Supplementary Materials

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Supplementary Table 1. Participating centers and principal investigators

Country	Site	Principal Investigator
All countries	**All sites**	
United States of America	**All**	
	Duke University Medical Center	Mitchell Horwitz
	Loyola University Medical Center	Patrick Stiff
	Dana Farber Cancer Institute	Corey Cutler
	University of Minnesota	Claudio Brunstein
	Cleveland Clinic	Rabi Hanna
	Oregon Health and Science University	Richard Maziarz
	Stanford University Cancer Institute	Andrew Rezvani
	City of Hope Comprehensive Cancer Center	Nicole Karras
	Kansas Medical Center	Joseph McGuirk
	University of California at Los Angeles	Gary Schiller
	Boston Children's Hospital	Christine Duncan
	Denver Children's Hospital	Amy Keating
	Methodist University Hospital (Tennessee)	Yasser Khaled
	Northwestern University	Olga Frankfurt
	Children's Medical Center of Dallas	Victor Aquino
	Duke University Medical Center Pediatrics	Joanne Kurtzberg
	Henry Ford Medical Center	Edward Peres
	Rutgers Cancer Institute of New Jersey	Dennis Cooper
	University of Virginia	Leonid Volodin
Spain	**All**	
	Hospital Universitario La Fe	Guillermo Sanz
	University Hospital Vall d'Hebron	David Valcarcel
	Hospital Sant Pau	Isabel Badell
Singapore	**All**	
	Singapore General Hospital	William Hwang
	National University Hospital	Liang Pui Koh
Netherlands	**All**	
	Princess Maxima Center for Pediatric Oncology	Caroline Lindemans

	Utrecht University	Caroline Lindemans
Brazil	**All**	
	Hospital Israelita Albert Einstein	Nelson Hamerschlak
	Hospital do Cancer de Sao Paulo Adults	Vanderson Rocha
	Hospital do Cancer de Sao Paulo Pediatrics	Juliana Folloni
Israel	**All**	
	Rabin Medical Center	Ron Ram
	Tel Aviv Sourasky Medical Center Adults	Moshe Yeshurun
United Kingdom	**All**	
	Manchester University Hospital	Robert Wynn
	The Royal Marsden Hospital	Emma Nicholson

Supplementary Table 2. BMT CTN Infection Severity Grading

APPENDIX 4-A

SEVERITY GRADING TABLE AND RECURRENCE INTERVAL DEFINITIONS

Type of Infection/ Severity Grade	Grade 1	Grade 2	Grade 3
Bacterial infections	Bacterial focus NOS requiring no more than 14 days of therapy for treatment (e.g urinary tract infection)	Bacteremia (except CoNS) without severe sepsis ***	Bacteremia with deep organ involvement (e.g. with new or worsening pulmonary infiltrates; endocarditis)
	Coag Neg Staph (S. epi), Corynebacterium, or Proprioniobacterium bacteremia	Bacterial focus with persistent signs, symptoms or persistent positive cultures requiring greater than 14 days of therapy	Severe sepsis with bacteremia.
	Cellulitis responding to initial therapy within 14 days	Cellulitis requiring a change in therapy d/t progression Localized or diffuse infections requiring incision with or without drain placement	Fasciitis requiring debridement
		Any pneumonia documented or presumed to be bacterial	Pneumonia requiring intubation
			Brain abscess or meningitis without bacteremia
	C. Difficile toxin positive stool with diarrhea < 1L without abdominal pain (child < 20 mL/kg)	C. Difficile toxin positive stool with diarrhea ≥ 1L (child ≥ 20 mL/kg) or with abdominal pain	C. Difficile toxin positive stool with toxic dilatation or renal insufficiency with/without diarrhea
Fungal infections	Superficial candida infection (e.g. oral thrush, vaginal candidiasis)	Candida esophagitis (biopsy proven). Proven or probable fungal sinusistis confirmed radiologically without orbital, brain or bone involvement.	Fungemia including Candidemia Proven or probable invasive fungal infections (e.g., Aspergillus, Mucor, Fusarium, Scedosporium).

Type of Infection/ Severity Grade	Grade 1	Grade 2	Grade 3
Fungal infections continued			Disseminated infections (defined as multifocal pneumonia, presence of urinary or blood antigen, and/or CNS involvement) with Histoplasmosis, Blastomycosis, Coccidiomycosis, or Cryptococcus. *Pneumocystis jiroveci* pneumonia (regardless of PaO2 level)
Viral infections	Mucous HSV infection		
	Dermatomal Zoster	VZV infection with 3 or more dermatomes	Severe VZV infection (coagulopathy or organ involvement)
	Asymptomatic CMV viremia untreated or a CMV viremia with viral load decline by at least 2/3 of the baseline value after 2 weeks of therapy	Clinically active CMV infection (e.g. symptoms, cytopenias) or CMV Viremia not decreasing by at least 2/3 of the baseline value after 2 weeks of therapy	CMV end-organ involvement (pneumonitis, enteritis, retinitis)
	EBV reactivation not treated with rituximab	EBV reactivation requiring institution of therapy with rituximab	EBV PTLD
	Adenoviral conjunctivitis asymptomatic viruria, asymptomatic stool shedding and viremia not requiring treatment	Adenoviral upper respiratory infection, viremia, or symptomatic viruria requiring treatment	Adenovirus with end-organ involvement (except conjunctivitis and upper respiratory tract)
	Asymptomatic HHV-6 viremia untreated or an HHV-6 viremia with a viral load decline by at least 0.5 log after 2 weeks of therapy	Clinically active HHV-6 infection (e.g. symptoms, cytopenias) or HHV-6 viremia without viral load decline 0.5 log after 2 weeks of therapy	
	BK viremia or viruria with cystitis not requiring intervention	BK viremia or viruia with clinical consequence requiring prolonged therapy and/or surgical intervention	

Type of Infection/ Severity Grade	Grade 1	Grade 2	Grade 3
Viral infections continued		Enterocolitis with enteric viruses	
		Symptomatic upper tract respiratory virus	Lower tract respiratory viruses
	Viremia (virus not otherwise specified) not requiring therapy	Any viremia (virus not otherwise specified) requiring therapy	
			Any viral encephalitis or meningitis
Parasitic infections			CNS or other organ toxoplasmosis
			Strongyloides hyperinfection
Nonmicrobiologically defined infections	Uncomplicated fever with negative cultures responding within 14 days		
	Clinically documented infection not requiring inpatient management	Pneumonia or bronchopneumonia not requiring mechanical ventilation	Any acute pneumonia requiring mechanical ventilation
		Typhlitis	
			Severe sepsis*** without an identified organism

*Concomitant or multimicrobial infections are graded according to the grade of the infection with the higher grade of severity.

**Therapy includes both PO and IV formulations

***Severe Sepsis:

Adults:

Hypotension

-A systolic blood pressure of <90 mm Hg or a reduction of >40 mm hg from baseline in the absence of other causes for hypotension

Multiple Organ Dysfunction Syndrome

-2 or more of the following: Renal failure requiring dialysis, respiratory failure requiring bipap or intubation, heart failure requiring pressors, liver failure

Supplementary Table 3. Treatment Emergent Adverse Events with Severity Grades 3-5*

	Treatment Received			
	Omidubicel (N=52)		Unmanipulated UCB (N=56)	
MedDRA Preferred Term by System Organ Class	Number of Participants	%	Number of Participants	%
Blood and lymphatic system disorders				
Febrile neutropenia	3	5.8	4	7.1
Thrombotic microangiopathy	1	1.9	3	5.4
Gastrointestinal disorders				
Diarrhea	1	1.9	3	5.4
Dysphagia	6	11.5	7	12.5
Gastrointestinal toxicity	10	19.2	19	33.9
Vomiting	3	5.8	2	3.6
General disorders and administration site conditions				
Asthenia	2	3.8	11	19.6
Mucosal inflammation	16	30.8	19	33.9
Oedema	1	1.9	4	7.1
Pain	17	32.7	10	17.9
Pyrexia	1	1.9	6	10.7
Hepatobiliary disorders				
Venoocclusive liver disease	2	3.8	4	7.1
Infections and infestations				
Cystitis	4	7.7	2	3.6
Human herpesvirus 6 infection	4	7.7	0	0.0
Pneumonia	4	7.7	5	8.9
Sepsis	3	5.8	1	1.8
Septic shock	1	1.9	7	12.5
Injury, poisoning and procedural complications				

	Treatment Received			
	Omidubicel (N=52)		Unmanipulated UCB (N=56)	
MedDRA Preferred Term by System Organ Class	Number of Participants	%	Number of Participants	%
Transplant failure	3	5.8	5	8.9
Investigations				
Transaminases increased	4	7.7	1	1.8
Metabolism and nutrition disorders				
Dehydration	3	5.8	2	3.6
Hyperglycaemia	4	7.7	8	14.3
Hypoalbuminaemia	1	1.9	3	5.4
Hypocalcaemia	1	1.9	3	5.4
Hypokalaemia	6	11.5	5	8.9
Hypophosphataemia	3	5.8	5	8.9
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Leukemia recurrent	4	7.7	5	8.9
Nervous system disorders				
Syncope	3	5.8	2	3.6
Psychiatric disorders				
Anxiety	1	1.9	3	5.4
Renal and urinary disorders				
Acute kidney injury	4	7.7	3	5.4
Respiratory, thoracic and mediastinal disorders				
Dyspnoea	4	7.7	9	16.1
Epistaxis	3	5.8	4	7.1
Hypoxia	5	9.6	13	23.2

	Treatment Received			
	Omidubicel (N=52)		Unmanipulated UCB (N=56)	
MedDRA Preferred Term by System Organ Class	**Number of Participants**	**%**	**Number of Participants**	**%**
Respiratory failure	2	3.8	5	8.9
Vascular disorders				
Hypertension	13	25.0	22	39.3
Hypotension	2	3.8	5	8.9

*reported in at least 3% of the safety (as-treated) population

Supplemental Table 4: Treatment Emergent Adverse Events Related to Cord Blood Infusion

Event	Treatment Received	
	Omidubicel (N=52)	**Unmanipulated UCB (N=56)**
Graft versus host disease	18 (35%)	14 (25%)
Pain	4 (8%)	1 (2%)
Hypertension	2 (4%)	10 (18%)
Transplant failure	2 (4%)	5 (9%)
Dyspnea	1 (2%)	4 (7%)

Supplementary Figure 1. Quantitative recovery (median cells/µl) of (A) CD3+, (B) CD4+, (C) CD8+, (D) CD19+ and (E) CD56+ CD16+ NK cells