

Dataset Legends

Dataset 1: Individual body weight measurements of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Dataset 2: Individual pre- and post-injection hematology parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Dataset 3: Individual pre- and post-injection coagulation parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Dataset 4: Individual pre- and post-injection clinical chemistry parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Dataset 5: Pre- and post-injection cytokine levels in individual cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Dataset 6: Individual dermal observations of cynomolgus monkeys treated with three doses AIRISE-02. Dermal observations were evaluated according to the method of Draize.

Dataset 1: Individual body weight measurements of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Animal number	Time (days)	Weight (kg)
1	-7	3.2
	1	3.1
	8	3.1
	15	3.0
	22	3.0
2	-8	2.9
	1	2.9
	8	3.1
	15	3.1
	22	3.1
3	-8	3.2
	1	3.2
	8	3.3
	15	3.4
	22	3.3

Dataset 2: Individual pre- and post-injection hematology parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Animal number	Time (days)	WBC (10 ³ /uL)	NEUT (10 ³ /uL)	LYMPH (10 ³ /uL)	MONO (10 ³ /uL)	EOS (10 ³ /uL)	BASO (10 ³ /uL)	LUC (10 ³ /uL)	RBC (10 ⁶ /uL)	HGB (g/dL)	HCT (%)	MCV (fL)	MCH (pg)
1	-4	7.51	1.77	5.02	0.32	0.32	0.03	0.05	5.59	13.8	46.5	83.3	24.8
	2	17.32	14.29	1.80	1.09	0.02	0.02	0.10	4.77	11.8	37.9	79.4	24.8
	7	12.37	9.51	2.50	0.22	0.09	0.02	0.03	4.81	11.7	38.2	79.5	24.3
	9	13.36	11.66	1.03	0.58	0.00	0.01	0.06	4.21	10.3	33.2	79.0	24.6
	14	7.43	3.93	3.19	0.20	0.06	0.01	0.03	4.73	11.6	38.2	80.7	24.4
	17	15.00	12.53	1.59	0.81	0.01	0.02	0.04	3.89	9.4	30.8	79.2	24.1
	22	12.02	5.03	6.34	0.41	0.15	0.03	0.05	4.25	10.2	35.1	82.6	24.0
2	-5	16.31	5.40	9.11	1.02	0.56	0.06	0.16	5.26	12.6	41.8	79.5	23.9
	2	14.33	10.31	3.11	0.67	0.09	0.03	0.12	4.85	11.5	37.8	78.0	23.6
	7	12.18	4.34	6.38	0.64	0.65	0.08	0.09	4.89	11.7	39.5	80.8	23.9
	9	19.23	14.38	3.44	0.94	0.32	0.05	0.12	4.46	10.7	36.3	81.5	23.9
	14	10.69	2.93	6.61	0.65	0.38	0.05	0.07	4.86	11.3	39.0	80.3	23.2
	17	19.57	16.30	2.24	0.78	0.10	0.03	0.12	4.58	10.8	37.0	80.9	23.5
	22	10.70	1.65	7.73	0.79	0.40	0.05	0.09	4.72	11.4	39.2	83.1	24.1
3	-5	12.54	3.35	8.33	0.71	0.05	0.04	0.05	5.61	13.7	45.5	81.0	24.4
	2	11.46	6.59	3.93	0.87	0.01	0.02	0.05	4.89	11.8	39.1	79.9	24.1
	7	13.65	5.33	7.59	0.59	0.03	0.04	0.07	4.80	11.6	38.9	81.1	24.1
	9	13.06	8.40	3.37	1.19	0.01	0.02	0.07	4.23	10.1	35.1	82.9	24.0
	14	10.82	2.61	7.31	0.77	0.02	0.05	0.05	4.51	10.9	36.6	81.2	24.2
	17	14.40	7.96	5.64	0.68	0.01	0.04	0.08	4.13	9.9	35.3	85.3	23.9
	22	13.49	3.44	8.91	0.99	0.01	0.05	0.09	4.47	10.5	37.7	84.5	23.5

Dataset 2: Individual pre- and post-injection hematology parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Animal number	Time (days)	MCHC (g/dL)	RDW (%)	PLT (10 ³ /uL)	RETIC (10 ⁹ /L)
1	-4	29.7	13.1	391	154.4
	2	31.2	13.4	302	109.0
	7	30.5	13.4	364	158.0
	9	31.1	13.4	317	163.8
	14	30.3	14.2	402	276.1
	17	30.5	14.3	349	176.9
	22	29.1	14.5	488	383.8
2	-5	30.1	13.9	453	101.9
	2	30.3	14.8	578	188.1
	7	29.6	14.6	896	339.6
	9	29.3	14.6	779	253.3
	14	28.9	14.5	602	323.6
	17	29.1	14.6	531	240.2
	22	28.9	14.2	656	262.9
3	-5	30.1	12.5	369	106.7
	2	30.2	12.8	339	106.6
	7	29.8	13.3	447	262.6
	9	28.9	13.4	383	273.3
	14	29.8	14.1	450	400.9
	17	28.1	14.1	428	445.7
	22	27.8	13.8	503	369.9

Dataset 2: Individual pre- and post-injection hematology parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

TABLE EXPLANATION

Abbreviation	Description
WBC	White blood cells
NEUT	Neutrophils
LYMPH	Lymphocytes
MONO	Monocytes
EOS	Eosinophils
LUC	Large unstained cells
RBC	Red blood cells
HGB	Hemoglobin
HCT	Hematocrit
MCV	Mean corpuscular volume
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
RDW	Red blood cell distribution width
PLT	Platelets
RETIC	Reticulocytes

Dataset 3: Individual pre- and post-injection coagulation parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Animal number	Time (days)	PT (sec)	APTT (sec)	FIB (mg/dL)	SAMQ Coagulation
1	-4	11.2	17.0	266	N
	2	11.0	17.6	374	N
	7	10.6	18.3	325	N
	9	10.9	17.5	327	N
	14	10.6	17.3	345	N
	17	10.9	18.7	374	I+
	22	10.6	17.9	332	N
2	-5	11.9	17.4	196	N
	2	11.6	18.9	289	N
	7	10.8	20.0	223	N
	9	11.1	19.5	319	N
	14	10.8	20.3	258	N
	17	11.2	19.3	276	N
	22	11.1	19.9	229	N
3	-5	11.7	16.9	214	N
	2	12.6	17.0	286	N
	7	11.5	17.8	272	N
	9	11.2	17.1	377	N
	14	11.2	18.4	317	N
	17	11.9	17.6	317	N
	22	11.5	18.3	338	N

TABLE EXPLANATION

Abbreviation	Description
PT	Prothrombin time
APTT	Activated partial thromboplastin time
FIB	Fibrinogen
SAMQ	Sample quality
N	Normal sample
I	Icterus sample
I+	Icterus sample slight (dark yellow)
I++	Icterus sample moderate (very dark yellow)
I+++	Icterus sample severe (dark yellow-green)

Dataset 4: Individual pre- and post-injection clinical chemistry parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Animal number	Time (days)	AST (U/L)	ALT (U/L)	ALP (U/L)	GGT (U/L)	CK (U/L)	TBIL (mg/dL)	DBIL (mg/dL)	IBIL (mg/dL)	UREA N (mg/dL)	CREAT (mg/dL)	GLUC (mg/dL)	CHOL (mg/dL)
1	-4	29	38	299	59	200	0.25	-	-	23	0.7	83	164
	2	187	112	230	46	1276	0.54	0.19	0.35	26	0.8	74	116
	7	43	58	215	43	228	0.25	-	-	39	0.7	57	131
	9	47	64	204	39	420	0.3	-	-	28	0.7	72	116
	14	46	48	234	38	444	0.24	-	-	27	0.6	48	160
	17	51	45	203	37	989	0.3	-	-	28	0.6	87	116
	22	37	40	225	44	336	0.17	-	-	26	0.7	72	140
2	-5	69	61	303	39	2710	0.16	-	-	26	0.5	114	135
	2	106	72	285	39	595	0.42	-	-	26	0.5	45	124
	7	52	52	235	37	414	0.17	-	-	24	0.5	91	124
	9	70	57	271	39	432	0.22	-	-	20	0.3	62	120
	14	50	56	244	37	200	0.17	-	-	26	0.4	67	127
	17	49	56	250	37	200	0.2	-	-	25	0.5	72	120
	22	41	40	217	40	949	0.13	-	-	24	0.4	79	122
3	-5	23	38	257	41	186	0.1	-	-	23	0.4	81	126
	2	61	37	289	34	391	0.37	-	-	16	0.7	99	111
	7	34	35	238	35	392	0.17	-	-	20	0.7	141	116
	9	45	40	278	40	179	0.18	-	-	20	0.5	88	105
	14	35	45	266	37	165	0.14	-	-	19	0.6	105	116
	17	39	39	263	33	136	0.15	-	-	22	0.6	105	110
	22	25	29	239	36	750	0.09	-	-	19	0.5	104	112

Dataset 4: Individual pre- and post-injection clinical chemistry parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Animal number	Time (days)	TRIG (mg/dL)	TPROT (g/dL)	ALB (g/dL)	GLOB (g/dL)	A/G (ratio)	CA (mg/dL)	PHOS (mg/dL)	PHOS/C REAT	CA/PHOS	NA (mEq/L)	K (mEq/L)	CL (mEq/L)
1	-4	36	7.8	4.9	2.9	1.7	10.8	6.4	9.1	1.7	151	5.1	108
	2	34	7.0	4.6	2.4	1.9	9.6	4.5	5.8	2.1	148	3.4	107
	7	60	7.1	4.5	2.6	1.7	9.2	5.5	8.0	1.7	146	4.0	109
	9	36	6.7	4.2	2.5	1.7	9.9	4.1	6.1	2.4	145	4.3	107
	14	42	7.3	4.3	3.0	1.4	9.4	6.3	9.8	1.5	144	4.3	108
	17	34	6.7	4.0	2.7	1.5	9.5	5.2	8.4	1.8	145	4.8	108
	22	43	6.3	3.9	2.4	1.6	9.4	5.9	9.1	1.6	144	4.9	107
2	-5	121	6.7	3.8	2.9	1.3	10.3	3.7	8.0	2.8	147	4.7	109
	2	39	7.1	4.0	3.1	1.3	9.4	6.3	14.0	1.5	148	3.9	112
	7	59	6.9	3.8	3.1	1.2	9.2	5.0	11.1	1.8	146	4.5	113
	9	52	7.0	3.8	3.2	1.2	9.5	6.2	18.2	1.5	150	4.7	113
	14	75	6.9	3.7	3.2	1.2	9.1	6.0	13.6	1.5	148	4.3	109
	17	50	7.0	3.8	3.2	1.2	8.7	6.4	13.6	1.4	148	3.9	109
	22	61	6.4	3.4	3.0	1.1	9.3	5.6	13.7	1.7	146	4.8	107
3	-5	76	7.0	4.4	2.6	1.7	10.4	4.9	11.7	2.1	146	5.9	113
	2	64	7.1	4.6	2.5	1.8	9.5	4.8	7.3	2.0	148	5.3	113
	7	50	6.9	4.4	2.5	1.8	9.3	5.0	7.4	1.9	144	4.2	108
	9	49	7.0	4.3	2.7	1.6	9.8	4.2	8.2	2.3	152	4.8	111
	14	56	7.1	4.3	2.8	1.5	9.0	5.9	10.4	1.5	146	4.5	108
	17	65	7.2	4.4	2.8	1.6	9.4	6.0	10.9	1.6	150	5.0	110
	22	62	6.9	4.1	2.8	1.5	9.4	5.8	12.9	1.6	144	5.0	109

Dataset 4: Individual pre- and post-injection clinical chemistry parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Animal number	Time (days)	Na/K (Serum) (mEq/L)	SAMQ	UREAN/CREAT (mmol/L)	A/H	ALT/AST (ratio)	CA/CREAT
1	-4	29.9	N	32.9	0.4	1.3	15.4
	2	43.0	N	33.5	0.4	0.6	12.5
	7	36.9	N	55.9	0.4	1.3	13.3
	9	34.1	N	41.0	0.4	1.4	14.8
	14	33.5	N	42.2	0.4	1.0	14.7
	17	30.0	H+	44.8	0.4	0.9	15.3
	22	29.1	N	40.0	0.4	1.1	14.5
2	-5	31.5	H+	56.5	0.3	0.9	22.4
	2	37.8	N	57.6	0.3	0.7	20.9
	7	32.4	N	54.0	0.3	1.0	20.4
	9	32.0	N	58.5	0.4	0.8	27.9
	14	34.6	N	58.4	0.3	1.1	20.7
	17	38.3	N	52.3	0.4	1.1	18.5
	22	30.5	N	58.3	0.3	1.0	22.7
3	-5	24.7	N	55.7	0.3	1.7	24.8
	2	27.7	H+++	24.2	0.4	0.6	14.4
	7	34.0	N	29.3	0.4	1.0	13.7
	9	31.9	N	39.0	0.4	0.9	19.2
	14	32.2	N	32.6	0.4	1.3	15.8
	17	30.2	H+	39.3	0.4	1.0	17.1
	22	28.7	N	42.7	0.4	1.2	20.9

Dataset 4: Individual pre- and post-injection clinical chemistry parameters of cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

TABLE EXPLANATION

Abbreviation	Description
AST	Aspartate aminotransferase
ALT	Alanine aminotransferase
ALP	Alkaline phosphatase
GGT	Gamma glutamyltransferase
CK	creatine kinase
TBIL	Total bilirubin
DBIL	Direct bilirubin
IBIL	Indirect bilirubin
UREA N	Urea nitrogen
CREAT	Creatinine
GLUC	Glucose
CHOL	Cholesterol
TRIG	Triglycerides
TPROT	Total protein
ALB	Albumin
GLOB	Globulin
A/G	Albumin/Globulin ratio
CA	Calcium
PHOS	Phosphorus
PHOS/CREAT	Phosphorus/Creatinine ratio
NA	Sodium
K	Potassium
CL	Chloride
NA/K	Sodium/Potassium ratio
SAMQ	Sample quality
UREAN/CREAT	Urea nitrogen/Creatinine ratio
ALT/AST	Alanine aminotransferase/Aspartate aminotransferase ratio
CA/CREAT	Calcium/Creatinine ratio
N	Normal sample
H+	Hemolyzed sample slight (pale/light red)
H++	Hemolyzed sample moderate (red)
H+++	Hemolysed sample severe (dark red)
-	No findings/Not evaluated

Dataset 5: Pre- and post-injection cytokine levels in individual cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

Animal number	Time (days)	TNF-alpha (pg/mL)	IFN-gamma (pg/mL)	IL-1 beta (pg/mL)	IL-6 (pg/mL)	MCP-1 (pg/mL)
1	1	<2.44	<2.44	<2.44	<2.44	278.65
	1.25	<2.44	<2.44	<2.44	<2.44	490.60
	2	<2.44	<2.44	<2.44	11.6	538.88
	8	<2.44	<2.44	<2.44	<2.44	607.83
	8.25	<2.44	<2.44	<2.44	<2.44	547.58
	9	<2.44	9.09	<2.44	22.01	1335.05
	10	<2.44	<2.44	<2.44	<2.44	509.91
	15	<2.44	<2.44	<2.44	<2.44	597.00
	15.25	<2.44	<2.44	<2.44	14.36	765.90
	16	<2.44	<2.44	<2.44	28.54	846.12
2	17	<2.44	<2.44	<2.44	103.56	825.26
	1	<2.44	<2.44	<2.44	<2.44	334.12
	1.25	<2.44	<2.44	<2.44	<2.44	824.21
	2	<2.44	<2.44	<2.44	<2.44	441.49
	8	<2.44	9.09	<2.44	<2.44	825.47
	8.25	<2.44	14.41	<2.44	<2.44	1384.21
	9	<2.44	<2.44	<2.44	12.61	1046.59
	10	<2.44	<2.44	<2.44	<2.44	886.03
	15	<2.44	<2.44	<2.44	<2.44	586.52
	15.25	<2.44	<2.44	<2.44	<2.44	1071.69
3	16	<2.44	<2.44	<2.44	20.52	2132.25
	17	<2.44	<2.44	<2.44	<2.44	568.66
	1	<2.44	<2.44	<2.44	<2.44	339.27
	1.25	<2.44	<2.44	<2.44	12.23	1068.12
	2	<2.44	<2.44	<2.44	<2.44	1052.64
	8	<2.44	<2.44	<2.44	<2.44	699.23
	8.25	<2.44	<2.44	<2.44	<2.44	1020.63
	9	<2.44	<2.44	<2.44	39.43	2285.00
	10	<2.44	<2.44	<2.44	10.32	653.85
	15	<2.44	<2.44	<2.44	<2.44	708.65
15.25	<2.44	<2.44	<2.44	<2.44	917.54	
16	<2.44	<2.44	<2.44	41.38	1669.22	
17	<2.44	<2.44	<2.44	33.86	725.91	

Dataset 5: Pre- and post-injection cytokine levels in individual cynomolgus monkeys treated with 3 doses of AIRISE-02 on days 1, 8 and 15.

TABLE EXPLANATION

Abbreviation	Description
TNF-alpha	Tumor necrosis factor alpha
IFN-gamma	Interferon gamma
IL-1 beta	Interleukin 1 beta
IL-6	Interleukin 6
MCP-1	Monocyte chemoattractant protein 1

Dataset 6: Individual dermal observations of cynomolgus monkeys treated with three doses AIRISE-02. Dermal observations were evaluated according to the method of Draize.

Dose	Animal number	Edema grade (Draize score 0-4)					Erythema grade (Draize score 0-4)				
		Day(s) Relative to Dose Start					Day(s) Relative to Dose Start				
		1	2	3	4	8	1	2	3	4	8
0.9 mg/kg AIRISE-02	1	-	-	-	-	-	-	-	-	-	-
	2	-	-	-	-	-	-	-	-	-	-
	3	-	-	-	-	-	-	-	-	-	-
2.7 mg/kg AIRISE-02	1	-	-	-	3	-	-	-	0	-	-
	2	-	-	3	3	-	-	-	0	0	-
	3	-	-	2	-	-	-	-	0	-	-
9.1 mg/kg AIRISE-02	1	1	2	2	3	3	1	0	1	1	1
	2	-	2	2	2	3	-	1	1	1	0
	3	-	1	2	2	-	-	1	1	1	0

TABLE EXPLANATION

Abbreviation	Description
-	No findings/Not evaluated

ERYTHEMA AND EDEMA OBSERVATIONS		
OBSERVATION	DEFINITION	CODE
Erythema - Grade 0	No erythema	0
Erythema - Grade 1	Very slight erythema (barely perceptible)	1
Erythema - Grade 2	Well-defined erythema	2
Erythema - Grade 3	Moderate to severe erythema	3
Erythema - Grade 4	Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Maximized Grade 4	Notable dermal lesions	M-4
Edema - Grade 0	No edema	0
Edema - Grade 1	Very slight edema (barely perceptible)	1
Edema - Grade 2	Slight edema (edges of area well defined by definite raising)	2
Edema - Grade 3	Moderate edema (raised approximately 1 millimeter)	3
Edema - Grade 4	Severe edema (raised more than 1 millimeter and extends beyond the area of exposure)	4