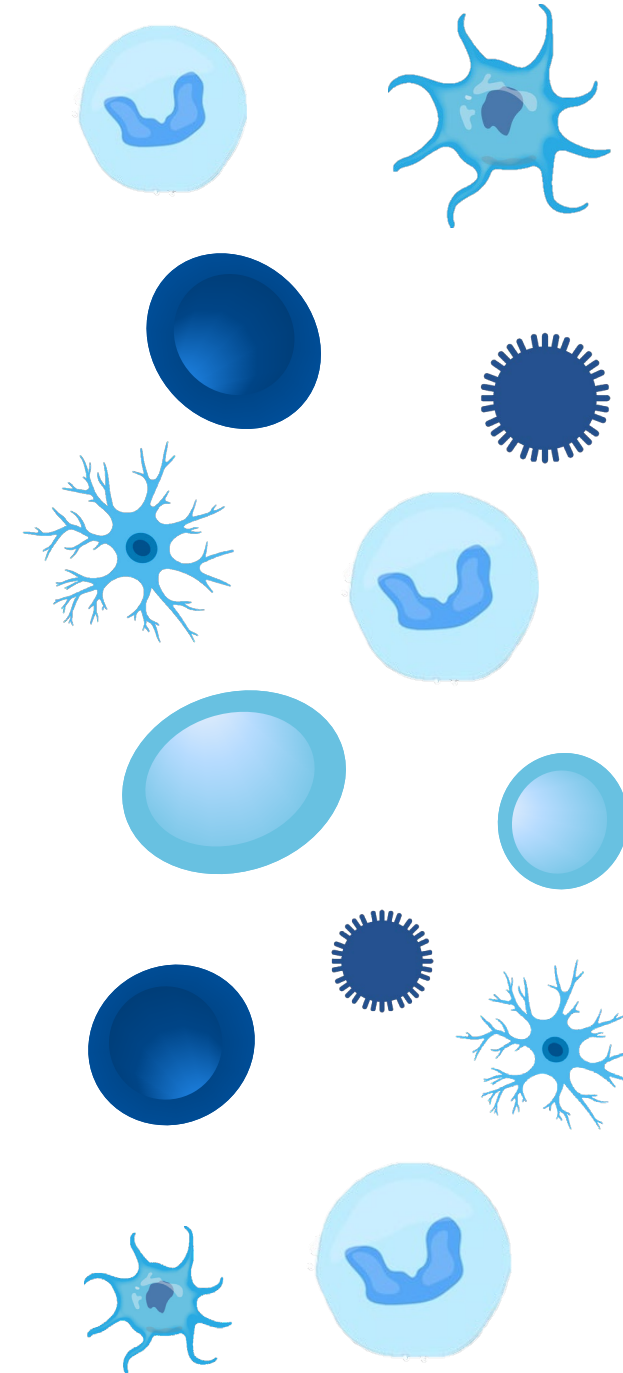


MaaT Pharma

# Boosting Survival Through Innovative Immune Modulation

April 2025



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# Management Team



**Hervé Affagard**

Co-Founder & CEO



**Eric Soyer**

Chief Financial Officer



**Gianfranco Pittari, MD, PhD**

Chief Medical Officer



**Carole Schwintner, PhD**

Chief Technology Officer

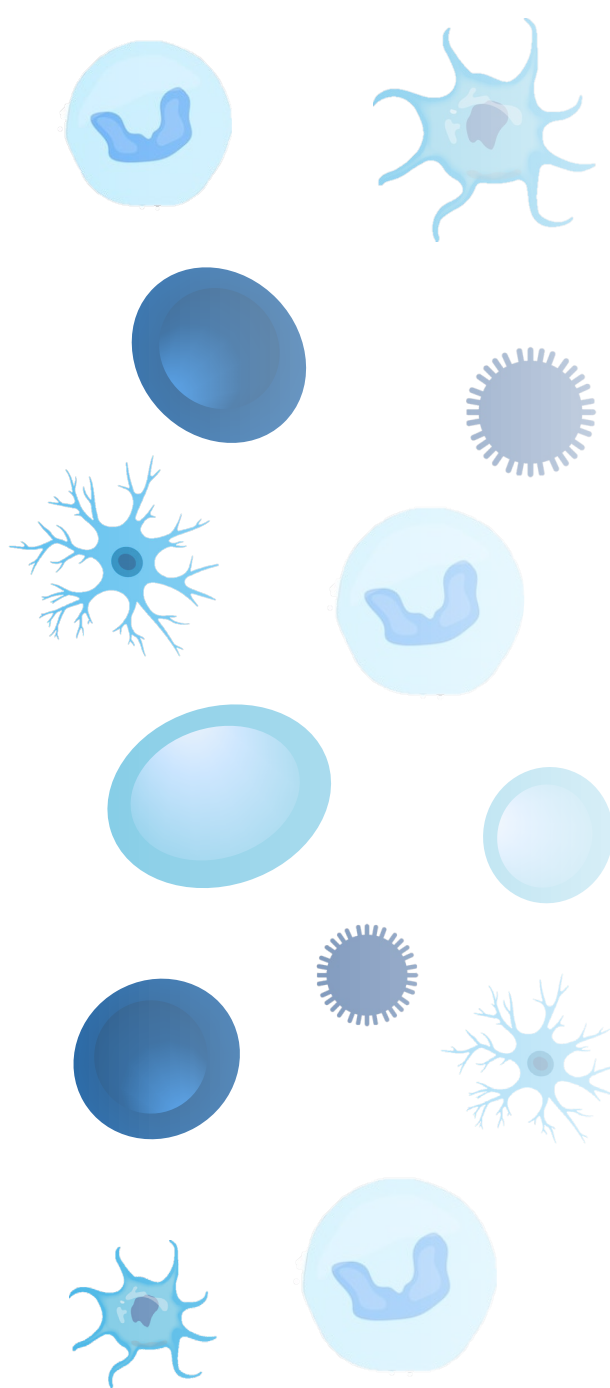
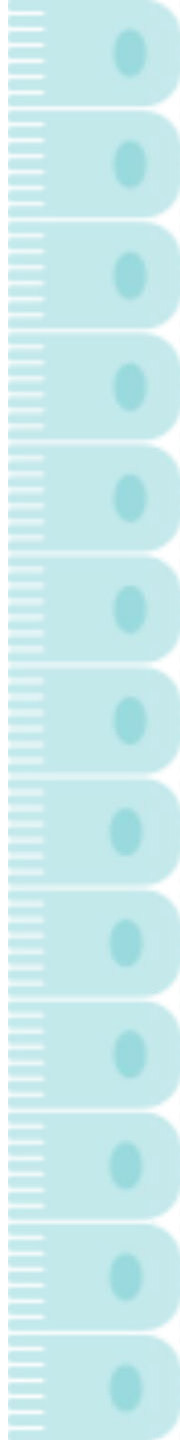
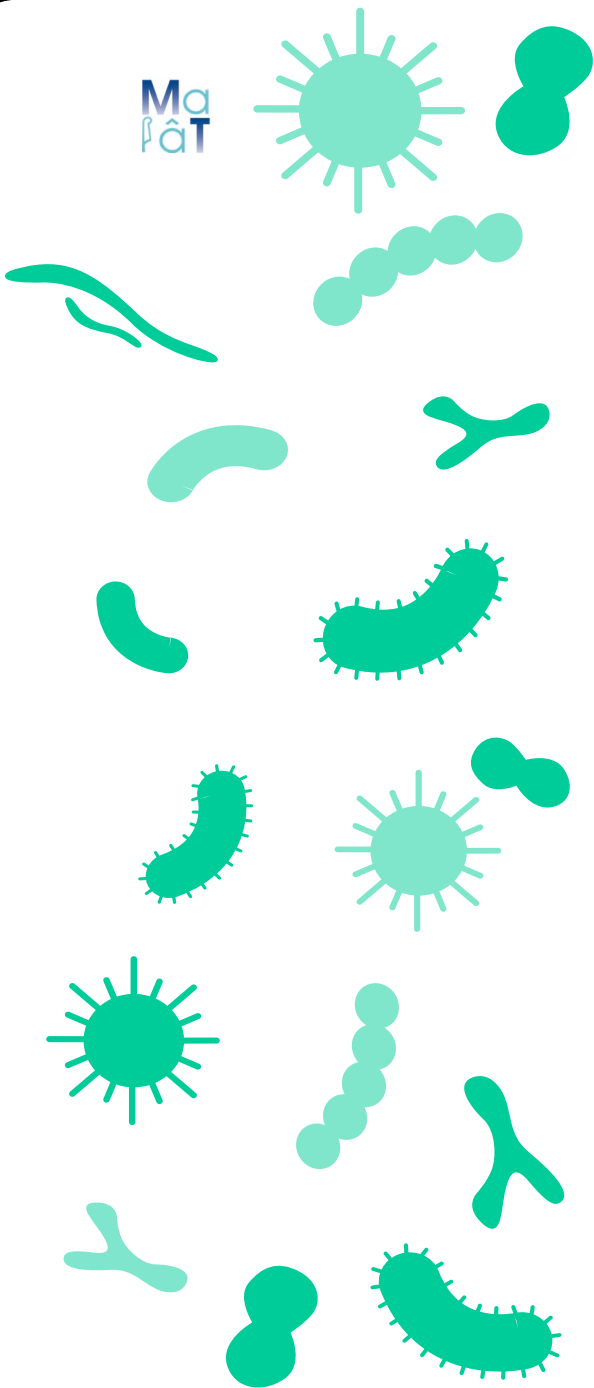


**Jonathan Chriqui, PharmD**

Chief Business Officer



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# Company Overview

# MaaT013 in aGvHD: Achieved Primary Endpoint of Phase 3 Study

## Registration in Europe Will Spearhead 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 June 2025**.

\*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



- > Potential **750m€ yearly peak sales Hemato-Onco franchise** for partnering: 250m€ for MaaT013 in GvHD and 500m€ for MaaT033 in allo-HSCT.
- > **Cash position** of **20.2m€** as of December 31, 2024. **Post capital increase in March 2025, (approx. €13m€) cash runway** extended into **October 2025**
- > Exploring **additional funding options** for future developments, including non-dilutive such as partnerships and other non-dilutive sources

# Correcting Dysbiosis: a New Pillar in Oncology

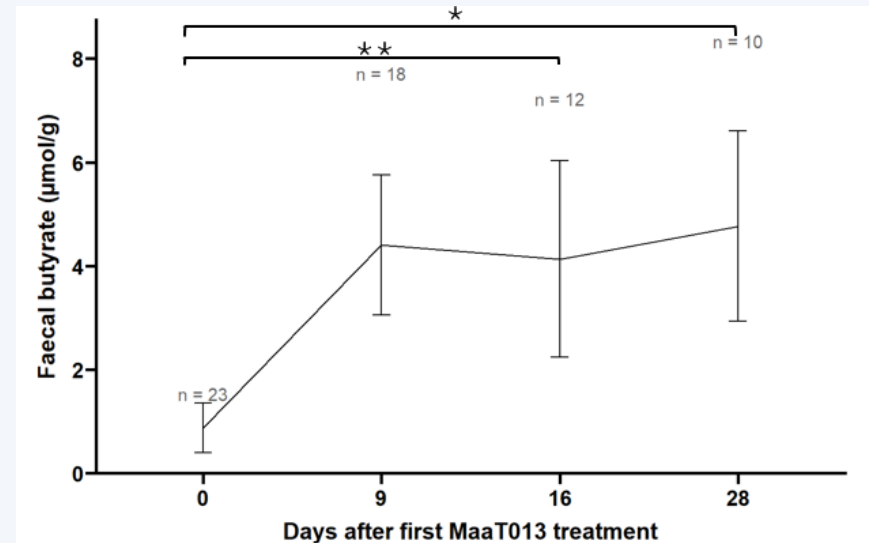
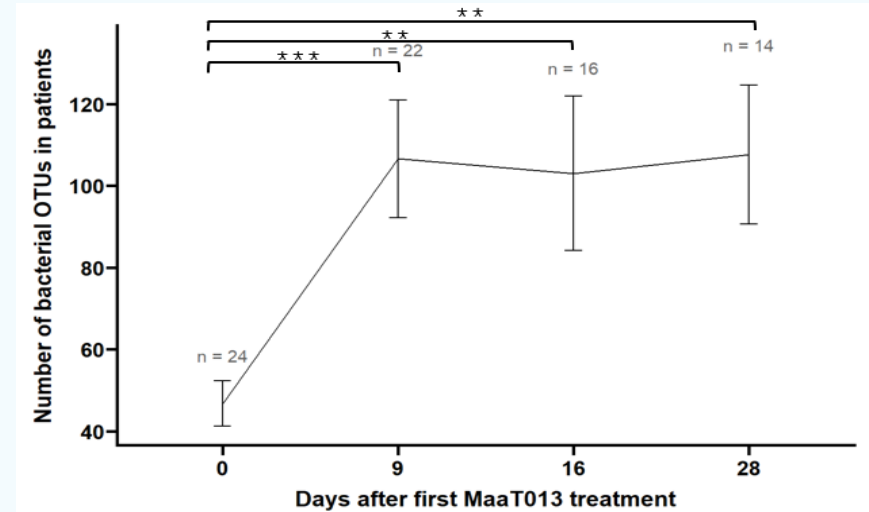
## Dysbiosis and disease

- 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  
v



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

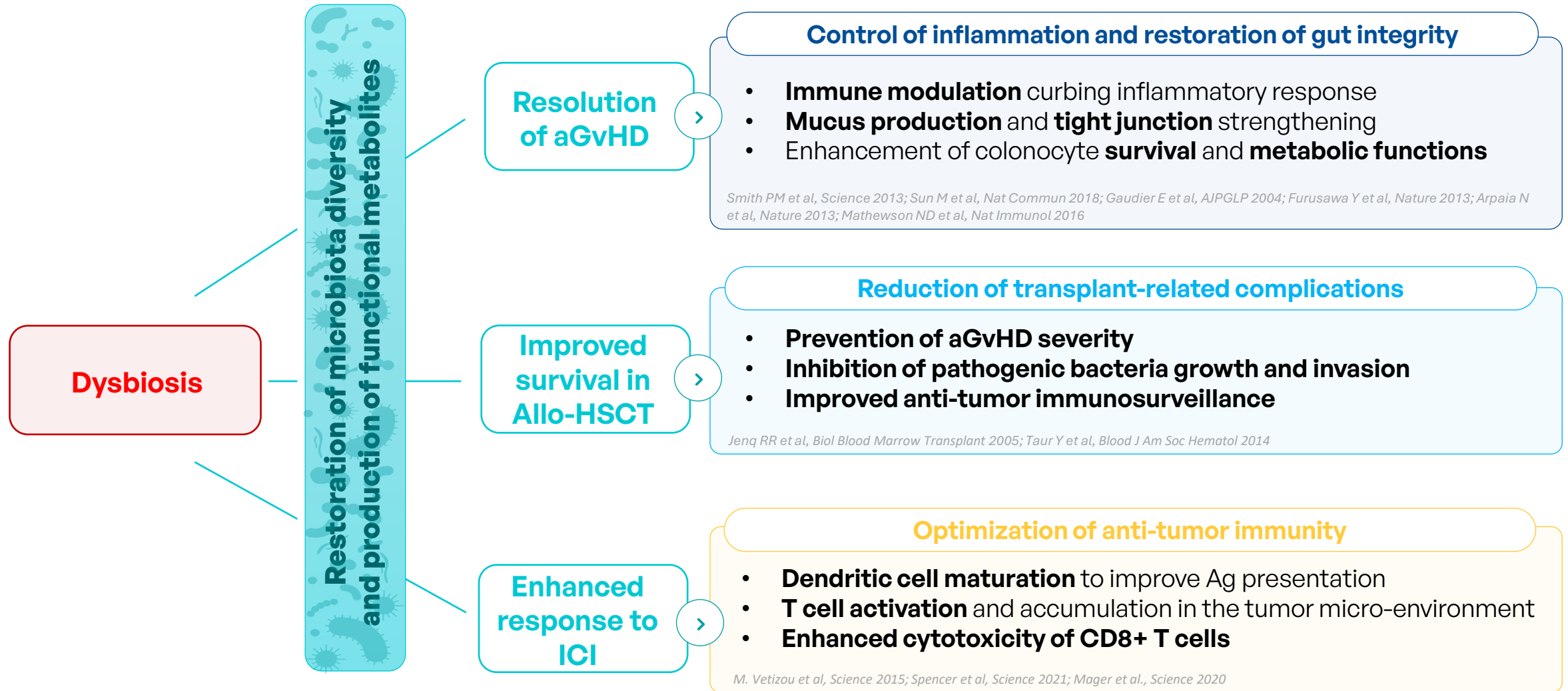
# A Strong Pipeline With Multiple Value Inflection Milestones and a Close-to-Market Asset

Program	Indication	Market potential	Preclinical	Phase 1	Phase 2	Phase 3	MAA	Status	Upcoming milestone
<div>MaaT013</div> <div></div>	aGvHD	~250m€ 1L : 10k patients <sup>2</sup> 2L : 5K patients <sup>2,3</sup> 3L : 3K patients <sup>2,3</sup>	ARES 					Primary endpoint met  Ongoing	EU MAA Submission June 2025
	ICI improvement Melanoma	POC	IST* - PICASSO 					Fully recruited Ongoing	Results H2.25
<div>MaaT033</div> <div></div>	Allo-HSCT	~500m€ 11k patients <sup>2</sup>	PHOEBUS 					Ongoing	Positive Unblinded Interim Analysis - April 2025 
	ICI improvement NSCLC	POC	IST** - IMMUNOLIFE 					Pending	FPI in H1.25
	ALS	Exploratory	IASO 					Primary endpoint met	Full data in Q1 2025
MaaT034	IO	~1 to 5b€ <sup>1</sup> 500k patients	PrClin 						Targeting FIH 2026

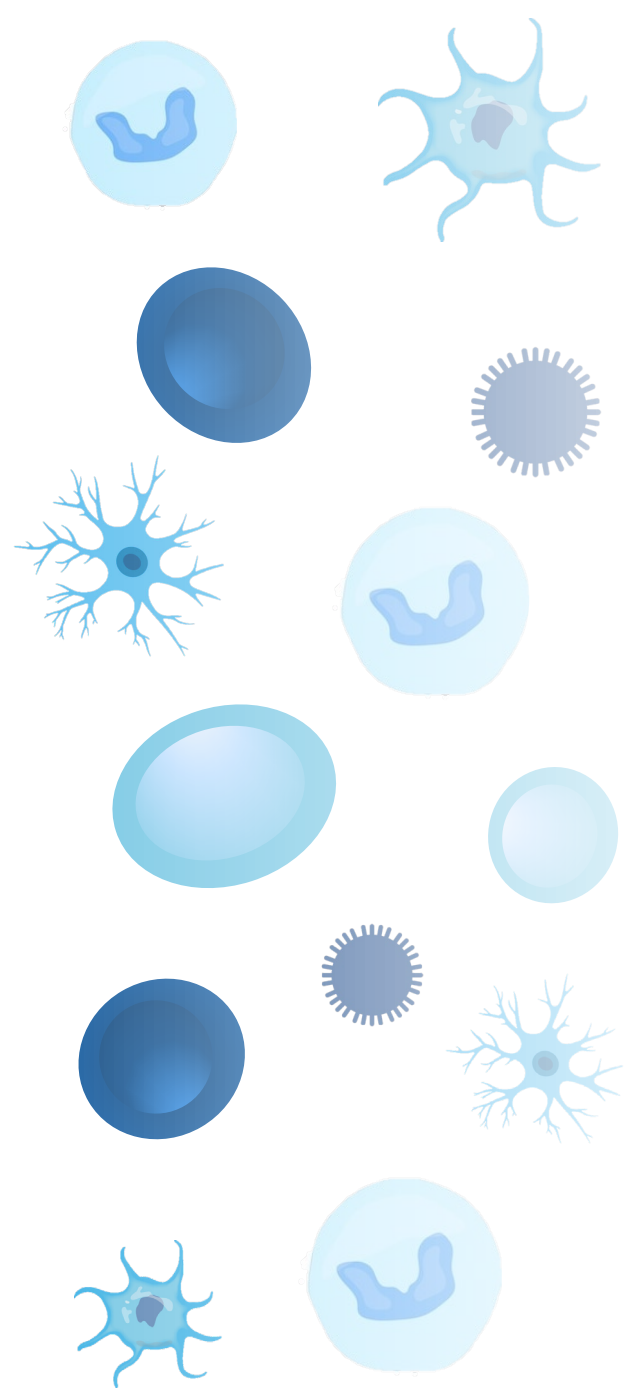
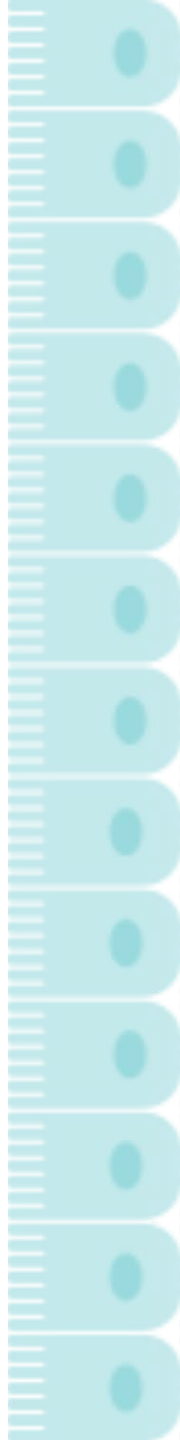
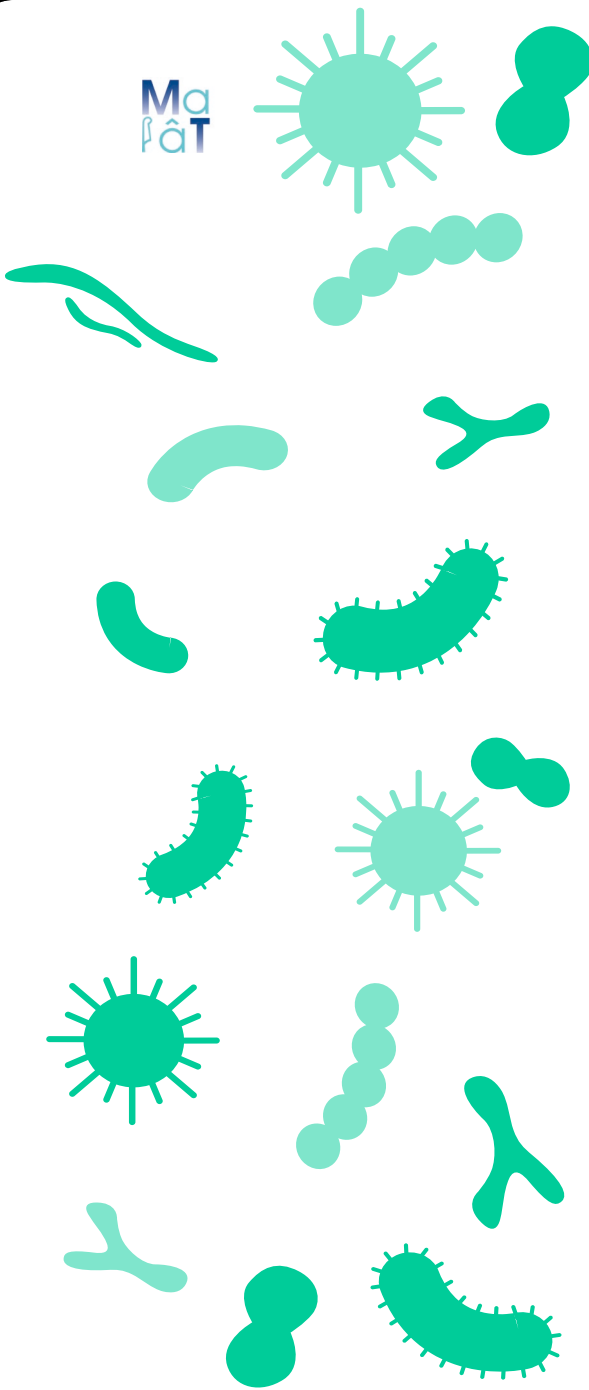
aGvHD: acute Graft versus Host Disease ; IO: Immuno-Oncology ; PoC: Proof of Concept; Allo-HSCT: Hematopoietic Stem Cell Transplantation ; ALS: Amyotrophic Lateral Sclerosis ; IST: Investigator Sponsored Trial; NSCLC: Non-small cell lung cancer  
ICI PICASSO: ipilimumab (Yervoy®) and nivolumab (Opdivo®)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

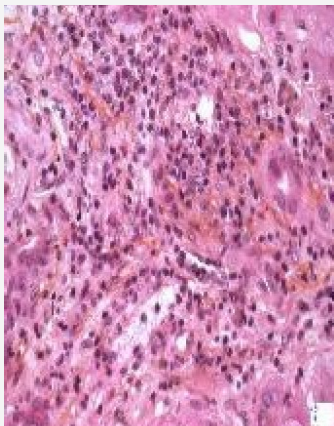
Common clinical manifestations typically involve the gastrointestinal tract, the skin and the liver

## 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*

<sup>1</sup>Abedin et al. 2021, BJHaem

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

## Treatment Paradigm

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

30%

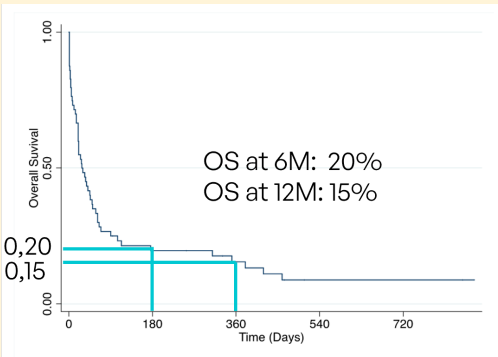
of aGvHD patients **eligible** for subsequent or alternative treatment



Approximately 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>

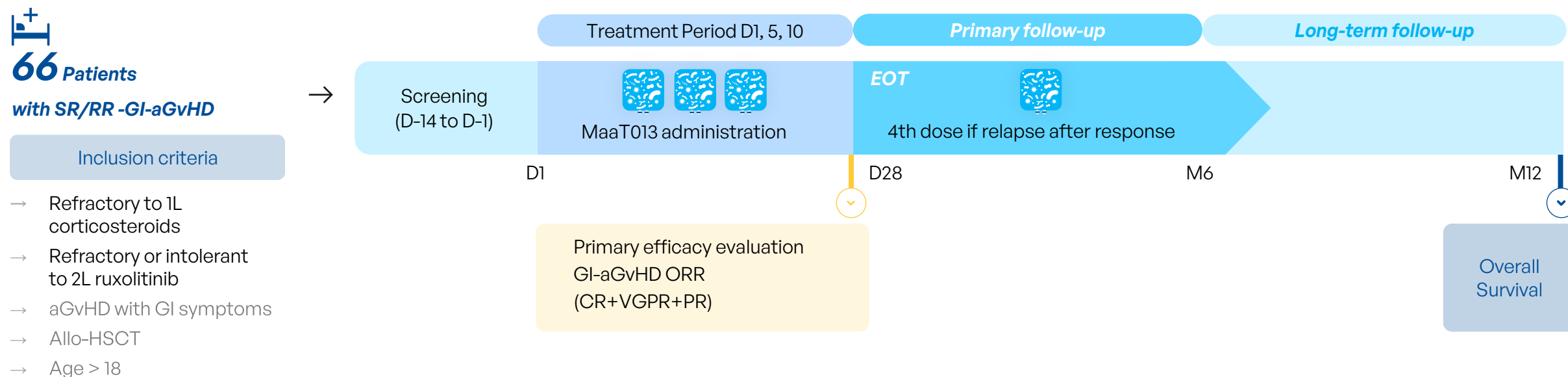
→ In the Early Access Program (EAP), MaaT013 showed efficacy in aGvHD patients who failed 1 to 6 lines of systemic treatment<sup>3</sup>

<sup>1</sup>Abedin et al., Br J Hematol 2021, <sup>2</sup>Peled et al., NEJM 2020; <sup>3</sup>Malard et al., ASH 2024

# ARES: a Pivotal Phase 3 Trial Exploring MaaT013 in 3<sup>rd</sup>-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 in **June 2025**



## March 25 Final DSMB main conclusions:

- Remarkable efficacy results
- Positive benefit/risk profile



Marketing Authorization Expected  
H2 2026: First Microbiome  
Product Approved in the EU



## 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>

\*MAGIC : Mount Sinai Acute GVHD International Consortium



Patients with severe aGvHD

**91% are Grade III-IV**



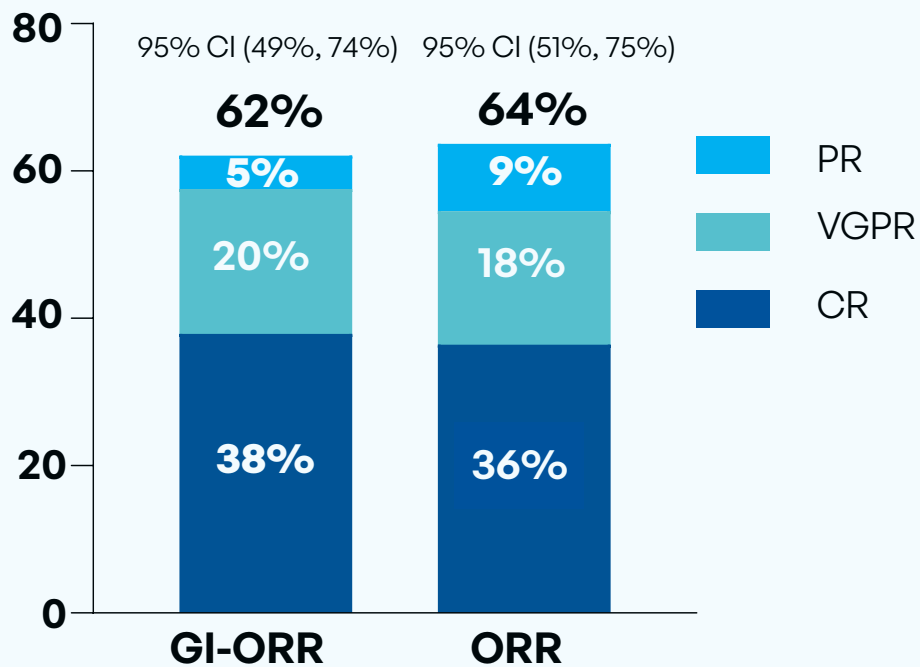
**100% are ruxolitinib refractory**



# ARES: Strong Response to MaaT013 in aGvHD Following Steroid and Ruxolitinib Failure

## Topline Results

### D28 Response Rate (%)



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

“These outcomes underscore the curative role of microbiota-based therapies in achieving durable responses leading to prolonged survival. As MaaT013 gains adoption in Europe, it has the potential to redefine care standards for patients facing this life-threatening complication.”

Prof. Malard, MD, hematology professor at Saint-Antoine Hospital and Sorbonne University, lead investigator for the Phase 3 ARES trial



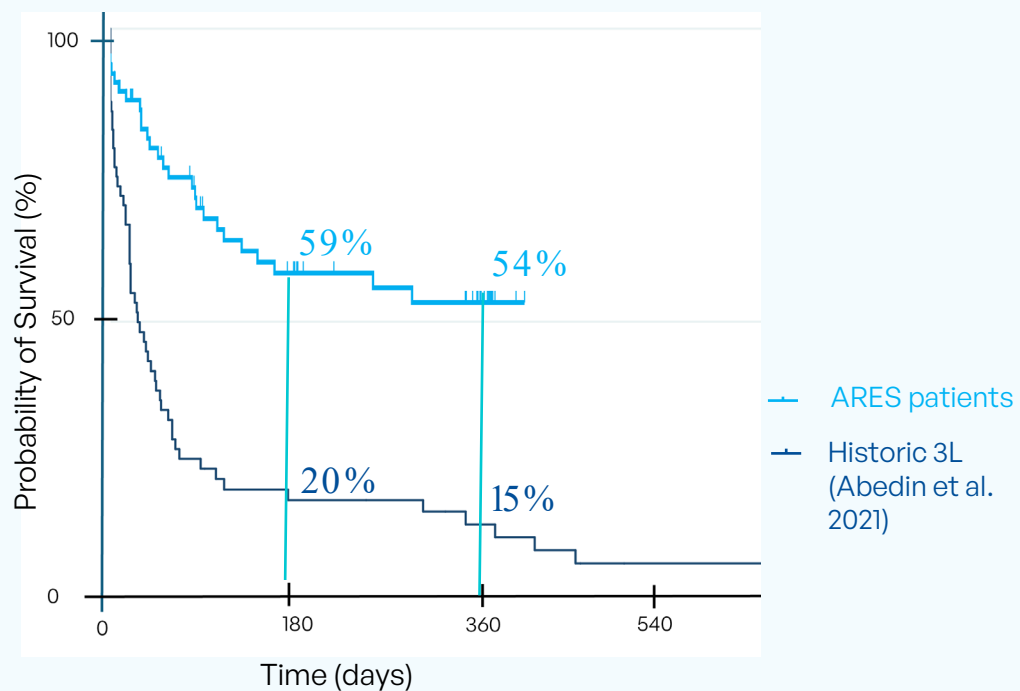
The study met its primary endpoint with a significant gastrointestinal overall response rate ( $p < 0.0001$ )



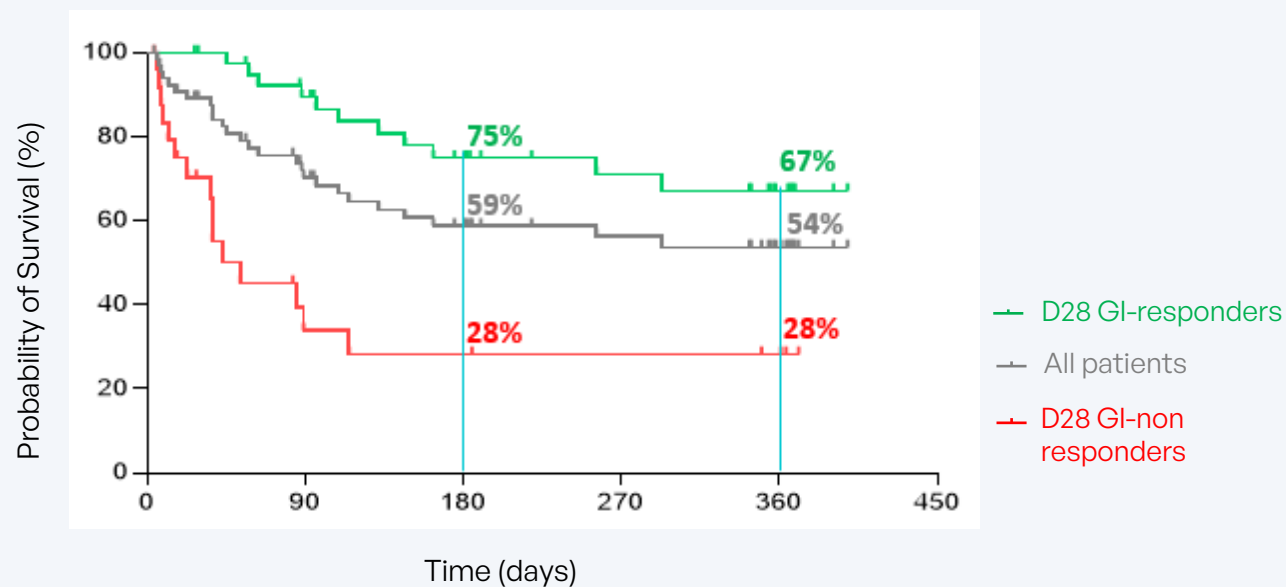


# ARES: Unprecedented Probability of Survival Compared to Historical Data with Best Available Therapy (BAT)

## 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

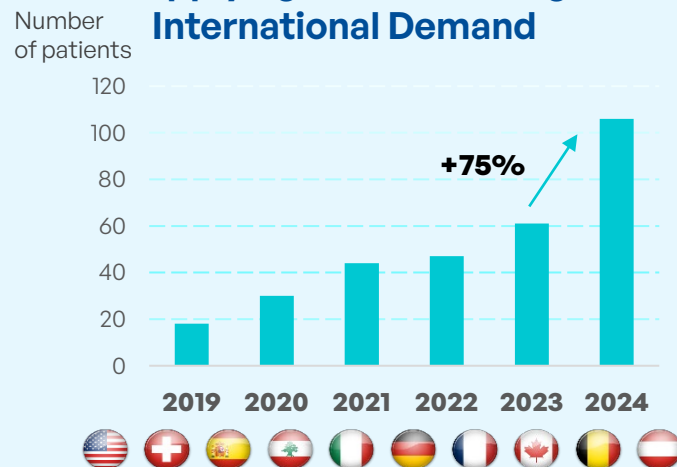
1

## 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%)**



# Regulatory Path for MaaT013 in Third-Line Refractory aGvHD: Established in Europe, Leveraging EU Results for Ongoing US Discussions

## In Europe



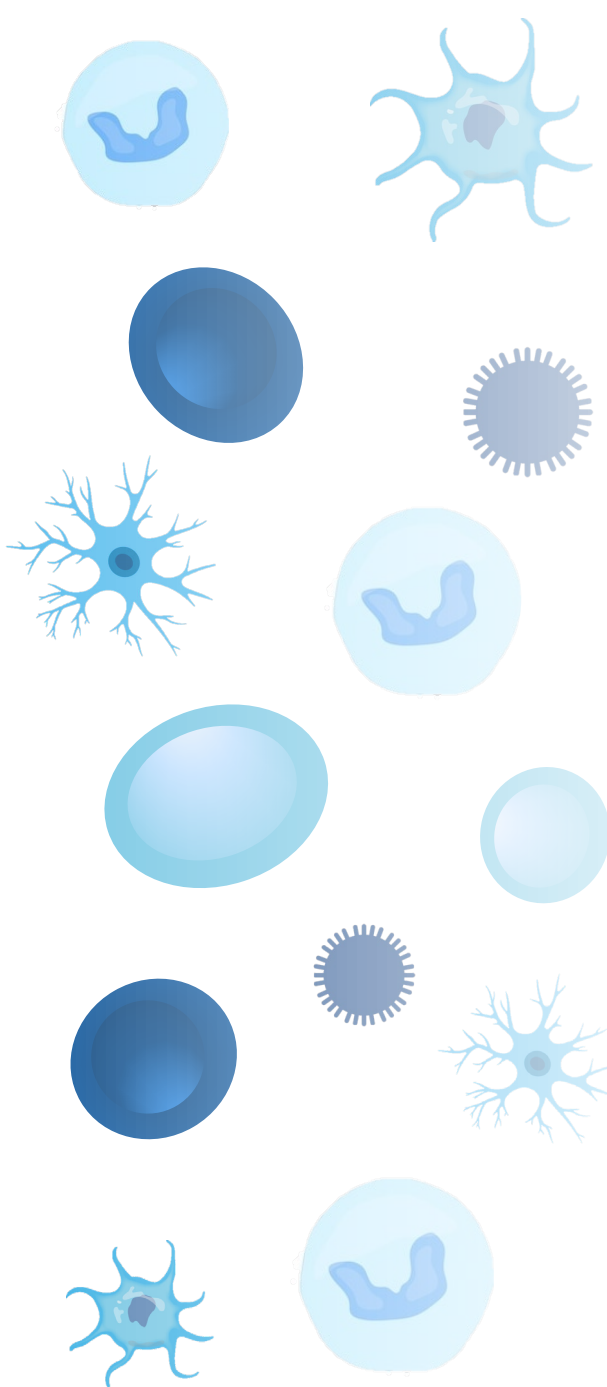
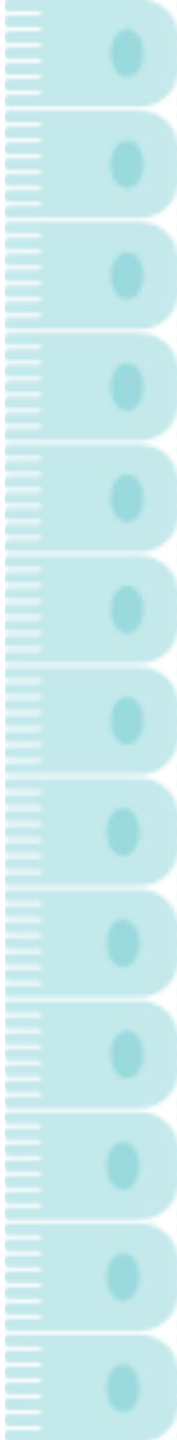
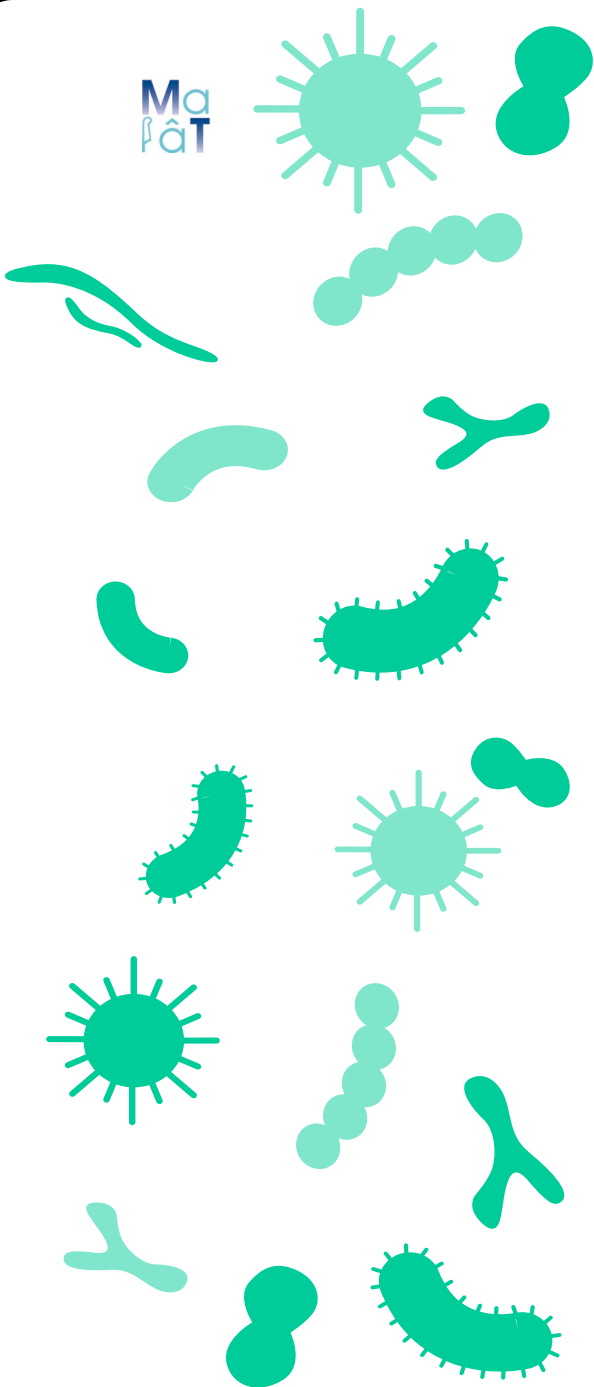
- Eligibility of MaaT013 for the **centralized procedure confirmed by EMA** (Medicinal product status) and rapporteurs and co-rapporteurs appointed
- **Target filing of the EMA Marketing Authorization Application for MaaT013 in June 2025** (6mths in advance vs previous plan)
- **Submission based on validated 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 including :
  - **Dedicated and optimized study for the US** leveraging ARES Phase 3 results. **Targeting potential launch of U.S. Phase 3 study in 2025.**
  - Plan to engage with the FDA to discuss a potential regulatory submission of a US Biologics License Application (BLA) with European Phase 3 data (subject to FDA's approval and confirmatory trial).
- Continue to support the **ongoing Expanded Access Program** to allow US patients early access to MaaT013

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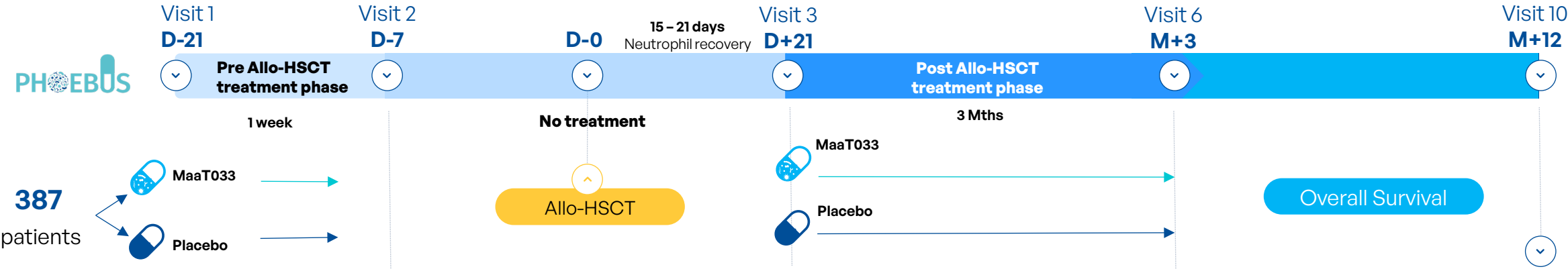
# A Multi-Asset Platform Focused on Oncology

# Phoebus: MaaT033 Phase 2b RCT

## Potential Adjunctive Treatment for Patients Receiving Allo-HSCT



Design presented at EBMT, SOHO and ASH



### Largest Microbiome RCT trial in oncology

- Multicenter Randomized Control Trial
- 60 sites / 6 countries

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



Ongoing Phase 2b PHOEBUS



April 2025: Positive Unblinded Interim Analysis by DSMB (n=60) – Trial To Continue as Planned



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

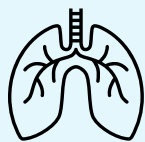


~ 11k patients per year

# 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*

## 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

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

## 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](#)**

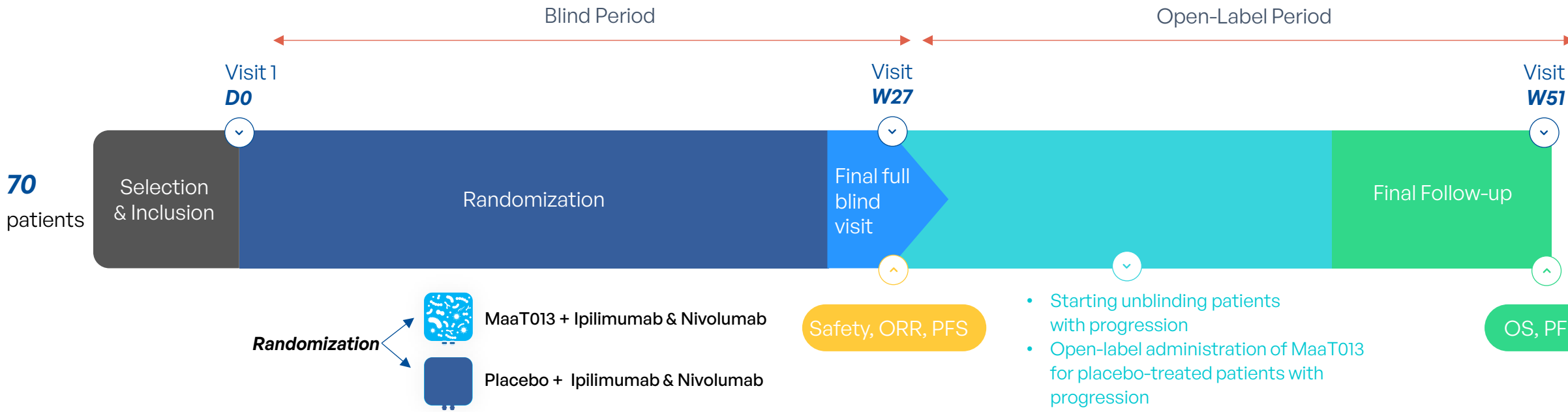
**Investigator Sponsored Trial** (Assistance Publique - Hôpitaux de Paris) in collaboration with Institut Gustave Roussy

→ **Data expected in H2.25**

**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)

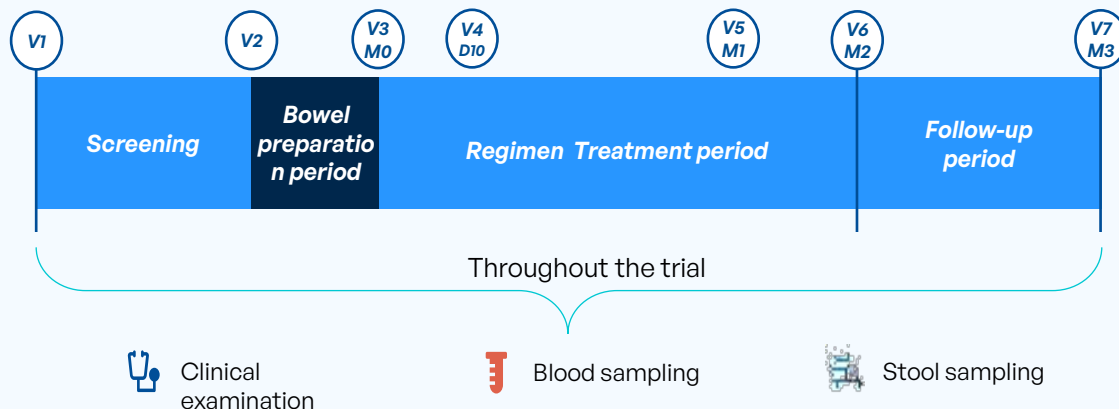
- Could affect up to 60,000 patients in US & EU by 2040<sup>1</sup>
- Paralysis and death 3 to 5 years after diagnostic<sup>2</sup>
- Currently no curative treatment and few symptomatic treatments

## 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



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



Study developed with:



In collaboration with:

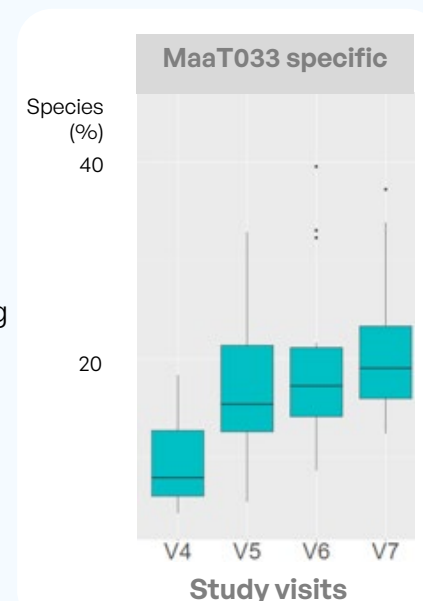


→ **Key study endpoints:** safety and tolerability of MaaT033 (**Primary**) | gut microbiota composition evolution | marker showing potential impact on disease progression

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

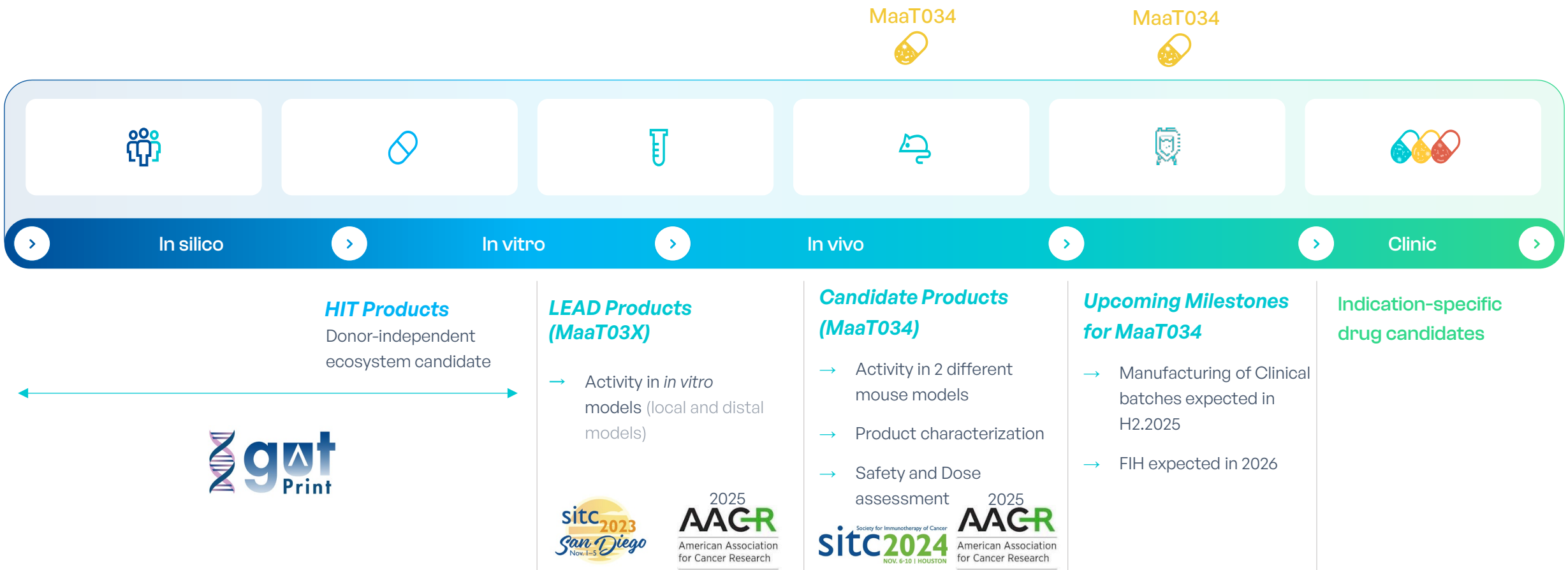
- MaaT033 found to be safe and well tolerated
- DSMB supports proceeding to Phase 2
- Successful engraftment characterized by the increasing MaaT033 species overtime

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

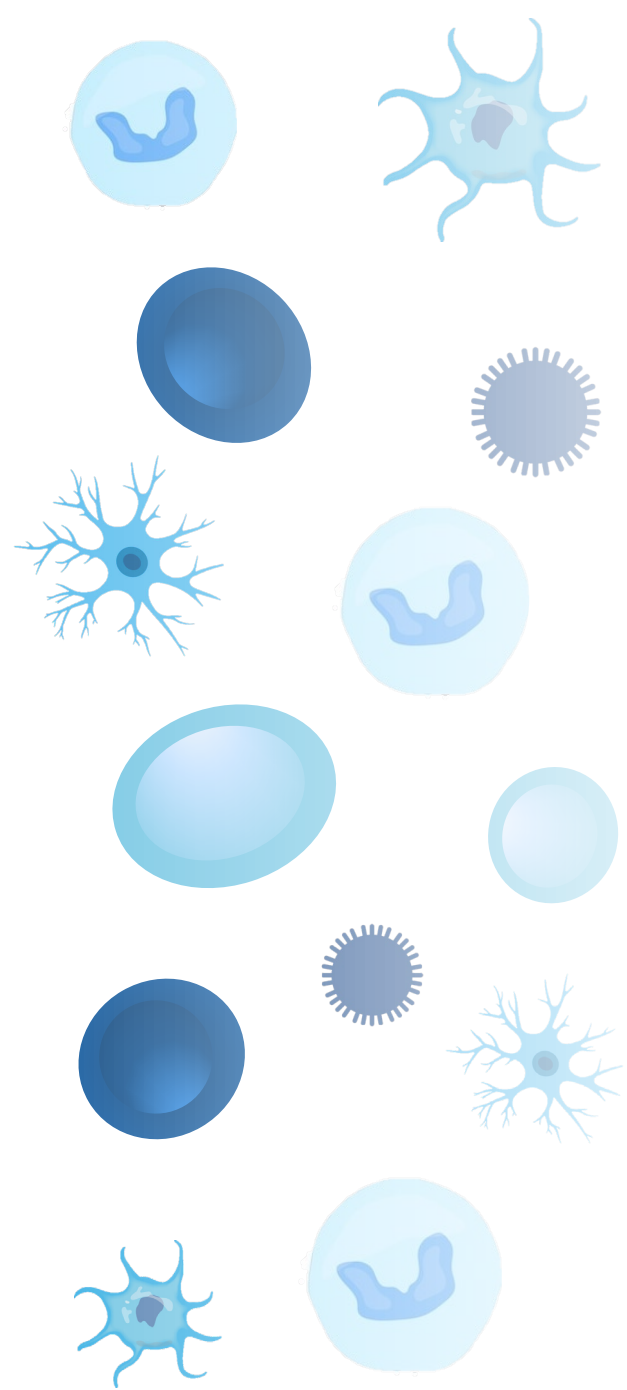
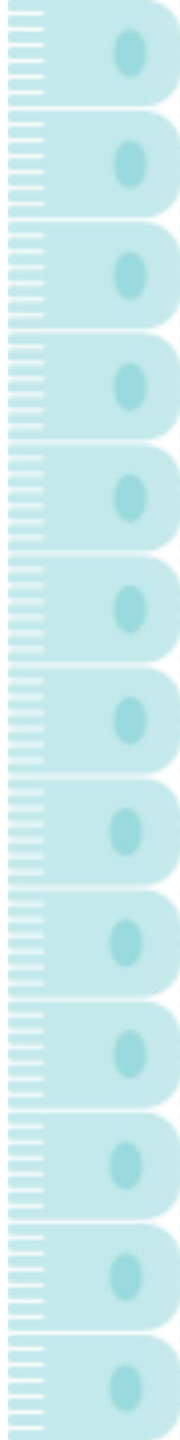
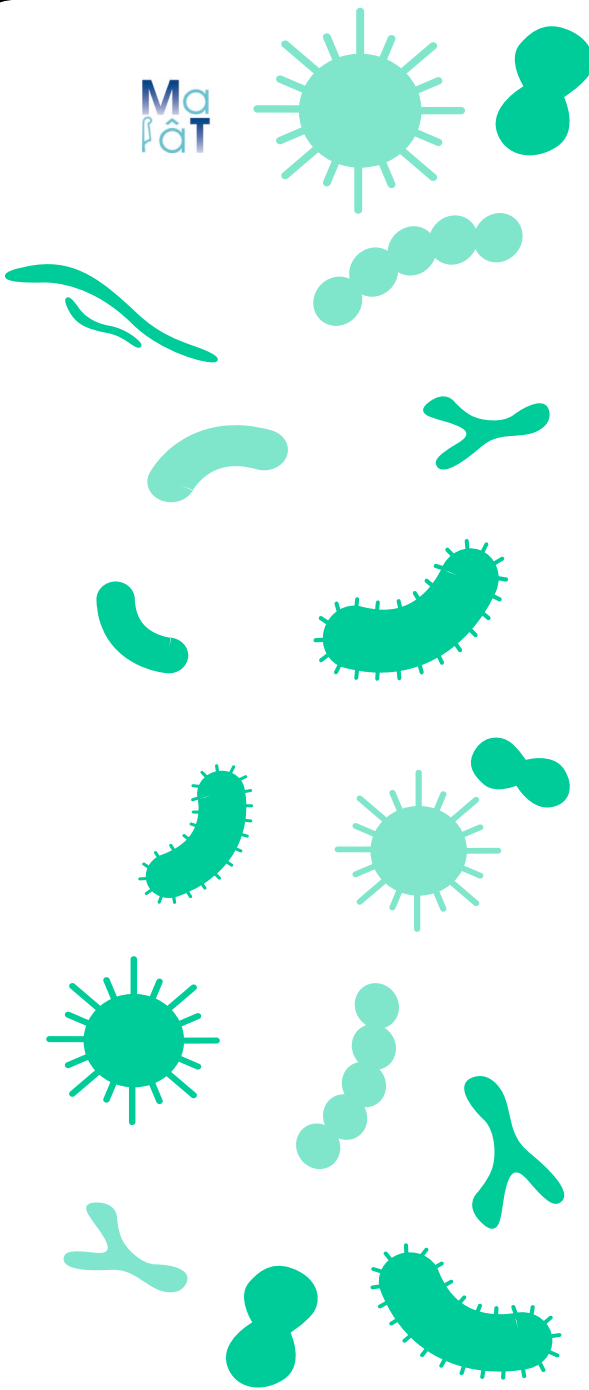


<sup>1</sup> Arthur, K., Calvo, A., Price, T. et al. Projected increase in amyotrophic lateral sclerosis - from 2015 to 2040. Nat Commun 7, 12408 (2016). <https://doi.org/10.1038/ncomms12408> <sup>2</sup> <https://tousensellescontrelasla.fr/la-sla-cest-quoi/>

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



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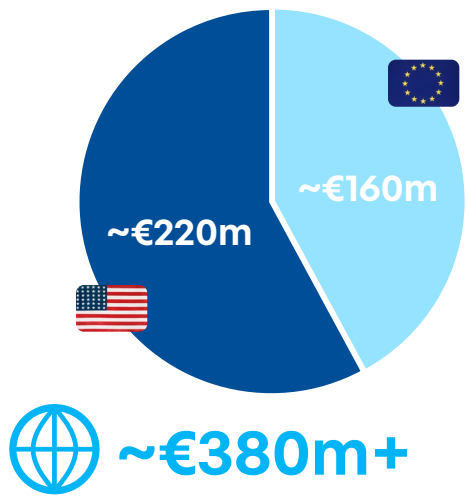
# Hemato- oncology Franchise Driving Value

# MaaT013: High-Margin Potential and Addressable Market Opportunity

## Addressable market in 3L\*

 ~3,000 patients

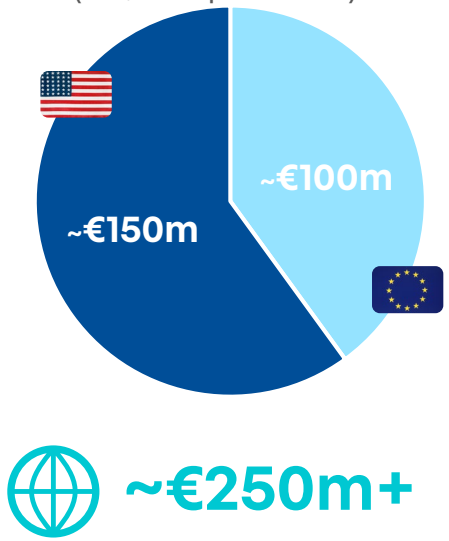
3L GI-SR-RR/I-aGvHD



## Estimated Annual Revenues

65% Market penetration

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



- Ruxolitinib: ~70% MS in the US within 2 years of approval
- Addressable population concentrated in transplant centers
- Potential for **premium pricing** supported by a well-optimized cost structure

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

\*: Excludes China, where 15,000 allo HSCT procedures are performed annually – the incidence of GvHD is expected to be similar to that of Europe

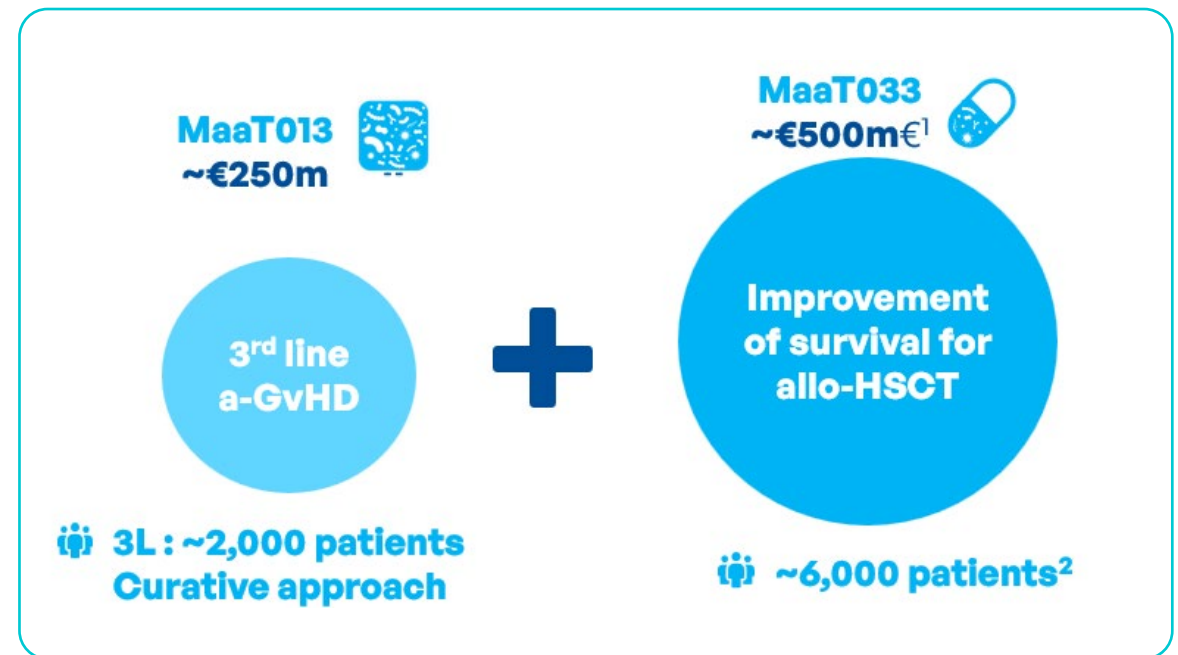
# Realizing Value through Partnership: Aligning Innovation with Unmet Medical Needs in Hematology

## 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

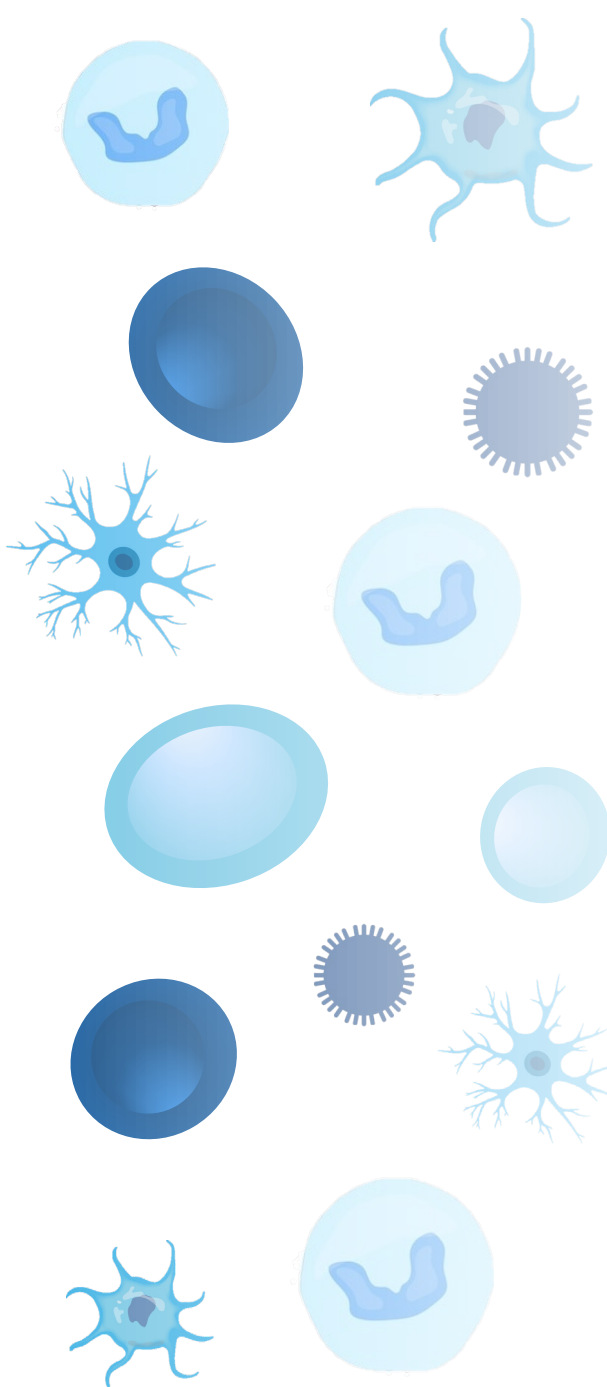
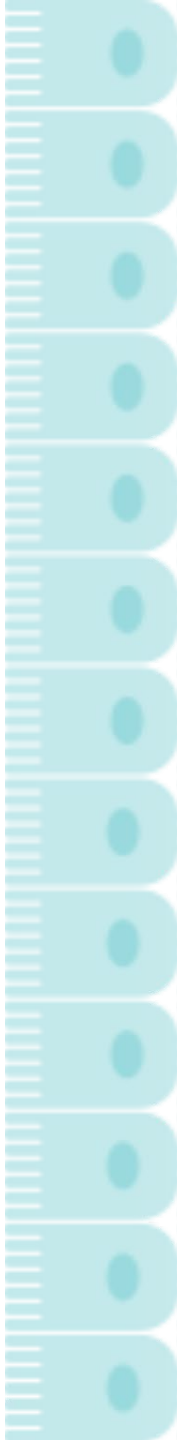
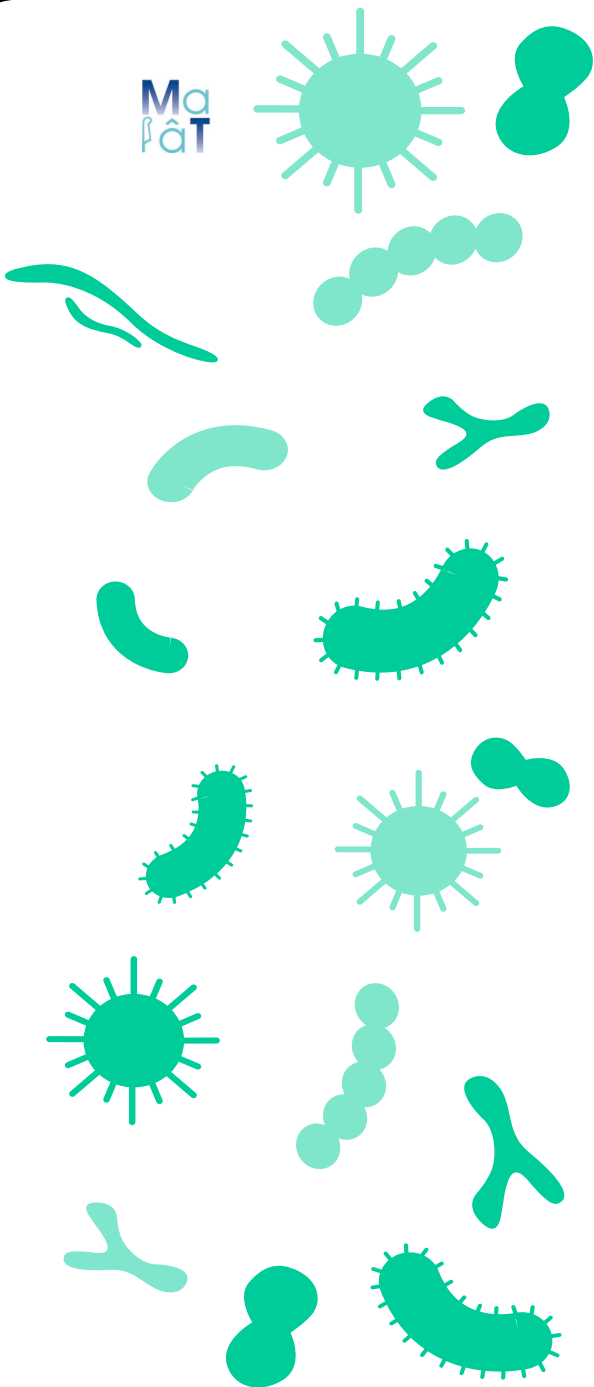
Significant potential to leverage partner's expertise in hematology, rare diseases, or hospital commercial operations.

## 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	Yield Variation
Campaign #1	<10%
Campaign #2	<10%
Campaign #3	<10%

Campaign #1 Campaign #2 Campaign #3

Manufacturing yield based on FDA/EMA authorized processes

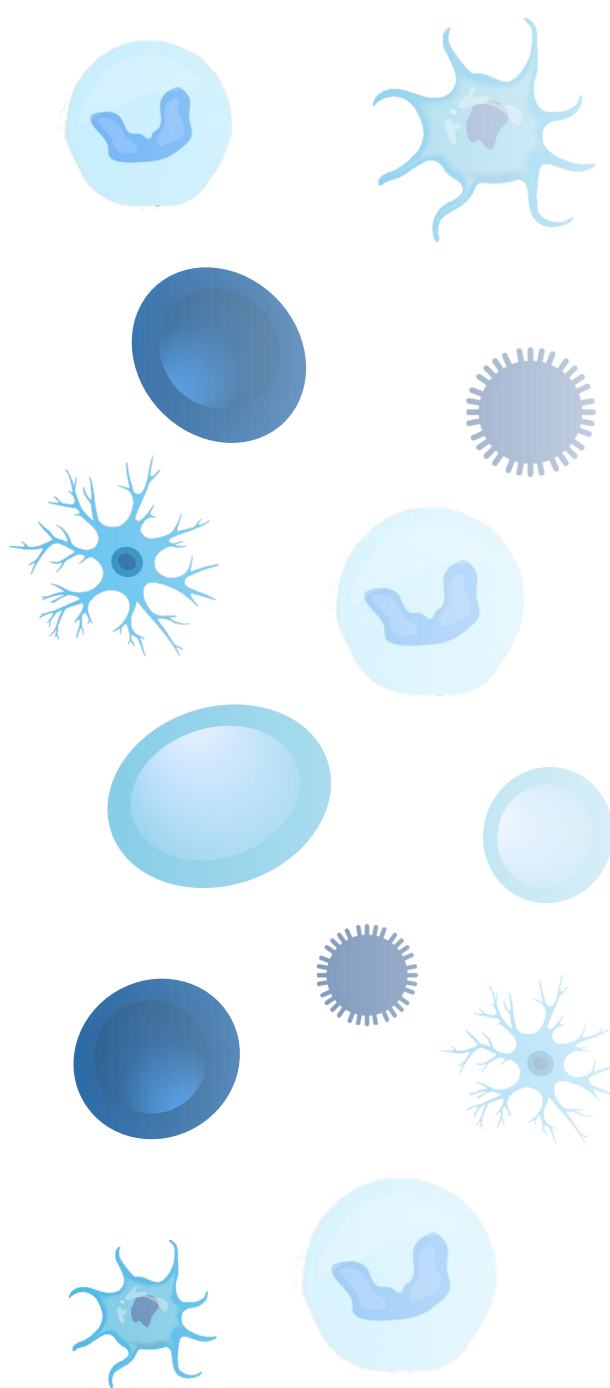
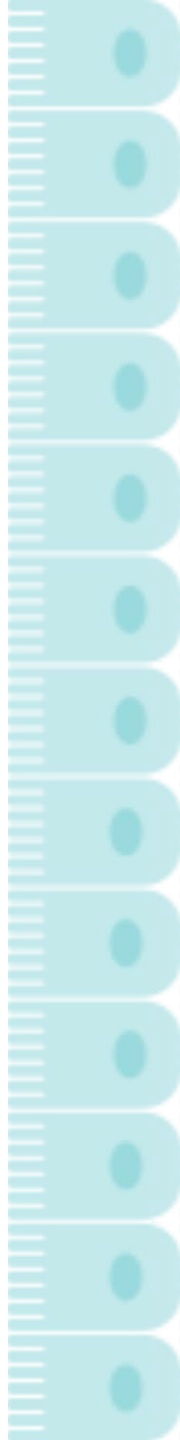
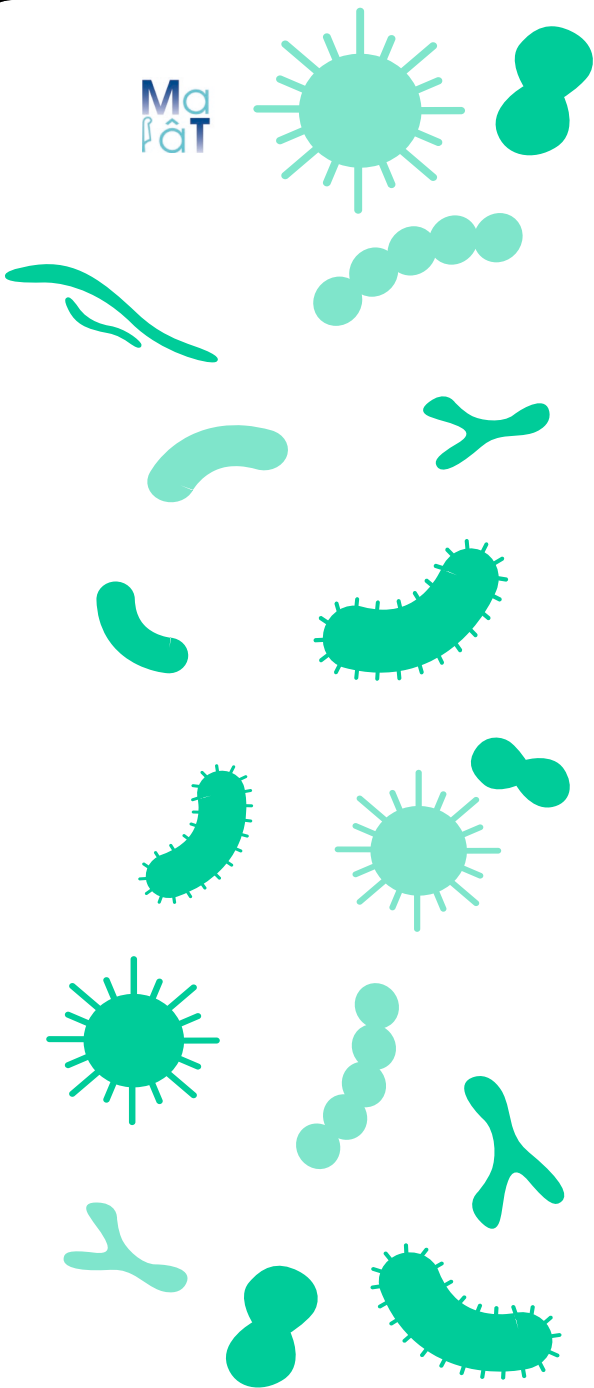
 04

Currently used at 10% capacity  
**Scalable up to commercial capacity**





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# Newsflow & Funding Opportunities

# Several Major Near-Term Value Inflection Expected Milestones

2025

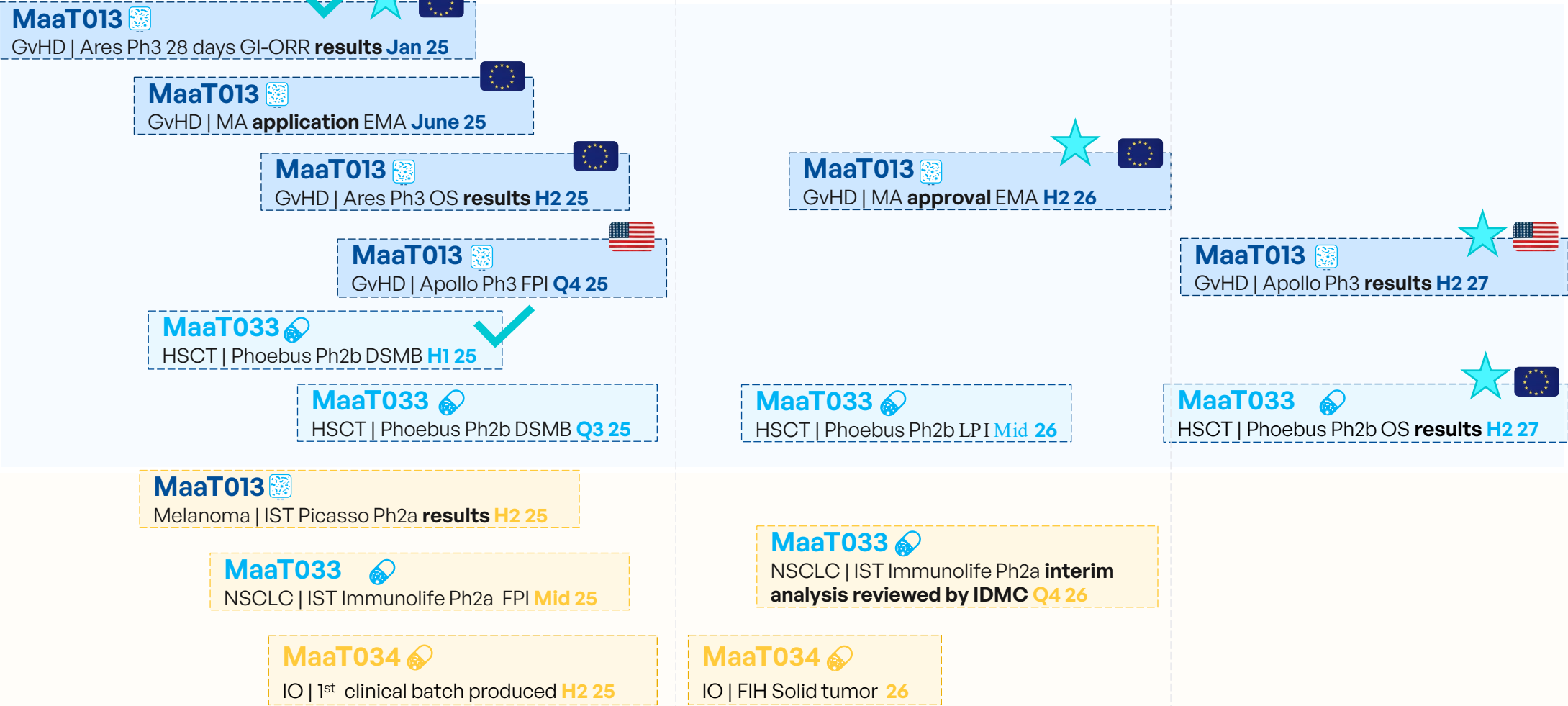
2026

2027



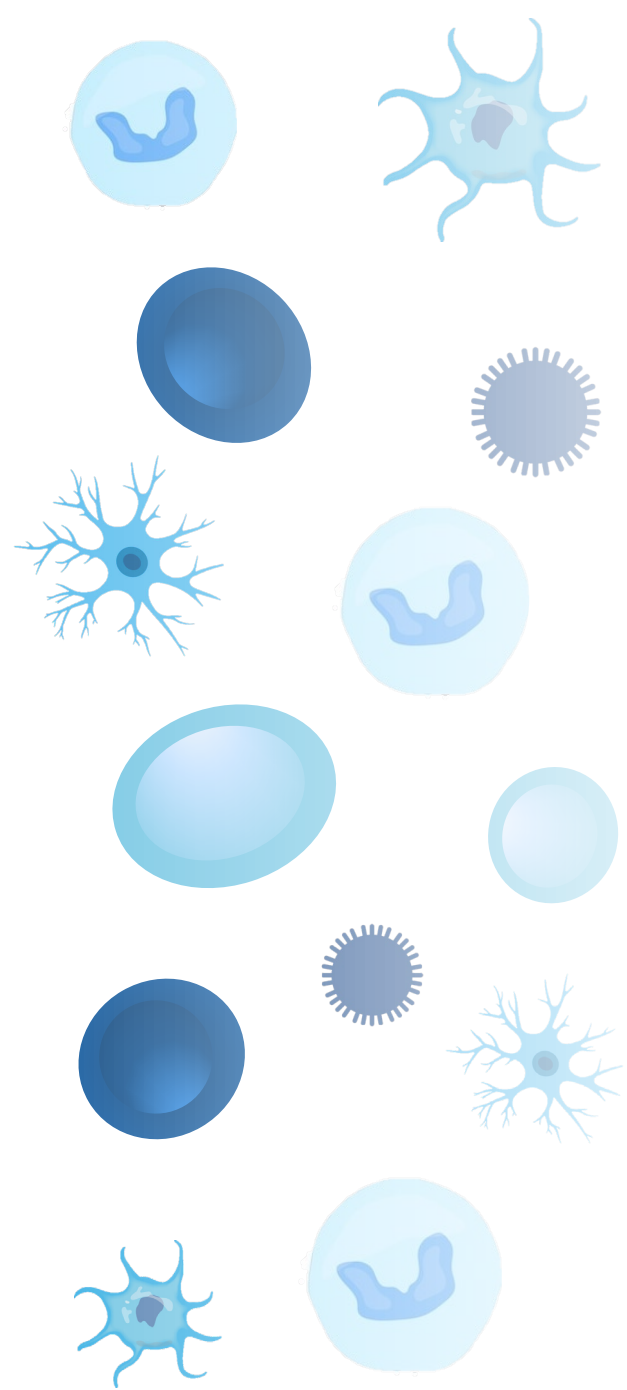
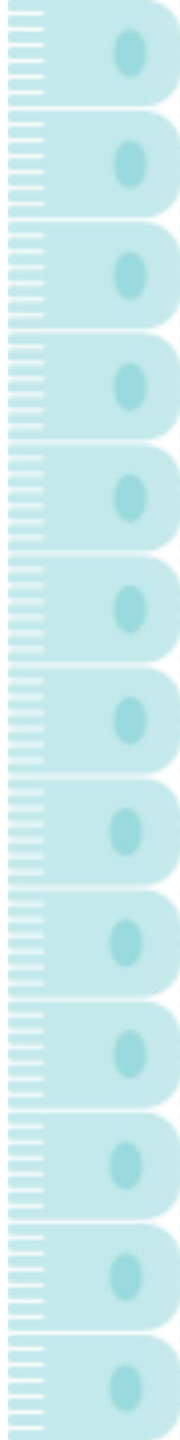
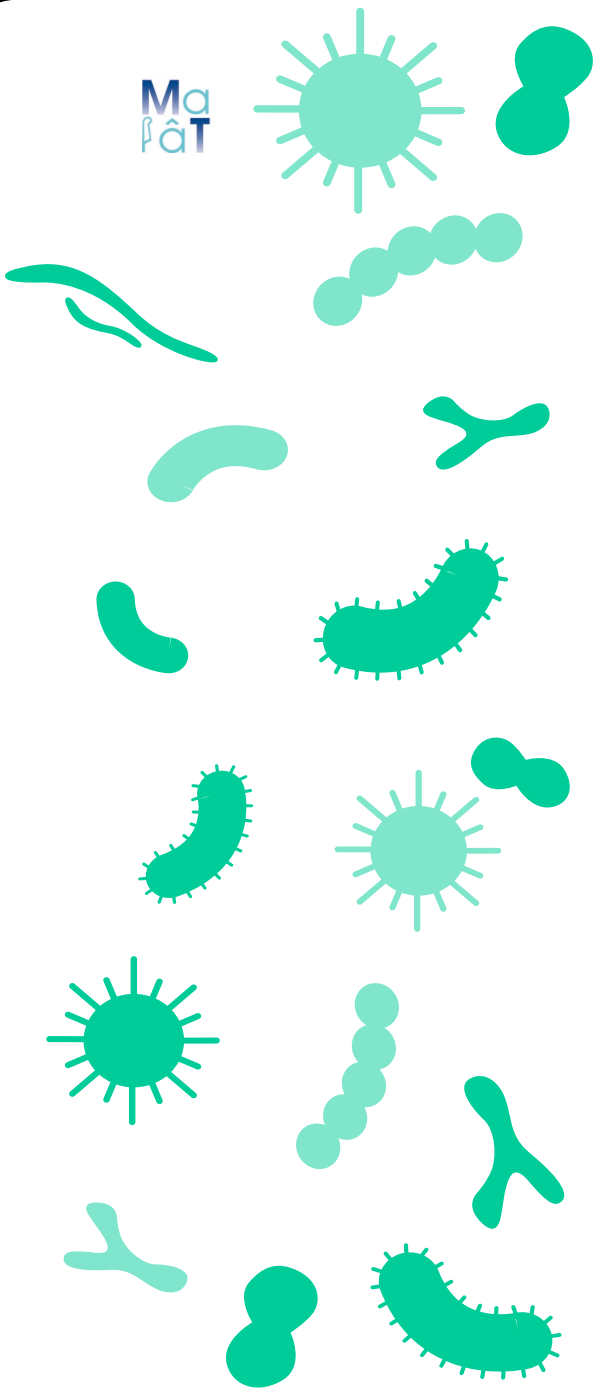
Hemato  
-  
Oncology

Immuno  
-  
Oncology



Legend : ★ Key milestone; ✓ Achieved 🇺🇸 US market ; 🇪🇺 EU market ; 🧴 MaaT013 (pooled enema) ; 🧊 MaaT033 (pooled capsule) ; 🧊 MaaT034 (co-cultivated capsule)

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# Thank you

