Comprehensive Cancer Center
Tübingen-Stuttgart

Post EBMT 2026

Post allo-SZT Immunrekonstitution / Infektionen

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Immunrekonstitution (IR) post allo-SZT, eine unterschätzte Ergebnisvariable

„A harmonization procedure to achieve a more balanced immune reconstitution might have a more profound impact on patient survival than any other novel maintenance therapy.“

- J. Kuball, EBMT Handbook-

- Diffizile Balance zwischen Infektionsrisiko, GvHD und GvL
- Häufig black box in der klinischen Routine
- Transplantstrategien haben auch immer Einfluss auf die IR
  - Konditionierungsintensität -> Thymopoese [2]
  - Konditionierung und GvHD Prophylaxe mit individueller Pharmakokinetik [3]
  - Konstitution des Grafts/Graft Engineering (CD34+ Selektion, αβ/CD19 Depletion)

→ Immunrekonstitution mehr als nur Outcome

→ Früher Indikator mit Steuerungsfunktion und Chance für personalisiertere Strategien

[1] Kuball J et al. The EBMT Handbook: Hematopoietic Cell Transplantation and Cellular Therapies, 8. Aufl., 2024, Kap. 10

[2] Douek DC et al. Assessment of thymic output in adults after haematopoietic stem-cell transplantation and prediction of T-cell reconstitution. Lancet. 2000 May 27;355(9218):1875-81.

[3] Admiraal R et al. Association between anti-thymocyte globulin exposure and CD4+ immune reconstitution in paediatric haemopoietic cell transplantation: a multicentre, retrospective pharmacodynamic cohort analysis. Lancet Haematol 2015;2(5):e194–e203

INFECTION RATES ACROSS THE FIRST-YEAR POST-TRANSPLANT IN PTCY AND NON-PTCY-BASED GVHD PROPHYLAXIS: A POST-HOC ANALYSIS OF A RANDOMIZED PHASE II STUDY - OS19-03

Jennifer I. Jensen1 , Yehseo Jung1 , Xinyi Fan2 , Ted A. Gooley2 , Michael Boeckh1,2, Marco Mielcarek2,1, Brenda M. Sandmaier2,1, Masumi Ueda Oshima1,2

Infektionen im ersten Jahr post PTCy – OS19-03

ORIGINAL REPORTS | October 03, 2025 | Latest version

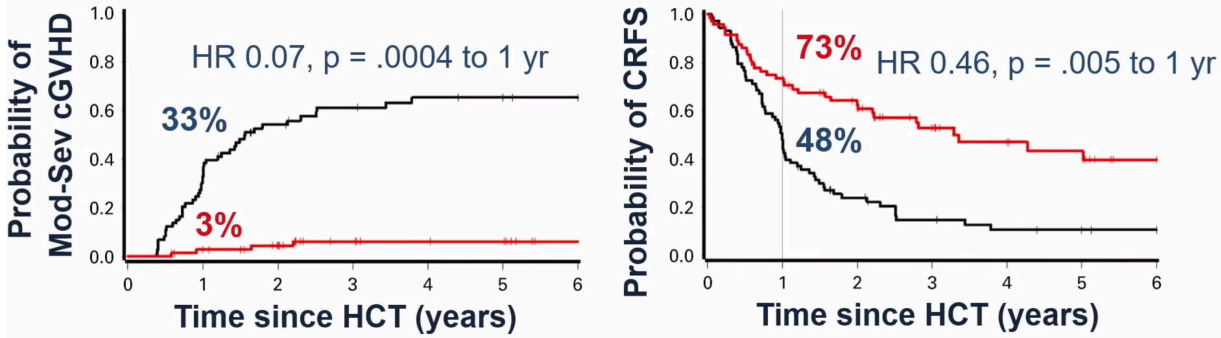
Sirolimus and Cyclosporine With Post-Transplant Cyclophosphamide or Mycophenolate Mofetil as Graft-Versus-Host Disease Prophylaxis in Unrelated Donor Hematopoietic Cell Transplantation

Authors: Masumi Ueda Oshima, MD, Phuong T. Vo, MD, Michael Boeckh, MD, Michelle E. Bouvier, RN, Paul A. Carpenter, MD, Marco Mielcarek, MD, Effie W. Petersdorf, MD, Rainer Storb, MD, Ted Gooley, PhD, and Brenda M. Sandmaier, MD | AUTHORS INFO & AFFILIATIONS

J Clin Oncol **43**, 3600-3609(2025) • Volume 43, Number 33 • DOI: 10.1200/JCO-25-01238

PTCy: Decreased risk of cGVHD but increased early infection

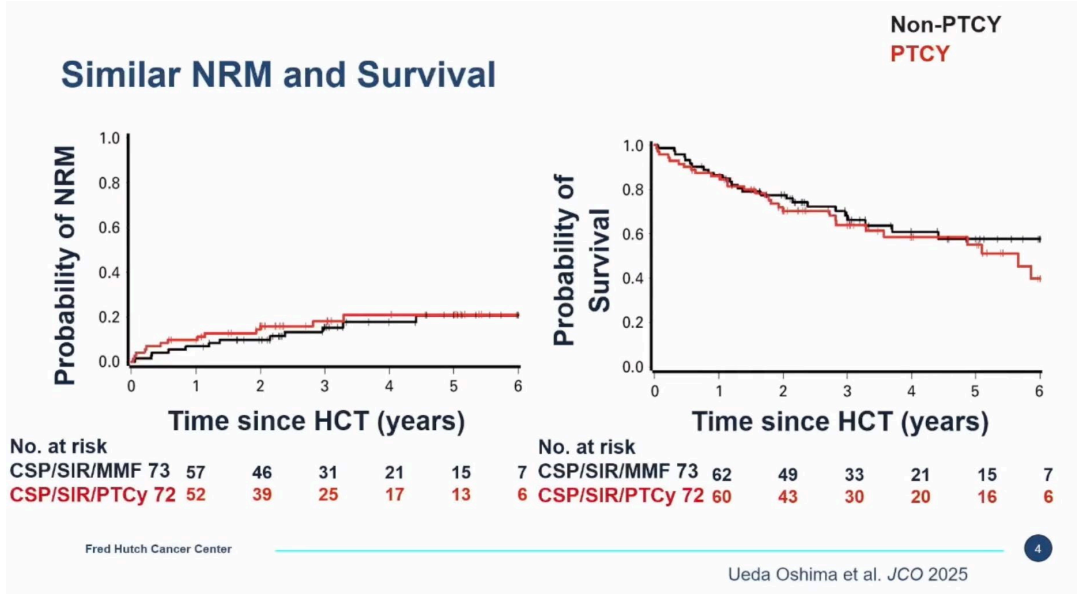
Ph II RCT: HLA-MUD/**m**MUD PBSC; Reduced intensity; Median age: 67 yrs
PTCy/SIR/CSP (n=72) vs. **MMF**/SIR/CSP (n=73)



Day 100 Gr ≥3 infections:
PTCy 44% vs. **non-PTCY 19%**
HR 2.65, p=0.003

Ueda Oshima et al. *JCO* 2025

Similar NRM and Survival



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Ueda Oshima et al. *JCO* 2025

--> Hypothese: **Geringerer Infectious Disease Burden** durch weniger GvHD-Therapie im ersten Jahr

Infektionen im ersten Jahr post PTCy – OS19-03

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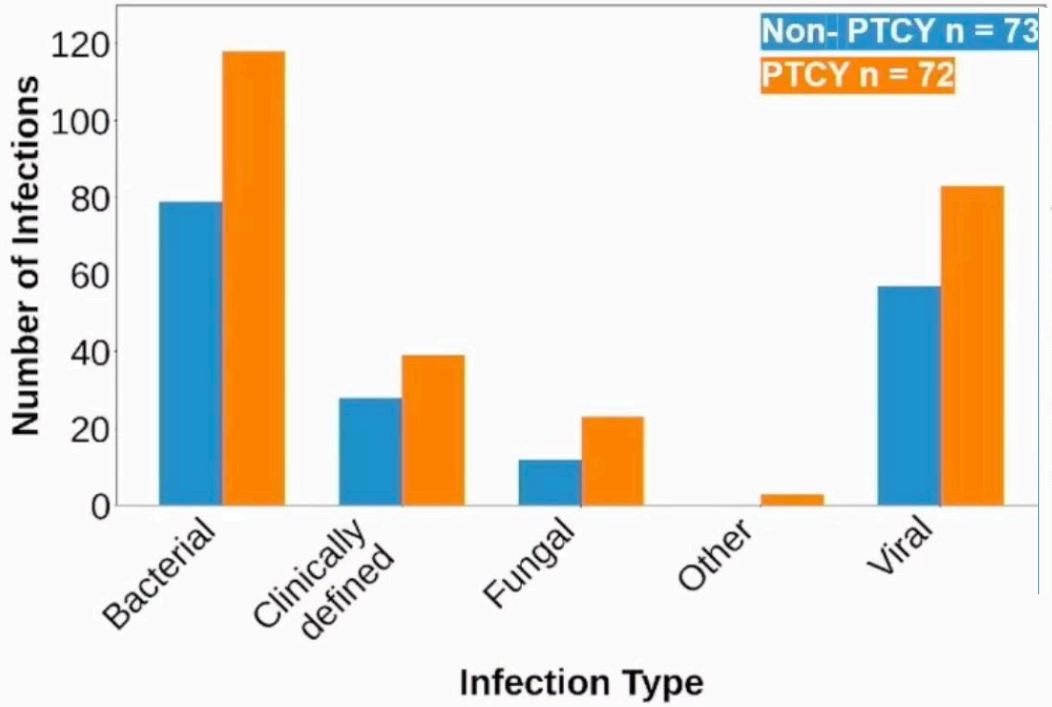
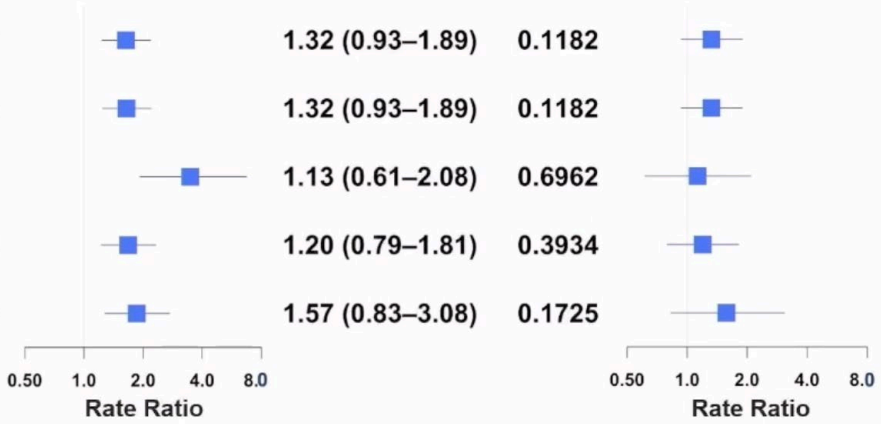
Post Hoc Analyse: Auswertung aller Infektereignisse im ersten Jahr post SZT



Infection Type	Day 0-30 RR (95% CI)	Day 0-30 p-value	Day 30-100 RR (95% CI)	Day 30-100 p-value
ALL	1.64 (1.24–2.19)	0.0007	1.32 (0.93–1.89)	0.1182
BMT 1-2	1.65 (1.24–2.20)	0.0006	1.32 (0.93–1.89)	0.1182
BMT 2-3	3.47 (1.93–6.71)	<0.0001	1.13 (0.61–2.08)	0.6962
CTCAE 2-5	1.68 (1.23–2.32)	0.0014	1.20 (0.79–1.81)	0.3934
CTCAE 3-5	1.86 (1.28–2.73)	0.0013	1.57 (0.83–3.08)	0.1725



→ Frühe Infektionen häufiger (verzögertes Neutrophilenengraftment)

→ Mehr Infektionen auch zwischen 180-360 Tagen (trotz deutlich niedrigerer cGvHD Inzidenz)

→ Wo liegt der Sweet Spot für PTCy?

EARLY IMMUNE RECOVERY IN MISMATCHED UNRELATED DONOR PERIPHERAL BLOOD STEM CELL TRANSPLANTATION USING REDUCEDDOSE POST-TRANSPLANTATION CYCLOPHOSPHAMIDE AS GRAFTVERSUS-HOST DISEASE PROPHYLAXIS: RESULTS FROM THE OPTIMIZE TRIAL OS05-02 + B074

Jeffery J. Auletta1 , Dillon Corrigan1 , Caitrin Bupp1 , Ray Sajugla1 , Brandan Butler1 , Alec Rose1 , Masumi Ueda Oshima2 , Monzr M. Al Malki3 , Rachel Cook4 , Mahasweta Gooptu5 , Karen Ballen6 , Shannon R. McCurdy7 , Betul Oran8 , Antonio Jimenez Jimenez9 , Dipenkumar Modi10 , Sameem Abedin11, Brian Shaffer12, Mark Juckett13, Heather E. Stefanski1 , Bronwen E. Shaw11, Stephen R. Spellman1 , Steven M. Devine1

Immune Recovery & Infection burden in MMUD SZT mit Dosisreduktion PTCy: OPTIMIZE TRIAL – OS05-02 + B074

Post-Transplant Cyclophosphamide-Based Graft-Versus-Host Disease Prophylaxis After Mismatched Unrelated Donor Peripheral Blood Stem Cell Transplantation

Authors: Monzr M. Al Malki, MD, Stephanie Bo-Subait, MPH, Brent Logan, PhD, Janelle Olson, PhD, Jianqun Kou, MS, Sarah Smith, BSN, Erin Leckrone, MBA, ... SHOW ALL ... , and Antonio Martin Jimenez Jimenez, MD | AUTHORS INFO & AFFILIATIONS

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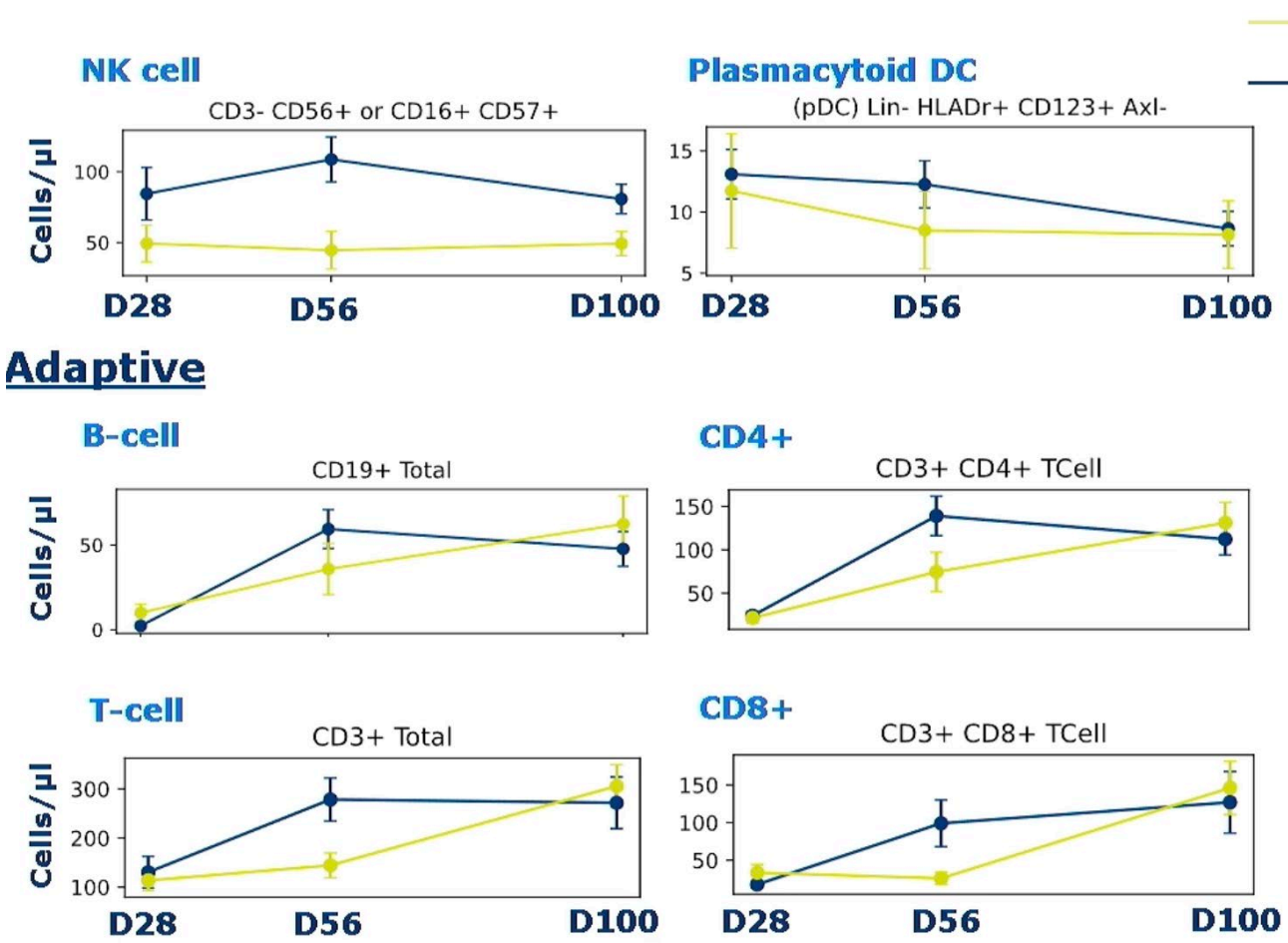
- Phase II ACCESS Trial: MMUD SZT mit PT-Cy 2x50mg/kg
  - 1 Jahres OS: 81%
  - Jedoch hohe Rate an Infektionen:
    - N=268 Adults: 183 (68%) experienced 465 CTCAE Grade 2-5 infections[3]
    - By D100, 155 (58%) experienced 296 (64%) CTCAE Grade 2-5 infections
    - Similar infection burden by conditioning intensity and level of donor HLA MM[3]

→ Dosisreduktion auf **2x 25mg/kg** (2x 37,5mg/kg für <7/8) im Phase II **OPTIMIZE Trial** mit dem Ziel besserer Immunrekonstitution

- 157 Patienten (75 MAC, 82 RIC/NMA)
- Endpunkte: Immunrekonstitution & Infektereignisse bis Tag 100, GvHD, NRM, OS
- Stratifiziert nach Konditionierungsintensität

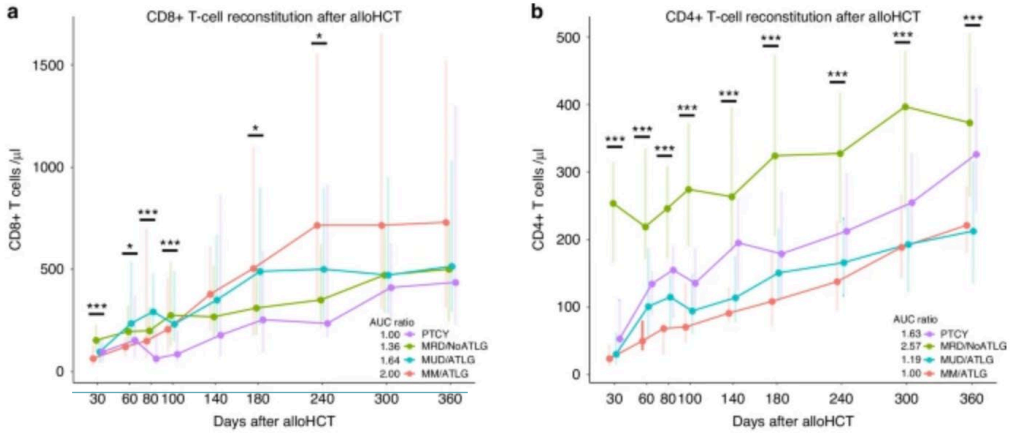
Immune Recovery & Infection burden in MMUD SZT mit Dosisreduktion PTCy: OPTIMIZE TRIAL – OS05-02 + B074



Parameter, median (IQR)	PTCY N=34	HD-ATG N=62	LD-ATG N=13	P
N of T cells/µL	153.0 (75.5-311.3)	261.5 (117.8-565.0)	315.0 (192.0-1,349.0)	0.018
N of CD4⁺ T cells/µL	70.5 (43.0-158.5)	40.0 (23.5-118.8)	53.0 (32.0-231.5)	0.091
N of CD8⁺ T cells/µL	52.5 (24.3-164.5)	176.0 (79.5-468.5)	245.0 (143.5-1,098.0)	<0.001
CD4/CD8 ratio	1.26 (0.78-2.62)	0.23 (0.16-0.46)	0.25 (0.18-0.37)	<0.001
N of B cells/µL,	2.0 (0.0-47.8)	1.5 (0.0-85.5)	1 (0.0-239.5)	0.897
N of NK cells/µL	194.5 (109.5-273.5)	184.0 (121.0-292.0)	194.0 (135.3-251.8)	0.905

IR nach PTCy 3 Monate

Bordat et al. 2026, Hematologica

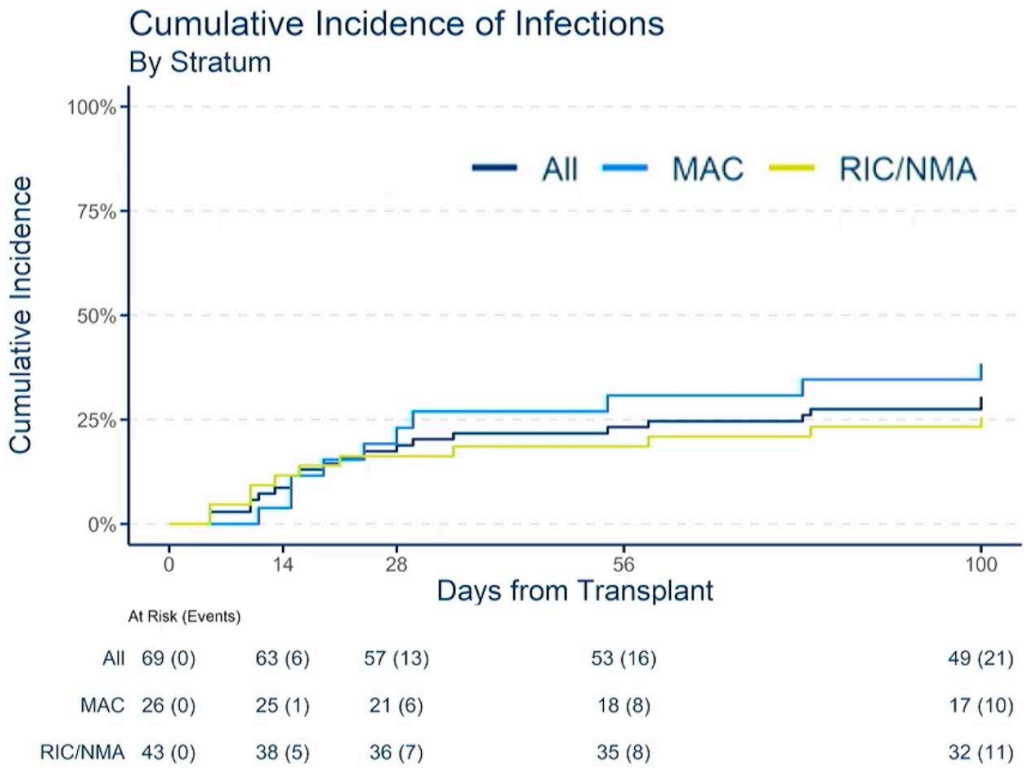


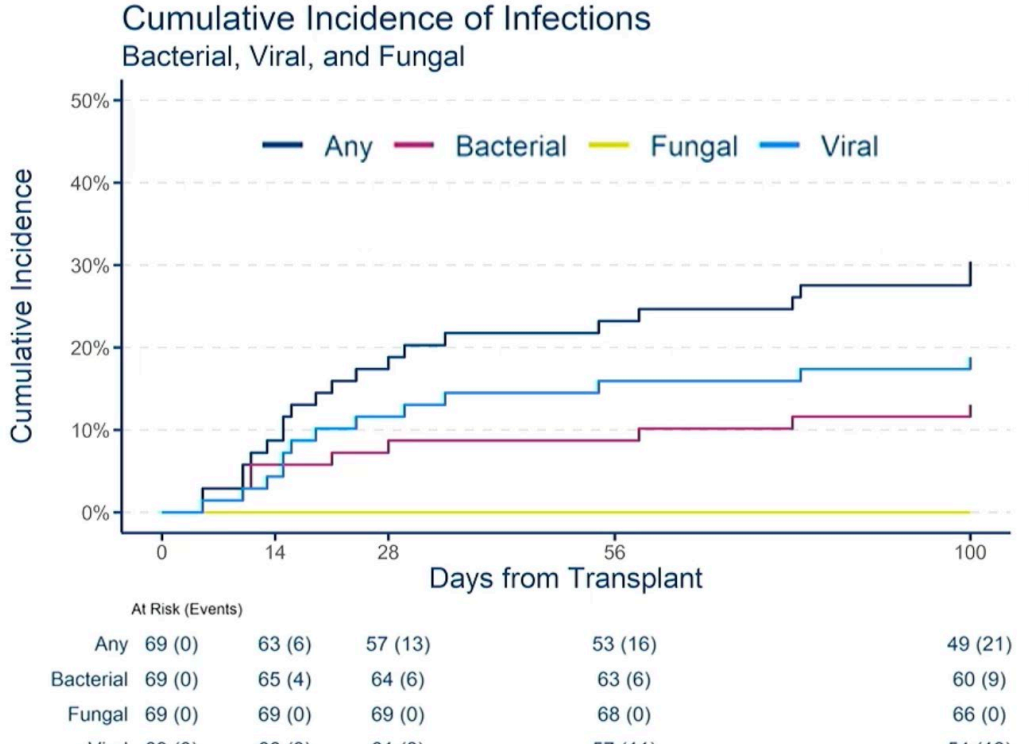
IR nach PTCy

Meyer et al. 2025, BMT

- Nur eingeschränkte Vergleichbarkeit zwischen Studien

Immune Recovery & Infection burden in MMUD SZT mit Dosisreduktion PTCy: OPTIMIZE TRIAL – OS05-02 + B074





- ACCESS Trial: Infektionen bei 56 bzw. 64% der Patienten mit 2x50mg/kg PTCy bis Tag 100

Table S10. Grade 2 or higher infections

Infection		MAC (N=75) # Recipients affected – n (% of N) Overall	First 100 days	100 days to 1 year	RIC/NMA (N=70) # Recipients affected – n (% of N) Overall	First 100 days	100 days to 1 year
Overall infections	Overall	49(65.3)	42(56)	17(22.7)	57(81.4)	45(64.3)	25(35.7)
By pathogen type	Bacterial	34(45.3)	32(42.7)	3(4)	36(51.4)	32(45.7)	9(12.9)
	Fungal	4(5.3)	2(2.7)	2(2.7)	8(11.4)	5(7.1)	3(4.3)
	No particular pathogen group identified	1(1.3)	0(0)	1(1.3)	11(15.7)	8(11.4)	3(4.3)
	Viral	29(38.7)	18(24)	15(20)	27(38.6)	17(24.3)	16(22.9)

Immune Recovery & Infection burden in MMUD SZT mit Dosisreduktion PTCy: OPTIMIZE TRIAL – OS05-02 + B074

A **Density of BMT CTN Grade 2-3 infections within 100 days by conditioning intensity**

				Cumulative infections		Infection Density (per 100 days at risk) (95% CI)	
Strata	Post-HCT time	No. patients at risk[1]	Cumulative days at risk	Grade 2-3	Grade 3	Grade 2-3	Grade 3
Total	Days 0-30	157	4867	65	14	1.34 (1.04-1.69)	0.29 (0.16-0.47)
	Days 31-100	157	15586	36	5	0.23 (0.16-0.31) #	0.03 (0.01-0.07) #
MAC	Days 0-30	75	2325	41	10	1.76 (1.28-2.36) ‡	0.43 (0.22-0.75)
	Days 31-100	75	7432	23	1	0.31 (0.2-0.45) #	0.01 (0-0.06) #
RIC/ NMA	Days 0-30	82	2542	24	4	0.94 (0.61-1.37) ‡	0.16 (0.05-0.37)
	Days 31-100	82	8154	13	4	0.16 (0.09-0.26) #	0.05 (0.02-0.11)

[1] For the calculation of days at risk, participants were considered at risk for infection while on-study.
‡ Indicates $p<0.05$ in comparing infection density between MAC and RIC/NMA at the given post-HCT time.
# Indicates significant pairwise comparisons (adjusted $p<0.05$) within each stratum to the Day 0-30 timepoint. P-values are adjusted using the Sidak method and result from generalized Poisson models with random intercepts for each subject.

Extensionskohorte – B074

POST-TRANSPLANT CYCLOPHOSPHAMIDE DOSE REDUCTION ENABLES FASTER GRANULOCYTE ENGRAFTMENT WHILE MAINTAINING EFFICACY IN PREVENTING GVHD - A073

Václav Heřman1,2, Veronika Válková1,2, Barbora Čemusová1 , Ludmila Nováková1 , Jan Vydra1,2

PTCy Dosisreduktion, Echtweltdaten - A073

- Retrospektive Auswertung einer real-world Kohorte von 367 Erwachsenen, transplantiert zwischen 2018 und 2025
  - Seit 06/2024 Reduktion von PTCy von 2x50mg/kg auf 2x35mg/kg an Tag +3 +4
  - N = 60 (70mg/kg) vs 307 (100mg/kg)
  - Baseline Unterschiede:
    - 70-mg/kg-Gruppe älter (Median 53 vs. 48 J.; p=0,005)
    - HCT-CI > 2 in 38 % vs. 24 % (p=0,04)
    - weniger Haplo-SZT (18 % vs. 32 %; p<0,001)
  - Endpunkte: Engraftment, GvHD und NRM

PTCy Dosisreduktion, Echtweltdaten - A073

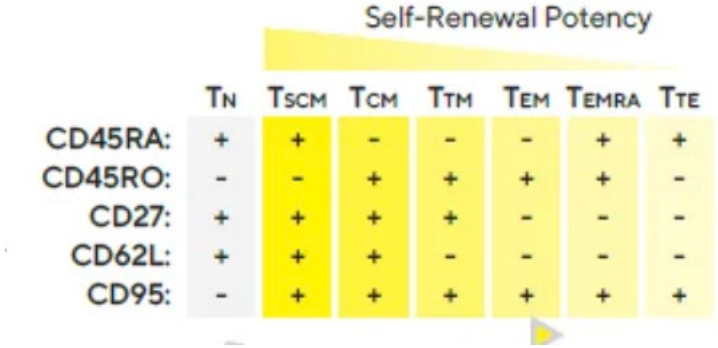
- Schnelleres **Neutrophilen Engraftment (18,5 vs 21 Tage; p <0.001)**
- Kumulative Inzidenz akuter GvHD bis Tag 120 gleich (48,3% vs 44,6%; p = 0.426)
- Kumulative Inzidenz chronischer GvHD nach 1 Jahr ohne signifikanten Unterschied (34,5% vs 28%; p=0,61)
- Kein Unterschied für NRM, 1-Jahres OS und DFS

→ Reduktion von PT-Cy basierend auf Echtweltdaten mit historischer Vergleichsgruppe nicht unterlegen mit schnellerem Neutrophilenengraftment

THE EFFICACY OF MEMORY T CELL DONOR LYMPHOCYTE INFUSION IN AUGMENTING IMMUNE FUNCTION FOLLOWING ALLOGENEIC HEMATOPOIETIC CELL TRANSPLANTATION – A113

Jiayu Huang1 , Chuanhe Jiang1 , Chengwei Jin2 , Luxiang Wang1 , Zilu Zhang1 , Haiyang Lu1 , Su Li2 , Xiaoxia Hu1

Memory T-cell Infusion post Allo SZT – A113

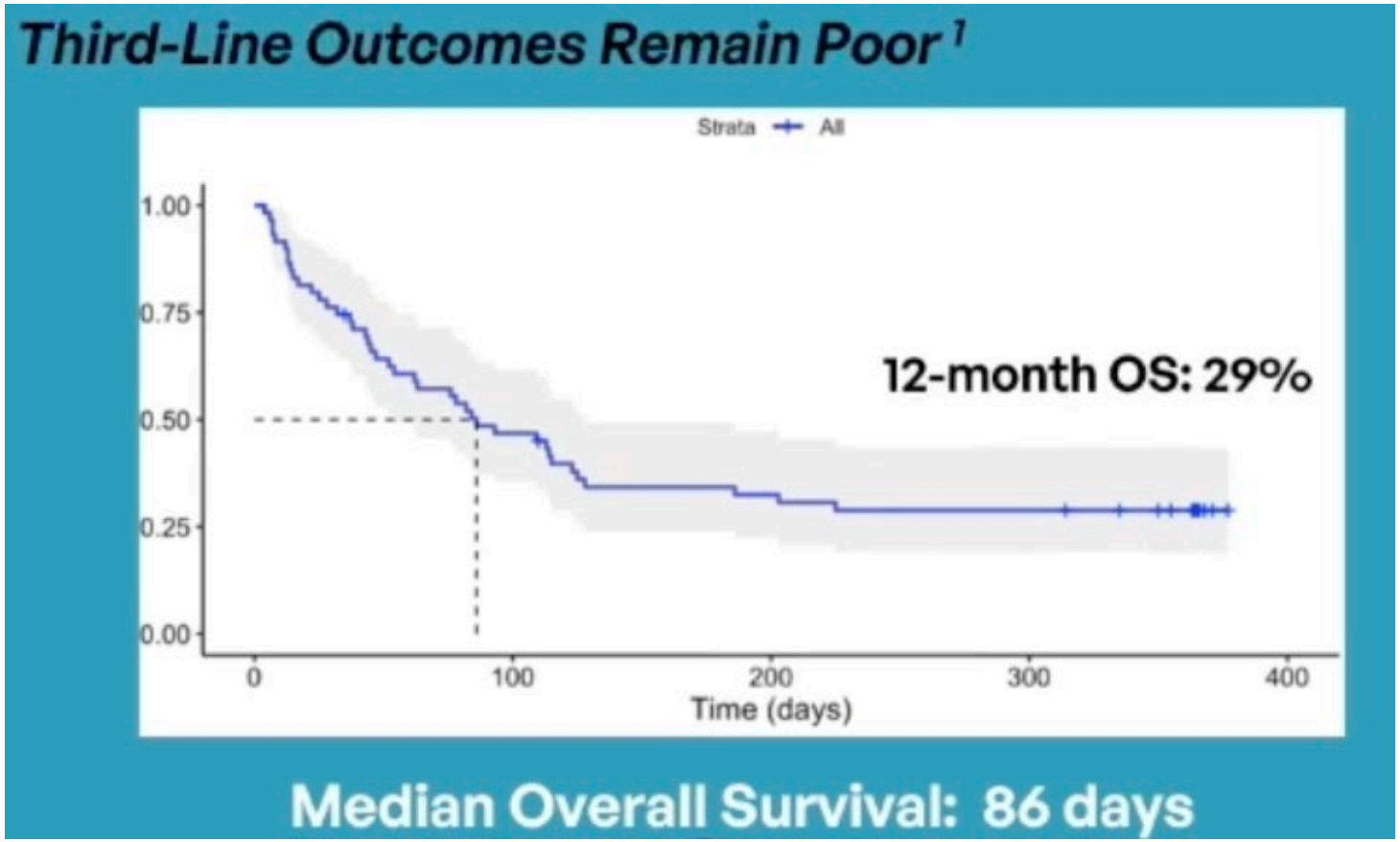


- Memory T Zellen besitzen in der Regel keine CD45RA Isoform
  - -> Depletion nativer, putativ eher alloreaktiver T-Zellen durch CD45RA Depletion
  - Retrospektive Auswertung von 20 Patienten, behandelt mit CD45RA DLIs
  - Indikation: Virusinfektionen (90%), Pilzinfektionen (15%)
  - 48 Applikationen, im Median 2/Patient mit durchschnittlich 23 Mio Zellen/kg
  - 75% aus SZ-Spender, 25% aus fremdem Spender, 50% innerhalb der ersten 100 Tage
  - 70% der Empfänger weiterhin unter Immunsuppression bei Infusion
  - Followup (Median 52 Tage): 90% am Leben, 60% mit CR der Infektion
  - In 13/18 Patienten mit Virusinfektionen negative PCR nach erster Infusion
    - Mediane Latenz teilweise unterschiedlich: CMV 5 Tage, ADV 10 Tage, HSV 35 Tage (nicht bei allen Ansprechen), HHV6 33 Tage, ParvoB19 38 Tage
  - aGvHD in einem Patienten (5%) , cGvHD in drei Patienten (15%), Rezidiv in einem Patienten (5%)

MAAT013 FOR RUXOLITINIB-REFRACTORY ACUTE GRAFT-VERSUSHOST DISEASE WITH GASTROINTESTINAL INVOLVEMENT: FINAL RESULTS FROM THE ARES PHASE III TRIAL– GS2-8

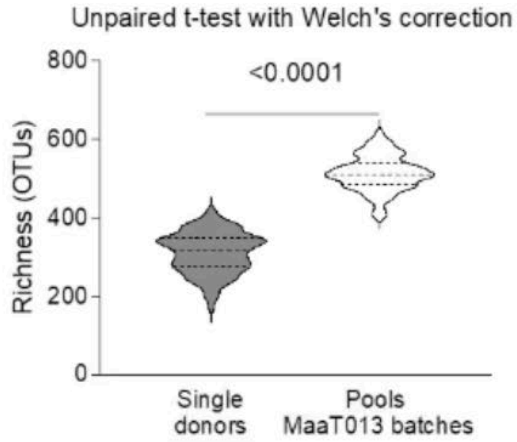
Florent Malard1,2, Jaime Sanz3,4, Clemence Mediavilla5 , Lucia Lopez-Corral6 , Alexander Schauwvlieghe7 , Marc Bernard8 , Michael Loschi9 , Chama Mokeddem10, Francesca Bonifazi11 , Daniela Heidenreich12, Verena Wais13, Elisa Sala13, Stefan Koeck14, Johannes Clausen15 , Mélanie Tilte16, Marion Bruelle16, Behzad Kharabi Masouleh16, Emilie Plantamura16, Ernst Holler17, Mohamad Mohty1,2

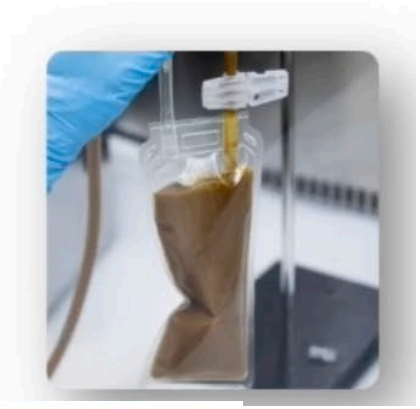
Fäkaler Mikrobiomtransfer in Ruxolitinib refraktärer GI-aGvHD: ARES Trial – GS2-8

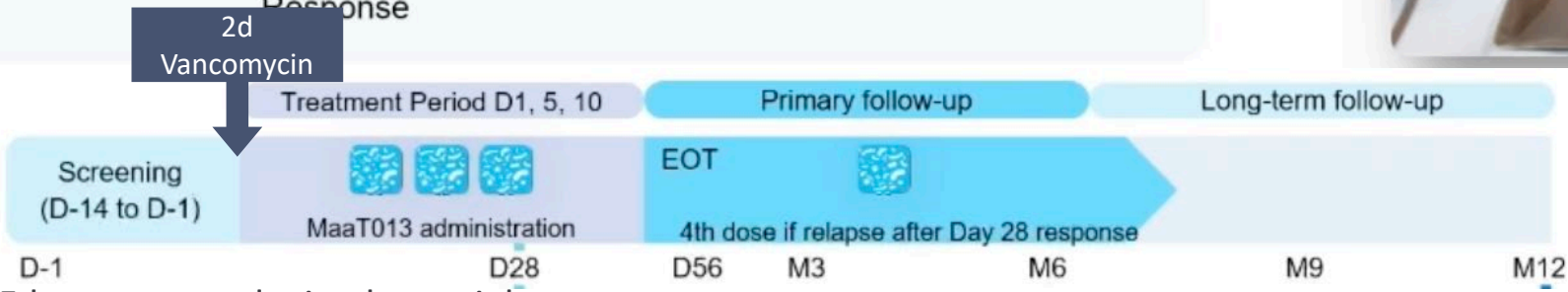


Fäkaler Mikrobiomtransfer in Ruxolitinib refraktärer GI-aGvHD: ARES Trial – GS2-8

Administration	✓ Rectal suspension (150 mL enema) ✓ 3 doses within 10 days
Characteristics: **Pooled allogeneic fecal microbiota**	✓ A high-richness, high-diversity, full ecosystem, containing Butycore™ and not less than 1.35 x 10^{11} viable bacteria. ✓ 36 months stability at -80°C
Available clinical data	✓ *HERACLES* (Phase 2) Trial, n=24 ✓ ***ARES* (Phase 3) Trial, n= 66** ✓ Ongoing Early Access Program (Europe – US (> 240 patients treated as of November 2025)
Efficacy Evaluation	✓ GI- and all-organ response rate (ORR) at Day 28 ✓ Complete response, Very Good Partial Response, Partial Response







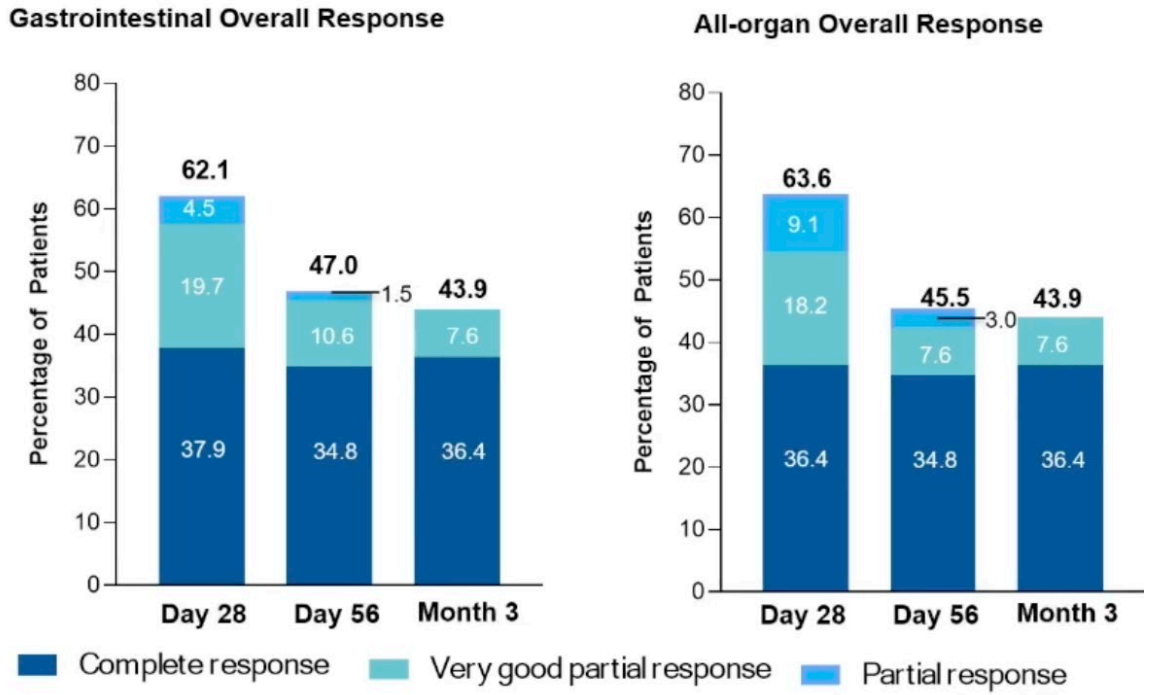
Butycore: a group of 15 butyrate producing bacterial genera

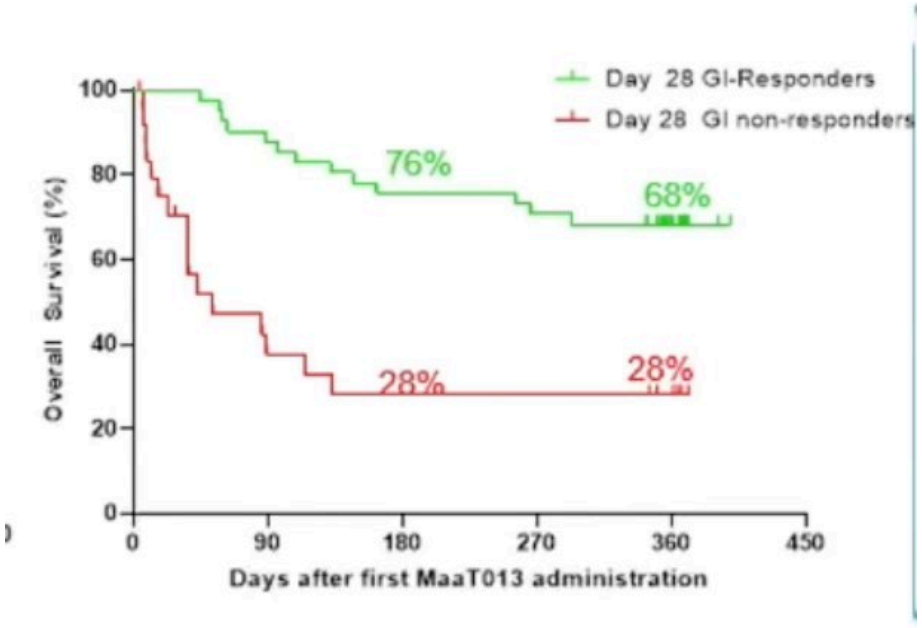
Fäkaler Mikrobiomtransfer in Ruxolitinib refraktärer GI-aGvHD: ARES Trial – GS2-8

Type of aGvHD	N (%)
Classical	58 (88)
Late onset	3 (4)
Post-DLI	4 (6)
Other	1 (2)

Organ involvement	N (%)
GI only	51 (77%)
GI + skin	11 (17%)
GI + liver	2 (3%)
GI + liver + skin	2 (3%)

Mean retention time	151.6 min
Median retention time	124.0 min





→ Historische Vergleichsgruppe mit 22% ORR in 3. Therapielinie

Fäkaler Mikrobiomtransfer in Ruxolitinib refraktärer GI-aGvHD: ARES Trial – GS2-8

Serious Adverse Events

SAEs reported in 80% of patients (n=53)

- 8 SAEs (in 7 patients) considered related to MaaT013 by investigators
- Among 17 infectious AEs (11 patients) deemed treatment-related,

2 events confirmed the same strain present in MaaT013 (infection monitoring process)

Deaths

29 patients (44%) died during the study- Causes of death:

- Severe infections: 13
- GvHD progression: 5
- General health deterioration: 4
- Rectal hemorrhage: 2
- Underlying malignancy relapse: 2
- Cerebral hemorrhage: 2Cardio-respiratory arrest: 1

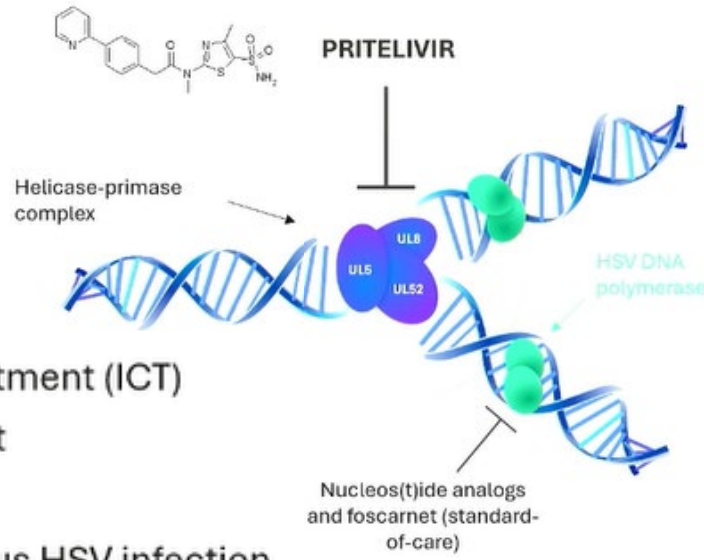
	Any Grade	Worst Grade >=3	Worst Grade 3	Worst Grade 4	Worst Grade 5
Any adverse event occurring up to 14 days after last MaaT013 administration, n (%)	**59 (89%)**	**47 (71%)**	**30 (45%)**	**10 (15%)**	**7 (11%)**
Bacterial bloodstream infection	34 (51%)	18 (27%)	9 (14%)	3 (4%)	6 (9%)
Gastrointestinal disorder	25 (38%)	8 (12%)	7 (11%)	0	1 (1%)
Other bacterial infection	17 (26%)	9 (14%)	9 (14%)	0	0
Viral infection	16 (24%)	3 (4%)	3 (4%)	0	0
Non-documented infection	13 (20%)	10 (15%)	9 (14%)	1 (1%)	0
Fungal infection	6 (9%)	3 (4%)	2 (3%)	1 (1%)	0
Other events	49 (74%)	31 (47%)	22 (33%)	9 (14%)	0

Refraktäre HSV Infektion: Phase 3 Studie Pritelivir

Pritelivir Demonstrated Superior Efficacy Compared to Investigator's Choice for Refractory HSV Infections in Immunocompromise Patients: PRIOH-1, Phase 3 Safety and Efficacy (OS09-04)

Genovefa A. Papanicolaou, Robin Avery, Kimberly Workowski, Karl S. Peggs, Yeon Joo Lee, Jean-Michel Molina, Dionysios Neofytos, Anum Abbas, Alma Perez-Rios, Jana Dickter, Sanjeet Dadwal, Stuart Cohen, Nicolas Issa, Palash Samanta, Alexander Birkmann, Cynthia Wat, Dilruwan Chaminda Herath, Alessandra Marini, Bernadette Surujbally, Melanie Sumner, Anna Wald, Roy Chemaly

Refraktäre HSV Infektion: Phase 3 Studie Pritelivir (OS09-04)

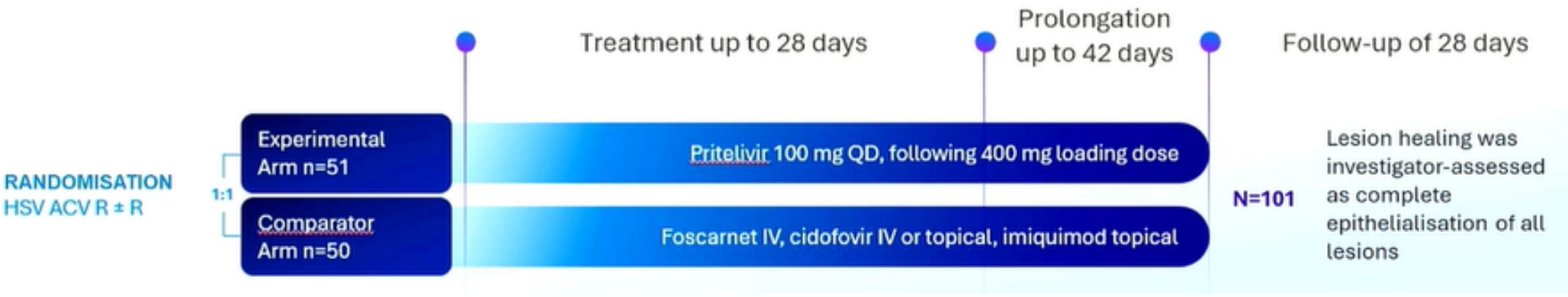


Phase 3 PRIOH-1 Study Design

Randomised, Open-label, Multicentre Trial

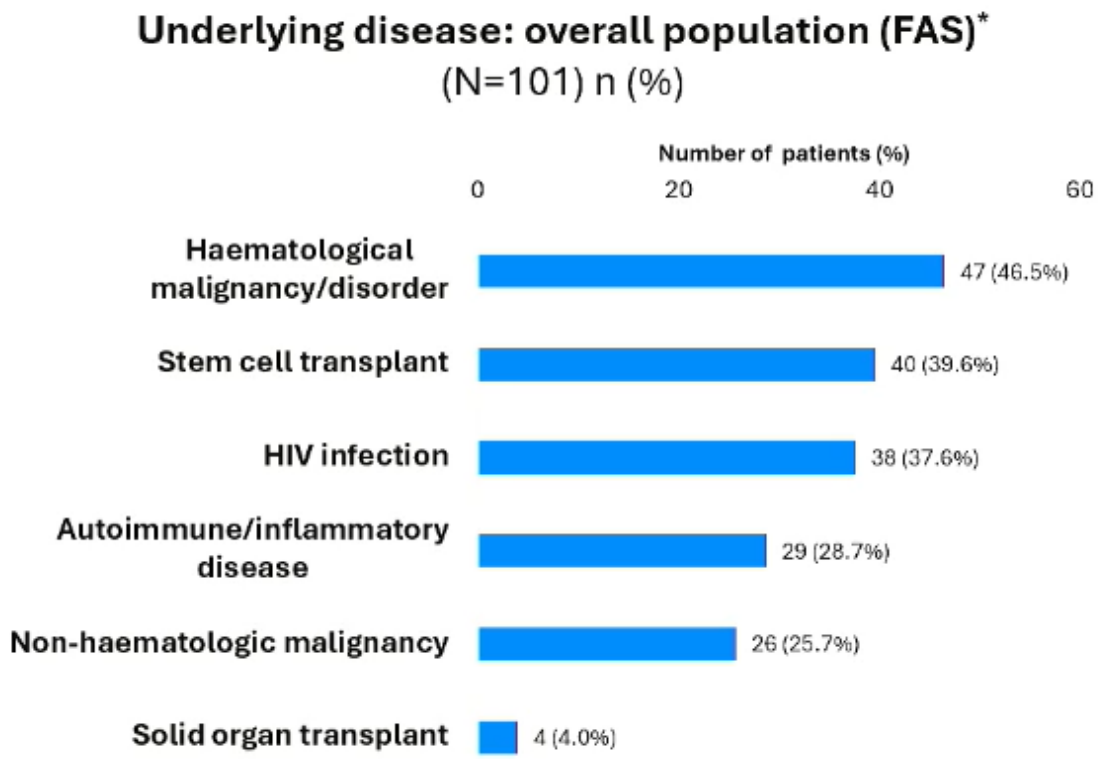
- **Study Aim:** To evaluate the efficacy and safety of pritelivir compared with investigator's choice treatment (ICT)
- **Primary endpoint:** % of patients with complete lesion healing (cure rate) up to 28 days of treatment
- **Secondary endpoints:** Include safety and tolerability
- **Key inclusion criteria:** Immunocompromised adults with ACV refractory ± resistant mucocutaneous HSV infection based on:
  - Refractory/Clinical Failure: No clinical improvement of HSV lesion(s) after ≥7 days with therapeutic doses of a nucleoside analogue*

  OR
  - Resistance; Local laboratory-confirmed genotypic/phenotypic ACV resistance testing for current lesion



Refraktäre HSV Infektion: Phase 3 Studie Pritelivir (OS09-04)

Reason for Treatment start	Pritelivir (N=51) n (%)	ICT (N=50) n (%)	Total (N=101) n (%)
Refractory HSV (clinical failure)	39 (76.5)	33 (66.0)	72 (71.3)
Lab confirmed ACV resistant	12 (23.5)	17 (34.0)	29 (28.7)



Refraktäre HSV Infektion: Phase 3 Studie Pritelivir (OS09-04)

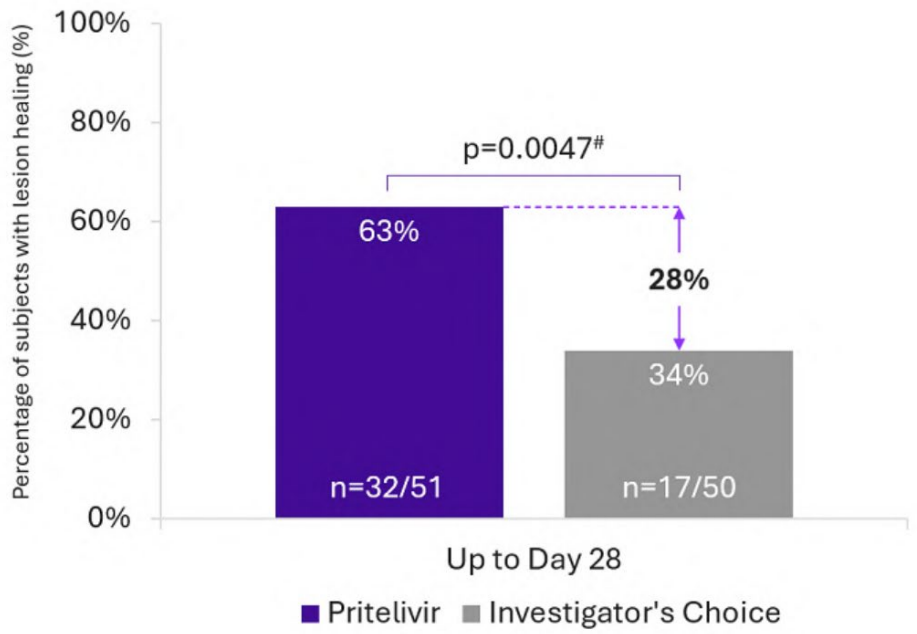
PRIOH-1: Pritelivir Demonstrated a Favourable Safety and Tolerability Profile

Lower rates of drug-related TEAE discontinuations on pritelivir (2%) vs ICT(20%)

Safety population	Pritelivir (N=51) n (%)	ICT (N=50) n (%)
Patients with any TEAE	41 (80.4)	45 (90.0)
Exposure-Adjusted Event Rate per patient year	42.8	102.0
Drug-Related TEAEs	**11 (21.6)**	**27 (54.0)**
Treatment-Emergent Serious Adverse Events	10 (19.6)	15 (30.0)
Treatment Discontinuation due to any TEAE	2 (3.9)	11 (22.0)
Treatment Discontinuation due to Drug-Related TEAEs	**1 (2.0)**	**10 (20.0)**
Patients with any TEAEs of Special Interest	13 (25.5)	27 (54.0)
Skin Disorders	5 (9.8)	8 (16.0)
Haematological AE	5 (9.8)	14 (28.0)
Renal/Urinary Disorders	3 (5.9)	13 (26.0)
Electrolyte Abnormalities	1 (2.0)	8 (16.0)

Refraktäre HSV Infektion: Phase 3 Studie Pritelivir (OS09-04)

Figure 1 Summary of lesion healing rate: primary efficacy endpoint (28 days)



Refraktäre HSV Infektion: Phase 3 Studie Pritelivir (OS09-04)

Fazit:

- Pritelivir als oraler Primase/Helikase-Inhibitor mit neuem Wirkmechanismus
- Effektivere Läsionsheilung als mit aktuell verfügbaren Medikamente in R/R HSV Infektion
- Relativ gute Verträglichkeit, kaum AE-bedingte Therapieabbrüche

Virus-spezifische T-Zellen für CMV/ADV/EBV nach Allo-HCT: Interimsreport Phase 3 Studie TRACE

Adoptive Transfer of Multivirus-Specific T cells against refractory CMV, ADV and EBV Infections after HCT – Interim results from the TRACE Phase-III Trial (OS18-08)

Theresa Kaeuferle, Federica Galaverna, Maria Giuseppina Cefalo, Peter van Balen, Tessa Kerre, Daniele Bensoussan, Peter Lang, Brigitte Strahm, Giuseppina LiPira, Chiara Agrati, Rosa de Groot, Mira Reger, Elvira Bodien, Markus Pfirrmann, Anna Tortolini, Linda Hanssens, Franco Locatelli, Tobias Feuchtinger

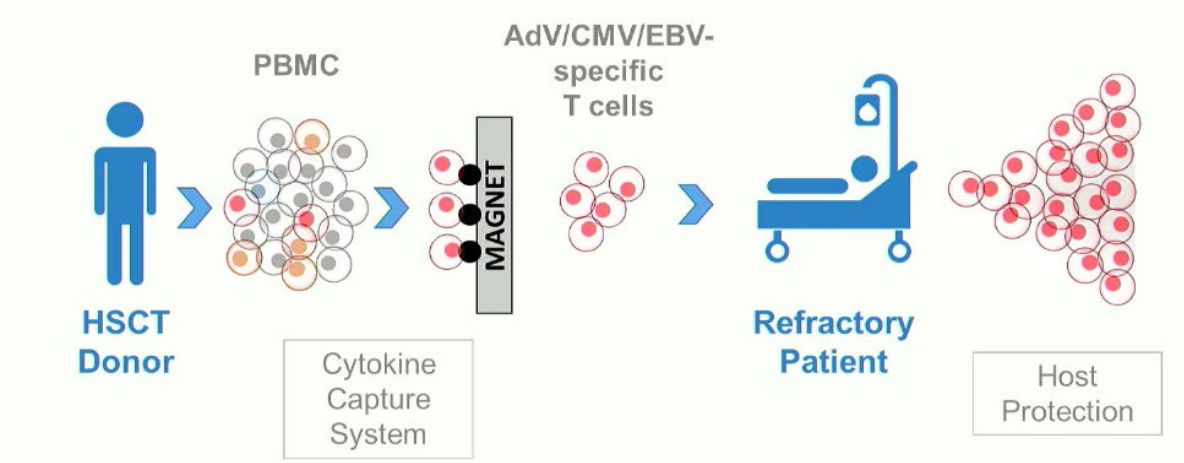
Virus-spezifische T-Zellen für CMV/ADV/EBV nach Allo-HCT: Interimsreport Phase 3 Studie TRACE (OS18-08)

ClinicalTrials.gov ID NCT04832607

Study Design	Double-blind Placebo controlled Randomized	
Phase	III	
Randomization	T-cell/Placebo 2:1	
Clinical Sites	35 sites	
Participating countries	6	
Endpoint	Viral clearance Viral progression	8 weeks

Inclusion Criteria:

- adult/pediatric post-allo HCT with refractory CMV/ADV/EBV (2 weeks)
- available HCT donor with respective T cell immunity



Virus-spezifische T-Zellen für CMV/ADV/EBV nach Allo-HCT: Interimsreport Phase 3 Studie TRACE (OS18-08)

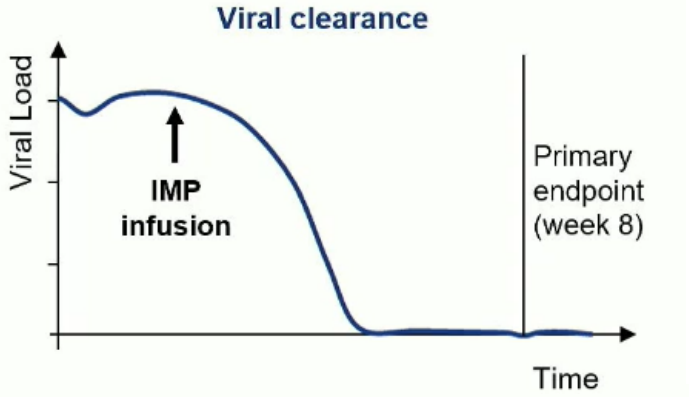
Safety Interim Analyses: aGvHD (Grade III/IV)

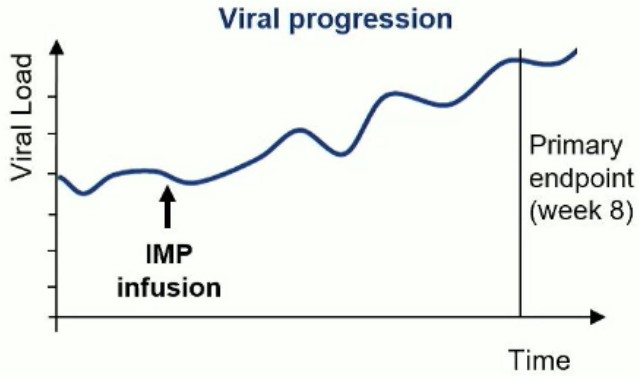
Sub-cohort	Patients per sub-cohort	Total number of patients	Critical value	Actual value
1	15	15	6	**0**
2	14	29	9	**0**
3	15	44	13	**1**
4	15	58	14	**tbd**

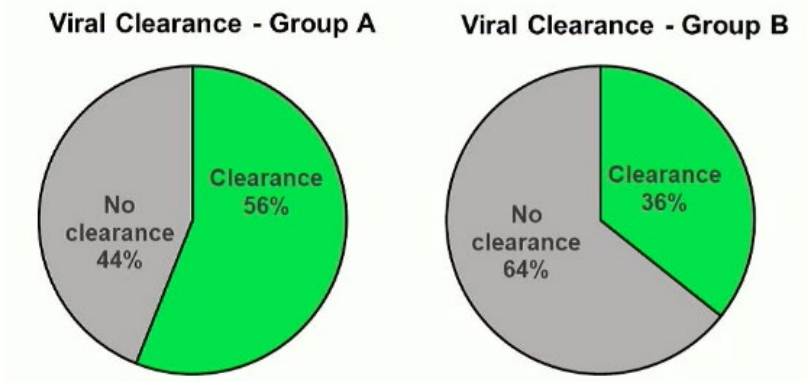
- ✓ GvHD (AESI) occurrence far below the critical values
- ✓ Stopping rules have not been met
- ✓ DSMB reviewed all cases

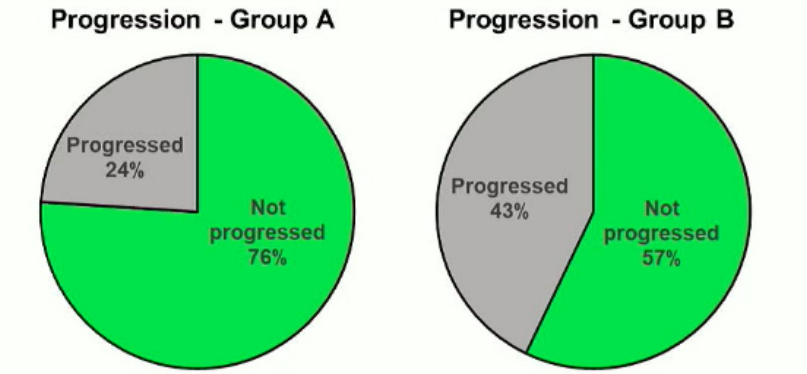
Virus-spezifische T-Zellen für CMV/ADV/EBV nach Allo-HCT: Interimsreport Phase 3 Studie TRACE (OS18-08)

Efficacy Interim Analysis – Viral clearance









- ✓ No statistical significance → Trial continues with both, verum and placebo
- ✓ DSMB recommended to continue the trial

Maribavir bei CMV nach Allo-HCT: Real-World Daten aus EBMT Register Studie

Maribavir for Clinically Significant Cytomegalovirus Infection in Allogeneic HSCT: A Retrospective International Real-World Study of the IDWP of EBMT (OS09-08)

Annalisa Paviglianiti, Per Ljungman, Rafael de la Camara, Gloria Tridello, Juana Schwartz, Nina Knelange, Arancha Bermudez Rodriguez, Maria Suarez-Lledo, Johan Maertens, Maria Stamouli, Francis Ayuk, Candela Ceballos, Maria Huguet, Felipe Peña-Muñoz, Pablo Granados, Alienor Xhaard, Jurgen Kuball, Chiara Nozzoli, Francesca Kinsella, Alejandro Avendano, Hakan Ozdogu, Jose Rifon Roca, Nicole Morrow, Marta Stanzani, Marina Popova, Jerome Cornillon, Tsila Zuckerman, Massimo Martino, Johannes Clausen, Jan Styczynski, Dina Averbuch

Maribavir bei CMV nach Allo-HCT: EBMT Register Studie (OS09-08)

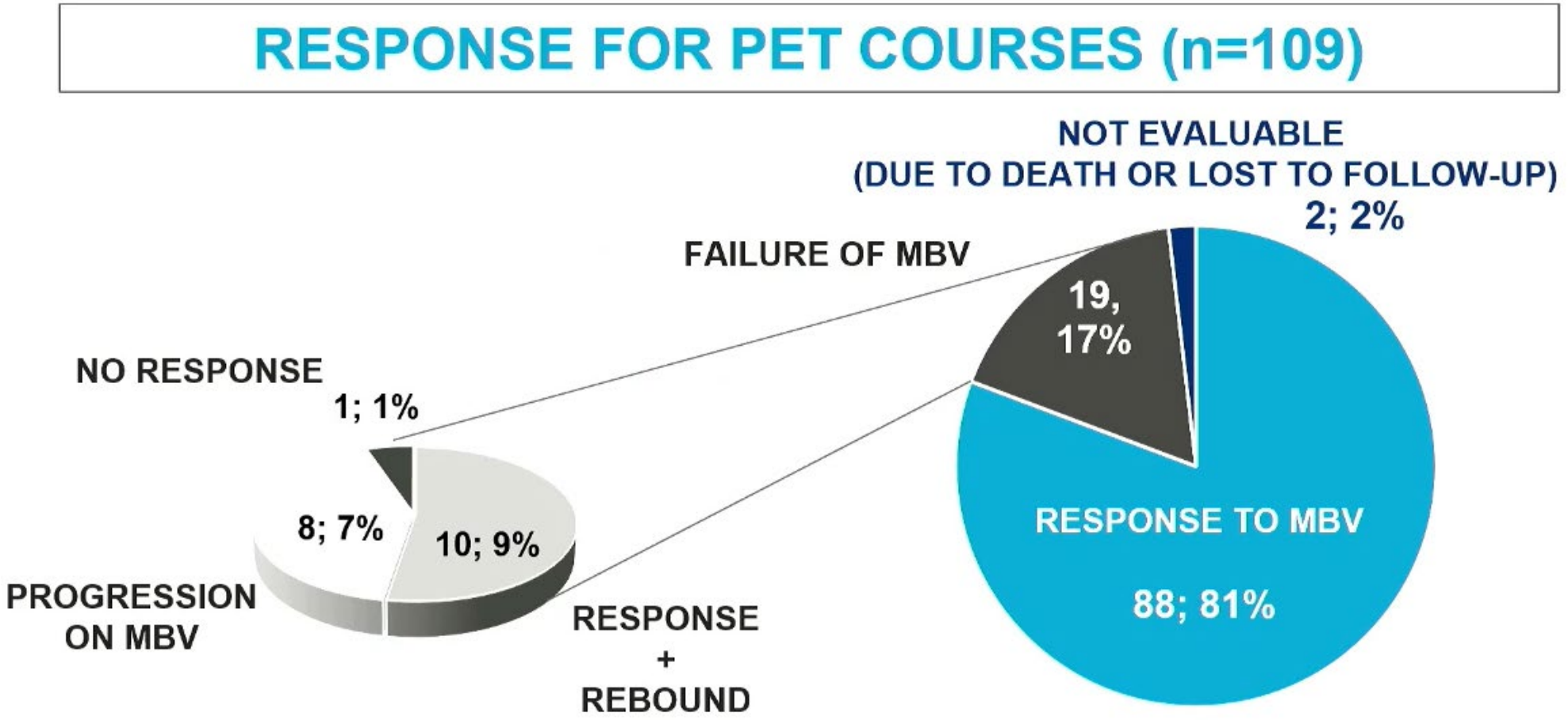
Patients were transplanted from March 2021 to October 2024
MBV treatment was given between December 2022 and January 2025

- **Study:** retrospective EBMT registry
- **Population**: Children and adults who received **MBV** post-HCT after EMA approval
- **Inclusion criteria**: Minimum **12 weeks of follow-up**
- **MBV indication**: Treatment of **clinically significant CMV infection**

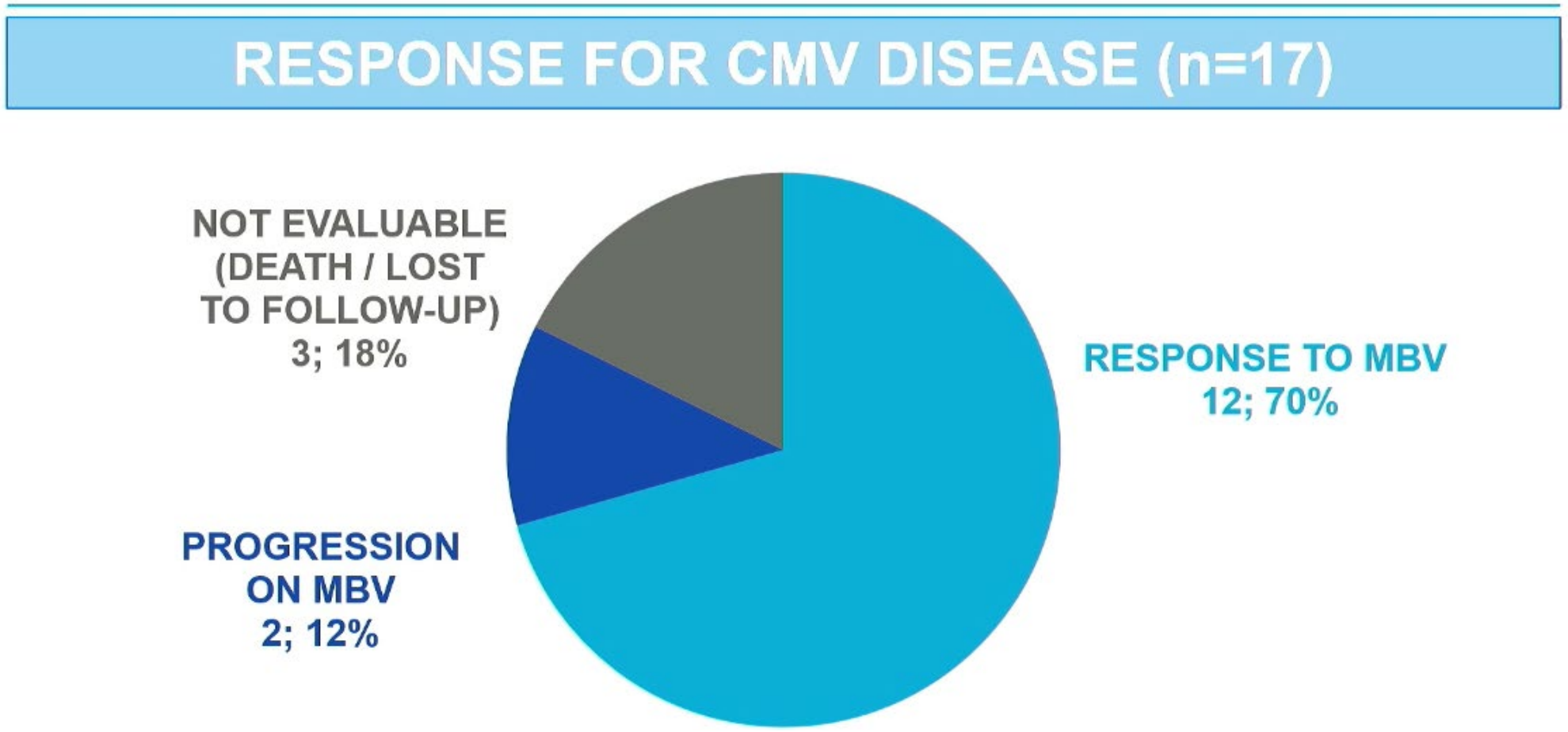
Maribavir bei CMV nach Allo-HCT: EBMT Register Studie (OS09-08)

Characteristics of the 126 MBV courses	Group	n (%)
Indication for MBV use	First line pre-emptive therapy (PET)	24 (19%)
	Second line PET	61 (48%)
	Third line PET	24 (19%)
	First line treatment of CMV disease	1 (1%)
	Second line treatment of CMV disease	6 (5%)
	Third line treatment of CMV disease	10 (8%)
Reason to use MBV	Refractory CMV infection	46 (37%)
	Neutropenia	31 (25%)
	Renal impairment	15 (12%)
	Other toxicities to previous antiviral agent	12 (10%)
	Refractory CMV disease	10 (8%)
	Resistant CMV infection	6 (5%)
	Resistant CMV disease	2 (2%)
	Other toxicity not related to previous antiviral agent	4 (3%)

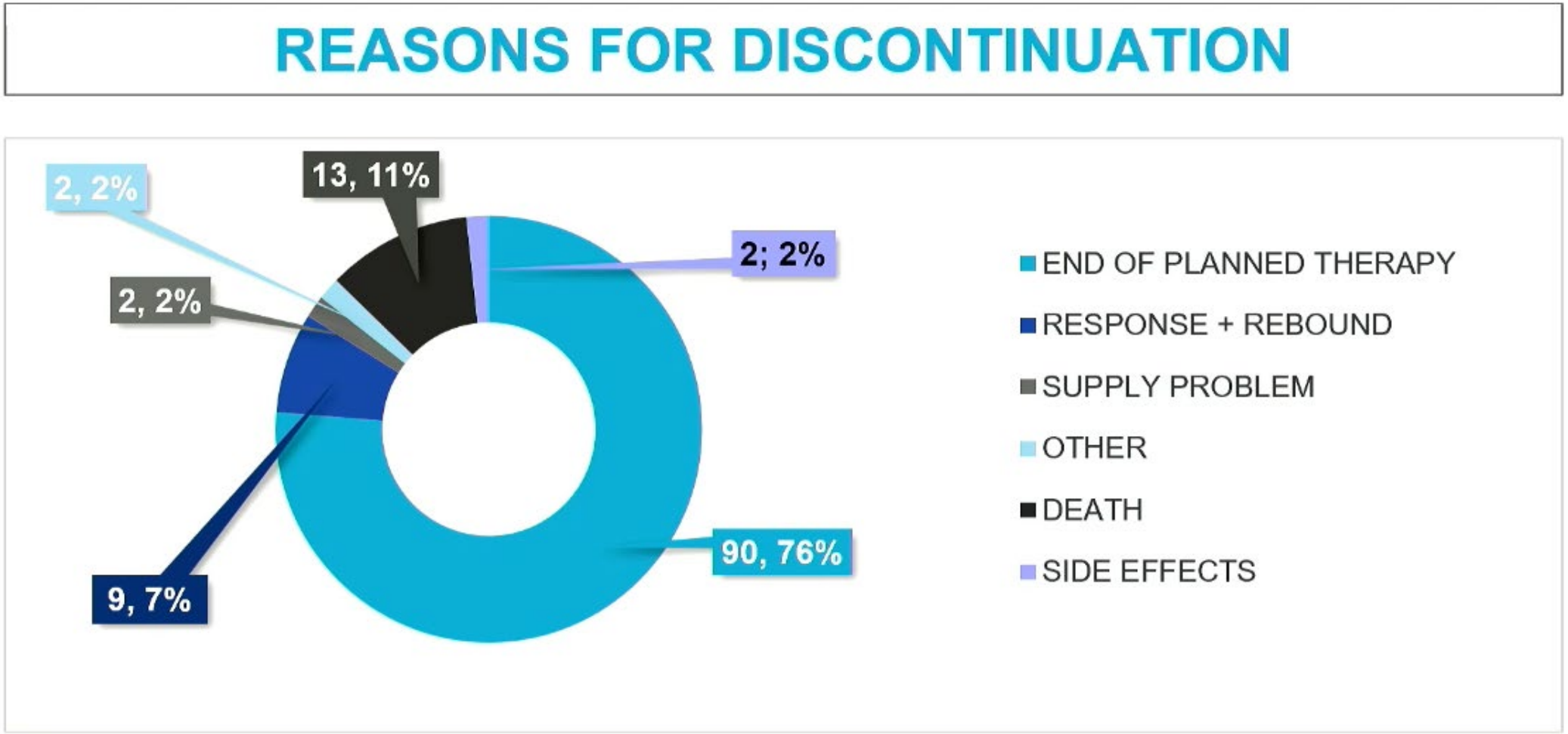
Maribavir bei CMV nach Allo-HCT: EBMT Register Studie (OS09-08)



Maribavir bei CMV nach Allo-HCT: EBMT Register Studie (OS09-08)



Maribavir bei CMV nach Allo-HCT: EBMT Register Studie (OS09-08)



Maribavir bei CMV nach Allo-HCT: EBMT Register Studie (OS09-08)

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In Press, Corrected Proof ? What's this?

Articles

Maribavir for clinically significant cytomegalovirus infection in haematopoietic cell transplant recipients in Europe: a real-world multicentre retrospective registry study

Annalisa Paviglianiti MD PhD [a] * ✉, Prof Per Ljungman MD [b], Rafael de la Camara MD [c], Gloria Tridello MSc [d], Juana Schwartz PhD [d], Nina Knelange MSc [d], Arancha Bermudez Rodriguez MD [e], María Suárez-Lledó MD [f], Prof Johan Maertens MD [g], Maria Stamouli MD [h], Prof Francis Ayuk MD [i], Candela Ceballos MD [j], Maria Huguet MD [k], Felipe Peña Muñoz MD [l], Pablo Granados MD [m], Alienor Xhaard MD [n], Prof Jurgen Kuball MD [o], Chiara Nozzoli MD [p], Prof Jan Styczynski MD [q], Prof Dina Averbuch MD [r s]...Johannes Clausen

Vielen Dank für Ihre Aufmerksamkeit

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