BACKGROUND

Axicabtagene ciloleucel (axi-cel) is an autologous anti-CD19 chimeric antigen receptor (CAR) T-cell therapy approved for the treatment of patients with relapsed/refractory large B-cell lymphoma (LBCL) after 2 or more prior therapies.

ZUMA-1 (NCT02386561) was a multinational, single-arm, registrational Phase I/II study of axi-cel in patients with refractory LBCL.

In the 2-year analysis of ZUMA-1 (19), median follow-up from axi-cel dosing to date of last evaluable follow-up was 24.2 months (95% CI, 21.1-28.5 months).

RESULTS

- With ≥5 years of follow-up, the 5-year OS rate was 42.6% (95% CI, 32.8-51.9) among patients treated with axi-cel.
- The 5-year OS rate among complete responders was 94.4% (95% CI, 83.2-97.8), while the median survival time among complete responders was not reached (95% CI, 64.8-NE).
- Since the 4-year data cutoff, 7 patients (0.7%) died and 8 patients (0.8%) were lost to follow-up.
- With ≥5 years of follow-up, 1 death at month 63 (CR) and 1 progressive disease at month 54 (PR) were reported.

OBJECTIVE

- To present the 5-year updated analysis of Cohorts 1 and 2 from Phase 2 of ZUMA-1
- To evaluate the potential role of OS at 12 months as a surrogate endpoint for OS

METHODS

Figure 1. ZUMA-1 Treatment Schema

RESULTS (continued)

Figure 3. 5-Year Overall Survival

Figure 4. 5-Year Time to Next Therapy (Exploratory Analysis)

Figure 5. Event-Free Survival (Exploratory Analysis)

CONCLUSIONS

- In this updated analysis of the Phase 2 pivotal cohorts of ZUMA-1, axi-cel induced long-term overall survival with no new safety signals in patients with refractory LBCL.
- In treated patients, the 5-year OS rate was 42.6%.
- Between the 4-year and 5-year analyses, the time to next therapy curve remained stable, and 93% of patients remained alive without need of subsequent therapy, which may be suggestive of a cure for these patients.
- Safety findings were similar to those in previous reports, with no new safety signals observed.
- Durable responses were strongly associated with peak CAR T-cell expansion.
- The exploratory analysis of long-term OS by EFS status appears highly correlated in refractory LBCL.
- These findings can potentially support use of 1- and 2-year EFS as a surrogate endpoint for long-term OS in R/R LBCL.

REFERENCES

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DISCLOSURS

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