Evaluation of Clinical Outcomes and Healthcare Resource Use of Outpatient Allogeneic Stem Cell Transplant in Older Adults with AML/MDS, Using Briquilimab (JSP191), an Anti-CD117 Monoclonal Antibody, in Combination with Low Dose Irradiation and Fludarabine Conditioning – a Single Center Analysis

Lori Muffly, MD, MS[1], Gary Goldstein, BA[2], Aaron Miller, BA[3], Anne Le, BS[3], David Ku, MD[3] and Wendy W. Pang, MD, PhD[3]

(1) Division of Blood and Marrow Transplantation & Cellular Therapy, Stanford University School of Medicine, Stanford, CA, (2) Blood & Marrow Transplant Program, Stanford Medicine, Palo Alto, CA, (3) Jasper Therapeutics, Inc., Redwood City, CA

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

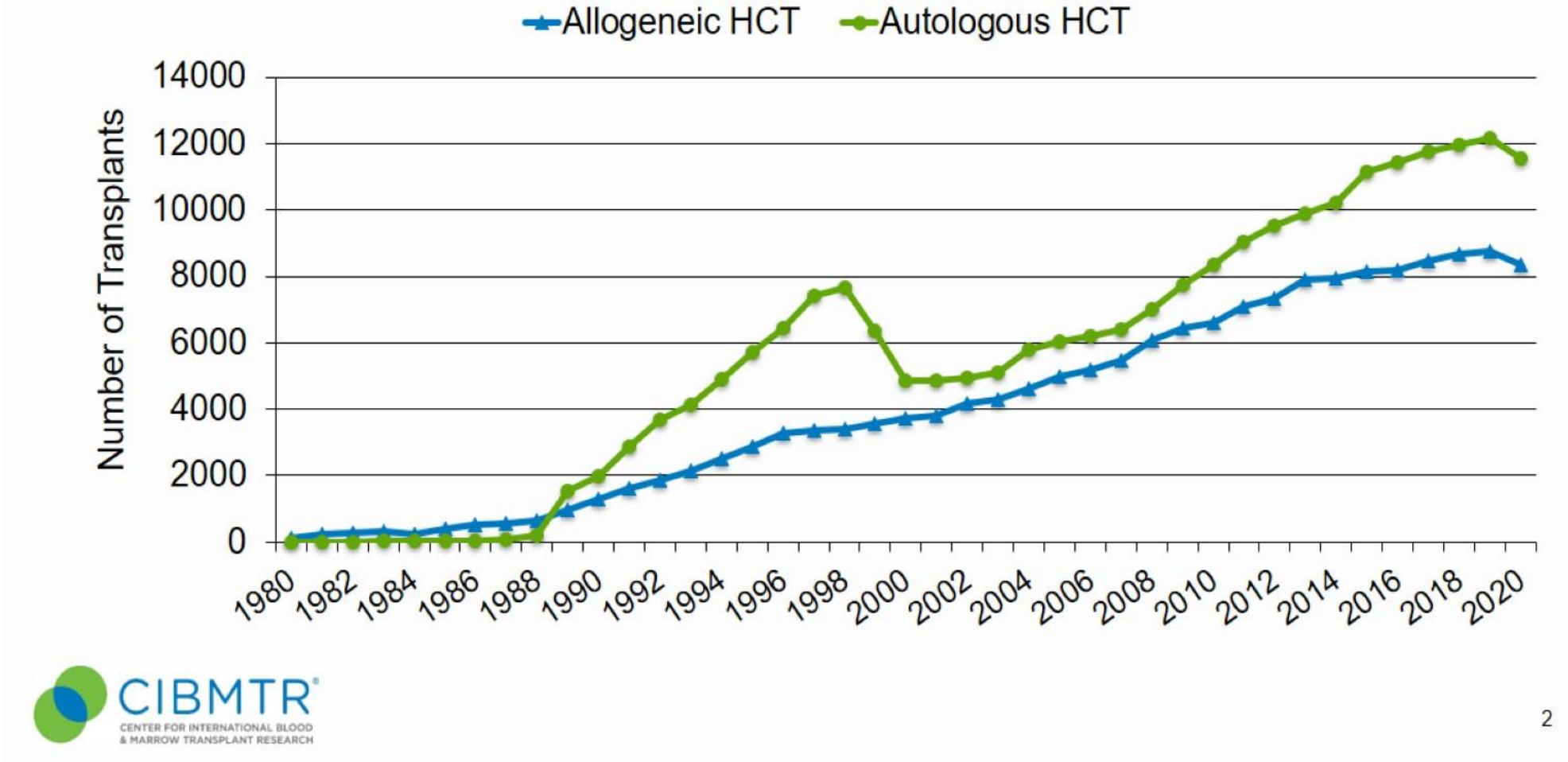
Conflict of Interest

Muffly –
Advisory Boards: Pfizer, Amgen, Jazz, Medexus, CTI Biopharma, Kite/Gilead
Research Funding: Astellas, Jasper, Adaptive, Kite, BMS
Consulting: Astellas

Goldstein –
Advisory Boards: Kite/Gilead
Consulting: Orca Bio, Atheneum, Gamida Cell

Miller, Le, Ku, Pang –
Employment: Jasper Therapeutics

Trends in the Number of Allogeneic HCTs Performed in the U.S.



Allogeneic HCT is a Resource-Intensive Procedure for Both Hospitals and Patients

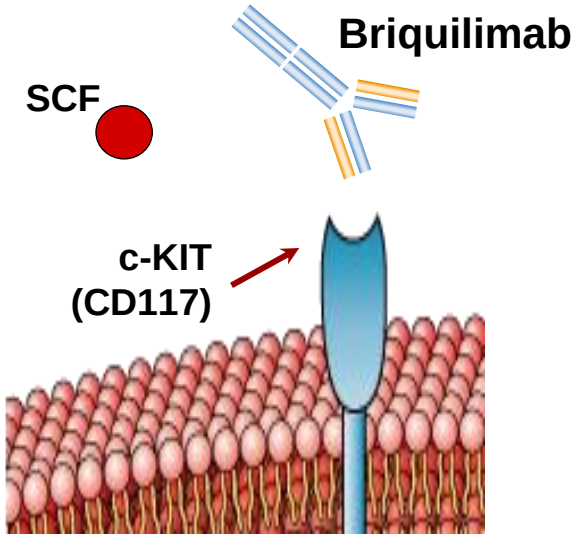
- Allogeneic stem cell transplantation (HCT) is typically done in the inpatient setting and is a resource-intensive procedure for hospitals and patients, associated with:
  - **Average inpatient length of stay of 35-45 days** in the first 100 days post-HCT (Broder et al., 2017)
  - **Costs greater than $250,000** (Broder et al., 2017)

- **Safe and efficacious outpatient allogeneic HCT may be an effective strategy to lower the overall clinical and economic burden of allogeneic HCT**

Briquilimab (JSP191) Designed to Block CD117 (Stem Cell Factor Receptor) Signaling, Leading to HSC Depletion without Significant Off-Target Toxicities

Briquilimab (JSP191)

Blocks SCF Binding to c-KIT (CD117) to directly inhibit receptor signaling



Mechanism of Action

Briquilimab is designed to directly block SCF from binding to c-KIT (CD117) with high affinity and avidity

- Aglycoslyated IgG1 antibody directly inhibits SCF from binding to the c-KIT receptor on stem cells
- Inhibition of SCF signaling leads to depletion of hematopoietic stem cells in the bone marrow

Favorable Drug Properties

- No Fc mediated ADCC or complement mediated cytotoxicity to reduce risk of adverse effects on germ, mast and Cajal (GI) cells that express CD117
- Kd <5 pM affinity to human c-KIT with IC50 ~70 pM

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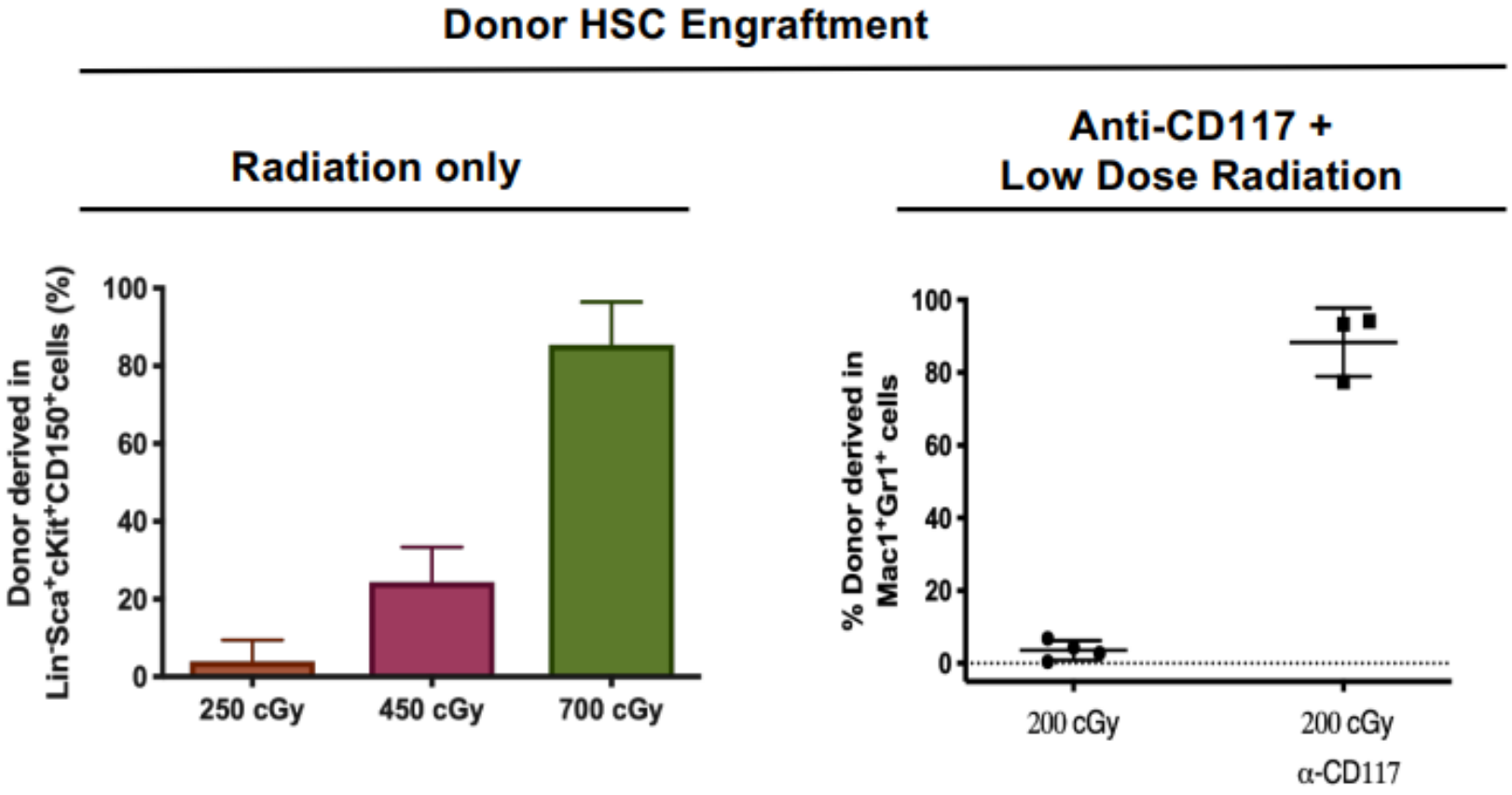
Blockade of CD117 is Synergistic with Low Dose Radiation Leading to Purified Donor HSC Engraftment in Immunocompetent Mouse Model



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

Phase 1 Study Design: Single-Arm, Open Label, in AML/MDS 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 pharmacokinetics

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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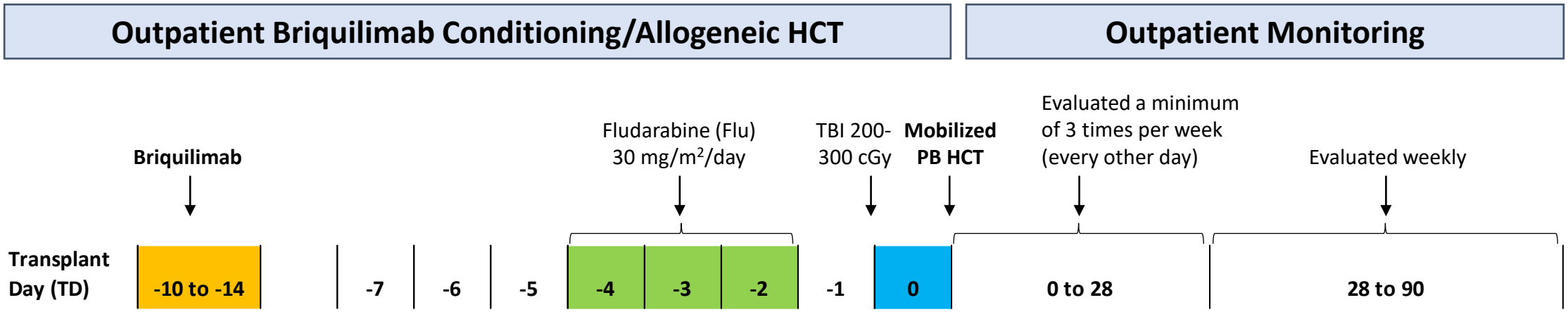
Outpatient Conditioning and Allogeneic Transplant at Stanford (Briquilimab, Fludarabine, TBI 2-3 Gy)



- 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 Hematology 2019)
- Monitoring is conducted in Stanford's outpatient Infusion Treatment Area

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Outpatient Monitoring Protocol at Stanford

- Through the pre-/post-HCT procedure, patients reside at home if they're within the Safe Zone (approximately 45-minute drive from Stanford) or at a local rental housing/hotel

- Post-HCT, monitoring is conducted in Stanford's outpatient Infusion Treatment Area. Patients are seen at the following intervals:
  - TD+0 to TD+28: minimum of 3 times per week
  - TD+28 to TD+90: minimum of 1 time per week

- Patients are given routine care, in addition to:
  - Reticulocytes ordered
  - Research kits at TD+28, 56, and 90

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AML/MDS Patient Characteristics of Those Patients Receiving Outpatient Conditioning and Allogeneic Transplant at Stanford (Briquilimab, Fludarabine, TBI 2-3 Gy)

Characteristic	All Patients (N=12)
Median Age (Range) – Year	70 (65-74)
Sex – no. (%)	
Male	8 (67%)
Female	4 (33%)
Disease History – no. (%)	
AML	4 (33%)
MDS	8 (67%)
Prior AML/MDS Therapy – no. (%)	
Untreated or growth factor supportive care only	1 (8%)
Hypomethylating agent-containing regimens only	8 (67%)
Anthracycline-based regimens (incl. liposomal formulations) only	1 (8%)
Multiple lines of therapy incl. both hypomethylating agent and anthracycline-based regimens	2 (17%)
Donor Type – no. (%)	
Matched related donor	3 (25%)
Matched unrelated donor	9 (75%)
TBI Dose – no. (%)	
200 cGy	3 (25%)
300 cGy	9 (75%)

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Safety and Tolerability of Outpatient Conditioning and Allogeneic Transplant at Stanford (Briquilimab, Fludarabine, TBI 2-3 Gy)

In patients who received outpatient conditioning (briquilimab, fludarabine, TBI 2-3 Gy) and allogeneic HCT at Stanford, we observed:

- No significant briquilimab infusion reactions
- No briquilimab-related SAEs
- Nine infections in five patients (as of TD+100)

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Patient-Level Hospitalization Summary for Patients Treated with Outpatient Conditioning and Allogeneic HCT, in the First 100 Days Post-HCT (Briquilimab, Fludarabine, TBI 2-3 Gy)

Patient #	Diagnosis	Age	Total Inpatient LOS	LOS of Index Admission	Number of Subsequent Hospitalizations	Reason for Subsequent Hospitalization
9	MDS	74	0 Days	0 Days	-	
13	AML	74	0 Days	0 Days	-	
24	AML	67	0 Days	0 Days	-	
33	MDS	70	0 Days	0 Days	-	
35*	MDS	70	0 Days	0 Days	-	
49	MDS	67	0 Days	0 Days	-	
10	AML	65	1 Day	0 Days	1	• Hyperkalemia
11	AML	69	2 Days	0 Days	2	• Enterocolitis • Recurrence of diverticulitis
50†	MDS	70	3 Days	0 Days	1	• Steroid-induced hyperglycemia
37	MDS	70	3 Days	0 Days	1	• Suspected fungal pneumonia
31	MDS	70	16 Days	0 Days	1	• Failure to thrive, fatigue
36	MDS	67	26 Days	0 Days	1	• Oral mucositis, CoNS bacteremia, neutropenic fever

LOS = Length of Stay; CoNS = Coagulase-Negative Staphylococci

* Off study due to relapse at TD+56.

† On study, patient follow-up only to TD+72.

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Summary of Key Results in Patients Receiving Outpatient Conditioning and Allogeneic HCT at Stanford (Briquilimab, Fludarabine, TBI 2-3 Gy)

- All 12 patients engrafted with neutrophil recovery occurring between TD+15 to TD+26
- All 12 patients received the briquilimab-based conditioning regimen and donor cell infusion outpatient and were discharged from the hospital the same day, requiring zero days inpatient
- We observed 6 of 12 patients (50%) that did not require an inpatient stay in the first 100 days
- The mean inpatient hospital stay in the first 100 days for all patients was 4 days. Seven total hospitalizations and zero intensive care unit stays have been observed

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Conclusion

- These early results demonstrate that outpatient allogeneic HCT is clinically feasible and may be associated with lower hospital resource use, while sparing hospitals and patients a lengthy hospitalization

- We believe that outpatient allogeneic HCT enabled by safe, targeted antibody-based conditioning can serve as a strategy to increase hospital bed availability and reduce the costs of HCT in the US

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Acknowledgments

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

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