

14.2.2.1 Secondary efficacy analysis by cohort

Table 14.2.2.1.1 Immune objective response rate - EEP set (N = 47)

		Cohort II Murlentamab + Trifluridine/tipiracil			
		Cohort I Murlentamab N = 13	Cohort II N = 13	Cohort II expansion N = 21	Total N = 34
Immune Objective Response Rate (iORR)					
iORR assessed by investigator	N	13	13	21	34
	Missing values	0	0	0	0
	No	13 (100.0%) [100.00 ; 100.00]	13 (100.0%) [100.00 ; 100.00]	20 (95.2%) [86.13 ; 100.00]	33 (97.1%) [91.38 ; 100.00]
	Yes	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	1 (4.8%) [0.00 ; 13.87]	1 (2.9%) [0.00 ; 8.62]
iORR assessed by IRC	N	13	13	21	34
	Missing values	0	0	0	0
	No	13 (100.0%) [100.00 ; 100.00]	13 (100.0%) [100.00 ; 100.00]	20 (95.2%) [86.13 ; 100.00]	33 (97.1%) [91.38 ; 100.00]
	Yes	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	1 (4.8%) [0.00 ; 13.87]	1 (2.9%) [0.00 ; 8.62]

iORR includes the notion of unconfirmed (iUPD) and confirmed progressive disease (iCPD)

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Table 14.2.2.1.15 Immune objective response rate - mITT set (N = 65)

		Cohort II Murlentamab + Trifluridine/tipiracil			
		Cohort I Murlentamab N = 21	Cohort II N = 18	Cohort II expansion N = 26	Total N = 44
Immune Objective Response Rate (iORR)					
iORR assessed by investigator	N	21	18	26	44
	Missing values	0	0	0	0
	No	21 (100.0%) [100.00 ; 100.00]	18 (100.0%) [100.00 ; 100.00]	25 (96.2%) [88.76 ; 100.00]	43 (97.7%) [93.32 ; 100.00]
	Yes	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	1 (3.8%) [0.00 ; 11.24]	1 (2.3%) [0.00 ; 6.68]
iORR assessed by IRC	N	21	18	26	44
	Missing values	0	0	0	0
	No	21 (100.0%) [100.00 ; 100.00]	18 (100.0%) [100.00 ; 100.00]	25 (96.2%) [88.76 ; 100.00]	43 (97.7%) [93.32 ; 100.00]
	Yes	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	1 (3.8%) [0.00 ; 11.24]	1 (2.3%) [0.00 ; 6.68]

iORR includes the notion of unconfirmed (iUPD) and confirmed progressive disease (iCPD)

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14.2.2.2 Secondary efficacy analysis according to the AMHR11 membrane expression

Table 14.2.2.2.1 Immune objective response rate - EEP set (N = 47)

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		Cohort I Murlentamab		Cohort II Murlentamab + Trifluridine/tipiracil	
		AMHR11 membrane expression < 20% N = 6	AMHR11 membrane expression ≥ 20% N = 3	AMHR11 membrane expression < 20% N = 17	AMHR11 membrane expression ≥ 20% N = 13
Immune Objective Response Rate (iORR)					
iORR assessed by investigator	N	6	3	17	13
	Missing values	0	0	0	0
	No	6 (100.0%) [100.00 ; 100.00]	3 (100.0%) [100.00 ; 100.00]	17 (100.0%) [100.00 ; 100.00]	12 (92.3%) [77.82 ; 100.00]
	Yes	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	1 (7.7%) [0.00 ; 22.18]
iORR assessed by IRC	N	6	3	17	13
	Missing values	0	0	0	0
	No	6 (100.0%) [100.00 ; 100.00]	3 (100.0%) [100.00 ; 100.00]	17 (100.0%) [100.00 ; 100.00]	12 (92.3%) [77.82 ; 100.00]
	Yes	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	1 (7.7%) [0.00 ; 22.18]

iORR includes the notion of unconfirmed (iUPD) and confirmed progressive disease (iCPD)

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Table 14.2.2.2.15 Immune objective response rate - mITT set (N = 65)

		Cohort I Murlentamab		Cohort II Murlentamab + Trifluridine/tipiracil	
		AMHR11 membrane expression < 20% N = 12	AMHR11 membrane expression ≥ 20% N = 4	AMHR11 membrane expression < 20% N = 24	AMHR11 membrane expression ≥ 20% N = 16
Immune Objective Response Rate (iORR)					
iORR assessed by investigator	N	12	4	24	16
	Missing values	0	0	0	0
	No	12 (100.0%) [100.00 ; 100.00]	4 (100.0%) [100.00 ; 100.00]	24 (100.0%) [100.00 ; 100.00]	15 (93.8%) [81.89 ; 100.00]
	Yes	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	1 (6.3%) [0.00 ; 18.11]
iORR assessed by IRC	N	12	4	24	16
	Missing values	0	0	0	0
	No	12 (100.0%) [100.00 ; 100.00]	4 (100.0%) [100.00 ; 100.00]	24 (100.0%) [100.00 ; 100.00]	15 (93.8%) [81.89 ; 100.00]
	Yes	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	0 (0.0%) [- ; -]	1 (6.3%) [0.00 ; 18.11]

iORR includes the notion of unconfirmed (iUPD) and confirmed progressive disease (iCPD)

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