Abstract 7515

Outcomes in ZUMA-5 With Axicabtagene Ciloleucel (Axi-Cel) in Patients With Relapsed/Refractory Indolent Non-Hodgkin Lymphoma Who Had the High-Risk Feature of Progression Within 24 Months From Initiation of First Anti-CD20–Containing Chemoimmunotherapy (POD24)

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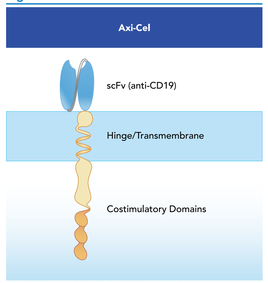
BACKGROUND

- Progression within 24 months from initiating the first anti-CD20–containing chemoimmunotherapy (POD24) is a risk factor for poor survival in patients with indolent non-Hodgkin lymphoma (iNHL)[1,2]
  - Approximately 20% of patients with follicular lymphoma (FL) have POD24[1]
  - In an observational analysis from the National LymphoCare Study, patients with FL who progressed early had a lower 5-year overall survival (OS) rate (50%) than those without early progression (90%)[2]
- Axicabtagene ciloleucel (axi-cel) is an autologous anti-CD19 chimeric antigen receptor (CAR) T-cell therapy (**Figure 1**) approved in the United States (US) for the treatment of adults with relapsed/refractory (R/R) FL after ≥2 lines of systemic therapy, and in the US and European Union for adults with R/R large B-cell lymphoma (LBCL) after ≥2 lines of systemic therapy[3,4]
  - In a long-term follow-up analysis of axi-cel in refractory LBCL, the 4-year OS rate was 44%[5]
- ZUMA-5 is a multicenter, single-arm Phase 2 study of axi-cel in patients with R/R iNHL, including FL and marginal zone lymphoma (MZL)[6]
  - In the primary analysis, overall response rates (ORR) after a 17.5-month median follow-up were similarly high among patients with and without POD24 (93% vs 92%)

Figure 1. Structure of Axi-Cel



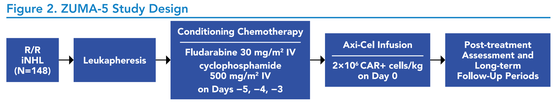
Axi-cel, axicabtagene ciloleucel; scFv, single chain variable fragment

OBJECTIVE

- To report safety and efficacy outcomes and pharmacokinetic/pharmacodynamic profiles with longer follow-up among patients in ZUMA-5 with and without POD24

METHODS

Figure 2. ZUMA-5 Study Design



Key ZUMA-5 Eligibility Criteria

- R/R FL (Grades 1–3a) or MZL (nodal or extranodal)[a]
- ≥2 Prior lines of therapy that must have included an anti-CD20 mAb combined with an alkylating agent[b]

Patients and Analysis

- The updated efficacy analysis occurred when ≥80 treated patients with FL had ≥18 months of follow-up[c]
- Data cutoff date: September 14, 2020
- Axi-cel–treated patients with FL or MZL and available data on progression after an anti-CD20 mAb + alkylating agent were included in the POD24 analysis (N=129)

[a] Patients with stable disease (without relapse) >1 year from completion of last therapy were not eligible. [b] Single-agent anti-CD20 antibody did not count as line of therapy for eligibility. [c] Efficacy-evaluable patients included ≥80 treated patients with FL who had ≥18 months of follow-up after axi-cel infusion and treated patients with MZL who had ≥4 weeks of follow-up after axi-cel infusion as of the data cutoff date.
Axi-cel, axicabtagene ciloleucel; CAR, chimeric antigen receptor; FL, follicular lymphoma; iNHL, indolent non-Hodgkin lymphoma; IV, intravenous; mAb, monoclonal antibody; MZL, marginal zone lymphoma; POD24, progression of disease <24 months from initiating the first anti-CD20–containing chemoimmunotherapy; R/R, relapsed/refractory.

RESULTS

Table 1. Baseline Disease Characteristics

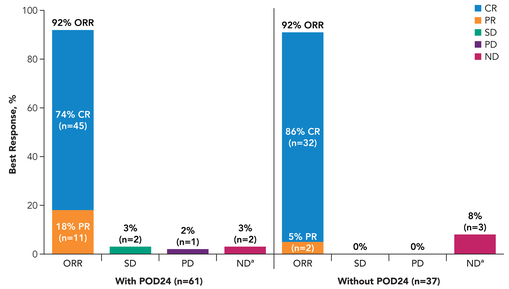
Characteristic	With POD24 (n=81)	Without POD24 (n=48)
Disease type, n (%)		
FL	68 (84)	40 (83)
MZL	13 (16)	8 (17)
Median age (range), years	60 (34–78)	62 (42–79)
≥65 years, n (%)	26 (32)	18 (38)
Male, n (%)	42 (52)	32 (67)
Stage III-IV disease, n (%)	67 (83)	45 (94)
≥3 FLIPI, n/n (%)	30/68 (44)	17/40 (43)
High tumor bulk (GELF criteria), n (%)[a]	41 (51)	21 (44)
Median no. of prior therapies (range)	3 (1–10)[b]	3.5 (2–8)
≥3, n (%)	49 (60)	36 (75)
Prior PI3Ki therapy, n (%)	22 (27)	17 (35)
Prior lenalidomide, n (%)	25 (31)	19 (40)
Prior autologous SCT, n (%)	16 (20)	11 (23)
Refractory disease, n (%)[c]	62 (77)	30 (63)

[a] Disease burden, as defined by GELF criteria: involvement of ≥3 nodal sites (≥3 cm diameter each); any nodal or extranodal tumor mass with ≥7 cm diameter; B symptoms; splenomegaly; pleural effusions or peritoneal ascites; cytopenias; or leukemia. [b] Enrollment of 3 patients with FL who had 1 prior line of therapy occurred in ZUMA-5 before a protocol amendment requiring ≥2 prior lines of therapy. [c] Patients with iNHL who progressed within 6 months of completion of the most recent prior treatment.
FL, follicular lymphoma; FLIPI, Follicular Lymphoma International Prognostic Index; GELF, Groupe d'Etude des Lymphomes Folliculaires; MZL, marginal zone lymphoma; PI3Ki, phosphoinositide 3-kinase inhibitor; POD24, progression of disease <24 months from initiating the first anti-CD20–containing chemoimmunotherapy; SCT, stem cell transplantation.

- Baseline characteristics were generally similar among patients with and without POD24 (**Table 1**)
  - Among evaluable patients with FL, median tumor burden by sum of product diameters was numerically similar in those with and without POD24 (2303 mm² vs 2839 mm²)
  - Among evaluable patients with MZL, median SPD appeared higher among those with POD24 than without POD24 (2028 mm² vs 954 mm²)

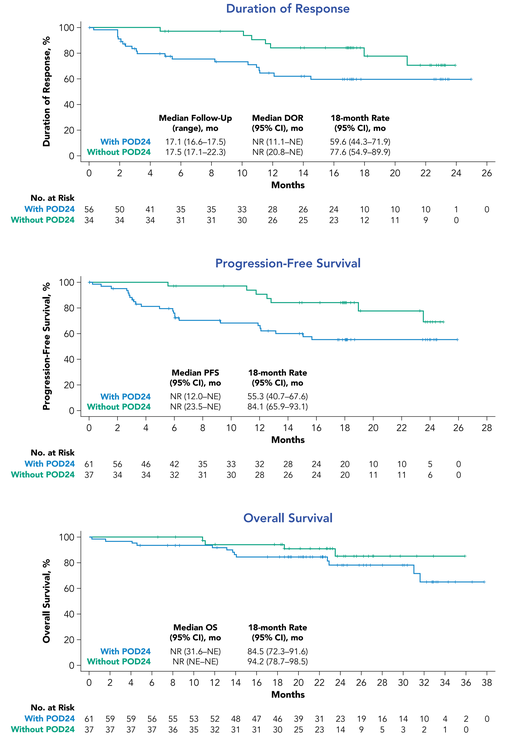
RESULTS *(continued)*

Figure 3. ORR by IRRC Assessment in Patients With iNHL by POD24 Status



Assessed by an IRRC according to the Lugano Classification.[7]
* Among the 5 patients reported as ND, 4 (1 FL without POD24; 3 MZL) had no disease at baseline and post-baseline per IRRC but were considered with disease by the investigator; 1 patient with FL and POD24 died before the first disease assessment.
CR, complete response; FL, follicular lymphoma; IRRC, Independent Radiology Review Committee; MZL, marginal zone lymphoma; ND, not done/undefined; ORR, overall response rate; POD24, progression of disease <24 months from initiating the first anti-CD20–containing chemoimmunotherapy; PD, progressive disease; PR, partial response; SD, stable disease.

Figure 4. DOR, PFS, and OS in Patients With iNHL by POD24 Status



DOR, duration of response; FL, follicular lymphoma; mo, month; MZL, marginal zone lymphoma; NE, not estimable; NR, not reached; OS, overall survival; PFS, progression-free survival; POD24, progression of disease <24 months from initiating the first anti-CD20–containing chemoimmunotherapy.

Table 2. Efficacy Outcomes Among Patients With FL and MZL by POD24 Status

Parameter	Follicular Lymphoma		Marginal Zone Lymphoma	
	With POD24 (n=49)	Without POD24 (n=29)	With POD24 (n=12)	Without POD24 (n=8)
ORR, n (%)	46 (94)	28 (97)	10 (83)	6 (75)
CR	38 (78)	26 (90)	7 (58)	6 (75)
PR	8 (16)	2 (7)	3 (25)	0
Median DOR (95% CI), months	NR (14.5–NE)	NR (20.8–NE)	11.1 (1.9–NE)	NR (10.6–NE)
18-mo rate (95% CI), %	63.9 (47.2–76.6)	78.2 (53.3–90.8)	NR (NE–NE)	75.0 (12.8–96.1)
Median PFS (95% CI), months	NR (13.1–NE)	NR (23.5–NE)	9.2 (2.8–NE)	NR (11.8–NE)
18-mo rate (95% CI), %	59.8 (43.7–72.6)	85.3 (65.4–94.2)	30.7 (5.1–62.6)	75.0 (12.8–96.1)
Median OS (95% CI), months	NR (31.6–NE)	NR (NE–NE)	NR (13.7–NE)	NR (18.7–NE)
18-mo rate (95% CI), %	85.7 (72.4–92.9)	93.1 (75.1–98.2)	76.4 (30.9–94.0)	100.0 (NE–NE)

CR, complete response; DOR, duration of response; FL, follicular lymphoma; MZL, marginal zone lymphoma; ND, not done/undefined; NE, not estimable; NR, not reached; OS, overall survival; PFS, progression-free survival; POD24, progression of disease <24 months from initiating the first anti-CD20–containing chemoimmunotherapy; PR, partial response.

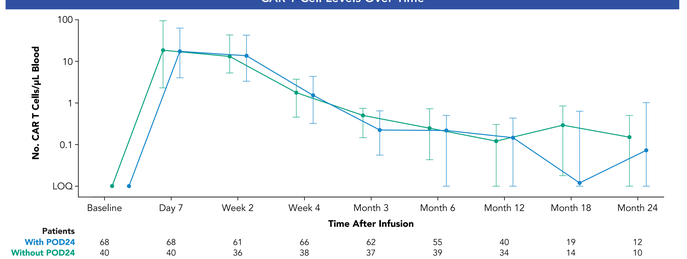
- The ORR was similar among efficacy-evaluable patients with and without POD24 (**Figure 3**; **Table 2**)
- Estimated median duration of response (DOR) was not reached for patients with and without POD24, after a median follow-up of 17.1 months and 17.5 months, respectively (**Figure 4**; **Table 2**)
  - Responses were ongoing in 52% of efficacy-evaluable patients with POD24 and 70% of those without POD24 at data cutoff
  - The 18-month DOR rates in patients with and without POD24 were 60% and 78%, respectively
- Median progression-free survival (PFS) and median OS were not reached in patients with and without POD24 (**Figure 4**; **Table 2**)
  - The 18-month PFS rates in patients with and without POD24 were 55% and 84%, respectively
  - The 18-month OS rates were 85% and 94%, respectively
- Incidences of Grade ≥3 adverse events were generally similar in patients with and without POD24 (**Table 3**)
  - Grade 5 events occurred in 3 patients with POD24, including 1 event in the context of cytokine release syndrome (CRS); no Grade 5 events occurred in patients without POD24
  - Grade 4 CRS occurred in 1 patient with POD24
  - Grade 4 neurologic events occurred in 2 patients with POD24
  - In patients without POD24, no Grade 4 CRS or neurologic events occurred

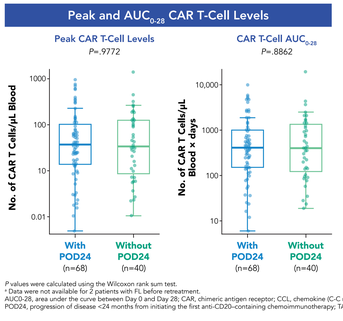
Table 3. Summary of Adverse Events in Patients With and Without POD24

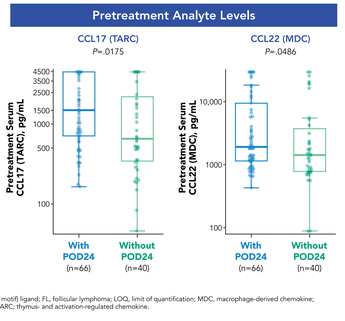
AE[a]	With POD24 (n=81)	Without POD24 (n=48)
Any AE, n (%)	80 (99)	48 (100)
Grade ≥3	68 (84)	42 (88)
Grade 5	3 (4)	0
Any serious AE, n (%)	37 (46)	26 (54)
Grade ≥3 cytopenias, n (%)	56 (69)	31 (65)
Grade ≥3 infections, n (%)	12 (15)	10 (21)
CRS, n (%)	66 (81)	42 (88)
Grade ≥3	7 (9)	1 (2)
Median time to onset, days	4	4
Median duration, days	7	5
Neurologic events, n (%)	46 (57)	31 (65)
Grade ≥3	14 (17)	8 (17)
Median time to onset, days	8	7
Median duration, days	11	13

[a] CRS was graded per Lee, et al. 2014.[8] Symptoms of CRS and any other AEs were graded per National Cancer Institute's Common Terminology Criteria for Adverse Events version 4.03.
AE, adverse event; CRS, cytokine release syndrome; POD24, progression of disease <24 months from initiating the first anti-CD20–containing chemoimmunotherapy.

Figure 5. CAR T-Cell Expansion and Key Pretreatment Serum Analytes in Patients With FL by POD24 Status







P values were calculated using the Wilcoxon rank sum test.
* Data were not available for 2 patients with FL before pretreatment.
AUC0-28, area under the curve between Day 0 and Day 28; CAR, chimeric antigen receptor; CCL, chemokine (C-C motif) ligand; FL, follicular lymphoma; LOQ, limit of quantification; MDC, macrophage-derived chemokine; POD24, progression of disease <24 months from initiating the first anti-CD20–containing chemoimmunotherapy; TARC, thymus- and activation-regulated chemokine.

Table 4. Peak Cytokine Levels in Patients With FL by POD24 Status

Peak Cytokine Levels (Range)	With POD24 (n=68)	Without POD24 (n=40)	*P* value
IL-6, pg/mL	15.0 (1.6[a]–976.0[b])	13.0 (1.6[a]–976.0[b])	.7574
IL-2, pg/mL	3.2 (0.9[a]–90.6)	2.7 (0.9[a]–63.7)	.6181
IFN-γ, pg/mL	122.8 (7.5[a]–1876.0[b])	67.8 (7.5[a]–1545.1)	.0789
Granzyme B, pg/mL	7.8 (1.0[a]–1062.7)	8.2 (1.0[a]–449.4)[c]	.9447
CXCL10, pg/mL	1001.9 (264.4–2000.0[b])	1093.2 (165.9–2000.0[b])	.5385
IL-10, pg/mL	10.7 (0.7[a]–331.5)	7.4 (0.7[a]–66.5)	.2255
TNF-α, pg/mL	4.6 (1.6–62.7)	4.1 (0.7[a]–11.0)	.1644
IL-1RA, pg/mL	1202.0 (221.0–9000.0[b])	982.5 (239.0–9000.0[b])	.2983
GM-CSF, pg/mL	1.9[a] (1.9[a]–23.2)	1.9[a] (1.9[a]–34.1)	.7177
CCL2 (MCP-1), pg/mL	790.1 (249.3–1500.0[b])	829.2 (249.4–1500.0[b])	.9975
IL-15, pg/mL	33.8 (9.3–93.3)	34.5 (12.0–104.3)	.5908
Ferritin, ng/mL	720.2 (86.4–5237.8)	658.9 (91.3–3459.9)	.4900
SAA, pg/mL	1.5×10[5] (1.5×10[4]–1.4×10[6b])	1.7×10[5] (4.9×10[4]–1.4×10[6b])	.9695
CRP, mg/L	68.3 (3.9–496.0[b])	71.2 (2.9–377.8)	.8164

P values were calculated using the Wilcoxon rank sum test.
[a] Lower limit of quantification in assay used. [b] Upper limit of quantification in assay used. [c] Data were not available for 2 patients with FL at peak.
CCL, chemokine (C-C motif) ligand; CRP, C-reactive protein; CXCL, C-X-C motif chemokine ligand; FL, follicular lymphoma; GM-CSF, granulocyte-macrophage colony-stimulating factor; IFN, interferon; IL, interleukin; MCP-1, monocyte chemoattractant protein 1; POD24, progression of disease <24 months from initiating the first anti-CD20–containing chemoimmunotherapy; RA, receptor agonist; SAA, serum amyloid A; TNF, tumor necrosis factor.

- In efficacy-evaluable patients with FL, median peak CAR T-cell levels were similar in patients with and without POD24 (36.9 cells/µL and 34.5 cells/µL, respectively; **Figure 5**)
  - Median AUCs were also similar among patients with and without POD24 (422.5 cells/µL × days and 407.6 cells/µL × days, respectively)
- Pretreatment levels of CCL17 (TARC) and CCL22 (MDC) appeared higher in patients with POD24 than without POD24 (**Figure 5**)
- Peak levels of key biomarkers associated with axi-cel toxicity appeared generally similar in all treated patients with and without POD24 (**Table 4**)
  - Pharmacokinetic/pharmacodynamic findings between groups were similar in patients with MZL
- Of the 14 patients (13 FL; 1 MZL) in broader ZUMA-5 population with available data at relapse after axi-cel, 100% had detectable CD19
  - Detectable CD19 was confirmed in all evaluable biopsies from patients with and without POD24

Table 5. Axi-Cel Product Characteristics in Patients with FL by POD24 Status

Characteristic (range)	With POD24 (n=68)	Without POD24 (n=40)
No. CCR7+CD45RA+ T cells, 10[6]	38.5 (6.4–268.6)[a]	46.6 (1.1–296.6)[a]
CD4/CD8 ratio	0.7 (0.1–31.3)[a]	0.8 (0.1–13.1)[a]
Transduction rate, %	60.5 (18.0–86.0)	60.5 (26.0–77.0)
IFN-γ in coculture, pg/mL	5511.0 (753.0–1.9×10[4])	6315.0 (1267.0–1.8×10[4])

[a] Based on available data: with POD24, n=57; without POD24, n=36 (CCR7+CD45RA+ cells) and n=35 (CD4/CD8 ratio).
Axi-cel, axicabtagene ciloleucel; FL, follicular lymphoma; IFN, interferon; POD24, progression of disease <24 months from initiating the first anti-CD20–containing chemoimmunotherapy.

- Axi-cel product attributes were generally similar among patients with and without POD24 (**Table 5**)

CONCLUSIONS

- Axi-cel demonstrated a high rate of durable responses in patients with POD24 iNHL
  - Although medians for PFS were not reached in either group, estimated PFS rates at 18 months appeared lower in patients with POD24 than those without POD24
  - Among patients with FL, higher median pretreatment levels of analytes previously associated with relapse (CC17 [TARC] and CCL22 [MDC])[9] were observed in patients with POD24 than without POD24, potentially contributing to differences in the 18-month PFS rate
- Safety profiles were similarly manageable in patients with and without POD24
- Among patients with FL, posttreatment pharmacokinetic and pharmacodynamic profiles appeared largely comparable in patients with and without POD24
- Axi-cel may be a promising option for patients with POD24 iNHL, a population with particularly high-risk disease[1]

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DISCLOSURES

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