

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.

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