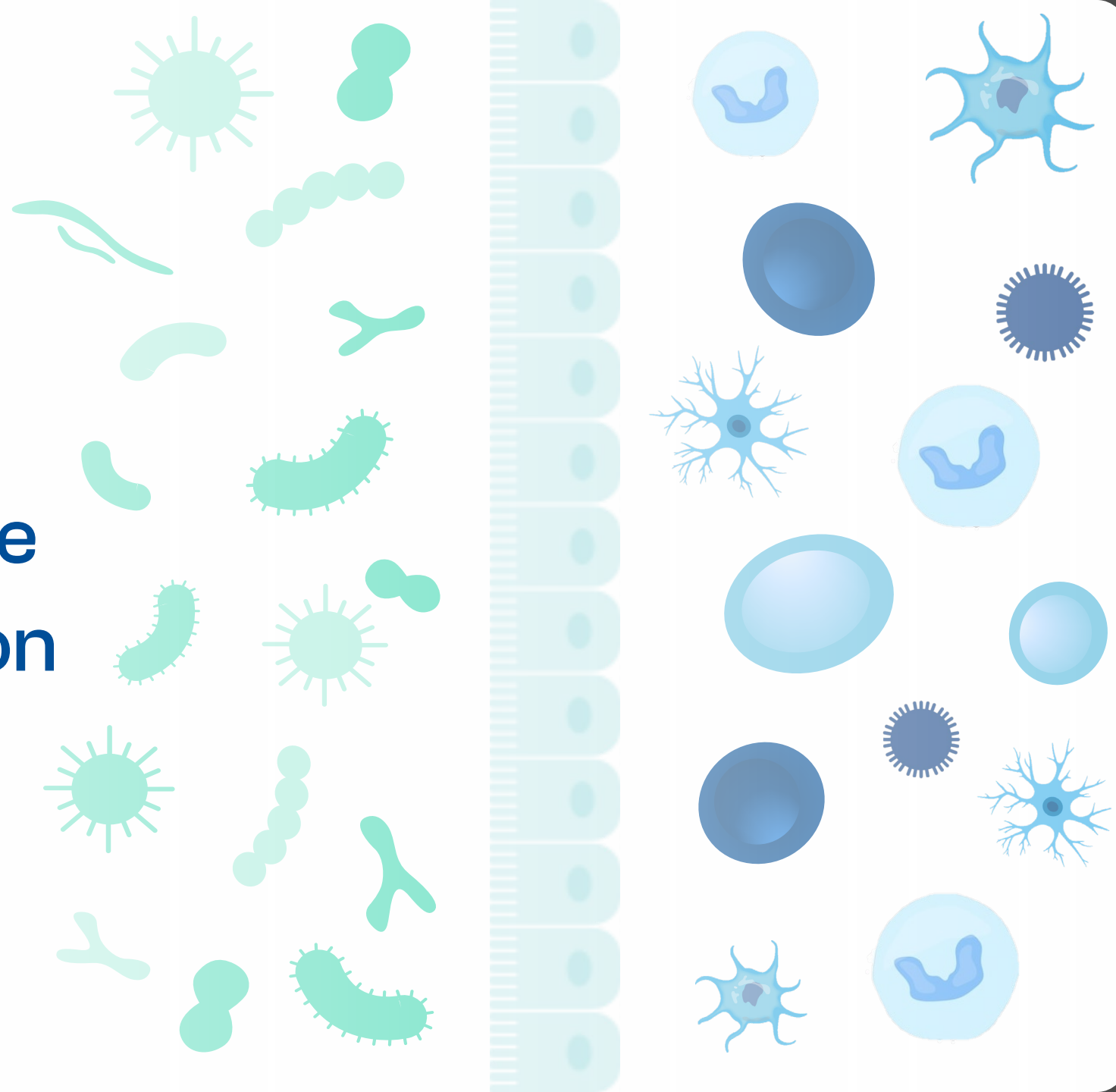




MaaT Pharma

# Boosting Survival Through Innovative Immune Modulation

January 2025



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# Management Team



**Hervé Affagard**

Co-Founder & CEO



**Eric Soyer**

Chief Financial Officer



**Gianfranco Pittari, MD, PhD**

Chief Medical Officer



Memorial Sloan Kettering Cancer Center



**Carole Schwintner, PhD**

Chief Technology Officer



**Sian Crouzet**

Chief of Staff

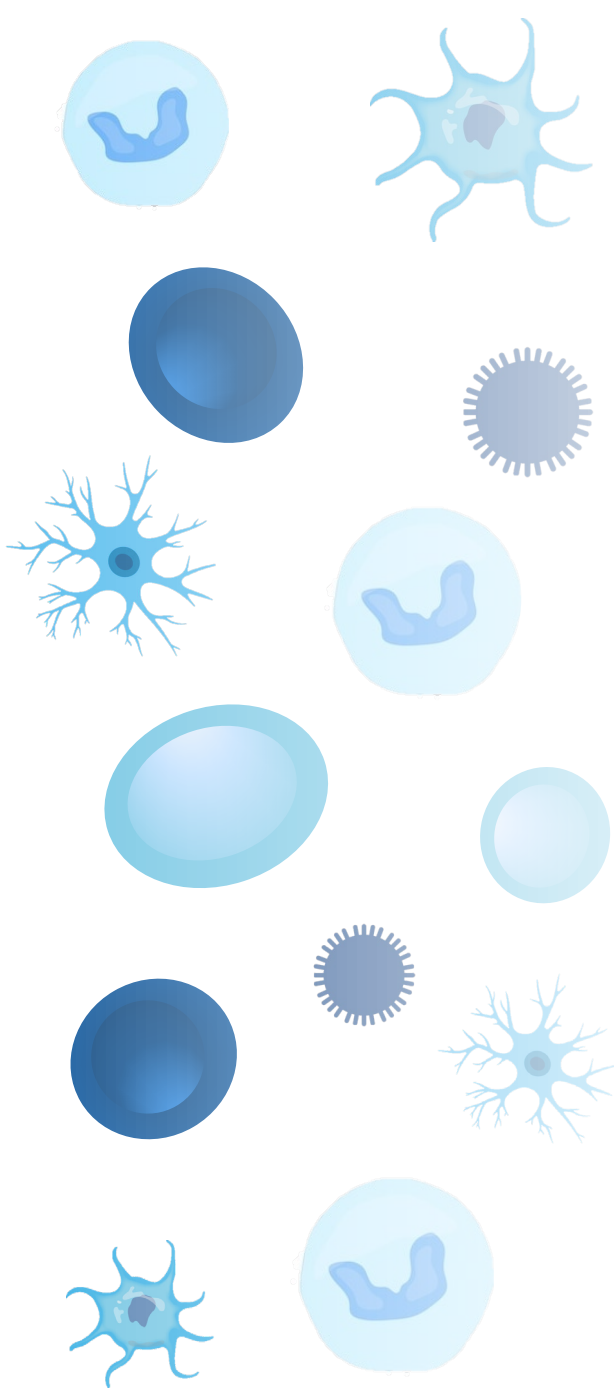
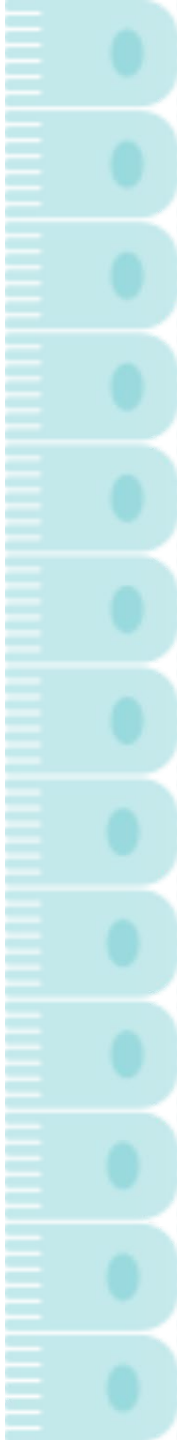
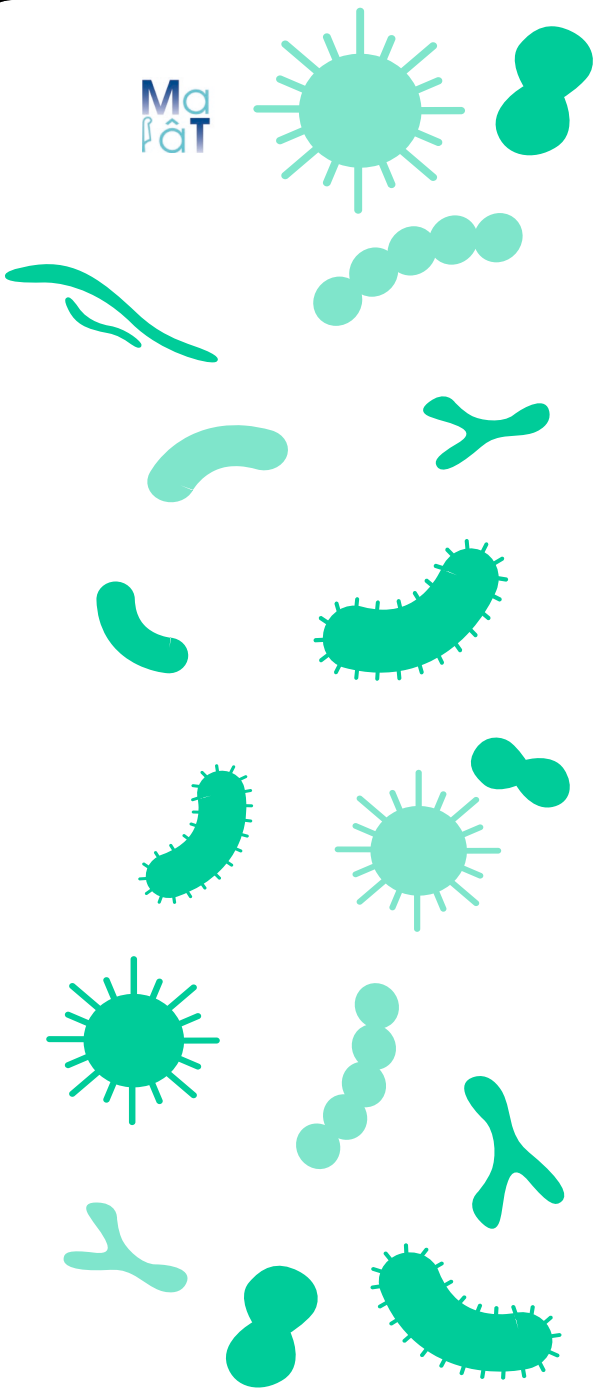


**Jonathan Chriqui, PharmD**

Chief Business Officer



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# Company Overview

# MaaT013 in aGvHD: Primary Endpoint of Phase 3 Study Achieved Registration in Europe Spearheading Microbiome Therapies in Oncology



## Now available: Phase 3 Data in aGvHD from the ARES study

- > **Primary endpoint:** unprecedented, GI-ORR\* of **62%** in patients having previously received steroids and ruxolitinib
- > High response rate leading **to prolonged survival**, highlighting MaaT013's potential to overcome the short-term mortality of third-line GI-aGvHD
- > Company anticipates **MAA submission in Europe, in mid-2025**, earlier than initially planned

\*IRC reviewed

<sup>1</sup>Malard, ASH 2024 <sup>2</sup>Abedin et al. 2021



## Multi-assets platform focused on oncology

- > **Full ecosystem donor-derived and co-culture** platforms **driving candidate development** with **2 clinical** and 1 preclinical assets
- > **gutPrint® AI**, linked to **co-culture platform**, poised to deliver, potentially, **clinically-ready candidates by 2026**
- > **Largest European cGMP** production facilities for Microbiome Ecosystem Therapies™



## Funding opportunities



- > **Cash position** of **27m€** as of September 30, 2024. **Cash runway** extends into **Q2/2025**
- > Potential **750m€ yearly peak sales Hemato-Onco franchise** for partnering: 250m€ for MaaT013 in GvHD and 500m€ for MaaT033 in allo-HSCT.
- > **Exploring several options to strengthen financing for future developments**, including non-dilutive and dilutive sources

# Correcting Dysbiosis: a New Pillar in Oncology

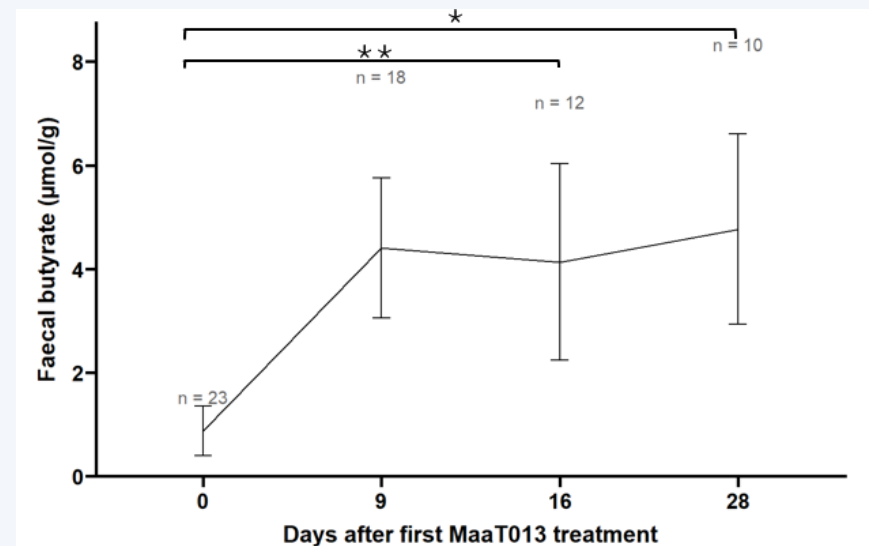
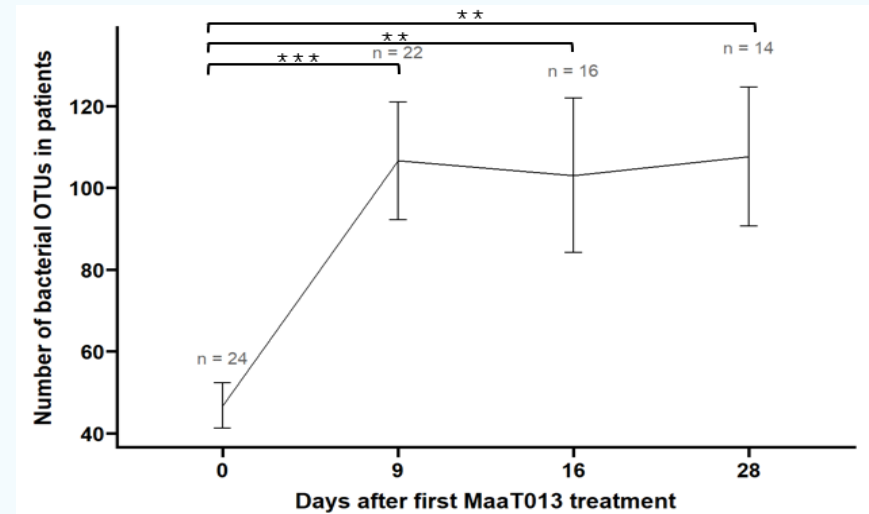
## Dysbiosis and disease

- Loss of microbial **diversity**
- Increase in **pathogens**
- Reduction of **microbial metabolites**
- Associated with **multiple conditions**

## Microbiome alterations in Oncology

- **Chemotherapy and antibiotics** are a major trigger of dysbiosis
- **Damage of the gut ecosystem disrupts** immune homeostasis and barrier integrity
- **Vulnerability to inferior clinical outcomes**

Microbiotherapy  
Restores Gut  
Microbiota Diversity  
and Production of  
Functional Metabolites





# Oncology-Focused Platform Fueling a Deep Pipeline of Drug Candidates



## Native Ecosystem

Driving near-term value with the donor-derived MET-N platform



MaaT013



MaaT033

## Co-cultured Ecosystem

Progressing next-generation co-cultured scalable MET-C platform



MaaT034



MaaT03X

## In-house Production

Leading capabilities in full ecosystem microbiome drug production



Capacity: ~11,000 treatable patients per year



### PROPRIETARY POOLING APPROACH



MaaT013



MaaT033

Pooled microbiota

→ Maximized richness

→ Standardized (450 OTU ± 3%)

Original microbial ecosystem

Master bank

Working Bank

Unlimited Co-Culture Scaling

MET-C product




Multistep co-culture cGMP proprietary process



A Premier Portfolio of Full Native and Co-cultured Microbiome Ecosystem Therapies™ Produced Internally at the Largest European Production Facility Designed for Easy Scalability to Meet Demand

# A Strong Pipeline With Multiple Value Inflection Milestones and a Close-to-Market Asset

Program → Indication → Market potential → Preclinical → Phase 1 → Phase 2 → Phase 3 → MAA → Status  Upcoming milestone

Program	Indication	Market potential	Preclinical	Phase 1	Phase 2	Phase 3	MAA	Status	Upcoming milestone
<b>MaaT013</b> 	aGvHD	~250m€ 1L : 10k patients <sup>2</sup> 2L : 5K patients <sup>2,3</sup> 3L : 3K patients <sup>2,3</sup>	ARES	EAP ongoing: 154 pts treated				Primary endpoint met 	EU MAA Submission Mid 2025
	ICI improvement Melanoma	POC	IST* - PICASSO					Fully recruited	Results Q1.25
<b>MaaT033</b> 	Allo-HSCT	~500m€ 11k patients <sup>2</sup>	PHOEBUS					Ongoing	Safety Interim H1.25
	ICI improvement NSCLC	POC	IST** - IMMUNOLIFE					Ongoing	FPI in H1.25
	ALS	Exploratory	IASO					Primary endpoint met	Full data in Q1 2025
<b>MaaT034</b> →	IO	~1 to 5b€ <sup>1</sup> 500k patients	PrClin						Targeting FIH 2026

aGvHD: acute Graft versus Host Disease ; IO: Immuno-Oncology ; PoC: Proof of Concept; Allo-HSCT: Hematopoietic Stem Cell Transplantation ; ALS: Amyotrophic Lateral Sclerosis ; IST: Investigator Sponsored Trial; NSCLC: Non-small cell lung cancer

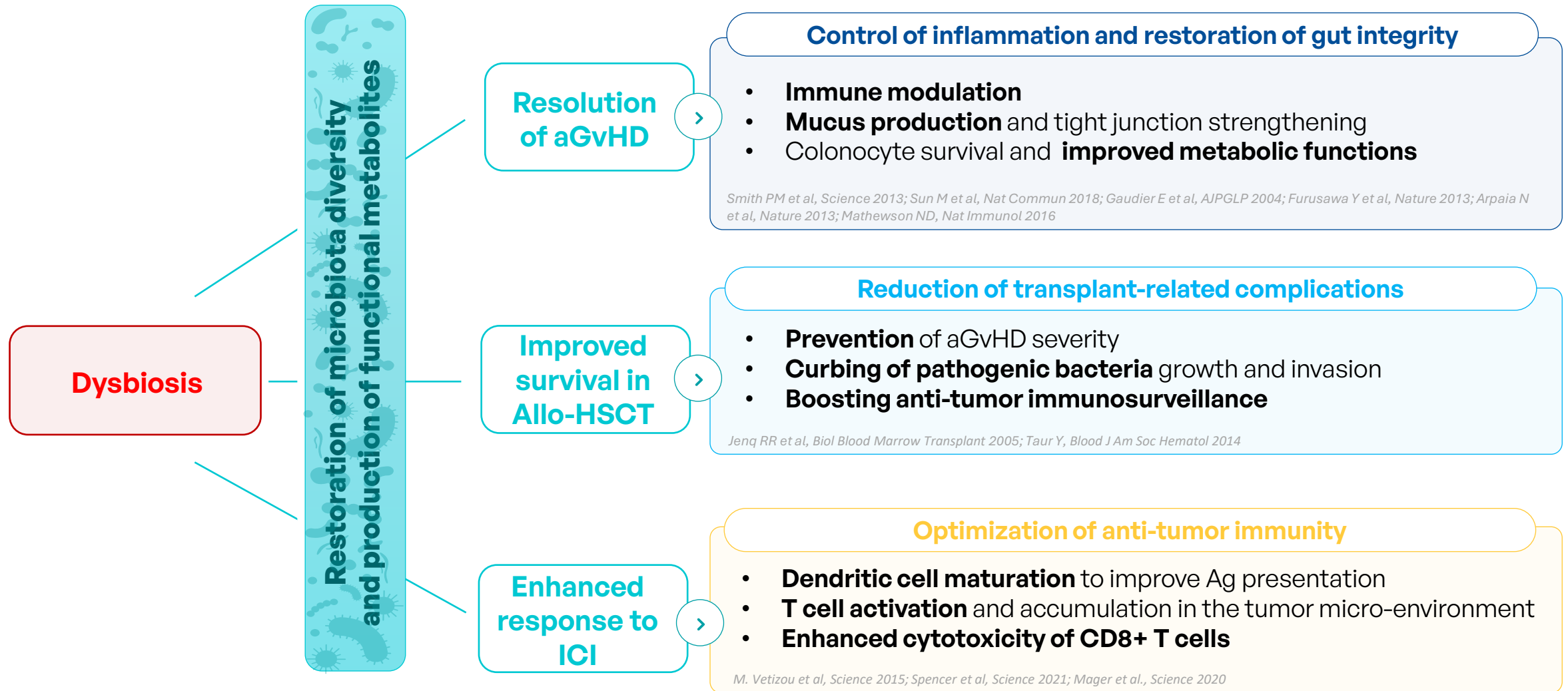
ICI PICASSO: ipilimumab (Yervoy®) and nivolumab (Opdivo®) ; ICI IMMUNOLIFE: cemiplimab

\* R&D partners include AP-HP, Institut Gustave Roussy

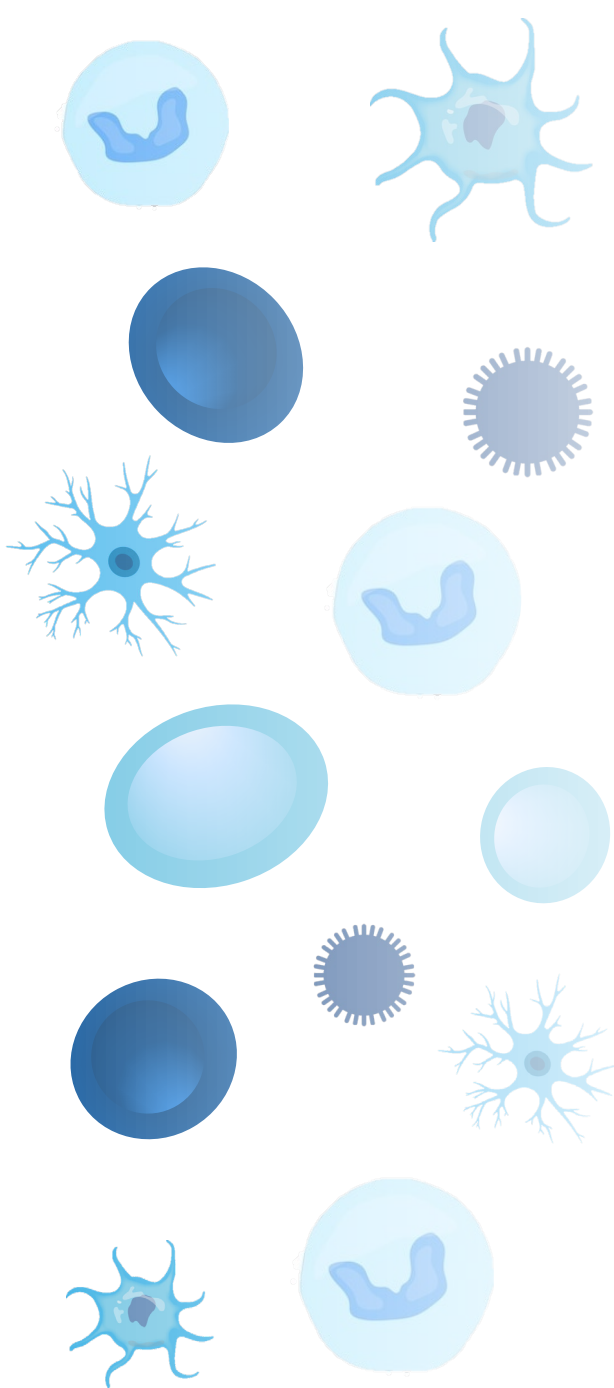
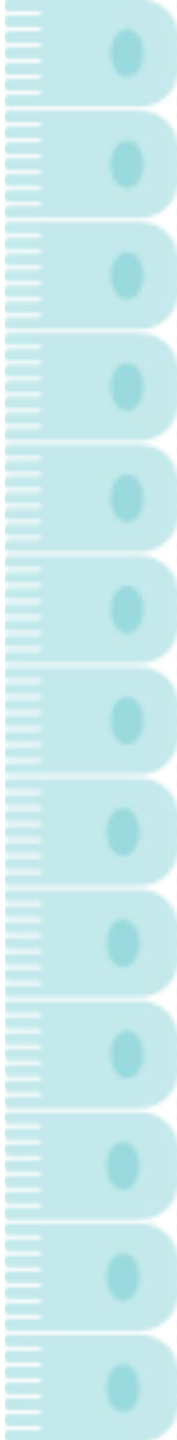
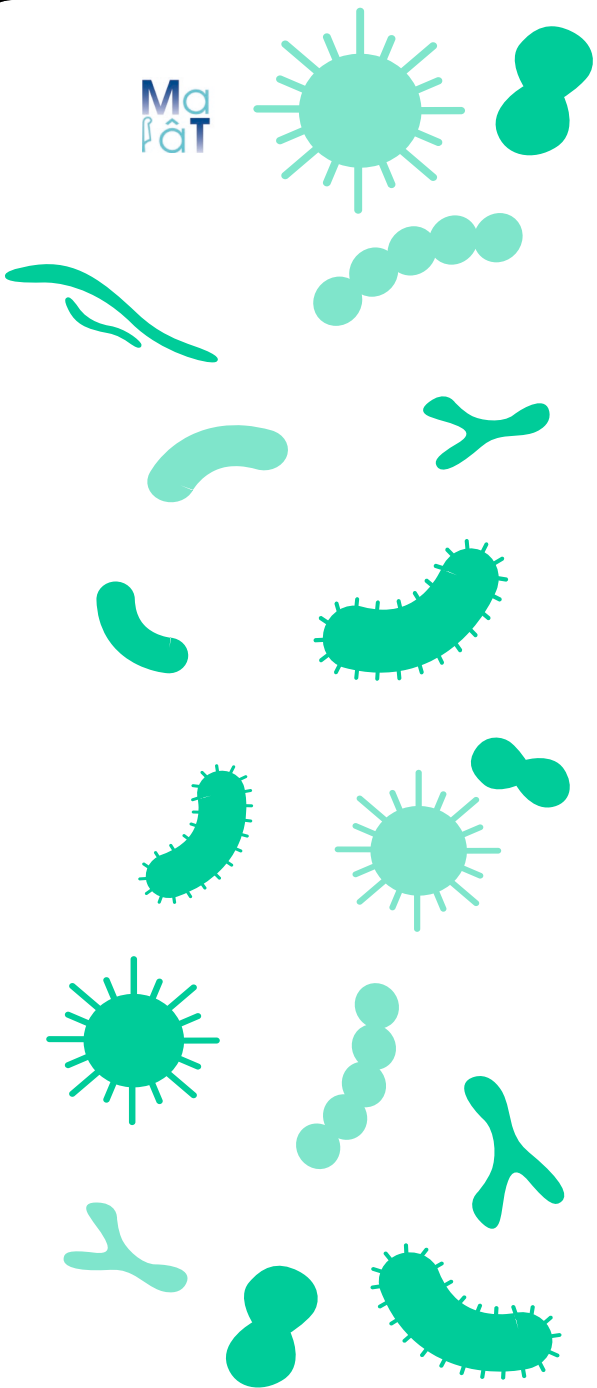
\*\* Institut Gustave Roussy, INSERM, Université Paris-Saclay, Bioaster, INRAe, IHU Méditerranée Infection



# Leveraging Microbiome Modulation in Oncology: Mechanisms for Enhanced Survival Outcomes in Multiple Settings



MaaT013



## MaaT013 in aGvHD



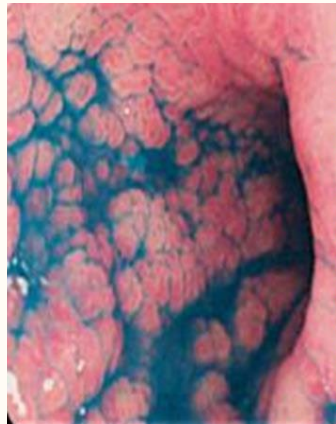
# Understanding and Addressing Acute Graft-versus-Host Disease (aGvHD)

- **A significant complication following allogeneic hematopoietic stem cell transplantation (Allo-HSCT)**
- **May occur in 50% of patients undergoing Allo-HSCT, presence detected typically within the first 100 days post-transplant**

In aGvHD, donor immune cells recognize the recipient's tissues as foreign leading to an immune-mediated attack

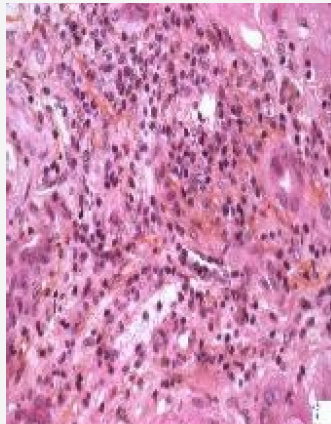
Common clinical manifestations typically involve the gastrointestinal tract, the skin and the liver

## GIGvHD



Severe diarrhea, abdominal pain

## Liver GvHD



Jaundice, liver dysfunction/failure

## Skin GvHD



Skin: Rash, itching



**~11,600**

GvHD Patients / year



**85%**

1 year mortality in  
3L+<sup>1</sup>

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



# aGvHD Refractory to Steroids and ruxolitinib (3<sup>rd</sup> line of treatment): A Substantial Unmet Medical Need Requiring Innovative Solutions

## Treatment Paradigm

- > Corticosteroids are the 1<sup>st</sup> line of treatment, but approximately 50% of patients do not achieve a sustained response
- > ruxolitinib is approved as 2<sup>nd</sup> line of treatment for steroid-refractory aGvHD (FDA, 2019 & EMA, 2022)

30%

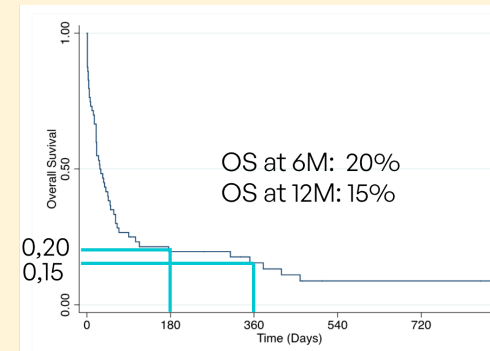
of aGvHD patients **eligible** for subsequent or alternative treatment



Around 3,000 per year EU/US

## Lack of effective therapy in 3<sup>rd</sup> line

- > **No** drug approved
- > Off-label options have shown limited benefit, notably in OS improvement



**Dismal outcome** with a median survival of **28 days** and **15% OS at 1 year**<sup>1</sup>

→ GvHD is characterized by intestinal dysbiosis which is associated with higher mortality in hemato-oncology<sup>2</sup>

→ In the Early Access Program (EAP), MaaT013 showed efficacy in aGvHD patients who failed 1 to 6 lines of systemic treatment<sup>3</sup>



# ARES: a Pivotal Phase 3 Trial Exploring MaaT013 in Third-Line aGvHD Following Steroid and ruxolitinib Failure

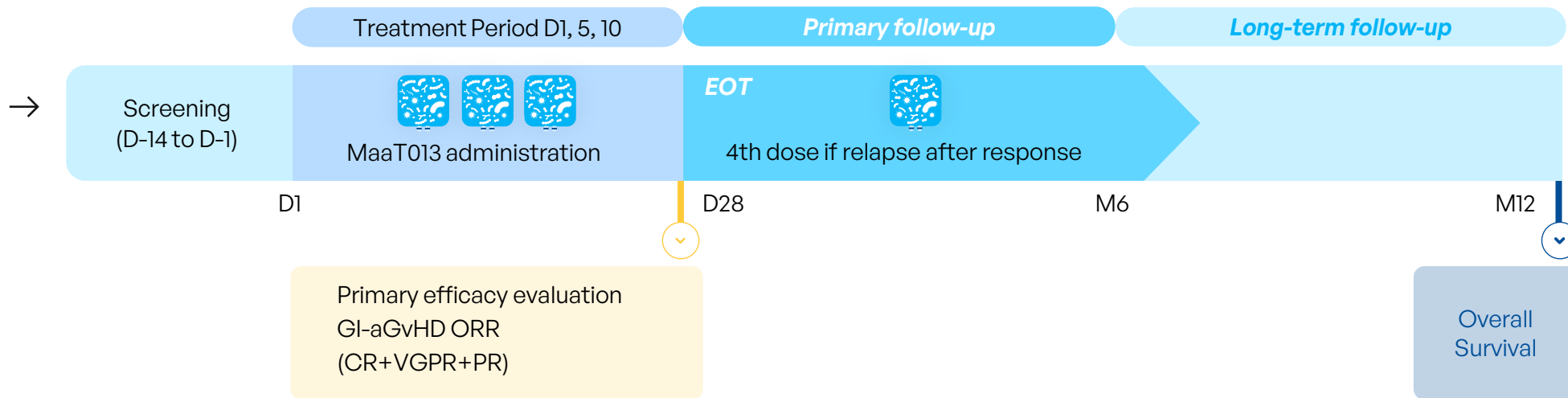


**Milestones: Topline results** announced **January 8<sup>th</sup> 2025** | OS expected by end of 2025 | Regulatory submission expected mid-2025

**66 Patients**  
with **SR/RR -GI-aGvHD**

### Inclusion criteria

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



### Oct. 23 DSMB main conclusions:

- Good safety profile
- ORR higher than pre-defined protocol



Marketing authorization anticipated in H2 2026



### Market potential:

~250 m€  
No Competitor in 3L



# ARES patients: Baseline Characteristics

Patients characteristics at baseline	All patients receiving MaaT013 (n=66)
Median age, years (range)	55.5 (24; 76)
Gender n (%)	Male: 35 (53%) Female: 31 (47%)
Steroid status n (%)	Steroid-refractory: 57 (86%) Steroid-dependent: 9 (14%)
Ruxolitinib status n (%)	<b>ruxolitinib refractory: 66 (100%)</b> ruxolitinib intolerant: 0
aGvHD grading (MAGIC*)	Grade I: 0
	Grade II: 6 (9%)
	<b>Grade III: 38 (58%)</b>
	<b>Grade IV: 22 (33%)</b>

Patients with severe aGvHD

**91% are Grade III-IV**

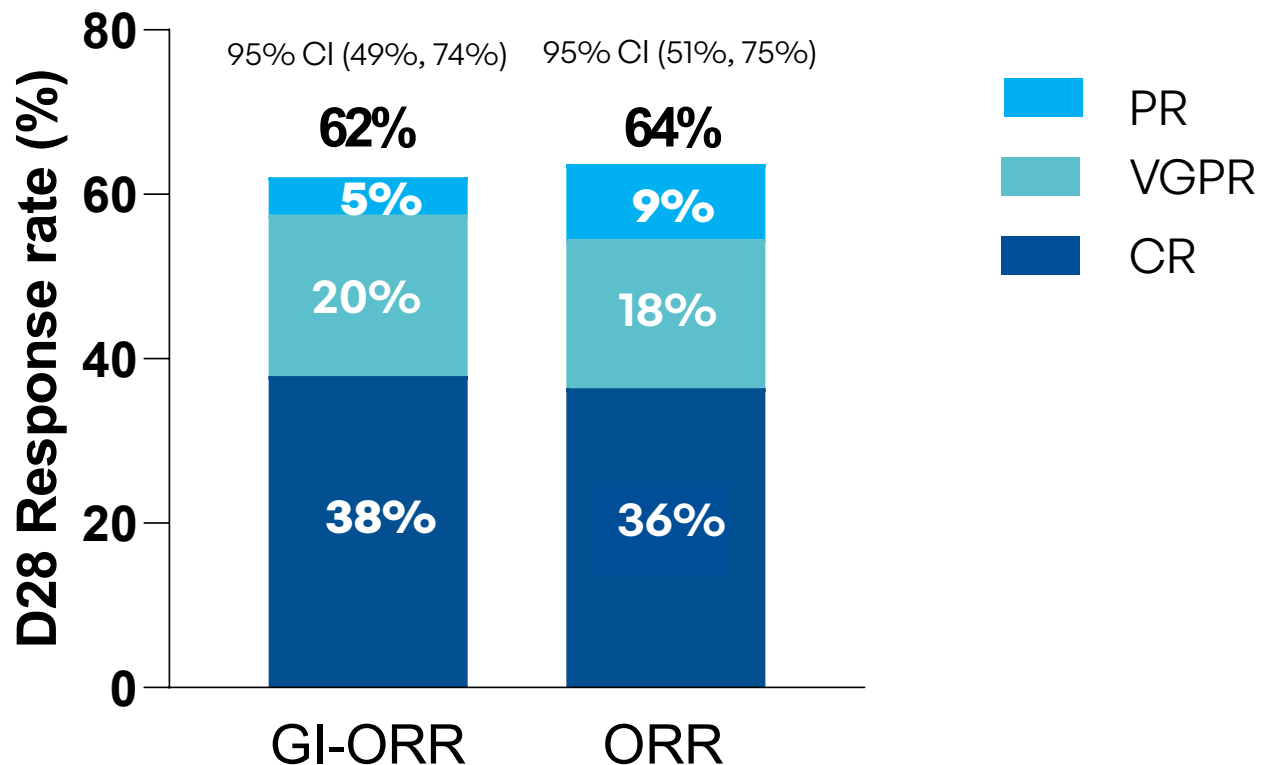
**100% are ruxolitinib refractory**

\*MAGIC : Mount Sinai Acute GVHD International Consortium





# ARES: Strong Response to MaaT013 in aGvHD following Steroid and ruxolitinib Failure



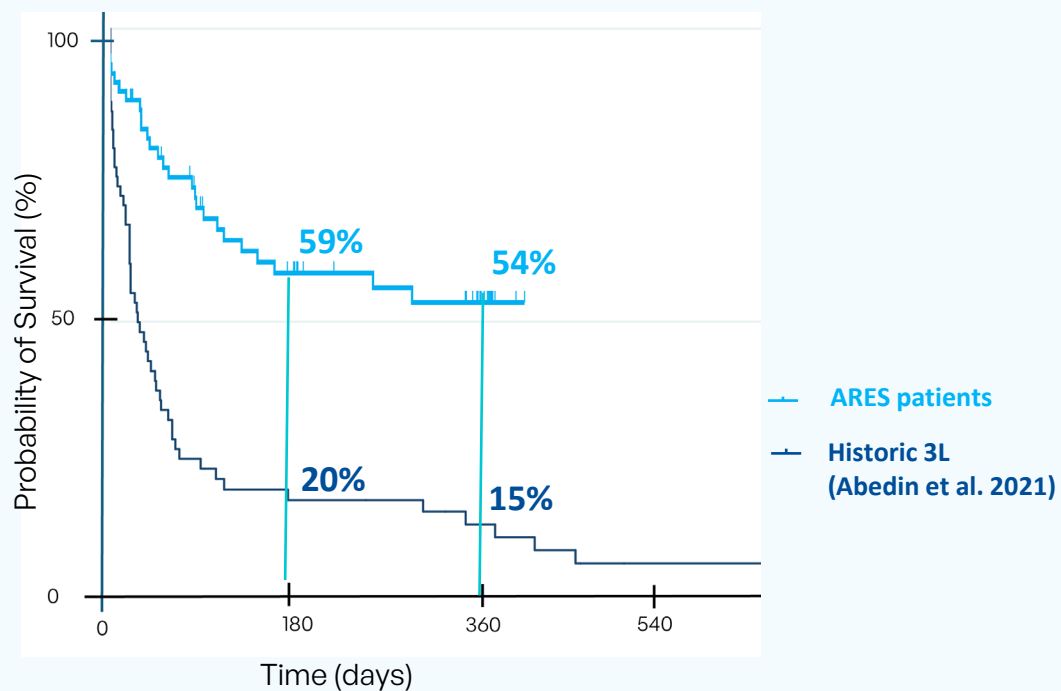
## Topline Results

- **62% GI-ORR** with high CR and VGPR rates
- **64% ORR** demonstrating a global systemic response

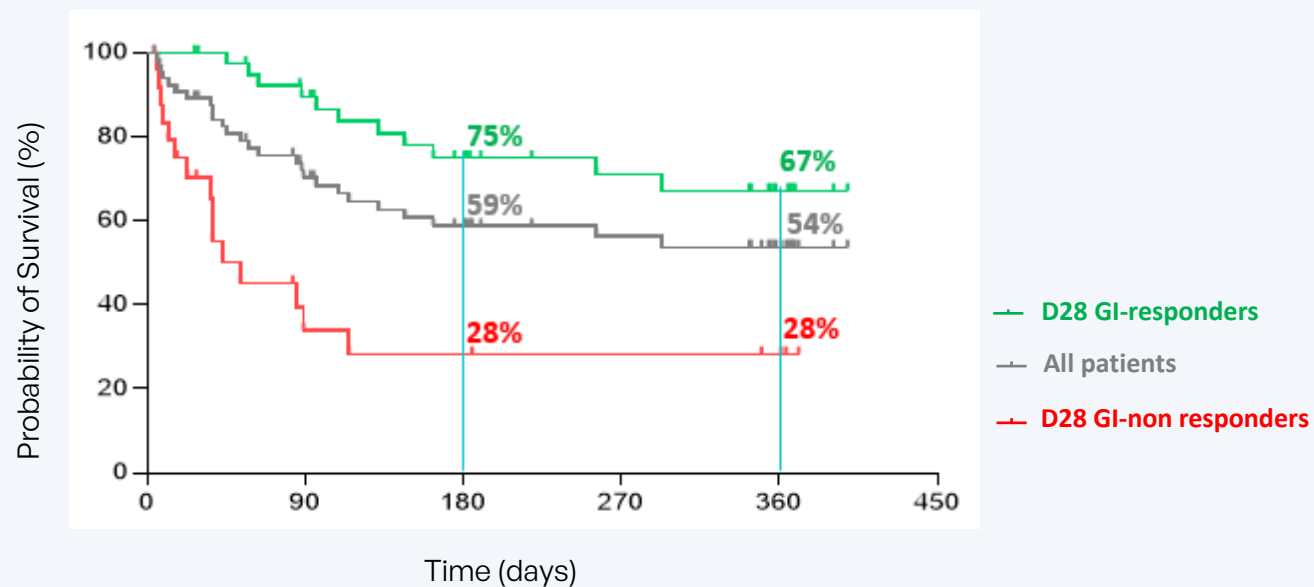


# ARES: Unprecedented Probability of Survival Compared to Historical Data with Best Available Therapy (BAT)

### Overall Survival, ARES vs BAT



### Probability of Survival by D28 Response



MaaT013 demonstrates response-driven prolonged survival, far exceeding expected outcomes in third-line aGvHD, with **54% probability of survival at 1 year compared to 15% survival in historical control**



# Early Access Program: meeting critical needs in GvHD today and shaping the future

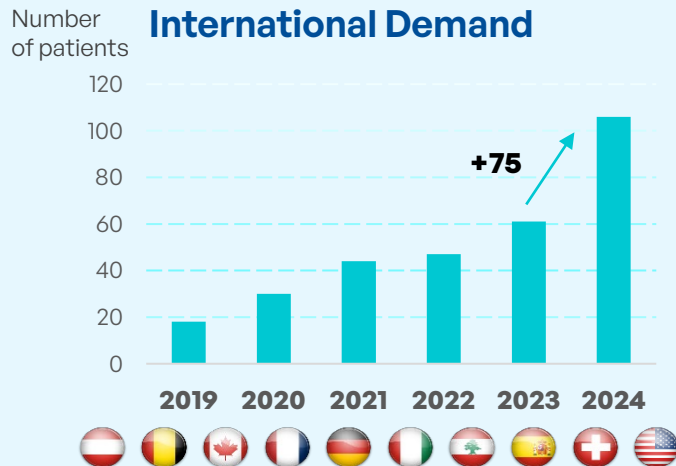
1

## Patients First

- **Unmet medical need:** no approved or efficacious treatment in 3L and beyond
- Patients with **dismal prognosis**

2

## Supplying The Increasing International Demand



3

## In Different Indications

- **95% in GvHD** (any line), including 7% for 2L aGvHD patients AND 79% for 3L aGvHD patients and beyond
- **5% outside the GvHD field** suggesting a larger adoption

4

## Clinical Value

**154** cumulative GvHD patients treated as of July 2024

- Safety = Favorable B/R ratio
- Efficacy (All lines) = GI-ORR at D28: 51%; 1Y OS: 47%
- **Efficacy (3L)** = GI-ORR at D28: **59%**; 1Y OS: 49% confirming the ARES Phase 3 data (GI-ORR D28: 62%, 1y OS: 54%)

-> Product positioning in 3L



## Supply chain & Manufacturing

- MaaT013 shipped to 10 countries
- 2 distribution centers: Horsham (USA) & Bordeaux (France)



## Increased Adoption

- Generate real world evidence
- Stakeholder engagement & advocacy support (10 countries and NCAs or ECs)
- First patient treated in the US: Dec. 2024



## Market Access Preparation

- Informed health economics modeling
- Preparation of narrative for payers
- Precise understanding of Cost of Goods
- Initiate early revenues (FR/social security): Q3/2024= 2.3 m€ (YTD)

**Communicated Phase 3 topline results (62%) in Refractory aGvHD confirm EAP signals (59%)**



# Clear Regulatory Path for MaaT013 in Third Line Refractory aGvHD

## In Europe



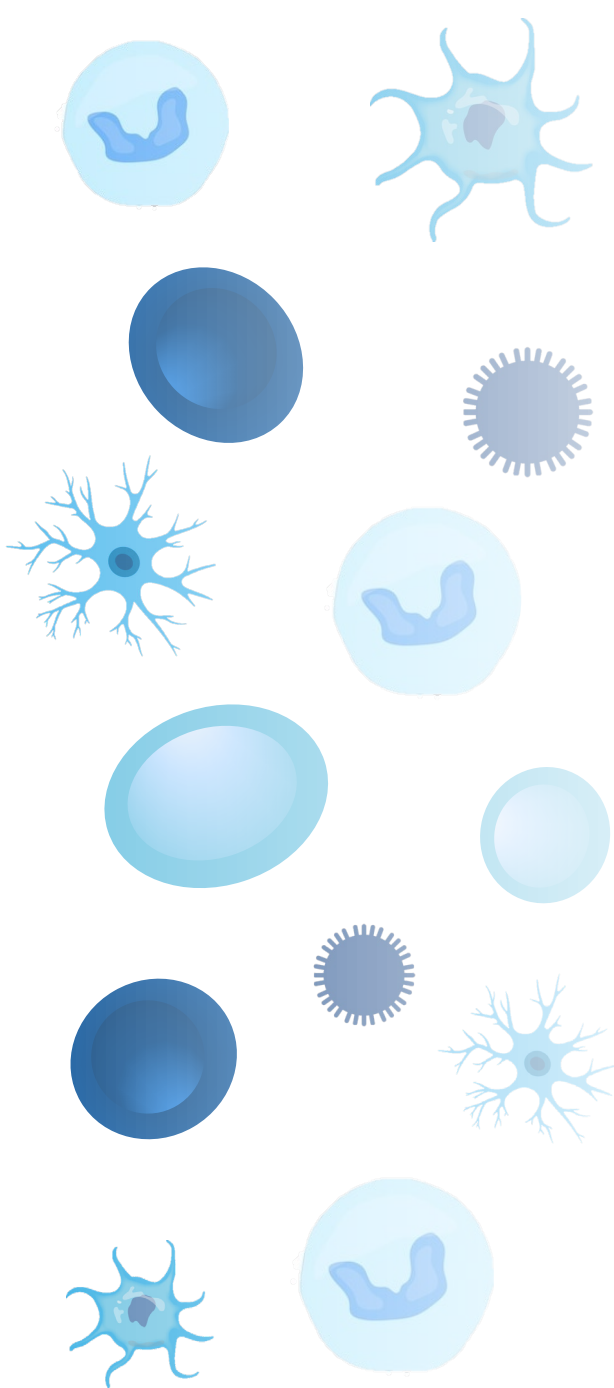
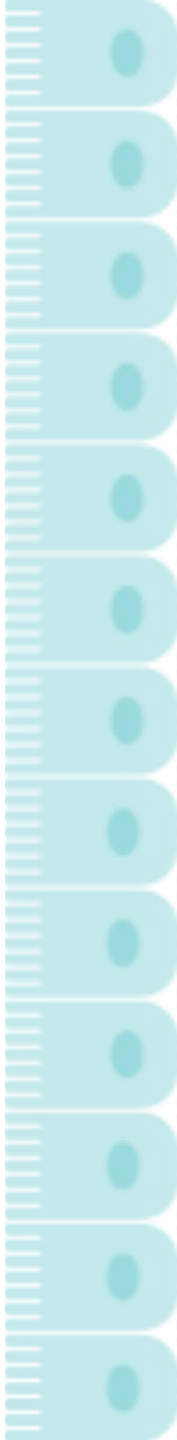
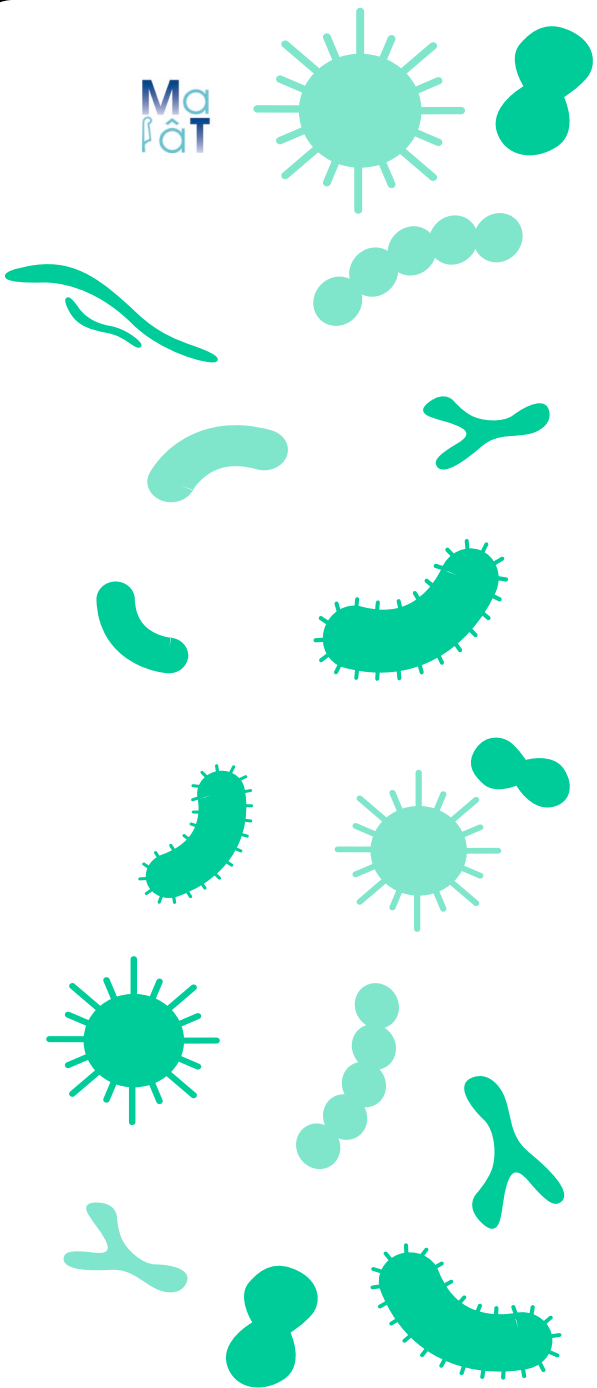
- › Eligibility of MaaT013 for the **centralized procedure confirmed by EMA** (Medicinal product status) and rapporteurs and co-rapporteurs appointed
- › **Target filing of the EMA Marketing Authorization Application** for MaaT013 **mid-2025** (6mths in advance vs previous plan)
- › **Submission based on validated primary endpoint** (28 days GI-ORR) complemented with data on 1y-OS
- › **Target H2 2026 for European marketing authorization, commence commercialization end of 2026**

## In the U.S.



- › **Open IND:** Ongoing dialogue with the FDA to expedite MaaT013 clinical development plan
- › **Dedicated and optimized study for the US** leveraging ARES Phase 3 results
- › Continue to support the **ongoing Expanded Access Program** to allow US patients early access to MaaT013
- › **Targeting potential launch of U.S. Phase 3 study in 2025**, subject to appropriate funding

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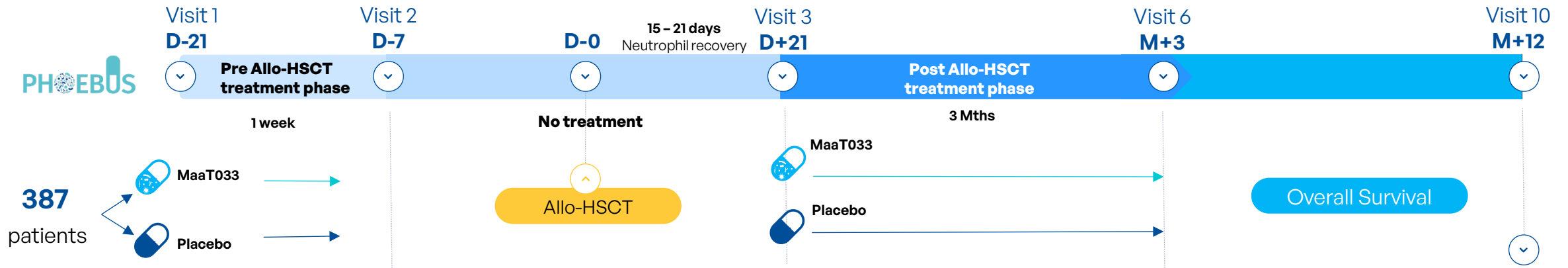
# A Multi-Asset Platform Focused on Oncology



# Phoebus: MaaT033 Phase 2b RCT Potential Adjunctive Treatment for Patients Receiving Allo-HSCT



Design presented at EBMT and ASH



## Largest Microbiome RCT trial in oncology

- Multicenter Randomized Control Trial
- 56 sites / 6 countries

- Primary endpoint: **1y-OS**
- Results : Q4-2027
- **Dec 24: 80 patients** (LPI target date: mid-26)



Ongoing Phase 2b  
PHOEBUS



Safety Interim analysis on  
60 patients in Q1 2025



Based on expected duration  
of recruitment, OS primary  
endpoint expected in 2027



~ 11k patients  
per year



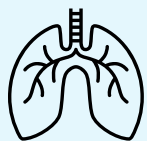


# Unlocking the Potential of Checkpoint Inhibitors: How Full-Ecosystem Gut Microbiome Overcomes Primary Resistance

**Immune Checkpoint Inhibitors (ICI) significantly improve outcomes in solid tumor patients**

**Leveraging full ecosystem microbiome could be a game-changer in immuno-oncology**

## Primary Resistance Rate to ICIs



Lung Cancer (NSCLC)

**35 - 40 %**



Skin Cancer (Melanoma)

**Up to 65 %**

→ Urgent need for new ICI combination therapies to boost response rates and survival

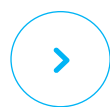
## 2021: FMT from ICI-responders could overcome resistance to ICI in non-responders with metastatic melanoma

✓ **6/15**

**Non-responders** -> Responders  
(Davar et al, 2021)

✓ **3/10**

**Non-responders** -> Responders  
(Baruch et al, 2021)



## 2023: Microbiotherapy from healthy donors boosts response to aPD1+aCTLA4 in ICI-naïve metastatic melanoma patients

✓ **15/20**

**ICI-naïve** → Responders  
(ORR=75 %, Routy, 2024)

✓ **.../35**

PICASSO studying  
MaaT013: 1<sup>st</sup> multicenter  
RCT **70 pts rand 1:1**



# MaaT013 Evaluated in Phase 2 Randomized, Multicenter Clinical Trial in Melanoma

**Phase 2a PICASSO trial, [fully recruited](#)**

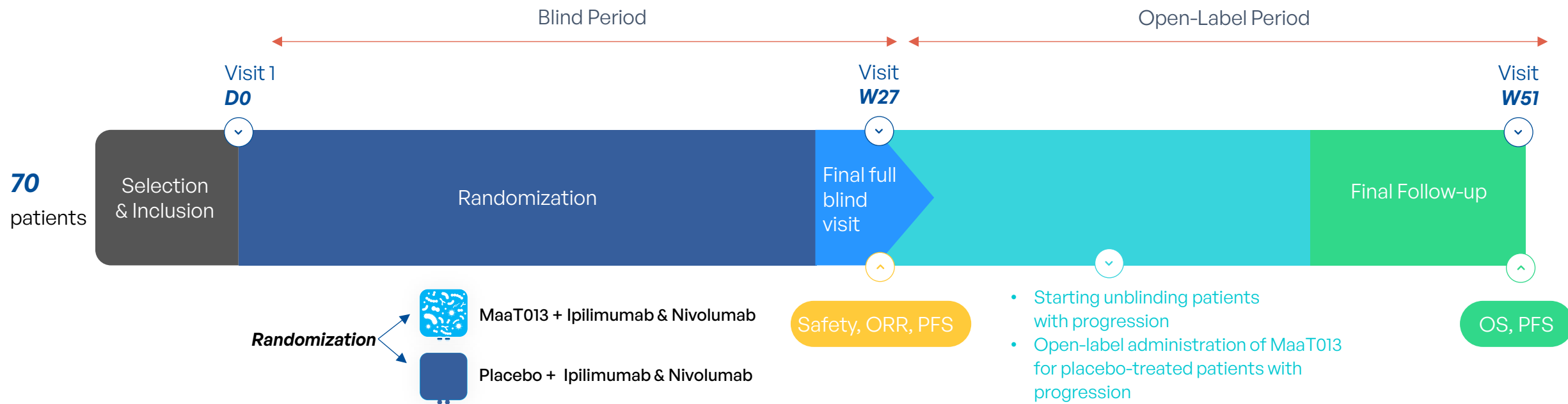
**Investigator Sponsored Trial** (Assistance Publique - Hôpitaux de Paris) in collaboration with Institut Gustave Roussy

→ **Data expected Q1.25 (positive DSMBs)**

**Key study endpoints after 23 weeks of treatment:**

MaaT013 safety profile and best-overall response rate vs placebo as add-on treatment to Ipilimumab + Nivolumab

## PICASSO RCT design





# MaaT033: Targeting Amyotrophic Lateral Sclerosis Progression



## Amyotrophic Lateral Sclerosis (ALS)

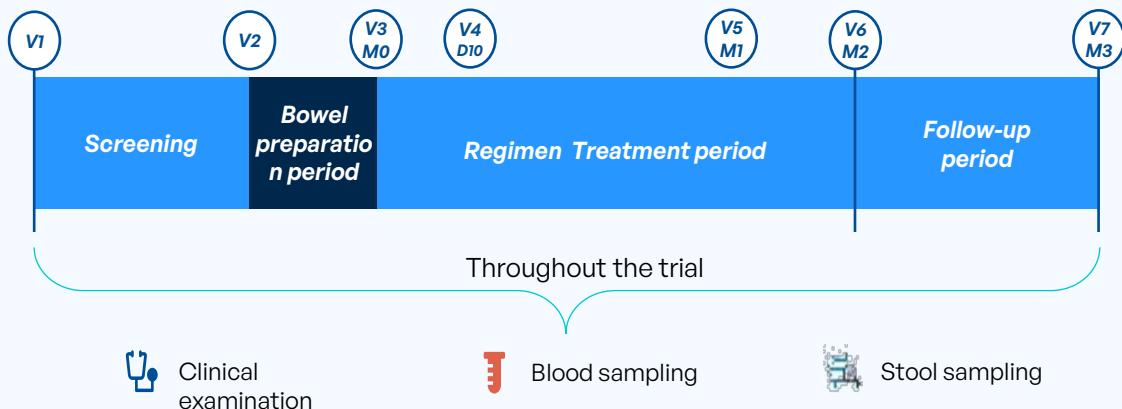
- Could affect up to 60,000 patients in US & EU by 2040<sup>1</sup>
- Paralysis and death 3 to 5 years after diagnostic<sup>2</sup>
- Currently no curative treatment and few symptomatic treatments

## Rationale for Exploratory Utilization of MaaT033 in ALS

- Microbiota-Gut-Brain axis is a multifactorial MoA which has the potential to become the new standard to treat neurodegenerative diseases, including ALS
- Strong support from medical community & patients
- A capital efficient way of testing neurodegenerative field in the most severe indication with high medical need with potential for expansion

### Study

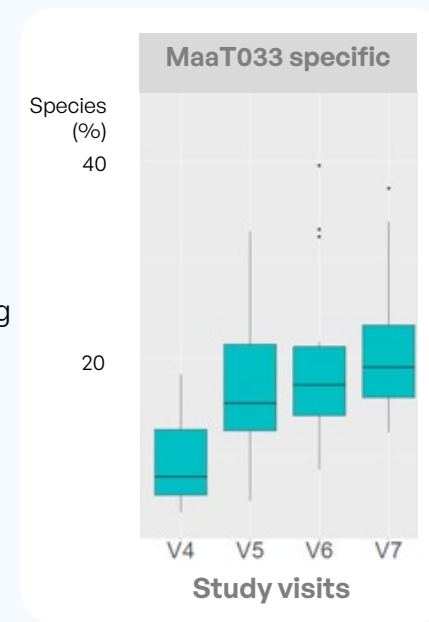
→ **Pilot, open-label, Phase 1b** study **in France, N=15** (NCT05889572)



→ **Key study endpoints:** safety and tolerability of MaaT033 (**Primary**) | gut microbiota composition evolution | marker showing potential impact on disease progression

→ **Primary endpoint met;** full data readout expected in **Q1 2025**

- MaaT033 found to be safe and well tolerated
- DSMB supports proceeding to Phase 2
- Successful engraftment characterized by the increasing MaaT033 species overtime



(Data published in a poster at MNDA, 35th International symposium on ALS/MND)

Study developed with:



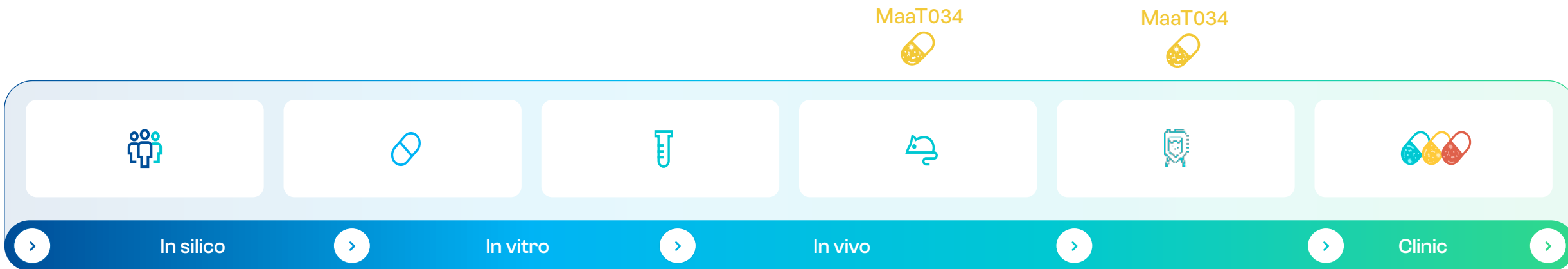
In collaboration with:



<sup>1</sup> Arthur, K., Calvo, A., Price, T. et al. Projected increase in amyotrophic lateral sclerosis - from 2015 to 2040. Nat Commun 7, 12408 (2016). <https://doi.org/10.1038/ncomms12408> <sup>2</sup> <https://tousensellescontrolasla.fr/la-sla-cest-quoi/>



# MET-C Product Generation is Driven by MaaT Pharma's Proprietary Predictive AI, Eubiotic Score and *in vitro* and *in vivo* Validation Processes



**HIT Products**  
Donor-independent ecosystem candidate

**LEAD Products (MaaT03X)**  
→ Activity in *in vitro* models (local and distal models)

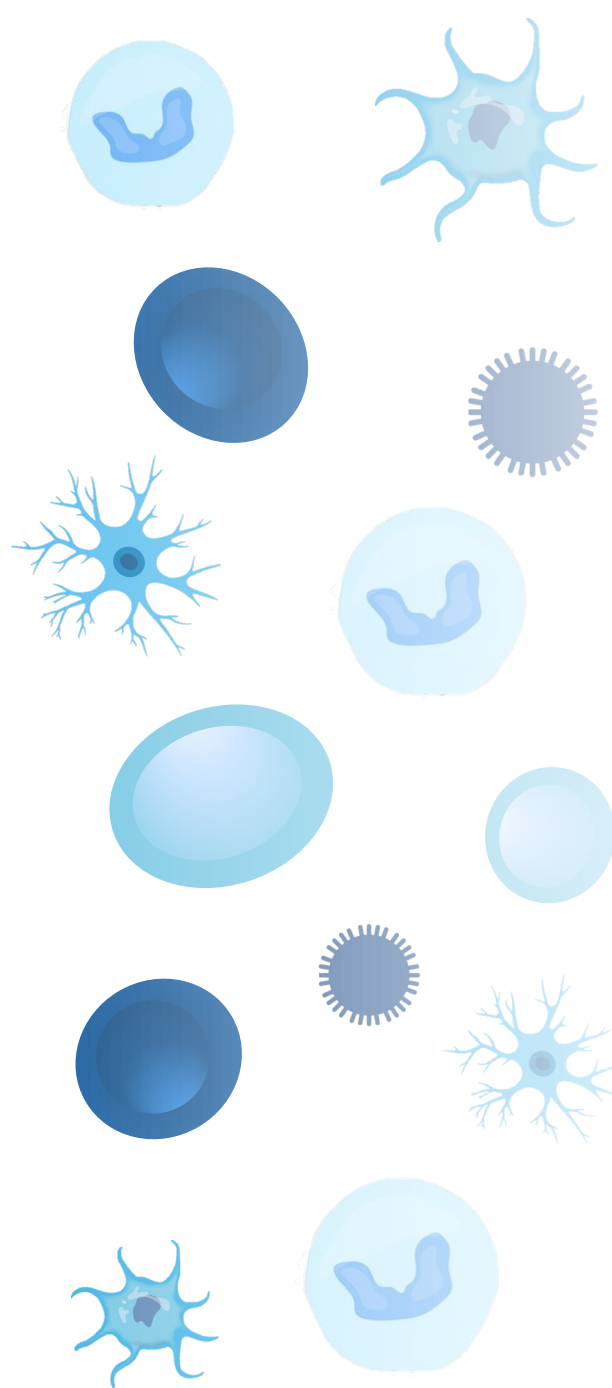
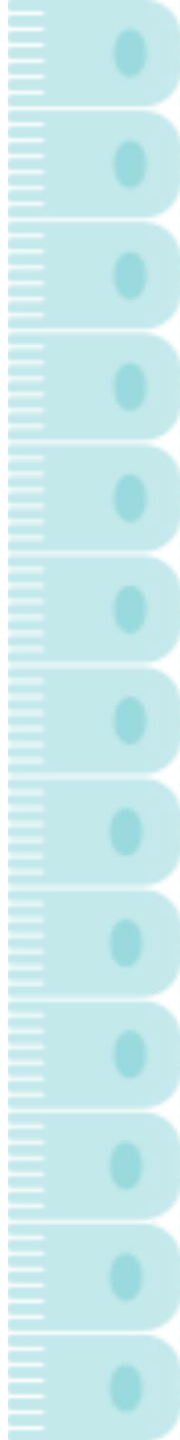
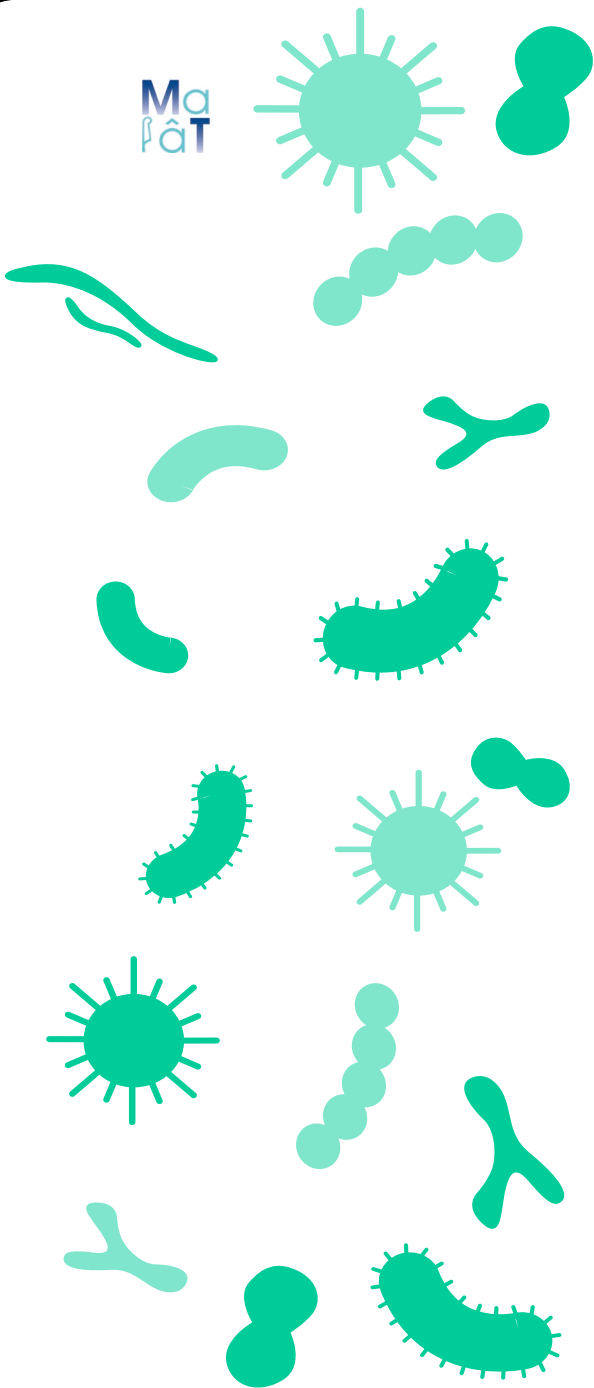
**Candidate Products (MaaT034)**  
→ Activity in 2 different mouse models  
→ Product characterization  
→ Safety and Dose assessment

**Upcoming Milestones for MaaT034**  
→ Manufacturing of Clinical batches expected in H2.2025  
→ FIH expected in 2026

Indication-specific drug candidates



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# Hemato- oncology Franchise Driving Value

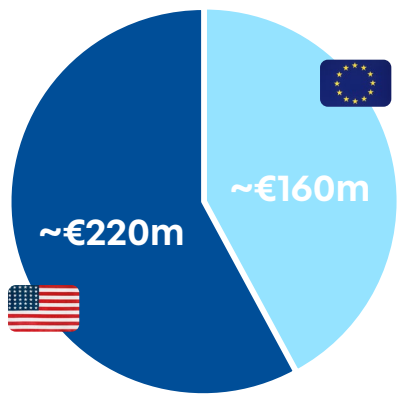


# MaaT013 Addressable Market and Revenues

## Addressable market in 3L

~3,000 patients

3L GI-SR-RR/I-aGvHD

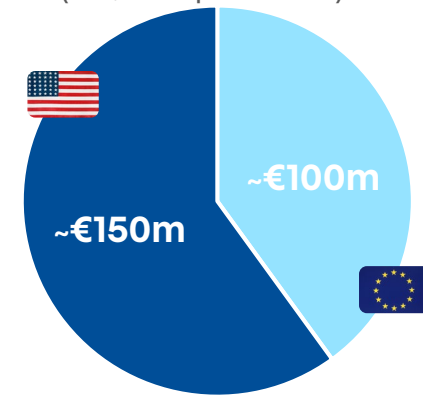


Total Worldwide  
**~€380m+**

## Estimated Annual Revenues

**65%** Market penetration

3L GI-SR-RR/I-aGvHD  
(~2,000 patients)



Total Worldwide  
**~€250m+**

- Ruxolitinib : **~70% MS in the US within 2 years of approval**
- Addressable population concentrated in **transplant centers**

Potential peak sales of **€250m+** worldwide with potential upside from 2L positioning (+1,400 patients)



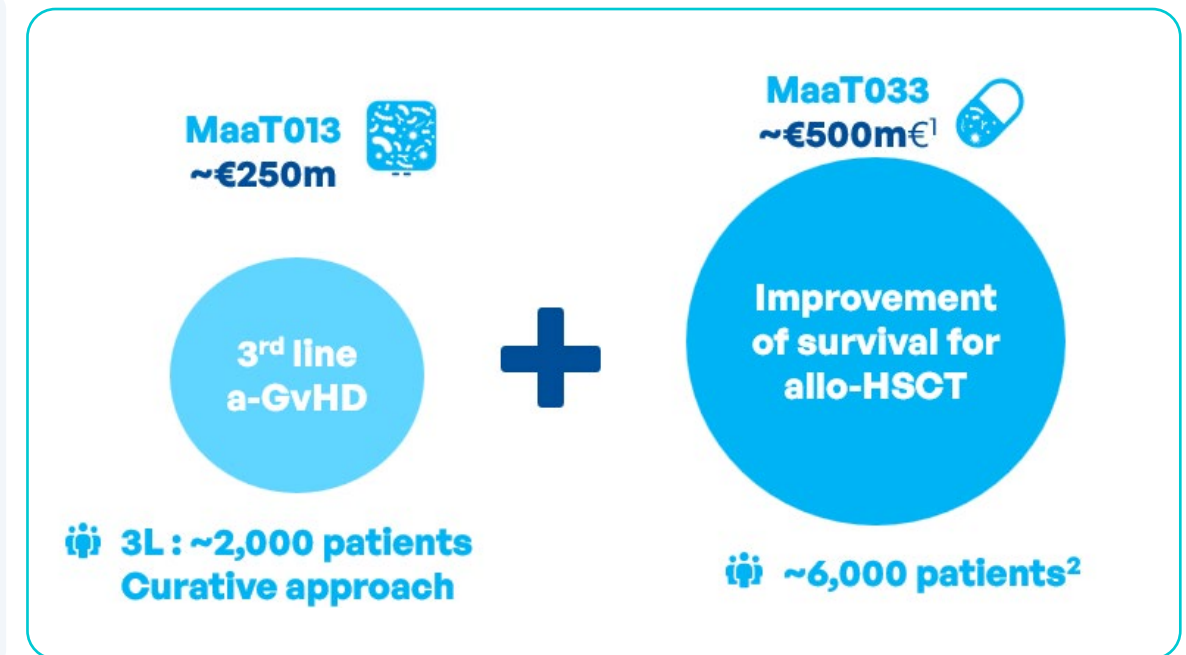
# Realizing value through partnership: Aligning innovation with unmet medical needs in hematology

## Unique Franchise Opportunity

- › Unique immunosuppressant-sparing, microbiome-based approach
- › Well defined **target population** for both products,
- › Prescribers **focused** on limited number of centers, many of them already using MaaT013
- › **Proven efficacy and safety** with potential to expand to other dysbiosis-linked hematological malignancies (e.g., CAR-T)
- › Multiple value catalysts over the next few months

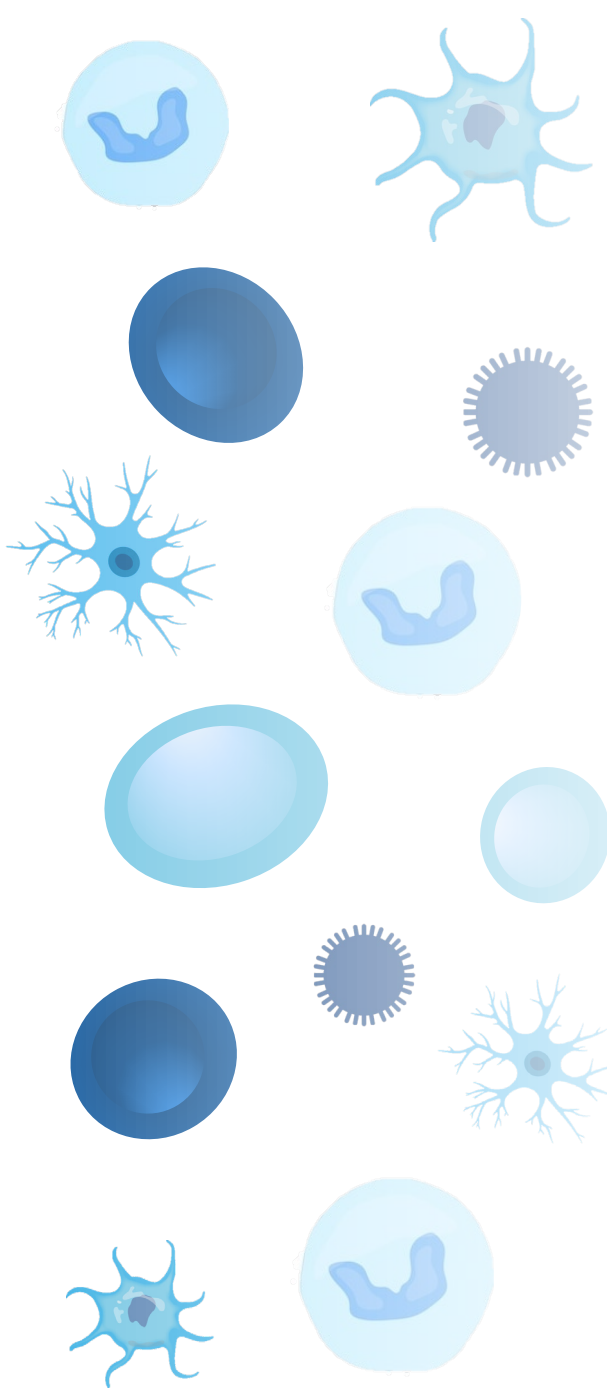
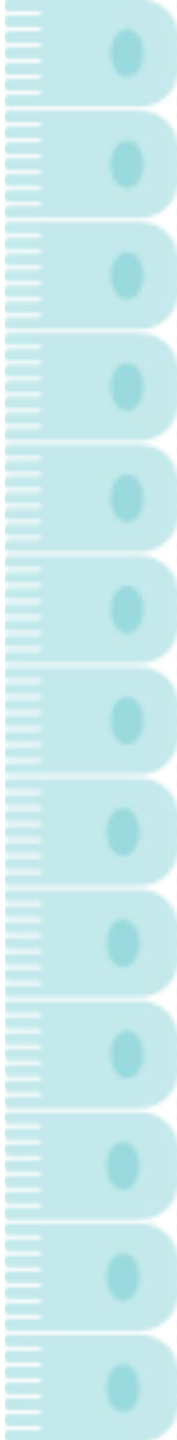
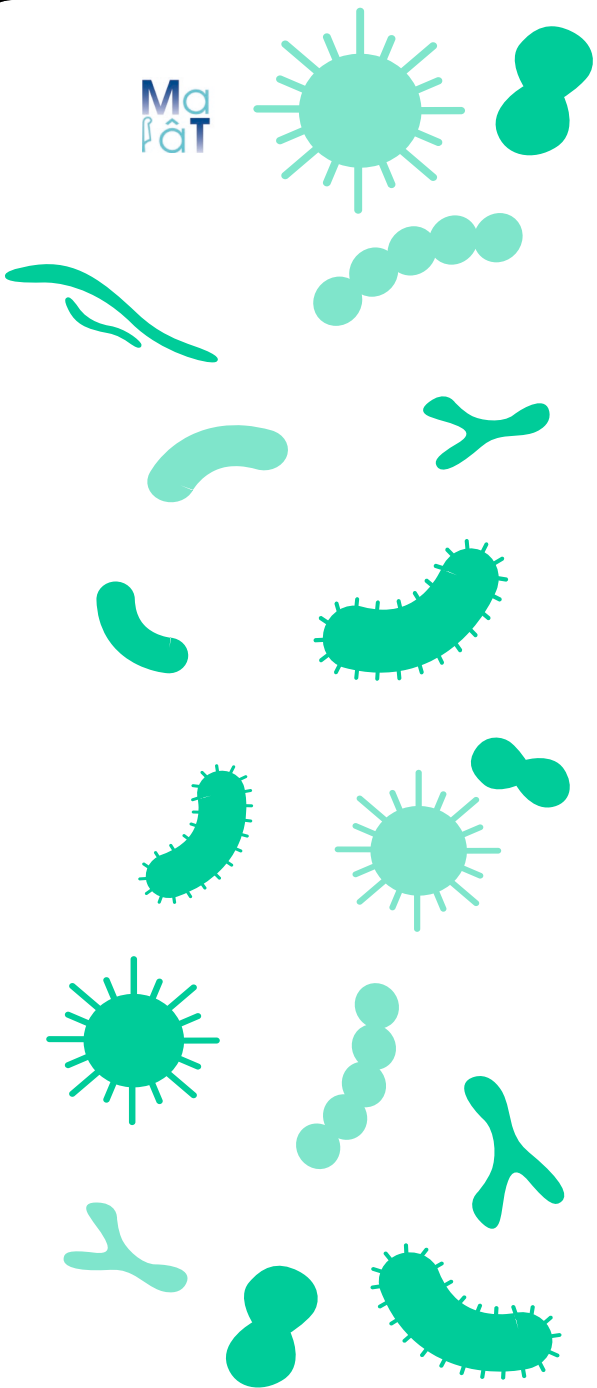
Significant potential to leverage partner's expertise in hematology, rare diseases, or hospital commercial operations.

## A very meaningful market opportunity



A Total market of  
**~€750 m+**

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**End-to-End  
In-house  
cGMP  
Manufacturing  
Capabilities**



# Europe's Largest Specialized cGMP Manufacturing Facility for Microbiome Ecosystem Therapies

A dedicated 1,600m<sup>2</sup> site (+17,000 sq ft), expandable, to support demands until 2034 for MET-N clinical and future commercial production, R&D, and clinical batches of MET-C products (MaaT034 & MaaT3X family)

~11,000 treatable patients per year

MaaT013

9,000 bags/ year

MaaT033

1,300,000 capsules / year

MaaT03X

Up to 300,000 capsules / year

## 01

**Leading microbiome therapies fully integrated manufacturing and development platform:**

streamlined product development, scaleup and GMP process.

## 02

**Option to expand manufacturing facilities** to double capabilities.

## 03

**Consistent yield (<10% variation)**



Campaign #1 Campaign #2 Campaign #3

Manufacturing yield based on FDA/EMA authorized processes

## 04

Currently used at 10% capacity

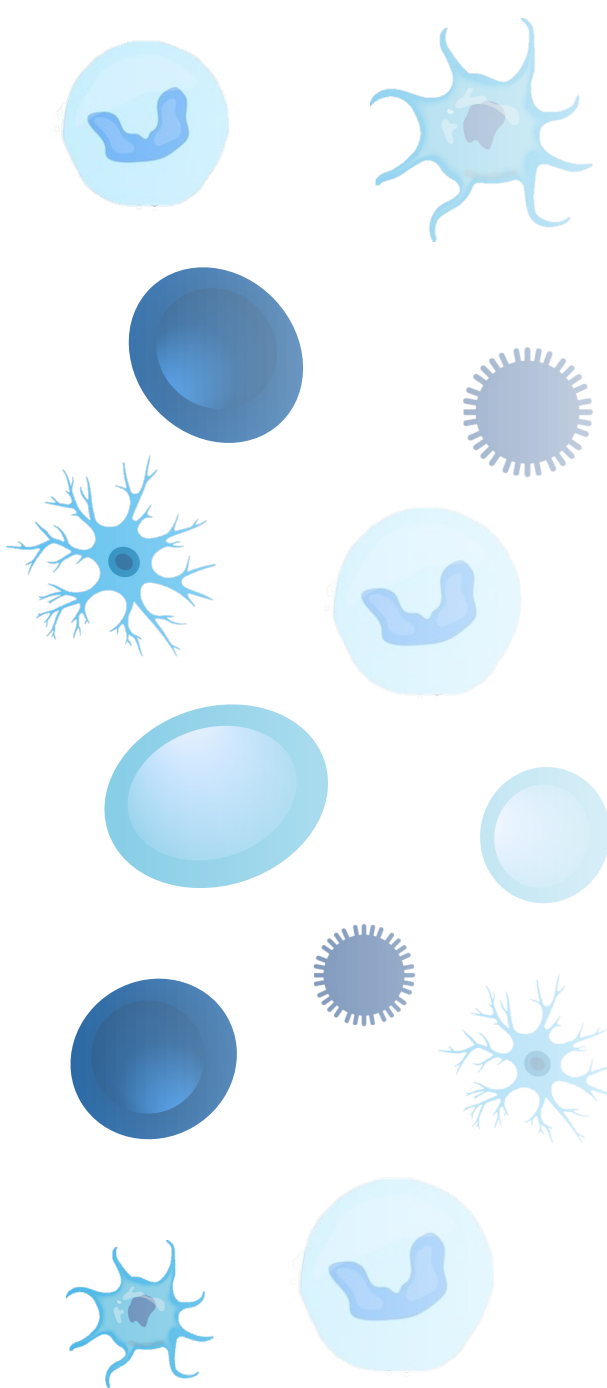
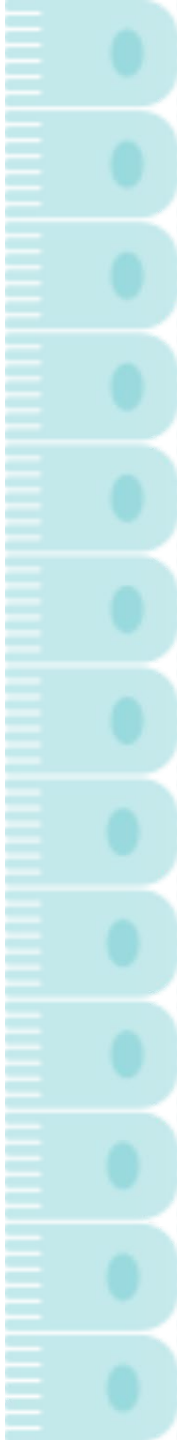
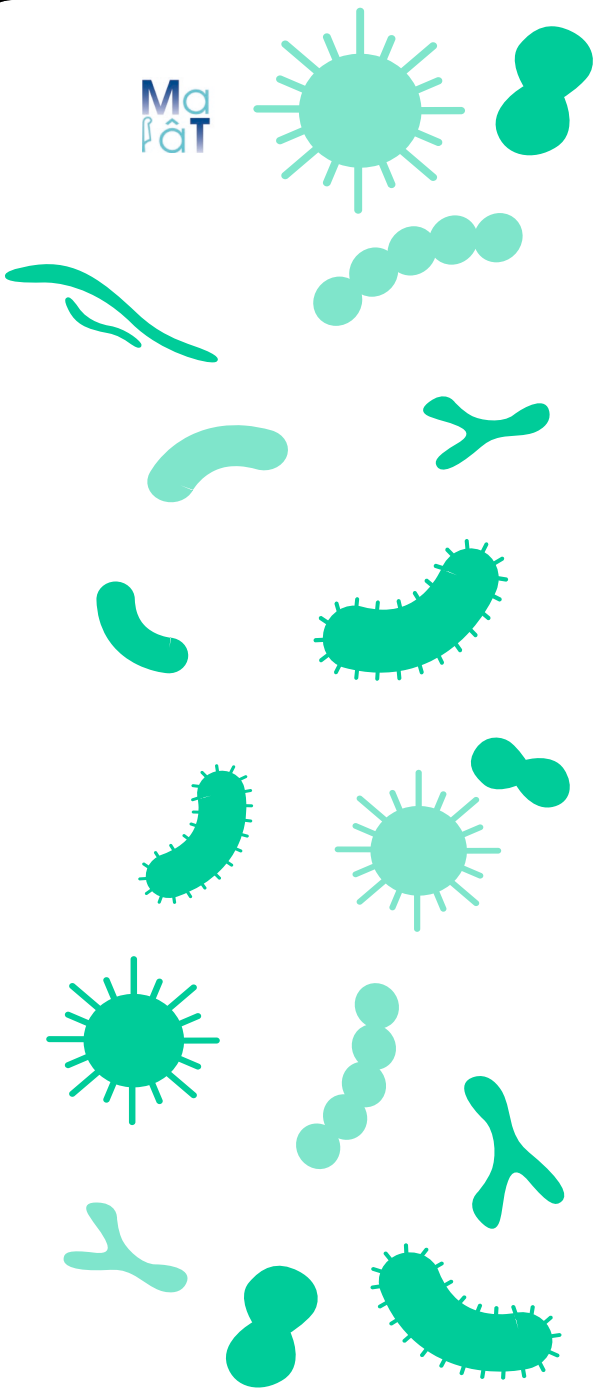
**Scalable up to commercial capacity**



Partnership with



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# Newsflow & Funding Opportunities

# Several Major Near-Term Value Inflection Milestones

2025

2026

2027



Hemato  
-  
Oncology

Immuno  
-  
Oncology

<p><b>MaaT013</b> </p> <p>GvHD   Ares Ph3 28 days GI-ORR <b>results Jan 25</b></p>		
<p><b>MaaT013</b> </p> <p>GvHD   MA <b>application</b> EMA Mid 25</p>		
<p><b>MaaT013</b> </p> <p>GvHD   Ares Ph3 OS <b>results H2 25</b></p>	<p><b>MaaT013</b> </p> <p>GvHD   MA <b>approval</b> EMA H2 26</p>	
<p><b>MaaT013</b> </p> <p>GvHD   Apollo Ph3 FPI <b>Q4 25</b></p>		<p><b>MaaT013</b> </p> <p>GvHD   Apollo Ph3 <b>results H2 27</b></p>
<p><b>MaaT033</b> </p> <p>HSCT   Phoebus Ph2b DSMB <b>Q1 25</b></p>		
<p><b>MaaT033</b> </p> <p>HSCT   Phoebus Ph2b DSMB <b>Q3 25</b></p>	<p><b>MaaT033</b> </p> <p>HSCT   Phoebus Ph2b LPI <b>Q2 26</b></p>	<p><b>MaaT033</b> </p> <p>HSCT   Phoebus Ph2b OS <b>results H2 27</b></p>

<p><b>MaaT013</b> </p> <p>Melanoma   IST Picasso Ph2a <b>results Q1 25</b></p>	
<p><b>MaaT033</b> </p> <p>NSCLC   IST Immunolife Ph2a FPI <b>Mid 25</b></p>	<p><b>MaaT033</b> </p> <p>NSCLC   IST Immunolife Ph2a <b>interim analysis reviewed by IDMC Q4 26</b></p>
<p><b>MaaT034</b> </p> <p>IO   1<sup>st</sup> clinical batch produced <b>H2 25</b></p>	<p><b>MaaT034</b> </p> <p>IO   FIH Solid tumor <b>26</b></p>

Legend: Key milestone; Achieved US market; EU market; MaaT013 (pooled enema); MaaT033 (pooled capsule); MaaT034 (co-cultivated capsule)

# Opportunities to fund the Company's development



**Cash position of €27m** as of September 30,2024



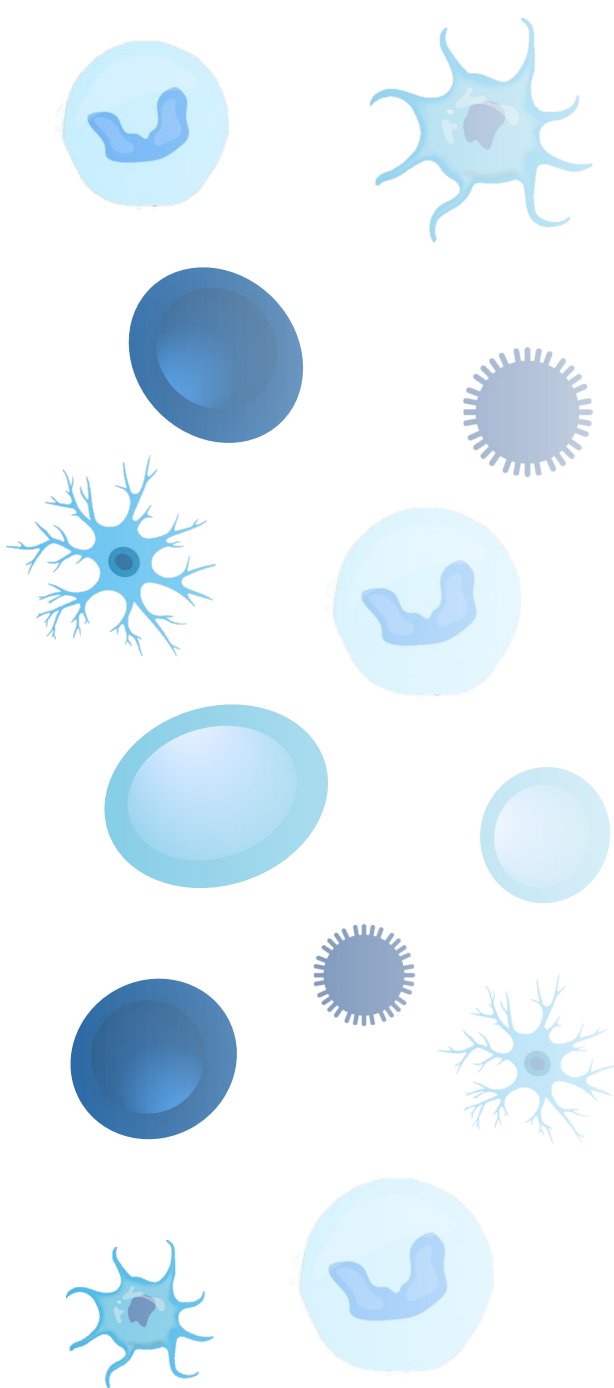
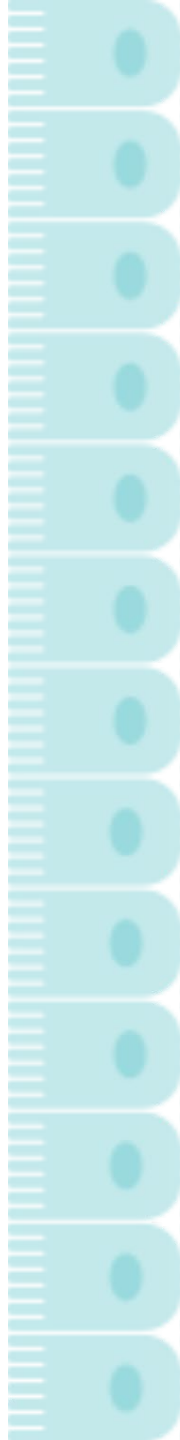
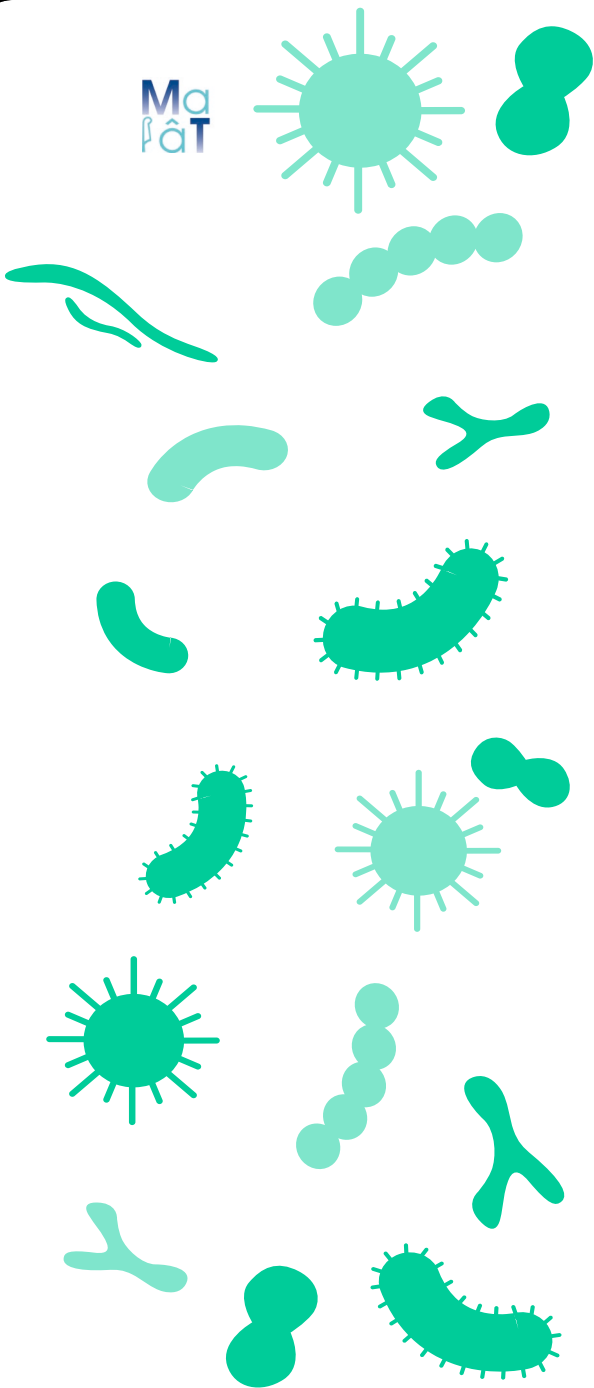
**Current cash runway into Q2 2025**



**Exploring several opportunities** to fund the Company's developments over the next coming years, **including dilutive and non-dilutive options**



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# Thank you

