

Table 14.2.1.1
Summary of Response
Efficacy Evaluable Population

Period Parameter Category	Safety Run-in (N=15)	R/R DLBCL Q3W (Cohort 1) (N=8)	Other subtypes of R/R NHL Q3W (Cohort 2) (N=11)	Relapsed DLBCL Q3W (Cohort A) (N=30)	Relapsed DLBCL QW (Cohort B) (N=30)	Overall (N=94)
During the Entire Efficacy Period						
Best Overall Response [1]						
Objective Response, n (%)	4 (26.7)	1 (12.5)	9 (81.8)	15 (50.0)	15 (50.0)	44 (46.8)
95% CI for ORR (%) [2]	(7.8, 55.1)	(0.3, 52.7)	(48.2, 97.7)	(31.3, 68.7)	(31.3, 68.7)	(36.4, 57.4)
P-value (H0: ORR <= 40%, H1: ORR > 40%) [2]						
				0.175	0.175	
P-value (H0: ORR >= 60%, H1: ORR < 60%) [2]						
				0.175	0.175	

Progressive Disease includes clinical disease progression.

CI = Confidence interval; DLBCL = Diffuse large B-cell lymphoma; H0 = Null hypothesis; H1 = Alternative hypothesis; N = Number of subjects in population; n (%) = Count and percentage; NHL = Non-Hodgkin lymphoma; ORR = Objective response rate; Q3W = Once every three weeks; QW = Once every week. R/R = Relapsed/Refractory.

[1] The best overall response is the best response recorded from the start of the treatment until disease progression or initiation of new anti-cancer therapy during the period of interest. The ORR is defined as the proportion of subjects with a best overall response of partial response or better.

[2] Clopper-Pearson method used to derive the 80% and 95% CI and the p-value.