CAR T-cell Therapy for B-ALL

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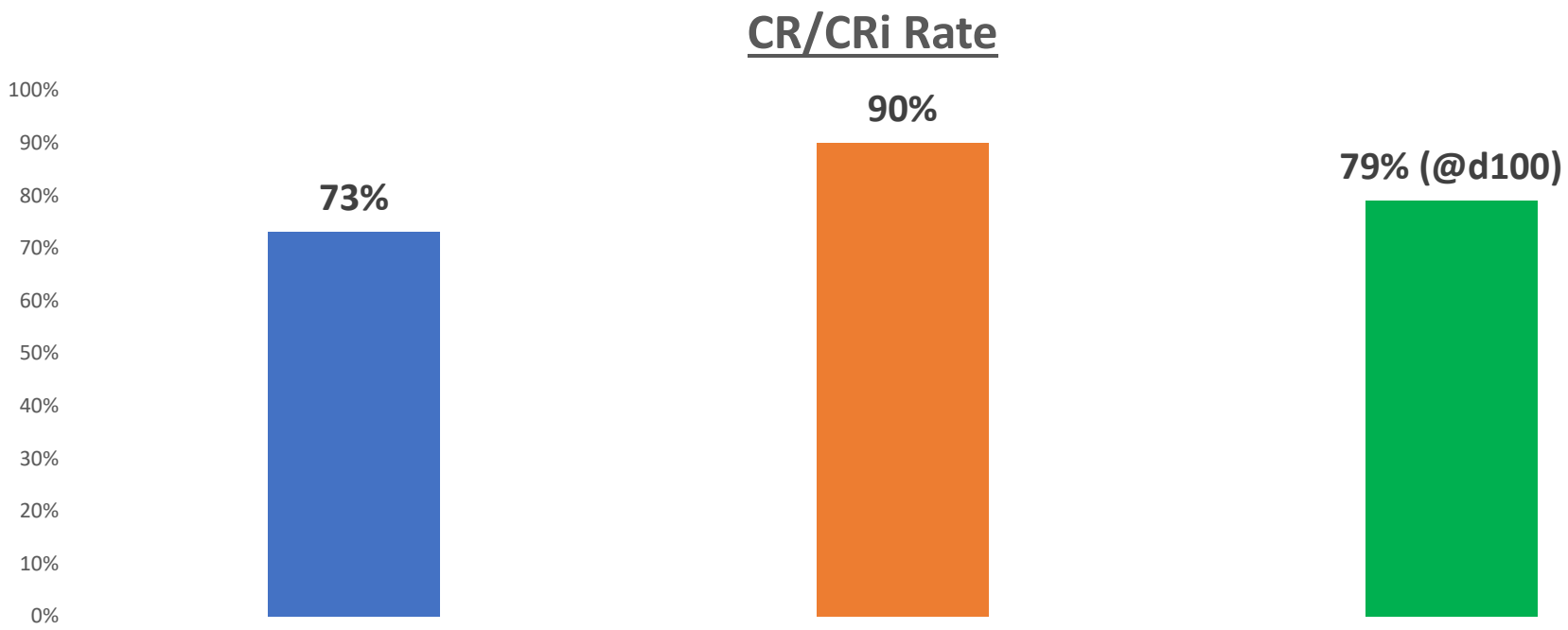
Disclosures

- Consulting & Education:
  - Amgen, Pfizer, Novartis, BMS, Kite/Gilead, Precision Biosciences, Jazz, Beigene, Adaptive, Century Therapeutics, Autolus, Deciphera, Lilly, Takeda, Astra Zeneca
- Grants and Investigator Initiated Trials
  - Kite/Gilead, Jazz, Servier
- Steering Committee
  - PeproMene Bio

ORR in Zuma-3 and in the Post-Approval Setting

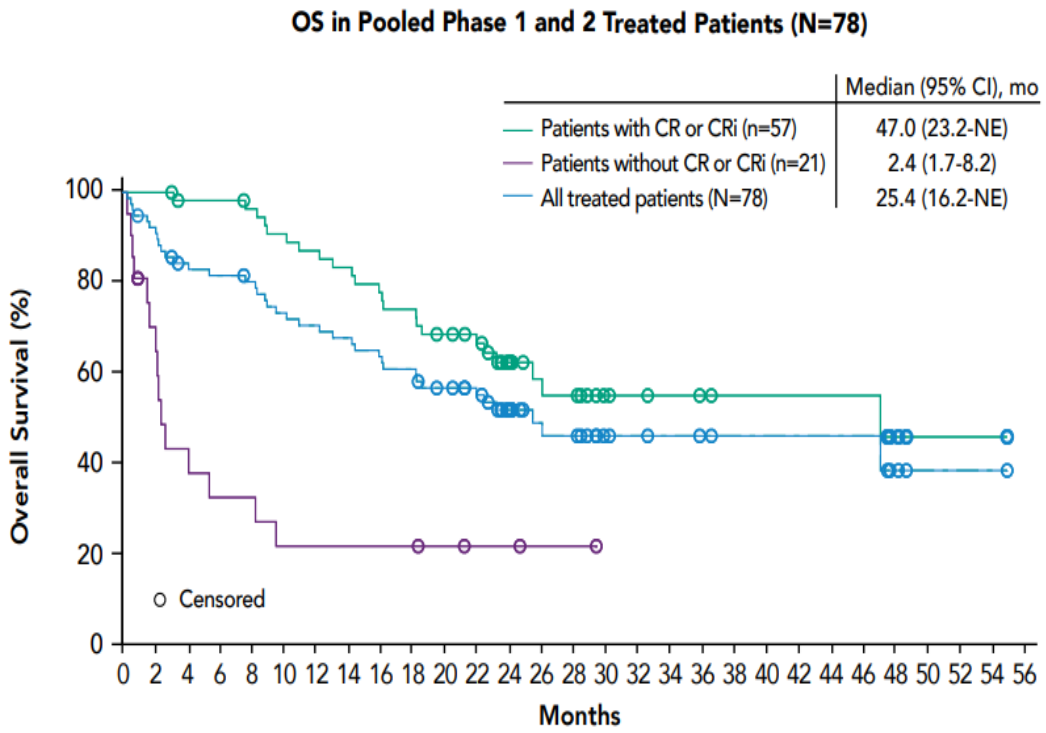


Zuma-3 (n=78)
In CR/CRi: 0%
EMD/CNS2-3: NR/0%
Prior Ino/Blina: 22%/49%
Prio Allo: 37%

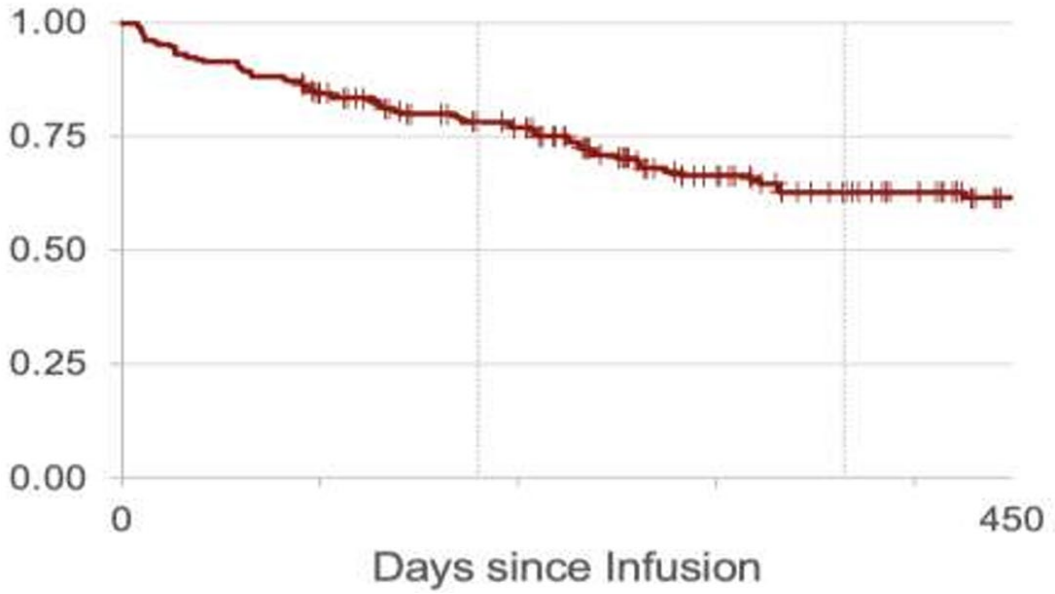
ROCCA (n=189)
In CR/CRi: 42%
EMD/CNS2-3: 23%/19%
Prior Ino/Blina: 48%/59%
Prio Allo: 41%

CIBMTR (n=150)
In CR/CRi: 31%
EMD/CNS2-3: 21%/9%
Prior Ino/Blina: 41%/51%
Prio Allo: 35%

Overall Survival in Zuma-3 and in ROCCA

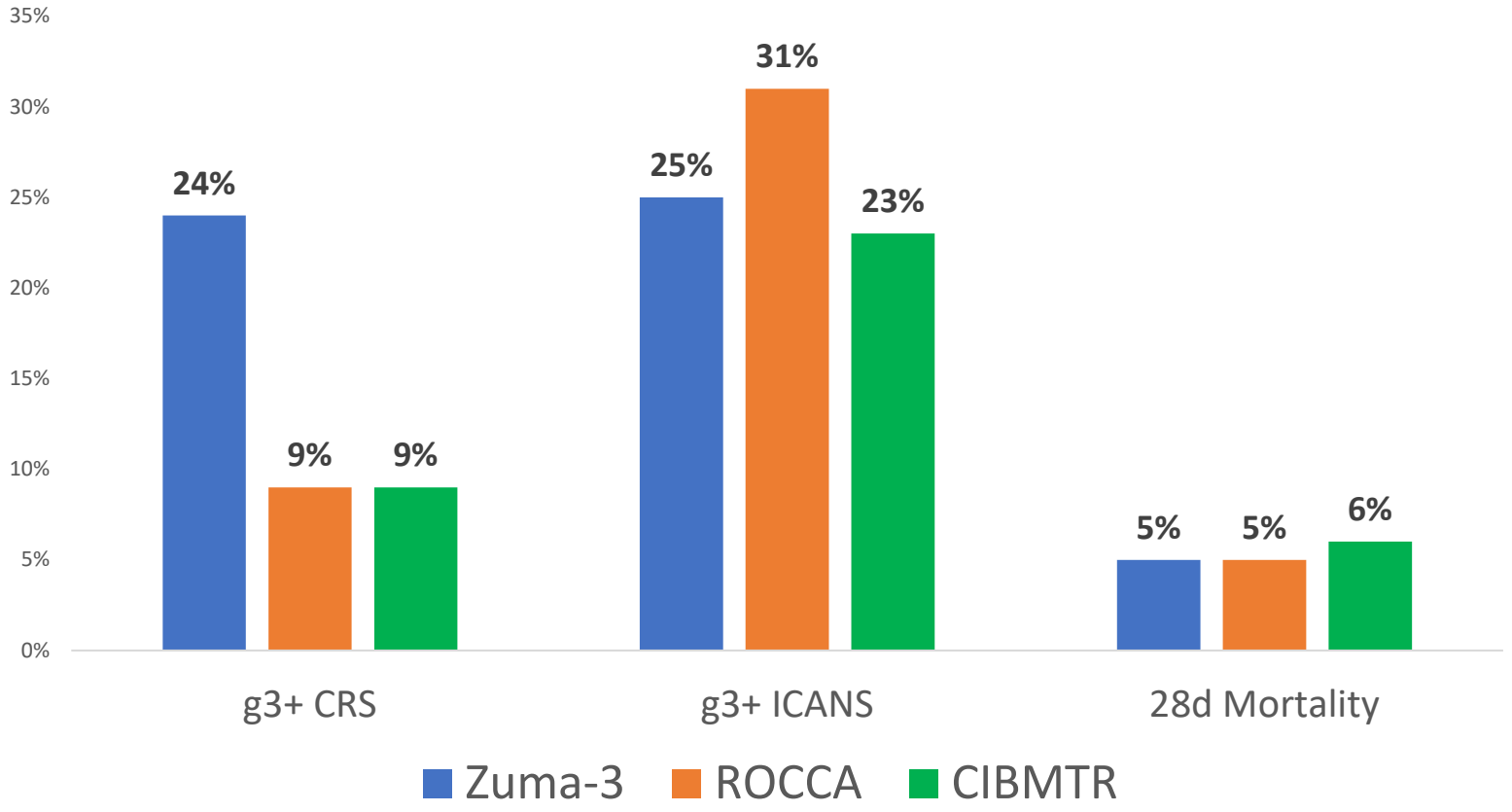


Median FU: 38.8mo, Est 12mo OS: 70%



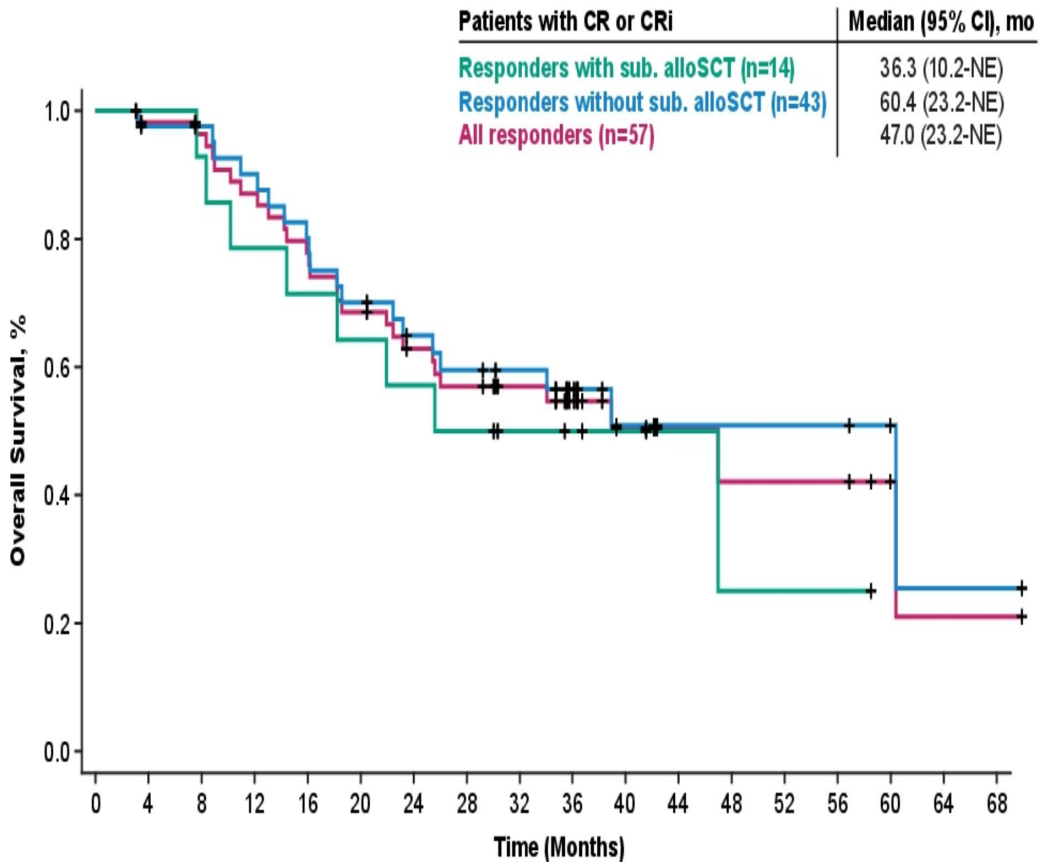
Median FU: 11.4mo, Est 12mo OS: 63%

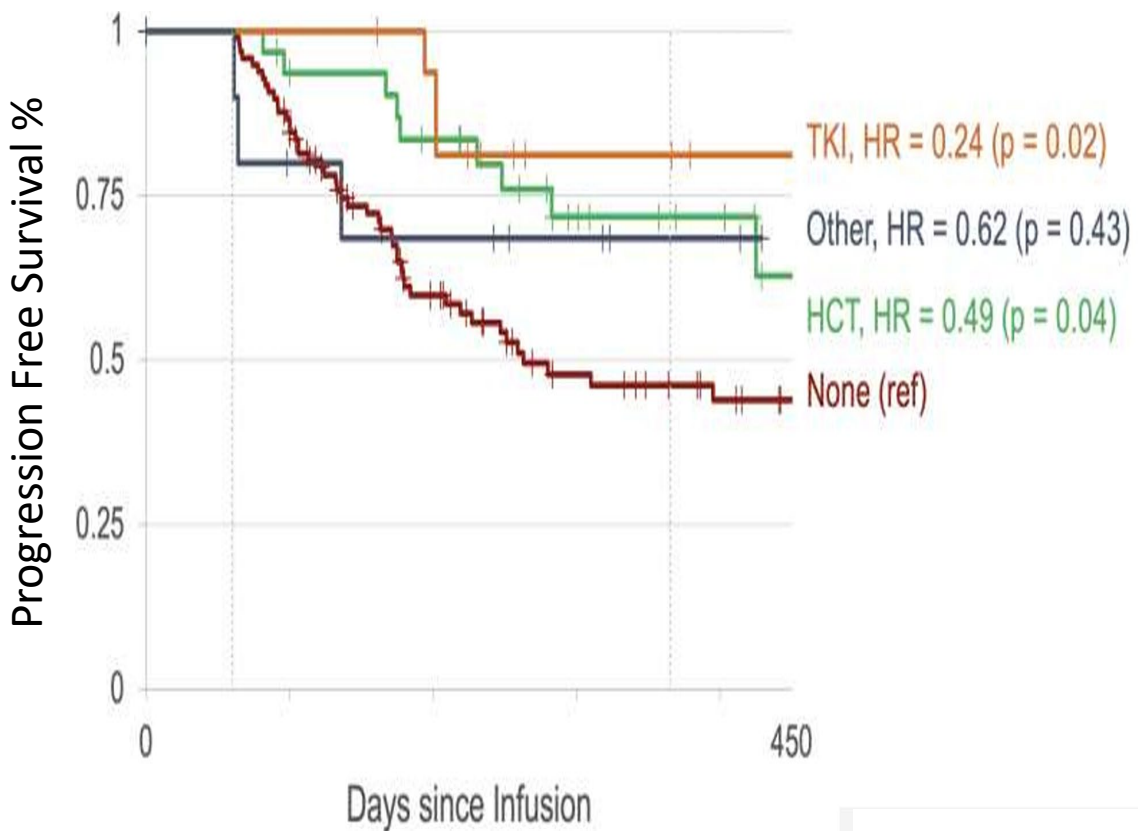
Toxicity Following Brexu-cel



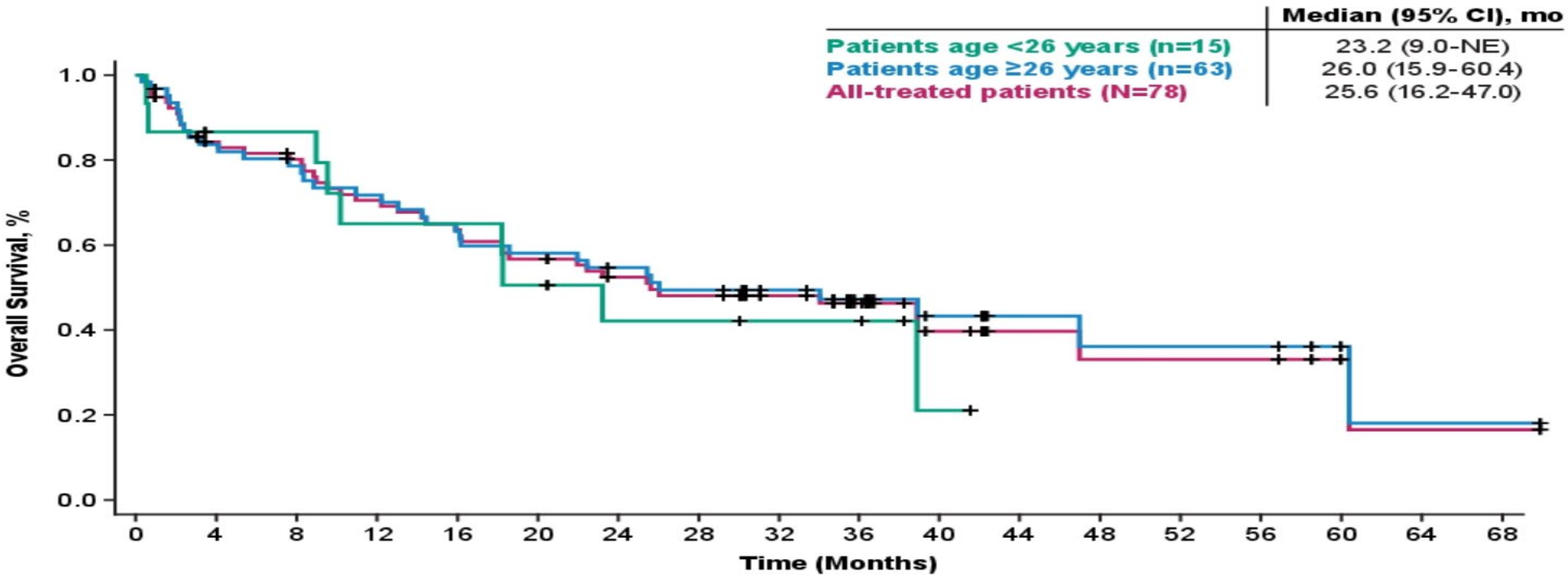
Among those in CR in the CIBMTR Registry, grade 3+ CRS was 0% & grade 3+ ICANS was 15%

AlloSCT Post Brexu-cel on Zuma-3 & ROCCA





Zuma 3: OS with Brexu-cel in AYA

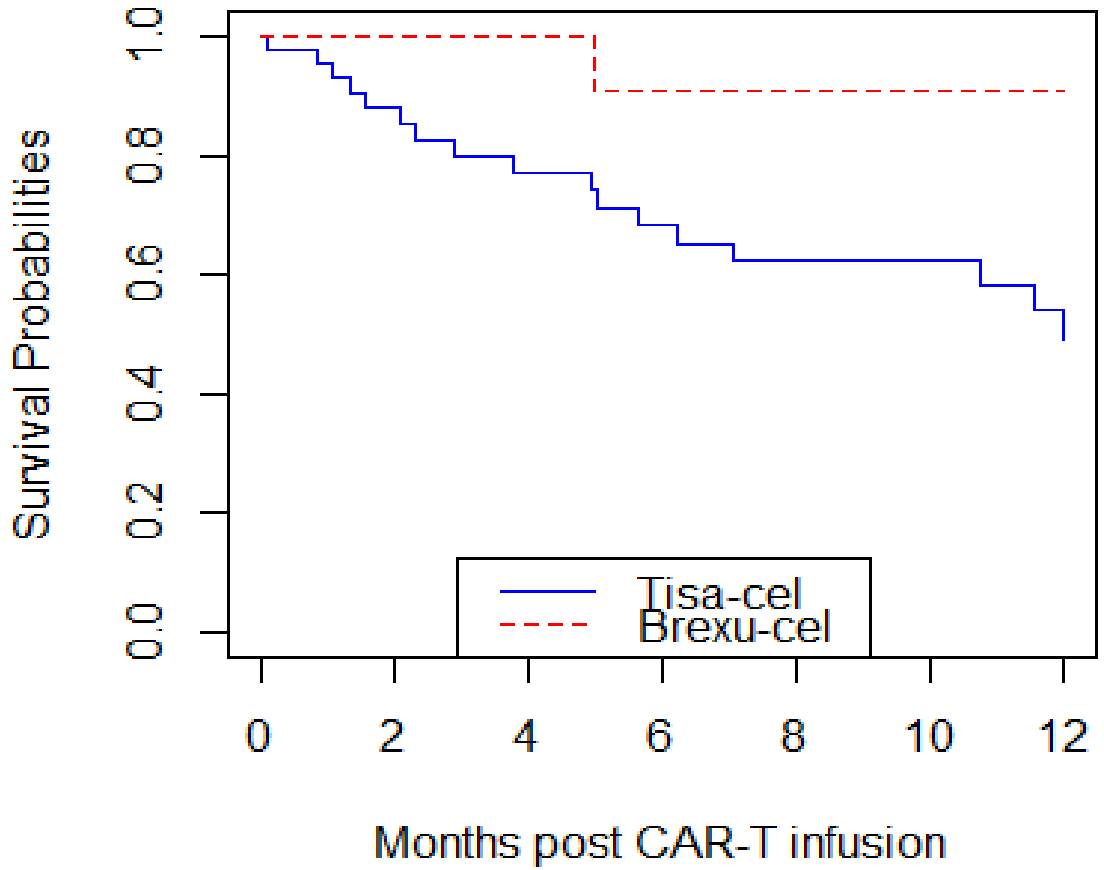


Phase 1 and 2[a,d]	78	57 (73)	47 (60)	10 (13)	6 (8)	12 (15)	18.6 (9.6-24.1)	11.7 (6.1-20.5)
Age								
<26 years	15	11 (73)	9 (60)	2 (13)	1 (7)	1 (7)	14.6 (0.7-NE)	15.5 (0.0-NE)
≥26 years	63	46 (73)	38 (60)	8 (13)	5 (8)	11 (17)	20.0 (9.4-24.1)	11.6 (5.6-22.1)

ROCCA: DOR with Brexu-cel in AYA

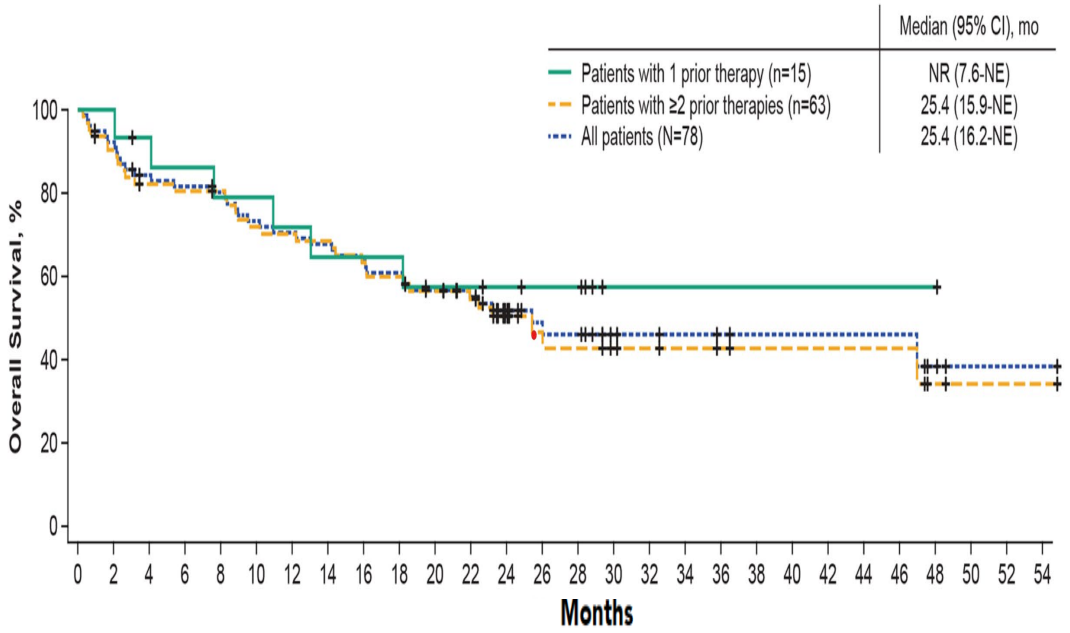
Median Follow-Up	
Tisa-cel (n=44)	Brexu-cel (n=16)
10.5 months (1.1-27.2)	9.7 months (1.7-15.1)

Median duration of remission	
Tisa-cel	Brexu-cel
12mo	Not reached



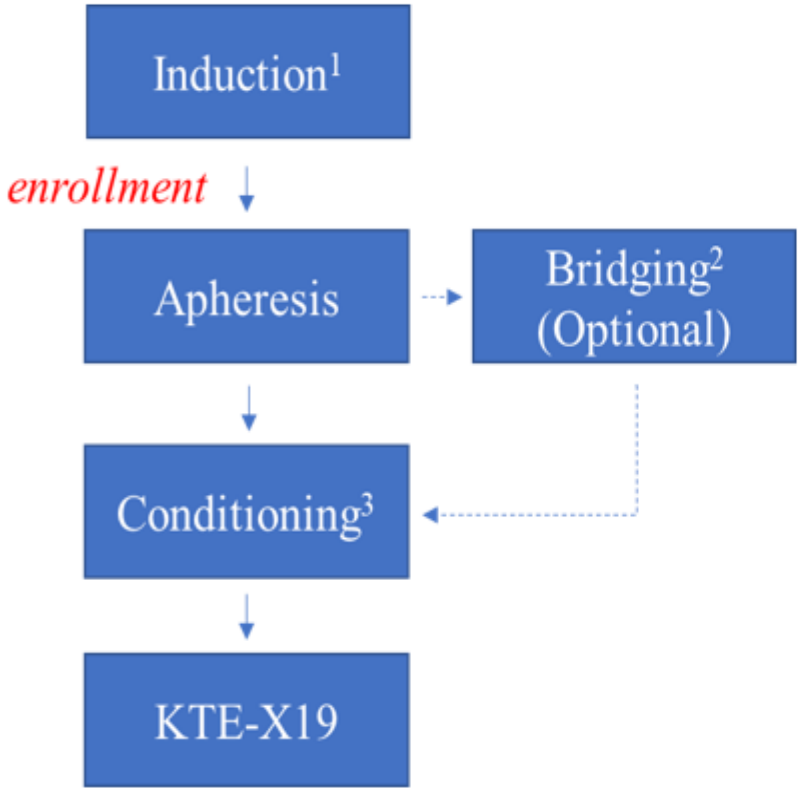
Brexu-cel in Primary Refractory vs Late Relapse

	Line	N	OCR	SCT	Med DOR	Med EFS/RFS	Med OS
Chemotherapy	1st Relapse	1618	40%	28%	-	-	5.8mo
Inotuzumab	1st Relapse		78%	52%	5.8mo	5.4mo	8.6mo
Blinatumomab	1st Relapse	104	51%	29%	10.7mo	1.9mo	11.1mo
Zuma3 (Phase 2)	Refractory, ≥2nd Relapse	55	71%	20%	18.6mo	11.6mo	26mo



Moving Forward

- Earlier integration of CAR with lower disease burden may allow for improved outcomes



[1]Induction options are predefined. Consolidation is not permitted.

[2]Bridging with vincristine and dexamethasone (for PH-) or a TKI (for PH+) is optional only for those with blasts 0.1%-5% post induction. Those with less than 0.1% blasts will be observed.

[3]A bone marrow biopsy with MRD quantification prior to conditioning therapy will be repeated for all patients independent of receipt of bridging therapy.

Summary

- Estimates of efficacy appear consistent with clinical trial data
- Post-approval, a higher percentage of patients are being treated with low marrow burden, which may be associated with improved safety
- Consolidation after Brexu-cel remains an active area of exploration