1761 Improved Overall Survival with Axicabtagene Ciloleucel Vs Standard of Care in Second-Line Large B-Cell Lymphoma Among the Elderly: A Subgroup Analysis of ZUMA-7

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Hematology Disease Topics & Pathways:
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Saturday, December 9, 2023, 5:30 PM-7:30 PM

Authors:
Marie José Kersten, MD, PhD[1], Umar Farooq[2], Aaron P. Rapoport, MD[3], Frederick L. Locke, MD[4], Lori A. Leslie, MD[5], Armin Ghobadi, MD[6], David B. Miklos, MD, PhD[7], Caron A Jacobson, MD, MMSc[8], Javier L. Munoz[9], Patrick B Johnston, MD, PhD[10]*, Samantha M. Jaglowski, MD, MPH[11], Ian W. Flinn, MD, PhD[12], Tom van Meerten, MD, PhD[13]*, Miguel-Angel Perales, MD[14], Peter Vandenberghe, MD, PhD[15], Peter A. Riedell, MD[16], Kathleen Dorritie, MD[17], David Szwajcer, MD[18]*, Dimitrios Tzachanis, MD, PhD[19], Saran Vardhanabhuti[20]*, Linqiu Du[20]*, Simone Filosto[20]*, Shilpa A. Shahani, MD[20]*, Christina To, MD[21] and Jason Westin, MD[22]

[1]Cancer Center Amsterdam, Amsterdam University Medical Centers, University of Amsterdam, Amsterdam, Netherlands
[2]Holden Comprehensive Cancer Center, University of Iowa Hospital and Clinics, Iowa City, IA
[3]University of Maryland, Baltimore, MD
[4]H. Lee Moffitt Cancer Center and Research Institute, Tampa, FL
[5]Lymphoma Division, John Theurer Cancer Center, Hackensack Meridian School of Medicine, Hackensack, NJ
[6]Division of Oncology, Washington University School of Medicine, Saint Louis, MO
[7]Division of Blood and Marrow Transplantation & Cellular Therapy, Stanford University, Palo Alto, CA
[8]Dana-Farber Cancer Institute, Boston, MA
[9]Banner MD Anderson Cancer Center, Phoenix, AZ
[10]Division of Hematology, Mayo Clinic, Rochester, MN
[11]Division of Hematology, Department of Internal Medicine, The Ohio State University, Columbus, OH
[12]Sarah Cannon Research Institute, Nashville, TN
[13]University Medical Center Groningen,, Groningen, Netherlands
[14]Adult Bone Marrow Transplantation Service, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, NY
[15]Department of Hematology, Department of Human Genetics, University Hospitals Leuven, KU Leuven, Leuven, Belgium
[16]David and Etta Jonas Center for Cellular Therapy, University of Chicago, Chicago, IL
[17]UPMC Hillman Cancer Center, Pittsburgh, PA
[18]Department of Internal Medicine, University of Manitoba, Winnipeg, Canada
[19]Moores Cancer Center, University of California San Diego, Carlsbad, CA
[20]Kite, a Gilead Company, Santa Monica, CA

[21]Kite Pharma, a Gilead company, Santa Monica, CA
[22]Department of Lymphoma and Myeloma, The University of Texas M D Anderson Cancer Center, Houston, TX

Introduction:

Historically, older patients (pts) with relapsed/refractory large B-cell lymphoma (R/R LBCL) were often deemed ineligible for curative-intent autologous stem cell transplant (ASCT) due to age and concern for increased toxicity related to comorbidities. We previously demonstrated in the pivotal ZUMA-7 study that older pts with R/R LBCL can safely receive axicabtagene ciloleucel (axi-cel) as second-line (2L) therapy with improved event-free survival (EFS), response rate, and quality of life compared with standard of care (SOC) based on results from the primary EFS analysis (Westin, et al. Clin Cancer Res. 2023). At a median follow-up of 47.2 months (mo), results from the ZUMA-7 primary overall survival (OS) analysis demonstrated superior OS in the intention-to-treat (ITT) analysis (hazard ratio [HR], 0.73; 95% CI, 0.54-0.98; stratified two-sided log-rank P=0.03; Westin, et al. N Engl J Med. 2023; NCT03391466). We now report updated efficacy and safety results from the primary OS analysis among ZUMA-7 pts aged ≥65 years (y) and ≥70 y.

Methods:

Eligible pts were randomized 1:1 to axi-cel or SOC (2-3 cycles of platinum-based chemoimmunotherapy; responding pts proceeded to high-dose chemotherapy with ASCT). The primary OS analysis occurred 5 y after the first pt was randomized (01/25/2018) per protocol. Other endpoints included progression-free survival (PFS) per investigator assessment and safety. A planned subgroup analysis of pts aged ≥65 y was conducted in addition to an analysis for those ≥70 y. Multivariate analyses were performed to examine treatment efficacy with axi-cel compared with SOC after adjusting for multiple covariates, including sex, disease type, molecular subgroup, lactate dehydrogenase (LDH), tumor burden, and age; strata for these analyses included second-line age-adjusted International Prognostic Index (aaIPI), and relapsed vs refractory disease. Exploratory analyses were conducted to determine the association between OS and axi-cel product characteristics for pts aged ≥65 y.

Results:

A total of 109 pts were included in the analysis (axi-cel: 51 were ≥65 y, 26 of whom were ≥70y, maximum age was 80 y; SOC: 58 were ≥65 y, 27 of whom were ≥70 y, maximum age was 81y). Compared with SOC pts at baseline, more axi-cel pts had high-risk features, including aaIPI 2-3, elevated LDH, and high-grade B-cell lymphoma. At a median follow-up of 46.6 mo, OS was prolonged in the axicel vs SOC arm in pts aged ≥65 y (HR, 0.691; 95% CI, 0.401-1.190) and for those ≥70 y (HR, 0.330; 95% CI, 0.135-0.809). Similar results were observed using the piecewise Cox regression model. The median OS for axi-cel and SOC pts was 43.5 mo (95% CI, 20.9-not estimable [NE]) and 19.6 mo (95% CI, 12.3-NE), respectively, among those aged ≥65y, and 24.7 mo (95% CI, 12.8-NE) and 11.2 mo (95% CI, 6.1-NE), respectively, among those aged

≥70 y. In the SOC arm, 57% and 52% of pts received subsequent cellular immunotherapy off protocol in pts aged ≥65 y and ≥70 y, respectively. Multivariate analyses demonstrated an even greater OS benefit with axi-cel over SOC when adjusting for differences in baseline characteristics in pts aged ≥65 y (HR, 0.526; 95% CI, 0.266-1.041) and in pts aged ≥70 y (HR, 0.184; 95% CI, 0.045-0.755). PFS assessed by investigator confirmed benefit of axi-cel over SOC in pts aged ≥65 y (HR, 0.406; 95% CI, 0.230-0.715) and in pts aged ≥70 y (HR, 0.206; 95% CI, 0.078-0.547). The median PFS for axi-cel and SOC pts was 28.7 mo (95% CI, 5.1-NE) and 5.0 mo (95% CI, 2.8-7.2), respectively, for those aged ≥65 y, and 11.4 mo (95% CI, 4.1-NE) and 2.7 mo (95% CI, 1.7-5.0), respectively, for those aged ≥70 y. No new treatment-related deaths occurred since the primary EFS analysis. There were no manufacturing failures for any pt who underwent leukapheresis. Similar associations between product characteristics and outcomes were observed among the elderly and overall populations, including improved OS associated with a greater (>median) proportion of juvenile or stem memory T-cell phenotype cells (CCR7+CD45RA+ T cells) in the axi-cel product among pts aged ≥65 y (HR, 0.369; 95% CI, 0.138-0.984).

Conclusion:

Axi-cel as 2L therapy prolonged survival over SOC in pts aged ≥65 y, including in pts aged ≥70y. These findings confirm that age alone should not be a barrier for consideration of CAR T-cell therapy, supporting the use of axi-cel as a curative-intent 2L therapeutic option for older pts with R/R LBCL.

Figure 1: Overall Survival of Axi-cel vs Standard of Care Patients Aged ≥65 Years

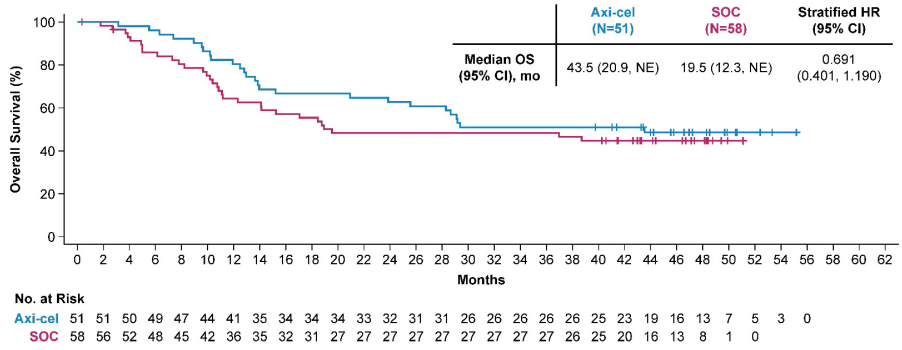
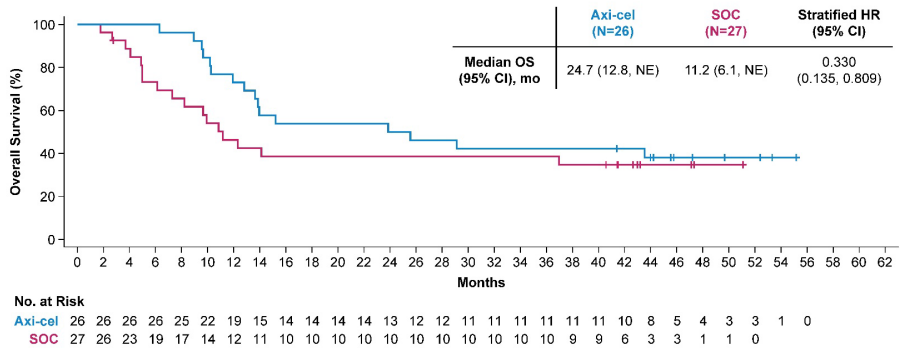


Figure 2: Overall Survival of Axi-cel vs Standard of Care Patients Aged ≥70 Years



Axi-cel, axicabtagene ciloleucel; CI, confidence interval; HR, hazard ratio; NE, not estimable; No., number; OS, overall survival; SOC, standard of care.

Disclosures:

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