Preliminary Data from a Phase 1 Study of JSP191, an Anti-CD117 Monoclonal Antibody, in Combination with Low Dose Irradiation and Fludarabine Conditioning: Well-Tolerated, Facilitates Chimerism and Clearance of Minimal Residual Disease in Older Adults with MDS/AML Undergoing Allogeneic HCT (NCT#04429191)

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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

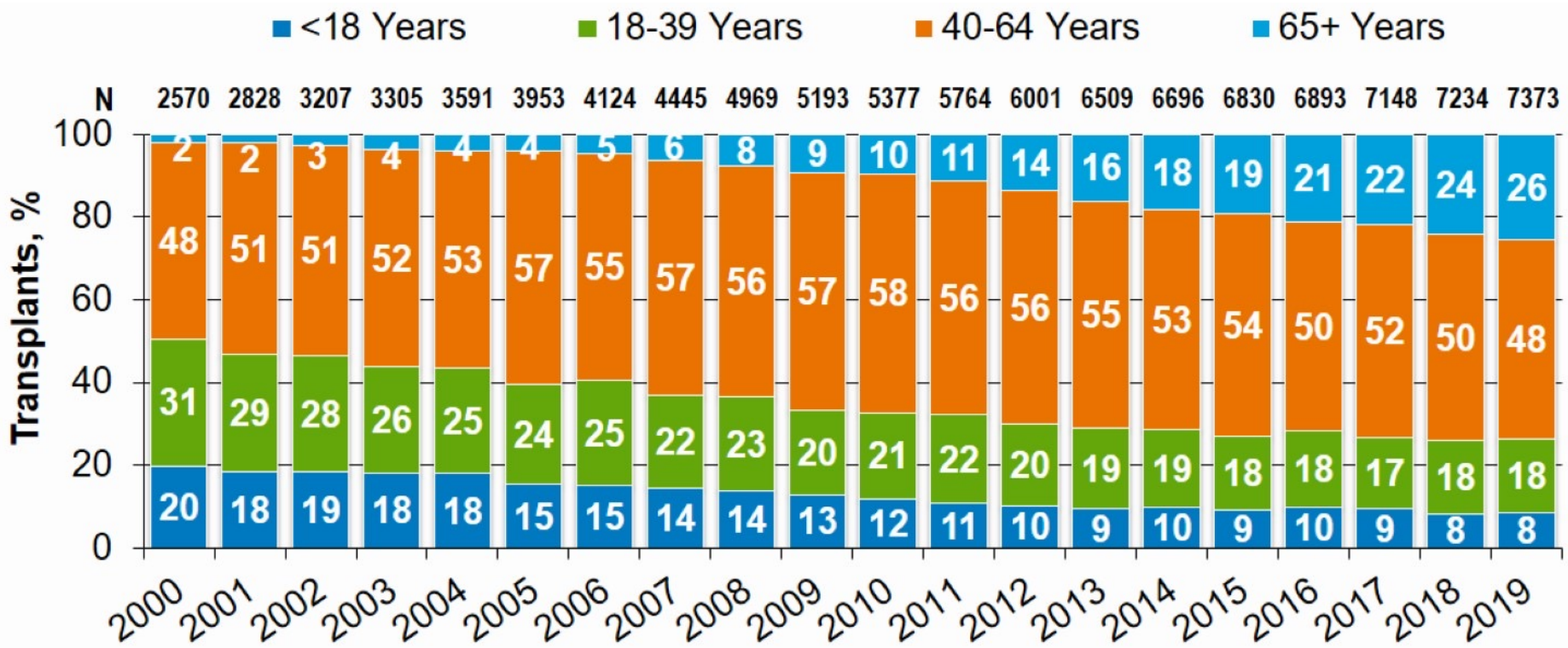
Lee - Advisory Boards: Kadmon, Kite, Jazz; Research Funding: Incyte; Consulting: Fresenius

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

Kwon, Yanagiba, Arulprakasam, Reddy, Heller, Pang - Employment: Jasper

Shizuru - Executive: Jasper; Royalties: FortySeven

Trends in Allogeneic HCT in the U.S. by Age



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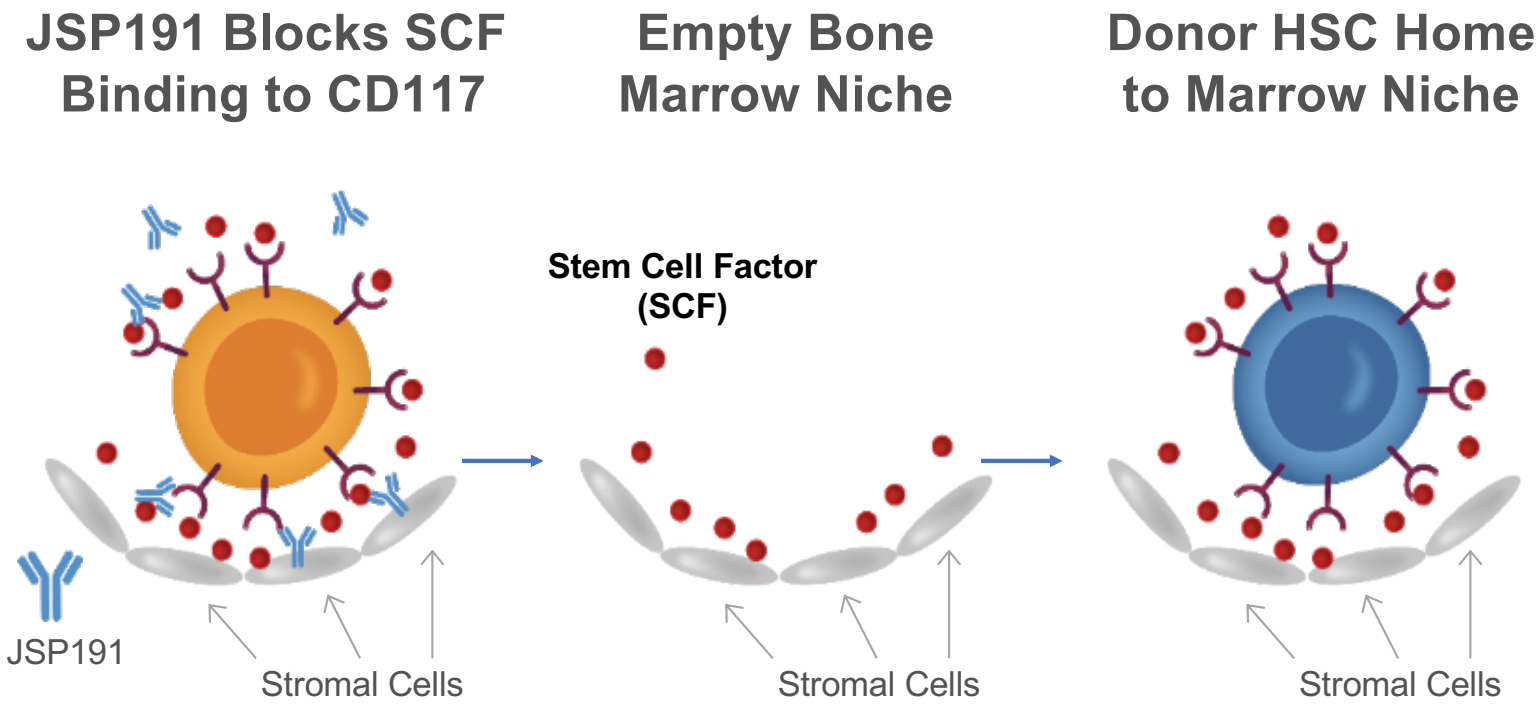
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

^Transplants for AML, ALL, MDS, NHL, HD, MM

JSP191 Designed to Block CD117 (Stem Cell Factor Receptor) Signaling

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



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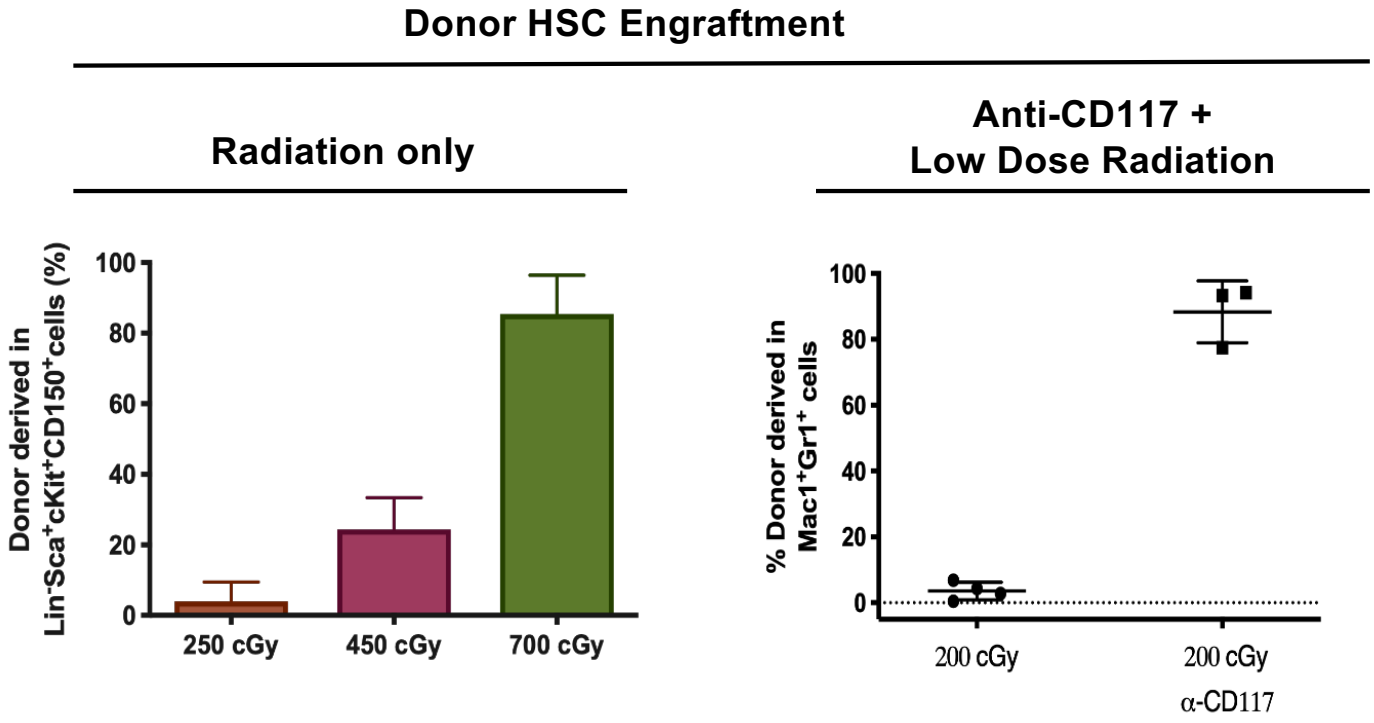
Blockade of CD117 is Synergistic with Low Dose Radiation Leading to Purified Donor HSC Engraftment in Immunocompetent Mouse Model



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:

JSP191 0.6 mg/kg
+ **Flu** 30 mg/m^2 x 3 days
+ **TBI** 200-300 cGy
+ HCT

Assessments:

Primary endpoints:

- Safety and tolerability of JSP191/TBI/Flu
- JSP191 pharmacokinetics

Secondary endpoints:

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

Exploratory endpoints:

- Depletion of HSPCs by JSP191

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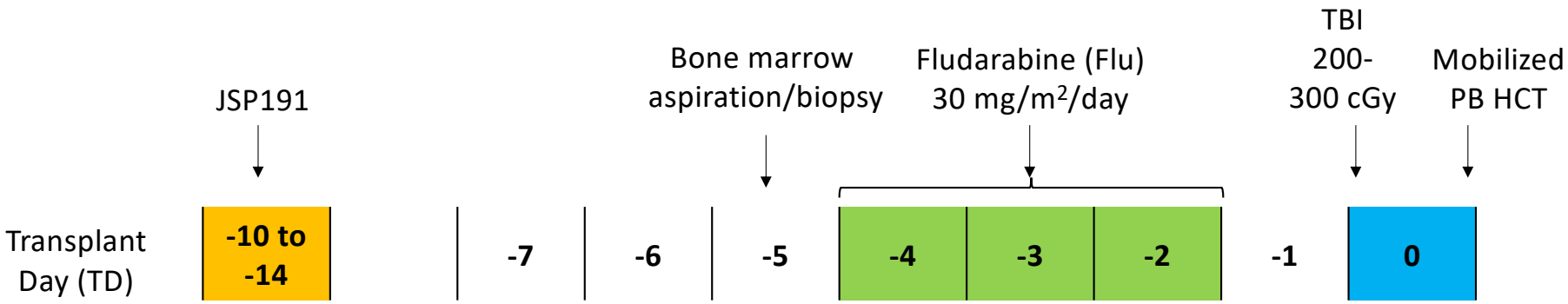
Treatment Schema

Outpatient Conditioning Regimen



- Real-time PK measurements and modeling were used to determine Flu start date
- TBI increased from 200 to 300 cGy after first 7 subjects to aid lymphoablation
- GVHD prophylaxis: Tacrolimus, Sirolimus, Mycophenolate Mofetil (Sandmaier et al, Lancet Haematology 2019)

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MDS & AML Patient Characteristics

Characteristic	All Patients (N = 24)	Patients with AML (N=11)*	Patients with MDS (N = 13)
Median age (range) - year	70 (62-79)	69 (62-79)	70 (67-77)
Sex – no. (%)			
Male	18 (75%)	8 (73%)	10 (77%)
Female	6 (25%)	3 (27%)	3 (23%
Prior AML/MDS Therapy – no. (%)			
Untreated or growth factor supportive care only	3 (13%)	0 (0%)	3 (23%)
Hypomethylating agent-containing regimens only	13 (54%)	4 (36%)	9 (69%)
Anthracycline-based regimens (incl. liposomal formulations) only	3 (13%)	2 (18%)	1 (8%)
Multiple lines of therapy incl. both hypomethylating agent- and anthracycline-based regimens	5 (21%)	5 (45%)	0 (0%)
Donor Type – no. (%)			
Matched related donor	5 (21%)	1 (9%)	4 (33%)
Matched unrelated donor	19 (79%)	10 (91%)	9 (67%)
TBI dose – no. (%)			
200 cGy	7 (29%)	3 (27%)	4 (31%)
300 cGy	17 (71%)	8 (73%)	9 (69%)

*Patients with de novo AML (N = 8) & AML from MDS (N = 3)

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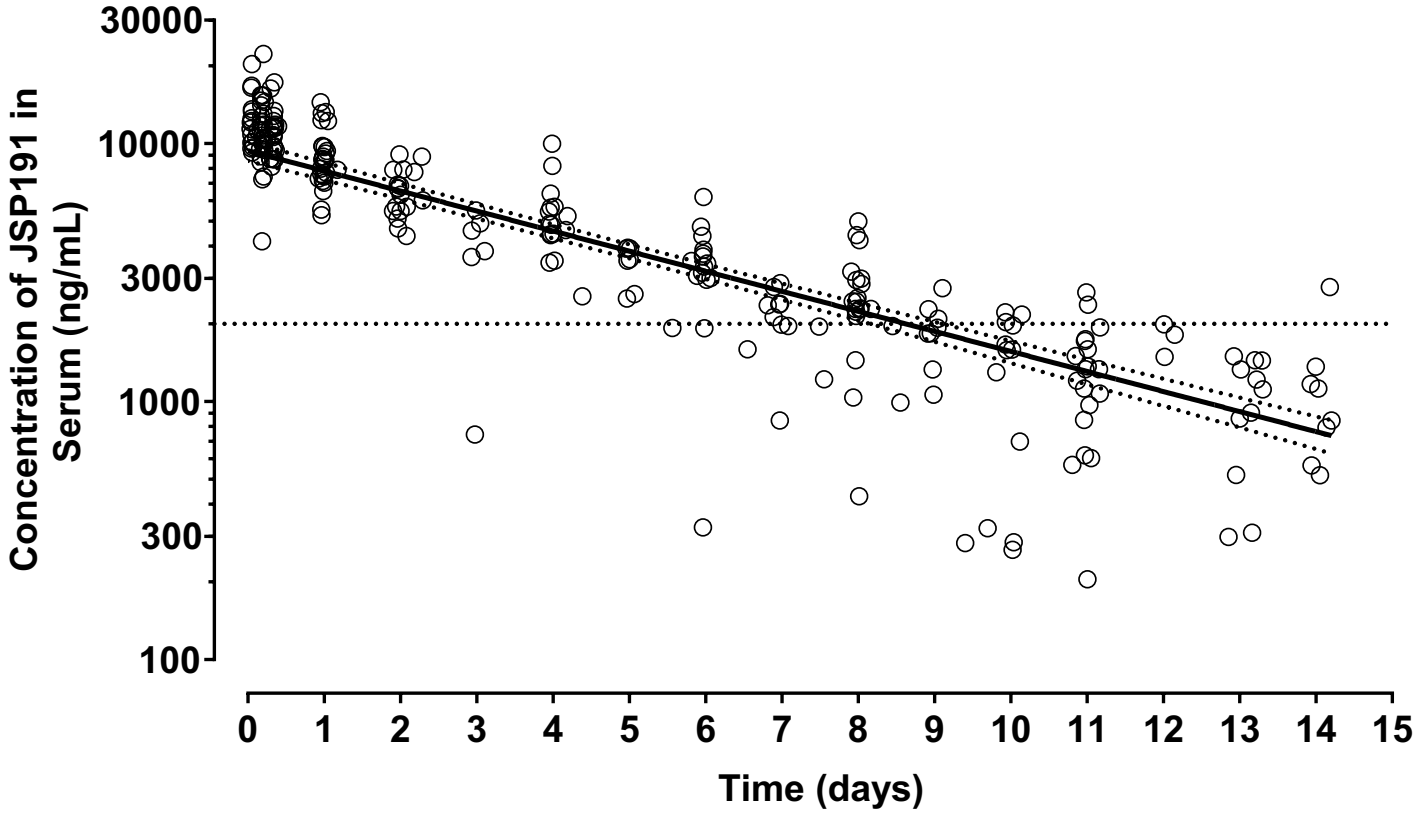
0.6 mg/kg JSP191 PK: Consistent and Predictable Clearance



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Safety and Tolerability

- No significant JSP191 infusion reactions
- No JSP191-related SAEs
- No primary graft failure (one case of secondary graft failure)

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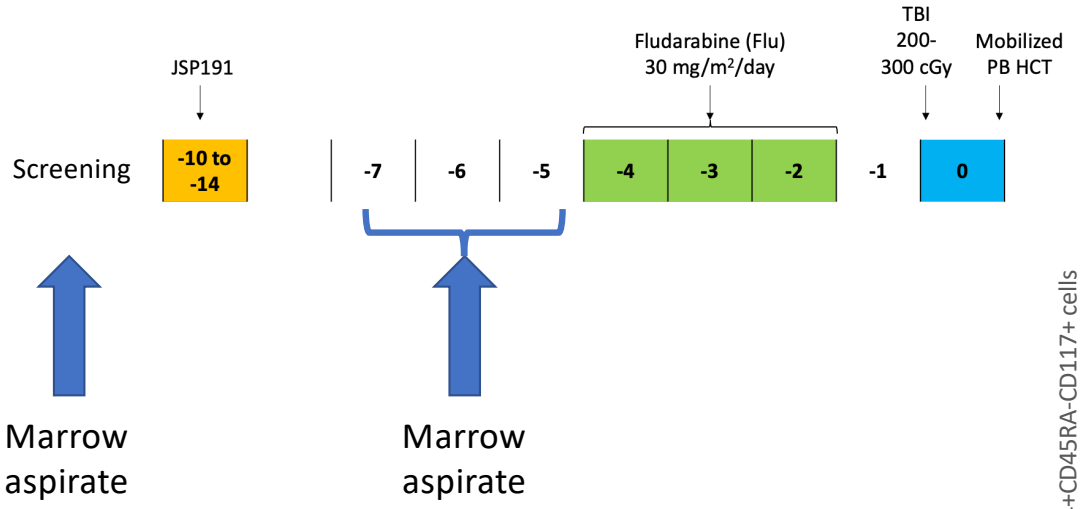
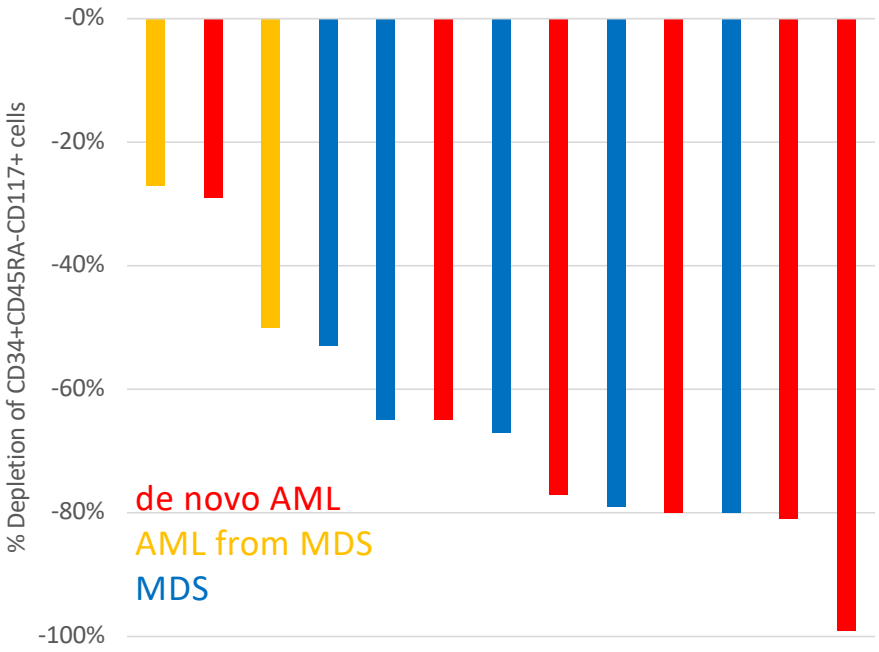
JSP191 Pharmacodynamics: Evaluation of JSP191 to Deplete HSPCs in Marrow of MDS and AML Patients

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



Mean HSPC depletion of 66%

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



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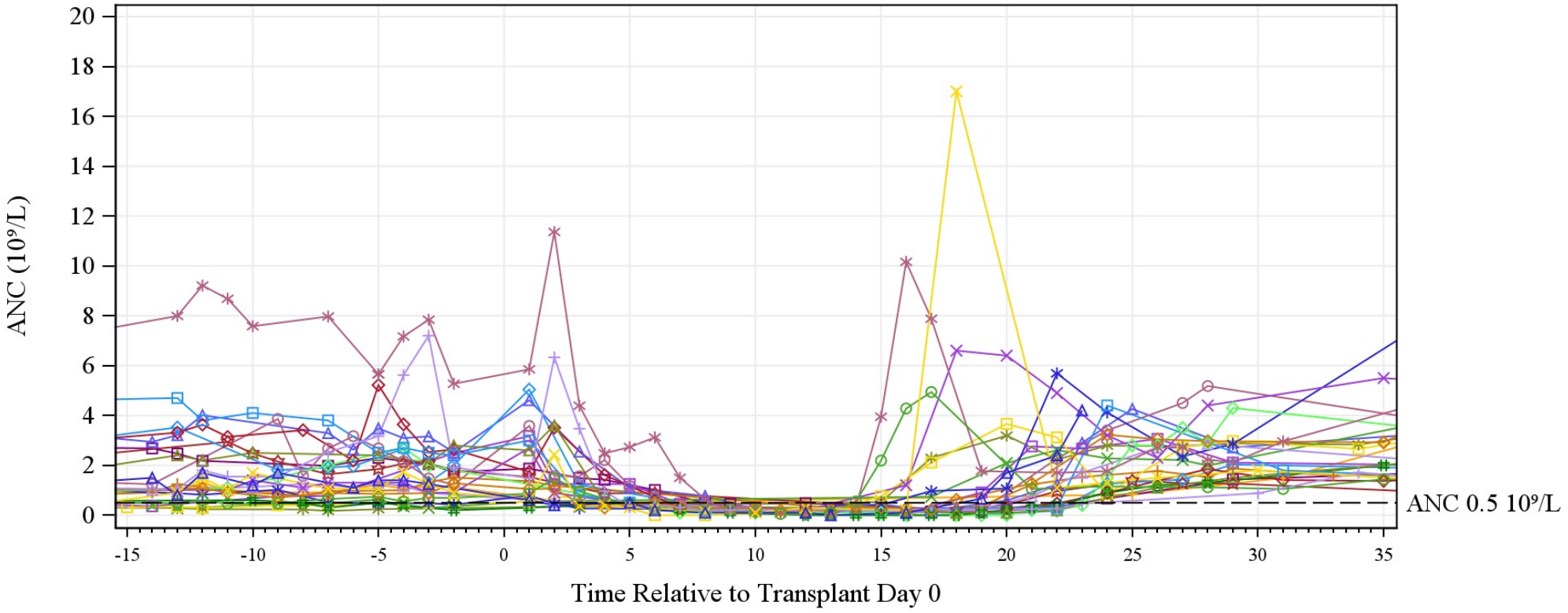
JSP191/Flu/TBI Conditioning in All Patients Dosed to Date Resulted in Neutropenia Followed by Neutrophil Engraftment by TD+26



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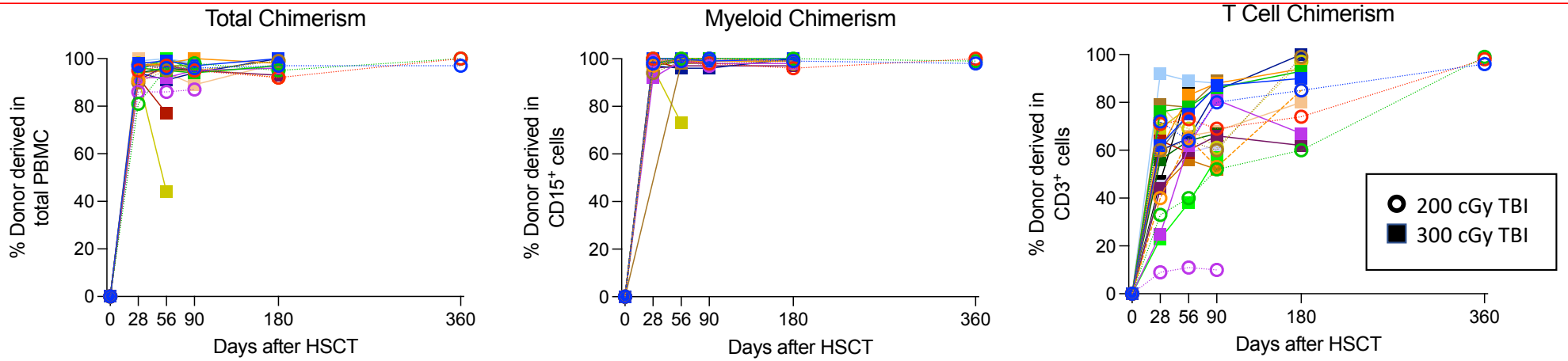
Donor Chimerism



Median Donor Chimerism:

	TD+28			TD+90			TD+180		
	Total	CD15	CD3	Total	CD15	CD3	Total	CD15	CD3
200 cGy TBI	91%	98%	60%	95%	98%	60%	97%	99%	85%
300 cGy TBI	95%	99%	60%	95%	99%	83%	98%	99%	89%

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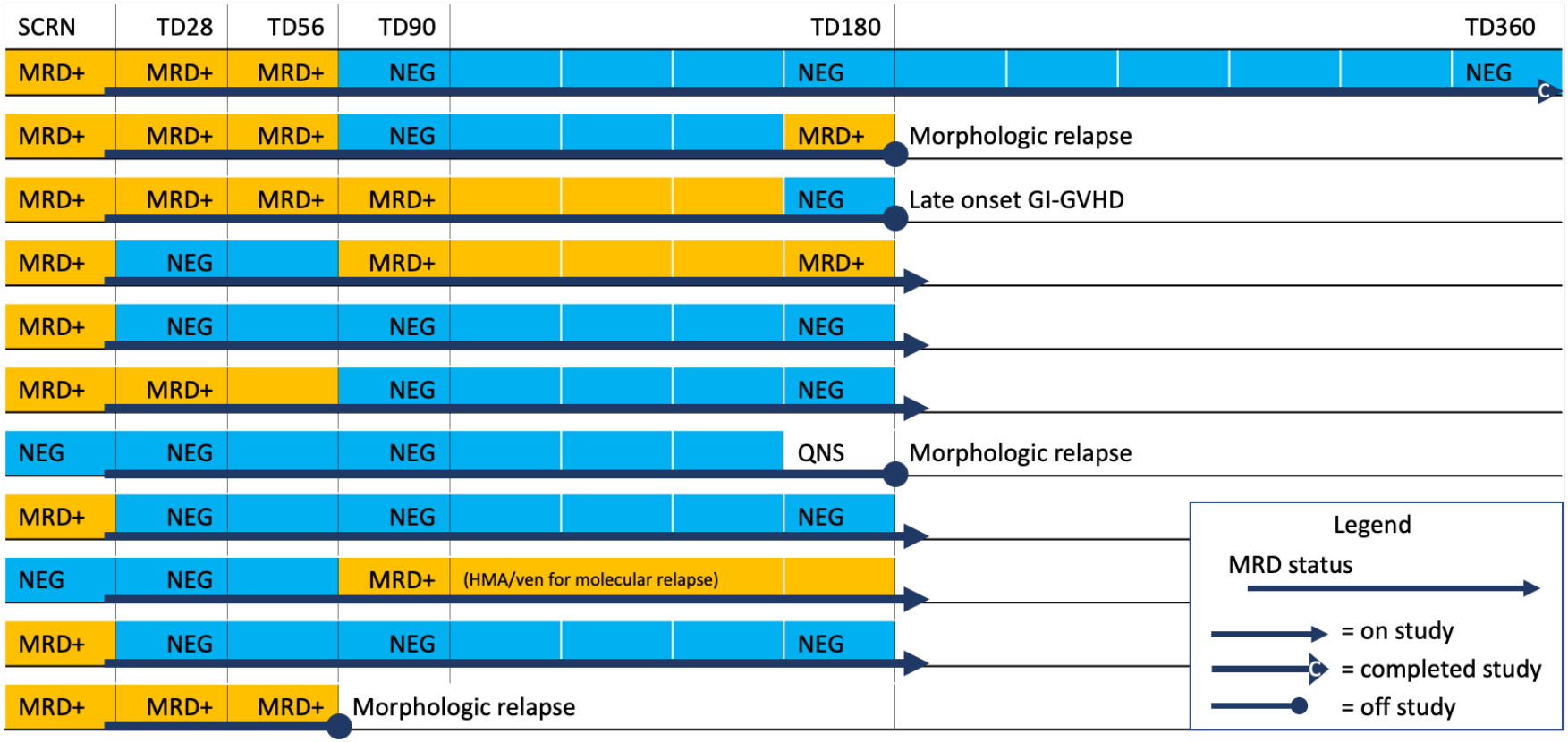
Multimodality Measurable Residual Disease (MRD) in patients with AML*

Cytogenetics, Flow Cytometry, Next Generation Sequencing



*Patients with de novo AML (N = 8) & AML from MDS (N = 3)

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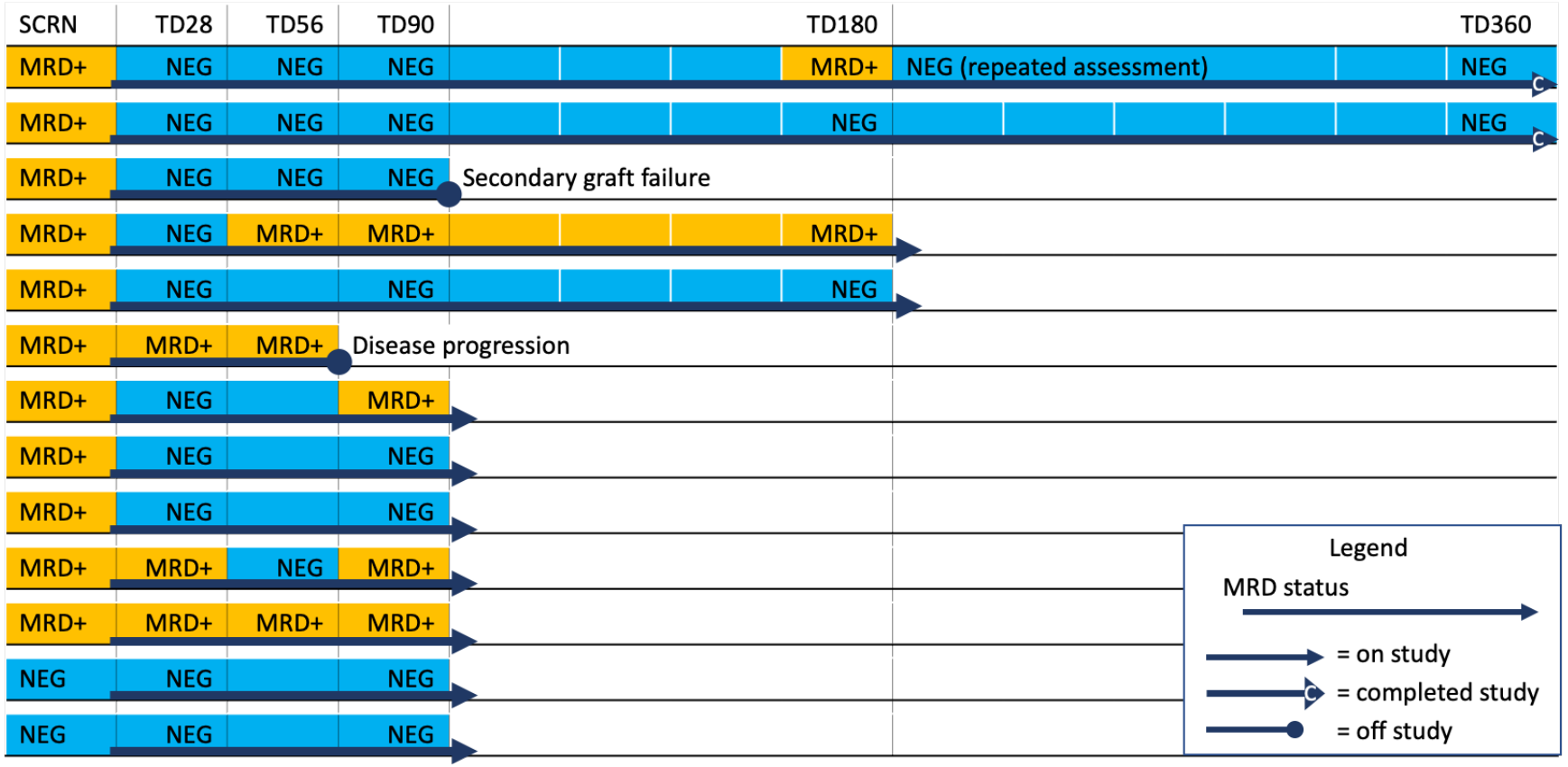
QNS = quantity not sufficient

Multimodality Measurable Residual Disease (MRD) in patients with MDS

Cytogenetics, Flow Cytometry, Next Generation Sequencing



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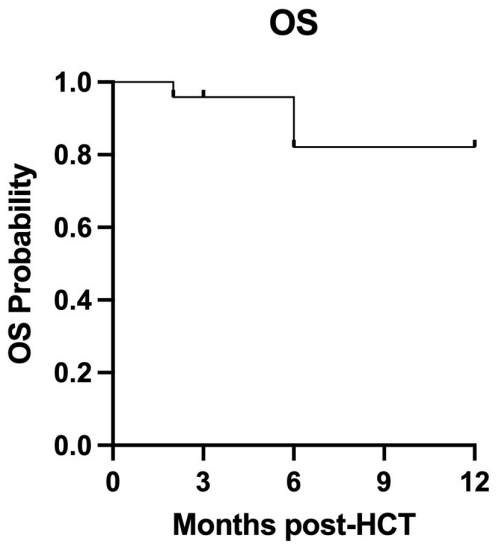
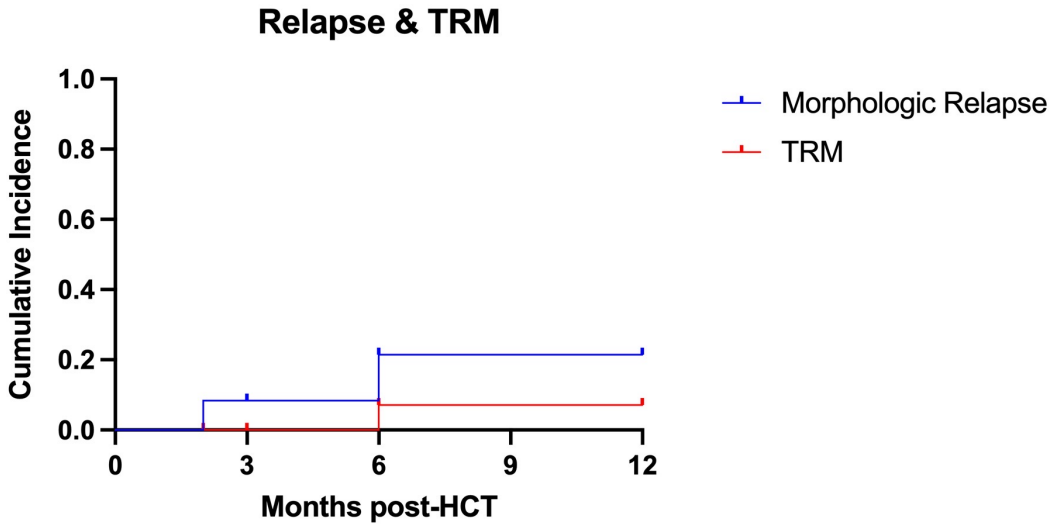
Outcomes & GVHD reported to date

N = 24, median follow-up of 6 months (range 2-12 months)





Evaluable patients: 22 14 22 14

- No classical grade II-IV acute GVHD reported to date
- 1 case of late onset grade III-IV acute GI GVHD reported to date
- Insufficient median follow up to draw conclusions regarding chronic GVHD

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Summary of Phase I Trial Results To Date

- 0.6 mg/kg JSP191 PK is predictable and allows donor cell infusion 9-14 days after JSP191
- All patients engrafted with neutrophil recovery before Transplant Day +26
- MRD clearance was observed in 12 of 20 evaluable patients at last follow-up
- JSP191/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 early MRD clearance

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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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