Outcomes of patients (pts) ≥ 65 years of age in ZUMA-1, a pivotal phase 1/2 study of axicabtagene ciloleucel (axi-cel) in refractory large B cell lymphoma (LBCL).

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Authors:
Sattva Swarup Neelapu, Caron A. Jacobson, Olalekan O. Oluwole, Javier Munoz, Abhinav Deol, David Bernard Miklos, Nancy L. Bartlett, Ira Braunschweig, Yizhou Jiang, Jenny J. Kim, Lianqing Zheng, John M. Rossi, Frederick Lundry Locke; The University of Texas MD Anderson Cancer Center, Houston, TX; Dana-Farber Cancer Institute, Boston, MA; Vanderbilt-Ingram Cancer Center, Nashville, TN; Banner MD Anderson Cancer Center, Gilbert, AZ; Blood and Marrow Transplant Program, Wayne State University/Karmanos Cancer Institute, Detroit, MI; Stanford University School of Medicine, Stanford, CA; Washington University School of Medicine and Siteman Cancer Center, St. Louis, MO; Montefiore Medical Center, Albert Einstein College of Medicine, Bronx, NY; Kite, a Gilead Company, Santa Monica, CA; H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL

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Abstract Disclosures

Background:
Axi-cel is a US FDA-approved, autologous anti-CD19 chimeric antigen receptor (CAR) T cell therapy for the treatment of pts with relapsed or refractory 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%, and 39% of pts were in ongoing response (Locke et al. Lancet Oncol. 2019). Here we report efficacy and safety outcomes by age.

Methods:
Eligible pts with refractory LBCL underwent leukapheresis and conditioning chemotherapy followed by a target dose of 2×10^6 anti-CD19 CAR T cells/kg. The Phase 2 primary endpoint was investigator-assessed ORR. Additional key endpoints were adverse events (AEs), overall survival (OS), and levels of CAR gene-marked cells in peripheral blood. Efficacy was evaluated for Phase 2 pts; safety was evaluated for all treated pts (Phases 1 and 2). Pts were analyzed by ≥ 65 y vs < 65 y of age.

Results:

As of 8/11/2018, 108 pts were treated. Pts ≥ 65 y (n = 27) vs < 65 y (n = 81) had a median age of 69 y vs 55 y, respectively, were 81% vs 63% male, 70% vs 36% had an IPI score 3-4, 59% vs 57% had ECOG 1, 67% vs 72% had ≥ 3 prior therapies, and median tumor burdens were 3790 mm^2 vs 3574 mm^2. Median follow-up was 27.1 mo for Phase 2 pts (n = 101). The ORR for pts ≥ 65 y (n = 24) and < 65 y (n = 77) was 92% and 81% (CR rate 75% and 53%), respectively, with ongoing responses in 42% and 38% of pts (ongoing CR 42% and 35%). The 24-mo OS rate was 54% for pts ≥ 65 y and 49% for pts < 65 y. Most pts experienced Grade ≥ 3 AEs (100% of pts ≥ 65 y; 98% of pts < 65 y), and 4% of each group (1/27 pts ≥ 65 y and 3/81 pts < 65 y) died due to AEs as previously reported. Grade ≥ 3 neurologic events and cytokine release syndrome occurred in 44% vs 28% and 7% vs 12% of pts ≥ 65 y vs < 65 y, respectively. CAR T cell expansion by peak level (43 vs 35 cells/μl) or area under the curve (562 vs 448 d × cells/μl) was similar in pts ≥ 65 y vs < 65 y, respectively.

Conclusions:

The 2-y follow-up of ZUMA-1 demonstrates that axi-cel can induce high rates of durable responses with a manageable safety profile for pts ≥ and < 65 y. Axi-cel offers substantial clinical benefit for older pts with refractory LBCL who otherwise have limited treatment options. Clinical trial information: NCT02348216