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Criteria for dose modifications

	Criteria
Dose adjustments	• Weight changes ≥10% at the beginning of each cycle
Dose withholding	• Grade 2 pneumonitis • Grade 2 or 3 colitis • Grade 2 symptomatic hypophysitis • Grade 2 nephritis • Grade 3 hyperthyroidism • AST or ALT greater than 3 and up to 5 times ULN or total bilirubin greater than 1.5 and up to 3 times ULN • Any other severe or grade 3 treatment-related adverse reaction except for asymptomatic laboratory abnormalities
Dose resumption*	• Phase 1A, Parts 1 and 2: AEs resolve to grade 0–1 within 6 weeks • Phase 1A, Part 3: AEs resolve to grade 0–1 within 12 weeks • Phase 1B: AEs resolve to grade 0–1 within 12 weeks

*Two dosing delays due to toxicity were permitted.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; ULN, upper limit of normal.

Definition of PD-L1 positivity

The rationale of cut-off selection for each indication was based on published PD-L1 algorithms.

PD-L1 expression was scored as:

1) Tumour cell (TC): the percentage of tumour cells with any membrane staining;

2) Immune cell (IC): the percentage of tumour-associated immune cells with staining at any intensity; or

3) IC/TA: the percentage of tumour area occupied by tumour-associated immune cells with staining at any intensity.

PD-L1 Cut-off (SP263)	Tumour Type	PD-L1 Cut-offs (Clones) Selected by Other Clinical Trials
TC ≥1%	HCC	TPS ≥1% (28-8) [1]
	CRC	TPS ≥1% (28-8) [2]
	CC	NA
TC ≥25%	NSCLC	TC ≥25% (SP263) [3, 4]
	HNSCC	TC ≥25% (SP263) [5]
TC or IC ≥25%	GC*	TC or IC≥25% (SP263) [6] CPS ≥1% (22C3) [7]
	EC*	CPS ≥10% (22C3) [8, 9]
	UC	TC ≥25% or IC≥25% ICP >1% or IC=100% and ICP≤1% (SP263) [10]
	OC*	CPS ≥10% (22C3)[11]
IC/TA ≥1%	TNBC	IC ≥1% (SP142)[12]
	RCC	IC ≥1% (SP142)[13]

*Published PD-L1 algorithms (22C3) supported using a combined score of PD-L1+ tumour cells and immune cells in GC, EC and OC, while the cut-off at 25% was identified using SP263. Thus, TC or IC ⩾25% was selected for these cohorts.

CC, cholangiocarcinoma; CRC, colorectal cancer, pancreatic cancer; CPS, combined positive score; CRC, colorectal cancer; EC, oesophageal cancer; GC, gastric cancer; HCC, hepatocellular carcinoma; HNSCC, head and neck squamous cells cancer; IC, immune cells; ICP, immune cells present; NA, not applicable; NSCLC, non-small cell lung cancer; OC, ovarian cancer; PD-L1, programmed death ligand 1; RCC, renal cell carcinoma; TA, tumour area; TC, tumour cells; TNBC, triple-negative breast cancer; TPS; tumour proportion score; UBC, urothelial cancer.

Tables

Table S1. Adverse events leading to dose modification in ≥2 patients (SAF)

	Phase 1A (*n*=116)	Phase 1B (*n*=335)	Overall (*N*=451)
Patients with ≥1 AE leading to dose modification	**35 (30.2)**	**88 (26.3)**	**123 (27.3)**
Infusion-related reaction	7 (6.0)	5 (1.5)	12 (2.7)
Pneumonia	2 (1.7)	6 (1.8)	8 (1.8)
Anaemia	0 (0.0)	7 (2.1)	7 (1.6)
Proteinuria	0 (0.0)	7 (2.1)	7 (1.6)
Alanine aminotransferase increased	2 (1.7)	4 (1.2)	6 (1.3)
Aspartate aminotransferase increased	0 (0.0)	5 (1.5)	5 (1.1)
Blood bilirubin increased	0 (0.0)	4 (1.2)	4 (0.9)
Blood creatinine increased	2 (1.7)	2 (0.6)	4 (0.9)
Vomiting	0 (0.0)	4 (1.2)	4 (0.9)
Abdominal pain	2 (1.7)	1 (0.3)	3 (0.7)
Diarrhoea	2 (1.7)	1 (0.3)	3 (0.7)
Dyspnoea	0 (0.0)	3 (0.9)	3 (0.7)
Pneumonitis	0 (0.0)	3 (0.9)	3 (0.7)
Pyrexia	1 (0.9)	2 (0.6)	3 (0.7)
Adrenal insufficiency	0 (0.0)	2 (0.6)	2 (0.4)
Arthralgia	1 (0.9)	1 (0.3)	2 (0.4)
Autoimmune hepatitis	0 (0.0)	2 (0.6)	2 (0.4)
Cachexia	0 (0.0)	2 (0.6)	2 (0.4)
Dehydration	0 (0.0)	2 (0.6)	2 (0.4)
Electrocardiogram QT prolonged	1 (0.9)	1 (0.3)	2 (0.4)
Fatigue	0 (0.0)	2 (0.6)	2 (0.4)
Hepatitis	0 (0.0)	2 (0.6)	2 (0.4)
Hyperthyroidism	1 (0.9)	1 (0.3)	2 (0.4)
Lower respiratory tract infection	0 (0.0)	2 (0.6)	2 (0.4)
Nausea	0 (0.0)	2 (0.6)	2 (0.4)
Small intestinal obstruction	1 (0.9)	1 (0.3)	2 (0.4)
Upper respiratory tract infection	1 (0.9)	1 (0.3)	2 (0.4)
Vision blurred	0 (0.0)	2 (0.6)	2 (0.4)
Weight decreased	0 (0.0)	2 (0.6)	2 (0.4)

AE, adverse event; SAF, safety analysis set.

Table S2. Summary of adverse events by study phase (SAF)

	Phase 1A *n*=116	Phase 1B *n*=335	Overall *N*=451
Patients with ≥1 AE	114 (98.3)	322 (96.1)	436 (96.7)
Patients with ≥1 AE with grade ≥3	50 (43.1)	159 (47.5)	209 (46.3)
Patients with ≥1 serious AE	40 (34.5)	129 (38.5)	169 (37.5)
Patients with fatal AE	1 (0.9)	13 (3.9)	11 (3.1)
Patients with AE leading to treatment discontinuation	6 (5.2)	31 (9.3)	37 (8.2)
Patients with AE leading to treatment interruption	36 (31.0)	89 (26.6)	125 (27.7)
Patients with ≥1 AE considered related to treatment	86 (74.1)	173 (51.6)	259 (57.4)
Patients with ≥1 AE with grade ≥3 considered related to treatment	14 (12.1)	27 (8.1)	41 (9.1)
Patients with ≥1 serious AE considered related to treatment	11 (9.5)	24 (7.2)	35 (7.8)
Patients with AE leading to treatment discontinuation considered related to treatment	5 (4.3)	19 (5.7)	24 (5.3)
Patients with AE leading to treatment interruption considered related to treatment	20 (17.2)	33 (9.9)	53 (11.8)
Patients with fatal AE considered related to treatment	0 (0.0)	2 (0.6)	2 (0.4)
Patients with immune-related AE*	58 (50.0)	100 (29.9)	158 (35.0)
Patients with infusion-related reaction	15 (12.9)	18 (5.4)	33 (7.3)

Data presented as *n* (%). Rows shaded in grey are AEs considered related to treatment.
*Potential immune-related treatment-emergent AEs were selected from a predefined list of preferred terms and excludes any AEs that were unrelated by investigator assessment.
AE, adverse event; SAF, safety analysis set.

Table S3. Summary of adverse events in phase 1A Part 1 (A) and Part 2 (B) from SAF*

A. Summary of adverse events by dose

Dose Escalation (Phase 1A – Part 1)	0.5 mg/kg Q2W (*n*=3)	2.0 mg/kg Q2W (*n*=6)	5.0 mg/kg Q2W (*n*=6)	10.0 mg/kg Q2W (*n*=7)	Overall (*N*=22)
Patients with ≥1 AE	3 (100.0)	6 (100.0)	6 (100.0)	7 (100.0)	22 (100.0)
Patients with ≥1 AE with grade ≥3	0 (0.0)	3 (50.0)	4 (66.7)	3 (42.9)	10 (45.5)
Patients with ≥1 serious AE	0 (0.0)	3 (50.0)	4 (66.7)	3 (42.9)	10 (45.5)
Patients with fatal AE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Patients with AE leading to treatment discontinuation	0 (0.0)	1 (16.7)	1 (16.7)	0 (0.0)	2 (9.1)
Patients with AE leading to treatment interruption	0 (0.0)	2 (33.3)	2 (33.3)	0 (0.0)	4 (18.2)
Patients with ≥1 AE considered related to treatment	0 (0.0)	5 (83.3)	4 (66.7)	5 (71.4)	14 (63.6)
Patients with ≥1 AE with grade ≥3 considered related to treatment	0 (0.0)	1 (16.7)	1 (16.7)	0 (0.0)	2 (9.1)
Patients with ≥1 serious AE considered related to treatment	0 (0.0)	2 (33.3)	1 (16.7)	0 (0.0)	3 (13.6)
Patients with fatal AE considered related to treatment	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Patients with AE leading to treatment discontinuation considered related to treatment	0 (0.0)	1 (16.7)	1 (16.7)	0 (0.0)	2 (9.1)
Patients with AE leading to treatment interruption considered related to treatment	0 (0.0)	2 (33.3)	2 (33.3)	0 (0.0)	4 (18.2)
Patients with immune-related AE	0 (0.0)	2 (33.3)	2 (33.3)	0 (0.0)	4 (18.2)
Patients with infusion-related reaction	0 (0.0)	2 (33.3)	0 (0.0)	1 (4.3)	3 (13.6)

B. Summary of adverse events by dose schedule (SAF)

Schedule Expansion (Phase 1A – Part 2)	Q2W			Q3W			Overall (*N*=81)
	2.0 mg/kg (*n*=20)	5.0 mg/kg (*n*=20)	Combined (*n*=40)	2.0 mg/kg (*n*=21)	5.0 mg/kg (*n*=20)	Combined (*n*=41)	
Patients with ≥1 AE	20 (100.0)	20 (100.0)	40 (100.0)	20 (95.2)	20 (100.0)	40 (97.6)	80 (98.8)
Patients with ≥1 AE with grade ≥3	9 (45.0)	9 (45.0)	18 (45.0)	5 (23.8)	10 (50.0)	15 (36.6)	33 (40.7)
Patients with ≥1 serious AE	10 (50.0)	8 (40.0)	18 (45.0)	6 (28.6)	9 (45.0)	15 (36.6)	33 (40.7)
Patients with fatal AE	1 (5.0)	0 (0.0)	1 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.2)
Patients with AE leading to treatment discontinuation	1 (5.0)	2 (10.0)	3 (7.5)	1 (4.8)	2 (10.0)	3 (7.3)	6 (7.4)
Patients with AE leading to treatment interruption	3 (15.0)	5 (25.0)	8 (20.0)	4 (19.0)	6 (30.0)	10 (24.4)	18 (22.2)
Patients with ≥1 AE considered related to treatment	15 (75.0)	14 (70.0)	29 (72.5)	15 (71.4)	16 (80.0)	31 (75.6)	60 (74.1)
Patients with ≥1 AE with grade ≥3 considered related to treatment	1 (5.0)	2 (10.0)	3 (7.5)	0 (0.0)	5 (25.0)	5 (12.2)	8 (9.9)
Patients with ≥1 serious AE considered related to treatment	2 (10.0)	2 (10.0)	4 (10.0)	0 (0.0)	4 (20.0)	4 (9.8)	8 (9.9)
Patients with fatal AE considered related to treatment	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Patients with AE leading to treatment discontinuation considered related to treatment	0 (0.0)	1 (5.0)	1 (2.5)	1 (4.8)	2 (10.0)	3 (7.3)	4 (4.9)
Patients with AE leading to treatment interruption considered related to treatment	0 (0.0)	4 (20.0)	4 (10.0)	2 (9.5)	2 (10.0)	4 (9.8)	8 (9.9)
Patients with immune-related AE*	7 (35.0)	7 (35.0)	14 (35.0)	7 (33.3)	7 (35.0)	14 (34.1)	28 (34.6)
Patients with infusion-related reaction	1 (5.0)	8 (40.0)	9 (22.5)	3 (14.3)	4 (20.0)	7 (17.1)	16 (19.8)

*Data from an intrim analysis; data cutoff, 28 Aug 2017.

AE, adverse event; Q2W, every 2 weeks; Q3W, every 3 weeks; SAF, safety analysis set.

Table S4. Adverse events considered at least possibly related to tislelizumab by the investigator occurring in ≥1% of total patients (SAF)

	Phase 1A *n*=116	Phase 1B *n*=335	Total *N*=451
Patients with ≥1 AE considered related to treatment	**86 (74.1)**	**173 (51.6)**	**259 (57.4)**
Fatigue	24 (20.7)	35 (10.4)	59 (13.1)
Rash	15 (12.9)	24 (7.2)	39 (8.6)
Nausea	13 (11.2)	20 (6.0)	33 (7.3)
Diarrhoea	16 (13.8)	15 (4.5)	31 (6.9)
Hypothyroidism	6 (5.2)	21 (6.3)	27 (6.0)
Infusion-related reaction	12 (10.3)	14 (4.2)	26 (5.8)
Decreased appetite	2 (1.7)	19 (5.7)	21 (4.7)
Pruritus	8 (6.9)	13 (3.9)	21 (4.7)
Pruritus generalised	8 (6.9)	10 (3.0)	18 (4.0)
Hyperthyroidism	5 (4.3)	13 (3.9)	18 (4.0)
Increased ALT	7 (6.0)	8 (2.4)	15 (3.3)
Rash maculo-papular	5 (4.3)	8 (2.4)	13 (2.9)
Pneumonitis	2 (1.7)	9 (2.7)	11 (2.4)
Arthralgia	3 (2.6)	8 (2.4)	11 (2.4)
Proteinuria	1 (0.9)	10 (3.0)	11 (2.4)
Increased AST	2 (1.7)	8 (2.4)	10 (2.2)
Pyrexia	3 (2.6)	6 (1.8)	9 (2.0)
Vomiting	2 (1.7)	7 (2.1)	9 (2.0)
Abdominal pain	5 (4.3)	3 (0.9)	8 (1.8)
Dry eye	4 (3.4)	3 (0.9)	7 (1.6)
Dry mouth	3 (2.6)	4 (1.2)	7 (1.6)
Dry skin	1 (0.9)	6 (1.8)	7 (1.6)
Dyspnoea	1 (0.9)	6 (1.8)	7 (1.6)
Lethargy	5 (4.3)	2 (0.6)	7 (1.6)
Colitis	4 (3.4)	2 (0.6)	6 (1.3)
Increased blood alkaline phosphatase	1 (0.9)	5 (1.5)	6 (1.3)
Alopecia	0 (0.0)	5 (1.5)	5 (1.1)
Constipation	3 (2.6)	2 (0.6)	5 (1.1)
Oedema peripheral	3 (2.6)	2 (0.6)	5 (1.1)
Rash erythematous	3 (2.6)	2 (0.6)	5 (1.1)
Rash papular	1 (0.9)	4 (1.2)	5 (1.1)
Arthritis	3 (2.6)	2 (0.6)	5 (1.1)

AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; SAF, safety analysis set.

Table S5. Adverse events considered related to tislelizumab by the investigator occurring in phase 1* (SAF)

A. Treatment-related adverse events by dose (Part 1)

Dose Escalation (Phase 1A – Part 1)†	0.5 mg/kg Q2W (*n*=3)	2.0 mg/kg Q2W (*n*=6)	5.0 mg/kg Q2W (*n*=6)	10.0 mg/kg Q2W (*n*=7)	Overall (*N*=22)
Fatigue	0 (0.0)	2 (33.3)	2 (33.3)	2 (28.6)	6 (27.3)
Diarrhoea	0 (0.0)	3 (50.0)	1 (16.7)	0 (0.0)	4 (18.2)
Nausea	0 (0.0)	0 (0.0)	1 (16.7)	2 (28.6)	3 (13.6)
Colitis	0 (0.0)	1 (16.7)	1 (16.7)	0 (0.0)	2 (9.1)
Rash	0 (0.0)	0 (0.0)	1 (16.7)	1 (14.3)	2 (9.1)

*Data from an intrim analysis; data cutoff, 28 Aug 2017; †Adverse events related to treatment occurring in ≥5% of the overall Part 1 population.

B. Treatment-related adverse events by treatment schedule (Part 2)

	Q2W			Q3W			
Schedule Expansion (Phase 1A – Part 2)†	2.0 mg/kg (*n*=20)	5.0 mg/kg (*n*=20)	Combined (*n*=40)	2.0 mg/kg (*n*=21)	5.0 mg/kg (*n*=20)	Combined (*n*=41)	Overall (*N*=81)
Fatigue	5 (25.0)	5 (25.0)	10 (25.0)	0 (0.0)	5 (25.0)	5 (12.2)	15 (18.5)
Diarrhoea	5 (25.0)	3 (15.0)	8 (20.0)	2 (9.5)	2 (10.0)	4 (9.8)	12 (14.8)
Infusion related reaction	0 (0.0)	7 (35.0)	7 (17.5)	2 (9.5)	1 (5.0)	3 (7.3)	10 (12.3)
Rash	1 (5.0)	5 (25.0)	6 (15.0)	1 (4.8)	3 (15.0)	4 (9.8)	10 (12.3)
Nausea	1 (5.0)	2 (10.0)	3 (7.5)	3 (14.3)	1 (5.0)	4 (9.8)	7 (8.6)
Pruritus	3 (15.0)	1 (5.0)	4 (10.0)	1 (4.8)	1 (5.0)	2 (4.9)	6 (7.4)
Hypothyroidism	1 (5.0)	2 (10.0)	3 (7.5)	2 (9.5)	0 (0.0)	2 (4.9)	5 (6.2)
Pruritus generalised	0 (0.0)	0 (0.0)	0 (0.0)	2 (9.5)	3 (15.0)	5 (12.2)	5 (6.2)
Rash maculo-papular	0 (0.0)	1 (5.0)	1 (2.5)	2 (9.5)	2 (10.0)	4 (9.8)	5 (6.2)

*Data from an intrim analysis; data cutoff, 28 Aug 2017; †Adverse events related to treatment occurring in ≥5% of the overall Part 1 population.

C. Treatment-related adverse events with fixed dose (Part 3)

Fixed-dose (Phase 1A – Part 3)‡	200 mg Q3W(*N*=13)
Fatigue	3 (23.1)
Pruritus generalised	3 (23.1)
Nausea	2 (15.4)

*Data from an intrim analysis; data cutoff, 28 Aug 2017; †Adverse events related to treatment occurring in ≥2 patients.

Q2W, every 2 weeks; Q3W, every 3 weeks; SAF, safety analysis set.

Table S6. Best overall response observed as assessed by the investigator in phase 1* (SAF)

Dose Escalation (Phase 1A – Part 1)	0.5 mg/kg Q2W (*n*=3)	2.0 mg/kg Q2W (*n*=6)	5.0 mg/kg Q2W (*n*=6)	10.0 mg/kg Q2W (*n*=7)	Overall (*N*=22)
ORR (CR, PR)					
n (%)	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	1 (4.5)
(Exact 95% CI)	(0, 70.8)	(0.42, 64.1)	(0, 45.9)	(0, 41.0)	(0.1, 22.8)
Best overall response - confirmed, n (%)					
CR	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
PR	0 (0.0)	1 (16.7)	0 (0.0)	0 (0.0)	1 (4.5)
SD	3 (100.0)	3 (50.0)	3 (50.0)	1 (14.3)	10 (45.5)
PD	0 (0.0)	2 (33.3)	3 (50.0)	6 (85.7)	11 (50.0)

A. Best overall response by dose (Part 1)

B. Best overall response by treatment schedule (Part 2)

	Q2W			Q3W			
Schedule Expansion (Phase 1A – Part 2)	2.0 mg/kg (*n*=20)	5.0 mg/kg (*n*=20)	Combined (*n*=40)	2.0 mg/kg (*n*=21)	5.0 mg/kg (*n*=20)	Combined (*n*=41)	Overall (*N*=81)
ORR (CR, PR)							
n (%)	2 (10.0)	3 (15.0)	5 (12.5)	8 (38.1)	3 (15.0)	11 (26.8)	16 (19.8)
(Exact 95% CI)	(1.2, 31.7)	(3.2, 37.9)	(4.2, 26.8)	(18.1, 61. 6)	(3.2, 37.9)	(14.2, 42.9)	(11.7, 30.1)
Best overall response - confirmed, n (%)							
CR	1 (5.0)	0 (0.0)	1 (2.5)	1 (4.8)	0 (0.0)	1 (2.4)	2 (2.5)
PR	1 (5.0)	3 (15.0)	4 (10.0)	7 (33.3)	3 (15.0)	10 (24.4)	14 (17.3)
SD	8 (40.0)	6 (30.0)	14 (35.0)	6 (28.6)	8 (40.0)	14 (34.1)	28 (34.6)
PD	9 (45.0)	10 (50.0)	19 (47.5)	7 (33.3)	7 (35.0)	14 (34.1)	33 (40.7)
NE	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing	1 (5.0)	1 (5.0)	2 (5.0)	0 (0.0)	2 (10.0)	2 (4.9)	4 (4.9)

C. Best overall response with fixed dose (Part 3)

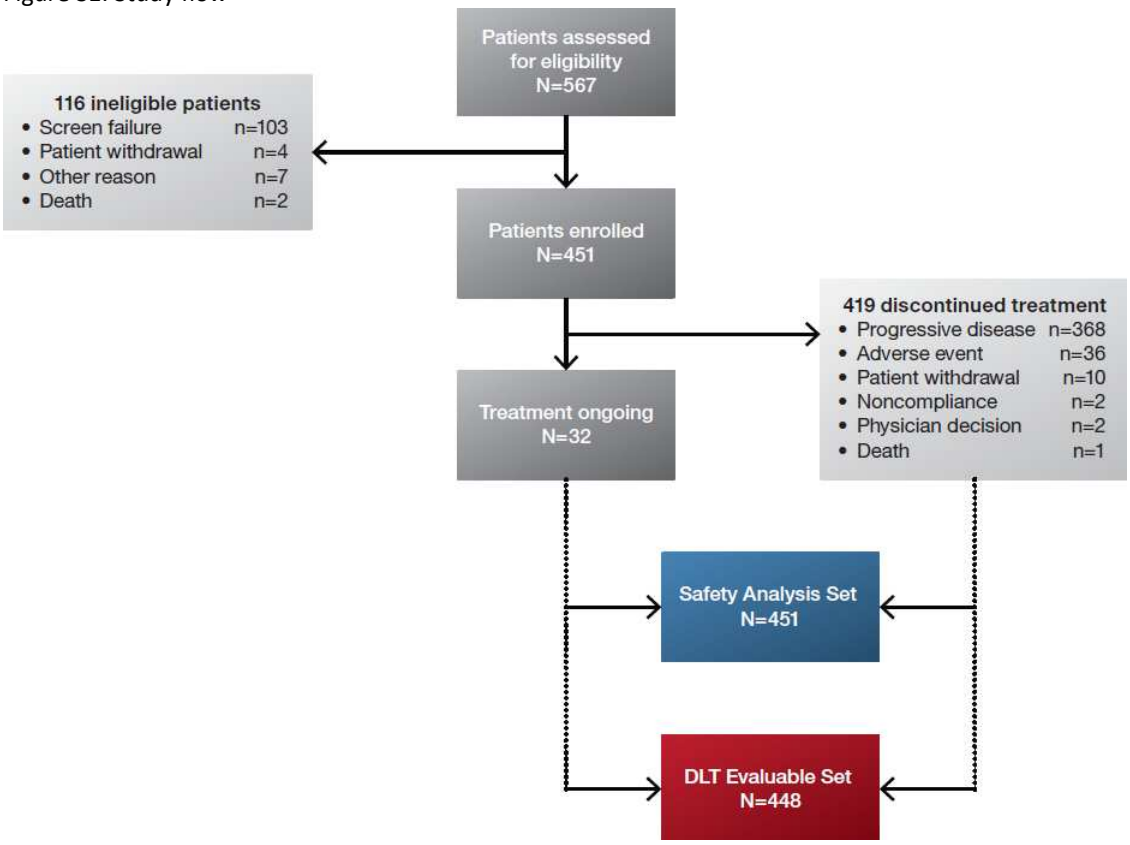
Fixed-dose (Phase 1A – Part 3)	200 mg Q3W (*N*=13)
ORR (CR, PR)	
n (%)	20 (17.2)
(Exact 95% CI)	(10.86, 25.36)
Best overall response - confirmed, n (%)	
CR	0 (0.0)
PR	3 (23.1)
SD	4 (30.8)
PD	6 (46.2)

*Data from an intrim analysis; data cutoff, 28 Aug 2017.

CI, confidence interval, CR, complete response; NE, not evaluable; ORR, objective response rate; PD, progressive disease; PR, partial response; Q2W, every 2 weeks; Q3W, every 3 weeks; SAF, safety analysis set; SD, stable disease.

Figures

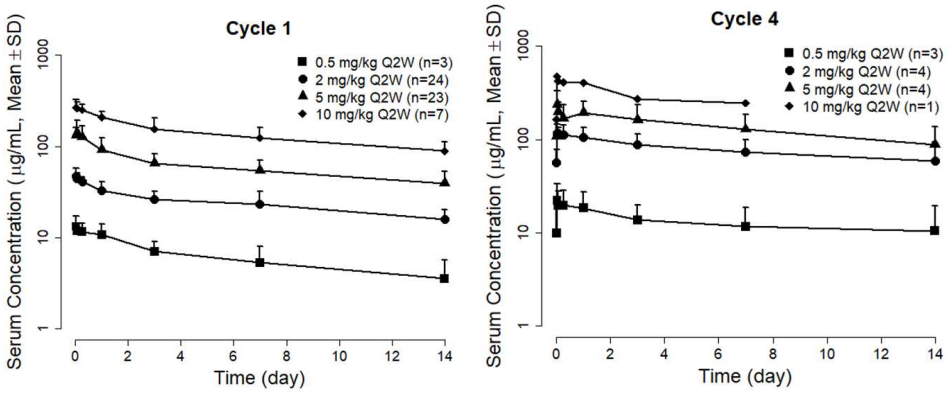
Figure S1. Study flow



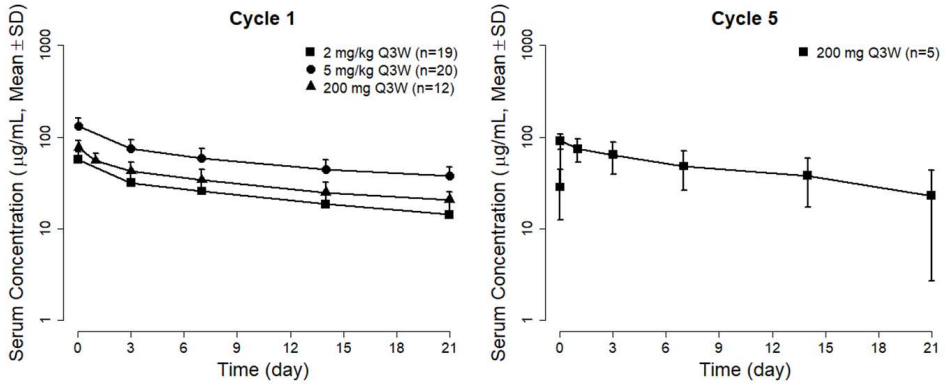
DLT, dose-limiting toxicity.

Figure S2. Tislelizumab concentration-time profiles at Day 1 (Cycle 1) and Day 85 (Cycle 4 [Q2W] or Cycle 5 [Q3W]) by dose schedule (PK analysis set)

A. Q2W dosing

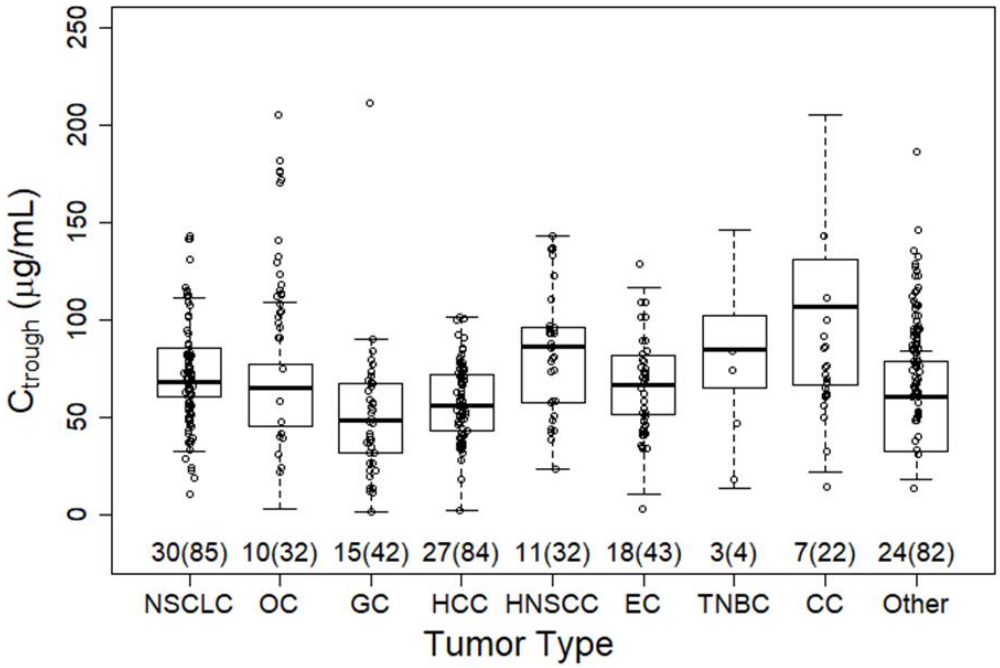


B. Q3W dosing



Footnote: Lower limit of quantitation=0.4 μg/mL.
PK, pharmacokinetic; Q2W, once every 2 weeks; Q3W, once every 3 weeks; SD, standard deviation.

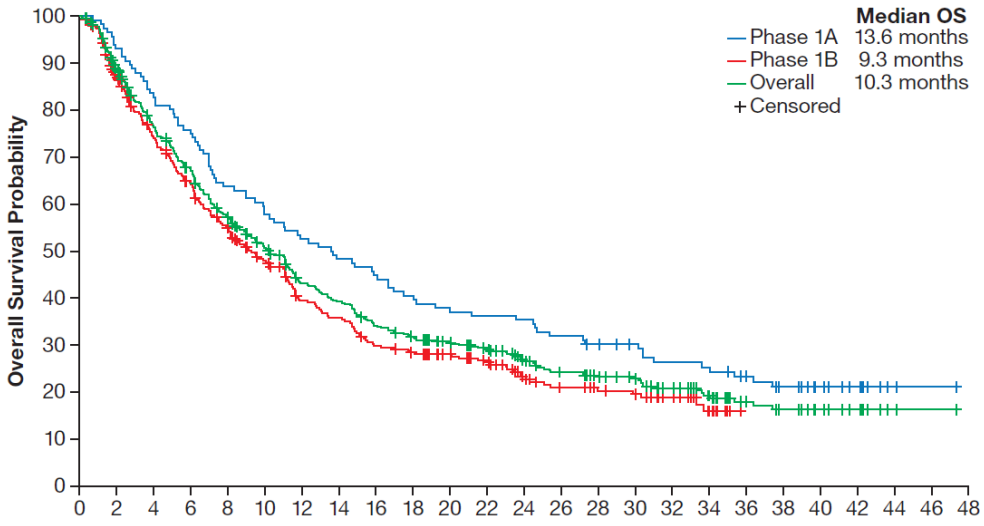
Figure S3. Steady-state tislelizumab C_{trough} across various advanced solid tumour types (PK analysis set)



Footnote: Lower limit of quantitation = 0.4 µg/mL.
CC, cholangiocarcinoma; C_{trough}, trough concentrations; EC, oesophageal carcinoma; GC, gastric cancer; HCC, hepatocellular carcinoma; HNSCC, head and neck squamous cell carcinoma; NSCLC, non-small cell lung carcinoma; PK, pharmacokinetic; OC, ovarian cancer; TNBC, triple-negative breast cancer.

Figure S4. Overall survival (A) and progression-free survival (B) (SAF)

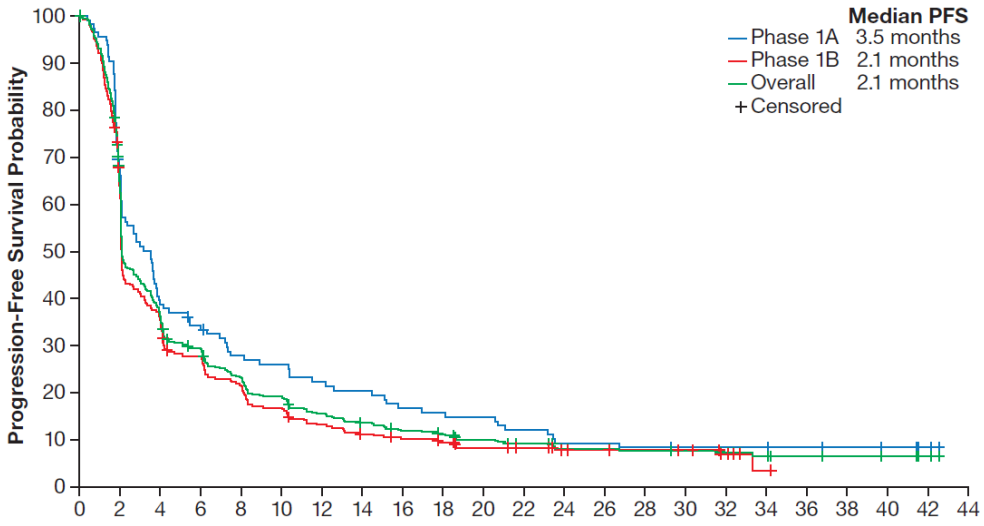
A) Overall survival



Patients at Risk (n)

Phase 1A	116	108	96	88	74	67	61	56	52	47	43	42	41	37	34	31	27	26	22	17	12	8	2	1	0
Phase 1B	335	280	228	194	163	137	108	98	81	75	67	57	43	34	30	28	19	9	0						
Overall	451	388	324	282	237	204	169	154	133	122	110	99	84	71	64	59	46	35	22	17	12	8	2	1	0

B) Progression-free survival



Patients at Risk (n)

Phase 1A	116	77	44	38	30	28	24	22	18	17	16	13	10	10	9	8	8	8	7	6	5	2	0
Phase 1B	335	203	112	86	67	52	40	33	29	26	21	19	15	13	12	11	5	1	0				
Overall	451	280	156	124	97	80	64	55	47	43	37	32	25	23	21	19	13	9	7	6	5	2	0

OS, overall survival, PFS, progression-free survival; PK, pharmacokinetic; SAF, safety analysis set.

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