



The 65th ASH Annual Meeting Abstracts

POSTER ABSTRACTS

705.CELLULAR IMMUNOTHERAPIES: LATE PHASE AND COMMERCIALY AVAILABLE THERAPIES

An Updated Comparison of Clinical Outcomes from 4-Year Follow-up of Zuma-5 (Axicabtagene Ciloleucel) and the International Scholar-5 External Control Cohort in Relapsed/Refractory Follicular Lymphoma

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Introduction: Axicabtagene ciloleucel (axi-cel; an autologous anti-CD19 chimeric antigen receptor T-cell therapy), led to durable responses in relapsed/refractory (R/R) follicular lymphoma (FL) in the pivotal ZUMA-5 trial. When 3-year efficacy data from ZUMA-5 were compared to the SCHOLAR-5 external control cohort (ASH 2022, Ghione et al.), axi-cel showed a substantial improvement in clinical endpoints including overall response rate, complete response, progression-free survival (PFS), time-to-next treatment (TTNT), and overall survival (OS). Here we provide an updated analysis of this comparison using an additional 12-months of follow-up data for ZUMA-5.

Methods: SCHOLAR-5 is an international, external control cohort of R/R FL patients who initiated a ≥ 3 rd line of therapy (LoT) after July 2014. Patients were recruited from seven institutions in five countries. In addition, patients initiating therapy after receiving idelalisib in the pivotal DELTA trial were included. ZUMA-5 eligibility criteria were applied to SCHOLAR-5 patients, and propensity score and standardized mortality ratio weighting were used to balance prognostic factors between both cohorts. A standardized mean difference (SMD) of < 0.1 was considered as balanced. Kaplan-Meier (KM) curves and weighted Cox proportional hazards models were used to evaluate OS, PFS, and TTNT. Best response did not change with longer follow-up, so is not included in the updated analysis.

Results: Following propensity score weighting, 143 patients from SCHOLAR-5 were reduced to 129 patients and were compared to the 127 patients from the intention-to-treat population of ZUMA-5. Median follow-up times for each cohort were 26.2 and 47.6 months, respectively. Progression of disease within 24 months of initiation of first-line chemoimmunotherapy (POD24), number of prior LoT, R/R to prior LoT, prior stem cell transplant, size of largest nodal mass, response to prior LoT, and time since last therapy were successfully balanced (SMD < 0.1).

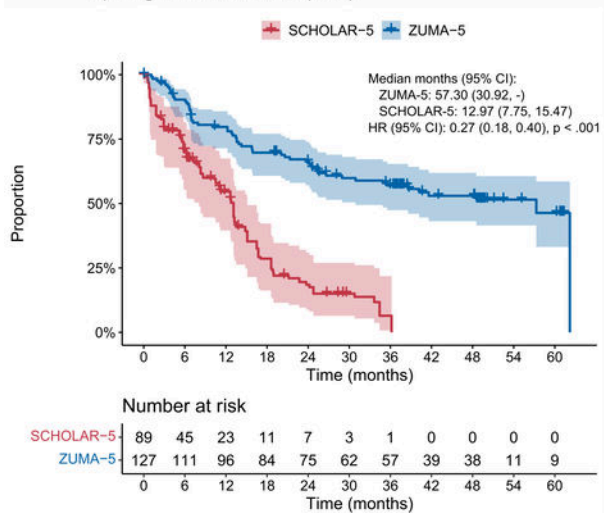
The median PFS was 57.3 months in ZUMA-5 compared to 13.0 months in SCHOLAR-5 (Figure 1a, hazard ratio [HR]: 0.27, 95% confidence interval [CI]: 0.18-0.40), and median TTNT was 62.2 months compared to 26.6 months (HR: 0.62, 95%CI 0.40-0.95), respectively. Median OS was not reached in ZUMA-5 or SCHOLAR-5 (Figure 1b, HR: 0.58, 95% CI: 0.35-0.96). At 48 months, PFS was 53.0% (95% CI: 43.1-61.9) in ZUMA-5 but was not evaluable in SCHOLAR-5, as all patients had progressed or been censored. Forty-eight-month TTNT was 56.6% (95% CI: 47.4-64.8) in ZUMA-5 compared to 41.9% (95% CI: 28.7-55.0) in SCHOLAR-5. Forty-eight-month OS was 72.4% (95% CI: 63.6-79.4) in ZUMA-5 compared to 61.4% (95% CI: 49.1-73.7) in SCHOLAR-5.

Conclusion: These results demonstrate that axi-cel continues to show superior efficacy for R/R FL compared to other available therapies. The response to axi-cel is durable, and offers a clinically meaningful and significant benefit in PFS, TTNT, and OS. These longer follow-up results are particularly important in this indolent disease, where survival outcomes take time to reach maturity. Axi-cel continues to address an unmet medical need for this population of R/R FL patients.

Disclosures Gribben: *AbbVie:* Consultancy, Speakers Bureau; *Bristol Myers Squibb:* Speakers Bureau; *Novartis:* Consultancy; *AstraZeneca:* Consultancy, Research Funding; *Janssen Pharmaceuticals, Inc:* Consultancy, Research Funding, Speakers Bureau; *Kite, A Gilead Company:* Consultancy, Speakers Bureau. **Ghione:** *AstraZeneca Pharmaceuticals:* Consultancy; *Kyowa Hakko Kirin:* Consultancy; *Secura Bio:* Consultancy; *Kite, A Gilead Company:* Research Funding. **Palomba:** *Garuda Therapeutics:* Honoraria; *MustangBio:* Honoraria; *Rheos:* Honoraria; *Seres Therapeutics:* Honoraria, Patents & Royalties; *Thymofox:* Honoraria; *Ceramedix:* Honoraria; *SyntheKine:* Honoraria; *Novartis:* Honoraria; *Cellectar:* Honoraria; *Pluto Immunotherapeutics:* Honoraria; *Smart Immune:* Honoraria; *Juno:* Honoraria, Patents & Royalties; *Kite:* Honoraria; *BMS:* Honoraria. **Ray:** *Kite, A Gilead Company:* Current Employment, Current holder of stock options in a privately-held company, Other: Current holder of stock in a privately-held company. **Limbrick-Oldfield:** *RainCity Analytics:* Current Employment. **Kanters:** *RainCity Analytics:* Current Employment. **Bobillo:** *Vall d'Hebron University Hospital:* Current Employment; *AstraZeneca, Abbvie:* Honoraria. **Jacobson:** *Axis:* Speakers Bureau; *Clinical Care Options:* Speakers Bureau; *Precision BioSciences:* Consultancy, Honoraria, Other: Travel support; *Nkarta:* Consultancy, Honoraria; *Humanigen:* Consultancy, Honoraria, Other: Travel support; *AbbVie:* Consultancy, Honoraria; *Daiichi Sanko:* Consultancy, Honoraria; *ImmPACT Bio:* Consultancy, Honoraria; *Instil Bio:* Consultancy, Honoraria; *Bluebird Bio:* Consultancy, Honoraria; *Epizyme:* Consultancy, Honoraria; *Ispen:* Consultancy, Honoraria; *Lonza:* Consultancy, Honoraria, Other: Travel support; *Celgene:* Consultancy, Honoraria, Other: Travel support; *Novartis:* Consultancy, Honoraria, Other: Travel support; *Bristol Myers Squibb:* Consultancy, Honoraria; *Kite, A Gilead Company:* Consultancy, Honoraria, Research Funding. **Neelapu:** *Fosun Kite:* Consultancy, Other: Advisory board member; *Astellas Pharma:* Consultancy, Other: Advisory board member; *Chimagen:* Consultancy, Other: Advisory board member; *Kite, A Gilead Company:* Consultancy, Other: Advisory Board Member, Research Funding; *Sellas Life Sciences:* Consultancy, Other: Advisory board member; *Incyte:* Consultancy, Other: Advisory board member; *Longbow Immunotherapy:* Current holder of stock options in a privately-held company; *Immunoadoptive Cell Therapy Private Limited:* Consultancy, Other: Scientific Advisory Board; *Bristol Myers Squibb:* Consultancy, Other: Advisory Board Member, Research Funding; *Allogene:* Consultancy, Other: Advisory board member, Research Funding; *SyntheKine:* Consultancy, Other: Advisory board member; *Caribou:* Consultancy, Other: Advisory board member; *Sana Biotechnology:* Consultancy, Other: Advisory board member, Research Funding; *Athenex:* Consultancy, Other: Advisory board member; *Janssen:* Consultancy, Other: Advisory board member; *Morphosys:* Consultancy, Other: Advisory board member; *Carsgen:* Consultancy; *Takeda:* Consultancy, Other: Advisory board member; *Merck:* Consultancy, Other: Advisory Board Member; *Orna Therapeutics:* Consultancy, Other: Advisory board member; *N/A:* Patents & Royalties: Related to cell therapy and the safety switch described (intellectual property); *Precision Biosciences:* Research Funding; *Bluebird Bio:* Consultancy, Other: Advisory board member; *Adicet Bio:* Consultancy, Other: Advisory board member, Research Funding. **Ghesquieres:** *Gilead, Roche:* Consultancy; *Gilead, Roche, Bristol Myers Squibb, AbbVie, Novartis:* Honoraria. **Nikolajeva:** *Gilead Sciences:* Current equity holder in publicly-traded company; *Kite, A Gilead Company:* Current Employment, Other: Travel support. **Yan:** *Kite, A Gilead Company:* Current Employment; *Gilead Sciences:* Current holder of stock options in a privately-held company. **Wang:** *Gilead:* Current Employment, Current holder of stock options in a privately-held company. **Patel:** *Kite, A Gilead Company:* Current Employment, Current holder of stock options in a privately-held company, Other: Current holder of stock in a privately-held company.

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A) Progress-free survival (PFS)



B) Overall survival (OS)

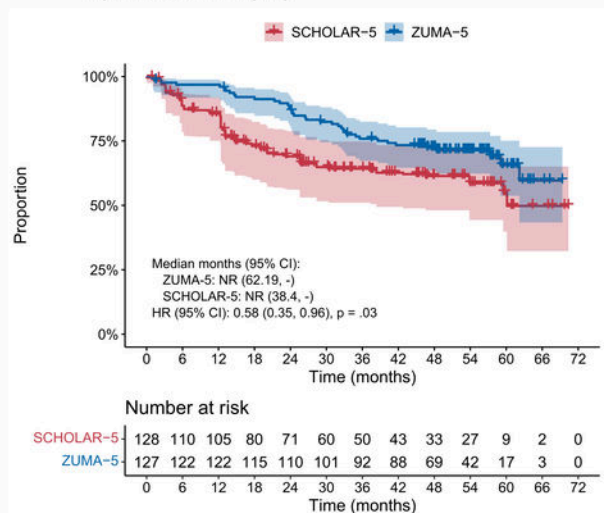


Figure 1

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