# Camidanlumab Tesirine: Updated Efficacy and Safety in an Open-Label, Multicenter, Phase 2 Study of Patients With Relapsed or Refractory Classical Hodgkin Lymphoma (R/R cHL)

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## INTRODUCTION

- There are limited treatment options available for patients with relapsed/refractory (R/R) cHL who have disease refractory to or that relapses following brentuximab vedotin and PD-1 inhibitor therapy[1,2]
- Camidanlumab tesirine (Cami) is an antibody-drug conjugate comprising a human IgG1 anti-CD25 monoclonal antibody conjugated to a pyrrolobenzodiazepine (PBD) dimer[3]
- In a phase 1 trial in patients with lymphoma, including patients with cHL, Cami demonstrated encouraging antitumor activity and manageable toxicity[3]
- Prior results of the phase 2 study evaluating Cami monotherapy in patients with R/R cHL showed an overall response rate of 66.3%, with a complete response rate of 27.7% (presented at ICML 2021)[4]

## OBJECTIVE

To present updated efficacy and safety data from the phase 2 study (NCT04052997)

## STUDY DESIGN

**Ongoing, Phase 2, Single-Arm, Multicenter, Open-Label Study in Patients With R/R cHL[a]**

**30-minute IV infusion of Cami on day 1 of each 3-week cycle**

**45 µg/kg** (Cycles 1 & 2) → **30 µg/kg** (Cycle 3 onwards, up to 1 year[b])

- Primary endpoint: ORR (per 2014 Lugano classification) assessed by central review
- Secondary endpoints: DoR, PFS, and safety (frequency and severity of adverse events)
- As of November 1, 2021, enrollment was complete (N = 117)

[a]Primary analysis of efficacy and safety in the all-treated population is defined as all patients who received ≥1 dose of Cami.[b] Or until discontinuation due to disease progression, unacceptable toxicity, or other reasons. Patients deriving clinical benefit (ie, 1 year may be able to continue treatment on a case-by-case basis.

Cami, camidanlumab tesirine; cHL, classical Hodgkin lymphoma; DoR, duration of response; IV, intravenous; ORR, overall response rate; PFS, progression-free survival; R/R, relapsed or refractory.

## METHODS

**Key Inclusion and Exclusion Criteria**

**Inclusion Criteria**

- Male or female
- ≥18 years (≥16 years in the US)
- Pathologic diagnosis of cHL
- Patients with R/R cHL who received ≥3 prior lines of systemic therapy (or ≥2 lines if ineligible for HSCT)
- Prior treatment with BV and PD-1 blockade therapy
- Measurable disease (2014 Lugano classification)
- Eastern Cooperative Oncology Group performance status score of 0-2
- Adequate organ function

**Exclusion Criteria**

- Allogeneic/autologous HSCT ≤60 days before the start of Cami treatment
- History of neuropathy considered of autoimmune origin (eg, polyradiculopathy, including GBS and myasthenia gravis) or other CNS autoimmune diseases, such as poliomyelitis or MS
- Recent infection (<4 weeks of cycle 1, day 1) that was considered caused by prespecified pathogens
- HIV, HBV, or HCV infection needing antiviral therapy/prophylaxis
- Clinically significant third-space fluid accumulation (ie, ascites requiring drainage, or pleural effusion requiring drainage or associated with shortness of breath)

BV, brentuximab vedotin; cHL, classical Hodgkin lymphoma; CNS, central nervous system; GBS, Guillain–Barré syndrome; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; HSCT, hematopoietic stem cell transplantation; MS, multiple sclerosis; PD-1, programmed cell death protein 1; R/R, relapsed or refractory.

## RESULTS

**Table 1:** Baseline characteristics

| Characteristic | Total (N = 117) |
|---|---|
| **Sex, n (%)** | |
| Female | 44 (37.6) |
| Male | 73 (62.4) |
| **Age, median (min, max)** | 37 (19, 87) |
| **ECOG score, n (%)** | |
| 0 | 64 (54.7) |
| 1 | 47 (40.2) |
| 2 | 6 (5.1) |
| **Disease stage (Ann Arbor criteria)[a], n (%)** | |
| I | 1 (0.9) |
| II | 22 (18.8) |
| III | 25 (21.4) |
| IV | 68 (58.1) |
| Missing | 1 (0.9) |

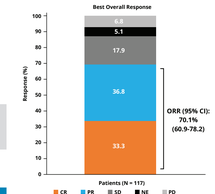
| Characteristic | Total (N = 117) |
|---|---|
| **Prior systemic therapies, n (%)** | |
| ≤3 prior lines | 5 (4.3) |
| 4 prior lines | 18 (15.4) |
| 5 prior lines | 22 (18.8) |
| ≥5 prior lines | 72 (61.5) |
| **Number of prior systemic therapies, median (min, max)[a]** | 6 (3-19) |
| **Prior HSCT, n (%)** | |
| Autologous | 59 (50.4) |
| Allogeneic | 3 (2.6) |
| Both | 12 (10.3) |
| **Disease status after first-line systemic therapy, n (%)** | |
| Relapsed | 79 (67.5) |
| Refractory | 29 (24.8) |
| Other[a] | 9 (7.7) |
| **Disease status after last-line systemic therapy, n (%)** | |
| Relapsed | 37 (31.6) |
| Refractory | 66 (56.4) |
| Other[a] | 14 (12.0) |

Data cutoff: November 1, 2021

[a]Includes prior HSCT; [b]Missing or not evaluable.

ECOG, Eastern Cooperative Oncology Group; HSCT, hematopoietic stem cell transplant.

**Figure 1.** Efficacy—overall response rate[a]




Data cutoff: November 1, 2021

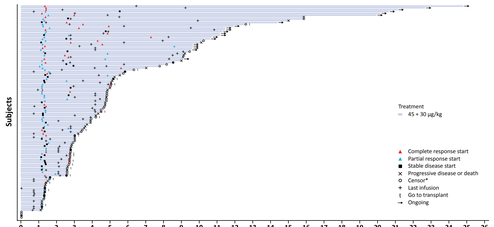
[a]The efficacy analysis set includes all treated patients. [b]One patient did not receive BV due to protocol deviation. [c]In contrast to CR, PR, or PD, a BOR of SD can only be made after a patient is on study for a minimum of 35 days after the first dose of the study drug. Any tumor assessment indicating SD before this time period will be considered as non-evaluable for BOR if no assessment after this time period is available.

BOR, best overall response; BV, brentuximab vedotin; CHPs, checkpoint inhibitors; CR, complete response; NE, not evaluable; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease; SCT, stem cell transplant.

**Table 2.** Best overall response in patients with or without prior SCT

| Best overall response, n (%)[a] | BV and CHPi with prior SCT (n = 73), n (%) | BV and CHPi without prior SCT (n = 43), n (%) |
|---|---|---|
| CR | 30 (41.1) | 8 (18.6) |
| PR | 24 (32.9) | 19 (44.2) |
| SD | 13 (17.8) | 8 (18.6) |
| NE[b] | 3 (4.1) | 3 (7.0) |
| PD | 3 (4.1) | 5 (11.6) |
| ORR<br>95% CI for ORR | 54 (74.0)<br>62.4-83.5 | 27 (62.8)<br>46.7-77.0 |

**Figure 2.** A sizeable proportion of patients experience long-lasting treatment effects




- Total number of cycles dosed, median (min, max): 5 (1, 15)
- Duration of treatment (days), median (min, max): 85 (1, 330)
- Most responses were observed after 2 cycles
- 15 patients who initially had a partial response had a subsequent complete response
- 14 patients discontinued treatment to receive a transplant (of which 12 received transplants)[a]

Data cutoff: November 1, 2021

Each bar represents one patient in the study. The response is determined by an independent reviewer. Includes all-treated patient population, defined as those patients who received ≥1 dose of Cami.*Only for censored patients who discontinued the study due to reasons other than progression, who went on to a different anticancer treatment other than a transplant, or who are ongoing but have no disease assessment yet. #Patients who received transplant were censored.

**Tables 3 and 4:** Transplant outcomes

| | Patients, n |
|---|---|
| Patients who discontinued treatment to move to HSCT | 14<br>(2 did not receive HSCT)[a] |
| Patients who discontinued treatment for other reasons while in PR/CR and moved to HSCT without intercurrent therapies | 4 |

- Overall, of the 16 patients who received a transplant
  - 12 received allogeneic transplants; 3 patients progressed 2-5 months after HSCT
  - 4 received autologous transplants; 1 patient progressed 2 months after HSCT
- 9 patients continued follow-up, 5 withdrew consent, and 2 died (causes of death: PD; septic shock)

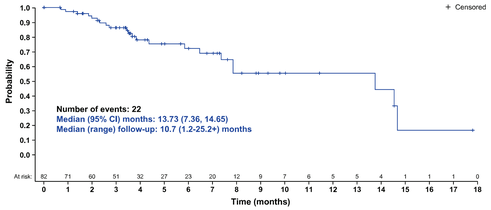
Data cutoff: November 1, 2021

[a]Transplant status of 1 patient was unknown at data cutoff, and 1 ultimately did not receive transplant.

| Relevant post-HSCT AEs (reported post data cutoff date) | Number of events |
|---|---|
| **Allogeneic (NMA conditioning, n = 7)** | |
| Grade 3 malnutrition | 1 |
| Grade 4 eye GVHD | 1 |
| **Allogeneic (MA conditioning, n = 4)** | |
| Grade 3 hemorrhagic cystitis, grade 4 myocarditis | 1 |
| Grade 3 diarrhea, febrile neutropenia, pericarditis | 1 |
| Grade 4 leukopenia, pericardial effusion, pericardial tamponade | 1 |
| Grade 4 Klebsiella and Pseudomonas sepsis, grade 5 septic shock | 1 |
| **Allogeneic (unknown conditioning, n = 1)** – No relevant AEs reported | |
| **Autologous (n = 4)** | |
| Grade 3 oral mucositis, atrial fibrillation, febrile neutropenia, AKI | 1 |

AE, adverse event; AKI, acute kidney injury; CR, complete response; GVHD, graft-versus-host disease; HSCT, hematopoietic stem cell transplant; NMA, myeloablative; MAA, nonmyeloablative; PD, progressive disease; PR, partial response.

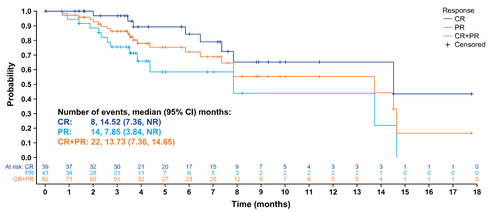
**Figure 3:** Duration of response—all-treated population




Data cutoff: November 1, 2021

CR, complete response; DOR, duration of response; PR, partial response.

**Figure 4:** Duration of response—all-treated population

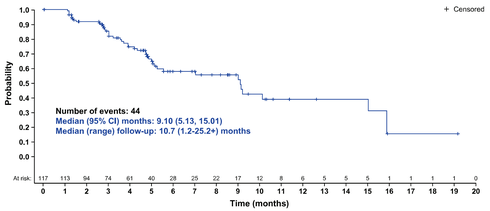



Data cutoff: November 1, 2021

BOR, best overall response; CR, complete response; NR, not reached; PR, partial response.

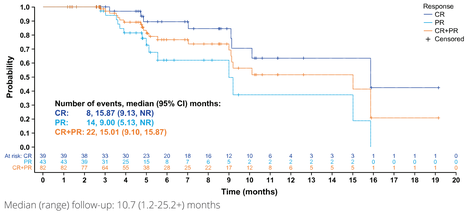
- The median time to first CR or PR was 41 days (range 32-148); the median time to first CR was 45 days (range 32-222)
- Median (range) follow-up: 10.7 (1.2-25.2+) months

**Figure 5:** Progression-free survival by independent reviewer—all-treated population




Data cutoff: November 1, 2021

**Figure 6:** Progression-free survival by independent reviewer—by BOR for responders




- Median (range) follow-up: 10.7 (1.2-25.2+) months

Data cutoff: November 1, 2021

BOR, best overall response; CR, complete response; NR, not reached; PR, partial response.

**Table 5:** Safety—TEAEs

| All-grade TEAEs in ≥25% of patients, n (%) | Total (N = 117) |
|---|---|
| Any TEAE | 116 (99.1) |
| Fatigue | 45 (38.5) |
| Maculopapular rash | 38 (32.5) |
| Pyrexia | 35 (29.9) |
| Nausea | 32 (27.4) |
| Rash | 31 (26.5) |

| Grade ≥3 TEAEs in ≥5% of patients, n (%) | Total (N = 117) |
|---|---|
| Thrombocytopenia | 11 (9.4) |
| Anemia | 10 (8.5) |
| Hypophosphatemia | 9 (7.7) |
| Neutropenia | 9 (7.7) |
| Maculopapular rash | 8 (6.8) |
| Lymphopenia | 6 (5.1) |

| All-grade PBD-related TEAEs | |
|---|---|
| Skin/nail reactions | 87 (74.4) |
| Hepatobiliary test abnormalities[a] | 34 (29.1) |
| Edema/effusion | 20 (17.1) |

| Grade ≥3 PBD-related TEAEs | |
|---|---|
| Skin/nail reactions | 24 (20.5) |
| Hepatobiliary test abnormalities[a] | 8 (6.8) |
| Edema/effusion | 0 (0) |

- TEAEs leading to a dose delay/reduction or withdrawal occurred in 66 patients (56.4%) and 32 patients (27.4%), respectively
- Serious TEAEs or fatal TEAEs occurred in 46 patients (39.3%) and 4 patients (3.4%), respectively

Data cutoff: November 1, 2021

[a]Includes preferred terms grouped under "liver function test": GGT increased, ALT increased, AST increased, blood alkaline phosphatase increased, hypoalbuminemia, blood bilirubin increased, ascites, and transaminases increased.

ALT, alanine aminotransferase; AST, aspartate aminotransferase; GGT, gamma-glutamyltransferase; PBD, pyrrolobenzodiazepine; TEAE, treatment-emergent adverse event.

**Table 6:** Safety—immune-related adverse events

| Patient | Grade ≥3 ir-AEs by preferred term | Max grade | Duration (days) | Outcome at last assessment |
|---|---|---|---|---|
| 1 | Autoimmune hemolytic anemia | 3 | 5 | Recovered |
| 2 | Autoimmune hepatitis | 4 | 52 | Recovered |
| 3 | Bone marrow failure | 5 | 9 | Fatal |
| 4 | Diabetic ketoacidosis | 4 | 3 | Recovered |
| 5 | Diabetic ketoacidosis/type 1 diabetes | 4 | 29 | Not recovered[b] |
| 6 | Drug-induced liver injury | 3 | 104 | Recovered |
| 7 | Drug-induced liver injury | 3 | 17 | Recovered |
| 8 | Lichenoid keratosis | 4 | 175 | Not recovered[b] |
| 9 | Tubulointerstitial nephritis | 3 | 6 | Recovered |
| 10 | Tubulointerstitial nephritis | 3 | 130 | Recovered |

Data cut off: November 1, 2021

[a]Ongoing, and decreased to grade 1; [b]Patient died of progressive disease.

PBD, pyrrolobenzodiazepine; TEAE, treatment-emergent adverse event.

- Immune-related TEAEs (ir-TEAEs) occurred in 38 patients (32.5%)
- Grade ≥3 ir-AEs (TEAEs and non-TEAEs) occurred in 10 patients:
  - Median age (range): 45.5 years (22-75)
  - 8/10 patients had prior autologous transplant
  - Median number of Cami cycles (range): 3.5 (2-12)
  - 50% grade ≥3 ir-AEs presented after 2-3 cycles, and 50% had onset after 30 days after the last dose
  - Median days since the last checkpoint inhibitor (range): 183 (76-2097)

**Table 7:** Safety—patients with Guillain–Barré Syndrome (GBS)/polyradiculopathy

| Patient | AE by preferred term | Max grade | Duration (days) | IVIG/PLEX/ steroids | Outcome at last assessment |
|---|---|---|---|---|---|
| 1 | GBS | 4 | 523 | Y/Y/Y | Ongoing at grade 1 |
| 2 | GBS | 4 | 43 | Y/Y/N | Recovered |
| 3 | GBS | 3 | 50 | Y/Y/Y | Not recovered; patient died of sepsis |
| 4 | GBS | 3 | 287 | Y/N/Y | Ongoing at grade 1 |
| 5 | GBS | 3 | 111 | Y/Y/Y | Ongoing at grade 1[a] |
| 6 | GBS | 2 | 119 | Y/N/N | Recovered |
| 7 | Polyneuropathy,[a] meningitis, facial paralysis, SIADH | 4 | 72 | Y/N/Y | Recovered |
| 8 | Radiculopathy | 2 | 165 | Y/Y/Y | Recovered |

[a]Also received rituximab with clinical improvement; Y=patient; polyradiculoneuritis; IVIG, intravenous immunoglobulin; PLEX, plasma exchange; SCT, stem cell transplant; SIADH, syndrome of inappropriate secretion of antidiuretic hormone

- Baseline characteristics:
  - Median age (range): 35 years (23-68)
  - 3/8 patients had prior SCT
  - Median days since last checkpoint inhibitor (range): 187 (50-377)
- Median number of Cami cycles (range): 3.5 (2-7)
  - 4/8 cases presented after 2 cycles; 3/8 had onset after 30 days after the last dose

## CONCLUSIONS

### Efficacy

- With a median follow-up of 10.7 months, Cami demonstrated an ORR of 70.1% (CR of 33.3%) in heavily pretreated patients with R/R cHL after BV and PD-1 blockade failure
- The median DOR was 13.7 months, and the median PFS was 9.1 months

### Safety

- Safety is consistent with prior findings, including similar incidence rates of GBS/polyradiculopathy
- Immune-related AEs, similar to those observed in patients treated with checkpoint inhibitors, were observed in patients treated with Cami
- With prompt management, such as intravenous immunoglobulin, plasma exchange, and/or high-dose steroids, GBS resolved in 4/8 patients and decreased in severity to grade 1 in 3/8 patients

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