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705.CELLULAR IMMUNOTHERAPIES: LATE PHASE AND COMMERCIALLY AVAILABLE THERAPIES

Efficacy and Safety of Axicabtagene Ciloleucel (Axi-cel) for the Treatment of Relapse/Refractory Non-Hodgkin Lymphoma: Real-World Data in Chinese Population

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Background: Autologous CD-19 directed chimeric antigen receptor (CAR) T-cell therapy has become the standard of care of patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) who have received two or more prior lines of therapy. In June 2021, Axi-cel was approved by the China National Medical Products Administration (NMPA) for the treatment of these patients as the first commercial CAR-T product in China. To better understand the efficacy and safety of commercial Axi-cel in Chinese R/R NHL patients in a real-world setting, we conducted this multi-center, non-interventional study (ChiCTR2100047990). The accrual goal is 200 patients, and the primary endpoint is mOS. Here we made the pre-specific interim analysis and the reported the clinical outcomes.
Methods: We included R/R NHL patients treated with commercial Axi-cel at 17 authorized treatment centers from November 2021 to February 2023. All the patients signed written informed consent. We reported best objective response rate (bORR), best complete response (bCR) rate and adverse events of special interest (AESI), including cytokine release syndrome (CRS) and neurological events (NE).
Results: To the cut-off date of June 8, 2023, a total of 101 R/R NHL patients had undergone efficacy evaluation at month 3. The median age of patients was 56.5 (22, 80) years, with 23 patients (22.8%) aged 65 years or older. Fifty-nine patients were male. The baseline characteristics of these patients included 81 (80.2%) with diffuse large B-cell lymphoma, 4 (4.0%) with primary mediastinal B-cell lymphoma, and 7 (6.9%) with high-grade B-cell lymphoma. More than 50% of patients had an International

Prognostic Index (IPI) score ≥3. The median number of prior treatment was 2. Thirty-eight patients (37.6%) had received 3 or more previous therapies and 10 patients (9.9%) had undergone autologous stem cell transplantation (ASCT). The primary refractory subgroup reached 46 (45.5%), and 41(40.6%) patients were refractory to second-line or subsequent therapy. Notably, compared to the baseline characteristics of Axi-cel real-world studies for R/R LBCL in other countries, a greater proportion of Chinese patients had an ECOG PS score ≥2 (32.7%), HBsAg (+) with normal HBV-DNA (23.1%), HBsAg (-) accompany with HBcAb (+) (37.1%). Bridging therapy was given in 73 patients (72.3%), while combination anti-lymphoma therapy was used after Axi-cel infusion and before disease progression in 52 patients (51.5%).

The median follow-up was 12.7 months. The bORR and bCR rate was 83.2% (95%CI, 74.4 - 89.9) and 63.4% (95%CI, 53.2 - 72.7), respectively (Fig 1). The bORR was consistent across covariates including disease type, cell of origin and refractory subgroup, ECOG PS score ≥2, HBsAg (+) and normal HBV-DNA, and HBsAg (-) accompany with HBcAb (+), etc..

The median duration of response (DOR) was 13.7 months (95% CI, 11.1 - NA). mDOR was not reached in bCR patients (95% CI, 11.2 - NA), while patients with best response as PR have a median DOR as 4.7 months (95% CI, 1.8- 6.7). Median progression-free survival (PFS) was 14.6 months (95% CI, 7.6 - NA). Patients with ECOG PS score ≥2 had a shorter median PFS [7.6 months (95%CI 3.0 - NA)] compared to patients with PS 0-1 [14.6 months (95%CI 12.1 - NA)]. Median PFS also differed among patients based on their response at month 3. Patients with CR/PR/non-response at month3 had a median PFS of NR (95% CI, 12.1 - NA), NR (95%CI, 6.1 - NA) and 3.0 months (95%CI, 2.4 - 3.3), respectively (Fig 2). The median OS was not reached, and the estimated OS at 12 months was 80.4% (95%CI, 70.5 - 87.2).

No new safety signals were observed in the Chinese population. The most common adverse events of grade ≥3 were decreased white blood cell count (82.2% of patients), neutropenia (81.3%) and lymphocytopenia (68.2%). CRS of any grade occurred in 90 patients (84.1%), with 15 patients (14.0%) experiencing grade ≥3. NE of any grade occurred in 27 patients (25.2%), with only 1 patient (0.9%) experiencing grade 4. No grade 5 CRS or NE appeared.

Conclusions: This pre-specific interim analysis demonstrated the consistent efficacy of Axi-cel in Chinese R/R NHL patients, while NE of any grade and ≥grade 3 were lower. Similar to the result of the ZUMA-1 study, response at month 3 may predict PFS in Chinese R/R NHL patients treated with Axi-cel in real-world practice.

Disclosures No relevant conflicts of interest to declare.

Fig 1. Objective Response Rate

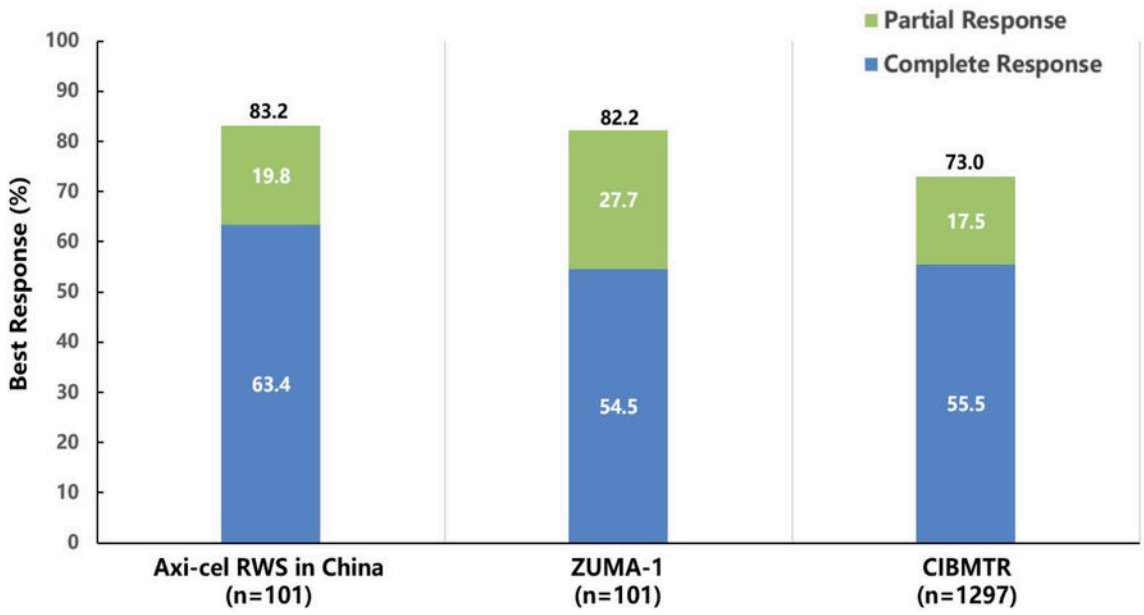

Fig 2. Median Progression Free Survival

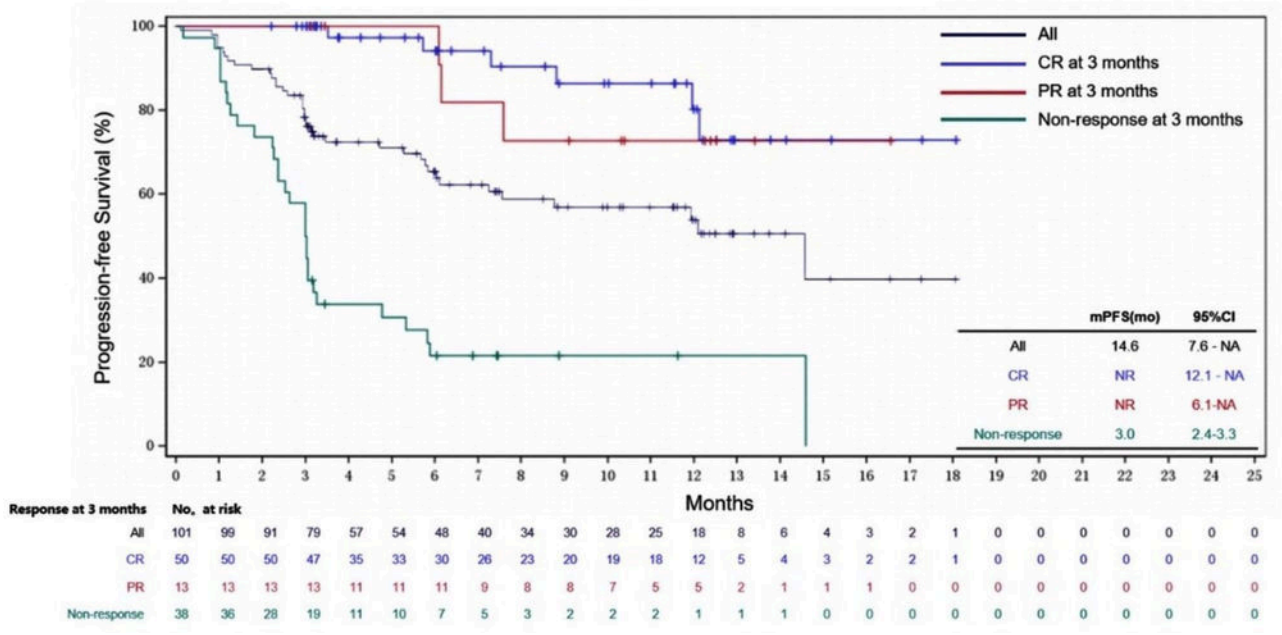

Figure 1

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