High-dose palifermin for chronic GVHD prevention after RIC MUD transplant

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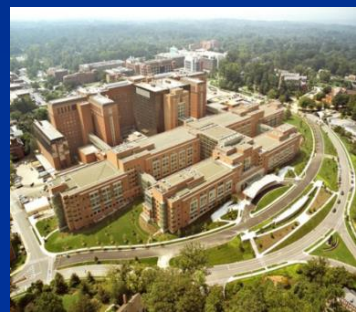
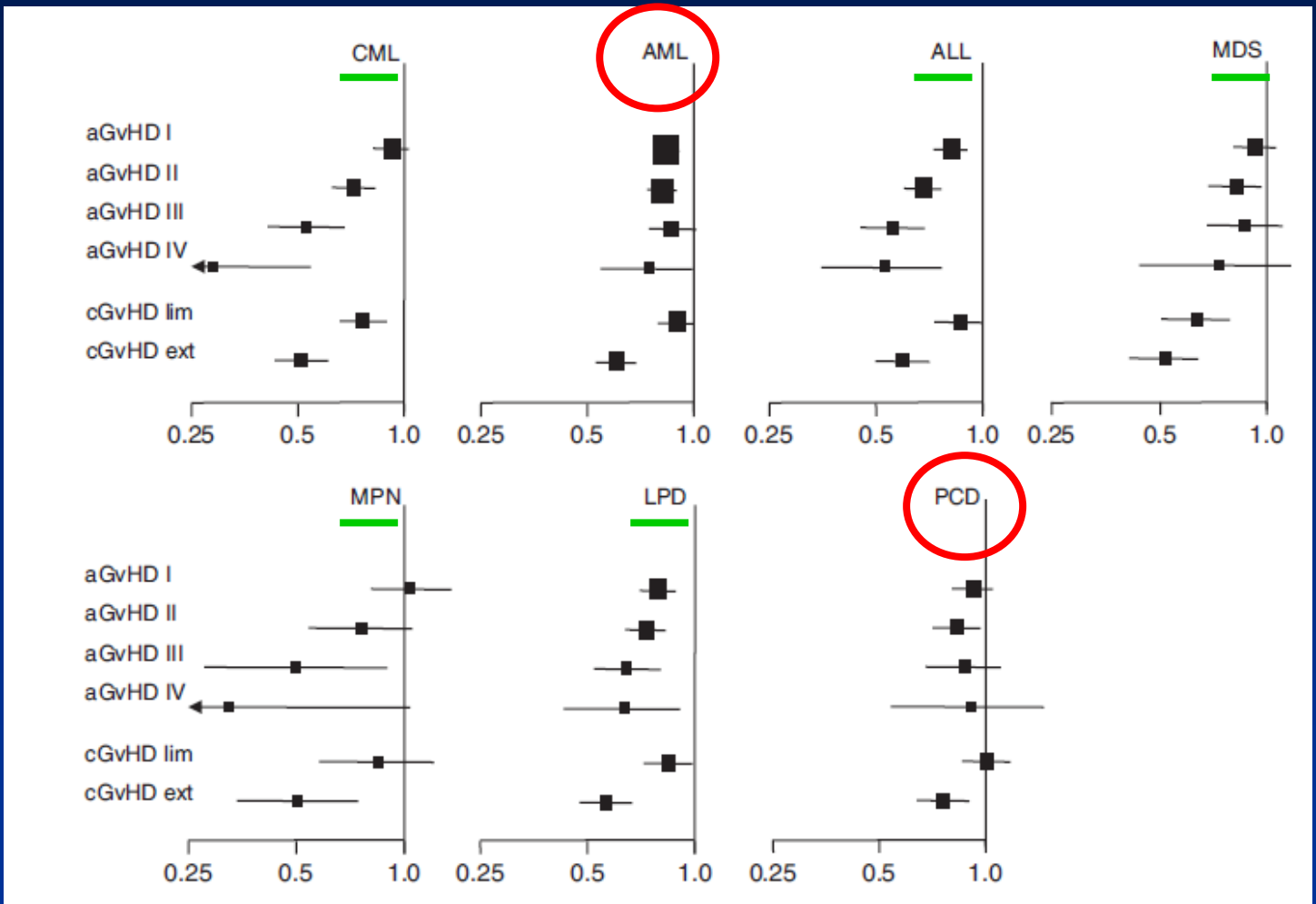
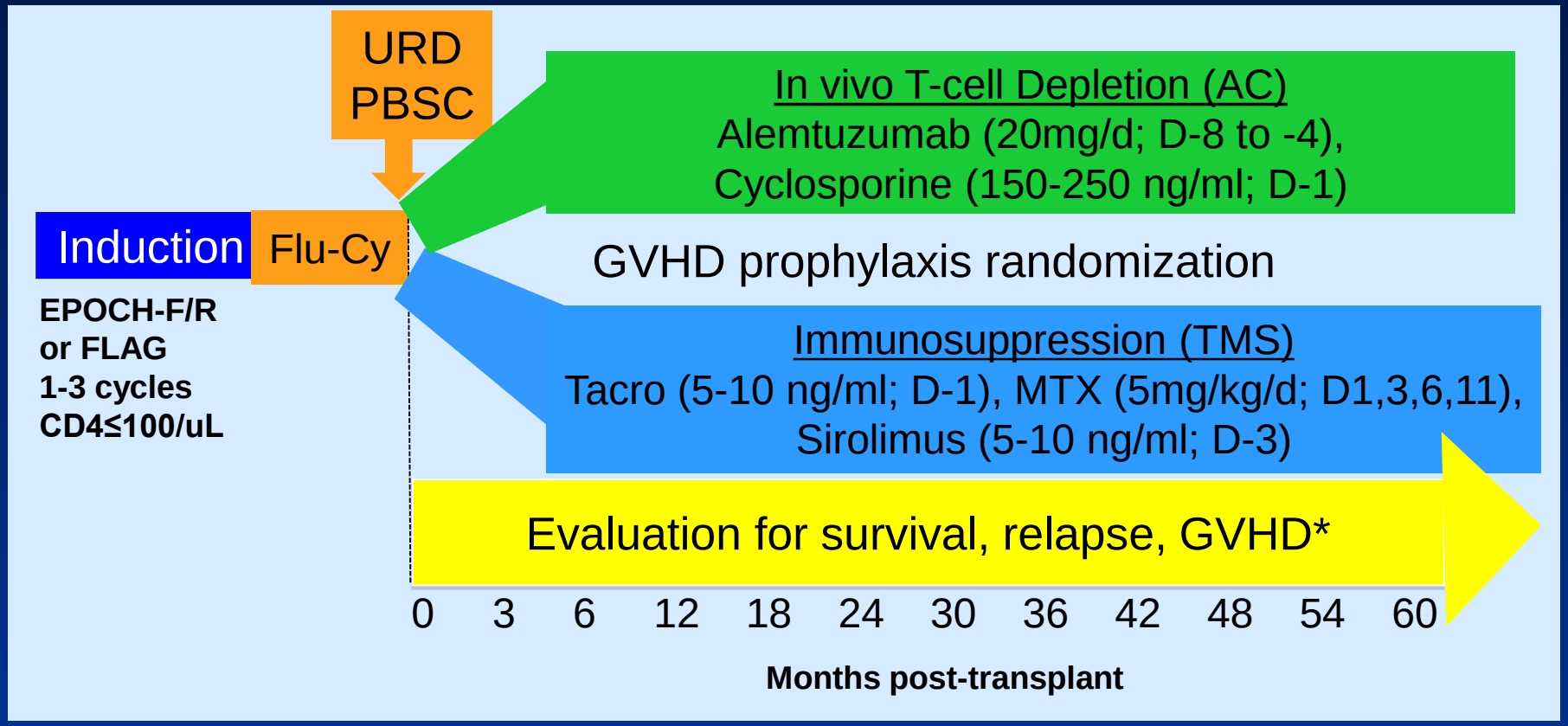


GVHD and risk of malignancy relapse after allogeneic HSCT – EBMT mega file analysis N=48111



Stern et al, BMT 2014; 28:2235

AC vs. TMS for GVHD Prophylaxis in RIC Unrelated Donor Allogeneic HSCT: Randomized Phase 2 Trial



EPOCH-Fludarabine +/- Rituximab (if CD20+): NHL, HL, CLL/PLL, MM

Salit RB et al, JCO 2012 May 1;30(13):1570

FLAG: AML/ALL, MDS (RAEB), MPD

*Chronic GVHD (cGVHD) is primary endpoint of study

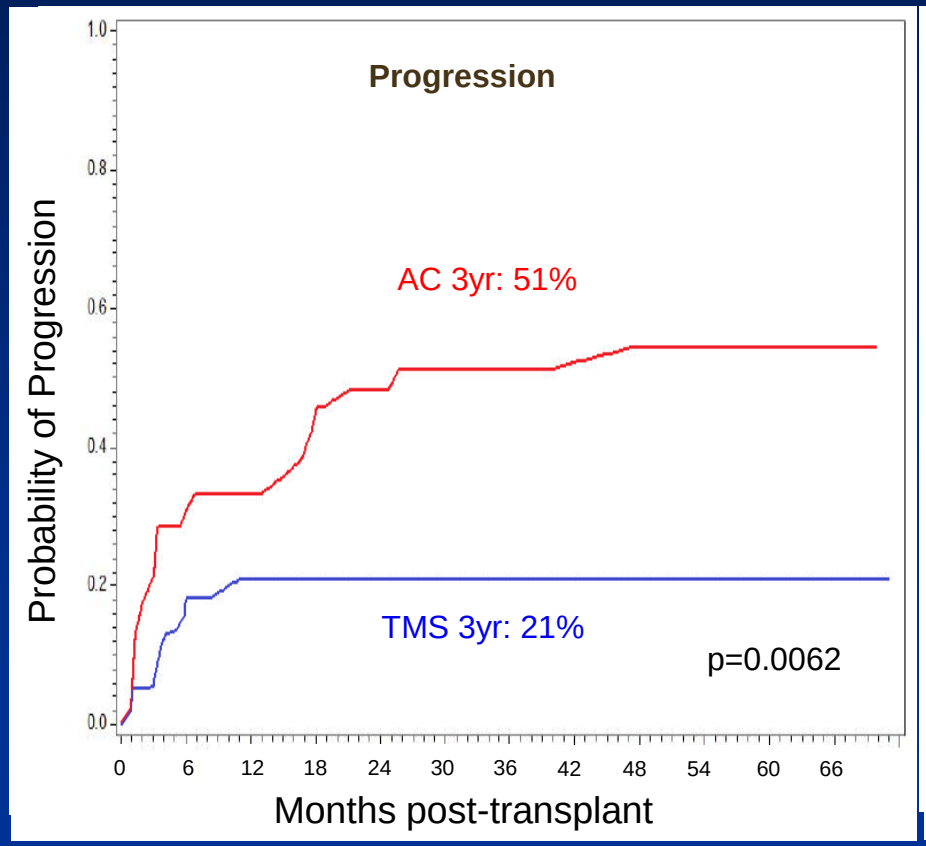
Patient Characteristics

Description	AC n=42	TMS n=39	p-value
Age (median, range)	50.55 (22.2-69.9)	49.5 (20.9-71.1)	0.78
Gender (n, %)			
Male	27 (64)	24 (62)	0.82
Female	15 (36)	15 (38)	
Disease (n, %)			
CLL, Indolent B-NHL	18	15	
Hodgkin's Lymphoma	5	3	
Aggressive B-NHL	4	5	
AML/ALL/MDS	6	7	
Other	9	9	
Kahl Relapse Risk (n, %)			
Low	11 (26)	14 (36)	0.24
Intermediate	11 (26)	12 (31)	
High	20 (48)	13 (33)	

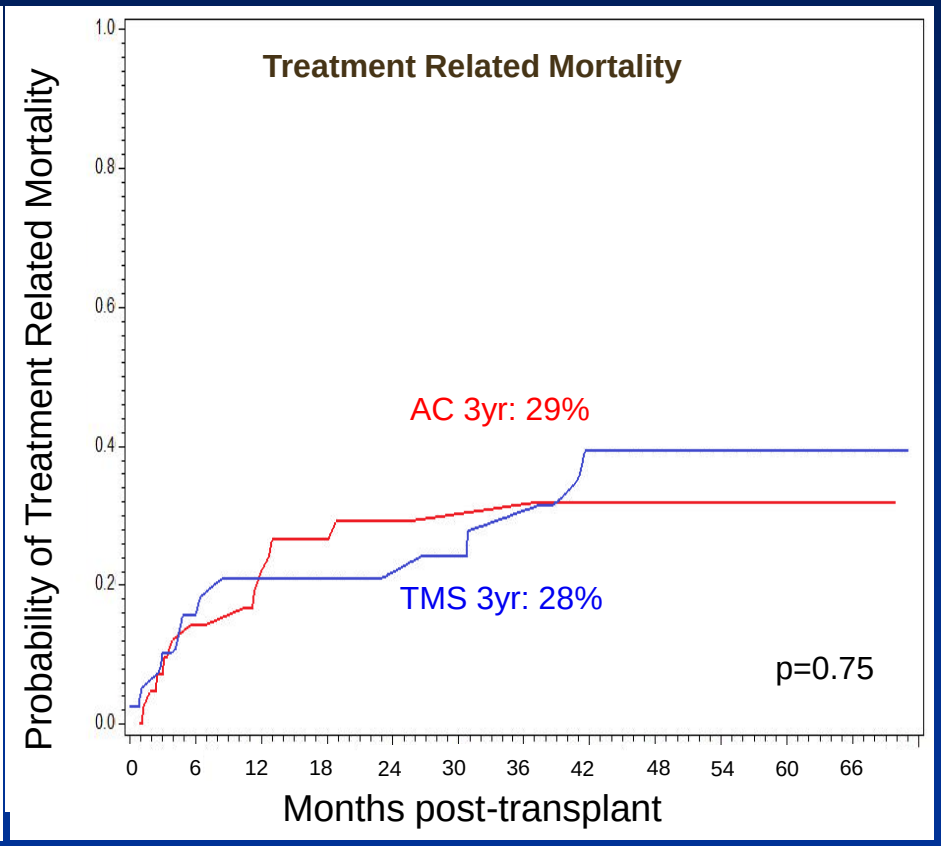
Patient characteristics

Description	AC, n=42	TMS, n=39	p-value
Sorror score (median, range)	3 (0-6)	2 (0-7)	0.62
Number of prior treatment regimens (n, %)			
0-2	14 (33)	24 (62)	
3-5	18 (43)	13 (33)	**0.0035**
≥6	10 (24)	2 (5)	
Cycles of induction chemotherapy			
EPOCH-FR (n, %)	20 (48)	16 (41)	0.52
Cycles (median, range)	2 (1-3)	1.5 (1-3)	
FLAG (n, %)	5 (12)	8 (21)	0.42
Cycles (median, range)	1 (1-2)	1.5 (1-3)	
HLA match (n, %)			
7/8	9 (21)	8 (21)	1.00
8/8	33 (79)	31 (79)	
Infusion cell dose (median, range)			
CD34+ (10^6 cells/kg)	7.46 (4.09-10)	6.4 (2.03-11.1)	**0.049**
CD3+ (10^6 cell/kg)	239 (107-532)	244 (79.6-810)	0.74
Baseline CD4 count (median, range)	93 (10-862)	98 (6-520)	0.87

Disease progression and TRM in AC vs. TMS arms

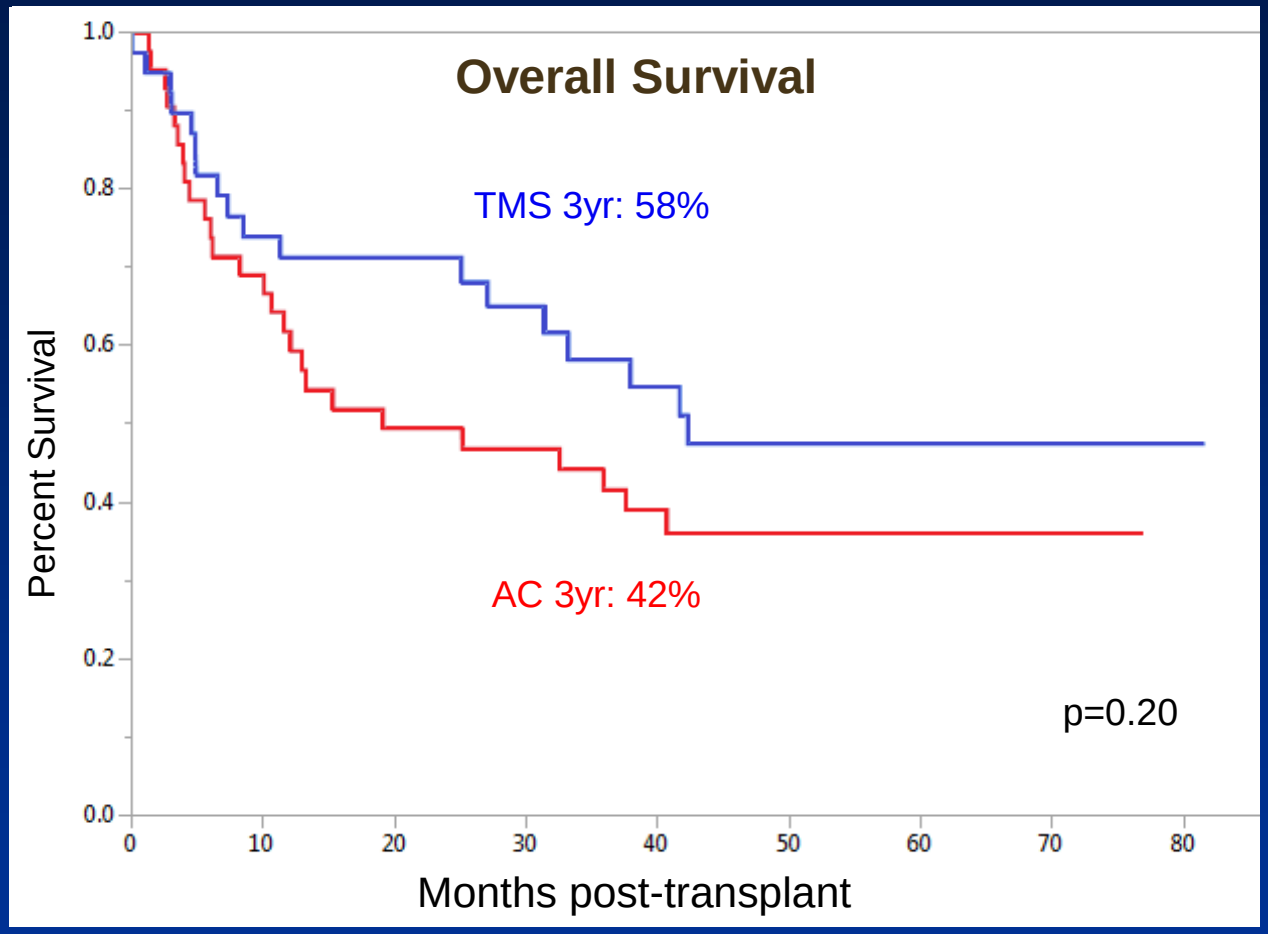


Competing risk: death



Competing risk: progression

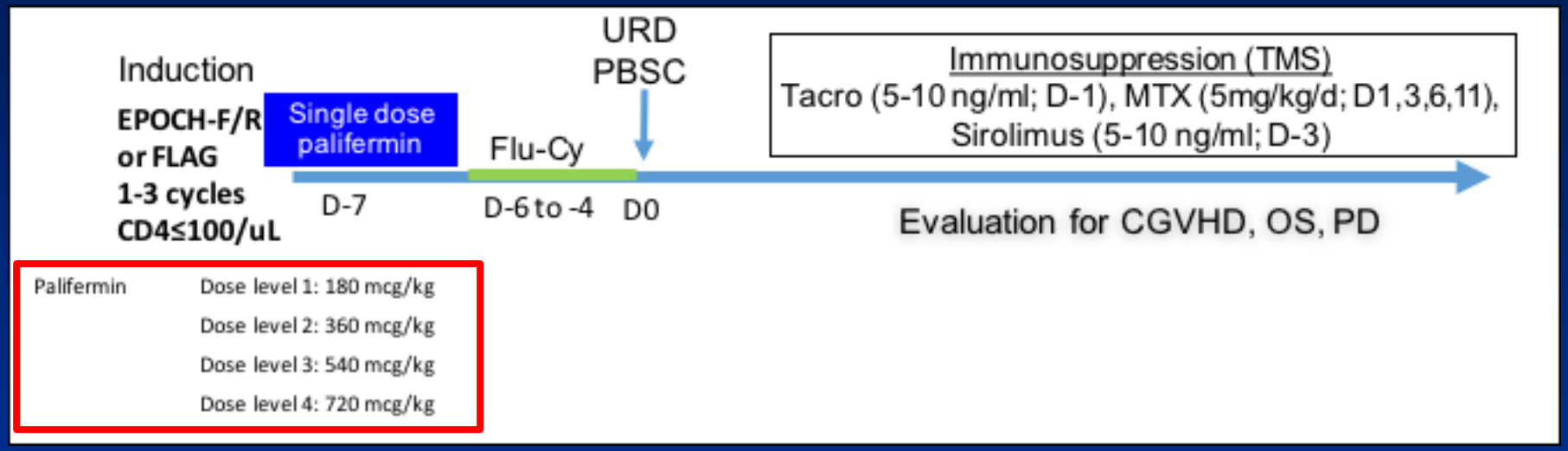
Overall survival in AC vs. TMS arm



Median follow-up of 52 months

CHRONIC GVHD PREVENTION: Phase 1/2 dose escalation study of palifermin (Kepivance) given pre-conditioning to pts with MUD allogeneic PB HCT with RIC Flu-Cy

Hypothesis: KGF may protect thymic and other epithelial cells and result in less CGVHD



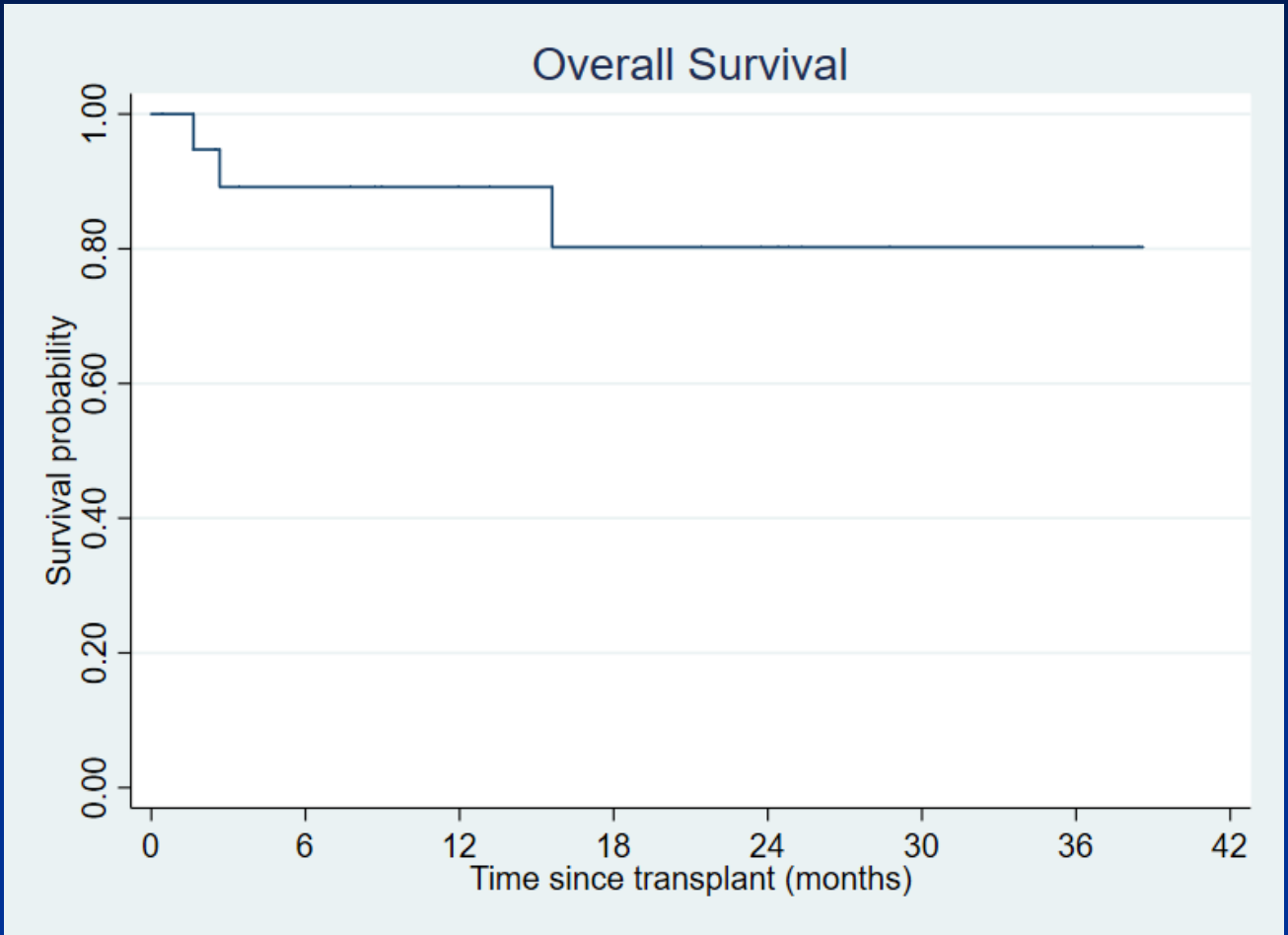
Assay for Immune Reconstitution

- Serial CT imaging of thymus volume on 1, 6 & 12 months
- TCR spectratyping
- TRECs
- Lymphocyte reconstitution
- Oral and skin biopsies

•Dose level 4 completed, 20 patients transplanted

Protocol 15-C-0067
PI Steven Pavletic

Palifermin for GVHD prevention N=20



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