

16.2.6 Individual efficacy response data

Not applicable.

16.2.7 Adverse events listings

16.2.7.1 Listing of all adverse events by patient

Subj ID	Sex	No	AE diagnosis/ AE description	AE start		Time after last IMP admin. [days]	AE end		Duration of AE		Relation to IMP	Relation to protocol		Intensity	Out.	SAE ?	Action taken with IMP
				Date	Time		Date	Time	Days	Time							
1	Female	1	D-dimer elevation: 3160/ D-dimer elevation: 3160, Before administration of the first dose of Conbriza, D-dimers decrease on Day 2 to value 1620	07APR 2021	12:00*	0	08APR 2021	23:59*	1	11:59	Not related	Not related	Mild (Grade 1)	Rec.	No		Dose not changed

Subj. = Subject, AE = Adverse event, SAE = Serious adverse event, Admin. = Administration, IMP = Investigational medical product, Out. = Outcome, Rec. = Recovered.

*Time imputed to calculate AE duration.

16.2.7.2 Listing of treatment-emergent adverse events by patient

No treatment-emergent adverse events occurred. Adverse event in patient 1 (D-dimer elevation 3160 ug/L) occurred before administration of the first dose of Conbriza[®].

16.2.7.3 Listing of treatment-emergent serious adverse events by patient

No serious adverse events occurred.

16.2.7.4 Listing of adverse events leading to treatment/study discontinuation

No adverse events leading to study/study treatment discontinuation occurred.

16.2.7.5 Listing of adverse events leading to deaths

No treatment-emergent adverse events leading to death occurred.

16.2.8 Listing of individual laboratory measurements

16.2.8.1 Listing of laboratory hematology parameters

16.2.8.1.1 Listing of laboratory hematology parameters 1: Hemoglobin, Hematocrit, Red blood cell count, White blood cell count, Platelet count

Subject ID	Sex	Visit	Date	Hemoglobin [g/L]	Hematocrit [L/L]	Red blood cell count [10 ¹² /L]	White blood cell count [10 ⁹ /L]	Platelet count [10 ⁹ /L]
1	Female	Screening (-5 to D1)	07APR2021	138	0.4	4.69	3.8 AV ^{NCS}	387
		Day 2	08APR2021	134	0.393	4.57	11.9 AV ^{NCS}	466 AV ^{NCS}
		Day 3	09APR2021	130	0.383	4.4	12.6 AV ^{NCS}	482 AV ^{NCS}
		Day 5	11APR2021	131	0.392	4.54	12.5 AV ^{NCS}	512 AV ^{NCS}
		Day 7	13APR2021	135	0.397	4.63	13.8 AV ^{NCS}	492 AV ^{NCS}
		Day 14	20APR2021	135	0.415	4.74	20.1 AV ^{NCS}	324
		EoS (Day 21-28)	04MAY2021	131	0.399	4.56	9.7	406 AV ^{NCS}
2	Male	Screening (-5 to D1)	20APR2021	147	0.412	4.82	7.4	238
		Baseline (D1)	20APR2021	147	0.412	4.82	7.4	238
		Day 2	21APR2021	144	0.406	4.67	7.6	253
		Day 3	22APR2021	149	0.421	4.82	8.4	301
		Day 7	26APR2021	165	0.457	5.21	8	382
		EoT	ND					
		EoS (Day 21-28)	17MAY2021	161	0.451	5.1	4.6	329
3	Female	Screening (-5 to D1)	01MAY2021	150	0.464	5.37 AV ^{NCS}	9.1	221
		Day 2	02MAY2021	145	0.435	5.08	13.3 AV ^{NCS}	262
		Day 3	03MAY2021	140	0.424	4.85	15.8 AV ^{NCS}	264
		Day 5	05MAY2021	135	0.408	4.76	12.1 AV ^{NCS}	223
		Day 7	07MAY2021	159	0.465	5.52 AV ^{NCS}	12.1 AV ^{NCS}	312
		EoT	07MAY2021	159	0.465	5.52 AV ^{NCS}	12.1 AV ^{NCS}	312
		Day 10	10MAY2021	163 AV ^{NCS}	0.482 AV ^{NCS}	5.7 AV ^{NCS}	14.3 AV ^{NCS}	261
		EoS (Day 21-28)	28MAY2021	151	0.465	5.39 AV ^{NCS}	14 AV ^{NCS}	227

ND = Not done, AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.

16.2.8.1.2 Listing of laboratory hematology parameters 2: Basophils, Eosinophils, Neutrophils, Monocytes, Lymphocytes

Subject ID	Sex	Visit	Date	Basophils [%]	Eosinophils [%]	Neutrophils [%]	Monocytes [%]	Lymphocytes [%]
1	Female	Screening (-5 to D1)	07APR2021	0.3	0	81.4 AV ^{NCS}	1.8 AV ^{NCS}	0.61 AV ^{NCS}
		Day 2	08APR2021	0.1	0	82.4 AV ^{NCS}	6.1	10.9 AV ^{NCS}
		Day 3	09APR2021	0.1	0	83.1 AV ^{NCS}	7.2	9.2 AV ^{NCS}
		Day 5	11APR2021	0.1	0	80.6 AV ^{NCS}	7.3	11.3 AV ^{NCS}
		Day 7	13APR2021	0.2	0	80.7 AV ^{NCS}	6.2	11.9 AV ^{NCS}
		Day 14	20APR2021	0.2	0	90.5 AV ^{NCS}	2.6	5.5 AV ^{NCS}
		EoS (Day 21-28)	04MAY2021	0.2	0.2	82.6 AV ^{NCS}	5.5	10.7 AV ^{NCS}
2	Male	Screening (-5 to D1)	20APR2021	0.1	0	84.2 AV ^{NCS}	4.8	9.7 AV ^{NCS}
		Baseline (D1)	20APR2021	0.1	0	84.2 AV ^{NCS}	4.8	9.7 AV ^{NCS}
		Day 2	21APR2021	0.3	0	72.9 AV ^{NCS}	10.4	15.3 AV ^{NCS}
		Day 3	22APR2021	0.2	0	70.9 AV ^{NCS}	10.5	16.6 AV ^{NCS}
		Day 7	26APR2021	0.3	0.9	54	11.6	31.3
		EoT	ND					
		EoS (Day 21-28)	17MAY2021	0.2	1.5	52.4	14.1 AV ^{NCS}	31.4
3	Female	Screening (-5 to D1)	01MAY2021	0.1	0	84.7 AV ^{NCS}	1.3 AV ^{NCS}	13.5 AV ^{NCS}
		Day 2	02MAY2021	0.1	0	83 AV ^{NCS}	3.3	13 AV ^{NCS}
		Day 3	03MAY2021	0.1	0	85.8 AV ^{NCS}	3.3	9.8 AV ^{NCS}
		Day 5	05MAY2021	0	0	77 AV ^{NCS}	4.6	13.8 AV ^{NCS}
		Day 7	07MAY2021	0.8	0.3	56.1	5.8	30.3
		EoT	07MAY2021	0.8	0.3	56.1	5.8	30.3
		Day 10	10MAY2021	0.2	0.8	62.2	5.7	28.9
		EoS (Day 21-28)	28MAY2021	0.2	0.9	77.9 AV ^{NCS}	4.1	16.3 AV ^{NCS}

ND = Not done, AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.

16.2.8.1.3 Listing of laboratory hematology parameters 3: Mean corpuscular volume, Mean corpuscular hemoglobin, Mean corpuscular hemoglobin concentration, Red cell distribution width, D/dimers

Subject ID	Sex	Visit	Date	Mean corpuscular volume [fL]	Mean corpuscular hemoglobin [pg]	Mean corpuscular hemoglobin concentration [g/L]	Red cell distribution width [%]	D/dimers [ug/L]
1	Female	Screening (-5 to D1)	07APR2021	85.3	29.4	345	12.7	3160 AV ^{CS}
		Day 2	08APR2021	86	29.3	341	12.8	1620 AV ^{NCS}
		Day 3	09APR2021	87	29.5	339	12.8	1250 AV ^{NCS}
		Day 5	11APR2021	86.3	28.9	334	12.7	1360 AV ^{NCS}
		Day 7	13APR2021	85.7	29.2	340	11.2	1610 AV ^{NCS}
		Day 14	20APR2021	87.6	28.5	325	13.2	1380 AV ^{NCS}
		EoS (Day 21-28)	04MAY2021	87.5	28.7	328	14.4	1470 AV ^{NCS}
2	Male	Screening (-5 to D1)	20APR2021	85.5	30.5	357	11.8	350
		Baseline (D1)	20APR2021	85.5	30.5	357	11.8	350
		Day 2	21APR2021	86.9	30.8	355	11.6	350
		Day 3	22APR2021	87.3	30.9	354	11.6	
		Day 7	26APR2021	87.7	31.7	361 AV ^{NCS}	12.4	460
		EoT	ND					
		EoS (Day 21-28)	17MAY2021	88.4	31.6	357	13	430
3	Female	Screening (-5 to D1)	01MAY2021	86.4	27.9 AV ^{NCS}	323	14.2	370
		Day 2	02MAY2021	85.6	28.5	333	14	450
		Day 3	03MAY2021	87.4	28.9	330	14.1	350
		Day 5	05MAY2021	85.7	28.4	331	13.6	430
		Day 7	07MAY2021	84.2	28.8	342	13.6	440
		EoT	07MAY2021	84.2	28.8	342	13.6	440
		Day 10	10MAY2021	84.6	28.6	338	14.5	350
		EoS (Day 21-28)	28MAY2021	86.3	28	325	15.9 AV ^{NCS}	460

ND = Not done, AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.

16.2.8.1.4 Listing of laboratory hematology parameters 4: Prothrombin time, Activated partial thromboplastin time, International normalized ratio

				Prothrombin	Activated partial		
				time	thromboplastin		
Subject ID	Sex	Visit	Date	[s]	time	International	
					[s]	normalized ratio	
1	Female	Screening (-5 to D1)	07APR2021	13.1	45.9	AV ^{NCS}	1.42
		Day 2	08APR2021				
		Day 3	09APR2021				
		Day 5	11APR2021				
		Day 7	13APR2021				
		Day 14	20APR2021	12.2	28.5		0.93
		EoS (Day 21-28)	04MAY2021	11.7	34.2		0.89
2	Male	Screening (-5 to D1)	20APR2021	16	40.1		1.24
		Baseline (D1)	20APR2021	16	40.1		1.24
		Day 2	21APR2021	15.8	38.8		1.22
		Day 3	22APR2021	15.5	37.2		1.20
		Day 7	26APR2021	12.3	29.6		0.94
		EoT	ND				
		EoS (Day 21-28)	17MAY2021	12.5	33.7		0.95
3	Female	Screening (-5 to D1)	01MAY2021	13.7	41.2		1.06
		Day 2	02MAY2021	13.6	41.2		1.04
		Day 3	03MAY2021	14.7	39.1		1.14
		Day 5	05MAY2021	14	42.5		1.08
		Day 7	07MAY2021	13.9	35.8		1.07
		EoT	07MAY2021	13.9	35.8		1.07
		Day 10	10MAY2021	13.4	33.1		1.03
		EoS (Day 21-28)	28MAY2021	25.7	AV ^{NCS}	39.8	2.01
ND = Not done, AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.							

16.2.8.2 Listing of laboratory biochemistry parameters

16.2.8.2.1 Listing of laboratory biochemistry parameters 1: Alanine aminotransferase, Aspartate aminotransferase, Alkaline phosphatase, Lactate dehydrogenase, Magnesium

Subject ID	Sex	Visit	Date	Alanine aminotransferase [ukat/L]	Aspartate aminotransferase [ukat/L]	Alkaline phosphatase [ukat/L]	Lactate dehydrogenase [ukat/L]	Magnesium [mmol/L]
1	Female	Screening (-5 to D1)	07APR2021	1.77 AV ^{NCS}	1.19 AV ^{NCS}	2.8 AV ^{NCS}	5.24 AV ^{NCS}	
		Day 2	08APR2021	1.34 AV ^{NCS}	0.58	2.4 AV ^{NCS}	4.33 AV ^{NCS}	
		Day 3	09APR2021	1.04 AV ^{NCS}	0.41	2 AV ^{NCS}	4.11	
		Day 5	11APR2021	0.74 AV ^{NCS}	0.28	1.6	3.77	
		Day 7	13APR2021	0.55	0.24		3.53	
		Day 14	20APR2021	0.74 AV ^{NCS}	0.32	1.6	4.7 AV ^{NCS}	0.86
		EoS (Day 21-28)	04MAY2021	0.72	0.34	1.7	3.97	0.89
2	Male	Screening (-5 to D1)	20APR2021	0.47	0.54		4.45 AV ^{NCS}	0.94
		Baseline (D1)	20APR2021	0.47	0.54		4.45 AV ^{NCS}	0.94
		Day 2	21APR2021	0.73	0.73		4.31 AV ^{NCS}	0.93
		Day 3	22APR2021	1.11 AV ^{NCS}	0.84		4.53 AV ^{NCS}	0.99
		Day 7	26APR2021	0.9 AV ^{NCS}	0.49	1.3	4.09	0.95
		EoT	ND					
		EoS (Day 21-28)	17MAY2021	0.51	0.47	1.6	3.9	
3	Female	Screening (-5 to D1)	01MAY2021	0.55	0.46	1.3	4.09	0.85
		Day 2	02MAY2021	0.47	0.36	1.2	3.88	0.92
		Day 3	03MAY2021	0.38	0.29	1	3.42	0.98
		Day 5	05MAY2021	0.4	0.32	0.9	4.41 AV ^{NCS}	0.9
		Day 7	07MAY2021	0.41	0.31	0.9	3.97	0.82
		EoT	07MAY2021	0.41	0.31	0.9	3.97	0.82
		Day 10	10MAY2021	0.49	0.34	1	3.73	
		EoS (Day 21-28)	28MAY2021	0.49	0.34	0.9	4.34 AV ^{NCS}	

ND = Not done, AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.

16.2.8.2.2 Listing of laboratory biochemistry parameters 2: Total bilirubin, Direct bilirubin, Blood urea nitrogen, Creatinine, Phosphorus

Subject ID	Sex	Visit	Date	Total bilirubin [umol/L]	Direct bilirubin [umol/L]	Blood urea nitrogen [mmol/L]	Creatinine [umol/L]	Phosphorus [mmol/L]
1	Female	Screening (-5 to D1)	07APR2021	6		4.5	53	
		Day 2	08APR2021	6	3.2	6.9	54	
		Day 3	09APR2021	6		6.5	53	
		Day 5	11APR2021	7		5.4	58	
		Day 7	13APR2021	7		4.9	60	
		Day 14	20APR2021	7		7.8	61	
		EoS (Day 21-28)	04MAY2021	4	<3	6.6	58	1.13
2	Male	Screening (-5 to D1)	20APR2021	8	4.4 AV ^{NCS}	6.7	68	0.93
		Baseline (D1)	20APR2021	8	4.4 AV ^{NCS}	6.7	68	0.93
		Day 2	21APR2021	8	4.3 AV ^{NCS}	5.7	66	1.21
		Day 3	22APR2021	10	5.3 AV ^{NCS}	6	71	1.05
		Day 7	26APR2021	10	4.9 AV ^{NCS}	5.1	80	0.94
		EoT	ND					
		EoS (Day 21-28)	17MAY2021	9		5.5	83	0.82
3	Female	Screening (-5 to D1)	01MAY2021	4	3	5.2	62	1.13
		Day 2	02MAY2021	3	3	6.4	54	1.07
		Day 3	03MAY2021	3	3	7.9	62	1.06
		Day 5	05MAY2021	6	3	6.7	56	0.92
		Day 7	07MAY2021	8	3.7 AV ^{NCS}	7.3	73	1.2
		EoT	07MAY2021	8	3.7 AV ^{NCS}	7.3	73	1.2
		Day 10	10MAY2021	8	3.7 AV ^{NCS}	8.2 AV ^{NCS}	80	1.25
		EoS (Day 21-28)	28MAY2021	7		8.2 AV ^{NCS}	77	
ND = Not done, AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.								

16.2.8.2.3 Listing of laboratory biochemistry parameters 3: Chloride, Calcium, Potassium, Sodium, Glucose

Subject ID	Sex	Visit	Date	Chloride [mmol/L]	Calcium [mmol/L]	Potassium [mmol/L]	Sodium [mmol/L]	Glucose [mmol/L]
1	Female	Screening (-5 to D1)	07APR2021	102		4.9	141	12.4 AV ^{NCS}
		Day 2	08APR2021	105		4.3	145	
		Day 3	09APR2021	105		4.2	145	
		Day 5	11APR2021	107		4.1	146 AV ^{NCS}	12.4 AV ^{NCS}
		Day 7	13APR2021	104		4.5	144	8.7 AV ^{NCS}
		Day 14	20APR2021	104	2.45	5.5 AV ^{NCS}	141	9.8 AV ^{NCS}
		EoS (Day 21-28)	04MAY2021	104	2.46	4.5	140	8.2 AV ^{NCS}
2	Male	Screening (-5 to D1)	20APR2021	107	2.25	3.7	143	
		Baseline (D1)	20APR2021	107	2.25	3.7	143	
		Day 2	21APR2021	106	2.2	4	142	
		Day 3	22APR2021	102	2.32	4.4	143	
		Day 7	26APR2021	105	2.37	4.6	144	4.9
		EoT	ND					
		EoS (Day 21-28)	17MAY2021	104		4.6	140	5.8 AV ^{NCS}
3	Female	Screening (-5 to D1)	01MAY2021	100	2.24	4.8	138	23.9 AV ^{NCS}
		Day 2	02MAY2021	105	2.22	4.1	143	16 AV ^{NCS}
		Day 3	03MAY2021	106	2.16	4.6	144	11.8 AV ^{NCS}
		Day 5	05MAY2021	105	2.05 AV ^{NCS}	4.1	141	9.9 AV ^{NCS}
		Day 7	07MAY2021	100	2.18	3.9	139	7.2 AV ^{NCS}
		EoT	07MAY2021	100	2.18	3.9	139	7.2 AV ^{NCS}
		Day 10	10MAY2021	101	2.29	4.5	138	7.1 AV ^{NCS}
		EoS (Day 21-28)	28MAY2021	100		4.6	140	8.5 AV ^{NCS}

ND = Not done, AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.

16.2.8.2.4 Listing of laboratory biochemistry parameters 4: CRP, Ferritin, Interleukin-6

Subject ID	Sex	Visit	Date	CRP [mg/L]	Ferritin [ug/L]	Interleukin-6 [ng/L]
1	Female	Screening (-5 to D1)	07APR2021	85.1 AV ^{NCS}	672 AV ^{NCS}	13.9 AV ^{NCS}
		Day 2	08APR2021	52.1 AV ^{NCS}	782 AV ^{NCS}	
		Day 3	09APR2021	25.8 AV ^{NCS}	797 AV ^{NCS}	
		Day 5	11APR2021	10.2 AV ^{NCS}	816 AV ^{NCS}	
		Day 7	13APR2021	4.2	885 AV ^{NCS}	
		Day 14	20APR2021	1.6	751 AV ^{NCS}	
		EoS (Day 21-28)	04MAY2021	12.6 AV ^{NCS}	255	4.41
2	Male	Screening (-5 to D1)	20APR2021	9.7 AV ^{NCS}	686 AV ^{NCS}	
		Baseline (D1)	20APR2021	9.7 AV ^{NCS}	686 AV ^{NCS}	
		Day 2	21APR2021	4.9	608 AV ^{NCS}	
		Day 3	22APR2021	2.9	648 AV ^{NCS}	
		Day 7	26APR2021	0.6	595 AV ^{NCS}	4.15
		EoT	ND			
		EoS (Day 21-28)	17MAY2021	0.6	309	4.47
3	Female	Screening (-5 to D1)	01MAY2021	111 AV ^{NCS}	454 AV ^{NCS}	3.50
		Day 2	02MAY2021	71.1 AV ^{NCS}	511 AV ^{NCS}	3.50
		Day 3	03MAY2021	31.1 AV ^{NCS}	582 AV ^{NCS}	3.50
		Day 5	05MAY2021	11.7 AV ^{NCS}	816 AV ^{NCS}	3.50
		Day 7	07MAY2021	5.2 AV ^{NCS}	697 AV ^{NCS}	6.90
		EoT	07MAY2021	5.2 AV ^{NCS}	697 AV ^{NCS}	6.9
		Day 10	10MAY2021	2.6	624 AV ^{NCS}	6.66
		EoS (Day 21-28)	28MAY2021	0.8	237	<3.50

ND = Not done, AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.

16.2.8.3 Listing of laboratory immunology parameters

16.2.8.3.1 Listing of laboratory immunology parameters: CD3+, CD4+, CD8+

Subject ID	Sex	Visit	Date	CD3+ abs [10 ⁹ /L]	CD3+ [%]	CD4+ abs [10 ⁹ /L]	CD4+ [%]	CD8+ abs [10 ⁹ /L]	CD8+ [%]
1	Female	Baseline (D1)	07APR2021	301 AV ^{NCS}	51 AV ^{NCS}	218 AV ^{NCS}	37	83 AV ^{NCS}	14
		Day 2	08APR2021	319 AV ^{NCS}	54 AV ^{NCS}	242 AV ^{NCS}	41	83 AV ^{NCS}	14
		Day 3	09APR2021	741 AV ^{NCS}	57	533	41	208	16
		Day 5	ND						
		Day 7	04MAY2021	1106	67	809	49	281	17
		Day 14	20APR2021	633 AV ^{NCS}	57	455	41	167 AV ^{NCS}	15
		EoS (Day 21-28)	04MAY2021	603 AV ^{NCS}	58	458	44	135 AV ^{NCS}	13
2	Male	Baseline (D1)	20APR2021	355 AV ^{NCS}	50 AV ^{NCS}	170 AV ^{NCS}	24	30 AV ^{NCS}	25
		Day 2	21APR2021	661 AV ^{NCS}	57	290 AV ^{NCS}	25	360	31
		Day 3	22APR2021	826	59	448	32	364	26
		Day 7	26APR2021	1643	66	896	36	747	30
		EoT	ND						
		EoS (Day 21-28)	17MAY2021	972	67	435	30	508	35
3	Female	Baseline (D1)	ND						
		Day 2	ND						
		Day 3	03MAY2021	837	54 AV ^{NCS}	481	31	341	22
		Day 5	05MAY2021	1090	63	692	40	398	23
		Day 7	07MAY2021	2599	71	2013 AV ^{NCS}	55	549	15
		EoT	07MAY2021	2599	71	2013 AV ^{NCS}	55	549	15
		Day 10	10MAY2021	3008 AV ^{NCS}	73	2101 AV ^{NCS}	51	865	21
		EoS (Day 21-28)	28MAY2021	1544	68	885	39	636	28

ND = Not done, AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.

16.2.8.4 Listing of laboratory urinalysis parameters

16.2.8.4.1 Listing of laboratory urinalysis parameters 1: Color, pH, Specific gravity, Red blood cell count, White blood cell count, Epithelial cells

Subject ID	Sex	Visit	Date	Color	pH	Specific gravity [kg/m ³]	Red blood cell count [10 ⁶ /L]	White blood cell count [10 ⁶ /L]	Epithelial cells [10 ⁶ /L]
1	Female	Screening (-5 to D1)	07APR2021	yellow	6.0	1009 AV ^{NCS}	8	103 AV ^{NCS}	3
2	Male	Screening (-5 to D1)	20APR2021	yellow	5.5	1034 AV ^{NCS}	0	1	1
3	Female	Screening (-5 to D1)	01MAY2021	yellow	5	1039 AV ^{NCS}	0	1	7

AV = Abnormal value, CS = Clinically significant, NCS = Not clinically significant.

16.2.8.4.2 Listing of laboratory urinalysis parameters 2: Glucose, Protein, Ketones

Subject ID	Sex	Visit	Date	Glucose	Protein	Ketones
1	Female	Screening (-5 to D1)	07APR2021	Negative	Negative	Negative
2	Male	Screening (-5 to D1)	20APR2021	Negative	Negative	Negative
3	Female	Screening (-5 to D1)	01MAY2021	Positive NCS	Negative	Negative

CS = Clinically significant, NCS = Not clinically significant.

16.2.8.4.3 Listing of laboratory urinalysis parameters 3: Blood, Casts, Bacteria, Crystals

Subject ID	Sex	Visit	Date	Blood	Casts	Bacteria	Crystals
1	Female	Screening (-5 to D1)	07APR2021	Positive NCS	Negative	Positive NCS	Negative
2	Male	Screening (-5 to D1)	20APR2021	Negative	Negative	Negative	Negative
3	Female	Screening (-5 to D1)	01MAY2021	Negative	Negative	Negative	Negative

CS = Clinically significant, NCS = Not clinically significant.

16.2.8.5 Listing of abnormal laboratory results

Subject ID	Sex	Visit	Date	Category	Parameter	Unit	Value	
1	Female	Screening (-5 to D1)	07APR2021	Hematology	White blood cell count	10 ⁹ /L	3.8	NCS
					Neutrophils	%	81.4	NCS
					Monocytes	%	1.8	NCS
					Lymphocytes	%	0.61	NCS
					D/dimers	ug/L	3160	CS
					Activated partial thromboplastin time	s	45.9	NCS
				Biochemistry	International normalized ratio		1.42	NCS
					Alanine aminotransferase	ukat/L	1.77	NCS
					Aspartate aminotransferase	ukat/L	1.19	NCS
					Alkaline phosphatase	ukat/L	2.8	NCS
					Lactate dehydrogenase	ukat/L	5.24	NCS
					Glucose	mmol/L	12.4	NCS
				Urinalysis	CRP	mg/L	85.1	NCS
					Ferritin	ug/L	672	NCS
					Interleukin-6	ng/L	13.9	NCS
					Specific gravity	kg/m ³	1009	NCS
					White blood cell count	10 ⁶ /L	103	NCS
					Blood		Positive	NCS
					Bacteria		Positive	NCS
		Baseline (D1)	07APR2021	Immunology	CD3+ abs	10 ⁹ /L	301	NCS
					CD3+	%	51	NCS
					CD4+ abs	10 ⁹ /L	218	NCS
					CD8+ abs	10 ⁹ /L	83	NCS
		Day 2	08APR2021	Hematology	White blood cell count	10 ⁹ /L	11.9	NCS
					Platelet count	10 ⁹ /L	466	NCS
					Neutrophils	%	82.4	NCS
					Lymphocytes	%	10.9	NCS
				Biochemistry	D/dimers	ug/L	1620	NCS
					Alanine aminotransferase	ukat/L	1.34	NCS
					Alkaline phosphatase	ukat/L	2.4	NCS
					Lactate dehydrogenase	ukat/L	4.33	NCS
				Immunology	CRP	mg/L	52.1	NCS
					Ferritin	ug/L	782	NCS
					CD3+ abs	10 ⁹ /L	319	NCS
					CD3+	%	54	NCS
		Day 3	09APR2021	Hematology	CD4+ abs	10 ⁹ /L	242	NCS
					CD8+ abs	10 ⁹ /L	83	NCS
					White blood cell count	10 ⁹ /L	12.6	NCS
					Platelet count	10 ⁹ /L	482	NCS
				Biochemistry	Neutrophils	%	83.1	NCS
					Lymphocytes	%	9.2	NCS
					D/dimers	ug/L	1250	NCS
					Alanine aminotransferase	ukat/L	1.04	NCS
				Immunology	Alkaline phosphatase	ukat/L	2	NCS
					CRP	mg/L	25.8	NCS
					Ferritin	ug/L	797	NCS
		Day 5	11APR2021	Hematology	CD3+ abs	10 ⁹ /L	741	NCS
					White blood cell count	10 ⁹ /L	12.5	NCS
				Hematology	Platelet count	10 ⁹ /L	512	NCS
					Neutrophils	%	80.6	NCS
					Lymphocytes	%	11.3	NCS
					D/dimers	ug/L	1360	NCS

Subject ID	Sex	Visit	Date	Category	Parameter	Unit	Value		
1	Male	Day 7	13APR2021	Biochemistry	Alanine aminotransferase	ukat/L	0.74	NCS	
					Sodium	mmol/L	146	NCS	
					Glucose	mmol/L	12.4	NCS	
					CRP	mg/L	10.2	NCS	
					Ferritin	ug/L	816	NCS	
				Hematology	White blood cell count	10 ⁹ /L	13.8	NCS	
					Platelet count	10 ⁹ /L	492	NCS	
					Neutrophils	%	80.7	NCS	
					Lymphocytes	%	11.9	NCS	
					D/dimers	ug/L	1610	NCS	
				Biochemistry	Glucose	mmol/L	8.7	NCS	
					Ferritin	ug/L	885	NCS	
					Hematology	White blood cell count	10 ⁹ /L	20.1	NCS
						Neutrophils	%	90.5	NCS
						Lymphocytes	%	5.5	NCS
				D/dimers		ug/L	1380	NCS	
		EoS (Day 21-28)	04MAY2021	Biochemistry	Alanine aminotransferase	ukat/L	0.74	NCS	
					Lactate dehydrogenase	ukat/L	4.7	NCS	
					Potassium	mmol/L	5.5	NCS	
					Glucose	mmol/L	9.8	NCS	
					Ferritin	ug/L	751	NCS	
				Immunology	CD3+ abs	10 ⁹ /L	633	NCS	
					CD8+ abs	10 ⁹ /L	167	NCS	
				Hematology	Platelet count	10 ⁹ /L	406	NCS	
					Neutrophils	%	82.6	NCS	
					Lymphocytes	%	10.7	NCS	
					D/dimers	ug/L	1470	NCS	
				Biochemistry	Glucose	mmol/L	8.2	NCS	
					CRP	mg/L	12.6	NCS	
					Immunology	CD3+ abs	10 ⁹ /L	603	NCS
						CD8+ abs	10 ⁹ /L	135	NCS
2	Male	Screening (-5 to D1)	20APR2021	Hematology	Neutrophils	%	84.2	NCS	
					Lymphocytes	%	9.7	NCS	
				Biochemistry	Lactate dehydrogenase	ukat/L	4.45	NCS	
					Direct bilirubin	umol/L	4.4	NCS	
					CRP	mg/L	9.7	NCS	
					Ferritin	ug/L	686	NCS	
				Urinalysis	Specific gravity	kg/m ³	1034	NCS	
				Hematology	Neutrophils	%	84.2	NCS	
					Lymphocytes	%	9.7	NCS	
				Biochemistry	Lactate dehydrogenase	ukat/L	4.45	NCS	
		Direct bilirubin	umol/L		4.4	NCS			
		CRP	mg/L		9.7	NCS			
		Ferritin	ug/L		686	NCS			
		Immunology	CD3+ abs	10 ⁹ /L	355	NCS			
			CD3+	%	50	NCS			
			CD4+ abs	10 ⁹ /L	170	NCS			
			CD8+ abs	10 ⁹ /L	30	NCS			
		Day 2	21APR2021	Hematology	Neutrophils	%	72.9	NCS	
					Lymphocytes	%	15.3	NCS	
				Biochemistry	Lactate dehydrogenase	ukat/L	4.31	NCS	
					Direct bilirubin	umol/L	4.3	NCS	
					Ferritin	ug/L	608	NCS	

Subject ID	Sex	Visit	Date	Category	Parameter	Unit	Value	
3	Female	Screening (-5 to D1)	01MAY2021	Immunology	CD3+ abs	10 ⁹ /L	661	NCS
					CD4+ abs	10 ⁹ /L	290	NCS
				Hematology	Neutrophils	%	70.9	NCS
					Lymphocytes	%	16.6	NCS
				Biochemistry	Alanine aminotransferase	ukat/L	1.11	NCS
					Lactate dehydrogenase	ukat/L	4.53	NCS
					Direct bilirubin	umol/L	5.3	NCS
					Ferritin	ug/L	648	NCS
				Hematology	Mean corpuscular hemoglobin concentration	g/L	361	NCS
					Alanine aminotransferase	ukat/L	0.9	NCS
				Biochemistry	Direct bilirubin	umol/L	4.9	NCS
					Ferritin	ug/L	595	NCS
		EoS (Day 21-28)	17MAY2021	Hematology	Monocytes	%	14.1	NCS
				Biochemistry	Glucose	mmol/L	5.8	NCS
		Day 2	02MAY2021	Hematology	Red blood cell count	10 ¹² /L	5.37	NCS
					Neutrophils	%	84.7	NCS
					Monocytes	%	1.3	NCS
					Lymphocytes	%	13.5	NCS
					Mean corpuscular hemoglobin	pg	27.9	NCS
				Biochemistry	Glucose	mmol/L	23.9	NCS
					CRP	mg/L	111	NCS
					Ferritin	ug/L	454	NCS
				Urinalysis	Specific gravity	kg/m ³	1039	NCS
					Glucose		Positive	NCS
				Hematology	White blood cell count	10 ⁹ /L	13.3	NCS
					Neutrophils	%	83	NCS
					Lymphocytes	%	13	NCS
		Day 3	03MAY2021	Biochemistry	Glucose	mmol/L	16	NCS
					CRP	mg/L	71.1	NCS
					Ferritin	ug/L	511	NCS
				Hematology	White blood cell count	10 ⁹ /L	15.8	NCS
					Neutrophils	%	85.8	NCS
					Lymphocytes	%	9.8	NCS
		Day 5	05MAY2021	Biochemistry	Glucose	mmol/L	11.8	NCS
					CRP	mg/L	31.1	NCS
					Ferritin	ug/L	582	NCS
				Immunology	CD3+	%	54	NCS
					White blood cell count	10 ⁹ /L	12.1	NCS
				Hematology	Neutrophils	%	77	NCS
					Lymphocytes	%	13.8	NCS
				Biochemistry	Lactate dehydrogenase	ukat/L	4.41	NCS
					Calcium	mmol/L	2.05	NCS
					Glucose	mmol/L	9.9	NCS
					CRP	mg/L	11.7	NCS
		Day 7	07MAY2021	Hematology	Ferritin	ug/L	816	NCS
					Red blood cell count	10 ¹² /L	5.52	NCS
					White blood cell count	10 ⁹ /L	12.1	NCS
					Direct bilirubin	umol/L	3.7	NCS
				Biochemistry	Glucose	mmol/L	7.2	NCS
					CRP	mg/L	5.2	NCS
					Ferritin	ug/L	697	NCS
				Immunology	CD4+ abs	10 ⁹ /L	2013	NCS

Subject ID	Sex	Visit	Date	Category	Parameter	Unit	Value	
		EoT	07MAY2021	Hematology	Red blood cell count	10 ¹² /L	5.52	NCS
					White blood cell count	10 ⁹ /L	12.1	NCS
				Biochemistry	Direct bilirubin	umol/L	3.7	NCS
					Glucose	mmol/L	7.2	NCS
					CRP	mg/L	5.2	NCS
					Ferritin	ug/L	697	NCS
			10MAY2021	Immunology	CD4+ abs	10 ⁹ /L	2013	NCS
		Day 10		Hematology	Hemoglobin	g/L	163	NCS
					Hematocrit	L/L	0.482	NCS
					Red blood cell count	10 ¹² /L	5.7	NCS
					White blood cell count	10 ⁹ /L	14.3	NCS
				Biochemistry	Direct bilirubin	umol/L	3.7	NCS
					Blood urea nitrogen	mmol/L	8.2	NCS
					Glucose	mmol/L	7.1	NCS
					Ferritin	ug/L	624	NCS
				Immunology	CD3+ abs	10 ⁹ /L	3008	NCS
					CD4+ abs	10 ⁹ /L	2101	NCS
		EoS (Day 21-28)		Hematology	Red blood cell count	10 ¹² /L	5.39	NCS
					White blood cell count	10 ⁹ /L	14	NCS
					Neutrophils	%	77.9	NCS
					Lymphocytes	%	16.3	NCS
					Red cell distribution width	%	15.9	NCS
					Prothrombin time	s	25.7	NCS
					International normalized ratio		2.01	NCS
				Biochemistry	Lactate dehydrogenase	ukat/L	4.34	NCS
					Blood urea nitrogen	mmol/L	8.2	NCS
					Glucose	mmol/L	8.5	NCS

CS = Clinically significant, NCS = Not clinically significant.

16.2.8.6 Listing of selected laboratory parameters and their time to the first normalization

First normalization										
Subject ID	Sex	Category	Parameter	Unit	Value at baseline		Y/N	Visit	Value	Time to first normalization (days)
1	Female	Hematology	White blood cell count	10 ⁹ /L	3.8	AV ^{NCS}	Yes	EoS (Day 21-28)	9.7	28
			Neutrophils	%	81.4	AV ^{NCS}	No			
			Lymphocytes	%	0.61	AV ^{NCS}	No			
			D/dimers	ug/L	3160	AV ^{CS}	No			
		Biochemistry	CRP	mg/L	85.1	AV ^{NCS}	Yes	Day 7	4.2	7
			Ferritin	ug/L	672	AV ^{NCS}	Yes	EoS (Day 21-28)	255	28
			Interleukin-6	ng/L	13.9	AV ^{NCS}	Yes	EoS (Day 21-28)	4.41	28
2	Male	Hematology	White blood cell count	10 ⁹ /L	7.4	NV	N/A			
			Neutrophils	%	84.2	AV ^{NCS}	Yes	Day 7	54	7
			Lymphocytes	%	9.7	AV ^{NCS}	Yes	Day 7	31.3	7
			D/dimers	ug/L	350	NV	N/A			
		Biochemistry	CRP	mg/L	9.7	AV ^{NCS}	Yes	Day 2	4.9	2
			Ferritin	ug/L	686	AV ^{NCS}	Yes	EoS (Day 21-28)	309	28
3	Female	Hematology	White blood cell count	10 ⁹ /L	9.1	NV	N/A			
			Neutrophils	%	84.7	AV ^{NCS}	Yes	Day 7	56.1	7
			Lymphocytes	%	13.5	AV ^{NCS}	Yes	Day 7	30.3	7
			D/dimers	ug/L	370	NV	N/A			
		Biochemistry	CRP	mg/L	111	AV ^{NCS}	Yes	Day 10	2.6	10
			Ferritin	ug/L	454	AV ^{NCS}	Yes	EoS (Day 21-28)	237	28
			Interleukin-6	ng/L	3.5	NV	N/A			

N/A = Not applicable, AV = Abnormal value, NV = Normal value, CS = Clinically significant, NCS = Not clinically significant.
Time to first normalization calculated as Date of first normalization - Date of baseline + 1.

16.2.8.7 Listing of NP smear (PCR) results

Subject ID	Sex	Visit	Date of PCR test	Result of PCR test
1	Female	Screening (-5 to D1)	28MAR2021	Positive
		Day 8	14APR2021	Negative
		EoS (Day 21-28)	04MAY2021	Negative
2	Male	Screening (-5 to D1)	13APR2021	Positive
		EoS (Day 21-28)	17MAY2021	Negative
3	Female	Screening (-5 to D1)	24APR2021	Positive
		EoS (Day 21-28)	28MAY2021	Negative

PCR = Polymerase Chain Reaction.