

AIRIS PHARMA Private Limited.
Protocol: 043-1810

Table 14.1.22 Best overall response (Safety Population)

Parameter		DRUG A (N = 3)	DRUG B (N = 3)	DRUG A (95% CI)	DRUG B (95% CI)	95% CI Difference	P-Value
Best Confirmed Overall Response bySD Investigator			1 (33.3)	(0.03, 1.00)	(0.03, 1.00)		
	PD	1 (33.3)		(0.03, 1.00)	(0.03, 1.00)		
Cancer Therapy	N	3 (100)	3 (100)	(0.29, 1.00)	(0.29, 1.00)		
Confirmed Response by Investigator	N	3 (100)	3 (100)	(0.29, 1.00)	(0.29, 1.00)		
Death	N	1 (33.3)	3 (100)	(0.09, 0.99)	(0.29, 1.00)		0.143
	Y	2 (66.7)		(0.09, 0.99)	(0.29, 1.00)		0.143
Last Disease Assessment by Investigator	PD	1 (33.3)	1 (33.3)	(0.03, 1.00)	(0.03, 1.00)		
Last Disease Assessment CensoredPD at First PD by Investigator		1 (33.3)	1 (33.3)	(0.03, 1.00)	(0.03, 1.00)		
Overall Response by Investigator	PR		1 (33.3)	(0.03, 1.00)	(0.01, 0.99)	(-1.00, 0.19)	0.480
	PD	1 (33.3)	1 (33.3)	(0.03, 1.00)	(0.01, 0.99)	(-1.00, 0.19)	0.480
Disease Progression by Investigator	N	2 (66.7)	2 (66.7)	(0.01, 0.91)	(0.01, 0.91)		0.678
	Y	1 (33.3)	1 (33.3)	(0.01, 0.91)	(0.01, 0.91)		0.678

CR = complete response, PR = partial response, SD = stable disease, PD = progressive disease.
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