Trends and outcomes by inpatient and outpatient infusion of axicabtagene ciloleucel (axi-cel) in the US for patients (pts) with relapsed/refractory large B-cell lymphoma (R/R LBCL).

Authors: Fateeha Furqan, Michael Hemmer, Michael Tees, John Baird, Jennifer Holter-Chakrabarty, Brian McClune, Caron Jacobson, Saurabh Dahiya, Frederick Locke, Jiali Yan, Jenny Kim, Elena Pizzi, Dafna Bonneh-Barkay, Hil Hsu, Waleska Perez, Zhongyu Feng, Marcelo Pasquini, Yi Lin

The University of Texas MD Anderson Cancer Center, Houston, TX, Kite, a Gilead Company, Santa Monica, CA, Colorado Blood Cancer Institute, Sarah Cannon Transplant and Cellular Therapy Network, Denver, CO, City of Hope National Medical Center, Duarte, CA, Stephenson Cancer Center at The University of Oklahoma Health Sciences Center, Oklahoma City, OK, Huntsman Cancer Institute at the University of Utah, Salt Lake City, UT, Dana-Farber Cancer Institute, Boston, MA, Stanford University, Stanford, CA, Moffitt Cancer Center, Tampa, FL, Medical College of WI, CIBMTR, Center for International Blood and Marrow Transplant Research, Medical College of Wisconsin, Milwaukee, WI, Mayo Clinic, Rochester, MN

Abstract

Research Funding:

Kite, a Gilead Company

Background:

Axi-cel is an autologous chimeric antigen receptor (CAR) T-cell therapy approved for adults with R/R LBCL after ≥ 1 prior line of therapy (LoT). Adverse events, such as cytokine release syndrome (CRS) and neurologic events (NEs), may deter centers from using axi-cel in an outpatient (OPT) setting, though individual centers have observed comparable safety and effectiveness in OPT and inpatient (IPT) care (Furqan et al. *Blood Adv.* 2024). Here, we present safety and effectiveness outcomes of axi-cel by intention to treat in OPT and IPT settings in a multicenter real-world dataset.

Methods:

Pts receiving axi-cel for R/R LBCL in the US from 01/2021-07/2023 with data in the Center for International Blood and Marrow Transplant Research (CIBMTR) registry were eligible for analysis. Pts with prior allogeneic transplant or unknown intended care setting were excluded.

Of potential pts, 119 OPT pts were identified from 29 centers where an increasing trend was seen (9.6% of pts in 2021 were OPT, 13.5% in 2022, 22.8% in 2023). Pts were matched to 119 IPT pts by propensity score matching on age, sex, comorbidities, lactate dehydrogenase (LDH), bulky disease, prior LoT, chemosensitivity, and infusion year (see table).

Results:

OPT pts had median age of 63 y (25% ≥ 70), 66% were male, and 67% had ≥ 1 comorbidity. Half (50%) had elevated LDH and 73% had 1 prior LoT. Bulky disease was reported in 3%, and 60% had chemo-resistant disease.

Outcomes were analyzed at median follow-up of 12 mo. Safety and effectiveness outcomes were similar between OPT and IPT pts (see table). In multivariate analyses, no differences were found between intended care setting and CRS (odds ratio [OR] 1.09 [95% CI 0.51-2.35]), CRS Gr ≥ 3 (OR 0.57 [0.12-2.60]), NEs (OR 1.14 [0.65-2.00]), or NEs Gr ≥ 3 (OR 0.98 [0.48-2.00]). Among OPT pts, 24% and 50% did not require hospital admission within 30 d and 3 d, respectively. In pts aged ≥ 70 y, only any Gr NEs were higher in the OPT group.

Conclusion:

After matching on key factors that may be used to select pts for OPT infusion, outcomes were comparable between intended care settings. These findings corroborate prior results and support the consideration of axi-cel in appropriate OPT care settings.

Outcomes between matched pts with R/R LBCL receiving axi-cel intended for OPT or IPT.

	OPT (n=119)[a]	OPT (n=119)[a]
CRS any Gr / Gr ≥ 3	83 (75–89) / 3 (<1–7)	83 (74–89) / 4 (1–10)
NE any Gr / Gr ≥ 3	47 (38–57) / 19 (12–27)	46 (37–56) / 21 (14–30)
Overall / complete response rates	78 (69–85) / 68 (59–76)	76 (67–83) / 62 (52-70)
Duration of response @ 12 mo	64 (52–74)	69 (58–78)
Progression-free survival @ 12 mo	53 (43–62)	53 (43–61)
Overall survival @ 12 mo	71 (61–78)	72 (62–79)
Non-relapse mortality @ 12 mo	6 (2–11)	4 (1–8)
Hospital admission within 30 days of infusion / median duration (range), d	76 (67–83) / 9 (2–53)	Not Applicable

[a]Percent (95% CI) unless otherwise specified.