

**Phase I CARLYSLE: Obe-cel in severe, refractory SLE**  
(NCT06333483)

**N = 9**  
50M dose: n = 6  
100M dose: n = 3

**Primary endpoints:** Dose-limiting toxicities within 28 days of infusion; AE frequency.

**Key eligibility:** Adults (aged 18–65 years) or adolescents\* (aged 12–17 years) with severe, refractory SLE with biopsy-confirmed active LN (if renal involvement).

\*Two were enrolled, but results are not presented here.

**TRIAL DESIGN**



**Obecabtagene autoleucel (obe-cel)**

**n = 6** 50M dose (50 × 10<sup>6</sup> CAR T-cells)

**n = 3** 100M dose (100 × 10<sup>6</sup> CAR T-cells)

**Median follow-up**  
(range, 8.5–16.3 months)\* **11.4 months**

**Median follow-up**  
(range, 3.1–7.2 months)\* **3.3 months**

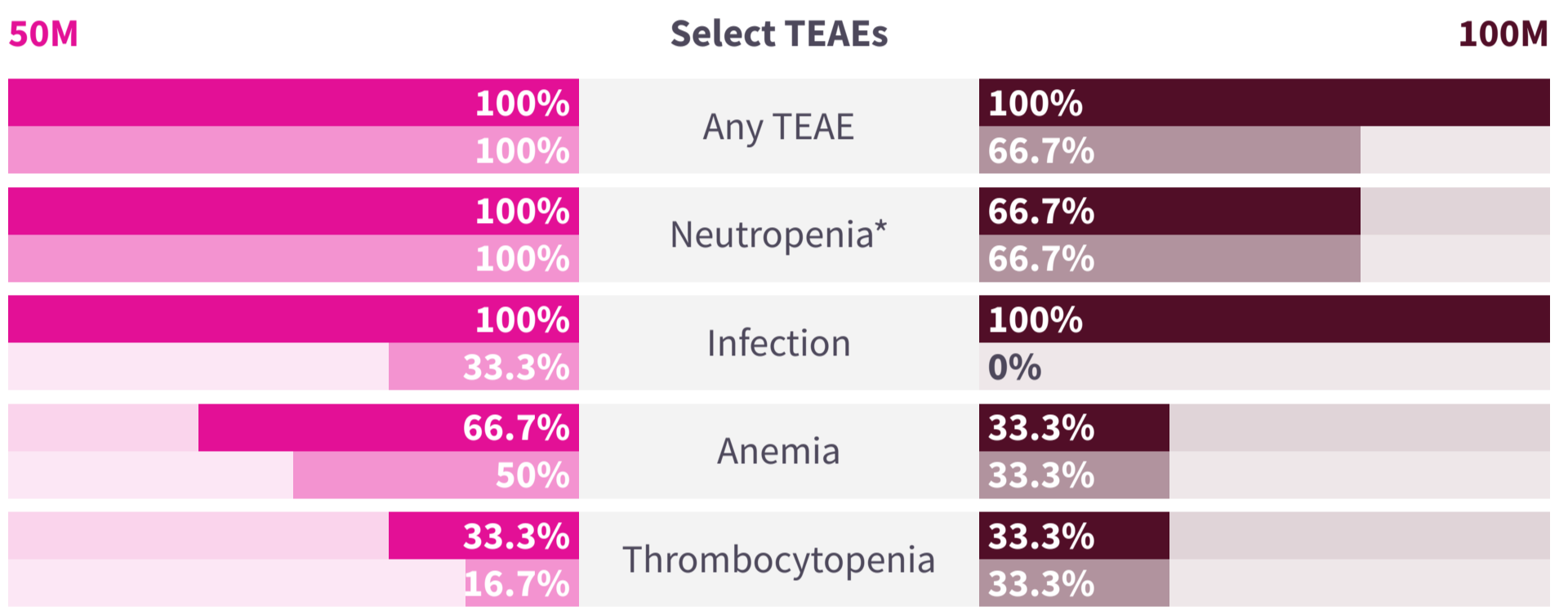
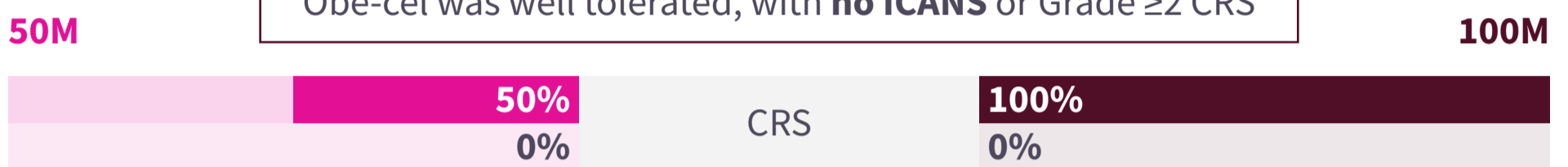
\*All patients will continue to be followed for at least 12 months.

**SAFETY**

Any Grade Grade ≥3

Any Grade Grade ≥3

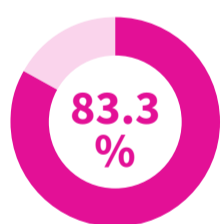
Obe-cel was well tolerated, with **no ICANS** or Grade ≥2 CRS



\*Includes febrile neutropenia.

**EFFICACY**

**DORIS (50M cohort)<sup>†</sup>**



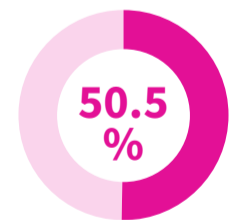
achieved DORIS

**Median time to onset**  
(range, 4.9–8.9 months)

**5.1 months**

**Renal response (50M cohort)<sup>†</sup>**

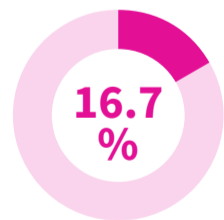
CRR



with onset at

**Month 1**

PRR



with onset at

**Month 7**

UPCR decreased and eGFR was maintained / stabilized over time

**SLEDAI-2K**

Clinically meaningful reductions in SLEDAI-2K were observed over time in both cohorts.

**CAR T-cell kinetics and B-cell depletion**

Rapid CAR T-cell expansion with loss of persistence by ~3 months.

Deep B-cell depletion with recovery by ~6 months.

Overall, >90% of reconstituted B cells at the time of recovery were transitional or naïve.

<sup>†</sup>Length of follow-up was insufficient to calculate DORIS or renal response for the 100M cohort.

**These preliminary phase I data suggest that obe-cel has potential as a treatment for severe, refractory SLE. Obe-cel is being evaluated in the phase II LUMINA trial (NCT07053800) in severe, refractory SLE; recruitment is ongoing.**

AE, adverse event; CAR, chimeric antigen receptor; CRR, complete renal response; CRS, cytokine release syndrome; DORIS, definition of remission in SLE; eGFR, estimated glomerular filtration rate; ICANS, immune effector cell-associated neurotoxicity syndrome; LN, lupus nephritis; obe-cel, obecabtagene autoleucel; PRR, partial renal response; SLE, systemic lupus erythematosus; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; TEAE, treatment-emergent AE; UPCR, urine protein-creatinine ratio.

Leandro M, et al. Oral Abstract #OP0341. EULAR 2026 Congress; Jun 3–6, 2026; London, UK.