MaaT Pharma

Addressing Unmet Needs in Acute GvHD: KOL insights and MaaT013 Data from the 66th ASH Annual Meeting

December 17th, 2024

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Speakers on Today's Call

Pr. Mohamad Mohty, M.D.[1]

Professor, Sorbonne University and Head of the Clinical Hematology and Cellular Department, Saint-Antoine Hospital (AP-HP), Paris, France

Monzr M. Al Malki M.D.[1]

Associate Professor and Director of Unrelated Donor BMT program at City of Hope, Los Angeles, CA, USA

Hervé Affagard

Co-Founder & CEO Of MaaT Pharma, Lyon, France

[1]Used MaaT013 for aGvHD treatment

Agenda

1. Introduction – Herve Affagard
2. Unmet Need for MaaT013 in GvHD in Europe and the US – Prof. Mohty & Dr. Al Malki
3. MaaT013: Results from the Early Access Program in Europe – Prof. Mohty
   Next steps for MaaT013 – Hervé Affagard
4. Q&A

Success in Refractory GvHD Will Pave the Way for Broad Therapeutic Advances with Exceptional Potential for MaaT Pharma

Breakthrough advances of MaaT013 in GvHD

- Recruitment completed for **Phase 3 in aGvHD in Europe, expecting primary endpoint readout in January 2025**
- **Positive data from Early Access Program (n=154)** has been presented in December at ASH 2024 (1y OS 47% vs 15% historical data, 42% at 2y)
- **First-in-Class treatment modality in the U.S.** supported by an open IND enabling enhanced patient access, **with first patient treated in December 2024**

Deep oncology pipeline

- **Full ecosystem donor-derived and co-culture** platforms **driving candidate development** with **2 clinical** and 1 preclinical assets
- **Leveraging immune modulation** to address complex conditions, with outstanding results on aGvHD confirming its strong potential
- **Advanced clinical pipeline** with multiple full-ecosystem restoration candidates, targeting severe, unmet medical needs

Strong platform differentiation

- **gutPrint® AI,** linked to **co-culture platform,** poised to deliver, potentially, **clinically-ready candidates by 2026**
- **Manufacturing leadership with largest European cGMP** production facility ensuring reliable and efficient production with potential to scale
- **Safe and reliable platform** designed to **accelerate time-to-market** for pharmaceutical innovations

A Strong Pipeline With Multiple Near-Term Value Inflection Milestones

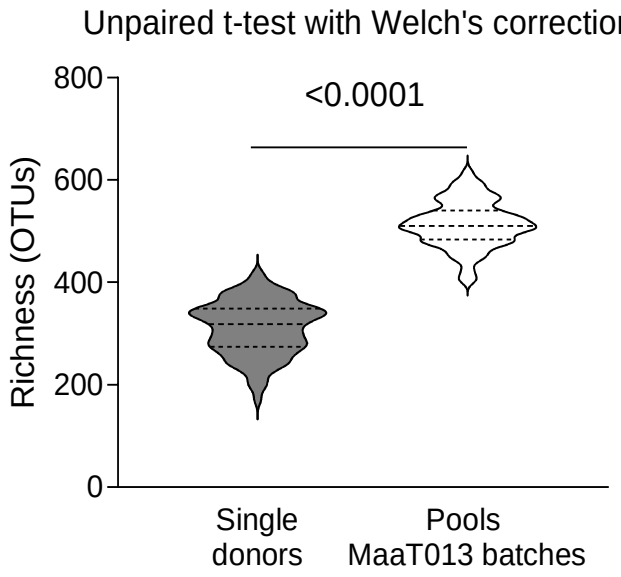
Program	Indication	Market potential	Preclinical	Phase 1	Phase 2	Phase 3	Status	Upcoming milestone
MaaT013	aGvHD ODD EMA/FDA	~250m€ 1L : 10k patients[2] 2L : 5K patients[2,3] 3L : 3K patients[2,3]	ARES →				Fully recruited	GI-ORR January 2025
			Focus EAP ongoing: 154 pts treated				Ongoing	
	ICI improvement Melanoma	Proof of Concept	***IST**** - PICASSO →				Fully recruited	Results Q1.25
MaaT033	HSCT ODD EMA	~500m€ 11k patients[2]	PHOEBUS →				Ongoing	Safety Interim H1.25
	ICI improvement NSCLC	Proof of Concept	***IST*** - IMMUNOLIFE RHU →				Ongoing	First Patient in H1.25
	ALS	Exploratory	IASO →				Primary endpoint met	Full data readout in Q1.25
MaaT034	IO	~1 to 5b€[1] 500k patients	PrClin →					Targeting FIH 2026

* R&D partners include AP-HP, Institut Gustave Roussy
** Institut Gustave Roussy, INSERM, Université Paris-Saclay, Bioaster, INRAe, IHU Méditerranée Infection

aGvHD: acute Graft versus Host Disease ; IO: Immuno-Oncology ; PoC: Proof of Concept ; HSCT: Hematopoietic Stem Cell Transplantation ; ALS: Amyotrophic Lateral Sclerosis ; IST: Investigator Sponsored Trial; NSCLC: Non-small cell lung cancer
ICI PICASSO: ipilimumab (Yervoy®) and nivolumab (Opdivo®) ; ICI IMMUNOLIFE: cemiplimab

MaaT013: Harnessing Immune Modulation to Transform aGvHD Treatment

ODD status from EMA and FDA



Significant increase of pooled product richness when compared to mono-donor products

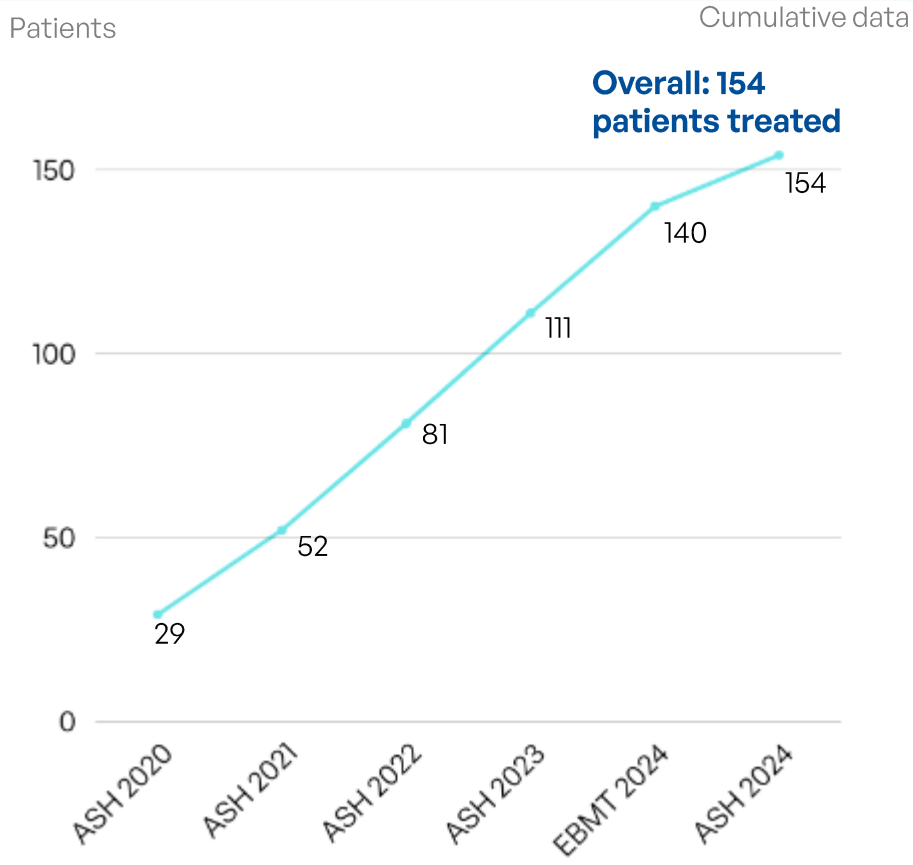
01 **Characteristics**	Pooled microbiota: a high-richness, high-diversity, full ecosystem, containing Butycore™, 24 months stability at -80°C
02 **Administration**	**3 doses** (enema bag), administered within 2 weeks
03 **Available Clinical Data**	✓ HERACLES Phase 2 Clinical Trial, n=24 ✓ Early Access Program, data on n=154, ongoing (> 170 patients treated as of October 2024)
04 **Efficacy evaluation (GI ORR at D28)**	Complete response, Very Good Partial Response, Partial Response
05 **Regulatory**	Countries having authorized the use of MaaT013 in a clinical trial: ANSM (FR), BfArM (DE), AIFA (IT), AEMPS (SP), MEB (NL), FAMHP (BE), BASG (AT), CPI (PL), MHRA (UK) and FDA (US).

Malard et al, eclinical medicine 2023

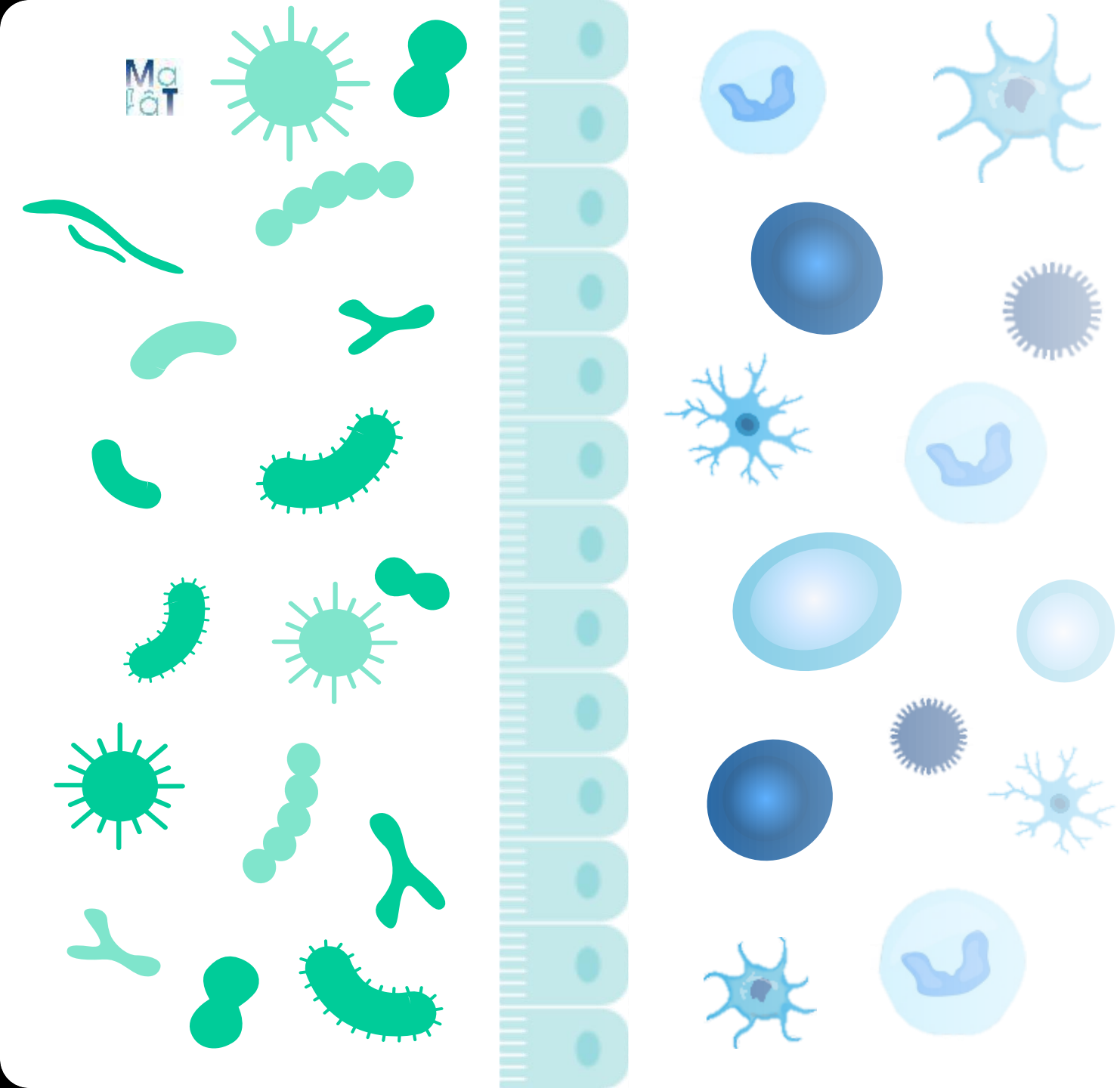
Since 2019: a positive trend in EAP showing clinical adoption

- **Increase requests from physicians** around the world especially in Europe & 1st US patient treated under SPU at City of Hope

- **Increase revenues for MaaT013 (year-on-year) -> 2.3m€ for the nine first months of 2024 compared to 1.8m€ in 2023**



Data presented at leading conferences



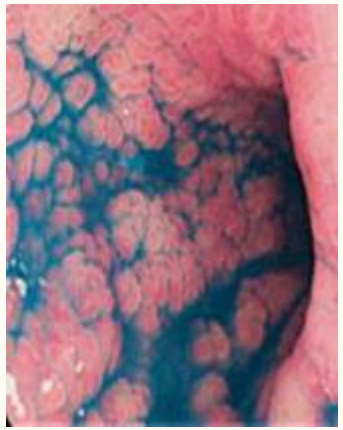
Unmet Need for MaaT013 in GvHD in Europe and in the US

AGvHD, a life-threatening complication following Allo-HSCT

→ It may occur in 50% of patients undergoing allogeneic hematopoietic stem cell transplantation (Allo-HSCT), typically presenting within the first 100 days post-transplant

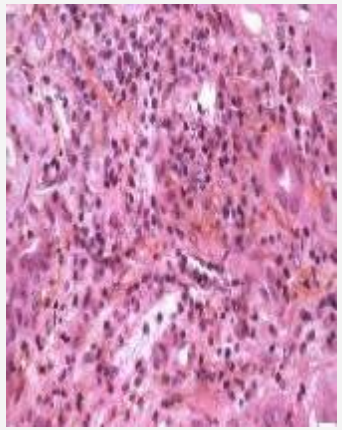
Common clinical manifestations typically involve the gastrointestinal tract, the skin and the liver

GI GvHD



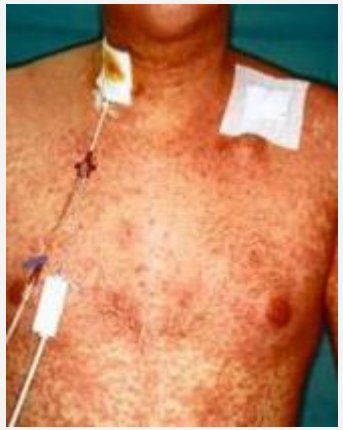
Severe diarrhea, abdominal pain

Liver GvHD



Jaundice, liver dysfunction/failure

Skin GvHD



Skin: Rash, itching

~20-50%

Allo HSCT patient develops aGvHD

~11,600

GvHD Patients / year

→ ***Mortality is primarily linked to the involvement of the gastrointestinal tract***

[1]Abedin et al. 2021, BJHaem

Current Challenges in GvHD Management

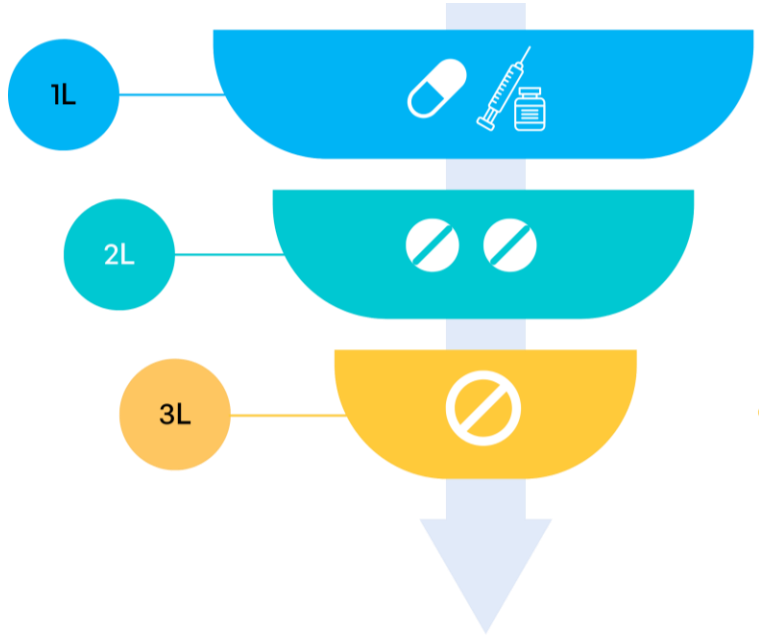
High Morbidity and Mortality

- Chronic GvHD impacts long-term quality of life and organ function.
- **Acute GvHD, especially steroid-refractory forms, is associated with high mortality rates.**

aGvHD approved drugs in adult population

Limited Therapeutic Options

Unmet Medical Need



- High-dose corticosteroids remain the standard but **fail in ~50% of cases.**
- Include ruxolitinib (FDA, 2019 & EMA, 2022) yet **~50% of cases failed to respond or lost response**
- Failed to achieve durable disease control, **leading to progressive disease and complications.**

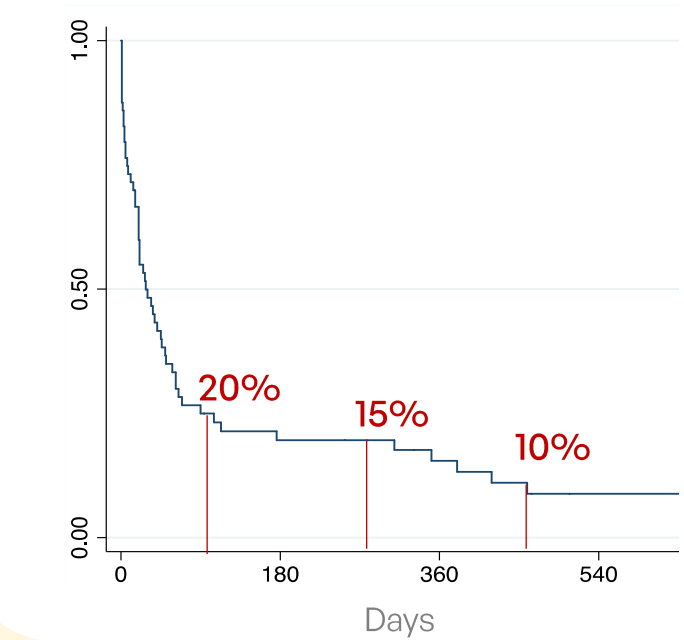
No approved therapies in 3L treatment

80% of 3L patients
with GI involvement

Around 3,000 per year

Limited Efficacy of Current Options
High Toxicity Profiles
Need for Novel Treatments

85% 1 year mortality in 3L+[1]



[1]Abedin et al., Br J Haem 2021

Urgent medical need in 3L treatment

aGvHD drugs in development – as of December 2024

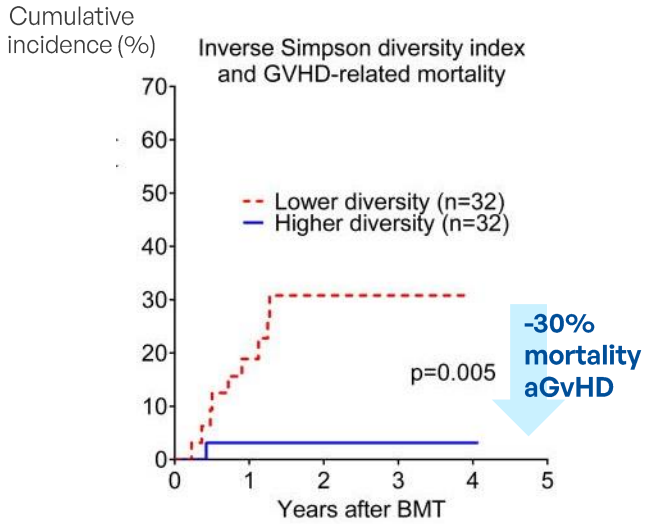
		Primary completion	End of Study
1L – in combination with corticosteroids	Itolizumab **- Phase III**	12/2024*	12/2025
	alpha-1 proteinase inhibitor **- Phase III**	06/2024	12/2024 ✓
	CYP-001 - **Phase II**	12/2024*	12/2026
2L	MC0518**- Phase III**	08/2027*	08/2030
	Apraglutide - **Phase II**	08/2025	08/2025
3L- grade II-IV SR GI-aGvHD	MaaT013 **- Phase III**	11/2024 ✓	11/2025

MaaT013 is the most advanced product in 3L

**Ongoing, active*

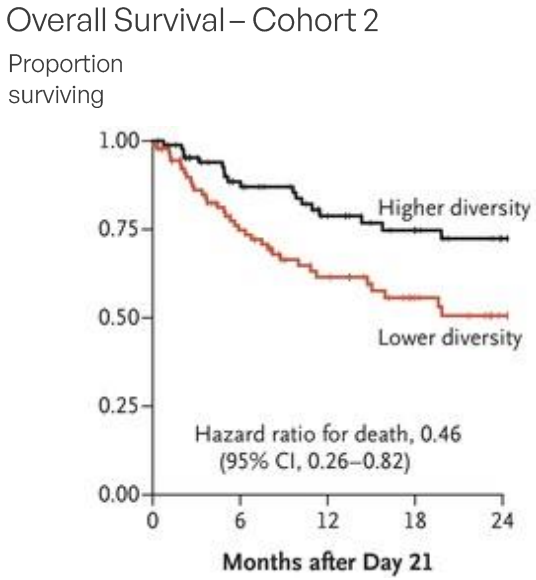
In Allo-HSCT, a Higher Gut Microbiome Diversity is Associated with Increased Survival

Lower incidence and lower mortality rate from aGvHD[2]



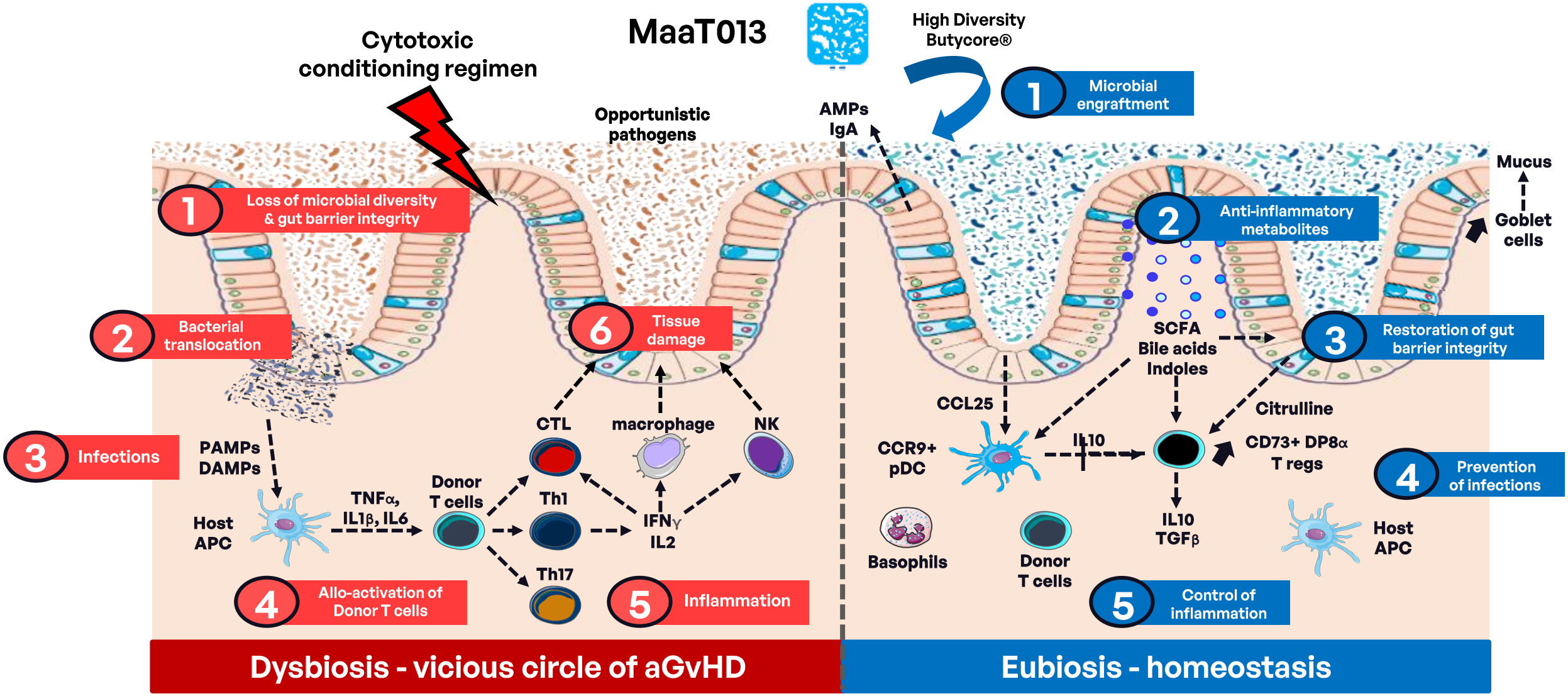
MaaT Pharma MET
Inverse Simpson (mean): **24**

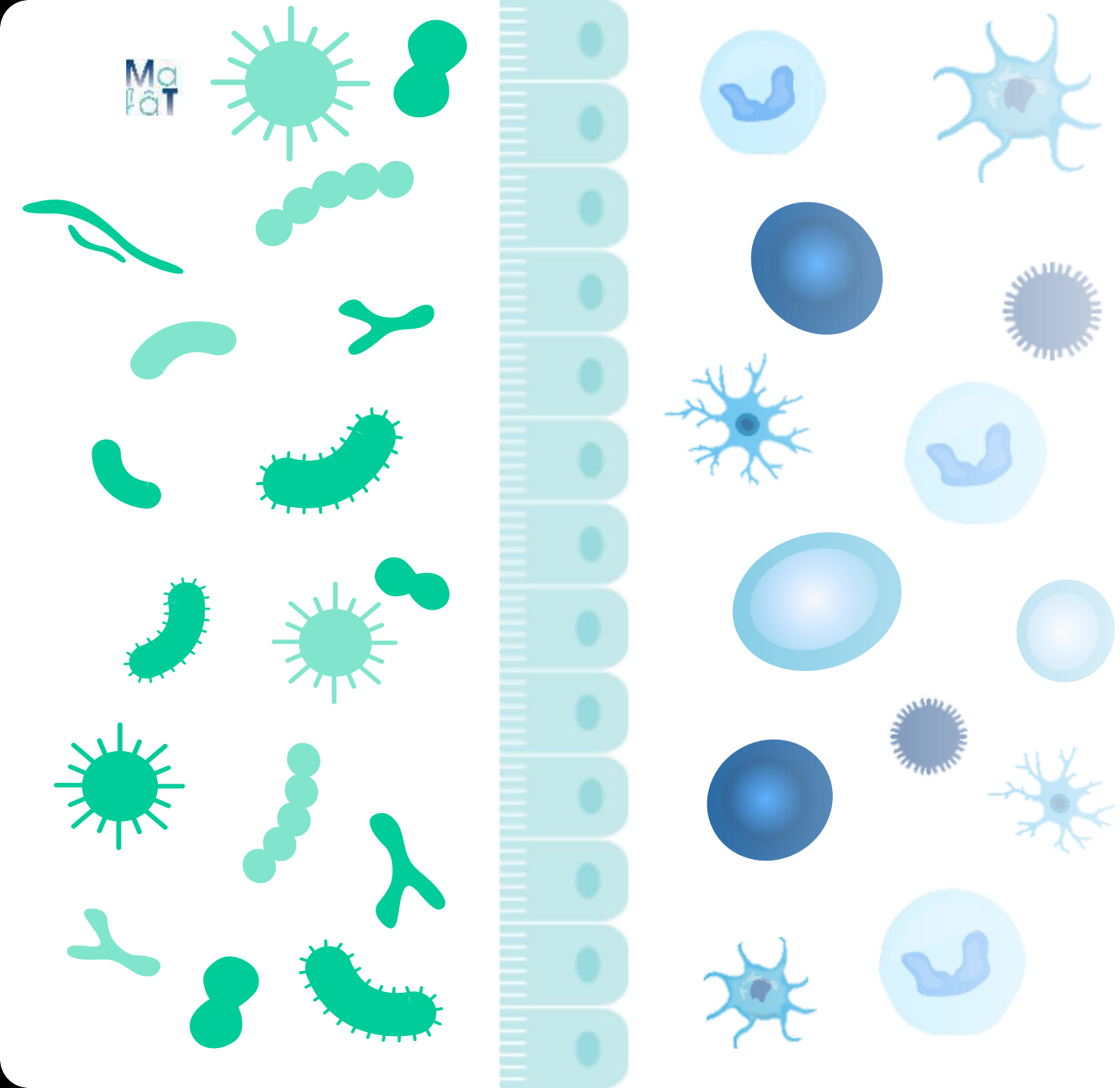
Higher survival rate in patients receiving allo-HSCT[1]



[1]; Peled, J.U. & al N Engl J Med 2020382:822-34; [2] Ghani, 2021 ; Jenq RR. et al, Biol Blood Marrow Transplant 21 (2015) 1373e1383; Pamer, Blood, 2014

MaaT013, mechanism of action with restoration of homeostasis





MaaT013: Results from the Early Access Program in Europe

Early Access Program (EAP): giving access to MaaT013 for patients with no options

- **In France: Authorized by the French regulator (ANSM) with Governing protocol for use**
- **In other countries in Europe: compassionate use**

Data from 154 patients treated from July 2018 to April 2024, in 27 European sites (France, Italy, Spain, Austria, Germany)

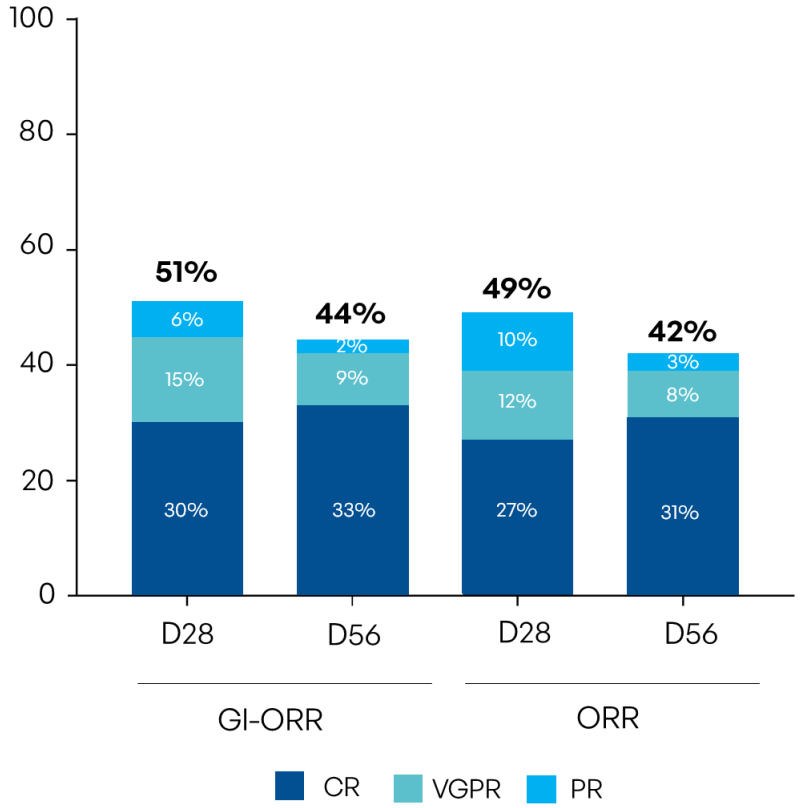
Main inclusion criteria

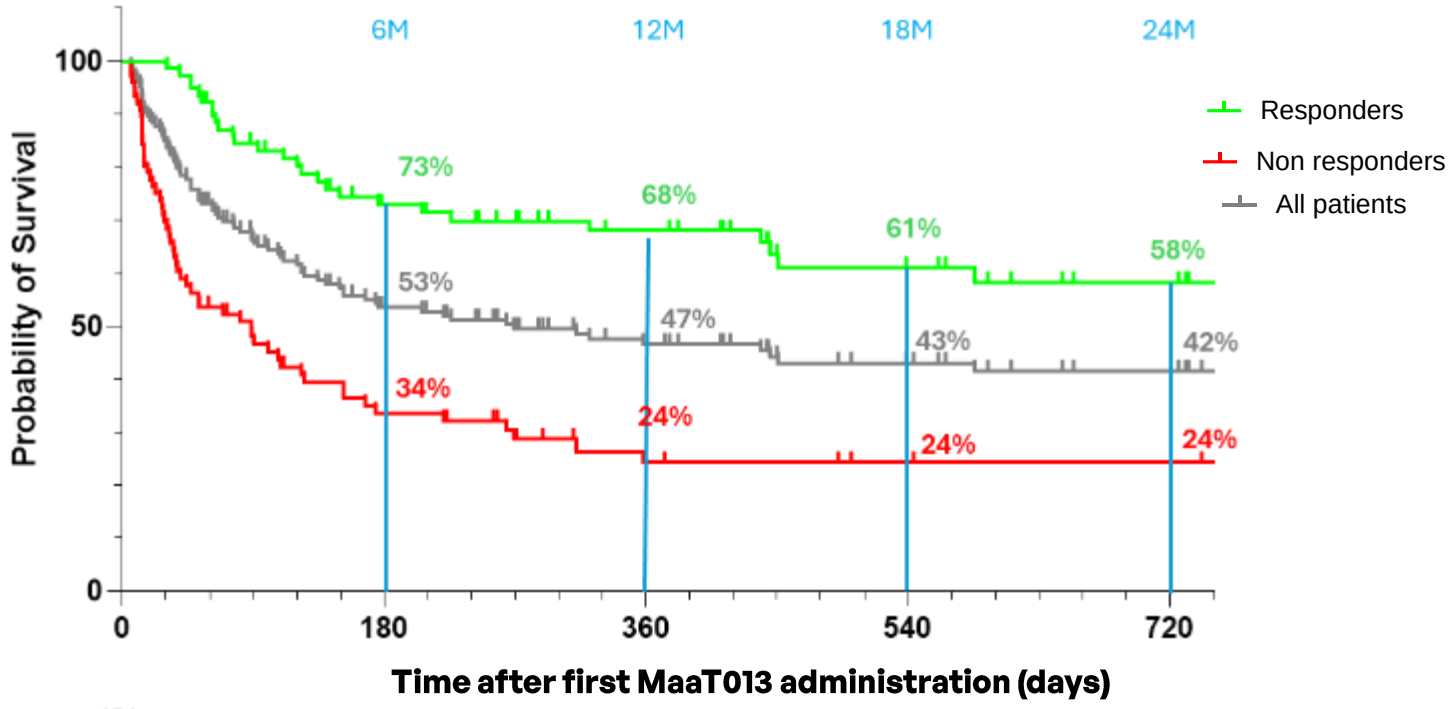
- Steroid refractory / dependent
- Acute GVHD with gut involvement, grade II to IV
- Any line of treatment
- MaaT013 used as a monotherapy and/or combination therapy
- ≥ 12 hours discontinuation of systemic antibiotics surrounding MaaT013 administration
- Patient not eligible to ongoing clinical trial (ARES - NCT04769895)

Patients Characteristics

Gender, n (%)	Male	84 (55%)
	Female	70 (45%)
Age at first MaaT013 administration (years)	Median [range]	57 [12;74]
Number of previous lines of treatment, n	Median [range]	**3 [1;6]**
Steroid status	**Steroid refractory-aGvHD**	**128 (83%)**
	Steroid dependent-aGvHD	**26 (17%)**
Type of aGvHD	Classical	93 (60%)
	Late onset	16 (10%)
	Hyper-acute	25 (16%)
	Overlap syndrome and cGvHD	21 (14%)
GvHD grading (MAGIC), n (%)	I	0
	II	20 (13%)
	III	**73 (47%)**
	IV	**61 (40%)**

aGvHD response (all EAP patients, n=154)

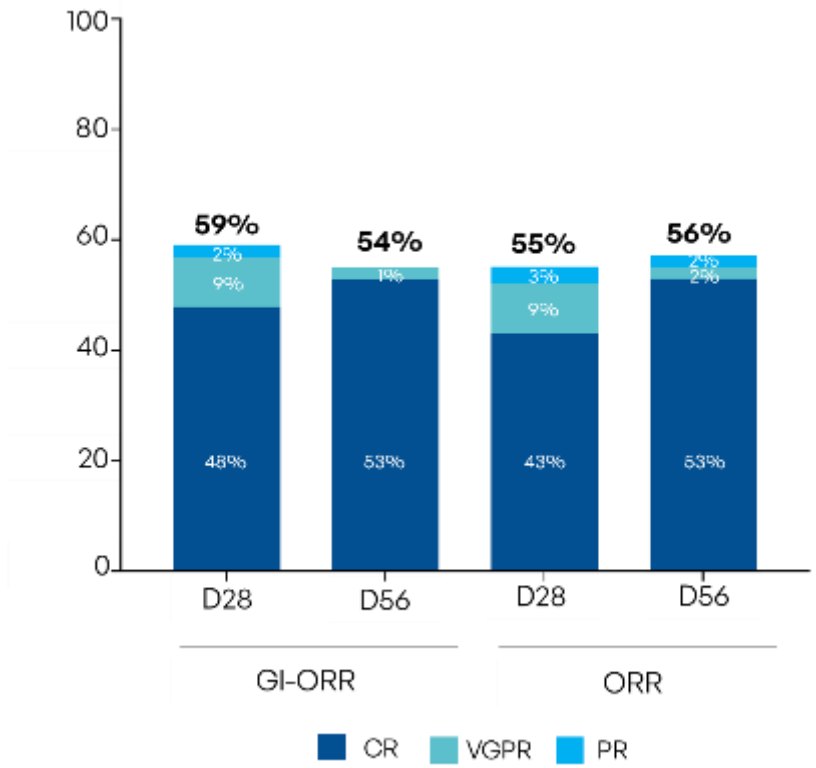


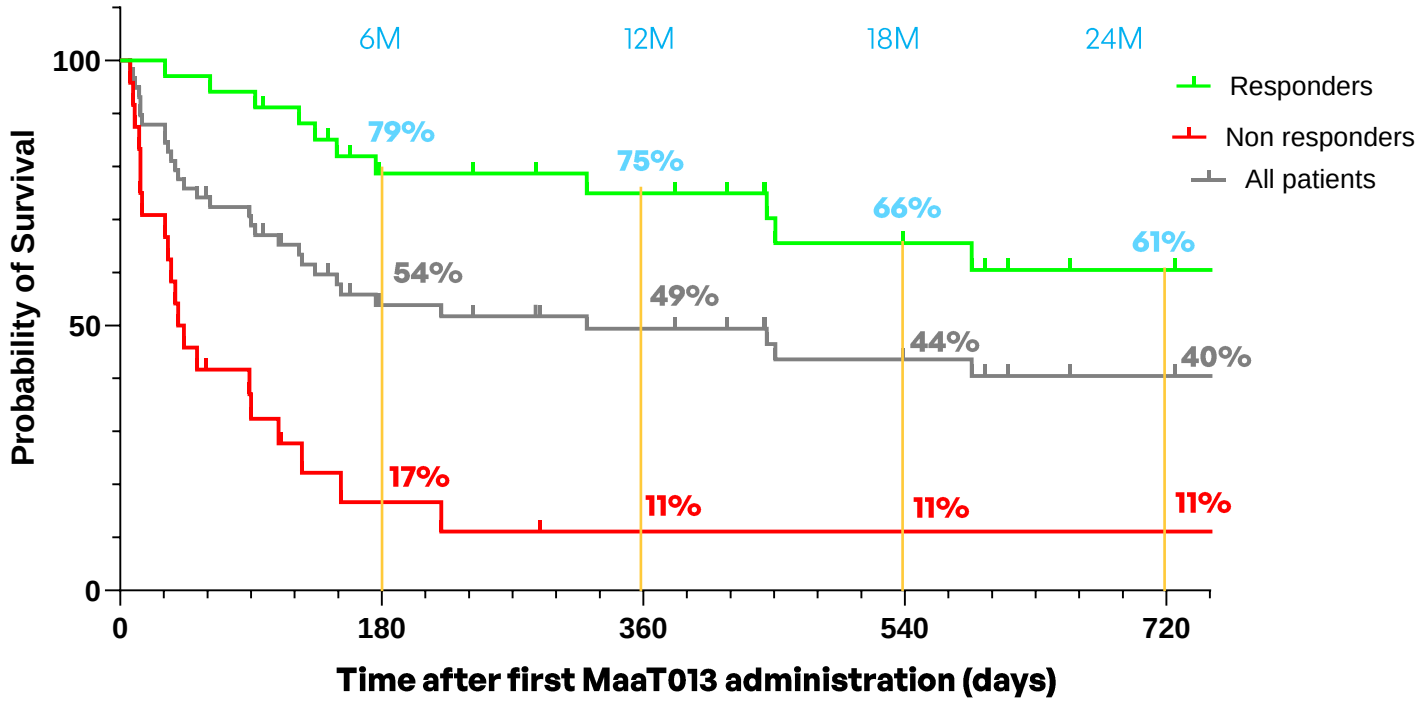


Sustainable response at D56

Abbreviations: CR, complete response; VGPR, very good partial response; PR, partial response; ORR, overall response rate; GI, gastro-intestinal

aGvHD response in the ruxolitinib-refractory patients treated with MaaT013 as 3rd line (n=58)





High rates of CR and VGPR
Sustainable response at D56

Abbreviations: CR, complete response; VGPR, very good partial response; PR, partial response; ORR, overall response rate; GI, gastro-intestinal

Conclusions

- **MaaT013 is highly effective therapy for SR- and SD-GI- aGvHD**
  - D28 GI-ORR 51% and ORR 49%

- **Excellent responses in the ruxolitinib-refractory patients (MaaT013 as 3rd line), with high rates of CR and VGPR at D28, maintained at D56**
  - D28 GI-ORR 59% and ORR 55%
  - D56 GI-ORR 54% and ORR 56%

- **High overall survival in this severe population**
- **Innovative mechanism of action based on immune modulation**
- **Overall safety is very good**
- **Further investigation currently ongoing in a phase 3 trial (NCT04769895)**
- **Initiation of the regulatory submission in Europe**

Abbreviations: ORR, overall response rate; GI, gastro-intestinal; SR-aGVHD, steroid-refractory acute graft-versus-host disease; SD-aGVHD, steroid-dependent acute graft-versus-host disease

ARES, a Pivotal Phase 3 Trial to Treat aGvHD in 3L with Topline Expected in January 2025

ARES

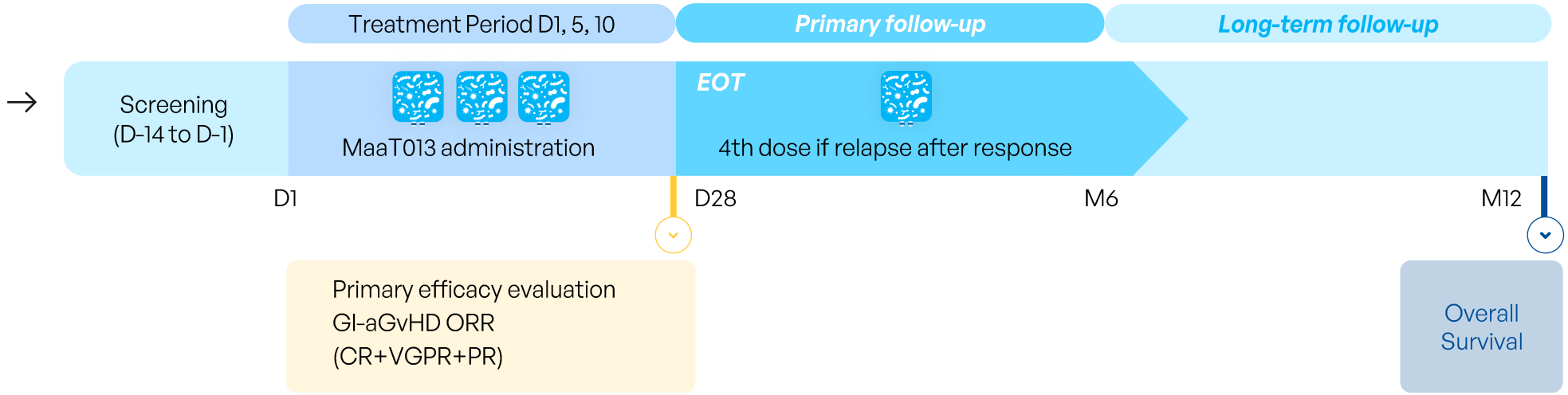
Upcoming milestones: GI-ORR expected in ***January 2025 I*** OS expected by end of 2025

66 Patients

with SR-GI-aGvHD (Europe)

Inclusion criteria

- → Refractory or intolerant to 2L ruxolitinib
- → Refractory to 1L corticosteroids
- → aGvHD with GI symptoms
- → Allo-HSCT
- → Age > 18



D: Day, M: Month, EOT: End of treatment ; SR-GI-aGvHD: Steroid-refractory gastro-intestinal acute Graft-versus-Host Disease ; GI-ORR: Gastrointestinal Overall Response Rate; CR: Complete Response; VGPR: Very Good Partial Response; PR: Partial Response

* DSMB review on 30 patients on October 2023

DSMB* main conclusions:

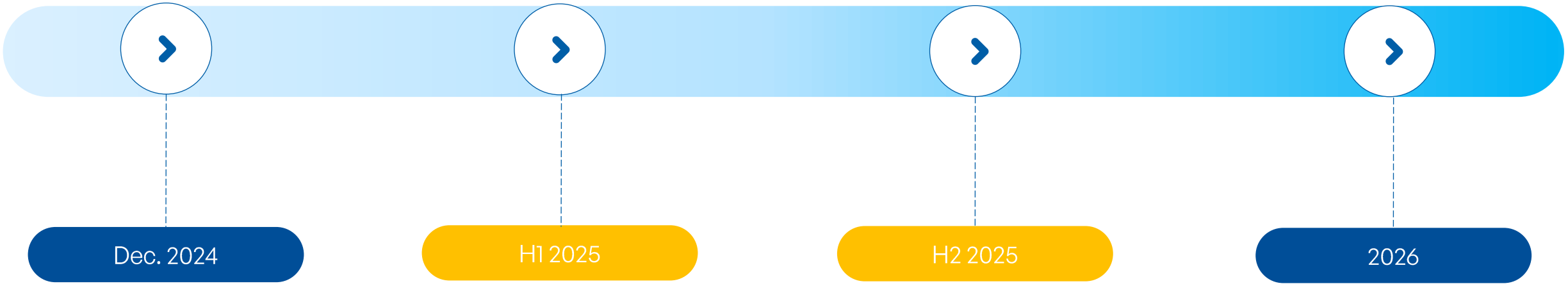
→Good safety profile

→ORR higher than pre-defined protocol

Market potential: in 3L

~ 250 m€ in 3 L only

Near-Term Value Inflection Milestones for MaaT013



GvHD | EAP Update ASH24 ✓

January: GvHD | ARES P3 GI-ORR

Q1: IO Mela. | PICASSO P2a Results

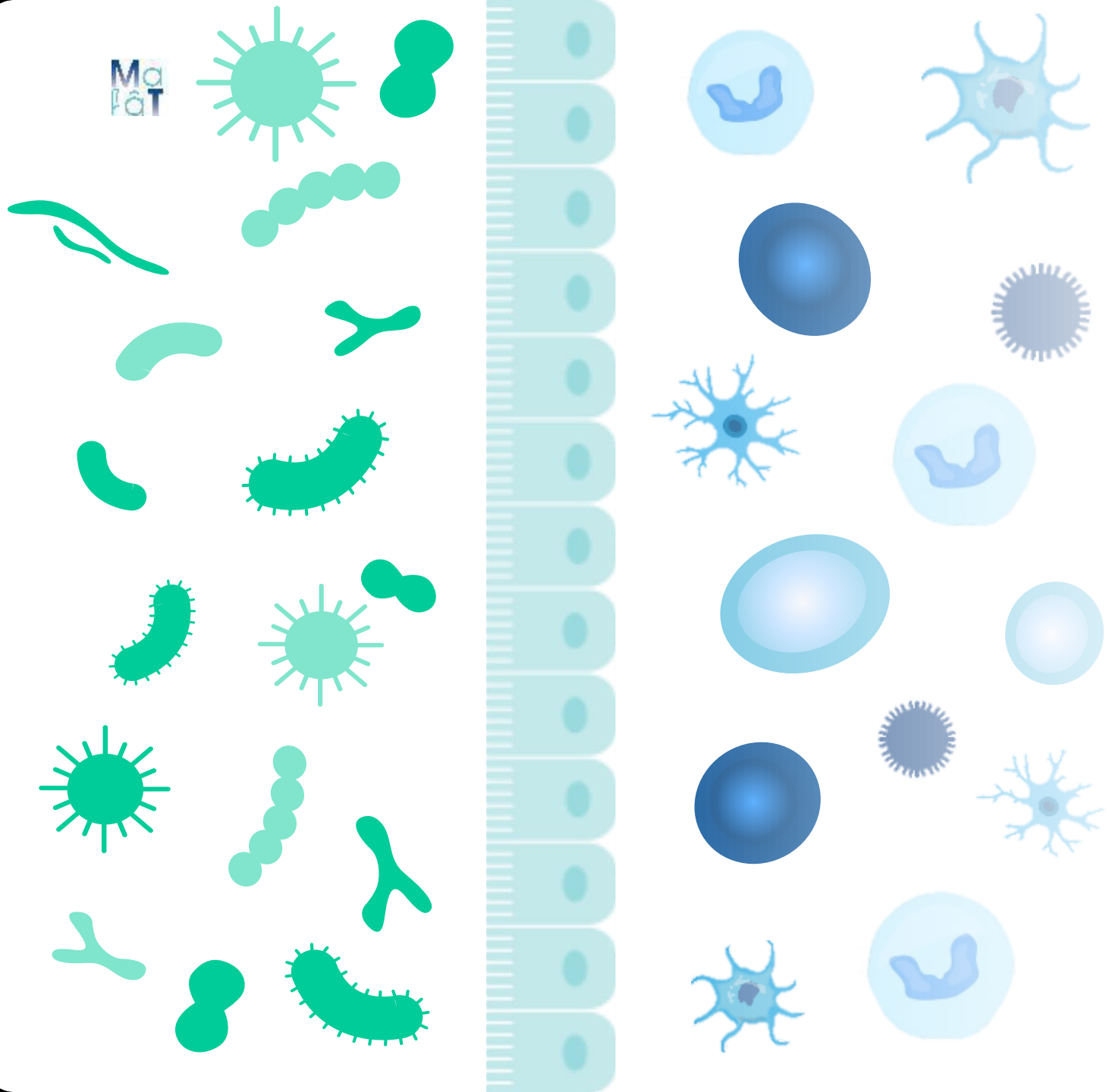
GvHD | ARES Final Results (OS)

GvHD | Filing to EMA

Marketing authorization in Europe anticipated

✓

Potential first Microbiome approval in oncology



Q&A session

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Thank you

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