# Preliminary results of earlier steroid use with axicabtagene ciloleucel (axi-cel) in patients with relapsed/refractory large B cell lymphoma (R/R LBCL).

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Abstract Disclosures

**Background:**
Axi-cel is an autologous anti-CD19 chimeric antigen receptor (CAR) T cell therapy approved in the EU and US for patients (pts) with R/R LBCL with ≥ 2 prior systemic therapies. In the 2-y follow-up of ZUMA-1, the objective response rate (ORR) was 83% with a complete response (CR) rate of 58%. Grade ≥ 3 cytokine release syndrome (CRS) and neurologic events (NE) occurred in 11% and 32% of pts, respectively; 26% of pts received steroids, and 43% received tocilizumab (Locke et al. Lancet Oncol. 2019). A safety expansion cohort was added to evaluate the effect of earlier steroid use on the rates of these adverse events (AEs).

**Methods:**
Eligible pts with R/R LBCL were leukapheresed and received conditioning chemotherapy followed by a target dose of $2 \times 10^6$ anti-CD19 CAR T cells/kg. Pts in this cohort received early steroid intervention starting at Grade 1 NE and at Grade 1 CRS when no improvement was observed after 3 days of supportive care. The primary endpoint for this cohort was incidence and severity of CRS and NE.

**Results:**

As of 9/14/2018, 21 of 40 planned pts received axi-cel with a minimum follow-up of 1 mo (median, 2.6 mo). The median age was 63 y (range, 36 – 73), 67% were male, 81% had disease stage III-IV, 76% were R/R to ≥ second-line therapy, and 10% had relapsed post-autologous stem cell transplantation. Seventy-six percent of pts received steroids and 81% received tocilizumab. Most pts (81%) had Grade ≥ 3 AEs, most commonly neutrophil count decreased (33%), anemia (29%), and pyrexia (24%). Grade ≥ 3 NE occurred in 10% of pts; the most common symptoms were somnolence (10%) and confusional state (10%). Grade 1 and 2 NE occurred in 38% and 5% of pts, respectively. No pt had Grade ≥ 3 CRS; 33% of pts had Grade 1 CRS and 67% had Grade 2. There were no deaths due to AEs; 1 pt died due to disease progression. The ORR per investigator assessment was 76% with 48% of pts achieving a CR. Pharmacokinetic data will be presented.

**Conclusions:**

Early use of steroids may help in managing severe CRS and NE by potentially reducing their incidence in pts treated with CAR T cell therapy without affecting response rates. Optimizing AE management may help to further improve the benefit:risk profile of CAR T cell therapy. Clinical trial information: NCT02348216