

Supplemental Digital Content 1. Patient laboratory data at baseline and end of study (hematology, chemistry, urinalysis, other)

		Observed Value		Change from baseline	
		Nivolumab 480 mg (N=5)	Nivolumab 960 mg (N=9)	Nivolumab 480 mg (N=5)	Nivolumab 960 mg (N=9)
Hematology					
Hemoglobin (g/L)	Baseline ^a	110.8 (11.9)	96.4 (14.9)		
	EOS ^b	105.8 (15.2)	95.2 (13.6)	-8.8 (5.7)	-4.6 (26.4)
Hematocrit (%)	Baseline ^a	34.8 (3.6)	28.8 (5.0)		
	EOS ^b	32.8 (4.3)	29.8 (4.3)	-3.4 (2.6)	-0.5 (8.0)
Leukocytes (10 ⁹ /L)	Baseline ^a	18.2 (11.8)	11.1 (2.7)		
	EOS ^b	8.3 (5.3)	8.2 (2.7)	-11.8 (7.8)	-2.5 (5.0)
Neutrophils/leukocytes (%)	Baseline ^a	88.2 (4.6)	87.9 (5.6)		
	EOS ^b	64.6 (12.1)	73.0 (9.6)	-22.6 (7.5)	-14.5 (7.4)
Lymphocytes/leukocytes (%)	Baseline ^a	7.4 (2.9)	5.8 (2.3)		
	EOS ^b	24.2 (9.5)	17.0 (7.9)	16.2 (7.0)	10.3 (6.4)
Eosinophils/leukocytes (%)	Baseline ^a	0.7 (1.2)	0.6 (1.1)		
	EOS ^b	2.1 (1.5)	3.9 (2.4)	1.2 (1.65)	3.5 (2.7)
Basophils/leukocytes (%)	Baseline ^a	0.2 (0.3)	0.1 (0.1)		
	EOS ^b	0.8 (0.2)	0.4 (0.5)	0.5 (0.4)	0.4 (0.5)
Monocytes/leukocytes (%)	Baseline ^a	2.7 (1.2)	4.5 (3.5)		
	EOS ^b	5.3 (1.7)	5.5 (3.4)	2.6 (1.5)	0.6 (1.1)
Neutrophils (10 ⁹ /L)	Baseline ^a	16.3 (11.3)	9.7 (2.6)		
	EOS ^b	5.7 (4.7)	6.2 (2.6)	-12.3 (7.7)	-3.2 (4.3)
Lymphocytes (10 ⁹ /L)	Baseline ^a	1.28 (0.4)	0.6 (0.3)		
	EOS ^b	1.8 (0.8)	1.3 (0.6)	0.4 (0.8)	0.6 (0.6)
Eosinophils (10 ⁹ /L)	Baseline ^a	0.1 (0.2)	0.1 (0.1)		
	EOS ^b	0.1 (0.1)	0.3 (0.1)	0.0 (0.2)	0.2 (0.1)
Basophils (10 ⁹ /L)	Baseline ^a	0.0 (0.1)	0.0 (0.0)		
	EOS ^b	0.1 (0.1)	0.0 (0.0)	0.0 (0.1)	0.0 (0.0)
Monocytes (10 ⁹ /L)	Baseline ^a	0.5 (0.3)	0.5 (0.4)		
	EOS ^b	0.4 (0.3)	0.4 (0.3)	-0.1 (0.1)	-0.1 (0.4)
Platelets (10 ⁹ /L)	Baseline ^a	147.6 (93.5)	91.9 (45.4)		
	EOS ^b	341.8 (143.0)	229.2 (148.9)	186.0 (177.0)	137.0 (170.4)
CD4/lymphocytes (%)	Baseline ^a	41.8 (10.5)	50.7 (8.9)		
	EOS ^b	60.3 (12.6)	52.8 (10.5)	14.3 (14.6)	0.5 (12.2)
CD8/lymphocytes (%)	Baseline ^a	14.6 (4.3)	12.0 (6.7)		
	EOS ^b	24.0 (12.2)	21.1 (10.0)	10.5 (8.3)	5.9 (8.5)
CD4 (10 ⁹ /L)	Baseline ^a	0.51 (0.23)	0.36 (0.17)		
	EOS ^b	1.1 (0.7)	0.8 (0.4)	0.5 (0.7)	0.3 (0.5)
CD8 (10 ⁹ /L)	Baseline ^a	0.2 (0.1)	0.1 (0.1)		
	EOS ^b	0.6 (0.4)	0.3 (0.2)	0.3 (0.4)	0.2 (0.1)
CD4/CD8	Baseline ^a	3.2 (1.5)	6.1 (4.1)		
	EOS ^b	2.9 (1.1)	3.1 (1.6)	-0.8 (1.0)	-0.9 (1.4)
Chemistry					
Albumin (g/L)	Baseline ^a	25.0 (4.5)	22.6 (4.4)		
	EOS ^b	24.5 (7.9)	25.0 (5.1)	0.8 (10.2)	3.2 (8.8)
Alkaline phosphatase (μkat/L)	Baseline ^a	7.0 (3.0)	4.5 (2.4)		
	EOS ^b	19.4 (28.8)	5.5 (2.0)	11.9 (25.8)	0.84 (2.2)
Aspartate aminotransferase (μkat/L)	Baseline ^a	1.4 (0.7)	3.5 (4.8)		
	EOS ^b	0.9 (0.9)	0.6 (0.4)	-0.6 (1.01)	-0.4 (0.6)
Alanine aminotransferase (nkat/L)	Baseline ^a	1716.7 (1338.0)	1660.5 (2388.6)		
	EOS ^b	1445.9 (2299.6)	523.3 (401.8)	-475.0 (1859.5)	-50.0 (581.8)
Bilirubin (μM/L)	Baseline ^a	12.4 (3.6)	33.5 (32.0)		
	EOS ^b	44.3 (68.7)	9.7 (8.1)	31.1 (37.1)	-5.1 (5.2)

Direct bilirubin (μ M/L)	Baseline ^a	6.4 (3.4)	24.6 (24.8)		
	EOS ^b	43.2 (69.2)	5.0 (5.9)	56.4 (80.0)	-3.1 (4.0)
Protein (g/L)	Baseline ^a	51.2 (6.6)	49.9 (6.7)		
	EOS ^b	57.5 (5.5)	61.6 (5.7)	8.0 (6.7)	12.2 (10.7)
Creatinine (μ M/L)	Baseline ^a	142.2 (100.1)	245.8 (233.2)		
	EOS ^b	176.8 (233.1)	154.2 (116.5)	65.9 (152.2)	-59.6 (141.7)
Lipase (μ kat/L)	Baseline ^a	0.7 (0.7)	1.7 (3.1)		
	EOS ^b	0.8 (0.7)	2.4 (4.3)	0.1 (1.2)	1.7 (4.7)
Amylase (μ kat/L)	Baseline ^a	2.3 (3.2)	2.1 (1.7)		
	EOS ^b	1.5 (0.9)	2.5 (3.3)	0.7 (0.7)	0.8 (4.1)
Glucose (mM/L)	Baseline ^a	10.7 (3.1)	7.3 (1.1)		
	EOS ^b	7.1 (3.1)	6.7 (2.1)	-4.3 (3.6)	-0.28 (2.3)
Lactate dehydrogenase (ukat/L)	Baseline ^a	7.1 (3.6)	10.3 (8.5)		
	EOS ^b	3.3 (0.7)	4.8 (2.6)	-4.2 (3.5)	-1.2 (2.0)
Urea nitrogen (mM/L)	Baseline ^a	15.1 (5.4)	15.2 (13.0)		
	EOS ^b	7.1 (4.9)	10.4 (6.1)	-7.0 (7.3)	-1.5 (3.9)
Phosphate (mM/L)	Baseline ^a	0.8 (0.3)	1.3 (0.5)		
	EOS ^b	1.2 (0.2)	1.0 (0.1)	0.4 (0.3)	-0.1 (0.4)
Calcium (mM/L)	Baseline ^a	2.07 (0.1)	1.91 (0.2)		
	EOS ^b	2.2 (0.1)	2.2 (0.1)	0.1 (0.2)	0.2 (0.2)
Sodium (mM/L)	Baseline ^a	144.0 (11.2)	138.5 (5.4)		
	EOS ^b	134.8 (7.6)	141.2 (4.5)	-10.0 (12.2)	2.6 (5.4)
Potassium (mM/L)	Baseline ^a	4.5 (0.6)	3.9 (0.7)		
	EOS ^b	3.9 (0.4)	3.8 (0.8)	-0.5 (0.4)	-0.0 (0.6)
Chloride (mM/L)	Baseline ^a	108.6 (4.4)	103.4 (5.8)		
	EOS ^b	98.8 (4.6)	105.0 (4.5)	-10.0 (6.4)	1.2 (5.8)
C Reactive Protein (mg/L)	Baseline ^a	94.1 (74.2)	203.4 (77.2)		
	EOS ^b	21.1 (23.2)	41.5 (54.7)	-64.9 (69.0)	-142.8 (86.1)
Magnesium (mM/L)	Baseline ^a	0.9 (0.1)	0.8 (0.2)		
	EOS ^b	0.7 (0.1)	0.8 (0.1)	-0.2 (0.2)	-0.0 (0.1)
Bicarbonate (mM/L)	Baseline ^a	24.4 (9.1)	22.2 (6.6)		
	EOS ^b	24.7 (4.9)	26.6 (3.8)	-0.8 (8.3)	2.7 (2.4)
Urinalysis					
Specific gravity	Baseline ^a	1.022 (0.008)	1.017 (0.008)		
	EOS ^b	1.010 (0.006)	1.020 (0.006)	-0.015 (0.005)	0.002 (0.012)
pH	Baseline ^a	6.8 (1.6)	5.9 (0.9)		
	EOS ^b	6.7 (0.6)	6.0 (1.2)	0.2 (1.8)	-0.2 (1.1)
Other					
Thyrotropin (mIU/L)	Baseline ^c	2.46 (1.09)	2.35 (2.61)		
	EOS ^d	2.80 (0.68)	3.31 (5.85)	0.69 (0.65)	0.63 (3.30)
Triiodothyronine, Free (pmol/L)	Baseline ^e	1.69 (0.27)	1.85 (0.28)		
	EOS ^b	2.85 (1.33)	3.42 (1.31)	0.79 (1.10)	1.54 (1.15)
Thyroxine, Free (pmol/L)	Baseline ^e	7.51 (1.24)	12.77 (3.24)		
	EOS ^b	12.55 (3.23)	15.83 (5.48)	4.59 (2.58)	3.96 (4.58)

Values are given as mean (SD). Significance in the differences between the groups is not determined as no statistical testing was conducted.

^a480 mg, n=5; 960 mg, n=9

^b480 mg, n=4; 960 mg, n=5

^c480 mg, n=4; 960 mg, n=8 (patients who were measured using a different unit were excluded from the summary)

^d480 mg, n=3; 960 mg, n=5 (patients who were measured using a different unit were excluded from the summary)

^e480 mg, n=3; 960 mg, n=8

EOS, end of study (Day 28); SD, standard deviation