Subanalysis from Phase 1 Study of Briquilimab (JSP191), an Anti-CD117 Monoclonal Antibody, in Combination with Low Dose Irradiation and Fludarabine Conditioning, Shows Durable Remissions in Older Adults with Acute Myeloid Leukemia in Complete Remission Undergoing Allogeneic Hematopoietic Cell Transplantation (NCT#04429191)

Lori Muffly, MD, MS[1], Catherine J. Lee, MD[2], Arpita Gandhi, MD[3], Ankur Varma, MD, MPH[4], Bart L. Scott, MD[5], Hye-Sook Kwon, PhD[6], Minyoung Youn, PhD[6], Chikako Yanagiba, MS[6], Jeyakavitha Arulprakasam, MS[6], Anne Le, BS[6], Judith A. Shizuru, MD, PhD[1], Wendy W. Pang, MD, PhD[6] and Andrew Artz, MD[7]

(1) Division of BMT and Cellular Therapy, Stanford University School of Medicine, Stanford, CA, (2) Division of Hematology and Hematologic Malignancies, Huntsman Cancer Institute, University of Utah, Salt Lake City, UT, (3) Oregon Health Sciences University, Portland, OR, (4) Division of Hematology, Oncology and Cellular Therapy, Rush University Medical Center, Chicago, IL, (5) Clinical Research Division, Fred Hutchinson Cancer Research Center, Seattle, WA, (6) Jasper Therapeutics, Inc., Redwood City, CA, (7) Department of Hematology/HCT, City of Hope National Medical Center, Duarte, CA

Briquilimab (JSP191) is an investigational agent and not approved for any indication.

Conflict of Interest

Muffly - Advisory Boards: Pfizer, Amgen, Jazz, Medexus, CTI Biopharma, Kite; Research Funding: Astellas, Jasper, Adaptive, Kite, BMS; Consulting: Astellas

Lee - Advisory Boards: Kadmon, Kite, Jazz; Research Funding: Incyte; Consulting: Fresenius

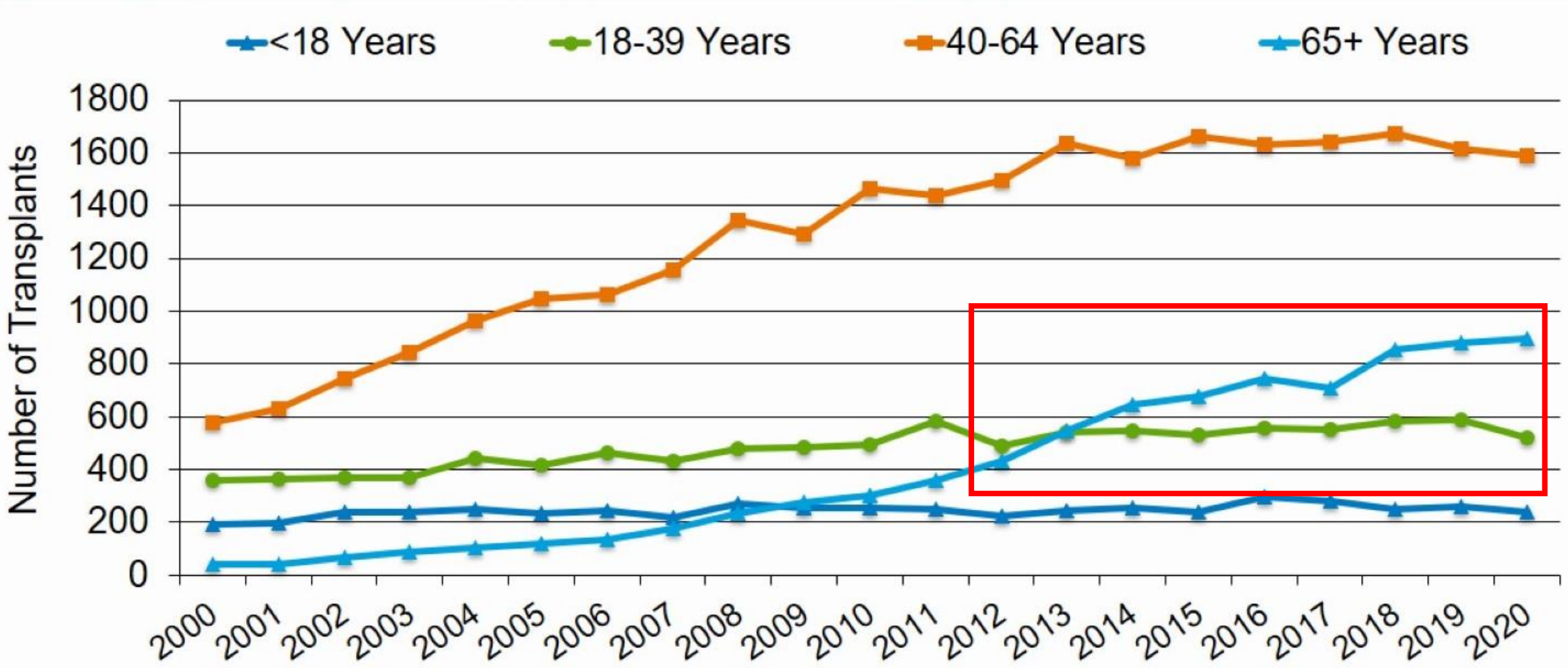
Scott - Advisory Boards: BMS, Alexion, Incyte, Taiho

Kwon, Yanagiba, Arulprakasam, Le, Pang - Employment: Jasper

Shizuru – Board of Directors: Jasper

Artz – Consulting: Magenta, Abbvie

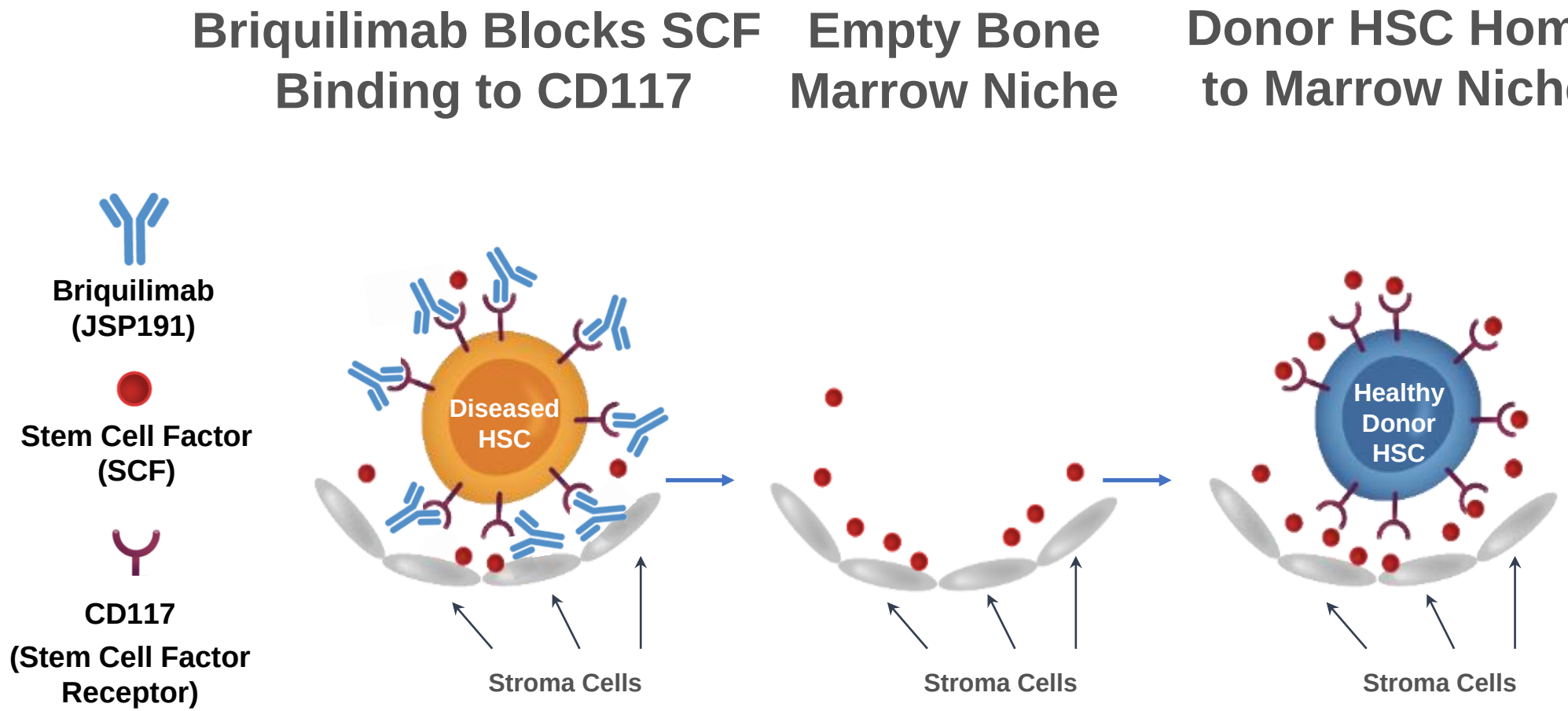
Number of Allogeneic HCTs for AML by Recipient Age in the US



CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Briquilimab Designed to Block CD117 Signaling

Leading to Hematopoietic Stem Cell (HSC) Depletion without Significant Off-Target Toxicities



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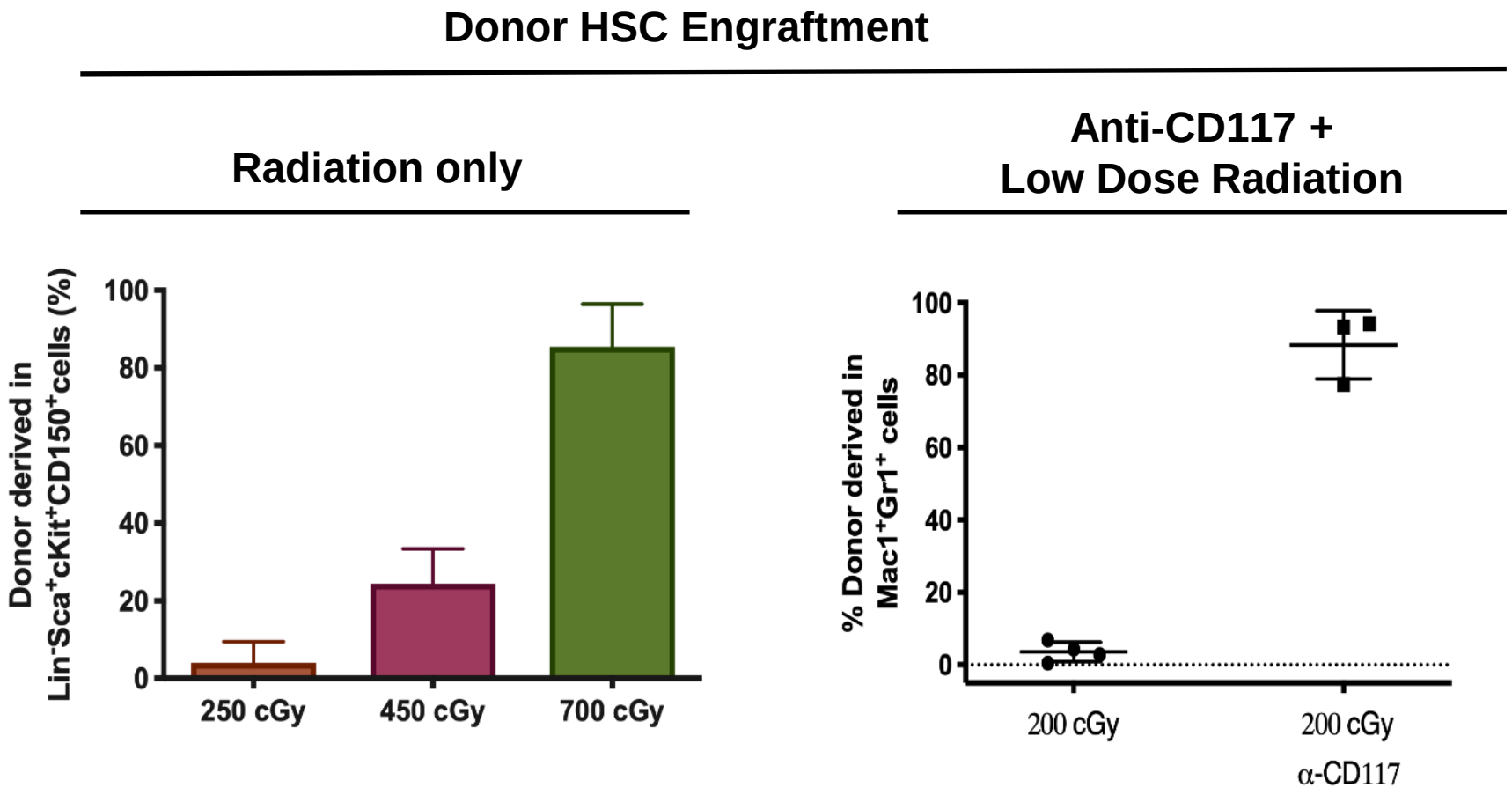
Blockade of CD117 is Synergistic with Low Dose Radiation Leading to Purified Donor HSC Engraftment in Immunocompetent Mouse Model



Chhabra et al. Sci Transl Med 2016; Pang et al. ASH 2019

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Study Design

Single-arm, Open Label, in MDS/AML Patients Not Eligible for Myeloablative Conditioning Regimens

Key inclusion criteria:

- MDS or AML
- ≥60 years or HCT-CI ≥3
- HLA matched related or unrelated donor
- Exclude prior HCT

→ N = 24-40 patients →

Experimental arm:

Briquilimab 0.6 mg/kg
+ **Flu** 30 mg/m^2 x 3 days
+ **TBI** 200-300 cGy
+ HCT

Assessments:

Primary endpoints:

- Safety and tolerability of Briquilimab/TBI/Flu
- Briquilimab PK

Secondary endpoints (follow up to 1 yr):

- Engraftment and donor chimerism
- Relapse-free survival
- GVHD, Non-relapse mortality, and Overall Survival
- MRD clearance

Exploratory endpoints:

- Depletion of HSPCs by briquilimab

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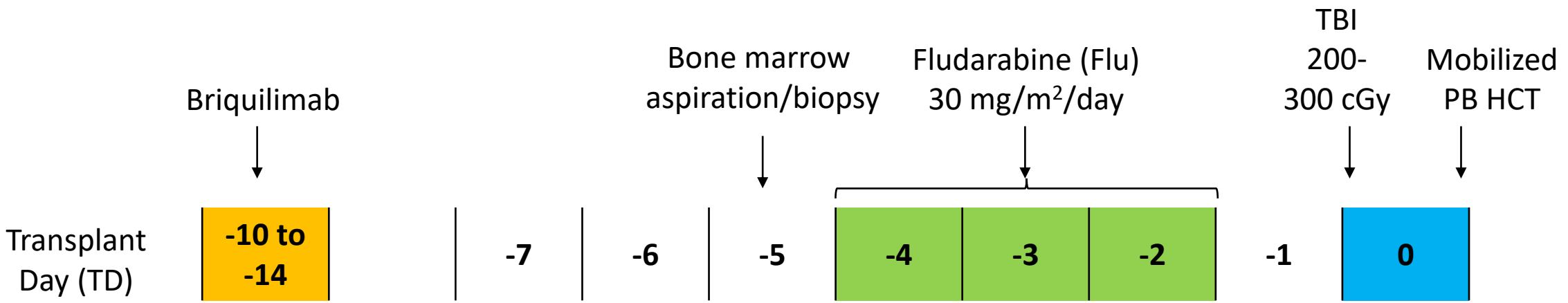
Treatment Schema

Conditioning Regimen



- Real-time PK measurements of briquilimab and modeling were used to determine Flu start date
- TBI increased from 200 to 300 cGy after first 7 subjects (3 AML from CR) to aid lymphoablation
- GVHD prophylaxis: tacrolimus, sirolimus, mycophenolate mofetil (Sandmaier et al, Lancet Haematology 2019)

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Subanalysis of 12 AML Patients with 1-Year Follow-up

Patient Characteristics

Characteristic	Patients with AML (N=12)
Median age (range) - year	70 (62-79)
Sex – no. (%)	
Male	9 (75%)
Female	3 (25%)
Prior AML/MDS Therapy – no. (%)	
Untreated or growth factor supportive care only	0 (0%)
Hypomethylating agent-containing regimens only	5 (42%)
Anthracycline-based regimens (incl. liposomal formulations) only	2 (17%)
Multiple lines of therapy incl. both hypomethylating agent- and anthracycline-based regimens	5 (42%)
Donor Type – no. (%)	
Matched related donor	1 (8%)
Matched unrelated donor	11 (92%)
TBI dose – no. (%)	
200 cGy	3 (25%)
300 cGy	9 (75%)

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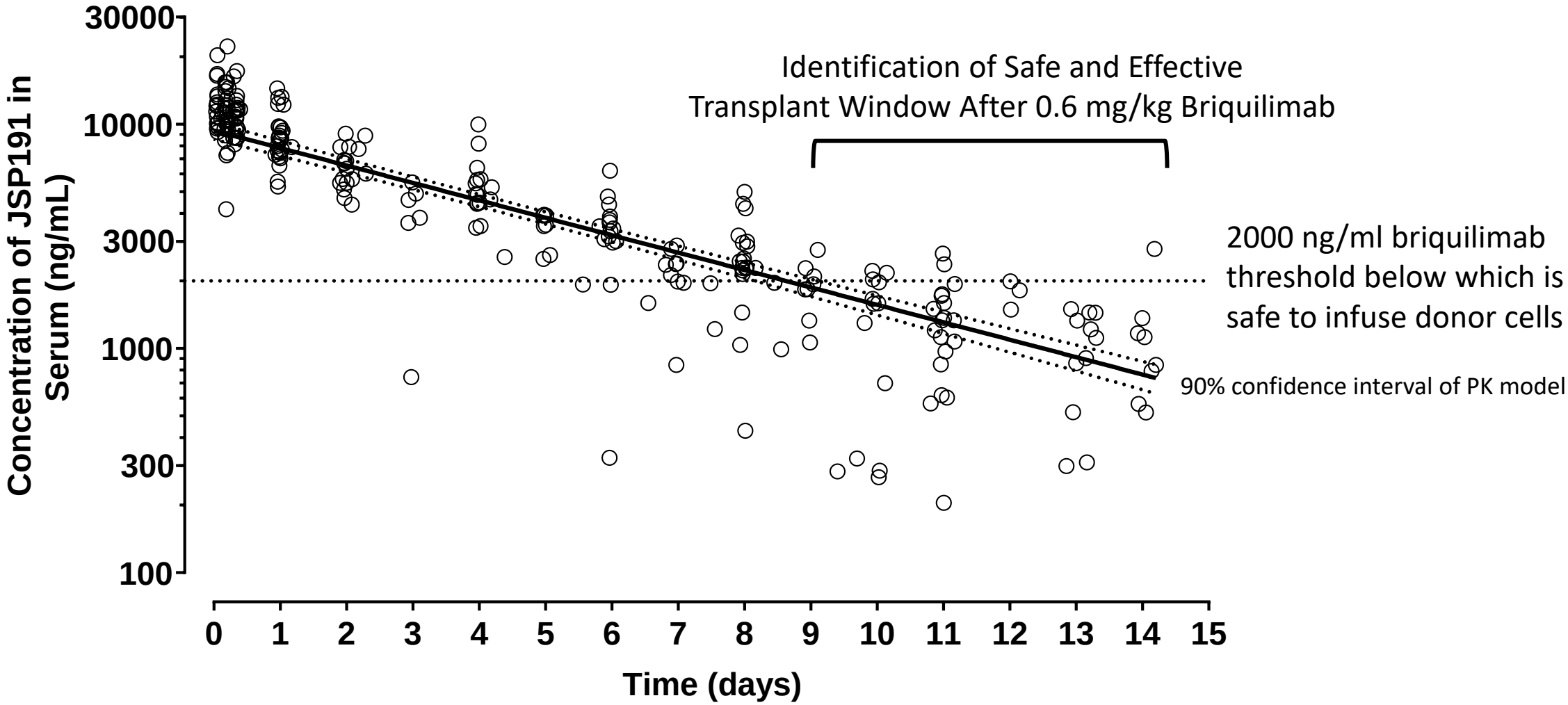
0.6 mg/kg Briquilimab PK: Consistent and Predictable Clearance



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Safety and Tolerability

- No significant briquilimab infusion reactions
- No briquilimab-related SAEs
- No primary graft failure

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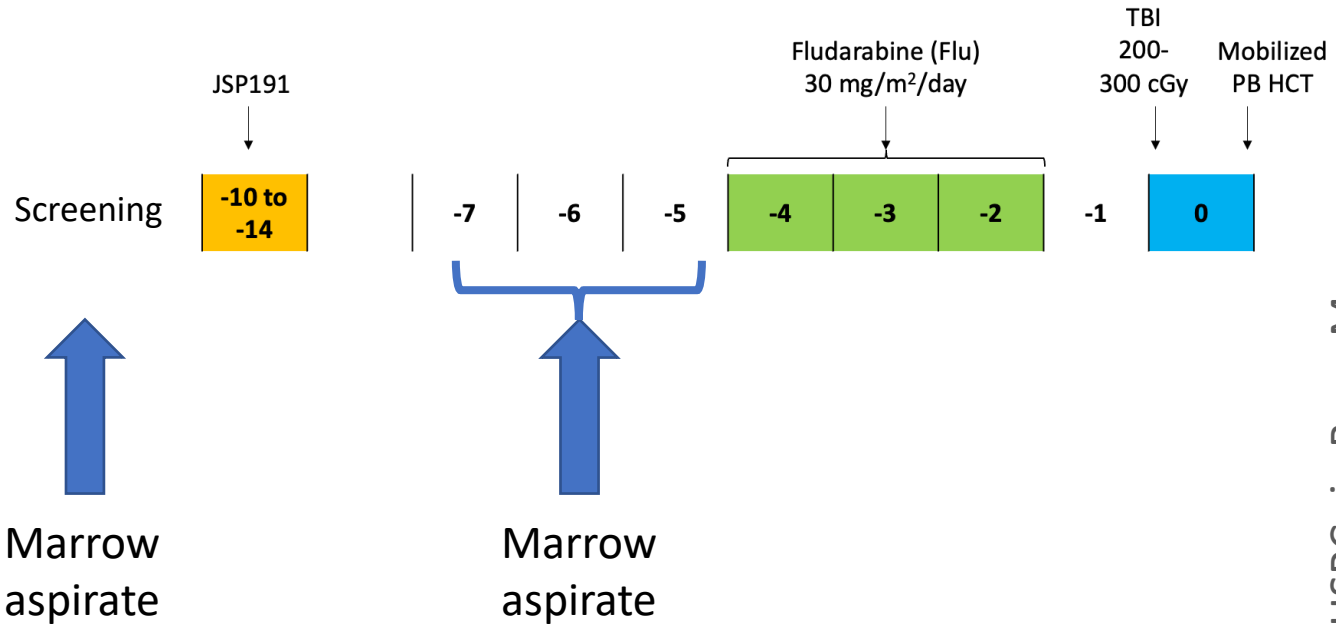
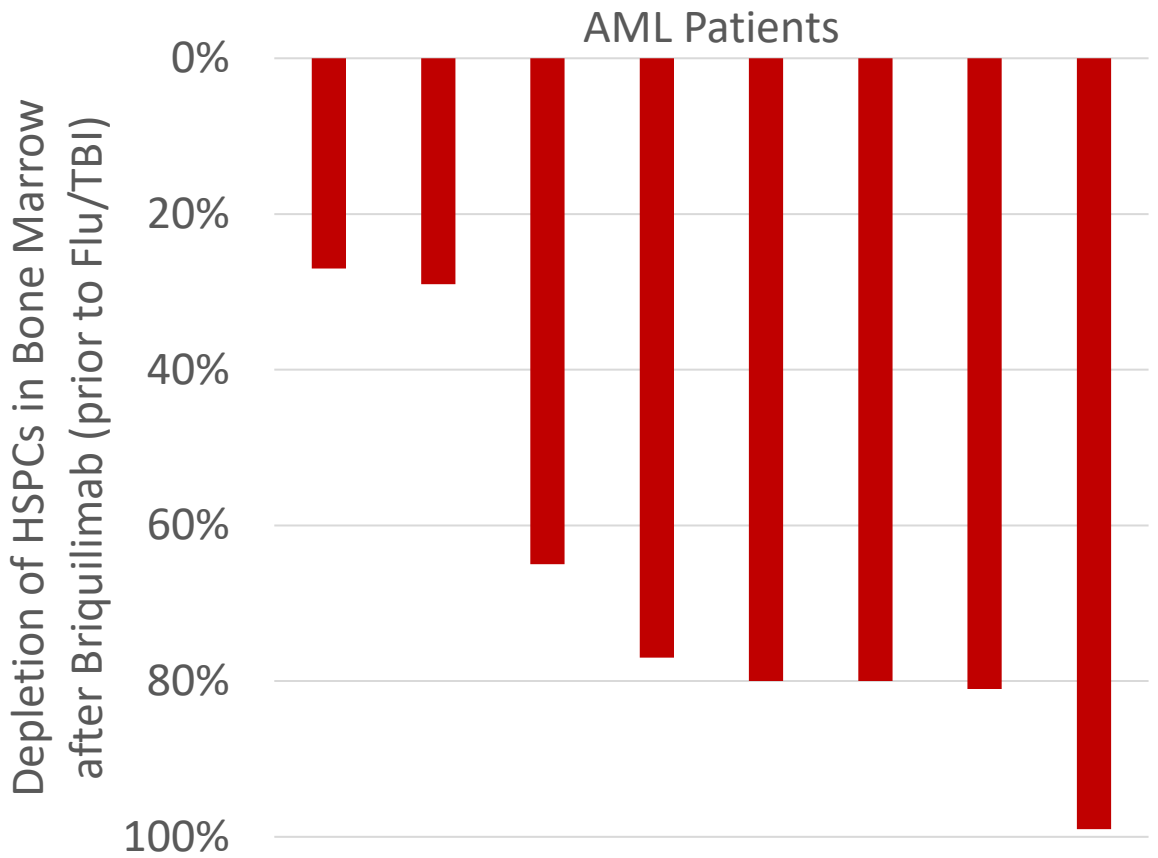
Briquilimab Pharmacodynamics: Evaluation of Briquilimab to Deplete HSPC in Marrow of AML Patients

Marrow aspirates collected at screening and prior to administration of Flu/TBI



Mean HSPC depletion of 67.3 ± 25.9%

(values do not necessarily reflect the nadir of HSPC depletion)



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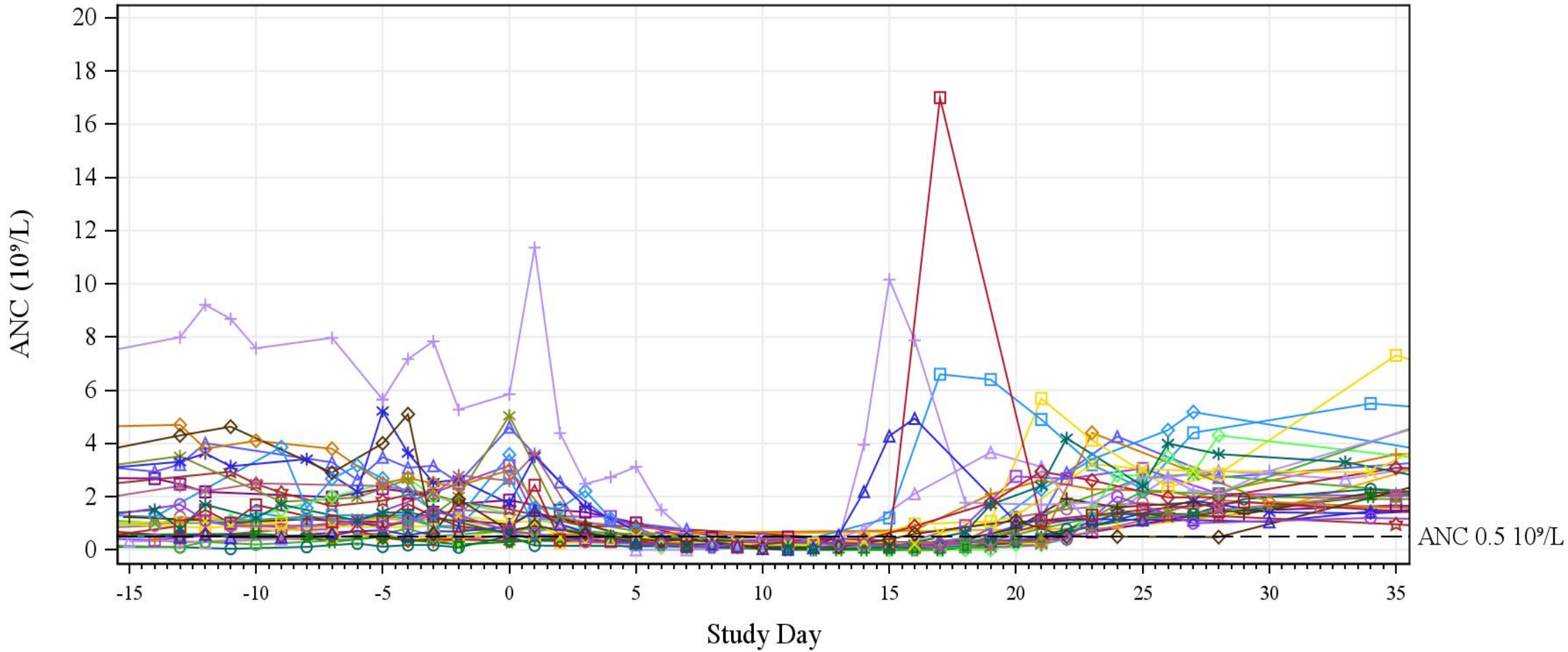
Briquilimab/Flu/TBI Conditioning in All Patients Dosed to Date Resulted in Neutropenia Followed by Neutrophil Engraftment



Median time to neutrophil engraftment: 19 days (range: 13-24 days)

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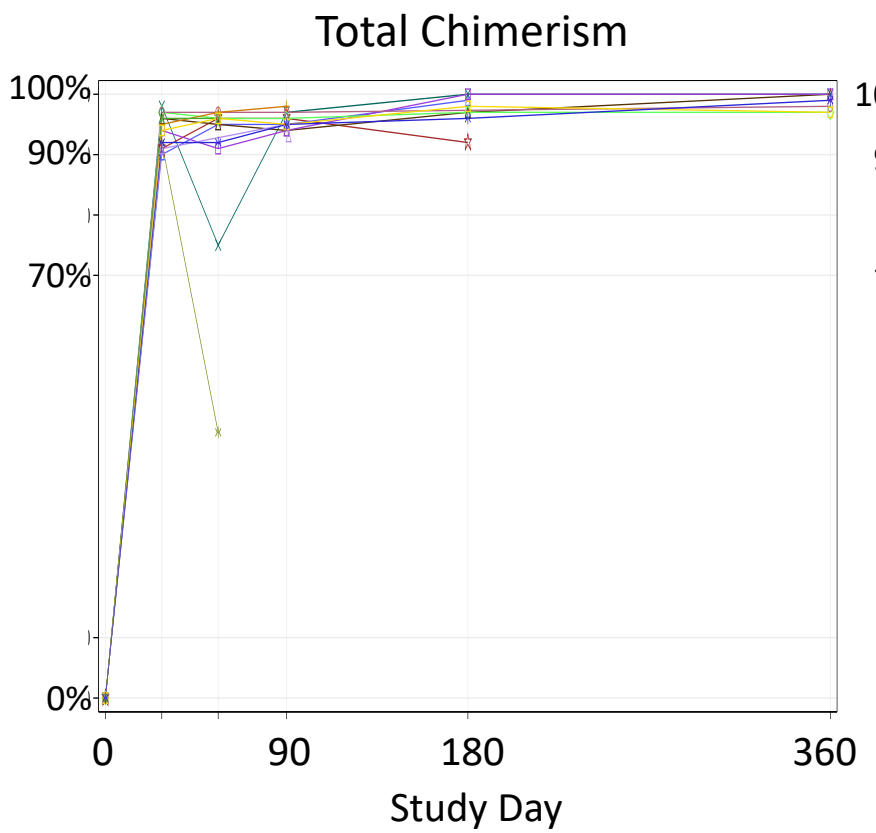
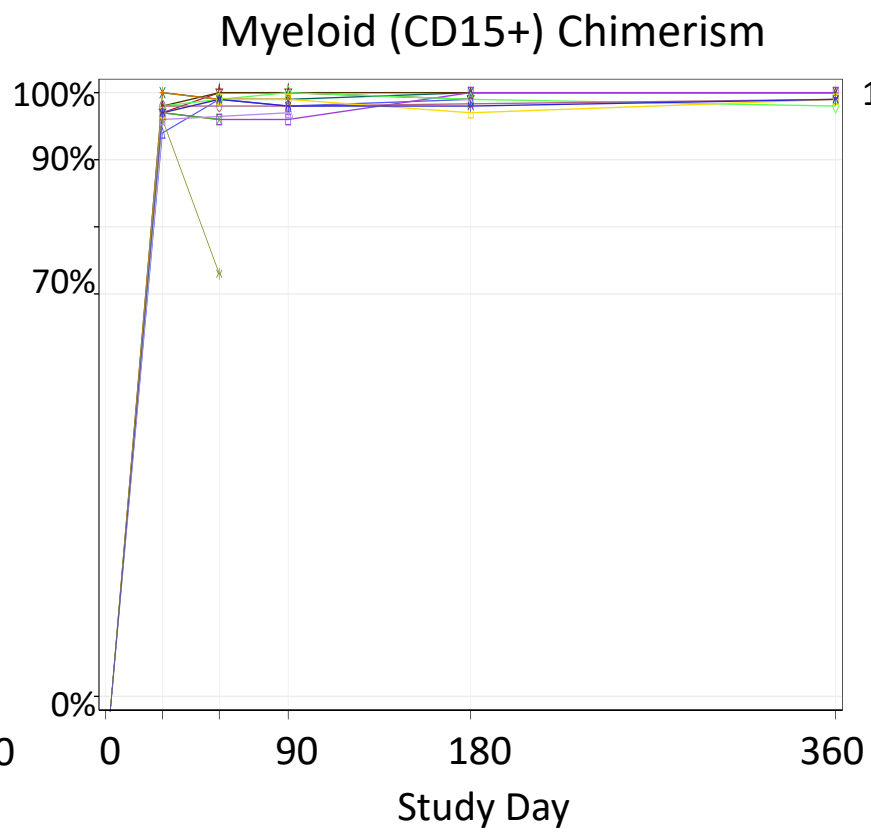
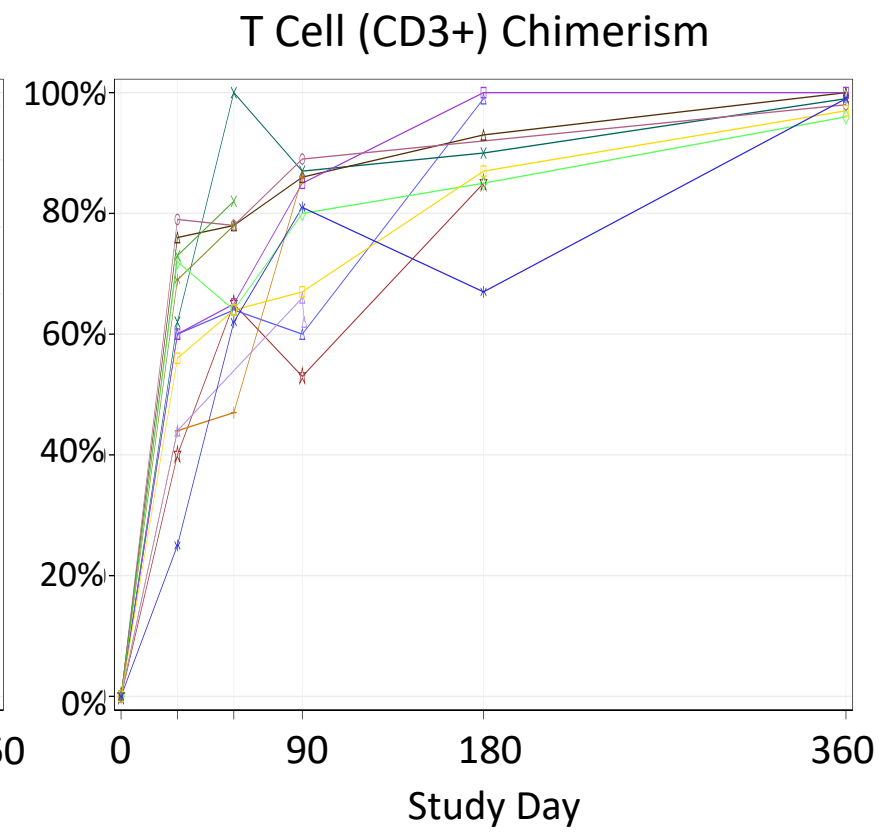
Donor Chimerism in AML Patients

N = 12, complete 1 year follow-up







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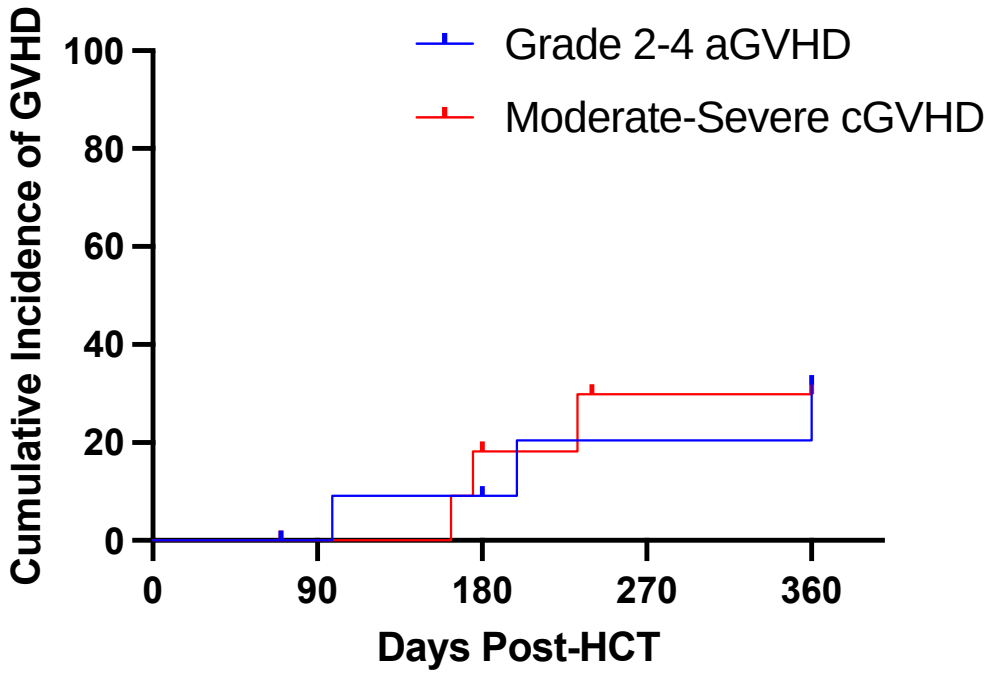
GVHD in AML patients

N = 12, complete 1 year follow-up



	Patients with AML (N=12)
Acute GVHD (per MAGIC)	
Grade 2-4	3 (25%)
Grade 2	2 (17%)
Grade 3	1 (8%)
Grade 4	0 (0%)
Chronic GVHD (per NIH Consensus)	
Mild	0 (0%)
Moderate	4 (33%)
Severe	0 (0%)

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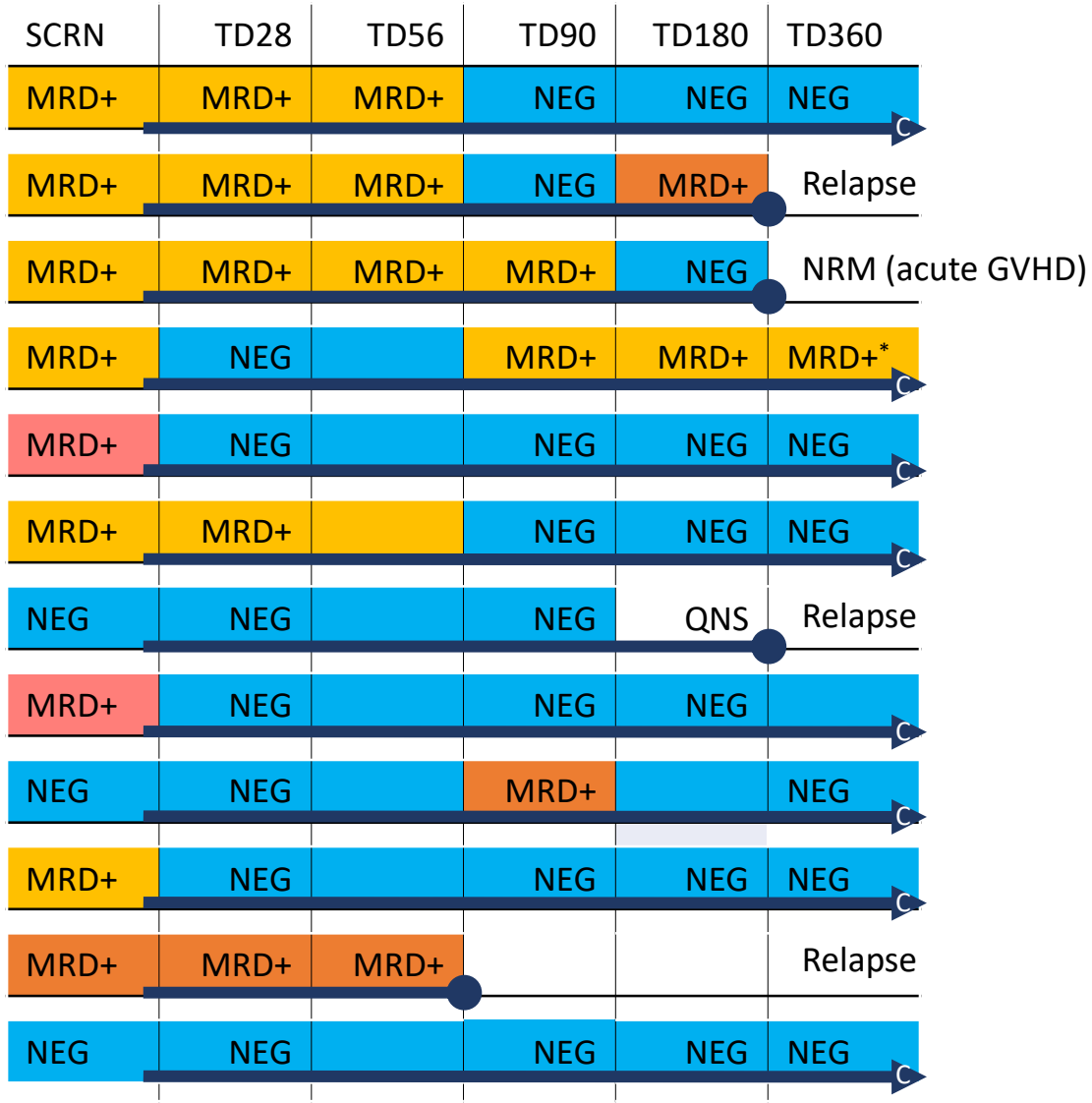
Multimodality Measurable Residual Disease (MRD) in AML patients

Cytogenetics, Flow Cytometry, Next Generation Sequencing



- MRD clearance in 6 of 9 (67%) at last follow-up
- Median time to MRD negativity: 90 days post-HCT
- 8 of 12 (67%) alive and MRD negative @ 1 yr post-HCT

MRD+	By NGS only
MRD+	By Flow only
MRD+	By Flow and NGS
NEG	MRD negative by all assays

* MRD+ for DNMT3A only

C = completed study

= off study

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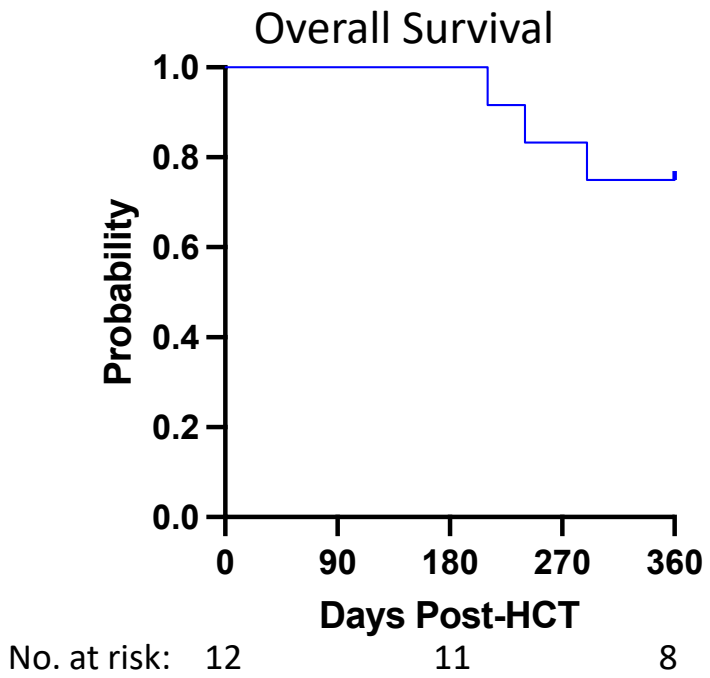
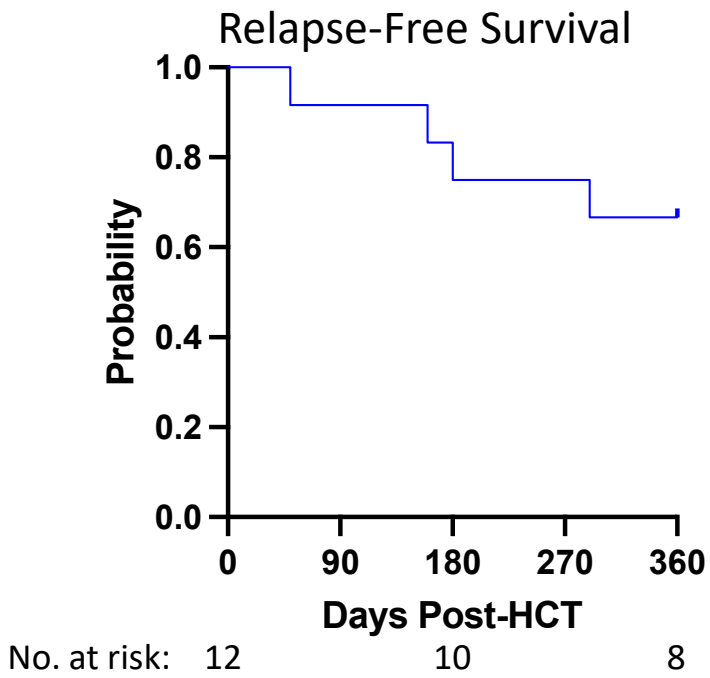
QNS = quantity not sufficient

Outcomes in AML patients

N = 12, complete 1 year follow-up

	Patients with AML (N=12)
Alive without AML @ 1 yr	8 (67%)
Alive and AML MRD negative @ 1 yr	8 (67%)
Alive without AML and off immunosuppression @ 1 yr	6 (50%)





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Summary: Subanalysis of AML Patients (N=12) Enrolled in Phase I Trial with Full 1 Year Follow-up

- 0.6 mg/kg briquilimab demonstrated predictable clearance, allowing safe and effective donor cell infusion 9-14 days after briquilimab
- RFS 67%, OS 75%, NRM 8% @ 1 yr post-HCT, with low rates of GVHD
- 67% alive without evidence of AML MRD @ 1 yr post-HCT
- MRD clearance observed in 6 of 9 patients at last available follow-up, with median time to MRD negativity of 90 days post-HCT
- Briquilimab/Flu/TBI is a novel conditioning regimen that appears safe, well-tolerated, has on target effects on HSPC depletion, permits full donor myeloid chimerism, and results in promising MRD clearance in older AML in CR patients

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Acknowledgements

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We would also like to thank the participating clinical sites, clinical staff, and collaborators.

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