Dossier zur Nutzenbewertung gemäß § 35a SGB V

Trastuzumab deruxtecan (Enhertu®)

Daiichi Sankyo Deutschland GmbH

Modul 4 A, Anhang 4-G

*Erwachsene Patient*innen mit fortgeschrittenem NSCLC, deren Tumoren eine aktivierende HER2 (ERBB2)-Mutation aufweisen und die nach einer platinbasierten Chemotherapie mit oder ohne Immuntherapie eine systemische Therapie benötigen.*

Datenschnitt vom 24.03.2022 und finaler Datenschnitt vom 23.12.2022

Stand: 15.11.2023

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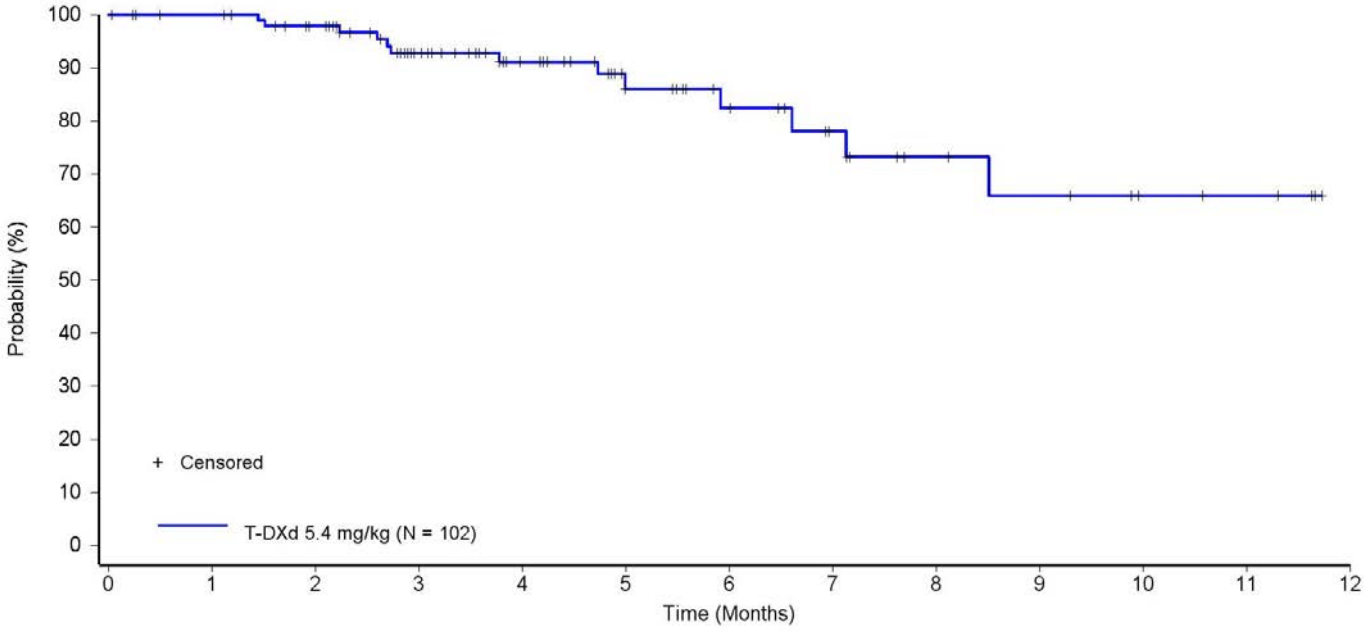
Anhang 4-G 1.1.1.1 Datenschnitt vom 24.03.2022

DE.F.1.1.2 Overall survival - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	102	97	88	66	48	29	23	16	11	9	5	4	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: f1_os_2_fas.sas; Output name: F1_OS_2_FAS.rtf

Anhang 4-G 1.1.2 Subgruppenanalysen – Gesamtüberleben

Anhang 4-G 1.1.2.1 Datenschnitt vom 24.03.2022

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	10 (13.3)	65 (86.7)	NE (8.5, NE)				
Subjects who received neither	27	3 (11.1)	24 (88.9)	NE (6.6, NE)				
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (6.6, NE)				
No	68	10 (14.7)	58 (85.3)	NE (8.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:08; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	13 (13.1)	86 (86.9)	NE (8.5, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	7 (11.3)	55 (88.7)	NE (7.1, NE)				
>=65 years	40	6 (15.0)	34 (85.0)	NE (6.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:08; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	12 (12.8)	82 (87.2)	NE (8.5, NE)				
>=75 years	8							
Sex								
Female	65	11 (16.9)	54 (83.1)	NE (7.1, NE)				
Male	37	2 (5.4)	35 (94.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:08; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	5 (10.6)	42 (89.4)	NE (NE, NE)				
Never	55	8 (14.5)	47 (85.5)	NE (6.6, NE)				
Race								
White	23	2 (8.7)	21 (91.3)	7.1 (7.1, NE)				
Non-White	79	11 (13.9)	68 (86.1)	NE (8.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:08; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	9 (14.3)	54 (85.7)	NE (8.5, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	6.6 (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:08; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

Anhang 4-G 1.1.2.2 Finaler Datenschnitt vom 23.12.2022

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	29 (38.7)	46 (61.3)	15.4 (12.0, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	19.5 (13.6, NE)				
Central nervous system (CNS) metastasis								
Yes	35	13 (37.1)	22 (62.9)	14.9 (11.0, NE)				
No	67	24 (35.8)	43 (64.2)	NE (13.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	35 (35.4)	64 (64.6)	19.5 (14.9, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	21 (33.9)	41 (66.1)	19.5 (12.0, NE)				
>=65 years	40	16 (40.0)	24 (60.0)	14.9 (13.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	35 (37.2)	59 (62.8)	19.5 (13.6, NE)				
>=75 years	8							
Sex								
Female	65	24 (36.9)	41 (63.1)	NE (12.0, NE)				
Male	37	13 (35.1)	24 (64.9)	15.4 (13.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	14 (29.8)	33 (70.2)	NE (15.4, NE)				
Never	55	23 (41.8)	32 (58.2)	14.9 (11.0, NE)				
Race								
White	23	10 (43.5)	13 (56.5)	NE (8.0, NE)				
Non-White	79	27 (34.2)	52 (65.8)	19.5 (14.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

DE.T.1.1.1 Overall survival - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	22 (34.9)	41 (65.1)	19.5 (14.9, NE)				
North America and Australia	6							
Europe	33	13 (39.4)	20 (60.6)	13.6 (10.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T1_OS_1_FAS.rtf

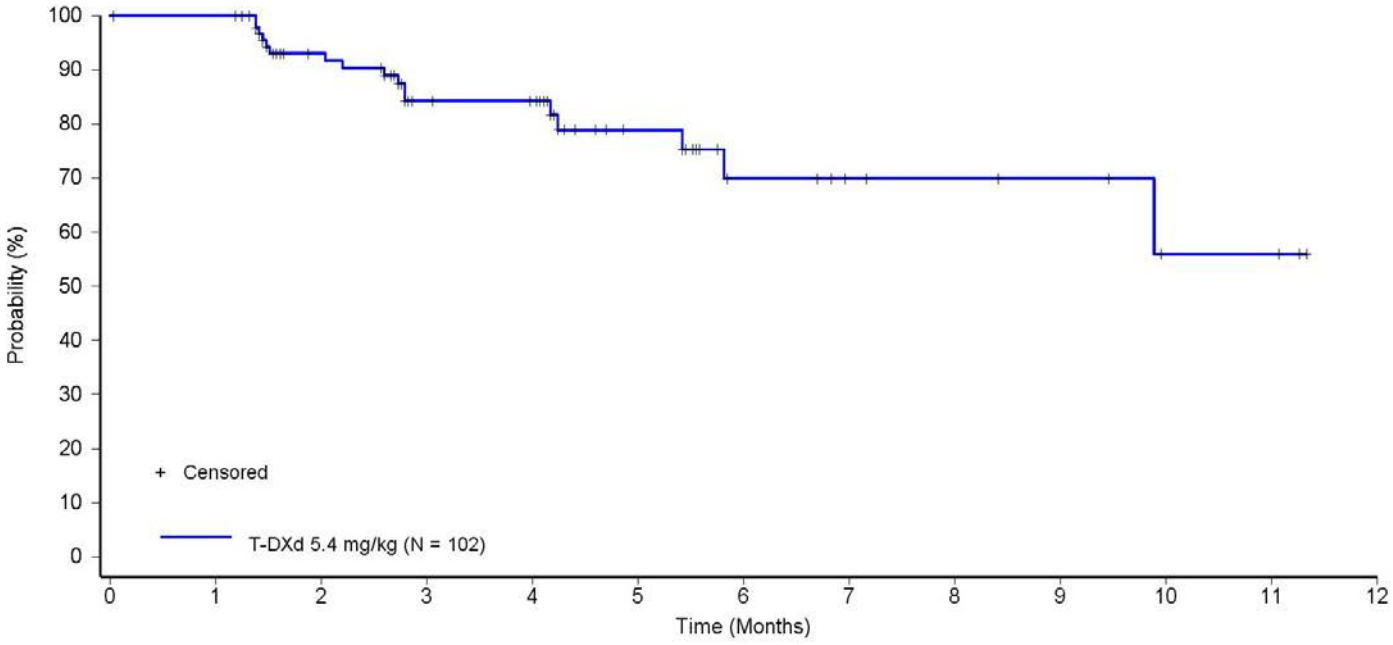
Anhang 4-G 2 Ergänzende Analysen DESTINY-Lung02 – Morbidität

Anhang 4-G 2.1 Progressionsfreies Überleben – weitere Untersuchungen

Anhang 4-G 2.1.1 Kaplan-Meier-Kurven – Progressionsfreies Überleben

Anhang 4-G 2.1.1.1 Datenschnitt vom 24.03.2022

DE.F.2.2.2 Progression-free survival based on BICR - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

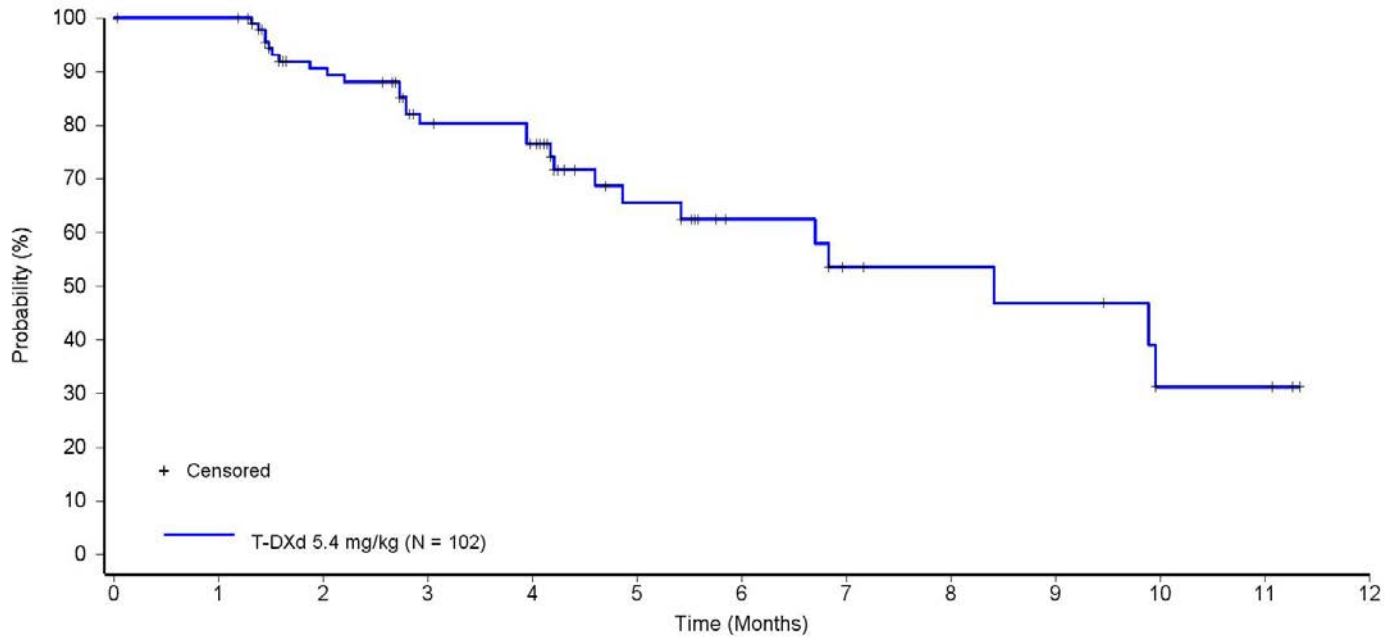


Number of subjects at risk:

T-DXd 5.4 mg/kg	102	94	69	44	40	22	12	8	7	6	3	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: f1_os_2_fas.sas; Output name: F2_PFS_BICR_2_FAS.rtf

DE.F.2.3.2 Progression-free survival based on investigator's assessment - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	102	94	70	45	40	21	14	9	8	7	3	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: f1_os_2_fas.sas; Output name: F2_PFS_INVE_2_FAS.rtf

Anhang 4-G 2.1.2 Subgruppenanalysen – Progressionsfreies Überleben

Anhang 4-G 2.1.2.1 Datenschnitt vom 24.03.2022

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	13 (17.3)	62 (82.7)	NE (9.9, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	5.8 (4.2, NE)				
Central nervous system (CNS) metastasis								
Yes	34	6 (17.6)	28 (82.4)	5.8 (4.2, NE)				
No	68	11 (16.2)	57 (83.8)	NE (9.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	16 (16.2)	83 (83.8)	NE (5.8, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	11 (17.7)	51 (82.3)	NE (5.4, NE)				
>=65 years	40	6 (15.0)	34 (85.0)	NE (9.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	15 (16.0)	79 (84.0)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	13 (20.0)	52 (80.0)	NE (5.4, NE)				
Male	37	4 (10.8)	33 (89.2)	9.9 (5.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	8 (17.0)	39 (83.0)	9.9 (9.9, NE)				
Never	55	9 (16.4)	46 (83.6)	NE (5.4, NE)				
Race								
White	23	3 (13.0)	20 (87.0)	NE (2.8, NE)				
Non-White	79	14 (17.7)	65 (82.3)	NE (9.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	12 (19.0)	51 (81.0)	NE (5.8, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	23 (30.7)	52 (69.3)	6.8 (4.6, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	10.0 (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	34	8 (23.5)	26 (76.5)	6.8 (3.9, NE)				
No	68	19 (27.9)	49 (72.1)	8.4 (4.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	26 (26.3)	73 (73.7)	8.4 (4.9, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	18 (29.0)	44 (71.0)	6.8 (4.6, NE)				
>=65 years	40	9 (22.5)	31 (77.5)	9.9 (6.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	25 (26.6)	69 (73.4)	8.4 (5.4, NE)				
>=75 years	8							
Sex								
Female	65	17 (26.2)	48 (73.8)	NE (4.6, NE)				
Male	37	10 (27.0)	27 (73.0)	8.4 (4.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	11 (23.4)	36 (76.6)	9.9 (4.9, NE)				
Never	55	16 (29.1)	39 (70.9)	6.7 (4.2, NE)				
Race								
White	23	5 (21.7)	18 (78.3)	4.6 (2.8, NE)				
Non-White	79	22 (27.8)	57 (72.2)	8.4 (5.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	19 (30.2)	44 (69.8)	8.4 (5.4, NE)				
North America and Australia	6							
Europe	33	7 (21.2)	26 (78.8)	4.2 (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

Anhang 4-G 2.1.2.2 Finaler Datenschnitt vom 23.12.2022

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	32 (42.7)	43 (57.3)	9.9 (7.1, NE)				
Subjects who received neither	27	12 (44.4)	15 (55.6)	11.0 (5.8, NE)				
Central nervous system (CNS) metastasis								
Yes	35	20 (57.1)	15 (42.9)	7.1 (5.8, 9.7)				
No	67	24 (35.8)	43 (64.2)	18.0 (8.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	42 (42.4)	57 (57.6)	10.0 (7.4, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	29 (46.8)	33 (53.2)	8.5 (6.9, NE)				
>=65 years	40	15 (37.5)	25 (62.5)	NE (7.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	41 (43.6)	53 (56.4)	10.0 (7.0, NE)				
>=75 years	8							
Sex								
Female	65	32 (49.2)	33 (50.8)	9.7 (6.9, NE)				
Male	37	12 (32.4)	25 (67.6)	NE (6.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	20 (42.6)	27 (57.4)	10.8 (6.9, NE)				
Never	55	24 (43.6)	31 (56.4)	9.7 (7.0, NE)				
Race								
White	23	11 (47.8)	12 (52.2)	7.7 (5.5, NE)				
Non-White	79	33 (41.8)	46 (58.2)	10.8 (7.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.2.1 Progression-free survival based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	28 (44.4)	35 (55.6)	10.8 (7.4, NE)				
North America and Australia	6							
Europe	33	16 (48.5)	17 (51.5)	7.7 (6.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_BICR_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	46 (61.3)	29 (38.7)	8.4 (6.8, 10.7)				
Subjects who received neither	27	14 (51.9)	13 (48.1)	12.3 (8.4, NE)				
Central nervous system (CNS) metastasis								
Yes	35	23 (65.7)	12 (34.3)	8.4 (6.7, 9.9)				
No	67	37 (55.2)	30 (44.8)	11.3 (7.1, 15.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	58 (58.6)	41 (41.4)	9.7 (7.1, 12.3)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	38 (61.3)	24 (38.7)	9.7 (7.0, 12.4)				
>=65 years	40	22 (55.0)	18 (45.0)	9.7 (6.2, 18.2)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	57 (60.6)	37 (39.4)	8.5 (7.1, 11.3)				
>=75 years	8							
Sex								
Female	65	40 (61.5)	25 (38.5)	9.7 (6.8, 12.4)				
Male	37	20 (54.1)	17 (45.9)	8.5 (8.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	26 (55.3)	21 (44.7)	9.9 (7.0, 15.3)				
Never	55	34 (61.8)	21 (38.2)	8.4 (6.8, 12.3)				
Race								
White	23	12 (52.2)	11 (47.8)	8.4 (5.4, NE)				
Non-White	79	48 (60.8)	31 (39.2)	9.7 (7.1, 12.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

DE.T.2.3.1 Progression-free survival based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	41 (65.1)	22 (34.9)	9.7 (6.7, 12.4)				
North America and Australia	6							
Europe	33	18 (54.5)	15 (45.5)	8.3 (7.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_PFS_INVE_1_FAS.rtf

Anhang 4-G 2.2 Tumoransprechen – weitere Untersuchungen

Anhang 4-G 2.2.1 Bestätigte objektive Ansprechrate – weitere Untersuchungen

Anhang 4-G 2.2.1.1 Subgruppenanalysen – Bestätigte objektive Ansprechrate

Anhang 4-G 2.2.1.1.1 Datenschnitt vom 24.03.2022

DE.T.2.4.1 Confirmed objective response rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF			
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	24 (32.0)	(21.7, 43.8)
Subjects who received neither	27	11 (40.7)	(22.4, 61.2)
Central nervous system (CNS) metastasis			
Yes	34	14 (41.2)	(24.6, 59.3)
No	68	21 (30.9)	(20.2, 43.3)
HER2 status			
Kinase domain	99	33 (33.3)	(24.2, 43.5)
Extracellular domain	3		
Transmembrane domain	0		

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_BICR_1_FAS.rtf

DE.T.2.4.1 Confirmed objective response rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Age I			
<65 years	62	23 (37.1)	(25.2, 50.3)
>=65 years	40	12 (30.0)	(16.6, 46.5)
Age II			
<75 years	94	34 (36.2)	(26.5, 46.7)
>=75 years	8		
Sex			
Female	65	22 (33.8)	(22.6, 46.6)
Male	37	13 (35.1)	(20.2, 52.5)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_BICR_1_FAS.rtf

DE.T.2.4.1 Confirmed objective response rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Smoking status			
Current	0		
Former	47	18 (38.3)	(24.5, 53.6)
Never	55	17 (30.9)	(19.1, 44.8)
Race			
White	23	5 (21.7)	(7.5, 43.7)
Non-White	79	30 (38.0)	(27.3, 49.6)
Region			
Asia	63	29 (46.0)	(33.4, 59.1)
North America and Australia	6		
Europe	33	5 (15.2)	(5.1, 31.9)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_BICR_1_FAS.rtf

DE.T.2.5.1 Confirmed objective response rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF			
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	21 (28.0)	(18.2, 39.6)
Subjects who received neither	27	7 (25.9)	(11.1, 46.3)
Central nervous system (CNS) metastasis			
Yes	34	10 (29.4)	(15.1, 47.5)
No	68	18 (26.5)	(16.5, 38.6)
HER2 status			
Kinase domain	99	26 (26.3)	(17.9, 36.1)
Extracellular domain	3		
Transmembrane domain	0		

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_INVE_1_FAS.rtf

DE.T.2.5.1 Confirmed objective response rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Age I			
<65 years	62	19 (30.6)	(19.6, 43.7)
>=65 years	40	9 (22.5)	(10.8, 38.5)
Age II			
<75 years	94	27 (28.7)	(19.9, 39.0)
>=75 years	8		
Sex			
Female	65	19 (29.2)	(18.6, 41.8)
Male	37	9 (24.3)	(11.8, 41.2)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_INVE_1_FAS.rtf

DE.T.2.5.1 Confirmed objective response rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Smoking status			
Current	0		
Former	47	13 (27.7)	(15.6, 42.6)
Never	55	15 (27.3)	(16.1, 41.0)
Race			
White	23	3 (13.0)	(2.8, 33.6)
Non-White	79	25 (31.6)	(21.6, 43.1)
Region			
Asia	63	24 (38.1)	(26.1, 51.2)
North America and Australia	6		
Europe	33	3 (9.1)	(1.9, 24.3)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_INVE_1_FAS.rtf

Anhang 4-G 2.2.1.1.2 Finaler Datenschnitt vom 23.12.2022

DE.T.2.4.1 Confirmed objective response rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF			
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	36 (48.0)	(36.3, 59.8)
Subjects who received neither	27	14 (51.9)	(31.9, 71.3)
Central nervous system (CNS) metastasis			
Yes	35	21 (60.0)	(42.1, 76.1)
No	67	29 (43.3)	(31.2, 56.0)
HER2 status			
Kinase domain	99	48 (48.5)	(38.3, 58.7)
Extracellular domain	3		
Transmembrane domain	0		

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_BICR_1_FAS.rtf

DE.T.2.4.1 Confirmed objective response rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Age I			
<65 years	62	31 (50.0)	(37.0, 63.0)
>=65 years	40	19 (47.5)	(31.5, 63.9)
Age II			
<75 years	94	46 (48.9)	(38.5, 59.5)
>=75 years	8		
Sex			
Female	65	30 (46.2)	(33.7, 59.0)
Male	37	20 (54.1)	(36.9, 70.5)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_BICR_1_FAS.rtf

DE.T.2.4.1 Confirmed objective response rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Smoking status			
Current	0		
Former	47	24 (51.1)	(36.1, 65.9)
Never	55	26 (47.3)	(33.7, 61.2)
Race			
White	23	13 (56.5)	(34.5, 76.8)
Non-White	79	37 (46.8)	(35.5, 58.4)
Region			
Asia	63	32 (50.8)	(37.9, 63.6)
North America and Australia	6		
Europe	33	15 (45.5)	(28.1, 63.6)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_BICR_1_FAS.rtf

DE.T.2.5.1 Confirmed objective response rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF			
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	35 (46.7)	(35.1, 58.6)
Subjects who received neither	27	12 (44.4)	(25.5, 64.7)
Central nervous system (CNS) metastasis			
Yes	35	17 (48.6)	(31.4, 66.0)
No	67	30 (44.8)	(32.6, 57.4)
HER2 status			
Kinase domain	99	45 (45.5)	(35.4, 55.8)
Extracellular domain	3		
Transmembrane domain	0		

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_INVE_1_FAS.rtf

DE.T.2.5.1 Confirmed objective response rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Age I			
<65 years	62	28 (45.2)	(32.5, 58.3)
>=65 years	40	19 (47.5)	(31.5, 63.9)
Age II			
<75 years	94	43 (45.7)	(35.4, 56.3)
>=75 years	8		
Sex			
Female	65	31 (47.7)	(35.1, 60.5)
Male	37	16 (43.2)	(27.1, 60.5)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_INVE_1_FAS.rtf

DE.T.2.5.1 Confirmed objective response rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Smoking status			
Current	0		
Former	47	20 (42.6)	(28.3, 57.8)
Never	55	27 (49.1)	(35.4, 62.9)
Race			
White	23	11 (47.8)	(26.8, 69.4)
Non-White	79	36 (45.6)	(34.3, 57.2)
Region			
Asia	63	31 (49.2)	(36.4, 62.1)
North America and Australia	6		
Europe	33	12 (36.4)	(20.4, 54.9)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

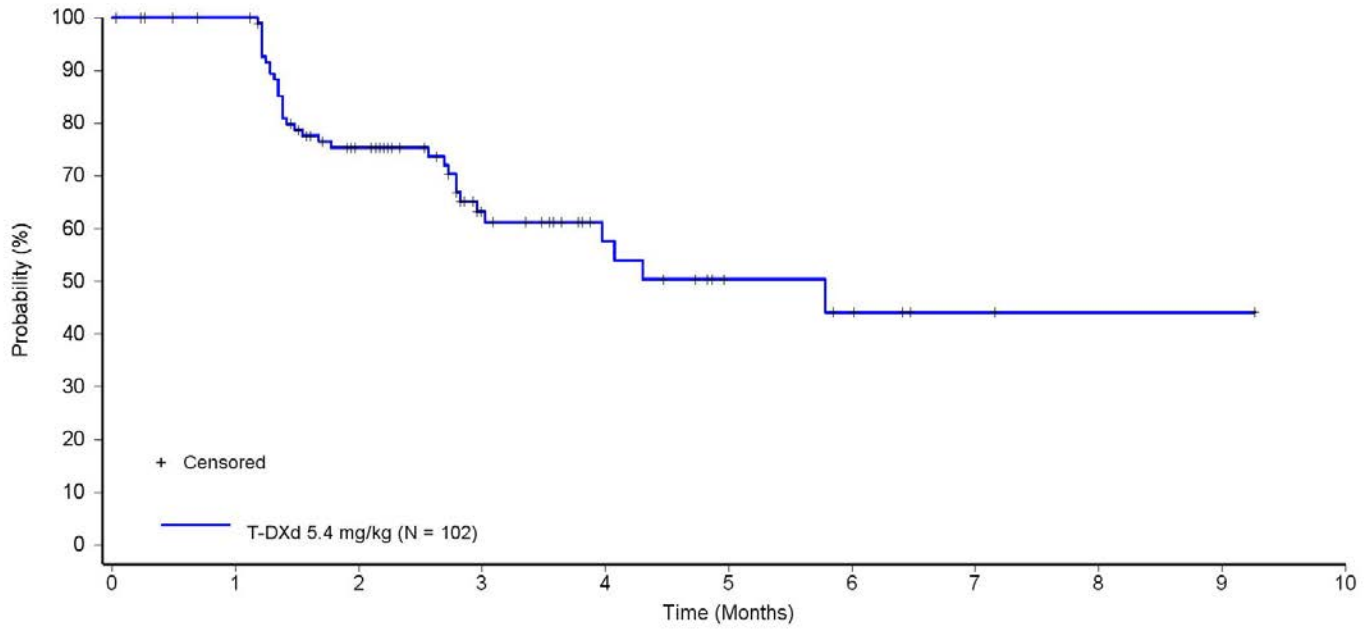
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_ORR_INVE_1_FAS.rtf

Anhang 4-G 2.2.2 Zeit bis zum bestätigten Tumoransprechen – weitere Untersuchungen

Anhang 4-G 2.2.2.1 Kaplan-Meier-Kurven – Zeit bis zum bestätigten Tumoransprechen

Anhang 4-G 2.2.2.1.1 Datenschnitt vom 24.03.2022

DE.F.2.12.2 Time to response based on BICR - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

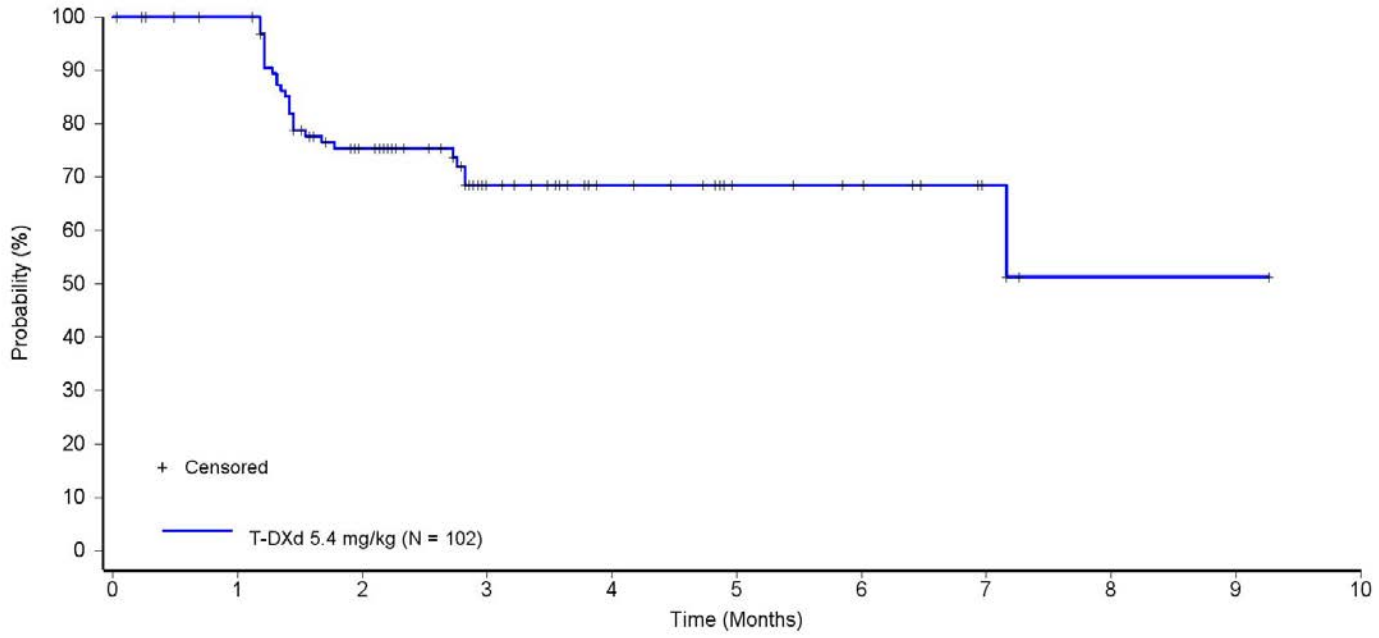


Number of subjects at risk:

T-DXd 5.4 mg/kg	102	96	60	31	16	8	6	2	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: f1_os_2_fas.sas; Output name: F2_TTR_BICR_2_FAS.rtf

DE.F.2.13.2 Time to response based on investigator's assessment - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	102	96	60	33	19	11	9	4	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: f1_os_2_fas.sas; Output name: F2_TTR_INV_2_FAS.rtf

Anhang 4-G 2.2.2.2 Subgruppenanalysen – Zeit bis zum bestätigten Tumoransprechen

Anhang 4-G 2.2.2.2.1 Datenschnitt vom 24.03.2022

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	24 (32.0)	51 (68.0)	5.8 (3.0, NE)				
Subjects who received neither	27	11 (40.7)	16 (59.3)	4.0 (1.5, NE)				
Central nervous system (CNS) metastasis								
Yes	34	14 (41.2)	20 (58.8)	3.0 (1.5, NE)				
No	68	21 (30.9)	47 (69.1)	5.8 (4.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	33 (33.3)	66 (66.7)	5.8 (3.0, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	23 (37.1)	39 (62.9)	4.1 (2.8, NE)				
>=65 years	40	12 (30.0)	28 (70.0)	NE (3.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	34 (36.2)	60 (63.8)	4.3 (3.0, NE)				
>=75 years	8							
Sex								
Female	65	22 (33.8)	43 (66.2)	5.8 (4.0, NE)				
Male	37	13 (35.1)	24 (64.9)	3.0 (2.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	18 (38.3)	29 (61.7)	5.8 (2.8, NE)				
Never	55	17 (30.9)	38 (69.1)	4.3 (3.0, NE)				
Race								
White	23	5 (21.7)	18 (78.3)	NE (2.6, NE)				
Non-White	79	30 (38.0)	49 (62.0)	4.3 (3.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	29 (46.0)	34 (54.0)	4.0 (2.7, 5.8)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	21 (28.0)	54 (72.0)	NE (7.2, NE)				
Subjects who received neither	27	7 (25.9)	20 (74.1)	NE (2.7, NE)				
Central nervous system (CNS) metastasis								
Yes	34	10 (29.4)	24 (70.6)	NE (2.7, NE)				
No	68	18 (26.5)	50 (73.5)	7.2 (7.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	26 (26.3)	73 (73.7)	NE (7.2, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	19 (30.6)	43 (69.4)	7.2 (7.2, NE)				
>=65 years	40	9 (22.5)	31 (77.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	27 (28.7)	67 (71.3)	NE (7.2, NE)				
>=75 years	8							
Sex								
Female	65	19 (29.2)	46 (70.8)	7.2 (7.2, NE)				
Male	37	9 (24.3)	28 (75.7)	NE (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	13 (27.7)	34 (72.3)	7.2 (7.2, NE)				
Never	55	15 (27.3)	40 (72.7)	NE (2.8, NE)				
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	79	25 (31.6)	54 (68.4)	7.2 (7.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	24 (38.1)	39 (61.9)	7.2 (2.8, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

Anhang 4-G 2.2.2.2.2 Finaler Datenschnitt vom 23.12.2022

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	36 (48.0)	39 (52.0)	5.5 (2.9, NE)				
Subjects who received neither	27	14 (51.9)	13 (48.1)	4.0 (1.5, NE)				
Central nervous system (CNS) metastasis								
Yes	35	21 (60.0)	14 (40.0)	2.9 (1.7, 7.0)				
No	67	29 (43.3)	38 (56.7)	5.8 (3.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	48 (48.5)	51 (51.5)	4.3 (2.9, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	31 (50.0)	31 (50.0)	4.1 (2.8, NE)				
>=65 years	40	19 (47.5)	21 (52.5)	4.3 (2.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	46 (48.9)	48 (51.1)	4.2 (2.9, NE)				
>=75 years	8							
Sex								
Female	65	30 (46.2)	35 (53.8)	5.5 (3.1, NE)				
Male	37	20 (54.1)	17 (45.9)	3.0 (2.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	24 (51.1)	23 (48.9)	4.2 (2.8, NE)				
Never	55	26 (47.3)	29 (52.7)	4.0 (2.8, NE)				
Race								
White	23	13 (56.5)	10 (43.5)	2.8 (1.8, NE)				
Non-White	79	37 (46.8)	42 (53.2)	5.8 (3.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.12.1 Time to response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	32 (50.8)	31 (49.2)	4.2 (2.8, NE)				
North America and Australia	6							
Europe	33	15 (45.5)	18 (54.5)	4.1 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_BICR_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	35 (46.7)	40 (53.3)	5.8 (2.8, NE)				
Subjects who received neither	27	12 (44.4)	15 (55.6)	8.1 (2.8, NE)				
Central nervous system (CNS) metastasis								
Yes	35	17 (48.6)	18 (51.4)	8.1 (1.8, NE)				
No	67	30 (44.8)	37 (55.2)	6.8 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	45 (45.5)	54 (54.5)	6.8 (3.1, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	28 (45.2)	34 (54.8)	5.5 (2.8, NE)				
>=65 years	40	19 (47.5)	21 (52.5)	6.8 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	43 (45.7)	51 (54.3)	6.8 (2.9, NE)				
>=75 years	8							
Sex								
Female	65	31 (47.7)	34 (52.3)	6.8 (2.8, NE)				
Male	37	16 (43.2)	21 (56.8)	5.8 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	20 (42.6)	27 (57.4)	7.2 (3.1, NE)				
Never	55	27 (49.1)	28 (50.9)	4.1 (2.8, NE)				
Race								
White	23	11 (47.8)	12 (52.2)	5.5 (1.8, NE)				
Non-White	79	36 (45.6)	43 (54.4)	6.8 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

DE.T.2.13.1 Time to response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	31 (49.2)	32 (50.8)	4.2 (2.8, NE)				
North America and Australia	6							
Europe	33	12 (36.4)	21 (63.6)	NE (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

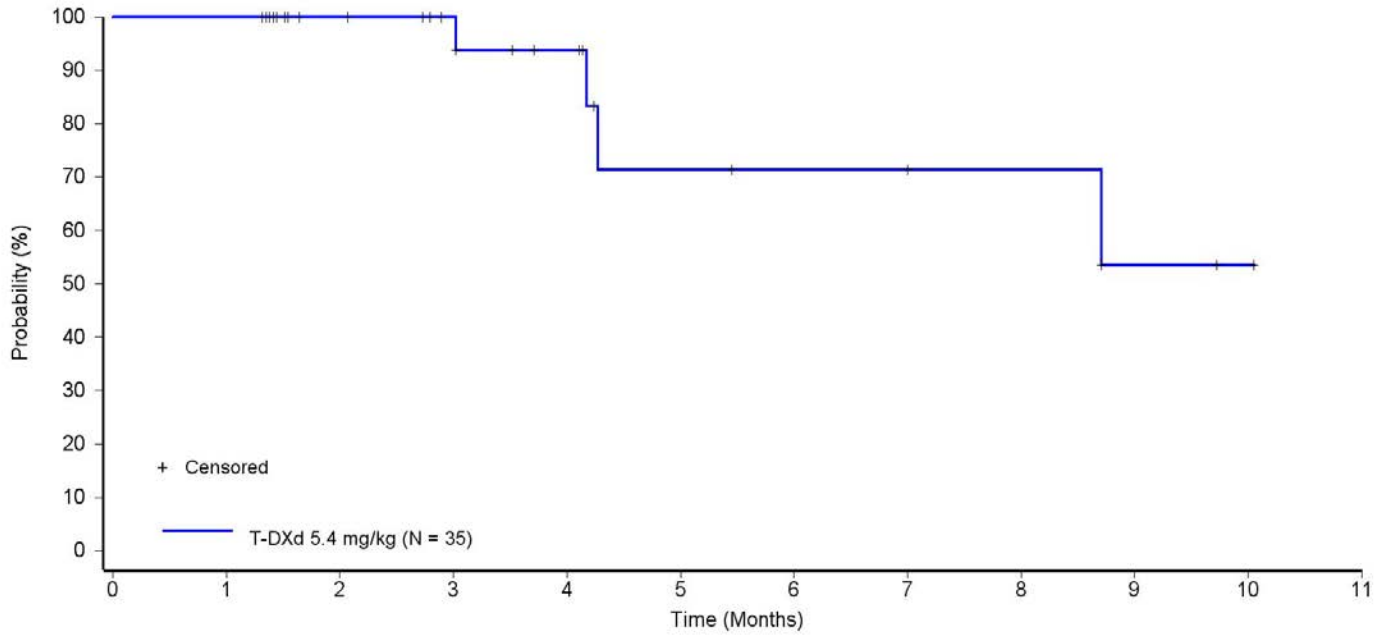
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:18; Program name: t1_os_1_fas.sas; Output name: T2_TTR_INV_1_FAS.rtf

Anhang 4-G 2.2.3 Dauer des bestätigten Tumoransprechens – weitere Untersuchungen

Anhang 4-G 2.2.3.1 Kaplan-Meier-Kurven – Dauer des bestätigten Tumoransprechens

Anhang 4-G 2.2.3.1.1 Datenschnitt vom 24.03.2022

DE.F.2.10.2 Duration of response based on BICR - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

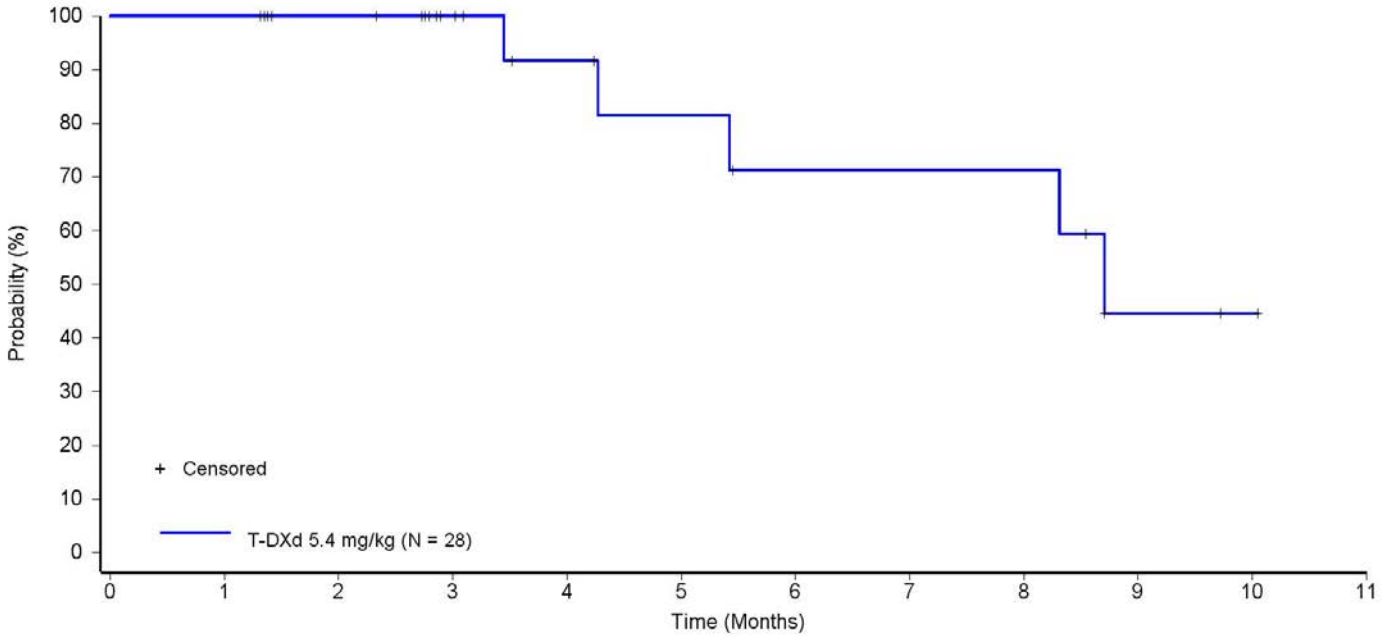


Number of subjects at risk:

T-DXd 5.4 mg/kg	35	35	23	16	11	6	5	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: f1_os_2_fas.sas; Output name: F2_DOR_BICR_2_FAS.rtf

DE.F.2.11.2 Duration of response based on investigator's assessment - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	28	28	22	14	10	8	6	6	6	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: f1_os_2_fas.sas; Output name: F2_DOR_INVE_2_FAS.rtf

Anhang 4-G 2.2.3.2 Subgruppenanalysen – Dauer des bestätigten Tumoransprechens

Anhang 4-G 2.2.3.2.1 Datenschnitt vom 24.03.2022

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=35)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	24	2 (8.3)	22 (91.7)	NE (4.3, NE)				
Subjects who received neither	11	2 (18.2)	9 (81.8)	4.2 (3.0, NE)				
Central nervous system (CNS) metastasis								
Yes	14	2 (14.3)	12 (85.7)	4.2 (3.0, NE)				
No	21	2 (9.5)	19 (90.5)	NE (4.3, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=35)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	33	3 (9.1)	30 (90.9)	NE (4.2, NE)				
Extracellular domain	2							
Transmembrane domain	0							
Age I								
<65 years	23	3 (13.0)	20 (87.0)	4.3 (3.0, NE)				
>=65 years	12	1 (8.3)	11 (91.7)	NE (8.7, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=35)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	34	3 (8.8)	31 (91.2)	NE (4.2, NE)				
>=75 years	1							
Sex								
Female	22	2 (9.1)	20 (90.9)	NE (4.3, NE)				
Male	13	2 (15.4)	11 (84.6)	8.7 (4.2, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=35)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	18	1 (5.6)	17 (94.4)	NE (8.7, NE)				
Never	17	3 (17.6)	14 (82.4)	NE (4.2, NE)				
Race								
White	5							
Non-White	30	4 (13.3)	26 (86.7)	NE (4.2, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=35)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	29	4 (13.8)	25 (86.2)	NE (4.2, NE)				
North America and Australia	1							
Europe	5							

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=28)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	21	4 (19.0)	17 (81.0)	NE (3.4, NE)				
Subjects who received neither	7							
Central nervous system (CNS) metastasis								
Yes	10	2 (20.0)	8 (80.0)	8.3 (5.4, NE)				
No	18	3 (16.7)	15 (83.3)	8.7 (3.4, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=28)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	26	4 (15.4)	22 (84.6)	NE (4.3, NE)				
Extracellular domain	2							
Transmembrane domain	0							
Age I								
<65 years	19	4 (21.1)	15 (78.9)	8.3 (3.4, NE)				
>=65 years	9							

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=28)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	27	4 (14.8)	23 (85.2)	NE (4.3, NE)				
>=75 years	1							
Sex								
Female	19	3 (15.8)	16 (84.2)	NE (3.4, NE)				
Male	9							

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=28)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	13	1 (7.7)	12 (92.3)	NE (8.7, NE)				
Never	15	4 (26.7)	11 (73.3)	8.3 (3.4, NE)				
Race								
White	3							
Non-White	25	4 (16.0)	21 (84.0)	8.7 (4.3, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=28)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	24	4 (16.7)	20 (83.3)	8.7 (4.3, NE)				
North America and Australia	1							
Europe	3							

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

Anhang 4-G 2.2.3.2.2 Finaler Datenschnitt vom 23.12.2022

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=50)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	36	14 (38.9)	22 (61.1)	16.8 (5.8, NE)				
Subjects who received neither	14	6 (42.9)	8 (57.1)	NE (4.2, NE)				
Central nervous system (CNS) metastasis								
Yes	21	15 (71.4)	6 (28.6)	4.6 (4.2, 6.4)				
No	29	5 (17.2)	24 (82.8)	16.8 (16.8, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=50)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	48	19 (39.6)	29 (60.4)	16.8 (5.8, NE)				
Extracellular domain	2							
Transmembrane domain	0							
Age I								
<65 years	31	15 (48.4)	16 (51.6)	9.5 (4.3, NE)				
>=65 years	19	5 (26.3)	14 (73.7)	NE (7.1, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=50)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	46	18 (39.1)	28 (60.9)	16.8 (5.7, NE)				
>=75 years	4							
Sex								
Female	30	12 (40.0)	18 (60.0)	16.8 (5.8, NE)				
Male	20	8 (40.0)	12 (60.0)	8.7 (4.2, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=50)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	24	9 (37.5)	15 (62.5)	NE (4.6, NE)				
Never	26	11 (42.3)	15 (57.7)	16.8 (5.5, NE)				
Race								
White	13	7 (53.8)	6 (46.2)	5.7 (4.1, NE)				
Non-White	37	13 (35.1)	24 (64.9)	16.8 (8.7, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.10.1 Duration of response based on BICR - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=50)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	32	12 (37.5)	20 (62.5)	16.8 (7.1, NE)				
North America and Australia	3							
Europe	15	8 (53.3)	7 (46.7)	6.4 (4.2, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_BICR_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=47)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	35	18 (51.4)	17 (48.6)	9.9 (6.9, 16.8)				
Subjects who received neither	12	4 (33.3)	8 (66.7)	NE (4.5, NE)				
Central nervous system (CNS) metastasis								
Yes	17	11 (64.7)	6 (35.3)	7.1 (4.6, 9.5)				
No	30	11 (36.7)	19 (63.3)	13.9 (9.5, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=47)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	45	21 (46.7)	24 (53.3)	9.9 (7.2, 17.0)				
Extracellular domain	2							
Transmembrane domain	0							
Age I								
<65 years	28	14 (50.0)	14 (50.0)	9.9 (6.9, NE)				
>=65 years	19	8 (42.1)	11 (57.9)	17.0 (5.9, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=47)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	43	20 (46.5)	23 (53.5)	13.9 (7.1, 17.0)				
>=75 years	4							
Sex								
Female	31	14 (45.2)	17 (54.8)	16.8 (5.9, NE)				
Male	16	8 (50.0)	8 (50.0)	9.5 (6.9, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=47)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	20	8 (40.0)	12 (60.0)	9.9 (7.1, NE)				
Never	27	14 (51.9)	13 (48.1)	9.5 (5.9, NE)				
Race								
White	11	6 (54.5)	5 (45.5)	7.1 (3.6, NE)				
Non-White	36	16 (44.4)	20 (55.6)	13.9 (8.7, 17.0)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

DE.T.2.11.1 Duration of response based on investigator's assessment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=47)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	31	15 (48.4)	16 (51.6)	13.9 (8.3, 17.0)				
North America and Australia	4							
Europe	12	6 (50.0)	6 (50.0)	7.2 (3.6, NE)				

N: number of subjects with response in analysis set; Nsub: number of subjects with response in subgroup category; %: proportion of number of subjects with response in subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t1_os_1_fas.sas; Output name: T2_DOR_INVE_1_FAS.rtf

Anhang 4-G 2.2.4 Summe der Durchmesser aller Zielläsionen – weitere Untersuchungen

Anhang 4-G 2.2.4.1 Subgruppenanalysen – Summe der Durchmesser aller Zielläsionen

Anhang 4-G 2.2.4.1.1 Datenschnitt vom 24.03.2022

DE.T.2.8.1 Best percent change in the sum of the diameter of measurable tumors based on BICR - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF						
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	68	-32.1 (25.2)	-29.0 (-46.0, -10.5)	-100.0	10.0
Subjects who received neither	27	25	-32.9 (22.6)	-37.0 (-53.0, -12.0)	-64.0	0.0
Central nervous system (CNS) metastasis						
Yes	34	30	-38.5 (22.5)	-45.0 (-51.0, -23.0)	-100.0	10.0
No	68	63	-29.4 (24.9)	-25.0 (-44.0, -9.0)	-100.0	6.0

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_BICR_1_FAS.rtf

DE.T.2.8.1 Best percent change in the sum of the diameter of measurable tumors based on BICR - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
HER2 status						
Kinase domain	99	90	-31.9 (24.6)	-29.0 (-48.0, -10.0)	-100.0	10.0
Extracellular domain	3					
Transmembrane domain	0					
Age I						
<65 years	62	54	-31.5 (23.8)	-29.0 (-46.0, -10.0)	-100.0	10.0
>=65 years	40	39	-33.4 (25.5)	-31.0 (-51.0, -11.0)	-100.0	6.0
Age II						
<75 years	94	86	-32.0 (24.5)	-29.0 (-48.0, -10.0)	-100.0	10.0
>=75 years	8					

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_BICR_1_FAS.rtf

DE.T.2.8.1 Best percent change in the sum of the diameter of measurable tumors based on BICR - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Sex						
Female	65	58	-31.7 (25.9)	-24.5 (-53.0, -9.0)	-100.0	6.0
Male	37	35	-33.3 (22.1)	-36.0 (-48.0, -14.0)	-100.0	10.0
Smoking status						
Current	0					
Former	47	46	-31.8 (26.3)	-30.5 (-48.0, -10.0)	-100.0	10.0
Never	55	47	-32.8 (22.7)	-28.0 (-51.0, -12.0)	-100.0	1.0
Race						
White	23	21	-33.3 (19.8)	-37.0 (-46.0, -22.0)	-66.0	1.0
Non-White	79	72	-32.0 (25.7)	-28.0 (-50.5, -9.5)	-100.0	10.0

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_BICR_1_FAS.rtf

DE.T.2.8.1 Best percent change in the sum of the diameter of measurable tumors based on BICR - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Region						
Asia	63	58	-35.8 (26.6)	-38.5 (-53.0, -10.0)	-100.0	10.0
North America and Australia	6					
Europe	33	31	-27.5 (19.5)	-24.0 (-41.0, -12.0)	-66.0	6.0

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_BICR_1_FAS.rtf

DE.T.2.9.1 Best percent change in the sum of the diameter of measurable tumors based on investigator's assessment - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF						
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	69	-30.6 (24.3)	-29.6 (-47.6, -11.9)	-83.7	16.7
Subjects who received neither	27	24	-23.2 (21.0)	-25.9 (-40.5, -1.7)	-62.6	15.0
Central nervous system (CNS) metastasis						
Yes	34	30	-33.4 (19.1)	-32.2 (-46.4, -17.7)	-67.8	3.0
No	68	63	-26.4 (25.3)	-25.9 (-43.9, -3.5)	-83.7	16.7

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_INVE_1_FAS.rtf

DE.T.2.9.1 Best percent change in the sum of the diameter of measurable tumors based on investigator's assessment - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
HER2 status						
Kinase domain	99	90	-28.1 (23.4)	-28.6 (-43.1, -10.0)	-83.7	16.7
Extracellular domain	3					
Transmembrane domain	0					
Age I						
<65 years	62	55	-27.8 (25.1)	-28.6 (-46.4, -3.5)	-83.7	16.7
>=65 years	40	38	-30.0 (21.6)	-27.9 (-43.9, -12.5)	-73.7	5.1
Age II						
<75 years	94	86	-28.8 (24.0)	-29.4 (-45.8, -10.0)	-83.7	16.7
>=75 years	8					

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_INVE_1_FAS.rtf

DE.T.2.9.1 Best percent change in the sum of the diameter of measurable tumors based on investigator's assessment - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Sex						
Female	65	57	-28.3 (24.0)	-26.7 (-42.2, -10.0)	-83.7	16.7
Male	37	36	-29.3 (23.3)	-29.4 (-46.1, -11.0)	-80.0	3.0
Smoking status						
Current	0					
Former	47	47	-28.6 (23.7)	-28.6 (-43.9, -10.0)	-80.0	5.1
Never	55	46	-28.8 (23.8)	-29.6 (-46.4, -10.3)	-83.7	16.7
Race						
White	23	21	-22.7 (18.6)	-25.8 (-38.8, -10.3)	-54.0	16.7
Non-White	79	72	-30.4 (24.7)	-29.4 (-49.3, -10.2)	-83.7	15.0

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_INVE_1_FAS.rtf

DE.T.2.9.1 Best percent change in the sum of the diameter of measurable tumors based on investigator's assessment - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Region						
Asia	63	59	-32.7 (25.5)	-33.3 (-53.2, -10.4)	-83.7	15.0
North America and Australia	6					
Europe	33	30	-21.1 (18.2)	-21.7 (-32.3, -5.3)	-54.0	16.7

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_INVE_1_FAS.rtf

Anhang 4-G 2.2.4.1.2 Finaler Datenschnitt vom 23.12.2022

DE.T.2.8.1 Best percent change in the sum of the diameter of measurable tumors based on BICR - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Systemic Therapy eCRF						
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	73	-39.9 (28.1)	-39.0 (-66.0, -17.0)	-100.0	6.0
Subjects who received neither	27	26	-41.1 (30.6)	-45.5 (-62.0, -16.0)	-100.0	12.0
Central nervous system (CNS) metastasis						
Yes	35	34	-40.6 (20.7)	-48.0 (-54.0, -19.0)	-71.0	0.0
No	67	65	-40.0 (32.2)	-28.0 (-71.0, -12.0)	-100.0	12.0

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_BICR_1_FAS.rtf

DE.T.2.8.1 Best percent change in the sum of the diameter of measurable tumors based on BICR - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
HER2 status						
Kinase domain	99	96	-40.1 (28.9)	-39.0 (-66.5, -16.0)	-100.0	12.0
Extracellular domain	3					
Transmembrane domain	0					
Age I						
<65 years	62	59	-39.2 (29.6)	-39.0 (-68.0, -12.0)	-100.0	12.0
>=65 years	40	40	-41.7 (27.5)	-43.5 (-62.0, -18.0)	-100.0	6.0
Age II						
<75 years	94	91	-39.4 (28.6)	-39.0 (-67.0, -16.0)	-100.0	12.0
>=75 years	8					

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_BICR_1_FAS.rtf

DE.T.2.8.1 Best percent change in the sum of the diameter of measurable tumors based on BICR - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Sex						
Female	65	63	-39.7 (30.9)	-37.0 (-68.0, -16.0)	-100.0	12.0
Male	37	36	-41.1 (24.6)	-48.0 (-58.5, -18.0)	-86.0	0.0
Smoking status						
Current	0					
Former	47	46	-40.5 (29.8)	-44.5 (-66.0, -12.0)	-100.0	6.0
Never	55	53	-39.9 (27.9)	-37.0 (-62.0, -20.0)	-100.0	12.0
Race						
White	23	22	-43.1 (26.8)	-44.5 (-60.0, -23.0)	-100.0	1.0
Non-White	79	77	-39.4 (29.3)	-37.0 (-66.0, -16.0)	-100.0	12.0

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_BICR_1_FAS.rtf

DE.T.2.8.1 Best percent change in the sum of the diameter of measurable tumors based on BICR - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Region						
Asia	63	61	-42.3 (30.3)	-43.0 (-70.0, -19.0)	-100.0	12.0
North America and Australia	6					
Europe	33	33	-37.5 (26.5)	-37.0 (-58.0, -15.0)	-100.0	6.0

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_BICR_1_FAS.rtf

DE.T.2.9.1 Best percent change in the sum of the diameter of measurable tumors based on investigator's assessment - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF						
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	74	-35.2 (26.2)	-38.8 (-53.2, -13.5)	-100.0	16.7
Subjects who received neither	27	25	-28.0 (22.3)	-30.4 (-43.9, -6.8)	-62.6	15.0
Central nervous system (CNS) metastasis						
Yes	35	34	-35.0 (20.6)	-39.2 (-54.0, -14.6)	-68.6	3.0
No	67	65	-32.5 (27.6)	-33.3 (-50.0, -11.8)	-100.0	16.7

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_INVE_1_FAS.rtf

DE.T.2.9.1 Best percent change in the sum of the diameter of measurable tumors based on investigator's assessment - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
HER2 status						
Kinase domain	99	96	-33.0 (25.3)	-36.2 (-51.3, -12.8)	-100.0	16.7
Extracellular domain	3					
Transmembrane domain	0					
Age I						
<65 years	62	60	-31.2 (25.6)	-38.8 (-49.3, -9.5)	-88.8	16.7
>=65 years	40	39	-36.8 (24.9)	-33.3 (-54.5, -17.7)	-100.0	5.1
Age II						
<75 years	94	91	-33.2 (25.7)	-38.3 (-52.2, -11.9)	-100.0	16.7
>=75 years	8					

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_INVE_1_FAS.rtf

DE.T.2.9.1 Best percent change in the sum of the diameter of measurable tumors based on investigator's assessment - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Sex						
Female	65	62	-31.4 (24.6)	-35.4 (-45.8, -12.1)	-88.8	16.7
Male	37	37	-36.8 (26.5)	-38.5 (-54.8, -16.2)	-100.0	3.0
Smoking status						
Current	0					
Former	47	47	-34.3 (26.1)	-28.6 (-53.1, -12.1)	-100.0	5.1
Never	55	52	-32.6 (24.8)	-37.9 (-49.3, -12.8)	-88.8	16.7
Race						
White	23	22	-30.7 (22.9)	-37.9 (-50.5, -12.1)	-61.0	16.7
Non-White	79	77	-34.2 (26.1)	-33.3 (-53.0, -13.5)	-100.0	15.0

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_INVE_1_FAS.rtf

DE.T.2.9.1 Best percent change in the sum of the diameter of measurable tumors based on investigator's assessment - Analysis of continuous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full analysis Set

	T-DXd 5.4 mg/kg (N=102)					
Subgroup	N/Nsub	n	Mean (SD)	Median (IQR)	Minimum	Maximum
Region						
Asia	63	62	-35.8 (26.0)	-40.0 (-54.5, -13.5)	-88.8	15.0
North America and Australia	6					
Europe	33	32	-28.8 (24.9)	-27.1 (-46.3, -10.5)	-100.0	16.7

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; n: number of subjects with an observation; IQR: interquartile range; Mean: arithmetic mean; SD: standard deviation

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_bchg_bicr_1_fas.sas; Output name: T2_BCHG_INVE_1_FAS.rtf

Anhang 4-G 2.2.5 Bestätigte Krankheitskontrollrate – weitere Untersuchungen

Anhang 4-G 2.2.5.1 Subgruppenanalysen – Bestätigte Krankheitskontrollrate

Anhang 4-G 2.2.5.1.1 Datenschnitt vom 24.03.2022

DE.T.2.6.1 Disease control rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF			
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	65 (86.7)	(76.8, 93.4)
Subjects who received neither	27	24 (88.9)	(70.8, 97.6)
Central nervous system (CNS) metastasis			
Yes	34	28 (82.4)	(65.5, 93.2)
No	68	61 (89.7)	(79.9, 95.8)
HER2 status			
Kinase domain	99	86 (86.9)	(78.6, 92.8)
Extracellular domain	3		
Transmembrane domain	0		

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_BICR_1_FAS.rtf

DE.T.2.6.1 Disease control rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Age I			
<65 years	62	51 (82.3)	(70.5, 90.8)
>=65 years	40	38 (95.0)	(83.1, 99.4)
Age II			
<75 years	94	82 (87.2)	(78.8, 93.2)
>=75 years	8		
Sex			
Female	65	55 (84.6)	(73.5, 92.4)
Male	37	34 (91.9)	(78.1, 98.3)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_BICR_1_FAS.rtf

DE.T.2.6.1 Disease control rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Smoking status			
Current	0		
Former	47	43 (91.5)	(79.6, 97.6)
Never	55	46 (83.6)	(71.2, 92.2)
Race			
White	23	20 (87.0)	(66.4, 97.2)
Non-White	79	69 (87.3)	(78.0, 93.8)
Region			
Asia	63	57 (90.5)	(80.4, 96.4)
North America and Australia	6		
Europe	33	28 (84.8)	(68.1, 94.9)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_BICR_1_FAS.rtf

DE.T.2.7.1 Disease control rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF			
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	63 (84.0)	(73.7, 91.4)
Subjects who received neither	27	24 (88.9)	(70.8, 97.6)
Central nervous system (CNS) metastasis			
Yes	34	29 (85.3)	(68.9, 95.0)
No	68	58 (85.3)	(74.6, 92.7)
HER2 status			
Kinase domain	99	84 (84.8)	(76.2, 91.3)
Extracellular domain	3		
Transmembrane domain	0		

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_INVE_1_FAS.rtf

DE.T.2.7.1 Disease control rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Age I			
<65 years	62	52 (83.9)	(72.3, 92.0)
>=65 years	40	35 (87.5)	(73.2, 95.8)
Age II			
<75 years	94	80 (85.1)	(76.3, 91.6)
>=75 years	8		
Sex			
Female	65	53 (81.5)	(70.0, 90.1)
Male	37	34 (91.9)	(78.1, 98.3)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_INVE_1_FAS.rtf

DE.T.2.7.1 Disease control rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Smoking status			
Current	0		
Former	47	44 (93.6)	(82.5, 98.7)
Never	55	43 (78.2)	(65.0, 88.2)
Race			
White	23	19 (82.6)	(61.2, 95.0)
Non-White	79	68 (86.1)	(76.5, 92.8)
Region			
Asia	63	56 (88.9)	(78.4, 95.4)
North America and Australia	6		
Europe	33	27 (81.8)	(64.5, 93.0)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:09; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_INVE_1_FAS.rtf

Anhang 4-G 2.2.5.1.2 Finaler Datenschnitt vom 23.12.2022

DE.T.2.6.1 Disease control rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF			
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	70 (93.3)	(85.1, 97.8)
Subjects who received neither	27	25 (92.6)	(75.7, 99.1)
Central nervous system (CNS) metastasis			
Yes	35	33 (94.3)	(80.8, 99.3)
No	67	62 (92.5)	(83.4, 97.5)
HER2 status			
Kinase domain	99	92 (92.9)	(86.0, 97.1)
Extracellular domain	3		
Transmembrane domain	0		

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_BICR_1_FAS.rtf

DE.T.2.6.1 Disease control rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Age I			
<65 years	62	56 (90.3)	(80.1, 96.4)
>=65 years	40	39 (97.5)	(86.8, 99.9)
Age II			
<75 years	94	87 (92.6)	(85.3, 97.0)
>=75 years	8		
Sex			
Female	65	59 (90.8)	(81.0, 96.5)
Male	37	36 (97.3)	(85.8, 99.9)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_BICR_1_FAS.rtf

DE.T.2.6.1 Disease control rate based on BICR - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Smoking status			
Current	0		
Former	47	44 (93.6)	(82.5, 98.7)
Never	55	51 (92.7)	(82.4, 98.0)
Race			
White	23	21 (91.3)	(72.0, 98.9)
Non-White	79	74 (93.7)	(85.8, 97.9)
Region			
Asia	63	59 (93.7)	(84.5, 98.2)
North America and Australia	6		
Europe	33	31 (93.9)	(79.8, 99.3)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_BICR_1_FAS.rtf

DE.T.2.7.1 Disease control rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF			
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	68 (90.7)	(81.7, 96.2)
Subjects who received neither	27	24 (88.9)	(70.8, 97.6)
Central nervous system (CNS) metastasis			
Yes	35	33 (94.3)	(80.8, 99.3)
No	67	59 (88.1)	(77.8, 94.7)
HER2 status			
Kinase domain	99	89 (89.9)	(82.2, 95.0)
Extracellular domain	3		
Transmembrane domain	0		

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_INVE_1_FAS.rtf

DE.T.2.7.1 Disease control rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Age I			
<65 years	62	56 (90.3)	(80.1, 96.4)
>=65 years	40	36 (90.0)	(76.3, 97.2)
Age II			
<75 years	94	84 (89.4)	(81.3, 94.8)
>=75 years	8		
Sex			
Female	65	57 (87.7)	(77.2, 94.5)
Male	37	35 (94.6)	(81.8, 99.3)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_INVE_1_FAS.rtf

DE.T.2.7.1 Disease control rate based on investigator's assessment - Analysis of dichotomous endpoints including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)		
Subgroup	N/Nsub	Number of subjects with event n (%)	95% Confidence Interval [a]
Smoking status			
Current	0		
Former	47	44 (93.6)	(82.5, 98.7)
Never	55	48 (87.3)	(75.5, 94.7)
Race			
White	23	20 (87.0)	(66.4, 97.2)
Non-White	79	72 (91.1)	(82.6, 96.4)
Region			
Asia	63	58 (92.1)	(82.4, 97.4)
North America and Australia	6		
Europe	33	29 (87.9)	(71.8, 96.6)

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category
[a] Based on Clopper-Pearson method for single proportion.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 14:17; Program name: t2_orr_bicr_1_fas.sas; Output name: T2_DCR_INVE_1_FAS.rtf

Anhang 4-G 2.3 Zeit bis zur Hospitalisierung – weitere Untersuchungen

Anhang 4-G 2.3.1 Subgruppenanalysen – Zeit bis zur Hospitalisierung

Anhang 4-G 2.3.1.1 Finaler Datenschnitt vom 23.12.2022

DE.T.2.14.1 Time to hospitalization - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	29 (38.7)	46 (61.3)	NE (5.9, NE)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	35	11 (31.4)	24 (68.6)	NE (7.0, NE)				
No	67	23 (34.3)	44 (65.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:36; Program name: t1_os_1_fas.sas; Output name: T2_HOSP_1_FAS.rtf

DE.T.2.14.1 Time to hospitalization - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	99	33 (33.3)	66 (66.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	62	15 (24.2)	47 (75.8)	NE (NE, NE)				
>=65 years	40	19 (47.5)	21 (52.5)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:36; Program name: t1_os_1_fas.sas; Output name: T2_HOSP_1_FAS.rtf

DE.T.2.14.1 Time to hospitalization - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	94	32 (34.0)	62 (66.0)	NE (10.2, NE)				
>=75 years	8							
Sex								
Female	65	25 (38.5)	40 (61.5)	NE (7.0, NE)				
Male	37	9 (24.3)	28 (75.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:36; Program name: t1_os_1_fas.sas; Output name: T2_HOSP_1_FAS.rtf

DE.T.2.14.1 Time to hospitalization - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	47	12 (25.5)	35 (74.5)	NE (NE, NE)				
Never	55	22 (40.0)	33 (60.0)	NE (6.1, NE)				
Race								
White	23	9 (39.1)	14 (60.9)	NE (4.2, NE)				
Non-White	79	25 (31.6)	54 (68.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:36; Program name: t1_os_1_fas.sas; Output name: T2_HOSP_1_FAS.rtf

DE.T.2.14.1 Time to hospitalization - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	63	16 (25.4)	47 (74.6)	NE (NE, NE)				
North America and Australia	6							
Europe	33	17 (51.5)	16 (48.5)	10.2 (1.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:36; Program name: t1_os_1_fas.sas; Output name: T2_HOSP_1_FAS.rtf

Anhang 4-G 2.4 Symptomatik anhand des EORTC QLQ-C30 – weitere Untersuchungen

Anhang 4-G 2.4.1 Subgruppenanalysen – Symptomatik anhand des EORTC QLQ-C30

Anhang 4-G 2.4.1.1 Finaler Datenschnitt vom 23.12.2022

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Cognitive Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	33 (44.0)	42 (56.0)	11.4 (2.3, NE)				
Subjects who received neither	27	18 (66.7)	9 (33.3)	6.9 (1.5, 9.7)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Cognitive Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	21 (60.0)	14 (40.0)	2.3 (1.4, 11.4)				
No	67	30 (44.8)	37 (55.2)	9.7 (3.1, NE)				
HER2 status								
Kinase domain	99	49 (49.5)	50 (50.5)	7.2 (3.0, 17.3)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Cognitive Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	31 (50.0)	31 (50.0)	8.5 (2.2, NE)				
>=65 years	40	20 (50.0)	20 (50.0)	6.7 (2.1, NE)				
Age II								
<75 years	94	45 (47.9)	49 (52.1)	8.5 (3.0, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Cognitive Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	37 (56.9)	28 (43.1)	6.7 (2.2, 9.7)				
Male	37	14 (37.8)	23 (62.2)	11.4 (3.0, NE)				
Smoking status								
Current	0							
Former	47	19 (40.4)	28 (59.6)	9.7 (3.0, NE)				
Never	55	32 (58.2)	23 (41.8)	4.2 (2.1, 11.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Cognitive Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	4.2 (1.5, NE)				
Non-White	79	40 (50.6)	39 (49.4)	7.2 (2.3, 17.3)				
Region								
Asia	63	31 (49.2)	32 (50.8)	8.5 (2.3, NE)				
North America and Australia	6							
Europe	33	16 (48.5)	17 (51.5)	9.7 (2.1, 11.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Emotional Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	22 (29.3)	53 (70.7)	NE (NE, NE)				
Subjects who received neither	27	12 (44.4)	15 (55.6)	10.6 (4.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Emotional Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	9 (25.7)	26 (74.3)	NE (7.6, NE)				
No	67	25 (37.3)	42 (62.7)	NE (4.9, NE)				
HER2 status								
Kinase domain	99	34 (34.3)	65 (65.7)	NE (9.9, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Emotional Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	21 (33.9)	41 (66.1)	NE (5.6, NE)				
>=65 years	40	13 (32.5)	27 (67.5)	NE (4.9, NE)				
Age II								
<75 years	94	33 (35.1)	61 (64.9)	NE (7.6, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Emotional Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	25 (38.5)	40 (61.5)	NE (4.9, NE)				
Male	37	9 (24.3)	28 (75.7)	NE (10.6, NE)				
Smoking status								
Current	0							
Former	47	14 (29.8)	33 (70.2)	NE (7.6, NE)				
Never	55	20 (36.4)	35 (63.6)	NE (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Emotional Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	NE (2.1, NE)				
Non-White	79	26 (32.9)	53 (67.1)	NE (9.9, NE)				
Region								
Asia	63	19 (30.2)	44 (69.8)	NE (10.6, NE)				
North America and Australia	6							
Europe	33	10 (30.3)	23 (69.7)	NE (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Physical Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	37 (49.3)	38 (50.7)	4.4 (2.3, NE)				
Subjects who received neither	27	14 (51.9)	13 (48.1)	10.4 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Physical Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	16 (45.7)	19 (54.3)	10.6 (2.1, NE)				
No	67	35 (52.2)	32 (47.8)	5.5 (2.3, NE)				
HER2 status								
Kinase domain	99	50 (50.5)	49 (49.5)	5.5 (2.3, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Physical Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	31 (50.0)	31 (50.0)	10.4 (2.8, NE)				
>=65 years	40	20 (50.0)	20 (50.0)	4.3 (1.6, NE)				
Age II								
<75 years	94	46 (48.9)	48 (51.1)	6.7 (2.7, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Physical Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	34 (52.3)	31 (47.7)	4.4 (2.2, NE)				
Male	37	17 (45.9)	20 (54.1)	10.4 (1.5, NE)				
Smoking status								
Current	0							
Former	47	19 (40.4)	28 (59.6)	10.6 (3.5, NE)				
Never	55	32 (58.2)	23 (41.8)	2.8 (1.9, 12.9)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Physical Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	10.6 (1.5, NE)				
Non-White	79	40 (50.6)	39 (49.4)	5.5 (2.3, NE)				
Region								
Asia	63	31 (49.2)	32 (50.8)	10.4 (2.8, NE)				
North America and Australia	6							
Europe	33	17 (51.5)	16 (48.5)	2.3 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Role Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	38 (50.7)	37 (49.3)	4.2 (2.2, NE)				
Subjects who received neither	27	13 (48.1)	14 (51.9)	9.1 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Role Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	15 (42.9)	20 (57.1)	11.4 (2.8, NE)				
No	67	36 (53.7)	31 (46.3)	4.3 (2.2, NE)				
HER2 status								
Kinase domain	99	50 (50.5)	49 (49.5)	7.5 (2.8, 18.0)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Role Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	24 (38.7)	38 (61.3)	12.2 (5.5, NE)				
>=65 years	40	27 (67.5)	13 (32.5)	2.8 (1.5, 7.5)				
Age II								
<75 years	94	45 (47.9)	49 (52.1)	9.1 (3.0, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Role Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	34 (52.3)	31 (47.7)	5.5 (2.8, 18.0)				
Male	37	17 (45.9)	20 (54.1)	11.4 (1.4, NE)				
Smoking status								
Current	0							
Former	47	18 (38.3)	29 (61.7)	NE (2.4, NE)				
Never	55	33 (60.0)	22 (40.0)	4.2 (2.2, 11.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Role Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	13 (56.5)	10 (43.5)	4.2 (1.6, 11.4)				
Non-White	79	38 (48.1)	41 (51.9)	9.1 (2.8, NE)				
Region								
Asia	63	27 (42.9)	36 (57.1)	12.2 (4.2, NE)				
North America and Australia	6							
Europe	33	19 (57.6)	14 (42.4)	2.3 (0.9, 11.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Social Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	36 (48.0)	39 (52.0)	4.2 (2.1, NE)				
Subjects who received neither	27	14 (51.9)	13 (48.1)	5.9 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Social Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	18 (51.4)	17 (48.6)	3.7 (1.4, NE)				
No	67	32 (47.8)	35 (52.2)	5.5 (2.1, NE)				
HER2 status								
Kinase domain	99	49 (49.5)	50 (50.5)	5.5 (2.2, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Social Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	32 (51.6)	30 (48.4)	4.2 (1.9, NE)				
>=65 years	40	18 (45.0)	22 (55.0)	10.4 (2.1, NE)				
Age II								
<75 years	94	45 (47.9)	49 (52.1)	5.9 (2.1, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Social Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	31 (47.7)	34 (52.3)	5.9 (2.1, NE)				
Male	37	19 (51.4)	18 (48.6)	3.2 (1.4, NE)				
Smoking status								
Current	0							
Former	47	19 (40.4)	28 (59.6)	NE (2.3, NE)				
Never	55	31 (56.4)	24 (43.6)	3.4 (1.5, 10.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Functional Scales: Social Functioning

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	4.2 (1.5, NE)				
Non-White	79	39 (49.4)	40 (50.6)	5.5 (2.1, NE)				
Region								
Asia	63	31 (49.2)	32 (50.8)	5.9 (2.1, NE)				
North America and Australia	6							
Europe	33	16 (48.5)	17 (51.5)	2.9 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Global Health Status: Global Health Status

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	36 (48.0)	39 (52.0)	4.2 (2.3, NE)				
Subjects who received neither	27	14 (51.9)	13 (48.1)	9.7 (3.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Global Health Status: Global Health Status

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	18 (51.4)	17 (48.6)	4.9 (1.5, NE)				
No	67	32 (47.8)	35 (52.2)	4.9 (2.8, NE)				
HER2 status								
Kinase domain	99	50 (50.5)	49 (49.5)	4.8 (2.9, 9.8)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Global Health Status: Global Health Status

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	32 (51.6)	30 (48.4)	4.9 (2.3, 9.8)				
>=65 years	40	18 (45.0)	22 (55.0)	4.8 (2.9, NE)				
Age II								
<75 years	94	45 (47.9)	49 (52.1)	4.9 (2.8, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Global Health Status: Global Health Status

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	30 (46.2)	35 (53.8)	5.9 (2.8, NE)				
Male	37	20 (54.1)	17 (45.9)	4.5 (2.3, NE)				
Smoking status								
Current	0							
Former	47	22 (46.8)	25 (53.2)	4.8 (2.7, NE)				
Never	55	28 (50.9)	27 (49.1)	4.9 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Global Health Status: Global Health Status

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	4.2 (2.3, NE)				
Non-White	79	39 (49.4)	40 (50.6)	5.9 (2.8, NE)				
Region								
Asia	63	30 (47.6)	33 (52.4)	9.7 (2.8, NE)				
North America and Australia	6							
Europe	33	16 (48.5)	17 (51.5)	3.7 (2.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite Loss

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	41 (54.7)	34 (45.3)	2.6 (2.1, 7.0)				
Subjects who received neither	27	14 (51.9)	13 (48.1)	4.5 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite Loss

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	15 (42.9)	20 (57.1)	5.5 (2.3, NE)				
No	67	40 (59.7)	27 (40.3)	2.2 (1.6, 3.5)				
HER2 status								
Kinase domain	99	53 (53.5)	46 (46.5)	2.8 (2.1, 7.0)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite Loss

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	31 (50.0)	31 (50.0)	3.5 (2.1, NE)				
>=65 years	40	24 (60.0)	16 (40.0)	2.2 (1.4, 5.5)				
Age II								
<75 years	94	49 (52.1)	45 (47.9)	2.8 (2.1, 7.3)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite Loss

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	34 (52.3)	31 (47.7)	2.8 (2.1, NE)				
Male	37	21 (56.8)	16 (43.2)	2.3 (1.4, 7.3)				
Smoking status								
Current	0							
Former	47	23 (48.9)	24 (51.1)	5.5 (2.1, NE)				
Never	55	32 (58.2)	23 (41.8)	2.2 (1.4, 3.5)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite Loss

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	2.9 (1.4, NE)				
Non-White	79	44 (55.7)	35 (44.3)	2.7 (2.0, 7.0)				
Region								
Asia	63	36 (57.1)	27 (42.9)	2.8 (2.0, 7.3)				
North America and Australia	6							
Europe	33	16 (48.5)	17 (51.5)	2.8 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Constipation

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	42 (56.0)	33 (44.0)	2.8 (2.1, 7.0)				
Subjects who received neither	27	21 (77.8)	6 (22.2)	2.9 (1.5, 6.5)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Constipation

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	18 (51.4)	17 (48.6)	3.5 (2.2, NE)				
No	67	45 (67.2)	22 (32.8)	2.9 (1.8, 6.2)				
HER2 status								
Kinase domain	99	62 (62.6)	37 (37.4)	2.9 (2.2, 6.2)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Constipation

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	37 (59.7)	25 (40.3)	2.9 (2.1, 7.0)				
>=65 years	40	26 (65.0)	14 (35.0)	2.9 (1.5, 6.3)				
Age II								
<75 years	94	57 (60.6)	37 (39.4)	2.9 (2.1, 6.2)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Constipation

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	41 (63.1)	24 (36.9)	3.5 (2.2, 6.5)				
Male	37	22 (59.5)	15 (40.5)	2.2 (1.4, 11.1)				
Smoking status								
Current	0							
Former	47	27 (57.4)	20 (42.6)	2.2 (1.4, 11.1)				
Never	55	36 (65.5)	19 (34.5)	3.5 (2.2, 6.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Constipation

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	12 (52.2)	11 (47.8)	2.8 (2.1, NE)				
Non-White	79	51 (64.6)	28 (35.4)	2.9 (1.8, 6.5)				
Region								
Asia	63	42 (66.7)	21 (33.3)	2.8 (1.5, 6.5)				
North America and Australia	6							
Europe	33	16 (48.5)	17 (51.5)	2.9 (2.1, 11.8)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Diarrhea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	38 (50.7)	37 (49.3)	3.7 (2.1, 10.4)				
Subjects who received neither	27	11 (40.7)	16 (59.3)	11.8 (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Diarrhea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	22 (62.9)	13 (37.1)	2.1 (1.4, 10.4)				
No	67	27 (40.3)	40 (59.7)	8.5 (3.5, NE)				
HER2 status								
Kinase domain	99	48 (48.5)	51 (51.5)	4.8 (3.0, 11.8)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Diarrhea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	33 (53.2)	29 (46.8)	4.2 (2.9, 8.5)				
>=65 years	40	16 (40.0)	24 (60.0)	NE (2.1, NE)				
Age II								
<75 years	94	45 (47.9)	49 (52.1)	4.8 (3.4, 11.8)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Diarrhea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	31 (47.7)	34 (52.3)	5.6 (2.8, NE)				
Male	37	18 (48.6)	19 (51.4)	3.7 (2.1, NE)				
Smoking status								
Current	0							
Former	47	23 (48.9)	24 (51.1)	4.2 (2.1, NE)				
Never	55	26 (47.3)	29 (52.7)	5.6 (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Diarrhea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	12 (52.2)	11 (47.8)	2.3 (0.9, NE)				
Non-White	79	37 (46.8)	42 (53.2)	7.4 (3.5, NE)				
Region								
Asia	63	29 (46.0)	34 (54.0)	5.6 (3.4, NE)				
North America and Australia	6							
Europe	33	18 (54.5)	15 (45.5)	2.3 (1.4, 11.8)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	33 (44.0)	42 (56.0)	10.9 (3.5, NE)				
Subjects who received neither	27	10 (37.0)	17 (63.0)	NE (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	15 (42.9)	20 (57.1)	8.3 (3.3, NE)				
No	67	28 (41.8)	39 (58.2)	NE (3.5, NE)				
HER2 status								
Kinase domain	99	42 (42.4)	57 (57.6)	NE (4.2, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	24 (38.7)	38 (61.3)	NE (3.5, NE)				
>=65 years	40	19 (47.5)	21 (52.5)	10.9 (2.2, NE)				
Age II								
<75 years	94	39 (41.5)	55 (58.5)	NE (4.1, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	28 (43.1)	37 (56.9)	NE (3.5, NE)				
Male	37	15 (40.5)	22 (59.5)	10.9 (2.8, NE)				
Smoking status								
Current	0							
Former	47	20 (42.6)	27 (57.4)	NE (2.3, NE)				
Never	55	23 (41.8)	32 (58.2)	NE (3.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	4.3 (1.1, NE)				
Non-White	79	32 (40.5)	47 (59.5)	NE (3.5, NE)				
Region								
Asia	63	24 (38.1)	39 (61.9)	NE (5.6, NE)				
North America and Australia	6							
Europe	33	17 (51.5)	16 (48.5)	4.2 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	38 (50.7)	37 (49.3)	2.8 (1.4, NE)				
Subjects who received neither	27	16 (59.3)	11 (40.7)	2.9 (0.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	19 (54.3)	16 (45.7)	2.5 (1.4, NE)				
No	67	35 (52.2)	32 (47.8)	3.5 (1.4, NE)				
HER2 status								
Kinase domain	99	52 (52.5)	47 (47.5)	3.5 (2.1, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	30 (48.4)	32 (51.6)	6.9 (1.4, NE)				
>=65 years	40	24 (60.0)	16 (40.0)	2.1 (1.3, 3.5)				
Age II								
<75 years	94	47 (50.0)	47 (50.0)	4.2 (1.4, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	31 (47.7)	34 (52.3)	4.2 (2.1, NE)				
Male	37	23 (62.2)	14 (37.8)	1.4 (1.1, 7.0)				
Smoking status								
Current	0							
Former	47	22 (46.8)	25 (53.2)	6.9 (1.4, NE)				
Never	55	32 (58.2)	23 (41.8)	2.8 (1.4, 5.6)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	14 (60.9)	9 (39.1)	2.8 (1.1, 6.9)				
Non-White	79	40 (50.6)	39 (49.4)	3.5 (1.4, NE)				
Region								
Asia	63	29 (46.0)	34 (54.0)	NE (1.4, NE)				
North America and Australia	6							
Europe	33	22 (66.7)	11 (33.3)	2.1 (0.9, 2.9)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Financial Difficulties

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	18 (24.0)	57 (76.0)	NE (NE, NE)				
Subjects who received neither	27	6 (22.2)	21 (77.8)	NE (13.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Financial Difficulties

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	9 (25.7)	26 (74.3)	NE (5.1, NE)				
No	67	15 (22.4)	52 (77.6)	NE (13.0, NE)				
HER2 status								
Kinase domain	99	24 (24.2)	75 (75.8)	NE (13.0, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Financial Difficulties

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	15 (24.2)	47 (75.8)	NE (NE, NE)				
>=65 years	40	9 (22.5)	31 (77.5)	NE (13.0, NE)				
Age II								
<75 years	94	23 (24.5)	71 (75.5)	NE (13.0, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Financial Difficulties

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	15 (23.1)	50 (76.9)	NE (13.0, NE)				
Male	37	9 (24.3)	28 (75.7)	NE (NE, NE)				
Smoking status								
Current	0							
Former	47	9 (19.1)	38 (80.9)	NE (NE, NE)				
Never	55	15 (27.3)	40 (72.7)	NE (13.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Financial Difficulties

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	4 (17.4)	19 (82.6)	NE (2.8, NE)				
Non-White	79	20 (25.3)	59 (74.7)	NE (13.0, NE)				
Region								
Asia	63	16 (25.4)	47 (74.6)	NE (13.0, NE)				
North America and Australia	6							
Europe	33	7 (21.2)	26 (78.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Insomnia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	22 (29.3)	53 (70.7)	NE (11.7, NE)				
Subjects who received neither	27	15 (55.6)	12 (44.4)	8.5 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Insomnia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	13 (37.1)	22 (62.9)	9.9 (2.6, NE)				
No	67	24 (35.8)	43 (64.2)	NE (5.9, NE)				
HER2 status								
Kinase domain	99	37 (37.4)	62 (62.6)	11.7 (5.9, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Insomnia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	21 (33.9)	41 (66.1)	NE (5.9, NE)				
>=65 years	40	16 (40.0)	24 (60.0)	10.1 (2.8, NE)				
Age II								
<75 years	94	34 (36.2)	60 (63.8)	11.7 (6.2, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Insomnia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	26 (40.0)	39 (60.0)	10.1 (4.4, NE)				
Male	37	11 (29.7)	26 (70.3)	11.7 (5.1, NE)				
Smoking status								
Current	0							
Former	47	14 (29.8)	33 (70.2)	NE (6.2, NE)				
Never	55	23 (41.8)	32 (58.2)	9.9 (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Insomnia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	7 (30.4)	16 (69.6)	NE (2.8, NE)				
Non-White	79	30 (38.0)	49 (62.0)	11.7 (6.2, NE)				
Region								
Asia	63	23 (36.5)	40 (63.5)	11.7 (8.5, NE)				
North America and Australia	6							
Europe	33	11 (33.3)	22 (66.7)	NE (2.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Nausea and Vomiting

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	45 (60.0)	30 (40.0)	2.1 (1.4, 3.5)				
Subjects who received neither	27	22 (81.5)	5 (18.5)	1.4 (0.8, 2.9)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Nausea and Vomiting

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	21 (60.0)	14 (40.0)	2.3 (1.0, 6.9)				
No	67	46 (68.7)	21 (31.3)	1.5 (1.4, 2.8)				
HER2 status								
Kinase domain	99	65 (65.7)	34 (34.3)	2.1 (1.4, 2.9)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Nausea and Vomiting

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	42 (67.7)	20 (32.3)	2.1 (1.4, 3.5)				
>=65 years	40	25 (62.5)	15 (37.5)	1.5 (0.9, 3.5)				
Age II								
<75 years	94	61 (64.9)	33 (35.1)	1.6 (1.4, 3.5)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Nausea and Vomiting

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	42 (64.6)	23 (35.4)	2.1 (1.4, 5.1)				
Male	37	25 (67.6)	12 (32.4)	1.5 (0.8, 2.3)				
Smoking status								
Current	0							
Former	47	30 (63.8)	17 (36.2)	2.1 (1.3, 3.5)				
Never	55	37 (67.3)	18 (32.7)	1.5 (1.4, 3.5)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Nausea and Vomiting

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	14 (60.9)	9 (39.1)	2.9 (0.9, 6.9)				
Non-White	79	53 (67.1)	26 (32.9)	1.5 (1.4, 2.8)				
Region								
Asia	63	44 (69.8)	19 (30.2)	1.5 (1.4, 3.5)				
North America and Australia	6							
Europe	33	18 (54.5)	15 (45.5)	2.3 (0.9, 6.9)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	37 (49.3)	38 (50.7)	4.4 (3.3, 13.2)				
Subjects who received neither	27	12 (44.4)	15 (55.6)	12.9 (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	13 (37.1)	22 (62.9)	10.6 (3.7, NE)				
No	67	36 (53.7)	31 (46.3)	4.4 (2.7, 12.9)				
HER2 status								
Kinase domain	99	49 (49.5)	50 (50.5)	6.2 (3.5, 12.9)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	28 (45.2)	34 (54.8)	7.9 (4.2, NE)				
>=65 years	40	21 (52.5)	19 (47.5)	4.1 (2.8, 13.2)				
Age II								
<75 years	94	44 (46.8)	50 (53.2)	7.9 (3.4, 13.2)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	31 (47.7)	34 (52.3)	7.9 (3.4, NE)				
Male	37	18 (48.6)	19 (51.4)	6.2 (1.6, NE)				
Smoking status								
Current	0							
Former	47	19 (40.4)	28 (59.6)	11.5 (4.4, NE)				
Never	55	30 (54.5)	25 (45.5)	4.2 (2.2, 12.9)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

DE.T.3.1.1 EORTC-QLQ-C30 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	6.2 (1.6, NE)				
Non-White	79	38 (48.1)	41 (51.9)	5.6 (3.4, 13.2)				
Region								
Asia	63	28 (44.4)	35 (55.6)	11.5 (3.4, NE)				
North America and Australia	6							
Europe	33	17 (51.5)	16 (48.5)	4.2 (2.1, 10.6)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:38; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQC30_FD_1_FAS.rtf

Anhang 4-G 2.5 Symptomatik anhand des EORTC QLQ-LC13 – weitere Untersuchungen

Anhang 4-G 2.5.1 Subgruppenanalysen – Symptomatik anhand des EORTC QLQ-LC13

Anhang 4-G 2.5.1.1 Finaler Datenschnitt vom 23.12.2022

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Alopecia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	45 (60.0)	30 (40.0)	2.1 (1.4, 2.9)				
Subjects who received neither	27	23 (85.2)	4 (14.8)	1.4 (0.8, 1.5)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Alopecia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	22 (62.9)	13 (37.1)	1.7 (1.4, 6.2)				
No	67	46 (68.7)	21 (31.3)	1.4 (1.4, 2.1)				
HER2 status								
Kinase domain	99	66 (66.7)	33 (33.3)	1.5 (1.4, 2.3)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Alopecia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	45 (72.6)	17 (27.4)	1.5 (1.4, 2.3)				
>=65 years	40	23 (57.5)	17 (42.5)	1.5 (1.4, 8.9)				
Age II								
<75 years	94	64 (68.1)	30 (31.9)	1.5 (1.4, 2.1)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Alopecia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	44 (67.7)	21 (32.3)	1.4 (1.4, 2.3)				
Male	37	24 (64.9)	13 (35.1)	1.5 (1.4, 2.8)				
Smoking status								
Current	0							
Former	47	30 (63.8)	17 (36.2)	1.5 (1.4, 2.8)				
Never	55	38 (69.1)	17 (30.9)	1.5 (1.4, 2.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Alopecia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	13 (56.5)	10 (43.5)	2.9 (1.4, 6.9)				
Non-White	79	55 (69.6)	24 (30.4)	1.4 (1.4, 2.1)				
Region								
Asia	63	45 (71.4)	18 (28.6)	1.4 (1.3, 1.5)				
North America and Australia	6							
Europe	33	19 (57.6)	14 (42.4)	2.3 (1.4, 3.7)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Coughing

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	22 (29.3)	53 (70.7)	NE (9.7, NE)				
Subjects who received neither	27	14 (51.9)	13 (48.1)	6.7 (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Coughing

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	9 (25.7)	26 (74.3)	NE (6.6, NE)				
No	67	27 (40.3)	40 (59.7)	10.4 (4.9, NE)				
HER2 status								
Kinase domain	99	35 (35.4)	64 (64.6)	13.3 (6.7, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Coughing

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	20 (32.3)	42 (67.7)	NE (6.7, NE)				
>=65 years	40	16 (40.0)	24 (60.0)	13.3 (4.1, NE)				
Age II								
<75 years	94	33 (35.1)	61 (64.9)	13.3 (7.9, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Coughing

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	18 (27.7)	47 (72.3)	NE (9.7, NE)				
Male	37	18 (48.6)	19 (51.4)	6.6 (3.0, NE)				
Smoking status								
Current	0							
Former	47	17 (36.2)	30 (63.8)	13.3 (4.9, NE)				
Never	55	19 (34.5)	36 (65.5)	NE (6.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Coughing

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	6.6 (2.1, NE)				
Non-White	79	28 (35.4)	51 (64.6)	NE (7.9, NE)				
Region								
Asia	63	19 (30.2)	44 (69.8)	NE (10.4, NE)				
North America and Australia	6							
Europe	33	14 (42.4)	19 (57.6)	6.2 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dysphagia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	19 (25.3)	56 (74.7)	NE (NE, NE)				
Subjects who received neither	27	9 (33.3)	18 (66.7)	14.3 (7.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dysphagia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	10 (28.6)	25 (71.4)	NE (4.2, NE)				
No	67	18 (26.9)	49 (73.1)	NE (11.1, NE)				
HER2 status								
Kinase domain	99	26 (26.3)	73 (73.7)	NE (14.3, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dysphagia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	18 (29.0)	44 (71.0)	14.3 (11.1, NE)				
>=65 years	40	10 (25.0)	30 (75.0)	NE (7.4, NE)				
Age II								
<75 years	94	26 (27.7)	68 (72.3)	NE (11.1, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dysphagia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	19 (29.2)	46 (70.8)	NE (9.2, NE)				
Male	37	9 (24.3)	28 (75.7)	NE (NE, NE)				
Smoking status								
Current	0							
Former	47	10 (21.3)	37 (78.7)	NE (11.1, NE)				
Never	55	18 (32.7)	37 (67.3)	14.3 (7.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dysphagia

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	79	26 (32.9)	53 (67.1)	14.3 (9.2, NE)				
Region								
Asia	63	23 (36.5)	40 (63.5)	14.3 (7.8, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	41 (54.7)	34 (45.3)	4.2 (1.4, 8.3)				
Subjects who received neither	27	14 (51.9)	13 (48.1)	3.0 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	15 (42.9)	20 (57.1)	8.3 (1.4, NE)				
No	67	40 (59.7)	27 (40.3)	3.0 (1.4, 4.9)				
HER2 status								
Kinase domain	99	54 (54.5)	45 (45.5)	3.6 (1.4, 5.6)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	34 (54.8)	28 (45.2)	4.2 (2.8, 10.4)				
>=65 years	40	21 (52.5)	19 (47.5)	1.5 (0.8, NE)				
Age II								
<75 years	94	53 (56.4)	41 (43.6)	3.4 (1.4, 5.5)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	34 (52.3)	31 (47.7)	4.2 (1.4, NE)				
Male	37	21 (56.8)	16 (43.2)	3.6 (1.4, 10.4)				
Smoking status								
Current	0							
Former	47	26 (55.3)	21 (44.7)	2.1 (1.4, 10.4)				
Never	55	29 (52.7)	26 (47.3)	4.4 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	10 (43.5)	13 (56.5)	5.0 (0.8, NE)				
Non-White	79	45 (57.0)	34 (43.0)	3.0 (1.4, 5.6)				
Region								
Asia	63	34 (54.0)	29 (46.0)	4.4 (2.8, NE)				
North America and Australia	6							
Europe	33	16 (48.5)	17 (51.5)	1.8 (0.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Haemoptysis

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	7 (9.3)	68 (90.7)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Haemoptysis

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	6 (17.1)	29 (82.9)	NE (9.2, NE)				
No	67	3 (4.5)	64 (95.5)	NE (NE, NE)				
HER2 status								
Kinase domain	99	9 (9.1)	90 (90.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Haemoptysis

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	5 (8.1)	57 (91.9)	NE (NE, NE)				
>=65 years	40	4 (10.0)	36 (90.0)	NE (NE, NE)				
Age II								
<75 years	94	8 (8.5)	86 (91.5)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Haemoptysis

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	6 (9.2)	59 (90.8)	NE (NE, NE)				
Male	37	3 (8.1)	34 (91.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	47	1 (2.1)	46 (97.9)	NE (NE, NE)				
Never	55	8 (14.5)	47 (85.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Haemoptysis

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (10.0, NE)				
Non-White	79	7 (8.9)	72 (91.1)	NE (NE, NE)				
Region								
Asia	63	6 (9.5)	57 (90.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (10.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in arm or shoulder

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	19 (25.3)	56 (74.7)	NE (10.4, NE)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in arm or shoulder

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	7 (20.0)	28 (80.0)	NE (10.4, NE)				
No	67	17 (25.4)	50 (74.6)	NE (NE, NE)				
HER2 status								
Kinase domain	99	23 (23.2)	76 (76.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in arm or shoulder

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	16 (25.8)	46 (74.2)	NE (NE, NE)				
>=65 years	40	8 (20.0)	32 (80.0)	NE (10.4, NE)				
Age II								
<75 years	94	23 (24.5)	71 (75.5)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in arm or shoulder

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	14 (21.5)	51 (78.5)	NE (NE, NE)				
Male	37	10 (27.0)	27 (73.0)	NE (7.0, NE)				
Smoking status								
Current	0							
Former	47	14 (29.8)	33 (70.2)	NE (5.6, NE)				
Never	55	10 (18.2)	45 (81.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in arm or shoulder

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	79	22 (27.8)	57 (72.2)	NE (10.4, NE)				
Region								
Asia	63	18 (28.6)	45 (71.4)	NE (10.4, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in Chest

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	19 (25.3)	56 (74.7)	NE (11.7, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in Chest

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	6 (17.1)	29 (82.9)	NE (NE, NE)				
No	67	17 (25.4)	50 (74.6)	NE (11.7, NE)				
HER2 status								
Kinase domain	99	23 (23.2)	76 (76.8)	NE (13.0, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in Chest

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	15 (24.2)	47 (75.8)	NE (NE, NE)				
>=65 years	40	8 (20.0)	32 (80.0)	NE (11.7, NE)				
Age II								
<75 years	94	23 (24.5)	71 (75.5)	NE (13.0, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in Chest

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	18 (27.7)	47 (72.3)	NE (10.3, NE)				
Male	37	5 (13.5)	32 (86.5)	NE (13.0, NE)				
Smoking status								
Current	0							
Former	47	8 (17.0)	39 (83.0)	NE (13.0, NE)				
Never	55	15 (27.3)	40 (72.7)	NE (10.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in Chest

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	11.7 (11.7, NE)				
Non-White	79	20 (25.3)	59 (74.7)	NE (13.0, NE)				
Region								
Asia	63	16 (25.4)	47 (74.6)	NE (NE, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (7.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in other parts

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	33 (44.0)	42 (56.0)	5.5 (2.7, NE)				
Subjects who received neither	27	12 (44.4)	15 (55.6)	12.6 (2.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in other parts

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	10 (28.6)	25 (71.4)	NE (3.7, NE)				
No	67	35 (52.2)	32 (47.8)	4.9 (2.1, 13.2)				
HER2 status								
Kinase domain	99	44 (44.4)	55 (55.6)	10.8 (3.4, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in other parts

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	30 (48.4)	32 (51.6)	4.9 (2.8, NE)				
>=65 years	40	15 (37.5)	25 (62.5)	13.2 (2.1, NE)				
Age II								
<75 years	94	42 (44.7)	52 (55.3)	10.8 (3.4, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in other parts

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	25 (38.5)	40 (61.5)	12.6 (3.9, NE)				
Male	37	20 (54.1)	17 (45.9)	2.8 (1.4, NE)				
Smoking status								
Current	0							
Former	47	21 (44.7)	26 (55.3)	5.6 (2.1, NE)				
Never	55	24 (43.6)	31 (56.4)	10.8 (3.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain in other parts

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	7 (30.4)	16 (69.6)	NE (2.1, NE)				
Non-White	79	38 (48.1)	41 (51.9)	5.6 (2.8, NE)				
Region								
Asia	63	31 (49.2)	32 (50.8)	5.6 (2.7, NE)				
North America and Australia	6							
Europe	33	10 (30.3)	23 (69.7)	NE (2.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Peripheral Neuropathy

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	27 (36.0)	48 (64.0)	8.1 (4.2, NE)				
Subjects who received neither	27	12 (44.4)	15 (55.6)	12.6 (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Peripheral Neuropathy

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	10 (28.6)	25 (71.4)	NE (3.7, NE)				
No	67	29 (43.3)	38 (56.7)	8.1 (4.2, NE)				
HER2 status								
Kinase domain	99	38 (38.4)	61 (61.6)	10.6 (4.7, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Peripheral Neuropathy

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	23 (37.1)	39 (62.9)	10.6 (4.2, NE)				
>=65 years	40	16 (40.0)	24 (60.0)	8.1 (4.1, NE)				
Age II								
<75 years	94	38 (40.4)	56 (59.6)	10.6 (4.5, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Peripheral Neuropathy

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	22 (33.8)	43 (66.2)	NE (5.8, NE)				
Male	37	17 (45.9)	20 (54.1)	7.0 (4.2, NE)				
Smoking status								
Current	0							
Former	47	21 (44.7)	26 (55.3)	7.0 (4.2, NE)				
Never	55	18 (32.7)	37 (67.3)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Peripheral Neuropathy

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	NE (1.6, NE)				
Non-White	79	34 (43.0)	45 (57.0)	8.1 (4.2, NE)				
Region								
Asia	63	28 (44.4)	35 (55.6)	8.1 (4.2, NE)				
North America and Australia	6							
Europe	33	7 (21.2)	26 (78.8)	NE (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Sore mouth

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	35 (46.7)	40 (53.3)	4.2 (2.8, 13.2)				
Subjects who received neither	27	13 (48.1)	14 (51.9)	9.0 (2.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Sore mouth

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	15 (42.9)	20 (57.1)	5.1 (3.5, NE)				
No	67	33 (49.3)	34 (50.7)	4.2 (2.4, 13.2)				
HER2 status								
Kinase domain	99	47 (47.5)	52 (52.5)	5.1 (3.0, 13.2)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Sore mouth

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	30 (48.4)	32 (51.6)	4.2 (2.8, 11.3)				
>=65 years	40	18 (45.0)	22 (55.0)	6.4 (1.5, NE)				
Age II								
<75 years	94	43 (45.7)	51 (54.3)	6.4 (3.5, 13.2)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Sore mouth

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	30 (46.2)	35 (53.8)	5.5 (2.8, NE)				
Male	37	18 (48.6)	19 (51.4)	5.1 (2.1, NE)				
Smoking status								
Current	0							
Former	47	22 (46.8)	25 (53.2)	7.7 (2.4, NE)				
Never	55	26 (47.3)	29 (52.7)	5.1 (2.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

DE.T.3.2.1 EORTC-QLQ-LC13 - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Sore mouth

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	7 (30.4)	16 (69.6)	9.0 (2.8, NE)				
Non-White	79	41 (51.9)	38 (48.1)	4.2 (2.7, 11.3)				
Region								
Asia	63	33 (52.4)	30 (47.6)	5.1 (2.3, 11.3)				
North America and Australia	6							
Europe	33	12 (36.4)	21 (63.6)	9.0 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T3_QLQLC13_FD_1_FAS.rtf

Anhang 4-G 2.6 Symptomatik anhand des NSCLC-SAQ – weitere Untersuchungen

Anhang 4-G 2.6.1 Subgruppenanalysen – Symptomatik anhand des NSCLC-SAQ

Anhang 4-G 2.6.1.1 Finaler Datenschnitt vom 23.12.2022

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	39 (52.0)	36 (48.0)	3.0 (2.0, 11.1)				
Subjects who received neither	27	15 (55.6)	12 (44.4)	2.9 (1.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	14 (40.0)	21 (60.0)	11.4 (2.6, NE)				
No	67	40 (59.7)	27 (40.3)	2.1 (1.4, 6.2)				
HER2 status								
Kinase domain	99	52 (52.5)	47 (47.5)	2.9 (2.1, 7.0)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	34 (54.8)	28 (45.2)	3.5 (2.0, 11.1)				
>=65 years	40	20 (50.0)	20 (50.0)	2.2 (1.4, NE)				
Age II								
<75 years	94	51 (54.3)	43 (45.7)	2.9 (1.7, 7.0)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	31 (47.7)	34 (52.3)	3.5 (2.1, NE)				
Male	37	23 (62.2)	14 (37.8)	2.3 (1.4, 6.6)				
Smoking status								
Current	0							
Former	47	24 (51.1)	23 (48.9)	3.5 (1.6, 11.1)				
Never	55	30 (54.5)	25 (45.5)	2.2 (1.5, 11.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Appetite

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	10 (43.5)	13 (56.5)	2.1 (1.4, NE)				
Non-White	79	44 (55.7)	35 (44.3)	2.9 (2.0, 7.0)				
Region								
Asia	63	36 (57.1)	27 (42.9)	3.5 (1.7, 7.0)				
North America and Australia	6							
Europe	33	14 (42.4)	19 (57.6)	2.6 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Cough

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	26 (34.7)	49 (65.3)	11.4 (6.9, NE)				
Subjects who received neither	27	16 (59.3)	11 (40.7)	3.5 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Cough

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	11 (31.4)	24 (68.6)	11.4 (6.6, NE)				
No	67	31 (46.3)	36 (53.7)	9.7 (2.8, NE)				
HER2 status								
Kinase domain	99	40 (40.4)	59 (59.6)	11.3 (6.6, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Cough

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	22 (35.5)	40 (64.5)	11.4 (6.9, NE)				
>=65 years	40	20 (50.0)	20 (50.0)	4.9 (1.3, NE)				
Age II								
<75 years	94	39 (41.5)	55 (58.5)	11.3 (3.5, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Cough

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	23 (35.4)	42 (64.6)	NE (6.9, NE)				
Male	37	19 (51.4)	18 (48.6)	4.9 (1.5, NE)				
Smoking status								
Current	0							
Former	47	18 (38.3)	29 (61.7)	11.1 (2.8, NE)				
Never	55	24 (43.6)	31 (56.4)	11.3 (3.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Cough

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	9 (39.1)	14 (60.9)	6.9 (0.9, NE)				
Non-White	79	33 (41.8)	46 (58.2)	11.3 (4.9, NE)				
Region								
Asia	63	24 (38.1)	39 (61.9)	NE (5.8, NE)				
North America and Australia	6							
Europe	33	13 (39.4)	20 (60.6)	9.7 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	34 (45.3)	41 (54.7)	10.4 (1.9, NE)				
Subjects who received neither	27	11 (40.7)	16 (59.3)	7.2 (3.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	8 (22.9)	27 (77.1)	NE (5.6, NE)				
No	67	37 (55.2)	30 (44.8)	3.0 (1.9, 10.4)				
HER2 status								
Kinase domain	99	44 (44.4)	55 (55.6)	7.2 (2.8, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	27 (43.5)	35 (56.5)	10.4 (2.8, NE)				
>=65 years	40	18 (45.0)	22 (55.0)	4.3 (1.4, NE)				
Age II								
<75 years	94	43 (45.7)	51 (54.3)	7.2 (2.8, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	29 (44.6)	36 (55.4)	5.6 (2.8, NE)				
Male	37	16 (43.2)	21 (56.8)	10.4 (1.6, NE)				
Smoking status								
Current	0							
Former	47	20 (42.6)	27 (57.4)	10.4 (1.6, NE)				
Never	55	25 (45.5)	30 (54.5)	5.6 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Dyspnea

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	NE (0.8, NE)				
Non-White	79	37 (46.8)	42 (53.2)	7.2 (2.8, NE)				
Region								
Asia	63	30 (47.6)	33 (52.4)	7.2 (3.0, NE)				
North America and Australia	6							
Europe	33	11 (33.3)	22 (66.7)	NE (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	38 (50.7)	37 (49.3)	3.7 (2.2, NE)				
Subjects who received neither	27	11 (40.7)	16 (59.3)	14.3 (3.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	16 (45.7)	19 (54.3)	5.5 (1.4, NE)				
No	67	33 (49.3)	34 (50.7)	7.0 (2.8, NE)				
HER2 status								
Kinase domain	99	48 (48.5)	51 (51.5)	7.0 (3.0, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	30 (48.4)	32 (51.6)	7.3 (3.5, NE)				
>=65 years	40	19 (47.5)	21 (52.5)	4.2 (2.1, NE)				
Age II								
<75 years	94	45 (47.9)	49 (52.1)	7.0 (3.0, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	30 (46.2)	35 (53.8)	8.5 (2.8, NE)				
Male	37	19 (51.4)	18 (48.6)	5.5 (2.1, NE)				
Smoking status								
Current	0							
Former	47	20 (42.6)	27 (57.4)	7.0 (3.0, NE)				
Never	55	29 (52.7)	26 (47.3)	4.2 (2.1, 14.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Fatigue

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	6 (26.1)	17 (73.9)	11.4 (2.1, NE)				
Non-White	79	43 (54.4)	36 (45.6)	4.2 (2.3, 14.3)				
Region								
Asia	63	35 (55.6)	28 (44.4)	4.9 (3.0, 14.3)				
North America and Australia	6							
Europe	33	12 (36.4)	21 (63.6)	11.4 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	37 (49.3)	38 (50.7)	5.6 (2.3, 13.0)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (11.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	15 (42.9)	20 (57.1)	9.1 (2.2, NE)				
No	67	27 (40.3)	40 (59.7)	13.0 (4.4, NE)				
HER2 status								
Kinase domain	99	41 (41.4)	58 (58.6)	11.3 (5.5, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	25 (40.3)	37 (59.7)	11.3 (4.4, NE)				
>=65 years	40	17 (42.5)	23 (57.5)	8.1 (2.1, NE)				
Age II								
<75 years	94	38 (40.4)	56 (59.6)	11.5 (5.5, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	25 (38.5)	40 (61.5)	11.5 (4.4, NE)				
Male	37	17 (45.9)	20 (54.1)	8.1 (2.3, NE)				
Smoking status								
Current	0							
Former	47	19 (40.4)	28 (59.6)	11.3 (3.6, NE)				
Never	55	23 (41.8)	32 (58.2)	9.1 (4.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Pain

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	7 (30.4)	16 (69.6)	11.3 (1.1, NE)				
Non-White	79	35 (44.3)	44 (55.7)	9.1 (4.4, NE)				
Region								
Asia	63	27 (42.9)	36 (57.1)	11.5 (5.5, NE)				
North America and Australia	6							
Europe	33	12 (36.4)	21 (63.6)	11.3 (1.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Total Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	30 (40.0)	45 (60.0)	11.4 (2.8, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (7.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Total Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	10 (28.6)	25 (71.4)	11.4 (7.7, NE)				
No	67	28 (41.8)	39 (58.2)	NE (2.8, NE)				
HER2 status								
Kinase domain	99	37 (37.4)	62 (62.6)	NE (5.5, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Total Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	22 (35.5)	40 (64.5)	NE (5.5, NE)				
>=65 years	40	16 (40.0)	24 (60.0)	7.7 (2.1, NE)				
Age II								
<75 years	94	35 (37.2)	59 (62.8)	NE (5.5, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Total Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	22 (33.8)	43 (66.2)	NE (5.5, NE)				
Male	37	16 (43.2)	21 (56.8)	11.4 (1.4, NE)				
Smoking status								
Current	0							
Former	47	15 (31.9)	32 (68.1)	NE (2.8, NE)				
Never	55	23 (41.8)	32 (58.2)	11.4 (3.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

DE.T.3.3.1 NSCLC-SAQ - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

Symptom Scales: Total Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	7 (30.4)	16 (69.6)	11.4 (0.8, NE)				
Non-White	79	31 (39.2)	48 (60.8)	NE (3.5, NE)				
Region								
Asia	63	23 (36.5)	40 (63.5)	NE (5.5, NE)				
North America and Australia	6							
Europe	33	12 (36.4)	21 (63.6)	11.4 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_NSCLC_FD_1_FAS.rtf

Anhang 4-G 2.7 EQ-5D-5L VAS – weitere Untersuchungen

Anhang 4-G 2.7.1 Subgruppenanalysen – EQ-5D-5L VAS

Anhang 4-G 2.7.1.1 Finaler Datenschnitt vom 23.12.2022

DE.T.2.15.1 EQ-5D-5L VAS - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

EQ-5D-5L Score: VAS Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	25 (33.3)	50 (66.7)	13.6 (10.6, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	13.6 (9.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T2_EQ5D_FD_1_FAS.rtf

DE.T.2.15.1 EQ-5D-5L VAS - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

EQ-5D-5L Score: VAS Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	9 (25.7)	26 (74.3)	11.8 (10.6, NE)				
No	67	24 (35.8)	43 (64.2)	13.6 (6.6, NE)				
HER2 status								
Kinase domain	99	33 (33.3)	66 (66.7)	13.6 (10.6, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T2_EQ5D_FD_1_FAS.rtf

DE.T.2.15.1 EQ-5D-5L VAS - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

EQ-5D-5L Score: VAS Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	20 (32.3)	42 (67.7)	13.6 (10.6, NE)				
>=65 years	40	13 (32.5)	27 (67.5)	18.2 (6.6, NE)				
Age II								
<75 years	94	33 (35.1)	61 (64.9)	13.6 (10.6, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T2_EQ5D_FD_1_FAS.rtf

DE.T.2.15.1 EQ-5D-5L VAS - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

EQ-5D-5L Score: VAS Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	19 (29.2)	46 (70.8)	18.2 (13.6, NE)				
Male	37	14 (37.8)	23 (62.2)	11.6 (5.6, NE)				
Smoking status								
Current	0							
Former	47	15 (31.9)	32 (68.1)	11.8 (9.0, NE)				
Never	55	18 (32.7)	37 (67.3)	13.6 (6.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T2_EQ5D_FD_1_FAS.rtf

DE.T.2.15.1 EQ-5D-5L VAS - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

EQ-5D-5L Score: VAS Score

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	10.6 (2.1, NE)				
Non-White	79	28 (35.4)	51 (64.6)	13.6 (11.6, NE)				
Region								
Asia	63	22 (34.9)	41 (65.1)	13.6 (9.0, NE)				
North America and Australia	6							
Europe	33	8 (24.2)	25 (75.8)	11.8 (10.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:35; Program name: t1_ttd_1_fas.sas; Output name: T2_EQ5D_FD_1_FAS.rtf

Anhang 4-G 2.8 PGI – weitere Untersuchungen

Anhang 4-G 2.8.1 Subgruppenanalysen – PGI

Anhang 4-G 2.8.1.1 Finaler Datenschnitt vom 23.12.2022

DE.T.3.4.1 PGI-S - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

PGI01-Severity

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	75	34 (45.3)	41 (54.7)	9.0 (2.2, NE)				
Subjects who received neither	27	10 (37.0)	17 (63.0)	10.8 (3.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_PGIS_1_FAS.rtf

DE.T.3.4.1 PGI-S - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

PGI01-Severity

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	35	14 (40.0)	21 (60.0)	11.3 (1.6, NE)				
No	67	30 (44.8)	37 (55.2)	9.7 (3.4, NE)				
HER2 status								
Kinase domain	99	44 (44.4)	55 (55.6)	9.7 (3.4, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_PGIS_1_FAS.rtf

DE.T.3.4.1 PGI-S - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

PGI01-Severity

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	62	24 (38.7)	38 (61.3)	11.3 (5.0, NE)				
>=65 years	40	20 (50.0)	20 (50.0)	4.2 (1.4, NE)				
Age II								
<75 years	94	41 (43.6)	53 (56.4)	9.7 (3.5, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_PGIS_1_FAS.rtf

DE.T.3.4.1 PGI-S - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

PGI01-Severity

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	27 (41.5)	38 (58.5)	9.7 (3.5, NE)				
Male	37	17 (45.9)	20 (54.1)	11.3 (1.5, NE)				
Smoking status								
Current	0							
Former	47	15 (31.9)	32 (68.1)	NE (11.3, NE)				
Never	55	29 (52.7)	26 (47.3)	5.0 (2.1, 10.8)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_PGIS_1_FAS.rtf

DE.T.3.4.1 PGI-S - First deterioration - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Full Analysis Set

PGI01-Severity

	T-DXd 5.4 mg/kg (N=102)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	11.3 (0.8, NE)				
Non-White	79	36 (45.6)	43 (54.4)	9.7 (3.4, NE)				
Region								
Asia	63	29 (46.0)	34 (54.0)	9.0 (3.4, NE)				
North America and Australia	6							
Europe	33	13 (39.4)	20 (60.6)	9.7 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 10MAY2023 – 12:39; Program name: t1_ttd_1_fas.sas; Output name: T3_PGIS_1_FAS.rtf

Anhang 4-G 3 Ergänzende Analysen DESTINY-Lung02 – Gesundheitsbezogene Lebensqualität

Anhang 4-G 3.1 Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30 – weitere Untersuchungen

Anhang 4-G 3.1.1 Subgruppenanalysen – Gesundheitsbezogene Lebensqualität anhand des EORTC QLQ-C30

Anhang 4-G 3.1.1.1 Finaler Datenschnitt vom 23.12.2022

Zur Verhinderung der Mehrfachablage werden die Auswertungen der für die Gesundheitsbezogene Lebensqualität relevanten Funktionsskalen sowie des Globalen Gesundheitszustandes des EORTC QLQ-C30 Fragebogens an dieser Stelle nicht dargestellt, sondern auf die gesamtheitliche Darstellung der Auswertung des EORTC QLQ-C30 unter Anhang 4-G 2.4 verwiesen.

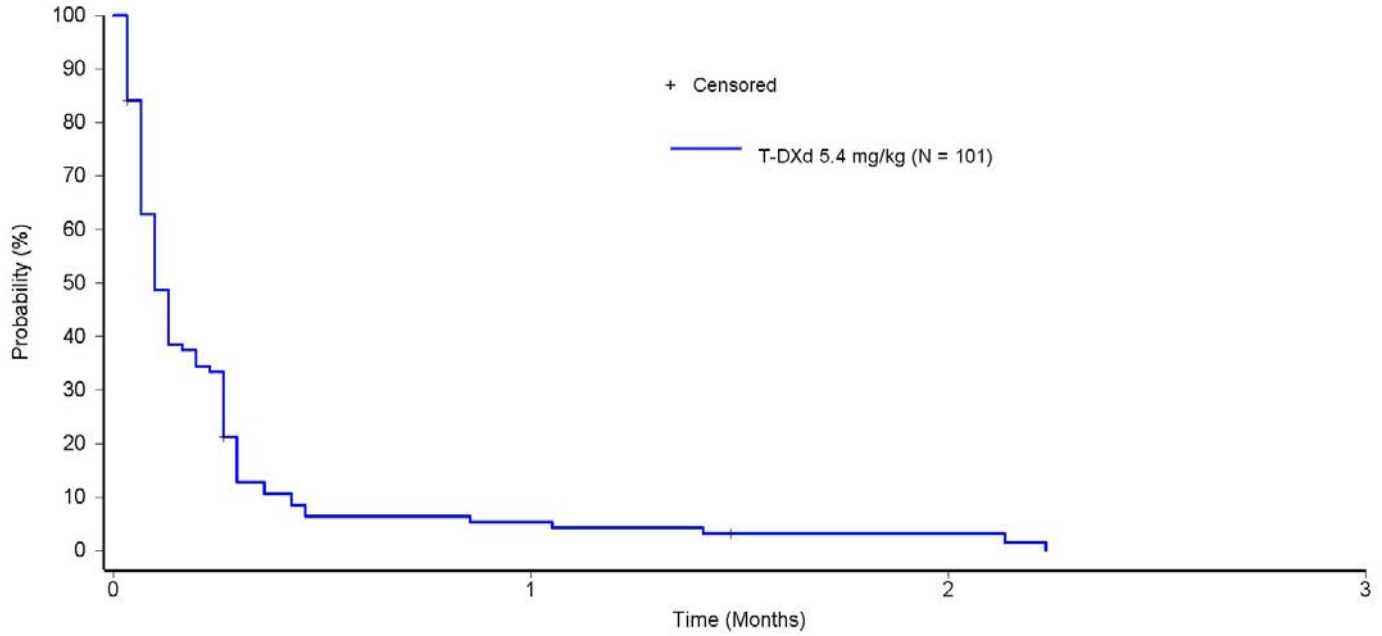
Anhang 4-G 4 Ergänzende Analysen DESTINY-Lung02 – Sicherheit anhand unerwünschter Ereignisse

Anhang 4-G 4.1 Sicherheit – Gesamtraten jeglicher unerwünschten Ereignisse – weitere Untersuchungen

Anhang 4-G 4.1.1 Kaplan-Meier-Kurven – Gesamtraten jeglicher unerwünschten Ereignisse

Anhang 4-G 4.1.1.1 Datenschnitt vom 24.03.2022

DE.F.4.1.2 Treatment-emergent adverse events - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

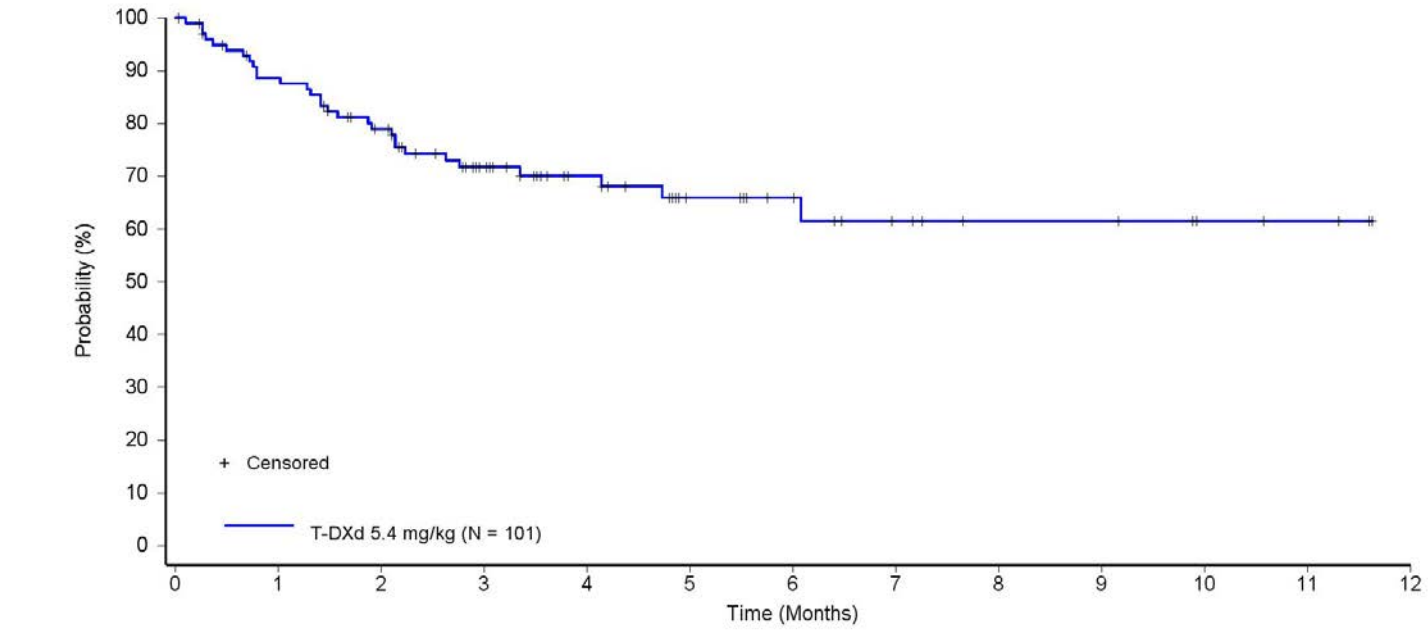


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	5	2	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: f4_teae_2_sas.sas; Output name: F4_TEAE_2_SAS.rtf

DE.F.4.2.2 Serious Treatment-emergent adverse events - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

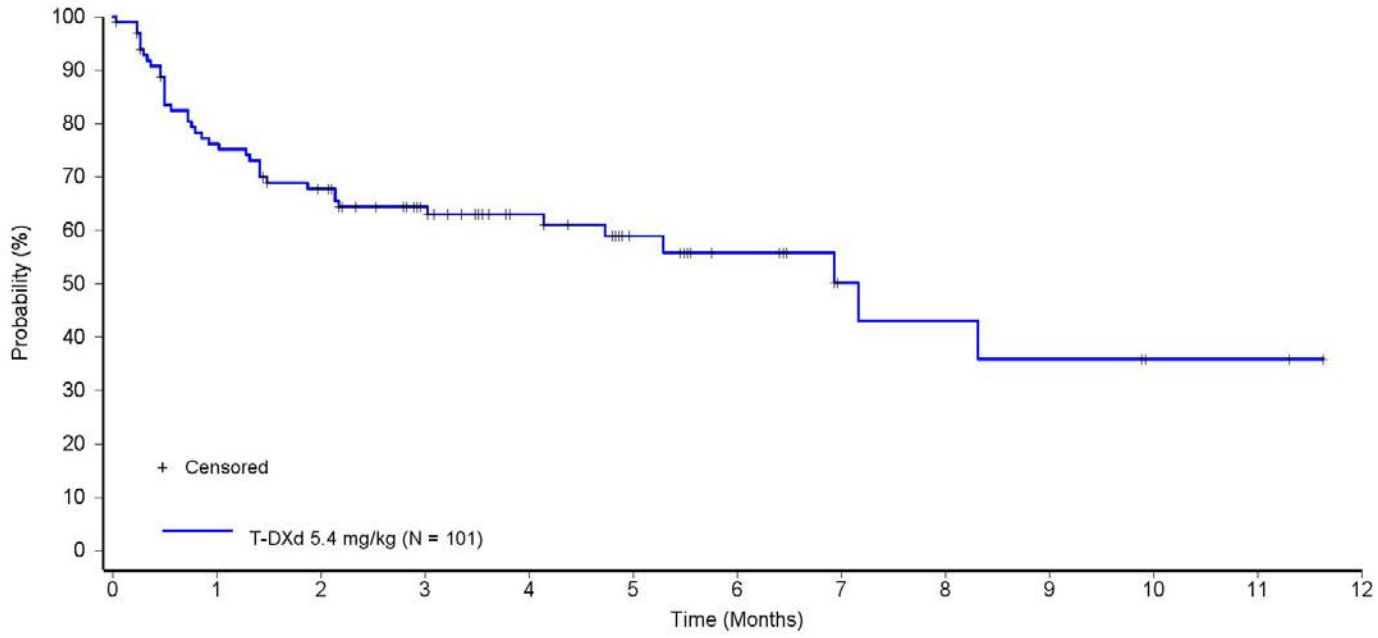


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	84	70	50	35	20	16	11	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_SAE_2_SAS.rtf

DE.F.4.3.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

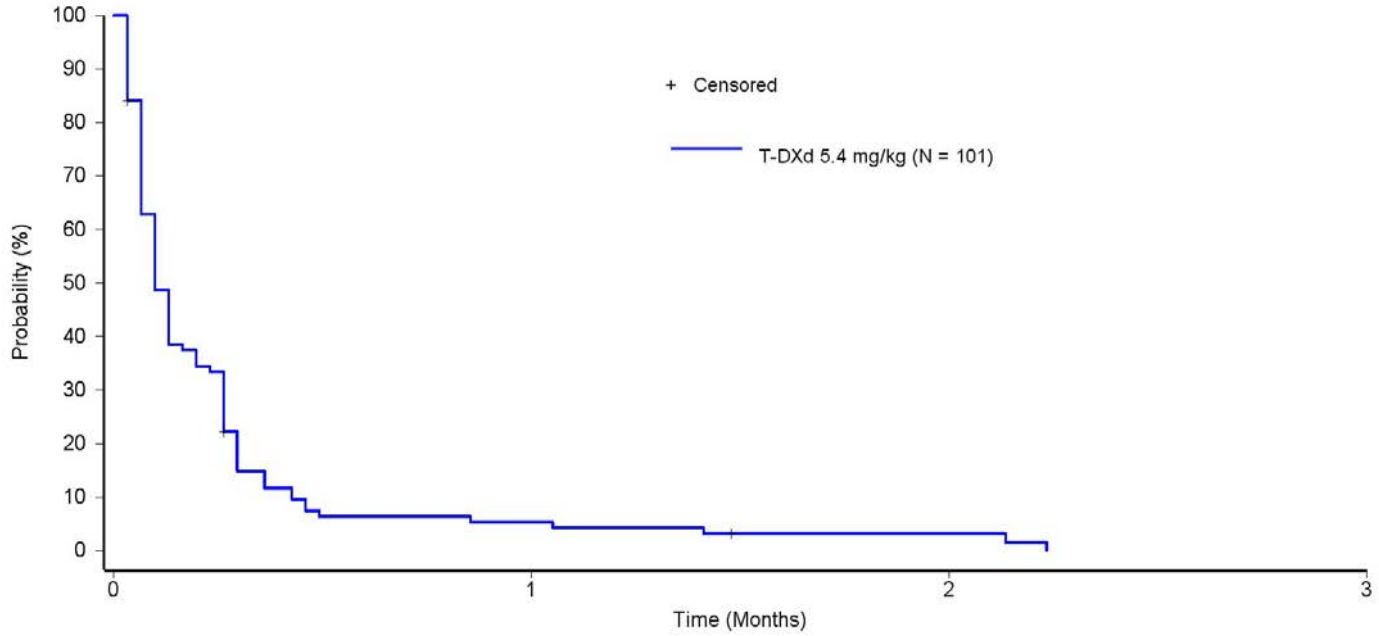


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	73	62	46	32	19	13	7	6	5	2	2	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_AESEV_2_SAS.rtf

DE.F.4.4.2 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	5	2	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_AENONSEV_2_SAS.rtf

Anhang 4-G 4.1.2 Subgruppenanalysen – Gesamtraten jeglicher unerwünschten Ereignisse

Anhang 4-G 4.1.2.1 Datenschnitt vom 24.03.2022

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	71 (95.9)	3 (4.1)	0.1 (0.1, 0.2)				
Subjects who received neither	27	26 (96.3)	1 (3.7)	0.1 (0.1, 0.2)				
Central nervous system (CNS) metastasis								
Yes	33	30 (90.9)	3 (9.1)	0.1 (0.1, 0.3)				
No	68	67 (98.5)	1 (1.5)	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	94 (95.9)	4 (4.1)	0.1 (0.1, 0.1)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	59 (96.7)	2 (3.3)	0.1 (0.1, 0.2)				
>=65 years	40	38 (95.0)	2 (5.0)	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	90 (96.8)	3 (3.2)	0.1 (0.1, 0.1)				
>=75 years	8							
Sex								
Female	65	61 (93.8)	4 (6.2)	0.1 (0.1, 0.2)				
Male	36	36 (100.0)	0	0.1 (0.1, 0.2)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	45 (97.8)	1 (2.2)	0.1 (0.1, 0.3)				
Never	55	52 (94.5)	3 (5.5)	0.1 (0.1, 0.1)				
Race								
White	23	22 (95.7)	1 (4.3)	0.3 (0.1, 0.4)				
Non-White	78	75 (96.2)	3 (3.8)	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	60 (96.8)	2 (3.2)	0.1 (0.1, 0.1)				
North America and Australia	6							
Europe	33	32 (97.0)	1 (3.0)	0.2 (0.1, 0.3)				
Liver metastases								
Yes	24	22 (91.7)	2 (8.3)	0.1 (0.1, 0.3)				
No	77	75 (97.4)	2 (2.6)	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	59 (98.3)	1 (1.7)	0.1 (0.1, 0.1)				
Abnormal, not clinically significant	41	38 (92.7)	3 (7.3)	0.1 (0.1, 0.3)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	80 (95.2)	4 (4.8)	0.1 (0.1, 0.2)				
Abnormal, not clinically significant	17	17 (100.0)	0	0.1 (0.0, 0.1)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	29 (96.7)	1 (3.3)	0.1 (0.1, 0.1)				
1	71	68 (95.8)	3 (4.2)	0.1 (0.1, 0.2)				
Renal function at baseline								
Within normal range	37	37 (100.0)	0	0.1 (0.1, 0.3)				
Mild impairment	40	37 (92.5)	3 (7.5)	0.1 (0.1, 0.3)				
Moderate impairment	22	21 (95.5)	1 (4.5)	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	74 (97.4)	2 (2.6)	0.1 (0.1, 0.2)				
Mild hepatic dysfunction	25	23 (92.0)	2 (8.0)	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	24 (32.4)	50 (67.6)	NE (4.7, NE)				
Subjects who received neither	27	6 (22.2)	21 (77.8)	NE (4.1, NE)				
Central nervous system (CNS) metastasis								
Yes	33	8 (24.2)	25 (75.8)	NE (4.7, NE)				
No	68	22 (32.4)	46 (67.6)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	28 (28.6)	70 (71.4)	NE (6.1, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	15 (24.6)	46 (75.4)	NE (6.1, NE)				
>=65 years	40	15 (37.5)	25 (62.5)	NE (2.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	29 (31.2)	64 (68.8)	NE (6.1, NE)				
>=75 years	8							
Sex								
Female	65	19 (29.2)	46 (70.8)	NE (6.1, NE)				
Male	36	11 (30.6)	25 (69.4)	NE (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	14 (30.4)	32 (69.6)	NE (4.7, NE)				
Never	55	16 (29.1)	39 (70.9)	NE (6.1, NE)				
Race								
White	23	5 (21.7)	18 (78.3)	NE (NE, NE)				
Non-White	78	25 (32.1)	53 (67.9)	NE (6.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	15 (24.2)	47 (75.8)	NE (6.1, NE)				
North America and Australia	6							
Europe	33	14 (42.4)	19 (57.6)	NE (1.3, NE)				
Liver metastases								
Yes	24	9 (37.5)	15 (62.5)	6.1 (2.2, NE)				
No	77	21 (27.3)	56 (72.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	17 (28.3)	43 (71.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	13 (31.7)	28 (68.3)	NE (2.8, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	25 (29.8)	59 (70.2)	NE (6.1, NE)				
Abnormal, not clinically significant	17	5 (29.4)	12 (70.6)	NE (2.1, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	5 (16.7)	25 (83.3)	NE (NE, NE)				
1	71	25 (35.2)	46 (64.8)	NE (4.1, NE)				
Renal function at baseline								
Within normal range	37	13 (35.1)	24 (64.9)	NE (2.1, NE)				
Mild impairment	40	12 (30.0)	28 (70.0)	NE (4.1, NE)				
Moderate impairment	22	5 (22.7)	17 (77.3)	NE (3.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	22 (28.9)	54 (71.1)	NE (NE, NE)				
Mild hepatic dysfunction	25	8 (32.0)	17 (68.0)	6.1 (2.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	34 (45.9)	40 (54.1)	6.9 (2.1, NE)				
Subjects who received neither	27	7 (25.9)	20 (74.1)	NE (4.1, NE)				
Central nervous system (CNS) metastasis								
Yes	33	15 (45.5)	18 (54.5)	4.7 (0.8, NE)				
No	68	26 (38.2)	42 (61.8)	7.2 (6.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	40 (40.8)	58 (59.2)	6.9 (4.1, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	22 (36.1)	39 (63.9)	7.2 (5.3, NE)				
>=65 years	40	19 (47.5)	21 (52.5)	4.1 (0.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	38 (40.9)	55 (59.1)	6.9 (4.7, NE)				
>=75 years	8							
Sex								
Female	65	24 (36.9)	41 (63.1)	7.2 (4.1, NE)				
Male	36	17 (47.2)	19 (52.8)	6.9 (1.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	20 (43.5)	26 (56.5)	7.2 (2.2, NE)				
Never	55	21 (38.2)	34 (61.8)	NE (2.1, NE)				
Race								
White	23	8 (34.8)	15 (65.2)	NE (1.0, NE)				
Non-White	78	33 (42.3)	45 (57.7)	6.9 (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	24 (38.7)	38 (61.3)	7.2 (4.7, NE)				
North America and Australia	6							
Europe	33	15 (45.5)	18 (54.5)	NE (0.9, NE)				
Liver metastases								
Yes	24	11 (45.8)	13 (54.2)	5.3 (1.5, NE)				
No	77	30 (39.0)	47 (61.0)	7.2 (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	23 (38.3)	37 (61.7)	7.2 (4.7, NE)				
Abnormal, not clinically significant	41	18 (43.9)	23 (56.1)	5.3 (0.8, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	33 (39.3)	51 (60.7)	7.2 (4.7, NE)				
Abnormal, not clinically significant	17	8 (47.1)	9 (52.9)	NE (0.6, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	10 (33.3)	20 (66.7)	7.2 (6.9, NE)				
1	71	31 (43.7)	40 (56.3)	5.3 (2.2, NE)				
Renal function at baseline								
Within normal range	37	15 (40.5)	22 (59.5)	7.2 (4.7, NE)				
Mild impairment	40	15 (37.5)	25 (62.5)	6.9 (2.2, NE)				
Moderate impairment	22	11 (50.0)	11 (50.0)	4.1 (0.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	31 (40.8)	45 (59.2)	7.2 (4.1, NE)				
Mild hepatic dysfunction	25	10 (40.0)	15 (60.0)	5.3 (2.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	71 (95.9)	3 (4.1)	0.1 (0.1, 0.2)				
Subjects who received neither	27	26 (96.3)	1 (3.7)	0.1 (0.1, 0.2)				
Central nervous system (CNS) metastasis								
Yes	33	30 (90.9)	3 (9.1)	0.1 (0.1, 0.3)				
No	68	67 (98.5)	1 (1.5)	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	94 (95.9)	4 (4.1)	0.1 (0.1, 0.1)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	59 (96.7)	2 (3.3)	0.1 (0.1, 0.2)				
>=65 years	40	38 (95.0)	2 (5.0)	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	90 (96.8)	3 (3.2)	0.1 (0.1, 0.1)				
>=75 years	8							
Sex								
Female	65	61 (93.8)	4 (6.2)	0.1 (0.1, 0.2)				
Male	36	36 (100.0)	0	0.1 (0.1, 0.2)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	45 (97.8)	1 (2.2)	0.1 (0.1, 0.3)				
Never	55	52 (94.5)	3 (5.5)	0.1 (0.1, 0.1)				
Race								
White	23	22 (95.7)	1 (4.3)	0.3 (0.1, 0.4)				
Non-White	78	75 (96.2)	3 (3.8)	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	60 (96.8)	2 (3.2)	0.1 (0.1, 0.1)				
North America and Australia	6							
Europe	33	32 (97.0)	1 (3.0)	0.2 (0.1, 0.3)				
Liver metastases								
Yes	24	22 (91.7)	2 (8.3)	0.1 (0.1, 0.3)				
No	77	75 (97.4)	2 (2.6)	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	59 (98.3)	1 (1.7)	0.1 (0.1, 0.1)				
Abnormal, not clinically significant	41	38 (92.7)	3 (7.3)	0.1 (0.1, 0.3)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	80 (95.2)	4 (4.8)	0.1 (0.1, 0.2)				
Abnormal, not clinically significant	17	17 (100.0)	0	0.1 (0.0, 0.1)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	29 (96.7)	1 (3.3)	0.1 (0.1, 0.1)				
1	71	68 (95.8)	3 (4.2)	0.1 (0.1, 0.2)				
Renal function at baseline								
Within normal range	37	37 (100.0)	0	0.1 (0.1, 0.3)				
Mild impairment	40	37 (92.5)	3 (7.5)	0.1 (0.1, 0.3)				
Moderate impairment	22	21 (95.5)	1 (4.5)	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	74 (97.4)	2 (2.6)	0.1 (0.1, 0.2)				
Mild hepatic dysfunction	25	23 (92.0)	2 (8.0)	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

Anhang 4-G 4.1.2.2 Finaler Datenschnitt vom 23.12.2022

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	74 (100.0)	0	0.1 (0.1, 0.2)				
Subjects who received neither	27	27 (100.0)	0	0.1 (0.1, 0.2)				
Central nervous system (CNS) metastasis								
Yes	34	34 (100.0)	0	0.1 (0.1, 0.3)				
No	67	67 (100.0)	0	0.1 (0.1, 0.2)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	98 (100.0)	0	0.1 (0.1, 0.1)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	61 (100.0)	0	0.1 (0.1, 0.1)				
>=65 years	40	40 (100.0)	0	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	93 (100.0)	0	0.1 (0.1, 0.1)				
>=75 years	8							
Sex								
Female	65	65 (100.0)	0	0.1 (0.1, 0.2)				
Male	36	36 (100.0)	0	0.1 (0.1, 0.2)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	46 (100.0)	0	0.1 (0.1, 0.3)				
Never	55	55 (100.0)	0	0.1 (0.1, 0.1)				
Race								
White	23	23 (100.0)	0	0.3 (0.1, 0.4)				
Non-White	78	78 (100.0)	0	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	62 (100.0)	0	0.1 (0.1, 0.1)				
North America and Australia	6							
Europe	33	33 (100.0)	0	0.2 (0.1, 0.3)				
Liver metastases								
Yes	24	24 (100.0)	0	0.1 (0.1, 0.3)				
No	77	77 (100.0)	0	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	58 (100.0)	0	0.1 (0.1, 0.1)				
Abnormal, not clinically significant	43	43 (100.0)	0	0.1 (0.1, 0.3)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	84 (100.0)	0	0.1 (0.1, 0.2)				
Abnormal, not clinically significant	17	17 (100.0)	0	0.1 (0.0, 0.1)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	29 (100.0)	0	0.1 (0.1, 0.2)				
1	72	72 (100.0)	0	0.1 (0.1, 0.2)				
Renal function at baseline								
Within normal range	37	37 (100.0)	0	0.1 (0.1, 0.3)				
Mild impairment	41	41 (100.0)	0	0.1 (0.1, 0.3)				
Moderate impairment	23	23 (100.0)	0	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.1.1 Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	76 (100.0)	0	0.1 (0.1, 0.2)				
Mild hepatic dysfunction	25	25 (100.0)	0	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_teae_1_sas.sas; Output name: T4_TEAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	30 (40.5)	44 (59.5)	NE (5.9, NE)				
Subjects who received neither	27	7 (25.9)	20 (74.1)	NE (6.8, NE)				
Central nervous system (CNS) metastasis								
Yes	34	13 (38.2)	21 (61.8)	NE (6.1, NE)				
No	67	24 (35.8)	43 (64.2)	NE (5.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	35 (35.7)	63 (64.3)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	17 (27.9)	44 (72.1)	NE (NE, NE)				
>=65 years	40	20 (50.0)	20 (50.0)	6.8 (3.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	35 (37.6)	58 (62.4)	NE (10.1, NE)				
>=75 years	8							
Sex								
Female	65	25 (38.5)	40 (61.5)	NE (6.1, NE)				
Male	36	12 (33.3)	24 (66.7)	NE (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	15 (32.6)	31 (67.4)	NE (NE, NE)				
Never	55	22 (40.0)	33 (60.0)	NE (5.9, NE)				
Race								
White	23	9 (39.1)	14 (60.9)	NE (4.2, NE)				
Non-White	78	28 (35.9)	50 (64.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	18 (29.0)	44 (71.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	18 (54.5)	15 (45.5)	5.9 (1.4, NE)				
Liver metastases								
Yes	24	11 (45.8)	13 (54.2)	NE (2.8, NE)				
No	77	26 (33.8)	51 (66.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	19 (32.8)	39 (67.2)	NE (10.1, NE)				
Abnormal, not clinically significant	43	18 (41.9)	25 (58.1)	NE (3.4, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	31 (36.9)	53 (63.1)	NE (10.1, NE)				
Abnormal, not clinically significant	17	6 (35.3)	11 (64.7)	NE (2.1, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	4 (13.8)	25 (86.2)	NE (NE, NE)				
1	72	33 (45.8)	39 (54.2)	10.1 (4.7, NE)				
Renal function at baseline								
Within normal range	37	13 (35.1)	24 (64.9)	NE (5.9, NE)				
Mild impairment	41	16 (39.0)	25 (61.0)	NE (4.1, NE)				
Moderate impairment	23	8 (34.8)	15 (65.2)	NE (5.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.2.1 Serious Treatment-emergent adverse events - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	28 (36.8)	48 (63.2)	NE (10.1, NE)				
Mild hepatic dysfunction	25	9 (36.0)	16 (64.0)	NE (4.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAE_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	45 (60.8)	29 (39.2)	5.3 (1.5, 9.0)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (7.5, NE)				
Central nervous system (CNS) metastasis								
Yes	34	22 (64.7)	12 (35.3)	4.2 (0.7, 10.1)				
No	67	31 (46.3)	36 (53.7)	NE (5.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	52 (53.1)	46 (46.9)	7.2 (4.1, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	29 (47.5)	32 (52.5)	10.1 (4.7, NE)				
>=65 years	40	24 (60.0)	16 (40.0)	4.9 (0.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	49 (52.7)	44 (47.3)	7.2 (4.2, NE)				
>=75 years	8							
Sex								
Female	65	35 (53.8)	30 (46.2)	7.2 (3.0, NE)				
Male	36	18 (50.0)	18 (50.0)	8.3 (1.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	23 (50.0)	23 (50.0)	8.3 (2.2, NE)				
Never	55	30 (54.5)	25 (45.5)	5.3 (1.9, NE)				
Race								
White	23	13 (56.5)	10 (43.5)	5.9 (1.4, NE)				
Non-White	78	40 (51.3)	38 (48.7)	7.5 (3.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	31 (50.0)	31 (50.0)	8.3 (4.7, NE)				
North America and Australia	6							
Europe	33	19 (57.6)	14 (42.4)	5.3 (1.0, NE)				
Liver metastases								
Yes	24	12 (50.0)	12 (50.0)	5.3 (1.5, NE)				
No	77	41 (53.2)	36 (46.8)	7.5 (3.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	29 (50.0)	29 (50.0)	9.0 (4.7, NE)				
Abnormal, not clinically significant	43	24 (55.8)	19 (44.2)	4.9 (0.7, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	44 (52.4)	40 (47.6)	7.5 (4.2, NE)				
Abnormal, not clinically significant	17	9 (52.9)	8 (47.1)	4.9 (0.6, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	11 (37.9)	18 (62.1)	NE (6.9, NE)				
1	72	42 (58.3)	30 (41.7)	5.3 (2.1, NE)				
Renal function at baseline								
Within normal range	37	18 (48.6)	19 (51.4)	9.0 (4.2, NE)				
Mild impairment	41	21 (51.2)	20 (48.8)	6.9 (1.9, NE)				
Moderate impairment	23	14 (60.9)	9 (39.1)	4.1 (0.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.3.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >= 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	40 (52.6)	36 (47.4)	7.2 (2.1, NE)				
Mild hepatic dysfunction	25	13 (52.0)	12 (48.0)	7.5 (2.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	74 (100.0)	0	0.1 (0.1, 0.2)				
Subjects who received neither	27	27 (100.0)	0	0.1 (0.1, 0.2)				
Central nervous system (CNS) metastasis								
Yes	34	34 (100.0)	0	0.1 (0.1, 0.3)				
No	67	67 (100.0)	0	0.1 (0.1, 0.2)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	98 (100.0)	0	0.1 (0.1, 0.1)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	61 (100.0)	0	0.1 (0.1, 0.1)				
>=65 years	40	40 (100.0)	0	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	93 (100.0)	0	0.1 (0.1, 0.1)				
>=75 years	8							
Sex								
Female	65	65 (100.0)	0	0.1 (0.1, 0.2)				
Male	36	36 (100.0)	0	0.1 (0.1, 0.2)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	46 (100.0)	0	0.1 (0.1, 0.3)				
Never	55	55 (100.0)	0	0.1 (0.1, 0.1)				
Race								
White	23	23 (100.0)	0	0.3 (0.1, 0.4)				
Non-White	78	78 (100.0)	0	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	62 (100.0)	0	0.1 (0.1, 0.1)				
North America and Australia	6							
Europe	33	33 (100.0)	0	0.2 (0.1, 0.3)				
Liver metastases								
Yes	24	24 (100.0)	0	0.1 (0.1, 0.3)				
No	77	77 (100.0)	0	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	58 (100.0)	0	0.1 (0.1, 0.1)				
Abnormal, not clinically significant	43	43 (100.0)	0	0.1 (0.1, 0.3)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	84 (100.0)	0	0.1 (0.1, 0.2)				
Abnormal, not clinically significant	17	17 (100.0)	0	0.1 (0.0, 0.1)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	29 (100.0)	0	0.1 (0.1, 0.2)				
1	72	72 (100.0)	0	0.1 (0.1, 0.2)				
Renal function at baseline								
Within normal range	37	37 (100.0)	0	0.1 (0.1, 0.3)				
Mild impairment	41	41 (100.0)	0	0.1 (0.1, 0.3)				
Moderate impairment	23	23 (100.0)	0	0.1 (0.1, 0.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

DE.T.4.4.1 Non-Severe Treatment-emergent adverse events (NCI CTCAE grade < 3) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	76 (100.0)	0	0.1 (0.1, 0.2)				
Mild hepatic dysfunction	25	25 (100.0)	0	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

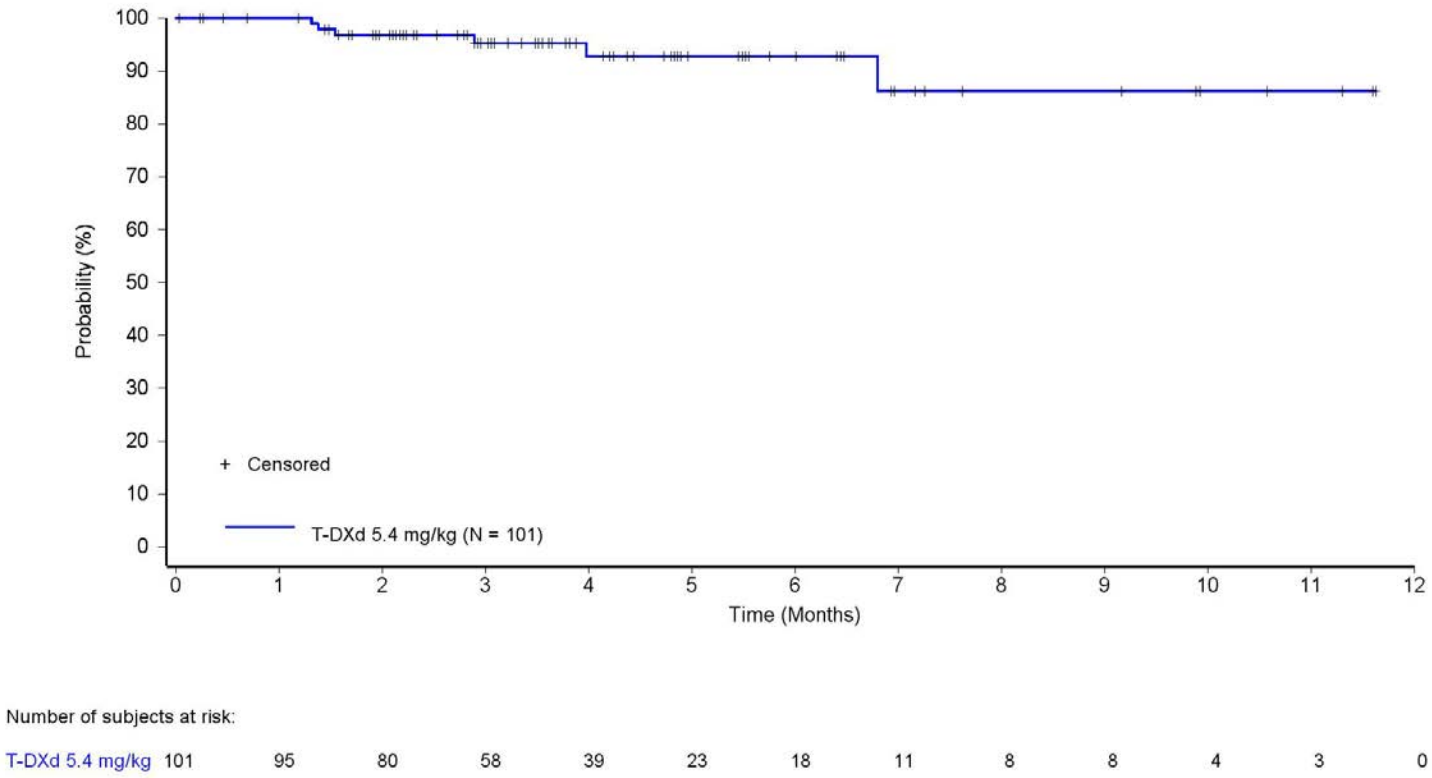
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AENONSEV_1_SAS.rtf

Anhang 4-G 4.2 Sicherheit – Unerwünschte Ereignisse von besonderem Interesse – weitere Untersuchungen

Anhang 4-G 4.2.1 Kaplan-Meier-Kurven – Unerwünschte Ereignisse von besonderem Interesse

Anhang 4-G 4.2.1.1 Datenschnitt vom 24.03.2022

DE.F.4.11.2 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD)) - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

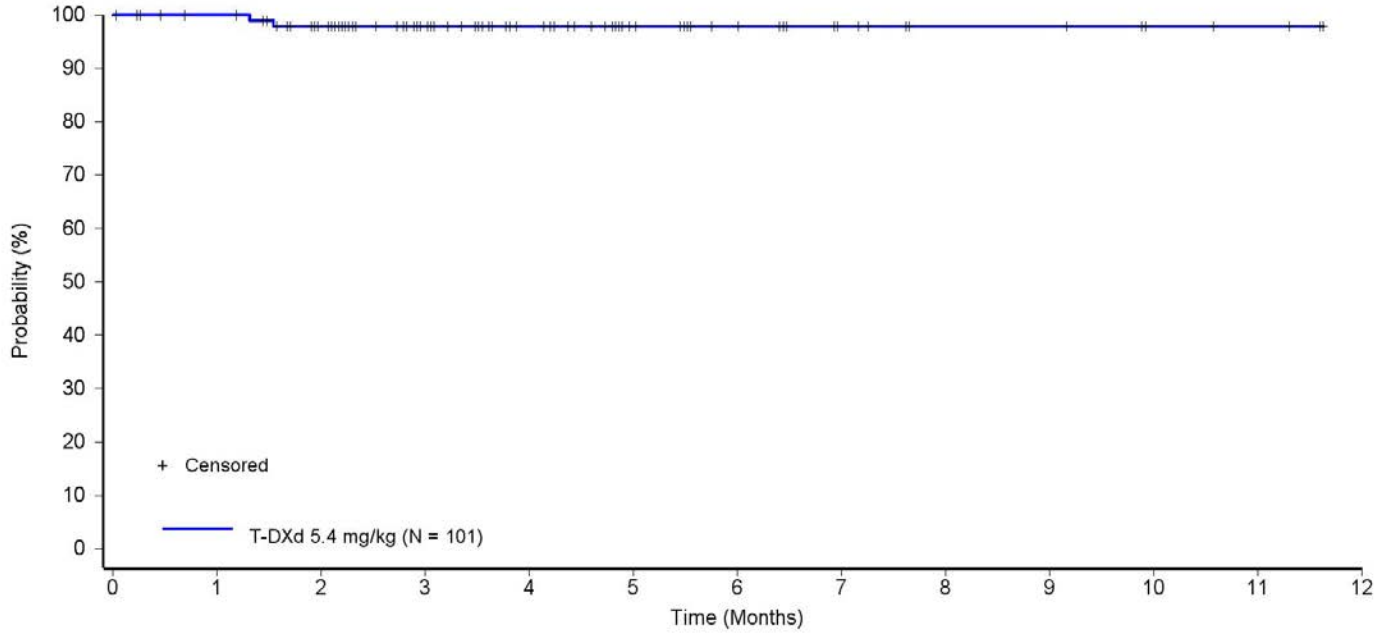


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	95	80	58	39	23	18	11	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_AESIILDAC_2_SAS.rtf

DE.F.4.13.2 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

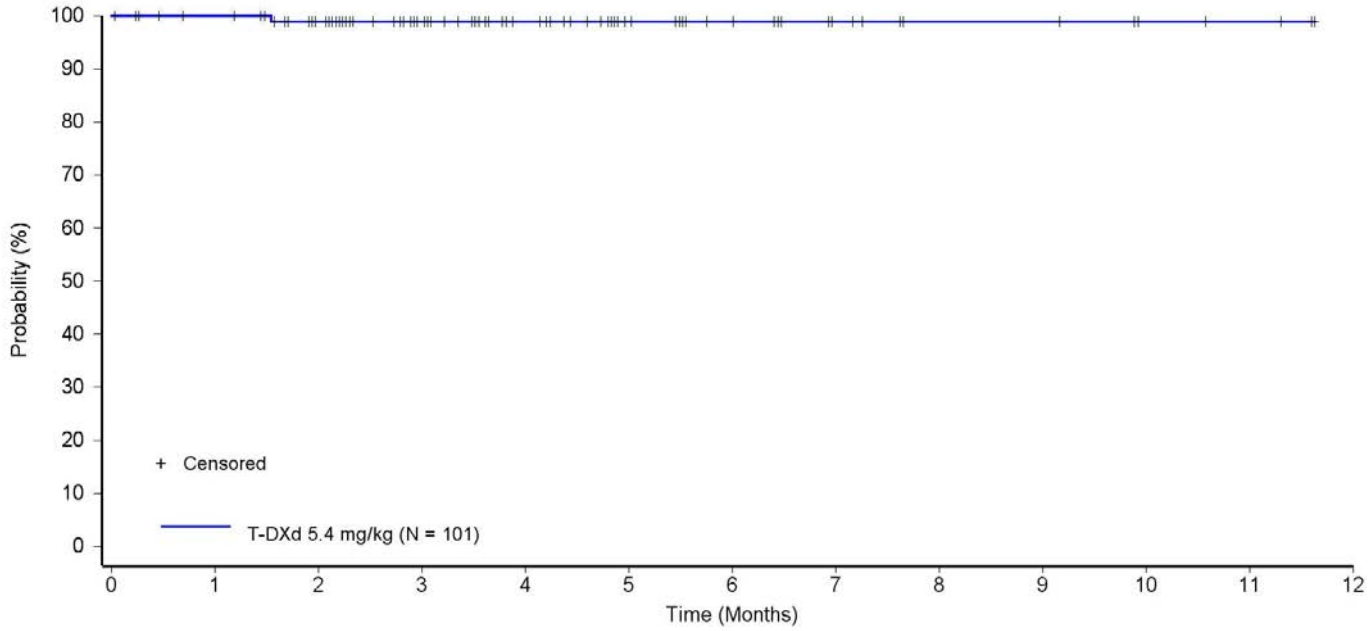


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	95	81	59	41	24	18	12	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_SAESIILDAC_2_SAS.rtf

DE.F.4.15.2 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

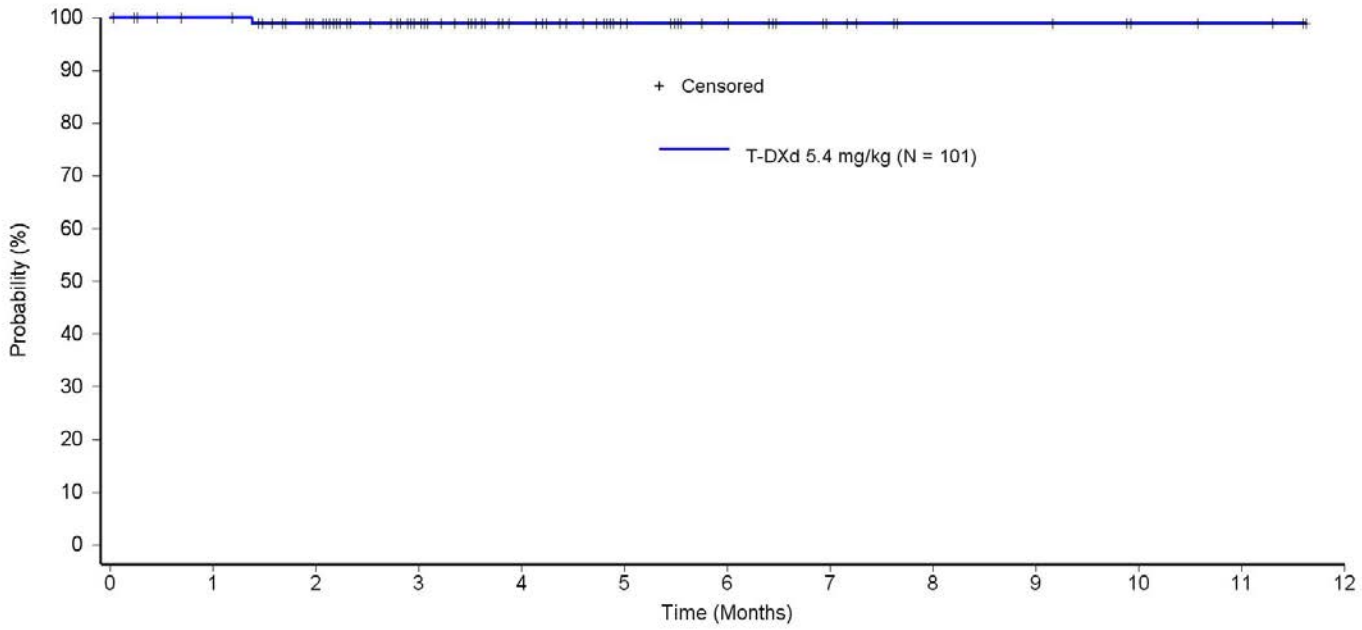


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	95	82	60	42	24	18	12	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_SEVAESIILDAC_2_SAS.rtf

DE.F.4.12.2 Adverse events of special interest - Left Ventricular Dysfunction - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

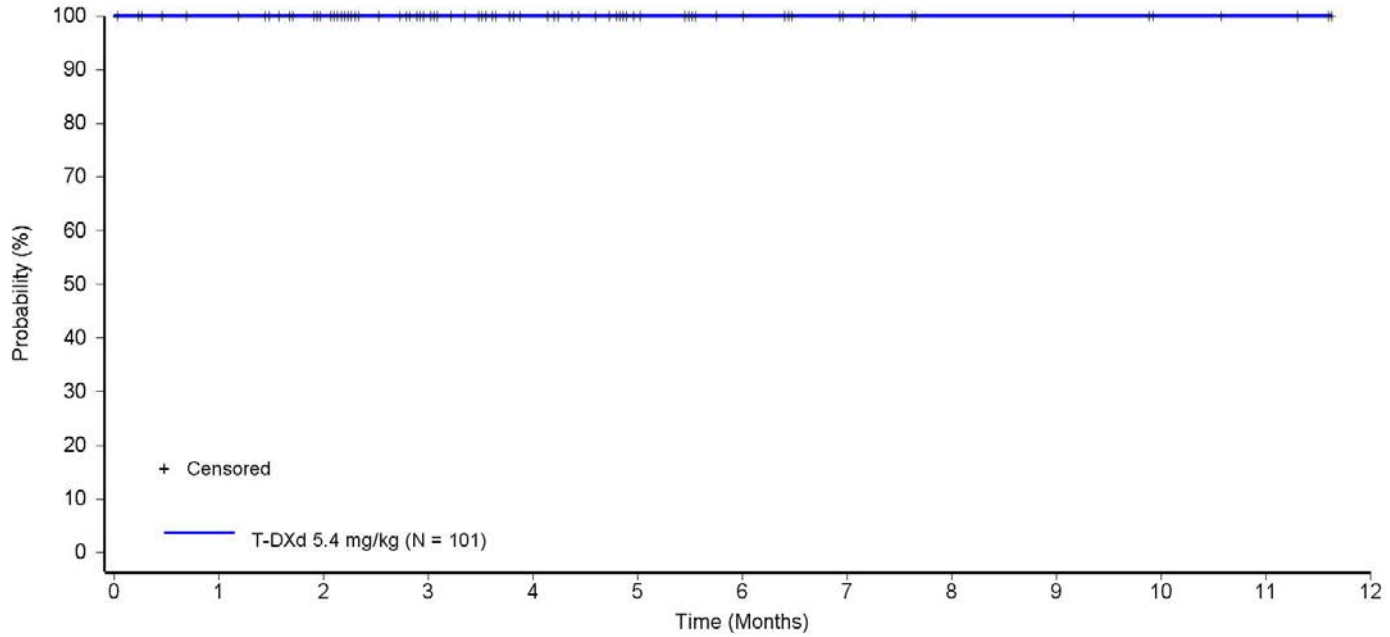


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	95	82	60	42	24	18	12	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_AESILVEF_2_SAS.rtf

DE.F.4.14.2 Serious Adverse events of special interest - Left Ventricular Dysfunction - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

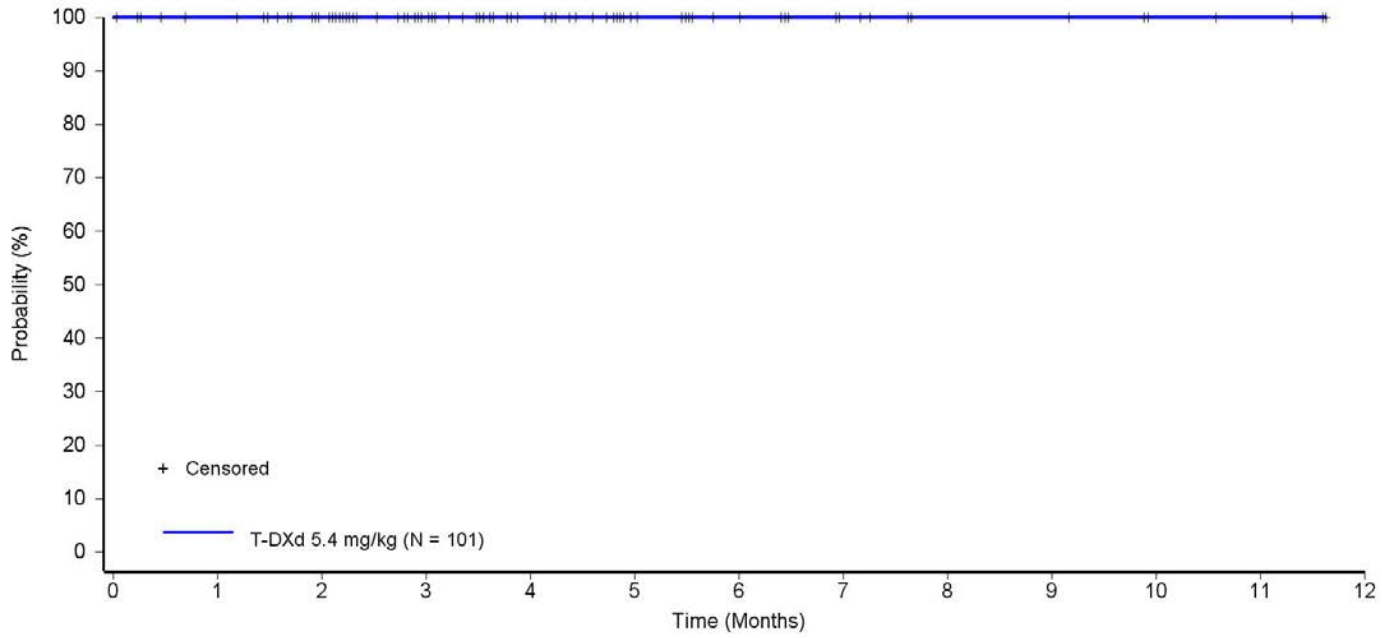


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	95	83	60	42	24	18	12	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_SAESILVEF_2_SAS.rtf

DE.F.4.16.2 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	95	83	60	42	24	18	12	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_SEVAESILVEF_2_SAS.rtf

Anhang 4-G 4.2.2 Subgruppenanalysen – Unerwünschte Ereignisse von besonderem Interesse

Anhang 4-G 4.2.2.1 Datenschnitt vom 24.03.2022

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	5 (6.8)	69 (93.2)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
No	68	5 (7.4)	63 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	5 (5.1)	93 (94.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	3 (4.9)	58 (95.1)	NE (6.8, NE)				
>=65 years	40	3 (7.5)	37 (92.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	6 (6.5)	87 (93.5)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	2 (3.1)	63 (96.9)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (6.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (6.8, NE)				
Never	55	2 (3.6)	53 (96.4)	NE (NE, NE)				
Race								
White	23	2 (8.7)	21 (91.3)	NE (4.0, NE)				
Non-White	78	4 (5.1)	74 (94.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	3 (4.8)	59 (95.2)	NE (NE, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	4 (5.2)	73 (94.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	3 (5.0)	57 (95.0)	NE (6.8, NE)				
Abnormal, not clinically significant	41	3 (7.3)	38 (92.7)	NE (NE, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	3 (3.6)	81 (96.4)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (2.9, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	1 (3.3)	29 (96.7)	NE (6.8, NE)				
1	71	5 (7.0)	66 (93.0)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (NE, NE)				
Mild impairment	40	3 (7.5)	37 (92.5)	NE (6.8, NE)				
Moderate impairment	22	1 (4.5)	21 (95.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	5 (6.6)	71 (93.4)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	1 (1.4)	73 (98.6)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
No	68	1 (1.5)	67 (98.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	1 (1.0)	97 (99.0)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	0	61 (100.0)	NE (NE, NE)				
>=65 years	40	2 (5.0)	38 (95.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	2 (2.2)	91 (97.8)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	0	65 (100.0)	NE (NE, NE)				
Male	36	2 (5.6)	34 (94.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	2 (4.3)	44 (95.7)	NE (NE, NE)				
Never	55	0	55 (100.0)	NE (NE, NE)				
Race								
White	23	1 (4.3)	22 (95.7)	NE (NE, NE)				
Non-White	78	1 (1.3)	77 (98.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	1 (1.6)	61 (98.4)	NE (NE, NE)				
North America and Australia	6							
Europe	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
Liver metastases								
Yes	24	1 (4.2)	23 (95.8)	NE (NE, NE)				
No	77	1 (1.3)	76 (98.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	1 (1.7)	59 (98.3)	NE (NE, NE)				
Abnormal, not clinically significant	41	1 (2.4)	40 (97.6)	NE (NE, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	1 (1.2)	83 (98.8)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	0	30 (100.0)	NE (NE, NE)				
1	71	2 (2.8)	69 (97.2)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	1 (2.7)	36 (97.3)	NE (NE, NE)				
Mild impairment	40	1 (2.5)	39 (97.5)	NE (NE, NE)				
Moderate impairment	22	0	22 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	2 (2.6)	74 (97.4)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	1 (1.4)	73 (98.6)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	33	0	33 (100.0)	NE (NE, NE)				
No	68	1 (1.5)	67 (98.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	1 (1.0)	97 (99.0)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	0	61 (100.0)	NE (NE, NE)				
>=65 years	40	1 (2.5)	39 (97.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	1 (1.1)	92 (98.9)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	0	65 (100.0)	NE (NE, NE)				
Male	36	1 (2.8)	35 (97.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	1 (2.2)	45 (97.8)	NE (NE, NE)				
Never	55	0	55 (100.0)	NE (NE, NE)				
Race								
White	23	1 (4.3)	22 (95.7)	NE (NE, NE)				
Non-White	78	0	78 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	0	62 (100.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
Liver metastases								
Yes	24	0	24 (100.0)	NE (NE, NE)				
No	77	1 (1.3)	76 (98.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	1 (1.7)	59 (98.3)	NE (NE, NE)				
Abnormal, not clinically significant	41	0	41 (100.0)	NE (NE, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	0	84 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	0	30 (100.0)	NE (NE, NE)				
1	71	1 (1.4)	70 (98.6)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	1 (2.7)	36 (97.3)	NE (NE, NE)				
Mild impairment	40	0	40 (100.0)	NE (NE, NE)				
Moderate impairment	22	0	22 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	1 (1.3)	75 (98.7)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	1 (1.4)	73 (98.6)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	33	0	33 (100.0)	NE (NE, NE)				
No	68	1 (1.5)	67 (98.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESILVEF_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	1 (1.0)	97 (99.0)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	1 (1.6)	60 (98.4)	NE (NE, NE)				
>=65 years	40	0	40 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AESILVEF_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	1 (1.1)	92 (98.9)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	0	65 (100.0)	NE (NE, NE)				
Male	36	1 (2.8)	35 (97.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	0	46 (100.0)	NE (NE, NE)				
Never	55	1 (1.8)	54 (98.2)	NE (NE, NE)				
Race								
White	23	0	23 (100.0)	NE (NE, NE)				
Non-White	78	1 (1.3)	77 (98.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	0	62 (100.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
Liver metastases								
Yes	24	0	24 (100.0)	NE (NE, NE)				
No	77	1 (1.3)	76 (98.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	1 (1.7)	59 (98.3)	NE (NE, NE)				
Abnormal, not clinically significant	41	0	41 (100.0)	NE (NE, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	0	84 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	0	30 (100.0)	NE (NE, NE)				
1	71	1 (1.4)	70 (98.6)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	1 (2.7)	36 (97.3)	NE (NE, NE)				
Mild impairment	40	0	40 (100.0)	NE (NE, NE)				
Moderate impairment	22	0	22 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	0	76 (100.0)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	0	74 (100.0)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SAESILVEF_1_SAS.rtf

DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	0	33 (100.0)	NE (NE, NE)				
No	68	0	68 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	0	98 (100.0)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	0	61 (100.0)	NE (NE, NE)				
>=65 years	40	0	40 (100.0)	NE (NE, NE)				
Age II								
<75 years	93	0	93 (100.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	0	65 (100.0)	NE (NE, NE)				
Male	36	0	36 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	0	46 (100.0)	NE (NE, NE)				
Never	55	0	55 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	0	23 (100.0)	NE (NE, NE)				
Non-White	78	0	78 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	0	62 (100.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	0	33 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SAESILVEF_1_SAS.rtf

DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	0	24 (100.0)	NE (NE, NE)				
No	77	0	77 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	0	60 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	41	0	41 (100.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	0	84 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	0	17 (100.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	0	30 (100.0)	NE (NE, NE)				
1	71	0	71 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	0	37 (100.0)	NE (NE, NE)				
Mild impairment	40	0	40 (100.0)	NE (NE, NE)				
Moderate impairment	22	0	22 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	0	76 (100.0)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SAESILVEF_1_SAS.rtf

DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	0	74 (100.0)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	0	33 (100.0)	NE (NE, NE)				
No	68	0	68 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	0	98 (100.0)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	0	61 (100.0)	NE (NE, NE)				
>=65 years	40	0	40 (100.0)	NE (NE, NE)				
Age II								
<75 years	93	0	93 (100.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	0	65 (100.0)	NE (NE, NE)				
Male	36	0	36 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	0	46 (100.0)	NE (NE, NE)				
Never	55	0	55 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	0	23 (100.0)	NE (NE, NE)				
Non-White	78	0	78 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	0	62 (100.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	0	33 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	0	24 (100.0)	NE (NE, NE)				
No	77	0	77 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	0	60 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	41	0	41 (100.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	0	84 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	0	17 (100.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	0	30 (100.0)	NE (NE, NE)				
1	71	0	71 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	0	37 (100.0)	NE (NE, NE)				
Mild impairment	40	0	40 (100.0)	NE (NE, NE)				
Moderate impairment	22	0	22 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	0	76 (100.0)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESILVEF_1_SAS.rtf

Anhang 4-G 4.2.2.2 Finaler Datenschnitt vom 23.12.2022

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	11 (14.9)	63 (85.1)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	34	4 (11.8)	30 (88.2)	NE (NE, NE)				
No	67	9 (13.4)	58 (86.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	12 (12.2)	86 (87.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	8 (20.0)	32 (80.0)	NE (13.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	11 (11.8)	82 (88.2)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (NE, NE)				
Male	36	6 (16.7)	30 (83.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	7 (15.2)	39 (84.8)	NE (13.8, NE)				
Never	55	6 (10.9)	49 (89.1)	NE (NE, NE)				
Race								
White	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Non-White	78	9 (11.5)	69 (88.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	8 (12.9)	54 (87.1)	NE (NE, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	10 (13.0)	67 (87.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	6 (10.3)	52 (89.7)	NE (NE, NE)				
Abnormal, not clinically significant	43	7 (16.3)	36 (83.7)	NE (13.8, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	8 (9.5)	76 (90.5)	NE (NE, NE)				
Abnormal, not clinically significant	17	5 (29.4)	12 (70.6)	NE (4.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	3 (10.3)	26 (89.7)	NE (13.8, NE)				
1	72	10 (13.9)	62 (86.1)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (13.8, NE)				
Mild impairment	41	5 (12.2)	36 (87.8)	NE (NE, NE)				
Moderate impairment	23	4 (17.4)	19 (82.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.11.1 Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	9 (11.8)	67 (88.2)	NE (NE, NE)				
Mild hepatic dysfunction	25	4 (16.0)	21 (84.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESIILDAC_1_SAS.rtf

DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	2 (2.7)	72 (97.3)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	34	1 (2.9)	33 (97.1)	NE (NE, NE)				
No	67	3 (4.5)	64 (95.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	3 (3.1)	95 (96.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	0	61 (100.0)	NE (NE, NE)				
>=65 years	40	4 (10.0)	36 (90.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	4 (4.3)	89 (95.7)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	2 (3.1)	63 (96.9)	NE (NE, NE)				
Male	36	2 (5.6)	34 (94.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	3 (6.5)	43 (93.5)	NE (NE, NE)				
Never	55	1 (1.8)	54 (98.2)	NE (NE, NE)				
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	2 (2.6)	76 (97.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	2 (3.2)	60 (96.8)	NE (NE, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				
Liver metastases								
Yes	24	1 (4.2)	23 (95.8)	NE (NE, NE)				
No	77	3 (3.9)	74 (96.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	2 (3.4)	56 (96.6)	NE (NE, NE)				
Abnormal, not clinically significant	43	2 (4.7)	41 (95.3)	NE (NE, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	3 (3.6)	81 (96.4)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	4 (5.6)	68 (94.4)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	1 (2.7)	36 (97.3)	NE (NE, NE)				
Mild impairment	41	2 (4.9)	39 (95.1)	NE (NE, NE)				
Moderate impairment	23	1 (4.3)	22 (95.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.13.1 Serious Adverse events of special interest - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	3 (3.9)	73 (96.1)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	2 (2.7)	72 (97.3)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	34	0	34 (100.0)	NE (NE, NE)				
No	67	2 (3.0)	65 (97.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	2 (2.0)	96 (98.0)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	0	61 (100.0)	NE (NE, NE)				
>=65 years	40	2 (5.0)	38 (95.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	2 (2.2)	91 (97.8)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	1 (1.5)	64 (98.5)	NE (NE, NE)				
Male	36	1 (2.8)	35 (97.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	2 (4.3)	44 (95.7)	NE (NE, NE)				
Never	55	0	55 (100.0)	NE (NE, NE)				
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	0	78 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	0	62 (100.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				
Liver metastases								
Yes	24	0	24 (100.0)	NE (NE, NE)				
No	77	2 (2.6)	75 (97.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	1 (1.7)	57 (98.3)	NE (NE, NE)				
Abnormal, not clinically significant	43	1 (2.3)	42 (97.7)	NE (NE, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	1 (1.2)	83 (98.8)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	2 (2.8)	70 (97.2)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	1 (2.7)	36 (97.3)	NE (NE, NE)				
Mild impairment	41	0	41 (100.0)	NE (NE, NE)				
Moderate impairment	23	1 (4.3)	22 (95.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.15.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Adjudicated Interstitial lung disease/pneumonitis (ILD) - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	2 (2.6)	74 (97.4)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESIILDAC_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	1 (1.4)	73 (98.6)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	34	0	34 (100.0)	NE (NE, NE)				
No	67	1 (1.5)	66 (98.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESILVEF_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	1 (1.0)	97 (99.0)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	1 (1.6)	60 (98.4)	NE (NE, NE)				
>=65 years	40	0	40 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESILVEF_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	1 (1.1)	92 (98.9)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	0	65 (100.0)	NE (NE, NE)				
Male	36	1 (2.8)	35 (97.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESILVEF_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	0	46 (100.0)	NE (NE, NE)				
Never	55	1 (1.8)	54 (98.2)	NE (NE, NE)				
Race								
White	23	0	23 (100.0)	NE (NE, NE)				
Non-White	78	1 (1.3)	77 (98.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESILVEF_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	0	62 (100.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
Liver metastases								
Yes	24	0	24 (100.0)	NE (NE, NE)				
No	77	1 (1.3)	76 (98.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESILVEF_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	1 (1.7)	57 (98.3)	NE (NE, NE)				
Abnormal, not clinically significant	43	0	43 (100.0)	NE (NE, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	0	84 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESILVEF_1_SAS.rtf

DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	1 (1.4)	71 (98.6)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	1 (2.7)	36 (97.3)	NE (NE, NE)				
Mild impairment	41	0	41 (100.0)	NE (NE, NE)				
Moderate impairment	23	0	23 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.12.1 Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	0	76 (100.0)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AESILVEF_1_SAS.rtf

DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	0	74 (100.0)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESILVEF_1_SAS.rtf

DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	0	34 (100.0)	NE (NE, NE)				
No	67	0	67 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESILVEF_1_SAS.rtf

DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	0	98 (100.0)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESILVEF_1_SAS.rtf

DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	0	61 (100.0)	NE (NE, NE)				
>=65 years	40	0	40 (100.0)	NE (NE, NE)				
Age II								
<75 years	93	0	93 (100.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESILVEF_1_SAS.rtf

DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	0	65 (100.0)	NE (NE, NE)				
Male	36	0	36 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	0	46 (100.0)	NE (NE, NE)				
Never	55	0	55 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	0	23 (100.0)	NE (NE, NE)				
Non-White	78	0	78 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	0	62 (100.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	0	33 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	0	24 (100.0)	NE (NE, NE)				
No	77	0	77 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	0	58 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	43	0	43 (100.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	0	84 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	0	17 (100.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	0	72 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	0	37 (100.0)	NE (NE, NE)				
Mild impairment	41	0	41 (100.0)	NE (NE, NE)				
Moderate impairment	23	0	23 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.14.1 Serious Adverse events of special interest - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	0	76 (100.0)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SAESILVEF_1_SAS.rtf

DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	0	74 (100.0)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESILVEF_1_SAS.rtf

DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	0	34 (100.0)	NE (NE, NE)				
No	67	0	67 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	0	98 (100.0)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	0	61 (100.0)	NE (NE, NE)				
>=65 years	40	0	40 (100.0)	NE (NE, NE)				
Age II								
<75 years	93	0	93 (100.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	0	65 (100.0)	NE (NE, NE)				
Male	36	0	36 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	0	46 (100.0)	NE (NE, NE)				
Never	55	0	55 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	0	23 (100.0)	NE (NE, NE)				
Non-White	78	0	78 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	0	62 (100.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	0	33 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	0	24 (100.0)	NE (NE, NE)				
No	77	0	77 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESILVEF_1_SAS.rtf

DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	0	58 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	43	0	43 (100.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESILVEF_1_SAS.rtf

DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	0	84 (100.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	0	17 (100.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESILVEF_1_SAS.rtf

DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	0	72 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESILVEF_1_SAS.rtf

DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	0	37 (100.0)	NE (NE, NE)				
Mild impairment	41	0	41 (100.0)	NE (NE, NE)				
Moderate impairment	23	0	23 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESILVEF_1_SAS.rtf

DE.T.4.16.1 Severe Adverse events of special interest (CTCAE Grade >= 3) - Left Ventricular Dysfunction - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	0	76 (100.0)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

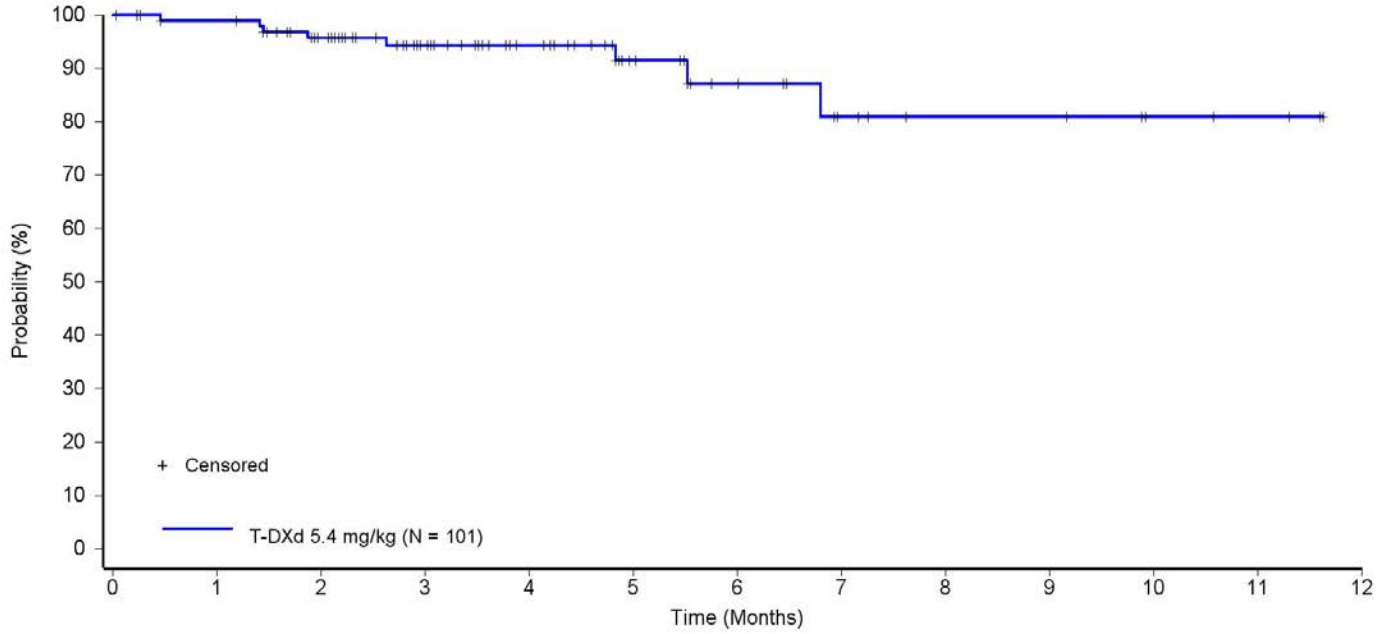
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_SEVAESILVEF_1_SAS.rtf

Anhang 4-G 4.3 Sicherheit – Unerwünschte Ereignisse, die zum Abbruch der Studienmedikation geführt haben – weitere Untersuchungen

Anhang 4-G 4.3.1 Kaplan-Meier-Kurven – Unerwünschte Ereignisse, die zum Abbruch der Studienmedikation geführt haben

Anhang 4-G 4.3.1.1 Datenschnitt vom 24.03.2022

DE.F.4.5.2 Treatment-emergent adverse events associated with discontinuation of study treatment - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	95	81	59	42	24	17	11	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_teae_2_sas.sas; Output name: F4_AEDISC_2_SAS.rtf

Anhang 4-G 4.3.2 Subgruppenanalysen – Unerwünschte Ereignisse, die zum Abbruch der Studienmedikation geführt haben

Anhang 4-G 4.3.2.1 Datenschnitt vom 24.03.2022

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	4 (5.4)	70 (94.6)	NE (NE, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	NE (5.5, NE)				
Central nervous system (CNS) metastasis								
Yes	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
No	68	7 (10.3)	61 (89.7)	NE (6.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	7 (7.1)	91 (92.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	4 (6.6)	57 (93.4)	NE (NE, NE)				
>=65 years	40	4 (10.0)	36 (90.0)	NE (5.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	8 (8.6)	85 (91.4)	NE (NE, NE)				
>=75 years	8							
Sex								
Female	65	5 (7.7)	60 (92.3)	NE (NE, NE)				
Male	36	3 (8.3)	33 (91.7)	NE (6.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	3 (6.5)	43 (93.5)	NE (6.8, NE)				
Never	55	5 (9.1)	50 (90.9)	NE (NE, NE)				
Race								
White	23	2 (8.7)	21 (91.3)	5.5 (NE, NE)				
Non-White	78	6 (7.7)	72 (92.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	4 (6.5)	58 (93.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				
Liver metastases								
Yes	24	1 (4.2)	23 (95.8)	NE (4.8, NE)				
No	77	7 (9.1)	70 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	60	4 (6.7)	56 (93.3)	NE (NE, NE)				
Abnormal, not clinically significant	41	4 (9.8)	37 (90.2)	NE (5.5, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	7 (8.3)	77 (91.7)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	30	3 (10.0)	27 (90.0)	NE (5.5, NE)				
1	71	5 (7.0)	66 (93.0)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (NE, NE)				
Mild impairment	40	5 (12.5)	35 (87.5)	NE (6.8, NE)				
Moderate impairment	22	1 (4.5)	21 (95.5)	NE (5.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	6 (7.9)	70 (92.1)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

Anhang 4-G 4.3.2.2 Finaler Datenschnitt vom 23.12.2022

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	11 (14.9)	63 (85.1)	NE (14.5, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	NE (NE, NE)				
Central nervous system (CNS) metastasis								
Yes	34	5 (14.7)	29 (85.3)	NE (NE, NE)				
No	67	10 (14.9)	57 (85.1)	NE (14.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
HER2 status								
Kinase domain	98	14 (14.3)	84 (85.7)	NE (14.5, NE)				
Extracellular domain	3							
Transmembrane domain	0							
Age I								
<65 years	61	7 (11.5)	54 (88.5)	NE (NE, NE)				
>=65 years	40	8 (20.0)	32 (80.0)	NE (14.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (14.5, NE)				
>=75 years	8							
Sex								
Female	65	9 (13.8)	56 (86.2)	NE (14.5, NE)				
Male	36	6 (16.7)	30 (83.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Smoking status								
Current	0							
Former	46	6 (13.0)	40 (87.0)	NE (14.5, NE)				
Never	55	9 (16.4)	46 (83.6)	NE (NE, NE)				
Race								
White	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Non-White	78	11 (14.1)	67 (85.9)	NE (14.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Region								
Asia	62	9 (14.5)	53 (85.5)	NE (14.5, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	13 (16.9)	64 (83.1)	NE (14.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
12-lead ECG								
Normal	58	6 (10.3)	52 (89.7)	NE (NE, NE)				
Abnormal, not clinically significant	43	9 (20.9)	34 (79.1)	NE (14.5, NE)				
Clinically significant findings	0							
Baseline ECHO/MUGA								
Normal	84	12 (14.3)	72 (85.7)	NE (14.5, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (6.7, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
ECOG performance status								
0	29	5 (17.2)	24 (82.8)	NE (14.5, NE)				
1	72	10 (13.9)	62 (86.1)	NE (NE, NE)				
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (14.5, NE)				
Mild impairment	41	6 (14.6)	35 (85.4)	NE (NE, NE)				
Moderate impairment	23	5 (21.7)	18 (78.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

DE.T.4.5.1 Treatment-emergent adverse events associated with discontinuation of study treatment - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Hepatic function at baseline								
Normal hepatic function	76	10 (13.2)	66 (86.8)	NE (14.5, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	NE (10.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

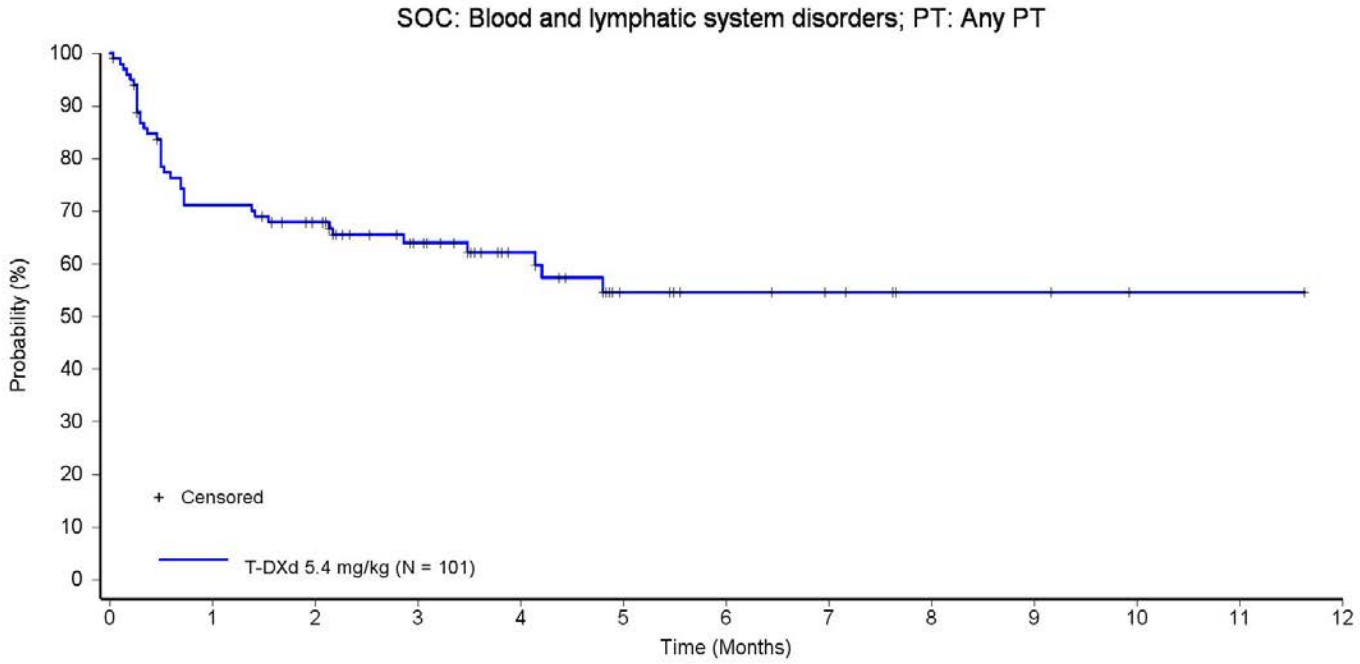
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:15; Program name: t4_teae_1_sas.sas; Output name: T4_AEDISC_1_SAS.rtf

Anhang 4-G 4.4 Sicherheit – Unerwünschte Ereignisse nach SOC und PT – weitere Untersuchungen

Anhang 4-G 4.4.1 Kaplan-Meier-Kurven – Unerwünschte Ereignisse nach SOC und PT

Anhang 4-G 4.4.1.1 Datenschnitt vom 24.03.2022

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

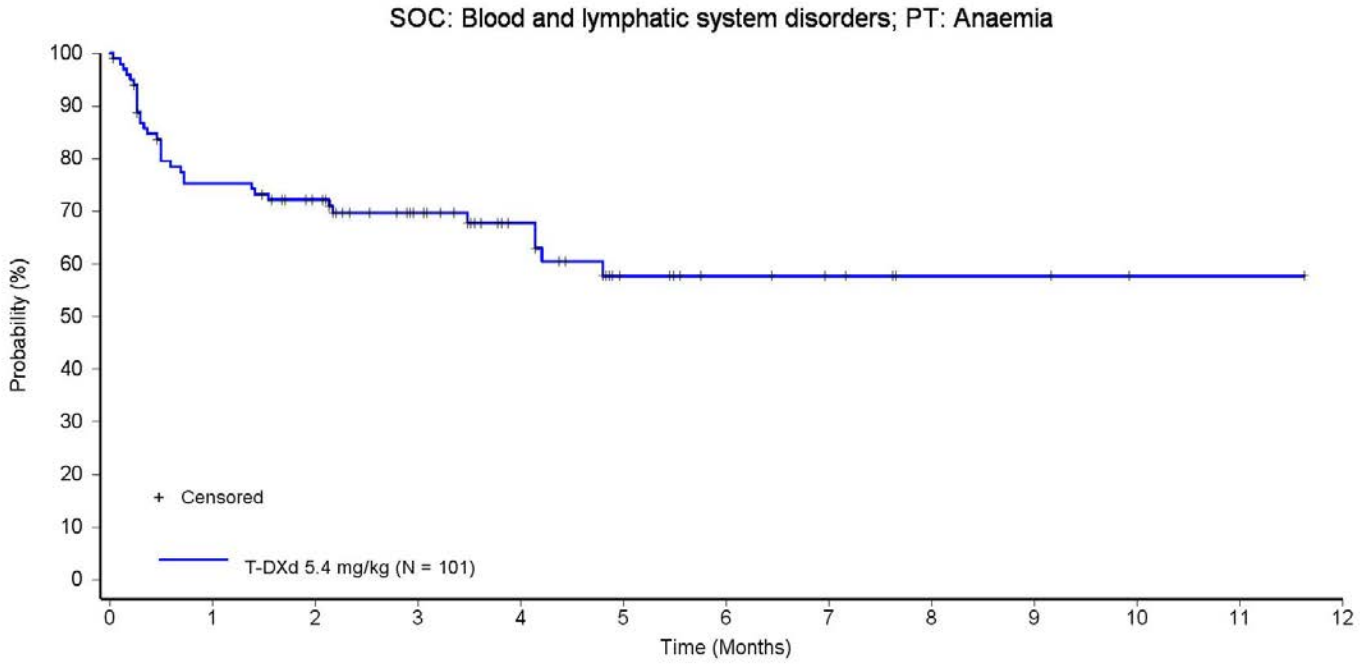


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	68	59	40	26	12	9	7	4	4	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

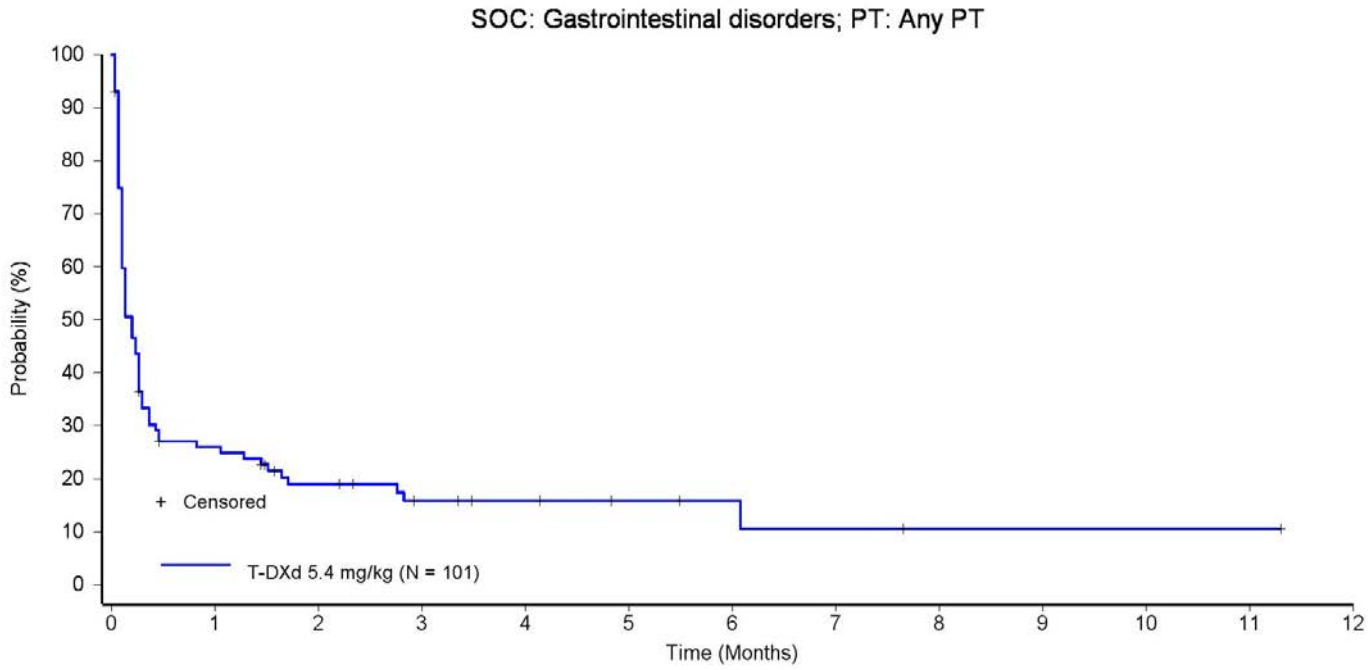


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	72	62	42	28	13	9	7	4	4	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

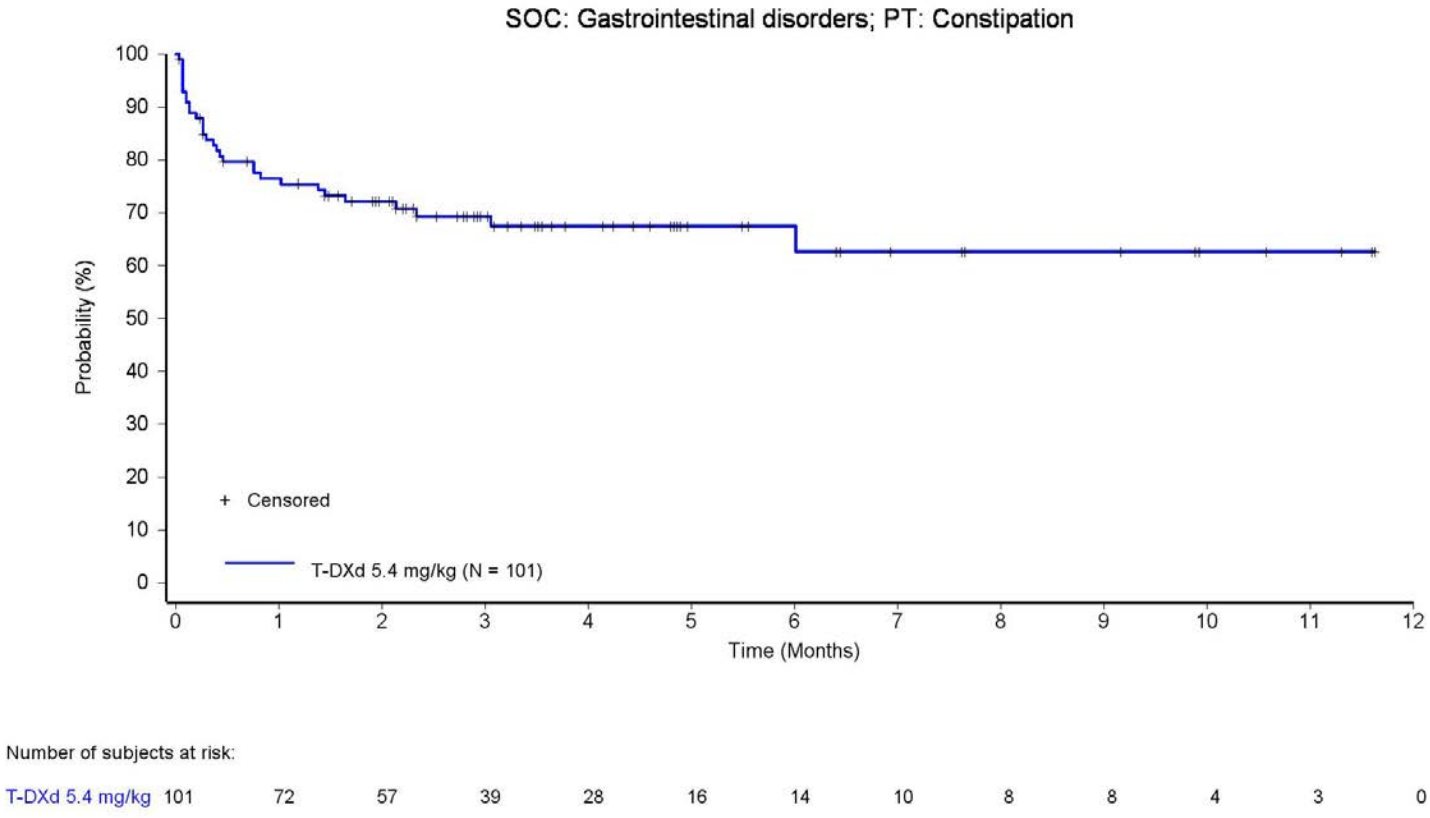


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	24	15	9	6	4	3	2	1	1	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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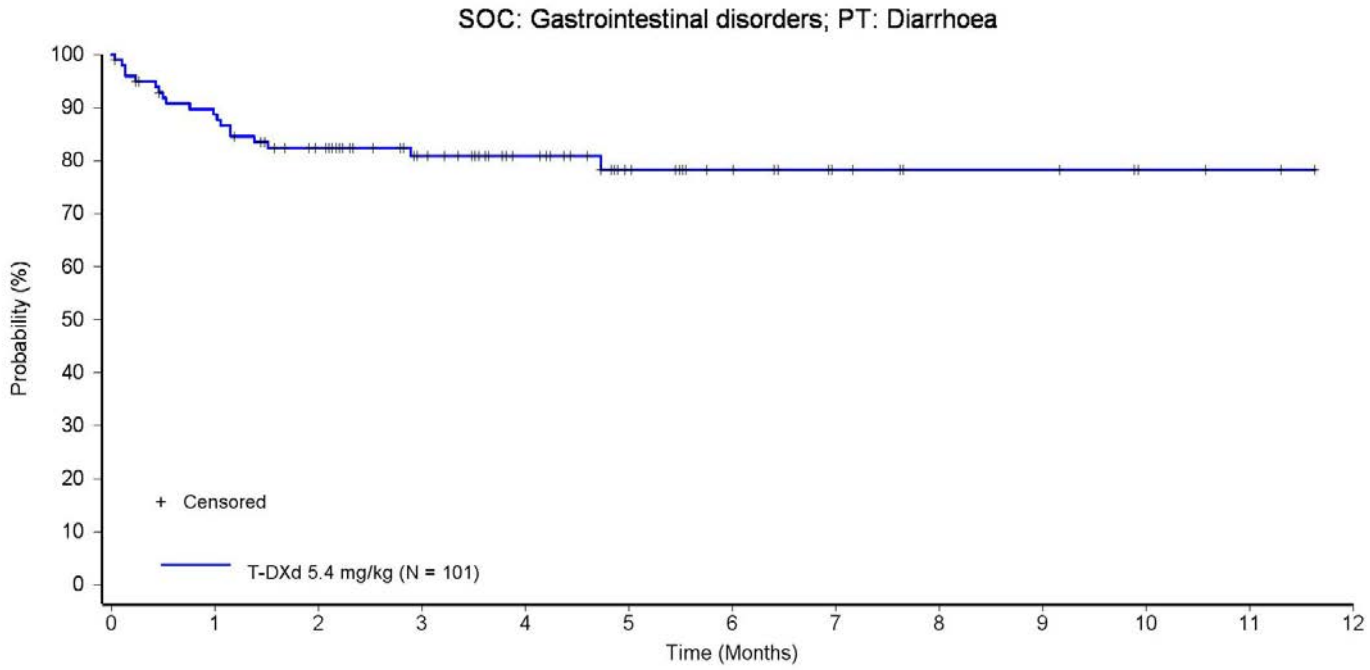
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

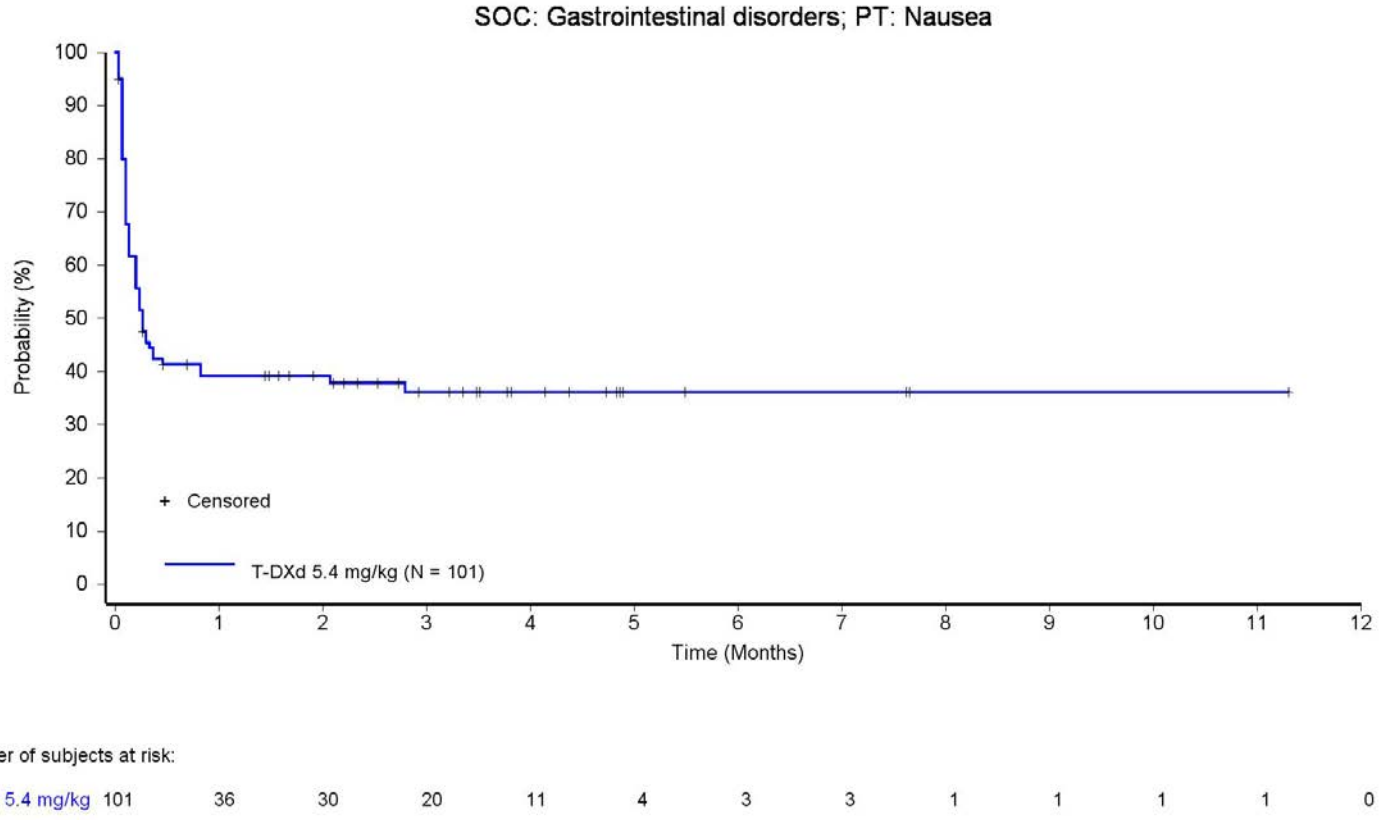


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	85	71	52	37	21	15	10	7	7	3	2	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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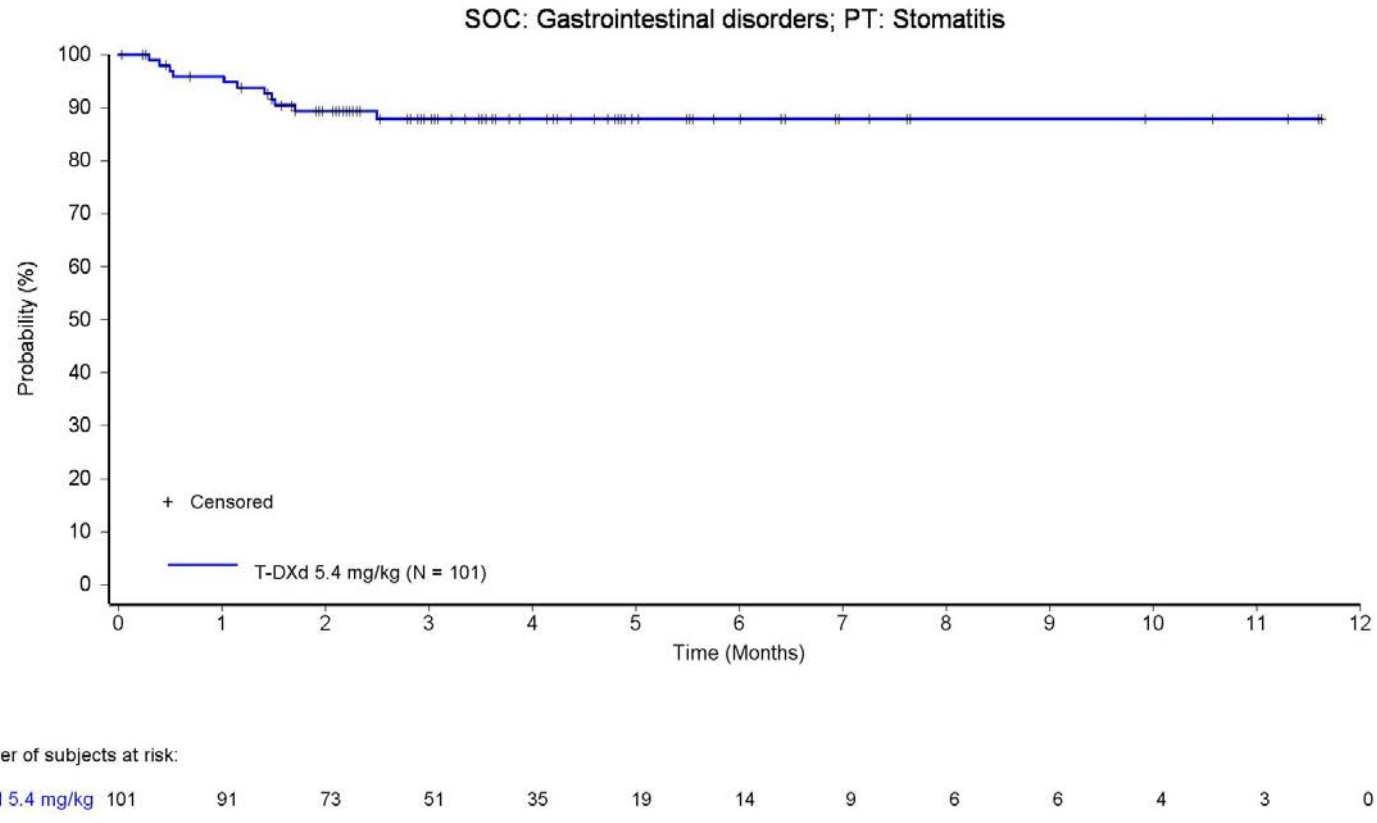
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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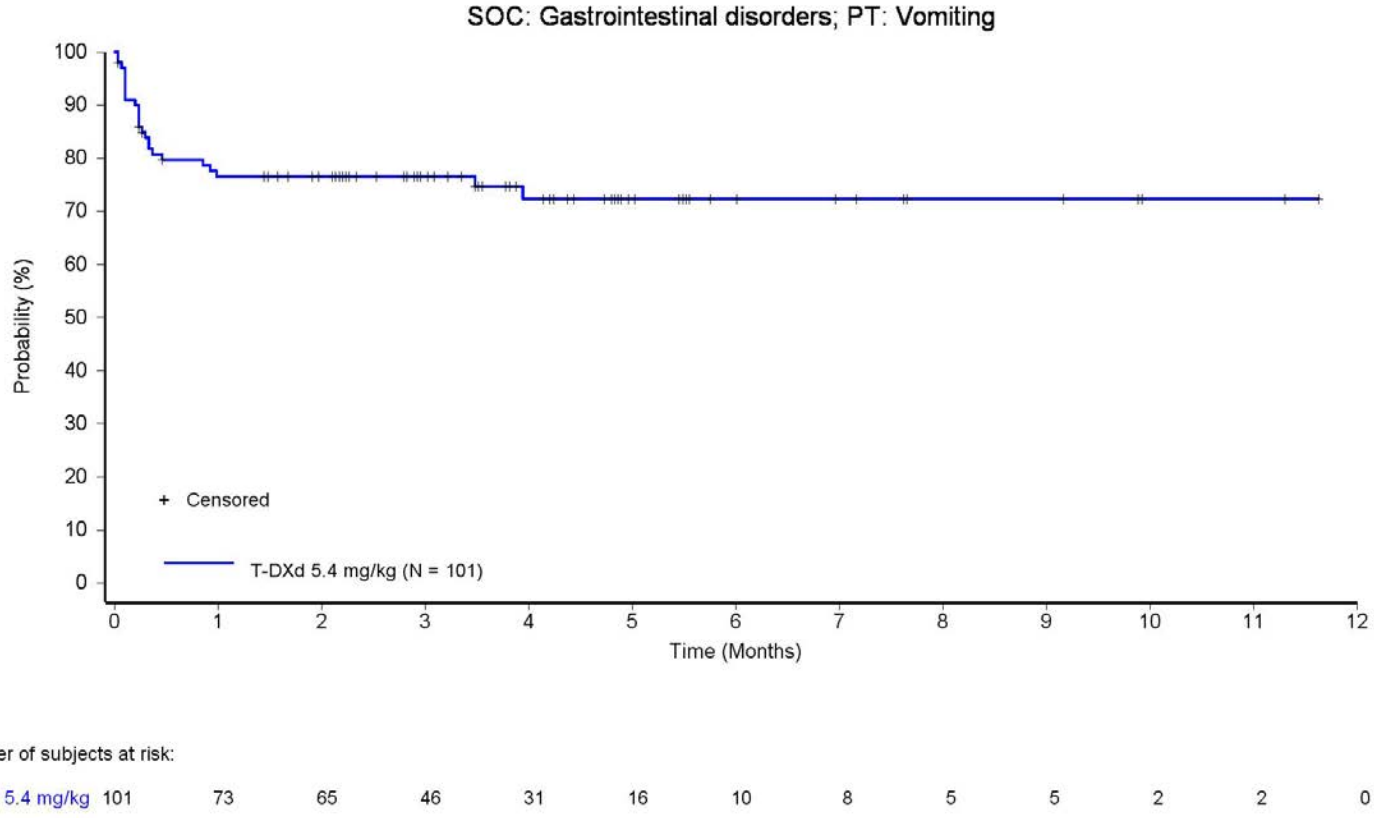
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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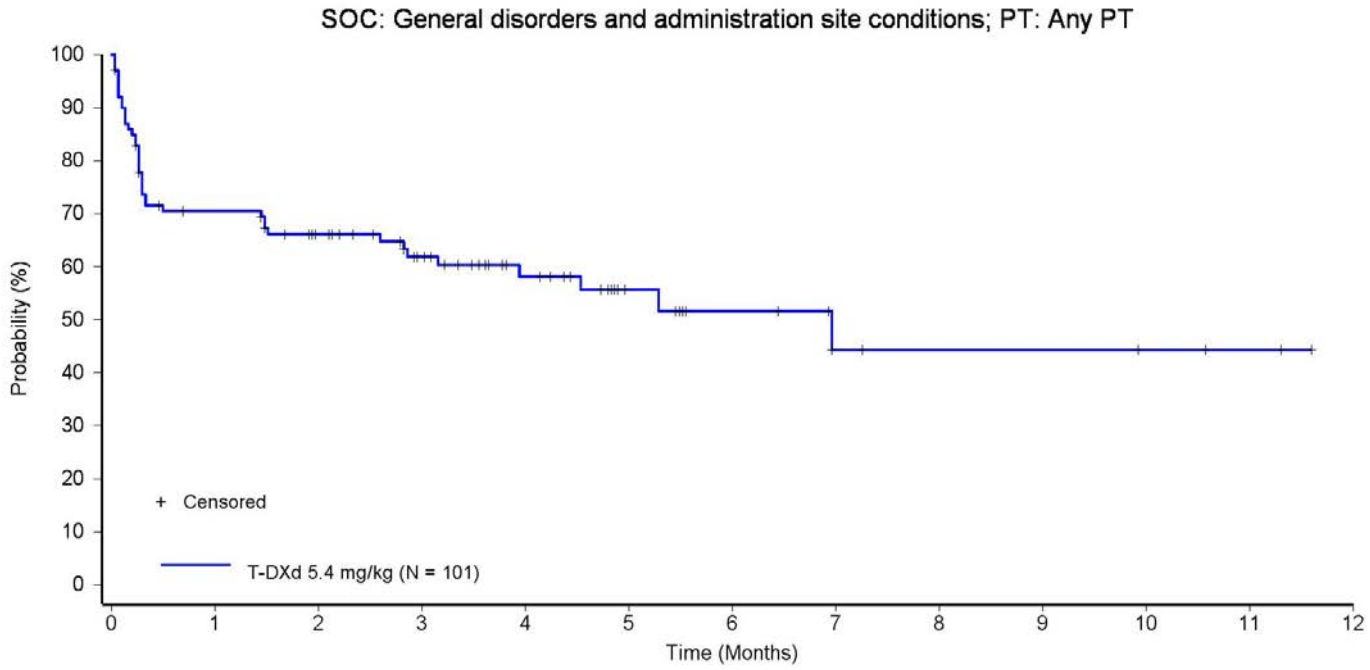
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

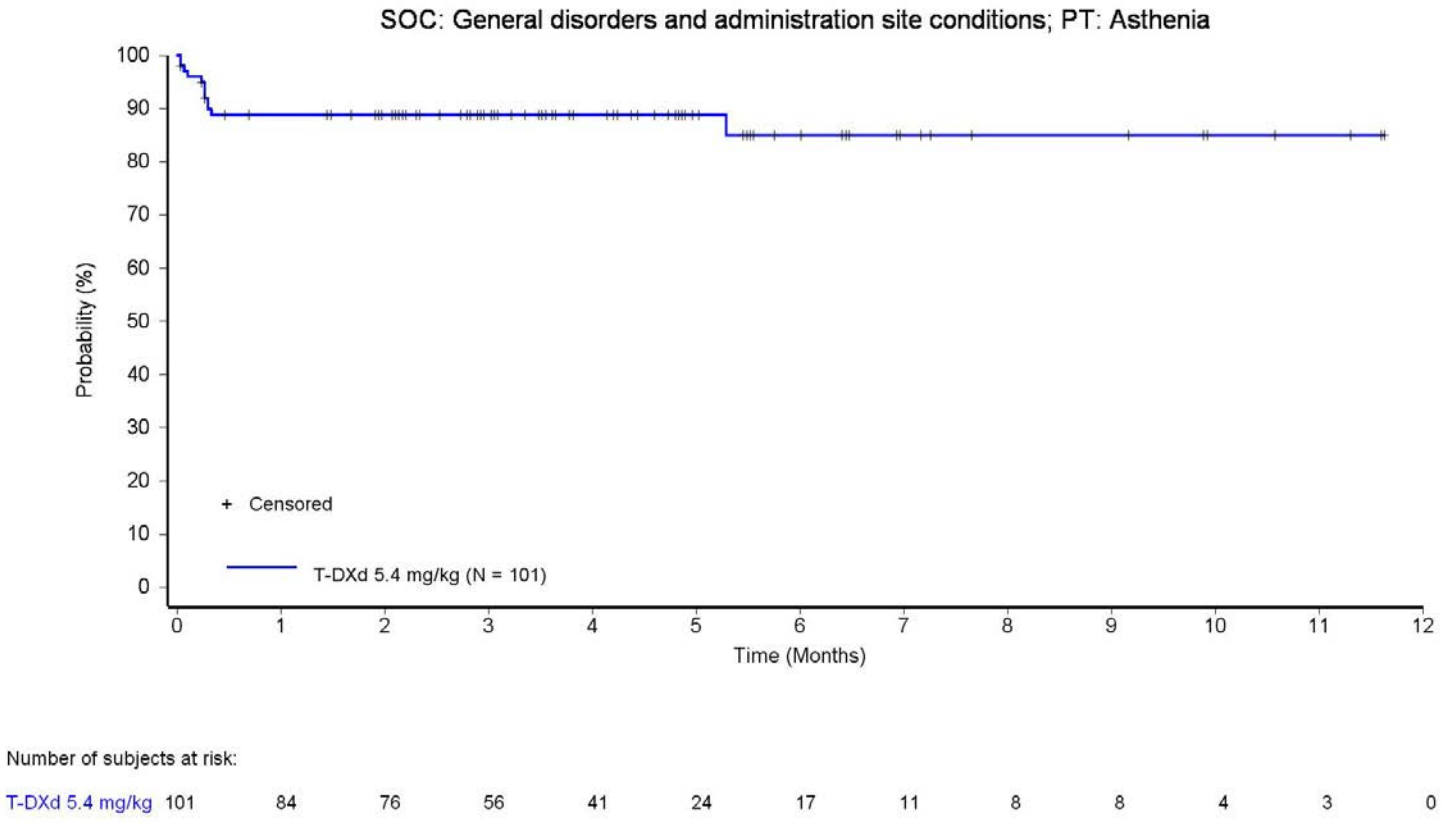


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	66	56	40	27	14	9	5	4	4	3	2	0

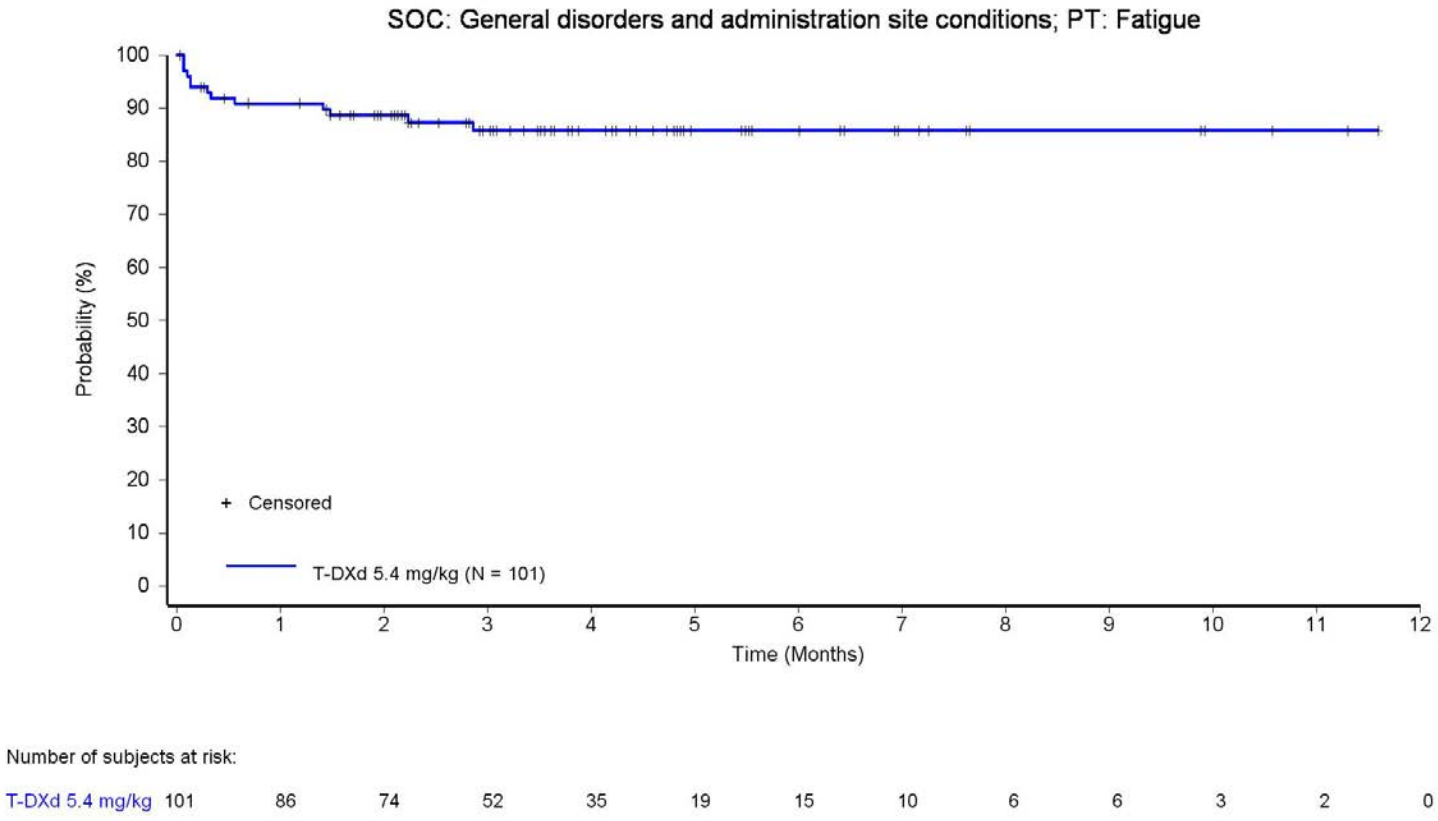
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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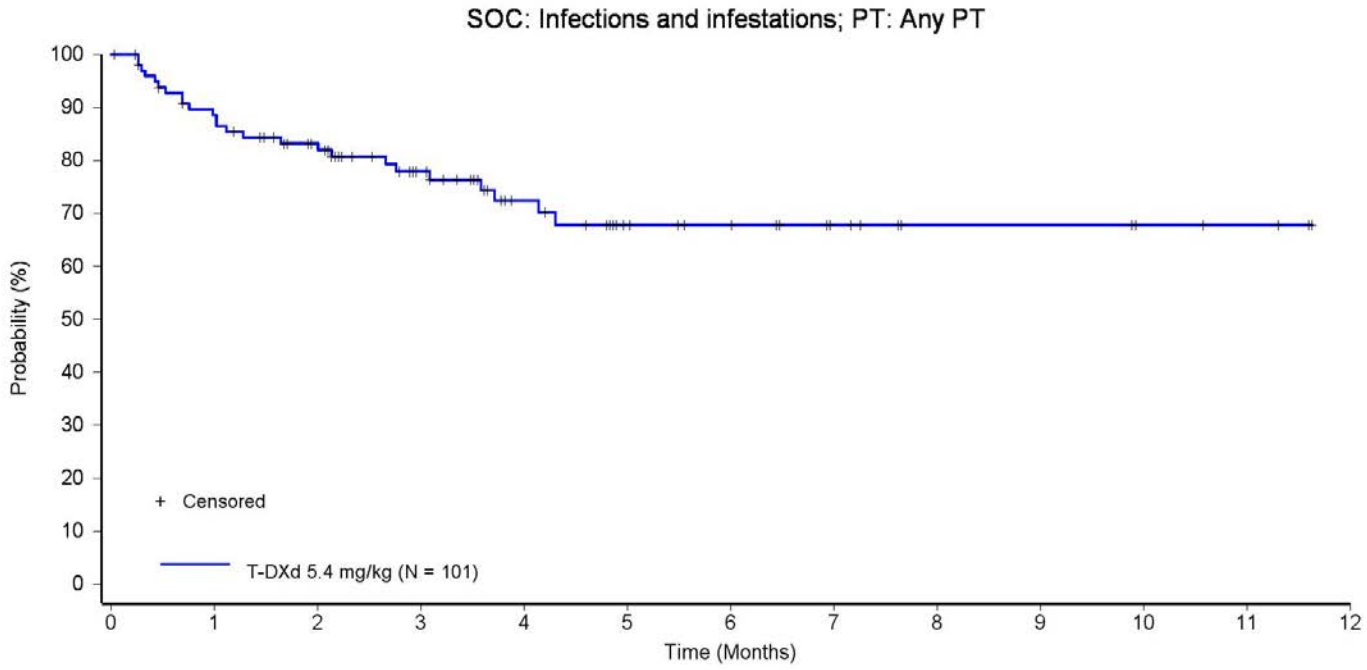
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

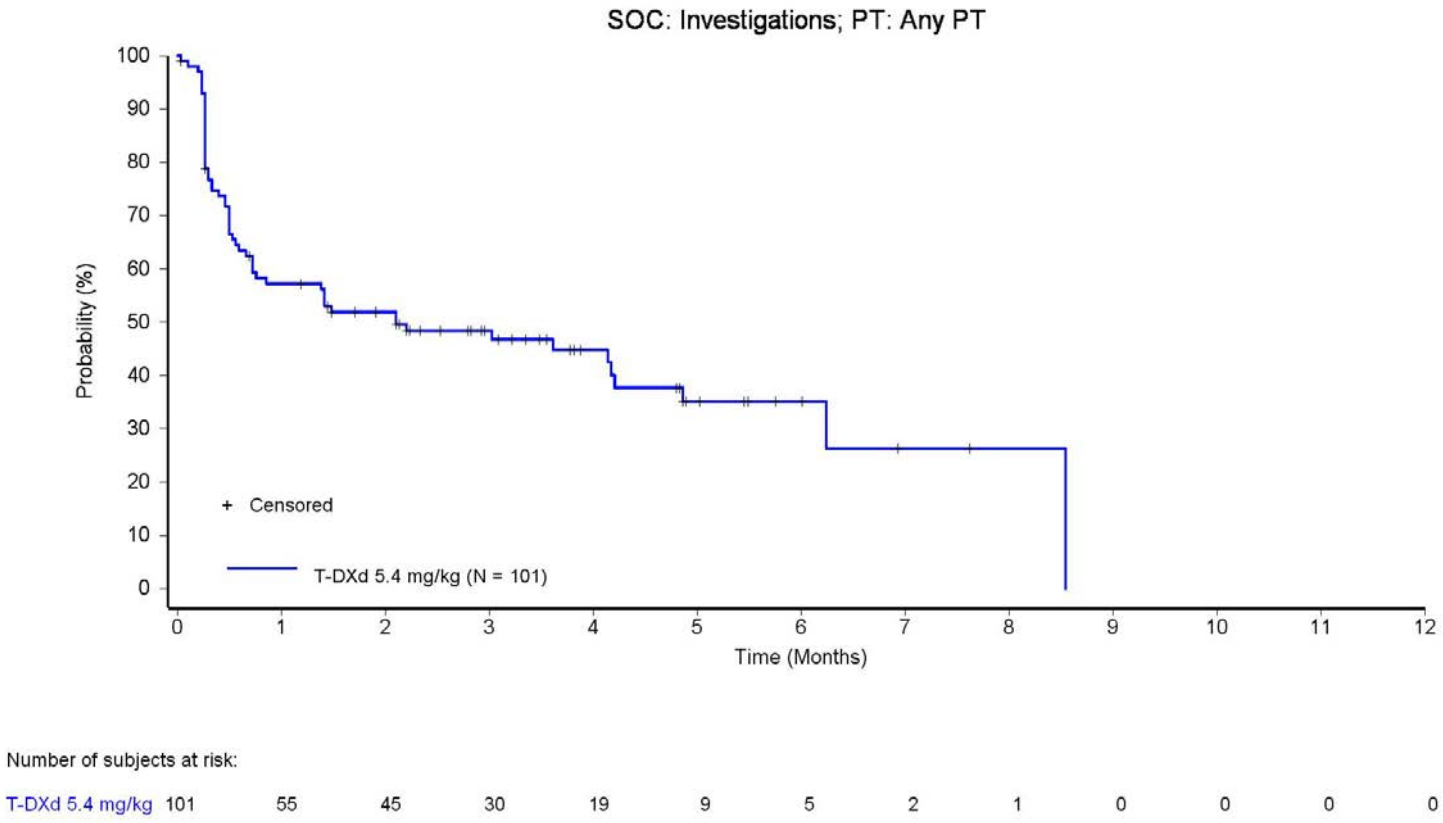


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	84	68	50	32	19	16	11	7	7	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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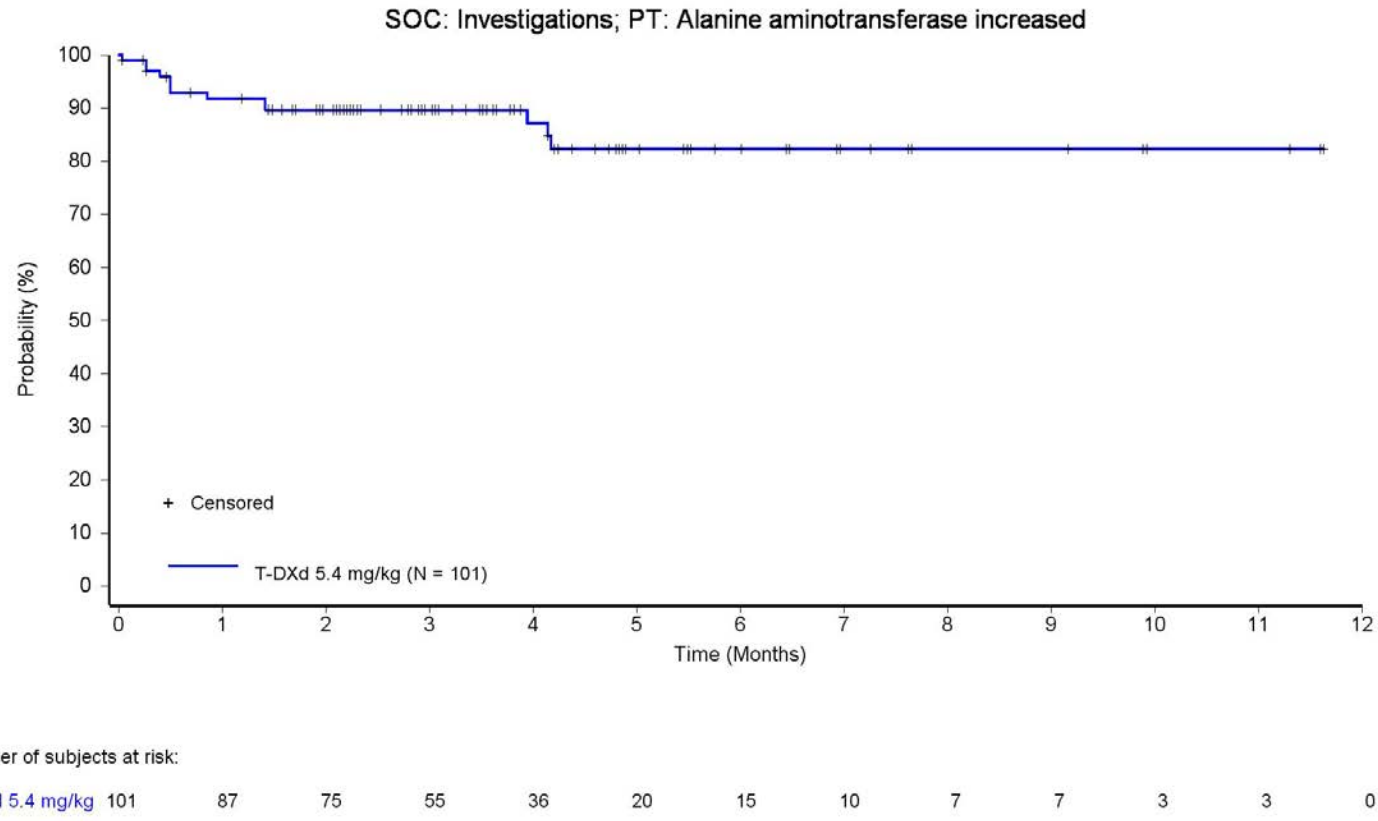
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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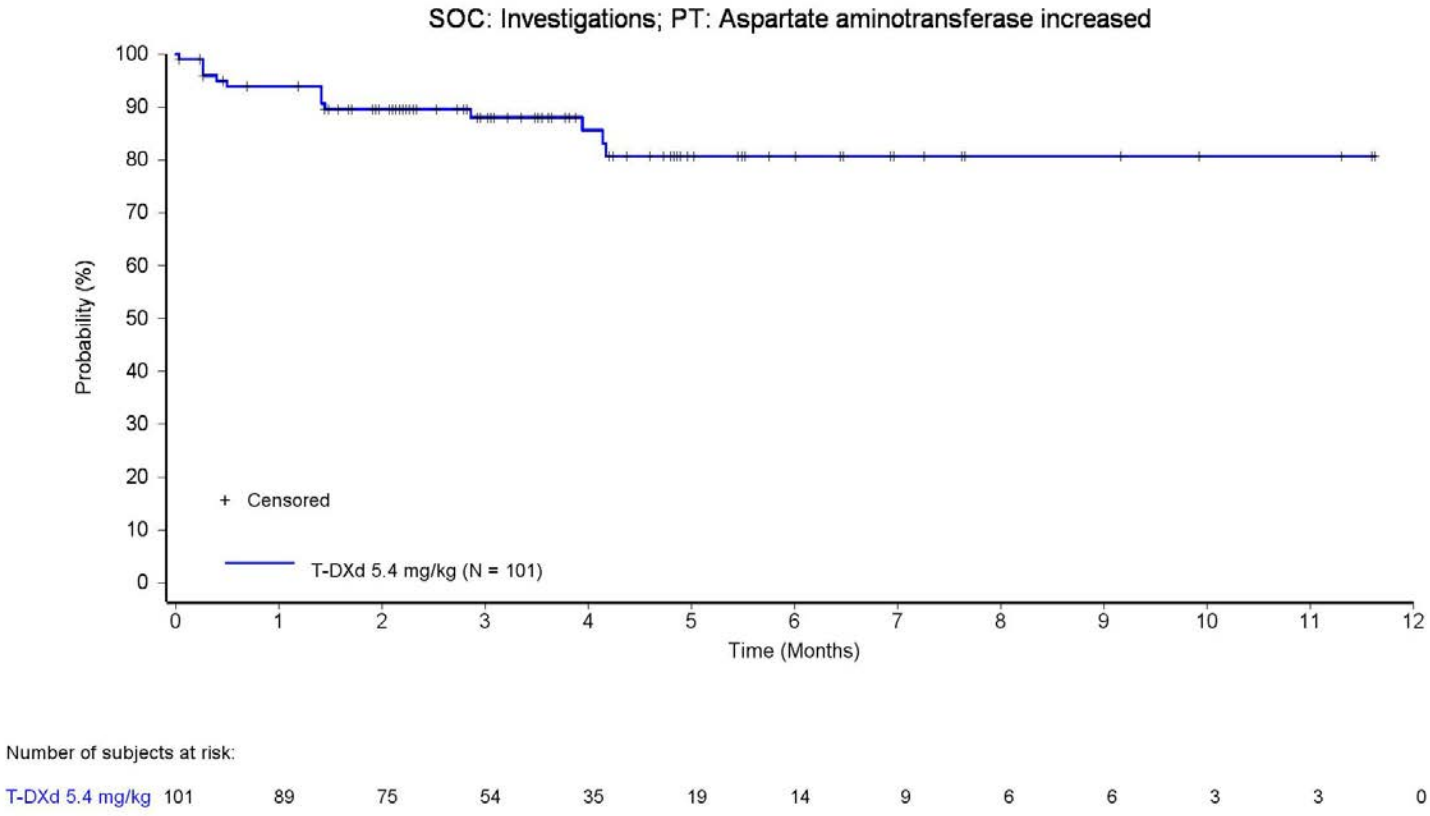
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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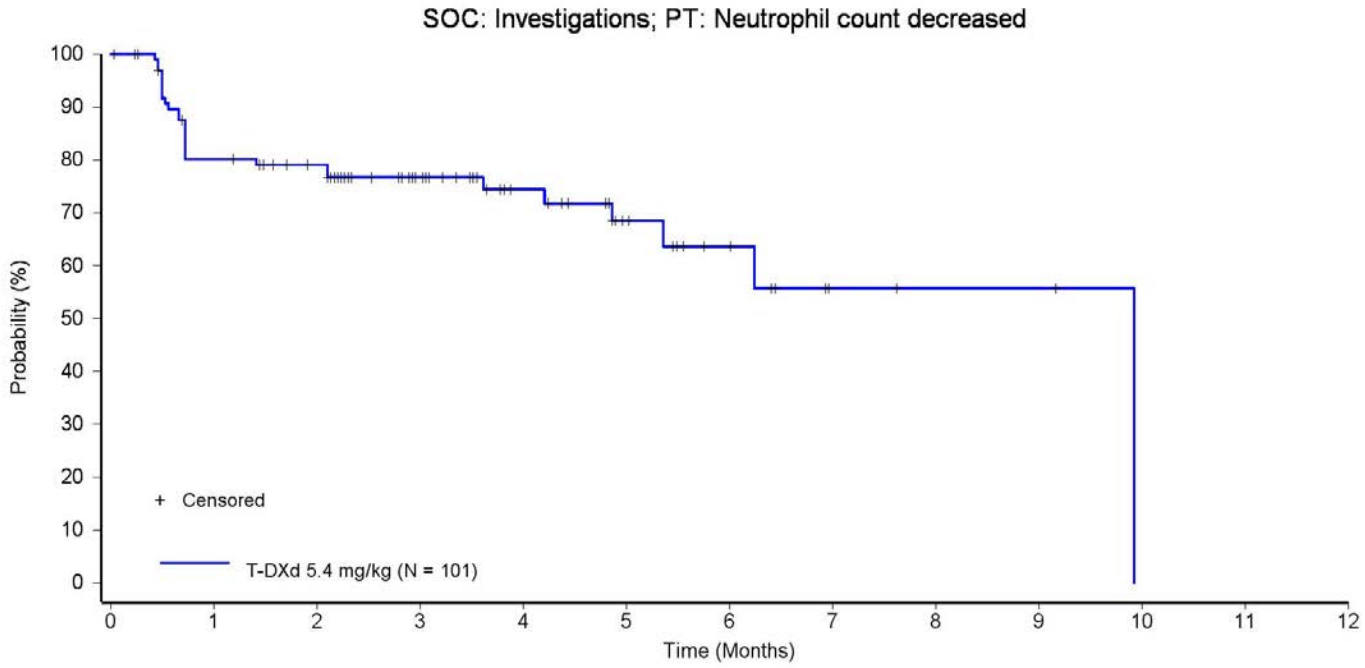
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

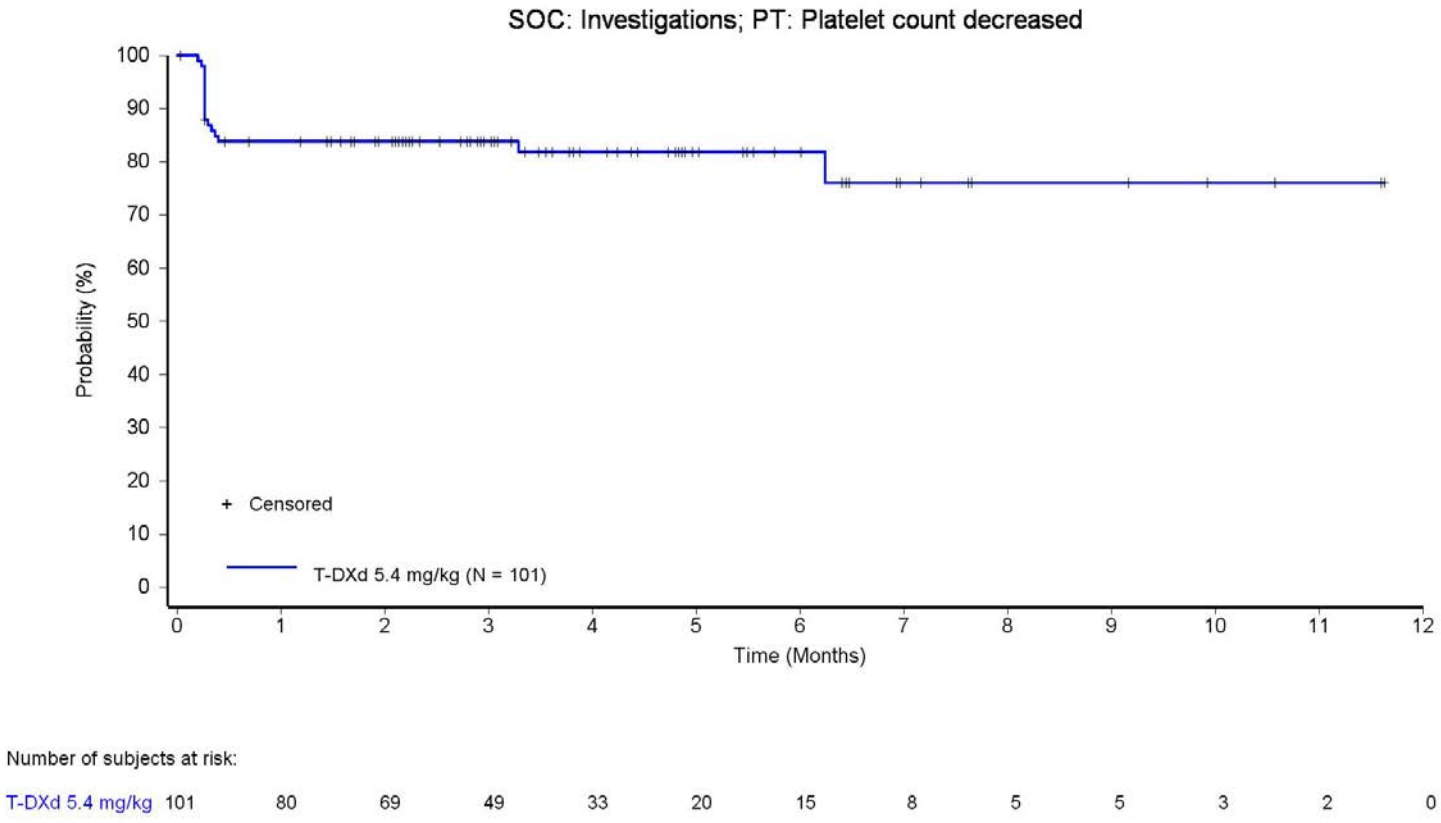


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	76	66	44	28	15	9	3	2	2	0	0	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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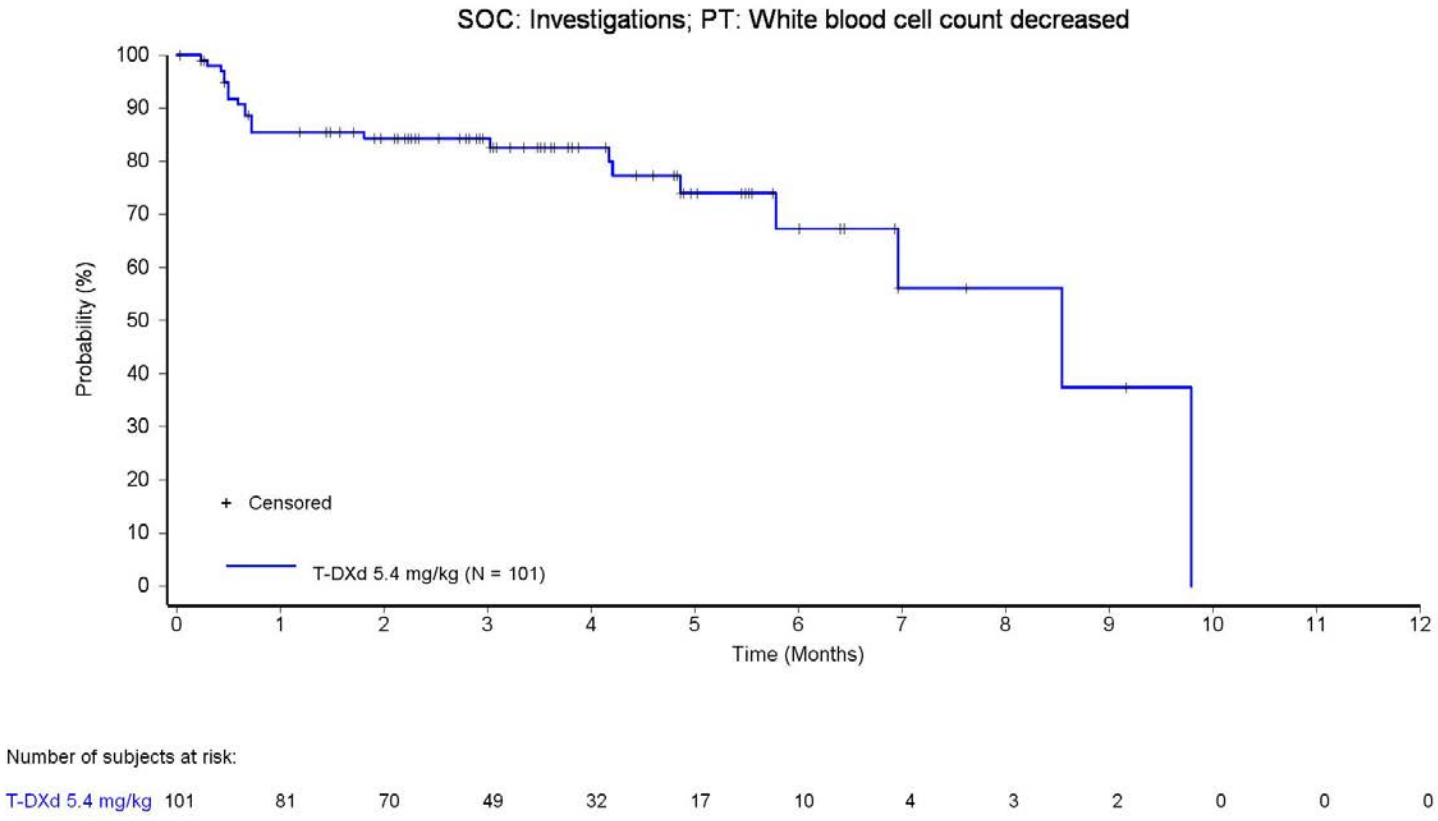
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



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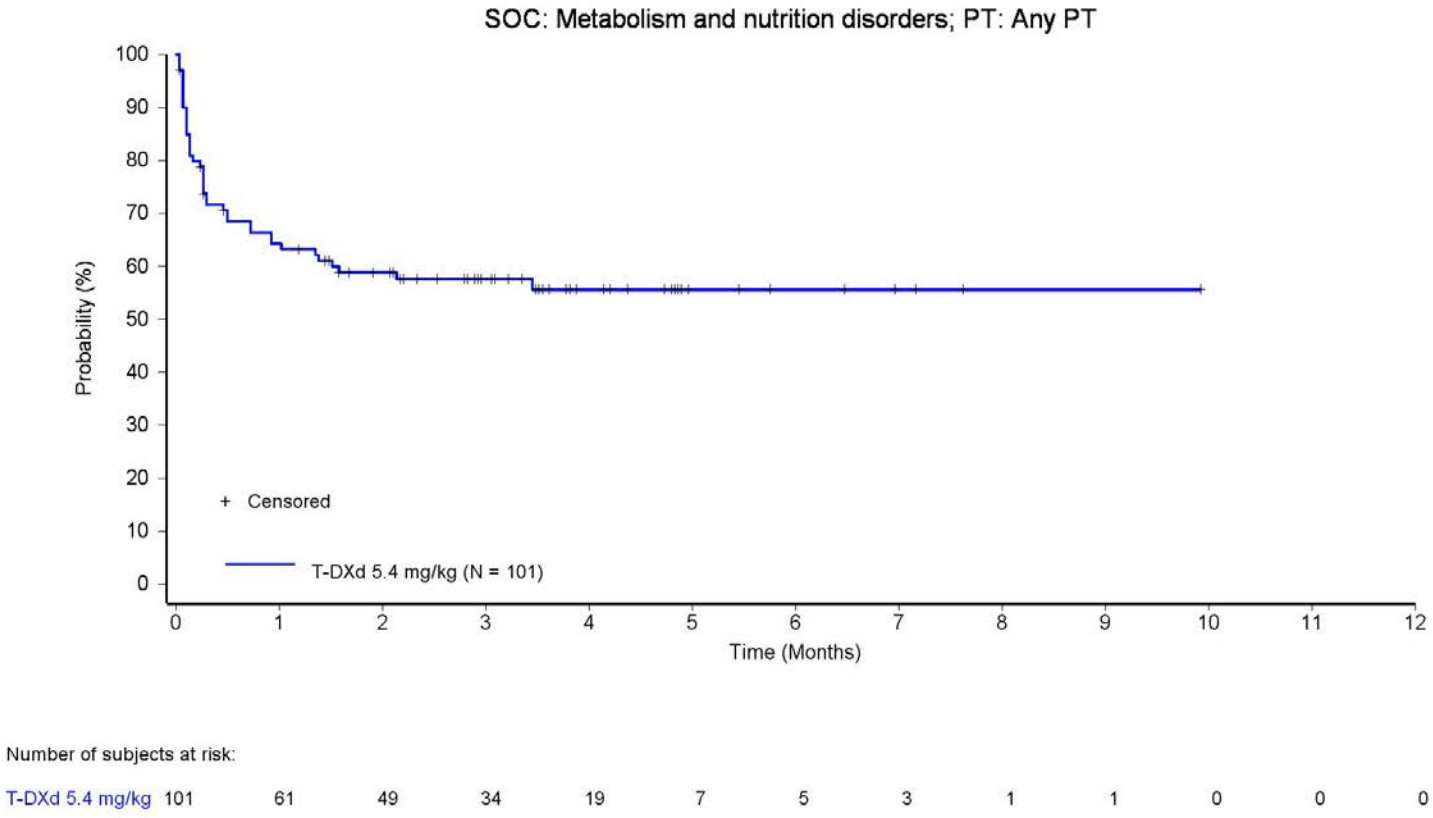
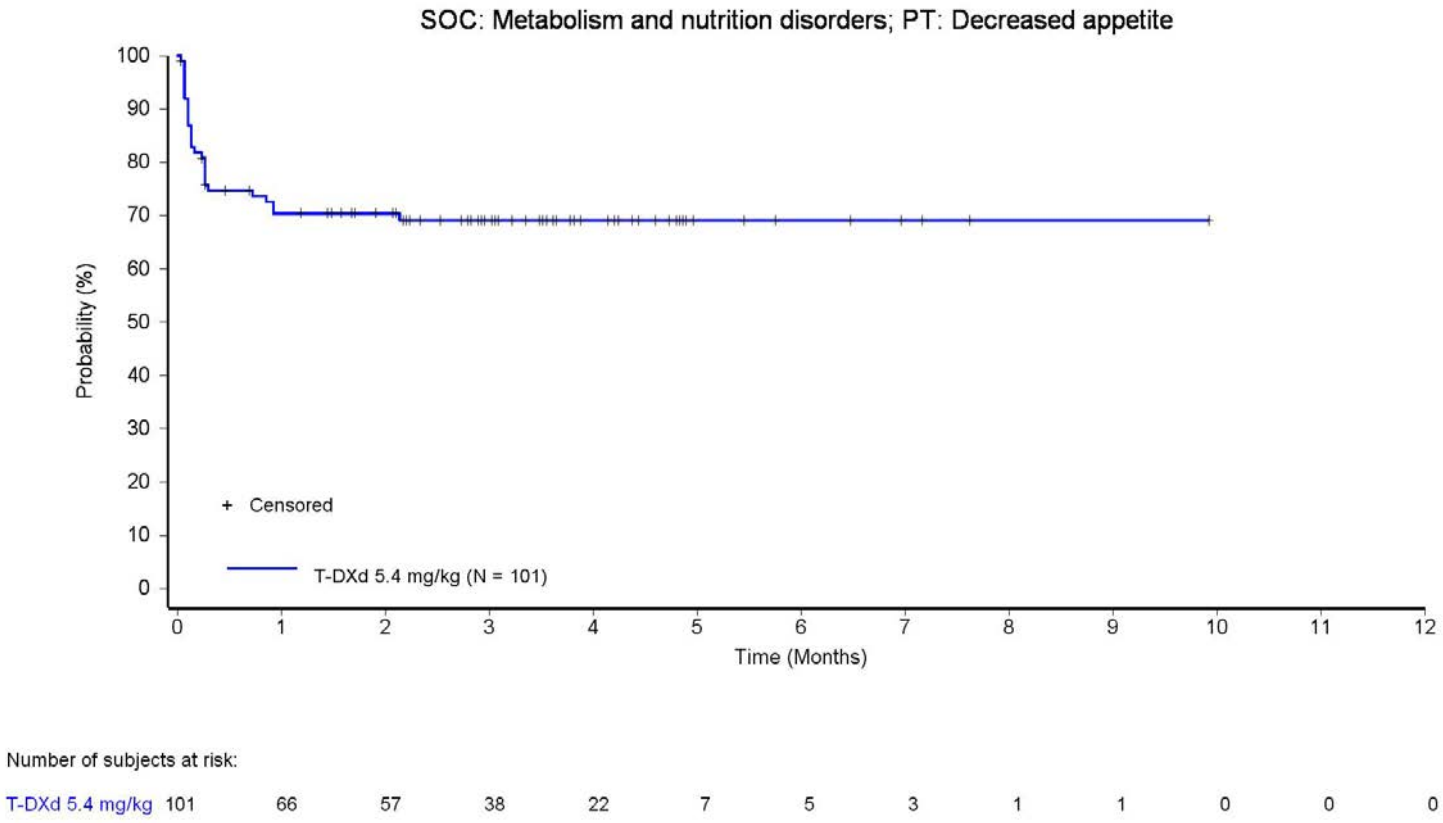
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



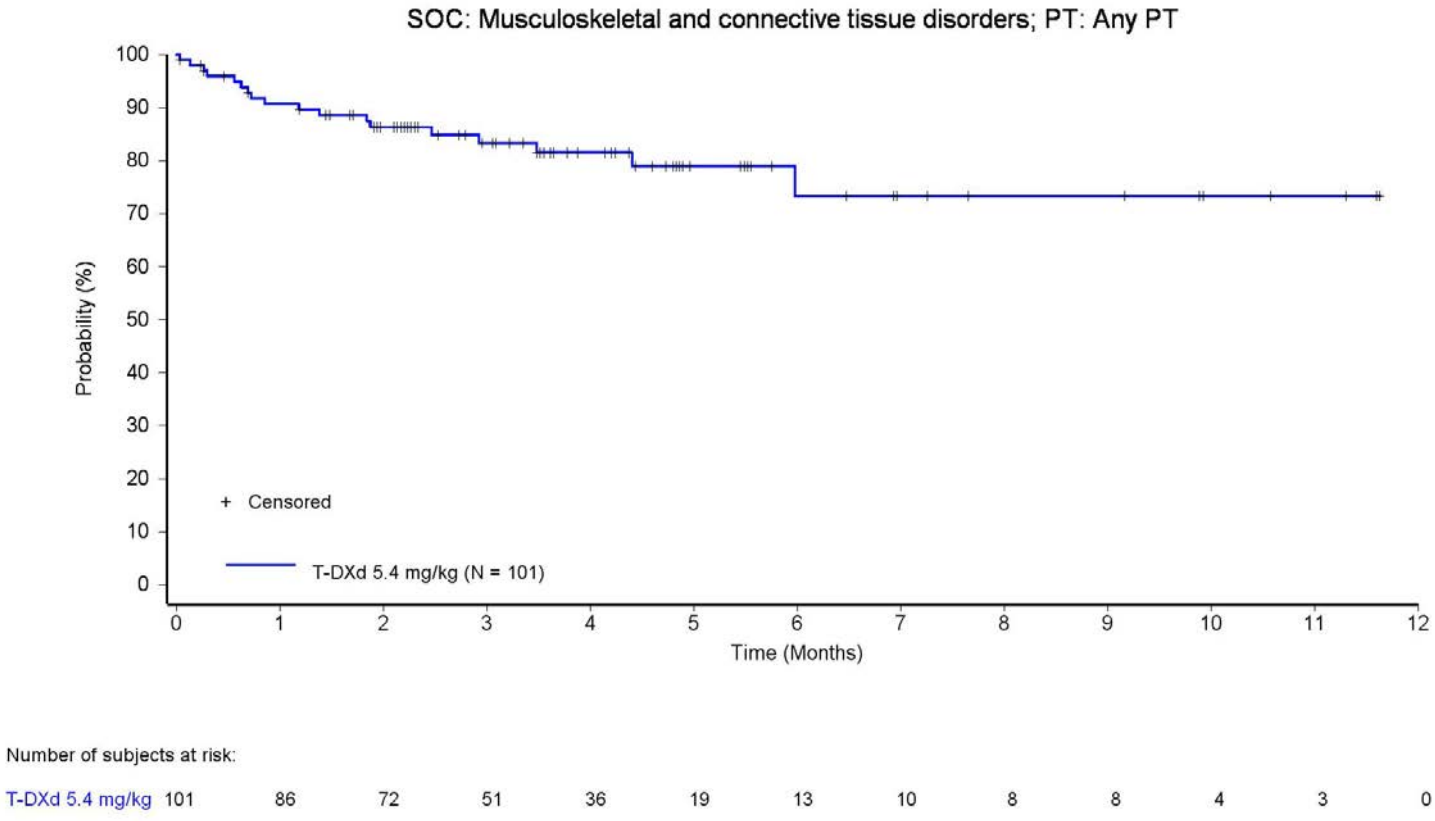
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



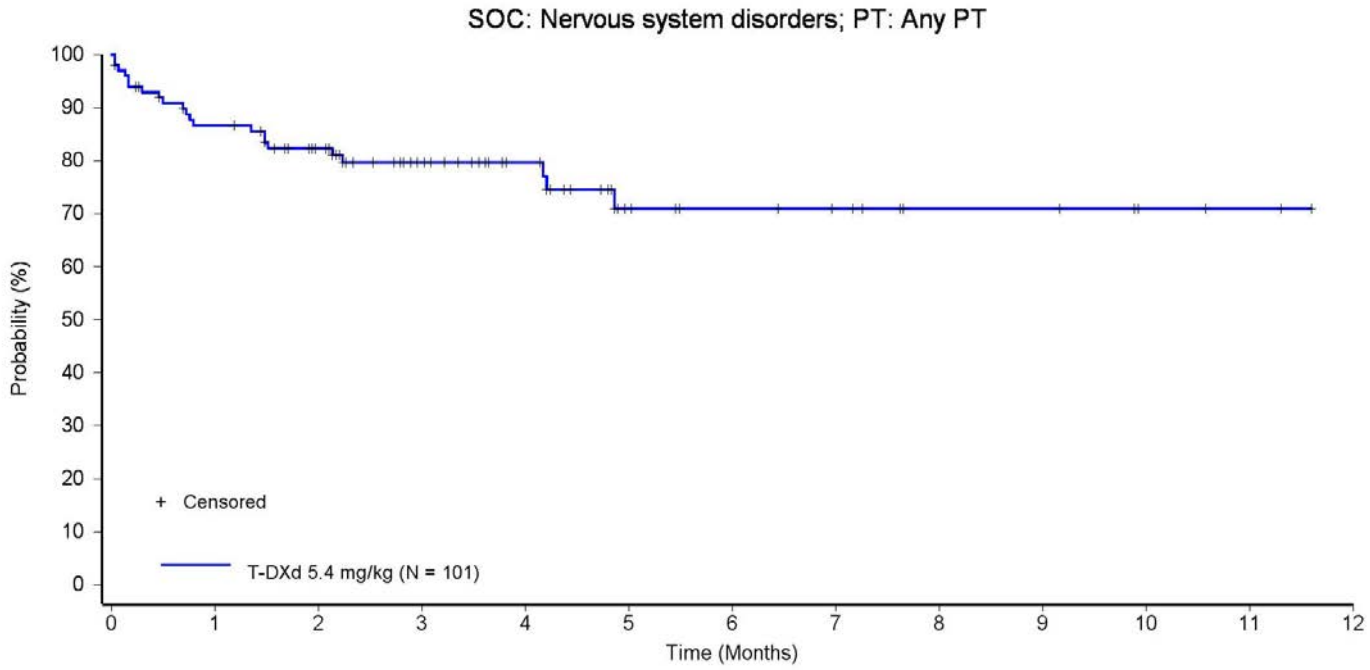
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

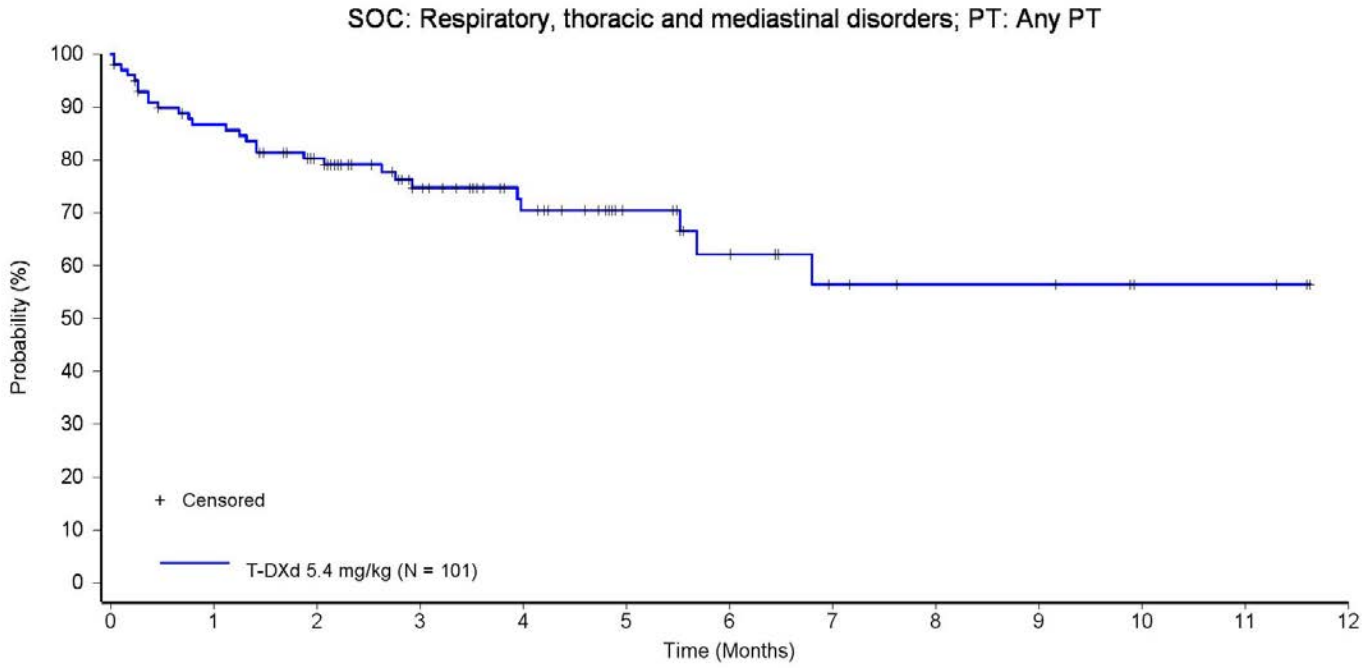


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	82	68	46	32	16	13	11	7	7	3	2	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

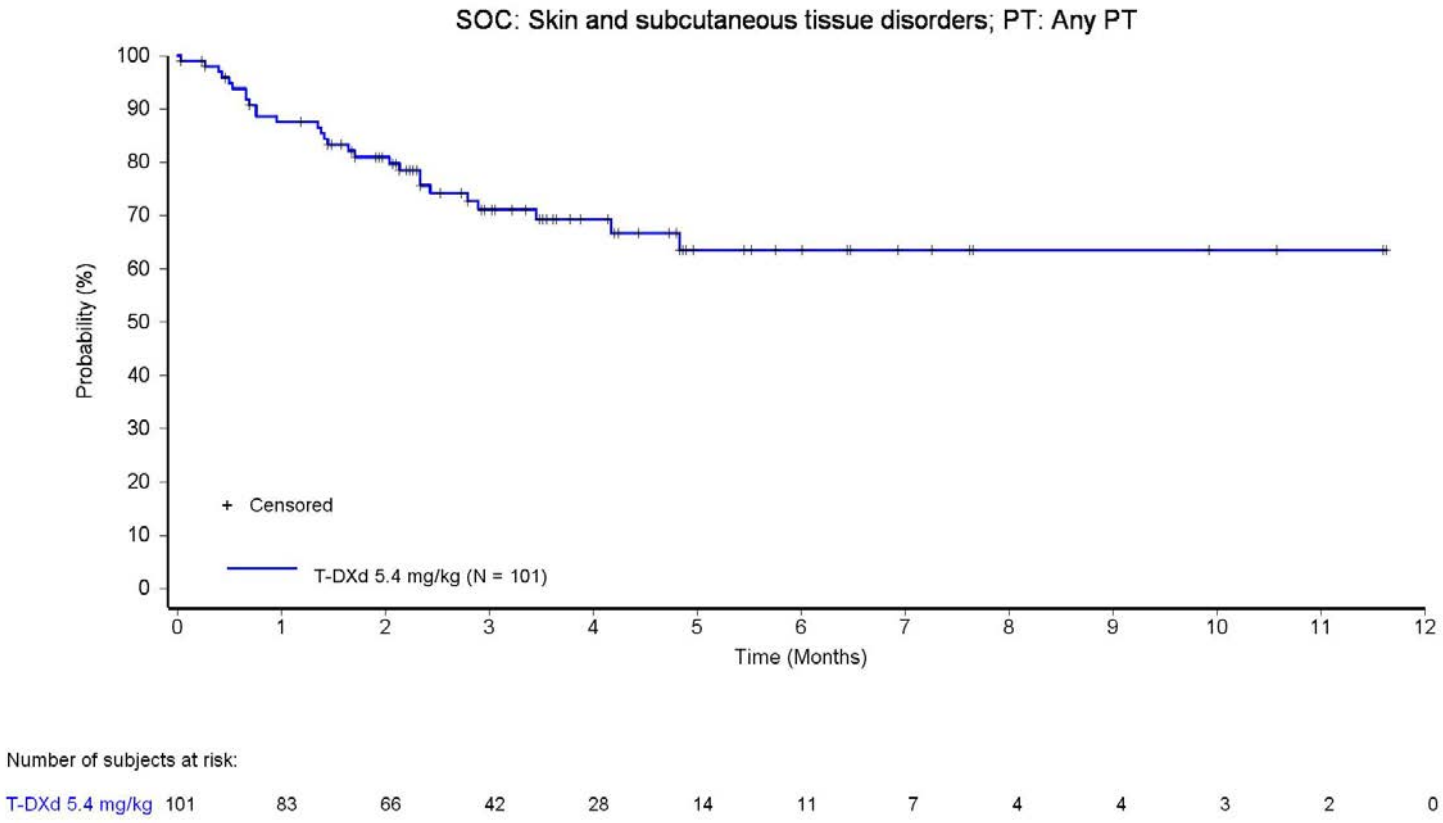


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	82	68	48	33	20	14	9	7	7	3	3	0

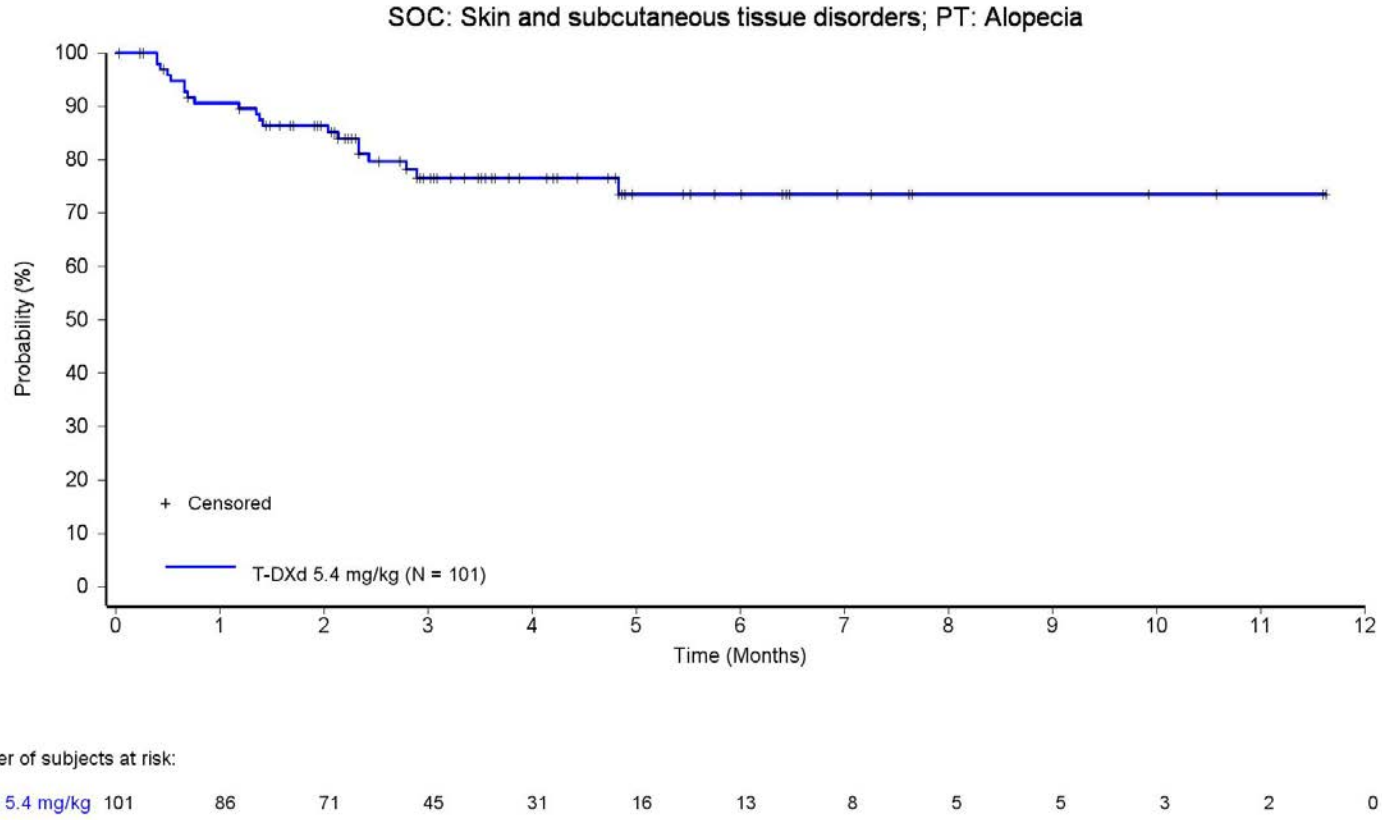
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



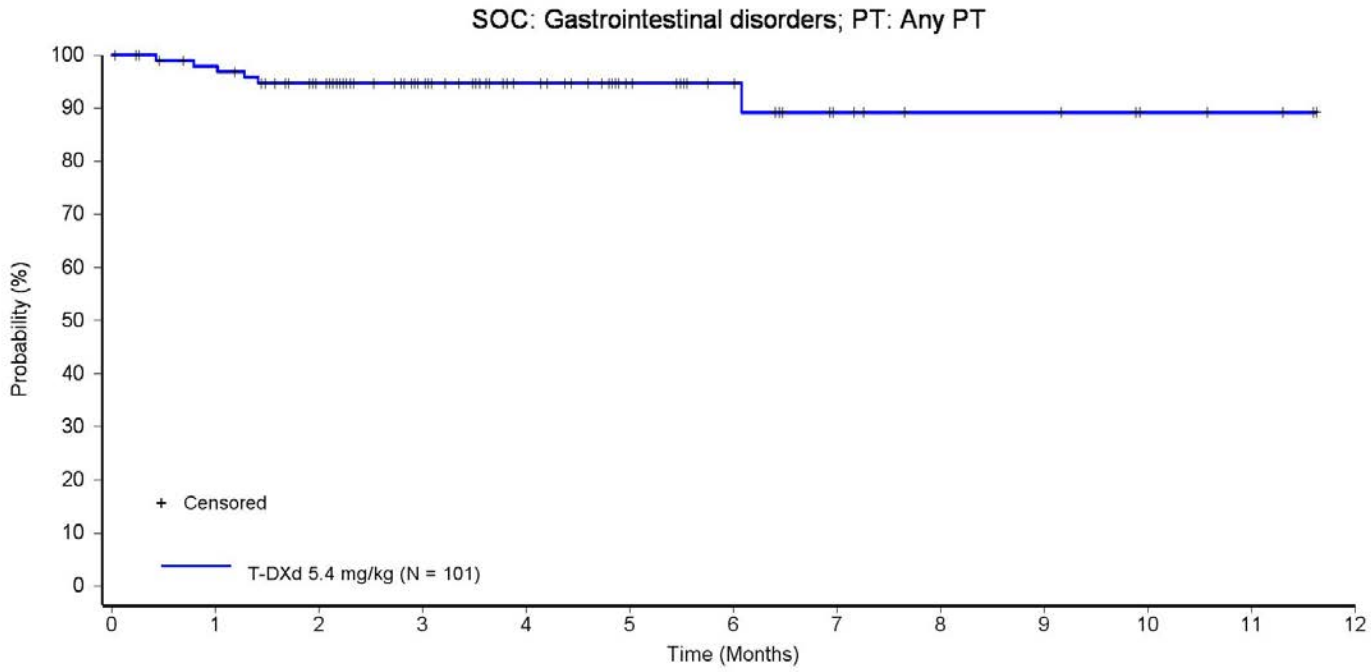
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:11; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.8.2 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

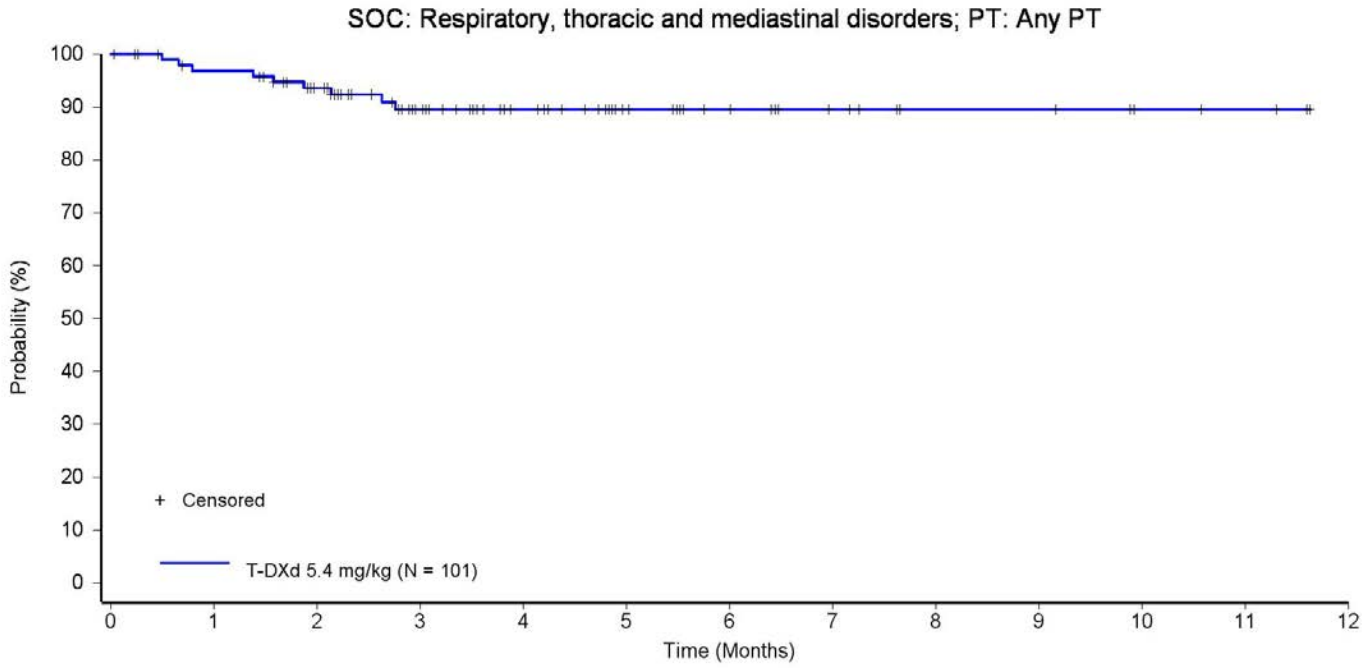


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	93	80	58	41	24	18	11	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_SAESOCPT5PER_2_SAS.rtf

DE.F.4.8.2 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

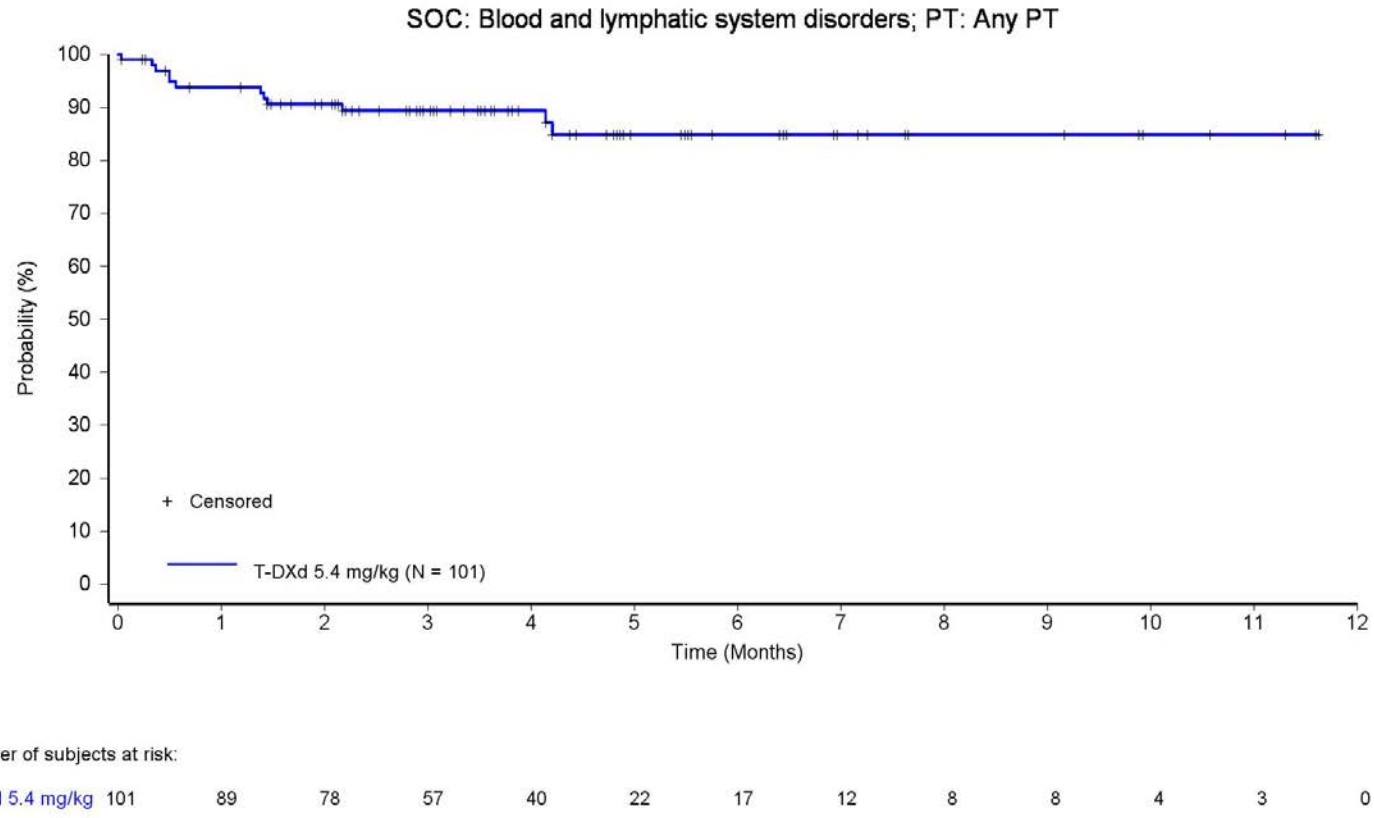


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	92	79	56	39	23	17	12	8	8	4	3	0

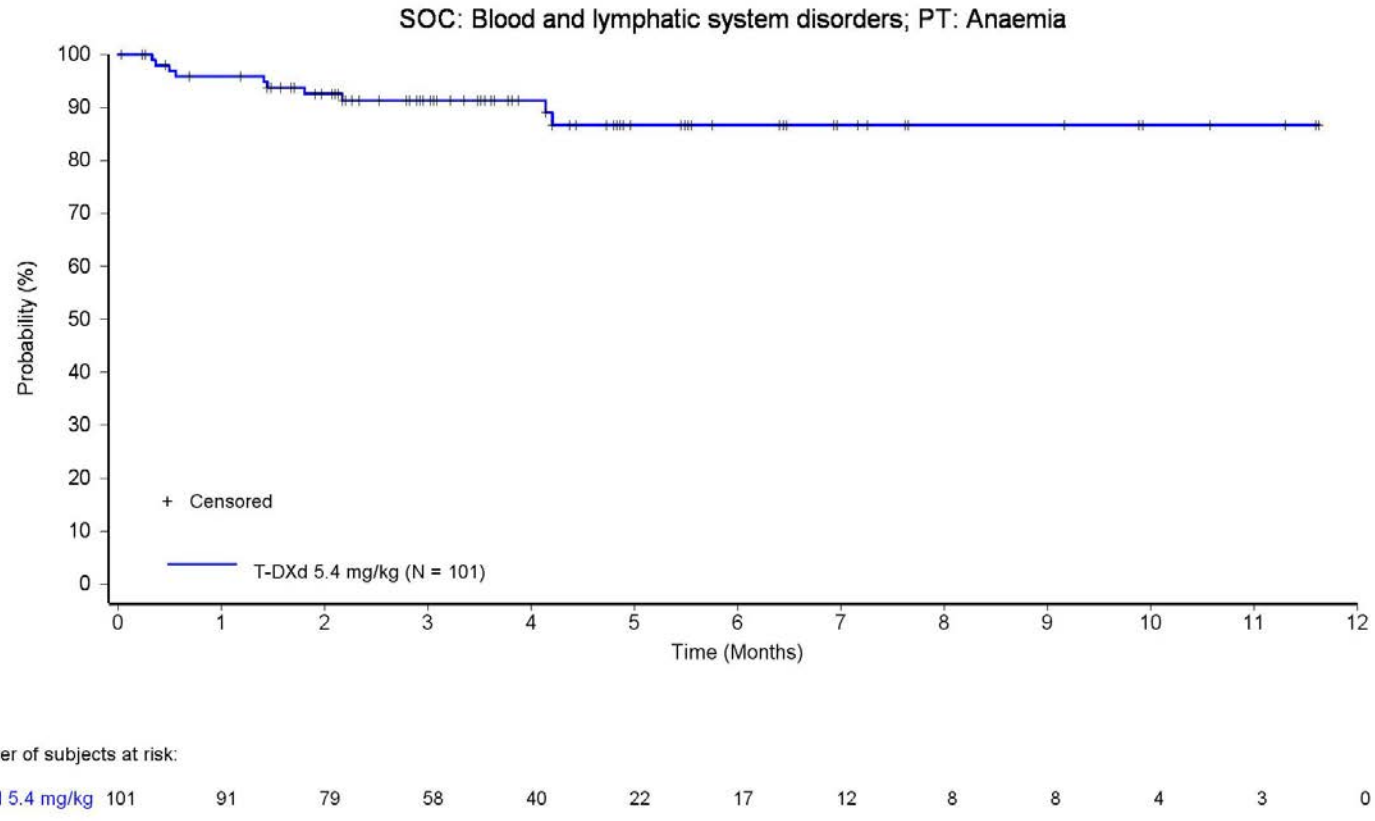
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_SAESOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



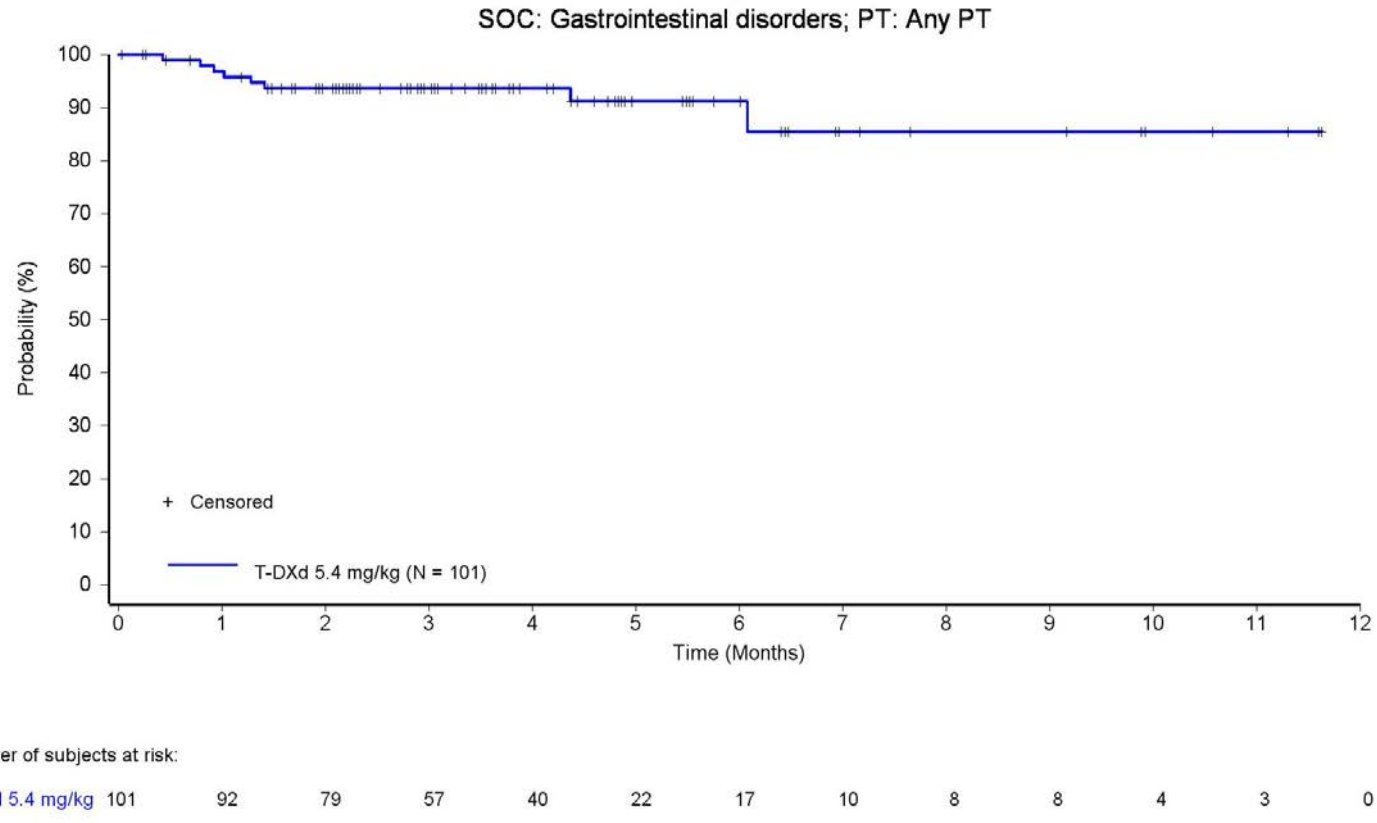
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



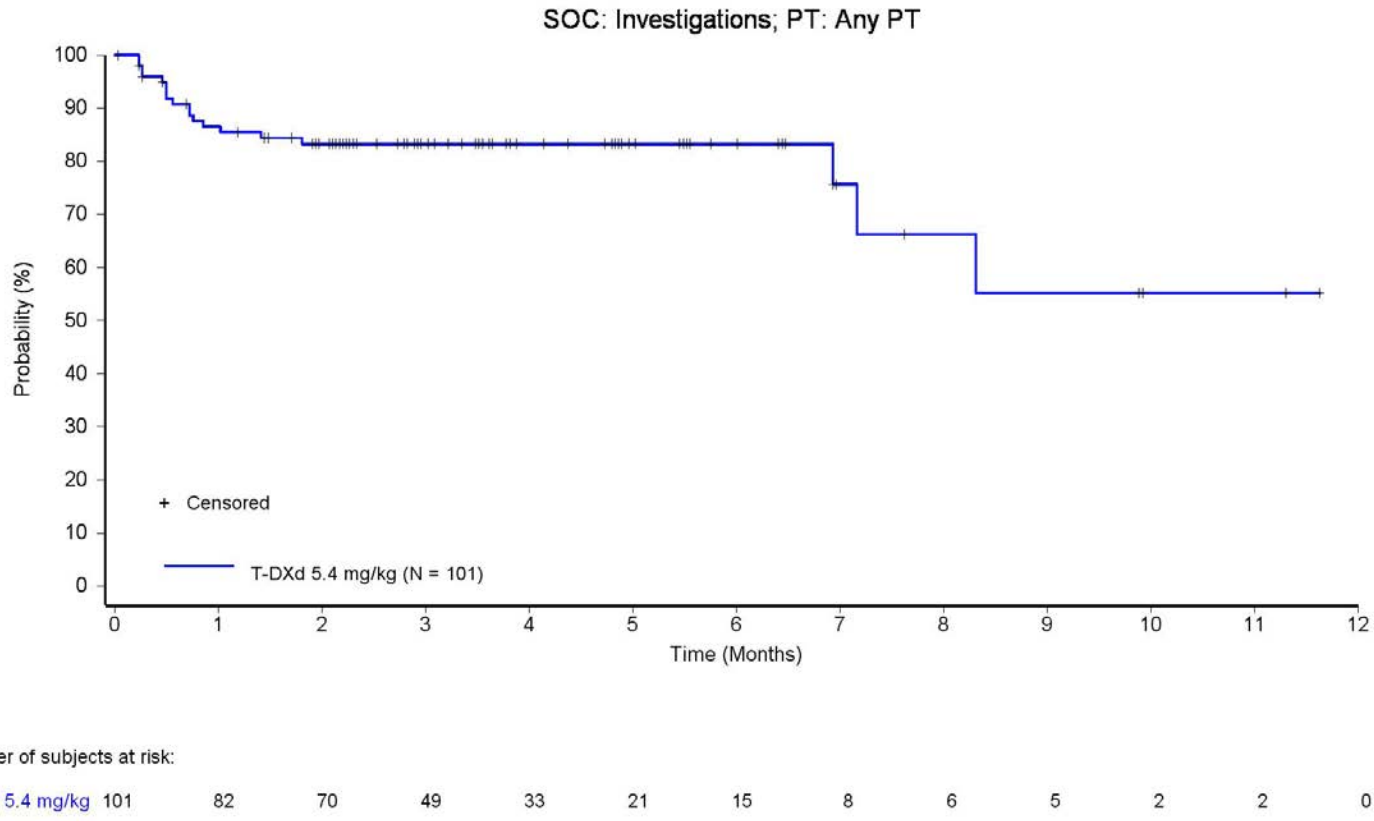
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



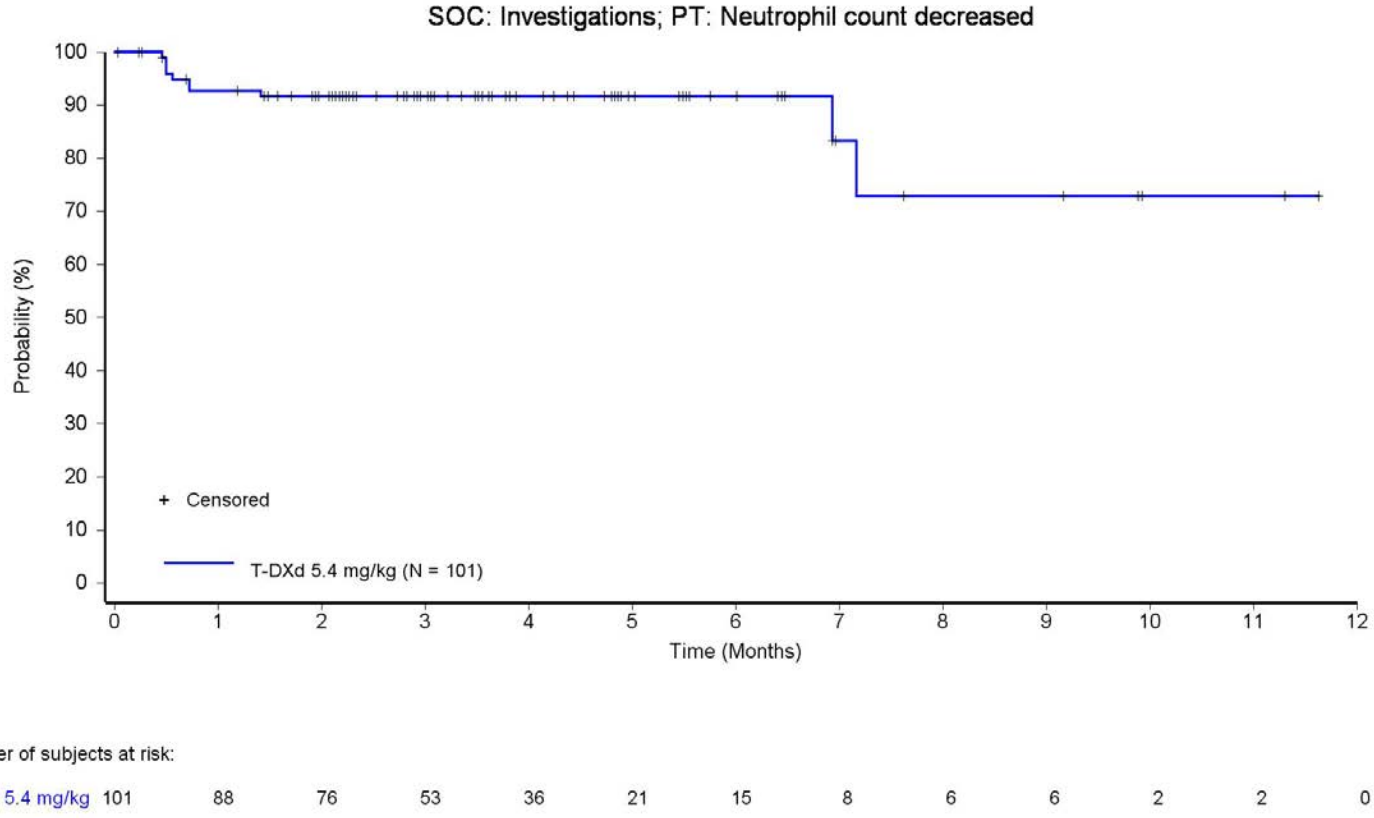
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



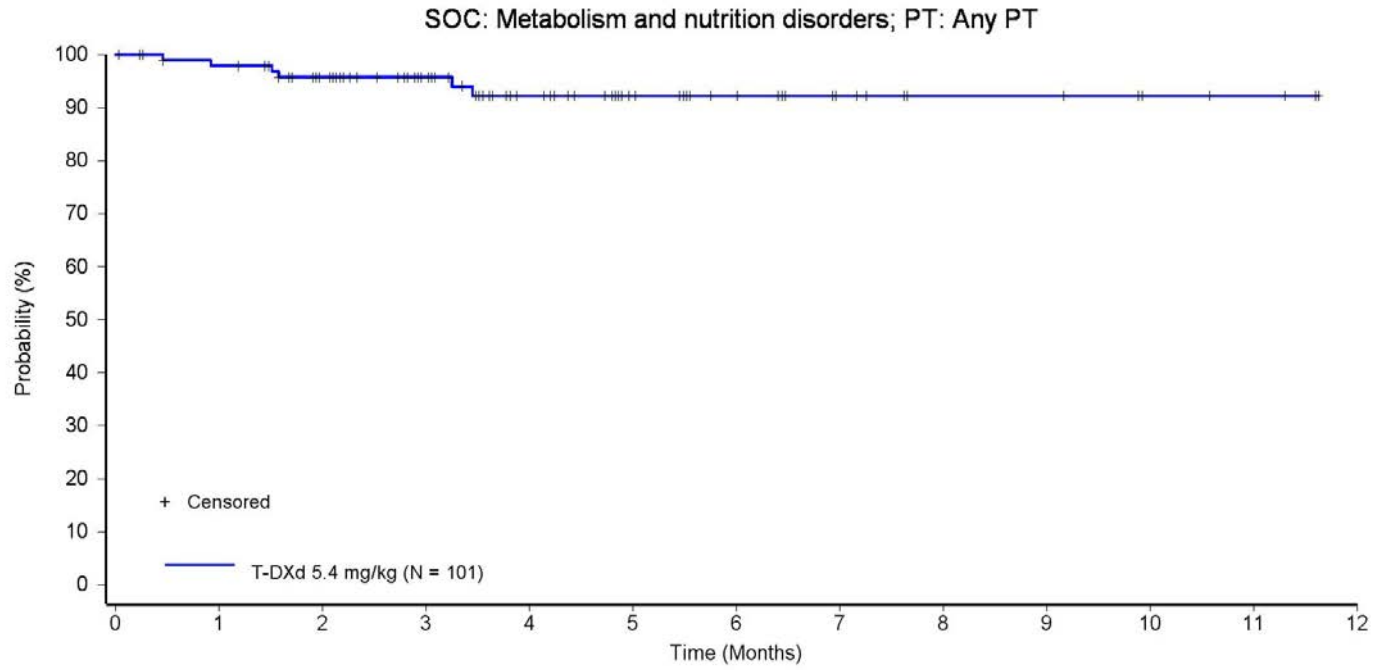
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

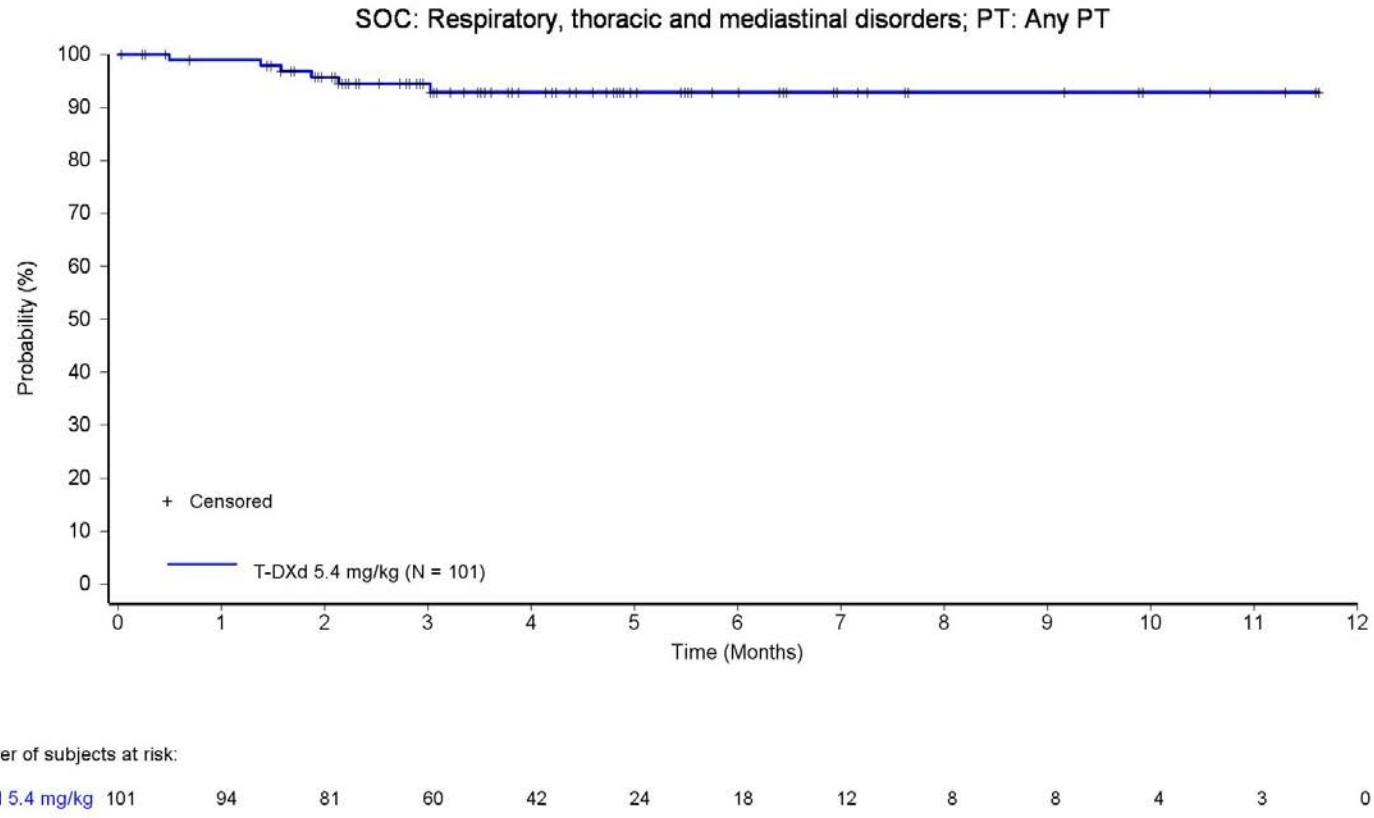


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	94	80	60	40	24	18	12	8	8	4	3	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

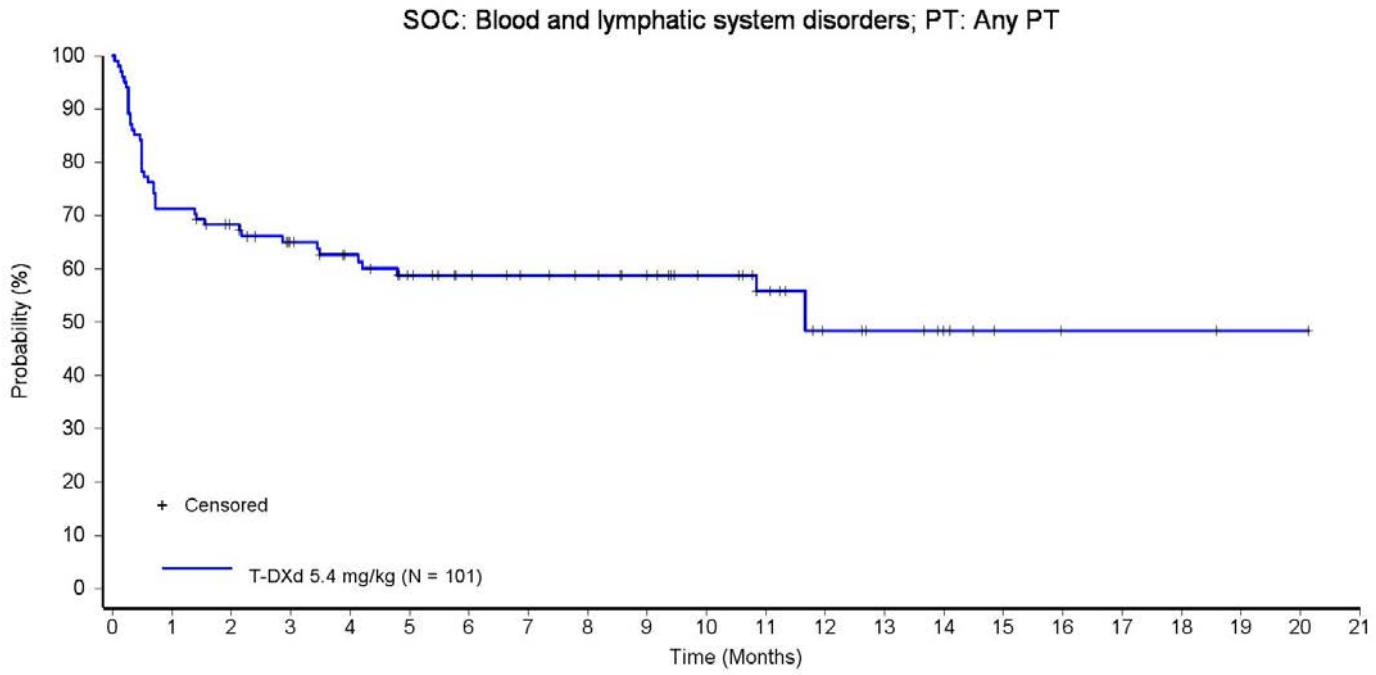
DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set



Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

Anhang 4-G 4.4.1.2 Finaler Datenschnitt vom 23.12.2022

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

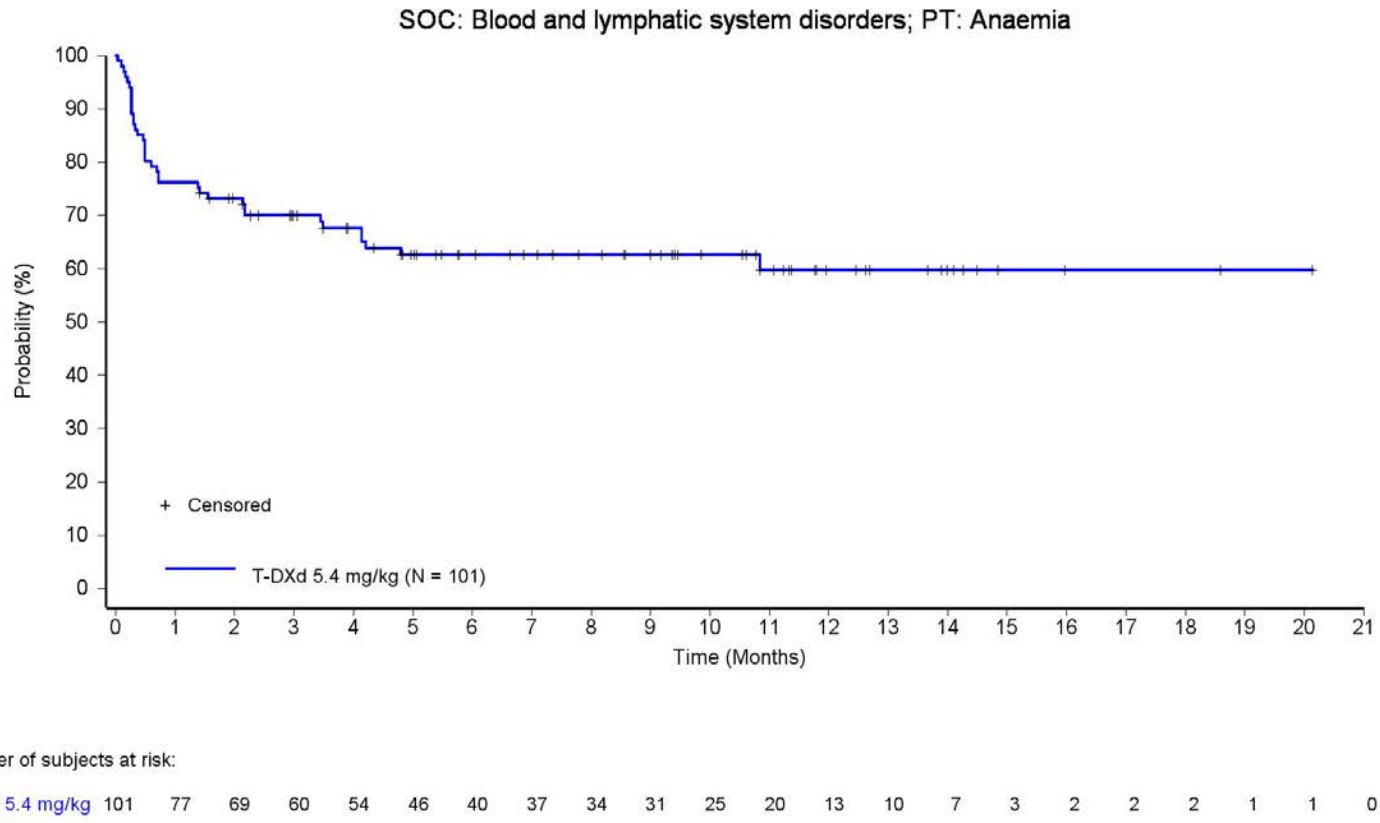


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	72	64	55	49	42	37	34	32	29	23	18	11	9	6	3	2	2	2	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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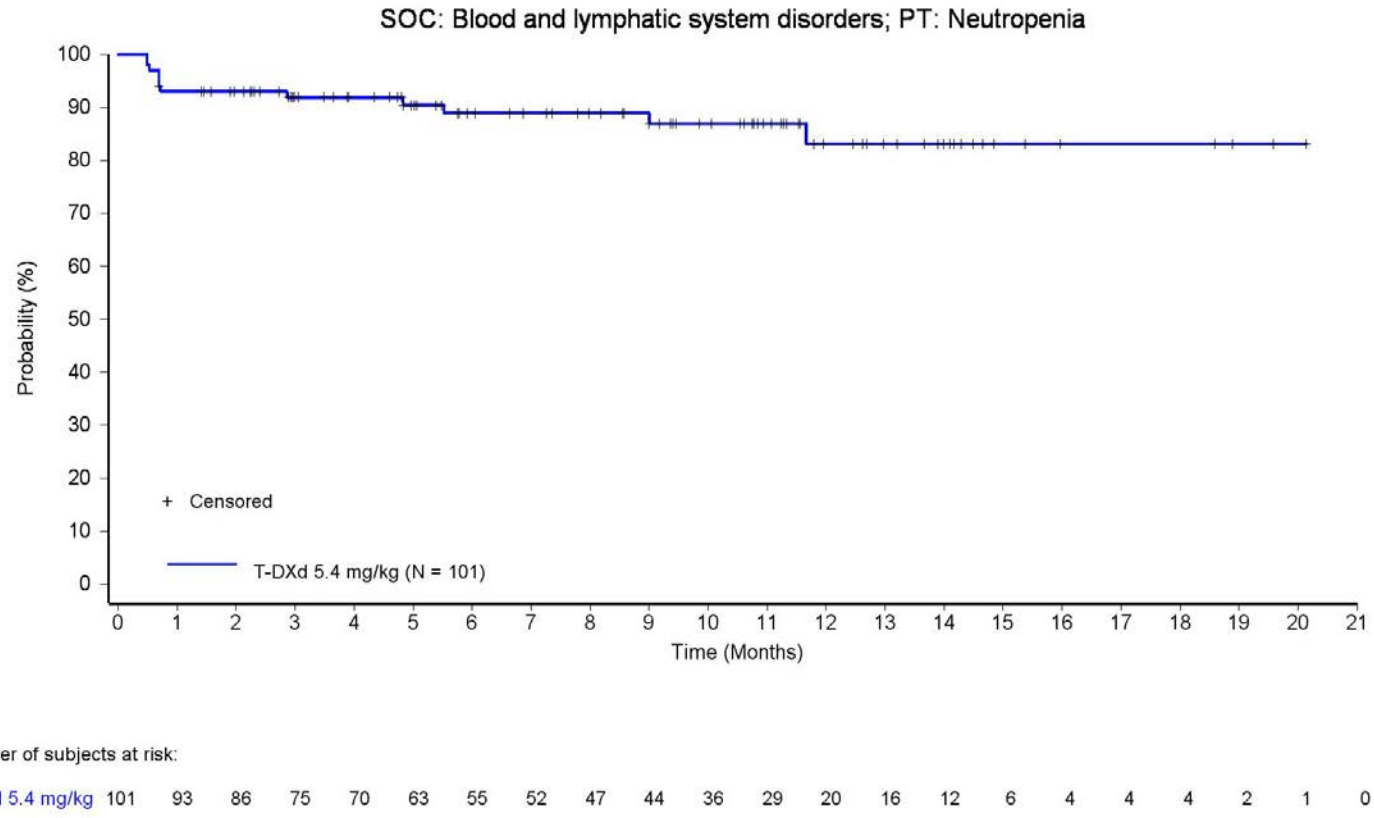
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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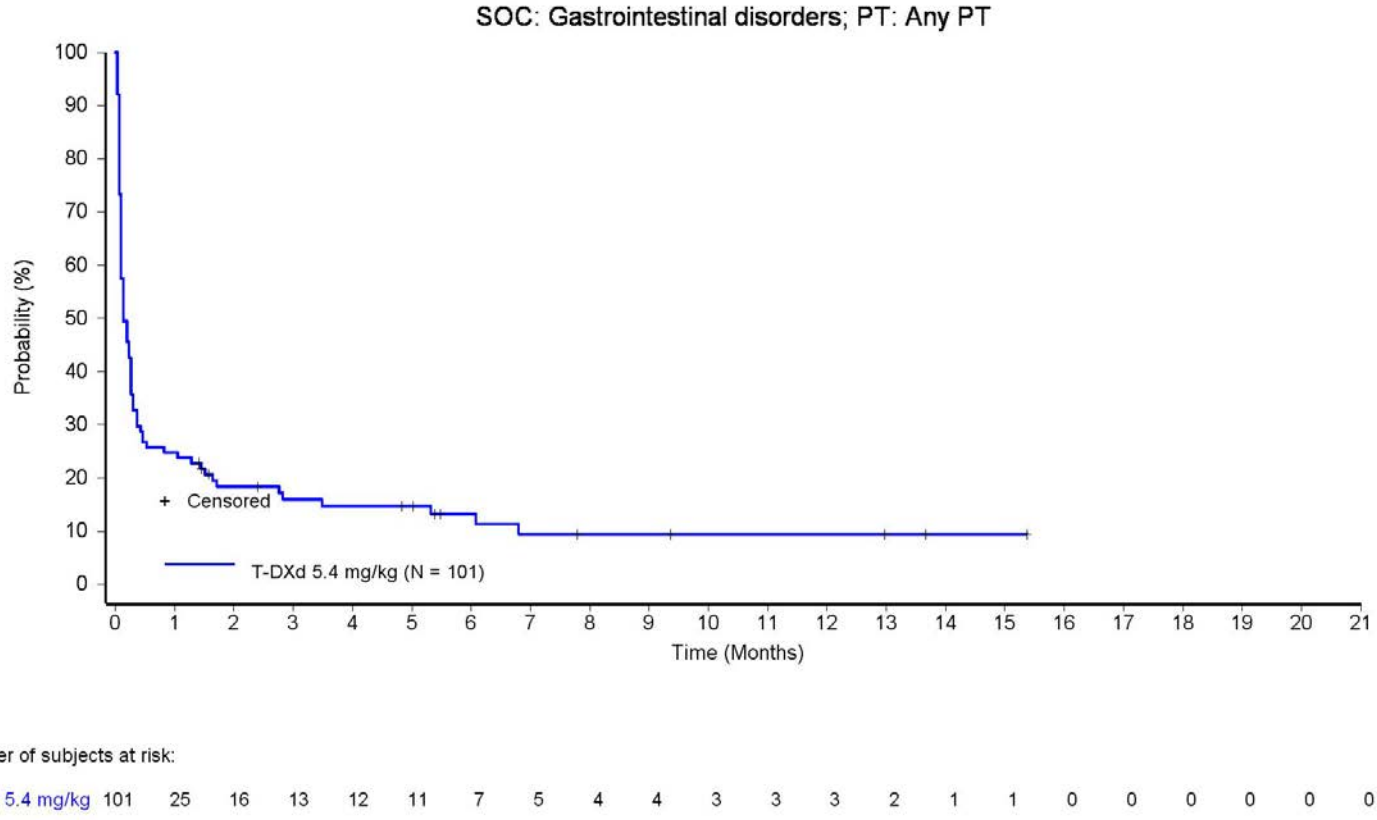
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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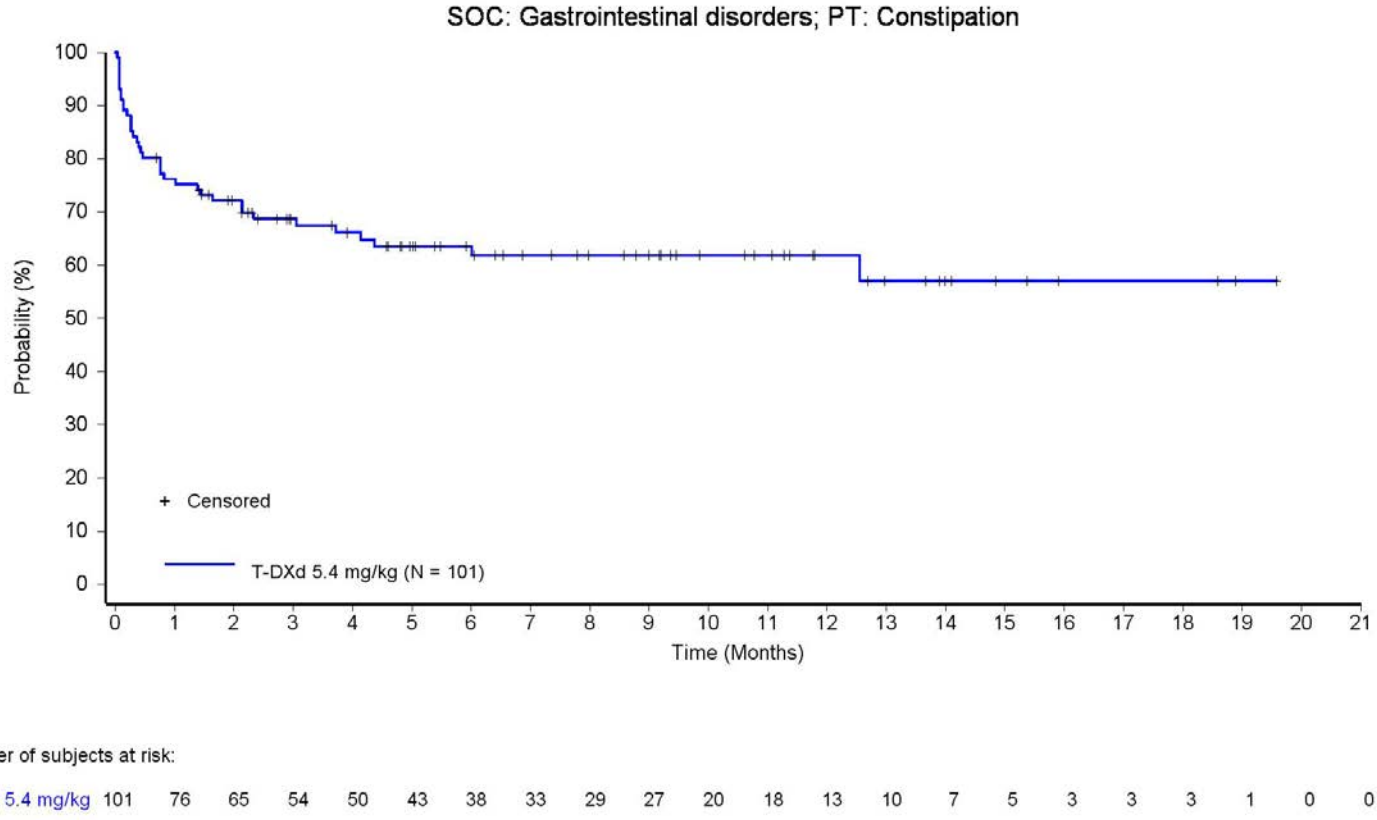
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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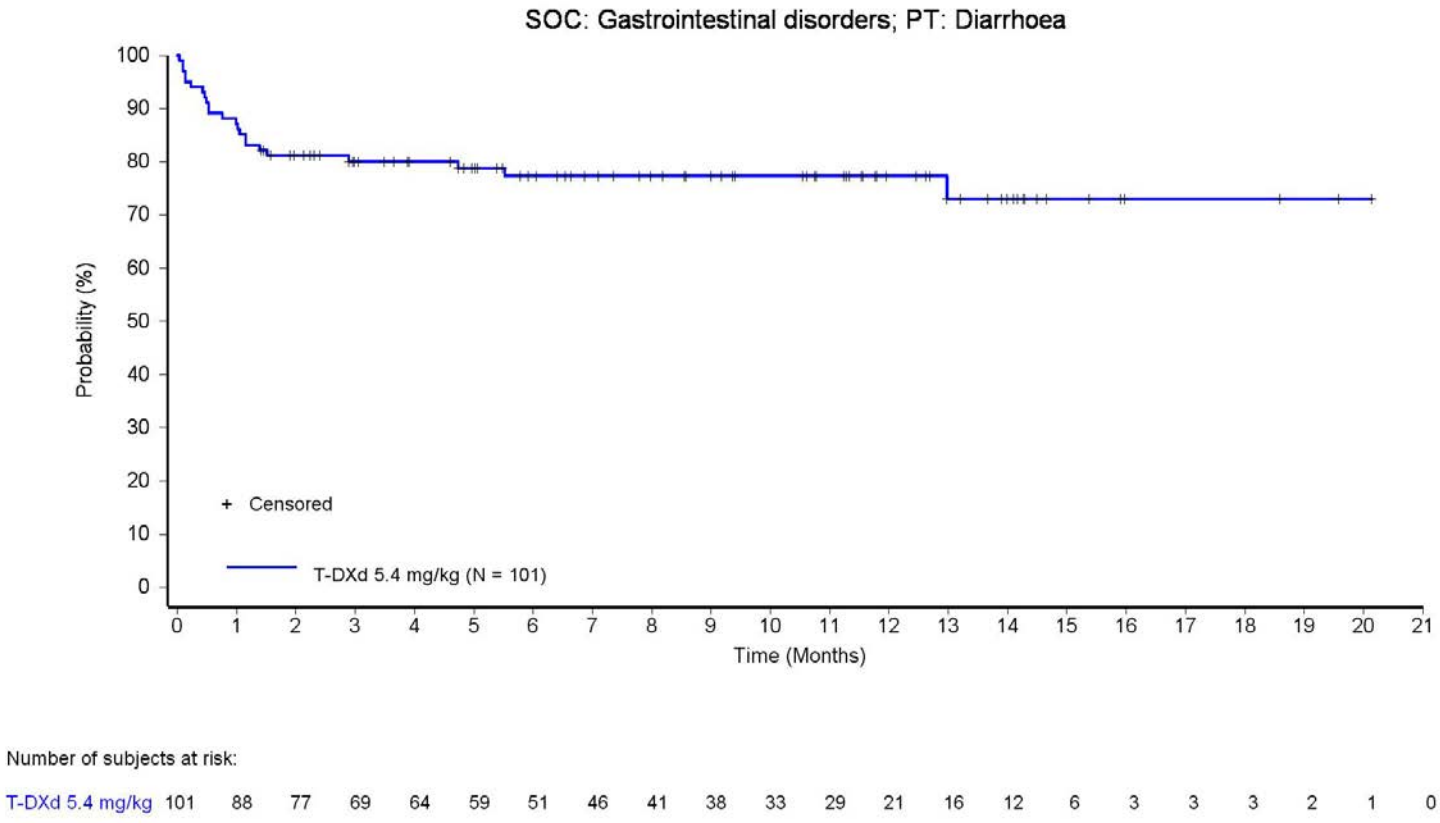
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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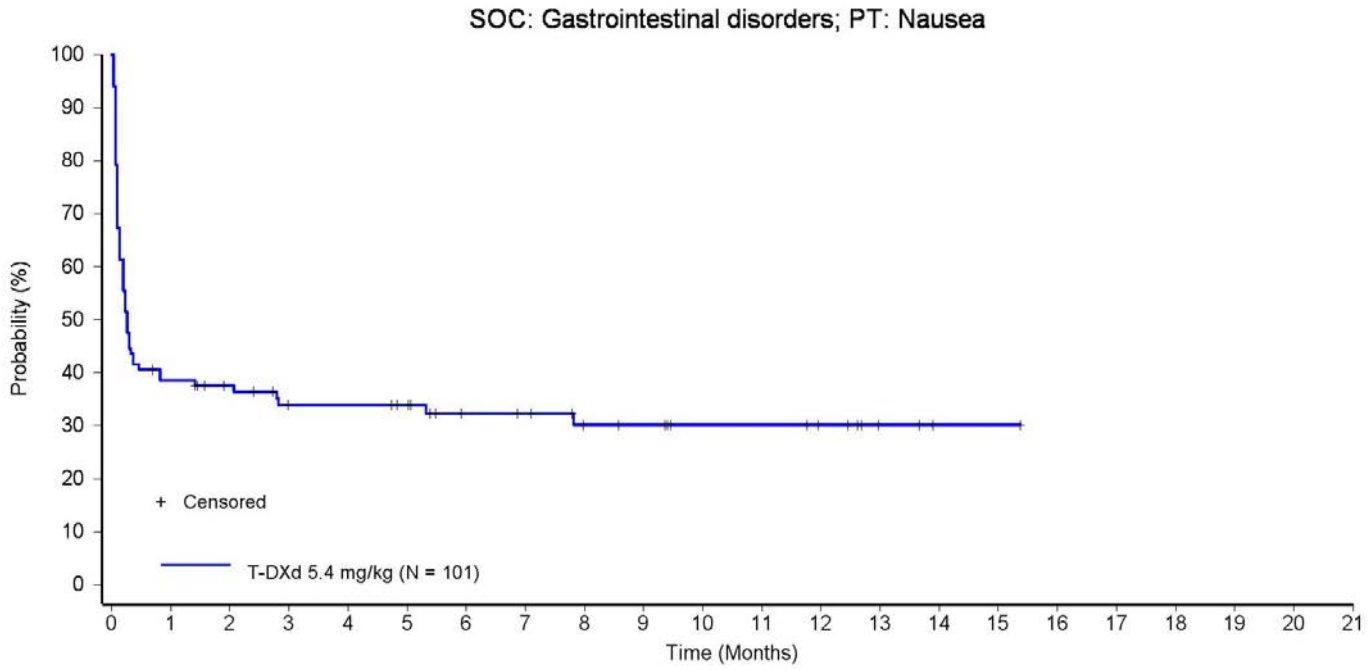
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	38	32	26	26	24	18	17	13	12	9	9	7	3	1	1	0	0	0	0	0	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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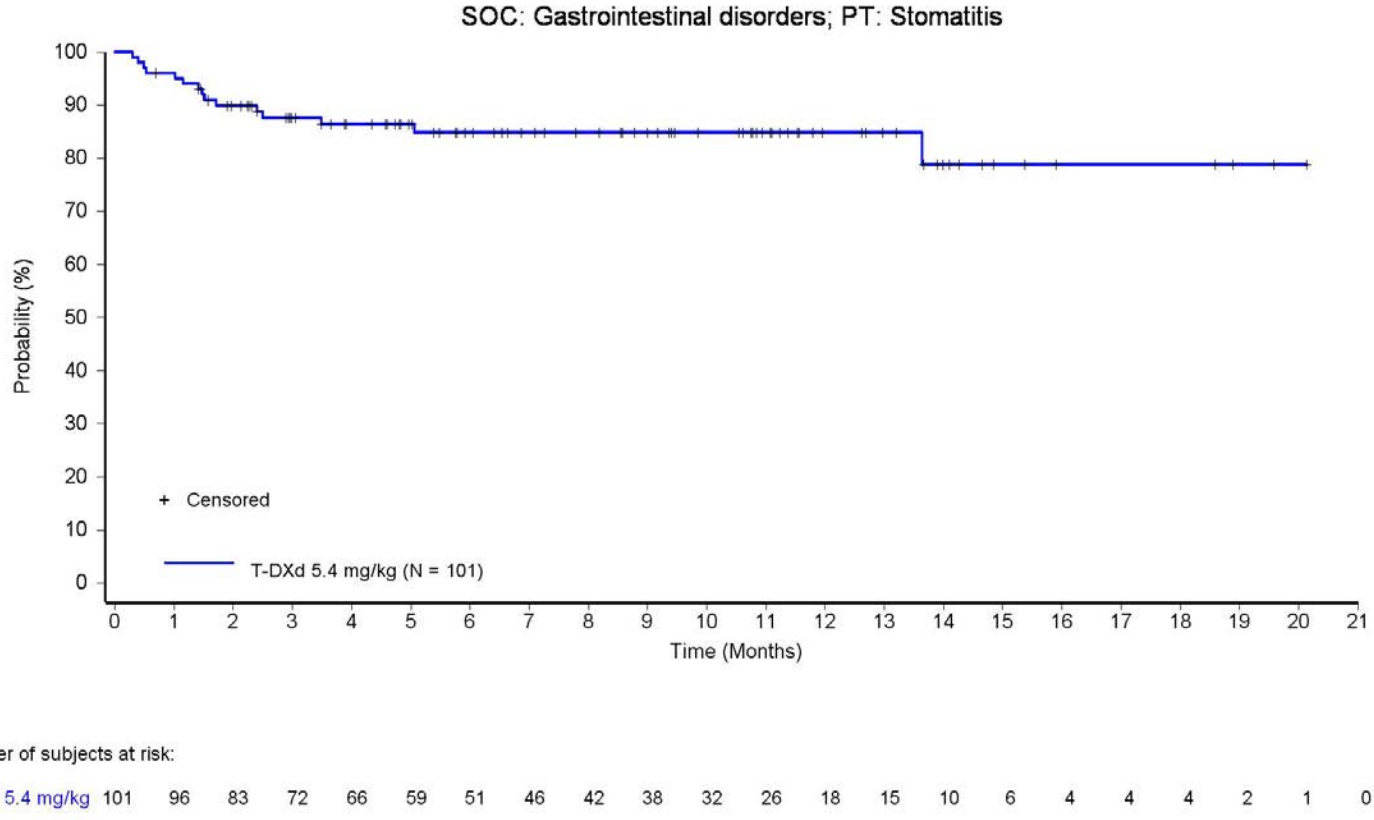
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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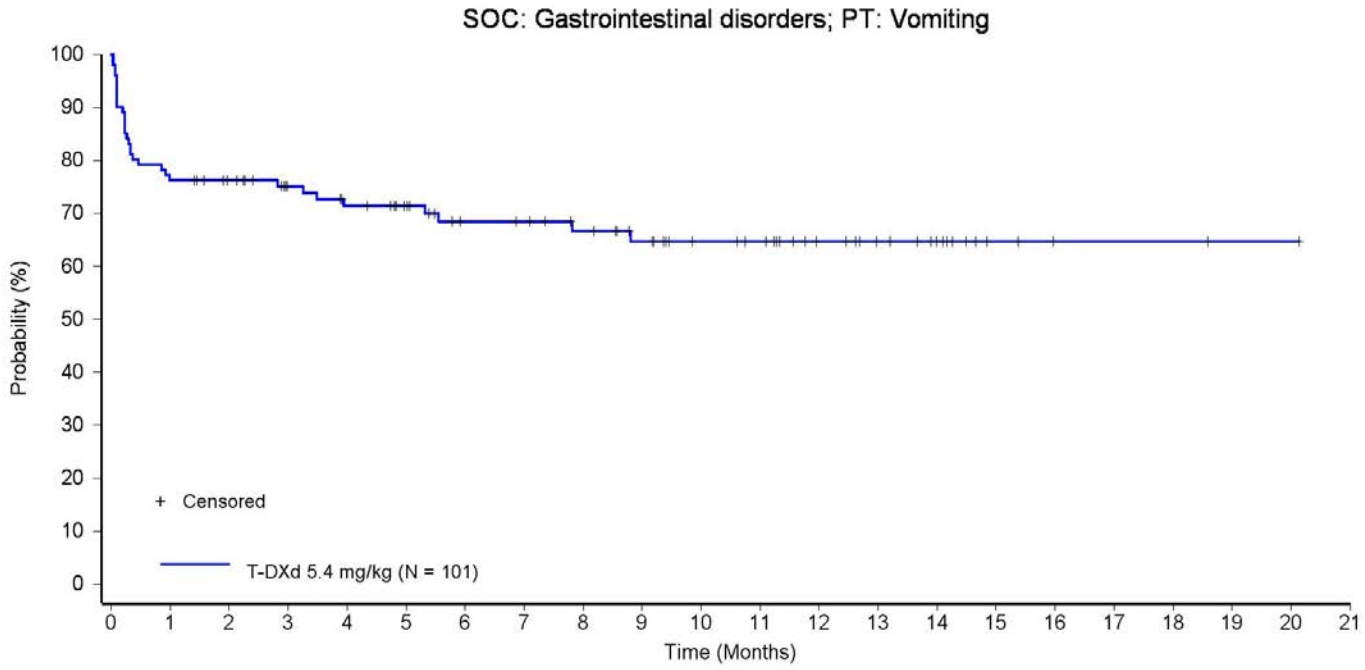
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	77	71	62	57	52	43	42	38	33	27	25	18	14	10	4	2	2	2	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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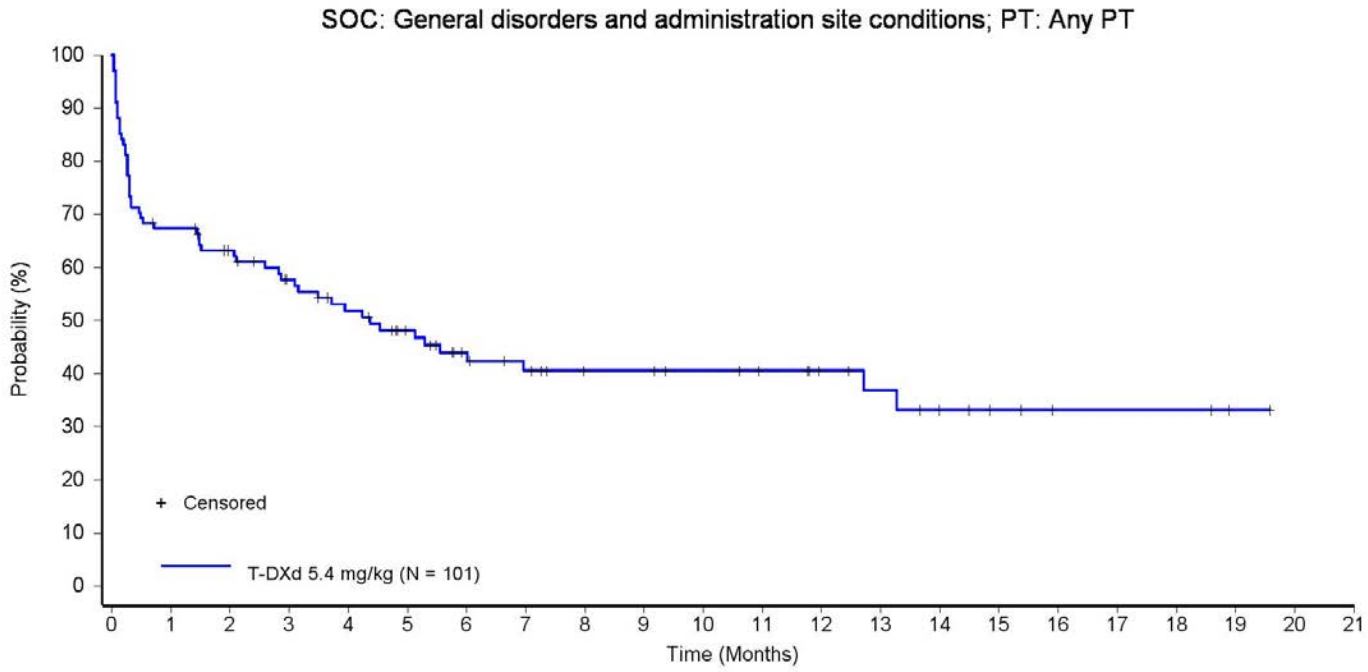
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	67	59	50	43	35	27	23	19	19	17	15	12	10	7	5	3	3	3	1	0	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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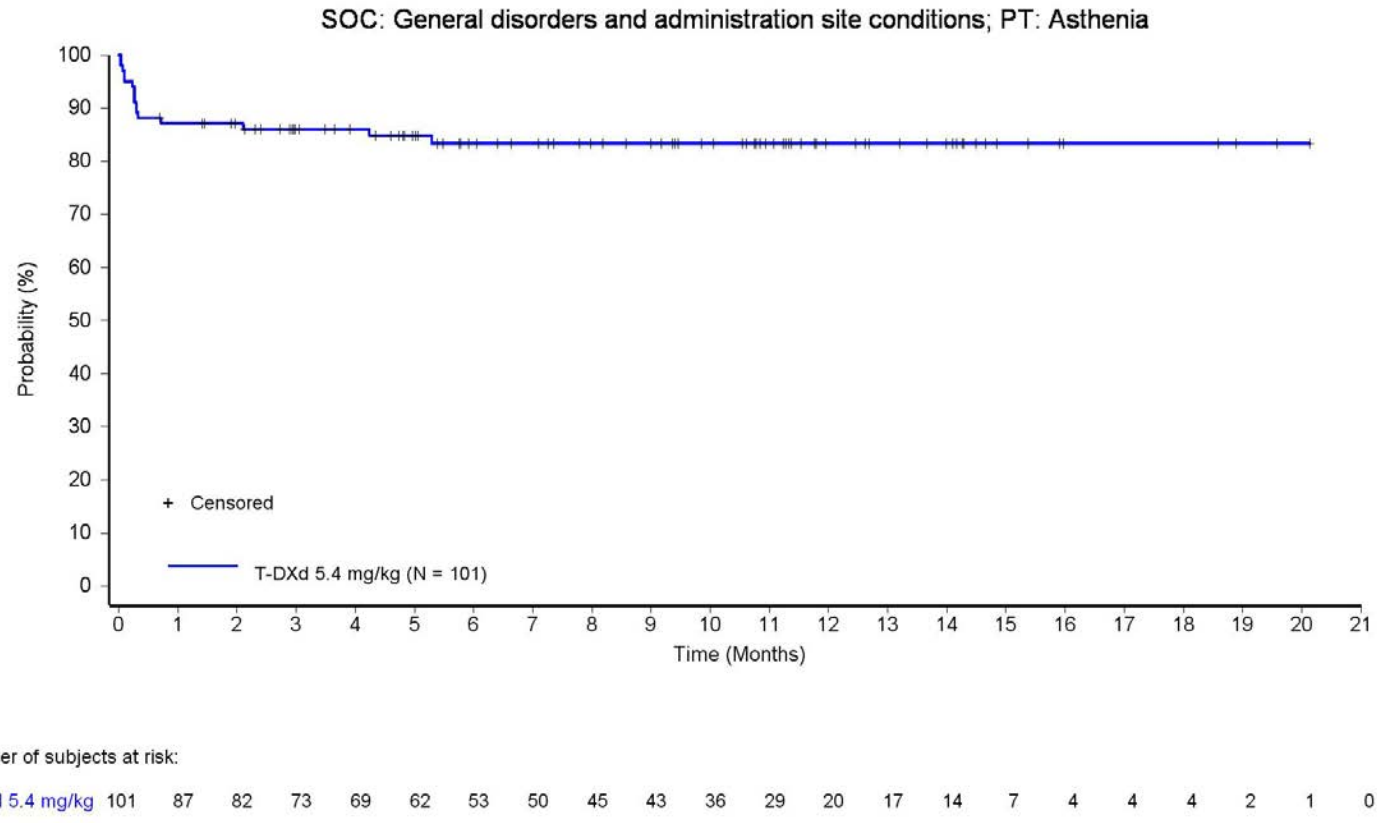
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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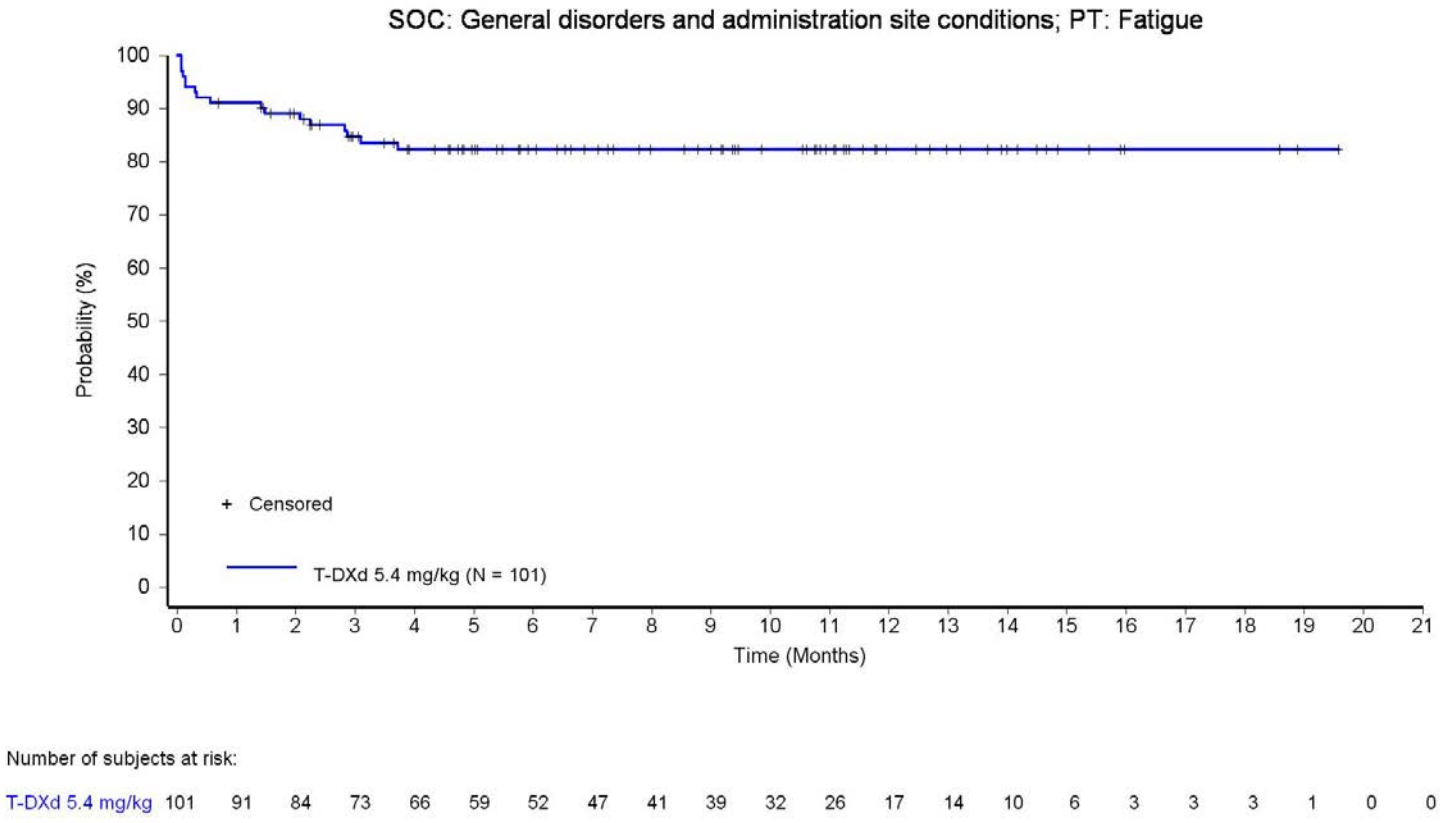
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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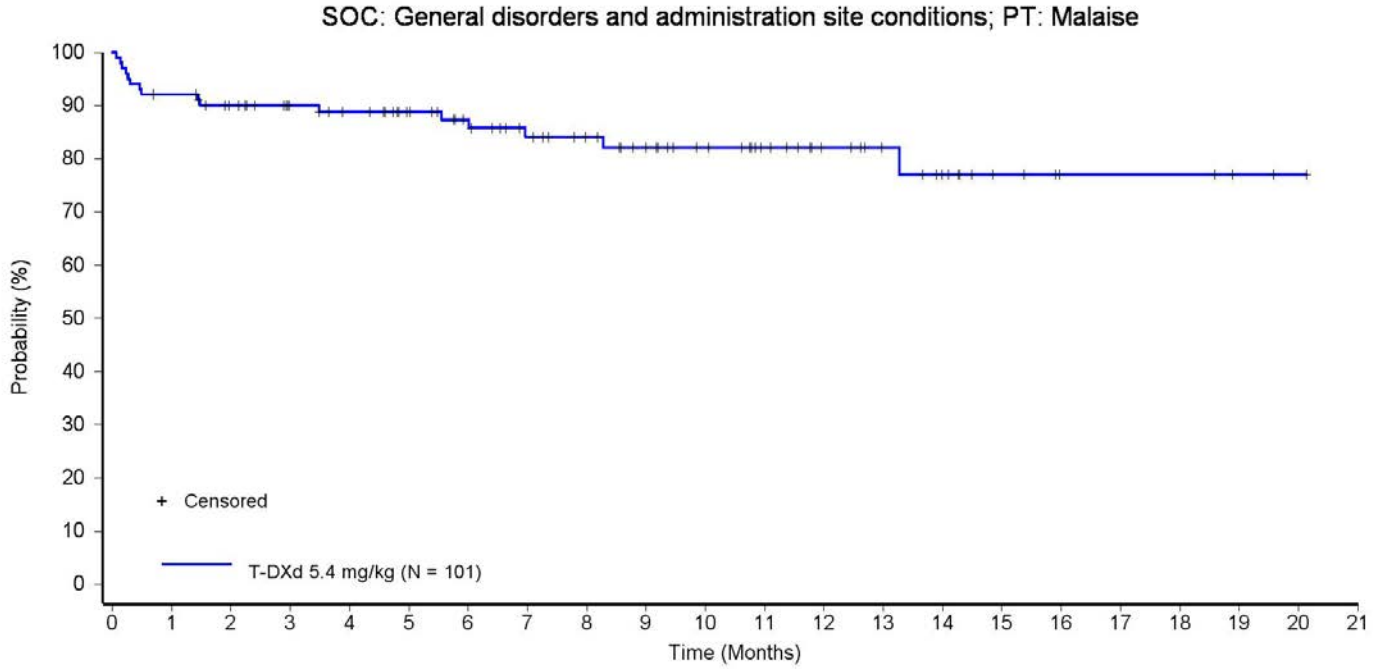
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

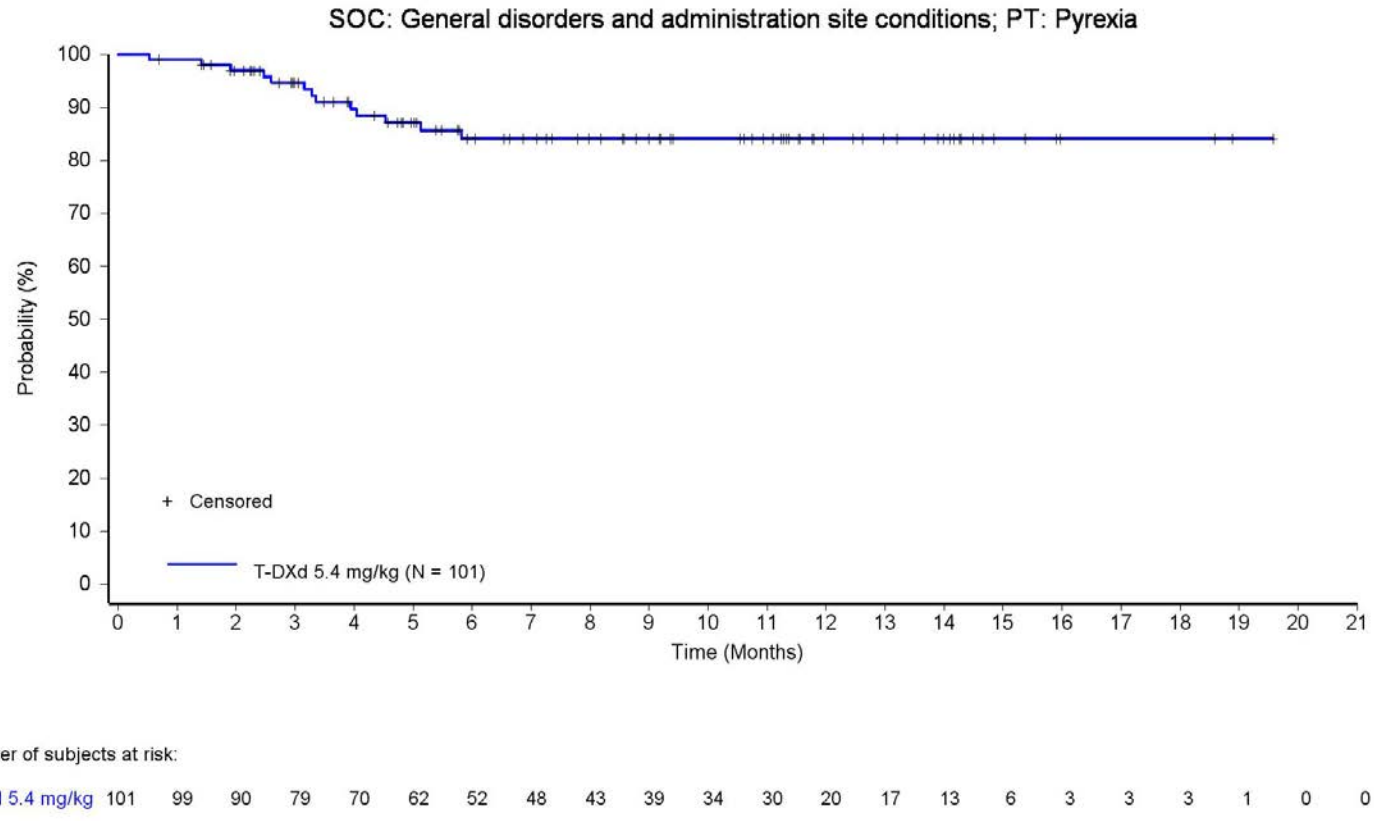


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	92	83	75	71	64	56	49	44	39	32	26	20	16	12	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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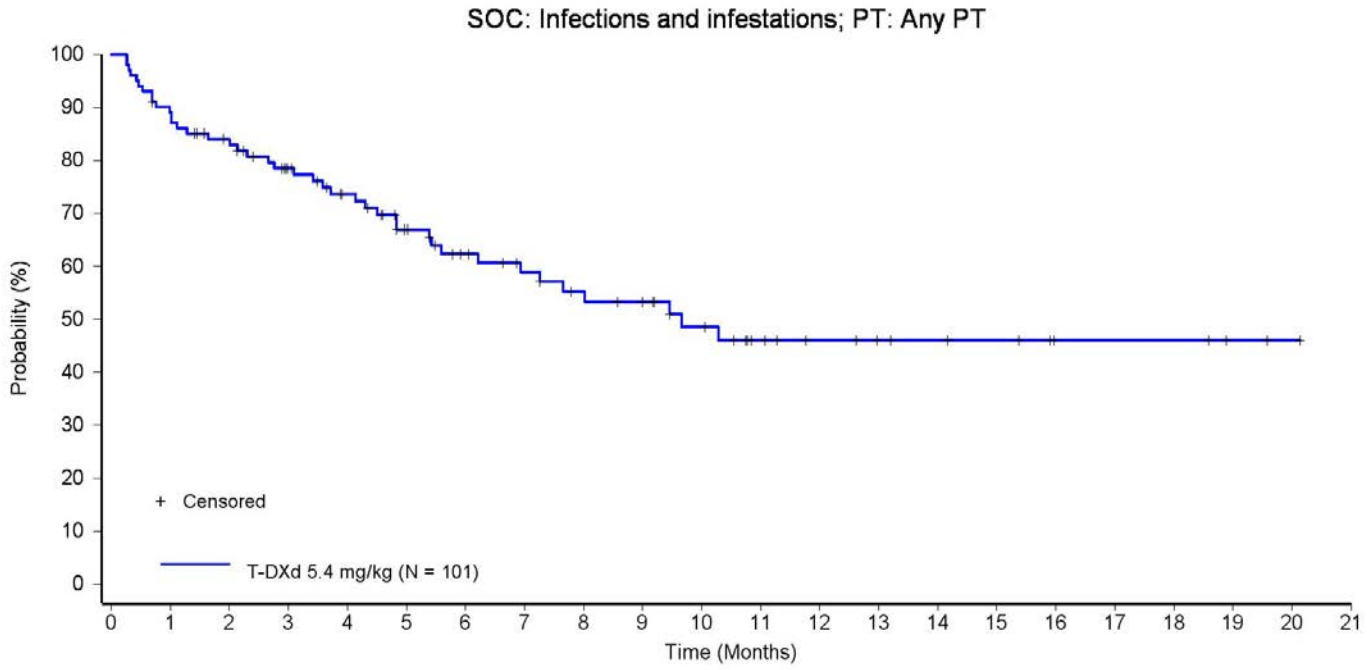
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	89	78	66	57	46	38	33	28	26	20	14	11	9	8	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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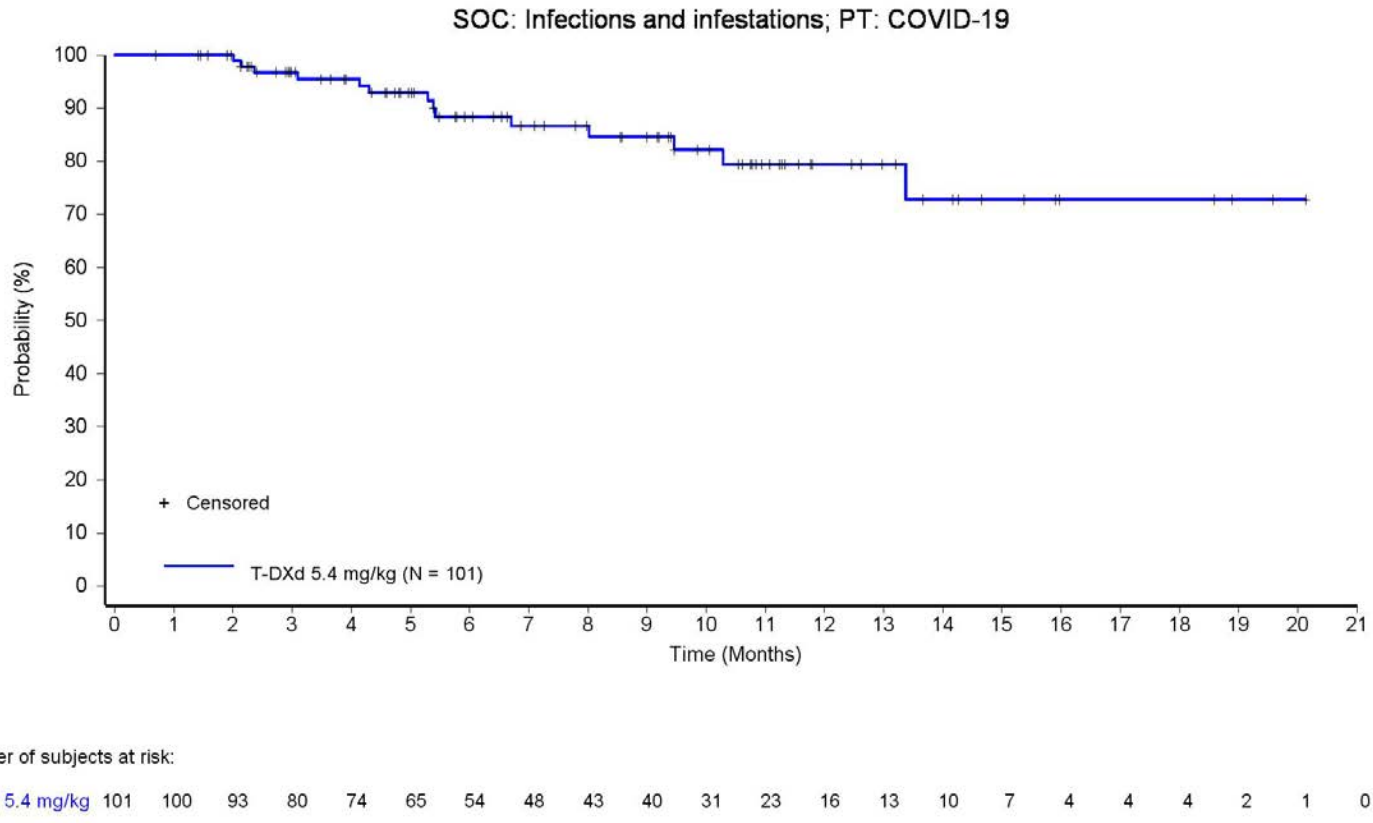
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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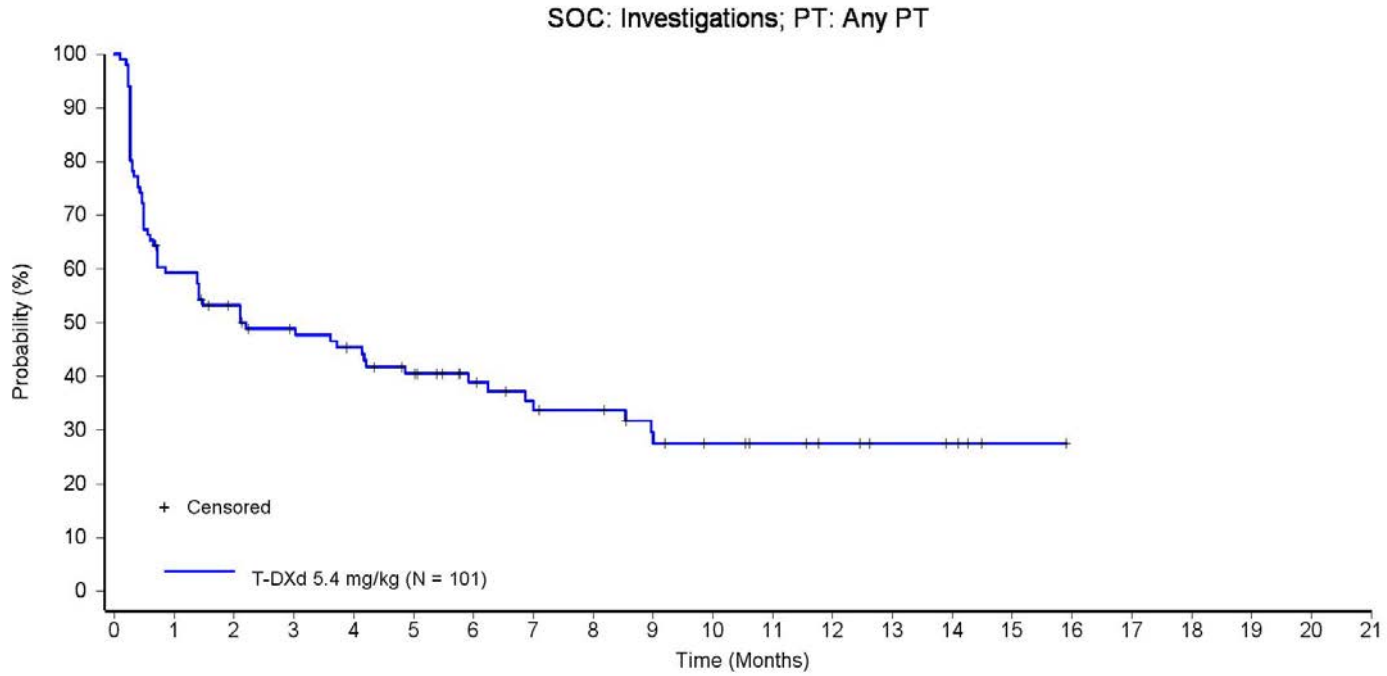
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	59	49	42	38	32	24	19	18	14	11	9	7	5	4	1	0	0	0	0	0	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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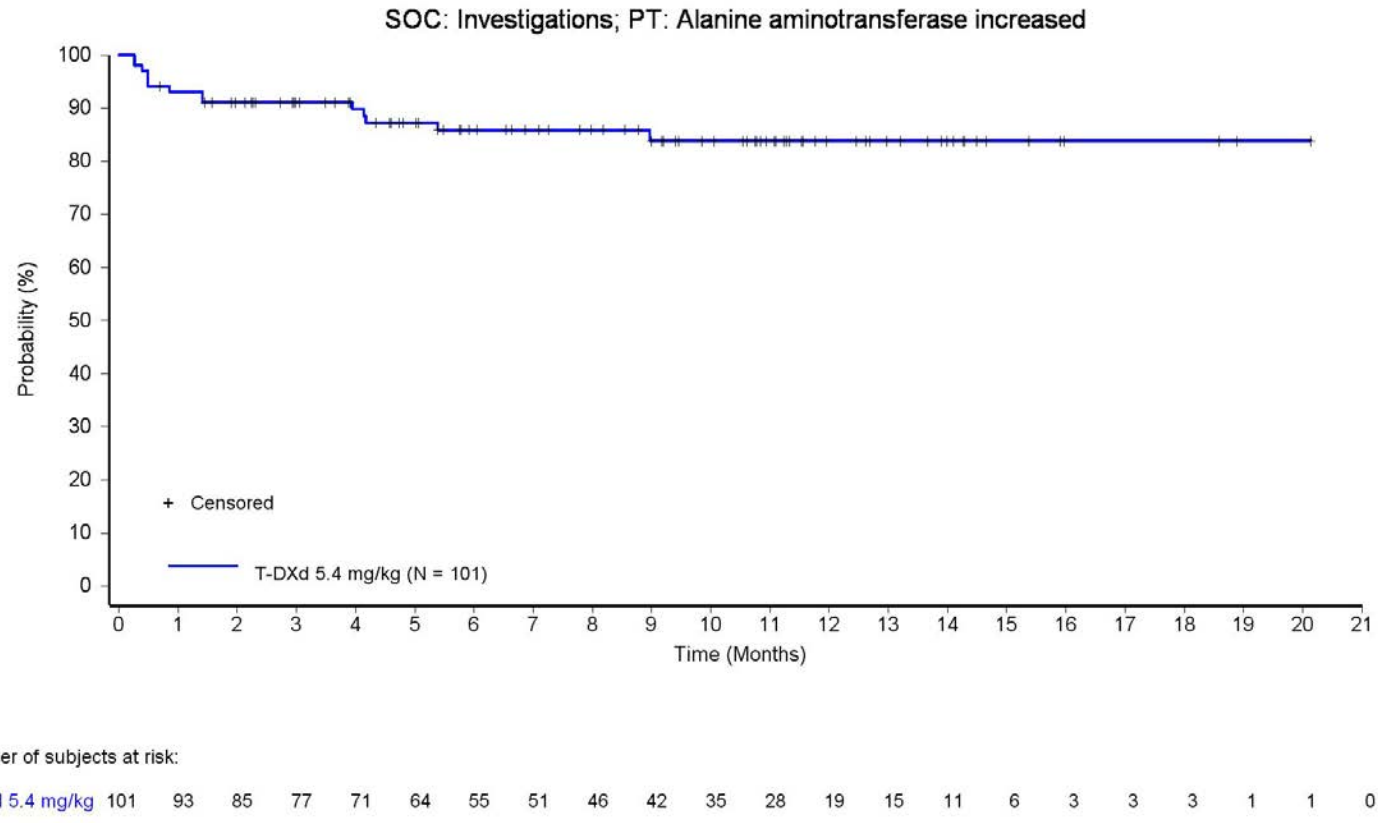
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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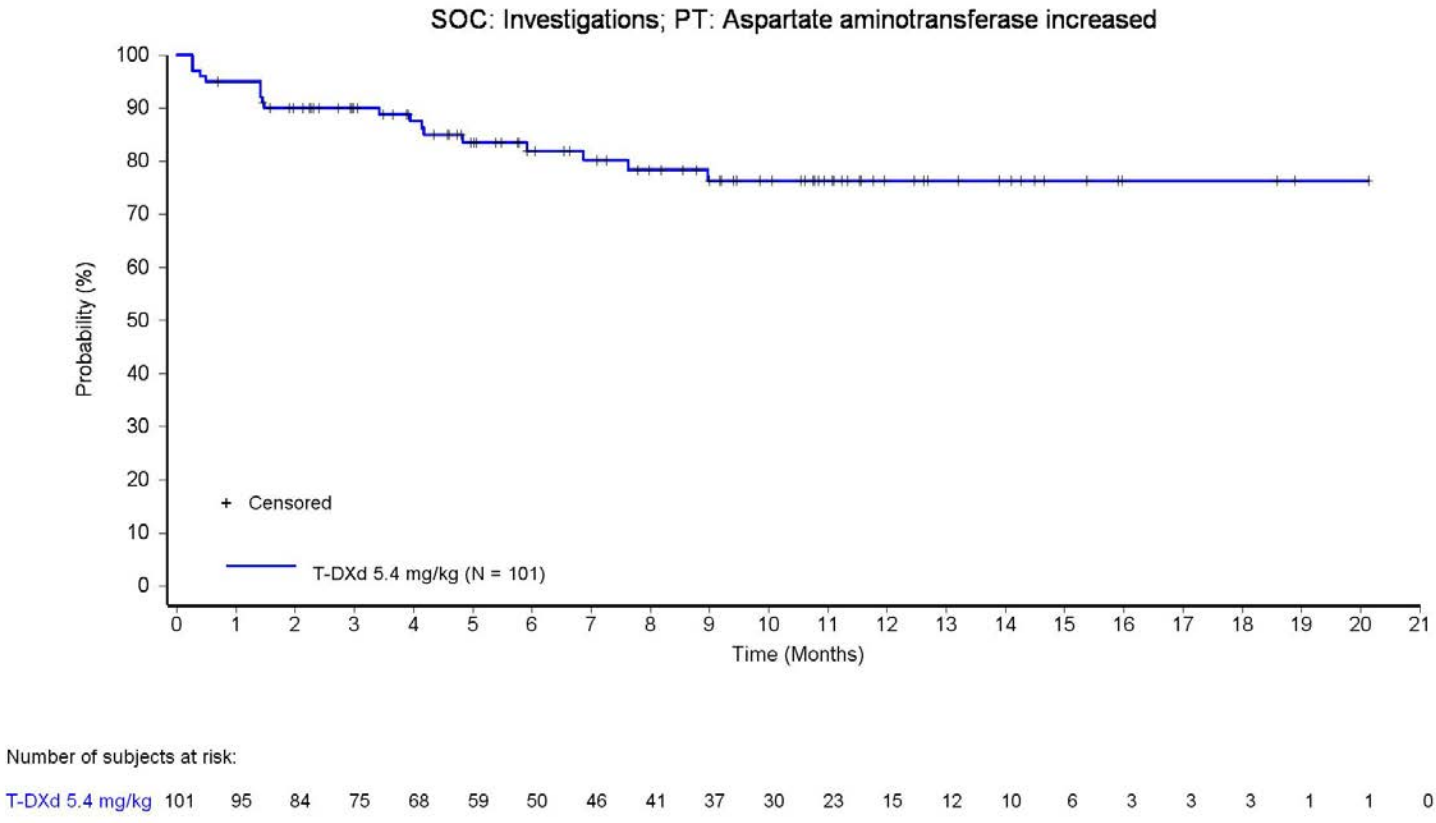
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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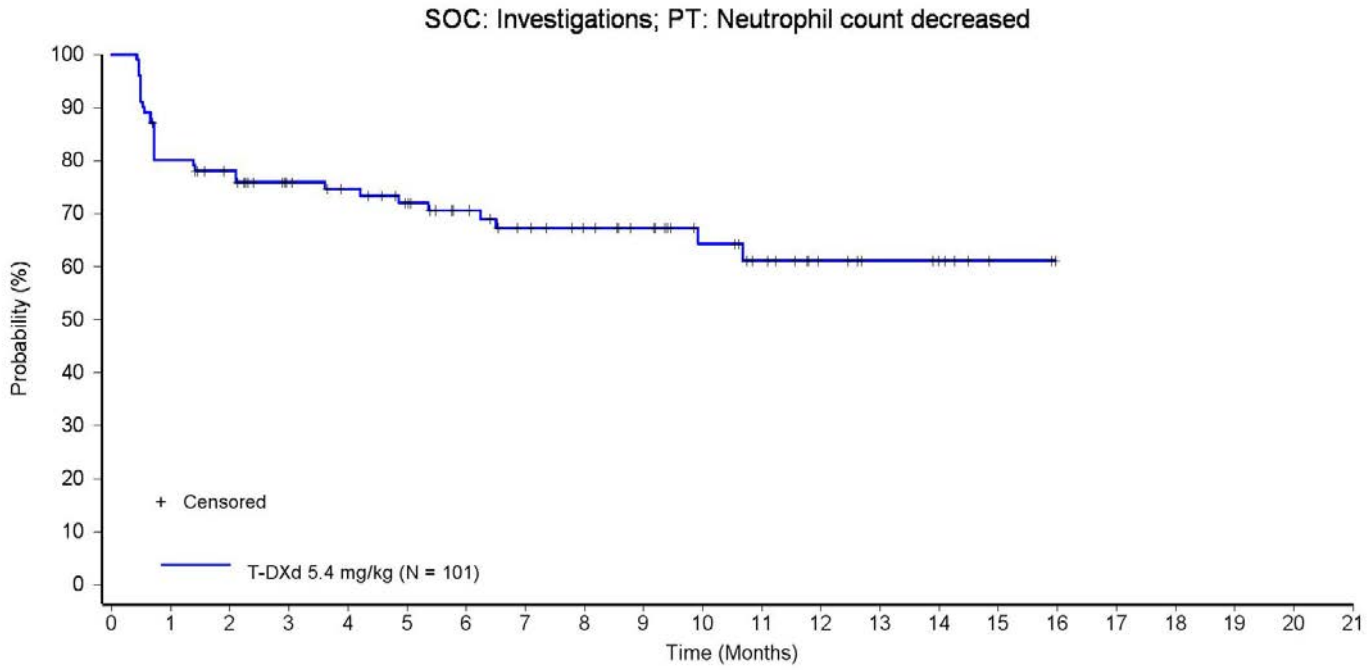
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

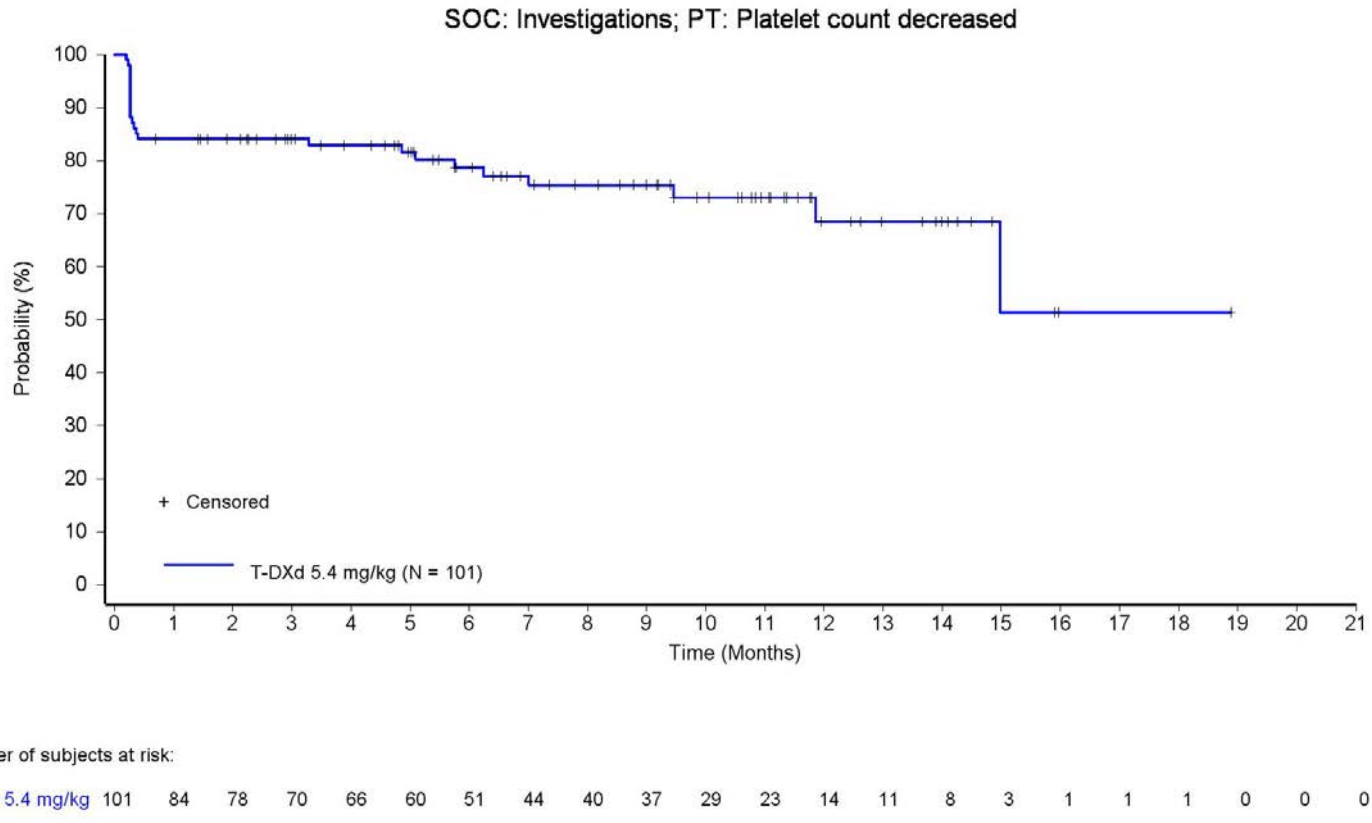


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	80	72	62	58	52	44	38	34	30	22	17	11	8	6	2	0	0	0	0	0	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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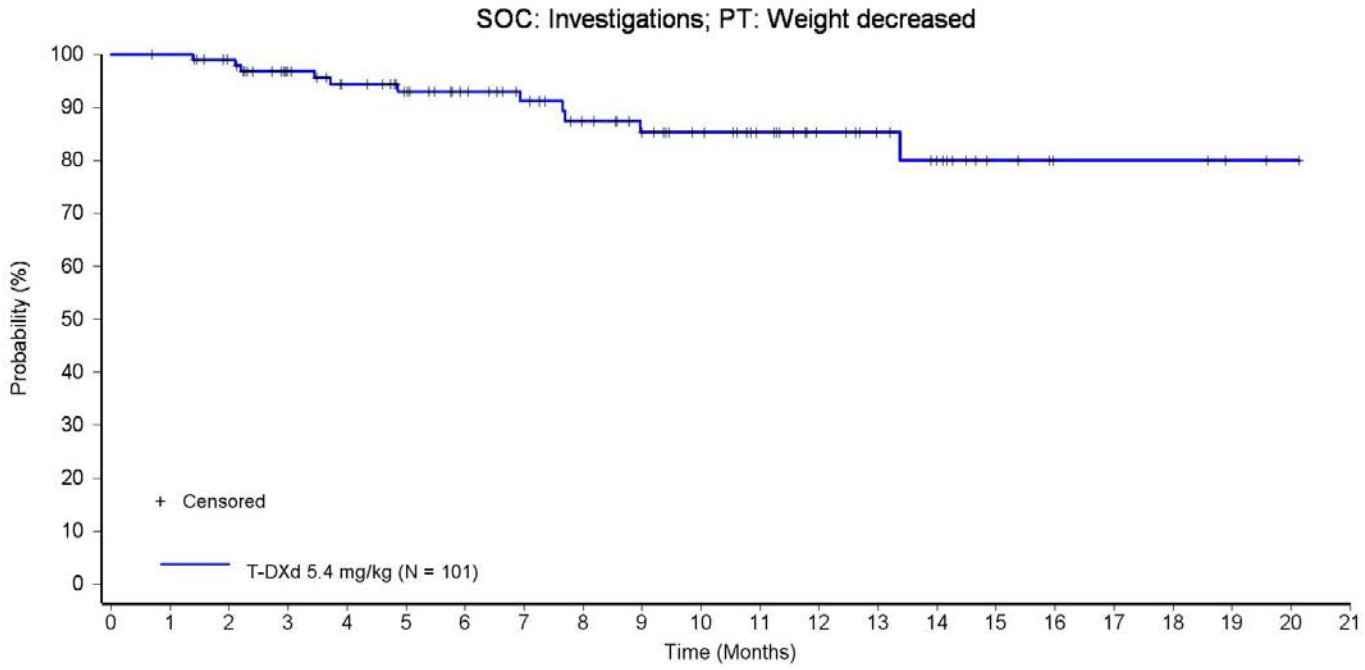
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

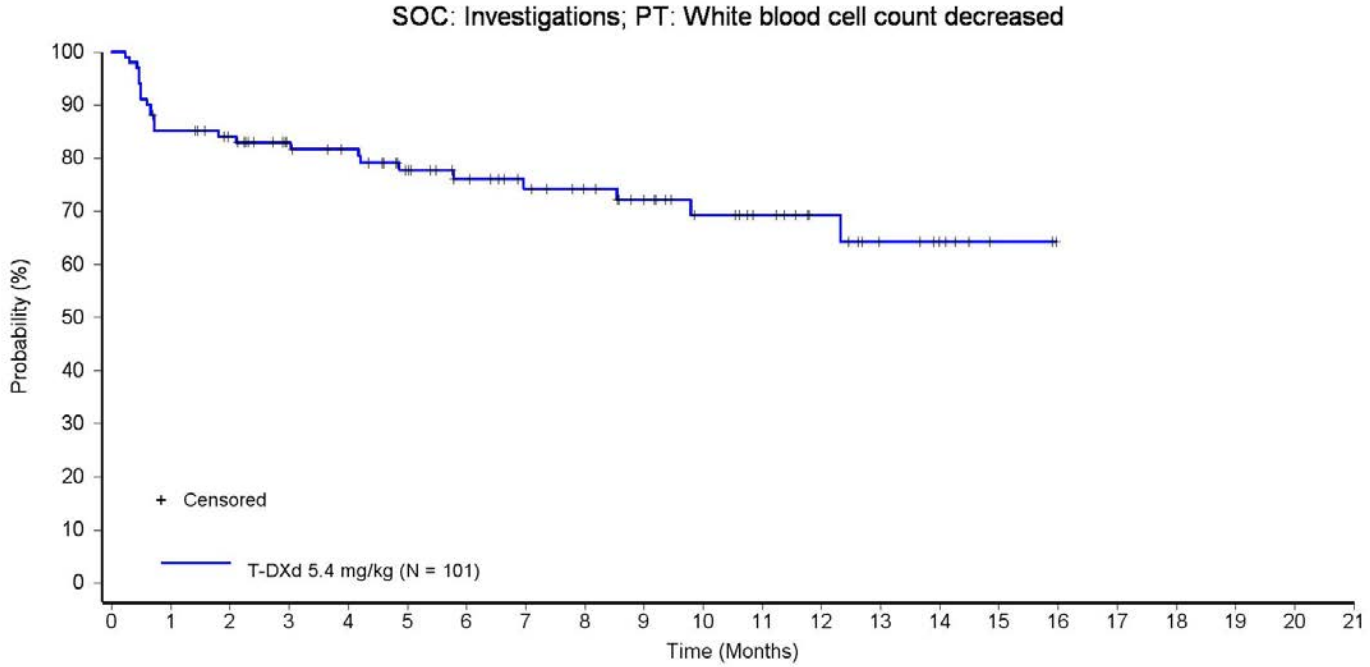


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	100	92	80	73	66	58	52	45	40	34	28	21	17	13	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

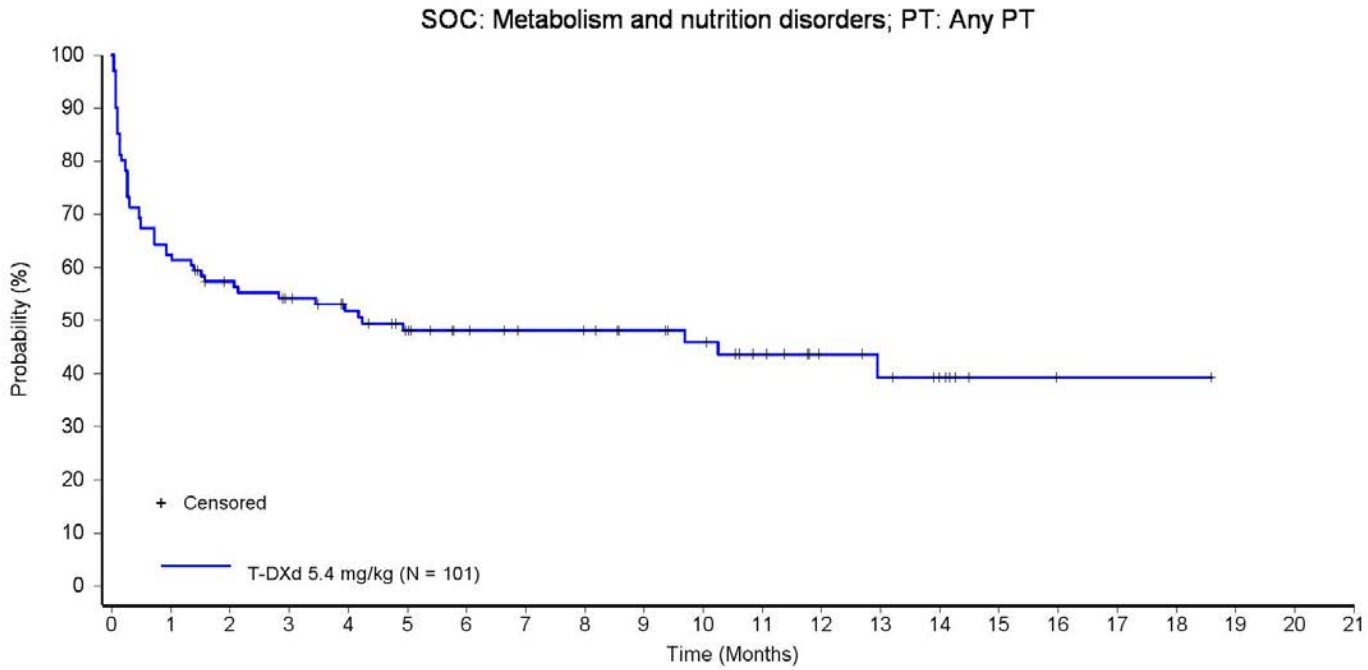


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	85	77	67	63	54	46	40	36	31	23	19	14	9	6	2	0	0	0	0	0	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	63	54	49	43	36	31	28	27	24	21	16	11	9	6	2	1	1	1	0	0	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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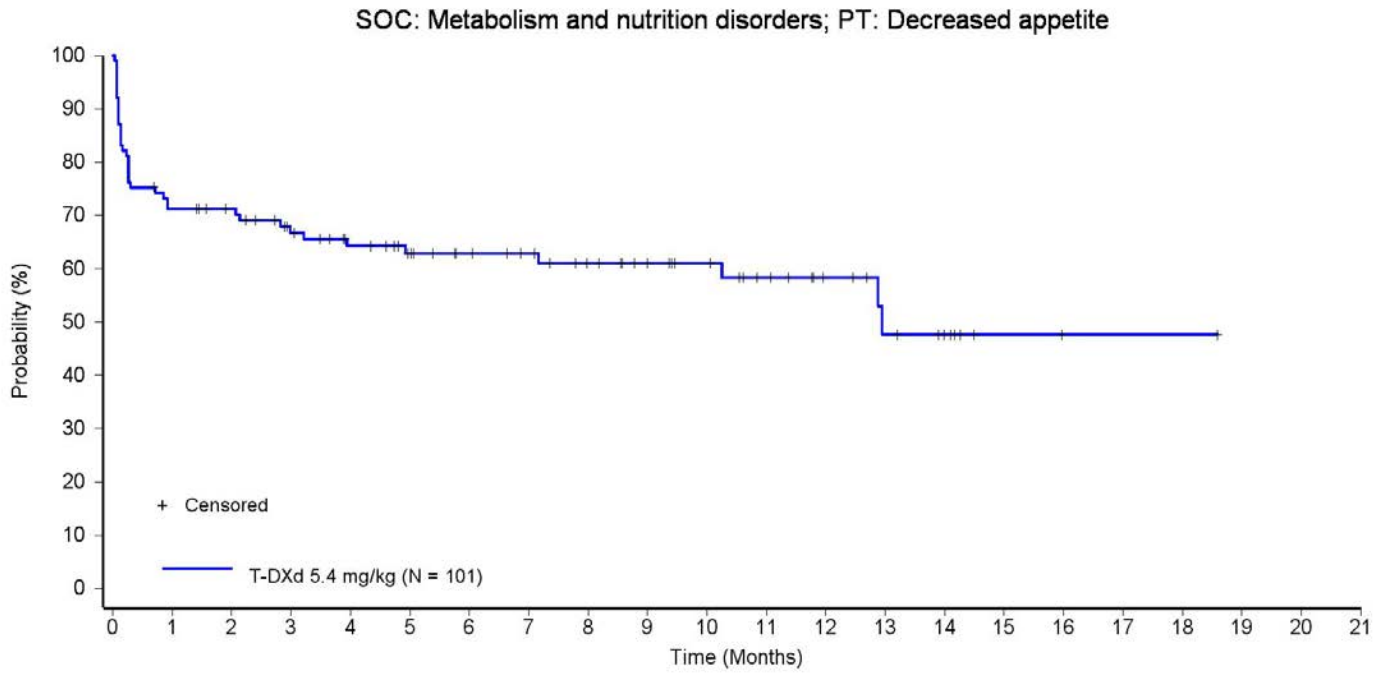
DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

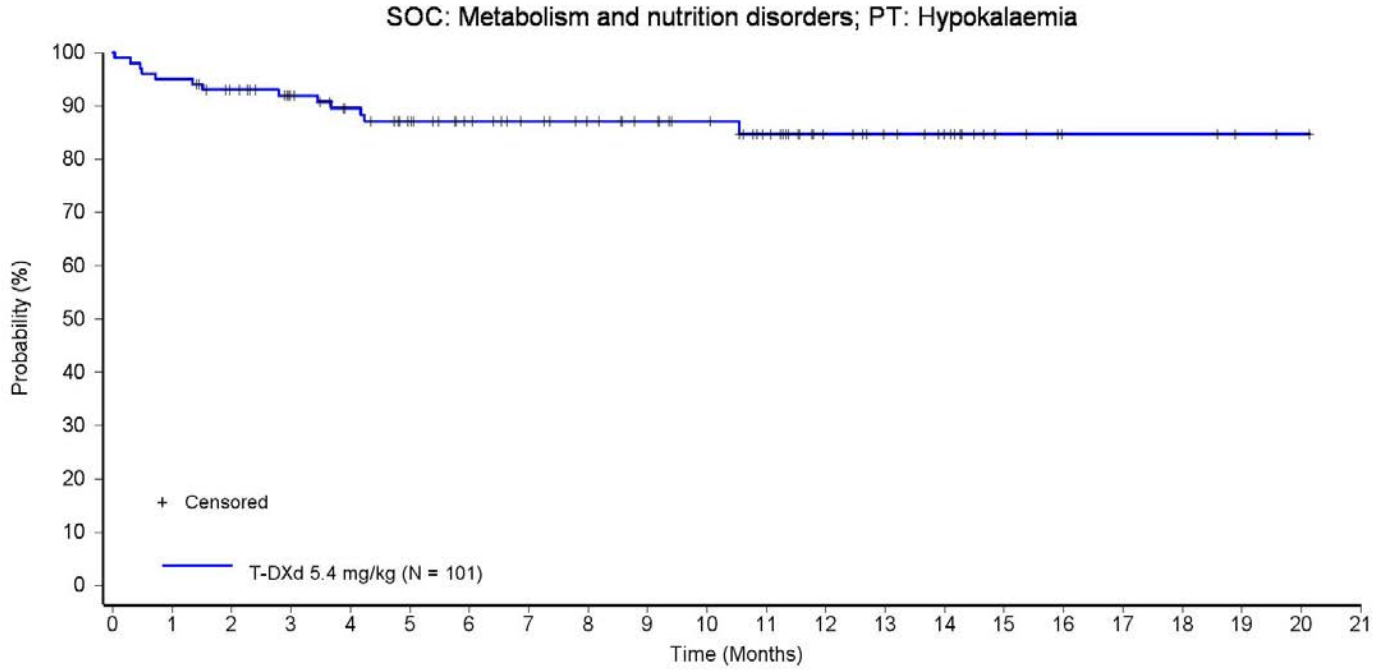


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	71	66	57	50	44	39	36	31	27	23	18	13	9	6	2	1	1	1	0	0	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

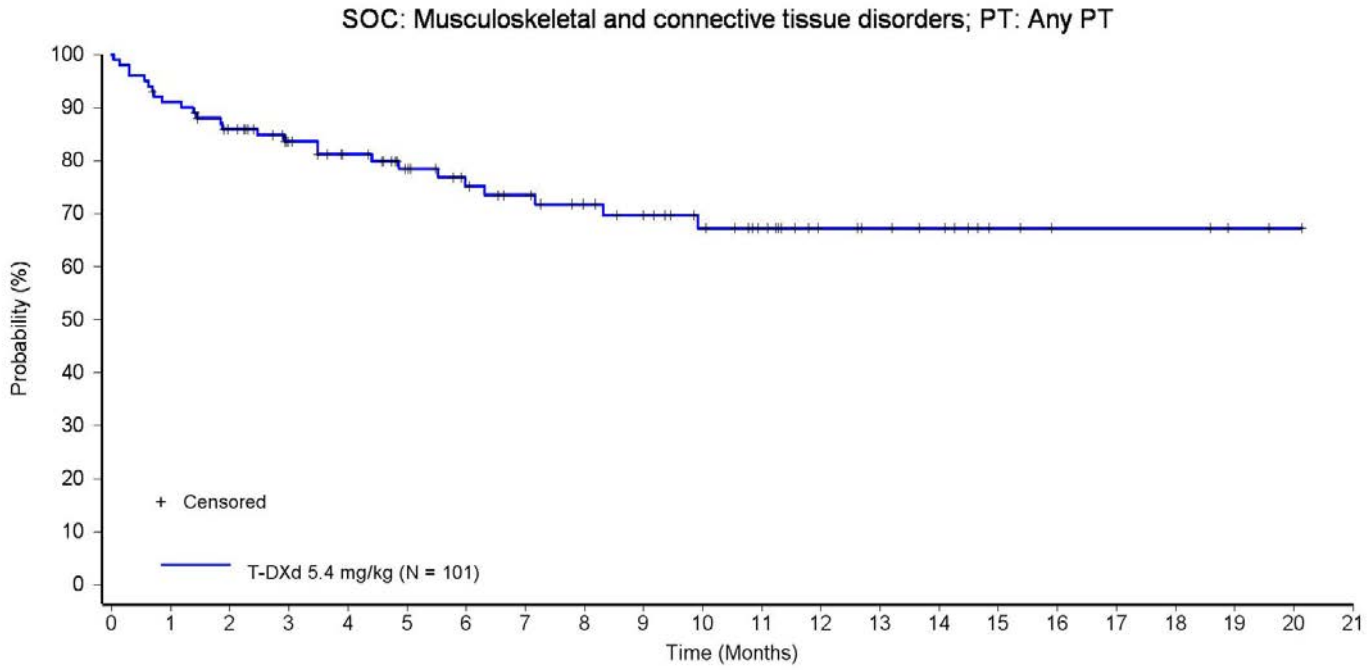


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	96	88	79	72	65	57	52	48	44	39	32	22	18	14	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

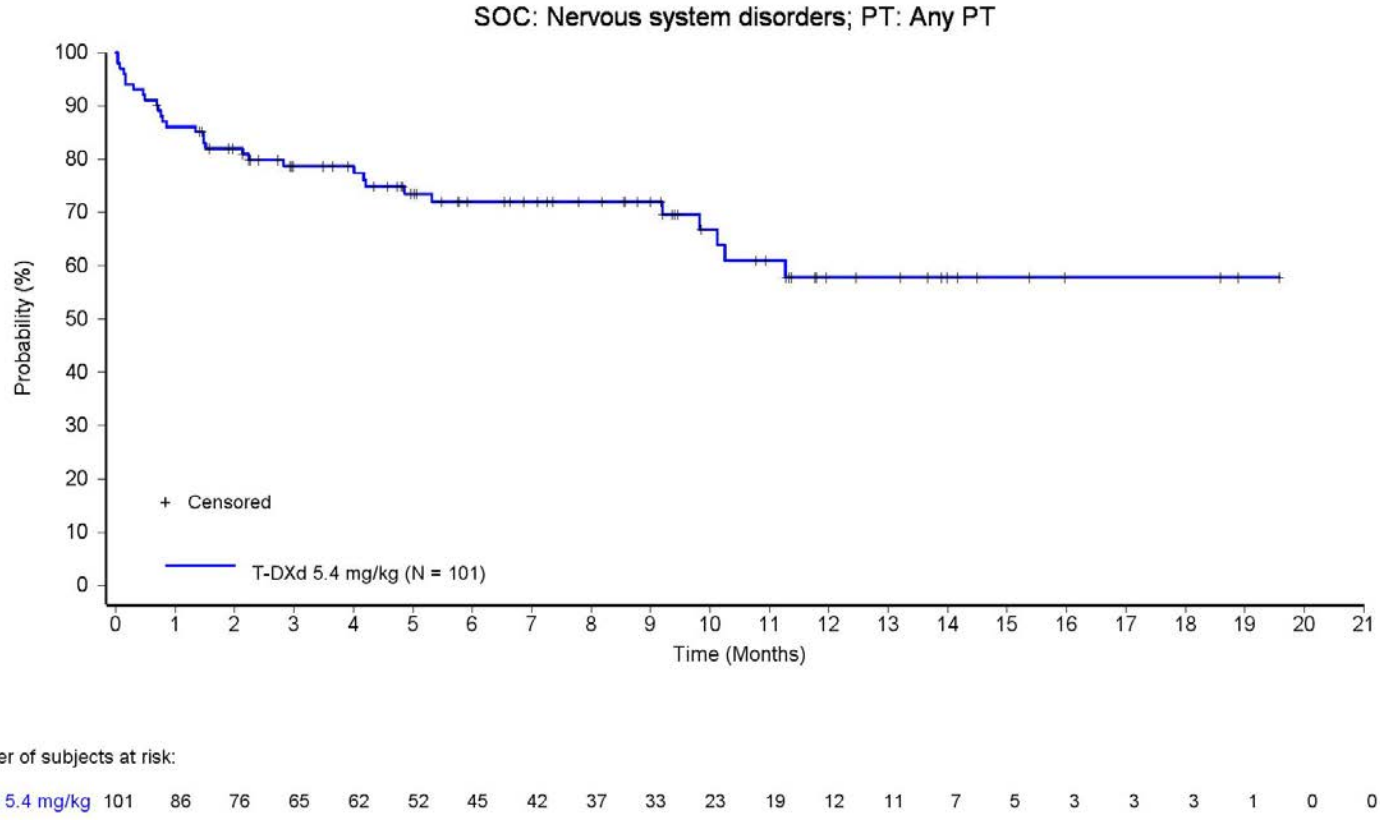


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	91	81	69	62	53	46	42	36	33	27	22	15	13	11	6	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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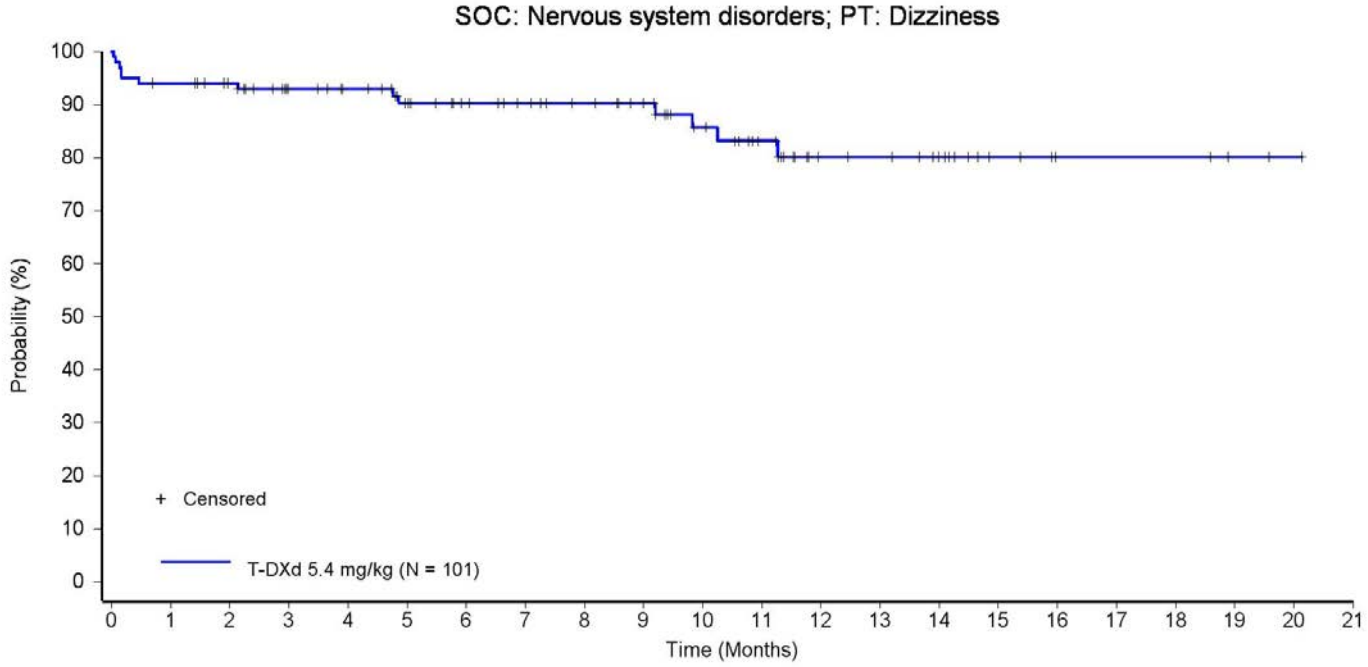
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

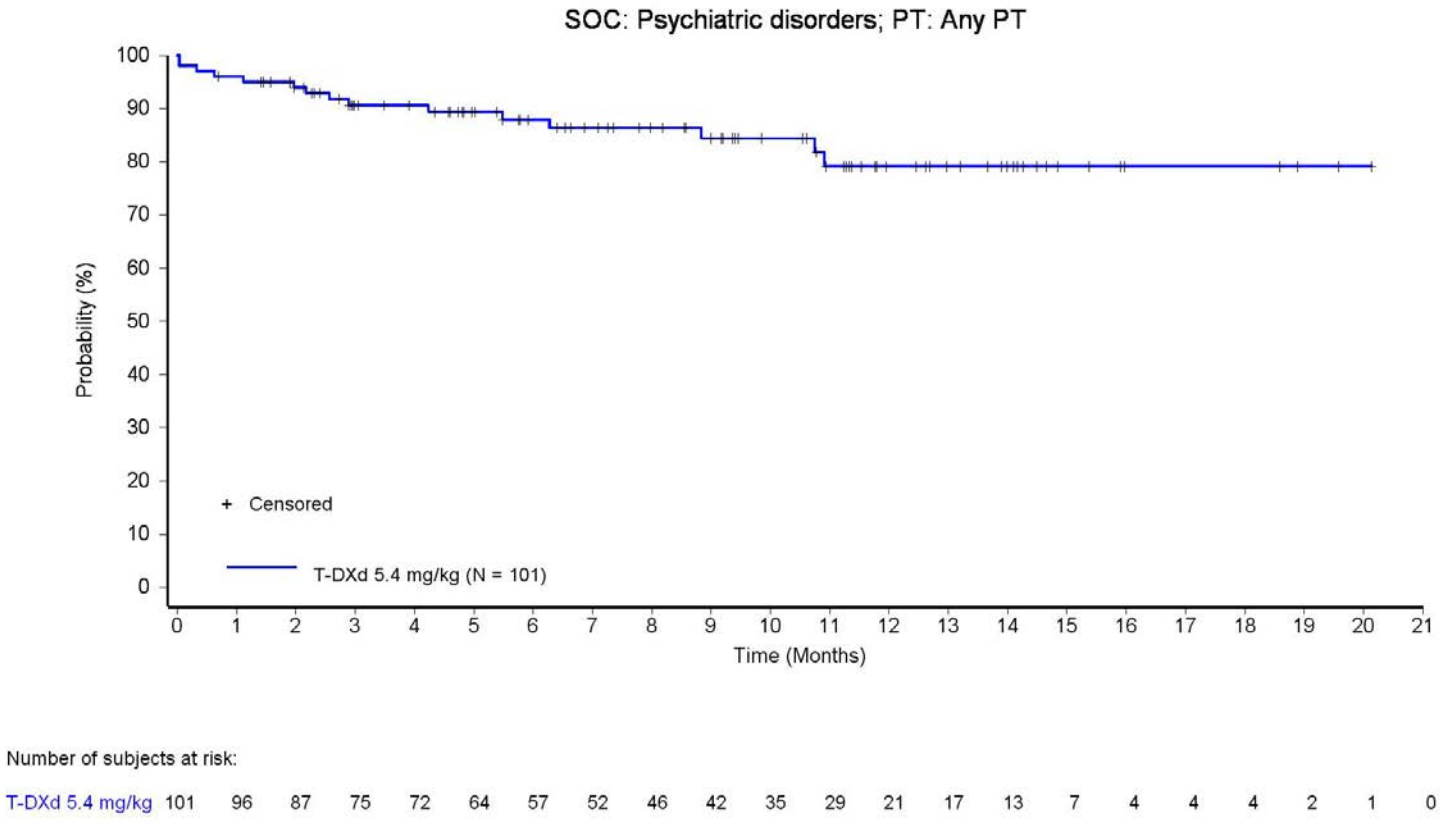


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	94	87	77	73	65	58	54	49	45	35	28	18	17	13	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



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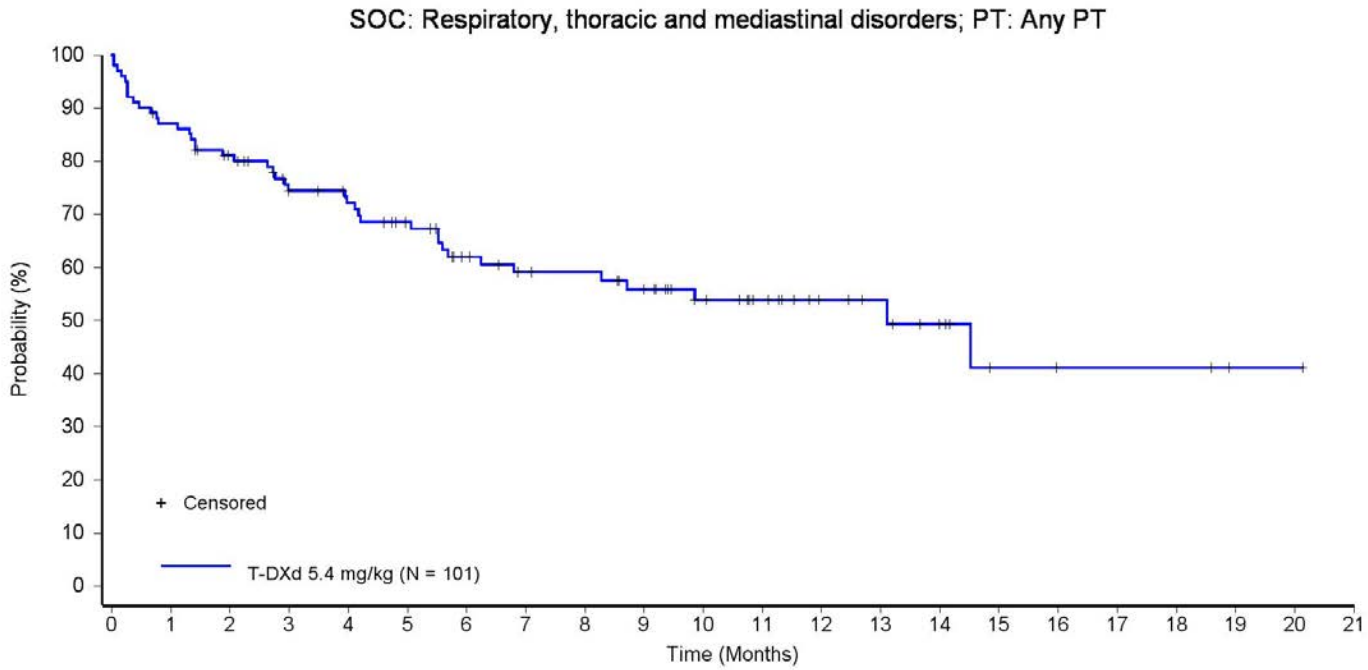
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

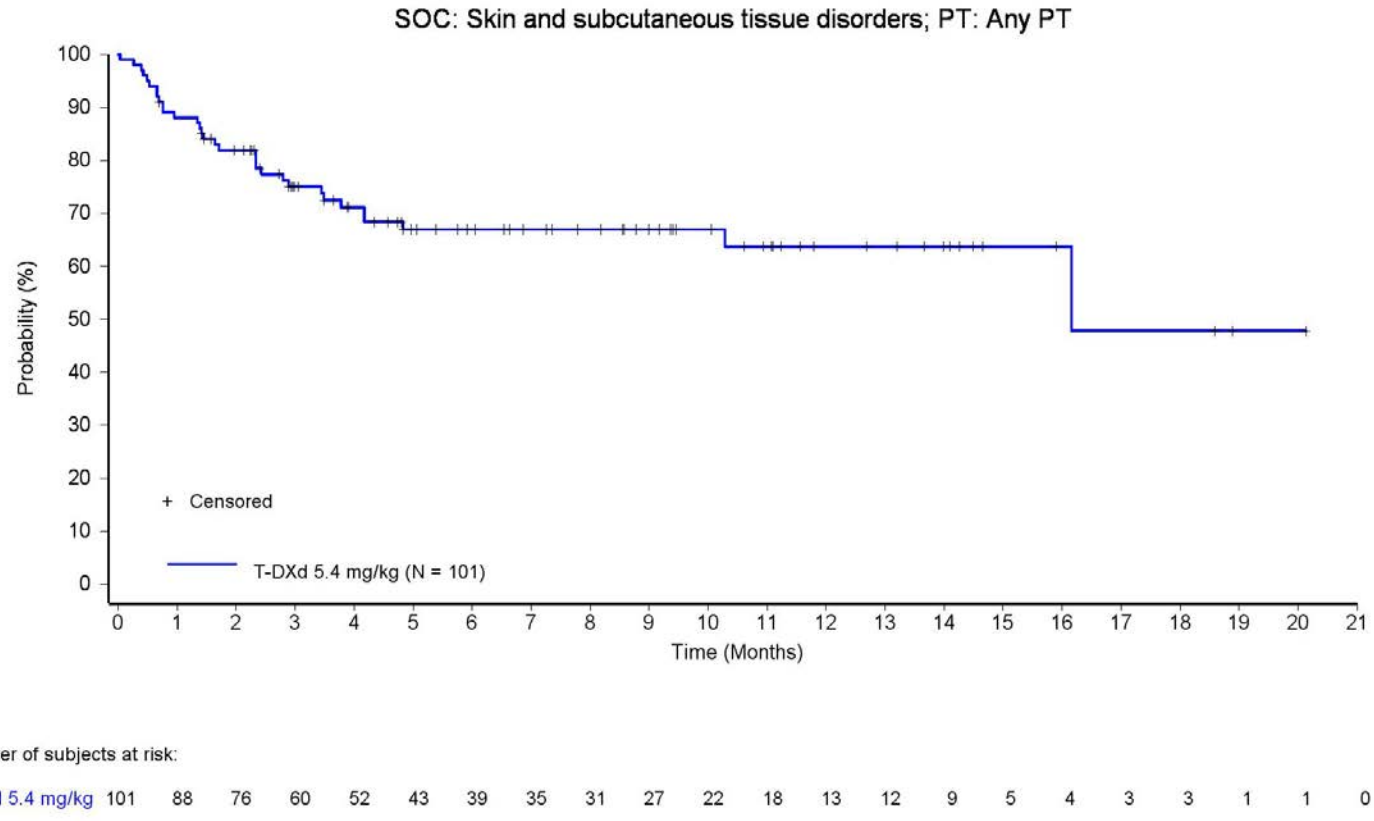


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	87	77	65	61	54	44	39	38	34	25	20	14	12	8	4	3	3	3	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

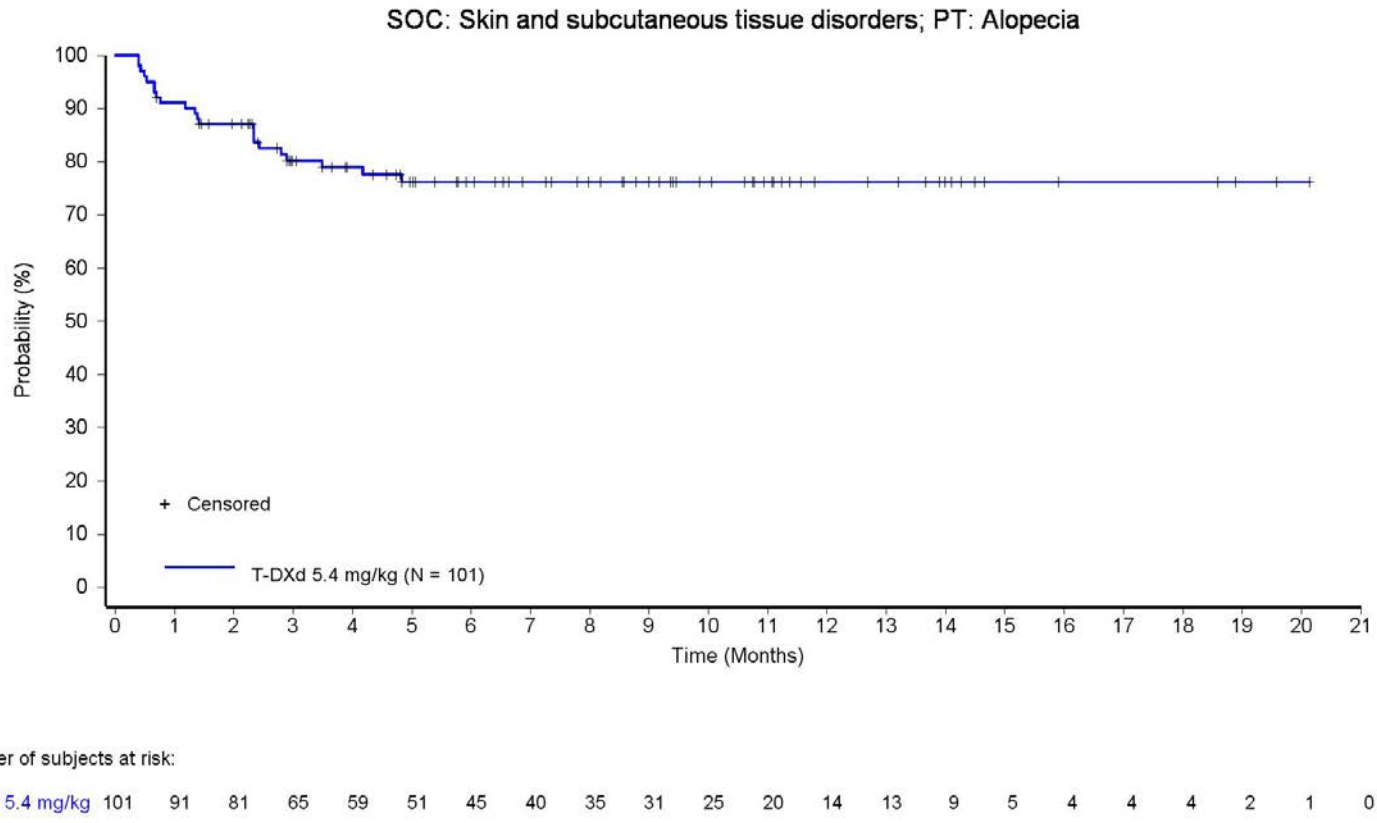


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	88	76	60	52	43	39	35	31	27	22	18	13	12	9	5	4	3	3	1	1	0

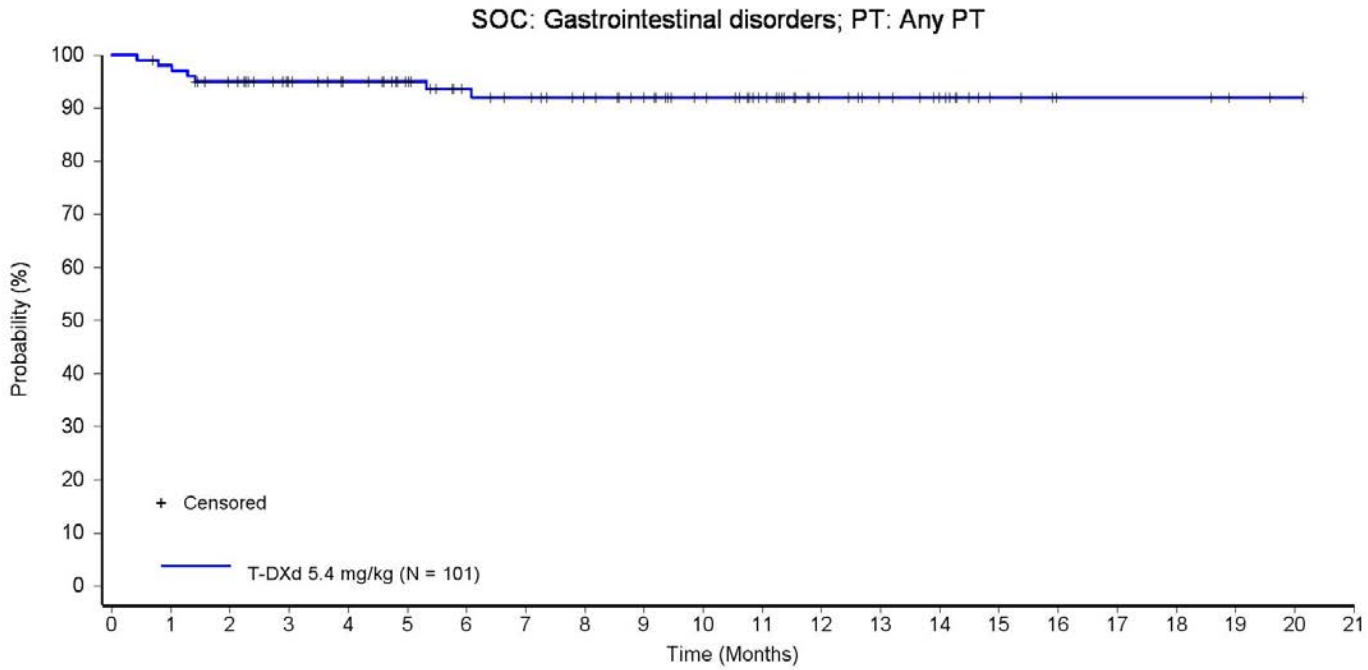
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.7.2 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESOCPT10PER_2_SAS.rtf

DE.F.4.8.2 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

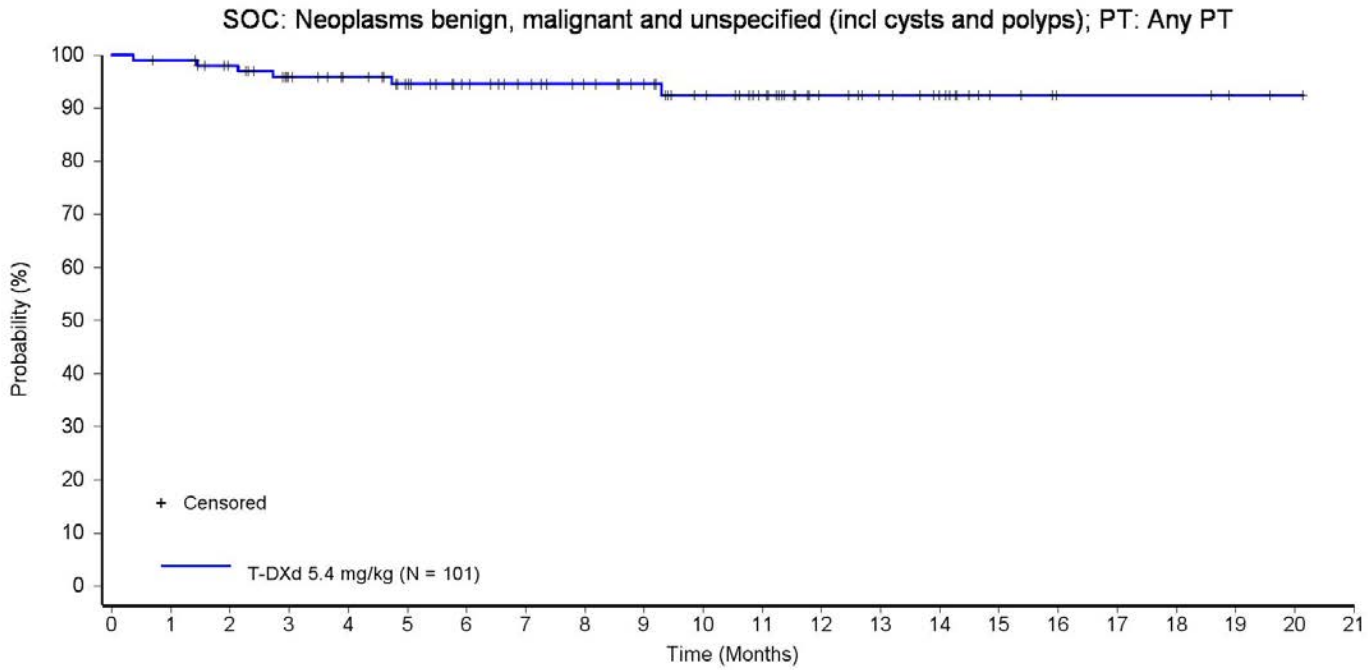


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	98	90	81	76	69	60	57	51	47	39	32	22	18	14	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_SAESOCPT5PER_2_SAS.rtf

DE.F.4.8.2 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

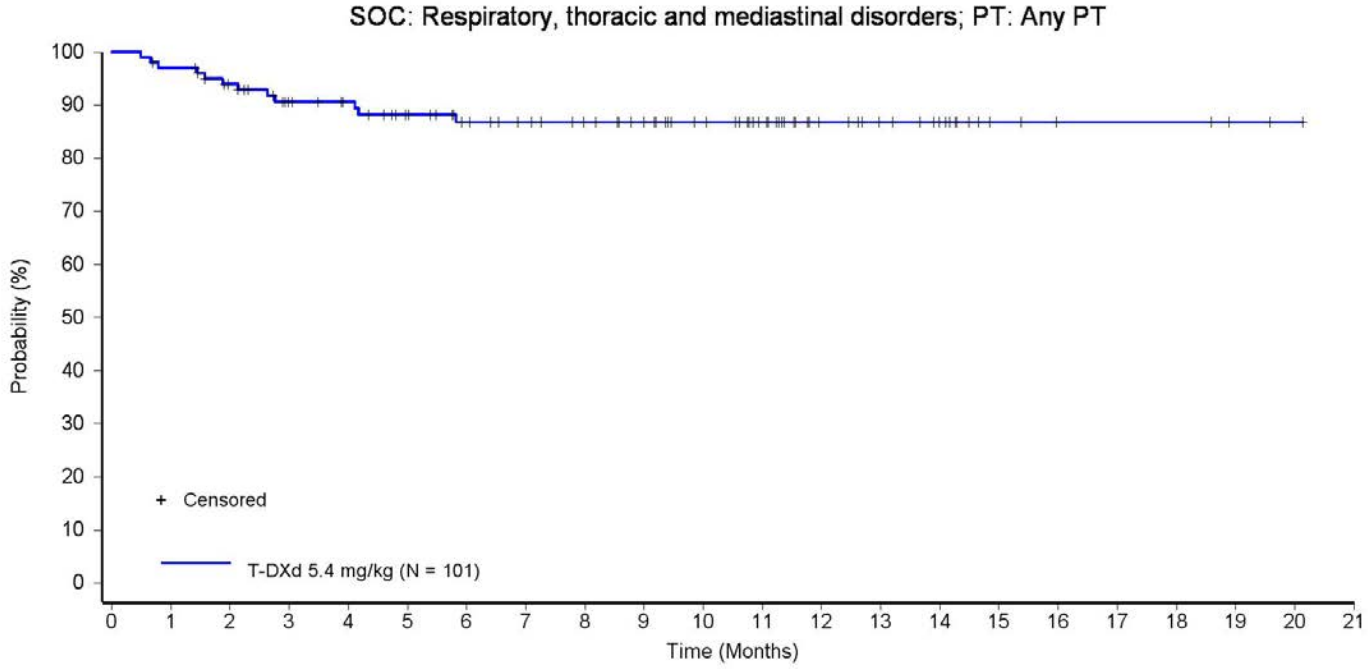


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	99	92	83	78	71	63	58	52	48	39	33	22	18	14	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_SAESOCPT5PER_2_SAS.rtf

DE.F.4.8.2 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

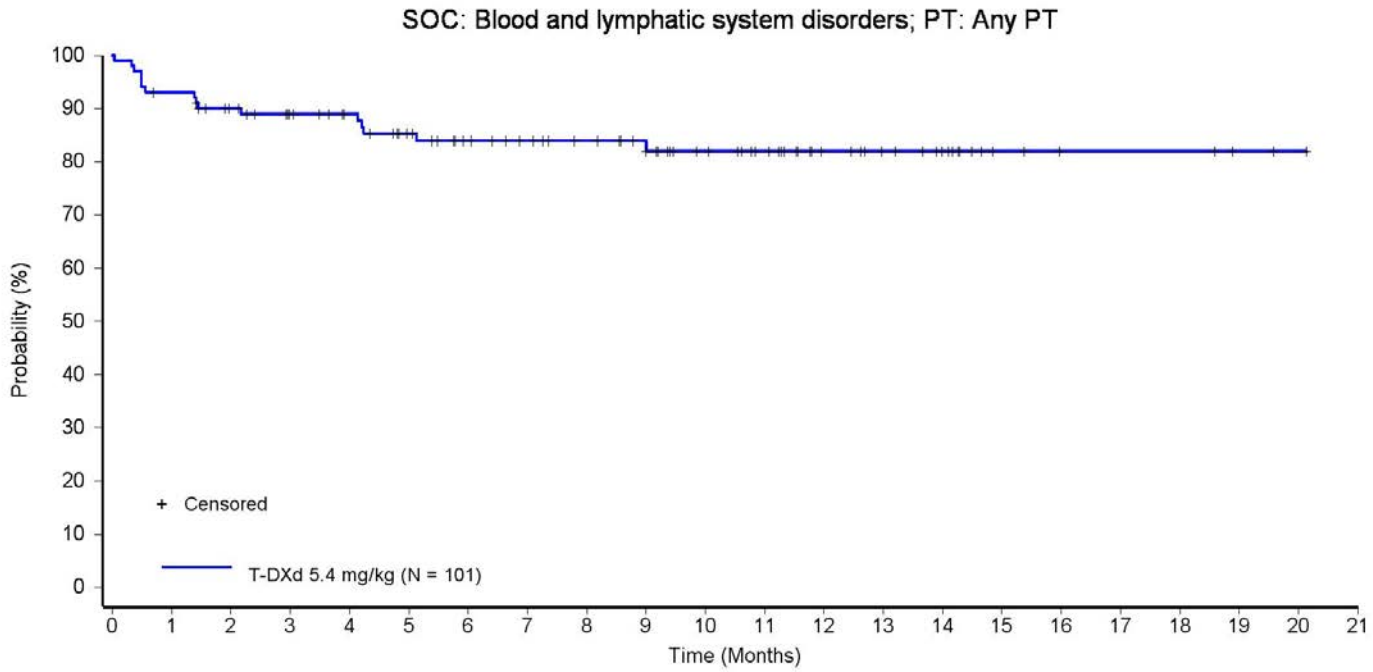


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	97	88	78	74	67	59	55	51	47	39	32	21	17	13	6	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_SAESOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

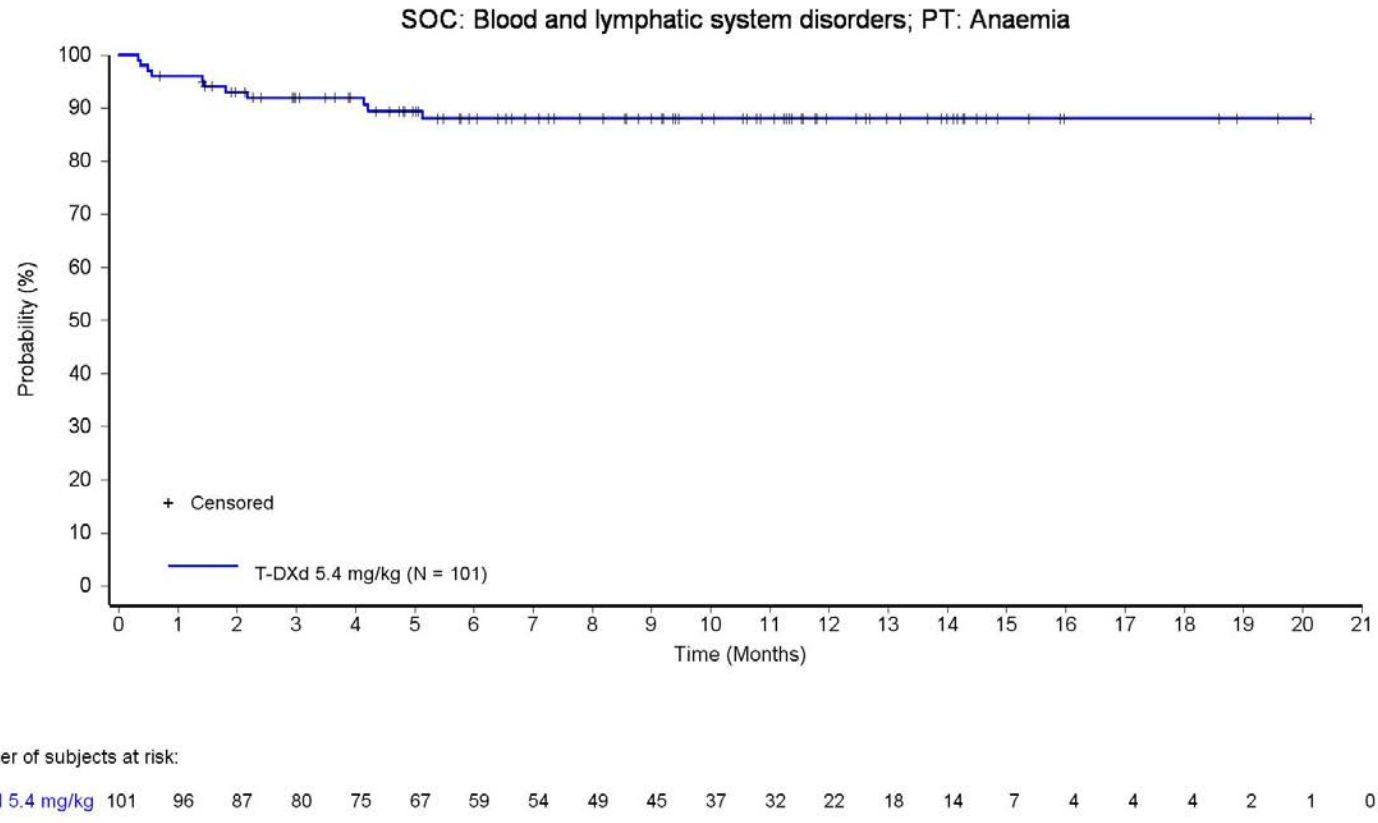


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	93	84	77	72	64	57	53	48	44	35	30	21	17	13	6	4	4	4	2	1	0

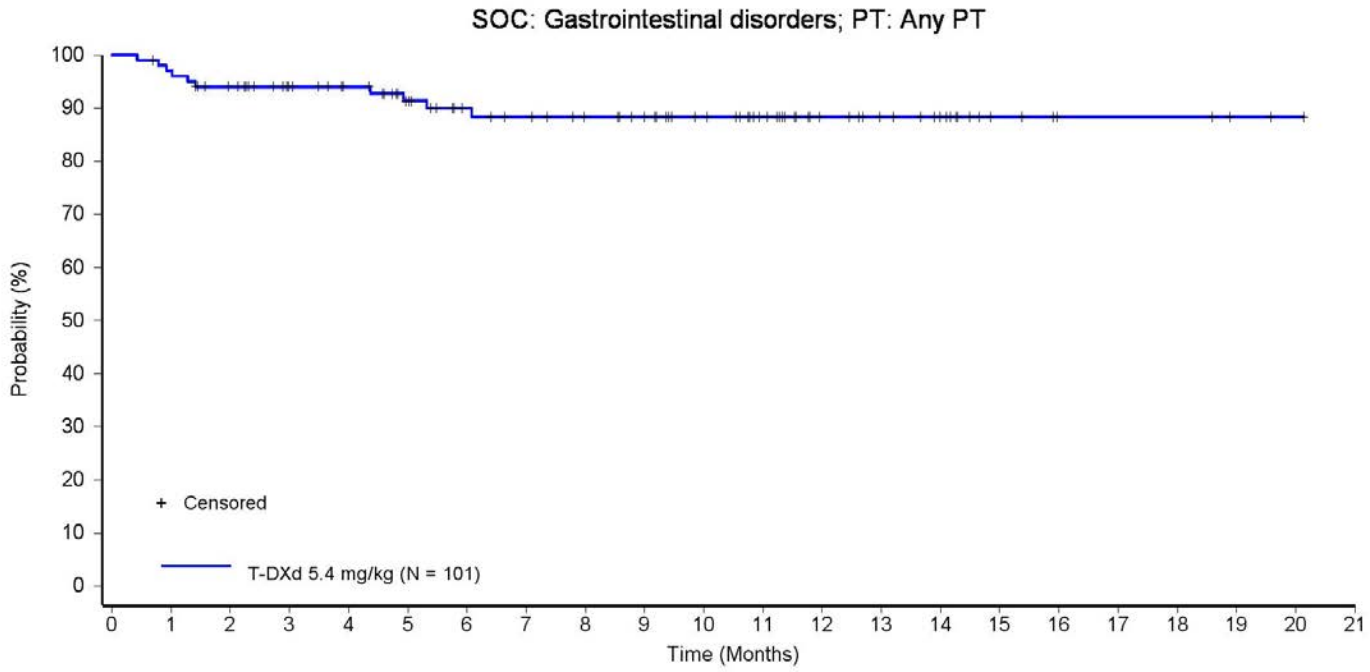
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

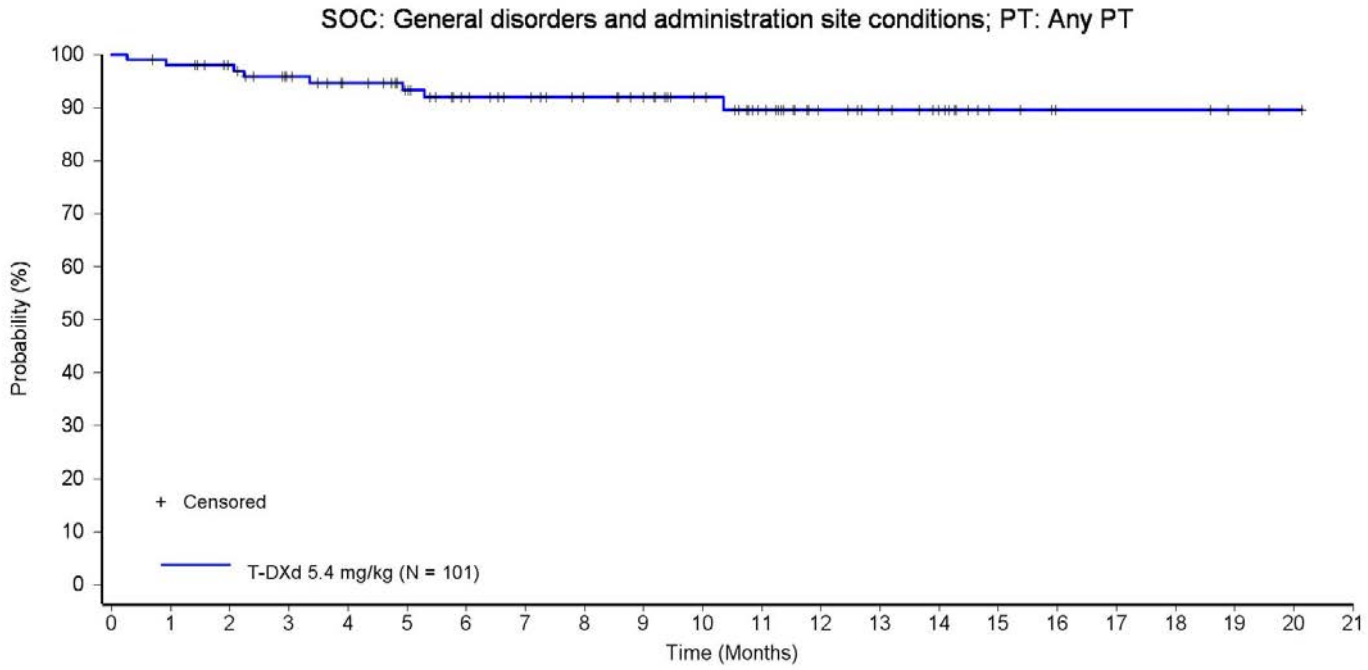


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	97	89	80	75	66	58	55	50	47	39	32	22	18	14	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

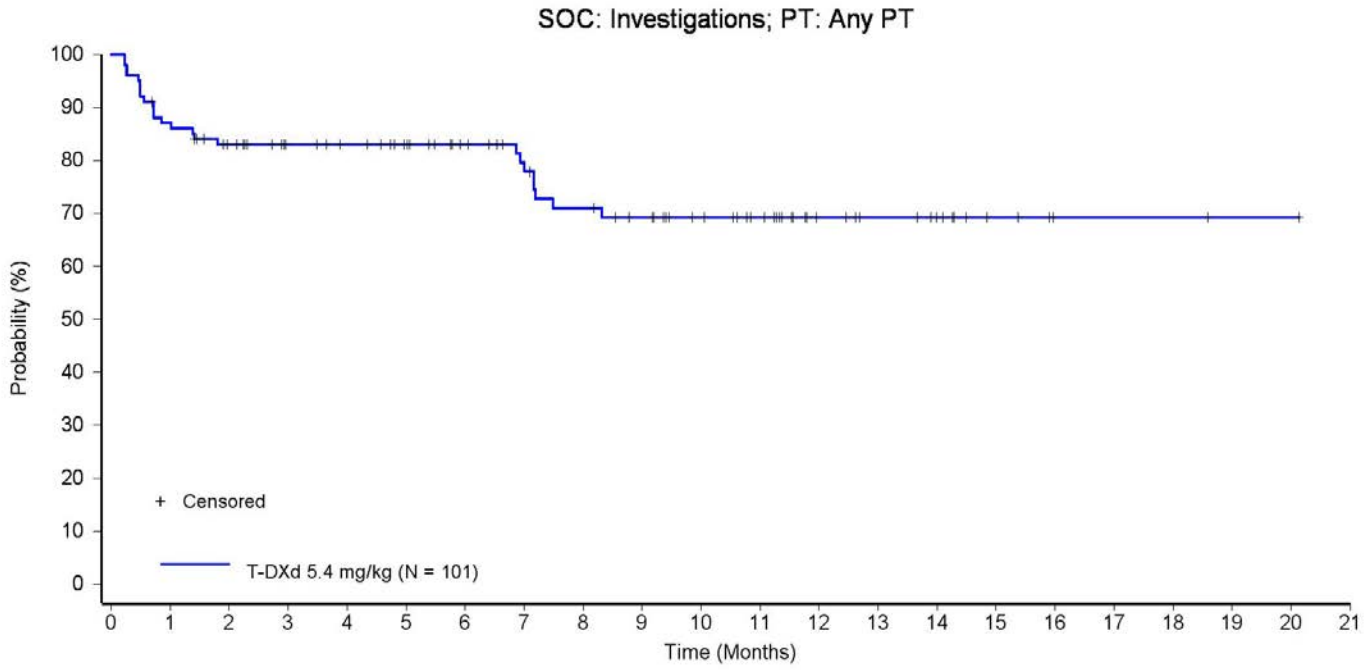


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	98	91	83	77	70	61	57	51	48	40	32	22	18	14	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

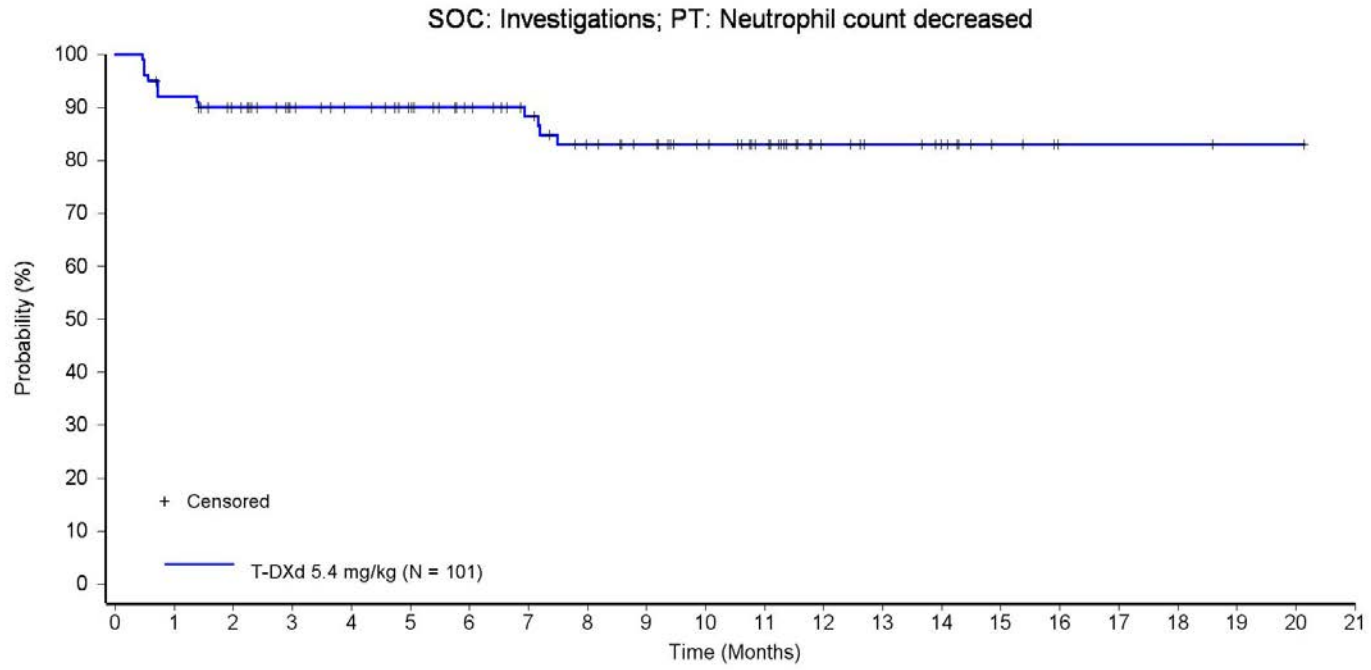


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	87	77	69	66	61	53	46	41	37	31	26	16	13	10	5	2	2	2	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

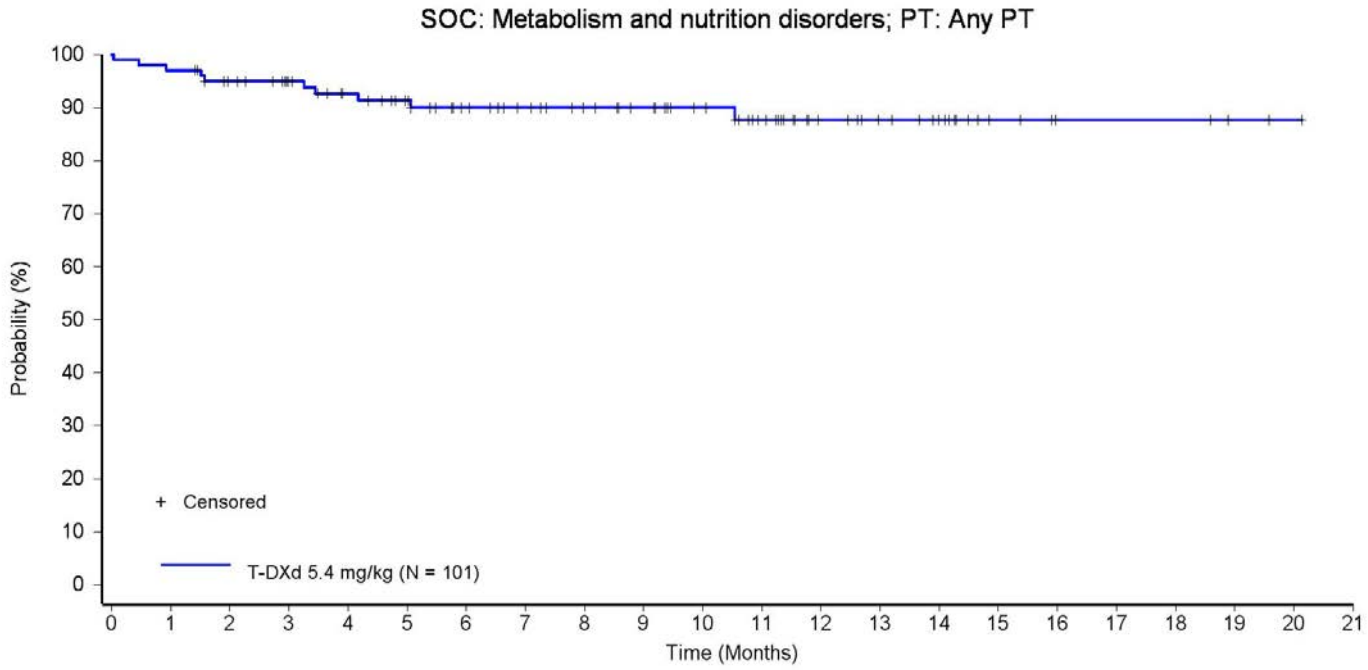


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	92	83	74	70	65	57	51	44	40	33	27	16	13	10	5	2	2	2	1	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

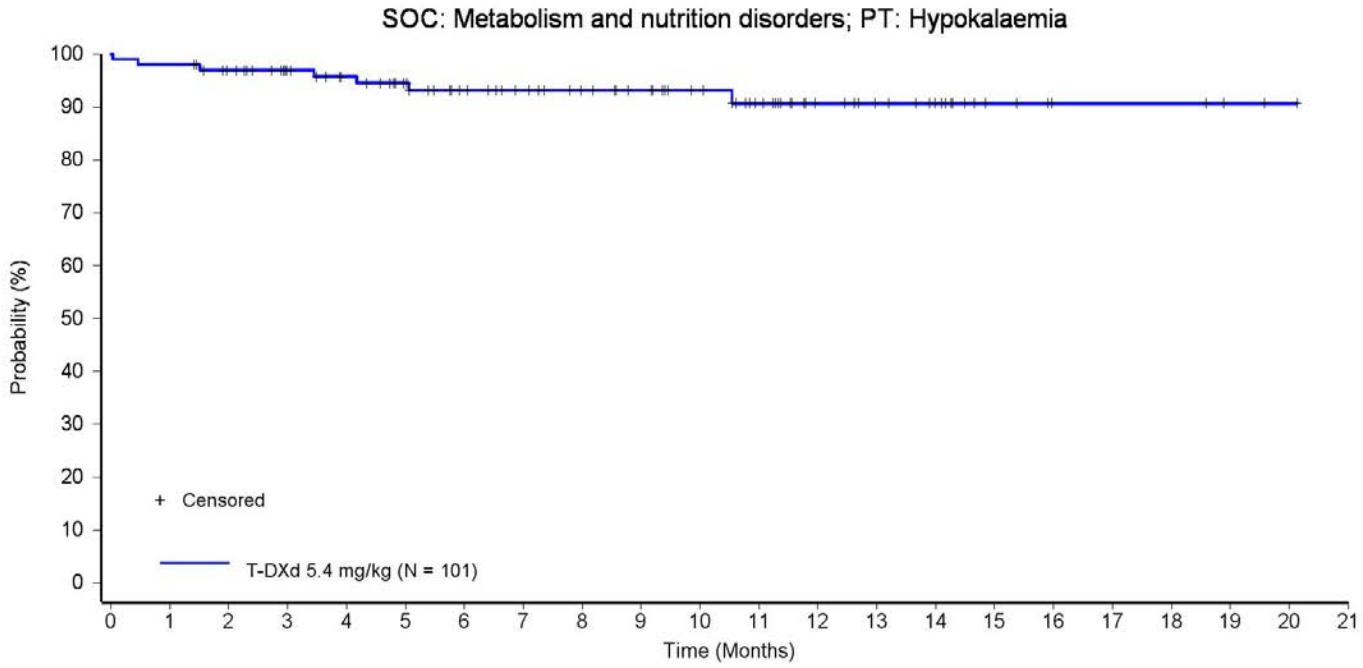


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	98	89	82	75	69	60	55	50	46	39	32	22	18	14	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

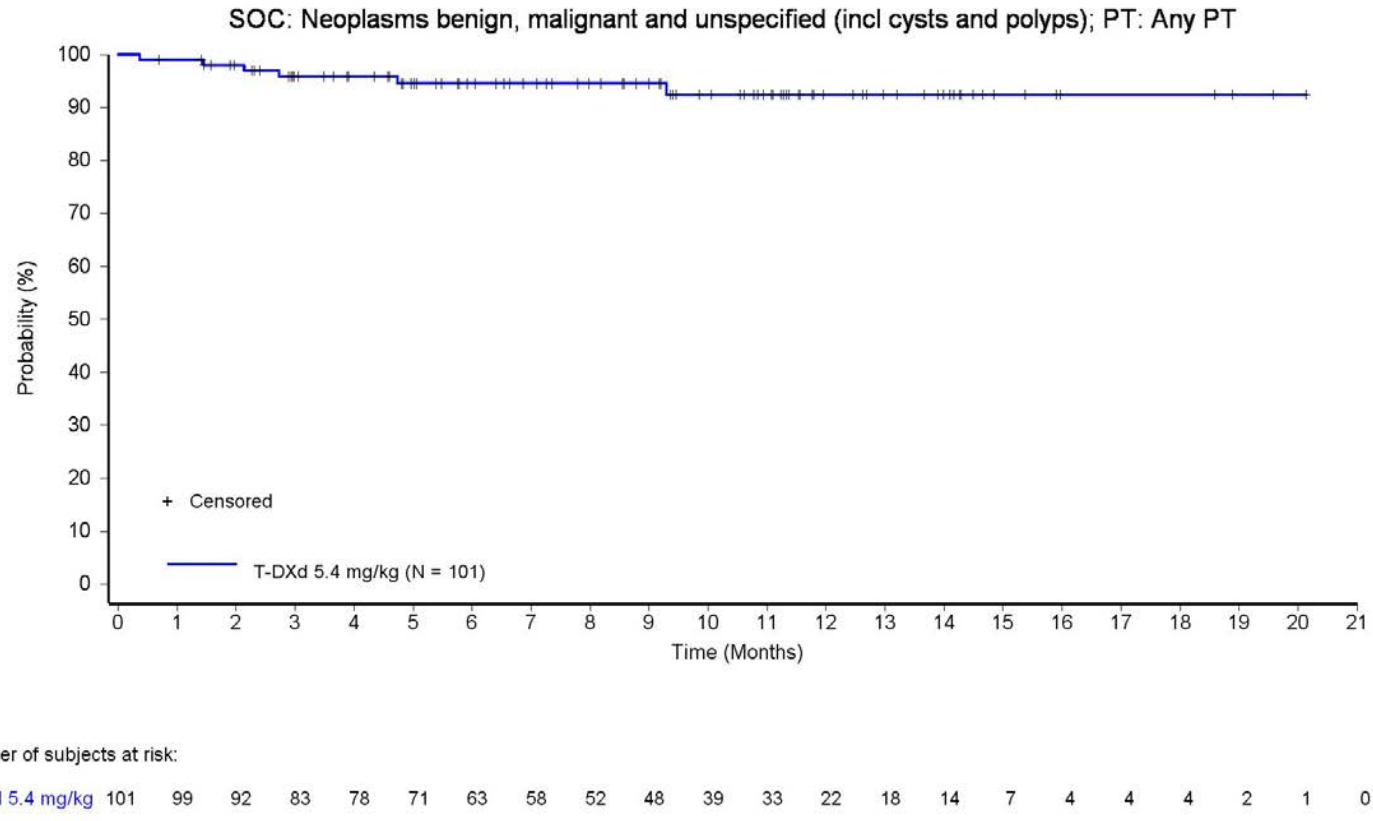


Number of subjects at risk:

T-DXd 5.4 mg/kg	101	99	91	82	76	69	60	55	50	46	39	32	22	18	14	7	4	4	4	2	1	0

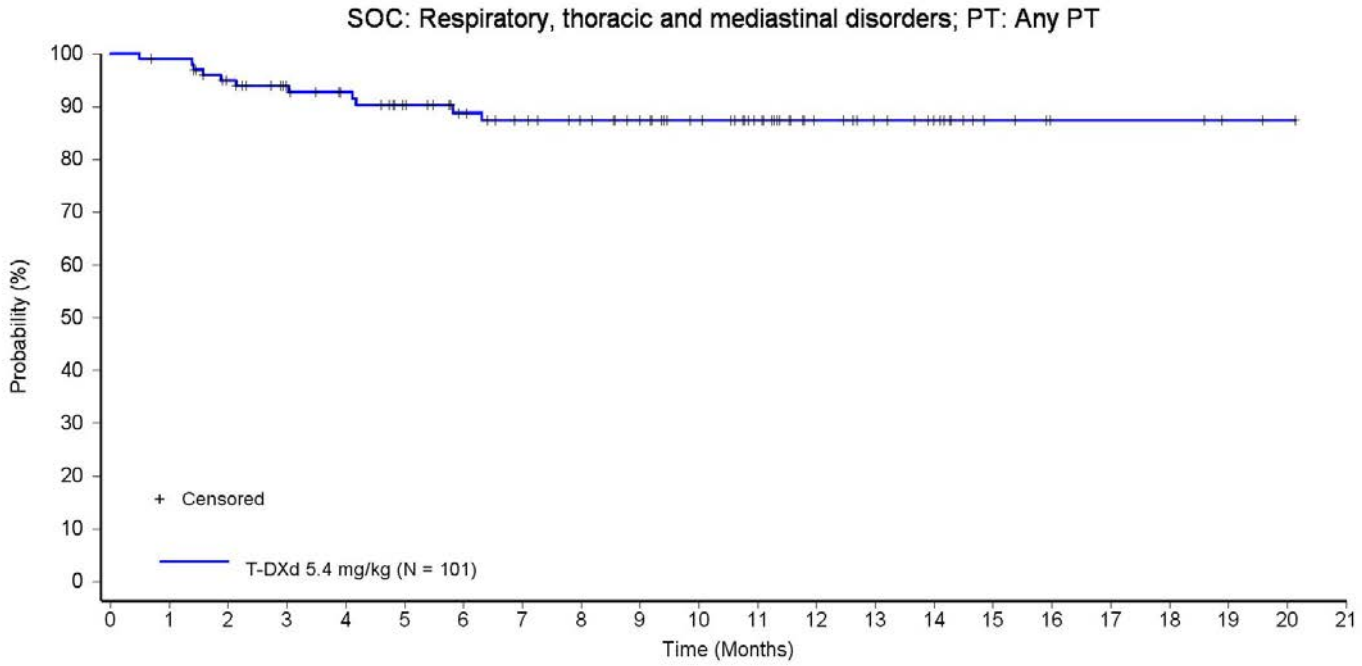
Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

DE.F.4.9.2 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Kaplan-Meier plot - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set



Number of subjects at risk:

T-DXd 5.4 mg/kg	101	99	89	81	76	69	61	56	52	48	40	33	22	18	14	7	4	4	4	2	1	0

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: f4_aesocpt10per_2_sas.sas; Output name: F4_AESEVSOCPT5PER_2_SAS.rtf

Anhang 4-G 4.4.2 Subgruppenanalysen – Unerwünschte Ereignisse nach SOC und PT

Anhang 4-G 4.4.2.1 Datenschnitt vom 24.03.2022

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	30 (40.5)	44 (59.5)	4.8 (2.2, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	15 (45.5)	18 (54.5)	4.8 (0.7, NE)				
No	68	23 (33.8)	45 (66.2)	NE (4.2, NE)				
HER2 status								
Kinase domain	98	37 (37.8)	61 (62.2)	NE (4.1, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	16 (26.2)	45 (73.8)	NE (4.8, NE)				
>=65 years	40	22 (55.0)	18 (45.0)	2.2 (0.5, NE)				
Age II								
<75 years	93	34 (36.6)	59 (63.4)	NE (4.1, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	27 (41.5)	38 (58.5)	4.8 (2.1, NE)				
Male	36	11 (30.6)	25 (69.4)	NE (2.9, NE)				
Smoking status								
Current	0							
Former	46	19 (41.3)	27 (58.7)	NE (1.4, NE)				
Never	55	19 (34.5)	36 (65.5)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	10 (43.5)	13 (56.5)	4.2 (0.7, NE)				
Non-White	78	28 (35.9)	50 (64.1)	NE (4.1, NE)				
Region								
Asia	62	20 (32.3)	42 (67.7)	NE (4.8, NE)				
North America and Australia	6							
Europe	33	13 (39.4)	20 (60.6)	NE (0.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	10 (41.7)	14 (58.3)	NE (0.7, NE)				
No	77	28 (36.4)	49 (63.6)	NE (3.5, NE)				
12-lead ECG								
Normal	60	21 (35.0)	39 (65.0)	NE (4.1, NE)				
Abnormal, not clinically significant	41	17 (41.5)	24 (58.5)	4.8 (1.4, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	34 (40.5)	50 (59.5)	NE (2.2, NE)				
Abnormal, not clinically significant	17	4 (23.5)	13 (76.5)	NE (4.8, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	11 (36.7)	19 (63.3)	NE (0.7, NE)				
1	71	27 (38.0)	44 (62.0)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	12 (32.4)	25 (67.6)	NE (2.9, NE)				
Mild impairment	40	12 (30.0)	28 (70.0)	NE (4.2, NE)				
Moderate impairment	22	13 (59.1)	9 (40.9)	0.7 (0.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	29 (38.2)	47 (61.8)	NE (3.5, NE)				
Mild hepatic dysfunction	25	9 (36.0)	16 (64.0)	NE (0.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	26 (35.1)	48 (64.9)	NE (4.2, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	13 (39.4)	20 (60.6)	4.8 (0.7, NE)				
No	68	21 (30.9)	47 (69.1)	NE (4.2, NE)				
HER2 status								
Kinase domain	98	33 (33.7)	65 (66.3)	NE (4.1, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	15 (24.6)	46 (75.4)	NE (NE, NE)				
>=65 years	40	19 (47.5)	21 (52.5)	4.1 (0.5, NE)				
Age II								
<75 years	93	31 (33.3)	62 (66.7)	NE (4.2, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	26 (40.0)	39 (60.0)	4.8 (3.5, NE)				
Male	36	8 (22.2)	28 (77.8)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	18 (39.1)	28 (60.9)	NE (2.2, NE)				
Never	55	16 (29.1)	39 (70.9)	NE (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	7 (30.4)	16 (69.6)	4.2 (4.1, NE)				
Non-White	78	27 (34.6)	51 (65.4)	NE (4.1, NE)				
Region								
Asia	62	20 (32.3)	42 (67.7)	NE (4.8, NE)				
North America and Australia	6							
Europe	33	10 (30.3)	23 (69.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	9 (37.5)	15 (62.5)	NE (1.4, NE)				
No	77	25 (32.5)	52 (67.5)	NE (4.1, NE)				
12-lead ECG								
Normal	60	19 (31.7)	41 (68.3)	NE (4.1, NE)				
Abnormal, not clinically significant	41	15 (36.6)	26 (63.4)	NE (3.5, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	31 (36.9)	53 (63.1)	NE (4.1, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (4.8, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	10 (33.3)	20 (66.7)	NE (3.5, NE)				
1	71	24 (33.8)	47 (66.2)	NE (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	10 (27.0)	27 (73.0)	NE (3.5, NE)				
Mild impairment	40	11 (27.5)	29 (72.5)	NE (4.2, NE)				
Moderate impairment	22	12 (54.5)	10 (45.5)	4.1 (0.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	26 (34.2)	50 (65.8)	NE (4.1, NE)				
Mild hepatic dysfunction	25	8 (32.0)	17 (68.0)	NE (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	60 (81.1)	14 (18.9)	0.2 (0.1, 0.3)				
Subjects who received neither	27	22 (81.5)	5 (18.5)	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	25 (75.8)	8 (24.2)	0.2 (0.1, 0.5)				
No	68	57 (83.8)	11 (16.2)	0.1 (0.1, 0.3)				
HER2 status								
Kinase domain	98	80 (81.6)	18 (18.4)	0.2 (0.1, 0.3)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	48 (78.7)	13 (21.3)	0.2 (0.1, 0.3)				
>=65 years	40	34 (85.0)	6 (15.0)	0.2 (0.1, 0.3)				
Age II								
<75 years	93	76 (81.7)	17 (18.3)	0.2 (0.1, 0.3)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	55 (84.6)	10 (15.4)	0.2 (0.1, 0.3)				
Male	36	27 (75.0)	9 (25.0)	0.1 (0.1, 0.4)				
Smoking status								
Current	0							
Former	46	35 (76.1)	11 (23.9)	0.2 (0.1, 0.3)				
Never	55	47 (85.5)	8 (14.5)	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	18 (78.3)	5 (21.7)	0.3 (0.1, 1.1)				
Non-White	78	64 (82.1)	14 (17.9)	0.1 (0.1, 0.2)				
Region								
Asia	62	53 (85.5)	9 (14.5)	0.1 (0.1, 0.2)				
North America and Australia	6							
Europe	33	24 (72.7)	9 (27.3)	0.3 (0.1, 1.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	19 (79.2)	5 (20.8)	0.2 (0.1, 1.6)				
No	77	63 (81.8)	14 (18.2)	0.1 (0.1, 0.3)				
12-lead ECG								
Normal	60	50 (83.3)	10 (16.7)	0.1 (0.1, 0.3)				
Abnormal, not clinically significant	41	32 (78.0)	9 (22.0)	0.2 (0.1, 0.4)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	69 (82.1)	15 (17.9)	0.2 (0.1, 0.3)				
Abnormal, not clinically significant	17	13 (76.5)	4 (23.5)	0.1 (0.1, 1.7)				
Clinically significant findings	0							
ECOG performance status								
0	30	21 (70.0)	9 (30.0)	0.1 (0.1, 0.8)				
1	71	61 (85.9)	10 (14.1)	0.2 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	30 (81.1)	7 (18.9)	0.2 (0.1, 0.4)				
Mild impairment	40	30 (75.0)	10 (25.0)	0.3 (0.1, 1.1)				
Moderate impairment	22	21 (95.5)	1 (4.5)	0.1 (0.1, 0.1)				
Hepatic function at baseline								
Normal hepatic function	76	63 (82.9)	13 (17.1)	0.1 (0.1, 0.3)				
Mild hepatic dysfunction	25	19 (76.0)	6 (24.0)	0.3 (0.1, 1.7)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	19 (25.7)	55 (74.3)	NE (6.0, NE)				
Subjects who received neither	27	12 (44.4)	15 (55.6)	NE (0.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	10 (30.3)	23 (69.7)	NE (6.0, NE)				
No	68	21 (30.9)	47 (69.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	31 (31.6)	67 (68.4)	NE (6.0, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	16 (26.2)	45 (73.8)	NE (NE, NE)				
>=65 years	40	15 (37.5)	25 (62.5)	NE (2.1, NE)				
Age II								
<75 years	93	28 (30.1)	65 (69.9)	NE (6.0, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	20 (30.8)	45 (69.2)	NE (NE, NE)				
Male	36	11 (30.6)	25 (69.4)	NE (3.1, NE)				
Smoking status								
Current	0							
Former	46	13 (28.3)	33 (71.7)	NE (NE, NE)				
Never	55	18 (32.7)	37 (67.3)	NE (6.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	NE (NE, NE)				
Non-White	78	26 (33.3)	52 (66.7)	NE (6.0, NE)				
Region								
Asia	62	22 (35.5)	40 (64.5)	NE (6.0, NE)				
North America and Australia	6							
Europe	33	6 (18.2)	27 (81.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	8 (33.3)	16 (66.7)	6.0 (1.6, NE)				
No	77	23 (29.9)	54 (70.1)	NE (NE, NE)				
12-lead ECG								
Normal	60	20 (33.3)	40 (66.7)	NE (6.0, NE)				
Abnormal, not clinically significant	41	11 (26.8)	30 (73.2)	NE (3.1, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	24 (28.6)	60 (71.4)	NE (6.0, NE)				
Abnormal, not clinically significant	17	7 (41.2)	10 (58.8)	NE (0.1, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	7 (23.3)	23 (76.7)	NE (NE, NE)				
1	71	24 (33.8)	47 (66.2)	NE (6.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	10 (27.0)	27 (73.0)	NE (NE, NE)				
Mild impairment	40	13 (32.5)	27 (67.5)	NE (3.1, NE)				
Moderate impairment	22	8 (36.4)	14 (63.6)	6.0 (1.4, NE)				
Hepatic function at baseline								
Normal hepatic function	76	22 (28.9)	54 (71.1)	NE (6.0, NE)				
Mild hepatic dysfunction	25	9 (36.0)	16 (64.0)	NE (0.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	16 (21.6)	58 (78.4)	NE (NE, NE)				
Subjects who received neither	27	3 (11.1)	24 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	10 (30.3)	23 (69.7)	NE (2.9, NE)				
No	68	9 (13.2)	59 (86.8)	NE (NE, NE)				
HER2 status								
Kinase domain	98	19 (19.4)	79 (80.6)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	10 (16.4)	51 (83.6)	NE (NE, NE)				
>=65 years	40	9 (22.5)	31 (77.5)	NE (NE, NE)				
Age II								
<75 years	93	17 (18.3)	76 (81.7)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	11 (16.9)	54 (83.1)	NE (NE, NE)				
Male	36	8 (22.2)	28 (77.8)	NE (4.7, NE)				
Smoking status								
Current	0							
Former	46	6 (13.0)	40 (87.0)	NE (NE, NE)				
Never	55	13 (23.6)	42 (76.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	NE (1.1, NE)				
Non-White	78	11 (14.1)	67 (85.9)	NE (NE, NE)				
Region								
Asia	62	8 (12.9)	54 (87.1)	NE (NE, NE)				
North America and Australia	6							
Europe	33	10 (30.3)	23 (69.7)	NE (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (NE, NE)				
No	77	14 (18.2)	63 (81.8)	NE (NE, NE)				
12-lead ECG								
Normal	60	11 (18.3)	49 (81.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	8 (19.5)	33 (80.5)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	15 (17.9)	69 (82.1)	NE (NE, NE)				
Abnormal, not clinically significant	17	4 (23.5)	13 (76.5)	NE (0.8, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	5 (16.7)	25 (83.3)	NE (NE, NE)				
1	71	14 (19.7)	57 (80.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	40	8 (20.0)	32 (80.0)	NE (NE, NE)				
Moderate impairment	22	7 (31.8)	15 (68.2)	NE (1.4, NE)				
Hepatic function at baseline								
Normal hepatic function	76	16 (21.1)	60 (78.9)	NE (NE, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	46 (62.2)	28 (37.8)	0.3 (0.2, 0.8)				
Subjects who received neither	27	16 (59.3)	11 (40.7)	0.2 (0.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	19 (57.6)	14 (42.4)	0.3 (0.1, NE)				
No	68	43 (63.2)	25 (36.8)	0.2 (0.1, 0.8)				
HER2 status								
Kinase domain	98	60 (61.2)	38 (38.8)	0.3 (0.2, 0.8)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	37 (60.7)	24 (39.3)	0.3 (0.1, 2.8)				
>=65 years	40	25 (62.5)	15 (37.5)	0.3 (0.2, NE)				
Age II								
<75 years	93	59 (63.4)	34 (36.6)	0.3 (0.2, 0.5)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	38 (58.5)	27 (41.5)	0.3 (0.2, NE)				
Male	36	24 (66.7)	12 (33.3)	0.3 (0.1, 2.8)				
Smoking status								
Current	0							
Former	46	28 (60.9)	18 (39.1)	0.3 (0.1, NE)				
Never	55	34 (61.8)	21 (38.2)	0.3 (0.1, 0.8)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	12 (52.2)	11 (47.8)	2.8 (0.2, NE)				
Non-White	78	50 (64.1)	28 (35.9)	0.2 (0.1, 0.4)				
Region								
Asia	62	41 (66.1)	21 (33.9)	0.2 (0.1, 0.3)				
North America and Australia	6							
Europe	33	17 (51.5)	16 (48.5)	2.8 (0.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	11 (45.8)	13 (54.2)	NE (0.1, NE)				
No	77	51 (66.2)	26 (33.8)	0.2 (0.1, 0.4)				
12-lead ECG								
Normal	60	38 (63.3)	22 (36.7)	0.2 (0.1, 0.8)				
Abnormal, not clinically significant	41	24 (58.5)	17 (41.5)	0.3 (0.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	52 (61.9)	32 (38.1)	0.3 (0.2, 0.8)				
Abnormal, not clinically significant	17	10 (58.8)	7 (41.2)	0.2 (0.1, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	16 (53.3)	14 (46.7)	0.8 (0.1, NE)				
1	71	46 (64.8)	25 (35.2)	0.3 (0.1, 0.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	24 (64.9)	13 (35.1)	0.3 (0.1, 0.8)				
Mild impairment	40	20 (50.0)	20 (50.0)	2.8 (0.1, NE)				
Moderate impairment	22	17 (77.3)	5 (22.7)	0.2 (0.1, 0.2)				
Hepatic function at baseline								
Normal hepatic function	76	48 (63.2)	28 (36.8)	0.3 (0.2, 0.8)				
Mild hepatic dysfunction	25	14 (56.0)	11 (44.0)	0.4 (0.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	9 (12.2)	65 (87.8)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	2 (6.1)	31 (93.9)	NE (NE, NE)				
No	68	9 (13.2)	59 (86.8)	NE (NE, NE)				
HER2 status								
Kinase domain	98	10 (10.2)	88 (89.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	6 (9.8)	55 (90.2)	NE (NE, NE)				
>=65 years	40	5 (12.5)	35 (87.5)	NE (NE, NE)				
Age II								
<75 years	93	9 (9.7)	84 (90.3)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	7 (12.7)	48 (87.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	1 (4.3)	22 (95.7)	NE (NE, NE)				
Non-White	78	10 (12.8)	68 (87.2)	NE (NE, NE)				
Region								
Asia	62	9 (14.5)	53 (85.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	1 (4.2)	23 (95.8)	NE (NE, NE)				
No	77	10 (13.0)	67 (87.0)	NE (NE, NE)				
12-lead ECG								
Normal	60	6 (10.0)	54 (90.0)	NE (NE, NE)				
Abnormal, not clinically significant	41	5 (12.2)	36 (87.8)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	9 (10.7)	75 (89.3)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	2 (6.7)	28 (93.3)	NE (NE, NE)				
1	71	9 (12.7)	62 (87.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	3 (8.1)	34 (91.9)	NE (NE, NE)				
Mild impairment	40	5 (12.5)	35 (87.5)	NE (NE, NE)				
Moderate impairment	22	3 (13.6)	19 (86.4)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	10 (13.2)	66 (86.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	19 (25.7)	55 (74.3)	NE (NE, NE)				
Subjects who received neither	27	6 (22.2)	21 (77.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	10 (30.3)	23 (69.7)	NE (3.9, NE)				
No	68	15 (22.1)	53 (77.9)	NE (NE, NE)				
HER2 status								
Kinase domain	98	24 (24.5)	74 (75.5)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	12 (19.7)	49 (80.3)	NE (NE, NE)				
>=65 years	40	13 (32.5)	27 (67.5)	NE (3.5, NE)				
Age II								
<75 years	93	23 (24.7)	70 (75.3)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	16 (24.6)	49 (75.4)	NE (NE, NE)				
Male	36	9 (25.0)	27 (75.0)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	12 (26.1)	34 (73.9)	NE (NE, NE)				
Never	55	13 (23.6)	42 (76.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Non-White	78	21 (26.9)	57 (73.1)	NE (NE, NE)				
Region								
Asia	62	18 (29.0)	44 (71.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (NE, NE)				
No	77	20 (26.0)	57 (74.0)	NE (NE, NE)				
12-lead ECG								
Normal	60	15 (25.0)	45 (75.0)	NE (NE, NE)				
Abnormal, not clinically significant	41	10 (24.4)	31 (75.6)	NE (3.9, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	22 (26.2)	62 (73.8)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (3.5, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	8 (26.7)	22 (73.3)	NE (NE, NE)				
1	71	17 (23.9)	54 (76.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	8 (21.6)	29 (78.4)	NE (NE, NE)				
Mild impairment	40	8 (20.0)	32 (80.0)	NE (NE, NE)				
Moderate impairment	22	9 (40.9)	13 (59.1)	NE (0.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	23 (30.3)	53 (69.7)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	30 (40.5)	44 (59.5)	7.0 (2.9, NE)				
Subjects who received neither	27	11 (40.7)	16 (59.3)	NE (2.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	13 (39.4)	20 (60.6)	5.3 (2.8, NE)				
No	68	28 (41.2)	40 (58.8)	7.0 (1.5, NE)				
HER2 status								
Kinase domain	98	40 (40.8)	58 (59.2)	5.3 (2.9, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	21 (34.4)	40 (65.6)	NE (4.5, NE)				
>=65 years	40	20 (50.0)	20 (50.0)	3.9 (1.4, NE)				
Age II								
<75 years	93	36 (38.7)	57 (61.3)	NE (3.9, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	25 (38.5)	40 (61.5)	NE (3.2, NE)				
Male	36	16 (44.4)	20 (55.6)	7.0 (0.3, NE)				
Smoking status								
Current	0							
Former	46	19 (41.3)	27 (58.7)	7.0 (0.5, NE)				
Never	55	22 (40.0)	33 (60.0)	5.3 (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	3.9 (1.4, NE)				
Non-White	78	33 (42.3)	45 (57.7)	7.0 (2.8, NE)				
Region								
Asia	62	22 (35.5)	40 (64.5)	7.0 (4.5, NE)				
North America and Australia	6							
Europe	33	15 (45.5)	18 (54.5)	NE (0.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	8 (33.3)	16 (66.7)	NE (1.5, NE)				
No	77	33 (42.9)	44 (57.1)	7.0 (2.8, NE)				
12-lead ECG								
Normal	60	22 (36.7)	38 (63.3)	7.0 (3.2, NE)				
Abnormal, not clinically significant	41	19 (46.3)	22 (53.7)	4.5 (0.3, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	35 (41.7)	49 (58.3)	7.0 (2.9, NE)				
Abnormal, not clinically significant	17	6 (35.3)	11 (64.7)	NE (0.3, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	15 (50.0)	15 (50.0)	3.9 (0.2, NE)				
1	71	26 (36.6)	45 (63.4)	7.0 (4.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	14 (37.8)	23 (62.2)	NE (0.3, NE)				
Mild impairment	40	18 (45.0)	22 (55.0)	4.5 (1.5, NE)				
Moderate impairment	22	9 (40.9)	13 (59.1)	7.0 (1.5, NE)				
Hepatic function at baseline								
Normal hepatic function	76	31 (40.8)	45 (59.2)	7.0 (2.9, NE)				
Mild hepatic dysfunction	25	10 (40.0)	15 (60.0)	5.3 (0.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	9 (12.2)	65 (87.8)	NE (NE, NE)				
Subjects who received neither	27	3 (11.1)	24 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	6 (18.2)	27 (81.8)	NE (5.3, NE)				
No	68	6 (8.8)	62 (91.2)	NE (NE, NE)				
HER2 status								
Kinase domain	98	12 (12.2)	86 (87.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	7 (11.5)	54 (88.5)	NE (NE, NE)				
>=65 years	40	5 (12.5)	35 (87.5)	NE (NE, NE)				
Age II								
<75 years	93	10 (10.8)	83 (89.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	9 (13.8)	56 (86.2)	NE (NE, NE)				
Male	36	3 (8.3)	33 (91.7)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	8 (14.5)	47 (85.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	10 (12.8)	68 (87.2)	NE (NE, NE)				
Region								
Asia	62	1 (1.6)	61 (98.4)	NE (NE, NE)				
North America and Australia	6							
Europe	33	11 (33.3)	22 (66.7)	NE (0.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	4 (16.7)	20 (83.3)	NE (5.3, NE)				
No	77	8 (10.4)	69 (89.6)	NE (NE, NE)				
12-lead ECG								
Normal	60	5 (8.3)	55 (91.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	7 (17.1)	34 (82.9)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	9 (10.7)	75 (89.3)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	4 (13.3)	26 (86.7)	NE (NE, NE)				
1	71	8 (11.3)	63 (88.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	7 (18.9)	30 (81.1)	NE (5.3, NE)				
Mild impairment	40	4 (10.0)	36 (90.0)	NE (NE, NE)				
Moderate impairment	22	1 (4.5)	21 (95.5)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	7 (9.2)	69 (90.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	NE (5.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	12 (16.2)	62 (83.8)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	2 (6.1)	31 (93.9)	NE (NE, NE)				
No	68	11 (16.2)	57 (83.8)	NE (NE, NE)				
HER2 status								
Kinase domain	98	13 (13.3)	85 (86.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	6 (9.8)	55 (90.2)	NE (NE, NE)				
>=65 years	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Age II								
<75 years	93	12 (12.9)	81 (87.1)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (NE, NE)				
Male	36	6 (16.7)	30 (83.3)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	5 (10.9)	41 (89.1)	NE (NE, NE)				
Never	55	8 (14.5)	47 (85.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Non-White	78	9 (11.5)	69 (88.5)	NE (NE, NE)				
Region								
Asia	62	7 (11.3)	55 (88.7)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	10 (13.0)	67 (87.0)	NE (NE, NE)				
12-lead ECG								
Normal	60	8 (13.3)	52 (86.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	5 (12.2)	36 (87.8)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	12 (14.3)	72 (85.7)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	4 (13.3)	26 (86.7)	NE (NE, NE)				
1	71	9 (12.7)	62 (87.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Moderate impairment	22	2 (9.1)	20 (90.9)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	10 (13.2)	66 (86.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	17 (23.0)	57 (77.0)	NE (NE, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (2.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	7 (21.2)	26 (78.8)	NE (3.7, NE)				
No	68	18 (26.5)	50 (73.5)	NE (NE, NE)				
HER2 status								
Kinase domain	98	25 (25.5)	73 (74.5)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	12 (19.7)	49 (80.3)	NE (NE, NE)				
>=65 years	40	13 (32.5)	27 (67.5)	NE (2.8, NE)				
Age II								
<75 years	93	22 (23.7)	71 (76.3)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	15 (23.1)	50 (76.9)	NE (NE, NE)				
Male	36	10 (27.8)	26 (72.2)	NE (3.7, NE)				
Smoking status								
Current	0							
Former	46	13 (28.3)	33 (71.7)	NE (3.6, NE)				
Never	55	12 (21.8)	43 (78.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	7 (30.4)	16 (69.6)	4.3 (2.1, NE)				
Non-White	78	18 (23.1)	60 (76.9)	NE (NE, NE)				
Region								
Asia	62	13 (21.0)	49 (79.0)	NE (NE, NE)				
North America and Australia	6							
Europe	33	10 (30.3)	23 (69.7)	4.3 (3.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	6 (25.0)	18 (75.0)	NE (3.1, NE)				
No	77	19 (24.7)	58 (75.3)	NE (NE, NE)				
12-lead ECG								
Normal	60	17 (28.3)	43 (71.7)	NE (4.1, NE)				
Abnormal, not clinically significant	41	8 (19.5)	33 (80.5)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	21 (25.0)	63 (75.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	4 (23.5)	13 (76.5)	NE (2.0, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	5 (16.7)	25 (83.3)	NE (NE, NE)				
1	71	20 (28.2)	51 (71.8)	NE (4.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	8 (21.6)	29 (78.4)	NE (4.3, NE)				
Mild impairment	40	9 (22.5)	31 (77.5)	NE (4.1, NE)				
Moderate impairment	22	7 (31.8)	15 (68.2)	NE (1.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	19 (25.0)	57 (75.0)	NE (NE, NE)				
Mild hepatic dysfunction	25	6 (24.0)	19 (76.0)	NE (3.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	45 (60.8)	29 (39.2)	1.4 (0.6, 4.2)				
Subjects who received neither	27	13 (48.1)	14 (51.9)	4.2 (0.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	15 (45.5)	18 (54.5)	4.2 (0.6, NE)				
No	68	43 (63.2)	25 (36.8)	1.4 (0.6, 4.1)				
HER2 status								
Kinase domain	98	55 (56.1)	43 (43.9)	2.2 (0.8, 4.9)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	34 (55.7)	27 (44.3)	2.2 (0.7, NE)				
>=65 years	40	24 (60.0)	16 (40.0)	1.4 (0.5, NE)				
Age II								
<75 years	93	54 (58.1)	39 (41.9)	2.2 (0.7, 4.2)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	30 (46.2)	35 (53.8)	4.2 (1.4, NE)				
Male	36	28 (77.8)	8 (22.2)	0.6 (0.3, 1.5)				
Smoking status								
Current	0							
Former	46	30 (65.2)	16 (34.8)	1.1 (0.5, 4.1)				
Never	55	28 (50.9)	27 (49.1)	4.2 (0.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	4.1 (0.9, NE)				
Non-White	78	47 (60.3)	31 (39.7)	1.4 (0.6, 4.2)				
Region								
Asia	62	41 (66.1)	21 (33.9)	1.4 (0.5, 4.2)				
North America and Australia	6							
Europe	33	15 (45.5)	18 (54.5)	NE (0.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	10 (41.7)	14 (58.3)	NE (0.5, NE)				
No	77	48 (62.3)	29 (37.7)	1.5 (0.7, 4.2)				
12-lead ECG								
Normal	60	37 (61.7)	23 (38.3)	2.1 (0.6, 4.9)				
Abnormal, not clinically significant	41	21 (51.2)	20 (48.8)	4.1 (0.6, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	51 (60.7)	33 (39.3)	1.5 (0.5, 4.1)				
Abnormal, not clinically significant	17	7 (41.2)	10 (58.8)	4.2 (0.9, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	22 (73.3)	8 (26.7)	1.4 (0.5, 4.1)				
1	71	36 (50.7)	35 (49.3)	3.6 (0.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	21 (56.8)	16 (43.2)	2.1 (0.6, NE)				
Mild impairment	40	23 (57.5)	17 (42.5)	3.0 (0.7, 6.2)				
Moderate impairment	22	14 (63.6)	8 (36.4)	0.5 (0.3, 4.1)				
Hepatic function at baseline								
Normal hepatic function	76	44 (57.9)	32 (42.1)	2.2 (0.7, 4.2)				
Mild hepatic dysfunction	25	14 (56.0)	11 (44.0)	1.4 (0.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	8 (10.8)	66 (89.2)	NE (NE, NE)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	3 (9.1)	30 (90.9)	NE (NE, NE)				
No	68	10 (14.7)	58 (85.3)	NE (NE, NE)				
HER2 status								
Kinase domain	98	12 (12.2)	86 (87.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	9 (14.8)	52 (85.2)	NE (NE, NE)				
>=65 years	40	4 (10.0)	36 (90.0)	NE (NE, NE)				
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	6 (9.2)	59 (90.8)	NE (NE, NE)				
Male	36	7 (19.4)	29 (80.6)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	8 (17.4)	38 (82.6)	NE (NE, NE)				
Never	55	5 (9.1)	50 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (4.1, NE)				
Non-White	78	10 (12.8)	68 (87.2)	NE (NE, NE)				
Region								
Asia	62	9 (14.5)	53 (85.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	11 (14.3)	66 (85.7)	NE (NE, NE)				
12-lead ECG								
Normal	60	7 (11.7)	53 (88.3)	NE (NE, NE)				
Abnormal, not clinically significant	41	6 (14.6)	35 (85.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	10 (11.9)	74 (88.1)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	4 (13.3)	26 (86.7)	NE (4.2, NE)				
1	71	9 (12.7)	62 (87.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	6 (16.2)	31 (83.8)	NE (NE, NE)				
Mild impairment	40	6 (15.0)	34 (85.0)	NE (NE, NE)				
Moderate impairment	22	1 (4.5)	21 (95.5)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	9 (11.8)	67 (88.2)	NE (NE, NE)				
Mild hepatic dysfunction	25	4 (16.0)	21 (84.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	9 (12.2)	65 (87.8)	NE (NE, NE)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	5 (15.2)	28 (84.8)	NE (NE, NE)				
No	68	9 (13.2)	59 (86.8)	NE (NE, NE)				
HER2 status								
Kinase domain	98	12 (12.2)	86 (87.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	10 (16.4)	51 (83.6)	NE (NE, NE)				
>=65 years	40	4 (10.0)	36 (90.0)	NE (NE, NE)				
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	6 (9.2)	59 (90.8)	NE (NE, NE)				
Male	36	8 (22.2)	28 (77.8)	NE (3.9, NE)				
Smoking status								
Current	0							
Former	46	8 (17.4)	38 (82.6)	NE (NE, NE)				
Never	55	6 (10.9)	49 (89.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	4 (17.4)	19 (82.6)	NE (4.1, NE)				
Non-White	78	10 (12.8)	68 (87.2)	NE (NE, NE)				
Region								
Asia	62	9 (14.5)	53 (85.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	12 (15.6)	65 (84.4)	NE (NE, NE)				
12-lead ECG								
Normal	60	8 (13.3)	52 (86.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	6 (14.6)	35 (85.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	12 (14.3)	72 (85.7)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	6 (20.0)	24 (80.0)	NE (4.2, NE)				
1	71	8 (11.3)	63 (88.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	5 (13.5)	32 (86.5)	NE (NE, NE)				
Mild impairment	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Moderate impairment	22	2 (9.1)	20 (90.9)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	10 (13.2)	66 (86.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	4 (16.0)	21 (84.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	21 (28.4)	53 (71.6)	6.2 (4.9, NE)				
Subjects who received neither	27	7 (25.9)	20 (74.1)	9.9 (5.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	10 (30.3)	23 (69.7)	9.9 (4.2, NE)				
No	68	18 (26.5)	50 (73.5)	NE (5.4, NE)				
HER2 status								
Kinase domain	98	26 (26.5)	72 (73.5)	9.9 (5.4, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	14 (23.0)	47 (77.0)	9.9 (NE, NE)				
>=65 years	40	14 (35.0)	26 (65.0)	6.2 (3.6, NE)				
Age II								
<75 years	93	24 (25.8)	69 (74.2)	9.9 (5.4, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	16 (24.6)	49 (75.4)	NE (5.4, NE)				
Male	36	12 (33.3)	24 (66.7)	9.9 (4.9, NE)				
Smoking status								
Current	0							
Former	46	15 (32.6)	31 (67.4)	NE (4.9, NE)				
Never	55	13 (23.6)	42 (76.4)	9.9 (6.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Non-White	78	24 (30.8)	54 (69.2)	9.9 (5.4, NE)				
Region								
Asia	62	23 (37.1)	39 (62.9)	6.2 (4.2, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	6 (25.0)	18 (75.0)	NE (NE, NE)				
No	77	22 (28.6)	55 (71.4)	9.9 (5.4, NE)				
12-lead ECG								
Normal	60	20 (33.3)	40 (66.7)	6.2 (4.9, NE)				
Abnormal, not clinically significant	41	8 (19.5)	33 (80.5)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	27 (32.1)	57 (67.9)	6.2 (4.9, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	15 (50.0)	15 (50.0)	4.9 (1.4, NE)				
1	71	13 (18.3)	58 (81.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	7 (18.9)	30 (81.1)	NE (NE, NE)				
Mild impairment	40	12 (30.0)	28 (70.0)	6.2 (4.2, NE)				
Moderate impairment	22	9 (40.9)	13 (59.1)	5.4 (0.6, NE)				
Hepatic function at baseline								
Normal hepatic function	76	23 (30.3)	53 (69.7)	9.9 (4.9, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	6.2 (5.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	13 (17.6)	61 (82.4)	NE (NE, NE)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	3 (9.1)	30 (90.9)	NE (NE, NE)				
No	68	15 (22.1)	53 (77.9)	NE (6.2, NE)				
HER2 status								
Kinase domain	98	16 (16.3)	82 (83.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	8 (13.1)	53 (86.9)	NE (NE, NE)				
>=65 years	40	10 (25.0)	30 (75.0)	NE (6.2, NE)				
Age II								
<75 years	93	17 (18.3)	76 (81.7)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	12 (18.5)	53 (81.5)	NE (NE, NE)				
Male	36	6 (16.7)	30 (83.3)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	7 (15.2)	39 (84.8)	NE (6.2, NE)				
Never	55	11 (20.0)	44 (80.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	1 (4.3)	22 (95.7)	NE (NE, NE)				
Non-White	78	17 (21.8)	61 (78.2)	NE (NE, NE)				
Region								
Asia	62	17 (27.4)	45 (72.6)	NE (6.2, NE)				
North America and Australia	6							
Europe	33	0	33 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	15 (19.5)	62 (80.5)	NE (NE, NE)				
12-lead ECG								
Normal	60	11 (18.3)	49 (81.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	7 (17.1)	34 (82.9)	NE (6.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	15 (17.9)	69 (82.1)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (3.3, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	6 (20.0)	24 (80.0)	NE (6.2, NE)				
1	71	12 (16.9)	59 (83.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	5 (13.5)	32 (86.5)	NE (6.2, NE)				
Mild impairment	40	6 (15.0)	34 (85.0)	NE (NE, NE)				
Moderate impairment	22	7 (31.8)	15 (68.2)	NE (0.4, NE)				
Hepatic function at baseline								
Normal hepatic function	76	13 (17.1)	63 (82.9)	NE (NE, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	20 (27.0)	54 (73.0)	7.0 (4.9, NE)				
Subjects who received neither	27	3 (11.1)	24 (88.9)	8.5 (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	7 (21.2)	26 (78.8)	8.5 (4.2, NE)				
No	68	16 (23.5)	52 (76.5)	7.0 (5.8, NE)				
HER2 status								
Kinase domain	98	22 (22.4)	76 (77.6)	8.5 (5.8, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	14 (23.0)	47 (77.0)	8.5 (5.8, NE)				
>=65 years	40	9 (22.5)	31 (77.5)	7.0 (7.0, NE)				
Age II								
<75 years	93	21 (22.6)	72 (77.4)	8.5 (5.8, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	13 (20.0)	52 (80.0)	9.8 (5.8, NE)				
Male	36	10 (27.8)	26 (72.2)	7.0 (4.9, NE)				
Smoking status								
Current	0							
Former	46	13 (28.3)	33 (71.7)	7.0 (4.9, NE)				
Never	55	10 (18.2)	45 (81.8)	8.5 (8.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	21 (26.9)	57 (73.1)	8.5 (5.8, NE)				
Region								
Asia	62	20 (32.3)	42 (67.7)	8.5 (5.8, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	6 (25.0)	18 (75.0)	NE (3.0, NE)				
No	77	17 (22.1)	60 (77.9)	8.5 (5.8, NE)				
12-lead ECG								
Normal	60	15 (25.0)	45 (75.0)	7.0 (5.8, NE)				
Abnormal, not clinically significant	41	8 (19.5)	33 (80.5)	NE (4.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	23 (27.4)	61 (72.6)	7.0 (5.8, NE)				
Abnormal, not clinically significant	17	0	17 (100.0)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	12 (40.0)	18 (60.0)	5.8 (4.9, NE)				
1	71	11 (15.5)	60 (84.5)	NE (7.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	6 (16.2)	31 (83.8)	NE (5.8, NE)				
Mild impairment	40	10 (25.0)	30 (75.0)	8.5 (4.9, NE)				
Moderate impairment	22	7 (31.8)	15 (68.2)	7.0 (1.8, NE)				
Hepatic function at baseline								
Normal hepatic function	76	18 (23.7)	58 (76.3)	7.0 (5.8, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	9.8 (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	31 (41.9)	43 (58.1)	NE (1.4, NE)				
Subjects who received neither	27	11 (40.7)	16 (59.3)	NE (0.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	10 (30.3)	23 (69.7)	NE (1.4, NE)				
No	68	32 (47.1)	36 (52.9)	NE (0.7, NE)				
HER2 status								
Kinase domain	98	39 (39.8)	59 (60.2)	NE (2.1, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	17 (27.9)	44 (72.1)	NE (NE, NE)				
>=65 years	40	25 (62.5)	15 (37.5)	0.9 (0.3, 3.4)				
Age II								
<75 years	93	38 (40.9)	55 (59.1)	NE (1.6, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	26 (40.0)	39 (60.0)	NE (1.4, NE)				
Male	36	16 (44.4)	20 (55.6)	NE (0.7, NE)				
Smoking status								
Current	0							
Former	46	20 (43.5)	26 (56.5)	NE (1.4, NE)				
Never	55	22 (40.0)	33 (60.0)	NE (0.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	10 (43.5)	13 (56.5)	NE (1.0, NE)				
Non-White	78	32 (41.0)	46 (59.0)	NE (0.9, NE)				
Region								
Asia	62	25 (40.3)	37 (59.7)	NE (0.9, NE)				
North America and Australia	6							
Europe	33	13 (39.4)	20 (60.6)	NE (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	11 (45.8)	13 (54.2)	NE (0.3, NE)				
No	77	31 (40.3)	46 (59.7)	NE (1.6, NE)				
12-lead ECG								
Normal	60	27 (45.0)	33 (55.0)	NE (0.7, NE)				
Abnormal, not clinically significant	41	15 (36.6)	26 (63.4)	NE (1.4, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	34 (40.5)	50 (59.5)	NE (1.4, NE)				
Abnormal, not clinically significant	17	8 (47.1)	9 (52.9)	3.4 (0.1, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	11 (36.7)	19 (63.3)	NE (0.3, NE)				
1	71	31 (43.7)	40 (56.3)	NE (1.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	16 (43.2)	21 (56.8)	NE (0.7, NE)				
Mild impairment	40	14 (35.0)	26 (65.0)	NE (0.3, NE)				
Moderate impairment	22	12 (54.5)	10 (45.5)	1.4 (0.5, NE)				
Hepatic function at baseline								
Normal hepatic function	76	33 (43.4)	43 (56.6)	NE (1.3, NE)				
Mild hepatic dysfunction	25	9 (36.0)	16 (64.0)	NE (0.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	21 (28.4)	53 (71.6)	NE (NE, NE)				
Subjects who received neither	27	9 (33.3)	18 (66.7)	NE (0.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	8 (24.2)	25 (75.8)	NE (NE, NE)				
No	68	22 (32.4)	46 (67.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	27 (27.6)	71 (72.4)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	14 (23.0)	47 (77.0)	NE (NE, NE)				
>=65 years	40	16 (40.0)	24 (60.0)	NE (0.3, NE)				
Age II								
<75 years	93	28 (30.1)	65 (69.9)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	19 (29.2)	46 (70.8)	NE (NE, NE)				
Male	36	11 (30.6)	25 (69.4)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	13 (28.3)	33 (71.7)	NE (NE, NE)				
Never	55	17 (30.9)	38 (69.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	27 (34.6)	51 (65.4)	NE (NE, NE)				
Region								
Asia	62	22 (35.5)	40 (64.5)	NE (2.1, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	8 (33.3)	16 (66.7)	NE (0.3, NE)				
No	77	22 (28.6)	55 (71.4)	NE (NE, NE)				
12-lead ECG								
Normal	60	22 (36.7)	38 (63.3)	NE (2.1, NE)				
Abnormal, not clinically significant	41	8 (19.5)	33 (80.5)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	25 (29.8)	59 (70.2)	NE (NE, NE)				
Abnormal, not clinically significant	17	5 (29.4)	12 (70.6)	NE (0.1, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	11 (36.7)	19 (63.3)	NE (0.3, NE)				
1	71	19 (26.8)	52 (73.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	11 (29.7)	26 (70.3)	NE (NE, NE)				
Mild impairment	40	12 (30.0)	28 (70.0)	NE (NE, NE)				
Moderate impairment	22	7 (31.8)	15 (68.2)	NE (0.9, NE)				
Hepatic function at baseline								
Normal hepatic function	76	22 (28.9)	54 (71.1)	NE (NE, NE)				
Mild hepatic dysfunction	25	8 (32.0)	17 (68.0)	NE (0.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	13 (17.6)	61 (82.4)	NE (NE, NE)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (6.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	8 (24.2)	25 (75.8)	NE (6.0, NE)				
No	68	10 (14.7)	58 (85.3)	NE (NE, NE)				
HER2 status								
Kinase domain	98	17 (17.3)	81 (82.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	12 (19.7)	49 (80.3)	NE (NE, NE)				
>=65 years	40	6 (15.0)	34 (85.0)	NE (6.0, NE)				
Age II								
<75 years	93	18 (19.4)	75 (80.6)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	11 (16.9)	54 (83.1)	NE (6.0, NE)				
Male	36	7 (19.4)	29 (80.6)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	8 (17.4)	38 (82.6)	NE (NE, NE)				
Never	55	10 (18.2)	45 (81.8)	NE (6.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	7 (30.4)	16 (69.6)	3.5 (1.8, NE)				
Non-White	78	11 (14.1)	67 (85.9)	NE (NE, NE)				
Region								
Asia	62	7 (11.3)	55 (88.7)	NE (NE, NE)				
North America and Australia	6							
Europe	33	8 (24.2)	25 (75.8)	NE (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	6 (25.0)	18 (75.0)	NE (2.9, NE)				
No	77	12 (15.6)	65 (84.4)	NE (NE, NE)				
12-lead ECG								
Normal	60	8 (13.3)	52 (86.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	10 (24.4)	31 (75.6)	NE (4.4, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	17 (20.2)	67 (79.8)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	8 (26.7)	22 (73.3)	NE (NE, NE)				
1	71	10 (14.1)	61 (85.9)	NE (6.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	6 (16.2)	31 (83.8)	NE (NE, NE)				
Mild impairment	40	5 (12.5)	35 (87.5)	NE (NE, NE)				
Moderate impairment	22	5 (22.7)	17 (77.3)	NE (6.0, NE)				
Hepatic function at baseline								
Normal hepatic function	76	16 (21.1)	60 (78.9)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	14 (18.9)	60 (81.1)	NE (NE, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	9 (27.3)	24 (72.7)	NE (4.2, NE)				
No	68	13 (19.1)	55 (80.9)	NE (NE, NE)				
HER2 status								
Kinase domain	98	22 (22.4)	76 (77.6)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	9 (14.8)	52 (85.2)	NE (NE, NE)				
>=65 years	40	13 (32.5)	27 (67.5)	NE (4.9, NE)				
Age II								
<75 years	93	21 (22.6)	72 (77.4)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	17 (26.2)	48 (73.8)	NE (4.9, NE)				
Male	36	5 (13.9)	31 (86.1)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	11 (23.9)	35 (76.1)	NE (4.9, NE)				
Never	55	11 (20.0)	44 (80.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	4.9 (4.9, NE)				
Non-White	78	17 (21.8)	61 (78.2)	NE (NE, NE)				
Region								
Asia	62	14 (22.6)	48 (77.4)	NE (NE, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	19 (24.7)	58 (75.3)	NE (4.9, NE)				
12-lead ECG								
Normal	60	12 (20.0)	48 (80.0)	NE (NE, NE)				
Abnormal, not clinically significant	41	10 (24.4)	31 (75.6)	NE (4.9, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	17 (20.2)	67 (79.8)	NE (NE, NE)				
Abnormal, not clinically significant	17	5 (29.4)	12 (70.6)	NE (1.5, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	4 (13.3)	26 (86.7)	NE (4.9, NE)				
1	71	18 (25.4)	53 (74.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	40	10 (25.0)	30 (75.0)	NE (4.2, NE)				
Moderate impairment	22	7 (31.8)	15 (68.2)	NE (2.1, NE)				
Hepatic function at baseline								
Normal hepatic function	76	13 (17.1)	63 (82.9)	NE (NE, NE)				
Mild hepatic dysfunction	25	9 (36.0)	16 (64.0)	NE (0.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	20 (27.0)	54 (73.0)	NE (5.7, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	10 (30.3)	23 (69.7)	NE (3.9, NE)				
No	68	18 (26.5)	50 (73.5)	NE (5.7, NE)				
HER2 status								
Kinase domain	98	27 (27.6)	71 (72.4)	NE (5.7, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	15 (24.6)	46 (75.4)	NE (6.8, NE)				
>=65 years	40	13 (32.5)	27 (67.5)	NE (2.9, NE)				
Age II								
<75 years	93	27 (29.0)	66 (71.0)	NE (5.7, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	18 (27.7)	47 (72.3)	NE (5.5, NE)				
Male	36	10 (27.8)	26 (72.2)	6.8 (5.7, NE)				
Smoking status								
Current	0							
Former	46	10 (21.7)	36 (78.3)	NE (5.5, NE)				
Never	55	18 (32.7)	37 (67.3)	NE (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	5.5 (1.4, NE)				
Non-White	78	20 (25.6)	58 (74.4)	NE (6.8, NE)				
Region								
Asia	62	12 (19.4)	50 (80.6)	NE (NE, NE)				
North America and Australia	6							
Europe	33	12 (36.4)	21 (63.6)	NE (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	8 (33.3)	16 (66.7)	NE (2.8, NE)				
No	77	20 (26.0)	57 (74.0)	NE (5.7, NE)				
12-lead ECG								
Normal	60	18 (30.0)	42 (70.0)	NE (6.8, NE)				
Abnormal, not clinically significant	41	10 (24.4)	31 (75.6)	NE (5.5, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	21 (25.0)	63 (75.0)	NE (5.7, NE)				
Abnormal, not clinically significant	17	7 (41.2)	10 (58.8)	NE (1.4, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	7 (23.3)	23 (76.7)	NE (5.5, NE)				
1	71	21 (29.6)	50 (70.4)	NE (5.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	10 (27.0)	27 (73.0)	NE (NE, NE)				
Mild impairment	40	15 (37.5)	25 (62.5)	5.7 (2.9, NE)				
Moderate impairment	22	3 (13.6)	19 (86.4)	NE (5.5, NE)				
Hepatic function at baseline								
Normal hepatic function	76	18 (23.7)	58 (76.3)	NE (6.8, NE)				
Mild hepatic dysfunction	25	10 (40.0)	15 (60.0)	5.7 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	17 (23.0)	57 (77.0)	NE (NE, NE)				
Subjects who received neither	27	11 (40.7)	16 (59.3)	NE (2.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	8 (24.2)	25 (75.8)	NE (NE, NE)				
No	68	20 (29.4)	48 (70.6)	NE (4.2, NE)				
HER2 status								
Kinase domain	98	27 (27.6)	71 (72.4)	NE (4.8, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	20 (32.8)	41 (67.2)	NE (2.9, NE)				
>=65 years	40	8 (20.0)	32 (80.0)	NE (4.8, NE)				
Age II								
<75 years	93	26 (28.0)	67 (72.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	20 (30.8)	45 (69.2)	NE (4.2, NE)				
Male	36	8 (22.2)	28 (77.8)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	12 (26.1)	34 (73.9)	NE (4.2, NE)				
Never	55	16 (29.1)	39 (70.9)	NE (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	10 (43.5)	13 (56.5)	4.2 (2.0, NE)				
Non-White	78	18 (23.1)	60 (76.9)	NE (NE, NE)				
Region								
Asia	62	17 (27.4)	45 (72.6)	NE (NE, NE)				
North America and Australia	6							
Europe	33	8 (24.2)	25 (75.8)	NE (3.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (2.8, NE)				
No	77	23 (29.9)	54 (70.1)	NE (4.2, NE)				
12-lead ECG								
Normal	60	15 (25.0)	45 (75.0)	NE (NE, NE)				
Abnormal, not clinically significant	41	13 (31.7)	28 (68.3)	NE (2.3, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	20 (23.8)	64 (76.2)	NE (NE, NE)				
Abnormal, not clinically significant	17	8 (47.1)	9 (52.9)	2.4 (0.8, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	10 (33.3)	20 (66.7)	NE (2.3, NE)				
1	71	18 (25.4)	53 (74.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	12 (32.4)	25 (67.6)	NE (2.9, NE)				
Mild impairment	40	10 (25.0)	30 (75.0)	NE (NE, NE)				
Moderate impairment	22	5 (22.7)	17 (77.3)	NE (4.2, NE)				
Hepatic function at baseline								
Normal hepatic function	76	23 (30.3)	53 (69.7)	NE (4.2, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	12 (16.2)	62 (83.8)	NE (NE, NE)				
Subjects who received neither	27	9 (33.3)	18 (66.7)	NE (2.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	4 (12.1)	29 (87.9)	NE (NE, NE)				
No	68	17 (25.0)	51 (75.0)	NE (4.8, NE)				
HER2 status								
Kinase domain	98	20 (20.4)	78 (79.6)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	14 (23.0)	47 (77.0)	NE (NE, NE)				
>=65 years	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Age II								
<75 years	93	19 (20.4)	74 (79.6)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	17 (26.2)	48 (73.8)	NE (4.8, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	9 (19.6)	37 (80.4)	NE (NE, NE)				
Never	55	12 (21.8)	43 (78.2)	NE (4.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	6 (26.1)	17 (73.9)	4.8 (2.1, NE)				
Non-White	78	15 (19.2)	63 (80.8)	NE (NE, NE)				
Region								
Asia	62	14 (22.6)	48 (77.4)	NE (NE, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (2.8, NE)				
No	77	16 (20.8)	61 (79.2)	NE (NE, NE)				
12-lead ECG								
Normal	60	11 (18.3)	49 (81.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	10 (24.4)	31 (75.6)	NE (2.9, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:10; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	14 (16.7)	70 (83.3)	NE (NE, NE)				
Abnormal, not clinically significant	17	7 (41.2)	10 (58.8)	2.9 (2.3, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	7 (23.3)	23 (76.7)	NE (4.8, NE)				
1	71	14 (19.7)	57 (80.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	9 (24.3)	28 (75.7)	NE (4.8, NE)				
Mild impairment	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Moderate impairment	22	4 (18.2)	18 (81.8)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	17 (22.4)	59 (77.6)	NE (NE, NE)				
Mild hepatic dysfunction	25	4 (16.0)	21 (84.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	6 (8.1)	68 (91.9)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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Run date: 24MAR2023 – 9:12; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	2 (6.1)	31 (93.9)	NE (6.1, NE)				
No	68	4 (5.9)	64 (94.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	6 (6.1)	92 (93.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	4 (6.6)	57 (93.4)	NE (NE, NE)				
>=65 years	40	2 (5.0)	38 (95.0)	NE (NE, NE)				
Age II								
<75 years	93	6 (6.5)	87 (93.5)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	5 (7.7)	60 (92.3)	NE (NE, NE)				
Male	36	1 (2.8)	35 (97.2)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	3 (6.5)	43 (93.5)	NE (NE, NE)				
Never	55	3 (5.5)	52 (94.5)	NE (6.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	4 (5.1)	74 (94.9)	NE (NE, NE)				
Region								
Asia	62	2 (3.2)	60 (96.8)	NE (NE, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (6.1, NE)				
No	77	4 (5.2)	73 (94.8)	NE (NE, NE)				
12-lead ECG								
Normal	60	2 (3.3)	58 (96.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	4 (9.8)	37 (90.2)	NE (6.1, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	5 (6.0)	79 (94.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	2 (6.7)	28 (93.3)	NE (NE, NE)				
1	71	4 (5.6)	67 (94.4)	NE (6.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (6.1, NE)				
Mild impairment	40	2 (5.0)	38 (95.0)	NE (NE, NE)				
Moderate impairment	22	2 (9.1)	20 (90.9)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	4 (5.3)	72 (94.7)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	6.1 (6.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	7 (9.5)	67 (90.5)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	2 (6.1)	31 (93.9)	NE (NE, NE)				
No	68	7 (10.3)	61 (89.7)	NE (NE, NE)				
HER2 status								
Kinase domain	98	8 (8.2)	90 (91.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	4 (10.0)	36 (90.0)	NE (NE, NE)				
Age II								
<75 years	93	9 (9.7)	84 (90.3)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	5 (7.7)	60 (92.3)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	5 (9.1)	50 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	6 (7.7)	72 (92.3)	NE (NE, NE)				
Region								
Asia	62	4 (6.5)	58 (93.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	7 (9.1)	70 (90.9)	NE (NE, NE)				
12-lead ECG								
Normal	60	7 (11.7)	53 (88.3)	NE (NE, NE)				
Abnormal, not clinically significant	41	2 (4.9)	39 (95.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	7 (8.3)	77 (91.7)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	0	30 (100.0)	NE (NE, NE)				
1	71	9 (12.7)	62 (87.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	5 (13.5)	32 (86.5)	NE (NE, NE)				
Mild impairment	40	3 (7.5)	37 (92.5)	NE (NE, NE)				
Moderate impairment	22	1 (4.5)	21 (95.5)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	7 (9.2)	69 (90.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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Run date: 24MAR2023 – 9:12; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	11 (14.9)	63 (85.1)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	3 (9.1)	30 (90.9)	NE (NE, NE)				
No	68	9 (13.2)	59 (86.8)	NE (NE, NE)				
HER2 status								
Kinase domain	98	12 (12.2)	86 (87.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	2 (3.3)	59 (96.7)	NE (NE, NE)				
>=65 years	40	10 (25.0)	30 (75.0)	NE (NE, NE)				
Age II								
<75 years	93	10 (10.8)	83 (89.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (NE, NE)				
Male	36	5 (13.9)	31 (86.1)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	8 (17.4)	38 (82.6)	NE (NE, NE)				
Never	55	4 (7.3)	51 (92.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (4.2, NE)				
Non-White	78	9 (11.5)	69 (88.5)	NE (NE, NE)				
Region								
Asia	62	6 (9.7)	56 (90.3)	NE (NE, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	9 (11.7)	68 (88.3)	NE (NE, NE)				
12-lead ECG								
Normal	60	4 (6.7)	56 (93.3)	NE (NE, NE)				
Abnormal, not clinically significant	41	8 (19.5)	33 (80.5)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	10 (11.9)	74 (88.1)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	1 (3.3)	29 (96.7)	NE (NE, NE)				
1	71	11 (15.5)	60 (84.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (NE, NE)				
Mild impairment	40	3 (7.5)	37 (92.5)	NE (NE, NE)				
Moderate impairment	22	7 (31.8)	15 (68.2)	NE (1.4, NE)				
Hepatic function at baseline								
Normal hepatic function	76	11 (14.5)	65 (85.5)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	9 (12.2)	65 (87.8)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
No	68	9 (13.2)	59 (86.8)	NE (NE, NE)				
HER2 status								
Kinase domain	98	10 (10.2)	88 (89.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	1 (1.6)	60 (98.4)	NE (NE, NE)				
>=65 years	40	9 (22.5)	31 (77.5)	NE (NE, NE)				
Age II								
<75 years	93	9 (9.7)	84 (90.3)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	6 (9.2)	59 (90.8)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	7 (15.2)	39 (84.8)	NE (NE, NE)				
Never	55	3 (5.5)	52 (94.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (4.2, NE)				
Non-White	78	8 (10.3)	70 (89.7)	NE (NE, NE)				
Region								
Asia	62	6 (9.7)	56 (90.3)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	8 (10.4)	69 (89.6)	NE (NE, NE)				
12-lead ECG								
Normal	60	4 (6.7)	56 (93.3)	NE (NE, NE)				
Abnormal, not clinically significant	41	6 (14.6)	35 (85.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	9 (10.7)	75 (89.3)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	0	30 (100.0)	NE (NE, NE)				
1	71	10 (14.1)	61 (85.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	1 (2.7)	36 (97.3)	NE (NE, NE)				
Mild impairment	40	3 (7.5)	37 (92.5)	NE (NE, NE)				
Moderate impairment	22	6 (27.3)	16 (72.7)	NE (4.1, NE)				
Hepatic function at baseline								
Normal hepatic function	76	9 (11.8)	67 (88.2)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	8 (10.8)	66 (89.2)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	3 (9.1)	30 (90.9)	NE (6.1, NE)				
No	68	5 (7.4)	63 (92.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	8 (8.2)	90 (91.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	3 (7.5)	37 (92.5)	NE (NE, NE)				
Age II								
<75 years	93	8 (8.6)	85 (91.4)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	6 (9.2)	59 (90.8)	NE (NE, NE)				
Male	36	2 (5.6)	34 (94.4)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	3 (6.5)	43 (93.5)	NE (NE, NE)				
Never	55	5 (9.1)	50 (90.9)	NE (6.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (4.4, NE)				
Non-White	78	5 (6.4)	73 (93.6)	NE (NE, NE)				
Region								
Asia	62	3 (4.8)	59 (95.2)	NE (NE, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	4 (16.7)	20 (83.3)	6.1 (4.4, NE)				
No	77	4 (5.2)	73 (94.8)	NE (NE, NE)				
12-lead ECG								
Normal	60	3 (5.0)	57 (95.0)	NE (NE, NE)				
Abnormal, not clinically significant	41	5 (12.2)	36 (87.8)	NE (6.1, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	7 (8.3)	77 (91.7)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	2 (6.7)	28 (93.3)	NE (NE, NE)				
1	71	6 (8.5)	65 (91.5)	NE (6.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (6.1, NE)				
Mild impairment	40	3 (7.5)	37 (92.5)	NE (NE, NE)				
Moderate impairment	22	3 (13.6)	19 (86.4)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	6 (7.9)	70 (92.1)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	6.1 (6.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	16 (21.6)	58 (78.4)	8.3 (6.9, NE)				
Subjects who received neither	27	3 (11.1)	24 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	7 (21.2)	26 (78.8)	NE (NE, NE)				
No	68	12 (17.6)	56 (82.4)	NE (7.2, NE)				
HER2 status								
Kinase domain	98	18 (18.4)	80 (81.6)	NE (7.2, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	11 (18.0)	50 (82.0)	8.3 (6.9, NE)				
>=65 years	40	8 (20.0)	32 (80.0)	NE (NE, NE)				
Age II								
<75 years	93	18 (19.4)	75 (80.6)	NE (7.2, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (7.2, NE)				
Male	36	12 (33.3)	24 (66.7)	8.3 (6.9, NE)				
Smoking status								
Current	0							
Former	46	12 (26.1)	34 (73.9)	8.3 (6.9, NE)				
Never	55	7 (12.7)	48 (87.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	16 (20.5)	62 (79.5)	NE (7.2, NE)				
Region								
Asia	62	12 (19.4)	50 (80.6)	NE (7.2, NE)				
North America and Australia	6							
Europe	33	7 (21.2)	26 (78.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	16 (20.8)	61 (79.2)	NE (7.2, NE)				
12-lead ECG								
Normal	60	10 (16.7)	50 (83.3)	8.3 (6.9, NE)				
Abnormal, not clinically significant	41	9 (22.0)	32 (78.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	15 (17.9)	69 (82.1)	NE (7.2, NE)				
Abnormal, not clinically significant	17	4 (23.5)	13 (76.5)	NE (0.9, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	8 (26.7)	22 (73.3)	NE (6.9, NE)				
1	71	11 (15.5)	60 (84.5)	8.3 (8.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	7 (18.9)	30 (81.1)	8.3 (7.2, NE)				
Mild impairment	40	7 (17.5)	33 (82.5)	NE (6.9, NE)				
Moderate impairment	22	5 (22.7)	17 (77.3)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	16 (21.1)	60 (78.9)	8.3 (6.9, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	8 (10.8)	66 (89.2)	NE (7.2, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	5 (15.2)	28 (84.8)	NE (NE, NE)				
No	68	5 (7.4)	63 (92.6)	NE (6.9, NE)				
HER2 status								
Kinase domain	98	9 (9.2)	89 (90.8)	NE (7.2, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (6.9, NE)				
>=65 years	40	5 (12.5)	35 (87.5)	NE (NE, NE)				
Age II								
<75 years	93	9 (9.7)	84 (90.3)	NE (7.2, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	4 (6.2)	61 (93.8)	NE (7.2, NE)				
Male	36	6 (16.7)	30 (83.3)	NE (6.9, NE)				
Smoking status								
Current	0							
Former	46	8 (17.4)	38 (82.6)	NE (6.9, NE)				
Never	55	2 (3.6)	53 (96.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	1 (4.3)	22 (95.7)	NE (NE, NE)				
Non-White	78	9 (11.5)	69 (88.5)	NE (7.2, NE)				
Region								
Asia	62	8 (12.9)	54 (87.1)	NE (7.2, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	7 (9.1)	70 (90.9)	NE (7.2, NE)				
12-lead ECG								
Normal	60	6 (10.0)	54 (90.0)	NE (6.9, NE)				
Abnormal, not clinically significant	41	4 (9.8)	37 (90.2)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	9 (10.7)	75 (89.3)	NE (7.2, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	5 (16.7)	25 (83.3)	NE (6.9, NE)				
1	71	5 (7.0)	66 (93.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	3 (8.1)	34 (91.9)	NE (7.2, NE)				
Mild impairment	40	3 (7.5)	37 (92.5)	NE (6.9, NE)				
Moderate impairment	22	4 (18.2)	18 (81.8)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	9 (11.8)	67 (88.2)	NE (7.2, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	4 (5.4)	70 (94.6)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
No	68	5 (7.4)	63 (92.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	5 (5.1)	93 (94.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	1 (1.6)	60 (98.4)	NE (NE, NE)				
>=65 years	40	5 (12.5)	35 (87.5)	NE (NE, NE)				
Age II								
<75 years	93	6 (6.5)	87 (93.5)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	4 (6.2)	61 (93.8)	NE (NE, NE)				
Male	36	2 (5.6)	34 (94.4)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	2 (3.6)	53 (96.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	4 (5.1)	74 (94.9)	NE (NE, NE)				
Region								
Asia	62	3 (4.8)	59 (95.2)	NE (NE, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	1 (4.2)	23 (95.8)	NE (NE, NE)				
No	77	5 (6.5)	72 (93.5)	NE (NE, NE)				
12-lead ECG								
Normal	60	2 (3.3)	58 (96.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	4 (9.8)	37 (90.2)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	4 (4.8)	80 (95.2)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (3.4, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	0	30 (100.0)	NE (NE, NE)				
1	71	6 (8.5)	65 (91.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	3 (8.1)	34 (91.9)	NE (NE, NE)				
Mild impairment	40	1 (2.5)	39 (97.5)	NE (NE, NE)				
Moderate impairment	22	2 (9.1)	20 (90.9)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	6 (7.9)	70 (92.1)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	5 (6.8)	69 (93.2)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	33	1 (3.0)	32 (97.0)	NE (NE, NE)				
No	68	5 (7.4)	63 (92.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	6 (6.1)	92 (93.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	3 (4.9)	58 (95.1)	NE (NE, NE)				
>=65 years	40	3 (7.5)	37 (92.5)	NE (NE, NE)				
Age II								
<75 years	93	6 (6.5)	87 (93.5)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	4 (6.2)	61 (93.8)	NE (NE, NE)				
Male	36	2 (5.6)	34 (94.4)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	2 (4.3)	44 (95.7)	NE (NE, NE)				
Never	55	4 (7.3)	51 (92.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	4 (5.1)	74 (94.9)	NE (NE, NE)				
Region								
Asia	62	2 (3.2)	60 (96.8)	NE (NE, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	1 (4.2)	23 (95.8)	NE (NE, NE)				
No	77	5 (6.5)	72 (93.5)	NE (NE, NE)				
12-lead ECG								
Normal	60	5 (8.3)	55 (91.7)	NE (NE, NE)				
Abnormal, not clinically significant	41	1 (2.4)	40 (97.6)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	4 (4.8)	80 (95.2)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	30	0	30 (100.0)	NE (NE, NE)				
1	71	6 (8.5)	65 (91.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	3 (8.1)	34 (91.9)	NE (NE, NE)				
Mild impairment	40	2 (5.0)	38 (95.0)	NE (NE, NE)				
Moderate impairment	22	1 (4.5)	21 (95.5)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	4 (5.3)	72 (94.7)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

Anhang 4-G 4.4.2.2 Finaler Datenschnitt vom 23.12.2022

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	33 (44.6)	41 (55.4)	11.7 (2.9, NE)				
Subjects who received neither	27	10 (37.0)	17 (63.0)	NE (3.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	15 (44.1)	19 (55.9)	NE (0.7, NE)				
No	67	28 (41.8)	39 (58.2)	11.7 (4.2, NE)				
HER2 status								
Kinase domain	98	41 (41.8)	57 (58.2)	11.7 (4.8, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	17 (27.9)	44 (72.1)	NE (11.7, NE)				
>=65 years	40	26 (65.0)	14 (35.0)	1.1 (0.5, 11.7)				
Age II								
<75 years	93	36 (38.7)	57 (61.3)	NE (10.8, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	31 (47.7)	34 (52.3)	11.7 (3.4, NE)				
Male	36	12 (33.3)	24 (66.7)	NE (2.9, NE)				
Smoking status								
Current	0							
Former	46	22 (47.8)	24 (52.2)	10.8 (1.4, NE)				
Never	55	21 (38.2)	34 (61.8)	NE (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	10 (43.5)	13 (56.5)	NE (1.5, NE)				
Non-White	78	33 (42.3)	45 (57.7)	11.7 (4.1, NE)				
Region								
Asia	62	23 (37.1)	39 (62.9)	NE (10.8, NE)				
North America and Australia	6							
Europe	33	15 (45.5)	18 (54.5)	11.7 (0.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	11 (45.8)	13 (54.2)	NE (0.7, NE)				
No	77	32 (41.6)	45 (58.4)	11.7 (4.8, NE)				
12-lead ECG								
Normal	58	21 (36.2)	37 (63.8)	NE (4.1, NE)				
Abnormal, not clinically significant	43	22 (51.2)	21 (48.8)	10.8 (1.4, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	37 (44.0)	47 (56.0)	NE (3.4, NE)				
Abnormal, not clinically significant	17	6 (35.3)	11 (64.7)	11.7 (4.8, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	13 (44.8)	16 (55.2)	11.7 (0.7, NE)				
1	72	30 (41.7)	42 (58.3)	11.7 (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	13 (35.1)	24 (64.9)	NE (3.5, NE)				
Mild impairment	41	14 (34.1)	27 (65.9)	NE (4.2, NE)				
Moderate impairment	23	16 (69.6)	7 (30.4)	0.7 (0.3, 11.7)				
Hepatic function at baseline								
Normal hepatic function	76	33 (43.4)	43 (56.6)	11.7 (3.5, NE)				
Mild hepatic dysfunction	25	10 (40.0)	15 (60.0)	11.7 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	28 (37.8)	46 (62.2)	NE (4.8, NE)				
Subjects who received neither	27	9 (33.3)	18 (66.7)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	13 (38.2)	21 (61.8)	NE (2.2, NE)				
No	67	24 (35.8)	43 (64.2)	NE (10.8, NE)				
HER2 status								
Kinase domain	98	35 (35.7)	63 (64.3)	NE (10.8, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	15 (24.6)	46 (75.4)	NE (NE, NE)				
>=65 years	40	22 (55.0)	18 (45.0)	3.5 (0.5, NE)				
Age II								
<75 years	93	32 (34.4)	61 (65.6)	NE (10.8, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	27 (41.5)	38 (58.5)	NE (4.1, NE)				
Male	36	10 (27.8)	26 (72.2)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	20 (43.5)	26 (56.5)	NE (2.1, NE)				
Never	55	17 (30.9)	38 (69.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	NE (3.4, NE)				
Non-White	78	29 (37.2)	49 (62.8)	NE (10.8, NE)				
Region								
Asia	62	21 (33.9)	41 (66.1)	NE (10.8, NE)				
North America and Australia	6							
Europe	33	12 (36.4)	21 (63.6)	NE (2.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	11 (45.8)	13 (54.2)	NE (0.7, NE)				
No	77	26 (33.8)	51 (66.2)	NE (10.8, NE)				
12-lead ECG								
Normal	58	17 (29.3)	41 (70.7)	NE (NE, NE)				
Abnormal, not clinically significant	43	20 (46.5)	23 (53.5)	10.8 (2.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	33 (39.3)	51 (60.7)	NE (4.2, NE)				
Abnormal, not clinically significant	17	4 (23.5)	13 (76.5)	NE (4.8, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	10 (34.5)	19 (65.5)	NE (3.5, NE)				
1	72	27 (37.5)	45 (62.5)	NE (4.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	11 (29.7)	26 (70.3)	NE (10.8, NE)				
Mild impairment	41	13 (31.7)	28 (68.3)	NE (4.8, NE)				
Moderate impairment	23	13 (56.5)	10 (43.5)	4.1 (0.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	29 (38.2)	47 (61.8)	NE (4.2, NE)				
Mild hepatic dysfunction	25	8 (32.0)	17 (68.0)	NE (4.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Neutropenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	11 (14.9)	63 (85.1)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Neutropenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	5 (14.7)	29 (85.3)	NE (NE, NE)				
No	67	7 (10.4)	60 (89.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	12 (12.2)	86 (87.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Neutropenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	4 (6.6)	57 (93.4)	NE (NE, NE)				
>=65 years	40	8 (20.0)	32 (80.0)	NE (11.7, NE)				
Age II								
<75 years	93	9 (9.7)	84 (90.3)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Neutropenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	8 (12.3)	57 (87.7)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	7 (15.2)	39 (84.8)	NE (NE, NE)				
Never	55	5 (9.1)	50 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Neutropenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	NE (4.8, NE)				
Non-White	78	7 (9.0)	71 (91.0)	NE (NE, NE)				
Region								
Asia	62	2 (3.2)	60 (96.8)	NE (NE, NE)				
North America and Australia	6							
Europe	33	8 (24.2)	25 (75.8)	NE (11.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Neutropenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	10 (13.0)	67 (87.0)	NE (NE, NE)				
12-lead ECG								
Normal	58	6 (10.3)	52 (89.7)	NE (NE, NE)				
Abnormal, not clinically significant	43	6 (14.0)	37 (86.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Neutropenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	10 (11.9)	74 (88.1)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (11.7, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	5 (17.2)	24 (82.8)	NE (NE, NE)				
1	72	7 (9.7)	65 (90.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: Blood and lymphatic system disorders; PT: Neutropenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	41	2 (4.9)	39 (95.1)	NE (NE, NE)				
Moderate impairment	23	6 (26.1)	17 (73.9)	NE (5.5, NE)				
Hepatic function at baseline								
Normal hepatic function	76	10 (13.2)	66 (86.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (11.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	64 (86.5)	10 (13.5)	0.2 (0.1, 0.3)				
Subjects who received neither	27	24 (88.9)	3 (11.1)	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	27 (79.4)	7 (20.6)	0.2 (0.1, 1.1)				
No	67	61 (91.0)	6 (9.0)	0.1 (0.1, 0.3)				
HER2 status								
Kinase domain	98	86 (87.8)	12 (12.2)	0.2 (0.1, 0.3)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	52 (85.2)	9 (14.8)	0.1 (0.1, 0.3)				
>=65 years	40	36 (90.0)	4 (10.0)	0.2 (0.1, 0.3)				
Age II								
<75 years	93	81 (87.1)	12 (12.9)	0.1 (0.1, 0.3)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	60 (92.3)	5 (7.7)	0.2 (0.1, 0.3)				
Male	36	28 (77.8)	8 (22.2)	0.1 (0.1, 0.4)				
Smoking status								
Current	0							
Former	46	38 (82.6)	8 (17.4)	0.2 (0.1, 0.3)				
Never	55	50 (90.9)	5 (9.1)	0.1 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	20 (87.0)	3 (13.0)	0.3 (0.1, 0.5)				
Non-White	78	68 (87.2)	10 (12.8)	0.1 (0.1, 0.2)				
Region								
Asia	62	54 (87.1)	8 (12.9)	0.1 (0.1, 0.2)				
North America and Australia	6							
Europe	33	28 (84.8)	5 (15.2)	0.3 (0.1, 0.5)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	20 (83.3)	4 (16.7)	0.2 (0.1, 1.6)				
No	77	68 (88.3)	9 (11.7)	0.1 (0.1, 0.3)				
12-lead ECG								
Normal	58	52 (89.7)	6 (10.3)	0.1 (0.1, 0.3)				
Abnormal, not clinically significant	43	36 (83.7)	7 (16.3)	0.2 (0.1, 0.4)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	73 (86.9)	11 (13.1)	0.2 (0.1, 0.3)				
Abnormal, not clinically significant	17	15 (88.2)	2 (11.8)	0.1 (0.1, 1.7)				
Clinically significant findings	0							
ECOG performance status								
0	29	24 (82.8)	5 (17.2)	0.1 (0.1, 0.4)				
1	72	64 (88.9)	8 (11.1)	0.2 (0.1, 0.3)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	31 (83.8)	6 (16.2)	0.2 (0.1, 0.3)				
Mild impairment	41	35 (85.4)	6 (14.6)	0.3 (0.1, 0.4)				
Moderate impairment	23	22 (95.7)	1 (4.3)	0.1 (0.1, 0.2)				
Hepatic function at baseline								
Normal hepatic function	76	66 (86.8)	10 (13.2)	0.1 (0.1, 0.3)				
Mild hepatic dysfunction	25	22 (88.0)	3 (12.0)	0.3 (0.1, 1.7)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	23 (31.1)	51 (68.9)	NE (12.6, NE)				
Subjects who received neither	27	14 (51.9)	13 (48.1)	4.1 (0.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	12 (35.3)	22 (64.7)	NE (4.1, NE)				
No	67	25 (37.3)	42 (62.7)	NE (4.4, NE)				
HER2 status								
Kinase domain	98	37 (37.8)	61 (62.2)	NE (6.0, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	19 (31.1)	42 (68.9)	NE (NE, NE)				
>=65 years	40	18 (45.0)	22 (55.0)	12.6 (3.1, NE)				
Age II								
<75 years	93	34 (36.6)	59 (63.4)	NE (12.6, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	24 (36.9)	41 (63.1)	NE (4.1, NE)				
Male	36	13 (36.1)	23 (63.9)	NE (3.7, NE)				
Smoking status								
Current	0							
Former	46	17 (37.0)	29 (63.0)	NE (4.1, NE)				
Never	55	20 (36.4)	35 (63.6)	NE (6.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	7 (30.4)	16 (69.6)	NE (2.1, NE)				
Non-White	78	30 (38.5)	48 (61.5)	NE (6.0, NE)				
Region								
Asia	62	24 (38.7)	38 (61.3)	NE (3.7, NE)				
North America and Australia	6							
Europe	33	10 (30.3)	23 (69.7)	NE (4.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	9 (37.5)	15 (62.5)	NE (1.6, NE)				
No	77	28 (36.4)	49 (63.6)	NE (12.6, NE)				
12-lead ECG								
Normal	58	24 (41.4)	34 (58.6)	NE (2.1, NE)				
Abnormal, not clinically significant	43	13 (30.2)	30 (69.8)	NE (4.4, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	30 (35.7)	54 (64.3)	NE (12.6, NE)				
Abnormal, not clinically significant	17	7 (41.2)	10 (58.8)	NE (0.1, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	9 (31.0)	20 (69.0)	NE (12.6, NE)				
1	72	28 (38.9)	44 (61.1)	NE (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Constipation

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	12 (32.4)	25 (67.6)	NE (2.3, NE)				
Mild impairment	41	14 (34.1)	27 (65.9)	NE (3.1, NE)				
Moderate impairment	23	11 (47.8)	12 (52.2)	6.0 (2.1, NE)				
Hepatic function at baseline								
Normal hepatic function	76	25 (32.9)	51 (67.1)	NE (NE, NE)				
Mild hepatic dysfunction	25	12 (48.0)	13 (52.0)	12.6 (0.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	19 (25.7)	55 (74.3)	NE (NE, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	NE (13.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	10 (29.4)	24 (70.6)	NE (NE, NE)				
No	67	13 (19.4)	54 (80.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	23 (23.5)	75 (76.5)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	13 (21.3)	48 (78.7)	NE (NE, NE)				
>=65 years	40	10 (25.0)	30 (75.0)	NE (NE, NE)				
Age II								
<75 years	93	21 (22.6)	72 (77.4)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	13 (20.0)	52 (80.0)	NE (NE, NE)				
Male	36	10 (27.8)	26 (72.2)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	7 (15.2)	39 (84.8)	NE (NE, NE)				
Never	55	16 (29.1)	39 (70.9)	NE (13.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	9 (39.1)	14 (60.9)	NE (1.1, NE)				
Non-White	78	14 (17.9)	64 (82.1)	NE (NE, NE)				
Region								
Asia	62	10 (16.1)	52 (83.9)	NE (NE, NE)				
North America and Australia	6							
Europe	33	12 (36.4)	21 (63.6)	NE (2.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (NE, NE)				
No	77	18 (23.4)	59 (76.6)	NE (NE, NE)				
12-lead ECG								
Normal	58	13 (22.4)	45 (77.6)	NE (NE, NE)				
Abnormal, not clinically significant	43	10 (23.3)	33 (76.7)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	18 (21.4)	66 (78.6)	NE (NE, NE)				
Abnormal, not clinically significant	17	5 (29.4)	12 (70.6)	13.0 (0.8, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	7 (24.1)	22 (75.9)	NE (NE, NE)				
1	72	16 (22.2)	56 (77.8)	NE (13.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Diarrhoea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	5 (13.5)	32 (86.5)	NE (NE, NE)				
Mild impairment	41	10 (24.4)	31 (75.6)	NE (13.0, NE)				
Moderate impairment	23	8 (34.8)	15 (65.2)	NE (4.7, NE)				
Hepatic function at baseline								
Normal hepatic function	76	18 (23.7)	58 (76.3)	NE (NE, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	NE (13.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	49 (66.2)	25 (33.8)	0.3 (0.2, 1.4)				
Subjects who received neither	27	19 (70.4)	8 (29.6)	0.2 (0.1, 7.8)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	22 (64.7)	12 (35.3)	0.3 (0.1, 7.8)				
No	67	46 (68.7)	21 (31.3)	0.2 (0.1, 0.5)				
HER2 status								
Kinase domain	98	66 (67.3)	32 (32.7)	0.3 (0.2, 0.8)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	40 (65.6)	21 (34.4)	0.2 (0.1, 0.8)				
>=65 years	40	28 (70.0)	12 (30.0)	0.3 (0.2, 2.1)				
Age II								
<75 years	93	64 (68.8)	29 (31.2)	0.2 (0.1, 0.4)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	44 (67.7)	21 (32.3)	0.3 (0.2, 0.8)				
Male	36	24 (66.7)	12 (33.3)	0.3 (0.1, 2.8)				
Smoking status								
Current	0							
Former	46	31 (67.4)	15 (32.6)	0.2 (0.1, 5.3)				
Never	55	37 (67.3)	18 (32.7)	0.3 (0.1, 1.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	15 (65.2)	8 (34.8)	2.8 (0.2, 7.8)				
Non-White	78	53 (67.9)	25 (32.1)	0.2 (0.1, 0.3)				
Region								
Asia	62	41 (66.1)	21 (33.9)	0.2 (0.1, 0.3)				
North America and Australia	6							
Europe	33	22 (66.7)	11 (33.3)	1.4 (0.2, 7.8)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	13 (54.2)	11 (45.8)	5.3 (0.1, NE)				
No	77	55 (71.4)	22 (28.6)	0.2 (0.1, 0.3)				
12-lead ECG								
Normal	58	40 (69.0)	18 (31.0)	0.2 (0.1, 0.8)				
Abnormal, not clinically significant	43	28 (65.1)	15 (34.9)	0.3 (0.2, 5.3)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	58 (69.0)	26 (31.0)	0.3 (0.2, 0.8)				
Abnormal, not clinically significant	17	10 (58.8)	7 (41.2)	0.2 (0.1, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	19 (65.5)	10 (34.5)	0.5 (0.1, NE)				
1	72	49 (68.1)	23 (31.9)	0.3 (0.1, 0.4)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Nausea

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	23 (62.2)	14 (37.8)	0.3 (0.1, NE)				
Mild impairment	41	27 (65.9)	14 (34.1)	0.4 (0.1, 2.8)				
Moderate impairment	23	18 (78.3)	5 (21.7)	0.2 (0.1, 0.3)				
Hepatic function at baseline								
Normal hepatic function	76	52 (68.4)	24 (31.6)	0.3 (0.1, 0.5)				
Mild hepatic dysfunction	25	16 (64.0)	9 (36.0)	0.4 (0.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	11 (14.9)	63 (85.1)	NE (NE, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	NE (13.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	2 (5.9)	32 (94.1)	NE (NE, NE)				
No	67	13 (19.4)	54 (80.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	14 (14.3)	84 (85.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	8 (13.1)	53 (86.9)	NE (NE, NE)				
>=65 years	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Age II								
<75 years	93	12 (12.9)	81 (87.1)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	10 (15.4)	55 (84.6)	NE (NE, NE)				
Male	36	5 (13.9)	31 (86.1)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	6 (13.0)	40 (87.0)	NE (NE, NE)				
Never	55	9 (16.4)	46 (83.6)	NE (13.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	13 (16.7)	65 (83.3)	NE (NE, NE)				
Region								
Asia	62	11 (17.7)	51 (82.3)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	1 (4.2)	23 (95.8)	NE (NE, NE)				
No	77	14 (18.2)	63 (81.8)	NE (NE, NE)				
12-lead ECG								
Normal	58	8 (13.8)	50 (86.2)	NE (NE, NE)				
Abnormal, not clinically significant	43	7 (16.3)	36 (83.7)	NE (13.6, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	11 (13.1)	73 (86.9)	NE (NE, NE)				
Abnormal, not clinically significant	17	4 (23.5)	13 (76.5)	13.6 (3.5, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	4 (13.8)	25 (86.2)	NE (NE, NE)				
1	72	11 (15.3)	61 (84.7)	NE (13.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Stomatitis

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	5 (13.5)	32 (86.5)	NE (13.6, NE)				
Mild impairment	41	6 (14.6)	35 (85.4)	NE (NE, NE)				
Moderate impairment	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	12 (15.8)	64 (84.2)	NE (NE, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	23 (31.1)	51 (68.9)	NE (NE, NE)				
Subjects who received neither	27	9 (33.3)	18 (66.7)	NE (7.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	15 (44.1)	19 (55.9)	8.8 (3.3, NE)				
No	67	17 (25.4)	50 (74.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	31 (31.6)	67 (68.4)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	16 (26.2)	45 (73.8)	NE (NE, NE)				
>=65 years	40	16 (40.0)	24 (60.0)	NE (3.5, NE)				
Age II								
<75 years	93	29 (31.2)	64 (68.8)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	22 (33.8)	43 (66.2)	NE (7.8, NE)				
Male	36	10 (27.8)	26 (72.2)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	14 (30.4)	32 (69.6)	NE (NE, NE)				
Never	55	18 (32.7)	37 (67.3)	NE (8.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	9 (39.1)	14 (60.9)	NE (3.3, NE)				
Non-White	78	23 (29.5)	55 (70.5)	NE (NE, NE)				
Region								
Asia	62	19 (30.6)	43 (69.4)	NE (NE, NE)				
North America and Australia	6							
Europe	33	9 (27.3)	24 (72.7)	NE (7.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	7 (29.2)	17 (70.8)	NE (5.3, NE)				
No	77	25 (32.5)	52 (67.5)	NE (NE, NE)				
12-lead ECG								
Normal	58	17 (29.3)	41 (70.7)	NE (NE, NE)				
Abnormal, not clinically significant	43	15 (34.9)	28 (65.1)	NE (5.3, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	28 (33.3)	56 (66.7)	NE (NE, NE)				
Abnormal, not clinically significant	17	4 (23.5)	13 (76.5)	NE (3.9, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	11 (37.9)	18 (62.1)	NE (2.8, NE)				
1	72	21 (29.2)	51 (70.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Vomiting

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	8 (21.6)	29 (78.4)	NE (NE, NE)				
Mild impairment	41	14 (34.1)	27 (65.9)	NE (5.3, NE)				
Moderate impairment	23	10 (43.5)	13 (56.5)	NE (0.9, NE)				
Hepatic function at baseline								
Normal hepatic function	76	28 (36.8)	48 (63.2)	NE (8.8, NE)				
Mild hepatic dysfunction	25	4 (16.0)	21 (84.0)	NE (7.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	42 (56.8)	32 (43.2)	4.4 (1.5, NE)				
Subjects who received neither	27	15 (55.6)	12 (44.4)	4.5 (2.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	20 (58.8)	14 (41.2)	4.4 (2.1, NE)				
No	67	37 (55.2)	30 (44.8)	3.9 (1.5, 13.3)				
HER2 status								
Kinase domain	98	56 (57.1)	42 (42.9)	4.2 (2.1, 12.7)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	31 (50.8)	30 (49.2)	5.3 (3.1, NE)				
>=65 years	40	26 (65.0)	14 (35.0)	2.5 (0.7, 13.3)				
Age II								
<75 years	93	50 (53.8)	43 (46.2)	5.1 (2.9, 13.3)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	35 (53.8)	30 (46.2)	4.4 (2.9, NE)				
Male	36	22 (61.1)	14 (38.9)	2.6 (0.3, NE)				
Smoking status								
Current	0							
Former	46	26 (56.5)	20 (43.5)	5.6 (0.3, NE)				
Never	55	31 (56.4)	24 (43.6)	3.7 (2.1, 12.7)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	13 (56.5)	10 (43.5)	3.9 (0.5, NE)				
Non-White	78	44 (56.4)	34 (43.6)	4.5 (2.1, 13.3)				
Region								
Asia	62	30 (48.4)	32 (51.6)	7.0 (3.2, NE)				
North America and Australia	6							
Europe	33	22 (66.7)	11 (33.3)	1.4 (0.3, 5.1)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	11 (45.8)	13 (54.2)	6.0 (1.5, NE)				
No	77	46 (59.7)	31 (40.3)	3.7 (1.5, 12.7)				
12-lead ECG								
Normal	58	26 (44.8)	32 (55.2)	13.3 (2.8, NE)				
Abnormal, not clinically significant	43	31 (72.1)	12 (27.9)	2.9 (0.3, 4.4)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	48 (57.1)	36 (42.9)	4.2 (2.1, 13.3)				
Abnormal, not clinically significant	17	9 (52.9)	8 (47.1)	4.5 (0.3, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	19 (65.5)	10 (34.5)	2.1 (0.2, 13.3)				
1	72	38 (52.8)	34 (47.2)	5.3 (3.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	17 (45.9)	20 (54.1)	12.7 (0.5, NE)				
Mild impairment	41	25 (61.0)	16 (39.0)	3.2 (1.4, 6.0)				
Moderate impairment	23	15 (65.2)	8 (34.8)	3.9 (0.7, NE)				
Hepatic function at baseline								
Normal hepatic function	76	43 (56.6)	33 (43.4)	4.2 (2.1, 12.7)				
Mild hepatic dysfunction	25	14 (56.0)	11 (44.0)	5.3 (0.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	12 (16.2)	62 (83.8)	NE (NE, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	9 (26.5)	25 (73.5)	NE (NE, NE)				
No	67	7 (10.4)	60 (89.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	16 (16.3)	82 (83.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	9 (14.8)	52 (85.2)	NE (NE, NE)				
>=65 years	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Age II								
<75 years	93	14 (15.1)	79 (84.9)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	11 (16.9)	54 (83.1)	NE (NE, NE)				
Male	36	5 (13.9)	31 (86.1)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	7 (15.2)	39 (84.8)	NE (NE, NE)				
Never	55	9 (16.4)	46 (83.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	13 (16.7)	65 (83.3)	NE (NE, NE)				
Region								
Asia	62	1 (1.6)	61 (98.4)	NE (NE, NE)				
North America and Australia	6							
Europe	33	15 (45.5)	18 (54.5)	NE (0.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (NE, NE)				
No	77	11 (14.3)	66 (85.7)	NE (NE, NE)				
12-lead ECG								
Normal	58	5 (8.6)	53 (91.4)	NE (NE, NE)				
Abnormal, not clinically significant	43	11 (25.6)	32 (74.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	13 (15.5)	71 (84.5)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	5 (17.2)	24 (82.8)	NE (NE, NE)				
1	72	11 (15.3)	61 (84.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Asthenia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	7 (18.9)	30 (81.1)	NE (NE, NE)				
Mild impairment	41	6 (14.6)	35 (85.4)	NE (NE, NE)				
Moderate impairment	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	11 (14.5)	65 (85.5)	NE (NE, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	14 (18.9)	60 (81.1)	NE (NE, NE)				
Subjects who received neither	27	3 (11.1)	24 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	4 (11.8)	30 (88.2)	NE (NE, NE)				
No	67	13 (19.4)	54 (80.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	17 (17.3)	81 (82.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	7 (11.5)	54 (88.5)	NE (NE, NE)				
>=65 years	40	10 (25.0)	30 (75.0)	NE (NE, NE)				
Age II								
<75 years	93	14 (15.1)	79 (84.9)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	10 (15.4)	55 (84.6)	NE (NE, NE)				
Male	36	7 (19.4)	29 (80.6)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	6 (13.0)	40 (87.0)	NE (NE, NE)				
Never	55	11 (20.0)	44 (80.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	6 (26.1)	17 (73.9)	NE (2.8, NE)				
Non-White	78	11 (14.1)	67 (85.9)	NE (NE, NE)				
Region								
Asia	62	9 (14.5)	53 (85.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	14 (18.2)	63 (81.8)	NE (NE, NE)				
12-lead ECG								
Normal	58	9 (15.5)	49 (84.5)	NE (NE, NE)				
Abnormal, not clinically significant	43	8 (18.6)	35 (81.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	14 (16.7)	70 (83.3)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (3.7, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	6 (20.7)	23 (79.3)	NE (NE, NE)				
1	72	11 (15.3)	61 (84.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: General disorders and administration site conditions; PT: Fatigue

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	5 (13.5)	32 (86.5)	NE (NE, NE)				
Mild impairment	41	9 (22.0)	32 (78.0)	NE (NE, NE)				
Moderate impairment	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	14 (18.4)	62 (81.6)	NE (NE, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Malaise

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	12 (16.2)	62 (83.8)	NE (NE, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	NE (13.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Malaise

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	2 (5.9)	32 (94.1)	NE (NE, NE)				
No	67	14 (20.9)	53 (79.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	15 (15.3)	83 (84.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Malaise

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	10 (16.4)	51 (83.6)	NE (NE, NE)				
>=65 years	40	6 (15.0)	34 (85.0)	NE (13.3, NE)				
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Malaise

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	8 (12.3)	57 (87.7)	NE (NE, NE)				
Male	36	8 (22.2)	28 (77.8)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	11 (23.9)	35 (76.1)	NE (13.3, NE)				
Never	55	5 (9.1)	50 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Malaise

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	14 (17.9)	64 (82.1)	NE (NE, NE)				
Region								
Asia	62	14 (22.6)	48 (77.4)	NE (13.3, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Malaise

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	4 (16.7)	20 (83.3)	NE (NE, NE)				
No	77	12 (15.6)	65 (84.4)	NE (NE, NE)				
12-lead ECG								
Normal	58	10 (17.2)	48 (82.8)	NE (NE, NE)				
Abnormal, not clinically significant	43	6 (14.0)	37 (86.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Malaise

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	16 (19.0)	68 (81.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	0	17 (100.0)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	6 (20.7)	23 (79.3)	NE (13.3, NE)				
1	72	10 (13.9)	62 (86.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Malaise

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	3 (8.1)	34 (91.9)	NE (NE, NE)				
Mild impairment	41	7 (17.1)	34 (82.9)	NE (NE, NE)				
Moderate impairment	23	6 (26.1)	17 (73.9)	13.3 (7.0, NE)				
Hepatic function at baseline								
Normal hepatic function	76	11 (14.5)	65 (85.5)	NE (NE, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	NE (13.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Pyrexia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	10 (13.5)	64 (86.5)	NE (NE, NE)				
Subjects who received neither	27	3 (11.1)	24 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Pyrexia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	5 (14.7)	29 (85.3)	NE (NE, NE)				
No	67	8 (11.9)	59 (88.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	13 (13.3)	85 (86.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Pyrexia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	8 (13.1)	53 (86.9)	NE (NE, NE)				
>=65 years	40	5 (12.5)	35 (87.5)	NE (NE, NE)				
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: General disorders and administration site conditions; PT: Pyrexia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	8 (12.3)	57 (87.7)	NE (NE, NE)				
Male	36	5 (13.9)	31 (86.1)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	9 (16.4)	46 (83.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Pyrexia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	10 (12.8)	68 (87.2)	NE (NE, NE)				
Region								
Asia	62	9 (14.5)	53 (85.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Pyrexia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	1 (4.2)	23 (95.8)	NE (NE, NE)				
No	77	12 (15.6)	65 (84.4)	NE (NE, NE)				
12-lead ECG								
Normal	58	5 (8.6)	53 (91.4)	NE (NE, NE)				
Abnormal, not clinically significant	43	8 (18.6)	35 (81.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Pyrexia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	11 (13.1)	73 (86.9)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	5 (17.2)	24 (82.8)	NE (NE, NE)				
1	72	8 (11.1)	64 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Pyrexia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (NE, NE)				
Mild impairment	41	9 (22.0)	32 (78.0)	NE (NE, NE)				
Moderate impairment	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	10 (13.2)	66 (86.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	28 (37.8)	46 (62.2)	9.5 (6.2, NE)				
Subjects who received neither	27	13 (48.1)	14 (51.9)	9.7 (4.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	12 (35.3)	22 (64.7)	NE (4.8, NE)				
No	67	29 (43.3)	38 (56.7)	9.5 (5.6, NE)				
HER2 status								
Kinase domain	98	41 (41.8)	57 (58.2)	9.5 (5.6, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	24 (39.3)	37 (60.7)	9.7 (5.6, NE)				
>=65 years	40	17 (42.5)	23 (57.5)	8.0 (2.8, NE)				
Age II								
<75 years	93	37 (39.8)	56 (60.2)	9.7 (6.2, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	23 (35.4)	42 (64.6)	NE (6.2, NE)				
Male	36	18 (50.0)	18 (50.0)	7.7 (4.3, NE)				
Smoking status								
Current	0							
Former	46	21 (45.7)	25 (54.3)	9.5 (4.8, NE)				
Never	55	20 (36.4)	35 (63.6)	NE (6.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	5.4 (3.7, NE)				
Non-White	78	30 (38.5)	48 (61.5)	10.3 (7.3, NE)				
Region								
Asia	62	24 (38.7)	38 (61.3)	10.3 (7.3, NE)				
North America and Australia	6							
Europe	33	14 (42.4)	19 (57.6)	5.4 (4.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	7 (29.2)	17 (70.8)	NE (3.6, NE)				
No	77	34 (44.2)	43 (55.8)	9.5 (5.4, NE)				
12-lead ECG								
Normal	58	28 (48.3)	30 (51.7)	8.0 (4.8, NE)				
Abnormal, not clinically significant	43	13 (30.2)	30 (69.8)	NE (5.6, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	35 (41.7)	49 (58.3)	9.5 (5.4, NE)				
Abnormal, not clinically significant	17	6 (35.3)	11 (64.7)	NE (2.0, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	12 (41.4)	17 (58.6)	9.7 (5.4, NE)				
1	72	29 (40.3)	43 (59.7)	9.5 (5.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	17 (45.9)	20 (54.1)	7.7 (5.4, NE)				
Mild impairment	41	14 (34.1)	27 (65.9)	10.3 (4.5, NE)				
Moderate impairment	23	10 (43.5)	13 (56.5)	NE (2.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	32 (42.1)	44 (57.9)	9.5 (5.4, NE)				
Mild hepatic dysfunction	25	9 (36.0)	16 (64.0)	10.3 (5.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: COVID-19

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	10 (13.5)	64 (86.5)	NE (13.4, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: COVID-19

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	2 (5.9)	32 (94.1)	NE (NE, NE)				
No	67	12 (17.9)	55 (82.1)	NE (13.4, NE)				
HER2 status								
Kinase domain	98	14 (14.3)	84 (85.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Infections and infestations; PT: COVID-19

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	8 (13.1)	53 (86.9)	NE (NE, NE)				
>=65 years	40	6 (15.0)	34 (85.0)	NE (13.4, NE)				
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

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SOC: Infections and infestations; PT: COVID-19

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	10 (15.4)	55 (84.6)	NE (13.4, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	5 (10.9)	41 (89.1)	NE (NE, NE)				
Never	55	9 (16.4)	46 (83.6)	NE (13.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: COVID-19

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	6 (26.1)	17 (73.9)	13.4 (5.4, NE)				
Non-White	78	8 (10.3)	70 (89.7)	NE (NE, NE)				
Region								
Asia	62	7 (11.3)	55 (88.7)	NE (NE, NE)				
North America and Australia	6							
Europe	33	6 (18.2)	27 (81.8)	NE (6.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: COVID-19

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (6.7, NE)				
No	77	11 (14.3)	66 (85.7)	NE (NE, NE)				
12-lead ECG								
Normal	58	10 (17.2)	48 (82.8)	NE (13.4, NE)				
Abnormal, not clinically significant	43	4 (9.3)	39 (90.7)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: Infections and infestations; PT: COVID-19

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	12 (14.3)	72 (85.7)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (10.3, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	3 (10.3)	26 (89.7)	NE (13.4, NE)				
1	72	11 (15.3)	61 (84.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Infections and infestations; PT: COVID-19

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	7 (18.9)	30 (81.1)	NE (13.4, NE)				
Mild impairment	41	5 (12.2)	36 (87.8)	NE (NE, NE)				
Moderate impairment	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	13 (17.1)	63 (82.9)	NE (13.4, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (10.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	47 (63.5)	27 (36.5)	1.5 (0.7, 4.2)				
Subjects who received neither	27	18 (66.7)	9 (33.3)	5.9 (0.7, 9.0)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	22 (64.7)	12 (35.3)	3.7 (0.7, 8.5)				
No	67	43 (64.2)	24 (35.8)	2.1 (0.6, 4.9)				
HER2 status								
Kinase domain	98	62 (63.3)	36 (36.7)	3.0 (1.4, 6.2)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	41 (67.2)	20 (32.8)	2.1 (0.7, 5.9)				
>=65 years	40	24 (60.0)	16 (40.0)	3.6 (0.5, NE)				
Age II								
<75 years	93	60 (64.5)	33 (35.5)	2.2 (0.7, 5.9)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	35 (53.8)	30 (46.2)	5.9 (2.1, NE)				
Male	36	30 (83.3)	6 (16.7)	0.6 (0.3, 1.5)				
Smoking status								
Current	0							
Former	46	30 (65.2)	16 (34.8)	1.4 (0.5, 4.9)				
Never	55	35 (63.6)	20 (36.4)	3.7 (1.4, 6.9)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	11 (47.8)	12 (52.2)	4.1 (1.4, NE)				
Non-White	78	54 (69.2)	24 (30.8)	1.8 (0.6, 4.9)				
Region								
Asia	62	47 (75.8)	15 (24.2)	1.1 (0.5, 4.2)				
North America and Australia	6							
Europe	33	15 (45.5)	18 (54.5)	NE (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	15 (62.5)	9 (37.5)	3.0 (0.5, NE)				
No	77	50 (64.9)	27 (35.1)	2.1 (0.7, 6.2)				
12-lead ECG								
Normal	58	38 (65.5)	20 (34.5)	2.1 (0.7, 7.0)				
Abnormal, not clinically significant	43	27 (62.8)	16 (37.2)	3.7 (0.7, 6.9)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	56 (66.7)	28 (33.3)	2.1 (0.7, 4.9)				
Abnormal, not clinically significant	17	9 (52.9)	8 (47.1)	9.0 (0.9, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	21 (72.4)	8 (27.6)	2.1 (0.5, 6.2)				
1	72	44 (61.1)	28 (38.9)	3.0 (0.7, 6.9)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	23 (62.2)	14 (37.8)	2.2 (0.7, 9.0)				
Mild impairment	41	27 (65.9)	14 (34.1)	2.1 (0.7, 8.5)				
Moderate impairment	23	15 (65.2)	8 (34.8)	3.6 (0.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	49 (64.5)	27 (35.5)	3.0 (0.7, 5.9)				
Mild hepatic dysfunction	25	16 (64.0)	9 (36.0)	1.4 (0.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	8 (10.8)	66 (89.2)	NE (NE, NE)				
Subjects who received neither	27	6 (22.2)	21 (77.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (NE, NE)				
No	67	11 (16.4)	56 (83.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	13 (13.3)	85 (86.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	10 (16.4)	51 (83.6)	NE (NE, NE)				
>=65 years	40	4 (10.0)	36 (90.0)	NE (NE, NE)				
Age II								
<75 years	93	14 (15.1)	79 (84.9)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	6 (9.2)	59 (90.8)	NE (NE, NE)				
Male	36	8 (22.2)	28 (77.8)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	9 (19.6)	37 (80.4)	NE (NE, NE)				
Never	55	5 (9.1)	50 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Non-White	78	10 (12.8)	68 (87.2)	NE (NE, NE)				
Region								
Asia	62	10 (16.1)	52 (83.9)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	12 (15.6)	65 (84.4)	NE (NE, NE)				
12-lead ECG								
Normal	58	8 (13.8)	50 (86.2)	NE (NE, NE)				
Abnormal, not clinically significant	43	6 (14.0)	37 (86.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	11 (13.1)	73 (86.9)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	5 (17.2)	24 (82.8)	NE (NE, NE)				
1	72	9 (12.5)	63 (87.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Alanine aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	8 (21.6)	29 (78.4)	NE (NE, NE)				
Mild impairment	41	5 (12.2)	36 (87.8)	NE (NE, NE)				
Moderate impairment	23	1 (4.3)	22 (95.7)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	11 (14.5)	65 (85.5)	NE (NE, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	11 (14.9)	63 (85.1)	NE (NE, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (7.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	7 (20.6)	27 (79.4)	NE (7.6, NE)				
No	67	12 (17.9)	55 (82.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	17 (17.3)	81 (82.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	14 (23.0)	47 (77.0)	NE (NE, NE)				
>=65 years	40	5 (12.5)	35 (87.5)	NE (NE, NE)				
Age II								
<75 years	93	18 (19.4)	75 (80.6)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	10 (15.4)	55 (84.6)	NE (NE, NE)				
Male	36	9 (25.0)	27 (75.0)	NE (9.0, NE)				
Smoking status								
Current	0							
Former	46	10 (21.7)	36 (78.3)	NE (NE, NE)				
Never	55	9 (16.4)	46 (83.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	NE (4.8, NE)				
Non-White	78	14 (17.9)	64 (82.1)	NE (NE, NE)				
Region								
Asia	62	12 (19.4)	50 (80.6)	NE (NE, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (6.9, NE)				
No	77	14 (18.2)	63 (81.8)	NE (NE, NE)				
12-lead ECG								
Normal	58	9 (15.5)	49 (84.5)	NE (NE, NE)				
Abnormal, not clinically significant	43	10 (23.3)	33 (76.7)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	17 (20.2)	67 (79.8)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	7 (24.1)	22 (75.9)	NE (9.0, NE)				
1	72	12 (16.7)	60 (83.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: Investigations; PT: Aspartate aminotransferase increased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	10 (27.0)	27 (73.0)	NE (7.6, NE)				
Mild impairment	41	7 (17.1)	34 (82.9)	NE (NE, NE)				
Moderate impairment	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	15 (19.7)	61 (80.3)	NE (NE, NE)				
Mild hepatic dysfunction	25	4 (16.0)	21 (84.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	24 (32.4)	50 (67.6)	NE (10.7, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (6.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	12 (35.3)	22 (64.7)	10.7 (9.9, NE)				
No	67	20 (29.9)	47 (70.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	30 (30.6)	68 (69.4)	NE (10.7, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	18 (29.5)	43 (70.5)	NE (10.7, NE)				
>=65 years	40	14 (35.0)	26 (65.0)	NE (5.4, NE)				
Age II								
<75 years	93	28 (30.1)	65 (69.9)	NE (10.7, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	18 (27.7)	47 (72.3)	NE (NE, NE)				
Male	36	14 (38.9)	22 (61.1)	10.7 (6.5, NE)				
Smoking status								
Current	0							
Former	46	16 (34.8)	30 (65.2)	NE (5.4, NE)				
Never	55	16 (29.1)	39 (70.9)	NE (9.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	10.7 (10.7, NE)				
Non-White	78	27 (34.6)	51 (65.4)	NE (9.9, NE)				
Region								
Asia	62	25 (40.3)	37 (59.7)	NE (5.4, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (10.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	6 (25.0)	18 (75.0)	NE (NE, NE)				
No	77	26 (33.8)	51 (66.2)	NE (9.9, NE)				
12-lead ECG								
Normal	58	20 (34.5)	38 (65.5)	NE (9.9, NE)				
Abnormal, not clinically significant	43	12 (27.9)	31 (72.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	31 (36.9)	53 (63.1)	NE (6.5, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	16 (55.2)	13 (44.8)	6.5 (2.1, 10.7)				
1	72	16 (22.2)	56 (77.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	9 (24.3)	28 (75.7)	NE (10.7, NE)				
Mild impairment	41	14 (34.1)	27 (65.9)	NE (6.2, NE)				
Moderate impairment	23	9 (39.1)	14 (60.9)	NE (0.7, NE)				
Hepatic function at baseline								
Normal hepatic function	76	26 (34.2)	50 (65.8)	NE (9.9, NE)				
Mild hepatic dysfunction	25	6 (24.0)	19 (76.0)	NE (6.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	17 (23.0)	57 (77.0)	15.0 (11.9, NE)				
Subjects who received neither	27	8 (29.6)	19 (70.4)	NE (7.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	6 (17.6)	28 (82.4)	NE (NE, NE)				
No	67	19 (28.4)	48 (71.6)	15.0 (11.9, NE)				
HER2 status								
Kinase domain	98	23 (23.5)	75 (76.5)	NE (15.0, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	12 (19.7)	49 (80.3)	NE (15.0, NE)				
>=65 years	40	13 (32.5)	27 (67.5)	NE (7.0, NE)				
Age II								
<75 years	93	23 (24.7)	70 (75.3)	NE (15.0, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	18 (27.7)	47 (72.3)	15.0 (11.9, NE)				
Male	36	7 (19.4)	29 (80.6)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	10 (21.7)	36 (78.3)	15.0 (15.0, NE)				
Never	55	15 (27.3)	40 (72.7)	NE (11.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	23 (29.5)	55 (70.5)	15.0 (11.9, NE)				
Region								
Asia	62	23 (37.1)	39 (62.9)	15.0 (7.0, NE)				
North America and Australia	6							
Europe	33	1 (3.0)	32 (97.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	4 (16.7)	20 (83.3)	NE (NE, NE)				
No	77	21 (27.3)	56 (72.7)	15.0 (11.9, NE)				
12-lead ECG								
Normal	58	17 (29.3)	41 (70.7)	15.0 (11.9, NE)				
Abnormal, not clinically significant	43	8 (18.6)	35 (81.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Platelet count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	22 (26.2)	62 (73.8)	15.0 (11.9, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (3.3, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	9 (31.0)	20 (69.0)	15.0 (11.9, NE)				
1	72	16 (22.2)	56 (77.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	8 (21.6)	29 (78.4)	15.0 (15.0, NE)				
Mild impairment	41	9 (22.0)	32 (78.0)	NE (11.9, NE)				
Moderate impairment	23	8 (34.8)	15 (65.2)	NE (3.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	18 (23.7)	58 (76.3)	NE (15.0, NE)				
Mild hepatic dysfunction	25	7 (28.0)	18 (72.0)	11.9 (5.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Weight decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	9 (12.2)	65 (87.8)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Weight decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	5 (14.7)	29 (85.3)	13.4 (13.4, NE)				
No	67	6 (9.0)	61 (91.0)	NE (NE, NE)				
HER2 status								
Kinase domain	98	10 (10.2)	88 (89.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Weight decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	6 (15.0)	34 (85.0)	NE (NE, NE)				
Age II								
<75 years	93	9 (9.7)	84 (90.3)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Weight decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	5 (7.7)	60 (92.3)	NE (NE, NE)				
Male	36	6 (16.7)	30 (83.3)	NE (13.4, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (13.4, NE)				
Never	55	7 (12.7)	48 (87.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Weight decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	13.4 (7.7, NE)				
Non-White	78	6 (7.7)	72 (92.3)	NE (NE, NE)				
Region								
Asia	62	3 (4.8)	59 (95.2)	NE (NE, NE)				
North America and Australia	6							
Europe	33	7 (21.2)	26 (78.8)	13.4 (13.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Weight decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	8 (10.4)	69 (89.6)	NE (NE, NE)				
12-lead ECG								
Normal	58	6 (10.3)	52 (89.7)	NE (NE, NE)				
Abnormal, not clinically significant	43	5 (11.6)	38 (88.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Weight decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	10 (11.9)	74 (88.1)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	5 (17.2)	24 (82.8)	NE (13.4, NE)				
1	72	6 (8.3)	66 (91.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Weight decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	41	4 (9.8)	37 (90.2)	NE (13.4, NE)				
Moderate impairment	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	11 (14.5)	65 (85.5)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	21 (28.4)	53 (71.6)	NE (9.8, NE)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (12.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	7 (20.6)	27 (79.4)	NE (NE, NE)				
No	67	19 (28.4)	48 (71.6)	NE (9.8, NE)				
HER2 status								
Kinase domain	98	25 (25.5)	73 (74.5)	NE (12.3, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	15 (24.6)	46 (75.4)	NE (NE, NE)				
>=65 years	40	11 (27.5)	29 (72.5)	NE (9.8, NE)				
Age II								
<75 years	93	23 (24.7)	70 (75.3)	NE (12.3, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	16 (24.6)	49 (75.4)	NE (12.3, NE)				
Male	36	10 (27.8)	26 (72.2)	NE (8.5, NE)				
Smoking status								
Current	0							
Former	46	14 (30.4)	32 (69.6)	NE (7.0, NE)				
Never	55	12 (21.8)	43 (78.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	23 (29.5)	55 (70.5)	NE (9.8, NE)				
Region								
Asia	62	22 (35.5)	40 (64.5)	NE (7.0, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	6 (25.0)	18 (75.0)	NE (NE, NE)				
No	77	20 (26.0)	57 (74.0)	NE (12.3, NE)				
12-lead ECG								
Normal	58	17 (29.3)	41 (70.7)	NE (9.8, NE)				
Abnormal, not clinically significant	43	9 (20.9)	34 (79.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	26 (31.0)	58 (69.0)	NE (9.8, NE)				
Abnormal, not clinically significant	17	0	17 (100.0)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	14 (48.3)	15 (51.7)	9.8 (2.1, NE)				
1	72	12 (16.7)	60 (83.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: White blood cell count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	7 (18.9)	30 (81.1)	NE (NE, NE)				
Mild impairment	41	11 (26.8)	30 (73.2)	NE (8.5, NE)				
Moderate impairment	23	8 (34.8)	15 (65.2)	12.3 (7.0, NE)				
Hepatic function at baseline								
Normal hepatic function	76	20 (26.3)	56 (73.7)	NE (NE, NE)				
Mild hepatic dysfunction	25	6 (24.0)	19 (76.0)	12.3 (9.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	38 (51.4)	36 (48.6)	4.2 (1.4, NE)				
Subjects who received neither	27	16 (59.3)	11 (40.7)	4.9 (0.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	17 (50.0)	17 (50.0)	12.9 (0.9, NE)				
No	67	37 (55.2)	30 (44.8)	3.4 (0.7, NE)				
HER2 status								
Kinase domain	98	51 (52.0)	47 (48.0)	4.9 (1.5, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	26 (42.6)	35 (57.4)	12.9 (4.2, NE)				
>=65 years	40	28 (70.0)	12 (30.0)	0.9 (0.3, 2.8)				
Age II								
<75 years	93	48 (51.6)	45 (48.4)	9.7 (1.4, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	32 (49.2)	33 (50.8)	9.7 (1.5, NE)				
Male	36	22 (61.1)	14 (38.9)	1.8 (0.5, NE)				
Smoking status								
Current	0							
Former	46	25 (54.3)	21 (45.7)	3.9 (1.3, NE)				
Never	55	29 (52.7)	26 (47.3)	4.2 (0.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	15 (65.2)	8 (34.8)	2.1 (0.7, NE)				
Non-White	78	39 (50.0)	39 (50.0)	9.7 (0.9, NE)				
Region								
Asia	62	28 (45.2)	34 (54.8)	10.3 (0.9, NE)				
North America and Australia	6							
Europe	33	21 (63.6)	12 (36.4)	2.8 (1.0, 12.9)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	13 (54.2)	11 (45.8)	4.2 (0.3, NE)				
No	77	41 (53.2)	36 (46.8)	4.2 (1.3, NE)				
12-lead ECG								
Normal	58	31 (53.4)	27 (46.6)	2.8 (0.7, NE)				
Abnormal, not clinically significant	43	23 (53.5)	20 (46.5)	4.2 (1.4, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	44 (52.4)	40 (47.6)	4.2 (1.0, NE)				
Abnormal, not clinically significant	17	10 (58.8)	7 (41.2)	9.7 (0.1, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	17 (58.6)	12 (41.4)	4.9 (0.3, NE)				
1	72	37 (51.4)	35 (48.6)	4.2 (1.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	20 (54.1)	17 (45.9)	3.9 (0.7, NE)				
Mild impairment	41	20 (48.8)	21 (51.2)	4.9 (0.3, NE)				
Moderate impairment	23	14 (60.9)	9 (39.1)	2.1 (0.7, NE)				
Hepatic function at baseline								
Normal hepatic function	76	43 (56.6)	33 (43.4)	3.9 (1.0, NE)				
Mild hepatic dysfunction	25	11 (44.0)	14 (56.0)	NE (0.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	27 (36.5)	47 (63.5)	NE (7.2, NE)				
Subjects who received neither	27	13 (48.1)	14 (51.9)	12.9 (0.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	14 (41.2)	20 (58.8)	12.9 (3.9, NE)				
No	67	26 (38.8)	41 (61.2)	NE (4.9, NE)				
HER2 status								
Kinase domain	98	37 (37.8)	61 (62.2)	12.9 (10.3, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	19 (31.1)	42 (68.9)	NE (12.9, NE)				
>=65 years	40	21 (52.5)	19 (47.5)	3.2 (0.9, NE)				
Age II								
<75 years	93	35 (37.6)	58 (62.4)	12.9 (10.3, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	22 (33.8)	43 (66.2)	NE (10.3, NE)				
Male	36	18 (50.0)	18 (50.0)	12.9 (2.1, NE)				
Smoking status								
Current	0							
Former	46	19 (41.3)	27 (58.7)	12.9 (3.9, NE)				
Never	55	21 (38.2)	34 (61.8)	NE (7.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	12.9 (3.2, NE)				
Non-White	78	32 (41.0)	46 (59.0)	NE (4.9, NE)				
Region								
Asia	62	24 (38.7)	38 (61.3)	NE (4.9, NE)				
North America and Australia	6							
Europe	33	13 (39.4)	20 (60.6)	12.9 (3.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	10 (41.7)	14 (58.3)	10.3 (0.3, NE)				
No	77	30 (39.0)	47 (61.0)	12.9 (7.2, NE)				
12-lead ECG								
Normal	58	25 (43.1)	33 (56.9)	12.9 (2.1, NE)				
Abnormal, not clinically significant	43	15 (34.9)	28 (65.1)	NE (4.9, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	33 (39.3)	51 (60.7)	12.9 (7.2, NE)				
Abnormal, not clinically significant	17	7 (41.2)	10 (58.8)	NE (0.1, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	15 (51.7)	14 (48.3)	4.9 (0.3, NE)				
1	72	25 (34.7)	47 (65.3)	NE (10.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Decreased appetite

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	14 (37.8)	23 (62.2)	NE (3.9, NE)				
Mild impairment	41	16 (39.0)	25 (61.0)	12.9 (4.9, NE)				
Moderate impairment	23	10 (43.5)	13 (56.5)	NE (0.9, NE)				
Hepatic function at baseline								
Normal hepatic function	76	31 (40.8)	45 (59.2)	12.9 (7.2, NE)				
Mild hepatic dysfunction	25	9 (36.0)	16 (64.0)	NE (0.7, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	11 (14.9)	63 (85.1)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	5 (14.7)	29 (85.3)	NE (NE, NE)				
No	67	8 (11.9)	59 (88.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	13 (13.3)	85 (86.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	8 (20.0)	32 (80.0)	NE (NE, NE)				
Age II								
<75 years	93	11 (11.8)	82 (88.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	8 (12.3)	57 (87.7)	NE (NE, NE)				
Male	36	5 (13.9)	31 (86.1)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	5 (10.9)	41 (89.1)	NE (NE, NE)				
Never	55	8 (14.5)	47 (85.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	6 (26.1)	17 (73.9)	NE (4.2, NE)				
Non-White	78	7 (9.0)	71 (91.0)	NE (NE, NE)				
Region								
Asia	62	3 (4.8)	59 (95.2)	NE (NE, NE)				
North America and Australia	6							
Europe	33	8 (24.2)	25 (75.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	10 (13.0)	67 (87.0)	NE (NE, NE)				
12-lead ECG								
Normal	58	4 (6.9)	54 (93.1)	NE (NE, NE)				
Abnormal, not clinically significant	43	9 (20.9)	34 (79.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	11 (13.1)	73 (86.9)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	1 (3.4)	28 (96.6)	NE (NE, NE)				
1	72	12 (16.7)	60 (83.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	41	4 (9.8)	37 (90.2)	NE (NE, NE)				
Moderate impairment	23	5 (21.7)	18 (78.3)	NE (10.5, NE)				
Hepatic function at baseline								
Normal hepatic function	76	12 (15.8)	64 (84.2)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	17 (23.0)	57 (77.0)	NE (NE, NE)				
Subjects who received neither	27	9 (33.3)	18 (66.7)	NE (7.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	9 (26.5)	25 (73.5)	NE (NE, NE)				
No	67	17 (25.4)	50 (74.6)	NE (9.9, NE)				
HER2 status								
Kinase domain	98	25 (25.5)	73 (74.5)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	17 (27.9)	44 (72.1)	NE (9.9, NE)				
>=65 years	40	9 (22.5)	31 (77.5)	NE (NE, NE)				
Age II								
<75 years	93	24 (25.8)	69 (74.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	18 (27.7)	47 (72.3)	NE (8.3, NE)				
Male	36	8 (22.2)	28 (77.8)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	10 (21.7)	36 (78.3)	NE (NE, NE)				
Never	55	16 (29.1)	39 (70.9)	NE (8.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	10 (43.5)	13 (56.5)	6.3 (2.9, NE)				
Non-White	78	16 (20.5)	62 (79.5)	NE (NE, NE)				
Region								
Asia	62	10 (16.1)	52 (83.9)	NE (NE, NE)				
North America and Australia	6							
Europe	33	13 (39.4)	20 (60.6)	NE (3.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	7 (29.2)	17 (70.8)	NE (3.5, NE)				
No	77	19 (24.7)	58 (75.3)	NE (NE, NE)				
12-lead ECG								
Normal	58	12 (20.7)	46 (79.3)	NE (NE, NE)				
Abnormal, not clinically significant	43	14 (32.6)	29 (67.4)	NE (7.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	22 (26.2)	62 (73.8)	NE (NE, NE)				
Abnormal, not clinically significant	17	4 (23.5)	13 (76.5)	NE (7.2, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	10 (34.5)	19 (65.5)	NE (4.9, NE)				
1	72	16 (22.2)	56 (77.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Musculoskeletal and connective tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	11 (29.7)	26 (70.3)	NE (8.3, NE)				
Mild impairment	41	9 (22.0)	32 (78.0)	NE (NE, NE)				
Moderate impairment	23	6 (26.1)	17 (73.9)	NE (6.0, NE)				
Hepatic function at baseline								
Normal hepatic function	76	23 (30.3)	53 (69.7)	NE (9.9, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	20 (27.0)	54 (73.0)	NE (10.1, NE)				
Subjects who received neither	27	11 (40.7)	16 (59.3)	11.3 (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	13 (38.2)	21 (61.8)	11.3 (5.3, NE)				
No	67	18 (26.9)	49 (73.1)	NE (10.3, NE)				
HER2 status								
Kinase domain	98	31 (31.6)	67 (68.4)	NE (10.1, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	13 (21.3)	48 (78.7)	NE (11.3, NE)				
>=65 years	40	18 (45.0)	22 (55.0)	10.3 (2.8, NE)				
Age II								
<75 years	93	28 (30.1)	65 (69.9)	NE (10.3, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	23 (35.4)	42 (64.6)	NE (9.8, NE)				
Male	36	8 (22.2)	28 (77.8)	NE (11.3, NE)				
Smoking status								
Current	0							
Former	46	15 (32.6)	31 (67.4)	NE (9.2, NE)				
Never	55	16 (29.1)	39 (70.9)	NE (9.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	8 (34.8)	15 (65.2)	10.1 (4.9, NE)				
Non-White	78	23 (29.5)	55 (70.5)	NE (10.3, NE)				
Region								
Asia	62	18 (29.0)	44 (71.0)	NE (10.3, NE)				
North America and Australia	6							
Europe	33	10 (30.3)	23 (69.7)	11.3 (9.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (10.3, NE)				
No	77	26 (33.8)	51 (66.2)	NE (9.8, NE)				
12-lead ECG								
Normal	58	17 (29.3)	41 (70.7)	NE (10.3, NE)				
Abnormal, not clinically significant	43	14 (32.6)	29 (67.4)	NE (9.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	25 (29.8)	59 (70.2)	NE (10.1, NE)				
Abnormal, not clinically significant	17	6 (35.3)	11 (64.7)	NE (1.5, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	7 (24.1)	22 (75.9)	NE (9.8, NE)				
1	72	24 (33.3)	48 (66.7)	11.3 (10.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	7 (18.9)	30 (81.1)	NE (11.3, NE)				
Mild impairment	41	15 (36.6)	26 (63.4)	10.1 (5.3, NE)				
Moderate impairment	23	9 (39.1)	14 (60.9)	NE (4.0, NE)				
Hepatic function at baseline								
Normal hepatic function	76	20 (26.3)	56 (73.7)	NE (10.3, NE)				
Mild hepatic dysfunction	25	11 (44.0)	14 (56.0)	NE (0.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Nervous system disorders; PT: Dizziness

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	9 (12.2)	65 (87.8)	NE (NE, NE)				
Subjects who received neither	27	4 (14.8)	23 (85.2)	NE (11.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Dizziness

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	5 (14.7)	29 (85.3)	NE (11.3, NE)				
No	67	8 (11.9)	59 (88.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	13 (13.3)	85 (86.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Dizziness

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	8 (20.0)	32 (80.0)	NE (10.3, NE)				
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Dizziness

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	9 (13.8)	56 (86.2)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (11.3, NE)				
Smoking status								
Current	0							
Former	46	6 (13.0)	40 (87.0)	NE (NE, NE)				
Never	55	7 (12.7)	48 (87.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Dizziness

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	10 (12.8)	68 (87.2)	NE (NE, NE)				
Region								
Asia	62	8 (12.9)	54 (87.1)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (11.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Nervous system disorders; PT: Dizziness

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (10.3, NE)				
No	77	11 (14.3)	66 (85.7)	NE (NE, NE)				
12-lead ECG								
Normal	58	7 (12.1)	51 (87.9)	NE (NE, NE)				
Abnormal, not clinically significant	43	6 (14.0)	37 (86.0)	NE (11.3, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Nervous system disorders; PT: Dizziness

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	10 (11.9)	74 (88.1)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (10.3, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	3 (10.3)	26 (89.7)	NE (NE, NE)				
1	72	10 (13.9)	62 (86.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Nervous system disorders; PT: Dizziness

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	41	4 (9.8)	37 (90.2)	NE (NE, NE)				
Moderate impairment	23	5 (21.7)	18 (78.3)	NE (9.2, NE)				
Hepatic function at baseline								
Normal hepatic function	76	12 (15.8)	64 (84.2)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Psychiatric disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	10 (13.5)	64 (86.5)	NE (NE, NE)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Psychiatric disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	8 (23.5)	26 (76.5)	NE (8.8, NE)				
No	67	7 (10.4)	60 (89.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	14 (14.3)	84 (85.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Psychiatric disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	4 (6.6)	57 (93.4)	NE (NE, NE)				
>=65 years	40	11 (27.5)	29 (72.5)	NE (10.7, NE)				
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Psychiatric disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	13 (20.0)	52 (80.0)	NE (NE, NE)				
Male	36	2 (5.6)	34 (94.4)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	5 (10.9)	41 (89.1)	NE (NE, NE)				
Never	55	10 (18.2)	45 (81.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Psychiatric disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	12 (15.4)	66 (84.6)	NE (NE, NE)				
Region								
Asia	62	7 (11.3)	55 (88.7)	NE (NE, NE)				
North America and Australia	6							
Europe	33	7 (21.2)	26 (78.8)	NE (10.9, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Psychiatric disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	4 (16.7)	20 (83.3)	NE (8.8, NE)				
No	77	11 (14.3)	66 (85.7)	NE (NE, NE)				
12-lead ECG								
Normal	58	5 (8.6)	53 (91.4)	NE (NE, NE)				
Abnormal, not clinically significant	43	10 (23.3)	33 (76.7)	NE (10.9, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Psychiatric disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	13 (15.5)	71 (84.5)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (8.8, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	3 (10.3)	26 (89.7)	NE (NE, NE)				
1	72	12 (16.7)	60 (83.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Psychiatric disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	3 (8.1)	34 (91.9)	NE (NE, NE)				
Mild impairment	41	7 (17.1)	34 (82.9)	NE (NE, NE)				
Moderate impairment	23	5 (21.7)	18 (78.3)	NE (10.7, NE)				
Hepatic function at baseline								
Normal hepatic function	76	11 (14.5)	65 (85.5)	NE (NE, NE)				
Mild hepatic dysfunction	25	4 (16.0)	21 (84.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	32 (43.2)	42 (56.8)	14.5 (5.5, NE)				
Subjects who received neither	27	10 (37.0)	17 (63.0)	13.1 (5.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	15 (44.1)	19 (55.9)	9.9 (3.9, NE)				
No	67	27 (40.3)	40 (59.7)	14.5 (5.7, NE)				
HER2 status								
Kinase domain	98	41 (41.8)	57 (58.2)	13.1 (6.2, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	20 (32.8)	41 (67.2)	NE (8.3, NE)				
>=65 years	40	22 (55.0)	18 (45.0)	5.7 (3.0, 14.5)				
Age II								
<75 years	93	38 (40.9)	55 (59.1)	14.5 (6.8, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	28 (43.1)	37 (56.9)	13.1 (5.5, NE)				
Male	36	14 (38.9)	22 (61.1)	NE (5.7, NE)				
Smoking status								
Current	0							
Former	46	18 (39.1)	28 (60.9)	13.1 (6.2, NE)				
Never	55	24 (43.6)	31 (56.4)	NE (4.0, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	13 (56.5)	10 (43.5)	5.6 (4.0, NE)				
Non-White	78	29 (37.2)	49 (62.8)	14.5 (8.3, NE)				
Region								
Asia	62	20 (32.3)	42 (67.7)	14.5 (13.1, NE)				
North America and Australia	6							
Europe	33	18 (54.5)	15 (45.5)	5.6 (1.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	10 (41.7)	14 (58.3)	6.2 (4.0, NE)				
No	77	32 (41.6)	45 (58.4)	13.1 (6.8, NE)				
12-lead ECG								
Normal	58	24 (41.4)	34 (58.6)	13.1 (6.8, NE)				
Abnormal, not clinically significant	43	18 (41.9)	25 (58.1)	14.5 (4.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	33 (39.3)	51 (60.7)	14.5 (8.3, NE)				
Abnormal, not clinically significant	17	9 (52.9)	8 (47.1)	4.2 (1.4, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	11 (37.9)	18 (62.1)	14.5 (9.9, NE)				
1	72	31 (43.1)	41 (56.9)	8.7 (5.1, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	13 (35.1)	24 (64.9)	14.5 (8.3, NE)				
Mild impairment	41	17 (41.5)	24 (58.5)	NE (3.9, NE)				
Moderate impairment	23	12 (52.2)	11 (47.8)	6.2 (4.2, NE)				
Hepatic function at baseline								
Normal hepatic function	76	29 (38.2)	47 (61.8)	14.5 (6.8, NE)				
Mild hepatic dysfunction	25	13 (52.0)	12 (48.0)	8.3 (2.6, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	20 (27.0)	54 (73.0)	NE (16.2, NE)				
Subjects who received neither	27	12 (44.4)	15 (55.6)	10.3 (2.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	9 (26.5)	25 (73.5)	NE (10.3, NE)				
No	67	23 (34.3)	44 (65.7)	16.2 (4.2, NE)				
HER2 status								
Kinase domain	98	31 (31.6)	67 (68.4)	16.2 (16.2, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	20 (32.8)	41 (67.2)	16.2 (16.2, NE)				
>=65 years	40	12 (30.0)	28 (70.0)	NE (4.8, NE)				
Age II								
<75 years	93	28 (30.1)	65 (69.9)	16.2 (16.2, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	24 (36.9)	41 (63.1)	16.2 (4.2, NE)				
Male	36	8 (22.2)	28 (77.8)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	14 (30.4)	32 (69.6)	16.2 (NE, NE)				
Never	55	18 (32.7)	37 (67.3)	NE (4.8, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	9 (39.1)	14 (60.9)	NE (2.3, NE)				
Non-White	78	23 (29.5)	55 (70.5)	NE (16.2, NE)				
Region								
Asia	62	20 (32.3)	42 (67.7)	16.2 (10.3, NE)				
North America and Australia	6							
Europe	33	9 (27.3)	24 (72.7)	NE (4.2, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (NE, NE)				
No	77	27 (35.1)	50 (64.9)	16.2 (10.3, NE)				
12-lead ECG								
Normal	58	18 (31.0)	40 (69.0)	16.2 (10.3, NE)				
Abnormal, not clinically significant	43	14 (32.6)	29 (67.4)	NE (4.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	23 (27.4)	61 (72.6)	NE (16.2, NE)				
Abnormal, not clinically significant	17	9 (52.9)	8 (47.1)	2.9 (0.8, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	12 (41.4)	17 (58.6)	16.2 (4.2, NE)				
1	72	20 (27.8)	52 (72.2)	NE (10.3, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	14 (37.8)	23 (62.2)	16.2 (2.9, NE)				
Mild impairment	41	10 (24.4)	31 (75.6)	NE (NE, NE)				
Moderate impairment	23	8 (34.8)	15 (65.2)	NE (3.8, NE)				
Hepatic function at baseline								
Normal hepatic function	76	26 (34.2)	50 (65.8)	16.2 (10.3, NE)				
Mild hepatic dysfunction	25	6 (24.0)	19 (76.0)	NE (3.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	13 (17.6)	61 (82.4)	NE (NE, NE)				
Subjects who received neither	27	9 (33.3)	18 (66.7)	NE (2.4, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (NE, NE)				
No	67	19 (28.4)	48 (71.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	21 (21.4)	77 (78.6)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	13 (21.3)	48 (78.7)	NE (NE, NE)				
>=65 years	40	9 (22.5)	31 (77.5)	NE (NE, NE)				
Age II								
<75 years	93	19 (20.4)	74 (79.6)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	18 (27.7)	47 (72.3)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	10 (21.7)	36 (78.3)	NE (NE, NE)				
Never	55	12 (21.8)	43 (78.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	NE (4.8, NE)				
Non-White	78	17 (21.8)	61 (78.2)	NE (NE, NE)				
Region								
Asia	62	14 (22.6)	48 (77.4)	NE (NE, NE)				
North America and Australia	6							
Europe	33	6 (18.2)	27 (81.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:13; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESOCPT10PER_1_SAS.rtf

DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (NE, NE)				
No	77	17 (22.1)	60 (77.9)	NE (NE, NE)				
12-lead ECG								
Normal	58	11 (19.0)	47 (81.0)	NE (NE, NE)				
Abnormal, not clinically significant	43	11 (25.6)	32 (74.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	14 (16.7)	70 (83.3)	NE (NE, NE)				
Abnormal, not clinically significant	17	8 (47.1)	9 (52.9)	3.5 (2.3, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	7 (24.1)	22 (75.9)	NE (NE, NE)				
1	72	15 (20.8)	57 (79.2)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.7.1 Treatment-emergent adverse events by SOC and PT observed for >= 10% of the patients in at least one arm and in addition treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Skin and subcutaneous tissue disorders; PT: Alopecia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	10 (27.0)	27 (73.0)	NE (NE, NE)				
Mild impairment	41	7 (17.1)	34 (82.9)	NE (NE, NE)				
Moderate impairment	23	5 (21.7)	18 (78.3)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	17 (22.4)	59 (77.6)	NE (NE, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	7 (6.9)	94 (93.1)	NE (NE, NE)	95.0 (88.4, 97.9)	93.6 (86.1, 97.1)	92.0 (83.7, 96.2)	92.0 (83.7, 96.2)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	7 (9.5)	67 (90.5)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (NE, NE)				
No	67	4 (6.0)	63 (94.0)	NE (NE, NE)				
HER2 status								
Kinase domain	98	7 (7.1)	91 (92.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	4 (6.6)	57 (93.4)	NE (NE, NE)				
>=65 years	40	3 (7.5)	37 (92.5)	NE (NE, NE)				
Age II								
<75 years	93	7 (7.5)	86 (92.5)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	6 (9.2)	59 (90.8)	NE (NE, NE)				
Male	36	1 (2.8)	35 (97.2)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	3 (5.5)	52 (94.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	4 (5.1)	74 (94.9)	NE (NE, NE)				
Region								
Asia	62	2 (3.2)	60 (96.8)	NE (NE, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	4 (5.2)	73 (94.8)	NE (NE, NE)				
12-lead ECG								
Normal	58	2 (3.4)	56 (96.6)	NE (NE, NE)				
Abnormal, not clinically significant	43	5 (11.6)	38 (88.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	6 (7.1)	78 (92.9)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	2 (6.9)	27 (93.1)	NE (NE, NE)				
1	72	5 (6.9)	67 (93.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (NE, NE)				
Mild impairment	41	3 (7.3)	38 (92.7)	NE (NE, NE)				
Moderate impairment	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	4 (5.3)	72 (94.7)	NE (NE, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	6 (5.9)	95 (94.1)	NE (NE, NE)	95.8 (89.3, 98.4)	94.6 (87.4, 97.7)	94.6 (87.4, 97.7)	92.4 (83.2, 96.7)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	5 (6.8)	69 (93.2)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (NE, NE)				
No	67	3 (4.5)	64 (95.5)	NE (NE, NE)				
HER2 status								
Kinase domain	98	6 (6.1)	92 (93.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	3 (4.9)	58 (95.1)	NE (NE, NE)				
>=65 years	40	3 (7.5)	37 (92.5)	NE (NE, NE)				
Age II								
<75 years	93	5 (5.4)	88 (94.6)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	5 (7.7)	60 (92.3)	NE (NE, NE)				
Male	36	1 (2.8)	35 (97.2)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	2 (3.6)	53 (96.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	0	23 (100.0)	NE (NE, NE)				
Non-White	78	6 (7.7)	72 (92.3)	NE (NE, NE)				
Region								
Asia	62	5 (8.1)	57 (91.9)	NE (NE, NE)				
North America and Australia	6							
Europe	33	1 (3.0)	32 (97.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	3 (3.9)	74 (96.1)	NE (NE, NE)				
12-lead ECG								
Normal	58	4 (6.9)	54 (93.1)	NE (NE, NE)				
Abnormal, not clinically significant	43	2 (4.7)	41 (95.3)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	5 (6.0)	79 (94.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	6 (8.3)	66 (91.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	3 (8.1)	34 (91.9)	NE (NE, NE)				
Mild impairment	41	2 (4.9)	39 (95.1)	NE (NE, NE)				
Moderate impairment	23	1 (4.3)	22 (95.7)	NE (9.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	5 (6.6)	71 (93.4)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	12 (11.9)	89 (88.1)	NE (NE, NE)	90.7 (82.8, 95.0)	86.8 (77.7, 92.3)	86.8 (77.7, 92.3)	86.8 (77.7, 92.3)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	10 (13.5)	64 (86.5)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (NE, NE)				
No	67	9 (13.4)	58 (86.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	11 (11.2)	87 (88.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Age II								
<75 years	93	11 (11.8)	82 (88.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (NE, NE)				
Male	36	5 (13.9)	31 (86.1)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	8 (14.5)	47 (85.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Non-White	78	8 (10.3)	70 (89.7)	NE (NE, NE)				
Region								
Asia	62	6 (9.7)	56 (90.3)	NE (NE, NE)				
North America and Australia	6							
Europe	33	6 (18.2)	27 (81.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	9 (11.7)	68 (88.3)	NE (NE, NE)				
12-lead ECG								
Normal	58	7 (12.1)	51 (87.9)	NE (NE, NE)				
Abnormal, not clinically significant	43	5 (11.6)	38 (88.4)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	9 (10.7)	75 (89.3)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	12 (16.7)	60 (83.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.8.1 Serious Treatment-emergent adverse events by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Serious Treatment-emergent adverse events by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm - Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	41	4 (9.8)	37 (90.2)	NE (NE, NE)				
Moderate impairment	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	10 (13.2)	66 (86.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_SAESOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	16 (15.8)	85 (84.2)	NE (NE, NE)	89.0 (81.0, 93.7)	83.9 (74.6, 90.0)	83.9 (74.6, 90.0)	82.0 (71.9, 88.7)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	15 (20.3)	59 (79.7)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	6 (17.6)	28 (82.4)	NE (NE, NE)				
No	67	10 (14.9)	57 (85.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	16 (16.3)	82 (83.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	11 (27.5)	29 (72.5)	NE (NE, NE)				
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	10 (15.4)	55 (84.6)	NE (NE, NE)				
Male	36	6 (16.7)	30 (83.3)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	9 (19.6)	37 (80.4)	NE (NE, NE)				
Never	55	7 (12.7)	48 (87.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Non-White	78	12 (15.4)	66 (84.6)	NE (NE, NE)				
Region								
Asia	62	9 (14.5)	53 (85.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	6 (18.2)	27 (81.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	13 (16.9)	64 (83.1)	NE (NE, NE)				
12-lead ECG								
Normal	58	7 (12.1)	51 (87.9)	NE (NE, NE)				
Abnormal, not clinically significant	43	9 (20.9)	34 (79.1)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	13 (15.5)	71 (84.5)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (5.1, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	3 (10.3)	26 (89.7)	NE (NE, NE)				
1	72	13 (18.1)	59 (81.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	41	4 (9.8)	37 (90.2)	NE (NE, NE)				
Moderate impairment	23	8 (34.8)	15 (65.2)	NE (1.4, NE)				
Hepatic function at baseline								
Normal hepatic function	76	14 (18.4)	62 (81.6)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	11 (10.9)	90 (89.1)	NE (NE, NE)	91.9 (84.4, 95.9)	88.1 (79.4, 93.3)	88.1 (79.4, 93.3)	88.1 (79.4, 93.3)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	10 (13.5)	64 (86.5)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	2 (5.9)	32 (94.1)	NE (NE, NE)				
No	67	9 (13.4)	58 (86.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	11 (11.2)	87 (88.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	2 (3.3)	59 (96.7)	NE (NE, NE)				
>=65 years	40	9 (22.5)	31 (77.5)	NE (NE, NE)				
Age II								
<75 years	93	10 (10.8)	83 (89.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	7 (15.2)	39 (84.8)	NE (NE, NE)				
Never	55	4 (7.3)	51 (92.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	9 (11.5)	69 (88.5)	NE (NE, NE)				
Region								
Asia	62	7 (11.3)	55 (88.7)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	9 (11.7)	68 (88.3)	NE (NE, NE)				
12-lead ECG								
Normal	58	4 (6.9)	54 (93.1)	NE (NE, NE)				
Abnormal, not clinically significant	43	7 (16.3)	36 (83.7)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	9 (10.7)	75 (89.3)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	11 (15.3)	61 (84.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Blood and lymphatic system disorders; PT: Anaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	1 (2.7)	36 (97.3)	NE (NE, NE)				
Mild impairment	41	4 (9.8)	37 (90.2)	NE (NE, NE)				
Moderate impairment	23	6 (26.1)	17 (73.9)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	9 (11.8)	67 (88.2)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	10 (9.9)	91 (90.1)	NE (NE, NE)	94.0 (87.2, 97.3)	89.9 (81.4, 94.7)	88.4 (79.3, 93.7)	88.4 (79.3, 93.7)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	10 (13.5)	64 (86.5)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	4 (11.8)	30 (88.2)	NE (NE, NE)				
No	67	6 (9.0)	61 (91.0)	NE (NE, NE)				
HER2 status								
Kinase domain	98	10 (10.2)	88 (89.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	5 (12.5)	35 (87.5)	NE (NE, NE)				
Age II								
<75 years	93	10 (10.8)	83 (89.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	8 (12.3)	57 (87.7)	NE (NE, NE)				
Male	36	2 (5.6)	34 (94.4)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	6 (10.9)	49 (89.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Non-White	78	6 (7.7)	72 (92.3)	NE (NE, NE)				
Region								
Asia	62	4 (6.5)	58 (93.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	5 (15.2)	28 (84.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (6.1, NE)				
No	77	5 (6.5)	72 (93.5)	NE (NE, NE)				
12-lead ECG								
Normal	58	3 (5.2)	55 (94.8)	NE (NE, NE)				
Abnormal, not clinically significant	43	7 (16.3)	36 (83.7)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	8 (9.5)	76 (90.5)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	2 (6.9)	27 (93.1)	NE (NE, NE)				
1	72	8 (11.1)	64 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Gastrointestinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (NE, NE)				
Mild impairment	41	5 (12.2)	36 (87.8)	NE (NE, NE)				
Moderate impairment	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	7 (9.2)	69 (90.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	8 (7.9)	93 (92.1)	NE (NE, NE)	95.8 (89.3, 98.4)	92.0 (83.8, 96.1)	92.0 (83.8, 96.1)	89.6 (79.5, 94.9)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	8 (10.8)	66 (89.2)	NE (NE, NE)				
Subjects who received neither	27	0	27 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (NE, NE)				
No	67	5 (7.5)	62 (92.5)	NE (NE, NE)				
HER2 status								
Kinase domain	98	8 (8.2)	90 (91.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	1 (1.6)	60 (98.4)	NE (NE, NE)				
>=65 years	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Age II								
<75 years	93	5 (5.4)	88 (94.6)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	4 (6.2)	61 (93.8)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	4 (7.3)	51 (92.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	6 (7.7)	72 (92.3)	NE (NE, NE)				
Region								
Asia	62	4 (6.5)	58 (93.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	5 (6.5)	72 (93.5)	NE (NE, NE)				
12-lead ECG								
Normal	58	2 (3.4)	56 (96.6)	NE (NE, NE)				
Abnormal, not clinically significant	43	6 (14.0)	37 (86.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	6 (7.1)	78 (92.9)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (4.9, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	8 (11.1)	64 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: General disorders and administration site conditions; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (NE, NE)				
Mild impairment	41	2 (4.9)	39 (95.1)	NE (NE, NE)				
Moderate impairment	23	4 (17.4)	19 (82.6)	NE (10.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	7 (9.2)	69 (90.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	25 (24.8)	76 (75.2)	NE (NE, NE)	83.0 (74.1, 89.1)	83.0 (74.1, 89.1)	69.2 (57.2, 78.5)	69.2 (57.2, 78.5)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	20 (27.0)	54 (73.0)	NE (NE, NE)				
Subjects who received neither	27	5 (18.5)	22 (81.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	12 (35.3)	22 (64.7)	NE (6.9, NE)				
No	67	13 (19.4)	54 (80.6)	NE (NE, NE)				
HER2 status								
Kinase domain	98	24 (24.5)	74 (75.5)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	15 (24.6)	46 (75.4)	NE (NE, NE)				
>=65 years	40	10 (25.0)	30 (75.0)	NE (7.5, NE)				
Age II								
<75 years	93	24 (25.8)	69 (74.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	12 (18.5)	53 (81.5)	NE (NE, NE)				
Male	36	13 (36.1)	23 (63.9)	NE (6.9, NE)				
Smoking status								
Current	0							
Former	46	14 (30.4)	32 (69.6)	NE (7.5, NE)				
Never	55	11 (20.0)	44 (80.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	3 (13.0)	20 (87.0)	NE (NE, NE)				
Non-White	78	22 (28.2)	56 (71.8)	NE (NE, NE)				
Region								
Asia	62	17 (27.4)	45 (72.6)	NE (8.3, NE)				
North America and Australia	6							
Europe	33	7 (21.2)	26 (78.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	5 (20.8)	19 (79.2)	NE (6.9, NE)				
No	77	20 (26.0)	57 (74.0)	NE (NE, NE)				
12-lead ECG								
Normal	58	12 (20.7)	46 (79.3)	NE (NE, NE)				
Abnormal, not clinically significant	43	13 (30.2)	30 (69.8)	NE (7.2, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	21 (25.0)	63 (75.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	4 (23.5)	13 (76.5)	NE (0.9, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	7 (24.1)	22 (75.9)	NE (7.5, NE)				
1	72	18 (25.0)	54 (75.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	8 (21.6)	29 (78.4)	NE (NE, NE)				
Mild impairment	41	9 (22.0)	32 (78.0)	NE (NE, NE)				
Moderate impairment	23	8 (34.8)	15 (65.2)	NE (7.0, NE)				
Hepatic function at baseline								
Normal hepatic function	76	20 (26.3)	56 (73.7)	NE (NE, NE)				
Mild hepatic dysfunction	25	5 (20.0)	20 (80.0)	NE (7.5, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	14 (13.9)	87 (86.1)	NE (NE, NE)	90.0 (82.3, 94.5)	90.0 (82.3, 94.5)	83.0 (72.3, 89.8)	83.0 (72.3, 89.8)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	11 (14.9)	63 (85.1)	NE (NE, NE)				
Subjects who received neither	27	3 (11.1)	24 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	6 (17.6)	28 (82.4)	NE (NE, NE)				
No	67	8 (11.9)	59 (88.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	13 (13.3)	85 (86.7)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	7 (11.5)	54 (88.5)	NE (NE, NE)				
>=65 years	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Age II								
<75 years	93	13 (14.0)	80 (86.0)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (NE, NE)				
Male	36	7 (19.4)	29 (80.6)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	10 (21.7)	36 (78.3)	NE (NE, NE)				
Never	55	4 (7.3)	51 (92.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	1 (4.3)	22 (95.7)	NE (NE, NE)				
Non-White	78	13 (16.7)	65 (83.3)	NE (NE, NE)				
Region								
Asia	62	11 (17.7)	51 (82.3)	NE (NE, NE)				
North America and Australia	6							
Europe	33	2 (6.1)	31 (93.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	11 (14.3)	66 (85.7)	NE (NE, NE)				
12-lead ECG								
Normal	58	7 (12.1)	51 (87.9)	NE (NE, NE)				
Abnormal, not clinically significant	43	7 (16.3)	36 (83.7)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	13 (15.5)	71 (84.5)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	5 (17.2)	24 (82.8)	NE (NE, NE)				
1	72	9 (12.5)	63 (87.5)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Investigations; PT: Neutrophil count decreased

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	41	4 (9.8)	37 (90.2)	NE (NE, NE)				
Moderate impairment	23	6 (26.1)	17 (73.9)	NE (7.2, NE)				
Hepatic function at baseline								
Normal hepatic function	76	12 (15.8)	64 (84.2)	NE (NE, NE)				
Mild hepatic dysfunction	25	2 (8.0)	23 (92.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	10 (9.9)	91 (90.1)	NE (NE, NE)	95.0 (88.4, 97.9)	90.0 (81.6, 94.7)	90.0 (81.6, 94.7)	87.7 (77.5, 93.4)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	7 (9.5)	67 (90.5)	NE (NE, NE)				
Subjects who received neither	27	3 (11.1)	24 (88.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	4 (11.8)	30 (88.2)	NE (NE, NE)				
No	67	6 (9.0)	61 (91.0)	NE (NE, NE)				
HER2 status								
Kinase domain	98	9 (9.2)	89 (90.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	3 (4.9)	58 (95.1)	NE (NE, NE)				
>=65 years	40	7 (17.5)	33 (82.5)	NE (NE, NE)				
Age II								
<75 years	93	10 (10.8)	83 (89.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (NE, NE)				
Male	36	3 (8.3)	33 (91.7)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	5 (10.9)	41 (89.1)	NE (NE, NE)				
Never	55	5 (9.1)	50 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	2 (8.7)	21 (91.3)	NE (NE, NE)				
Non-White	78	8 (10.3)	70 (89.7)	NE (NE, NE)				
Region								
Asia	62	4 (6.5)	58 (93.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	4 (12.1)	29 (87.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	8 (10.4)	69 (89.6)	NE (NE, NE)				
12-lead ECG								
Normal	58	3 (5.2)	55 (94.8)	NE (NE, NE)				
Abnormal, not clinically significant	43	7 (16.3)	36 (83.7)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	8 (9.5)	76 (90.5)	NE (NE, NE)				
Abnormal, not clinically significant	17	2 (11.8)	15 (88.2)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	10 (13.9)	62 (86.1)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	3 (8.1)	34 (91.9)	NE (NE, NE)				
Mild impairment	41	3 (7.3)	38 (92.7)	NE (NE, NE)				
Moderate impairment	23	4 (17.4)	19 (82.6)	NE (10.5, NE)				
Hepatic function at baseline								
Normal hepatic function	76	10 (13.2)	66 (86.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	7 (6.9)	94 (93.1)	NE (NE, NE)	97.0 (91.0, 99.0)	93.1 (85.2, 96.9)	93.1 (85.2, 96.9)	90.7 (80.5, 95.7)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	5 (6.8)	69 (93.2)	NE (NE, NE)				
Subjects who received neither	27	2 (7.4)	25 (92.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (NE, NE)				
No	67	4 (6.0)	63 (94.0)	NE (NE, NE)				
HER2 status								
Kinase domain	98	7 (7.1)	91 (92.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	3 (4.9)	58 (95.1)	NE (NE, NE)				
>=65 years	40	4 (10.0)	36 (90.0)	NE (NE, NE)				
Age II								
<75 years	93	7 (7.5)	86 (92.5)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	6 (9.2)	59 (90.8)	NE (NE, NE)				
Male	36	1 (2.8)	35 (97.2)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	3 (6.5)	43 (93.5)	NE (NE, NE)				
Never	55	4 (7.3)	51 (92.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	1 (4.3)	22 (95.7)	NE (NE, NE)				
Non-White	78	6 (7.7)	72 (92.3)	NE (NE, NE)				
Region								
Asia	62	2 (3.2)	60 (96.8)	NE (NE, NE)				
North America and Australia	6							
Europe	33	3 (9.1)	30 (90.9)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	1 (4.2)	23 (95.8)	NE (NE, NE)				
No	77	6 (7.8)	71 (92.2)	NE (NE, NE)				
12-lead ECG								
Normal	58	1 (1.7)	57 (98.3)	NE (NE, NE)				
Abnormal, not clinically significant	43	6 (14.0)	37 (86.0)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	6 (7.1)	78 (92.9)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	7 (9.7)	65 (90.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	2 (5.4)	35 (94.6)	NE (NE, NE)				
Mild impairment	41	2 (4.9)	39 (95.1)	NE (NE, NE)				
Moderate impairment	23	3 (13.0)	20 (87.0)	NE (10.5, NE)				
Hepatic function at baseline								
Normal hepatic function	76	7 (9.2)	69 (90.8)	NE (NE, NE)				
Mild hepatic dysfunction	25	0	25 (100.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	6 (5.9)	95 (94.1)	NE (NE, NE)	95.8 (89.3, 98.4)	94.6 (87.4, 97.7)	94.6 (87.4, 97.7)	92.4 (83.2, 96.7)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	5 (6.8)	69 (93.2)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (NE, NE)				
No	67	3 (4.5)	64 (95.5)	NE (NE, NE)				
HER2 status								
Kinase domain	98	6 (6.1)	92 (93.9)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	3 (4.9)	58 (95.1)	NE (NE, NE)				
>=65 years	40	3 (7.5)	37 (92.5)	NE (NE, NE)				
Age II								
<75 years	93	5 (5.4)	88 (94.6)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	5 (7.7)	60 (92.3)	NE (NE, NE)				
Male	36	1 (2.8)	35 (97.2)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	4 (8.7)	42 (91.3)	NE (NE, NE)				
Never	55	2 (3.6)	53 (96.4)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	0	23 (100.0)	NE (NE, NE)				
Non-White	78	6 (7.7)	72 (92.3)	NE (NE, NE)				
Region								
Asia	62	5 (8.1)	57 (91.9)	NE (NE, NE)				
North America and Australia	6							
Europe	33	1 (3.0)	32 (97.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	3 (12.5)	21 (87.5)	NE (NE, NE)				
No	77	3 (3.9)	74 (96.1)	NE (NE, NE)				
12-lead ECG								
Normal	58	4 (6.9)	54 (93.1)	NE (NE, NE)				
Abnormal, not clinically significant	43	2 (4.7)	41 (95.3)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	5 (6.0)	79 (94.0)	NE (NE, NE)				
Abnormal, not clinically significant	17	1 (5.9)	16 (94.1)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	6 (8.3)	66 (91.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	3 (8.1)	34 (91.9)	NE (NE, NE)				
Mild impairment	41	2 (4.9)	39 (95.1)	NE (NE, NE)				
Moderate impairment	23	1 (4.3)	22 (95.7)	NE (9.3, NE)				
Hepatic function at baseline								
Normal hepatic function	76	5 (6.6)	71 (93.4)	NE (NE, NE)				
Mild hepatic dysfunction	25	1 (4.0)	24 (96.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Overall	101	11 (10.9)	90 (89.1)	NE (NE, NE)	93.9 (86.9, 97.2)	88.8 (80.1, 93.9)	87.4 (78.2, 92.9)	87.4 (78.2, 92.9)
Prior therapy based on entries on Prior Cancer Systemic Therapy eCRF								
Subjects who received prior anti PD-1 and/or anti PD-L1 treatment	74	10 (13.5)	64 (86.5)	NE (NE, NE)				
Subjects who received neither	27	1 (3.7)	26 (96.3)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Central nervous system (CNS) metastasis								
Yes	34	3 (8.8)	31 (91.2)	NE (NE, NE)				
No	67	8 (11.9)	59 (88.1)	NE (NE, NE)				
HER2 status								
Kinase domain	98	11 (11.2)	87 (88.8)	NE (NE, NE)				
Extracellular domain	3							
Transmembrane domain	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
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					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Age I								
<65 years	61	5 (8.2)	56 (91.8)	NE (NE, NE)				
>=65 years	40	6 (15.0)	34 (85.0)	NE (NE, NE)				
Age II								
<75 years	93	10 (10.8)	83 (89.2)	NE (NE, NE)				
>=75 years	8							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Sex								
Female	65	7 (10.8)	58 (89.2)	NE (NE, NE)				
Male	36	4 (11.1)	32 (88.9)	NE (NE, NE)				
Smoking status								
Current	0							
Former	46	2 (4.3)	44 (95.7)	NE (NE, NE)				
Never	55	9 (16.4)	46 (83.6)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Race								
White	23	5 (21.7)	18 (78.3)	NE (6.3, NE)				
Non-White	78	6 (7.7)	72 (92.3)	NE (NE, NE)				
Region								
Asia	62	4 (6.5)	58 (93.5)	NE (NE, NE)				
North America and Australia	6							
Europe	33	7 (21.2)	26 (78.8)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Liver metastases								
Yes	24	2 (8.3)	22 (91.7)	NE (NE, NE)				
No	77	9 (11.7)	68 (88.3)	NE (NE, NE)				
12-lead ECG								
Normal	58	7 (12.1)	51 (87.9)	NE (NE, NE)				
Abnormal, not clinically significant	43	4 (9.3)	39 (90.7)	NE (NE, NE)				
Clinically significant findings	0							

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Baseline ECHO/MUGA								
Normal	84	8 (9.5)	76 (90.5)	NE (NE, NE)				
Abnormal, not clinically significant	17	3 (17.6)	14 (82.4)	NE (NE, NE)				
Clinically significant findings	0							
ECOG performance status								
0	29	0	29 (100.0)	NE (NE, NE)				
1	72	11 (15.3)	61 (84.7)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

DE.T.4.9.1 Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 5% of the patients in at least one arm and in addition Severe Treatment-emergent adverse events (NCI CTCAE grade >=3) by SOC and PT observed for >= 10 patients and >= 1% of the patients in at least one arm- Time-to-event analysis including subgroup analysis - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

SOC: Respiratory, thoracic and mediastinal disorders; PT: Any PT

	T-DXd 5.4 mg/kg (N=101)							
					Kaplan-Meier estimates of survival rates (95% CI)			
Subgroup	N/ Nsub	Number of subjects with event n (%)	Number of subjects censored n (%)	Median time to first event (months) (95% CI) [a]	At 3 months	At 6 months	At 9 months	At 12 months
Renal function at baseline								
Within normal range	37	4 (10.8)	33 (89.2)	NE (NE, NE)				
Mild impairment	41	3 (7.3)	38 (92.7)	NE (NE, NE)				
Moderate impairment	23	4 (17.4)	19 (82.6)	NE (NE, NE)				
Hepatic function at baseline								
Normal hepatic function	76	8 (10.5)	68 (89.5)	NE (NE, NE)				
Mild hepatic dysfunction	25	3 (12.0)	22 (88.0)	NE (NE, NE)				

N: number of subjects in analysis set; Nsub: number of subjects in subgroup category; %: proportion of number of subjects in analysis set / subgroup category; CI: confidence interval; NE: not estimable
[a] Median time to first event is from Kaplan-Meier estimate. Confidence Interval for median was computed using the Brookmeyer-Crowley method.

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
Run date: 15MAY2023 – 17:16; Program name: t4_aesocpt10per_1_sas.sas; Output name: T4_AESEVSOCPT5PER_1_SAS.rtf

Anhang 4-G 4.5 Sicherheit – Unerwünschte Ereignisse nach SOC und PT, die zum Abbruch der Studienmedikation geführt haben – weitere Untersuchungen

Anhang 4-G 4.5.1 Unerwünschte Ereignisse nach SOC und PT, die zum Abbruch der Studienmedikation geführt haben

Anhang 4-G 4.5.1.1 Datenschnitt vom 24.03.2022

DE.T.4.10.1 Treatment-emergent adverse events associated with discontinuation of study treatment by SOC and PT - Descriptive summary - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

MedDRA System Organ Class / Preferred Term	T-DXd 5.4 mg/kg (N=101) n (%)
Subjects with any treatment-emergent adverse events associated with study drug discontinuation	8 (7.9)
Respiratory, thoracic and mediastinal disorders	6 (5.9)
Interstitial lung disease	3 (3.0)
Pneumonitis	2 (2.0)
Pulmonary toxicity	1 (1.0)
Cardiac disorders	1 (1.0)
Myocarditis	1 (1.0)
Gastrointestinal disorders	1 (1.0)
Diarrhoea	1 (1.0)
Vomiting	1 (1.0)

N: number of subjects in analysis set, n: number of subjects with at least one event; %: proportion of number of subjects in analysis set

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_discsocpt_sas.sas; Output name: T4_AEDISCSOCPT_1_SAS.rtf

DE.T.4.10.1 Treatment-emergent adverse events associated with discontinuation of study treatment by SOC and PT - Descriptive summary - Destiny Lung 02 - DCO 24-Mar-2022 - Safety Analysis Set

MedDRA System Organ Class / Preferred Term	T-DXd 5.4 mg/kg (N=101) n (%)
Metabolism and nutrition disorders	1 (1.0)
Hypokalaemia	1 (1.0)
Hypomagnesaemia	1 (1.0)

N: number of subjects in analysis set, n: number of subjects with at least one event; %: proportion of number of subjects in analysis set

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20220324/rstrct_eg_valos/20230201_AMNOG_01/rstrct_adam
Run date: 24MAR2023 – 9:12; Program name: t4_discsocpt_sas.sas; Output name: T4_AEDISCSOCPT_1_SAS.rtf

Anhang 4-G 4.5.1.2 Finaler Datenschnitt vom 23.12.2022

Daiichi Sankyo
Data Intelligence – Evidence Generation
DS8201-A-U206 – Destiny Lung 02 - (DCO 23DEC2022)

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Final
Statistical analyses for AMNOG (HTA Germany)

DE.T.4.10.1 Treatment-emergent adverse events associated with discontinuation of study treatment by SOC and PT - Descriptive summary - Destiny Lung 02 - DCO 23-Dec-2022 - Safety Analysis Set

MedDRA System Organ Class / Preferred Term	T-DXd 5.4 mg/kg (N=101) n (%)
Subjects with any treatment-emergent adverse events associated with study drug discontinuation	15 (14.9)
Respiratory, thoracic and mediastinal disorders	13 (12.9)
Interstitial lung disease	6 (5.9)
Pneumonitis	5 (5.0)
Pleural effusion	1 (1.0)
Pulmonary toxicity	1 (1.0)
Cardiac disorders	1 (1.0)
Myocarditis	1 (1.0)
Metabolism and nutrition disorders	1 (1.0)
Hypokalaemia	1 (1.0)

N: number of subjects in analysis set, n: number of subjects with at least one event; %: proportion of number of subjects in analysis set

Data source: DS8201-A-U206/restricted/rstrct_eg/rstrct_DCO_20221223/rstrct_eg_valos/20230414_AMNOG_01/rstrct_adam
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