

Complete Remission Rate in BCRi-naïve Subjects – Final Analysis

The primary efficacy endpoint was the complete remission (CR) rate (CR + complete remission with incomplete marrow recovery [CRi]) in subjects who were not previously treated with BCR inhibitor (BCRi) therapy, as assessed by the investigator. The following hypothesis test was performed at the $\alpha = 0.025$ level:

$$H_0: \text{CR rate} \leq 6\% \text{ versus (vs.) } H_1: \text{CR rate} > 6\%$$

Hence, if the p-value for this test is < 0.025 , we reject the null hypothesis and conclude in favor of the alternative, i.e., that the CR rate for BCRi-naïve subjects is greater than 6%.

Summary of Complete Remission Rate in BCRi-naïve Subjects (Treated Subjects)

	BCRi-naïve (N = 191) n (%) [95% CI] P-value
Complete remission rate (CR+CRi)	66 (34.6) [27.8, 41.8]
P-value	$< 0.001^{***}$

BCRi = B-cell receptor inhibitor; CI = confidence interval; CR = complete remission; CRi = complete remission with incomplete marrow recovery

***, Statistically significant at 0.001 level.

95% CI is from the exact binomial distribution.

P value is from Binomial test (H_0 : CR rate $\leq 6\%$ vs H_1 : CR rate $> 6\%$).