NE (NE , NE)
	Region		
	North America	6/ 34 (17.6)	NE (NE , NE)
	EU	13/ 45 (28.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	11/ 46 (23.9)	NE (NE , NE)
	>=65 years	8/ 33 (24.2)	NE (3.7, NE)
	Age (Category 2)		
	<75 years	17/ 75 (22.7)	NE (NE , NE)
	>=75 years	2/ 4 (50.0)	NE (0.4, NE)
	Sex		
	female	9/ 22 (40.9)	NE (1.4, NE)
	male	10/ 57 (17.5)	NE (NE , NE)
	ECOG PS		
	0	8/ 29 (27.6)	NE (NE , NE)
	1	11/ 50 (22.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	18/ 68 (26.5)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (0.5, NE)
	Primary tumor location		
	Gastric	11/ 27 (40.7)	NE (1.0, NE)
	GEJ	8/ 52 (15.4)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	5/ 19 (26.3)	NE (1.5, NE)
	other	14/ 59 (23.7)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.3, NE)
	>=2	18/ 74 (24.3)	NE (NE , NE)
	Previous total gastrectomy		
	no	19/ 79 (24.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	4/ 9 (44.4)	NE (0.0, NE)
	no	15/ 70 (21.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (1.5, NE)
	no	17/ 73 (23.3)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (1.5, NE)
	no	17/ 72 (23.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	NE (NE , NE)
	no	9/ 29 (31.0)	NE (2.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Skin and subcutaneous tissue disorders, PT: Alopecia	Renal impairment at baseline		
	normal	7/ 32 (21.9)	NE (NE , NE)
	mild	6/ 25 (24.0)	NE (3.7, NE)
	moderate	1/ 8 (12.5)	NE (2.1, NE)
	Hepatic impairment at baseline		
	normal	15/ 64 (23.4)	NE (NE , NE)
	mild	4/ 14 (28.6)	NE (0.5, NE)
	Race		
	White	15/ 69 (21.7)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	3/ 8 (37.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.7, NE)
	Non-Hispanic/Non-Latino	16/ 70 (22.9)	NE (NE , NE)
	Unknown	2/ 4 (50.0)	NE (0.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Vascular disorders	Overall	13/ 79 (16.5)	NE (NE , NE)
	Region		
	North America	6/ 34 (17.6)	NE (NE , NE)
	EU	7/ 45 (15.6)	NE (10.6, NE)
	Age (Category 1)		
	<65 years	7/ 46 (15.2)	NE (10.6, NE)
	>=65 years	6/ 33 (18.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	10/ 75 (13.3)	NE (NE , NE)
	>=75 years	3/ 4 (75.0)	5.3 (1.2, NE)
	Sex		
	female	5/ 22 (22.7)	NE (6.3, NE)
	male	8/ 57 (14.0)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	11/ 50 (22.0)	NE (10.6, NE)
	HER2 Status in central laboratory		
	IHC 3+	11/ 68 (16.2)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (1.4, NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	NE (NE , NE)
	GEJ	9/ 52 (17.3)	NE (10.6, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (6.3, NE)
	other	10/ 59 (16.9)	NE (10.6, NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (3.0, NE)
	>=2	12/ 74 (16.2)	NE (NE , NE)
	Previous total gastrectomy		
	no	13/ 79 (16.5)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (3.0, NE)
	no	12/ 70 (17.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	2/ 6 (33.3)	NE (2.8, NE)
	no	11/ 73 (15.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	3/ 7 (42.9)	NE (0.0, NE)
	no	10/ 72 (13.9)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	11/ 50 (22.0)	NE (10.6, NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Vascular disorders	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	6/ 25 (24.0)	NE (10.6, NE)
	moderate	1/ 8 (12.5)	NE (6.3, NE)
	Hepatic impairment at baseline		
	normal	10/ 64 (15.6)	NE (NE , NE)
	mild	3/ 14 (21.4)	10.6 (4.2, NE)
	Race		
	White	11/ 69 (15.9)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	4.2 (NE , NE)
	Other	1/ 8 (12.5)	NE (2.8, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.0, NE)
	Non-Hispanic/Non-Latino	11/ 70 (15.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
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Protocol DS8201-A-U205
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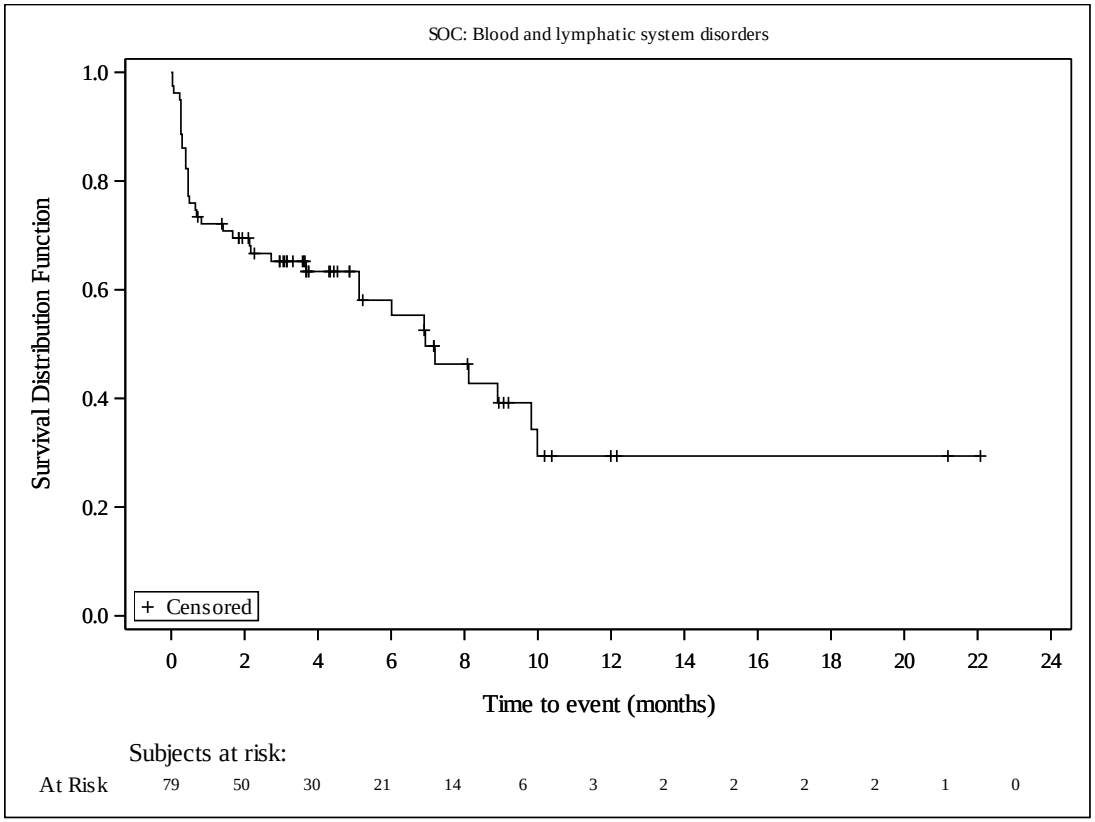
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
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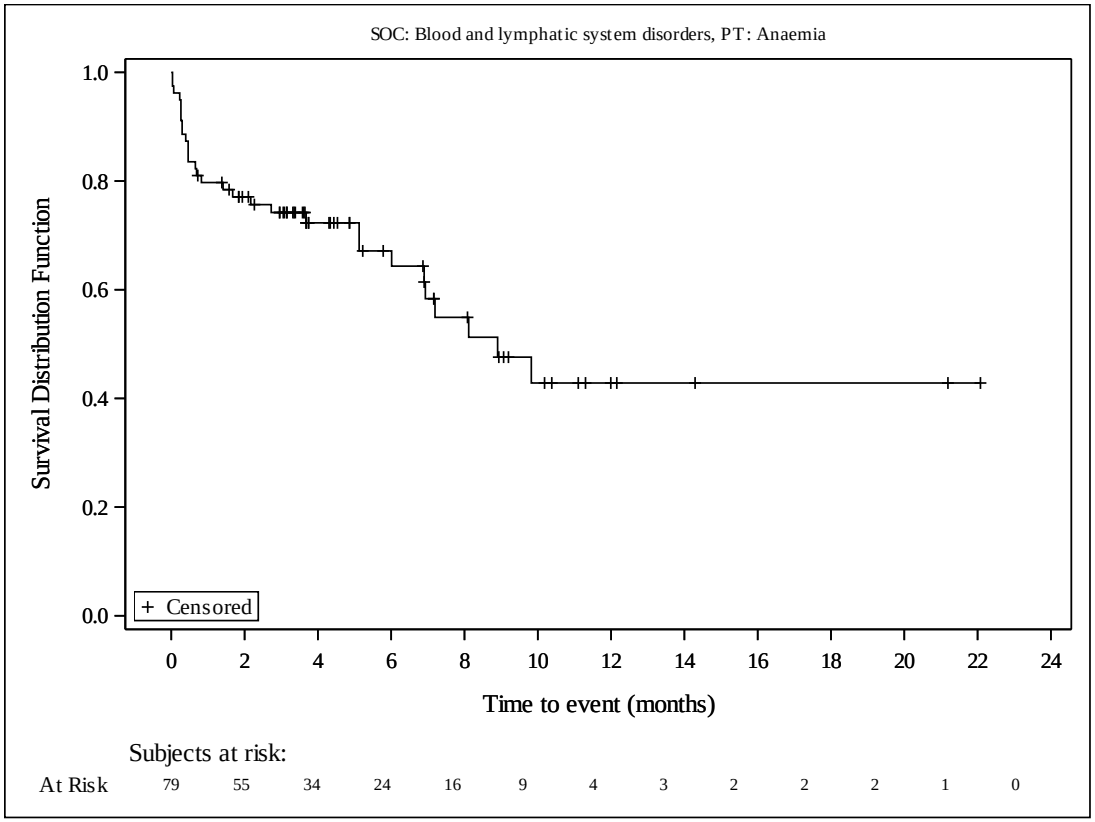
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
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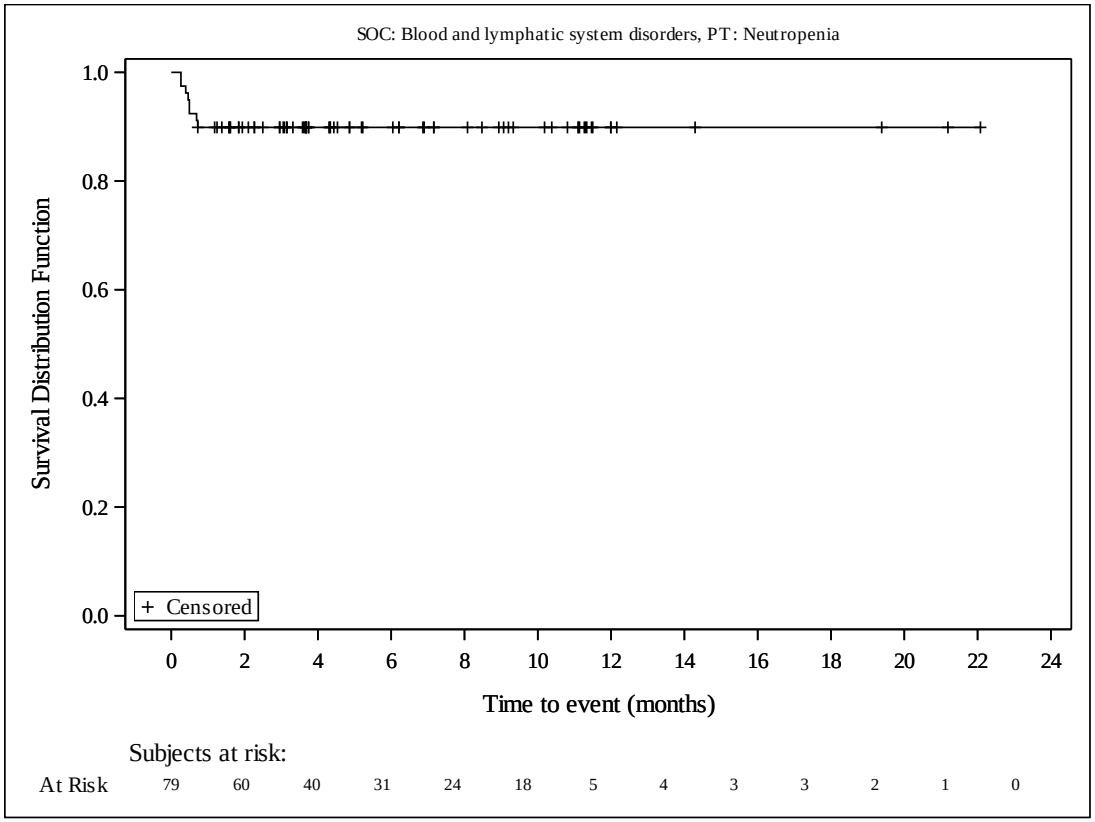
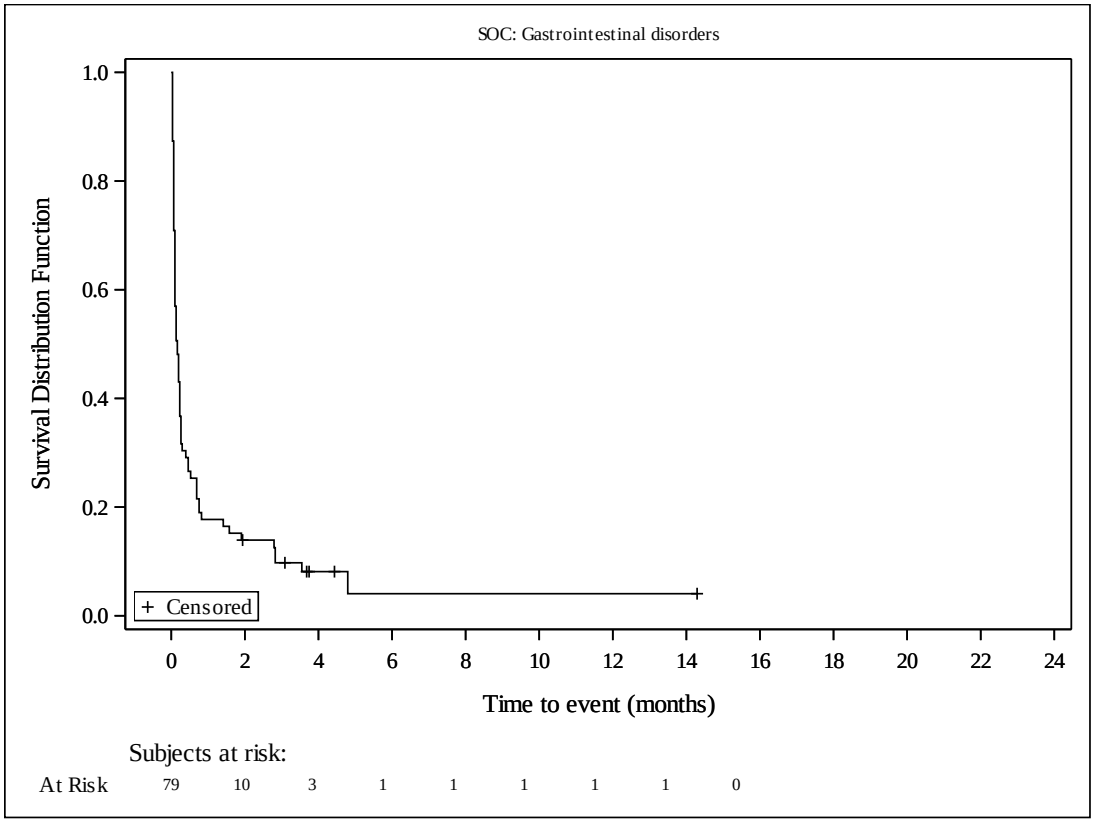
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
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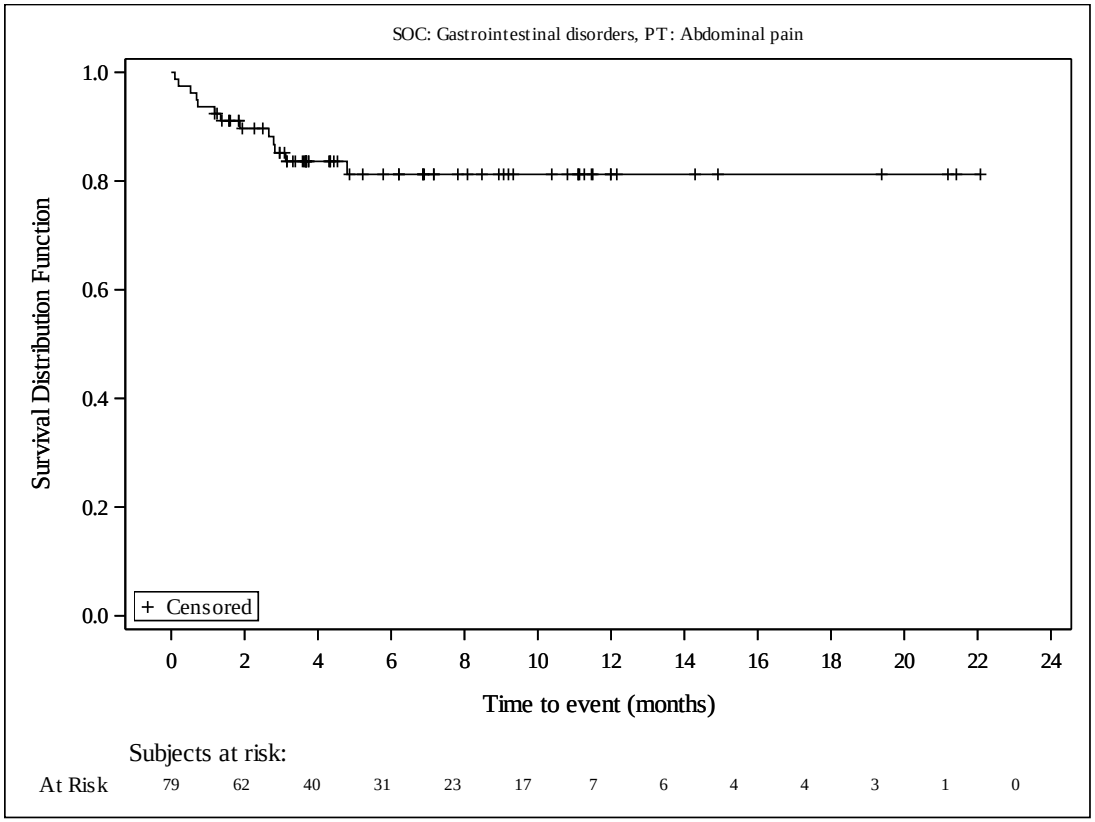
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

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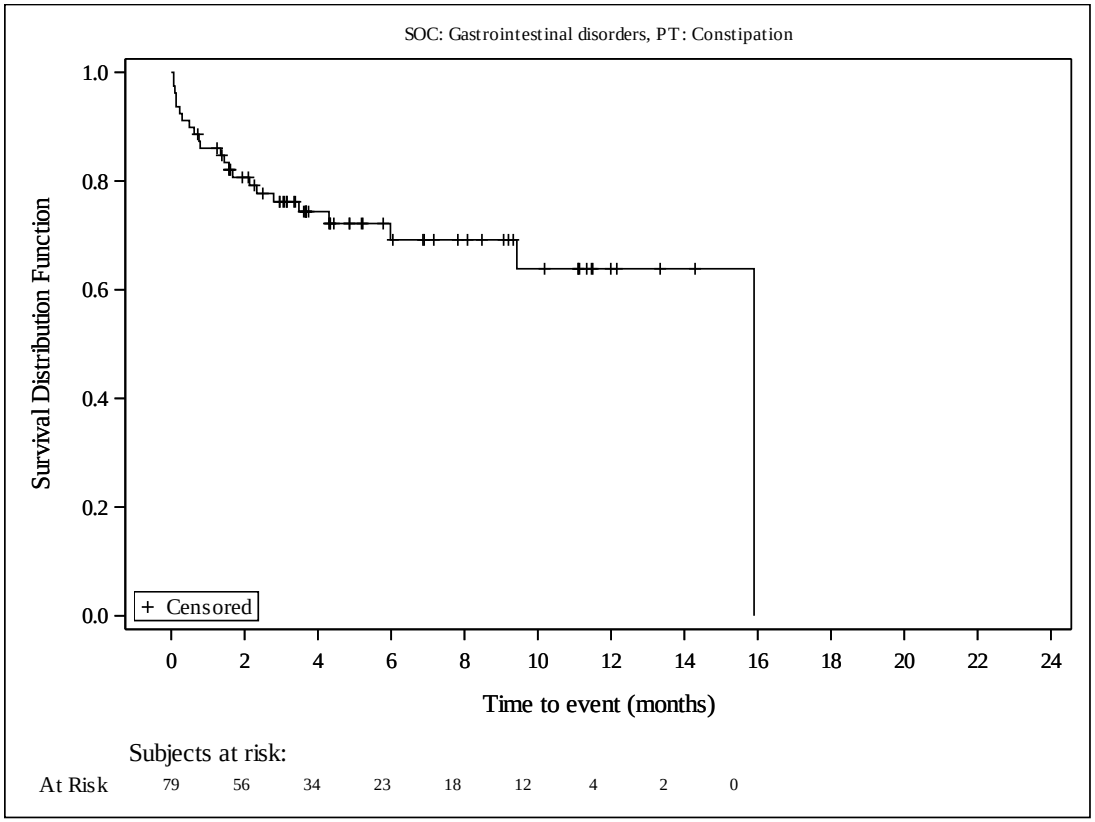
Safety Analysis Set



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Protocol DS8201-A-U205
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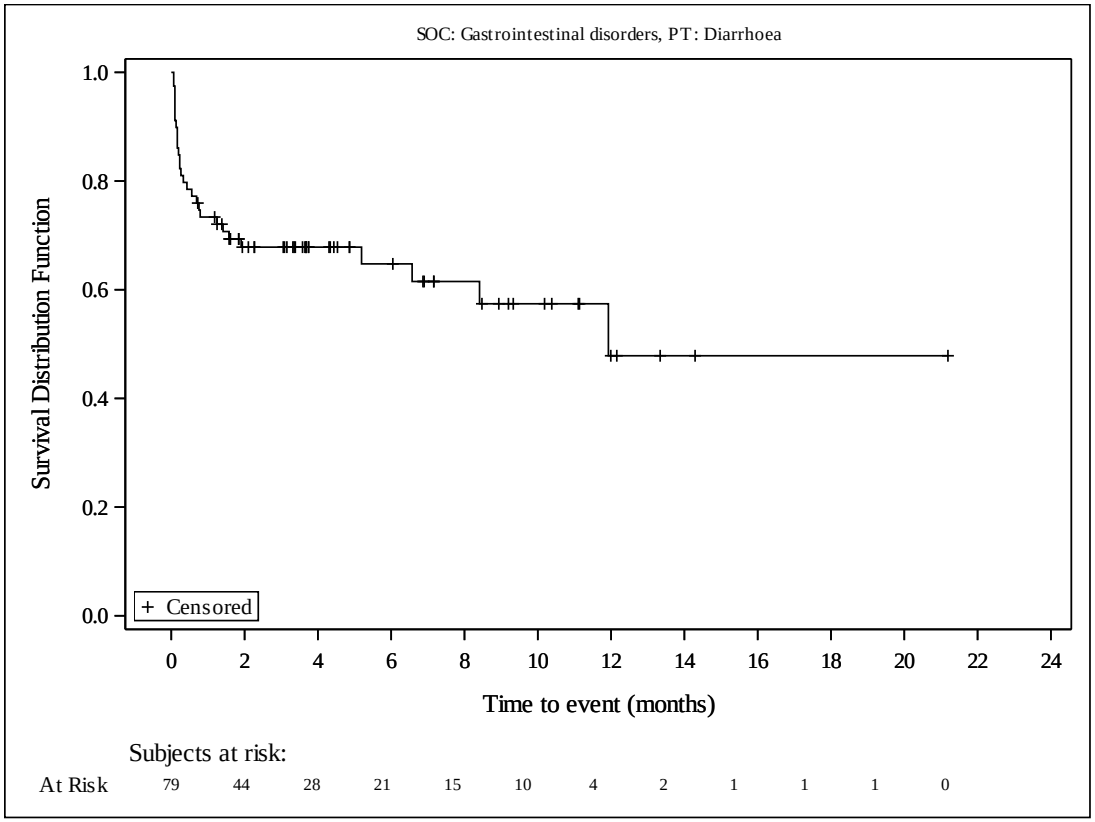

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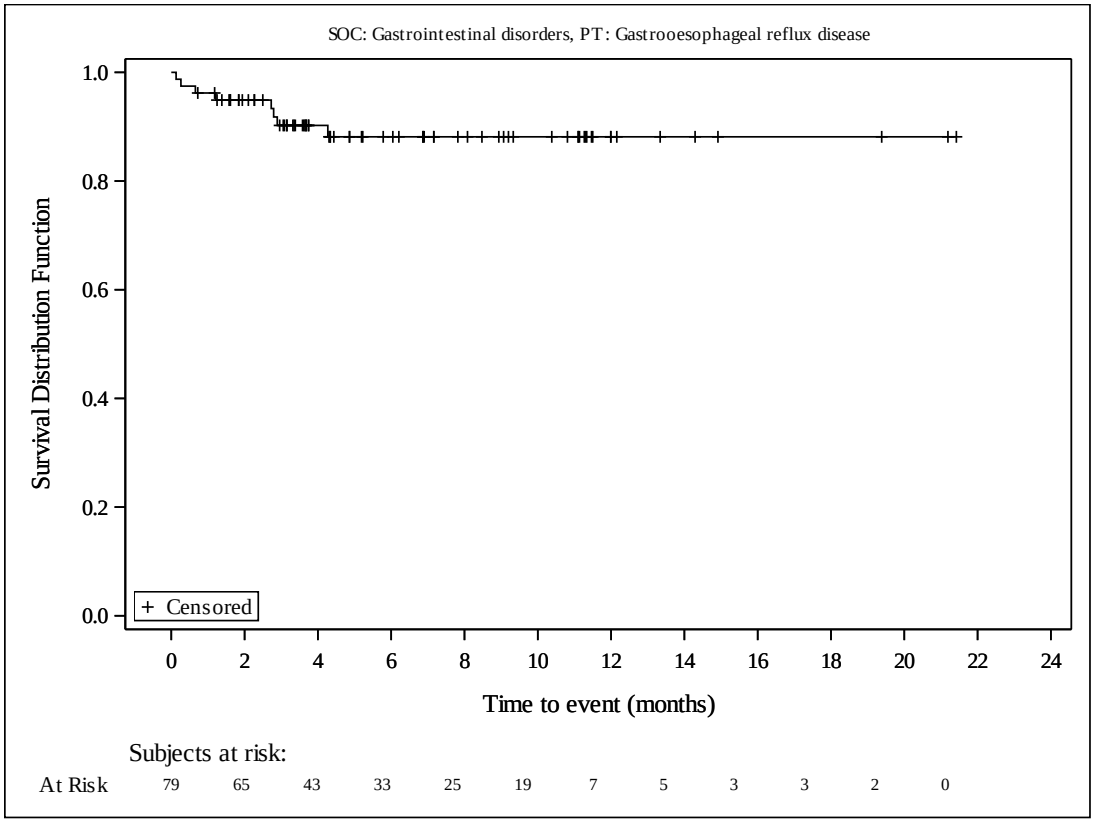

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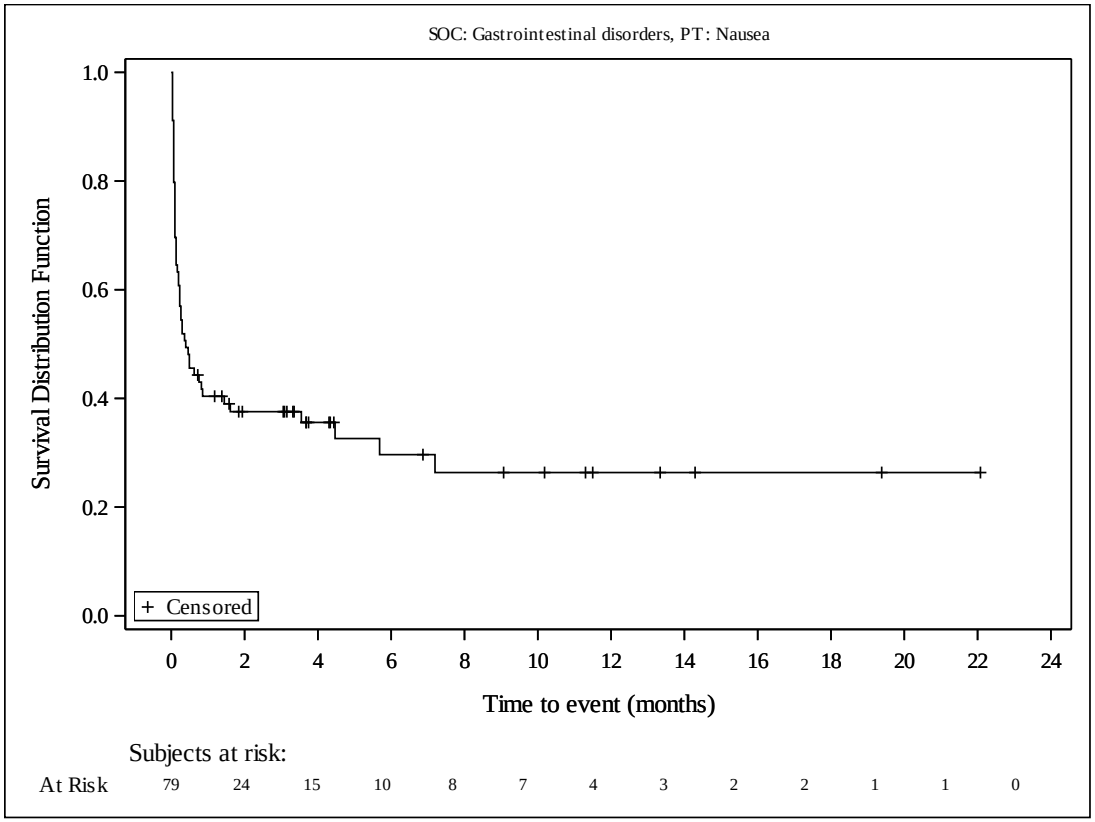

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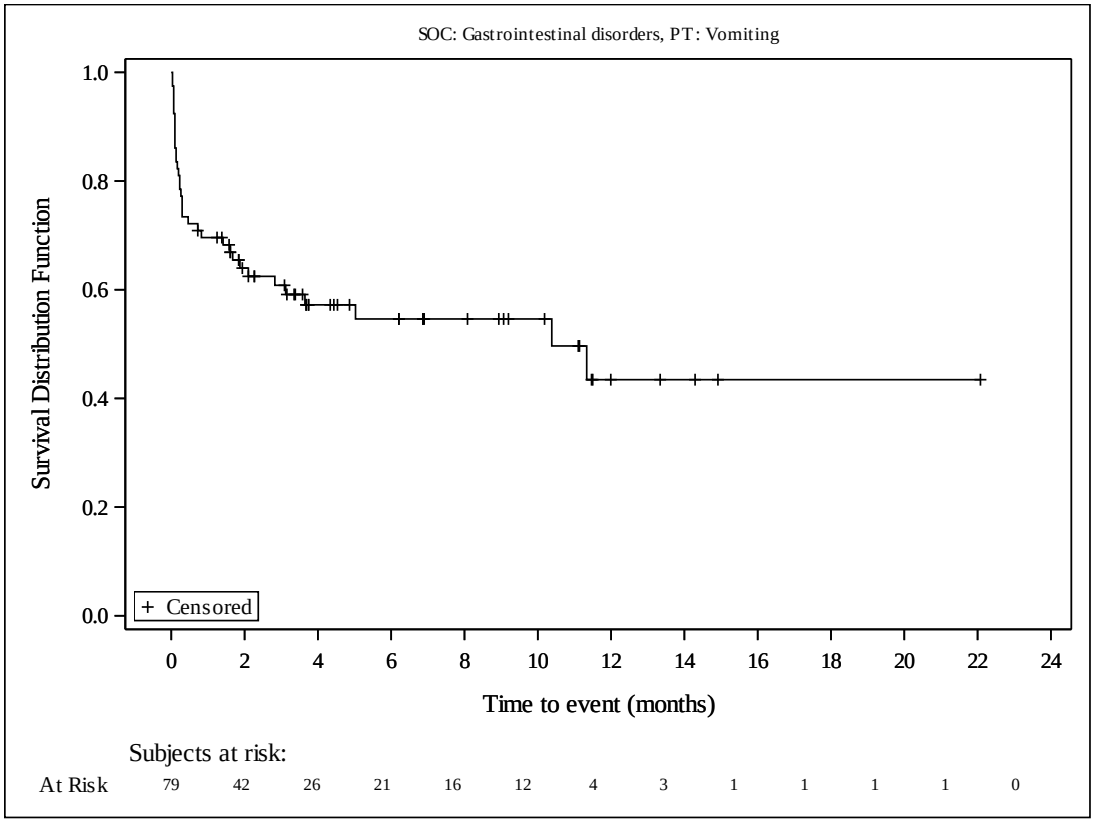

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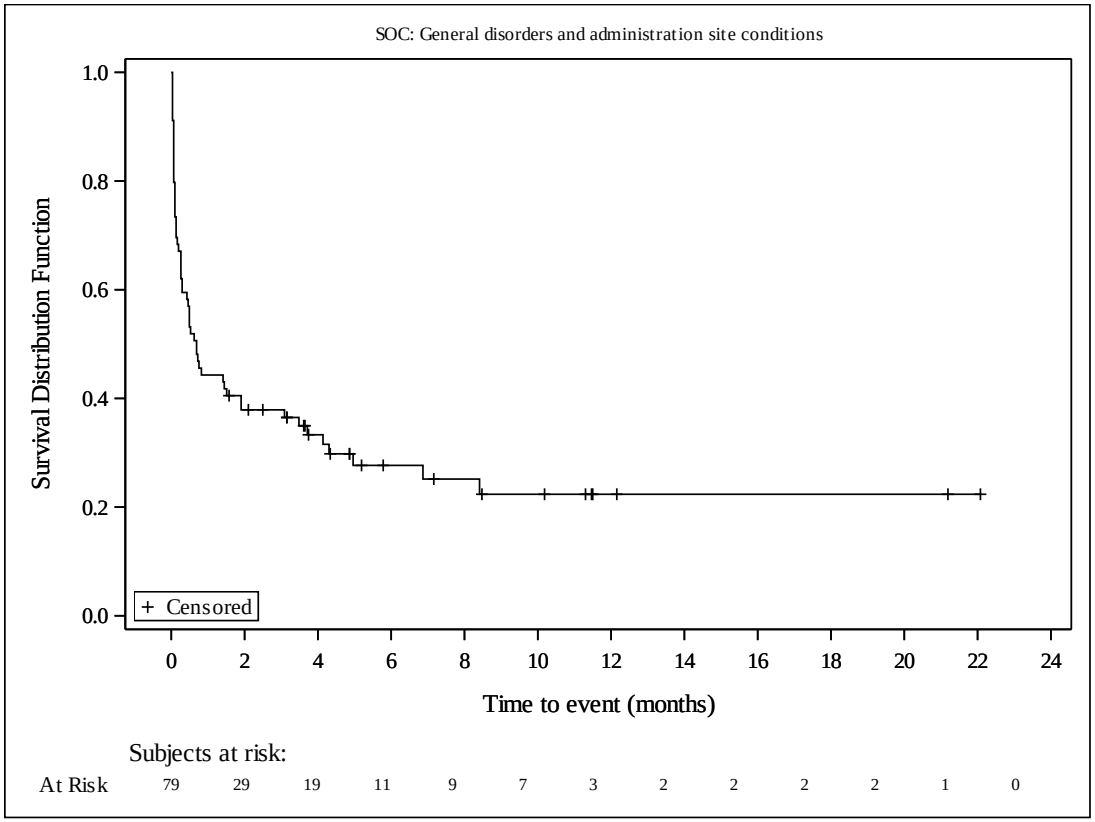

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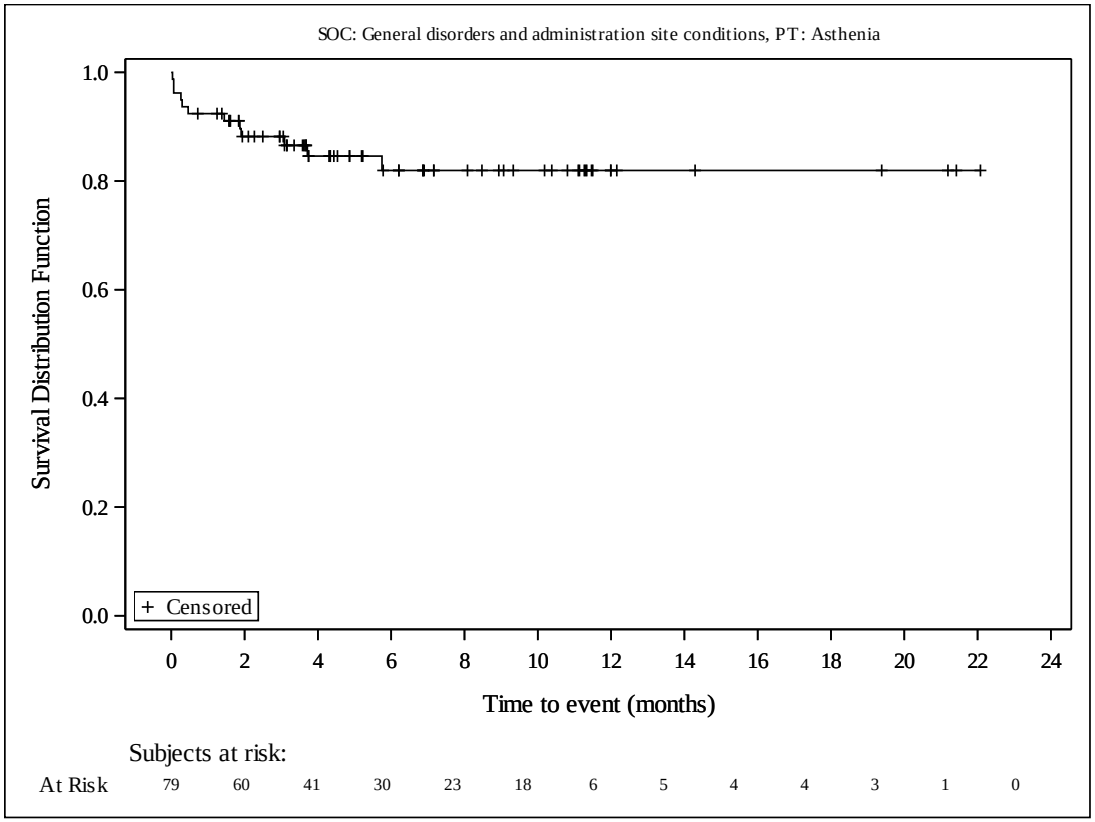

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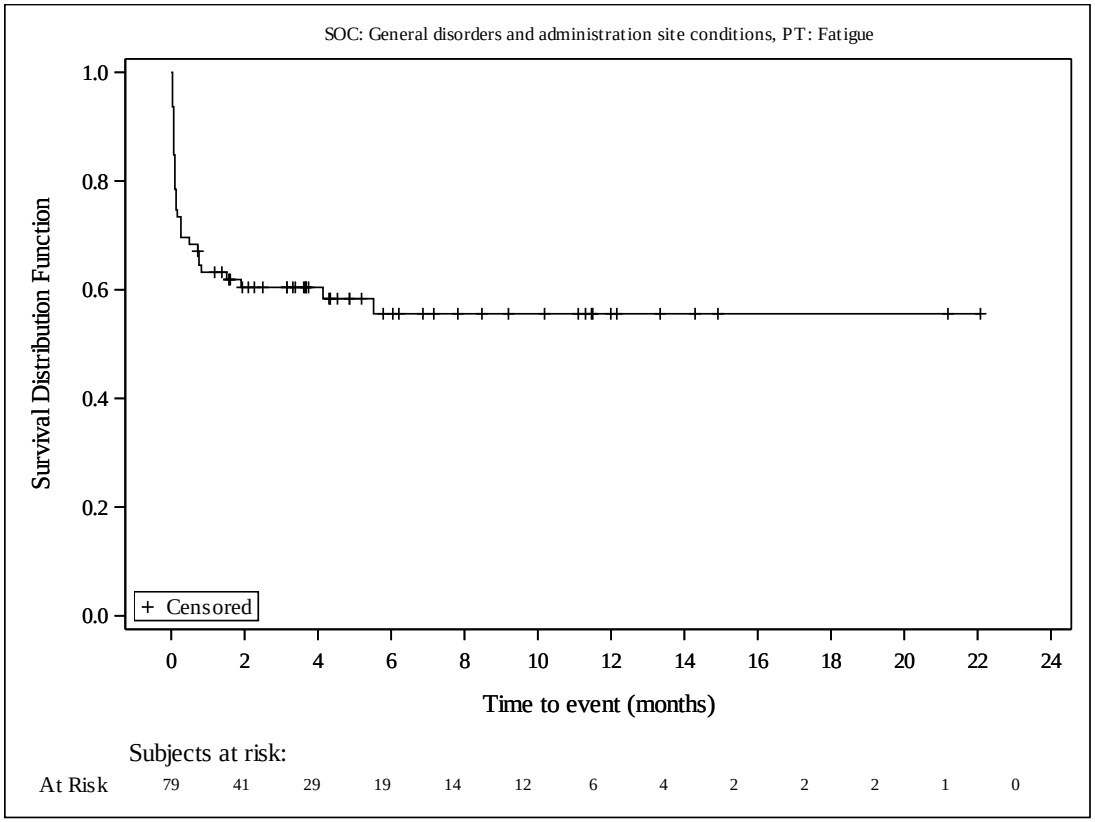

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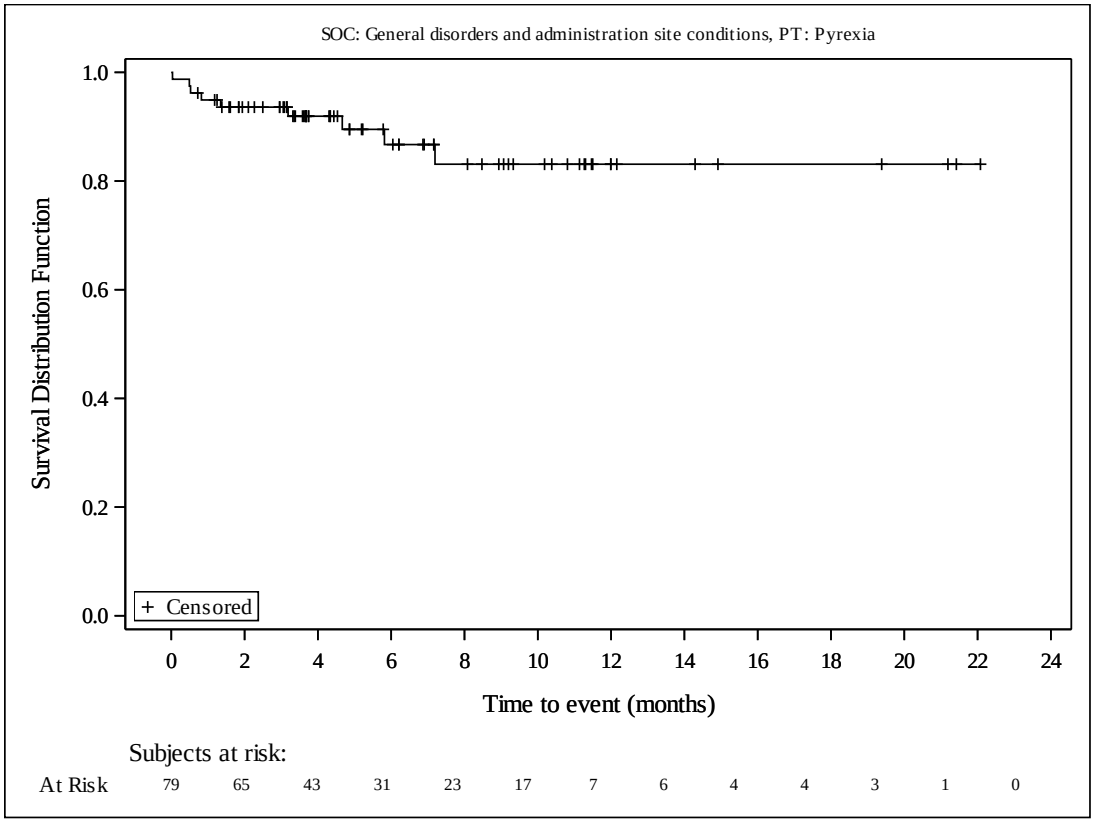

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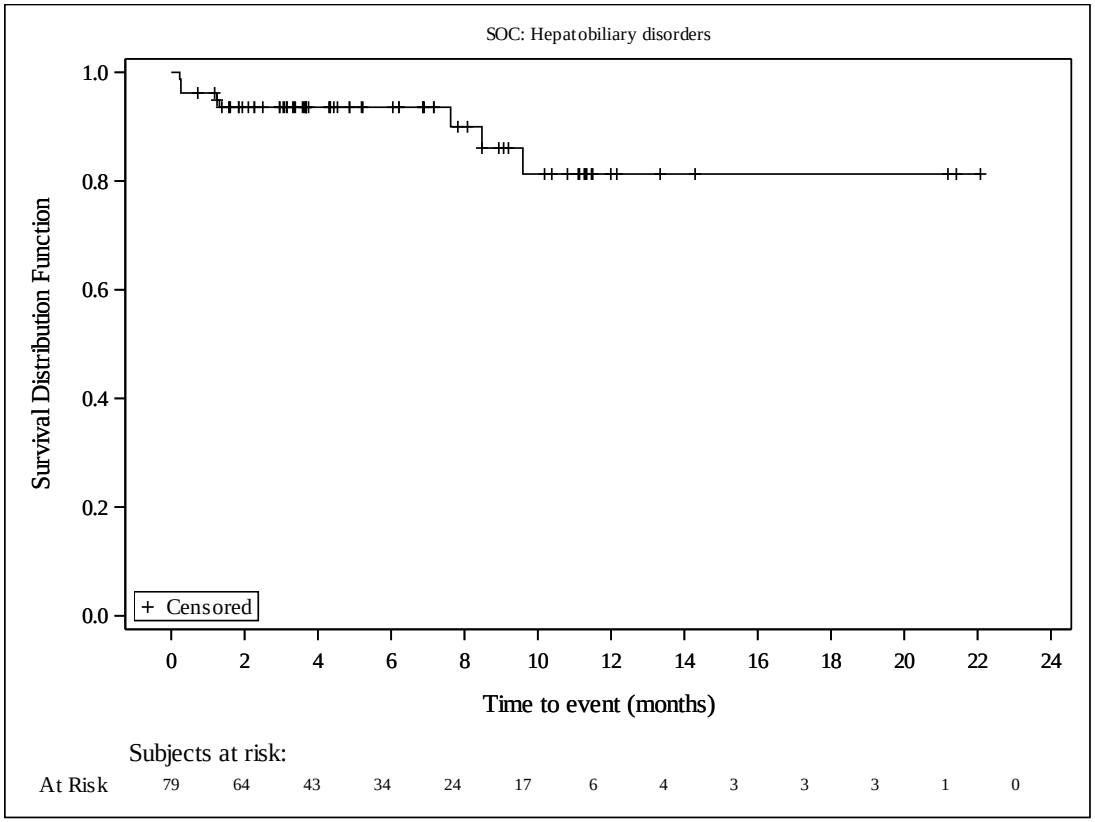

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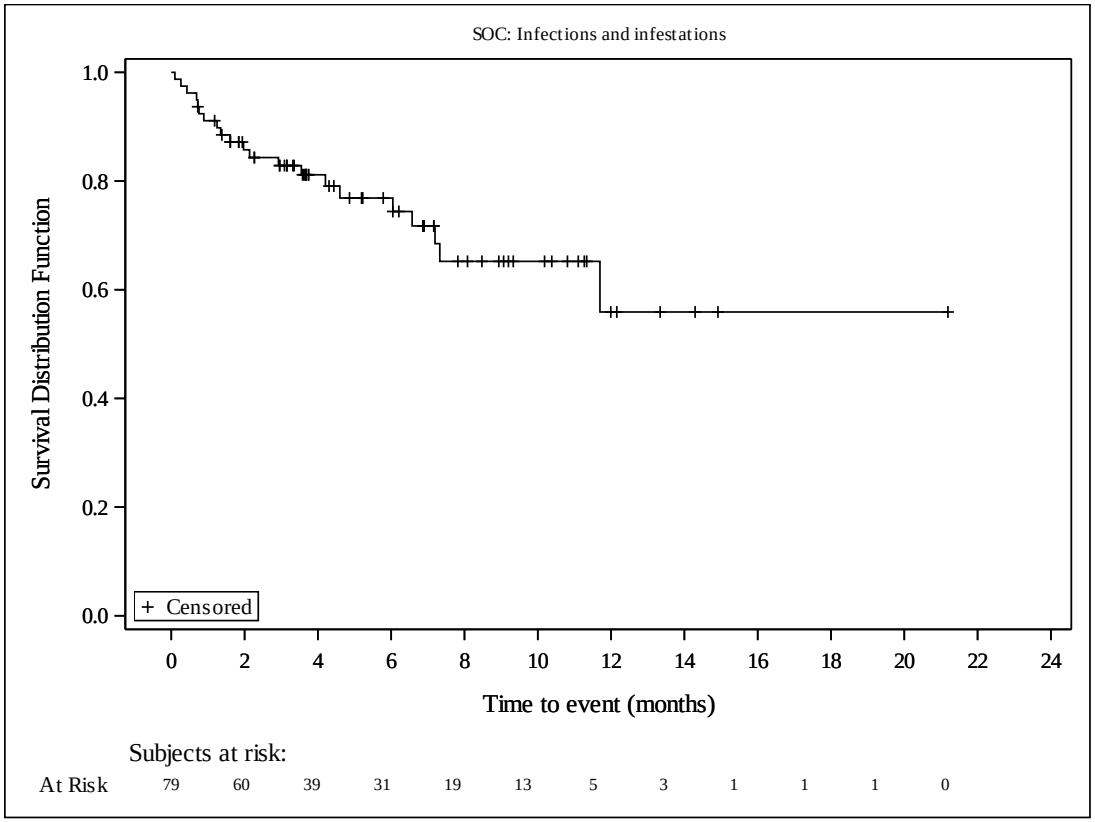

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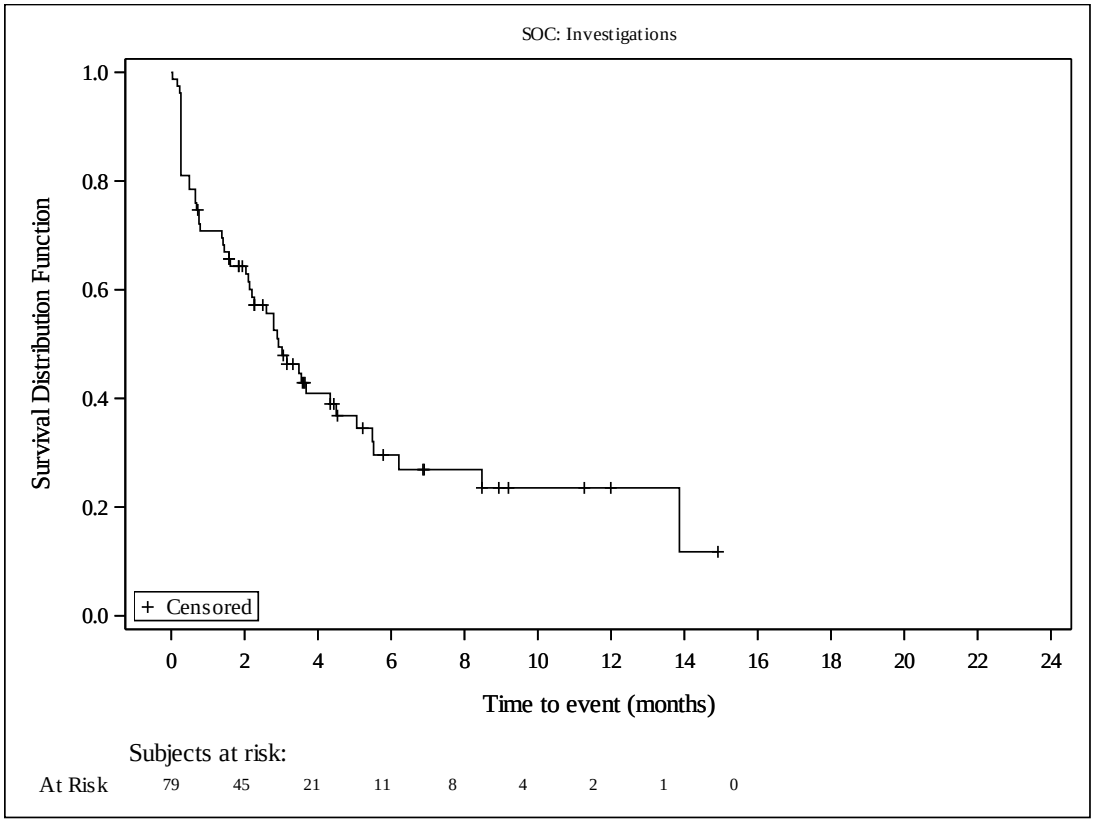

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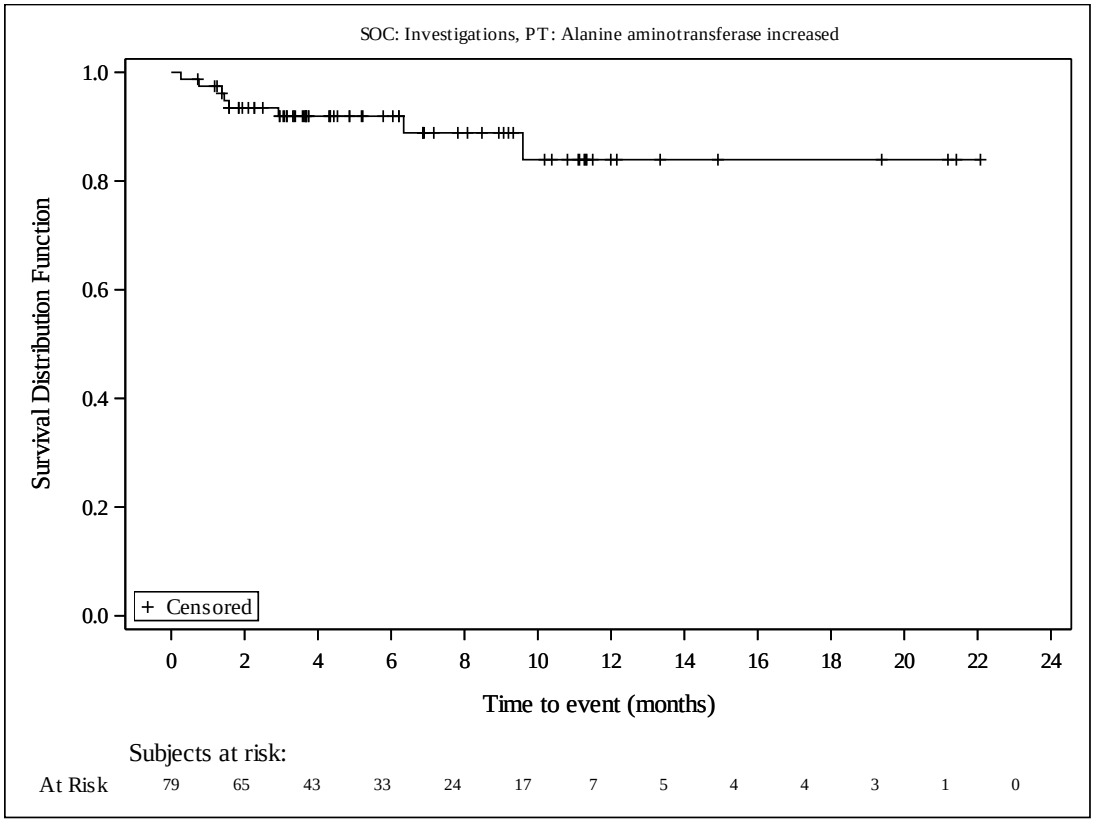

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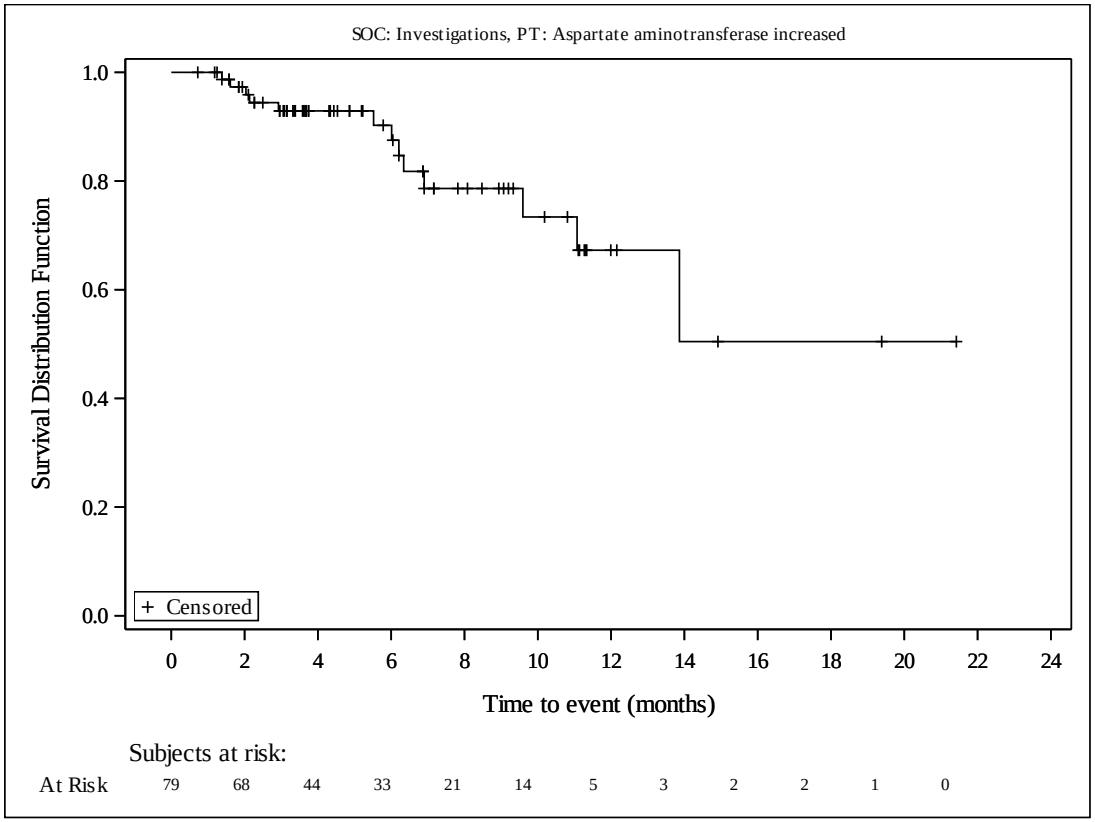

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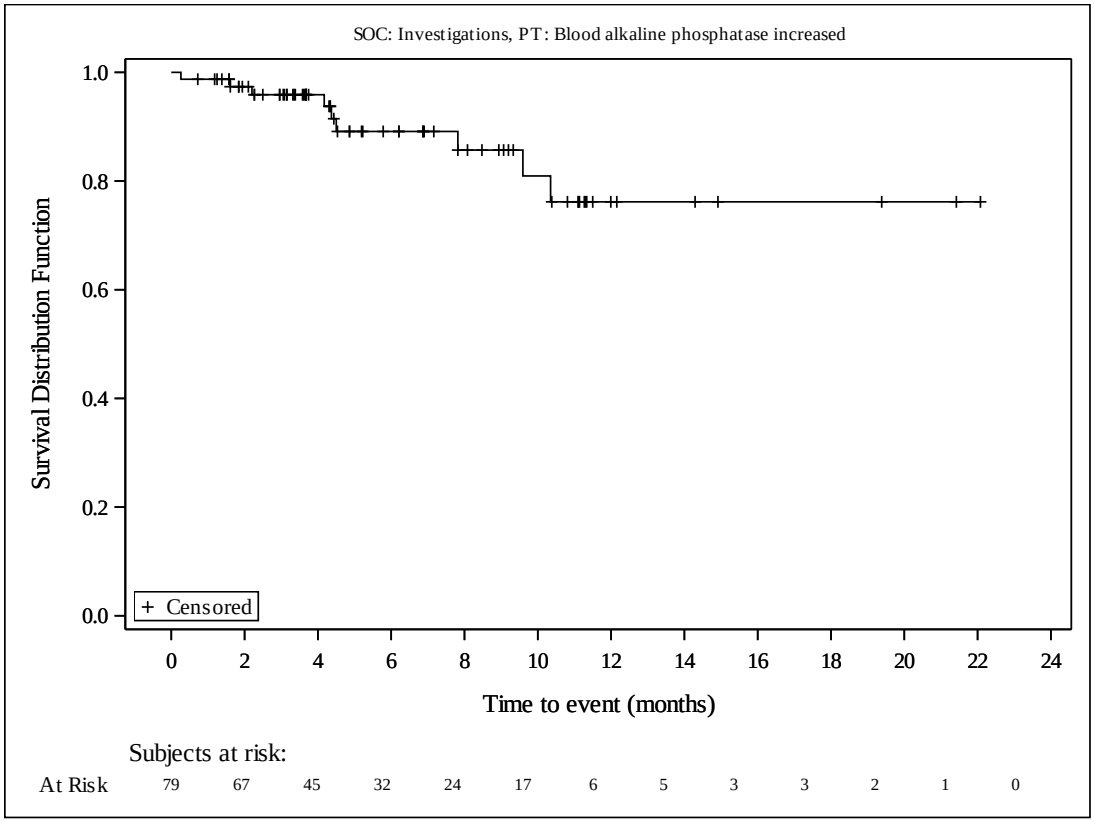

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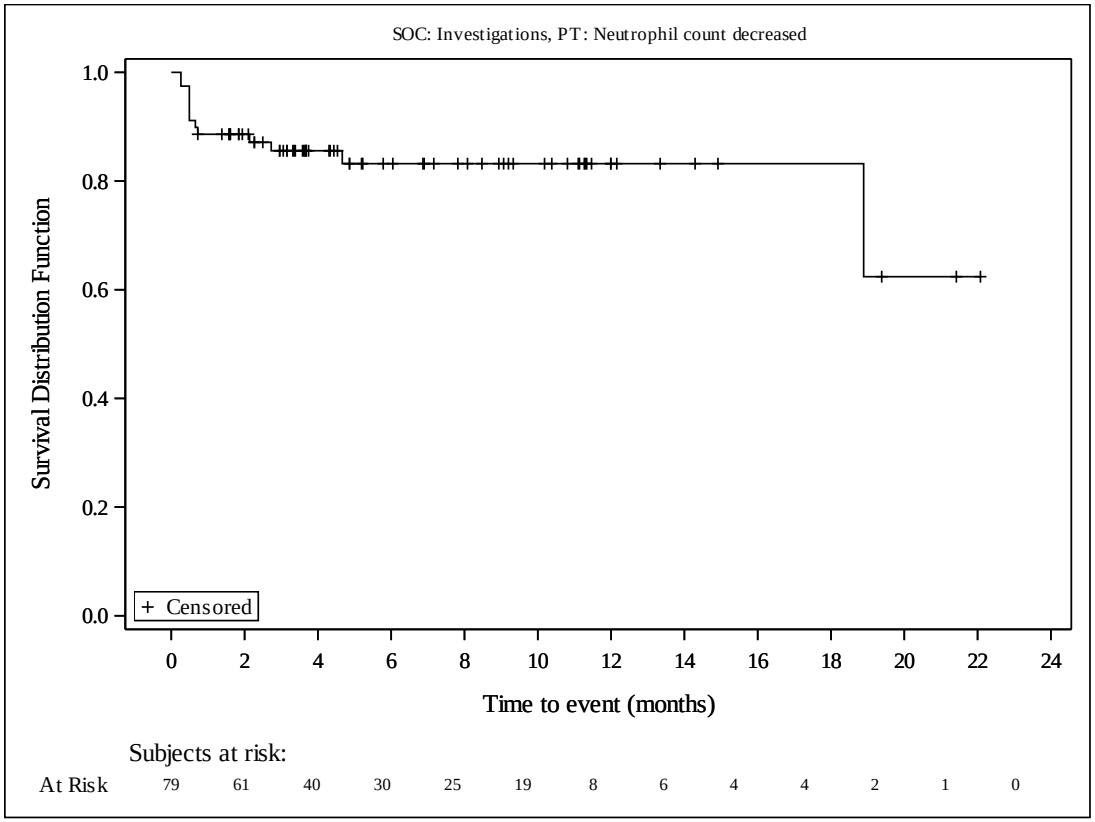

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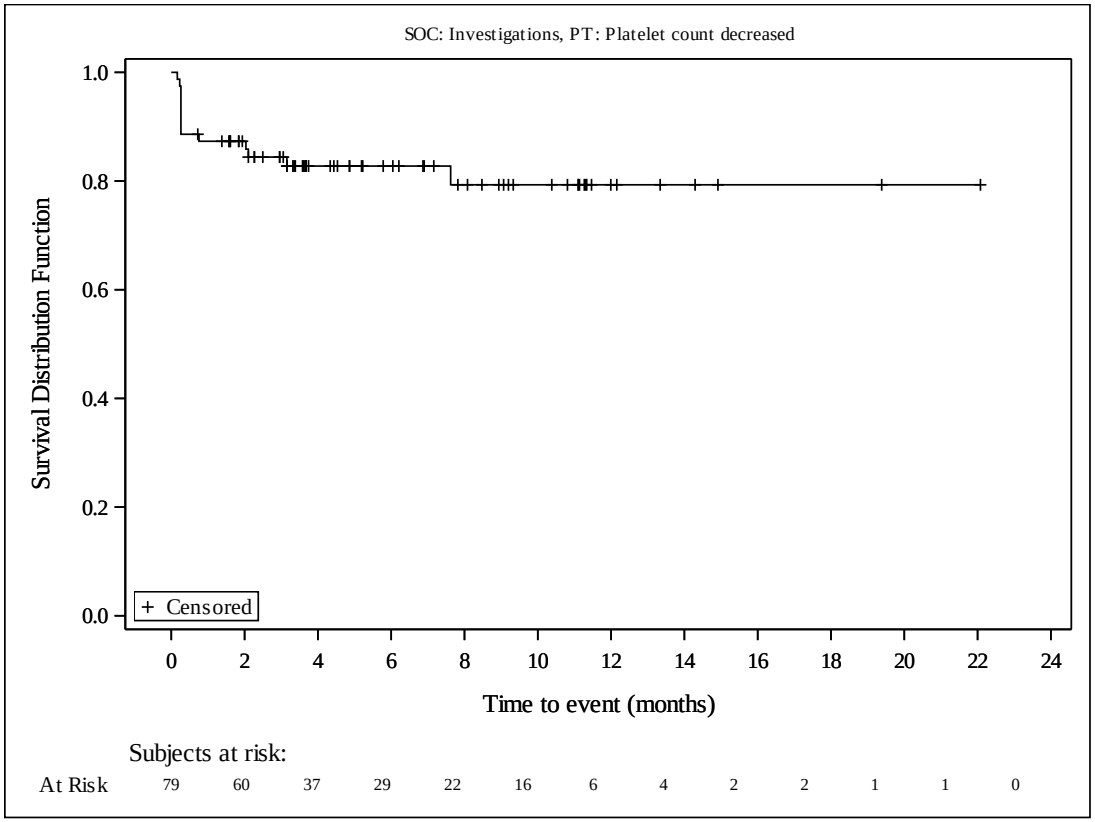

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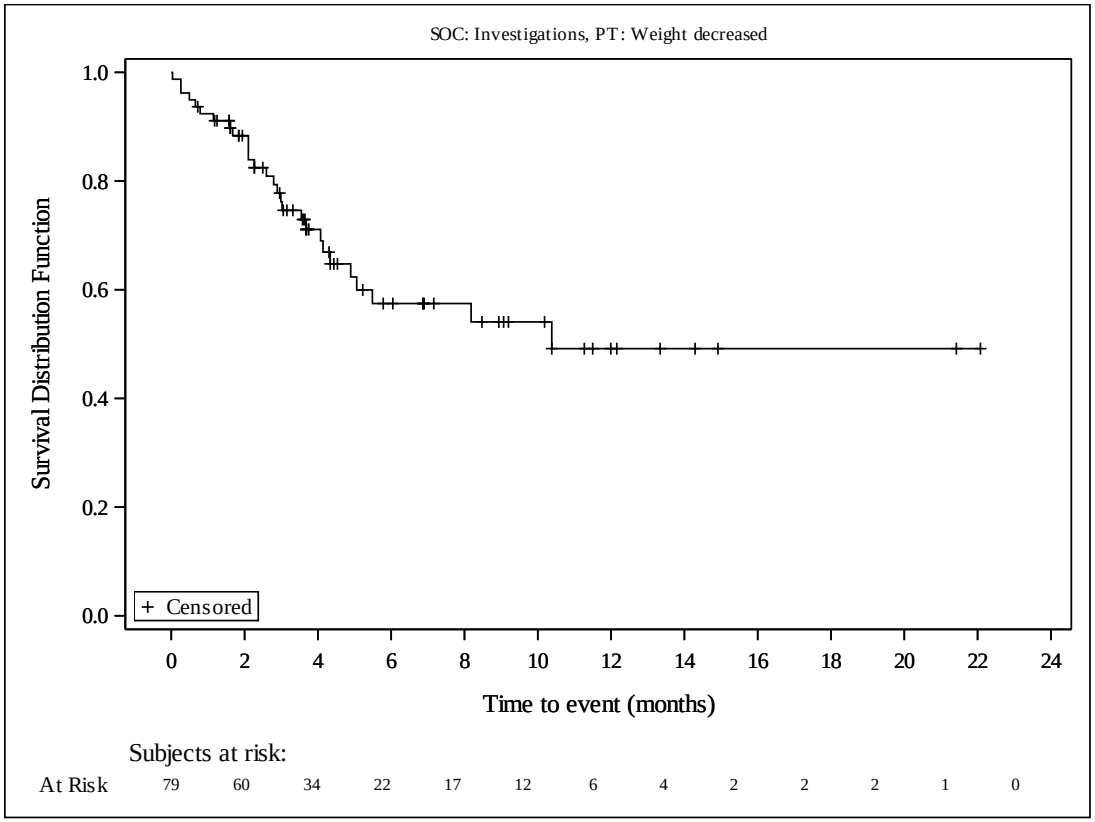

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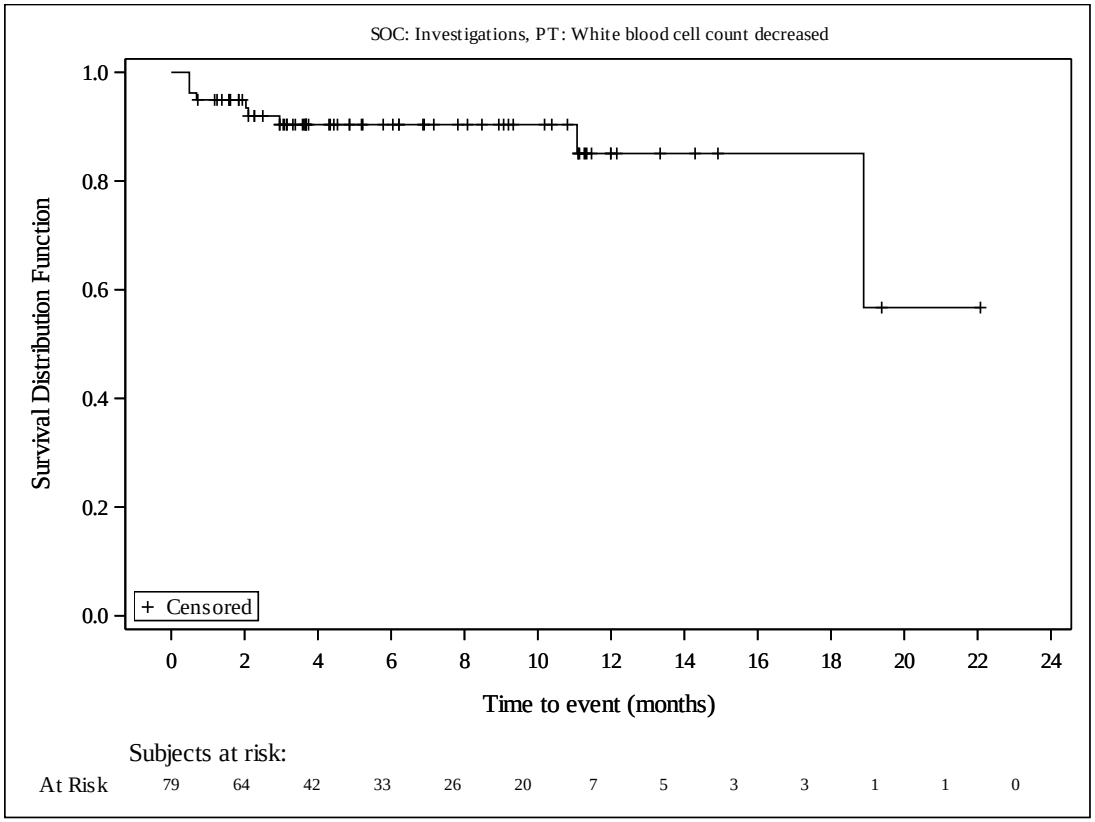

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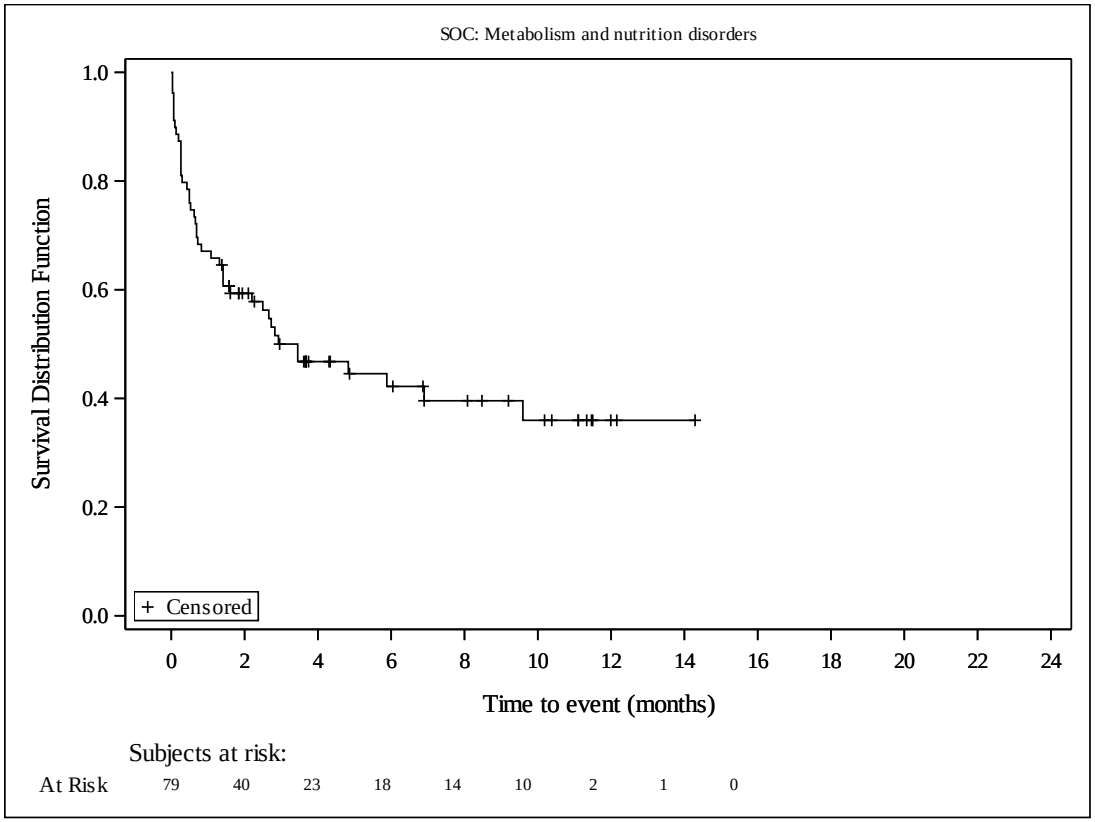

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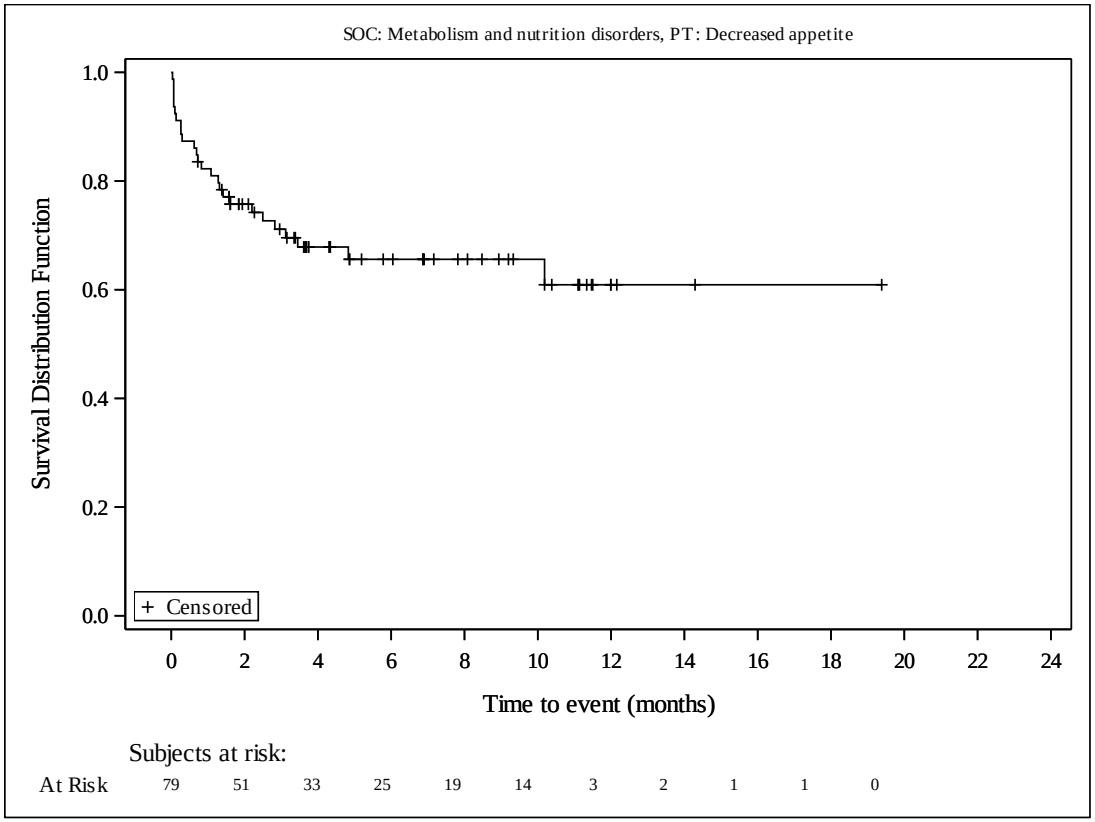

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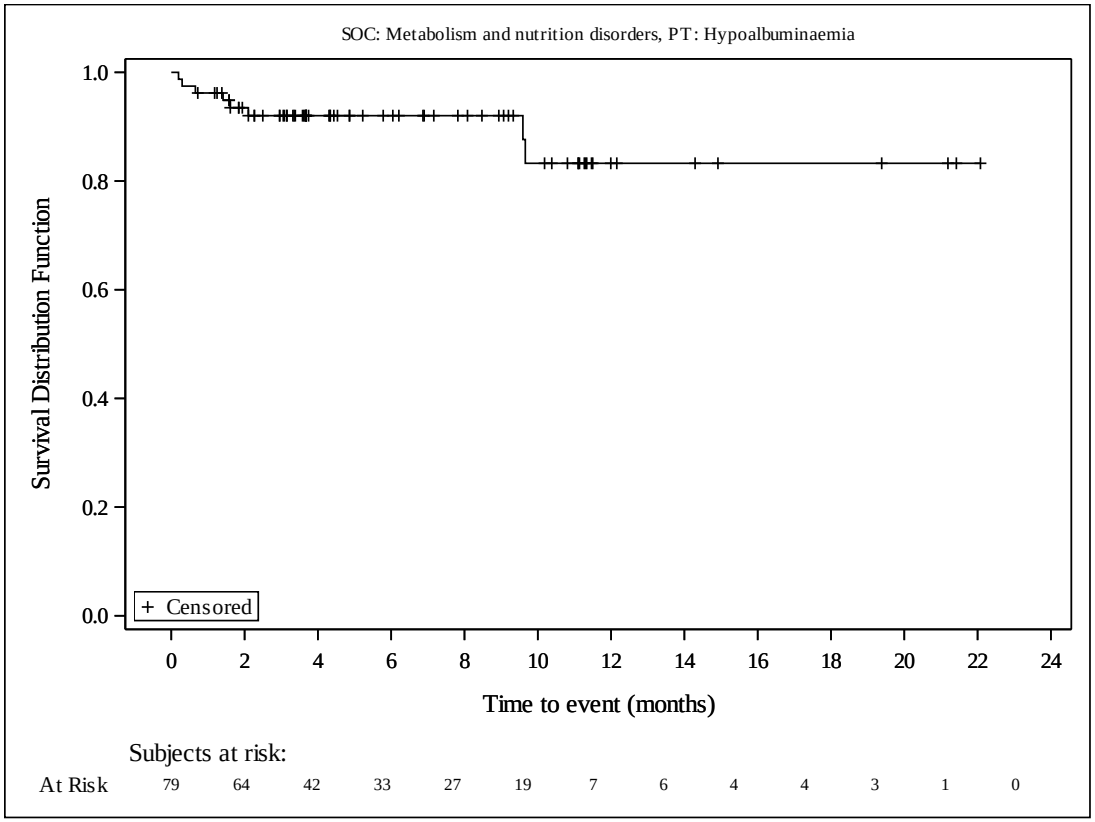

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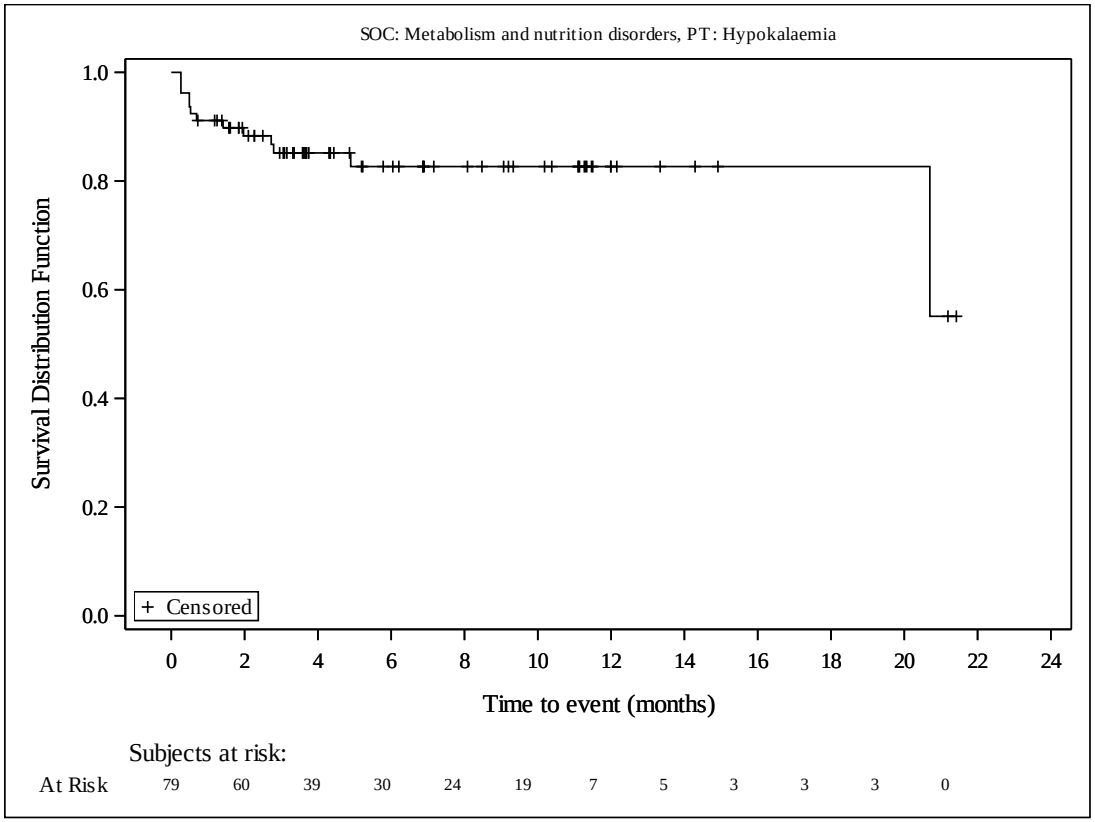

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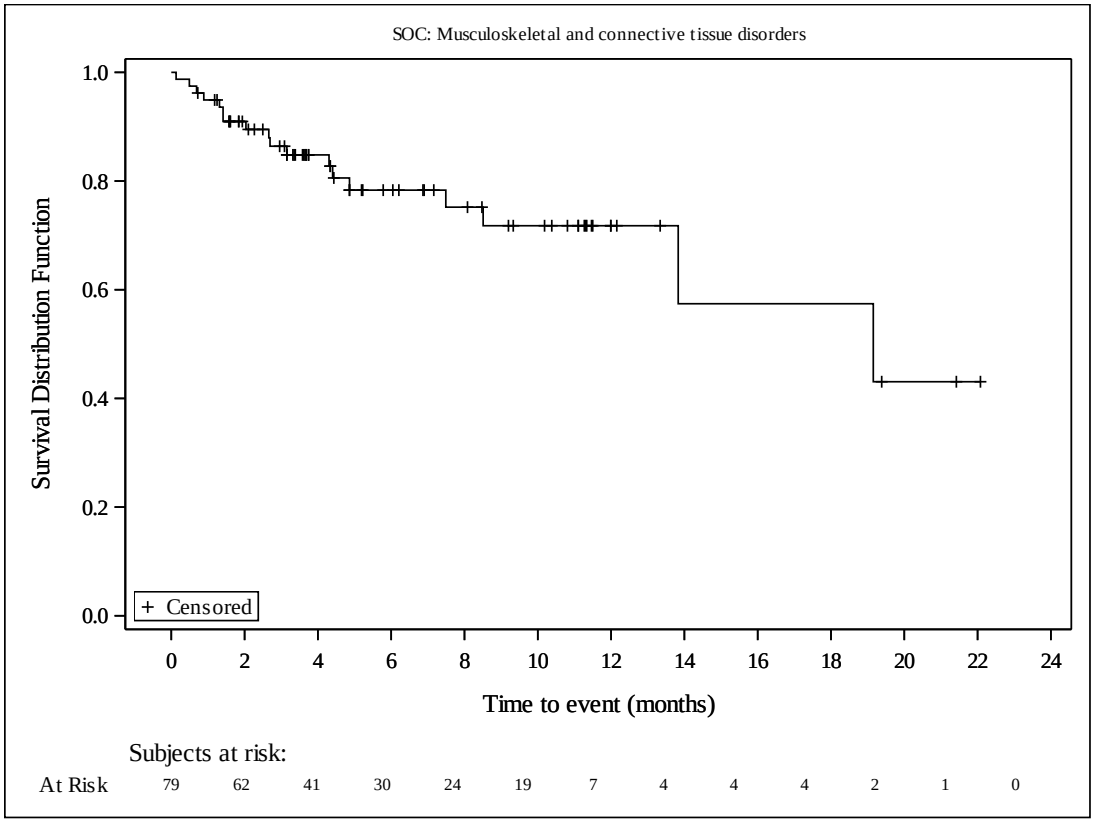

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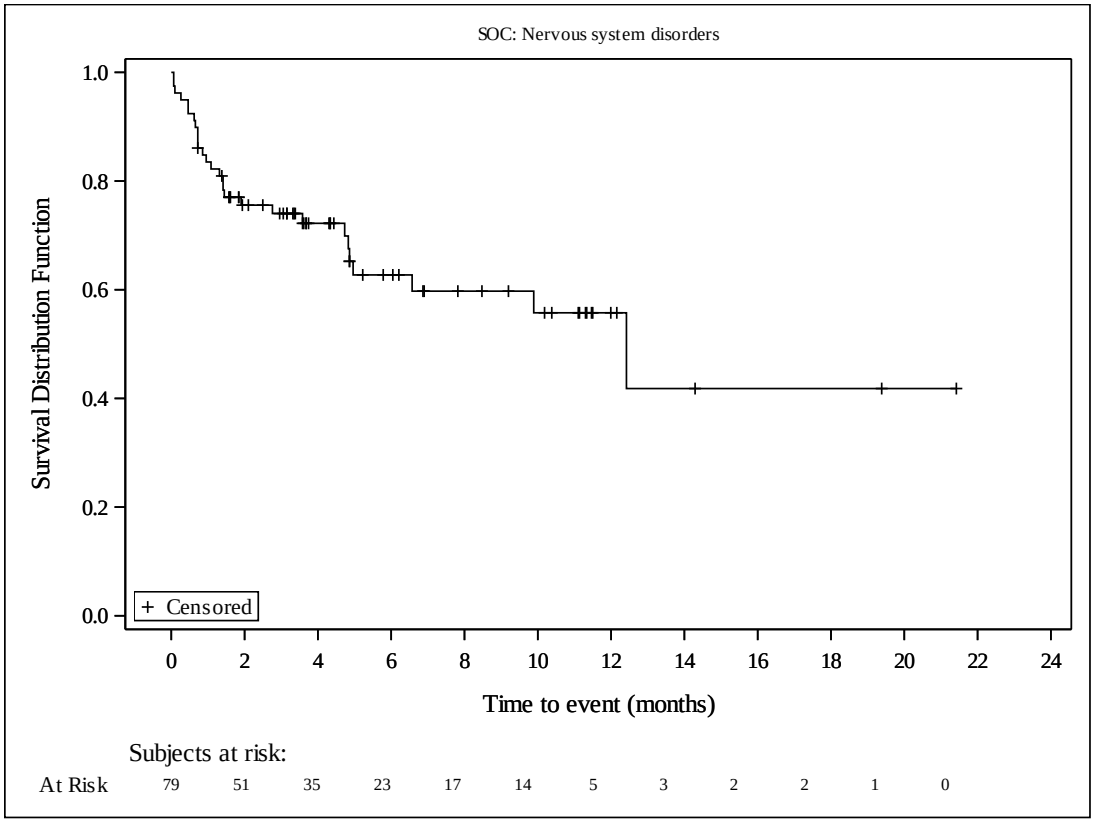

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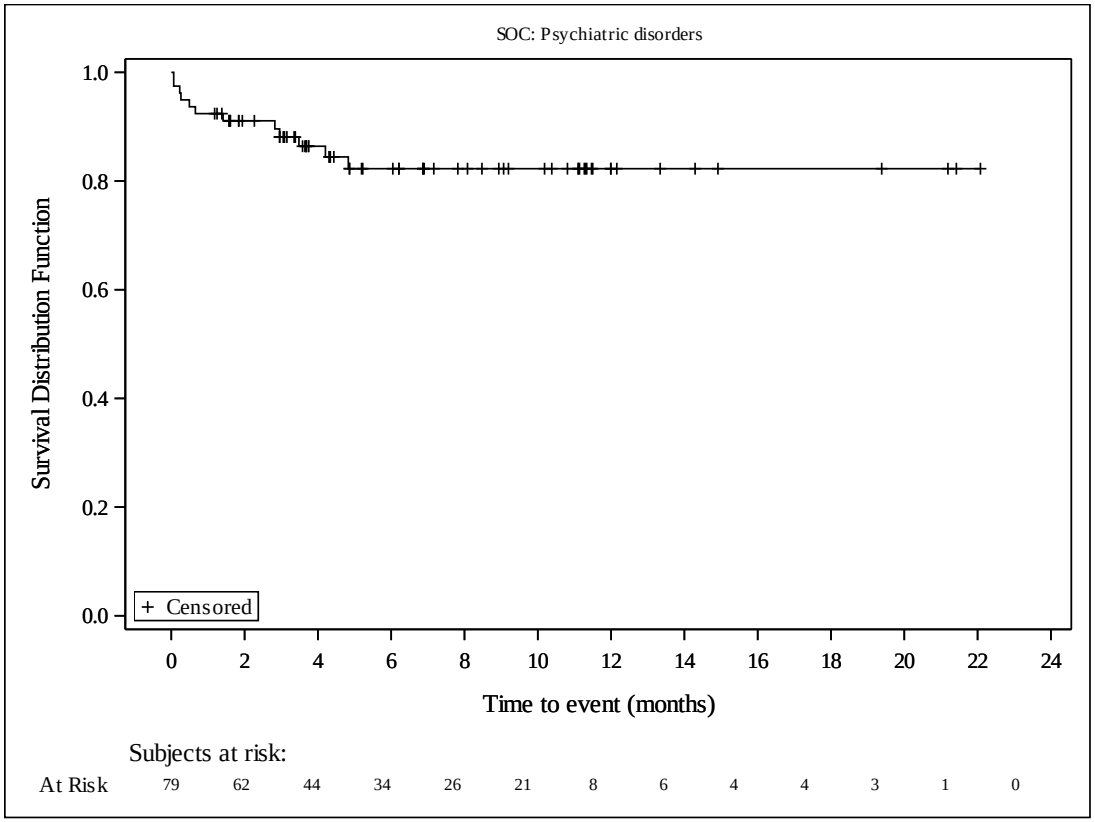

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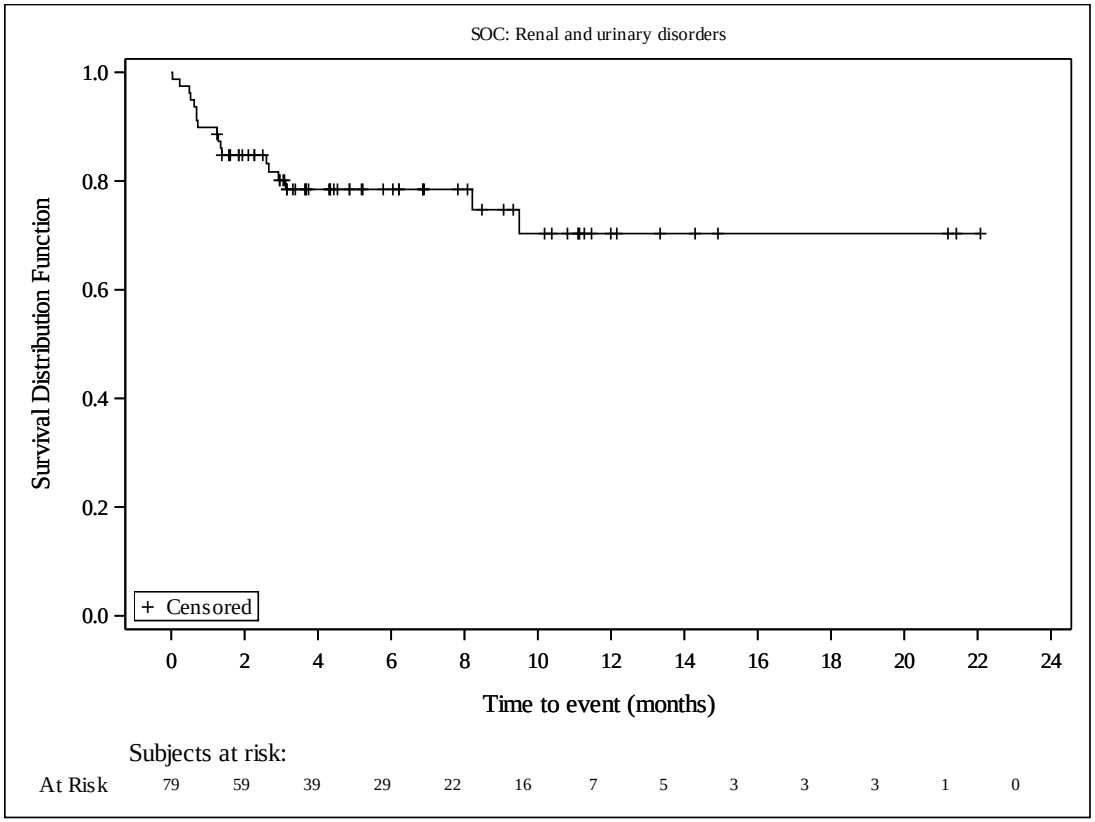
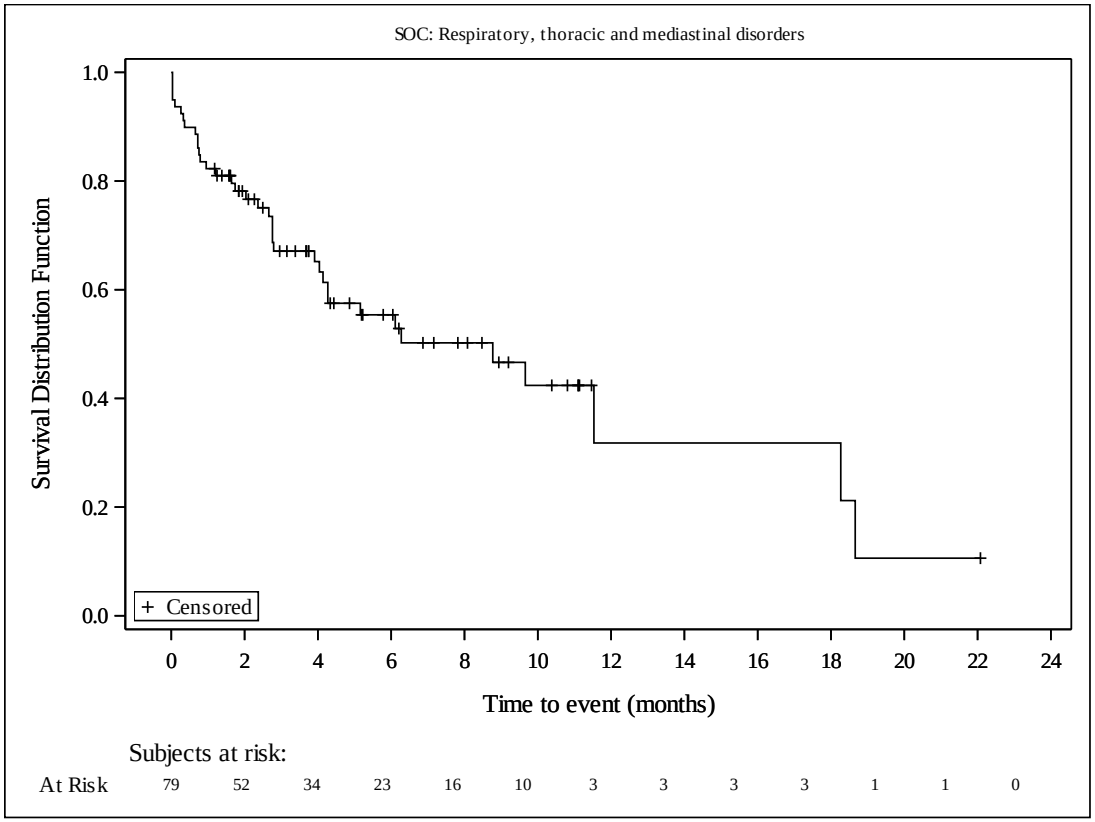


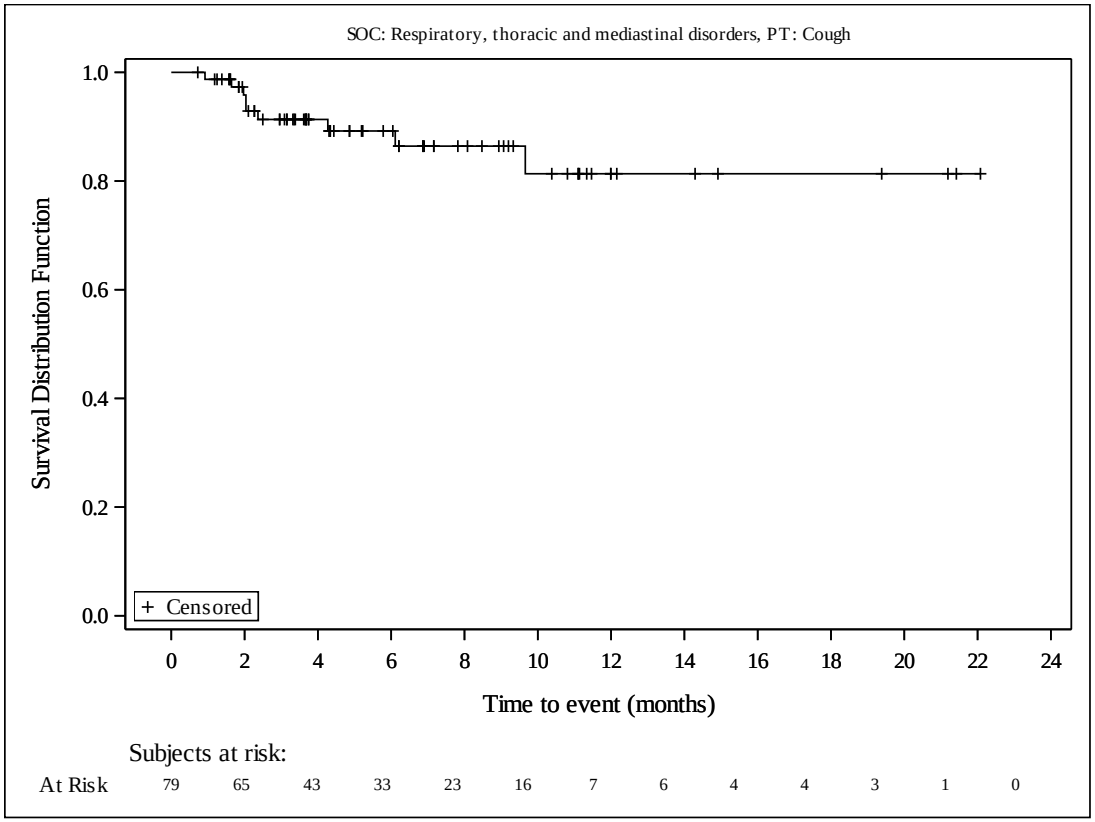
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



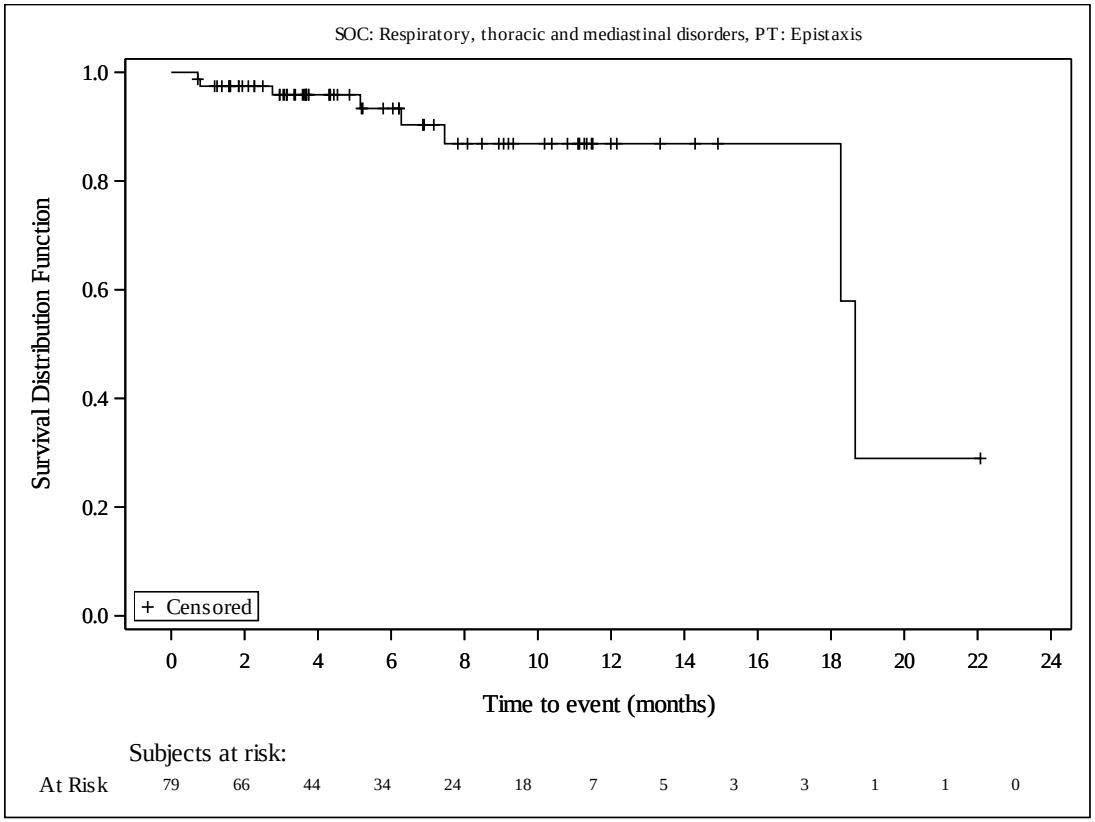
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



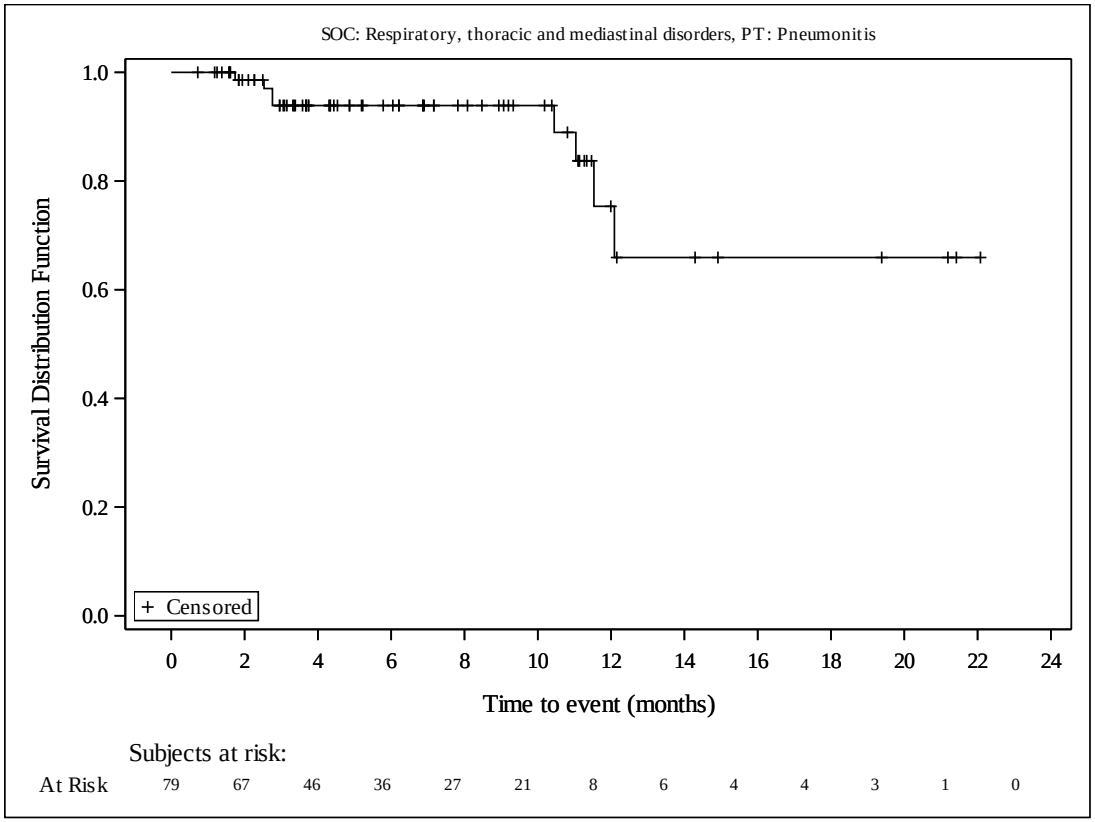
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



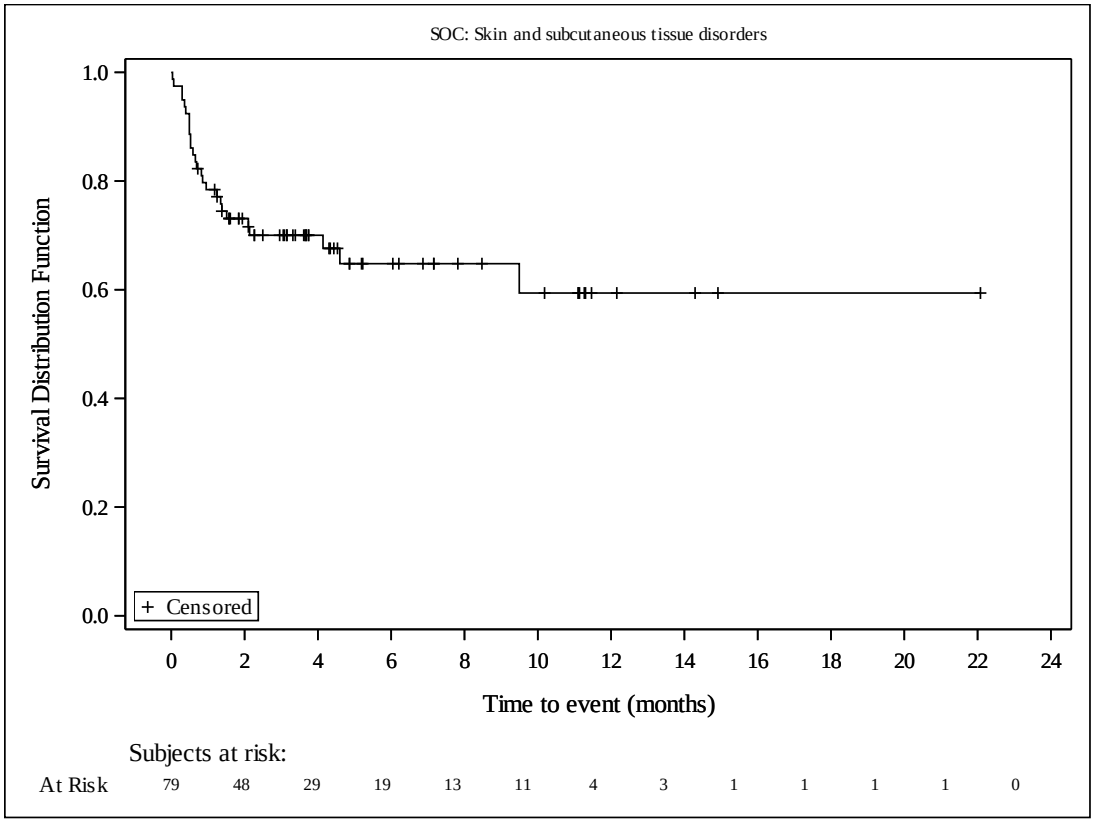
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



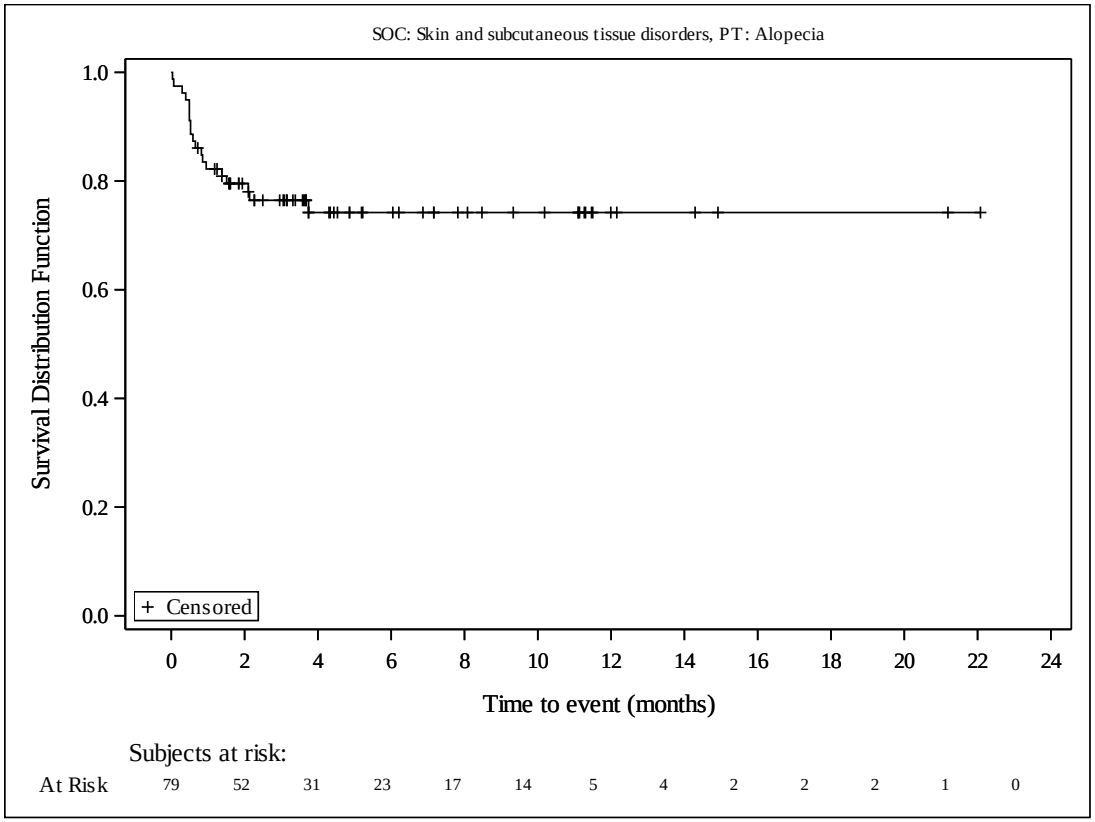
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



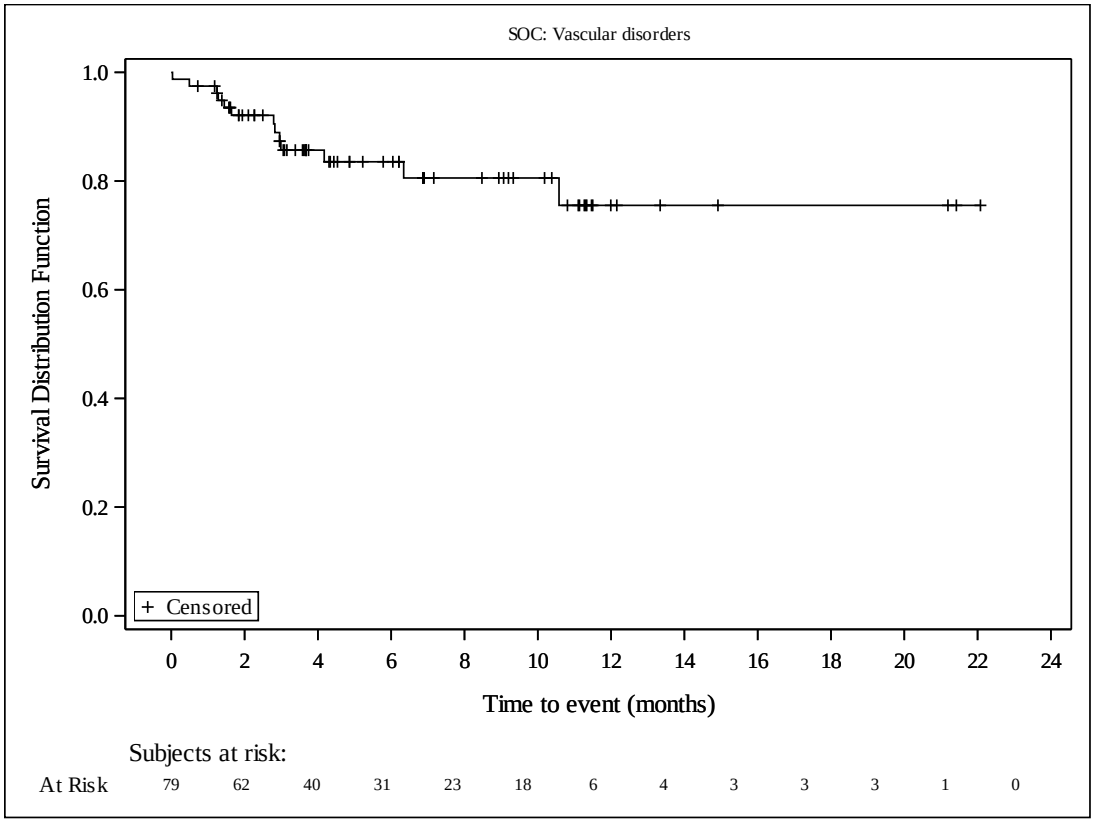
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Treatment-Emergent Adverse Events (TEAE) by SOC, PT (incidence >= 10% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Overall	12/ 79 (15.2)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	10/ 45 (22.2)	NE (NE , NE)
	Age (Category 1)		
	<65 years	8/ 46 (17.4)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	11/ 75 (14.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.2, NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	10/ 57 (17.5)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	12/ 50 (24.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	10/ 68 (14.7)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.4, NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	10/ 52 (19.2)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (5.2, NE)
	other	10/ 59 (16.9)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	12/ 74 (16.2)	NE (NE , NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.1, NE)
	no	10/ 70 (14.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	12/ 73 (16.4)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	12/ 72 (16.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	7/ 50 (14.0)	NE (NE , NE)
	no	5/ 29 (17.2)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	5/ 25 (20.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (3.5, NE)
	Hepatic impairment at baseline		
	normal	10/ 64 (15.6)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (NE , NE)
	Race		
	White	12/ 69 (17.4)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (1.2, NE)
	Non-Hispanic/Non-Latino	10/ 70 (14.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	0/ 34 (0.0)	NE (NE , NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	4/ 50 (8.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	0/ 27 (0.0)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	0/ 19 (0.0)	NE (NE , NE)
	other	4/ 59 (6.8)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.1, NE)
	no	3/ 70 (4.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	4/ 73 (5.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	4/ 72 (5.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	3/ 64 (4.7)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	4/ 69 (5.8)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Infections and infestations	Overall	11/ 79 (13.9)	NE (11.7, NE)
	Region		
	North America	5/ 34 (14.7)	NE (NE , NE)
	EU	6/ 45 (13.3)	NE (11.7, NE)
	Age (Category 1)		
	<65 years	6/ 46 (13.0)	NE (11.7, NE)
	>=65 years	5/ 33 (15.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	10/ 75 (13.3)	NE (11.7, NE)
	>=75 years	1/ 4 (25.0)	NE (7.2, NE)
	Sex		
	female	1/ 22 (4.5)	NE (7.2, NE)
	male	10/ 57 (17.5)	NE (11.7, NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	9/ 50 (18.0)	NE (11.7, NE)
	HER2 Status in central laboratory		
	IHC 3+	9/ 68 (13.2)	NE (11.7, NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	8/ 52 (15.4)	NE (11.7, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (7.2, NE)
	other	9/ 59 (15.3)	NE (11.7, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	11/ 74 (14.9)	NE (11.7, NE)
	Previous total gastrectomy		
	no	11/ 79 (13.9)	NE (11.7, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.9, NE)
	no	10/ 70 (14.3)	NE (11.7, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	11/ 73 (15.1)	NE (11.7, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	11/ 72 (15.3)	NE (11.7, NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	NE (11.7, NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Infections and infestations	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (11.7, NE)
	moderate	2/ 8 (25.0)	NE (6.0, NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	6/ 14 (42.9)	11.7 (1.2, 11.7)
	Race		
	White	9/ 69 (13.0)	NE (11.7, NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (0.4, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	10/ 70 (14.3)	NE (11.7, NE)
	Unknown	1/ 4 (25.0)	NE (3.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
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Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	2/ 57 (3.5)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	2/ 50 (4.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	0/ 27 (0.0)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (3.6, NE)
	no	3/ 70 (4.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (3.4, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (3.4, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	3/ 50 (6.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (3.6, NE)
	Hepatic impairment at baseline		
	normal	2/ 64 (3.1)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (3.1, NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (3.4, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Renal and urinary disorders	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	2/ 46 (4.3)	NE (NE , NE)
	>=65 years	2/ 33 (6.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	3/ 75 (4.0)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.2, NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	4/ 50 (8.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	1/ 52 (1.9)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	4/ 73 (5.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	4/ 72 (5.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	1/ 50 (2.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Renal and urinary disorders	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	3/ 64 (4.7)	NE (NE , NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (1.3, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.2, NE)
	Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Overall	6/ 79 (7.6)	NE (12.1, NE)
	Region		
	North America	4/ 34 (11.8)	NE (10.4, NE)
	EU	2/ 45 (4.4)	NE (12.1, NE)
	Age (Category 1)		
	<65 years	2/ 46 (4.3)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (10.4, NE)
	Age (Category 2)		
	<75 years	5/ 75 (6.7)	NE (12.1, NE)
	>=75 years	1/ 4 (25.0)	NE (4.0, NE)
	Sex		
	female	2/ 22 (9.1)	12.1 (12.1, NE)
	male	4/ 57 (7.0)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (10.4, NE)
	1	5/ 50 (10.0)	NE (12.1, NE)
	HER2 Status in central laboratory		
	IHC 3+	5/ 68 (7.4)	NE (12.1, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.7, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (12.1, NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	12.1 (3.9, NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	6/ 74 (8.1)	NE (12.1, NE)
	Previous total gastrectomy		
	no	6/ 79 (7.6)	NE (12.1, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	6/ 70 (8.6)	NE (12.1, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	6/ 73 (8.2)	NE (12.1, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	6/ 72 (8.3)	NE (12.1, NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (12.1, NE)
	no	2/ 29 (6.9)	NE (10.4, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

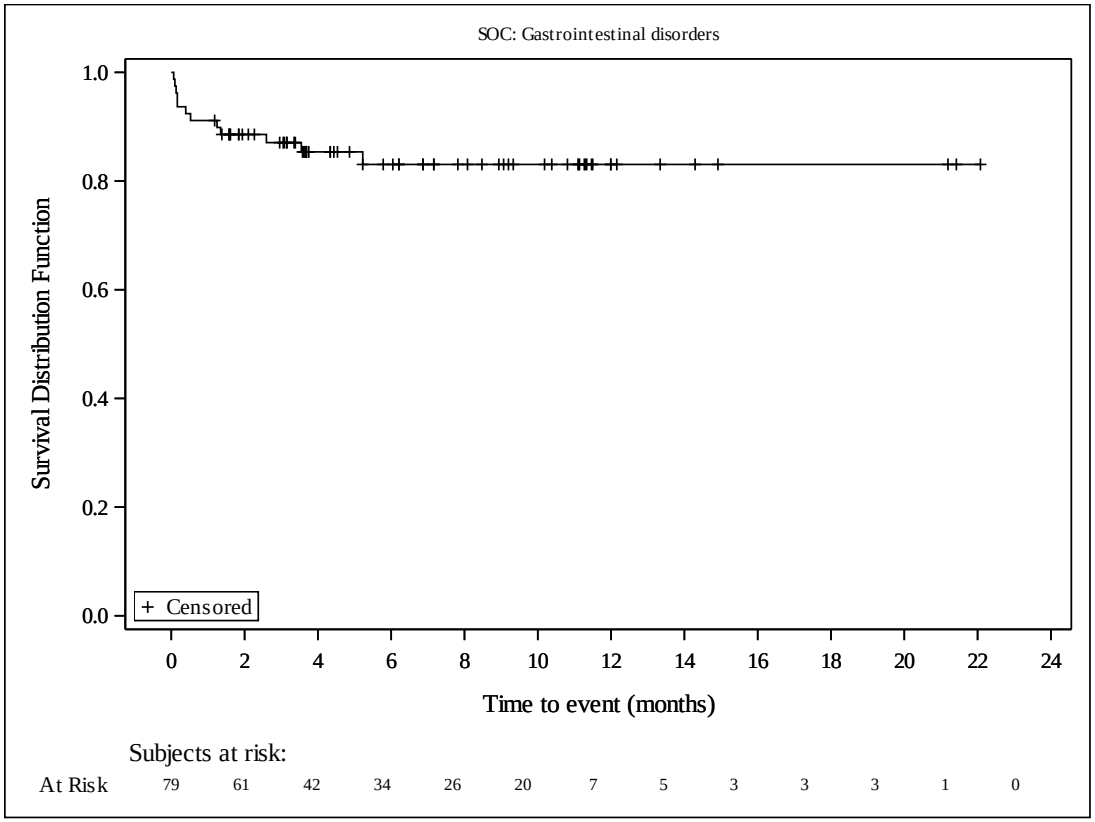
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (3.9, NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (12.1, NE)
	mild	2/ 14 (14.3)	NE (3.6, NE)
	Race		
	White	5/ 69 (7.2)	NE (12.1, NE)
	Black or African American	1/ 1 (100.0)	4.0 (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.9, NE)
	Non-Hispanic/Non-Latino	5/ 70 (7.1)	NE (12.1, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

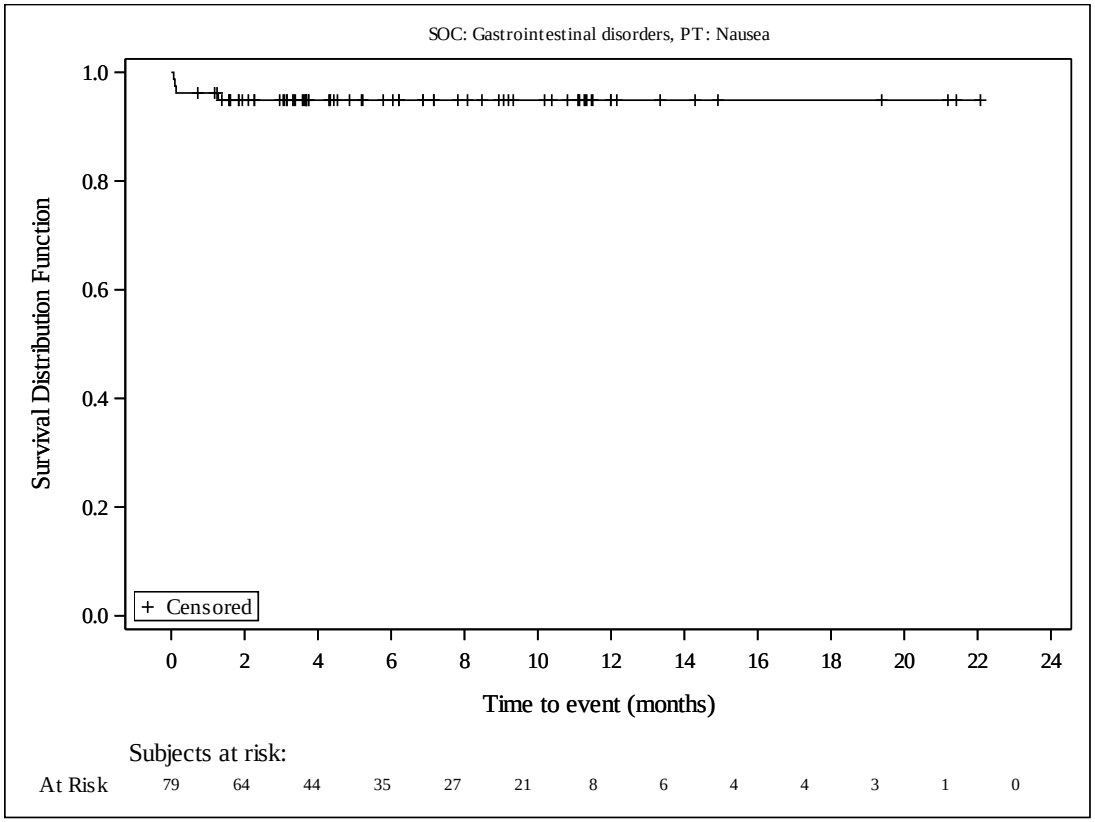
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



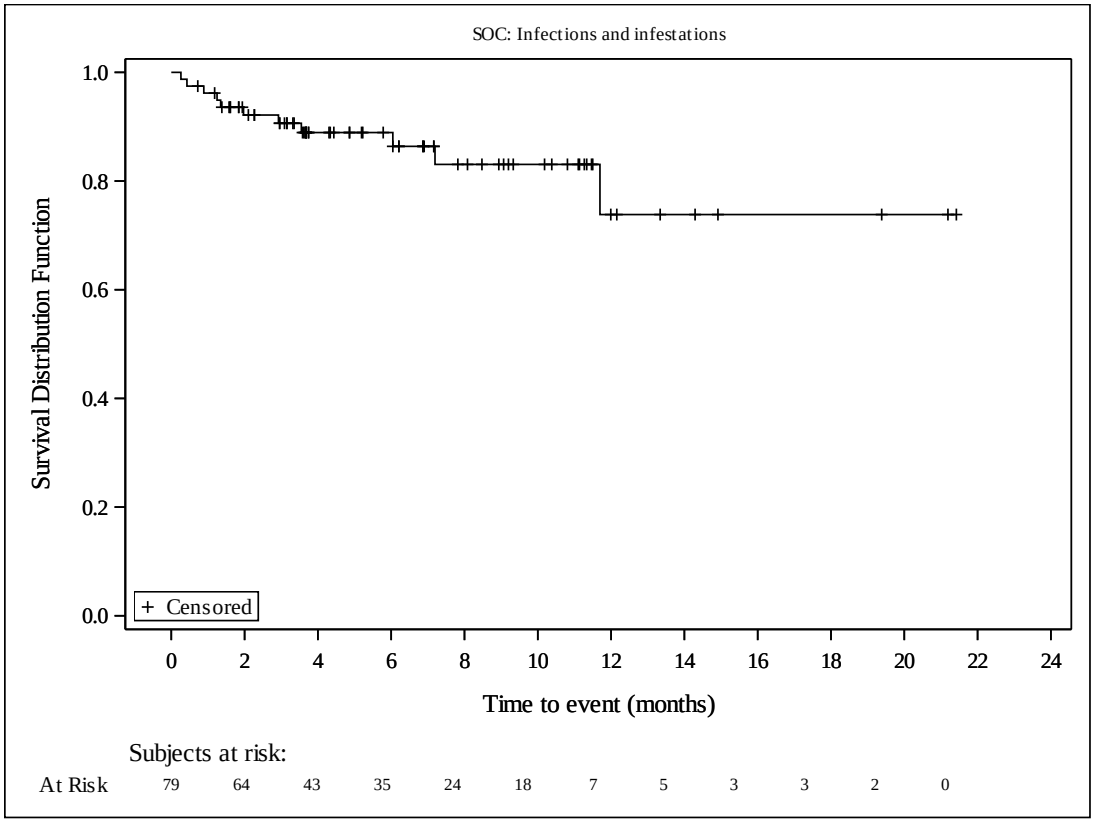
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



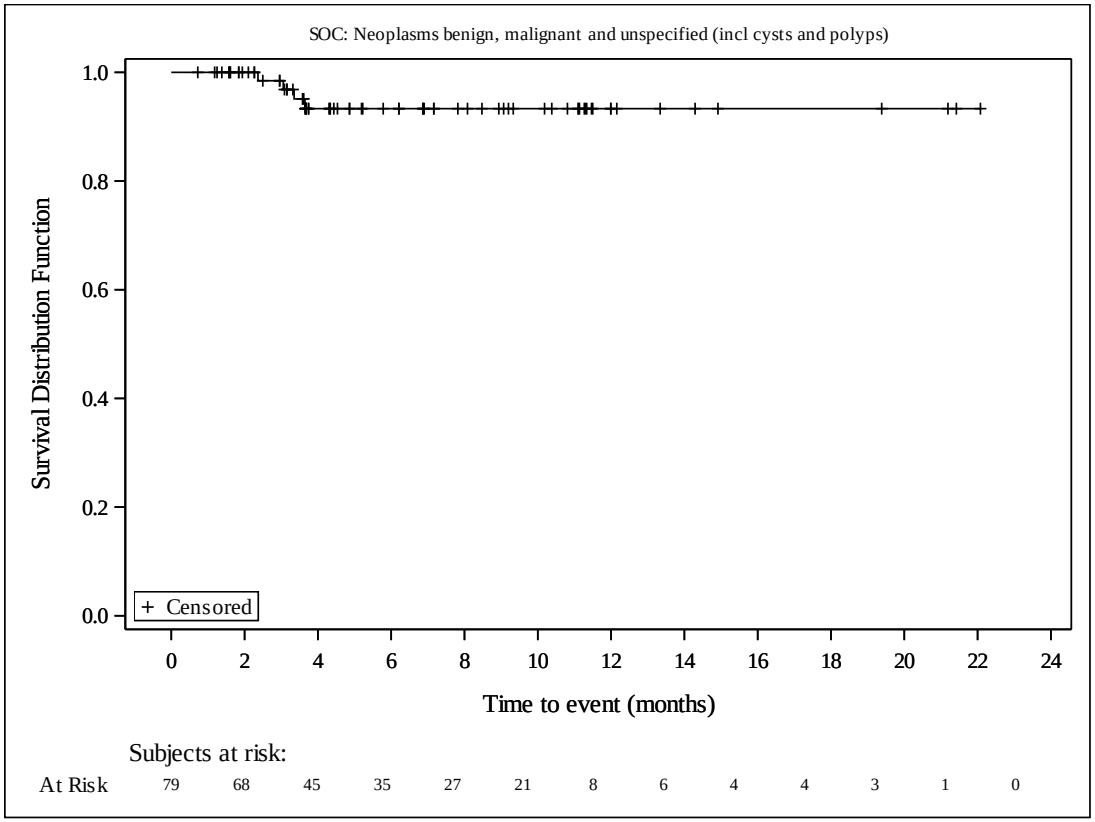
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



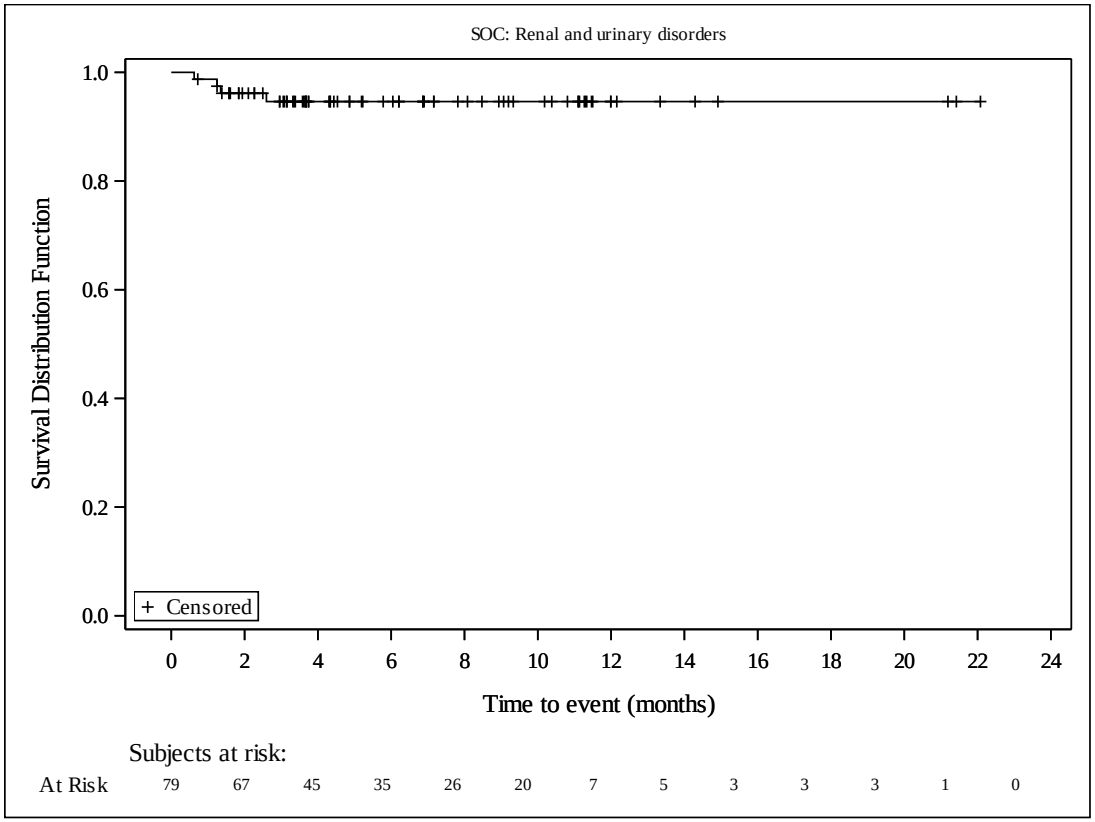
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



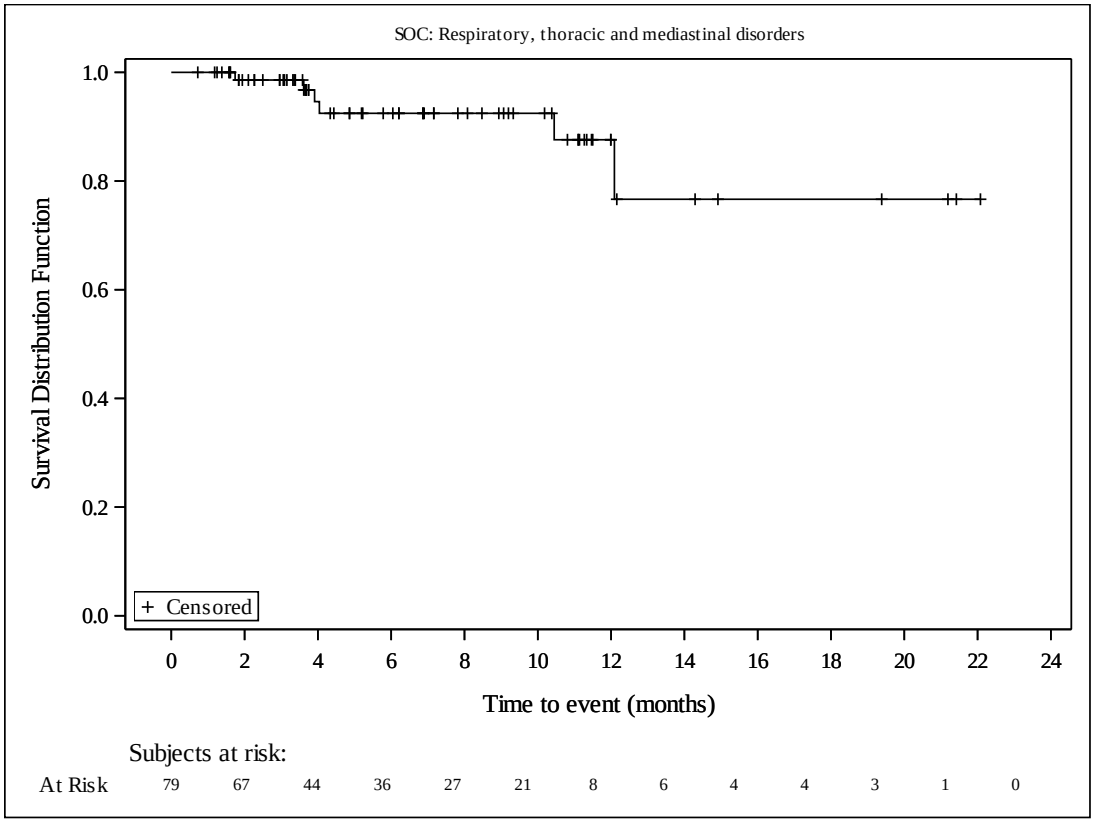
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Serious TEAE by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders	Overall	18/ 79 (22.8)	NE (11.3, NE)
	Region		
	North America	7/ 34 (20.6)	NE (9.8, NE)
	EU	11/ 45 (24.4)	NE (11.3, NE)
	Age (Category 1)		
	<65 years	11/ 46 (23.9)	NE (9.8, NE)
	>=65 years	7/ 33 (21.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	16/ 75 (21.3)	NE (11.3, NE)
	>=75 years	2/ 4 (50.0)	NE (0.3, NE)
	Sex		
	female	7/ 22 (31.8)	NE (3.7, NE)
	male	11/ 57 (19.3)	NE (11.3, NE)
	ECOG PS		
	0	4/ 29 (13.8)	NE (9.8, NE)
	1	14/ 50 (28.0)	NE (5.1, NE)
	HER2 Status in central laboratory		
	IHC 3+	16/ 68 (23.5)	NE (11.3, NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	11/ 27 (40.7)	NE (2.7, NE)
	GEJ	7/ 52 (13.5)	NE (11.3, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	6/ 19 (31.6)	11.3 (5.1, NE)
	other	12/ 59 (20.3)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.5, NE)
	>=2	17/ 74 (23.0)	NE (11.3, NE)
	Previous total gastrectomy		
	no	18/ 79 (22.8)	NE (11.3, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	5/ 9 (55.6)	11.3 (0.0, 11.3)
	no	13/ 70 (18.6)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.5, NE)
	no	17/ 73 (23.3)	NE (11.3, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.5, NE)
	no	17/ 72 (23.6)	NE (11.3, NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	NE (11.3, NE)
	no	8/ 29 (27.6)	NE (4.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders	Renal impairment at baseline		
	normal	6/ 32 (18.8)	NE (9.8, NE)
	mild	4/ 25 (16.0)	NE (11.3, NE)
	moderate	3/ 8 (37.5)	NE (0.4, NE)
	Hepatic impairment at baseline		
	normal	13/ 64 (20.3)	NE (11.3, NE)
	mild	4/ 14 (28.6)	NE (1.3, NE)
	Race		
	White	12/ 69 (17.4)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	5/ 8 (62.5)	4.6 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	7.5 (5.1, 9.8)
	Non-Hispanic/Non-Latino	15/ 70 (21.4)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (4.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Overall	11/ 79 (13.9)	NE (NE , NE)
	Region		
	North America	4/ 34 (11.8)	NE (9.8, NE)
	EU	7/ 45 (15.6)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	6/ 33 (18.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	9/ 75 (12.0)	NE (NE , NE)
	>=75 years	2/ 4 (50.0)	NE (0.3, NE)
	Sex		
	female	5/ 22 (22.7)	NE (4.2, NE)
	male	6/ 57 (10.5)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (9.8, NE)
	1	9/ 50 (18.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	9/ 68 (13.2)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.2, NE)
	Primary tumor location		
	Gastric	7/ 27 (25.9)	NE (5.1, NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (9.8, NE)
	other	8/ 59 (13.6)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	11/ 74 (14.9)	NE (NE , NE)
	Previous total gastrectomy		
	no	11/ 79 (13.9)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	3/ 9 (33.3)	NE (0.0, NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	11/ 73 (15.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	11/ 72 (15.3)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	6/ 50 (12.0)	NE (NE , NE)
	no	5/ 29 (17.2)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Anaemia	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (9.8, NE)
	mild	3/ 25 (12.0)	NE (NE , NE)
	moderate	2/ 8 (25.0)	NE (2.7, NE)
	Hepatic impairment at baseline		
	normal	7/ 64 (10.9)	NE (NE , NE)
	mild	3/ 14 (21.4)	NE (5.1, NE)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	0.3 (NE , NE)
	Other	3/ 8 (37.5)	5.1 (0.2, NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	7.5 (5.1, 9.8)
	Non-Hispanic/Non-Latino	8/ 70 (11.4)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (4.2, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	2/ 45 (4.4)	NE (11.3, NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (11.3, NE)
	>=65 years	0/ 33 (0.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	2/ 57 (3.5)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (11.3, NE)
	1	2/ 50 (4.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	2/ 52 (3.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (11.3, NE)
	other	2/ 59 (3.4)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (0.5, NE)
	>=2	3/ 74 (4.1)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	11.3 (0.5, 11.3)
	no	2/ 70 (2.9)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.5, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.5, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Blood and lymphatic system disorders, PT: Neutropenia	Renal impairment at baseline		
	normal	1/ 32 (3.1)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (11.3, NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (NE , NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders	Overall	18/ 79 (22.8)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (NE , NE)
	EU	13/ 45 (28.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	13/ 46 (28.3)	NE (5.2, NE)
	>=65 years	5/ 33 (15.2)	NE (NE , NE)
	Age (Category 2)		
	<75 years	18/ 75 (24.0)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	6/ 22 (27.3)	NE (5.2, NE)
	male	12/ 57 (21.1)	NE (NE , NE)
	ECOG PS		
	0	4/ 29 (13.8)	NE (NE , NE)
	1	14/ 50 (28.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	15/ 68 (22.1)	NE (NE , NE)
	IHC 2+/ISH +	3/ 10 (30.0)	NE (0.4, NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (NE , NE)
	GEJ	13/ 52 (25.0)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	5/ 19 (26.3)	NE (3.5, NE)
	other	13/ 59 (22.0)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	18/ 74 (24.3)	NE (NE , NE)
	Previous total gastrectomy		
	no	18/ 79 (22.8)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.1, NE)
	no	16/ 70 (22.9)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.8, NE)
	no	17/ 73 (23.3)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.8, NE)
	no	17/ 72 (23.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	9/ 50 (18.0)	NE (NE , NE)
	no	9/ 29 (31.0)	NE (3.7, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Gastrointestinal disorders	Renal impairment at baseline		
	normal	8/ 32 (25.0)	NE (NE , NE)
	mild	4/ 25 (16.0)	NE (NE , NE)
	moderate	2/ 8 (25.0)	NE (3.5, NE)
	Hepatic impairment at baseline		
	normal	13/ 64 (20.3)	NE (NE , NE)
	mild	4/ 14 (28.6)	NE (0.8, NE)
	Race		
	White	16/ 69 (23.2)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (2.8, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.5, NE)
	Non-Hispanic/Non-Latino	16/ 70 (22.9)	NE (NE , NE)
	Unknown	1/ 4 (25.0)	NE (4.1, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Overall	6/ 79 (7.6)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	5/ 45 (11.1)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	6/ 75 (8.0)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	4/ 57 (7.0)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	6/ 50 (12.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (0.6, NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (NE , NE)
	GEJ	5/ 52 (9.6)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	6/ 74 (8.1)	NE (NE , NE)
	Previous total gastrectomy		
	no	6/ 79 (7.6)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.1, NE)
	no	5/ 70 (7.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	6/ 72 (8.3)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	3/ 50 (6.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Gastrointestinal disorders, PT: Nausea	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	6/ 69 (8.7)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	6/ 70 (8.6)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: General disorders and administration site conditions	Overall	6/ 79 (7.6)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	2/ 4 (50.0)	NE (0.3, NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	4/ 57 (7.0)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	5/ 50 (10.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	6/ 68 (8.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	NE (NE , NE)
	GEJ	2/ 52 (3.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	4/ 59 (6.8)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (4.1, NE)
	>=2	5/ 74 (6.8)	NE (NE , NE)
	Previous total gastrectomy		
	no	6/ 79 (7.6)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	2/ 9 (22.2)	NE (0.7, NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	6/ 72 (8.3)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	1/ 50 (2.0)	NE (NE , NE)
	no	5/ 29 (17.2)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: General disorders and administration site conditions	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (4.3, NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	6/ 69 (8.7)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	2/ 5 (40.0)	NE (0.3, NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Infections and infestations	Overall	12/ 79 (15.2)	NE (11.7, NE)
	Region		
	North America	6/ 34 (17.6)	NE (6.0, NE)
	EU	6/ 45 (13.3)	NE (11.7, NE)
	Age (Category 1)		
	<65 years	6/ 46 (13.0)	NE (11.7, NE)
	>=65 years	6/ 33 (18.2)	NE (7.2, NE)
	Age (Category 2)		
	<75 years	10/ 75 (13.3)	NE (11.7, NE)
	>=75 years	2/ 4 (50.0)	NE (4.2, NE)
	Sex		
	female	2/ 22 (9.1)	NE (7.2, NE)
	male	10/ 57 (17.5)	NE (11.7, NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	10/ 50 (20.0)	NE (11.7, NE)
	HER2 Status in central laboratory		
	IHC 3+	10/ 68 (14.7)	NE (11.7, NE)
	IHC 2+/ISH +	2/ 10 (20.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	4/ 27 (14.8)	NE (NE , NE)
	GEJ	8/ 52 (15.4)	NE (11.7, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (7.2, NE)
	other	10/ 59 (16.9)	NE (11.7, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	12/ 74 (16.2)	NE (11.7, NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (11.7, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.9, NE)
	no	11/ 70 (15.7)	NE (11.7, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	12/ 73 (16.4)	NE (11.7, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	12/ 72 (16.7)	NE (11.7, NE)
	Presence of liver metastasis at baseline		
	yes	11/ 50 (22.0)	NE (11.7, NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Infections and infestations	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (11.7, NE)
	moderate	2/ 8 (25.0)	NE (6.0, NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	7/ 14 (50.0)	11.7 (1.2, 11.7)
	Race		
	White	9/ 69 (13.0)	NE (11.7, NE)
	Black or African American	1/ 1 (100.0)	4.2 (NE , NE)
	Other	1/ 8 (12.5)	NE (0.4, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	11/ 70 (15.7)	NE (11.7, NE)
	Unknown	1/ 4 (25.0)	NE (3.5, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations	Overall	12/ 79 (15.2)	NE (18.9, NE)
	Region		
	North America	6/ 34 (17.6)	NE (18.9, NE)
	EU	6/ 45 (13.3)	NE (NE , NE)
	Age (Category 1)		
	<65 years	8/ 46 (17.4)	18.9 (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	11/ 75 (14.7)	NE (18.9, NE)
	>=75 years	1/ 4 (25.0)	NE (0.5, NE)
	Sex		
	female	4/ 22 (18.2)	NE (NE , NE)
	male	8/ 57 (14.0)	NE (18.9, NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	10/ 50 (20.0)	NE (18.9, NE)
	HER2 Status in central laboratory		
	IHC 3+	10/ 68 (14.7)	NE (18.9, NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.6, NE)
	Primary tumor location		
	Gastric	5/ 27 (18.5)	NE (NE , NE)
	GEJ	7/ 52 (13.5)	18.9 (18.9, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	5/ 19 (26.3)	NE (3.0, NE)
	other	7/ 59 (11.9)	NE (18.9, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	12/ 74 (16.2)	NE (18.9, NE)
	Previous total gastrectomy		
	no	12/ 79 (15.2)	NE (18.9, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.5, NE)
	no	11/ 70 (15.7)	NE (18.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.5, NE)
	no	11/ 73 (15.1)	NE (18.9, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.5, NE)
	no	10/ 72 (13.9)	NE (18.9, NE)
	Presence of liver metastasis at baseline		
	yes	10/ 50 (20.0)	NE (18.9, NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations	Renal impairment at baseline		
	normal	5/ 32 (15.6)	18.9 (NE , NE)
	mild	4/ 25 (16.0)	NE (NE , NE)
	moderate	2/ 8 (25.0)	NE (0.3, NE)
	Hepatic impairment at baseline		
	normal	6/ 64 (9.4)	NE (18.9, NE)
	mild	6/ 14 (42.9)	NE (0.5, NE)
	Race		
	White	8/ 69 (11.6)	NE (18.9, NE)
	Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
	Other	3/ 8 (37.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	11/ 70 (15.7)	NE (18.9, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Investigations, PT: Neutrophil count decreased	Overall	6/ 79 (7.6)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	4/ 45 (8.9)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	5/ 75 (6.7)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (0.5, NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	5/ 57 (8.8)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	5/ 50 (10.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	6/ 68 (8.8)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	4/ 59 (6.8)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	6/ 74 (8.1)	NE (NE , NE)
	Previous total gastrectomy		
	no	6/ 79 (7.6)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (0.5, NE)
	no	5/ 70 (7.1)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (0.5, NE)
	no	5/ 72 (6.9)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	5/ 50 (10.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: Neutrophil count decreased	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (0.5, NE)
	Hepatic impairment at baseline		
	normal	1/ 64 (1.6)	NE (NE , NE)
	mild	5/ 14 (35.7)	NE (0.5, NE)
	Race		
	White	4/ 69 (5.8)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
	Other	1/ 8 (12.5)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	5/ 70 (7.1)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: White blood cell count decreased	Overall	5/ 79 (6.3)	NE (18.9, NE)
	Region		
	North America	4/ 34 (11.8)	NE (18.9, NE)
	EU	1/ 45 (2.2)	NE (NE , NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	18.9 (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (18.9, NE)
	>=75 years	1/ 4 (25.0)	NE (0.5, NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (18.9, NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	4/ 50 (8.0)	NE (18.9, NE)
	HER2 Status in central laboratory		
	IHC 3+	5/ 68 (7.4)	NE (18.9, NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	18.9 (18.9, NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (18.9, NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	5/ 74 (6.8)	NE (18.9, NE)
	Previous total gastrectomy		
	no	5/ 79 (6.3)	NE (18.9, NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	5/ 70 (7.1)	NE (18.9, NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (0.5, NE)
	no	4/ 73 (5.5)	NE (18.9, NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	2/ 7 (28.6)	NE (0.5, NE)
	no	3/ 72 (4.2)	NE (18.9, NE)
	Presence of liver metastasis at baseline		
	yes	5/ 50 (10.0)	NE (18.9, NE)
	no	0/ 29 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Investigations, PT: White blood cell count decreased	Renal impairment at baseline		
	normal	4/ 32 (12.5)	18.9 (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	2/ 64 (3.1)	NE (18.9, NE)
	mild	3/ 14 (21.4)	NE (3.0, NE)
	Race		
	White	2/ 69 (2.9)	NE (18.9, NE)
	Black or African American	1/ 1 (100.0)	0.5 (NE , NE)
	Other	2/ 8 (25.0)	NE (0.5, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (0.5, NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (18.9, NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Metabolism and nutrition disorders	Overall	8/ 79 (10.1)	NE (NE , NE)
	Region		
	North America	3/ 34 (8.8)	NE (NE , NE)
	EU	5/ 45 (11.1)	NE (NE , NE)
	Age (Category 1)		
	<65 years	4/ 46 (8.7)	NE (NE , NE)
	>=65 years	4/ 33 (12.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	7/ 75 (9.3)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.4, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	5/ 57 (8.8)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	6/ 50 (12.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	5/ 52 (9.6)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (NE , NE)
	other	5/ 59 (8.5)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	8/ 74 (10.8)	NE (NE , NE)
	Previous total gastrectomy		
	no	8/ 79 (10.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	8/ 70 (11.4)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.9, NE)
	no	7/ 73 (9.6)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.9, NE)
	no	7/ 72 (9.7)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	5/ 50 (10.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders	Renal impairment at baseline		
	normal	5/ 32 (15.6)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	5/ 64 (7.8)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (3.4, NE)
	Race		
	White	7/ 69 (10.1)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (2.9, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.4, NE)
	Non-Hispanic/Non-Latino	7/ 70 (10.0)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	1/ 46 (2.2)	NE (NE , NE)
	>=65 years	3/ 33 (9.1)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	3/ 50 (6.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	4/ 73 (5.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	0/ 7 (0.0)	NE (NE , NE)
	no	4/ 72 (5.6)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Metabolism and nutrition disorders, PT: Decreased appetite	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	2/ 64 (3.1)	NE (NE , NE)
	mild	1/ 14 (7.1)	NE (NE , NE)
	Race		
	White	4/ 69 (5.8)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	1/ 34 (2.9)	NE (NE , NE)
	EU	3/ 45 (6.7)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	2/ 22 (9.1)	NE (NE , NE)
	male	2/ 57 (3.5)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	2/ 50 (4.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	0/ 27 (0.0)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (3.6, NE)
	no	3/ 70 (4.3)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (3.0, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (3.0, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	3/ 50 (6.0)	NE (NE , NE)
	no	1/ 29 (3.4)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (3.6, NE)
	Hepatic impairment at baseline		
	normal	2/ 64 (3.1)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (3.1, NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (3.0, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Nervous system disorders	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	2/ 45 (4.4)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	0/ 29 (0.0)	NE (NE , NE)
	1	4/ 50 (8.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	4/ 68 (5.9)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	1/ 27 (3.7)	NE (NE , NE)
	GEJ	3/ 52 (5.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	2/ 19 (10.5)	NE (NE , NE)
	other	2/ 59 (3.4)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	0/ 6 (0.0)	NE (NE , NE)
	no	4/ 73 (5.5)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (3.6, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Nervous system disorders	Renal impairment at baseline		
	normal	4/ 32 (12.5)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	1/ 64 (1.6)	NE (NE , NE)
	mild	2/ 14 (14.3)	NE (3.6, NE)
	Race		
	White	4/ 69 (5.8)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	0/ 8 (0.0)	NE (NE , NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.6, NE)
	Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Renal and urinary disorders	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	2/ 34 (5.9)	NE (NE , NE)
	EU	2/ 45 (4.4)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	3/ 75 (4.0)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (1.2, NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	1/ 29 (3.4)	NE (NE , NE)
	1	3/ 50 (6.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.3, NE)
	Primary tumor location		
	Gastric	2/ 27 (7.4)	NE (NE , NE)
	GEJ	2/ 52 (3.8)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.9, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.9, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	2/ 50 (4.0)	NE (NE , NE)
	no	2/ 29 (6.9)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Renal and urinary disorders	Renal impairment at baseline		
	normal	2/ 32 (6.3)	NE (NE , NE)
	mild	2/ 25 (8.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (NE , NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	2/ 69 (2.9)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	2/ 8 (25.0)	NE (1.3, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (1.2, NE)
	Non-Hispanic/Non-Latino	3/ 70 (4.3)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Overall	7/ 79 (8.9)	NE (NE , NE)
	Region		
	North America	5/ 34 (14.7)	NE (10.4, NE)
	EU	2/ 45 (4.4)	NE (NE , NE)
	Age (Category 1)		
	<65 years	5/ 46 (10.9)	NE (NE , NE)
	>=65 years	2/ 33 (6.1)	NE (10.4, NE)
	Age (Category 2)		
	<75 years	6/ 75 (8.0)	NE (NE , NE)
	>=75 years	1/ 4 (25.0)	NE (4.0, NE)
	Sex		
	female	3/ 22 (13.6)	NE (NE , NE)
	male	4/ 57 (7.0)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (10.4, NE)
	1	5/ 50 (10.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	7/ 68 (10.3)	NE (NE , NE)
	IHC 2+/ISH +	0/ 10 (0.0)	NE (NE , NE)
	Primary tumor location		
	Gastric	3/ 27 (11.1)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	3/ 19 (15.8)	NE (3.9, NE)
	other	4/ 59 (6.8)	NE (NE , NE)
	Number of metastatic sites		
	<2	1/ 5 (20.0)	NE (4.1, NE)
	>=2	6/ 74 (8.1)	NE (NE , NE)
	Previous total gastrectomy		
	no	7/ 79 (8.9)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	1/ 9 (11.1)	NE (4.1, NE)
	no	6/ 70 (8.6)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.7, NE)
	no	6/ 73 (8.2)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.7, NE)
	no	6/ 72 (8.3)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (NE , NE)
	no	3/ 29 (10.3)	NE (10.4, NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	T-DXd (N=79) Median (95% CI) [a]
SOC: Respiratory, thoracic and mediastinal disorders	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	0/ 25 (0.0)	NE (NE , NE)
	moderate	1/ 8 (12.5)	NE (3.9, NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (NE , NE)
	mild	3/ 14 (21.4)	NE (3.4, NE)
	Race		
	White	5/ 69 (7.2)	NE (NE , NE)
	Black or African American	1/ 1 (100.0)	4.0 (NE , NE)
	Other	1/ 8 (12.5)	NE (2.7, NE)
	Ethnicity		
	Hispanic/Latino	1/ 5 (20.0)	NE (3.9, NE)
	Non-Hispanic/Non-Latino	6/ 70 (8.6)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Vascular disorders	Overall	4/ 79 (5.1)	NE (NE , NE)
	Region		
	North America	3/ 34 (8.8)	NE (NE , NE)
	EU	1/ 45 (2.2)	NE (NE , NE)
	Age (Category 1)		
	<65 years	3/ 46 (6.5)	NE (NE , NE)
	>=65 years	1/ 33 (3.0)	NE (NE , NE)
	Age (Category 2)		
	<75 years	4/ 75 (5.3)	NE (NE , NE)
	>=75 years	0/ 4 (0.0)	NE (NE , NE)
	Sex		
	female	1/ 22 (4.5)	NE (NE , NE)
	male	3/ 57 (5.3)	NE (NE , NE)
	ECOG PS		
	0	2/ 29 (6.9)	NE (NE , NE)
	1	2/ 50 (4.0)	NE (NE , NE)
	HER2 Status in central laboratory		
	IHC 3+	3/ 68 (4.4)	NE (NE , NE)
	IHC 2+/ISH +	1/ 10 (10.0)	NE (1.4, NE)
	Primary tumor location		
	Gastric	0/ 27 (0.0)	NE (NE , NE)
	GEJ	4/ 52 (7.7)	NE (NE , NE)
	Histological subtype		
	diffuse	0/ 1 (0.0)	NE (NE , NE)
	intestinal	1/ 19 (5.3)	NE (NE , NE)
	other	3/ 59 (5.1)	NE (NE , NE)
	Number of metastatic sites		
	<2	0/ 5 (0.0)	NE (NE , NE)
	>=2	4/ 74 (5.4)	NE (NE , NE)
	Previous total gastrectomy		
	no	4/ 79 (5.1)	NE (NE , NE)
	Prior adjuvant/ neoadjuvant therapy		
	yes	0/ 9 (0.0)	NE (NE , NE)
	no	4/ 70 (5.7)	NE (NE , NE)
	Prior nivolumab or pembrolizumab treatment		
	yes	1/ 6 (16.7)	NE (2.8, NE)
	no	3/ 73 (4.1)	NE (NE , NE)
	Prior treatment with checkpoint inhibitor or other immuno-oncology therapy		
	yes	1/ 7 (14.3)	NE (2.8, NE)
	no	3/ 72 (4.2)	NE (NE , NE)
	Presence of liver metastasis at baseline		
	yes	4/ 50 (8.0)	NE (NE , NE)
	no	0/ 29 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo
Date of Table Generation: 16AUG2022

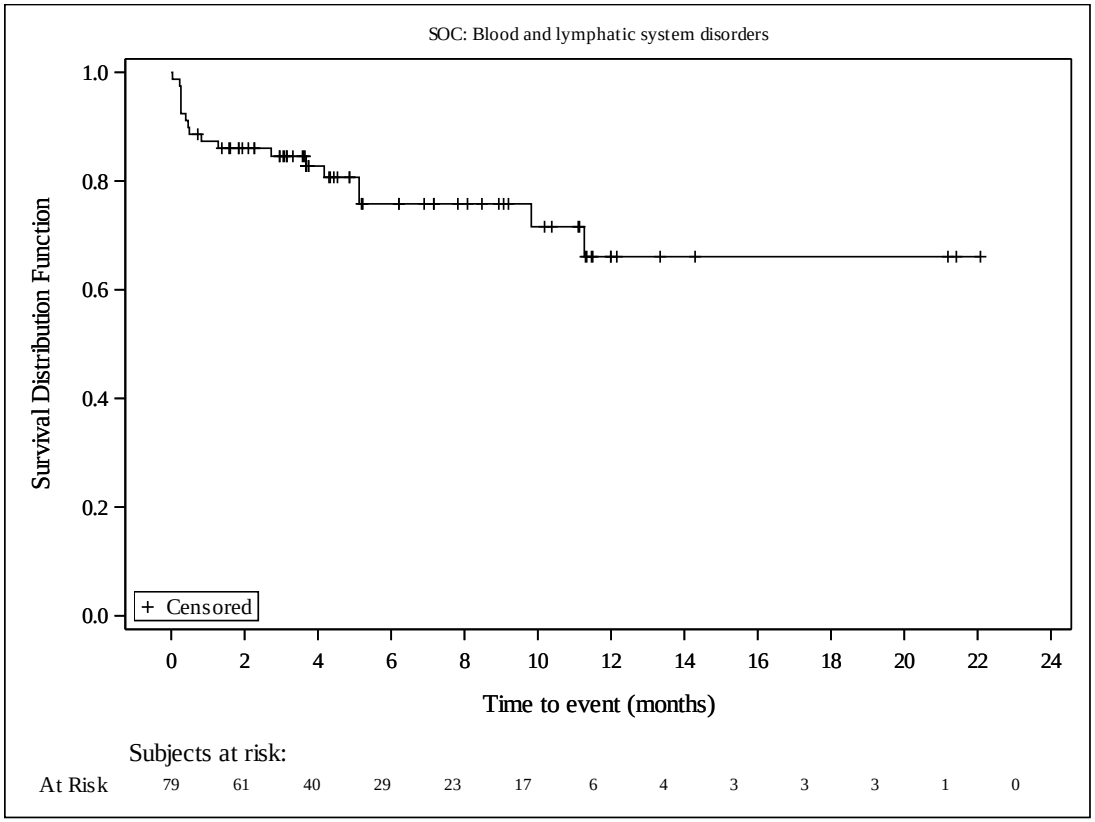
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set

SOC/PT	Subgroup Level	T-DXd (N=79) n/ N (%)	Median (95% CI) [a]
SOC: Vascular disorders	Renal impairment at baseline		
	normal	3/ 32 (9.4)	NE (NE , NE)
	mild	1/ 25 (4.0)	NE (NE , NE)
	moderate	0/ 8 (0.0)	NE (NE , NE)
	Hepatic impairment at baseline		
	normal	4/ 64 (6.3)	NE (NE , NE)
	mild	0/ 14 (0.0)	NE (NE , NE)
	Race		
	White	3/ 69 (4.3)	NE (NE , NE)
	Black or African American	0/ 1 (0.0)	NE (NE , NE)
	Other	1/ 8 (12.5)	NE (2.8, NE)
	Ethnicity		
	Hispanic/Latino	0/ 5 (0.0)	NE (NE , NE)
	Non-Hispanic/Non-Latino	4/ 70 (5.7)	NE (NE , NE)
	Unknown	0/ 4 (0.0)	NE (NE , NE)

Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE
Daiichi Sankyo

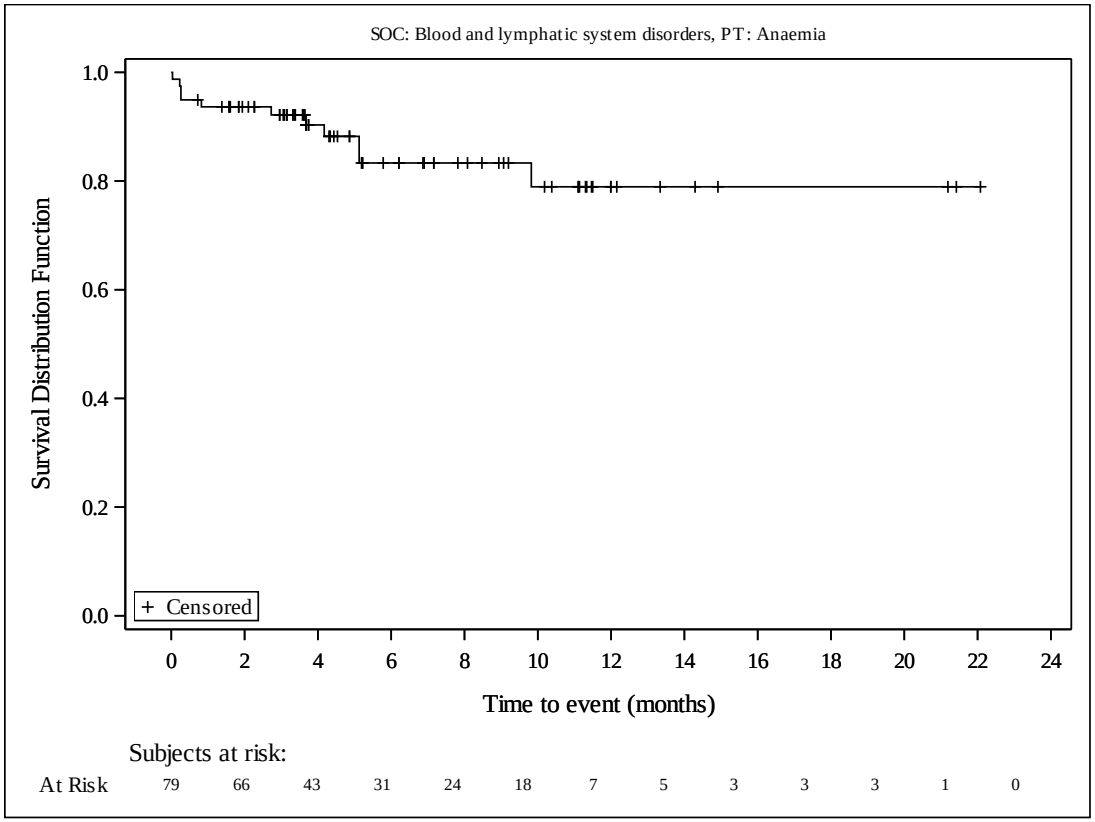
Date of Table Generation: 16AUG2022

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



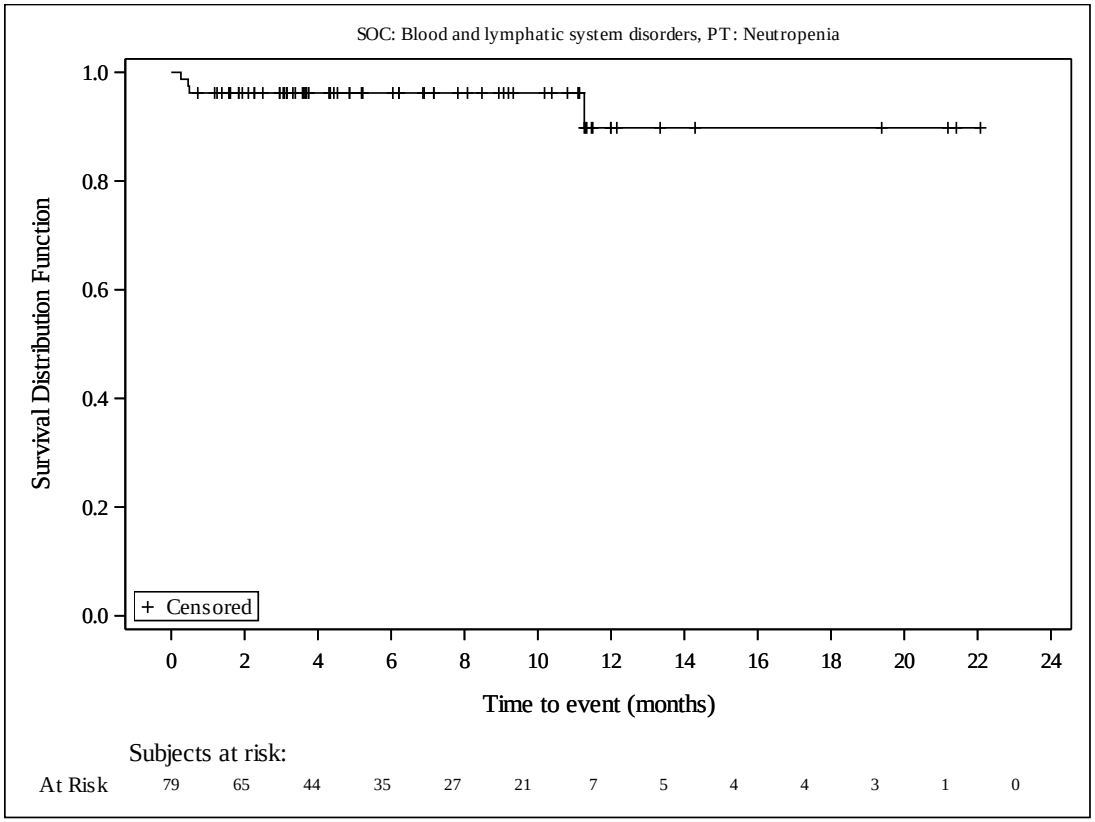
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



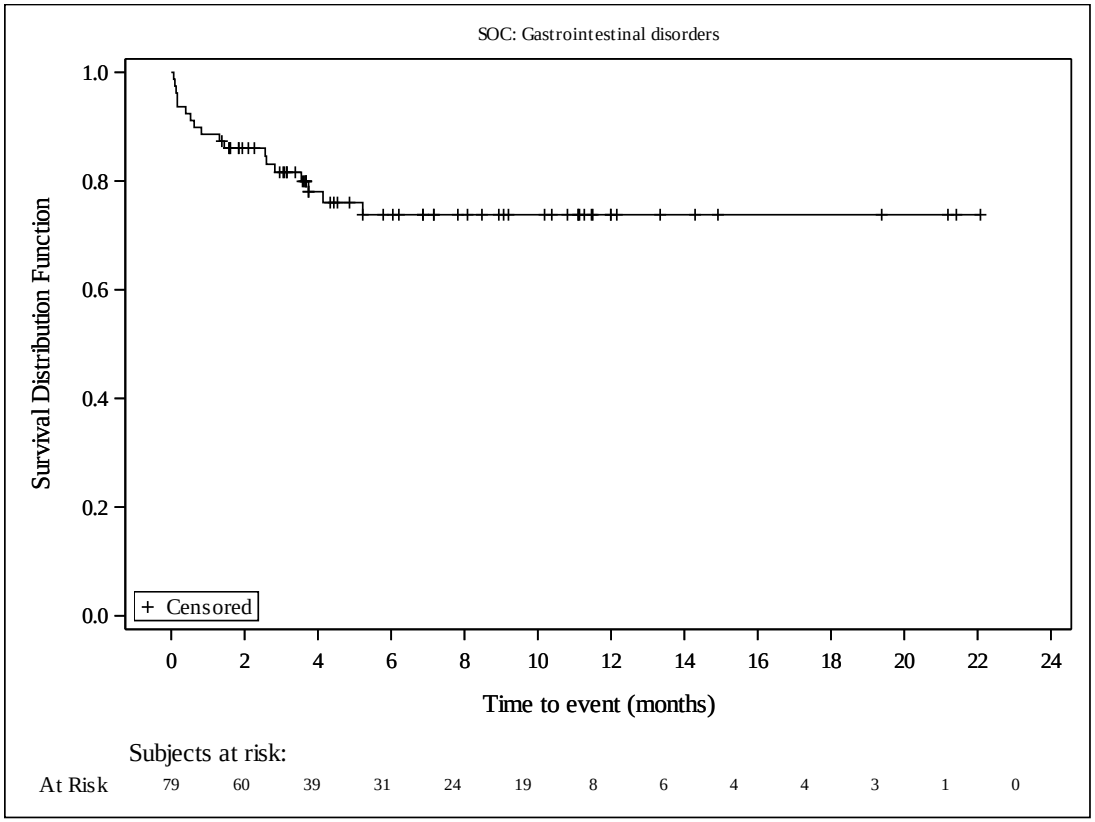
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



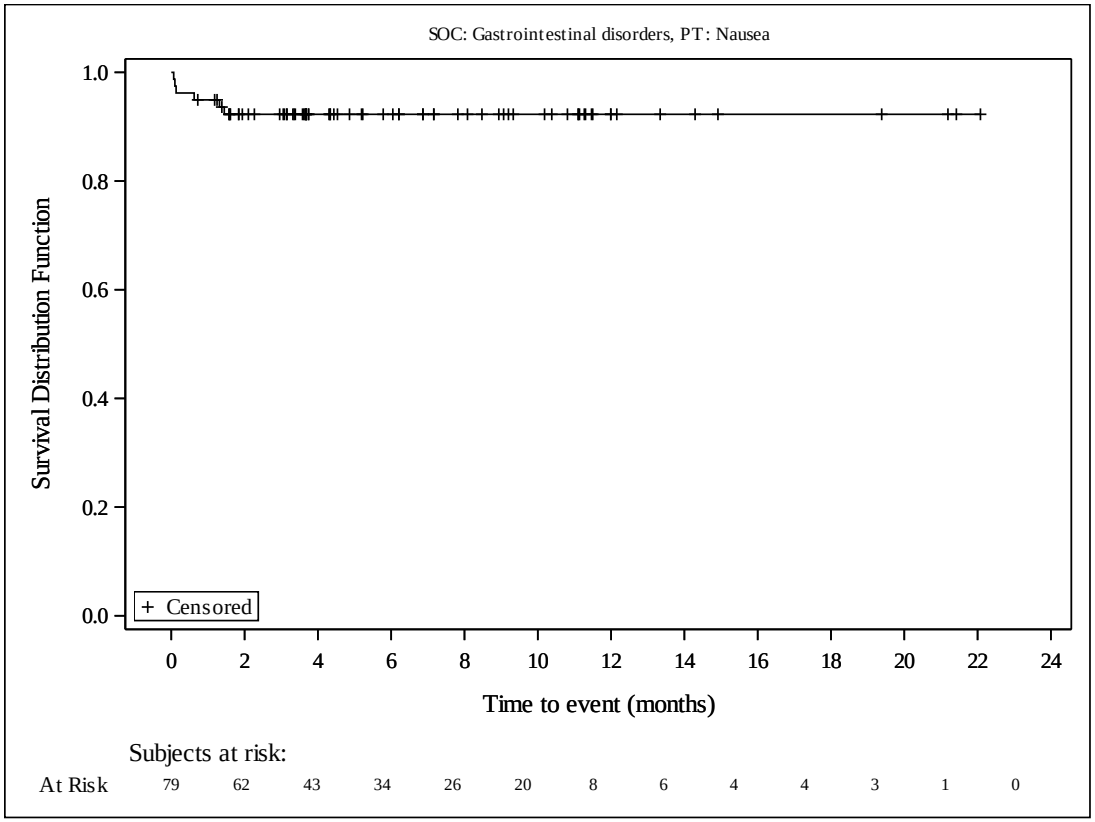
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



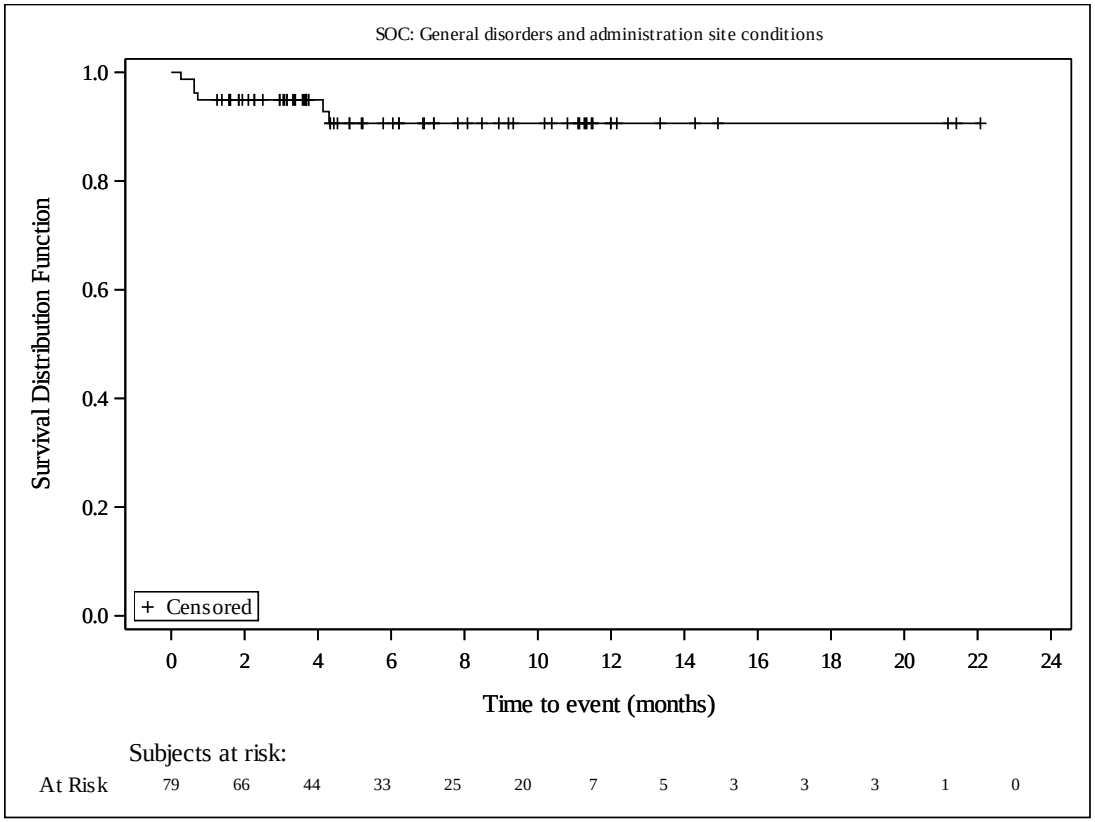
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



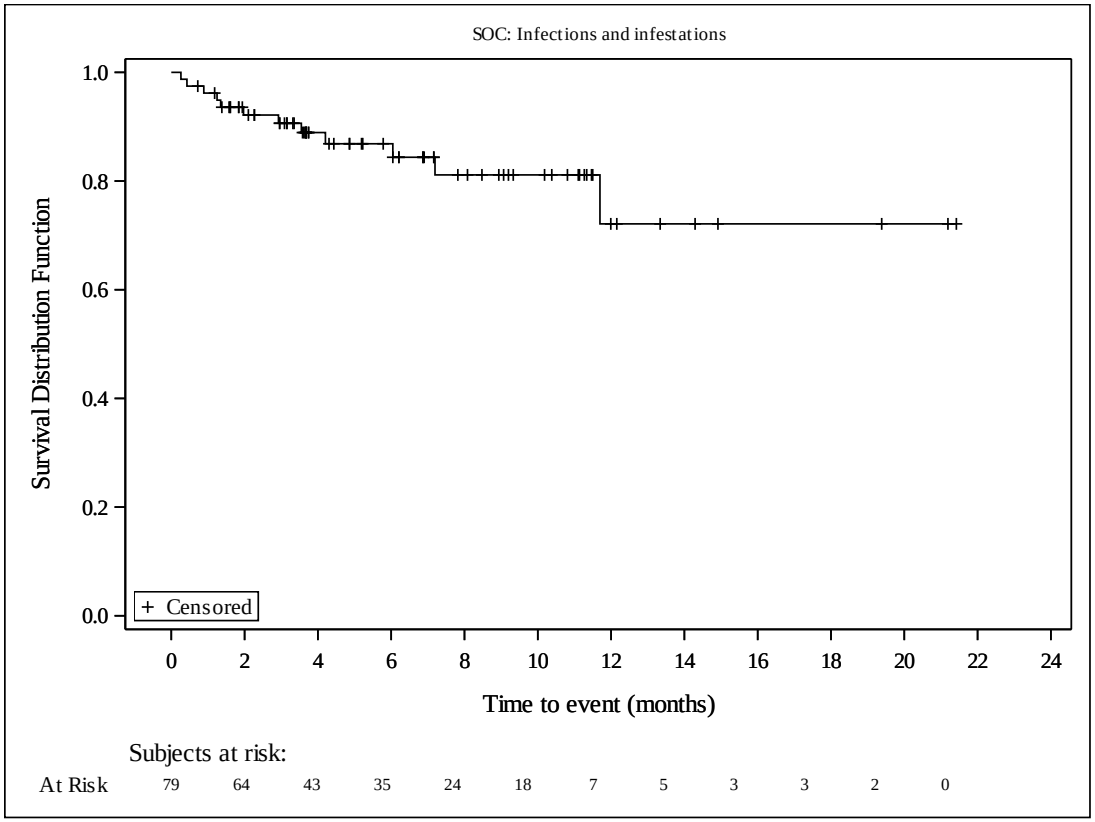
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



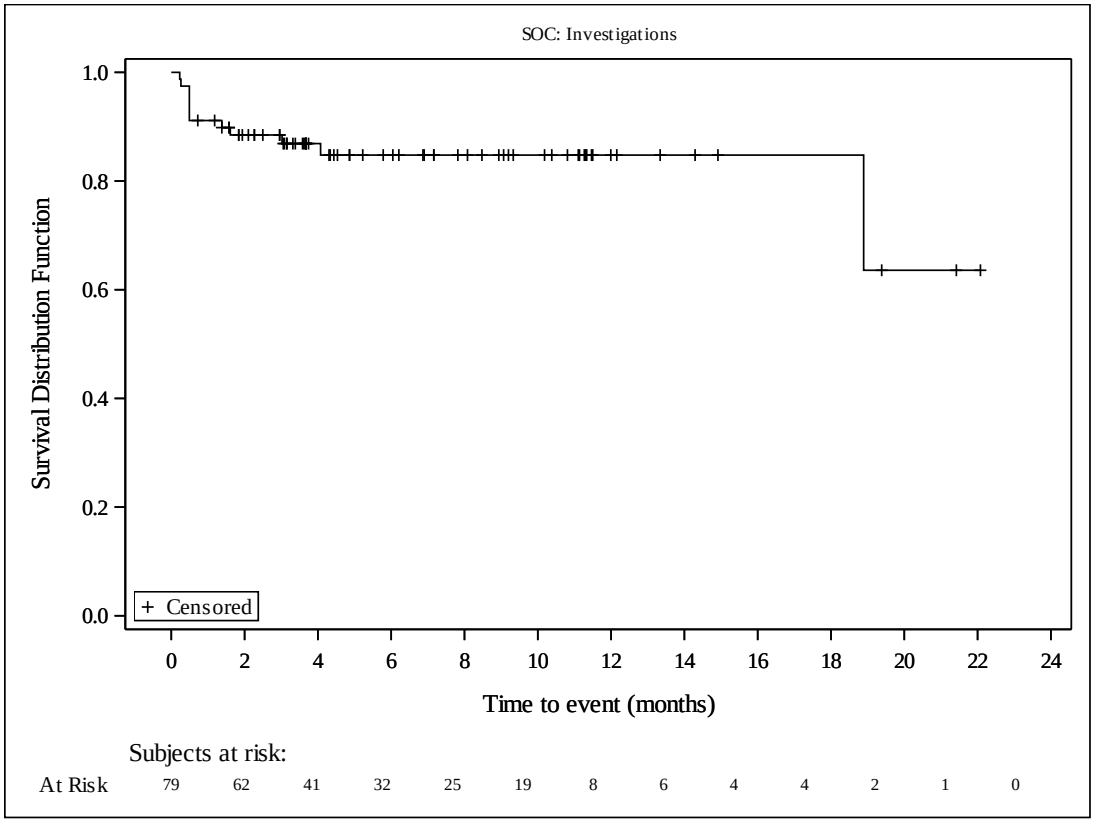
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



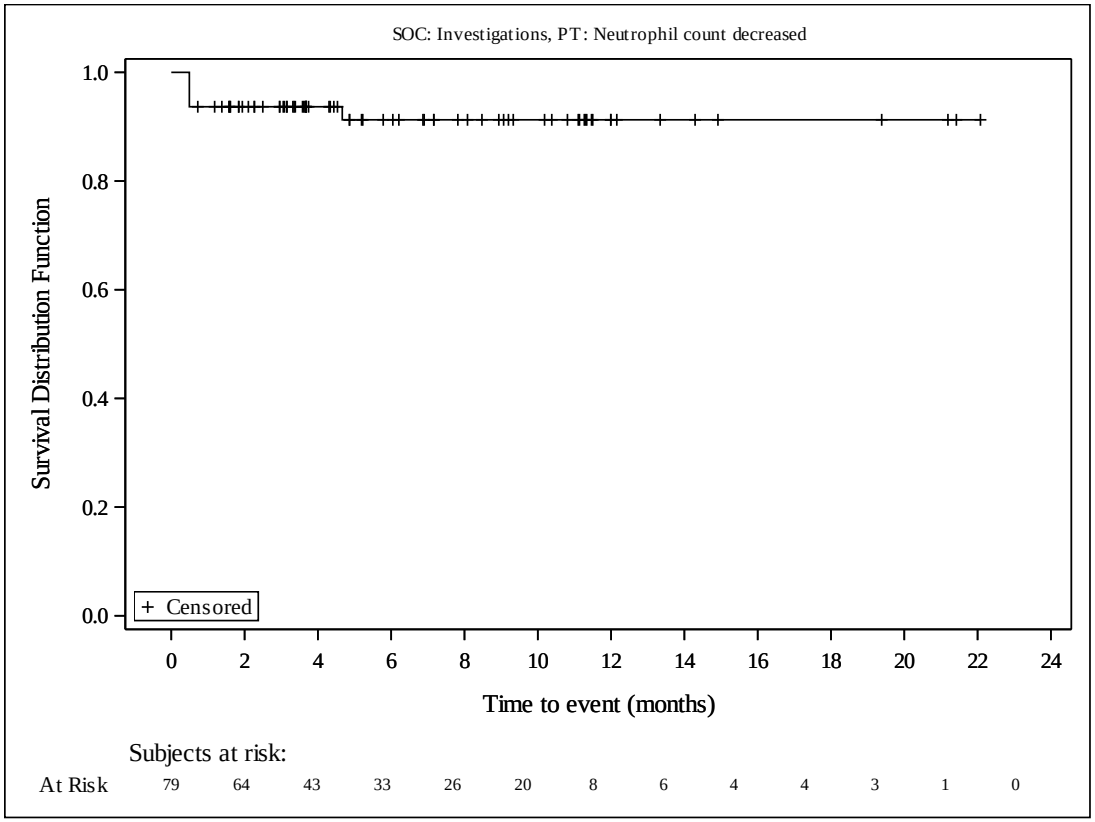
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



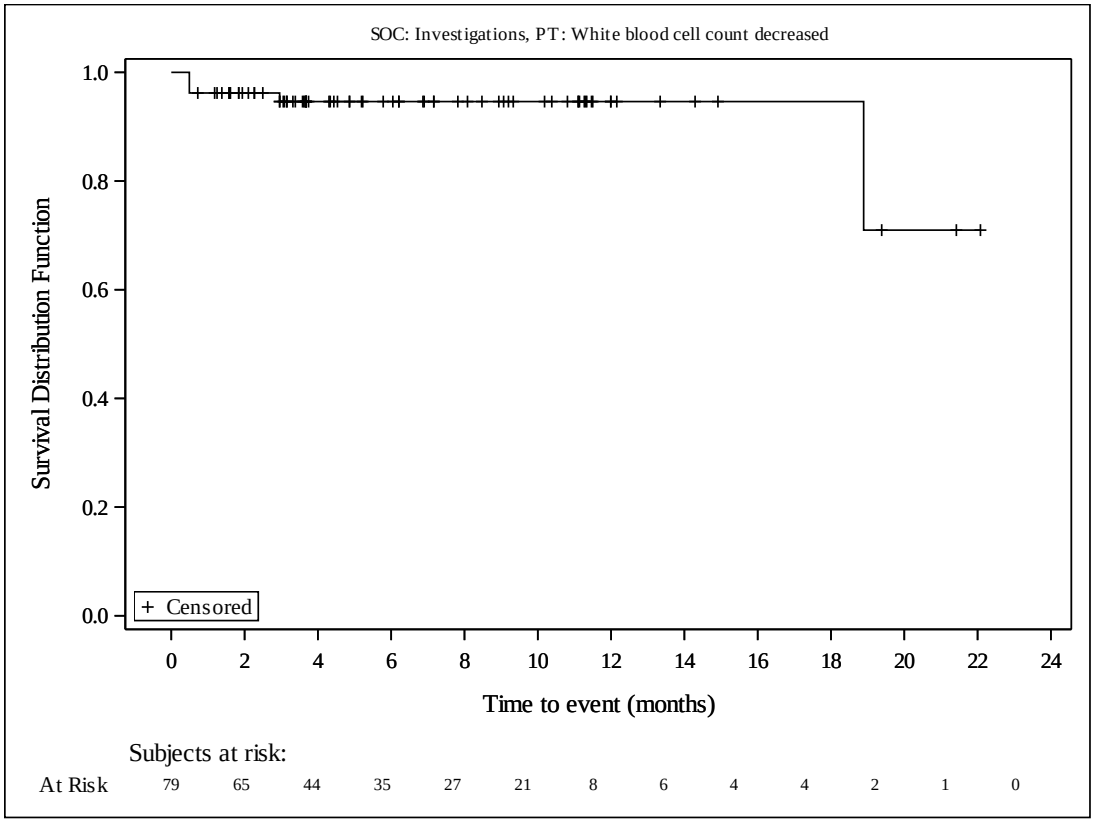
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



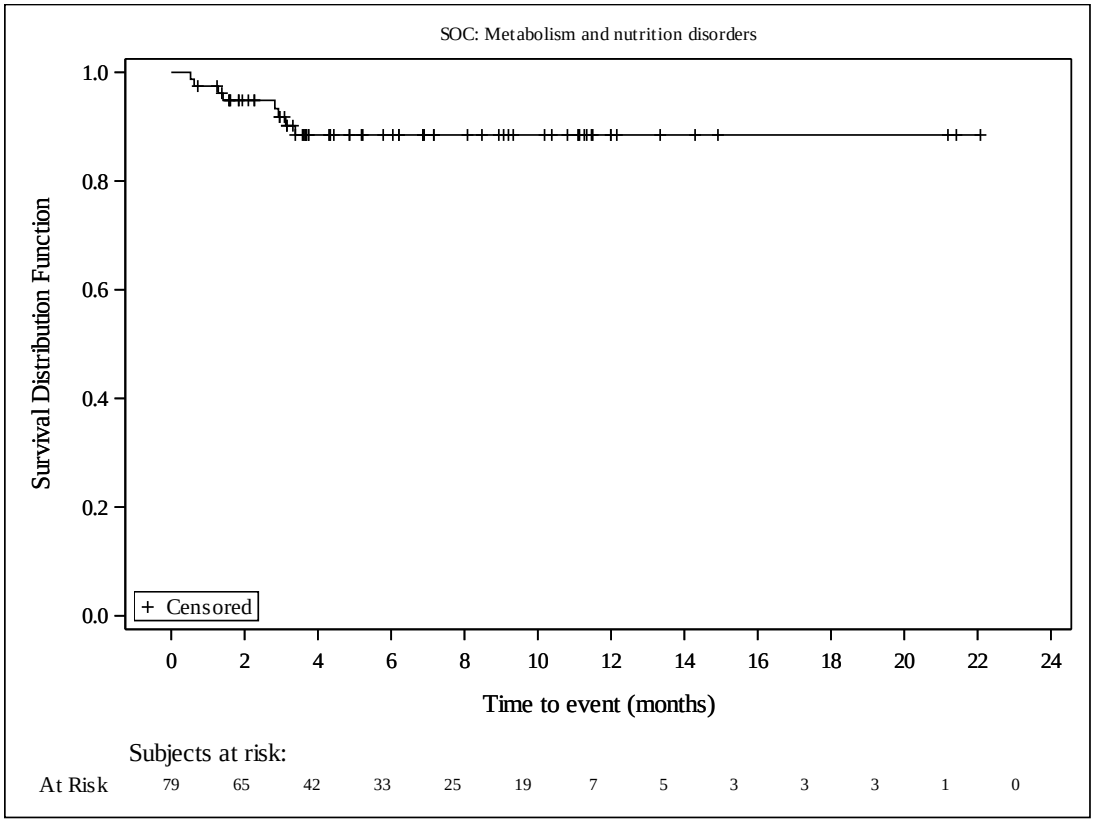
Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



Adverse events were coded using the MedDRA dictionary, Version 24.0 and graded according to NCI CTCAE v5.0.
NE: Not estimable.
[a] CI for median is computed using the Brookmeyer-Crowley method.
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



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NE: Not estimable.
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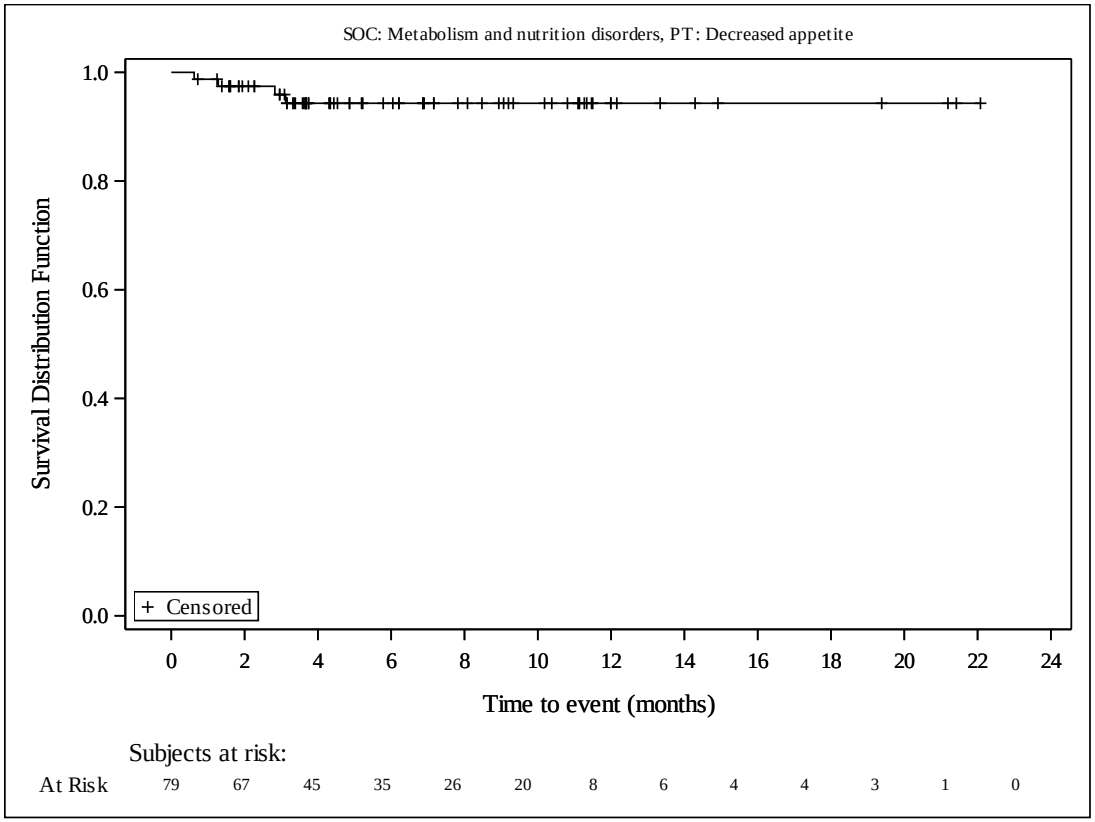
Source data: ADAM.ADSL and ADAM.ADAE

Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



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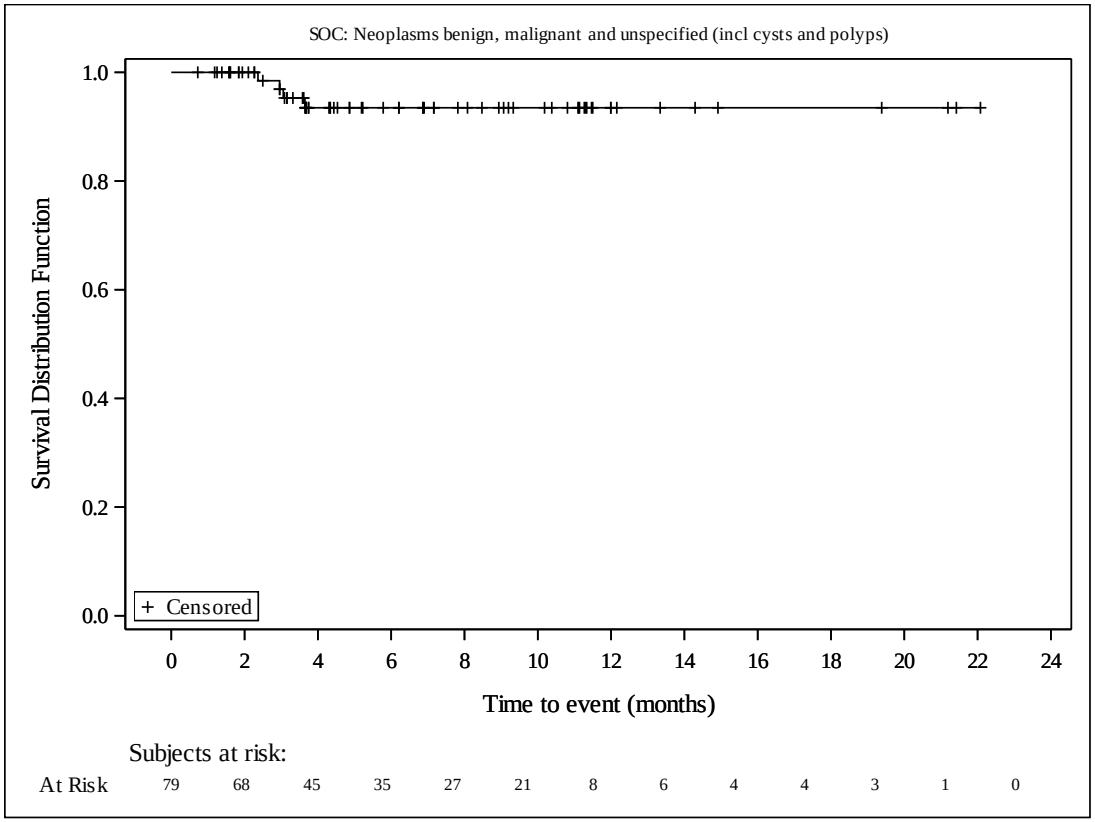
Protocol DS8201-A-U205
Trastuzumab deruxtecan - (Cutoff Date: 08NOV2021)
Study Population
Overall Summary of frequent Severe TEAE (NCI CTCAE grade >= 3) by SOC, PT (incidence >= 5% or >=10 patients)
Safety Analysis Set



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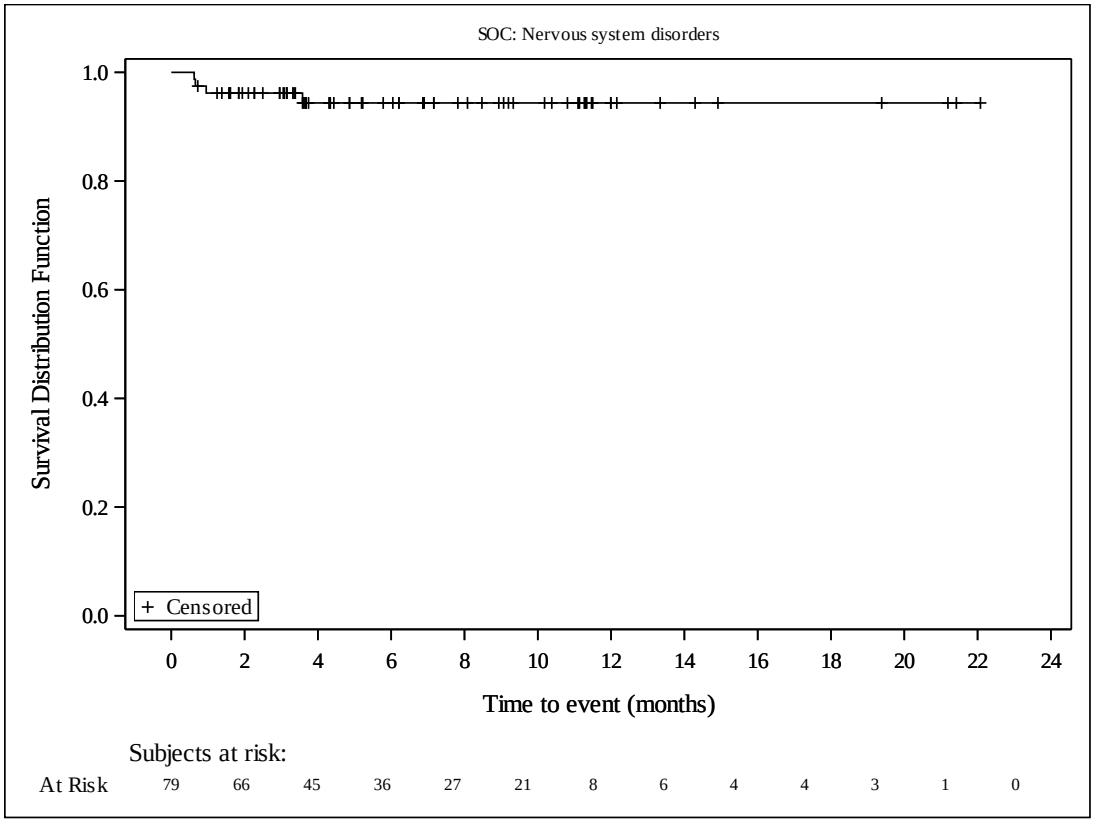
Safety Analysis Set



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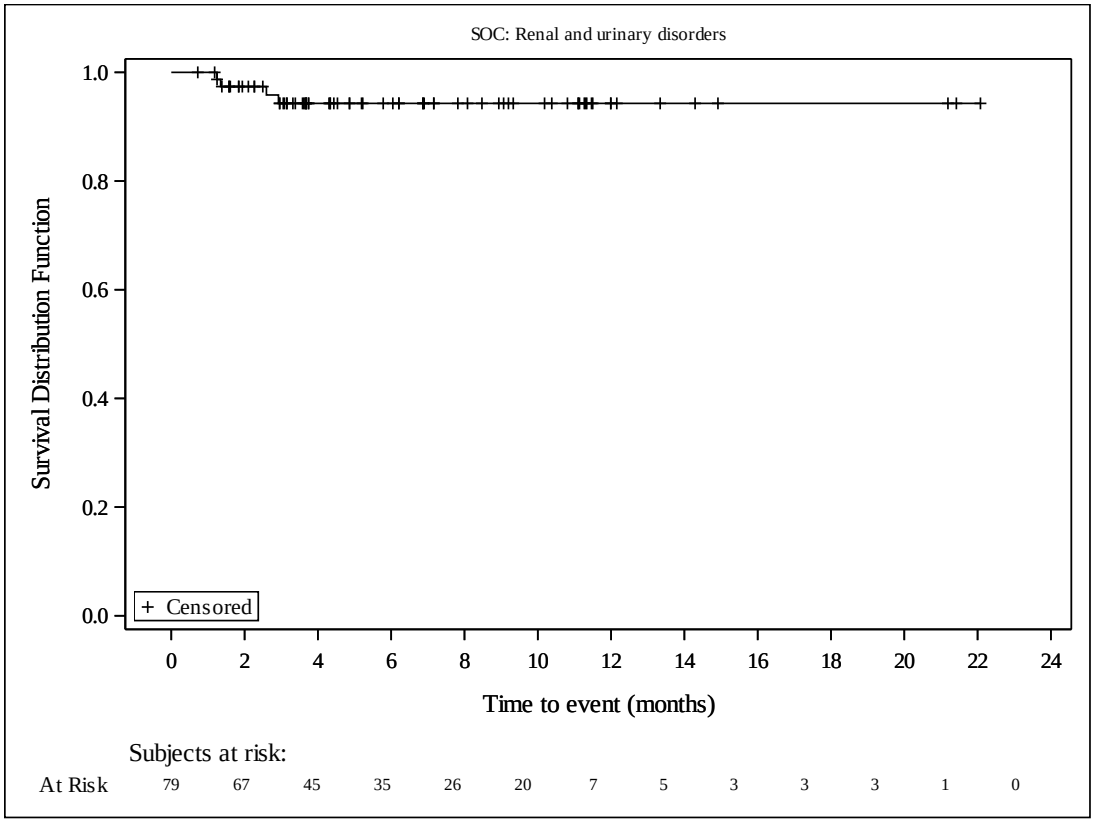

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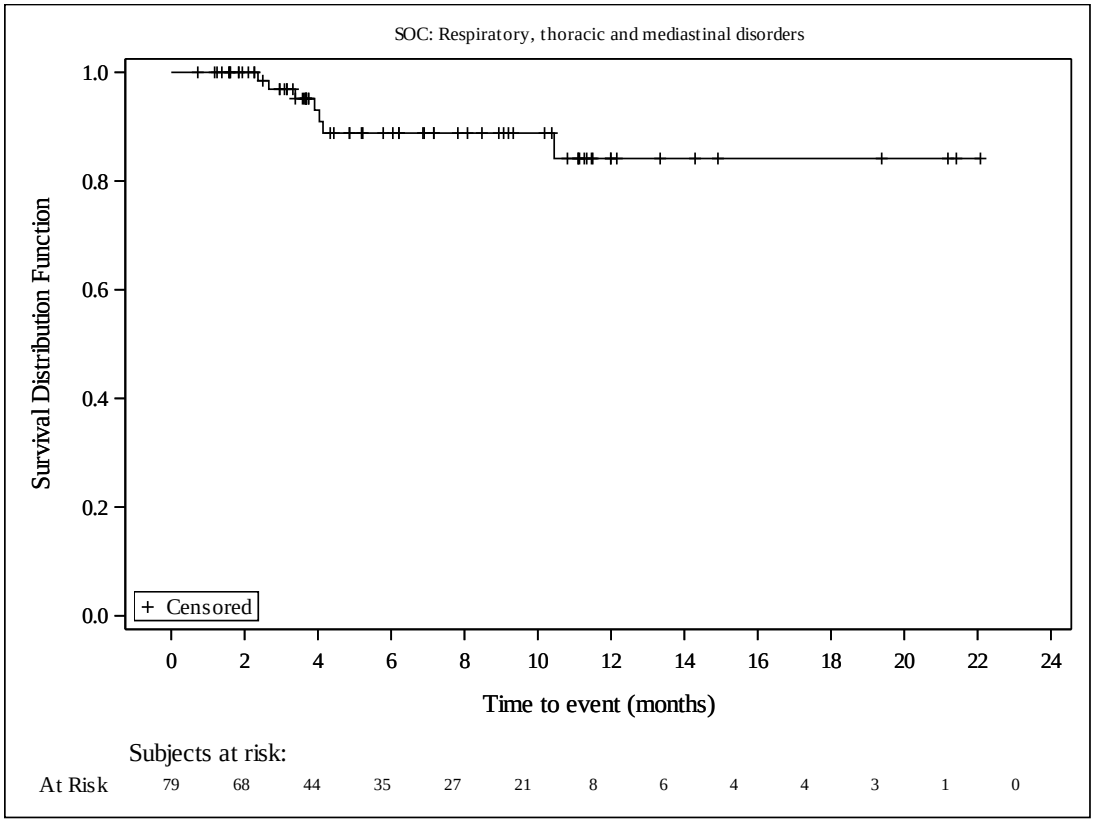

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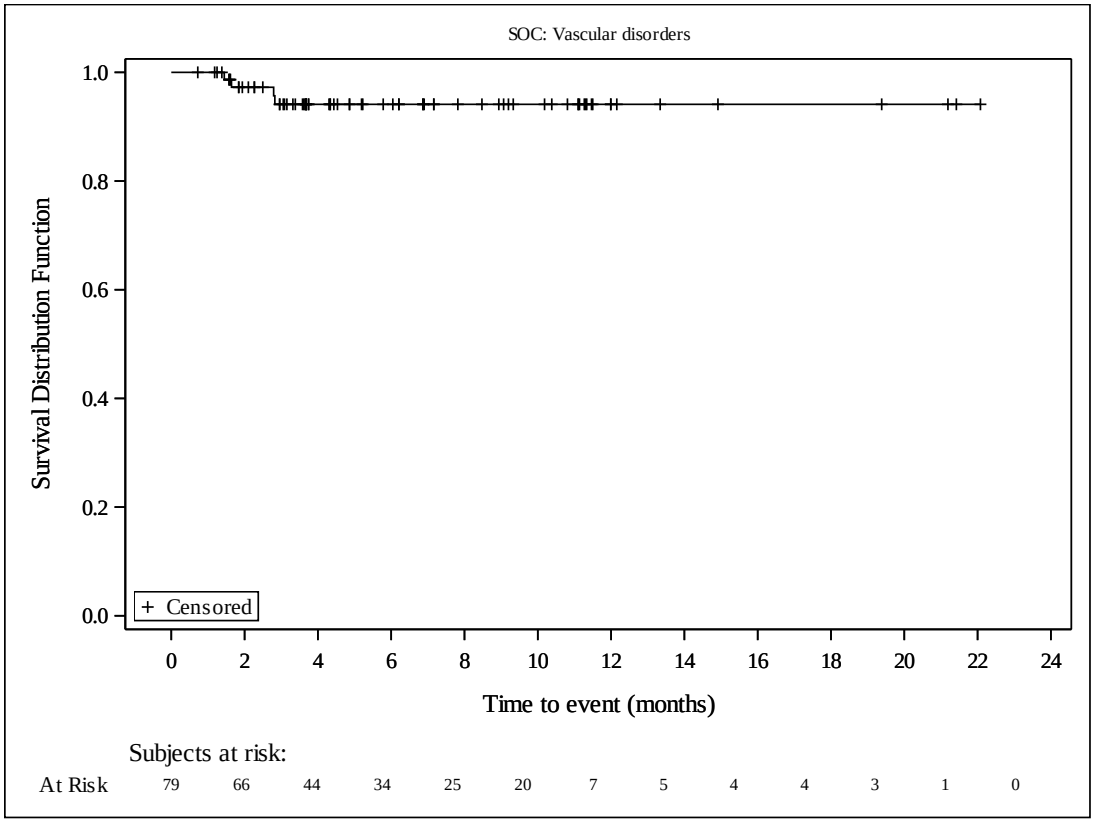

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