

AIRIS PHARMA Private Limited.

Protocol: 043-1810

Table 14.1.16 Summary of Changes in Vital Signs from Baseline to Final Visit (Safety Population)

Parameter: Body Surface Area (m)

			Observed					CFB					
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Planned Treatment	Visit	n	Mean	Median	SD	Min	Max	n	Mean	Median	SD	Min	Max
AIRIS-101 1	SCREENING	3	2.0	2.1	0.19	2	2	0	.	.	.	.	.
	CYCLE 1 DAY 1	3	2.0	2.1	0.18	2	2	0	.	.	.	.	.
	CYCLE 1 DAY 8	2	2.1	2.1	0.00	2	2	2	-0.0	-0.0	0.02	-0	0
	END OF TREATMENT1	2.1	2.1	.	2	2	1	0.0	0.0	.	0	0	
	SAFETY FOLLOW-UP1	2.0	2.0	.	2	2	1	-0.0	-0.0	.	-0	-0	
AIRIS-101 1A	SCREENING	2	1.7	1.7	0.50	1	2	0	.	.	.	.	.
	CYCLE 1 DAY 1	2	1.7	1.7	0.49	1	2	0	.	.	.	.	.
	CYCLE 1 DAY 8	2	1.7	1.7	0.51	1	2	2	0.0	0.0	0.01	0	0
	CYCLE 1 DAY 15	2	1.7	1.7	0.49	1	2	2	-0.0	-0.0	0.01	-0	-0
	CYCLE 1 DAY 22	1	2.0	2.0	.	2	2	1	-0.0	-0.0	.	-0	-0
	CYCLE 2 DAY 1	2	1.7	1.7	0.51	1	2	2	-0.0	-0.0	0.01	-0	-0
	CYCLE 2 DAY 8	2	1.7	1.7	0.49	1	2	2	-0.0	-0.0	0.00	-0	-0
	CYCLE 2 DAY 15	2	1.7	1.7	0.49	1	2	2	-0.0	-0.0	0.00	-0	-0
	CYCLE 3 DAY 1	1	2.0	2.0	.	2	2	1	-0.1	-0.1	.	-0	-0
	END OF TREATMENT1	2.0	2.0	.	2	2	1	-0.1	-0.1	.	-0	-0	
AIRIS-101 2A	SCREENING	1	2.0	2.0	.	2	2	0	.	.	.	.	.
	CYCLE 1 DAY 1	1	2.0	2.0	.	2	2	0	.	.	.	.	.
	CYCLE 1 DAY 8	1	1.9	1.9	.	2	2	1	-0.0	-0.0	.	-0	-0
	CYCLE 1 DAY 15	1	1.9	1.9	.	2	2	1	-0.0	-0.0	.	-0	-0

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Table 14.1.16 Summary of Changes in Vital Signs from Baseline to Final Visit (Safety Population)

Parameter: Diastolic Blood Pressure (mmHg)

			Observed					CFB					
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Planned Treatment	Visit	n	Mean	Median	SD	Min	Max	n	Mean	Median	SD	Min	Max
AIRIS-101 1	SCREENING	3	75.7	79.0	14.29	60	88	0	.	.	.	.	.
	CYCLE 1 DAY 1	3	72.3	75.0	15.18	56	86	0	.	.	.	.	.
	CYCLE 1 DAY 8	2	78.0	78.0	2.83	76	80	2	-2.5	-2.5	4.95	-6	1
	END OF TREATMENT	2	71.5	71.5	21.92	56	87	2	0.5	0.5	0.71	0	1
	SAFETY FOLLOW-UP	1	90.0	90.0	.	90	90	1	4.0	4.0	.	4	4
AIRIS-101 1A	SCREENING	3	74.7	76.0	10.07	64	84	0	.	.	.	.	.
	CYCLE 1 DAY 1	3	84.7	79.0	10.69	78	97	0	.	.	.	.	.
	CYCLE 1 DAY 8	3	82.3	81.0	3.21	80	86	3	-2.3	2.0	7.51	-11	2
	CYCLE 1 DAY 15	3	84.3	87.0	8.33	75	91	3	-0.3	-3.0	11.24	-10	12
	CYCLE 1 DAY 22	2	76.5	76.5	7.78	71	82	2	-11.0	-11.0	5.66	-15	-7
	CYCLE 2 DAY 1	3	78.3	82.0	11.93	65	88	3	-6.3	-9.0	8.33	-13	3
	CYCLE 2 DAY 8	2	85.5	85.5	0.71	85	86	2	-2.5	-2.5	12.02	-11	6
	CYCLE 2 DAY 15	2	82.0	82.0	5.66	78	86	2	-6.0	-6.0	18.38	-19	7
	CYCLE 3 DAY 1	1	76.0	76.0	.	76	76	1	-21.0	-21.0	.	-21	-21
	END OF TREATMENT	1	77.0	77.0	.	77	77	1	-20.0	-20.0	.	-20	-20
AIRIS-101 2A	SCREENING	1	69.0	69.0	.	69	69	0	.	.	.	.	.
	CYCLE 1 DAY 1	1	44.0	44.0	.	44	44	0	.	.	.	.	.
	CYCLE 1 DAY 8	1	63.0	63.0	.	63	63	1	19.0	19.0	.	19	19
	CYCLE 1 DAY 15	1	70.0	70.0	.	70	70	1	26.0	26.0	.	26	26

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Table 14.1.16 Summary of Changes in Vital Signs from Baseline to Final Visit (Safety Population)

Parameter: Heart Rate (beats/min)

Observed														CFB				
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Planned Treatment	Visit	n	Mean	Median	SD	Min	Max	n	Mean	Median	SD	Min	Max					
AIRIS-101 1	SCREENING	3	77.3	78.0	3.06	74	80	0	.	.	.	.	.					
	CYCLE 1 DAY 1	3	99.7	93.0	14.22	90	116	0	.	.	.	.	.					
	CYCLE 1 DAY 8	2	76.0	76.0	9.90	69	83	2	-15.5	-15.5	7.78	-21	-10					
	END OF TREATMENT	2	99.0	99.0	18.38	86	112	2	-5.5	-5.5	2.12	-7	-4					
	SAFETY FOLLOW-UP	1	78.0	78.0	.	78	78	1	-15.0	-15.0	.	-15	-15					
AIRIS-101 1A	SCREENING	3	101.0	92.0	19.16	88	123	0	.	.	.	.	.					
	CYCLE 1 DAY 1	3	90.0	75.0	25.98	75	120	0	.	.	.	.	.					
	CYCLE 1 DAY 8	3	90.7	93.0	16.62	73	106	3	0.7	-2.0	16.17	-14	18					
	CYCLE 1 DAY 15	3	101.3	102.0	18.01	83	119	3	11.3	8.0	14.29	-1	27					
	CYCLE 1 DAY 22	2	97.0	97.0	25.46	79	115	2	-0.5	-0.5	6.36	-5	4					
	CYCLE 2 DAY 1	3	109.3	109.0	5.51	104	115	3	19.3	29.0	21.22	-5	34					
	CYCLE 2 DAY 8	2	113.0	113.0	1.41	112	114	2	15.5	15.5	30.41	-6	37					
	CYCLE 2 DAY 15	2	107.0	107.0	7.07	102	112	2	9.5	9.5	38.89	-18	37					
	CYCLE 3 DAY 1	1	121.0	121.0	.	121	121	1	1.0	1.0	.	1	1					
	END OF TREATMENT	1	120.0	120.0	.	120	120	1	0.0	0.0	.	0	0					
AIRIS-101 2A	SCREENING	1	49.0	49.0	.	49	49	0	.	.	.	.	.					
	CYCLE 1 DAY 1	1	50.0	50.0	.	50	50	0	.	.	.	.	.					
	CYCLE 1 DAY 8	1	45.0	45.0	.	45	45	1	-5.0	-5.0	.	-5	-5					
	CYCLE 1 DAY 15	1	50.0	50.0	.	50	50	1	0.0	0.0	.	0	0					

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Table 14.1.16 Summary of Changes in Vital Signs from Baseline to Final Visit (Safety Population)

Parameter: Height (cm)

			Observed					CFB					
Planned			-----					-----					
Treatment	Visit	n	Mean	Median	SD	Min	Max	n	Mean	Median	SD	Min	Max
AIRIS-101 1	SCREENING	3	171.9	172.7	3.88	168	175	0	.	.	.	.	.
AIRIS-101 1A	SCREENING	3	162.6	162.6	10.20	152	173	0	.	.	.	.	.
AIRIS-101 2A	SCREENING	1	165.1	165.1	.	165	165	0	.	.	.	.	.

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Table 14.1.16 Summary of Changes in Vital Signs from Baseline to Final Visit (Safety Population)

Parameter: Systolic Blood Pressure (mmHg)

Planned Treatment	Visit	n	Observed					n	CFB				
			Mean	Median	SD	Min	Max		Mean	Median	SD	Min	Max
AIRIS-101 1	SCREENING	3	115.7	120.0	17.90	96	131	0	.	.	.	.	.
	CYCLE 1 DAY 1	3	115.7	122.0	25.11	88	137	0	.	.	.	.	.
	CYCLE 1 DAY 8	2	122.5	122.5	4.95	119	126	2	-7.0	-7.0	5.66	-11	-3
	END OF TREATMENT	2	122.5	122.5	24.75	105	140	2	10.0	10.0	9.90	3	17
	SAFETY FOLLOW-UP	1	132.0	132.0	.	132	132	1	-5.0	-5.0	.	-5	-5
AIRIS-101 1A	SCREENING	3	106.3	105.0	3.21	104	110	0	.	.	.	.	.
	CYCLE 1 DAY 1	3	143.0	149.0	14.93	126	154	0	.	.	.	.	.
	CYCLE 1 DAY 8	3	118.0	118.0	3.00	115	121	3	-25.0	-31.0	12.17	-33	-11
	CYCLE 1 DAY 15	3	134.3	131.0	15.28	121	151	3	-8.7	-3.0	17.21	-28	5
	CYCLE 1 DAY 22	2	132.0	132.0	14.14	122	142	2	-19.5	-19.5	10.61	-27	-12
	CYCLE 2 DAY 1	3	115.7	113.0	5.51	112	122	3	-27.3	-32.0	12.66	-37	-13
	CYCLE 2 DAY 8	2	123.0	123.0	1.41	122	124	2	-17.0	-17.0	21.21	-32	-2
	CYCLE 2 DAY 15	2	115.0	115.0	7.07	110	120	2	-25.0	-25.0	26.87	-44	-6
	CYCLE 3 DAY 1	1	125.0	125.0	.	125	125	1	-29.0	-29.0	.	-29	-29
	END OF TREATMENT	1	117.0	117.0	.	117	117	1	-37.0	-37.0	.	-37	-37
AIRIS-101 2A	SCREENING	1	98.0	98.0	.	98	98	0	.	.	.	.	.
	CYCLE 1 DAY 1	1	108.0	108.0	.	108	108	0	.	.	.	.	.
	CYCLE 1 DAY 8	1	105.0	105.0	.	105	105	1	-3.0	-3.0	.	-3	-3
	CYCLE 1 DAY 15	1	111.0	111.0	.	111	111	1	3.0	3.0	.	3	3

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Table 14.1.16 Summary of Changes in Vital Signs from Baseline to Final Visit (Safety Population)

Parameter: Temperature (C)

		Observed						CFB						
Planned														
Treatment	Visit	n	Mean	Median	SD	Min	Max	n	Mean	Median	SD	Min	Max	
AIRIS-101 1	SCREENING	3	36.5	36.7	0.35	36	37	0	.	.	.	.	.	
	CYCLE 1 DAY 1	3	36.6	36.6	0.47	36	37	0	.	.	.	.	.	
	CYCLE 1 DAY 8	2	36.6	36.6	0.31	36	37	2	-0.3	-0.3	0.63	-1	0	
	END OF TREATMENT	2	36.8	36.8	0.27	37	37	2	0.4	0.4	0.63	0	1	
	SAFETY FOLLOW-UP	1	36.4	36.4	.	36	36	1	-0.2	-0.2	.	-0	-0	
AIRIS-101 1A	SCREENING	3	36.5	36.6	0.11	36	37	0	.	.	.	.	.	
	CYCLE 1 DAY 1	3	36.6	36.6	0.23	36	37	0	.	.	.	.	.	
	CYCLE 1 DAY 8	3	37.2	37.2	0.14	37	37	3	0.6	0.4	0.30	0	1	
	CYCLE 1 DAY 15	3	36.9	36.9	0.15	37	37	3	0.4	0.3	0.35	0	1	
	CYCLE 1 DAY 22	2	36.9	36.9	0.18	37	37	2	0.4	0.4	0.51	0	1	
	CYCLE 2 DAY 1	3	37.2	37.1	0.33	37	38	3	0.7	0.7	0.19	0	1	
	CYCLE 2 DAY 8	2	36.8	36.8	0.47	36	37	2	0.3	0.3	0.31	0	1	
	CYCLE 2 DAY 15	2	36.5	36.5	0.20	36	37	2	0.1	0.1	0.04	0	0	
	CYCLE 3 DAY 1	1	37.3	37.3	.	37	37	1	0.9	0.9	.	1	1	
	END OF TREATMENT	1	36.6	36.6	.	37	37	1	0.2	0.2	.	0	0	
AIRIS-101 2A	SCREENING	1	36.4	36.4	.	36	36	0	.	.	.	.	.	
	CYCLE 1 DAY 1	1	36.2	36.2	.	36	36	0	.	.	.	.	.	
	CYCLE 1 DAY 8	1	36.3	36.3	.	36	36	1	0.1	0.1	.	0	0	
	CYCLE 1 DAY 15	1	36.4	36.4	.	36	36	1	0.2	0.2	.	0	0	

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Table 14.1.16 Summary of Changes in Vital Signs from Baseline to Final Visit (Safety Population)

Parameter: Weight (kg)

		Observed						CFB					
Planned		-----						-----					
Treatment	Visit	n	Mean	Median	SD	Min	Max	n	Mean	Median	SD	Min	Max
AIRIS-101 1	SCREENING	3	83.6	90.3	15.14	66	94	0	.	.	.	.	.
	CYCLE 1 DAY 1	3	83.7	89.5	14.42	67	94	0	.	.	.	.	.
	CYCLE 1 DAY 8	2	91.6	91.6	1.86	90	93	2	-0.4	-0.4	1.54	-1	1
	END OF TREATMENT1		89.9	89.9	.	90	90	1	0.4	0.4	.	0	0
	SAFETY FOLLOW-UP1		86.0	86.0	.	86	86	1	-3.5	-3.5	.	-4	-4
AIRIS-101 1A	SCREENING	3	65.3	56.7	30.19	40	99	0	.	.	.	.	.
	CYCLE 1 DAY 1	3	66.5	57.2	30.65	42	101	0	.	.	.	.	.
	CYCLE 1 DAY 8	3	67.3	57.8	31.44	42	102	3	0.8	0.6	0.80	0	2
	CYCLE 1 DAY 15	3	65.4	57.2	29.39	41	98	3	-1.1	-0.6	1.42	-3	0
	CYCLE 1 DAY 22	2	79.5	79.5	25.20	62	97	2	0.6	0.6	5.56	-3	5
	CYCLE 2 DAY 1	3	65.1	56.6	30.84	39	99	3	-1.3	-1.4	0.74	-2	-1
	CYCLE 2 DAY 8	2	68.0	68.0	40.54	39	97	2	-3.1	-3.1	1.28	-4	-2
	CYCLE 2 DAY 15	2	67.3	67.3	39.96	39	96	2	-3.9	-3.9	1.86	-5	-3
	CYCLE 3 DAY 1	1	93.3	93.3	.	93	93	1	-7.3	-7.3	.	-7	-7
	END OF TREATMENT1		90.3	90.3	.	90	90	1	-10.4	-10.4	.	-10	-10
AIRIS-101 2A	SCREENING	1	88.5	88.5	.	89	89	0	.	.	.	.	.
	CYCLE 1 DAY 1	1	88.7	88.7	.	89	89	0	.	.	.	.	.
	CYCLE 1 DAY 8	1	87.2	87.2	.	87	87	1	-1.5	-1.5	.	-2	-2
	CYCLE 1 DAY 15	1	86.4	86.4	.	86	86	1	-2.4	-2.4	.	-2	-2